



Be sure to read the instruction before use.



Non Sterile

**Intended use**

These products are made of stainless steel coated with small diamond crystals. It is a rotary cutting device designed to fit a dental handpiece and used to cut hard structures in the mouth. It can also be used to cut hard metals, plastics, porcelain and similar materials.

Produced for all kinds of carving and cutting operations which are used by dentists during medical treatments. Area of application

These general instructions for use and safety recommendations apply to all products and have to be generally observed. Nonobservance of these instructions for use and safety recommendations increases the risk of injury and may impair the proper function of the instruments.

Separate locations of use are available on our web site [www.bosphorus.com.tr](http://www.bosphorus.com.tr) for products that require more detailed information.

These take precedence over the general instructions.

**Packaging**

Packing in a box: 5 pcs

**Possible Combinations with the Dental Handpiece**

Use a dental handpiece that will ensure full grip of the shaft. (Friction shaft shank diameter is 1.60mm, Contra Angle shaft diameter is 2.35mm.) Use a handpiece that can be controlled at the allowable engine speed.

**Contraindications and Prohibitions**

Do not use this product for a patient with sensitization or allergic reaction.

For professional use only. Use it for its intended use.

**Indications**

**1. Proper use**

- The instruments have to be prepared prior to first use.
- Make sure that only technically and hygienically perfect and cleaned power systems (hand pieces and contra-angles) are used.
- Depending on their shank type, insert the instrument into the chuck as deeply as possible. Make sure that they are properly locked.
- The instrument must be rotating at the desired speed before contact is made with the tissue or material.
- Avoid jamming and using the instrument as a lever. Excessive contact pressure has to be avoided.
- For eye protection wear safety glasses. Use appropriate respiratory protection (mouth and nose). In the dental laboratory, use appropriate suction unit.
- Avoid contact with the instruments' working parts as this may increase the risk of injury.

Make sure to provide sufficient cooling by means of air/water spray. Additional external cooling is required when using instruments with extra-long shanks or oversized working parts. Damaged or corroded instruments have to be discarded.

**2. Recommended speeds**

HEAD DIAMETER(ISO Ø (1/10 mm))	FG(Max. RPM)	HP(Max. RPM)
007-014	300,000	160,000
016-023	280,000	120,000
025-045	180,000	100,000
047-065	80,000	80,000
066-093	60,000	50,000

For optimum results when using Bosphorus branded burs, 50% of the maximum speed should be used...

**3. Contact pressure**

Excessive contact pressure (> 2N) has to be avoided.

- In cutting instruments, this can lead to damage to the working part and to chips of the diamond as well as an excessive generation of heat.

**4. Number of times rotary instruments reprocessing and shelf life**

Diamond dental burs: - Recommended reprocessing Max 15 x

The recommended shelf life of diamond dental burs is 10 years.

**5. Reprocessing (cleaning disinfection, and sterilisation)**



Those instruments that are supplied non-sterile have to be prepared prior to first use.

**Limitations on reprocessing**

The service life of tools is not unlimited. The service life of instruments is normally determined by wear and tear from their intended surgical use, not by their rework. Instruments should be meticulously inspected prior to each use to ensure they are fully functional.

**Required materials and equipment:**

Washers-Disinfectors (WDs) according to ISO 15883-Cleaning Detergents Detergents with a pH between 7-10 are recommended; The maximum pH should be 12.



**Caution**

Avoid any contact with H2O2 (hydrogen peroxide). Make sure that the specified immersion times in the cleaning and disinfecting agents are not exceeded.

**5.1. Manual cleaning and disinfections**

Bu işlem sırasında frezlerin birbiriyile temas etmemesine dikkat edin.

**Pre-Cleaning**

1. Rinse the contaminated device under cold running tap water for at least three minutes. Use a soft brush to help remove most dirt and debris.

**Manual cleaning**

2. Immerse the device in an alkali cleaner or detergent solution for at least 10 minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for the correct exposure time, temperature, water quality, and degree of concentration.

3. Manually clean the device until no residue is visible on its surface. Use a soft brush to remove dirt and debris. If applicable, activate joints and all other movable device features to expose all areas to the detergent solution.

4. Prepare an ultrasonic bath with a fresh detergent solution using an enzymatic cleaner or detergent at the concentration and temperature specified in the detergent manufacturer's instructions.

5. Ultrasonically clean instruments using a minimum frequency of 30 kHz for at least 10 minutes.

6. Visually check the device. Repeat steps 2-5 until no visible residue remains on the device.

**Manual disinfection:**

6. Immerse the device in an enzymatic cleaner/ disinfection solution for at least 15 minutes. Follow the manufacturer's directions for use for the correct exposure time, temperature, water quality, and degree of concentration.

7. Rinse the device thoroughly in purified water for at least two minutes.

8. Dry the instruments.

**5.2. Automatic cleaning / disinfection**

When automatic cleaning is required for highly contaminated medical devices, it is recommended to perform a pre-cleaning procedure similar to the manual cleaning method in addition to the ultrasonic bath.

**Minimum program parameters :**

1. Pre-rinse with cold tap water for at least 3 minutes
2. Main wash at least 2 minutes below 40°C. add detergent
3. Washing with detergent at 55°C for at least 5 minutes
4. Pre-rinse for at least 1 minute with tap water above 40°C
5. Rinsing with cold demineralized water for at least 1 minute

**5.3 Drying**

Dry the burs with paper towels or using dry heat not exceeding 140°C.

**5.4 Control**

After each cleaning/disinfection, the products must be completely free of visible residues and other contaminants. After cleaning, inspect the burs, preferably with a magnifying glass. If necessary, the cleaning process should be repeated until the product is visually clean.

Function: Before each use, it should be checked for cracks, cracks, deformation, corrosion and proper function.

**5.5 Packaging and labeling**

After reprocessing, pack products in a sterilization pack or equivalent container as soon as possible in accordance with ISO11607 and label the packaging appropriately in accordance with ISO 15223-1.

**5.6. Sterilization**

Sterilization should be carried out in accordance with ISO 17665 and in approved steam sterilizers maintained in required conditions.

- We recommend using the following steam sterilization parameters
- Minimum holding time of 5 minutes at 134°C



**Caution:** Operative burs must be sterilized **before each use** to avoid potential transfer of infectious organisms.

**Storage**

Tools should be stored in a clean, dry environment protected from direct sunlight, germs/insects, extreme temperatures and humidity. Instruments in their original packaging, away from light and heat in a clean and dry environment. Do not store in the same room as solvents or chemicals. Do not damage the packaging material. The product is subject to improvement/change without notice. For this reason, it is recommended to use the first purchased products first.



**7. Potential effects of using worn instruments**

- Discard any instruments with damaged or worn working parts as the use of damaged or worn instruments would have a negative effect on the work result.
- Damaged and deformed burs will cause the instrument to vibrate and lead to poor preparation margins and rough surfaces.
- Please avoid excessive contact pressure during use as this may result in damage to the working part (Nicks on the blades, premature blunting and excessive heat generation).
- To avoid undesirable heat generation during preparation, make sure to provide sufficient cooling by means of air/water spray (at least 50 ml/min).
- Additional external cooling is required when using instruments with a total length of more than 22 mm or a head diameter exceeding 2,5 mm.
- Not observing the maximum permissible speed will result in an increased risk of injury.
- There is an increased risk of infection in reusable instruments which have not been properly reprocessed.

**8. Safety and possible side effects**

The above mentioned recommendations with respect to cooling, contact pressure, disinfection, cleaning and sterilization are to be strictly observed. The instruments should only be used for the intended application, as per the symbolic identification.

Non-observance of these safety recommendations may lead to damage of the power system and/or injury, such as thermal necrosis, undesired preparation of tissue, damage to tissue or nerves, violation of the biological width, or infections. During preparation, some instruments may generate metallic abrasion which may lead to the presence of artifacts in MRI diagnostics.

**9. Liability**

It is the responsibility of the user to check the products prior to use to ensure that they are suited for the intended purpose. In case of contributory negligence by the user, Bosphorus partially or totally declines liability for all resulting damages, particularly if these are due to non-observance of our recommendations for use or warnings as well as inadvertent misuse by the user.

Store products out of children's reach.

For dental use only



Any serious adverse event occurring during use and/or life cycle of the device should be reported to the manufacturer, notified body and the local component authority.



Dispose of as contaminated medical waste.

**Symbols of Label:**

	5.7.7 Medical device
	5.7.10 Unique device identifier
	5.1.1 Manufacturer
	5.1.6 Catalogue Number
	5.1.5 BATCH CODE
	5.1.3 Date of manufacture
	5.1.11 Country of manufacture
	5.4.3 Consult Instructions For Use
	Electronic Instructions For Use
	5.4.4 CAUTION
	5.2.7 Non-Sterile
	5.3.1 Fragile, handle with care
	5.3.4 Keep dry
	5.3.2 Keep away from sunlight
	5.2.8 Do not use if package is damaged and consult instructions for use
<b>ISO NO</b>	According to EN ISO 6360-1,2,3,5,6,7
<b>TYPE</b>	Defines type of operative burs

**TEK METAL SAN. VE TIC. A.S.**  
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San.Sit C-2 Blok No:209 İkitelli-  
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**DENTAL DIAMOND BURS  
USER MANUAL**



**Model Information: Reference**

[www.bosphorus.com.tr](http://www.bosphorus.com.tr)

**MILLING MODELS AND APPLICATIONS**

No	Product Model	Product Images	Length Measure	Colour	Prophylaxis	Crowns Preparations (cutting)	Old Fill Removal (carving)	Crowns and Bridge Technique (cutting)	Model Casting Technique (cutting-claving)	Cavity Preparations (carving)	Mouth Surgery (cutting)	Acrylic Technique (carving)	Tooth Orthopedic (cutting)	Model Making (cutting)	
1	Mumalev		Standard short L XL	Green Black Yellow Blue Red	X	X		X	X						
2	Cylinder				X	X	X	X		X	X				
3	Topbaş				X	X	X	X		X	X	X	X		
4	Reverse Tapered				X		X	X	X	X					
5	Torpedo					X						X			
6	Conical				X	X	X					X			
7	Needle				X	X			X	X					X
8	Egg				X	X	X	X	X	X					
9	Wheel							X				X			

