

# Instructions For Use

# SAF SYSTEM



## Self-Adjusting File

### Instructions for Use

#### A. Product description:

Self-Adjusting File (SAF), a motorized endodontic file.

#### B. Indication for use:

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



Figure 1: SAF 1.5mm (left); SAF 2.0mm (right)

### C. Device description:

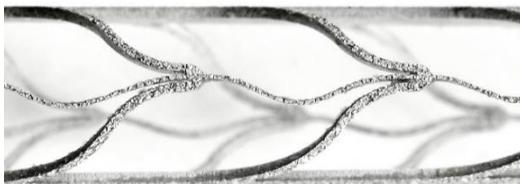
The SAF is an endodontic file that is indicated for use in root canal treatment for cleaning and shaping of the root canal. The hollow file is designed as an elastically-compressible, thin-walled pointed cylinder and is composed from medical grade nickel-titanium-alloy ("NiTi"). The file's cylindrical lattice structure makes it extremely flexible, to best fit the cross-section of the canal at any location.

The SAF shapes the canal by scrubbing the dentin walls and filing dentin from the canal's interior surface (Figure 2), an action that relies on (a) its compressibility and the subsequent gradual radial expansion to circumferentially adapt to the root canal three-dimensional morphology; (b) its abrasive sandblasted surface; (c) its operation in vertical vibration at 3000-5000 opm (oscillations per minute) at an amplitude of 0.4mm, provided by a designated vertical-vibrating contra-angle handpiece; (d) its operation by the user in short vertical pecking motions to allow repositioning of the SAF when unbound from within the root canal walls.

The SAF cleans and disinfects the canal by continuous pressure-less irrigation that flows through its hollow lumen, carried to the apical area mechanically, by the fluid's surface tension, where it is constantly refreshed.

The SAF is available in 2 diameters: 1.5mm (in lengths of 21mm, 25mm and 31mm) and 2.0mm (in lengths of 21mm and 25mm).

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



*Figure 2: The SAF's abrasive surface*

## **D. D. Precautions:**

1. The law restricts this device to sale for use by or on the order of a dentist.
2. Self-Adjusting files should not be used in any manner other than that detailed in Manufacturer's Instructions.
3. The Self-Adjusting file is designed for a single use only. Multiple uses, disinfection and sterilization cycles may lead to transfer of infection and to an increased risk of file separation.
4. Recommended working speed for all Self-Adjusting files – Vertical vibration at 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 1.5mm diameter SAF if the initial diameter of the root canal allows the insertion of an ISO #35 K-file or larger to its full working length, or on teeth that do not have fully formed roots with a mature apex – in such canals the SAF 2.0mm should be used.
2. The SAF is not to be used in working lengths greater than 31mm.

**F. Protocol for Use 1.5mm and 2.0mm 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 properly, using a rubber dam.
3. Prepare a standard access cavity, with clear, unobstructed access to the orifice of each of the root canals.
4. Locate root canal orifices and adjust the access cavity walls to allow clear and unobstructed access to each canal.
5. Use an orifice shaper (Figure 3) to funnel the coronal third of the canal to an adequately flared shape, by light brushing motions.
6. Establish the working length of the root canal, using an X-ray, an electronic apex locator or both.
7. Select an SAF with the appropriate length and width to match tooth working length and width.

SAF 1.5mm should be used for canals with initial width of up to ISO #35.

SAF 2.0mm should be used for canals starting from size ISO #35 to ISO #60. SAF 2.0mm can also be suitable for canals sized ISO #70 and over, in which case it should be more carefully observed to assure that it doesn't rotate inside the canal during its operation.



*Figure 3: Pre-SAF OS (orifice shaper)*

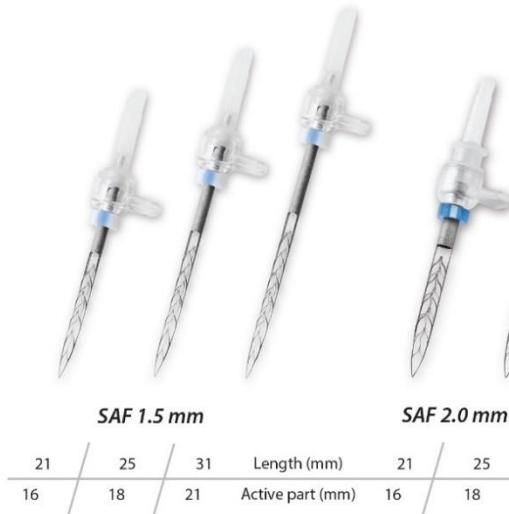


Figure 4: The various SAF sizes

8. When using a 1.5mm SAF, a preliminary reproducible glidepath should be established using one of two methods:
  - a. Hand files to ISO #20 /.02 size.
  - b. In curved canals, an apical ISO #20 /.04 taper glide path preparation is advised. Preparing a larger glidepath is unadvised, as it may diminish the minimally-invasive properties of the SAF instrumentation (Figure 5).



Figure 5: #20/.02 hand file

Pre-SAF 2 (#20/.04)

9. Prior to using 2.0 mm SAF, use ISO #30 instruments to remove gross pulp tissue.
10. Adjust the rubber stopper on the SAF to indicate the desired working length (Figure 6).



Figure 6: Rubber-stopper adjustment

11. The glidepath preparation (Figure 7) should be verified manually by insertion of the SAF to full working length, prior to its connection to the handpiece. The manual verification should assure that the SAF can reach working length and evaluate the vertical axis of the canal, according to which the SAF should be operated.



Figure 7: Manual verification

The manual verification should be carried in a vertical motion, while avoiding "clock-winding" movements that are commonly used in similar operation of hand files. In curved canals, horizontal repositioning of the SAF when it is unbound from the canals walls may be required, to allow the SAF to get past the curvature.

12. Attach irrigation tube from any approved medical irrigation device to the SAF irrigation barb (Figure 8).



Figure 8: Irrigation tube attachment

13. Continuous irrigation should be applied throughout the procedure. The choice of irrigant is at the discretion of the dental professional.

14. Insert the SAF gently into the canal while operating. Do not force the SAF apically. Working length will be reached while operating. Work is performed using light pecking motions (Figure 9) for 4 minutes in each canals. The pecking motions will shift the SAF's horizontal position and will propagate the flow of the irrigant.



Figure 9: Vertical pecking motions

15. If resistance to insertion is noted, or if the working length is not reached in any of the in-bound motions within the first minute of operation - stop and re-establish glide path.

16. The advised irrigation protocol to be used is combination of sodium hypochlorite (NaOCl) to dissolve and remove organic materials (residual pulp tissue, bacteria) and EDTA, to remove the remaining debris and smear layer. The following graph indicates the recommended irrigation protocol:

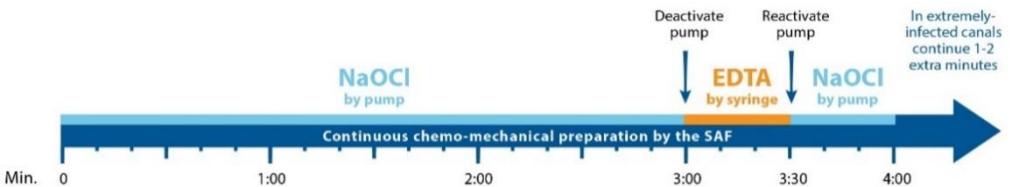


Figure 10: Recommended irrigation protocol

The SAF is expected to enlarge the apical size of the canal by 2-3 ISO sizes. Gauge the apical region of the canal using either a gutta-percha master cone or NiTi hand files (Figure 11), 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.

*Figure 11: Gauging of the apical size*

Your preferred method of obturation may be used.

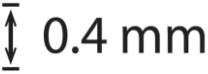
## **G. Sterilization:**

1. The SAF is provided non-sterile and must be sterilized before use.
2. Steam autoclave temperature at 134 °C (273 °F) for a period of 4 minutes is the sterilization method required before use.

### **Note:**

Avoid using disinfection reagents, as some disinfection reagents may cause deformation of the SAF's plastic parts. Avoid using an ultrasonic bath. Do not place the SAF in a glass bead sterilizer.

Symbols in use:

Symbol	Description
	For Single use only. Do not re-use
	Date of manufacture
	Nickel Titanium alloy
	Vertical stroke of 0.4mm
3000 ≤ OPM ≤ 5000	3,000 to 5,000 OPM
X.X-XX-XX-XX-XXX	Catalog Number
	Read Instruction for use prior use
	Lot Number
Non-sterile	The package is not sterile
Sterilizable 	The product is sterilizable at 134 °C
21mm / 25mm / 31mm	File Length
1.5 mm, 2.0 mm	File Diameter
#20 #35	Adjustable to ISO #20 size Adjustable to ISO #35 size
X 10 / X 5	5 or 10 SAFs in the package
	CE mark

**H. Updated information:** The SAF System Clinical Guidelines, as well as the most updated version of the IFU, are available at: [www.redentnova.com/IFU](http://www.redentnova.com/IFU)

**I. Catalog numbers:**

**SAF 1.5 mm – single endodontic file (available in packages of 5 or 10 units):**

1.51621 ; 1.51825 ; 1.52131

**SAF 2.0 mm - single endodontic file (available in packages of 5 or 10 units):**

2.01621 , 2.01825

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