You have just started working as a staff nurse for a free-standing ambulatory surgery center specializing in ENT cases. It is a small center with 3 OR's, 5 RN's and 3 scrub technologists. The center is jointly owned by the 4 surgeons who practice there.

During your first day of orientation, your preceptor tells you that it is the practice of the facility to re-process suture which has been opened on the back table but hasn’t been used, and use it for subsequent cases. The practice has been endorsed by the surgeons, who view this as a way to control costs. When you question this practice, your preceptor says, "What's wrong with the way we're doing this? We autoclave the suture, so it's sterile.”

What is your response, based on best practices? Use current literature (Hint: the answer may not lie entirely in AORN's Standards and Recommended Practices) to support your answer.

Response
This topic generated the most discussion to date for our questions of the week, and I thank all of you who took the time to share your thoughts and expertise. As expected, a wide range of opinions was evident in the responses.

For facilities in the United States, single use devices come under the auspices of the Food and Drug Administration (FDA), whose job, understandably, is helping to ensure the safety of the public. With the double-pronged impetus of cost containment and reduction of hospital waste, the FDA has provided standards for reprocessing instruments and supplies that in the past would have been discarded if not used. “Third party” companies have sprung up who take opened but unused supplies, clean and sterilize them, and return them to the facility to be used again. But before medical devices can be reprocessed and reused, a third-party or hospital reprocessor must comply with the same requirements that apply to original equipment manufacturers, including:

- Submitting documents for premarket notification or approval
- Registering reprocessing firms and listing all products
- Submitting adverse event reports
- Tracking devices whose failure could have serious outcomes
- Correcting or removing from the market unsafe devices
- Meeting manufacturing and labeling requirements

Even though at first blush it may appear to be more cost-effective to serve as the reprocessing center, any cost-benefit analysis must also include labor costs, program management costs, quality assurance expenses (which in our case would include testing for tensile strength) and any potential costs associated with device failure. These criteria discourage many facilities from serving as their own reprocessing centers.

An interesting aspect of reposables which was not mentioned in the discussion was the issue of reimbursement. The Centers for Medicare and Medicaid Services (CMS) will approve reprocessed devices for reimbursement exactly the same as new devices as long as the reprocessing was done in compliance with FDA standards. Unless the suture reprocessing practice in our example is meeting FDA requirements, this facility’s billing practice may be both fraudulent and unethical.

To get a perspective from our industry partners, I contacted both Ethicon and US Surgical. Unfortunately, I did not have a reply from US Surgical, but Ethicon’s e-mail is below.

RE: Ethicon.com: Contact Request from SR1-5ZDN5I

Thank you for contacting ETHICON, Inc. It is always important to hear from our customers, and we appreciate the time you have taken to contact us.

ETHICON Suture is indicated for single patient use. Per the Instructions for Use, suture should not be resterilized (re-processed). Open packages and unused suture should be discarded.

Please contact us at 877-384-4266, option 6, if you require further assistance.

Sincerely,

Missy
Customer Support Center
Phone: 800-USE-ENDO
   877-ETHICON
   513-337-8901 (International customers only)
Email: customersupport@eesus.jnj.com

I also spoke with a representative from eSutures, a clearinghouse for outdated and overstocked suture. Suture must be in the original sterile packaging. Outdated suture is used for non-human experimental or research purposes. They do not re-process suture. More information can be found at http://www.esutures.com/product/2-indate-expired/
The group did a great job identifying the patient safety risks to our scenario. Another issue that was not so readily apparent is the risk the facility takes in serving as the manufacturer, which is the way it is viewed if it chooses to reprocess single-use items. A defect in a reprocessed item and/or harm to a patient as a result of that defect then becomes the responsibility of the surgical facility, not the original manufacturer. Few hospitals are willing to take on that responsibility once they are aware of the level of legal accountability. In addition, it becomes impossible to track and remove from service any recalled items from the manufacturer.

“Reposables” are not going away. A balance must be met between cost and patient rights and safety. If there are any questions about the safe reprocessing of a single use item, the advice of the original manufacturer and a reputable third-party reprocessor should be obtained.

References and resources


