Instructions
for Cleaning, Sterilization, Inspection and Maintenance

of Trauma & Extremities Medical Devices
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The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com.
1. Introduction

This document is created based on the requirements of EN ISO 17664, Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices.

This document is intended to give general guidance on how medical devices supplied by one of the Stryker Trauma & Extremities manufacturing locations (see manufacturer addresses in section 6) may be processed to prepare them for use. It also gives instructions for inspection to determine when an instrument has reached the end of its serviceable life and must be replaced.

This document is provided in conjunction with the assembly and disassembly instructions for multi-component instruments which must be disassembled prior to cleaning, and the instructions for use, which come with the products. Stryker Trauma & Extremities has demonstrated the processes described in these instructions to be effective.

Equipment, operators, cleaning agents and procedures all have a contribution to the efficacy of the processing and the healthcare facility should ensure that the combination actually in use results in a medical device which is safe and effective for use. Alternative methods of processing may be equally suitable, however, these must be validated by the end user. In the event of conflicting national cleaning and sterilization requirements, these shall prevail over Stryker Trauma & Extremities’ recommendations. This applies particularly to the different procedures for inactivation of prions.

Warnings and Precautions

- If a single-use device is supplied non-sterile and needs to be sterilized by the customer prior to its first and only use, the appropriate sections of these instructions may be applied unless other specific instructions are provided in the package insert. Cleaning and re-sterilization of a single use device, may compromise the integrity of the design and/or material characteristics.
- Single use devices must not be reused, as they are not designed to perform as intended after the first usage. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use may lead to diminished safety, performance and/or compliance with relevant specifications. Please refer to the device label to identify single or multiple use and/or cleaning and re-sterilization release.
- Stryker Trauma & Extremities medical devices are not normally used in surgical procedures where they contact low or high risk TSE (Transmissible Spongiform Encephalopathies) infective tissue as defined by World Health Organization (WHO), Robert Koch Institute (RKI) etc.. Therefore decontamination procedures with highly aggressive agents [i.e. sodium hydroxide (NaOH), sodium hypochloride (NaOCl)] are not necessary and, for normal processing, are not recommended because material degradation may occur. The sterilization parameters recommended in this document are not intended and not suitable for inactivation of prions.
2. Processing Instructions

The sequence of steps required to prepare medical devices for re-use or to prepare new devices for initial use are summarized in the chart below.

More detailed instructions for each step are given on the following pages.
3. Cleaning

Two methods of cleaning Stryker Trauma & Extremities medical devices are provided in these instructions, a manual method and a method using an automated washer disinfector. Whenever possible the automated method should be used. The automated cleaning process is more reproducible and therefore more reliable, and staff are less exposed to the contaminated devices and the cleaning agents used.

Whichever method is used, staff should use suitable protective clothing and equipment at all times. In particular take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

The guidance concentrations and times for device immersion in the cleaning solutions and/or disinfectants given by the detergent manufacturers shall be observed. If these concentrations and times are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient.

For cleaning or disinfecting medical devices only specifically formulated cleaning agents and/or disinfectants (detergents) should be used.

As not all cleaning agents and disinfectants may be available around the globe, criteria for the selection of appropriate detergents are provided in Appendix 1. A list of cleaning agents and disinfectants which Stryker Trauma & Extremities used in the validation of these processing instructions is also provided in Appendix 1. Stryker Trauma & Extremities does not recommend any specific cleaning and/or disinfection agent. A general description of suitable agents is included in Appendix 1.

The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing medical devices should be carefully considered. Application of freshly prepared purified water/highly purified water or sterile water for rinsing purposes (according to the pharmacopeias) with less than 10 cfu/ml and 0.25 EU/ml is highly recommended.

Mineral residues from hard water as well as higher contamination with microorganisms and endotoxins can result in staining of the device or prevent effective cleaning and decontamination.

Specific instructions for flexible reamers are provided in Appendix 3.

Caution:
Stryker Trauma & Extremities trays are intended for sterilization, transport and storage of medical devices. They are not designed for cleaning and disinfection in the fully equipped state. The devices must be removed from the tray for adequate cleaning results.

Point of use

Directly after application (within a maximum of 2 hours postoperatively) remove gross soil using absorbent paper wipes. Additionally, intensive rinsing of the medical devices with fluent water or transfer of the medical devices into a bath with an aldehyde-free disinfectant solution meeting the criteria given in Appendix 1 is highly recommended.

Transport to processing area

Avoid mechanical damage, e.g. do not mix heavy devices with delicate ones. Pay particular attention to cutting edges, both to avoid injury and damage to the medical device. Get the medical devices to the point where cleaning is to be performed as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the medical devices with a damp cloth or store the medical devices in closed boxes to avoid drying of soil.

Preparation for cleaning

Disassemble the device where required. See instructions provided in the operative technique or separate information available from your Stryker representative.

Pre-Cleaning

Remark:
The pre-cleaning step can be omitted in case of direct subsequent manual cleaning and disinfection. In case of highly contaminated medical devices to be subjected to an automatic cleaning process, pre-cleaning in an ultrasonic bath is recommended.

Equipment required:
- Cleaning bath or vessel large enough to allow complete immersion of the instruments.
- Freshly prepared cleaning solution using a cleaning agent intended for manual cleaning which meets the criteria given in Appendix 1, with concentration, temperature, and soaking time not less than specified in the detergent manufacturer’s instructions (but temperature not exceeding 50 °C)
- Brushes – soft and firm, bottle brushes or cleaning wires for cannulations etc.
- Personal protective equipment as recommended by the cleaning agent supplier (minimum overalls, gloves, face/eye shield)
- Absorbent paper
- Syringes (volumes 1 to 50 ml depending on the size of the cannulations to be rinsed)

Caution:
Never use metal brushes or steel wool for cleaning.
3. Cleaning

Procedure
- Immerse medical device in solution of cleaning agent.
- Remove gross soil using paper wipes and solution of cleaning agent.
- Ensure that all surfaces are thoroughly wetted, using a syringe to ensure that solution reaches all parts of cannulations etc. Ensure that air is not trapped within features of the device when immersing in the solution.
- Soak at minimum for the time recommended by the detergent manufacturer(s) instructions.

Using suitable brushes (only soft brushes, never metal brushes or steel wool) or cleaning wires clean the medical device thoroughly paying particular attention to rough surfaces and features where soil may be shielded from the brushing.
- Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes and the teeth of broaches.
- Use a bottle brush of appropriate diameter for cannulations. Ensure that the brush passes the whole length of each cannulation at least three times.

Remote articulating devices and those with moving parts.
- Rinse in running water for at least 1 min until all traces of cleaning solution are removed.
- Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. At least three times complete rinsing by application of a syringe (volume 1-50 ml) is required.
- Visually inspect for any remaining soil and repeat the steps above if necessary.
- Allow to drain on absorbent paper or transfer immediately to cleaning step.

Manual cleaning and disinfection

Cleaning

Equipment required:
- Ultrasonic bath large enough to allow complete immersion of the medical device. Frequency 25 – 50 kHz, temperature according to detergent manufacturer(s) instructions.
- Cleaning agent intended for manual cleaning and suitable for ultrasonic treatment which meets the criteria given in Appendix 1; concentration as specified in detergent manufacturer(s) instructions.
- Suitable brushes (only soft brushes, never metal brushes or steel wool) or cleaning wires (for small channels) to reach all parts of the device.
- Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed)
- Freshly prepared purified water/highly purified water or sterile water for rinsing purposes.

Procedure:
- Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified in the detergent manufacturer(s) instructions.
- Immerse the device completely and activate the bath for at least 15 minutes.
- Using suitable brushes (only soft brushes, never metal brushes or steel wool) or cleaning wires (for small channels) clean the device paying particular attention to rough surfaces and features that may be shielded from the brushing action. Additionally, pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. Rinse cannulations at least three times with a syringe (volume 1-50ml).
- If, after completion of the cleaning step in the ultrasonic bath, encrusted soil remained on the device which had to be removed with the brush, the cleaning step must be repeated as described above.
- Rinse for at least 1 min in running water of the specified quality until all traces of cleaning solution are removed. Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts.
3. Cleaning

Disinfection

Equipment required:
- Bath large enough to allow complete immersion of the medical device, temperature according to detergent manufacturer’s instructions.
- Disinfectant intended for manual disinfection and compatible with the applied cleaning detergent which meets the criteria given in Appendix 1; concentration according to the detergent manufacturer’s instructions.
- Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed).
- Freshly prepared purified water/highly purified water or sterile water for rinsing purposes.
- Filtered medical compressed air (if available) or clean and lint-free single use wipes.

Procedure:
- Prepare a bath with a disinfectant solution at the concentration and temperature specified in the detergent manufacturer’s instructions.
- Immerse the device completely for at least the time specified in the detergent manufacturer’s instructions.
- Rinse cannulations at least three times with a syringe.
- Rinse for at least 1 min in running water of the specified quality until all traces of disinfectant solution are removed. Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. Rinse at least five times with a syringe (volume 1-50ml).
- Dry the medical device using medical compressed air and clean and lint-free single use wipes (if required supplemented by post-drying at a clean place for up to 2 hours) or by heating in an oven below 110°C.
- Visually inspect and repeat complete manual cleaning and disinfection if necessary.

Automated cleaning and disinfection using washer-disinfector (recommended)

Equipment required:
- Washer-disinfector with fundamentally approved efficiency (e.g. CE mark or FDA approval according to ISO 15883 series), properly installed, qualified and regularly subjected to maintenance and testing
- Approved thermal disinfection program (A0 value > 3000 or – in case of older devices – application of at least 5 min at 90 °C; chemical disinfection program not recommended due to danger of remnants of the disinfectant on the instruments) with sufficient rinsing steps and filtered air for an active drying program (application of rinsing aids not recommended, danger of remnants)
- Final rinsing/disinfection only with freshly prepared purified water/highly purified water
- Cleaning agent intended for automated cleaning which meets the criteria given in Appendix 1, concentration as specified in the detergent manufacturer’s instructions.

Procedure:
- Load the medical devices into the washer-disinfector.
- Connect cannulations to the rinsing ports of the washer-disinfector. If no direct connection is possible, locate the cannulations directly on injector jets or in injector sleeves of the injector basket.
- Avoid contact between devices (movement during washing could cause damage, and washing action could be obstructed).
- Arrange medical devices so that cannulations are not horizontal and blind holes incline downwards (to assist drainage).
- Articulating devices should be in the open position.
- Operate the washer-disinfector cycle.
- On completion unload the washer-disinfector. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process including the pre-cleaning stage. Remaining wetness may be removed with medical grade compressed air, clean and lint-free single use wipes (if required supplemented by post-drying at a clean place for up to 2 hours) or by heating in an oven below 110°C.
- Chemical disinfection programs are not recommended due to the potential for chemical residues to remain on the instruments. These residues could interfere with sterilization efficacy.
3. Cleaning

Inspection

Before preparing for sterilization, all medical devices should be inspected. Generally un-magnified visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion.

Particular attention should be paid to:
- Soil “traps” such as mating surfaces, hinges, shafts of flexible reamers.
- Recessed features (holes, cannulations).
- Features where soil may be pressed into contact with the device, e.g. drill flutes adjacent to the cutting tip, sides of teeth on broaches and rasps.
- Cutting edges should be checked for sharpness and damage.

Functional checks should be performed where possible:
- Mating devices should be checked for proper assembly.
- Medical devices with moving parts should be operated to check correct operation (medical grade lubricating oil suitable for steam sterilization can be applied as required).
- Rotating instruments (e.g. multiple use drill bits, reamers) should be checked for straightness (this can be achieved by simply rolling the instrument on a flat surface).
- “Flexible” instruments, e.g. IM reamers, should be checked for damage to the spiral element.*

Note:
Detachable Drawer Trays may require a modified drying process due to load and packaging configurations. Stryker Trauma & Extremities recommends either extending the drying time to 45 minutes or detaching the Detachable Drawer Trays into two pieces and placing them next to each other in full size containers. It is the hospital’s responsibility to validate the appropriate drying time with the sterilization equipment used. For the use of the Rigid Sterilization Containers please consult the Instructions for Use of the Manufacturer (Aesculap).

4. Packaging

Double Wrapped

Where appropriate the cleaned, disinfected, and checked medical devices should be assembled into the dedicated trays provided. Stryker Trauma & Extremities trays should be double wrapped. In the USA, Stryker Trauma & Extremities recommends compliance with ANSI/AAMI ST79 and the use of FDA cleared sterilization wrap.

The packaging for terminally sterilized medical devices should fulfill the following requirements:
- EN ISO 11607
- Suitable for steam sterilization
- Sufficient protection of the instruments as well as of the sterilization packagings to mechanical damage
- Grade appropriate for weight of instrument and implant tray.

Note:
For trays that contain large polymer components Stryker Trauma & Extremities recommends extending the drying time to 45 minutes.

Rigid Sterilization Container

In addition to the commonly used double wrap sterilization method, Aesculap JK Series Rigid Sterilization Containers may be used for the same purpose to sterilize any reusable medical devices provided by Stryker Trauma & Extremities in stainless steel trays (see Examples 1 & 2).

Note:
Stryker Trauma & Extremities typically does not specify the maximum number of uses appropriate for reusable medical devices. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses.

For devices that may be impacted check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves.

Careful inspection and functional test of the device before use is the best method of determining the end of serviceable life for the medical device. See Appendix 2 for further details.

* See Appendix 3 for further inspection instructions.
5. Sterilization

Caution:
Medical Devices containing thermolabile materials must not be exposed to additional loads in the autoclave.

Steam sterilization (moist heat) is recommended.
An autoclave cycle has been validated by Stryker as being capable of achieving sterile medical devices; however autoclave design and performance can affect the efficacy of the process. Healthcare facilities should validate sterilization equipment according to instructions from the manufacturer, and verify that sterility can be achieved using parameters supplied by Stryker in combination with the equipment and processes of the healthcare facility.

Sterilization process
Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated, maintained and checked in accordance with EN 285/EN 13060, EN ISO 17665, and ANSI AAMI ST79.

Stryker has validated an autoclave cycle for sterilization of complete medical device cases/trays. Instruments shall be sterilized in the mounting condition as stored on the tray, i.e. if the brackets or recessions in the tray are designed to accommodate multi-component instruments in their assembled state, there is no need to disassemble these instruments for sterilization. The process parameters shown on the right are validated and recommended by Stryker Trauma & Extremities for sterilization:

Caution:
Stryker Trauma & Extremities does not recommend the use of ‘flash’ sterilization for re-usable instruments.

Warning:
• Stryker Trauma & Extremities does not recommend the use of rigid containers for steam sterilization unless it has been validated by Trauma & Extremities (see approved configurations in chapter 4 “Packaging”). Otherwise configuration could limit steam penetration and prevent effective sterilization and drying of the medical devices.
• Single-use implants and instruments must not be reused.

### USA*

<table>
<thead>
<tr>
<th>Method</th>
<th>Moist heat sterilization according to EN ISO 17665 and ANSI/AAMI ST79</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Pre-Vacuum (Pre-Vac)</td>
</tr>
<tr>
<td>Temperature</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td>Exposure Time¹</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Drying Time²</td>
<td>30 minutes (minimum, in chamber)</td>
</tr>
<tr>
<td>Cool Time</td>
<td>60 minutes (minimum, at room temperature)</td>
</tr>
</tbody>
</table>

### Outside USA*

<table>
<thead>
<tr>
<th>Method</th>
<th>Moist heat sterilization according to EN ISO 17665</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Saturated steam with fractional forced air removal</td>
</tr>
</tbody>
</table>
| Exposure Time¹ | 4 minutes
Exposure time can be extended to 18 minutes to comply with the recommendation from World Health Organization (WHO), Robert Koch Institute (RKI) etc. Stryker Trauma & Extremities medical devices are able to sustain such sterilization cycles. |
| Temperature | 132-137°C (270-277°F) |
| Drying Time² | recommended: 30 minutes (minimum, in chamber) |

¹ Exposure time: Period for which the load and entire chamber is maintained at the sterilization temperature
² Drying time: Period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. Because drying time varies due to load configuration, wrapping method and material, the healthcare facility should verify the appropriate drying time, with the sterilization equipment used.
5. Sterilization

Final responsibility for verifying sterility, using the equipment and processes of the healthcare facility, and the parameters supplied by Stryker, lies with the healthcare facility. To ensure optimal processing all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

* Caution:
These parameters are not applicable to the entire Stryker Trauma & Extremities portfolio. There are exceptions for which other validated sterilization cycles are applicable. These are described in the instructions for use and have binding character. If a product is supplied without a package insert and if you are in doubt about the applicable sterilization parameters for a particular product, please contact the manufacturer. Manufacturer addresses are provided in section 7.

### Alternative (e.g. UK, NL)*

<table>
<thead>
<tr>
<th>Method</th>
<th>Moist heat sterilization according to EN ISO 17665</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Saturated steam with fractional forced air removal</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>3 minutes Exposure time can be extended to 18 minutes to comply with the recommendation from World Health Organization (WHO), Robert Koch Institute (RKI) etc. Stryker Trauma &amp; Extremities medical devices are able to sustain such sterilization cycles</td>
</tr>
<tr>
<td>Temperature</td>
<td>134°C-138°C (273°F-280°F)</td>
</tr>
<tr>
<td>Drying Time</td>
<td>recommended: 30 minutes (minimum, in chamber)</td>
</tr>
</tbody>
</table>

6. Storage before Use

After sterilization, please store the medical devices in the sterilization packagings in a dry and dust-free place. The shelf life depends on the sterile barrier employed, storage manner, environmental and handling conditions. A maximum shelf life for sterilized medical devices before use should be defined by each healthcare facility.

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1 Exposure time: Period for which the load and entire chamber is maintained at the sterilization temperature

2 Drying time: Period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. Because drying time varies due to load configuration, wrapping method and material, the healthcare facility should verify the appropriate drying time, with the sterilization equipment used.
7. Manufacturers of Stryker Trauma & Extremities Medical Devices

Stryker Trauma GmbH
Prof.-Küntscher-Str. 1 - 5
D-24232 Schönkirchen
Germany
phone: +49-4348-702 0

Stryker GmbH
Bohnackerweg 1
CH-2545 Selzach,
Switzerland
phone: +41-32-641 6666

8. References (for some countries only)

1. EN ISO 11607 (ANSI AAMI ISO 11607): Packaging for terminally sterilized medical devices
2. EN ISO 17665 (ANSI AAMI ISO 17665): Sterilization of health care products, moist heat
3. ISO 15883 series: Washer-disinfec-
tors
4. ANSI/AAMI ST77: Containment devices for reusable medical device sterili-
5. ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
6. EN ISO 17664 (ANSI AAMI ST81): Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
7. ANSI AAMI ST81: Sterilization Of Medical Devices - Information To Be Provided By The Manufacturer For The Processing Of Resterilizable Medical Devices
Appendix 1

Cleaning agents and disinfectants used during validation of the processing instructions

For cleaning and/or disinfection of medical devices manufactured from aluminium alloys a pH neutral agent should be used*. Contact with strong alkaline detergents or solutions containing iodine or chlorine should be avoided, since the aluminium can be chemically attacked and the instrument may be damaged.

For automatic (washer-disinfector) cleaning mild alkaline agents (up to pH 10.9) should be preferred, however use only agents recommended for use in these machines.

In all cases
- follow the indications, instructions and warnings provided by the supplier of the cleaning agent and/or disinfectant,
- select only detergents intended for cleaning and/or disinfection of medical devices made of metals and plastics, and
- select only disinfectants with approved efficiency (VAH/DGHM or FDA approval or CE mark).

Ensure that the substances listed below are not ingredients of the cleaning or disinfection detergent chosen:
- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- strong lye (maximum admitted pH-value 10.9*)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxides, hypochloride)
- halogens (chlorine, iodine, bromine)
- aromated, halogenated hydrocarbons.

Notes:
- The cleaning agents listed below were used by Stryker Trauma & Extremities when validating the instructions for processing provided in this document.
- Stryker Trauma & Extremities does not recommend these products in preference to others that are available. Other products may perform equally in conjunction with the equipment being used.
- The instructions provided by the supplier of the detergents should be followed.
- Personal protection for operators should be provided in accordance with the supplier’s instructions and safety data sheets
- Suitability of alternative agents should be checked by reference to the supplier’s information and/or physical testing.

Agents for pre-cleaning and manual cleaning (used for validation)

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Designation</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson and Johnson</td>
<td>Cidezyme/Enzol</td>
<td>Suitable for aluminium instruments</td>
</tr>
</tbody>
</table>

Agents for manual disinfection (used for validation)

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Designation</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson and Johnson</td>
<td>Cidex OPA</td>
<td>Suitable for aluminium instruments</td>
</tr>
</tbody>
</table>

Agents for automatic cleaning/disinfection in a washer disinfector (used for validation)

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Designation</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Weigert</td>
<td>neodisher Mediclean forte</td>
<td>Not recommended for aluminium medical devices*</td>
</tr>
</tbody>
</table>

* In case of aluminium instruments neutral/enzymatic detergents are recommended
(for example Neodisher Medizym)
Appendix 2

Guidelines to check proper functionality of the medical devices

The following guidelines should be applied to all Stryker Trauma & Extremities instruments which are labeled for multiple use. All functional checks and inspections described below also cover the interfaces with other instruments or components.

The failure modes below may be caused by end of life of the product, improper use or improper maintenance.

Stryker Trauma & Extremities does not typically specify the maximum number of uses for re-usable medical devices. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the device before use is the best method of determining the end of serviceable life for the medical device. However, for certain instruments end of life has been defined, verified and specified with either a number of uses or an expiration date.

Functional check for multiple use Drill Bits

Description and Function:
Multiple use drill bits, cannulated drill bits, burrs, taps, core drills

Potential Failure Modes:
- Defective coupling end (eroded)
- Blunt and dull cutting flutes
- Tips, helix coil, bent

Preventive Maintenance:
Regular functional check and visual inspection. In case of failure, the instrument must be replaced and not be used.

Coupling end eroded

Blunt / dull tip
Please check at tip of drill (see mark)

Dents on cutting flutes
Appendix 2

Drill Bit: Overview

Drill bit: twisted

Drill bit: blunt / dull cutting flutes

Drill bit: helix coil - the cutting flutes change direction

Drill bit: blunt / dull cutting flutes and helix
Appendix 2

Functional Check for Reamers

Description and Function:
Intramedullary reamer, reamer heads, reamer shaft

Potential Failure Modes:
• Defective coupling end
• Blunt and dull cutting flutes
• Tips, helix coil of reamer shaft deformed

Preventive Maintenance:
Regular functional check and visual inspection. In case of failure, the instrument must be replaced and not be used. If soil is not removed from shafts right after use, incrustation is likely to occur which will be baked permanently in subsequent sterilizations.

In order to avoid damage of the flexible reamer do not overbend the shaft. As a reference the maximum bending diameter should not exceed the length divided by 2.

For detailed guidance for re-processing of re-usable flexible reamers see Appendix 3.

Reamer shaft: deformed
Reamer bit: blunt / dull cutting flutes
Chunking in cutting flutes
Blunt / dull cutting flutes and tip
Appendix 2

Functional Check for Screwdriver Blades

Description and Function:
Screwdrivers with drive connections of various designs with or without self-retaining function.

Potential Failure Modes:
- Deformation of the blade (twisted)
- Deformation of the blade (rounded)
- Breakage of the blade’s self-retaining mechanism without function
- Corresponding drive connection of screw head is rounded or worn.

Preventive Maintenance:
Appendix 2

Hexagon drive connection: deformed

Hexagon drive connection: deformed

Gamma Lag Screwdriver: deformed/broken off pegs
Appendix 2

Connection rod of Gamma Lag Screw Driver: damaged and squeezed thread

As above

As above

Functional Check for Torque Limiters

Description and Function:
Includes all torque limiting or indicating devices with or without a releasing mechanism.

Potential Failure Modes:
- Malfunction due to wear
- Corrosion or contamination

Preventive Maintenance:
Use an appropriate instrument spray for the mechanism of the self-retaining screwdrivers. Frequent control of torque accuracy with torque tester, if indicated regular functional and visual inspection. In case of failure, the instrument must be replaced and not be used.
Appendix 2

Functional Check for Bending Instruments

Description and Function:
Instruments used for bending implants

Potential Failure Modes:
- Corrosion between adjacent surfaces
- Corrosion between pairings of different metals
- Corrosion on frequently used functional surfaces
- Corrosion on the laser engraving
- Bent or damaged edges imply a risk of damaging the implant, especially in functional area

Preventive Maintenance:
Regular functional check and visual inspection. Use an appropriate instrument spray for the mechanism of all moving parts and articulating surfaces. Check and if necessary eliminate all gaps for residuals and moisture after usage or cleaning. In case of failure, the instrument must be replaced and not be used.

Bending Forceps with surface corrosion at cutting device and in the gap between the two parts of the forceps.
Functional Check for Scissors and Cutting Instruments

Description and Function:
All instruments which are used to cut tissue and bone material (like scissors or osteotomes) and also all instruments which are used to cut implants (like cutters)

Potential Failure Modes:
- Cutting edge is damaged, cutting function is no longer fully given
- Spring is damaged, articulation does not work properly

Preventive Maintenance:
Use an appropriate instrument spray for the mechanism of all moving parts and articulating surfaces. Handle the instruments with care. The cutting edge of the instrument should be inspected prior to clinical use. The cutting function could be restricted if the cutting edge or the tip of the instrument is damaged. Stryker recommends the use of silicone-free, non-mineral oil based lubricant for the maintenance of articulated instruments. In case of failure, the instrument must be replaced and not be used.
Appendix 2

Functional Check for Targeting Devices

Description and Function:
Target Devices to aim at the locking holes of implants (nails, plates)

Potential Failure Modes:
• Marks caused by hitting on the device
• Cracks in the polymer
• Damage of threads
• Deformation of nail adapter
• Displacement of connection pin

Preventive Maintenance:
Use an appropriate instrument spray for the mechanism of all moving parts and articulating surfaces. Handle with care. Do not hit on Target Devices. In case of failure, the instrument must be replaced and not be used.

Marks on the metal part of the device

Crack in the polymer

Hit marks on functional surface

Crack
Appendix 2

Deformation of nail adapter

Damaged threads

Connection pin displaced (should be flush with surface)
Appendix 2

Functional Check for Drill Guides

Description and Function:
Soft tissue protection sleeves used during drilling

Potential Failure Modes:
• Scratched outer surfaces, dents at the sleeve tips

Preventive Maintenance:
Use an appropriate instrument spray for the mechanism of all moving parts and articulating surfaces. In case of failure, the instrument must be replaced and not be used.

Drill Guide: overview

Drill Guide Sleeve: dents on the sleeve tip

Soft Tissue Protector: overview

Tissue Protection Sleeve: dents on the sleeve tip

Drill Guide Sleeve: scratches on the surface

Soft Tissue Protector: dents on the soft tissue protector tips

Tissue Protection Sleeve: surface damaged by assembly part

Drill Guide: dents on the drill guide tip
**Appendix 2**

**Functional Check for Forceps, Clamps and Holding Instruments**

**Description and Function:**
- Repositioning of bone fragments
- Clamping of wire after the wire has been put under tension with the wire tensioner

**Potential Failure Modes:**
- Deformed functional surfaces (e.g., teeth and locking mechanism)
- Clearance between the handles
- Corrosion between adjacent surfaces
- Corrosion between pairings of different components
- Corrosion on frequently used functional surfaces
- Corrosion on the laser engraving
- Corrosion of clamping disk may lead to breakage of the disk when put under stress

**Preventive Maintenance:**
Use an appropriate instrument spray for the mechanism of all moving parts and articulating surfaces. In case of failure, the instrument must be replaced and not be used.

Always examine the wire post and especially the clamping disk before reuse. In case of corrosion signs or crack, the wire post shall not be used.

Bent teeth and damaged locking mechanism on a forceps

Deformed handles on a forceps

Stress corrosion on clamping disc of Tenxor wire tensioner

Bent teeth of a forceps
Reprocessing of re-usable flexible reamers

Reprocessing:
Re-useable flexible reamer shafts are considered as demanding instruments in regards to cleaning. In each case the Instructions for Cleaning, Sterilization, Inspection and Maintenance shall be strictly followed. In addition the following technical tips should be incorporated:

- Directly after application gross soil should be removed with paper wipes. Additionally it is highly recommended to rinse the devices or transfer the devices in a bath with an aldehyde free disinfectant solution. If soil is not removed from shafts right after use, incrustation is likely to occur which will be baked permanently in subsequent sterilizations.
- The flexible reamer shaft should be flexed and rotated each time it is brushed or rinsed to facilitate the removal of soil.
- The automated cleaning process should be preferred over the manual method and used whenever possible. The automated cleaning process has a higher reproducibility and reliability.
- Automated method: Connect the cannulation to the rinsing ports of the washer-disinfector. If no direct connection is possible, locate the cannulations directly on injector jets or in injector sleeves of the injector basket.
- When the manual method is applied the pre-cleaning step should be conducted. It is recommended to conduct this step in an ultrasonic bath.

- Preventive Maintenance: Careful inspection and functional tests of the device before preparation for sterilization is the best method of determining the end of serviceable life for the medical device. Especially the spiral element should be visually checked for damage, since a deformed spiral might compromise the cleanability of the device and enable soil to penetrate into the spiral.
- The flexible reamer shafts are manufactured using established stainless instrument steels in a controlled process environment and welded under inert gas conditions to avoid oxidation (corrosion) throughout their service life.

Qualification of Cleaning and Disinfection Process:
In order to qualify the described manual and automated method the flexible reamer shafts were subjected to standardized microbiological efficiency control studies. The shafts were contaminated under worst case conditions with an artificial soil containing spores. After reprocessing of the shafts according to the instructions the reduction of the spores was determined. The manual and the automated method were qualified separately. A reduction of the spore count of at least 3 log steps is considered as acceptable. In all test series the reamer shafts achieved a log reduction of at least 3.4 log steps. Based on the acquired data both cleaning processes were successfully qualified in conjunction with the re-useable flexible reamer shafts.

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a EN 10270-3 / EN 10088-1
b AAMI TIR 30-2011, section 7.5
c Test Reports #083333-10A/B, #114764-10A/B, Medical Device Services GmbH, Gilching, Germany. Reports available on request.
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