

Preforms

1 Scope

These instructions for use apply to ICX-Preforms.

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.

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.

The abutments are available for various milling system holders. (MDK: Medentika, MED: medentis, AGH: Amann Girrbach).

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

Titanium-preforms:

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

CoCr-preforms:

- Cobalt-chromium alloy (material no. 9.9135HN) according to ISO 5832-12. CTE: $14,1 \times 10^{-6}$ (20-500°C)

Connection screw:

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

3.5 Accessories

Connection screws:

C-007-000001, C-007-000002, C-011-000001, N-011-000001, N-007-000002

Torque transmitting instruments:

960001, 950097, 950098, 950099, C-015-100023, C-015-100024, C-015-100025, C-015-100030, C-015-100033, C-015-100036, C-015-100005, C-015-100020, C-015-100043

Auxillary instruments:

C-014-000004, 960007

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-030-000001, 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 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 CAD-CAM technically individually designed and milled ICX-Preform abutments are connected to inserted implants and are used to fabricate customized dental restorations. This serves to rehabilitate esthetics and function in the maxilla and/or mandible. 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
Preforms		titanium					
Preforms		CoCr					

○ = 2.9 mm Implant diameter, ● = 3.3 mm Implant diameter, ●●●● = 3.45/3.75/4.1/4.8 mm Implant diameter

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 base screw
- Breakage of the lower hexagon of the superstructure
- Cold welding of the abutment to the implant in the hex area
- Fracture of one flank of the implant

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.

Cement or adhesive residues that are not removed can lead to peri-implantitis.

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-disinfectant 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.

After scanning, designing and final milling of the preform abutments, the prosthetic restoration is fabricated. Suitable milling tools in perfect condition under low pressure must be used to machine the abutments to a responsible degree. The minimum wall thickness of 0.4 mm must not be undercut. Burrs and edges must be avoided. The contact surfaces of the abutments to the implant must not be blasted or machined. To protect the connection geometry, it is recommended to fix the abutments on laboratory implants. We recommend the abutment holder from medentis medical (TW1000100) for this purpose. Before final insertion of the dental work, the abutments are fixed in the implants with recommended 30 Ncm and the final base screw. A check after 72 hours and possible retightening of the base screw is recommended. The prosthetic restoration is then finally cemented to the abutment in the patient's mouth.

Telescope restoration: Final insertion of the primary telescopes and subsequent secondary locking by the prosthesis.

Please refer to the following table for the connection screws, the compatible laboratory screws and tools, and the recommended torques:

Abutment	Torque	Connection screw	Tool
ICX-Preforms	30 Ncm	connection screw red: C-011-000001 lab screw blue: C-007-000002	size 1.4 mm 950099 950098 950097 C-015-100023 C-015-100025 C-015-100024
ICX-3.3 Preforms	30 Ncm	connection screw pink: N-011-000001 lab screw green: N-007-000002	size 1.2 mm C-015-100033 C-015-100030 C-015-100036

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

Caution: The blue lab screw is always used until the final restoration. Only then is the base screw finally used.

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 abutment fracture and tearing out of the connection screw and the resulting breakage of the head of the connection screw can be eliminated by inserting a new abutment, provided that the connection screw can be unscrewed. Otherwise, the implant must be removed.

Overtightening or breakage of the connection screw due to excessive force leads to a lack of fixation of the abutment and poses the risk of swallowing. This can be remedied by replacing the connection screw. To do this, turn an ultrasonic tip counterclockwise over the screw. The connection screw should only be tightened with the hand screwdriver according to the torques specified above.

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












All rights reserved. No part of these instructions for use may be reproduced in whole or in part in any form (by photocopying, microfilming or other methods) or processed, duplicated or distributed using electronic systems without the prior written consent of medentis medical GmbH. Subject to change without notice.

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.

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

17 Symbols used and their meaning

CE0197 CE marking with identification number of the notified body

	Manufacturer
	Date of manufacture
	Article number
	LOT-Number
	Not sterile
	Sterilized by irradiation
	Do not resterilize
	Do not use if the packaging is damaged and follow electronic instructions for use
	Do not reuse
	Expiration date
	Note electronic operating instructions



Protect from direct sunlight



Store in dry place



Importeur



EU Representative



Simple sterile barrier system



Medical device



Unique identifier of a medical device

		M
		(T)
		IC
		P

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)

		M
		C

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)

		M
		IC
	F	

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)

	L	M
		C
	AT	

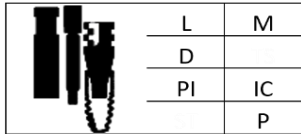
Model Analogue

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)

	L	M
	D	
	PI	IC
		P

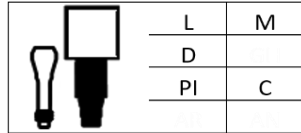
Impression Post Closed, Implant

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)



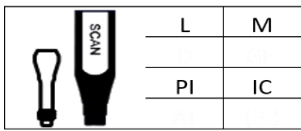
Impression Post Open, Implant

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)



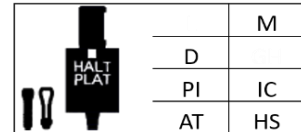
ICX-Scan Body 1. Generation

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



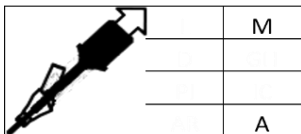
ICX-Scan Body 2. Generation

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-Preform

M: material (Ti5: titanium grade 5, CoCr: cobalt chrome)
 D: diameter
 PI: parts included (screw, Ti5: titanium grade 5)
 IC: implant connection (ICX: 3.45, 3.75, 4.1, 4.8 mm, 3.3: 3.3 mm)
 AT: emergence profile (ALL: all, BL: Bone Level, TL: Tissue Level)
 HS: holder systems (MED: medentis, MDK: medentika, AGH: Amann Girrbach, ARU: Arum)



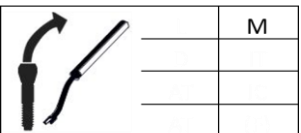
Removal Tool

M: material (SS: stainless steel)
 A: applicable (A: abutment)



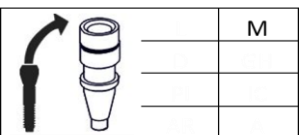
Screw extractor

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



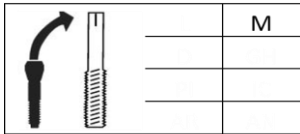
Holder for drill sleeve

M: Material (SS: stainless steel)

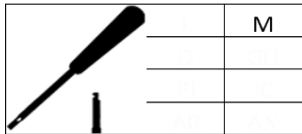


Drill sleeve

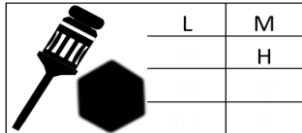
M: Material (SS: stainless steel)



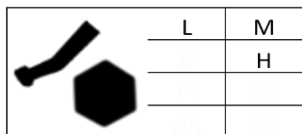
Thread cutter
M: Material (SS: stainless steel)



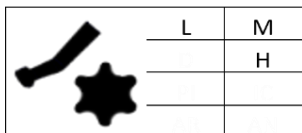
Surgical Driver with ISO Shaft
M: material (SS: stainless steel)



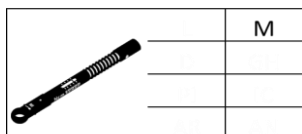
Screw Driver
L: length
M: material (SS: stainless steel)
H: hex size



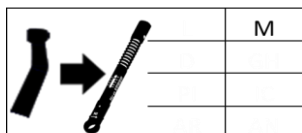
Screw Driver ISO Hex
L: length
M: material (SS: stainless steel)
H: hex size



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



Ratchet
M: material (SS: stainless steel)



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)

