


- U.S Federal law restricts this device to sale by or on the order of a physician.
- The Limited Use Acetabular Reamers are provided NON-STERILE  and must be used in accordance with ISO 15848-1 (oper) 5.3 (I) 14.5 (y)

Instructions For Use and Reprocessing for Tecomet Limited Use Acetabular Reamers

These instructions are in accordance with ISO 17664 and AAMI ST81. They apply to the Acetabular Reamer Instruments (provided as non-sterile) supplied by Tecomet intended for reprocessing in a health care facility setting. All Tecomet instruments and accessories may be safely and effectively reprocessed using the manual or combination manual/automated cleaning instructions and sterilization parameters provided in this document **UNLESS otherwise noted in instructions and accompanying a specific instrument.**

In countries where reprocessing requirements are more stringent than those provided in this document, it is the responsibility of the user/processor to comply with those prevailing laws and ordinances.

These reprocessing instructions have been validated as being capable of preparing reusable Tecomet instruments and accessories for surgical use. It is the responsibility of the user/hospital/health care provider to ensure that reprocessing is performed using the appropriate equipment, materials and that personnel have been adequately trained in order to achieve the desired result; this normally requires that equipment and processes are validated and routinely monitored. Any deviation by the user/hospital/health care provider from these instructions should be evaluated for effectiveness to avoid potential adverse consequences.

DESCRIPTION

The Limited Use Acetabular Reamers are reusable hand instruments designed to help the surgeon prepare the patient's acetabulum to receive an implant during total hip arthroplasty (THA). The acetabular reamers are provided in incrementally increasing sizes to accommodate different patient needs, and each has a common interface for attaching to a reamer driver. The acetabular reamer and driver assembly may be driven manually or by means of a powered surgical driver with a compatible interconnect fitting. The Limited Use Acetabular Reamers are offered in two distinct surface finishes: Gold and natural stainless-steel Silver.

INTENDED USE

The Limited Use Acetabular Reamers are intended for use during Total Hip Arthroplasty (THA) prescribed to treat various diseases of the hip joint. The instruments provide a means for preparation of the acetabulum to receive an implant. The Acetabular Reamers are intended to be attached to a reamer driver which then can be operated manually or by means of a powered surgical driver.

INTENDED PATIENT POPULATION

The Limited Use Acetabular Reamers are prescriptive; therefore, knowledgeable orthopedic surgeon may utilize the device on any patient he or she deems applicable. The device is to be used on patients undergoing total hip arthroplasty.

INDICATIONS FOR USE

The Limited Use Acetabular Reamers are used in hip arthroplasty to gradually increase the spherical diameter of the acetabulum through their cutting action (reaming) in preparation for an acetabular implant. The surgeon controlling the driving device is responsible for determination of the diameter and depth of the cut and its position.

CONTRA-INDICATIONS

The Limited Use Acetabular Reamers are prescription use. The instruments are only to be used by qualified health care personnel. There are no contra-indications for the Acetabular Reamers.

INTENDED USER

The Limited Use Acetabular Reamers are prescriptive and therefore to be used by qualified orthopedic surgeons trained in the respective surgical technique.

EXPECTED CLINICAL BENEFITS

When used as intended, the Limited Use Acetabular Reamers aids in the reaming of acetabulum in preparation for an acetabular implant. The Acetabular Reamers are not specific to any acetabular cup implant. Each Acetabular Reamer creates a spherical cavity of the corresponding size. It is the responsibility of the implant manufacturer and their surgeon panel.

PERFORMANCE CHARACTERISTICS

The Limited Use Acetabular Reamers are used in hip arthroplasty to gradually increase the spherical diameter of the acetabulum through their cutting action (reaming) in preparation for an acetabular implant. The surgeon controlling

- Caution should be exercised when wiping
- As soon as possible after use, set instrument damp towels.

A. MANUAL CLEANING FOR THE ACETABULAR REAMER INSTRUMENTS

1. Prepare a solution of proteolytic enzymatic detergent such as Erzol (or equivalent) according to the manufacturer's recommendations.
2. Before cleaning, disassemble the reamer from the reamer driver.
3. Immerse instruments and soak for the time recommended by the detergent manufacturer.
4. Use a soft bristle cleaning brush and scrub the instruments until all visible contamination has been removed. Scrub the device below the surface of the cleaning solution to prevent aerosolization of contaminants. Pay particular attention to the features of each device that will pose a challenge to effective cleaning; e.g. crevices on the Acetabular Reamers.
5. Rinse all parts thoroughly with distilled or sterile water until all traces of cleaning solution are removed.
6. Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature recommended by the detergent manufacturer.
7. Submerge the instruments and activate the bath for a minimum of 10 minutes. A frequency of 25 – 50 kHz is recommended.
8. Remove and rinse the instruments in distilled or sterile water for at least one (1) minute or until all traces of cleaning solution are removed.
9. Visually inspect the instruments for visible soil and repeat these cleaning steps if remaining soil is observed.
10. Dry the instruments with clean, lint-free wipes in preparation for sterilization. Use clean pressurized air to remove moisture from hard to reach areas.
 - a. Caution should be exercised when drying the reamers, as the teeth are sharp.

B. AUTOMATIC CLEANING FOR THE ACETABULAR REAMER INSTRUMENTS USING WASHER-DISINFECTOR

1. Prepare a solution of proteolytic enzymatic detergent such as Erzol (or equivalent) according to the manufacturer's recommendations.
2. Before cleaning, disassemble the reamer from the reamer driver.
3. Immerse instruments and soak for the time recommended by the detergent manufacturer.
4. Use a soft bristle cleaning brush and scrub the instruments until all visible contamination has been removed. Scrub the device below the surface of the cleaning solution to prevent aerosolization of contaminants. Pay particular attention to the features of each device that will pose a challenge to

STERILIZATION

Moist heat/steam sterilization is the preferred and recommended method for the Reamers.

- Instruments must be properly cleaned before sterilization.
- Instruments should be disassembled from the reamer driver before sterilization.
- Use only approved sterilization wraps or pouches when processing single devices.

If the device is sterilized as part of an instrument set in a rigid container, it is the responsibility of the health care facility to ensure that the minimum recommended sterilization parameters are achieved since changes in instrument load size may affect sterilization efficacy. Use only approved sterilization wraps when processing rigid containers that require them.

The recommended parameters for steam sterilization are:
