



Type "BF"
Applied Part



Caution: Federal Law restricts this device to sale by or on the order of a properly licensed practitioner.

Parkell, Inc.

THERMIQUE™

Thermal Gutta Percha Condenser



DESCRIPTION:

Parkell's THERMIQUE™ is a battery-powered (rechargeable) device that provides a reliable heat source to accompanying tips which are used within appropriately instrumented root canals. It will maintain the selected temperature as long as the activator ring is depressed and will begin to cool as soon as the ring is released. Used according to instructions, THERMIQUE enhances the flow of gutta percha so accessory canals are readily filled and sealed. The heated tips are convenient for use as condensation instruments. They are supplied in three (3) sizes (tapers); small, medium and large. Sizes are easily identified by darkened rings on the tip shaft as follows: 1 ring = small, 2 rings = medium, 3 rings = large. THERMIQUE tips are activated within the root canal, so the risk of patient burns is greatly reduced. The heated tips can also be used to sear off excess gutta percha after canals are filled and sealed.

THERMIQUE SHOULD BE CHARGED OVERNIGHT BEFORE FIRST USE.

PRECAUTIONS:

- Prior to use, examine the cable. Do not use if the cable is damaged or frayed.
 - Do not use broken or damaged tips in the device.
 - Do not use excessive heat for extended periods in a root canal.

Tissues may be damaged by prolonged exposure to heat.

- This device should be employed for described uses only.
- Do not activate the handpiece without a tip being inserted.
- Do not activate the handpiece until a chosen tip has been inserted into a root canal.
- Do not allow activated tips to come into contact with oral mucosa.
- Do not touch heated tips.

NOTE: USE ONLY THE SUPPLIED CHARGER

WARNING: Do not spend excessive time heating gutta percha. Overheating can damage teeth and their supporting tissues.

HOW SUPPLIED:

- Thermique: Model D530
- Battery Charger: Model D534 (120V input, 12VDC 500ma output)
- Three autoclavable calibrated tips
 - Small: Stock No. D531
.08 taper
 - Medium: Stock No. D532
.010 taper
 - Large: Stock No. D533
.12 taper
- Instructions
- Warranty registration card

CONFORMANCE TO STANDARDS:

The Parkell THERMIQUE conforms to UL60601-1 and CAN/CSA C22.2 No. 601.1. Parkell's quality system is certified to ISO9001/13485.

DIRECTIONS:

1. Rubber dam application is recommended. Some clinicians prefer to anesthetize patients before using THERMIQUE, but this is not essential for use of the device.

2. Choose the THERMIQUE tip that best matches the final instrument size and taper (see "How Supplied"). Slide a rubber stopper onto the tip. Insert the tip into the prepared canal until it binds slightly. Tips are soft and can be gently bent to conform to slight root curvatures. Mark the binding point with the stopper and remove tip from the canal.

Typically the tip end will be about 5mm-7mm from a canal's apex.

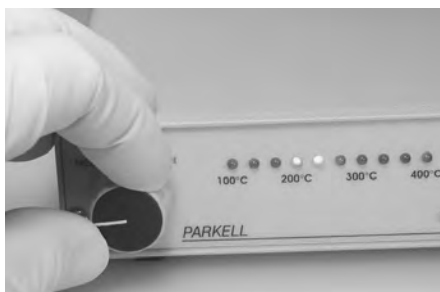
3. Check that THERMIQUE temperature knob is in the "OFF" position. Insert tip into the handpiece and make certain that it is fully seated. Hand-tighten the attachment collet. Be sure collet is tight before proceeding.

4. Adjust the master gutta percha point, coat with root canal sealer of choice, and place into the prepared canal, as usual. Place as many accessory gutta percha points as convenient using appropriate hand spreaders.

WARNINGS:

- Do not modify this device in any way. Modification will violate safety codes and endanger operators and/or patients. Any modifications void the warranty.

5. Set THERMIQUE to 200°C-225°C (LED on the front panel of the device



will light to indicate chosen temperature) and place the cool tip adjacent to the gutta percha points. Activate the device by pressing the ring on the hand-piece. You will hear a series of beeps and the lit LED will flash as the tip warms. When heated to the chosen temperature, the beeps will be heard only occasionally as the unit maintains temperature. Gently push the heated tip into the gutta percha in the root canal holding the activator ring down the entire time. Press the tip into the canal with a smooth, even motion until you reach the binding point marked by the rubber stopper. This will cause the fill material to flow and fill primary and secondary canals. This should take about 4-5 seconds.



6. Release the activator ring BEFORE removing the tip from the canal. This will begin the cool-down period. **To prevent gutta percha from sticking to the tip as you withdraw it:** With your finger OFF the activator ring, rotate the tip about 90° ... push it slight-

ly into the canal ... and then withdraw it. This simple motion (rotate, push, pull) will separate the tip without causing gutta percha pull-back.

7. Excess gutta percha may be seared off with the THERMIQUE.

8. Turn control knob to "OFF" when procedure is complete.

IMPORTANT!

After use, ALWAYS turn off the switch on the front panel and remove the tip. (This is very important before shipping or storing.)

Reason: If the switch is left "on", accidental depression of the activator ring may cause the condenser tip to get hot.

CLEANING AND DISINFECTION:

The handpiece and cable may be cleaned with an EPA registered spray disinfectant that will not harm the steel surface. They should then be wiped down with a damp clean cloth. DRY THE HANDPIECE THOROUGHLY BEFORE EACH USE. Handpiece and cable are not autoclavable.

The exterior case of the Thermique may be wiped with a cloth dampened by any standard surface spray cleaner as desired.

TIP MAINTENANCE:

THERMIQUE tips must be washed and autoclaved after each use.

DO NOT USE DRY HEAT OR CHEMICAL STERILIZATION. THESE WILL DESTROY TIPS.

BATTERY OPERATION AND CHARGING:

The THERMIQUE may remain connected to its charger for extended periods with no ill effects. It should be maintained at "FULL CHARGE" so it's always ready for use. If the "LOW BAT-


TERY" indicator illuminates, re-charge as soon as possible. The device will continue to operate on "LOW BATTERY" for a limited period, but it is not recommended. In addition, the device is equipped with low battery cut-out that will stop its functioning if there is not a sufficient charge. A full recharge will take several hours. To recharge the battery, simply plug the supplied charger into a wall outlet and then plug the adaptor into the rear of the device. The "CHARGE" indicator will illuminate. An over night charge will fully restore the battery.

AS A SAFETY FEATURE, THERMIQUE IS DESIGNED TO NOT FUNCTION WHEN THE CHARGER ADAPTOR IS PLUGGED INTO THE DEVICE. YOU MUST UNPLUG THE ADAPTOR FROM THE DEVICE BEFORE USE.

THERE ARE NO USER SERVICE-ABLE PARTS INSIDE THE UNIT. FOR SERVICE CONTACT PARKELL @ 1-800-243-7446

SPECIFICATIONS:

- Power: 12v DC @ 500ma
- Operating: 10°C - 38°C
10% - 80% RH (non-condensing)
- Transport and Storage conditions: 10-40°C, 10-80% RH (non-condensing)
- Weight: 43oz. excluding charger
Size: H 1 5/8" x W 5 1/2" x D 7 1/2"
- Tip temperature: 100°C - 400°C
± 15°C

The symbol  is intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying the scaler.

The symbol  indicates warning that tip may be hot!

The power supply line cord is the AC power disconnect device for the scaler.

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ADDITIONAL SPECIFICATIONS

- Protection Against Electric Shock - Class 1, Type BF applied part
- Equipment not suitable for use in the presence of a flammable anesthetic gas, or with any substance that promotes combustion
- Protection Against Ingress of Liquids - IPX0 (Ordinary)
- Mode of Operation of Equipment - Continuous

This equipment produces electromagnetic energy and may cause interference with other electronic devices. Should this occur, changing the positioning or location of the device may be necessary.

TROUBLESHOOTING

Unit does not operate (no lights when turned on).

1. Confirm that the charger is disconnected from the rear of the unit.
2. If charger is disconnected, charge the battery overnight.

Unit lights up, but no heat at tip.

1. Is low battery light on? If yes, charge overnight.
2. Is finger switch depressed?
3. Is tip fully inserted in collet?

IF YOUR THERMIQUE REQUIRES SERVICE:

The tips and battery charger are detachable and may be replaced by the user. Otherwise, there are No User Serviceable components in this unit.

For service, return the unit freight prepaid and carefully packed to **Parkell Repair Dept., 300 Executive Drive, Edgewood NY 11717**, with an explanation of problem. During the warranty period, the unit will be repaired and returned to you. After the warrantee period, we will call with an estimate and request approval.

WARRANTY:

Parkell will replace defective material. **This warranty is in lieu of all warranties of merchantability, fitness for purpose or other warranties, express or implied.** Parkell does not accept liability for any loss or damage, direct, consequential or otherwise, arising out of the use of or the inability to use the product herein described. Before using, the user shall determine the suitability of the product for its intended use and the user assumes all risk and liability whatsoever in connection herewith.



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