



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 increasingly 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.

REUSABLE COMPONENTS LIST

All instruments listed are non-sterile.

- 420 SS Acetabular Reamer Non-Hemisphere 36mm-80mm
- 420 SS Acetabular Reamer Full-Hemisphere 36mm-80mm
- 420 SS Acetabular Reamer Low Rider 36mm-80mm
- Parabolic Acetabular Reamer 46mm-66mm
- Smooth Cut Acetabular Reamer 36mm-80mm
- Cross Bar Acetabular Reamer 36mm-80mm

WARNINGS AND PRECAUTIONS

Warnings

- The Acetabular Reamers are provided 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.

PRECAUTIONS

- US 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 ON 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

	US Federal law restricts this device to sale by or on the order of a physician		Non-Sterile
	Symbol for "Manufacturer"		European Representative
	Catalog Number		Date of Manufacture
	CE Mark with Notified Body number		Medical Device
	Caution		Packaging Unit
	Consult Instructions for Use		Country of Manufacture
	Lot Number		Distributor



Manufactured By
 Legal Name:
 Symmetry Medical Manufacturing, Inc.
 486 West 350 North,
 Warsaw, IN 46582, USA
 Phone: +1 574 267 8700
 www.tecomet.com

European Representative:
 Symmetry Medical Polyvac S.A.S
 Parc d'Activités du Moulin
 139, Avenue Clément Ader,
 Wambrechies
 59118
 France
 Phone: +33 3 28 09 94 54

Distributed by:



Zimmer Inc.
 1800 W. Center Street
 Warsaw, Indiana 46580 USA
 Phone: 1-800-348-2759 (US Only)
 Phone: +1-574-372-4999
 www.zimmer.com