

**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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# <u>'Sterile' Single Use Diamond Dental Burs</u> IFU - Instructions For Use

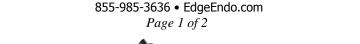
### DESCRIPTION

**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.



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## **DIAMOND BURS - guidance for maximum RPM:**

| Instrument head<br>diameter 1/10 mm | Maximum permissible<br>speed<br>(RPM) | Recommended operational<br>speed<br>(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**

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