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AdvaMed
Advanced Medical Technology Association

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

**Re: Medical Device User Fee and Modernization Act (MDUFAMA)**
**Docket Number 02N-0534**

Dear Sir/Madam:

As FDA begins implementation of key provisions of the Medical Device User Fee and Modernization Act (MDUFAMA), in particular Sec. 302, establishing new requirements for the reprocessing of single-use devices, AdvaMed appreciates your consideration of our views and comments in this area.

The Medical Device User Fee and Modernization Act of 2002 requires FDA to review by April 26, 2003 the types of critical and semi-critical reprocessed single-use devices that are currently exempt from 510(k) and determine which of these exemptions is to be terminated.

In general, single-use devices that are reprocessed pose risks of cross-infection, cross-contamination and impaired performance if they are not properly cleaned and resterilized, and capable of withstanding the stress of repeated uses.

The following list of devices and accompanying rationale are those 510(k) devices that AdvaMed recommends be included on the list of 510(k) devices that FDA will publish in the Federal Register whose exemptions will be terminated.

This list was compiled from individual comments from AdvaMed members. In order to ensure that all of this information is available to the agency, the information is ordered by specific CFR number and includes all member comments regarding the effect of reprocessing on their individual devices. While this makes the document longer than if we had consolidated the information, we did this in order to ensure that any subtle nuances provided by individual members would be available to the agency.

## 21 CFR 874.4140(b) Ear, nose, and throat burrs

### DISPOSABLE ARTHROSCOPIC SURGERY BLADES AND BURRS

### ENT BURRS/BLADES

**Concerns After Initial Use**
Initial use of arthroscopy blades and ENT burrs/blades may result in damage that cannot be effectively repaired resulting in potentially inferior performance during subsequent reuse. These instances of damage may include:

- Cracking or fatigue of plastic hubs
- Blunting of and damage to blade edgeforms
- Removal of the proprietary lubricant

**Cleaning Concerns**
Used arthroscopy blades and ENT burrs/blades cannot be effectively cleaned, resulting in tissue and other residues inside the device.

- All inner blades have a narrow, inaccessible lumen. It is difficult to insert a device for cleaning into this lumen. For many devices, it is impossible to actually clean the blades resulting in the potential of contamination from one patient to another.
- Manual cleaning combined with chemical cleaning and disinfection agents may score the plated surfaces of the devices causing interference/ resistance of moving parts during operation. Further, curved blades cannot be disassembled for cleaning -- the spring section cannot be accessed or cleaned.
- Manual cleaning of the inner blades will remove the proprietary lubricant resulting in decreased performance of the blade. There have also been observations of damage and destruction to motor drive units (MDU) caused by non-lubricated and misaligned blades.

**Sterilization Concerns**
Resterilization of arthroscopy blades and ENT burrs/blades results in performance and safety issues:

- During repeated gamma irradiation, chemical cross-linking to the inner mold of disposable arthroscopy blades may detrimentally affect the strength of the tang employed in the rotation of the blade in the MDU. Breakage of the tang during use prevents the turning of the inner blade assembly, detrimentally affecting tissue removal.
- Long mated surfaces and friction/interference fit of inner and outer blades make ethylene oxide and vapor phase hydrogen peroxide penetration difficult. Due to the fit of these inner and outer blades, certain sterilization systems cannot be used as the sterilant can not effectively penetrate spaces smaller than 3 mm.
- Build-up of liquid and gaseous sterilant residuals in excess of the ISO 10993-7 maximum allowable levels may initiate toxicity reactions in the patient.

**Performance Concerns**
Since these devices are designed to cut through bone and soft tissue, it is imperative that reprocessing be fully validated. The process needs to ensure that all tissue is removed and that the devices will be suitable for their intended use after reprocessing.

Demonstration that the devices will be suitable for their intended use is hindered by the following:

- Magnified visual inspection of burrs or chipped cutting edges alone does not demonstrate that the device is still sharp enough for reuse. Device testing must be undertaken that will demonstrate that the device is still effective.
- The healthcare organization/reprocessor responsible for reprocessing must have a means to verify that device shafts are still true (in alignment).

## 21 CFR 876.1075(b)(2) Gastroenterology-urology biopsy instrument

### NON-ELECTRIC BIOPSY FORCEPS

**Cleaning and Sterilization Concerns**
Single-use, non-electric biopsy forceps are difficult, if not impossible, to thoroughly clean or adequately sterilize for safe reuse in patients without adversely affecting the structural integrity of the device. The very design of non-electric biopsy forceps impedes adequate cleaning and sterilization after use.

**Sterilization Concerns**
Studies have consistently demonstrated that a significant number of reprocessed, single-use biopsy forceps contain residual debris and fail to meet the sterility assurance level established by FDA. Studies conducted by FDA's Office of Science and Technology using three types of single-use gastrointestinal biopsy forceps demonstrated that residual water remained in the device following cleaning with a sequence of bleach, ultrasonic bath with detergent and enzyme, and water rinse. The inability to adequately dry the device lumen decreases the effectiveness of sterilization. Thus, even when debris can be removed from these devices, the presence of residual water compromises the ability to effectively sterilize them.

**Performance Concerns**
In addition, the harsh conditions of reprocessing diminish the performance and structural integrity of the device. Reprocessed devices have a high potential for residual debris, non-sterility, and compromised functionality and, as a result, present an increased risk to patients. This risk necessitates 510(k) clearance to provide reasonable assurance that these devices are safe and effective for reuse after reprocessing.

Due to the risk of infection and unacceptable device performance, FDA, in its February 2000 Draft Enforcement Prioritization Guidance, identified reprocessed, single-use biopsy forceps as high risk devices. Accordingly, the safety and effectiveness of

reprocessed forceps cannot adequately be assured without premarket review to ensure their substantial equivalence to the single-use predicate device. FDA, therefore, must terminate the exemption for reprocessed, single- use, non-electric biopsy forceps pursuant to Title III of MDUFAMA.

## 21 CFR 876.4680(b) Ureteral stone dislodger

### URETERAL STONE DISLODGER

**Cleaning Concerns**
Single-use ureteral stone dislodgers are difficult, if not impossible, to thoroughly clean and adequately sterilize for safe reuse in patients. The very design of ureteral stone dislodgers impedes adequate cleaning and sterilization after use. During use, tissue, blood and other organic materials may be drawn into the very narrow sheath, into which the capture wire of the retrieval tip is retracted. These biological materials cannot be adequately removed due to the very small diameter of the sheath (3 fr or approximately 1 mm), and the small clearance (.002 inches) between the wire and sheath. This inevitable and variable bioburden presents a significant barrier to adequate, reproducible and verifiable sterilization by commonly used methods. Thus, the presence of residue of biological material in used devices presents the risk of cross-contamination, infection, or pyrogenic reaction to the residue.

**Performance Concerns**
Residual material may have a deleterious effect on the performance of the devices by interfering with the smooth extension and retraction of the retrieval tip within the sheath. This may decrease the effectiveness of the device and increase the risk of malfunction.

In addition, the harsh conditions of reprocessing diminish the performance and structural integrity of ureteral stone dislodgers. These devices are designed for first use performance, rather than amenability to cleaning and sterilization.

Harsh conditions and stress resulting from cleaning and sterilization techniques may create the potential for device degradation and impaired performance. The capture wires of the retrieval tip are very fine, approximately .004 to .008 inches, and are not designed or tested for multiple-use. Breakage of the stainless steel retrieval wires during reuse may pierce, scrape, or sever the ureter, causing significant injury to the patient.

Reprocessed, single-use ureteral stone dislodgers have a high potential for residual debris, non-sterility, and compromised functionality. As a result, they present an increased risk to patients. Accordingly, their safety and effectiveness cannot adequately be assured without premarket review to ensure their substantial equivalence to the single-use predicate device. FDA, therefore, should terminate the exemption for reprocessed, single-use ureteral stone dislodgers.

## 21 CFR 878.4760(b) Removable skin staple

### STAPLERS & CLIP APPLIERS

**Cleaning Concerns**
The inner cavities are difficult to clean. Partially used disposable loading units should also not be reused due to difficulty in cleaning the inner cavities which can harbor contaminants, and their removal will affect performance. Disassembly for the devices is not possible as this would destroy them. The disposable loading units currently are not cleared for reuse due to the remanufacturing steps required to add new staples or clips.

## 21 CFR 878.4800(b) Manual surgical instrument for general use

### STAPLERS & CLIP APPLIERS

**Cleaning Concerns**
The inner cavities are difficult to clean. Partially used disposable loading units should also not be reused due to difficulty in cleaning the inner cavities which can harbor contaminants and their removal will affect performance. Disassembly for the devices is not possible as this would destroy them. The disposable loading units currently are not cleared for reuse due to the remanufacturing steps required to add new staples or clips.

## 21 CFR 878.4820(b) Surgical instrument motors and accessories/attachments

### DISPOSABLE ARTHROSCOPIC SURGERY BLADES AND BURRS

### ENT BURRS/BLADES

**Concerns After Initial Use**
Initial use of arthroscopy blades and ENT burrs/blades may result in damage that cannot be effectively repaired resulting in potentially inferior performance during subsequent reuse. These instances of damage may include:

- Cracking or fatigue of plastic hubs
- Blunting of and damage to blade edgeforms
- Removal of the proprietary lubricant

**Cleaning Concerns**
Used arthroscopy blades and ENT burrs/blades cannot be effectively cleaned resulting in tissue and other residues inside the device.

- All inner blades have a narrow, inaccessible lumen. It is difficult to insert a device for cleaning into this lumen. For many devices, it is impossible to actually clean the blades resulting in the potential of contamination from one patient to another.

- Manual cleaning combined with chemical cleaning and disinfection agents may score the plated surfaces of the devices causing interference/ resistance of moving parts during operation. Further, curved blades cannot be disassembled for cleaning -- the spring section cannot be accessed or cleaned.
- Manual cleaning of the inner blades will remove the proprietary lubricant, resulting in decreased performance of the blade. There have also been observations of damage and destruction to motor drive units (MDU) caused by non-lubricated and misaligned blades.

**Sterilization Concerns**
Resterilization of arthroscopy blades and ENT burrs/blades results in performance and safety issues:

- During repeated gamma irradiation, chemical cross-linking to the inner mold of disposable arthroscopy blades may detrimentally affect the strength of the tang employed in the rotation of the blade in the MDU. Breakage of the tang during use prevents the turning of the inner blade assembly, detrimentally affecting tissue removal.
- Long mated surfaces and friction/interference fit of inner and outer blades make ethylene oxide and vapor phase hydrogen peroxide penetration difficult. Due to the fit of these inner and outer blades, certain sterilization systems cannot be used as the sterilant can not effectively penetrate spaces smaller than 3 mm.

**Performance Concerns**
Since these devices are designed to cut through bone and soft tissue, it is imperative that reprocessing be fully validated. The process needs to ensure that all tissue is removed and that the devices will be suitable for their intended use after reprocessing.

Demonstration that the devices will be suitable for their intended use is hindered by the following:

- Magnified visual inspection of burrs or chipped cutting edges alone does not demonstrate that the device is still sharp enough for reuse. Device testing must be undertaken that will demonstrate that the device is still effective.
- The healthcare organization/reprocessor responsible for reprocessing must have a means to verify that device shafts are still true (in alignment).

## SAGITTAL SAW BLADES

**Concerns After Initial Use**
Minor changes to the geometry of the cutting edge of the sagittal saw blades due to damage during use can detrimentally affect the cutting efficiency of the blades. In addition, slight misalignment of the teeth of the cutting edge due to handling and reprocessing may result is unexpected tissue damage during reuse by physicians.

**DISPOSABLE DRILL BITS, DRILL TIP PASSING PINS, GUIDEWIRES**

**Concerns After Initial Use**
In the case of guidewires marked "for single use only," reuse increases the risk of employing a damaged guidewire with possible fatal consequences (MDA Safety Notice SN2001(14)).

## 21 CFR 888.4540(b) Orthopedic manual surgical instruments

**ORTHOPEDIC MANUAL SURGICAL INSTRUMENTS (INCLUDING CARPAL TUNNEL RELEASE KNIVES)**

**Cleaning Concerns**
Carpal tunnel knives were recalled several years ago because their geometry combined with the chemicals used for cleaning and sterilization caused embrittlement.

AdvaMed appreciates the opportunity to provide these comments and would like to work with the agency to ensure the appropriate implementation of this key provision of MDUFAMA.

Sincerely,

Tara Federici

Tara Federici
Associate Vice President
Technology & Regulatory Affairs