Multilingual
Instruction for use
XP-4D®

Contents

FKG REF. 99.FX4.10.01A.XX_REV0_2025-12-05

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EN

FOR DENTAL USE ONLY

INSTRUCTIONS FOR USE – XP-4D®

1) DESCRIPTION

XP-4D®			
STARTER	**STANDARD**	**MEDIUM**	**LARGE**
20/.03v	30/.03v	40/.03v	50/.03v
			
Working part of the file rather yellowish		*Working part of the file rather bluish*	
Recommended speed: 800-1’000 rpm			
Torque limit: 1 Ncm			

2) REFERENCES

					Length in mm		
References	**Designation**	**Sizes**	**Sterile**	**Reusable***	**21**	**25**	**31**
S1.XB0.00.0xx.FK	XP-4D STARTER	020/.03v	YES	YES	X	X	X
	XP-4D STANDARD	030/.03v	YES	YES	X	X	X
	XP-4D MEDIUM	040/.03v	YES	YES	X	X	X
	XP-4D LARGE	050/.03v	YES	YES	X	X	X
S1.XB0.00.SAx.FK	XP-4D Assortment	020/030/040/050/.03v	YES	YES	X	X	X
	XP-4D Sequence	020/030/.03v	YES	YES	X	X	X
	Promo Set XP-4D	020/030/040/050/.03v	YES	YES		X	

* These devices can be used for a maximum of 8 canals and can be reprocessed up to 10 times.

3) PARAMETERS FOR USE

Recommended speed: 800-1’000 rpm continuous rotation
Torque limit: 1 Ncm
XP-4D® instruments are compatible with endodontic motors compliant with ISO 1797.

4) INTENDED USE

XP-4D® endodontic instruments are intended for root canal treatment and retreatment.

5) INDICATIONS FOR USE

XP-4D® endodontic instruments are indicated in case of pulp or periapical diseases that require root canal treatment.
All instruments are designed for preparation, shaping and retreatment of root canals.
XP-4D® endodontic instruments are intended for use in medical or hospital facilities, by qualified health professionals.

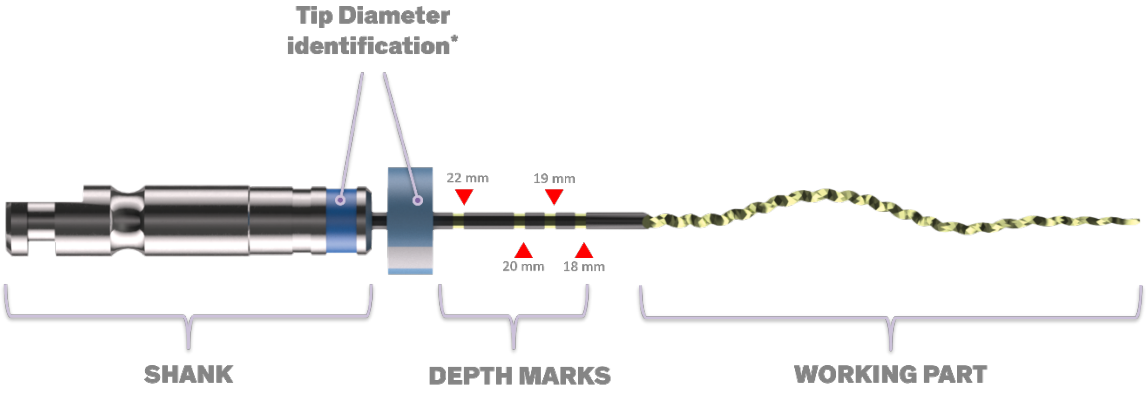
FKG REF. 99.FX4.10.01A.XX_REV0_2025-12-05

6) KEY PERFORMANCES

XP-4D® instruments are compliant with all applicable testing requirements of the ISO 3630 series of standards.

7) COMPOSITION

The working part of these instruments is made of Nickel-Titanium and carries a shank (Crominox-platted maillechort). XP-4D® endodontic instruments carry a silicone endo stop to determine the working length of root canal preparation.



** Only applicable for final shaping files (STANDARD/MEDIUM/LARGE)*

8) CONTRAINDICATION

No contraindication based on the patient population is known.

9) ADVERSE REACTIONS

None known.

10) WARNINGS AND PRECAUTIONS

For your safety, the safety of your patients and the safety of third parties, observe the safety notes below to minimize the following risks to XP-4D® endodontic instruments:

User qualification and patient population

- The instructions for use are a component of the product and must be read carefully prior to use and be accessible at all times.
- XP-4D® endodontic instruments may only be used in accordance with the intended use, any other type of use is not permitted.
- These instruments have not been tested on children, pregnant nor breastfeeding women.

Infection / Toxic or allergic reaction hazards

- XP-4D® endodontic instruments must not be used on individuals with a known allergic sensitivity to Nickel-Titanium and silicone.
- For your own safety, wear personal protective equipment (masks, gloves, and goggles) during the treatment and reprocessing of the instrument.
- Do not use if sterile packaging seal is broken, damaged or wet.

FKG REF. 99.FX4.10.01A.XX_REV0_2025-12-05

- Do not use the instruments after expiration date.
- For reusable instruments, use approved cleaning and disinfecting agents:
    - Washing: Neodisher® Mediclean Forte (0.5 % concentration)
    - Thermal disinfection: Neodisher® Mediklar Special (0.03 % concentration)

  in accordance with the reprocessing instructions (see section 13).
- Reprocess the instrument appropriately before disposal.

Breakage / Deterioration / Inhalation or swallowing hazards

A damaged instrument or components could injure patients, users and third parties.

- Carefully read the label, marking on the packaging and this instruction for use to ensure the correct identification and use of device.
- Use a dental dam when using XP-4D® endodontic instruments to avoid inhalation or ingestion by the patient.
- Take several radiographs from different angles to determine the anatomy of the root canals (length, width and curvature).
- Always inspect the instrument(s) before use, and discard (it) them if there are any visible defect(s).
- Cracks, deformations, signs of corrosion, loss in color or marking are signs that the device is no longer able to achieve the required performance level and should be discarded.
- Regularly clean flutes and inspect instrument during use, and discard if it shows any signs of distortion or wear.
- If XP-4D® endodontic instrument is not progressing easily, withdraw it from the canal, clean it, check its cutting edges, then irrigate the canal and repeat the process.
- Do not exceed a sterilization temperature of 135°C.

Device packaging

- The packaging of the instruments should be carefully examined before opening (packaging integrity, no humidity, no visual degradation of instruments) to ensure that the packaging's integrity has not been compromised during transport and storage.
- If the packaging has been opened, damaged, become wet or the expiry date has passed, the sterile state of the instruments inside the packaging is not guaranteed. Discard the device(s) that are single use and consult the reprocessing instructions available on FKG's website for multiple use device(s).

Warnings and precautions for the (re)processing of instruments

- XP-4D® endodontic instruments that are provided sterile, may be reprocessed for multi-usage following reprocessing instructions available on FKG's website

Furthermore, it is the responsibility of the practitioner to always check its instruments before each use to identify possible signs of defects.

In case of accident

- All serious events occurring in relation to the product must be reported to the manufacturer and the competent authority according to local regulations.

FKG REF. 99.FX4.10.01A.XX_REV0_2025-12-05

11) PROTOCOL FOR USE

Root canal treatment

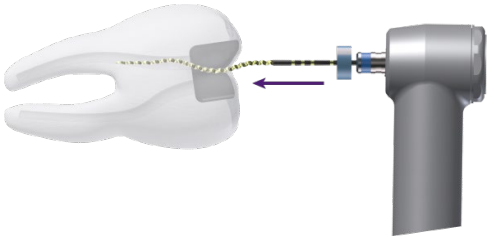


Figure 1

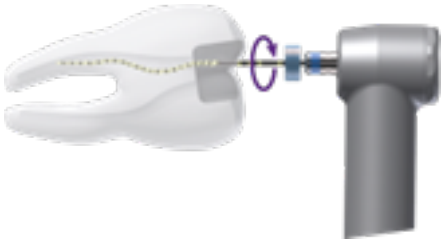


Figure 2

1. Create straight-line coronal and radicular access.
2. If necessary, use Barbed Broach to remove pulp tissue. *Barbed Broach must always enter the root canal gently.*
3. Use an ISO 010 hand file to explore the canal.
4. Determine the working length using a radiograph. In addition, electronical working length determination can be achieved.
5. Establish a glide path with the **XP-4D® STARTER** until the file reaches the pre-established working length. **XP-4D® STARTER** is to be used with long strokes until working length, remove entirely the file from canal, clear away debris and return to working length.
6. Start the shaping procedure, applying your usual irrigation protocol.
7. Insert the shaping file **XP-4D® STANDARD** into the canal until resistance (Fig. 1), retract (tip loose) and start the motor.
8. Use very long gentle strokes to progress down to working length (WL) (Fig. 2). Apply very light apical pressure and allow the file to progress passively along the canal. Repeat until the working length is reached. Usually, it should be reached in one or two attempts. Clean the flutes from any debris prior to re-insertion.
   Never force the file and always keep it spinning and moving while in the canal. Always keep the canal filled with irrigant while using the files to avoid debris accumulation in the canal space.
9. Once the working length is reached, remove the file.
10. Irrigate the canal in order to eliminate suspended debris.
11. If necessary, repeat instructions 6 to 9 with file **XP-4D® MEDIUM** and **XP-4D® LARGE** in sequence, based on the expected apical diameter of the root canal.
12. Choose the gutta percha cone matching the size of the last shaping file's used and confirm that the preparation has the right size; **XP-4D® Bio GP Cones** are color-coded to match **XP-4D®** files.
13. Apply your usual disinfection protocol.

Once all the canals have been shaped, proceed with the deep cleaning of the canals. *For an optimal result, the use of Finisher is recommended.*

Once the cleaning of the canals is completed, proceed to the next phase of treatment:

14. Obturate with **XP-4D® Bio GP cone** and sealer. *TotalFill® BC Sealer™ is recommended.*

FKG REF. 99.FX4.10.01A.XX_REV0_2025-12-05

Root canal retreatment

Figure 1

Figure 2

Figure 3

Figure 4

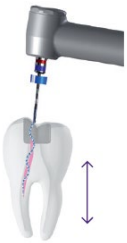


Figure 5

Figure 6

1. Gently engage a retreatment instrument into the obturation material in order to create a 3-4 mm starting point for the XP-4D tip (Fig. 1). *For an optimal result, the use of DR1 (D-Race) is recommended.*
2. Place one drop of solvent in the coronal space created and wait for at least 1 minute (Fig. 2).
3. Place the tip of **XP-4D® STANDARD** into the prepared space in the gutta percha, disengage slightly and start the motor (Fig. 3). *Recommended: 800-1'000 rpm - 1 Ncm.*
4. Use pecking motion until the **XP-4D® STANDARD**´s tip engages the gutta percha. Then use light pressure to help advance the **XP-4D® STANDARD** down the canal until working length or the end of the previous filling material is reached (Fig. 4). Add solvent if needed.
5. Allow the **XP-4D® STANDARD** to gently corkscrew around the gutta percha and tease out large strands of gutta percha using long gentle strokes (Fig. 5). Note: you may need to remove gutta percha from the surface of the instrument.
6. After the removal of the gutta percha, determine the working length (WL) with an electronic apex locator.
7. Once the WL is confirmed, achieve this length with the **XP-4D® STANDARD**, irrigate and fill the pulp chamber and canals with NaOCl.
8. Use the **XP-4D® STANDARD** for long gentle strokes to WL and irrigate the canal to eliminate suspended debris.
9. Once the working length is reached, remove the file.
10. Irrigate the canal in order to eliminate suspended debris.
11. If necessary, repeat instructions 8-9 with file **XP-4D® MEDIUM** and **XP-4D® LARGE** in sequence, based on the expected apical diameter of the root canal.
12. Choose the gutta percha cone matching the size of the last shaping file's used and confirm that the preparation has the right size; **XP-4D® Bio GP Cones** are color-coded to match **XP-4D®** files.
13. Apply your usual disinfection protocol.

Once all the canals have been shaped, proceed with the deep cleaning of the canals. *For an optimal result, the use of Finisher R is recommended.*

Once the cleaning of the canals is completed, proceed to the next phase of treatment:

14. Obturate with **XP-4D® Bio GP cone** and sealer. *TotalFill® BC Sealer™ is recommended.*

12) CONDITIONS AND TERM OF STORAGE, SHELF-LIFE

The shelf-life is 5 years for sterile instruments. The use-by date is indicated on the packaging.
Sterility is preserved and guaranteed for the whole shelf life unless the packaging is broken, or the storage conditions are not respected.

FKG REF. 99.FX4.10.01A.XX_REV0_2025-12-05

13) REPROCESSING PROTOCOL

Instruments must be reprocessed following reprocessing instructions available on FKG's website.
Due to the design of the instruments and/or materials used and in the absence of contrary indications in the labeling or instructions for use of the device, the number of uses is maximum 8 canals and can be reprocessed up to 10 times.

14) DISPOSAL

When a device reaches the end of its life, make sure that it is discarded in accordance with the applicable laws and regulations.

15) SYMBOLS

For explanation of symbols for IFUs and labels, please consult the document "Glossary of the symbols used by FKG Dentaire" available on FKG's website.

EC REP
EMERGO EUROPE
Westervoortsedijk 60,
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