

Important Product Information OsteoBridge™ IKA (Package Insert OsteoBridge™ IKA - Intramedullary Knee Arthrodesis)

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

1. Explanations to used symbols

	Manufacturer
	Use-by date
	Batch code
	Catalogue number
	Sterilized using irradiation
	Do not resterilize
	Do not use if package is damaged
	Keep dry
	Do not reuse
	Consult instructions for use
	Caution
	Quantity
	Caution: Federal law (USA) restricts this device to sale by or on order of a physician
	Keep away from sunlight
	MR Conditional
	Single sterile barrier system with protective packaging outside
	Unique device identifier

2. Product Description

Warning: Use of damaged or defective implants. Risk of injury due to premature implant failure! Implants with identifiable damage may not be used. Avoid notches, scratches or bending of the implant in order to preserve its stability.

Warning: Use of damaged or defective instruments. Risk of injury due to premature implant failure! Instruments with identifiable damage may not be used.

Warning: Use of implants which have been previously used. Risk of injury due to premature implant failure! Risk of sepsis! Implants are only approved for single use, not reuse.

The OsteoBridge™ IKA system provides arthrodesis of the knee. The system includes two nails and a spacer. Users can choose between straight collared nails and conical non-collared nails. The spacer is available with 10° flexion angle. All nails and the spacer can be combined freely. In situations wherein the bone has a trumpet-shaped opening as a result of previous prostheses, and the medullary canal is cylindrical, straight collared nails ensure that the nail will be well-supported within the bone. Non-collared nails taper along the unclamped length, which ensures good distribution of force within tapered medullary cavities.

The design of the implant system is modular with regard to the treatment of joint defects of different sizes, taking into account different bone qualities. The goal is to adapt the implant to the defect, since this type of restoration aims to preserve as much bone as possible. The nails can be combined with the spacer in various designs, diameters and lengths. All nail types can also be freely combined with each other to take into account the individual bone qualities. Only the curved nails are limited to the femur.

2.1. Intended Purpose /Use

Warning: Use of implants contrary to intended purpose. Risk of injury due to implant failure! Implant must only be used in accordance with intended purpose.

Intramedullary knee arthrodesis

2.1.1. Indications

Indications include:

- Irretrievably failed total knee arthroplasty
- Limb salvage
- Oncology surgery
- 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.

2.1.2. Intended patient target groups

- Age: when the bone growth is completed
- Body weight: obesity or pre-obesity can interfere with the success of the implant
- Activity: observe aftercare, physical activities associated with strong shocks which could result in the implant being exposed to impacts and/or excessive loads (e.g., hard physical labour, certain types of sport)

2.2. 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 preoperative treatment instructions

2.3. Warnings

Warning: Improper use of an implant/instrument. Damage to/destruction of instrument/implant and injury to patient! Ensure correct handling of implant/instrument. Do not misuse.

Warning: Combination with products from other manufacturers. Risk of injury due to implant failure! Do not combine the implant components with products from other manufacturers.

Warning: Implantation of trial implants. Risk of injury due to failure of trial implant! Only use trial implants in order to select a suitable permanent implant. Trial implants are not suitable for permanent implantation.

Warning: Incorrect preparation of the medullary cavity. Risk of implant failure (lengthening/shortening of the extremity)! Drill out the medullary cavity as specified in the surgical technique and use a cement restrictor when using bone cement to ensure a proper cement mantle.

Warning: Improper use of bone cement. Risk of injury due to premature implant failure! Pay attention to the information given by the cement manufacturer. The cement mantle should be spread evenly 2 mm on each side. Cement protection caps must be placed on the nails before cementing to avoid contamination of the clamping surfaces.

Warning: Foreign bodies (e.g. cement residues, tissue, bones) between implant components. Risk of injury due to implant failure! Thoroughly clean any foreign bodies from implant components.

Warning: Incorrect or improper assembly of implant. Risk of increased wear to implant! Risk of implant failure! Perform the implantation with care. Observe correct handling of implant components and instruments. A bicortical anchoring is essential for a stable implant when using interlocking screws. The interlocking screws must be completely tightened. Make sure there is at least 5 cm of cortical bone contact of the nail within the bone, in order to ensure stable anchorage. 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. It is essential to ensure that the implant nails are clamped in the spacer at their minimum respective clamp lengths and the spacer is flush with the clamping areas of the nails. The instructions for the assembling of the spacer with the spacer screws are to be followed exactly. All eight screws must be used for spacer assembly. Use the guiding pins during assembly to ensure the spacer half-shells remain parallel to each other. When screwing in the guiding pins or spacer screws, be careful not to damage the spacer threads. Use the distance holder during assembly to maintain the necessary gap between nail collar and spacer. Do not allow nails to contact each other inside spacer. In case of defective bone structure, the nail must be long enough to bridge over the damaged region.

Warning: Torque limiter not used or incorrectly used during implant assembly. Risk of increased wear to implant! Risk of implant failure! Use the torque limiter during assembly and follow the sequence instructed for tightening the screws to ensure even and sufficient clamping of the spacers. Tighten all eight screws three times in the given order until the correct torque has been reached. When reaching the correct torque a “pop” sound is triggered.

Warning: Use of instruments with electrical energy. Risk of injury due to implant failure! Do not damage the surfaces of the implants under any circumstances.

* This product is for single use only. An internal fixation device must never be reused. The reuse of explanted components is not permitted under any circumstances.

• During the implantation and repositioning, the operating surgeon should pay attention that the surfaces of implant are not damaged due to nicks and scratches. Even a slight scratch can considerably reduce the lifespan of an implant.

2.4. Cautions

- The devices are designed for use by surgeons experienced in the appropriate specialized procedures. It is the responsibility of the surgeon to read the surgical technique handbook as well as become familiar with the correct use of the instrumentation for this implant.
- Training in the correct handling of implants and instruments is only to be executed by an authorized Merete representative.
- Additional precautions include those applicable to any surgical procedure. In general, careful attention must be paid to asepsis and avoidance of anatomical hazards.
- Non-sterile instruments 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 room temperature to cool but above frost-formation.
- The implantation must be performed with the corresponding Merete instruments. The use of Merete instruments for other than the intended purposes is not permitted.
- Use trial components during the operation in order to check correct implants size and positioning.
- Curved nails must only be used in the femur. Also, curved nails extend past the length of the Nail Guiding/Impacting Instrument (Ref. GA90100), their corresponding interlocking screws must be inserted under fluoroscopy without a guide.

Implantation in adolescents:

- Complete bone growth is a prerequisite for the application of the OsteoBridge™ IKA system.
- Only use the OsteoBridge™ IKA system for adolescents in exceptional cases. The decision is up to the user.
- Adjust the size and type of the implant as best as possible to the age, height, weight and bone development of the adolescent.
- Due to growth, a subsequent operation for removal and/or revision is more likely in adolescents.
- Perform follow-up checks at shorter intervals.

CAUTION: (not recommended) Interlocking of nails with cementation leads to:

- Loosening or breakage of the locking screw
- Loosening or breakage of the nail
- Breakage of the cement mantle
- Heat generation
- Breakage of the drill (drill in the instrument tray is not designed for use in bone cement) can occur.

Prior to using Merete products, surgeons and assisting staff must study in detail the safety information in this product information sheet, as well as the product-specific guidelines listed in the surgical technique. The relevant documentation is available from Merete on request. Surgeons must also be aware of any remaining risks associated with the products he or she intends to use and must inform patients of such risks in advance. Implant operations must only be performed by surgeons who are not only qualified to carry out such operations, but also have extensive verified knowledge and experience in this field. The surgeon bears all responsibility for adverse effects or complications arising from misdiagnosis, improper surgical technique, incorrect implant selection or handling, or failure to observe the safety instructions provided in the product information sheet. Neither the manufacturer nor authorized Merete product representatives may be held liable in such cases. Before operating, study the techniques outlined in the surgical technique carefully. The patient has to be informed about alternative methods of treatment and other systems with adequate intended uses.

Preoperative Planning

Surgery planning should be done on the basis of in-depth evaluations of patient X-rays which provide the information necessary for determining the appropriate implant type, size, and possible combinations. If desired, X-ray templates for preoperative planning are available from Merete. It should be examined preoperatively whether the existing implant sizes are suitable for the patient.

It is also important to carry out preoperative tests on the patient to rule out allergic reaction to the implant materials. Use trial components during the operation in order to check correct implants size and positioning. The components planned for implantation must be on hand in all available sizes. It is absolutely essential to check the implant label (type, item number, material and size) against the information on the package before insertion. Use the additional enclosed labels for documentation in surgery reports and for re-ordering. Check that all implant surfaces are free of soiling.

Important: Always check sterilization expiration dates! Do not use if expiration date has passed.

Application Environment

The implants and instruments are to be used in a standardized operating room. The products may only be used by qualified surgeons having a profound knowledge and experience in the field of orthopedics.

Revision Surgery

If the revision surgery involves replacement of all the implant components, the same instructions apply to the treatment of the implants as for a first implantation. A partial change of implants leads to the mixing of old, pre-damaged components and new implants. In such cases, it is important that the component mating surfaces be in excellent condition. It is always recommended to completely replace all components.

NOTE For explanation, please order the instrument trays.

Patient Information

The patient must be informed by the doctor of the information provided in this document regarding factors which could interfere with the success of a surgery as well as possible complications which could result from such an indication. The patient must be informed about which measures they can take to reduce the possible effects of these factors. The patient has to be informed about alternative methods of treatment and other systems with adequate intended uses. All information given to the patient must be documented by the operating surgeon in writing.

All metal components are made of the following material:

- TiAl6V4 ELI alloy (ASTM F 136, DIN EN ISO 5832-3)

Further information about the chemical composition and the mechanical properties of the used materials can be requested from Merete.

2.5. Factors which could impair the Success of the Operation

- Allergies to the implant materials (particularly metals, but also bone cement)
 - Obesity or pre-obesity of the patient
 - Osteoporosis or osteomalacia
 - Systemic or metabolic disorders
 - Smoking, alcohol or drug abuse
 - A strong curvature of the medullary canal increases the risk of fractures during insertion of straight nails into bone
 - Physical activities associated with strong shocks which could result in the implant being exposed to impacts and/or excessive loads (e.g. hard physical labour, certain types of sports)
 - Patients with pathological mental or neurological conditions, or patients who are not capable of following the necessary postoperative care instructions
 - Inadequate soft tissue in implant area which would impede closure of the wound
- 2.6. 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
 - Loosening of the implant resulting from changed conditions of the load transfer or wearing and fracture of the cement mantle and/or tissue reaction to the implant and the associated metal abrasion products
 - Corrosion with local tissue reaction and/or pain
 - Failure or subsidence of the implant in case of over-loading
 - Early and late infection
 - Undesired shortening, lengthening or malalignment of the relevant extremity as a result of suboptimal positioning of the implant
 - Bone fractures due to unilateral overuse or weakened bone substance
 - Reduced bone density due to stress shielding or bone resorption as a tissue response to metal abrasion particles
 - Temporary or permanent nerve damage due to pressure or hematoma
 - Wound hematoma and slow wound healing
 - Vascular disorders, including vein thrombosis, pulmonary embolism and heart failure
 - Heterotopic ossification
 - Nerve damage as a result of surgical trauma
 - For non-cemented implantation lack of bony ongrowth onto the nails can lead to overloading of the locking screws

NOTE Because of their funnel-shaped design, nails with a collar may cause a splitting or shattering effect (fissure) in the distal femur (condylar region) and the proximal tibia (plateau region) during implantation. Careful preparation of these bone regions, with the correct instrument and if applicable a proper cement mantle, are required.

3. MRI Safety Information

	MRI Safety Information/Indications for Use
	Non-clinical testing has demonstrated that the Merete OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) System (consisting of two cemented or non-cemented intramedullary stems and one spacer made of TiAl6V4 ELI (ISO 5832-3)) is MR conditional.
	A patient with the entire assembled Merete OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) System can be safely scanned in an MR system meeting the following conditions:
	– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
	– Maximum spatial gradient field of 3,000 Gauss/cm (30 T/m).
	– Maximum MR system reported whole-body-averaged specific absorption rate (SAR) at 1.5 Tesla or 3 Tesla of 1 W/kg for 15 minutes of scanning. Under the scan conditions defined above, the Merete OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) System is expected to produce a maximum temperature rise of less than 6° C after 15 minutes of continuous scanning.
	– In non-clinical testing, the image artifact caused by the Merete OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) System extends at least 1 cm and up to approximately 7 cm from the device and exhibits substantial geometric distortion in the image when imaged with a gradient echo pulse sequence or a fast-spin echo pulse sequence and a 1.5 Tesla MRI system or a 3.0 Tesla MRI system.

4. Instrumentation

Please refer to instrumentation instructions for use (PTI0027) for information regarding cleaning, disinfection and sterilization. All instruments are supplied non-sterile and must be sterilized prior to use according to the following recommended sterilization parameters.

Recommended sterilization parameters

Method	Temperature	Time	Drying Time
Steam Sterilization	270°F (132°C)	4 minutes	30 minutes

4.1. Process

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

4.2. Warnings

Warning: Use of damaged or defective instruments. Risk of injury due to premature implant failure! Instruments with identifiable damage may not be used.

Warning: Use of contaminated instruments. Risk of Sepsis! Use only instruments without visible contamination.

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

4.3. Restrictions regarding Reprocessing

Warning: Resterilization of implants. Risk of injury due to premature implant failure caused by adverse material changes! Implants delivered sterile by Merete® GmbH must not be resterilized and/or repacked. Products or which expiry date has passed may be returned to Merete Technologies Inc. (MTI).

Warning: Use of damaged or defective instruments. Risk of injury due to premature implant failure! Instruments with identifiable damage may not be used.

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. Instructions and recommendations of the manufacturer are to be observed.

4.4. Point-of-use-Processing

It is advisable to prepare instruments 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 disposable towel.

Keep instruments moist after use to prevent contamination from drying. Instruments 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.

4.5. Preparation for Cleaning

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

4.6. 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:

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

When choosing a cleanser, make sure that it is compatible with instruments materials. Follow manufacturer's instructions when loading cleaning machines. Place instruments 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 from the machine and, if necessary, dry them with a soft absorbent, lint-free cloth. Ensure to allow sufficient drying time.

4.7. Automatic Disinfection

Choose a program for an A0 value > 3000, or at least 10 min 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.

4.8. Manual Cleaning

Begin by removing major surface contamination from the instruments 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 in the cleaning solution, following manufacturer's instructions regarding concentration, soaking time, and compatibility with all instrument materials. Ensure that the instruments are completely submerged in the cleaning solution. Be sure to vent all cavities, lumens and openings. Clean lumens and drill holes using appropriate brushes. After cleaning, rinse using deionized water, and dry thoroughly. For subsequent ultrasonic cleaning, be sure that ultrasonic bath is preheated according to device manufacturer or cleaning-agent manufacturer instructions. When loading the bath, make sure that the cleaning solution completely covers the instruments, and that all cavities, lumens and openings are fully vented. Clean instruments at 35-40 kHz for 5 min. After ultrasonic cleansing has finished, rinse instruments thoroughly with deionized water, making sure to flush out cavities, lumens and openings wherever applicable.

4.9. Instruments Maintenance

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

4.10. Checking Functionality

After each cleaning / disinfection, inspect the instruments 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.

4.11. Cleaning and Disinfecting Empty Trays

Clean and disinfect empty trays using the same procedure and under the same conditions as for instruments. Be sure that the tray is completely dry prior to inserting instruments. The instrument trays must be checked for completeness on the basis of the attached tray inserts.

4.12. Packing

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

5. Sterilization

Warning: Risk of infection due to non-sterile implants! Do not use implants for whose packaging is damaged. Do not use implants for whose expiry date has passed.

Warning: Use of contaminated implants/instruments. Risk of Sepsis! Use only implants/instruments without visible contamination.

Warning: Use of damaged or defective implants. Risk of injury due to premature implant failure! Implants with identifiable damage may not be used. Avoid notches, scratches or bending of the implant in order to preserve its stability.

Warning: Resterilization of implants. Risk of injury due to premature implant failure caused by adverse material changes! Implants delivered sterile by Merete® GmbH must not be resterilized and/or repacked. Products for which expiry date has passed may be returned to Merete Technologies Inc. (MTI)

NOTE Observe symbol on packaging:

OsteoBridge™ IKA Nails, Spacers and Interlocking Screws are delivered in sterile packaging, sterilized by Gamma Radiation:	
Method	Gamma Radiation
Radiation Dose	2.5 Mrad
Sterility Assurance Level	10 ⁻⁶
Sterility Validation Method	ISO 11137-2/VD _{max} 25
Packaging	Triple Peel PE Pouch (Nails) Double Peel PE Pouch (Other components)
Pyrogenicity	Not labeled pyrogen free

Instruments are delivered non-sterile. Following sterilization method is recommended

Method	Steam Sterilization
Temperature	270°F [132°C]
Expose Time	4 minutes
Drying Time	20 – 30 minutes
Sterility Assurance Level (SAL)	10 ⁻⁶
Sterility Validation Method	Overkill method per ISO 17665-1:2006
Wrapping	FDA cleared wrap

The trays containing instruments are only provided for packaging, not to maintain sterility.

6. Storage

After sterilization, the instruments must be kept in their sterilization packaging and stored in a dry, dustfree environment.

The implants must be stored in the original packaging in a dry, clean place and at a temperature ranging from room temperature to cool but above frost-formation.

7. Disposal

Disposal of implants according to standard hospital procedures.

8. Preparation Instructions in accordance with DIN EN ISO 17664

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.

9. Updates of information

We want to advise, that it is required to inform Merete about any serious incidents resulting from the use of the OsteoBridge Intramedullary Knee Arthrodesis (IKA) system. In case of such events please contact your local Merete sales representative, contact us under +49 (0)30 – 77 99 80 -0, or service@merete.de.

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