












# Reamer System Instructions for Use

- 1) **INSTRUMENT DESCRIPTION:**
  - a) The Reamer System is an instrument system that consists of multiple size concave and convex reamers, guide wires, and measuring tools. The Reamer System may be used by surgeons to prepare congruent bone surfaces for joint fusions.
- 2) **INFORMATION FOR USE:**
  - a) Instruments must be inspected prior to and after each use for sharpness of cutting surfaces, corrosion, proper cleaning, damage, integrity of the connecting mechanism.
- 3) **WARNINGS:**
  - a) The surgeon using the Reamer System must be familiar with the instruments and the recommended surgical technique for safe and effective use.
- 4) **CLEANING AND STERILIZATION:**
  - a) Reamer System is supplied non-sterile and must be cleaned and sterilized before use.
    - i) Soak instruments in warm water for a minimum of 10 minutes.
    - ii) Disassemble instruments, as appropriate.
    - iii) Hand wash in a neutral pH (7.0) or mild detergent.
    - iv) Scrub with a soft bristle brush. Pay careful attention to any pivots, recesses or hard to reach areas on the instruments.
    - v) If the product is cannulated insert a nylon brush or chenille pipe cleaner into the passage to ensure no debris resides inside the hole.
    - vi) Immediately and thoroughly rinse and dry after washing.
    - vii) Visually inspect the instruments under room lighting conditions to ensure instruments are suitable for use and free of debris.
    - viii) Sterilize with steam sterilization. The following steam sterilization cycle is recommended based upon validation of a single, wrapped, dual or multiple tray instrument case within a properly maintained autoclave. Each facility's process parameters should be validated for the type of sterilization equipment and product load configuration.
      - (1) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
      - (2) Recommended dry time: forty five minutes.
- 5) **LOANER AND CONSIGNMENT SET SHIPMENTS:**
  - a) All instruments must be placed back in their respective trays within their appropriate sterilization case and sterilized per the sterilization instructions above prior to shipping back to the manufacturer. Any implants or instrumentation damaged due to neglect from mishandling or packaging will be billed to the customer.

Symbol	Meaning
	Catalog Number
	Batch Code
	Authorized Representative of the European Community
	Caution, Consult Accompanying Documents
	Consult Instructions for Use
	Do Not Reuse
	Not Made with Natural Rubber Latex
	Do Not Use if package is damaged
	Non-Sterile
	Caution: Federal Law (USA) restricts this device to sale by or order of a physician
	Manufacturer

 **Manufacturer:**  
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