

G10 Castable Gold Abutments

1 Scope

These instructions for use apply to castable ICX-Gold abutments.

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 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 device data, such as length, height and diameter.

3.2 Intended users

The devices 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/). 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 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

Gold abutments:

· Gold/HSL alloy (Ceramicor®)

Plastic sleeve:

Polyoxymethylene (POM)





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

Torque transmitting instruments:

960001, 950097, 950098, 950099, C-015-100023, C-015-100024, C-015-100025, C-015-100005, C-015-100020

Auxillary instruments:

C-014-000004, 960007

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, C-006-010008

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

Broken packages are excluded from exchange.

The following transport and storage conditions must be observed:

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

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

5 Indications / intended use

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





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

The ICX-HSL abutments, which can be cast on with gold alloys, are connected to inserted implants and are used to fabricate customized dentures. This serves to rehabilitate esthetics and function in the maxilla and/or mandible. The abutments are intended for the following indications:

Abutme	nt 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
Castable gold		Ceramicor				(30	(
= 2.9 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

- · 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)
- 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)
- · allergies, sensitivities or toxicity reactions
- · galvanic reactions due to different types of alloys
- · aspiration or swallowing of parts used in the patient's mouth





- irritations and inflammations due to insufficient fitting accuracy of the restoration
- bone resorption (e.g. due to prosthetic misloading and overloading)
- fatigue fracture of the implant
- · micromovements (e.g. due to misloads)
- implant loss (e.g. due to misloads)
- · breakage of the base screw
- · 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

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.

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.

9.2 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 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.

9.3 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.

With a platform-switch restoration, the plate of the abutment does not rest directly on the implant shoulder, but with a platform-match restoration it does. The ICX abutments in these instructions for use are only suitable for a platform switch, not for a platform match restoration.

The abutments can be individualized according to the subsequent restoration anatomically reduced.

Telescopic restoration: For the fabrication of the primary telescopes, the respective abutments are individualized in parallel on the master cast and cast in the respective alloy.

The use of normal investment material instead of speed investment material is recommended. Do not preheat higher than 1100°C. After individualization by casting, the abutments can be machined to a responsible degree with suitable perfect milling tools under low pressure. 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. Please refer to the following table for the connection screws, the compatible lab screws and tools, and the recommended torques:

Abutment	Torque	Connection screw	Tool
Castable abutment gold	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

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.



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

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 devices 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 devices intended for single use are reused.

12 MRI (Magnetic Resonance Imaging) compatibility notes

The device has not been tested for safety and compatibility in MRI examinations. The device 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 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.

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17 Symbols used and their meaning

C€0197 European Conformity mark with identification number of the notified body



Manufacturer



Date of manufacture



Catalouge number



Batch code



Non-sterile



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



Medical device



Unique identifier of a medical device



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)







	L	М
	D	GH
TYT	PI	IC
	AR	AN

Μ

IC



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-Abutment Gold/Plastic/CoCr

L: lenath

M: material (CC: ceramicor, POM: polyoxymethylene, Ti5: titanium grade 5, CoCr: colabt chrome)

PI: parts included (screw and/or pin, Ti5: titanium grade 5)

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

AR: anti rotation (AR: anti rotation, NAR: no anti rotation)

ICX-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-

(AT): only for abutment level: emergence profile (ALL: all, BL: Bone Level, TL: Tissue Level)

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И 🗐	PI	IC
• 1	ST	Р

Impression Post Closed, Implant

L: length

M: material (Ti5: titanium grade 5)

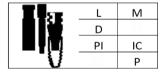
D: diameter

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)

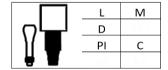
D: diameter

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)



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ICX-Scan Body 1. Generation

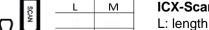
L: length

M: material (PEEK: polyetheretherketone)

D: diameter

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

C: connection (MU: Multi)



IC

ICX-Scan Body 2. Generation

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)







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)



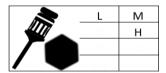
Thread cutter

M: Material (SS: stainless steel)



Surgigal Driver with ISO Shaft

M: material (SS: stainless steel)

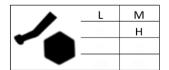


Screw Driver

L: length

M: material (SS: stainless steel)

H: hex size

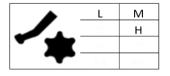


Screw Driver ISO Hex

L: length

M: material (SS: stainless steel)

H: hex size

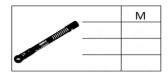


Screw Driver ISO Torx

L: length

M: material (SS: stainless steel)





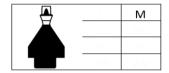
Ratchet

M: material (SS: stainless steel)



Ratchet Adapter

M: material (SS: stainless steel)



ICX-Abutment Holder

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)