maxx orthopedics

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RECOMMENDATIONS FOR CLEANING, STERILIZATION AND CARE OF SURGICAL INSTRUMENTATION

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CONTENTS

GENERAL INFORMATION 3

RECOMMENDATIONS AND INSTRUCTIONS FOR CLEANING AND DISINFECTION 4

Device Categories 4

Instrument cases and trays 5

Cleaning Agents/Equipment 5

Initial Treatment / Preparation for Cleaning 5

MANUAL CLEANING 6

AUTOMATED WASHING 7

RECOMMENDED STERILIZATION INSTRUCTIONS 8

Preparation for Sterilization 8

Sterilization Methods 8

Recommended Sterilization Method by Instrument Type 8

INSPECTION AND MAINTENANCE 9

GOODS FOR RETURN OR REPAIR 9

CONTACT INFORMATION 9

Purpose

The purpose of this document is to provide recommended decontamination and sterilization protocols using both manual and automated decontamination procedures. The following procedures have been developed for reusable devices including surgical instruments, trays and cases and do not apply to single use devices such as orthopaedic implants. **Maxx Orthopedics does not endorse the reuse of single-use devices.**

Scope

The information provided is only applicable to Surgical Instrumentation (including trays and cases) supplied by Maxx Orthopedics. It does not cover the surgical use of the instruments. Refer to the surgical technique brochures for further information.

Maxx Orthopedics declares that the supplied instruments are in compliance with Quality Management System requirements of ISO 13485.

It is the responsibility of the user to ensure that the reprocessing of the instruments achieves the desired result.

Unless otherwise described in the supplementary documentation, all non-metal and metal instruments are reprocessed following the same guidelines described in this document.

Symbols

Symbols used in this document.

CAUTION / WARNING

General Information

Although Maxx Orthopedics surgical instruments are provided in a clean state, the following procedures are recommended both prior to, and following surgical use.

The cleaning methods described here have been validated by the quality assurance department of Maxx Orthopedics in accordance with ASTM E1766. Validation of other methods of cleaning needs to be carried out by the user of the device.

Cleaning is one of the most essential steps in the preparation of an instrument for reuse and it is essential that correct and effective steps be taken, to achieve proper decontamination and sterilization. It is vital to thoroughly clean and rinse a reusable instrument. All visible adherent soil needs to be removed to reduce the number of microorganisms, pyrogens and particulates. Thorough rinsing of the instrument is required at the end of the cleaning process to remove any residual cleaning agents.

RECOMMENDATIONS AND INSTRUCTIONS FOR CLEANING AND DISINFECTION

Device Categories

One of the factors affecting the successful cleaning of medical devices is its design features. The Maxx Orthopedics instruments sets contain instruments that represent varied levels of challenge to the cleaning process. Following are examples of different types of devices supplied by Maxx Orthopedics:

1. Instruments ***with simple design features***. These instruments have simple design features e.g. angel wing, impactors, box cut guides, etc.

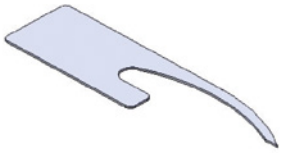

Figure 1a Angel Wing Figure 1b. Universal Handle

2. Instruments ***with challenging design features***. These have complicated design features that could present a challenge to cleaning and/or required to be dismantled before cleaning e.g. tibial cut guide, distal femoral cut guide, femoral sizing guide. Instruments with crevices, blind holes, cannulations, and cutting slots. All type 2 devices must be put through the ultrasonic cleaner as specified in Manual Cleaning, note 4.

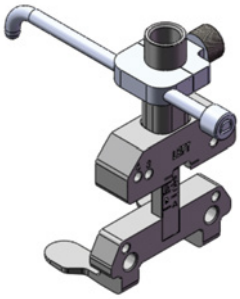

Figure 2a Femoral Sizing Guide Figure 2b Broach Handle

3. Instruments ***that must be dismantled***. These are required to be dismantled before cleaning. All type 3 devices must be put through the ultrasonic cleaner as specified in Manual Cleaning, note 4.

Figure 3a Tibial Cutting Guide

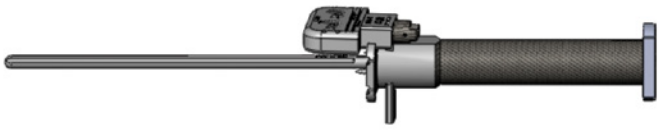

Figure 3b Distal Femoral Cutting Guide

Figure 3c Stem Inserter

Instrument cases and trays	Instrument cases and trays are reusable devices and should be cleaned prior to use either manually or in an automatic washer using a pH neutral detergent.
Cleaning Agents/Equipment	**Water** It is preferable to use de-mineralized water when decontaminating the devices as hard water may leave a residue on devices resulting in subsequent ineffective decontamination.
	Detergents Detergents with a pH range between 6.0 and 8.0 are recommended, as higher or lower pH detergents can damage instruments, instrument trays and cases. Enzymatic detergents aid the removal of organic material such as blood and tissue particles. At all times detergents should be used at the concentrations recommended on the label by the manufacturer.
	Ultrasonic Equipment Ultrasonic cleaners are designed for fine cleaning of instruments. They should not be used to initially remove gross soil from instruments, but after gross soil has been removed by other means. Ultrasonic cleaners will aid removal of soil from difficult access locations such as joints, crevices, channels and lumens in instruments. All type 2 and 3 devices (see Figures 2a through 3c) must be put through the ultrasonic cleaner. It is recommended to use enzymatic detergents in ultrasonic cleaners.
Initial Treatment / Preparation for Cleaning  CAUTION	Begin thorough cleaning and rinsing as soon as possible after the use of the instrument (at place of use). Keep instruments moist after use to prevent soil from drying. Instruments that are capable of being disassembled **must be** disassembled prior to cleaning. **Note:** If required, further information on disassembly may be obtained by contacting Maxx Orthopedics' Quality Assurance Department. Automated washing is the preferred method of cleaning, however manual cleaning is also acceptable. It is difficult and sometimes impossible to remove dried on soil with automatic washing, especially for challenging design features, or instruments with cannulae, interfaces, crevices, joint, hinged/mating surfaces etc. Therefore, it is critical to manually remove gross soil from these areas by cleaning cannulae and other design features with appropriate brushes prior to washing in the automatic washer (refer to section on Manual Cleaning). Automated washer / disinfectors clean devices and also provide moderate to high level of disinfection with a hot water rinse. It is essential that the devices be fully immersed in cleaning agent. Note that cleaning performance is also dependent on the force of the water spray. All cleaning should be performed in such a way as to minimise exposure to blood borne pathogens. All personnel involved in the cleaning and decontamination process should use appropriate Personal Protection Equipment (PPE).

MANUAL CLEANING

Low linting cloths, general-purpose nonabrasive non-metallic brushes, lumen brushes and scouring pads are recommended for manual cleaning of instruments.

All Maxx Orthopedics instruments have been developed to allow all sections of the instruments to be accessible for ease of cleaning, penetration of cleaning fluids, and drying.

Clean instruments as follows.

1. Rinse under running water.
2. Soak instrument in enzymatic detergent.
3. Use cleaning brushes to remove visible soil.
    a. If the instruments can be disassembled, retracted or opened it is necessary to do so prior to cleaning.
    b. Scrub inside all cannulae and holes with a tight-fitting brush using a rotating action. It is essential to reach the full depth of the cannula or hole using an appropriately sized brush.
    c. Scrub instruments, hinging and mating surface areas with a brush.
    d. For instruments with flexible shafts, bend the shaft into a "C" shape to open up crevices. Use cleaning brushes to remove any additional soil using a scrubbing action on the surface and crevices.
4. All type 2 and 3 (see Figures 2a through 3c) instruments must be put through an ultrasonic cleaner containing warm enzymatic detergent in fully open or dismantled position for 10-15 minutes.
5. Rinse all instruments thoroughly inside and out using warm to hot running water making sure to irrigate all challenging design features.
6. Dry instruments in the drying cabinet within the temperature range 65˚C to 75˚C.

Visually check instruments for residual soil and if present repeat cleaning process until instruments are visually clean.

AUTOMATED WASHING	***Pre-cleaning of Instruments.*** 1. Immerse instruments in enzymatic detergent and scrub all cannulae, holes, hinge mating surfaces and joints and crevices using cleaners and tight-fitting brushes. 2. All type 2 and 3 (see Figures 2a through 3c) instruments must be put through an ultrasonic containing warm enzymatic detergent in fully open or dismantled position for 10-15 minutes. 3. Thoroughly rinse the device with warm running water. Pre-cleaning is not essential for used instruments that do not have dried on soil. These instruments can be placed directly into the automatic washer.
	Automated Washing Cycle 1. Load the instruments in the washer making sure that all design features are accessible to cleaning. Pay special attention to the instruments with features that can retain liquid e.g. holes and cannulated and ensure these instruments are positioned in such a way that all liquid can be drained. 2. Run the automatic wash cycle to include the following minimum cycle parameters: a. Cold pre-wash b. Warm water wash in accordance with the manufacturer's instructions using recommended cleaning agent c. Rinse at least once with hot water at 80˚C to 90˚C d. Drain and dry On completion of the automatic wash cycle check instruments for visible soil. Repeat the cleaning process, if necessary, until instruments are visually clean.

RECOMMENDED STERILIZATION INSTRUCTIONS

Sterilization methods recommended in this document have been validated in compliance with recognized standards. If other sterilization cycles are required to be used to process Maxx Orthopedics instruments, the individuals or hospitals are advised to validate these cycles.

<table>
<tr><td> 
WARNING</td><td colspan="2">Reprocessing of implants is not endorsed by Maxx Orthopedics.</td></tr>
<tr><td>Preparation for Sterilization</td><td colspan="2">• Perform adequate cleaning process prior to sterilization.
• Place all reusable devices on perforated trays making sure all hinges and ratchets are open or unlocked.
• Sterilization trays should be wrapped following ANSI/AAMI ST79 prior to sterilization to prevent any recontamination.
• Follow ANSI/AAMI ST79 when loading sterilizer. Do not stack trays during sterilization.</td></tr>
<tr><td rowspan="2">Sterilization Methods</td><td colspan="2">High Temperature Pre-Vacuum Steam
• 4 pulses (Maximum-26.0 psig (2.8 bars), Minimum-10.0 in Hg [339 mbars])
• Exposure Temperature: 132°C (270°F)
• Exposure Time: 4 minutes
• 1 minute purge
• 20 minutes of vacuum drying</td></tr>
<tr><td colspan="2">High Temperature Gravity Steam
• Exposure Temperature: 132°C (270°F)
• Exposure Time:
– 15 minutes for Instruments and Nonporous Coated Devices
– 30 minutes for Loaded Sterilization Cases
• 1 minute purge
• 25 minutes of vacuum drying</td></tr>
<tr><td rowspan="3">Recommended Sterilization Method by Instrument Type</td><td>Metal Reusable Instruments</td><td>High Temperature Gravity Steam
High Temperature Pre-vacuum Steam</td></tr>
<tr><td>Plastic Reusable Instruments</td><td>High Temperature Gravity Steam
High Temperature Pre-vacuum Steam</td></tr>
<tr><td>Loaded Sterilization Cases</td><td>High Temperature Gravity Steam
High Temperature Pre-vacuum Steam</td></tr>
</table>

INSPECTION AND MAINTENANCE

Inspection	Prior to use inspect each instrument for soil or rust and verify its functionality.
Maintenance	For hinged instruments, surgical grade lubricant could be added to hinged areas while in the open position. Return blunted or damaged instruments to Maxx Orthopedics.

GOODS FOR RETURN OR REPAIR

DO NOT attempt to use or repair damaged instruments. Contact Maxx Orthopedics (or authorized representative) regarding the replacement or shipping of broken or damaged instruments.

All Product returned to Maxx Orthopedics should be safely packed in protective wrapping. For contaminated instruments, clean, sterilize, and label the goods before returning them to Maxx Orthopedics.

Customer must supply a statement of the problem or reason when returning instrument(s).

CONTACT INFORMATION

Maxx Orthopedics, Inc.
2460 General Armistead Ave
Suite 100
Norristown, PA 19403

Maxx Medical Pvt. Ltd.
Office No. A/01
Ground Floor, Elite House
Behind Crisil House
Near Sanofi Aventis
Chakala, Andheri East
Mumbai 400 059
(INDIA)

EC REP

AJW Consulting GmbH
Breite Straße 3
40213 Düsseldorf, Germany
Phone: +49(0) 211 54059 6030
Email: info@ajwtech.com

CE 2460