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#### 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 screwdriver inserts are intended exclusively for screwing in and unscrewing stoma® titanium screws, micro screws or tenting screws.

For easier and faster screwing in and screwing out of bone screws in the context of implantological interventions, we have developed inserts for use with the hand-piece / contra-angle of the dental unit for use by experienced implantologists.

#### Indication

The screwdriver insert is used to screw in and screw out cross-slot screws and square head screws.

#### 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!
- Small parts, such as bone screws, screwdriver tips or other small products, can be swallowed or aspirated by patients if they fall into the mouth.

In case of misuse, all liability is excluded.



**Prior to turning in the bone screws, the use of a drill becomes necessary.**

It is up to the surgeon to decide on the use of the insert for mechanically screwing in or out screws during augmentation. The supplied insert can also be used manually in conjunction with our handle (Article No. 13389.00).

The screw driver insert has to be in straight line to the screw in order to prevent an increased risk of damage through mechanical impacts for the screw.

If the insert is used for mechanical screwing in, a hand-held screwdriver or the handle 13389.00 is recommended for the final screwing phase.

After the sensible increase of resistance during the final phase of the turning-in of the Stoma bone screw, the bone screw should be twisted in carefully in order to prevent a damage of the screw or the bone construction through mechanical forces.

#### Recommended rotation speed / torque

Rotation speed for screwing in/unscrewing the bone screws: 10 – 15 RPM (also when using the angle piece), with a torque of max. 0.030 Nm for the micro screws and tenting screws. The torque for titanium screws is max. 0.080 Nm.



**If the admitted rotation speed is not respected, this leads to an increased safety risk.**

**If the recommended rotation speed or the max. torque is not respected, this can lead to unfavorable work results**

#### 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. Before use, it must be checked if the correct fit in the angle piece is guaranteed. The instructions for use of these devices must be respected. The products should not be fixed more deeply than necessary.

#### Sorting out worn products



**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!**

#### 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<sub>2</sub>O<sub>2</sub> (hydrogen peroxide)) to prevent damage.

#### Returns, complaints and repairs

Returns are only accepted in the original packaging.

Complaints and repairs 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.

#### 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



# Instructions for use

## Contra-angle piece for screwdriver

### 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
	Article number		Lot number
	Medical device		Registration number of the manufacturer in the EUDAMED database
	CE marking and notified body		Health Industry Bar Code
	Store in a dry place		Non-sterile
	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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