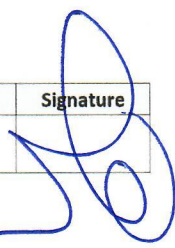




**CONTROLLED  
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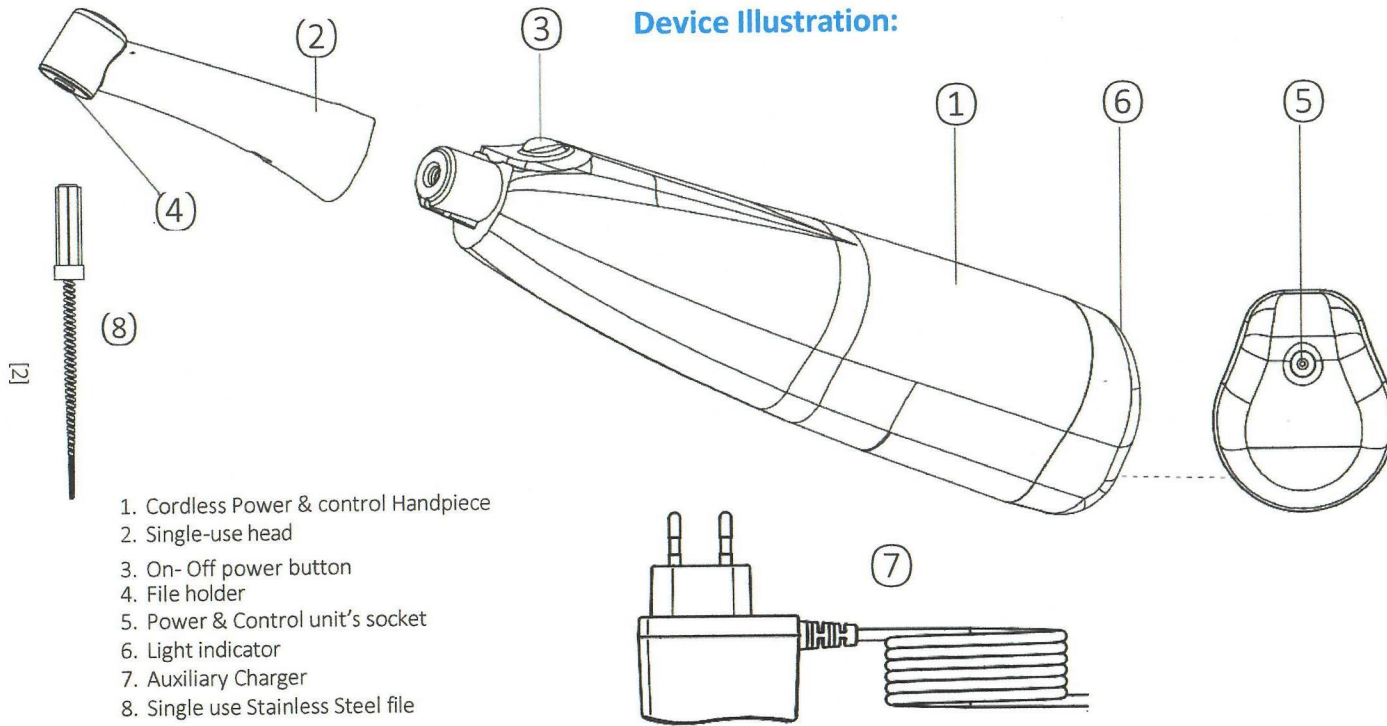
## Instructions for Use

**Approvals:**

	<b>Name</b>	<b>Position</b>	<b>Date</b>	<b>Signature</b>
Reviewed and Approved By:	Pini Lahav	QA/RA Director	12.11.2024	

**Pini Lahav, M.Sc.**  
CTO QA RA  
Director, PRRC  
MDT Micro Diamond Technologies Ltd.

Device Illustration:



## Product Description

Gentlefile is a Rotary cordless filing system for root canal treatment. A product of MedicNRG, Gentlefile system, comprised of a cordless rechargeable handpiece, a single use disposable head (Contra-Angle), a set for flexible Stainless Steel files, and endo clean stand. In addition there are two manual abrasive NiTi file- tip size -25# & 17# length 25 mm.

## Intended Purpose

The intended purpose of Gentlefile™ System is to clean the dentinal walls of a root canals and disinfect its surface prior obturation.

This is achieved by spinning the file with a rotational handpiece which creates a centrifugal force on the root inner walls.

### Indication for Use

Gentlefile system is intended for use in root canal preparation in accordance with the Protocol for Use described herein.

### Intended User

Gentlefile™ Endo Rotary Instruments are intended for use by Healthcare Dental Professionals and must only be used by a Dentists or certified Dentalp practitioner

### Intended population

The Gentlefile™ Endo Rotary Instruments are intended for all patients diagnosed by a dentist as requiring root canal treatment.

## Contra indications

- N/A

## Device Description:

The Gentlefile system is comprised of the following assemblies:

- Cordless Power & control Handpiece assembly **(1)** contains: a rechargeable Li-ion battery, DC motor, electronic control circuit, and an On-Off power switch /button **(3)**. The handpiece generates the low torque, high speed rotation movement of 6,500 rpm that rotates the files.
- Disposable single-use head **(2)** connects to the handpiece, holds the file, and serves as a power transmission element.
- File **(8)** set: Each file made of multi layered Stainless Steel coiled wires, a colored handle and an easy to place length

marker. Intended for single use and available in sizes and colors as follows:

File/ Tip Size	Handle Color		Length	Cat.No
022 Coronal*	Grey		20 mm	GF-01-FILE
034	Black		25 mm	GF-02-FILE
029	Green		25 mm	GF-03-FILE
026	Blue		25 mm	GF-04-FILE
023	Red		25 mm	GF-05-FILE
021	Yellow		25 mm	GF-06-FILE
025-Finisher**	Black		25 mm	GF-09BR-FILE

\* for the preparation of the coronal and the mid part of the root canal; length of 20 mm

\*\* The optional Gentlefile brush GF-09-BR07 can be used to scrub the canal walls to finish or fine-tune the canal. It has separate protocol of use.

- 2 manual abrasive NiTi file tip size #17 GF-08-HR01 & #25 GF-08-HY01- length 25 m
- An auxiliary item is added to the system, Charger (7): Used to charge the Li-Ion battery in the handpiece assembly.

## Control and Safety

The Gentlefile system includes inherent safety mechanisms

1. intended to limit the forces and torque applied by the file. Motor Power – Motor is selected to produce no more than 70 Gr-Cm of torque, when resistance is encountered, the motor's rotation speed declines, reaching a full stop in the presence of high resistance.
2. Motor Load Control – When the resistance in the canal rises' controller firmware detects the increase in load and limits the motor power to a safe predefined value.
3. While stoppage, the file may be released manually pulling it outward.

## Precautions

- ! This device is to be used by qualified Dentist or Endodontic professionals only.
- ! The file is Single Patient Use and reuse is not permitted. For every new treatment and patient ,use a new disposable head (2) and a new set of files. Multiple use along sterilization cycles may lead to a risk of malfunctions and file separation
- ! Dispose of used instruments in accordance with the applicable regulations for infected waste in your country.
- ! Always clean the Handpiece and contra-angle head before use according the herein cleaning
- ! Before operating the Handpiece make sure the handpiece head is tightly secured in position.
- ! **Do not immerse the Handpiece in disinfection bathes or any liquids.**
- ! Do not use the Handpiece if the battery indicator light is

- blinking.
- ! Charge the Handpiece while not in use and disconnect charger before use.
  - ! Sterilize files before use.
  - ! **Exposing the handpiece to Autoclave is prohibited! It may cause battery leakage and inflammation.**
  - ! **Handpiece must not be altered disassembled or fixed. In case of malfunction contact the supplier for service.**
  - ! Battery may be replaced by the manufacturer only!  
In case the battery exhausted the Handpiece shall be disposed to electronic disposal area and replaced by a new one.
  - ! Do not use without a rubber dam.
  - ! Use the Gentlefile™ handpiece with Gentlefile™ heads and files only. Ensure Gentlefile™ files are used solely with the Gentlefile handpiece and heads.
  - ! Make sure device is activated only after positioning the file inside the canal.
  - ! Do not use at altitudes above 4,000 m (13,120 feet).
  - ! Do not operate handpiece for a continuous period longer than 30 sec.

### Technical Operating Instructions

1. Connection of head (contra-Angle): Insert the head **(2)** onto Handpiece joint and push firmly to ensure complete connection.
1. Insertion of File: Insert the file into its place **(4)** on the handpiece-head **(2)** by gently pushing the file into the head.
1. Rotary operation (make sure to follow Protocol of Use included here-in): Place the file in the canal and press the power switch briefly **(3)**. Verify that the light indicator **(6)** is on, and not blinking. The handpiece will work until the power switch is pressed again briefly.
1. Before extracting the file from the canal, push the power switch **(3)** again to stop operation.

## Protocol of use

**Note:** The root canal preparation shall be done using the crown-down method.

### File for Shaping procedure:

#### Purpose:

Shaping procedure in a crown down method to remove the pulp and clear the root canal volume up to the Apex ,to prepare for obturation.

#### Function:

The Gentlefile set includes flexible, wound-wire files that are sandblasted having a roughened surface. When rotated at high speeds, these files expand to engage the dentinal walls, efficiently scrubbing to clean, shape, and clear the root canal with minimal invasiveness, preparing it for obturation. The set is color-coded, starting with the Gray file: 0.23 mm diameter, 20 mm length for the initial stages of the procedure, progressing to the Red file :0.23 mm diameter, 25 mm length, and may potentially ending with the Blue file :0.26 mm diameter, 25 mm length; depend on the root canal and apex size. Additionally, two sandblasted manual files, K#17 (Yellow) and K#25 (Red), are included to assist with crown-down opening.

#### Protocol of use:

1. Scout the root canal with K- file (usually 0.10) to evaluate the anatomy. Measure the working length using electronic apex locator.
2. Then use the Manual – Gentlefile (M-GF) by up and down pecking motion, first the yellow 017, if it does not reach the apex then repeat with the K-file and again with #17 M-GF and if necessary with #25 M-GF

**Note:** Always irrigate the canal prior to file and work in wet conditions and confirm patency using #17-25 hand Gentlefile

3. Secure the Gentlefile® in the Handpiece head by friction force and Insert the Gentlefile® into the canal and activate the handpiece by pressing the on-off button.
4. Work along the root canal up to the apex, up and down slowly. in a pecking motion but Never push the handpiece.

5. The recommended working sequence is to start with the gray coronal Gentlefile® as far as it will go 1-3 sequences. If the gray file doesn't penetrate to the apical third, a #17-25 M-Gentlefile - can be used to help clear debris and enable the Gentlefile® to progress down the canal. Attempt to get within 1 mm of the apex with the GF. For best tactile feedback the fine tuning of the last mm should be done with the manual GF.
6. Proceed with crown-down sequence. Depending on how far the grey file penetrated into the canal, the next file is chosen. If the gray file neared the working length, then a final file will be the next file chosen, based on the estimated apical diameter (commonly blue or red).
7. If the canals need more exploration and shaping then a stiffer file, the, green or blue will be next, to proceed towards the working length.
8. Always use copious irrigation and manual patency files.
9. When the file no longer advances, switch to the next smaller file in the sequence until about -1.0 mm from the working length is reached.
10. If you face difficulties penetrating the canal then try the M-GF. Start with M-GF # 17 and the #25 according the canal condition. Then repeat crown-down sequence with the Gentlefile®
11. At the end of the cleaning procedures, irrigate with EDTA or
12. citric acid.
13. Activate the solution by running the Gentlefile®. in each canal for about 20-30 seconds with the smallest file used to prepare the canals(recommended to locate the GF about 2 mm from the apex to get the best result from the activation process). Irrigate again with sodium hypochlorite and activate with the Gentlefile® for about 20-30 seconds.
14. Irrigate the canals with 95% alcohol, dry the canals, and fill.

**Notes:**

- Always use copious irrigation and manual patency files. When the file no longer advances, switch to the next smaller file in the sequence until about -1.0 mm from the working length is reached.
- This is a basic protocol only, it is recommended for all



users to review the video presentations available on Gentlefile® web site: [www.gentlefile.com](http://www.gentlefile.com)

## Brush for cleaning and Disinfection procedure:

### Purpose:

Activation of disinfection and cleaning solutions on the dentinal walls of root canals; reaching its irregular spaces.

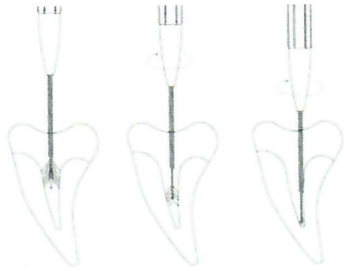
### Function:

At revolution speed above 5000 RPM the 7 strands the brush core is made off is getting open to a full variable diameter reaching the full scope of the root canal dentinal walls. This allows cleans the remaining debris and biofilm left in the root canal and brings the irrigants into intimate contact with the dentinal surface.

### Protocol:

1. Complete the shaping procedure clearing the pulp and the effective root canal space that the canal is ready to be obturated.
2. Rinse the root canal and make first observation of its condition before use.  
verify no perforation to the root or any other mechanical flaw require prior fixation. verify length and apical diameter.
3. Cleaning residues and irregular space left with 'Gentlefile' Red :
  - Introduce the 'Gentlefile®' red into the root canal priorly shaped to its full length about 1 mm distant from the Apex location, though no damage will occur.
  - Then introduce the red 'Gentlefile' into the coronal 3rd and operate the Handpiece. Progress with vertical pecking motion towards the apex about 10 seconds.
  - Irrigate and repeat this step until the irrigant is clear without dentinal dust.
4. Irrigate with 15% EDTA or citric acid to get smooth and clean Root Canal Surface.
5. Introduce GF Finisher Brush about 1 – 2 mm from the apex and activate Gentlefile Drive.
6. Note: The 7 strands expand by friction with the inner wall surface due to centrifugal force when rotated.
7. Move GF Finisher Brush in a smoothly and slowly up and down motion for 20- 30 seconds.
8. Note: Always Irrigate before applying for GF Finisher Brush.

9. Irrigate the canal again with sodium hypochlorite, then apply the GF Finisher Brush for an additional 20–30 seconds to ensure the irrigant penetrates the entire canal for effective disinfection.
10. Dry the canals and obturate.



**Note:** Don't stop the withdrawal movement backward in the canal. Don't try to push into the canal while operating GF-Brush. If the GF-Brush stays in one place, a ledge can develop.

## Charging, Storage & Maintenance

### Charging

Connect the charger's plug (7) to the power & control unit's socket, located on the back lid of the unit (5). When the battery is full, charging will stop automatically (Green light indication on the charger will appear). (7). When charging is completed, unplug the unit from the charger.

Note: It is recommended to charge the device prior to each treatment.

**Note:** To prolong the battery lifetime, it is recommended to disconnect the device from the charger after 4-5 hours. **Alerts:** When the battery charge is low, the indicator light (6) on the back lid of the unit will blink. **Recommended:** if the handpiece is not in use for long period you have to recharge at list once a month.

### Maintenance

The handpiece does not require any special maintenance or service, except for charging and cleaning as described above.

**Note:** Do not open or disassemble the power & control unit under any circumstances. In case of malfunction, contact the supplier.

### Cleaning

By the end of any use cleaning procedure is required for the Handpiece to keep it function and avoid cross contamination by applying a standard cleaning non- woven wipes soaked with alcohol 70%.

### Storage

The power & control unit (1) and head (2) should be wiped clean before use with a disinfectant cloth soaked with Alcohol 70%.

**Note:** The handpiece is not suitable for disinfection in an autoclave.

### Sterilization

1. Gentlefile files are provided non-sterile **and must be sterilized before use.**
2. Use gravity displacement autoclave equipment, set to Temperature 134°C, Pressure of 20 Psi for 5 minutes or

Temperature 123°C, Pressure of 15 Psi for 20 minutes.

## Disposal

After any patient treatment used, dispose the handpiece head **(2)** and files used. The head is intended for a single treatment and should not be sterilized for additional use.

- Dispose the replaceable head in accordance with standard waste recycling procedures applicable in your country Do not store or reuse a used head.
- Dispose of files in accordance with the applicable regulations for infected waste including sharp objects which apply in your country.
- Dispose of multi-use Handpiece in case of battery exhausted or any device termination to electronic waste location which apply in your country.

## Technical Specification

### Handpiece:

**Speed:** Speed (no load): 6,500 rpm +-10%

**Max torque :** 60 gr\*cm

**Torque control:** Automatically adapts the torque according to the load:30-50 Gr.\*Cm.

**Speed control:** preset electronically in factory .

### Environmental Conditions:

	Temperature	Humidity	Pressure
Operational	0-50°C Charge 0- 40°C Operate	<85%	60- 110 K-Pascal
Storage	-20- 60°C Short -5- 35°C Long term	45-85%	60- 110 K-Pascal
Transportation	-20- 50°C	45-85%	60- 110 K-Pascal

### Charger:

**Input:** 100-240 VAC. 50/60 Hz 0.1A

**Output:** DC 4.2v--- 0.6 A.

**Charging mode:** Red light- charging.

Green light – charging completed.

Use only charger supplied with the Handpiece or included in the table of approved chargers below:

**Battery:** Li-On 3.7V, 1100mA LIR17500

## Protocol for Use

**Note:** The root canal preparation shall be done using the crown-down protocol.

i.e. The files are used sequentially, each subsequent file has a smaller diameter and penetrate deeper in the canal.

There is no need to use the whole set of files in each treatment; Files may be selected to match the anatomy of the canal.

### Content of the file Set includes:

One coronal file of 20 mm working length, and 5 files of 25 mm working length suitable for all root canal sizes and shapes:

**Coronal file**, grey color, for the preparation of the coronal and middle parts of the root canal, 022 tip 20 mm

**Black file** 034 tip 25 mm

**Green file** 029 tip 25 mm

**Blue file** 026 tip 25 mm

**Red file** 023 tip 25 mm

**Yellow file** 021 tip 25 mm

### Protocol of use:




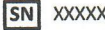






- Scout the root canal with K- file (usually 0.10) to evaluate the anatomy. Measure the working length using electronic apex locator.
- Then use the Manual – Gentlefile (M-GF) by “push-pull” process , first the yellow 017, if it does not reach the apex then repeat with the K-file and again with #17 M-GF and if necessary with #25 M-GF
- Always irrigate the canal before you operate the handpiece, and confirm patency using #17-25 hand Gentlefile
- Secure the Gentlefile® in the Handpiece head by friction force.
- Insert the Gentlefile® into the canal and activate the handpiece by pressing the on-off button.
- Start vertical quick pecking motions with slight apical pressure for about 5 seconds.
- Never push the handpiece, JUST maintain slight apical pressure with a pecking motion.
- Always work in a wet canal, maintain awareness of lubrication of the canals





- The recommended working sequence is to start with the gray coronal Gentlefile® as far as it will go 1-3 sequences. If the gray file doesn't penetrate to the apical third, a #17-25 M-Gentlefile - can be used to help clear debris and enable the Gentlefile® to progress down the canal. Attempt to get within 1 mm of the apex with the GF. For best tactile feedback the fine tuning of the last mm should be done with the manual GF.
- Proceed with crown-down sequence. Depending on how far the grey file penetrated into the canal, the next file is chosen. If the gray file neared the working length, then a final file will be the next file chosen, based on the estimated apical diameter (commonly blue or red).
- If the canals need more exploration and shaping then a stiffer file, the, green or blue will be next, to proceed towards the working length.
- Always use copious irrigation and manual patency files.
- When the file no longer advances, switch to the next smaller file in the sequence until about -1.0 mm from the working length is reached.
- If you face difficulties penetrating the canal then try the M-GF. Start with M-GF # 17 and the #25 according the canal condition. Then repeat crown-down sequence with the Gentlefile®
- At the end of the cleaning procedures, irrigate with EDTA or citric acid.
- Activate the solution by running the Gentlefile®. in each canal for about 20-30 seconds with the smallest file used to prepare the canals(recommended to locate the GF about 2 mm from the apex to get the best result from the activation process). Irrigate again with sodium hypochlorite and activate with the Gentlefile® for about 20-30 seconds.
- Irrigate the canals with 95% alcohol, dry the canals, and fill.
- **This is a basic protocol only, it is recommended for all users to review the video presentations available on Gentlefile® web site: [www.gentlefile.com](http://www.gentlefile.com)**

**Principle of operation and precautions**

- Insert a file into the handpiece head. The file is secured in position solely by friction force.
- The file uses rotational motion at 6,500 rpm polishing and grinding the dentin of the canal wall.
- Insert the file in the canal and only after file is inside the canal activate the handpiece by pressing the On-Off button.
- Do not initiate file rotation before the file is positioned in the canal opening.



Symbol in use	Description:
	Read Instructions for use prior use
	Medical Device
	Catalog Number
	Serial Number
	Do not re-use.
	Needs to be sterilizable in a steam sterilizer
	Non-Sterile Product
	Keep Dry
	Do not use if package is damaged and consult instructions for use
RxOnly	Use by certified physician only
	Electrical Safe for human

	Electronic disposal requirement
	CAUTION! Consult accompanying documents
	Date of manufacture
	<b>Manufacturer:</b> <b>MedicNRG Ltd.</b> Hamal 2 Afula 1857107 ISRAEL Tel: +972-4-6094422 Fax: +972-4-6597812 Email: <a href="mailto:info@medicnrg.com">info@medicnrg.com</a>



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**MEDICNRG™**  
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