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#### NASPE's Mission Statement

The mission of the North American Society of Pacing and Electrophysiology, an organization of physicians, scientists, and allied professionals throughout the world dedicated to the study and management of cardiac arrhythmias, is to improve the care of patients by promoting research, education and training, and providing leadership toward optimal healthcare policies and standards.

#### Executive Director

Carol J. McGlinchey

April 10, 2000

Docket No. 00D-0053

Dockets Management Branch

Division of Management Systems and Policy

Office of Human Resources and Management Services

Food and Drug Administration

5630 Fishers Lane

Room 1061, (HFA-305)

Rockville, MD 20852

### RE: Docket No. 00D-0053 "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals"

The North American Society of Pacing and Electrophysiology (NASPE) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on its "*Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme*" and the "*Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*" published on February 11, 2000 in the *Federal Register* (65 Fed Reg 7027).

NASPE is a not-for-profit professional organization of physicians, scientists, and allied health professionals expert in the study and management of cardiac rhythm disorders. Patients with cardiac arrhythmias are generally referred by primary care physicians and cardiologists to specialists in pacing and electrophysiology. NASPE members are the primary medical sub-specialty performing electrophysiology studies and cardiac ablations using electrophysiology recording and ablation catheters. Our comments focus exclusively on the reprocessing of electrophysiology recording catheters and cardiac ablation catheters as listed in FDA's List of Frequently Reprocessed Single-Use Devices (Appendix 2).

NASPE's primary goal is to promote optimal patient care, research, and education in the field of cardiac arrhythmias. NASPE members perform complex electrophysiology and pacing procedures on patients to improve their quality of life and in many cases, preserve patient's lives. NASPE's interest in the medical device reprocessing and re-use issue predates the current controversy and reflects our ongoing interest in ensuring patient safety and the promotion of quality cardiovascular care for patients.

Electrophysiologists have been performing electrophysiology studies and ablation procedures for over twenty and ten years respectively. During this time, complications arising from the use of a reprocessed catheter have not been identified with the procedure. NASPE has previously submitted to the FDA previously published clinical studies which indicate that, if resterilized appropriately, electrophysiology catheters can be reprocessed and re-used without

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compromising patient safety. NASPE realizes that "resterilized appropriately" is the key phrase and we support the FDA's efforts to provide regulatory oversight to ensure that electrophysiology catheters are reprocessed to a level that can assure sterility and functionality. However, NASPE would like to re-emphasize that to date, problems associated with inadequate electrophysiology reprocessing and reuse are extremely rare, and in fact, has not appeared in peer-reviewed medical literature.

We also understand that the hospital control professionals at the U.S. Centers for Disease Control and Prevention do not recognize this issue as a public health problem at this time. The CDC is regarded as the nation's preeminent body of expertise in the field of sterilization, disinfection and surveillance of hospital acquired infections. It is important to emphasize that despite the focus on public health issues stemming from hospital acquired infections, the reprocessing of electrophysiology catheters has not been identified as a cause of infection.

NASPE utilized the FDA's draft guidance document and flowcharts to evaluate electrophysiology recording catheters and the cardiac ablation catheters. After careful consideration and review, NASPE recommends that FDA move electrophysiology recording catheters and cardiac ablation catheters from the high risk category to the moderate risk category. In general, we have responded to the FDA questions and responses where NASPE disagrees with FDA's analysis or if the FDA did not respond at all to the question posed.

#### ***I. Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme***

##### **Purpose**

FDA states that the "risk of infection and risk of inadequate performance following reprocessing" are the primary criteria in evaluating a device's level of risk. This policy was developed in response to the concern that a device's performance, safety, specifications, or intended use might be compromised during reprocessing procedures. NASPE would like to emphasize that there are no documented cases demonstrating reprocessed electrophysiology catheters increase a patient's risk of infection, nor is there evidence that any adverse patient outcomes are increased when the use of reprocessed catheters is compared to single use catheters. Conversely, there is scientific evidence, published in peer reviewed medical literature, that the use of reprocessed electrophysiology catheters is safe and cost-effective. Moreover, the hypothetical risks associated with the use of reprocessed catheters are so low that they become insignificant relative to the inherent risks of the procedure.

Medical Device Reports (MDRs) submitted to the FDA contain information about three cases involving EP catheter malfunction. One case involved a reprocessed catheter. The other two occurred with new single-use catheters. It is appropriate

to emphasize that despite the reuse of hundreds of thousands of catheters, only one MDR report has been submitted to the FDA that involved a reused catheter.

**General Approach:**

**Flow Chart 1 - Evaluating the Risk of Infection:**

**Question 2: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of a SUD that has not been reprocessed?**

FDA's response to this question is appropriate for Cardiac Ablation Catheters and EP recording catheters as stated; "At this time, FDA does not know of any postmarket data on cardiac ablation catheters that may suggest that using the reprocessed catheter may present an increased risk of infection compared to the use of a catheter that has not been reprocessed".

**Question 3: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?**

The FDA states that cardiac ablation catheters have features that could impede thorough cleaning and adequate sterilization. NASPE disagrees with this assumption. The experience of more than twenty years of reprocessing standard non-luminal electrophysiology catheters is that they are not difficult to clean when accepted methods are employed. The focus of FDA's regulatory efforts should be to establish standards to assure that all reprocessing is done uniformly and with the same level of quality control.

**Flow Chart 2: Inadequate Performance Risk**

The other FDA major concern with reprocessing is the risk of inadequate performance during reuse of a reprocessed SUD.

**Question 1: Does postmarket information suggest that using the reprocessed Single Use Device (SUD) may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?**

FDA states that "Significant postmarket data (published literature) exists that suggest that the reprocessed cardiac ablation catheter may present an increased risk of patient injury."

NASPE disagrees with this response and the FDA's interpretation of the medical literature. Each of the peer reviewed publications concluded that diagnostic and ablation catheters could be safely reused provided that they are carefully inspected and tested after each use. The literature does raise concern about the level of ethylene oxide residuals that depends on the duration of aeration, but this

can be resolved through appropriate quality control standards. Reprocessors must confirm that their methods reduce ethylene oxide residuals to levels that meet FDA guidelines. NASPE also recognizes that some catheter designs differ from those previously studied and that major changes in catheter design require further study to demonstrate that they can be safely reprocessed.

The correct answer to this question is post market studies have found no increased risk of injury. In that case, one would proceed through the FDA's proposed flowchart and answer the following questions. A summary of the published literature is attached as an appendix.

**Question 2: Could failure of the device cause death, serious injury, or permanent impairment?**

It is extremely unlikely that a reprocessed catheter that has been properly tested and inspected would increase the risk for death, serious injury or permanent impairment. This has never been reported despite a wide body of medical literature and thousands of abstracts presented at the scientific sessions of the American Heart Association, American College of Cardiology, and North American Society of Pacing and Electrophysiology. The most common problems with new or reprocessed catheters are related to suboptimal deflection characteristics that affect the maneuverability of the catheter. Difficulty with pacing or recording is rare and immediately apparent. In these cases, the physician simply exchanges the catheter without risk to the patient.

There are occasions when brand new catheters do not function properly. If after visual inspection, the new or reprocessed catheter seems to be functioning normally, and then a problem becomes evident during the procedure the following would occur. During an EP study, a recording catheter would not be able to record the electrical signal adequately; however, this would not result in death, serious injury or permanent impairment. For a cardiac ablation catheter, if the new or reprocessed catheter did not function properly (such as a failure of the distal end to properly flex or deflect) after visual inspection indicated it did, then the ablation catheter would be exchanged during the procedure for a different catheter. There is no increased risk of death or serious injury in these instances.

**Question 2a: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?**

There are no recognized consensus performance standards that could be used to determine if the performance of electrophysiology catheters or cardiac ablation catheters are functioning properly after reprocessing. NASPE would like to offer

the expertise of its members in working with the FDA, original equipment manufacturers and reproducers to establish these standards.

**Question 2b: Can visual inspection determine if performance has been affected?**

According to the FDA guidance document, “if visual, critical failure of the device may be self-evident before or during use of the device and measures can then be implemented to correct the failure” then risk of inadequate performance is low.

At times, the inner wire to deflect the catheter tip may not work properly and this will effect catheter function. However, if the catheter tip does not deflect properly after the catheter is removed from its packaging, it is usually discovered before being placed in the patient. There are some occasions when the catheter is placed in the patient and the inner wire fails to work at that time. In these cases, the electrophysiologist removes the catheter through the indwelling sheath and a new catheter is placed through the sheath. This is commonly done when the initial ablation catheter chosen does not reach its intended target because of the patient’s anatomy. In this situation, the second ablation catheter with a different configuration is used in place of the original catheter to achieve a successful result.

Based on NASPE’s revised answers to the questions posed by the FDA regarding sterility and functionality, electrophysiology recording catheters and ablation catheters are more appropriately categorized as moderate risk. A detailed description of electrophysiology procedures follows:

***Electrophysiology Procedures***

Clinical cardiac EP studies are performed to diagnose and treat abnormal heart rhythms referred to as arrhythmias. Typically, three to six catheters are used during these procedures. Each catheter incorporates four to 20 platinum electrodes to record electrical signals or pace the heart. The standard EP catheters are solid nonluminal designs, which means they do not have a hollow inner core. Some catheters have special mechanisms used to deflect the tip to help guide the catheter to a specific target. Catheters with these deflection mechanisms are often used to deliver radiofrequency energy – a high frequency electrical current – to destroy a small amount of tissue on the lining of the heart that has been identified as the cause of a patient’s abnormal heart rhythm. This curative technique is referred to as an arrhythmia ablation procedure.

The first EP procedures were performed more than 30 years ago. The early experience showed that EP catheters were quite durable and could be sterilized for reuse, as has been the practice for many surgical instruments. The obvious motives were to reduce cost and eliminate the waste of catheters that could be reused without compromising patient safety. The physicians who perform these

studies have no direct or indirect personal financial incentives to reuse catheters, and there are ethical, medical, and legal reasons to avoid any practices that would add material risk to EP studies.

Arrhythmia ablation procedures typically take three to ten hours to perform. In order to advance the EP catheters to the heart, tube-like sheaths are inserted into the arteries and veins to provide vascular access for EP catheters. The catheters are then inserted through the sheaths and advanced to the heart. The sheaths allow cardiovascular specialists to remove, exchange, or reinsert the EP catheters as needed during the procedure. Sometimes catheters – new or reprocessed – must be exchanged because they do not have the necessary configuration to reach a specific target in the heart, or because they have become less maneuverable during the course of the procedure. Sometimes several catheters are tried during a procedure before the optimal catheter is identified. Reprocessing allows the flexibility to use several catheters during an EP study safely and free of fiscal concerns.

In some cases, the catheter is easily positioned at the target site and is subjected to very little manipulation. In more difficult cases, a catheter may be removed and reinserted several times during the course of a procedure and is subjected to considerably more stress when extensive efforts are required to reach the target. Because the stresses that can be imposed on an individual catheter can vary considerably during a study, EP catheters are manufactured to be very durable. It is their durability which makes them suitable to reprocess. Regardless of the amount of stress imposed on a catheter during a study, each one is carefully evaluated by the reprocessor to determine whether it is suitable for reuse.

## ***II. Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals***

FDA has used its enforcement discretion not to enforce premarket review requirements against third-party reproprocessors and will continue to use the same enforcement discretion to "phase in" the enforcement of premarket review requirements against third-party reproprocessors and hospitals. It is important to note that the reason for this approach is precisely because FDA has not found sufficient evidence to suggest that reprocessing, absent FDA premarket review, presents a threat to public health.

### **D. Why is FDA phasing in the enforcement of regulatory requirements for SUD reproprocessors?**

The FDA states in its *Enforcement Priorities* document that, "Within 6 months of issuance of final guidance if the reprocessed device is categorized as high risk, within twelve (12) months if the device is categorized as moderate risk, and within eighteen (18) months if the device is categorized as low risk. Although

FDA has not previously enforced premarket requirements for third party reproprocessors, FDA currently enforces all other requirements applicable to manufacturers (such as registration, adverse event reporting, and quality system regulations) against third party reproprocessors. The issuance of this draft or any final guidance will not change the continuing obligation of third party reproprocessors to comply with those provisions of the Act. However, FDA would not enforce these requirements for hospitals until six (6) months from the issuance of a final guidance document.”

NASPE commends the FDA for establishing a phased in approach and recognizing the value in allowing hospitals a longer phase in period. However, the phased approach should begin 12 months, as opposed to 6 months after FDA’s guidance is finalized. The FDA has a regulatory history in establishing gradual phase in periods. In the case of reprocessing electrophysiology catheters, hospitals and commercial reproprocessors already meet previously established regulatory standards, and there is no evidence that the public welfare has been harmed by these standards.

As the FDA clearly states in its guidance document, “nothing in this guidance precludes FDA from taking immediate action against any particular product that is causing harm”. In that case, there does not appear to be a public health need for such a rapid implementation schedule, and if one arises, FDA already has the regulatory authority to speed up the implementation schedule.

**Labeling (Section 502 of the Act; 21 CFR Part 801**

NASPE urges the FDA to examine the original equipment manufacturers (OEM’s) justification for using the single-use label on medical devices. NASPE understands that this is a relatively recent development by the OEM’s and may be used arbitrarily at the OEM’s discretion for financial reasons.

**Premarket Requirements (Sections 513 and 515 of the Act; 21 CFR Parts 807 and 814**

NASPE would like to work with the FDA as it establishes these requirements for electrophysiology recording catheters and cardiac ablation catheters. NASPE members are the primary physicians who use these catheters on a daily basis and are the most familiar, besides the OEM’s, on these devices functionality and medical utility. According to NASPE’s analysis within FDA’s proposed regulatory framework, electrophysiology recording catheters and cardiac ablation catheters would not require a Pre-Market Approval (PMA) application but may require a 510K application.

**Additional Comments**

Medicare Reimbursement: The FDA is silent in the proposed regulatory guidance on the issue of Medicare reimbursement for reprocessed medical devices.

Although NASPE realizes that the Health Care Financing Administration (HCFA) is responsible for establishing and enforcing Medicare reimbursement policies for medical procedures, NASPE strongly encourages the FDA to work with HCFA to issue a clarifying statement regarding reimbursement for procedures involving reprocessed devices. In particular, it is important that FDA provide a safety-related rationale for its historical and ongoing use of "enforcement discretion" with respect to premarket review requirements. NASPE would like the FDA to note in its guidance documents that the FDA has not found sufficient evidence to suggest that reprocessing, absent FDA premarket review, presents a threat to public health.

**Conclusion:** NASPE's foremost priority is to support policies that optimize the care of patients. In accordance with this mission, NASPE recognizes the need for the FDA to provide regulatory oversight to ensure that uniform quality control standards are applied when electrophysiology catheters are reprocessed so that the public welfare is protected. NASPE recommends that the FDA revise its guidance documents to reflect our comments and suggestions. In particular, NASPE believes that electrophysiology catheters constitute an intermediate level of risk for reprocessors when appropriate safeguards and standards are implemented.

Electrophysiologists have been using reprocessed electrophysiology recording catheters and cardiac ablation catheters for many years with no documented evidence of adverse patient outcomes. NASPE encourages the FDA to work with NASPE physicians to evaluate the infection and functionality risks of electrophysiology catheters. NASPE recommends that FDA revise its guidance documents to reflect our comments related to the infection risk and inadequate performance risk of electrophysiology recording catheter and cardiac ablation catheters and move them to the moderate risk category.

NASPE looks forward to working with the FDA as it seeks to finalize the proposed regulatory guidance documents *Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme* and the *"Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals"*. My NASPE colleagues and I would be happy to meet with you to discuss these issues further. Please contact Amy Melnick, Director, Government Relations at 202-416-1871 or [amelnick@naspe.org](mailto:amelnick@naspe.org) if you have any questions about our comments or would like to arrange a meeting with NASPE members expert in this area.

Sincerely,

  
Gerald V. Naccarelli, MD

President

North American Society of Pacing and  
Electrophysiology (NASPE)

## APPENDIX 1

### *NASPE Summary and Review of Published Clinical Studies on the Reprocessing of Electrophysiology Catheters*

There are studies, all of which have been published in peer-reviewed scientific medical journals, which have evaluated the safety of reusing catheters for EP studies. All have found no evidence that the sterility of reprocessed catheters is a concern or that the incidence of infection is increased. The results of four clinical studies are summarized:

1. The results of a study of 12 medical centers were published in the medical journal *Pacing and Clinical Electrophysiology* in 1988. The study looked at the safety of reusing catheters. The incidence of infection related to a total of 14,640 EP procedures involving 48,075 catheter uses was reported. At three centers, catheters were automatically discarded after a single use. These centers carried out 1,245 EP procedures using 3,125 catheters. At the other nine centers, catheters were sterilized for reuse. There were 13,395 procedures using 44,950 catheters in the reuse group. The incidence of bacteremia (blood borne infection) and superficial skin infection at the site of catheter insertion is shown below.

Table 1: Incidence of Infection During EP Studies.

Group	Bacteremia	Superficial Skin
Single Use Catheters 1,245 studies 3,125 catheters	1 (0.03%)	1 (0.03%)
Reused Catheters 13,395 studies 44,950 catheters	8 (0.018%)	1 (0.002%)

The authors of the study concluded that sterilization and reuse of the catheters employed in this study did not result in any increase in the risk of infection. They felt the catheters were sufficiently durable to be reused well in excess of five times, and that one-time use of such catheters appeared to be a medically unnecessary and expensive policy to adopt.

2. Similar results in a prospective study were published in the *Journal of the American College of Cardiology* in 1987. The study evaluated catheter reuse over a five-year period during which 178 catheters were used 1,576 times for 847 EP procedures. Detailed records of catheter testing and use were maintained. No complications were encountered during the study period. All reused catheters functioned for cardiac pacing and recording of cardiac electrical signals. Surveillance cultures and biologic indicators revealed that adequate sterilization procedures were used. The authors concluded that EP catheters may be safely

reused provided a thorough cleaning, testing and record-keeping system is instituted. They also concluded that the practice of reusing catheters would result in substantial cost savings to hospitals.

3. The studies mentioned above were conducted in patients undergoing diagnostic EP studies before the advent of deflectable catheters and arrhythmia ablation procedures. A study published in the *Journal of the American College of Cardiology* in 1993 prospectively investigated the time course of electrical, physical and mechanical changes in ablation catheters to determine the affect of reuse on safety and efficacy. The study included 69 ablation catheters made by a single manufacturer that were used in 336 procedures. Testing of physical integrity consisted of visual and stereoscopic (X30 magnification) examination of handle function, catheter shaft and the deflectable tip. Specific attention was paid to the ablation electrode attachment to the catheter shaft, and the ablation tip electrode was scrutinized for pitting. The electrical integrity of the catheters was measured by electrical resistance from the handle connector to the recording rings and to the tip electrode. Deflection and torque measurements were made to assess mechanical integrity.

During the course of this study 36 catheters (52 percent) were rejected at some point because of mechanical or electrical failure. Eighteen catheters were repeatedly sterilized and eleven of the catheters were used 10 or more times. The most common reasons for catheter rejection were tip electrode glue separation after an average of 4.3 uses and loss of deflection after an average of five uses. Electrical discontinuity was observed after an average of 10 uses. There was no significant decrease in catheter torquing ability that determines the steering responsiveness of the catheter. The medical records of 140 patients who had arrhythmia ablation procedures in this study revealed only one case (0.7 percent) of local infection at the insertion site that was treated effectively by antibiotics. There were no other complications.

The authors of the study concluded that the catheter model used in this study could be reused an average of five times. They recommended that after each use catheters be carefully examined under magnification with special attention to the tip electrode. They also recommended that the catheters be tested for deflection and electrical integrity after each use.

4. Another study published in the *American Journal of Cardiology* in 1994 looked at the effects of reprocessing on mechanical integrity, sterility, and chemical residuals. The study was part of an internal quality review process conducted by a hospital to establish and validate an institutional policy for reuse. A total of 12 commercially available catheters from two manufacturers were analyzed. Eleven of the catheters were randomly selected from the catheter inventory of the clinical EP laboratory after being used one to four times. They were manually cleaned, repackaged, and gas sterilized with ethylene oxide. To

assess the sterility of reused catheters, three were cut into two-inch segments, placed in bacterial culture media, and incubated for five days. Six of the catheters were analyzed for chemical residuals after gas sterilization. Two catheters were examined for evidence of component failure. Visual inspection and microscopy were used to determine mechanical integrity of the catheter surface, and x-ray inspection was performed to assess interior structures.

The results showed no bacterial growth detected on any of the cultures, which indicated that reprocessed EP catheters are effectively sterilized. The chemical analysis demonstrated that the concentrations of ethylene oxide detected in extraction liquid exceeded standards established by the FDA. Microscopic examination of reprocessed catheters demonstrated inconsequential metal and fiber particulates on the catheter surface and at some electrode-catheter interfaces. The shaft of the catheters and the electrodes remained intact. There was no evidence of electrical discontinuity, and the integrity of internal structures was confirmed by x-ray inspection.

The authors concluded that, with sterilization techniques frequently used by hospitals, the potential for chemical residual contamination might exist after sterilization with ethylene oxide. Based on these results the hospital changed its policy to single use. It should be noted that the hospital subsequently resumed multiple use of catheters that were reprocessed by a commercial vendor whose chemical residuals after reprocessing met FDA standards.

**INASP**

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