Instructions for use
Pilot drills

Article attribution: 23070.10 – 23072.08

Available diameters of the pilot drills:

Ref.No.	Ø	Usable length:
23070.10	1,0 mm	15 mm
23070.13	1,3 mm	15 mm
23070.16	1,6 mm	12 mm
23072.08	0,8 mm	15 mm

General information
Read the instructions for use carefully prior to use. The attending doctor, buyer, or user is responsible for selecting the products for the intended application and/or operational use. The attending doctor and all persons involved in the handling of the product are responsible, within their field of activity, for having corresponding product knowledge based on the current state of technology. This enables the correct handling of the products and prevents health or safety risks for the patient, user, or third parties.

Intended use
The pilot drill is intended as a starter for implants. It is used for pre-drilling autologous bone blocks prior to implantation for their fixation in the augmentation process by means of a bone screw.

Indication
To establish the position, direction and depth of the implant bed. Pre-drilling in bones in order to subsequently secure bone transplants with osteosynthesis screws for various augmentation techniques. Generally applicable precautionary measures and rules of conduct have to be explained to the patients prior to surgery. In order to determine the exact position and depth of the bore hole, computer tomography examinations are recommended in addition to taking a bite impression and orthopantomogram. The area surrounding the product usage site must be examined in detail to exclude hazards to adjacent structures. Apply local anaesthetic at the product usage site. Position the incision and prepare the mucous membrane and periosteum according to the surgical procedure for the augmentation. The pilot drill is applied at the established location. It is used for initial drilling in the planned procedure.

- The products should not be clamped deeper than necessary.
- The products must be brought up to the rotational speed before they are applied to the object.
- Wearing safety goggles is recommended depending on the application.
- Unprotected contact with the products by the user must be avoided (wear protective gloves).
- Thermal damage due to rotating products must be avoided under all circumstances (work at low speed and with adequate cooling, see the section “Cooling”).

Make sure that the drill does not can’t or jam during use (increased risk of breakage). Use low pressure and the recommended rotational speed below for drilling to the desired depth. Complying with the rotational speed prevents product fractures.

Contraindication
Persons with the following contraindications should be excluded from treatment:

- Patients who lack willingness to cooperate in the treatment and healing phases (for example, in case of drug abuse, mental illness and personality changes, etc.).
- The treatment of risk groups where fundamentally incalculable operating risks exist is not advisable (for example: active treatment of malignancy, immune suppression, recent myocardial infarction, severe liver dysfunction, etc.).
- Patients with florid infection.
- Patients during pregnancy.
- In children and adolescents, an implantation or bone augmentation should only be performed in exceptional cases (trauma) because of incomplete bone growth.

Possible side effects and complications
- Improper application can lead to tissue damage, premature wear, destruction of the product and danger to the patient, user or third parties.
- The materials that are used can cause allergic reactions, for example, chrome/nickel allergy.

Recommendations and warnings to be respected

⚠ **If these warnings are not respected, this can lead to an increased safety risk.**
- Only to be used for the intended purpose indicated.
- All instructions described here must be absolutely followed.
- Use only by specialized personnel!
In case of misuse, all liability is excluded.

Recommended rotational speed
- We recommend an optimum rotational speed of 1,000 min^{-1} for implant pilot drills; the maximum rotational speed of 2,000 min^{-1} must not be exceeded.
- Using the product-specific recommended rotational speed $n_{opt.}$ leads to the best work results.
- Long and pointed products tend towards forced resonance vibrations in the area of the tip that can destroy the products when the maximum allowable rotational speed $n_{max.}$ is exceeded.

⚠ **Failure to comply with the maximum allowable rotational speed leads to an increased safety risk.**
Failure to comply with the recommended rotational speed can lead to unfavourable work results.
Only axial loads may be applied to the pilot drills!

Connections/interfaces
The shaft connections are designed according to DIN EN ISO 1797-1 and intended for use in suitable standardised handpieces and contra-angle pieces.

Contact pressures
Excessive contact pressures have to be avoided. With cutting products, they can cause damage of the working part and rupturing of the blade. Heat development increases as well.
Excessive contact forces, twisting and levering can cause breakage of the respective product, with the risk of fragments remaining inside the patient’s body.

Cooling
Drilling should be carried out intermittently and under continuous exterior cooling with sterile physiological saline solution. Exterior cooling prevents excessive heating of the bone tissue and also dissipates or flushes away the bone fragments.

⚠ **Insufficient water cooling can cause the pilot drill to become clogged with chips, leading to increased heat development and, in the worst case, irreversible damage to the bone and surrounding tissue (thermal necrosis). Bone damage may occur at temperatures of 47°C and up. The service life of the products is reduced as well.**

Guiding values for the frequency of use
Products made of stainless steel can be used approximately 4 times. This guiding value may deviate from the actual service life depending on the application and/or the material being processed. In some cases the products can be used longer if there is no apparent wear.

Material used
Stainless steel: DIN EN ISO 7153-1

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Sorting out worn products
- Broken and deformed blades cause vibrations and high contact pressures, leading to broken incision edges and rough surfaces.
- Products that are bent or do not run smoothly should be rejected promptly.
- Dull products encourage excessive contact forces and thus increase the working temperature. This can cause damage to the surrounding bone as well as the transplant due to excessive heat input.

⚠ **Please check the products for identity, completeness, integrity and function. Immediately after the detection of a damage, the products may not be used any longer!**
The products are designed to be sharp and pointed. There is a risk of cutting injuries. Dispose of the products in suitable containers.

Delivery state
The product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

Safekeeping/storage
- Until the first use, it should be stored in the original package at normal room conditions.
- To prevent contamination, the storage areas for the products, both non-sterile and sterilised, should be kept dry and free of dust. Already sterilised products should be put into and stored in suitable, hygienic containers such as trays, stands or similar. To prevent damage caused by UV radiation, do not store the products near windows or direct sunlight. It is important to protect the products against mechanical strain and contact with chemicals (in particular H_2O_2 (hydrogen peroxide)) to prevent damage.

Returns, complaints and repairs
Returns are only accepted in the original packaging.
Complaints are only accepted if the products are declared as “hygienically safe”. The products must be fully reconditioned before they are returned, that is, cleaned, disinfected, and safely packaged. A certificate of hygienic safety that confirms proper reprocessing in writing must be included with returned products.
Pilot drills cannot be repaired.

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Disposal
Defective, obsolete and worn products must be disposed of in accordance with the applicable regulations and national or regional legal provisions. Products for disposal must be disposed of in a hard container to prevent the risk of injury. Contamination control requirements have to be observed.

Liability
Liability on the part of the manufacturer is excluded in the following cases among others:
- Application of the products outside their intended use
- Improper handling
- Failure to observe the notices in these instructions
- Use of unsuitable or unapproved chemicals and equipment for reconditioning
- Product modifications and repairs by unauthorised parties

Graphic symbols
The graphic symbols used for identification correspond to the following significations:

	Optimal rotation speed		Maximum rotation speed
	Read the instructions for use		Attention, important information relevant for safety
	Manufacturer information		Date of manufacture
REF	Article number	LOT	Lot number
MD	Medical device	SRN	Registration number of the manufacturer in the EUDAMED database
CE 0297	CE marking and notified body		Health Industry Bar Code
	Store in a dry place		Non-sterile
UDI	Unique Device Identification		Prescription only (USA)

For information on reconditioning the products, please see our preparation instructions WAA_0001_en_Preparation_stoma_medical_devices.

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