

[product name]
Endo file removalsystem

[Scope of application]

For the removal of fractured root canal files during endodontic treatment in dentistry. This product should only be used by professional dentists in hospitals or dental clinics.

[Contraindications]

- 1.Prohibited when the fractured instrument is located in a curved part of the root canal and cannot be viewed under the microscope;
- 2.When the root canal wall is thin;
- 3.When the fractured instrument is located in the apical position;
- 4.When there is a risk of perforation of the root canal wall during use.

[Caution]

- 1.Read all the contents of this instruction manual carefully before use;
- 2.Please use the original needle cannula to avoid damage to the equipment;
- 3.Consider the curvature of the root canal, the thickness of the root canal wall and the depth of the fractured instrument before and during use.
- 4.Check the direction of advancement of the instrument and the bending direction of the fractured instrument during use;
- 5.The instrument should be inspected before and after each use and replaced if the needle cannula or needle core is found to be damaged by fatigue and cannot be used properly;
- 6.Select the appropriate size of needle cannula according to the diameter of the crown side of the separating instrument in the tube;
- 7.The product is not sterilised at the factory, please sterilise it before use.

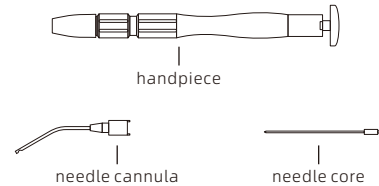
— 1 —

Product Performance

- 1.The device can be used under a microscope, by pushing the push cap at the end of the handpiece and clamping the broken instrument with the clamping sleeve, to remove the broken instrument or other foreign objects from the root canal;
- 2.The bending wrench can be used to adjust the bending angle of the clamping sleeve according to the position of the affected tooth, the factory bend is 45 degrees, the maximum angle can be adjusted to 90 degrees;
- 3.The device is reusable and is not supplied aseptically.

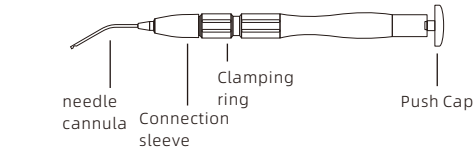
Product Components

This product consists of a sleeve and a pin and is made of stainless steel.



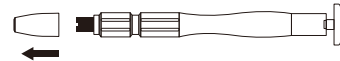
— 2 —

Product Installation and Disassembly

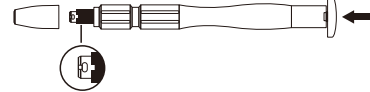


1.Product installation

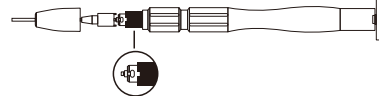
Step 1: Removal of the connection sleeve.



Step 2: Push the cap forward to expose the circular groove.

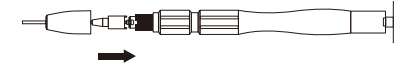


Step 3: After inserting the needle core into the exposed circular groove, loosen the push cap so that it snaps into place.



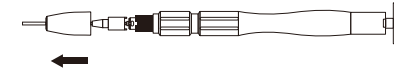
— 3 —

Step 4: Install the connection sleeve after aligning the needle cannula with the slot.

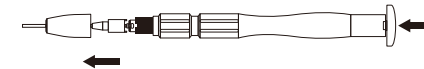


2.Product disassembly

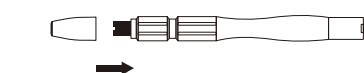
Step 1: Removal of the connection sleeve.



Step 2: Push the push cap forward to remove the needle cannula.



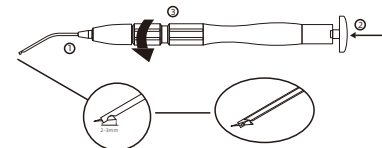
Step 3: Tighten the connecting tubes.



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Instructions for use

1. Use the G-drill to remove the dentin until the tip of the G-drill is close to or touches the section of the broken file.
2. Continue to remove the dentin channel using a path drill of the appropriate size(80, 90, 110 sizes)
3. After incising the dentin, depending on the size of the section of the broken file, select a cutting drill of the appropriate size and grind the filing channel at low reverse speed (recommended speed 150 rpm).
4. Remove the dentin around the broken file by reversing the cutting cannula at low speed until the file is exposed by 2-3 mm. In the case of curved root canals where the cutting cannula cannot penetrate deeply, the dentin around the broken filing can be removed by using a path drill (size 60-70) at low speed and positive rotation until the file is exposed by 2-3 mm.
5. Fitting a suitable size of needle cannula.
6. Clamp the broken file with cannula window (as in step 1 of the diagram).
7. Pushing the push cap forward so that the needle cannula clamps the broken file (as in step 2 of the diagram, taking care to press it into place).
8. The clamping ring can be turned in the direction shown by the arrow to tighten the needle cannula and then (taking care to tighten it) press the pushing cap firmly to pull out the broken file (as shown in step 3).
9. Sterilise after use.



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Cleaning, Disinfection and Sterilisation

1.Cleaning

Rinse the handpiece and any visible dirt from the surfaces of the components with water <38°C; clean the needle cannula with a through-needle. Dry the cleaned parts with a clean rag.

2. Disinfection

Wipe the surfaces of the components with medical alcohol.



caution

Do not use disinfectants containing chlorine to clean the equipment as it may corrode metal parts.

3.Drying

After cleaning and disinfection, please dry, using compressed air is recommended.

4.Packaging

Immediately after the drying process, place the components in steam sterilised bags and pack tightly.



caution

Steam sterilised bags conforming to ISO 11607-1 should be used and the packaging must be sealed using a sealing machine.

5. Sterilisation

Sterilization components: sterilization box, handpiece, needle cannula, needle core

Sterilization method: Autoclaving recommended

Sterilisation conditions: 134°C, not less than 5 min



caution

- 1.Can be re-sterilised at least 250 times
- 2.After sterilisation, the equipment is kept in a dry and dust-free environment until the next use

Maintenance and Care

The equipment and accessories must be wiped down and disinfected after each use;

The instruments must be cleaned with water <38C after each use.

Accessory Specifications

Pin diameter(mm)	φ0.45	φ0.55	φ0.60
Clamping sleeve inner diameter*Outer iameter(mm)	φ0.5*φ0.8	φ0.6*φ0.9	φ0.7*φ1.1
Minimum number of bends	10 times	10 times	10 times

Cutting drill	F8 red	19mm φ0.8
	F9 greed	19mm φ0.9
	F11 yellow	19mm φ1.1

Cutting cannula	H8 red	19mm φ0.5*φ0.8
	H9 greed	19mm φ0.6*φ0.9
	H11 yellow	19mm φ0.7*φ1.1

Path drill	T6 blue	19mm 60.04
	T7 greed	19mm 70.03
	T8 black	19mm 80.02
	T9 white	19mm 90.02
	T11 red	19mm 110.01

Operating Environment and Transport, Storage

1.Operating environment

Operating temperature	5°C ~ 40°C
Operating humidity	20%RH ~ 80%RH
Atmospheric pressure	86kPa ~ 106kPa

2.Storage and transport conditions

Storage temperature	-10°C ~ 55°C
Storage humidity	≤93%RH
Atmospheric pressure	50kPa ~ 106kPa

Date of Manufacture and Use by Date

This product has a 5 year lifespan.

The date of manufacture of this product is detailed on the body or product label.

Product Repair

The warranty for the handpiece is 12 months from the date of purchase, the rest of the accessories are not guaranteed.

Description of symbols

	Caution / Warning		Specified sterilisable temperature		Refer to the manual
	Serial No.		Lot number		Manufacturer
	Fragile items gently place		Keep dry		Vertical up

Description of symbols



Dispose of used equipment in accordance with national regulations and standards. Ensure that no contamination is generated during the disposal of all parts.

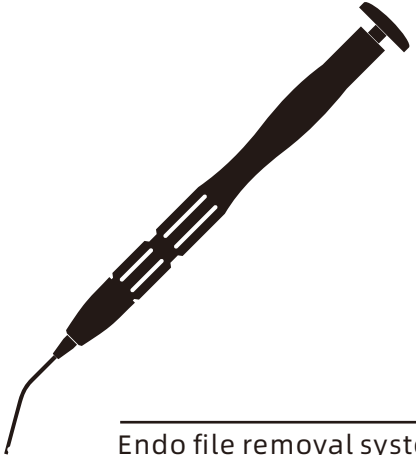
Packing list

handpiece	× 1	Instructions for use	× 1	Needle cannula	× 3
needle core	× 3	Cutting drill	× 3	Cutting cannula	× 3
Sterilisation box	× 1	Path drill	× 5		

Manufacturing filing number:

Medical device filing number:

Product technical requirements No:



Endo file removal system
Instruction