IMPORTANT PRODUCT FOR THE USA

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 outlined in the manual carefully.

2. Basic Principals

2.1 Characteristics

Merete instruments have been developed in regard to the special requirements of orthopedic surgeons. When instruments are carefully handled and correctly treated they can be used for several times. Merete instruments are being produced from stainless steel or titanium alloy for surgical instruments according to national and international standards. Some instruments contain or are fully made of surgical plastics (POM, PPSU, PPSU XRO, PEEK, PEEK XRO, Silicon, UHMWPE). They are not known to interact with any medications.

2.2 Description

- Merete instruments are supplied sterile or non-sterile. The non-sterile instruments have to be sterilized before each use.
- The function of any instrument must be proven before starting to use.
- Any force on the instrument can influence the function. Force on the instrument can lead to an incorrect function.
- The connection of instruments to active devices (e.g. drill tips and drilling machine) has to be done in such way, that the connection cannot open/loosen while in use.
- When using a screw-driver the exact size and the correct fit from the screw to the screw-driver has to be assured.
- Instruments associated with a system may only be used with this system. For the correct usage of the instruments the information provided by the respective system product information and manual has to be followed.
- Instruments made of plastic with the extension XRO (PPSU XRO, PEEK XRO) are visible on fluoroscopy and x-ray.

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 containing 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 instrument’s 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

Instruments 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

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

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

Storage
After sterilization, the instruments 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.

3.2 Sterile instruments
Instruments which are delivered sterile, either individually or in trays, are clearly labeled "STERILE". All sterile instruments should be stored unopened in their original packaging in a cool – but frost-free – dark, dry place until they are to be used. Before using any instruments, check the sterilization expiration date on the product label, and check the protective packaging for damage. The red steri-dot on the package serves as an indicator that the product is sterile. Products in damaged packages must not be used. Observe all asepsis-related guidelines when removing products from their protective packaging.

Sterile delivered instruments are for single use only. Reuse or resterilization is prohibited.

3.3 Reusable instruments
Handle instruments with care in order to ensure their long-term functionality. Insofar as Merete has not specified otherwise. Instruments may be reused indefinitely, provided that they are fully functional (see 3.1). instruments, that are limited in their service life to a certain time, are marked with the following nomenclature: e.g. Q1/2019. After the stated quarter has expired, the instrument must be tested and approved of by Merete to maintain proper function. Merete offers a two-year torque maintenance warranty on torque limiters. After the warranty period, we recommend checking torque at regular intervals. Operators are to use instruments in accordance with RKI guidelines and MPBetreibV regulations.

3.4 Materials of the instruments
a.) 1.4057 (X17CrNi16-2) DIN EN 10088-1,-2,-3
b.) 1.4021 (X20Cr13) DIN EN 10088-1,-2,-3
c.) 1.4571 (XCrNiMoTi17-12-2) DIN EN 10088-1,-2,-3
d.) 1.4310 (X10CrNi18-8) DIN EN 10088-1,-2,-3
e.) 1.4112 (X90CrMoV18) DIN EN 10088-1,-2,-3
f.) 1.4441 (XCrNiMo18-15-3) DIN 17443
g.) 1.4108 (X30CrMoN15-1) AMS 5898; ASTM F899 /A276
h.) 1.4301 (X5CrNi18-10) AMS 5513; ASTM A 240; ASTM A 666
i.) 1.4006 (X12Cr13) DIN EN 10088-1,-2,-3
j.) 1.4435 (X2CrNiMo18-14-3) DIN EN 10088-1,-2,-3
k.) 1.4404 (X2CrNiMo17-12-2) DIN EN 10088-3
l.) 1.4542 (X5CrNiCuNb 16-4) DIN EN 10088-3
m.) 1.4034 (X46Cr13) DIN EN 10088-3
n.) TiAl6V4-alloy (ASTM F 136, ISO 5832-3)
o.) POM, PPSU, PEEK, Silicone, UHMWPE

Additional information on the chemical composition and mechanical properties of the materials used is available from Merete on request.

CAUTION (USA):
Federal Law restricts this device to sale by or on the order of a physician.
The instrument Trays are only provided for packaging, not for sterilization.

4. 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.

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PTI0027-0117