Instructions For Use And Reprocessing For The 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 Tecomet 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.

INTENDED USE
The 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 Acetabular Reamers are prescriptive; therefore, knowledgeable orthopedics 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 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 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 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 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 to evaluate the compatibility and fit of the cavity to their implant.

ADVERSE EVENTS & COMPLICATIONS
All surgical operations carry risk. The following are frequently encountered adverse events and complications related to having a surgical procedure in general:

- Delay to surgery caused by missing, damaged or worn instruments.
- Tissue injury and additional bone removal due to blunt, damaged or incorrectly positioned instruments.
- Infection and toxicity due to improper processing.

Adverse events to user:

- Cuts, abrasions, contusions or other tissue injury caused by burs, sharp edges, impaction, vibration or jamming of instruments.

ADVERSE EVENTS & COMPLICATIONS – REPORTING OF SERIOUS INCIDENTS
Serious Incident Reporting (EU)
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Serious incident means any incident that directly or indirectly led, might have led or might lead to any of the following:

- The death of a patient, user, or other person,
- The temporary or permanent serious deterioration of a patient's, user's, or other person's state of health,
- A serious public health threat.

Where further information is desired, please contact your local Tecomet sales representative. For instruments produced by another legal manufacturer, reference the manufacturer's instructions for use.

PERFORMANCE CHARACTERISTICS
The 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. 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 to evaluate the compatibility and fit of the cavity to their implant.

DISPOSAL
- At the end of the device's life safely dispose of the device in accordance with local procedures and guidelines.
- Any device that has been contaminated with potentially infectious substances of human origin (such as bodily fluids) should be handled according to hospital protocol for infectious medical waste. Any device that contains sharp edges should be discarded according to hospital protocol in the appropriate sharps container.

REUSABLE COMPONENTS LIST
All instruments listed are non-sterile. NON STERILE

- Cross Bar Acetabular Reamer 36mm-80mm

WARNINGS AND PRECAUTIONS
⚠ Warnings
- The Acetabular Reamers are provided NON-STERILE NON STERILE and must be properly cleaned and sterilized prior to each use.
- **Read these instructions completely before using the devices.**
- The Acetabular Reamer must be disconnected from the reamer driver before cleaning and sterilization.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated instruments.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of the devices.
- Never use metal brushes or steel wool for cleaning.
- Do not re-sharpen or alter the cutting teeth geometry, height or alignment from the original design specifications.

MATERIALS & RESTRICTED SUBSTANCES
- For indication that the device contains a restricted substance or material of animal origin see product label.

COMBINATION OF MEDICAL DEVICES
- The Acetabular Reamers are designed to connect with reamer drivers or handles that feature the Cross Bar connection. Ensure firm connection with the reamer driver/handle and powered hand piece prior to use.

PRECAUTIONS
- ℞ ONLY U.S Federal law restricts this device to sale by or on the order of a physician.
- The instruments should be inspected for damage and wear before each use. Pay particular attention to the cutting edges and quick connection bar of the reamers. Instruments that show signs of damage or excessive wear should not be used.
- As with any surgical instrument, careful attention should be exercised to ensure that excessive force is not placed on the instrument during use. Excessive force can result in instrument failure.
- Careful attention must be paid to asepsis and avoidance of anatomical hazards.
- Caution should be exercised while cleaning or wiping the reamers, as the cutting edges (i.e. teeth) are sharp.

LIMITATIONS OF REPROCESSING
- End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended use or misuse, and not reprocessing.

CLEANING
- Tecomet recommends that the instruments be cleaned as soon as possible after each surgical procedure in order to limit the drying time of residue biologic soil left on the instruments.
- Water quality used for diluting cleaning agents and for rinsing instruments should be carefully considered. Use of distilled water for cleaning and distilled or sterile water for rinsing is recommended. Avoid using hot water as this will coagulate and harden protein based soil.
- Cleaning agents and disinfectants must be prepared according to the recommendations of their manufacturer. Only use cleaning agents and disinfectants that have a nearly neutral pH and are approved for use on surgical instruments.

POINT OF USE PRE-CLEANING
- Remove excess biologic soil and tissue from instruments using disposable wipes.
  - Caution should be exercised when wiping the reamers, as the cutting edges (i.e. teeth) are sharp.
- As soon as possible after use, set instruments in a basin of distilled water or in a tray covered with damp towels.

A. MANUAL CLEANING FOR THE ACETABULAR REAMER INSTRUMENTS
1. Prepare a solution of proteolytic enzymatic detergent such as Enzol (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 Enzol (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. Load instruments in an automated washer-disinfector in a manner that maximizes exposure of the instrument surfaces.
7. Operate the washer-disinfector according to the manufacturer's instructions to ensure all cycle parameters (i.e. time, temperature) are followed.
8. Remove instruments and check for remaining soil or wetness. If soil remnants are observed repeat the automated cleaning cycle. If remaining wetness is observed, dry the instruments with clean, lint-free wipes in preparation for sterilization.
    a. Caution should be exercised when drying the reamers, as the teeth are sharp.

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:

Cycle Type	Temperature	Exposure Time	Dry Time	Cool Time
United States Recommended Parameters				
Pre-vacuum / Vacuum Pulse	132°C / 270°F	4 minutes	30 minutes	30 minutes
Cycle Type	**Temperature**	**Exposure Time**	**Dry Time**	**Cool Time**
European Recommended Parameters				
Pre-vacuum / Vacuum Pulse	134°C / 273°F	3 minutes	30 minutes	30 minutes

Drying & Cooling

- The recommended drying time for single wrapped instruments is 30 minutes unless otherwise noted in device specification instructions.
- Drying times for instruments processed in containers and wrapped trays can vary depending upon the type of packaging, type of instruments, type of sterilizer and total load. A minimum dry time of 30 minutes is recommended, but to avoid wet packs, extended dry times greater than 30 minutes may be needed for larger loads under certain conditions or if otherwise recommended in accompanying documentation. For large loads verification of dry times by the health care provider is recommended.
- A 30 minute minimum cooling time is recommended after drying but longer times may be necessary because of load configuration, ambient temperature and humidity, device design and packaging used.

SYMBOLS USED ON LABELING

U.S Federal law restricts this device to sale by or on the order of a physician

Manufacturer

Catalog Number

CE Mark with Notified Body number

Caution

Consult Instructions for Use

Lot Number

Non-Sterile

European Representative

Date of Manufacture

Medical Device

Packaging Unit

Country of Manufacture[1]

Distributor

Swiss Authorized Representative[2]

Importer

Unique Device Identifier

[1]See label for country of manufacture code

[2]See label for Swiss Authorized Representative

TECOMET CE 2797

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