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AdvaMed
Advanced Medical Technology Association

February 7, 2003

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.

AdvaMed, the Advanced Medical Technology Association, represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion in health care technology products consumed yearly in the United States and nearly 50 percent of the $159 billion purchased around the world annually.

The Medical Device User Fee and Modernization Act of 2002 requires FDA to review by April 26, 2003, the types of single-use devices now subject to 510(k) clearance that may be reprocessed to identify those devices that FDA will require submission of "validation data...regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent...after the maximum number of times the device is reprocessed as intended" by the person who submits the 510(k). FDA's list of 510(k) devices requiring validation for reuse will be published in the Federal Register.

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

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Federal Register and which should be required to submit validation data in order to permit reuse.

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.

CFR 21 870.1220 Electrode recording catheter or electrode recording probe

ELECTROPHYSIOLOGY (EP) CATHETERS

EP catheters are precision instruments used to measure fine electrical signals within the human heart. The primary working mechanism of these catheters consists of various types of electrodes positioned at or near the distal end that detect and feedback electrical signals via delicate wires to a central console for processing and displaying the electrical activity of the heart. The continuity of these electrical connections is critical for proper operation of this device. Electrical signals are also sent from the console to the heart for pacing procedures. In addition, the tips of these catheters are precisely constructed of a progression of materials with different durometers that ensure appropriate maneuverability of the catheters to properly position the catheter tips within the heart. The catheters are also manufactured in a range of diameters and lengths. Some EP catheters are deflectable and therefore include a mechanism (pull wire) to control deflection inside the catheter. Many therapeutic decisions on how to best treat the patient are based on the information provided by these diagnostic catheters. Although the 510(k)-cleared EP catheters are extensively tested to ensure they are robust for one time use as claimed by the manufacturer, there is no assurance that repeated use or repeated cleaning and sterilization will maintain such confidence.

Cleaning Concerns
It is not known if standard cleaning procedures are capable of removing all contaminants from the electrodes and catheter surfaces.

Performance Concerns
Impaired performance could be derived from residues remaining after incomplete cleaning of the device (e.g., leading to compromised ability to detect electrical signals leading to patient misdiagnosis), wear and tear on the device during repeated use (e.g., adversely impacting the ability to accurately position the probe within the heart), and/or physical/chemical changes to the device from repeated exposure to the temperatures and other conditions involved in reprocessing these devices for reuse (e.g., resulting in an increased risk of debris being released into the heart during use).

21 CFR 870.1390 Trocar

TROCARS

Cleaning Concerns
The numerous inner cavities of trocars (e.g., of the stopcock) render these devices extremely difficult to thoroughly clean and sterilize and thus warrant premarket review of the validation of these difficult processes.

Performance Concerns
The cutting ability of trocars also diminishes over time and this performance aspect of the device must be validated. Also, the materials and designs change periodically and the validation protocol must take these changes into account.

21 CFR 870.2700 Oximeter

PULSE OXIMETRY SENSORS

Performance Concerns
FDA should require validation data for these sensors because methods used for reprocessing can adversely affect system accuracy. Inaccurate displayed values of oxygen saturation may lead to patient mismanagement and possible serious patient injury. Sensor calibration can be affected during reprocessing by materials used, sensor construction and handling processes. For example, the sterilization procedure utilized can create wavelength shifts in the light emitting diodes (LED) that constitute one of the critical calibration factors of sensors. Wavelength changes of as little as one or two nanometers result in loss of proper calibration of the sensor and cause errors in the displayed oxygen saturation.

21 CFR 870.5800 Compressible Limb Sleeve

SEQUENTIAL COMPRESSION DEVICE (SCD) SLEEVES

Concerns After Initial Use
Repeated use of the sleeve will cause the plastic film from which the sleeve is fabricated to stretch. This stretching will change the pressure profiles of the sleeve, reducing efficacy.

Cleaning and Sterilization Concerns
This product is designed to increase blood flow in the legs and has been clinically proven to reduce the incidence of deep vein thrombosis. The product is fabricated from materials which can not be readily cleaned or disinfected. The risk of infection from improper cleaning, disinfection or sterilization is moderate. Cleaning, sterilization or disinfecting agents reduce product reliability and may result in product failure. For example, reprocessing agents may weaken the bond between the tubing and sleeve as well as damage the gasket on the tubing

connector. This will result in air leakage from the device which in many instances may not be readily detectable. Air leakage affects product efficacy and may compromise patient safety. The sleeve is designed to inflate in a sequential manner starting at the ankles. An air leak will alter the compression profile and could turn the sleeve into a tourniquet. In newer models that actually detect each patient's vascular refill rate, air leakage would play an even greater role in patient safety.

21 CFR 876.1500 Endoscope and accessories

TROCARS

Cleaning Concerns
The numerous inner cavities of trocars (e.g., the stopcock) render these devices extremely difficult to thoroughly clean and sterilize and thus warrant premarket review of the validation of these difficult processes.

Performance Concerns
The cutting ability of trocars also diminishes over time and this performance aspect of the device must be validated. Also, the materials and designs change periodically and the validation protocol must take these changes into account.

HAND-ASSIST LAPAROSCOPY DEVICES

Cleaning Concerns
Used hand-assist laparoscopy devices cannot be effectively cleaned, resulting in tissue and other residues inside the device.

- Due to the nature of use of the device, high-level disinfection due to fluid/tissue contact may contribute to scoring and embrittlement of plastic molded components.
- Scoring of the hand-assist laparoscopy device sleeve provides crevices for microbiological contamination or residue build-up that may not be effectively removed during subsequent reuse.

Sterilization Concerns
Resterilization of the hand-assist laparoscopy system results in performance and safety issues:

- During repeated gamma irradiation, chemical cross-linking in plastic parts may detrimentally affect the strength of the plastic, specifically the sleeve wall. This embrittlement may potentially expose the peritoneum to infection.
- Build-up of liquid and gaseous sterilant residuals in excess of the ISO 10993-7 maximum allowable levels on the hand-assist laparoscopy device sleeve may initiate toxicity reactions in the patient.
- Due to the complex mated surfaces of the sleeve in its retracted configuration, ethylene oxide or vapor phase hydrogen peroxide sterilization efficacy would need to be

demonstrated by the placement of an indicator organism (inoculum) into the geometric center of the sleeve during validation. Reprocessing centers would need to demonstrate methods to effectively inoculate and recover this inoculum during device validation.

PNEUMOPERITONEUM NEEDLES

Cleaning and Performance Concerns
These needles are included with the trocar kits and consist of a safety-shielded needle for establishing insufflation during the insertion of the trocar. Cleaning and performance validations are necessary to demonstrate the inner areas of the safety shield are clean and the needle is not too dull.

ENDOSCOPIC INSTRUMENTS INCLUDING SCISSORS, GRASPERS & DISSECTORS

Cleaning Concerns
All endoscopic hand instruments have a shaft that runs the length of the instrument and ends at the jaw hinge. Body fluids exposed to the shaft are carried up into the instrument during use where they cannot be cleaned.

Performance Concerns
These instruments are prone to decreased performance with multiple uses. The scissors dull with repeated use. The devices are not intended to withstand the stress of reuse and the validations must consider the damage caused by repeated use. If these devices fail during use, in most cases a simple endoscopic procedure will have to become an open procedure. This adds additional time to the procedure, risk to the patient and cost to the health care system.

The devices must also be validated for sterilization requirements. In many cases these devices are manufactured with materials which are not designed to withstand the stresses of multiple sterilizations.

21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories

RF PROBES FOR ARTHROSCOPY

ELECTROTHERMAL PROBES FOR SPINAL PROCEDURES

ELECTROSURGICAL SWITCHPENS

Concerns After Initial Use
Initial use of these products may result in damage to the dielectric coating resulting in potentially inferior performance during subsequent reuse. Damage or partial removal of dielectric coating of these products may result in electrical discharge in areas of the device

unintended during device design, thus resulting in a device that is no longer compliant to the applicable requirements of IEC 60601-2-2 and ANSI/AAMI HF-18. Furthermore, this weakening of the dielectric integrity can result in electrical arcing with adjacent steel instruments.

Cleaning Concerns
Continued manual cleaning and reuse of electrosurgical switchpens and probes affect the manner in which the probes are seated into the switchpen. Reduction of the force required to remove or unseat these probes detrimentally affects the electrical integrity of the unit. Continued manual cleaning can also lead to damage in the fingerswitches of the switchpen allowing unwanted ingress of liquids, a safety hazard as identified in IEC 60601-2-2 and ANSI/AAMI HF-18.

Sterilization Concerns
These products will need to be validated to ensure that the circuitry and physical integrity of the device remains intact. The integrity of the devices themselves must also be validated. The devices could also begin to corrode if they are reprocessed. For extremely delicate devices such as electrothermal probes for spinal procedures, it is possible that the tip may fall off if it is subjected to excessive force during reprocessing. This catastrophic event could occur either during the reprocessing or later when the device is being used.

IEC 60601-2-2 and ANSI/AAMI HF18 identifies several specific test requirements, each with associated safety limits for reusable electrosurgical accessories. These tests are mainly related to insulation integrity and fingerswitch function. As part of a reprocessing validation protocol, reprocessed single-use devices must be tested to the reusable device criteria in the aforementioned standards to be considered safe and effective for reprocessing.

Performance Concerns
In addition, device non-pyrogenicity of the electrothermal probes for spinal procedures in compliance with USP <85> must be demonstrated.

Build-up of liquid and gaseous sterilant residuals in excess of the ISO 10993-7 maximum allowable levels on these devices may initiate toxicity reactions in the patient and result in decreased transfer of energy.

ELECTROSURGICAL ARTHROSCOPY BLADES

Concerns After Initial Use
In addition to the above concerns, the reprocessing of electrosurgical arthroscopy 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
- Damage to blade edgeforms

- Removal of the proprietary lubricant
- Damage to dielectric coating

Cleaning Concerns
These products also cannot be effectively cleaned after use resulting in tissue and other residues inside the device.

- The inner blades have a narrow, inaccessible lumen. It is difficult to insert a device for cleaning into this lumen.
- 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.
- Manual cleaning of the inner blades will remove the proprietary lubricant resulting in decreased performance of the blade.

Sterilization Concerns
Resterilization of the electrosurgical arthroscopy blades results in performance and safety issues:

- During repeated gamma irradiation, chemical cross-linking to the inner molded hub of the device may detrimentally affect the strength of the tang employed in the rotation of the blade in the motor drive unit (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 the use of certain sterilization systems impossible 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 on these devices may initiate toxicity reactions in the patient and result in decreased transfer of energy.

Performance Concerns
Since the electrosurgical arthroscopy blade is 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 electrosurgical arthroscopy blade 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 responsible for reprocessing must have a means to verify that device shafts are still true (in alignment).

ELECTROSURGICAL ACTIVE ACCESSORIES (PENCILS AND ELECTRODES)

Performance Concerns
Many of these single-use devices have components that are designed to make an electrical connection, such as electrosurgical pencils. When this product is manufactured, it is tested for proper continuity and is subjected to high voltage breakdown testing to assure that with the high levels of energy that are delivered during its use, patient and user safety are maintained. Depending on the methods of reprocessing or re-sterilization, materials and connections can be affected, compromising the integrity of the product and resulting in its improper function. For example, if fluids found their way into the interior electrical components of the pencil, it is possible that an electrical short might occur. Thus, the products would have to be tested to assure that these types of reprocessing conditions could be tolerated.

ULTRASONIC HANDPIECES

Cleaning and Performance Concerns
There are no cleared 510(k)s for reuse of these devices but there have been reports of their reuse in Europe. These devices require the same types of validation as the endoscopic instruments but in addition, the performance must be carefully scrutinized. Minor damage to the inner components can cause significant changes to the performance.

21 CFR 878.4750 Implantable staple

STAPLERS & STAPLE LOADING UNITS

Cleaning Concerns
The inner cavities of the staplers and staple loading units 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 880.5725 Infusion Pump

FLUID PUMP TUBE SETS WITH PRESSURE SENSING FEEDBACK MECHANISMS

ALL OTHER TUBING

Cleaning Concerns
Used tube sets cannot be effectively cleaned resulting in tissue and other residues inside the device.

- The tortuous pathway of tube sets prohibits the manual or mechanical removal of contaminant material to ensure sterility and safety during future use. There is a potential that germicidal disinfectants employed may affect bond integrity between tube sets and the incorporated components such as in-line filters and y-connectors.
- Due to the nature of use of the device, high-level disinfection due to fluid/tissue contact may contribute to embrittlement of plastic molded components.

Sterilization Concerns
Resterilization of the tube sets results in performance and safety issues:

- During repeated gamma irradiation, chemical cross-linking to the molded cassette may detrimentally affect the strength of the plastic resulting in cracking and potential separation of the cassette from the tube set during use.
- Build-up of liquid sterilant residuals in excess of the ISO 10993-7 maximum allowable levels on the tubing may initiate toxicity reactions in the patient.
- Due to the tortuous pathway of the accompanying tube set, ethylene oxide or vapor phase hydrogen peroxide sterilization efficacy would need to be demonstrated by the placement of an indicator organism (inoculum) into the geometric center of the tubing during validation. Reprocessing centers would need to demonstrate methods to effectively inoculate and recover this inoculum during device validation.

21 CFR 884.1730 Laparoscopic insufflator

FLUID PUMP TUBE SETS WITH PRESSURE SENSING FEEDBACK MECHANISMS

ALL OTHER TUBING

Cleaning Concerns
Used tube sets cannot be effectively cleaned resulting in tissue and other residues inside the device.

- The tortuous pathway of tube sets prohibits the manual or mechanical removal of contaminant material to ensure sterility and safety during future use. There is a potential that germicidal disinfectants employed may affect bond integrity between tube sets and the incorporated components such as in-line filters and y-connectors.
- Due to the nature of use of the device, high-level disinfection due to fluid/tissue contact may contribute to embrittlement of plastic molded components.

Sterilization Concerns
Resterilization of the tube sets results in performance and safety issues:

- During repeated gamma irradiation, chemical cross-linking to the molded cassette may detrimentally affect the strength of the plastic resulting in cracking and potential separation of the cassette from the tube set during use.
- Build-up of liquid sterilant residuals in excess of the ISO 10993-7 maximum allowable levels on the tubing may initiate toxicity reactions in the patient.

Due to the tortuous pathway of the accompanying tube set, ethylene oxide or vapor phase hydrogen peroxide sterilization efficacy would need to be demonstrated by the placement of an indicator organism (inoculum) into the geometric center of the tubing during validation. Reprocessing centers would need to demonstrate methods to effectively inoculate and recover this inoculum during device validation.

Performance Concerns
For tube sets with a pressure sensing feedback mechanism, continued cleaning and sterilization could affect the sensitivity of the feedback mechanism. This would be impossible to detect until the pump itself does not operate at the correct pressure thus placing the patient at risk.

21 CFR 888.1100 Arthroscope

VEIN RESECTORS

ARTHROSCOPIC BLADES

Concerns After Initial Use

Initial use of vein resectors or arthroscopic 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 or damage to blade edgeforms
- Removal of the proprietary lubricant

Cleaning Concerns
Used vein resectors and arthroscopic blades cannot be effectively cleaned, resulting in tissue and other residues inside the device.

- The inner blades have a narrow, inaccessible lumen. It is difficult to insert a device for cleaning into this lumen.

- 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.
- 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 caused by non-lubricated and misaligned blades.
- Due to the nature of use of the device, high-level disinfection due to blood contact may contribute to embrittlement of plastic molded components.

Sterilization Concerns
Resterilization of the vein resector/arthroscopic blade results in performance and safety issues:

- During repeated gamma irradiation, chemical cross-linking to the inner molded hub of the device may detrimentally affect the strength of the tang employed in the rotation of the blade in the motor drive unit. 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 the use of certain sterilization systems impossible as the sterilant can not effectively penetrate spaces smaller that 3 mm.
- Build-up of liquid sterilant residuals in excess of the ISO 10993-7 maximum allowable levels on the blade and tubing may initiate toxicity reactions in the patient.

Performance Concerns
Since the vein resector/arthroscopic blade is designed to cut through soft tissue and/or bone, 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 vein and blade 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 or reprocessor responsible for reprocessing must have a means to verify that device shafts are still true (in alignment).

TROCARS

Cleaning Concerns
The numerous inner cavities of trocars (e.g., of the stopcock) render these devices extremely difficult to thoroughly clean and sterilize and thus warrant premarket review of the validation of these difficult processes.

Performance Concerns
The cutting ability of trocars also diminishes over time and this performance aspect of the device must be validated. Also, the materials and designs change periodically and the validation protocol must take these changes into account.

NO CFR REFERENCE ASSIGNED

CUSA SINGLE-USE DISPOSABLE ACCESSORIES

Performance Concerns
Many of these single use devices have components that are designed to make an electrical connection, such as electrosurgical pencils. When this product is manufactured, it is tested for proper continuity and is subjected to high voltage breakdown testing to assure that with the high levels of energy that are delivered during its use, patient and user safety are maintained. Depending on the methods of reprocessing or re-sterilization, materials and connections can be affected, compromising the integrity of the product and resulting in its improper function. For example, if fluids found their way into the interior electrical components of the pencil, it is possible that an electrical short might occur. Thus, the products would have to be tested to assure that these types of reprocessing conditions could be tolerated.

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