RP MEDICAL
PIVOT IMPLANT EXTRACTION OSTEOTOME SYSTEM™
PREPARATION AND REPROCESSING INSTRUCTIONS

Introduction

This document contains instructions for use of the RP Medical Pivot Implant Extraction Osteotome System™ including the cleaning, disinfection and sterilization of all manual surgical instruments manufactured by RP Medical Inc.

1. Fundamental Points

All instruments are to be cleaned, disinfected, and sterilized prior to each use. In addition, cleaning, disinfection, and sterilization is also required for the first use of non-sterile instruments after removal from the protective packaging. Effective cleaning and disinfection is an indispensable requirement for proper instrument sterilization.

The user is responsible for the sterility of the instruments. Therefore, please ensure that only validated procedures are used for cleaning, disinfection, and sterilization. The sterilization equipment must also be maintained and checked regularly, as well as the validated parameters applied to each cleaning and sterilization cycle.

These instructions provide instructions on use of an **automated washer disinfector**. The staff should use suitable **protective clothing and equipment** at all times. Take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

2. Warnings and Precautions

- Medical products are only to be used for the purpose that they have been designed for and not to be abused or misused for any other purpose.
- The function of the product can be impaired if components are dented or bent in use due to improper handling.
- Instruments should be inspected after cleaning and prior to sterilization. Any instrument with corrosion, discoloration, scratches, flaws, bent or distorted should be discarded.

3. Cleaning Preparation

STEP 1 - Prepare All-In-One 4 Enzyme Detergent per manufacturer's instructions.

STEP 2 - Immerse and soak the instruments in the hospital grade enzymatic detergent for 14 to 15 minutes at room temperature.

STEP 3 - Clean all instruments thoroughly in a hospital grade enzymatic detergent at room temperature. Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that the flutes are effectively cleaned. Use a small diameter brush or pipe cleaner to clean cannulation holies. Inspect for visible soil on exposed surfaces.

STEP 4 – Rinse all instruments for 2 to 3 minutes using warm water as delivered from the hot water tap.

4. Automatic Cleaning

STEP 1 – Turn on Washer and follow operator's manual to set washer to DETERGENT "ON" Mode.

STEP 2 – Run Washer per the below pre-programmed parameters

Cycle	Solution	Time (sec)	Temperature
Wash	Hospital Grade Enzymatic Detergent Wash	210	180°F
Rinse	Potable Tap Water	10	180°F

5. Reusability & Inspection

Reusability

- RP Medical does not define 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 of the device after each use is the best method of determining the end of life for the instrument, due to the forces exerted on the devices. The pitting of the cutting edge and/or the blade portion is bent determines the end of life for the instrument.
- Always consult the device package label for restrictions on processing within a health care setting. RP Medical uses this symbol to indicate if a product is Single Use only:

- Any product indicated as Single Use only and has come into contact with blood, bone, tissue is not re-usable and **must be discarded** in a safe manner using the facilities' standard "discarding of sharps" safety instructions.

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Inspection of Reusable Instruments

After cleaning and prior to sterilization, all reusable medical devices must be inspected. Generally un-magnified visual inspection under good light conditions is sufficient. All parts of the devices should be inspected for completeness and function, specifically the following:

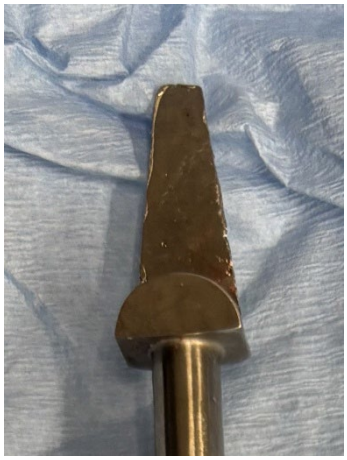
a) Pitting
b) Bending
c) Rust/Discoloration
d) Pivot Handle Function; Handle and Tool Rod Thread Damage
e) Readability of markings

The indicators identified above are signs of wear and damage on reusable instruments. For aid in assessing the instrument, the following instructions must be followed. Images are presented as an aid in showing instruments NOT suitable for use.

If the reusable instrument is determined not suitable for use it must be scrapped and replaced with a new instrument.

a) Pitting: The instrument sharpness is an integral part of the successful use of the instrument. If pitting such as shown in the images below is present the instrument must be scrapped and replaced.

Examples of pitting:



b) Bending: If any cutting portion of the osteotome/shaft shows signs of bending the instrument must be scrapped and replaced.

Example of bending:

c) Rust/Discoloration: Any visual rust must be inspected either by rubbing the instrument with a cloth or using a pencil eraser. If the rust is still present after inspection, the instrument must be scrapped and replaced.

In the event that discoloration occurs and is preventing proper reading of the markings on the instrument, the instrument must be scrapped and replaced.

d) Pivot Handle Function: If there is any separation at the junction of the black handle material from the metal (indicated by red arrow in image below), the handle must be scrapped and replaced. The handle metal side pins should be flush with the handle material. If a pin is not flush with the handle material (indicated by the blue circle in image below), the handle must be scrapped and replaced.

Example:

e) Pivot Handle & Tool Rod Threading: If there is any type of thread damage to either the Tool Rod or the Handle which prevents the device to thread into the Pivot osteotomes, the Handle and/or the Tool Rod must be scrapped and replaced.

Example:

f) Readability of Markings: All marking on the instrument must be legible. If any part of the marking is not legible, the instrument must be scrapped and replaced.

6. Packaging

The cleaned, disinfected, and inspected instruments should be placed into the dedicated case provided. The cases should be double wrapped according to AAMI/CSR technique.

The packaging for terminally sterilized medical devices should fulfill the following requirements:

- EN ISO 11607
- Suitable for steam sterilization (temperature resistance up to at least 141 °C, sufficient steam permeability)
- Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage

7. Sterilization

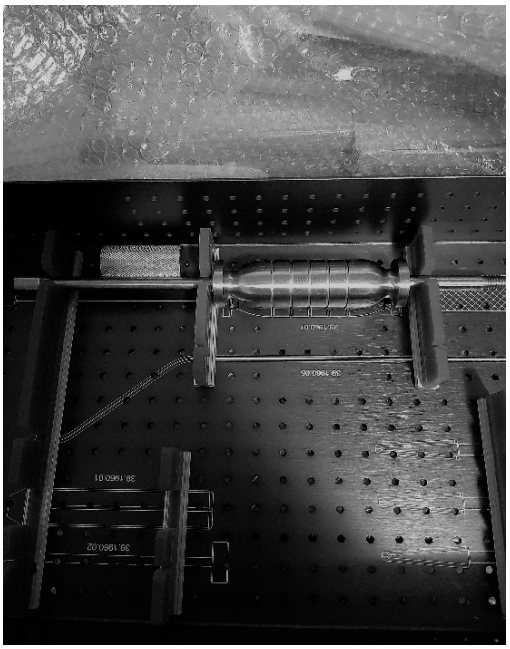
Steam sterilization (moist heat) is recommended.

An autoclave cycle has been validated as being capable of achieving sterile medical devices; however, autoclave design and performance can affect the efficacy of the process.

Sterilization process
Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended.

Instruments shall be sterilized mounted in the case. Each instrument should be placed in the specified location. The case is designed to accommodate multi-component instruments in their assembled state. There is no need to disassemble these instruments for sterilization. The one exception to this is the Slap hammer. The slap hammer must be disassembled and placed in case as shown in the picture below.

Slap hammer:



The process parameters shown below are validated and recommended for sterilization of the Pivot Implant Extraction Osteotome System:

CANADA/EUROPE

Method	Moist heat sterilization according to EN ISO 17665
Cycle	Saturated steam with fractional forced air removal
Exposure Time	4 minutes
Temperature	132-137C (270-277F)
Drying Time	Recommended: 30 minutes (minimum, in chamber)

USA

Method	Moist heat sterilization according to EN ISO 17665
Cycle	Pre-Vacuum (Pre-Vac)
Temperature	270F (132C)
Exposure Time	4 minutes
Pressure	2-15 PSIA
Drying Time	30 minutes (minimum, in chamber)
Cool Time	60 minutes (minimum, at room temperature)

8. Storage of instruments

- Always store instruments in the case provided.

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9. Alterations Policy/Disclaimer

Any modification, alteration or repair of any part of the Pivot Implant Extraction Osteotome System™ including, but not limited to, sharpening osteotomes, alterations to instrumentation or the sterilization container other than done by the manufacturer are strictly prohibited and will void all warranties of workmanship. Modifications or alterations of any kind to the Pivot Implant Extraction Osteotome System™ are at your own risk. You will indemnify and defend RP Medical Inc. from any resulting claims, including product liability claims, that may arise from any alterations or modifications.