KontrolFlex Endodontic Rotary Files

KontrolFlex Endodontic Rotary Files are available Non-Sterile with various ISO tip sizes and working lengths. The devices are intended to be cleaned and sterilized using steam sterilization in a gravity or prevacuum cycle prior to initial use. The devices are for single patient use only.

Intended Use

KontrolFlex Endodontic Rotary Files fit into a dental handpiece allowing the user to perform root canal debridement.

Warnings

- The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
- Failure to follow these instructions may cause the following: apex perforation, insufficient cleaning of the root canal, preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the file.
- Attention should be paid to the speed of work (RPM) and torque:
  - RPM range (500-600 RPMs). Use of the file beyond the RPM range may cause the file to break and result in patient or user harm.
  - Torque range 1.8-2.3 Ncm. Use of the file beyond the torque range may cause the file to break and result in patient or user harm.
  - Operating an Endodontic File with too high of an RPM may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- NON STERILE KontrolFlex Endodontic Rotary Files must be thoroughly cleaned and steam sterilized prior to the first use to prevent infection or contamination.
- Do not use chemical or dry heat to sterilize KontrolFlex Endodontic Rotary Files, as these processes have not been validated for use. Use of these processes may be corrosive to the files and could result in premature file failure.
- 2 KontrolFlex Files are for single patient use only. Use on more than one patient may cause file failure or infection/ cross-contamination.
- Irrigation with ultrasonics is recommended. Inadequate use of irrigation may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Always clean the file after every engagement. Failure to clean the file may cause the file to break or unwind causing patient or user harm or may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Use a rubber dental dam while using Endodontic Files to avoid possible aspiration or swallowing of the file.
- Do not apply excessive pressure on the Endodontic Files as this could cause undesirable heat or may cause the file to fail and cause patient or user injury.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause patient or user injury.
- Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated which could cause user injury.
- Eye protection must be worn to protect against eject particles which could cause user injury.

Contraindications

- NiTi KontrolFlex Files contain nickel and should not be used for individuals with known allergic sensitivity to this metal at it may cause hypersensitivity.
- This product contains nickel, a chemical known to the state of California to cause cancer, birth defects or other reproductive harm.

Precautions

- Do not use if the package is damaged. Files may become damaged or contaminated if the packaging is compromised.
- Use on more than three canals (single patient) may cause the file to break or unwind and cause patient or user injury.
- Do not use Endodontic Files that are worn-out, dull or that exhibit “unwinding” as this could cause undesirable heat or may cause the file to fail.
- Move the Endodontic File continuously when in use to avoid localized heating and/or damage to the file. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to patient discomfort, injury of the patient or user, aspiration or swallowing of the Endodontic File or damage to the preparation site due to vibration of a worn chuck or turbine.
- Ensure the Endodontic File is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the File to “walk out” of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the Endodontic File.
- Never force a file into a handpiece as this could cause damage to the handpiece collet.

General Instructions

- RPM range is 500-600 RPMs. Use of the file beyond the suggested RPM range may cause the file to break and result in patient or user harm.
- Torque range is 1.8-2.3 Ncm. Use of the file beyond the suggested torque range may cause the file to break and result in patient or user harm.

Shaping and Cleaning

Crown Down Technique with Constant Tapers

1. Establish working length using radiographs and an apex locator.
2. Reach full working length with a #15/.02 file noting the level of resistance to achieve working length.
3. Proceed utilizing a crown down technique using the following file sizes based on the level of engagement to achieve working length with the #15/.02 file.

    - Significant resistance to reach working length= Small File Assortment (30, 25, 20).
    - Moderate resistance to reach working length= Medium File Assortment (40, 35, 30).
    - Minimal resistance to reach working length= Large File Assortment. (45, 40, 35).

4. Begin crown down with the largest file.

    - Use each file with 4-5 strokes of 1 single gentle engagement.
    - After each engagement clean the flutes prior to reengagement (single stroke and clean).
    - Move to the next smallest file after 4-5 single engagements.
    - Irrigate between each rotary file with your irrigant of choice.

5. The first file to working length with resistance completes the preparation.*

    *If desired finish the preparation to the next largest size rotary file.

Variable Tapered Technique

1. Establish working length using radiographs and an apex locator.
2. Reach full working length with a #15/.02 file noting the level of resistance to achieve working length.
3. Begin sequence with the 19/07 orifice shaper taking it only 2-3 mm into the canal (do not take to working length).
4. Proceed utilizing a variable tapered technique using the following files in a progressive series (move to the next file after the previous file reaches working length): 17/05, 20/06, 25/05, 30/05. See technique notes below:

   Technique Notes:

   - After each engagement clean the flutes prior to reengagement (single stroke and clean).
   - Irrigate between each rotary file with your irrigant of choice.

5. If it is desired to finish the preparation to a larger apical size utilize the 35, 40 or 45 .04 KontrolFlex files to complete the preparation utilizing the same single stroke and clean technique.

Obturation

Obturate the canals using BC Sealer™ and the corresponding BC Point™.

- Select the EndoSequence® BC Point™ that matches the last rotary file taken to working length.
- Deliver BC Sealer throughout the canal using a small file.
- Coat the selected BC Point™ with BC Sealer™ and slowly seat the BC Point™ to full working length.

Cleaning and Sterilization Instructions

Scope	These instructions are applicable to all KontrolFlex Rotary Files. KontrolFlex Files are provided mechanically clean, but are not sterile. Therefore, KontrolFlex Files should be sterilized before first use.
Warnings	1. Cleaning agents with chlorine or chloride as the active ingredients are corrosive to NiTi and must not be used. Cleaning agents with neutral pH are recommended. 2. Do not use Cold Sterilizing Methods for the sterilization of NiTi files. These agents often contain strong oxidizing chemicals that may dull or weaken NiTi files. 3. Vigorous scrubbing of the files may cause damage. Care should be taken to ensure that files are not broken or damaged during the cleaning process.
Reprocessing Limitations	The end of life is determined by the wear and damage in use. NiTi files should be inspected for defects during the cleaning process.
Containment/ Transportation	Not applicable for single use devices
Manual Cleaning Procedure	If hand cleaning is the only available option, NiTi files should be cleaned in a sink reserved for cleaning instruments. Rinse the NiTi File (and dedicated instrument block, if applicable) under cool running water for at least one (1) minute. Prepare a fresh bath of neutral-pH cleaning solution. Follow the cleaning agent's manufacturer's instructions. Immerse the NiTi File (and instrument block) and soak for at least ten (10) minutes. After soaking, and keeping it immersed, brush thoroughly away from the body using the neutral cleaning agent for at least one (1) minute. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use wire brushes with caution as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel. Special care should be taken to clean crevices and other hard to reach areas thoroughly. Visually inspect to confirm the removal of debris. Repeat the cycle if needed.

Thoroughly rinse the NiTi file under running warm water for at least one (1) minute and until visibly clean.

Dry the device using a non-shedding wipe or clean compressed air.

Ultrasonic Cleaning Procedure

Prepare a fresh pH-neutral cleaning solution; place the NiTi File in the dedicated instrument block (if applicable) and then place in a sonication unit. Follow the cleaning agent manufacturers' instructions for correct concentration, exposure time, temperature, and water quality. Completely submerge the device in the cleaning solution and sonicate for at least fifteen (15) minutes.

Perform a final thorough rinse of the device under running warm tap water for at least (1) minute.

Visually inspect to confirm the removal of debris. Repeat the cycle if needed.

Dry the device using a non-shedding wipe or clean compressed air.

Inspection Testing

1. Carefully inspect each device to ensure that all debris has been removed.
2. Visually inspect the device for damage/ wear that would prevent proper operation.
    a. Do not use if the tip is broken.
    b. Do not use if there is a broken section of a file.
    c. Do not use if there is evidence of corrosion.
    d. Do not use if the reference markings are illegible.

Packaging

Singly: Pack the NiTi File in pouches validated for sterilization

Sterilization

Use the following cycle for steam sterilization

Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)
Gravity	10	135°C (275°F)	30
Pre-vacuum (4 Pulses)	3	134°C (273°F)	30

Ensure that the sterilizer manufacturer's maximum load is not exceeded.
The minimum dry time has been validated to ensure that the files will not be left wet. Failure to achieve the minimum dry time may cause moisture to remain on the files that could result in corrosion.

Storage

The NiTi File should be stored in the sterilization pouch until required.

Additional Information

These processes have been validated as being capable of preparing NiTi Files for use. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.

Glossary of Symbols

Symbol	Meaning	Standard
	Catalogue Number	ISO 15223-1
	Use-by date	ISO 15223-1
	Batch Code	ISO 15223-1
	Revolution (RPM)	ISO 21531
	Quantity	N/A
	Consult instructions for use	ISO 15223-1
	Caution	ISO 15223-1
	Non-sterile	ISO 15223-1
	Do not re-use	ISO 15223-1
	Do not use if package is damaged	ISO 15223-1
	Files contain nickel and should not be used for individuals with known allergic sensitivity to this metal	ISO 15223-1
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a "dentist/physician" licensed by the law of the State in which he/she practices to use or order the use of the device.	FDA 21 CFR Part 801.109 (b)(1)
	Manufacturer/Legal Manufacturer	ISO 15223-1

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