

FG & CA (Diamond instruments and carbide instruments)



*Example

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FG & CA (Diamond instruments and carbide instruments)**1. User group**

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

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

2. Target patient group

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

3. Materials / Components

- Solid carbide instruments
- Instruments with carbide working piece (corrosion-resistant steel shank, martensitic / CrS)
- Medical grade steel instruments (corrosion-resistant steel, martensitic / CrS) with diamond coating
 - Even two-layer coating, Swiss Goldies with three-layer coating (natural or synthetic diamond)

Additional coating: gold plating

4. Product description**Diamond instruments**

FG/CA diamonds, FG Swiss Goldies, FG turbo grinders, FG reducers and depth markers, FG microprep, FG preparation tools with guide pin, FG for zirconia, Zirconia crown cutters, Trepanation instrument for zirconia, Perio instruments (CA)

Carbide instruments

FG / CA carbides, Finishing burs, Crown cutters, Orthodontic carbide bur

5. Indication

- Treatment of carious teeth
- Tooth preparation for prosthetic treatment
- Removal of fillings (Amalgam, composites, etc.) from already restored teeth
- Removal of denture
- Separating of teeth or denture
- Removal of residual adhesives (Orthodontic carbide bur)

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

7. Application mode

- The instruments must be inserted and locked into the chuck of the turbine / handpiece as deeply as possible. (If clamping is too short, there is a risk of injury!)
- 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
- Water cooling of min. 50ml/min is compulsory for 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.

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8. Speed specification

Maximum speed for diamond instruments

Connection type	Head diameter	Speed	Connection type	Instrument	Speed
FG	≤ 023	300.000 rpm	CA	Diamonds	150.000 rpm
FG	> 023 to 031	160.000 rpm	CA	Perio instruments	60.000 rpm
FG	> 031 to 045	120.000 rpm			
FG	> 045	90.000 rpm			

Maximum speed for carbide instruments

Connection type	Head diameter	Speed
FG	≤ 018	300.000 rpm
FG	> 018	200.000 rpm
CA	≤ 023	30.000 rpm
CA	> 023	20.000 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.

- Diamond instruments **30x**
- Carbide instruments **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.

FG & CA (Diamond instruments and carbide instruments)**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.

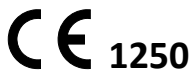
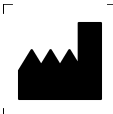









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17. Explanation of symbols

Pictogram	Standard / Directive	Explanation
	EU RL 93/42/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
	DIN EN ISO 15223-1 (Reference number 5.1.6)	Catalogue number
	DIN EN ISO 15223-1 (Reference number 5.1.5)	Batch code
	-	Reference to a medical device