Instructions for Use

BoneTrust® Drills

Scope of these Instructions for Use

BoneTrust® drills and tools of the BoneTrust® implant system of 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	Devices	Basic UDI-DI	Instructions for Use
Drills	Punches, Marking drills, Crestal drills, Threaders, Pre-drills, Extension drills, Flat drills	++EMEI0800SV	BoneTrust® Product Brochure, BoneTrust® guide Product Brochure and Instructions for Reprocessing
Tools	Drill extension	++EMEI1000RU	
Drill stops	Drill stops	++EMEI0700SQ	

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® drills and tools of the BoneTrust® implant system include the following products:

Non-implantable accessories

- Tools, sterilizable before use
- Drills, sterilizable before use

The products are available in several different model variants.

The products of the BoneTrust® product family (abutments, drills, dental implants, gingiva formers, screws and tools) are only to be used in combination with each other and are not intended for use with other products. The sterilizable products can be cleaned and sterilized.

Intended Use

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.

Indication of the BoneTrust® implant system

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. The implants should be removed after a maximum period of 9 months.

Contraindications of the BoneTrust® implant system

Absolute contraindications include infected extraction sockets, apical osteitis (bone inflammation) and bone 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 willingness for 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
- 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 manufacturers)

* 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 bridges/crowns (mesial or distal)
- Pontic width between two abutments greater than a premolar width
- Implant diameter of 4.0 mm for single-tooth implants in gaps wider than a premolar width
- Implant diameter of 4.0 mm for upper central incisors, canines, molars, or bridge abutments
- No reliable protective measures possible for one-piece implants 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 implants 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;
- bleeding (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

Only to be used as intended 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 be carefully assessed from both a general medical and dental point of view. Before implant treatment, pathological conditions in the jaw and on the remaining teeth must have healed or the healing process must have already begun. Bone quality and quantity, local infections or disturbances of the incipient healing process are factors that can influence the healing of the implant. To determine the optimum implant length and to avoid nerve damage, the available space must be clarified in advance (X-ray check). The application and selection of suitable implants should only be evaluated and carried out by surgically trained medical specialists.

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 color coding and lettering to prevent confusion over device models.

Inspect the devices for damage prior to use. Devices that are damaged must not be used.

USE

General preparations

The implant procedure as a whole is described in the *Instructions for Use* for the implant system.

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

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

If the actual drilling depth is not correctly determined in the case of drills in relation to the X-ray image, this can cause permanent damage to nerves or other vital structures. If drilling is performed beyond the intended depth, this can lead, in mandibular procedures, among other things, to permanent paraesthesia of the lower lip or chin or to bleeding, such as at the floor of the mouth.

Drills are intended for specific implants and implant diameters. The various diameters are identified by color coding (Table 2). The use for other implants or other diameters can lead to mechanical failure of system components, tissue damage, or unsatisfactory aesthetic results.

Table 2: Color coding of the BoneTrust® implant system and drills

Color coding[1]	Drill Ø	Implant Ø
Without	1.30 mm	2.3/2.5 mm
Grey	2.00 mm	-
Green	2.80 mm	3.00 mm
Yellow	3.10 mm	3.40 mm
Red	3.25 mm	4.00 mm
Orange	3.70 mm	4.00 mm
Blue	4.25 mm	5.00 mm

Drilling sequences

The specified torques must be strictly adhered to. Exceeding or falling short of the torques can lead to structural damage and premature implant loss.

The drilling sequence of the BoneTrust® drills corresponds to the order shown in Table 3. This table also shows the optimum and maximum rotation speeds of the drills.

Table 3: Permissible rotational speeds

#	Drill	Optimal rotational speed min^{-1}	Maximum permissible rotational speed min^{-1}
1	Marking drill, short	800	100.000
	Marking drill	1.000	6.000
2	Pre-drill Ø 1.3 Exclusively for use with BoneTrust® mini/mini+	1.000	6.000
3	Pre-drill Ø 2.0 Not for use with BoneTrust® mini/mini+	1.000	6.000
4	Extension drill **Not** for use with BoneTrust® mini/mini+	300-600	6.000
5	Crestal drill **Not** for use with BoneTrust® mini/mini+	300-600	6.000
6	Threader **Not** for use with BoneTrust® mini/mini+	30	6.000
7	Drill extension **Not** for use with BoneTrust® mini/mini+	The optimal rotational speed is shown on the drill to be used.	6.000

[1] The color coding applies to the BoneTrust® plus, cone+, cone PWR, hex PWR and BoneTrust® balance implant system. The implant system BoneTrust® mini has no color coding.

Use

Marking drill

After preparation of the mucosa, the exact implantation site is marked with the aid of the 1.2 mm marking drill in order to deter-mine the exact position of the drill socket.

Pre-drill

The pre-drill is positioned at the site determined using the marking drill. It is used for the initial depth drilling of the intended preparation.

Extension drill

The extension drill is used to conically expand the cavity up to the final width. The drilling should be done intermittently and with continuous external cooling using sterile physiological saline solution. The external cooling prevents the bone tissue from becoming excessively heated. In addition, bone slivers can be removed or rinsed away. The preparation is performed under slight pressure to the desired depth with a rotational speed according to the information in Table 3. The rotational speed must be adhered to avoid instrument fractures.

If drilling templates are used, it should be ensured that the instrument does not become wedged, in order to prevent possible instrument fracture.

Crestal drill

If compact cortical bone is present, the crestal drill can be used to enlarge the cavity in this area in connection with the BoneTrust® plus, cone+, cone PWR, hex PWR and BoneTrust® balance implant systems. The insertion depth (markings) can be used to react to the different bone qualities.

Threader

In the case of an implant site in D1 bone quality (according to Misch), the use of a threader is recommended to avoid excessively high screw-in forces. The diameter-specific threader is inserted to the upper end of the cutting working part in proper axial alignment and then removed in reverse.

It can be used in an automated manner with a contra-angle piece (max. 30 rpm) or manually with the ratchet adapter and the torque ratchet.

Drill extension

All instruments of the implantology drill set which have an angled shank according to ISO 1797 can be connected to the drill extension. It extends the instrument by 15 mm.

Further treatment is safely guaranteed only when the locking hook of the drill extension audibly snaps into place.

Depth stops

The drill stops are designed for usage with the pre-drills and extension drills. The drill stops are placed as needed on the corresponding pre-drills or extension drills and they facilitate the execution of the desired drilling depth. By doing so, it should be ensured that the drill stop corresponds to the desired drilling depth.

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.

MATERIAL INFORMATION

Table 6: Information on materials

Device group	Devices	Material	Safety notice
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	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.

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 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.

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 | Catalogue number (REF) | Batch Code (LOT)

Optimal and maximum rotational speed

Contains hazardous substances

Refer to Instructions for use

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

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