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SRN: LI-MF-000011937

IFUs for Surgery Burs

Basic-UDI-DI: **++E31211341CT**

Use: Reusable instruments, delivered non-sterile - reprocess before first use.

Detailed re-processing recommendations DIN EN ISO 17664 www.edenta.com

Storage: Protect packaged instruments from high temperatures and UV radiation. Store dry and clean, do not store in a room with solvents or chemicals. Storage temperature: 15°C – 25°C | Transport temperature: 10°C – 35°C.

Intended use:
For use in dentistry practice for users with appropriate qualification (dental medicine study). The surgery burs are universally suitable for various preparations in the dental surgery. These include, among others, bone milling, the uncovered tooth (and s tooth not broken through for some reason (including lack of space), and the elimination of anomalies. Surgical instruments are offered in various shapes and designs.

Description:
Surgery burs are rotating instruments with a shank made of stainless steel and a working part made of carbide or steel with toothing. The instruments are offered in different shapes, head diameters and working lengths. The shanks are designed to fit in standard dental handpieces. The shanks of the instruments are designed exclusively for use in handpieces/contra-angle and turbines in accordance with the EN ISO 14457:2017 standard.

Application:
Surgery burs for work in the dentist's practice/clinic. The surgery burs are universally suitable for various preparations in the dental surgery. These include, among others, bone milling, the uncovered tooth (and s tooth not broken through for some reason (including lack of space), and the elimination of anomalies.

Jaw surgery

Safety instructions:

- Use of the instruments only by qualified personnel (dental medical students).
- Before being used on patients for the first time and immediately after each use, the instruments must be disinfected, cleaned, dried and sterilized.
- See validated procedure below:

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B30_Medical devices critical B / Invasive use

- Surgery burs should not be sterilized using chemical agents or dry heat as these procedures have not been validated for use.
- Unfavorable instrument shapes result in incorrect preparation shapes.
- Pay attention to the working speed (RPM) - the maximum speed is stated on the product packaging. Using the instruments outside the speed range can lead to instrument breakage and injury to the patient and user. Speeds that are too high near the pulp of the tooth endanger its vitality.
- Ensure sufficient water spray cooling (min. 50ml/min) on the working part at all speeds above 1500 rpm. For instruments with a total length of >19 mm and a head diameter of >1.8 mm (ISO -018), additional external cooling is required.

- Depending on the type of preparation, work with a contact force of 0.3 – 2N.
- Blocking of the instruments due to excessive contact pressure as well as tilting and levering must be avoided (increased risk of breakage).
- The drive systems (dental handpieces) must be in perfect technical condition.
- Clamp instruments as deeply as possible in the dental handpieces and check that they are firmly seated.
- Instruments that are damaged, bent or no longer run smoothly must be sorted out immediately and no longer used.
- The use of safety glasses is recommended.

Possible side effects:
The information on instrument handling mentioned under safety instructions, especially water-spray cooling, contact force, disinfection, cleaning and sterilization, must always be observed and adhered to. The instruments may only be used for their intended purpose (application symbols). Failure to follow the safety instructions can result in injuries such as heat necrosis, tissue or nerve damage, as well as violations of the biological width or infections. Furthermore, ignoring the safety instructions can lead to damage to the instrument drive.

Storage of reprocessed instruments:
Reprocessed instruments should be stored in hygienically maintained stands, trays or other suitable containers and in the original packaging at room temperature until they are used for the first time. The same applies to sterilized instruments and those with packaging for sterilized items. Storage must be protected from dust, moisture and re-contamination.

Disposal:
For safe disposal, the instruments must be placed in break-proof, puncture-proof and leak-proof containers (contamination protection). The local, official regulations for the disposal of medical instruments must be observed!

 Contains dangerous substances

CAS 7440-48-4: Cobalt

Contains dangerous substances:
The products marked with the CAS number (CAS:7440-48-4) contain more than 0.1% by mass of cobalt, which is classified as a CMR substance of class 1B as possibly carcinogenic, mutagenic and/or toxic to reproduction. Tests show that the amounts of cobalt released by appropriately used medical devices are so low that they pose no danger and no precautionary measures need to be taken.

Serious incidents:
Notice to the user and/or patient that any serious incidents related to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Description of symbols used:

MD	Medical product		Manufacturer	2019-09	Date of manufacture
	Contents		Observe the instructions for use: www.edenta.com	REF	Order No.
ISO	ISO – Number	LOT	Lot number - for traceability	max.	Maximum permissible speed
opt.	Speed recommendation		Ultrasonic bath		Washer disinfektor
134 °C	Autoclave				

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