t-bona Abutments

1 Scope

These instructions for use apply to ICX-t-bona abutments.

2 Safety instructions / disclaimer

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

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

3 Product description

3.1 General

The abutments contain prosthetic and laboratory components and can be processed with appropriate instruments. The abutments are available in different diameters, heights, lengths and for different ICX-implants from medentis. The abutments are identified by label, incl. lot number and the exact product data, such as length, height and diameter.

3.2 Intended users

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

3.3 Intended patient target group

The use of the products is intended for patients in whom a restoration with implants is to be performed or has already been performed (see chapters "Indications/Intended use" and "Contraindications").

3.4 Materials

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

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

3.5 Accessories

Torque transmitting instruments:
960001, 960002, C-015-100007, C-015-100029
Auxillary instruments:
960007, T-10571, DP-072609

Articles for impression taking:
EK-833100
Matrix sets and accessories:
T-13825, T-13836, T-13833, T-13846, T-13845, DP-055890, DP-055643, DP-050068, DP-055687
If the above products are also offered sterile, this is indicated in the article number by the appended letter "S" (e.g. non-sterile: C-015-100000 and sterile: C-015-100000S).

4 Form of delivery / sterilization / storage / return
Caution: The general rule for all products is that they must not be used if the sterile packaging has been opened or damaged!

Caution: The abutments, connection screws and impression-taking items are intended for single patient use only and are offered both non-sterile and gamma sterilized. The abutments and connection screws must be cleaned, disinfected and sterilized according to the sections "Cleaning/Disinfection" and "Recommended Sterilization" before use on the patient, unless the packaging is marked as sterile. Unless the packaging is labeled as sterile, impression-taking items must be cleaned and disinfected prior to patient use in accordance with the "Cleaning/Disinfection" section. In the case of sterilely supplied abutments, connection screws and articles for impression taking, 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 products marked as reusable is determined by their use. Dispose damaged, worn or corroded products. Consider the information in the section "Risks and effects of multiple use of disposable products".

Broken packages are excluded from exchange.

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

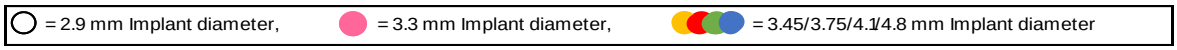
We recommend storing products made of plastic (PEEK, POM, PA) protected from sunlight.

5 Indications / intended use
ICX-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 t-bona abutments are connected to inserted implants and serve as supporting abutments for unconditionally removable dentures for the rehabilitation of esthetics and function in the maxilla and/or mandible. This applies to use in implant-retained, mucosa-supported prosthetics in conjunction with suitable matrix systems. The abutments are intended for the following indications:

Abutment type		Material	Single-tooth restoration anterior region	Single-tooth restoration posterior region	Multiple-unit restoration anterior region	Multiple-unit restoration posterior region	Full arch restoration
Ball head		titanium					



The indications for the different implant variants must be observed (URL:ifu.medentis.de).

6 Contraindications

There are no absolute contraindications to the use of ICX-abutments, except those that apply to implant surgery, among others:

- 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

Allergies or sensitivities in connection with the materials used cannot be ruled out in very rare individual cases. Different alloy types in the same oral cavity may lead to galvanic reactions in case of occlusal or approximal contact. Prosthetic misloading and overloading can lead to increased bone resorption. This may result in fatigue fracture of the implant. Micromovements caused by incorrect loading can lead to loosening of the base screw in the implant, which loosens the abutment. Thus, the frictional connection to the implant is lost. This possibly leads to:

- Fracture of one flank of the implant
- Breakage of the superstructure threaded shaft

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 Cleaning / disinfection

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

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

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

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

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

Preparation before manual and automatic cleaning/disinfection
Equipment: water bath, soft plastic brush
Multi-part instruments must be disassembled according to the respective instructions for use (e.g. ratchet, see https://ifu.medentis.de/).
Preparation: Use a soft brush for this purpose only and tap water to pre-clean the products. Rinse the products under running cold water (< 25 °C) (approx. 1 minute). Clean all external and internal surfaces with the plastic brush for approx. 2 minutes. Rinse all cavities at least five times (5x) with deionized water using a disposable syringe (minimum volume 20 ml)(approx. 1 min).
Caution: Tissue residues or blood must never be allowed to dry on. Never use metal brushes or steel wool to remove contamination manually.

Manual cleaning and disinfection

Equipment: Ultrasonic bath, plastic brush, syringe, almost pH-neutral, enzymatic cleaning agent (e.g. 0.8 % Cidezyme (pH value: 7.8-8.8, Johnson & Johnson Medical, Norderstedt) or 1.5% Medizym, (pH value: 8.2, Chemische Fabrik Dr.Weigert, Hamburg)), disinfectant with the active ingredient ortho-phthalaldehyde (e.g. Cidex OPA, Johnson & Johnson Medical, Norderstedt), lint-free cloth.
The instructions for use of the cleaning agent manufacturer and the disinfectant manufacturer as well as the ultrasonic bath manufacturer must be observed!
Cleaning: Place the products for at least 5 minutes at a frequency of 25-50 kHz and a temperature lower than 45°C in an ultrasonic bath that has been mixed with (almost) pH-neutral, enzymatic cleaning agent. Deionised water (DI water) should be used. If the products have an opening/cavity, make sure that the cleaning solution can drain off after the treatment. All products should be covered by the cleaning solution. The temperature of the cleaning solution must not exceed 45°C. Then rinse 3x with running, deionised water (rinse cavities 3x with 20ml deionised water with a syringe). A fresh, unused cleaning solution should be used for each product. The previous steps should be repeated until there is no visible contamination left. Then rinse each product (and cavity, if applicable) thoroughly with deionised water (approx. 1 min).
Disinfection: The products are disinfected in a disinfectant with the active ingredient ortho-phthalaldehyde for 12 min (rinse cavities and lumen 3 times with 20 ml disinfectant (syringe) at the beginning and end of the disinfection). Then rinse again five times under running deionised water (deionised water) Rinse cavities five times with 20ml deionised water (deionised water) using a syringe. A fresh, unused disinfectant solution should be used for each product.
Drying: The products are then dried completely with a soft lint-free cloth.
Next step: Examination, inspection and tests

Automatic cleaning and disinfection

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

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

Disinfection should be carried out at a maximum of 95°C for 10 minutes.
Drying: We recommend drying for 10 minutes at 80 - 90°C. Make sure that all instruments are completely dry after automatic drying in the WD. Cavities that are difficult to access can be dried with residue-free compressed air.
After cleaning, check the products, especially cavities and blind holes. Repeat the cleaning process if there is still visible contamination.

9.2 Sterilisation

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

Place the sealed products prepared for use in the steriliser. The steam sterilisers used must bear a CE marking and comply with the requirements of EN 13060 or EN 285. Only device- or product-specific validated procedures in accordance with ISO 17665 may be used. The instructions for use of the steriliser must be followed and the device should be serviced and checked regularly.
We recommend sterilisation by the fractionated vacuum method with the following parameters:
- Temperature: 134°C
- Pressure: 3 pre-vacuum phases with min. 60 millibar pressure, during holding time 3 bar
- Holding time: min. 5 minutes
- Drying time: min. 20 minutes

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

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

9.3 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.

9.4 Prosthetic application

After the implants have healed, the impression is taken at implant level. The dental technician then produces the master cast and fabricates the denture.

If the impression is taken at abutment level, the abutments remain in the patient's mouth and the master cast is made with the appropriate ball head laboratory analogs. Before the final insertion of the dental work, the ball abutments are screwed in with recommended 30 Ncm. A check after 72 hours and possible retightening to 30 Ncm is recommended. The prosthetic restoration is then finally placed in the patient's mouth. Please refer to the following table for the connection screws and tools as well as the recommended torques:

Abutment	Torque	Connection screw	Tool
ICX-t-bona ball head abutment	30 Ncm	N/A	C-015-100007
ICX-3.3 t-bona ball head abutment	30 Ncm	N/A	C-015-100007
ICX-Mini t-bona ball head abutment	30 Ncm	N/A	C-015-100007

Caution: Any dental work must be fixed to the abutments without tension.

Caution: we especially point out that we only guarantee our products if all items used are original medentis medical products.

Caution: any type of reworking of the connection geometry to the implant will result in fit inaccuracies that preclude further use. Do not use any products that do not match the connection geometry.

10 Information on the avoidance of risks

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

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 products intended for single use are reused.

12 MRI (Magnetic Resonance Imaging) compatibility notes

The product has not been tested for safety and compatibility in MRI examinations. The product has not been tested for heating or migration in MRI examinations.

13 Note on reporting serious incidents

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

14 Measures in case of malfunction

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

15 Disposal

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

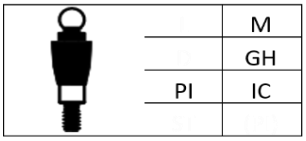
16 Other

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

17 Symbols used and their meaning

CE 0197	CE marking with identification number of the notified body
	Manufacturer

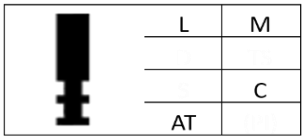
	Date of manufacture
REF	Article number
LOT	LOT-Number
NON STERILE	Not sterile
STERILE R	Sterilized by irradiation
	Do not resterilize
	Do not use if the packaging is damaged and follow electronic instructions for use
	Do not reuse
	Expiration date
	Note electronic operating instructions
	Protect from direct sunlight
	Store in dry place
	Importeur
EC REP	EU Representative
	Simple sterile barrier system
MD	Medical device
UDI	Unique identifier of a medical device



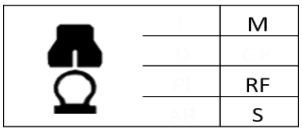
ICX-Ball Head Abutment
M: material (Ti5: titanium grade 5)
GH: gingival height
PI: parts included (model analogue, BR: brass)
IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, MI: Mini)

CE 0197

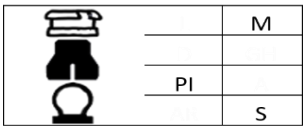
Hersteller: medentis medical GmbH
Walporzheimer Str. 48-52, 53474 Bad Neuenahr-Ahrweiler, Tel: 02641 / 9110-0
www.medentis.de info@medentis.de



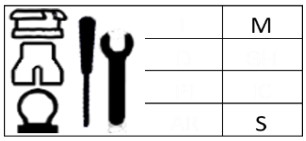
Model Analogue
L: length
M: material (Ti4: titanium grade 4B, Ti5: titanium grade 5, BR: brass)
C: connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm, MU: Multi, MA: Maximus, TB: t-bona)
(AT): only for abutment level: emergence profile (ALL: all, BL: Bone Level, TL: Tissue Level)



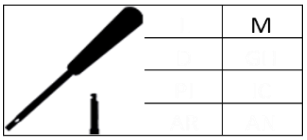
t-ecco/Dalbo Lamelle Insert
M: material (EL: Elitor®, AuPt: gold-platinum alloy, Ti5: titanium grade 5, PEEK: polyetheretherketone)
RF: retention force (S: Strong, M: Medium, L: Low)
S: dystem (DB: Dalbo, TE: t-ecco)



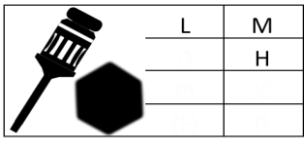
t-ecco/Dalbo Retention Set
M: material (EL: Elitor®, AuPt: gold-platinum alloy, Ti5: titanium grade 5, PEEK: polyetheretherketone)
PI: parts included (modelanalogue, BR: brass)
S: system (DB: dalbo, TE: t-ecco)



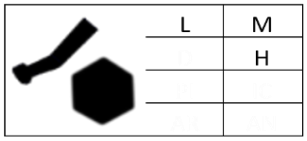
Dalbo Activation Tool
M: material (SS: stainless steel)
S: system (DB: dalbo, TE: t-ecco)



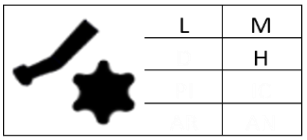
Surgigal Driver with ISO Shaft
M: material (SS: stainless steel)



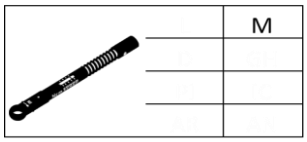
Screw Driver
L: length
M: material (SS: stainless steel)
H: hex size



Screw Driver ISO Hex
L: length
M: material (SS: stainless steel)
H: hex size



Screw Driver ISO Torx
L: length
M: material (SS: stainless steel)



Ratchet
M: material (SS: stainless steel)

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Walporzheimer Str. 48-52, 53474 Bad Neuenahr-Ahrweiler, Tel: 02641 / 9110-0
www.medentis.de info@medentis.de

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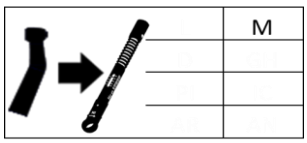
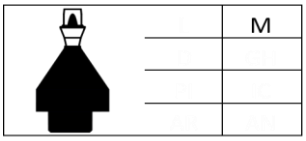


Ratchet Adapter
M: material (SS: stainless steel)



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

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