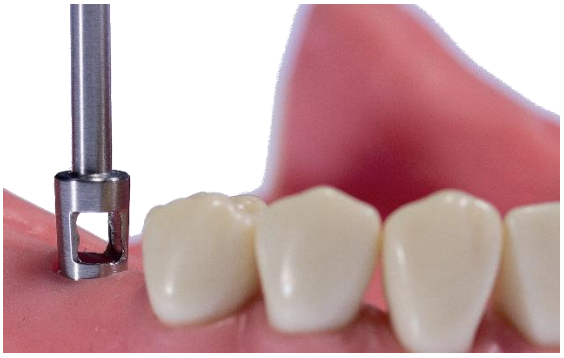
Surgical instruments

Tissue punches

Date of issue: 09.09.2013
Last revision date: 16.12.2020



**Example application*

**Example*

CONTENT

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1. User group

The instruments may only be used by appropriately qualified personnel in dental surgery or clinics.

- Maxillo-facial surgeons / dental/oral surgeons
- Dentist

2. Target patient group

Patients with dental medical indications in the area of the described indications and applications.

3. Materials / Components

- Medical grade steel instruments (corrosion-resistant steel, martensitic / CrMoV)

4. Product description

The tissue punches are used in dental surgery and offers high stability and long-lasting sharpness. The instruments are available in various diameters and show convincing quality in non-flap implantology.

5. Indication

- Tissue punches for cutting defined openings into the gingiva (soft tissue) for non-flap introduction of implants into bone material
- Biopsies of soft tissue

6. Contraindication

- The instruments may not be used for any other than the described indication or application area.
- Excessive temperatures due to insufficient water cooling must be avoided (risk of injury)
- The indicated speed may not be exceeded (risk of fracture/injury)
- The cutting edge must be checked for fractures prior to each use:
- Do not use the instrument in case of recognizable damages, visual irregularities or wear and tear of the cutting edge

7. Application mode

- Insert the instrument into the turbine/handpiece as deeply as possible. (There is a risk of injury if not inserted deeply enough!)
- Make sure that the instrument is correctly inserted and fixated in the lock of the head of the right angle handpiece (observe the instructions of the drive unit manufacturer)
- For best results observe the recommended speeds as per the attached chart
- Insert the instrument into the mouth prior to rotation to avoid risk of injury
- Instrument must be rotating before touching the gingiva (soft tissue)
- Place the instrument to the gingiva with an angle of approx. 90°

8. Speed specification

Maximum speed for tissue punches

Connection type	Instrument	Speed
CA / RA	Tissue punches (035, 040, 050)	**2‘ – 4.000 rpm**

9. Frequency benchmark for the application of rotary instruments

The following values serve as a reference only; the actual service life may differ depending on the application, usage and material but must not exceed the maximum number of reprocessing cycles.

- Tissue punches **15x**

10. Reprocessing

For reprocessing (cleaning, disinfection and sterilization) see the separate instructions for reprocessing.

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11. Storage

- Do not store instruments in plastic pouches (damaged pouches can cause contamination of the instruments)
- Store in dry conditions

12. Protective measures / Warnings

Protect yourself by wearing appropriate protective gear (gloves, goggles, mask)

13. Residual risks

Possible residual risks are fracture of working piece due to gross faulty handling or contamination due to inappropriate sterilization which may lead to harm of the patient, user or third persons.

In addition, there are the following further residual risks with regard to possible foreseeable application errors, which may result in harm to the patient:

- Incorrect use of speed (too low/too high)
- Contraindicated applications
- Applying excessive pressure

These residual risks are highly unlikely and are not expected in case of appropriate use and handling over the lifecycle of the instrument.

14. Traceability

We recommend keeping the original packaging over the entire lifetime of the instrument in order to ensure traceability via the lot number.

15. Disposal

Used and/or defective instruments need to be sterilized before disposal to avoid transmission of germs. Please be careful with sharp edges or tips.

After sterilization instruments can be discarded with general clinical waste.

16. Notification to competent authorities

Competent national authorities and the manufacturer need to be notified about all serious incidents occurring in the context of the product without delay.

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CE 0297

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17. Explanation of symbols

Pictogram	Standard / Directive	Explanation
CE 0297	EU RL 93/42/EWG (MDD)	Proof of product conformity with the mentioned European directive/regulation and the identification number of the notified body having confirmed this product conformity.
	DIN EN ISO 15223-1 (Reference number 5.1.1)	Manufacturer
	DIN EN ISO 15223-1 (Reference number 5.1.3)	Date of manufacture
	DIN EN ISO 15223-1 (Reference number 5.4.3)	Observe instructions for use
	DIN EN ISO 15223-1 (Reference number 5.3.4)	Keep dry
	DIN EN ISO 15223-1 (Reference number 5.4.4)	Caution!
REF	DIN EN ISO 15223-1 (Reference number 5.1.6)	Article number
LOT	DIN EN ISO 15223-1 (Reference number 5.1.5)	Batch code
MD	-	Medical device