

Safety precautions for use of Rotary Dental Instruments

Rotary instruments (medical products for dental and maxillary surgery) 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 in maxillary surgery and/or other surgical fields including diagnosis, preoperative planning and surgical techniques.

All 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. The products must not be used outside their intended purpose.

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.

Correct application

As a rule, rotary instruments are re-usable unless there is explicit proof and information to the contrary. Rotary instruments are subject to wear and tear. It is the sole responsibility of the doctor using the devices to decide on the possibility of and the justification for multiple use as well as on the frequency of use, based on the respective situation (indication) and the potential wear and tear of the products. If in doubt, it is always best to discard the products early and to replace them.

Ensure that only technically perfect, serviced and clean turbines, handpieces and contra-angles are used. The instruments must be inserted as far as possible must be checked for secure seating of the product in the turbine, handpiece or angled piece before use. The instruments must be rotating when applied on material. They should not be placed on material and then brought to rotation. Avoid wedging or levering the instruments as this increases the risk of breakage. Inappropriate use of the products leads to increased risk and bad work results.

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.

It is advisable to wear safety glasses, depending on the application.

The instruments shall only be touched with protective gloves.

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. 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.

The specified maximum speeds must not be exceeded.

Bent or non-concentric rotary instruments and instruments with fractured and incorrectly shaped blades must be disposed of. Broken off cutting edges of instruments cause vibrations and great forces of pressure, which, in turn, leads to broken preparation corners and rough surfaces.

When working with dry materials, it is recommended to use a suction cleaning device.

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.

When using FG instruments that are more than 22 mm long or whose head diameter exceeds 2 mm, additional external cooling is required.

Insufficient cooling will lead to irreversible damage to the bone and/or the adjacent tissue.

Storage, Disinfection, Cleaning and Sterilization

To avoid any damage of the instruments you should separately break open the blister packing only for taking out the instruments.

All ELA Products are supplied in non-sterile packaging. Prior to their first use on the patient and immediately after each use, they need to be cleaned, disinfected and, depending on the application, they need to be sterilised. Details about the preparation of rotating instruments are described in separate preparation instructions. These can be submitted upon request at any time and they are available under www.emil-lange.de. Inappropriate cleaning and sterilising of the instruments exposes the patient to an increased risk of infection.

During storage the products must be protected against dust, moisture and contamination. The maximum storage period must not be exceeded.

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.

Avoid contact with H₂O₂ (hydrogen peroxide). It attacks and damages tungsten carbide working parts, which curtails their service life.

Avoid sterilization temperatures exceeding 180°C. Exceeding this temperature reduces the hardness of the working parts and curtails its service life.

Rotary instruments may corrode in a thermal disinfection unit. This may cause discolouration and curtail the service life.

Recommended speeds

Maximum permissible speed has to be observed. 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. The maximum permissible speed on the packages has to be observed necessarily. Non-compliance with the maximum admissible speed puts safety at risk.

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 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.
- Surgical instruments: suitable for geared down micro-motor hand and angle pieces 10:1 with stable ball bearings. The instruments are used with physiological, possibly with sterile external cooling or internal cooling if an appropriate handpiece is used.

Warnings

The instructions for use described above, 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.

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).

Notes on Product labeling



CAS: 7440-48-4

Contains hazardous substances: Cobalt

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.

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