EN

Rev. 12/20

Surgical instruments

PreciCut® - Soft tissue trimmer

Date of issue: 09.09.2013
Last revision date: 16.12.2020

**Examples*

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

- Instruments with medical-grade steel shank (corrosion-resistant steel shank, martensitic / CrS) and yttrium-stabilized zirconia (ZrO_2) working piece

Additional coating: gold plating

4. Product description

The Precicut® precision tissue trimmer is an efficient alternative to scalpels and electric surgery.

Contrary to conventional tissue trimmers with a round tip, the Precicut® features a sharp tip. As a consequence, a smaller cut is needed and the operating precision improves.

When using the Precicut® soft tissue trimmer only the tip made of a special ceramic consisting of yttrium-stabilized zirconia will heat up because of the tissue friction. This causes immediate tissue coagulation at the surface of the cut and thereby prevents bleeding almost entirely, provided that no water cooling is used.

5. Indication

- Cutting of oral soft tissue without or with minimal bleeding

6. Contraindication

- The instruments may not be used for any other than the described indication or application area.
- Water cooling needs to be avoided so that the blood coagulation effect of the instrument can be effective
- The indicated speed may not be exceeded (risk of fracture/injury)
- Jamming or using the instrument as a lever must be avoided (risk of fracture/injury)

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!)
- Before each use makes sure the tip of the instrument is intact.
- 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 soft tissue
- No water cooling should be used to achieve the positive effect of tissue coagulation (see contraindication).

8. Speed specification

Maximum speed for PreciCut® soft tissue trimmer

Connection type	Instrument	Speed
FG	PreciCut® - Soft tissue trimmer	**100‘ – 300.000 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.

- Ceramic instruments **20x**

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10. Reprocessing

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

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.

DFS-Diamon GmbH
Ländenstraße 1
93339 Riedenburg
Germany

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