Bojin America

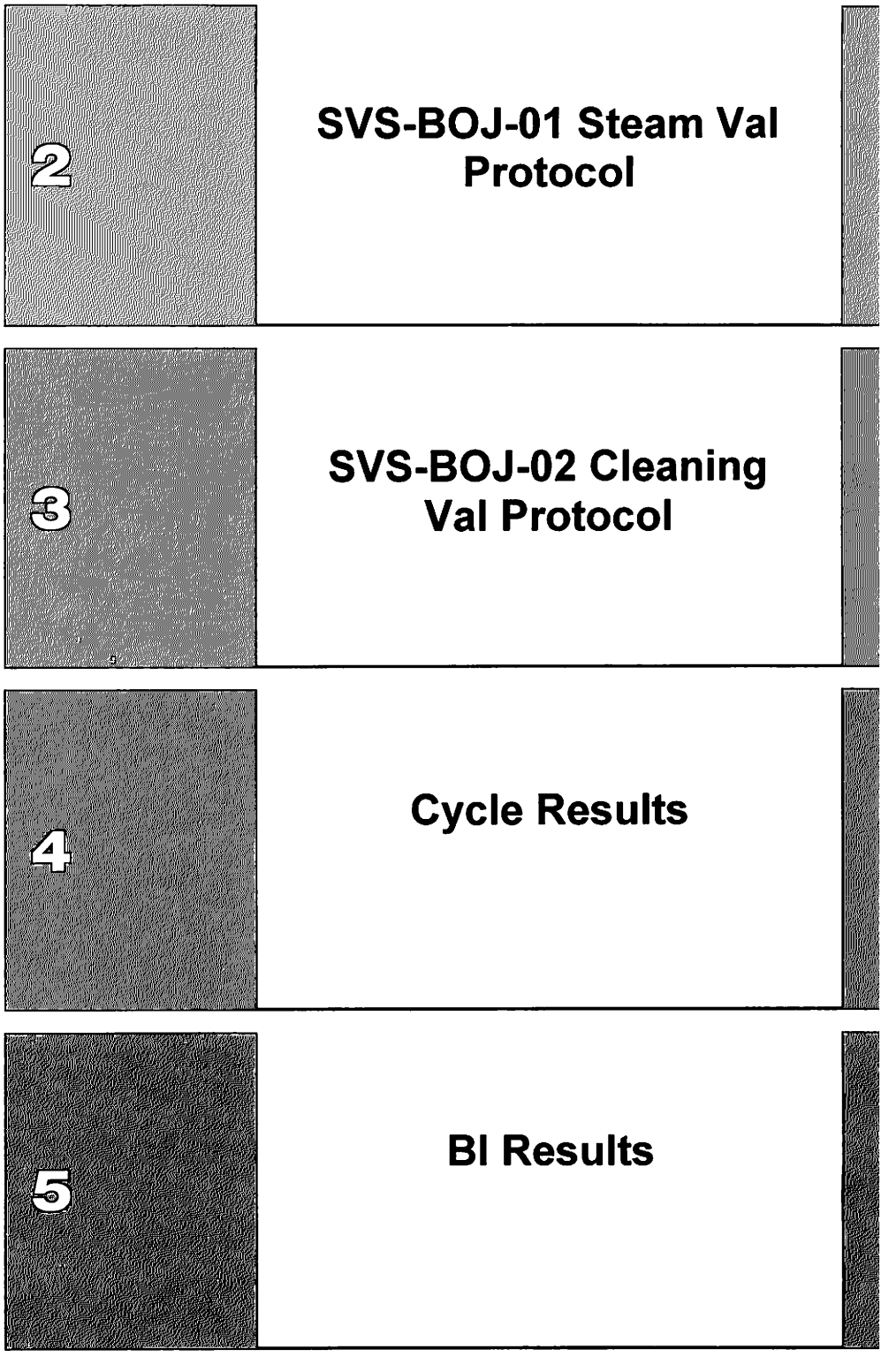
Extraction Set

Adoption Report into Existing Steam Cycle and Cleaning Process Validations

SVS-BOJ-08

May 18, 2016

Executive Summary



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Executive Summary

An adoption evaluation was successfully completed by LSO on behalf of Bojin America to assess the new Extraction Set for the purpose of adopting into validated steam sterilization and cleaning instruction previously performed by LSO for the Reamer Set under SVS-BOJ-01 & SVS-BOJ-02. This report provides the details of the evaluation and rationale for the adoption. Therefore, the Extraction Set is adopted into the SVS-BOJ-01 & SVS-BOJ-02 validation.

Written by:

5/19/16

Andrew Gladd
Project Leader, Sterilization Validation Services
Life Science Outsourcing, Inc.

Date

Reviewed by:

05/19/16

Armando Arriaga
Director, Sterilization Validation Services
Life Science Outsourcing, Inc.

Date

05/19/16

Latha Chelvakumar
Director, Quality and Regulatory
Life Science Outsourcing, Inc.

Date

05-20-16

Barry Kazemi
President & CEO
Life Science Outsourcing, Inc.

Date

Approved by:

Darryl M. Hurwitz
Director of Sales
Bojin America

Date

THERE IS NO WARRANTY EXPRESSED OR IMPLIED WITH THE SUBMISSION OF THIS REPORT AND CUSTOMER ASSUMES ALL LIABILITIES FOR USE OF DATA CONTAINED HEREIN. FOR COMPLETE WARRANTY INFORMATION, REFER TO LSO SOP-F-14.

Final Analysis:

Summary of Process

1. On behalf of Bojin America, LSO previously validated steam sterilization and cleaning instructions for the Reusable Reamer Set under Protocol SVS-BOJ-01 & SVS-BOJ-02. The original validation was performed using the Reamer Set (the "Master Product"). See Section 2 & 3 for Original Validation Protocol's.
2. Subsequently, Bojin America designed and developed a new Extraction Set (the "Candidate Product") and provided a tray sample to LSO to perform an evaluation.
3. LSO performed a steam sterilization half cycle at the validated parameters consisting of one Pre-Vac condition. 10 BIs were placed in difficult to sterilize places as shown in Figure 1: BI Placement. The tray was then double wrap in CSR wrap as shown in Figure 2. The BI's were recovered after the cycle and cultured for 7 days. See Section 4 & 5: Half Cycle and BI Test Records.

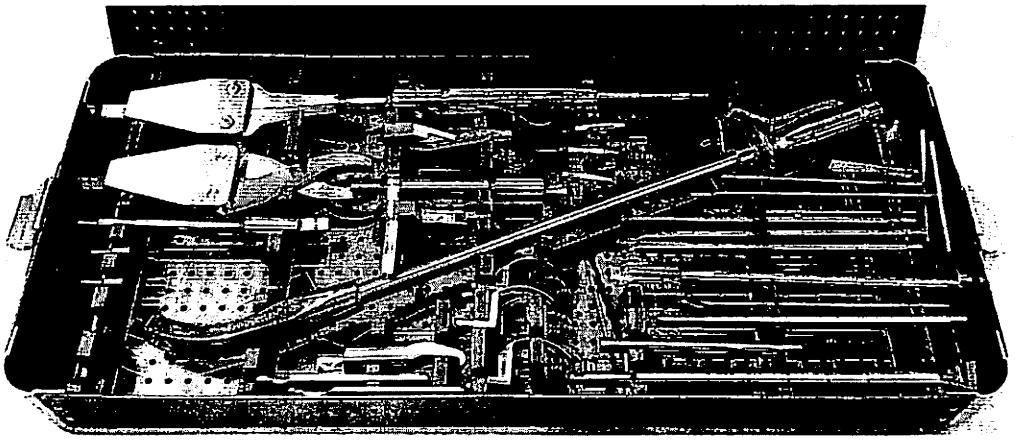

Figure 1: BI Placement

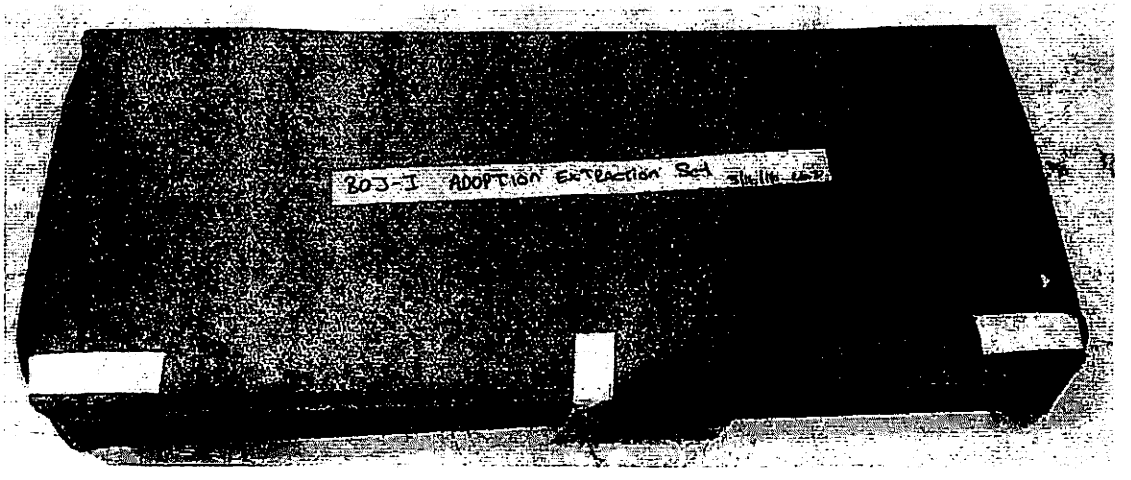

Figure 2: Tray Wrap

Analysis:

The following criteria were considered and analyzed for this adoption report:

1. The Candidate Product design including: materials, configuration, size and instrument complexity
2. Ease of cleaning
3. Ease of Sterilization

A. **Materials:** The Candidate Product and the Master Product use virtually the same material primarily consisting of stainless steel and aluminum. The Candidate Product does not present any more difficulty to clean and sterilize than the Master Product based on materials.

B. **Size & Configuration:** The Candidate Product is a shallow single level tray system and the Master Product is a deep two level tray system. They are both similar in length. The Candidate Product presents a lesser challenge than the Master Product based on the size and configuration of the trays.

C. **Instrument Complexity:** The Master Product has multiple instruments with long cannulas that would prove difficult to clean and sterilize. The Candidate Product instrument set is comprised of devices with large pathways that would allow for steam flow and ease of cleaning. The Candidate Product presents a lesser challenge than the Master Product based on the instrument complexity of the trays.

D. **Ease of Cleaning:** By comparing the design features of the Master Product to the design features of the Candidate Product, a justification is made that the Master Product presents the worse case to clean between the two Tray Systems. Therefore, the Candidate Product can be adequately cleaned using the same cleaning process as validated for the Master Product.

E. **Ease of Sterilization:** The Candidate Product was steam exposed at the same parameters as the Master Product validation to demonstrate sterilization is achieved. All BI's used in the cycles were inactivated confirming the Candidate Product does not present any more of a challenge than the Master Product to sterilize. See Section 4 & 5 for cycle records and BI test results.

Conclusion:

The Extraction Set is adopted to the validated steam sterilization cycles and cleaning process as specified in LSO validation report SVS-BOJ-01 & SVS-BOJ-02.

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Bojin America

Reamer Set

Steam Sterilization
Cycle Validation Protocol

SVS-BOJ-01

October 10, 2013

1.0 Scope

1.1 Objective: To validate steam sterilization cycles to a Sterility Assurance Level (SAL) of 10^{-6} using the microbial inactivation approach and a drying cycle both as specified in an Instruction for Use provided by the Sponsor to health care providers using the reusable Product specified herein.

1.2 Sponsor: Bojin America, Ronkonkoma, NY.

1.3 Product: Product Name - See Attachment 1: Product Description

1.4 Strategy: Half-cycle overkill validation by inactivation of biological indicators with a 10^6 population.

1.5 Project Manager: Life Science Outsourcing, Inc. ("LSO") Brea, CA.

1.6 Sterilizer Location: LSO, Brea, CA.

1.7 Test Lab: LSO, Brea, CA.

2.0 Reference Documents

2.1 Primary:

2.1.1 ANSI/AAMI/ISO 17665-1:2006 Sterilization of health care Instruments – Moist Heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

2.1.2 AAMI TIR12:2010, Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

2.1.3 ANSI/AAMI ST79:2010, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

2.2 Secondary:

2.2.1 ISO 11138-1-2006 Sterilization of health care product -- Biological indicators -- Part 1 General.

2.2.2 Premarket Notification [510(K)] Submission for Medical Sterilization Packaging Systems in Health care Facilities; Draft Guidance for Industry and FDA. Office of Device Evaluation, draft released for comment on March 7, 2002.

2.2.3 ISO 11737-2:2009 Sterilization of Medical devices-Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process. Geneva: ISO, 2009

2.2.4 ISO 14161:2009 Sterilization of health care products-Biological indicators-Guidance for the selection, use, and interpretation of results. Geneva: ISO, 2009.

2.2.5 ISO 11138-1:2006/(R) 2010 Sterilization of health care products-Biological Indicators-Part 1: General Requirements. Geneva: ISO, 2006.

2.2.6 ISO 11138-3:2006/(R) 2010 Sterilization of Healthcare products-Biological indicators-Part 3: Biological indicators for moist heat sterilization processes. Geneva. ISO, 2006

2.2.7 ISO 17665-2:2009 Sterilization of health care products-Moist heat-Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1. Geneva: ISO, 2009

2.3 LSO Quality Documents:

Life Science Outsourcing Work Instruction WI-LSO-MSI-062, for *Sterility Testing of Biological Indicators.*

2.4 Relevant Project Documents: None

3.0 Resources

3.1 Test Load Materials

3.1.1 See Attachment 2: Load Configuration and BI Placement.

3.2 Equipment

3.2.1 Sterilizer: Amsco Steam Sterilizer, LSO-469T, of the type used in health care facilities.

3.2.2 Thermal Recording:

3.2.2.1 Thermal recording using independent sensors will not be performed during this validation. Print tapes from the sterilizer will be utilized as evidence of the parameters achieved during the sterilization cycle. The chamber temperature will be recorded in 1 minute intervals on the print tape during all cycles.

3.2.2.2 Data Trace temperature and pressure sensors were used during the sterilizer's Operation Qualification proving that the sterilizer operated properly and that the print tape outputs matched the actual temperature inside the chamber.

3.2.3 Biological Indicator Processing

3.2.3.1 HEPA Test Bench, LSO-118T.

3.2.3.2 Incubator Oven, LSO-305T, (55-60 °C).

3.3 Supplies

3.3.1 Biological indicator spore strip (BI), *Geobacillus stearothermophilus*: , of the type cleared by the FDA for use in healthcare facilities (See – Attachment 2: Load Configuration and BI Placement). The spore strip used is certified by the indicator manufacturer to have a minimum population of 10^6 and the Certificate will be available for review during any site audit at LSO.

3.3.2 Microbiological culture media, SVS-STM-013, of the type cleared by the FDA for use in healthcare facilities.

3.3.3 CSR Wrap, SVS-MIS-002, of the type cleared by the FDA for use in healthcare facilities.

3.4 External Laboratory Tests: None

4.0 Validation Process

4.1 Pre-cycle Tasks

4.1.1 Calibration

4.1.1.1 All **instrumentation used in the validation** requiring calibration will be calibrated. Records will be available for review during any site audit at LSO.

4.1.1.2 **BI lot population** will be verified by the certificate of population from the BI supplier, available for inspection during any site audit at LSO.

4.2 Cycle Tasks

4.2.1 Biological Indicator Preparation

4.2.1.1 **Half and Full Cycles:** BI's will be used in all half cycles and one full cycle at each parameter condition to confirm repeatability in all cycles. BI's will be numbered and be placed per Attachment 2: Load Configuration and BI

Placement. One (1) BI will be marked as the positive control and set aside for testing with the sample BI's.

4.2.2 Load Preparation:

4.2.2.1 See Attachment 2: Load Configuration and BI Placement.

4.2.2.2 Wrap the tray in accordance with ANSI/AAMI ST79:2010.

4.2.2.3 Print out a complete Parameter Listing from the Autoclave after the initial set-up for each set of Cycle parameters.

4.3 Half Cycles: Perform three (3) half cycles at each of the following Cycle number parameters [six (6) total cycles]:

Cycle #	Cycle Type	Temp (C°)	Exposure Time (Minutes)	Dry Time (Minutes)
1	Pre-Vac, wrapped	132	2	0
2	Pre-Vac , wrapped	135	1.5	0

4.4 Full Cycles: Perform three (3) full cycles at each of the following Cycle number parameters [six (6) total cycles], remove the CSR wrap, inspect for dryness and complete the Autoclave Drying Inspection Form.

Cycle #	Cycle Type	Temp (C°)	Exposure Time (Minutes)	Dry Time (Minutes)
1	Pre-Vac, wrapped	132	4	30
2	Pre-Vac , wrapped	135	3	30

4.5 BI Testing

4.5.1 After each half cycle and one full cycle at each parameter condition, collect and test BI's per WI-LSO-MSI-062.

5.0 Acceptance Criteria

5.1 All Sterilization processes must meet the specified parameters and loading instructions herein. All printed data results from validation equipment and recorders are to be complete and legible (signed and reviewed).

5.2 Any deviations are to be documented for review by the Sponsor. However, the validation of any cycle that does meet the acceptance criteria shall not fail due to any other cycle not meeting the acceptance criteria.

5.3 There must be no BI positives in the half cycles or full cycle. The positive controls must have growth. (All data sheets with BI, Sterilization Indicator or any other test results will be signed and reviewed).

5.4 Temperature and Time data must be analyzed to identify any cycle abnormalities. The acceptable Temperature range will be from 1 degree below to 3 degrees above the parameter Temperature setting. The acceptable time range will be +/-10% of the parameter Time settings.

5.5 After the full cycle, the test load must be dry with no visible condensate moisture upon removal of the Product from the full cycle. Products with lumens will be tapped on a dry cloth to confirm no visual moisture comes from the inside of the lumen.

5.6 The Final Report must approved by LSO and the Sponsor.

Written By:

Andrew Gladd — 10/10/13
Andrew Gladd — Date
Project Leader, Sterilization Validation Services
Life Science Outsourcing, Inc.

Reviewed By:

Rod Webb — 10/10/13
Rod Webb — Date
Director, Sterilization Validation Services
Life Science Outsourcing, Inc.

John Popplewell by Rod Webb — 10/10/13
John Popplewell — Date
Validation Quality Engineer/Microbiologist
Life Science Outsourcing, Inc.

Mireya Lozano — October 10, 2013
Mireya Lozano — Date
Director, Incubator Services, Quality & Regulatory
Life Science Outsourcing, Inc.

Approved By:

DH — 10/16/2013
Darryl M. Hurwitz — Date
Director of Sales
Bojin America

Attachment 1: Product Description

The Reamer Set is a 2 layered reusable kit made up of 9 Reamers per level. All instruments are listed in Table 1 below and pictured in Figure 1.

Figure 1: Reamer Kit

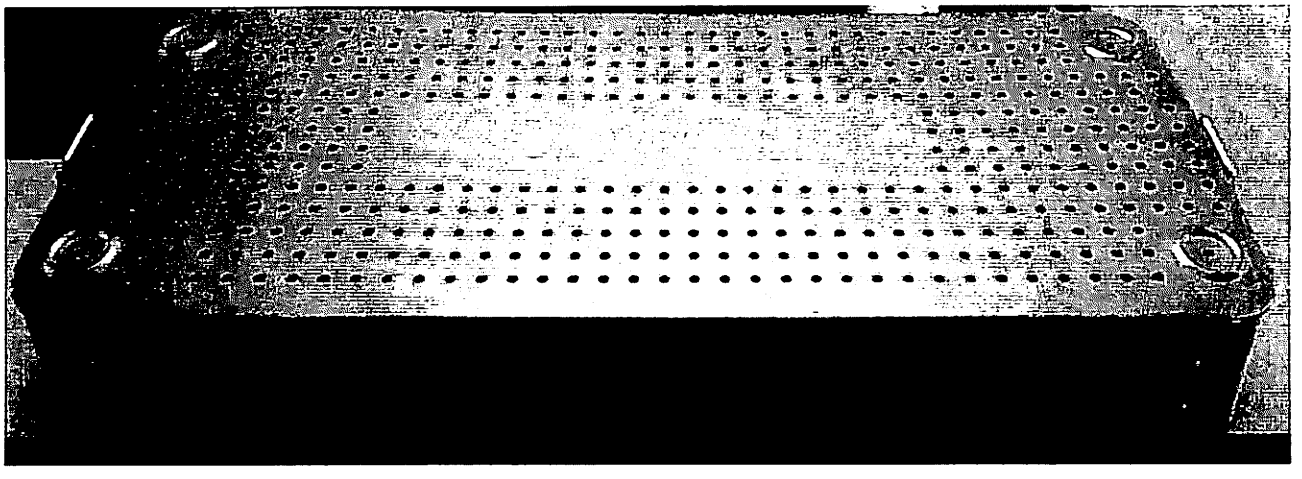


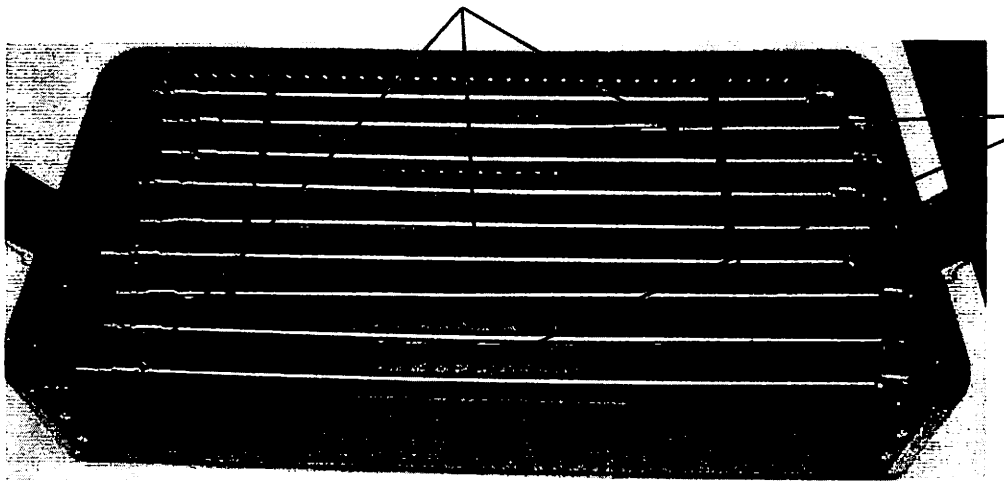
Table 1: List of Products

Serial Number	Description
BJ1103B1-7	7 mm Reamer
BJ1103B1-7.2	7.2 mm Reamer
BJ1103B1-7.5	7.5 mm Reamer
BJ1103B1-8	8 mm Reamer
BJ1103B1-8.5	8.5 mm Reamer
BJ1103B1-9	9 mm Reamer
BJ1103B1-9.5	9.5 mm Reamer
BJ1103B1-10	10 mm Reamer
BJ1103B1-10.5	10.5 mm Reamer
BJ1103B1-11	11 mm Reamer
BJ1103B1-11.5	11.5 mm Reamer
BJ1103B1-12	12 mm Reamer
BJ1103B1-12.5	12.5 mm Reamer
BJ1103B1-13	13 mm Reamer
BJ1103B1-13.5	13.5 mm Reamer
BJ1103B1-14	14 mm Reamer
BJ1103B1-14.5	14.5 mm Reamer
BJ1103B1-15	15 mm Reamer

Attachment 2: Load Configuration and BI Placement

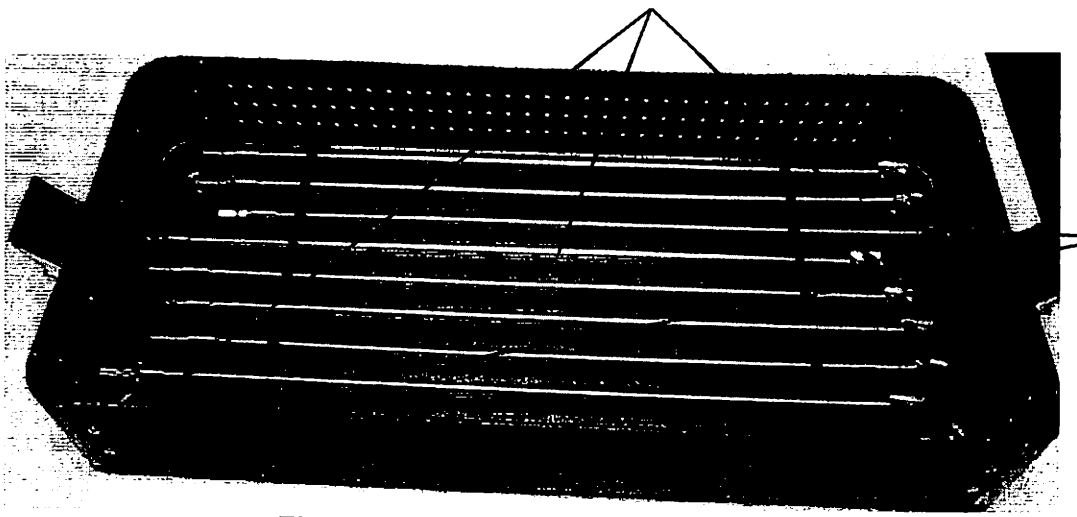
1. *A single Reamer Set will be double wrapped using an appropriately cut size of CSR sheet for each layer.*
2. *BI's will be placed as shown below prior to wrapping.*
3. *The double wrapped kit will be placed in the center of the autoclave chamber directly over the drain for the test cycle exposure.*

#1, #2 and # 3 Mini BI placed within drill cannulation on the top level



 # 4 & # 5 BI placed randomly in the top level of the tray

#6, #7, #8 Mini BI placed within drill cannulation on the bottom level



#9 & #10 BI placed randomly in the bottom level of the tray

Figure 2: Load with BI Placement

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Bojin America

Reamer Set

Cleaning Process Validation Protocol

SVS-BOJ-02

October 1, 2013

1.0 Scope

1.1 Objective: To validate a cleaning process performed by healthcare providers as specified in Instructions for Use prior to sterilization of the reusable Product specified herein.

1.2 Sponsor: Bojin America, Ronkonkoma, NY.

1.3 Product: Reamer Set - See Attachment 1: Product Description

1.4 Strategy: Manual cleaning validation of the Product.

1.5 Project Manager: Life Science Outsourcing, Inc. ("LSO") Brea, CA.

1.6 Sterilizer Location: LSO, Brea, CA.

1.7 Test Lab: SGS Life Science Services ("SGS"), Lincolnshire, IL

2.0 Reference Documents

2.1 AAMI TIR12:2010, Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

2.2 AAMI TIR 30:2011, A Compendium of Processes, Materials, Test Methods, and acceptance Criteria for Cleaning Reusable Medical Devices.

2.3 LSO Quality Documents:

2.3.1 QSP 6-17 Cleaning & Disinfection of Reusable Medical Devices by SVS.

2.3.2 QSP 6-19 Mixing and Disposal of Solutions.

3.0 Resources

3.1 Test Load Materials

3.1.1 All-in-One 4 Enzyme Detergent, SVS-DEC-003

3.2 Equipment

3.2.1 HEPA filtered laminar flow hood

3.3 Supplies

3.3.1 Potable tap water

3.3.2 Disposable Soft bristle brush, appropriately sized

3.3.3 Disposable cloth

3.3.4 Clean polyethylene bags

4.0 Validation Process

4.1 Sample Preparation

4.1.1 LSO will receive four (4) uncontaminated samples of the Product from the Sponsor. The samples will be sent to the Test Lab with instruction for application of controlled levels of contamination markers on each of the four (4) samples. See Attachment 2: Inoculation Locations.

4.1.2 The Test Lab will titer the suspension to verify the 6 $\log_{10}$ spore level on each sample. After inoculation, the samples will remain in the hood and are allowed to air dry overnight.

4.1.3 Under a HEPA filtered laminar flow hood, the Test Lab will inoculate each sample with a range between 0.1 to 1.0 ml of ATS solution, depending on part size, using a syringe, using best efforts to achieve a protein inoculation level greater than 20 ug/cm^2.

4.1.4 After drying, the Test Lab will uniquely label each sample, designate and conspicuously mark one (1) of the samples as the positive control, package each in a clean polyethylene bag, and return all samples to LSO for cleaning.

4.1.5 Upon receipt of the inoculated samples by LSO, the POSITIVE CONTROL SAMPLE WILL BE IDENTIFIED AND SET ASIDE. IT IS NOT TO BE PROCESSED. All labels and packaging materials will be removed from the remaining samples and these samples will be cleaned per Section 4.2 below.

4.2 Cleaning Instructions:

4.2.1 Prepare All-in-One 4 Enzyme Detergent, SVS-DEC-003, per manufacturer's instructions and LSO QSP 6-19, Mixing and Disposal of Solutions.

4.2.2 Perform cleaning per the steps listed in the following table.

Step	Solution	Time (Minutes)	Temperature	Instruction
1	Hospital Grade Enzymatic Detergent	14-15	Room Temperature	Immerse and soak for required time.
2	Hospital Grade Enzymatic Detergent	As Required	Room Temperature	Clean thoroughly - Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that the flutes are effectively cleaned. Use a small diameter brush or pipe cleaner to clean cannulation holes. Inspect for visible soil on exposed surfaces.
3	Water	2-3	Warm, as delivered from hot water tap	Rinse thoroughly for required time immediately after Step 2.
4	Air	As required	Ambient	Allow to air dry in clean area. Blow lumens with clean air using filtered air source or syringe.

4.3 Packaging Instructions

4.3.1 Immediately after the cleaning process specified in Section 4.2 above, the three (3) cleaned samples will be placed in clean polyethylene bags, sealed and sent to the Test Lab for residue analysis. The clearly marked positive control sample will be sent to the Test Lab with the cleaned samples in the same shipper box.

4.4 Sampling Plan, Testing and Reporting

4.4.1 The Test Lab will extract any remaining ATS residual and challenge organism spores from the surface of all cleaned samples and the control sample by immersing each sample in a sterile saline bath and mechanically shaking for 15 minutes. An aliquot of the extraction fluid will then be heat shocked to activate the spores and membrane

filtered to recover the residual bacterial spores. The filter plates will be incubated at 55 - 60°C for at least two (2) and up to five (5) days. At the conclusion of the incubation period the plates will be counted for *Geobacillus stearothermophilus* spores. The remaining aliquot will be analyzed for residual protein per the bicinchoninic acid assay (BCA) method.

4.4.2 The Test Lab will report data only for all samples, including the positive control. All sample results will be reported individually and identified as labeled. LSO will review the data and report the Pass/Fail status in the final report.

5.0 Acceptance Criteria

5.1 The cleaning process must demonstrate the following to be considered validated:

5.1.1 There must be no visible soil on any cleaned Product sample surface.

5.1.2 The residual protein shall be less than 20 $\mu g/cm^2$ based on a surface area of 136.77 cm^2.

5.2 As a confirmatory reference only, the target organism reduction for *Geobacillus stearothermophilus* is 3 $\log_{10}$ based on the recovered counts of the test samples compared to the recovered counts from the positive control. While current industry guidelines recognize spore reduction as an acceptable criterion for cleaning effectiveness, the FDA Draft Guidance issued May 2, 2011 recommends against it; thus, the results are reference only.

6.0 Deviations

6.1 Any deviations or discrepancies must be documented. The Sponsor must be contacted prior to continuing the procedure in such an event. However, unless documented as post validation follow-up items, all discrepancies must be resolved prior to final sign off approval.

End of Protocol

Written By:

Andrew Gladd — 10/1/13 Date
Project Leader, Sterilization Validation Services
Life Science Outsourcing, Inc.

Reviewed By:

Rod Webb — 10/1/13 Date
Director, Sterilization Validation Services
Life Science Outsourcing, Inc.

John Popplewell — 01Oct2013 Date
Validation Quality Engineer/Microbiologist
Life Science Outsourcing, Inc.

Mireya Lozano — October 2, 2013 Date
Director, Incubator Services, Quality & Regulatory
Life Science Outsourcing, Inc.

Approved By:

Darryl M. Hurwitz — 10/16/2013 Date
Director of Sales
Bojin America

Attachment 1: Product Description

The Reamer Set is a 2 layered reusable kit made up of 9 Reamers per level. All instruments are listed in Table 1 below and pictured in Figure 1.

Figure 1: Reamer Set

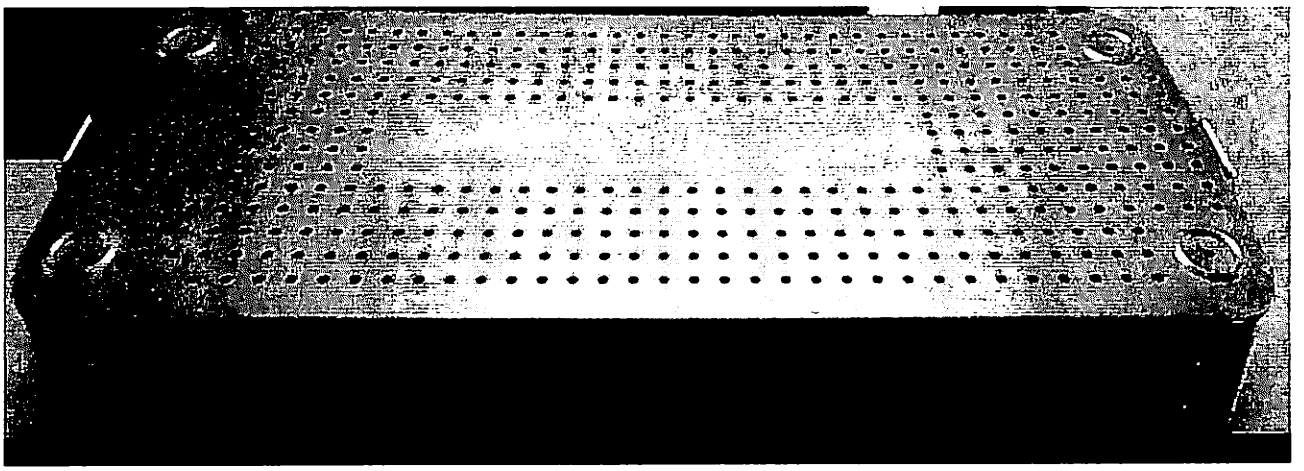

Table 1: List of Products

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BJ1103B1-9.5	9.5 mm Reamer
BJ1103B1-10	10 mm Reamer
BJ1103B1-10.5	10.5 mm Reamer
BJ1103B1-11	11 mm Reamer
BJ1103B1-11.5	11.5 mm Reamer
BJ1103B1-12	12 mm Reamer
BJ1103B1-12.5	12.5 mm Reamer
BJ1103B1-13	13 mm Reamer
BJ1103B1-13.5	13.5 mm Reamer
BJ1103B1-14	14 mm Reamer
BJ1103B1-14.5	14.5 mm Reamer
BJ1103B1-15	15 mm Reamer

The Product Family was assessed to determine the Worse Case member. This assessment considered the complexity of the device, the size, the mass, through holes, blind holes, use within surgery, and overall difficulty to Sterilize. Based on this assessment the Product listed in Table 2 was determined to be the Worse Case.

Table 2: Worse Case Product

Serial Number	Description	Rationale
BJ1103B1-15	15 mm Reamer	*The BJ1103B1-15 is larger in surface area than the BJ1103B1-14.5, and has been assessed as the Worse Case member. All 18 reamers are similar in through holes, blind holes, use in surgery, and difficulty to sterilizer. Therefore surface area was the deciding factor in choosing the worse case member.*

Attachment 2: Inoculation Locations

The Product will be inoculated by SGS at the locations indicated in Figure 2 below.

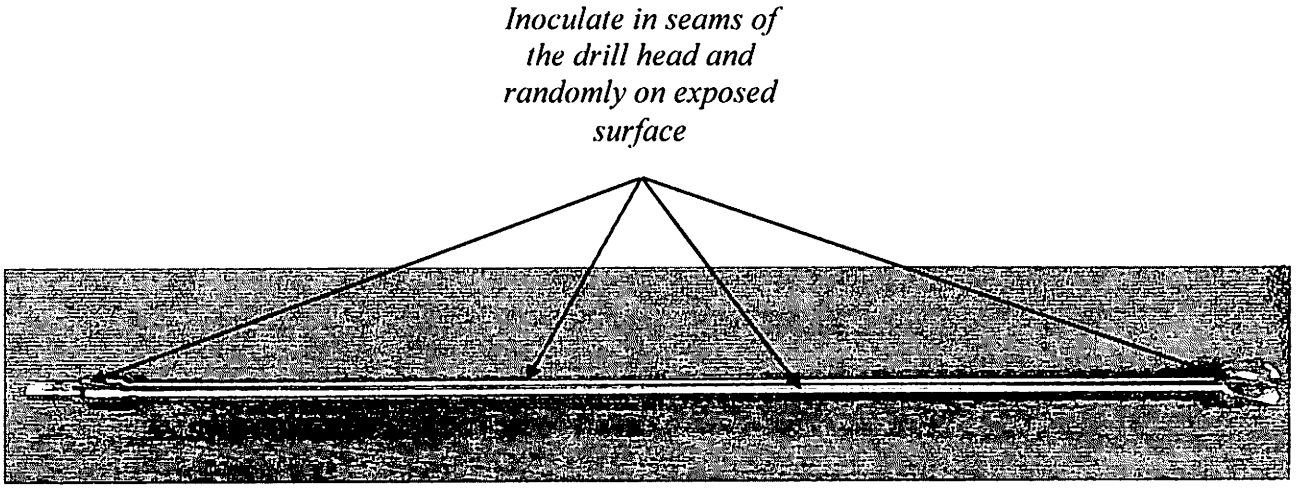

Figure 2: 15 mm Reamer

4

Life Science Outsourcing, Inc.

Sterilization Cycle Record

Work Order#: 57132-2	Sterile Lot#: E075-16	Run#: 01112

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========================
====== P R E V A C =====
========================
CYCLE START AT 12:12:23
            ON  3/16/16

CYCLE COUNT      01112
OPERATOR ___Lm Z_______
STERILIZER    _Eagle__

   STER TEMP = 132.0°C
CONTROL TEMP = 133.2°C
   STER TIME =  0:02:00
   DRY  TIME =  0:00:00

                      P=bar
- TIME       T=°C   V=bar
------------------------
C 12:12:23P   59.7   0.0P
C 12:13:24P  124.9   1.5P
C 12:14:38P   79.1   0.7V
C 12:14:54P  118.4   1.3P
C 12:16:05P   88.4   0.8V
C 12:16:21P  118.4   1.3P
C 12:17:36P   93.1   0.8V
S 12:18:10P  132.1   2.0P
S 12:19:10P  133.3   2.1P
S 12:20:10P  133.3   2.0P
E 12:20:11P  133.0   1.8P
E 12:20:29P  104.9   0.1P
E 12:20:29P  103.4   0.1P
Z 12:20:40P  103.1   0.2P

LOAD              31603

  TEMP MAX=133.7°C
  TEMP MIN=132.1°C

CONDITION    = 5:47
STERILIZE    = 2:01
EXHAUST      = 0:29
TOTAL CYCLE = 8:17
```

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13
O°C.

Life Science Outsourcing, Inc.

Steam Sterilization Line Clearance

Customer Code: BOJ-I	W/O No.: 57132-2	Run Date: 3/16/16
Sterile Lot No.: E075-16	Run No: 01112	Product Lot No: N/A

No	Pre-Sterilization Steps	Initial/Date
1.	Verify all water system valves are in labeled position (open or closed): a.) Check 3 valves at water source (near shed). b.) Check 2 valves at water softener. c.) Check 8 valves at DI water system. d.) Check 7 valves at boiler and 1 located between soft water and DI system on wall. e.) Check 4 valves at sterilizer (1 is air) – For Getinge Sterilizer Only f.) Turn on the switch for the low air alarm.	3/16/16 JM
2.	**Boiler**: a.) Turn on control switch on front of boiler. b.) Verify pump comes on and lvl of water in sight-glass (on front of the boiler) is between "L" and "H". c.) Check pressure gauge on top of boiler is reading 50 psi (takes 15-20 min)	3/16/16 JM
3.	**Getinge and Lancer Sterilizer**: a.) Verify there is enough printer paper to complete the cycle. b.) Turn on control switch on sterilizer. The steam will go to the steam generator at this time. (Note for Getinge: If an alarm sounds for low steam generator pressure, push P4 on front of sterilizer to turn off the alarm.) c.) In 15 – 20 minutes, check the pressure gauge above the generator is reading a minimum of 40 psi. d.) Check if the ready light is lit on the front of the sterilizer. (Note for Getinge: If the pressure is reading 40 psi and the yellow light is not lit, push P4.) The sterilizer will now be ready to start. Refer to the work order for further processing instructions. e.) Run a test cycle at the beginning of the day, prior to running any product. **Amsco Sterilizer**: a.) Verify there is enough printer paper to complete the cycle. b.) Turn on control switch on sterilizer (located on the front of the sterilizer under the top panel). The steam will go to the steam generator at this time. c.) Before starting the cycle, ensure that the jacket pressure is at: 1c.) 19-20 PSI for 121°C cycle 2c.) 29-30 PSI for 132°C cycle 3c.) For other temperature settings, please refer to WI-LSO-469T d.) Ensure that the valve on the copper pipe by the floor on the left side of the Sterilizer is open before starting the cycle. e.) In 15-20 minutes, check the pressure gauge above the generator is reading a minimum of 40 PSI. f.) Run a test cycle at the beginning of the day, prior to running any product. g.) Check to make sure the water knob and the steam knob are turned to the left.	3/16/16 JM
4.	Cycle Parameter verified by: JM	3/16/16

NOTE: ORIGINAL COPY ON GREEN PAPER

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Life Science Outsourcing, Inc.

Biological Indicator Test Report (Validation)

Run Date	3/16/16	Sterile Lot No.	E075-16	Run No.	01112

Customer Code	BOJ-I	WO Number	57132-2
Protocol No.	SVS-BOJ-08	Cycle Type: ☐ Fractional ☒ Half ☐ Full ☐ Development	
Product Description	ADOPTION REAMER SET	Lot Number	N/A
BI Lot No.	S96100.Z	Exp. Date	1/2/18
TSB Lot No.	5217849.A	Exp. Date	2/4/17
Date on Test:	3/16/16	Date Due Off Test:	3/23/16

Tested by: LAURA M IPPOLITO Date: 3/16/16 Total Number of Samples: 10

Not including control samples.

BI Sample #	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1.	–	–			–	–	–
2.	–	–			–	–	–
3.	–	–			–	–	–
4.	–	–			–	–	–
5.	–	–			–	–	–
6.	–	–			–	–	–
7.	–	–			–	–	–
8.	–	–			–	–	–
9.	–	–			–	–	–
10.	–	–			–	–	–
11.	N/A 03/17/16 JM	N/A 03/18/16 JM	Sat 03/19/16 JM	Sun 03/20/16 JM	N/A 03/21/16 JM	N/A 03/22/16 JM	N/A 03/23/16 JM
12.			03/21/16 JM	03/21/16 JM			
13.							
14.							
15.							
16.							
17.							
18.							
19.							
20.							
Positive Control	+	+			+	+	+
Negative Control	–	–			–	–	–
Total No. Positive	0	0			0	0	0
Inspected By / Date	03/17/16 JM	03/18/16 JM	03/21/16 JM	03/21/16 JM	03/21/16 JM	03/22/16 JM	03/23/16 JM

No. Of Additional Pages: 0 Test Result: (Pass) / Fail

Comments: N/A 03/23/16 JM

Completed By: James Magaña Date: 03/23/16

Quality Reviewed By: Steve Henley Date: 3-25-16