Instructions for use
Trephine drills with internal cooling

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Available diameters of the trephine drills:

Ref.no.	Inner diameter	Outer diameter
22349.02	2 mm	3 mm
22349.03	3 mm	4 mm
22349.04	4 mm	5 mm
22349.05	5 mm	6 mm
22349.06	6 mm	7 mm
22349.07	7 mm	8 mm
22349.08	8 mm	9 mm
22349.09	9 mm	10 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
Trephine drills are intended for removing endosseous implants or for taking bone implants from suitable donor areas in the mouth area, e.g. at the chin or in the jaw crest. It is up to the user to decide in what area bone is removed. They are operated with the hand/angle piece of the dentist unit.

Indication
Trephine drills are used to take out autologous bone material within an implantological, periodontal or oral-surgical treatment. The trephine drills can effectuate a targeted removal of drill cores, e.g. at the chin or in the jaw crest, and transplant them to places where a bone defect must be compensated for. Targeted removal of bone, for example, for examination purposes, is also possible using the trephine drill. The semilunar technique is not supported by this product.

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.

Recommendation:
The diameter and the drilling depth (max. 8.0 mm) should be established with the help of X-ray images / computer tomography examinations. Endangering the stability of the jaw has to be reliably excluded.

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.

Recommendation:
To minimise the risk of slipping off when applying the trephine drills, a first cut can be made with a bone cutter.

Used material
Stainless steels | 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.

Connections/interfaces
The shaft connections are designed according to DIN EN ISO 1797-1 and to be used with a hand or angle piece corresponding to the applicable norms. The trephine drills have an inner bore for cooling, which means that handpieces / contra-angles with external and internal cooling can be used. Before use, it must be checked if the correct fit in the hand / angle piece is guaranteed. The instructions for use of these devices must be respected. The products should not be fixed more deeply than necessary.
Before approaching the object, the products must be brought up to the right rotational speed.
Please make sure that the trephine drill does not jam and get stuck (increased danger of breakage). The preparation is carried out under low pressure down to the desired depth with the rotational speed recommended below. To avoid product breakage, the rotational speed should be respected.
User-friendly application:
depth marking applied at 2-4-6-8 mm for orientation.

Recommended rotation speed
We recommend a speed of 1000 rpm for the use of the trephine drill in connection with a contra-angle handpiece. The maximum permissible speed is 1200 rpm.

⚠ **If the admitted rotation speed is not respected, this leads to an increased safety risk.**
If the recommended rotation speed is not respected, this can lead to unfavorable work results.

Pressing forces
As a guideline, we recommend a maximum contact pressure of 2N. Blocking due to excessive contact pressure as well as tilting and levering must be avoided.
An even chip formation during the operating procedure can serve as a guideline. The pressure must be adapted to the condition of the removal site and to the patient's bone quality.
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
The trephine drills should be cooled by sprinkling them with sterile physiological saline solution. The cooling prevents the bone tissue from heating up too much. The cooling can take place by internal and / or external cooling. The cooling must take place continuously.

⚠ **Insufficient water cooling can lead to excessive heating and, in the worst case, to irreversible damage to the bone and the adjacent tissue (thermal necrosis). Bone damage may occur at temperatures of 47°C and up. In addition, the lifespan of the products is reduced.**

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.

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,

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disinfected, and safely packaged. A certificate of hygienic safety that confirms proper reprocessing in writing must be included with returned products.
Trephine drills cannot be repaired.

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:

opt.	Optimal rotation speed	max.	Maximum rotation speed
eIFU	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	HIBC	Health Industry Bar Code
	Store in a dry place	NON STERILE	Non-sterile
UDI	Unique Device Identification	Rx Only	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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