

# Operation Manual

## Create a straight path

Equipment can not continue to use after fatigue.

5. Before use the SuperPass dredge file, should went through the high temperature and high pressure sterilization. The glutaraldehyde should not be used for sterilization.

2. Use SU file to open the upper section of the root canal, create a straight path to reduce the difficulty of work. During preparing, lubricate the root canal by EDTA. Use SU file and starts the motor at the orifice of root canal, do up and down movement 3-4 times in 3-5 seconds to prepare the root 1/3 part.

3. During preparing, use EDTA to fill the pulp and root canal, when dredging, rinse the root canal with a large amount of sodium hypochlorite solution.

## Determination of root canal length(Aplexlocator)

Determination of root canal length(Aplex locator), use the stainless steel files to dredge the root canal till the apical, determine the exact working length by apical locator.

## The dredge of SuperPass to the root canal SuperPass

1. Make sure 10# stainless steel K file fully dredging the root canal and reach the working length.

2. Use 025/13# root canal files to do 3-4 times pull movement in 3-5 seconds till reach the working length.

3. Use 025/17# root canal files to do 3-4 times pull movement in 3-5 seconds to make till reach the working length.

## Techniques

1. Gently going along in root canal until reach the working length when feel no resistance in the root canal. The operation process always use up and down technique to prepare, each prepared 3-4 times then move the files out from the root canal and rinse the root canal.

2. When have resistance during preparation, should be prepared with a slight force, move 1 mm each time, till reach the working length. During the mechanical preparation process, root canal file should not stay in the same position for a long time, to avoid channel offset and instrument separation; Gently use "pecking" way to prepare, can prevent the blade edge been stucked, and bring the shards back to the crown, it also can keep the blade clean. The preparation time for each files should not more than 3-5 seconds.

## Attention

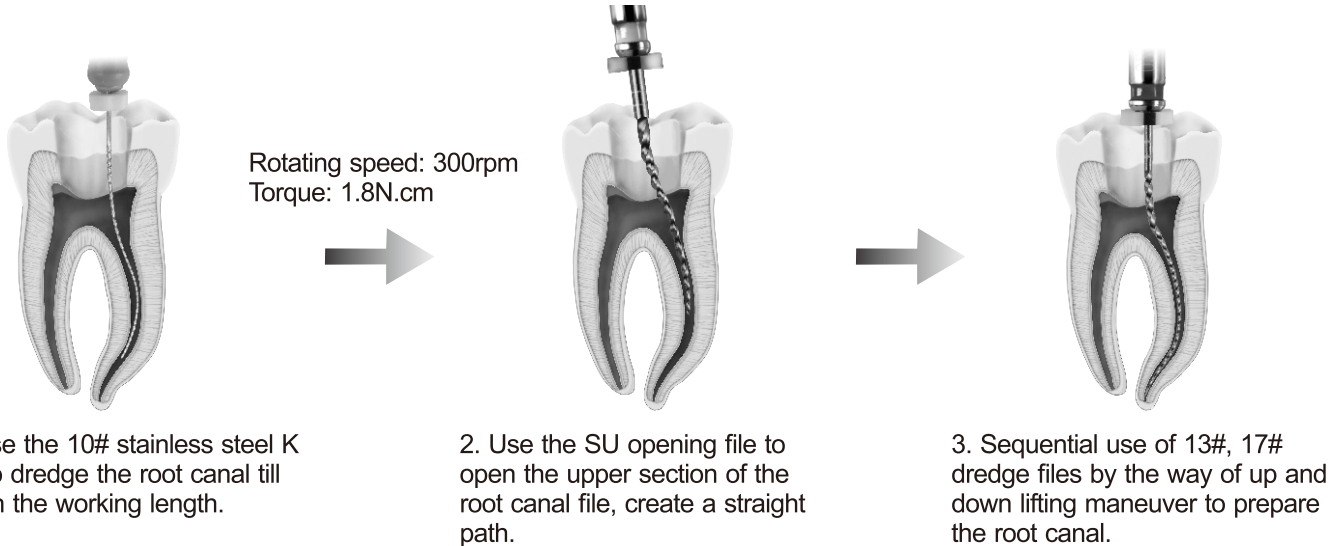
1. Before use the machine nickel titanium equipment to prepare the root canal should make sure that the root canal had been fully prepared.

2. Each SuperPass file should be operated at the speed of 300rpm and torque 1.8-2.0Ncm under the factory guide.

3. Each time the root canal should be lubricated and rinsed.

4. For all nickel titanium equipment can not continue to use after fatigue.
5. Before use the SuperPass dredge file, should went through the high temperature and high pressure sterilization. The glutaraldehyde should not be used for sterilization.

# Method of Operation of The Root Canal File



In the process of using the SuperPass rotary file, it should be fully lubricated with EDTA, if the needle sticks in the preparation of root canal, it can be retreated from the root canal, when fully rinse the debris in the root canal, it can into the root canal to prepare again.

## Instruction For Use

【Product Name】 Rotary Endo File

【Model Specifications】 See Attachment

【Product Performance and the Main Structure】 It is made of working part, indicating piece and handle, and the working part is made of nickel-titanium memory alloy. The indicator piece is made of silicone rubber and the handle is made of stainless steel or brass. Reusable.

【Indications for use】 These instruments are to be used only in a clinical or hospital environment, by qualified users.

Application field: For root canal treatment, the root canal cleaning and shaping.

【Contraindications】 None known.

【Warnings】 This product contains nickel and should not be used for individuals with known allergic sensitivity to this metal.

【Adverse reactions】 In the present technical state, no adverse reaction has been reported so far.

【Production Date】 See label

【shelf life】 5 years

【Equipment used in conjunction with rotary endo files】

The rotary endo file is used in conjunction with a curved handset of the root canal preparation machine, and the rotary endo file is electrically connected to the bending handset and is only mechanically connected. Methods as below:

- 1) Insert the rotary endo file so that its handle is fully accessible.
- 2) Rotate the root canal until the root canal is completely locked. Insert inward until the buckle is in place.
- 3) Remove the rotary endo file: press the button to remove the rotary endo file. As shown below



### 【Instructions】

1. Insert the rotary endo file into the root canal and start the root canal preparation machine.
2. Slightly press the root canal to move along the root canal to the apical.
3. When the rotary endo file reaches the length of the root canal after the root canal wall to do the upper and lower pulling movements 3-4 times and then switch to the next model rotary endo file.

### 【Precautions】

1. The product is cleaned and sterilized by the user before the first use and re-use of

the product.

2. Irrigate abundantly and frequently. Clean flutes frequently and check for signs of distortion or wear.

3. Repeated use and treatment of rotary endo file have a certain impact, the rotary endo file life depends on the use of wear or damage, it is recommended to re-use 10 times. At the same time, when the product is damaged, such as cracks, deformations (bent, unwound), corrosion, loss of color coding or marking, are indications that the devices are not able to fulfil the intended use with the required safety level and must therefore be discarded.;

4. Ni-Ti instrument will be corrosive by hydrogen peroxide solution, if soaked in more than 5% concentration of sodium hypochlorite solution for more than 5 minutes, nickel titanium equipment performance will be affected

5. These instruments are to be used only by trained professional department of Stomatology doctor

6. For dental use only.

7. Used products and expired products, should be professional institutions to recover, should not be discarded arbitrarily.

8. The patient can not move freely during treatment

#### 【Cleaning and Sterilization Method】












For hygiene and sanitary safety purposes, all instruments must be cleaned and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent ones. Disinfect the environment and control the hospital infection. The following procedures must be followed

Operating	Method of operation	Precautions	First Use	Following Use
Recycling	Rotary endo file and the use of waste items placed separately, timely recovery.	- Rotary endo file should be placed moisturizing, moisturizing liquid selection of drinking water. - Recycling containers should be cleaned, sterilized and dried after each use.	—	+
Disassembling	Dismantle rotary endo file	Remove the indicator from the rotary endo file	—	+
Flush 、 rinsing	Equipment: soft brush, flowing water 1. Flush: rotary endo file placed in the flow of water rinse, the initial removal of pollutants; 2. After rinsing, brush the root canal surface with a soft brush, brush the surface of the dirt; 3. Poaching: After washing, rinse with	- Rinse water should meet local water quality standards; - Wash the water temperature should be 15 °C ~ 30 °C; - Brush should be carried out under water to prevent aerosol generation.	—	+

	running water.			
Clean	Rinse with distilled water			
Drying	Dry the rotary endo file with a low fiber flaking cloth and also dry with a drying or filtered compressed air	- Drying temperature (drying cabinet) 70 ~ 90 °C	+	+
Inspection	1. Inspect devices and sort out those with defects.; 2. Assemble the indicator on the root canal file.	- The rotary endo file root canal file that is not qualified for cleaning quality should be reprocessed; - damaged, such as cracks, deformations (bent, unwound), corrosion, loss of color coding or marking, are indications that the devices are not able to fulfil the intended use with the required safety level and must therefore be discarded.	+	+
Packaging	Place the rotary endo file to be sterilized in the box or bag and do the "to be sterilized" logo	- Sterilization should be placed in the instrument box, to avoid contact with each other. - Check whether the sterilization bag is valid for the specified time. - Sterilized bags should be able to withstand temperatures of 134 °C and meet EN ISO 11607 requirements.	+	+
Sterilization	Pressure steam sterilization Sterilization temperature: 134 °C , Minimum sterilization time: 3min	-The instruments, posts and the plastic supports must be sterilized according to the packaging labelling.; - Use only autoclaves that are matching the requirements of EN 13060, EN 285.; -Respect the maintenance procedure of the autoclave device given by the manufacturer. -Use only this recommended sterilization procedure. Among them, the upper temperature limit and the relative fluctuation range of pressure can be referred to the instruction manual of sterilizer -Use a validated sterilisation procedure according ISO 17665 - to comply with the provisions of the manufacturer's operating procedures for operation, which use the upper temperature limit, the relative pressure fluctuation range can refer to the sterilizer instructions; - must be operated in accordance with the prescribed sterilization procedure; -Control the efficiency (packaging integrity, no humidity, colour change	+	+

		of sterilisation indicators, physico-chemical integrators, digital records of cycles parameters). -Traceability of procedure records		
Storage	Keep devices in sterilization packaging in a dry and clean environment.	-Sterility cannot be guaranteed if packaging is open, damaged or wet. - Check the packaging and the medical devices before using them (packaging integrity, no humidity and validity period).	+	+
Remark: “+” Indicate apply; “—” Indicate not apply.				

### 【 Symbols and Explanations 】

Symbol	Symbol Description	Symbol	Symbol Description	Symbol	Symbol Description
	<b>Manufacturer</b>		<b>Authorised representative in the european community</b>		<b>use by</b>
	<b>Batch Code</b>		<b>Date of manufacture</b>		Autoclavable at the specified temperature
	Handle Right angle RA		Nickel titanium		Recommended rotation speed
	<b>Caution</b>		<b>Non-Sterile</b>		

【 Storage Method 】 Rotary endo files should be stored in a dry and clean environment..

【 Disposal Method 】 According to local regulations to deal with.

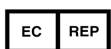
【 After-sales Service 】 If you have any problems in the course of use, please contact the manufacturer or local dealer.



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