

**Boston
Scientific**
MICROVASIVE

20 September 2000
Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508.650.8711
www.bsci.com

Greg Barrett
President, Microvasive Endoscopy

CITIZEN PETITION

Boston Scientific Corporation ("BSC") submits this petition under 21 C.F.R. §§ 10.25 and 10.30 to request that the Commissioner of the Food and Drugs amend 21 C.F.R. § 876.1075(b)(2) which classifies biopsy forceps covers and non-electric biopsy forceps as Class I devices that are exempt from the premarket notification procedures.

A. **ACTION REQUESTED**

BSC requests that the Commissioner of Food and Drugs amend 21 C.F.R. § 876.1075(b)(2) to limit the exemption from premarket notification requirements to two specified situations: 1) non-electric biopsy forceps which are labeled for single-use and are not reprocessed, and 2) non-electric biopsy forceps which are originally designed and labeled to be reusable.¹ Specifically, BSC requests that 21 C.F.R. § 876.1075 be amended as follows:

(b) *Classification.*

(2) Class I for the biopsy forceps cover and the non-electric biopsy forceps.

Biopsy forceps covers subject to this paragraph are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. Non-electric biopsy forceps subject to this paragraph are exempt only if the forceps are labeled

¹ This petition requests an amendment to 21 C.F.R. § 876.1075(b)(2) only with respect to non-electric biopsy forceps, and not to biopsy forceps covers.

OOP-1535

CPI

055500 SEP 22 18:41

for single-use and are not reprocessed, or if the forceps are originally designed and labeled to be reusable.

B. STATEMENT OF GROUNDS

1. Introduction

Reprocessed single-use non-electric biopsy forceps are designed to be safe and effective for use in a single patient during a single procedure. These devices were not designed to be reprocessed, and the materials were chosen for its labeled use - as a single-use device. The material selection and mechanical design of these devices are optimized to provide a safe and efficacious device for use on a single patient during a single procedure. Accordingly, certain design elements result in difficult to clean areas, and materials which cannot tolerate rigorous cleaning techniques. Not surprisingly, reprocessed single-use non-electric biopsy forceps tested by BSC have demonstrated a high level of residual debris and lack of sterility.

a. Design of Single-Use Non-Electric Biopsy Forceps

BSC manufactures various single-use biopsy forceps. Pursuant to 21 C.F.R. § 876.1075, BSC's non-thermal biopsy forceps are Class I devices that have been exempted from the premarket notification procedures and BSC's thermal biopsy forceps are Class II devices that have not been exempted from the premarket notification procedures. Based on the characteristics of single-use biopsy forceps described below, it is BSC's position that single-use biopsy forceps, whether thermal or non-thermal, are extremely difficult, if not impossible, to thoroughly clean or adequately sterilize for safe reuse in patients. Accordingly, reprocessed single-use biopsy forceps need to be subject to the 510(k) premarket notification requirements in order to ensure that these devices are safe and effective for reuse after reprocessing.

In general, single-use non-electric biopsy forceps are comprised of two long, thin steel wires which are surrounded, at the distal end, by a lubricious-coated plastic sheath. The wires and inner sheath are located inside a tightly wound metal coil which is then encased in an outer polymer sheath. At the distal end, the wires are attached to the sample collection jaws of the forceps. A plastic handle control and spool assembly by which the device is controlled are located at the proximal end.

The jaw assembly often includes a needle for anchoring the biopsy into the mucosa. The needle is also used to stack biopsy samples for detainment in the jaw assembly. The needle directly penetrates the mucosal layer of the GI tract and should be considered in the same manner as all medical device "Sharps" classification.

The outer sheath covering the device creates a long (up to 240 cm) and very narrow lumen with a cross sectional profile as small as 2.2 mm. These long, narrow lumens are one of the hallmark features that make certain single-use devices difficult to reprocess. The coil that surrounds the inner plastic sheath creates many difficult-to-access interstices in which debris accumulates during use. The metal coil which surrounds the steel wires attaches to the jaw assembly by crimping at the proximal end of the jaw assembly. While a crimped design is sufficiently durable for a single-use device, devices designed for reuse typically employ a highly durable welded design. Single-use non-electric biopsy forceps also have very small interlocking parts and crevices in the hinge where the jaw mechanism of the biopsy forceps is attached to the wire assembly. The wires are connected to the jaw assembly by a "z-bend" in which the wires are inserted through a hole in the assembly and bent into a fixed position.

Each of the design features discussed above impedes thorough cleaning of the device. In fact, an exhaustive 1996 report from ECRI found 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].”² These features listed by ECRI characterize single-use, non-electric biopsy forceps.

BSC is aware that a common reprocessing technique employed with lumened devices involves flushing cleaning fluid through the lumen. Because the lumen of the biopsy forceps is open only at the distal end, however, flushing is not a viable option. In fact, attempts to clean the biopsy forceps by flushing and aspirating cleaning fluid through the single opening have been shown to spread contaminants further throughout the instrument.³ Furthermore, single-use biopsy forceps cannot be disassembled for cleaning without destroying the device.

Because biopsy forceps break the mucosal barrier and come in contact with the blood stream, sterility is critical. New single-use non-electric biopsy forceps are sterilized with ionizing radiation. Such sterilization is effective on devices that have not come in contact with a patient and are thus free of human debris. BSC has conducted several studies (discussed in detail below) which show that reprocessed single-use biopsy forceps do contain residual tissue. Because neither ionizing radiation nor ethylene oxide gas (EtO) – a sterilization method commonly used by reprocessors – can penetrate biological tissues, both methods are rendered ineffective.⁴ This leaves only radiation and steam sterilization as sterilization alternatives. Since the device has undergone one

² ECRI, “Evaluating the Feasibility of Reusing a Single-Use Device,” Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions, at 55 (1996).

³ 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).

⁴ It is BSC’s understanding that single-use biopsy forceps are currently reprocessed using EtO sterilization.

radiation dose, the cumulating dose would likely damage the device. Radiation is not a possible sterilization method for used devices since this method is only effective when the bioburden present on devices is relatively consistent and known. In devices likely to have highly variable levels of bacteria – such as biopsy forceps due to their many crevices and interlocking parts – radiation would have to be conducted at doses so high that portions of the instrument would likely be damaged or destroyed. Steam sterilization is similarly not a viable option since the handle and spool assembly as well as the inner plastic sheath that surround the steel wires are plastic and thus would melt if sterilized using steam. Therefore, all available methods of sterilization are ineffective for used single-use biopsy forceps.

In addition to compromising sterility, reuse or reprocessing are likely to adversely affect the performance of single-use non-electric biopsy forceps due to the materials and components that make up the device. The metals used in manufacturing the jaw and needle of the device were not selected for their ability to remain sharp through repeated use and cleaning. Dulled teeth would impair the device's ability to collect usable samples during the biopsy procedure. Similarly, a dull needle would result in the inability of the biopsy forceps to hold the tissue in place while the jaws cut the sample, and thus failure to retrieve a test sample. Moreover, exposure to excessive heat and chemicals can melt the inner plastic sheath onto the wires which it encases and impair the ability of the jaws to open and close. Finally, the crimped coil attachment and "z-bend" attachment of the wires to the jaw mechanism are not designed for multi-use durability. While these attachment techniques result in safe and effective single-use devices, they lack sufficient strength for reuse and reprocessing. Proprietary lubricant is placed in a new device. During the cleaning process it is removed and this reprocessing impairs functionality.

Because the very design of the non-electric biopsy forceps impedes adequate sterilization after use, and because performance and structural integrity of the forceps is

diminished, reprocessed single-use non-electric biopsy forceps present an incremental, unreasonable (and unnecessary) risk of illness or injury to patients. Accordingly, the reprocessor must be required to submit a 510(k) in order that the agency may evaluate whether the reprocessed device is safe and effective prior to its use in patients.

b. **Studies Show Reprocessed Single-Use Biopsy Forceps Present an Increased Infectious Risk to Patients**

BSC has funded several studies to determine whether reprocessed single-use biopsy forceps are sufficiently clean and sterile for use in patients (copies of six detailed study reports enclosed). The results of the investigations have demonstrated that a significant number of reprocessed single-use devices contain residual debris and fall far below the sterility standard established by FDA despite sterilization with EtO.⁵ Within the past four years, BSC has sponsored six separate studies of reprocessed single-use biopsy forceps. Overall, of the 88 devices examined, more than 64 percent failed the sterility tests and over 94 percent tested positive for the presence of residual tissue. All of the testing was conducted by independent laboratories.

While the testing was performed at various centers, the testing methodology was similar among the six studies.⁶ All test devices were obtained from hospitals by BSC

⁵ For most devices, manufacturers must validate that the sterilization process used in manufacturing provides a sterility assurance level (SAL) of at least 10^{-6} and that the process does not adversely affect the product and/or package functionality. This standard applies to both original equipment manufacturers and reprocessors. While reprocessors claim to have validation data indicating that they meet an SAL of 10^{-6} , BSC has learned that they test for sterility by evaluating the distal and proximal ends rather than the center of the device where the bacteria is harbored. Proper validation would require segmenting the device into small sections prior to testing for sterility.

⁶ For detailed methodological discussion, refer to the appended study reports.

representatives who provided a new replacement device for each reprocessed device. Devices were selected at random by hospital personnel. Upon arrival at BSC, the devices were immediately shipped to the testing laboratory in their reprocessor packaging. For studies in which residual debris testing was to be conducted as well as sterility testing, devices were randomly assigned to either the debris testing group or the sterility testing group. Devices to be tested for sterility were cut into 30 cm and 10 cm segments and subjected to a 14-day modified USP sterility test using Soybean Casein Digest. A second test was performed where devices were cut into 30 cm and 10 cm segments placed into Soybean Casein Digest Broth and agitated to remove organisms and broth was filtered and incubated for growth. Devices to be tested for residual debris were subjected to light microscopy, scanning electron microscopy and photoelectron spectroscopy.

Table: Results from Six Separate Investigations of Reprocessed Single-Use Biopsy Forceps

| Investigating Laboratory | Study Date | Number of Devices Studied | Percentage Found Not Sterile ⁷ | Percentage With Residual Tissue | Percentage That Failed Overall |
|--|----------------|---------------------------|---|---------------------------------|--------------------------------|
| Viomed | May 26, 1997 | 4 | 75 (3/4) | --- | 75 (3/4) |
| SteriLogics | Oct. 20, 1997 | 9 | 50 (2/4) | 80 (4/5) | 66 (6/9) |
| The Center for Testing of Medical Products | March 31, 1999 | 18 | 64 (9/14) | 100 (4/4) | 72 (13/18) |
| The Center for Testing of Medical Products | March 31, 1999 | 17 | 100 (9/9) | 100 (8/8) | 100 (17/17) |
| Viomed | July 15, 1999 | 20 | 45 (9/20) | --- | 45 (9/20) |
| Viomed | Sept. 24, 1999 | 20 | 70 (14/20) | --- | 70 (14/20) |
| TOTAL: | | 88 | 64.79 (46/71) | 94.12 (16/17) | 70.45 (62/88) |

⁷ Bacteria present on the tested devices includes *staphylococcus aureus*, *coagulase negative, staphylococcus*, *corynebacterium, sp.*, *fungi*, *enterococcus faecium*, *micrococcus, sp.*, *alpha hemolytic streptococci*, *bacillus, sp.*, *bacillus cereus*, *acinetobacter, sp.*, *pseudomonas putida*, *micrococcus luteus*, *staphylococcus epidermis*, *gram positive rods and gram positive cocci*.

In addition to this testing, FDA's Office of Science and Technology ("OST") has also studied reprocessed single-use biopsy forceps. In a recently published abstract, OST discussed the results obtained from examining a cleaning and sterilization process for three types of single-use gastrointestinal biopsy forceps. OST found that cleaning these devices with a sequence of bleach, ultrasonic bath with detergent and enzyme, and water rinse appears to remove residual debris, but OST did not discuss the effects of these harsh chemicals on device integrity. OST also found that drying the lumens of these devices is very difficult. In conclusion, OST states "[r]esidual water may decrease the effectiveness of sterilization."⁸ Thus, even when the debris is removed, which BSC's data indicate is extremely difficult, the existence of residual water may compromise the ability of EtO to effectively sterilize the device.

2. FDA's Position Regarding Non-Electric Biopsy Forceps as Stated in Relevant Guidance Documents

a. FDA's Final Single-Use Device Regulatory Strategy

On August 14, 2000, FDA published a notice in the Federal Register announcing the availability of a guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" which finalized the agency's policy for the regulation of third party and hospital reprocessors engaged in reprocessing single-use devices for reuse.⁹ This guidance document sets forth FDA's priorities for enforcing premarket submission requirements for reprocessed single-use devices, based on the device's classification as established in the Code of Federal Regulations. For Class I and

⁸ CDRH, "Reprocessing Single Use Biopsy Forceps for Reuse," Abstract for the 2000 FDA Science Forum from OST.

⁹ FDA, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (Aug. 2, 2000) <<http://www.fda.gov/cdrh/comp/guidance/1168.pdf>>.

II exempt devices, the guidance document states that “[a]t a later date, the agency will evaluate, on a case-by-case basis, the need to revoke exemptions from premarket submission requirements for class I and class II exempt products . . . [as is] necessary to ensure that these devices are safe and effective for reuse after reprocessing.”¹⁰ Therefore, FDA acknowledges in this guidance document that certain exempt Class I and Class II devices require agency review once they are reprocessed.

Based on the results of testing discussed above, it is clear that single-use non-electric biopsy forceps reprocessed without 510(k) clearance are not safe or effective for reuse. It is BSC’s position that FDA must immediately revise the regulation which exempts all non-electric biopsy forceps from premarket notification procedures to exclude single-use non-electric biopsy forceps that have been reprocessed.

b. Non-Electric Biopsy Forceps Are Considered a High Risk When Reprocessed

On February 8, 2000, FDA published a draft guidance document entitled “Single-Use Devices, Reprocessing and Reuse: Review Prioritization Scheme” which proposed the process FDA would use to categorize the risk associated with single-use devices that are reprocessed.¹¹ According to the draft guidance, FDA would assign an overall risk to each single-use device by analyzing two factors of a device following reprocessing: (1) the risk of infection; and (2) the risk of inadequate performance. This analysis would be performed by answering a series of questions presented in flow charts which were attached as an appendix to the draft guidance. The questions, intended to determine the risk level of reprocessing, varied from whether the device is intended to make only

¹⁰ Id. at 10.

¹¹ FDA, “Single-Use Devices, Reprocessing and Reuse: Review Prioritization Scheme” (Feb. 8, 2000) <<http://www.fda.gov/cdrh/guidance>>.

topical contact or penetrate the skin, to whether a reusable device with an equivalent design and same intended use already exists, to whether failure of the device could cause death or serious injury.

In a second appendix to the draft guidance, FDA listed frequently reprocessed single-use devices to which FDA applied the analysis and categorized their risk as either low, moderate or high. Reprocessed non-electric biopsy forceps were included in the 26 devices FDA identified as presenting a high risk when reprocessed. Thus, based on an analysis of the device's risk of infection and risk of inadequate performance following reprocessing, FDA has already determined that non-electric biopsy forceps pose a high risk if reprocessed.

In the August 2000 final guidance document, FDA determined that its review policy will be based on the traditional device classification scheme rather than the risk prioritization scheme proposed in the draft guidance. Nonetheless, the analysis used by FDA in categorizing reprocessed non-electric biopsy forceps, and the conclusion FDA reached when categorizing devices are significant. Even if the regulatory construct has changed, FDA's conclusion remains valid: reprocessing these devices is hazardous to the health of patients. The reprocessing of single-use non-electric biopsy forceps should not be permitted without 510(k) clearance.

c. Non-Electric Biopsy Forceps are Frequently Reprocessed

As discussed above, FDA appended to the draft guidance a list of devices that it categorized by risk and identified as frequently reprocessed. Non-electric biopsy forceps are one of the 66 devices that FDA listed as a frequently reprocessed single-use device. While the August 2000 final guidance document includes a similar list, the title has been changed to "List of SUDs Known to be Reprocessed." Non-electric biopsy forceps are

still included on this list. This high level of reprocessing underscores the need for the agency to take prompt action on this petition.

3. Precedent Exists for FDA To Limit a Class I Exemption

FDA has the power to limit exemptions and the agency has exercised this power in the past. There are a number of examples in the regulations where FDA has limited an exemption for a Class I device. One example is the nonpowered breast pump, regulated under 21 C.F.R. § 884.5150. This Class I device is exempt so long as the device is “using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects.”¹² Another example is the keratoscope regulated under 21 C.F.R. § 886.1350. This Class I device is exempt from the premarket notification procedures “only when the device does not include computer software in the unit.”¹³

Both of these examples illustrate how FDA has limited the scope of exemptions of Class I devices. FDA deemed it necessary to limit the exemption because the device’s characteristics present an increased risk to the patient. A nonpowered breast pump with greater suction capability and a keratoscope which measures the corneal curvature of the eye with computer software clearly present different concerns of safety and effectiveness than their conventional counterparts. Thus, while the devices are still classified as Class I, the manufacturer of a device that has high risk characteristics is required to submit a 510(k) premarket notification.

¹² 21 C.F.R. § 884.5150(b).

¹³ 21 C.F.R. § 886.1350(b).

Likewise, FDA must exclude from the Class I categorical exemption granted to non-electric biopsy forceps, those units that are labeled for single-use, but are reprocessed. A reprocessed non-electric biopsy forceps that has been approved by FDA for only one use will present substantially greater risk to patients. Reprocessed single-use non-electric biopsy forceps, with their attendant risks of residual debris, non-sterility and compromised functionality, should not be exempted from 510(k) review.

Section 510(l) of the Federal Food, Drug and Cosmetic Act ("FDC Act") provides that Class I devices are exempt from 510(k) requirements unless the Class I device "is intended for a use which is of substantial importance in preventing impairment of human health, or to any Class I device that presents a potential unreasonable risk of illness or injury."¹⁴ This section was added to the FDC Act in 1997 when the Food and Drug Administration Modernization Act ("FDAMA") was enacted into law. While this standard for Class I exemption was enacted after non-electric biopsy forceps were exempted, it still clarifies the factors that FDA considered when it made the decision to exempt non-electric biopsy forceps in 1996, and should be used in reviewing this petition.¹⁵ Based on the reprocessing data described above, reprocessed single-use biopsy forceps clearly present "a potential risk of illness or injury" and thus should be excepted from the exemption as established under FDAMA.

4. Conclusion

BSC generally supports FDA's single-use device reprocessing policy as published in FDA's August 2000 guidance document. However, BSC believes that FDA must take immediate action with respect to revoking the exemption from premarket notification

¹⁴ 21 U.S.C. § 360(l).

¹⁵ See 61 Fed. Reg. 1117 (Jan. 16, 1996).

procedures for reprocessed single-use non-electric biopsy forceps due to the high risk that the device presents to patients if it is reused.

C. ENVIRONMENTAL IMPACT

Neither an environmental assessment nor an environmental impact statement is required for the action requested of the agency because the requested agency action is categorically excluded pursuant to 21 C.F.R. § 25.30(h) in that it is concerned with amendment of procedural or administrative regulations.

D. ECONOMIC IMPACT

According to 21 C.F.R. § 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of the petition.

E. CERTIFICATION

BSC certifies that, to the best of its knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Signature



Greg Barrett

Boston Scientific Corporation

One Boston Scientific Place

Natick, MA 02019

(508) 650-8711

Reference Material

SPECIAL REPORT

Reuse of Single-Use Medical Devices:

Making Informed Decisions

ECRI

A NONPROFIT AGENCY

Editorial and Technical Staff

Publisher: ECRI

JOEL J. NOBEL, M.D., President, ECRI

MICHAEL ARGENTIERI, M.S.B.M.E., Vice President,
Business Development

SUSAN BASTNAGEL, B.S., Senior Risk Management
Analyst

MARK E. BRULEY, B.S., Vice President, Accident and
Forensic Investigation

VIVIAN H. COATES, M.B.A., Vice President, Technology
Assessment

GREGORY W. GRASDEN, Intern, Health Technology
Assessment Information Service

SHANNA HALPERN, Esq., Director, Center for Healthcare
Environmental Management

JEAN K. JAMANOW, M.B.A., Editor and Publishing
Services Director

CHRISTIAN LAVANCHY, B.S.M.E., Engineering
Director, Health Devices Group

ANTHONY J. MONTAGNOLO, M.S., Vice President,
Technology Planning

THOMAS E. SKORUP, B.S., Senior Associate, Health
Systems Group

RONNI P. SOLOMON, Esq., Vice President, Legal
Affairs, and Director, Risk Management Services

MELANIE MOYER SWAN, M.P.H., Senior Associate,
Health Technology Assessment Information Service

MICHELE R. THOMAS, M.S., M.B.A., Senior Analyst,
Program Development for Health Services

CHARLES M. TURKELSON, Ph.D., Chief Research Analyst,
Health Technology Assessment Information Service

Production and Promotional Staff

NIKKI DIAMOND, B.F.A., Graphic Designer

ADRIENNE W. FENTON, B.A., Director, Communications
and Circulation

SARAH GANTZ, Supervisor, Word Processing

JILL GRESHES, M.A., M.Ed., Copyediting Coordinator

JENNIFER EHLERS, ROBIN HENRY, ALISON LANDIS,
Copyeditors

JOHN C. HALL, Manager, In-House Printing and
Fulfillment Services

MARLENE P. HARTZELL, Desktop Publishing
Coordinator

DONALD S. PETTIT III, Graphic Artist

Editorial Policy Statement

Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions is published by ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298, U.S.A.; telephone (610) 825-6000; fax (610) 834-1275; e-mail ecri@hslc.org.

ECRI is an independent, nonprofit health services research agency established in 1955. It is committed to improving the safety, efficacy, and cost-effectiveness of patient care through its focused research, analysis, scientific studies, and education in medical technology and healthcare risk management. The institute has a long and distinguished history in making healthcare safer.

ECRI services support thousands of hospitals, healthcare practitioners, healthcare organizations, ministries of health, government and planning agencies, insurance companies, voluntary sector organizations, and associations worldwide. Its more than 30 databases, publications, and information services have set the quality standard for the healthcare community. Its technical assistance and advisory projects reflect the combined experience of more than 200 professional, technical, and support staff. ECRI's programs alert the healthcare community to risks and hazards; disseminate the results of ECRI laboratory evaluations, risk analyses, and technology assessments; offer professional certification of healthcare environmental managers; maintain a comprehensive clearinghouse of healthcare standards and guidelines; and provide a forum for high-quality information exchange. ECRI maintains strict ground rules for avoiding conflicts of interest. These rules help to ensure the independence, integrity, and quality of its work.

In 1987, the World Health Organization accorded ECRI the status of Collaborating Center — a designation that recognizes ECRI's international role in the healthcare community.

The information in this *Report* does not constitute legal advice.

Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions

Copyright 1996 by ECRI.

All rights reserved.

ISBN 0-941417-52-2

Chapter 7

Evaluating the Feasibility of Reusing a Single-Use Device

The reuse committee should perform a feasibility evaluation for each device and model of that device being considered for reuse. While in some cases it may be possible to establish parallels between models, thus simplifying the process, subtle differences in materials or design among models can affect feasibility of reuse.

Recently, the Cleveland Clinic Foundation completed a feasibility study for the reuse of perfusion cannulas. A brief synopsis of this study is presented in Appendix I.

We recommend that the first step of the feasibility evaluation be to contact the device's manufacturer to gain essential product information, including

- the sterilization method used,
- the device's component materials, and
- any recommendations for reprocessing.

Although most manufacturers will decline to provide information that supports reuse of a product they label for single use,¹ some may cooperate on a limited basis. For example, some manufacturers will provide recommendations on resterilizing open, but unused, products. In addition, manufacturers may provide additional insight on why it may be inadvisable to reuse the device — insight that may be valid and deserving of thoughtful consideration, despite the manufacturers' financial self-interest in recommending against reuse.

Next, the reuse committee should assess the reusability of the device being considered and whether the healthcare organization has the resources necessary to make reuse safe and effective. For example:

- Can the device be adequately cleaned?
- Is there a practical way to inspect and test the function of the device?
- Will the device require reconditioning (e.g., sharpening)?
- What method will be used for sterilization/disinfection?
- Is there a practical way to track the number of reuses?

- Can the healthcare organization provide the expertise, staff, and equipment necessary for reuse?

Below we discuss each of these concerns with respect to evaluating a single-use product strictly for its reusability.

Cleaning

The device should be easy to clean. As is true for reusable devices, adequate cleaning entails removal of visible soil from body fluids, tissues, and other debris that remain following use of the device. All surfaces of the device, including channels and lumens that may have been in contact with the patient or physiologic fluids, must be accessible to ensure proper cleaning. Devices with long and/or small-diameter lumens, with rough or textured surfaces and deep grooves 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. **If the product cannot be adequately cleaned, sterilization will not be reliable, and pyrogenic reactions may occur even if the device is sterile. Moreover, if all potentially contaminated surfaces of a critical or semicritical device cannot be inspected for cleanliness after each use, then it should not be reused.** In evaluating a device for cleaning, take into account the methods available in the healthcare organization and the types of cleaning agents that might be used. Consider features of the device and whether the standard methods used can effectively clean all device surfaces without causing damage. Bear in mind that disassembly for cleaning may not be an option if the device is not intended for disassembly. Even if the device could be disassembled, attempting this may result in damage that could predispose the device to failure during use.

Table 1 provides criteria and recommendations for examining the cleanability of specific categories of single-use devices. It is not, however, an exhaustive list of concerns. Instead, it illustrates common concerns that

Internationale Zeitschrift
für Aufbereitung
und Sterilgutversorgung

ZENTRAL STERILISATION

International Journal
of Processing
and Sterile Supply

Offizielles Mitteilungsorgan der
Deutschen Gesellschaft für
Sterilgutversorgung e.V. (DGSV)

CENTRAL SERVICE

Official Publication of the
German Society for
Sterile Supply e.V. (DGSV)

K. Roth, P. Heeg, R. Reichl, P. Cogdill, W. Bond

Quality Assurance on Reprocessing Accessories for Flexible Endoscopes - Just How Clean are Cleaned Instruments Really?

OFFPRINT

Central Service 1999;7:(2)84-96

K. Roth*, P. Heeg, R. Reichl, P. Cogdill and W. Bond

Quality Assurance on Reprocessing Accessories for Flexible Endoscopes – Just How Clean are Cleaned Instruments Really?

The efficacy and safety of a to a large extent standardised manual procedure for reprocessing artificially contaminated endoscopy accessories were investigated with the aid of the radionuclide method and of microbiological procedures. Based on data in the literature, the costs were also taken into consideration, in order to be able to estimate the economic feasibility of reprocessing. Neither adequate cleaning nor adequate disinfection was achieved in the majority of the medical devices inspected. Single-use papillotomes could no longer be rinsed in some cases after contamination. Of the 90 accessories that had undergone preliminary treatment in this manner, only 30 could be rendered free of microbes in the half cycle during steam or EO sterilisation. It was demonstrated that often the design of the instruments impeded reliable reprocessing. It was furthermore established that the potential savings were considerably lower than those commonly assumed.

Keywords: medical devices, endoscopy accessories, cleaning, disinfection, sterilisation, quality assurance

1 Introduction

Reports on cross contamination and infections with *Helicobacter pylori* or with the hepatitis C virus caused by reprocessed accessories for flexible endoscopes have been focusing attention increasingly in recent times on the quality of reprocessing for these instruments (1, 2). In addition to the problem of an instrument's design that is scarcely amenable to cleaning, the manufacturer's instructions for reprocessing these instruments often appear to be inadequate or hardly practicable in the everyday hospital setting.

Economic pressures and the major price differences between single- and multiple-use instruments provide a powerful incentive to reprocess single-use instruments, in order to reduce costs. To comply with legal demands for a validated reprocessing method (3), microbiological investigation methods are generally employed. These have been devised for the investigation of disinfection and sterilisation, i. e. antimicrobial processes, and are also suited to, and endowed with the necessary power for this field of application. In the absence of suitable alternatives, these methods

Klaus Roth, Sektion und Steinbeis-Transferzentrum für Minimal Invasive Chirurgie, Universitätsklinikum Tübingen, Waldhörlestrasse 22, D-72072 Tübingen, Prof. Dr. Peter Heeg, Klinikhygiene, Universitätsklinikum Tübingen, Calwer Strasse 7, 72076 Tübingen, Dr. Rudolf Reichl, Naturwissenschaftliches und Medizinisches Institut NMI, Markwiesenstrasse 55, D-72770 Reutlingen, C. Phillip Cogdill, Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 0176-1537, USA, Walter W. Bond M.S., RSCA Inc., 3366 Station Court, Lawrenceville, GA 30044, USA

are being employed to check the quality of cleaning, despite the fact that only subject to certain conditions do they permit sound conclusions to be drawn.

Set against this background, a study was conducted, to elucidate the potentials and limitations residing in the reprocessing of endoscopic accessories, at the Prüfzentrum für Medizinprodukte (PMP: Test Centre for Medical Devices) – a collaboration project by the Naturwissenschaftliches und Medizinisches Institut (NMI: Scientific and Medical Institute), Reutlingen, the Sektion and Steinbeis-Transferzentrum for Minimally Invasive Surgery and the department of hospital infection control of the University Hospital Tübingen.

The aim of the study was to ascertain the safety offered by the reprocessing of endoscopic accessories following a standardised reprocessing method, which was based on the customary hospital practice. To this effect, instruments were investigated which, by virtue of their intended clinical use and as per the classification by Spaulding (4) had to be used in a sterile condition, as they would penetrate the mucosa on being used as directed. Both multiple- and single-use instruments were selected. Attention was paid to ensuring that both types of instruments had been designed for the same application spectrum. According to the European requirements (5) and the German medical devices legislation (6), each reprocessing step, i. e. cleaning, disinfection and sterilisation, must be validated with suitable processes.

A further imperative targeted by the study was to highlight differences in the quality of reprocessing and to clarify whether and under what circumstances a safe device could be guaranteed. A preliminary cost evaluation was intended as a means of clarifying the economic feasibility of reprocessing.

2 Economic Feasibility Considerations

Various studies, both in the USA and in Germany, have in recent times focused on the financial investments for reprocessing endoscope accessories, with the reprocessing costs of reusable instruments being compared with those incurred on using single-use instruments as directed. In the case of reprocessing of single-use items, the same costs were assumed as those incurred for reprocessing reusable instruments.

Having compared the costs for employment of single-use biopsy forceps and reprocessable biopsy forceps,

Table 1 Cost comparison between reusable and single use biopsy forceps

| Study | Olympus | Yang | Yang | Birkner 1 | Birkner 2 | Birkner 3 | Birkner 4 |
|---------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| Device | Biopsyforceps |
| Purchase costs | 368.- DM | 415 \$ | 38 \$ | 38.81 DM | 449.46 DM | 563.50 DM | 353.12 DM |
| Repair costs | - | - | - | - | 1 352.7 DM | 221.35 DM | - |
| Number of uses | 27 | 19 | 1 | 1 | 212 | 68 | 141 |
| Purchase and repair costs | 13.63 DM | 21.85\$ | 38 \$ | 38.81 DM | 8.70 DM | 11.53 DM | 2.51 DM |
| Reprocessing costs | unknown | 16.56\$ | - | 0.01 DM | 3.33 DM | 17.33 DM | 14.36 DM |
| Costs per use | | 38.40 \$ | 38 \$ | 38.82 DM | 12.03 DM | 28.86 DM | 16.87 DM |

Table 2 Cost comparison between reusable and single use snares

| Study | Schwarck | Schwarck | Birkner 1 | Birkner 2 | Birkner 3 | Birkner 4 |
|--------------------|-----------|----------|-----------|-----------|-----------|-----------|
| Device | Snare | Snare | Snare | Snare | Snare | Snare |
| Purchase costs | 390.30 DM | 56.35 DM | 47.90 DM | 390.31 DM | 400.00 DM | 405.95 DM |
| Number of uses | 9 | 1 | 1 | 11 | 31 | 43 |
| Costs per use | 43.37 DM | - | - | 35.95 DM | 13.06 DM | 9.44 DM |
| Reprocessing costs | 9.22 DM | - | - | 4.95 DM | 16.18 DM | 19.84 DM |
| Costs per use | 52.59 DM | 56.35 DM | 47.90 DM | 40.90 DM | 30.39 DM | 30.64 DM |

Yang (7) came to the conclusion that only after a 20-fold deployment of reusable instruments could a price advantage be obtained over the use of single-use forceps. The observed service life of the reprocessed forceps was on average 20 deployments, with malfunctioning rapidly increasing already as from the 16th deployment. In addition to costs, Yang also focused on the quality of reprocessing and, after reprocessing, discovered on many locations on the reusable biopsy forceps microscopically still visible contaminants, deposits and rust. Some of the inspected instruments also evidenced kink points, which in some cases were possibly responsible for malfunctioning.

Yang's findings are in concordance with those of a study conducted in a gastroenterological practice in Germany with instruments of the same type (8). The first breakdowns were registered here already after the 12th use. But some forceps were still fully functional after 45 deployments. On completion of the study, 189 interventions had been performed with a total of 7 forceps, corresponding to an average service life of 27 deployments. No study indicated how many biopsies were conducted during an intervention with a single forceps.

Schwarck (9) compared in a study the costs for single- and multiple-use snares. Here too it was revealed that the potential savings per deployment were greatly dependent on the service life of the snares. Depending on manufacture, the cost savings per deployment ranged between DM 3.76 and DM 11.65. In the case of one type of snare, the costs of DM 17.92 incurred during use of reusable snares were even markedly higher than those of single-use snares.

A further study (10) at two hospitals and one medical practitioner's office produced similar findings as regards the costs for reusable polypectomy snares. Since the single-use snares used here as a comparison could, however, be procured for markedly more favourable prices, the deployment costs were accordingly lower and were less than those incurred for use of reusable snares.

On the other hand, the savings potential residing in reusable biopsy forceps in this study was greater than that of Yang's study. The costs per establishment ranged between DM 12.03 and DM 28.86 per deployment compared with DM 38.82 and DM 44.01 for use of single-use forceps.

The major differences in costs can be explained, on the one hand, by the markedly greater frequency of use which, however, was mostly associated with high repair costs. On the other hand, the cost component for reprocessing was also apparent, ranging in Germany between DM 3.33 and DM 17.33, but in the USA between \$ 10.83 and \$ 16.80 per reprocessing procedure. Major study-dependent differences have also been discerned as regards the procurement prices, both for reusable and single-use instruments (table 1 and 2).

Some users have hopes for making additional savings by repeatedly using single-use items. In general, after once using these instruments the user has the impression that further use is still by all means possible. A basic prerequisite for safe reuse is, however, validated reprocessing procedures and a high-performance quality assurance system, which monitors the success

Table 3 Description and material of the tested devices

| | Single use | Length [mm] | ø [mm] | Luer-Lock | Internal Lumen | Interior | Cover sheet |
|----------------|------------|-------------|--------|-----------|----------------|---------------------------------|--------------------|
| Biopsy forceps | Yes | 2400 | 2.2 | No | 1 | 2 polyfile steel wires | covered metal coil |
| Biopsy forceps | No | 2300 | 2.2 | No | 1 | 2 polyfile steel wires | metal coil |
| Papillotoms | Yes | 2000 | 2.0 | 2 | 3 | Cutting wire | PTFE tube |
| Papillotoms | No | 1820 | 1.8 | 1 | 1 | Cutting wire | PTFE tube |
| Dormia Basket | No | 2100 | 2.4 | 1 | 1 | polyfile steel wire with basket | PTFE tube |

of cleaning and makes provision for reproducible and reliable findings. Hence to the costs of reprocessing must also be added the costs of process validation and of implementation and maintenance of the quality assurance system.

The Canadian Healthcare Association estimated the validation costs alone to be US\$ 7584 per instrument type (11). In a similar study (12), these costs were even calculated to be between US\$ 39 000 and 51 000 depending on the instrument type. A German company conducting validated reprocessing on a wage basis estimates similar costs. The validation costs alone are around DM 23,000 per device group. The costs for process development, calibration of systems and test equipment, monitoring of process parameters, personnel training etc. must still be added.

3 Material and Methods

3.1 Inspected Instruments

Various types of instrument designs were inspected to determine their suitability for reprocessing. By way of example, the results obtained for 2 biopsy forceps and 2 papillotomes are described here, consisting of one single-use and one reusable instrument in each case. In addition, one reusable dormia basket was included in the inspection (table 3). The single-use instruments were delivered in a sterile condition, while the reusable instruments were sterilised before use with steam as per the manufacturer's instructions.

3.2 Methods of Detection

To verify the cleaning outcome, various methods of detection were employed and were selected as a function of their power.

3.2.1 Radionuclide Method (RNM)

The radionuclide method (RNM) serves to furnish proof of the cleaning action. A contamination of coagulable human blood with addition of radioactively marked macroalbumins permitted a quantitative evaluation of the cleaning quality with spatial resolution (13). Based on our own investigations, a surface was defined as being clean if the residual contaminants were not more than 5 counts per second.

3.2.2 Microbiological Inspection Methods

To verify the disinfection outcome, *S. aureus* ATCC 6538 and *P. aeruginosa* ATCC 15442 (10^6 to 10^7 cfu/ml baseline suspension) were employed according to the recommendation of the German Society for Hygiene and Microbiology (DGHM) (14). The instruments were contaminated with a suspension of heparinised sheep blood with addition of protamine and with the corresponding test organisms (15).

To verify the results of sterilisation, spore suspensions (0.5 to 5×10^6 /ml) of *B. stearothermophilus* ATCC 12980 were used for steam sterilisation and of *B. subtilis* var. *niger* ATCC 9372 (producer: Simicon, Munich) for gas sterilisation. The instruments were contaminated only with the spore suspension without blood challenge. To ascertain the recovery rate of the test organisms, corresponding investigations were conducted.

3.2.3 Test Procedure

The instruments were contaminated in a simulation model mimicking a worst case scenario. This model consists of a plexiglass box, with 30 cm long silicon tubes fitted on its upperside, via which the instruments are introduced into the box. Inside the box is a glass beaker in which the jaw parts of the instruments are immersed. A seal at the distal end of the tubes prevents loss of gas on insufflating air up to 15 mm Hg, in order to simulate the intraluminal pressure.

The markers needed for the individual detection methods are added to the coagulable blood and injected via another tube into the glass container in the box. The functional parts of the instruments are fully immersed in the blood and are repeatedly manipulated. As soon as the blood has coagulated, the instruments are removed from the box.

The reprocessing procedure has been standardised according to manufacturers' instructions, while calling upon our own experiences:

- 3 min preliminary rinsing with water at 30 °C
- 4 × rinsing of instruments (syringe) with enzymatic detergent (Terg-A-Zyme, Alconox, Inc., New York) if possible

- 10 min immersion in enzymatic detergent
- 5 min ultrasound with enzymatic detergent
- 3 min rinsing with tap water (on the outside)
- irrigation (syringe) with tap water, if possible
- drying by blowing out with compressed air
- drying of outside (towel)

The following concomitant measures were taken for disinfection after cleaning:

- Filling of the instruments (syringe) with 2% glutaraldehyde solution (Cidex; manuf.: Johnson & Johnson Medical, Arlington, Texas)
- Immersion in glutaraldehyde solution, 25 min at 20 °C (pH value: 7.9–8.9)
- 3 min rinsing with warm water at 30–35 °C
- Blowing out of internal lumens with compressed air
- Drying of instruments with compressed air

Sterilisation of the contaminated instruments was effected in the half cycle with steam (134 °C) or ethylene oxide (6% EO, 94% CO₂).

3.2.4 Investigation of Clinically Deployed Instruments

To furnish at least orientational data on the reprocessing quality of endoscopic accessories in clinical practice, reprocessed "critical" instruments from different hospitals were investigated for sterility. The instruments – predominantly biopsy forceps – had either been sterilised with steam or gas or subjected to high-level disinfection.

Inspected concomitantly were 10 single-use forceps, which had been reprocessed by a contractor. The instruments were dismantled into segments under sterile conditions in the laboratory and placed in typticase soybean broth. For some instruments, the segments were combined in sections in order to obtain a certain spatial resolution. The size of the entire 3 sections was chosen according to the RNM findings.

4 Results

4.1 Cleaning

In all cases, 7 instruments of each type were tested with RNM. With the exception of 2 papillotomes, the limit value of 5 counts/s was not achieved by any of the medical devices inspected. The instruments were considerably above the limit value in some cases. For example, the dormia basket after a very high baseline challenge, pointing to a large internal lumen, harboured more test contamination after cleaning than all other instruments before cleaning. The reusable biopsy forceps nonetheless achieved an average reduction to 13 counts/s, while there was hardly any perceptible reduction of contamination evidenced in the single-use version (figure 1).

The spatial resolution of the RNM provides information on the distribution of the contamination. Particularly

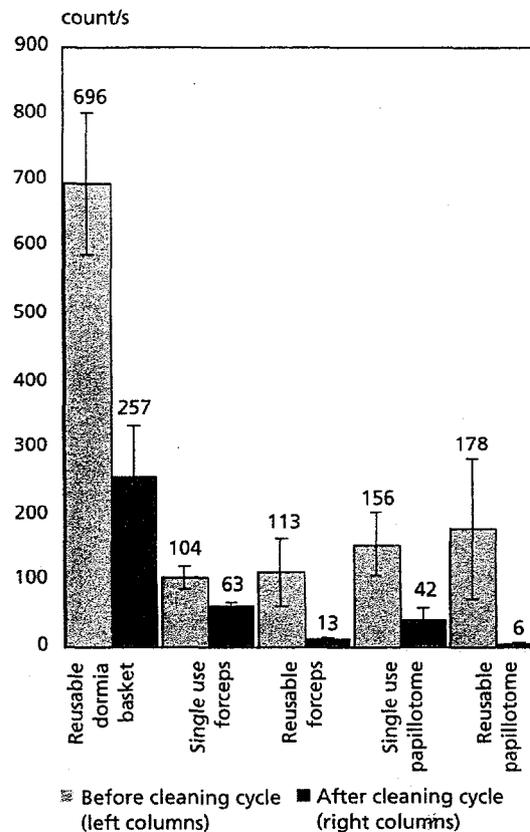


Figure 1 Mean activity

conspicuous in this respect is the single-use forceps which, while showing a slight reduction in activity, the latter was distributed over a greater length (figure 2).

4.2 Disinfection

The first test with *P. aeruginosa* for single-use instruments furnished such poor results that testing was discontinued. The single-use papillotomes could no longer in some cases be rinsed after contamination, with complete disinfection being achieved only for one instrument. Neither could one of the reusable papillotomes be rinsed, whereas the other 5 instruments of similar design were all satisfactorily disinfected (table 4).

4.3 Sterilisation

Examination of the control instruments showed that not all the instruments achieved the required baseline contamination of > 6 logs. Despite the, in some cases, markedly lower microbial contamination, it was possible to sterilise only 30 of the total 90 instruments (table 5).

4.4 Clinically Deployed Instruments

Only some of the instruments reprocessed within the hospital were sterile. Of the 25 multiple-use biopsy forceps inspected, 5 were sterile, 12 evidenced slight growth (less than 100 cfu/device); streptococci, enterococci or pseudomonads were detected in 7 devices

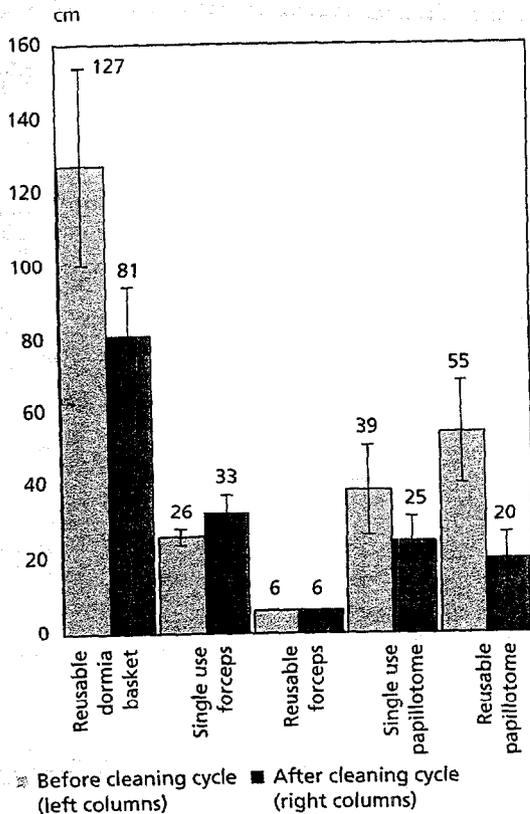


Figure 2 Mean distribution of contamination

(table 6). Overall, 10 reprocessed single-use biopsy forceps were also inspected. As opposed to the reusable forceps, these had been sterilised with EO. Only one forceps was sterile, with all others evidencing residuals microbial counts up to 50 cfu/device.

The scanning electron microscopic examination of the pull wire of a biopsy forceps in new condition and after reprocessing also proves that reprocessing was not successful (Figures 3 and 4).

5 Discussion

In view of the high costs for validation and quality management, reuse of single-use articles appears reasonable only in the case of expensive devices. At the same time, a certain minimum requirement must be assured, in order to distribute the costs among as many applications as possible. If the device is changed by the manufacturer, a new validation procedure is required, something which should be borne in mind in respect of the ephemeral life span of many medical devices.

The adoption of already validated procedures can be contemplated only if identical conditions are prevailing on one's own facilities; otherwise one has to conduct one's own validation. Our investigations also clearly indicate that even the manufacturers' instructions for reprocessing reusable instruments are totally inadequate. We are not aware of any detailed national guidelines for verification of cleaning.

Table 4 Results of the disinfection experiments

| Device | Reusable | <i>Pseudomonas aeruginosa</i> Disinfection results | | | <i>Staphylococcus aureus</i> Disinfection results | | |
|----------------|----------|---|---------|------|--|----|----|
| | | 1 | 2 | 3 | 1 | 2 | 3 |
| Biopsy forceps | No | -(0) | -(0) | -(0) | | | |
| Biopsy forceps | Yes | ++ | ++ | ++ | ++ | ++ | ++ |
| Papillotom | No | ++ | -(2.96) | -(0) | | | |
| Papillotom | Yes | -(4.52) | ++ | ++ | + | + | + |
| Dormia basket | Yes | ++ | + | ++ | ++ | ++ | ++ |

++ = reduction > 5 lg (no growth in quantitative and enrichment cultures)
 + = reduction > 5 lg (growth of test organisms in enrichment cultures only)
 - = reduction < 5 lg (reduction factor in brackets)

Table 5 Results of the sterilisation experiments

| Device | Reusable | <i>B. subtilis</i> ETO sterilisation results | | | <i>B. stearothermophilus</i> Steamsterilisation results | | |
|----------------|----------|---|--------|-----------|--|--------|-----------|
| | | Contr. (cfu) | Growth | No growth | Contr. (cfu) | Growth | No growth |
| Biopsy forceps | No | 6.14 | 7 | 2 | 4.36 | 4 | 5 |
| Biopsy forceps | Yes | 4.68 | 9 | 0 | 4.24 | 3 | 6 |
| Papillotom | No | 6.18 | 6 | 3 | 5.95 | 8 | 1 |
| Papillotom | Yes | 6.41 | 3 | 6 | 5.30 | 9 | 0 |
| Dormia basket | Yes | 5.95 | 2 | 7 | 6.34 | 9 | 0 |

Table 6 Results of the test with clinically used devices. Number of tested devices: 57, sterile: 15, unsterile: 42.

| | Third Party Reprocessor | | USA | | Japan | | Germany | |
|------------------------------|-------------------------|-----------|---------|-----------|---------|-----------|---------|-----------|
| | sterile | unsterile | sterile | unsterile | sterile | unsterile | sterile | unsterile |
| Single Use Biopsy Forceps | 1 | 9 | | | | | | |
| Reusable Biopsy Forceps | 2 | 8 | 2 | 5 | 3 | 11 | 2 | 5 |
| Single Use Ultratome | | | | | | | | 1 |
| Reusable Papillotome | | | | | | | | 1 |
| Reusable Dormia basket | | | | | | | 1 | |
| Single Use Dilatation Ballon | 4 | 1 | | | | | | |
| Single Use Guidewire | | 1 | | | | | | |
| Total | 7 | 19 | 2 | 5 | 3 | 11 | 3 | 7 |

For a number of reasons, manual reprocessing was chosen for the present investigation: many hospitals have no suitable washer/disinfectors for reprocessing endoscopes, cleaning performance varies for the different types of washer/disinfectors, and finally the advantage of manual reprocessing resides in the fact that a very high cleaning pressure (up to 5 bar) can be achieved, which is generally not possible in washer/disinfectors (0.3 to 0.5 bar). Ultrasonic cleaning was limited to 5 minutes, since a longer sonication period results in marked heating of the cleaning water, resulting in turn in protein denaturation and hence detracting from the cleaning performance.

The business management data collected here show that repeated use of the inspected single-use devices do not hold out prospects for financial savings due to the high validation costs. The differences in procurement prices of in some cases identical items, show that there is currently great movement in the market. A realistic cost estimate must absolutely take account of the individual needs of individual establishments. Skilled negotiations and corresponding acceptance commitments can secure considerable discounts in some cases. It is therefore difficult to estimate costs on a flat rate basis.

Especially the service life of the instruments, which ultimately exerts greatest influence on the costs, is frequently overestimated. Generally it is shorter than that normally assumed and hence poses a certain risk when making calculations. The service life of up to 200 deployments and more given in some studies is made possible only at the cost of high repairs. Concomitantly, logistics costs (e. g. dispatch for repair) are not featured in any study. Neither are costs emanating from prolonged operations due to failure of instruments taken into consideration. The potential savings, which even now are in some cases small, are quickly negated by these costs. Single-use instruments, conversely, permit accurate calculation of costs.

If in the case of some devices, the paucity of potential savings is a disincentive to using reusable endoscopy accessories, their use is all the more questionable from

the hygienic viewpoint. None of the inspected instrument types could be reprocessed reliably and safely. This failure was attributed less to an inadequate cleaning technique than to the instrument design.

If one considers the cleaning results obtained for the single-use biopsy forceps it becomes clear that the enzymatic detergent certainly does generate its action. The blood coagula were dissolved and the once again liquefied contaminants were able to spread out further in the instrument. The forceps makes no provision for cleaning the internal lumen, hence the dissolved soils are inevitably retained within the instrument. The ensuing disinfection results in renewed protein denaturation, which in all probability prevents the disinfectant from being distributed in the instrument. Conversely, while it was possible to rinse the dormia basket, adequate cleaning could not be assured due to the instrument design (247 counts/s). On the other hand, the disinfectant could apparently reach all inner surfaces, making provision for an adequate disinfection outcome.

The unsatisfactory sterilisation results achieved for these instruments are not unexpected, since effective cleaning is the prime precondition for successful sterilisation. It is precisely this example that clearly indicates that adequate cleaning cannot be necessarily inferred from good disinfection results. Furthermore, there were no reprocessing instructions available for this device. The manufacturer pointed out that the label "autoclavable" was enough. On further scrutiny, it was established that the device could be dismantled, thus considerably enhancing the cleaning effect. However, two persons were needed to assemble the instrument, as also confirmed by experienced endoscopy nurses.

Inspections of instruments reprocessed in the hospital confirm the impression of a completely inadequate outcome quality. For this reason, the following conclusions must be drawn:

- Due to the design features of these devices, effective quality assurance is currently not possible when reprocessing endoscopy accessories.

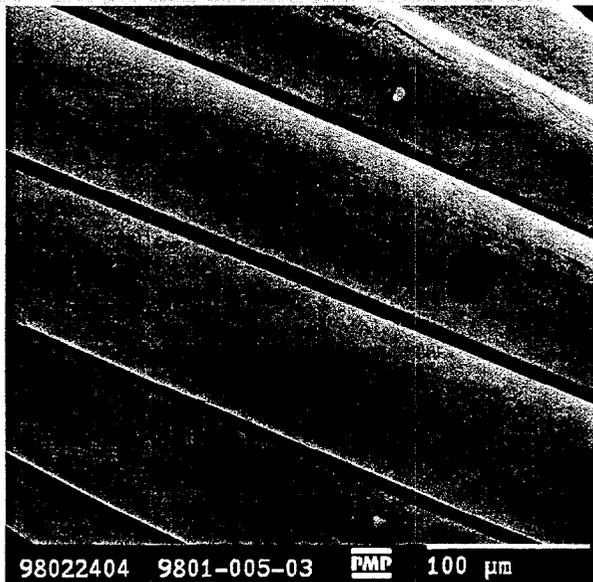


Figure 3 Pullwire in a reprocessible biopsy forceps in initial setting; location: 100 mm above the tip.

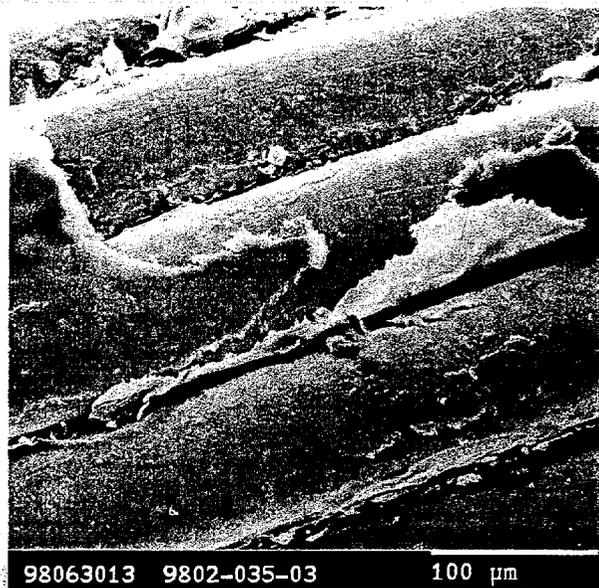


Figure 4 Pullwire in biopsy forceps, reprocessed after clinical use; location: 100 mm above the tip.

- The potential savings to be made from reprocessing single-use medical devices are on closer scrutiny – at least in the domain of endoscopy – essentially lower than generally assumed.
- The deployment costs for single- or multiple-use instruments often differ only minimally.
- As regards risk calculation, one must ask oneself whether, in view of the low potential savings, a risk to the patient's health should be recklessly disregarded.

Acknowledgement

The authors wish to thank Susanne Wagner for her carefully carrying out the microbiological tests, as well as the department of nuclear medicine of the University Hospital, Tübingen, especially Prof. Dr. Bares and Mr. Logemann, for their support. ■

References/Literatur

1. Bronowicki JP, Venard V, Botté C et al.: Patient-to-patient transmission of hepatitis C virus during colonoscopy. *N Engl J Med* 1997; 337: 237–240.
2. Akamatsu T, Tabata K, Hironaga M et al.: Transmission of *Helicobacter pylori* infection via flexible fiberoptic endoscopy. *Am J Infect Control* 1996; 24: 396–401.
3. Verordnung über das Errichten, Betreiben und Anwenden von Medizinprodukten (Medizinprodukte-Betreiberverordnung – MPBetreibV). BGBl 1998, I, 1762.
4. Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence CA, Block SS (eds.): *Disinfection, sterilization and preservation*. Philadelphia: Lea and Febiger, 1968: 517–531.
5. Richtlinie des Rates über Medizinprodukte vom 14. Juni 1993 (93/42 EWG). *AbI EG* 1993, Nr L 169, 1.
6. Gesetz über Medizinprodukte (Medizinproduktegesetz – MPG). BGBl 1994, I, 1963.
7. Yang RA: Cost and performance evaluation of disposable and reusable biopsy forceps in gastrointestinal endoscopy. Abstract Nr. 135; *Digestive Disease Week, 1997* Washington D.C.
8. Waldherr A, Fallstudie: die Biopsiezange; *Olympus informiert* 1/98: 4–5.
9. Schwark S: Einmalartikel oder Wiederaufbereitung. *Endoskopie heute* 1998; 11: 14–20.
10. Birkner B: Kostenvergleichsstudie verschiedener endoskopischer Accessoires in der gastrointestinalen Endoskopie. *Gastro-Nachrichten* 1998 Nr. 20: 3–6.
11. Canadian Healthcare Association: *The reuse of single use medical devices: Guidelines for Health Care Facilities*. Ottawa: CHA Press, 1996.
12. Reichert M: Single use devices – Program development. *AAMI & FDA Meeting* 14.–16. Nov. 1996, Los Angeles.
13. Schrimm H, Sieber JP, Heeg P, Roth K, Müller-Schauburg W, Keller KD, Bueß G: A new method for validating and verifying the cleaning of tubular instruments. *Zentr Steril* 1994; 2: 313–324.
14. Deutsche Gesellschaft für Hygiene und Mikrobiologie: *Richtlinie für die Prüfung und Bewertung chemischer Desinfektionsverfahren*. 1. Teilabschnitt (Stand 1. 1. 1981). Stuttgart: Fischer, 1981.
15. Deutsche Gesellschaft für Krankenhaushygiene: *Prüfung und Bewertung der Reinigungs- und Desinfektionswirkung von Endoskop-Dekontaminationsautomaten sowie -Desinfektionsautomaten*. *Hyg Med* 1995; 20: 40–47.

Abstracts for the 2000 FDA science forum from the OST room-mab.

Effects of Use and Reprocessing on Single Use Coronary Catheters. S. A. Brown¹, K. Merritt², V. M. Hitchins², and T. O. Woods¹. ¹*Division of Mechanics and Materials Science and* ²*Division of Life Sciences, CDRH/ FDA, Rockville Md-20852.*

Although sold for single use only, some medical devices, such as coronary catheters, are being processed for reuse. Over 400 PTCA and 300 EP catheters have been retrieved after single patient use at Walter Reed Army Hospital. After disinfection and cleaning, a variety of performance characteristics were determined, and then some were subjected to ETO sterilization and simulated reuse. The results demonstrated that cleaning was not a trivial problem. The balloon compliance data demonstrated model specific changes. Some catheters became more sticky making insertion more difficult. Some models of EP's were non-lumen, whereas others had hollow cores sometimes contaminated with blood. Damage to electrode seals exposed the lumens as well as copper wires connected to the electrodes. Unbeknownst to the user, subtle changes in device appearance may be associated with major changes in the performance of a used or reused device.

Effects of Different Sterilization Methods on Materials Used for Single Use Devices (SUDs) S. A. Brown¹, K. Merritt², T. O. Woods¹, and V. M. Hitchins². ¹*Division of Mechanics and Materials Science and* ²*Division of Life Sciences, CDRH/ FDA, Rockville Md-20852*

Driven by economic and time constraints, some medical centers and third parties are re-sterilizing SUDs for reuse. The steam autoclave is quick, but most plastics used in SUDs can not survive the temperature. Thus, a number of new methods are being introduced on the market. To date, this program has studied the effects of five: ETO, peracetic acid + peroxide (Steris), high temp formaldehyde, (Chemclave), low temp peroxide gas plasma - (Sterrad), and low temp peracetic acid gas plasma (Abtox). Tensile strength testing has shown that silicone elastomer is unaffected, whereas the strength of nylon, polyethylene and latex was reduced by some of the methods. Depending on the formulation the strength of polyurethane either increased or decreased. The results demonstrate that the effect of sterilization depends on the method and the materials used in the device.

The Effect of Repeated Ethylene Oxide Sterilization on the Mechanical Strength of Synthetic Absorbable Sutures T.O. Woods¹, S.A. Brown¹, K. Merritt², & V.M. Hitchins².

¹*Division of Mechanics & Materials Science,* ²*Division of Life Sciences, CDRH, FDA, Rockville, MD 20850*

Sutures that are opened but not used are commonly reprocessed for reuse, though they are labeled for single use. The effect of repeated ethylene oxide (EO) sterilization on the knot strength of three types of absorbable sutures was tested. Suture inner packs were repacked and EO sterilized using a clinical protocol. Mean knot strength was measured out of package and after 1 and 2 Re-EO cycles. As is true for other devices, it is not possible to make general conclusions. Suture strength was not affected for some sutures; others increased or decreased in strength. Seals on some inner packs were destroyed during reprocessing, exposing the absorbable sutures to ambient humidity. While seal loss might not cause an initial strength loss, exposure to increased humidity for an extended time will cause suture degradation and loss of strength.

The Effect of Reprocessing on Single Use Electrophysiology Catheters T.O. Woods¹, S.A. Brown¹, K. Merritt², & V.M. Hitchins². ¹*Division of Mechanics & Materials Science,* ²*Division of Life Sciences, CDRH, FDA, Rockville, MD 20850*

Electrophysiology catheters (EPs) are one of the single use devices that are most often reported to be reprocessed and reused. Once it has been established that a used device can be cleaned and re-sterilized, it is necessary to show that its mechanical behavior has not been adversely affected. Torque and trackability, two clinically relevant mechanical properties of EPs, will be determined for a solid and hollow configuration of one model of EP catheter. The two types reflect a manufacturing change that was made without a change in model name. The two properties will be determined for new, unused catheters; for catheters after use in a single patient; and for used catheters subjected to a number of cycles of

ethylene oxide sterilization, simulated reuse and reprocessing cycles. Results for the two catheter types will be compared.

Reprocessing Single Use Biopsy Forceps for Reuse K.Merritt, V.M. Hitchins, S.A. Brown, T.O. Woods *Division of Life Sciences, Division of Mechanics and Material Science, CDRH, FDA, Rockville MD 20852*

Economic considerations in the delivery of health care are enticing some facilities to reuse single use devices. Biopsy forceps, used together with an endoscope in gastrointestinal procedures, are among the devices that some entities are reprocessing. If these forceps are to be reused on another patient, they must be adequately cleaned and sterilized. We have been examining 3 types of single use GI biopsy forceps. These have an external polymer sheath covering the spring that operates either jaws or a snare. The snares have an open lumen. The jaw forceps appear sealed but actually there is an open lumen. Cleaning of these devices with a sequence of bleach, ultrasonic bath with detergent and enzyme, and water rinse appears to remove residual debris. However, drying the lumens of these devices is very difficult. Residual water may decrease the effectiveness of sterilization.

TEST REPORT

RP00418B Bioburden testing of GBF Biopsy Forceps re-processed by Vanguard Med. Concepts, Inc. Page 1 of 3

**BIOBURDEN TESTING OF GBF BIOPSY FORCEPS RE-PROCESSED BY
VANGUARD MEDICAL CONCEPTS, INC.**

- 1. OBJECTIVE:** The purpose of this test was to determine if these GBF Biopsy Forces that have been processed by Vanguard Medical Concepts, Inc. were in fact free of microorganisms.
- 2. RATIONALE:** The GBF Biopsy Forceps are disposable "single use" medical devices used to obtain biopsy tissue samples from different parts on the body. Each forceps is to be used on one patient only and then it is discarded properly. [REDACTED] has sent used biopsy forceps to Vanguard Medical Concepts for cleaning and decontamination and possible re-use on new patients.
- 3. SAMPLES:** Four (4 ea.) GBF Biopsy Forceps processed by Vanguard Medical Concepts, Inc. These forceps had outer jacket sleeves on them. Two had Yellow sleeves, one Orange, and one Red.

VENDOR: Boston Scientific Corporation
VENDOR LOT #: Vanguard Process Lot #'s 219919 and 220327

4. STERILIZATION: Units were sterilized with ETO by Vanguard on December 1996.

5. TEST PERFORMED:

Bioburden (aerobic and fungal)
Microbial ID of colony growth (Species and Germs)

6. RESULTS: Three out of four units tested had bioburden. Sample #1 had 32 CFU's, sample #2 had 12 CFU's and sample #4 had 8 CFU's. Fungal count was < 4 on all units. (See pages 2 and 3 for data)

The microbial identification detected the presence of Staphylococcus Aureus, Coagulase Neg. Staph., and a Corynebacterium species.

7. REFERENCE DOCUMENTS:

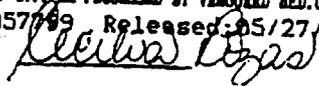
Viomed Laboratories Report Number R70144

8. CONCLUSIONS: Based on the results obtained from this bioburden test, it is obvious that the tested units were contaminated and not suitable to be used on new patients even though it was claimed that the units were sterilized with ETO.


VICTOR PEREIRA
Biocompatibility Engineer

DATE: 5-20-92

RELEASED

RP00418B
B.T. GBF B.F. RE-PROCESSED BY VANGUARD MED. CONCEPTS
EC 057/99 Released: 05/27/97
By: 

VIROMED

Mar 11.97 13:24 No.040 P-01/01

R 8004188
Re 2 + 3

ACCT #: 1128370

BOSTON SCIENTIFIC CORP.-MIAMISAMPLE: SYM01, VANGAURD PRO BIOPSY FORCEP

ATTN: VICTOR PEREIRA LOT #: 219929,220827,219929ACCESSION NO.: R70144

92

8600 NW 41 STREET
MIAMI FL 33166

ID: [REDACTED]
STERILITY DATE:

DATE COLLECTED: 02/20/97
TIME COLLECTED: NO TIME
DATE RECEIVED: 03/04/97
DATE REPORTED: 03/11/97

STERILITY METHOD:
MANUF SOURCE: BSC/SYMBIOSIS

P.O.:1201
NOTES:

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

AEROBIC AND FUNGAL BIOBURDEN

DATE:030497

| | | | | | |
|---------|---|----------------|--------|---|----------------|
| AEROBIC | 1 | < 4 CFU YELLOW | FUNGAL | 1 | < 4 CFU YELLOW |
| AEROBIC | 2 | 12 CFU YELLOW | FUNGAL | 2 | < 4 CFU YELLOW |
| AEROBIC | 3 | 32 CFU CRANGE | FUNGAL | 3 | < 4 CFU ORANGE |
| AEROBIC | 4 | 8 CFU RED | FUNGAL | 4 | < 4 CFU RED |

TECH/REVIEWER J.MACKCOW/I.KOENDERS

VIROMED

Mar 13.97 17:41 No.058 P.01/01

12900418B
Mx 293

ACCT #: 1128370
 BOSTON SCIENTIFIC CORP. - MIAMI SAMPLE: SYM01, VANGAURD PRO BIOPSY FORCEP
 ATTN: VICTOR PEREIRA LOT #: 219929, 220827, 219929 ACCESSION NO.: R70145
 09
 8600 NW 41 STREET ID: [REDACTED] DATE COLLECTED: 02/20/97
 MIAMI FL 33166 STERILITY DATE: TIME COLLECTED: NO TIME
 DATE RECEIVED: 03/04/97
 DATE REPORTED: 03/13/97

STERILITY METHOD:
 MANUF SOURCE: BSC/SYMBIOSIS

P.O.: 1201
 NOTES:

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

BACTERIAL ID 1

- BACTERIAL ID 1 - STAPHYLOCOCCUS AUREUS
- BACTERIAL ID 2 - COAGULASE NEGATIVE STAPH
- BACTERIAL ID 3 - CORYNEBACTERIUM SPECIES

TECH/REVIEWER J. HICKMAN/J. MACKCOW



ANALYSIS OF REPROCESSED SINGLE USE DEVICES

Summary of Study Activities (10/20/97)

Nine reprocessed devices were received from Boston Scientific. All of these devices were biopsy forceps manufactured by several different manufacturers and reprocessed by several different companies.

These devices were reprocessed using both steam and Ethylene Oxide and came packaged ready for use.

The devices were separated into two groups. Group 1 consisted of 4 instruments that would be subjected to laboratory testing to determine sterility and cytotoxicity. Group 2 consisted of 5 instruments that would be subjected to functionality testing and destructive visual (microscopic) analysis.

Group 1

The 4 instruments in Group 1 have been subjected to laboratory testing and the results have been received.

Instrument BSC 97820A: A Microvasive Radial Jaw biopsy forceps.
Processed by: *Vanguard Medical Concepts*
Sterilized using: *Ethylene Oxide*
Date: *April 97* Lot #: *222876*

Testing and Results: The instrument was subjected to a USP Product Sterility Test (SCD-FTM) by immersion. Testing was performed by ViroMED Laboratories. This instrument showed positive on day 7. Organism was identified as fungal.

Instrument BSC 97820B: An Olympus biopsy forceps.
Processed by: *Unknown Healthcare Facility*
Sterilized using: *Steam*
Date: *Unknown* Lot #: *Unknown*

Instrument BSC 97820B (cont)

Testing and Results: The instrument was subjected to a USP Product Sterility Test (SCD-FTM) by immersion. Testing was performed by ViroMED Laboratories. This instrument showed positive on day 7. Organism was identified as gram-positive cocci.

Instrument BSC 97820C: A Wilson-Cook biopsy forceps.
Processed by: *Unknown Healthcare Facility*
Sterilized using: *Steam*
Date: *July 18, 97* Lot #: *44*

Testing and Results: The instrument was subjected to a USP Product Sterility Test (SCD-FTM) by immersion. Testing was performed by ViroMED Laboratories. This instrument showed no growth through the 14 day incubation period.

Instrument BSC 97820D: A Microvase Radial Jaw biopsy forceps.
Processed by: *Vanguard Medical Concepts*
Sterilized using: *Ethylene Oxide*
Date: *April 97* Lot #: *222876*

Testing and Results: The instrument was subjected to Cytotoxicity Testing USP MEM Elution Using L-929 Mouse Fibroblast Cells. Testing was performed by ViroMED Laboratories. This instrument showed no signs of toxicity.

Group 2

The 5 instruments in Group 2 have been visually inspected, subjected to the functionality testing outlined in Boston Scientific Corporation/Symbiosis Quality Assurance Procedure QP90123S "Functional and Visual Lot Audit, GBF". If a device fails one functionality test it is considered unacceptable for use. **NOTE:** Boston Scientific quality acceptance standards may exceed those of other manufacturers and if a device manufactured by a third party fails, it may not be due to reprocessing, but due to lower manufacturing standards.

Once functionality testing of the devices was completed, the devices were subjected to destructive visual analysis. In this portion of the study the devices are disassembled and examined using a microscope (maximum magnification is 40X). Additionally, hardened particles found on the devices during this examination that were expected of being blood were tested.

Instrument BSC 97820E: An American Catheter biopsy forceps.
Processed by: *American Catheter, Corp.*
Sterilized using: *Ethylene Oxide*
Date: *Unknown* Lot #: *707411*

Visual Examination: The end cap had fallen off the end effector in the bag; No apparent damage to the sheath, however there was a slight dust on the sheath that came off when the coil was pulled between two fingers; No damage or plaque build up on the end effector; Distal end was free of debris and deterioration.

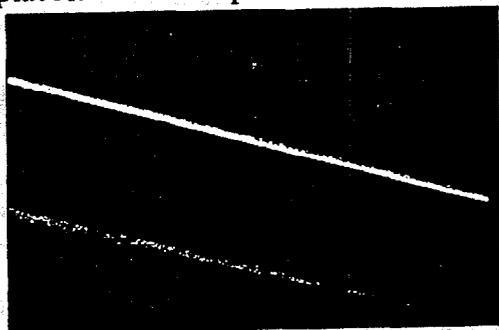
Testing and Results:

| | |
|------------------------|------|
| Loop Test: | Pass |
| Ring Gage: | Fail |
| Rotation & Engagement: | Pass |
| Bite Test: | Pass |
| Pull Test: | Fail |



Microscopic Examination: The microscopic evaluation of the instrument revealed debris build-up on the end effector as well as the interior of the clevis where the pull wire attaches to the end effector actuators. Samples of this debris were removed and found to contain blood residue. The pull wire was removed and found to be coated with rust and other debris from the bottom of the end effector

to 48 cm up the coil. This debris was tested and found to contain blood residue. Examination of the sheath found debris, as well as fibers adhering to it's outside. The sheath was removed from the coil and rust was found on the surface of the coil in several places. Microscopic examination of the



distal end and handle revealed stress fractures in the plastic of the handle that could lead to failure of the instrument during use.

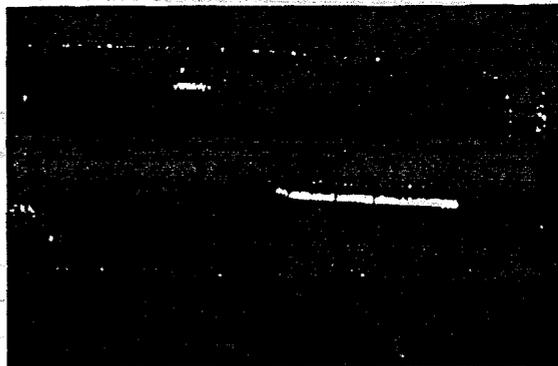
Instrument BSC 97820F: An Olympus biopsy forceps.
Processed by: *Unknown Healthcare Facility*
Sterilized using: *Steam*
Date: *Unknown* Lot #: *21533*

Visual Examination: No apparent damage to the coil; No damage or plaque build up on the end effector; Distal end was free of debris and deterioration, however, there were several black dots on the thumb hole, that will be examined further.

Testing and Results:

| | |
|------------------------|------|
| Loop Test: | Pass |
| Ring Gage: | Pass |
| Rotation & Engagement: | Pass |
| Bite Test: | Fail |
| Pull Test: | Pass |

Microscopic Examination: The microscopic evaluation of the instrument revealed debris build-up on the end effector as well as the interior of the clevis where the pull wire attaches to the end effector actuator. Samples of this debris was removed and found to contain blood residue. The pull wire was removed and found to be coated with rust and other debris from the bottom of the end effector to 12 cm up the coil. This debris was tested and found to contain blood residue. Examination of the coil found debris, as well as fibers adhering to it's outside. Microscopic examination of the distal end and handle did not reveal any debris or other discrepancies.



Instrument BSC 97820G: An Pentax biopsy forceps.
Processed by: *Unknown Healthcare Facility*
Sterilized using: *Steam*
Date: *July 23, 97* Lot #: *42*

Visual Examination: No apparent damage to the coil; No damage or plaque build up on the end effector; Distal end was free of debris and deterioration, however, there were several black dots on the shaft, that will be examined further.

Testing and Results:

| | |
|------------------------|------|
| Loop Test: | Pass |
| Ring Gage: | Pass |
| Rotation & Engagement: | Pass |
| Bite Test: | Pass |
| Pull Test: | Pass |

Instrument BSC 97820G (cont)

Microscopic Examination: The microscopic evaluation of the instrument revealed debris build-up on the end effector as well as the interior of the clevis where the pull wire attaches to the end effector actuator.



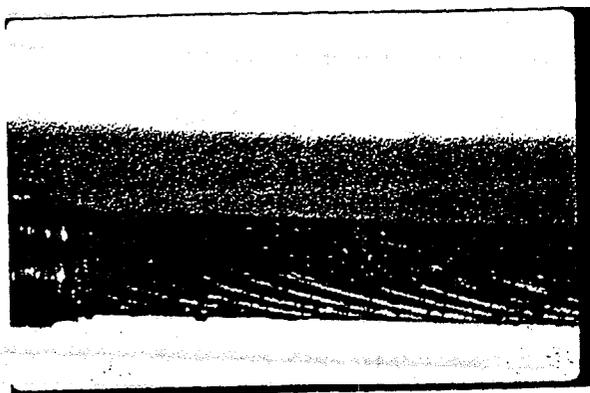
Samples of this debris was removed and found to contain blood residue. The pull wire was removed and found to be coated with rust and other debris from the bottom of the end effector to 5.5 cm up the coil. This debris was tested and found to contain blood residue. Examination of the coil found debris, as well as fibers adhering to it's outside. Microscopic examination of the spot on the handle is consistent with blood, and

the spot was tested and found to be positive for blood residue.

Instrument BSC 97820H: An Pentax biopsy forceps.
Processed by: *Unknown Healthcare Facility*
Sterilized using: *Steam*
Date: *July 23, 97* Lot #: *43*

Visual Examination: There is a double "kink" in the coil approximately 40 cm from the bottom of the strain relief; The tip of the needle within the jaws of the end effector is broken; Distal end was free of debris and deterioration.

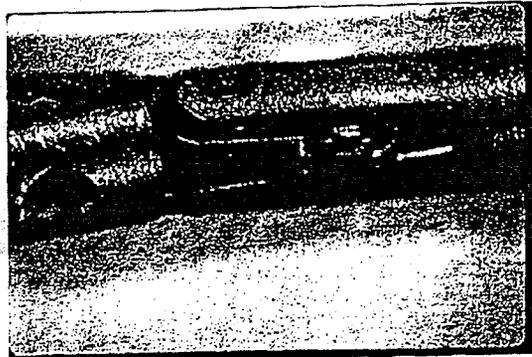
| | | |
|-----------------------------|------------------------|------|
| Testing and Results: | Loop Test: | Pass |
| | Ring Gage: | Pass |
| | Rotation & Engagement: | Pass |
| | Bite Test: | Fail |
| | Pull Test: | Pass |



Microscopic Examination: The microscopic evaluation of the instrument revealed debris build-up on the end effector as well as the interior of the clevis where the pull wire attaches to the end effector actuator. Samples of this debris was removed and found to contain blood residue. The needle was examined and found to be broken. The pull wire was removed and found to be coated with rust and other debris from the bottom of the

end effector to 7 cm up the coil. This debris was tested and found to contain blood

residue. Examination of the coil found debris, as well as fibers adhering to it's outside. Microscopic examination of the distal end and handle did not reveal any debris or other discrepancies.



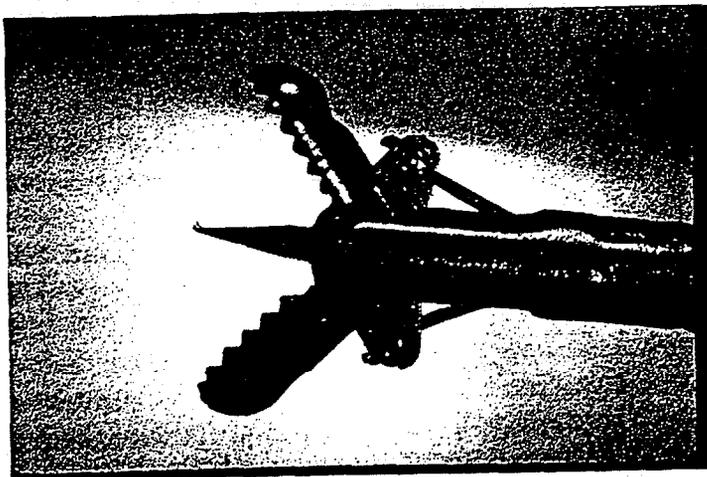
Instrument BSC 97820I: A Microvasive Radial Jaw biopsy forceps.
Processed by: *Orris Inc.*
Sterilized using: *Ethylene Oxide*
Date: *Unknown* Lot #: *97051211*

Visual Examination: No apparent damage to the sheath; No damage or plaque build up on the end effector, however the end effector appears to be corroded; Distal end was free of debris and deterioration.

Testing and Results:

| | |
|------------------------|------|
| Loop Test: | Pass |
| Ring Gage: | Pass |
| Rotation & Engagement: | Pass |
| Bite Test: | Pass |
| Pull Test: | Pass |

Microscopic Examination: The microscopic evaluation of the instrument did not reveal any debris build-up on the end effector or the interior of the clevis where the pull wire attaches to the end effector actuator. Some fibers were present on the needle and the jaws. When tested these fibers did not indicate the presence of blood residue. The pull wire was removed and found to be



free of debris or corrosion. Microscopic examination of the distal end and handle did not reveal any debris or other discrepancies. These findings are consistent with a device that had not been used prior to sterilization.

OBJECT #: 1128065
 STERIOLOGICS
 ATTN: CHRIS COMBS
 10248 NW 47TH ST
 SUNRISE FL 33351

SAMPLE: STE15, BSC 970820D
 LOT #: NA
 ID:
 STERILITY DATE:

ACCESSION NO.: R7057785
 DATE COLLECTED: NO DATE
 TIME COLLECTED: NO TIME
 DATE RECEIVED: 08/26/97
 DATE REPORTED: 09/04/97

STERILITY METHOD: ETHYLENE OXIDE
 MANFU SOURCE:

NO.: 970821-6
 NOTES:

| TEST REPORT | RESULT | METHOD |
|-------------------------------|---------------------|--|
| MEM ELUTION L-929 CELLS (USP) | | |
| POSITIVE CONTROL | | |
| 24 HR RESULTS | 4/4 ; 48 HR RESULTS | "4" SEVERE TOXICITY OBSERVED 4/4 |
| INTERMEDIATE CONTROL | | |
| 24 HR RESULTS | 2/2 ; 48 HR RESULTS | "2" MILD TOXICITY OBSERVED 2/2 |
| NEGATIVE CONTROL | | |
| 24 HR RESULTS | 0/0 ; 48 HR RESULTS | "0" NO TOXICITY OBSERVED 0/0 |
| CELL CONTROL | | |
| 24 HR RESULTS | 0/0 ; 48 HR RESULTS | "0" NO TOXICITY OBSERVED 0/0 |
| SAMPLE | | |
| 24 HR RESULTS | 0/0 ; 48 HR RESULTS | "0" NO TOXICITY OBSERVED - PASS 0/0 |

RELEASED AT 48 HOURS PER USP 23 GUIDELINES.

INTERPRETATION

| GRADE | REACTIVITY | CELL APPEARANCE |
|-------|------------|---|
| 0 | NONE | DISCRETE INTRACYTOPLASTIC GRANULES; NO CELL LYSIS |
| 1 | SLIGHT | NOT MORE THAN 20% OF CELLS ARE ROUND, LOOSELY ATTACHED, WITHOUT GRANULES, OCCASIONAL CELL LYSIS |
| 2 | MILD | PRESENT NOT MORE THAN 50% OF CELLS ARE ROUND, LOOSELY ATTACHED, SOME PLAQUES AND MODERATE CELL LYSIS |
| 3 | MODERATE | NOT MORE THAN 70% OF THE CELLS ARE |

OBJECT #: 1128065
STERIOLOGICS
ATTN: CHRIS COMBS
248 NW 47TH ST
SUNRISE FL 33351

SAMPLE: STE15, BSC 970820D
LOT #: NA
ID:
STERILITY DATE:

ACCESSION NO.: R7057785
DATE COLLECTED: NO DATE
TIME COLLECTED: NO TIME
DATE RECEIVED: 08/26/97
DATE REPORTED: 09/04/97

STERILITY METHOD: ETHYLENE OXIDE
MANFU SOURCE:

Q.O.: 970821-6

NOTES:

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

| | | |
|---|--------|--|
| 4 | SEVERE | LYSED OR DISPLAY CPE TOTAL OR NEARLY TOTAL DESTRUCTION OF THE CELL LAYER |
|---|--------|--|

SAMPLES DISPLAYING SCORES OF "0", "1", OR "2" THROUGHOUT THE 72 HOUR TEST PERIOD ARE CONSIDERED NONTOXIC FOR THE TEST SYSTEM.
SAMPLES DISPLAYING A SCORE OF "3" DURING THE TEST PERIOD ARE CONSIDERED MODERATELY TOXIC FOR THIS TEST SYSTEM.
SAMPLES DISPLAYING A SCORE OF "4" AT ANY POINT IN THE 72 HOUR TEST PERIOD ARE CONSIDERED TOXIC FOR THIS TEST SYSTEM.

SAMPLES ARE EXTRACTED AT 37 PLUS OR MINUS 1 DEGREE, 85 PLUS OR MINUS 15 PERCENT HUMIDITY AND 6 PLUS OR MINUS 1 PERCENT CO2. ONCE EXTRACTS ARE INOCULATED ONTO CELL LINE THE CELLS ARE INCUBATED UNDER THE SAME CONDITIONS.

62.4 GRAMS OF SAMPLE WERE EXTRACTED IN 312 ML OF MEM.

EXTRACTION RATIO BY WEIGHT IS 4 GRAMS PER 20 ML.
EXTRACTION RATION BY SURFACE AREA IS 60 CM2 PER 20 ML FOR TUBING OR FILM > 0.5 MM THICK AND 120 CM2 FOR TUBING OR FILM < 0.5 MM THICK.
CONCLUSION: SAMPLE IS CONSIDERED NONTOXIC PER VIROMED SOP.

TECH/REVIEWER J.MACKCOW/I.KOENDERS

*** FINAL REPORT ***

VIROMED

ALCT #: 1128065
STERIOLOGICS
ATTN: CHRIS COMBS
10248 NW 47TH ST
SUNRISE FL 33351

SAMPLE: STE15,BSC 970820A,970820B,970820C
LOT #: NA
ID:
STERILITY DATE:

ACCESSION NO.: R7057794
DATE COLLECTED: NO DATE
TIME COLLECTED: NO TIME
DATE RECEIVED: 08/26/97
DATE REPORTED: 09/09/97

STERILITY METHOD: ETHYLENE OXIDE
MANFU SOURCE:

P.O.:970821-6
NOTES:

| TEST REPORT | RESULT | METHOD |
|-----------------------------------|--------|--------|
| USP PRODUCT STERILITY-EXTRA LARGE | | |

PROCEDURE/TEST METHOD:
11-CONT-02-8300D / Product Sterility by Immersion

TEST ACCEPTANCE CRITERIA:
1. Positive controls must be positive
2. Negative controls must be negative

| MEDIA TYPE | INCUBATION | |
|----------------------|------------|------|
| | TEMP (C) | DAYS |
| Tryptic Soy Broth | 23-25 | 14 |
| Thioglycollate Broth | 33-35 | 14 |

TEST RESULTS:
Positive Media Control:
Control Organism - B. Subtilis
Positive in Tryptic Soy Broth
Positive in Thioglycollate Broth
Negative Media Control
No growth after 14 days

| CYCLE INFORMATION | NUMBER OF TESTS | NUMBER OF POSITIVES |
|-------------------|-----------------|---------------------|
| | 3 | 2 |

PRODUCT A WAS POSITIVE ON DAY 7. ORGANISM WAS FUNGAL GROWTH.
PRODUCT B WAS POSITIVE ON DAY 7. ORGANISM WAS GRAM POSITIVE COCCI.

TECH/REVIEWER J.MACKCOW/I.KOENDERS

BSC97820A



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

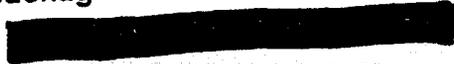
CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Tracking No: 865784

Desc: BIOPSY FORCEP LOWER GI WNEEDLE

Uses: 1

Caution: Federal Law (USA) restricts the use of
this device to use by or on order of a physician.
Follow recommended hospital procedure.



Peel Here

Baxter

Sterilization Pouch

BSC 97820B

STAIN & WASH
12 169 5

tear rate

100-1000

BSC 97820C



STATE KILLS
PARADES OR OTHERS
6-8-17-77

REPT APPROV

BSC 97820D

LOT NO.

2876



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Tracking No: 865789

Desc: BIOPSY FORCEP LOWER GI W/NEEDLE

Uses: 1

Caution: Federal Law (USA) restricts the use of
this device to use by or on order of a physician.

Follow recommended hospital procedure.



Peel Here.

BSC 97820E

Consignment Forceps

| | | | | | | |
|----------|-------|-------|-------|-------|-------|-------|
| PART # - | 7200 | 7210 | 7220 | 7230 | 7240S | 7250 |
| | 7200S | 7210S | 7220S | 7230S | 7245S | 7250S |

DESCRIPTION -

BIOPSY FORCEPS
NEEDLE / NO NEEDLE
COLD / HOT

LENGTH - 160 cm / 230 cm

DIAMETER - 2.4 mm / 3.3 mm

LOT # - 7074 SERIAL # - 463

NOTE - STERILIZED WITH ETO.

CAUTION - FEDERAL USA LAW RESTRICTS THIS DEVICE TO THE SALE BY OR ON THE ORDER OF A PHYSICIAN. FOR ONE TIME USE ONLY

STERILE - CONTENTS STERILE UNLESS PACKAGE IS OPENED OR DAMAGED.



AMERICAN CATHETER, CORP.

10061 Amberwood Road • Ft. Myers, FL 33913 USA

(800) 345-6714

FAX (941) 768-9286

A Subsidiary of International Medical Enterprises

Tower DualPeel® Sterilization Pouch

Blue bar darkens when Steam processed.
Circle appears when Gas processed.

BSC 9 / 820F



STERILIZATION POUCH
BSC 9 / 820F
2 153 3

BSC 97320G

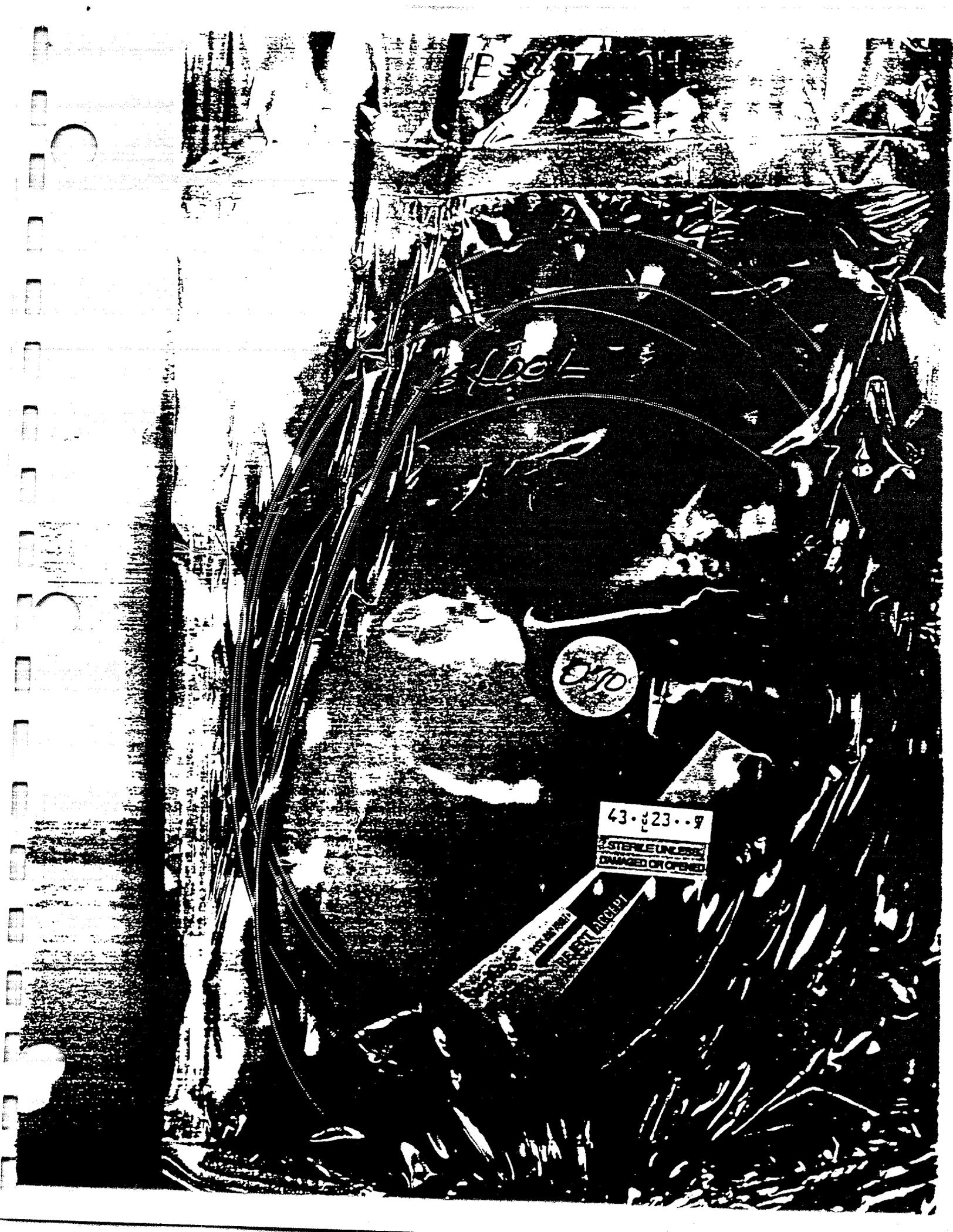
KW 2415

MOBIL BOOK II

3400

069

42.423.0.9
STERILE UNLESS
INDICATED OTHERWISE



3-1001

EVO

43-23007

STERILE UNLESS
DAMAGED OR OPENED

STERILE
UNLESS
DAMAGED OR
OPENED

BSC 978201

ORRIS

MICROVASCULAR
SURGICAL INSTRUMENT

ST. LOUIS HEALTH CENTER
ST. LOUIS
MISSOURI
63103

MANUFACTURED BY
MICROVASCULAR BOSTON SCIENTIFIC
WATON MA 01760

Single Use Only

Sterile: Sterilized with ethylene oxide gas.

Contents sterile unless package has been opened or damaged. Do not use open or damaged packages.

Reprocessed by: ORRIS, Inc., Houston, TX, 77099

Caution: Federal law restricts sale of this device to or on the order of a physician.

PMP



Prüfzentrum für Medizinprodukte

ein Projekt des

Naturwissenschaftlichen und Medizinischen Instituts,
Reutlingen, Leitung: Dr. R. E. Müller
in Kooperation mit



der Sektion und dem Steinbeis-Transferzentrum
für Minimal Invasive Chirurgie, Tübingen
Leitung: Prof. Dr. G. Bueß



der Klinikhygiene, Tübingen
Leitung: Prof. Dr. P. Heeg



Leitung: Dr. R. Reichl 0 71 21 / 51 53 00

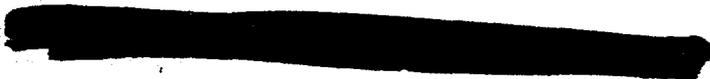
Klaus Roth 0 70 71 / 2 98 12 39

Tübingen, den 31. März 1999

EXAMINATION OF DEVICES, REPROCESSED BY VANGUARD

DECLARED TO BE STERILE

DEVICES EVALUATED WERE REPROCESSED & REPACKAGED FOR :



PERFORMING LABORATORY:

PMP

THE CENTER FOR THE TESTING OF MEDICAL PRODUCTS
UNIVERSITY OF TUEBINGEN
WALDHOERNLESTRASSE 22
D - 72072 TUEBINGEN

Eighteen single use devices, which were reprocessed by a third party reprocessor, were obtained from the hospital at random and sent to PMP, and tested for claims of sterility and cleanliness. All of these devices are originally labeled for single use and have been manufactured by Microvasive, Boston Scientific Corporation.

Reprocessing was performed by Vanguard, Medical Concepts, Inc. Lakeland Florida. The devices have been reprocessed, repacked and registered and were at the hospital awaiting patient use. The following data are documented on the package (See Attachment I), the hospital believed the reprocessor's label claims:

- the reprocessor
- the customer (hospital)
- the manufacturer
- Tracking No.
- Mfg-Cat-No:
- Description of the device
- Lot Number
- Sterilization Date
- Number of Uses

The label includes a bar code sticker for documentation.

Tests were performed in

February/March 1999

For sterility testing, standard microbiological procedures with aseptic technic have been used.

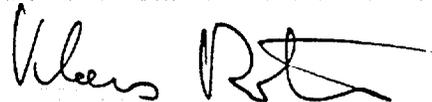
Light microscopy, Scanning electron microscopy and photoelectron spectroscopy delivers additional information on the cleanliness of the devices. Results of these technics are documented in attachment 2.

The selection of the devices for the different procedures has been done by random selection.

For documentation and identification of the devices the sterile bags were numbered by the laboratory.

Director of study:

Klaus Roth



Microbiological testing:

Prof. Dr. Peter Heeg

Microscopy and spectroscopy

Dr. Rudolf Reichl

Sterility testing

We used the following procedure

Recovery

Radial jaw and Hot biopsy forceps:

- Aseptically cut 30 cm of the tip and also the following 30 cm segment and put them into separate sterile tubes (containing 50 ml broth)
- Aseptically cut the rest of the instrument also into 10 cm segments and collect them in another tube (containing 50 ml broth)
- vortex the 50 ml-tubes for 30 seconds and shake them again 30 seconds manually
- shake the beakers for 15 mins at 300 mins -1
- plate 1 ml and spiralplate also 92 µl on Columbia-blood-agar (the controls and also the controll-dilutions only need to be spiralplated)
- incubate the broth for 7 days at 37°C

Examination of reprocessed devices (declared to be sterile)
 reprocessed by Vanguard Medical Concepts, Inc. Lakeland, Florida

22.2.99

| Nr.: | Typ2 | cfu/ml (1 ml) | Volume (ml) Growth (+/-) | Differentiation cfu per device |
|------|---|------------------|-------------------------------------|---|
| 1 | Radial Jaw 0 - 10 cm 10 - 20 cm rest of device | 0 0 15 | 50 ml (-) 50 ml (+) 50 ml (+) | totally: 750 - 800 0 < 50 Mkz, α-hemolytic streptococci 750 Mkz, < 50 E. faecium |
| 2 | Radial Jaw 0 - 10 cm 10 - 20 cm rest of device | 0 0 0 | 50 ml (-) 50 ml (-) 50 ml (+) | totally: < 50 0 0 < 50 E. faecium |
| 3 | Radial Jaw 0 - 10 cm 10 - 20 cm rest of device | 0 0 1 | 50 ml (-) 50 ml (+) 50 ml (+) | totally: 50 - 100 0 < 50 E. faecium < 50 E. faecium, 50 Mkz |

| | | | | |
|---|---|-------------|-------------------------------------|---|
| 1 | Hot Biopsy 0 - 10 cm 10 - 20 cm rest of device | 0 0 1 | 50 ml (-) 50 ml (-) 50 ml (+) | totally: 50 - 100 0 0 50 Mkz, < 50 E. faecium |
| 2 | Hot Biopsy 0 - 10 cm 10 - 20 cm rest of device | 0 0 0 | 50 ml (-) 50 ml (-) 50 ml (+) | totally: < 50 0 0 < 50 E. faecium |
| 3 | Hot Biopsy 0 - 10 cm 10 - 20 cm rest of device | 5 0 0 | 50 ml (+) 50 ml (-) 50 ml (+) | totally: 250 - 300 100 Mkz, 150 Spo 0 < 50 E. faecium, Spo |

Spo = aerobic spore forming organism

Mkz = micrococcaceae

Examination of reprocessed devices (declared to be sterile)
 reprocessed by Vanguard Medical Concepts, Inc. Lakeland, Florida

3.3.99

| Nr.: | Type | cfu/ml (1 ml) | Volume (ml) Growth (+/-) | Differentiation cfu per device |
|------|----------------|------------------|-----------------------------|--|
| 9 | Radial Jaw | | | totally: < 50 |
| | 0 - 10 cm | 0 | 50 ml (-) | 0 |
| | 10 - 20 cm | 0 | 50 ml (-) | 0 |
| | rest of device | 0 | 50 ml (+) | < 50 Corynebakterium |
| 10 | Radial Jaw | | | totally: 0 |
| | 0 - 10 cm | 0 | 50 ml (-) | 0 |
| | 10 - 20 cm | 0 | 50 ml (-) | 0 |
| | rest of device | 0 | 50 ml (-) | 0 |
| 12 | Radial Jaw | | | totally: 0 |
| | 0 - 10 cm | 0 | 50 ml (-) | 0 |
| | 10 - 20 cm | 0 | 50 ml (-) | 0 |
| | rest of device | 0 | 50 ml (-) | 0 |
| 13 | Radial Jaw | | | totally: < 100 |
| | 0 - 10 cm | 0 | 50 ml (+) | < 50 Mkz |
| | 10 - 20 cm | 0 | 50 ml (+) | < 50 gram-negative non fermenting rods |
| | rest of device | 0 | 50 ml (-) | 0 |
| 15 | Hot Biopsy | | | totally: 0 |
| | 0 - 10 cm | 0 | 50 ml (-) | 0 |
| | 10 - 20 cm | 0 | 50 ml (-) | 0 |
| | rest of device | 0 | 50 ml (-) | 0 |
| 16 | Hot Biopsy | | | totally: 0 |
| | 0 - 10 cm | 0 | 50 ml (-) | 0 |
| | 10 - 20 cm | 0 | 50 ml (-) | 0 |
| | rest of device | 0 | 50 ml (-) | 0 |
| 17 | Hot Biopsy | | | totally: < 50 |
| | 0 - 10 cm | 0 | 50 ml (-) | 0 |
| | 10 - 20 cm | 0 | 50 ml (-) | 0 |
| | rest of device | 0 | 50 ml (+) | < 50 Mkz |
| 18 | Hot Biopsy | | | totally: 0 |
| | 0 - 10 cm | 0 | 50 ml (-) | 0 |
| | 10 - 20 cm | 0 | 50 ml (-) | 0 |
| | rest of device | 0 | 50 ml (-) | 0 |

Conclusion:

The study has shown that

- only 5 of 14 reprocessed devices were steril.
- reprocessing did not result in clean devices all the time as a prerequisite for effective disinfection or sterilization.
- equal standard patient care, (universal precaution), assuring that each patient should have a clean device to prevent infection from cross contamination.

All these results, investigating the present state of the art of reprocessing endoscopic accessories, show that these single use biopsy forceps cannot be reprocessed safely and reproducibly to sterile condition, even with so called validated reprocessing methods.

Attachement 1: Copies of the sterile packages for documentation

Attachement 2: Results of light microscopy, scanning electron microscopy and photoelectron spectroscopy

1



VANGUARD

Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33816
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 954721

Uses: 1

**Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN: 240CM - OUTSIDE DIA: 2.2MM
REQ. BIOPSY CHANNEL: 2.0MM**

**Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.**

**Lot Number: 241093
sterilization Date: 12/98
For One Procedure Only**



9 5 4 7 2 1



9 5 3 1 2 1



9 5 1 2 1



9 5 1 2 1

2



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

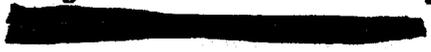
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 954675

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 241093

Sterilization Date: 1/99

For One Procedure Only



3



VANGUARD

Medical Concepts, Inc.
Lakeland, Florida

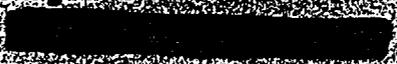
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - WILMINGTON, MA 01973

Mfg-Cat-No: 1537

Tracking No: 954728

Uses: 1

**DEEP RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
RHD BIOPSY CHANNEL-2.8MM**

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 241093

Sterilization Date: 12/98

For One Procedure Only



Feb 99

4



VANGUARD

Medical Concepts, Inc.
Lakeland, Florida

NMI
KPS
SEM

CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 954700

Uses: 1

Desc: RADIAL LAW 3 BIOPSY FORCEPS
STERILIZED W/ NEEDLE ENDOGLIDE SHE
WORK LEN 240CM, OUTSIDE DIA-2.2MM
REC BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.

Follow recommended handling instructions.

Lot Number: 241093

Sterilization Date: 1/99

For One Procedure Only



1



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Waterlown, MA 02172

Mfg-Cat-No: 1276

Tracking No: 954765

Uses: 1

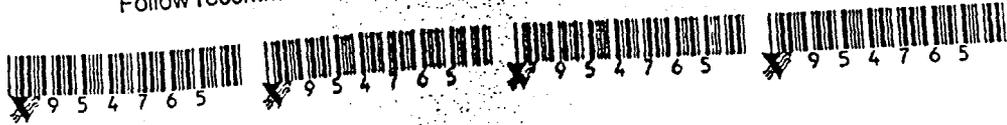
Desc: HOT BIOPSY FORCEPS LOWER GI
JAW O.D.-2.2 LENGTH - 240CM
REQUIRED BIOPSY CHANNEL - 2.8MM
MICROVASIVE CONNECTOR

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 241093

Sterilization Date: 12/98

For One Procedure Only



2



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33816
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVABIVE - Watertown, MA 02177

Mfg-Cat-No: 1278

Tracking No: 054750

Uses: 1

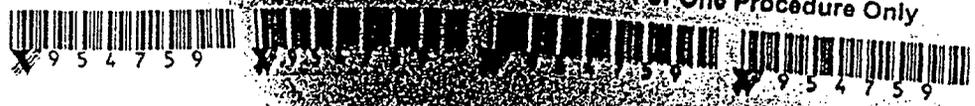
DESC: HOT BIOPSY FORCEPS LOWER GI
JAW O.D. - 2.2 LENGTH - 240CM
REQUIRED BIOPSY CHANNEL - 2.8MM
MICROVABIVE CONNECTOR

Caution: Federal Law (USA) restricts this device to use by or on the order of a physician.
Follow recommended handling instructions.

Lot Number: 241093

Sterilization Date: 12/98

For One Procedure Only



3



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1276

Tracking No: 954761

Uses: 1

Desc: HOT BIOPSY FORCEPS LOWER GI

JAW O.D.- 2.2 LENGTH - 240CM

REQUIRED BIOPSY CHANNEL - 2.8MM

MICROVASIVE CONNECTOR

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 241093

Sterilization Date: 1/99

For One Procedure Only



9 5 4 7 6 1

9 5 4 7 6 1

9 5 4 7 6 1

9 5 4 7 6 1

Feb 99

4



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

NMI
XPS
SEM

CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1276

Tracking No: 954758

Uses: 1

Desc: HOT BIOPSY FORCEPS LOWER GI
JAW O.D. - 2.2 LENGTH - 240CM

REQUIRED BIOPSY CHANNEL - 2.8MM
MICROVASIVE CONNECTOR

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 241093

Sterilization Date: 12/98

For One Procedure Only





VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

9.

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 955669

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM ØOUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416

Sterilization Date: 1/99

For One Procedure Only



10



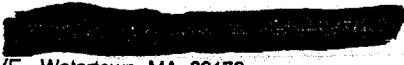
CONTENTS STERILE UNLESS PACKAGE IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 955665

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416
Sterilization Date: 1/99
For One Procedure Only



11

XPS
EDK



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

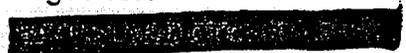
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1550

Desc: RADIAL JAW 3 HOT BIOPSY FORCEPS
SERRATED

Tracking No: 955681

WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Uses: 1

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416

Sterilization Date: 1/99

For One Procedure Only



12



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE -Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 955674

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416

Sterilization Date: 1/99

For One Procedure Only



13



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

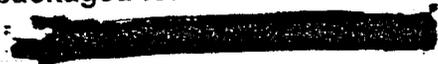
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 955675

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416
Sterilization Date: 1/99
For One Procedure Only



XPS
EDX
14



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

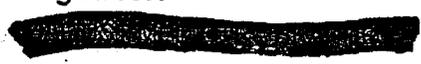
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 955676

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416

Sterilization Date: 1/99

For One Procedure Only



15



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1550

Desc: RADIAL JAW 3 HOT BIOPSY FORCEPS
SERRATED

Tracking No: 955683

WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Uses: 1

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416

Sterilization Date: 1/99

For One Procedure Only



16



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

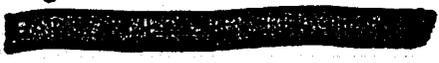
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1550

Tracking No: 955682

Uses: 1

Desc: RADIAL JAW 3 HOT BIOPSY FORCEPS
SERRATED

WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416

Sterilization Date: 1/99

For One Procedure Only



17



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

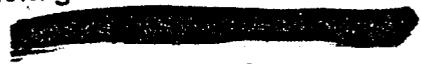
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1550

Tracking No: 955680

Uses: 1

Desc: RADIAL JAW 3 HOT BIOPSY FORCEPS
SERRATED
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416

Sterilization Date: 1/99

For One Procedure Only



18



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

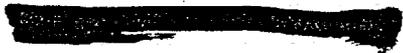
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1550

Tracking No: 955679

Uses: 1

Desc: RADIAL JAW 3 HOT BIOPSY FORCEPS
SERRATED

WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 242416

Sterilization Date: 1/99

For One Procedure Only



INVESTIGATION OF
CONTAMINATION AND MATERIAL ANALYSIS
ON MEDICAL DEVICES SOILED UNDER CLINICAL USE
AND REPROCESSED

Instrument: Biopsy Forceps

Report of Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

PREPARED FOR

Boston Scientific Corporation
Microvative Endoscopy
One Boston Scientific Place
Natick, MA 01760-1537

PERFORMING LABORATORY

PMP
The Center for the Testing of Medical Products
University of Tübingen
Markwiesenstr. 55
D - 72770 Reutlingen

20.03.99

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

Purpose of study:

The purpose of this study is to analyze the condition of single use biopsy forceps after clinical use and reprocessing by Vanguard, Medical Concepts, Inc. Lakeland, Florida. Microbiological and instrumental methods of surface analysis to analyze the device condition after reprocessing has been used.

According to the Spaulding/CDC¹ method of classification for medical devices, the devices in this study are classified as critical use devices, because they brake intact mucous membranes or are introduced directly into the sterile areas of the body. Sterility at the time of use is required for these items; consequently, a 10⁻⁶ sterility assurance level (the probability of one non-sterile unit out of one million units reprocessed) is the acceptable risk basis for critical devices. In response to the need for cost containment, many healthcare facilities are faced with the decision of reprocessing single-use medical devices.

The study evaluates contamination effects caused by the reuse of single-use devices, as compared with devices designed for reprocessing because good cleaning results are a predictor of adequate disinfection and sterilization. Measurable endpoints for evaluation will include contamination identification, bioburden, sterility, design evaluation and material analysis.

¹ Spaulding EH. Chemical disinfection and antiseptis in the hospital. J. Hosp. Res.,1972, vol.9, p.5-31

Table of contents:

| | | |
|-----|--|----|
| 1 | Conclusion:..... | 3 |
| 2 | Samples:..... | 4 |
| 3 | Sample preparations | 5 |
| 4 | Analytical Methods | 5 |
| 4.1 | Light Microscopy (LM) | 5 |
| 4.2 | Scanning Electron Microscopy (SEM) | 5 |
| 4.3 | Photoelectron Spectrometry (XPS)..... | 5 |
| 5 | Results..... | 6 |
| 5.1 | Light Microscope Images (LM) | 6 |
| 5.2 | Scanning Electron Micrographs (SEM)..... | 23 |
| 5.3 | Element Concentrations (XPS)..... | 52 |

Name: Biopsy Forceps
Manufacturer: Microvasive

1 Conclusion:

Light micrographs showed residues in the joint region of the forceps of sample 9901-040 (Radial Jaw 3 Biopsy Forceps).

Scanning electron micrographs confirmed these investigations and showed additional residual layers on the outer surface of the wire plastic sheath 100 mm above the distal end of the devices as well as residual layers on the coil spring up to 100 mm above the distal end of all devices.

XPS measurements yielded carbon, oxygen and silicon as the important elements of the chemical composition of the surface. Nitrogen which could be a marker for protein, was not identified. The detected silicon may indicate residues from the cleaning agent as well as from lubricants, e.g. silicone.

The residual layer thickness was sufficient to cover the bulk material (stainless steel) on the investigated devices.

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

2 Samples:

ID: 9901-010:

Name: Hot Biopsy Forceps
Description: Lower GI Jaw O.D. 2.2
Manufacturer: Microvasive
Order-No./Ref.: 1276
Lot: 241093
Setting: Soiled under clinical use
Reprocessed by Vanguard
Uses: 1

ID: 9901-020:

Name: Radial Jaw 3 Biopsy Forceps
Description: Serrated w/needle Engoglide She
Manufacturer: Microvasive
Order-No./Ref.: 1537
Lot: 241093
Setting: Soiled under clinical use
Reprocessed by Vanguard
Uses: 1

ID: 9901-030:

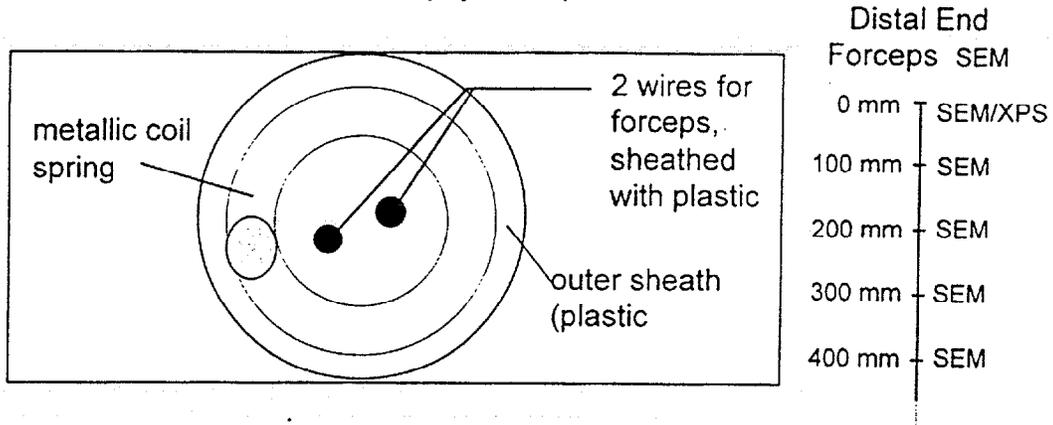
Name: Radial Jaw 3 Hot Biopsy Forceps
Description: Serrated
Manufacturer: Microvasive
Order-No./Ref.: 1550
Lot: 242416
Setting: Soiled under clinical use
Reprocessed by Vanguard
Uses: 1

ID: 9901-040:

Name: Radial Jaw 3 Biopsy Forceps
Description: Serrated w/needle Engoglide She
Manufacturer: Microvasive
Order-No./Ref.: 1537
Lot: 242416
Setting: Soiled under clinical use
Reprocessed by Vanguard
Uses: 1

3 Sample preparations

Cross-sectional structure of Biopsy Forceps:



The catheters were cut off with scalpels at the defined locations. For cutting the coil spring a wire shear was used.

4 Analytical Methods

4.1 Light Microscopy (LM)

Device: Zeiss, Axiophot
Zeiss, Stereomicroscope SV 8

4.2 Scanning Electron Microscopy (SEM)

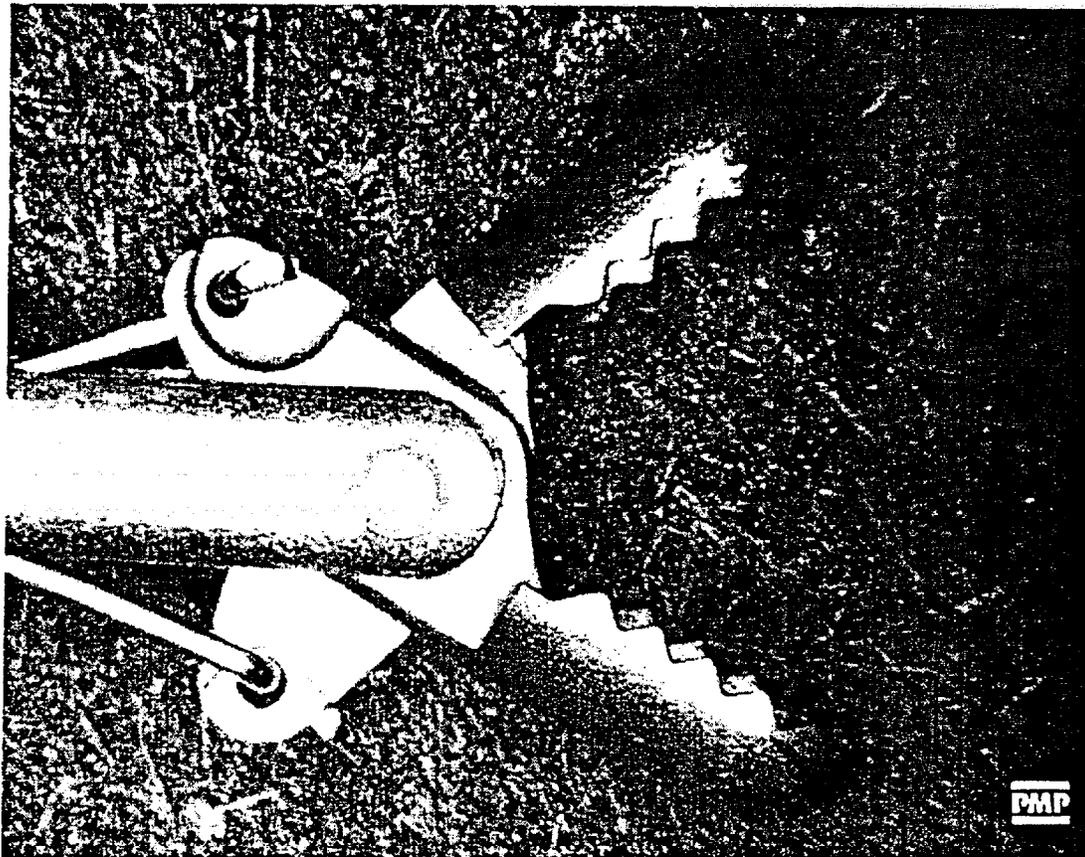
Device: Cambridge S 90
Acceleration voltage: 25 kV
Sputtering: Gold/Palladium
Observation angle: 45°

4.3 Photoelectron Spectrometry (XPS)

Device: VG ESCALAB 200 A
Irradiation: MgK α
Area of measurement: \varnothing 1 mm
Residual gas pressure: 10⁻¹⁰ mbar

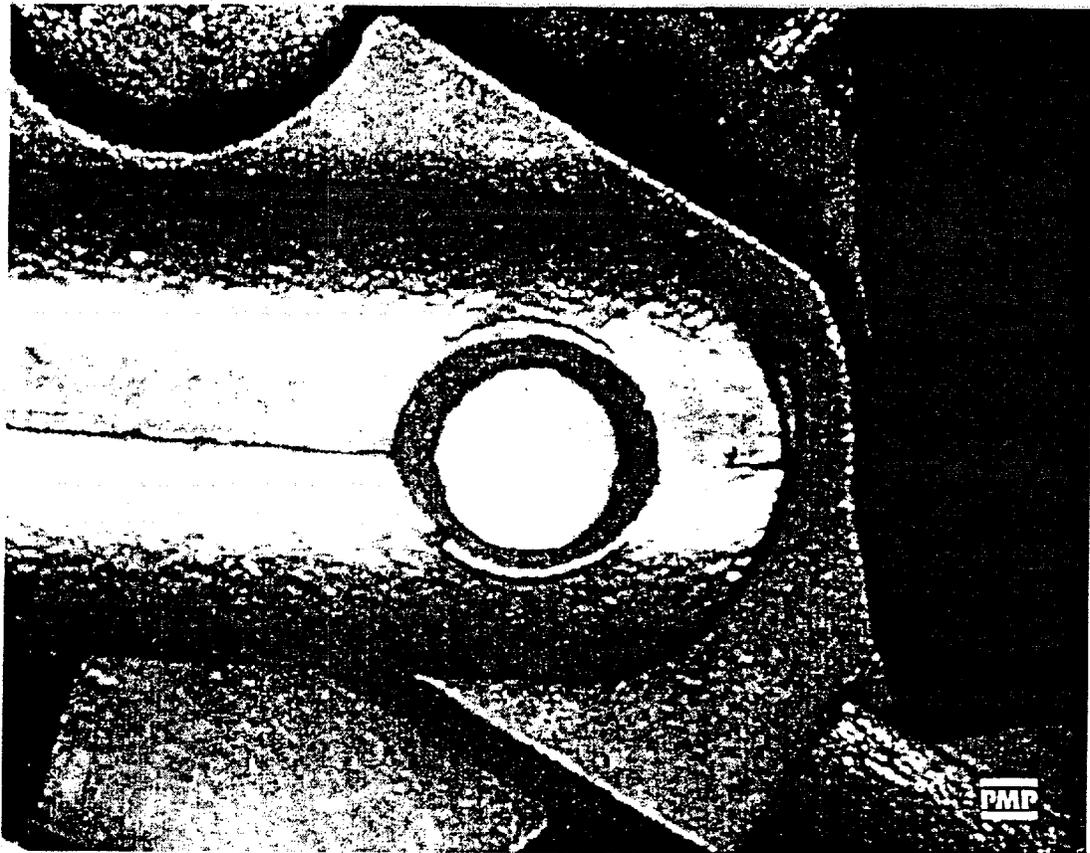
5 Results

5.1 *Light Microscope Images (LM)*



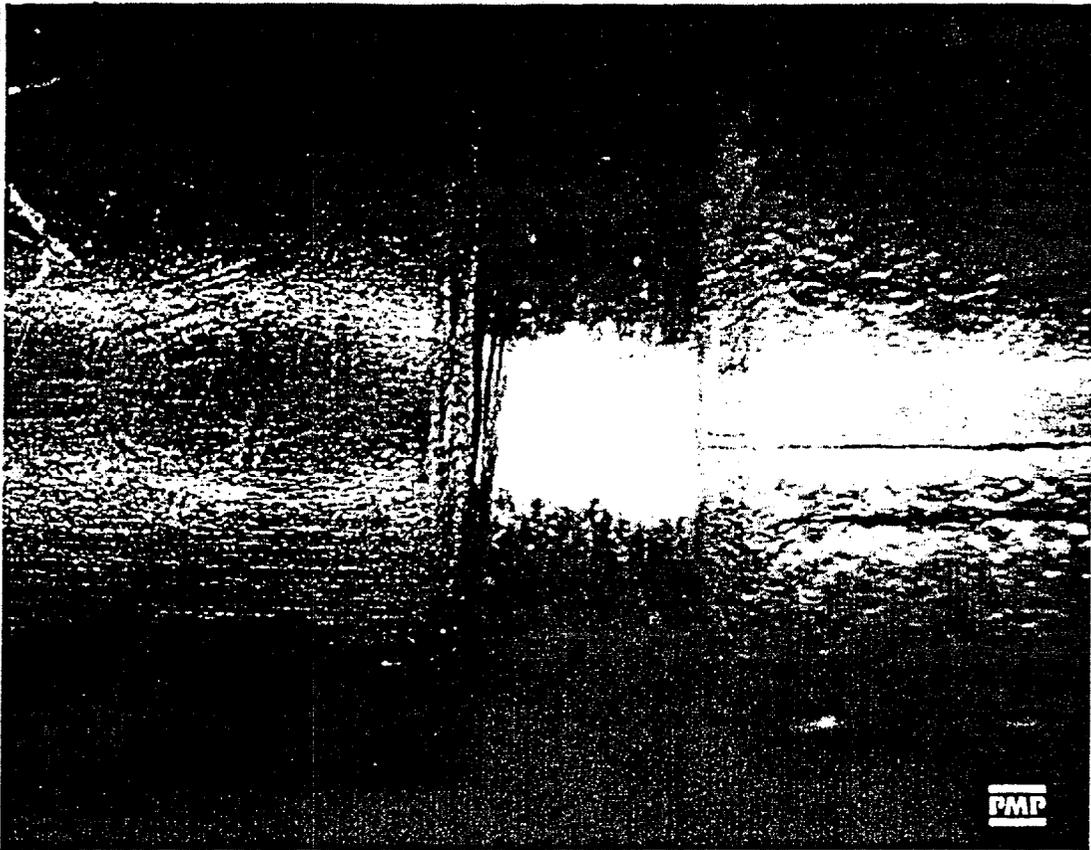
Sample: 9901 – 010
Biopsy Forceps, soiled and reprocessed
Location: Forceps
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



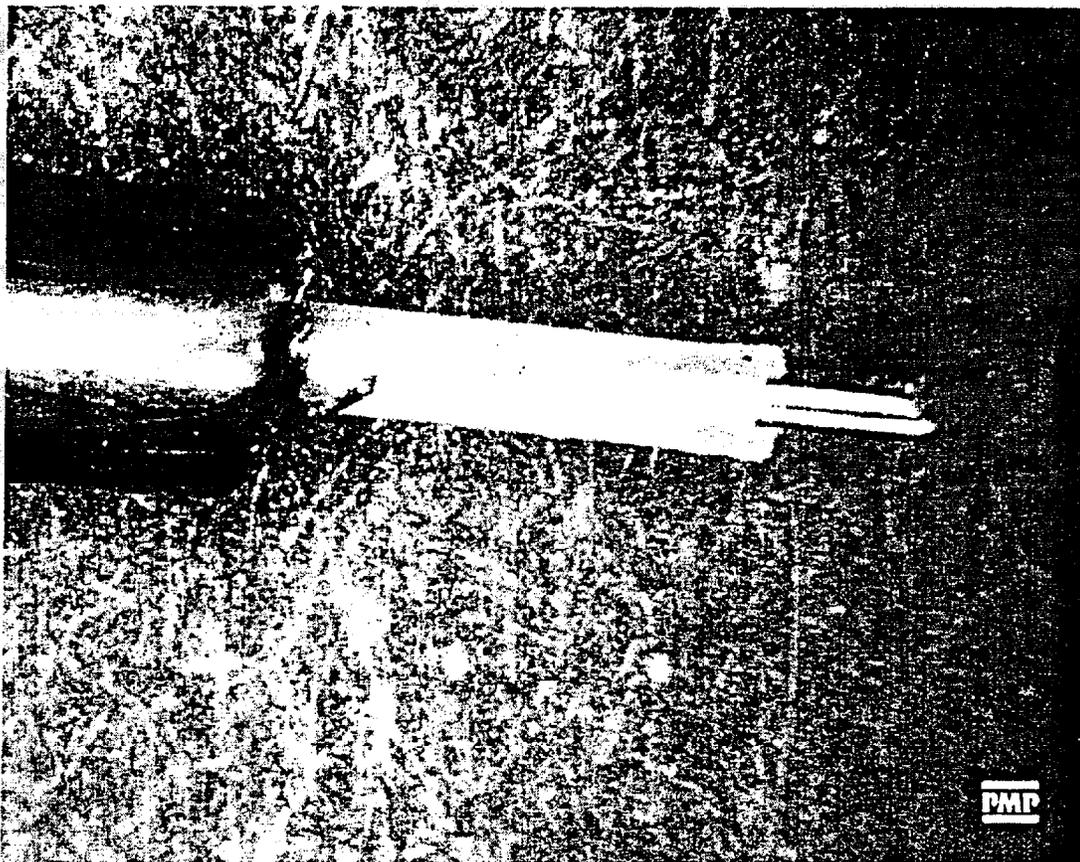
Sample: 9901 – 010
Biopsy Forceps, soiled and reprocessed
Location: Forceps (detail)
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



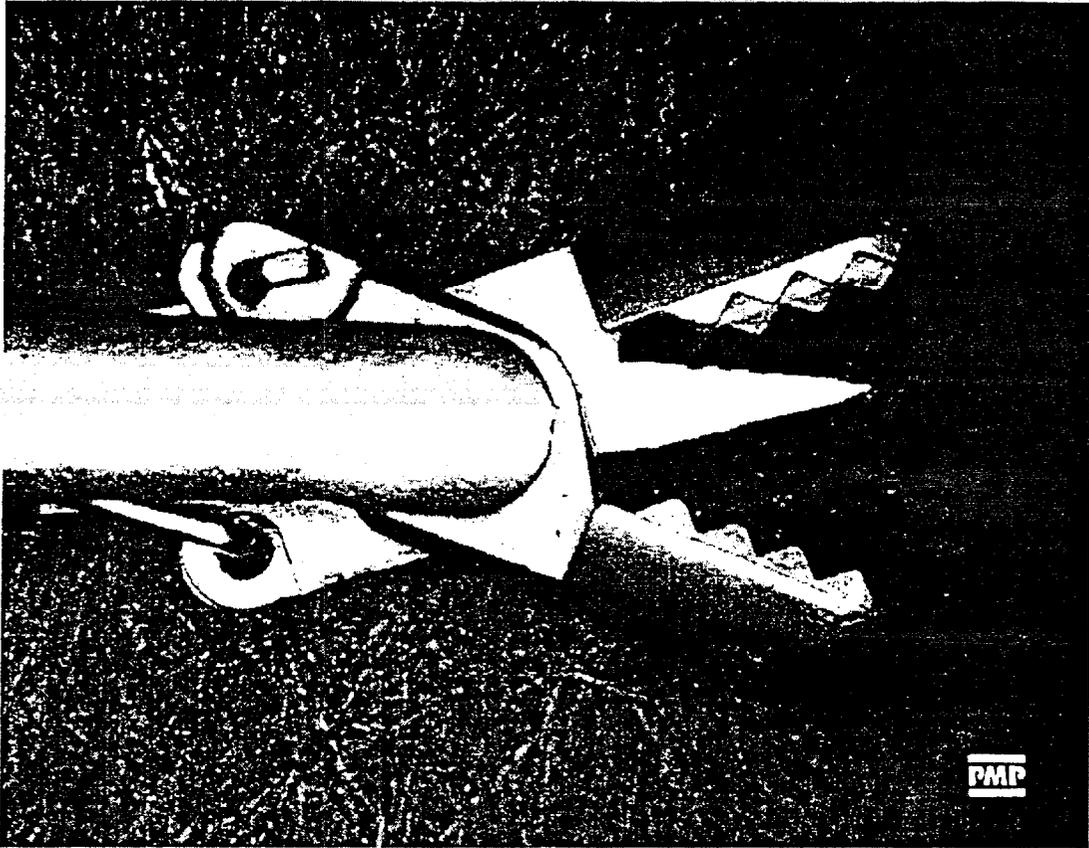
Sample: 9901 – 010
Biopsy Forceps, soiled and reprocessed
Location: Transition forceps – coil with plastic sheath (detail)
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



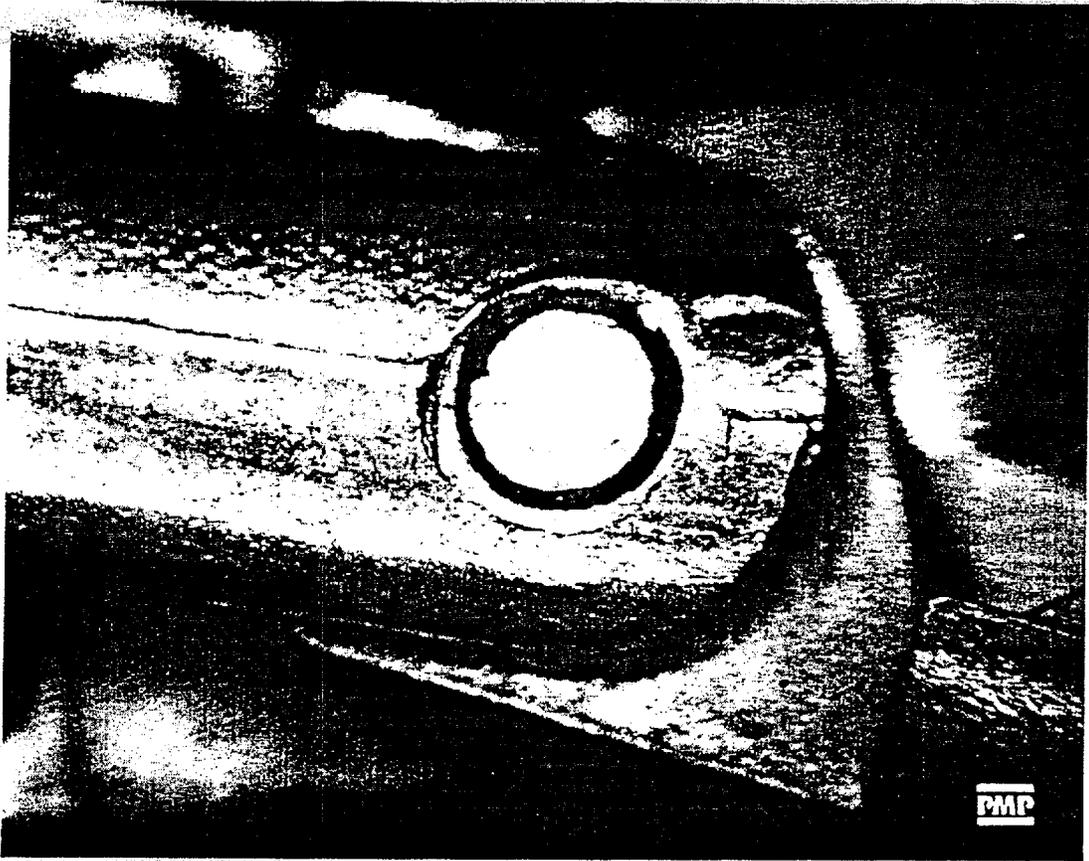
Sample: 9901 - 010
Biopsy Forceps, soiled and reprocessed
Location: about 100 mm above the distal end
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



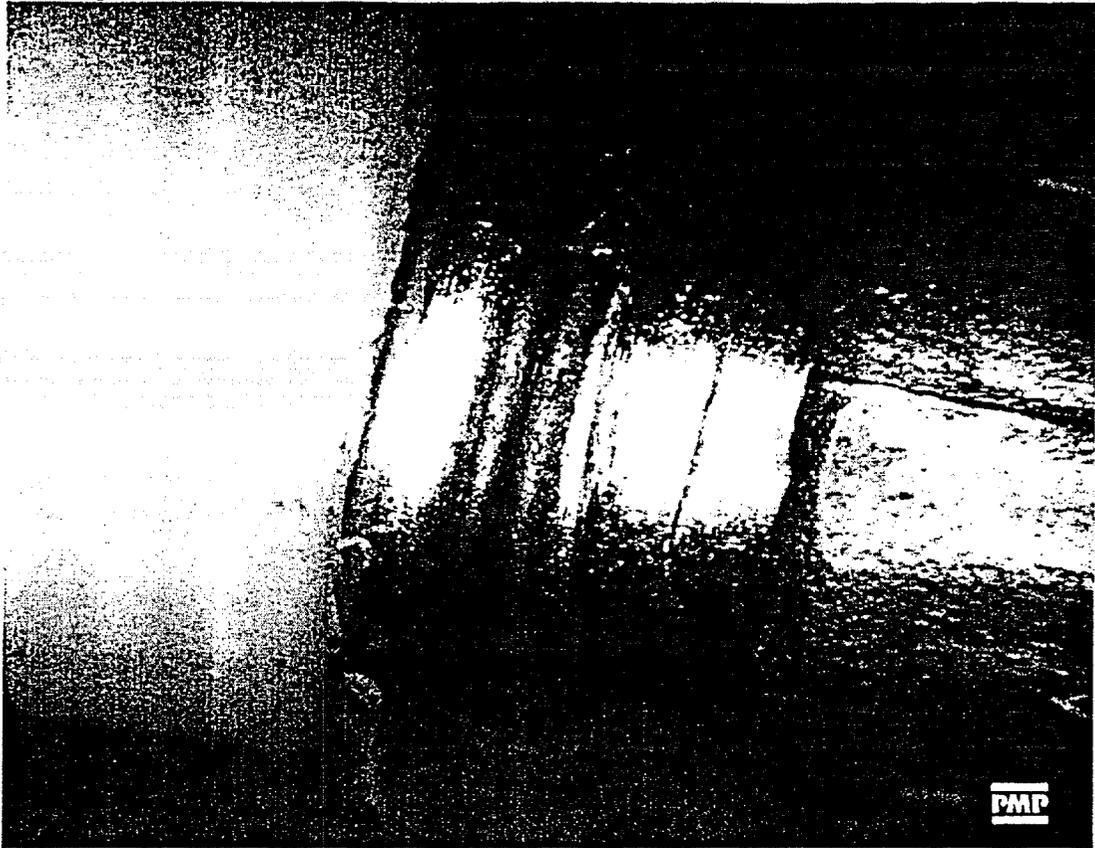
Sample: 9901 - 020
Biopsy Forceps, soiled and reprocessed
Location: Forceps
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



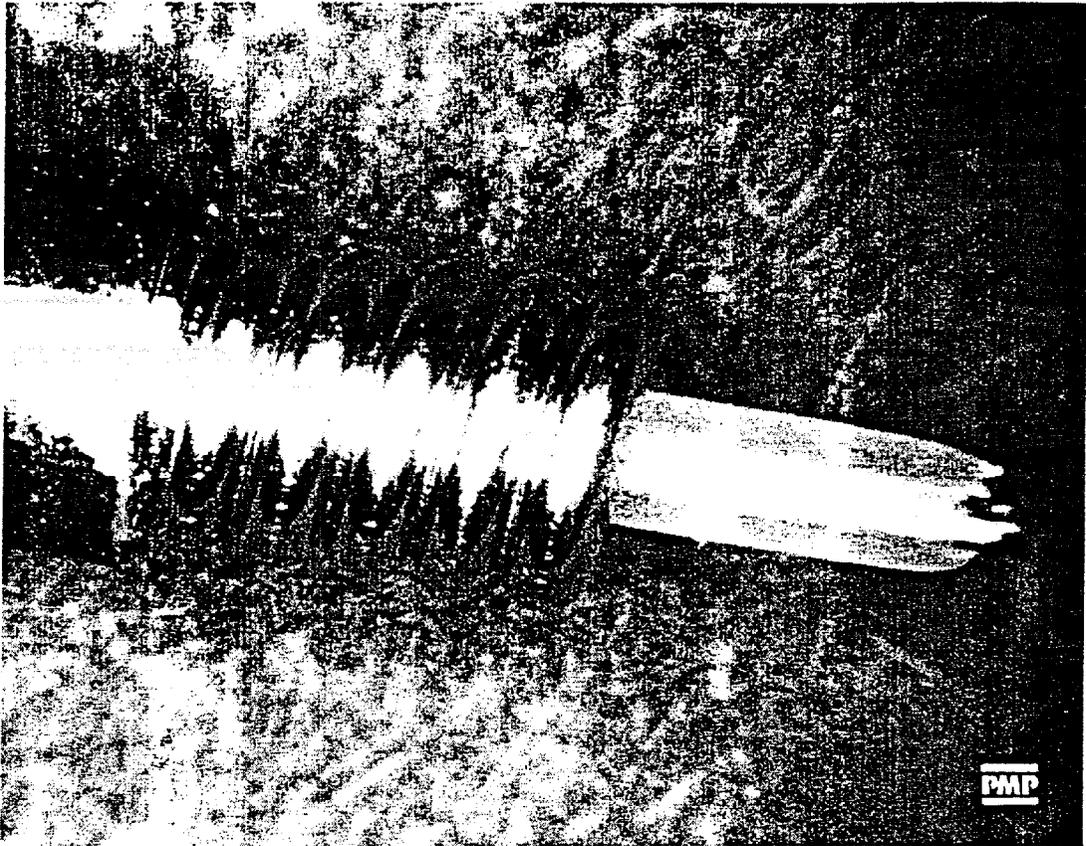
Sample: 9901 – 020
Biopsy Forceps, soiled and reprocessed
Location: Forceps (detail)
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



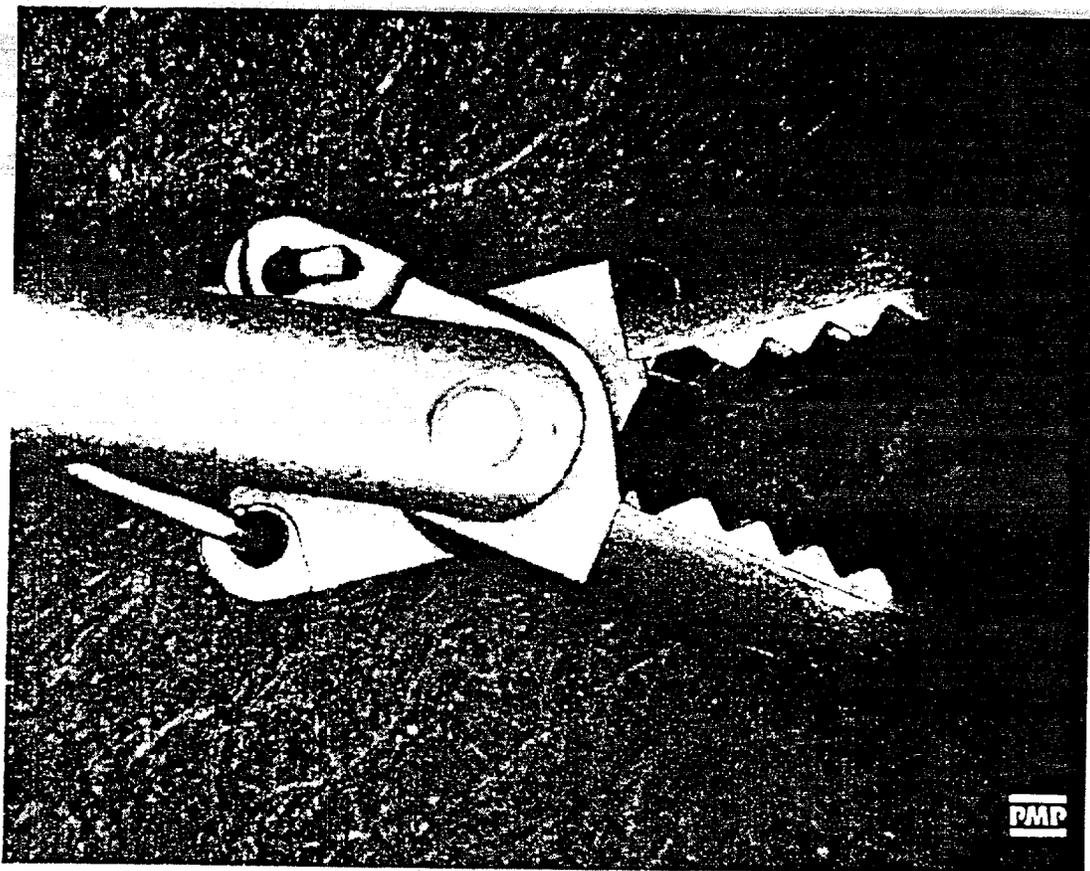
Sample: 9901 – 020
Biopsy Forceps, soiled and reprocessed
Location: Transition forceps – coil with plastic sheath (detail)
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



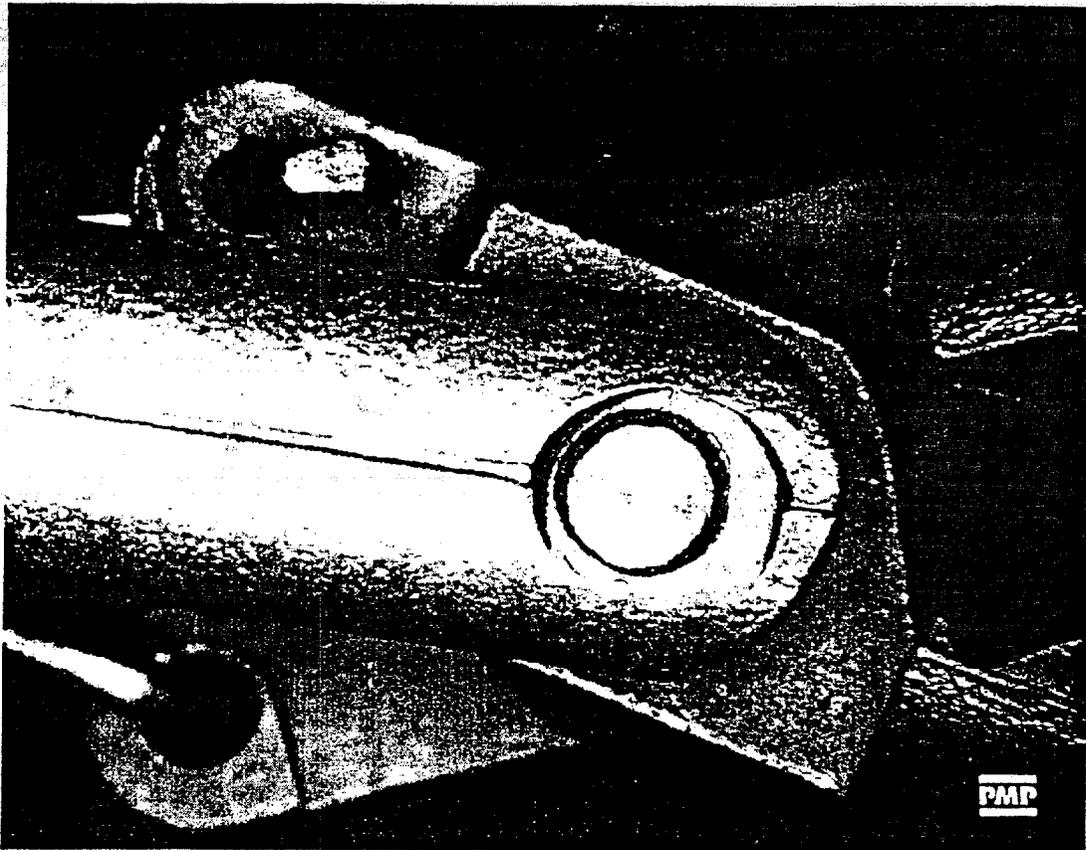
Sample: 9901 – 020
Biopsy Forceps, soiled and reprocessed
Location: about 100 mm above the distal end
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



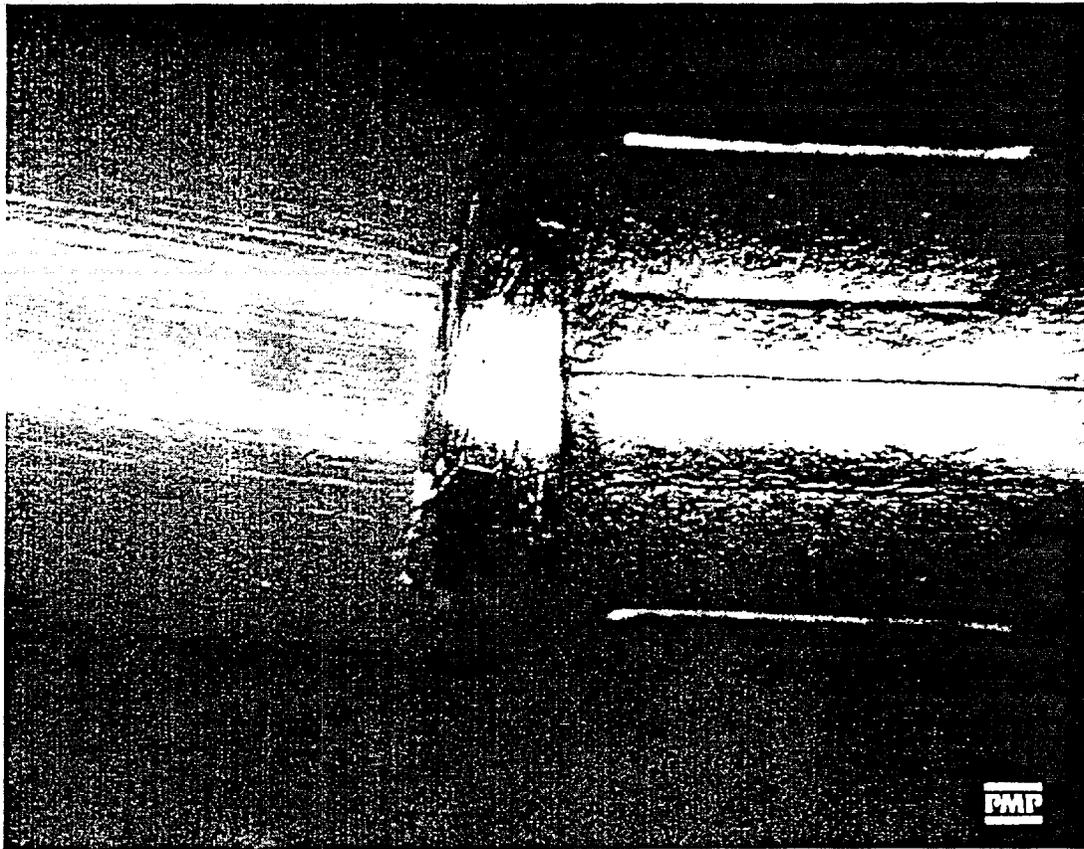
Sample: 9901 – 030
Biopsy Forceps, soiled and reprocessed
Location: Forceps
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



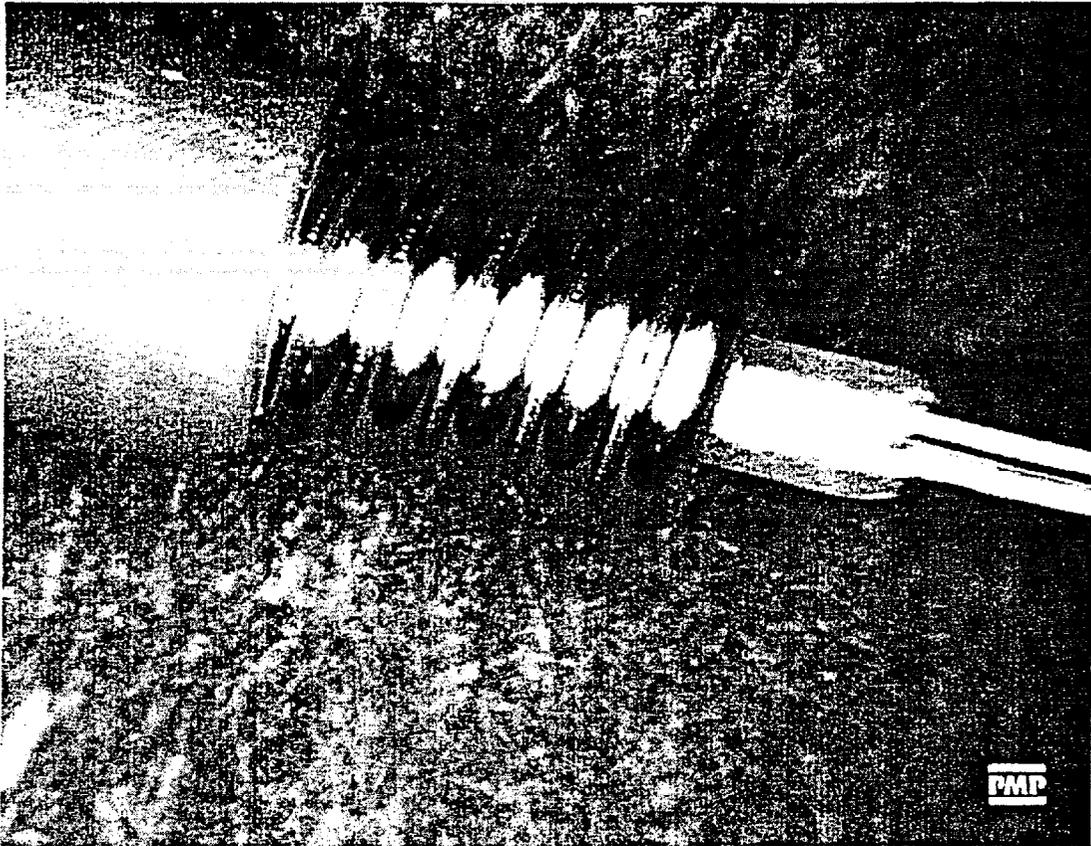
Sample: 9901 – 030
Biopsy Forceps, soiled and reprocessed
Location: Forceps (detail)
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



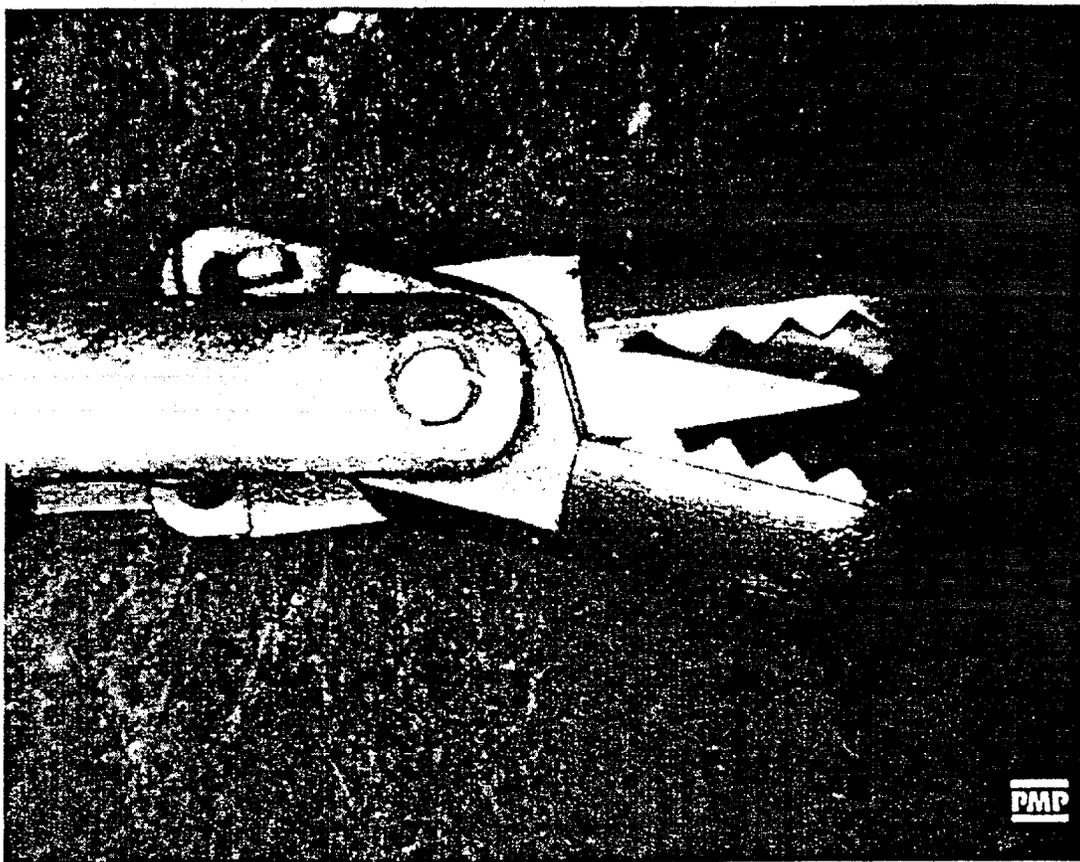
Sample: 9901 – 030
Biopsy Forceps, soiled and reprocessed
Location: Transition forceps – coil with plastic sheath (detail)
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



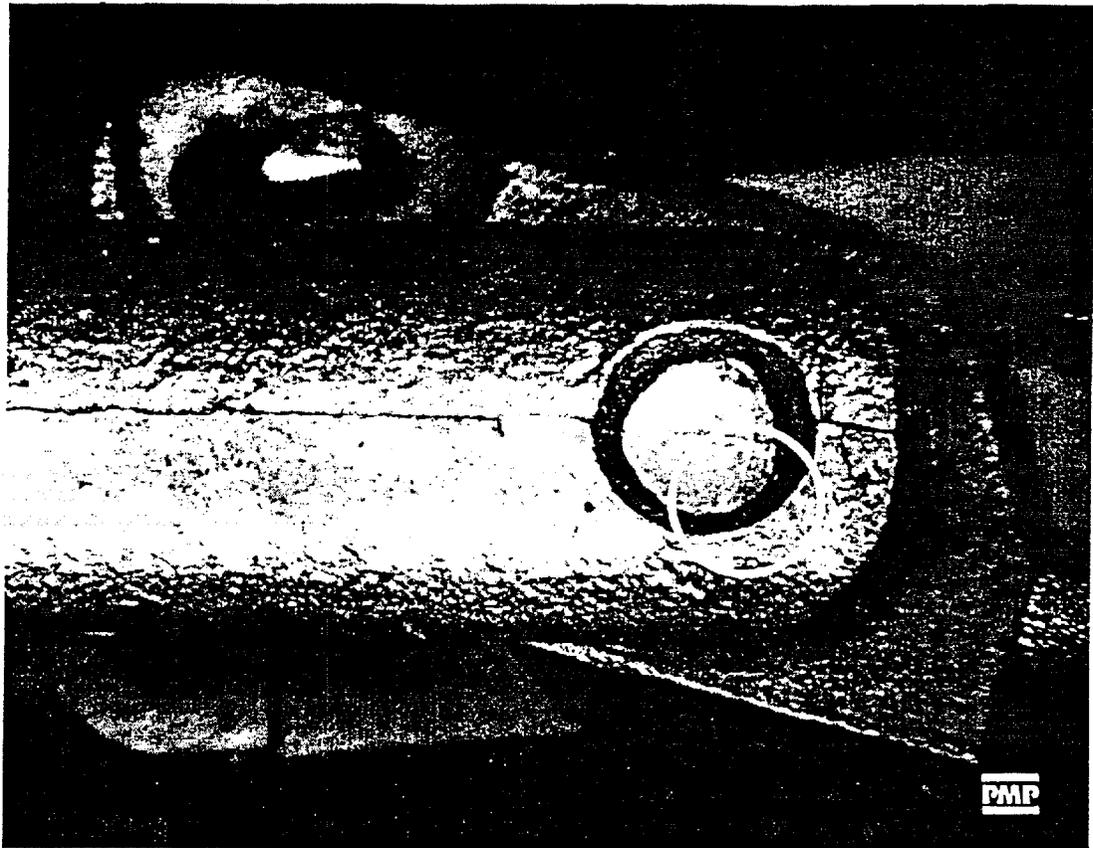
Sample: 9901 – 030
Biopsy Forceps, soiled and reprocessed
Location: about 100 mm above the distal end
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



Sample: 9901 – 040
Biopsy Forceps, soiled and reprocessed
Location: Forceps
Visible residues (encircled)

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



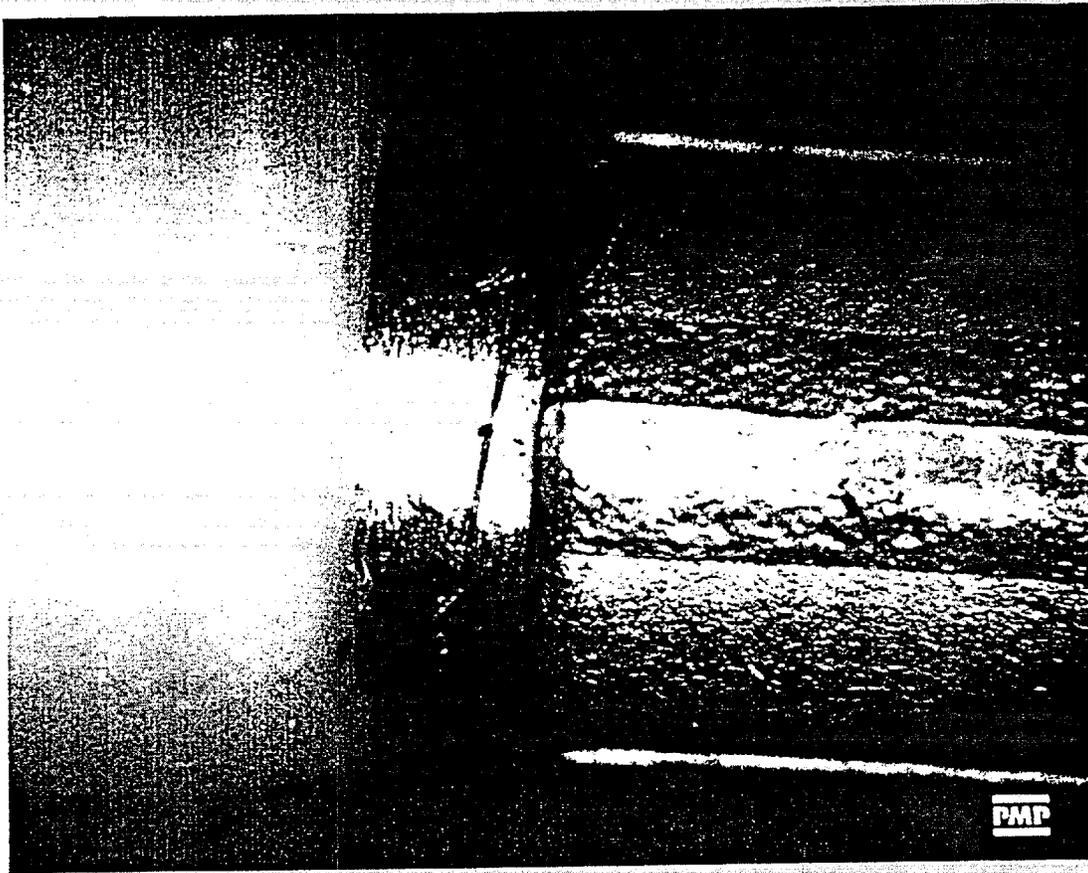
Sample: 9901 – 040
Biopsy Forceps, soiled and reprocessed
Location: Forceps (detail)
No visible residues (encircled)

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



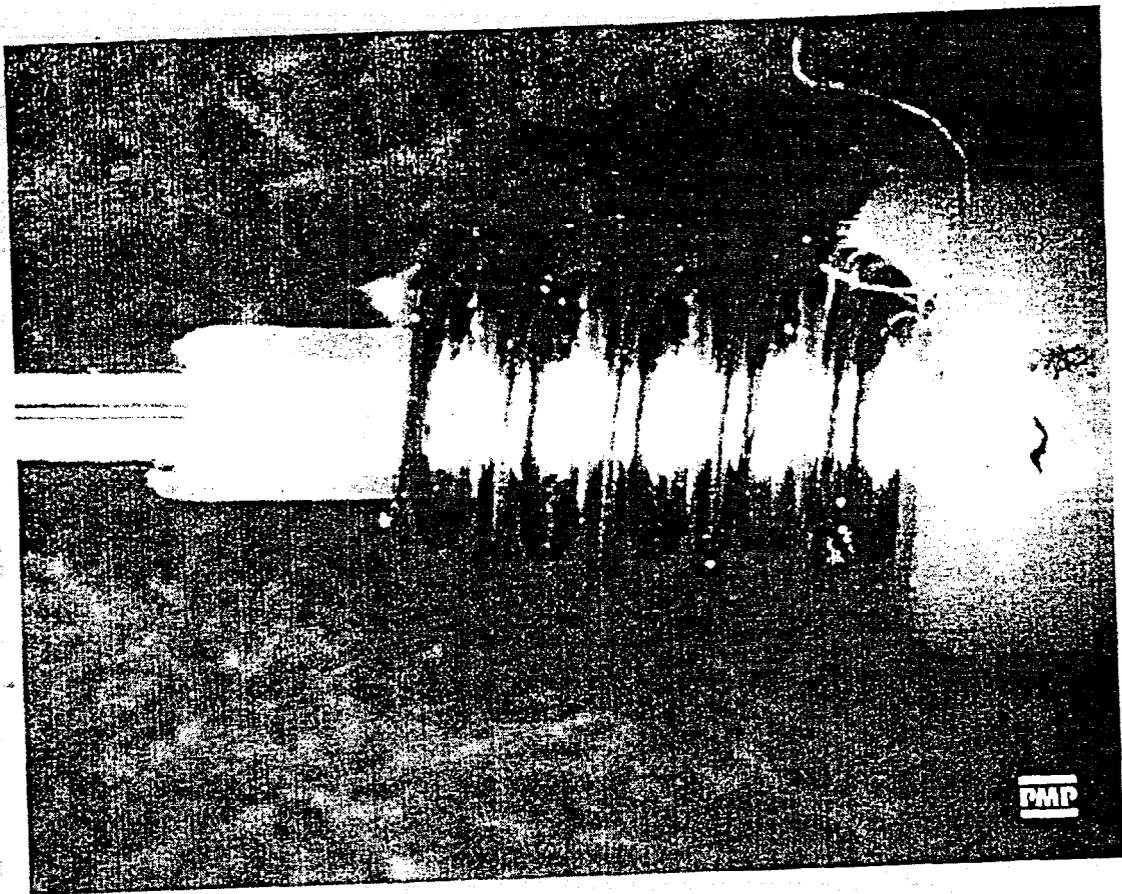
Sample: 9901 – 040
Biopsy Forceps, soiled and reprocessed
Location: Forceps (detail)
Visible residues (encircled)

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



Sample: 9901 – 040
Biopsy Forceps, soiled and reprocessed
Location: Transition forceps – coil with plastic sheath (detail)
No visible residues

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

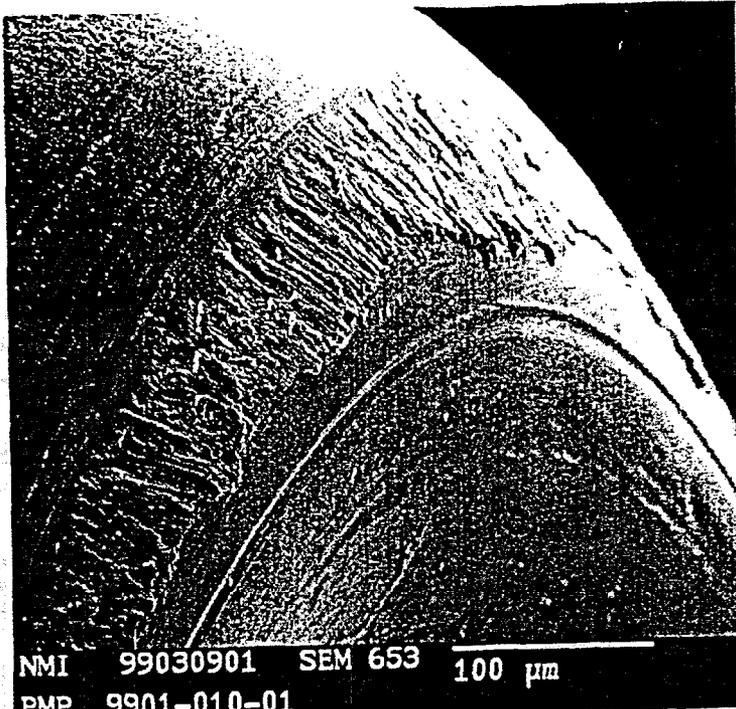


Sample: 9901 – 040
Biopsy Forceps, soiled and reprocessed
Location: about 100 mm above the distal end
No visible residues

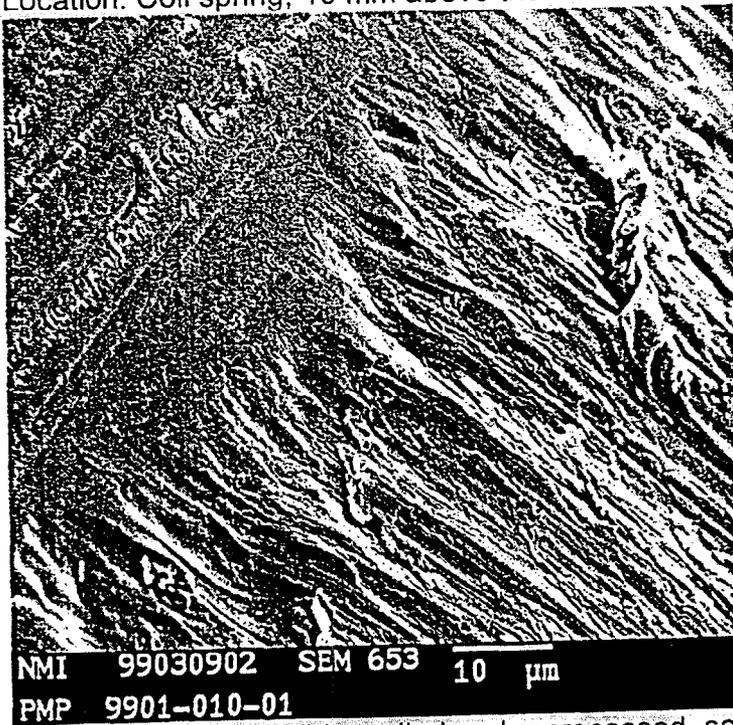
Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

5.2 Scanning Electron Micrographs (SEM)

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

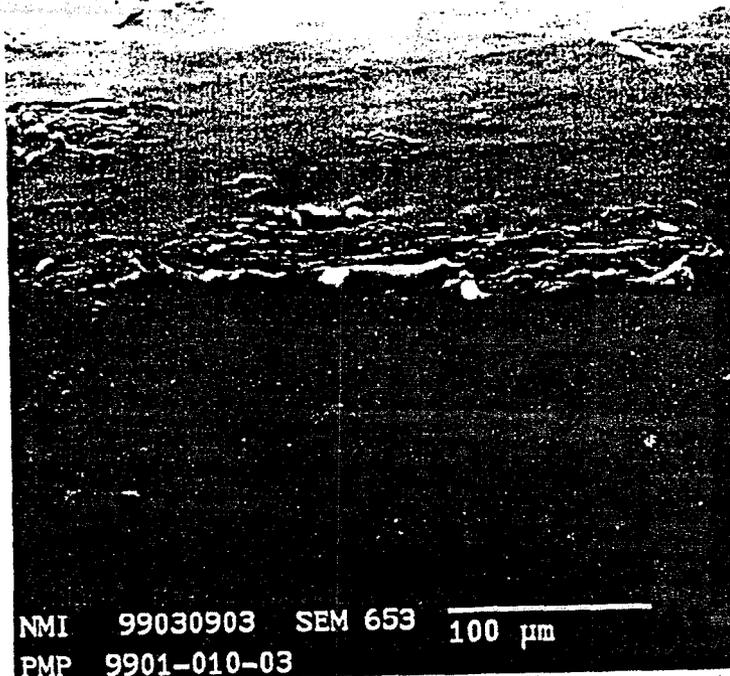


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-01
Location: Coil spring, 10 mm above the distal end

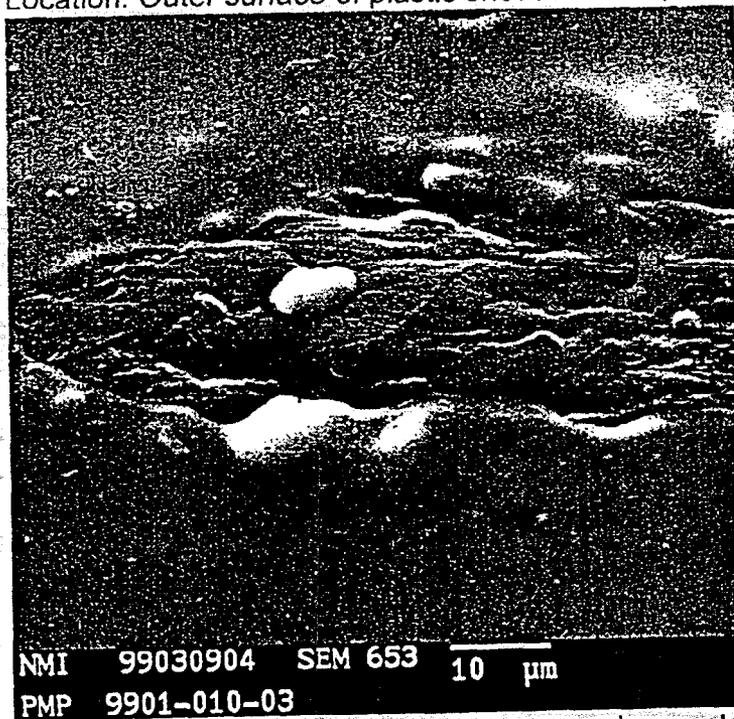


Biopsy Forceps Rinsible, soiled and reprocessed, sample 9901-010-01
Location: Coil spring, 10 mm above the distal end
No visible contamination, coil with structured surface at the contact area

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

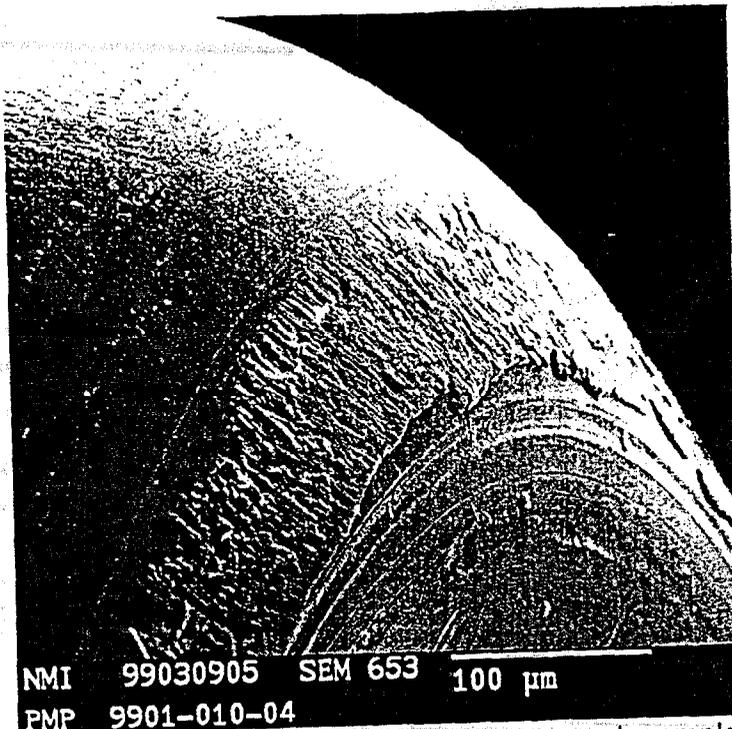


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-03
Location: Outer surface of plastic sheath of wire, 100 mm above the distal end

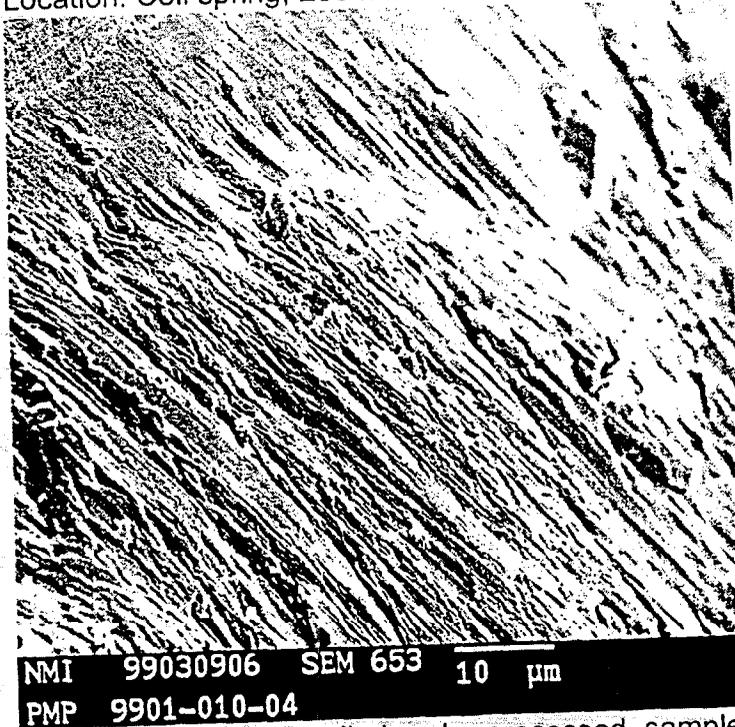


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-03
Location: Outer surface of plastic sheath of wire, 100 mm above the distal end
Visible residual layer

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

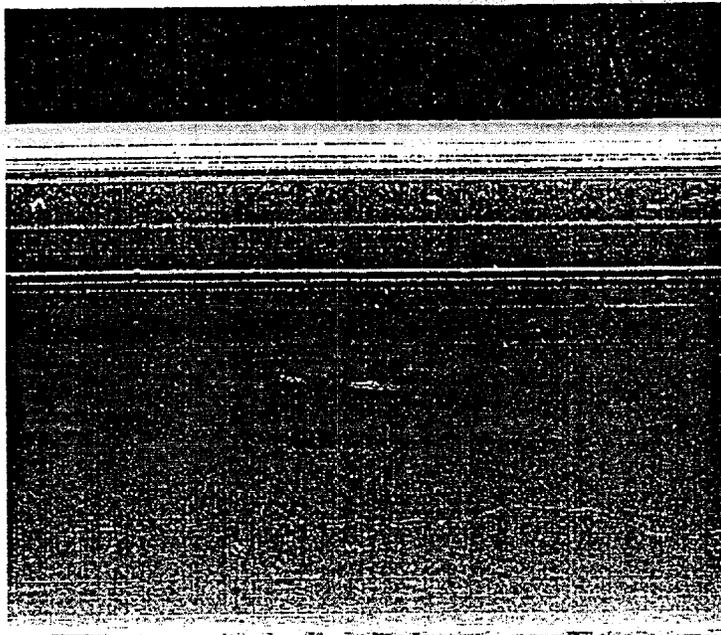


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-04
Location: Coil spring, 200 mm above the distal end



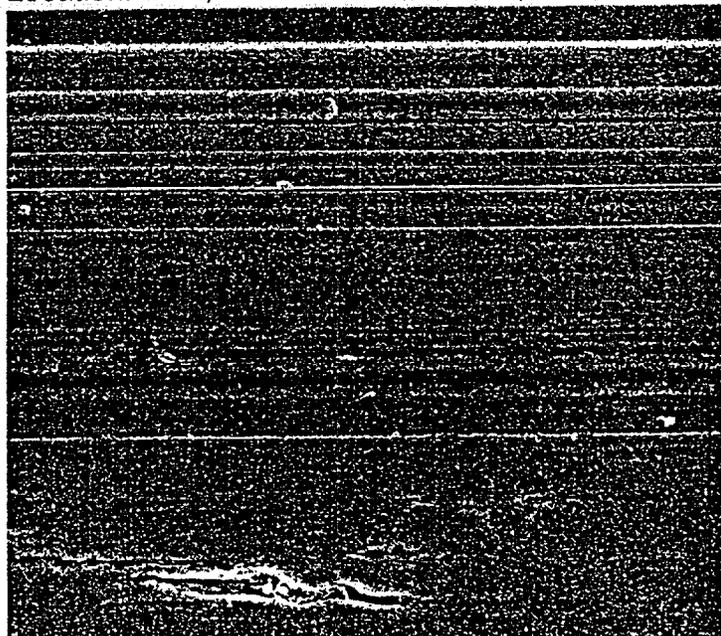
Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-04
Location: Coil spring, 200 mm above the distal end
No visible contaminations, coil with structured surface at the contact area

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



NMI 99030907 SEM 653 100 μm
PMP 9901-010-05

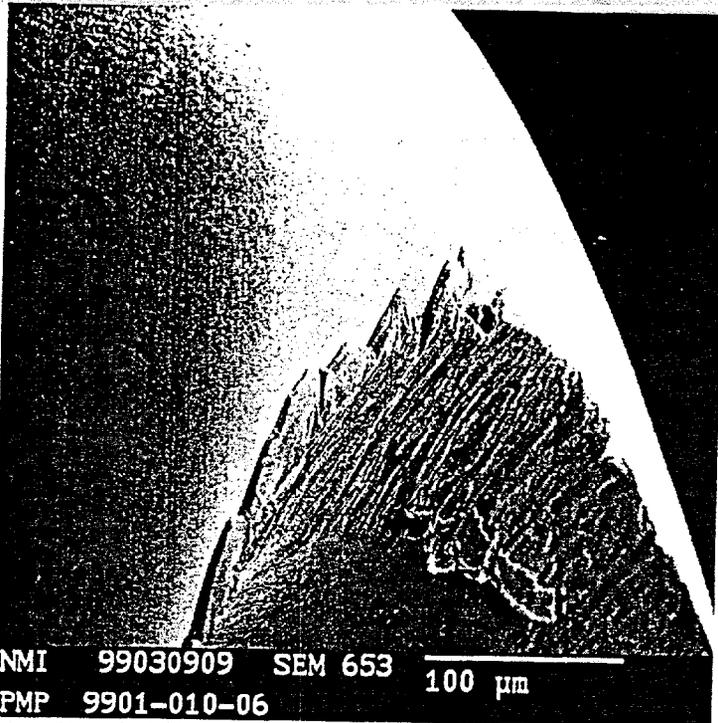
Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-05
Location: Wire, 200 mm above the distal end



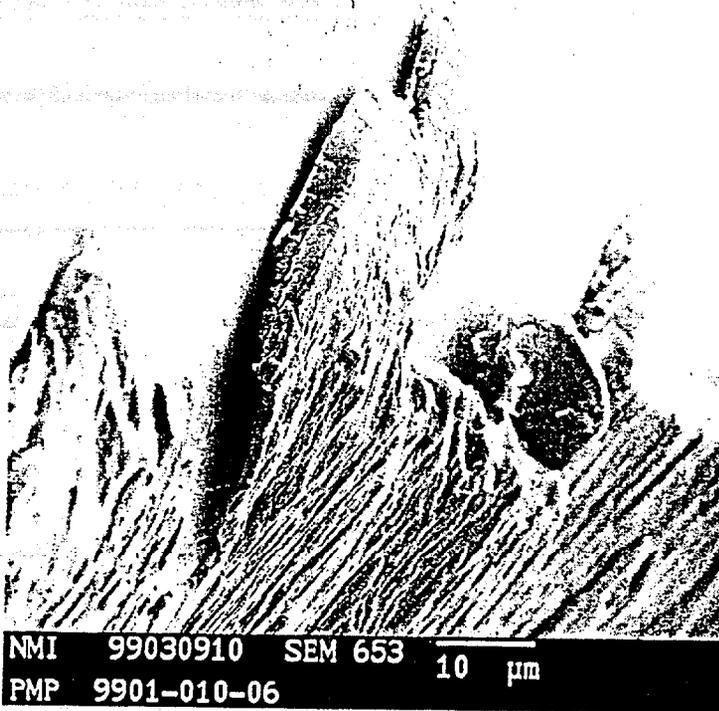
NMI 99030908 SEM 653 10 μm
PMP 9901-010-05

Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-05
Location: Wire, 200 mm above the distal end
No visible contamination

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

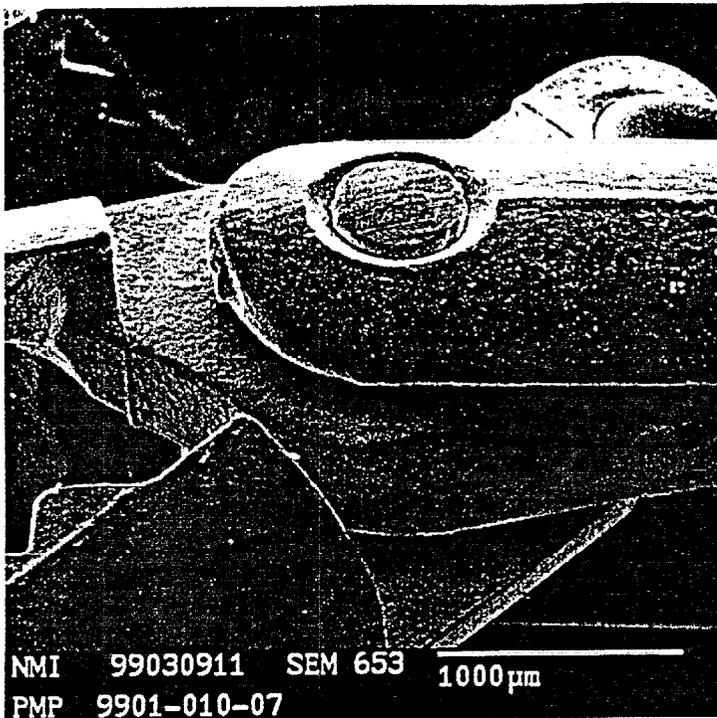


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-06
Location: Coil spring, 400 mm above the distal end

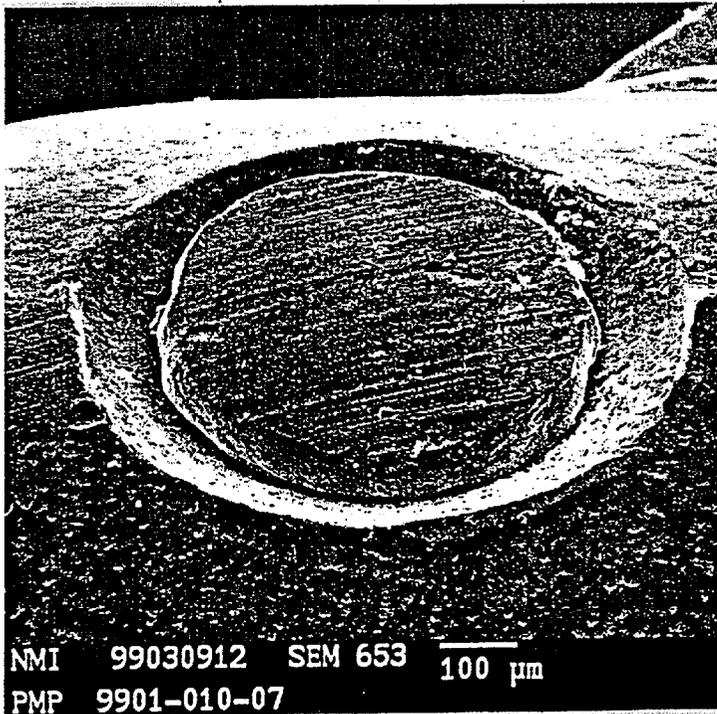


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-06
Location: Coil spring, 400 mm above the distal end
No visible contaminations, coil with structured surface at the contact area

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

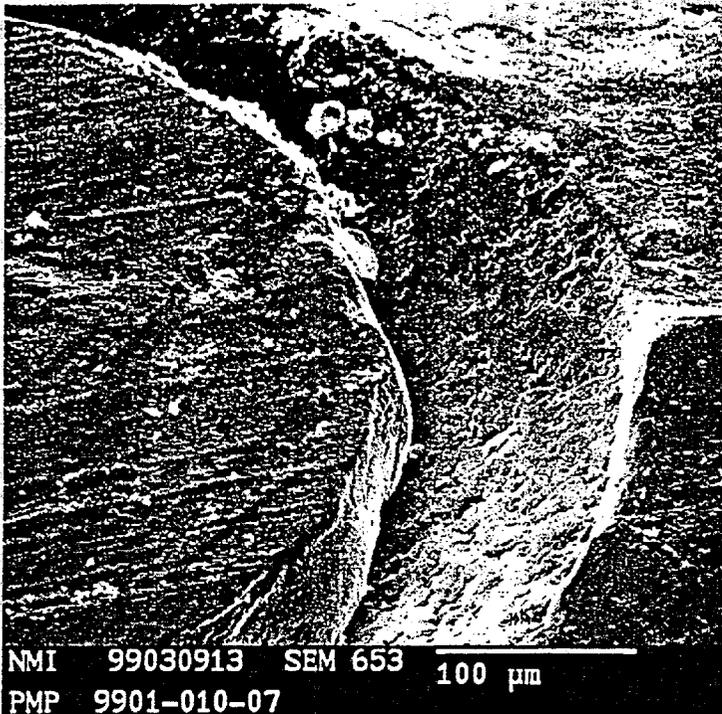


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-07
Location: Forceps at the distal end

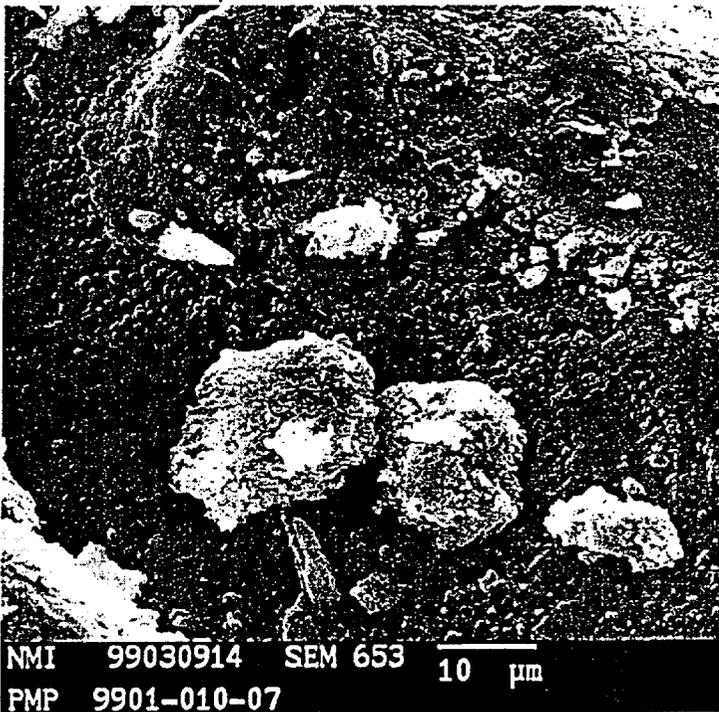


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-07
Location: Forceps at the distal end
Visible small particles

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

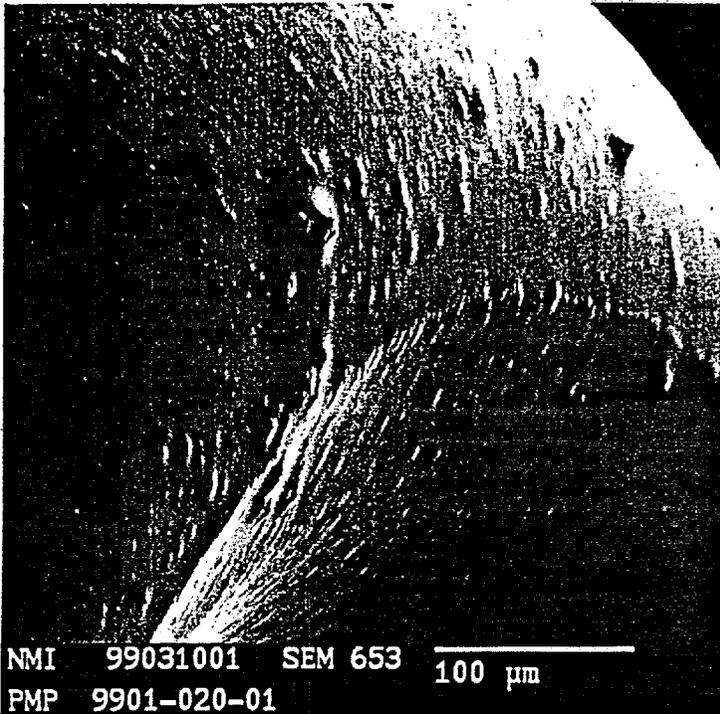


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-07
Location: Forceps at the distal end

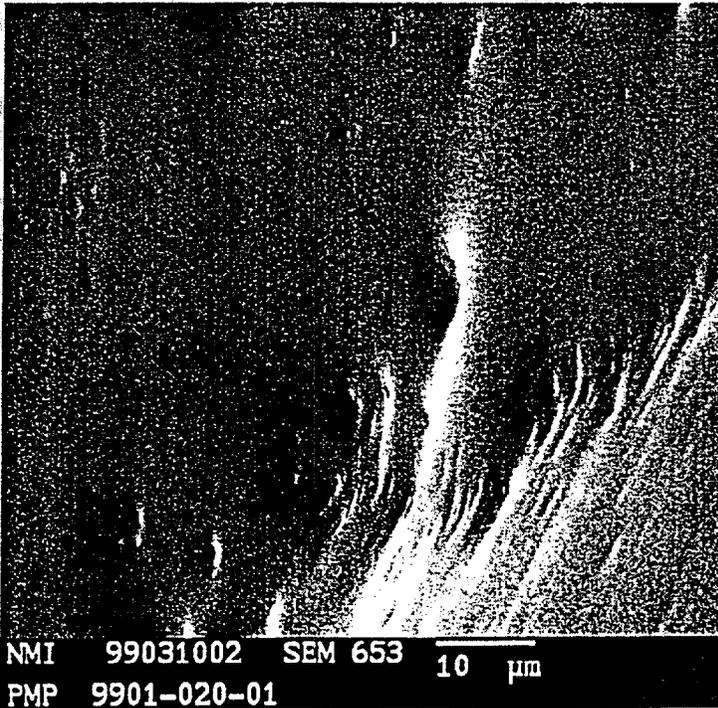


Hot Biopsy Forceps, soiled and reprocessed, sample 9901-010-07
Location: Forceps at the distal end
Visible small particles

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

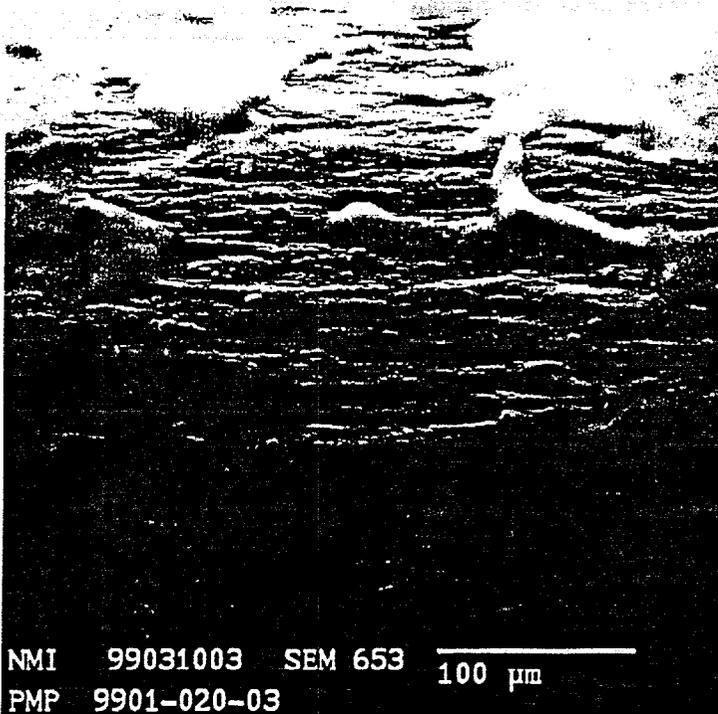


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-01
Location: Coil spring, 10 mm above the distal end



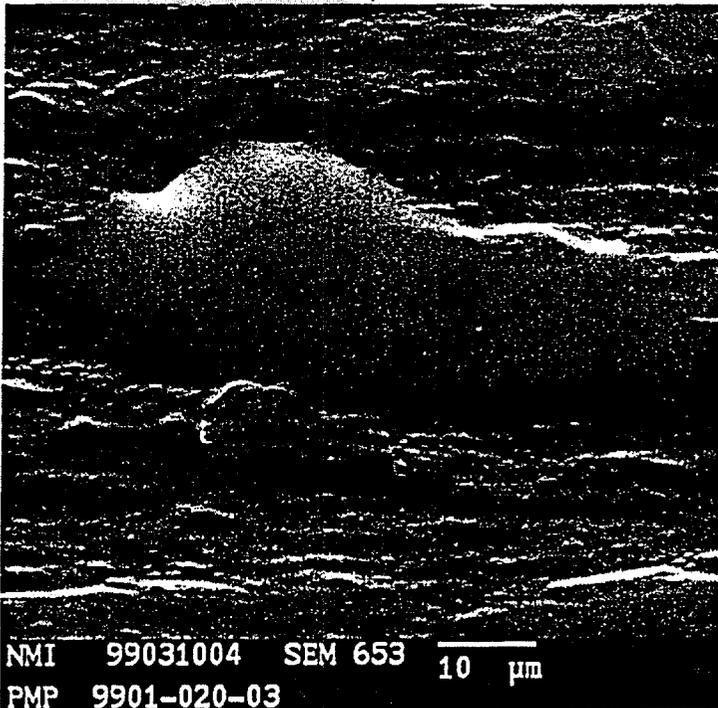
Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-01
Location: Coil spring, 10 mm above the distal end
Surface covered with residual layer

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



NMI 99031003 SEM 653 100 μm
PMP 9901-020-03

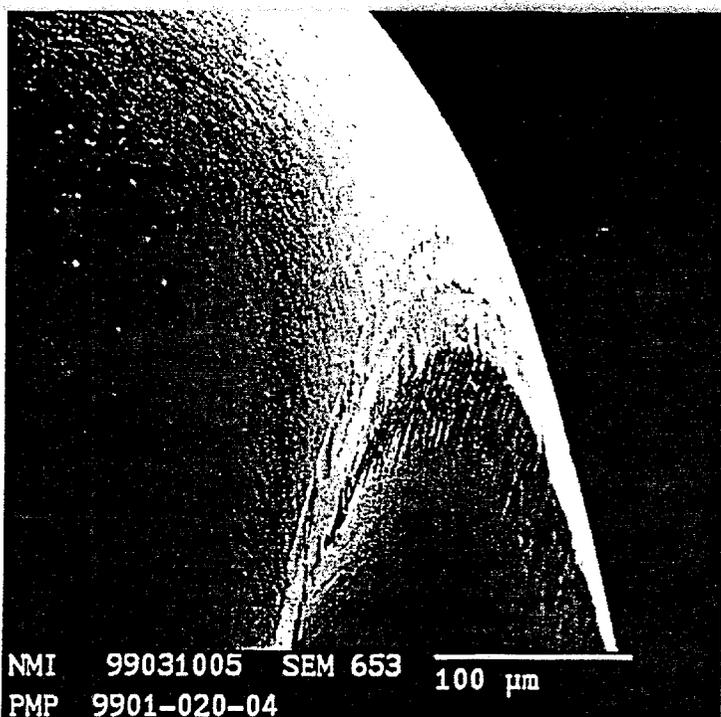
Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-03
Location: Outer surface of plastic sheath of wire, 100 mm above the distal end



NMI 99031004 SEM 653 10 μm
PMP 9901-020-03

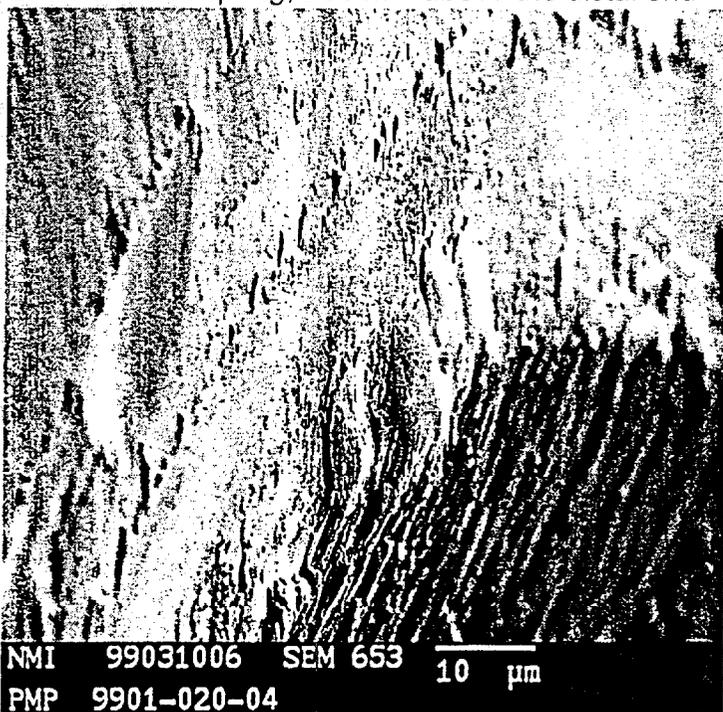
Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-03
Location: Outer surface of plastic sheath of wire, 100 mm above the distal end
Visible residual layer

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



NMI 99031005 SEM 653 100 μm
PMP 9901-020-04

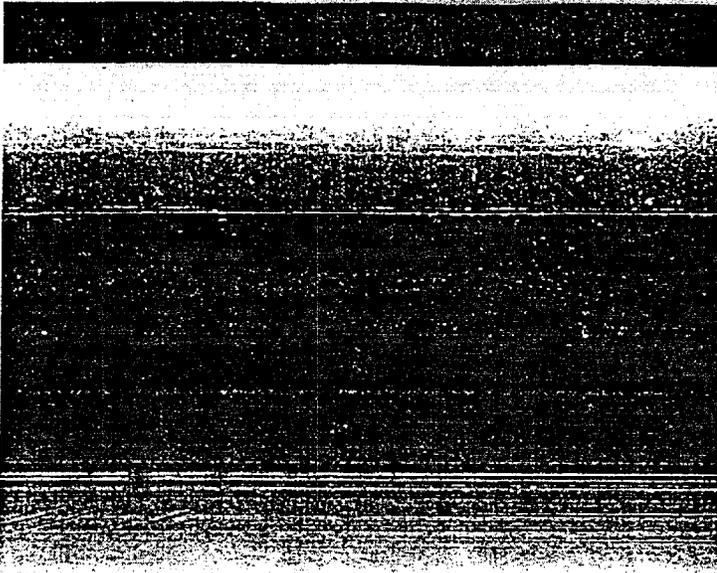
Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-04
Location: Coil spring, 200 mm above the distal end



NMI 99031006 SEM 653 10 μm
PMP 9901-020-04

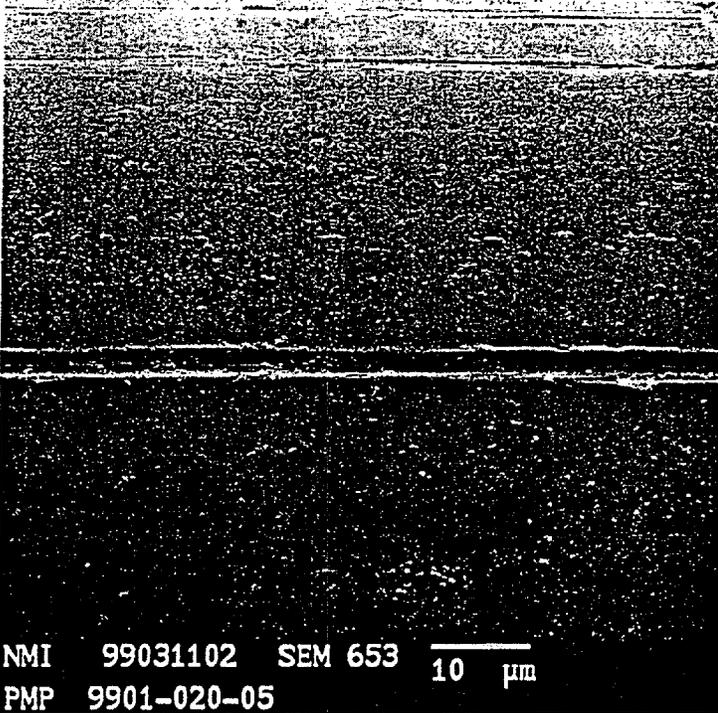
Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-04
Location: Coil spring, 200 mm above the distal end
No visible contamination, coil with structured surface at the contact area

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



NMI 99031101 SEM 653 100 μm
PMP 9901-020-05

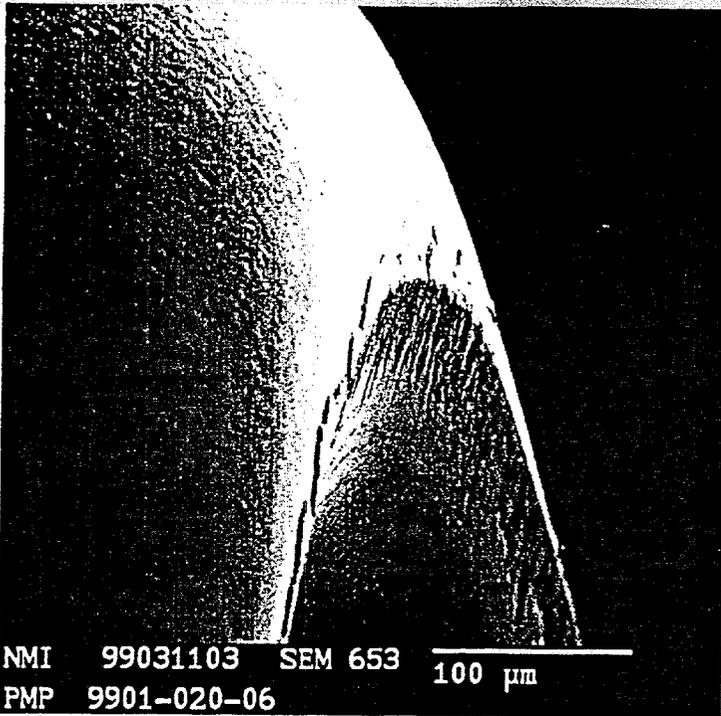
Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-05
Location: Wire, 200 mm above the distal end



NMI 99031102 SEM 653 10 μm
PMP 9901-020-05

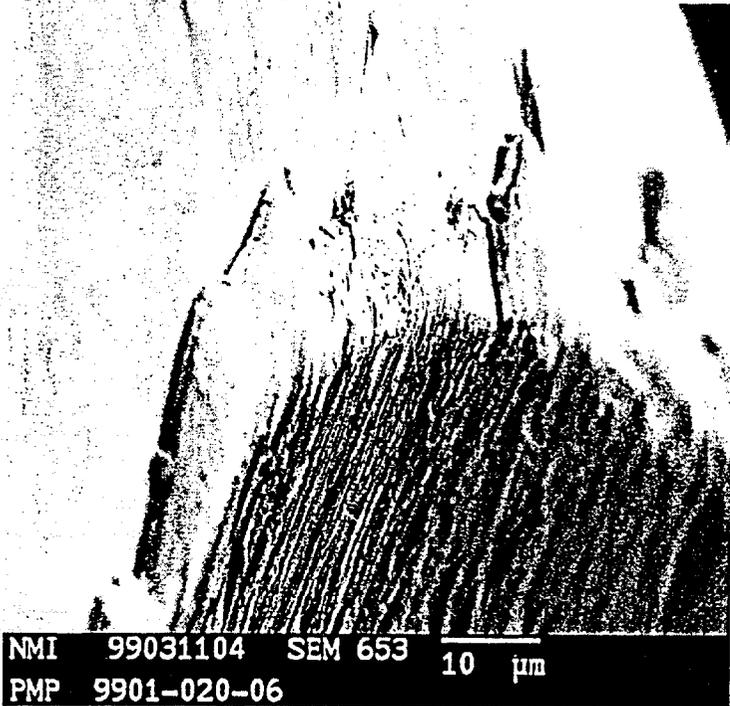
Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-05
Location: Wire, 200 mm above the distal end
No visible contamination

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



NMI 99031103 SEM 653 100 μm
PMP 9901-020-06

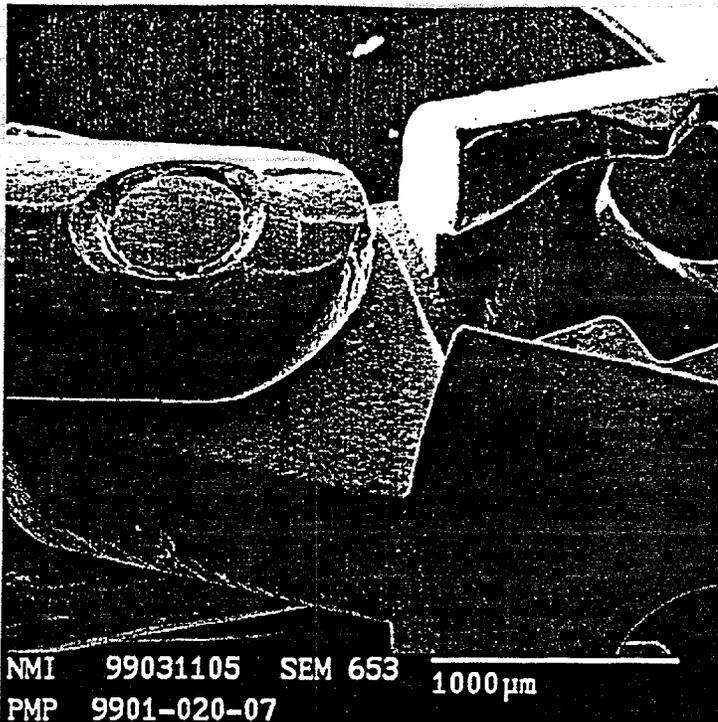
Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-06
Location: Coil spring, 400 mm above the distal end



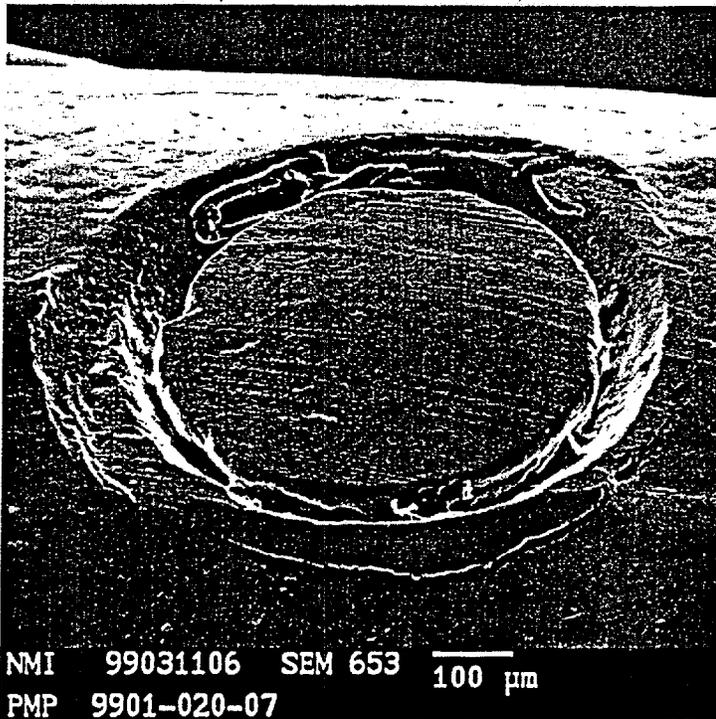
NMI 99031104 SEM 653 10 μm
PMP 9901-020-06

Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-06
Location: Coil spring, 400 mm above the distal end
No visible contamination, coil with structured surface at the contact area

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

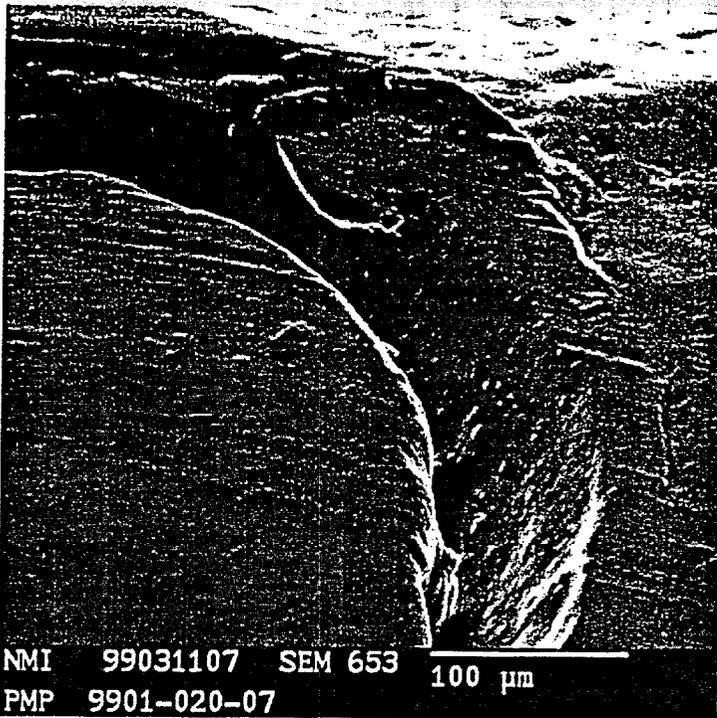


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-07
Location: Forceps at the distal end

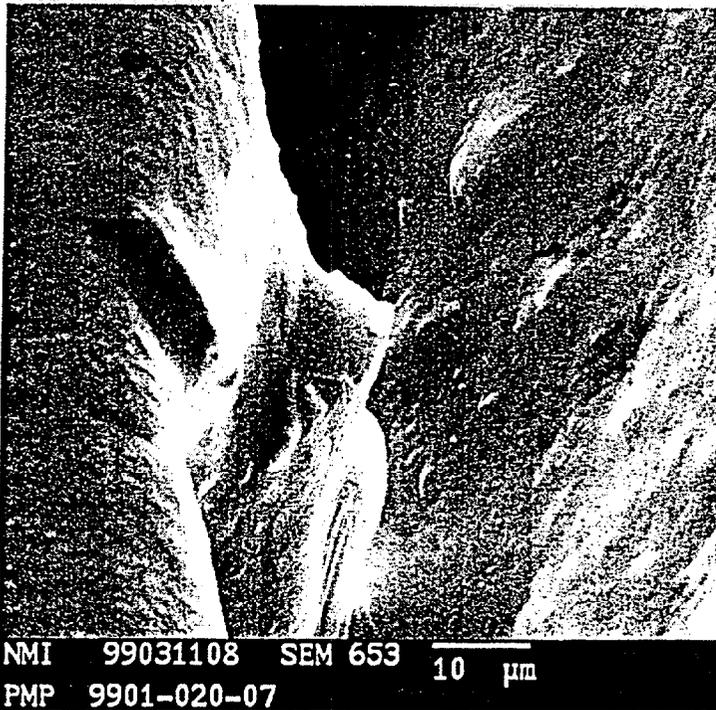


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-07
Location: Forceps at the distal end
Visible contaminations at the joint region

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

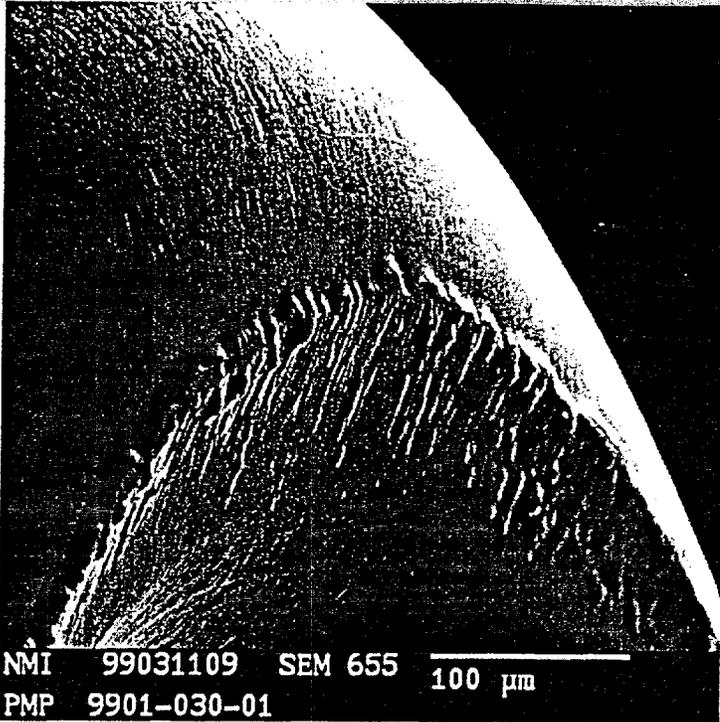


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-07
Location: Forceps at the distal end



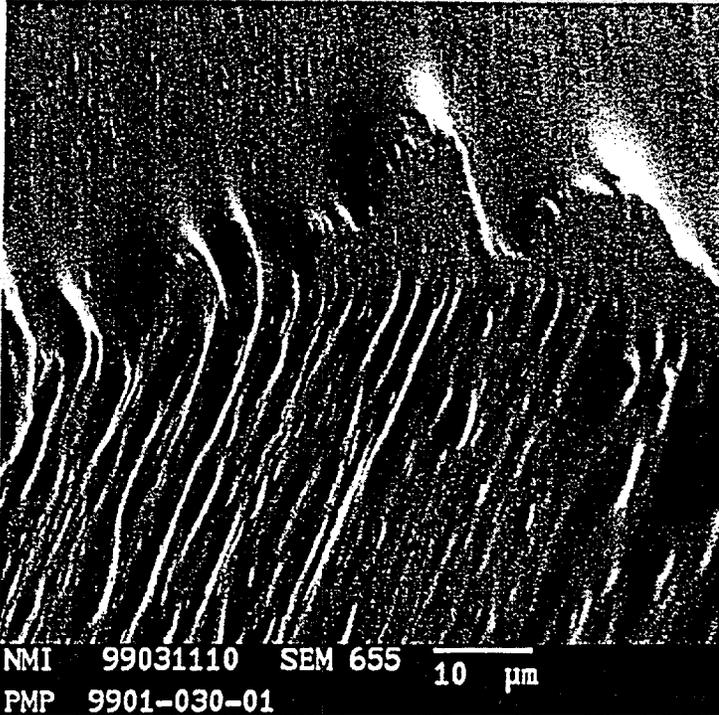
Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-020-07
Location: Forceps at the distal end
Visible contaminations at the joint region

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-01

Location: Coil spring, 10 mm above the distal end



Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-01

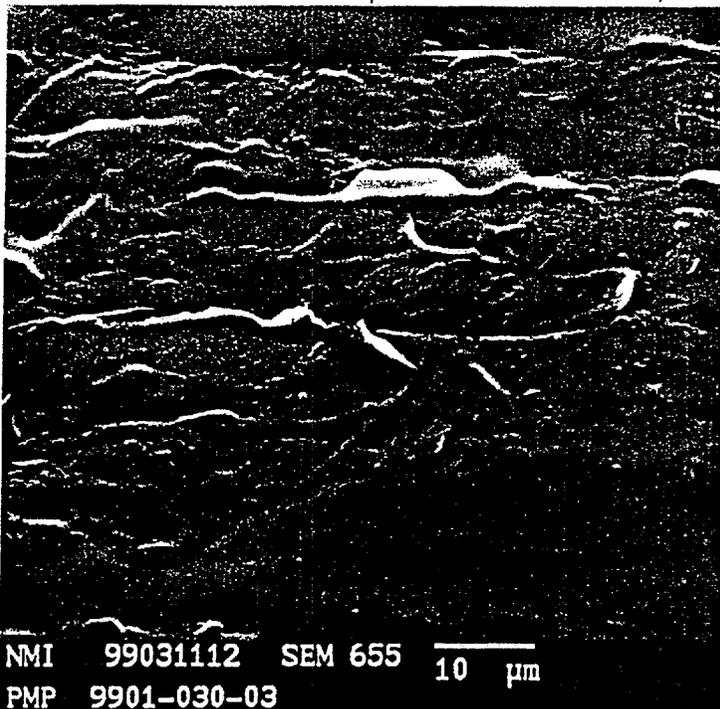
Location: Coil spring, 10 mm above the distal end
Surface coated with residual layer

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-03

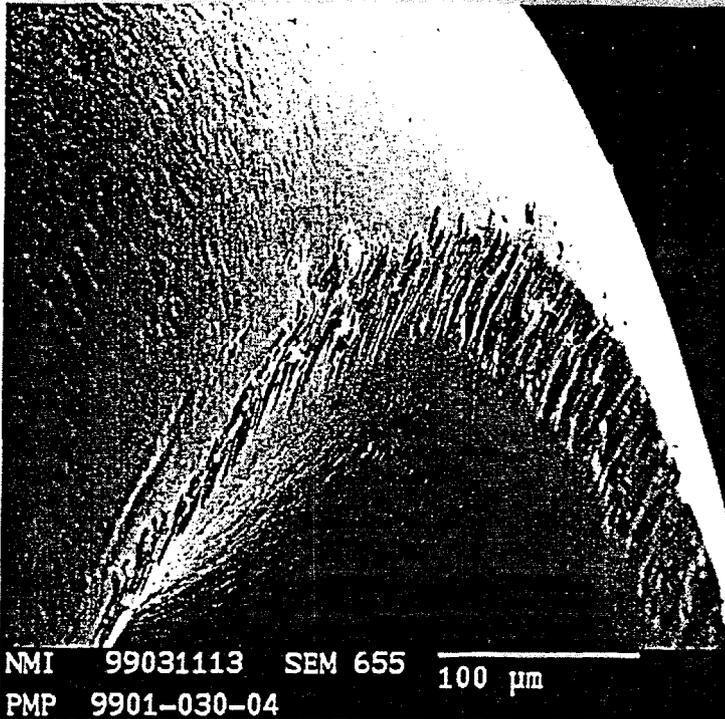
Location: Outer surface of plastic sheath of wire, 100 mm above the distal end



Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-03

Location: Outer surface of plastic sheath of wire, 100 mm above the distal end
Visible residual layer

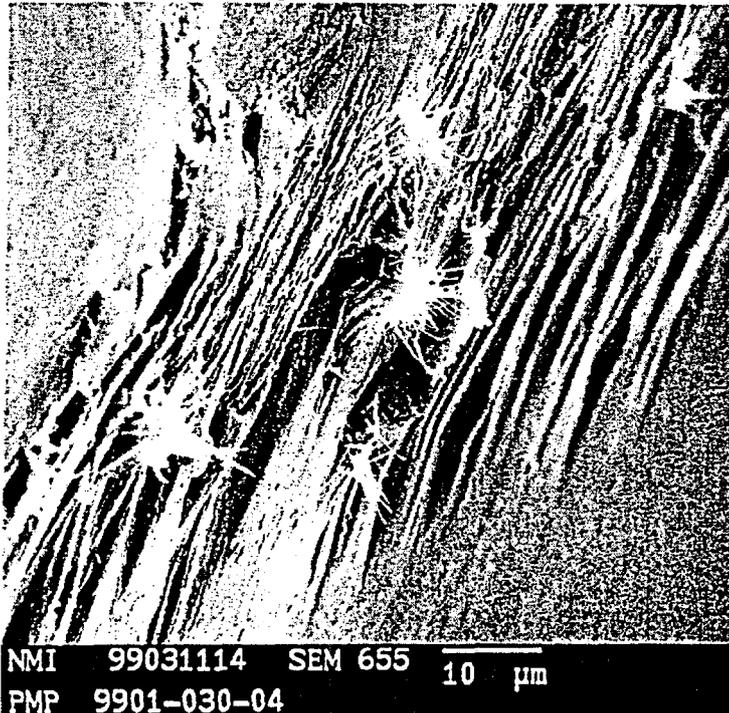
Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



NMI 99031113 SEM 655 100 μ m
PMP 9901-030-04

Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-04

Location: Coil spring, 200 mm above the distal end



NMI 99031114 SEM 655 10 μ m
PMP 9901-030-04

Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-04

Location: Coil spring, 200 mm above the distal end
Visible contaminations

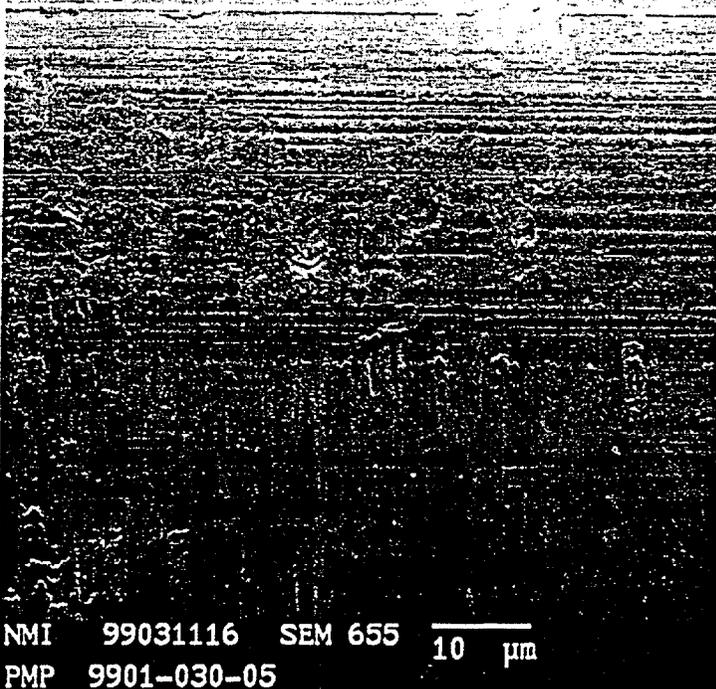
Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



NMI 99031115 SEM 655 100 μm
PMP 9901-030-05

Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-05

Location: Wire, 200 mm above the distal end



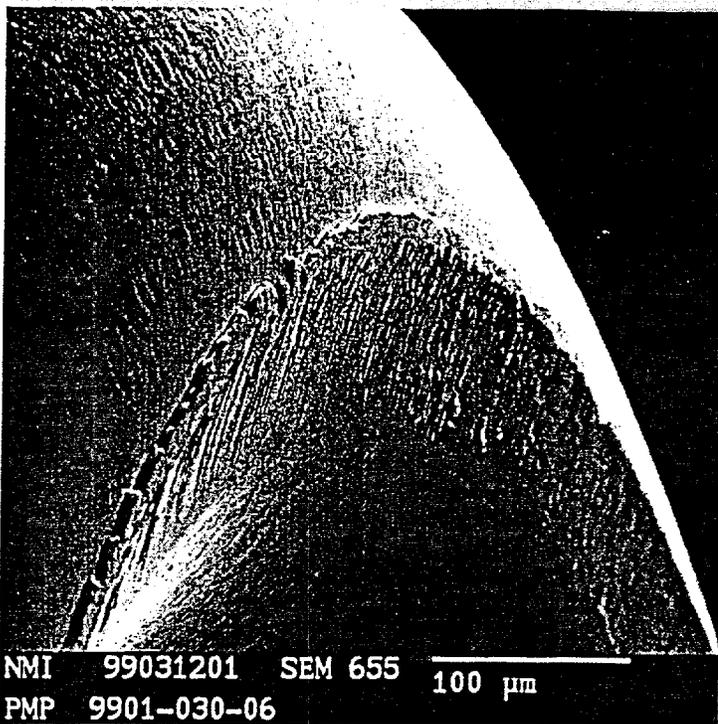
NMI 99031116 SEM 655 10 μm
PMP 9901-030-05

Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-05

Location: Wire, 200 mm above the distal end

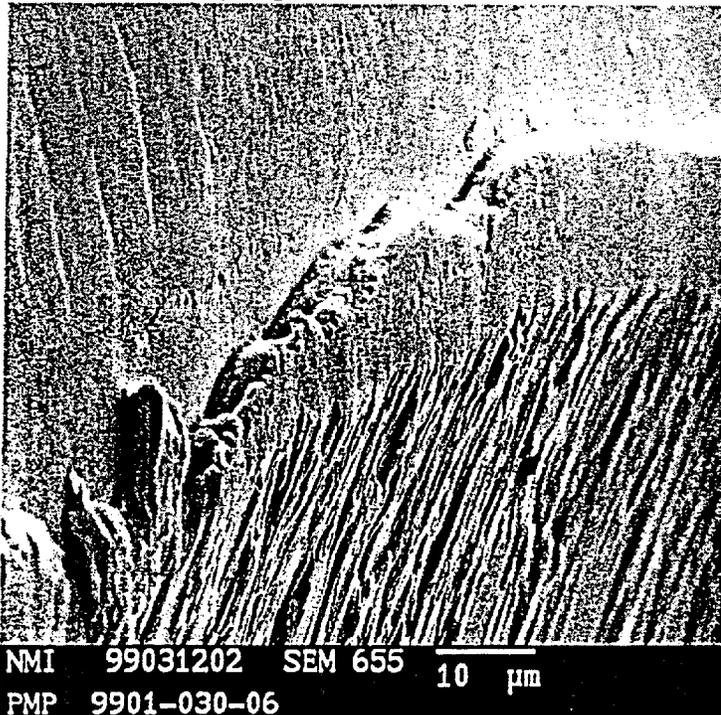
No visible contamination

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-06

Location: Coil spring, 400 mm above the distal end

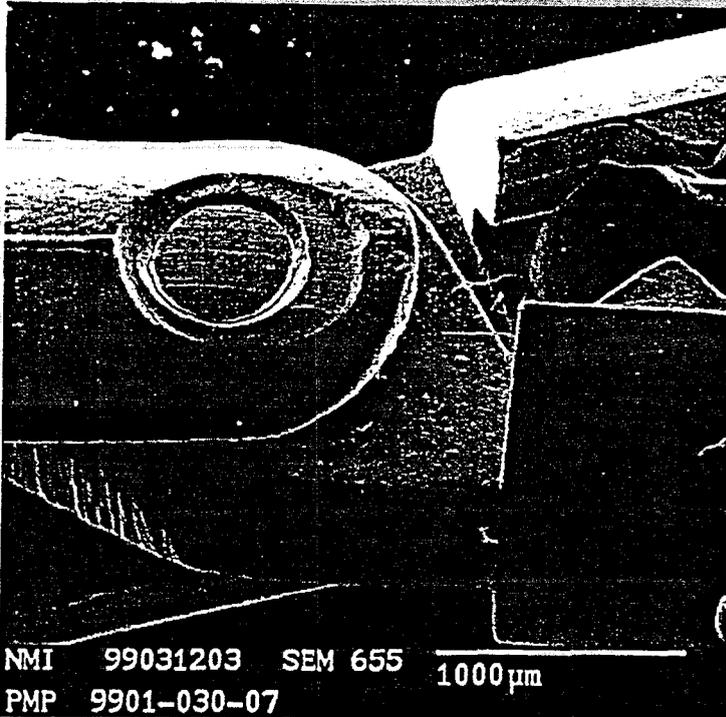


Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-06

Location: Coil spring, 400 mm above the distal end

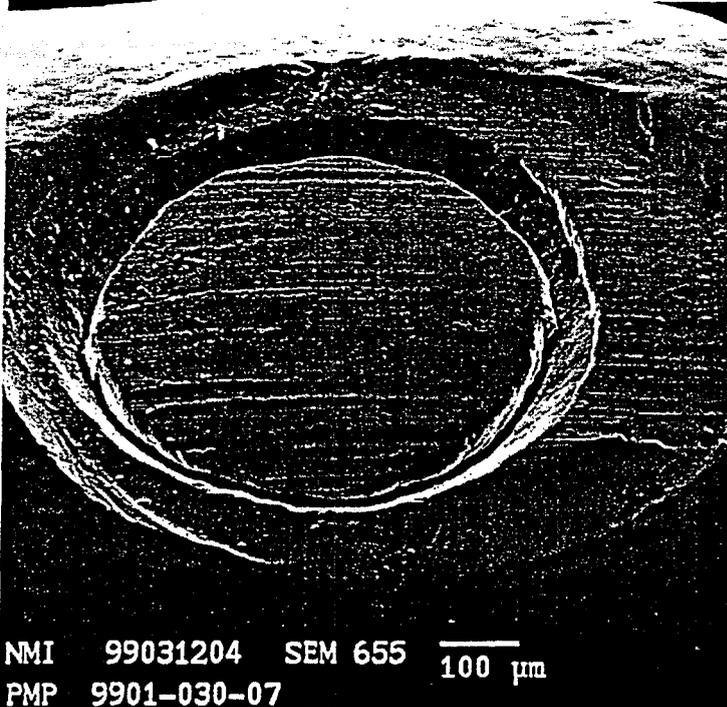
No visible contamination, coil with structured surface at the contact area

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-07

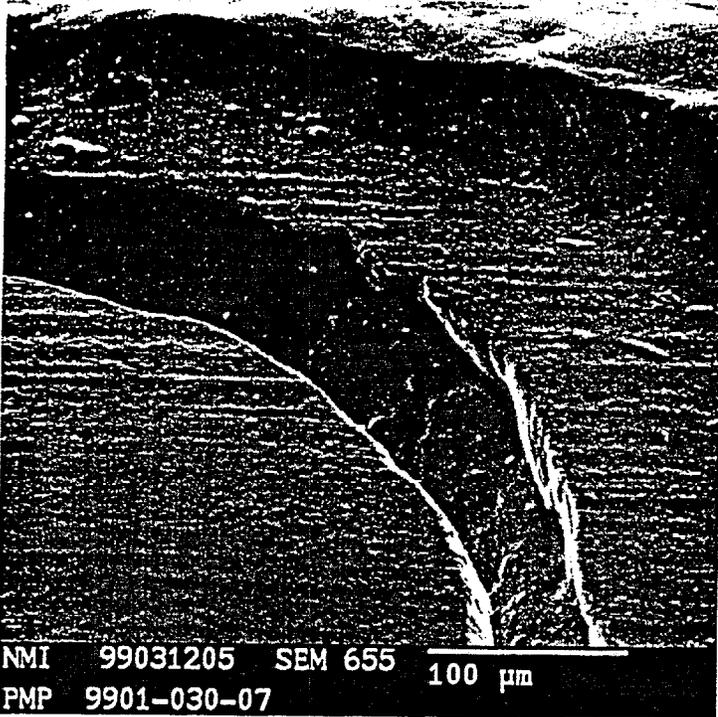
Location: Forceps at the distal end



Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-07

Location: Forceps at the distal end

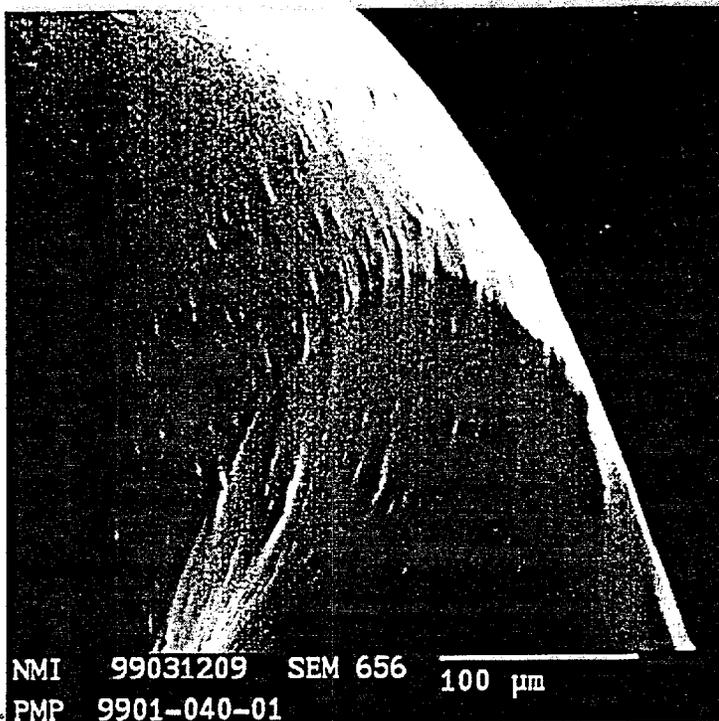
Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



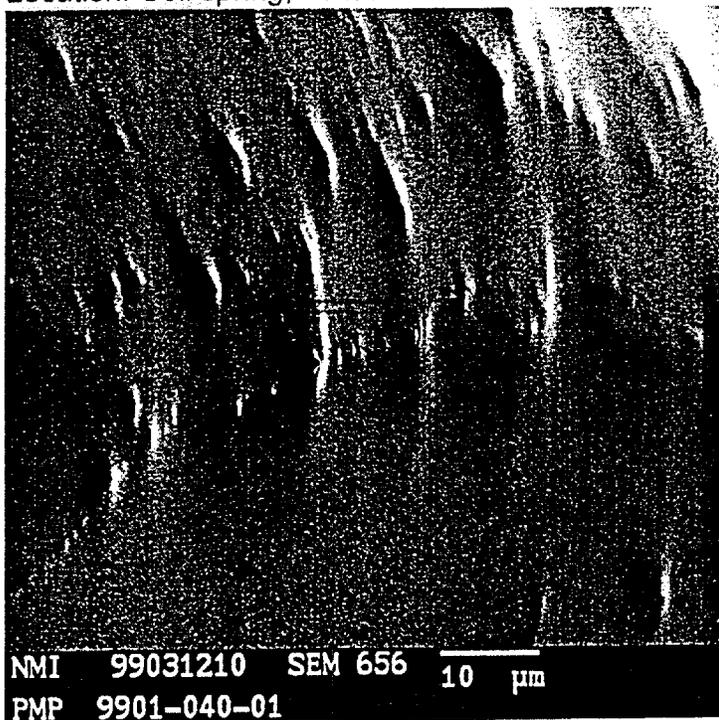
Radial Jaw 3 Hot Biopsy Forceps, soiled and reprocessed, sample 9901-030-07

Location: Forceps at the distal end
No visible contamination

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

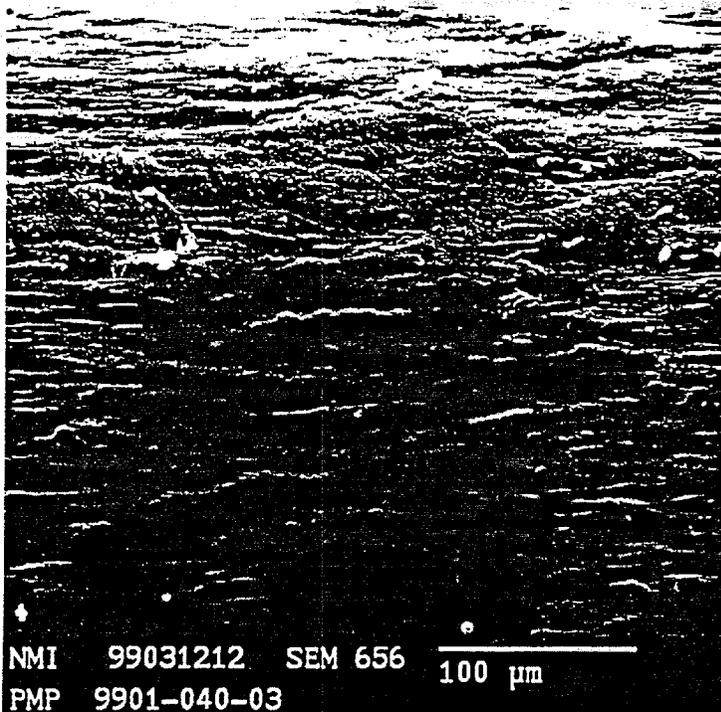


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-01
Location: Coil spring, 10 mm above the distal end

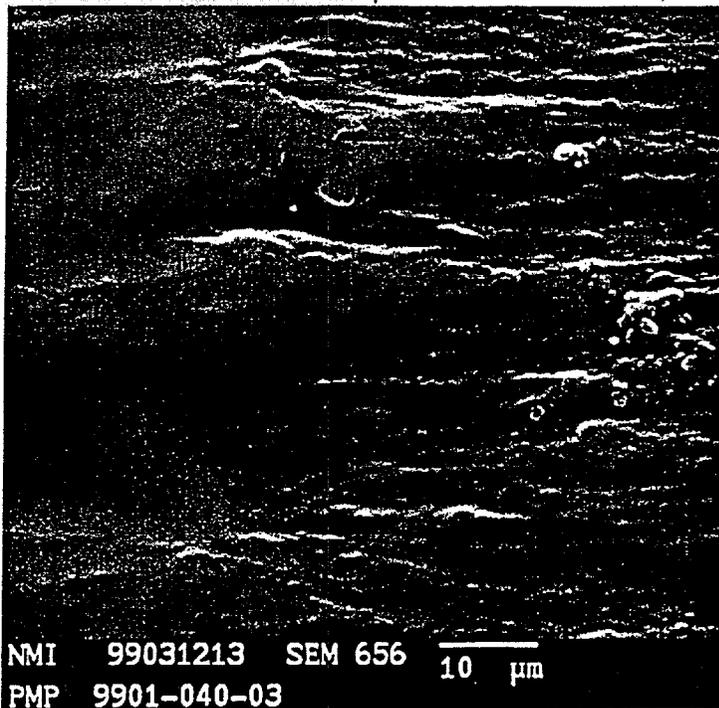


Biopsy Forceps Rinsible, soiled and reprocessed, sample 9901-040-01
Location: Coil spring, 10 mm above the distal end
Surface covered with residual layer

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

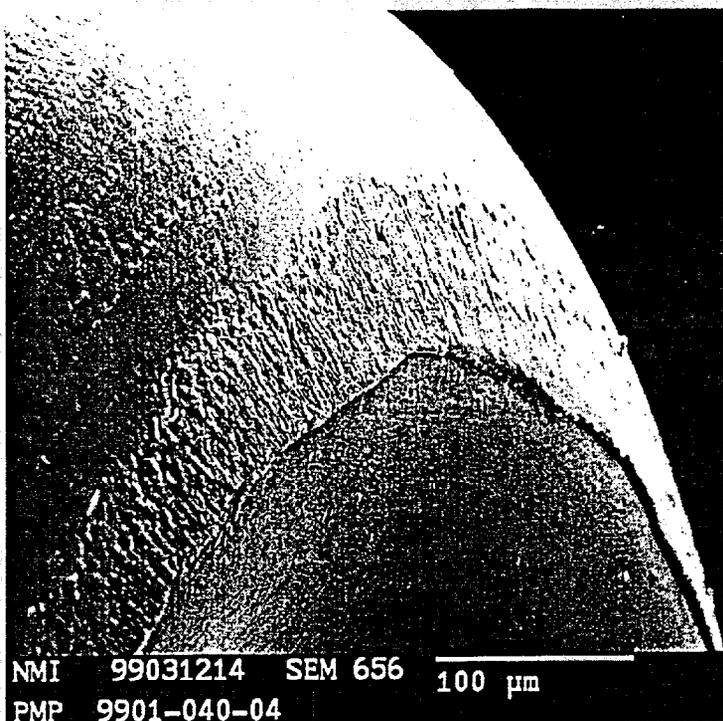


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-03
Location: Outer surface of plastic sheath of wire, 100 mm above the distal end

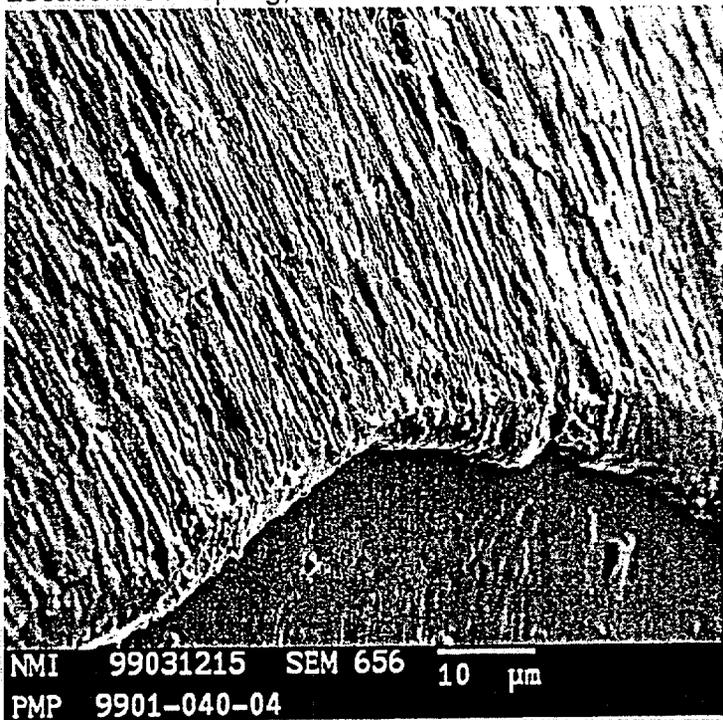


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-03
Location: Outer surface of plastic sheath of wire, 100 mm above the distal end
Visible residual layer

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

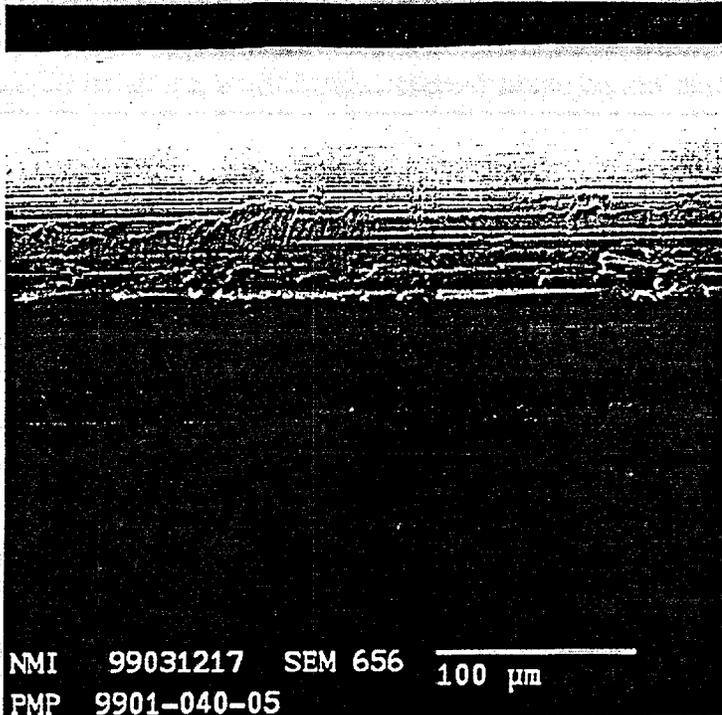


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-04
Location: Coil spring, 200 mm above the distal end

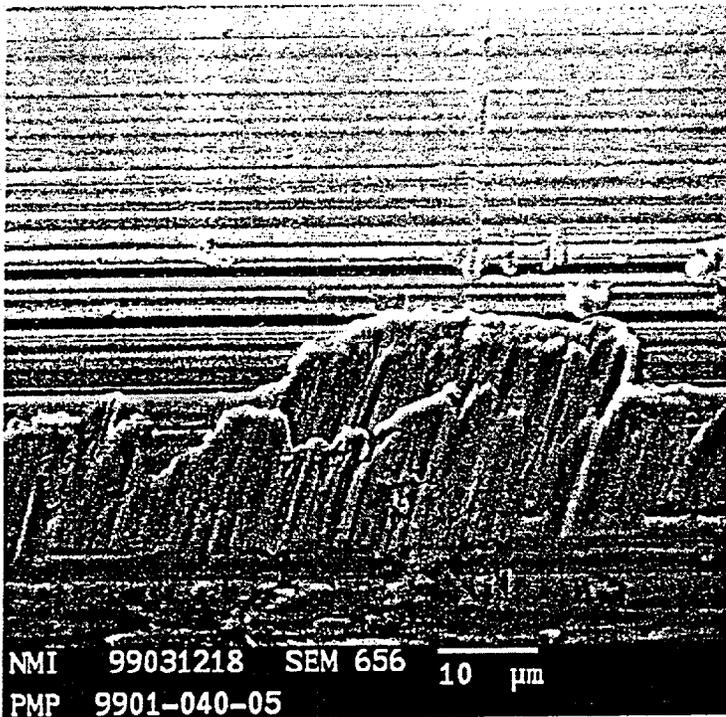


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-04
Location: Coil spring, 200 mm above the distal end
No visible contaminations, coil with structured surface at the contact area

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

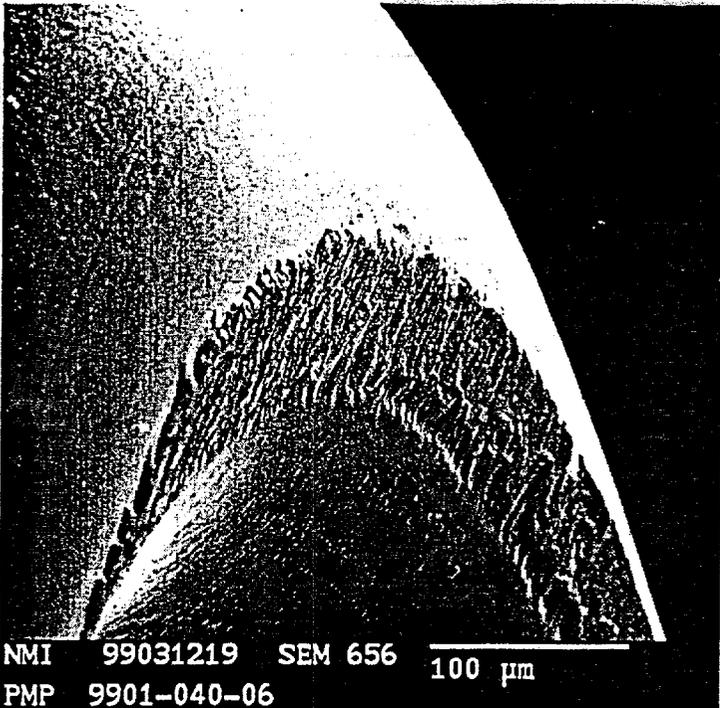


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-05
Location: Wire, 200 mm above the distal end

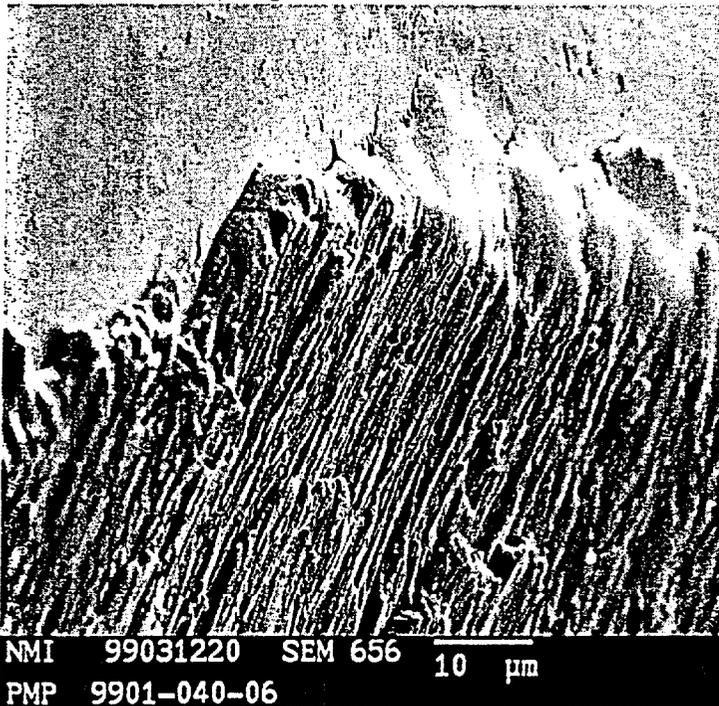


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-05
Location: Wire, 200 mm above the distal end
No visible contamination, structured surface

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

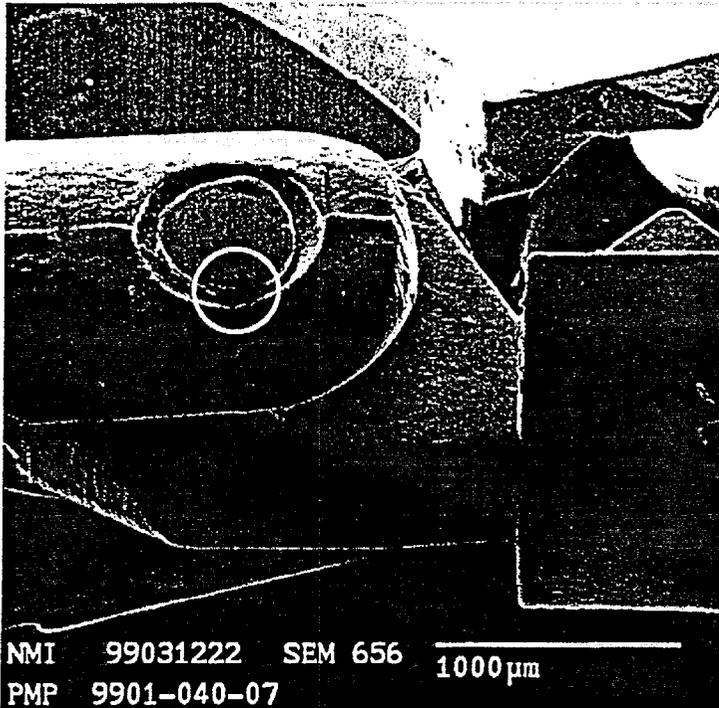


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-06
Location: Coil spring, 400 mm above the distal end

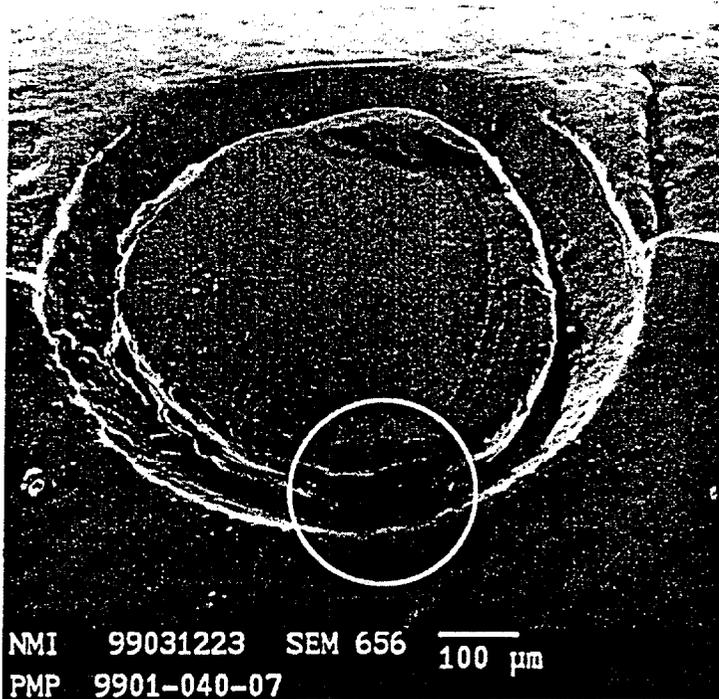


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-06
Location: Coil spring, 400 mm above the distal end
No visible contamination, coil with structured surface at the contact area

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

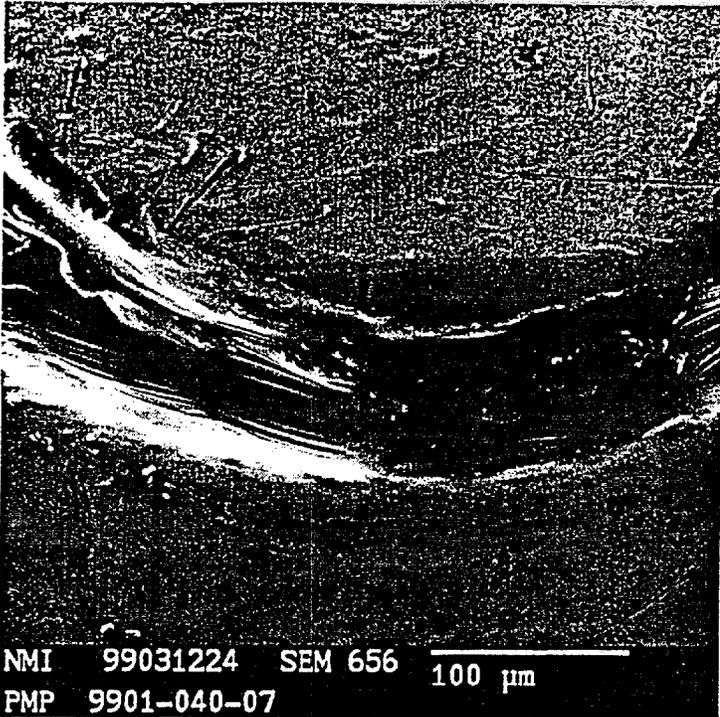


Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-07
Location: Forceps at the distal end



Radial Jaw 3 Biopsy Forceps, soiled and reprocessed, sample 9901-040-07
Location: Forceps at the distal end
Visible contamination at the joint region (encircled)

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research



Hot Biopsy Forceps, soiled and reprocessed, sample 9901-020-07
Location: Forceps at the distal end
Visible contamination at the joint region

5.3 *Element Concentrations (XPS)*

A survey spectrum of the surfaces was carried out and evaluated qualitatively. Subsequent from the identified and suspected elements a sectional spectrum was performed and the concentration of the elements was determined.

For quantification of the elements a homogeneous distribution of the elements were assumed. Hydrogen was not taken into account.

The calculated concentrations of elements at the surface of the samples are listed in the following table:

| Sample | Concentration of elements [at%] | | | | |
|---|---------------------------------|----|----|-------|---|
| | C | O | Si | N | F |
| Biopsy Forceps 9901-010-02 Soiled and reprocessed | 63 | 19 | 17 | < 0,1 | 1 |
| Biopsy Forceps 9901-020-02 Soiled and reprocessed | 56 | 22 | 22 | < 0,1 | 1 |
| Biopsy Forceps 9901-030-02 Soiled and reprocessed | 62 | 19 | 19 | < 0,1 | 1 |
| Biopsy Forceps 9901-040-02 Soiled and reprocessed | 67 | 17 | 16 | < 0,1 | 1 |

Tab. 1: Concentration of elements
Surface of wire about 10 mm above the distal end.

Report on Light Microscopy, Scanning Electron Microscopy
and X-ray Photoelectron Spectroscopy Research

XPS measurements yielded carbon, oxygen and silicon as the important elements of the chemical composition of the surface. Nitrogen which could be a marker for protein, was not identified. The detected silicon may indicate residues from the cleaning agent as well as from lubricants, e.g. silicone. The residual layer thickness was sufficient to cover the bulk material (stainless steel) on the investigated devices and locations.

PMP

PMP

Prüfzentrum für Medizinprodukte

ein Projekt des

Naturwissenschaftlichen und Medizinischen Instituts.
Reutlingen, Leitung: Dr. R. E. Müller
in Kooperation mit

NMI

der Sektion und dem Steinbeis-Transferzentrum
für Minimal Invasive Chirurgie, Tübingen
Leitung: Prof. Dr. G. Bueß

MIC

STW

der Klinikhygiene, Tübingen
Leitung: Prof. Dr. P. Heeg

Leitung: Dr. R. Reichl 0 71 21 / 51 53 00

Klaus Roth 0 70 71 / 2 98 12 39

Tübingen, den 31. März 1999

EXAMINATION OF DEVICES, REPROCESSED BY VANGUARD

DECLARED TO BE STERILE

DEVICES EVALUATED WERE REPROCESSED & REPACKAGED FOR :

[REDACTED]

PERFORMING LABORATORY:

PMP

**THE CENTER FOR THE TESTING OF MEDICAL PRODUCTS
UNIVERSITY OF TUEBINGEN
WALDHOERNLESTRASSE 22
D - 72072 TUEBINGEN**

16 single use devices, which were reprocessed by a third party reprocessor, were obtained from the hospital at random and sent to PMP, and tested for claims of sterility and cleanliness. All of these devices are originally labeled for single use and have been manufactured by Microvasive, Boston Scientific Corporation.

Reprocessing was performed by Vanguard, Medical Concepts, Inc. Lakeland Florida. The devices have been reprocessed, repacked and registered and were at the hospital awaiting patient use. The following data are documented on the package (See Attachment I), the hospital believed the reprocessor's label claims:

- the reprocessor
- the customer (hospital)
- the manufacturer
- Tracking No.
- Mfg-Cat-No:
- Description of the device
- Lot Number
- Sterilization Date
- Number of Uses

The label includes a bar code sticker for documentation.

Tests were performed in

February/March 1999

For sterility testing, standard microbiological procedures with aseptic technic have been used.

Light microscopy, Scanning electron microscopy and photoelectron spectroscopy delivers additional information on the cleanliness of the devices. Results of these technics are documented in attachment 2.

The selection of the devices for the different procedures has been done by random selection. 9 underwent sterility testing and 7 were examined by the other procedures.

For documentation and identification of the devices the sterile bags were numbered by the laboratory.

Director of study:

Klaus Roth



Microbiological testing:

Prof. Dr. Peter Heeg

Microscopy and spectroscopy

Dr. Rudolf Reichl

Sterility testing

We used the following procedure

Recovery

Radial jaw:

- Aseptically cut 30 cm of the tip and also the following 30 cm segment and put them into separate sterile tubes (containing 50 ml broth)
- Aseptically cut the rest of the instrument also into 10 cm segments and collect them in another tube (containing 50 ml broth)
- vortex the 50 ml-tubes for 30 seconds and shake them again 30 seconds manually
- shake the beakers for 15 mins at 300 mins⁻¹
- plate 1 ml and spiralplate also 92 μ l on Columbia-blood-agar (the controls and also the control-dilutions only need to be spiralplated)
- incubate the broth for 7 days at 37°C

Examination of reprocessed devices (declared to be sterile)

16.6.98

| Nr: | Type | cfu/ml (1 ml) | Volume (ml) Growth (+/-) | Diffeentiation cfu per device |
|-----|---|------------------|-------------------------------------|---|
| 1 | Radial Jaw 0 - 30 cm 30 - 60 cm rest of device | 0 0 0 | 50 ml (-) 50 ml (-) 50 ml (+) | - - < 50 Spo |
| 5 | Radial Jaw 0 - 30 cm 30 - 60 cm rest of device | 0 0 0 | 50 ml (+) 50 ml (-) 50 ml (+) | < 50 Mkz - < 50 Spo |
| 7 | Radial Jaw 0 - 30 cm 30 - 60 cm rest of device | 0 0 1 | 50 ml (-) 50 ml (-) 50 ml (+) | - - 50 Mkz |
| 8 | Radial Jaw 0 - 30 cm 30 - 60 cm rest of device | 0 0 0 | 50 ml (-) 50 ml (-) 50 ml (+) | - - < 50 Spo |
| 11 | Radial Jaw 0 - 30 cm 30 - 60 cm rest of device | 0 0 0 | 50 ml (-) 50 ml (+) 50 ml (+) | - < 50 Mkz < 50 Spo |
| 13 | Radial Jaw 0 - 30 cm 30 - 60 cm rest of device | 0 0 0 | 50 ml (-) 50 ml (-) 50 ml (+) | - - < 50 Spo and α -hemolytic streptococci |
| 14 | Radial Jaw 0 - 30 cm 30 - 60 rest of device | 0 1 0 | 50 ml (+) 50 ml (+) 50 ml (+) | < 50 α -hemolytic streptococci 50 Spo < 50 Spo |
| 16 | Radial Jaw 0 - 30 cm 30 - 60 cm rest of device | 0 0 0 | 50 ml (-) 50 ml (+) 50 ml (-) | - < 50 Mkz 0 |
| 17 | Radial Jaw 0 - 30 cm 30 - 60 cm rest of device | 0 0 0 | 50 ml (-) 50 ml (-) 50 ml (+) | - - < 50 Spo |

Spo = aerobic spore forming organism
Mkz = micrococcaceae

Conclusion:

The study has shown that

- none of the reprocessed devices was steril.
- reprocessing did not result in clean devices as a prerequisite for effective disinfection or sterilization.
- equal standard patient care, (universal precaution), assuring that each patient should have a clean device to prevent infection from cross contamination.

All these results, investigating the present state of the art of reprocessing endoscopic accessories, show that these single use biopsy forceps cannot be reprocessed safely and reproducibly to sterile condition, even with so called validated reprocessing methods.

Attachement 1: Copies of the sterile packages for documentation

Attachement 2: Results of light microscopy, scanning electron microscopy and photoelectron spectroscopy



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:

Mfg Name: MICROVASIVE - Watertown, MA 02172
Tracking No: 866892 **Mfg-Cat-No:** 1537
Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHEAT
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM
Lot Number: 223823 **Sterilization Date:** 6/97
Uses: 1

Caution: Federal Law (USA) restricts the use of
this device to use by or on order of a physician.
Follow recommended hospital procedure.



Peel Here.

5



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 869599

Uses: 2

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 227264

Sterilization Date: 11/97

For One Procedure Only



8 6 9 5 9 9



8 6 9 5 9 9



8 6 9 5 9 9



8 6 9 5 9 9



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**

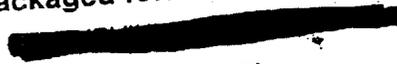
7



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

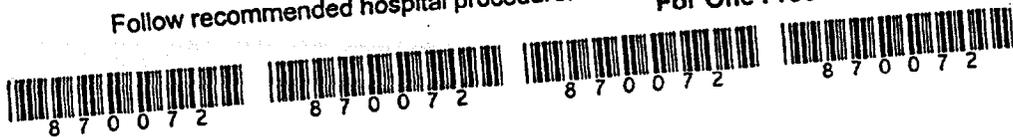
Desc: BIOPSY FORCEPS LOWER GI W/NEEDLE

Tracking No: 870072

Uses: 1

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 226471
Sterilization Date: 10/97
For One Procedure Only





VANGUARD
 Medical Concepts, Inc.
 Lakeland, Florida

8

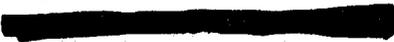
**CONTENTS STERILE UNLESS PACKAGE
 IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
 Lakeland, FL 33815
 (800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg at-No: 1537

Trading No: 869091

Uses: 2

Desc: RADIAL JAW 3 BIOPSY FORCEPS
 SERRATED W/NEEDLE ENDOGLIDE SHE
 WORK LEN-240CM OUTSIDE DIA-2.2MM
 REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
 device to use by or on order of a physician.
 Follow recommended hospital procedure.

Lot Number: 226471

Sterilization Date: 10/97

For One Procedure Only



11



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

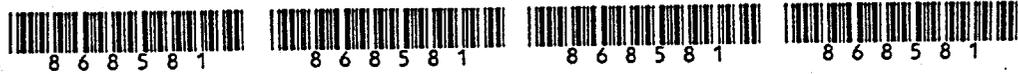
Tracking No: 868581

Uses: 2

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 226471
Sterilization Date: 10/97
For One Procedure Only



13



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

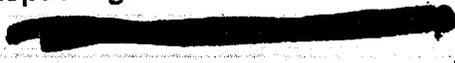
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Desc: BIOPSY FORCEPS LOWER GI W/NEEDLE

Tracking No: 870071

Uses: 1

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 226471
Sterilization Date: 10/97
For One Procedure Only



14



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

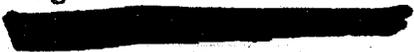
**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Desc: BIOPSY FORCEPS LOWER GI W/NEEDLE

Tracking No: 870067

Uses: 1

Caution: Federal Law (USA) restricts the use of this device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 226471
Sterilization Date: 10/97
For One Procedure Only



16



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:

Mfg Name: MICROVASIVE - Watertown, MA 02172
Tracking No: 867688 **Mfg-Cat-No:** 1537
Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHEATH
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Lot Number: 225483

Sterilization Date: 8/97

Uses: 2

Caution: Federal Law (USA) restricts the use of
this device to use by or on order of a physician.

Follow recommended hospital procedure.



8 6 7 6 8 8

Peel Here.



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

17

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:

Mfg Name: MICROVASIVE - Watertown, MA 02172
Tracking No: 869606 **Mfg-Cat-No:** 1274
Desc: BIOPSY FORCEPS LOWER GI W/NEEDLE

Lot Number: 225926

Sterilization Date: 9/97

Uses: 1

Caution: Federal Law (USA) restricts the use of
this device to use by or on order of a physician.

Follow recommended hospital procedure.



Peel Here.

**COMPARISON OF CONTAMINATION AND MATERIAL ANALYSIS
BETWEEN „SINGLE USE“ DEVICES AND REUSABLE DEVICES
SOILED UNDER CLINICAL USE AND REPROCESSED**

Instrument: Radial Jaw 3

**Report of Light Microscopy, Scanning Electron Microscopy
and Photoelectron Spectroscopy Research**

PREPARED FOR

**Boston Scientific Corporation
Microvative Endoscopy
One Boston Scientific Place
Natick, MA 01760-1537**

PERFORMING LABORATORY

**PMP
The Center for the Testing of Medical Products
University of Tübingen
Markwiesenstr. 55
D - 72770 Reutlingen**

02.08.98

Purpose of study:

The purpose of this study is to analyze the condition of single use Radial Jaw biopsy forceps after clinical use and reprocessing by different third party reprocessors. Microbiological and instrumental methods of surface analysis to analyze the device condition after reprocessing has been used.

According to the Spaulding/CDC¹ method of classification for medical devices, the devices in this study are classified as critical use devices, because they brake intact mucous membranes or are introduced directly into the sterile areas of the body. Sterility at the time of use is required for these items; consequently, a 10^{-6} sterility assurance level (the probability of one non-sterile unit out of one million units reprocessed) is the acceptable risk basis for critical devices. In response to the need for cost containment, many healthcare facilities are faced with the decision of reprocessing single-use medical devices.

The study evaluates contamination effects caused by the reuse of single-use devices, as compared with devices designed for reprocessing because good cleaning results are a predictor of adequate disinfection and sterilization. Measurable endpoints for evaluation will include contamination identification, bioburden, sterility, design evaluation and material analysis.

¹ Spaulding EH. Chemical disinfection and antisepsis in the hospital. J. Hosp. Res., 1972, vol.9, p.5-31

Table of contents:

| | |
|--|----|
| 1 Conclusion:..... | 3 |
| 2 Samples: | 4 |
| 3 Sample preparations | 6 |
| 4 Analytical Methods | 6 |
| 4.1 Light Microscopy (LM) | 6 |
| 4.2 Scanning Electron Microscopy (SEM) | 6 |
| 4.3 Photoelectron Spectroscopy (XPS) | 6 |
| 5 Results | 6 |
| 5.1 Light Microscope Images (LM) | 6 |
| 5.2 Scanning Electron Micrographs (SEM)..... | 17 |
| 5.3 Element Concentrations (XPS) | 50 |

Name: Radial Jaw 3
Description: Large Capacity, w/needle
Manufacturer: Microvasive

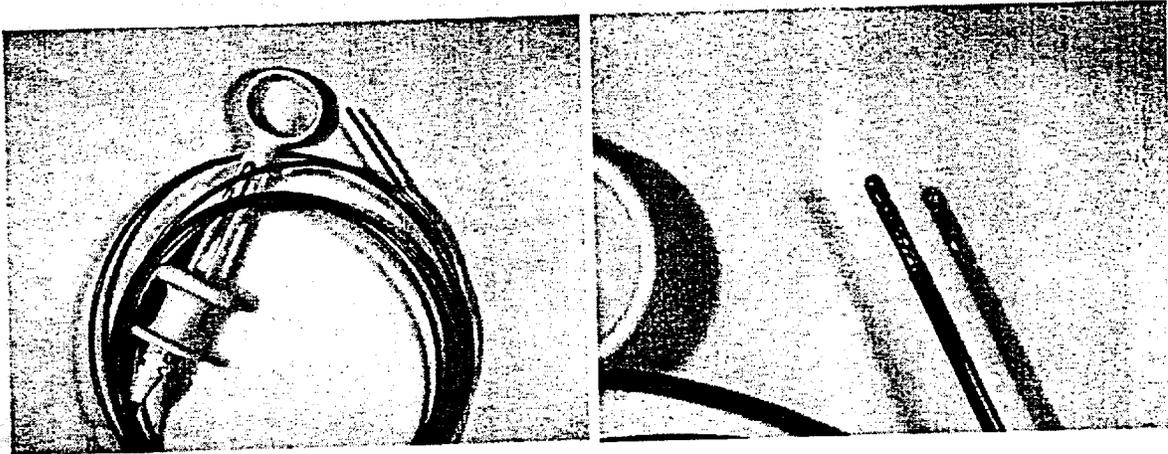


Fig. 1: Radial Jaw 3 catheter

1 Conclusion:

Eight soiled and reprocessed catheters ID: 9802-021 – 9802-028 were analyzed.

Using light microscopy contamination appeared locally on several catheters.

Scanning electron micrographs showed contaminations on local areas.

The photoelectron spectroscopy yielded no significant change in the measured concentrations of elements.

2 Samples:

ID: 9802-021:
Name: Radial Jaw 3
Description: Large capacity, w/needle
Manufacturer: Microvasive
Order-No./Ref.:
Lot:
Setting: Clinical use
Reprocessed by Orris
Sterilized with ethylene oxide gas

ID: 9802-022:
Name: Radial Jaw 3
Description: Large capacity, w/needle
Manufacturer: Microvasive
Order-No./Ref.:
Lot:
Setting: Clinical use
Reprocessed by Vanguard
Sterilized with ethylene oxide gas

ID: 9802-023:
Name: Radial Jaw 3
Description: Large capacity, w/needle
Manufacturer: Microvasive
Order-No./Ref.:
Lot:
Setting: Clinical use
Reprocessed by Vanguard
Sterilized with ethylene oxide gas

ID: 9802-024:
Name: Radial Jaw 3
Description: Large capacity, w/needle
Manufacturer: Microvasive
Order-No./Ref.:
Lot:
Setting: Clinical use
Reprocessed by Vanguard
Sterilized with ethylene oxide gas

ID: 9802-025:
Name: Radial Jaw 3
Description: Large capacity, w/needle
Manufacturer: Microvasive
Order-No./Ref.:
Lot:
Setting: Clinical use
Reprocessed by Vanguard
Sterilized with ethylene oxide gas

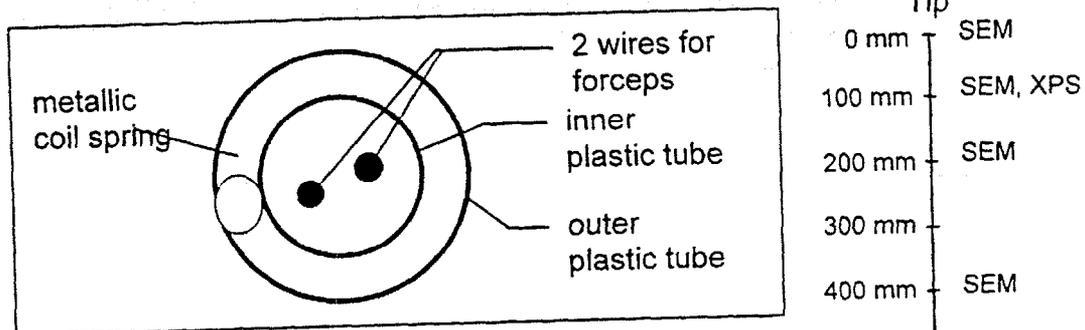
ID: 9802-026:
Name: Radial Jaw 3
Description: Large capacity, w/needle
Manufacturer: Microvasive
Order-No./Ref.:
Lot:
Setting: Clinical use
Reprocessed by Vanguard
Sterilized with ethylene oxide gas

ID: 9802-027:
Name: Radial Jaw 3
Description: Large capacity, w/needle
Manufacturer: Microvasive
Order-No./Ref.:
Lot:
Setting: Clinical use
Reprocessed by Vanguard
Sterilized with ethylene oxide gas

ID: 9802-028:
Name: Radial Jaw 3
Description: Large capacity, w/needle
Manufacturer: Microvasive
Order-No./Ref.:
Lot:
Setting: Clinical use
Reprocessed by Vanguard
Sterilized with ethylene oxide gas

3 Sample preparations

Cross-sectional structure of Radial Jaw 3 catheter:



The catheters were cut off with scalpels at the defined locations. For cutting the coil spring a wire shear was used. To examine the inner surface of the catheter a longitudinal section was carried out.

4 Analytical Methods

4.1 Light Microscopy (LM)

Device: Zeiss, Stereomicroscope SV 8

4.2 Scanning Electron Microscopy (SEM)

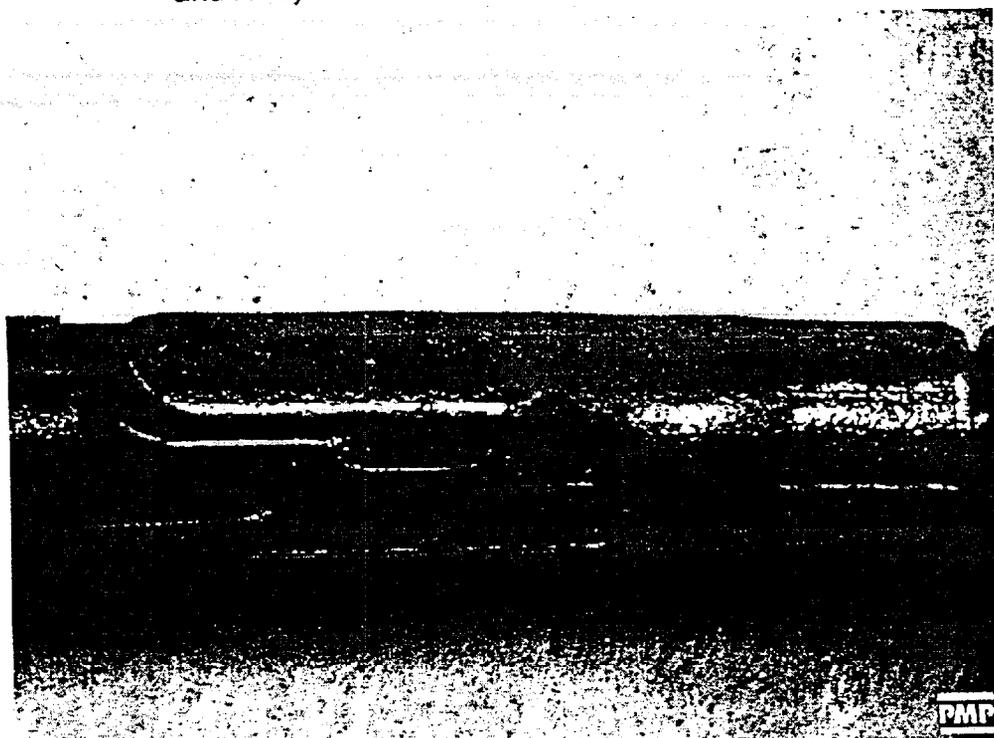
Device: Cambridge S 90
Acceleration voltage: 25 kV
Sputtering: Gold/Palladium
Observation angle: 45°

4.3 Photoelectron Spectroscopy (XPS)

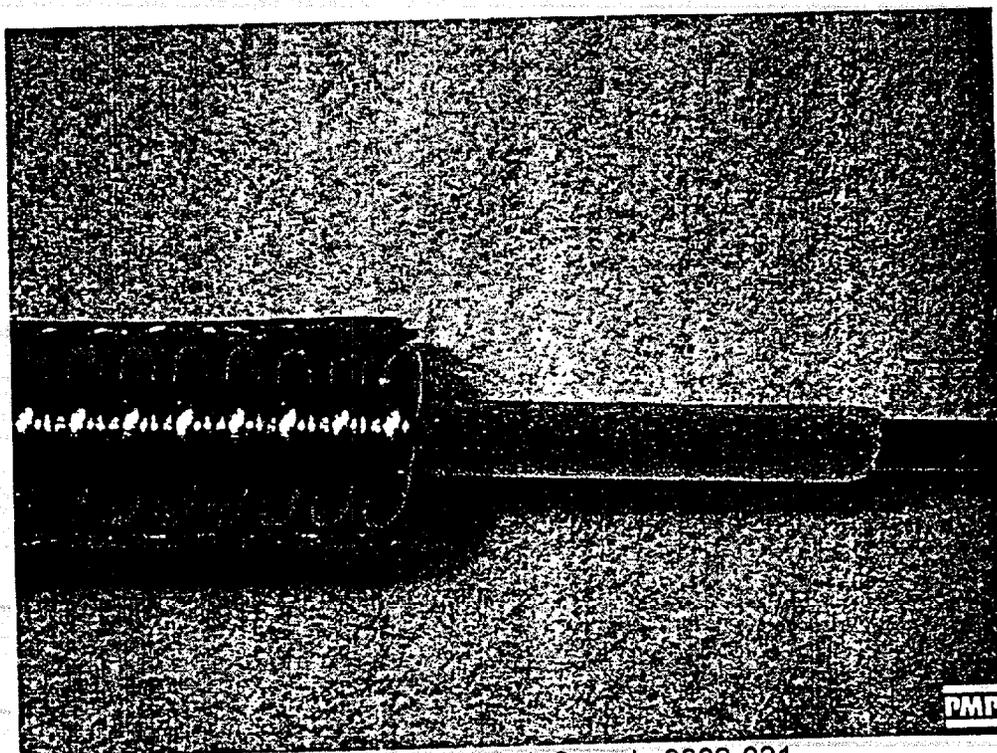
Device: VG ESCALAB 200 A
Irradiation: MgK α
Area of measurement: \varnothing 1 mm
Residual gas pressure: 10⁻¹⁰ mbar

5 Results

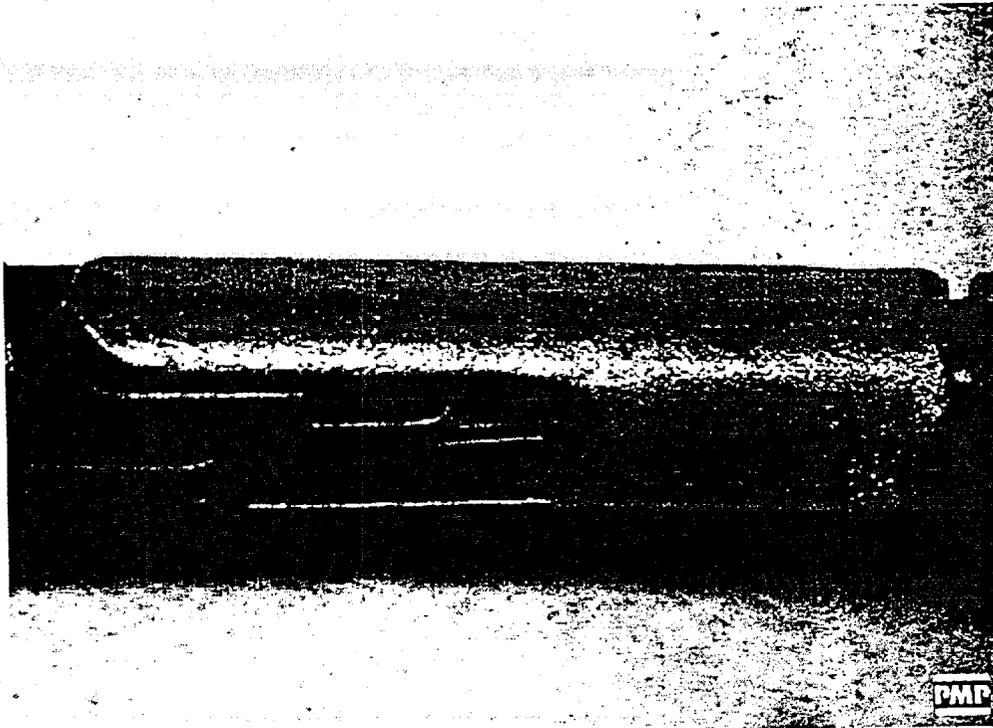
5.1 Light Microscope Images (LM)



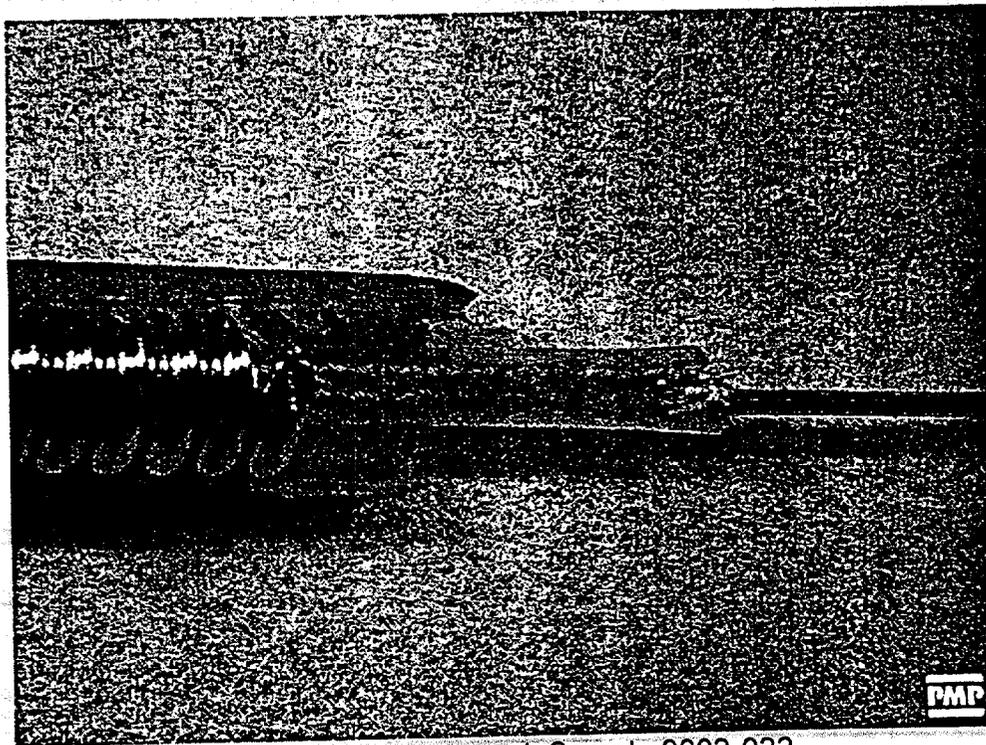
Radial Jaw 3, soiled and reprocessed, Sample 9802-021
Location: forceps
No visible contaminations



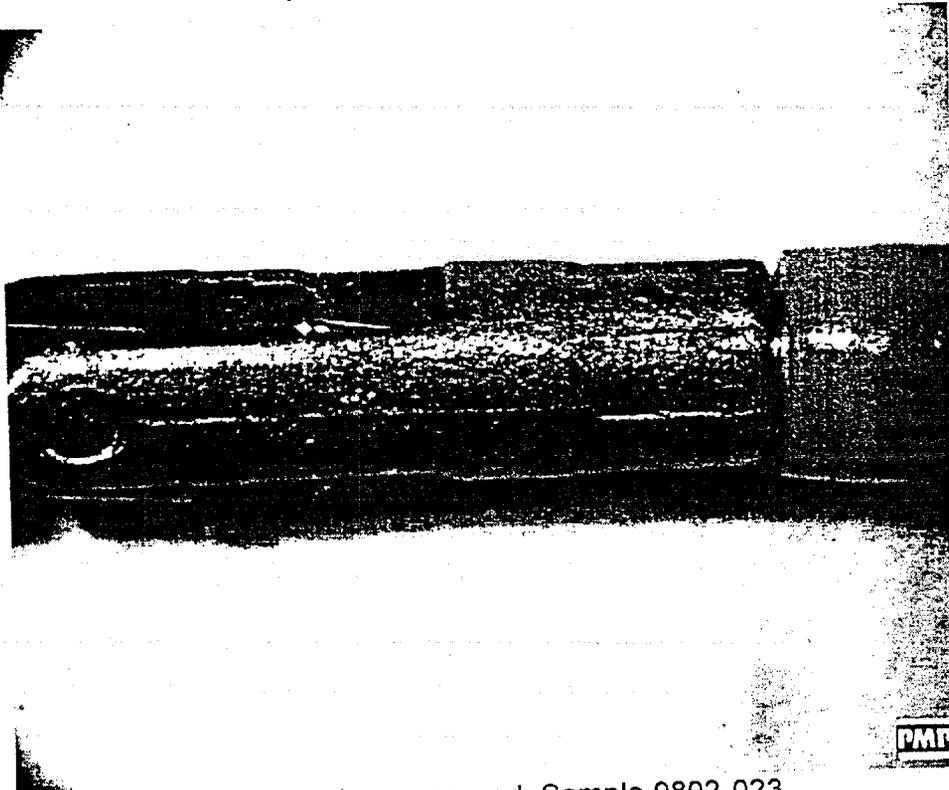
Radial Jaw 3, soiled and reprocessed, Sample 9802-021
Location: 100 mm above the tip
No visible contaminations



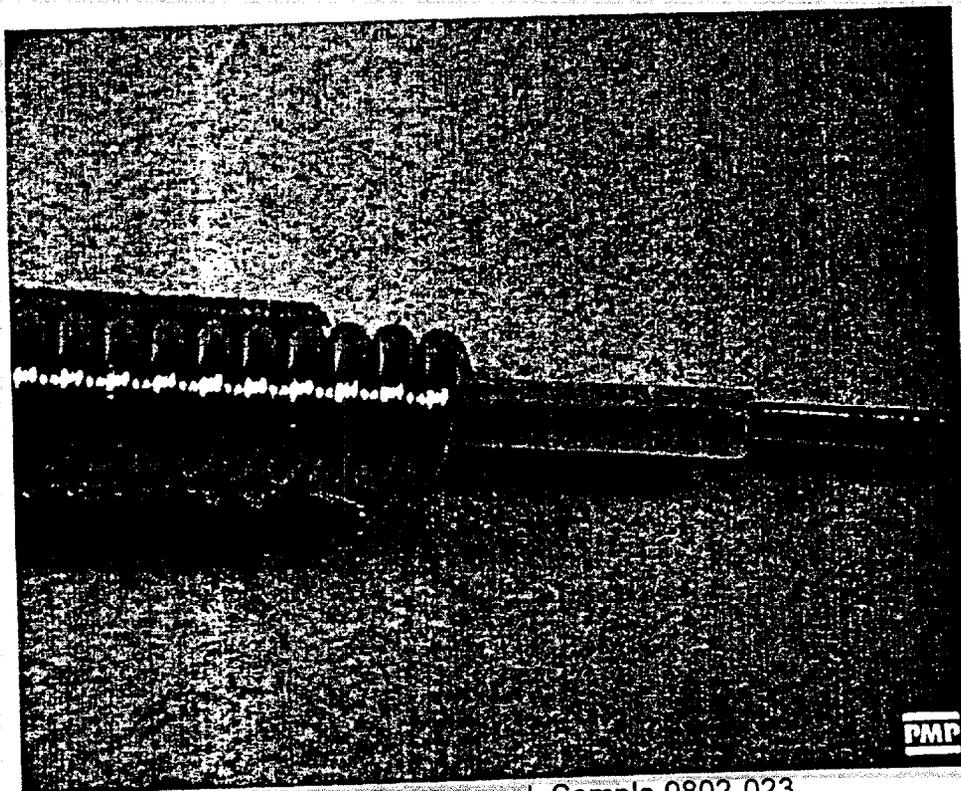
Radial Jaw 3, soiled and reprocessed, Sample 9802-022
Location: forceps
No visible contaminations



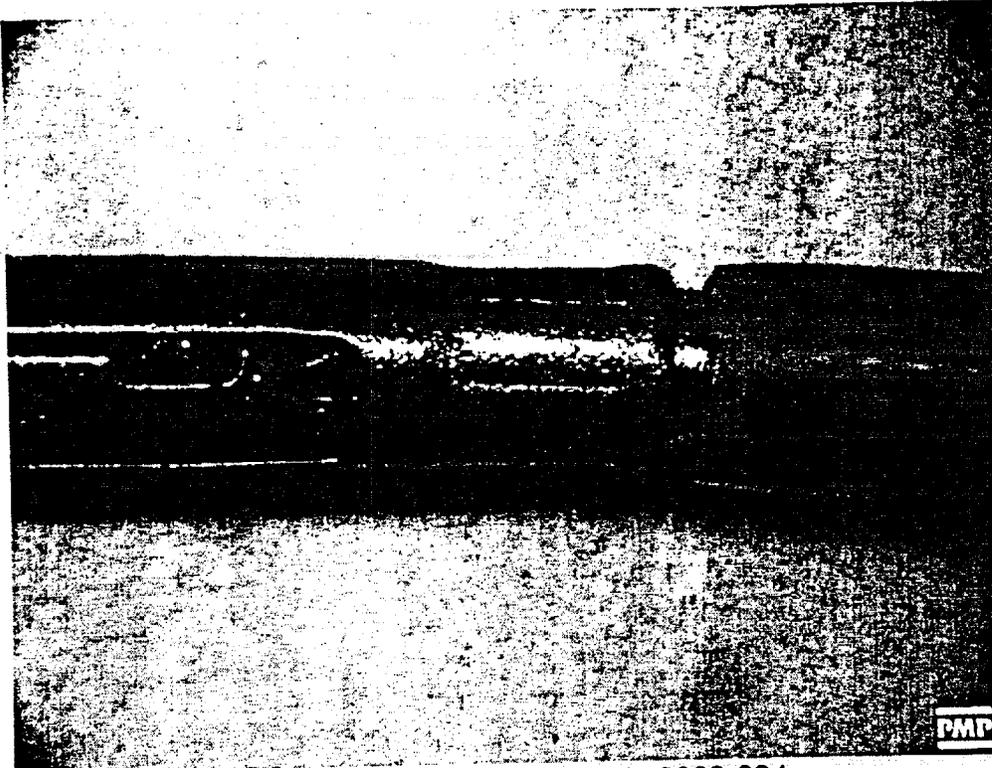
Radial Jaw 3, soiled and reprocessed, Sample 9802-022
Location: 100 mm above the tip
No visible contaminations



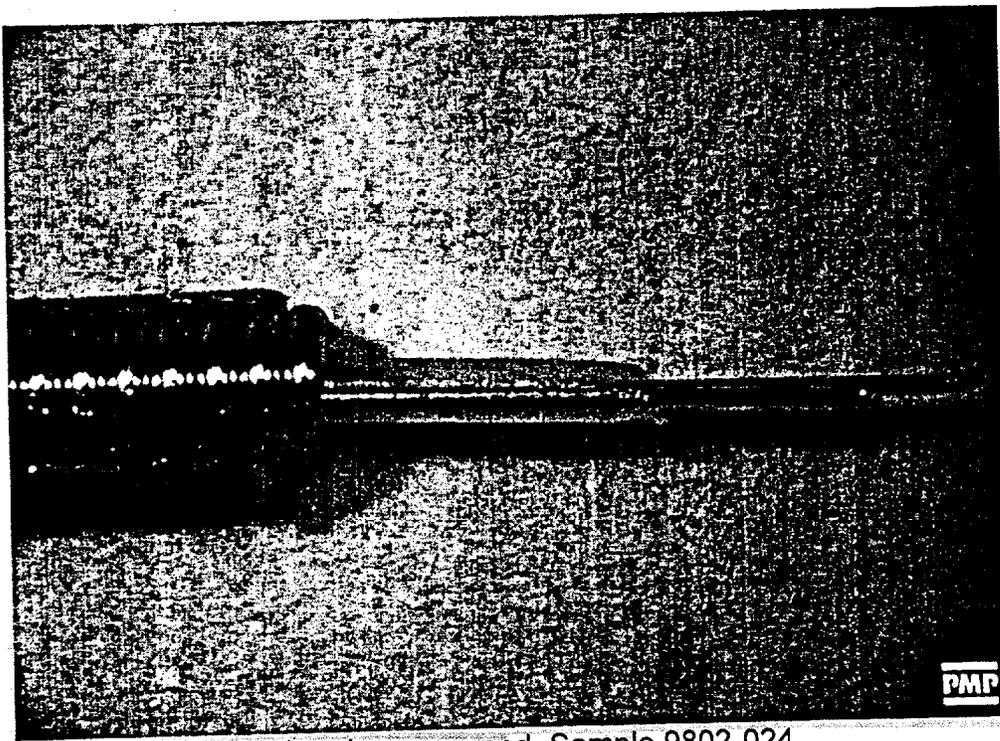
Radial Jaw 3, soiled and reprocessed, Sample 9802-023
Location: forceps
No visible contaminations



Radial Jaw 3, soiled and reprocessed, Sample 9802-023
Location: 100 mm above the tip
No visible contaminations



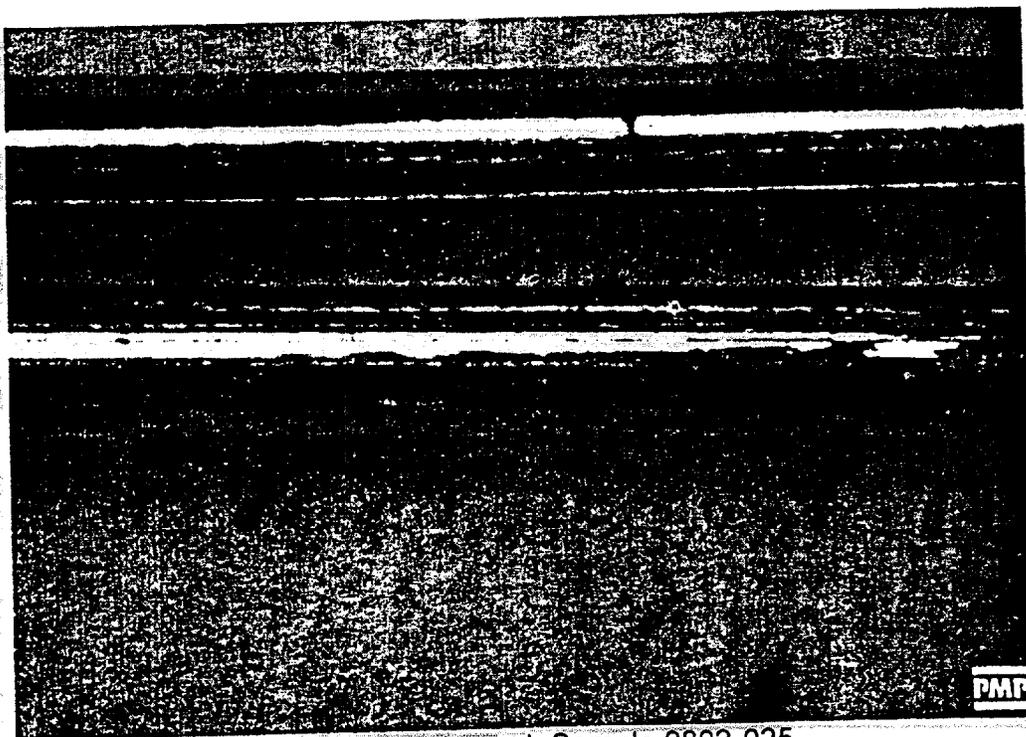
Radial Jaw 3, soiled and reprocessed, Sample 9802-024
Location: forceps
No visible contaminations



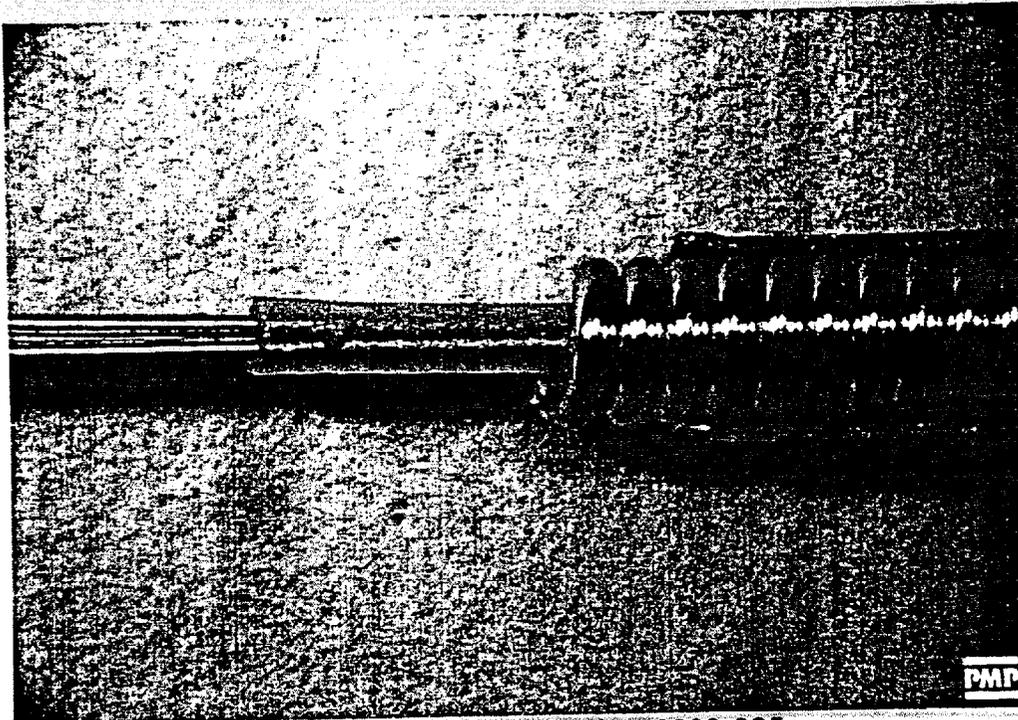
Radial Jaw 3, soiled and reprocessed, Sample 9802-024
Location: 100 mm above the tip
No visible contaminations



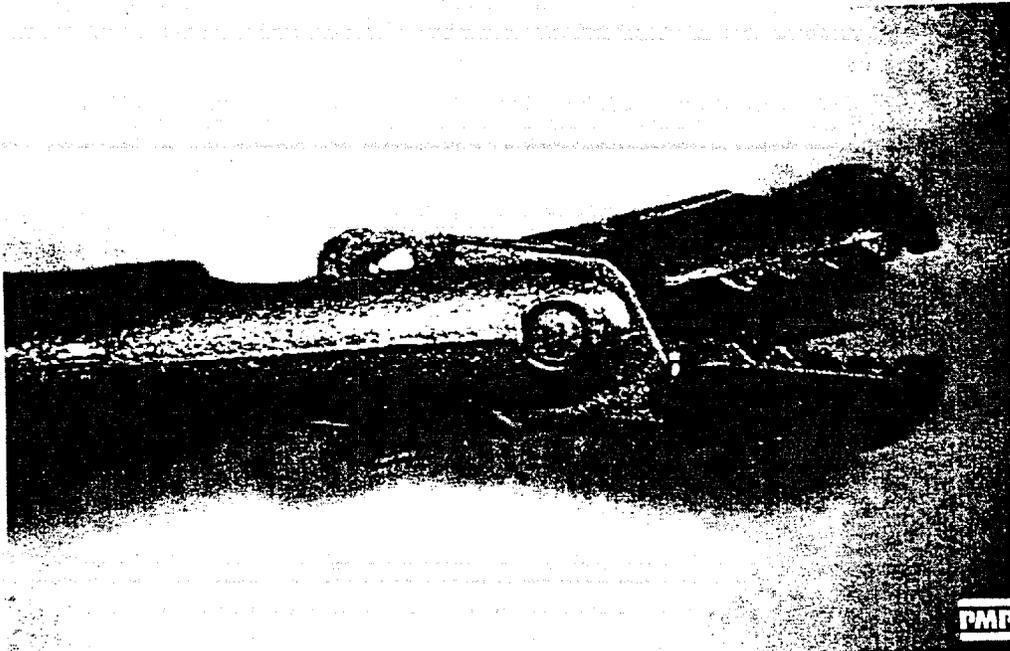
Radial Jaw 3, soiled and reprocessed, Sample 9802-025
Location: forceps
No visible contaminations



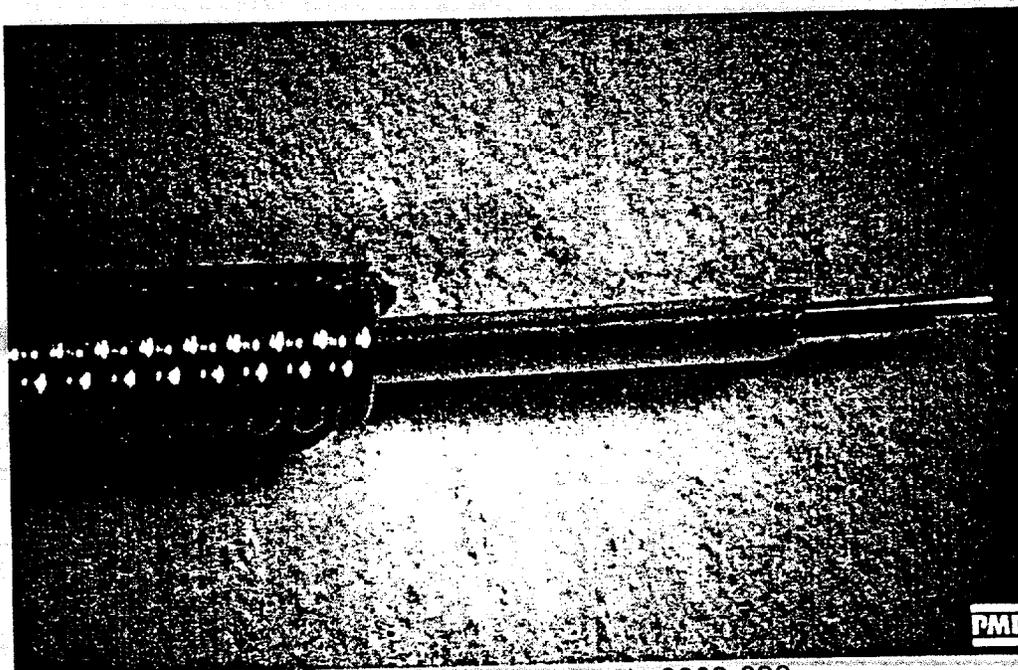
Radial Jaw 3, soiled and reprocessed, Sample 9802-025
Location: wire, 10 mm above the tip
Visible contaminations



Radial Jaw 3, soiled and reprocessed, Sample 9802-025
Location: 100 mm above the tip
No visible contaminations



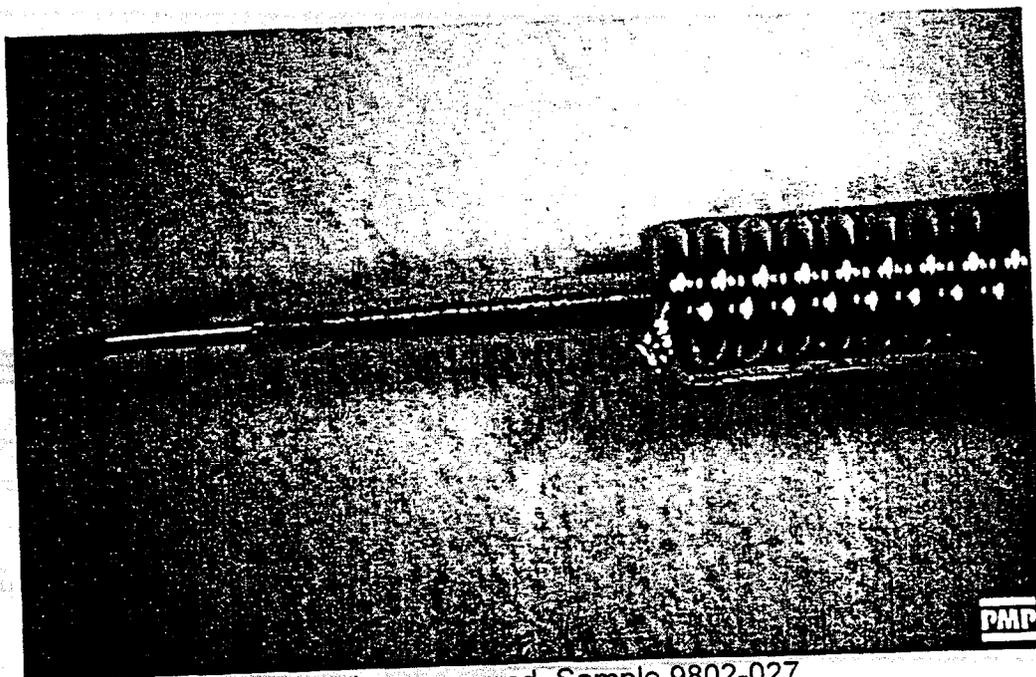
Radial Jaw 3, soiled and reprocessed, Sample 9802-026
Location: forceps
No visible contaminations.



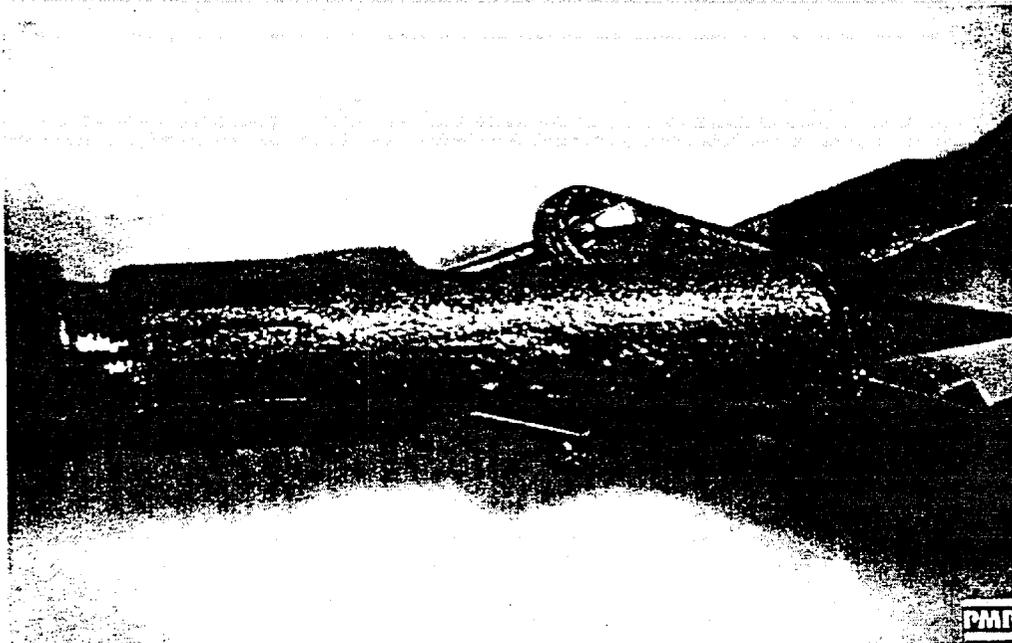
Radial Jaw 3, soiled and reprocessed, Sample 9802-026
Location: 100mm above the tip
No visible contaminations



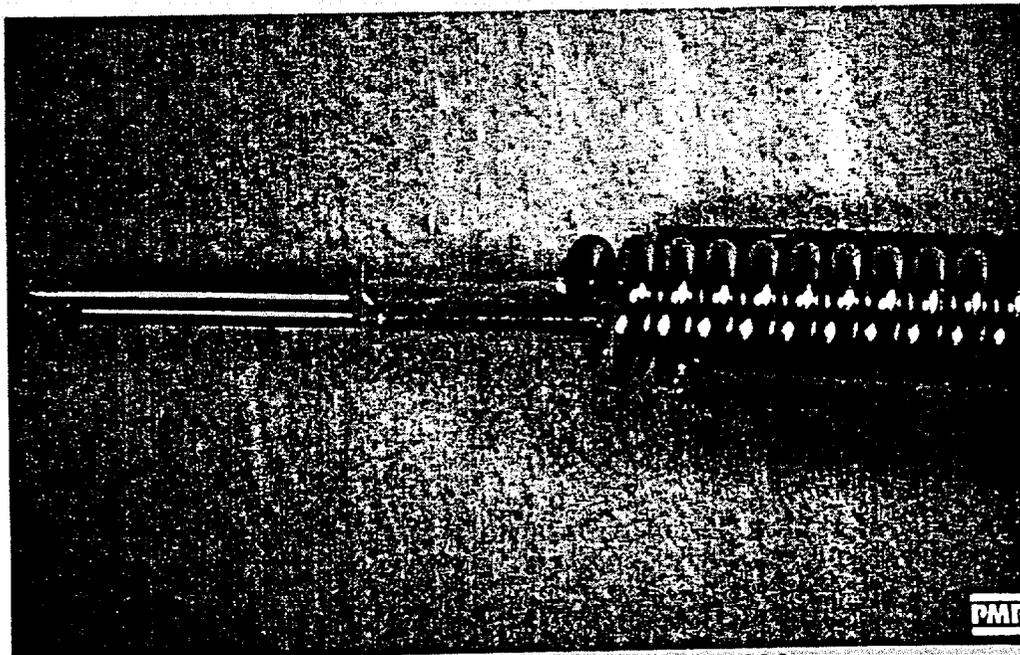
Radial Jaw 3, soiled and reprocessed, Sample 9802-027
Location: forceps
No visible contaminations.



Radial Jaw 3, soiled and reprocessed, Sample 9802-027
Location: 100 mm above the tip
No visible contaminations

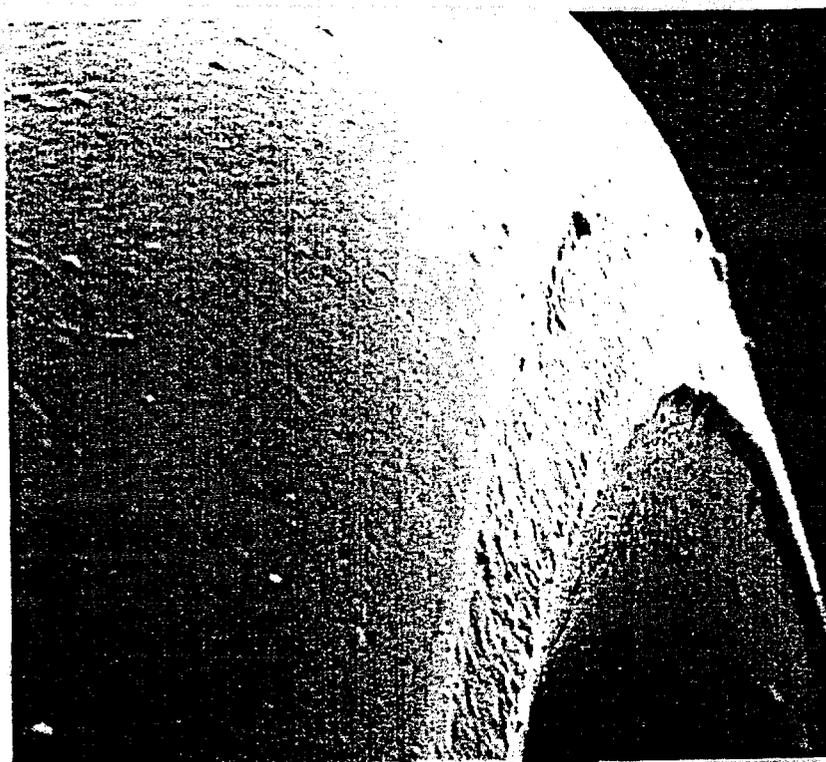


Radial Jaw 3, soiled and reprocessed, Sample 9802-028
Location: forceps
No visible contaminations.



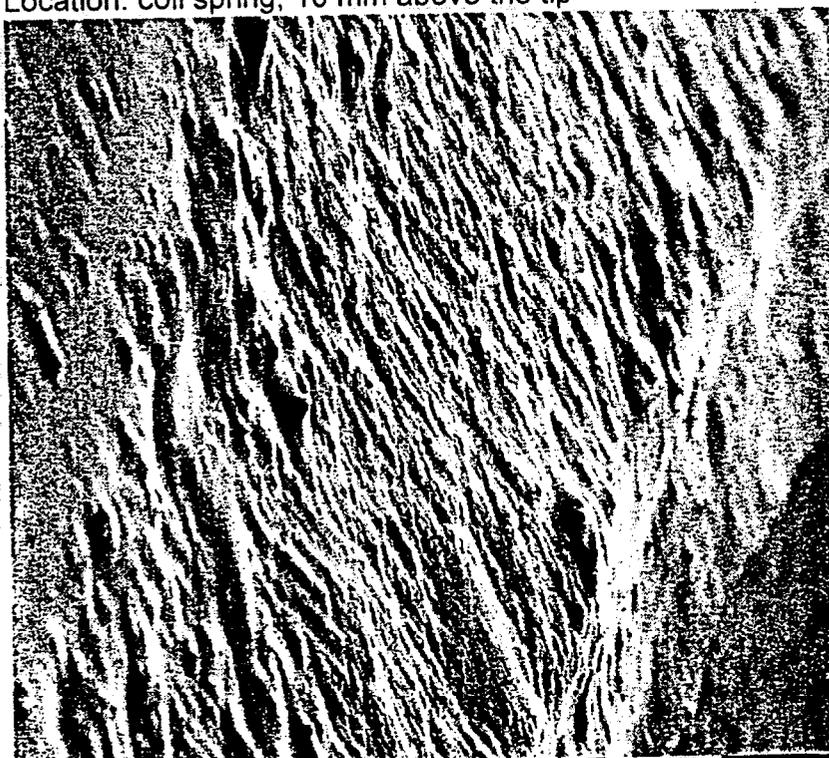
Radial Jaw 3, soiled and reprocessed, Sample 9802-028
Location: 100 mm above the tip
No visible contaminations

5.2 Scanning Electron Micrographs



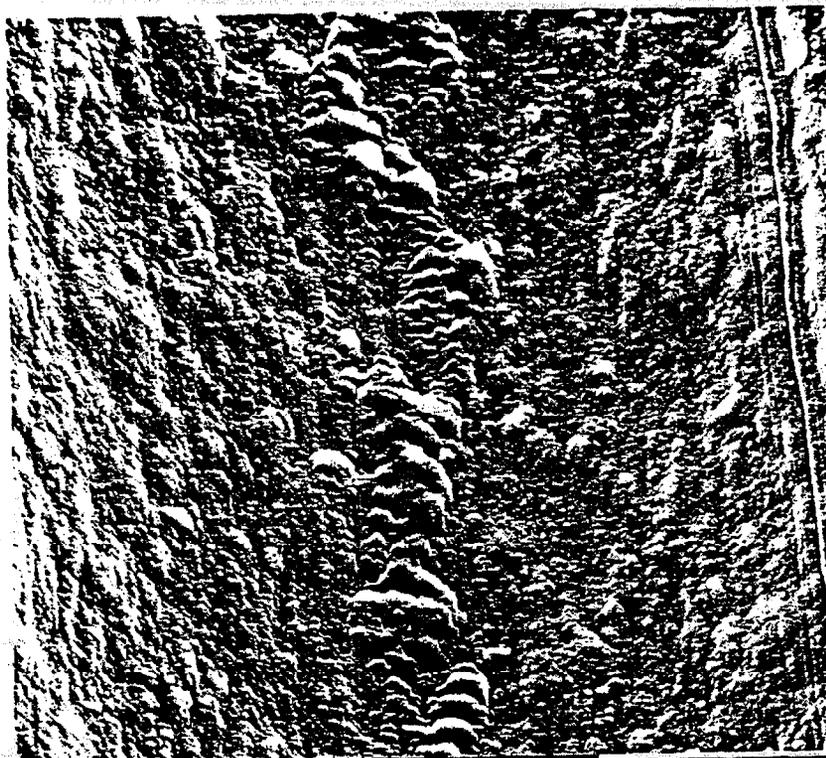
98062301 9802-021-01 PMP 100 μ m

Radial Jaw 3, soiled and reprocessed, sample 9802-021
Location: coil spring, 10 mm above the tip



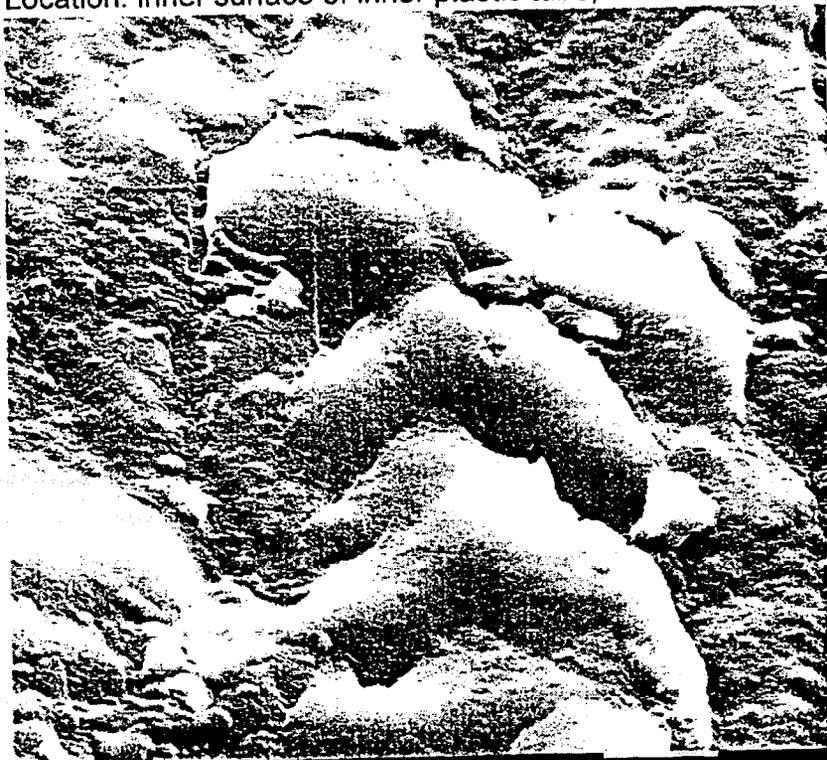
98062302 9802-021-01 PMP 10 μ m

Radial Jaw 3, soiled and reprocessed, sample 9802-021
Location: coil spring, 10 mm above the tip.
No visible contaminations.



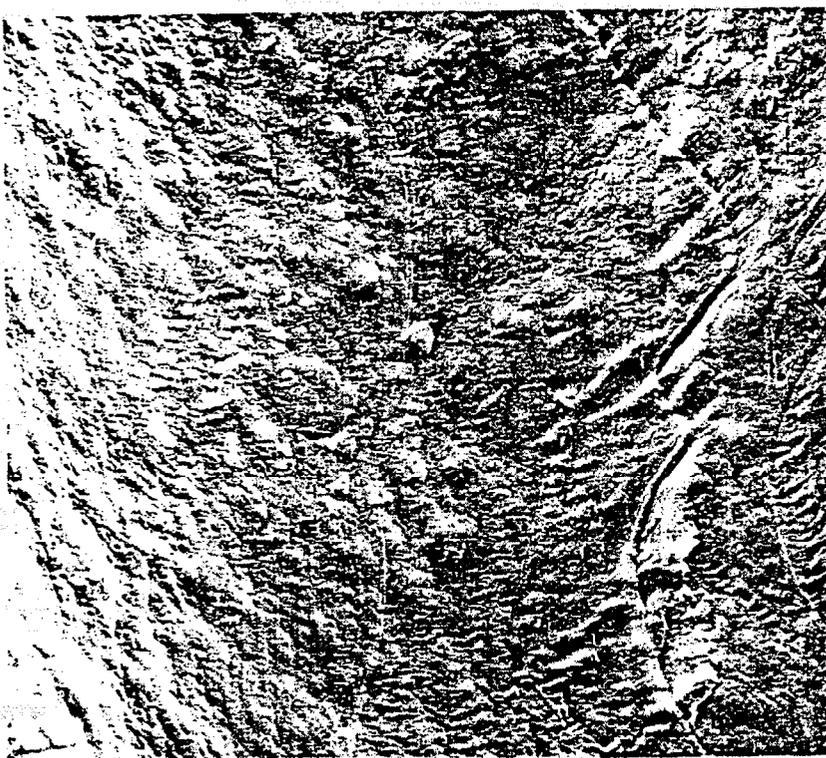
98062303 9802-021-03 PMP 100 μm

Radial Jaw 3, soiled and reprocessed, sample 9802-021
Location: inner surface of inner plastic tube, 100 mm above the tip



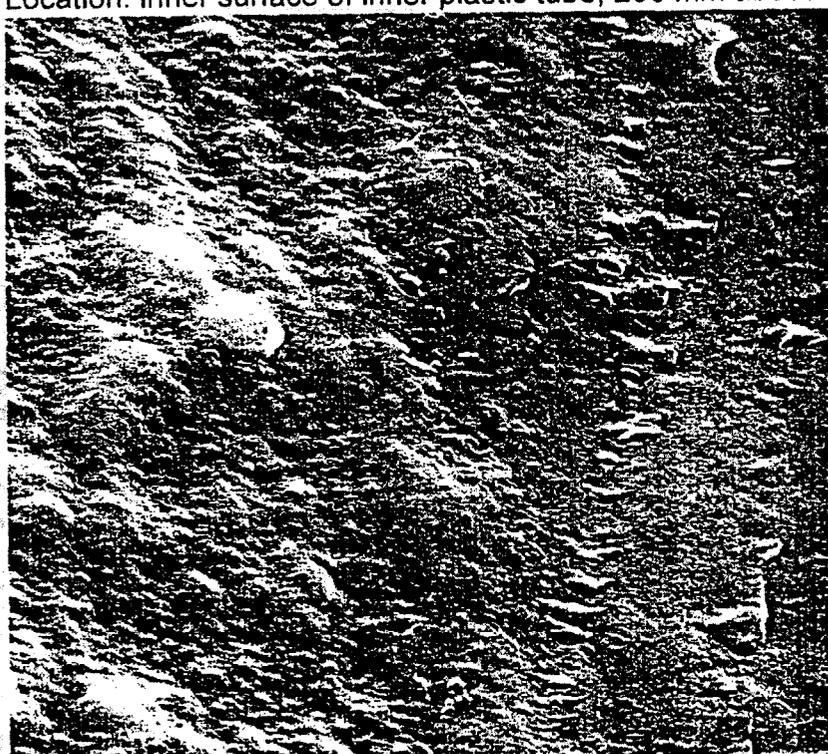
98062304 9802-021-03 PMP 10 μm

Radial Jaw 3, soiled and reprocessed, sample 9802-021
Location: inner surface of inner plastic tube, 100 mm above the tip
No visible contaminations.



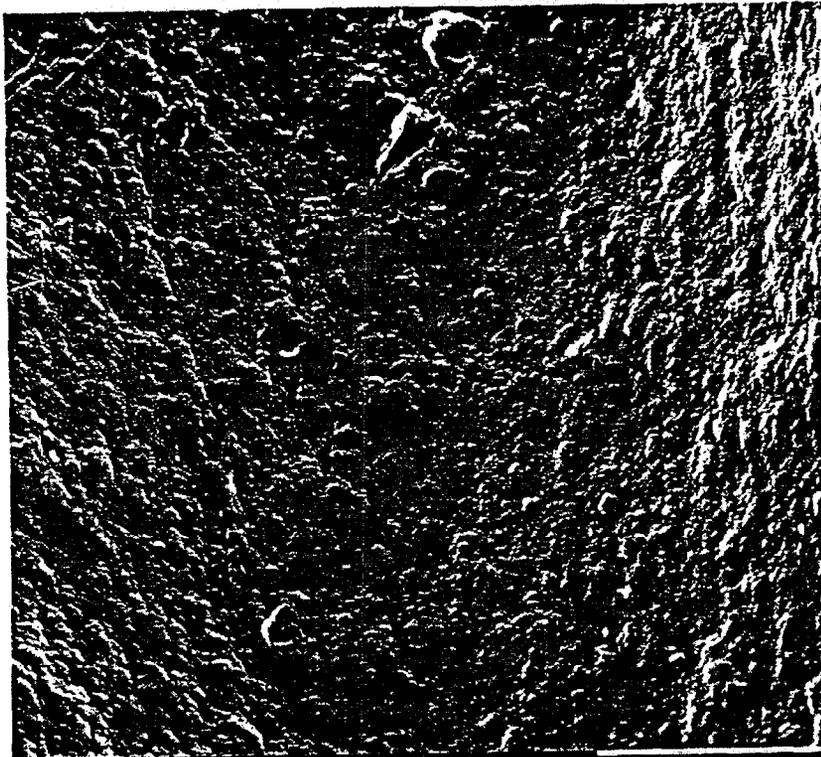
98062305 9802-021-06 **PMP** 100 μm

Radial Jaw 3, soiled and reprocessed, sample 9802-021
Location: inner surface of inner plastic tube, 200 mm above the tip



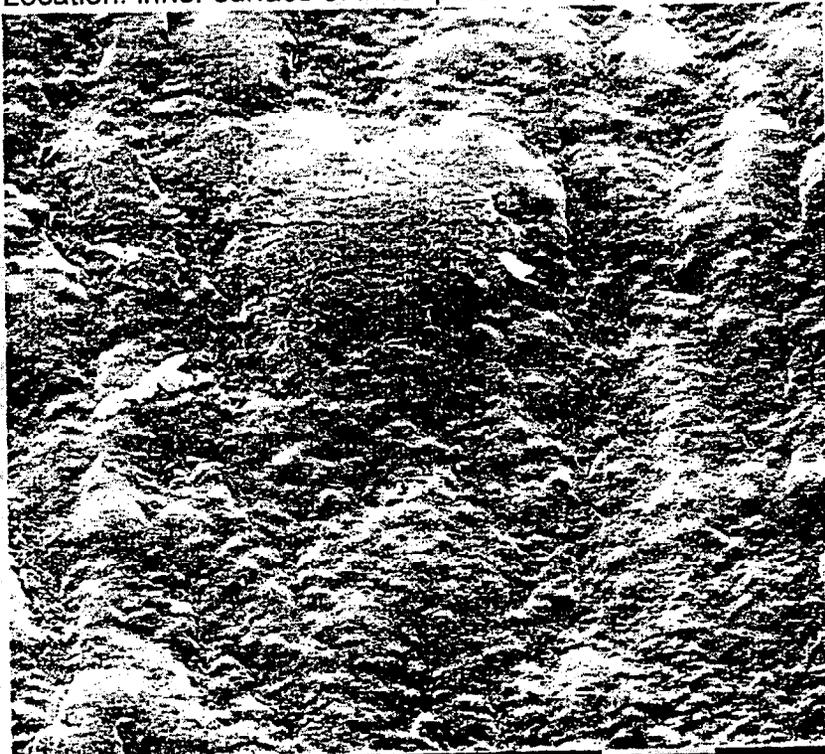
98062306 9802-021-06 **PMP** 10 μm

Radial Jaw 3, soiled and reprocessed, sample 9802-021
Location: inner surface of inner plastic tube, 200 mm above the tip
No visible contaminations.



98062307 9802-021-08 100 μm

Radial Jaw 3, soiled and reprocessed, sample 9802-021
Location: inner surface of inner plastic tube, 400 mm above the tip

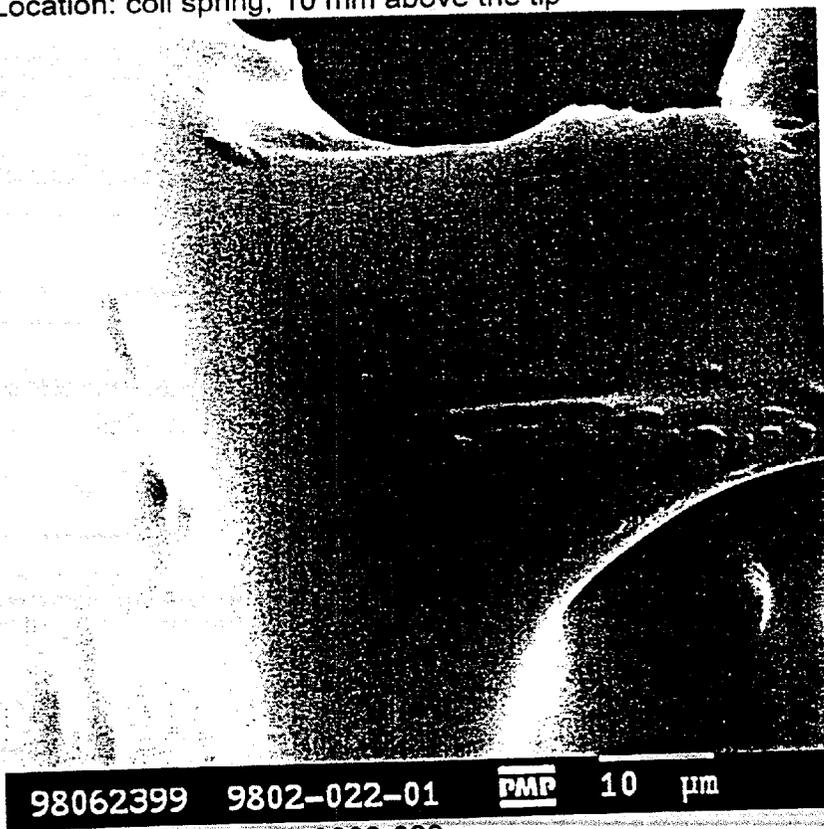


98062308 9802-021-08 **PMP** 10 μm

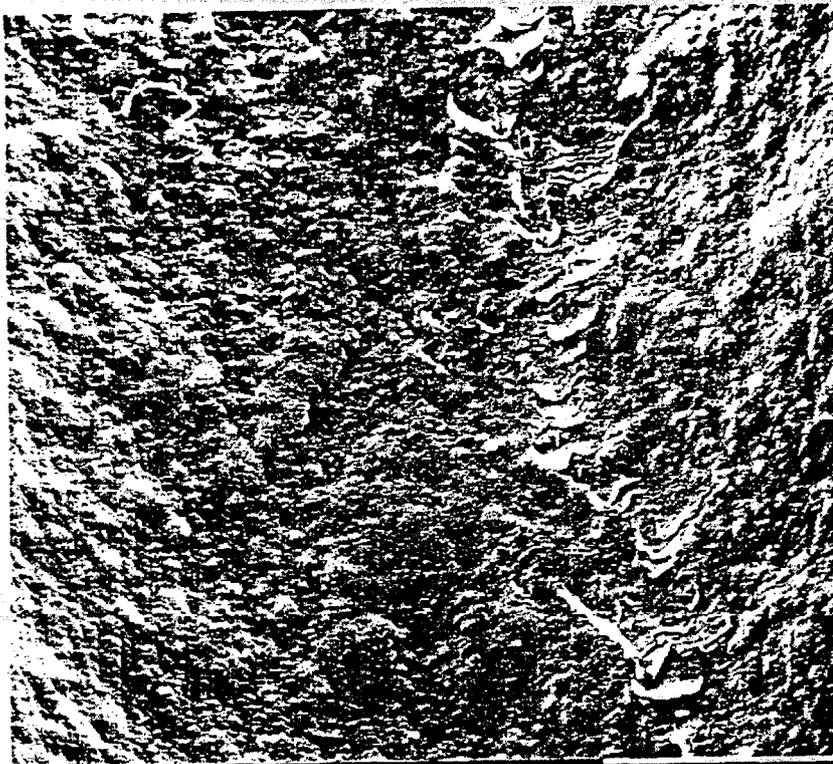
Radial Jaw 3, soiled and reprocessed, sample 9802-021
Location: inner surface of inner plastic tube, 400 mm above the tip
No visible contaminations.



Radial Jaw 3, sample 9802-022
Location: coil spring, 10 mm above the tip



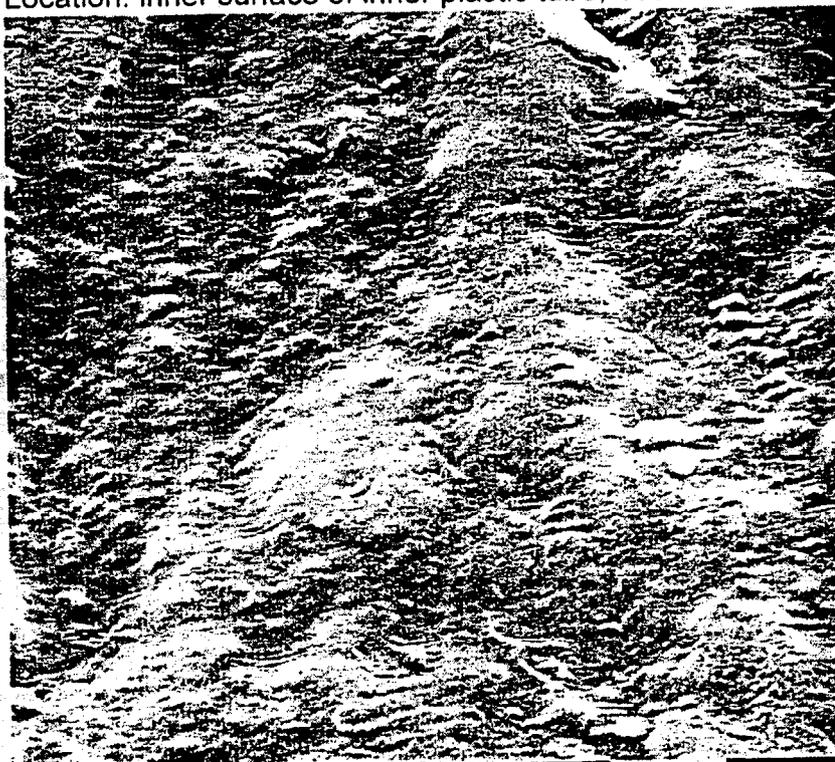
Radial Jaw 3, sample 9802-022
Location: coil spring, 10 mm above the tip
Presumably contaminations.



98062313 9802-022-03 PMP 100 μm

Radial Jaw 3, sample 9802-022

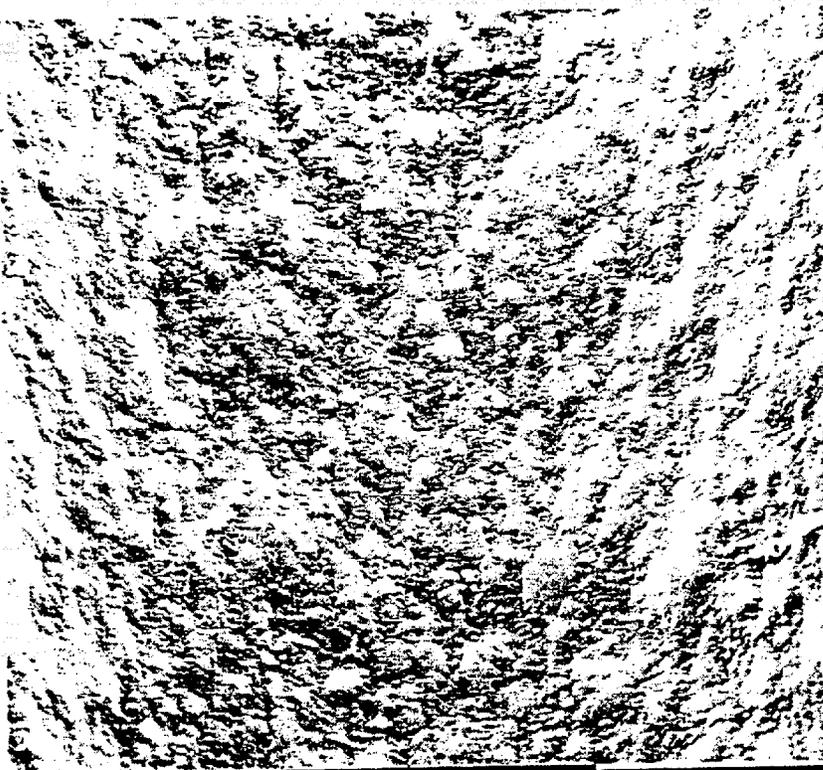
Location: inner surface of inner plastic tube, 100 mm above the tip



98062314 9802-022-03 PMP 10 μm

Radial Jaw 3, sample 9802-022

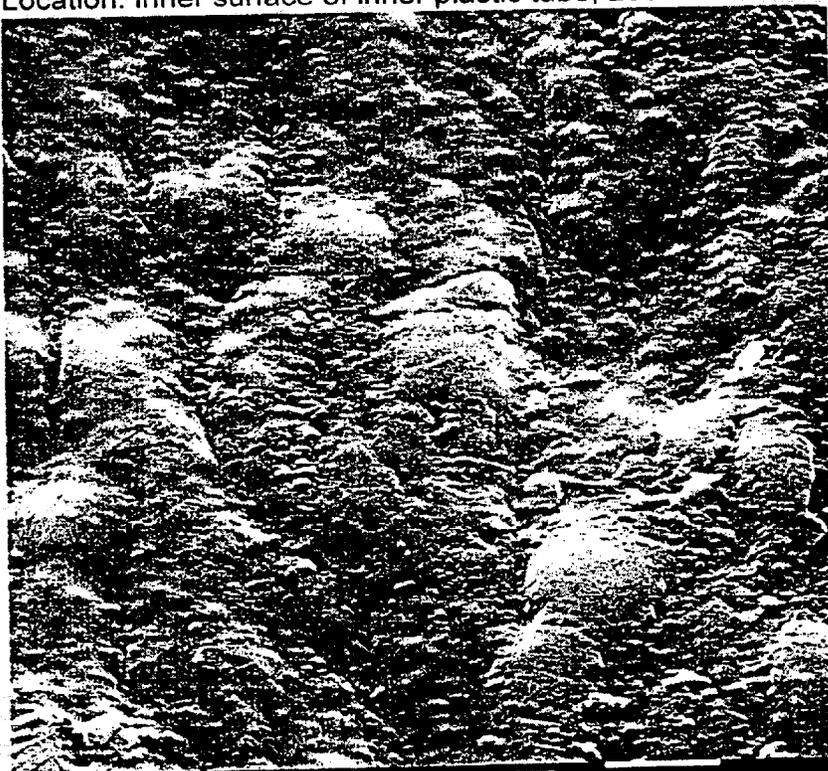
Location: inner surface of inner plastic tube, 100 mm above the tip
No visible contaminations.



98062315 9802-022-06 PMP 100 μm

Radial Jaw 3, sample 9802-022

Location: inner surface of inner plastic tube, 200 mm above the tip

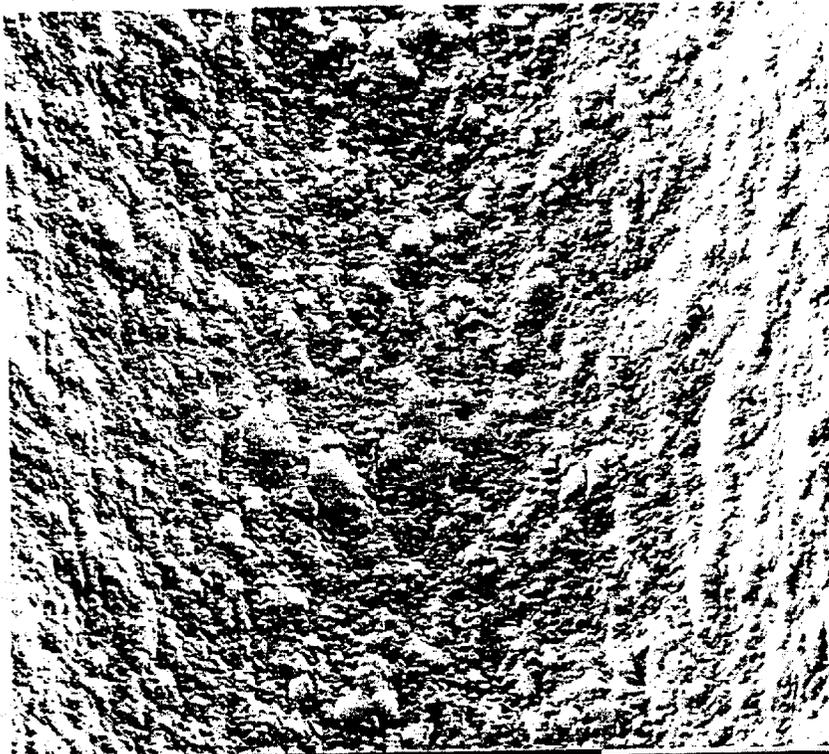


98062316 9802-022-06 PMP 10 μm

Radial Jaw 3, sample 9802-022

Location: inner surface of inner plastic tube, 200 mm above the tip

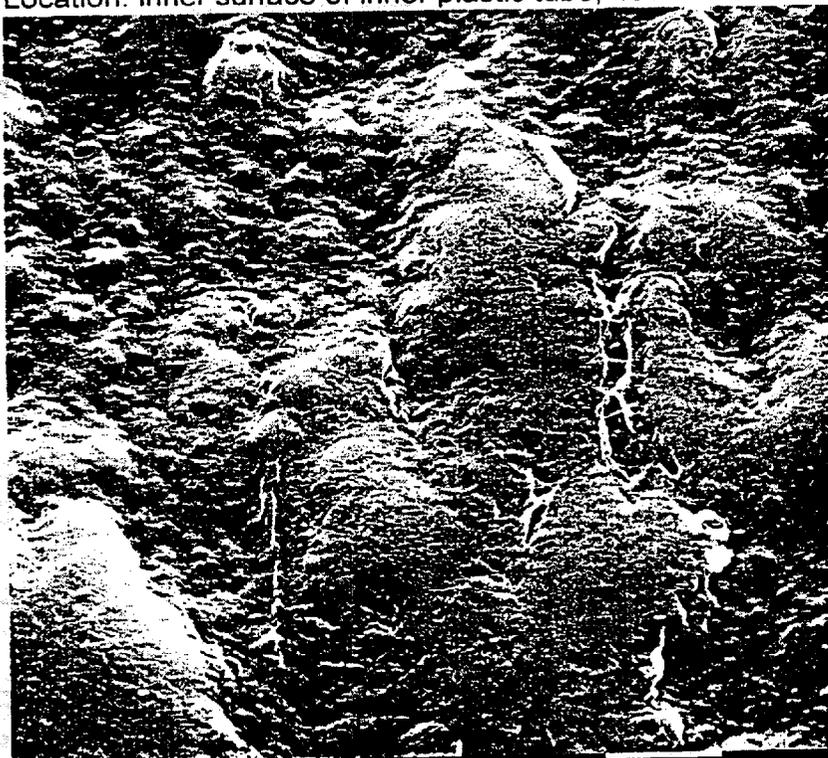
No visible contaminations.



98062317 9802-022-08 PMP 100 μm

Radial Jaw 3, sample 9802-022

Location: inner surface of inner plastic tube, 400 mm above the tip

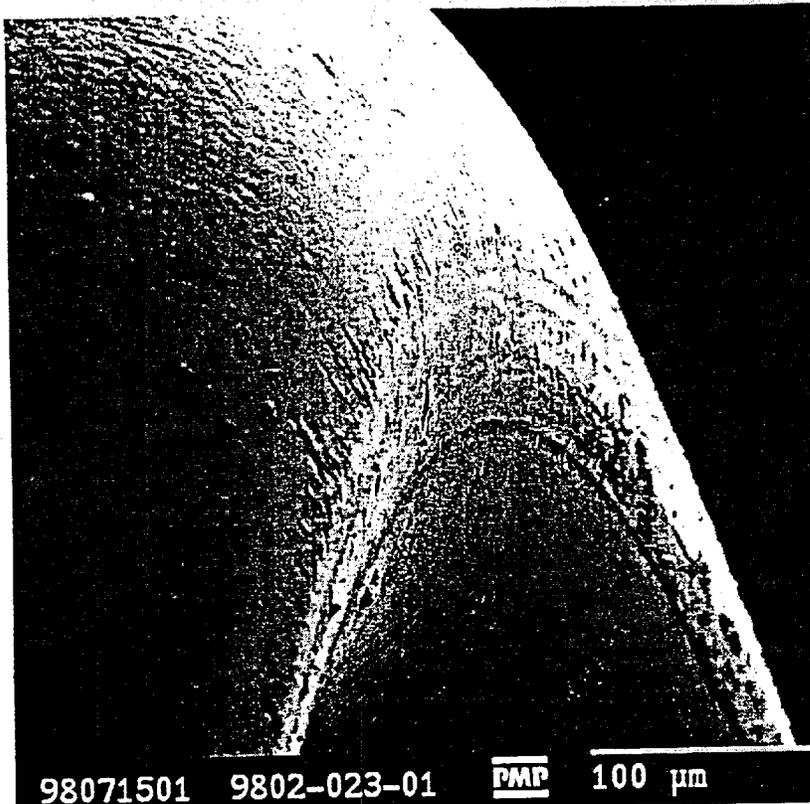


98062318 9802-022-08 PMP 10 μm

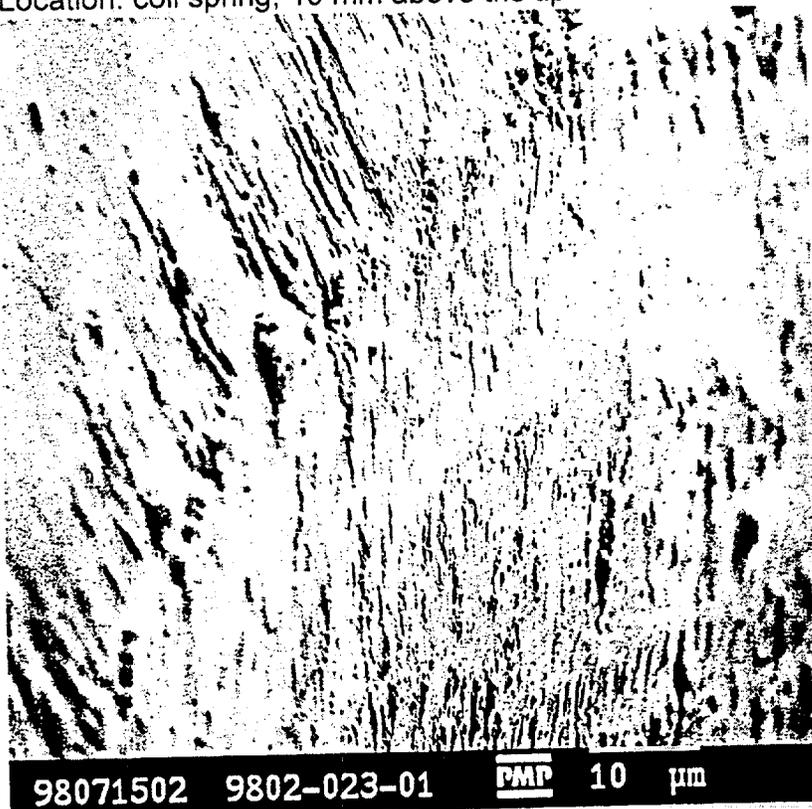
Radial Jaw 3, sample 9802-022

Location: inner surface of inner plastic tube, 400 mm above the tip

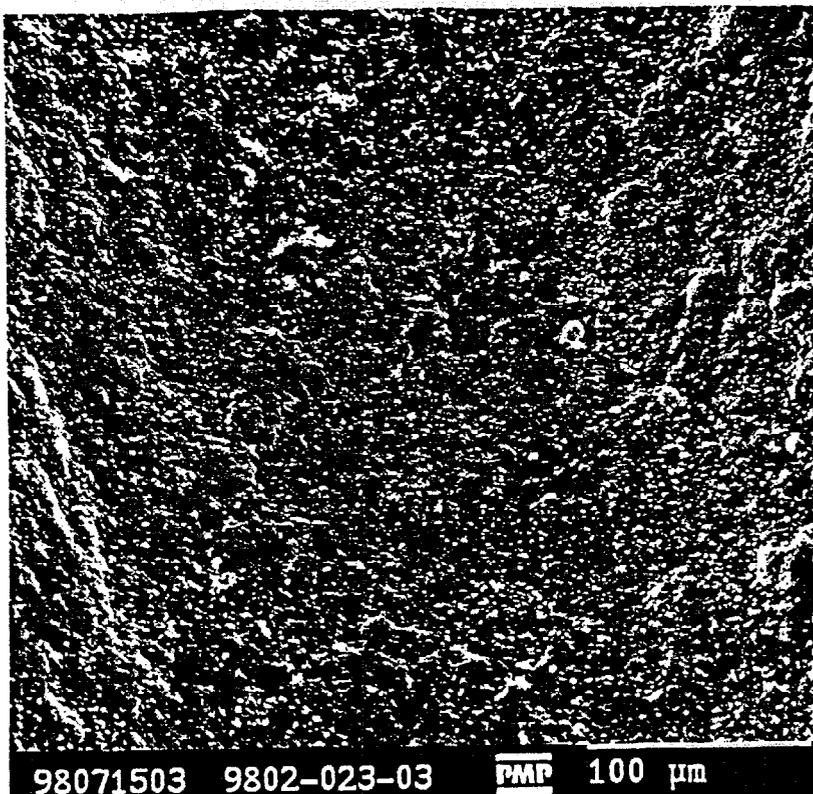
No visible contaminations.



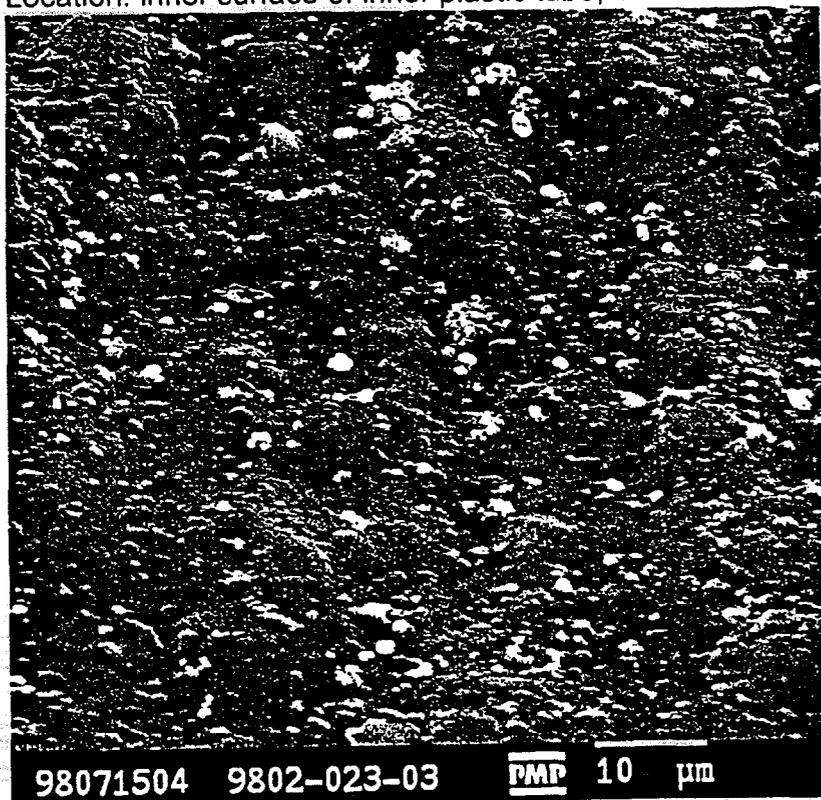
Radial Jaw 3, sample 9802-023
Location: coil spring, 10 mm above the tip



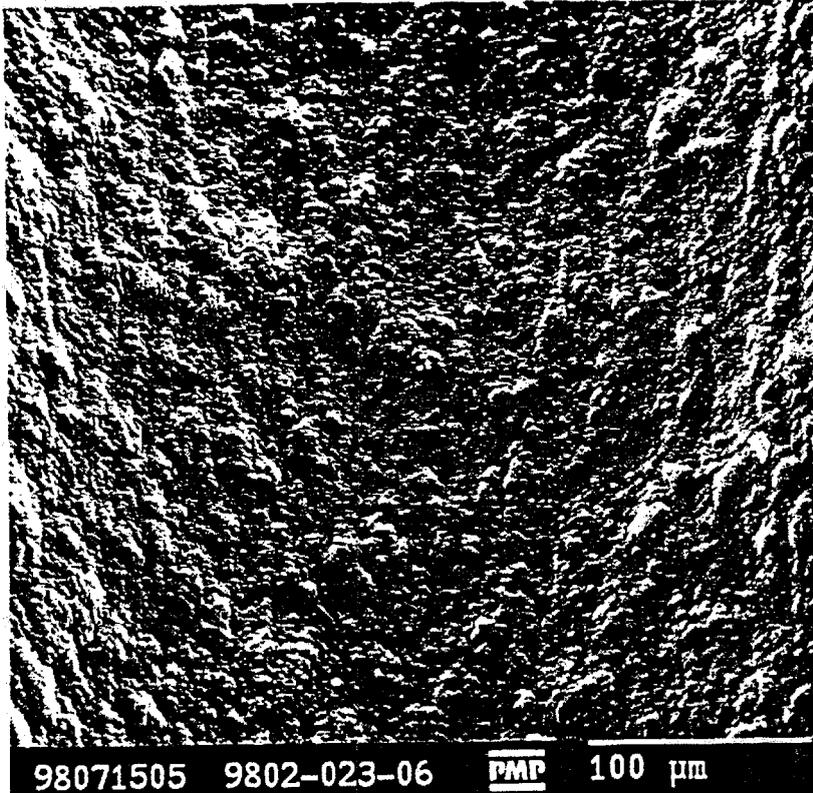
Radial Jaw 3, sample 9802-023
Location: coil spring, 10 mm above the tip
No visible contaminations.



98071503 9802-023-03 PMP 100 μm
Radial Jaw 3, sample 9802-023
Location: inner surface of inner plastic tube, 100 mm above the tip

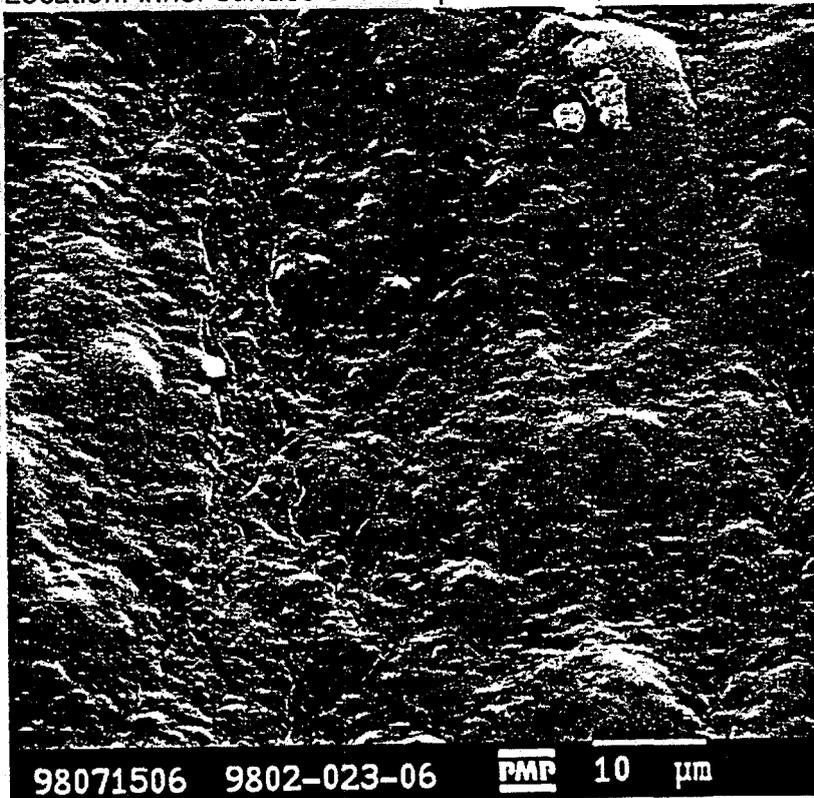


98071504 9802-023-03 PMP 10 μm
Radial Jaw 3, sample 9802-023
Location: inner surface of inner plastic tube, 100 mm above the tip
Separated contaminations.



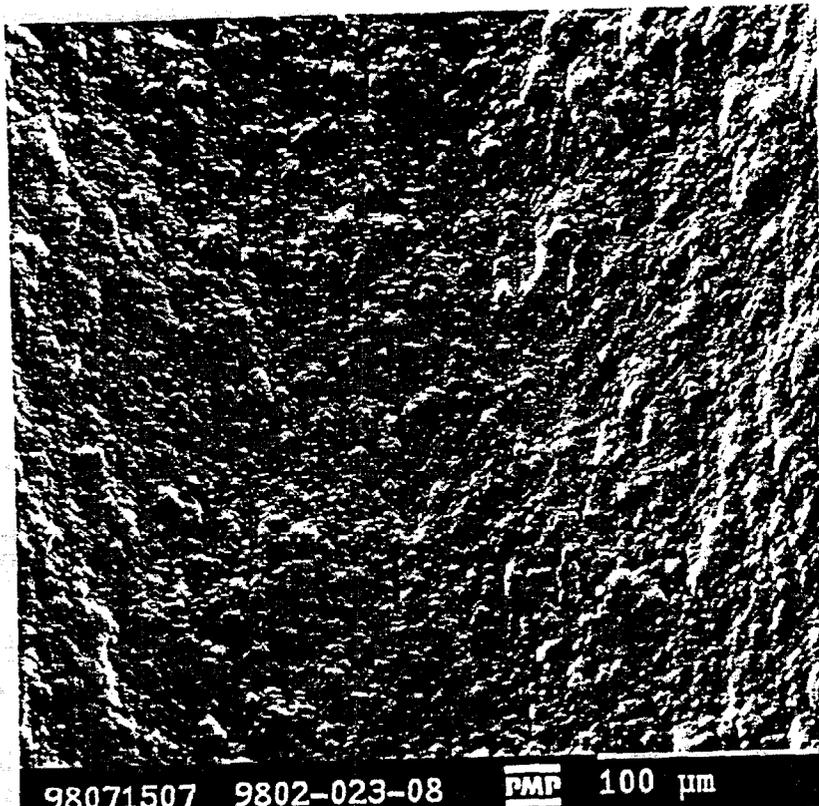
Radial Jaw 3, sample 9802-023

Location: inner surface of inner plastic tube, 200 mm above the tip

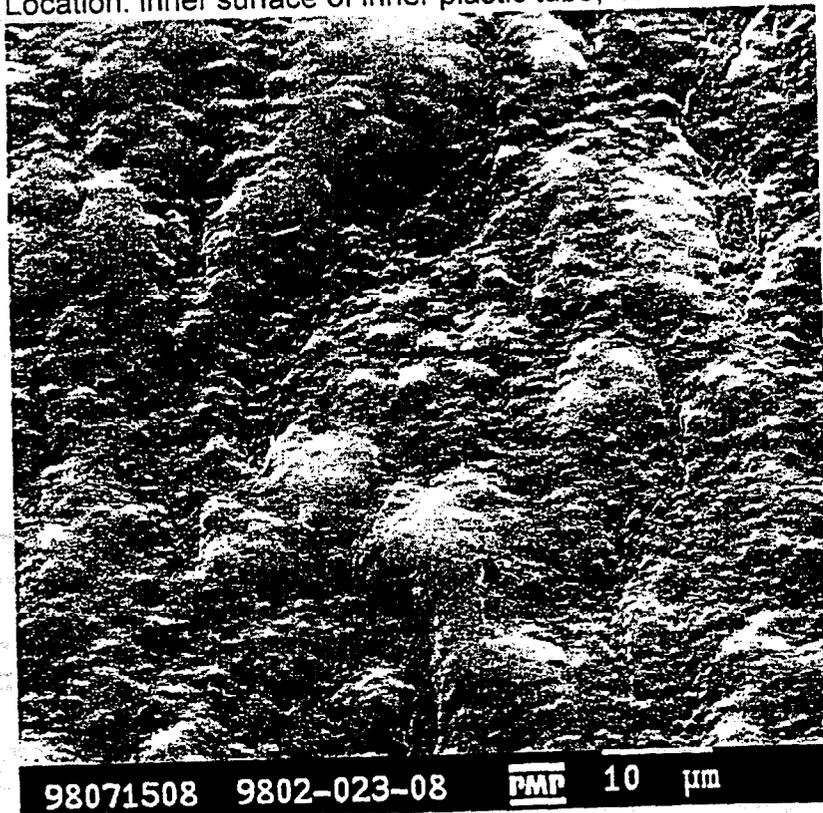


Radial Jaw 3, sample 9802-023

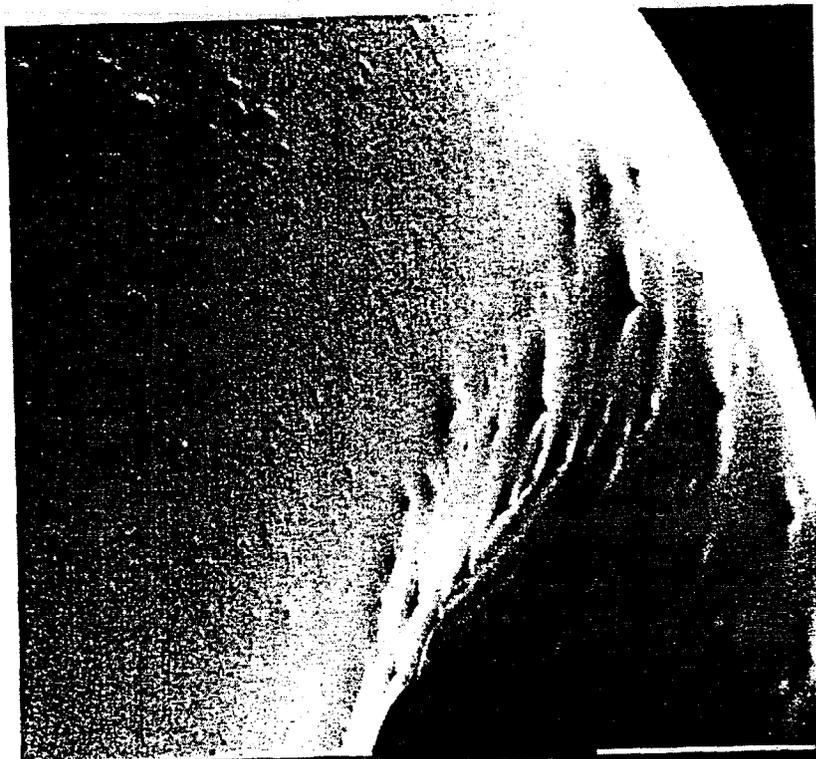
Location: inner surface of inner plastic tube, 200 mm above the tip
Separated contaminations.



98071507 9802-023-08 PMP 100 μm
Radial Jaw 3, sample 9802-023
Location: inner surface of inner plastic tube, 400 mm above the tip



98071508 9802-023-08 PMP 10 μm
Radial Jaw 3, sample 9802-023
Location: inner surface of inner plastic tube, 400 mm above the tip
No visible contaminations.



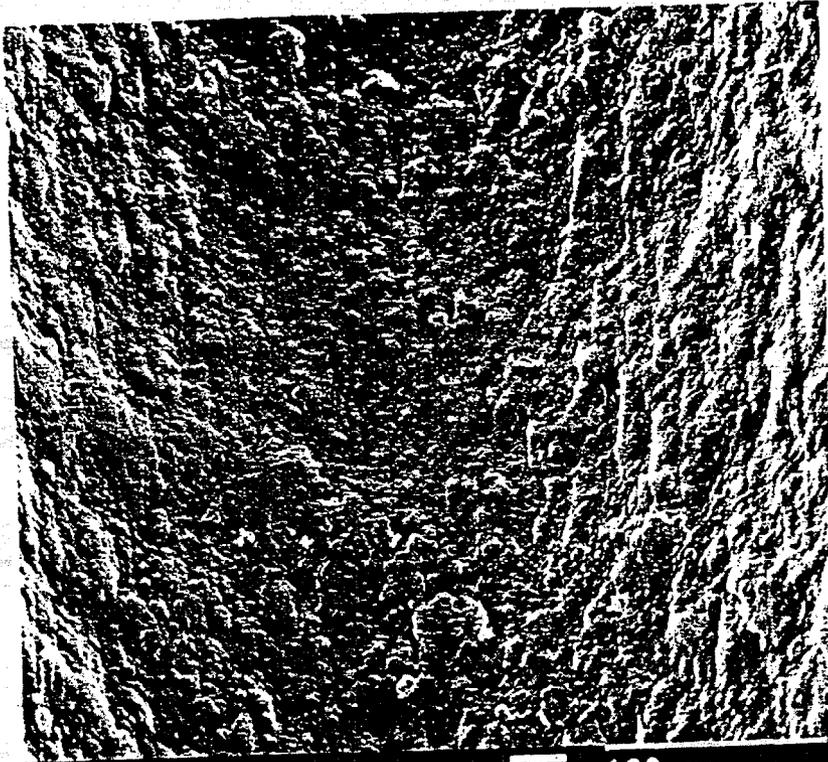
98071509 9802-024-01 PMP 100 μm

Radial Jaw 3, sample 9802-024
Location: coil spring, 10 mm above the tip



98071510 9802-024-01 PMP 10 μm

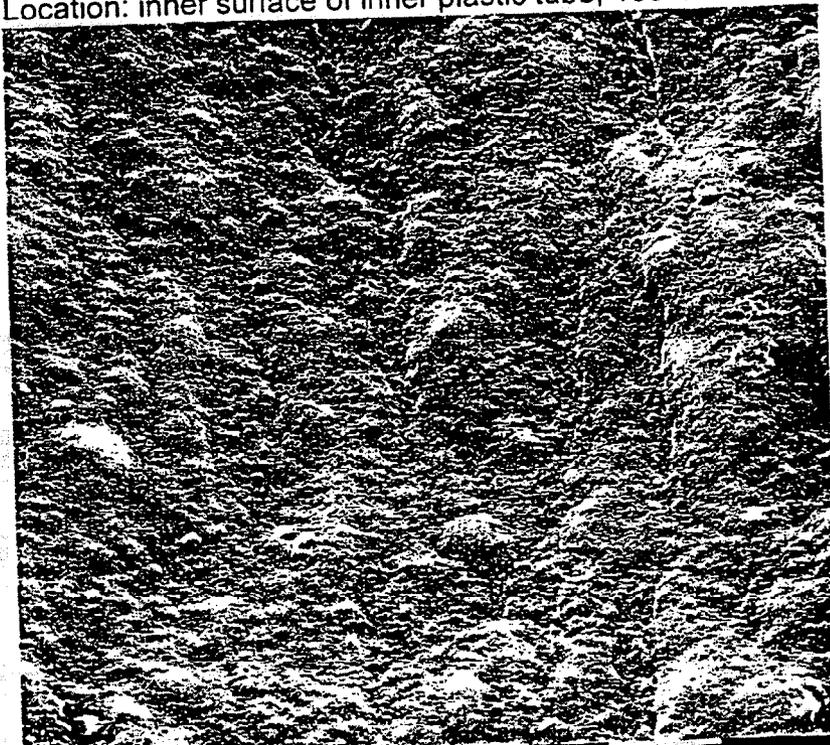
Radial Jaw 3, sample 9802-024
Location: coil spring, 10 mm above the tip
No visible contaminations.



98071511 9802-024-03 PMP 100 μm

Radial Jaw 3, sample 9802-024

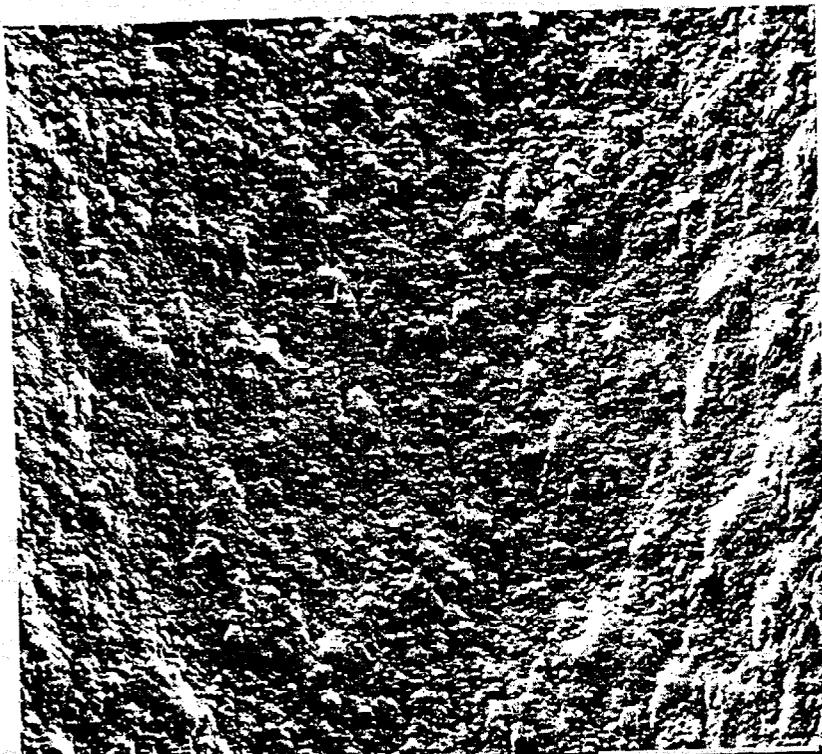
Location: inner surface of inner plastic tube, 100 mm above the tip



98071512 9802-024-03 PMP 10 μm

Radial Jaw 3, sample 9802-024

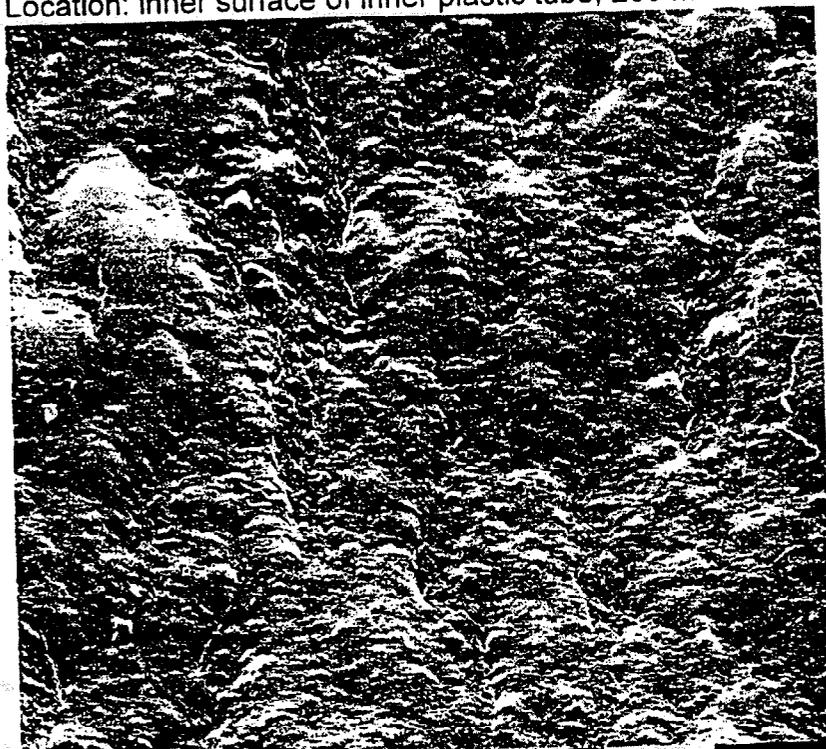
Location: inner surface of inner plastic tube, 100 mm above the tip
No visible contaminations.



98071513 9802-024-06 **PMP** 100 μm

Radial Jaw 3, sample 9802-024

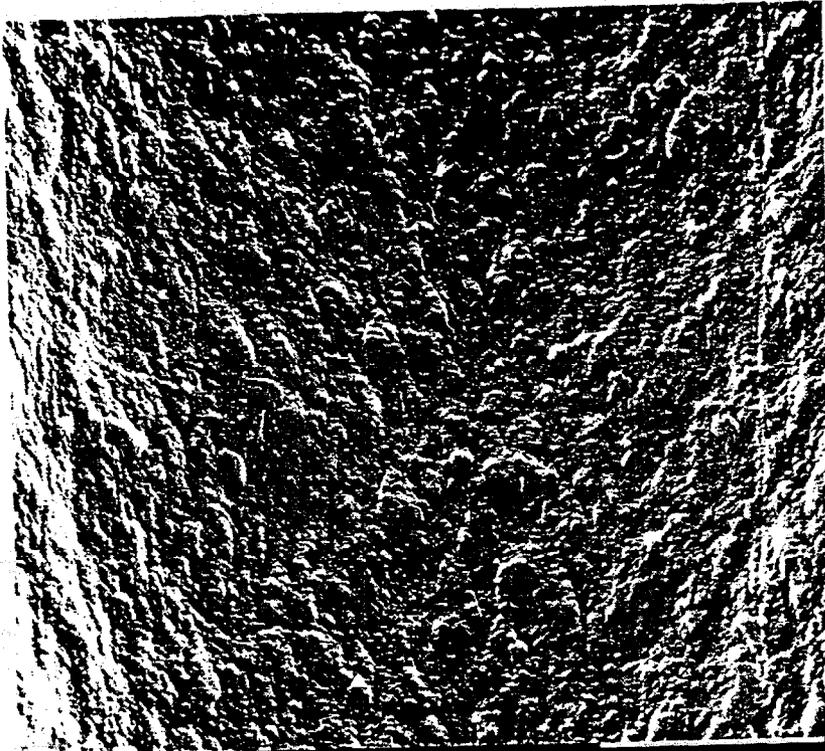
Location: inner surface of inner plastic tube, 200 mm above the tip



98071514 9802-024-06 **PMP** 10 μm

Radial Jaw 3, sample 9802-024

Location: inner surface of inner plastic tube, 200 mm above the tip
No visible contaminations.



98071515 9802-024-08 PMP 100 μm

Radial Jaw 3, sample 9802-024

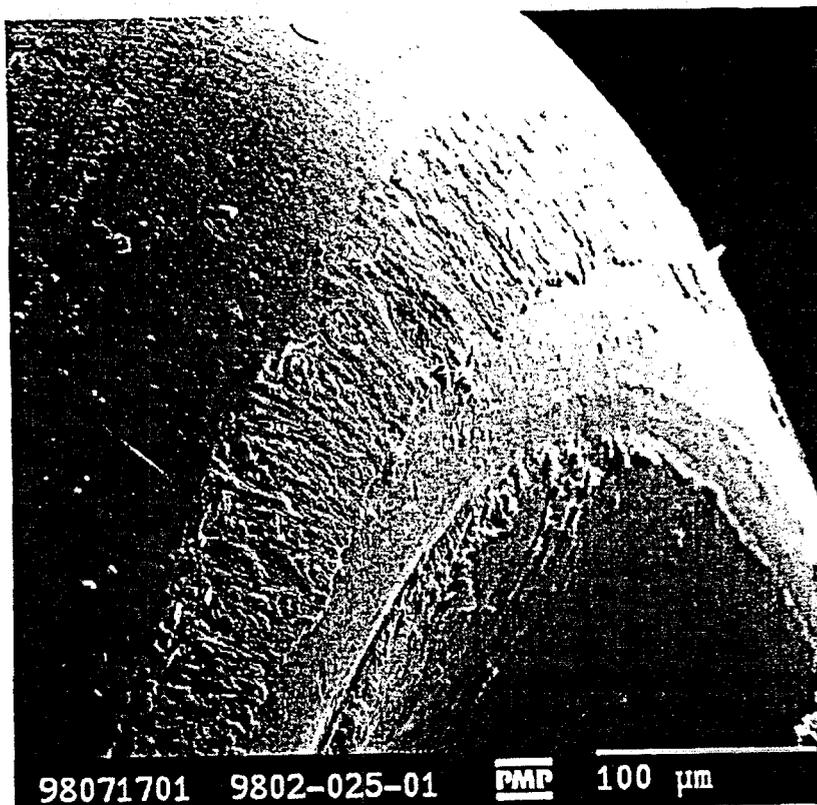
Location: inner surface of inner plastic tube, 400 mm above the tip



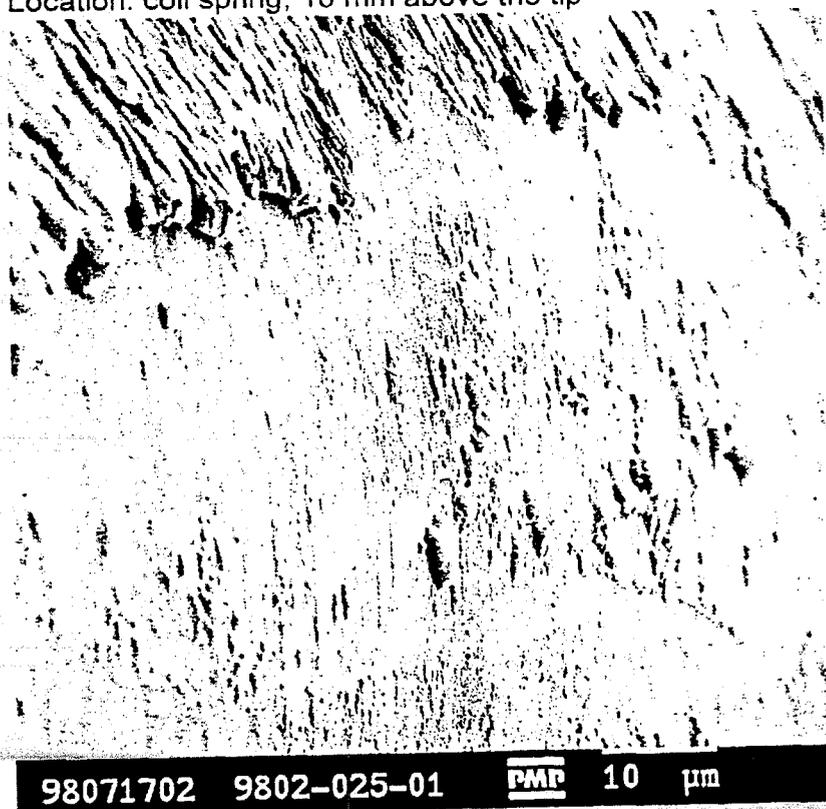
98071516 9802-024-08 PMP 10 μm

Radial Jaw 3, sample 9802-024

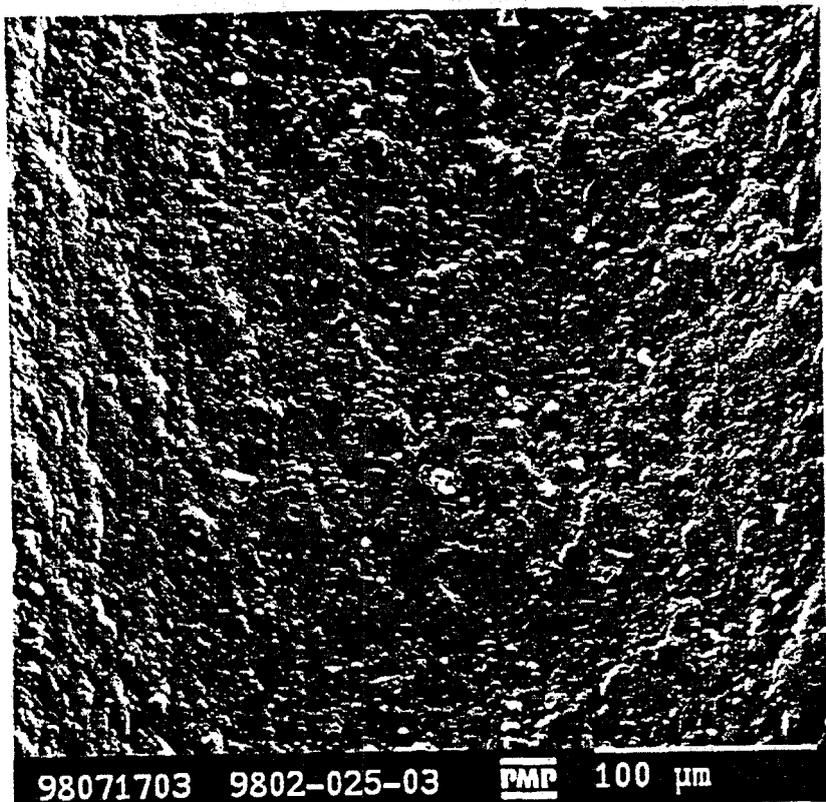
Location: inner surface of inner plastic tube, 400 mm above the tip
No visible contaminations.



Radial Jaw 3, sample 9802-025
Location: coil spring, 10 mm above the tip



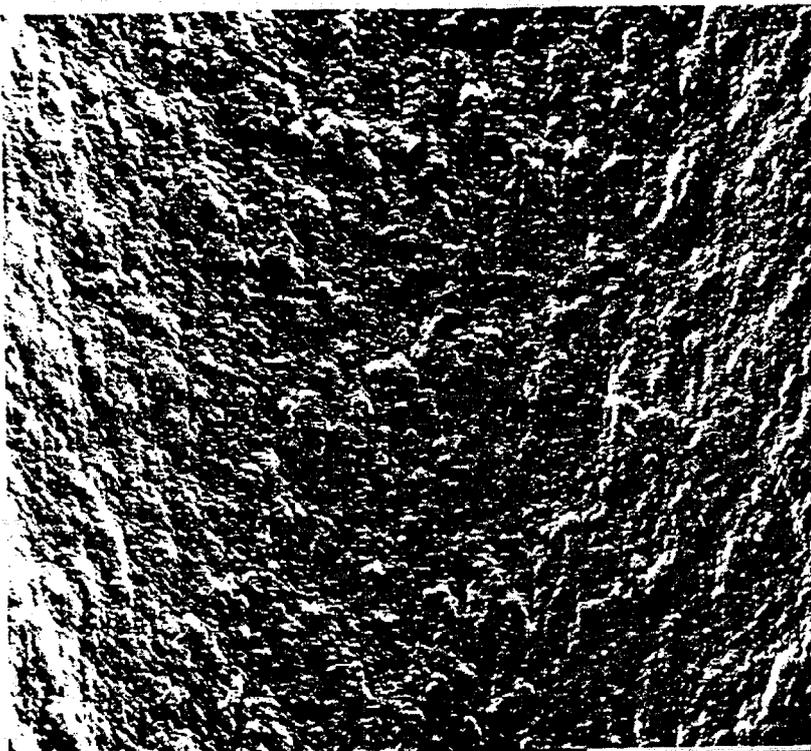
Radial Jaw 3, sample 9802-025
Location: coil spring, 10 mm above the tip
No visible contaminations.



98071703 9802-025-03 PMP 100 μ m
Radial Jaw 3, sample 9802-025
Location: inner surface of inner plastic tube, 100 mm above the tip



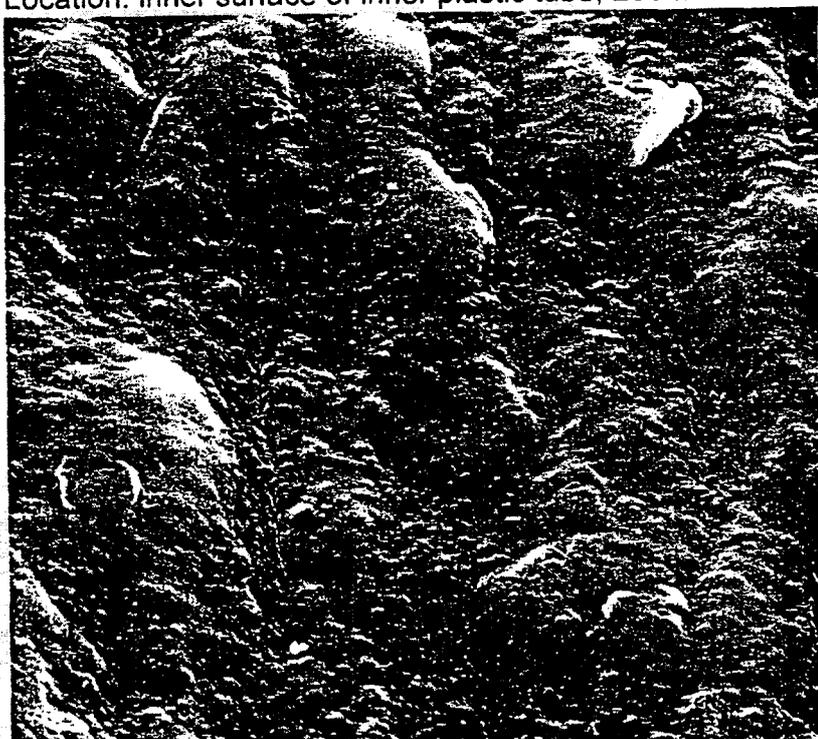
98071704 9802-025-03 PMP 10 μ m
Radial Jaw 3, sample 9802-025
Location: inner surface of inner plastic tube, 100 mm above the tip
Small contaminations.



98071705 9802-025-06 PMP 100 μm

Radial Jaw 3, sample 9802-025

Location: inner surface of inner plastic tube, 200 mm above the tip

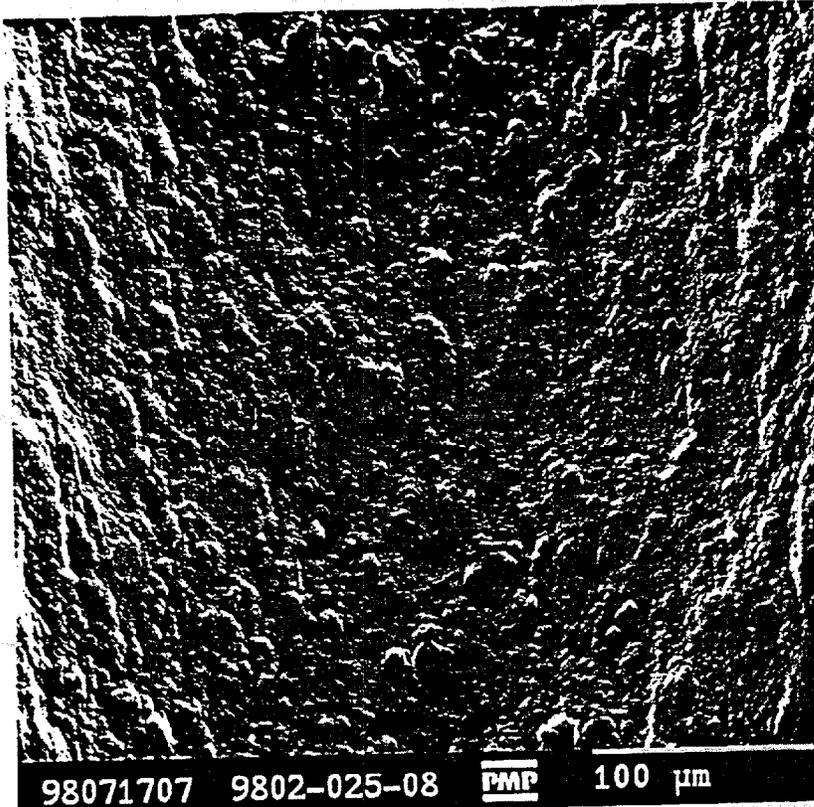


98071706 9802-025-06 PMP 10 μm

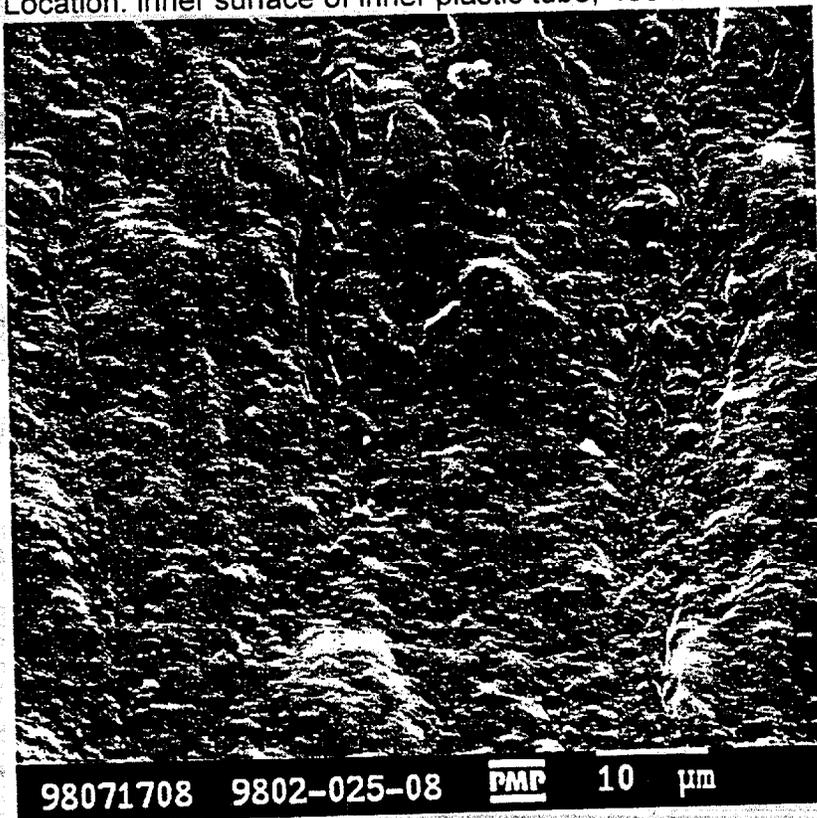
Radial Jaw 3, sample 9802-025

Location: inner surface of inner plastic tube, 200 mm above the tip

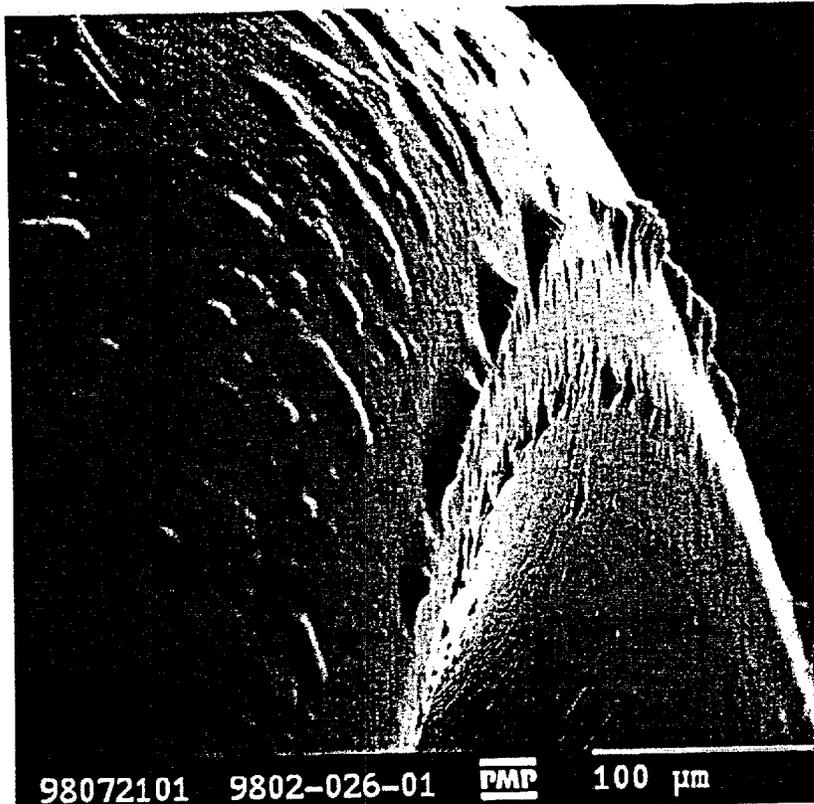
No visible contaminations.



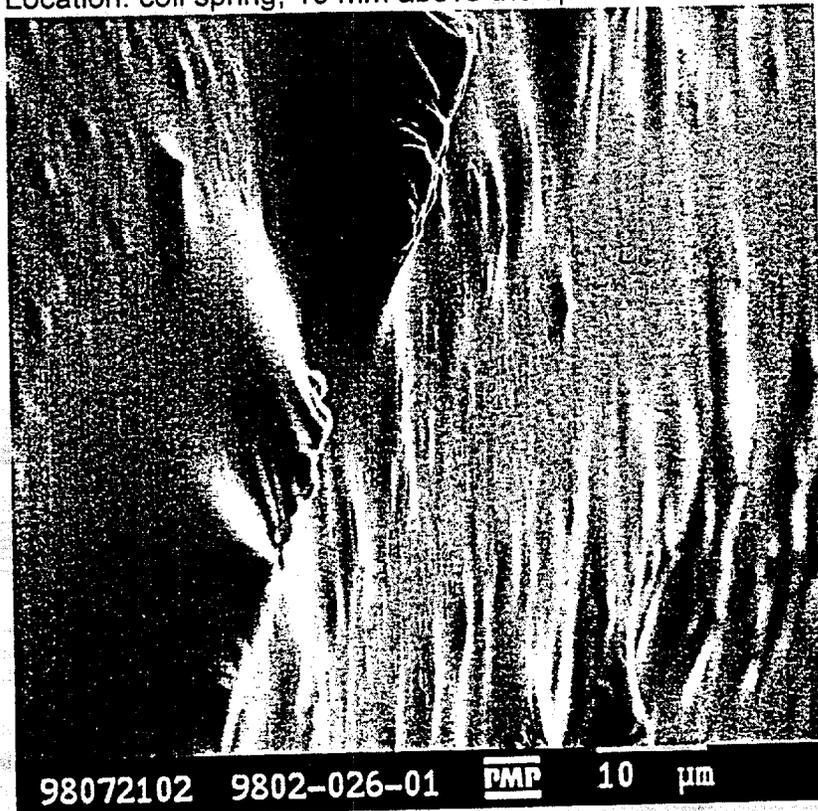
Radial Jaw 3, sample 9802-025
Location: inner surface of inner plastic tube, 400 mm above the tip



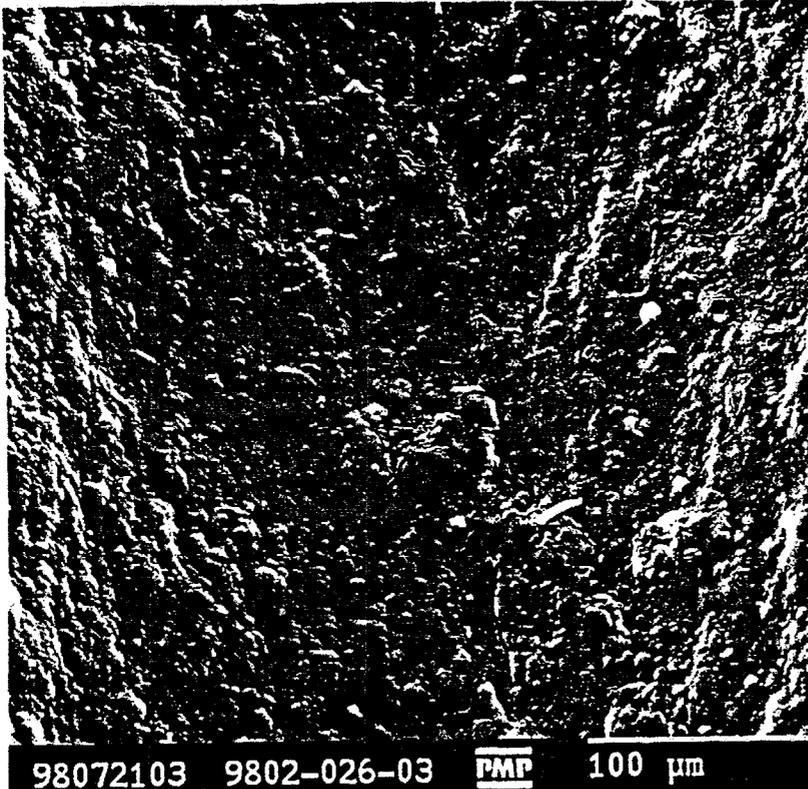
Radial Jaw 3, sample 9802-025
Location: inner surface of inner plastic tube, 400 mm above the tip
No visible contaminations.



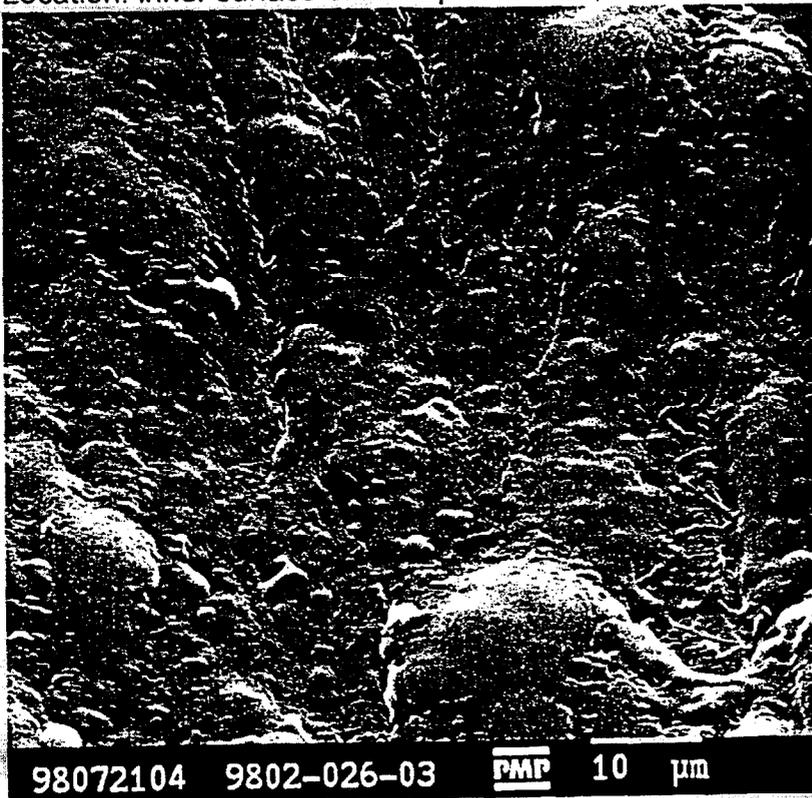
98072101 9802-026-01 PMP 100 μ m
Radial Jaw 3, sample 9802-026
Location: coil spring, 10 mm above the tip



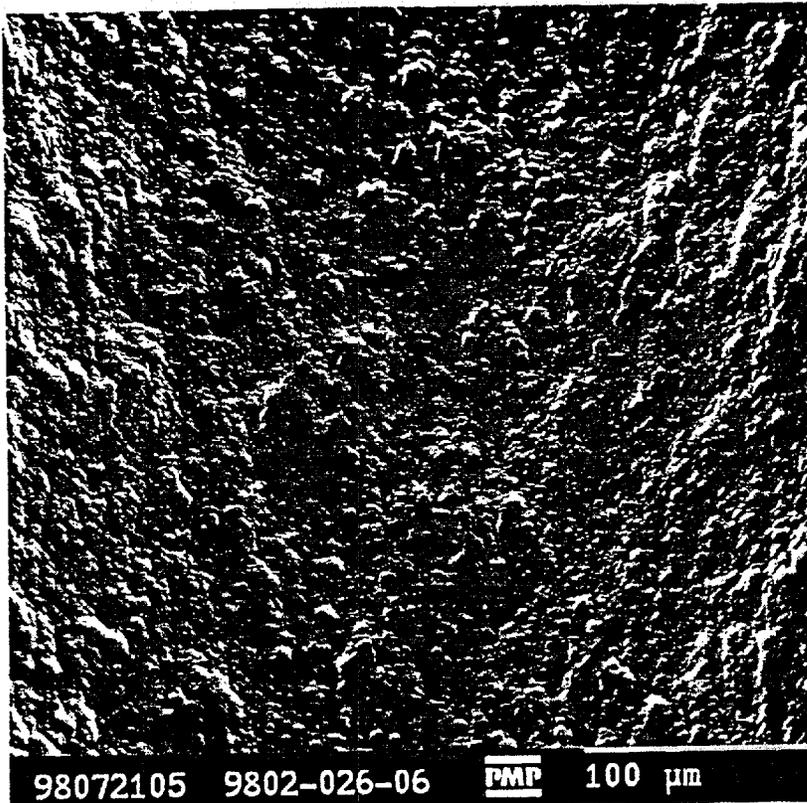
98072102 9802-026-01 PMP 10 μ m
Radial Jaw 3, sample 9802-026
Location: coil spring, 10 mm above the tip
No visible contaminations.



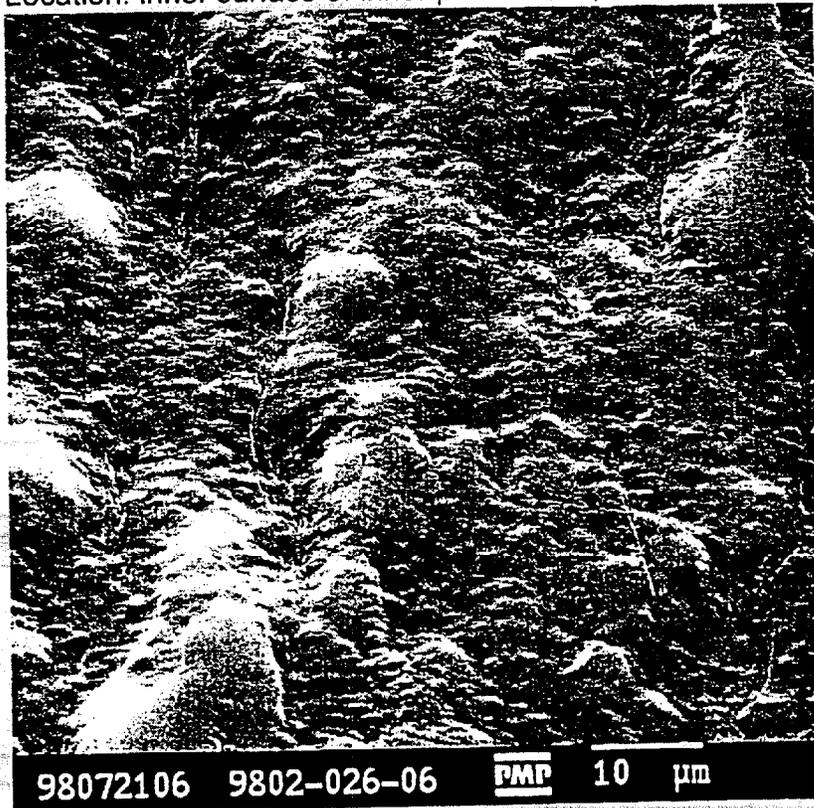
98072103 9802-026-03 PMP 100 μm
Radial Jaw 3, sample 9802-026
Location: inner surface of inner plastic tube, 100 mm above the tip



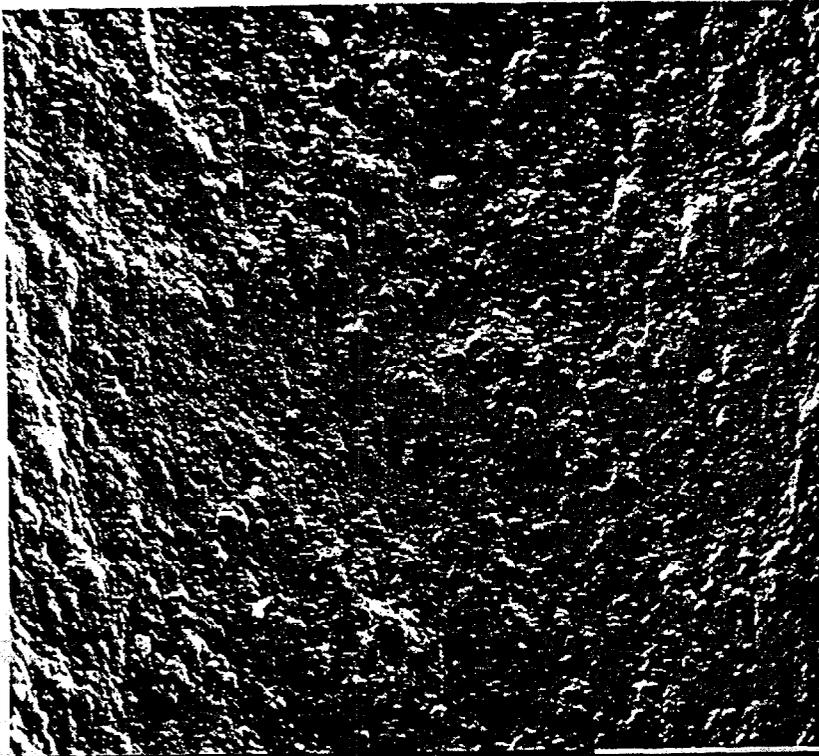
98072104 9802-026-03 PMP 10 μm
Radial Jaw 3, sample 9802-026
Location: inner surface of inner plastic tube, 100 mm above the tip
Small contaminations.



Radial Jaw 3, sample 9802-026
Location: inner surface of inner plastic tube, 200 mm above the tip



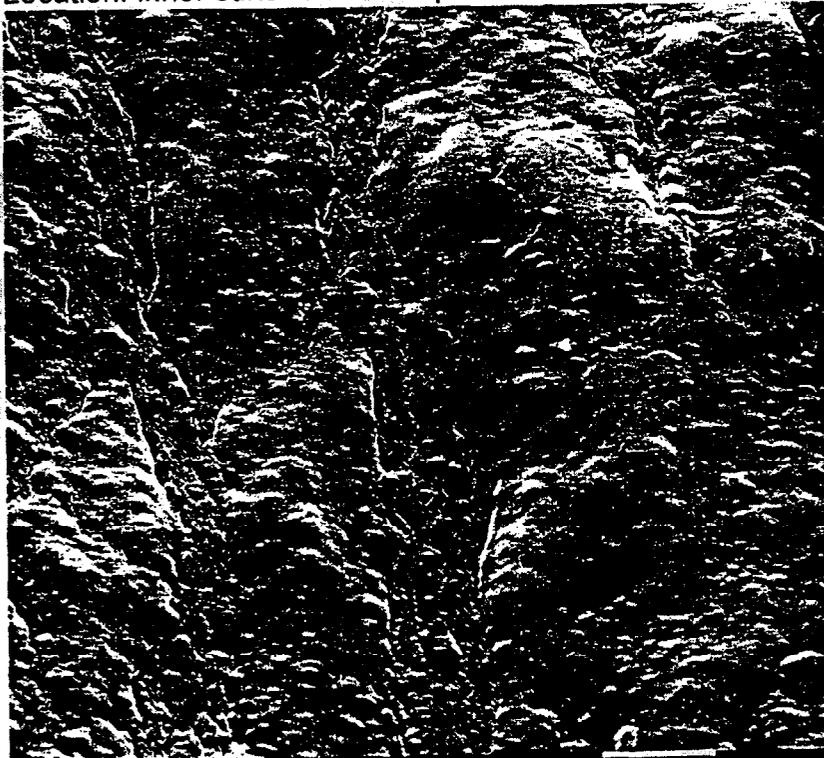
Radial Jaw 3, sample 9802-026
Location: inner surface of inner plastic tube, 100 mm above the tip
No visible contaminations.



98072107 9802-026-08 PMP 100 μm

Radial Jaw 3, sample 9802-026

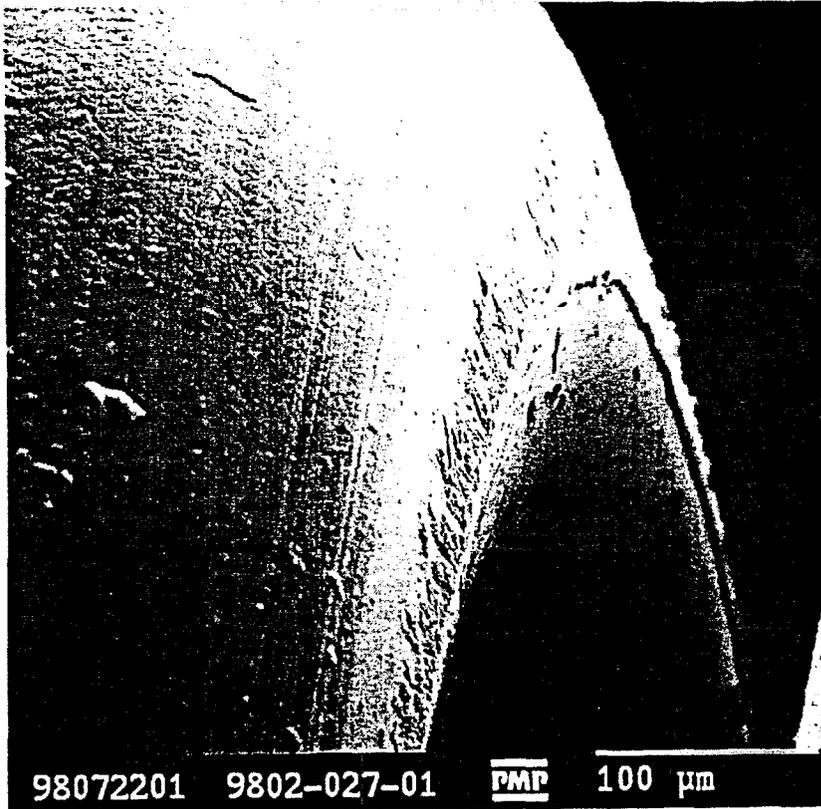
Location: inner surface of inner plastic tube, 400 mm above the tip



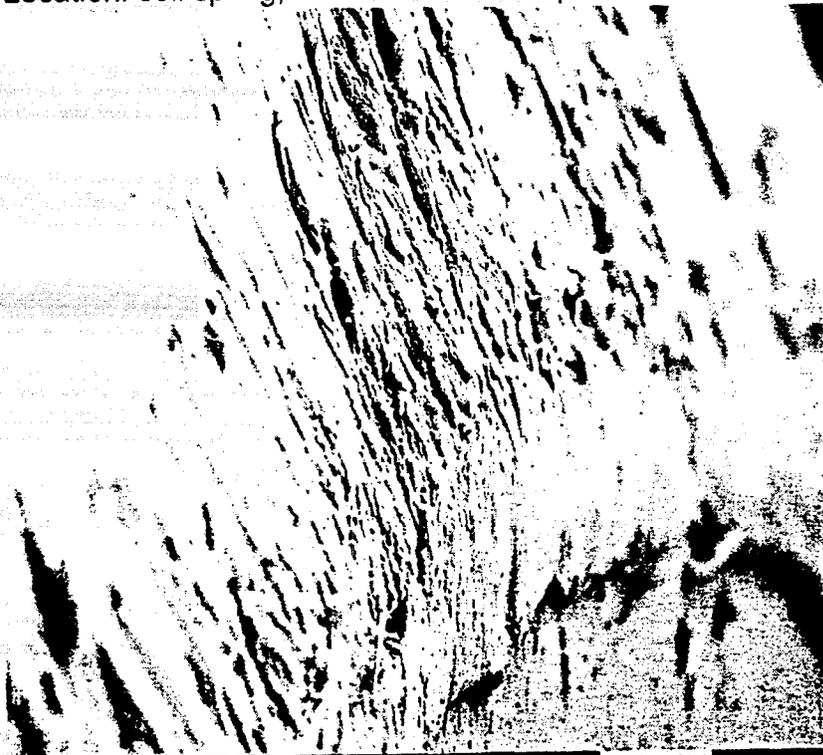
98072108 9802-026-08 PMP 10 μm

Radial Jaw 3, sample 9802-026

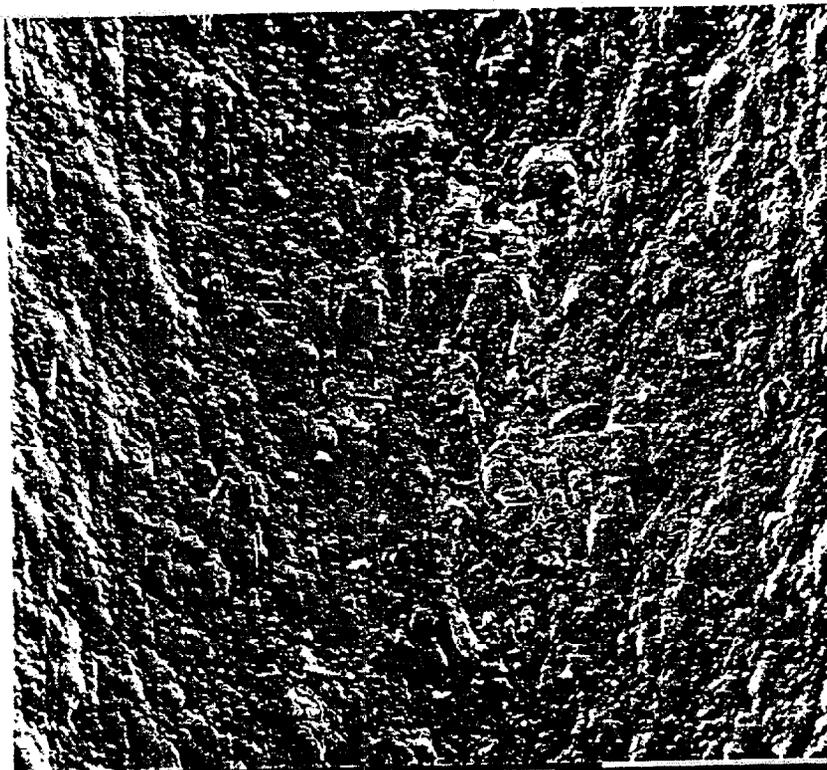
Location: inner surface of inner plastic tube, 400 mm above the tip
No visible contaminations.



98072201 9802-027-01 PMP 100 μm
Radial Jaw 3, sample 9802-027
Location: coil spring, 10 mm above the tip



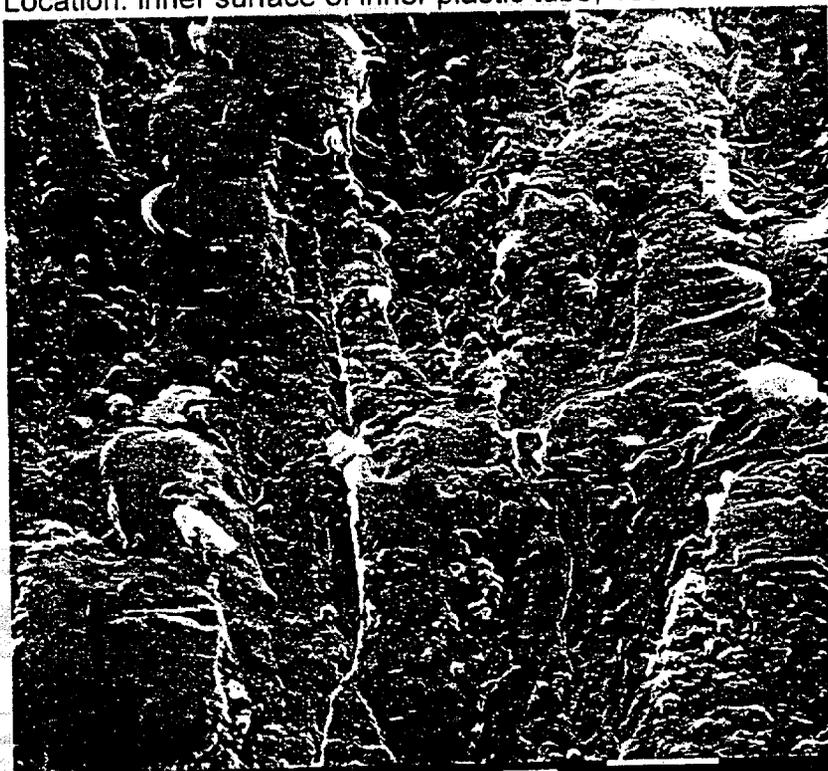
98072202 9802-027-01 PMP 10 μm
Radial Jaw 3, sample 9802-027
Location: coil spring, 10 mm above the tip
No visible contaminations.



98072203 9802-027-03 PMP 100 μm

Radial Jaw 3, sample 9802-027

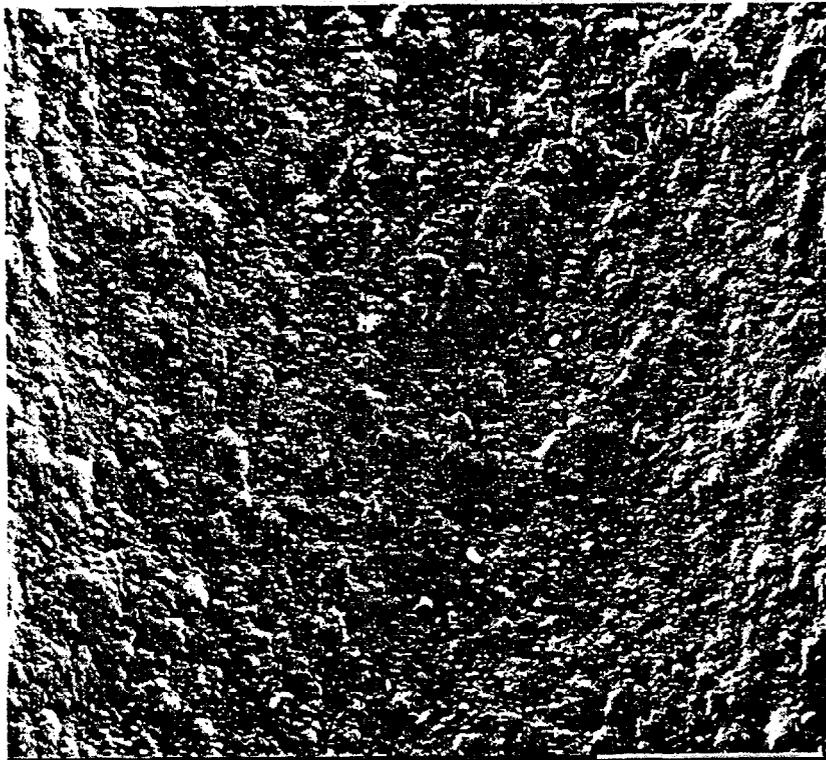
Location: inner surface of inner plastic tube, 100 mm above the tip



98072204 9802-027-03 PMP 10 μm

Radial Jaw 3, sample 9802-027

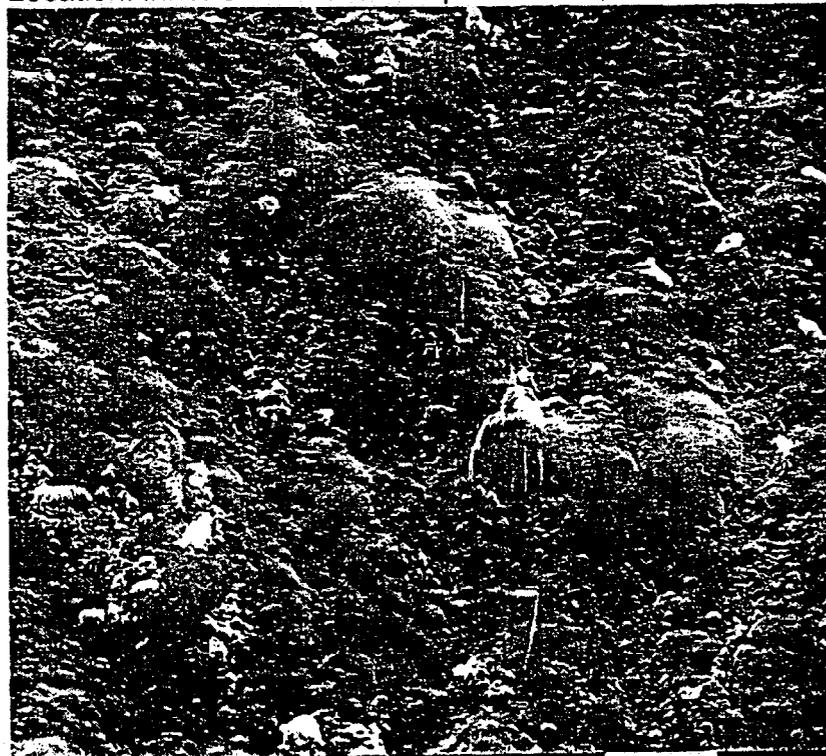
Location: inner surface of inner plastic tube, 100 mm above the tip
No visible contaminations.



98072205 9802-027-06 PMP 100 μm

Radial Jaw 3, sample 9802-027

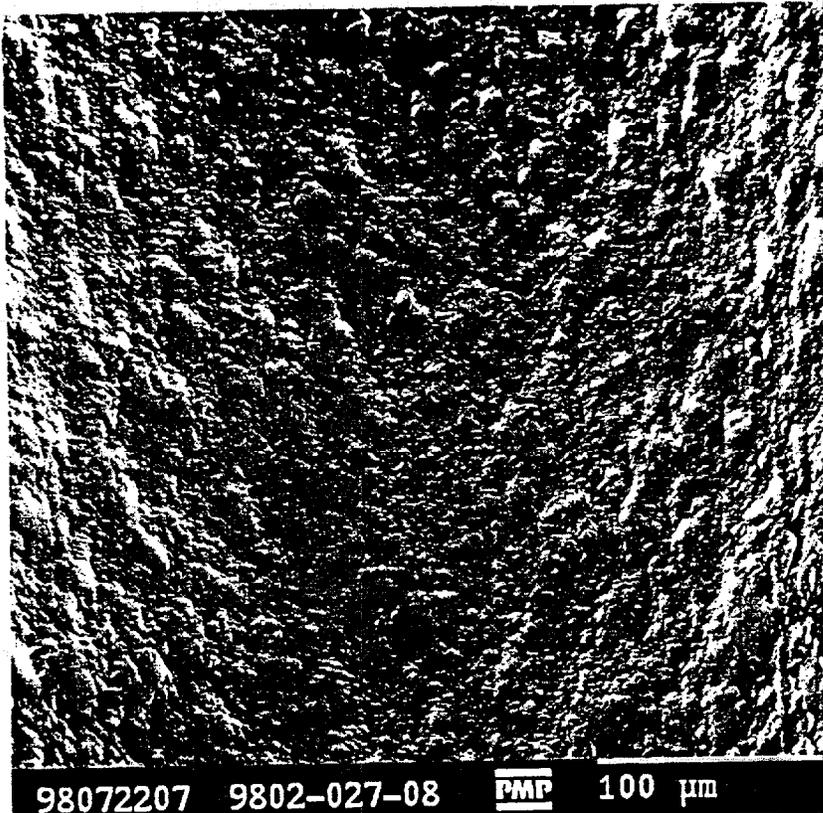
Location: inner surface of inner plastic tube, 200 mm above the tip



98072206 9802-027-06 PMP 10 μm

Radial Jaw 3, sample 9802-027

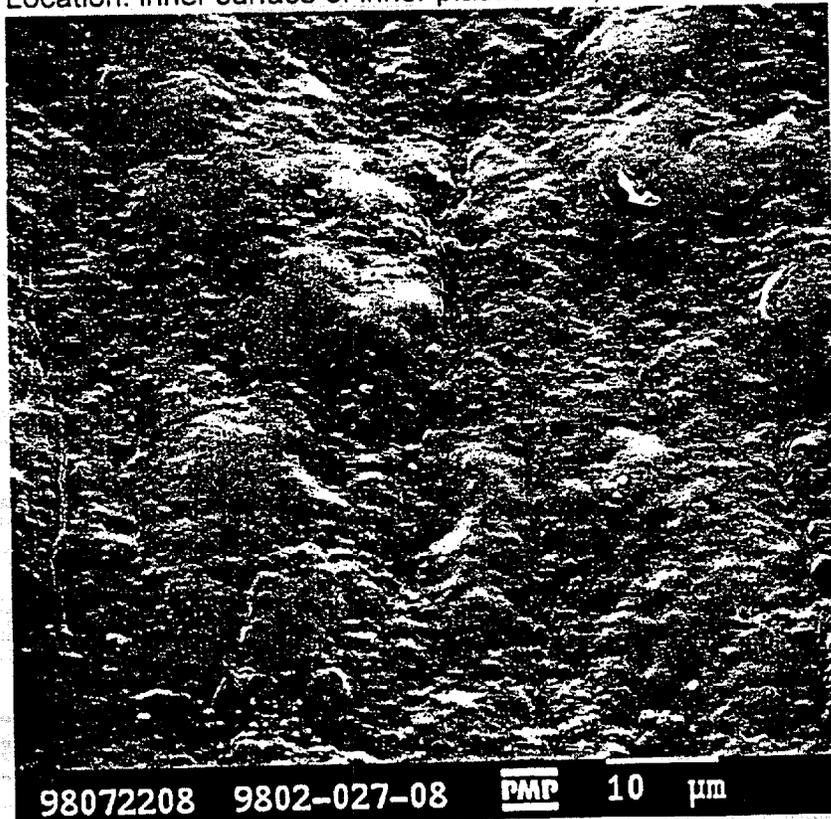
Location: inner surface of inner plastic tube, 200 mm above the tip
Local contaminations.



98072207 9802-027-08 PMP 100 μm

Radial Jaw 3, sample 9802-027

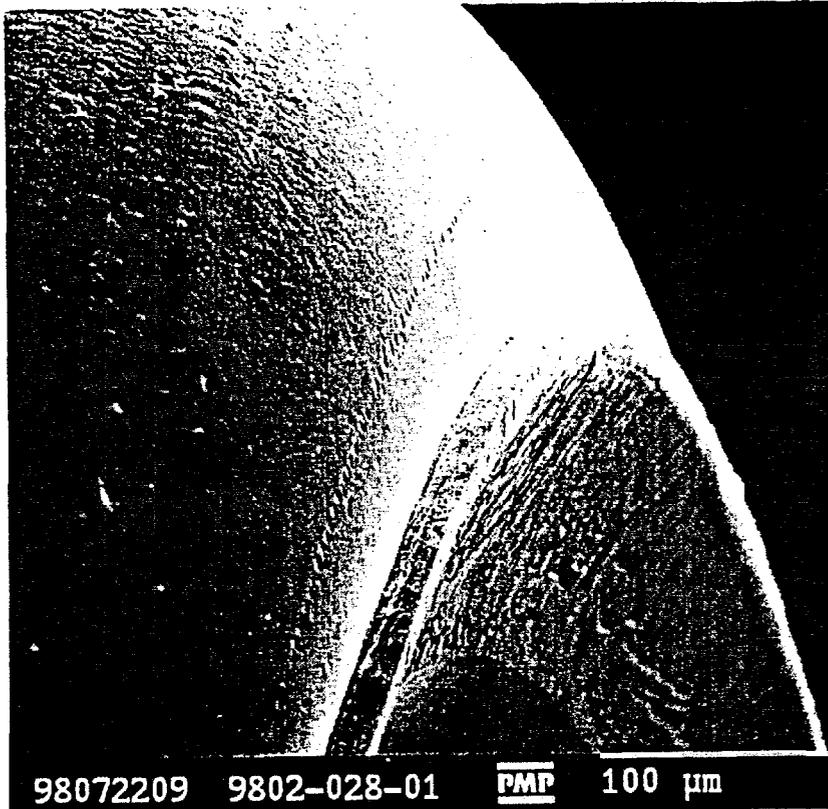
Location: inner surface of inner plastic tube, 400 mm above the tip



98072208 9802-027-08 PMP 10 μm

Radial Jaw 3, sample 9802-027

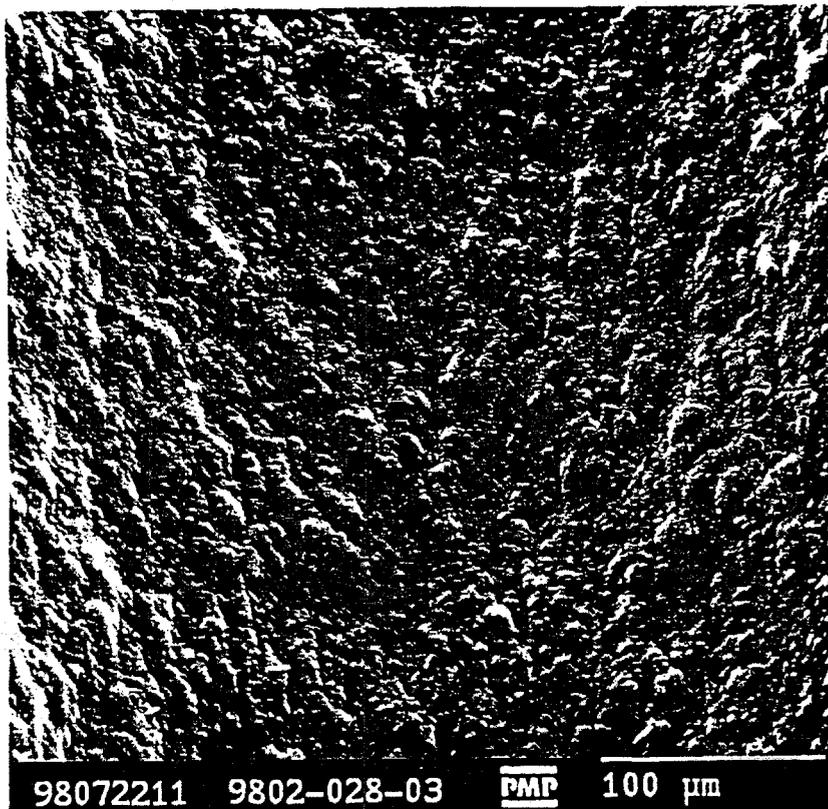
Location: inner surface of inner plastic tube, 400 mm above the tip
No visible contaminations.



Radial Jaw 3, sample 9802-028
Location:coil spring, 10 mm above the tip

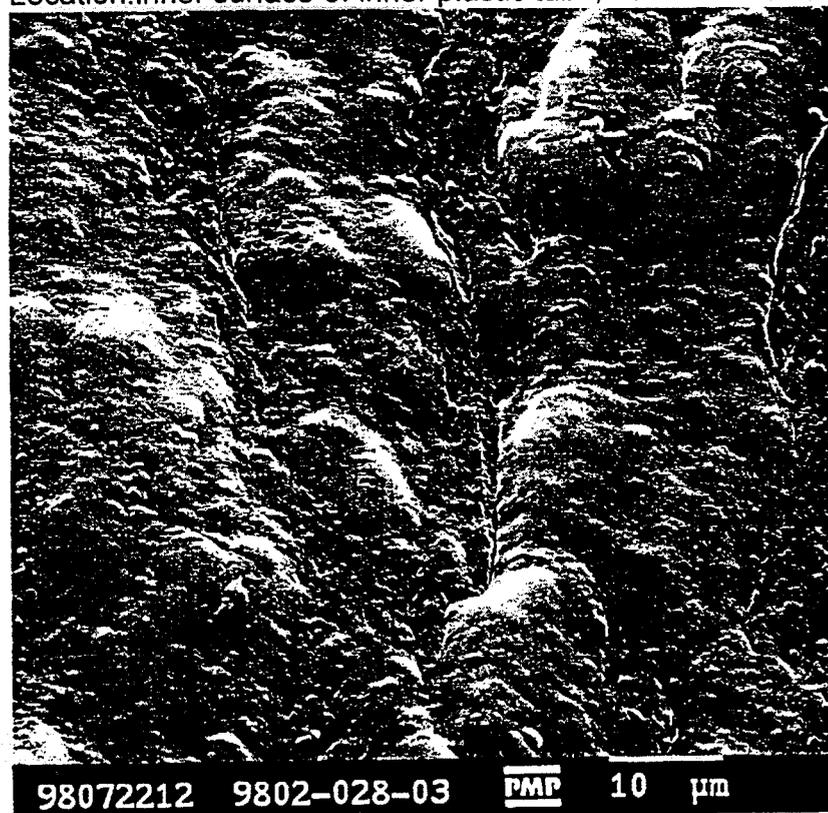


Radial Jaw 3, sample 9802-028
Location:coil spring, 10 mm above the tip
No visible contaminations.



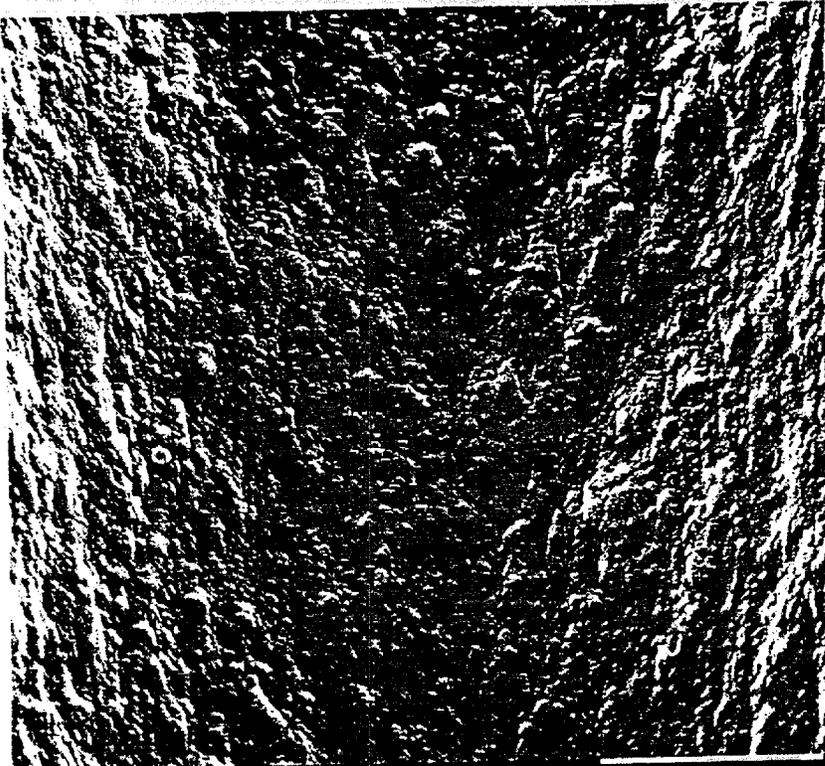
Radial Jaw 3, sample 9802-028

Location: inner surface of inner plastic tube, 100 mm above the tip



Radial Jaw 3, sample 9802-028

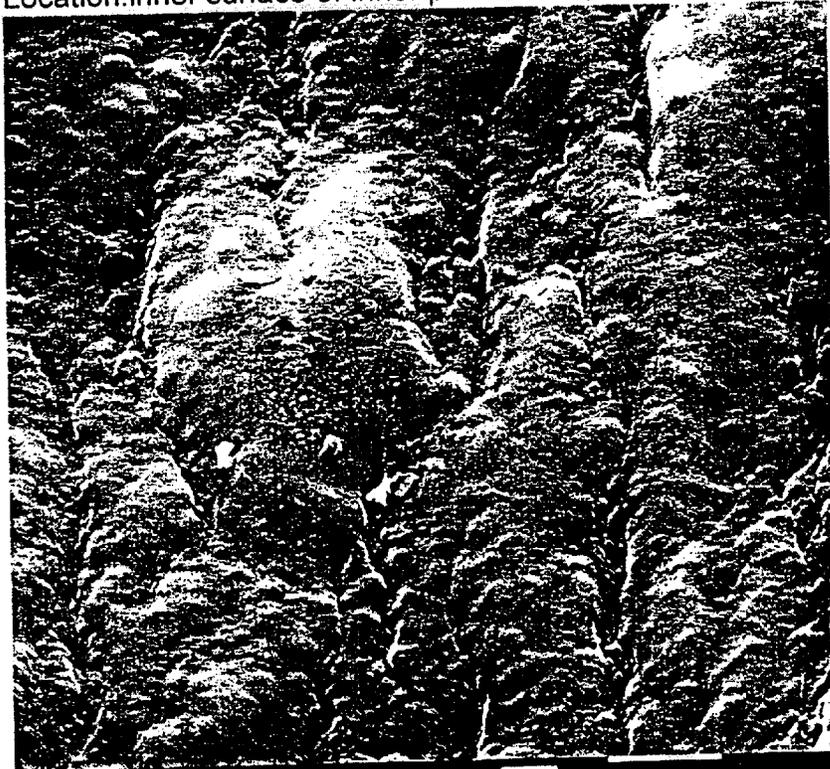
Location: inner surface of inner plastic tube, 100 mm above the tip
No visible contaminations.



98072213 9802-028-06 **PMP** 100 μm

Radial Jaw 3, sample 9802-028

Location: inner surface of inner plastic tube, 200 mm above the tip

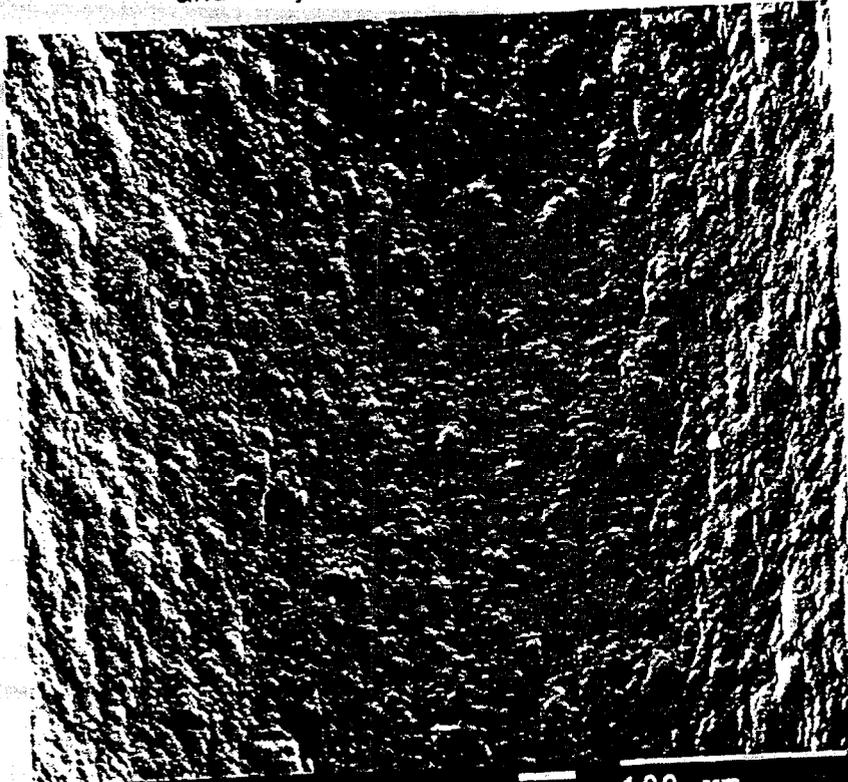


98072214 9802-028-06 **PMP** 10 μm

Radial Jaw 3, sample 9802-028

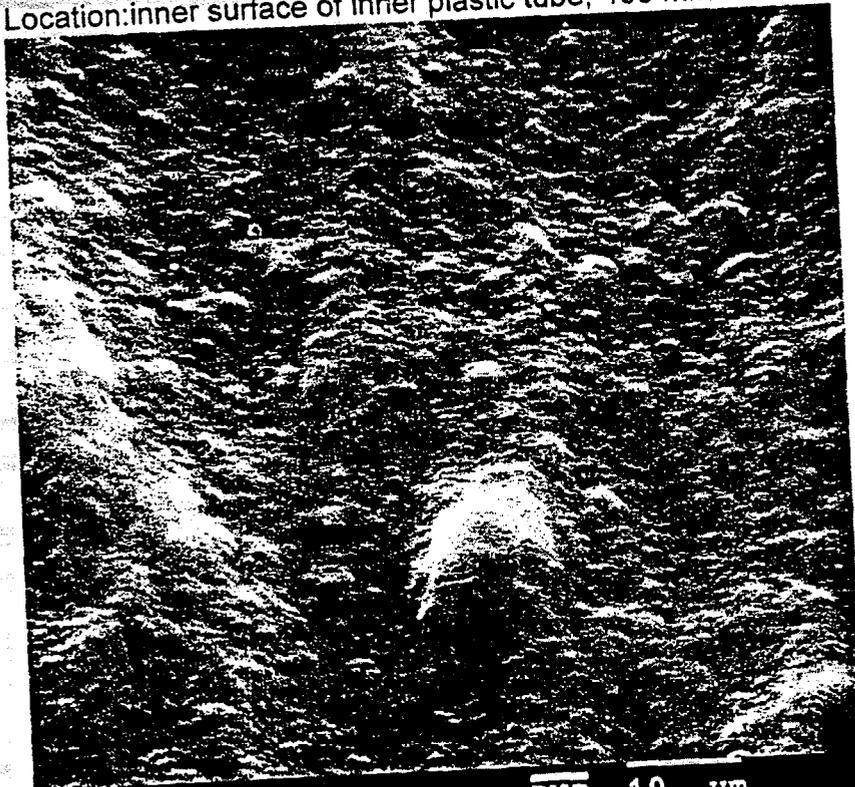
Location: inner surface of inner plastic tube, 200 mm above the tip

No visible contaminations.



98072215 9802-028-08 PMP 100 μm

Radial Jaw 3, sample 9802-028
Location: inner surface of inner plastic tube, 400 mm above the tip



98072216 9802-028-08 PMP 10 μm

Radial Jaw 3, sample 9802-028
Location: inner surface of inner plastic tube, 400 mm above the tip
No visible contaminations.

5.3 Element Concentrations (XPS)

A survey spectrum of the surfaces was carried out and evaluated qualitatively. Subsequent from the identified and suspected elements a sectional spectrum was performed and the concentration of the elements was determined.

For quantification of the elements a homogeneous distribution of the elements was assumed. Hydrogen was not taken into account.

The calculated concentrations of elements at the surface of the samples are listed in the following table:

| Sample | Concentration of elements [at%] | | | | |
|--|---------------------------------|----|----|-------|-------|
| | C | O | Si | N | F |
| Radial Jaw 3 9801-001-04 Initial setting | 66 | 19 | 16 | < 0,1 | < 0,1 |
| Radial Jaw 3 9802-021-04 Soiled and reprocessed | 67 | 18 | 15 | <0,1 | <0,1 |
| Radial Jaw 3 9802-022-04 Soiled and reprocessed | 66 | 18 | 16 | <0,1 | <0,1 |
| Radial Jaw 3 9802-023-04 Soiled and reprocessed | 69 | 18 | 13 | <0,1 | <0,1 |
| Radial Jaw 3 9802-024-04 Soiled and reprocessed | 71 | 17 | 12 | <0,1 | <0,1 |

| Sample | C | O | Si | N | F |
|--|----|----|----|------|------|
| Radial Jaw 3 9802-025-04 Soiled and reprocessed | 72 | 16 | 12 | <0,1 | <0,1 |
| Radial Jaw 3 9802-026-04 Soiled and reprocessed | 61 | 23 | 17 | <0,1 | <0,1 |
| Radial Jaw 3 9802-027-04 Soiled and reprocessed | 66 | 21 | 13 | <0,1 | <0,1 |
| Radial Jaw 3 9802-028-04 Soiled and reprocessed | 63 | 22 | 15 | <0,1 | <0,1 |

Tab. 1: Concentration of elements
Radial Jaw 3 catheter, inner surface of
inner plastic tube about 100 mm above the tip

XPS measurements yielded no significant change in the measured concentration
of elements.

MICROBIOLOGICAL TEST PROTOCOL

DOCUMENT NO.: 9912701

REVISION NO.: A

INITIATED BY: Phil Cogdill

Page 1 of 3

TITLE: Sterility and Bioburden Testing for Vanguard Reprocessed Biopsy Forceps [REDACTED]

1.0 Purpose

This protocol provides the steps to be followed in order to evaluate sterility and the quantitative microbial recovery for the Vanguard Reprocessed Biopsy Forceps products supplied by [REDACTED]. This testing will be performed using the following facility:

ViroMed Biosafety Laboratories
2540 Executive Drive
St. Paul, MN 55120

Phone: 612-931-0077

2.0 Reference Documents:

- 2.1 ISO 11737-1:1995 "Sterilization of Medical Devices –Microbiological methods – Part 1: Estimation of the population of microorganisms on product"
- 2.2 ISO 11737-2(in press) "Sterilization of Medical Devices –Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process"
- 2.3 USP 23; The United States Pharmacopoeia, <1211> Sterilization and Sterility Assurance of Compndial Articles, 1995, pg1980.
- 2.4 Association for the Advancement of Medical Instrumentation (AAMI). Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: a guide for device manufacturers. AAMI TIR No. 12. Arlington (VA): AAMI; 1994.

3.0 Scope:

Manufacturers are required to conduct very stringent testing processes for reusable products. They must meet FDA criteria, which follow the Association for the Advancement of Medical Instrumentation (AAMI)¹ guidance document with four fundamental aspects of device design that manufacturers should consider when developing a medical device intended to be reused. These include physical, material, total system, and user-related design considerations. Good device design accounts for the environment in which the device will be used and the environment in which it will be reprocessed within the healthcare facility.

Cleaning and decontamination are recognized as the crucial first steps in any effective reprocessing protocol, and devices must be designed to be compatible with these protocols. The size, shape, a configuration of an instrument can significantly affect how adequately it can be cleaned. Fine surface crevices, porous materials, or other physical features that encourage the retention of microbes, toxic sterilants, cleaning solution residues, and physiological fluids or residues must be avoided. Biofilms that form on instrument surfaces contacting body fluids can be tenacious and require vigorous scrubbing

¹ Association for the Advancement of Medical Instrumentation (AAMI). Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: a guide for device manufacturers. AAMI TIR No. 12. Arlington (VA): AAMI; 1994.

effectively remove. The design must also take into account variations in technique and skill of central sterile supply personnel, and any design that does not allow unobstructed access to surfaces for cleaning cannot be considered for a reusable medical device.

Adequate cleaning entails removal of visible and non-visible soil from body fluids, tissues, and other debris that remain following use of the device. All surfaces of the device, including channels and lumens that may have been in contact with the patient or physiologic fluids, must be accessible to ensure proper cleaning. If the product cannot be adequately cleaned, sterilization will not be reliable, and pyrogenic reactions may occur even if the device is sterile². Moreover, if all potentially contaminated surfaces of a critical or semicritical device cannot be inspected for cleanliness after each use, then it should not be reused³.

This study will evaluate the Vanguard Reprocessed Biopsy Forceps biopsy forceps which have been reprocessed for [REDACTED]. The reprocessed biopsy forceps must be sterile after reprocessing per validated reprocessing instructions.

4.0 Equipment and Materials

- 4.1 Tryptic Soy Agar or Tryptic Soy Agar with 5% Sheep Blood
- 4.2 Tryptic Soy Broth
- 4.3 Sterile Containers
- 4.4 Rotary Shaker
- 4.5 30-35°C incubator
- 4.6 20-25°C room temperature Cabinet

5.0 Procedure:

Bioburden\Sterility test of Reprocessed Biopsy Forceps Units

- 5.1 ViroMed Labs will perform a Bioburden\Sterility testing at (30-35°C) on the 10 single pouch reprocessed biopsy forceps units.
- 5.2 Aseptically cut forceps into approximately 30 cm segments and put each device into ster containers (containing a minimum of 500 mL of TSB).
- 5.3 Rotary shaker the containers (do not allow media to contact the lid of the container) for 15 minu at 150 rpm at room temperature.
- 5.4 Aseptically filter 50 mL onto a 0.45µ or smaller filter media and place on TSA or BAP plate Bioburden testing (Aerobic and Fungal).
- 5.5 Additionally, Plate duplicate 1 mL aliquots and incorporate with molten, tempered TSA.
- 5.6 Incubate all plates for 72 hours at 30-35°C and then transfer the plates to room temperature (25°C) for an additional 4 days.
- 5.7 If any plates or broth are positive, Streak out all positive broth for isolation of bacteria, and hav colony morphologies identified to species.

Protocol # 9912701
Page 3 of 3

Modified USP Sterility Testing (Thioglycollate Broth will not be used as per USP guidelines).

- 5.6 ViroMed Labs will perform a 14 day USP Sterility test (20-25°C) on 10 single pouched reprocessed U.S. biopsy forceps units.
- 5.8 Aseptically cut forceps into approximately 30 cm segments and put each device into sterile containers (containing a minimum of 500 mL of TSB).
- 5.9 Incubate all broth for 14 days at (20-25°C).
- 5.10 If any broth containers are positive, Streak for isolation of bacteria, and have all colony morphologies identified to species.

6.0 Acceptance Criteria

For these tests to be acceptable, there must be no units with positive microbial growth on both the bioburden and the sterility test samples.

7.0 Approval

Submitted By:

**Boston Scientific
One Boston Scientific Place
Natick, MA 01760-1537**

NAME: Phil Cogdill

TELEPHONE: 508-650-8137

TITLE: Corp. Director of Sterilization and Microbiology

FACSIMILE: 508-650-8935

SIGNATURE: *Phil Cogdill*

DATE: 5/28/99

Laboratory:

**ViroMed Biosafety Laboratories
2540 Executive Drive
St. Paul, MN 55120**

NAME: Julie Makcow

TELEPHONE: 612-939-4236

TITLE: Supervisor of Microbiology

FACSIMILE: 612-563-3289

SIGNATURE: *Julie Makcow*

DATE: 5/28/99

REPORT TITLE

**FINAL REPORT FOR STERILITY AND BIOBURDEN TESTING OF BIOPSY FORCEPS
FROM [REDACTED]
REPROCESSED BY VANGUARD MEDICAL CONCEPTS, INC.**

DATE

July 15, 1999

PERFORMING LABORATORY

ViroMed Laboratories, Inc.
2540 Executive Drive
St. Paul, MN 55120

SPONSOR

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
For

FINAL REPORT NO.

BSC-9919601

FINAL REPORT FOR STERILITY AND BIOBURDEN TESTING OF BIOPSY FORCEPS
REPROCESSED BY VANGUARD MEDICAL CONCEPTS, INC.

TEST FACILITY: ViroMed Laboratories, Inc.
2540 Executive Drive
St. Paul, MN 55120

PROFESSIONAL PERSONNEL INVOLVED:

J. Mackcow - Lab Supervisor
D. Pauly - Research Assistant

SPONSOR: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
For [REDACTED]

DATE SAMPLES RECEIVED: May 10, 1999
TEST COMPLETION DATE: June 09, 1999

SAMPLE NAME AND CODE: Radial Jaw 3 Biopsy Forceps Reprocessed by Vanguard Medical Concepts, Inc. See attached copies of package identification.

TEST ARTICLE CHARACTERIZATION

The material submitted for testing was identified as above by Sponsor. The identity, purity, solubility, stability and chemical composition of the test item were not provided to ViroMed Laboratories, Inc. by the Sponsor.

DATA RETENTION

A certified copy of the original final report and all raw data pertinent to the study will be stored at ViroMed Laboratories, Inc 2540 Executive Drive St. Paul, MN 55120. All test materials and packaging were discarded following the study.

1.0 PURPOSE

The purpose was to perform sterility confirmation of Biopsy Forceps products supplied by [REDACTED] post reprocessing by Vanguard Medical Concepts, Inc.

2.0 METHOD/RESULTS

BIOBURDEN\STERILITY TEST OF REPROCESSED BIOPSY FORCEPS UNITS

ViroMed Labs performed a Bioburden\Sterility test at (37±2°C) for seven days on the 10 single pouched reprocessed biopsy forceps units.

RESULTS: A total of Five positives for growth, out of ten (10) biopsy forceps, or 50% were NON-STERILE (Reference Accession No. R8144802).

BIOBURDEN TESTING:

ViroMed Labs performed a Bioburden test by cutting the devices into approximately 30 cm segments. The segments were aseptically placed into a jar of 500 ml of TSB and placed on a rotary shaker at 150 rpm for 15 minutes. 50 ml of the extract was then filtered and plated onto TSA and another 1 ml sample of the extract was plated in duplicate on TSA. Both plates and the devices in the TSB were incubated for seven days at (37±2°C).

RESULTS: The results are listed in Table 1 below (Reference Accession No.'s R8144802 & R8135410):

TABLE 1

| <u>Product Code #</u> | <u>Sample #</u> | <u>Estimated Total Bioburden (cfu's/device)</u> | <u>Microorganism Identifications</u> |
|-----------------------|-----------------|---|--|
| 953867 | 1 | 0 | |
| 953866 | 2 | >1 and <10 | Bacillus sp, Bacillus cereus, Acinetobacter radioresistens, Pseudomonas putida |
| 953865 | 3 | 0 | |
| 953862 | 4 | 10 | Pseudomonas putida |
| 953861 | 5 | >1 and <10 | Micrococcus luteus |
| 953859 | 6 | 40 | Staphylococcus epidermidis |
| 953858 | 7 | 0 | |
| 953857 | 8 | 0 | |
| 953856 | 9 | >1 and <10 | Staphylococcus epidermidis and S. aureus |
| 953855 | 10 | 0 | |

MODIFIED USP STERILITY TESTING (Thioglycollate Broth will not be used as per USP guidelines)

ViroMed Labs performed a 14 day USP Sterility test. Ten (10) single pouched reprocessed biopsy forceps units were aseptically cut into approximately 30 cm segments. The segments were aseptically placed into a jars of 500 ml of TSB and incubated at (20-25°C) for 14 days.

RESULTS: A total of four devices supported growth, out of ten (10) biopsy forceps, or 40% were NON-STERILE (Reference Accession No. R8132848). The results are listed in Table 1 below:

TABLE 2
TEST RESULTS FOR USP PRODUCT STERILITY - EXTRA LARGE

| Product Code # | Sample # | Bacterial Growth | Microorganism Identifications |
|----------------|----------|------------------|-------------------------------|
| 952534 | 1 | No | |
| 952530 | 2 | Yes, On Day 4 | Paenibacillus apiarius |
| 952533 | 3 | No | |
| 952536 | 4 | Yes, On Day 4 | Staphylococcus epidermidis |
| 952531 | 5 | No | |
| 952529 | 6 | No | |
| 952528 | 7 | No | |
| 952527 | 8 | Yes, On Day 8 | Brevibacterium stationis |
| 952535 | 9 | No | |
| 952537 | 10 | Yes, On Day 7 | Staphylococcus hominis |

3.0 CONCLUSION

This provides evidence the Radial Jaw Biopsy Forceps, reprocessed by Vanguard Medical Concepts, Inc. are **not sterile** and do not meet the required sterility assurance level of 10^{-6} , implied by the Sterile listing on the label. These results would indicate that the Radial Jaw Biopsy Forceps do not meet the FDA criteria for a medical device intended to be reused.

4.0 APPROVALS

PREPARED BY:

C. Philip Cogdill
C. Philip Cogdill
Director Corporate Sterilization and Microbiology

7/15/99
Date

Attachments

ATTACHMENT 1
VIROMED PROJECT REPORTS

ACCT #: 1128377
 BOSTON SCIENTIFIC
 ATTN: MIKE LANGE
 6470 SYCAMORE CT
 MAPLE GROVE MN 55369

SAMPLE: BSC01, VANGUARD MEDICAL CONCEPTS REPROCESSED
 LOT #: 240334
 ID: RADIAL JAW BIOPSY
 STERILITY DATE:
 ACCESSION NO.: R8144802
 DATE COLLECTED: NO DATE
 TIME COLLECTED: NO TIME
 DATE RECEIVED: 05/14/99
 DATE REPORTED: 06/09/99

STERILITY METHOD: ETHYLENE OXIDE
 MANFU SOURCE:

P.O.: 9913301

NOTES: FORCEPS, STERILITY DATE 11-98, SEE ATTACHED LETTER. STERILITY PORTION.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

USP PRODUCT STERILITY-EXTRA LARGE

TEST ACCEPTANCE CRITERIA:

1. Positive controls must be positive
2. Negative controls must be negative

| MEDIA TYPE | INCUBATION | |
|-------------------|------------|------|
| | TEMP (C) | DAYS |
| TRYPTIC SOY BROTH | 20-25 | 14 |

TEST RESULTS:

Positive Media Control:
 Control Organism - B. Subtilis
 Positive in Tryptic Soy Broth
 Negative Media Control
 No growth after 14 days

| CYCLE INFORMATION | NUMBER OF TESTS | NUMBER OF POSITIVES |
|-------------------|-----------------|---------------------|
|-------------------|-----------------|---------------------|

| | | |
|--|----|---|
| | 10 | 5 |
| PRODUCT 953866 WAS POSITIVE ON DAY 3 WITH GRAM POSITIVE RODS. | | |
| PRODUCT 953862 WAS POSITIVE ON DAY 3 WITH GRAM POSITIVE RODS. | | |
| PRODUCT 953861 WAS POSITIVE ON DAY 3 WITH GRAM POSITIVE COCCI. | | |
| PRODUCT 953859 WAS POSITIVE ON DAY 3 WITH GRAM POSITIVE COCCI. | | |
| PRODUCT 953856 WAS POSITIVE ON DAY 3 WITH GRAM POSITIVE COCCI. | | |
| PRODUCTS WERE TESTED IN TSB ONLY PER CLIENT REQUEST. | | |

STERILITY PORTION OF TESTING PERFORMED PER BOSTON SCIENTIFIC PROCEDURE.

SEE ACCESSION NUMBER R8135410 FOR THE BIOBURDEN PORTION OF THE TESTING. PRODUCTS WERE ON TEST AT 37 PLUS OR MINUS 2 DEGREES CELCIUS FOR 7 DAYS PER CLIENT REQUEST.

ACCT #: 1128377
 BOSTON SCIENTIFIC
 ATTN: MIKE LANGE
 6470 SYCAMORE CT
 MAPLE GROVE MN 55369

SAMPLE: BSC01, VANGUARD MEDICAL CONCEPTS REPROCESSED
 LOT #: 240334
 ID: RADIAL JAW BIOPSY
 STERILITY DATE:
 ACCESSION NO.: R8135410
 DATE COLLECTED: NO DATE
 TIME COLLECTED: NO TIME
 DATE RECEIVED: 05/14/99
 DATE REPORTED: 06/09/99

STERILITY METHOD: ETHYLENE OXIDE
 MANFU SOURCE:

P.O.: 9913301

NOTES: FORCEPS, STERILITY DATE 11-98, SEE ATTACHED LETTER. BIOBURDEN PORTION.

| TEST REPORT | RESULT | METHOD |
|-------------------|--------|--------|
| AEROBIC BIOBURDEN | | |

| | |
|------------|---------|
| AEROBIC 1 | <10 CFU |
| AEROBIC 2 | <10 CFU |
| AEROBIC 3 | <10 CFU |
| AEROBIC 4 | 10 CFU |
| AEROBIC 5 | <10 CFU |
| AEROBIC 6 | 40 CFU |
| AEROBIC 7 | <10 CFU |
| AEROBIC 8 | <10 CFU |
| AEROBIC 9 | <10 CFU |
| AEROBIC 10 | <10 CFU |

DEVICES WERE PUT ON TEST PER BOSTON SCIENTIFIC PROCEDURE.

DEVICES WERE CUT INTO APPROXIMATELY 30 CM SEGMENTS. THE DEVICES WERE PLACED INTO 500 ML OF TSB AND WERE PLACED ON A ROTARY SHAKER AT 150 RPM FOR 15 MINUTES. 50 ML OF THE EXTRACT WAS THEN FILTERED AND PLATED ONTO TSA. 1 ML OF THE EXTRACT WAS ALSO PLATED IN DUPLICATE ON TSA. BOTH THE PLATES AND THE DEVICES IN TSB WERE INCUBATED FOR 7 DAYS AT 37 PLUS OR MINUS 2 DEGREES CELCIUS. SEE ACCESSION NUMBER R8144802 FOR 7 DAY STERILITY PORTION OF TESTING.

SEE SEPARATE MICROCHECK REPORT FOR IDENTIFICATION RESULTS.

0 CFU = <10 CFU

ALL RESULTS ARE IN COLONY FORMING UNITS.

DILUTION FACTOR = 500 ML/50 ML = 10

TEST START DATE 5-14-99 TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

Juni Mack Cow
 *** FINAL REPORT ***



ACCT #: 1128381

BOSTON SCIENTIFIC CORP.

ATTN: PHILIP COGDILL

ONE BOSTON SCIENTIFIC PLACE

NATRICK, MA 01760-1537

SAMPLE: SYM01, REPROCESSED RADIAL JAW BIOPSY FORCEPS

LOT #: 238282

ID:

STERILITY DATE:

ACCESSION NO.: R8132848

DATE COLLECTED: NO DATE

TIME COLLECTED: NO TIME

DATE RECEIVED: 05/10/99

DATE REPORTED: 06/09/99

STERILITY METHOD: ETHYLENE OXIDE

MANFU SOURCE:

P.O.: 9912701

NOTES: STERILITY DATE 10/98, KEEP PACKAGING FOR ID, BY VANGUARD MEDICAL CONCEPT

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

USP PRODUCT STERILITY-EXTRA LARGE

TEST ACCEPTANCE CRITERIA:

1. Positive controls must be positive
2. Negative controls must be negative

MEDIA TYPE

INCUBATION

| TEMP (C) | DAYS |
|----------|------|
| 20-25 | 14 |

TRYPTIC SOY BROTH

TEST RESULTS:

Positive Media Control:
 Control Organism - B. Subtilis
 Positive in Tryptic Soy Broth
 Negative Media Control
 No growth after 14 days

| CYCLE INFORMATION | NUMBER OF TESTS | NUMBER OF POSITIVES |
|-------------------|-----------------|---------------------|
|-------------------|-----------------|---------------------|

10

4

PRODUCT 952530 WAS POSITIVE ON DAY 4 WITH GRAM POSITIVE RODS.

PRODUCT 952536 WAS POSITIVE ON DAY 4 WITH GRAM POSITIVE COCCI.

PRODUCT 952527 WAS POSITIVE ON DAY 8 WITH GRAM POSITIVE COCCI.

PRODUCT 952537 WAS POSITIVE ON DAY 7 WITH GRAM POSITIVE COCCI.

PRODUCTS WERE TESTED IN TSB ONLY PER CLIENT REQUEST.

SEE SEPARATE MICROCHECK REPORT FOR IDENTIFICATION INFORMATION.

TEST START DATE 5-10-99

TEST COMPLETION DATE 5-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

Chiu Mack w/1999

ACCT #: 1128381
BOSTON SCIENTIFIC CORP.
ATTN: PHILIP COGDILL
ONE BOSTON SCIENTIFIC PLACE
NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS
LOT #: 238282
ID: 952537
STERILITY DATE:
ACCESSION NO.: R8144929
DATE COLLECTED: NO DATE
TIME COLLECTED: NO TIME
DATE RECEIVED: 05/10/99
DATE REPORTED: 06/09/99

STERILITY METHOD:
MANFU SOURCE:

P.O.: 9912701

NOTES: REFERENCE R8132848-10 MICORBIAL ID.

| TEST REPORT | RESULT | METHOD |
|------------------------|--------|--------|
| MICROBIAL ISOLATE ID 1 | | |

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99 TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

June Mackcow 6/9/99
*** FINAL REPORT ***

ACCT #: 1128381
BOSTON SCIENTIFIC CORP.
ATTN: PHILIP COGDILL
ONE BOSTON SCIENTIFIC PLACE
NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS
LOT #: 238282
ID: 952530
STERILITY DATE:
ACCESSION NO.: R8144910
DATE COLLECTED: NO DATE
TIME COLLECTED: NO TIME
DATE RECEIVED: 05/10/99
DATE REPORTED: 06/09/99

STERILITY METHOD:
MANFU SOURCE:

P.O.: 9912701

NOTES: REFERENCE R8132848-2 MICROBIAL ID.

TEST REPORT

RESULT

METHOD

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99

TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

Juli Mackcow 6/9/99
*** FINAL REPORT ***

ACCT #: 1128381
BOSTON SCIENTIFIC CORP.
ATTN: PHILIP COGDILL
ONE BOSTON SCIENTIFIC PLACE
NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS
LOT #: 238282
ID: 952536
STERILITY DATE:

ACCESSION NO.: R8144901
DATE COLLECTED: NO DATE
TIME COLLECTED: NO TIME
DATE RECEIVED: 05/10/99
DATE REPORTED: 06/09/99

STERILITY METHOD:
MANFU SOURCE:

P.O.: 9912701

NOTES: REFERENCE R8132848-4 MICROBIAL ID.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99 TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

John Mackcow 6/19/99
*** FINAL REPORT ***

ACCT #: 1128381

BOSTON SCIENTIFIC CORP.

ATTN: PHILIP COGDILL

ONE BOSTON SCIENTIFIC PLACE

NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS

LOT #: 238282

ID: 952527

STERILITY DATE:

ACCESSION NO.: R8144894

DATE COLLECTED: NO DATE

TIME COLLECTED: NO TIME

DATE RECEIVED: 05/10/99

DATE REPORTED: 06/09/99

STERILITY METHOD:

MANFU SOURCE:

P.O.: 9912701

NOTES: REFERENCE R8132848-8 MICROBIAL ID.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99

TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

Julie Mack 6/9/99
*** FINAL REPORT ***



ACCT #: 1128381
 BOSTON SCIENTIFIC CORP.
 ATTN: PHILIP COGDILL
 ONE BOSTON SCIENTIFIC PLACE
 NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS
 LOT #: 240334
 ID: R8135410-5 953861
 STERILITY DATE:
 ACCESSION NO.: R8144885
 DATE COLLECTED: NO DATE
 TIME COLLECTED: NO TIME
 DATE RECEIVED: 05/14/99
 DATE REPORTED: 06/09/99

STERILITY METHOD:
 MANFU SOURCE:

P.O.: 9913301

NOTES: REFERENCE STERILITY PORTION OF TESTING R8144802.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99 TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

John Mackcow 6/9/99
 *** FINAL REPORT ***



ACCT #: 1128381

BOSTON SCIENTIFIC CORP.

ATTN: PHILIP COGDILL

ONE BOSTON SCIENTIFIC PLACE

NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS

LOT #: 240334

ID: R8135410-4 953862

STERILITY DATE:

ACCESSION NO.: R8144876

DATE COLLECTED: NO DATE

TIME COLLECTED: NO TIME

DATE RECEIVED: 05/14/99

DATE REPORTED: 06/09/99

STERILITY METHOD:

MANFU SOURCE:

P.O.: 9913301

NOTES: REFERENCE STERILITY PORTION OF TESTING R8144802.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99 TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

James Mackcow 6/9/99
*** FINAL REPORT ***

ACCT #: 1128381
BOSTON SCIENTIFIC CORP.
ATTN: PHILIP COGDILL
ONE BOSTON SCIENTIFIC PLACE
NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS
LOT #: 240334
ID: R8135410-9 953856
STERILITY DATE:
ACCESSION NO.: R8144867
DATE COLLECTED: NO DATE
TIME COLLECTED: NO TIME
DATE RECEIVED: 05/14/99
DATE REPORTED: 06/09/99

STERILITY METHOD:
MANFU SOURCE:

P.O.: 9913301

NOTES: REFERENCE STERILITY PORTION OF TESTING R8144802.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99 TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

Final report
*** FINAL REPORT ***

ACCT #: 1128381
BOSTON SCIENTIFIC CORP.
ATTN: PHILIP COGDILL
ONE BOSTON SCIENTIFIC PLACE
NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS
LOT #: 240334
ID: R8135410-2 953866
STERILITY DATE:
ACCESSION NO.: R8144858
DATE COLLECTED: NO DATE
TIME COLLECTED: NO TIME
DATE RECEIVED: 05/14/99
DATE REPORTED: 06/09/99

STERILITY METHOD:
MANFU SOURCE:

P.O.: 9913301

NOTES: REFERENCE STERILITY PORTION OF TESTING R8144802.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99 TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

John Mackcow 6/9/99
*** FINAL REPORT ***

ACCT #: 1128381

BOSTON SCIENTIFIC CORP.

ATTN: PHILIP COGDILL

ONE BOSTON SCIENTIFIC PLACE

NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS

LOT #: 240334

ID: R8135410-2.1 953866

STERILITY DATE:

ACCESSION NO.: R8144849

DATE COLLECTED: NO DATE

TIME COLLECTED: NO TIME

DATE RECEIVED: 05/14/99

DATE REPORTED: 06/09/99

STERILITY METHOD:

MANFU SOURCE:

P.O.: 9913301

NOTES: REFERENCE STERILITY PORTION OF TESTING R8144802.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99

TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

Final Report 6/14/99
*** FINAL REPORT ***

ACCT #: 1128381

BOSTON SCIENTIFIC CORP.

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS

ATTN: PHILIP COGDILL

LOT #: 240334

ACCESSION NO.: R8144830

ONE BOSTON SCIENTIFIC PLACE

ID: R8135410-2.2 953866

DATE COLLECTED: NO DATE

NATRICK, MA 01760-1537

STERILITY DATE:

TIME COLLECTED: NO TIME

DATE RECEIVED: 05/14/99

DATE REPORTED: 06/09/99

STERILITY METHOD:

MANFU SOURCE:

P.O.: 9913301

NOTES: REFERENCE STERILITY PORTION OF TESTING R8144802.

TEST REPORT

RESULT

METHOD

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99

TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

Final Report
*** FINAL REPORT ***

ACCT #: 1128381
BOSTON SCIENTIFIC CORP.
ATTN: PHILIP COGDILL
ONE BOSTON SCIENTIFIC PLACE
NATRICK, MA 01760-1537

SAMPLE: BSC02, REPROCESSED RADIAL JAW BIOPSY FORCEPS
LOT #: 240334
ID: R8135410-2.3 953866
STERILITY DATE:
ACCESSION NO.: R8144821
DATE COLLECTED: NO DATE
TIME COLLECTED: NO TIME
DATE RECEIVED: 05/14/99
DATE REPORTED: 06/09/99

STERILITY METHOD:
MANFU SOURCE:

P.O.: 9913301

NOTES: REFERENCE STERILITY PORTION OF TESTING R8144802.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

MICROBIAL ISOLATE ID 1

SEE SEPARATE MICROCHECK REPORT.

TEST START DATE 5-19-99 TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

Joni Mack 6/9/99
*** FINAL REPORT ***

ACCT #: 1128377
BOSTON SCIENTIFIC
ATTN: MIKE LANGE
6470 SYCAMORE CT
MAPLE GROVE MN 55369

SAMPLE: BSC01, VANGUARD MEDICAL CONCEPTS REPROCESSED
LOT #: 240334
ID: RADIAL JAW BIOPSY
STERILITY DATE:
ACCESSION NO.: R8144802
DATE COLLECTED: NO DATE
TIME COLLECTED: NO TIME
DATE RECEIVED: 05/14/99
DATE REPORTED: 06/09/99

STERILITY METHOD: ETHYLENE OXIDE
MANFU SOURCE:

P.O.: 9913301

NOTES: FORCEPS, STERILITY DATE 11-98, SEE ATTACHED LETTER. STERILITY PORTION.

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

SEE SEPARATE MICROCHECK REPORT FOR IDENTIFICATION INFORMATION.

TEST START DATE 5-14-99 TEST COMPLETION DATE 6-9-99

TECH/REVIEWER D. PAULY/J. MACKCOW

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

Juni Mackcow 6/9/99
*** FINAL REPORT ***

ATTACHMENT 2
MICROCHECK\ VIROMED MICROORGANISM ID REPORT

| LINE NO. | SAMPLE ID LABEL | ✓ | MICROORGANISM IDENTIFICATION | SI / SD | TYPE | MEDIA | CONFIRM TEST | LAB COMMENTS |
|----------|-----------------|------------------|--|--|------|-------|----------------|--|
| 1 | R8132848-10 | ✓ | <i>Staphylococcus hominis</i> R 8144929 952537 R 8132848 Example | 0.546 | B | TSBA | | |
| 2 | R8132848-2 | | <i>Paenibacillus apiarius</i> <i>Virgibacillus pantothenicus</i> <i>Bacillus lentimorbus</i> 952530 R 8144910 | 0.441 0.310 0.274 | B | TSBA | | |
| 3 | R8132848-4 | ✓2 2 | <i>Staphylococcus epidermidis</i> <i>Staphylococcus capitis ureolyticus</i> <i>Staphylococcus aureus</i> GC subgroup C 952536 R 8144901 | 0.735 0.555 0.531 | B | TSBA | coag | our coagulase test result supports marked (2) FAME identification |
| 4 | R8132848-8 | | <i>Brevibacterium stationis</i> R 8144894 952527 | 0.122 | B | TSBA | | |
| 5 | R8135410-5 | 1 1 1 1 | <i>Micrococcus lylae</i> GC subgroup A <i>Micrococcus luteus</i> GC subgroup B <i>Micrococcus luteus</i> GC subgroup C <i>Micrococcus luteus</i> GC subgroup A <i>Brevibacillus laterosporus</i> <i>Deinococcus erythromyxa</i> 953861 R 8144885 | 0.556 0.434 0.349 0.219 0.381 0.338 | B | TSBA | GPC in tetrads | our stain result supports marked (1) FAME identification; see Lab Director's Notes at end of Results Table |
| 6 | R8135410-4 | ✓ | <i>Pseudomonas putida</i> biotype A 953862 R 8144874 | 0.568 | B | TSBA | | |
| 7 | R8135410-9 | ✓2 2 | <i>Staphylococcus epidermidis</i> <i>Staphylococcus aureus</i> GC subgroup C <i>Staphylococcus capitis ureolyticus</i> 953856 R 8144867 | 0.835 0.766 0.664 | B | TSBA | coag | our coagulase test result supports marked (2) FAME identification |

| LINE NO. | SAMPLE ID LABEL | ✓ | MICROORGANISM IDENTIFICATION | SI / SD | TYPE | MEDIA | CONFIRM TEST | LAB COMMENTS |
|----------|---------------------------------|---|--|----------------|------|-------|--------------|--|
| 8 | R8135410-2 | | NO MATCH to <i>Exiguobacterium acetylicum</i> GC subgroup B see lines 8a, 8b, 8c below 953866 R8144858 | 20.4 SD | B | TSBA | | different colony types apparent after analysis |
| 8a | R8135410-2.1 (large tan colony) | ✓ | <i>Bacillus cereus</i> GC subgroup B R8144849 953866 | 0.724 | B | TSBA | | |
| 8b | R8135410-2.2 (cream colony) | ✓ | <i>Acinetobacter radioresistens</i> R8144830 953866 | 0.721 | B | TSBA | | |
| 8c | R8135410-2.3 (yellow colony) | ✓ | <i>Pseudomonas putida</i> biotype A 953866 R8144821 | 0.496 | B | TSBA | | |
| 9 | R8135410-6 | | <i>Staphylococcus epidermidis</i> <i>Staphylococcus warneri</i> 953859 R8144811 | 0.480 0.286 | B | TSBA | | |

Lab Director's Notes:

The fatty acid profile of the organisms in the sample at LINE NO. 5 in the Results Table was compared to several species of *Micrococcus*, *Brevibacillus laterosporus*, and *Deinococcus erythromyxa*. Although *Micrococcus* is commonly known to form cocci in tetrads *Deinococcus* may also occasionally form cocci in tetrads too. However, the colonies of this isolate are yellow, which is characteristic of *Micrococcus luteus*, and are not the red or orange of *Deinococcus*. The comparisons to *Micrococcus luteus* thus represent the best choice for the identity of this isolate.

Results represent only the sample(s) as received. All analytical data and reports are client confidential and available only to the client. Authorization for publication of excerpts, statements, or conclusions regarding our reports is reserved pending written approval from Microcheck, Inc.

Key to Symbols and Abbreviations in the Microcheck Results Table

FAME ANALYSIS Automated fatty acid methyl ester (FAME) analysis by gas liquid chromatography for identification of aerobic and anaerobic bacteria, yeast, and actinomycetes.

✓ A check mark next to a microorganism name indicates an excellent FAME match (See SI and SD)

SI The Similarity Index (SI) is a value between 0.001 and 0.999 which expresses the FAME similarity between the unknown isolate and the database match.

0.500 to 0.999 excellent match for genus and species

0.300 to 0.999 excellent for a single match to genus and species

0.100 to 0.300 good match for genus

0.001 to 0.099 weak match for genus

NO MATCH A NO MATCH analysis occurs when the unknown isolate has no close comparisons in the database.

SD The Standard Deviation (SD) value is listed for a NO MATCH analysis. The SD is a mathematical expression of the distance between the fatty acid profile of the unknown and the mean profile of the closest database entry. A NO MATCH with no SD indicates that the microorganism was not even distantly related to any of the 2,000 entries in the databases.

TYPE Microorganism TYPE

AC actinomycete

AN anaerobic bacterium

B aerobic bacterium

F fungus

() Parentheses () around an entry in the TYPE column indicates that the microorganism was a different type than listed on the Test Request Form.

FAN facultative anaerobe

M mycobacterium

TH thermophilic bacterium

Y yeast

MEDIA The subculture MEDIA used by our laboratory to grow microorganisms.

BHIA brain heart infusion blood agar

CLIN blood agar

MB7 Middlebrook 7H10 agar

MRSA MRS *Lactobacillus* agar

PPP potato dextrose agar, and phosphate glucose agar

PYG peptone-yeast-glucose broth

() Parentheses () around an entry in the MEDIA column indicates that growth of the microorganism on this medium was insufficient for analysis.

PYGT peptone-yeast-glucose broth w/ Tween 80

R2A defined minimal nutrient agar

SDA Sabouraud dextrose agar

TSB trypticase soy broth

TSBA trypticase soy broth agar

CONFIRM TEST CONFIRMATION TESTING is done on an isolate whose FAME analysis result is inconclusive.

1 = stain

2 = coagulase test

3 = oxidase test

4 = API 20E test

CONFIRM TEST RESULTS **GPR** Gram positive rods

GNR Gram negative rods

GVR Gram variable rods

coag⁺ coagulase positive

ox⁺ oxidase positive

API 20E Metabolic characterization which is done to confirm FAME results for members of the family Enterobacteriaceae. API 20E results often provides a more reliable identification than FAME analysis because this group of microorganisms is very similar in their FAME.

GPC Gram positive cocci

GNC Gram negative cocci

coag⁻ coagulase negative

ox⁻ oxidase negative

We encourage you to call our Lab Director with any questions you may have about the analyses or the results:
Dr. Mike Sinclair - 802/485-6600 @ ext.22

12520

VRB R8132848-10 (1, 5/20)

Date of run: 01-JUN-99 11:48:03

4

SAMPLE [TSBA40]

| RT | Area | Ar/Ht | Respon | ECL | Name | % | Comment 1 | Comment 2 |
|--------|-----------|-------|--------|--------|--------------|-------|---------------------|------------------|
| 1.626 | 466133040 | 0.030 | . . . | 6.983 | SOLVENT PEAK | . . . | < min rt | |
| 2.518 | 793 | 0.028 | . . . | 8.810 | . . . | . . . | < min rt | |
| 5.358 | 1427 | 0.032 | 1.038 | 12.612 | 13:0 ISO | 0.93 | ECL deviates -0.002 | Reference 0.005 |
| 5.461 | 643 | 0.034 | 1.035 | 12.704 | 13:0 ANTEISO | 0.42 | ECL deviates 0.002 | Reference 0.009 |
| 6.619 | 8459 | 0.036 | 1.002 | 13.618 | 14:0 ISO | 5.32 | ECL deviates -0.001 | Reference 0.004 |
| 7.131 | 779 | 0.039 | 0.989 | 14.001 | 14:0 . . . | 0.48 | ECL deviates 0.001 | Reference 0.005 |
| 8.071 | 9141 | 0.038 | 0.972 | 14.624 | 15:0 ISO | 5.58 | ECL deviates 0.001 | Reference 0.005 |
| 8.207 | 53617 | 0.039 | 0.969 | 14.714 | 15:0 ANTEISO | 32.65 | ECL deviates 0.001 | Reference 0.005 |
| 9.664 | 2392 | 0.045 | 0.948 | 15.627 | 16:0 ISO | 1.42 | ECL deviates -0.000 | Reference 0.003 |
| 10.274 | 3131 | 0.041 | 0.941 | 16.000 | 16:0 . . . | 1.85 | ECL deviates -0.000 | Reference 0.002 |
| 11.349 | 5022 | 0.045 | 0.930 | 16.630 | 17:0 ISO | 2.94 | ECL deviates 0.000 | Reference 0.002 |
| 11.507 | 5962 | 0.045 | 0.929 | 16.723 | 17:0 ANTEISO | 3.48 | ECL deviates 0.000 | Reference 0.002 |
| 11.980 | 642 | 0.043 | 0.925 | 17.000 | 17:0 . . . | 0.37 | ECL deviates 0.000 | Reference 0.002 |
| 13.076 | 2198 | 0.046 | 0.918 | 17.631 | 18:0 ISO | 1.27 | ECL deviates -0.001 | Reference -0.001 |
| 13.716 | 19619 | 0.046 | 0.915 | 17.999 | 18:0 . . . | 11.28 | ECL deviates -0.001 | Reference -0.001 |
| 14.814 | 4221 | 0.046 | 0.911 | 18.634 | 19:0 ISO | 2.42 | ECL deviates -0.000 | Reference -0.000 |
| 14.980 | 2787 | 0.046 | 0.911 | 18.730 | 19:0 ANTEISO | 1.59 | ECL deviates -0.001 | |
| 15.450 | 4392 | 0.045 | 0.910 | 19.002 | 19:0 . . . | 2.51 | ECL deviates 0.002 | Reference 0.001 |
| 16.540 | 645 | 0.044 | 0.908 | 19.636 | 20:0 ISO | 0.37 | ECL deviates 0.001 | Reference 0.000 |
| 17.163 | 44001 | 0.048 | 0.908 | 19.999 | 20:0 . . . | 25.11 | ECL deviates -0.001 | Reference -0.002 |
| 17.573 | 813 | 0.035 | . . . | 20.878 | . . . | . . . | > max rt | |
| 17.417 | 1925 | 0.156 | . . . | 21.312 | . . . | . . . | > max rt | |
| 17.603 | 1003 | 0.033 | . . . | 21.419 | . . . | . . . | > max rt | |
| 19.746 | 226 | 0.063 | . . . | 21.503 | . . . | . . . | > max rt | |

| Solvent Ar | Total Area | Named Area | % Named | Total Amnt | Nbr Ref | ECL Deviation | Ref ECL Shift |
|------------|------------|------------|---------|------------|---------|---------------|---------------|
| 466133040 | 169079 | 169079 | 100.00 | 159168 | 17 | 0.001 | 0.004 |

| TSBA40 [Rev 4.10] | Staphylococcus | Ref | ECL Shift |
|-------------------|-----------------|-------|-----------|
| | S. hominis* | 0.546 | 0.546 |
| | S. epidermidis* | 0.426 | 0.426 |
| | S. warneri* | 0.397 | 0.397 |

Date of run: 21-MAY-99 14:22:08

2195 VRB R8132848-4 (3, 5/20)
11 SAMPLE [TSBA40]

| RT | Area | Ar/Ht | Respon | ECL | Name | % | Comment 1 | Comment 2 |
|--------|-----------|-------|--------|--------|--------------|-------|---------------------|------------------|
| 1.594 | 409402368 | 0.029 | . . . | 6.978 | SOLVENT PEAK | . . . | < min rt | |
| 2.482 | 594 | 0.026 | . . . | 8.784 | . . . | . . . | < min rt | |
| 5.336 | 2561 | 0.032 | 1.047 | 12.608 | 13:0 ISO | 1.51 | ECL deviates -0.006 | |
| 6.609 | 8758 | 0.035 | 1.012 | 13.616 | 14:0 ISO | 4.98 | ECL deviates -0.003 | |
| 7.124 | 2270 | 0.037 | 1.000 | 13.997 | 14:0 | 1.28 | ECL deviates -0.003 | |
| 8.074 | 29578 | 0.038 | 0.982 | 14.623 | 15:0 ISO | 16.34 | ECL deviates -0.000 | Reference -0.013 |
| 8.211 | 50434 | 0.039 | 0.980 | 14.713 | 15:0 ANTEISO | 27.78 | ECL deviates -0.000 | Reference -0.013 |
| 9.686 | 2580 | 0.040 | 0.957 | 15.628 | 16:0 ISO | 1.39 | ECL deviates 0.001 | Reference -0.010 |
| 10.301 | 5575 | 0.042 | 0.949 | 16.000 | 16:0 | 2.97 | ECL deviates -0.000 | Reference -0.011 |
| 11.388 | 7569 | 0.045 | 0.936 | 16.631 | 17:0 ISO | 3.98 | ECL deviates 0.001 | Reference -0.009 |
| 11.546 | 5061 | 0.044 | 0.935 | 16.723 | 17:0 ANTEISO | 2.66 | ECL deviates -0.000 | Reference -0.010 |
| 13.131 | 1010 | 0.046 | 0.920 | 17.631 | 18:0 ISO | 0.52 | ECL deviates -0.001 | Reference -0.010 |
| 13.777 | 18231 | 0.046 | 0.915 | 17.999 | 18:0 | 9.38 | ECL deviates -0.001 | Reference -0.010 |
| 14.888 | 6504 | 0.047 | 0.908 | 18.634 | 19:0 ISO | 3.32 | ECL deviates -0.000 | Reference -0.009 |
| 15.056 | 1531 | 0.047 | 0.907 | 18.730 | 19:0 ANTEISO | 0.78 | ECL deviates -0.001 | |
| 15.529 | 712 | 0.040 | 0.904 | 19.001 | 19:0 | 0.36 | ECL deviates 0.001 | Reference -0.007 |
| 17.258 | 45073 | 0.047 | 0.898 | 20.000 | 20:0 | 22.75 | ECL deviates -0.000 | Reference -0.007 |
| 18.300 | 589 | 0.033 | . . . | 20.602 | . . . | . . . | > max rt | |
| 18.749 | 376 | 0.052 | . . . | 20.861 | . . . | . . . | > max rt | |
| 19.056 | 206 | 0.062 | . . . | 21.039 | . . . | . . . | > max rt | |
| 8 | 150 | 0.030 | . . . | 21.184 | . . . | . . . | > max rt | |
| 9 | 1676 | 0.043 | . . . | 21.387 | . . . | . . . | > max rt | |

| Solvent Ar | Total Area | Named Area | % Named | Total Amnt | Nbr Ref | ECL Deviation | Ref ECL Shift |
|------------|------------|------------|---------|------------|---------|---------------|---------------|
| 409402368 | 187448 | 187448 | 100.00 | 177885 | 11 | 0.002 | 0.010 |

| | | |
|-------------------|------------------------|-------|
| TSBA40 [Rev 4.10] | Staphylococcus | 0.735 |
| | S. epidermidis* | 0.735 |
| | S. capitis ureolyticus | 0.555 |
| | S. aureus | 0.531 |
| | S. a. GC subgroup C* | 0.531 |

12196 VRB R8135410-5 (5, 5/20)
 12 SAMPLE [TSBA40]

Date of run: 21-MAY-99 14:22:08

| RT | Area | Ar/Ht | Respon | ECL | Name | % | Comment 1 | Comment 2 |
|--------|-----------|---------|---------|--------|------------------|---------|---------------------|----------------------|
| 1.611 | 484099344 | 0.031 | | 6.959 | SOLVENT PEAK | | < min rt | |
| 2.507 | 391 | 0.022 | | 8.788 | | | < min rt | |
| 5.358 | 1351 | 0.032 | 1.044 | 12.614 | 13:0 ISO | 0.97 | ECL deviates -0.000 | Reference -0.003 |
| 5.457 | 1427 | 0.031 | 1.040 | 12.702 | 13:0 ANTEISO | 1.02 | ECL deviates 0.000 | Reference -0.002 |
| 6.621 | 4077 | 0.036 | 1.008 | 13.618 | 14:0 ISO | 2.81 | ECL deviates -0.001 | Reference -0.001 |
| 7.001 | 773 | 0.033 | 0.999 | 13.901 | 14:1 w5c | 0.53 | ECL deviates 0.000 | |
| 7.133 | 4361 | 0.037 | 0.996 | 14.000 | 14:0 | 2.97 | ECL deviates -0.000 | Reference -0.001 |
| 7.856 | 2369 | 0.038 | 0.982 | 14.478 | Sum In Feature 1 | 1.59 | ECL deviates -0.000 | 15:1 ISO I/13:0 30H |
| 8.075 | 41843 | 0.038 | 0.978 | 14.623 | 15:0 ISO | 28.00 | ECL deviates 0.000 | Reference 0.000 |
| 8.213 | 84527 | 0.039 | 0.975 | 14.714 | 15:0 ANTEISO | 56.43 | ECL deviates 0.001 | Reference 0.001 |
| 9.401 | 894 | 0.048 | 0.956 | 15.462 | 16:1 ISO H | 0.59 | ECL deviates 0.001 | |
| 9.672 | 2463 | 0.041 | 0.953 | 15.627 | 16:0 ISO | 1.61 | ECL deviates -0.000 | Reference 0.000 |
| 9.985 | 2681 | 0.047 | 0.948 | 15.818 | Sum In Feature 3 | 1.74 | ECL deviates -0.004 | 16:1 w7c/15 iso 20H |
| 10.283 | 1052 | 0.043 | 0.945 | 16.000 | 16:0 | 0.68 | ECL deviates 0.000 | Reference 0.000 |
| 11.515 | 1680 | 0.039 | 0.931 | 16.723 | 17:0 ANTEISO | 1.07 | ECL deviates -0.000 | Reference -0.001 |
| 18.854 | 1212 | 0.064 | | 20.971 | | | > max rt | |
| 19.409 | 350 | 0.050 | | 21.294 | | | > max rt | |
| ***** | 2369 | | | | SUMMED FEATURE 1 | 1.59 | 15:1 ISO H/13:0 30H | 13:0 30H/15:1 i I/H |
| ***** | | | | | | | 15:1 ISO I/13:0 30H | |
| ***** | 2681 | | | | SUMMED FEATURE 3 | 1.74 | 16:1 w7c/15 iso 20H | 15:0 ISO 20H/16:1w7c |

| Ent Ar | Total Area | Named Area | % Named | Total Amnt | Nbr Ref | ECL Deviation | Ref ECL Shift |
|-----------|------------|------------|---------|------------|---------|---------------|---------------|
| 484099344 | 149499 | 149499 | 100.00 | 146082 | 9 | 0.001 | 0.001 |

TSBA40 [Rev 4.10] Micrococcus 0.556

 M. lylae 0.556

 M. l. GC subgroup A 0.556

 M. l. GC subgroup C* 0.370

 M. l. GC subgroup B* 0.366

 M. luteus 0.434

 M. l. GC subgroup B* 0.434

 M. l. GC subgroup C* 0.349

 M. l. GC subgroup A* 0.219

Brevibacillus 0.381 (Bacillus)

 B. laterosporus* 0.381 (Bacillus)

 B. brevis* 0.307 (Bacillus)

 B. agri** 0.256 (Bacillus)

Deinococcus 0.338

 D. erythromyxa* 0.338

Date of run: 21-MAY-99 14:48:12

2198 VRB R8135410-9 (7, 5/20)
14 SAMPLE [TSBA40]

| RT | Area | Ar/Ht | Respon | ECL | Name | % | Comment 1 | Comment 2 |
|--------|-----------|-------|--------|--------|--------------|-------|---------------------|------------------|
| 1.630 | 480693552 | 0.031 | . . . | 6.978 | SOLVENT PEAK | . . . | < min rt | |
| 2.525 | 948 | 0.027 | . . . | 8.810 | . . . | . . . | < min rt | |
| 5.368 | 3966 | 0.032 | 1.044 | 12.613 | 13:0 ISO | 2.05 | ECL deviates -0.001 | Reference 0.006 |
| 5.468 | 866 | 0.036 | 1.040 | 12.703 | 13:0 ANTEISO | 0.45 | ECL deviates 0.001 | Reference 0.008 |
| 6.631 | 9718 | 0.036 | 1.008 | 13.619 | 14:0 ISO | 4.84 | ECL deviates -0.000 | Reference 0.006 |
| 7.140 | 6810 | 0.037 | 0.996 | 13.999 | 14:0 | 3.35 | ECL deviates -0.001 | Reference 0.004 |
| 8.082 | 28226 | 0.038 | 0.978 | 14.623 | 15:0 ISO | 13.64 | ECL deviates 0.000 | Reference 0.005 |
| 8.218 | 55138 | 0.039 | 0.975 | 14.714 | 15:0 ANTEISO | 26.58 | ECL deviates 0.001 | Reference 0.005 |
| 9.677 | 2368 | 0.042 | 0.953 | 15.627 | 16:0 ISO | 1.12 | ECL deviates 0.000 | Reference 0.003 |
| 10.287 | 13134 | 0.042 | 0.945 | 16.000 | 16:0 | 6.13 | ECL deviates -0.000 | Reference 0.003 |
| 11.362 | 5220 | 0.043 | 0.933 | 16.630 | 17:0 ISO | 2.41 | ECL deviates 0.000 | Reference 0.002 |
| 11.520 | 4217 | 0.046 | 0.931 | 16.723 | 17:0 ANTEISO | 1.94 | ECL deviates -0.000 | Reference 0.002 |
| 13.091 | 665 | 0.044 | 0.918 | 17.632 | 18:0 ISO | 0.30 | ECL deviates -0.000 | Reference 0.001 |
| 13.731 | 27039 | 0.045 | 0.914 | 18.000 | 18:0 | 12.22 | ECL deviates -0.000 | Reference 0.001 |
| 14.829 | 3351 | 0.051 | 0.909 | 18.634 | 19:0 ISO | 1.51 | ECL deviates 0.000 | Reference 0.001 |
| 14.986 | 649 | 0.048 | 0.908 | 18.726 | 19:0 ANTEISO | 0.29 | ECL deviates -0.005 | |
| 15.350 | 2010 | 0.109 | . . . | 18.936 | . . . | . . . | > max ar/ht | |
| 15.372 | 290 | 0.017 | . . . | 18.949 | . . . | . . . | < min ar/ht | |
| 15.460 | 1850 | 0.060 | 0.906 | 18.999 | 19:0 | 0.83 | ECL deviates -0.001 | Reference -0.001 |
| 17.178 | 49998 | 0.048 | 0.904 | 20.000 | 20:0 | 22.34 | ECL deviates 0.000 | Reference -0.001 |
| 17.178 | 997 | 0.061 | . . . | 20.876 | . . . | . . . | > max rt | |
| 17.178 | 4034 | 0.150 | . . . | 20.973 | . . . | . . . | > max rt | |
| 17.178 | 4344 | 0.113 | . . . | 21.056 | . . . | . . . | > max rt | |
| 19.589 | 2819 | 0.054 | . . . | 21.405 | . . . | . . . | > max rt | |
| 19.729 | 379 | 0.056 | . . . | 21.487 | . . . | . . . | > max rt | |

| Solvent Ar | Total Area | Named Area | % Named | Total Amnt | Nbr Ref | ECL Deviation | Ref ECL Shift |
|------------|------------|------------|---------|------------|---------|---------------|---------------|
| 480693552 | 215516 | 213215 | 98.93 | 202270 | 15 | 0.001 | 0.004 |

| TSBA40 [Rev 4.10] | Staphylococcus | ECL Deviation |
|-------------------|--------------------------|---------------|
| | S. epidermidis* | 0.835 |
| | S. aureus | 0.766 |
| | S. a. GC subgroup C* | 0.766 |
| | S. a. GC subgroup A & B* | 0.446 |
| | S. a. GC subgroup B | 0.405 |
| | S. capitis ureolyticus | 0.664 |

12199 VRB R8135410-2 (8, 5/20)
 15 SAMPLR [TSBA40]

Date of run: 21-MAY-99 15:14:07

| RT | Area | Ar/Ht | Respon | ECL | Name | % | Comment 1 | Comment 2 |
|--------|-----------|-------|--------|--------|----------------------------|-------|---------------------|----------------------|
| 1.612 | 410204160 | 0.029 | . . . | 7.010 | SOLVENT PBAK | . . . | < min rt | |
| 1.768 | 880 | 0.029 | . . . | 7.329 | | . . . | < min rt | |
| 1.805 | 2143 | 0.028 | . . . | 7.404 | | . . . | < min rt | |
| 2.497 | 401 | 0.029 | . . . | 8.812 | | . . . | < min rt | |
| 4.302 | 700 | 0.032 | 1.086 | 11.609 | 12:0 ISO | 0.78 | ECL deviates 0.000 | Reference -0.013 |
| 4.654 | 2575 | 0.033 | 1.070 | 11.999 | 12:0 | 2.83 | ECL deviates -0.001 | Reference -0.013 |
| 5.347 | 3946 | 0.033 | 1.047 | 12.614 | 13:0 ISO | 4.25 | ECL deviates 0.000 | Reference -0.011 |
| 5.447 | 1001 | 0.033 | 1.044 | 12.703 | 13:0 ANTRISO | 1.07 | ECL deviates 0.001 | Reference -0.010 |
| 6.022 | 700 | 0.038 | 1.027 | 13.178 | 12:0 20H | 0.74 | ECL deviates 0.001 | |
| 6.394 | 1969 | 0.036 | 1.018 | 13.454 | 12:0 30H | 2.06 | ECL deviates -0.000 | |
| 6.617 | 3794 | 0.036 | 1.012 | 13.619 | 14:0 ISO | 3.95 | ECL deviates -0.000 | Reference -0.010 |
| 7.131 | 3152 | 0.058 | 1.000 | 14.000 | 14:0 | 3.24 | ECL deviates -0.000 | Reference -0.010 |
| 8.080 | 13168 | 0.040 | 0.982 | 14.623 | 15:0 ISO | 13.30 | ECL deviates 0.000 | Reference -0.009 |
| 8.218 | 3899 | 0.039 | 0.980 | 14.714 | 15:0 ANTRISO | 3.93 | ECL deviates 0.001 | Reference -0.008 |
| 8.655 | 605 | 0.041 | 0.972 | 15.001 | 15:0 | 0.60 | ECL deviates 0.001 | Reference -0.008 |
| 9.294 | 1286 | 0.049 | 0.963 | 15.388 | 16:1 w7c alcohol | 1.27 | ECL deviates 0.001 | |
| 9.454 | 2667 | 0.043 | 0.960 | 15.484 | Sum In Feature 2 | 2.63 | ECL deviates -0.004 | 14:0 30H/16:1 ISO I |
| 9.689 | 5023 | 0.045 | 0.957 | 15.626 | 16:0 ISO | 4.94 | ECL deviates -0.001 | Reference -0.009 |
| 10.003 | 9236 | 0.042 | 0.953 | 15.816 | Sum In Feature 3 | 9.05 | ECL deviates -0.006 | 16:1 w7c/15 iso 20H |
| 10.069 | 5089 | 0.041 | 0.952 | 15.856 | Sum In Feature 3 | 4.98 | ECL deviates 0.004 | 15:0 ISO 20H/16:1w7c |
| 10.075 | 9938 | 0.042 | 0.949 | 15.999 | 16:0 | 9.69 | ECL deviates -0.001 | Reference -0.009 |
| 10.075 | 1726 | 0.044 | 0.941 | 16.388 | ISO 17:1 w10c | 1.67 | ECL deviates -0.000 | |
| 11.100 | 1767 | 0.046 | 0.940 | 16.461 | ISO 17:1 w5c | 1.71 | ECL deviates -0.000 | |
| 11.240 | 822 | 0.044 | 0.938 | 16.542 | 17:1 ANTRISO A | 0.79 | ECL deviates 0.002 | |
| 11.389 | 3667 | 0.044 | 0.936 | 16.629 | 17:0 ISO | 3.53 | ECL deviates -0.001 | Reference -0.009 |
| 11.552 | 1132 | 0.045 | 0.935 | 16.723 | 17:0 ANTRISO | 1.09 | ECL deviates -0.000 | Reference -0.007 |
| 11.670 | 1755 | 0.048 | 0.933 | 16.791 | 17:1 w8c | 1.68 | ECL deviates -0.001 | |
| 12.032 | 853 | 0.038 | 0.930 | 17.002 | 17:0 | 0.82 | ECL deviates 0.002 | Reference -0.005 |
| 12.669 | 1563 | 0.055 | . . . | 17.365 | | . . . | . . . | |
| 13.376 | 18560 | 0.045 | 0.918 | 17.768 | 18:1 w9c | 17.51 | ECL deviates -0.001 | |
| 13.471 | 1355 | 0.045 | 0.917 | 17.821 | 18:1 w7c | 1.28 | ECL deviates -0.002 | |
| 13.784 | 634 | 0.034 | 0.915 | 18.000 | 18:0 | 0.60 | ECL deviates 0.000 | Reference -0.006 |
| 18.851 | 242 | 0.077 | . . . | 20.917 | | . . . | > max rt | |
| 19.661 | 369 | 0.192 | . . . | 21.385 | | . . . | > max rt | |
| ***** | 2667 | . . . | . . . | . . . | SUMMED FEATURE 2 | 2.63 | 12:0 ALDE ? | unknown 10.928 |
| ***** | . . . | . . . | . . . | . . . | | . . . | 16:1 ISO I/14:0 30H | 14:0 30H/16:1 ISO I |
| ***** | 14325 | . . . | . . . | . . . | SUMMED FEATURE 3 | 14.03 | 16:1 w7c/15 iso 20H | 15:0 ISO 20H/16:1w7c |

| Solvent Ar | Total Area | Named Area | % Named | Total Amnt | Nbr Ref | ECL Deviation | Ref ECL Shift |
|------------|------------|------------|---------|------------|---------|---------------|---------------|
| 410204160 | 102585 | 101022 | 98.48 | 97275 | 15 | 0.002 | 0.009 |

TSBA40 [Rev 4.10] * NO MATCH *

Date of run: 27-MAY-99 23:56:58

12463
47

VRB R8135410-2.1 LARGE TAN (8, 5/20)
SAMPLE [TSBA40]

| RT | Area | Ar/Ht | Respon | ECL | Name | % | Comment 1 | Comment 2 |
|--------|-----------|-------|--------|--------|----------------------------|-----------|---------------------|----------------------|
| 1.611 | 391231080 | 0.029 | . . . | 7.016 | SOLVENT PEAK | | < min rt | |
| 1.767 | 1754 | 0.025 | . . . | 7.333 | | | < min rt | |
| 1.803 | 7503 | 0.029 | . . . | 7.407 | | | < min rt | |
| 1.922 | 793 | 0.027 | . . . | 7.649 | | | < min rt | |
| 2.494 | 370 | 0.028 | . . . | 8.814 | | | < min rt | |
| 4.295 | 828 | 0.032 | 1.093 | 11.608 | 12:0 ISO | 1.16 | ECL deviates -0.001 | Reference -0.013 |
| 5.339 | 6304 | 0.032 | 1.044 | 12.614 | 13:0 ISO | 8.41 | ECL deviates -0.000 | Reference -0.011 |
| 5.440 | 1540 | 0.034 | 1.040 | 12.703 | 13:0 ANTBISO | 2.05 | ECL deviates 0.001 | Reference -0.010 |
| 6.609 | 4874 | 0.037 | 1.004 | 13.619 | 14:0 ISO | 6.25 | ECL deviates -0.000 | Reference -0.010 |
| 7.122 | 2443 | 0.040 | 0.990 | 14.000 | 14:0 | 3.09 | ECL deviates -0.000 | Reference -0.010 |
| 8.070 | 20304 | 0.039 | 0.971 | 14.624 | 15:0 ISO | 25.21 | ECL deviates 0.001 | Reference -0.008 |
| 8.208 | 6014 | 0.039 | 0.969 | 14.714 | 15:0 ANTBISO | 7.45 | ECL deviates 0.001 | Reference -0.008 |
| 8.643 | 646 | 0.035 | 0.961 | 14.999 | 15:0 | 0.79 | ECL deviates -0.001 | Reference -0.009 |
| 9.284 | 1229 | 0.042 | 0.951 | 15.388 | 16:1 w7c alcohol | 1.49 | ECL deviates 0.001 | |
| 9.443 | 2791 | 0.041 | 0.949 | 15.484 | Sum In Feature 2 | 3.39 | ECL deviates 0.004 | 16:1 ISO I/14:0 30H |
| 9.677 | 6802 | 0.046 | 0.946 | 15.626 | 16:0 ISO | 8.22 | ECL deviates -0.001 | Reference -0.010 |
| 10.059 | 8280 | 0.042 | 0.941 | 15.857 | Sum In Feature 3 | 9.96 | ECL deviates 0.005 | 15:0 ISO 20H/16:1w7c |
| 10.295 | 4892 | 0.043 | 0.938 | 15.999 | 16:0 | 5.86 | ECL deviates -0.001 | Reference -0.009 |
| 10.964 | 2680 | 0.044 | 0.930 | 16.389 | ISO 17:1 w10c | 3.19 | ECL deviates 0.001 | |
| 11.091 | 2755 | 0.048 | 0.929 | 16.463 | ISO 17:1 w5c | 3.27 | ECL deviates 0.002 | |
| 11.099 | 1059 | 0.046 | 0.928 | 16.542 | 17:1 ANTBISO A | 1.26 | ECL deviates 0.002 | |
| 11.500 | 5677 | 0.043 | 0.926 | 16.630 | 17:0 ISO | 6.72 | ECL deviates 0.000 | Reference -0.008 |
| 11.541 | 1877 | 0.044 | 0.925 | 16.724 | 17:0 ANTBISO | 2.22 | ECL deviates 0.001 | Reference -0.007 |
| 18.230 | 1476 | 0.108 | . . . | 20.564 | | | > max rt | |
| 19.469 | 121 | 0.021 | . . . | 21.279 | | | > max rt | |
| 19.770 | 603 | 0.122 | . . . | 21.453 | | | > max rt | |
| ***** | 2791 | . . . | . . . | . . . | SUMMED FEATURE 2 | 3.39 | 12:0 ALDE ? | unknown 10.928 |
| ***** | . . . | . . . | . . . | . . . | | | 16:1 ISO I/14:0 30H | 14:0 30H/16:1 ISO I |
| ***** | 8280 | . . . | . . . | . . . | SUMMED FEATURE 3 | 9.96 | 16:1 w7c/15 iso 20H | 15:0 ISO 20H/16:1w7c |

| Solvent Ar | Total Area | Named Area | % Named | Total Amnt | Nbr Ref | ECL Deviation | Ref ECL Shift |
|------------|------------|------------|---------|------------|---------|---------------|---------------|
| 391231080 | 80997 | 80997 | 100.00 | 78215 | 12 | 0.002 | 0.009 |

TSBA40 [Rev 4.10] Bacillus 0.724

 B. cereus 0.724

 B. c. GC subgroup B** 0.724

 B. c. GC subgroup A* 0.489

 B. thuringiensis kenyae sv.** 0.397

 B. thuringiensis kurstakii** 0.392

Date of run: 21-MAY-99 15:14:07

12200
16

VRB R8135410-6 (9, 5/20)
SAMPLE [TSBA40]

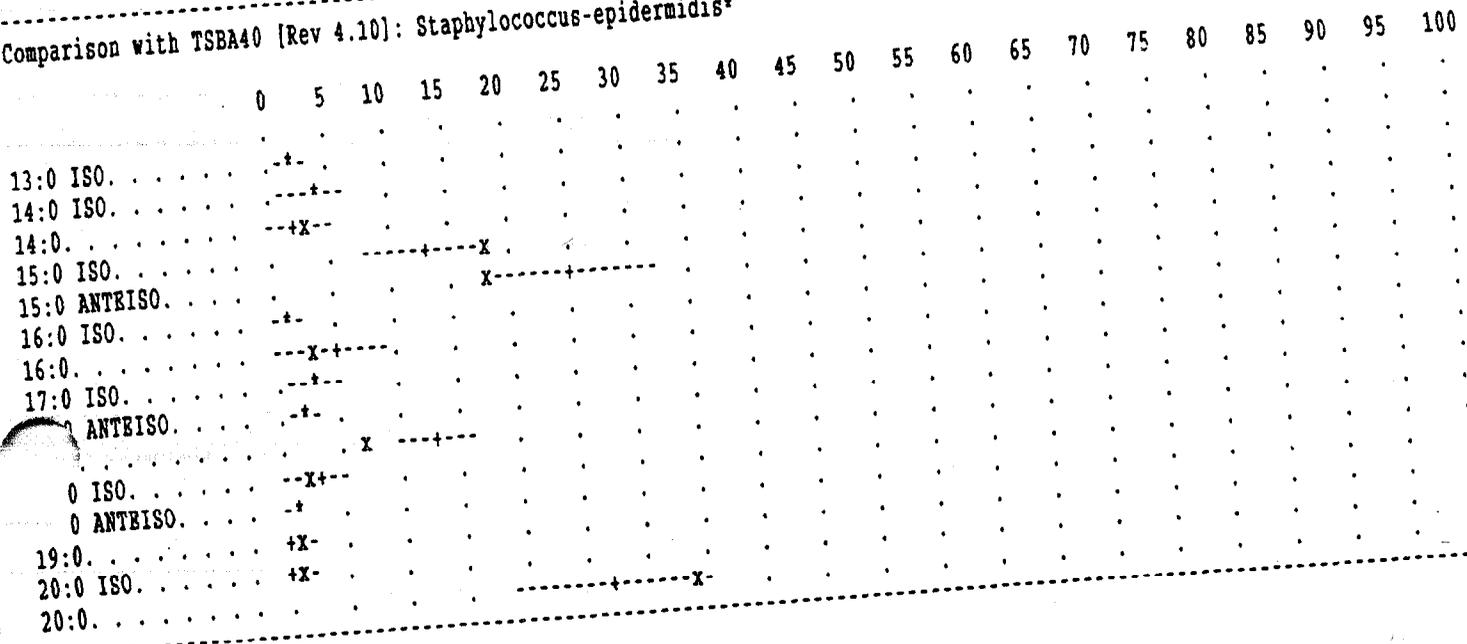
| RT | Area | Ar/Rt | Respon | ECL | Name | % | Comment 1 | Comment 2 |
|--------|-----------|--------|--------|--------|--------------|-------|---------------------|------------------|
| 1.628 | 489513696 | 0.030 | | 6.978 | SOLVENT PEAK | | < min rt | |
| 2.523 | 1302 | 0.025 | | 8.809 | | | < min rt | |
| 5.367 | 3533 | 0.032 | 1.044 | 12.614 | 13:0 ISO | 1.99 | ECL deviates -0.000 | Reference 0.006 |
| 6.629 | 6987 | 0.037 | 1.008 | 13.619 | 14:0 ISO | 3.79 | ECL deviates -0.001 | Reference 0.004 |
| 7.139 | 5920 | 0.040 | 0.996 | 13.999 | 14:0 | 3.18 | ECL deviates -0.001 | Reference 0.003 |
| 8.080 | 34287 | 0.039 | 0.978 | 14.623 | 15:0 ISO | 18.05 | ECL deviates 0.000 | Reference 0.004 |
| 8.217 | 34688 | 0.039 | 0.975 | 14.714 | 15:0 ANTEISO | 18.22 | ECL deviates 0.001 | Reference 0.004 |
| 9.675 | 2067 | 0.041 | 0.953 | 15.627 | 16:0 ISO | 1.06 | ECL deviates 0.000 | Reference 0.002 |
| 10.286 | 6754 | 0.042 | 0.945 | 16.000 | 16:0 | 3.44 | ECL deviates -0.000 | Reference 0.002 |
| 11.361 | 5004 | 0.045 | 0.933 | 16.630 | 17:0 ISO | 2.51 | ECL deviates 0.000 | Reference 0.001 |
| 11.519 | 3302 | 0.046 | 0.931 | 16.723 | 17:0 ANTEISO | 1.66 | ECL deviates -0.000 | Reference 0.001 |
| 13.729 | 15050 | 0.045 | 0.914 | 17.999 | 18:0 | 7.41 | ECL deviates -0.001 | Reference -0.001 |
| 14.827 | 5077 | 0.047 | 0.909 | 18.634 | 19:0 ISO | 2.48 | ECL deviates -0.000 | Reference -0.001 |
| 14.997 | 1293 | 0.045 | 0.908 | 18.732 | 19:0 ANTEISO | 0.63 | ECL deviates 0.001 | Reference 0.001 |
| 15.463 | 1272 | 0.047 | 0.906 | 19.002 | 19:0 | 0.62 | ECL deviates 0.002 | Reference -0.002 |
| 16.549 | 1150 | -0.046 | 0.904 | 19.634 | 20:0 ISO | 0.56 | ECL deviates -0.001 | Reference -0.001 |
| 17.177 | 70658 | 0.047 | 0.904 | 20.000 | 20:0 | 34.40 | ECL deviates 0.000 | Reference -0.001 |
| 18.224 | 3585 | 0.042 | | 20.610 | | | > max rt | |
| 18.364 | 1102 | 0.037 | | 20.692 | | | > max rt | |
| 18.678 | 858 | 0.039 | | 20.874 | | | > max rt | |
| 18.678 | 291 | 0.036 | | 21.099 | | | > max rt | |
| 18.678 | 7649 | 0.028 | | 21.403 | | | > max rt | |
| 18.678 | 434 | 0.117 | | 21.622 | | | > max rt | |

| Solvent Ar | Total Area | Named Area | % Named | Total Amnt | Nbr Ref | ECL Deviation | Ref ECL Shift |
|------------|------------|------------|---------|------------|---------|---------------|---------------|
| 489513696 | 197044 | 197044 | 100.00 | 185670 | 14 | 0.001 | 0.003 |

TSBA40 [Rev 4.10] Staphylococcus
 S. epidermidis* 0.480
 S. warneri* 0.286

Distance: 4.306

Comparison with TSBA40 [Rev 4.10]: Staphylococcus-epidermidis*



ATTACHMENT 3
COPIES OF TEST SAMPLE IDENTIFICATION



VANGUARD
 Medical Concepts, Inc.
 Lakeland, Florida

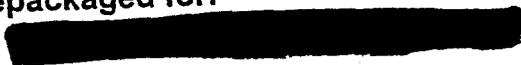
**CONTENTS STERILE UNLESS PACKAGE
 IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
 Lakeland, FL 33815
 (800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 953867

Uses: 1

0176

Desc: RADIAL JAW 3 BIOPSY FORCEPS
 SERRATED W/NEEDLE ENDOGLIDE SHE
 WORK LEN-240CM OUTSIDE DIA-2.2MM
 REQ. BIOPSY CHANNEL-2.8MM

**Caution: Federal Law (USA) restricts the use of this
 device to use by or on order of a physician.
 Follow recommended hospital procedure.**

Lot Number: 240334
 Sterilization Date: 11/98

For One Procedure Only



9 5 3 8 6 7



9 5 3 8 6 7



9 5 3 8 6 7



9 5 3 8 6 7

**COPY CERTIFIED
 BY 236**

5/17/99 DP

EXACT COPY
 INITIALS AM DATE 10/16/99

3410



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED

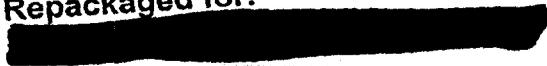
2



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172
Mfg-Cat-No: 1537
Tracking No: 953866
Uses: 1

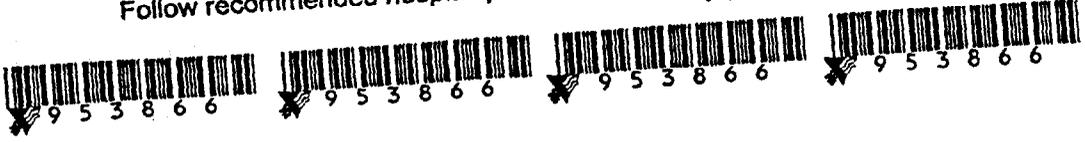
Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Lot Number: 240334

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Sterilization Date: 11/98

For One Procedure Only



EXACT COPY
INITIALS AM DATE 11/10/99

COPY CERTIFIED
BY 236
5/17/99 *dr*



VANGUARD
 Medical Concepts, Inc.
 Lakeland, Florida

CONTENTS STERILE UNLESS PACKAGE
 IS OPENED OR DAMAGED

3



Vanguard Medical Concepts, Inc.
 Lakeland, FL 33815
 (800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 953865

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
 SERRATED W/NEEDLE ENDOGLIDE SHE
 WORK LEN-240CM OUTSIDE DIA-2.2MM
 REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
 device to use by or on order of a physician.
 Follow recommended hospital procedure.

Lot Number: 240334

Sterilization Date: 11/98

For One Procedure Only



0176

EXACT COPY
 INITIALS AM DATE 6/16/99

COPY CERTIFIED
 BY 236

5/17/99 OP

5410



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**

4



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 953862

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 240334

Sterilization Date: 11/98

For One Procedure Only



**COPY CERTIFIED
BY 236**

5/17/99 DP

EXACT COPY
INITIALS AM DATE 6/16/99

5410



VANGUARD
Medical Concepts, Inc.
Lakeland, Florida

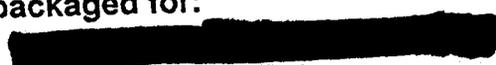
CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 953861

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 240334

Sterilization Date: 11/98

For One Procedure Only



COPY CERTIFIED

BY 236

5/17/99 DP

EXACT COPY
INITIALS AM DATE 6/1/97



VANGUARD
 Medical Concepts, Inc.
 Lakeland, Florida

CONTENTS STERILE UNLESS PACKAGE
 IS OPENED OR DAMAGED

6



Vanguard Medical Concepts, Inc.
 Lakeland, FL 33815
 (800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 953859

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
 SERRATED W/NEEDLE ENDOGLIDE SHE
 WORK LEN-240CM OUTSIDE DIA-2.2MM
 REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
 device to use by or on order of a physician.
 Follow recommended hospital procedure.

Lot Number: 240334

Sterilization Date: 11/98

For One Procedure Only



**COPY CERTIFIED
 BY 236**

EXACT COPY
 INITIALS AM DATE 6/17/99

5/17/99 OP



VANGUARD
 Medical Concepts, Inc.
 Lakeland, Florida

547

**CONTENTS STERILE UNLESS PACKAGE
 IS OPENED OR DAMAGED**

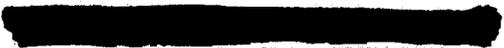
7



Vanguard Medical Concepts, Inc.
 Lakeland, FL 33815
 (800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 953858

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
 SERRATED W/NEEDLE ENDOGLIDE SHE
 WORK LEN-240CM OUTSIDE DIA-2.2MM
 REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
 device to use by or on order of a physician.
 Follow recommended hospital procedure.

Lot Number: 240334

Sterilization Date: 11/98

For One Procedure Only



**COPY CERTIFIED
 BY 236**

EXACT COPY
 INITIALS AM DATE 6/16/99

5/17/99 DP



VANGUARD

Medical Concepts, Inc.
Lakeland, Florida

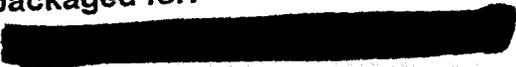
CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 953857

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 240334

Sterilization Date: 11/98

For One Procedure Only



COPY CERTIFIED

BY 236

5/17/99 DP

EXACT COPY
INITIALS am DATE 01/16/99

5410



VANGUARD

Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 953856

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 240334

Sterilization Date: 11/98

For One Procedure Only



9 5 3 8 5 6



9 5 3 8 5 6



9 5 3 8 5 6



9 5 3 8 5 6

EXACT COPY
INITIALS AV DATE 5/16/99

**COPY CERTIFIED
BY 236**

5/17/99 OP



VANGUARD

Medical Concepts, Inc.
Lakeland, Florida

**CONTENTS STERILE UNLESS PACKAGE
IS OPENED OR DAMAGED**



Vanguard Medical Concepts, Inc.
Lakeland, FL 33815
(800) 887-9073

CONTENTS STERILE UNLESS OPENED OR DAMAGED.

Reprocessed & Repackaged for:



Mfg Name: MICROVASIVE - Watertown, MA 02172

Mfg-Cat-No: 1537

Tracking No: 953855

Uses: 1

Desc: RADIAL JAW 3 BIOPSY FORCEPS
SERRATED W/NEEDLE ENDOGLIDE SHE
WORK LEN-240CM OUTSIDE DIA-2.2MM
REQ. BIOPSY CHANNEL-2.8MM

Caution: Federal Law (USA) restricts the use of this
device to use by or on order of a physician.
Follow recommended hospital procedure.

Lot Number: 240334

Sterilization Date: 11/98

For One Procedure Only



EXACT COPY
INITIALS gym DATE 5/17/99

**COPY CERTIFIED
BY 236
5/17/99 DP**



Fax

To: Phil Cogdill **From:** Julie Mackcow

Fax: (508) 650-8935 **Pages:** 1

Phone: (508) 650-8137 **Date:** 07/15/99

Re: Sterility Report # R8132848 **CC:**

Urgent For Review Please Comment Please Reply Please Recycle

Dear Phil,

The packages that the devices were received in for testing were not photocopied. The technician did retain the ID numbers on the raw data, they are as follows:

- Product 1 – 952534
- Product 2 – 952530
- Product 3 – 952533
- Product 4 – 952536
- Product 5 – 952531
- Product 6 – 952529
- Product 7 – 952528
- Product 8 – 952527
- Product 9 – 952535
- Product 10 – 952537

If you need anything else please call me (612) 939-4236.

Thanks,

Julie Mackcow
Julie A. Mackcow

October 11, 1999

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

RE: Sterility of Reprocessed Single Use Medical Devices

Dear Mr. Spears:

Financial pressures on hospitals are immense and continue to increase every day. As Director of the Gastrointestinal (G.I.) laboratory for Baptist Montclair Hospital, I am always pursuing ways to cut expenses while continuing to provide the highest quality care to our patients. Some months ago, a major, ISO 9002 certified, third party reprocessor suggested that I consider contracting with them to reprocess single use endoscopic biopsy forceps as one potential way of safely reducing expenses.

I have spent the last five months thoroughly studying the issue of reuse of single use medical devices, especially endoscopic biopsy forceps. Because patient safety is our number one priority, I began my analysis as a skeptic. However, I visited the third party reprocessor's facility and learned more about their processes and procedures. After having the opportunity to personally evaluate their processes and question their engineers and sterility experts, I became convinced that this was a safe, cost cutting alternative.

However, due to the paramount importance of patient safety, I did not stop there. I continued to investigate. I met with manufacturers, sterility experts, and other hospital personnel. The manufacturers and some of the sterility experts argued that reprocessed single use biopsy forceps had the strong potential for compromised sterility. Although some of these arguments held merit, I was still convinced that reprocessing single use biopsy forceps through this particular third party reprocessor was a viable option.

As a final check, I sent a batch of used biopsy forceps to the third party reprocessor for reprocessing. These devices were used only once. I then sent 25 of the reprocessed devices to Viomed Biosafety Laboratories in St. Paul, MN to have them tested for sterility using the United States Pharmacopeial (USP) standard procedure, as well as the Kinetic Chromogenic LAL (KAL) test. I was truly shocked when 14 out of 20 devices were determined to be non-sterile. The five items subjected to the KAL test were determined to be within acceptable limits. The results of this testing are attached.

These results have forced me to change my point of view concerning the reprocessing of disposable biopsy forceps. I am now convinced that current technology does not allow the effective

reprocessing of single use biopsy forceps. Continuing to allow this practice is an all too real threat to patient safety. I am disappointed that the FDA has not acted before now to establish guidelines to follow and standards to meet concerning the reprocessing of single use devices. Because FDA has not acted, I and countless other hospital personnel have gone through the arduous task of determining if a particular single use medical device can be safely reused. In this case, it was a waste of my time because the sterility testing showed the biopsy forceps were not properly sterilized. I fear that other hospitals may stop much earlier in the evaluation process than I did. This particular third party reprocessor's facility was modern, and the engineers and biochemist believed in their process, as did I. If I had not had the biopsy forceps evaluated by an independent laboratory, my hospital would have most likely decided to begin using their services.

We only studied biopsy forceps and do not have the time or resources to study every device that this or any other third party reprocessor says it can reprocess. Obviously, someone needs to establish standards that must be met by third party reproprocessors before allowing these devices to be used in patients. My understanding is that this is FDA's responsibility. With FDA oversight, reproprocessors would only be able to market devices that FDA verifies are safe and working properly, and the burden would be removed from hospitals. We could simply ask the reprocessor for a list of FDA approved reprocessed single use devices and feel confident that we were providing patients the highest quality of care.

I understand that FDA will be announcing a new proposal to regulate reproprocessors in the near future. I look forward to reviewing this proposal.

Sincerely,



R. David Hambrick III, R.N
Director, Gastrointestinal Laboratory
Montclair Center for Digestive Diseases
Montclair Baptist Medical Center
800 Montclair Road
Birmingham, Alabama 35213
Phone: 205-592-5824
Fax: 205-599-4669

Encl: Test Results

| | |
|--|------------------------|
| GROUP: MICROBIOLOGICAL TEST PROTOCOL | |
| DOCUMENT NO.: | REVISION NO.: A |
| INITIATED BY: | Page 1 of 4 |
| TITLE: Sterility and Pyrogen Testing for Quality Assurance Evaluation of Reprocessed Biopsy Forceps | |

1.0 Purpose

This protocol provides the steps to be followed in order to evaluate sterility and the absence of pyrogens (LAL Test) for Biopsy Forceps post reprocessing.

Test Article:

The sponsor will submit the test article to be evaluated. Detailed information about the test article will be provided by the sponsor, i.e., product label.

2.0 Reference Documents:

- 2.1 ISO 11737-1:1995 *"Sterilization of Medical Devices –Microbiological methods – Part 1: Estimation of the population of microorganisms on product"*
- 2.2 ISO 11737-2 (in press) *"Sterilization of Medical Devices –Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process"*
- 2.3 USP 23; *The United States Pharmacopeial, <1211> Sterilization and Sterility Assurance of Compendial Articles, 1995, pg1980.*
- 2.4 *Association for the Advancement of Medical Instrumentation (AAMI). Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: a guide for device manufacturers. AAMI TIR No. 12. Arlington (VA): AAMI; 1994.*

3.0 Scope:

Manufacturers are required to conduct very stringent testing processes for reusable products. They must meet FDA criteria which follow the Association for the Advancement of Medical Instrumentation (AAMI)¹ guidance document with four fundamental aspects of device design that manufacturers should consider when developing a medical device intended to be reused. These include physical, material, total system, and user-related design considerations. Good device design accounts for the environment in which the device will be used and the environment in which it will be reprocessed within the healthcare facility.

Cleaning and decontamination are recognized as the crucial first steps in any effective reprocessing protocol, and devices must be designed to be compatible with these protocols. The size, shape, and configuration of an instrument can significantly affect how adequately it can be cleaned. Fine surface crevices, porous materials, or other physical features that encourage the retention of microbes, toxic sterilants, cleaning solution residues, and physiological fluids or residues must be avoided. Biofilms that form on instrument surfaces contacting body fluids can be tenacious and require vigorous scrubbing

¹ Association for the Advancement of Medical Instrumentation (AAMI). Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: a guide for device manufacturers. AAMI TIR No. 12. Arlington (VA): AAMI; 1994.

to effectively remove. The design must also take into account variations in technique and skill of central sterile supply personnel, and any design that does not allow unobstructed access to surfaces for cleaning cannot be considered for a reusable medical device.

Adequate cleaning entails removal of visible and non-visible soil from body fluids, tissues, and other debris that remain following use of the device. All surfaces of the device, including channels and lumens that may have been in contact with the patient or physiologic fluids, must be accessible to ensure proper cleaning. If the product cannot be adequately cleaned, sterilization will not be reliable, and pyrogenic reactions may occur even if the device is sterile². Moreover, if all potentially contaminated surfaces of a critical or semicritical device cannot be inspected for cleanliness after each use, then it should not be reused³.

This study will evaluate the biopsy forceps, which have been used and reprocessed. The reprocessed biopsy forceps must meet the same sterility and non-pyrogenic state per the validated reprocessed instructions.

4.0 Equipment and Materials

Equipment

- 4.1 Face masks
- 4.2 Gloves, sterile surgeon's latex
- 4.3 Bunsen burner
- 4.4 Scissors, sterile
- 4.5 Forceps
- 4.6 Wire Cutters, flame sterilized
- 4.7 Graduated cylinder, various sizes as needed, sterile
- 4.8 Pipets, various sizes as needed, sterile
- 4.9 Test tubes, various sizes as needed, sterile
- 4.10 Petri dishes, 100 mm x 15 mm, sterile
- 4.11 Incubator, 30-35°C
- 4.12 20-25°C room temperature Cabinet
- 4.13 Colony Counter
- 4.14 Laminar Flow Biological Cabinet, Class 100
- 4.15 Standard Clean Room Garments, sterile
- 4.16 Rotary Shaker

Culture Media and Reagents

- 4.1 Tryptic Soy Broth (TSB) or Soybean Casein Digest Broth (SCDB), pH 7.3 ± 0.2
 - 500 ml screw-cap containers
 - Terminally sterilize at 121°C, liquid cycle
- 4.1 Tryptic Soy Agar (TSA) or Tryptic Soy Agar with 5% Sheep Blood or Soybean Casein Digest Agar (SCDA), pH 7.3 ± 0.2
 - Screw-cap containers
 - Terminally sterilize at 121°C, liquid cycle
- 4.1 Disinfectant - Sodium hypochlorite, minimum 0.2% solution

² ECRI. Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions. Plymouth Meeting (PA):ECRI;1997.

³ Joint Commission on Accreditation of Healthcare Organizations (JCAHO). 1996 accreditation manual for hospitals, section 2. Surveillance, prevention and control of infection (IC). Oakbrook Terrace (IL): JCAHO:453-66.

5.0 Procedure:

Bioburden\Sterility test of Reprocessed Clinically used Biopsy Forceps units

- 5.1 Perform a Bioburden\Sterility testing on the 10 single pouched reprocessed biopsy forceps units.
- 5.2 Aseptically cut forceps into approximately 30-50 cm segments and put each device into sterile containers (containing a minimum of 500 mL of TSB).
- 5.3 Rotary shaker the containers (do not allow media to contact the lid of the container) for 15 minutes at approximately 150 rpm at room temperature.
- 5.4 Aseptically filter 50 mL onto a 0.45 μ or smaller filter media and place on TSA or BAP plate for Bioburden testing (Aerobic and Fungal).
- 5.5 Additionally, Plate duplicate 1 mL aliquots and incorporate with molten, tempered TSA (pour plate method).
- 5.6 Incubate all plates for 72 hours at 30-35°C and then transfer the plates to room temperature (20-25°C) for an additional 4 days.
- 5.7 If any plates or broth are positive, Streak out all positive broth for isolation of bacteria, and have all colony morphologies identified to species.

Modified USP Sterility Testing (Thioglycollate Broth will not be used as per USP guidelines).

- 5.8 Perform a 14-day USP Sterility test (20-25°C) on additional 10 pouched reprocessed biopsy forceps units.
- 5.9 Aseptically cut the forceps into 30-50 cm section and aseptically place the device into sterile containers (containing a minimum of 500 mls of TSB). Repeat procedure for all remaining devices;
- 5.10 Incubate all broth for 14 days at (20-25°C).

Bacterial Endotoxin (LAL) Testing

- 5.11 Perform a quantitative determination of pass/fail endotoxin limit on 5 units single-pouched, reprocessed biopsy forceps units.
- 5.12 Aseptically cut each biopsy forcep and place into 40 mL SWFI volume to cover the device. The devices will not be pooled into one container, but tested as individual units for the each extraction.

6.0 Acceptance Criteria

For these tests to be acceptable, there must be no units with positive microbial growth for the 14 day USP sterility test and the bioburden\sterility test should correspond to the USP Sterility test data. The endotoxin level must be 0.5 EU/ml or less for the samples tested.

6.1 Approval

SPONSOR: HOSPITAL NAME AND CONTACT

NAME: _____

TELEPHONE: _____

TITLE: _____

FACSIMILE: _____

SIGNATURE: _____

DATE: _____

ACCT #: 1126195

MONTECLAIR BAPTIST MED CENTERSAMPLE: MTC01, REPROCESSED BIOPSY FORCEPS AND SNARES
800 MONTECLAIR ROAD LOT #: MIT BATCH ACCESSION NO.: R8186553
BIRMINGHAM, AL 35213 ID: DATE COLLECTED: NO DATE

STERILITY DATE: TIME COLLECTED: NO TIME
DATE RECEIVED: 09/09/1999
DATE REPORTED: 09/24/1999

STERILITY METHOD: ETHYLENE OXIDE
MANFU SOURCE:

P.O.: MNT1001845

NOTES: PLEASE MIX SAMPLES RANDOMLY

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

USP PRODUCT STERILITY-LARGE

TEST ACCEPTANCE CRITERIA:

1. Positive controls must be positive
2. Negative controls must be negative

| MEDIA TYPE | INCUBATION | |
|-------------------|------------|------|
| | TEMP (C) | DAYS |
| TRYPTIC SOY BROTH | 20-25 | 14 |

TEST RESULTS:

Positive Media Control:
Control Organism - B. Subtilis
Positive in Tryptic Soy Broth
Negative Media Control
No growth after 14 days

| CYCLE INFORMATION | NUMBER OF TESTS | NUMBER OF POSITIVES |
|-------------------|-----------------|---------------------|
| | 10 | 7 |

ON DAY 3, PRODUCTS 1,2,5,6, AND 10 SHOWED GROWTH. GRAM STAIN SHOWED GRAM POSITIVE RODS.
ON DAY 3, PRODUCT 8 SHOWED GROWTH. GRAM STAIN SHOWED GRAM POSITIVE COCCI.
ON DAY 10, PRODUCT 4 SHOWED GROWTH. GRAM STAIN SHOWED GRAM POSITIVE RODS.

TEST START DATE 9-10-99 TEST COMPLETION DATE 9-24-99

TECH/REVIEWER: J. REEDY/J. RUHME

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN

011

ACCT #: 1126195

MONTECLAIR BAPTIST MED CENTERSAMPLE: MTC01, REPROCESSED BIOPSY FORCEPS AND SNARES

800 MONTECLAIR ROAD

LOT #: MIT BATCH

ACCESSION NO.: R8186562

BIRMINGHAM, AL 35213

ID:

DATE COLLECTED: NO DATE

STERILITY DATE:

TIME COLLECTED: NO TIME

DATE RECEIVED: 09/09/1999

DATE REPORTED: 09/24/1999

STERILITY METHOD: ETHYLENE OXIDE

MANFU SOURCE:

P.O.: MNT1001845

NOTES: PLEASE MIX SAMPLES RANDOMLY

| TEST REPORT | RESULT | METHOD |
|-------------|--------|--------|
|-------------|--------|--------|

USP PRODUCT STERILITY-LARGE

TEST ACCEPTANCE CRITERIA:

- 1. Positive controls must be positive
- 2. Negative controls must be negative

MEDIA TYPE

INCUBATION

TEMP (C) DAYS

TRYPTIC SOY BROTH

20-25

14

TEST RESULTS:

Positive Media Control:
 Control Organism - B. Subtilis
 Positive in Tryptic Soy Broth
 Negative Media Control
 No growth after 14 days

| CYCLE INFORMATION | NUMBER OF TESTS | NUMBER OF POSITIVES |
|-------------------|-----------------|---------------------|
| | 10 | 7 |

ON DAY 3, PRODUCTS 4,7,9 AND 10 SHOWED GROWTH. GRAM STAIN SHOWED GRAM POSITIVE RODS.

ON DAY 3, PRODUCT 1 SHOWED GROWTH. GRAM STAIN SHOWED GRAM POSITIVE COCCI.

ON DAY 6, PRODUCT 2 SHOWED GROWTH. GRAM STAIN SHOWED GRAM POSITIVE RODS.

ON DAY 9, PRODUCT 5 SHOWED GROWTH. GRAM STAIN SHOWED GRAM POSITIVE COCCI.

TEST START DATE 9-10-99 TEST COMPLETION DATE 9-24-99

TECH/REVIEWER: J. REEDY/J. RUHME

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN

*** FINAL REPORT ***

ACCT #: 1126195
 MONTECLAIR BAPTIST MED CENTERSAMPLE: MTC01, REPROCESSED BIOPSY FORCEPS AND SNARES
 800 MONTECLAIR ROAD LOT #: MIT BATCH ACCESSION NO.: R8186571
 BIRMINGHAM, AL 35213 ID: DATE COLLECTED: NO DATE
 STERILITY DATE: TIME COLLECTED: NO TIME
 DATE RECEIVED: 09/09/1999
 DATE REPORTED: 09/10/1999
 STERILITY METHOD: ETHYLENE OXIDE
 MANFU SOURCE:

P.O.: MNT1001045
 NOTES:

| TEST REPORT | RESULT | METHOD |
|---|-------------|--------|
| KINETIC CHROMOGENIC LAL LIMIT TEST-FINISHED PRODUCT TESTING | | |
| KINETIC LAL SAMPLE RESULT | | |
| | 0.174 EU/ML | |

KINETIC LAL POSITIVE CONTROL

A PRODUCT POSITIVE CONTROL WAS RUN AND AN ACCEPTABLE LEVEL OF ENDOTOXIN WAS RECOVERED IN THE CONTROL SAMPLE.

THE CSE DILUTION SERIES, THE SAMPLE AND THE CONTROLS WERE TESTED IN DUPLICATE.

THE RESULTS OF THE CSE DILUTION SERIES AND CONTROLS INDICATE A VALID TEST SYSTEM.

IF THE KINETIC CHROMOGENIC LAL METHOD HAS BEEN VALIDATED FOR THE DEVICE, THIS SAMPLE DEMONSTRATES AN ACCEPTABLE LEVEL OF ENDOTOXIN FOR MEDICAL DEVICES ACCORDING TO THE FDA GUIDELINES IF THE ENDOTOXIN LEVEL IS < 0.5 EU/ML FOR BLOOD CONTACTING DEVICES AND < 0.06 EU/ML FOR DEVICES CONTACTING CEREBRAL SPINAL FLUID. IF FOLLOWING THE USP 23 GUIDELINES, THE ACCEPTABLE LEVEL OF ENDOTOXIN FOR DEVICES CONTACTING CEREBRAL SPINAL FLUID IS < 0.05375 EU/ML.

TEST START DATE 9-10-99 TEST COMPLETION DATE 9-10-99

TECH/REVIEWER J. RUMME/L. PETERSON

TESTING FACILITY: 2540 EXECUTIVE DRIVE / ST. PAUL MN 55120

*** FINAL REPORT ***

MICROVASIVE ENDOSCOPY
BOSTON SCIENTIFIC
1 BOSTON SCIENTIFIC PLACE
NATICK MA 01760
(508)650-8000

SHIP DATE: 21SEP00
ACC# 179026600

ACTUAL WGT: 12 LBS SCALE

TO: ~~DOCKETS MANAGEMENT BRANCH~~
~~FOOD & DRUG ADMINISTRATION~~
~~DEPARTMENT OF HEALTH & HUMAN SERV.~~
12420 PARKLAWN DRIVE, ROOM 1-23
ROCKVILLE MD 20857

(508)650-8456

4743 3171 5881

FedEx

4743 3171 5881

REF: 10018SET

PRIORITY OVERNIGHT

FRI.

CAO# 0082379 21SEP00

TRK# 4743 3171 5881 Form 0201

Deliver by:
22SEP00

20857 -MD-US

IAD

19 GAIA

AA

15307-377 RIT 02/00

