



Hollow Spherical Single-Use Acetabular Reamer - INSTRUCTIONS FOR USE

USE

The Hollow Spherical Single-Use Acetabular Reamer is intended for shaping the acetabular cavity in hip replacement surgery for use with surgeon recognized hip surgical techniques and associated instrumentation. Prior to using the reamer, the surgeon shall have given careful consideration to all aspects of the surgical intervention as well as to the limits of the reamer.

Technique for Surgical Use:

- Remove the reamer from the sterile package by opening and inverting the inner blister.
- Grasp the reamer at the edge of the molded baseplate and push onto the reamer shaft while pulling back on the locking sleeve, making a quarter turn to lock the reamer in place.
- Insert the reamer, in proper orientation, into the bony acetabulum and activate the surgical drill, advancing the reamer to the correct depth.
- Remove the reamer from the acetabulum and insert the properly sized prosthetic acetabular component.
- Remove the reamer from the reamer shaft by grasping the edge of the base plate, pulling back on the locking sleeve and rotating a quarter turn and pulling the reamer off the reamer shaft.
- Dispose of the reamer after a single use.

REUSE

DO NOT REUSE OR REPROCESS. The Hollow Spherical Acetabular Reamer is for use in a single procedure. A second procedure use is prohibited and may reduce the performance of the instrument and puts the patient and the surgeon at risk. The reamer must be properly disposed of after each procedure.

EXAMINATION PRIOR TO USE

Hollow Spherical Single-Use Acetabular Reamer (sold sterile):

- Before utilization, it is necessary to verify the sterility expiration date, which is indicated as the “use by” date. The company cannot be held responsible for the use of its products after their expiration date.
- It is recommended to verify the integrity of the instrument and original package before use. Sterility is ensured only if there is no trace of damage to the packaging.
- In case of damage to the packaging, or after opening of the packaging, re-sterilization of the instrument is strictly forbidden, regardless of the method that might be employed.
- Instrument should be visually examined for damage by surgeons and staff in operating centers prior to surgery.

PACKAGING

The Hollow Spherical Single-Use Acetabular Reamer is sold sterile and will be clearly labelled as sterile on the product label. The sterilization method applied is indicated on the product label. The sterile instrument packaging must be intact at the time of receipt and the integrity of the packaging shall be checked prior to use.

MATERIAL INFORMATION

The Hollow Spherical Single-Use Acetabular Reamer is manufactured from Stainless Steel and Polycarbonate. The materials are commercially available, are biocompatible, corrosion-resistant, and non-toxic in the biological environment.

STERILIZATION

The Hollow Spherical Single-Use Acetabular Reamer is supplied by the company in a sterile condition. The instrument has been sterilized by Ethylene Oxide Gas Sterilization (noted as STERILE-EO on the label).

For shelf-life expiration, refer to the date printed on the product label. Meticulously inspect the package before use. Do not use the instrument if the package has been opened, is torn, or punctured, or if the seal has been broken.

Steam sterilization, including flash sterilization of Hollow Spherical Single-Use Acetabular Reamer is NOT recommended.

STORAGE AND HANDLING














The Hollow Spherical Single-Use Acetabular Reamer should be handled with care at all times. Storage zones for surgical instruments should be away from areas of humidity and must be out of contact with UV rays and sources of electro-magnetic radiation.

Do not use the Hollow Spherical Single-Use Acetabular Reamer after the expiration date indicated on the package and label. After this date, the sterility of the instruments can no longer be assured.

CAUTION

Federal Law (USA) restricts these instruments to sale by or on the order of a physician.

PACKAGING LABELS LEGEND

| | |
|--|--|
|  | Manufactured by |
|  | Catalog Number |
|  | Manufacturer's lot number |
|  | Unique Device Identifier |
|  | Caution |
|  | Consult instructions for use |
|  | Use by date |
|  | Quantity |
|  | Do not reuse / Single use only |
|  | Do not use if package is damaged |
|  | Keep Dry |
|  | Sterile unless the package is damaged or open. Method of sterilization – Ethylene Oxide Gas |
|  | Federal law (USA) restricts this device to sale by or on the order of a physician. |



OsteoFit LLC
24 Sherwood Lane, Fairfield, NJ 07004
862.210.8435