Instructions for Use

BoneTrust® implant systems

Scope of these Instructions for Use

BoneTrust® implant system from the manufacturer Medical Instinct® Deutschland GmbH (Graseweg 24 - D-37120 Bovenden - www.medical-instinct.com) in accordance with the Medical Device Regulation 2017/745:

Table 1: Product groups and additional information

Device group	Basic UDI-DI	Gebrauchsinformationen
Dental implants	++EMEI0100RS	BoneTrust® Product Brochure, BoneTrust® mini Product Brochure, BoneTrust® guide Product Brochure
Abutments	++EMEI0300S4	BoneTrust® Product Brochure, BoneTrust® mini Product Brochure, Prosthetic Manual
Healing Abutments	++EMEI0400S9	BoneTrust® Product Brochure, Prosthetic Manual
Retaining Screws	++EMEI0600SK	BoneTrust® Product Brochure, Prosthetic Manual
Cover Screws	++EMEI0650T2	BoneTrust® Product Brochure
Drills	++EMEI0800SV	BoneTrust® Product Brochure, Instructions for Use BoneTrust® Drills and BoneTrust® guide Product Brochure
Machine tools	++EMEI1000RU	BoneTrust® Product Brochure, Prosthetic Manual and BoneTrust® guide Product Brochure
Manual tools	++EMEI0900T2	BoneTrust® Product Brochure, Prosthetic Manual and BoneTrust® guide Product Brochure
Impression components	++EMEI0500SE	BoneTrust® Product Brochure, BoneTrust® mini Product Brochure, Prosthetic Manual
Drill stops	++EMEI0700SQ	BoneTrust® Product Brochure, Instructions for Use BoneTrust® Drills

For further information and schematic illustrations, please refer to the relevant product brochures. These can be requested at *info@medical-instinct.de*.

Product Information

Patient population

The BoneTrust® implant system is intended for functional and esthetic oral rehabilitation in edentulous and partially edentulous jaws with completed alveolar growth.

Product description

The BoneTrust® implant system (BoneTrust® product family) comprises the following products:

Implantable medical devices

- Dental implant, sterile
  - Always in a packaging unit with accessories: retaining screws, cover screws, insertion posts (model of the abutment)
- Abutments, sterilisable before use

The products are each available in several model variants.

Implantable accessories

- Healing abutment, sterilisable before use
- Retaining screws, sterilisable before use
  - in case of delivery with dental screws in packaging unit: sterile
- Cover screws, sterilisable before use
  - in case of delivery with dental screws in packaging unit: sterile

The products are each available in several model variants.

Non-implantable accessories

- Tools, sterilisable before use
- Drills, sterilisable before use

The products are each available in several model variants.

The products of the BoneTrust® product family are only to be used in combination with each other and are not intended for use with other products. The sterilisable products can be cleaned and sterilised.

Intended Use

Intended purpose implantable medical devices

BoneTrust® dental implants and abutments are intended for oral implant placement and are used as a structural support for the prosthetic treatments.

Intended purpose implantable accessories

Cover screws are used to prevent soft tissue from growing into the dental implant during the healing phase.

Retaining screws are used to anchor abutments to dental implants and dentures to abutments.

Healing abutments are used to form the soft tissue after the dental implant has been exposed and to prevent the mucosa from growing over the dental implant again.

The application is limited to the combination with BoneTrust® dental implants and abutments.

Intended purpose accessories

Tools are used for mechanical insertion, screwing in or loosening of implantable dental products.

Drills are used for the osseous preparation of the bone bed for dental implants.

The application is limited to the combination with BoneTrust® dental implants, abutments and implantable accessories.

Application indication

BoneTrust® implants are used after the loss of one or more teeth as a tooth root replacement for the functional and aesthetic restoration of partially edentulous or edentulous upper or lower jaws.

Provided there are no contraindications, BoneTrust implants can be used for immediate implant placement, early implant placement and late implant placement.

The BoneTrust® implants with a reduced diameter (Ø 3.0 mm and 3.4 mm) are limited in terms of their indication and are intended for use in patients with a small alveolar ridge (at least 5.0 mm) with low stress. Owing to the lower mechanical strength compared to the implants with a diameter of Ø 4.0 mm, these implants are only suitable for the following indications:

- single tooth replacement for the lateral incisors in the maxilla and mandible, and of the central incisors in the mandible
- fixed dental prosthesis, in blocked prosthetic constructions and in conjunction with implants with a standard diameter of Ø 4.0 mm
- removable dental prosthesis, with at least 4 implants in primary blocking
- as supplementary abutment

BoneTrust® mini/mini+ implants are interim implants exclusively for the provisional treatment of bridges and dental prostheses.

Contraindications

Absolute contraindications include infected extraction sockets, apical osteitis (bone inflammation) and bony defects as well as untreated periodontitis and, in addition, the contraindications that apply to implant surgery in general.

The following situations may reduce the chances of successful implant treatment:

- General disorders and pathological maxillary diseases
- Shortfall of the required bone availability of the jaw
- Endangerment of the anatomical structures in the area of the planned procedure
- Infections at the implantation site
- Insufficient oral hygiene, lack of commitment to overall oral rehabilitation
- Allergies or hypersensitivity to the materials used
- Impaired healing capacity and malnutrition due to disease or (radiation) therapy and due to alcohol/drug abuse
- Smoking can also impair the success of the implantation.
- Bruxism
- Bridge connection between natural tooth and implant
- Healing time shorter than 3 months in the mandible and shorter than 6 months in the maxilla*
- Use of non-compatible tools
- Use of incompatible combination products (third-party manufacturer)

* Not applicable for BoneTrust® mini and mini+ implants.

Furthermore, the following situations can reduce the probability of success of the implant treatment for BoneTrust Balance implants:

- Cantilever dental bridges/crowns (mesial or distal)
- Pontic width between two implant pillars greater than one premolar width
- Implant diameter 4.0 mm for single-tooth implants with gaps greater than premolar width
- Implant diameter 4.0 mm for upper central incisors, canines, molars or bridge abutments
- No protection for one-piece implants possible or lack of patient compliance

Although the materials used are biocompatible materials, there is a low risk common to all types of implant dentistry that im-plants will not integrate into the bone. Implants or bone grafts may occasionally fail due to overloading of the bone or bacterial infections; in rare cases this may cause damage to sensory nerves or adjacent dental roots. Risks include poorly controlled diabetes with fluctuating blood sugar levels, poor oral hygiene and osteoporosis. There is an increased risk of implant failure during oral and/or intravenous administration of bisphosphonates.

Risks and side effects

The risks, complications and side effects may be intra-operative or post-operative.

Intra-operative risks, side effects and complications

Damage to major structures:

- inferior alveolar nerve (nervus alveolaris inferior);
- lingual nerve (nervus lingualis);
- adjacent teeth;
- soft tissue;
- maxillary sinus;
- hemorrhaging (vascular).

Post-operative risks, side effects and complications

Early-onset complications:

- secondary bleeding/hematoma
- edema;
- infection;
- wound healing impairment.

Late-onset complications:

- periimplantitis;
- implant failure.

Safety

General

Use only within the scope of the intended use in dental practices or dental clinics by dentists or oral and maxillofacial surgeons.

Read these Instructions for Use in full. Retain the Instructions for Use for reference. Failure to follow the Instructions for Use may lead to injuries or damage to the device.

Prior to the start of treatment each patient must undergo diligent medical and dental assessment. Prior to the implant treatment any pathological diseases of the jaw and remaining dentition must be fully healed, or the healing process must have begun. Bone quality/quantity, local infections or impairment

of the initial healing process are factors that may affect integration of the implant. In order to determine the optimum implant length and to prevent damage to the nerve, the available space must be clarified in advance (x-ray). Application and selection of appropriate implants must be carried out by surgically trained medical specialists only.

Safety instructions

NOTE The word NOTE indicates general precautions, which, if not followed, may lead to impairment or temporary inconvenience.

CAUTION The word CAUTION indicates dangers which, if ignored, could lead to injury or impairment of therapy.

General safety instructions, liability and warranty

Use of third-party components may impair the function of the BoneTrust® implant system and invalidates any warranty or liability for damages by Medical Instinct® Deutschland GmbH. This applies particularly to application techniques other than those recommended. The processing and application of Medical Instinct® Deutschland GmbH devices are conducted outside of our control and are the sole responsibility of the user. No liability is accepted for damage so caused.

Before each treatment, take a patient medical history including diagnostic imaging and inform the patient of all risks, side effects and intolerances.

When applied intraorally, ensure that measures are taken to prevent devices from being aspirated or falling out.

Prior to application, check that the device is suitable for use in accordance with its intended use. Check the colour coding and lettering to prevent confusion over device models.

The implants are single-use devices and are supplied sterile. Re-use or re-sterilization of the implants are not permitted. The implants are sterilized by gamma radiation. Re-using single-use devices increases the risk of infection and risk-free functional safety cannot be guaranteed.

Inspect the devices and the inner packaging for damage prior to use. Devices that are damaged devices or arrive with damaged packaging must not be used. Sterility is not guaranteed if packaging is damaged or opened. Use of the devices after the expiration date is not permitted.

The implants must be protected from moisture in their intact sealed packaging.

USE

General preparations

Information on reprocessing the drills and tools can be found in the corresponding *Instructions for Reprocessing.*

Inspect the device for damage prior to use. Damage may lead to injury and may impair the effectiveness of the treatment.

The implants have been sterilised by beta radiation (titanium implants) or ethylene oxide (ceramic implants) and may no longer be used after the expiry date has passed.

The abutments and implantable accessories are supplied non-sterile and must therefore be sterilised before use.

Treatment plan

Deficiencies in the patient's medical history, pre-operative diagnostics and treatment plan may lead to implant failure at an early stage.

Clinical and radiological examination of the patient, as well as a model analysis, are essential prerequisites for successful implant treatment. Conduct pre-operative diagnostics carefully and document the treatment plan.

Procedure for implant placement

Before using the drill bits, refer to the *Instructions for Use "Drills"* to study the general safety instructions.

Primary implant stability is essential after the implant is inserted. Drills and tools must be secured in order to prevent them being inadvertently aspirated by the patient.

Under the normal expected conditions of use, a guideline value derived from practical experience of approx. 10 applications and reconditioning cycles applies for the service life of the drills.

Treatment must be hard and soft tissue friendly to ensure optimum conditions are met for integration of the BoneTrust® im-plant systems. The intervention should be conducted as atraumatically as possible and requires a high degree of precision and care. Parallel drilling with suitably sharp drills must, depending on the drill model, be carried out at various rotational speeds (cf. Instructions for Use "Drills"), ensuring the drill tip is adequately cooled to avoid thermal trauma, which can prevent successful osseointegration of the implant. We recommend using physiologic, sterile saline solution as coolant.

For the instructions for use, guides and documents, make sure that they have a current revision.

The implants must be inserted at a torque of optimally 35 Ncm, max. 50 Ncm (25 rpm), regardless of whether they are inserted mechanically or manually.

Surgical procedure

Any contamination of the implant must be avoided.

Implantation is a surgical procedure. It must be performed in accordance with the rules of surgery (explanation, sterility, aftercare). It is essential that treatment is hard and soft tissue friendly to ensure optimum osseointegration conditions are met.

1. Prepare the implant site in accordance with the selected surgical procedure and implant size and length.
2. Remove the outer paper packaging, open the blister pack and carefully take out the glass container.
3. Remove the implant unit from the glass tube by pulling gently on the stopper.
4. Next, place the implant into the prepared implant side by rotating the stopper gently and then, once the implant is held in the drill hole, remove the stopper by pulling the mount or implant head (BoneTrust® balance and BoneTrust® mini).
5. Place the corresponding tool all the way onto the hexagon of the implant insertion post or, in the case of the one-piece BoneTrust® balance and BoneTrust® mini implants, onto the implant head. Screw in the implant at a low speed (max. 25 rpm, opt. 35 Ncm, max. 50 Ncm). For final positioning, the ratchet can be used for exact alignment.
6. Labial/buccal alignment of one corner is necessary to allow positioning of the superstructures later on.
7. The implants are to be placed slightly subcrustal.
8. The recommended torque for implant placement is opt. 35 Ncm, max. 50 Ncm (25 rpm), irrespective of the implant diameter.

The specified torques must be strictly adhered to. If the torque is exceeded or not reached, this can lead to structural damage and premature implant loss.

Wound closure

The implant must be locked in place before the gingiva is sutured post-placement. This may be accomplished using a screw plug or healing abutment.

Inspect the inside of the implant for any blood or tissue residues. Any residues visible inside the implant must be removed before the implant is locked in place. The retaining screw plug and the healing abutment must be screwed gently by hand only.

Next, complete a saliva-proof suture that is free of tension. The suture may be removed after 8 to 10 days with normally healing of the soft tissue. Prompt surgical revision with coverage is required if there is potential onset of wound dehiscence.

Healing phase

The mandibular healing phase normally lasts three months, the maxillary phase six months. It may be shorter or longer than this depending on bone quality and anatomy. Once the healing phase and gingival formation are complete, prosthetic restoration can start.

Attaching the superstructure

1. Place the selected abutment into the implant. Ensure that the abutment is positioned correctly. There should be no visible gap between the superstructure and the implant. If a visual check is not possible, check that it is seated correctly using a probe or if necessary, by x-ray.
2. Connect the screwdriver to the torque ratchet and introduce the retaining screw into the designated hole on the abutment.
3. You can then attach the abutment to the implant with the retaining screw. The recommended torque for superstructure retaining screws is 20 Ncm.
4. Ensure that the screwdriver is located exactly in the screw head. Worn, third-party or screwdrivers that have been tampered with will damage the screw when it is tightened. A new, unused retaining screw must always be used for the final placement to help prevent it from loosening later on.
5. Alternatively, the retaining screw may also be placed using a handpiece. To do this, attach the screwdriver to the handpiece. The retaining screw is placed in the screw channel and tightened with the handpiece (20 Ncm).

Check the precise torque is used when the handpiece is used to screw the mount in place. If your handpiece does not support torque measurement, we recommend screwing manually with the torque ratchet.

Once the mount is screwed in place the screwdriver can be detached from the retaining screw by pulling gently.

Post-processing / final meeting

Inform the patient in detail on the oral hygiene measures required. Recommend that the patient should attend follow-up examinations regularly.

Before the final prosthetic implantation, the attachment screw should be tightened once more. Ideally, the attachment screw on the prosthetic implant should be given another final tightening after 3 months, wherever possible.

After implantation, one of the stickers (label) on the blister pack must be removed and stuck onto the implantation pass. All other information must be added to this by hand.

Information on MRI Safety

The implant system has not been tested for safety and compatibility in the MRI environment. It has not been tested for heating, migration or image artefacts. The safety of the product in the MRI environment is therefore unknown. Scanning a patient with this product may result in injury to the patient.

According to currently available scientific literature, it can be assumed that titanium as a material reflects the state of the art. Furthermore, current findings suggest that only minor effects are to be expected from titanium. Ceramic implants represent a metal-free implant treatment. However, the individual decision on the use of magnetic resonance imaging is the responsibility of the radiologist in each individual case.

Other Information

Documentation

For documentation purposes, the punched part of the product label must be removed. Stick this onto the implantation pass and the patient card.

Information on materials

Table 1: Information on materials

Device group	Devices	Material	Safety notice
Dental implants	BoneTrust® plus/ cone+/ cone PWR/ hex PWR/mini/ mini+ implants	Titanium Grade 4 (3.7065)	-
	BoneTrust® balance	Zirconium oxide	-
Abutments	Esthetic Abutments, Ceramic Base, Wide Body Abutments, Ti-Bases, Telescopic Abutment, Direct Abutments "Lucky Lock" Abutments, patrices/matrices	Titanium Grade 5 (3.7165)	-
	BoneTrust balance Provi Cap	TECAPEEK MT classix white	-
	UCLA Abutments PA	Platinum/Gold	-
	UCLA Abutments NPA	Platinum/Iridium	-
	"Lucky Lock" matrices	Polyamide	-
	O-Ring for Ball Attachment	Silicone	-
Healing Abutments	BoneTrust balance Healing Abutment, Provi Cap	TECAPEEK MT classix white	-
	Direct Healing Abutments, Healing Abutments, Healing Abutments "Swiss", Healing Abutments Wide Body, Healing Abutments cone+, Healing Abutments cone+ "Swiss", Healing Abutments Wide Body cone+	Titanium Grade 5 (3.7165)	-
Screws	Healing Cap, Seating Copings and Retaining Screws	Titanium Grade 5 (3.7165)	-
Drills	Punches, Marking drills, Crestal drills, Threaders, Pre-drills, Extension drills, Flat drills	1.4197	may contain ≤1% Co CAS-No. 7440-48-4
Tools	Insertion Instruments, Screwdrivers	1.4034S/1.4035	
	Insertion Instruments BoneTrust Balance, Drill Extension+	1.4197	
	Drill Extension, Drill stops	1.4034S /1.4035/ 1.4305	

Service life

The service life of BoneTrust® drills and tools depends on the stresses which occur within the scope of their application. It must therefore be considered individually for each individual device.

Under normally expected conditions of use, a reference value derived from practical experience of approximately 10 applications and reprocessing cycles applies to the service life.

The final assessment of the cutting capacity is the responsibility of the expert user, since various influencing factors which cannot be controlled by the manufacturer (such as bone quality, contact pressure, rotational speed, etc.) can affect the number of possible reuses. The service life for dental implants and abutments is as listed below:

Table 2: Service life

Devices	Service life
BoneTrust® plus/cone+ /cone PWR/hex PWR	20 years
BoneTrust® balance	10 years
Abutments for BoneTrust® plus/ /cone+ /cone PWR/hex PWR	20 years
BoneTrust® mini/mini+	9 months
Abutments for BoneTrust® mini/mini+	9 months
Provisional Abutments	180 days

Replacement parts

Please refer to the company's homepage for the latest information on additional replacement parts and order numbers relating, for example to the tools.
www.medical-instinct.com

Disposal

The products must be disposed of in accordance with the locally applicable regulations and environmental regulations, taking into account the respective degree of contamination.

Information on Serious Incidents

Please report any serious incident that has occurred in connection with the BoneTrust® implant system in an EU country to Medical Instinct® Deutschland GmbH (Graseweg 24 - D-37120 Bovenden) and the competent authority in your country.

"Serious incident" means any incident that directly or indirectly led, might have led or might lead to any of the following:

a. the death of a patient, user or other person,
b. the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
c. a serious public health threat;

The *Summary of Safety and Clinical Performance (SSCP)* can be found at https://ec.europa.eu/tools/eudamed under the corresponding basic UDI-DI (see Table 1). Until the database is fully functional, the SSCP will be provided by Medical Instinct® Deutschland GmbH on request. Please contact the manufacturer by telephone or e-mail. Phone: +49(0)5593.95196
E-mail: info@medical-instinct.de

Validity

Please always use the current instructions for use at www.medical-instinct.com.

Changes compared to the previous version are marked with:

Explanation of Symbols

Manufacturer

Manufacturing date

Expiration date

medical ins+inct®

REF — Catalogue number

LOT — Batch code

Keep dry

Do not re-use

Do not resterilize

Contains hazardous substances

Single sterile barrier system

STERILE R — Radiation sterilized

STERILE EO — Sterilized using ethylene oxide

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

Refer to instructions for use

R_x only — Medical prescription

MD — Medical device

CE — Conformity with the General Safety and Performance Requirements

CE 0297 — Conformity with the General Safety and Performance Requirements; with the Notified Body identification number of DQS Medizinprodukte GmbH, Frankfurt, Germany

Rev. 05 – 12/2024