



## Product Name : MANI MICRO FILES TYPE U



READ THE INSTRUCTION BEFORE USE

NON STERILE

Before using the MANI MICRO FILES TYPE U, please see the instruction manual as indicated below.

### <Warnings>

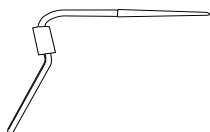
1. Only skilled dentists are allowed to use.
2. Be sure to sterilize this product for each use.
3. Do not use this product except for the dental service and treatment. Use it in accordance with the intended use.

### <Contraindications and prohibitions>

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

### <Structures and principals>

1. This is the dental file used with active medical instruments (multipurpose ultrasonic scalers) for enlarging root canal. It is used by the movements of lifting and vertical reciprocation. It is non-sterile instrument.
2. Main materials
  - 1) Metal base: Stainless steel (including nickel and chromium)
  - 2) Shank: Stainless steel (including nickel and chromium)
  - 3) Cutting part :  
TYPE UD : Diamond is attached to metal base.  
TYPE UE : Stainless steel



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

This is the dental instrument used with active medical instruments for enlarging root canal and making smooth and flat root canal wall through grinding and polishing. It is used by the movements of vertical reciprocation, ultrasonic oscillation or lifting movement.

### <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 MICRO FILES TYPE U with active medical device(multipurpose ultrasonic scaler) and use it for enlarging root canal.

### Requirements for active medical device(multipurpose ultrasonic scaler)

1. Use active medical device which could hold the shank correctly. (MANI MICRO FILES TYPE U shank diameter :  $\phi$  0.8mm)
2. Active medical device should equip power-adjustment knob.

### <Precautions for use>

1. To prevent infection, sterilize the product by autoclave and make sure sterilization is completed before using.
2. Insert the shank correctly in accordance with the instruction of active medical device (multipurpose ultrasonic scaler) manufacturers. Make sure that there is no half chucking.
3. Use this product with active medical device(multipurpose ultrasonic scaler) in accordance with its instruction for use.
4. Choose the most appropriate type for each case and follow the general method.
5. Before using, rotate the product in advance to ensure it has not been bent or deformed.
6. Before using, make sure the instrument outside of oral cavity that there are no deformations, scratches and cracks.
7. 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.
8. Wear safety glasses to protect your eyes from damage. Also, wear a dust protective mask to prevent inhaling dust.
9. Wear rubber dam etc. to avoid accidental ingestion and falling.

10. Do not use this instrument for any purposes except for listed applications above.
11. Only for use by dentists.
12. This product should be treated as medical waste when disposed.
13. Dispose the product if damaged or contaminated.
14. After using, wash it with medical cleaning agent and brush, then wash away foreign substances like adherent body fluids and body tissues.
15. Active medical device(multipurpose ultrasonic scaler) should be started with minimum output power. Take care to use since there is possibility for breakage if the power is too high.
16. Set the product to a stand when cleaned by ultrasonic cleaner to avoid deterioration of cutting part.
17. Use this product with great care to avoid puncturing fingers because of its possession of sharp-edged part.
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 hurt or make a pinhole to packaging materials.
3. The product is subject to be improved without notice. Employ 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 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>

Minimum packaging unit: 6pcs. per package (Single, double and 3F)

### <Legal manufacturer >

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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.