

# 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 : φ 2.35mm)\*\*
- 2. Use the active device which could control at allowable engine speed.

### <Pre><Pre>cautions for use>

- To prevent infection, sterilize the product by autoclave and make sure sterilization is completed before using.
- 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<sup>-1</sup>.\*\*
- 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.
- $3. \hspace{0.5cm} \hbox{Dispose the product if damaged or decreased in performance}.$
- Regarding use of medical cleaning agent, follow the instruction manual by its manufacturer strictly.
- $5. \hspace{0.5cm} \hbox{Dispose the products if damaged or decreased performance}.$

## <Packagings>

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

### <Legal manufacturer >

MANI, INC

 $8 \hbox{-} 3$  KIYOHARA INDUSTRIAL PARK, UTSUNOMIYA, TOCHIGI,  $321 \hbox{-} 3231, \mathrm{JAPAN}$ 

inquiry and reference: dental department phone: +81-28-667-8592  $\,$  fax: +81-28-667-8596

# $\leq$ EU representative >

Obelis s.a. \*

Bd. Général Wahis 53, 1030 Brussels, Belgium

- \*\* 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.