G3 Zygoma-Implant Systems

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)
	coronal	apical	
Partial thread	4.8	3.95	30 / 35 / 40 / 45 / 50
Full thread	4.8	3.95	30 / 35 / 40 / 45 / 50
	4.1	3.9	30 / 32.5 / 35 / 37.5 / 40 / 42.5 / 45 / 47.5 /
	3.75	3.43	

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 (except the Dalbo®-PLUS products).

3 device description

3.1 General

The ICX-Zygoma implant system includes surgical, prosthetic and laboratory components and instruments. The ICX-Zygoma implants, partially threaded or fully threaded, are made of pure titanium and have a partially or completely sandblasted and acid-etched surface, possibly in combination with a machined surface. They are surgically anchored in the Os zygomaticum. Appropriate drills, insertion instruments and other aids are provided for this purpose. After a healing phase, if necessary, the ICX-Zygoma implants are connected to abutments via a conical, hexagonal internal connection and prosthetically restored to restore the patient's masticatory function. The ICX-Zygoma implant variants (variant 1: fully threaded; variant 2: partially threaded) are available in different lengths. These are identified by label, incl. lot number and the exact device data.

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

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

3.5 Accessories

ICX-Premium drills:
C-014-005480, C-014-003375, C-014-003480, C-014-006290, C-014-006375, C-014-006480, C-014-007290, C-014-007375, C-014-007480, C-014-103375, C-014-103480, C-014-106290, C-014-106375, C-014-106480, C-014-107290, C-014-107375, C-014-107480

Zygoma drills:
ZYG-014-009020, ZYG-014-009028, ZYG-014-009033, ZYG-014-009035, ZYG-014-009048, ZYG-014-005520, ZYG-014-005528, ZYG-014-005533, ZYG-014-005535, ZYG-014-007520, ZYG-014-007528, ZYG-014-007533, ZYG-014-007535

Other drills:
FIL-186RF, C-014-000003, C-014-000005

Cover screws:
C-003-000001, C-003-000002, C-003-000005, C-003-000021

Connection screws:
C-007-000001, C-011-000001

Healing caps:
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

Torque transmitting instruments:
960001, C-015-100040, C-015-100001, C-015-100002, C-015-100004, C-015-100021, C-015-100035, C-015-110000, C-015-100000, C-015-100020, C-014-006002

Auxillary instruments:
ZYG-015-100026, 960004, 960007, C-015-100017, ZYG-015-100041

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-030-000001, C-030-000003, C-030-000004, C-006-010001, C-006-010003

Surgical boxes:
ACM-018-000006, C-018-100001, C-018-100003, C-018-100004, ZYG-018-100003, C-018-100002

Instrument boxes:
C-018-000017, C-018-000911, C-018-100019, C-018-000105

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: 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.

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 (ICX-Premium as well as ICX-Zygoma) are intended for single patient use only. This means that they can be used to prepare multiple cavities in one patient during a single surgical procedure. The ICX-Premium drills are offered both non-sterile and gamma sterilized, the ICX-Zygoma drills are offered non-sterile only. Unless the packaging is labeled as sterile, the drills must be cleaned, disinfected and sterilized prior to patient use according to the sections "Cleaning/Disinfection" and "Sterilization". For ICX-Premium drills supplied sterile, the one-time reprocessing is not required.

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 for use

The ICX-Zygoma implants are used in patients with edentulous or partially edentulous atrophied maxilla.

ICX-Zygoma implants can be used in the following (anatomical) situations:

- When there is sufficient anterior bone substance for the insertion of standard ICX implants and when there is advanced resorption of the posterior alveolar ridge that would require an onlay or inlay augmentation for additional implants
- In cases where an anterior onlay augmentation is required for implant placement and where the need for posterior extension of the augmentation can be avoided by placing the ICX Zygoma implant
- In the maxilla with unilateral and bilateral absence of premolars and molars in conjunction with high-grade bone resorption. In such situations, a restoration with ICX zygoma implants with at least two normal ICX implants provides adequate support for a fixed restoration.

ICX-Zygoma drills are designed for use in the maxilla and zygoma and are used during surgery to prepare the implant bed for ICX-Zygoma implants.

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.

Immediate, delayed immediate, or late implantation is possible.
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 recommend the bilateral placement of at least one ICX-Zygoma implant in combination with at least 2 ICX-implants in the anterior region of the maxilla, which are rigidly splinted in order to distribute the acting horizontal loads as optimally as possible. The selection of a suitable treatment protocol depends primarily on the degree of bone loss of the maxilla. The insertion path of ICX-Zygoma implants is usually from the alveolar ridge in the region of the second premolar or first molar through the maxillary sinus or its wall into the zygomatic bone. The apical part of the implant body is inserted directly into the wider and thicker cancellous bone of the zygoma.

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
- Preoperatively diagnosed acute sinusitis

Intrasinusal implant placement is not recommended for patients with pronounced buccal concavities on the lateral maxillary sinus wall. The extrasinusal or exteriorized surgical technique is particularly suitable for this patient group.

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

The following side effects and complications may occur as a side effect:

- edema, hematoma
- temporary limitations of sensation, the masticatory and speaking function
- local swelling and pain (inflammation)
- intra- and postoperative bleeding
- systemic infection
- wound or peri-implant infections (e.g. peri-implant mucositis, peri-implantitis, osteomyelitis)
- suture dehiscences, wound dehiscences
- iatrogenic trauma
- periodontal complications (e.g. due to insufficient width of the mucogingival restoration)
- implant loss (e.g. due to insufficient osseointegration, excessive or low insertion forces or insufficient primary stability)
- lack or absence of osseointegration (e.g. due to non-compliance with oral hygiene, insufficient care of the prosthesis, diseases such as diabetes and any kind of drug abuse)
- inflammation of the tissue around the implant
- bone damage/compression
- bone deficit (e.g. fenestration or dehiscence defect)
- augmentative dehiscence
- perforation of sinus membrane
- injury of adjacent teeth
- soft tissue recession
- sinusitis (e.g. after augmentation)
- temporary or permanent nerve injury (e.g., anesthesia, paresthesia, or dysesthesia)
- hyperplasia
- buccal exostosis
- loosening or loss of the connecting screw between implant and abutment or healing cap or loss of the abutment or healing cap (e.g. due to extremely unfavorable loading conditions or trapped gingival tissue)
- fracture of the abutment, healing cap, implant body or connection screw (e.g. due to extremely unfavorable loading conditions or trapped gingival tissue)
- allergies, sensitivities or toxicity reactions
- galvanic reactions due to different types of alloys
- aspiration or swallowing of parts used in the patient's mouth
- breakage of the lower Hex of the abutment or healing cap
- cold welding of the abutment or healing cap to the implant in the hex area
- fracture of one flank of the implant, possible injury to the tissue
- peri-implantitis (e.g. due to inadequate oral hygiene and care or due to cement or adhesive residues that have not been removed)
- bone dehiscence

Occurring side effects and complications may require further surgical intervention.

9 Application

The intrasinusal surgical technique, the extrasinusal surgical technique and the extramaxillary surgical technique and all related and proven variants are suitable for the implantation of zygoma implants.

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.

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.

The plastic surgical boxes are only suitable for the sterilisation described below and the steel wash trays (C-018-010001, C-018-010002, C-018-010003) are only suitable for automatic cleaning and disinfection and sterilisation.

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

After use on the patient, place the instruments directly in a container of water. The water should not be warmer than max. 40°C. Coarse contaminants must be removed from the instruments immediately after use under running, cold (<25°C, 2 minutes) tap water until no visible residue is visible (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

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

Equipment: Water bath, soft plastic brush.

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) for 2 minutes. Clean all exterior and interior surfaces with the plastic brush for 2 minutes. Rinse all cavities at least five times (5x) with cold (<25°C) tap water using a disposable syringe (minimum volume 20 ml). Finally, rinse the products again under cold (<25°C), running water for 10 seconds.

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

Note: For cleaning in a steel wash tray, the manually pre-cleaned products are placed in the correct position in the box and then the display is removed. This is cleaned and disinfected separately from the box using the same procedure.

Equipment: washer-disinfector (RDG), almost pH-neutral, enzymatic cleaning agent (e.g. Neodisher MediZym 0.2%, Chemische Fabrik Dr. Weigert, Hamburg).

The instructions for use of the cleaning agent manufacturer and the WD manufacturer must be followed!

Suitable washer-disinfectors (WDs) that meet the requirements of EN ISO 15883 and bear a CE mark should be used for cleaning. The programme should be validated (A0 value > 3000, at least 5 min. at 93°C). The WD should be regularly maintained and checked. Deionised water (DI water) should always be used.

Parameters:

- Pre-rinse with cold water (<25°C) for 5 min.
- Wash for 10 minutes with 45°C water and pH-neutral detergent.
- 5 minutes intermediate rinse with cold water (<25°C)
- 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 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 (<134°C)

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.

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.

9.5 Implant bed preparation for ICX-Zygoma fully threaded implants

The vertical incision should be made along the ridge area below the zygomatic bone and then continued downward. In this way, exposure of the maxilla and zygoma is simplified and the parotid duct is protected. Alternatively, the incision can be made on the bone crest or 10 mm palatal from the bone crest to prepare the soft tissue and periosteum up to the level of the zygomatic arch. This will expose the lateral surface of the maxilla and allow identification of the infraorbital foramen to ensure anatomical orientation of the area prior to insertion.

Caution: It is imperative to pay attention to the adjacent arteries, veins and nerves in the surgical field. Injuries to these anatomical structures can lead to complications such as eye injuries, severe bleeding and nerve-related dysfunction.
The alveolar ridge, including its palatal aspect, must be exposed for the drill sequence.
A 10 x 5 mm window should be exposed in the lateral wall of the sinus, immediately adjacent to the ridge located below the zygomatic bone.
Ideally, the sinus mucosa should remain intact during this procedure. The sinus mucosa should be carefully elevated from the area where the implant will pierce the sinus-from the bottom of the sinus to the roof-without perforating the mucosa.

Caution: If the sinus mucosa cannot be kept intact, it is very important to prevent the mucosa from entering the implant bed. Mucosal debris that has entered the implant bed can prevent osseointegration of the implant.
Ideally, implant placement should be planned as far posterior as possible, with the implant head as close to the alveolar ridge as possible. The implant must penetrate the sinus near the zygomatic crest while perforating the cortical bone of the zygoma near the previously described incision. Adjustment of this optimal placement may be necessary due to anatomic differences.

The exact point on the alveolar ridge must be determined for the start of the drill sequence and the direction of the long implant axis based on the known anatomy of the sinus, zygomatic bone and its processes. A retractor should be placed at the incision to facilitate proper three-dimensional alignment of the implant bed bone, taking special care not to perforate the orbital floor. During the drilling procedure, it is important to protect all oral soft tissue along the drill shaft to avoid contact of the rotating drill shaft with the soft tissue. Drilling into the bone should be performed under intense cooling with light variable pressure. To prepare the implant cavity, we recommend first preparing to a depth of 15 mm using the following drill protocol: ICX pre-drill (FIL-186RF), ICX parallel drill white (C-014-006290 or C-014-007290), ICX parallel drill red (C-014-003375 or C-014-006375 or C-014-007375), ICX parallel drill blue (C-014-003480 or C-014-006480 or C-014-007480). The ICX parallel drills are to be used according to the bone quality in the single-ring (soft D4 bone), double-ring (medium-hard D2/D3 bone) or triple-ring (hard D1 bone) design at a rotation of 400 rpm. Subsequently, the ICX-Zygoma parallel drills can be used to prepare to the final implant length using the following drill protocol: ICX-Zygoma parallel drill Ø2.0, ICX-Zygoma parallel drill Ø2.8, ICX-Zygoma parallel drill Ø3.25 and ICX-Zygoma parallel drill Ø3.5. A rotation of 300 rpm is recommended for the ICX-Zygoma parallel drill Ø2.0, and a rotation of 100 rpm is recommended for the ICX-Zygoma parallel drills with larger diameters. Finally, prepare the cortical bone with the ICX stop drill blue (C-014-005480) at 400 rpm up to the marking.

For orientation of the drilling depth adjusted to the implant length, the ICX-Zygoma parallel drills are provided with 5 depth markings, which are oriented to the implant lengths 30mm, 35mm, 40mm, 45mm and 50mm: For insertion of an ICX-Zygoma implant 30mm (ZYG-455300), countersink the drill to the first depth mark. For the insertion of an ICX-Zygoma implant 35mm (ZYG-455350 or ZYG-458350), the drill must be countersunk to the second depth mark. For the insertion of an ICX-Zygoma implant 40mm (ZYG-455400 or ZYG-458400), the drill must be countersunk to the third depth mark. For insertion of an ICX-Zygoma implant 45mm (ZYG-455450 or ZYG-458450), countersink the drill to the fourth depth mark. For the insertion of an ICX-Zygoma implant 50mm (ZYG-455500 or ZYG-458500), the drill must be countersunk to the fifth depth mark.

Caution: The laser markings are oriented to the nominal dimensions of the implant lengths and are not used to determine the exact drilling depth! To determine the exact depth of the implant bed, a depth gauge with legal SI metric units should be used.
After the drill sequence, use a straight depth gauge to determine the length of the required ICX-Zygoma implant.
The depth of the implant bed should be checked with an angled depth gauge to ensure that the selected implant length will be fully seated without interference from the apical bone.
Continue to section "Insertion of ICX-Zygoma implants (fully and partially threaded)".

9.6 Implant bed preparation for ICX-Zygoma partially threaded implants

We recommend using the ICX-Zygoma parallel drill ZYG-014-0055xx and/or ZYG-014-0075xx in combination with the ICX-Zygoma diamond burr ZYG-014-009048. We recommend a speed of 300 rpm for the ICX-Zygoma parallel drill Ø2.0 and the ICX-Zygoma diamond burr, and a speed of 100 rpm for the ICX-Zygoma parallel drill with larger diameter.

1. blockade of the infraorbital nerve by means of extraoral or intraoral conduction anesthesia
2. blockade of the palatal nerve as well as the incisive nerve by means of palatal conduction anesthesia
3. blockade of the retro nerve plexus by means of local anesthesia
4. incision on the alveolar ridge displaced palatally by approx. 1 cm, relief incision in regio 7er into the vestibulum
5. preparation of a mucoperiosteal flap with exposure of the exit point of the infraorbital nerve, the bony nasal entrance and the zygomatic bone and zygomatic arch,
6. hemostasis by electrocoagulation, if necessary
7. if necessary, determination of the crestal end position on the alveolar bone crest in region 6 using an osteotomy rose drill
8. if necessary, pre-drill the hole in the zygomatic body using the osteotomy rose drill as far disto-caudally as possible in the zygoma to allow space for possible positioning of a second zygoma implant (4-regio)
9. drilling with ICX Zygoma diamond burr to create a guide groove in the ventral sinus wall up to the entry point into the zygomatic bone
+. If necessary, sinus lift using appropriate sinus instruments or balloon lift and, if necessary, insertion of a collagen membrane to protect the Schneiderian membrane in the following drilling protocol.
10. Drill with ICX-Zygoma parallel drill Ø2.0 starting from exit point 6 in the alveolar ridge. Check the zygomatic arch and lateral orbita with the second hand to avoid perforation.
11. further implant bed preparation using the following drills: ICX-Zygoma parallel drill Ø2.8, ICX-Zygoma parallel drill Ø3.25 and ICX-Zygoma parallel drill Ø3.5.

If the ICX Zygoma partially threaded implant contacts or is inserted through the alveolar bone, the blue ICX parallel drill for hard bone (three rings) can be used as a final step prior to implant insertion, if necessary, to expand the cavity in the alveolar bone, especially in the cortical region, to the coronal implant diameter.
Continue to section "Insertion of ICX-Zygoma implants (fully and partially threaded)".

9.7 Insertion of ICX-Zygoma implants (fully and partially threaded)
After preparing the drilling cavity and before inserting the implant, the resulting cavity should be thoroughly rinsed with physiological saline solution (aseptic).
Using the insertion instrument placed in the contra-angle handpiece, the ICX-Zygoma implant is removed from the packaging and inserted into the bone cavity at 15 rpm.

Caution: If a screwable insertion instrument is used for implant placement, please note that the fixation screw of the screwable insertion instrument 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.

Caution: The torque values of 15 Ncm should not be undercut, likewise the values of 55 Ncm should not be exceeded, both will most likely lead to premature loss of the ICX-Zygoma implant. In both cases, the implantation should be discontinued, continued in another region, or an attempt should be made to subsequently achieve the values by suitable surgical measures and then re-insert the zygoma implant.

The correct insertion angle of the implant must be checked while continuing insertion through the sinus until the implant tip tightens in the cortical area of the zygomatic bone.
Note: If the additional insertion of conventional implants is planned, they are implanted according to the G1 Instructions for Use for standard implants in the most current version (URL:ifu.medentis.de).
After implantation has been completed, the various abutments can be inserted for a one-stage procedure. Here, a parallel insertion direction of the abutments must be observed; if necessary, one or the other abutment must be processed individually.

9.8 Healing

Subgingival, 2-phase healing:
Once the correct position of the implant has been verified, the implant can be covered with a cover screw for a two-stage procedure to prevent bone ingrowth into the internal threads of the implant head.
Check the cover screw for tightness with the hand screwdriver at 5-10 Ncm.

Caution: The cover screw must be fully tightened to prevent bone ingrowth into the internal threads of the implant head. Such ingrowth may prevent full seating of the permanent abutment at the time of uncovery.
The wound margins are tightly closed with atraumatic suture material. Do not tie the sutures too tightly. They must be placed so that the wound margins over the cover screw are tension-free.

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 insertion of the Zygoma implant, the surgical region is professionally closed using individual suturing techniques.

9.9 Prosthetic application

After successful healing of the implant, uncovery 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 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.

Patients with Zygoma implants may develop an upper respiratory tract infection that could close the maxillary ostium resulting in sinusitis. If this occurs, the sinusitis could become chronic and require surgical intervention to restore sinus ventilation.

The risk of ICX-Zygoma implants giving way under horizontal forces can be reduced by rigidly splinting the ICX-Zygoma implants with at least two standard ICX-implants placed in the anterior region of the maxilla.

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).

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

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

MR unsafe
Non-clinical testing showed that a Zygoma implant can heat up to 6.8 °C during a 15-minute MR scan at 1.5 Tesla. Therefore, ICX-Zygoma implants are considered MR unsafe.
The test object consisted of an ICX-Zygoma implant 50 mm in length with a maximum microrough surface (ZYG-455500, Ti size 4), an ICX-Multi abutment (C-020-750030, Ti size 5) installed on it, and a tertiary ICX-Multi prosthetic abutment (C-020-951120, Ti size 5) installed on it.
The following scan parameters were tested:

- Static magnetic field strength of 1.5 and 3.0 Tesla and
- Maximum spatial gradient field of 12,800 G/cm (128 T/m).
- Maximum device force of 211,000,000 G2/cm (211 T2/m)
- Theoretically calculated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg.

Under the scan conditions defined above, the ICX-Zygoma 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.

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	European Conformity mark with identification number of the notified body
	Manufacturer
	Date of manufacture
REF	Catalouge number

LOT — Batch code

NON STERILE — Non-sterile

STERILE R — Sterilized using irradiation

Do not resterilize

Do not use if the product sterile barrier system or its packaging is compromised and consult instructions for use

Do not re-use

Use-by date

Consult instructions for use or consult electronic instructions for use

Keep away from sunlight

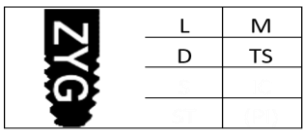
Keep dry

Single sterile barrier system

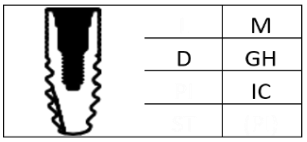
MD — Medical device

UDI — Unique identifier of a medical device

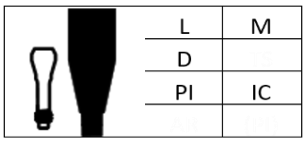
MR — MR unsuitable



ICX-Zygoma implant
L: length
M: material (Ti4: titanium grade 4B)
D: diameter
TS: thread style (A: all over, PA: partial)



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 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)

CE 0197

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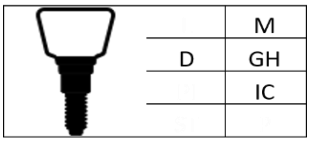
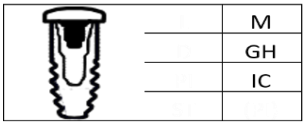
www.medentis.de info@medentis.de

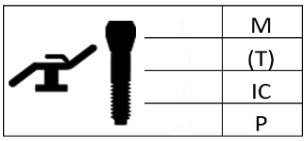
ICX-Healing Cap Individually
M: material (PEEK: polyetheretherketone)
D: diameter
GH: gingival height in mm
PI: parts included (screw, Ti5: titanium grade 5)
IC: omplant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm. 3.3: 3.3 mm)
AR: anti rotation (AR: anti rotation, NAR: no anti rotation)



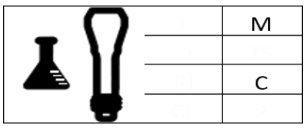
CerICX-Healing Cap
M: material (Ti5: titanium grade 5)
D: diameter
GH: gingiva height in mm
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)



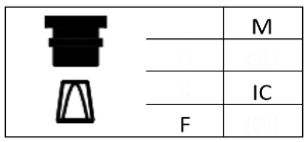
ICX-Bone Ring Set
M: material (Ti5: titanium grade 5)
GH: gingival height in mm
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm)



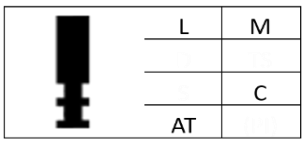
Connection Screw for Patient
M: material (Ti5: titanium grade 5)
(T): type (only for standard prosthetic; A: silver, B: red)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
P: prosthetic (S: Standard, MU: Multi, MA: Maximus)



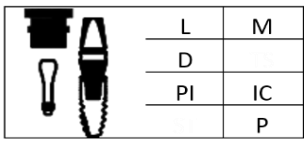
Connection Screw Laboratory
M: material (Ti5: titanium grade 5)
C: connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, ID: Index SQ, IHGB: IntraHex & Gold&Blue, FT: flatTop, FOFT: flatOne/flatTop)



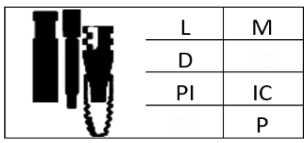
ICX-Impression Cap
M: material (POM: polyoxymethylene, PPSU: polyphenylene sulfone, GTR: grilamide TR90)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, RYL: Royal)
F: form (R: round, S: slim)



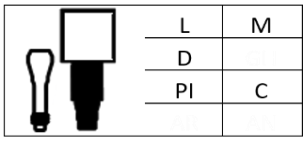
Model Analogue
L: length
M: material (Ti4: titanium grade 4B, Ti5: titanium grade 5, BR: brass)
C: connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, MU: Multi, MA: Maximus, TB: t-bona)
(AT): only for abutment level: emergence profile (ALL: all, BL: Bone Level, TL: Tissue Level)



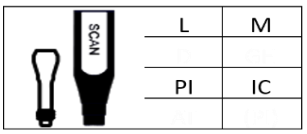
Impression Post Closed, Implant
L: length
M: material (Ti5: titanium grade 5)
D: diameter
PI: parts included (not for XS and XT posts, screw, Ti5: titanium grade 5 and cap, GTR: grilamide TR90)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
P: prosthetic (S: Standard, CICX: CERICX)



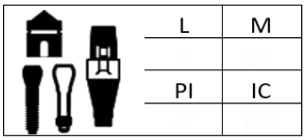
Impression Post Open, Implant
L: length
M: material (Ti5: titanium grade 5)
D: diameter
PI: parts included (nor for XS and XT implants, Screw, Ti5: titanium grade 5 and/or pin, POM: polyoxymethylene)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
P: prosthetic (S: Standard, CICX: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



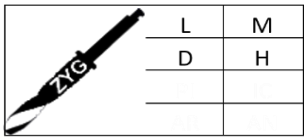
ICX-Scan Body 1. Generation
L: length
M: material (PEEK: polyetheretherketone)
D: diameter
PI: parts included (not for XS implants, screw, Ti5: titanium grade 5)
C: connection (MU: Multi)



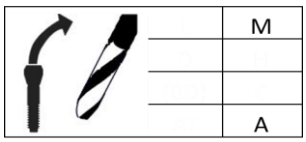
ICX-Scan Body 2. Generation
L: length
M: material (Ti4: titanium grade 4B)
PI: parts included (screw, Ti5: titanium grade 5)
IC: omplant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)



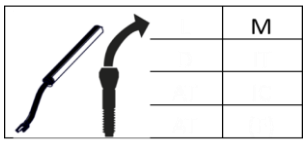
ICX-Cerec Scanpost
L: length
M: material (Ti5: titanium grade 5)
PI: parts included (laboratory screw, patient screw, Ti5: titanium grade 5 and scan cap, ABS: acrylonitrile butadiene styrene)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)



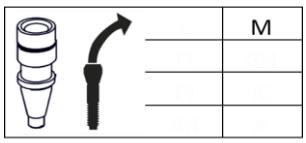
ICX-Zygoma Drill
L: length
M: material (SS: stainless steel, ZD: zirconium dioxide)
D: diameter
H: handling (ISO: ISO Shaft, SH: straight handpiece)



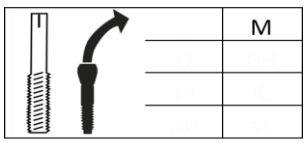
Screw extractor
M: Material (SS: stainless steel)
A: Application (V: V-gripper, L: left-hand drill)



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



Drill sleeve
M: Material (SS: stainless steel)



Thread cutter
M: Material (SS: stainless steel)

CE0197

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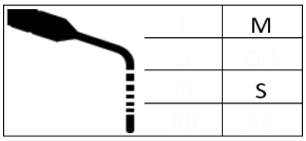
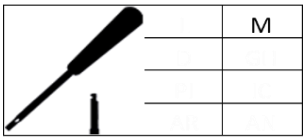
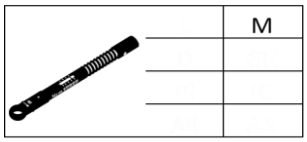


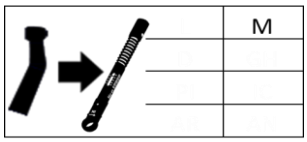
Depth Measuring Tool
M: material (Ti4: titanium grade 4)
S: System (ICX: 3.45, 3.75, 4.1, 4.8 mm, ZYG: Zygoma)



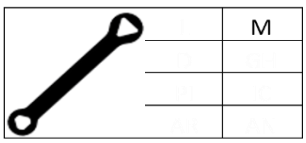
Surgigal Driver with ISO Shaft
M: material (SS: stainless steel)



Ratchet
M: material (SS: stainless steel)

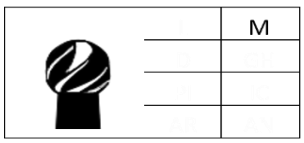


Ratchet Adapter
M: material (SS: stainless steel)



ICX-Zygoma Opening Aid
M: material (SS: stainless steel)

ICX-Box
C: composition (EM: empty, EQ: equipped, PEQ: partly 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, WT: Wash Tray)
(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)



ICX-Zygoma rose drill
M: material (SS: stainless steel)