Implant systems
Guided Surgery
(ICX-Magellan)

1 Scope

All information in these Instructions for use is valid for the following products, unless otherwise specified (hereinafter referred to as ICX-implants or ICX-implant systems):

In the following, all products stored in NaCl solution are summarised as ICX-Liquid products.

Implant type	Implant diameter (mm)	Implant length (mm)
ICX-Premium (incl. ICX-Diamond Premium)	3.3 3.75 / 4.1 / 4.8	8 / 10 / 12.5 8 / 10 / 12.5 / 15
ICX- Premium TL* (incl. ICX-Diamond Premium TL)	3.3 3.45 (formerly ICX-plus)	8 / 10 / 12.5 6,5 / 8 / 10 / 12.5
ICX-Active Master (incl. ICX-Diamond Active Master)	3.3 3.75 / 4.1 / 4.8	8 / 10 / 12.5 8 / 10 / 12.5 / 15
ICX-Active Liquid	3.3 3.75 / 4.1 / 4.8	8 / 10 / 12.5 8 / 10 / 12.5 / 15

* TL = Tissue Level

2 Safety instructions / disclaimer

These instructions for use must be read before using the products! The products may only be used according to their indication in accordance with the general rules for dental & surgical practice and in compliance with the occupational health and safety and accident prevention regulations. If there is any uncertainty regarding the indication or the type of application, do not use the product until all points have been clarified. Within the framework of our sales and delivery conditions, we guarantee the perfect quality of our products. Before each procedure, ensure that all necessary parts, instruments and aids are complete, functional and available in the required quantity. All parts used in the patient's mouth must be secured against aspiration and swallowing. Since the use of the products is beyond our control, any liability for damage caused in the process is excluded. The responsibility lies exclusively with the practitioner.

The ICX-products of medentis medical GmbH are not compatible with products of other manufacturers.

3 Product description

3.1 General

The implant systems include surgical, prosthetic and laboratory components and instruments. ICX-implants are endosseous, screw-shaped implants made of pure titanium with a sandblasted and acid-etched surface (exception: tulip of TL implants), which are surgically inserted into the (partially) edentulous jawbone. Appropriate drills, insertion instruments and other aids are provided for this purpose. After a healing phase, if necessary, the implants are connected to abutments via a conical, hexagonal internal connection and finally fitted with crowns, bridges or complete dentures according to the indication in order to restore the patient's chewing function. The articles are available in various diameters, heights and lengths. These are identified by labels, including lot number and the exact product data, such as length, height and diameter.

3.2 Intended users

The products should only be used by dentists and physicians who are familiar with dental implantology, including diagnosis and preoperative planning.
The descriptions below are not sufficient for inexperienced practitioners in implantological procedures to ensure proper use. Therefore, we recommend instruction by experienced users and/or participation in various curricula of diverse universities and implant professional associations. In addition, regular training courses and seminars for users are offered on the medentis website (https://medentis.com/events/category/fortbildungen/).

3.3 Intended patient target group

The use of the products is intended for patients with teeth not worthy of preservation or missing teeth, provided that implant-supported rehabilitation is indicated (see the chapters "Indication/intended use" and "Clinical benefit").
In principle, treatment with implants is only recommended in patients with completed growth of the jaw bone.

3.4 Materials

Implants:
- Titanium grade 4B (material no. 3.7065) according to DIN EN ISO 5832-2
- ICX-Diamond: Titanium grade 4B (material no. 3.7065) according to DIN EN ISO 5832-2 with higher strength

Drills:
- ICX-Magellan: stainless steel (material no. 1.4542) according to DIN EN 10088-3

Dental instruments:
- stainless steel (material no. 1.4034 / 1.4197 / 1.4301) according to DIN EN 10088-3 or ASTM F899
- Titanium grade 4B (material no. 3.7065) according to DIN EN ISO 5832-2
- Titanium grade 5 (material no. 3.7165) according to DIN EN ISO 5832-3

Cover screws and healing caps:
- Titanium grade 5 (material no. 3.7165) according to DIN EN ISO 5832-3

Individual and customizable healing caps:
- PEEK (TEKAPEEK MT Classix White®)

ICX-Bone-Spreader:
- stainless steel (material no. 1.4542) according to DIN EN 10088-3

Drill guide:
- VisiJet M2S-HT90
- VisiJet M3 Stoneplast

Guiding sleeve:
- Titanium grade 5 (material no. 3.7165) according to DIN EN ISO 5832-3

Adhesive:
- ICX-Flow Cem (composite cement)

3.5 Accessories

ICX-Magellan drills:
C-032-000009, C-032-000013, C-032-020110, C-032-000020, C-032-000021, C-032-000022, C-032-000050, C-032-000051, C-032-020110, C-032-022110, C-032-022150, C-032-034500, C-032-034506, C-032-034508, C-032-034510, C-032-034512, C-032-037500, C-032-037508, C-032-037510, C-032-037512, C-032-037515, C-032-041000, C-032-041008, C-032-041010, C-032-041012, C-032-041015, C-032-048000, C-032-048008, C-032-048010, C-032-048012, C-032-048015, C-032-134506, C-032-134508, C-032-134510, C-032-134512, C-032-137508, C-032-137510, C-032-137512, C-032-137515, C-032-141008, C-032-141010, C-032-141012, C-032-141015, C-032-148008, C-032-148010, C-032-148012, C-032-148015, C-032-234500, C-032-237500, C-032-241000, C-032-248000, C-032-334506, C-032-334508, C-032-334510, C-032-334512, C-032-337508, C-032-337510, C-032-337512, C-032-337515, C-032-341008, C-032-341010, C-032-341012, C-032-341015, C-032-348008, C-032-348010, C-032-348012, C-032-348015
Cover screws:
C-003-000001, C-003-000002, C-003-000004, C-003-000021, N-003-000001, N-003-000002, N-003-000021, C-003-000100

Healing caps:
C-004-004510, C-004-004520, C-004-004530, C-004-004540, C-004-004550, C-004-004560, C-004-006020, C-004-006030, C-004-006040, C-004-006050, C-004-006060, C-004-008030, C-004-008050, C-004-444720, C-004-444730, C-004-444740, C-004-444750, C-004-504720, C-004-504740, C-004-514720, C-004-514740, C-004-524706, C-004-524708, C-004-524710, C-004-526006, C-004-526008, C-004-526010, C-004-034550, C-004-116001, C-004-116002, C-004-116003, C-004-116004, N-004-004120, N-004-004130, N-004-004150, N-004-116003, N-004-116004, N-004-
Connection screws:
C-007-000001, C-011-000001
Torque transmitting instruments:
C-032-000014, C-032-000015, C-032-000016, C-032-000017, N-015-110000, N-015-110020, N-015-110025, C-015-110000, C-015-100000, C-015-110020, C-015-110025
Auxillary instruments:
C-032-000001, C-032-000002, C-032-000003, C-032-000004, C-032-000006, C-032-000008, C-032-999001, C-032-999002, C-032-999011, C-032-999012, C-032-999021, C-032-999022, C-032-999023, C-032-999031, C-032-999032, C-032-999041, C-032-000007

Article for impression taking / model analogues:
C-005-020002, C-005-040010, C-005-030001, C-005-030002, C-005-020005, C-005-030012, C-005-030011, C-030-000052, C-030-000053, C-030-000001, C-030-000003, C-030-000004, C-006-010001, C-006-010003, C-006-010008

If the above products are also offered sterile, this is indicated in the article number by the appended letter "S" (e.g. non-sterile: C-015-100000 and sterile: C-015-100000S).

4 Form of delivery / sterilization / storage / return
Caution: For all products supplied sterile, the blister serves as a sterile barrier!

Caution: The general rule for all products is that they must not be used if the sterile packaging has been opened or damaged!

Caution: Implants are delivered gamma sterilized and are for single use only.

ICX-Liquid implants are delivered gamma sterilized in NaCl solution.

Caution: Healing caps and cover screws are intended for single patient use only and are offered both non-sterile and gamma sterilized. Unless the packaging is labeled as sterile, healing caps and cover screws must be cleaned, disinfected and sterilized prior to use on the patient according to the sections "Cleaning/Disinfection" and "Sterilization". The one-time reprocessing is not required for healing caps and cover screws supplied in sterile condition.

Caution: Drills are intended for single patient use only. This means that they may be used to prepare multiple cavities in a patient during a single surgical procedure. Drills are supplied both non-sterile and gamma sterilized and, unless the packaging is labeled sterile, must be cleaned, disinfected and sterilized prior to patient use in accordance with the "Cleaning/Disinfection" and "Sterilization" sections. The one-time reprocessing is not required for drills supplied sterile.

Caution: Reusable instruments are offered both non-sterile and gamma sterilized. If the packaging is not marked as sterile, the instrument must be cleaned, disinfected and sterilized in accordance with the sections "Cleaning/Disinfection" and "Recommended Sterilization" before the first use and, if necessary, before each subsequent use on the patient. The initial reprocessing is not required for instruments supplied in sterile condition. The service life of products marked as reusable is determined by their use. Dispose damaged, worn or corroded products. Consider the information in the section "Risks and effects of multiple use of disposable products".

Caution: ICX-Bone Spreaders are intended for multiple use and are offered both non-sterile and gamma sterilized. Unless the packaging is labeled as sterile, ICX-Bone Spreaders must be cleaned, disinfected, and sterilized according to the sections "Cleaning/Disinfection" and "Recommended Sterilization" prior to the first use and, if necessary, prior to each subsequent use on the patient. In the case of ICX-Bone Spreaders supplied in sterile condition, initial reprocessing is not required. If the sterile packaging is broken or damaged, the product must not be used!
Dispose of the ICX-Bone Spreaders after five uses or reprocessing at the latest.

Caution: Drill templates are intended for single patient use only and are supplied cleaned and disinfected. They may need to be cleaned and disinfected again according to RKI recommendations after checking for proper fit and prior to surgical use.
Broken packages are excluded from exchange.

The following transport and storage conditions must be observed:

- Storage at room temperature and normal humidity
- The products must not be removed from the packaging during storage
- The products must be stored under lock and key
- The products may only be accessible to authorized persons
- The products should be transported at a temperature of -25°C to 35°C

We recommend storing products made of plastic (PEEK, POM, PA) protected from sunlight.

5 Indications / intended use

ICX-implants and ICX-Liquid implants are placed in the partially edentulous or edentulous maxilla and/or mandible and are used to secure dentures for the rehabilitation of masticatory function and esthetics in the maxilla and/or mandible.

In the following initial situations, ICX-implants with a diameter ≥ 3.45 mm are indicated:

- Absence of a single tooth
- Absence of several teeth in a row of teeth
- Completely edentulous upper and/or lower jaw.

ICX-implants and ICX-Liquid implants with a diameter of 3.3 mm may only be used for the following indications:

- Single tooth replacement: canine and incisor teeth in the maxilla and mandible
- Partially edentulous jaws: for implant-supported fixed restorations: Combination with implants with a diameter of 4.1 mm and splinted superstructure
- Edentulous jaws: at least four implants must be connected together

The ICX-Mini implants are intended for stabilization of mucosa-supported dentures in the edentulous maxilla and/or mandible and are used for rehabilitation of masticatory function and esthetics. The ICX-Mini implant should be used only in case of lower mechanical loading. Use in the molar region is generally not recommended.The use of the ICX-Mini 2.9 mm as an additional bridge abutment cannot be recommended, in exceptional cases at most as an additional abutment to replace an pontic or pendant and then only if the number of standard implants (larger than 3.75 mm diameter) is at least twice as high as the ICX-Mini implants.

The machine-polished ICX-Mini implants are placed in the edentulous maxilla and/or mandible and are suitable for temporary, mucosa-supported immediate restoration during the healing phase of the permanent implants due to their smooth surface.
The machine-polished ICX-Mini implant should only be used in cases of lower mechanical loading. Use in the molar region is generally not recommended. The use of the machined ICX-Mini implants as an additional bridge abutment cannot be recommended.

The permanent implants must be inserted first to ensure optimal positioning. A minimum distance of 2 mm to the permanent implant should be maintained. The placement of a total of 4 to 6 machined ICX-Mini implants in the maxilla and/or mandible is recommended.
As soon as the permanent implants have healed and are prosthetically restored, but after 6 months at the latest, we recommend unscrewing and removing the machined ICX-Mini implants. The progress of healing of the temporary implants must be monitored regularly, e.g. radiographically.

Drills (all types) are intended for use in the maxilla and/or mandible and are used during the surgical procedure to prepare the implant bed for ICX-implants.
The gingival punches are intended for use in the maxilla and/or mandible and are used during the surgical procedure to remove the mucosa.

ICX-cover screws and healing caps are intended for use in the maxilla and/or mandible and are used to protect the implant cavity during the healing phase and to preserve or shape the soft tissue. They are indicated for:

- Absence of a single tooth
- Absence of several teeth in a dental row
- Completely edentulous upper and/or lower jaw

Healing caps made of PEEK can be used for temporary, esthetic rehabilitation without occlusion and may only remain in the patient's mouth for a maximum of 180 days. Care must be taken to ensure that there is no proximal or occlusal contact with adjacent teeth. The customizable PEEK healing caps can be adapted to the emergence profile before use (C-004-524706, C-004-524708, C-004-524710, C-004-526006, C-004-526008, C-004-526010). The individual and customizable PEEK healing caps can be fitted with a crown (C-004-524706, C-004-524708, C-004-524710, C-004-526006, C-004-526008, C-004-526010, C-004-504720, C-004-504740, C-004-514720, C-004-514740, C-004-034550).

ICX-torque transmitting instruments are used in the (partially edentulous) maxilla and/or mandible for inserting implants or connecting components to implants.

ICX-auxiliary instruments are used in the (partially edentulous) maxilla and/or mandible for control or guidance during implant bed preparation.

The ICX-Bone Spreaders are intended for the widening of the alveolar process in the case of a horizontal bone deficit and simultaneous bone compression.
The ICX-Bone Spreaders are intended for use with an ICX-Magellan drill guide and may only be used in manual mode in conjunction with the ratchet.

Caution: The ICX-Bone Spreaders may only be used in soft to medium-hard bone (D3, D4).

The rule of thumb is always to use the largest possible implant diameter.
Immediate, delayed immediate, or late implant placement is possible in conjunction with bridges, telescopic tapered crowns, dentures, and bar constructions.
Immediate loading, early or late loading of the implants is possible. For immediate loading, the implant should have been placed with a final torque of at least 35 Ncm.

The healing period can be both covered and transgingival with gingiva-forming components.

We generally recommend using ICX-Premium or ICX-Active Master for single-tooth restorations.

6 Contraindications

When selecting patients, general contraindications to dental/surgical procedures should be considered. These include:

- Decreased blood clotting such as: Anticoagulant therapies, congenital or acquired coagulation disorders

• Systemic disorders and metabolic diseases (e.g. uncontrolled diabetes mellitus) with influence on wound healing and bone regeneration
• Above-average tobacco or alcohol abuse
• Immunosuppressive therapies such as chemotherapy and radiotherapy
• Infections and inflammations in the oral cavity such as periodontitis, gingivitis and periimplantitis
• Untreated parafunctions such as bruxism
• Inadequate oral hygiene and/or insufficient willingness to perform oral hygiene
• Lack of occlusion and/or articulation and insufficient interocclusal distance
• Insufficient bone volume and/or insufficient soft tissue coverage
• Allergy to one or more materials as described in the "Material" chapter

The following contraindications refer exclusively to the use of bone spreaders:
• Insufficient bone supply: residual bone height < 12 mm / alveolar ridge width < 2 mm.
• Application directly after extraction
• Application of unstable substantia compacta

7 Clinical benefit

The expected clinical benefits include improvement of impaired body function, i.e. restoration of masticatory function and esthetics after tooth loss.

8 Side effects / Complications

Temporary side effects of surgical procedures may include: local swelling and pain, edema, hematoma, temporary limitations of sensation, temporary limitations of masticatory function.

The following complications have been observed in isolated cases of endosseous implant use: Intra- and postoperative bleeding, wound or peri-implant infections (e.g. peri-implant mucositis, peri-implantitis, osteomyelitis), suture dehiscence, iatrogenic trauma, allergic reactions or symptoms, periodontal complications due to insufficient width of the mucogingival attachment, implant loss (e.g. due to insufficient osseointegration or excessive or too low insertion forces, see section "surgical procedure"), aspiration or ingestion of parts used in the patient's mouth, fracture of the mandible, bone deficit (e.g. fenestration or dehiscence defect), perforation of the sinus membrane, injury to adjacent teeth, soft tissue recession, sinusitis (e.g. after augmentation), permanent nerve injury and associated sensory disturbance, hyperplasia.

In extremely unfavorable loading conditions (prosthetic overloading due to extreme angulation of the abutment for example, severe bone resorption), the abutment, implant body or the connection screw that joins the abutment and implant may break in extremely rare cases.

Failure to maintain oral hygiene and inadequate care of the prosthesis can lead to inflammation of the tissue around the implant. Inflammation around the implant can initiate peri-implantitis, which in turn can lead to implant failure.

9 Application

9.1 Preoperative planning and dental technology

Diagnostics, preoperative planning:
Ideally, immediate provisional immediate restoration requires precise planning in the preoperative phase. In all other indications, two-stage therapy is recommended.

Preoperative dental technique:
Preoperative dental technology should fabricate a waxup incl. esthetic try-in, a veneer provisional or similar, a relineable long-term provisional or similar, and an ideal drill guide.

Procedure for planning the drilling template:

- Fill out order form planning proposal
- Create the situation impression, model plaster format, STL format or intraoral scans
- DVT / CT image of the relevant complete jaw in DICOM standard
- Import of the STL and DICOM files into the ICX Magellan / ICX Magellan X 3D planning software
- Planning proposal is sent by compressed file to respective email address (alternative by mail)
- Confirmation by release from liability form by fax or email to medentis with specified data
- We recommend checking the template against the oral situation before performing the surgical procedure.

Caution: independent adjustment of the template may result in incorrect position/alignment/depth of the implant!

9.2 Cleaning / disinfection

Detailed reprocessing instructions are described in the document "R1 reprocessing instructions (medentis medical)". In summary, the reprocessing procedures are described below.

Method:
Manual or automatic cleaning and disinfection followed by moist heat sterilization. The automated reprocessing method in the washer-disinfector (WD) is preferable to the manual method. The reprocessing of critical medical devices must always be carried out mechanically in the washer-disinfector.

Warnings:
The use of non-sterile components can lead to tissue infections or infectious diseases.
Medical devices intended for single use and already supplied sterile must not be cleaned and resterilized.
Without performing the pre-cleaning of the products described below (see section "Preparation prior to manual and mechanical cleaning/disinfection"), the necessary cleaning result cannot be guaranteed.

Limitation of reprocessing:
The service life of products marked as reusable is determined by their use. Dispose of damaged, worn or corroded products.

Procedure after use
Place instruments directly into containers of water after use on the patient. The water should not be warmer than max. 40°C. Coarse contaminants must be removed from the instruments immediately after use (within max. 2 hours).
Caution: Instruments made of stainless steel must never be placed in isotonic solution (such as physiological saline solution), as prolonged contact will lead to pitting corrosion and stress corrosion cracking.
Transport: After use, take the products to the place where cleaning is to take place. Avoid allowing contaminants to dry on. Transport should take place in a closed vessel/container to protect the products, the environment as well as the users.

Preparation before manual and automatic cleaning/disinfection

Equipment: water bath, soft plastic brush

Multi-part instruments must be disassembled according to the respective instructions for use (e.g. ratchet, see https://ifu.medentis.de/).

Preparation: Use a soft brush for this purpose only and tap water to pre-clean the products. Rinse the products under running cold water (< 25 °C) (approx. 1 minute). Clean all external and internal surfaces with the plastic brush for approx. 2 minutes. Rinse all cavities at least five times (5x) with deionized water using a disposable syringe (minimum volume 20 ml)(approx. 1 min).

Caution: Tissue residues or blood must never be allowed to dry on. Never use metal brushes or steel wool to remove contamination manually.

Manual cleaning and disinfection

Equipment: Ultrasonic bath, plastic brush, syringe, almost pH-neutral, enzymatic cleaning agent (e.g. 0.8 % Cidezyme (pH value: 7.8-8.8, Johnson & Johnson Medical, Norderstedt) or 1.5% Medizym, (pH value: 8.2, Chemische Fabrik Dr.Weigert, Hamburg)), disinfectant with the active ingredient ortho-phthalaldehyde (e.g. Cidex OPA, Johnson & Johnson Medical, Norderstedt), lint-free cloth.

The instructions for use of the cleaning agent manufacturer and the disinfectant manufacturer as well as the ultrasonic bath manufacturer must be observed!

Cleaning: Place the products for at least 5 minutes at a frequency of 25-50 kHz and a temperature lower than 45°C in an ultrasonic bath that has been mixed with (almost) pH-neutral, enzymatic cleaning agent. Deionised water (DI water) should be used. If the products have an opening/cavity, make sure that the cleaning solution can drain off after the treatment. All products should be covered by the cleaning solution. The temperature of the cleaning solution must not exceed 45°C. Then rinse 3x with running, deionised water (rinse cavities 3x with 20ml deionised water with a syringe). A fresh, unused cleaning solution should be used for each product. The previous steps should be repeated until there is no visible contamination left. Then rinse each product (and cavity, if applicable) thoroughly with deionised water (approx. 1 min).

Disinfection: The products are disinfected in a disinfectant with the active ingredient ortho-phthalaldehyde for 12 min (rinse cavities and lumen 3 times with 20 ml disinfectant (syringe) at the beginning and end of the disinfection). Then rinse again five times under running deionised water (deionised water) Rinse cavities five times with 20ml deionised water (deionised water) using a syringe. A fresh, unused disinfectant solution should be used for each product.

Drying: The products are then dried completely with a soft lint-free cloth.

Next step: Examination, inspection and tests

Automatic cleaning and disinfection

Equipment: Cleaning and disinfection device (WD), almost pH-neutral, enzymatic cleaning agent (e.g. Neodisher MediZym, Chemische Fabrik Dr. Weigert, Hamburg).
The instructions for use of the cleaning agent manufacturer and the WD manufacturer must be observed!
Suitable washer-disinfectors (WDs) that meet the requirements of EN ISO 15883 and bear a CE mark should be used for cleaning. The washing programme should be validated (A0 value > 3000, at least 5 min. at 90°C). The washer-disinfector should be regularly maintained and checked. Deionised water (DI water) should always be used.

Parameters:

- Pre-rinse with cold water for 5 min.
- Wash for 10 minutes with 40-45°C water and pH-neutral detergent
- 5 minutes intermediate rinse with cold water
- 5 minutes thermal disinfection with water at min. 93°C

Disinfection should be carried out at a maximum of 95°C for 10 minutes.

Drying: We recommend drying for 10 minutes at 80 - 90°C. Make sure that all instruments are completely dry after automatic drying in the WD. Cavities that are difficult to access can be dried with residue-free compressed air.
After cleaning, check the products, especially cavities and blind holes. Repeat the cleaning process if there is still visible contamination.

9.3 Sterilisation

The items supplied non-sterile are suitable for steam sterilisation. However, the original packaging is not suitable for steam sterilisation. Therefore, before sterilisation, the products intended for sterilisation must be packed in sterilisation packaging according to EN 868 or ISO 11607, e.g. in a transparent bag according to standard EN 868-5. The bag must be large enough for the product to be sterilised. The seal must not be under tension. When using clear packaging, ensure that the sealing process is validated (see manufacturer information).

Place the sealed products prepared for use in the steriliser. The steam sterilisers used must bear a CE marking and comply with the requirements of EN 13060 or EN 285. Only device- or product-specific validated procedures in accordance with ISO 17665 may be used. The instructions for use of the steriliser must be followed and the device should be serviced and checked regularly.
We recommend sterilisation by the fractionated vacuum method with the following parameters:

- Temperature: 134°C
- Pressure: 3 pre-vacuum phases with min. 60 millibar pressure, during holding time 3 bar
- Holding time: min. 5 minutes
- Drying time: min. 20 minutes

After sterilisation, the sterile packaging must be checked for damage, sterilisation indicators must be checked.
Caution: During sterilisation, a temperature of 137°C should not be exceeded.

Suitable storage should be ensured until the sterilised product is used. The products should be stored in a dry place at room temperature. The maximum storage time is determined by the type of packaging and the storage conditions and is the responsibility of the user. We recommend using the product immediately after sterilisation. Information on storage conditions and expiry dates can be found in the instructions of the manufacturer of the sterilisation container or the sterilisation packaging.
Caution: The products must no longer be used if the packaging is damaged or has been opened.

9.4 Testing and inspection

Visually inspect all instruments for damage and wear. Ensure that the markings are legible.
Locking mechanisms (ratchets, etc.) should be checked for function.
Maintain and lubricate the ratchet as described (https://ifu.medentis.de/).
Check long slender instruments (especially rotary instruments) for distortion.
If instruments are part of a larger assembly, check assembly with matching components.
Dispose of damaged or corroded instruments.

9.5 Information on colors and markings on the drills

The ICX-Magellan drills are available in different lengths according to the implant lengths. The exception is the ICX-Magellan universal drills, which are provided with length markings (C-032-022110: 6.5/8/10 mm; C-032-022150: 3.5/8/10/12.5/15 mm).
Furthermore, the number of dots on the ICX-Magellan drills provides information on bone quality:

- One point: very soft bone
- Two points: soft to medium hard bone
- Three points: hard bone

The stop drills and gingival punches are marked with a colored ring. The color ring refers to the implant diameter, not to the bone quality.

9.6 Surgical procedure

Implant bed preparation and implant placement

The gingival punch should be used at a speed of 15 rpm. Drilling into the bone should be performed under constant, intensive cooling with a recommended speed of 500 rpm (blue drills) or 400 rpm (all other drills) and slight variable pressure.

Caution: The drills are up to 0.25 mm longer than the inserted implant. It must be ensured that this additional length is permissible when working in the area of important anatomical structures.

Both simple pilot drilling and fully navigated implant bed preparation are possible with the help of the ICX-Magellan drill guide.

Pilot drilling

- Positioning of the ICX-Magellan drilling template on the prepared oral situation
- If provided: Fasten the ICX-Magellan surgical template with the aid of the fastening pins (C-032-000013). For the attachment pins, drill cavities are prepared beforehand with the attachment drill (C-032-000020) using the guide sleeve provided for this purpose
- Perform pilot drilling through universal drill guide sleeve with universal drill C-032-022110 (for implant lengths up to and including 10 mm) or C-032-022150 (for implant lengths up to and including 15 mm) to desired implant length
- Remove ICX-Magellan drill guide and continue freehand surgical preparation

Fully navigated preparation

Depending on bone availability, one of the methods described below can be used for implant bed preparation.

Preparation using the ICX-Magellan drills:

1a. Procedure with flap formation:

- Perform according to individual surgical procedure
- Continue with point 2

1b. Procedure without flap formation:

- Positioning of the ICX-Magellan surgical guide on the prepared oral situation.
- If provided: Fasten the ICX-Magellan surgical template with the aid of the fastening pins (C-032-000013). For the attachment pins, drill cavities are prepared beforehand with the attachment drill (C-032-000020) using the guide sleeves provided for this purpose.
- Use the gingival punch according to the implant diameter to punch the mucosa. Then remove the ICX-Magellan surgical template and remove punched mucosa.

2. (Re-)position and, if necessary, fix the ICX-Magellan surgical template.
3. Use the ICX-Magellan center drill C-032-000021 to center the bone
4. Perform predrilling using the ICX-Magellan predrill C-032-000022 (except TL implant with Ø 3.45 mm).
5. Use the ICX-Magellan drill with the smallest drill length (8 mm) according to the final implant diameter and bone quality to prepare the implant bed for the final implant diameter.
6. Continue with each additional ICX-Magellan drill according to implant diameter and bone quality until desired implant length is achieved.
7. Use ICX-Magellan stop drill according to implant diameter
8. Continue to the section "Implant placement

Preparation with the aid of the ICX-Bone Spreaders:
For preparation of the implant bed with different diameters, the ICX-Bone Spreader are provided with markings:

Article number (mark)	Diameter min. (mm)	Diameter max. (mm)	length (mm)
C-014-600001	1.2	2.5	8, 12
C-014-600002	1.8	3.5	10, 15
C-014-600003	2.5	3.8	10, 15
C-014-600004	2.6	4.15	10, 15

1. Positioning the ICX-Magellan surgical template on the prepared oral situation.
2. Fasten the ICX-Magellan surgical template with the aid of the fastening pins (C-032-000013). For the attachment pins, drill cavities are prepared beforehand with the 1.5 mm attachment drill (C-032-000020) using the guide sleeve provided for this purpose. The fixing pins and the drilling template are then removed.
3. The gingiva at the affected position is prepared in such a way that it can be opened.
4. The surgical template is repositioned and fixed in place using the fixing pins.
5. Pre-drilling is performed with the ICX-Magellan reducing adapter (C-032-000007) and the 2.0 mm ICX-Magellan universal drill bit short (C-032-020110). Subsequently, the fixing pins and the drilling template are removed.
6. A crestal relief incision is made in the affected area.
7. The surgical template is repositioned and fixed in place using the fixing pins.
8. The desired position is now processed using the ICX-Bone Spreader. For this purpose, the torque ratchet (960001) is connected to (1.) the ICX-universal handpiece adapter (960007) and to (2.) the ICX-four socket wrench (C-021-000002) and the (3.) the ICX-Bone Spreader.
9. The implant bed preparation can now be performed sequentially in an ascending order of the ICX-Bone Spreaders. The ICX-Bone Spreader C-014-600001 is always used at the beginning.
10. Work your way up to the desired width, using the ICX-Bone Spreaders C-014-600002, C-014-600003 and C-014-600004 if necessary. A torque of 35 Ncm should not be exceeded.
11. Continue to the "Implant placement" section

After drilling is completed, the packaging (blister) of the implant is opened.
For all ICX-implants, except ICX-Liquid implants, the vial is opened by unscrewing the cap. A variant for the professional opening of ICX-Liquid vials is described below:

- Push up the seal cap with the inside of the thumb at the notch and break the seal.
- Open the sealing cap completely and pull it off in a straight, axial direction to the rear and then downwards.
- Detach aluminum ring under slight pressure (predetermined breaking point at the back)
- Remove gray stopper

Caution: Opening the ICX-Liquid sealing cap is a mechanical process. Therefore, please always check your personal protective equipment (gloves) for integrity after opening.

Now the implant is removed from the packaging with the insertion instrument (ISO shaft) inserted in the contra-angle handpiece or handpiece or with the insertion instrument. The implant is then inserted into the bone cavity (contra-angle handpiece: 25 rpm).

Caution: It is possible to actively adjust the alignment of the ICX-Active Master, ICX-Active Liquid Implants and ICX-Diamond Active Master. However, during insertion, these implants may 1) penetrate deeper into the bone than originally intended during implant bed preparation or 2) be unintentionally deflected from the original, ideally placed osteotomy. Therefore, we recommend the use of the screwable insertion instruments especially for the ICX-Active Master, ICX-Active Liquid and ICX-Diamond Active Master implants. Furthermore, theICX-Active Master, ICX-Active Liquid and ICX-Diamond Active Master implants can be inserted faster than the other ICX implants, as fewer turns are required to achieve the desired placement due to the double thread.

Caution: The fixation screw of the screw-retained placement instruments is only intended for screwing the placement instrument to the implant and may only be tightened **hand-tight**! To do this, insert the hexagon of the insertion instrument into the implant and turn the fixation screw clockwise. As soon as the insertion instrument starts to rotate, the screw is completely fixed to the implant and the implant can be removed from the sleeve without touching it.

Please use the insertion instruments listed for insertion of the respective implants:

Implants	Insertion instruments
for diameter 3.75 / 4.1 / 4.8 mm: • ICX-Premium • ICX-Diamond Premium BL • ICX-Active Master • ICX-Diamond Active Master BL • ICX-Active Liquid	C-032-000014 C-032-000016 screwable: C-015-100000 C-015-110000 C-015-110020 C-015-110025
for diameter 3.45 mm: • ICX-Premium TL • ICX-Diamond Premium TL	C-032-000015 C-032-000017
for diameter 3.3 mm: • ICX-Premium • ICX-Diamond Premium BL • ICX-Active Master • ICX-Diamond Active Master BL • ICX-Active Liquid	C-032-000026 screwable: N-015-110000 N-015-110020 N-015-110025

Caution: The torque value of 15 Ncm should not be undercut, nor should the value of 55 Ncm (or 40 Ncm for ICX-Active Master, ICX-Active Master TL and ICX-Active Liquid implants in the interforaminal region) be exceeded, both of which will most likely lead to premature loss of the implant. In both cases, the implantation should be discontinued, continued in another region, or suitable surgical measures should be attempted to subsequently achieve the values and the implant subsequently reinserted.

Note on insertion: For ideal alignment of the angled abutments, one of the internal hexagonal planar surfaces in the implant should be placed in a buccal/facial position. Correct alignment is facilitated by the hexagonal surfaces on the insertion instrument.

After implantation has been completed, the various abutments are inserted. The parallel insertion direction of the abutments must be observed; if necessary, one or the other abutment must be processed individually.

Subgingival, 2-phase healing

Insert the cover screw with the hand screwdriver with 5-10 Ncm (hand-tight). The wound edges are tightly closed with atraumatic suture material. Do not tie the sutures too tightly. They must be placed in such a way that the wound edges fit over the cover screw without tension.

Transgingival, 1-phase healing

A healing cap with the corresponding soft tissue height is inserted instead of the cover screw. The healing cap must match the implant diameter and is screwed in by hand. Make sure that the healing cap fits exactly. The mucosa must lie tightly against the healing cap. After successful insertion of the implant, the surgical region is professionally closed using individual suture techniques.

9.7 Prosthetic application

After successful healing of the implant, uncovery and impression taking take place.

For 2-phase healing, insert the healing cap as follows:

1. expose implant
2. remove the cover screw
3. clean the interior of the implant
4. hand-tighten the titanium healing cap to 5-10 Ncm.

A torque of 15 Ncm is recommended for the healing caps made of PEEK. The healing cap must match the implant diameter and the soft tissue thickness of the patient. Make sure that the healing cap fits exactly. The mucosa must lie tightly against the healing cap.

After taking the impression, the dental technician makes the model and fabricates the denture. Before insertion of the dental technical work, the implants are fixed with the abutments by the connection screw. We would like to point out in particular that we only provide a warranty for our products if all the items used are original items of medentis implant systems.

The customizable PEEK healing caps can be adapted to the emergence profile before use. The extraoral adaptation can be performed with a cross-toothed bur.

The individual and customizable PEEK healing caps can be fitted with a crown. The temporary crown or bridge can be attached to the healing cap with a suitable composite material.

10 Information on the avoidance of risks

The risk of insufficient primary stability of the implant due to a qualitatively insufficient bone supply and the resulting lack of fixation possibility of the implant can be eliminated, if possible, by repairing the insufficient bone supply.

After an implant fracture due to improper multiple insertion and removal of the implant, the implant can be removed by unscrewing it with extraction forceps.

The risk of excessively high applied insertion forces and the resulting bone resorption and implant loosening can be eliminated by preparing the implant site with a larger drill diameter.

The static prerequisite should be observed, i.e. sufficient implants must be inserted on which the forces are evenly distributed. Loosening of an implant does not necessarily lead to loss; if there is no pain, the loosened implant should be left in place.

The risk of overtightening the rotation protection due to improper handling can be eliminated by proper application of the insertion instrument. The instrument must be properly countersunk in the hexagon.

After overtightening the rotation protection during explantation, the implant must be explanted with other available instruments. The correct fit of the insertion instrument should be checked before use.

The risk of overheating the bone in the preparation phase of the implant site can reduced by sufficient cooling and reduced pressure. Sufficient cooling of the drill with saline solution in the preparation phase is automatically taken over by the commercially available surgical machines.

The risk of confusion between implants, abutments and the respective accessories can be avoided by observing the labeling instructions.

The risk of bone growing into the internal thread of the implant head preventing the permanent abutment from complete seating can be minimized during a two-stage approach by ensuring that the cover screw is fully tightened after insertion.

In the event that the fixation screw of the screw-retained insertion instrument becomes jammed after insertion in the implant due to excessive torque, the fixation screw can be loosened and released from the implant using the counter instrument C-015-100009 or one of the available ICX-hex instruments (SW 1.4 mm).

When opening the ICX-Liquid sealing cap, make sure that it is pulled straight and in an axial direction to the rear and then downwards. Incorrect pulling or twisting of the sealing cap can lead to failure of the opening process.

The risk of preparing the implant cavity too long or too short can be minimized by orienting it to the depth markings of the ICX-parallel drills. To determine the exact depth of the implant bed, a depth gauge with legal, metric SI units should be used.

11 Risks and effects of multiple use of single-use devices

Drills: Multiple use of the drills, i.e. multiple preparation for use in several patients, can blunt them. As a result, there is a risk of bone necrosis due to overheating, which may impair osseointegration of the implants.

All articles marked for single use may become imprecise if used more than once. Furthermore, the effects of the material resistance of repeated cleaning and sterilization processes have not been tested, i.e. the material properties may possibly change as a result. There is a risk of inflammation and infection if products intended for single use are reused.

12 MRI (Magnetic Resonance Imaging) compatibility notes

ICX implants can be considered "conditionally MRI capable". A patient with ICX implants can be safely scanned for 15 minutes in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla
- Maximum spatial gradient of 12,800 G/cm (128 T/m)
- Maximum force product of 211,000,000 G²/cm (211 T2/m)
- Theoretically estimated maximum whole body specific absorption rate (SAR) (WBA) of 2 W/kg (normal operating mode)

Under the scanning conditions defined above with a body coil, the implant is expected to have a maximum temperature rise of less than

- 6.8 °C (2 W/kg) with a background temperature rise of approximately 1.4 °C (2 W/kg) at 1.5 Tesla and
- 4.4 °C (2 W/kg) with a background temperature rise of approximately 0.6 °C (2 W/kg) at 3 Tesla

during a 15-minute scan.
FDA general note: If the dimensions of the implants are less than 2 cm and they are spaced at least 3 cm apart, the maximum temperature rise in a 3 Tesla MRI is 2°C.

In non-clinical tests, the image artefact caused by the device extends approximately 20.0 mm from the implant when imaged with a gradient echo pulse sequence, a body coil and a 3 Tesla MR system.
It is recommended that patients undergoing an MRI scan be thoroughly monitored for perceived temperature and/or pain sensations.
For safety reasons, any removable prosthetic restoration should be removed or unscrewed prior to the MR scan.

The above information is based on non-clinical tests with ICX-Zygoma implants of length 50 mm and diameter 4.8 mm and an ICX-Multi abutment.

13 Note on reporting serious incidents

Patients/users/third parties residing in a member state of the European Union should report any serious incident that has occurred in connection with a medentis medical product to medentis medical GmbH and the competent authority.

14 Measures in case of malfunction

In the event of a malfunction of the product or changes in performance that may affect safety, please complete the complaint and feedback form (see download area on www.medentis.de) and return it to medentis medical GmbH.

15 Disposal

Disposal of products must be carried out in accordance with international and national regulations, taking into account the waste code and hazard classification.

16 Other

The summary of safety and clinical performance of the product can be viewed in the European Database for Medical Devices (EUDAMED, https://ec.europa.eu/tools/eudamed) as soon as it is available.

17 Symbols used and their meaning

CE 0197	CE marking with identification number of the notified body
	Manufacturer
	Date of manufacture
	Article number
	LOT-Number
	Not sterile
	Sterilized by irradiation
	Do not resterilize
	Do not use if the packaging is damaged and follow electronic instructions for use
	Do not reuse
	Expiration date
	Note electronic operating instructions
	Protect from direct sunlight
	Store in dry place

Importeur

EC REP EU Representative

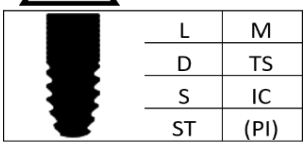
Simple sterile barrier system with inner protective packaging

Simple sterile barrier system

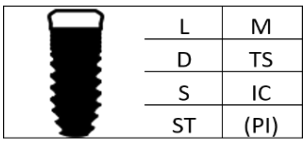
MD Medical device

UDI Unique identifier of a medical device

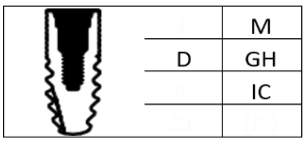
MR MR conditional



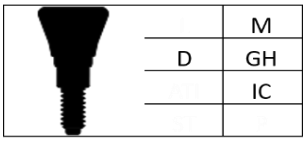
ICX-Implant
L: length
M: material (Ti4: titanium grade 4B, GTi4: titanium grade 4B with higher strength)
D: diameter
TS: thread style (P: Premium, AM: Active Master)
S: surface (SP: Sputtered, S: Standard)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
ST: storage (standard storage in air, NaCl: Liquid)
(PI): parts included (cover screw only included in single packaging, Ti5: titanium grade 5)



ICX-TL Implant
L: length
M: material (Ti4: titanium grade 4B, GTi4: titanium grade 4B with higher strength)
D: diameter
TS: thread style (P: Premium, AM: Active Master)
S: surface (SP: Sputtered, S: Standard)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
ST: storage (standard storage in air, NaCl: Liquid)
(PI): parts included (Cover Screw, only for Single Implants)



Cover Screw
M: material (Ti5: titanium grade 5)
D: diameter
GH: gingival height
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, MI: Mini, SB: SlimBoy)



ICX-Healing Cap Conical
M: material (Ti5: titanium grade 5)
D: diameter
GH: gingival height
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, SB: SlimBoy)

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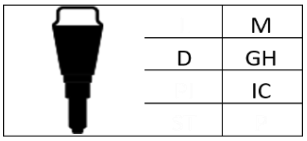
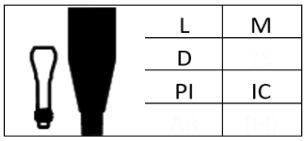
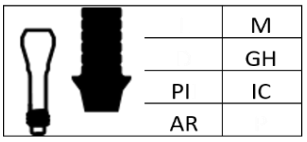


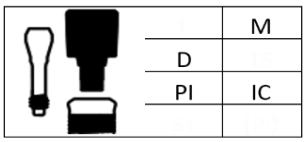
ICX-Healing Cap Bottle Size
M: material (Ti5: titanium grade 5)
D: diameter
GH: gingival height
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm)



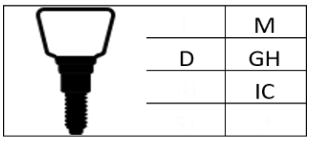
ICX-Healing Cap Customizable
L: length
M: material (PEEK: polyetheretherketone)
D: diameter
PI: parts included (screw, Ti5: titanium grade 5)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm)



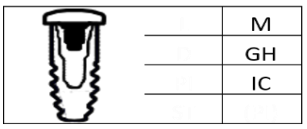
ICX-Healing Cap Individually
M: material (PEEK: polyetheretherketone)
D: diameter
GH: gingival height
PI: parts included (screw, Ti5: titanium grade 5)
IC: omplant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm. 3.3: 3.3 mm)
AR: anti rotation (AR: anti rotation, NAR: no anti rotation)



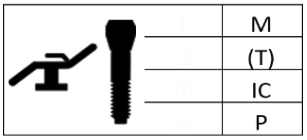
ICX-TL Healing Cap
M: material (PEEK: polyetheretherketone)
D: diameter
PI: parts included (screw, Ti5: titanium grade 5)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm)



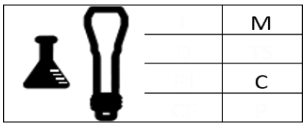
CerICX-Healing Cap
M: material (Ti5: titanium grade 5)
D: diameter
GH: gingivalheight
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)



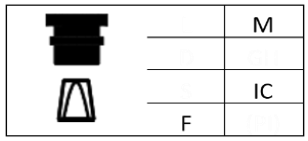
ICX-Bone Ring Set
M: material (Ti5: titanium grade 5)
GH: gingival height
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm)



Connection Screw for Patient
M: material (Ti5: titanium grade 5)
(T): type (only for standard prosthetic; A: silver, B: red)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
P: prosthetic (S: Standard, MU: Multi, MA: Maximus)



Connection Screw Laboratory
M: material (Ti5: titanium grade 5)
C: connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, ID: Index SQ, IHGB: IntraHex & Gold&Blue, FT: flatTop, FOFT: flatOne/flatTop)



ICX-Impression Cap
M: material (POM: polyoxymethylene, PPSU: polyphenylene sulfone, GTR: grilamide TR90)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, RYL: Royal)
F: form (R: round, S: slim)

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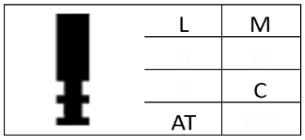
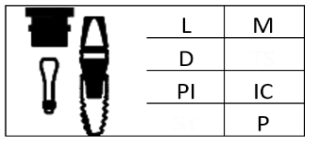
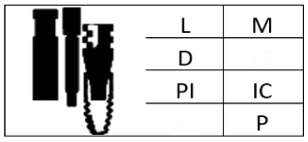


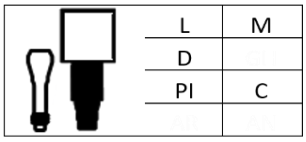
Model Analogue
L: length
M: material (Ti4: titanium grade 4B, Ti5: titanium grade 5, BR: brass)
C: connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, MU: Multi, MA: Maximus, TB: t-bona)
(AT): only for abutment level: emergence profile (ALL: all, BL: Bone Level, TL: Tissue Level)



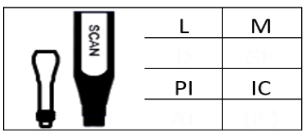
Impression Post Closed, Implant
L: length
M: material (Ti5: titanium grade 5)
D: diameter
PI: parts included (not for XS and XT posts, screw, Ti5: titanium grade 5 and cap, GTR: grilamide TR90)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
P: prosthetic (S: Standard, CICX: CERICX)



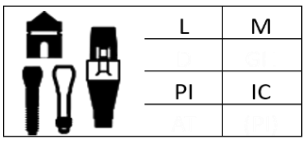
Impression Post Open, Implant
L: length
M: material (Ti5: titanium grade 5)
D: diameter
PI: parts included (nor for XS and XT implants, Screw, Ti5: titanium grade 5 and/or pin, POM: polyoxymethylene)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
P: prosthetic (S: Standard, CICX: CERICX)



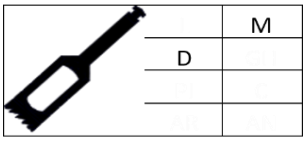
ICX-Scan Body 1. Generation
L: length
M: material (PEEK: polyetheretherketone)
D: diameter
PI: parts included (not for XS implants, screw, Ti5: titanium grade 5)
C: connection (MU: Multi)



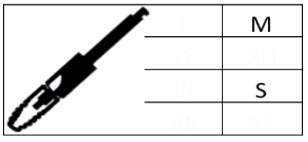
ICX-Scan Body 2. Generation
L: length
M: material (Ti4: titanium grade 4B)
PI: parts included (screw, Ti5: titanium grade 5)
IC: omplant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)



ICX-Cerec Scanpost
L: length
M: material (Ti5: titanium grade 5)
PI: parts included (laboratory screw, patient screw, Ti5: titanium grade 5 and scan cap, ABS: acrylonitrile butadiene styrene)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)



Trephine Drill
M: material (SS: stainless steel)
D: diameter



Boneprofiler
M: material (SS: stainless steel)
S: System (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)

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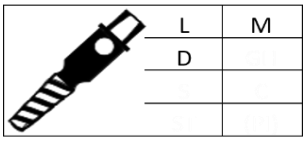
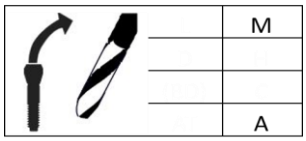
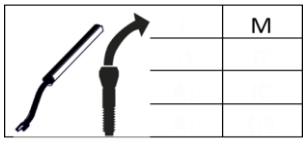


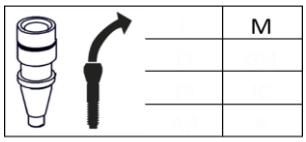
Bone Spreader
L: length
M: material (SS: stainless steel)
D: diameter



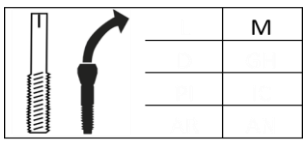
Screw extractor
M: Material (SS: stainless steel)
A: Application (V: V-gripper, L: left-hand drill)



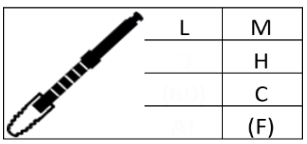
Holder for drill sleeve
M: Material (SS: stainless steel)



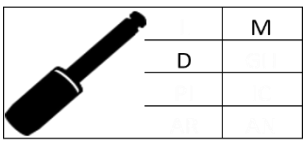
Drill sleeve
M: Material (SS: stainless steel)



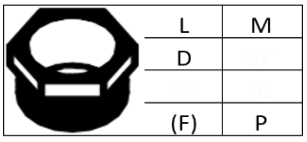
Thread cutter
M: Material (SS: stainless steel)



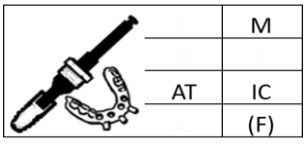
Insertion Tool
L: length
M: material (SS: stainless steel)
H: handling (R: ratchet, ISO: ISO shank)
C: connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, MI: Mini, MA: Maximus, TB: t-bona, MU: Multi, AW+MAS: Active White and massive abutment, SB: SlimBoy)
(F): features (B: ball lock, E: eccentric)



ICX-Magellan Gingival Punch
M: material (SS: stainless steel)
D: diameter



ICX-Magellan Sleeve
L: length
M: material (Ti5: titanium grade 5)
D: diameter
(F): features (H: Hex, W: Window)
P: prosthetic (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, C: Cerec, XC: Camlog, XL: Straumann, XF: Nobel, XT: Xive, AN: Ankylos



ICX-Magellan Insertion Tool
M: material (SS: stainless steel)
AT: emergence profile (BL: Bone Level, TL: Tissue Level)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
(F): features (B: ball lock system)

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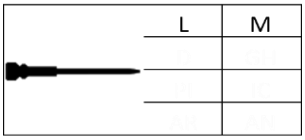
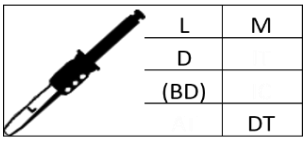
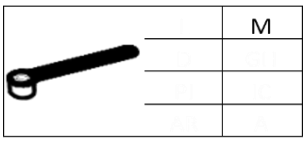


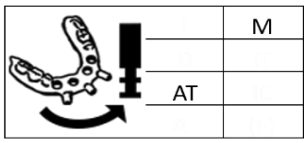
ICX-Magellan Fixation Pin
L: length
M: material (SS: stainless steel)



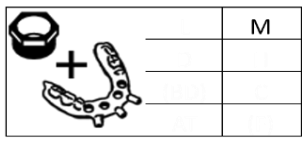
ICX-Magellan Drill
L: length
M: material (SS: stainless steel)
D: diameter
(BD): bone density (only for Magellan Drill; D1: hard bone, D2/3: standard bone, D4: soft bone)
DT: drill type (SD: Stop Drill, MD: Magellan Drill, U: Universal Drill, PI: Pilot Drill)



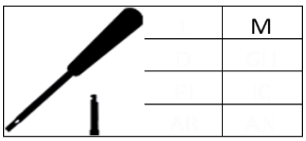
ICX-Magellan Reducing Adapter
M: material (Ti5: titanium grade 5)



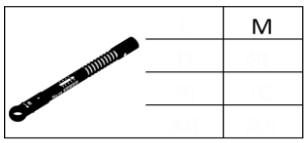
ICX-Magellan Positioner
M: material (Ti5: titanium grade 5)
AT: emergence profile (BL: Bone Level, TL: Tissue Level)



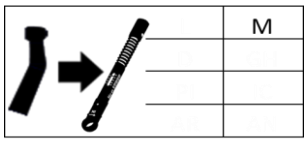
ICX-Magellan Placement Tool
M: material (SS: stainless steel)



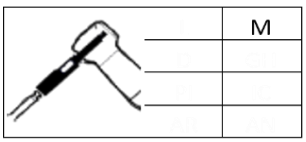
Surgigal Driver with ISO Shaft
M: material (SS: stainless steel)



Ratchet
M: material (SS: stainless steel)



Ratchet Adapter
M: material (SS: stainless steel)



Drill Extension
M: material (SS: stainless steel)

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ICX-Box
C: composition (EM: empty, EQ: equipped)
T: type (SU: surgical box, DS: drill stop sleeves box, IN: instrument ox, RS: rescue set, TI: try in box, BS: bone spreader box)
(S): system (only for surgical boxes; P: ICX-Premium, AM: ICX-Active Master, ZYG: ICX-Zygoma, AIO: ICX-All in One Bohrer, M: ICX-Magellan, C: China, INT: International)

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