Instructions for Use

Intended Use

Tecomet Hip Revision System is a comprehensive solution for femoral and acetabular revision surgery. The System is designed to facilitate the removal of cemented and non-cemented femoral and acetabular hip implants. It includes the following:

- Femoral Revision Instruments
- Femoral Extraction Instruments
- Acetabular Revision Instruments
- Flexible Osteotomes
- Trephines

Intended Patient Population

The System is prescriptive; therefore, a knowledgeable orthopedic surgeon may utilize the device on any patient he or she deems applicable. The instruments are used at the discretion of the surgeon based upon their best medical judgment to accommodate the patient condition and fixation of the old devices.

Indications For use

The System is indicated for use to extract previously failed femoral and acetabular him implant components.

Contra-Indications

The System is prescription use and are only to be used by qualified health care personnel. There are no contra-indications for the system.

Intended User

The System is prescriptive and therefore to be used by qualified orthopedic surgeons trained in the respective surgical technique.

Expected Clinical Benefits

When used as intended, the System aids the safe removal of the previously failed hip and femoral implant components.

Performance Characteristics

The System is designed to facilitate the removal of cemented and non-cemented femoral and acetabular hip implants. The System performance and safety is established, and it represent the current state of the art when used as intended.

Combination of Medical Devices

For the combinations listed below, ensure firm connection with the assembled device prior to use.

- The Threaded Slaphammer connects to the Acetabular Component Gripper
- The Treaded Slaphammer with Zimmer/Tri-Shank Quick Connect End Connects to Trephines. The assembly can be used under power via connection to power handpiece or manually via connection to the T-Handle.
- The Slaphammer Adapter connects to the Slaphammer via thread.
- The Femoral Extractor Slaphammer connects to the below instruments:
    - One Piece Stem Adapter
    - Closed Loop Extractor
    - Hook Stem Extractor
    - Universal Modular Hip Stem Adapter
- The Osteotome Quick Coupling Handle connects to the Osteotome Blades
- The Twist Drills connects to power handpiece via quick connection end.

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 and 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.

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.

Material and Restricted Substances

For indication that the device contains a restricted substance or material of animal origin see product label.

Recommendations for Care, Cleaning and Sterilization of Tecomet Surgical Instruments

Tecomet recommends that the cleaning and decontamination of instruments follow the guidelines set forth by AORN/HIMA and AAMI. Both physical and chemical (detergent) processes are necessary to minimize the bioburden on all soiled items. Chemical (detergent) cleaners alone cannot remove all soil and debris, therefore a careful manual cleaning of each item with a soft sponge or cloth is essential for maximum decontamination. Carefully inspect hidden areas such as cannulations and recesses to assure any residual materials are removed. Once the items have been cleaned and decontaminated, they should be thoroughly rinsed with clean water to remove any detergent or chemical residue before sterilization. Tecomet recommends the use of a mild enzymatic detergent with a low pH.

Special Instructions

Even with proper handling, correct care and maintenance, surgical instruments should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., drills, gouges, reamers, and chisels), driving instruments (e.g., impactors, extractors and mallets). These items are often subjected to high loads and/or impact forces. Before each use carefully inspect all instruments. Do not use a driving instrument that is severely marred and worn or cutting instrument with dull edges.

Note: that at some point in time, instruments wear out and should be replaced. For guidelines related to care and handling of surgical instruments, see AORN recommended practices, AORN Journal 55(3):838, 1992

Single use instruments ⊗

- NON STERILE Trephines are intended for **Single Use** ⊗**.**
  - Unused Trephines can be re-processed multiple times prior to first use.
- All Osteotomes **Not Labeled** STERILE for **Single Use** ⊗ are NON STERILE **Single Use** ⊗ devices.
  - Unused, non-sterile, single use Osteotomes can be re-processed multiple times prior to first use.
  - Sterile Osteotomes in visibly damaged sterile packaging should be discarded.

Materials used in Tecomet's instruments have been used in nearly all modern sterilization methods with excellent results. For typical steam autoclave cycles, the following are recommended times and temperatures developed from outside testing using AORN/HIMA and AAMI established guidelines:

1. High Vacuum Sterilizer

Wrapped cases, trays and instruments should be exposed to a minimum of 132 degree C (270 degrees F) for a minimum of 4 minutes.

Tecomet's recommendations for proper steam autoclave sterilization are based upon AORN/HIMA and AAMI guidelines. Proper load sizes, weights and mass should follow OSHA's and AAMI's recommended guidelines.

1. After the autoclave door is opened, all instruments must be allowed to cool thoroughly. The amount of dry time required is dependent upon the load size and its mass. Place instruments on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the case is not allowed to cool properly.
2. If condensation is observed check to ensure that step 1 has been followed and verify that the steam that is being used for sterilization processing has a quality of more than 97%. Also confirm that the sterilizers have been inspected for routine maintenance in accordance with manufacturer's recommendations.

Symbols Used on Labeling:

 Caution

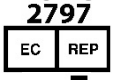
Non-Sterile

Sterile

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

 CE Mark[1]

CE Mark with Notified Body #[1]



Authorized Representative in the European Community

 Manufacturer

 Date of Manufacture

Lot Number

Catalog Number

 Consult Instructions for Use

 Single Use; Do Not Reuse

 Distributor

Sterilized by irradiation

Medical Device

Packaging Unit

Country of Manufacture

 Do not use if package is damaged and consult instructions for use

 Use by

Swiss Authorized Representative[2]

 Importer

Unique Device Identifier

[1]Refer to the labeling for CE information
[2]Refer to the labeling for Swiss Authorized Representative

Manufactured By:

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

EC REP European Representative
Symmetry Medical Polyvac S.A.S
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