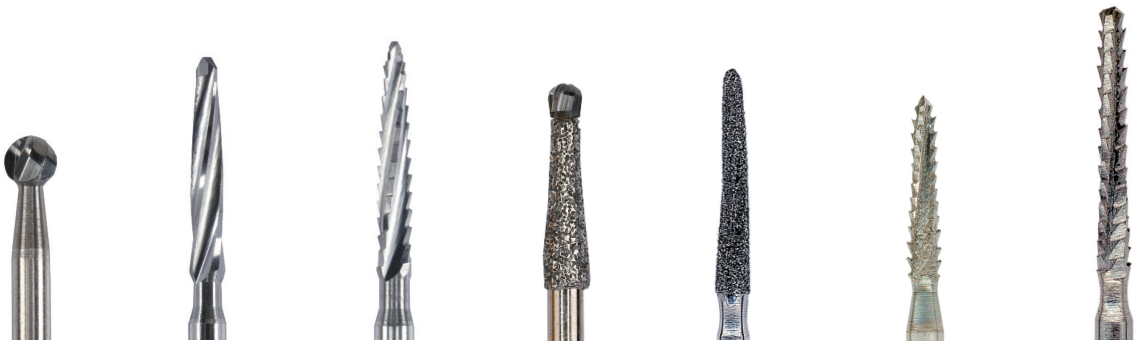

**Beispielabbildungen*

CONTENT OVERVIEW

Surgical instruments // Bone cutters (steel/carbide), ENDO

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

- Solid carbide instruments
- Carbide working piece (corrosion-resistant steel shank, martensitic / CrS)
- Medical grade steel instruments (corrosion-resistant steel, martensitic / CrMoV)
- Medical grade steel instruments (corrosion-resistant steel, martensitic / CrS) with diamond coating
  - Even two-layer coating with natural diamond

Additional coating: gold plating

4. Product description

Bone cutter (steel/carbide)

- Medical grade steel bone cutters
- Carbide bone cutters / Solid carbide bone cutters
- Allport
- Diamond coated bone cutters

Endodontic instruments

- Diamond coated carbide endo access burs

5. Indication

- Cutting of human hard tissue, i.e. bone material and teeth
- Excavation and cutting of retained teeth
- Dissections and separations in case of difficult extractions
- Root resections
- All operations which require removal/cutting of bone or teeth
  (e.g. minimally invasive preparation of bone tissue, preparation of bone tissue in the context of preparatory steps of implantation)

To be used in a turbine, right angle or straight handpiece.

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)
- Processing of soft materials must be avoided
- Contact with soft tissue must be avoided (high risk of 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 bone or tooth
- Water cooling of min. 50ml/min is compulsory for bone or tooth preparation
- We recommend water cooling of min. 150ml/min for instruments with a head diameter of 3,1mm or larger
- 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.

8. Speed specification

Maximum speed for bone cutters (steel/carbide/diamond coated) and endodontic instruments

Connection type	Instrument	↻ Speed
FG	Bone cutter, endodontic instruments	max. 100.000 rpm
CA/HP	Bone cutter	max. 30.000 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.

Bone cutters (steel/carbide/diamond coated)

- Carbide instruments **20x**
- Medical grade steel instruments **5x**

Endodontic instruments

- Diamond coated carbide instruments and FG-diamonds **20x**

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 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.

The Diamonds of the electroplated instruments are embedded into a nickel layer. Using diamond instruments whose diamond coating has already been used up or disappeared may result in an intro-oral nickel contamination resulting in possible sensitive reactions of the patient. No allergic reactions have been reported when instruments are used correctly.

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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CE 1250

17. Explanation of symbols

Pictogram	Standard / Directive	Explanation
CE 1250	**EU RL 93/42/EEC** (MDD)	Confirmation of product conformity in relation to the European directive mentioned as well as the identification number of a notified body that has 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)	Consult 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, consult accompanying documents
REF	**DIN EN ISO 15223-1** (Reference number 5.1.6)	Catalogue number
LOT	**DIN EN ISO 15223-1** (Reference number 5.1.5)	Batch code
MD	-	Reference to a medical device