Important Product Information Chronoceptor™ (Package Insert Chronoceptor™)

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

1. Symbols

	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 reuse
	Consult instructions for use
	Caution, consult accompanying documents
QTY 1	Quantity
R_x only	Caution: Federal Law (USA) restricts this device to sale by or on order of a physician

2. General Infomation

Merete's Chronoceptor™ combines K-wire, pilot drill, countersink and length gauge in a single instrument. This reduces the number of needed surgery steps and instruments needed while limiting OR and anesthesia times for clinicians and patients. Identifying and handling instruments intraoperatively is simplified and bone preparation is enhanced with this novel device. Generally the AO (Association for the Study of Internal Fixation) sequence requires: 1) K-wire placement; 2) Screw length determination; 3) Pilot drill insertion and 4) Countersink application to implant a cannulated of bone screw. Identifying the correct instrument, mounting it in compatible power equipment and handing it to the operator is time consuming. Merete integrated these four instruments into one. The Chronoceptor™ is a trocar tip guided pilot drill with a countersink that slides over its cutting flutes after the desired depth is reached to, subsequently, measure the displacement on its laser-marked shaft.

Drill diameters and countersink geometries are directly adapted from the corresponding MECRON™ Cannulated Screw. Thus, the risk of instrument misidentification and, consequently, stripping, plunging or fracturing screws is reduced while their interoperative handling is minimized. The countersink is fitted into a handle that advances over the drill and along a laser marked with length scale (2 mm increments from 8-50 mm) to determine the screw lengths. A ratcheting function then secures the handle axially while countersinking, thus screw length determination may be obtained after removing the instrument from the operating site.

2.1. Intended Purpose

***Warning:* Use of Instruments contrary to intended purpose. Risk of injury due to instrument failure! Instruments must only be used in accordance with intended purpose.**

The Chronoceptor™ is used for the operative preparation of bone prior to the implantation of bone screws.

2.2. Indications (bone screws)

- Bone reconstruction
- Osteotomy
- Arthrodesis
- Joint fusion
- Ligament fixation
- Fracture repair and facture fixation

2.3. Contraindications (bone screws)

- Osteoarthritis
- Primary chronic polyarthritis
- Osteoporotic bone

2.4. Materials of the Chronoceptor™

- 1.4571 (X6CrNiMoTi17-12-2) conform to DIN EN 10088-1, -3
- 1.4112 (X90CrMoV18) conform to DIN EN ISO 7153-1, DIN EN ISO 16061, DIN EN 10088-1, -3, ASTM F899, AISI440B
- TECASON P MT ivory (PPSU) conform to USP Class VI and EN ISO 10993.

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

2.5. System Compatibility

***Warning:* Use of Instruments contrary to intended purpose. Risk of injury due to instrument failure! Instruments must only be used in accordance with intended purpose.**

The color-coated Chronoceptor™ is selected according to the corresponding screw diameter (Tab. 1) and applied through a short sequence of steps.

Table 1: Chronoceptor™ Color Codes. Marked on the AO Connection of each corresponding pilot drill before the component is assembled with handle and countersink.

Screw-Ømm	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm
Instrument Color	CH15100S	CH15100S	CH15101S	CH15102S	CH15102S
Screw Color Markings	White	Magenta	Blue	Green	Gold

3. Use

3.1. General Instructions

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

***Warning:* Use of single use instruments which have been previously used. Risk of injury due to premature instrument failure! Risk of sepsis! This instrument is only permitted for single use, not for reuse.**

***Warning:* Use of instruments contrary to intended purpose. Risk of injury due to instrument failure! Instruments must only be used in accordance with intended purpose.**

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

The described surgical technique must be strictly followed.
Prior to using Merete products, surgeons and assisting staff are to study the safety information and product specific guidelines listed in this product information as well as 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. Operations must only be performed by surgeons who are not only qualified to carry out such interventions but also have extensive 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. Training in the correct handling of instruments by an authorized Merete representative is essential.

The Chronoceptor™ has been developed in regard the special requirements of orthopedic surgeons. Merete instruments are being produced from stainless steel for surgical instruments according to national and international standards. The handle of the Chronoceptor is made of surgical plastic (PPSU). The materials are not known to interact with any medications.

- The Chronoceptor™ is supplied sterile.
- The ratcheting function of the Chronoceptor™ 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. drilling machine) has to be done in such way, that the connection cannot open/loosen while in use.
- When using the Chronoceptor™ the exact size from the screw to the Chronoceptor™ has to be assured.
- For the correct usage of the instruments the information provided by the respective system product information and manual has to be followed.

3.2. Sterile Instruments

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

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

***Warning:* Use of single use instruments which have been previously used. Risk of injury due to premature instrument failure! Risk of sepsis! This instrument is only permitted for single use, not for reuse.**

NOTE	Observe symbol on packaging: "Do not reuse".

Instruments which are delivered sterile, are clearly labelled "STERILE". Sterile instruments have been sterilized with 25 to 42 kGy (2.5 to 4.2 Mrad) gamma rays. 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. Resterilization

***Warning:* Resterilization of single use instruments. Risk of injury due to premature instrument failure caused by adverse material changes! Single use instruments delivered sterile by Merete must not be resterilized and/or repackaged. Products whose expiry date has passed may be returned to Merete.**

Merete wishes to provide patients with cutting-edge technology products at all times. As such, we do not offer product resterilization.

3.4. Storage and Handling

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

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

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

Store instruments in their unopened original packaging at room temperature or below (but frost-free) in a clean and dry environment. Check the sterilization expiration date on the product label and ensure that the protective packaging is intact before using any instrument. Do not use products in damaged packaging. Observe the rules of asepsis when removing products from their protective packaging. Instruments must be handled with the greatest of care. Any mechanical manipulation or alteration of instruments negates their approval for use and is not permitted. Do not use any instrument that have been handled incorrectly or show signs of damage.

Distributor USA:

Merete Technologies Inc. (MTI)
One Lincoln Centre
18W140 Butterfield Road, 15th Floor
Oakbrook Terrace, IL 60181

Phone: 630-869-1091
Customer Service Tel: 855-637-3831
Fax: 630-445-1752

E-Mail: order@merete-medical.com
www.mereteUSA.com

Manufacturer:

Merete GmbH
Alt-Lankwitz 102
12247 Berlin, Germany

Phone +49 (0)30 77 99 80-0
Fax +49 (0)30 76 68 03 61

service@merete.de
www.merete.de