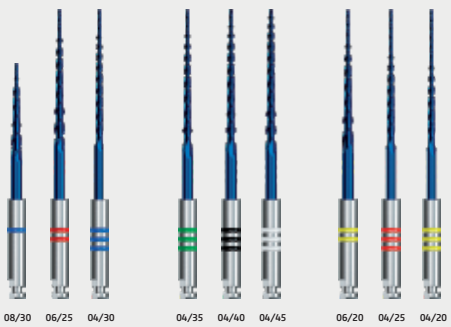
E3 *Azure*

HT Technology

EN

endo★star



08/30 06/25 04/30

Endostar E3 *Azure* Basic

04/35 04/40 04/45

Endostar E3 *Azure* Big

06/20 04/25 04/20

Endostar E3 *Azure* Small

Instruction for use

Endostar E3 Azure

AZURE HT Technology by Poldent - innovative heat treatment technology designed by Poldent

1. Important information regarding the system

Endostar E3 Azure is a set of modern rotary files used for effective and efficient root canal preparation. They are manufactured from a highest quality nickel-titanium alloy, which additionally subject to a special heat treatment called AZURE HT Technology by Poldent, which resulted in very high flexibility and durability. The files can easily fit even strongly curved canals, this way minimizing the risk of canal perforation. The modified shape of the NiTi S file with two cutting edges ensures efficient cutting, transport of debris up the canal and decreases preparation time. The inactive tip allows safe preparation, minimizing the risk of a via falsa, perforations and zipping. Easy-to-read taper value (number of stripes on the handle) and ISO size (color stripes) enables effortless use of the instruments.

Endostar E3 Azure Basic

Should be used with normal width, straight or slightly curved canals.

Endostar E3 Azure Big

Is not a separate rotary system. This is an extension of the Endostar E3 Azure Basic and is used for shaping wide canals, for which final preparation to size 30 is not sufficient. It should always be preceded by initial preparation performed with the Endostar E3 Azure Basic or Endostar E3 Basic.

Endostar E3 Azure Small

is not a separate rotary system. This is an extension of the Endostar E3 Azure Basic for use with very narrow and curved canals. The canal should be first shaped with the use of Endostar E3 Azue Basic files or Endostar E3 Basic.

> A handpiece, which can provide 300 rpm, should be used. The operating speed of the handpiece should be constant throughout the shaping process.
> Do not apply excessive force. An up-and-down motion should be used when operating the files.
> Shaping time should be as short as possible.
> Always use a lubricating agent when shaping the canal.
> The files are very sharp and should be used very carefully, with little force and without excessive "pushing" down the canal.
> Operate the instruments and handpieces according to their operating instructions (especially torque and speed settings).
> Use the type and amount of instruments that is truly needed in a given clinical situation.
> Before using the instruments, be sure to see them working outside the oral cavity to check for deformations, and/or cracks.
> Dispose of as medical waste.
> The Endostar E3 Azure files may remain bend and may not straighten at room temperature as the non-modified NiTi alloy files do. This is a normal feature of the instrument.
> The Endostar E3 Azure files can be pre-bent, the same way as the steel files, before inserting them into the root canal in order to bypass the existing ledges.
> It is also acceptable to insert pre-bent file into the canal and then start the micromotor, this simplifies the access to the root canals in molars.

2. Recommended movements

All instruments have been designed and manufactued in such a way that they can be used in three types of movements depending on the individual preferences of the dentist, the case diagnosis and the type of a handpiece available in the dental practice.

> Rotary movement - the instrument rotates continuously 360° in a clockwise direction (CW - Clock Wise).

> Reciprocal right cutting movement - the instrument performs alternating movements: clockwise (CW) and anti-clockwise (CCW – Counter Clock Wise) except that the CW movement angle must be larger than CCW angle, e.g. 90° CW and 30° CCW. It is recommended that the rotation in the CW direction should be between of 90° to 270° and in the CCW direction between 30° to 90°, so that the net rotation in the CW direction in each cycle is between 60° to 240°, that means a full 360° CW rotation is achieved after 1.5 to 6 cycles.

CCW CW

90°≤CW≤270°

30°≤CCW≤90°

> Complex movement - it is a kind of movement that combines the rotary movement with the reciprocal movement. After inserting file into the root canal, the file performs a rotary motion, and if the resistance for the file in the canal is too high, the rotary motion changes to the reciprocating movement. When the resistance decreases, the rotary motion returns. An example of this is OTR movement.

3. Recommended torque settings

System	File number	Standard Torque (Ncm)	Advanced Torque (Ncm)
E3 Azure Basic	1 (08/30)	2.4	3.0
	2 (06/25)	2.1	3.0
	3 (04/30)	1.2	2.1
E3 Azure Big	1 (4/35)	2.1	3.0
	2 (4/40)	2.1	3.0
	3 (4/45)	2.1	3.0
E3 Azure Small	1 (06/20)	1.2	2.1
	2 (04/25)	1.2	2.1
	3 (04/20)	1.2	2.1

Files should be used with motor speed at 300 rpm.

The torque settings indicated in the table above are only suggestions and may vary according to each user preferences and endodontic motor capabilities. Do not exceed the upper torque limit which is different for each instrument. If precise torque settings cannot be set, and only manufacturer-specific torque levels are available, be sure to select one that does not exceed the recommended limit.

4. Recommended number of usage

Endostar E3 Azure instruments can be sterilized and used many times, provided that the visual inspection performed by the dentist prior to next usage shows that the instrument remains undamaged, it is not bent, deformed, does not show signs of blade wear and can be securely attached to the handpiece. The special attention has to be paid to the excessive unwinding (or winding) of the instrument.
The instrument flutes should be regularly spread along the entire length of the blade. If at some point of the blade, the flutes are too close or too far apart (there is no regularity in the flutes pitch as compared to an unused instrument), this means that instrument can break in the canal.

It is very important to notice any permanent deformations on the instrument, especially those, when the instrument curvature does not have the form of a smooth arc, but is sharply bent and has a visible breaking point. Re-usage of such an instrument can lead to its breaking. The heat-treated NiTi alloy naturally allows these instruments to be bent in the form of a smooth arc.
In case of doubt, the file can be placed in any environment (fluid, air) at a temperature slightly above 40°C for a few seconds. The blade should straighten or remain smoothly curved. If the file is still deformed, it means it is permanently damaged and must not be used again.

After each usage, check that the blade is securely fixed in the shank. If the file has been subjected to a high torsion force, especially in highly curved canals, the instrument should be used only once.

Dispose the file which appears to be defective.

5. Clinical instruction for use

Rinse the canal each time after the file is used.
Clean the files of any debris frequently.

Endostar E3 Azure Basic

A. Cavity preparation.
Prepare the cavity. Use a rubber dam.

B. Location of canals.
Locate all canal orifices. Lubricate the canals.

C. Specifying the working length of the canal.
Specify the working length of the canal using your method of choice.

D. Preparing the canal with hand instruments.
Continue to shape the root canal with hand files up to size 20. This way, you will create a glide path for rotary instruments instruments. This will also reduce the risk of breaking the rotary file.

E. Preparation of the upper part of the root canal.
Shape the canal orifice with the Endostar E3 Azure Basic File No. 1 (08/30) until you reach a maximum of 1/2 of the total canal depth. Do not use this file when the canal is highly curved (in such cases use the Endostar E3 Azure Small).

F. Preparation of the middle part of the root canal.
Begin to work with file No. 2 (06/25). Perform up-and-down movements. Shape the canal up to 2/3 of the working length. Inspect the working length with the size 15 hand file and apex locator. Next, insert file No. 2 at full working length.

G. Shaping of the apical part of the root canal.
Use file No. 3 (04/30) to widen the apical portion of the canal until full working length is reached. Confirm that full working length was reached with hand file size 15 and apex locator. Next, finish work with a nickel-titanium hand file size 30. Insert the file at the working length (vertical movement without rotation). If you feel a slight resistance to the further movement of the file at the working length, this means that the preparation can be finished on size 04/30. If a wider preparation of the apex is needed, continue to work with larger hand instruments size 35, 40 etc. or consider using the Endostar E3 Azure Big

Endostar E3 Azure Big

A. After preparation of the canal with the use of file No. 3 (04/30) from the set of Endostar E3 Azure Basic is completed, shape the canal with instrument No. 1 from the Endostar E3 Azure Big (04/35) until full working length is reached. Finish with hand NiTi file size 35.
Insert the file at the working length (vertical movement without rotation). If you feel a slight resistance to the further movement of the file at the working length, this means that the preparation can be finished on size 04/35. If you feel that the file does not encounter resistance at the working length, it is advisable to expand the canal described in point B.

B. Shape the canal by inserting instrument No. 2 from the Endostar E3 Azure Big (04/40) at full working length. Finish with hand NiTi file size 40. Insert the file at the working length (vertical movement without rotation). If you feel a slight resistance to the further movement of the file at the working length, this means that the preparation can be finished on size 04/40. If you feel that the file does not encounter resistance at the working length, it is advisable to expand the canal described in point C.

C. Shape the canal using instrument No. 3 from the Endostar E3 Azure Big (04/45) until you reach full working length. Finish with hand NiTi file size 45. Insert the file at the working length (vertical movement without rotation). If you feel a slight resistance to the further movement of the file at the working length, this means that the preparation can be finished on size 04/45. If you feel that the file does not encounter resistance at the working length, it is advisable to expand the canal larger-sized hand files such as size 50, 60 etc.

Endostar E3 Azure Small

A. Prepare the cavity.
Locate the orifices and specify the working length of the canal. Next, prepare the canal with hand instruments as specified in the Endostar E3 Azure Basic clinical instruction.

B. Preparation of the upper part of the root canal.
Shape the canal orifice with the use of the Endostar E3 Azure Basic No. 1 (08/30) file until delicate resistance is detectable. Do not apply excessive force to the instrument especially in highly curved canals.

C. Preparation of the middle portion of the root canal.
Begin to work with file No. 2 from the Endostar E3 Azure Basic (06/25). Perform up and down movements. Work to maximum of 1/2 of working length. Inspect the working length with the size 15 hand file and apex locator. Next, with the use of file No. 3 which is part of the E3 Azure Basic (04/30), try to go a few millimeters deeper down the canal. If the file cannot go deeper down the canal, do not force it. Finish the preparation with the Endostar E3 Azure Basic and continue with the Endostar E3 Azure Small.

D. Shaping of the apical part of the root canal.
With the use of file No. 1 from the Endostar E3 Azure Small (06/20) shape the canal a few millimeters down. Do not force the instrument down the canal. Take file No. 2 (04/25) and continue to shape the canal. Stop working 2 mm before reaching full working length. Use file No. 3 (04/20) until full working length is reached. File No. 3 (04/20) allows shaping even of very narrow and extremely curved canals. Next, go back to file No. 2 (04/25) and use it until full working length is reached.

E. Widening the root canal.
After checking the apical width with the NiTi file, consider widening the canal with file No. 3, which is part of the Endostar E3 Azure Basic (04/30) set. Skip this step in extremely curved canals and finish shaping at size 04/25.

6. Warnings

This product is for professional dental use only.

7. Cleaning and disinfection

Detailed instructions for cleaning, disinfection and sterilization can be found on the website www.poldent.pl and www.endostar.eu in the download tab.

8. Sterilization

This is a non-sterile product. Sterilize before use. The instruments can be sterilized in a steam sterilizer (autoclave) at 134°C. Recommended sterilization time: 3 minutes at 2.1 bar overpressure. Instruments can be disinfected with mild disinfectants and washed in ultrasonic cleaners.

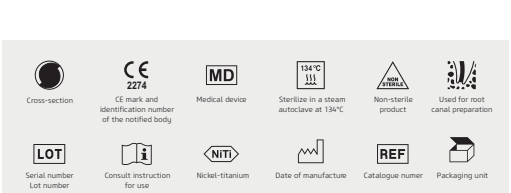
9. Storage

Instruments should be stored at room temperature in a dry, dust-free and clean environment.

10. Product claims

Please notify the distributor and manufacturer of any claims or adverse events which occurred as a result of operating this device. Each serious incident connected with this product should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

Files in the package may vary slightly in color, and the blades may be slightly curved. These differences do not affect the quality of the product. They are natural results of the applied heat treatment - Azure HT Technology by Poldent.



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