Boston Scientific

January 21, 2003

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Food & Drug Administration
Dockets Management Branch
CDRH/OHIP/DSMICA (HFZ-220)
1350 Piccard Drive
Rockville, MD 20850-4307

Attn: Bill Sutton

Re: Docket No. 02N-0534

Dear Sir or Madam:

Boston Scientific Corporation ("BSC") is submitting (in duplicate) these comments in support of the listing of reprocessed single-use, non-electric biopsy forceps as critical, single-use devices for which the exemption from premarket review pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA) should be terminated in accordance with Title III, Section 301(b)(2) of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). Recent studies demonstrate that more than 30 percent of the reprocessed forceps tested were not adequately sterilized by existing reprocessing procedures. 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. 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 must therefore terminate the exemption for reprocessed, single-use, non-electric biopsy forceps pursuant to Title III of MDUFMA.

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I. FDA MUST EVALUATE THE EXEMPTIONS FOR CRITICAL REPROCESSED, SINGLE-USE DEVICES AND IDENTIFY THOSE WHICH MUST BE TERMINATED TO ASSURE SAFETY AND EFFECTIVENESS

Pursuant to FDA regulations at 21 C.F.R. § 876.1075(b)(2), biopsy forceps covers and non-electric biopsy forceps are classified as exempt Class I medical devices. Under FDA's Enforcement Guidance for Reprocessed Single-Use Devices, the reprocessing and reuse of these devices are exempt from premarket review under Section 510(k) of the FFDCA.[1]

Congress enacted Title III of MDUFMA in response to significant safety concerns regarding the reprocessing and reuse of devices that are cleared or approved by FDA for single-use only. Title III requires FDA to "identify [critical or semi-critical reprocessed single-use devices that are exempt from premarket notification requirements] for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices." Under MDUFMA, FDA is required to "publish in the Federal Register a list of the devices so identified."[2] The exemption for each device included on the list is terminated upon publication of the list.[3] In order to provide reasonable assurance of their safety and effectiveness when reused, these reprocessed devices will be subject to review pursuant to section 510(k) to ensure that they remain substantially equivalent to the single-use, predicate device.

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1 *See* FDA, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (August 14, 2000).

2 MDUFMA § 302(b)(2).

3 Manufacturers and distributors of reprocessed single-use devices will have fifteen (15) months from the date on which a device is included on the list to submit to FDA a 510(k) premarket notification including validation data supporting the maximum number of times the device may be used safely and effectively. *Id.*

II. REPROCESSED, SINGLE-USE, NON-ELECTRIC BIOPSY FORCEPS ARE CRITICAL REPROCESSED SINGLE-USE DEVICES THAT PRESENT A HIGH DEGREE OF RISK TO PATIENT SAFETY

A. Characteristics of Single-Use, Non-Electric Biopsy Forceps[4]

Single-use, non-electric biopsy forceps are used to extract tissue samples from the gastrointestinal tract. They generally are made of two long, thin steel wires that are covered at the distal end by a lubricious-coated plastic sheath. The lubricious-coated plastic sheath has an extremely narrow cross sectional profile, which may be as minute as 2.2 mm. A tightly-wound metal coil covers the wires and sheath, and the metal coil is itself covered by an outer polymer sheath. The distal end of the wires are separately attached by means of a 'z-bend' to a hole located at the proximal end of each of the two hinged metal jaw-like structures designed to collect tissue samples. The collection jaws are attached to the metal coil covering the wires by "crimping." At the proximal end of the device are a plastic handle and spool assembly designed to control the collection jaws.

A needle used to anchor the device often is located inside the collection jaws. The needle is inserted into the normally-sterile mucosa, or lining, of the gastrointestinal tract. Once the needle is anchored, the collection jaws may be closed to extract a sample of the gastrointestinal tissue. The needle also may be used to stack tissue samples from the individual undergoing the biopsy.

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[4] A diagram of typical single-use, non-electric biopsy forceps is included in Attachment 1.

In order to accomplish their intended use, single-use, non-electric biopsy forceps must break through the mucosa barrier of the gastrointestinal tract, contact the blood stream, and remove a sample of tissue, thus contacting normally-sterile tissue or body spaces. Although the forceps are intended for single-use only, they are frequently reprocessed and reused on multiple patients. An FDA survey on reuse and reprocessing of single-use devices found that biopsy forceps are among the single-use devices most commonly reused by U.S. hospitals.[5] Thus, biopsy forceps are critical, reprocessed, single-use devices subject to review under section 301(B)(2) of MDUFMA.[6]

B. Reprocessing Methods Do Not Assure the Cleanliness or Sterility of Reprocessed, Single-Use, Non-electric Biopsy Forceps

Several structural features of single-use biopsy forceps may prevent the thorough removal of residual tissue from used devices. During use, biopsy forceps enter the harsh environment of the gastrointestinal tract which, even in healthy individuals, harbors a wide variety of bacterial species. The device must penetrate the mucosal barrier of the gastrointestinal tract coming into contact with blood and tissue. Transfer of bacteria into this normally sterile environment would present a significant risk of infection. Blood, tissue and bacteria may enter the long, narrow lumen of the forceps that is created by the plastic sheath covering the wires. This area cannot be cleaned by flushing with cleaning fluid because it is opened only at one end.

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5 CDRH, "Survey on the Reuse and Reprocessing of Single-Use Devices (SUDs) in U.S. Hospitals" (December 2002) (www.fda.gov/cdrh/reuse).

6 MDUFMA defines a "critical reprocessed single-use device" as "a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use." MDUFMA § 302(d). "Single-use devices" are defined in MDUFMA as "device[s] that [are] intended for one use, or on a single patient during a single procedure." *Id.*

Attempts to flush and aspirate cleaning fluid through the single opening have been shown to further distribute blood and contaminated tissue throughout the device.[7] Additionally, the wire coil can trap and hold minute particles of tissue as can the intersection of the wires to the collection jaws at the z-bend.

These attributes of non-electric biopsy forceps present a significant barrier to their adequate sterilization for reuse.[8] Most reprocessors use ethylene oxide gas to sterilize single-use, non-electric biopsy forceps. Ethylene oxide sterilization is a bioburden-based method that is limited by the inability of ethylene oxide gas to penetrate tissue. To ensure effective ethylene oxide sterilization, the bioburden must be below that needed to achieve a sterility assurance level (SAL) of 10^{-6}.[9] As a result, forceps which contain residual tissue cannot adequately be sterilized with ethylene oxide gas. Residual liquid in the lumen of the forceps also impedes ethylene oxide sterilization. After use, blood, bile or water is likely to be present in the device as a result of scope suction or the wicking effect. As recognized by FDA's Office of Science and Technology (OST), even if tissue is removed by rigorous cleaning using a sequence of bleach, ultrasonic bath

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7 Roth, K. *et al.*, "Quality Assurance on Reprocessing Accessories for Flexible Endoscopes – Just How Clean are Cleaned Instruments Really?," Central Service 7(2), at 7 (1999).

8 *See* ECRI, "Evaluating the Feasibility of Reusing a Single-Use Device," Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions, at 55 (1996) (noting that "[d]evices with long and/or small-diameter lumens, with rough or textured surfaces and deep groves or crevices, that are composed of porous materials and constructed with hinges or other features that may interfere with cleaning should probably not be considered [for reprocessing].").

9 The SAL of 10^{-6} is the level at which there is a one in a million chance that a device is non-sterile. It is considered to be an industry standard. *See, e.g.*, BSEN Standard 556, "Sterilization of Medical Devices: Requirements for Medical Devices to be Considered Sterile," Section 4.1.

with detergent and enzymes, and water rinse, drying the lumen of the device is very difficult. According to OST, "residual water may decrease the efficacy of sterilization."[10]

Other sterilization methods are also unlikely to be effective in sterilizing used biopsy forceps. Ionizing radiation, the sterilization method used for new, unused non-electric biopsy forceps, also is a bioburden-based method, that requires the device to have a very consistent level of bacterial contamination in order to achieve a 10^{-6} SAL. When tissue and organic material are not adequately removed from the device, bacteria may remain and the SAL is not achieved reproducibly. Additionally, due to the variable levels of bacteria that may be found on used biopsy forceps, the radiation level necessary for reprocessing must be very high. The cumulative effect of a second radiation treatment to resterilize used, single-use forceps that were previously radiation-sterilized likely would destroy the physical integrity of the devices. Steam sterilization is also unlikely to be effective because the plastic components of the forceps melt if subjected to high-temperature steam sterilization.

C. Studies Demonstrate that More than 30 Percent of Reprocessed, Single-Use Biopsy Forceps Were Not Adequately Sterilized

Since 1997, BSC has funded nine separate studies to evaluate the sterility of reprocessed, single-use, non-electric biopsy forceps. Overall, 216 reprocessed devices were examined and more than 31 percent failed sterility tests performed by independent laboratories.

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[10] CDRH, "Reprocessing Single Use Biopsy Forceps for Reuse," abstract for the 2000 FDA Science Forum from OST.

BSC obtained reprocessed devices for testing from hospitals in their in-tact reprocessor packaging and replaced each reprocessed device it received with a new replacement device. Devices for testing were selected at random by hospital personnel. BSC immediately shipped the devices to the testing laboratory in their reprocessor packaging. The devices to be tested for sterility were cut in 30 cm and 10 cm segments and subjected to a 14-day modified USP sterility test using Soybean Casein Digest and incubated for growth. Overall, 68 of the 216 devices tested ***(31.9 percent)*** were found ***not to be sterile.*** The reprocessed forceps in the studies tested positive for various types of bacteria and fungi, including staphylococcus aureus, coagulase negative staphylococcus, corynebacterium, sp., enterococcus faecium, micrococcus, sp., alpha hemolytic streptococci, bacillus, sp., bacillus cerus, acinetobacter, sp., pseudomonas putida, micrococcus luteus, staphylococcus epidermis, and gram positive rods and cocci.

Seventeen devices were also tested for residual debris. These devices were subjected to light microscopy, scanning electron microscopy and photoelectron spectroscopy. Of the 17 devices tested, 16 or 94.1 percent were found to have residual tissue.

The results of these studies are summarized in Table 1, shown on the following page.

Table 1: Results of Evaluation of Reprocessed Single-Use Biopsy Forceps

Investigating Laboratory	Study Date	Number of Devices Studied for Sterility	Percentage Found Not Sterile	Percentage With Residual Tissue
Viromed	May 1997	4	75 (3/4)	--
SterilLogics	October 1997	4	50 (2/4)	80 (4/5)
PMP – The Center for Testing of Medical Products	March 1999	14	64 (9/14)	100 (4/4)
PMP – The Center for Testing of Medical Products	March 1999	9	100 (9/9)	100 (8/8)
Viromed	July 1999	20	45 (9/20)	--
Viromed	September 1999	20	70 (14/20)	--
PMP – The Center for Testing of Medical Products	January 2000	7	14 (1/7)	--
PMP – The Center for Testing of Medical Products	January 2000	23	13 (3/23)	--
PMP – The Center for Testing of Medical Products	July-August 2000	115	16 (18/115)	--
TOTAL		**216**	**31.9 (68/216)**	**94.1 (16/17)**

These results are supported by other published studies. The Montclair Baptist Medical Center in Birmington, Alabama conducted an evaluation of the feasibility of reusing

reprocessed, single-use biopsy forceps and snares.[11] The study evaluated 23 biopsy forceps which underwent preliminary cleaning after use at the facility before shipment to an independent ISO 9002-certified reprocessor. The devices were cleaned, ethylene oxide sterilized using the Association for the Advancement of Medical Instrumentation guidelines for reprocessing reusable devices, and tested for sterility. Fourteen of the 20 devices tested for sterility (70%) were found to have microbial growth. According to the authors, "Despite a rigorous selection process and a thorough review of the quality-control techniques and validated processes of a licensed reprocessing facility, the single-use devices fell far below standards considered acceptable for reuse at our facility."[12]

Similarly, a study of reprocessed biopsy forceps by Heeg *et al.* concluded that "none of the reprocessed single-use instruments was suitable for use with subsequent patients."[13] Disinfection and sterilization of disposable devices failed to meet required levels. In addition, reprocessing procedures resulted in material changes which contribute to degradation and impaired function of the devices.[14]

These data demonstrate that existing reprocessing methods using common sterilization techniques do not reasonably assure the cleanliness or sterility of reprocessed,

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11 Hambrick, D. 3rd. "Reprocessing of Single Use Endoscopic Biopsy Forceps and Snares. One hospital's study," 24(3) Gastroenterol. Nurs. 112-5 (May – June 2001).

12 *Id.*

13 Heeg, P., *et al*, "Decontaminated Single-Use Devices: An Oxymoron that May be Placing Patients at Risk for Cross-Contamination," 22(9) Infect. Cont. and Hosp. Epidem. 542-49 (Sept. 2001).

14 *Id.*

single-use, non-electric biopsy forceps. As a result, these reprocessed devices present a significant risk of infection when reused.

D. Reprocessing Methods May Damage Single-Use, Non-Electric Biopsy Forceps and Cause Them To Malfunction

Reprocessed forceps also are likely to have a higher incidence of malfunctioning than single-use, non-electric biopsy forceps that are used only once. Sterilization methods used to reprocess the forceps can dull the sides of the collection jaws because the metal used in their manufacture was not selected to withstand reprocessing. If the jaws do not remain sharp, they will be unable properly to extract tissue samples from the body. The forceps' needles also can be dulled by sterilization methods. Dull needles will not properly anchor the forceps to the tissue sample and may not effectively attach to the sample for removal. Sterilization methods using heat and chemicals also may cause the plastic sheath to melt onto the wires inside the forceps and cause the collections jaws to malfunction. Additionally, reprocessing can have a deleterious effect on the lubricant placed on the device, impairing its function.[15] Finally, the attachment methods used to hold the single-use forceps together (i.e., the 'z-bend' and 'crimping'), while capable of withstanding a single use, are relatively delicate and not designed to withstand reprocessing.[16] Premarket review of these reprocessed devices is therefore required to provide reasonable assurance of their continued effectiveness.

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[15] *See* Heeg *et al.* (2001)

[16] Photographs of damaged, reprocessed single-use forceps are included in Attachment 2.

E. FDA Has Recognized that Reprocessed Biopsy Forceps Pose a High Degree of Risk to Patients

In February 2000, FDA published a draft guidance document setting forth its enforcement strategy for reprocessing and reusing single-use devices. [17] The draft Review Prioritization Scheme ("RPS") set forth a flow chart and questionnaire by which reviewers could determine the risk category of reprocessed single-use devices. FDA developed the risk categories to evaluate the "risk of disease transmission during reuse of a reprocessed [single-use device]."[18] The RPS evaluated the two types of risks that may arise as a result of the reprocessing and reuse of a single-use device: (1) the risk of infection; and (2) the risk of inadequate or unacceptable device performance. Based on these criteria, the RPS placed reprocessed single-use devices into low, moderate, or high overall risk categories. Those devices that posed the greatest risk of infection and that were most likely to malfunction after reprocessing were classified as "high risk." Using the RPS, FDA identified reprocessed, single-use, non-electric biopsy forceps as high risk devices.[19]

FDA subsequently decided to use established regulatory classifications for medical devices (Class I, II, or III) rather than the RPS risk categories as the basis for its enforcement strategy.[20] Nonetheless, FDA's risk categories remain a useful tool for identifying

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17 *See* FDA, "Draft Guidance for Industry and FDA Reviewers: Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" (February 8, 2000).

18 *Id.*

19 *Id.*

20 *See* FDA, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (August 14, 2000).

high risk devices. As FDA's own risk analysis demonstrates and the available data confirm, the safety and effectiveness of reprocessed, single-use biopsy forceps cannot reasonably be assured without premarket review of the reprocessing procedures for these devices.

F. Foreign Authorities and Health Care Professionals Have Recognized the Risk of Reprocessing Biopsy Forceps

The risks of reprocessing single-use devices generally and critical devices such as non-electric biopsy forceps, in particular, are well-recognized by foreign authorities and health care professionals. Several countries, including France, England and China, have banned the practice of reusing single-use devices. Notably, due to the risks associated with the reuse of biopsy forceps, France prohibits the reuse of all biopsy forceps, even those that are designed and intended for reuse, based on the conclusion that these devices cannot adequately be prepared for the next use.

As noted in the article by Hambrick, "the Society of Gastroenterology Nurses and Associates (SGNA) has recommended that . . . critical devices labeled for single-use not be reused."[21] In a letter to CDRH dated April 6, 2001, SGNA reiterated its concern regarding the designation of biopsy forceps as Class I exempt devices. Because biopsy forceps are "critical devices," intended to break the mucosal barrier, "SGNA believes that it is imperative that the reprocessing of biopsy forceps manufactured and labeled as single-use instruments, receive rigorous review by FDA."[22]

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21 *See* Hambrick (2001).

22 See SGNA's Letter to CDRH, dated April 6, 2001 in Attachment 3.

III. QUALITY SYSTEM REGULATIONS ALONE DO NOT ENSURE THE SAFETY AND EFFECTIVENESS OF REPROCESSED SINGLE USE NON-ELECTRIC BIOPSY FORCEPS.

In response to BSC's Citizen's Petition dated September 20, 2000, FDA declined to withdraw the exemption for reprocessed, single-use, non-electric biopsy forceps because the agency believed that "it is not the reprocessed status itself but a lack of sterility and a propensity for performance failure that [BSC] asserts present a risk requiring premarket submission."[23] This statement does not take into consideration the fact that existing reprocessing techniques do not provide adequate assurance of the sterility and effectiveness of the reprocessed forceps on a consistent basis. The data demonstrate that reprocessing is precisely what causes the "lack of sterility and a propensity for performance failure."

FDA stated that "when produced in compliance with general controls, particularly Quality System requirements, reprocessed biopsy forceps will attain proper sterility and performance..."[24] The Quality System Regulations (QSR) include "validating manufacturing processes..., instituting quality control over incoming products used to create marketed devices..., and using procedures to identify, evaluate, and control final product that does not meet specifications."[25] However, the QSR ensure the sterility and performance of biopsy forceps on a post-market basis only if FDA determined, on a premarket basis, that the proposed reprocessing procedures ensure the sterility of the device and do not impact its performance even

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23 Letter from Linda Kahan, Deputy Director for Regulations and Policy at CDRH, to Beatrice Biebuyck Regarding BSC's Citizen's Petition of September 20, 2000 (June 28, 2001).

24 *Id.*

25 *Id.*

though the device was designed and cleared for one use only. As demonstrated by the high rate of insterility in BSC's studies, and FDA's own OST data, existing procedures do not provide adequate assurance of safety.

Moreover, there is no "standardized" method or procedure for reprocessing single-use biopsy forceps and reprocessing companies all reprocess the devices differently. Indeed, reprocessors may use different methods for sterility testing and some of those claiming to have validation data indicating that they meet a sterility assurance level of 10^{-6}, test for sterility by evaluating the distal and proximal ends rather than the center of the device where the bacteria are harbored. Proper validation would require segmenting the device into small sections prior to sterility testing in accordance with United States Pharmacopoeia (USP) standards.[26]

FDA's reliance on QSR to ensure that patients do not face increased risk of infection or malfunctioning forceps is misplaced. Congress, in passing Section 302(b) of MDUFMA, recognized that reliance on post-market controls for reprocessed versions of exempt, single-use devices does not, in all cases, adequately protect patients. The QSR is designed and intended to be a post-market manufacturing control. It was never intended to supplant FDA's premarket review that is the cornerstone of FDA's mission to ensure that products are both safe and effective before they are used on patients. Indeed, in its Annual Report for Fiscal Year 1999,

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[26] Although prions, which cause spongiform encephalopathies such as Creutzfeld-Jakob disease, infect the central nervous system, it should be noted that traditional sterilization methods used to destroy bacterial and viral pathogens do not appear to destroy prions. As FDA has stated, "routine materials and processes that destroy traditional human and animal pathogens do not appear to destroy prions. Presently, no established methods can reliably decontaminate or sterilize articles contaminated with prions." FDA Action Plan: Transmissible Spongiform Encephalopathies including Bovine Spongiform Encephalopathy and Chronic Wasting Disease (April 24, 2001).

FDA reported that a study at Walter Reed Army Hospital of the reprocessing and reuse of single-use coronary catheters and endoscope accessories, including biopsy forceps, demonstrated model-specific cleaning and disinfection problems as well as varied effects of disinfection on performance characteristics. According to FDA, the "research [was] demonstrating that device-specific issues of reuse of single-use devices must be addressed on a model-by-model basis."[27] These issues can only be effectively addressed by a premarket review of the validation data and procedures. Postmarket enforcement of the QSR requirements – which presume the device is both safe and effective to enter the market place - is inadequate to ensure that sterility and performance testing is appropriate for a particular device.

IV. CONCLUSION

MDUFMA requires FDA to evaluate the exemptions from premarket notification requirements for all exempt, critical reprocessed single-use devices to determine whether to terminate those exemptions. Reprocessed, single-use, non-electric biopsy forceps are critical, reprocessed, single-use devices that present a high degree of risk to patients. The available data demonstrate that reliance on post-market controls alone for the reprocessing of single use non-electric biopsy forceps does not provide adequate assurance of the safety and effectiveness of these devices. Reprocessing methods are generally not adequate to ensure the sterility of these devices without damaging their structural integrity and effectiveness. Premarket review of reprocessed single-use forceps is essential to provide reasonable assurance of the devices'

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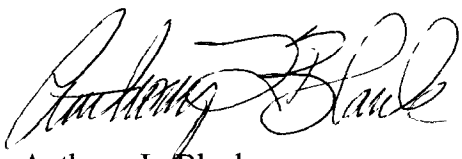
[27] FDA, "Annual Report Fiscal Year 1999" (November 30, 1999).

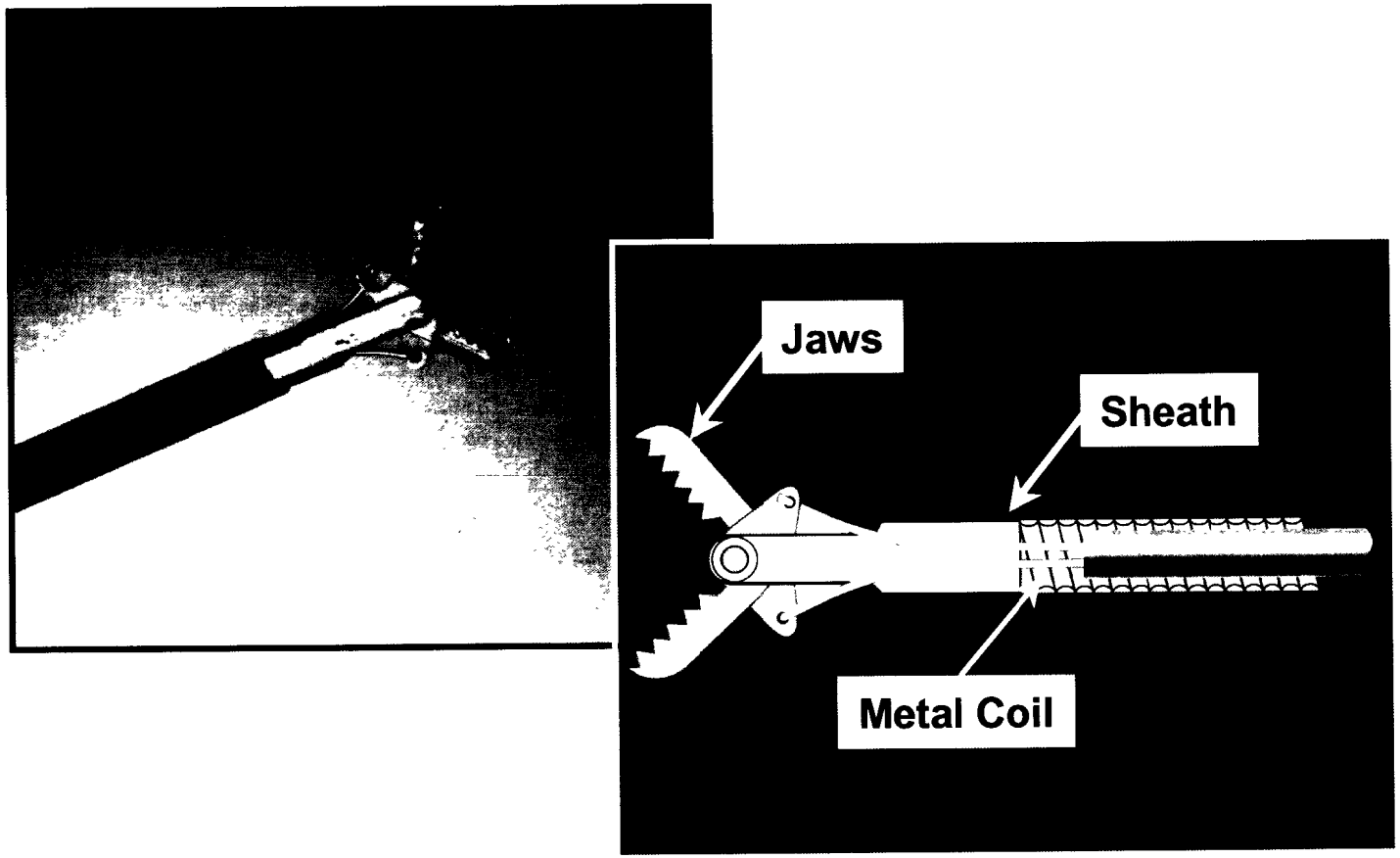
continued safety and effectiveness. Thus, MDUFMA requires that the exemption for reprocessed, single-use, non-electric biopsy forceps be terminated. As a result, BSC urges FDA to list reprocessed single-use non-electric biopsy forceps pursuant to Section 301(b)(2) of MDUFMA.

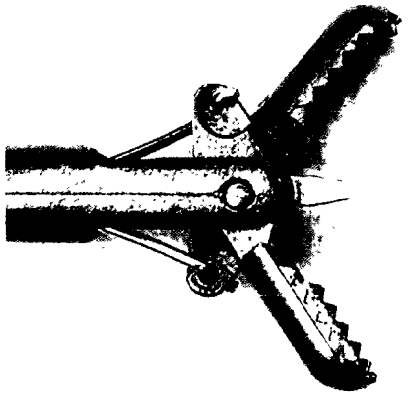
Respectfully submitted,



Anthony L. Blank
Manager, Corporate Regulatory Affairs

cc (by email): Timothy A. Ulatowski





Single-Use Biopsy Forceps

Photograph of Damag
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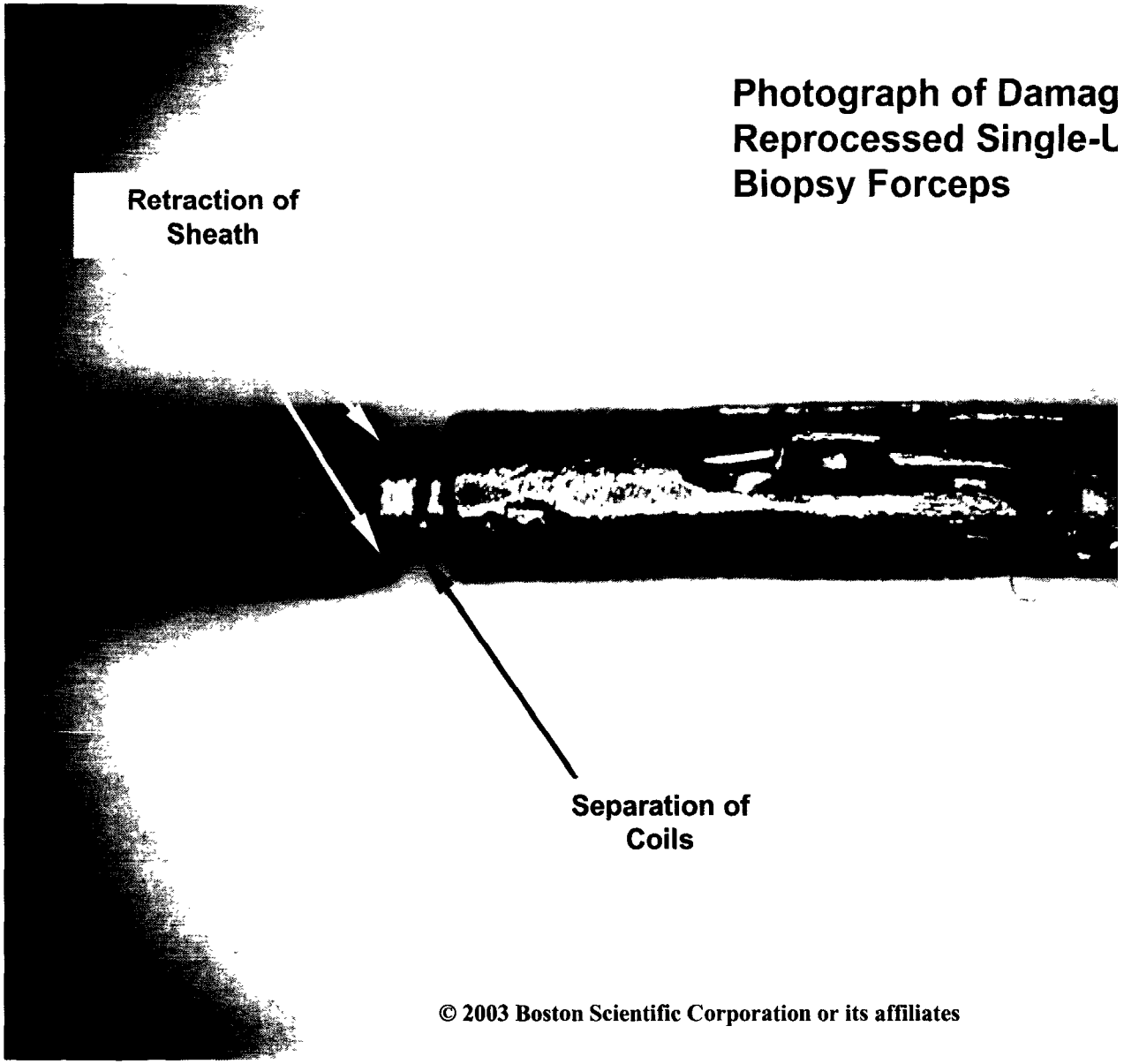
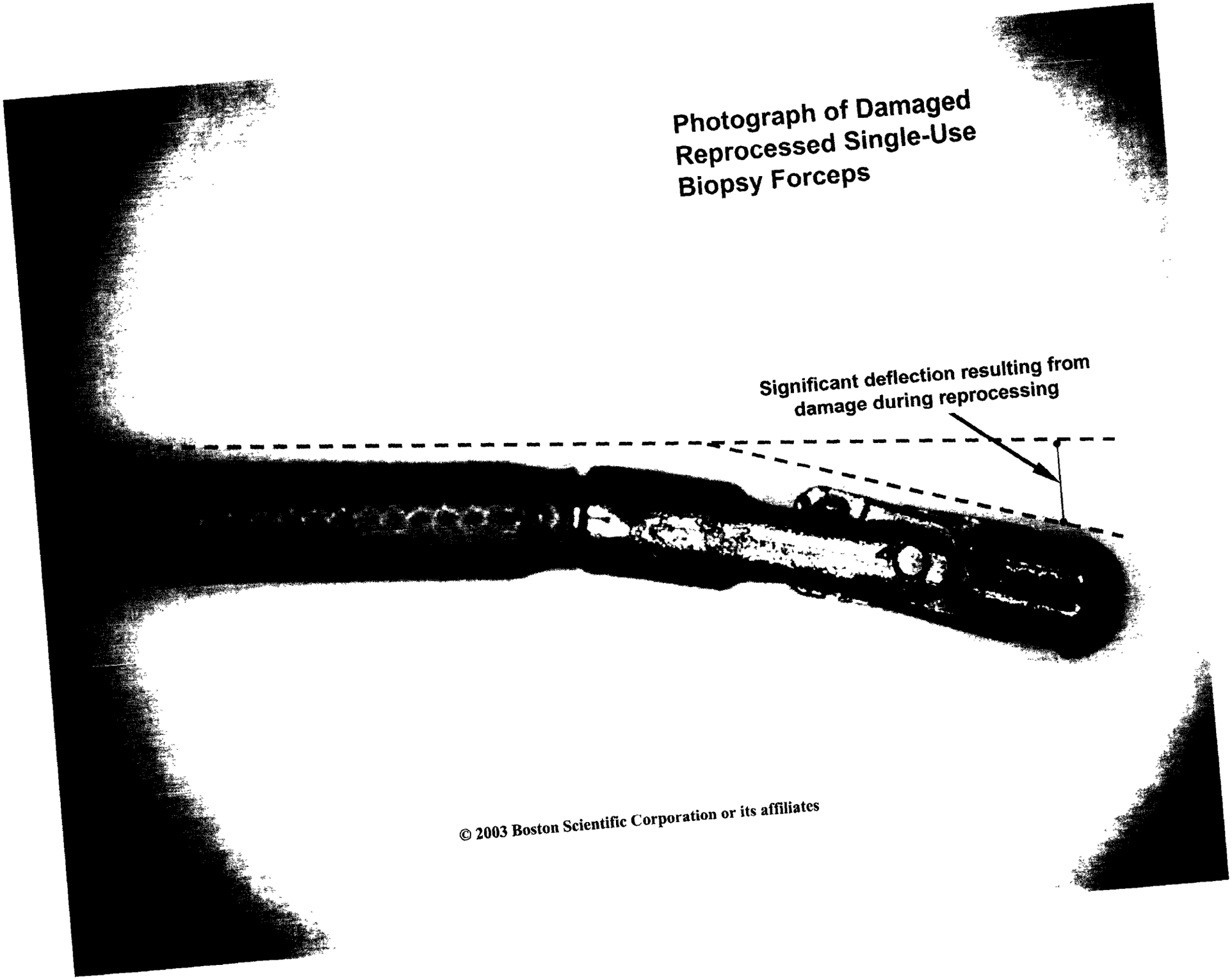


Photograph of Damaged Reprocessed Single-Use Biopsy Forceps



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6 April 2001

Larry D. Spears, Acting Director
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Dear Mr. Spears,

The Society of Gastroenterology Nurses and Associates, Inc. (SGNA) has closely followed the issue of reuse of single use medical devices and the FDA's strategy to oversee reprocessing of these devices. SGNA has sent representatives to several FDA-sponsored meetings and formally responded to the agency's draft guidelines during the comment period.

SGNA voiced support for the classification system proposed in the draft document. However, we strongly disagree with the decision to abandon the original classification of single-use devices according to the risk of infection. Public safety is not protected when gastroenterology accessories cannot be adequately reprocessed or fail to perform acceptably as a result of the rigors of reprocessing.

Gastrointestinal endoscopy units have been targeted by third party reprocessors for the past several years. Yet under the classification system adopted in the final regulations, most gastroenterology accessories are designated Class II, and will not be subject to regulation until August 2001 or later.

Of particular concern to SGNA is the designation of biopsy forceps as Class I exempt. We urge the FDA to rethink this classification of biopsy forceps. This particular device is intended to break the mucosal barrier and thus falls into the Spaulding Classification as a critical device. Any endoscopy nurse can attest to the difficulty of cleaning biopsy forceps, even those that have 510(k) clearance as reusable devices. SGNA believes that it is imperative that the reprocessing of biopsy forceps manufactured and labeled as single use instruments receive rigorous review by the FDA. Reprocessors must provide data demonstrating the efficacy of cleaning and sterilization of biopsy forceps and verify their functionality before allowing these devices back into the marketplace. In the absence of such guidance and direction, SGNA will advise members not to reuse critical devices manufactured and labeled for single use.

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SGNA is further concerned about the FDA's decision not to extend its oversight into reprocessing of single use devices by ambulatory care centers and physicians' offices. This sets the stage for a dual standard of care that will put at risk patients receiving care in these settings versus the hospital setting. While we are mindful of the FDA's budget constraints, we are also cognizant of its mandate to protect the public health.

On behalf of its membership, which includes professional nurses, citizens and constituents, the Society of Gastroenterology Nurses and Associates urges the FDA to take these concerns into consideration in a timely manner. We ask that the FDA act to revise its Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals accordingly.

Sincerely,

Nancy Schlossberg, BA BSN RN CGRN
SGNA President

Sallie Walker, BA RN CGRN
Chair, SGNA Practice Committee

Enclosure: SGNA Position Statement, Reuse of Single Use Critical Medical Devices, 2001