

**Boston
Scientific**
MICROVASIVE

Microvasive Endoscopy
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Greg Barrett
President, Microvasive Endoscopy

October 24, 2000

Lyle D. Jaffe
Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

Re: Supplement to Citizen Petition/Docket No. 00P-1535/CP 1

Dear Mr. Jaffe:

Pursuant to 21 C.F.R. § 10.30(g), this letter supplements the Citizen Petition filed by Boston Scientific Corporation (BSC) on September 22, 2000, which requested the Food and Drug Administration (FDA) amend 21 C.F.R. § 876.1075(b)(2), the regulation which classifies biopsy forceps covers and non-electric biopsy forceps as Class I devices exempt from the premarket notification procedures.¹

Attached please find three more recent studies which supplement the six studies BSC submitted in the Citizen Petition. These studies corroborate the need to amend the regulations because reprocessed single-use biopsy forceps present an increased infectious risk to patients. The three studies were sponsored by BSC this year and are summarized in the following chart.

¹ As was the case in the Citizen Petition, this supplement provides further support for FDA to amend 21 C.F.R. § 876.1075(b)(2) only with respect to non-electric biopsy forceps, and not to biopsy forceps covers.

00P-1535

30/1

0974 10 091 25 18

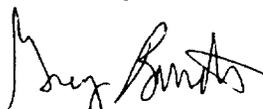
Table: Results From Three Separate Investigations of Reprocessed Single-Use Biopsy Forceps

LOCATION OF HOSPITAL FOR WHICH DEVICES WERE REPROCESSED	INVESTIGATING LABORATORY	STUDY DATE	NUMBER OF USED DEVICES STUDIED	PERCENTAGE OF USED DEVICES FOUND NOT STERILE	NUMBER OF CONTROL DEVICES STUDIED	PERCENTAGE OF CONTROL DEVICES FOUND NOT STERILE
Ranson, WV	PMP-Center for the Testing of Medical Products	January 2000	7	14 (1/7)	8	0
Moorehead, KY	PMP-Center for the Testing of Medical Products	January 2000	23	13 (3/23)	6	0
Fort Worth, TX	PMP-Center for the Testing of Medical Products	July-August 2000	115 ²	16 (18/115)	8	0
TOTAL			145	15 (22/145)	22	0

As seen by the chart, of the 145 reprocessed single-use devices examined by an independent laboratory, 15 percent failed the sterility tests. The results of the attached three studies support the results of the six studies submitted in the Citizen Petition in that they demonstrate that a significant number of reprocessed single-use biopsy forceps fall below the sterility standards established by FDA. Thus, these new data provide further grounds for FDA to amend 21 C.F.R. § 876.1075(b)(2) to limit the exemption from premarket notification requirement 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.

Please do not hesitate to call if you have any questions about this supplement or the Citizen Petition, or if we can provide any additional information to assist FDA in responding to our request.

Sincerely,



Greg Barrett

Attachment

² Of the 115 devices reprocessed for the hospital located in Fort Worth, Texas, 6 are guidewires, 4 are spares and all remaining devices are biopsy forceps.



PMP

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 1. Juni 2000

EXAMINATION OF DEVICES, REPROCESSED BY VANGUARD

DECLARED TO BE STERILE

DEVICES EVALUATED WERE REPROCESSED & REPACKAGED FOR :

HOSPITAL LOCATED IN MOOREHEAD, KENTUCKY

PERFORMING LABORATORY:

PMP

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



23 single use biopsy forceps, which were reprocessed by a third party reprocessor, were randomly selected and sent to PMP, and tested for claims of sterility and cleanliness. All of these devices were originally labeled for single use and have been manufactured by Bard Covington.

Reprocessing was performed by Vanguard. The devices were reprocessed, repacked and registered and were at the hospital awaiting patient use. The following data are documented on the package (see Attachment I):

- Name of the reprocessor
- Name of the customer (hospital)
- Name of 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 January 2000.

For sterility testing, standard microbiological procedures with aseptic technique have been used. Additionally, six new single use biopsy forceps (large capacity radial jaw 3, w/needle) manufactured by Microvasive Boston Scientific Corporation underwent the tests as control devices.

For documentation and identification of the devices, the sterile bags were numbered by the laboratory. Numbers are listed in Attachment 2.

Director of study: Klaus Roth

Microbiological testing: Prof. Dr. Peter Heeg



Sterility testing

The following procedure was used:

Recovery

- The first 30 cm of the tip and the following 30 cm segment were aseptically cut and placed into separate sterile tubes (containing 50 ml broth). The rest of the instrument was aseptically cut into 10 cm segments and collected in another tube (containing 50 ml broth).
- The 50 ml-tubes were vortexed for 30 seconds and shaken manually for 30 seconds.
- The beakers were shaken for 15 mins at 300 mins⁻¹.
- 1 ml was plated and 92 µl was spiralplated on Columbia-blood-agar (the controls and also the control dilutions only need to be spiralplated).
- The broth was incubated for 7 days at 37°C.

Conclusion:

The study has shown that:

- 3 of 23 (13%) reprocessed devices were non-sterile;
- all six control devices were sterile.

These results, indicate that it is difficult to reprocess these single use biopsy forceps safely and consistently, even with so-called validated reprocessing methods.

Attachment 1: Control Sheet and Description of the Devices

Attachment 2: Microbiological Results of Reprocessed and Control Devices



Attachment 1

Received from: BSC
 Sender: Phil Cogdill
 Hospital Location: Moorehead, KY

Date: 1/5/00
 Reprocessor: Vanguard

Received by: Klaus Roth
 Projektnr: 45005
 Page : 1

Manufacturer:	Mfg Nr.:	Description:	Date of reprocessing	Lot Nr.:	Tracking Nr.:	Uses	Int. Nr.
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	897828	1	SCH 1
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	897829	1	SCH 2
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	897831	1	SCH 3
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	926209	2	SCH 4
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	926211	2	SCH 5
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	926222	2	SCH 6
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	926224	2	SCH 7
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	926226	2	SCH 8
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	926227	2	SCH 9



Received from:	BSC	Date:	1/5/00	Received by:	Klaus Roth
Sender:	Phil Cogdill	Reprocessor:	Vanguard	Projektnr.:	45005
Hospital Location:	Moorehead, KY			Page :	2

Manufacturer:	Mfg Nr.:	Description:	Date of reprocessing	Lot Nr.:	Tracking Nr.:	Uses	Int. Nr.
Bard Covington	854	Hot Biopsy Forceps; Precisor Hot Jaw O.D-2.3 Length 230cm Alligator Cup	Oct-99	257118	965612	2	SCH 10
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	924928	2	SCH 11
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	959367	3	SCH 12
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	964240	2	SCH 13
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	964245	2	SCH 14
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	964247	2	SCH 15
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	964248	2	SCH 16
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	964371	2	SCH 17
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	964374	2	SCH 18



Received from: BSC
 Sender: Phil Cogdill
 Hospital Location: Moorehead, KY

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Received by: Klaus Roth
 Projektnr: 45005
 Page : 3

Manufacturer:	Mfg Nr.:	Description:	Date of reprocessing	Lot Nr.:	Tracking Nr.:	Uses	Int. Nr.
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	964377	2	SCH 19
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep-99	255967	965715	2	SCH 20
Bard Covington	8892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	968519	2	SCH 21
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	968523	2	SCH 22
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Oct-99	257118	968524	2	SCH 23



Attachment 2

Boston Scientific Corporation

Hospital Location: Moorehead, KY

Reprocessor: Vanguard

Microbiological Quality Assurance Testing of Reprocessed Samples

Date: 17.01.2000

Projektnr.: 45005

Manufacturer:	Mfg Nr:	Description:	Date of reprocessing	Lot. Nr.:	Tracking Nr.:	Uses	Int. Nr.:	Results				
								Segment	CFU/mL (1mL)	Volume(mL) Growing(+/-)	CFU pro Segment	Differentiation
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	897828	1	SCH1	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	897829	1	SCH2	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	897831	1	SCH3	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	926209	2	SCH4	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	926211	2	SCH5	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	926222	2	SCH6	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	926224	2	SCH7	1	0	50mL (-)		Asperg.sp.
								2	0	50mL (+)		
								3	0	50mL (-)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	926226	2	SCH8	1	0	50mL (-)		Asperg.sp.
								2	0	50mL (+)		
								3	0	50mL (-)		



Boston Scientific Corporation

Hospital Location: Moorehead, KY

Reprocessor: Vanguard

Microbiological Quality Assurance Testing of Reprocessed Samples

Date: 17.01.2000

ProjektNr.: 45005

Manufacturer:	M f g Nr:	Description:	Date of reprocessing	Lot. Nr.:	Tracking Nr.:	Uses	Int. Nr.:	Results				
								Segment	CFU/mL (1mL)	Volume(mL) Growing(+/-)	CFU pro Segment	Differentiation
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	25711 8	926227	2	SCH9	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	854	Hot Biopsy Forceps; Precisor Hot Jaw O.D-2.3 Length 230cm Alligator Cup	Okt 99	25711 8	965612	2	SCH10	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	817	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	25596 7	924928	2	SCH11	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	25596 7	959367	3	SCH12	1	0	50mL (-)		
								2	0	50mL (-)		
								3	0	50mL (-)		
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	25596 7	964240	2	SCH13	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	25596 7	964245	2	SCH14	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	25596 7	964247	2	SCH15	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	25596 7	964248	2	SCH16	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		



Boston Scientific Corporation
Microbiological Quality Assurance Testing of Reprocessed Samples

Hospital Location: Moorehead, KY
Date: 17.01.2000

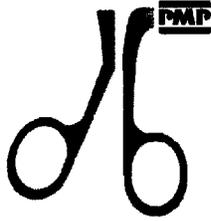
Reprocessor: Vanguard
ProjektNr.: 45005

Manufacturer:	M f g Nr:	Description:	Date of reprocessing	Lot. Nr.:	Tracking Nr.:	Uses	Int. Nr.:	Results				
								Seg-ment	CFU/mL (1mL)	Volumn(mL) Growing(+/-)	CFU pro Segment	Differentiation
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	255967	964371	2	SCH17	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	255967	964374	2	SCH18	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	255967	964377	2	SCH19	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		
Bard Covington	817	Biopsy Forceps; Lower GI Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Sep 99	255967	965715	2	SCH20	1	0	50mL(-)		Acinetobacter
								2	0	50mL(-)		
								3	0	50mL(+)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	968519	2	SCH21	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Length 230cm Oval Cup W/Needle	Okt 99	257118	968523	2	SCH22	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		
Bard Covington	892	Biopsy Forceps; Lower GI W/Needle Jaw O.D-2.3 Lengt230cm Oval Cup W/Needle	Okt 99	257118	968524	2	SCH23	1	0	50mL(-)		
								2	0	50mL(-)		
								3	0	50mL(-)		



Boston Scientific Corporation Hospital Location: Moorehead, KY
Negative Control Samples for Microbiological Quality Assurance Testing of Reprocessed Samples ProjektNr.: 45005
 Date: 17.01.2000

Manufacturer:	Nr:	Description:	Date of reprocessing	Lot. Nr.:	Tracking Nr.:	Int. Nr.:	Results				
							Segment	CFU/mL (1mL)	Volume(mL) Growing(+/-)	CFU pro Segment	Differentiation
Radial Jaw single use biopsy forceps	1	New Device	N/A			KO 15	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	2	New Device	N/A			KO 16	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	3	New Device	N/A			KO 17	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	4	New Device	N/A			KO 18	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	5	New Device	N/A			KO 19	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	6	New Device	N/A			KO 20	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		



Prüfzentrum für MedizinProdukte

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Naturwissenschaftlichen und Medizinischen Instituts,
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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 1. Juni 2000

EXAMINATION OF DEVICES, REPROCESSED BY VANGUARD

DECLARED TO BE STERILE

DEVICES EVALUATED WERE REPROCESSED & REPACKAGED FOR :

HOSPITAL LOCATED IN RANSON, WEST VIRGINIA

PERFORMING LABORATORY:

PMP

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



7 single use biopsy forceps, which were reprocessed by a third party reprocessor, were randomly selected and sent to PMP, and tested for claims of sterility and cleanliness. All of these devices were originally labeled for single use and have been manufactured by Microvasive Boston Scientific Corporation.

Reprocessing was performed by Vanguard. The devices were reprocessed, repacked and registered and were at the hospital awaiting patient use. The following data are documented on the package (see Attachment I):

- Name of the reprocessor
- Name of the customer (hospital)
- Name of 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 January 2000.

For sterility testing, standard microbiological procedures with aseptic technique have been used. Additionally, eight new single use biopsy forceps (large capacity radial jaw 3, w/needle) manufactured by Microvasive Boston Scientific Corporation underwent the tests as control devices.

For documentation and identification of the devices, the sterile bags were numbered by the laboratory. Numbers are listed in Attachment 2.

Director of study: Klaus Roth

Microbiological testing: Prof. Dr. Peter Heeg



Sterility testing

We used the following procedure:

Recovery

- The first 30 cm of the tip and the following 30 cm segment were aseptically cut and placed into separate sterile tubes (containing 50 ml broth).
- The rest of the instrument was into 10 cm segments and collected in another tube (containing 50 ml broth).
- The 50 ml-tubes were vortexed for 30 seconds and shaken manually for 30 seconds.
- The beakers were shaken for 15 mins at 300 mins⁻¹.
- 1 ml was plated and 92 µl was spiralplated on Columbia-blood-agar (the controls and also the control dilutions only need to be spiralplated).
- The broth was incubated for 7 days at 37°C.

Conclusion:

The study has shown that:

- 1 of 7 (14%) reprocessed devices were non-sterile;
- all of the eight control devices were sterile.

These results, indicate that it is difficult to reprocess these single use biopsy forceps safely and consistently, even with so-called validated reprocessing methods.

Attachment 1: Control Sheet and Description of the Devices

Attachment 2: Microbiological Results of Reprocessed and Control Devices



Attachment 1

Received from: BSC
 Sender: Phil Cogdill
 Hospital Location: Ranson, WV

Date: 1/5/00
 Reprocessor: Vanguard

Received by: Klaus Roth
 Projektnr: 45005
 Page : 1

Manufacturer:	Mfg Nr.:	Description:	Date of reprocessing	Lot Nr.:	Tracking Nr.:	Uses	Int. Nr.
Microvasive Watertown		Biopsy Forceps Lower GI; Large Cup	May-98	232933	876853	1	JM 1
Microvasive Watertown		Biopsy Forceps Lower GI; Large Cup	May-98	232933	876856	1	JM 2
Microvasive Watertown		Biopsy Forceps Lower GI;	Jun-98	233551	877518	1	JM 3
Microvasive Watertown		Biopsy Forceps Lower GI;	Jun-98	233551	877519	1	JM 4
Microvasive Watertown		Biopsy Forceps Lower GI;	Jun-98	233551	877520	1	JM 5
Microvasive Watertown		Biopsy Forceps Lower GI;	Jun-98	233551	877521	1	JM 6
Microvasive Watertown		Biopsy Forceps Lower GI;	Jun-98	233551	877522	1	JM7



Attachment 2

Boston Scientific Corporation
Microbiological Quality Assurance Testing of Reprocessed Samples

Hospital Location: Ranson, WV
 Projektnr.: 45005

Reprocessor: Vanguard
 Date: 17.01.2000

Manufacturer:	Description:	Date of reprocessing	Lot. Nr.:	Tracking Nr.:	Uses	Int. Nr.:	Results				
							Segment	CFU/mL (1mL)	Volume(mL) Growing(+/-)	CFU pro Segment	Differentiation
Microvasive Watertown	Biopsy Forceps Lower GI; Large Cup	Mai 98	232933	876853	1	JM1	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Microvasive Watertown	Biopsy Forceps Lower GI; Large Cup	Mai 98	232933	876856	1	JM2	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Microvasive Watertown	Biopsy Forceps Lower GI	Jun 98	233551	877518	1	JM3	1	0	50mL (-)		S.pasteuri
							2	0	50mL (-)		
							3	0	50mL (+)		
Microvasive Watertown	Biopsy Forceps Lower GI	Jun 98	233551	877519	1	JM4	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Microvasive Watertown	Biopsy Forceps Lower GI	Jun 98	233551	877520	1	JM5	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Microvasive Watertown	Biopsy Forceps Lower GI	Jun 98	233551	877521	1	JM6	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Microvasive Watertown	Biopsy Forceps Lower GI	Jun 98	233551	877522	1	JM7	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		



Boston Scientific Corporation

Control Devices

Negative Control Samples for Microbiological Quality Assurance Testing of Reprocessed Samples

Projektnr.: 45005

Date:

17.01.2000

Manufacturer:	Nr:	Description:	Date of reprocessing	Lot. Nr.:	Tracking Nr.:	Int. Nr.:	Results				
							Segment	CFU/mL (1mL)	Volume(mL) Growing(+/-)	CFU pro Segment	Differentiation
Radial Jaw single use biopsy forceps	1	New Device	N/A			KO 7	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	2	New Device	N/A			KO 8	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	3	New Device	N/A			KO 9	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	4	New Device	N/A			KO 10	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	5	New Device	N/A			KO 11	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	6	New Device	N/A			KO 12	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	7	New Device	N/A			KO 13	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		
Radial Jaw single use biopsy forceps	8	New Device	N/A			KO 14	1	0	50mL (-)		
							2	0	50mL (-)		
							3	0	50mL (-)		

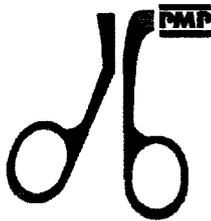


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Naturwissenschaftlichen und Medizinischen Instituts,
Reutlingen, Leitung: Dr. R. E. Müller
in Kooperation mit



der Sektion und dem Steinbels-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 4. Oktober 2000

EXAMINATION OF DEVICES, REPROCESSED BY MEDICAL INSTRUMENTS TECHNOLOGY

DECLARED TO BE STERILE

DEVICES EVALUATED WERE REPROCESSED & REPACKAGED FOR :

HOSPITAL LOCATED IN FORT WORTH, TEXAS

PERFORMING LABORATORY:

PMP

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



115 single use devices (105 biopsy forceps, 6 Guidewires, and 4 Snares) were reprocessed by Medical Instruments Technology, a third party reprocessor. These devices were obtained from a hospital and represent all of the reprocessed devices at the hospital at that time. The head endoscopy nurse manager said that the hospital had not used any reprocessed devices but it wanted Boston Scientific Corporation to send the devices to a contract testing facility to test for sterility. All of the devices were originally labeled for single use and were manufactured by Microvasive Boston Scientific Corporation.

The devices were reprocessed, repacked and registered and were at the hospital awaiting patient use. The following data are documented on the package (see Attachment I):

- Name of the reprocessor
- Name of the customer (hospital)
- Name of the manufacturer
- Tracking No.
- Sterilization Date

The label includes a bar code sticker for documentation.

Tests were performed over a two month duration, July-August 2000, due to the large number of samples which required a great deal of glassware and incubator space.

For sterility testing, standard microbiological procedures with aseptic technique have been used. Additionally, eight new single use biopsy forceps (large capacity radial jaw 3, w/needle) manufactured by Microvasive Boston Scientific Corporation underwent the tests as control devices.

For documentation and identification of the devices, the sterile bags were numbered by the laboratory. Numbers are listed in Attachment 2.

Director of study: Klaus Roth

Microbiological testing: Prof. Dr. Peter Heeg



Sterility testing

Test Procedure used:

Recovery

- The first 30 cm of the tip and the following 30 cm segment were aseptically cut and placed into separate sterile tubes (containing 50 ml broth).
- The rest of the instrument was aseptically cut into 10 cm segments and collected in another tube (containing 50 ml broth).
- The 50 ml-tubes were vortexed for 30 seconds and shaken manually for 30 seconds.
- The beakers were shaken for 15 mins on an orbital shaker at 300 RPM.
- 1 ml was plated and 92 µl was spiralplated on Columbia-blood-agar (the controls and the control dilutions only need to be spiralplated).
- The broth was incubated for 7 days at 37°C.

Positive Controls

The following positive controls were carried out:

All devices used for negative controls (3 test tubes/device) as well as 1 sample taken from each type of product (3 test tubes/device), which had been tested negative after 7 days of incubation, were inoculated with 10^1 to 10^2 cfu of the following test organisms:

Staphylococcus aureus	ATCC 6538 p
Escherichia coli	ATCC 8739
Candida albicans	ATCC 10231

Growth of the respective test organism could be demonstrated for all controls after 24 hours.

Conclusion:

- 15 out of 105 (14.3%) reprocessed biopsy forceps were non-sterile
- 2 out of 4 (50%) reprocessed Snares were non-sterile
- 1 out of 6 (16.7%) reprocessed Guidewires were non-sterile
- all of the five control devices were sterile

This study investigated a current, state-of-the-art method for reprocessing endoscopic accessories used by third-party reprocessors. The data shows that it is not possible to reprocess these single use devices safely. The practice of reprocessing and sterilizing used single use devices, even with so-called validated reprocessing methods, does not consistently sterilize the devices so that they are safe and effective for reuse in patients.



Device Number		Devices	Article Description	Sterilization Date	Lot Nr.
From	To	Total			
1001	1077	64	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.02.00	01984-0002
1	75				
2001	2004	4	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	15.02.00	02024-0002
76	79				
3001	3020	20	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	18.02.00	02024-0003
80	99				
4001	4010	10	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	24.03.00	02170-0004
100	109				
1101	1105	5	Microvasive 1550 240cm Biopsy Forceps (Hot); BLACK CAP/ RED TEFL,W/O Needle,	10.02.00	01984-0002
110	114				
3101	3102	2	Microvasive 1550 240cm Biopsy Forceps (Hot); BLACK CAP/ RED TEFL,W/O Needle,	18.02.00	02024-0003
115	116				
4501	4503	3	Microvasive Jagwire Guidewire Yello / Black	24.03.00	02170-0004
117	119				
5201	5202	2	Microvasive Snare (Hot), Captivator Orange Handle	27.03.00	02174-0002
120	121				
5301	5302	2	Microvasive Snare White Handle	27.03.00	02174-0003
122	123				
5401	5403	3	Microvasive 5343 0,018"x450cm Glidewire, Angled, Endoscopic Wire	27.03.00	02174-0004
124	126				

Total

115



Attachment 2: Microbiological Quality Assurance Testing of Reprocessed Samples 20.7.2000 Table 1

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
1	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	Micrococcus sp. Micrococcus sp.
				2	0	50mL (+)	<50	
				3	0	50mL (+)	<50	
2	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
3	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
4	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
5	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	*CNS
				2	0	50mL (+)	<50	
				3	0	50mL (-)	0	
6	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
7	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
8	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
9	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
10	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	

*Coagulase-negative Staphylococcus



Microbiological Quality Assurance Testing of Reprocessed Samples 20.7.2000 Table 2

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
11	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
12	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
13	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
14	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
15	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
16	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
17	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
18	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
19	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
20	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	



Microbiological Quality Assurance Testing of Reprocessed Samples

20./27.7.2000

Table 3

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
21	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
22	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
23	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	Bacillus sp.
				2	0	50mL (-)	0	
				3	0	50mL (+)	<50	
24	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
25	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	20.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
26	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
27	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
28	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
29	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
30	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	



Microbiological Quality Assurance Testing of Reprocessed Samples 27.7.2000 Table 4

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
31	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
32	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
33	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
44	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
45	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
46	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
48	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
49	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
50	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	



Microbiological Quality Assurance Testing of Reprocessed Samples

27.7.2000

Table 5

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
51	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
52	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
53	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
54	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
55	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
56	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
57	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
58	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
59	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
60	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	



Microbiological Quality Assurance Testing of Reprocessed Samples 27.7./3.8.2000 Table 6

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
61	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	27.07.00	10.02.00	1	0	50mL (-)	0	*CNS
				2	0	50mL (-)	0	
				3	0	50mL (+)	<50	
62	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	*CNS
				2	0	50mL (-)	0	
				3	2	50mL (+)	100	
63	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
64	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	Micrococcus sp.
				2	0	50mL (-)	0	
				3	0	50mL (+)	<50	
65	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	*CNS
				2	0	50mL (-)	0	
				3	1	50mL (+)	50	
66	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	*CNS
				2	0	50mL (-)	0	
				3	0	50mL (+)	<50	
67	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
68	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
69	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	*CNS
				2	0	50mL (-)	0	
				3	1	50mL (+)	50	
70	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	

*Coagulase-negative Staphylococcus



Microbiological Quality Assurance Testing of Reprocessed Samples 3.8.2000 Table 7

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
71	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
72	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
73	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
74	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (+)	<50	
75	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
76	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	15.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
77	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	15.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
78	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	15.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
79	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	15.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
80	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (+)	<50	*CNS
				2	0	50mL (+)	<50	*CNS
				3	3	50mL (+)	150	*CNS



Microbiological Quality Assurance Testing of Reprocessed Samples 3.8.2000 Table 8

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
81	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
82	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	*CNS
				2	0	50mL (-)	0	
				3	0	50mL (+)	<50	
83	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
84	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
85	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
86	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
87	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
88	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
89	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
90	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	



Microbiological Quality Assurance Testing of Reprocessed Samples

3./10.8.2000

Table 9

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
91	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
92	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
93	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
94	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
95	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
96	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
97	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
98	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
99	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	3.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
100	Microvasive 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	



Microbiological Quality Assurance Testing of Reprocessed Samples 10.8.2000 Table 10

Nr.	Article Description:	Test date	Sterilization	Results				Identification
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	
101	Microvative 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
102	Microvative 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
103	Microvative 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (+)	<50	Bacillus sp.
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
104	Microvative 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
105	Microvative 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (-)	0	*CNS *CNS
				2	0	50mL (+)	<50	
				3	0	50mL (+)	<50	
106	Microvative 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
107	Microvative 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
108	Microvative 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
109	Microvative 1599 240cm Biopsy Forceps; Orange CAP/TEF W/Needle, Position Markers	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
110	Microvative 1550 240cm Biopsy Forceps; (Hot) BLACK CAP/ RED TEFL, W/O Needle	10.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	



Microbiological Quality Assurance Testing of Reprocessed Samples 10.8.2000 Table 11

Nr.	Article Description:	Test date	Sterilization	Results				
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	Identification
111	Microvasive 1550 240cm Biopsy Forceps; (Hot) BLACK CAP/ RED TEFL, W/O Needle	10.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
112	Microvasive 1550 240cm Biopsy Forceps; (Hot) BLACK CAP/ RED TEFL, W/O Needle	10.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
113	Microvasive 1550 240cm Biopsy Forceps; (Hot) BLACK CAP/ RED TEFL, W/O Needle	10.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
114	Microvasive 1550 240cm Biopsy Forceps; (Hot) BLACK CAP/ RED TEFL, W/O Needle	10.08.00	10.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (+)	<50	
115	Microvasive 1550 240cm Biopsy Forceps; (Hot) BLACK CAP/ RED TEFL, W/O Needle	10.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
116	Microvasive 1550 240cm Biopsy Forceps; (Hot) BLACK CAP/ RED TEFL, W/O Needle	10.08.00	18.02.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
117	Microvasive Jagwire Guidewire Yello / Black	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
118	Microvasive Jagwire Guidewire Yello / Black	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
119	Microvasive Jagwire Guidewire Yello / Black	10.08.00	24.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
120	Microvasive Snare (Hot) Captivator Orange Handle	10.08.00	27.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (+)	<50	



Microbiological Quality Assurance Testing of Reprocessed Samples 10.8.2000 Table 12

Nr.	Article Description:	Test date	Sterilization	Results				Identification
				Segment	cfu/mL (1mL)	Growth +/- in 50 mL	cfu / segment	
121	Microvase Snare (Hot) Captivator Orange Handle	10.08.00	27.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
122	Microvase Snare White Handle	10.08.00	27.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
123	Microvase Snare White Handle	10.08.00	27.03.00	1	0	50mL (+)	<50	Bacillus sp.
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
124	Microvase 5343 0,018"x450 cm Glidewire, Angled, Endoscopic Wire	10.08.00	27.03.00	1	0	50mL (+)	<50	Bacillus sp.
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
125	Microvase 5343 0,018"x450 cm Glidewire, Angled, Endoscopic Wire	10.08.00	27.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
126	Microvase 5343 0,018"x450 cm Glidewire, Angled, Endoscopic Wire	10.08.00	27.03.00	1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
1	Negative Control Large capacity Radial Jaw 3, W/Needle Endoglide™ sheath order No. 1599	20.07.00		1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
2	Negative Control Large capacity Radial Jaw 3, W/Needle Endoglide™ sheath order No. 1599	27.07.00		1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
3	Negative Control Large capacity Radial Jaw 3, W/Needle Endoglide™ sheath order No. 1599	3.08.00		1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
4	Negative Control Large capacity Radial Jaw 3, W/Needle Endoglide™ sheath order No. 1599	10.08.00		1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	
5	Negative Control Large capacity Radial Jaw 3, W/Needle Endoglide™ sheath order No. 1599	10.08.00		1	0	50mL (-)	0	
				2	0	50mL (-)	0	
				3	0	50mL (-)	0	

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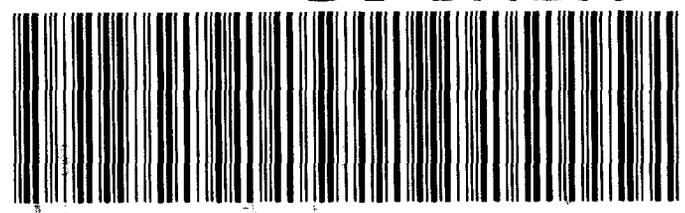
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