STABILIZORTHO

Cleaning, Sterilization, Inspection & Maintenance Instructions

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Introduction

This document contains instructions for processing reusable surgical instruments provided by Stabiliz Orthopaedics. All Stabiliz Orthopaedics reusable instruments must be cleaned and sterilized prior to use.

This document contains assembly and disassembly instructions for multi-component reusable instruments that must be disassembled, cleaned and sterilized prior to use.

Stabiliz Orthopaedics has validated the process provided in these instructions as adequate when implemented correctly. Equipment, operators, cleaning agents and procedures all contribute to processing efficacy. The processing facility should ensure that the selected processing steps are safe and effective.

While alternative processing methods beyond those described herein may be effective, such alternative methods may only be used if validated by the healthcare facility. In the case of conflicting national cleaning and sterilization standards, those standards shall take precedence over instructions provided by Stabiliz Orthopaedics.

This document also provides instructions for inspection to determine when an instrument has reached the end of its serviceable life and must be replaced.

Warnings and Precautions

Please note that single use devices, such as k-wires and implants, should not be reused as their performance cannot be assured beyond the initial use.

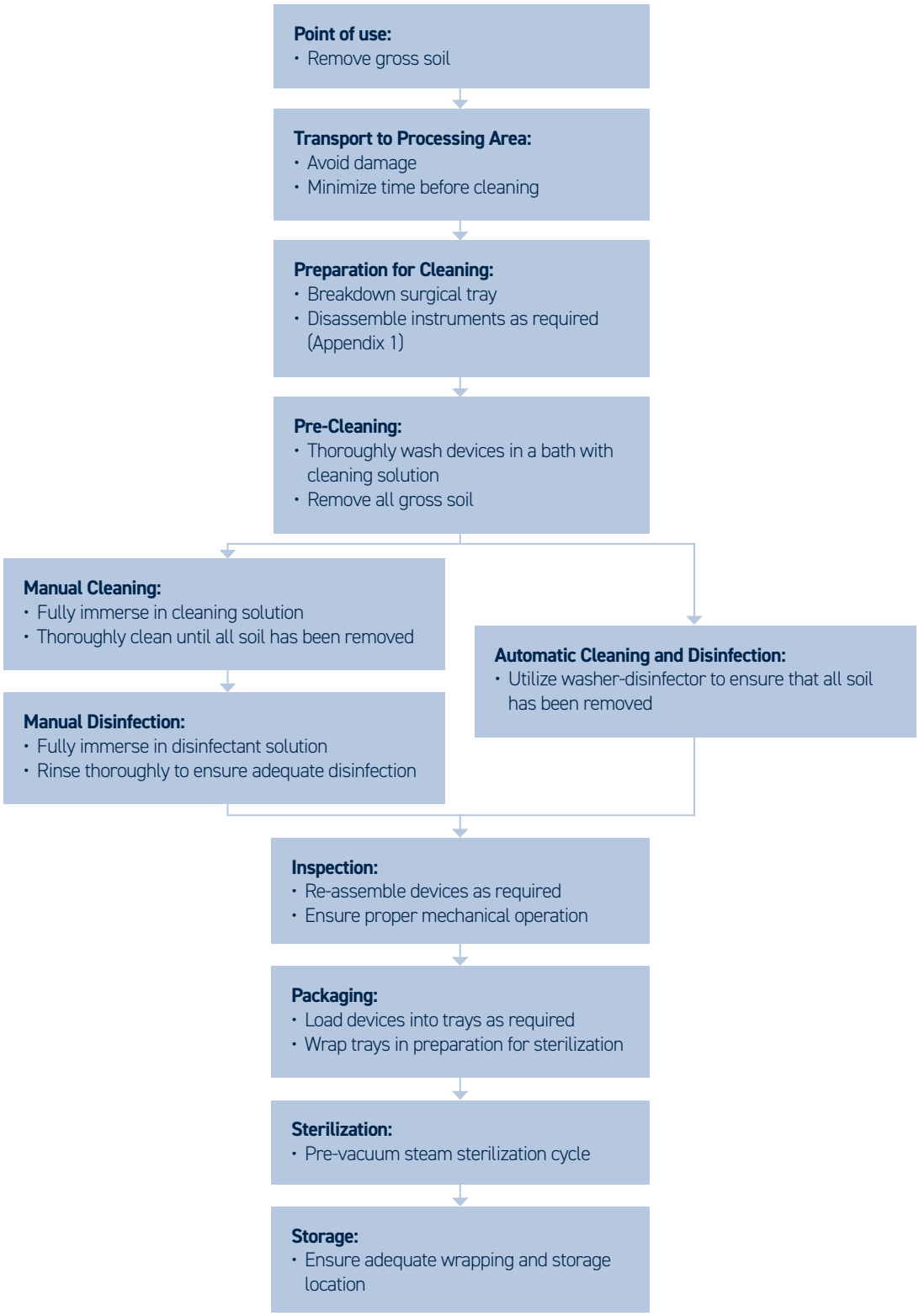
Repeated use, cleaning, and re-sterilization of instruments and repeated re-sterilization of implants may result in mechanical and/or physical changes that can compromise product integrity and/or performance. Please refer to device labels to identify reusable components.

The procedure contained herein is NOT intended to denature, or render inactive, prions or prion related diseases.

Cleaning

The following is a general procedure intended to prepare multi-use instruments for use or to prepare new devices for initial use.[1,2]

This procedure must be followed in its entirety. Detailed instructions are contained in the sections that follow this diagram.



1 The SPL Locking Screw is provided sterile and cannot be re-sterilized. All other Stabiliz Fixation System components are provided non-sterile.

2 SimpliFix Hip System implants are provided sterile. Drills and pins may be provided sterile or non-sterile. All other SimpliFix components are provided non-sterile.

Processing Instructions

Processing instructions for reusable devices provides for both a Manual and Automated method for cleaning and disinfection. Whenever possible the automated method should be used as the cleaning process as it is more reproducible and more reliable; with staff potentially less exposed to the contaminated devices and cleaning agents.

Regardless of the cleaning method used, staff should always use adequate personal protective clothing and equipment in accordance with the recommendations put forth by the manufacturer of the cleaning agent that is used.

Failure to observe the detergent manufacturer's guidance regarding concentrations, temperatures, or rinsing may cause undesirable results and may irreversibly damage devices.

Specific cleaning and/or disinfecting agents are not recommended due to the varying availability of such products.

It is recommended that only sterile water or freshly prepared purified water with less than 100 cfu/ml and 0.5 EU/ml be used for the dilution of cleaning/disinfecting agents and for rinsing reusable instruments. Please note that failure to use adequate water as stated above, including the use of hard water, may result in staining of the device and/or impede effective cleaning and disinfection.

Point of Use: Remove all gross soil within two hours, post-operatively. Gross soil may be removed using absorbent paper wipes. Devices should be intensively rinsed with fluent water or transferred into a bath utilizing an aldehyde-free disinfectant solution.

Transport to Processing Area: Transport devices to the appropriate cleaning area as soon as possible. Consider covering reusable devices with a damp cloth to avoid drying of soil if transport is delayed. Ensure that devices are treated delicately to prevent mechanical damage, as well as, personal injury. Heavy instruments should be kept separate from delicate ones and particular attention should be paid to cutting edges.

Preparation for Cleaning: Instructions for devices requiring disassembly are provided in Appendix 1

Required Equipment:

- Bath or vessel of adequate size to permit full immersion of devices
- Cleaning solution using an agent that is intended for manual cleaning and prepared per the manufacturer's instructions
- Soft brushes, firm brushes, and bottle brushes or cleaning wires
- Personal protective equipment per the recommendations of the cleaning agent's manufacturer
- Lint-free single use wipes
- Syringes of adequate size for flushing cannulations and any potential soil traps

Caution: ***Do NOT use steel wool and/or metal brushes to clean devices.***

Pre-Cleaning

- Remove gross soil by wiping with cleaning solution
- Immerse re-usable device in cleaning solution
- Confirm that all surfaces are thoroughly soaked
- A syringe may be used to ensure that the cleaning solution reaches all cannulated parts
- Be sure no air is trapped within the device when immersing in solution
- Be sure to soak for detergent manufacturer's minimum recommended time
- Soft bristle brushes may be used to thoroughly clean reusable devices
- Particular attention should be given to rough surfaces and features where soil may be trapped.
- Firm bristle brushes may be used to cleaning bone-cutting features such as drill tips
- An appropriate diameter and length bottle brush may be used for cannulations, confirm that the brush passes the whole length of the cannulation
- Operate articulating devices and those with moving parts
- Rinse in running water until all cleaning solution is removed
- Give attention to cannulations, blind holes and hinges/joints between mating parts
- Visually inspect for any remaining soil and repeat the steps above, if necessary
- Allow to drain on absorbent paper or transfer immediately to cleaning ste

Manual Cleaning

Required Equipment:

- Ultrasonic bath of adequate size to permit full immersion of the re-usable device. (Follow the operation instructions provided by the ultrasonic bath manufacturer. Do not exceed the temperature stated by the detergent manufacturer.)
- Cleaning agent intended for manual cleaning and suitable for ultrasonic treatment. Do not exceed the concentration specified by the detergent manufacturer.
- Suitable brushes or cleaning wires to reach all parts of the device
- Syringes
- Highly purified water or sterile water for rinsing purpose.

Procedure

- Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified by the detergent manufacturer
- Immerse the device completely and activate the bath for minimum of 15 minutes per bath manufacturer's instructions
- Using suitable brushes or cleaning wires, clean the device paying particular attention to rough surfaces and features that may be shielded from the brushing action
- Rinse for at least 1 minute in running water until all cleaning solution is removed. Pay particular attention to cannulations, blind holes and hinges/joints between mating parts. Rinse cannulations at least three times with a syringe (volume 1-50ml)
- If soil remains on device after completion of ultrasonic bath cleaning, the cleaning step must be repeated as described above

Manual Disinfenction

Required Equipment:

- Bath of adequate size to permit full immersion of the device as well as temperature regulation per the detergent manufacturer's instructions
- Disinfectant for manual disinfection, compatible with detergent used and in proper concentration (per the detergent manufacturer's instructions)
- Syringes of adequate size for the channels to be rinsed
- Highly purified water or sterile water for rinsing purposes
- Medical grade compressed air and/or clean, lint-free single use wipes

Procedure

- Prepare a bath with a disinfectant solution using the concentration and temperature per the detergent manufacturer's instructions
- Fully immerse the device into the bath for at least the minimum period of time specified by the detergent manufacturer
- Rinse cannulations, grooves, and any soil traps at least three times with a syringe
- Rinse the device with running purified or sterile water for at least one minute ensuring that all detergent has been removed. Rinse cannulations, blind holes and hinges/joints with a syringe a minimum of five times.
- Dry the reusable devices using medical grade compressed air or clean, lint-free single use wipes
- Should additional drying be required, lay instruments in a clean area to dry
- Visually inspect for any remaining soil. Repeat manual cleaning and disinfection, if necessary

Automated Cleaning & Disinfection

Required Equipment:

- Approved washer/disinfector (e.g. CE mark or FDA approval according to ISO 15883) properly installed, validated and regularly maintained and tested
- Approved thermal disinfection program, including proper rinsing steps (A0 value greater than or equal to 3,000 or application of at least 5 minutes at 90 °C)
- Cleaning agent for use in washer/disinfector using the concentration and temperature per the detergent manufacturer's instructions

Caution: ***Chemical disinfection is NOT recommended due to the potential for chemical residues to remain on the instruments. These residues could interfere with sterilization efficacy.***

Procedure

- Load re-usable instruments into washer/disinfector
- Connect cannulations to rinsing ports of washer/disinfector. Locate cannulations directly on injector jets or in injector sleeves of the injector basket if direct connection is not possible
- Avoid contact between devices as movement during washing could cause damage and/or obstruction to washing
- Arrange reusable instruments so cannulations are vertical and blind holes incline downwards, assisting drainage
- Articulating devices should be in the open position
- Complete washer-disinfector cycle
- After completion, unload washer/disinfector. Visually inspect devices for remaining soil and dryness. If soil remains repeat the cleaning process. Remaining wetness may be removed with medical grade compressed air or clean, lint-free single use wipes
- Should additional drying be required, lay instruments in a clean area to dry or heat in an oven below 110 degrees Celsius until dry.

Inspection

Prior to sterilization, the facility must inspect reusable devices for satisfactory function/condition. All devices should be carefully checked for visible soil and/or corrosion. Inspections can typically be performed visually without magnification given sufficient lighting.

- Verify that any potential soil traps including mating surfaces, holes, and cannulations are clean
- Verify that no soil is impacted in device, such as drill flutes adjacent to cutting tip
- Verify that cutting edges are undamaged and sharp
- Verify that no burrs or other sharp edges that could damage tissues and/or gloves have formed due to instrument damage

Functional checks should be performed regularly:

- Mating devices, such as drill guides and depth gauge,s must be checked for proper assembly.
- Instruments with moving parts must be operated to verify satisfactory performance.
- All markings appearing on the instruments, including depth markings and device identifiers, must be legible.
- Rotating instruments, such as drill bits, should be checked for straightness.

Note: ***Stabiliz Orthopaedics does not define the maximum number of uses for reusable devices. Device service life depends on many factors, including method and duration of use and handling between uses. Devices must be carefully inspected and functionally tested before each use to determine the end of serviceable life.***

Packaging

When appropriate, the cleaned, disinfected, and checked reusable devices should be assembled into the dedicated trays provided. Stabiliz Orthopaedics cases/trays should be double wrapped according to AAMI/ CSR technique. The packaging for terminally sterilized reusable instruments should meet the following requirements:

- ISO 11607-1
- CE Mark or FDA clearance
- Suitable for steam sterilization
- Appropriate grade for weight of instrument case

Sterilization

Sterilization Method		
The below recommended process parameters have been validated by the manufacturer for sterilization of this device only in its complete medical device case/tray. Instruments should be sterilized in the mounting configuration provided in the tray. If other products are added to the sterilizer, the recommended parameters are not valid and the processor must establish new parameters.		
Pre-Vacuum	Minimum Exposure Time	4 minutes
	Minimum Temperature	270° F (132° C)
	Minimum Drying Time[1]	30 minutes
[1] Drying times may vary. The processor must validate the appropriate drying time for the sterilizer used.		

Only legally marketed, FDA-cleared sterilization barriers (e.g. wraps, pouches, or containers) should be used for packaging these sterilized devices.

The processor must be responsible to:

- Follow ANSI/AAMI ST77, ANSI/AAMI ST79, ANSI/AAMI ST81
- Follow the manufacturer's operating instructions and maximum load instructions
- Ensure that sterilizer is properly installed, maintained, and calibrated
- Perform ongoing testing to confirm inactivation of all forms of viable microorganisms
- Verify that the sterilizer can achieve the validated process parameters

Any deviation by the processor from the recommendations provided must be properly evaluated for effectiveness and potential adverse consequences.

Caution: ***Stabiliz Orthopaedics does not recommend the use of 'flash' sterilization for reusable devices.***

Warning: ***Single-use implants and instruments should not be re-sterilized.***

Warning: ***Stabiliz Polymer Locking (SPL) Screws are provided sterile and CANNOT be re- sterilized. All other Stabiliz Fixation System components are provided non-sterile.***

Warning: ***SimpliFix Hip System implants and certain instruments are provided sterile. All other SimpliFix components are provided non-sterile.***

Warning: ***Stabiliz Orthopaedics does not recommend the use of rigid containers for steam sterilization as they could limit steam penetration and prevent effective sterilization.***

Storage

Devices that have been sterilized and are ready to be used should be stored in the sterilization wrap in a suitable location that is dry and dust-free.

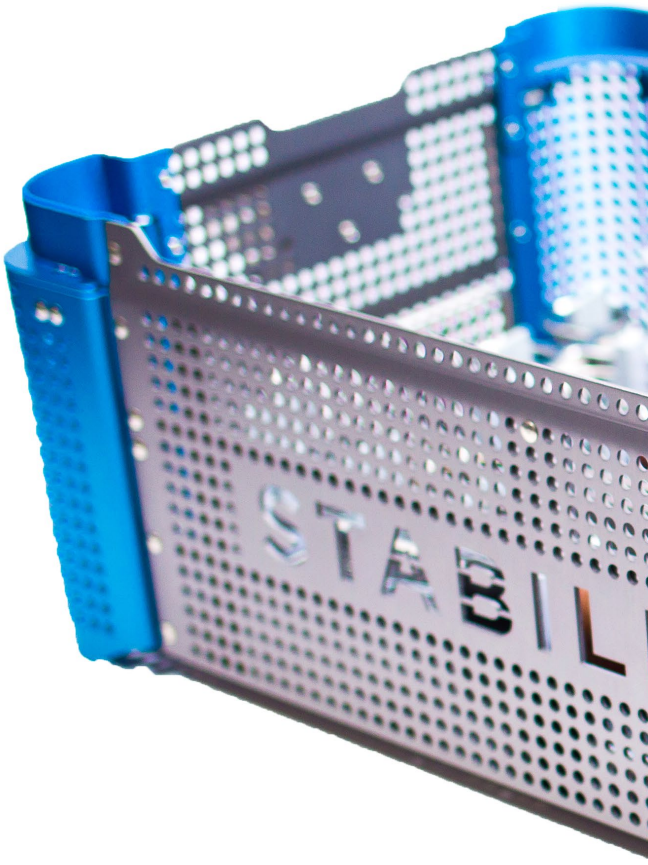
The shelf-life of sterilized devices depends upon the methods and techniques employed, including but not limited to the sterile barrier used, environmental factors and handling techniques. Each facility should define a maximum shelf-life for sterilized devices.

Appendix 1:
Instruments Requiring Disassembly for Cleaning

SKU	Instrument Name	Surgical System	Disassembly Instructions
DVHT.15	Torque Limiting Driver Handle	Stabiliz Fixation System	Pull hex bit from handle
DVHF.00	Standard Driver Handle		Pull hex bit from handle
DRGH.00	Drill Guide Handle		Depress button to remove drill guide. Ensure button is not depressed and is in the up position for cleaning.
DRGT.35.052	3.5mm Threaded Drill Guide, Short		Depress button on drill guide handle (DRGH.00) and pull drill guide
DRGT.35.098	3.5mm Threaded Drill Guide, Long		Depress button on drill guide handle (DRGH.00) and pull drill guide
DRGN.35.052	3.5mm Non-threaded Drill Guide, Short		Depress button on drill guide handle (DRGH.00) and pull drill guide
DRGN.35.098	3.5mm Non-threaded Drill Guide, Long		Depress button on drill guide handle (DRGH.00) and pull drill guide
DRGN.40.052	4.0mm Non-threaded Drill Guide, Short		Depress button on drill guide handle (DRGH.00) and pull drill guide
DRGN.40.098	4.0mm Non-threaded Drill Guide, Long		Depress button on drill guide handle (DRGH.00) and pull drill guide
DPGB.00	Depth Gauge Body		Remove depth gauge hook
DPGH.35.052	Short Depth Gauge Hook		Pull hook below 10mm marking and lift to disengage from depth gauge body
DPGH.35.098	Long Depth Gauge Hook		Pull hook below 10mm marking and lift to disengage from depth gauge body

Appendix 1:
Instruments Requiring Disassembly for Cleaning

SKU	Instrument Name	Surgical System	Disassembly Instructions
DRB.27.270	ø2.7mm Calibrated Drill	SimpliFix Hip System	Pull drill from power drill
DRBC.62.250	Ø6.2mm Cannulated Drill		Pull drill from power drill
DRV.S8.153	SFX Power Driver		Pull driver bit from power drihandle (DVHC.00)
DRV.T8.165	T8 Driver		Pull driver bit from power drill or paddle handle (DVHC.00)
DRV.T8.195	T8 Calibrated Driver		Pull driver bit from power drill or paddle handle (DVHC.00)
DVHC.00	Cannulated Paddle Driver Handle		Pull driver bit from handle
DVHC.01	SFX T-Handle		Pull SFX Retaining Bolt (DVHC.IC) by thumb screw until retaining bolt is completely removed from T-handle
DVHC.IC	SFX Retaining Bolt		Pull SFX Retaining Bolt (DVHC.IC) by thumb screw until retaining bolt is completely removed from T-handle
STA.00	Targeting Arm		Rotate screw sleeve (STA.CSS.37.135) from locked position and pull screw sleeve from targeting arm (STA.00) Unscrew thumb screw (STA.TS.00) from targeting arm (STA.00) Pull retaining clip (STA.RC.00) from targeting arm (STA.00)
STA.TS.00	Targeting Arm, Thumb Screw		Unscrew thumb screw (STA.TS.00) from targeting arm (STA.00)
STA.TRO.140	Targeting Arm, Trocar		Pull trocar (STA.TRO.140) from drill guide (STA.DRG.37.140)
STA.DRG.37.140	Targeting Arm, Drill Guide		Pull drill guide (STA.DRG.37.140) from screw sleeve (STA.CSS.37.135)
STA.CSS.37.135	Targeting Arm, Screw Sleeve		Rotate screw sleeve (STA.CSS.37.135) from locked position and pull screw sleeve from targeting arm (STA.00)



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