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Attorneys for Plaintiff
INNOVATIVE HEALTH LLC

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA, SOUTHERN DIVISION**

INNOVATIVE HEALTH LLC,

Plaintiff,

vs.

BIOSENSE WEBSTER, INC.,

Defendant.

Case No. 8:19-cv-1984 JVS (KES)

**DECLARATION OF MATTHEW D.
READE IN SUPPORT OF
PLAINTIFF INNOVATIVE
HEALTH LLC'S MOTION FOR
PERMANENT INJUNCTION**

Date: July 21, 2025

Time: 1:30 p.m.

Crtrm: 10C

Action Filed: October 18, 2019

Trial Date: May 6, 2025

1 I, Matthew D. Reade, declare as follows:

2 1. I am an attorney admitted to the bars of the State of Texas and the
3 District of Columbia. I am admitted *pro hac vice* to practice before this Court. I
4 practice law at Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C., and represent
5 the plaintiff, Innovative Health LLC, in this matter.

6 2. I make this declaration in support of Plaintiff Innovative Health LLC's
7 Motion for Permanent Injunction.

8 3. The facts I state here are true and correct. They are based on my own
9 personal knowledge or knowledge I gleaned from reviewing files pertinent to this
10 matter. If called as a witness to testify, I could and would competently testify to
11 these facts.

12 4. **JX-216** is a true and correct copy of the trial exhibit bearing Bates
13 numbers BWI-INN00058999 to BWI-INN00059000, which was produced by
14 Biosense and admitted into evidence in this case.

15 5. **JX-219** is a true and correct copy of the trial exhibit bearing Bates
16 numbers BWI-INN00060483 to BWI-INN00060484, which was produced by
17 Biosense and admitted into evidence in this case.

18 6. **JX-220** is a true and correct copy of the trial exhibit bearing Bates
19 numbers BWI-INN00338742 to BWI-INN00338743, which was produced by
20 Biosense and admitted into evidence in this case.

21 7. **JX-221** is a true and correct copy of the trial exhibit bearing Bates
22 numbers BWI-INN00105448 to BWI-INN00105451, which was produced by
23 Biosense and admitted into evidence in this case.

24 8. **JX-298** is a true and correct copy of the trial exhibit bearing Bates
25 numbers BWI-INN00044794 to BWI-INN00044794, which was produced by
26 Biosense and admitted into evidence in this case.

1 9. **JX-535** is a true and correct copy of the trial exhibit bearing Bates
2 numbers IH00697079 to IH00697081, which was produced by Innovative and
3 admitted into evidence in this case.

4 10. **JX-3099** is a true and correct copy of the trial exhibit bearing Bates
5 numbers BWI-INN00047565 to BWI-INN00047571, which was produced by
6 Biosense and admitted into evidence in this case.

7 11. **JX-3114** is a true and correct copy of the trial exhibit bearing Bates
8 numbers BWI-INN00057216 to BWI-INN00057217, which was produced by
9 Biosense and admitted into evidence in this case.

10 12. **JX-3207** is a true and correct copy of the trial exhibit bearing Bates
11 numbers BWI-INN00075788 to BWI-INN00075788, which was produced by
12 Biosense and admitted into evidence in this case.

13 13. **JX-3270** is a true and correct copy of the trial exhibit bearing Bates
14 numbers BWI-INN00105170 to BWI-INN00105171, which was produced by
15 Biosense and admitted into evidence in this case.

16 14. **JX-3673** is a true and correct copy of the trial exhibit bearing Bates
17 numbers BWI-INN00468482 to BWI-INN00468486, which was produced by
18 Biosense and admitted into evidence in this case.

19 15. **JX-3912** is a true and correct copy of the trial exhibit bearing Bates
20 numbers IH00568087 to IH00568088, which was produced by Innovative and
21 admitted into evidence in this case.

22 16. **JX-3969** is a true and correct copy of the trial exhibit bearing Bates
23 numbers IH00697211 to IH00697214, which was produced by Innovative and
24 admitted into evidence in this case.

25 17. **Exhibit 1** is a true and correct copy of an email exchange between
26 counsel for Innovative and counsel for Biosense with the subject line, "IH v. BWI –
27 Injunction & Global Schedule."
28

1 18. **Exhibit 2** is a true and correct excerpt of the deposition designation
2 report reflecting the testimony of Joseph Koenig that I understand was played at trial
3 in this case.

4 19. **Exhibit 3** is a true and correct excerpt of the trial testimony of Dr. Eric
5 Forister in this matter.

6 20. **Exhibit 4** is a true and correct excerpt of the trial testimony of
7 Meredith Snider in this matter.

8 21. **Exhibit 5** is a true and correct excerpt of the trial testimony of Rick
9 Ferreira in this matter.

10 22. **Exhibit 6** is a true and correct excerpt of the trial testimony of Dave
11 Distel in this matter.

12 23. **Exhibit 7** is a true and correct excerpt of the trial testimony of Dr.
13 Rahul Doshi in this matter.

14 24. **Exhibit 8** is a true and correct excerpt of the trial testimony of Mary
15 Roberts in this matter.

16 25. **Exhibit 9** is a true and correct excerpt of the trial testimony of Blessan
17 Joseph in this matter.

18 26. **Exhibit 10** is a true and correct excerpt of the trial testimony of Avi
19 Shalgi in this matter.

20 27. **Exhibit 11** is a true and correct excerpt of the trial testimony of Fairy
21 Zare in this matter.

22 28. **Exhibit 12** is a true and correct excerpt of the trial testimony of Conrad
23 Ramos in this matter.

24 29. **Exhibit 13** is a true and correct excerpt of Innovative's closing
25 argument at trial in this matter.

26 30. Innovative's counsel met and conferred about the proposed injunction
27 with Biosense's counsel on May 27, May 30, and June 4, 2025. The parties did not
28 reach agreement regarding the relief sought in this motion.

1 I declare under penalty of perjury that the foregoing is true and correct.

2
3 Executed on this 12th day of June, 2025, at Arlington, Virginia.

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5 /s/ Matthew D. Reade

6 Matthew D. Reade
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From: Koenig, Joseph [BWIUS] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=374E1A0355C747AC884D8FA91AA4A811-JKOENIG4>
To: Urman, Roy [BWIUS]
Sent: 8/13/2019 5:10:13 PM
Subject: Clinical Coverage Policy
Attachments: Position Statement on Clinical Account Specialist Case Support of Reprocessed Single Use Devices (SUD)_[REDACTED] 20181010.pdf

Roy-

Per our discussion. S3 does reprocess SoundStar in the US, however, our clinical team will not support the cases if the account pulls the S3 product. The strategy has been very effective in combatting S3. I'm attaching our approved customer letter which details the policy. Let me know if you have any further questions.

Joe Koenig

Product Director
US Commercial Marketing
M. (714) 878-1975
E. jkoenig4@its.jnj.com

Biosense Webster, Inc.

Part of the Johnson & Johnson Family of Companies
33 Technology Drive
Irvine, CA 92618, USA
www.biosensewebster.com



Innovative v. Biosense

No. 8:19-cv-01984-JVS

JX-216



Date: XX/XX/XXXX

RE: Position Statement on Clinical Account Specialist Case Support of Reprocessed Single Use Devices (SUD)

Dear Valued Customer,

This letter is to inform you of Biosense Webster, Inc.'s position regarding case support of reprocessed Single-Use-Devices (SUD) distributed by third parties. Biosense Webster's commitment to providing high-quality products and services requires that we properly train all Clinical Account Specialists on the capabilities, limitations, and proper functioning of all our devices and equipment. Electrophysiologists ask Clinical Account Specialists to assist with reconstructing cardiac anatomy using our technology and interpreting maps and providing insight on the images generated by the CARTO® 3 System. It is critical that our personnel possess a competent base of knowledge of the design intent of each device feature and a thorough understanding of how each device is designed to work with our capital equipment to help achieve the best possible outcome for each patient. This base of knowledge is especially important when it comes to providing product technical support for the CARTO® 3 System, and troubleshooting the CARTO® 3 System in the midst of a procedure, which requires accurate inputs from diagnostic mapping and ultrasound catheters. Most hospital facilities also recognize the critical nature of vendor product competency as it relates to patient safety and consequently require vendor representatives to provide documentation attesting to their competency with their company's products as part of the vendor credentialing process. Reprocessing is a manufacturing process regulated by the U.S. Food and Drug Administration, and reprocessed single use devices generally require a new regulatory submission before they can be distributed. The regulatory clearance for reprocessed devices is owned by the reprocessing company that manufactures and distributes the devices, not the original equipment manufacturer. Therefore, once Biosense Webster's single use devices are subjected to the reprocessing process of another company, those devices are no longer our products.

To offer our customers a portfolio of both new and reprocessed devices, Biosense Webster has partnered with a reprocessing company that is also a member of the Johnson & Johnson Family of Companies. We have shared our calibration methods and product testing methods with our affiliated reprocessing company, and we distribute those products along with new Biosense Webster devices. We are confident that the reprocessed devices we distribute meet our quality standards. However, we have no knowledge of the manufacturing operations or specifications of reprocessed devices manufactured by third parties with which we are not affiliated. As such, Biosense Webster cannot attest to the safety, effectiveness, and accuracy of these devices.

Accordingly, our Clinical Account Specialists can only provide product technical support in cases that use diagnostic mapping and ultrasound catheters distributed by Biosense Webster. Our Clinical Account Specialists understand the capabilities, limitations, and proper functioning of these devices and are able to deliver on our commitment of high-quality support for these products.

For any questions related to the information contained in this letter, please contact your local Biosense Webster, Inc. representative.

Thank you for your continued partnership and for choosing the Biosense Webster, Inc.

Sincerely,

Biosense Webster, Inc.

097317-180821

Biosense Webster, Inc.
33 Technology Drive
Irvine, CA 92618, USA
www.biosensewebster.com
TEL: 1-909-839-8500
TEL: 1-800-729-9010

ID #: 25452

From: Fine, Marius [SMDUS] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6ED86FEC476C4A5485E37D984434DA87-MFINE2>
To: Koenig, Joseph [SYNNA]
Sent: 12/3/2018 4:41:24 PM
Subject: RE: Request: Soundstar reprocessing by Stryker & status of Falcon chip

Thanks. I thought I heard that the team was working on a new version because the previous version was defeated by S3

Marius Fine
Sr. Reprocessing Marketing Manager



Johnson & Johnson Health Care Systems, Inc.
T: +1 763 488 3239
M: +1 952 826 9659
mfine2@its.jnj.com
<http://www.jnj.com>

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From: Koenig, Joseph [SYNNA]
Sent: Monday, December 03, 2018 10:40 AM
To: Fine, Marius [SMDUS] <mfine2@ITS.JNJ.com>
Subject: RE: Request: Soundstar reprocessing by Stryker & status of Falcon chip

S3 is reprocessing SS 8F and 10F. Let me see if I can get more details around Falcon.

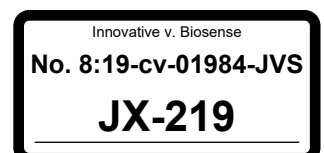
Joe Koenig
Product Director, Sustainability
M. (714) 878-1975
E. jkoenig4@its.jnj.com

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Part of the Johnson & Johnson Family of Companies
33 Technology Drive
Irvine, CA 92618, USA
www.biosensewebster.com



From: Fine, Marius [SMDUS]
Sent: Monday, December 3, 2018 7:45 AM
To: Koenig, Joseph [SYNNA] <JKOENIG4@its.jnj.com>
Subject: Request: Soundstar reprocessing by Stryker & status of Falcon chip

Joe,



Please confirm that the SS 8Fr & 10Fr are still being reprocessed by Stryker S3 & the status of the Falcon chip anti-reprocessing technology?

Thanks,

Marius Fine
Sr. Reprocessing Marketing Manager



Johnson & Johnson Health Care Systems, Inc.
T: +1 763 488 3239
M: +1 952 826 9659
mfine2@its.jnj.com
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From: Galdonik, Jason [SMDUS]
Sent: Monday, December 03, 2018 9:32 AM
To: Fine, Marius [SMDUS] <mfine2@ITS.JNJ.com>
Subject: Soundstar

Hi Marius –

Question for you - Is Stryker still reprocessing 8F and 10F Soundstar catheters? Do you know if BWI ever modified the Falcon security chip feature that prevents S3 reprocessing?

I am getting questions from Heather Rodriguez and HTC on this.

Thanks
Jason

Jason A. Galdonik
Sr. Engineering Manager

Johnson & Johnson
Medical Devices Companies

Sterilmed, Inc
5010 Cheshire Parkway N, Ste. 2
Plymouth, MN 55446 - USA
T: +1 763 488 3218
jgaldoni@its.jnj.com

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From: Koenig, Joseph [SYNNA] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=374E1A0355C747AC884D8FA91AA4A811-JKOENIG4>
To: Zare, Fairy [BWIUS]
Sent: 12/3/2018 4:48:46 PM
Subject: RE: Request: Soundstar reprocessing by Stryker & status of Falcon chip

Ok.

Joe Koenig

Product Director, Sustainability

M. (714) 878-1975

E. jkoenig4@its.inj.com

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33 Technology Drive

Irvine, CA 92618, USA

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From: Zare, Fairy [BWIUS]

Sent: Monday, December 3, 2018 8:41 AM

To: Koenig, Joseph [SYNNA] <JKOENIG4@its.inj.com>

Subject: RE: Request: Soundstar reprocessing by Stryker & status of Falcon chip

Let's speak live.

From: Koenig, Joseph [SYNNA]

Sent: Monday, December 03, 2018 8:41 AM

To: Zare, Fairy [BWIUS] <fzare@its.inj.com>

Subject: FW: Request: Soundstar reprocessing by Stryker & status of Falcon chip

What's Falcon?

Joe Koenig

Product Director, Sustainability

M. (714) 878-1975

E. jkoenig4@its.inj.com

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Innovative v. Biosense

No. 8:19-cv-01984-JVS

JX-220

From: Fine, Marius [SMDUS]

Sent: Monday, December 3, 2018 7:45 AM

To: Koenig, Joseph [SYNNA] <JKOENIG4@its.jnj.com>

Subject: Request: Soundstar reprocessing by Stryker & status of Falcon chip

Joe,

Please confirm that the SS 8Fr & 10Fr are still being reprocessed by Stryker S3 & the status of the Falcon chip anti-reprocessing technology?

Thanks,

Marius Fine
Sr. Reprocessing Marketing Manager



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<http://www.jnj.com>

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From: Galdonik, Jason [SMDUS]

Sent: Monday, December 03, 2018 9:32 AM

To: Fine, Marius [SMDUS] <mfine2@ITS.JNJ.com>

Subject: Soundstar

Hi Marius –

Question for you - Is Stryker still reprocessing 8F and 10F Soundstar catheters? Do you know if BWI ever modified the Falcon security chip feature that prevents S3 reprocessing?

I am getting questions from Heather Rodriguez and HTC on this.

Thanks

Jason

Jason A. Galdonik
Sr. Engineering Manager

Johnson & Johnson
Medical Devices Companies

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From: Koenig, Joseph [BWIUS] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=374E1A0355C747AC884D8FA91AA4A811-JKOENIG4>
To: Fanger, Jonathan [BWIUS]
Sent: 4/20/2020 8:35:06 PM
Subject: Re: Certified Performance Dashboard through March, 2020 - and other topics!
Attachments: image002.png; image004.png; image006.jpg; image008.png

Haha! For sure.

Joe Koenig
Product Director
US Commercial Marketing
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E. jkoenig4@its.jnj.com

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www.biosensewebster.com

On Apr 20, 2020, at 1:32 PM, Fanger, Jonathan [BWIUS] <JFanger@its.jnj.com> wrote:

Thanks Joe, I appreciate it. This took off fast. This quarantine has only created more work!

From: Koenig, Joseph [BWIUS] <JKOENIG4@ITS.JNJ.COM>
Sent: Monday, April 20, 2020 1:27 PM
To: Fanger, Jonathan [BWIUS] <JFanger@its.jnj.com>
Subject: RE: Certified Performance Dashboard through March, 2020 - and other topics!

Looks awesome! Nice work, man! 6/4 should provide enough time to get something ready. I'll be checking in with Kim and Tracy a week from today, will likely setup regular touchpoints thereafter to make sure content is ready. Let me know if you need any other support with the curriculum.

Joe Koenig
Product Director
US Commercial Marketing
M. (714) 878-1975
E. jkoenig4@its.jnj.com

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www.biosensewebster.com

<image002.png>

From: Fanger, Jonathan [BWIUS] <JFanger@its.jnj.com>
Sent: Monday, April 20, 2020 1:15 PM

Innovative v. Biosense

No. 8:19-cv-01984-JVS

JX-221

To: Koenig, Joseph [BWIUS] <JKOENIG4@ITS.JNJ.COM>
Page ID #: 25457

Subject: RE: Certified Performance Dashboard through March, 2020 - and other topics!

Hi Joe,

Yes, I'm aligned. We have to put together 8 weeks of training curriculum for UCASs now that we aren't having the June training. One of the days is best practice sharing. There will be 2-3 topics. The UCASs are asking about LAAO specifically, so we thought to include it. I reviewed the overall plan with Fairy and Sarita last week. Today I shared it with Michael and the ADs. It was approved. We will be moving very fast and want to get session leaders locked in for each weekly call. Attached is a first draft of the schedule. I'll be setting up some meetings to push this forward once it's finalized.

Thanks,
Jon

From: Koenig, Joseph [BWIUS] <JKOENIG4@ITS.JNJ.COM>

Sent: Monday, April 20, 2020 10:06 AM

To: Fanger, Jonathan [BWIUS] <JFanger@its.jnj.com>

Subject: FW: Certified Performance Dashboard through March, 2020 - and other topics!

I have a call with Kim and Tracy today regarding status of our LAA training. Just double checking that you're aligned to a UCAS specific internal LAAO training call/meeting?

Joe Koenig

Product Director

US Commercial Marketing

M. (714) 878-1975

E. jkoenig4@its.jnj.com

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<image004.png>

From: Bradshaw, Gillian [BWIUS] <gbradsh2@ITS.JNJ.com>

Sent: Friday, April 10, 2020 2:51 PM

To: Koenig, Joseph [BWIUS] <JKOENIG4@ITS.JNJ.COM>

Subject: RE: Certified Performance Dashboard through March, 2020 - and other topics!

Hi Joe,

WOW on the return rate, the highest ever, I think – maybe the EP CASs had them lined up in their garages and found the time due to COVID vs. case coverage?!

Thanks for letting me know you couldn't get on the UCAS call yesterday and I hope whoever had the dental visit is fine?! We had 50 participants on the call – the most ever, again thanks to COVID!

Do you happen to know which of our accounts buy Stryker or Innovative Health AcuNavs? The question came up with regard to providing a target list of accounts that purchase AcuNav, to switch out legacy systems before Philips arrives in our space – we want to be sure they are targeting those systems too, and I know some accounts only buy competitive RPO ULS catheters.

Also, FYI, during a discussion with Siemens about branding the new AcuNav Crystal catheter, they stated that we cannot create a logo using the product name (like we do with SOUNDSTAR and our other products, i.e. the orange

Hmmmm, I've just seen how they do it for AcuNav Volume ... in orange as well (but I know that's a color they use)! They don't have anything for 2D AcuNav (and I'm pretty sure it's only us that sell it) (but it would be good if we could even present it this way for the 2D one that we sell):
<image006.jpg>

Finally, we were thinking of having a UCAS call for LAA, with Tracy going through her presentation – I learned from Kim that it's not copy approved and that she is working with Dr. Gidney to gather more images (I think you are involved in this too?). However, I imagine that could take a while – what do you think about us trying to get her current version copy approved, at least to present to the UCAS team, then updating it later for broader use?

Thanks,
Gillian

From: Koenig, Joseph [BWIUS] <JKOENIG4@ITS.JNJ.COM>

Sent: Friday, April 10, 2020 2:19 PM

To: Haydel, David [BWIUS] <DHaydel@its.jnj.com>; Rathod, Sharad [BWIUS] <SRathod@its.jnj.com>; Gonzalez, Deidre [BWIUS] <dgonza55@its.jnj.com>; Lech, Tom [BWIUS] <TLech@its.jnj.com>; Patel, Amit [BWIUS] <APatel7@its.jnj.com>; Lubinsky, Susan [BWIUS] <SLubinsk@its.jnj.com>; DL-BWIUS Regional Business Directors <DL-ASPUS-BWIUS-Regional-Business-Directors@ITS.JNJ.com>

Cc: Bodner, Michael [BWIUS] <mbodner@ITS.JNJ.com>; Zare, Fairy [BWIUS] <fzare@ITS.JNJ.com>; Martin, Noah [BWIUS] <NMarti12@its.jnj.com>; Geer, Dawn [BWIUS] <DGeer1@its.jnj.com>; Zambrano, Juan [BWIUS] <JZambra2@its.jnj.com>; Quipones, Janet [BWIUS] <jquipone@ITS.JNJ.com>; Davis, Jordan [BWIUS] <jdavi124@ITS.JNJ.com>; Balabaeva, Marina [BWIUS] <MBalabae@its.jnj.com>; Dela Cruz Jr, Romeo [BWIUS] <RDelac10@ITS.JNJ.COM>; Berkowick, Ben [BWIUS] <BBerkowi@ITS.JNJ.COM>; Huang, Shan [BWIUS] <yhuang89@ITS.JNJ.com>; Miller, Jeanne [BWIUS] <JMiller7@ITS.JNJ.com>; Den, Dan [BWIUS] <DDen@its.jnj.com>; Hashimoto, Lance [BWIUS] <lhashimo@ITS.JNJ.com>; Vargas, Ana [BWIUS] <Avarga22@ITS.JNJ.com>; Espinoza, Alexander [MNTUS] <aespin26@ITS.JNJ.com>; Slechta, Timothy [BWIUS] <tslechta@ITS.JNJ.com>; Williams, Ray [ETHUS] <RWillia@its.jnj.com>; Bradshaw, Gillian [BWIUS] <gbradsh2@ITS.JNJ.com>; Zambrano, Juan [BWIUS] <JZambra2@its.jnj.com>; Trejo, Daniel [BWIUS] <DTrejo8@its.jnj.com>; Balabaeva, Marina [BWIUS] <MBalabae@its.jnj.com>; Sobotka, Christopher [JJCUS] <csobot1@ITS.JNJ.com>; Calvert, Christopher [BWIUS Non-J&J] <CCalver1@its.jnj.com>; Miller, Jeanne [BWIUS] <JMiller7@ITS.JNJ.com>; Guadeloupe, Judy [HCS] <JGuadelo@its.jnj.com>; Monico, Sarita [BWIUS] <SMonico@its.jnj.com>; Koenig, Joseph [BWIUS] <JKOENIG4@ITS.JNJ.COM>

Subject: Certified Performance Dashboard through March, 2020

AVPs and RBDs,

Please find attached Certified Performance Dashboard for **March, 2020**.

HIGHLIGHTS

- **91%** of ULS catheters were returned in **March** by Certified Performance customers. Rolling 6 months is at **71%** which is short of our **80%** goal, so it is important to stay on top of collections/regular returns and ensure the CASs keep the "Bag & Bin" training up with their EP lab staff (training materials are on Connect and OneBWL).
- March: **74%** AcuNav, **92%** SOUNDSTAR; Rolling 6 months: **64%** AcuNav, **71%** SOUNDSTAR
- **95 Customers have fully transitioned (BWL purchases shut off) to Quoting since January, 2019.**
- **3 Buy Back Program** agreements have been executed YTD, **7** are pending.

CHALLENGES/OPPORTUNITIES

1. **Please stay focused on collections. If we control supply, we can greatly minimize**

competitive activity. Let's shoot to keep the number north of 70%!

2. **Non-compliance** - Please monitor/manage the ratio, **37 accounts** did not meet the minimum purchase requirement of (at least) 1 new: 2 reprocessed ULS catheters in January, in other words they are buying too much RPO– **THESE ACCOUNTS MUST BE ADDRESSED TO PREVENT BO's/manage our overall supply of ULS – transitioning these accounts to quoting also resolves this issue.**
3. **Quoting Transition: Please transition your remaining accounts who are still purchasing RPO direct from BWI to Sterilmed quoting NOW, connect with your Sustainability Specialist for support. The transition to quoting is NOT optional.**

ACTIONS

1. **Drive collections**, ensuring the CAS/ EP staff "Bag & Bin" their catheters (training materials on Connect and OneBWI).
2. **Drive transition to quoting ASAP.**
3. Ensure remaining ratio customers purchase at least one new for every two reprocessed ultrasound catheters.
4. Address any discrepancies in the returns data with Sterilmed Customer Service (sterilmedcs@its.jnj.com; 1-877-541-0078). Note: Shipments made after the 20th of the month typically go on the following month's Dashboard.
5. **Promote RPO and Buy Back Programs! In the past 6 months, over 25,000 ULS catheters have NOT been returned – we need these in our pipeline and not someone else's!**

Joe Koenig

Product Director

US Commercial Marketing

M. (714) 878-1975

E. jkoenig4@its.jnj.com

Biosense Webster, Inc.

Part of the Johnson & Johnson Family of Companies

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Irvine, CA 92618, USA

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<image008.png>

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Innovative v. Biosense

No. 8:19-cv-01984-JVS

JX-298

BWI 2019 Kickoff Meeting



2018 YEAR IN REVIEW

Michael Bodner

UNBEATABLE



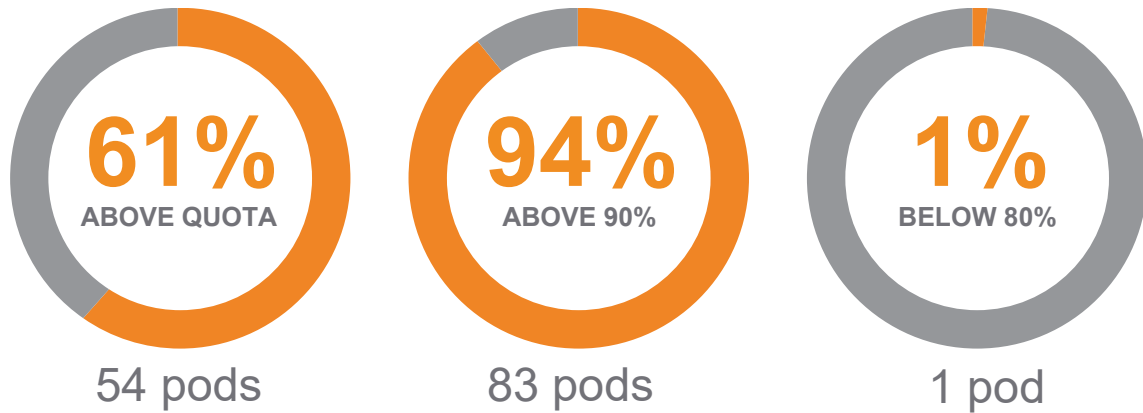
THANK YOU!

\$1.173BILLION!

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Strong 2018 Quota Achievement



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2018 Year in Review

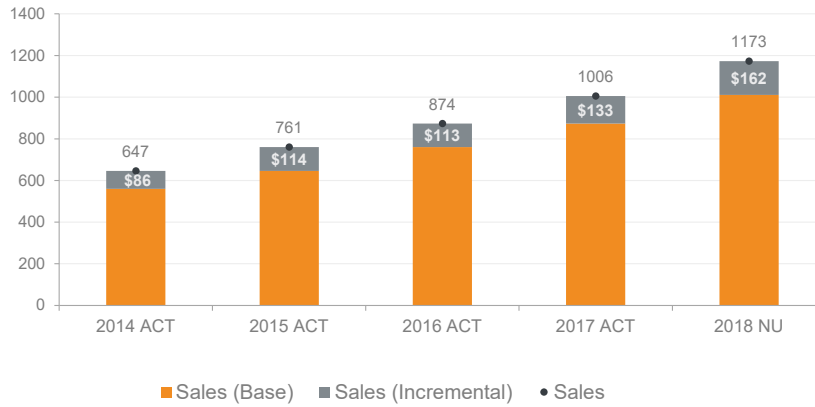


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OVER \$0.5 BILLION Growth in 4 Years

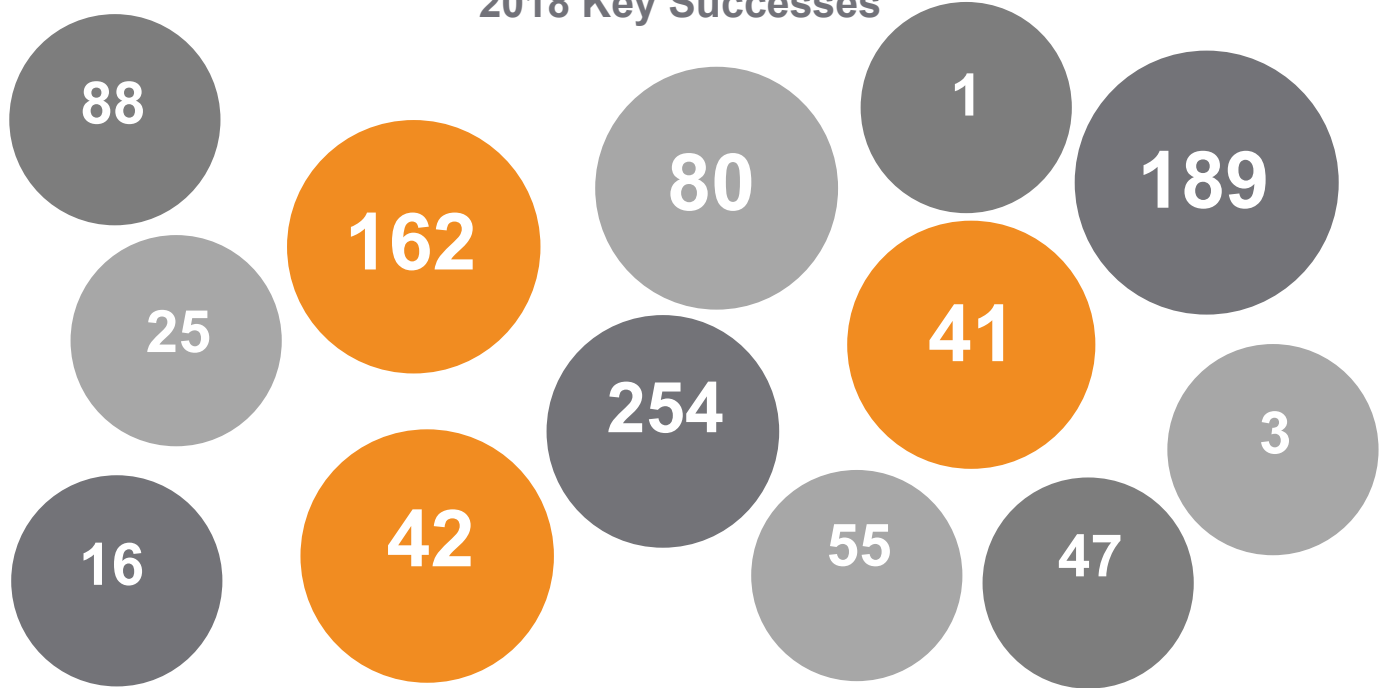
SALES GROWTH TREND 2014-2018



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2018 Key Successes



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2018 Key Successes



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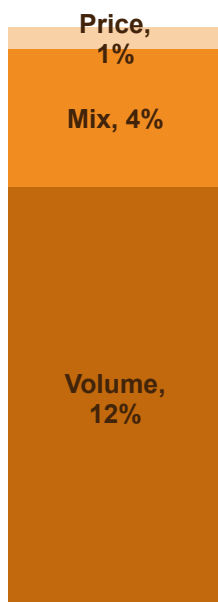
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Unstoppable!

	Q1 GROWTH	Q2 GROWTH	Q3 GROWTH	Q4 GROWTH	FY GROWTH
 Biosense Webster <small>PART OF THE Johnson & Johnson FAMILY OF COMPANIES</small>	14%	18%	21%	13%	16%
 Abbott	12%	10%	13%	12%	12%
 Medtronic	14%	17%	18%	TBD	TBD
 Boston Scientific	10%	14%	9%	8%	11%

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2018 Growth

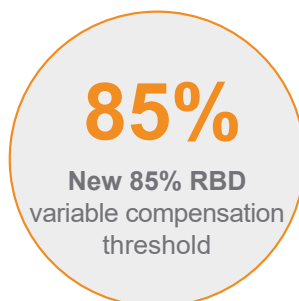


- \$6MM: Contract Compliance
- \$38MM: OCE/ “Own the Case”
- \$118MM: Case Coverage, competitive conversions
- 16% top line sales growth, 19% growth on bottom line

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Organizational Enhancements



New roles to upskill organization, enhance career progression, improve span of control

RTS • NTM • KAM • Executive TM • ATM

Expanding resources to drive growth

104+ CAS, 1 UCAS/Region, 1 MD/Area

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KEY ACCOUNTS ENHANCEMENTS



- Fellow's Bounty: \$3,000
- Career acceleration
- Separate ranking
- Haifa Award Trip
- KAMs

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REWARD AND RECOGNITION



- Credo Award
- Quarterly Spotlight
- Winning Spirit Award
- Case Buster
- OCE Contest
- Competitive Conversion Contest
- Trade Out Bounty

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PEOPLE

189
New Hires



218
Promotions



New Leaders

Kent MacKay– **KAM to RBD**

Jason Motes – **MDM to RBD**

Wade Williamson– **RBD to ACL**

Navarro Jordan – **TM to GES**

John Shields – **ETM to RBD**

Callie Parker– **AD to CSS**

Stephenie Orsini– **DPY to GES**

Deidre Gonzalez – **CEM to West AD**

Amit Patel – **RBD to NE AD**

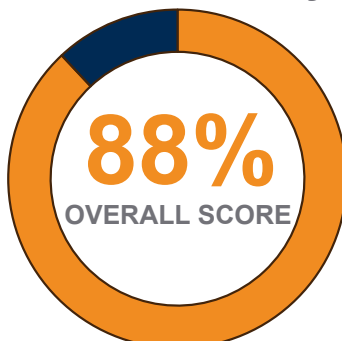
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172, 20, 69, 261

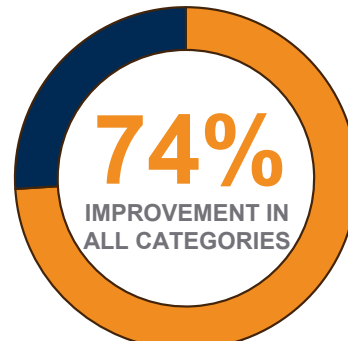
2018 Our Credo Survey Results



= compared to 2016



Up by 2% points
compared to 2016



Improvement in 25 out of
34 categories from 2016

Top Areas:

We are delivering in are our **commitment to patients, doctors and nurses**, as well as our stockholders. Another area clearly called out as a strength was in **launching new products**.

Improvement Areas:

Providing **compensation that is fair** and our commitment to **helping you fulfill your family responsibilities**.

Action Planning:

- We are partnering with Total Rewards and Sales Compensation for external benchmarking insights.
- We will also focus on helping you fulfill your family responsibilities, which will ultimately drive further employee engagement.

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Our Credo



We raised **\$60,000**
providing **252 smiles**
to children in the world's
most marginalized areas.

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175,000
Patients Treated

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2019 Goals

Continuing Momentum of Double Digit Growth and Share Gain

\$1,358MM

**\$175MM
Incremental**

**15%
Growth**

**0.5pt
share gain**

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2019 Commercial Objectives



Drive
OCE

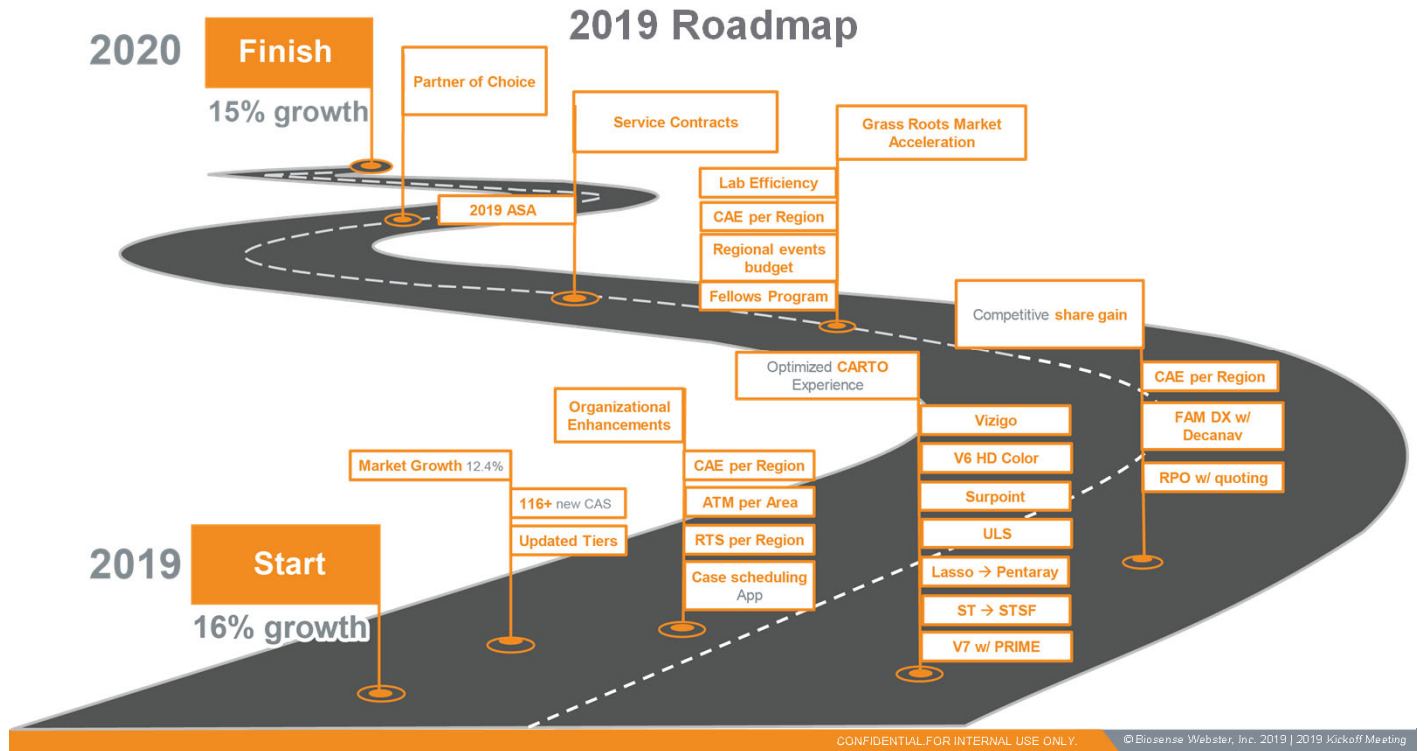
Gain
Competitive
Share

Accelerate
Procedure
Growth

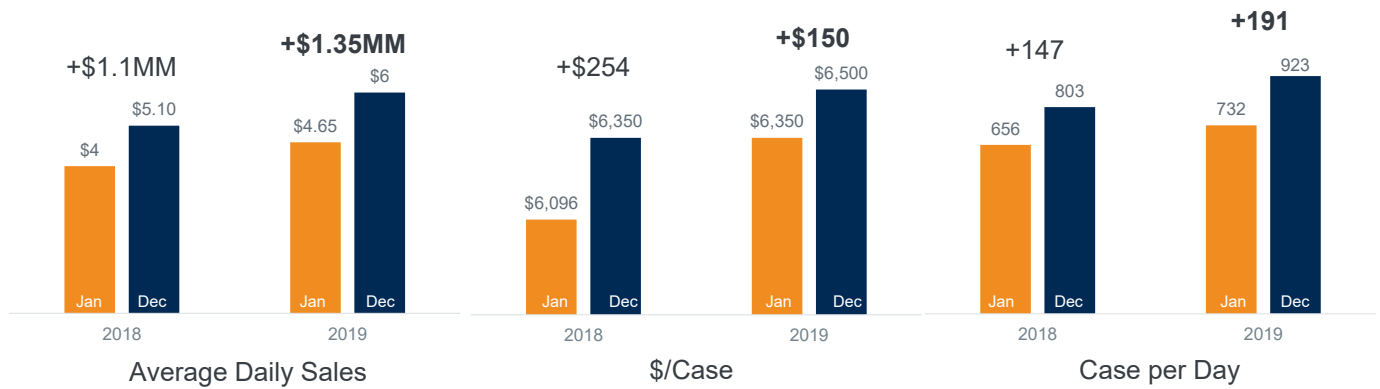
Enhance
SFE

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Daily Requirements

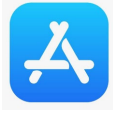


+220 2018/19



Upskilling

Mindset



Scheduling App

1 more Case

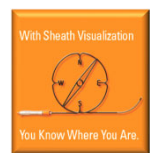


CAE

Conversions



SURPOINT™



VIZIGO™

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Squeezing the Juice to Drive Growth



OCE Strategy Fueled Significant Growth for Past Two Years



THERMOCOOL® SMARTTOUCH® SF
Catheter

**CARTO®
PENTARAY®**
Catheter

**CARTO®
SOUNDSTAR®**
Catheter

	2016 EXIT	2018 EXIT	2019 BP
	37% Penetration of Total TC Nav	80%	85%
	51% Penetration vs Lasso Nav	70%	75%
	57% Penetration in Total AF proc.	75%	80%
OCE Mix	15%	55%	65%
\$/CASE	\$5,851	\$6,350	\$6,500

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Key Tactics



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New Product Introductions – OCE 2.0!

VISITAG SURPOINT™ Module

Simplifying Your
AF Ablation Workflow



Mindshare = market share!

- **Workflow efficiency**
- **Treat like a therapeutic launch e.g. STSF**

Biosense Webster.
your way to better ablation. your way to success.

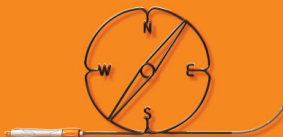
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CARTO

VIZIGO™

Bi-Directional Guiding Sheath

With Sheath Visualization



You Know Where You Are.

Biosense Webster.
your way to better ablation. your way to success.

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**Confidence to know
where you are!**

- **Fluoro reduction tool**
- **Increased efficiency**
- **Competitive share gain**
- **Drive \$/case**
- **Gain 10 case commitment**

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RPO Priorities for 2019



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1 – Don't put your head in the sand

2 - Transition to quoting

- Industry standard in Reprocessing, including S3 customers. Efficient for customers, they don't like buying RPO from two different sources.
- Eliminates backorders – customer can buy everything off the quote.
- Competitors have been using the 'ratio' model against us – saying we control what they buy;
- The onus is on the customer – they have control over what they want to order off their quote

3- Pull through the entire EP RPO portfolio

- Shift in mindset, don't just think about ULS, you now have a portfolio of 250+ SKUs to leverage and offer savings to your customers. So as you transition your customers to quoting, don't stop at ULS, sell it all!

4- Go after the competition

- We've had two different distribution models from different sources with different compliance metrics. This all changes in 2019! You now have all products under one roof with the simple to understand, industry standard distribution model (Quoting). Leverage this with an attractive new RPO customer incentive (the RPO accelerator) and go after the big fish! And Maximize collections The RPO market is unique in the way that there is a

finite amount of raw materials. If we control AcuNav collections, we control the market. In fact, it's not far fetched to believe that if we were able to collect back 75% of the OEM AcuNav we sell, we could drive Stryker out of the RPO EP business altogether.

Market Acceleration:

Increase # Patients Treated with CARTO
Increase # Procedures/EP

Develop Compelling Case for EP Program Expansion

Empower EPs with demographic, financial, and OCE procedural data to engage hospital admin to increase investment in EP program

Create Lab Efficiency TEC sites

Leverage physician consultants to improve peri-operative efficiency at OCE labs and increase cases/month

Invest in Fellows & Referring HCP Education

- Create robust fellows program
- Increase procedure volume via targeted grass roots education of referring HCPs (cardiologist, ER, etc.)

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METRICS: WHAT YOU MEASURE GETS DONE

Drive OCE

- **OCE penetration:** +10pp vs 18 exit (65%)
- **V6 penetration:** 75%
- **Vizigo:** \$15MM
- **\$/case:** +\$150
- **Surpoint Penetration:** 500 installs, 30% exit PAF penetration

Gain Competitive Share

- **Gain Revenue Share:** 0.5pts
- **Vizigo:** 35% exit share in CARTO FAM/DX w/ Decanav: \$5MM
- **Competitive Mapping Trade-Outs:** 12
- **Competitive account growth:** 15%+, \$15MM+
- **Total RPO growth of 20%. ULS RPO growth of 20%**
- **90 C3 installs, 80 ULS installs**
- Hire 18 Afterburners

Accelerate Procedure Growth

- **CEE:** 200+ physicians/fellows trained
- **Market Dev:** Procedure growth exceeds national average, 1 FB live event/month
- **ULS Pilot:** Hire 3 ULS I/C focused

Enhance Sales Force Effectiveness

- **116+ CAS** expansion
- **Cases/CAS/Mo +1, Cases/POD/mo >market (8%+)**
- **1 RTS/region**
- **1 CAE/region** (hunter CAS)(pilot)
- **1 ATM per Area**
- **Regrettable loss <5%**

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2019 Contest Pillar #1

**OCE**

OCE Penetration Contest

- **STSF+PRN+SS in PAF:**
- Exit Sept '19 +12pts vs Dec '18, maintain avg. in Q4
 - If Dec '18 $\geq 70\%$ +6pts (11 pods)
 - If Dec '18 $\geq 80\%$ +3pts (9 pods)
 - If Dec '18 $\geq 90\%$ maintain (7 pods)
- \$1,000 / POD member

Eligible:**AD/NTM/RBD/RTS/TM/CAS/UCAS**

SURPOINT Contest

- **SURPOINT:** 40% penetration in AFIB Dec '19 Exit
- \$1,000 / POD member

Eligible:**AD/NTM/RBD/RTS/TM/CAS**

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2019 Contest Pillar #2



Competitive Conversion Contest

- **2 Accounts** (+\$350K YoY & 15% growth each), **or Docs in KA** (+60 Cases YoY max 2 docs)

- If 2019 Account - \$5,000 per POD (Q4 run rate + 15%)

- If new Account - \$10,000 per POD

Eligible:
RBD/TM/CAS

Competitive Hardware Bounty

	TM	Lead CAS	UCAS
C3 - swapout	\$2,000	\$1,000	n/a
Bonus: Precision	\$3,000	\$1,500	n/a
Bonus: Rhythmia/CRYO	\$4,000	\$2,000	n/a
VividIQ/SC2000/P500 – purchase / upgrade	n/a	n/a	\$500
Bonus - VividIQ/SC2000/ P500 trade out for Zonare	n/a	n/a	\$1,000

Eligible:
TM/CAS/UCAS

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2019 Organizational Enhancements

Expanding resources to drive growth

Compensation Plan

- No FAB for Sales: \$10K moved to HSS
- Capital +2% TM (4%), +1% RBD (2%), +0.4% AD (0.8%), paid as earned
- CAS FAB: drive case volume vs PY faster than market
- KA CAS \$10K vs \$5K MBO, paid quarterly
- No UCAS FAB, \$2K moved into ULS disposable pool

Spotlight Trip

- 2 per Area per quarter

116+ CAS, 1 RTS/Region, Regional CAE, Promotions 2x per year

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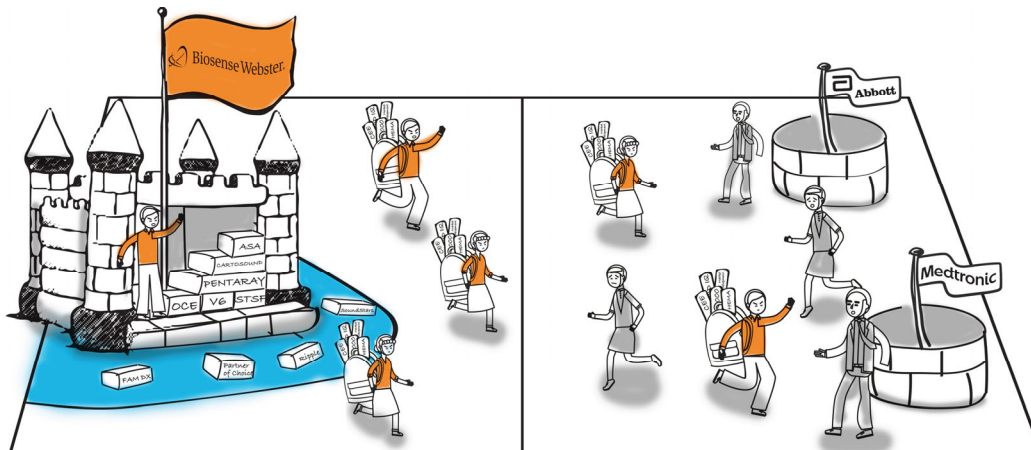
Regional CAE



Goal: Gain competitive share, incremental \$1MM/160 cases per year

Objective: Provide dedicated resources for competitive conversions

Tactics: Win cases from Splitters/Competitive: TM Tags, CAE Bags the target: *tagging and bagging*



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Mindset - Unicorn



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- I am personally committed to ...

- I want **YOU** and each BWI employee to be personally committed to ...

- **We** have resources to ...

LEAD & WIN *with* INTEGRITY

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Talking Points:

- We are market leaders and we want to be seen as leaders also in the way we conduct our business – which is, at the highest ethical standards. We cannot afford to lose trust of the patients, our customers and the general public by doing things that would undermine our Integrity.
- I am personally committed to – and I want each of YOU and each of your people to be personally committed – to Lead & Win with Integrity.
- Regulatory and compliance environment is very complex but we have resources to ensure that we do the right thing. Rest assured that every BWI program – be it sales, marketing or professional education-related – is thoroughly vetted by the relevant internal functions (HCC, Legal, Medical Affairs, Regulatory Affairs, etc.). And, we need to make sure that we execute all those programs within the approved parameters.
- As I said, the environment can be very challenging, and so, it is important that if you have any questions or concerns, you reach out to our HCCO or Legal counterparts for guidance. They are there to help you be successful and Win with Integrity!

Leadership Philosophies

Leadership is about making others better as a result of your presence and making sure that impact lasts in your absence.

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MICHAEL BODNER:

- Quick overview of agenda/purpose
- Why leadership is critical during times of change
- Why everyone in this room must lead their respective teams to success
- Today is the first day of your leadership path going forward

3 Requirements of Leadership



Lou Holtz, football coach, University of Notre Dame

1. Do you care about me?
2. Can I trust you?
3. Are you committed to excellence?

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Can I Trust You?



$$T = \frac{C + R + I}{S}$$

T = Trust

C = Credibility

R = Reliability

I = Intimacy

S = Self Orientation

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JAMI MILLER

[This is from the AMA article about Lou Holtz, “3 Requirements of Leadership” specifically about TRUST]

Can I Trust You? (10-15 minutes)

Once your direct reports are sure that you are committed to personal and professional excellence, they will need to determine whether or not they can trust you. This particular question is especially important, since to a large extent, their livelihood, job satisfaction and future depend on the answer, which obviously needs to be, “yes.” What you’re telling them is, “You can trust me to be:

- open when I can be
- honest and ethical all the time
- predictable when I can be and to admit my mistakes.”

Nobody is perfect, and nobody gets it right every time. Your direct reports know you aren’t perfect; they just don’t tell you that they know. If you try to cover your mistakes, pretend they didn’t happen or, worse yet, blame them on someone else, you can forget about building trust for a long, long time.

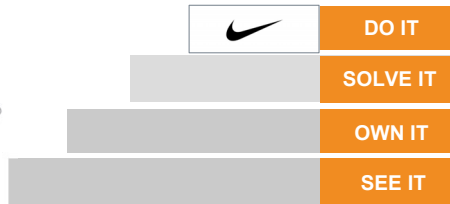
Winston Churchill said it best: “Success is the ability to go from failure to failure without losing your enthusiasm.” Churchill’s name lives on because of his successes, but those who know history understand that he was not without his critics. You won’t be either; it’s just one of the realities of being in

charge.

The Steps To Accountability

Above the line:

Steps to accountability



The Oz principle

THE LINE

Below the line:

The blame game



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It doesn't make sense
to hire smart people
and then tell them
what to do; we hire
smart people so they
can tell us what to do."

- Steve Jobs



LEADERSHIP AND EMPOWERMENT

Leaders empower others to act.

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THANK YOU



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Message

From: Aaron DeTate [aarondetate@outlook.com]
Sent: 1/15/2024 1:26:12 PM
To: Jay Farris [jfarris@innovative-health.com]
CC: Dave Distel [ddistel@innovative-health.com]
Subject: [EXTERNAL]FW: Updated RPO ULS Coverage Policyler
Attachments: 097317-220518 BWI Coverage Policy Update (1).pdf

Jay here is the letter as well as some correspondence with the Biosense Rep where he clearly states Reprocessed Acunavs are ok to use.

From: Beebe, Tyler [BWIUS] <TBeebe@ITS.JNJ.com>
Sent: Thursday, March 16, 2023 6:05 PM
To: Detate, Aaron <Aaron.Detate@tmmc.com>
Cc: Benis, Emma [BWIUS] <EBenis@ITS.JNJ.com>; Rocha, Eduardo <Eduardo.Rocha@tmmc.com>; Ollivier, Ann [BWIUS] <AOllivie@its.jnj.com>
Subject: RE: Updated RPO ULS Coverage Policyler

Aaron,

I've attached the coverage policy. Happy to connect you with our Area Vice President, Ben Berkowick, for more clarification as needed.

Thanks for your help with this – let me know what you need.

Tyler

From: Detate, Aaron <Aaron.Detate@tmmc.com>
Sent: Thursday, March 16, 2023 3:20 PM
To: Beebe, Tyler [BWIUS] <TBeebe@ITS.JNJ.com>
Cc: Benis, Emma [BWIUS] <EBenis@ITS.JNJ.com>; Rocha, Eduardo <Eduardo.Rocha@tmmc.com>
Subject: [EXTERNAL] RE: Updated RPO ULS Coverage Policyler

Tyler,
Thank you for the update, on this.

I must say I am not sure how a Soundstar that is not communicating with the Carto system is any different than a Acunav.

But I look forward to hearing the rationale behind this.

Can you send over a revised case coverage policy on company letterhead with this updated statement and explanation. Then I can forward that along to my supply chain and legal department.

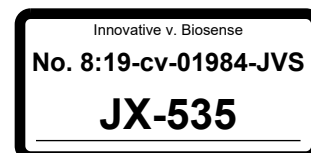
Aaron DeTate

Cardiac Cath Lab-EP Specialist

714-642-3125 cell

310-784-4937 work

aaron.detate@tmmc.com



From: Beebe, Tyler [BWIUS] <TBeebe@ITS.JNJ.com>
Sent: Thursday, March 16, 2023 12:59 PM
To: Detate, Aaron <Aaron.Detate@tnmc.com>
Cc: Benis, Emma [BWIUS] <EBenis@ITS.JNJ.com>
Subject: Updated RPO ULS Coverage Policy

Hey Aaron –

Just heard about this today and wanted to pass it along –

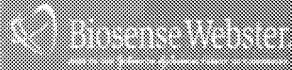
BWI just passed down guidance on CAS coverage for support of RPO SoundStar – we are not allowed to support a case using RPO SoundStar, even if it not being used for visualization or contours, unless it is Sterilemed RPO. We are still allowed to support cases using Acunav RPO by any vendor, and of course OEM SoundStar.

I know in the past we have been supporting the Innovative Health RPO SoundStar and simply disabling visualization, contours, etc. Unfortunately this is something we are no longer allowed to do. In my mind, the best alternative for you is to use Innovative Health RPO Acunav for those cases where you previously would have used the RPO SoundStar, but I am happy to talk about other alternatives.

Let me know when you will be in the lab, and I'll stop by to talk in person. I'm also happy to put you in touch with anyone in BWI leadership to discuss this – I can set up a meeting in-person or virtual.

Thank you –
Tyler

Territory Manager
Los Angeles County
(720) 244-5419



Biosense Webster, Inc.
31 Technology Drive,
Suite 200
Irvine, CA 92618 USA
www.biosensewebster.com

Date: 03/16/2023

RE: Position Statement on Clinical Account Specialist Case Support of Reprocessed Single Use Devices (SUD)

Dear Valued Customer,

This letter is to inform you of Biosense Webster, Inc.'s position regarding case support of reprocessed Single-Use-Devices (SUD) distributed by third parties. Biosense Webster's commitment to providing high-quality products and services requires that we properly train all Clinical Account Specialists on the capabilities, limitations, and proper functioning of all our devices and equipment. Electrophysiologists ask Clinical Account Specialists to assist with reconstructing cardiac anatomy using our technology and interpreting maps and providing insight on the images generated by the CARTO® 3 System. It is critical that our personnel possess a competent base of knowledge of the design intent of each device feature and a thorough understanding of how each device is designed to work with our capital equipment to help achieve the best possible outcome for each patient. This base of knowledge is especially important when it comes to providing product technical support for the CARTO® 3 System and troubleshooting the CARTO® 3 System in the midst of a procedure, which requires accurate inputs from diagnostic mapping catheters, ultrasound catheters, and devices that utilize a CARTO-based software pairing. Most hospital facilities also recognize the critical nature of vendor product competency as it relates to patient safety and consequently require vendor representatives to provide documentation attesting to their competency with their company's products as part of the vendor credentialing process. Reprocessing is a manufacturing process regulated by the U.S. Food and Drug Administration, and reprocessed single use devices generally require a new regulatory submission before they can be distributed. The regulatory clearance for reprocessed devices is owned by the reprocessing company that manufactures and distributes the devices, not the original equipment manufacturer. Therefore, once Biosense Webster's single use devices are subjected to the reprocessing process of another company, those devices are no longer our products.

To offer our customers a portfolio of both new and reprocessed devices, Biosense Webster, Inc. has partnered with a reprocessing company that is also a member of the Johnson & Johnson Family of Companies. We have shared our calibration methods and product testing methods with our affiliated reprocessing company, and we distribute those products along with new Biosense Webster devices. We are confident that the reprocessed devices we distribute meet our quality standards. However, we have no knowledge of the manufacturing operations or specifications of reprocessed devices manufactured by third parties with which we are not affiliated. As such, Biosense Webster cannot attest to the safety, effectiveness, and accuracy of these devices.

Accordingly, our Clinical Account Specialists can only provide product technical support in cases that use diagnostic mapping catheters, ultrasound catheters, and devices that utilize a CARTO-based software pairing distributed by Biosense Webster. Our Clinical Account Specialists understand the capabilities, limitations, and proper functioning of these devices and are able to deliver on our commitment of high-quality support for these products.

For any questions related to the information contained in this letter, please contact your local Biosense Webster, Inc. representative.

Thank you for your continued partnership and for choosing Biosense Webster, Inc.

Sincerely,

Biosense Webster, Inc.

097317-220518

From: Garcia, Mario [BWIUS] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D6F2C5D2CB3843AF8D523179A70B7EFC-MGARCI59>
To: Shalgi, Avi [BWIL]
CC: Giles, Cruz [BWIUS]; Hsueh, Hugh [BWIUS]; Tang, Raymond [BWIUS]; O'Sullivan, Martin [BWIUS]; Stanley, Mark [BWIUS]; Kuhns, Jesse [BWIUS]; Kelly, Christopher [BWIUS]; Bruce, Doug [BWIUS]; Atias, Meiron [BWIUS]
Sent: 4/11/2018 6:11:18 AM
Subject: RE: Ad-Hoc PIB for Vizigo Gate 3 & 5
Attachments: RE: Vizigo EEPROM

Hello Avi,

Attached an email that helps as a follow up to your question in regards to the decision of not implementing the Falcon EEPROM (secured EEPROM) into Vizigo that came up during the meeting this Monday, please take into account that this assessment was done at the end of May last year so a new assessment would be required for current system capabilities and implementation timelines should that be the path that the team elects to take.

Thank you in advance for your time and help.

Best Regards

Mario Garcia

-----Original Appointment-----

From: PIB [BWIUS]

Sent: Monday, April 9, 2018 10:18 AM

To: PIB [BWIUS]; Giles, Cruz [BWIUS]; Hsueh, Hugh [BWIUS]; Tang, Raymond [BWIUS]; Garcia, Mario [BWIUS]; O'Sullivan, Martin [BWIUS]; Stanley, Mark [BWIUS]; Kuhns, Jesse [BWIUS]; Kastin, Vadim [BWIUS]; Kelly, Christopher [BWIUS]; Bordley, Diana [BWIUS]; Bishara, Moe [BWIUS]; Rabbitt, Margot [BWIUS]; Darling, Stacey [ASPUS]; Soto, Nathan [ASPUS]; Bruce, Doug [BWIUS]; Shalgi, Avi [BWIL]; Dickinson, Mark [BWIUS]; McInnis, Kendra [BWIUS]

Subject: FW: Ad-Hoc PIB for Vizigo Gate 3 & 5

When: Monday, April 9, 2018 4:00 PM-5:00 PM (UTC-08:00) Pacific Time (US & Canada).

Where: CR-GC-USIrwindale, Bldg 15815, Rm 712 (15); Bldg 25B1, Rm 1030 (12)

-----Original Appointment-----

From: PIB [BWIUS]

Sent: Wednesday, April 4, 2018 1:36 PM

To: PIB [BWIUS]; O'Sullivan, Martin [BWIUS]; Stanley, Mark [BWIUS]; Kuhns, Jesse [BWIUS]; Kastin, Vadim [BWIUS]; Kelly, Christopher [BWIUS]; Bordley, Diana [BWIUS]; Bishara, Moe [BWIUS]; Rabbitt, Margot [BWIUS]; Darling, Stacey [ASPUS]; Soto, Nathan [ASPUS]; Bruce, Doug [BWIUS]; Shalgi, Avi [BWIL]; Dickinson, Mark [BWIUS]; McInnis, Kendra [BWIUS]

Subject: Ad-Hoc PIB for Vizigo Gate 3 & 5

When: Monday, April 9, 2018 4:00 PM-5:00 PM (UTC-08:00) Pacific Time (US & Canada).

Where: CR-GC-USIrwindale, Bldg 15815, Rm 712 (15); Bldg 25B1, Rm 1030 (12)

All – Your attendance is requested to review the Stage Gate 3 & 5 presentations for the Vizigo project. I have only invited the team presenting as well as the required PIB Quorum. Please forward to an additional attendees are required.

-- Do not delete or change any of the following text. --

Ad-Hoc PIB Meeting
Monday, April 09, 2018, 3:30 PM | 2 hr
(UTC-08:00) Pacific Time (US & Canada)

JOIN USING ONLINE MEETING

Go to:

REDACTION: OTHER

Meeting number **REDACTION: OTHER**

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Video address:

REDACTION: OTHER

GLOBAL CONNECT ROOMS INVITED
CR-GC-USIrvine, Bldg 25B1, Rm 1030 (12)
CR-GC-USIrwindale, Bldg 15815, Rm 712 (15)

AUDIO CONNECTION

Toll ----
Toll-free **REDACTION: OTHER**

Access code **REDACTION: OTHER**

Global call-in numbers:

REDACTION: OTHER

IMPORTANT NOTICE: This online meeting service includes a feature that allows audio and any documents and other materials exchanged or viewed during the session to be recorded. By joining this session, you automatically consent to such recordings. If you do not consent to the recording, discuss your concerns with the meeting host prior to the start of the recording or do not join the session. Please note that any such recordings may be subject to discovery in the event of litigation.

From: Goldstein, Avichai [BWIL] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7AB2057E2BE497DB0301795EF759E85-AGOLDSTE>
To: Garcia, Mario [BWIUS]
CC: Tang, Raymond [BWIUS]; Atias, Meiron [BWIUS]; Goldenberg, Ilan [BWIL]; Hen, Tomer [BWIL]
Sent: 6/13/2017 2:09:06 PM
Subject: RE: Vizigo EEPROM

Hi Mario,

Last time I had an AI to verify if we need to change the CARTO version for supporting your requirement! I am afraid things are not easy as we think; releasing another SW branch is complicated especially when we handle US and non US V6 revisions.

I have received an answer from SW management that we do need to make a CARTO change for supporting your below requirement. I have discussed also with Pesach and we are not planning to add such a support. (version is closed and the new coming version is about to close as well)

At this point changing the EEPROM burner station is at risk in timelines if we open it and add support; please note that there are the possible additional risks that we did not think of.

Regarding working with a non-locking EEPROM means repeating V&V and PODs; we do not have any resources for performing it.

Regards,
 Avichai

From: Garcia, Mario [BWIUS]
Sent: Tuesday, June 13, 2017 1:36 AM
To: Goldstein, Avichai [BWIL] <agoldste@its.jnj.com>
Cc: Tang, Raymond [BWIUS] <rtang10@ITS.JNJ.com>; Atias, Meiron [BWIUS] <matias29@ITS.JNJ.COM>
Subject: RE: Vizigo EEPROM

Hello Avichai,

I do not understand how one thing relates to the other, last time we spoke, you indicated that Carto can work with the locking EEPROM even if used as a "normal" (non-lockable) EEPROM, with that being the case, we discussed it was just a timeline issue. The criticality of introducing the Falcon EEPROM into the Vizigo platform is so it is part of the design ASAP and then just wait for the Carto version to handle the locking mechanism to be released and implement the locking later on.

Thank you in advanced for your time and help.

Best Regards

Mario Garcia

Sr. Engineer, New Process Development

T. 1-909-839-8830

E. mgarci59@its.jnj.com

From: Goldstein, Avichai [BWIL]
Sent: Sunday, May 28, 2017 4:02 AM
To: Garcia, Mario [BWIUS] <MGarci59@ITS.JNJ.COM>; Pressman, Assaf [BWIL] <apressm1@ITS.JNJ.COM>
Cc: Stanley, Mark [BWIUS] <MStanley@ITS.JNJ.COM>; Susel, Pesach [BWIL] <psusel@its.jnj.com>; Tang, Raymond [BWIUS] <rtang10@ITS.JNJ.com>; Edrei, Yinon [BWIL] <yedrei@ITS.JNJ.COM>; Atias, Meiron [BWIUS] <matias29@ITS.JNJ.COM>; Goldenberg, Ilan [BWIL] <igoldenb@its.jnj.com>; Noam Shapira

Hi Mario,
I was OOO on vacation for a long time.
Please note that I have clarified with the team and the CARTO® does not support the locking meaning that even if we develop a new EEPROM Burner then the CARTO will not stamp the EEPROM; doing this is opening a CARTO application version which is not planned as the version is released.
I do not think there is a point to continue with the below due to the above,
Avichai

From: Garcia, Mario [BWIUS]
Sent: Wednesday, May 17, 2017 6:14 PM
To: Goldstein, Avichai [BWIL] <agoldste@its.jnj.com>; Pressman, Assaf [BWIL] <apressm1@ITS.JNJ.COM>
Cc: Stanley, Mark [BWIUS] <MStanley@ITS.JNJ.COM>; Susel, Pesach [BWIL] <psusel@its.jnj.com>; Tang, Raymond [BWIUS] <rtang10@ITS.JNJ.com>; Edrei, Yinon [BWIL] <yedrei@ITS.JNJ.COM>; Atias, Meiron [BWIUS] <matias29@ITS.JNJ.COM>; Goldenberg, Ilan [BWIL] <igoldenb@its.jnj.com>; Noam Shapira (noam@smart-solutions.co.il) <noam@smart-solutions.co.il>
Subject: RE: Vizigo EEPROM

Hello Avichai,

Last time we met I clarified the main driver of implementing the Falcon EEPROM is preventing our competitors to reprocess the Vizigo Sheath and not as previously understood as to reprocess them ourselves, and you requested a couple of weeks to follow up with the HTC team to assess the different scenarios we discussed, since those couple of weeks have gone by could you please provide an update those items and their timelines?

Quick reminder of the three situations you were going to review with the team:

1. Replace current EEPROM with Falcon EEPROM ASAP without the locking process in place since they both behave the same when not locked, allowing us to in parallel develop the locking mechanism in the EEPROM burner, which as discussed should be easy and quick from the technical point of view plus whatever is the average process time for such ECO revising the EEPROM burner software.
2. Replace current EEPROM and if the timeline of the software revision allows it, implement before launch or ASAP after launch.
3. Do not replace current EEPROM and launch without it while in parallel working on the development of the EEPROM software, implementing the Falcon EEPROM as soon as the timelines allow.

As discussed in the meeting each scenario has its own risks and timelines that would either allow their execution or not within the project timelines, and for all of them we would need to present them to the rest of the team to see what other impacts the "chosen" scenario will bring, looking forward to your response.

Assaf,

I just saw a note that Avichai is on vacation so could you please let us know who from the HTC team can follow up with this matter?

Thank you in advanced for your time and help.

Best Regards

Mario Garcia
Sr. Engineer, New Process Development
T. 1-909-839-8830
E. mgarci59@its.jnj.com

From: Goldstein, Avichai [BWIL]

Sent: Wednesday, April 19, 2017 11:47 PM

To: Garcia, Mario [BWIUS]

Cc: Stanley, Mark [BWIUS]; Susel, Pesach [BWIL]; Tang, Raymond [BWIUS]; Edrei, Yinon [BWIL]; Atias, Meiron [BWIUS]; Goldenberg, Ilan [BWIL]; Noam Shapira (noam@smart-solutions.co.il)

Subject: RE: Vizigo EEPROM

Mario,

I'll try to make order as perhaps I was not so clear; our reprocessing unit is the CCS so we have no choice but using it for the sheath reprocessing even if it is not a magnetic catheter; meaning we shall need to add its PN to the reprocessing process.

CCS as part of the PN also locks the EEPROM; as the sheath is burnt using the EEPROM burner and it does not have any SW for locking the EEPROM, the risk that one can take the unlocked VIZIGO chip and install it on a used catheter and as this EEPROM is not unlocked, the catheter can be reused in CARTO for unlimited times, is still valid.

The decision back at the time was to continue with not supporting the falcon chip. If we change the decision now, my personal recommendation is to perform business risk analysis and understand the timelines as DHF for the EEPROM burner will take months as mentioned below.

Having the fact that the falcon chip was tested as a standalone or on a catheter and not testing it in VIZIGO is not something I recommend to count on. Out of my experience over the years we have learned that what is not tested is not working.

There is a huge process for the supporting of the VIZIGO which will definitely shall include verification; please note we shall need also to perform repression tests.

Ilan and Noam I appreciate your comments as well

BR,
Avichai

From: Garcia, Mario [BWIUS]

Sent: Wednesday, April 19, 2017 7:00 PM

To: Goldstein, Avichai [BWIL] <agoldste@its.jnj.com>

Cc: Stanley, Mark [BWIUS] <MStanley@ITS.JNJ.COM>; Susel, Pesach [BWIL] <psusel@its.jnj.com>; Tang, Raymond [BWIUS] <rtang10@ITS.JNJ.com>; Edrei, Yinon [BWIL] <yedrei@ITS.JNJ.COM>; Atias, Meiron [BWIUS] <matias29@ITS.JNJ.COM>

Subject: RE: Vizigo EEPROM

Attached the files for ease of access, and a screenshot of the description of the ECO that contains all this info below, keep in mind this was done for the falcon project in which it is being implemented in the Penta Ray NAV catheter family, and I am suggesting we use the same strategy for Vizigo, from all the topics touched in the previous e-mail, the only one I do not have any documentation on is the EEPROM burner.

Note: DM-2824-92F in Agile will be M-5836-02 in cPDM.

ECO-0032635: Properties

Owner	ARMENTA, MARY (marment1)
Originator	GARCIA, MARIO (mgarci59)
State	Approve
ECO Description	1) Create Part M-5836-02 and release it to Rev. A. 2) Create Material specification M-5836-00 and release it to Rev. A. 3) Obsolete M-5836-01 material specification document only. 4) Include M-5836-01 part number on M-5836-00.
Change Type	Design
Approval Type	General
Affected Site	All
Affected Product Family	PentaRay NAV 7FR Catheter (D-1282)
Reason For Change	Other
Describe Reason for Change	1) Part needs to be setup in our system before it can be used and for its part qualification. 2) Keep the same part numbers within one document in case they required revisions in the future. 3/4) Obsolescing M-5836-01 document only. The part will remain active and will be included in future revisions. 1,2,3,4) Catheter specific EEPROM's register serialization, Enhances OEM identification, and a V&V documents are under the "Attached Files" of this ECO, altogether with documentation per M-5836-02. A) EEPROMs drawing B) CCS release notes (UG-9900-040). C) "Falcon" EEPROM testing at HTC (REP8001). D) Vendors letter. E) Change assessment with signatures
Justification for Change	Protocols under "Related Protocols" section are the IQ, OQ and PQ performed in one of the CC documents. *As part of the requirements per FORM-0960 a full text search was performed using the existing ECO that is impacted by such changes. This full text search is attached to this ECO under "Attachments".
Verified or Validated	Yes (Attach data or application test report no)
Priority	Normal
Priority Justification	
Comments	All action tasks associated with obsolescing a M-Spec are not applicable as the document for M-5836-01 is obsolete.
Affected Regions	Not Applicable
PMA Annual Reports	Not Reportable
Regulatory Comments	This ECO is to take a new raw material part to production level. This part is not being added to replace an existing part. This ECO does not impact any device specifications, device functionality, manufacturing flow diagrams, manufacturing process, or product recall. This ECO is not a response to serious adverse event, product malfunction, or recall. As such, no regulatory action is required.

Mario Garcia

Sr. Engineer, New Process Development

T. 1-909-839-8830

E. mgarci59@its.jnj.com

From: Garcia, Mario [BWIUS]**Sent:** Wednesday, April 19, 2017 6:56 AM**To:** Goldstein, Avichai [BWIL]**Cc:** Stanley, Mark [BWIUS]; Susel, Pesach [BWIL]; Tang, Raymond [BWIUS]; Edrei, Yinon [BWIL]; Atias, Meiron [BWIUS]**Subject:** Re: Vizigo EEPROM

Thank you for your quick response Avichai,

I believe we need a meeting to discuss further, first of all we already have a POD for the "Falcon" EEPROM I am suggesting to be used (you can reference REP attached and specifications of M-5826-02 in cPDM inside ECO-0032635 for the details), this EEPROM is already setup in the CCS (validations attached to ECO-00032635), although I do not understand why would it matter for Vizigo since CCS is not needed for the Vizigo sheath, and last but not least from what I recall from a previous conversation with Noam and you about the EEPROM Burner was that it was ready to communicate with the "Falcon" EEPROM so maybe after reviewing the specification for what I am referring to as the Falcon EEPROM we can reassess accordingly.

Mario G.

On Apr 19, 2017, at 3:04 AM, Goldstein, Avichai [BWIL] <agoldste@its.jnj.com> wrote:

Guys,
There is a risk doing it as one can take the unlocked VIZIGO chip and install it on a used catheter and as this EEPROM is not unlocked, now the catheter can be reused in CARTO for unlimited times!!
Part of the development is to add to the EEPROM burner the code for locking the EEPROMS. According to the latter, until development is not finished this risk applies!
Let's assume we take the risk and install it then, we will need to repeat some POD tests and some functional tests as the EEPROM was replaced.
In addition supporting the falcon chip would require a new EEPROM Burning station SW and there is plenty of code to write (as this is not a minor change).
In addition we will need the CCS supporting the locking the EEPROM.
Releasing a new EEPROM burner will take lots of months as we would need to develop a new DHF for it.
For CARTO it is transparent as long as we keep the same D-specs thought we will need to test the recognition is well.

We have discussed it I think a year ago or more; now to my opinion is too late going this direction

FYI,
Avichai

From: Stanley, Mark [BWIUS]**Sent:** Monday, April 17, 2017 10:52 PM**To:** Goldstein, Avichai [BWIL] <agoldste@its.jnj.com>; Susel, Pesach [BWIL] <psusel@its.jnj.com>**Cc:** Tang, Raymond [BWIUS] <rtang10@ITS.JNJ.com>; Garcia, Mario [BWIUS] <MGarci59@ITS.JNJ.COM>**Subject:** Vizigo EEPROM

Avichai,

If we were to switch to the Falcon EEPROM for Vizigo, will that require a software update for CARTO?

-Mark

From: Koenig, Joseph [SYNNA] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=374e1a0355c747ac884d8fa91aa4a811-JKOENIG4>
To: Landers, Andrew [ETHUS]
Sent: 6/27/2018 11:13:15 PM
Subject: CPC Request - Expand ULS Buyback program to Decanav and Pentaray
Attachments: CPC - Add DecaNav and Pentaray to Buyback Program.pptx

Andrew-

Could you give me your thoughts on this request? Would love your thoughts/support prior to submitting to the full committee. Any feedback would be greatly appreciated.

Joe Koenig

Product Director, Sustainability

M. (714) 878-1975

E. jkoenig4@its.jnj.com

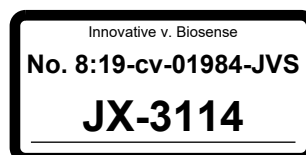
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33 Technology Drive

Irvine, CA 92618, USA

www.biosensewebster.com



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CPC – Expand ULS Buyback program to include DecaNav & Pentaray

June 27, 2018

Current Situation

Current Situation

- Innovative Health, an independent SUD (single use device) Reprocessor, has just received 510k approval to reprocess BWI DecaNav Catheter
- We suspect that multiple competitive SUD Reprocessors are actively working to submit Pentaray 510k's within the next 12 months
- Current Rolling 12 sales of DecaNav are \$9.5M, growing at 33% over PY
- Current Rolling 12 Sales of Pentaray are \$90.2M, growing at 39% over PY
- Typical RPO device ASP is 50% of OEM ASP
- Today we have a ULS buyback program available to single use accounts
 - In place to bolster RPO supply and limit supply from competitors
 - Buy back for \$100/catheter
 - Pay CAS \$15/catheter

Request, Impact & Justification

Request

- Expand ULS Buyback program to include DecaNav and Pentaray
- Buy from Pentaray and DecaNav from account for \$75/unit
- Pay CAS \$15/unit for collections

Impact

- Projected annual financial impact @\$75/unit to account and 15\$/unit to CAS :
 - Pentaray: \$133,052
 - DecaNav: \$24,598
 - Based on analysis of proportion of ULS customers/units to total

Justification

- Incentivizing customers for collections will increase BWI supply and restrict supply from competitors
- Mitigate immediate risk of negative impact to \$100M combined OEM business from competitive reprocessed devices

Backup Data

Impact Assessment Comparing to ULS

ULS Buyback Customers	Total SUD ULS Customers	Buyback customers percentage of total			
16	672	2.4%			
Total Rolling 12 ULS units bought back	Total Rolling 12 OEM ULS Units sold	Percentage of total ULS SUD bought back	Annual \$ Impact @ \$100/catheter	CAS Payment \$15/catheter	Total Annual \$ Impact
2630	92802	2.8%	\$263,000.00	\$39,450.00	\$302,450.00
Total SUD DecaNav Customers	Potential DecaNav Buyback Customers				
269	6				
Total Rolling 12 OEM DecaNav Units sold	Potential DecaNav Buyback units	Potential Annual \$ Impact @ \$75/Catheter	Potential Annual Impact CAS Payment @ \$15/catheter	Total Potential Annual \$ Impact	
9644	273	\$20,498	\$4,100	\$24,598	
Total SUD Pentaray Customers	Potential Pentaray Buyback Customers				
495	12				
Total Rolling 12 OEM Pentaray Units Sold	Potential Pentaray Buyback Units	Potential Annual \$ Impact @ \$75/Catheter	Potential Annual Impact CAS Payment @ \$15/catheter	Total Potential Annual \$ Impact	
52165	1478	\$110,876	\$22,175	\$133,052	
Total Projected Annual Impact		\$157,650			

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Certified Performance Portfolio

National Training Meeting
January 30, 2016



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Why Did We Start Doing This?

Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs. In order to maintain reasonable prices, Customers' orders must be serviced promptly and our suppliers and distributors must be paid promptly. Our suppliers and distributors must make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfill their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management and their actions must be just and fair.

We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens — support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

patients

customers

communities

shareholders

 **Biosense Webster**
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

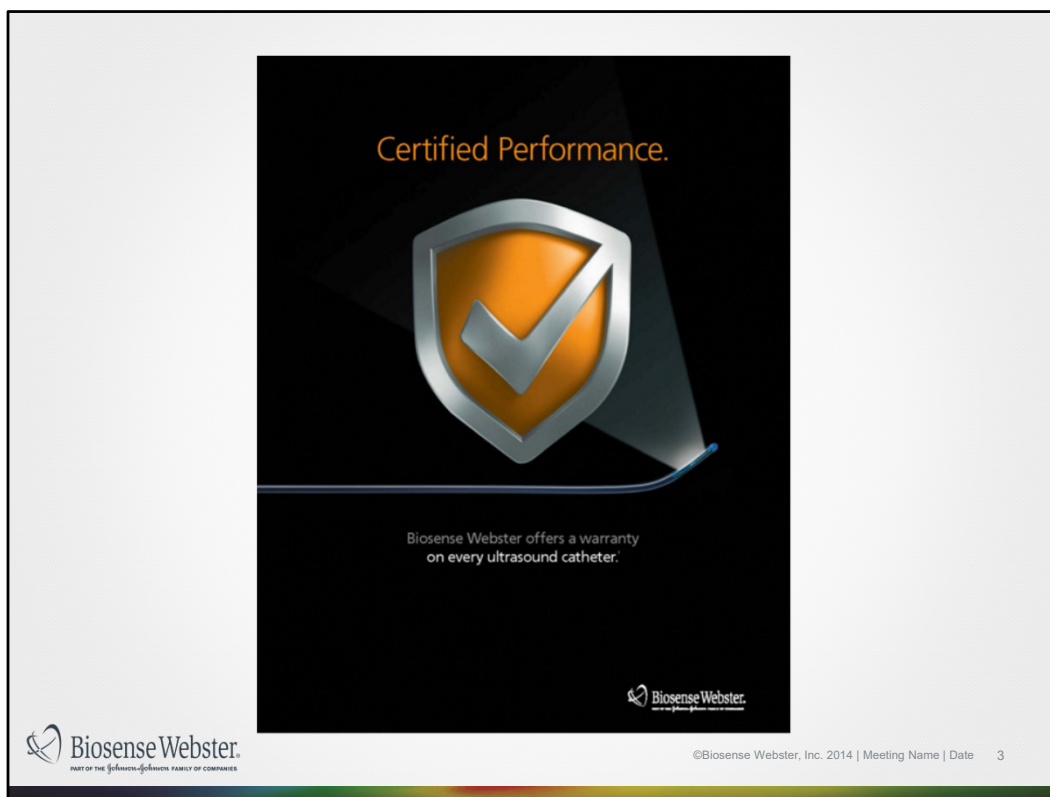
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Patients: By providing quality ultrasound catheters that have passed our performance criteria we ensure patient safety

Customers: Hospitals need to consider costs as we know reprocessing is here to stay.

Communities: Customers looking for sustainable solutions

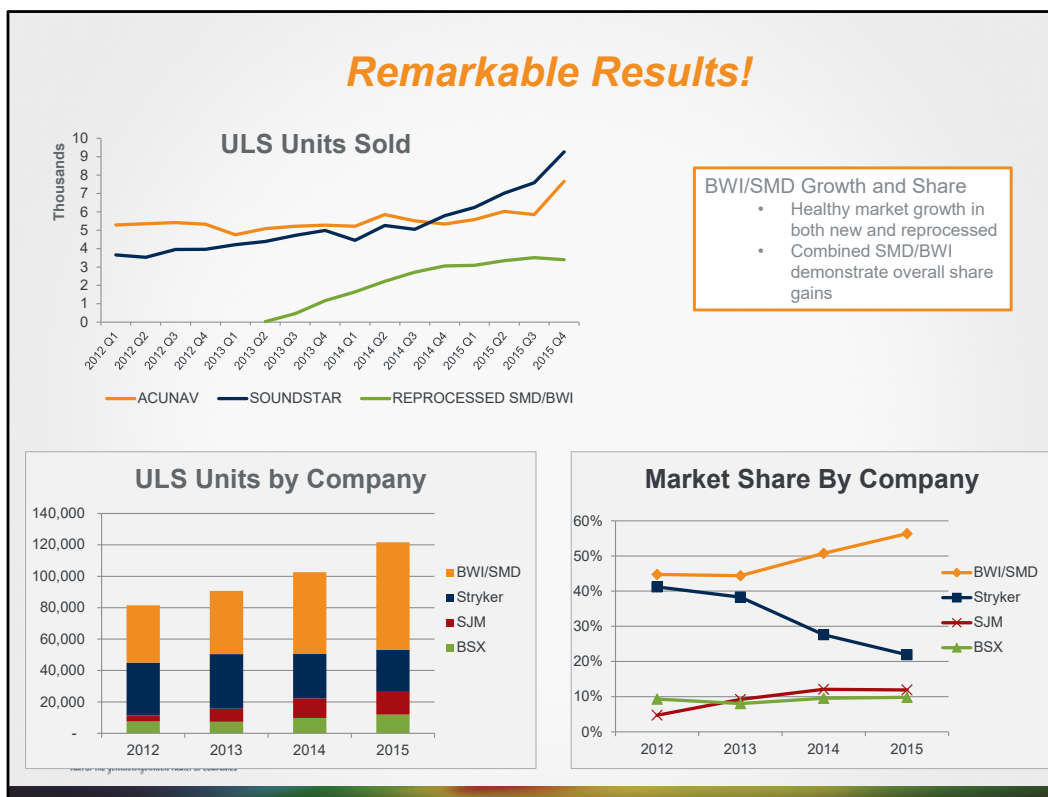
Shareholders: Every reprocessed catheter sold contributes to bottom line



At launch ULS was growing 2-3% each year

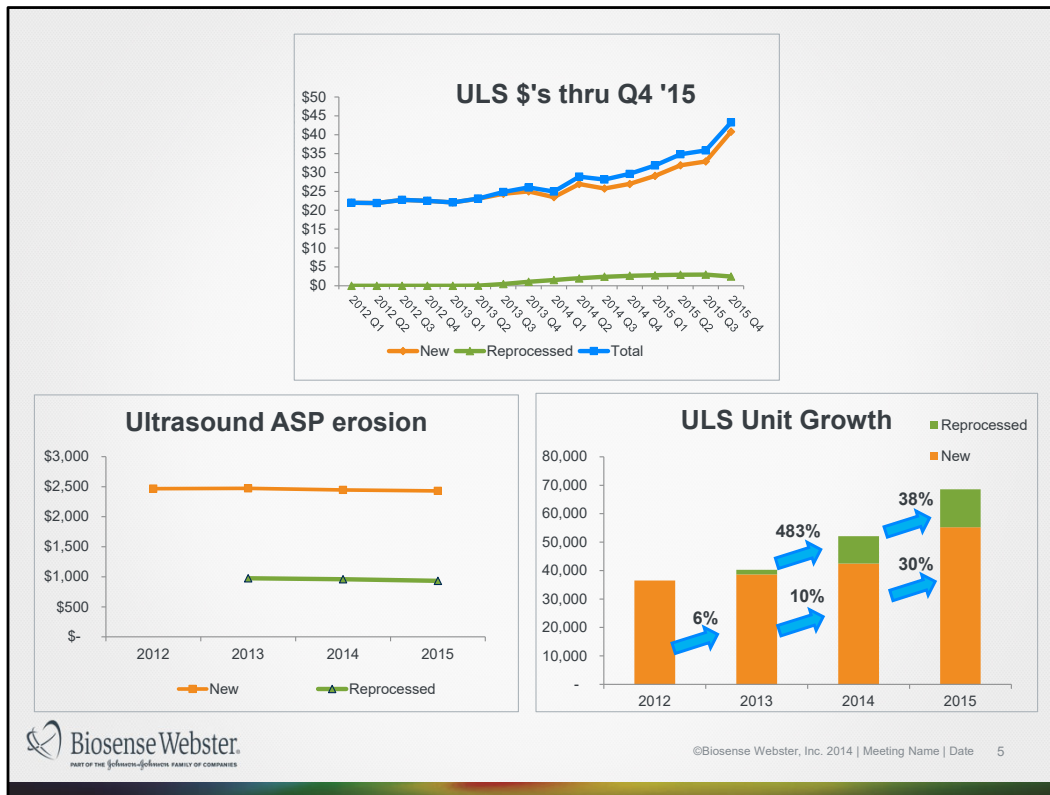
We wanted to offer customers a simple solution for all their EP lab needs by providing a way to purchase a portfolio of new and reprocessed EP lab products.

The goal of this program is to increase customer loyalty to BWI products, and thereby increase BWI share and revenue



Demonstrate the Impact of the Program

- Success taking share from Stryker
 - Ex: Stryker has stopped selling Acunav 10F due to supply constraints (caused by BWI collections)



Additional Share Info

Share of Reprocessed Market	2012	2013	2014	2015
Stryker		95%	75%	67%
SMD/BWI		5%	25%	33%

Share of OEM Market	2012	2013	2014	2015
BWI	76%	71%	66%	68%
SJM	8%	15%	19%	18%
BSX	16%	13%	15%	15%

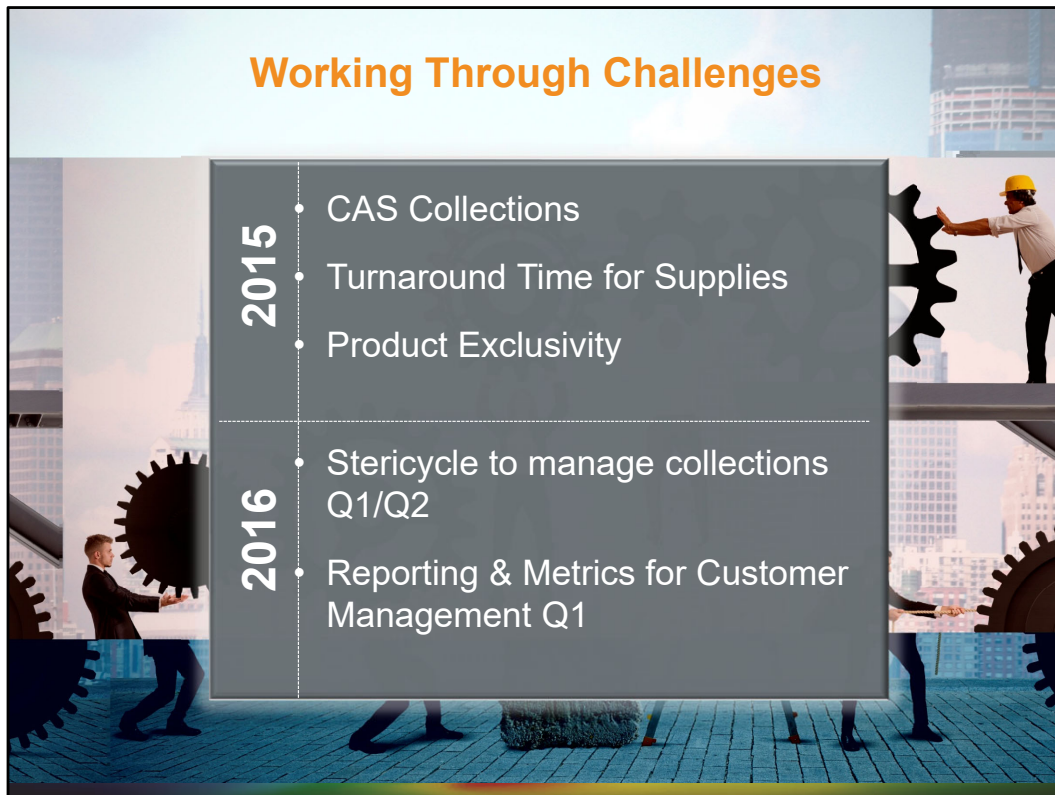


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Sandor Palfi



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- Adding CAS Collections
- Collections turnaround time for bins, supplies
- Reports & Dashboard accuracy (reports will now be automated and have 1 week delay in collections rather than 1 month)
- Customers blocked from ordering ULS in SMD system to reduce confusion and competition between field forces
- In 2016 Stericycle will take over collections for SMD's ASR's. Customers have been notified. No action required from BWI team.
- We are working to improve reporting and metrics to improve dashboard accuracy

Market Landscape



Stryker

- Estimated 15K LASSO® catheters in 2016
- Variable customer experience

Customers

- View reprocessed catheters as safe and a way to cut costs
- Focused on lowering costs to meet triple aim guidelines

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Reprocessing isn't going away



Understand how products were selected

- VOC research journey and highlights
 - In total, 10 Electrophysiologists and 28 Administrator types participated
 - Program Interest & Opinions: Introduction of the program was supported by strong positive reactions from respondents
 - For many participation was dependent on overall cost savings, Physician buy-in & how it would impact other reprocessing efforts in hospital
 - Unprompted, customers named quality, cost, support and guarantee as the reason they were most interested in the program
 - The majority of respondents would like the Full EP Portfolio discount; this was the highest rated option. Other options included savings off new catheters, annual rebates, and blended pricing

In summary – we are providing customers what they asked for.
Anticipating customer excitement around the expanded offering

Program Requirements Refresh

- **2:1 ratio**


Customer must purchase a minimum of 1 new catheter for every 2 reprocessed catheters they purchase

- **80% returns requirement**

Customers must return 80% of the new products they purchase




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Expansion in 2016

		<u>Now</u>		<u>Future</u>	
		Sell	Collect	Sell	Collect
Certified Performance	SS & ACUNAV ULS	✓	✓	✓	✓
	WEBSTER® CS Catheter	✓	✓	✓	✓
	LASSO® Catheter			✓	✓
	SOUNDSTAR® eco 8F Catheter			✓	✓

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Target Customer: Certified Performance



1 Customer currently purchasing reprocessed products from **Stryker**

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Clarify rebate target

Over 250 Soundchoice customers also purchase Lasso and/or CS

Key Segments:


1. Current Sound Choice Customers that currently purchase Lasso and/or CS catheters from Stryker
2. Current Stryker customers that have not converted ULS business to BWI

Single use customers are not a target. However, when a single use customer initiates a discussion on reprocessing we want to serve them as well



Expansion in 2016


		<u>Now</u>		<u>Future</u>	
		Sell	Collect	Sell	Collect
Certified Performance	SS & ACUNAV ULS	✓	✓	✓	✓
	WEBSTER® CS Catheter	✓	✓	✓	✓
	LASSO® Catheter			✓	✓
	SOUNDSTAR® 8F eco Catheter			✓	✓

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Collections Rebate


		<u>Now</u>		<u>Future</u>	
		Sell	Collect	Sell	Collect
Certified Performance	SS & ACUNAV ULS				
	WEBSTER® CS Catheter				
	LASSO® Catheter				
	SOUNDSTAR® 8F eco Catheter				

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Collections Rebate				
<u>Now</u>		<u>Future</u>		
	Sell	Collect	Sell	Collect
SS & ACUNAV ULS		✓		
LASSO® Catheter		✓		



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Collections Rebate

Now

	Sell	Collect	
SS & ACUNAV ULS		✓	
LASSO® Catheter		✓	



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Details of Collections Rebate

Timing	March 1 – June 1
ULS Target Customers	Single use customers who purchase new ULS from BWI. <i>Current Sound Choice customers are not eligible for a Collections Rebate on ULS products</i>
LASSO Target Customers	Single Use LASSO® customers, or purchase LASSO from Stryker
Rebate Amount	\$25 / LASSO (<i>list of all product families in backup</i>) \$75 / ULS (<i>list of all product families in backup</i>)



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Specify LASSO vs ULS target customer

Rebate Payout

- Customer must sign rebate agreement in order to be eligible for the program
- Rebate will be processed within 90 days from the end of measurement period
- SMD and BWI Marketing will reconcile and provide collection report necessary to validate rebate amount
- HCS will process rebate payment and send check to the account



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Send reminder end of June to remind you to send all catheters by June 1; postmarked
Remove Cas training

This program will run from March 1 – June 1

The rebate will be a cash payment to customers at the end of the three months

\$25/Lasso & \$75/ULS

We have made sure this will be easy for you. Here is what you need to do:

- First, Identify the accounts that would be the right targets. Do this right away and make sure this is completed by the end of Feb.
- Second, Request the contract through the contracts mailbox on March 1, which is the start date of this program
- Third, return the signed contract to the contracts mailbox

At this point your account the account will be setup internally following the same process we use to setup Sound Choice accounts. Sterilmed will assign someone to collections and

will ship supplies.

If you sign up a single use account that does not have a SMD ASR then a CAS will be assigned.

Collections Rebate Example

My customer already returns ULS to us. They also buy all their new and reprocessed ULS from BWI. Can they receive the rebate for ULS catheters they return?

No. The rebate is for single use ULS customers only. If a customer is already purchasing Certified Performance ULS from BWI then they are already required to return 80% of their products.



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Collections Rebate Example

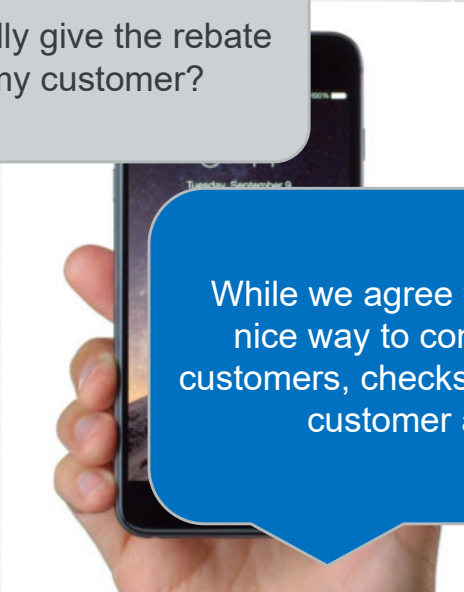
My customer is buying 100% of LASSO® from Stryker. They only buy reprocessed LASSO®. Can I sign them up for the rebate?

Customer must return 80% of the new catheters they buy in order to participate. If you have a customer that is buying 100% reprocessed products, they won't have anything for us to collect.




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Collections Rebate Example



Can I personally give the rebate check to my customer?

While we agree this would be a nice way to connect with our customers, checks will be mailed to customer accounts

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Collections

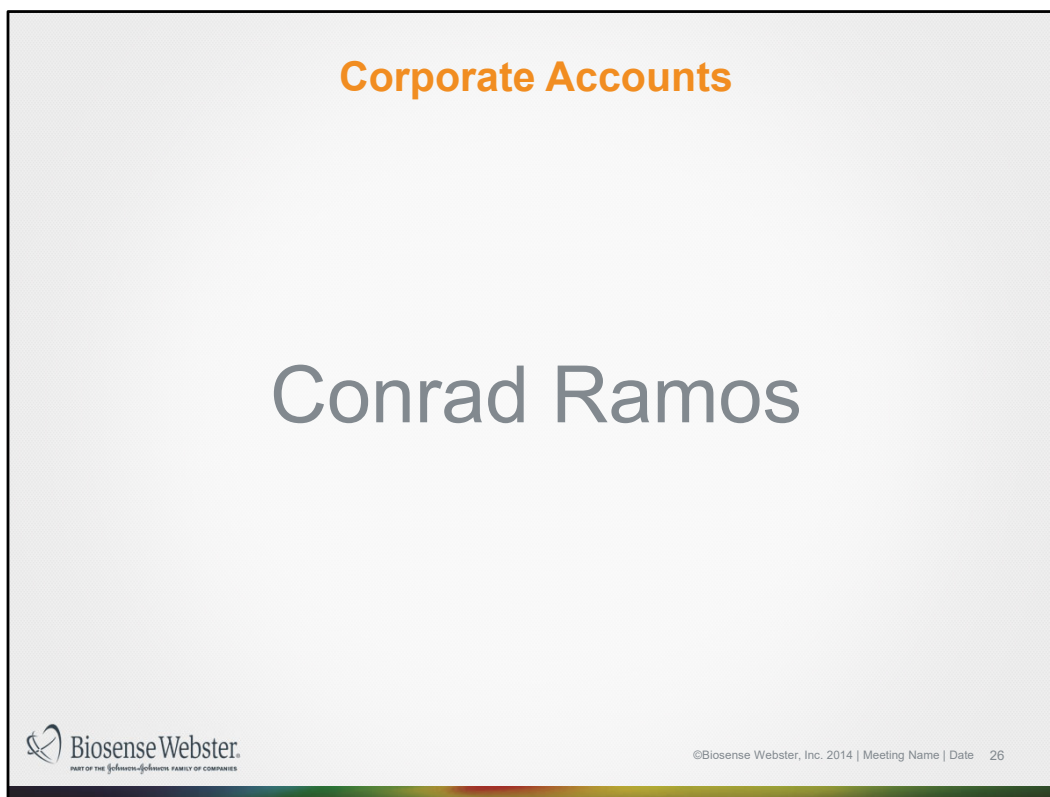
- Customers
- Products
- Training



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15 min break



Corporate accounts participating in program

Corporate Accounts

21 Sterilmed Certified Performance Accounts:

- Premier GPO (8): Focus on:
 - Simplified ordering process
 - Competitive pricing
 - BWI contract performance leverage
 - Efficient collections

- Catholic Healthcare Initiative IDN (13): Focus on all the above plus:
 - Fact of 40% IDN wide standardization to BWI Certified Performance
 - Ease of program implementation under HPG #4467
 - HPG Standardization Incentive Program (SIP)



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Corporate Accounts

SIP Details:

- Announced to HPG membership on 11/21/2014 via HPG Response Newsletter
- \$60 rebate paid per unit of new ultrasound catheter
- Available to eLOC HPG members only
- Requires signature of four (4) page HPG SIP acknowledgment document
 - 2:1 ratio requirement
 - 80% new ULS catheter collections
- Rebate paid out to member every 6 months
- Available to single use members as well



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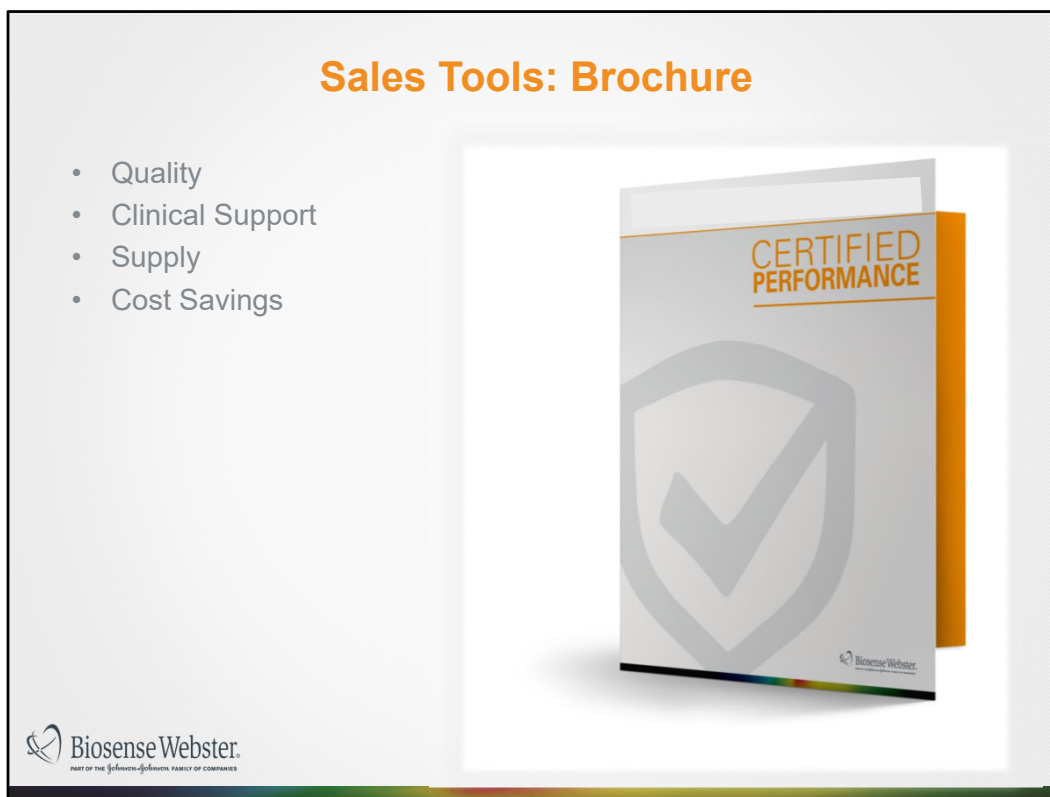
Corporate Accounts

Tenet Healthcare Transition to HPG:

- Effective 2/1/2016
- Tenet version vs. HPG version of Sound Choice
 - 2:1 ratio requirement
 - 80% new ULS catheter collections
- BWI Action Plan (Drive Value):
 1. Transition accounts to HPG pricing (eLOC/S-2)
 2. Secure No Charge PO's for ASA Eligible Accounts & install **Carto® 3 ConfIDENSE™ /Carto® 3 Replay™** (90 day spread)
 3. Conduct HPG overall Sound Choice compliance review after 5/1/2016
 4. Address non-compliance at HPG corporate level before local level



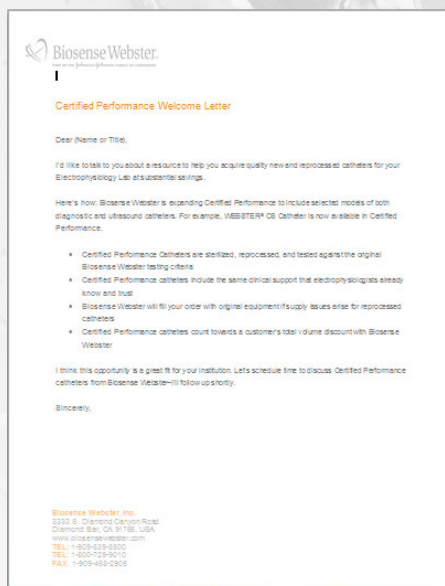
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Brochure

Sales Tools: Customer Letter


- 3 Versions
- Customizable for your physician



Sales Tools

- Ordering Information
- Specifications
- Product Codes

Product Ordering Card
Coming Soon!

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Images coming

Sales Tools

- Describes Dx catheters offered by Sterilmed.
 - Fixed
 - Steerable
- Current users of RPO Dx EP catheters
- Customer initiated requests to start reprocessing Dx EP catheters

Diagnostic EP Catheters

Simple solutions. Proven results.

Sterilmed offers a great solution for your diagnostic devices and cable reprocessing needs, which complements the Certified Performance Portfolio. Sterilmed reduces costs without sacrificing patient care by utilizing proven cleaning, reprocessing, and testing methods. These methods allow the single-use devices Sterilmed reprocesses to deliver the clinical outcomes you need. Sterilmed offers a broad selection of devices, which helps you cater to your electrophysiologist's preferences and save more for your department.

Diagnostic EP Catheter Devices Available for Reprocessing

Manufacturer	Fixed/Curve	Steerable
Biosense Webster, Inc.	•	•
C.R. Bard, Inc.	•	•
Boston Scientific/EP Technologies, Inc.	•	•
Medtronic, Inc.	•	•
St. Jude Medical, Inc./Diag Corporation/Vincel Biomedical, Inc.	•	•

Diagnostic EP catheters are Class II medical devices. Sterilmed is a Class II medical device. Sterilmed is not a Class II medical device. Sterilmed is not a Class II medical device. Sterilmed is not a Class II medical device.

Reprocessing Method
Catheters are pre-washed, manually cleaned, and undergo a progressive ultrasonic cleaning process. The finished reprocessed product meets the clean, free of debris, damage, or debris. Every device is inspected and tested for functionality including continuity and isolation, using a series of rigorous procedures. Under these validated protocols, most devices can be reprocessed multiple times.

Packaging and Distribution
Catheters are packaged within a molded plastic tray sealed with a "Tweak" lid or a rigid plastic tube attached to a bucket and sealed in an airtight "Tweak" pouch. To safeguard tip shape integrity, the distal end of certain catheters includes a tip protector. Devices are sterilized via 100% ethylene oxide (EO).

For more information regarding specific product codes offered please contact your Sterilmed Account Manager or the Sterilmed Customer Care Team at customerservice@sterilmed.com or 888.541.0078.

STERILMED
A Division of
Biosense Webster, Inc.

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www.sterilmed.com
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Final version coming soon!

Sales Tools

- BWI / SMD contacts by account

Paper	Address	City	State	Zip	Phone	Fax
1 Little River News	PO Box 608	Adrian	AR	71822-0608	870-898-3462	870-898-6213
2 Atkins Chronicle	PO Box 188	Atkins	AR	72822-0188	479-641-7161	479-641-1604
3 Bald Knob Banner	PO Box 1480	Bald Knob	AR	72016-1480	501-724-2398	501-724-8382
4 White County Record	PO Box 1480	Bald Knob	AR	72016-1480	501-724-2398	501-724-8382
5 Arkansas Weekly	300 Harrison St # C	Batesville	AR	72501-4894	870-793-4196	870-793-5222
6 The Beebe News	PO Box 910	Beebe	AR	72015-0910	501-482-6414	501-482-3576
7 The Weekly Vista	313 Town Ctr W	Bella Vista	AR	72714-2444	479-865-3724	479-865-8992
8 Rogers HomeTown News	PO Box 929	Bentonville	AR	72712-0929	479-616-5511	
9 Carroll County News	PO Box 232	Berryville	AR	72616-0232	870-423-6630	870-423-6640
10 Booneville Democrat	PO Box 209	Booneville	AR	72027-0209	479-475-4455	479-475-5457
11 Bradley Argus	PO Box 711	Briarclay	AR	72027-0711	870-734-1055	870-734-1494
12 Cabot Star Herald	903 S Pine St	Cabot	AR	72023-3801	501-843-3534	501-843-6447
13 White River Current	PO Box 570	Carroll Rock	AR	72519-0570	870-297-3010	870-297-3070
14 Carlisle Independent	220 W Main St	Carlisle	AR	72024-9702	501-552-3111	870-552-3111
15 Charleston Express	PO Box 39	Charleston	AR	72333-0039	479-965-7380	479-965-7206
16 Monroe County Sun	PO Box 315	Claiborne	AR	72229-0315	870-747-3373	870-747-1434
17 Johnson County Graphic	PO Box 289	Clarksville	AR	72336-0289	479-754-2005	479-754-2098
18 Van Buren County Democrat	PO Box 119	Cleburn	AR	72015-0119	501-745-6175	501-745-6865
19 Clay County Courier	PO Box 85	Conning	AR	72422-0085	870-867-3531	870-867-5204
20 Ashley Times Observer	PO Box 798	Crossett	AR	71636-0798	870-364-5186	870-364-2116
21 Yell County Record	PO Box 189	Cravette	AR	72823-0189	479-495-2384	479-495-3501
22 Post Dispatch	PO Box 270	Dardanelle	AR	72834-0270	479-229-2250	479-229-1159
23 De Queen News	PO Box 1020	De Queen	AR	71832-1020	870-642-2111	870-642-2138
24 DeWitt Eye Enterprise	PO Box 431	De Witt	AR	72443-0431	870-946-3241	870-946-1888
25 Decatur Herald	PO Box 7	Decatur	AR	72722-0007	479-752-3875	479-756-8352
26 White River Journal	PO Box 1051	Des Arc	AR	72040-1051	870-256-4254	
27 Dover Times	PO Box 547	Dover	AR	72837-0547	479-331-3875	479-331-4728
28 Dumas Citizen	Po Box 220	Dumas	AR	71639-0220	870-352-4025	870-352-6421
29 England Democrat	PO Box 250	England	AR	72046-0250	501-842-3111	501-842-3081
30 Lenoir Co. Citizen	PO Box 679	Enter Springs	AR	72522-0679	479-253-0070	479-253-0080
31 Fairfield Bay News	PO Box 1370	Fairfield Bay	AR	72088-1370	501-884-6012	501-884-8019
32 Washington Co. Enterprise Leader	PO Box 664	Farmington	AR	72736-0664	479-267-6502	479-267-5549
33 Free Weekly	207 N College Ave	Fayetteville	AR	72701-4227	479-521-6560	479-544-7289
34 Mountaineer Echo	PO Box 1199	Flippin	AR	72634-1199	870-453-3731	870-453-3071
35 Faulkner News-Advocate	PO Box 569	Fortuna	AR	71743-0569	870-352-3144	870-352-8091
36 Pressing Times	PO Box 132	Franklin	AR	72536-0132	870-470-6397	870-470-7223
37 Glenwood Herald	PO Box 1120	Glenwood	AR	71943-1120	870-266-2111	870-266-4490
38 Westside Eagle Observer	PO Box 640	Gravette	AR	72736-0640	479-797-5300	479-797-5332
39 Greenwood Democrat	PO Box 298	Greenwood	AR	72536-0298	479-896-4494	479-896-4122
40 Ashley County Ledger	PO Box 471	Hamburg	AR	71646-0471	870-653-3424	
41 South Arkansas Sun	306 E Main	Hampton	AR	71444-8900	870-718-3788	
42 The Modern News	PO Box 400	Henningsburg	AR	72430-0400	870-676-1121	870-676-9415



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- Contact info shared with SMD so there are no excuses for lack of communication between teams

Certified Performance Simulations



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3

Certified Performance Simulation

- **Select a real account sales opportunity**
- **Who are your “5.4”?**
 - Identify the various stakeholders, as well as their “Customer Stakeholder Profile”
 - Target a “Mobilizer”
 - Facilitates group discussions
 - Helps others realized shared needs/goals
 - Teaches colleagues something new that we address
 - Resolves disagreements between colleagues
- **Create your Commercial Teaching**



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3

Challengers/High-Performers Target Differently

High Performer Focus Zone



Go-Getter



Teacher



Skeptic

Core Performer Focus Zone



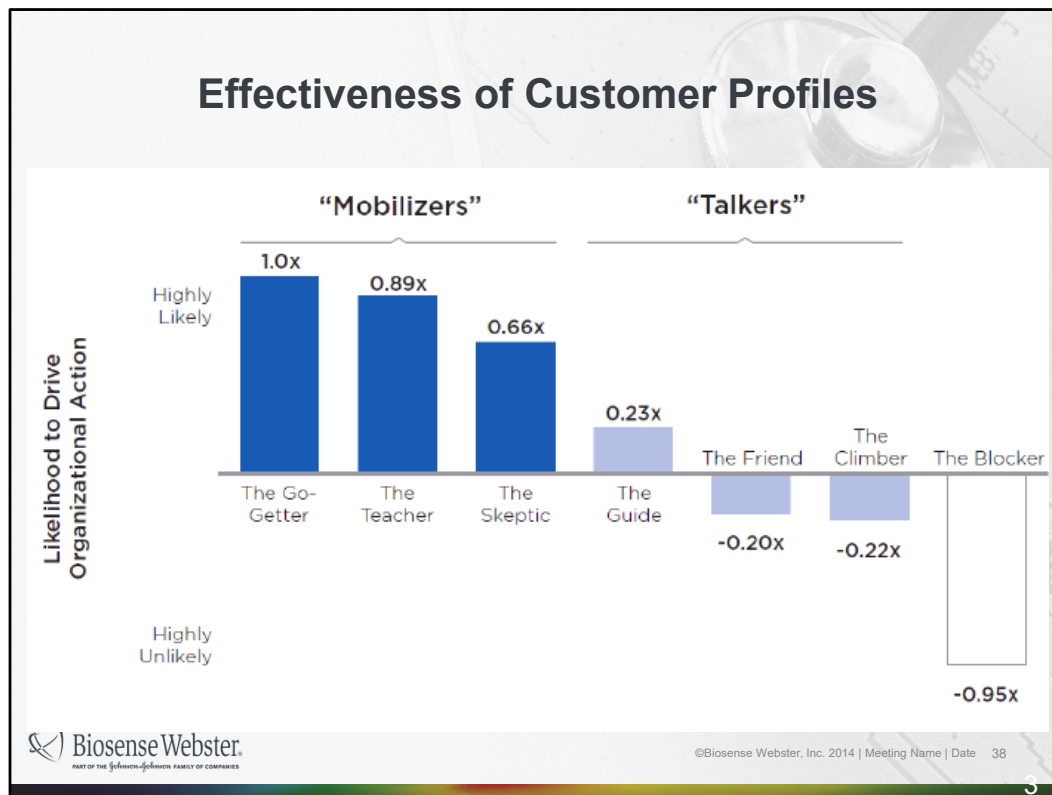
Friend

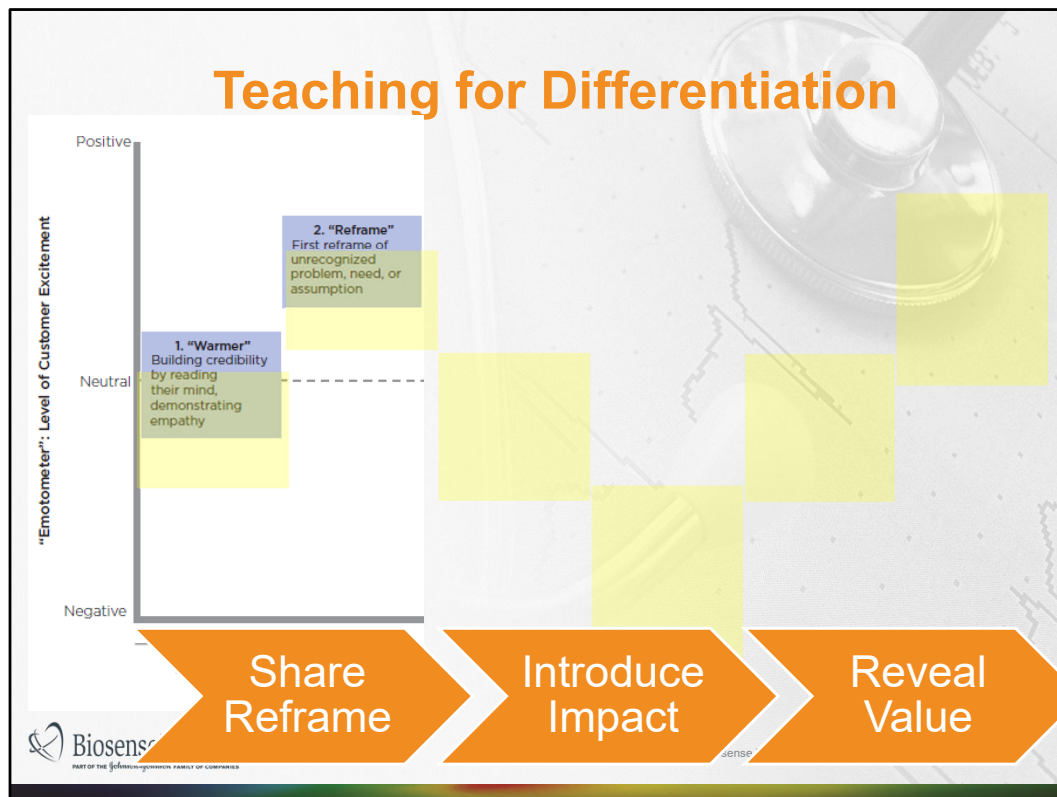


Guide



Climber



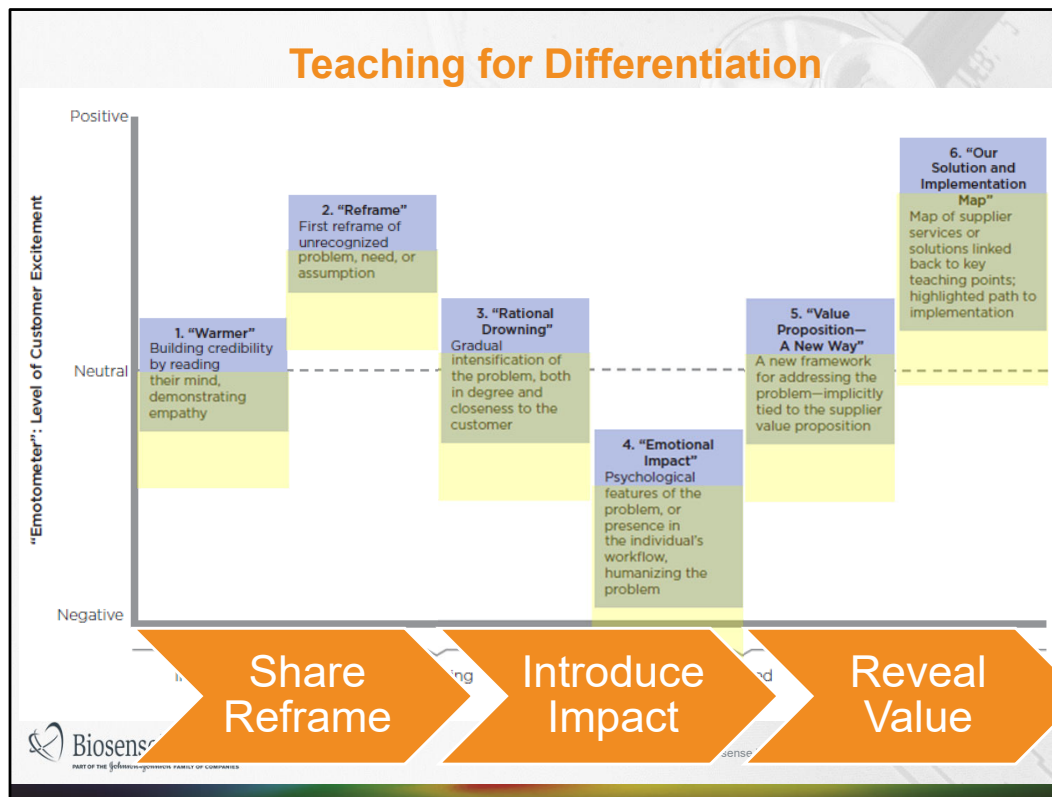


Reframing Your Customers' Thinking

- Reframe: An idea that **changes** how your customer views their situation or problem
- Reframes answers questions around:
 - What mistakes does the Customer make today
 - What should the Customer be doing differently?
 - What incorrect assumptions has your customer made?
 - What might the Customer be underestimating?
 - What needs might the Customer not realize they have?
- Reframes have the following components:
 - Links together FACTS and CUSTOMER NEEDS

Reframing Your Customers' Thinking, cont.

- Reframes should be:
 - Focused on getting from “A” to “B”
 - Know the “A” and what is causing it
 - New and different for the customer
 - Rooted in persuasive facts or information
 - Linked to a customer need
 - Creative
 - Something that creates Constructive Tension
 - The three “Ohs”



Certified Performance Simulation

- Example (5 min)



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4

Certified Performance Simulation

- Preparation (10 min.):
 - Review account's business goals, complete a SWOT analysis
 - Review sales history
- Simulation (10 min.)
 - Review
 - Identify the customer you are simulating the call for
 - Provide account's buyer style (if known)
 - SWOT analysis
- Feedback (5 min.)
 - Quality of Challenger Insights
 - Tailoring to account's styles and business
 - Overall effectiveness

SWOT Analysis – For your target account's reprocessing purchases			
Helps Achieve Business Obj.		Hinders Achieving Business Obj.	
Internal	Strengths	Weaknesses	
	<ul style="list-style-type: none">• Perceived cost savings• Other	<ul style="list-style-type: none">• % of non-functioning• Case support• Other	
External	Opportunities	Threats	
	<ul style="list-style-type: none">• Increased savings• Other	<ul style="list-style-type: none">• Supply• Increased training costs• Other	

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4





From: Koenig, Joseph [SYNNA] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=374e1a0355c747ac884d8fa91aa4a811-JKOENIG4>

To: Somers, Nathan [BWIUS]; Richey, Mark [BWIUS]; Lee, Travis [BWIUS]; Munoz, Amy [BWIUS]; Dawes, Courtney [BWIUS]; Mahaffey, Nathanael [BWIUS]; Gaughan, Terence [BWIUS]; Terrazas, Katie [BWIUS]; Burnham, Paul [BWIUS]; Junaid, Shoaib [BWIUS]; Krivor, Simon [BWIUS]; Shellabarger, Howard [BWIUS]; Iorio, Joseph [BWIUS]; Conlon, Melissa [BWIUS]; Pinkey, Joshua [BWIUS]; Lee, Michael [BWIUS]; Leventis III, Andrew P. [BWIUS]; Malone, Michael [BWIUS]; Karka, Michael [BWIUS]; Scoville, Natalie [BWIUS]; Bennett, Jeffrey [ACCUS]; Parker, James [BWIUS]; Young, Molly [BWIUS]; Nussbaum, Jonathan [BWIUS]; Hoogenstyn, Ross [BWIUS]; Okazaki, Lonnie [BWIUS]; Vetrano, Robert [BWIUS]; Goff, Benjamin [BWIUS]; Osberg, James [BWIUS]

CC: Matelski, Jayme [BWIUS]; Barlow, Chris [BWIUS]; Krenek, Marcus [BWIUS]; Weir, Jennifer [BWIUS]; Patel, Amit [BWIUS]; Zoe, Chuck [BWIUS]; Hudson, David [BWIUS]; O'Quinn, Derek [BWIUS]; Barone, Richard [BWIUS]; Stilwell, Thomas [BWIUS]; Gonzalez, Deidre [BWIUS]; Emmerich, Matthew [BWIUS]; Wannamaker, Kenneth [BWIUS]; Lubinsky, Susan [BWIUS]; Brady, Emily [BWIUS]; Wells, Kevin [BWIUS]; Allen, Brandon [BWIUS]; Walker, Krista [BWIUS]; Tucker, Derek [BWIUS]; MacIntosh, Scott [BWIUS]

Sent: 7/10/2018 12:07:38 AM

Subject: Field Intel Requested - DecaNav Collections

Attachments: Copy of DecaNav Account Level Sales_\$50K+ - EDIT.xlsx

Field Sales Leaders-

If you are receiving this, it means that you have an account in your geography that purchases \$50K+ in BWI DecaNav annually (see attached file). In an effort to better understand how Innovative Health will source the supply for their RPO iteration, could you please reply if you are aware of any collections in the EP lab besides us or Stryker? Based on your feedback, we may consider proposing programs that could divert these collections to us. Any information would be greatly appreciated. Thank you.

Best,

Joe Koenig

Product Director, Sustainability

M. (714) 878-1975

E. jkoenig4@its.inj.com

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Innovative v. Biosense

No. 8:19-cv-01984-JVS

JX-3270

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UCN	RBD	TM	Account	Prior Rolling 12 Months	Rolling 12 Months	Change	Growth	Rolling 12 Months & Prior
1 78872	Jayne Matelski	Nathan Somers	ABBOTT NORTHWESTERN HOSP	\$693,360	\$831,786	\$138,426	19.96%	\$1,525,146
2 4186	Chris Barlow	Mark Richey	SAINT DAVIDS MEDCL CTR	\$595,764	\$627,380	\$31,616	5.31%	\$1,223,144
3 3692	Mark Krenek	Travis Lee	CHI BYLR ST LUKES HOSP	\$511,494	\$582,888	\$71,394	13.96%	\$1,094,382
4 3682	Jennifer Weir	Amy Munoz	BAYLOR ALL STS MEDCL CTR	\$241,200	\$480,765	\$239,565	99.32%	\$721,965
5 26974	Mark Krenek	Courtney Dawes	MEML HERMANN TX MEDCL CTR	\$296,759	\$333,180	\$36,421	12.27%	\$629,939
6 1092357	Amit Patel	Nathanael Mahaffey	NEW YORK - PRESBY HOSP	\$308,568	\$271,343	(\$37,225)	-12.06%	\$579,911
7 3693	Mark Krenek	Travis Lee	HOUSTON METHODIST HOSP	\$321,762	\$266,994	(\$54,768)	-17.02%	\$588,756
8 3834	Chuck Zoe	Terry Gaughan	SCRIPPS MEML HOSP	\$233,148	\$249,390	\$16,242	6.97%	\$482,538
9 72371	David Hudson	Katie Terrazas	SAINT VINCENT HOSP CATH	\$196,641	\$232,162	\$35,521	18.06%	\$428,803
10 13951	Derek O'Quinn	Paul Burnham	PRVDNCE ALASKA MEDCL CTR	\$250,536	\$211,387	(\$39,149)	-15.63%	\$461,923
11 62587	Rick Barone	Shoaib Junaid	THE COOPER HLTH SYST	\$17,025	\$209,975	\$192,950	1,133.33%	\$227,000
12 2514	Amit Patel	Simon Krivor	MONTEFIORE MEDCL CTR	\$48,177	\$141,804	\$93,627	194.34%	\$189,981
13 1007180	Conor Stilwell	Howard Shellabarger	CHANDLER REGL HOSP	\$98,879	\$132,007	\$33,128	33.50%	\$230,886
14 1113974	Conor Stilwell	Joseph Iorio	ARIZONA HEART HOSP	\$25,144	\$131,108	\$105,964	421.43%	\$156,252
15 2530	Deidre Gonzalez	Melissa Bergold	LONG ISLE JWSH MEDCL CTR	\$52,116	\$128,451	\$76,335	146.47%	\$180,567
16 6261	Matt Emmerich	Josh Pinkey	MERCY HOSP ANDERSON	\$93,200	\$118,980	\$25,780	27.66%	\$212,180
17 1326478	Mark Krenek	Travis Lee	BAY AREA REGL MEDCL CTR	\$128,192	\$110,550	(\$17,642)	-13.76%	\$238,742
18 2434	Deidre Gonzalez	Michael Lee	HACKENSACK UNIV MEDCL CTR	\$100,395	\$110,526	\$10,131	10.09%	\$210,921
19 3766	Conor Stilwell	Howard Shellabarger	TUCSON MEDICAL CTR	\$59,400	\$109,728	\$50,328	84.73%	\$169,128
20 52320	Mark Krenek	Courtney Dawes	KINGWOOD MED CTR	\$67,712	\$105,225	\$37,513	55.40%	\$172,937
21 7088	Mark Krenek	Travis Lee	CLEAR LK REGL MEDCL CTR	\$42,826	\$93,863	\$51,037	119.17%	\$136,689
22 1116	Conor Stilwell	Howard Shellabarger	BANNER GOOD SAMARITAN	\$24,896	\$91,872	\$66,976	269.02%	\$116,768
23 426629	Ken Wannamaker	Andrew Leventis	GREENVILLE HLTH SYST	\$14,400	\$91,800	\$77,400	537.50%	\$106,200
24 72501	Matt Emmerich	Josh Pinkey	UNIVERSITY OF CINCINNATI	\$5,844	\$91,556	\$85,712	1,466.67%	\$97,400
25 1030173	Susan Lubinsky	Michael Malone	NWN MEML HOSP	\$89,930	\$76,898	(\$13,032)	-14.49%	\$166,828
26 4879	Emily Simmons	Michael Karka	MUNROE REGL MEDCL CTR	\$4,140	\$76,590	\$72,450	1,750.00%	\$80,730
27 3647	Kevin Wells	Nataile Scoville	HILLCREST MEDCL CTR	\$0	\$75,150	\$75,150	/0	\$75,150
28 7038	Brandon Allen	Jeff Bennett	FAWCETT MEML HOSP	\$39,312	\$72,892	\$33,580	85.42%	\$112,204
29 381667	Brandon Allen	Jeff Bennett	VA HOSP TAMPA SSF	\$78,602	\$72,737	(\$5,866)	-7.46%	\$151,339
30 44570	Krista Walker	Molly Young	UCHEALTH UNIV OF CO HOSP	\$23,276	\$71,944	\$48,668	209.09%	\$95,220
31 6690	Jennifer Weir	Amy Munoz	PLZ MEDCL CTR OF FT WORTH	\$48,900	\$70,587	\$21,687	44.35%	\$119,487
32 16509	Mark Krenek	Courtney Dawes	TX CHLDS HOSP	\$111,735	\$68,760	(\$42,975)	-38.46%	\$180,495
33 57774	Rick Barone	Shoaib Junaid	PROSPECT CCM LLC	\$44,640	\$66,960	\$22,320	50.00%	\$111,600
34 6680	Derek Tucker	James Parker	MEDICAL CITY DALLAS HOSP	\$46,345	\$64,350	\$18,005	38.85%	\$110,695
35 2685	Scott Macintosh	Jonathat Nussbaum	THE HOSP OF THE UNV OF PA	\$58,995	\$63,971	\$4,976	8.43%	\$122,966
36 410762	Joel Criner	Ross Hoogenstyn	MERCY GEN HLTH PARTNERS	\$0	\$63,889	\$63,889	/0	\$63,889
37 1072988	Jennifer Weir	Amy Munoz	AM HOSP CATH LABS LLP	\$0	\$57,408	\$57,408	/0	\$57,408
38 3947	Derek O'Quinn	Lonnie Okazaki	THE QUEEN'S MEDCL CTR	\$43,200	\$55,946	\$12,746	29.50%	\$99,146
39 7163	Rick Barone	Robert Vetrano	SAINT BARNABAS MEDCL CTR	\$15,648	\$52,812	\$37,164	237.50%	\$68,460
40 4205	Marlene Washington	Ben Goff	SANTA BARBARA COTGE	\$27,508	\$52,688	\$25,180	91.54%	\$80,196
41 4152	Jayne Matelski	James Osberg	CENTRACARE ST CLOUD HOSP	\$33,396	\$50,600	\$17,204	51.52%	\$83,996

From: Haydel, David [BWIUS] </O=JNJ/OU=EESUSCI/CN=RECIPIENTS/CN=DHAYDEL>
To: Zare, Fairy [BWIUS]
Sent: 3/18/2016 1:34:57 AM
Subject: Re: BWI to take over collections in this sound choice account
Attachments: image001.png

Let's talk in 5 min?

David Haydel
Sent from iPhone

On Mar 17, 2016, at 6:10 PM, Zare, Fairy [BWIUS] <fzare@ITS.JNJ.com> wrote:

Hi Dave,
I just saw your note; I'll call you in a few minutes (if too late, I can chat as early as you can talk tomorrow morning)
Looking forward to it,
Fairy

From: Haydel, David [BWIUS]
Sent: Thursday, March 17, 2016 1:41 PM
To: Zare, Fairy [BWIUS]
Subject: RE: BWI to take over collections in this sound choice account

Fairy,

Can you call me when you have a minute?
Planning to send this to all my CAS given the full implementation of the case coverage policy, the new performance certified user accounts, and the lack of SterilMed access to these accounts.
Thanks,

David Haydel
Regional Business Director
Biosense Webster, Inc.
M. 985.789.3717

From: Zare, Fairy [BWIUS]
Sent: Monday, February 15, 2016 5:25 PM
To: Urwiler, Kelly [BWIUS]
Cc: Haydel, David [BWIUS]; Crouch, Michael [BWIUS]
Subject: BWI to take over collections in this sound choice account

Innovative v. Biosense

No. 8:19-cv-01984-JVS

JX-3673

Hello Kelly,

Thank you for making the Certified Performance product line a success by ensuring our catheters are collected regularly so we have a steady supply of reprocessed catheters back to the customers and as importantly, prevent the competition from getting access to our catheters.

Please review the training on this link – where instructions on collections are outlined.

<https://connect.biosensewebster.com/Connect/MediaLib?path=%3D%3DL1VsdHJhc291bmQgQ2F0aGV0ZXJzIFByb2R1Y3QgUGFnZSBNYXRlcmIhbHMvQ0FTIENvbGxlY3Rpb24gUHJvZ3JhbS8%3D>

The forms you'll need to request the packaging/labels for the catheters are attached – use the excel or pdf – whichever is easier;

Remember when you send in your request to SterilMed for packaging/labels, it'll take up to 7-10 business days for the goods to arrive – so order as much as you need so you don't have to wait too long for the boxes. Please keep tabs on how many catheters you've shipped to Sterilmed in case we need to refer to your log; you'll be reimbursed \$15/catheter for what you ship back to Sterilmed. For the time being, the payments will be processed bi-annually.

Any questions, please let me know.

Thank you,

Fairy Zare

Group Product Director, Ultrasound & Diagnostics

M. 949-557-7246

T. 909-839-7384

E. fzare@its.jnj.com

Biosense Webster, Inc.

Part of the Johnson & Johnson Family of Companies

3333 S. Diamond Canyon Road

Diamond Bar, CA 91765, USA

www.biosensewebster.com

<image001.png>

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From: Stilwell, Thomas [BWIUS]

Sent: Monday, February 15, 2016 4:01 PM

To: Zare, Fairy [BWIUS]

Cc: Haydel, David [BWIUS]; Crouch, Michael [BWIUS]; Urwiler, Kelly [BWIUS]

Subject: Re: BWI to take over collections in this sound choice account

Hello Fairy,

The CAS will be Kelly Urwiler

(480) 433-3244

KUrwiler@ITS.jnj.com

Thank you.

Best Regards,

Conor Stilwell

Territory Manager

M. 713-823-5304

E. tstilwel@its.jnj.com

On Feb 15, 2016, at 4:40 PM, Zare, Fairy [BWIUS] <fzare@ITS.JNJ.com> wrote:

Hello,

BWI will be taking over the catheter collection in accounts that are ONLY Sound Choice (i.e. SterilMed doesn't sell any products into). Therefore the following account will no longer be serviced by Sterilmed.

UCN

6967 Mayo Clinic (Phoenix, AZ)

68506

We need your help to get a CAS assigned to collect in this account. The CAS will be compensated a rate of \$15/catheter for each unit returned to SterilMed.

Please provide me with the name of the CAS who will be taking over so I can direct them to the training and forms needed to order product box/labels and get them set up.

Thank you,

Fairy

Fairy Zare

Group Product Director, Ultrasound & Diagnostics

M. 949-557-7246

T. 909-839-7384

E. fzare@its.jnj.com

<image003.png>

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Message

From: Sadler, Lynn [LSadler@IUHealth.org]
Sent: 8/15/2017 8:40:06 AM
To: Amy Ferreira [/O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Alferreirae2]
CC: Berardi, Kimberly [kberardi@IUHealth.org]
Subject: RE: Methodist Device Usage

I'm not sure what products you are talking about. If it is a Biosense Webster product and it has a sensor we cannot use reprocess items...well we can but Biosense will not support the case. We are not the Mayo Clinic our physicians are not ready to take the stand against Biosense and say support the case "or else". The Cables on the list are reprocessed in house. We can do it more economically then sending them to a reprocessor. That only leaves a couple other items and the usage on those was minimal. If there are other items I am missing please let me know I will be happy to look at anything you have. Have you received any word on the Halo catheters? Currently we are OK but that will change by the end of the month.

Lynn

From: Amy Ferreira [mailto:alferreira@innovative-health.com]
Sent: Tuesday, August 15, 2017 11:18 AM
To: Sadler, Lynn
Subject: Re: Methodist Device Usage

**** EXTERNAL Message From alferreira@innovative-health.com. DO NOT open attachments or click links from unknown senders or unexpected emails. ****

Thank you Lynn, I appreciate you getting back to me so quickly!

Are you able to share with me the reasoning behind why Methodist does not purchase reprocessed product on all devices used? Physician preference, issues in the past, etc?

Thanks,
Amy

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From: "Sadler, Lynn" <LSadler@IUHealth.org>
Date: Tuesday, August 15, 2017 at 10:08 AM
To: Amy Ferreira <alferreira@innovative-health.com>
Subject: FW: Methodist Device Usage

Amy,

The items highlighted in green are pretty much what we currently reprocess. I added one item at the bottom. The usage is minimal but we do use a few a year.

Lynn

From: Amy Ferreira [mailto:alferreira@innovative-health.com]
Sent: Tuesday, August 15, 2017 10:05 AM
To: Sadler, Lynn
Subject: Methodist Device Usage

Innovative v. Biosense
No. 8:19-cv-01984-JVS
JX-3912

*** EXTERNAL Message From alferreira@innovative-health.com. DO NOT open attachments or click links from unknown senders or unexpected emails. ***

Hi Lynn,

Hope your week is off to a great start!

I am hoping you can help me to gather some information prior to the meeting in Phoenix next week. I was reviewing the device usage data that IU supply chain provided to me, and I want to verify with you whether or not Methodist uses all 27 of these product codes, attached. Can you please verify that this information is accurate? If I am missing any products, or have some listed that you might not use anymore, please let me know.

I have highlighted in green the items that Methodist currently reprocesses. Are you able to provide me with any background information on why Methodist currently only reprocesses 11 products out of the 27 listed? I want to make sure that we look at all possible opportunities to increase your savings.

Any information you can provide would be greatly appreciated! Thank you in advance for your help, Lynn!

Amy



Amy Ferreira
Director, Business Development
www.innovative-health.com

(Office)
602.549.6400 (Mobile)

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Message

From: Rick Ferreira [rferreira@innovative-health.com]
on behalf of Rick Ferreira <rferreira@innovative-health.com> [rferreira@innovative-health.com]
Sent: 6/20/2022 4:58:16 AM
To: Amy Ferreira [alferreira@innovative-health.com]; Jay Farris [jfarris@innovative-health.com]; Michael Ferreira [mferreira@innovative-health.com]; Meredith Snider [msnider@innovative-health.com]
CC: Dave Distel [ddistel@innovative-health.com]; Lars Thording [lthording@innovative-health.com]
Subject: FW: [EXTERNAL]Query
Attachments: BWI Letter on Reprocessed Catheter Support.docx

Great note from Dave to one of his customers!

I would keep this in your "cut & paste" file as you will undoubtedly have this come up at one or more of your accounts.

Have a great day guys!

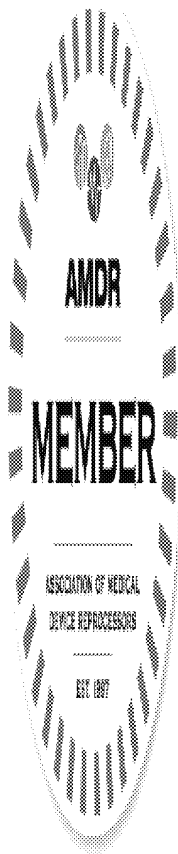
Rick



Rick Ferreira
CEO

480.525.5910 (Office)
480.467.8517 (Mobile)

www.innovative-health.com



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2019-2020

From: Dave Distel <ddistel@innovative-health.com>

Date: Monday, June 20, 2022 at 4:22 AM

Innovative v. Biosense

No. 8:19-cv-01984-JVS

JX-3969

To: "Meder, Risa" <MederR@centracare.com>, "Manning, Nate" <ManningN@centracare.com>
Cc: "Coldiron, Donald R. (Don), M.B.A." <Coldiron.Donald@mayo.edu>, "Ali, Barket" <Ali.Barket@mayo.edu>
Subject: RE: [EXTERNAL]Query

Hi Risa,

Thanks for the note and very unfortunate Biosense Webster is putting their profit motivation in front of your hospitals ability to control costs while preserving clinician satisfaction and patient outcomes. I will certainly credit you for the Vizigo as you are a valued client and I respect your hospitals need to maximize profitability to offset negative margin service lines that must be offered to be a full service acute care provider to the community. Returning stuff through Medline is a challenge. Just let me know what you can use of approximate equal value to the 3 Vizigo and will get it to you no charge. No need to return the Vizigo as I can't resell them out of the packaging.

That said, please allow me to set the facts straight in regards to Biosense's position:

- Biosense launched their case coverage policy in October 2014. It addresses sensor enabled products which the Vizigo is not.
- Ascent reprocessing which was sold to Stryker in 2009 received FDA clearance to reprocess the SoundStar 3D in 2009. Between that event and the implementation of the case coverage policy, Biosense covered tens of thousands of reprocessed 3D SoundStar's without any issues. For if there were issues they would have presented the data to the FDA and shut down the practice vs using a case coverage policy that says the mapping techs can only provide coverage for products they are "trained on". When the FDA grants a 510K to a reprocessor they have validated through the 510K process that the product is "substantially equivalent", i.e: same performance and specifications. The sensor enabled products perform fine reprocessed because the sensors (3 magnetic coils) are in the extruded shaft of the catheter. Not only can they not move but they are not exposed to O2 or electrolytes to oxidize. The calibration information for the catheter is not changed. The reprocessor just verifies its accuracy to specified tolerances.
- **The Vizigo is not sensor enabled!** All it has in it is an auto ID chip that is the same as in all the Webster CS and like catheters. There is no EPROM like in the SoundStar or Pentaray. An EPROM by the way is only for device security to lock the device 24 hours after being plugged in and encryption to make it more difficult for the reprocessor to reset. **The Vizigo is simply a steerable sheath and a Quad catheter combined. No fascinating technology here.**

I know they will not back down. But please know they have no basis for their claims and are simply lying to make more money. Biosense has covered hundreds of thousands of reprocessed Agilis and reprocessed quads. Put the two together and OMG, we can't cover this! Please let us know what products you can use and Tracy will get them to you.

I am in the St. Cloud area Thursday afternoon and Friday if Nate and yourself have time to meet to review program progress and additional opportunities for increased savings?

I have cc'd Don Coldiron and Barket Ali who manage the cardiology portfolio for Captis so they are aware of Biosense Webster's new unfounded position.

Thanks,

Dave

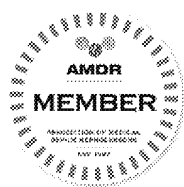


Dave Distel

VP, Business Development

480.525.5970 (Office)

507.358.5289 (Mobile)

www.innovative-health.com

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2019-2020

From: Meder, Risa <MederR@centracare.com>**Sent:** Thursday, June 16, 2022 3:03 PM**To:** Dave Distel <ddistel@innovative-health.com>**Subject:** [EXTERNAL]Query

Good afternoon Dave,

I have a question for you. I was so excited about saving money by ordering the reprocessed Vizigo sheaths that I forgot that Carto won't back up our cases if we use a reprocessed product that has a chip. I have 3 of them. 😞 Is there any way we can return them? They are out of their box but the packaging is still intact. I totally understand if we can't but thought I'd ask. Thanks so much for your consideration.

Risa Meder

Electrophysiology

320-251-2700 ext 59958

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Date: XX/XX/XXXX

RE: Position Statement on Clinical Account Specialist Case Support of Reprocessed SUD Catheters

Dear Valued Customer,

This letter is to inform you of Biosense Webster, Inc.'s position regarding clinical support of reprocessed Single-Use-Devices (SUD). Biosense Webster's commitment to providing high quality products and services requires that we properly train all clinical account specialists on the capabilities, limitations, and proper functioning of all our devices and equipment. It is critical that our personnel possess a competent base of knowledge of the design intent of each device feature and a thorough understanding of how each disposable product is designed to work with our capital equipment to ensure the best possible outcome for each procedure that we support. This base of knowledge is especially important when it comes to troubleshooting the CARTO® System in the midst of a procedure. In fact, most hospital facilities also recognize the critical nature of vendor product competency as it relates to patient safety and consequently require vendor representatives to provide documentation attesting to their competency with their company's products as part of the vendor credentialing process.

Accordingly, Biosense Webster's clinical account specialists can only provide clinical support for cases that use catheters they have been trained to support. Biosense Webster's portfolio of products includes a combination of both new and reprocessed devices. Biosense Webster's clinical account specialists have been trained to understand the capabilities, limitations, and proper functioning of these devices and hence, are able to deliver on our commitment of high quality support. However, this support by Biosense Webster's clinical account specialists does not extend to products manufactured or reprocessed by another company.

Electrophysiology catheters provided by another original equipment manufacturer or reprocessing company are not Biosense Webster products. Reprocessing is a manufacturing process (reference the FDA guidance documents on reprocessing of SUDs). Therefore, once Biosense Webster's products are subjected to the reprocessing operations of another company, these devices are no longer Biosense Webster's products. The 510(k) clearance for reprocessed devices is owned by the reprocessing company that manufactures and distributes the devices. Biosense Webster has no knowledge of the third party's manufacturing operations, nor of the product specifications of its devices and as such, Biosense Webster cannot attest to the safety or efficacy of these devices.

For any questions related to the information contained in this letter, please contact your local Biosense Webster representative.

Thank you for your continued partnership and for choosing the Biosense Webster, Inc. Family of Products.

Sincerely,

.....
Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Biosense Webster, Inc. | 3333 Diamond Canyon Road, Diamond Bar, CA 91765 USA
Tel: 909-839-8500 | Tel: 800-729-9010 | Fax: 909-468-2905
www.biosensewebster.com

EXHIBIT 1

From: [Harper, Christine \(x2286\)](#)
To: [Schiffman, Kelley C.](#); [Reade, Matthew D.](#); [Kirschenbaum, Andrew \(x2831\)](#); [Morales-Kimball, Annamaria M.](#); [Anderson, Rachel T.](#); ["Matthew Summers"](#); ["Panteha Abdollahi"](#); [Ho, Derek T.](#); [Sella, Chandler J.](#); ["Joshua P. Davis"](#); [Goldsmith, Andrew E.](#); [Quirk, Sean P.](#); [Berhold Jeffrey](#)
Cc: [Weingram, Isaac \(x2626\)](#); [Cruz, Alejandro \(x7613\)](#); [~muhammad.faridi@linklaters.com](#); [Xu, Diane \(x2657\)](#); [Cavanaugh, William F. \(x2793\)](#); [~kkraft@stradlinglaw.com](#); ["Inorthrup@stradlinglaw.com"](#); ["stlobb@stradlinglaw.com"](#); [Tso, Charles \(x2321\)](#); [~nadav.benzur@linklaters.com](#)
Subject: [EXTERNAL] RE: IH v. BWI - Injunction & Global Schedule
Date: Wednesday, June 11, 2025 9:35:29 AM

Kelley:

There is nothing inaccurate in our email, and we disagree with your recounting of our conferral. Moreover, we have never refused to provide you with our reasoning. In fact, we explained our positions to you during our last call on this topic and you told us that you did not understand them, which is far from a refusal on our part.

In any case, as we said before, we think the best path forward is for IH to make its motion for injunctive relief, and we will respond in due course. And we see no issue with IH reflecting the parties' positions to the court, to the extent relevant, so long as IH does so accurately.

Regards,
Christine

Christine Harper
She | Her | Hers
Associate

Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036

T 212.336.2286
charper@pbwt.com

From: Schiffman, Kelley C. <kschiffman@kellogghansen.com>
Sent: Wednesday, June 11, 2025 7:24 AM
To: Harper, Christine (x2286) <charper@pbwt.com>; Reade, Matthew D. <mreade@kellogghansen.com>; Kirschenbaum, Andrew (x2831) <akirschenbaum@pbwt.com>; Morales-Kimball, Annamaria M. <amorales-kimball@kellogghansen.com>; Anderson, Rachel T. <randerson@kellogghansen.com>; 'Matthew Summers' <msummers@bm.net>; 'Panteha Abdollahi' <pabdollahi@tocounsel.com>; Ho, Derek T. <dho@kellogghansen.com>; Sella, Chandler J. <csella@kellogghansen.com>; 'Joshua P. Davis' <jdavis@bm.net>; Goldsmith, Andrew E. <agoldsmith@kellogghansen.com>; Quirk, Sean P. <squirk@kellogghansen.com>; Berhold Jeffrey <jeff@berhold.com>
Cc: Weingram, Isaac (x2626) <iweingram@pbwt.com>; Cruz, Alejandro (x7613) <acruz@pbwt.com>; ~muhammad.faridi@linklaters.com <muhammad.faridi@linklaters.com>; Xu, Diane (x2657) <dxu@pbwt.com>; Cavanaugh, William F. (x2793) <wfcavanaugh@pbwt.com>; ~kkraft@stradlinglaw.com <kkraft@stradlinglaw.com>; 'Inorthrup@stradlinglaw.com' <Inorthrup@stradlinglaw.com>; 'stlobb@stradlinglaw.com' <stlobb@stradlinglaw.com>; Tso, Charles

(x2321) <ctso@pbwt.com>; ~nadav.benzur@linklaters.com <nadav.benzur@linklaters.com>

Subject: RE: IH v. BWI - Injunction & Global Schedule

External: Think before you click.

Counsel, you describe our meet and confers inaccurately. You conveyed your concerns before seeing a draft of the proposed order. Thus, many of them were pitched at a high level and not all were clearly relevant. Hoping for further engagement and dialogue, we made adjustments targeted at the concerns we felt we understood and then shared a copy of the proposed permanent injunction order, weeks in advance of the filing date for our moving papers, inviting a redline from you. We were hopeful that inviting a redline would allow for more concrete, productive engagement. That is not what we received from you. Nor is it accurate to say that the proposed order we shared with you did not address a significant number of your concerns. For example, the section on collections was streamlined to reflect your previous feedback – indeed so much so that you were not able to articulate a clear objection to that section of the proposed order at our subsequent meet and confer. At that meet and confer, we repeatedly asked to better understand your concerns, offered to consider alternative proposals, and earnestly expressed multiple times that we would welcome a redline with further feedback. You refused, signaling that we were at an impasse. We were upfront that we would raise your refusal to engage in further dialogue with the Court for its consideration.

Kelley C. Schiffman

KELLOGG, HANSEN, TODD, FIGEL & FREDERICK, PLLC

Sumner Square | 1615 M Street, NW | Suite 400 | Washington, DC 20036

Tel: (202) 326-7943 | Fax: (202) 326-7999

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From: Harper, Christine (x2286) <charper@pbwt.com>

Sent: Tuesday, June 10, 2025 6:45 PM

To: Reade, Matthew D. <mreade@kellogghansen.com>; Kirschenbaum, Andrew (x2831) <akirschenbaum@pbwt.com>; Schiffman, Kelley C. <kschiffman@kellogghansen.com>; Morales-Kimball, Annamaria M. <amorales-kimball@kellogghansen.com>; Anderson, Rachel T. <randerson@kellogghansen.com>; 'Matthew Summers' <msummers@bm.net>; 'Panteha Abdollahi' <pabdollahi@tocounsel.com>; Ho, Derek T. <dho@kellogghansen.com>; Sella, Chandler J. <csella@kellogghansen.com>; 'Joshua P. Davis' <jdavis@bm.net>; Goldsmith, Andrew E. <agoldsmith@kellogghansen.com>; Quirk, Sean P. <squirk@kellogghansen.com>; Berhold Jeffrey <jeff@berhold.com>

Cc: Weingram, Isaac (x2626) <iweingram@pbwt.com>; Cruz, Alejandro (x7613) <acruz@pbwt.com>;

~muhammad.faridi@linklaters.com <muhammad.faridi@linklaters.com>; Xu, Diane (x2657) <dxu@pbwt.com>; Cavanaugh, William F. (x2793) <wfcavanaugh@pbwt.com>;
~kkraft@stradlinglaw.com <kkraft@stradlinglaw.com>; 'Inorthrup@stradlinglaw.com'
<lnorthrup@stradlinglaw.com>; 'stlobb@stradlinglaw.com' <stlobb@stradlinglaw.com>; Tso, Charles (x2321) <ctso@pbwt.com>; ~nadav.benzur@linklaters.com <nadav.benzur@linklaters.com>

Subject: [EXTERNAL] RE: IH v. BWI - Injunction & Global Schedule

Matthew:

To follow up on the parties' call last week, we write to confirm that Biosense will not be proposing any redline edits to IH's draft permanent injunction order. Biosense has made clear its position that the terms of IH's proposed injunction are vague, overbroad, and/or unsupported by law. During our call on May 30, Biosense identified a host of issues regarding IH's contemplated requests for injunctive relief, the resolution of which Biosense views as critical before any relief is ordered. While during that lengthy call IH indicated it would consider these issues, the proposed order IH circulated on June 2 did nothing to acknowledge the vast majority of the key issues and concerns Biosense raised. In light of those discussions and IH's choice to decline to reflect Biosense's concerns in its June 2 draft injunction, we have no reason to believe that providing a redline to IH of the draft injunction, as requested on June 4, will create a more productive path forward between the parties, nor would it bridge the fundamental disagreements between the parties as to necessity and scope of injunctive relief in this case. Accordingly, we believe the parties' ability to confer meaningfully on these issues is exhausted.

As per the schedule agreed upon by the parties, we think the best path at this point is for IH to file its motion for injunctive relief on June 12, which Biosense will oppose on June 26. Thank you.

Regards,
Christine

Christine Harper
She | Her | Hers
Associate

Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036

T 212.336.2286
charper@pbwt.com

From: Reade, Matthew D. <mreade@kellogghansen.com>

Sent: Wednesday, June 4, 2025 10:45 AM

To: Kirschenbaum, Andrew (x2831) <akirschenbaum@pbwt.com>; Schiffman, Kelley C. <kschiffman@kellogghansen.com>; Morales-Kimball, Annamaria M. <amorales-kimball@kellogghansen.com>; Anderson, Rachel T. <randerson@kellogghansen.com>; 'Matthew Summers' <msummers@bm.net>; 'Panteha Abdollahi' <pabdollahi@tocounsel.com>; Ho, Derek T. <dho@kellogghansen.com>; Sella, Chandler J. <csella@kellogghansen.com>; 'Joshua P. Davis'

<jdavis@bm.net>; Goldsmith, Andrew E. <agoldsmith@kellogghansen.com>; Quirk, Sean P. <squirk@kellogghansen.com>; Berhold Jeffrey <jeff@berhold.com>

Cc: Weingram, Isaac (x2626) <iweingram@pbwt.com>; Cruz, Alejandro (x7613) <acruz@pbwt.com>; ~muhammad.faridi@linklaters.com <muhammad.faridi@linklaters.com>; Xu, Diane (x2657) <dxu@pbwt.com>; Cavanaugh, William F. (x2793) <wfcavanaugh@pbwt.com>; ~kkraft@stradlinglaw.com <kkraft@stradlinglaw.com>; 'Inorthrup@stradlinglaw.com' <lnorthrup@stradlinglaw.com>; 'stlobb@stradlinglaw.com' <stlobb@stradlinglaw.com>; Tso, Charles (x2321) <ctso@pbwt.com>; Harper, Christine (x2286) <charper@pbwt.com>; ~nadav.benzur@linklaters.com <nadav.benzur@linklaters.com>

Subject: Re: IH v. BWI - Injunction & Global Schedule

External: Think before you click.

Andy:

We are available at 4:30 today, and I will send an invitation shortly. We look forward to discussing your client's position on the proposed injunction's provisions and what injunctive relief, if any, your client would accept.

Thanks,
Matthew

Matthew D. Reade

Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C.
ph: (202) 326-7913 | fx: (202) 326-7999

From: Kirschenbaum, Andrew (x2831) <akirschenbaum@pbwt.com>

Date: Wednesday, June 4, 2025 at 9:59 AM

To: Reade, Matthew D. <mreade@kellogghansen.com>, Schiffman, Kelley C. <kschiffman@kellogghansen.com>, Morales-Kimball, Annamaria M. <amorales-kimball@kellogghansen.com>, Anderson, Rachel T. <randerson@kellogghansen.com>, 'Matthew Summers' <msummers@bm.net>, 'Panteha Abdollahi' <pabdollahi@tocounsel.com>, Ho, Derek T. <dho@kellogghansen.com>, Sella, Chandler J. <csella@kellogghansen.com>, 'Joshua P. Davis' <jdavis@bm.net>, Goldsmith, Andrew E. <agoldsmith@kellogghansen.com>, Quirk, Sean P. <squirk@kellogghansen.com>, Berhold Jeffrey <jeff@berhold.com>

Cc: Weingram, Isaac (x2626) <iweingram@pbwt.com>, Cruz, Alejandro (x7613) <acruz@pbwt.com>, ~muhammad.faridi@linklaters.com <muhammad.faridi@linklaters.com>, Xu, Diane (x2657) <dxu@pbwt.com>, Cavanaugh, William F. (x2793) <wfcavanaugh@pbwt.com>, ~kkraft@stradlinglaw.com

<kkraft@stradlinglaw.com>, 'lnorthrup@stradlinglaw.com'
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<stlobb@stradlinglaw.com>, Tso, Charles (x2321) <ctso@pbwt.com>, Harper, Christine
(x2286) <charper@pbwt.com>, ~nadav.benzur@linklaters.com
<nadav.benzur@linklaters.com>

Subject: [EXTERNAL] RE: IH v. BWI - Injunction & Global Schedule

Matthew,

Thank you. Please confirm whether you are available to speak at 4:30 this afternoon, or if there is another time when you would like to set a call.

We appreciate you sharing the draft injunction, but we do not intend to send a redline before our call. We do not view the draft as addressing the core concerns and issues we discussed during our last call, so we see the parties as quite far apart in how we are conceptualizing an injunction, to the extent any is necessary. For that reason, we do not think a redline would be productive. We are happy to discuss further on our call.

Best,
Andy

From: Reade, Matthew D. <mreade@kellogghansen.com>

Sent: Tuesday, June 3, 2025 10:23 PM

To: Kirschenbaum, Andrew (x2831) <akirschenbaum@pbwt.com>; Schiffman, Kelley C. <kschiffman@kellogghansen.com>; Morales-Kimball, Annamaria M. <amorales-kimball@kellogghansen.com>; Anderson, Rachel T. <randerson@kellogghansen.com>; 'Matthew Summers' <msummers@bm.net>; 'Panteha Abdollahi' <pabdollahi@tocounsel.com>; Ho, Derek T. <dho@kellogghansen.com>; Sella, Chandler J. <csella@kellogghansen.com>; 'Joshua P. Davis' <jdavis@bm.net>; Goldsmith, Andrew E. <agoldsmith@kellogghansen.com>; Quirk, Sean P. <squirk@kellogghansen.com>; Berhold Jeffrey <jeff@berhold.com>

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Subject: Re: IH v. BWI - Injunction & Global Schedule

External: Think before you click.

Andy:

Thank you for your scheduling proposal. We are considering it.

With respect to the injunction, will Biosense provide a redline or comments on the draft in advance? We expect that this will help focus the parties' discussions.

Thanks,
Matthew

Matthew D. Reade

Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C.
ph: (202) 326-7913 | fx: (202) 326-7999

From: Kirschenbaum, Andrew (x2831) <akirschenbaum@pbwt.com>

Date: Tuesday, June 3, 2025 at 4:22 PM

To: Reade, Matthew D. <mreade@kellogghansen.com>, Schiffman, Kelley C. <kschiffman@kellogghansen.com>, Morales-Kimball, Annamaria M. <amorales-kimball@kellogghansen.com>, Anderson, Rachel T. <randerson@kellogghansen.com>, 'Matthew Summers' <msummers@bm.net>, 'Panteha Abdollahi' <pabdollahi@tocounsel.com>, Ho, Derek T. <dho@kellogghansen.com>, Sella, Chandler J. <csella@kellogghansen.com>, 'Joshua P. Davis' <jdavis@bm.net>, Goldsmith, Andrew E. <agoldsmith@kellogghansen.com>, Quirk, Sean P. <squirk@kellogghansen.com>, Berhold Jeffrey <jeff@berhold.com>

Cc: Weingram, Isaac (x2626) <iweingram@pbwt.com>, Cruz, Alejandro (x7613) <acruz@pbwt.com>, ~muhammad.faridi@linklaters.com <muhammad.faridi@linklaters.com>, Xu, Diane (x2657) <dxu@pbwt.com>, Cavanaugh, William F. (x2793) <wfcavanaugh@pbwt.com>, ~kkraft@stradlinglaw.com <kkraft@stradlinglaw.com>, 'lnorthrup@stradlinglaw.com' <lnorthrup@stradlinglaw.com>, 'stlobb@stradlinglaw.com' <stlobb@stradlinglaw.com>, Tso, Charles (x2321) <ctso@pbwt.com>, Harper, Christine (x2286) <charper@pbwt.com>, ~nadav.benzur@linklaters.com <nadav.benzur@linklaters.com>

Subject: [EXTERNAL] RE: IH v. BWI - Injunction & Global Schedule
Matthew,

Thank you for sharing IH's draft proposed injunction, which we are reviewing. We are available to discuss it tomorrow afternoon, Wednesday, at 4:30pm. Please let us know if that works on your end.

Following up on scheduling regarding equitable relief, attorney's fees, and Rule 50:

1. July 7 and 14 do not work for the key people on our end for the injunction hearing. We can, however, do the following Monday, July 21, as well as July 28. Please confirm that one of those dates work for your team. Assuming we can agree on one of those two dates, below are proposed briefing schedules for each that we can put into a stipulation for the court.

INJUNCTION		
Filing	Proposed date (July 21 hr'g)	Proposed date (July 28 hr'g)
IH motion/proposed injunction	June 16, 2025	June 23, 2025
BWI opposition	June 30, 2025	July 7, 2025
IH reply	July 7, 2025	July 14, 2025
Hearing	July 21, 2025	July 28, 2025

2. In response to your question from our last phone call, we are amenable to negotiating a schedule to fully submit and argue the remaining motions/issues by the end of the summer. To that end, for IH's motion for attorney's fees and Biosense's Rule 50(b) motion, we propose an August 25 hearing date. Below is a proposed briefing schedule for the August 25 hearing date.

ATTORNEYS' FEES and RULE 50(b) MOTION	
Filing	Proposed date (August 25 hr'g)
BWI Rule 50(b) motion and IH fees motion	July 21, 2025
BWI fees opposition and IH 50(b) opposition	Aug. 4, 2025
BWI 50(b) reply and IH fees reply	Aug. 11, 2025
Hearing	Aug. 25, 2025

Please let us know if we can agree on these dates, and we are happy to discuss the schedule further tomorrow if necessary.

Best,
Andy

From: Reade, Matthew D. <mreade@kellogghansen.com>

Sent: Monday, June 2, 2025 4:12 PM

To: Weingram, Isaac (x2626) <iweingram@pbwt.com>; Cruz, Alejandro (x7613) <acruz@pbwt.com>; ~muhammad.faridi@linklaters.com <muhammad.faridi@linklaters.com>; Xu, Diane (x2657) <dxu@pbwt.com>; Cavanaugh, William F. (x2793) <wfcavanaugh@pbwt.com>; ~kkraft@stradlinglaw.com <kkraft@stradlinglaw.com>; 'lnorthrup@stradlinglaw.com' <lnorthrup@stradlinglaw.com>; 'stlobb@stradlinglaw.com' <stlobb@stradlinglaw.com>; Tso, Charles (x2321) <ctso@pbwt.com>; Harper, Christine (x2286) <charper@pbwt.com>; ~nadav.benzur@linklaters.com <nadav.benzur@linklaters.com>; Kirschenbaum, Andrew (x2831) <akirschenbaum@pbwt.com>

Cc: Schiffman, Kelley C. <kschiffman@kellogghansen.com>; Morales-Kimball, Annamaria M.

<amorales-kimball@kellogghansen.com>; Anderson, Rachel T. <randerson@kellogghansen.com>; 'Matthew Summers' <msummers@bm.net>; 'Panteha Abdollahi' <pabdollahi@tocounsel.com>; Ho, Derek T. <dho@kellogghansen.com>; Sella, Chandler J. <csella@kellogghansen.com>; 'Joshua P. Davis' <jdavis@bm.net>; Goldsmith, Andrew E. <agoldsmith@kellogghansen.com>; Quirk, Sean P. <squirk@kellogghansen.com>; Berhold Jeffrey <jeff@berhold.com>

Subject: IH v. BWI - Injunction & Global Schedule

External: Think before you click.

Counsel:

To continue our discussions regarding Innovative's forthcoming request for injunctive relief, I attach a preliminary draft of the proposed order Innovative intends to submit with its motion for permanent injunction.

Please let us know when this week you can discuss this draft and any changes you would propose, which we would ask you to provide through track changes and comments. If there are provisions on which we have reached agreement, please identify those too so we can focus on the open issues during our next call.

This draft reflects revisions made after our discussion last week. Innovative reserves the right to further revise its proposal as it sees fit.

Regarding scheduling, we had proposed a July 7 or July 14 hearing date on our motion for injunction. Please let us know your position on those dates at your earliest convenience. Also, please let us know your availability for hearings on Rule 50 and attorney's fees motions. Per our call, we are willing to negotiate a global schedule that resolves all those outstanding issues by the last available hearing date in August, which is August 25.

Thank you,
Matthew

Matthew D. Reade

Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C.
1615 M Street, N.W. | Suite 400 | Washington, D.C. 20036
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EXHIBIT 2

Koenig rev. 2025-05-04 915pm

Designation List Report



Koenig, Joseph

2021-08-17

Innovative Final Designations	00:29:46
BioSense Final Designations	00:02:19
TOTAL RUN TIME	00:32:04



Documents linked to video:

JX-211
JX-215
JX-216
JX-219
JX-220
JX-221
JX-222
JX-223



ID: Koenig

DESIGNATION	SOURCE	DURATION	ID
84:10 - 84:10	Koenig, Joseph 2021-08-17 84:10 A. No.	00:00:01	Koenig.100
84:14 - 84:16	Koenig, Joseph 2021-08-17 84:14 Q. Do you know whether 84:15 Biosense still publishes a U.S. Commercial 84:16 Marketing Newsletter?	00:00:06	Koenig.101
84:18 - 84:24	Koenig, Joseph 2021-08-17 84:18 A. Yes. 84:19 BY MR. BERHOLD: 84:20 Q. And how often does it publish? 84:21 A. It varies. It can be up to once a week, 84:22 but sometimes less. 84:23 Q. And it's an internal newsletter to field 84:24 sales?	00:00:28	Koenig.102
85:02 - 85:02	Koenig, Joseph 2021-08-17 85:02 A. Yes.	00:00:02	Koenig.103
85:04 - 85:05	Koenig, Joseph 2021-08-17 85:04 Q. Including the clinical account 85:05 specialists?	00:00:03	Koenig.104
85:07 - 85:07	Koenig, Joseph 2021-08-17 85:07 A. I believe so.	00:00:02	Koenig.105
85:09 - 85:16	Koenig, Joseph 2021-08-17	00:00:36	Koenig.106
 JX-222.3.1	85:09 Q. Can you turn to 73721? 85:10 A. Yes. 85:11 Q. Do you see the headline Certified 85:12 Performance Collections - June Dashboard? 85:13 A. Yes. 85:14 Q. And can you read the second to last		
 JX-222.3.2	85:15 paragraph on the page that starts "That's almost 85:16 1500 catheters"?		
85:18 - 85:24	Koenig, Joseph 2021-08-17 85:18 A. The paragraph that says "That's almost 85:19 1,500 catheters between the 5 of them. Let's get 85:20 all of our ULS, Lasso and Webster CS catheters back 85:21 so someone else doesn't grab them." 85:22 BY MR. BERHOLD: 85:23 Q. And isn't that the real reason for 85:24 Biosense's buyback programs?	00:00:17	Koenig.107

DESIGNATION	SOURCE	DURATION	ID
86:01 - 86:04	Koenig, Joseph 2021-08-17 86:01 A. That's a side benefit of the program, I 86:02 guess you could say, but the primary goal of the 86:03 program is to secure the necessary inputs to keep a 86:04 consistent supply to our customer satisfaction.	00:00:15	Koenig.108
86:05 - 86:09	Koenig, Joseph 2021-08-17 86:05 BY MR. BERHOLD: 86:06 Q. And your customers continue to tell your 86:07 field sales that they're not getting enough of the 86:08 reprocessed AcuNavs and reprocessed SOUNDSTARs? 86:09 A. Yes, they always want more.	00:00:13	Koenig.109
88:18 - 88:18  JX-223.2	Koenig, Joseph 2021-08-17 88:18 Can you take a look at Exhibit 223?	00:00:04	Koenig.110
88:19 - 88:25	Koenig, Joseph 2021-08-17 88:19 A. Yes. 88:20 Q. Does Exhibit 223 refresh your 88:21 recollection on when Biosense raised its buyback 88:22 price to single-use accounts for the AcuNav and 88:23 SOUNDSTAR ultrasound catheters from 75 to 100 88:24 dollars? 88:25 A. Yes, it was in 2018.	00:00:25	Koenig.111
89:01 - 89:02	Koenig, Joseph 2021-08-17 89:01 Q. It was effective January 1st, 2018? 89:02 A. Yes.	00:00:05	Koenig.112
89:16 - 90:04  Clear	Koenig, Joseph 2021-08-17 89:16 Q. And do you recall testifying in response 89:17 to "And isn't that the real reason for Biosense's 89:18 buyback program?" "That's a side benefit of the 89:19 program, I guess you could say, but the primary 89:20 goal of the program is to secure the necessary 89:21 inputs to keep a consistent supply to our customer 89:22 satisfaction"? 89:23 A. Yes. 89:24 Q. What do you mean by "a side benefit"? 89:25 A. The meaning of side benefit is that by us 90:01 purchasing these catheters and being able to offer 90:02 them to our customers for purchase and bolster our 90:03 supply, our competition is not able to do the same 90:04 thing.	00:00:42	Koenig.113

EXHIBIT 3

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

- - -

THE HONORABLE JAMES V. SELNA, JUDGE PRESIDING

INNOVATIVE HEALTH, LLC,) CERTIFIED TRANSCRIPT
Plaintiff,)
vs.)
BIOSENSE WEBSTER, INC.,) SACV-19-01984-JVS
Defendant.) TRIAL DAY 5, VOL. I
-----)

REPORTER'S TRANSCRIPT OF PROCEEDINGS

Santa Ana, California

May 13, 2025

SHARON A. SEFFENS, RPR
United States Courthouse
411 West 4th Street, Suite 1-1053
Santa Ana, CA 92701
(612) 804-8655

09:31 1 A That would be anticompetitive conduct. Nothing would
2 be better about that company's product. It would just be
3 harming or eliminating the ability or reducing the ability
4 of customers to buy another company's chips.

09:31 5 Q Now, Dr. Forister, with that distinction in mind, could
6 you please summarize why Biosense's conduct, the three forms
7 of conduct that you have on Slide 2, was anticompetitive and
8 not competition on the merits?

09:31 9 A Yeah. The short summary would be that none of those
10 three things -- the blocking technology, the collection and
11 withholding, and the Case Coverage Policy -- none of those
12 things made Biosense's products better. They just
13 eliminated or restricted the choice of customers to buy
14 their preferred catheters, which happened to be offered by
09:31 15 other companies.

16 Q So let's start with the blocking technology, which is
17 the first of three on your list.

18 Could you please explain what the blocking
19 technology was?

09:32 20 A Yes. The blocking technology consisted of hardware and
21 software elements embedded on a chip that's in the device.
22 And that included some encryption of the information on the
23 chip.

09:32 24 Q On what catheters did Biosense install that blocking
25 technology?

09:32 1 A They installed it on the SOUNDSTAR, the LASSO NAV, and
2 the PENTARAY. They were intending to put it on the OCTARAY,
3 so those catheters.

09:32 4 Q Why in your opinion is that blocking technology
5 anticompetitive and not competition on the merits?

6 A Going back to that fundamental principle, did it do
7 something that the customers wanted? Did it enable a new
8 feature that customers wanted? And the evidence I've seen
9 points to the opposite.

09:32 10 MR. HO: Could we put up Slide 6, please.

11 BY MR. HO:

12 Q Have you prepared a slide to explain the basis for your
13 opinion?

09:33 14 A Yes. This walks through three topics that economists
15 would look at to evaluate whether the blocking technology
16 was competition on the merits or anticompetitive.

17 Q Okay. Could you start with the first of three topics?
18 "Function of the technology," what does that mean, and how
19 is it relevant?

09:33 20 A Yes. It's asking the question what does the technology
21 do? Does it provide a function or benefit a feature that
22 customers want? And that the answer is simply no.

23 Q Moving on to the second topic, it says: "No positive
24 consumer feedback."

09:33 25 Can you explain what you mean by that?

09:37 1 Q Could you point us to the language that reflects that,
2 please?

3 A Yes. If we go to page 4 of the exhibit, the second
4 e-mail on the page from Mario Garcia.

09:37 5 In the first line of that e-mail, he writes:
6 "Last time we met, I clarified the main driver of
7 implementing the Falcon EEPROM" -- which is just another
8 word for a chip -- "is preventing our competitors to
9 reprocess."

09:38 10 Q Can you actually read on a little bit further?

11 A Sure. "To reprocess the VIZIGO sheath and not, as
12 previously understood, as to reprocess them ourselves."

13 Q Okay. And what is the significance of that to your
14 opinion?

09:38 15 A So this is in their own words. The main driver of the
16 Falcon chip for the anti -- or the blocking technology is to
17 prevent reprocessing, and even for a device they didn't plan
18 to reprocess.

09:38 19 Q If we could go back to Slide 2, I want to move on now
20 to catheter collections, the second form of conduct that you
21 describe as anticompetitive.

22 Can you please summarize why Biosense's collection
23 practices were anticompetitive and not competition on the
24 merits?

09:38 25 A Yes. And to be clear, it's not just that they were

09:39 1 collecting catheters. It was that they were collecting and
2 withholding catheters. And as you may have gathered, in
3 order to reprocess catheters, the reprocessors need to get
4 used catheters. And so if a company is able to withhold
09:39 5 those used catheters, they can restrict the supply available
6 to the rivals and to the market.

7 Q Okay. Could I ask you to turn to JX298, please?
8 Is this a document you relied in forming your
9 opinions?

09:39 10 A It is.

11 MR. HO: We move the admission of JX298.

12 THE COURT: Any objection?

13 MR. CAVANAUGH: No objection.

14 THE COURT: 298 will be received.

09:39 15 (Exhibit 298 received in evidence)

16 BY MR. HO:

17 Q Dr. Forister, what is Exhibit 298?

18 A This is a Biosense 2019 kickoff meeting and internal
19 presentation.

09:40 20 Q And could you refer us to the portion of the
21 presentation that's significant for your opinion?

22 A Yes. If we go to page 28 of that and we start at the
23 bottom, there is some text that straddles the two pages if
24 we start at the bottom line of that first text box.

09:40 25 "Maximize collections. The RPO, the reprocessed market, is

09:40 1 unique in the way that there is a finite amount of raw
2 materials. If we control ACUNAV collections, we control the
3 market. In fact, it's not far-fetched to believe that if we
4 were able to collect back 75 percent of the OEM that is new
09:40 5 ACUNAV we sell, we could drive Stryker out of the
6 reprocessed electrophysiology business altogether."

7 Q And could you explain what that means and why it's
8 significant to your opinion?

9 A Yes. This is Biosense's internal discussion confirming
09:41 10 what we just discussed, that if a company is able to collect
11 back enough catheters, it can drive its rivals out of the
12 business.

13 Q Now, this is relating to ACUNAV collections.

14 Were you here in the courtroom when Mr. Dave
09:41 15 Distel testified about -- I'm sorry, I skipped one thing.

16 Did you consider data about Sterilmed's
17 reprocessing of ACUNAV catheters?

18 A Yes, I did.

19 Q Okay.

09:41 20 MR. HO: Could we put up Slide 7, please.

21 BY MR. HO:

22 Q What does Slide 7 show?

23 A So this shows Sterilmed's collection and sales of the
24 ACUNAV catheter from 2015 to 2020. And it's significant
09:41 25 that we start on the left. They collected about 156,000

09:41 1 catheters. They discarded, starting at the top on the
2 right, about 42,000 as not fit for reprocessing. They sold
3 59,000. But then they ended up with 54,000 catheters in
4 excess, and they just withheld those from the market. And
09:42 5 that's anticompetitive because customers wanted those
6 reprocessed catheters, and so Biosense/Sterilmed is
7 restricting the supply and restricting their choice.

8 Q And were you here in the courtroom when Mr. Dave Distel
9 testified about Innovative facing shortages of ACUNAV
09:42 10 catheters?

11 A Yes.

12 Q And how is that relevant to your opinion?

13 A So that's relevant because it tells us that this
14 withholding of catheters had an effect on a rival, and it
09:42 15 had an effect that there were customers who wanted the
16 choice of an Innovative reprocessed ACUNAV, and they were
17 denied that choice because all of those catheters that they
18 would have liked to buy were sitting at Sterilmed, not being
19 sold.

09:43 20 Q Just to be clear, I think you said "an effect on a
21 rival."

22 In antitrust economics, what does a "rival" refer
23 to?

24 A So it refers to a company that's competing with it, so
09:43 25 it's an effect on competition more broadly.

09:43 1 Q Could I now ask you to turn to Exhibit 3114?

2 A Okay.

3 Q Did you rely on Exhibit 3114?

4 A Yes, I did.

09:43 5 MR. HO: Move to admit Exhibit 3114.

6 MR. CAVANAUGH: No objection.

7 THE COURT: 3114 will be received.

8 (Exhibit 3114 received in evidence)

9 BY MR. HO:

09:43 10 Q Dr. Forister, what is Exhibit 3114?

11 A This is an e-mail with an attachment from Joseph
12 Koenig, the Product Director of Biosense, sent to Andrew Landers on June 27, 2018, with the Subject:
13 "Expand ULS" -- that is ultrasound, which would include the
14 ACUNAV -- "buy-back program" -- which is their collections
09:44 15 -- "to DECANAV and PENTARAY."

16
17 Q Okay. And how does this document relate to your
18 opinion?

19 A Well, bear with me because I need to introduce a few
09:44 20 other facts. So this is 2018, a time when Innovative has
21 clearance to reprocess the DECANAV and the PENTARAY. At
22 that same time, Sterilmed does not have that clearance, so
23 Sterilmed and Biosense cannot reprocess these catheters.

24 So they are suggesting to expand the collections
09:44 25 policy, which we saw restricted supply in the ACUNAV

09:44 1 business to the DECANAV and PENTARAY business. And because
2 Sterilmed wasn't going to be reprocessing these catheters at
3 that time, this simply eliminated the choice of those
4 reprocessed catheters from customers.

09:45 5 Q So given that Biosense/Sterilmed didn't reprocess the
6 DECANAV, was there any purpose in terms of competition on
7 the merits for them to collect those catheters?

8 A No, there is no evidence that it was competition on the
9 merits.

09:45 10 Q Now, if we could turn, please, to Exhibit 3270, is this
11 another document you relied on?

12 A It is.

13 MR. HO: We move the admission of Exhibit 3270.

14 MR. CAVANAUGH: No objection.

09:45 15 THE COURT: 3270 will be received.

16 (Exhibit 3270 received in evidence)

17 BY MR. HO:

18 Q Dr. Forister, what is Exhibit 3270?

09:45 19 A It's an e-mail with an attachment from Joseph Koenig
20 again at Biosense to Nathan Summers and others at Biosense
21 sent July 10, 2018, with the Subject field "Intel requested
22 - DECANAV collections."

23 Q So we're still on the topic of DECANAV collections.

24 How is this e-mail relevant to your opinion?

09:46 25 A We can see how Biosense is describing these efforts if

09:46 1 we go to the second sentence starting with: "In an effort
2 to better understand how Innovative Health will source the
3 supply for their reprocess iteration, could you please reply
4 if you are aware of any collections in the electrophysiology
09:46 5 lab besides us or Stryker? Based on your feedback, we may
6 consider proposing programs that could divert these
7 collections to us."

8 Q Why is that significant?

9 A It's significant because it tells you in Biosense's own
09:47 10 words what they're doing. And it's -- they're looking to
11 collect and divert supply from a competitor and thereby harm
12 or eliminate competition.

13 Q If we could go back to Slide 2, please, the third form
14 of conduct that you address here is the Case Coverage
09:47 15 Policy.

16 Did you prepare slides to explain why the Case
17 Coverage Policy is anticompetitive?

18 A Yes.

19 Q Okay, let's start with this one.

09:47 20 Could you please explain to the jury what a tying
21 arrangement is?

22 A Yes, and we're going to start with the definition from
23 economics. What is tying or a tying arrangement? And
24 economists use that to describe a situation like this. A
09:47 25 company, on one hand, has a must-have product, a product

09:58

1 Q Can I ask you to turn to Exhibit JX3626?

2 A Okay.

3 Q Did you rely on that exhibit in reaching your opinions
4 on this issue?

09:59

5 A Yes.

6 MR. HO: Your Honor, we move 3626 into evidence.

7 MR. CAVANAUGH: No objection.

8 THE COURT: 3626 will be received.

9 (Exhibit 3626 received in evidence)

09:59

10 BY MR. HO:

11 Q Okay, let's go to your timeline on Slide 11, please.

12 A Okay.

13 Q Could you explain what happened at Ascension Health
14 beginning with the first event on the timeline from
15 April 2014?

09:59

16 A Sure. So in April 2014, a Biosense mapper walked out
17 of a procedure because a doctor chose to use an
18 independently reprocessed sensor-enabled catheter. In
19 response, the doctor didn't want to stop the procedure. He
20 wanted the mapper to stay, and so they did away with the
21 independently reprocessed catheter, and they opened and used
22 a new Biosense catheter.

09:59

23 Q And do the documents show that that was a single
24 episode?

10:00

25 A No. Ascension had seen this happen several times in or

10:00 1 around April 2014.

2 Q Okay. What happened next?

3 A So you can imagine Ascension was furious about this,
4 and so they e-mailed Biosense to resolve this problem.

10:00 5 Q Okay. And if I could ask you to turn to Exhibit 153,
6 please.

7 MR. HO: And we can publish this to the jury
8 because it's already in evidence.

9 BY MR. HO:

10:00 10 Q Do you recognize Exhibit 153?

11 A I do.

12 Q And does 153 contain Biosense's response to Ascension?

13 A Yes, it does. We can see at the top an e-mail from
14 Neil Warman at Biosense.

10:00 15 Q Could you please read the underlined sentence in the
16 response?

17 A And to be clear, this was underlined by the Biosense
18 person, Neil Warman, who is sending the e-mail. "There is
19 no specific corporate policy that prohibits our people from
10:01 20 supporting cases, as we view this as part of our credo
21 responsibility to patients."

22 Q And so just to be clear, he is saying that there is no
23 such thing as what we now have been referring to in this
24 case as the Case Coverage Policy, right?

10:01 25 A Correct. He is essentially saying the opposite of

10:01 1 that.

2 Q And he's saying that the reason is J&J's credo
3 responsibility to patients.

4 Could you explain what the J&J credo is?

10:01 5 A Yeah. The credo is a promise or oath to patients to
6 take care of them, to compete fairly for their business by
7 providing better healthcare.

8 Q How does J&J advertise or disclose the credo?

9 A For example, it's on their website.

10:01 10 Q So what is the economic significance of the J&J credo?

11 A So the economic significance is that they're making a
12 promise to take care of patients, and that's something that
13 patients, doctors, hospitals would find attractive. And it
14 gets back to is this competition on the merits? Is it

10:02 15 attracting patients to you because your product is being
16 improved?

17 Q Now, did Mr. Warman's e-mail satisfy Ascension?

18 A No, it did not.

19 Q So then what happened?

10:02 20 A There was continued back and forth e-mails because
21 Biosense -- not Biosense, Ascension wanted a stronger
22 promise.

23 Q And did it receive one?

24 A It did.

10:02 25 Q Could you please explain?

10:02 1 A Sure. In May, Biosense promised that its mappers would
2 support cases even if independently reprocessed
3 sensor-enabled catheters were used.

4 Q What happened after that?

10:03 5 A Well, this was in the context of a contract
6 renegotiation. And so after receiving that promise,
7 Ascension in July signed a three-year contract to buy
8 catheters and other disposables from Biosense.

9 Q After the contract was signed, did Biosense follow
10 through on its assurance to Ascension?

11 A No. Almost immediately, Ascension noticed Biosense's
12 mappers were back to walking out or refusing to map on cases
13 involving independently reprocessed catheters.

14 Q What happened then?

10:03 15 A So then a few months later in October, the first Case
16 Coverage Policy letter was written and sent to Ascension.

17 MR. HO: Your Honor, we move the admission of
18 JX173.

19 THE COURT: Any objection?

10:04 20 MR. CAVANAUGH: No objection.

21 THE COURT: 173 will be received.

22 (Exhibit 173 received in evidence)

23 MR. HO: I would like to play a portion of the
24 audio clip that's now been admitted as Exhibit 143. In
10:04 25 particular, 58:37 to 59:30. And we have slides that

10:04 1 transcribe the words in the audio recording.

2 (Video clip played)

3 BY MR. HO:

4 Q So, Dr. Forister, could you explain what we just heard?

10:05 5 A Yes. So this is Conrad -- can we have the slide back
6 up?

7 So this is Conrad Ramos, the Corporate Account
8 Director at Biosense, describing what happened at Ascension
9 when they imposed the Case Coverage Policy. And if we go
10:05 10 back one slide, they see Ascension didn't like it, and they
11 spent the next six to nine months trying to drive the
12 business away from us.

13 So Ascension didn't like it. They tried to move
14 their business elsewhere, but they couldn't. Ultimately
10:06 15 what happened, even though Ascension didn't like it, was
16 Ascension spent another \$4 million with Biosense because of
17 the Case Coverage Policy.

18 Q And how was that significant to you in terms of whether
19 the Case Coverage Policy is anticompetitive?

10:06 20 A So circling back, was this something the customers
21 liked? And the answer from Biosense is, no, they didn't
22 like it. They didn't want it. They wanted to buy from
23 independent reproprocessors. And so this wasn't competition on
24 the merits. This was about eliminating choice and reducing
10:06 25 or harming competition.

10:07 1 Q Now, after the Ascension episode, did Biosense expand
2 the implementation of the Case Coverage Policy?

3 A They did. Ultimately, in April of 2016, they began
4 enforcing the policy nationwide.

10:07 5 Q Now, when you say "enforcing the policy nationwide,"
6 did Biosense tell all of its customers about the policy in
7 April 2016?

8 A No, and this is an important distinction. Biosense is
9 not announcing to the world, to the market, that we have
10:07 10 this policy. Evidence shows that they are waiting until a
11 hospital wants to use an independently reprocessed catheter,
12 and then they tell them, hey, you have a CARTO 3. You've
13 been using it for a while, but now you want to do this new
14 thing, buy independently reprocessed catheters. No, you
10:07 15 don't have that choice.

16 Q Did you see documents showing that Biosense was
17 concerned about Innovative Health in particular as a
18 competitor?

19 A Yes.

10:08 20 Q Could you please turn to Exhibit 3193 in your binder?
21 Did you rely on Exhibit 3193?

22 A I did.

23 MR. HO: We move that in evidence.

24 MR. CAVANAUGH: No objection.

10:08 25 THE COURT: 3193 will be received.

10:28 1 Q How much?

2 A Biosense itself estimates that each mapper earns
3 Biosense \$1.5 to \$2 million each year.

10:28 4 Q And how does that compare to the cost of providing a
5 mapper?

6 A So that's much higher than the cost of providing a
7 mapper. Biosense's internal calculations are that a mapper
8 pays for their full year of cost in just two months of work.

10:29 9 Q Dr. Forister, did you reach any conclusions about the
10 effect of the Case Coverage Policy on the combined prices
11 that hospitals paid for mapping machines, mappers, and
12 catheters?

13 A Yes.

14 Q And what was your conclusion?

10:29 15 A My conclusion was that the Case Coverage Policy had the
16 effect of raising the total price or total cost to hospitals
17 of the machine, the clinical support, and the catheters.

18 Q And what, if any, is your opinion about the effect of
19 the tying arrangement on the individual and average prices
10:29 20 hospitals pay for catheters?

21 A So both the individual and the average prices were
22 inflated by the Case Coverage Policy.

23 Q If we could turn back to Slide 17, please.

24 THE COURT: Before we do that, why don't we take
10:29 25 the mid-morning break here.

10:49

1 A Okay.

2 Q Did you create Exhibit 4419?

3 A I did.

4 MR. HO: We move Exhibit 4419 in evidence.

10:50

5 MR. CAVANAUGH: No objection, Your Honor.

6 THE COURT: 4419 will be received.

7 (Exhibit 4419 received in evidence)

8 BY MR. HO:

9 Q What does Exhibit 4419 show?

10:50

10 A So this shows the complaint rates for the SOUNDSTAR,
11 PENTARAY, and LASSO NAV separately for Innovative, Biosense,
12 and Sterilmed.

13 Q And how do the complaint rates for Innovative compare
14 to the complaint rates for Biosense and Sterilmed?

10:50

15 A You can see that the complaint rates for Innovative on
16 that top line are significantly lower than the complaint
17 rates for Biosense or Sterilmed. And you may recall these
18 complaint rate numbers from the testimony of Innovative's
19 representative last week.

10:51

20 Q I'll ask you now to turn to JX4421.

21 Did you also create Exhibit 4421?

22 A Yes.

23 MR. HO: We move 4421 in evidence.

24 MR. CAVANAUGH: No objection.

10:51

25 THE COURT: 4421 will be received.

1 (Exhibit 4421 received in evidence)

2 BY MR. HO:

3 Q Could you explain what Exhibit 4421 is?

4 A Yes. So this shows the adverse events, the injury and
5 death rates, recorded in the FDA's database for the
6 catheters and manufacturers at issue. So you can see
7 Biosense SOUNDSTAR, 116 injuries, ten deaths, from 2013 to
8 2023.

9 Q And how do the adverse events, the injuries and deaths,
10 compare for Biosense and Sterilmed versus Innovative?

11 A So Biosense and Sterilmed's rates are higher than
12 Innovative's both in terms of the total number in that
13 column with the green highlighting, and then if we go over
14 to the number of events per 10,000 catheters that were sold,
15 Innovative's rate of zero is lower than that of Biosense or
16 Sterilmed -- or lower or equal to.

17 Q How do the two tables that you just showed about the
18 complaint rates and about the FDA MAUDE data relate to your
19 opinion as to whether the Biosense conduct in this case
20 decreased quality in the market?

21 A So both of those data sources indicate that Innovative
22 has higher quality than Biosense or Sterilmed. And so
23 excluding Innovative from the market, preventing customers
24 from choosing them, reduced the quality that was available
25 to their customers.

10:55 1 sure that the catheter is good to use.

2 BY MR. HO:

3 Q Now, if we could go back to Slide 17, please, and move
4 on to decreased innovation. What do you mean by that?

10:55 5 A Well, we can start with a fundamental economic
6 principle, which is competition spurs innovation. Companies
7 come out with new and better products because they're facing
8 competitive pressure to convince customers to buy from them.
9 So reducing competition on a theoretical basis would reduce
10 innovation.

11 Q And do you see real-world examples of that here?

12 A Yes, and real-world experience here confirms that, and
13 I'll give two examples. First, you heard testimony last
14 week about Innovative's patented technology for cleaning the
10:56 15 lumen, this narrow tube that's in the catheter that's really
16 hard to get clean. They came up with a way to clean it that
17 was new, so a new process that made it even cleaner than a
18 new catheter's lumen. By excluding Innovative's sales, they
19 prevented that technology from getting to customers.

10:56 20 Q Are there other examples?

21 A Yes. A second example would be because of the Case
22 Coverage Policy, that convinced companies like Innovative
23 and Stryker not to reprocess the OCTARAY because they knew
24 they would be excluded from the market. And so that
10:56 25 innovation of a reprocessed OCTARAY has not occurred, and it

10:56 1 looks like that is due to the Case Coverage Policy.

2 Q Now, lastly, if we could talk about the fourth bullet
3 point, decreased choice, how did Biosense's conduct decrease
4 choice?

10:57 5 A Well, the Case Coverage Policy itself is cutting off
6 choice. The customer that wants to choose independently
7 reprocessed and use Biosense's mappers can't do so, so that
8 choice is removed.

9 And I can give you an example of why that choice
10 matters. You heard last week the testimony that there was a
11 shortage at one point of the 8 French SOUNDSTAR, the 8
12 French being the narrow diameter. And instead of letting
13 doctors go and get their preferred catheter size, the 8
14 French, from an independent reprocessor, doctors were forced
10:57 15 to use a different catheter or the larger diameter catheter.

16 And looking at the medical research, larger
17 diameter catheters are associated with needing to make a
18 larger incision in the patient to put them in. And so we
19 can see that decrease in the choice can have a direct impact
10:57 20 on customer health and safety.

21 Q Now, Dr. Forister, what did you calculate to be
22 Innovative's lost profits from Biosense's anticompetitive
23 conduct?

24 A I calculated that their lost profits were at least
10:58 25 \$147 million.

10:58 1 Q Over what time period?

2 A And that was about a ten-year period from 2016 through
3 until now last week.

4 Q Okay. Could you please put up Slide 29.

10:58 5 Dr. Forister, you prepared Slide 29?

6 A I did.

7 Q What does it show?

8 A So this breaks out the lost profit for these three sets
9 of catheters: the SOUNDSTAR at approximately \$95 million,
10 the PENTARAY and OCTARAY at approximately \$43 million, and
11 the LASSO NAV at about \$9 million.

12 Q Did you prepare a slide to help illustrate your lost
13 profits calculation?

14 A I did.

10:58 15 Q Could we put up Slide 30.

16 Could you explain generally what Slide 30 shows?

17 A Yes. So to get to that \$147 million in total lost
18 profits, I started by looking at just what was the effect of
19 the Case Coverage Policy, and that had \$139 million in lost
10:59 20 profits. I then asked, well, what effect did the blocking
21 technology have? And the blocking technology delayed entry.
22 And so if the blocking technology was removed, Innovative
23 could have started selling earlier. It would have had more
24 months of sales. And so I calculated how much that would
10:59 25 be, and it was about \$8 million.

11:06 1 market share of catheter sales, and there were a hundred
2 thousand catheters sold, they would have sold 10,000
3 catheters. So that's how we calculate the quantity they
4 would have sold.

11:06 5 The next question is what price they would have
6 sold it at. So we again look to the benchmark market. And
7 for reprocessed devices like this, they're often sold at --
8 the reprocessed is often sold at a discount off the new
9 price. So we look at what that discount was for the
11:06 10 benchmarks, and we apply that discount in the markets at
11 issue to get our price that they would have sold it. So
12 then we multiply the quantity they would have sold times the
13 price they would have sold it at, subtract off costs, and we
14 have their profits.

11:06 15 Q Okay. So if we could put Slide 30 back up.

16 I think you've now explained how you arrived at
17 the blue box and the green box and, as a result, how you got
18 to lost profits from tying.

19 How did you determine the an additional lost
11:07 20 profits from blocking, the red box in the middle?

21 A Yes. So I talked about lining up that market share --
22 the benchmark market share performance with the actual entry
23 date of Innovative for these catheters. I simply moved that
24 back by however many months the blocking technology was
11:07 25 causing a delay. So if there was a three-month delay, I

11:07 1 just shifted that back three months, and they made sales for
2 an additional three months.

3 Q Okay. And I think you said in the summary of your
4 opinions that the total lost profits that you calculated was
11:07 5 at least \$147.4 million.

6 Could you explain why you said at least?

7 A Yes. There's a variety of factors that make it an
8 underestimate of what the true lost profit is. For example,
9 I didn't include the ACUNAV catheter, the DECANAV catheter,
11:08 10 and the VIZIGO Steerable Sheath. I didn't calculate damages
11 due to the collections policy. And I also didn't include
12 damages from the additional cost, the monetary cost, of
13 overcoming the blocking technology. You heard from
14 Innovative's engineer last week that it took time and effort
11:08 15 to overcome the blocking technology. I only accounted for
16 that time delay. I didn't account for the cost of
17 overcoming the blocking delay.

18 Q Now, Dr. Forister, I think you've heard since you've
19 been sitting in this courtroom Biosense's counsel offer a
11:08 20 number of arguments as to why the Case Coverage Policy was
21 legitimate. Do you recall those?

22 A Yes.

23 Q And do you recall Biosense's attorney discussing free
24 riding in his opening statement?

11:09 25 A He did.

11:28 1 A So the financial part of the switching cost is the cost
2 to buy a new machine. If you don't have that other machine,
3 you have to buy it. They cost hundreds of thousands of
4 dollars.

11:28 5 Q And what the non-financial switching costs?

6 A So these are particularly challenging to deal with, and
7 you heard from Dr. Doshi on Friday describing them. The
8 hospital, or the situation, would have to convince the
9 doctor to switch away from the machine they were planning to
11:28 10 use to a new machine. And the doctors are comfortable with
11 one machine. They might not have training on another
12 machine, which is another barrier or cost to switching.

13 They may want to stick with the mapper on the CARTO 3 and
14 not switch to a new mapper on, say, an Abbott machine. So
11:29 15 these are all costs to switching that indicate that lock-in
16 is happening.

17 Q Okay. The third item on your list is the difficulty of
18 lifecycle pricing.

19 Before we get to the difficulty part, what is
11:29 20 lifecycle pricing?

21 A So that's just predicting the total cost over the life
22 of a CARTO 3.

23 Q And why in your opinion is it difficult for hospitals
24 to accurately engage in lifecycle pricing?

11:29 25 A Well, there's a few factors. The first is that the

11:29 1 CARTO 3 is a long-lived device. It has a lifespan of ten or
2 more years. And you can imagine it's difficult to predict
3 ten years in the future, particularly in light of the fact
4 that the hospital would need to predict when new and more
11:30 5 expensive catheters are coming online, when reproprocessors
6 might enter at lower prices. They need to figure out what
7 patient demand is going to be, what reimbursements are going
8 to be, so a host of challenges to predicting a ten-year or
9 more lifecycle price.

11:30 10 Q You heard some testimony in court during the trial that
11 hospitals tried to engage in lifecycle pricing. Did that
12 affect your opinion?

13 A No.

14 Q Why not?

11:30 15 A Well, one would expect the purchaser of a product to
16 make some attempts to do lifecycle pricing, but for all the
17 reasons I mentioned, it's challenging to do that accurately.
18 And if it's -- if you can't accurately predict those things,
19 you may not be able to avoid the choice of buying the CARTO
11:30 20 3 and getting locked in.

21 Q Now, the last factor on your list is cross-elasticity
22 of demand. Could you explain what that means?

23 A Yeah. So that's just a fancy economic way of saying if
24 the price of one product goes up, do customers switch to
11:31 25 another product?

11:45 1 A Yes.

2 Q What is Biosense's market share in those three catheter
3 markets?

4 A So for the sensor-enabled circular mapping, 92 percent.
11:45 5 For those high-density mapping catheters, PENTARAY, OPTRELL,
6 OCTARAY, over 99 percent. And for the SOUNDSTAR, the
7 sensor-enabled ultrasound, 99 percent.

8 Q Can that share also be calculated in terms of the money
9 spent on these catheters?

11:45 10 A Yes. That's another way to look at the economic
11 footprint of the companies.

12 Q Okay. Could we please go to the next slide.

13 So what does this slide show?

14 A So this shows the revenues that Biosense/Sterilmed
11:45 15 earned as opposed to independent reproprocessors for these
16 catheters from 2016 to 2023. And I break out the SOUNDSTAR,
17 the PENTARAY/OCTARAY, and the LASSO NAV. If we look at just
18 the total Biosense/Sterilmed received, it's \$3.6 billion of
19 revenue for these catheters, and the independent
11:46 20 reproprocessors less than one percent, just under \$26 million.

21 Q What barriers to entry exist in these markets?

22 A Well, there is the technical difficulty of entering,
23 and the cost, approximately half a million dollars to get
24 FDA clearance, but the bigger barrier is the Case Coverage
11:46 25 Policy. Even if you brought your own independently

11:46 1 reprocessed catheter to market, the Case Coverage Policy
2 would exclude you from almost the entire market.

3 Q Did you see evidence that Biosense can inflate prices
4 and exclude competition in these catheter markets?

11:46 5 A Yes.

6 Q What evidence?

7 A Well, so the Case Coverage Policy and what happened in
8 those markets is one, and the economic analysis that we've
9 been talking about thus far is another.

11:47 10 Q In your opinion, Dr. Forister, did Biosense's
11 anticompetitive conduct allow Biosense to achieve its
12 monopoly power in these markets?

13 A Yes.

14 Q What is the basis for your opinion?

11:47 15 A Well, the economic analysis we discussed, as well as a
16 few specific quantitative comparisons of shares across
17 different markets and over time.

18 Q Okay. Let's go to the first of those quantitative
19 analyses.

11:47 20 Could we put up Slide 44, please.

21 Did you prepare Slide 44?

22 A Yes.

23 Q And could you please explain what this shows?

24 A Okay. So one point of comparison would be to say what
11:47 25 happened to independently reprocessed market share before

1 the tie and after the tie? And here's what it was for
2 sensor-enabled ultrasound, that is, the SOUNDSTAR. 2013 and
3 2014, independent reproprocessors had a 23 percent share of
4 that market. After the tie, 2022-2023, down to one percent.

5 Q Did you find similar trends with respect to the other
6 CARTO 3 catheters?

7 A Yes. The LASSO NAV, we also see a decrease in the
8 share over time.

9 Q Would you please find JX4457 in your binder.

10 Did you prepare 4457?

11 A I did.

12 MR. HO: We move 4457 into evidence.

13 MR. CAVANAUGH: No objection.

14 THE COURT: 4457 will be received.

15 (Exhibit 4457 received in evidence)

16 BY MR. HO:

17 Q Could you please explain what 4457 shows?

18 A Yes. So we've been talking about several catheters,
19 the SOUNDSTAR, the PENTARAY, and the LASSO NAV. So if we
20 roll up those in a bigger group, we can look at third-party
21 or independent reproprocessor share in 2013 to 2014,
22 16 percent, and that gets taken down to one percent in 2022
23 to 2023 after the tie. So we can see a before the tie and
24 after the tie comparison shows independent reproprocessors'
25 share of the navigational catheters going down

11:49 1 significantly.

2 Q Did you do a second quantitative analysis?

3 A Yes.

4 Q Could we please put up Slide 45.

11:49 5 What does Slide 45 show?

6 A So this compares independent reproprocessors' share for
7 catheters that were unaffected -- CARTO 3 catheters that
8 were unaffected by the policy. So one might have been
9 concerned in that previous slide that we see this decline,
11:49 10 but what if it's due to something else? What if people are
11 just becoming less interested in reprocessing? And this
12 answers that question. The share of independent
13 reprocessing went up between 2013 to 2014 and 2022 to 2023
14 for the catheters on the CARTO 3 that weren't covered by the
11:50 15 Case Coverage Policy.

16 Q Dr. Forister, to summarize, in your opinion, was
17 Biosense's Case Coverage Policy anticompetitive or
18 competition on the merits?

19 A It was anticompetitive.

11:50 20 Q And what about Biosense's Project Falcon, the blocking
21 technology?

22 A The blocking technology was anticompetitive.

23 Q What about Biosense's catheter collections practices?

24 A The catheter collection and withholding was
11:50 25 anticompetitive.

1 different manufacturers of catheters.

2 Q. I think, Dr. Forister, there might have been some
3 comment made that this data reporting to the FDA is
4 voluntary. Is that accurate?

03:22PM 5 A. No, it is not.

6 Q. Could you please explain.

7 A. To the contrary. The manufacturer and the user -- that
8 is, the hospitals -- are required to report this data.

9 Q. Is it common for economists to rely on data that
03:22PM 10 companies are legally required to report to the government?

11 A. Yes, it is.

12 Q. Do you recall when you were cross-examined about the
13 limitations on using the MAUDE data for death and injury?

14 A. Yes.

03:23PM 15 MR. HO: Put up the next slide, please.

16 BY MR. HO:

17 Q. Do you recall this question and this answer?

18 A. Yes.

19 Q. And how does this relate to --

03:23PM 20 MR. CAVANAUGH: Your Honor, objection. This is not
21 a proper rebuttal.

22 MR. HO: Your Honor --

23 MR. CAVANAUGH: He's trying to clean up what
24 happened on direct examination.

03:23PM 25 THE COURT: Just a minute.

1 Sustained.

2 BY MR. HO:

3 Q. Turning from the MAUDE data to the complaint data, do
4 you recall testimony about the possibility that the complaint
03:23PM 5 data was unreliable?

6 MR. CAVANAUGH: Your Honor, again, there's no
7 testimony given by Dr. Wu regarding complaint data.

8 MR. HO: Your Honor, he's a rebuttal witness not
9 just for Dr. Wu but for their case. There was ample
03:24PM 10 testimony --

11 THE COURT: Overruled.

12 MR. HO: Thank you.

13 THE WITNESS: Yes. And another way in which I
14 overcame that limitation of the MAUDE death and injury data,
03:24PM 15 of not relying solely on it, was to confirm those results
16 using the complaint data.

17 BY MR. HO:

18 Q. And you recall that there was another source of data
19 that you relied on in addition to the MAUDE data and the
03:24PM 20 complaint data?

21 A. Yes.

22 Q. Could you explain what that is.

23 A. Yeah. So that was academic research studies on the
24 reliability or safety of reprocessed medical devices as
03:24PM 25 compared to new OEM medical devices.

1 Q. Now, if I could ask you to look at Exhibit JX4316 in
2 your binder, please.

3 A. (Witness complies.)

4 Q. Do you see it?

03:24PM 5 A. I do.

6 Q. Do you recall Ms. Zare testifying about this document
7 earlier?

8 A. I wasn't in the courtroom, but I heard that she did.

03:25PM 9 Q. Now, could I ask you to look at the bottom of the first
10 page.

11 A. (Witness complies.) Okay.

12 Q. Do you see the language starting with OEM?

13 A. Yes.

03:25PM 14 Q. Could you just explain to the jury what this means in
15 plain English.

16 A. Sure. So this meant that for one of the studies of
17 reprocessed and new medical devices, they found that the
18 reprocessed devices -- sorry. They found that the OEM
19 devices were defective 4.9 times more frequently than the
03:25PM 20 reprocessed devices.

21 MR. CAVANAUGH: Your Honor --

22 BY MR. HO:

23 Q. Were there other studies --

24 THE COURT: Just a minute.

03:25PM 25 MR. CAVANAUGH: Objection, Your Honor. This

EXHIBIT 4

1 Snider.

2 **Meredith Snider, Plaintiff's witness, sworn**

3 THE CLERK: Please state your full name, spelling
4 your last name for the record.

01:24PM 5 THE WITNESS: Meredith Snider, S-n-i-d-e-r.

6 MS. MORALES-KIMBALL: Permission to approach,
7 Your Honor.

8 THE COURT: You may.

9 **DIRECT EXAMINATION**

01:25PM 10 BY MS. MORALES-KIMBALL:

11 Q. Good afternoon.

12 A. Good afternoon.

13 Q. Please introduce yourself to the jury.

14 A. My name is Meredith Snider.

01:26PM 15 Q. Where do you work?

16 A. I work at Innovative Health.

17 Q. What is that?

18 A. That is a reprocessing device company.

19 Q. What is your role there?

01:26PM 20 A. I am the senior director of sales operations.

21 Q. Other than Innovative Health, have you worked at other
22 reprocessing companies?

23 A. Yes, I have.

24 Q. Which ones are those?

01:26PM 25 A. I worked at Alliance. I worked at Ascent Healthcare

1 and hearsay. We're clearly going to get testimony here based
2 on conversations from third parties.

3 THE COURT: Sustained.

4 BY MS. MORALES-KIMBALL:

02:31PM

5 Q. Ms. Snider, hospitals have -- have hospitals conveyed
6 their state of mind with respect to Sterilmed?

7 MR. CRUZ: Objection, Your Honor. This is not
8 state of mind. These are opinions of third parties.

9 THE COURT: Sustained.

02:31PM

10 BY MS. MORALES-KIMBALL:

11 Q. Are you aware of any other customers beside University
12 Hospital that had made a plan to move product from Biosense
13 Webster to another manufacturer's mapping machine?

14 A. Yes.

02:32PM

15 Q. And generally were they successful in doing so?

16 A. No.

17 Q. And why is that?

18 A. The majority of the time it comes down to physician
19 preference. Other times it's too much of a capital -- too
20 costly for them.

02:32PM

21 Q. Besides UH, are there any current Innovative customers
22 that will not purchase sensor-enabled catheters from
23 Innovative due to Biosense's policy?

24 A. Oh, yes.

02:32PM

25 Q. How would you know that?

1 A. Well, I work with all of our customers at some sort of
2 level and go through their data.

3 Q. And approximately how many customers will not purchase
4 sensor-enabled catheters because of Biosense's policy?

02:33PM 5 A. Almost all of them.

6 Q. How many would that be?

7 A. Over 200.

8 Q. Has that impact been tied to any specific region?

9 A. No. It's across the United States.

02:33PM 10 Q. And are any located in California?

11 A. Yes. Several of them are.

12 Q. Which ones?

13 A. Kaiser Permanente, Stanford Health, Sharp Health,
14 Torrance Memorial. Those are the ones that come to mind
02:33PM 15 right now.

16 Q. Does Biosense's policy come up with potential customers?

17 A. Oh, yes.

18 Q. How often?

19 A. Pretty much with each potential customer.

02:34PM 20 Q. Let's focus just on 2025 so far.

21 A. Okay.

22 Q. So in the last five months, about how many potential
23 customers have you interacted with about Biosense's case
24 coverage policy?

02:34PM 25 A. I would have to say about probably, like, 10 to 15

EXHIBIT 5

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE JAMES V. SELNA, JUDGE PRESIDING

INNOVATIVE HEALTH, LLC,

Plaintiff,

Vs.

BIOSENSE WEBSTER, INC.,

Defendant.

No. SACV-19-01984-JVS

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

DAY 2, VOLUME II

SANTA ANA, CALIFORNIA

WEDNESDAY, MAY 7, 2025

MIRIAM V. BAIRD, CSR 11893, CCRA
OFFICIAL U.S. DISTRICT COURT REPORTER
350 WEST FIRST STREET
FOURTH FLOOR
SANTA ANA, CA 92701

1 were paying for it.

2 Q. Okay. When you say that, that the case coverage policy
3 was not free to them, what do you mean by that?

4 A. Well, they were -- in effect the hospital is paying for
03:00PM 5 it by the price of the catheters that they were being
6 charged.

7 Q. Do you recall discussing in your e-mail Biosense
8 Webster's market share?

9 A. Yes.

03:00PM 10 Q. And what do you recall about that?

11 A. I think I said in the e-mail that they have the dominant
12 market share, that they do have good products, and they've
13 got a loyal physician following.

14 Q. What did you mean by that?

03:00PM 15 A. Well, physicians like the products from Biosense
16 Webster, and they're -- they do a lot of work to keep the
17 physicians happy.

18 Q. What do you mean when you say that Biosense Webster has
19 dominant market share?

03:00PM 20 A. They're in all the labs. I mean, every lab that I go to
21 across the country, they're in the lab.

22 Q. Do you recall writing to Ms. Roberts about whether the
23 case coverage policy was an industry standard?

24 A. I think I told her it was an industry standard. Still
03:01PM 25 currently today Biosense Webster is the only one that has

1 by Biosense Webster.

2 Q. Give us a sense in a given case of how much, if you're
3 able to sell reprocessed catheters, what percentage of the
4 equipment in a given case are you providing?

03:21PM 5 A. About 25 percent.

6 Q. Okay. And can you explain why that makes it
7 economically infeasible for you to provide a map for the
8 entire case?

9 A. We're not selling the rest of the catheters. We're
03:22PM 10 selling a small sliver of the catheters that are to be used.

11 Q. Mr. Ferreira, is Biosense's case coverage policy still
12 affecting Innovative Health's business today?

13 A. Yes, it is.

14 Q. Give us a sense of what the magnitude of that impact is.

03:22PM 15 A. I think our business could be double the size as it is
16 today if I was able to sell these sensor-enabled catheters.
17 Again, remember, each dollar of sales for me is a dollar of
18 savings for the hospital because they're not having to buy
19 brand-new catheters. So it's pretty impactful.

03:22PM 20 Q. If you could look in your binder and find JX3887.

21 A. (Witness complies.) Yes. I have it here.

22 Q. Do you recognize JX3887?

23 A. Yes. This is an e-mail from Ken Blenis at MarinHealth
24 dated March the 6th, 2020, to Jay Farris.

03:23PM 25 MR. HO: Your Honor, we move to admit 3887.

1 We'll then break up the analysis to show here's what's
2 really -- here's what the total savings opportunity could be,
3 but in reality here's what you should be able to realize off
4 the stuff that's not covered by the case coverage policy.

03:28PM

5 Q. In your experience, when hospitals buy reprocessed
6 catheters from Innovative Health, who is going to use the
7 catheters?

8 A. The physician.

03:28PM

9 Q. And in your experience, if the doctors at the hospital
10 don't want to use Innovative Health's reprocessed catheters,
11 would a hospital be interested in buying them?

12 A. No.

13 Q. Why not?

03:28PM

14 A. Because they would be spending the money and the
15 catheters wouldn't get utilized.

16 Q. Mr. Ferreira, could you summarize, please, for the jury
17 the impact of Biosense Webster's case coverage policy on
18 Innovative Health.

19 A. It's been devastating to our business.

03:28PM

20 MR. HO: Pass the witness.

21 THE COURT: Very well.

22 Cross-examination.

23 MR. CAVANAUGH: Your Honor, may I approach the
24 witness?

03:29PM

25 THE COURT: You may.

EXHIBIT 6

1 MR. GOLDSMITH: Your Honor, Innovative calls Dave
2 Distel. We're getting him now.

3 THE COURT: Good.

4 MR. GOLDSMITH: Your Honor, Ms. Schiffman will
02:12PM 5 inquire.

6 MS. SCHIFFMAN: Your Honor, may I approach with the
7 binders?

8 THE COURT: You may.

9 **Dave Distel, plaintiff's witness, sworn**

02:12PM 10 THE CLERK: Would you please state your full name,
11 spelling your last name for the record.

12 THE WITNESS: Name is Dave Distel, D-i-s-t-e-l.

13 **DIRECT EXAMINATION**

14 BY MS. SCHIFFMAN:

02:13PM 15 Q. Good afternoon, Mr. Distel.

16 A. Good afternoon.

17 Q. Please tell the jury where you work.

18 A. I work at Innovative Health.

19 Q. How long have you worked at Innovative?

02:13PM 20 A. A little over eight years.

21 Q. What do you do there?

22 A. I'm the vice president of business development.

23 Q. What degrees do you hold?

24 A. I have a bachelor's in nursing from Duquesne University.

02:13PM 25 I have a master's in nursing with an emphasis in anesthesia

1 sensor-enabled catheters?

2 A. Not anymore.

3 Q. Did that used to be different?

4 A. They were buying them, yes, for several years there
02:31PM 5 before things changed.

6 Q. Why the difference?

7 A. In the beginning there were Mayo personnel, so EP techs
8 that were employed by Mayo that knew how to map, they were
9 mapping the cases. So they were able to use the NAV LASSOs
02:31PM 10 and the SOUNDSTARS, but that changed when they were no longer
11 mapping cases.

12 Q. Does Innovative Health have FDA clearance to reprocess
13 the VIZIGO steerable sheath?

14 A. We do.

02:32PM 15 Q. What is the VIZIGO steerable sheath?

16 A. The VIZIGO steerable sheath in the simplest term is a
17 long device that you can think of as a straw that's
18 steerable. The physician inserts it in a blood vessel in the
19 groin, and it will go up to the heart so that the physician
02:32PM 20 can take catheters and go up through the sheath like a
21 channel to get them into the heart and position them in the
22 heart where they need them.

23 Q. When did Innovative get clearance to reprocess the
24 VIZIGO?

02:32PM 25 A. March of 2022.

1 Q. Did you sell VIZIGOs after that?

2 A. I did.

3 Q. How were those sales?

4 A. I had several clients that initially contacted me with
02:32PM 5 great interest, like Erlanger, CentraCare, and several
6 others.

7 Q. What happened after that?

8 A. Shortly after I started selling them, the sales stopped.
9 And then I learned that it was now being included in the
02:33PM 10 Biosense Webster case coverage policy.

11 Q. If you could please look in your binder and find
12 Exhibit 3957.

13 A. (Witness complies.) Yes.

14 Q. What is this?

02:33PM 15 A. This is an e-mail chain with the top e-mail being from
16 Jeff Loy to myself dated July 13th, 2022, with the subject
17 matter being, re, Innovative Health.

18 MS. SCHIFFMAN: Your Honor, we'd move to admit
19 Exhibit 3957.

02:33PM 20 MR. FARIDI: No objection, Your Honor.

21 THE COURT: 3957 will be received.

22 **(Exhibit 3957 received)**

23 BY MS. SCHIFFMAN:

24 Q. Who is Mr. Jeff Loy?

02:33PM 25 A. Jeff Loy is the director of supply chain management for

1 Erlanger Health in Chattanooga, Tennessee.

2 Q. And do you remember receiving this e-mail from him?

3 A. Yes, I do.

4 Q. Is there an attachment to the e-mail?

02:34PM 5 A. Yes. There were two things attached.

6 Q. Let's look at the second attachment, please.

7 A. (Witness complies.)

8 Q. What is this?

9 A. This is a listing of the catheters that Biosense had
02:34PM 10 considered that could not be covered as sensor-enabled
11 catheters, but for first time it now had the VIZIGO sheath
12 products listed on it.

13 Q. What about the other attachment? What is that?

14 A. It's a case coverage policy. There's some new verbiage
02:35PM 15 in it that now talks about a term called software pairing.

16 Q. Can you please direct us to that language.

17 A. It would be down in the base right there (indicating).
18 Yes, please.

19 Q. What do you remember thinking about that language?

02:35PM 20 A. Well, I'd never heard the term software pairing before,
21 nor had any of my friends in the industry. It felt like it
22 was a phrase being used to justify why a client could not use
23 the VIZIGO as it was not a sensor-enabled sheath.

24 Q. Is there a date on this version of the letter?

02:35PM 25 A. There is. It's -- hang on. It's June 8th of 2022.

1 Q. Remind us, please, when did Innovative get FDA clearance
2 to reprocess the VIZIGO.

3 A. That would have been March of 2022.

4 Q. How did receiving this version of the case coverage
5 policy letter make you feel?

6 A. Well, I was crushed in that we pursue devices that our
7 clients want so that they can save more money in their
8 procedures. And we spent hundreds of thousands of dollars to
9 pursue the clearance to get the VIZIGO, thinking that it
10 would sell remarkably well because a competitive product from
11 Abbott sells amazingly well. And I was shut down in a matter
12 of, like, three months.

13 Q. After receiving this letter, did Erlanger Hospital
14 purchase VIZIGO sheaths?

15 A. They did not.

16 Q. If you could please look in your binder and find
17 Exhibit 3969.

18 A. (Witness complies.) Yes.

19 Q. What is this?

20 A. This is an e-mail string with the top e-mail being from
21 Rick Ferreira to the members of our sales team on June 20th
22 of 2022. Subject matter, forward external query.

23 MS. SCHIFFMAN: Your Honor, we'd move to admit
24 Exhibit 3969.

25 MR. FARIDI: No objection, Your Honor.

1 THE COURT: 3969 will be received.

2 (Exhibit 3969 received)

3 BY MS. SCHIFFMAN:

4 Q. MR. Distel, could you please look at page 3.

02:37PM 5 A. (Witness complies.) Yes.

6 Q. Who is this e-mail from?

7 A. This is from Risa Meder.

8 Q. Who is Risa Meder?

9 A. Risa Meder is one of the EP techs at CentraCare
02:37PM 10 Hospital. She also does all of the ordering of products for
11 their labs.

12 Q. I'd like you to read the first four sentences in
13 Ms. Reder's e-mail.

14 A. I have a question for you. I was so excited about
02:37PM 15 saving money by ordering the reprocessed VIZIGO sheaths that
16 I forgot that CARTO won't back up cases if we use a
17 reprocessed product that has a chip. I have three of them.
18 Sad face. Is there any way we can return them?

19 Q. What happened after you received this e-mail?

02:38PM 20 A. Innovative Health did the return and credited them money
21 back.

22 Q. Has CentraCare bought VIZIGOs from Innovative since?

23 A. They have not.

24 Q. Do you recall any other recent notable incidents
02:38PM 25 involving the case coverage policy?

02:45PM 1 A. This e-mail is about Sterilmed had been actually
2 collecting at Lakeland, and this was an account that Medline
3 and I were now bringing on board. They were contacted and
4 saw that the catheters were not being collected in a very
5 good way.

6 Q. Is there a picture included in the e-mail?

7 A. There is.

8 Q. What does this show?

02:45PM 9 A. It shows a trash can being used for collections, and
10 it's overflowing with both EP catheters and ultrasound
11 catheters.

12 Q. What does this picture tell you?

13 A. It's not a very serious reprocessing program because,
14 one, you would never let anything like this overflow for many
02:46PM 15 reasons, but this is setting all the catheters up to be
16 damaged. Then you would have a low yield rate of what you
17 could send back to the client.

18 Q. Have Biosense's collection practices impacted
19 Innovative?

02:46PM 20 A. That depends on which catheters and products you're
21 talking about.

22 Q. How about with the ACUNAV?

23 A. The ACUNAV, it has greatly impacted us because they
24 require many clients to collect the ACUNAV, many of which are
02:46PM 25 not even buying it back. And that's a very high-in-demand

1 catheter with clients.

2 Q. What about the SOUNDSTAR?

3 A. The SOUNDSTAR, while they're collecting it, many of
4 their clients, there are still enough SOUNDSTARS that come in
02:47PM 5 to me. And because of the Biosense Webster case coverage
6 policy and not really being able to sell them back, I'm
7 swimming in SOUNDSTARS.

8 Q. You just mentioned the case coverage policy?

9 A. Yes.

02:47PM 10 Q. At a high level, from your perspective how has the case
11 coverage policy impacted Innovative Health?

12 A. It's really been devastating to both Innovative and our
13 clients that had views that they wanted to have substantial
14 savings.

02:47PM 15 We as a company, when we started, we didn't want to
16 be a me, too, reprocessor. We wanted to do the high-end
17 items that would bring the most value to the client because
18 there's always new technologies that are coming to the
19 marketplace which continue to drive the costs in healthcare.

02:47PM 20 So we've pursued those, like the mapping catheters,
21 the SOUNDSTARS. We got the clearances, and we fully expected
22 to be able to sell them. And not only are they the products
23 that would generate the absolute most savings for the
24 hospital, but they also would have generated the most revenue
02:48PM 25 for us.

EXHIBIT 7

1
2
3
4 UNITED STATES DISTRICT COURT
5 CENTRAL DISTRICT OF CALIFORNIA
6 SOUTHERN DIVISION

7 - - -

8 THE HONORABLE JAMES V. SELNA, JUDGE PRESIDING

9 INNOVATIVE HEALTH, LLC,) CERTIFIED TRANSCRIPT
10 Plaintiff,)
11 vs.)
12 BIOSENSE WEBSTER, INC.,) SACV-19-01984-JVS
13 Defendant.) TRIAL DAY 4, VOL. I
14 -----)

15 REPORTER'S TRANSCRIPT OF PROCEEDINGS

16 Santa Ana, California

17 May 9, 2025

18
19 SHARON A. SEFFENS, RPR
20 United States Courthouse
21 411 West 4th Street, Suite 1-1053
22 Santa Ana, CA 92701
23 (612) 804-8655
24
25

09:24

1 A It was after.

2 Q How long have you been practicing EP again?

3 A 25 years.

4 Q Were you surprised to learn of the policy last year?

09:24

5 A I was.

6 Q Why was it a surprise to you?

7 A It's mostly around the idea of as absolute as it was,

8 right. If we are being told that we're not going to get

9 coverage to perform a procedure that we feel is in the best

09:24

10 interest, of course, of patient care and sometimes is

11 life-saving, that, of course, creates a great deal of angst.

12 And all of us are in the business of taking care of

13 patients, and so, yeah, I was surprised.

14 Q What do you think of the Case Coverage Policy,

09:25

15 Dr. Doshi?

16 A I don't think it's appropriate.

17 Q Why not?

18 A Number 1, I do feel that we can use reprocessed

19 catheters safely, effectively. But importantly, it does

09:25

20 affect our ability to support patient care. It does

21 represent of course a cost savings as you can imagine, and

22 that is incredibly important for hospitals and hospital

23 systems these days. So that is something that -- I mean,

24 it's one of the prime reasons why we do reprocessing.

09:25

25 There are several others as well of course. We do

09:25 1 think about the bigger picture as far as whether this is a
2 reduction of a carbon footprint or a reduction of waste or
3 even supporting our local business.

09:26 4 Innovative Health is based in Phoenix, and they
5 had developed a relationship with some of the folks at
6 HonorHealth when we were initially looking at this, and we
7 were very impressed with their facilities and their work, et
8 cetera. So obviously, it's nice to think about supporting
9 somebody locally, right.

09:26 10 But the bigger picture here is that we want to be
11 able to take care of patients, but we need to do this in a
12 cost-effective manner. We're all aware of the high cost of
13 healthcare. And quite frankly, unless we look at trying to
14 manage that cost-effectiveness as best as possible, we
09:26 15 simply can't do other things. We can't support certain
16 types of procedures. We can't get new technology. We can't
17 advance patient care. It's really that simple.

18 Q Are you aware of any other cardiac mapping machine
19 manufacturer that has a policy like this one?

09:27 20 A I'm not.

21 Q During your entire time practicing at hospitals and
22 teaching at medical schools, has any other cardiac mapping
23 machine maker that you can think of had a policy like this
24 one?

09:27 25 A Not that I'm aware of.

09:35 1 technician to operate Biosense's CARTO?

2 A I'm not aware they have any such people, and I'm not
3 sure -- well, I don't have any experience with a non-CARTO
4 person or one that has not been appropriately trained by
09:35 5 Johnson & Johnson to operate those machines, so I just don't
6 know how competent they would be. As I mentioned before, I
7 think all the companies do an incredible job at training
8 their own personnel.

9 Q What about hiring and training hospital staff at
09:36 10 HonorHealth to operate the machine when the doctor wants to
11 use the CARTO?

12 A It would be a potential solution for this, but it is
13 virtually impossible, again, for some of the reasons I had
14 outlined previously. We just don't have the bandwidth
09:36 15 related to the personnel we have, their availability, their
16 ability, to focus that time on a particular procedure and to
17 go through that adequate training.

18 It would, of course, just related to even
19 man-hours but even the appropriateness or the level of
09:36 20 capacity for a particular staff to be able to do this would
21 be very expensive, very difficult, and, quite frankly, right
22 now virtually impossible.

23 Q Dr. Doshi, why don't you just buy Biosense reprocessed
24 catheters from Sterilmed?

09:37 25 A It's a great question. I do not know the details of

09:37 1 cost or other issues that might be associated with this, but
2 I do know that obviously we have a contractual relationship
3 that we have developed with Innovative Health.

09:37 4 Part of that cost is, of course, driven by volume
5 or the number of different catheters that we reprocess, and
6 that does drive down costs. And so adding another vendor to
7 do reprocessing might increase that cost. If you asked me
8 what those numbers were, I have no idea.

09:38 9 Q Were you involved in the decision to reprocess EP
10 devices with Innovative Health?

11 A Yes.

12 Q Why did HonorHealth pick Innovative Health?

13 A I think they were -- and this was not driven by me.
14 This was more sort of essentially presented to me as part of
09:38 15 this, you know, committee, if you will. HonorHealth had
16 done a fair amount of due diligence. And when I say
17 HonorHealth, our folks in our Procurement Department and the
18 folks that are responsible for ordering catheters and making
19 these types of decisions, that they were both very impressed
09:38 20 with the facilities, and they were very impressed with the
21 workflow and the personnel support.

22 And again, they were a local company that was
23 looking to partner with us, and so they were very
24 enthusiastic about using them. And what they presented to
09:38 25 me when I was seeing this was equally impressive, or I felt

09:42 1 even, quite frankly, just maintenance of the equipment that
2 we have currently. So it allows us to not just -- you know,
3 it allows us to continue to do what we do but to also keep
4 up with a very rapidly evolving technology space.

09:42 5 Q Would HonorHealth reprocess sensor-enabled catheters
6 with Innovative if Biosense did not -- well, let me rephrase
7 this.

8 So would HonorHealth reprocess sensor-enabled
9 catheters from Biosense with Innovative if Biosense did not
09:42 10 condition CARTO 3 support on using its own new or
11 reprocessed versions of those catheters?

12 A If I followed you correctly, yes.

13 Q Does Biosense's Case Coverage Policy increase or
14 decrease choice for your doctors and hospitals?

09:43 15 A Decrease.

16 MR. BERHOLD: Your witness.

17 MR. FARIDI: Your Honor, may I approach with some
18 cross-examination documents?

19 THE COURT: You may.

09:43 20 CROSS-EXAMINATION

21 BY MR. FARIDI:

22 Q Dr. Doshi, it's good to meet you in person today. We
23 met over Zoom a couple of months ago for your deposition.

24 A Yes.

09:44 25 Q I just want to clean up a couple of things before I

EXHIBIT 8

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE JAMES V. SELNA, JUDGE PRESIDING

INNOVATIVE HEALTH, LLC,

Plaintiff,

Vs.

BIOSENSE WEBSTER, INC.,

Defendant.

No. SACV-19-01984-JVS

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

DAY 3, VOLUME II

SANTA ANA, CALIFORNIA

THURSDAY, MAY 8, 2025

MIRIAM V. BAIRD, CSR 11893, CCRA
OFFICIAL U.S. DISTRICT COURT REPORTER
350 WEST FIRST STREET
FOURTH FLOOR
SANTA ANA, CA 92701

1 Q. Are you currently employed?

2 A. I am.

3 Q. Who is your employer?

4 A. Providence St. Joseph Health.

03:36PM 5 Q. What is Providence St. Joe's Health?

6 A. Providence is a faith-based nonprofit organization that
7 provides health and social services for our communities
8 through five western states.

9 Q. Does Providence have any hospitals?

03:37PM 10 A. Yes.

11 Q. How many?

12 A. 51. We refer to them as ministries.

13 Q. Does Providence have ministries in Orange County?

14 A. Yes.

03:37PM 15 Q. Which ones?

16 A. We have St. Jude in Fullerton and St. Joseph's in
17 Orange.

18 Q. Where are you personally based?

19 A. I'm out of Irvine, California.

03:37PM 20 Q. What is your position?

21 A. I am director of clinical resource integration.

22 Q. What is the scope of your job?

23 A. I oversee the reprocessing program, which includes
24 medical devices.

03:37PM 25 Q. Are you active in any professional associations?

1 procedures.

2 Q. Do you know which catheters are included in this case
3 coverage policy?

4 A. Yes. It's the PENTARAY, SOUNDSTAR, and LASSO.

03:41PM

5 Q. What financial impact, if any, does Biosense's case
6 coverage policy have on Providence?

7 A. Oh, millions of dollars.

8 Q. Total?

9 A. No. Yearly.

03:41PM

10 Q. And does Providence sometimes operate at a loss?

11 A. Yes.

12 Q. How much? Do you have any sense?

13 A. At a loss by not being able to purchase the reprocessed
14 product?

03:41PM

15 Q. Let me rephrase it. Does Providence as a whole
16 sometimes operate at a loss?

17 A. Yes.

18 Q. And do you have a sense generally --

19 A. I do not have a sense for that.

03:41PM

20 Q. Let's step back for a minute. How long has St. Joseph's
21 or St. Joe's been in Orange County?

22 A. Since 1929.

23 Q. How long have you been with the organization?

24 A. Since 2003.

03:42PM

25 Q. Have you been involved in reprocessing that whole time?

1 A. Yes.

2 Q. And Providence and St. Joseph's merged when?

3 A. 2016.

4 Q. You said earlier Providence reprocesses surgical
03:42PM 5 instruments?

6 A. Correct.

7 Q. What are some examples of reprocessed surgical
8 instruments in use at your ministries?

9 A. Tissue sealers, harmonic scalpels, trocars, forceps --
03:42PM 10 to name a few.

11 Q. You said earlier Providence buys reprocessed EP
12 catheters?

13 A. Yes.

14 Q. How long has Providence been buying reprocessed EP
03:42PM 15 catheters?

16 A. At least since I've been there -- 2003.

17 Q. Based on your more than 20 years at Providence, how
18 common is reprocessing generally in the ministries of
19 Providence?

03:43PM 20 A. Very common.

21 Q. Why is that?

22 A. It's a way for us to be able to make healthcare more
23 affordable and be able to divert those funds into community
24 services, even retain staff.

03:43PM 25 Q. You said earlier that you oversee implementation of the

1 have the resources to be able to do it ourselves.

2 Q. What is your view of Biosense's case coverage policy?

3 A. I'm not a fan. Don't like it.

4 Q. Why not?

03:47PM

5 A. It stops us from being able to meet our goal of making
6 healthcare affordable to everyone. We're paying full price
7 for something that we can get at a fraction of the cost in
8 order to be able to save money.

03:48PM

9 Q. And can you describe for the jury how exactly Providence
10 would use those savings.

11 A. Well, we would divert those savings to other programs.
12 We would retain staff. We would be able to get products
13 within our ministry, even if it's capital equipment, with
14 that money that we are saving.

03:48PM

15 Q. You testified earlier that you first learned of the
16 policy in 2016; is that right?

17 A. Yes.

18 Q. What were the circumstances?

03:48PM

19 A. Well, in 2016 we merged. St. Joseph's Health and
20 Providence merged. So we were collaborating to see how we
21 may be able to reach our goal in being financially stable,
22 and this was an area that we identified.

03:49PM

23 The physicians were on board, and it was something
24 that we were going to move forward to. At that time Biosense
25 was made aware of what we were planning on doing, and they

1 someone common on site and train our staff to be able to do
2 so.

3 Q. At that time, 2018, what catheters did Providence want
4 to reprocess with Innovative?

03:50PM

5 A. All of them.

6 Q. Once you on-boarded the contract with Medline, was
7 Providence able to buy all the Innovative catheters it wanted
8 to buy?

9 A. No.

03:50PM

10 Q. Which Innovative catheters could Providence not buy?

11 A. The PENTARAY, the SOUNDSTAR, and the LASSO.

12 Q. And why could Providence not buy those Innovative
13 catheters?

03:51PM

14 A. Because of the policy that was in place by Biosense
15 Webster.

16 Q. Was there any Providence ministry that did not have an
17 issue with Biosense's case coverage policy?

18 A. Yes. Alaska.

19 Q. Why was Alaska different?

03:51PM

20 A. They had their own mapper who had the knowledge to be
21 able to do it himself.

22 Q. Did you buy Innovative's reprocessed Biosense
23 sensor-enabled catheters in Alaska?

24 A. Yes.

03:51PM

25 Q. Did your doctors use them?

EXHIBIT 9

1
2
3
4 UNITED STATES DISTRICT COURT
5 CENTRAL DISTRICT OF CALIFORNIA
6 SOUTHERN DIVISION

7 - - -

8 THE HONORABLE JAMES V. SELNA, JUDGE PRESIDING

9 INNOVATIVE HEALTH, LLC,) CERTIFIED TRANSCRIPT
10 Plaintiff,)
11 vs.)
12 BIOSENSE WEBSTER, INC.,) SACV-19-01984-JVS
13 Defendant.) TRIAL DAY 3, VOL. I
14 -----)

15 REPORTER'S TRANSCRIPT OF PROCEEDINGS

16 Santa Ana, California

17 May 8, 2025

18
19 SHARON A. SEFFENS, RPR
20 United States Courthouse
21 411 West 4th Street, Suite 1-1053
22 Santa Ana, CA 92701
23 (612) 804-8655
24
25

11:39 1 LASSO NAV?

2 A Yes, I'm very familiar with that catheter.

3 Q How did you become familiar with it?

4 A This was one of my earlier projects when I joined
11:39 5 Innovative, so I remember it well.

6 Q What year was that?

7 A This was most of 2015.

8 Q How did that project for the LASSO NAV compare to
9 research on other catheters?

11:39 10 A Well, LASSO NAV, in comparison to the other
11 electrophysiology catheters that I worked on had an extra
12 component in there that gave us a surprise, as well as took
13 us extra time and effort to figure out in order to bring
14 that to market as a reprocessed option.

11:39 15 Q What took extra time and effort?

16 A So LASSO devices had an electronic chip that was inside
17 that device that specifically had what I call a kill switch
18 methodology that was used that combined software as well as
19 encryption methodologies to prevent that device from being
11:40 20 reused after it was used the first time.

21 Q What did Innovative have to do to address these chips?

22 A One, we had to add expertise. Given that this would
23 add software components and it was encrypted, we needed --
24 definitely added individuals and experts from the field. We
11:40 25 had to seek out experts in cryptography to understand the

11:40 1 data, as well as electronics specific in this electronic
2 chip. It's an EEPROM in there, so we needed experts who
3 understood EEPROM.

4 Q What does EEPROM stand for?

11:40 5 A EEPROM, spelled E-E-P-R-O-M, stands for Electronically
6 Erasable Programmable Read-Only Memory.

7 MR. QUIRK: May I approach the witness, Your Honor
8 with an exhibit?

9 THE COURT: You may.

11:41 10 BY MR. QUIRK:

11 Q I've handed you JX4136 already admitted in evidence.
12 What is that?

13 A This is a LASSO catheter.

14 Q Is it a new or a reprocessed catheter?

11:41 15 A This is a reprocessed LASSO catheter.

16 Q Can you show the jury on this reprocessed LASSO
17 catheter where the chip is located?

18 A The chip is actually located inside this connector, and
19 it's inside this housing, and this is the part that gets
11:41 20 plugged into the CARTO system.

21 Q Have you worked with counsel to prepare a demonstrative
22 to assist in describing these chips?

23 A Yes, I have.

24 Q If we can we go to Slide 5, please, in the
11:42 25 demonstrative, what is this?

11:42 1 A This is a picture, a representation, of the delay that
2 was caused by these kill switches for us for the -- in our
3 projects.

4 Q What does the red line represent?

11:42 5 A The red shows the extra time it took us to complete
6 that given project.

7 Q What does the green line represent?

8 A The green represents a standard project that would
9 have -- a standard project without that electronic component
11:42 10 in there.

11 Q How was Biosense using these chips when you first
12 encountered them?

13 A So electronic chips were used in the earlier models of
14 the Biosense Webster catheter, but it was used as an auto-ID
11:42 15 function, automatic identification function. Since then, it
16 evolved to add more details and add more software-based
17 functions. That turned into being used as a single use,
18 where after that use is done, the chip will lock that
19 device. When it's being plugged in, it will say that the
11:43 20 device is already used and expired.

21 Q You mentioned the chips evolved. Can you explain how
22 they evolved.

23 A Well, in this case, for LASSO, it's a 3-pin EEPROM that
24 is being used versus a simple one for auto-ID. And in this
11:43 25 scenario, it had -- or this chip, the data within the

11:43 1 chip -- first, we had to understand the chip. We had to
2 figure out how to read the information within the chip, and
3 when we read it, it was a whole bunch of jumbled up letters
4 and numbers, so we needed to understand how to unscramble
11:43 5 that puzzle. We needed to figure out the decryption
6 methodology. Once we understood that, there was -- that's
7 when we know that there is a time stamp that is being used
8 as a method to block that device from being reused.

9 Q What did you and the Innovative team have to do to
11:44 10 decrypt and resolve the chips?

11 A In this case, we had to get the experts externally as
12 well as internally. I had my electrical engineer internally
13 as well as I reached out to external experts -- one would be
14 Nathan Einwechter -- to get through these software-related
11:44 15 issues to understand how to resolve it.

16 Q Who is Nathan Einwechter?

17 A Nathan Einwechter is our CFO, Tim Einwechter's son.

18 Q How did you get connected with Nathan Einwechter?

19 A As I mentioned earlier, when this project was tasked to
11:44 20 me, and when I understood about the software concerns, and
21 when I provided that update to management, Tim asked me to
22 reach out to Nathan. And in his words, he said Nathan does
23 something with computers. Later, I learned he's actually a
24 cryptography expert. And since then, I've been working with
11:45 25 him.

11:45 1 Q How did the Innovative overcome the chip on the LASSO
2 NAV?

3 A So once we understood the decryption methodology, and
4 once we read the information, and once we found out the time
11:45 5 stamp, which was the time at which that device was plugged
6 in, and we knew the location at where it was, we were able
7 to remove that time stamp and install a new chip in the
8 LASSO and put all of the information back into the chip,
9 minus the time stamp obviously, and then proceed with the
11:45 10 rest of the process to get that device reprocessed.

11 Q And if we can advance to the next slide, please. You
12 can go all the way.

13 Are the chips you've been describing on this
14 slide?

11:45 15 A Yes. The picture that is showing next to the device
16 that is highlighted, that is the electronic chip, what I
17 call the EEPROM.

18 Q What did Innovative have to do for the PENTARAY down in
19 the bottom right?

11:46 20 A With PENTARAY, we first attempted to replace the chip
21 by separating the device and the handle. The handle design
22 itself is complex where we saw certain features that were
23 used to prevent that removal. But again, understanding the
24 software was important, we understood the decryption
11:46 25 methodology, given that it's a different model, we had to

11:46 1 use different methodology there. But it, again, added that
2 time due to the electronic chip.

3 Q How about for the SOUNDSTAR 3D?

11:46 4 A SOUNDSTAR 3D, similarly, the information in the chip is
5 encrypted. But as you see, the chip evolved from the 3-pin
6 EEPROM to now it's an 8-pin EEPROM. I am emphasizing the
7 numbers here, because the more complex the EEPROM, the more
8 advanced the chip is, and the more effort it takes to
9 understand how that chip works.

11:47 10 So in this case, for SOUNDSTAR 3D, once we
11 understood that chip, we were able to reset the time stamp.
12 In this scenario, the electronic chip used was not locked,
13 so we were able to remove the time stamp and reset that
14 device.

11:47 15 Q How about for the SOUNDSTAR Eco?

16 A That was our longest effort and went through a few
17 hurdles. Similar to SOUNDSTAR 3D, in this case, we figured
18 out the decryption methodology. And as you see, the chip
19 was even further evolved. Now, it is 16-pin EEPROM. And
11:47 20 once we understood the data within it, we were able to
21 secure the chip directly from the manufacturer, Maxim, and
22 we were sourcing it.

23 Once we got as close as figuring out and resolving
24 the issue, we learned that Biosense went to a custom chip,
11:48 25 which cut us out of the supply chain. We couldn't source

11:48 1 the chip now, and now we were back to square one, and we had
2 to figure out additional methods to supplement that to reset
3 the time stamp, which added that time for us.

11:48 4 Q Were you able to resolve the chip issues in the
5 SOUNDSTAR Eco?

6 A Yes, eventually we did.

7 Q At the time that Innovative started reprocessing the
8 SOUNDSTAR Eco, were other reprocessors already reprocessing
9 it?

11:48 10 A When we started reprocessing SOUNDSTAR Eco, I believe
11 Sterilmed already had the clearance for SOUNDSTAR Eco.

12 Q Who is Sterilmed?

13 A Sterilmed is the reprocessing wing for Biosense
14 Webster.

11:48 15 Q Was anyone not affiliated with Biosense reprocessing
16 the SOUNDSTAR Eco?

17 A No.

18 Q Would you say that you're hacking the catheters?

19 A No, I won't say I'm hacking the catheters.

11:49 20 Q Why not?

21 A Because it makes it sound like I'm doing something
22 nefarious, and in this scenario, I don't believe I am.

23 Q Where did you get the catheters?

11:49 24 A We got the catheters from our hospital partners. We
25 bought it from them.

11:52 1 manufacturers?

2 A Yes, we do.

3 Q Which manufacturers?

4 A We do reprocess advanced mapping catheters from Abbott,
11:52 5 from Boston Scientific, and from Medtronic to list a few.

6 Q How did Biosense's blocking chips compare to the
7 technology for these manufacturers?

8 A Well, Biosense Webster was the first to start using
9 this methodology, and as you see, they have evolved heavily.
11:52 10 Other manufacturers have followed suit as well as of now.

11 Q How long did the kill switches delay Innovative in
12 taking the LASSO NAV to market?

13 A Six months.

14 Q Did Innovative not move forward on other aspects of
11:53 15 reprocessing the LASSO NAV until your team resolved the kill
16 switch issue?

17 A No. My team was working on efforts in parallel because
18 we already know the other efforts we need to complete
19 anyway, so this effort for EEPROM was done in parallel.

11:53 20 Q How can you say then that the chip caused a particular
21 delay?

22 A Well, as I mentioned, in comparison to other
23 electrophysiology catheters, even ones with the electronic
24 chip, these specific catheters had these blocks, and we can
11:53 25 account for the time that it took for these efforts because

11:53 1 it was done separately and parallel, so we can calculate
2 that and figure that out.

3 Q How long did the chips delay Innovative in taking
4 PENTARAY to market?

11:53 5 A For PENTARAY, it added six months.

6 Q How about for SOUNDSTAR 3D?

7 A SOUNDSTAR 3D was 19 additional months.

8 Q And how about for SOUNDSTAR Eco?

9 A Like I mentioned earlier, Eco was the longest for us,
11:54 10 37 months in addition.

11 Q Let's move on to one final topic. You mentioned
12 earlier that you worked at CR Bard.

13 Did you work in reprocessing there?

14 A No. CR Bard was an original equipment manufacturer.
11:54 15 They did not do reprocessing.

16 Q Based on your experience having worked for an original
17 equipment manufacturer and data reprocessor, how do you
18 think reprocessing affects industry competition?

19 A After putting in the time with the industry, now I
11:54 20 believe it pushes -- it accelerates competition.

21 Q How so?

22 A Well, while reproprocessors like Innovative is working on
23 adding another life or two on the devices that still can be
24 effectively used, the original equipment manufacturer could
11:54 25 focus on innovating, on working on the next version of these

EXHIBIT 10

01:51PM 1 A. The purpose of the Falcon chip is -- I can mention three
2 main goals. One is to secure the integrity of quality and
3 accuracy of our system. As I said before, accuracy is the
4 foundation of our brand. It's everything. It's the most
5 important component that brings everything together. It
6 integrates everything together.

7 So to keep the accuracy, the second thing is
8 traceability, to know that this is our own device. And the
9 third one is to control the number of reprocessed cycle and
01:52PM 10 that it would be done by a certified reprocessor.

11 Q. Now, when you were considering implementing the Falcon
12 chip, how did you anticipate this would affect third-party
13 reproprocessors?

14 A. Oh, we knew from the very beginning that it would stop a
01:52PM 15 non-authorized, non-certified reprocessor from reprocessing
16 our catheter.

17 Q. Did you think that was appropriate?

18 A. Yes.

19 Q. Why?

01:52PM 20 A. Because of everything I explained, that accuracy is the
21 most important thing to provide the best treatment to the
22 patient.

23 Q. Notwithstanding your efforts with the Falcon chip, were
24 third-party reproprocessors able to get around the Falcon chip?

01:53PM 25 A. Now they can get around it.

EXHIBIT 11

1
2
3
4 UNITED STATES DISTRICT COURT
5 CENTRAL DISTRICT OF CALIFORNIA
6 SOUTHERN DIVISION

7 - - -

8 THE HONORABLE JAMES V. SELNA, JUDGE PRESIDING

9 INNOVATIVE HEALTH, LLC,) CERTIFIED TRANSCRIPT
10 Plaintiff,)
11 vs.)
12 BIOSENSE WEBSTER, INC.,) SACV-19-01984-JVS
13 Defendant.) TRIAL DAY 7, VOL. I
14 -----)

15 REPORTER'S TRANSCRIPT OF PROCEEDINGS

16 Santa Ana, California

17 May 15, 2025

18
19 SHARON A. SEFFENS, RPR
20 United States Courthouse
21 411 West 4th Street, Suite 1-1053
22 Santa Ana, CA 92701
23 (612) 804-8655
24
25

09:39 1 And the slide itself has the headline "Remarkable
2 Results "
3 A Yes.
4 Q Do you see that?
09:39 5 A Yes, I do.
6 Q And then there are talking points below the slide,
7 right?
8 A Yes.
9 Q And part of those notes say: "Success taking share
09:39 10 from Stryker," right?
11 A Yes.
12 Q The next line below that reads "Ex," meaning example,
13 right?
14 A Yeah.
09:39 15 Q "Stryker has stopped selling ACUNAV 10F due to supply
16 constraints (caused by BWI collections)." Do you see that?
17 A Yes.
18 Q And ACUNAV 10F, 10F refers to the size?
19 A In French, yes.
09:39 20 Q So you understand this sentence to mean that Stryker
21 was unable to sell reprocessed ACUNAV 10 French catheters
22 because of its inability to collect used ACUNAV catheters?
23 A It means they were constrained on supply because they
24 -- we collected more. And so, yes, that's the implication.
09:40 25 Q They were constrained, meaning they couldn't get them,

09:40 1 the catheters?

2 A Yeah, in the reprocessing world, what you collect is
3 what feeds the product you sell back. And so the fewer you
4 have, the fewer you'll sell, and that's the impact, yes.

09:40 5 Q And it's saying here that Biosense's collections
6 limited the collections that Stryker was able to do, right?

7 A Yes.

8 Q If you could turn, please, to JX4316 in your binder.

9 This is an e-mail among you and your colleagues,
09:41 10 right?

11 A Yes.

12 Q From April 2016, right?

13 A From -- yes, correct.

14 Q All right. And let's not put this up quite yet.

09:41 15 Ms. Zare, in this e-mail chain, one of your
16 colleagues sent you an academic study, right?

17 A Yes. It looks like they have attached a study, yes.

18 Q Right. And in the bottom e-mail, that colleague
19 described it was "a general study on the RPO device
09:41 20 quality." Do you see that?

21 A Yes.

22 Q He said he was going to add it to his slide deck about
23 Sterilmed products, right?

24 A Let me just make sure I know where you are, but I'm
09:41 25 sure that's correct if you're reading it.

EXHIBIT 12

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

- - -

THE HONORABLE JAMES V. SELNA, JUDGE PRESIDING

INNOVATIVE HEALTH, LLC,) CERTIFIED TRANSCRIPT
Plaintiff,)
vs.)
BIOSENSE WEBSTER, INC.,) SACV-19-01984-JVS
Defendant.) TRIAL DAY 7, VOL. I
-----)

REPORTER'S TRANSCRIPT OF PROCEEDINGS

Santa Ana, California

May 15, 2025

SHARON A. SEFFENS, RPR
United States Courthouse
411 West 4th Street, Suite 1-1053
Santa Ana, CA 92701
(612) 804-8655

08:40 1 Q "We just need to align on how much RPO we want to allow
2 the customers to access. If they could get more, they
3 wouldn't need S3, but that obviously needs to be balanced
4 with OEM business."

08:40 5 Do you see that?

6 A Yes, I do.

7 Q And I know we discussed this yesterday.
8 RPO is reprocessed?

9 A Correct.

08:40 10 Q The OEM business is Biosense's new products?
11 A Correct.

12 Q Now, let's go to the first page in the middle.
13 This is your response to Mr. Koenig, right?

14 A Yes.

08:41 15 Q Could you please read the first two sentences for us?
16 A "I agree. If we went all in and offered unrestricted
17 access to strategically essential accounts in exchange for a
18 high OEM market share commitment and sole source on EP RPO
19 (only SMD bins in the EP lab), we could cut off S3's supply
08:41 20 and crush them. Boo Haha Ha Ha Ha."

21 Q When you refer to "offering unrestricted access to
22 strategically essential accounts," you meant allowing some
23 customers to buy as much reprocessed product as they want,
24 right?

08:41 25 A To buy off of our excess available product.

08:41

1 Q As much as they wanted?

2 A Yes, that's correct.

3 Q Which is contrary to the normal policy of setting caps
4 on how much they could buy, correct?

08:41

5 A Based off their collections, correct.

6 Q You suggested those customers who were permitted to buy
7 as much as they want could do two things in exchange, right?

8 A Correct.

08:42

9 Q The second one, I want to focus on that. You wrote,
10 "Sole source on EP RPO (only SMD bins in the EP lab),"
11 right?

12 A Correct.

13 Q That meant that those customers would give all of their
14 used electrophysiology products, like catheters, to
15 Sterilmed, right?

08:42

16 A The devices that we provided that were on contract, we
17 collected, correct.

18 Q "Only SMD bins in the EP lab" meant that only Sterilmed
19 collection bins would be there, right?

08:42

20 A Yes.

21 Q And not collection bins from, for example, Innovative,
22 right?

23 A Yes.

24 Q All right. Now, that meant that those customers --

08:42

25 that meant that that would, as you said, cut off Stryker's

EXHIBIT 13

1
2
3
4 UNITED STATES DISTRICT COURT
5 CENTRAL DISTRICT OF CALIFORNIA
6 SOUTHERN DIVISION

7 - - -

8 THE HONORABLE JAMES V. SELNA, JUDGE PRESIDING

9 INNOVATIVE HEALTH, LLC,) CERTIFIED TRANSCRIPT
10 Plaintiff,)
11 vs.)
12 BIOSENSE WEBSTER, INC.,) SACV-19-01984-JVS
13 Defendant.) TRIAL DAY 8
14 -----)

15 REPORTER'S TRANSCRIPT OF PROCEEDINGS

16 Santa Ana, California

17 May 16, 2025

18
19 SHARON A. SEFFENS, RPR
20 United States Courthouse
21 411 West 4th Street, Suite 1-1053
22 Santa Ana, CA 92701
23 (612) 804-8655
24
25

10:26 1 Dr. Thomas whose videotaped testimony you saw. He was
2 Biosense's medical safety officer. Why did he not know
3 anything about it? Because it's not about patient safety.
4 It's just about Biosense stopping reproprocessors from
10:26 5 competing just as the documents say.

6 Now, Project Falcon wasn't enough. Biosense said
7 on top of that let's use another strategy. Let's grab up
8 all the catheters ourselves to prevent Innovative from
9 making its products. Again, let's look at their internal
10:27 10 e-mails. You saw the internal slides outlining reprocessing
11 priorities. And what did it say? It said if they control
12 ACUNAV collections, they controlled the market. And they
13 explicitly said that they would use collections to "drive
14 Stryker" -- another reprocessing company -- "out of the RPO
10:27 15 EP business altogether." Those are aren't my words. Those
16 are Biosense's words.

17 Let's look at JX3114, which Dr. Forister talked
18 about. It showed that Biosense started collecting used
19 DECANAV catheters even though Sterilmed, it's affiliate,
10:27 20 didn't even reprocess the DECANAV. There's no reason to do
21 that other than preventing other reproprocessors like
22 Innovative from doing the same.

23 You saw Dr. Forister show that Sterilmed withheld
24 a large number of ACUNAV catheters from the market, and you
10:28 25 heard Mr. Distel testify that Innovative suffered ACUNAV

10:28 1 shortages during that same time period. And when Stryker's
2 ACUNAV sales came to a screeching halt, what did Biosense
3 say was the cause? Biosense said that Stryker's supply
4 constraints were "caused by BWI collections."

10:28 5 This was not an isolated incident, and it wasn't
6 just a handful of e-mails. You can look at JX221, JX222,
7 JX223, JX3673. All these documents talk about Biosense
8 using collections to prevent competition. And those
9 collections efforts were directly targeted at Innovative.

10:28 10 Look at 3720 talking about diverting collections
11 away from Innovative. And they did not try to hide it.
12 This is the e-mail that you saw. There's a saying that
13 there's a grain of truth behind every joke. And this e-mail
14 is Biosense showing you who they are and what their motives
10:29 15 are for collecting these catheters. It's to quash
16 competition and drive competitors out of the market.

17 To put the nail in the coffin, Biosense came up
18 with the third strategy, which is the case coverage policy
19 or the tie. You heard Dr. Forister explain that Biosense
10:29 20 cornered the market for mappers, the clinical support
21 technicians that support doctors during EP procedures. In
22 2009 when the CARTO 3 came out, there were lots of
23 independent mappers. Hospitals had their own mappers.
24 Independent providers sent per diem mappers to hospitals.
10:30 25 That gave hospitals choices. But Biosense put a stop to