



Article attribution: 13388.03 – 13388.06

Available diameters of the tissue punches:

Ref.no.	Inner diameter
13388.03	3 mm
13388.04	4 mm
13388.05	5 mm
13388.06	6 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/ Indication

The tissue punches according to Dr. Ady Palti are used for the targeted minimally invasive removal of gums in the field of oral implantology or periodontology.

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 rotation speed

For the use of the tissue punches in connection with an angle piece, we recommend a low rotation speed of c. 800 to 1000 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

Connections/interfaces

The tissue punches can be used in conjunction with an angle piece or manually. 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. Before approaching the object, the products must be brought up to the right rotational speed. The preparation is carried out under low pressure down to the desired depth with the rotational speed recommended below.

Pressing forces

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

The tissue punches should be cooled by spraying with sterile physiological saline solution.



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). In addition, the lifespan of the products is reduced.

Guide values for the frequency of use

Products made of non-corroding stainless steel can be used ca. 4 times, but this value can deviate from the actual standing times depending on the type of use and/or the material treated. Sometimes, the products can even be used longer as long as no wear is visible.

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.

Sorting out worn products

- Chipped and deformed cutting edges cause vibrations leading to uneven preparation edges and coarse surfaces.
- Products that are bent or do not run smoothly should be rejected promptly.



Dull and chipped products encourage excessive contact forces and thus increase the working temperature. This can cause damage to the dental pulp. Therefore, damaged products have to be discarded promptly.

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 H₂O₂ (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.

Tissue punches 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



Instructions for use

Tissue punches Dr. Ady Palti

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.



Storz am Mark GmbH
Emminger Str. 39
78576 Emmingen-Liptingen
Germany
Tel: +49 (0) 7465/9260-70
Fax: +49 (0) 7465/9260-7770
sam@stoma.de
www.stoma.de
SRN: DE-MF-000005620

