Product Name : MANI® NiTi FILES

CE 0197

Do not use if package is damaged

The contents of this instruction manual are subject to be revised without notices.

Before using the MANI® NiTi FILES, please see the instruction manual as indicated below.

【Contraindications and prohibitions】

Do not use this product for a patient who indicates sensitization and allergic reaction.
Do not use unsterilized.

【Intended user】

Only qualified dentists are allowed to use these instruments.

【Target patient group】

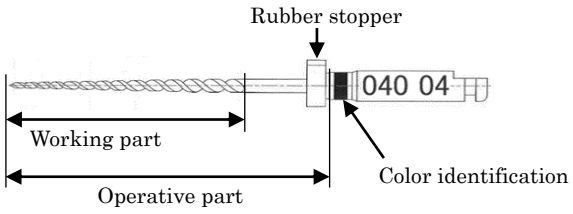
All patients who need a root canal treatment.

【Clinical efficacy】

Improvement, recovery and alleviation of medical conditions according to the root canal treatment.

【Descriptions】

There are two types of MANI® NiTi FILES, JIZAI and JIZAI GLIDER. *
Shape drawing (typical example)



Raw materials : Nickel titanium alloy（CMR: Nickel containing）

【About CMR】

CMR materials are included in nickel titanium alloys. However, according to this product quality and material, there is no affected treatment by it.

【Intended use】

This product is for enlarging root canal and making smooth and flat root canal wall through grinding and polishing. It is produced by the movements of vertical reciprocation and lifting. Also, it is a dental instrument which is used by connecting to an active device.

【Directions for use】

Usage preparations

1. Check that the product has been sterilized and dried.
2. Select an appropriate diameter and taper according to the intended use.
3. Attach instrument shank to contra-angle handpiece.

Usage instructions

1. Make root canal cutting, polishing and enlarging and enlarging by this product.
2. If root canal treatment has already been performed, remove the filling material and perform root canal preparation again.

After use

1. Remove the instrument from contra-angle handpiece.
2. Wash the instrument after removing foreign substances.
3. Sterilize and dry the instrument.

Possible combinations with active device

1. Use the active device which can hold the shank of this instrument precisely.
   (contra-angle handpiece)
2. Use the active device which could control at allowable engine speed.
3. Use the active device which could control at allowable torque settings.

Allowable engine speed and torque settings*

1. JIZAI
   Allowable engine speed: 500min^{-1} or less
   Allowable torque settings : 3.0N・cm or less

2. JIZAI GLIDER*
   Allowable engine speed: 300min^{-1} or less
   Allowable torque settings : 1.0N・cm or less

【Precautions for use】

1. Wear safety glasses to protect your eyes from damage. Also, wear a dust protective mask to prevent inhaling dust.
2. Attach rubber dam etc. to avoid accidental ingestion and falling.
3. According to the manufacturer's instructions for active device, insert the shank into the chuck of the active device and check if it is securely attached.
4. Make sure before use that there is no extreme bending, and make a preliminary rotation outside the oral cavity to confirm that there is no shake. If there is any abnormality, dispose the instrument.
5. Confirm enough the length of working part by X-ray.
6. Keep the allowable engine speed strictly as over speed can cause injury or root damage due the fracture.
7. When make root canal enlargement by this instrument, use the hand files to secure glide path constantly.

8. If this product is rotated at a certain part for a long time the risk of the tissue damage due to heat influence, risk of the fracture, etc. may be increased.
9. When reuse this product, check it for signs of damage and deterioration before using it, as excessive use may cause a breakage.
10. If the instrument is scratched, damaged or if the cutting ability is reduced, replace it and dispose it.
11. Note that this instrument may be corroded if it is immersed in a corrosive solution such as EDTA solution or sodium hypochlorite for a long time.
12. When reuse, completely remove foreign substances and sterilize by high pressure steam.

【Cleaning method】

After using, wash this instrument to remove foreign substances like blood and body tissues by below protocol.

1. Soak in medical detergent (enzyme system). Follow the instruction manual for the detergent concentration, temperature, immersion time, etc.
2. Use a brush for manual cleaning, remove foreign substances such as blood and tissue, and carefully perform the cleaning in areas where the brush cannot reach. (Rubbing with a brush while soaking in a medical detergent)
3. Clean by ultrasonic cleaner using a medical detergent (enzyme system). Follow the instruction manual of the medical detergent for the time, etc.
4. Wash away the medical detergent completely.
5. Visually check if there are no deposits such as blood or body tissue. If such deposits are confirmed, repeat steps from 1 to 4.
6. Dry the Instrument. (Air blow, etc.)

【Sterilization method】

Wash before use and sterilize by the following method.

1. Place in a sterilization tray or stand, etc., and then put in a sterilization pack or sterilization foil and perform high-pressure steam sterilization under any of the following conditions.

Sterilization conditions

Condition (1) Treatment temperature:
121 ° C Time: 20 minutes or more

Condition (2) Treatment temperature:
126 ° C Time: 15 minutes or more

Condition (3) Treatment temperature:
134 ° C Time: 3.0-3.5 minutes

2. When performing a drying process, dry at 175 ° C or less for less than 30 minutes.

【Storage method】

1. Store at room temperature avoiding high temperature, high humidity, direct sunlight and water.
2. Avoid storage under germicidal light as the instrument may be deteriorated.

【Disposal method】

1. Because this instrument has a sharp blade handle it with care when dispose.
2. This product must be properly disposed as medical waste.

【Notification of serious accident】

All serious accidents related to this instrument should be reported to the manufacturer and to the regulatory authorities of the Member State in which the user and / or patient resides.

【Manufacturer's name and address】

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【EU representative's name and address】

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E-mail:mail@obelis.net

※Always keep this document near at hand. In case of loss, please contact the manufacturer by the above contact information.

※The specifications, structures and materials of this instrument maybe changed without notices for the demands of improvement.

※ *marks indicate revised points.*