Instructions for use
micro-screw Screwdriver with gripper

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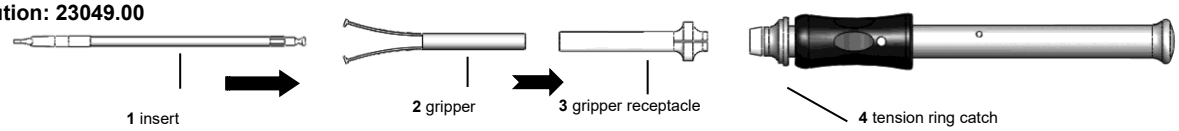


General information
Read the instructions for use carefully prior to use. The attending doctor, buyer, or user is responsible for selecting the products for the intended application and/or operational use. The attending doctor and all persons involved in the handling of the product are responsible, within 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 is intended exclusively for screwing in and unscrewing stoma® micro-screws.

Indication
The screwdriver serves to implement the stoma® micro-screws (to screw in or out). The gripper embraces the micro-screw and thus guarantees a secure hold and effortless application.

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.

Used material
Stainless steels | DIN EN ISO 7153-1
PEEK

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.

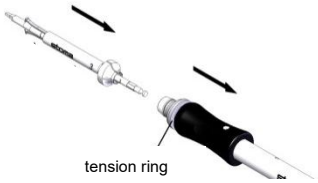
Application/handling
For optimal power transfer and to prevent damage to screws the screw-driver must be oriented to the screw in a straight line always.

Components of the screwdriver
The screwdriver consists of a handle, into which the gripper with its holder and the insert are inserted in the corresponding sequence according to the assembly instructions that follow.

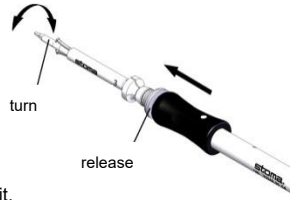
Mounting/Dismounting
1. Introduce the insert with square key (1) into the gripper (2) from the front.

2. Insert the gripper with square key again from the front into the receptacle (3).

3. Pull the tension ring (4) back and insert the mounted gripper device into the designated opening.



4. Release the tension ring and trigger the catch by slightly turning the gripper.



5. Check the unit for a firm fit.
6. To dismount: repeat 1 to 3 in reverse order

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_2O_2 (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.

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GA_0039_en_ micro-screw Screwdriver with gripper

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:

	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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