



## Product Name : MANI ENGINE H-FILES



READ THE INSTRUCTION BEFORE USE

NON STERILE

Before using the MANI ENGINE H-FILES, please see the instruction manual as indicated below.

### <Warnings>

1. 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>

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

### <Structures and principals>

1. This product is used by connecting to active device and rotates to enlarge root canal. It is produced by the movement of vertical reciprocation and lifting. It is the engine driven file with stainless steel shank and non-sterile instrument.
2. Main materials
  - 1) Working part : Stainless steel (including nickel and chromium)
  - 2) Shank : Stainless steel (including nickel and chromium)



### <Purpose of use and effect-efficacy>

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. This is a dental instrument which is used by connecting to medical active device.

### <Specifications>

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

### <Method of manipulating or method of use>

According to its intended use, choose the most appropriate MANI ENGINE H-FILES and use it for enlarging and cleaning root canal.

### Possible Combinations with active device

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

### <Precautions for use>

1. 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. (※2)
4. The active device should be used in accordance with its instructions..
5. 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.
7. Before using, make sure the instruments outside of oral cavity that there are no deformations, scratches and cracks.
8. 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.
11. 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.
15. After using, wash it with medical cleaning agent and brush, then wash away foreign substances like adherent body fluids and body tissues completely.
16. Set the product to a stand when cleaned by ultrasonic cleaner to avoid working part deterioration.

17. Use this product with great care to avoid puncturing fingers because of its possession of sharp-edged part.  
(※1)Allowable engine speed: less than 800min<sup>-1</sup>.\*\*  
(※2)MANI ENGINE H-FILES are used by connecting with contra head by vertical reciprocation movement.
18. This product has possibility that be corrosive if sunk into NAOCL, EDTA and etc. for a long time.\*\*

### <Storages and duration of use>

1. 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.
4. Do not store the product under a germicidal lamp to avoid deterioration.

### <Maintenances and inspections>

1. 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:  
term(1) temperature: 121degrees Celsius time: 20 minutes or more  
term(2) temperature: 126degrees Celsius time: 15 minutes or more
2. 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.
4. 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 (#10~#80)
2. Assortment: 1pc. each ×6= 6pcs. per package (#15~#40, #45~#80)

### <Legal manufacturer >

MANI, INC.  
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### <EU representative >

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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.