



Subject: Technical file according to the medical device directive 93/42/EEC

Document Name: Instructions For Use for Sterile single use Diamond Dental Burs

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'Sterile' Single Use Diamond Dental Burs
IFU - Instructions For Use

DESCRIPTION

Diamond dental burs are made of a single piece of hardened stainless steel, coated with diamonds, for dental clinic applications.

SAFETY IN USE –

Read precautions carefully:

- The device is to be used on the instruction of and by physician or licensed practitioner. **Rx only.**
- Always wear gloves when handling contaminated instruments.
- Eye protection must be worn to protect against ejected particles.
- Do not use 'sterile' labeled burs if package is opened or damaged. You may clean and sterile them according to EdgeEndo multi use Diamond Dental Burs IFU.
- Surgical masks must be worn to avoid inhalation of aerosol or dust generated.
- Ensure that the bur is securely gripped in the handpiece collet.
- Do not use worn-out burs.
- Maintain handpieces in good working order and correctly lubricated.
- Do not exceed the maximum speeds tabulated in this leaflet.
- Do not apply excessive pressure on the bur.
- Avoid removing the bur at too sharp an angle to avoid leverage and breakage.
- Move the bur continuously when in use to avoid localized heating and/or damage to the bur.
- Do not reuse. Read carefully the labels on the packaging.

5600 Wyoming Blvd. NE, Suite 100, Albuquerque, NM, 87109, USA Tel: +1
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DIAMOND BURS - guidance for maximum RPM:

Instrument head diameter 1/10 mm	Maximum permissible speed (RPM)	Recommended operational speed (RPM)
007 - 010	450,000	100,000 - 220,000
011 - 014	450,000	70,000 - 220,000
015 - 018	450,000	55,000 - 160,000
019 - 023	300,000	40,000 - 120,000
024- 027	160,000	35,000 - 110,000
028 - 031	140,000	30,000 - 95,000
032 - 040	120,000	25,000 - 75,000
041 - 054	95,000	15,000 - 60,000
055 - 070	60,000	12,000 - 40,000
080 - 100	45,000	10,000 - 20,000

CONTACT INFORMATION

EdgeEndo®
 5600 Wyoming Blvd. NE, Suite 100,
 Albuquerque, NM, 87109 USA
 Tel: +1 855-985-3636
 EdgeEndo.com

DENTEQ Medical Technologies
 Hafenstrasse 12 76344,
 Egenstien-Leopoldshafen, Germany
 Fax: +49-7247 944843

Manufactured for EdgeEndo®



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