

# Softy-longlife crown cutter

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\*Example

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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 / CrS) with sintered diamond disc as working piece

## 4. Product description

Softy-longlife crown cutters are soft-cutting sintered diamond discs for separating crowns and bridges. A major advantage of these instruments is that no cutting effect is achieved in case of accidental contact with soft tissue which prevents injury.

## 5. Indication

- Removal of dentures (crowns and bridges) from already restored teeth

## 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 (possible damage of pulp)
- 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!)
- 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 tooth or the dental material
- We recommend water cooling of min. 150ml/min as the disc diameter is larger than 3,1 mm
- Contact pressure and speed (rpm) depend on the material (tooth hardness, etc.) and the drive unit. Contact pressure and speed (rpm) are inversely related, i.e. the higher the speed the lower the pressure. Please observe the instructions for use and recommendations of the handpiece or turbine manufacturer.
- Once crown/bridge structures are cut to app. 50% the structures can easily be removed by cracking the crown.

## 8. Speed specification

### Maximum speed for Softy-longlife crown cutters

Connection type	Instrument	 Speed
RA / CA / HP	Softy-longlife crown cutters	<b>15' – 25.000 rpm</b>

## 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.

- Diamond instruments **30x**

## 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 or deformation due to gross faulty handling or contamination due to inappropriate sterilization which may lead to harm of the patient, user or third persons.

Usage of these instruments with worn-out diamonds cause no sensitization of the patient, as they are not embedded in a nickel layer.

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
- Missing / insufficient water cooling

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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## 17. Explanation of symbols

Pictogram	Standard / Directive	Explanation
	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!
	DIN EN ISO 15223-1 (Reference number 5.1.6)	Article number
	DIN EN ISO 15223-1 (Reference number 5.1.5)	Batch code
	-	Medical device