

AdvaMed Principles on Reprocessing of Single Use Devices

(Reaffirmed by the Technology & Regulatory Group May 2012)

The reprocessing of a single use device can present a serious risk to patients if it does not result in a product that is as safe and effective as that of the original manufacturer. Single use devices (SUDs) are designed and manufactured for use in a single patient and are intended by the original manufacturer to be disposed of permanently after use. Their use has been reported to reduce the risk of nosocomial infections.^{1,2,3} Single use devices were not designed to be effectively cleaned and resterilized, may contain areas not accessible to thorough cleaning, and may fail to withstand the harsh conditions (e.g., exposure to solvents and extreme temperatures) encountered during reprocessing. With the passage of the Medical Device User Fee and Modernization Act (MDUFMA), reprocessing of single use devices is now regulated by FDA. AdvaMed supports rigorous implementation and enforcement of the MDUFMA reprocessing provisions. Because of the health risks inherent in the use of an inadequately reprocessed single use device, patients have the right to know and to choose whether a reprocessed single use device should be used in their medical care.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products and medical information systems, ranging from the largest to the smallest innovators and companies. AdvaMed's more than 1,000 members and subsidiaries manufacture nearly 90 percent of the \$75 billion in health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world.

Single Use Devices Are Difficult to Reprocess

Single use devices are designed for optimal performance and safety under their intended conditions of use – not ease of cleaning. They typically have characteristics that make them extremely difficult to effectively clean and resterilize. Among these characteristics are small, difficult to access areas, such as long, narrow lumens, acute angles, crevices, coils and joints, reinforcing meshes and rough, porous or occluded surfaces. These inaccessible areas create barriers to cleaning and allow for the collection of organic matter, such as blood, feces, respiratory secretions and gastric mucin. Subsequent sterilization of previously used and cleaned single use devices may seriously compromise their safety and performance and even destroy some single-use devices.

- Past studies performed by both original equipment manufacturers and independent third parties on reprocessed products show a variety of defects caused by reprocessing. These include lack of sterility, contamination with tissue and bodily fluids, lack of functionality, and the potential for transmission of viral and bacterial infections.⁴

- In a recently conducted independent laboratory study of reprocessed single-use only arthroscopic shaver blades, the reprocessed blades were found to be contaminated with DNA and protein.⁵

MDUFMA Requires Reprocessed SUDs To Be As Safe and Effective As the Original SUD

The Medical Device User Fee and Modernization Act passed by Congress in 2002 requires FDA to apply premarket controls to reprocessed single use devices to ensure that reprocessed single use devices are held to the same standards of safety and efficacy as all other devices. To fully implement congressional intent, FDA oversight must include stringent review of both the appropriateness of the device design for reprocessing and a review of cleaning, sterilization and packaging validation data and labeling/instructions for use to ensure that the reprocessed single use device is safe and effective for the maximum number of times the reprocessor claims the single use device can be reprocessed.

Full Implementation of MDUFMA is Needed to Protect Patients

In the interests of patient safety, AdvaMed expects FDA to implement the provisions of MDUFMA using fact-based, scientific methods to ensure that reprocessed single use devices are held to the same standards as all other devices. To do anything else would foster a two- tiered system wherein one patient group receives treatment with medical devices held to one standard of safety and efficacy and the other patient group receives treatment with medical devices held to a separate and lower standard of safety and efficacy.

While FDA has taken some necessary first steps to implement the reuse provisions, there is significant work yet to be done to ensure patient safety and to fully realize congressional intent. Specifically:

- FDA’s own laboratories have previously concluded that the decision to reuse a single use medical device is not a “category” decision but rather a “model specific” decision which is consistent with bundling comments previously submitted by AdvaMed.⁷
- In a study to develop a model to evaluate the potential for reuse of single use devices conducted by the Biomedical Engineering Department at the Cleveland Clinic Foundation, the authors concluded some single use devices were “rendered . . . unusable” because the “SUD’s materials had been affected by the reprocessing.” The material effects included brittleness, tackiness, “crimp and kink deformations,” and “material stresses that led to cracks.” Interestingly, the authors found that one of the most difficult aspects of reprocessing was the cleaning and decontamination phase because it relied on busy personnel to follow a specific subprotocol to “maximize the removal of clinical soil from the devices” including aspiration, flushing and soaking of the single use device.⁸
- For these reasons, FDA must revisit its determination of which single use devices, when reprocessed, will require cleaning and sterilization validation data by incorporating consideration of the unique design characteristics of each device into its determination. The current FDA scheme fails to take design characteristics into account and thus, fails to adequately identify devices for which established premarket controls, (e.g., review of validation data) are necessary to ensure patient safety.⁹
- FDA must apply the MDUFMA provisions to all reprocessed single use devices – including opened but unused medical devices that have not been indicated by the original

equipment manufacturer as suitable for resterilization. Recent incidents have starkly illustrated the dangers of reprocessing devices – even unused ones – that were never designed for reprocessing.¹⁰

- FDA must apply the principals set forth in its proposed Validation Guidance¹¹ to the same level of scientific review as any other medical device validation. Fundamentally, reprocessors must be able to present objective evidence that all validation requirements have been met and that the processes which must be validated can capably and repeatedly produce medical devices which meet specifications. To this end, a reprocessor must be able to demonstrably account for and accommodate OEM changes and variations to the design and manufacture of the original single use device.

Finally, patients have the right to know – and to choose – whether or not a medical device designed for single use that has already been used on another patient will be used on them. Otherwise, only additional risk (e.g., nosocomial infections and device failures) – and not benefit – are conferred on the patient.

REFERENCES

1. Jernigan JA, Siegman-Igra Y, Guerrant RC, Farr BM. 1998. A randomized crossover study of disposable thermometers for prevention of *Clostridium difficile* and other nosocomial infections. *Infect Control Hosp Epidemiol.* 19(7): 494-9.
2. Nosocomial Hepatitis B virus infection associated with reusable fingerstick blood sampling devices – Ohio and New York City, 1996. *MMWR Weekly*, March 14, 1997/46(10): 217-221.
3. Brooks SE, Veal RO, Kramer M, Dore L, Shupf N, Adachi M. February 1992. Reduction in the incidence of *Clostridium difficile*-associated diarrhea in an acute care hospital and a skilled nursing facility following replacement of electronic thermometers with single-use disposables. *Infect Control Hosp Epidemiol.* 13(2): 98-103.
4. Luijt DS, Schirm J, Savelkoul PH, Hoekstra A. 2001. Risk of infection by reprocessed and resterilized virus-contaminated catheters; an in-vitro study. *Eur Heart J.* 22(5): 378-84.
5. King JS, Green LM, Bianski BM, Pink MM, Jobe CM. Assessment of reprocessed arthroscopic shaver blades. *Arthroscopy, The Journal of Arthroscopic and Related Surgery* (submitted for publication).
6. Brown SA, Merritt K, Woods TO, Hitchins VM. 2001. The effects of use and simulated reuse on percutaneous transluminal coronary angioplasty balloons and catheters. *Biomedical Instrumentation & Technology.* 312-322.
7. See AdvaMed Comments to FDA MDUFMA Docket 02N-0534 (January 22, 2003) from Carolyn D. Jones, Associate Vice President, Technology and Regulatory Affairs at http://www.advamed.org/publicdocs/bundling_proposal1-22-03.pdf.
8. Abreu EL, Haire DM, Malchesky PS, Wolf-Bloom DF, Cornhill JF. 2002. Development of a program model to evaluate the potential for reuse of single-use medical devices: results of a pilot test study. *Biomedical Instrumentation & Technology.* 36(6): 389-404.
9. See AdvaMed Comments to FDA MDUFMA Docket 02N-0534 (August 7, 2003) from Tara Federici, Associate Vice President, Technology and Regulatory Affairs at <http://www.advamed.org/publicdocs/correctionstolists080703.pdf>.
10. See August 5, 2003 Boston Scientific letter to Commissioner McClellan at (reference to be added).
11. See Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices at <http://www.fda.gov/cdrh/ode/guidance/1216.html>.

ANNOTATED BIBLIOGRAPHY TO ACCOMPANY ADVAMED'S POSITION PAPER ON REPROCESSING OF SINGLE USE DEVICES

1. Jernigan JA, Siegman-Igra Y, Guerrant RC, Farr BM. July 1998. "A randomized crossover study of disposable thermometers for prevention of *Clostridium difficile* and other nosocomial infections." *Infect Control Hosp Epidemiol.* 19(7):494-9.

It is known that contaminated thermometers have been implicated in several outbreaks of nosocomial infections. Several of these outbreaks have been resolved through replacing electronic thermometers with single-use disposable ones. The study concluded that implementing disposable thermometers reduced the relative risk of *Clostridium difficile*. However, utilization of these disposable thermometers gave no reduction in the overall rates of infection.

2. March 1997. "Nosocomial Hepatitis B virus infection associated with reusable fingerstick blood sampling devices – Ohio and New York City, 1996." *MMWR Weekly*, March 14, 1997/46(10); 217-221.

This article focused on nosocomial HBV infection through improper use/handling of reusable fingerstick blood sampling devices. Several investigations found that mishandling (e.g., "*used lancet capes were placed in the same box as unused lancet caps*"), reuse of single use components to test other patients ("*...but after the initial supply of end caps for each device had been used, end caps were no longer changed*") were the causes for the outbreaks. The study also found that when hospitals instituted completely disposable, non-reusable fingerstick devices, no further nosocomial HBV infections have been reported.

3. Brooks SE, Veal RO, Kramer M, Dore L, Shupf N, Adachi M. February 1992. "Reduction in the incidence of *Clostridium difficile*-associated diarrhea in an acute care hospital and a skilled nursing facility following replacement of electronic thermometers with single-use disposables." *Infect Control Hosp Epidemiol.* 13(2):98-103.

Brooks et. Al reported "a significant reduction in the incidence of nosocomial *C difficile* in both acute and chronic care facilities following replacement of electronic thermometers with single-use disposable thermometers." They also concluded that "because the statistically significant reduction in the *C difficile* outbreak began immediately following the intervention with single use thermometers...the most likely explanation that transmission was via contaminated electronic rectal thermometers."

4. Luijt DS, Schirm J, Savelkoul PH, Hoekstra A. March 2001. "Risk of infection by reprocessed and resterilized virus-contaminated catheters; an in-vitro study." *Eur Heart J.* 22(5):378-84.

This in-vitro study "demonstrated...that, even after rigorous cleaning and sterilization, virus was still present in the catheter. Reuse of catheters, labeled for single-use only, is dangerous and should be prevented." They determined that, using commonly used procedures for cleaning and sterilization, the virus could still be detected, which proves

that when catheters are actually used in medical practice, blood proteins, lipids, etc., may easily attach to the substrate, creating the potential for virus or bacterial transmission during reuse.

5. King JS, Green LM, Bianski BM, Pink MM, Jobe CM. Assessment of reprocessed arthroscopic shaver blades. *Arthroscopy, The Journal of Arthroscopic and Related Surgery* (Submitted for publication)

This study examined reprocessed arthroscopic shaver blades for contaminants and quality. They found that reprocessed shaver blades sustained significant structural damage as well as nucleic acid and protein contamination, which would pose a high risk to patients if reused.

6. Brown SA, Merritt K, Woods TO, Hitchins VM. 2001. "The Effects of Use and Simulated Reuse on Percutaneous Transluminal Coronary Angioplasty Balloons and Catheters." *Biomedical Instrumentation and Technology*. 35; 312-322

This study's data concluded that "the effects of use and reuse are model specific. One cannot generalize regarding the effects of reprocessing and reuse on PTCAs as a class."

8. Abreu EL, Haire EM, Malchesky PS, Wolf-Bloom DF, Cornhill JF. November/December 2002. "Development of a program model to evaluate the potential for reuse of single-use medical devices: results of a pilot test study." *Biomedical Instrumentation & Technology*. 36(6):389-404.

This study reviews various factors involved in evaluating the reuse of single use devices including cost-analysis and device evaluation. Hospitals have turned to reprocessing of single use devices for cost-cutting reasons but in many cases, no cost-analyses have been performed, therefore preventing certainty of economic savings. "Prior to reusing a given SUD, a comprehensive evaluation of that device should be done to determine the potential for safety and efficacy for reprocessing the device." The authors present a program model to evaluate single use devices for reprocessing. They point out that the Centers for Disease Control uses a critical, semi-critical, or non-critical system to classify devices based on the degree of risk of infection involved in their use. The paper concludes by offering an answer to reuse – responsibilities – which would theoretically consist of disposable and reusable parts.

Types of Peer-Reviewed Articles:

- 1) Focusing on decreased risk of nosocomial infections when using single use devices (as opposed to reprocessed single use devices)
- 2) Dealing with damage or defects caused by the reprocessing single use devices.
- 3) Focusing on increased risk of nosocomial infections when utilizing reprocessed single use devices.
- 4) Factors involved in analyzing reprocessing of single use devices.

The Articles cited above fall into one of the above:

Type of Article	Number of Referenced Article
1) Decreased nosocomial infection risk when using single use devices	1,2,3,
2) Damage/defects that occur during reprocessing	5
3) Increased nosocomial infection when using reprocessed single use devices	4,6
4) Factors involved in analyzing reprocessing single use devices	8