

November 26th, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Opened-but-Unused Medical Devices
Docket # 02N-0456

To Whom It May Concern:

This letter is in regards to the Food & Drug Administration's call for comments concerning hospital practices of reuse of opened-but-unused medical devices. We appreciate this opportunity to comment on the reuse of these devices and believe that if done correctly, it is a safe and effective way to cut costs in healthcare facilities, reduce medical waste, and continue to provide for patient safety.

General Overview:

Providing for safe and effective care is the ultimate goal of hospitals, health systems, original device manufacturer (OEM's), reprocessors, and other groups and individuals in the healthcare field. As the use of Single Use Medical Devices (SUD's) has become more prevalent in healthcare facilities the need for Guidelines and Regulatory requirements has grown. Through the FDA's rigid and thorough Enforcement Priorities for Single-Use Devices Reprocessed by Hospitals and Third Parties, the guidelines and regulations for ensuring safe reuse is now in place. Also, the recent enactment of the Medical Device User Fee and Modernization Act (MDUFMA) of 2002 further regulates the industry to ensure that any perceived or actual safety risks associated with SUD's are addressed and that reprocessed devices work as safely and effectively as a new device.

Reprocessing of Single-Use Devices is now tightly controlled and reprocessors are required to meet the same standards as the original device manufacturers. Validation of the reprocessing methods increases the guarantee of device safety. These requirements are a welcome insurance to the industry and patient safety.

Open-but-Unused

Ensuring that SUD's can be reprocessed and meets its intended use safely and effectively is challenged by its use. Thus all the regulatory controls ensuring it's safe reprocessing.

Open-but Unused devices fall into a different category altogether and should not be required to meet the same level of regulatory requirements, nor do we feel this is the FDA's intent by requesting comments.

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Hospitals have a long history of resterilizing Open-but-Unused devices. Some OEM's have even provided instructions to the hospitals for just this possibility. Many hospitals routinely open SUD's prior to use and assemble them together with other devices as part of a procedure tray.¹ After assembly these trays are then wrapped and sterilized, therefore information on resterilization from the OEM is very important. It would be costly and not to the advantage of the patient if the creation of these packs was limited. The ability to create these procedural trays is often critical for the effectiveness of a medical procedure.

Furthermore, SUD's are often opened but not used when procedures are cancelled or a device is just not needed. Throwing these devices away would further the economic burden on an already suffering healthcare industry, and would do nothing to ensure patient safety. Quite the opposite, it would only increase cost on an already economically burdened healthcare system. This practice would then affect patient safety, as healthcare providers would be less able to provide the quality care a patient deserves.

There are currently wonderful programs in place at some hospitals to resell SUD's to Developing Countries. "Instead of being discarded, these materials are collected and, through hospital-charity Partnerships, shipped to developing countries where they are so desperately needed."² From the REMEDY website the following is quoted:

Why do hospitals discard these supplies, anyway?

Many of the supplies used by hospitals are labeled as "single-use only". They are intended to be used only on one patient, and only once on that patient. The manufactures that make these supplies will honor the warranties on them for a single-use only. The question becomes what constitutes "use" of these products. Manufacturers have held that if supplies are opened and prepared for a surgical procedure, whether they have come in contact with a patient or not, this product has been "used."

Given the litigiousness of our society, hospitals have feared the risk of liability for diverting these materials back into the inventory. Thus, for decades, if materials were opened yet unused by a surgeon, they were discarded - the disposal of hundreds of thousands of dollars of unused supplies per year was considered a better "hit" than being sued if something went wrong in a situation where these supplies had been "re-used." This applied also to cases that are canceled...disposable supplies from an entire prepared room would be discarded.²

There is no doubt on the good of these organizations. However, while these types of programs serve a great need and are ultimately concerned with the welfare of humanity it does seem unethical that we would consider a device safe and effective for use in another

¹ Re:Docket No.00D-0053; Healthcare Association for New York State; April 11, 2000.

² <http://www.remedyinc.org/faq.cfm#FDAREMEDY> (Recovered Medical Equipment for the Developing World), 333 Cedar Street, P.O. Box 20805, New Haven, CT 06520-805. Contact: Darryl Kuperstock. Phone (203) 785-2802. Fax (203) 785-6664. E-mail: REMEDY@Biomed.Med.Yale.edu.

country but not in our own. It is also unethical and unfortunate that we allow ourselves to be governed by the “litigiousness of our society.” Hospitals in the US should be able to reap the same benefits of increased saving with safe products from resterilizing its open and unused devices.

So, where do we go from here? Let’s look at the concerns regarding the reuse of SUD’s. Ensuring that a device is fully functional to perform the duties for which it was originally meant is a significant factor in reprocessing. “For a device to be considered safe for multiple use, functional performance must be restored to original specifications...”³ (Josephine M. Torrente). With open-but-unused medical devices, the original specifications should be the same since the product has never been taken out of tolerance. An opened but unused device will remain tuned to the same specifications guaranteed by the Original Equipment Manufacturer (OEM).

As for the resterilization of the device with respect to functionality, the original manufacturer usually builds into its products a margin of safety in the case it needs to be resterilized by the OEM due to a sterilization malfunction, tracking error, or other manufacturing problem. As a part of physical testing of devices, such things as balloon angioplasty catheters are required to be blown up 40 times to test durability and functionality after many uses. Therefore every time the device is blown up, the catheter is one use closer to failure (Torrente). The reuse of an opened but unused balloon catheter does not compromise this margin of safety simply because the device was never used in the first place. The device will be just as safe and effective after a second sterilization as it was after the first sterilization.

Furthermore, the rigorous cleaning and disinfecting process applied to used SUD’s may not apply to opened but unused devices since their need for decontamination is also significantly smaller. As a result, device materials are not altered in any way by cleaning procedures.

Opened but unused medical devices that have passed expiration date and are still in the original packaging pose different questions as to whether or not they should be resterilized. In this case, before reprocessing or resterilization takes place, the device should be carefully inspected in order to determine whether or not it is believed the device materials are capable of being fully functional after the proposed expiration date has passed. There also may be drug coatings or materials that could no longer be effective after expiration. No instrument should be reprocessed if there is not sufficient evidence that it would survive, and be 100% safe and effective.

We believe that the FDA’s call for comments on the use of Open-but-Unused SUD’s a opportunity for Healthcare industry to further ensure patient safety. As a third party reprocessor, MediSISS™ has strict guidelines with regard to all devices that are processed through our facility.

³ Josephine M. Torrente, M.S , J.D.; President, Association of Disposable Device Manufacturers before the Health, Education, Labor, and Pensions Committee; United States Senate; June 27th, 2000.

Within our own facility all devices that are received open-but-unused are carefully inspected. To be considered “Open-but-Unused” the device must arrive in separate packaging from used SUD’s. Devices and their original packaging are inspected for, water damage, splash-back, and physical damage to the device and packaging. Damaged devices are either repaired and treated as used or discarded. Contaminated devices are also treated as used.

Packaging is also inspected for any specific OEM temperature, sterilization or handling instructions. If a device is received past it’s expiration date, it goes through the same inspection criteria with an additional research step into the materials. This is used to help ensure that the expiration date is limited to the device packaging and not the device itself. Instruments that are light, heat, and time sensitive are carefully researched to help ensure they have the ability to undergo further sterilization and extended life. If a device that is light sensitive and the packaging has been breached or the device is determined to have been stored improperly, then that device is discarded. No risk is considered warranted.

Further, a device that has an expired date and is considered critical in nature, is researched for field failures. Any device with a significant number of failures in the field due to instrument malfunction is discarded.

If devices are received as open-but-unused yet have been packaged with used devices we automatically consider them no longer in that category but instead treat them as contaminated, used devices. Even if a device is still in it’s original packaging but again has been placed alongside contaminated devices, we believe risk is too high to treat it as anything but contaminated as there is no guarantee that the packaging integrity has not been breached. Packaging integrity could easily have been breached if it had gotten wet or due to a packaging puncture by a contaminated device.

We would like to offer some suggestions that would keep in the spirit of reducing unnecessary regulatory requirements and further burdening the healthcare industry with undue cost, and limiting the impact on the ultimate consumer, the patient. The negative economic impact of further regulating SUD’s without scientific proof of a need will not improve the healthcare industries ability to serve it’s patients. Further burdening of the industry, on the contrary, will in fact reduce the hospitals ability to provide adequate services and staffing, which is key to patient safety and care. Also, increased regulations do not necessarily imply safe products. Therefore, MediSISS™ wishes to suggest the following guidelines and definitions for open-but-unused medical devices:

Definitions

We believe that clear definitions are important to reduce the chances of miscommunication and misuse of medical devices.

We believe that Open-but-Unused products can be defined into the four following categories:

- Past its expiration date.

- Opened-but-Unused on the patient – were the surgical process has been cancelled.
- Opened-but-Unused – were the SUD is opened to make a surgical procedural tray with other devices which are then wrapped together and require sterilization.
- Opened-but-Unused on a patient – were the device was located on the surgical field but not used on the patient.

Placing clear definitive definitions on the categories of Open-but-Unused devices will help the hospitals and reprocessors better address it's reesterilization needs.

We also believe that it is in the best interest of the patient, that OEM's provide labeling that states re-sterilization parameters if they are critical (ie: if certain parameters will change the effectiveness of the device) and whether the expiration date is packaging or device specific. However, having said this, we believe the OEM's should have to provide proof of their claim. If a label claims that the device expiration date is two years after the manufacturer date than the OEM should have to have provided data to substantiate that claim. Since there is a history of devices that were once reusable having changed their status to single-use, OEM's need to be responsible for justifying this claim and providing the guidelines for handling SUD's known to have a longer life span.

Willingness of the OEM's to work with hospitals and third party reprocessors would ensure safe and effective products.

It is for - the ultimate goal of all - patient safety - that healthcare providers should work together to ensure cost sensitive, safe and effective products. The re-use of open and unused devices is a needed practice for multiple reasons ranging from effective surgeries to reducing landfill to limiting the economic burden on the health care industry and ultimately the patient.

While establishing recommended definitions and setting guidelines for labeling by OEM's, further regulation would bog down an already burdened system without adding value.

We at MediSISSTTM want to emphasize our focus on safe handling and reprocessing practices. We maintain that open and unused medical devices should remain separate from used SUD's and not be burdened by regulatory constraints.

We thank you for this opportunity to voice our opinions and share our methods.

Sincerely,


 Mary Ann Barker
 Director of Quality and Regulatory Affairs
 MediSISSTTM


 Brandi James
 Quality Assurance Technician
 MediSISSTTM

541-549-4164



Reprocessing Opened-but-Unused Single Use Medical Devices

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*By: Mary Ann Barker
&
Brandi James
MediSISS™.*
