

NanoShaper[®]

Before using the products, please see the instruction manual as indicated below.

1. PRODUCT DESCRIPTION

The NanoShaper is a root canal instrument designed for canal enlargement. It is mounted on the contra-angle of an endodontic motor and operates through lifting and vertical reciprocating movements.

It features a non-uniform taper (greater than 1%), classified as Type 4 according to ISO 3630-1:2019.

The product is sterile. It has been sterilized by irradiation and has undergone a special heat treatment to form a nanocoated alloy, providing unique flexibility.

2. PRODUCT STRUCTURE AND MATERIALS

The NanoShaper file is composed of three parts: the operative part, the stopper, and the shank.

Main materials:

- 1) Operative part: Nickel-Titanium alloy (NiTi)
- 2) Stoppers: Colorless translucent rubber (CAN19-259705.001).
- 3) Shank: Brass C3604



3. BEFORE USING

Warnings

- 3.1 This product is intended for use by qualified dental professionals only.
- 3.2 Do not use this product for any purpose other than dental treatment.
Use it in accordance with its intended use.

Contraindications and prohibitions

Do not use this product on patient with known hypersensitivity or allergic reactions to any of its components.

4. RE-PROCESSING

The Dental Root Canal Instruments are intended for single use only and are not approved for reuse.

The product has been terminally sterilized by irradiation and is ready for immediate use.

5. SPECIFICATIONS AND METHOD OF USE

5.1 The Specifications of NanoShaper are listed in the table below (based on ISO 3630-1 and ISO 3630-5):

NanoShaper®				
Size	Working Length (mm)	Tip Diameter (mm)	Taper (%)	Color of ring
15/03	21mm 25mm 31mm	0.15	3%	White
20/03		0.20	3%	Yellow
25/03		0.25	3%	Red
30/03		0.30	3%	Blue
35/03		0.35	3%	Green
40/03		0.40	3%	Black
50/03		0.50	3%	Yellow

- 5.2. NanoShaper files should only be used in regions of the canal that have a confirmed and reproducible glide path.
- 5.3. Establish a reproducible glide path using hand files of at least an ISO 08 size.
- 5.4. Use instrumentation files (ZN1, ZN2) with light apical pressure, withdraw it slightly and again apply apical pressure slightly deeper.
- 5.5. Use NanoShaper files (ZN3, ZN4, ZN5, ZN6 and ZN7) without brushing action.
- 5.6. Use NanoShaper files to passively reach working length and then withdraw immediately.
- 5.7. NanoShaper files are manufactured with a process that results in a rainbow appearance (nanocoating). Due to this process, NanoShaper files may appear slightly curved. This is not a manufacturing defect. While the file can be easily straightened using only your fingers, it is not necessary to straighten the file prior to use. Once inside the canal, NanoShaper files will follow the anatomy.
- 5.8. Always use minimal apical pressure. Never force the files inside the canal.
- 5.9. For optimal usage, torque control devices are recommended.
- 5.10. NanoShaper rotary files can be used at motor speeds between 300 rpm and 500 rpm.
- 5.11. **Recommended motor settings:**
NanoShaper ZN1-ZN7 Speed: 500rpm, torque: 3N/cm
- 5.12. The speed and torque settings indicated in the table above are demonstrative and can be modified according to user preferences and equipment possibilities.
- 5.13. NanoShaper files comply with ISO 3630 performance testing. Their durability against twisting and bending exceeds the minimum values specified mentioned standard

6. PRECAUTIONS FOR USE

- 6.1 Choose the most appropriate type of file for each case and follow the general method.
- 6.2 Before use, ensure that the instruments intended for use outside the oral cavity are free from deformations, scratches, and cracks.
- 6.3 If the tip of the file is thin, long or large, there is a risk of breakage or twisting. To prevent this, avoid excessive force and improper angulation during use.
- 6.4 These instruments should not be immersed in a sodium hypochlorite solution for cleaning.
- 6.5 Clean files frequently during instrumentation, inspecting for any signs of distortion or wear, such as missing flutes or nicks.
- 6.6 Irrigate frequently, recapitulate and irrigate the canal throughout the whole procedure.
- 6.7 Use a rubber dam and other protective measures to prevent accidental ingestion or aspiration caused by instrument falling or failure.
- 6.8 Do not use this instrument for any purpose other than the applications listed above.
- 6.9 For use by dentists only.
- 6.10 This product should be treated as medical waste upon disposal.
- 6.11 Dispose of the product if it becomes damaged or contaminated.
- 6.12 After use, clean the instrument with a medical-grade cleaning agent and brush, then remove any foreign substances such as adherent body fluids or tissues
- 6.13 Handle this product with great care to avoid finger injuries due to its sharp-edged components.
- 6.14 NanoShaper files are provided sterile and are single-use only. Reuse may increase the risk of cross-contamination or breakage.

7. CLEANING, DISINFECTION AND STERILIZATION

- 7.1 Not applicable.
- 7.2 NanoShaper file is provided sterile and intended for single use only.
- 7.3 Disinfection, cleaning and sterilization procedures are not recommended
- 7.4 Reuse of NanoShaper file may increase the risk of cross-contamination and instrument breakage

8. TRANSPORTATION

- 8.1 To prevent damage to the medical device during transit, the use of specific racks, trays, or rigid containers is recommended.
- 8.2. If the packaging is compromised, the product shall be considered non-sterile and must be discarded.

9. STORAGES AND SHELF LIFE

- 9.1 Avoid storing in places with high temperatures, humidity and/or direct sunlight.
- 9.2 Keep liquids away. Store at ambient temperature.
- 9.3 Do not damage or puncture the packaging materials.
- 9.4 Apply the “first in, first out” approach to inventory management.
- 9.5 Do not store under a germicidal lamp to prevent deterioration.
- 9.6 The shelf life of endodontic files is 5 years.
- 9.7 Do not use the product after the expiration date indicated on the label.

10. DISPOSAL

The product must be disposed of in accordance with local regulations for the safe disposal of sharp and potentially contaminated medical devices.

11. SERIOUS INCIDENT REPORTING


















Any serious incident related to the product must be reported immediately to the manufacturer and the competent authority, in accordance with local regulations



12. PACKAGING

12.1 Minimum packaging unit: 6 pcs or 3 pcs per aluminium blister pack.

12.2 Assortment: 1 pc of each size per package.

12. EXPLANATION OF RELATED SYMBOLS

Symbols	Explanation
	Caution
	Do not reuse
	Nickel-Titanium alloy
	Rotary Use shank
	Medical Device
	Material of the stoppers: Silicone
	Opened packages are not replaced
	Batch code
	Catalogue Number
	Expiry Date
	Authorized representative in the European Community
	Authorized Representative in United Kingdom
	Manufacturer
	Sterilized using irradiation
	Do not use if package is damaged
	Unique Device Identifier
	Consult electronic instructions for use

Symbols	Explanation
Rx only	Prescription device
	CE Marking and Notified Body identification
	Importer

The specifications, structure, and materials are subject to change without prior notice in response to improvement requirements.

The contents of this instruction manual may be revised without prior notice.



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