

Product Name: MANI DIA-BURS





The instruction for use can be additionally requested.

Before using MANI DIA-BURS, please see the following instruction manual.

[Contraindications and prohibitions]

Do not use in patients who are sensitive or allergic to this product.

Do not use the product unsterilized.

(Intended user)

This product shall be used only by dentists who are familiar with dental techniques.

[Target patient group]

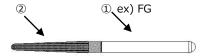
All patients receiving dental treatment.

[Clinical benefits]

It contributes to the removal/shaping of natural teeth affected by caries and to the grinding/polishing and removal of prostheses in dental treatment.

(Shape and materials)

- ① Shank (Metal base)(FG, CA): Stainless steel
- Working part: Fine diamond crystals attached to metal base



[Intended use or effects]

Rotary grinding instruments having a steel working component coated with minute diamond crystals, attached to a dental handpiece, and used to grind such hard tissues as teeth and bones. They can also be used to grind metal, plastic, porcelain, and other similar materials.

[Instructions for use]

Select an optimal product number according to the intended use, and use it to grind teeth, etc.

Dental handpiece capable of combination use

- Use a dental handpiece that can accurately hold the shank of this product. (Diameter of friction grip shank: φ 1.6 mm, Diameter of contra angle shank: φ 2.35 mm)
- 2. Use a dental handpiece that can control the allowable rotation speed.
- 3. The water injection function must be installed.

[Precautions for use]

- Sterilize by autoclaving to prevent infection, and confirm that the product is sterilized before use.
- 2. Use the product with great care not to puncture fingers, etc. due to having a sharp blade.
- If the rotation speed exceeds the allowable one, it may break and cause injury. Thus, strictly observe the allowable rotation speed, and use it with "feather touch." (※1)
- 4. Use this product while cooling its working component and

- the grinding object by injecting water.
- 5. Completely insert the shank of this product as instructed by the dental handpiece manufacturer, and confirm that it is not halfway chucking.
- 6. Strictly observe the instructions for use when handling the dental handpiece that is to be connected to this product.
- Use protective glasses, etc. to prevent eye damage. Wear a dust mask during operation to prevent sucking dust generated during operation.
- 8. Perform preliminary operation (rotation) outside the oral cavity before use, and confirm that there is no swaying.
- Before and after use, check the product for deformation, scratch, crack, etc. outside the patient's mouth, and if any scratch or damage is found on the product or if the cutting performance is decreased, replace and discard the product.
- If the head is slim, long, or large, avoid using the product at an excessive angle or under increased pressure that may cause breaking or bending.
- 11. Use a rubber dam or gauze screen to prevent accidental ingestion/aspiration. For patients with a high risk of accidental ingestion/aspiration, the sitting position shall be used for treatment as much as possible, avoiding the horizontal position.
- 12. When reusing, completely remove adhered foreign matters by washing and sterilize by autoclaving.
- 13. Long-time immersion in a corrosive solution such as EDTA and sodium hypochlorite may cause corrosion; thus, attention should be paid to such solution.
- 14. Do not use the product if the packaging is damaged.
- (%1) Since the allowable rotation speed varies depending on each form, the package label should be checked.

[Cleaning method (including treatment before sterilization)]

- After use, immediately perform cleaning by the following procedure to prevent drying and solidification of blood, body tissues, etc. adhered to the product.
- Immerse in medical detergent (enzymatic). The concentration, temperature, immersion time, etc. should be according to the instruction manual of the detergent.
- Remove foreign matters such as blood and body tissues by using a brush, and carefully clean the areas where it is difficult for the brush to reach. (Rub with a brush while immersed in medical detergent.)
- 4. Clean by ultrasonic with medical detergent (enzyme system). The cleaning time, etc. should be according to the instruction manual of the medical detergent.
- When performing ultrasonic cleaning, hold it on a stand, etc. so that the working components of products do not touch each other.
- 6. Thoroughly rinse off the medical detergent.
- 7. Check visually whether there remain any adhered substances such as blood and body tissues, etc. If any

adhered substance is found, repeat the above procedure from ${\bf 1}$ to ${\bf 4}$.

8. Dry the product. (Air blow, etc.)

(Sterilization method)

- 1. Before use, clean and sterilize by the following method.
- 2. Sterilization method: Put it in a sterilization tray or stand, and place it in a sterilization pack (or foil) to autoclave under either of the following conditions:

Sterilization conditions

Condition (1) Temperature = 121°C, time = not less than 20 min

Condition (2) Temperature = 126°C, time = not less than 15 min

Condition (3) Temperature = 134°C, time = not less than 3.5 min

When performing the drying process, dry at 175°C or lower for less than 30 min.

[Disposal]

- 1. Carefully handle when disposing of this product due to having a sharp blade.
- 2. This product should be discarded appropriately as medical waste.

[Notification of serious incidents]

All serious incidents occurred in connection with the instruments shall be reported to the manufacturer and the regulatory authorities of the Member States where the user and/or patient resides.

[Manufacturer's name and address]

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