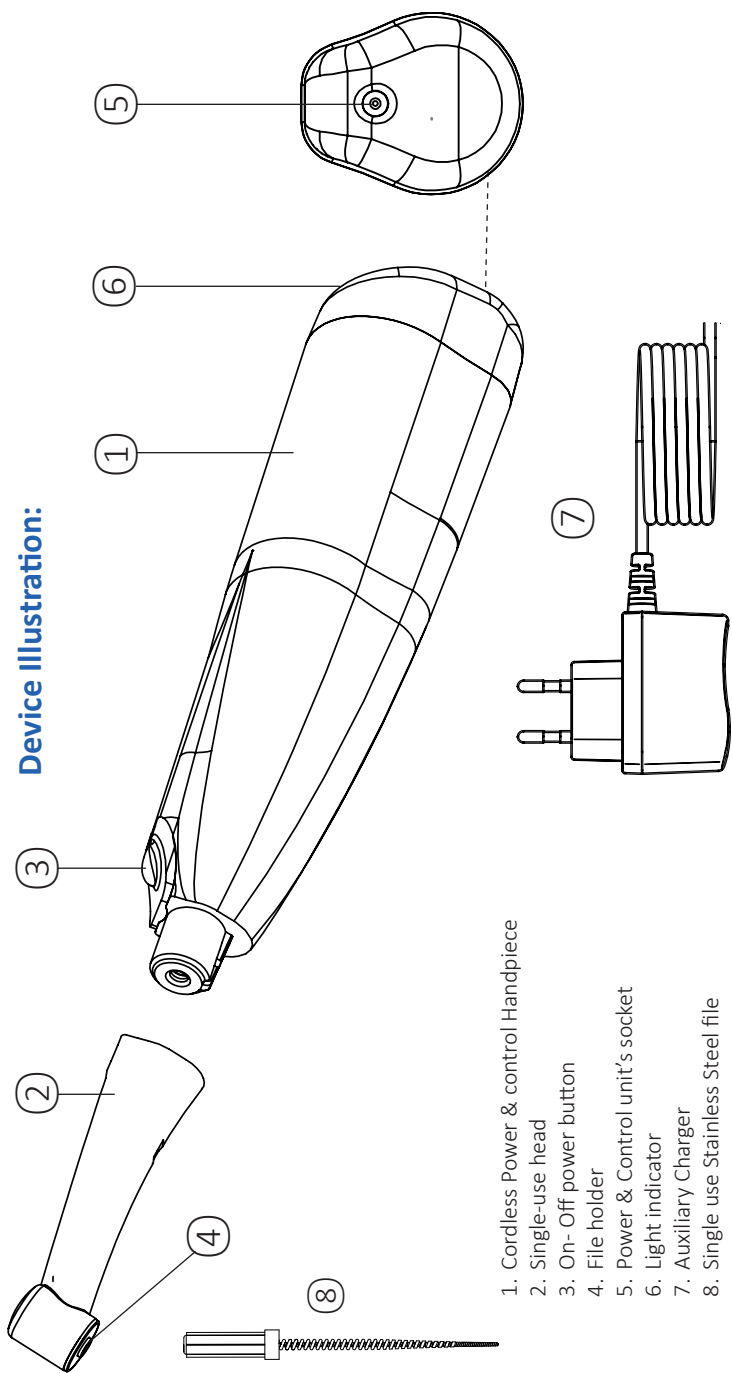




Gentlefile[®] System

Instructions for Use

Device Illustration:



- 1. Cordless Power & control Handpiece
- 2. Single-use head
- 3. On- Off power button
- 4. File holder
- 5. Power & Control unit's socket
- 6. Light indicator
- 7. Auxiliary Charger
- 8. Single use Stainless Steel file

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), and a set for flexible Stainless Steel files.







Indication for Use

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

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)** which 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

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

- 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, intended to limit the forces and torque applied by the file.

1. Motor Power – Motor is selected to produce no more than 90 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. After stoppage of the file (should that occur), the file may be released by manually pulling it clock-wise.

Precautions

- ▲ This device is to be used by qualified Dentist or Endodontic professionals only.
- ▲ Do not store or reuse a used head and / or a used file. For every treatment use a new disposable head (2) (Contra-Angle) and new set of files.
The Gentlefile head and files are designed for a single use only. Multiple uses, disinfection and sterilization cycles may lead to increased risk of malfunctions and file separation
- ▲ Dispose of files in accordance with the applicable regulations for infected waste including sharp objects which apply in your country. Dispose of replaceable head in accordance with standard waste recycling procedures applicable in your country.
- ▲ Always clean the Handpiece and contra-angle (head) before use by applying a standard cleaning cloth soaked with alcohol 70%.
- ▲ 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.

- ▲ **The handpiece is not suitable for Autoclave environment.**
Exposing the handpiece to Autoclave may cause battery leakage and inflammation.
- ▲ **Handpiece must not be altered disassembled or fixed.** In case of malfunction – contact the supplier for service.
- ▲ Rechargeable battery may be replaced **by manufacturer only.**
- ▲ Do not use without a rubber dam.
- ▲ Use Handpiece with Gentlefile heads and files only.
- ▲ Use Gentlefile files with Gentlefile handpiece and heads only.
- ▲ 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 15 sec.

Contra indications

- N/A

Technical Operating Instructions

1. Connection of head (contra-Angle): Insert the head **(2)** onto Handpiece joint and push firmly to ensure complete connection.
2. Insertion of File: Insert the file into its place **(4)** on the handpiece-head **(2)** by gently pushing the file into the head.
3. 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.
4. Before extracting the file from the canal, push the power switch **(3)** again to stop operation.

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.

Storage & Cleaning

After the treatment, dispose of the handpiece head (2). The head is intended for a single treatment and should not be sterilized for additional use. Dispose of 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.

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

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

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.

Technical Specification

Handpiece:

Speed: Speed (no load): 6,500 rpm

Max torque (theoretical): 90 gr*cm

Torque control: Automatically adapts the torque according to the load (40-65 Gr.*Cm').

Speed control: Factory preset and electronically controlled.

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:

Approved Chargers:

	Manufacturer	Part Number
1	HCT Electric Co. LTD	H00370002
2		
3		

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 penetrates 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 canals 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:








- Gain a straight line access to the root canal following a standard procedure (burs and Gates Glidden drills)
- Scout the root canal with a small hand file to evaluate the anatomy and measure the working length using electronic apex locator.
- Secure the Gentlefile in the Handpiece head by friction force.
- Insert the Gentlefile in the canal and activate the Handpiece by pressing the on-off button.
- Start vertical pecking motions with very slight apical pressure. Stop after 3-5 movements lasting no more than 5 seconds combined
- Rinse the canal and confirm patency using #10-15 or larger hand K-files.
- Repeat the process with the consequent Gentlefile.
- The recommended working sequence is starting with the gray coronal Gentlefile approximately to the apical third of the canal, than proceed with the larger to the smaller Gentlefiles until the working length is reached.

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.

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.
3. Files must be wiped with wipes without fibers moistened with 70% Ethanol for one minute, and packaged in an individual pouch before placement in the Autoclave.

Symbol in use	Description:
	Read Instructions for use prior use
 XXXXXX	Catalog Number
 XXXXX	Serial Number
	CAUTION! Consult accompanying documents
	CE mark
	Manufacturer: MedicNRG Ltd. Kibbutz Afikim 15148 ISRAEL Tel: +972-4-675-4217 Fax: +972-4-675-4278 E-mail: info@medicnrg.com Web: www.medicnrg.com
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