



The instruction for use can be additionally requested.

Before using MANI H-FILES, 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]

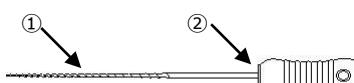
All patients receiving dental treatment.

[Clinical benefits]

It contributes to the pulpectomy or penetration/enlargement of the root canal in dental treatment.

[Shape and materials]

- ① Working part: Stainless steel
- ② Handle: Polybutylene terephthalate(PBT)

**[Intended use or effects]**

Hand dental instruments to enlarge the root canal and to smooth the root canal wall by cutting/polishing with vertical reciprocating motion or plucking motion.

[Instructions for use]

Select instruments with an optimal size according to the intended use, and use it to debride or to enlarge and smooth the root canal wall by penetrating, cutting, and polishing with vertical reciprocating motion or lifting motion.

[Precautions for use]

1. 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.
3. Use protective glasses, etc. to prevent eye damage. Wear a dust mask during operation to prevent sucking dust generated during operation.
4. 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.
5. If the head is slim, long, or large, avoid using the product at an unreasonable angle or under excessive pressure that may cause breaking or bending.
6. Attach a chain, thread, etc. to the opening hole of the handle to prevent fall into the oral cavity.
7. 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.

8. When reusing, completely remove adhered foreign matters by washing and sterilize by autoclaving.
9. Long-time immersion in a corrosive solution such as EDTA and sodium hypochlorite may cause corrosion; thus, attention should be paid to such solution.
10. Do not store the product under a germicidal lamp to avoid degradation.
11. Do not use the product if the packaging is damaged.

[Cleaning method (including treatment before sterilization)]

1. After use, immediately perform cleaning by the following procedure to prevent drying and solidification of blood, body tissues, etc. adhered to the product.
2. Immerse in medical detergent (enzymatic). The concentration, temperature, immersion time, etc. should be according to the instruction manual of the detergent.
3. 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.
5. 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 1 to 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

3. 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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