

General application and safety instructions for the medical device produced by ENGINEERED ENDODONTICS.

ENGINEERED ENDODONTICS medical products must only be used by dentists, doctors and/or the respective experts who, due to their training and experience, are intensely familiar with the use of these products and who have the corresponding expertise in the respective specialist fields. The use of surgical products requires relevant expertise and experience.

- It is the sole responsibility of the doctor in charge who, depending on the respective situation (indication), decides on the actual use of the ENGINEERED ENDODONTICS products for each individual case.
- Any serious-incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- For information on possible applications of ENGINEERED ENDODONTICS products, please refer to the manufacturer's specifications (see catalogue)
- Courses providing further training on the possible uses of ENGINEERED ENDODONTICS products are organized on a regular basis. You will find relevant information about these events as well as further information on Engineered Endodontics products on the Internet at www.engineeredendo.com.
- All Engineered Endodontics products have been developed for specific applications. Therefore, inappropriate use can result in the premature wear and tear of the products and put patients and users at risk.

Warnings

The described instruction for use, in particular for pressure force, cooling, disinfection, cleaning and sterilization as well as speeds, must be observed. The instruments should only be used as intended. Failure to comply with the safety instructions may result in damage to the drive and / or injury, such as heat necrosis, undesirable tissue dissection, nerve or tissue damage or infection.

Application

- Care must be taken to use only functional, technically and hygienically flawless, maintained and cleaned turbines, straight and contra-angle handpieces.
- Rotating instruments must be clamped as low as possible and must be checked for secure seating of the product in the turbine, handpiece or angled piece before use.
- The rotating instruments may only be used with transmission instruments (e.g. handpieces, contra-angles) that are approved as medical devices and suitable for the intended purpose. The transfer instruments must have a standardized interface for rotating instruments. The manufacturer's application and safety instructions must be observed.
- The instruments must be rotating when applied on material. They should not be placed on material and then brought to rotation.
- Rotating instruments need to be clamped as far down as possible with their speed set before applying them on the object. are used with the rotary instruments.
- Using the instruments for canting or leveraging should be avoided as it increases the risk of breakage.
- Depending on the application, it is recommended to use protective goggles while using the instruments. Users of diamond disks should use a disk protection device.
- Inappropriate use of the products leads to increased risk and bad work results.
- When working with dry materials, it is recommended to use a suction cleaning device.
- In particular, users of hand tools should take care to use them gently and with consideration.
- The instruments shall only be touched with protective gloves.
- During intraoral application attention has to be made to the fact that the products are protected against aspiration or falling on the floor.

Contraindications

The products must not be used outside their intended purpose and range of indications. The specified maximum speeds must not be exceeded.

Use of Pressure

- Users of the instruments should at all times avoid applying excessive pressure. This can damage the working part of the instruments and cause the cutting edges to break off. At the same time, it generates excessive heat.
- The use of excessive pressure when using grinding tools can cause the abrasive particles to break off or the instrument to become clogged and lead to heat generation.
- Due to overheating, excess pressure can damage the dental pulp or, due to broken off cutting edges, it can result in undesired rough surfaces. In such cases, even instrument breakage cannot be excluded. Cooling
- In order to avoid excessive heat generation during preparation, a sterile water/sodium chloride solution supplied via a permanent external feeding device should be used to ensure sufficient cooling during use of the instruments.
- Insufficient cooling will lead to irreversible damage to the bone and/or the adjacent tissue.

Manufactured for:

**engineered
endodontics**

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Disinfection, Cleaning and Sterilization

- Unless there is explicit information to the contrary, all ENGINEERED ENDODONTICS products are supplied in non-sterile packaging and, depending on the application, they need to be sterilized prior to use. Prior to their first use on the patient and immediately after each use, all products need to be disinfected and sterilized. Improper cleaning and sterilization of instruments exposes the patient to an increased risk of infection.
- You will find detailed instructions for the disinfecting, cleaning and sterilizing of products in the Instructions for the processing of medical devices produced by Engineered Endodontics We would be happy to provide you with these instructions at your request. They are also available on the Internet at www.engineeredendo.com.

Speed Recommendations For Rotary Instruments

- Following the instrument-specific speed recommendations produces the best results.
- Exceeding the maximum admissible speed (RPM) when using long and pointed instruments tends to produce vibrations that can lead to the destruction of the instrument.

When using working parts with diameters exceeding the thickness of the shaft, excessive speed can release great centrifugal forces that may cause the shaft to bend and/or the instrument to break. Therefore, the maximum admissible RPM must never be exceeded.

Generally, the Following Rules Apply:

- The larger the working part of an instrument the lower the speed
- The larger the working part of an instrument the greater the force of pressure
- Instruments with a maximum speed of 300,000-450,000 rpm are suitable for micro-motor hand pieces and turbines with stable ball bearings. Not to be recommended for turbines with air bearings.
- Instruments with a maximum speed of 30,000 to 160,000 rpm are suitable for micro-motor hand pieces or technical hand pieces up to the indicated rpm. Not to be recommended for turbines.

Discarding Worn Instruments and Parts

- ENGINEERED ENDODONTICS products can principally be reused several times – unless specifically indicated and labeled otherwise. Rotating instruments are subject to wear. The option of and accountability for multiple use of a product and the frequency of application is solely the decision and own responsibility of the treating clinician based on the application in each case and the possible wear of the products. If in doubt, the products should always be sorted out early and replaced.
- Broken off cutting edges of instruments cause vibrations and great forces of pressure, which, in turn, leads to broken preparation corners and rough surfaces.
- Instruments that are bent and/or do not run true should be discarded forthwith.
- With the reuse of disposable products the risk of infection cannot be excluded and a risk-free functional safety cannot be guaranteed.

Storage

- During storage the products must be protected against dust, moisture and contamination. The maximum storage period must not be exceeded.
- Products delivered non-sterile are marked with a standardized symbol „non sterile“. If stored in accordance with regulations, the products can be stored for an unlimited period of time. For reasons of possible changes in material properties with regard to corrosion resistance or the like, as well as the topicality of product design and suitability for archiving, the storage stability is set at a maximum of 10 years.

Additional Instructions for the Use of Rotating Root Canal Instruments

Root canal instruments are only to be used for preparing and shaping the coronal part of the root canals. The mechanical extension takes place in the coronal third of the root canal and the root canal entrance. The instruments are used for the mechanical preparation of the access to the root canal entrances by completely removing the pulp wax. The use of the instruments is only permitted in the straight portion of the root canals.

Disposal

When disposing of the instruments (at the end of their service life or after the specified shelf life has expired), ensure that the product is disposed of in the waste for biological hazardous substances. All packaging components are disposed of in accordance with national regulations (e.g. Dual Waste System).

Further Comments:

- Due to legal requirements, returned goods can generally only be accepted in a sealed original packaging with the indication of the complete lot number. This can be found on the product packaging.

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Manufacturer



Manufacturing date



Item number



Batch number



Non sterile



Caution



Consult instructions for use



Medical device



Unique Device Identification



Do not use if the packaging is damaged



U.S. federal law restricts this device to sale by or on the order of a dental professional.



Cobalt, CAS: 7440-48-4, (*) Contains hazardous substances:

(*) This product contains more than 0.1% by mass of cobalt and therefore must be labelled as CMR substance class 1B (carcinogenic, mutagenic, reprotoxic) according to current regulations.

It has been demonstrated that there is no increased risk of cancer or adverse reproductive or genetic effects when used as directed.