Scanlan Cleaning and Sterilization Instructions

per ISO 17664

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Scanlan Cleaning and Sterilization Instructions

Contents

Scanlan Cleaning and Sterilization Instructions

1 Symbols

Symbol	Definition
	Medical Device
	Device is not sterile
	Caution

2 Scope

These instructions are for the cleaning and sterilization of reusable Scanlan® surgical instruments and accessories. Scanlan has validated the processes presented in this document as being effective. The information is intended to assist those facilities responsible for developing procedures for safe and effective reprocessing of Scanlan® surgical instruments and accessories.

For further information on maintaining the quality of your surgical instrumentation, contact Scanlan International, Inc.

3 Processor Responsibilities

The instructions provided below have been validated by Scanlan International as being capable of processing reusable Scanlan surgical products. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials, and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the processes.

4 Hygiene and Maintenance Prior to Initial Use

The medical device is delivered non-sterile.
The packaging is not sterilizable. Do not sterilize in the packaging.

Clean, inspect, lubricate, and sterilize instruments and trays as instructed in this document.

5 Instrument Groups

SCANLAN® instrumentation is divided into groups based upon intended use and design elements as they relate to cleaning and sterilization. The Product Lists are a comprehensive record of the catalog numbers that correspond to each instrument type.

If you are uncertain which group represents the instrument of concern, please contact your local Scanlan representative. Additionally, Product Lists can be made available upon request.

Group	Description	Instrument Types	Product Lists
1	no hidden surfaces, no lumens, or blind holes	probes, dilators, memory instruments (except mirror)	FRMTCF4S
		retractors	FRMTCF5S
2	hidden surfaces such as sliding shaft (VATS/MIS) or box lock, difficult to inspect	forceps (non-suction), clamps, clip appliers	FRMTCF1S
		needle holders	FRMTCF2S
		scissors, rib cutters, rongeurs	FRMTCF3S
		vascular tunnelers	FRMTCF11aS
		memory mirror	FRMTCF25S
3	instruments with lumens and/or flush ports	suction forceps	FRMTCF1S
		needle holders	FRMTCF2S

		tube shaft MIS/VATS with flush port		FRMTCF3S
		suction instruments		FRMTCF27S
4	temporary vascular clips	Heifetz™, Yasargil, Reliance bulldog, and shunt clips		FRMTCF1S
5	sealed tube shaft (VATS/MIS)	instruments having a sealed tube shaft		FRMTCF3S
6	dismantlable retractors	Loftus™ retractor, M.D.™ Retractor System		FRMTCF5S
7	sterilization trays	N/A. Trays are accessories for instruments.		FRMTCF6S
8	Scanturian® MIS	flushable minimally invasive surgical instruments	clamps/forceps	FRMTCF1S
			needle holders	FRMTCF2S
			scissors	FRMTCF3S

⚠ 6 Cautions/Warnings

Group	Instrument Types	Caution Statement
None	None	Devices labeled “for single use only” must not be reprocessed for re-use.
All	All	Instruments must be reprocessed in an open or disassembled state. *Exceptions*: tunneler, Yasargil, Heifetz™, bulldog, shunt, & Reliance clips
All	All	Scanlan® surgical instruments are not intended for implantation.
All	All	Make certain that all blood and debris are removed from the instrument as soon as possible after use. Do not allow blood to dry on the instrument.
All	All	Instrument must be cleaned, inspected, and sterilized before first and after each subsequent use. 10 X magnification may be utilized to inspect all instruments after cleaning for accumulating debris.
All	All	Do not use a fixating agent, fixating detergent, or hot water (>40°C) as these can cause fixation of biological residues and hinder the effectiveness of reprocessing.
All	All	If instrument is damaged or worn, have it repaired, refurbished, or sharpened only by a Scanlan authorized facility. See section 16 for instructions to send instruments to a Scanlan authorized facility.
All	All	Discard instruments that have exceeded their service life in accordance with local regulations.
All	All	Destroy instruments that might have been contaminated with prions (CJD) Do not reuse.
All	All	Delicate SCANLAN® instrumentation may be damaged if care is not taken if using an ultrasonic bath. Instruments should not be allowed to contact other instruments or hard surfaces within the bath.
1, 2	Memory instruments	Before sterilization, bend instrument back to approximate original shape. Use of SCANLAN® Tip-Guard™ instrument protector is recommended.
1, 2, 3	probes, dilators, memory instruments, forceps (all), clamps, clip appliers, needle holders, scissors, rib cutters, rongeurs	Be certain all delicate tipped instruments are covered with a device specially designed for instrument protection (such as SCANLAN® Tip-Guard™ instrument protectors) during storage and sterilization.
2	forceps (non-suction), clamps, clip appliers, needle holders, scissors, rib cutters, rongeurs	After a thorough cleaning and rinsing, treat the instrument with an antimicrobial water-soluble instrument lubricant. Do not use petroleum-based lubricants.
2	Memory mirror	Ultrasonic cleaning or dry heat sterilization of the SCANLAN® MEMORY Mirror will cause permanent damage.
2, 3, 5	Sliding or tube shafted VATS, MIS and lumens	Use suction/irrigation ported systems or racks when cleaning MIS, VATS, and cannulated instruments. 10 X magnification may be utilized to inspect all instruments after cleaning for accumulating debris.

<table>
<tr><td rowspan="4">7</td><td rowspan="4">Sterilization trays (plastic, only)</td><td colspan="5">Enzymatic detergent may not be as effective as alkaline detergent. See below for standards compliance concluded from processing validations for Group 7 instruments.</td></tr>
<tr><td>Detergent</td><td>AAMI TIR30*</td><td>RKI, 2012†</td><td>DIN ISO 15883‡</td><td>DGKH, DGSV, AKI, 2017§</td></tr>
<tr><td>enzymatic</td><td>No</td><td>N/A</td><td>No</td><td>No</td></tr>
<tr><td>alkaline</td><td>Yes</td><td>N/A</td><td>Yes</td><td>Yes</td></tr>
<tr><td>2, 3, 6, 7</td><td>MEMORY, Sundt™ suction, A/V punch, retractors, sterilization trays</td><td colspan="5">Refer to Section 19 for a list of dismantlable Scanlan instruments by catalog number.</td></tr>
<tr><td rowspan="4">5</td><td rowspan="4">sealed tube shaft VATS/MIS without flush port</td><td colspan="5">Enzymatic detergent may not be as effective as alkaline detergent. See below for standards compliance concluded from processing validations for Group 5 instruments.</td></tr>
<tr><td>Detergent</td><td>AAMI TIR30*</td><td>RKI, 2012†</td><td>DIN ISO 15883‡</td><td>DGKH, DGSV, AKI, 2017§</td></tr>
<tr><td>enzymatic</td><td>Yes</td><td>No</td><td>No</td><td>Yes</td></tr>
<tr><td>alkaline</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
</table>

*,†,‡,§ Standards/guidance documents are listed in Section 17 under Ref #'s 3, 30, 17-18, & 24, respectively.

7 Limitations on Processing

Reprocessing according to the instructions has minimal effect on the reuse of Scanlan® surgical instruments.

Useful life is therefore determined by the function / wear of the instrument. Instruments which have been reprocessed 500 cycles or been in use for 10 years should be returned to a Scanlan authorized facility for manufacturer's inspection.

Instruments must be inspected after each use per section 13 of these instructions. Inadequate function may be an indication of improper cleaning, residual soil accumulation or wear.

If the instrument needs service or repair, the instrument must be decontaminated before sending to a Scanlan authorized facility. See section 16 for instructions to send instruments to a Scanlan authorized facility.

8 Initial Treatment at the Point of Use

Make certain that gross blood and debris are removed from the instrument as soon as possible after use. Do not allow blood to dry on the instrument. Remove gross soiling and submerge the instrument in cold water (<40°C) as soon as possible after use.

Do not use a fixating detergent or hot water (>40°C) as these can cause fixation of biological residues and hinder the effectiveness of reprocessing.

Safe storage and transportation in a closed container to the reprocessing area is advised for the safety of clinical associates, to avoid instrument damage, and to minimize contamination of the clinical environment.

9 Manual Pre-Cleaning

(*See Scanturian® Addendum for Scanturian® reprocessing instructions*)

Instruments must be manually pre-cleaned prior to Automated Cleaning. Certain instruments must be disassembled prior to cleaning. Particular attention must be made to the hidden surfaces of instruments, including lumens, and sliding shafts. Refer to Section 19 of this document for a list of Scanlan instruments that can be disassembled. Brushes or stylets must be used when cleaning the interior surfaces of suction instruments.

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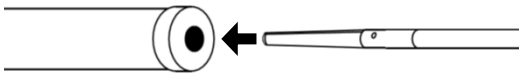
Step	Description	Temperature	Time
1	Submerge instrument in cold tap water for at least five (5) minutes. While submerged, articulate the instrument at least ten (10) times. Take care that the interior of luminal devices are filled with water.	10°C to 25°C	≥5 min
2	Brush the instrument in cold tap water with a soft-bristled nylon brush for at least thirty (30) seconds, removing all visible contamination. Brush any lumens, threads, and holes.	10°C to 25°C	≥30 sec
3	Spray all surfaces of the instrument for at least thirty (30) seconds with a stream of pressurized water, such as a water jet pistol (1.5 to 2.0 bar / 22 to 30 psi) in cold tap water. Flush the interior of luminal instruments for at least thirty (30) additional seconds.	10°C to 25°C	≥30 sec
4	Place the instrument in an ultrasonic bath (~35kHz) with alkaline or enzymatic detergent***** at 38 to 42°C for at least fifteen (15) minutes. Take care that the interior of luminal devices are filled with water. **Warning:** Ultrasonic cleaning the detachable SCANLAN® MEMORY Mirror will cause permanent damage.	38°C to 42°C	≥15 min
5	Rinse instrument with cold running tap water for at least fifteen (15) seconds	10°C to 25°C	≥15 sec
	***Note:** Prepare detergent solution according to manufacturer recommendation		

10 Automated Cleaning

Instruments

Step	Description	Temperature	Time
	Place instruments on the washer-disinfector rack. Sliding shaft and luminal instruments should use an MIS rack. Insert the distal end of the instrument into the holder as shown below:  If present, connect flush lines to luer ports. A program with the following parameters should be used for automated cleaning. If possible, instruments must be reprocessed in an open or disassembled state:		
1	At least two (2) minutes pre-cleaning with cold tap water. Drain.	10°C to 25°C	≥2 min
2	At least five (5) minutes cleaning with alkaline or enzymatic detergent***** at setpoint of 50°C. Drain.	50°C ±5°C	≥5 min
3	Rinse 1: At least three (3) minutes rinse with cold deionized water. Drain. Can be used as a neutralization step if required by the detergent manufacturer.	10°C to 25°C	≥3 min
4	Rinse 2: At least two (2) minutes rinse with cold deionized water. Drain.	10°C to 25°C	≥2 min
	***Note:** Prepare detergent solution according to manufacturer recommendation		

Sterilization Trays

Step	Description	Temperature	Time
	Disassemble tray, as applicable, and place tray parts on the appropriate rack for the washer-disinfector. A program with the following parameters should be used for automated cleaning. Do NOT stack tray parts on top of one another:		
1	At least two (2) minutes pre-cleaning with cold tap water. Drain.	10°C to 25°C	≥2 min

2	At least ten (10) minutes cleaning with alkaline or enzymatic detergent† at setpoint of 50°C. Drain.	50°C ±5°C	≥10 min
3	At least three (3) minutes rinse with cold deionized water. Drain. If required by the detergent manufacturer, use this as the neutralization step.	10°C to 25°C	≥3 min
4	At least two (2) minutes rinse with cold deionized water. Drain.	10°C to 25°C	≥2 min
	†**Note:** Prepare detergent solution according to manufacturer recommendation		
	†**Note:** Enzymatic detergent may not have the same level of effectiveness as alkaline detergent.		

11 Thermal Disinfection

Thermal disinfection is commonly programmed before the conclusion of an automated washer/disinfector cycle. The following automated washer/disinfector parameters were used to achieve an A_0 value of not less than 3,000.

Description	Temperature	Time
Standalone process or as part of an automated washer/disinfector cycle:		
At least five (5) minutes of thermal disinfection at 90°C with deionized water. Drain.	≥90°C	≥5 min

Note: Consider national regulations in regard to A_0-Values (See ISO 15883) as requirements may vary.

12 Drying

Dry the instrument through the drying cycle of washer / disinfector using the following parameters:

Description	Temperature	Time
Standalone process or as part of an automated washer/disinfector cycle:		
At least fifteen (15) minutes drying at 115°C	≥115°C	≥15 min

If needed, additional manual drying can be performed with a lint free towel. Bores or lumens of instruments can be dried by using sterile compressed air.

13 Inspection, Maintenance, and Testing

Inspection

- Inspect for cleanliness. 10X magnification may be utilized. Particular attention must be made to the hidden surfaces of instruments, including lumens, and sliding shafts. If necessary, perform reprocessing procedures again until the instruments are clean.
- Inspect each device for damage, excessive wear, fractures, or missing parts and residual soil accumulation. If damage or wear is observed that might impact function of the device, return to a Scanlan authorized facility for assessment, refurbishment, or replacement. See section 16 for instructions to send instruments to a Scanlan authorized facility.
- Functionally inspect each device for smooth actuation when used as intended. Inadequate function may be an indication of improper cleaning, residual soil accumulation or wear. Evidence of damage and excessive wear on the device may include corrosion (rust, pitting), discoloration, excessive scratches, flaking, wear, and cracks.
- If applicable, visually inspect accessory items such as identification or color-coding systems for wear. Refer to manufacturer's instructions for maintenance of instrument accessory items.

Improperly functioning devices, devices with unrecognizable markings, missing or removed part numbers, damaged, or showing excessive wear should not be used.

Return devices that inadequately function to a Scanlan authorized facility for assessment, refurbishment, or replacement. See section 16 for instructions to send instruments to a Scanlan authorized facility. Do not use devices repaired or serviced by a facility not authorized by Scanlan International.

Maintenance

Have SCANLAN® instruments repaired, refurbished, or sharpened only by a Scanlan authorized facility. See section 16 for instructions to send instruments to a Scanlan authorized facility.

Scanlan can provide safe and appropriate instrument identification marking system(s) upon request. Do not use a mechanical engraver to mark the instrument.

Be certain all delicate tipped instruments are covered with a device specially designed for instrument protection (such as SCANLAN® Tip-Guard™ instrument protectors) during storage and sterilization.

Lubrication

An antimicrobial water-soluble instrument lubricant may be used, as needed after cleaning and prior to sterilization.

Testing

Assemble (if necessary) and verify functional performance according to intended use.

Refer to Section 18, of this document for a list of Scanlan instruments that are intended to be disassembled for reprocessing and assembled for use.

14 Sterilization

Packaging

Use appropriate packaging for sterilization according to one or more of the following applicable standards: ISO 17665-1, ISO 11607-1, and EN 868.

Single devices may be packaged in an approved (e.g. FDA cleared or ISO 11607-1 compliant) medical grade sterilization pouch or wrap. Use care when packaging so that the pouch or wrap is not torn.

Instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607-1 compliant) general-use perforated tray or case with other devices under the following conditions:

- The container manufacturer's recommendations should be followed regarding preparation, maintenance, and use of the container.
- Arrange instruments to permit steam access on all surfaces. Ensure instruments are in open position or are disassembled. One exception would be temporary occlusion clips which are normally closed (i.e. spring shut).

Instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607-1 compliant) rigid container system (with filters or valves) with other devices under the following conditions:

- The container manufacturer's recommendations should be followed regarding preparation, maintenance, and use of the container.
- Arrange instruments to permit steam access on all surfaces. Ensure instruments are in open position or are disassembled. One exception would be temporary occlusion clips which are normally closed (i.e. spring shut).

Process / Equipment

Sterilize Scanlan® surgical instruments using a steam sterilizer, calibrated, and validated per EN 285/ISO 17665-1, by performing one of the following validated autoclave cycles:

Cycle	Cycle Description	Exposure Temperature	Exposure Time	Drying Time
A	Pre-vacuum phases: 3	132 to 134°C	4 min	≥10 min
B		134 to 137°C	3 min	

15 Storage

Instruments should always be sterilized and stored in an ”open” and unlocked position. This increases the life of the instrument, prevents possible breakage, and is recommended by established standards.

Sterile packaged instruments should be stored in a controlled area that is well ventilated providing protection from dust, moisture, pests, and temperature/humidity extremes in accordance with AAMI/ANSI ST79.

Inspect every package before use to ensure that the sterile barrier (e.g. wrap, pouch, or filter) is not compromised. If the sterile barrier appears compromised, the contents are considered non-sterile and should be reprocessed through cleaning, packaging, and sterilization.

16 Repair and Refurbishment

To ensure your SCANLAN® instrument continues to perform as intended, have it repaired and refurbished by a Scanlan authorized facility. Contact the Scanlan Customer Service team for assistance sending instruments to a Scanlan authorized facility.

Please make sure all items are DECONTAMINATED and affix a Certificate of Decontamination to the outside of the shipping package in a clear plastic packing list holder. SCANLAN® instruments which have been processed per this document are considered decontaminated. The latest instructions may be obtained at: www.scanlaninternational.com.

If for whatever reason, the instrument cannot be fully decontaminated, it must be handled in a safe manner to prevent the spread of possible infection. Appropriate Personal Protective Equipment (PPE), (e.g. gloves, gown, and face shield), are to be worn. The instrument is to be placed in a leak and puncture proof container and labeled as biohazard. Instruments should be individually packaged, using original packaging, if possible, to prevent damage during the shipping process. Items must be shipped in accordance with applicable local, national, and international regulations. Contact the Scanlan Customer Service team for assistance.

17 Reprocessing Validation Study Information

Cleaning and sterilization validations supporting the reprocessing methods below were performed by an ISO 17025 accredited, independent laboratory following industry standards and guidelines.

The following equipment and materials were used to validate the cleaning process:

Detergent	Groups	Identification
Alkaline	All	0.5 % neodisher MediClean forte (Chemische Fabrik Dr. Weigert GmbH & Co. KG, REF 405033)
Enzymatic		0.5 % neodisher MediZym (Chemische Fabrik Dr. Weigert GmbH & Co. KG, REF 404033)

Equipment	Groups	Identification
Washer / Disinfector	1 – 6	Miele Professional G 7836 CD
	7	Steelco DS1000
Instrument Rack	1 – 6	MIS rack (Miele G 7836 CD) E450
	7	4-level rack (Steelco DS1000) C100W
Ultrasonic Cleaner	1 – 6	Bandelin Sonorex RK 1028 H

The following equipment was used to validate the sterilization process:

Equipment	Identification
Autoclave	Selectomat HP 666-1HR (MMM)
Heat Sealer	hawo HM 2010 DC

This document should be used in addition to any product information supplied with the instrument to be reprocessed.

It is the responsibility of the user to validate their processing methods. Many different combinations of detergents, equipment, and processes may be suitable for reprocessing Scanlan® instrumentation. This document does not disqualify reprocessing methods validated by the user.

It is the responsibility of the user to ensure that the reprocessing procedures including resources, materials, and personnel are capable of reaching the required results. Regulatory requirements compel the end user to properly control, validate, and maintain their equipment, processes, and resources.

18 Standards and Guidelines

The reprocessing validations were based upon the following standards and guidelines:

Ref #	Document #	Title
1	Alfa et al AJIC 1999	Alfa MJ, DeGagne P, Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning
2	AAMI TIR 12	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
3*	AAMI TIR 30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical device
4	ANSI/AAMI ST79	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
5	ANSI/AAMI ST81	Sterilization of medical devices–Information to be provided by the manufacturer for the processing of resterilizable medical devices
6	DGKH Recommendation: Moist heat	DGKH recommendations for the validation and routine monitoring of sterilization processes with moist heat for medical devices, July 2009
7	DGKH, DGSV and AKI	Guideline for Validation of Manual Cleaning and Manual Chemical Disinfection of Medical Devices – DGKH, DGSV, AKI in cooperation with VAH (2013)
8	DIN EN 285	Sterilization – Steam sterilizers – Large sterilizers
9	DIN EN 556-1	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices
10	DIN EN 556-1 Corrigendum 1: 2006-12	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices Corrigenda to DIN EN 556-1: 2002-03
11	DIN EN ISO 11138-1	Sterilization of health care products – Biological indicators – Part 1: General requirements
12	DIN EN ISO 11138-3	Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes
13	DIN EN ISO 11607-1	Packaging for terminally sterilized medical devices; Part 1: Requirements for materials, sterile barrier systems and packaging systems
14	DIN EN ISO 11737-1	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
15	DIN EN ISO 11737-2	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Ref #	Document #	Title
16	DIN EN ISO 14937	Sterilization of health care products – general criteria for characterization of a sterilizing agent and development, validation and routine control of a sterilization process
17‡	DIN EN ISO 15883-1	Washer-disinfectors – Part 1: General requirements, terms and definitions and tests
18‡	DIN EN ISO 15883-2	Washer-disinfectors – Part 2: Cleaning disinfection devices
19	DIN ISO/TS 15883-5	Washer-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy
20	DIN EN ISO 17664	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664:2017)
21	DIN EN ISO 17665-1	Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
22	DIN ISO/TS 17665-2	Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1
23	FDA guideline	Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff, June 9, 2017
24§	Guideline of DGKH, DGSV and AKI, thermostable devices	Guideline of DGKH, DGSV und AKI for the validation and routine control of automated cleaning and disinfection processes for thermostable medical devices, Zentralsterilisation Suppl. 2017
25	ISO 14937	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices
26	ISO 15883-1	Washer-disinfectors, Part 1: General requirements, terms and definitions and tests
27	ISO 15883-2	Washer-disinfectors, Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
28	ISO 17664	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
29	ISO 17665-1	Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routing control of a sterilization process for medical devices
30†	KRINKO-BfArM-Recommendation Reprocessing Medical Devices	Hygiene requirements for the reprocessing of medical devices – recommendation of Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) Bundesgesundheitsbl. 2012, 55 :1244-1310

19 Instruments Requiring Disassembly

Instruments	Catalog Numbers			
Retractors	8008-41, -42, -43, -45, -46, 47, -54, -55, -81, -903, -905			
Sundt™ Graduated Suction Sets	9009-940, -950, -960, -970, -980, -990			
Reusable AV Punch	1001-03, -04, -05, -06			
Memory Instruments	8008-410, -420			
Sterilization Trays	2081-11, -12, -21, -23, -24	2135-03, -04	2142-03	2151-03
	2082-10, -20	2138-01, -03	2145-02, -03	2160-03
	2083-01, -02, -03, -05, -16, -19	2139-03	2146-03	2161-03
	2133-03	2140-01, -03	2150-03	9009-934

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Scanturian® Addendum

20 Scanturian® Manual Pre-Cleaning

Scanturian® Instruments must be manually pre-cleaned prior to Automated Cleaning.

Step	Description	Temperature	Time
1	Internal lumens should be slowly pre-flushed (approximately 3cc/second) through luer four (4) times with enzymatic detergent* using an appropriately sized syringe with at least at 50cc of detergent using the flush port.	ambient	17 sec per 50cc flush
2	Immerse the instrument in a bath with alkaline or enzymatic detergent* for a minimum of five (5) minutes at approximately 40°C.	40°C	5 min
3	After soaking, the MIS internal lumens should be slowly flushed (approximately 3cc/second) through luer four (4) times with enzymatic detergent* then four (4) times with clean water using an appropriately sized syringe connected to the flush port.	ambient	17 sec per 50cc flush
4	The instrument is taken out of the bath and rinsed with cold demineralized water for fifteen (15) seconds.	10°C to 25°C	15 sec
	***Note:** Prepare detergent solution according to manufacturer recommendations		

21 Scanturian® Automated Cleaning

Step	Description	Temperature	Time
	A) Place instruments in open state on instrument tray; place tray on instrument rack in washer disinfector and start cycle –OR– B) Place instruments in an open state on a special keyhole surgery rack. Instruments not suited are placed on an instrument tray below; start cycle. Automatic washers can cause damage to delicate SCANLAN® instrumentation if care is not taken. Instruments should not be allowed to contact other instruments or hard surfaces within the washer, preventing damage.		
1	One (1) minute pre-cleaning with cold water. Drain.	10°C to 25°C	1 min
2	Three (3) minute pre-cleaning with cold water. Drain.	10°C to 25°C	3 min
3	Five (5) minute cleaning with alkaline detergent* at 55°C or with enzymatic detergent* at 45°C. Drain.	alkaline 55°C enzyme 45°C	5 min
4	Three (3) minute neutralization with warm water (>40°C) and neutralizer. Drain.	>40°C	3 min
5	Two (2) minute rinse with warm water (>40°C). Drain.	>40°C	2 min
	***Note:** Please follow the operation instructions of the detergent manufacturer.		

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22 Scanturian® Reprocessing Validation Study Information

Cleaning and sterilization validations supporting the reprocessing methods below were performed by an ISO 17025 accredited, independent laboratory following industry standards and guidelines.

The following equipment and materials were used to validate the cleaning process:

Detergent	Identification
Alkaline	0.2 % Neodisher FA (Dr. Weigert)
Enzymatic	0.8 % Endozime (Ruhof Corp.)
Neutralizer	0.1 % Neodisher Z (Dr. Weigert)

Equipment	Identification
Washer / Disinfector	HAMO, LS-1000
Instrument Rack	not specified

The following equipment was used to validate the sterilization process:

Equipment	Identification
Autoclave	Consolidated Sterilizer Systems SR-24A-ADVPRO

This document should be used in addition to any product information supplied with the instrument to be reprocessed.

It is the responsibility of the user to validate their processing methods. Many different combinations of detergents, equipment, and processes may be suitable for reprocessing Scanlan® instrumentation. This document does not disqualify reprocessing methods validated by the user.

It is the responsibility of the user to ensure that the reprocessing procedures including resources, materials, and personnel are capable of reaching the required results. Regulatory requirements compel the end user to properly control, validate, and maintain their equipment, processes, and resources.

23 Scanturian® Standards and Guidelines

The reprocessing validations were based upon the following standards and guidelines:

Ref #	Document #	Title
1	AAMI TIR12	Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers, 7 September 2010.
2	AAMI TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical device
3	ANSI/AAMI/ISO 11138-1	Sterilization of Health Care Products – Biological Indicators - Part 1: General Requirements.
4	ANSI/AAMI/ISO 11138-3	Sterilization of Health Care Products – Biological Indicators - Part 3: Biological Indicators for Moist Heat Sterilization Processes.
5	ANSI/AAMI/ISO 11607-1	Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging, Amendment 1.
6	ANSI/AAMI/ISO 11607-1	Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging.
7	ISO 15883-1	Washer-disinfectors, Part 1: General requirements, terms and definitions and tests

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Ref #	Document #	Title
8	ISO 15883-5	Washer-disinfectors -- Part 5: Test soils and method for demonstrating cleaning efficacy
9	ANSI/AAMI/ISO 17665-1	Sterilization of Health Care Products – Moist Heat - Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices.
10	ANSI/AAMI ST79	Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
11	FDA Guidance March 17, 2015	Guidance for Industry and Food and Drug Administration Staff, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Document issued on March 17, 2015, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluations.
12	ISO 17664	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
13	USP <1035>	United States Pharmacopeia 42, National Formulary 37, 2019. <1035> Biological Indicators for Sterilization.