IMPORTANT PRODUCT INFORMATION FOR THE USA

Important Product Information Implant (Package Insert Implant)
Caution:

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

1. General Information
Prior to using Merete products, surgeons and assisting staff are to study the safety information and product specific guidelines listed in this product information sheet (surgical technique) in detail. 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 proven knowledge of and experience in, this field. The surgeon bears all responsibility for negative consequences or complications arising from misdiagnosis, improper surgical technique; incorrect implant selection or handling, or failure to observe the safety instructions provided in this product information sheet. Neither the manufacturers nor authorized Merete product representatives may be held liable in such cases. Before operating, study the techniques outlines in the manual carefully.

1.1 Device description
All plates of the Locking Bone Plate Systems are made of TiAl6V4 ELI and have at least 2 K-wire holes for temporary bone fixation with K-wires.

Merete MetaFix™ Small Fragment Locking Bone Plate System:
- MetaFix™ I Plates are T-oblique plates to be used with 4 MetaFix™ LS Locking Screws

Merete BLP™ Small Fragment Locking Bone Plate System:
- MetaFix™ BLP Plates are U-oblique plates to be used with 4 MetaFix™ LS Locking Screws

Merete Locking Bone Plate System I:
- Style 1 plates (MetaFix™ Ludloff) are U-oblique plates to be used with 2 MetaFix™ LS Locking Screws and 2 non-locking Merete® Cannulated PCS screws
- Style 2 plates (MetaFix™ MTP) are H-oblique plates to be used with 6 or 7 MetaFix™ LS Locking Screws and either 1 non-locking Merete® Cannulated PCS Screw or 1 non-locking Merete® CS Cortical Screw

Merete Locking Bone Plate System II:
- Style 1 plates (MetaCun II™) are straight plates to be used with 2 MetaFix™ LS Locking screws
- Style 2 plates (DuoMetaCun II™) are U-shaped plates to be used with 4 MetaFix™ LS Locking screws
- Style 6 plates (MetaFix™ OpenWedge) are H-oblique plates to be used with 4 MetaFix™ LS Locking Screws

Merete Locking Bone Plate System III:
- Style 10 plates (MetaFix™ BG10) are L-oblique plates to be used with 4 MetaFix™ LS Locking Screws
- Style 11 plates (MetaFix™ PlantarMAX™) are U-oblique plates to be used with 4 MetaFix™ LS Locking Screws and 1 non-locking Merete® Cannulated PCS Screw
- Style 13 plates (MetaStep™ Calcaneus Plate) are stepped H-plates to be used with 5 MetaFix™ LS Locking Screws
- Style 14 plates (SCARFix™) are L-oblique plates to be used with 2 MetaFix™ LS Locking Screws and 2 or 3 Merete® Cannulated PCS Screws

1.2. Intended use (Plates and Screws)
All Merete Locking bone plates are used in combination with Merete screws for adult and pediatric patients. Indications for use include fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes.

The Merete Locking Screws, (MetaFix™ LS), are solely intended to be used in combination with Merete Locking plates for adult and pediatric patients as indicated above.

The Merete Compression Screws (CS, HCS and PCS) can be used in combination with Merete Locking bone plates or individually. They are indicated for fracture fixation and reconstruction of various bones, including, osteotomies in the foot (as Hallux Valgus treatment) or hand, arthrodesis in hand, foot or ankle surgery, fixation of bone fragments in long bones or small bone fractures.

The Merete TwistCut™ Snap-Off Bone Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include: Fixation of Small Bone Fragments, Weil-Osteotomy, Mono-Cortical Fixation, Osteotomies and fractures fixation in the foot and hand.

The DuoThread Bone Screw is intended for small bone fracture fixation, fixation and stabilization of bones of the feet. In case of an osteotomy or fusion it is used for procedures like Scarf-Osteotomy, Chevron-Austin Osteotomy, Akin-Osteotomy, closing wedge osteotomy, MPG-Arthrodesis as well as for the fixation of almost all common osteotomies of the first metatarsal.

1.3. Contraindications (Plates and Screws)
- Osteoarthritis
- Primary chronical Polyarthritis
- Osteoporotic bone

1.4. Warnings
- The Merete Locking Screws are intended to be used in combination with Merete Locking Plates only
- Plates and Screws are for single use only. An internal fixation device must never be re-used
- Non-sterile devices must be properly cleaned and sterilized before use

1.5. 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
- Prior to use examine device and check for proper functioning
- For the implantation of the Merete Screws use only the original Merete Locking Bone Plate System Instruments
- Additional precautions include those applicable to any surgical procedure. In general, careful attention must be paid to asepsis and avoidance of anatomical hazards
- For use in pediatric patients this product should not be placed across the growth plate

1.6. MRI Safety Information
The MetaFix™ LS Locking Screws, Merete® Cannulated PCS, Merete® CS Cortical Screws, Merete® Cannulated HCS, DuoThread™ Scarf and TwistCut™ Snap-Off Screws have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the screws in the MR environment is unknown. Scanning a patient who has the screws may result in patient injury.

Further information for use
Cleaning, disinfection, and sterilization instructions for reusable surgical instruments and non-sterile implants.

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

Warnings
Instruments that are supplied non-sterile are clearly marked with “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 pH for Instruments made of metal). Instruments 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 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 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.

Preparation for cleaning
Dismantle 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/implant for at least 1 min 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:

- 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.

Automatic disinfection
Choose a program for an A0 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.

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 in regards to concentration, soaking time, and compatibility with the Instruments 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 cleansing, rinse using deionized water, and dry thoroughly. Subsequent ultrasonic cleaning. Be sure that the 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 five minutes. After ultrasonic cleansing has finished, rinse Instruments 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 for cleanliness, functionality, and damage (e.g., bent, broken, worn or missing parts). Never use damaged instruments or implants.

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.

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

Sterilization

Osteosynthesis implants are delivered in sterile packing, sterilized by Gamma Radiation:	
Method	Gamma Radiation
Radiation Dose	2.5 Mrad
Sterility Assurance Level	10-6
Sterility Validation Method	ISO 11137-2 / VDmax25
Packaging	Double Peel PE Pouch
Pyrogenicity	Not labeled pyrogen free

Implants and Instruments are delivered non-sterile. Following sterilization method is recommended:	
Method	Steam Sterilization
Cycle	Pre-Vacuum
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

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 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.

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Definition of Symbols

CE 0482	CE mark
	Manufacturer
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
	Do not resterilize
	Non-sterile
	Do not use if package is damaged
	Keep dry
	Temperature limit
	Do not re-use
	Consult instructions for use
	Caution, consult accompanying documents
QTY 1	QTY
R_x only	**Caution:** Federal law (USA) restricts this device to sale by, or on order of a physician.