January 12, 2018

AMDR Members Unaffected by FDA Recall of Reprocessed Agilis Steerable Introducers from SterilMed

- The U.S. Food and Drug Administration issued a recall of reprocessed Agilis Steerable Introducers from SterilMed, a unit of Johnson & Johnson, on product lots manufactured between January 1 and May 5, 2017.
- SterilMed is not an AMDR member and therefore AMDR cannot speak to the specifics of this recall, speak on behalf of SterilMed, or address quality issues at SterilMed.
- Agilis Introducer Sheaths reprocessed by AMDR member companies Innovative Health, Stryker Sustainability Solutions and Vanguard AG are NOT the subject of this recall and remain on the market.
- Quality representatives from AMDR member companies have assured us that they are aware of the recall and that their strict quality control mechanisms, including 100 percent inspections, ensure that devices reprocessed by these companies continue to meet safety and efficacy expectations.
- AMDR members have an outstanding safety record. Our member companies are in full compliance with FDA's medical device manufacturer requirements, meet FDA or international standards for quality systems and all have demonstrated such to AMDR as a condition of membership.
- AMDR and its member companies are committed to working with our healthcare delivery partners to identify new areas of cost-savings. Reprocessing new types of devices is a critical part of this. However, reprocessing technologies such as the Agilis Sheath requires strong scientific and technological capabilities that may not be possessed by all companies in the industry.
- As with all other reprocessed devices, AMDR and its members urge hospitals to ensure their reprocessing partners have the right quality systems in place, possess the right level of sophistication in cleaning, testing and inspecting devices, and prioritize safety beyond anything else.