Pamela Furman

ASSOCIATION OF MEDICAL DEVICE REPROCESSORS' POSITION ON REPROCESSING SINGLE-USE MEDICAL DEVICES

Editor's note: This column and the next present two associations' opposing viewpoints on the reprocessing issue. The first details the Association of Medical Device Reprocessors' position, and the second that of the Health Industry Manufacturers Association. We give equal space to both viewpoints and, to be fair, we have put the articles in alphabetical order.

Today more than ever health care providers are confronted with a daunting challenge: how to provide the highest quality care at the lowest possible cost. The era of managed care has permanently changed the economics of health care. The days of expecting and providing health care at any cost are gone. As a result, providers are under growing pressure to extract the greatest value from every health care dollar.

In their efforts to achieve cost savings while maintaining the highest level of patient care, hospitals increasingly are relying on reprocessed medical devices. Three categories of medical devices labeled for single use typically are reprocessed:

- unopened devices whose expiration date has passed;
- opened devices that have never been used; and
- used devices.

Traditionally, reprocessing has been an in-house function, conducted primarily by in-hospital reprocessing centers. In recent years, however, hospitals have been turning to third party reprocessors to meet their reprocessing needs. Hospitals have found that third party reprocessing typically is more cost-effective than in-hospital reprocessing and provides an equivalent, if not a higher, level of sterility assurance.

The discussion that follows provides some background on the third party reprocessing industry and describes the benefits hospitals can expect from outsourcing their reprocessing needs. It also addresses the challenge of selecting a suitable third party reprocessor and provides a number of characteristics hospitals should look for when making this important decision.

THE ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

The Association of Medical Device Reprocessors (AMDR) is a Washington, DC, based trade association representing the legal and regulatory interests of third party reprocessors of single-use medical devices. Members of AMDR perform approximately 85% of the third party reprocessing in the United States. Member companies of AMDR serve a nationwide customer base of hospitals and outpatient surgery centers and reprocess a broad range of devices for all clinical areas (eg, perioperative, cardiology, orthopedics, respiratory therapy).

Every AMDR member is registered with the FDA and complies with both MDR and applicable QSR requirements.

The AMDR defines a third party reprocessor as an entity that, at the request of a customer, inspects, functionally tests, cleans, packages, and sterilizes devices labeled for single use in such a manner that

- the quality, physical characteristics, and performance functions of the device are not significantly affected, and
- the device remains safe and effective for its appropriate clinical use.

Reprocessors do not take title to devices, but simply return reprocessed devices to the owner who requested reprocessing.

In AMDR's view, an important measure of a third party reprocessor's commitment to safe, high quality reprocessing is the degree to which it adheres to relevant US Food and Drug Administration (FDA) requirements. The FDA currently requires third party reprocessors to register with the agency, to comply with medical device reporting (MDR) requirements, and to adhere to applicable Quality System Regulation (QSR) requirements (ie, provisions governing all aspects of device quality assurance, including process validation, acceptance activities, internal audits, personnel training, and complaint handling, among other things). The FDA does not require hospitals to obtain patients' consent before using reprocessed devices.

Every AMDR member, therefore, is registered with the FDA and complies with both MDR and applicable QSR requirements. Thus, AMDR members comply with all FDA requirements currently applicable to third party reprocessing. In addition, all AMDR members must maintain a minimum of $5 million in liability insurance.

Compliance with relevant FDA regulations requires a significant capital investment on the part of AMDR members. The highest quality equipment must be purchased and maintained, personnel must be trained, and extensive record keeping systems must be established. Members of AMDR are committed to making these investments, and they possess the financial resources to do so.

BENEFITS OF THIRD PARTY REPROCESSING

Third party reprocessing offers hospitals a way to realize significant cost savings without compromising patient safety. A hospital that understands the value of reprocessing can maintain the highest level of patient care while conserving scarce resources that otherwise might needlessly have been spent to purchase new devices.

As a threshold matter, it is important to understand that device manufacturers are permitted to label any device as single use. There are no FDA

regulations or formal standards distinguishing the quality or functionality of reusable devices from single-use products. At their discretion, manufacturers may label devices as single use rather than reusable.

Given the arbitrary nature of the single-use designation, the wisdom of reprocessing is evident. When it can be scientifically proven and validated that a device can be cleaned, functionally tested, sterilized, and used again without harm to the patient, the fact that the device is labeled for single use only is irrelevant. The device can and should be reprocessed, because not doing so wastes scarce health care dollars that could be spent on other aspects of patient care.

When done properly, reprocessing is safe. There is not a single documented case of patient injury resulting from the use of a device reprocessed by an AMDR member company.

From a perspective of quality, hospitals give up nothing by moving from in-house to third party reprocessing, and may, in fact, gain a higher level of sterility assurance. Due to economies of scale, third party reprocessors often have more capital available than hospitals to invest in state of the art cleaning, sterilization, and testing equipment.[1] In addition, AMDR members reprocess devices in compliance with applicable QSR requirements. Because of budget concerns, many hospital reprocessing centers do not strictly adhere to all the FDA's QSR requirements.

With respect to cost considerations, third party reprocessing offers hospitals savings opportunities in several ways. First, by using third party reprocessors, hospitals avoid the considerable costs associated with establishing an in-house reprocessing center on their own. Furthermore, because of economies of scale, third party reprocessors typically have significantly lower operating costs than in-hospital reprocessing centers. Thus, third party reprocessors are usually able to offer hospitals reprocessing services at a significant cost savings compared with in-house reprocessing.

Third party reprocessing also provides hospitals with advantages from a risk management perspective. As described previously, AMDR members must maintain a minimum of $5 million in liability insurance, but some carry $25 million or more. A hospital that outsources its reprocessing needs to an AMDR member effectively frees itself from malpractice costs that could be incurred because of problems caused by improper reprocessing of devices.

Third party reprocessing offers a way to maintain quality patient care while also achieving substantial cost savings.

How to Choose a Third Party Reprocessor

Significant differences exist among third party reprocessors. As described, third party reprocessing offers hospitals a way to maintain the highest quality patient care while also achieving substantial cost savings. To maximize the benefits of third party reprocessing, however, a hospital must know what to look for in a reprocessor. The list below is designed to aid hospitals in asking the right questions before engaging the services of a third party reprocessor.[2]

- ▲ Is the company registered with the FDA?
- ▲ Does the company comply with applicable QSR requirements?
- ▲ Will the company permit you to visit its plant and review its quality manual?
- ▲ Is sterilization performed by a commissioned and certified sterilization system, in accordance with ANSI/AAMI/ISO ST 11135 ST 1994?
- ▲ Is the sterilization cycle requalified annually?
- ▲ Are biological indicators used to monitor routine sterilization?
- ▲ Are the sterilization systems routinely calibrated?
- ▲ Is residual sterilant level routinely tested?
- ▲ Does the company have reprocessing procedures tailored to the specific types of devices you wish to have reprocessed, and has the company validated these procedures?
- ▲ Is product functionality routinely tested ?
- ▲ Does the company track the number of uses per device?
- ▲ Does the company comply with MDR requirements?
- ▲ Does the company have adequate liability insurance coverage?

Conclusion

In today's cost-conscious hospital environment, third party reprocessing offers a safe and sensible means of conserving precious health care dollars. As compared to in-hospital reprocessing, third party reprocessing is typically more cost-effective and offers at least as high, if not higher, levels of sterility assurance. In choosing a reprocessor, a hospital should look for a company that complies with relevant FDA regulations and maintains a minimum of $5 million in liability insurance. In AMDR's view, these characteristics demonstrate a commitment to safe, high quality reprocessing and will ensure that the hospital obtains the maximum possible benefits from third party reprocessing. △

1. L Andersen et al, "Outsourcing sterile reprocessing," *Infection Control and Sterilization Technology* 3 (July 1997) 24.
2. *Ibid*, 28.

Pamela Furman *is executive director of the Association of Medical Device Reprocessors, Washington, DC.*