

BoneTrust® implantology drill set

Instructions for use

DISCLAIMER

This drill set is a part of a comprehensive treatment concept and may be used exclusively in combination with the associated original devices according to the instructions and recommendations of Medical Instinct Deutschland GmbH (Medical Instinct). The use of devices from third-party suppliers in combination with devices from Medical Instinct – which is not recommended – invalidates the warranty and other express or implicit obligations from Medical Instinct become null and void. The user of devices from Medical Instinct must determine whether the device is suitable for a particular patient under the given conditions. Medical Instinct assumes no liability, either express or implicit, for direct or indirect damages, penalties including compensation, or other damages which occur due to or in connection with errors in the expert assessment or practice in the scope of use of Medical Instinct devices. The user is additionally obligated to obtain information regularly on the latest further developments with regard to this Medical Instinct implantology drill set and its application. Medical Instinct should be contacted in case of doubt. Since the user must ensure monitoring of the use of the device, he/she assumes responsibility. Medical Instinct does not assume any liability for damage from the use of the devices. Please note that some devices listed in these instructions for use may, under certain circumstances, not be licensed in all markets or be approved for sale.

These instructions for use apply to the devices described in Table 1.

Table 1: Area of application of the instructions for use

Article number	Product name
191-001200	Marking drill 1.2 mm
191-001210	Marking drill 1.2 mm short

Article number	Product name
191-001300	Pre-drill 1.3 mm for BoneTrust Mini
191-103000	Crestal drill 3.0 mm
191-103300	Crestal drill 3.3 mm
191-103750	Crestal drill 3.75 mm
191-104750	Crestal drill 4.75 mm
191-203000	Threader 3.0 mm
191-203400	Threader 3.4 mm
191-204000	Threader 4.0 mm
191-205000	Threader 5.0 mm
193-002000	Pre-drill 2.0 mm long
193-002800	Extension drill 2.8 mm long
193-003100	Extension drill 3.1 mm long
193-003250	Extension drill 3.25 mm long
193-003700	Extension drill 3.7 mm long
193-004250	Extension drill 4.25 mm long
193-S02000	Pre-drill 2.0 mm short
193-S02800	Extension drill 2.8 mm short
193-S03100	Extension drill 3.1 mm short
193-S03250	Extension drill 3.25 mm short
193-S04250	Extension drill 4.25 mm short
191-202880	Drill stop 8 mm for pre-drill/extension drill 2.0/2.8 mm
191-202810	Drill stop 10 mm for pre-drill/extension drill 2.0/2.8 mm
191-202811	Drill stop 11.5 mm for pre-drill/extension drill 2.0/2.8 mm

Article number	Product name
191-202813	Drill stop 13 mm for pre-drill/extension drill 2.0/2.8 mm
191-202865	Drill stop 6.5 mm for pre-drill/extension drill 2.0/2.8 mm

191-313265	Drill stop 6.5 mm for extension drill 3.1/3.25 mm
191-313280	Drill stop 8 mm for extension drill 3.1/3.25 mm
191-313210	Drill stop 10 mm for extension drill 3.1/3.25 mm
191-313211	Drill stop 11.5 mm for extension drill 3.1/3.25 mm
191-313213	Drill stop 13 mm for extension drill 3.1/3.25 mm
190-303070	Drill extension+
191-425065	Drill stop 6.5 mm for extension drill 4.25 mm
191-425080	Drill stop 8 mm for extension drill 4.25 mm
191-425010	Drill stop 10 mm for extension drill 4.25 mm
191-425011	Drill stop 11.5 mm for extension drill 4.25 mm
191-425013	Drill stop 13 mm for extension drill 4.25 mm

DESCRIPTION

Drills



Figure 1: Drills from the BoneTrust® implantology drill set

The drills (Figure 1) from Medical Instinct are made of stainless steel (1.4197) and may be used only in combination with the Medical Instinct BoneTrust® implant systems.

Drill stop



Figure 2: Drill stops from the BoneTrust® implantology drill set

The drill stops (Figure 2) from Medical Instinct are made of stainless steel (1.4305) and may be used only in combination with the pre-drills and extension drills of the BoneTrust® implantology drill set.

Drill extension



Figure 3: Drill extension+ of the BoneTrust® implantology drill set

The drill extension (Figure 3) from Medical Instinct is made of stainless steel (1.4197) and may be used only in combination with rotary cutting instruments of the BoneTrust® implantology drill set.

INTENDED PURPOSE

Drills

The drills of the implantology instrument set are surgically invasive dental drill heads which are used for the preparation and conditioning of the implant bed in the patient's jaw.

Drill stop

The drill stops are used for depth limitation during the drilling processes in connection with the corresponding surgically invasive dental drill heads.

Drill extension

The drill extension is used to extend surgically invasive dental drill heads during application.

INDICATIONS

Functional and aesthetic rehabilitation of the maxilla and/or mandible.

The device can be used for the purposes of preparation of the implant bed in fully or partially edentulous patients, taking the contraindications and warnings into account.



The indication results from the specific, existing findings. It should therefore be developed individually from patient to patient. In doing so, various factors should be taken into account which can be identified and objectively assessed only by the treating physician on site. Based on these circumstances, it is the responsibility of the practitioner to make the indication and to select the necessary technique and instrument set in each case.

CONTRAINDICATIONS

All known contraindications within the scope of dental procedures must be observed.

The drills and drill stop of the BoneTrust® implantology drill set should not be used in cases of:

- Contact allergy to the materials used
- Shortfall of the required bone availability of the jaw
- Infections at the implantation site
- Endangerment of the anatomical structures in the area of the planned procedure

In the case of bruxism, systemic diseases (e.g. diabetes mellitus, chemotherapy, osteoporosis, bisphosphonate therapy), the indication is considered to be limited.

The *shank extension* should not be used in connection with:

- Instruments for inserting implants
- Instruments with a plastic shank
- Instruments which do not have an angled shank according to ISO 1797
- Non-rotating instruments

WARNINGS

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, for example, to permanent paraesthesia of the lower lip or chin or to bleeding, such as at the floor of the mouth.

Along with the obligatory measures during a surgical procedure (such as asepsis), it must absolutely be ensured that no nerves or blood vessels are damaged when drilling into the jawbone, taking into account anatomical knowledge and medical images (such as X-rays) taken prior to the procedure.

IMPORTANT

If the instrument set (or parts thereof) used were purchased as part of a fully or partially equipped tray (BoneTrust® WashTray, BoneTrust® surgery tray), the associated instructions for use must be studied beforehand for the planned use in any case.

General information

There is no 100% guarantee of success for implants. The failure to observe the usage restrictions and work steps indicated can lead to malfunction.

The insertion of implants can lead to bone loss as well as biological or mechanical failure, such as a fatigue fracture of the implant.

The close collaboration between the surgeon, prosthodontist and dental technician is essential for a successful implant treatment.

Improper procedures in the case of surgery and prosthetics can lead to damage to the dental implant or bone loss. The BoneTrust® implantology drill set may be used only by dentists, physicians and surgeons who are familiar with the system since the use of the BoneTrust® implantology drill set requires special knowledge and skills in implantology.

In the case of intraoral application, it should be ensured that the instruments, tools and generally movable parts are secured against aspiration or falling.

The components of the BoneTrust® implantology drill set are delivered only to physicians/dentists and dental technology laboratories or on their behalf. This is to ensure that the special knowledge which enables safe use is present.

The use of third-party components and instruments can impair the function and safety of the BoneTrust® implantology drill sets. If third-party components are used, no guarantee or compensation can be granted.

Drills, instruments and system components are intended for specific implants and implant diameters. The various diameters are identified by colour 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: Colour coding of the BoneTrust® implant system

Colour 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

¹The colour coding applies to the das BoneTrust® plus, cone+, cone PWR, hex PWR, one and BoneTrust® balance implant system. The implant system BoneTrust® mini has no colour coding.

Use

The Medical Instinct drill sequence corresponds to the sequence shown in Table 3. The recommended rotational speeds of the drills can also be found in this table.

Table 3: Medical Instinct optimal and maximum permissible rotational speeds min

#	Drill	Optimal rotational speed min ⁻¹	Maximum permissible rotational speed min ⁻¹	Comments
1	Marking drill, short	800	100.000	For use with the BoneTrust implant system
	Marking drill	1.000	6.000	
2	Pre-drill Ø 1.3	1.000	6.000	Exclusively for the BoneTrust mini implant system
	Pre-drill Ø 2.0	1.000	6.000	For use with the BoneTrust implant systems, except BoneTrust mini
3	Extension drill	300-600	6.000	For use with the BoneTrust implant systems, except BoneTrust mini
4	Threader	30	6.000	For use with the BoneTrust implant systems, except BoneTrust mini
5	Crestal drill	300-600	6.000	For use with the BoneTrust implant systems, except BoneTrust mini

#	Drill	Optimal rotational speed min ⁻¹	Maximum permissible rotational speed min ⁻¹	Comments
6	Drill extension	-	6.000	For use with the BoneTrust implant systems, except BoneTrust mini the optimal rotational speed is shown on the drill to be used

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 determine 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 should be adhered in order 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.



It should be ensured that the drill does not become wedged and stuck during use, since otherwise there can be an increased risk of breakage.

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.

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, one and BoneTrust® balance implant systems. The various bone qualities can be responded to via the insertion depth (markings).

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.

Useful life

The service life of these medical devices 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 4 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.

MATERIALS

Table 4 shows the materials of the individual system parts.

Table 4: Materials of the individual system parts

System part	Material
Drill	1.4197
Drill extension	
Drill stop	1.4305

INSTRUCTIONS FOR CLEANING AND STERILIZING



All system components in these instructions for use are delivered in a non-sterile condition. They must be disinfected and sterilized before each use. Before the first use, the instruments are to be processed as described below.

After use on the patient, the system components are to be placed in a container with physiological saline solution or water.

To prepare them for thermal disinfection, remove them from the container and wipe with a lint-free disposable wipe. After wiping, place them in a second container with unused physiological saline solution or water.

All system components are intended to be used multiple times. The devices must be sterilized prior to reuse. This can be done using the BoneTrust® WashTray. A detailed description of the reprocessing in connection with the tray must be found in the correspondingly valid instructions for use. This is enclosed with the device.

Thermal disinfection

No blood or tissue residues may dry on the trays. Coarse contaminants on the tray should be removed immediately.

The thermal disinfection must be started within 2 hours after the surgery.



If visible contamination can still be detected after automatic processing, repeat cleaning and disinfection until no more contamination is visible.

Sterilization

The sterilization must be performed using the fractionated vacuum method (small steam sterilizer, class B, according to DIN EN 13060). The sterilization hold time (exposure time at sterilization temperature) is at least 5 minutes at least 134°C (273°F). The drying time is at least 10 minutes.

The processing of medical devices ends with the documented release for use.



The devices should be considered to be contaminated until processing has been completed.

HANDLING AND STORAGE

The device must be stored in a dry place in the original packaging at room temperature and without exposure to direct sunlight. Improper storage can affect the device characteristics and lead to failure of the treatment.

DISPOSAL

The device must be disposed of according to locally applicable regulations and environmental regulations and the degree of contamination in each case must be taken into account.



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SYMBOL GLOSSARY



Caution



Consult instructions for use



Catalogue number



Batch code



Quantity



Non-sterile



Optimal rotational speed



Maximum rotational speed



0297



Unique Device Identification



Medical Device

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