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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

By its swivel head, the stoma® swivel head blade holder serves to hold scalpel blades and to facilitate interventions at places that are difficult to access.

Indication

The stoma® swivel head blade holder has been developed to make a surgical intervention at a hardly accessible place possible. The head of the blade holder can be swiveled in all directions and thus also be used for all surgical interventions at hardly accessible locations.

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.

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

All normed standard scalpel blades, micro blades and mini-micro blades available from Stoma.

Assembly/Disassembly

- The blade is taken out of the sterile packaging by means of sterile pliers, pushed from behind forward into the rotatable metal head and fixed with an Allen key.

- Now, the rear part of the blade is broken off and disposed of.
- Please observe the insertion length of the blade for the planned application.



- Release the blade fixation and, using sterile forceps, position the blade in the swivel head so that the fracture edge is fully enclosed within the swivel head. This prevents injuries to the user, patient, and third parties caused by the fracture edge.



- The positioning and fixing of the swiveling head is done by means of a metal spindle inside the round grip.



There is a risk of cutting injuries.

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 sterilized, should be kept dry and free of dust. Already sterilized 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 H₂O₂ (hydrogen peroxide)) to prevent damage.



Instructions for use

Swivel head scalpel blade holder

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 unauthorized 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
	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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