Instructions for Use (Product Insert)

CAUTION:
Federal Law restricts this device to sale by or on the order of a physician.

DESCRIPTION:
OsteoBridge® Intramedullary Knee Arthrodesis Rod Fixation System (IKA) is a series of modular intramedullary rod segments that may be used as either proximal or distal segments. The segments are designed to be attached together to form a complete intramedullary rod using a semicircular hollow angled attachment shell that is clamped together with multiple screws to create a firm fixation of the bone. We strongly recommend covering the attachment shell with bone graft to enhance callus formation. All components are manufactured from Ti-6Al-4V ELI conforming to ISO 5832-3. The intramedullary rods can be fixed with interlocking screws without or with bone cement.

INTENDED USE:
Intramedullary knee arthrodesis
Indications include:
1. Irretrievably failed total knee arthroplasty
2. Limb salvage
3. Oncology surgery
4. Any other condition where there is little soft tissue or bony tissue available for support and arthrodesis is the treatment of choice

• The intramedullary rods can be fixed with interlocking screws without or with bone cement.

CONTRAINDICATIONS:
• Acute or chronic, local or systemic infections
• Severe muscle, nerve or vascular diseases, which would endanger the affected extremities
• Defective bone structures which would impede adequate anchoring of the implant
• All accompanying diseases which could endanger the function and success of the implant
• Patients with mental or neurological disease conditions or patients who are not capable of following the necessary post-operative treatment instructions

WARNINGS:
• Non-sterile devices must be properly cleaned and sterilized before use.
• Implants are for single use only.
• During the implantation and repositioning the operating surgeon should pay attention that the surfaces of the implant are not damaged due to nicks and scratches. Even a slight scratch can considerably reduce the lifespan of an implant.
• Follow the described surgical technique strictly; especially the instructions for the assembling of the spacer with the spacer screws are to be followed exactly. Screws must be tightened with the required torque in the given order. The spacer half-shells have to be aligned parallel.

PRECAUTIONS:
• The device is designed for use by surgeons experienced in the appropriate specialized procedures. It is the responsibility of the surgeon to become familiar with the proper techniques.
• Additional precautions include those applicable to any surgical procedure. In general, careful attention must be paid to asepsis and avoidance of anatomical hazards.
• The non-sterile devices must be properly cleaned and sterilized before use.
• The implants must be stored in the original packaging in a dry, clean place and at a temperature ranging from temperature to cool but above freezing.
• Prior to use examine device and check for proper functioning.
• For the implantation of OsteoBridge™ IKA use only the original OsteoBridge™ IKA Instruments. The use of Merete instruments for other than the intended purposes is not permitted. The reuse of explanted components is not allowed.
• Curved nails must only be used in the femur. The nail guiding/impacting instrument is not to be used with curved nails. These must be locked free hand using an image converter.
• If using bone cement:
  – Pay attention to the information given by the cement manufacturer
  – The cement bed should be spread evenly.
• Prior to assembling the spacer wash the clamping surface in order to completely remove all kinds of debris, including bone splinters, soft tissue parts, bone cement and others.
• For fixing the attachment shell multiple screws, the torque limiting screw driver must be used and the correct torque applied to assure complete locking of the attachment shell rods.

MRI SAFETY INFORMATION:
The OsteoBridge™ System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the OsteoBridge™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POTENTIAL ADVERSE EFFECTS:
The potential adverse effects associated with this device are the same as with any metallic internal fixation device. These include but are not limited to the following:
• Delayed or non-union which may lead to breakage of the implant
• Bending or fracture of the implant
• Metal sensitivity or allergic reaction to a foreign body
• Pain, discomfort, or abnormal sensation due to the presence of the device

FURTHER INFORMATION FOR USE
Cleaning, disinfection, and sterilization instructions for re-usable surgical instruments and non-sterile implants

PROCESS
• Cleaning
• Disinfection
• Sterilization with hot steam (DIN EN ISO 17665-1)

WARNINGS
Instruments/implants that are supplied non-sterile are clearly marked with “NON-STERILE” and must be cleaned, disinfected and sterilized prior to use. The instruments/implants may only be processed by qualified personnel. Only approved cleaning agents and disinfectants (FDA) are to be used (pH ≤ 12 pH for instruments/implants made of metal). Instruments/implants made from synthetic materials or ones that contain components made from synthetic materials are not to be sterilized using dry heat.

RESTRICTIONS REGARDING REPROCESSING
The presented cleaning processes have been validated. Other methods of cleaning may be suitable but need to be validated by the user of the device. Differing instructions and recommendations of the manufacturer are to be observed.

POINT-OF-USE PROCESSING
It is advisable to prepare instruments/implants for reuse as soon as possible after having used them. Macroscopic surface contamination can be difficult to remove by automated cleaning procedures. Prior to cleaning remove macroscopic contamination with a disposable towel/paper towel.
Keep instruments/implants moist after use to prevent contamination from drying. Instruments/implants may be placed in a disinfectant solution or hot water 176°F (80°C) immediately after use in order to facilitate cleaning and to reduce risk of infection.

PREPARATION FOR CLEANING
Dismantle all instruments/implants as far as possible. Ensure to keep all small components and screws. Pre-cleaning of instruments:
• Completely immerse the instruments/implants in an enzymatic or alkaline cleaning solution (pH ≤ 12) and soak for 10 minutes
• Clean the instruments/implants with a surgical scrub brush
• Then rinse the instrument/implant for at least 1 minute with deionized water

AUTOMATIC CLEANING
Automatic cleaning is preferable to manual cleaning, if this is an option. The machine should offer a suitable thermal disinfection program. Minimum cycle steps and parameters are:
STERILIZATION:

- 1 minute with cold water < 109.4°F (< 43°C)
- Cleaning 5 minutes with cleaning agent (131°F (55°C) or follow the manufacturer's instructions)
- 1 minute neutralization with warm water
- 1 minute rinse (note: final rinsing is to be carried out with deionized water)

When choosing a cleanser, make sure that it is compatible with instrument/implants materials. Follow manufacturer's instructions when loading cleaning machines. Place instruments/implants in such a way so as to allow complete, thorough rinsing of all ducts and cavities. Use deionized water for the final rinse. Immediately after the program has completed, remove instruments/implants from the machine and, if necessary, dry them with a soft, absorbent, lint-free cloth. Ensure to allow sufficient drying time.

AUTOMATIC DISINFECTION

Choose a program for an A5 value > 3000, or at least 10 minutes at 200°F (93°C) in older machines. Alternatively, if using a chemical disinfection method, bear in mind the risk of residue being left on the instruments/implants.

MANUAL CLEANING

Begin by removing major surface contamination from the instruments/implants using a soft nylon brush or a soft, lint-free cloth, along with either clear running water or a cleaning solution. Never use abrasive cleaning agents or metal brushes.

Place the instruments/implants in the cleaning solution, following manufacturer's instructions as regards concentration, soaking time, and compatibility with the instruments/implants materials. Ensure that the instruments/implants is completely submerged in the cleaning solution. Be sure to vent all cavities, lumens and openings. Clean lumens and drill holes using appropriate brushes. After cleansing, rinse using deionized water, and dry thoroughly.

Subsequent ultrasonic cleaning. Be sure that the ultrasonic bath is pre-heated according to device manufacturer or cleaning-agency manufacturer instructions. When loading the bath, make sure that the cleaning solution completely covers the instruments/implants, and that all cavities, lumens and openings are fully vented. After ultrasonic cleansing has finished, rinse instruments/implants thoroughly with deionized water, making sure to flush out cavities, lumens and openings wherever applicable.

INSTRUMENTS MAINTENANCE

Allow instruments to cool down to room temperature. Lubricate moving parts lightly with sterilizable, steam-penetrable surgical lubricating oil.

CHECKING FUNCTIONALITY

After each cleaning/disinfection, inspect the instruments/implants for cleanliness, functionality, and damage (e.g., bent, broken, worn or missing parts). Never use damaged instruments or implants. The completeness of instrument trays and cases should be assessed using the provided tray insert sheets.

CLEANING AND DISINFECTING EMPTY TRAYS

Clean and disinfect empty trays using the same procedure and under the same conditions as for instruments/implants. Be sure that the tray is completely dry prior to inserting instruments/implants.

PACKING

Prior to steam sterilization, cleaned, disinfected instruments/implants should be inserted into suitable containers or sterilization packages (DIN EN ISO 11607-1).

STERILIZATION:

| Implants/Instruments which are delivered in a sterile condition are clearly labeled with “STERILE”. Sterile implants have been sterilized with gamma rays. |
|---|---|
| **Method** | Gamma Radiation |
| **Radiation Dose** | 2.5 Mrad |
| **Sterility Assurance Level** | 10^-6 |
| **Sterility Validation Method** | ISO 11137-2/VD_no_25 |
| **Packaging** | Double Peel PE Pouch |
| **Pyrogenicity** | Not labeled pyrogen free |

The trays containing implants and instruments are only provided for packaging, not for sterilization.

STORAGE

After sterilization, the instruments/implants must be kept in their sterilization packaging and stored in a dry, dust-free place.

PREPARATION INSTRUCTIONS IN ACCORDANCE WITH DIN EN ISO 17764

The preparer is responsible for ensuring that the preparation procedure actually employed (using the materials, equipment, and personnel available in the preparation facilities) achieves the desired results. Normally, this means that the procedure must be validated and subject to routine monitoring. Likewise, any deviation from the instructions provided should be carefully evaluated by the preparer to determine its effectiveness and possible negative consequences.

DEFINITION OF SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE mark</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>Date of manufacture</td>
<td>Use-by date</td>
</tr>
<tr>
<td>Batch code</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>Sterilized using ethylene oxide</td>
<td>Sterilized using irradiation</td>
</tr>
<tr>
<td>Do not re-sterilize</td>
<td>Non-sterile</td>
</tr>
<tr>
<td>Do not use if package is damaged</td>
<td>Keep dry</td>
</tr>
<tr>
<td>Temperature limit</td>
<td>Do not re-use</td>
</tr>
<tr>
<td>Consult instructions for use</td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td>QTY</td>
<td>R, only</td>
</tr>
</tbody>
</table>

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