

INSTRUCTIONS FOR USE

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RAZOR Reusable Instruments



Federal law (USA) restricts this device to sale or use by or on the order of a physician.

DESCRIPTION

The following RAZOR instruments are supplied by RAZOR Medical Instruments, Inc. specifically for use in hip replacement surgery and are user sterilized and reusable (collectively “Reusable Instruments”):

- Adapter for RAZOR Acetabular Reamers (“Adapter”)
- Calcar Planers
- Calcar Planer Removable Handle (“CP Handle”)
- Head Trials

MATERIAL

- The Adapter, Calcar Planers, and CP Handle are manufactured from medical grade stainless steel. The Head Trials are made from medical grade Propylux HS.

INTENDED USE

The Adapter and Calcar Planers are designed to facilitate bone preparation and placement of an acetabular or hip implant during hip replacement surgery. The Head Trials are designed to facilitate the correct head size and offset for the final implant to restore hip head center location during hip replacement surgery.

EXAMINATION PRIOR TO USE

The Reusable Instruments should be carefully examined for wear or damage by surgeons and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection. It should also include verifying the cleanliness of the device, as well as the absence of any cracks, distortion, wear, corrosion, or other change.

Like any precision surgical device, the Reusable Instruments should undergo regular checks by knowledgeable personnel to ensure that they remain in good condition and continue to act as intended. Do not use any instrument or device that is damaged, incomplete, showing signs of excessive wear and tear, or that has been repaired outside the control of RAZOR Medical Instruments, Inc.

CLEANING AND STERILIZATION

The Reusable Instruments are supplied non-sterile. Remove the Reusable Instruments from all individual sales packaging, clean and place in the appropriate instrument pan prior to sterilization.

Autoclave sterilization is recommended. The autoclave must be properly maintained by the hospital and checked regularly to assure the recommended sterilization temperatures are reached for the entire exposure time. Other sterilization methods are possible but must be maintained by the user.

The following Cleaning and Sterilization parameters have been validated and are recommended for the Reusable Instruments:

Point-of-Use	Prompt, initial treatment to remove and/or prevent drying of soil and contaminants is recommended to facilitate subsequent cleaning steps after each use.
Pre-Clean	<ul style="list-style-type: none"> - Disassemble any instrumentation that requires disassembly per manufacturer’s instructions provided before cleaning. -Thoroughly Clean all instruments before sterilization, including the instrument tray. -Submerge instruments in enzymatic detergent & soak for 10 minutes per manufacturer’s instructions. - Scrub submerged articles with a soft sponge & agitate. -Use a pipe cleaner or brush in any lumens and crevices. -Actuate any moving parts to loosen trapped contaminants. -Rinse in warm (38-49°C, 100-120 °F) water for 1 minute. Thoroughly flush all lumens & other difficult to reach areas. Actuate while rinsing.
Cleaning (manual)	<ul style="list-style-type: none"> -Ultrasonically clean the instruments for 10 minutes in a neutral pH detergent per manufacturer’s instructions. -Rinse with final rinse water quality of reverse osmosis or distilled water, actuating any moving parts while rinsing for 1 minute. Repeat rinse twice. -Dry instruments thoroughly with a clean, lint free cloth.
Cleaning (automated)	<p>Execute the cycle using a pH neutral enzymatic detergent according to the following parameters:</p> <p>Step 1: Pre-Wash: Minimum Temperature: Cold Tap Water Minimum cycle time: 2 minutes</p> <p>Step 2: Enzyme Wash: Minimum Temperature: Hot Tap Water Minimum cycle time: 4 minutes</p> <p>Step 3: Wash (Detergent percentage according to manufacturer specification): Minimum Temperature: 65.5 °C (149.9°F) Minimum cycle time: 2 minutes</p> <p>Step 4: Neutralization: Minimum Temperature: Hot Tap Water Minimum cycle time: 2 minutes</p> <p>Step 5: Rinse: Minimum Temperature: Hot Tap Water Minimum cycle time: 15 seconds</p> <p>Step 6: Thermal Rinse (A0 = 3000): Minimum Temperature: 82.2 °C (180.0°F) with Lubricant (percentage Lubricant according to manufacturer specification) Minimum cycle time: 1 minute</p> <p>Step 7: Hot Air Dry: Minimum Temperature: HIGH Minimum cycle time: 6 minutes</p>
Visual Inspection	<ul style="list-style-type: none"> -Inspect instruments for any damage or remaining contaminants, Instruments must be visually clean and without visual contaminants. -Repeat cleaning if contamination remains. -Contact RAZOR Medical Instruments, Inc. (customerservice@RazorMI.com) if instruments are damaged.
Sterilization Preparation	<ul style="list-style-type: none"> -Place instruments in the correct location in the instrument pan. -Do not stack pans for sterilization -Wrap the pan in a double layer of FDA cleared CSR wrap. OR -Place instruments into a SterilContainer
Sterilization	<ul style="list-style-type: none"> -Pre-vacuum cycle -Temperature: 132°C (270°F) to 137°C (279°F) -Exposure time: 4 minutes to 18 minutes -Dry time: 40 minutes
Storage	Store wrapped or in SterilContainer prior to immediate use.

WARNINGS AND PRECAUTIONS

- The Reusable Instruments must only be used by surgeons who have been trained in the surgical technique and are familiar with the instruments provided.
- The surgeon must take care not to exert inappropriate stress on the device and must comply with the operating procedure described in the surgical technique.
- Use care in handling and storage. Some instruments are sharp and incorrect use or handling may result in puncture wounds.
- Do not use the Reusable Instruments with drills that exceed 1500 rpm.
- Improper use may result in breakage of the instrumentation during operation.
- Remove all broken instrument fragments. As a result of mechanical features required, the device is made of medical grade but not implant grade materials. Failure to remove broken instruments from the patient could result in patient complications and further intervention.
- Incorrect maintenance, cleaning or handling may render the instrument unsuitable for its intended use, cause corrosion, dismantling, distortion and/or instrument breakage or injury to the patient or operating staff. Potential complications include device breakage, leaching of debris, lack of component engagement, infection, and damage to tissue.

STORAGE AND HANDLING

After use and cleaning, instruments must be stored in a clean, dry, and temperate place.

FURTHER INFORMATION

Please contact the manufacturer at QA@RazorMI.com or call (800) 358-0434 to report any issues relating to the use of the Reusable Instruments.

Visit www.RazorMI.com or use the QR Code to locate the RAZOR Single-Use Acetabular Reamer Surgical Technique.



MANUFACTURER

RAZOR Medical Instruments, Inc.

1055 Mariners Drive

Warsaw, IN 46582

Tel: (574) 295-9359

(800) 358-0434

www.RazorMI.com