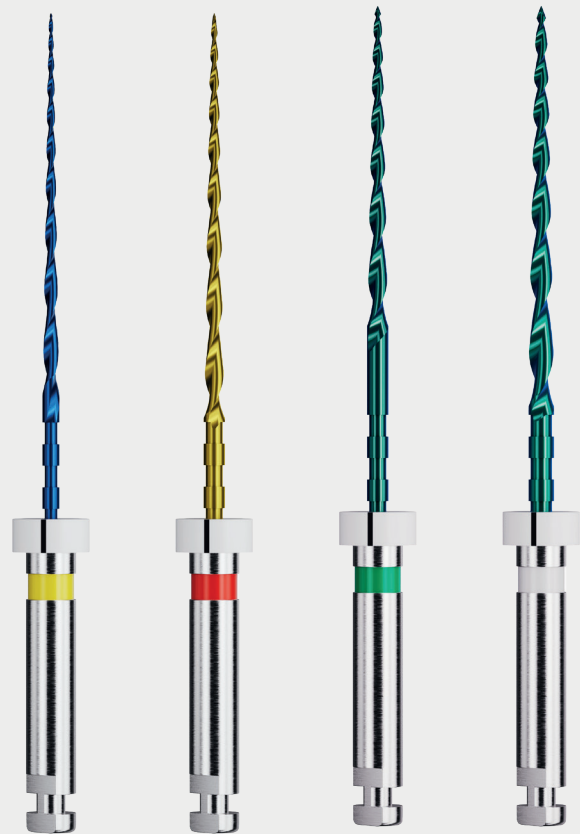




EV1
19/05v

EV2
25/06v

EV3
33/07v

EV4
43/08v

Endostar Vision

Instructions for use

EN

ver. 10, valid from: 19.01.2026



1. Intended purpose

Intended use:

Rotary endodontic files intended for mechanical preparation of root canals during root canal treatment with a compatible endodontic contra-angle handpiece:

- Permanent teeth (adults and adolescents with permanent dentition): mechanical shaping and preparation of root canals as part of endodontic treatment.
- Deciduous teeth (pedodontics, children aged 4–9 years): pulpectomy in selected deciduous teeth with irreversible pulpitis or pulp necrosis, provided there is minimal/no root resorption and there are conditions that allow for tight crown closure.

Contraindications:

- Deciduous teeth with advanced physiological or pathological root resorption.
- Teeth that cannot be predictably restored with a tight crown filling after endodontic treatment.
- Any medical or dental condition for which endodontic treatment is clinically inadvisable in the opinion of a doctor.
- Hypersensitivity to nickel.
- Inability to isolate with a dental dam or gain adequate access.

Intended patient group:

- Adults and adolescents with permanent dentition.
- Children aged 4–9 years – only for pulpectomy of deciduous teeth.

Users:

Rotary endodontic files are intended for use only by professional stomatologists (e.g., dentists, including endodontists). If using in children, the operator should have relevant experience and knowledge in the field of pedodontics.

2. Possible adverse effects

- Canal transportation, ledge or canal perforation.
- Postoperative pain, hypersensitivity or exacerbation (temporary).
- Hypersensitivity reactions to nickel (very rare).

3. Clinical benefits

- Enabling root canal treatment and preserving tooth function.
- Low recurrence rate between visits with appropriate control of working length and careful sequence of procedures.

4. System description

Endostar Vision is a range of advanced rotary files for efficient and effective root canal shaping. They are manufactured from the highest-quality nickel-titanium alloy, which additionally underwent heat treatments selected specifically for the given instrument size and character of work to be performed in the canal. The instruments also differ in taper, core thickness and cutting edge depth (these parameters were individually selected for each instrument). As a result, a very high degree of flexibility and durability of the instruments has been achieved, with their properties correlated to the function the instrument performs in the set. The system's files easily fit into even very curved canals, minimizing the risk of canal perforation. The modified shape of the NiTi S file with two cutting edges ensures effective cutting and transport of dentin outwards and speeds up canal shaping. The non-cutting tip allows for safe canal shaping, reducing the risk of *via falsa* (deviation from the original root canal), perforation and/or ledge formation.

Endostar Vision includes three essential instruments: EV1, EV2 and EV3, designed to work in all canals, according to the doctor's clinical assessment:

EV1 – *Azure HT Technology by Poldent*, blade color: azure/bluish; shaft marking: single yellow stripe (ISO 19),

EV2 – *Citrine HT Technology by Poldent*, blade color: lemon yellow/yellow; shaft marking: single red stripe (ISO 25),

EV3 – *Opal HT Technology by Poldent*, blade color: green, opalescent, shaft marking: single green stripe (ISO 33),

and an additional instrument EV4 designed to work in very wide canals:

EV4 – *Opal HT Technology by Poldent*, blade color: green, opalescent, shaft marking: single white stripe (ISO 43).

All instruments have millimeter markings. These are grooves/cuts starting at the 19th millimeter, just above the cutting edges. Each groove/cut is 1 mm wide. The first ends at 20 mm, the second at 22 mm, and the third at 24 mm – counting from the tip of the instrument. They provide an additional indication, for doctors who want to use these markings, of the current depth of work in the canal. All instruments have a variable taper that decreases towards the shaft (the lower-case "v" stands for taper variable, and appears next to file size designations).

5. General recommendations regarding root canal work

- Work inside the canal for the shortest time possible.
- The files are very sharp and should be used very carefully, applying minimal force, without being "pushed" excessively into the root canal.

- Use the number of instruments that is actually required for the specific clinical situation.
- It is natural for pre-curved Endostar Vision files not to straighten at room temperature, in contrast to non-heat treated NiTi alloy files.
- Similar to e.g. steel files, Endostar Vision files may be pre-curved prior to insertion into the canal in order to bypass a ledge in the canal.
- It is also acceptable to insert a pre-curved file into the canal before turning on the endodontic handpiece, as this greatly facilitates access to canals in molars.

6. Recommended movements

The instruments may be operated with three types of motion, depending on the dentist's individual preferences, the diagnosis in a specific case and the endodontic handpiece available at the practice:

- Rotational clockwise motion.
- Reciprocal net clockwise motion.
- Complex clockwise motion (e.g. OTR).

7. Recommended torque settings

Instrument	Torque (Ncm)
EV1	1.0-1.5
EV2	1.5-2.0
EV3	2.0-3.0
EV4	

The files can be used at 300–500 rpm. The more experienced the doctor is, the higher the speed and torque (within the specified ranges) can be used.

The torque values provided in the table should be treated as a reference.

Use the closest values available for the specific type of equipment used at your practice but do not exceed the upper limit for a given instrument size.

8. Compatibility

The instruments are compatible with endodontic handpieces which meet the following conditions:

- Design compliant with ISO 14457:2017.
- Allow parameter setting in accordance with section 7 of the instructions for use.

- Perform at least one of the motion types listed in section 6 of the instructions for use.

9. Recommended number of uses of a single instrument

The Endostar Vision instruments may be sterilized and used up to 10 times, provided that a visual inspection performed by a dentist prior to a subsequent use indicates that the instrument has not been damaged due to previous use. Special attention should be paid to:

- Visible unwinding (or excessive twisting) of the instrument flutes as compared to a new instrument. Flute irregularity is a sign that reusing the instrument may lead to its fracture inside the canal.
- Permanent deformation of the instrument, especially bends which are not gentle arches but have a visible breaking point.
- Check whether the cutting part is securely attached to the shank.
- If the instrument has been subjected to high torsional forces, especially in highly curved canals, consider using it only once.



Using the instrument more times than recommended may result in blade fracture within the canal.

Always dispose of any file that appears to be damaged.

For detailed recommendations on the number of uses per instrument, visit www.ifu.poldent.pl, as well as www.poldent.pl and www.endostar.eu.

10. Clinical instructions for use



Flush the canal after each use of the file.

Clean the files frequently to remove dentin debris.

1. Develop access to root canals.
2. Locate canal orifices and widen them* (use, for example, Gates-Glidden drills, openers, ultrasound, etc.)

**Through its design, the Endostar Vision system allows tissue-preserving canal shaping in the crown area; as a result, penetration without previous widening of the canal orifices is possible.*

3. Perform an initial penetration of the canal with a K10 file at approximately 2/3 of the estimated canal length* – do not move the file toward the apex)

**The canals are most often between 18 and 22 mm long, therefore 2/3 of their length will be 12–15 mm.*

4. Perform an initial widening of approximately 2/3 of the estimated canal length (approx. 12–15 mm), working alternately with the EV1 and EV2 files:*
- a. with an EV1 file, make 3 up-and-down movements in the canal, irrigate, recapitulate with a K10 file and irrigate the canal again,
- b. with an EV2 file, make 3 up-and-down movements in the canal, irrigate, recapitulate with a K10 file and irrigate the canal again,
- c. repeat steps a. and b. until you reach about 2/3 of the estimated canal length with the EV2 file.*

**If the canal is very narrow from the start, the use of Endostar EP Easy Path instrument is recommended before using the EV1 and EV2 instruments.*

It is recommended to move into the canal gradually and not to apply excessive pressure on the instruments. Make 3 up-and-down movements with each instrument, using a brushing technique, i.e. pressing the instrument against the outer wall of the canal (distal from the furcation) while pulling out of the canal.

5. Use a K10 file to ream the canal out and determine the working length (WL). Further treatment will depend on how the K10 file behaves in the canal:
 - if the K10 file easily moves toward the apex, proceed to step 7,
 - if reaching the apex with the K10 file is constricted, work longer with it to achieve the working length; proceed to step 6.
6. This means that the canal is quite narrow and difficult – in such a case, it is recommended to increase the size of the glide path with the Endostar EP Easy Path nickel-titanium mechanical instrument instead of steel hand instruments. Shape the canal using this instrument to achieve the working length, with the following work sequence: 3 up-and-down movements with the Endostar EP Easy Path instrument, irrigation, recapitulation with the K10 file and re-irrigation of the canal, 3 up-and-down movements with the Endostar EP Easy Path instrument etc. until WL is achieved. Proceed to step 8.
7. This means that the canal is not difficult and the size of the glide path can be increased with a K15 steel hand instrument or the Endostar EP Easy Path mechanical instrument. Shape the canal with the selected instrument to achieve the working length so that the instrument moves easily along the WL when pulled out for a few mm from the canal.
8. Using an EV1 file, shape the canal to achieve the working length. Follow the work sequence: 3 up-and-down movements with the EV1 instrument, irrigation, recap-

tulation with the K10 file and re-irrigation of the canal. Repeat this sequence until the working length is achieved with the EV1 instrument.

9. Using an EV2 file, shape the canal to achieve the working length. Follow the work sequence: 3 up-and-down movements with the EV2 instrument, irrigation, recapitulation with the K10 file and re-irrigation of the canal. Repeat this sequence until the working length is achieved with the EV2 instrument. Finish the preparation and proceed to step 13, unless reaching the working length with the EV2 instrument was very easy and the instrument seemed to work loosely along the WL* – in such a case, it is advisable to widen the canal with the EV3 instrument; proceed to step 10.

**Such a situation will often involve quite wide canals such as in maxillary central incisors or palatine canals in maxillary molars or canals with periapical lesions, etc. If in doubt as to whether the work in a particular canal can be completed with the EV2 instrument or should be continued with the EV3 instrument, a test with a size 25 hand instrument (nickel-titanium) can be performed. Passively insert the file until the working length is reached (with a vertical motion, without rotation). If you can feel slight resistance while sliding the file further along the working length, this means that preparation may be completed with the EV2 instrument. If you feel the file encounters no resistance when the working length is reached, further widening of the canal using the EV3 instrument is recommended (step 10).*

10. Using an EV3 file, shape the canal to achieve the working length. Follow the work sequence: 3 up-and-down movements with the EV3 instrument, irrigation, recapitulation with the K10 file and re-irrigation of the canal. Repeat this sequence until the working length is achieved with the EV3 instrument.
11. If reaching the working length with the EV3 instrument was very easy and the instrument seemed to work loosely, it may be advisable to widen the canal with the EV4 instrument; proceed to step 12. If the preparation is to be completed with the EV3 instrument, proceed to step 13.
12. Using an EV4 file, shape the canal to achieve the working length. Follow the work sequence: 3 up-and-down movements with the EV4 instrument, irrigation, recapitulation with the K10 file and re-irrigation of the canal. Repeat this sequence until the working length is achieved with the EV4 instrument.
13. Perform a final disinfection of the canal.
14. Fill the canal with any technique, using a size 25/04 gutta-percha cone if the preparation was completed with the EV2 instrument, a size 35/04 gutta-percha cone if the preparation was completed with the EV3 instrument, or a size 45/04 gutta-percha cone if the work was completed with the EV4 instrument. The colors of the gutta-percha cone markings should be identical to the colors of the markings on the shafts of the EV2, EV3 and EV4 mechanical instruments. Remember that preparing the canal using only the EV1 instrument is not sufficient for its proper cleaning; therefore, the work may not be finished

and the canal cannot be filled after this instrument.

Please also note that in particularly difficult canals, the 2-1-0 working technique works well. It involves the following: using a given mechanical instrument, when approaching the apex, interrupt the work at WL -2 mm, irrigate, recapitulate with a K10 instrument and repeat irrigation. Then, using the same mechanical instrument, reach one millimeter deeper, i.e. to WL -1 mm, irrigate, recapitulate with a K10 instrument, repeat irrigation and only then insert the mechanical instrument at the entire WL depth.

11. Warnings

This device is intended for professional dental practice use.

12. Cleaning, disinfection and sterilization

Non-sterile devices. They should be cleaned, disinfected and sterilized prior to first use and after each use in accordance with the instructions available at www.ifu.poldent.pl, as well as at www.poldent.pl and www.endostar.eu.

13. Device lifetime, storage conditions

The device lifetime is 10 years (date of manufacture is included on the label). Instruments should be stored at room temperature in a dry, dust-free, clean environment.

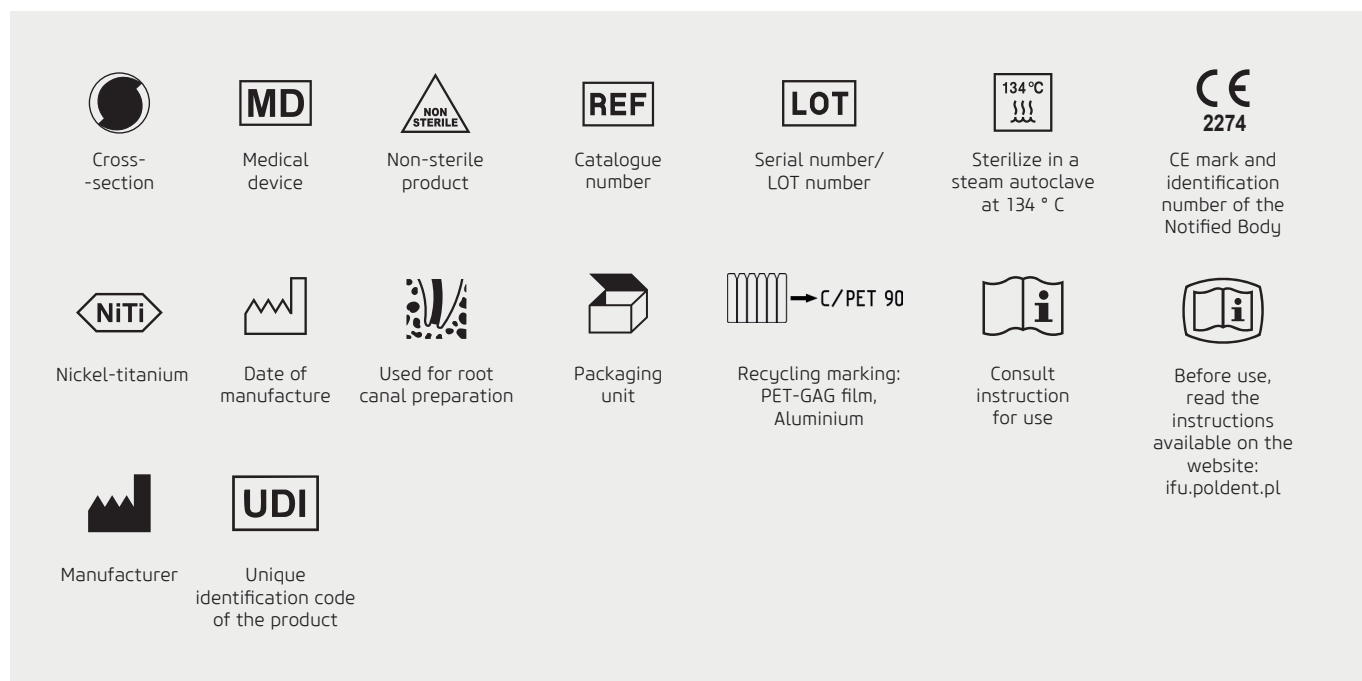
14. Disposal

Used instruments are classified as sharp medical waste. After use, they must be placed in a puncture-resistant, rigid-walled container. Disposal should then proceed in accordance with local regulations regarding medical waste management.

15. Complaints

Complaints and the occurrence of adverse device effects should be reported directly to the distributor or manufacturer. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

There may be slight differences in color between files manufactured using a given HT technology, and their blades may be slightly arched; this does not affect the product quality in any way.



Upon user's request, the instruction for use in paper form can be provided free of charge within the European Union. The document will be sent within 7 days from the order submission. A paper version order form is available on each product site at www.ifu.poldent.pl.



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