

HyFlex CM 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 CM 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 CM 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 CM 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 CM 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 CM files can be used in continuous rotation at 500 rpm and at a torque of up to 2.5 Ncm (25 mNm). All HyFlex files are specifically programmed in the CanalPro Jeni for use with the Jeni Move. The spirals of the HyFlex CM 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 CM files must not be used after the expiration date. HyFlex CM 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

The HyFlex CM files may be used with the crowdown and stepback techniques or using the recommended hybrid and single length techniques as described below.

Step by step instructions:

STEP 1: Begin with the 25/.08 file (Orifice Opener). Proceed forward slowly using tapping movements and without applying pressure. Proceed to Step 2 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.

Optional step: If the working length is reached in large canals it is possible to proceed directly to Step 4.

STEP 2: Use the 20/.04 file for apical enlargement up to the working length. Proceed forward slowly using tapping movements and without applying pressure. 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 25/.04 file for apical enlargement up to the working length. Proceed forward slowly using tapping movements and without applying pressure. 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 4: Use the 20/.06 file to shape the middle section of the canal until the working length is reached. Proceed forward slowly using tapping movements and without applying pressure. 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 5: Use the 30/.04 file to enlarge the apical section until the working length is reached. Proceed forward slowly using tapping movements and without applying pressure. 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 6: Perform final preparation up to the working length using the 40/.04 file. Proceed forward slowly using tapping movements and without applying pressure. 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-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 ultrasound apparatus:

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.

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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.



0483

| Glossary | |
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| | Consult instructions for use |
| | Marking of Conformity Europe |
| | Restricted device for professional use only |
| | Legal Manufacturer |
| | Medical Device |
| | Reference Number |
| | Batch Code |
| | Manufacturing Date |
| | Expiry Date |
| | Unique Device Identifier |
| | Sterile |
| | Do not use if package is damaged |
| | Keep dry |
| | Keep away from sun light |
| | Temperature limitation |
| | Swiss Authorized Representative |
| | Single sterile barrier system |

Address of registered place of business

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