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Boston Scientific Corporation

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 Date: 11/23/99  
 Number of pages including cover sheet: 25

To: Mr. Larry Spears

Re: Reprocessing of Single-Use  
Cannulotomes Data

Phone:

Fax phone:

CC:

From: Phil Coghill

Phone:

Fax phone:

REMARKS:  Urgent  For your review  Reply ASAP  Please comment

One Boston Scientific Place, MS A7  
Natick, MA 01760-1537

Phone: 508-650-8137  
FAX: 508-650-8935

# Boston Scientific

November 23, 1999

Mr. Larry Spears  
Food and Drug Administration  
Office of Compliance  
2094 Gaither Rd.  
Rockville MD 20850

VIA FAX: 301-594-4672

Dear Mr. Spears:

As a follow-up to our telephone discussion, I talked with Dr. Michelle Alpha of Saint Basile General Hospital in Canada yesterday. She has very similar data on "The reprocessing of patient used cannulatomes" (Attached), which is being processed in the German Journal Central Sterilization in the near future. She said I can share the draft article with you and that the published article would only differ editorially, not scientifically.

I believe this information is supportive of the data I have provided you, because it uses the same microbiological recovery methods and sterility testing procedures, and obtains similar microorganisms. Dr. Alpha had not registered for the Dec. 14th meeting, but I encouraged her to register and to request a speaking slot.

Sincerely,



C. Philip Cogdill  
Director of Corporate Sterilization and Microbiology

**PROCESS VALIDATION FOR REPROCESSING OF PATIENT-USED CANNULATOMES**

**Michelle J. Alfa**

**St. Boniface Research Centre  
Winnipeg, Manitoba  
Canada**

## **Introduction:**

Flexible endoscopic procedures for the gastrointestinal tract have radically changed how many diagnostic and surgical procedures are performed. The significant reduction in infection rates using endoscopic procedures versus routine surgical procedures has made this a popular and ever expanding approach for gastrointestinal (GI) disease. Accessories for the GI endoscopic procedures have likewise expanded over the years. In particular development of accessory medical devices for endoscopic retrograde cholangio-pancreatography (ERCP) procedures has greatly expanded. These devices may be reusable medical devices (eg biopsy forceps) or they may be single-use disposable medical devices. The design of these devices is constrained by the dimensions of the lumen of the endoscope as the ERCP accessories must thread down this endoscope channel. Often the small lumen diameter and long length makes cleaning of such complex endoscopic accessory devices extremely difficult.

Fiscal constraints are prompting many centres to consider reprocessing of devices that were purchased as single-use medical devices (eg ERCP cannulatomes, ERCP balloon catheters etc). There is a great deal of controversy regarding adequate labelling, cleaning and sterilization of those medical devices that have been used in patients and hence are soiled (as opposed to devices that have an expired sterilization date, or devices that were opened but were not used and require re-sterilization). One major aspect that is critical to undertaking reprocessing of such soiled patient-used devices is

whether the cleaning and sterilization processes that are used by the centre can be "process validated". The goal of such validation is not to assess the sterility of each reprocessed device, but rather to demonstrate quantitatively that the process to be used can be expected to reliably remove patient soil and adequately kill any microorganisms that may be present. This basic documentation is necessary to ensure that the reprocessed single-use medical devices are patient-safe after reprocessing. The issue of reuse of single-use medical devices is a multifaceted problem requiring validation from many aspects including: ethical, legal, device integrity, risk of infection, and economic (3,4,7,10). Despite these multiple areas of concern, it is estimated that approximately 41% of Canadian centres had reused single-use devices in 1986 (10). One representative type of single-use ERCP accessory that is frequently re-processed is the ERCP cannulotome. The objective of this study was to determine if it was possible to validate a cleaning/sterilization process that could reliably provide sterile ERCP cannulotomes that were marketed as single-use devices and had been patient-used.

### **Materials and Methods:**

#### **Simulated-Use Cannulotome Inoculation Method:**

Papillotome knives (referred to in this document as cannulotomes) were the single-use medical devices that were evaluated. Both new, unused cannulotomes (Wilson-Cook Medical Inc., Winston-Salem, NC) as well as patient-used cannulotomes were utilized in this study. The cannulotomes that had been used for ERCP procedures were provided from three centres including the Health Sciences Centre, and St Boniface Centre in

Winnipeg Manitoba, as well as the Brandon General Hospital in Brandon, Manitoba. Both monofilament and braided filament cannulatomes of various knife-wire lengths were included in the evaluation.

The test organisms included *Bacillus subtilis* (spore suspension; ATCC 9372, from Presque Isle Cultures, Erie, Pa), and *Enterococcus faecalis* (ATCC 29212). The test soil was an artificial endoscope soil (AES) formulated to have the protein, sodium ion, carbohydrate and hemoglobin levels consistent with "worst-case" soil levels found in patient-used endoscopes (2). The simulated-use inoculation of the cannulatome was done by suspending the test organism in AES to a final concentration of  $10^7$  to  $10^8$  cfu/ml and injecting 2 mls of the inoculum fluid through the lumen of the cannulatome. The excess inoculum fluid was allowed to drain from the lumen and the inoculated cannulatome was allowed to sit at room temperature for 30 minutes. The lumen was then rinsed with 10 mls of water, and the cannulatome was connected to the ViraPump2 (Viatro Corp., Cleveland OH) via tubing with Luer lock connectors. The pump circulates fluid through the tubing and into the lumen of the cannulatome. The cannulatome was immersed in detergent and the detergent solution was circulated through the lumen for 15 minutes at room temperature, followed by immersion in water which was circulated through the lumen for 5-10 minutes at room temperature. The cannulatome was then dried using a vacuum source for 10 minutes. Each cannulatome was packaged in peel pouch wrap and sterilized using a Sterivac 5XL 100% ethylene oxide sterilizer (3M, Minneapolis, Minn). The details of the three different cleaning/sterilization methods

from patient material, or organisms introduced during the cleaning/rinsing procedure. The three reprocessing methods used for patient-used cannulatomes have been summarized in Table 1.

#### **Soil Determinations for patient-used cannulatomes:**

To determine the level of viable bacteria and various soil parameters on patient-used cannulatomes, samples were collected immediately after patient-use by flushing 5 ml of sterile water through the lumen of the cannulotome. This sample was then evaluated for cfu/ml using the spread plate technique, and the levels of protein, bilirubin, hemoglobin, sodium ion, carbohydrate and endotoxin were determined as previously described (1).

#### **Ethylene Oxide Off-Gassing Testing of Reprocessed Cannulatomes:**

The Gastec sampler and Gastec detector tube #163L (Gastec Corporation, Fukaya, Japan) were used in conjunction with the Gastec multi-stroke gas sampling pump to detect residual ETO from reprocessed cannulatomes. Sampling of ETO was done by opening the peel pouch containing the cannulotome and placing the detector tube at the suction channel opening of the cannulotome and measuring two pump strokes (200 ml of air sampled). The readings were corrected for temperature according to the manufacturer's instructions. The accuracy tolerance is  $\pm 25\%$  at 1, 2 and 3 times the threshold limit value (TLV).

### **Residual Testing of Reprocessed Cannulatomes:**

To determine if there was any residual toxic material on reprocessed patient-used cannulatomes, five patient-used reprocessed cannulatomes reprocessed by Study Method 3, were sampled by passing 2 mls of endotoxin free water through the lumen. These samples were tested for cytotoxicity by inoculating 25  $\mu$ l of each sample onto a well of a 96-well tissue culture tray containing Human Foreskin Fibroblast cells and incubating the inoculated monolayer for 5 days to assess whether any cytotoxic effect was evident. In addition the samples were evaluated for the presence of hemoglobin, protein, sodium ion, carbohydrate and endotoxin as previously described (1).

### **RESULTS:**

To determine if the current manual cleaning and ETO sterilization procedures used by the hospitals was adequate, braided and monofilament cannulatomes (not inoculated with any simulated use test organisms) were assessed for sterility only after patient-use (Table 2). It was apparent that the reprocessing procedures used by the hospitals for reprocessing cannulatomes were not adequate to ensure sterility of the cannulatomes.

To determine the level of soil and viable bacteria in patient-used cannulatomes, samples were collected from 7 patient-used (one use only) cannulatomes (Table 3). It is apparent that the average viable bacterial count remaining in a cannulotome after exposure to a patient's gastrointestinal tract is relatively low (range; < limit of detect to  $-5 \times 10^3$  cfu/device). Likewise, the protein bilirubin, Na<sup>+</sup>, LPS and carbohydrate were not

excessive compared to those that are found in patient-used flexible endoscopes (2). This suggests that if the single-use device is kept moist to prevent drying out, then adequate cleaning should be achievable.

The first approach taken was that of a standard manufacturing approach using simulated-use testing (8,6). Replicates of patient-used cannulatomes that had been cleaned and ETO sterilized by the hospitals' routine manual method were inoculated with *B.subtilis* spores or *E.faecalis* suspended in a test soil that provided a protein and blood challenge reflective of the soil levels found in patient-used endoscopes (2). The residual bacterial load was assessed at three stages in the reprocessing; after inoculation, after washing with detergent and rinsing and finally after sterilization (Tables 4, 5). Although a 7 log reduction in bacterial load was achieved, the cannulatomes were NOT sterile as residual *B.subtilis* and *Staphylococcus* sp. were detected. Assessment of the organisms growing indicated that it was likely that organisms introduced as part of the manipulation during cleaning, or from patient-use remained despite cleaning/sterilization. In addition, the inoculated spores were not totally killed. This raised questions as to whether there might have been residual patient organisms left after the hospitals' routine cleaning/sterilization method.

To determine if our more controlled cleaning/sterilization method would be more effective than the hospitals manual routine method, patient-used cannulatomes that had been used once on a patient and sent within 1 hour for reprocessing were tested using

that were marketed as single-use medical devices. There are published data that indicate that reliable reprocessing of single-use coronary angioplasty catheters can be achieved using a highly controlled process (3,4,) and others indicating reuse of such catheters is unwise (7). However, the reprocessing of single-use medical devices is often undertaken without the necessary process validation to confirm that the reprocessing method is effective. There is little published data regarding reprocessing of cannulatomes used for ERCP procedures. The data in our current study indicate that it is very difficult to reliably reprocess/sterilize cannulatomes used for endoscopic sphincterotomy procedures. It is apparent that the patient-used cannulatomes reprocessed by a routine manual cleaning method, similar to what may be used in many hospitals, followed by ETO sterilization were not sterile. Only by incorporating flow of detergent using an automated pump as part of the cleaning process and combining this with an alcohol rinse and two cycles of ETO sterilization was successful reprocessing of these medical devices possible. The advantage of this reprocessing method is that the pump controls the time of fluid circulation, thereby ensuring adequate contact time with the detergent and making shortcuts less likely. The flow rates are faster and more consistent than would be achieved by manual flushing using a syringe. This approach improves the cleaning efficacy of these complex devices. The need to address this issue has been pointed out by Mostafa and Chackett (9). An added feature of the pump is that the fluid splitter adaptor, allows processing of up to five cannulatomes at the same time. The critical nature of cleaning validation cannot be over-emphasized no matter what single-use device is being reprocessed. As indicated by Grimandi et al (7), even with

adequate cleaning and sterilization, there will likely be dead microbes that remain adherent to the surfaces of the reprocessed device. They found residual endotoxin, but the amounts detected were not reported, therefore, it is difficult to determine if the levels would have exceeded FDA guidelines or not. Although we found low levels of endotoxin, the amount detected was within FDA acceptable limits and no cytotoxic activity was associated with the reused cannulatomes.

The residual low levels of viable "skin" and "environmental" organisms post-processing/sterilization of the cannulatomes reprocessed by Methods 1 and 2 suggested that there may be a few "sequestered" organisms that were difficult to kill by ETO. Sequestering might be due to the wire (Figure 1) or due to the known difficulties of ETO penetration down narrow lumens (1). The potential for organisms to be protected from ETO sterilization emphasizes that adequate training of reprocessing staff is a critical aspect for centres attempting to reprocess such single-use devices. The difficulty of validating reprocessing of ERCP cannulatomes even using Method 3, should "sound a warning" to centres who currently reprocess such devices, or who are about to submit a process for consideration by their re-use committee. The argument is often made that it is likely of little consequence if a few residual organisms remain after reprocessing, since the cannulotome will come into contact with the gut mucosa when it is used on a patient, and will be exposed to far greater levels of microorganisms. This is a true statement, however, patients getting new cannulatomes will have sterile devices whereas patients getting re-used cannulatomes may get ones that are not sterile if the reprocessing method has not been validated. The organisms encountered in the

**Disclaimer:** The information presented in this manuscript was a research project undertaken for the Winnipeg re-use committee. This data is intended for information only. The author should not be construed as advocating either reuse or nonreuse of single-use medical devices.

**Acknowledgements:** The skilled technical assistance of Nancy Olson, Pat Degagne, Michele Jackson and Rachal Suarez is acknowledged. The support of Sylvia Dolynchuk at St. Boniface General Hospital, Susan Hadfield at the Health Sciences Centre, and Ilana Warner at the Brandon General Hospital for the provision of patient-used cannulatomes is gratefully acknowledged. The ETO offgassing measurements were performed by Mike Lysyk the Environmental Hygienist at St. Boniface General Hospital.

**Table 1 Reprocessing methods evaluated.**

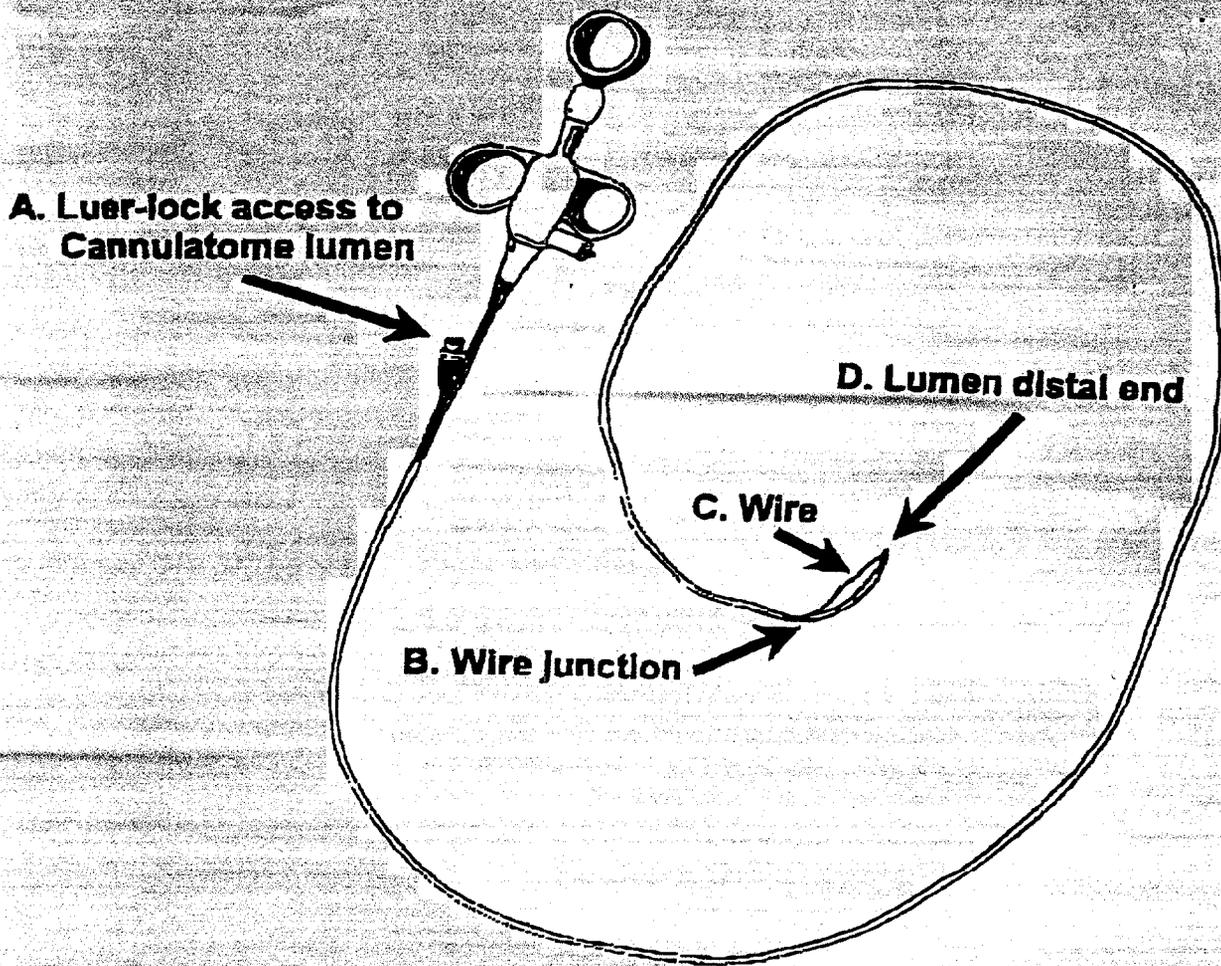
|                            | <b>Method 1:</b>   | <b>Method 2:</b>   | <b>Method 3:</b>   |
|----------------------------|--|--|--|
| <b>Pre-rinse:</b>          | 10 mls tap water   | 10 mls tap water   | 10 mls distilled water   |
| <b>ViraPump2 detergent</b> | Aseptizyme for 15 mins at room temperature                                       | VIROX 5 for 15 mins at room temperature  | VIROX 5 for 15 mins at room temperature  |
| <b>ViraPump 2 rinse:</b>   | tap water 5 mins   | tap water 10 minutes   | distilled water 10 mins  |
| <b>Alcohol rinse:</b>      | No   | No   | 5 mls flushed through lumen, also exterior wiped                                 |
| <b>Dry:</b>                | 10 mins vacuum   | 10 mins vacuum   | 10 mins vacuum   |
| <b>Sterilization:</b>      | 100% ETO once  | 100% ETO TWICE   | 100% ETO TWICE   |
| <b>Sterility Test:</b>     | Aseptically cut up into 100mls broth and cfu/ml* as well as sterility determined | Aseptically cut up into 100mls broth and cfu/ml* as well as sterility determined | Aseptically cut up into 100mls broth and cfu/ml* as well as sterility determined |

These reprocessing methods were evaluated using cannulatomes that had been used only once for patient procedures, were rinsed with water, kept moist and were transported within 1 hour to the site for reprocessing. In addition, Method 1 and Method 3 were evaluated using simulated-use testing experiments.

\* The limit of detection for the quantitative plate count method was 1 cfu/100µl or 10 cfu/ml. For the broth cultures that showed growth but had plate counts that were below the limit of detection for plate counts, it was possible to determine what load of organisms had remained on the device. The 10 ml aliquot removed for the plate counts was incubated separately, and if it was sterile, but the remaining 90 mls showed growth, then there were < 10 cfu/device in the original flask. If both the 10 ml aliquot and the 90 ml flask showed growth, but the plate count was less than the limit of detection, then there were between 10 to 1000 cfu/device remaining.

Aseptizyme is an enzymatic detergent (Huntington Laboratories of Canada Ltd., Bramalea, ON), and VIROX 5 is a detergent that is an accelerated hydrogen peroxide product (Virox Technologies Inc., Mississauga, Ont.).

**Figure 1 Cannulatome used for ERCP Procedures**



**Table 2 Sterility testing of cannulatomes that had been reprocessed by centres using their manual cleaning method followed by ethylene oxide sterilization**

| <b>SITE:</b> | <b>Type of cannulatome:</b> | <b>Days to Detectable growth in broth</b> | <b>Organism(s) detected:</b>               |
|--------------|-----------------------------|---|--|
| Hospital 1   | Monofilament                | 1   | Gram (+) bacilli                           |
| Hospital 1   | Monofilament                | 1   | Three types of Gram (+) cocci in clumps    |
| Hospital 1   | Monofilament                | 1   | Two types of Gram (+) cocci in clumps      |
| Hospital 1   | Monofilament                | 7   | Fungus                                     |
| Hospital 1   | Monofilament                | 2   | Gram (+) bacilli                           |
| Hospital 2   | Monofilament                | 2   | Gram (-) bacilli                           |
| Hospital 2   | Braided-wire                | 1   | Gram (+) cocci in clumps                   |
| Hospital 2   | Braided-wire                | 1   | Gram (+) bacilli, Gram (+) cocci in clumps |
| Hospital 2   | Braided-wire                | 1   | Gram (+) bacilli, Gram (+) cocci in clumps |

The cannulatomes from hospital 2 had been re-processed (cleaned and sterilized) and re-used multiple times, whereas the ones from Hospital 1 had been patient-used only once prior to being cleaned/sterilized by the routine manual reprocessing method used at each hospital.

**TABLE 3 PATIENT-USED CANNULATOME DATA\***

| No:  | Cannul. Type:     | Procedure Length (mins) | Viable count cfu/ml | Hg: g/L      | Bilirubin $\mu$ moles/L | Protein g/L  | Na <sup>+</sup> mmol/L | LPS EU/ml   | Carbohydrate $\mu$ g/ml |
|------|-------------------|-------------------------|---------------------|--------------|-------------------------|--------------|------------------------|-------------|-------------------------|
| C1   | wire-guided       | 32                      | 10                  | 0.02         | 9                       | 0.204        | 9                      | 32.7        | 4.46                    |
| C2   | non wire          | 25                      | 2700                | 0            | 0                       | 0.016        | 3                      | 0.54        | 6.06                    |
| C3   | non wire          | 24                      | 110                 | 0            | 0                       | 0.031        | 3                      | 0.56        | 0                       |
| C4   | non wire          | 13                      | 50                  | 0            | 0                       | 0.023        | 2                      | 0.08        | 1.99                    |
| C5a+ | non wire, braided | 25                      | 0                   | 0            | 0                       | 0.006        | 3                      | 0.05        | 3.34                    |
| C5b+ | mono-filament     | 25                      | 0                   | 0            | 0                       | 0.012        | 4                      | 0.22        | 0                       |
| C5c+ | .21-wire guided   | 25                      | 0                   | 0.03         | 19                      | 0.113        | 13                     | 1.97        | 7.63                    |
|      | <b>Average:</b>   | <b>24.1</b>             | <b>410</b>          | <b>0.007</b> | <b>4</b>                | <b>0.058</b> | <b>5.29</b>            | <b>5.16</b> | <b>3.21</b>             |

\* All cannulatomes were used once for sphincterotomy procedures with either balloon manipulation or stent insertion. Each cannulatome lumen sample was 5 ml total volume. (+ Same patient.)

**TABLE 4 Simulated Use: *Enterococcus faecalis***

| TEST STAGE                                | Number of cannulatomes Tested | Average residual bacteria/Device (cfu/device) |
|---|-------------------------------|---|
| Recoverable Bioburden (after inoculation) | 5                             | $5.4 \times 10^7$                             |
| After Detergent/rinse treatment           | 5                             | $1.2 \times 10^5$                             |
| After EtO Sterilization                   | 5                             | 0*  |

\* No *E.faecalis* was detected, however there was < 10 cfu/ml of Coagulase negative *Staphylococcus* species in 4/5 cannulatomes and *Bacillus* species detected in 1/5 cannulatomes. This simulated use testing was done using reprocessed cannulatomes that had been cleaned/sterilized and provided by the various hospitals.

**TABLE 5 Simulated Use: *Bacillus subtilis***

| TEST STAGE                                | Number of cannulatomes Tested | Average residual bacteria/Device (cfu/device) |
|---|-------------------------------|---|
| Recoverable Bioburden (after inoculation) | 5                             | $7.70 \times 10^7$                            |
| After Detergent/rinse treatment           | 5                             | $7.35 \times 10^4$                            |
| After EtO Sterilization                   | 5                             | - 5*  |

\* *B.subtilis* was detected in 3/5 cannulatomes tested in the incubated flask only, and no detectable colonies were detected on the spread plates (ie < limit of detection for the spread plate technique). In addition, < 10 cfu/ml of a coagulase negative *Staphylococcus* sp. was detected in 5/5 cannulatomes. This simulated use testing was done using reprocessed cannulatomes that had been cleaned/sterilized and provided by the various hospitals.

**TABLE 6 STERILITY TESTING OF PATIENT-USED CANNULATOMES PROCESSED BY STUDY METHOD 1**

| Number            | Type         | Days to growth | Result:<br>(Gram stain of positive broth culture)                   |
|-------------------|--------------|----------------|---|
| Hospital 1, Can-1 | Braided wire | 1              | large Gram (+) bacilli,   |
| Hospital 1, Can-2 | Braided wire | 2              | large Gram (-) coccobacilli   |
| Hospital 1, Can-3 | Braided wire | 1              | two types of Gram (+) cocci in clusters                             |
| Hospital 1, Can-4 | Braided wire | 2              | Gram (+) cocci in clusters  |
| Hospital 1, Can-5 | Braided wire | 1              | large Gram (+) spore forming rods                                   |
| Hospital 2, Can-1 | Monofilament | Sterile        | Sterile   |
| Hospital 2, Can-2 | Monofilament | 1              | Gram (+) cocci in clusters  |
| Hospital 2, Can-3 | Monofilament | 1              | Gram (+) cocci in clusters and two types of Gram (+) cocci in pairs |
| Hospital 2, Can-4 | Monofilament | Sterile        | Sterile   |
| Hospital 2, Can-5 | Monofilament | 2              | Gram (+) cocci in pairs and tetrads                                 |

\*Cannulatomes were used only once on patients, kept moist, transported within one hour and then processed by Method 1 and tested for sterility.

**TABLE 7 STERILITY TESTING OF PATIENT-USED CANNULATOMES PROCESSED BY STUDY METHOD 2**

| Number            | Type         | Days to growth | Result:<br>(Gram stain of positive broth culture) |
|-------------------|--------------|----------------|---|
| Hospital 1, Can-1 | Braided wire | Sterile        | Sterile   |
| Hospital 1, Can-2 | Braided wire | Sterile        | Sterile   |
| Hospital 1, Can-3 | Monofilament | Sterile        | Sterile   |
| Hospital 1, Can-4 | Braided wire | 1              | Gram (+) cocci *                                  |
| Hospital 1, Can-5 | Braided wire | 4              | Gram (+) cocci **                                 |
| Hospital 1, Can-6 | Braided wire | Sterile        | Sterile   |

Cannulatomes were used only once on patients, kept moist and transported within one hour and then processed by Method 2 and tested for sterility.

\* During processing, this cannulatomes was accidentally in contact with the wall of the biosafety hood

\*\* No problems were noted to indicate accidental contamination.

**TABLE 8 STERILITY TESTING OF PATIENT-USED CANNULATOMES PROCESSED BY STUDY METHOD 3**

| Number            | Type         | Days to growth | Result:<br>(Gram stain of positive broth culture) |
|-------------------|--------------|----------------|---|
| Hospital 1, Can-1 | Braided      | Sterile        | Sterile   |
| Hospital 1, Can-2 | Monofilament | Sterile        | Sterile   |
| Hospital 1, Can-3 | Braided      | Sterile        | Sterile   |
| Hospital 1, Can-4 | Monofilament | 2 days         | Two types of Gram positive aerobic rods           |
| Hospital 1, Can-5 | Braided      | Sterile        | Sterile   |

Cannulatomes were used only once on patients, kept moist, transported within one hour and then processed by Method 3 and tested for sterility

**TABLE 9 Simulated Use Testing using New Cannulatomes and Study Method 3 with *Bacillus subtilis* as the test organism.**

| TEST STAGE                                | Number of cannulatomes Tested | Average residual <i>B.subtilis</i> /Device (cfu/device) |
|---|-------------------------------|---|
| Recoverable Bioburden (after inoculation) | 5                             | $1.3 \times 10^8$                                       |
| After Detergent/rinse treatment           | 5                             | $1.9 \times 10^4$                                       |
| After ETO Sterilization (2 ETO cycles)    | 5                             | 0*  |

\* *B.subtilis* was not detected in any of the cannulatomes tested by either the spread plate counts or in the flasks incubated to test for sterility. However, there were < 10 cfu/device of a coagulase negative *Staphylococcus* sp. detected in 3/5 incubated flasks (ie 3 of the 5 test cannulatomes that were cut up into broth and then incubated were not sterile). The cannulatomes used in this part of the evaluation were new and had not been previously used on patients. The low levels of *Staphylococcus* detected only in the broth cultures were likely contaminants accidentally introduced during the manipulation of the cannulatome when it was being cut up to test for sterility.

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tested are summarized in Table 1.

#### **Sterility Testing of reprocessed cannulatomes:**

Once sterilized, peel pouch wrap was opened and the cannulotome was aseptically cut into 3 - 5 cm pieces using a pair of sterile wire snippers. The cut cannulotome segments were immersed in a sterile flask containing 100 mls of tryptic soy broth. This flask containing the cannulotome segments was mixed and then a sample removed for serial 1:10 dilutions. Each dilution was assessed quantitatively to determine the residual amount of viable bacteria using the spread plate technique. The limit of detection using the spread plate technique was 1 colony per 0.1 mls (10 cfu/ml). To detect lower residual levels of bacteria, the flask containing the cut segments in tryptic soy broth was incubated for 5 days and if no growth was detected on either the plates or in the broth, the cannulotome was determined to be sterile. If growth was detected in the flask during the 5 days of incubation, an aliquot was subcultured to determine what organism was growing. Extensive identification of the organisms detected was not performed, but Gram stain reactions, and coagulase testing of Gram positive cocci in clusters was done.

#### **Patient-used Cannulotome Test Method:**

This testing is different from the simulated-use testing in that NO test organisms were inoculated. Briefly this part of the study was designed to determine if cannulatomes that had been used once in a patient procedure could be reliably sterilized by the cleaning/sterilization study method being evaluated. Any residual organisms would be

from patient material, or organisms introduced during the cleaning/rinsing procedure.

The three reprocessing methods used for patient-used cannulatomes have been summarized in Table 1.

#### **Soil Determinations for patient-used cannulatomes:**

To determine the level of viable bacteria and various soil parameters on patient-used cannulatomes, samples were collected immediately after patient-use by flushing 5 ml of sterile water through the lumen of the cannulotome. This sample was then evaluated for cfu/ml using the spread plate technique, and the levels of protein, bilirubin, hemoglobin, sodium ion, carbohydrate and endotoxin were determined as previously described (1).

#### **Ethylene Oxide Off-Gassing Testing of Reprocessed Cannulatomes:**

The Gastec sampler and Gastec detector tube #163L (Gastec Corporation, Fukaya, Japan) were used in conjunction with the Gastec multi-stroke gas sampling pump to detect residual ETO from reprocessed cannulatomes. Sampling of ETO was done by opening the peel pouch containing the cannulotome and placing the detector tube at the suction channel opening of the cannulotome and measuring two pump strokes (200 ml of air sampled). The readings were corrected for temperature according to the manufacturer's instructions. The accuracy tolerance is  $\pm 25\%$  at 1, 2 and 3 times the threshold limit value (TLV).