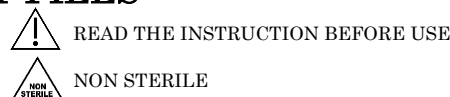




Product Name : MANI NRT FILES



Before using the MANI NRT 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.
2. Do not use if damaged or contaminated.

<Structures and principals>

1. MANI NRT FILES are the nickel titanium alloy and stainless steel files with stainless steel shank. It is non-sterile instrument.
2. MANI NRT FILES(Nickel Titanium Alloy)
 - ① Blade: Nickel Titanium Alloy
 - ② Shank: Stainless steel (Contains Nickel, Chrome and 24 Gold)
: Aluminums
- MANI NRT FILES(Stainless Steel)
 - ① Blade: Stainless steel(Contains Nickel and Chrome)
 - ② Shank: Stainless steel (Contains Nickel and Chrome)
: Aluminums
3. Shapes and structures

Specification	Taper	Tip #	Length(mm)	Groove (Color)
MANI NRT-NiTi	.04	20,25,30	21,25	2(Gold)
	.06	35,40	21,25	3(Gold)
MANI NRT-SUS	.08	20,25,30	21,25	4
	.10		21,25	5
	.12	35,40	21,25	6
	.14		21,25	0
MANI NRT-GPR**	.04	70(1S)	16	1(Green)
		50(2S)	18	1(Yellow)
		40(3N)	21	2(Black)
		30(4N)	21	2(Blue)
MANI NRT-NiTi TYPE A**	.04	20,25,30	21,25	2 (Gold)
	.06	35,40	21,25	3 (Gold)
	.08	25	18,21,25	4 (Gold)

<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. Also, it is a dental instrument which is used by connecting to an active medical 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 NRT FILES and insert the shank into a contra angle handpiece. This product is used for enlarging 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 : ϕ 2.35mm)**
2. Use the active device which could control at allowable engine speed.

Usage instructions for NRT-NiTi-TYPE A **

When using NRT-NiTi-TYPE A, strictly adhere to the instructions given below.

1. Remove the pulp chamber ceiling using MANI DIA-BURS or MANI CARBIDE BURS and obtain access to the root canal orifice.
2. Confirm the location, number and curvature of the canal with the help of radiograph and microscope.
3. Locate the root canal orifice using the orifice opener. Enlargement by the opener is possible until it reaches to the curved position of the canal. Perform irrigation where appropriate to remove debris out of

- the canal. As for the cervical triangle, remove it using MANI STAINLESS BURS etc, and establish the best possible straight access for file insertion.
4. Establish the glide path using MANI K-FILES #10. If penetration is not sufficient, enlarge the canal with MANI D-FINDERS up to the apical third. Perform irrigation where appropriate to remove debris out of the canal.
5. Enlarge the canal using MANI K-FILES #15 or MANI H-FILES #15 up to the apical third. Perform irrigation where appropriate to remove debris out of the canal.
6. Based on the curvature of the canal confirmed with the radiograph image, choose the most appropriate NRT-NiTi-TYPE A Kit (*1) and shape the canal with the instruments starting from No.1 then No.2. Use the smaller instruments first and subsequently larger ones. Appropriate setting of the motor (*2 and 3) shall be strictly adhered to (Adjust the speed arbitrarily between 300 and 500min-1 for the inexperienced operators or if special attention is needed). Perform irrigation where appropriate to remove debris out of the canal. Perform shaping 3 times and remove debris out of the canal one time by using MANI-K-FILE #15 or MANI-H-FILE #15.
7. When shaping is completed, remove the residual debris inside the canal using the instruments such as ultrasonic files.
8. Apply the sealer inside the canal with MANI PASTE CARRIERS.
9. Place the root canal filler such as gutta-percha and complete the procedures.

(*1) List of the Kit

Root canal type	Orifice opener	No1	No2
Simple	08#25	06#25	06#30
Standard	08#25	06#20	06#25
Complex	08#25	04#20	04#25

<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. (*2)**
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.
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. Make sure the instruments outside of oral cavity that there are no deformations, scratches and cracks before use.
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. Confirm the length of working part by X-ray.
10. Follow the general method, form the guide path by hand files to #15.
11. Use the torque controllable active device.(excluding GPR) (*3)**
12. Wear safety glasses to protect your eyes from damage. Also, wear a dust protective mask to prevent inhaling dust.
13. Wear rubber dam etc. to avoid accidental ingestion and falling.
14. Do not use this instrument for any purposes except for listed applications above.
15. Only for use by dentists.
16. This product should be treated as medical waste when disposed.
17. Dispose the product if damaged or contaminated.
18. After using, wash this product with medical cleaning agent and brush, then wash away foreign substances like adherent body fluids and body tissues completely.
19. Set the product to a stand when cleaned by ultrasonic cleaner to avoid working part deterioration.
20. Use this product with great care to avoid puncturing fingers because of its possession of sharp-edged part.
21. This product has possibility that be corrosive if sunk into NaOCl, EDTA and etc. for a long time. *
22. Avoid excessive pressure toward root canal apex.
23. Remove debris on files constantly.
24. Use the hand files to secure guide path constantly.

25. Heat by rotation on the same region for a long time has possibility to damage tissue or cause files fracture. Use this product with great care to avoid such risk.

(*2) Allowable engine speed:

MANI NRT-NiTi, SUS : 300min⁻¹ or less

GPR Series: 500~1,500min⁻¹ (Recommended: 1,000 min⁻¹)

NRT-NiTi-TYPE A : 500min⁻¹ or less**

(*3) MANI NRT FILES are used by connecting with rotational contra head.**

NRT NiTi : 1.0N or less NRT-SUS : 1.0N or less

NRT-NiTi-TYPE A : 3.0N or less

<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 conditions for each use.
Method of sterilization:
Put this product in a sterilization bag (or foil) and place it on a sterilization tray or file stand for autoclave sterilization with reference to the following conditions.
Conditions for sterilization:
(1) Temperature: 121 degrees Celsius time: 20 minutes or more
(2) Temperature: 126 degrees 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. When reusing the instrument, wash away foreign substances completely and sterilize.
4. Regarding use of medical cleaning agent, follow the instruction manual by its manufacturer strictly.
5. Dispose the product if damaged or decreased in performance.

<Packaging>

MANI NRT-NiTi

1. Minimum packaging unit: 6pcs. per package (#20~#40)

MANI NRT-SUS

1. Minimum packaging unit: 6pcs. per package (#40,#30)
2. Assortment: Taper .14(*.02) .02 .04 .06, 1pc. each per package
*The size of .02 is #30. Use this size when needed.

MANI NRT-GPR

1. Minimum packaging unit: 4pcs. per package
2. Assortment: 1S, 2S, 3N, 4N, 1pc each=4pcs. per package
* 1S, 2S SUS
* 3N, 4N nickel titanium alloy

MANI NRT-NiTi-TYPE A**

1. Minimum packaging unit: 3pcs. per package
2. Standard : 06#20, 06#25, 08#25 1pc each per package
3. Simple : 06#25, 06#30, 08#25 1pc each per package
4. Complex : 04#20, 04#25, 08#25 1pc each per package

<Legal manufacturer >



MANI, INC.

8-3 KIYOHARA INDUSTRIAL PARK, UTSUNOMIYA, TOCHIGI,

321-3231, JAPAN

inquiry and reference: dental department

phone: +81-28-667-8592 fax: +81-28-667-8596

<EU representative >



Obelis s.a.

Bd. Général Wahis 53, 1030 Brussels, Belgium

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