

G1 Implant Systems - Freehand Surgery

1 Scope

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

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) 3.75 / 4.1 4.8	8 / 10 / 12.5 6.5 / 8 / 10 / 12.5 8 / 10 / 12,5 4.9 / 6.5 / 8 / 10 / 12.5
ICX-Mini, ICX-Mini machine polished	2.9	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 Master TL* (incl. ICX-Diamond Active Master TL)	3.3 3.75 / 4.1 / 4.8	8 / 10 / 12.5 8 / 10 / 12.5
ICX-Active Liquid	3.3 3.75 / 4.1 / 4.8	8 / 10 / 12.5 8 / 10 / 12.5 / 15

* TL = Tissue Level

In the following, all devices stored in NaCl solution (ICX-Diamond Premium, ICX-Diamond Premium TL, ICX-Diamond Active Master, ICX-Diamond Active Master TL and ICX-Active Liquid) are summarised as ICX-Liquid devices.

2 Safety instructions / disclaimer

These instructions for use must be read before using the devices! The devices 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 device until all points have been clarified. Within the framework of our sales and delivery conditions, we guarantee the perfect quality of our devices. 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 devices is beyond our control, any liability for damage caused in the process is excluded. The responsibility lies exclusively with the practitioner.

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

3 device 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 and ICX-Mini machine-polished implant), 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 inner connection (exception: ICX-Mini implant only conical inner 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 device data, such as length, height and diameter.

3.2 Intended users

The devices 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/>). If the offers on the website are not available in your language, please contact your distribution partner or medentis medical directly to obtain the offer in your language.

3.3 Intended patient target group

The use of the devices 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-Premium: stainless steel (material no. 1.4542) according to DIN EN 10088-3
- ICX-Active Master: stainless steel (material no. 1.4542) according to DIN EN 10088-3
- ICX-All in one: stainless steel (material no. 1.4108) according to ASTM F899 with a zirconium nitride coating

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®)

3.5 Accessories

ICX-Premium drills:

C-014-005345, C-014-005375, C-014-005410, C-014-005480, C-014-003345, C-014-003375, C-014-003410, C-014-003480, C-014-006290, C-014-006345, C-014-006375, C-014-006410, C-014-006480, C-014-007290, C-014-007345, C-014-007375, C-014-007410, C-014-007480, C-014-003330, C-014-005330, C-014-006330, C-014-007330, C-014-103345, C-014-103375, C-014-103410, C-014-103480, C-014-106290, C-014-106345, C-014-106375, C-014-106410, C-014-106480, C-014-107290, C-014-107345, C-014-107375, C-014-107410, C-014-107480

ICX-Active Master drills:

ACM-014-003290, ACM-014-003375, ACM-014-003410, ACM-014-003480, ACM-014-006375, ACM-014-006410, ACM-014-006480, ACM-014-007375, ACM-014-007410, ACM-014-007480, ACM-014-004375, ACM-014-004410, ACM-014-004480, ACM-014-005375, ACM-014-005410, ACM-014-005480, ACM-014-003330, ACM-014-005330, ACM-014-006330, ACM-014-007330

ICX-All in one drills:

AIO-014-004330, AIO-014-004375, AIO-014-004410, AIO-014-004480, AIO-014-007330, AIO-014-007345, AIO-014-007375, AIO-014-007410, AIO-014-007480, AIO-014-200000, AIO-014-290080, AIO-014-290100, AIO-014-290125, AIO-014-330080, AIO-014-330100, AIO-014-330125, AIO-014-345065, AIO-014-345080, AIO-014-345100, AIO-014-345125, AIO-014-375080, AIO-014-375100, AIO-014-375125, AIO-014-375150, AIO-014-410080, AIO-014-410100, AIO-014-410125, AIO-014-410150, AIO-014-480049, AIO-014-480065, AIO-014-480080, AIO-014-480100, AIO-014-480125, AIO-014-480150

Other drills:

FIL-186RF, C-014-000003, C-014-000005, C-014-006004, C-014-006005

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-015-100001, C-015-100002, C-015-100004, C-015-100006, C-015-100009, C-015-100020, C-015-100021, C-015-100029, C-015-100035, C-015-100040, C-015-110000, C-015-100000, 960001, 960002, N-015-100002, N-015-100039, N-015-100040, N-015-110000, C-014-006002, C-014-006003

Auxillary instruments:

960004, 960007, C-015-100003, C-014-230315, C-014-350410, C-027-129049, C-027-129065, C-027-129080, C-027-129100, C-027-129125, C-027-135049, C-027-135065, C-027-135080, C-027-135100, C-027-135125, C-027-138049, C-027-138065, C-027-138080, C-027-138100, C-027-138125, C-027-141049, C-027-141065, C-027-141080, C-027-141100, C-027-141125, C-027-148049, C-027-148065, C-027-148080, C-027-148100, C-027-148125, C-014-000007, C-015-100017

Article for impression taking / model analogues:

N-005-020002, N-005-040010, N-005-030001, N-005-030002, 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, N-030-000003, C-006-010001, C-006-010003, C-006-010008, N-006-010003, N-006-010008

If the above devices 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 devices supplied sterile, the blister serves as a sterile barrier!

Caution: The general rule for all devices 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 devices marked as reusable is determined by their use. Dispose damaged, worn or corroded devices. Consider the information in the section "Risks and effects of multiple use of disposable devices".

Broken packages are excluded from exchange.

The following transport and storage conditions must be observed:

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

We recommend storing devices 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.

ICX-Premium drills are intended for use in combination with the following implants:

- ICX-Premium / ICX-Premium TL
- ICX-Mini / ICX-Mini machine-polished

ICX-Active Master drills are only intended for use in combination with the ICX-Active Master, ICX-Active Master TL and ICX-Liquid implants.

ICX-All in one drills are intended for use in combination with the following implants:

- ICX-Premium / ICX-Premium TL
- ICX-Active Master / ICX-Active Master TL / ICX-Liquid
- ICX-Mini / ICX-Mini machine-polished

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 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

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 relinable long-term provisional or similar, and an ideal drill guide.

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 devices 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 devices marked as reusable is determined by their use. Dispose of damaged, worn or corroded devices.

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 devices 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 devices, 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 devices. Rinse the devices 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 devices 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 devices have an opening/cavity, make sure that the cleaning solution can drain off after the treatment. All devices 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 device. The previous steps should be repeated until there is no visible contamination left. Then rinse each device (and cavity, if applicable) thoroughly with deionised water (approx. 1 min).

Disinfection: The devices 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 device.

Drying: The devices 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-disinfectors 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 devices, 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 devices 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 device 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 devices 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 device-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 device is used. The devices 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 device 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 devices 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.

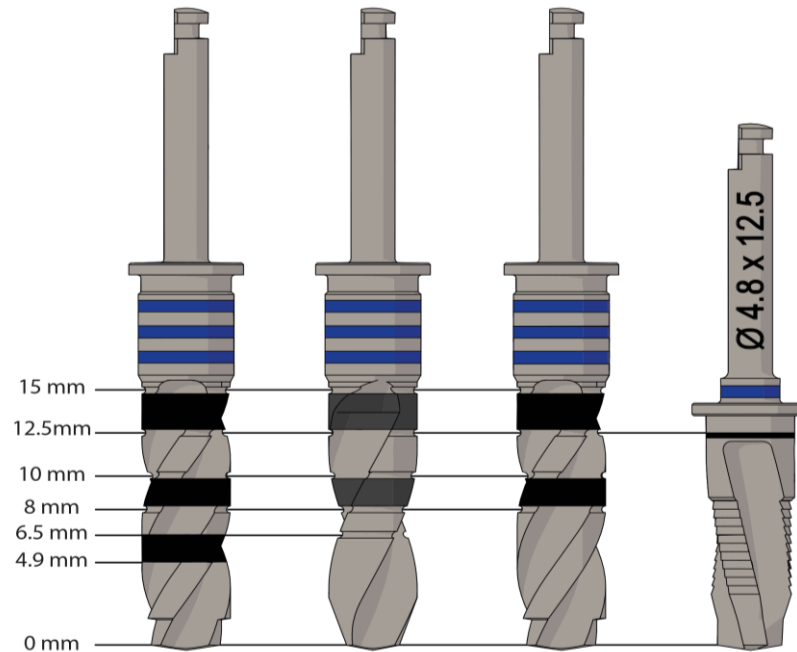
Dispose of damaged or corroded instruments.

9.5 Information on colors and markings on the drills

For preparation of the implant bed with different diameters, the ICX-Premium, ICX-Active Master and ICX-All in one drills are provided with colored markings:

Ø 2.9 mm  3.3 mm  3.45 mm  3.75 mm  4.1 mm  4.8 mm

The laser markings/grooves on the ICX-Premium, ICX-Active Master and ICX-All in one drills are based on the nominal dimensions of the implant lengths shown as examples below:



Caution: however, the laser markings on the ICX-drills do not serve to determine the exact drilling depth! To determine the exact depth of the implant bed, a depth gauge with legal, metric SI units should be used.

Furthermore, the number of rings on the parallel drills provides information on bone quality:

- One ring: very soft bone
- Two rings: soft to medium-hard bone
- Three rings: hard bone

The stop drills, taps and ICX-All in one drills for one implant length are also 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

Drilling into the bone should be performed under constant, intensive cooling with a recommended speed of 400 rpm (ICX-Premium, ICX-Active Master drills and ICX-All in one drills, 25 rpm for threaded drills) and light, variable pressure. The drilling depth of the stop drill should be 1 to 6 mm and should adapt to the thickness of the corticalis. Check the depth of the drilling cavity with the depth probe.

Caution: The drills are up to 0.4 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.

Standard implantation:

ICX-Premium, ICX-Premium TL, ICX-Mini (machine polished), ICX-Active Master, ICX-Active Master TL and ICX-Active Liquid

We recommend the following drilling sequences according to the implant diameter, implant type and bone quality:

Implant- Ø (mm)	D4		D2/D3		D1	
	Mini / Premium (TL)	Active Master (TL) ¹	Mini / Premium (TL)	Active Master (TL) ¹	Mini / Premium (TL)	Active Master (TL) ¹
2.9	Fil-186RF C-014-006290	-	Fil-186RF C-014-006290	-	Fil-186RF C-014-007290	-
3.3	Fil-186RF C-014-003330 C-014-005330	Fil-186RF ACM-014-003330 ACM-014-005330	Fil-186RF C-014-006330 C-014-005330	Fil-186RF ACM-014-006330 ACM-014-005330	Fil-186RF C-014-006330 C-014-007330 C-014-005330	Fil-186RF ACM-014-006330 ACM-014-007330 ACM-014-005330
3.45	Fil-186RF C-014-006290 C-014-003345 C-014-005345	-	Fil-186RF C-014-006290 C-014-006345 C-014-005345	-	Fil-186RF C-014-007290 C-014-007345 C-014-005345	-
3.75	Fil-186RF C-014-006290 C-014-003375 C-014-005375	Fil-186RF ACM-014-003290 ACM-014-003375 ACM-014-005375 ACM-014-004375*	Fil-186RF C-014-006290 C-014-006375 C-014-005375	Fil-186RF ACM-014-003290 ACM-014-006375 ACM-014-005375 ACM-014-004375*	Fil-186RF C-014-007290 C-014-007375 C-014-005375	Fil-186RF ACM-014-003290 ACM-014-007375 ACM-014-005375 ACM-014-004375
4.1	Fil-186RF C-014-006290 C-014-003375 C-014-003410 C-014-005410	Fil-186RF ACM-014-003290 ACM-014-003375 ACM-014-003410 ACM-014-005410 ACM-014-004410*	Fil-186RF C-014-006290 C-014-006375 C-014-063410 C-014-005410	Fil-186RF ACM-014-003290 ACM-014-006375 ACM-014-063410 ACM-014-005410 ACM-014-004410*	Fil-186RF C-014-007290 C-014-007375 C-014-007410 C-014-005410	Fil-186RF ACM-014-003290 ACM-014-007375 ACM-014-007410 ACM-014-005410 ACM-014-004410
4.8	Fil-186RF C-014-006290 C-014-003375 C-014-003480 C-014-005480	Fil-186RF ACM-014-003290 ACM-014-003375 ACM-014-003480 ACM-014-005480 ACM-014-004480*	Fil-186RF C-014-006290 C-014-006375 C-014-006480 C-014-005480	Fil-186RF ACM-014-003290 ACM-014-006375 ACM-014-006480 ACM-014-005480 ACM-014-004480*	Fil-186RF C-014-007290 C-014-007375 C-014-007480 C-014-005480	Fil-186RF ACM-014-003290 ACM-014-007375 ACM-014-007480 ACM-014-005480 ACM-014-004480

¹ and Liquid variant

* optional use

Immediate implant placement: ICX-Active Master, ICX-Active Master TL and ICX-Active Liquid

We recommend the following drilling sequence according to the bone quality and implant diameter:

Implant-Ø (mm)	Bone quality		
	D4	D2/D3	D1
3.75	ACM-014-003290	ACM-014-003290	-
	ACM-014-003375	ACM-014-003375	
	ACM-014-004375*	ACM-014-003410 ACM-014-004375*	
4.1	ACM-014-003290	ACM-014-003290	-
	ACM-014-003410	ACM-014-003375	
	ACM-014-004410*	ACM-014-007375 ACM-014-004410*	
4.8	ACM-014-003290	ACM-014-003290	-
	ACM-014-003480	ACM-014-003480	
	ACM-014-004480*	ACM-014-006480 ACM-014-004480*	

* optional use

Standard implantation using ICX-All in one drills:

ICX-Premium, ICX-Premium TL, ICX-Mini (machine polished), ICX-Active Master, ICX-Active Master TL and ICX-Active Liquid

Implant-Ø (mm)	Bone quality	Implant length (mm)						
		4.9	6.5	8	10	12,5	15	
2.9	D1	D2			AIO-014-200000	AIO-014-200000	AIO-014-200000	
		D3			AIO-014-290080	AIO-014-290100	AIO-014-290125	
		D4			AIO-014-007290	AIO-014-007290	AIO-014-007290	
3.3	D1	D2			AIO-014-200000	AIO-014-200000	AIO-014-200000	
		D3			AIO-014-330080	AIO-014-330100	AIO-014-330125	
		D4			AIO-014-007330	AIO-014-007330	AIO-014-007330	
3.45	D1	D2		AIO-014-200000	AIO-014-200000	AIO-014-200000	AIO-014-200000	
		D3		AIO-014-345065	AIO-014-345080	AIO-014-345100	AIO-014-345125	
		D4		AIO-014-007345	AIO-014-007345	AIO-014-007345	AIO-014-007345	
3.75	D1	D2			AIO-014-200000	AIO-014-200000	AIO-014-200000	AIO-014-200000
		D3			AIO-014-330080	AIO-014-330100	AIO-014-330125	AIO-014-330125
		D4			AIO-014-375080	AIO-014-375100	AIO-014-375125	AIO-014-375150
4.1	D1	D2			AIO-014-007375	AIO-014-007375	AIO-014-007375	AIO-014-007375
		D3			AIO-014-004375*	AIO-014-004375*	AIO-014-004375*	AIO-014-004375*
		D4			AIO-014-200000	AIO-014-200000	AIO-014-200000	AIO-014-200000
	D2	D2	AIO-014-200000	AIO-014-200000	AIO-014-200000	AIO-014-200000	AIO-014-200000	AIO-014-200000
		D3	AIO-014-330080	AIO-014-330100	AIO-014-330125	AIO-014-330125	AIO-014-330125	AIO-014-330125
		D4	AIO-014-410080	AIO-014-410100	AIO-014-410125	AIO-014-410150	AIO-014-410150	AIO-014-410150
	D1	D2			AIO-014-007410	AIO-014-007410	AIO-014-007410	AIO-014-007410
		D3			AIO-014-004410*	AIO-014-004410*	AIO-014-004410*	AIO-014-004410*
		D4			AIO-014-004410*	AIO-014-004410*	AIO-014-004410*	AIO-014-004410*



4.8	D1	D3	AIO-014-480049	AIO-014-330065	AIO-014-330080	AIO-014-330100	AIO-014-330125	AIO-014-330125
		D4		AIO-014-480065	AIO-014-480080	AIO-014-480100	AIO-014-480125	AIO-014-480150
		AIO-014-007480	AIO-014-007480	AIO-014-007480	AIO-014-007480	AIO-014-007480	AIO-014-007480	AIO-014-007480
			AIO-014-004480*	AIO-014-004480*	AIO-014-004480*	AIO-014-004480*	AIO-014-004480*	AIO-014-004480*

* optional use

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 the ICX-Liquid vials is described below:

- Press up the seal cap with the inside of the thumb at the notch and break the seal.
- Open the sealing cap completely
- Grasp the sealing cap with thumb and forefinger and remove the aluminium ring by applying slight pressure in a radial direction.
- Remove the grey stopper



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

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 Master TL, ICX-Active Liquid, ICX-Diamond Active Master and ICX-Diamond Active Master TL implants. 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 Master TL and ICX-Active Liquid, ICX-Active Master Diamond and ICX-Active Master Diamond TL implants. Furthermore, the ICX-Active Master, ICX-Active Master TL, ICX-Active Liquid, ICX-Diamond Active Master and ICX-Diamond Active Master TL 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 3.45 / 3.75 / 4.1 / 4.8 mm: <ul style="list-style-type: none"> • ICX-Premium, ICX-Premium TL • ICX-Diamond Premium BL, ICX-Diamond Premium TL • ICX-Active Master, ICX-Active Master TL • ICX-Diamond Active Master BL, ICX-Diamond Active Master TL • ICX-Active Liquid 	C-015-100001 C-015-100002 C-015-100004 C-015-100021 C-015-100040 C-015-100035
for diameter 3.75 / 4.1 / 4.8 mm: <ul style="list-style-type: none"> • ICX-Premium • ICX-Diamond Premium BL • ICX-Active Master • ICX-Diamond Active Master BL • ICX-Active Liquid 	screwable: C-015-100000 C-015-110000
for diameter 3.3 mm: <ul style="list-style-type: none"> • ICX-Premium, ICX-Premium TL • ICX-Diamond Premium BL, ICX-Diamond Premium TL • ICX-Active Master, ICX-Active Master TL • ICX-Diamond Active Master BL, ICX-Diamond Active Master TL • ICX-Active Liquid 	N-015-100001 N-015-100002 N-015-100004 N-015-100040 N-015-100035
for diameter 3.3 mm: <ul style="list-style-type: none"> • ICX-Premium • ICX-Diamond Premium BL • ICX-Active Master • ICX-Diamond Active Master BL • ICX-Active Liquid 	screwable: N-015-110000
for diameter 2.9 mm: <ul style="list-style-type: none"> • ICX-Mini, ICX-Mini machine polished 	C-015-100006

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.

Removing the machine-polished ICX-Mini implants

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 machine-polished ICX-Mini implants. The machine-polished ICX-Mini implants are unscrewed counterclockwise using the insertion tool (C-015-100006) and the fixed ratchet.

9.7 Prosthetic application

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

Both the open and closed impression posts fit ICX and ICX-TL implants. Only the model analogues differ. Especially if the mucosa height is very low, it is imperative that the dental technician is told which implant is an ICX-TL implant. We recommend that the dental technician is always informed whether the implants are ICX or ICX-Tissue Level (TL) implants.

We have developed the straight titanium abutment with 0 mm mucosa height especially for ICX-TL implants. This only fits ICX-TL implants - all other prosthetic parts fit ICX and ICX-TL implants.

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 devices 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 be 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.

Opening the ICX-Liquid sealing cap is a mechanical process. Due to possible damage, please change your personal protective equipment (gloves) after opening.

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 devices intended for single use are reused.

12 MRI (Magnetic Resonance Imaging) compatibility notes



The ICX implants including ICX-Mini, ICX-Premium, ICX-Active Master, ICX-3.3 and ICX-Liquid implants can be safely scanned in a 1.5 T or 3 T MRI for 15 minutes under the conditions mentioned in chapter 12.3, with no other implant within a distance of 3 cm. The ICX-Implant has not been tested in simultaneous combination with other devices and could result in MR-unsafe use.

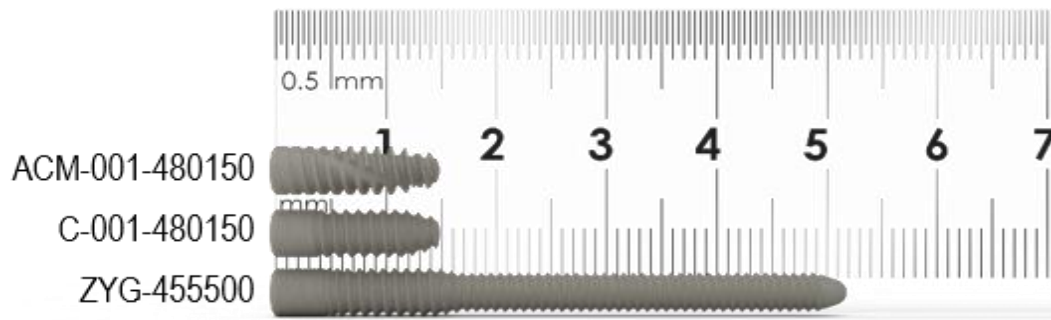
The following non-clinical tests were performed:

12.1 Information about tested devices

- Implant: ICX-Zygoma Implant 50 mm, REF ZYG-455500, LOT 20160510-100
- Abutment (connected to the implant): ICX Multi Abutment Straight 3mm Titanium, REF C-020-750030, LOT 20180131-03
- Tertiary construction (connected to the abutment for the fixation of prosthesis): ICX Multi Prosthetic Abutment 12mm Titanium, REF C-020-951120, LOT 20171220-02.

The ICX-implants from chapter 1 and the ICX-Zygoma implants are identical in material, surface finish and diameter. They only differ in length, which is why the ICX-implants from chapter 1 with a maximum length of 15 mm can be subordinated to the tested ICX-Zygoma implant with a length of 50 mm with regard to the MR compatibility tests.

For a better classification of the size ratios, the different implant types are shown below with the largest diameter 4.8 mm and the largest length 15 mm.



12.2 Used MR-System

MR artifacts:

Achieva, Philips Healthcare, Best, The Netherlands

3 Tesla, horizontal static magnetic field, short-bore, actively shielded

Static magnetic gradient field $|\nabla B| \leq 17$ Tesla/meter

Static magnetic gradient field device $|B| \cdot |\nabla B| \leq 48$ Tesla²/meter.

Gradient system:

Mode 1: gradient 40 mT/m, slew rate 200 mT/m/ms, rise time 0.2 ms, dB/dt 56 T/s (IEC 60601-2-33)

Mode 2: gradient 80 mT/m, slew rate 100 mT/m/ms, rise time 0.8 ms, dB/dt 29 T/s (IEC 60601-2-33)

Software: Release 2.6.3.9 2013-10-30

MR coil: Body coil for transmitting & receiving signals

MR Artifacts - MR Sequence Protocols:

Sequence	Fast Field Echo (FFE, Philipps, gradient echo)	Spin Echo (SE)
Time of echo (TE) [ms]	15	20
Time of repetition (TR) [ms]	500	500
Max B1 Amplitude [μ T]	13.5	13.5

RF heating:

Intera, Philips Healthcare, Best, The Netherlands

1.5 Tesla, horizontal static magnetic field, short-bore, actively shielded

Static magnetic gradient field $|\nabla B| \leq 8$ Tesla/meter

Static magnetic gradient field device $|B| \cdot |\nabla B| \leq 12$ Tesla²/meter.

Gradient system: gradient 33 mT/m, slew rate 80 mT/m/ms, rise time 0.4125 ms, dB/dt 37.5 T/s (IEC 60601-2-33)

Software: Release 12.6.1.4, 2012-05-22

MR coil: Q-Body for transmitting & receiving signals (RF heating test)

Information of stimulation display (for the used sequence): PNS = 44%

Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

RF Heating 1,5 T - MR Sequence Protocol:

Sequence	Turbo Spin Echo (TSE)
TSE Factor	17
Time of echo (TE) [ms]	60
Time of repetition (TR) [ms]	4555
TSE echo Spacing [ms]	6.7

Magnetom Trio, Siemens AG, Erlangen, Germany

3 Tesla, horizontal static magnetic field, short-bore, actively shielded

Static magnetic gradient field $|\nabla B| \leq 7$ Tesla/meter

Static magnetic gradient field device $|B| \cdot |\nabla B| \leq 20$ Tesla²/meter.

Gradient system: gradient 40 mT/m, slew rate 200 mT/m/ms, rise time 0.2 ms, dB/dt 56 T/s (IEC 60601-2-33)

Software: Numaris/4, syngo MR B17

MR coil: Body for transmitting & receiving signals (RF heating test),

Stimulation level: 56.67%

Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

RF Heating 3,0 T - MR Sequence Protocol:

Sequence	Turbo Spin Echo (TSE)
TSE Factor	17
Time of echo (TE) [ms]	59
Time of repetition (TR) [ms]	5960
Echo Spacing [ms]	6.57

Displacement force and torque:

Magnetom Verio, Siemens AG, Erlangen, Germany

3 Tesla, horizontal static magnetic field, actively shielded

Static magnetic gradient field $|\nabla B| \leq 15$ Tesla/meter

Static magnetic gradient field device $|B| \cdot |\nabla B| \leq 27$ Tesla²/meter.

Gradient system: gradient 45 mT/m (per gradient coil), slew rate 150 mT/m/ms, rise time 225 μ s, dB/dt 56 T/s (IEC 60601-2-33)

Software: Numaris/4 MR B19 Latest_20121201:P5 (SP1)

12.3 Test results

Non-clinical testing has demonstrated that the ICX-Implant is MR conditional.

By testing of magnetically induced displacement force and torque the devices showed a magnetically induced force of 3 % (equal to $\approx 1.5^\circ$) of the limit and a magnetically induced torque of 2 % of the limit; static magnetic field of 3 Tesla with a static spatial field gradient $|\nabla B| \approx 4.5$ Tesla/meter and a force device $|B| \cdot |\nabla B| \approx 7.4$ Tesla²/meter. According to these test results, entering the MR magnet can be considered safe directly after

implantation without safety discussion only for static magnetic fields of 3 Tesla only, with a $|\nabla B| \leq 128$ Tesla/meter and a $|B| \cdot |\nabla B| \leq 211$ Tesla²/meter (values extrapolated). Non-clinical testing has not been performed to rule out the possibility of implant migration at static gradient magnetic fields stronger than mentioned above.

In non-clinical testing with a 1.5 Tesla Intera, Philips MR system - implant in lateral "worst-case" phantom position, laser indicator at torso center - the "ICX-Zygoma" produced a temperature rise of $\approx 6.3^\circ\text{C}$ in a static phantom with a background temperature increase of $\approx 1.6^\circ\text{C}$ at a whole body averaged (WBA) specific absorption rate (SAR) software displayed of " $<2,4$ " W/kg (≈ 2.1 W/kg in a phantom calorimetric test) for 15 min. of continuous MR scanning with transmit/receive body coil.

In non-clinical testing with a 3 Tesla Magnetom Trio, Siemens MR system - implant in lateral "worst-case" phantom position, laser indicator at torso center - the "ICX-Zygoma" produced a temperature rise of $\approx 4.9^\circ\text{C}$ in a static phantom with a background temperature increase of $\approx 0.9^\circ\text{C}$ at a whole body averaged (WBA) specific absorption rate (SAR) software displayed of "2,6" W/kg (≈ 2.5 W/kg in a phantom calorimetric test) for 15 min. of continuous MR scanning with transmit/receive body coil. No other RF heating testing than 1.5 & 3 Tesla only was performed.

From literature: local temperature increases in the torso should be limited to 2°C ; thermal lesions can occur from temperature rises $> 4^\circ\text{C}$.

Note: the WBA-SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed. Measurement inaccuracies and additional safety margins should be taken into account. Before each individual MR procedure, it might be necessary to discuss the situation with regard to the patient benefit consulting medical experts and MR physicists.

Gradient magnetic fields: stimulation level of $\approx 56\%$ (3 Tesla Magnetom Trio, Siemens) and parameter PNS = 44 % (1.5 Tesla Intera, Philips) were used during RF heating testing from above.

Deviating scan conditions could result in MR-unsafe use.

We recommend to remove the abutment.

Note: dB/dt is not expressed in T/s; instead the distance from the stimulation threshold is given in %. No tests have been performed on possible nerve or other tissue stimulation possible to be activated by strong gradient magnetic fields and resulting induced voltages. However, due to a compact dimension of the "ICX-Zygoma" it can be assumed that induced voltages would result in eddy currents and thus would rather contribute to heating of the device.

MR image artifacts can affect the device surrounding on each side from the device surface as follows:

Worst-case artifacts of	Spin Echo	Gradient Echo
Test object length	8.49 mm	9.68 mm
Test object diameter	11.9 mm	20.0 mm
The MR image artifacts affect the object surrounding according to above magnitudes.		

The ICX-Implant has not been tested in simultaneous combination with other devices and could result in MR-unsafe use.



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 device to medentis medical GmbH and the competent authority.

14 Measures in case of malfunction

In the event of a malfunction of the device 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 devices must be carried out in accordance with international and national regulations, taking into account the waste code and hazard classification.

16 Other

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

ICX® is a registered trademark of medentis medical GmbH. Subject to change without notice.

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



Simple sterile barrier system with inner protective packaging



Simple sterile barrier system



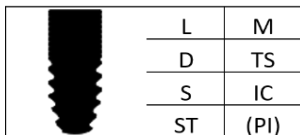
Medical device



Unique identifier of a medical device



MR conditional



ICX-Implant

L: length

M: material (Ti4: titanium grade 4B, GTi4: titanium grade 4B with higher strength)

D: diameter

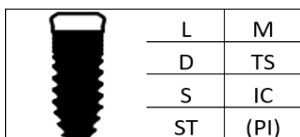
TS: thread style (P: Premium, AM: Active Master)

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

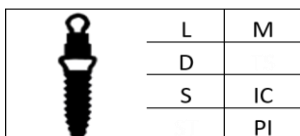
TS: thread style (P: Premium, AM: Active Master)

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)



ICX-Mini Implant

L: length

M: material (Ti4: titanium grade 4B, GTi4: titanium grade 4B with higher strength)

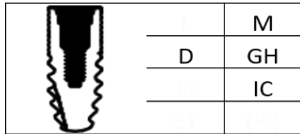
D: diameter

S: surface (S: standard, P: polished)

IC: implant connection (MI: Mini)

PI: parts included (ball head, Ti5: titanium grade 5)





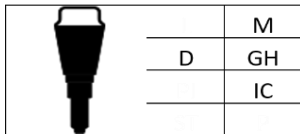
Cover Screw

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



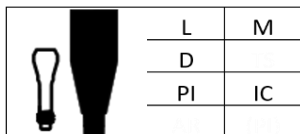
ICX-Healing Cap Conical

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



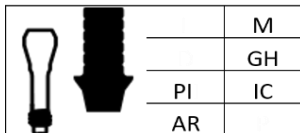
ICX-Healing Cap Bottle Size

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



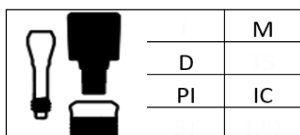
ICX-Healing Cap Customizable

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 in mm
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)



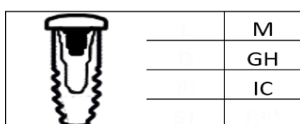
ICX-TL Healing Cap

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: gingiva height in mm
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)



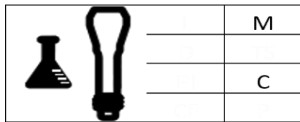
ICX-Bone Ring Set

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



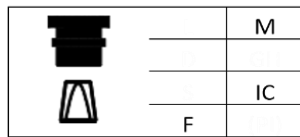
Connection Screw for Patient

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)

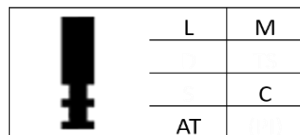
C: connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, ID: Index SQ, IHGB: IntraHex & Gold&Blue, FT: flatTop, FOFT: flatOne/flatTop)


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)

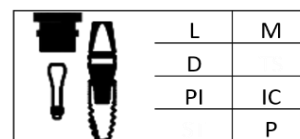

Model Analogue

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

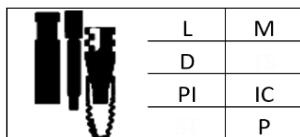
M: material (Ti5: titanium grade 5)

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

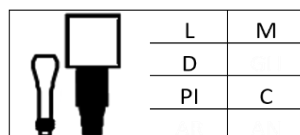
M: material (Ti5: titanium grade 5)

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

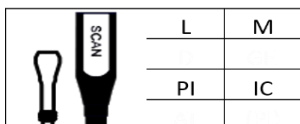
L: length

M: material (PEEK: polyetheretherketone)

D: diameter

PI: parts included (not for XS implants, screw, Ti5: titanium grade 5)

C: connection (MU: Multi)

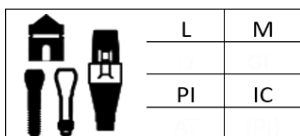

ICX-Scan Body 2. Generation

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)

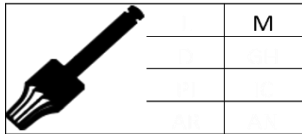

ICX-Cerec Scanpost

L: length

M: material (Ti5: titanium grade 5)

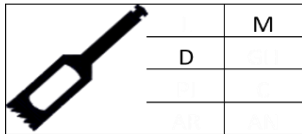
PI: parts included (laboratory screw, patient screw, Ti5: titanium grade 5 and scan cap, ABS: acrylonitrile butadiene styrene)

IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)



Crestotom Drill

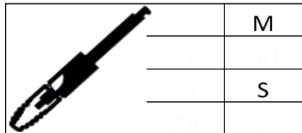
M: material (SS: stainless steel)



Trephine Drill

M: material (SS: stainless steel)

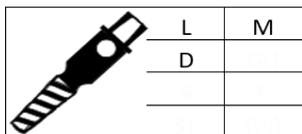
D: diameter



Boneprofiler

M: material (SS: stainless steel)

S: System (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)

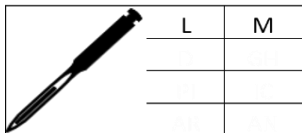


Bone Spreader

L: length

M: material (SS: stainless steel)

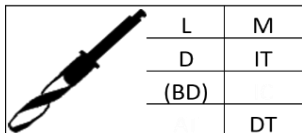
D: diameter



ICX-Cortical Drill

L: length

M: material (SS: stainless steel)



ICX-Drill

L: length (M: medium, S: short, XS: extra short)

M: material (SS: stainless steel, SS+ZrN: Stainless steel with zirconium nitride coating)

D: diameter

IT: implant type (P: Premium, AM: Active Master, AIO: All in One)

(BD): bone density (only for Parallel Drill and All in One Drill; D1: hard bone, D2/3: standard bone, D4: soft bone)

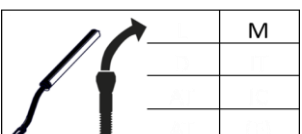
DT: drill type (SD: Stop Drill, PA: Parallel Drill, ST: Screw Tap, PI: Pilot Drill, AIO: All in One Drill)



Screw extractor

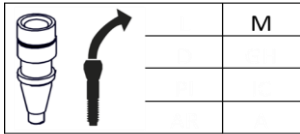
M: Material (SS: stainless steel)

A: Application (V: V-gripper, L: left-hand drill)



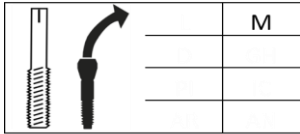
Holder for drill sleeve

M: Material (SS: stainless steel)



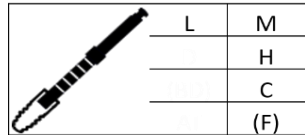
Drill sleeve

M: Material (SS: stainless steel)



Thread cutter

M: Material (SS: stainless steel)



Insertion Tool

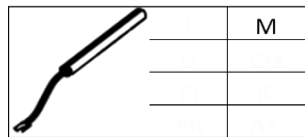
L: length

M: material (SS: stainless steel)

H: handling (R: ratchet, ISO: ISO shank)

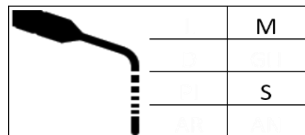
C: connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, MI: Mini, MA: Maximus, TB: t-bona, MU: Multi, AW+MAS: Active White and massive abutment, SB: SlimBoy)

(F): features (B: ball lock, E: eccentric)



ICX-Mini Fixing Tool

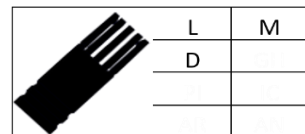
M: material (SS: stainless steel)



Depth Measuring Tool

M: material (Ti4: titanium grade 4)

S: System (ICX: 3.45, 3.75, 4.1, 4.8 mm, ZYG: Zygoma)

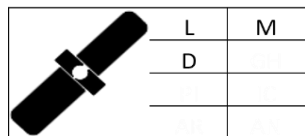


ICX-Drill Stop Sleeve

L: length

M: material (Ti5: titanium grade 5)

D: diameter

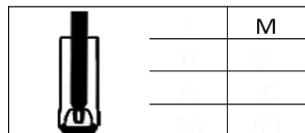


Parallel Pin

L: length

M: material (Ti4: titanium grade 4)

D: diameter



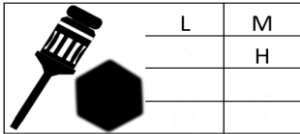
ICX-Multi Fixation Pin

M: material (POM: polyoxymethylene)



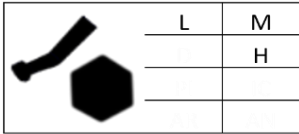
Surgical Driver with ISO Shaft

M: material (SS: stainless steel)



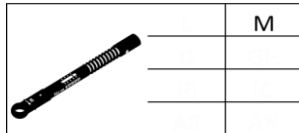
Screw Driver

L: length
M: material (SS: stainless steel)
H: hex size



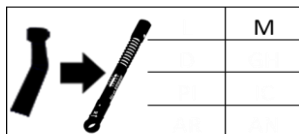
Screw Driver ISO Hex

L: length
M: material (SS: stainless steel)
H: hex size



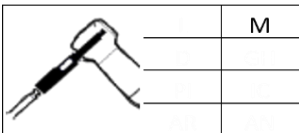
Ratchet

M: material (SS: stainless steel)



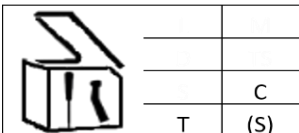
Ratchet Adapter

M: material (SS: stainless steel)



Drill Extension

M: material (SS: stainless steel)



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-Zygora, AIO: ICX-All in One Bohrer, M: ICX-Magellan, C: China, INT: International)

