



Basic Preparation Method

Dredge The
Root Canal

10# 15#



Straight Channel
Establishment

SU



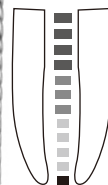
20/10
(17mm)

Use SU file(Open file) to
open the top of the root
canal, establish the straight
channel into the root canal.



Determine The
Working Length

15#



S3 System To Prepare Root Canal

1S



2S



3S



20/04

25/06

35/04

(21mm/25mm/28mm/31mm)

Each canal all reaches
the working length of root canal.

Operation Manual

Straight Channel Establishment

Simple root canal preparation:

- a: Use stainless steel K file to establish the root canal , and reach the working length.
- b: Use SU(Open file) to open the top of root canal, establish the straight channel.
- b: Start endo motor after put root canal file into the root canal.
- d: Using a unified speed of 600 rpm, 2.5N.CM.

Curved root canal preparation:

- a: According to the initial working length of the X-ray, in preparation can use EDTA to fill the pulp chamber and root canal,then prepare with stainless steel K file. Select the appropriate initial file to reach the temporary working length.
- b: Use SU (open file10/20) open the top of the root canal, establish the straight channel, reduce the difficulty and risks: Use EDTA to lubricate the root canal, start the endo motor after put SU file into the root canal.Prepare the 1/3 part of working length by pulling in one second.
- c: Use stainless steel K file to prepared until 15 #.Every time the exact working length need to be reached .And rinse for a long time.

Determine The Working Length.(Apex Locator)

Determine the working length(Apex locator).Use stainless steel file to dredge till reach the apical. Determine the exact working length by apical locator.

S3 Nickel Titanium File System Preparation

First, use EDTA to fill the pulp chamber and root canal. Put the 1S (04/20)into the root canal,then start the endo motor to prepare till reach the working length.The approach is moving along the root canal file to the apical. When the root canal file reaches the working length, it needs to do a up and down movements for 3-4 times, and rinse with sodium hypochlorite solution.

Techniques

A.Gently going along in root canal until reach the working length when feel no resistance in the root canal, and retreat by the way as“Brush” for each side of the root canal.Finish this step by brush 3—4times.

b. When feeling the resistance, should be prepared with a slight force. Use the way “pecking” to prepare , 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 , also can bring the shards back to the crown, and keep the blade clean. The preparation time for each files should less than 3-5 seconds.

2S (06/25) Use the 2S by the same way when 1S

reaches the working length.

3S (04/35) For prepare the apical part, use the same way to prepare root canal and reach the working length when 2S reached.

Attention

1. Because of S3's excellent cutting performance, it will produce a lot of shards in the root canal during preparation .Should use large quantities of sodium hypochlorite solution to rinse.
2. Use EDTA to lubricate the root canal, conclusive the preparation of root canal.
3. S3 root canal file has a good adaptability in the root canal shape, root canal file bending is a normal phenomenon, above 60 degrees temperature heating, the root canal file will go straight automatically.

Method of operation of the root canal file

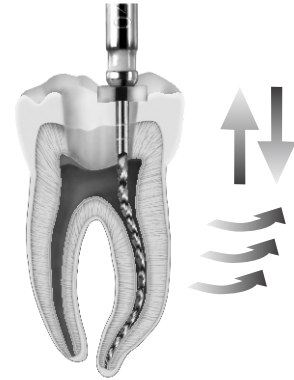


1.Insert S3 to the root canal,
start the motor.

Rotating speed: 500rpm
Torque: 2.5N.cm



Slightly press, make S3 root
canal file move along the
root canal toward the top of
the root canal



When the S3 root canal file reaches
the working length , it needs to do the
up and down movements 3-5 times,
then change to next size.

In the process of using S3 root canal file , the root canal should be full lubricated with EDTA,.In the process of root canal preparation , if file stuck , can move it out from the root canal. Root canal file moves into the root canal after completely rinse the shards in the root canal.

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

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

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

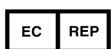
【 After-sales Service 】 If you have any problems in the course of use, please contact the manufacturer or local dealer.



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