

Instructions For Use

SAF SYSTEM




ReDentNOVA
Minimally Invasive Endodontics

Self Adjusting File

Instructions for Use

A. Product description:

SAF, Self-Adjusting File, a mechanically-operated endodontic file.

B. Indication for use:

The Self Adjusting file (SAF) is a mechanically operated endodontic file to be used for cleaning and shaping of root canals, as part of the procedure of root canal treatment.



Figure 1: SAF 1.5mm (left); SAF 2mm (right)

C. Device description:

The ReDent NOVA SAF is an endodontic file that is indicated for use in root canal treatment for cleaning and shaping of the root canal. The file portion of the SAF consists of a metal lattice hollow cylinder and is constructed from medical grade nickel-titanium-alloy. The file's cylindrical lattice structure permits compression when inserted into the root canal followed by gradual radial expansion to fill the root canal profile. The file is surface treated by sandblasting, enabling it to file dentin from the canal's interior surface (Figure 2).

The SAF is available in 2 diameters 1.5mm (in lengths of 21mm, 25mm and 31mm) and 2mm (in lengths of 21mm and 25mm).

The SAF should be mounted on a vertical-vibrating contra-angle handpiece with 0.4mm stroke and 3000- 5000 OPM [oscillations per minute].

The file is attached to the handpiece via a polypropylene shank (Figure 1).

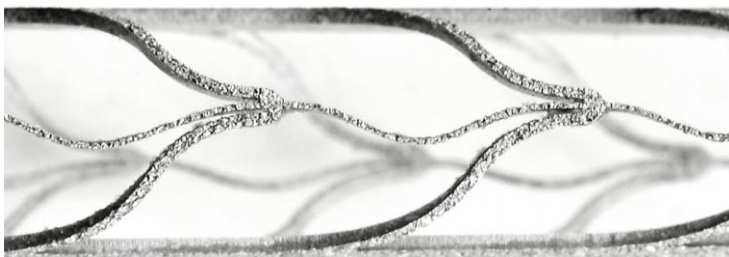


Figure 2: The SAF abrasive surface

D. Precautions:

1. The law restricts this device to sale for use by or on the order of a dentist.
2. SAF files should not be used in any manner other than that detailed in Manufacturer's Instructions.
3. The SAF file is designed for a single use only. Multiple uses, disinfection and sterilization cycles may lead to increased risk of file separation.
4. Recommended working speed for all SAF files – Reciprocation of 3000- 5000 OPM [oscillations per minute].
5. Irrigation should be applied while operating the SAF in the root canal.
6. When alternating between canals, inspect the instrument for any signs of wear.

E. Contraindications:

1. Do not use the 1.5 mm diameter SAF if the initial diameter of the root canal allows the insertion of an ISO 045 K-file to its full working length, or on teeth that do not have fully formed roots with a mature apex.
2. The SAF is not to be used in working lengths greater than 31mm.

F. Protocol for Use 1.5 mm and 2 mm diameter SAF:

Root canal structure should be evaluated before treatment and the procedure should be adopted accordingly.

1. A pre-operative X-ray should be taken in order to estimate working length of the root canal and tooth anatomy.
2. Isolate the tooth, using a rubber dam.
3. Prepare a standard access cavity.
4. Locate root canal orifices and adjust the access cavity walls to allow clear and unobstructed access to each canal.
5. Use a Gates-glidden #3 or equivalent to prepare the coronal third of the canal to an adequately flared shape.
6. Establish the working length of the root canal using either an X-ray or an electronic apex locator.
7. Select a SAF file with the appropriate length and width to match tooth working length and width.

SAF 1.5 should be used for canals with initial width of up to ISO 035.

SAF 2 mm should be used for canals starting from size ISO 035 to ISO 060.

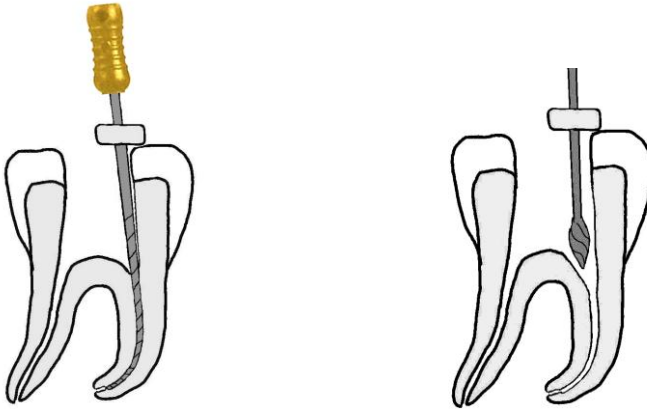


21, 25 & 31mm SAF

8. When using 1.5 mm SAF a preliminary reproducible glide path should be established using one of two methods:

a. Hand files to ISO 020 / .02 size.

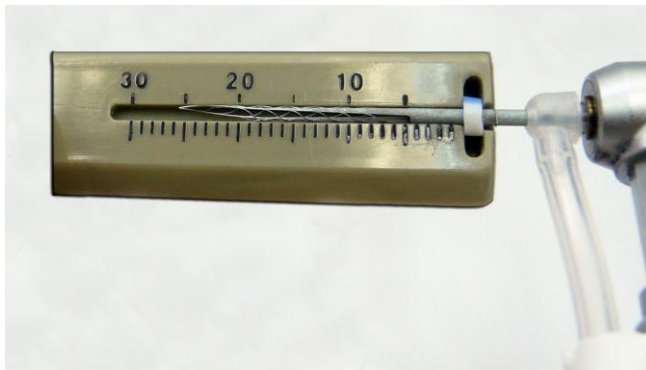
Funneling the coronal orifice of the root canal should be performed using an orifice shaper of your choice.



b. Create an apical ISO 020 / .04 taper glide path preparation.

9. Prior to using 2 mm SAF, use ISO 030 instruments to remove gross pulp tissue.

10. Adjust the rubber stopper on the SAF to indicate the desired working length.

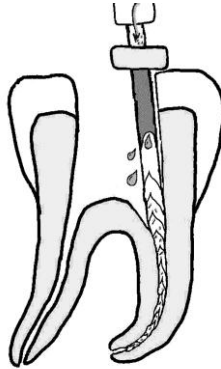


11. Attach irrigation tube from any approved medical irrigation device to the SAF irrigation barb (Figure 3).

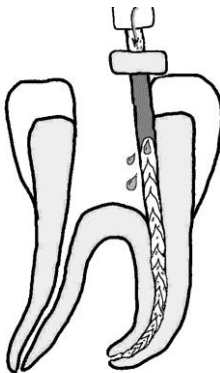


Figure 3: Attaching the irrigation tube to the SAF irrigator

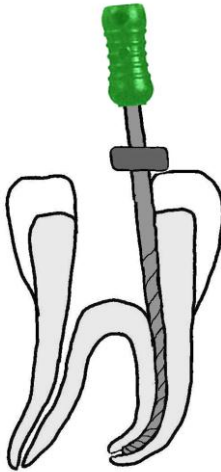
12. Continuous irrigation should be applied throughout the procedure. The choice of irrigant is at the discretion of the treating dental professional.
13. Insert the SAF gently into the canal while operating. Do not force the SAF apically. Working length will be reached while operating.



14. If resistance to insertion is noted, stop and re-establish glide path.
15. Work is performed using light pecking motions for 4 minutes in each canal.



16. Gauge the apical region of the canal using hand files to confirm that the desired root canal enlargement has been achieved. If enlargement is less than desired, another 1 minute of work may be applied.



17. Canal shaping is now complete.
18. Your preferred obturation method may be used.









G. Sterilization:

1. The SAF is provided non-sterile and must be sterilized before use.
2. Steam autoclave temperature at **121 °C** (250 °F) for a period of **20 minutes** is the sterilization method required before use.

Note:

Avoid using disinfection reagents. Some disinfection reagents may cause deformation of the SAF plastic parts.

Symbols in use:

Symbol	Description
	For Single use only. Do not reuse
	Date of manufacture
	Nickel Titanium alloy
	Vertical stroke of 0.4mm, up to 5,000 OPM
X.X-XX-XX-XX-XXX	Catalog Number
	Read Instruction for use prior use
	Lot Number
	The package is not sterile
21mm / 25mm / 31mm	File Length
1.5 mm, 2.0 mm	File Diameter
#20 #35	Adjustable to ISO 020 size Adjustable to ISO 035 size
X 10 / X 3	3 or 10 SAF's in the package
	CE mark

H. Catalog numbers:

SAF 1.5 mm - Package of 3 endodontic files:

1.5162112030 ; 1.5182512030 ; 1.5213112030

SAF 1.5 mm - Package of 10 endodontic files:

1.5162112100 ; 1.5182512100 ; 1.5213112100

SAF 2.0 mm - Package of 3 endodontic files:

2.0162115030 , 2.0182515030

SAF 2.0 mm - Package of 10 endodontic files:

2.0162115100, 2.0182515100

I. Manufacturer:

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