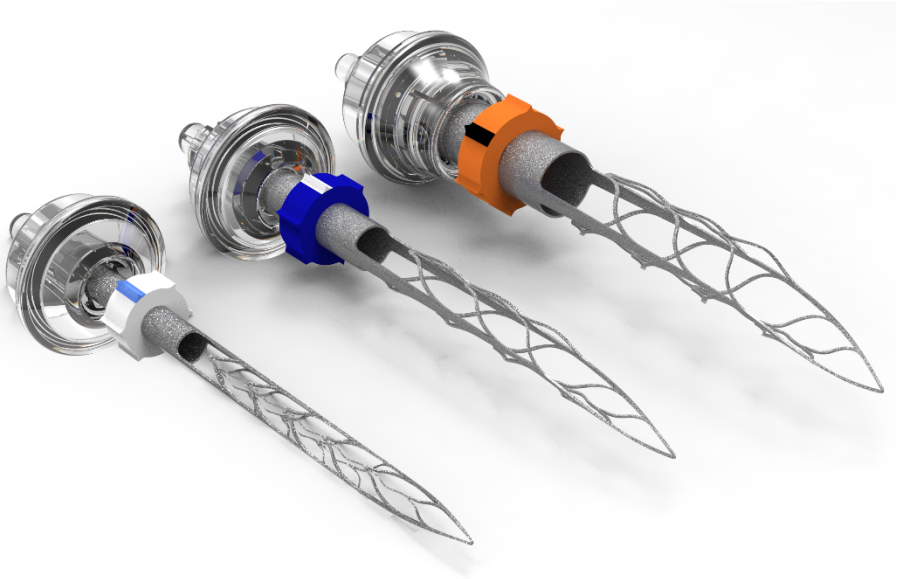
ReDentNOVA

Instructions For Use

Self-Adjusting File (SAF)



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CE 0297

These Instructions for Use do not come to replace the clinical guidelines and instructions for use of the various equipment – Self-Adjusting Files (SAF) and Rotary instruments.

Updates to this document, as well as further instructions, guidelines and videos for the various instrumentation systems, may be found on www.redentnova.de

Self-Adjusting File

Instructions for Use

A. Product description:

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

B. Statement of Intended Use:

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

Fig. 1 – Self-Adjusting Files

C. Device description:

The SAF is an endodontic file 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 of medical grade nickel-titanium-alloy ("NiTi"). The file's cylindrical lattice structure makes it extremely flexible, to best adapt to the cross-section of the canal at any location. The SAF shapes the canal by vertical scrubbing motions, gently filing the dentin walls of 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 ~5000 rpm (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 the file is unbound from within the root canal walls.

The SAF provides simultaneous cleaning and disinfection of the canal by continuous pressure-less irrigation. The irrigant is delivered through the shank, into the coronal part of the file, flows through its hollow lumen, and is carried to the apical area mechanically, affected by the fluid's surface tension, the continuous vibration motions of the file and the vertical pecking motions applied by the operator. The refreshment of the irrigant at working length is supported by intermittent suction that is conducted around the base of the file, through the shank of the SAF. The evacuated fluid is carried into the handpiece head and then through irrigation tubes into a suction pump.

The SAF is available in 3 diameters: 1.5mm (in lengths of 21mm, 25mm and 31mm), in 2.0mm (in lengths of 21mm, 25mm and 31mm) and in 3.0mm (in lengths of 21mm and 25mm).

The file is attached to the handpiece head via a plastic shank (Fig. 1).

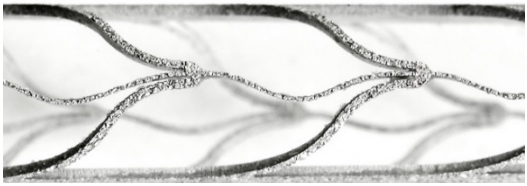

Fig. 2: The SAF's abrasive surface

D. Precautions:

1. SAF (Self-Adjusting File) is intended for use in dental offices.
2. The law restricts this device to sale for use by or on the order of a dentist.
3. Self-Adjusting files should not be used in any manner other than those detailed in the Manufacturer's Instructions.
4. The Self-Adjusting file is designed for single use only. Multiple uses, disinfection and sterilization cycles may lead to transfer of infection and to an increased risk of file separation.
5. Recommended working speed for all Self-Adjusting files – Vertical vibration at 3500- 5500 OPM [oscillations per minute].
6. Irrigation should be applied while operating the SAF in the root canal.
7. When alternating between canals, inspect the instrument for any signs of wear.
8. If any of the precautions were not implemented correctly, the SAF file device should be disposed to the biohazard bin.
9. In case, that SAF File's connection and/or Handpiece's connection port are deformed or/and broken upon first use of the File or the Handpiece, the user should report to the Manufacturer and should avoid using the File and dispose of it in the biohazard trash bin.
10. The SAF Infinitum Self-Adjusting File is compatible with conventional dental irrigation solutions, including Sodium Hypochlorite (2.5% to 6%), Ethylenediaminetetraacetic acid (EDTA), HEDP (Etidronic Acid), Chlorhexidine Gluconate (up to 2%), Hydrogen Peroxide (H_2O_2), Citric Acid, Iodine, Saline and distilled water. If you intend to use a different type of solution, please confirm its compatibility with the manufacturer beforehand.
11. The product must not be used if its surface temperature exceeds 43°C. An excessively high surface temperature may occur, for example, if the product is not used in accordance with the instructions for use.

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 or SAF 3.0mm should be used.
2. The SAF should not be used in working lengths greater than 31mm.
3. If the SAF's package is damaged or unintentionally opened, consider it as non-sterile. Do not use the product thereafter.

F. Storage, transport and operating conditions:

1. The product must be stored and transported in its unopened original packaging. The original packaging must be handled with care and protected from mechanical damage.
2. The product may be stored and transported at temperatures between −20 °C and +50 °C. The permitted relative humidity range is 20% to 90%. The permitted atmospheric pressure range is 500 hPa to 1060 hPa.
3. The product is supplied in a single sterile barrier system. Sterilization is performed by irradiation. The sterile barrier must only be opened immediately before use.
4. Do not use the product if the packaging is damaged, opened, or if the sterile barrier has been compromised. Before use, verify that the packaging is intact and that the indicated use-by date has not expired.
5. The product may be used until the indicated use-by date. The product must not be used after the use-by date has expired.
6. The product is intended for single use only. It must not be reused and must not be resterilized.

7. Consult the instructions for use before use. The product must only be used in accordance with these instructions for use and by qualified professional personnel.

G. Protocol for Use 1.5mm, 2.0mm and 3.0mm diameter SAF:

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

1. A pre-operative X-ray should be taken in order to estimate the 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 the root canal orifices and adjust the access cavity to allow clear and unobstructed access to each canal.
5. If the access to the root canals' orifice and to its vertical axis is limited, consider the use of PreSAF FLARE (Figure 3) to funnel the orifice of the canal to a lightly flared shape, by light brushing motions.

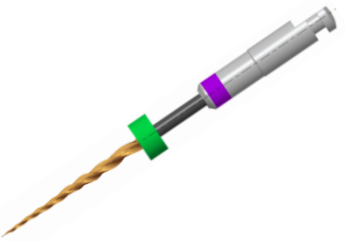

Fig. 3: PreSAF FLARE

6. Establish the working length of the root canal, using an X-ray, an electronic apex locator or preferably the combination of both. Choose a reference point that allows the hand file to conform with the root canal's vertical axis.
7. Assess the apical size of each root canal, according to the instrument with the largest apical size that reaches working length and choose a SAF with the appropriate length and width to match tooth working length and diameter. SAF 1.5mm should be used for canals with initial width of up to ISO #30 (incl.).

SAF 2.0mm should be used for canals starting from size ISO #35 to ISO #55. SAF 3.0mm should be used for canals sized ISO #60 (incl.) and over. If the canal is not fully developed, even SAF 3.0mm might rotate inside the canal, in which case the SAF should be observed carefully during work, and it is advised to press it laterally against the root canal walls during its operation.

8. When the root canal is narrower than ISO #20, or when a 1.5mm SAF is unable to reach working length, a preliminary reproducible glidepath should be established, using PreSAF PREP (heat-treated ISO #21 rotary instrument with an alternating taper starting at .05 and reducing to .04 and .02) or an equivalent file. If the root canal is narrower than ISO #15, it is advised to start by using PreSAF GLIDE (ISO #14 /.03 taper rotary instrument), followed by PreSAF PREP.

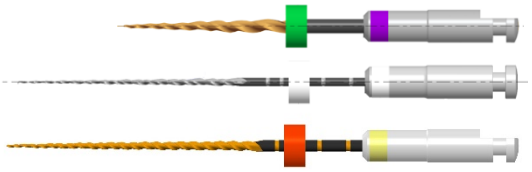

Fig. 4: PreSAF instruments (top to bottom): FLARE / GLIDE / PREP

9. Prior to using 2.0 mm SAF, use an ISO #30 instrument to remove gross pulp tissue.
10. Prior to using 3.0 mm SAF, use an ISO #45 instrument to remove gross pulp tissue.
11. Adjust the rubber stopper on the SAF to indicate the desired working length and connect the SAF to the handpiece head.
12. The SAF can be operated either when outside of the canal, similarly to other motorized instruments, but can also be operated after it is placed inside the root canal. This can be helpful in cases of limited mouth opening or when reaching working length while operating is difficult. It should be inserted gently into the canal, without excessive pressure applied to it vertically.

13. Working length should be reached while operating, within the first 30 seconds of operation – if it does not, or if resistance to entry is experienced, it is advised to make sure that the glidepath preparation was sufficient and to irrigate the canal with tissue-dissolving irrigants, to remove any possible blockage by pulp tissue remnants.
14. Work is performed using light pecking motions (Fig. 5) for 2 minutes in each root canal. The pecking motions should be sufficient to allow disengagement and rotation of the file, to then re-position the file in the inbound pecking motion. The pecking motions are important to assure circumferential shaping, as well as to propagate the movement of irrigant inside the canal.

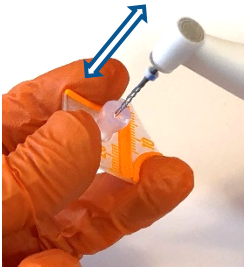

Fig. 5: vertical pecking motions

15. The advised irrigation protocol to be used is combination of sodium hypochlorite (NaOCl) and etidronic acid (HEDP, "Dual Rinse"), to dissolve and remove both organic residue (pulp tissue, bacteria) and inorganic residue (debris, smear layer). The irrigation solution should be mixed immediately prior to the treatment and used within 1 hour from mixing time. In cases where a higher level of disinfection is desired, further work of 1-2 minutes per canal is advised.

16. During its operation, the SAF is expected to expand 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 in the expected size (Fig. 6), 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.

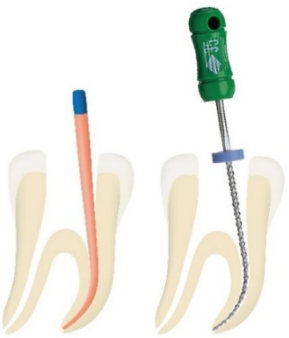

Fig. 6: Gauging of the apical size

17. Canal shaping is now complete. Your preferred method of obturation may be used.
18. The SAF can also be used for re-treatment. In such a case, glidepath preparation that includes the removal of the main bulk of the prior obturation materials (gutta-percha or other) is initially required. An instrument size of ISO #25/06 (Fig. 7) is advised for use for this purpose. Once glidepath to working length has been established, the correct size of SAF should be ensured, as in many cases wider SAFs (2.0 mm or 3.0 mm) may be required, due to the larger diameter of the canal in retreatment cases. In re-treatments of canals obturated by gutta-percha, after the glidepath preparation, 1 minute of work with the SAF with continuous irrigation in the standard protocol is advised. Then, it is advised to turn off the irrigation and suction, to soak the canal with an organic solvent (such as chloroform) and operate the SAF for 30-60 seconds without irrigation, to

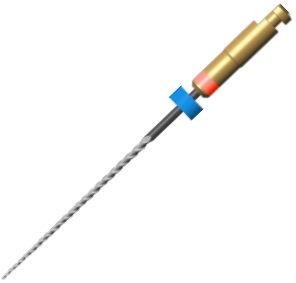

Fig. 7: Example of an initial file for retreatment

soften the gutta-percha and remove it. Then, re-activation of the pump is advised, and the SAF should be operated for another minute. If the canal still has visible remnants of gutta-percha (as seen with optical magnification or a dental x-ray), it can be advised to continue operating the SAF until the residual obturation material is removed.

19. Upon finishing the clinical use of the SAF, it should be disconnected from the SAF Infinitum Handpiece, by holding its base and pulling it away from the Handpiece.

H. Sterilization:

1. The SAF is provided as a pre-sterilized instrument.

I. Disposal

1. The used SAF must be disposed of to a biohazard bin.

J. Reporting

1. Any serious incident that has occurred in relation to the medical device, must be reported to the manufacturer and the authority having jurisdiction in their locale.

Symbols in use:

Symbol	Description
	Do not resterilize
	Do not re-use
	Manufacturer
	Medical Device
	Do not use if package is damaged
	Catalog Number
 XXXXX	Lot Number
	Sterilized using irradiation
	Use-by date
	CE mark
	Read the instructions for use

	Single sterile barrier system
	Humidity limitation
	Atmospheric pressure limitation
	Temperature limit
	Fragile; handle with care

Fig. 8: Symbols

K. **Updated information**: The SAF System Clinical Guidelines, as well as the most updated version of this IFU, are available at: **https://www.redentnova.de/media-center/instructions-for-use**

L. Catalog numbers (#REF):

REF	APPEARANCE	DESCRIPTION
SF-10-150-021-0057		Self-Adjusting File (SAF) 1.5/21 mm (10 pack)
SF-10-150-025-0058		Self-Adjusting File (SAF) 1.5/25 mm (10 pack)
SF-10-150-031-0059		Self-Adjusting File (SAF) 1.5/31 mm (10 pack)
SF-10-200-021-0060		Self-Adjusting File (SAF) 2.0/21 mm (10 pack)
SF-10-200-025-0061		Self-Adjusting File (SAF) 2.0/25 mm (10 pack)
SF-10-200-031-0062		Self-Adjusting File (SAF) 2.0/31 mm (10 pack)
SF-10-300-021-0063		Self-Adjusting File (SAF) 3.0/21 mm (10 pack)
SF-10-300-025-0064		Self-Adjusting File (SAF) 3.0/25 mm (10 pack)

Fig. 9: Self-Adjusting file catalog numbers

M. Manufacturer:

ReDent Nova GmbH & Co. KG.

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Website: www.redentnova.de

Revision Level History

No. rev	Changes
001	Initial version
002	Hermon labs updates
003	ECO #004. Language, IFU symbol first page, Reference numbers
004	Removal of needle
005	CE mark update, minor grammar revisions
006	Addition of the CE marking and clarification of disposal, damaged-packaging and elevated-surface-temperature instructions; adaptation of logos