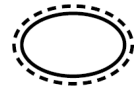


Steel Rotary Dental Bur (sterile)

Instructions for Use (IFU)

EC REP
Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



1. SCOPE

Prima Dental Steel Rotary Dental Bur (sterile) are a type of rotary cutting instrument manufactured from a single piece of heat treated carbon steel. These devices are intended to be coupled with a rotary dental handpiece which results in the rotation of the bur. These devices are supplied sterile, for single-use only. They should NOT be re-processed and/or re-used.

The bur pattern selected will be chosen to cut a specific material in a specific application. Table 1 gives guidance to the user.

Table 1: Recommended applications and operational speeds.

Application	Bur Type	Material	Head Size (mm)	Speed (RPM)
Excavation	Standard	Enamel/Dentine/Bone	010 to 023	< 2,000
Finishing Restorations	Finishing	Amalgam	012 to 023	18,000 to 30,000
Crown & Bridge Metal Trimming	Standard	Metals	018 to 027	< 30,000
Prosthetic Polymer Trimming	Standard	Polymer	018 to 027	< 20,000

2. INTENDED PURPOSE

The device is intended for use in combination with a dental rotary handpiece for a wide range of restorative procedures. The device can be used to cut/grind hard tissue such as tooth and bone or materials used in dental prostheses such as metal, plastic, porcelain and other hard materials. In line with the classification, the device is intended for transient use (i.e. Device is intended for continuous use for less than 60 minutes).

3. INDICATIONS

Indications for use are patients, both adult and children that are suffering from caries, tooth decay or those undergoing procedures for a malocclusion. Malocclusion covers the following conditions; crowded teeth, crossbite, overbite, underbite and open bite. Dental burs can also be used in the removal of crowns, fillings and other dental hardware and adhesives that may no longer be required or are causing pain and discomfort to the patient. Oral surgery burs may be utilised in those requiring endodontic procedures, implantology or traumatology.

4. CONTRAINDICATIONS

No contraindications have been identified for the device.

5. WARNINGS AND PRECAUTIONS

- Sterisafe steel dental burs are sold in a sterile condition for single-use only and should NOT be re-processed and/or re-used.
- Used burs shall be considered as contaminated and as such, appropriate precautions shall be taken during disposal.
- Suitable PPE including gloves and eye protection should be worn when using these devices.
- During use eye protection shall be worn to protect against ejected particles.
- During use surgical masks shall be worn to avoid inhalation of dust and/or dust generated.
- Never exceed the maximum speeds as indicated by the manufacturer as it may result in generation of excessive heat.
- Do not apply excessive pressure on the bur during use as this can cause excessive heat generation and/or may cause the bur to fail.
- Beware of moving parts and the risk of laceration and entrapment type injuries.
- Ensure the bur is fully seated and gripped into the collet of the handpiece prior to use.
- Prior to use inspect the bur for broken and or damaged flute and discard any defective burs.
- Proper irrigation is required while using the device. Inadequate irrigation may generate excessive heat and cause patient discomfort, necrosis or patient burns.
- Ensure handpiece(s) is in good working condition prior to conducting the procedure. Failure to use a properly maintained handpiece can lead to procedural delays, injury to the user and injury to the patient through aspiration, swallowing or damage to the preparation site due to the vibration.
- During use ensure that the bur is moved continuously to avoid excessive heat generation caused by friction.
- Never force a bur into a handpiece as this could damage both the bur and handpiece collet.
- Do not use a bur for any application other than its intended use.
- Damage to the packaging may indicate the sterile barrier has been compromised
- Prolonged duration between opening of the packaging and use of the device may impact the sterility of the device
- Device should not be used after the date of expiry identified on the device labelling.

6. INSPECTION OF BURS

Inspect the bur for any signs of damage or deterioration such as corrosion. Pay particular attention to the head of the bur for any loose material, coating abnormalities, wear, chips, flute damage, cracks or bending. Any burs found with any damage or deterioration which may cause concern should be discarded.

The labelling enables identification and traceability of the device, where identification is not possible the device(s) should be disposed of as per the instructions.

7. INSPECTION OF PACKAGING

The packaging of the device, both from the supplier and after sterilisation should be examined for damage. Damage to the packaging on receipt from the supplier should be reported to Prima Dental and the device should not be used. The labelling should enable identification and traceability of the device, where identification is not possible the device(s) should be disposed of as per the instructions herein.

8. CONTAINMENT AND TRANSPORTATION

Steel burs can be transported wet or dry, although if transported wet, there is an increased risk of staining and/or corrosion. In order to prevent damage and/or deterioration during transportation suitable protection must be used. Burs must be contained in a clean, dry and well-maintained bur block/stand or dedicated instrument tray. To minimise the risk of cross contamination, avoid storing clean and soiled burs in the same bur block/stand or instrument tray.

9. STORAGE

Storage should be in dry, clean conditions at ambient temperature.

10. DISPOSAL

Used burs are considered as biohazard and need to be discarded as bio-hazard waste in accordance with local regulations.











11. PRODUCT SHELF LIFE




With appropriate storage and handling to all unopened pouches, product sterility will be maintained for five (5) years as indicated on the labelling.

12. TRACEABILITY

Each package includes lot number **LOT** on its label. This number must be quoted in any correspondence regarding to the bur.

13. EXPLANATION OF SYMBOLS

Symbol	Explanation	Symbol	Explanation
	Batch Code		Catalogue Number
	Manufacturer	Prima Dental Manufacturing Ltd. Gemba House, Stephenson Drive, Gloucester, GL2 2HA, United Kingdom	
	Sterilised Using Irradiation		Consult Instructions for Use
	Do Not Re-use		Single Sterile Barrier System with Protective Packaging Outside
	Date of Manufacture	Rx ONLY	Device for Professional Use Only (US FDA)
	Caution		Do Not Use if Packaging is Damaged

Symbol	Explanation	Symbol	Explanation
	Medical Device		EU Authorised Representative
	Use-by Date		

14. CONTACT US

For further support, please contact us quoting the LOT number printed on the device label:

Phone: +44 1452 729751

Email: sales@primadental.com

DOC: IFU-44

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