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 stopper. Due to different taper sizes the colour of the stopper can vary. Due to different processing steps the blank of the file can vary in different colours. Additionally, the shaft exhibits different colour 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. Coltène CanalPro X-Move handpiece). All HyFlex EDM files can be used in continuous rotation at 400 - 500 rpm and at a torque of up to 2.5 Ncm (25 mNm) excepted the Glidepath files which can be used with 300 rpm and at a torque of up to 1.8 Ncm (18 mNm).
All HyFlex files are specifically programmed in the CanalPro Jeni for use with the Jeni Move. The spirals of the HyFlex EDM files may lengthen in response to force. Unlike common available NiTi instruments, the shape of the files can be restored during autoclaving, depending on its deformation type.

⚠**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 must not longer be used (see Step-by-step card). HyFlex EDM files must not be used after the expiration date. HyFlex EDM files contain Nickel and Titanium and should not be used on patient with known allergic sensitivity to these metals.

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 re-sterilizable 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. Safety and effectiveness of use have not been established in pregnant or breast-feeding women.

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 **O**rifice 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 **G**lidepath 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 **S**haping 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 **F**inishing 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 1 mm 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 fileis correctly fixed in the contra angle.

12. REPROCESSING, CLEANING, DISINFECTION, MAINTENANCE
Processing of re-sterilizable medical devices

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

Risk assessment/classification recommendation:
Due to contact with injured tissue and blood, classification of the medical device as critical B is recommended.
The following processing measures are recommended: mechanical cleaning in combination with thermal disinfection (washer/disinfector) and steam sterilization before use.

Warnings:
During reprocessing, there is a risk of transmitting pathogens via blood and tissue residues. Suitable protective equipment (gloves, face mask, goggles) is absolutely essential.

Processing limitations:
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. If the products show visible changes in material or shape after reprocessing or if their functionality is restricted, the products must no longer be used. The number of times a product can be reused depends on its reprocessing and handling. The condition of the products should always be verified before and after every use.

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:
Safely store the instruments in a closed container for transport to the processing location, in order to avoid damage to the instruments and environmental contamination.

Preparation for decontamination:
Remove silicone rubber stopper from the file and clean and disinfect them separated from each other.

Pre-cleaning:
No particular requirements.

Manual cleaning and disinfection in the ultrasoundapparatus:
Attention: The manual cleaning and disinfection procedure may only be used for this product group in countries outside Germany. In Germany, the automated cleaning and disinfection method is to be used as a matter of principle.
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)

Manual disinfection:
If no disinfectant cleaner is available for manual cleaning, separate disinfection must be performed after cleaning by placing in a suitable disinfectant (observe the instructions for use of the disinfectant with regard to effective concentration and exposure time). Then rinse thoroughly with reverse osmosis water and dry.

Manual drying:
Drying with low-germ / sterile filtered compressed air

Mechanical cleaning and disinfection in the washer/disinfector
Place the instruments in a suitable sterilization tray in the washer/disinfector 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

Inspection and maintenance:
Visual 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:
Reassemble the silicone rubber stopper to the file and place the instruments for sterilization on a suitable sterilization tray. Standardized packaging of instruments for sterilization according to ISO 11607 and EN 868.

Sterilization:
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

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 E 142
Covering net A 3 1/4 (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. STORAGE
Store sterilized instruments in a dry, clean, and dust-free environment at moderate temperatures of 2 °C to 25 °C (follow the instructions of the packaging supplier regarding storage temperature and duration).

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
CE 0483	Marking of Conformity Europe
Rx ONLY	Restricted device for professional use only
	Legal Manufacturer
MD	Medical Device
REF	Reference Number
LOT	Batch Code
	Manufacturing Date
	Expiry Date
UDI	Unique Device Identifier
STERILE R	Sterile
	Do not use if package is damaged
	Keep dry
	Keep away from sun light
2°C 37°F 25°C 77°F	Temperature limitation
CH REP	Swiss Authorized Representative
	Single sterile barrier system
	Continuous rotation (only step by step card OGSF)

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