

Product Name: MANI GATES DRILLS



READ THE INSTRUCTION BEFORE USE

NON STERILE

Before using the MANI GATES DRILLS, please see the instruction manual as indicated below.

<Warnings>

- . Only skilled dentists are allowed to use
- 2. Be sure to sterilize this product for each use.
- 3. Do not use this product except for the dental service and treatment.

 Use it in accordance with the intended use.

<Contraindications and prohibitions>

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

<Structures and principals>

- This product is used by connecting to active device and rotates to enlarge root canal orifice. It is the dental drill with stainless steel shank. It is non-sterile instrument.
- 2. Main materials
 - 1) Cutting part: Stainless steel (including nickel and chromium)
 - 2) Shank: Stainless steel (including nickel and chromium)



<Purpose of use and effect-efficacy>

This instrument gains access to the root canal and enlarges root canal orifice. This is a dental instrument which is used by connecting to an active device.

<Specifications>

Under the provisions of ISO 3630 performance test, products' durability for twisting must exceed specified value of our standard.

<Method of manipulating or method of use>

According to its intended use, choose the most appropriate MANI GATES DRILLS and use it for enlarging root canal orifice.

Possible Combinations with active device

- Use the active device which can hold the shank precisely. (Diameter of Contra Angle shank : \$\phi\$ 2.35mm)**
- 2. Use the active device which could control at allowable engine speed.

<Pre><Pre>cautions for use>

- $1. \qquad \hbox{To prevent infection, sterilize the product by autoclave and make sure sterilization is completed before using.}$
- 2. Keep the allowable engine speed strictly as over speed could cause fractures and injury (%1)
- 3. Follow the instructions of active device manufacturer strictly and insert the shank all the way to avoid its half-way chucking.
- 4. The active device should be used in accordance with its instructions.
- Choose the most appropriate type for each case and follow the general method.
- 6. Before using, run the instruments outside of oral cavity to make sure that there is no distortion.
- Before using, make sure the instruments outside of oral cavity that there are no deformations, scratches and cracks.
- If the head of product is thin, long or large, there are possibilities for breaking or twisting. Because of this, be sure to avoid using unreasonable angle and excessive pressure.
- 9. Wear safety glasses to protect your eyes from damage. Also, wear a dust protective mask to prevent inhaling dust.
- 10. Wear rubber dam etc. to avoid accidental ingestion and falling.
- Do not use this instrument for any purposes except for listed applications above.
- 12. Only for use by dentists.
- 13. This product should be treated as medical waste when disposed.
- 14. Dispose the product if damaged or contaminated.

- After using, wash it with medical cleaning agent and brush, then wash away foreign substances like adherent body fluids and body tissues completely.
- Set the product to a stand when cleaned by ultrasonic cleaner to avoid working part deterioration.
- Use this product with great care to avoid puncturing fingers because of its possession of sharp-edged part. (%1)Allowable engine speed: MAX 800min⁻¹.**
- This product has possibility that be corrosive if sunk into NAOCL, EDTA and etc. for a long time.**

<Storages and duration of use>

- Avoid storing at high temperature, humidity and direct sunlight. Keep liquids away. Store it at room temperature.
- 2. Do not damage or make a pinhole to packaging materials.
- 3. The product is subject to be improved without previous notice. Enforce the first-in first-out method for stock management.
- Do not store the product under a germicidal lamp to avoid deterioration.

<Maintenances and inspections>

 Sterilize this product by autoclave under established method and term for each use.**

Method of sterilization:

Put this product in a sterilization pack(or foil) and place it on a sterilization tray, or files stand for autoclave sterilization with reference to the following terms .**

Terms for sterilization:

 $\begin{array}{ll} term(1) \ temperature: \ 121 degrees \ Celsius & time: \ 20 \ minutes \ or \ more \\ term(2) \ temperature: \ 126 degrees \ Celsius & time: \ 15 \ minutes \ or \ more \end{array}$

- Do not use high pressure steam sterilizer which heats more than 200 degrees Celsius including drying process.
- 3. Dispose the product if damaged or decreased in performance.
- Regarding use of medical cleaning agent, follow the instruction manual by its manufacturer strictly.
- 5. Dispose the products if damaged or decreased performance.

<Packagings>

- 1. Minimum packaging unit: 6 pcs. per package (#1~#6)
- 2. Assortment: 1pc. each \times 6= 6pcs. per package
- 3. Special packaging : quantity is listed on the package label.**

<Legal manufacturer >

MANI, INC

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- * Always keep this document near at hand. In case of loss, please contact dental department of the manufacturer for a copy.
- * The specifications, structures and materials are subject to be changed without previous notices for the demands of improvement.
- The contents of this instruction manual are subject to be revised without previous notices.
- * and ** mark indicate revised point.