# Hospitals could save two millions - if someone acted…

Andreja Rednak

12.11.2014 00:01 / Finance 219/2014

**How to achieve that goal? By reprocessing of some of the expensive medical single-use devices, which for example - safe for the patients – has already been done many years in US and Germany**

In some countries savings are generated in health care also in this way, by cleaning, testing, sterilizing, and ensuring traceability of a small number of expensive medical devices for single use; these devices can be then safely used again for another patient. Why this is not happening in our country yet, where health care is in the red figures and patients waiting list is getting longer every day?

**Tone Lovšin, Trokar company**: The longer the state of reprocessing remains vague in the EU – as well as in our country, the longer Europe market will remain an Eldorado for manufacturers

As it turned out, none of the persons we interviewed is actually against well regulated reprocessing of certain medical devices, on the contrary, they support the idea, but nobody is willing to take the first necessary step.

## It is not forbidden, but…

Do we just wait for the legislation at EU level, which has already been negotiated for some years now, and the negotiations will probably continue for another few years, even if the state could regulate this field by itself? The Ministry of Health has now promised to act. Legislation in Slovenia does not mention the reprocessing of single use medical device. So it does not prohibit it explicitly, but however, it is not explicitly allowed, nor regulated. And until it is not regulated, all Slovenian hospitals decide agains it, and potential savings are lost.

## Lost millions

"The annual savings in the Slovenian health care could amount to approximately two million euros," estimates Tone Lovšin from the Trocar Company, who is in Slovenia representing Vanguard AG, a German company for the reprocessing of medical devices. By his estimation,

the Slovenian market for single use devices is worth around 130 million euros per year; about two to three per cent of these instruments are actually suitable for the reprocessing and reuse.

In Slovenia it would amount to approximately four million euros per year. Reprocessing can bring savings for about 40 percent of the new devices.

Let us say that two million euros in Slovenia could, for example, used for over 100 operations on open heart (Health Insurance is paying to hospitals for one surgery up to 23 thousand euros, and less for less demanding surgeries). For two million EUR many patients could also benefit through a 350 hip endoprosthesis (at an average price of around 5,500 euros), or 1,700 operations of varicose veins could be performed. So this is by no means negligible a saving.

## Mrs. Kolar inclined to change

The Ministry of Health, which is now led by Mrs. Milojka Kolar Celarc, said that they had in the previous month meeting with representatives of the clinical profession and the company which is reprocessing medical devices.  The clinical specialists advocate the opinion that reprocessing should be introduced in Slovenia. The ministry listened to the proposal, and promised "to prepare a proposal amendment to the regulations governing the area of medical devices in Slovenia". The precise date was not given. They intend to first inspect in detail the rules of at least three countries that have a high level of health care and have already established scope reprocessing, or their hospitals are already using such devices, and have at least one-year experience. The Ministry stressed that equal safety for the patients should be ensured after reprocessing. Advantage is seen in reducing costs for medical devices.

## Agency of the Republic of Slovenia for Medicines and Medical Devices (ARSZMP) has no opinion

Agency of the Republic of Slovenia for Medicines and Medical Devices (ARSZMP) has formed no opinion, or is unable to give an opinion about reprocessing. They say they only took care of the regulations on medical devices, and reprocessing is not regulated at this moment. Otherwise new European legislation and regulation is "expected to be adopted in the second half of 2015". This should ensure the smooth functioning of the market, i.e. the establishment of uniform rules and work in practice for all Member States. The legislation will also regulate the area of reprocessing of medical devices for single use, said the representatives of the ARSZMP.

## The UKC Ljubljana is in favour, but not without opinion

The University Clinic Ljubljana paid in the first nine months of this year for expensive single use medical devices 922 thousand EUR. They said that they dealt discussed the issue of reprocessing extensively, just as the National Commission for the Control of infections. "We believe that properly implemented reprocessing may be a way to ensure the safe treatment of patients, at lower costs" claim the representatives of the UKC Ljubljana. These could be reduced by half. They have already tried to obtain the opinion of the ARSZMP and the Ministry of Health .The Council of Experts and UKC Ljubljana executives believe that prior to the introduction of reprocessing the opinion of ARSZMP must be obtained. The representatives of the UKC Ljubljana say that the "professional public in general is in favor of this measure". However, safety for the reprocessed instruments should be ensured, both in terms of sterility and technical characteristics, the contractor reprocessing company must ensure conformity of the device with the standards, and give the same warranty as for a new product, including traceability. Reprocessing company must have evidence that the process has been certified, the selection of the devices must be in accordance with professional recommendations, and reprocessing must also be economically viable.

## EU (and Slovenia) is now the manufacturers Eldorado

"If the reprocessing would be allowed and regulated in Slovenia, it would bring savings to the hospitals, with no disadvantages for patients. Environmental burden caused by medical waste would decrease, and the benefits would be gained by reduced consumption of new expensive and scarce rare metals. As a specialist for reprocessing I argue that this is a win-win situation for all participants. Except perhaps for manufacturers of expensive single use medical devices and their vendors in Slovenia. The longer the state of reprocessing remains vague in the EU – as well as in our country, the longer Europe market will remain an Eldorado for manufacturers" stresses Tone Lovšin from the company Trokar.

## *Half a billion market in the US, the EU forced Germany*

*In the US, reprocessing of medical devices was regulated in 2000, when the local FDA prescribed exact requirements which must be met by reprocessor, and has also demanded that an instrument for single use should maintain, after reprocessing, the same clinical and functional quality as at its first use.*

*According to the  Association of Medical Device Reprocessors (AMDR), the US reprocessing market is today worth close to half a billion dollars, and is growing due to savings trends in health care. The market is dominated by two companies – Stryker and Johnson & Johnson (who several years ago bought reprocessing company Sterilmed).*

*At the EU level, reprocessing has not been regulated yet, it is left to individual countries. At one extreme pole is France with the explicit ban on reprocessing, the situation in Germany is quite opposite: in Germany this area was carefully arranged in 2002. The German company Vanguard AG is the EU leader in reprocessing of medical devices. They have developed special machines for cleaning, and give guarantee that the reprocessed instrument is such as a new, high-quality and safe for patients and the hospital. Vanguard AG has hitherto successfully reprocessed over four million single-use instruments. It has a German certificate for reprocessing of 3,700 medical devices.*

*And how reprocessing is carried out in practice? Hospitals are collecting specific used single use medical devices with original packaging. The logistic company delivers them to Vanguard in Berlin. There the instruments are individually identified, traceability ensured, including the name of the owner, and all the steps taken in reference to the instrument. The medical device is then cleaned, tested and inspected, sterilized, packed, and for all the necessary steps the processes are standardized and validated. Hospital gets back their own instrument, ready for safe reuse.*

*The most expensive medical devices (from 500 to several thousand euros per piece) suitable for reprocessing are used in surgery, cardiology, and ophthalmology - for example electrophysiological, ablation and other catheters, staplers, coagulating shears, guide wires, laparoscopic instruments, laser probes ... Among the manufacturers of these medical devices global manufacturers can be found, as Johnson & Johnson, Boston Scientific, Alcis, Covidien, Medtronic, Alcon ...*

*The University Clinical Center in Ljubljana this year spent 922,000 EUR for expensive single use medical devices in nine months only. They could save a half of the sum.*

*1000 EUR and more costs radiofrequency ablation catheter, which is used only once and then discarded. (It is used for management of hearth rhythm disorder).This device is suitable for reprocessing.*

*The savings in the amount of two millions of EUR would allow:*

*100 open heart surgery operations*

*Or*

*1,.700 operations of varicose veins*

*Or*

*350 hip replacements*