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HyFlex EDM OGSF NiTi Root Canal Instruments

Instructions for use **EN**

Please read the Instructions for Use carefully before using the product. Keep for later reference.

1. PRODUCT DESCRIPTION
HyFlex EDM files are engine-driven tapered NiTi instruments with cutting edges used for mechanically shaping and preparing the root canals during endodontic treatments.

2. INTENDED USE / CLINICAL BENEFIT
HyFlex EDM files are used for removal of infected tissue and dentin, root canal cleaning and shaping.
Opener Files: Create space for coronal access
Glidepath Files: Create a glidepath up to working length before shaping operations
Shaping and Finishing Files: Enlargement and Shaping of the root canal.

3. COMPOSITION
HyFlex EDM files consist of three different parts. Namely, a NiTi-alloy wire eroded blank, a plated brass shaft and a silicone rubber stop. Due to different taper sizes the color of the stopper can vary. Due to different processing steps the blank of the file can vary in different colors. Additionally the shaft exhibits different color coding's for the tip diameter sizes.

4. INDICATION
Treatment of endodontic disease.

5. CONTRAINDICATION
N.A

6. SAFETY INSTRUCTIONS
HyFlex EDM files are supplied presterilized using gamma irradiation. Sterility is guaranteed until use if the packaging has not been damaged or opened. Make sure to dispose of packages damaged prior to use.
A low-speed contra angle is required in order to use the files (e.g. Coltene CanalPro X-Move handpiece). All HyFlex EDM files can be used at 400 rpm and at a torque of up to 2.5 N-cm (25 mN-m) excepted the Glidepath files which can be used with 300 rpm and at a torque of up to 1.8 N-cm (18 mN-m).
The spirals of the HyFlex EDM files may lengthen in response to force. This prevents binding blockages to the canal walls and considerably reduces the risk of breakage. Unlike common available NiTi instruments, the shape of the files can be restored, depending on its deformation type. The files regain their original shape during autoclaving (or when a glass bead sterilizer is used for 10 seconds), if they have been only elastically deformed.

⚠WARNING
It must be ensured that the spirals of the files do not wind in the opposite direction during use, as otherwise they are plastically deformed and will not regain their original shape. If several spirals of a file appear to have lengthened after autoclaving or if they appear to be faulty in any other way, the file should no longer be used (see Step-by-step card).

HyFlex EDM files should no longer be used after the expiration date.

NOTICE
The number of times a file can be re-used depends on processing and treatment. The condition of the files should always be verified before and after use.
- Process files prior to re-use (see instructions for processing resterilizable medical devices).
- Place irrigant into canal prior to shaping
- When using the files, irrigate the root canal frequently and ensure lubrication.
- Clean the spirals of the file every time after insertion into the root canal.
- Repeat after each step. The files should be used with our recommended step by step technique described below.

7. SIDE EFFECTS/INTERACTIONS
No harmful reactions or secondary effect on the patients and/or dental personnel are known.

8. USER / PATIENT GROUP
Use by dental professionals only.

9. PREPARATION
After straight-line coronal access has been established, it is useful to use a hand file (maximum size 20/.02) or a rotary glidepath file to establish an apical glide path and place irrigant, such as NaOCl in the canal.

10. PROPER USE
Step by step instructions:

STEP 1:
To create the coronal access use the Orifice Opener 18/11. Place the file in the canal without running engine. When the file cannot proceed any further move it back 1mm until it is free of the walls. Then start the engine and proceed forward slowly using tapping movements and without applying pressure. Proceed to Step 2 as soon as resistance is felt. Do not use this file in the curved part of the root canal. Check patency using a hand file. While doing so, ensure that the root canal always remains irrigated and lubricated.

STEP 2:
Use the 15/.03 Glidepath File up to the working length to create a glidepath. Place the file in the canal without running the engine. When the file cannot proceed any further move it back 1mm until it is free of the walls. Then start the engine and proceed forward slowly using tapping movements and without applying pressure. This file is extremely thin and therefore not as breakage resistant as the other HyFlex EDM files. Because of this the file should be used very carefully and not as often as the other HyFlex EDM files. As soon as resistance is felt, check patency using a hand file. While doing so, ensure that the root canal always remains irrigated and lubricated.

STEP 3:
Use the Shaping File 18/.045 for enlargement of the root canal up to the working length. Place the file in the canal without running engine. When the file cannot proceed any further move it back 1mm until it is free of the walls. Then start the engine and proceed forward slowly using tapping movements and without applying pressure. Return to the previous step as soon as resistance is felt. Check patency using hand file. While doing so, ensure that the root canal always remains irrigated and lubricated.

STEP 4:
Use the Finishing File 30/.04 for enlargement of the root canal up to the working length. Place the file in the canal without running engine. When the file cannot proceed any further move it back 1mm until it is free of the walls. Then start the engine and proceed forward slowly using tapping movements and without applying pressure. Return to the previous step as soon as resistance is felt. Check patency using a hand file. While doing so, ensure that the root canal always remains irrigated and lubricated.

11. TESTMETHOD FOR CORRECT APPLICATION
Before use, perform a manual check that the file is correctly fixed in the contra angle.

12. REPROCESSING, CLEANING, DISINFECTION, MAINTENANCE

Processing of re-sterilisable medical devices (acc. to ISO 17664)

Procedure:
Manual and mechanical procedure for processing re-sterilisable medical devices

Instructions:
Due to the product design and the materials used, no definite limit to the maximum number of performable processing cycles can be specified. The service life of the medical devices is determined by their function and careful handling.

Instructions for reprocessing
Preparation procedure at the site of application:
Remove general soiling from the instruments directly after application. Do not use fixating agents or hot water (>40°C), as this causes fixation of residues and can impair successful cleaning. In order to avoid contamination drying on, soak the used instruments in a disinfectant bath.

Transport:
Safe storage in a closed container and transport of the instruments to the processing location, in order to avoid damage to instruments and environmental contamination.

Preparation for decontamination:
No particular requirements.

Pre-cleaning:
No particular requirements.

Manual cleaning and disinfection in the ultrasound apparatus:
For cleaning the instruments in the ultrasound apparatus, put the instruments in a beaker filled with the cleaning liquid, place in the ultrasound apparatus sufficiently filled with water and 2% contact liquid and start the ultrasound cleaning process.
1. 30 min primary cleaning at 25°C, stage 5 with 2% cleaning agent concentration
2. Generous manual rinsing under running water (reverse osmosis water)
3. Dry using compressed air

Mechanical cleaning and disinfection in the washer/disinfector
Place the instruments in a sterilization tray on the slide-in trolley and start the cleaning process.
1. Pre-cleaning with 10 l cold water
2. 10 min primary cleaning at 55°C (10.5 l water and 62 ml cleaning agent (DOS 1))
3. Rinse with 9.0 l cold water and 13 ml cleaning agent (DOS 3)
4. Rinse with 9.0 l cold reverse osmosis water
5. Thermal disinfection for 5 min at 90-93°C with 9.5 l reverse osmosis water
6. Dry for 35 min at 99°C

Functional testing, maintenance:
Optical inspection for cleanliness, care and functional testing according to the operating instructions. If necessary, repeat the reprocessing procedure until the instrument is visually clean.

Packaging:
Place instruments for sterilization on an Endo Procedure Block or Organizer. Standardized packaging of instruments for sterilisation according to ISO 11607 and EN 868.

Sterilisation:
Steam sterilization of instruments, observing the respective national requirements.
3 pre-vacuum phases
Heat up to a sterilization temperature of 134°C
Shortest hold time: 3 min
Drying time: at least 20 min

Storage:
Store sterilised instruments in a dry, clean, and dust-free environment at moderate temperatures of 5°C to 40°C.

Information on validation of reprocessing
The following test instructions, materials and machines were used during the validation:
Cleaning agents:
Tickopur TR 13 (contact fluid), Dr. H. Stamm GmbH
Stammopur DR 8 (disinfectant cleaner), Dr. H. Stamm GmbH
Neodisher Mediclean forte, Dr. Weigert Co. (dosing system DOS 1)
Neodisher Z (neutralisation agent), Dr. Weigert Co. (dosing system DOS 3)
SonoCheck (BAG Health Care) (indicator for ultrasound effectiveness)
Cleaning/Sterilization devices:
RDG: cleaning and disinfecting apparatus: Miele G7892 CD
Powersonic® P 2600 D ultrasound cleaning apparatus (Martin Walter Ultraschalltechnik AG)
Autoclave Systec VX-95 (Systec GmbH)
Item carriers for washing:
Upper basket/injector O177 / 1
Tray E 520 for 18 Root Canal Instruments
Tray ½ E142
Covering net A 3 ¼ (if needed)
Sieve with cover for small parts E473/1

Additional instructions:
If the above-mentioned chemicals and machines are not available, the user is obliged to validate his procedure accordingly.

It is the obligation of the user to ensure that the reprocessing procedure, including resources, materials and personnel, is suitable to achieve the required results.
State-of-the-art technology and national laws require the compliance with validated processes.

13. SHELF LIFE / STORAGE
Store sterilized instruments in a dry, clean, and dust-free environment at moderate temperatures of 5 °C to 40 °C.
Expiration date: see file packaging

14. DISPOSAL
After use, instruments must be placed in a secure container, used to collect cutting or sticking instruments (like needles or disposal bistouries) as per good dentistry practices.

15. REPORTING OBLIGATION
All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.

CE 0483

Glossary

Consult instructions for use
Marking of Conformity Europe
RX only
Legal Manufacturer
Reference Number
Manufacturing Date
Expiry Date
Batch Code
Unique Device Identifier
Sterile
Do not use if package is damaged

Address of registered place of business

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