GENERAL INSTRUMENTATION

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DESCRIPTION / MATERIAL COMPOSITION

This document provides the instructions for processing general instruments (including, but not limited to, trials and inserters) made of stainless steel, polymer (PPSU), or other sterilizable material provided by OsteoRemedies®.

OPERATION

Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques. In addition, consult medical literature relative to techniques, complications and hazards prior to performance of any surgical procedure. Before using the product, all instructions regarding its safety features as well as surgical techniques must be read carefully. The instrument must be operated only by trained personnel. Please observe general operating room technique.

PACKAGING

Instruments may be supplied in non-sterile instrument containers or individual packaging. Instruments sold sterile are always presented in individual packaging and will be clearly labelled as sterile on the package label.

The containers and the packaging of the instruments must be intact when received. The packaging materials must be removed prior to sterilization.

CLEANING & STERILIZATION

All instruments are provided nonsterile.
Before each use, the device must be cleaned, sterilized and visually inspected.
After use, the device must be cleaned, resterilized and visually inspected.

POINT OF USE

Excess soil should be removed as soon as possible after use with a disposable cloth, wipe, or gauze.

CONTAINMENT AND TRANSPORTATION

It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

PREPARATION FOR CLEANING AND STERILIZATION

- Disassembly of simple assemblies is necessary to allow more complete cleaning and sterilization.
- Disassembly should not require any mechanical tooling (i.e. screwdriver, pliers, etc.).
- Follow cleaning instructions below before sterilization.

CLEANING RECOMMENDATIONS

1. Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.

2. Completely submerge the instrument in enzyme solution and allow it to soak for at least 1 minute, or the minimum soak time recommended by the cleaning agent manufacturer. Use a soft-bristled brush to gently clean the device (paying close attention to all threads, crevices and other hard-to-clean areas) until all visible soil has been removed. Any instruments with lumens or cannulas should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush). The enzyme solution should be changed when it becomes grossly contaminated.

3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.

4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.

5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 40-45 kHz.

6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.

CLEANING RECOMMENDATIONS (continued)

7. Repeat steps 5 and 6 with freshly prepared cleaning solution until the instruments are thoroughly clean.

8. Dry instrument with a clean, disposable, absorbent, non-shedding wipe.

9. If the device is determined not to be visually clean at the end of step 8, the cleaning steps should be repeated or the device should be safely discarded.

In case of use of automatic cleaning cycle, check the compatibility with the above mentioned instructions.

RECOMMENDED STERILIZATION CYCLE*:

Method:	Moist Heat (steam)
Cycle:	Dynamic Air Removal (Prevacuum) Steam
Temperature:	132°C (270°F)
Exposure Time:	4 Minutes
Dry Time:	Wrapped Devices** – 30 Minutes

** An FDA-cleared sterilizer should be used.*
*** Prior to sterilization, the trials should be placed in an FDA-cleared wrap.*
The above sterilization cycle achieves a sterility assurance level (SAL) of 10^{-6}.

STORAGE

After sterilization, instruments should remain in sterilization wrap and be stored in a clean, dry cabinet or storage case.

WARNING: The general instruments must not be implanted. Instruments must always be examined by the user pre/post cleaning and prior to surgery. Examination should be thorough and must include a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, deformation, or distortion, and that all components are complete. Do not use the instrument if it appears damaged (deformation, loss of the information marked on the device, etc.). The instrument needs to be replaced if it appears damaged after a visual inspection. Use only in an operating environment. Do not reuse single use instruments. Before the initial use and

before every further usage, the entire device, including its accessories must be decontaminated. An inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or the user.

DISPOSAL: For single use instruments and when the device has to be disposed follow national or local guidelines for disposal of surgical waste materials.

NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING IS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY ACHIEVE THE DESIRED RESULT. THIS REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKEWISE ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.

Symbols:



Nonsterile



Catalog Number



Batch Number

Rx only

Caution: Federal Law Restricts This Device To Sale By Or On The Order Of A Physician



Consult Instructions For Use

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Keep out of reach of children.

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