

Obtura MAXPACK

Gutta Percha Heating System



Instructions for Use

PLEASE READ ALL INSTRUCTIONS PROVIDED FOR THIS DEVICE BEFORE USING IT.

Caution: This product should only be used by dental professionals. The Obtura Spartan Maxpack is intended for injection of Gutta-percha into a prepared root canal for obturation.

FULLY CHARGE BATTERY IMMEDIATELY UPON RECEIPT AND PRIOR TO FIRST USE.

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CAUTIONS

This equipment conforms to the requirements of Medical Device Directive 93/42/EEC and satisfies the electrical safety requirements of EN 60601-1 and Electromagnetic emissions and immunity standards of EN 60601-1-2.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radiofrequency transmitting equipment and other sources of electrical noise in healthcare environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

WARNING

Risk of Fire, Risk of Burning.

Keep the heated tip away from skin and anything that is flammable.

WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING

No modification of this equipment is allowed.

WARNING

The maximum use time of the product is 5 seconds.

Introductions

Thank you for purchasing the MaxPack obturation device from Obtura Spartan End-odontics. The MaxPack supports obturation techniques that require heating gutta percha or Resilon® READ THIS MANUAL CAREFULLY AND BE FAMILIAR WITH ALL SAFETY PRECAUTIONS PRIOR TO USING THIS DEVICE.

Safety Instructions

- 1 Improper usage of this device may cause injury to patients, operators and dental assistants, and/or damage to the product.
- 2 It is intended exclusively for use by licensed dentists and endodontists only. Plugger Tips are very hot when device is activated, thus care must be taken by the dentist, assistant and patient not to contact the tip while hot. Usage of a rubber dam is strongly recommended for proper isolation of the tooth.
- 3 The temperature of the Plugger can reach 230°C, therefore, it should not be used inside the root canal for more than 5 seconds at a time.
Plugger Tips must be sterilized before first use and between patient uses. For sterilization of tip, temperature must not exceed more than 132°C in the autoclave.
We shall not assume any responsibility for malfunction, damage, or accident caused by using parts or accessories from other manufacturers.
- 4 Do not operate if there is external damage or any malfunction found when replacing battery; this can result explosion.

Cautions

- 1 Do not use any other Plugger Tips except the ones supplied by Obtura Spartan Endodontics labeled for use with the MaxPack. Use of any Plugger or battery that is not supplied by Obtura Spartan Endodontics may result in electrical shock, fire, or explosion and void Warranty.
- 2 Do not use the MaxPack device on patients with pacemakers.
- 3 Do not use the MaxPack device when the battery level displays red light. Charge the unit and wait for the device to display the green light.
- 4 It is recommended that battery be fully charged before using the MaxPack device for the first time. Allow approximately 3 hours for full charge.
- 5 The actual temperature of a MaxPack Plugger is within a range of +/- 40°C of the temperature displayed on the unit.
- 6 DO NOT use disinfectants that contain Bleach or Ammonium Chloride to clean the device.
- 7 DO NOT autoclave the Heating Unit or Charging Base.

Features

Intended use

Cordless obturation device for optimal warm vertical condensation.

Obtura Spartan MaxPack PACKAGE CONTENTS

- Heating Unit (824-700)
- Charging Base (824-701)
- Battery (824-702)
- Adapter (824-704)
- Power Cord (824-705)
- Instructions For Use
- Pluggers 55/06 (824-714)

Available Pluggers Include (Tip Size / Taper):

- 30/04 (824-710) • 35/04 (824-711) • 40/04 (824-712) • 45/04 (824-713)
- 55/06 (824-714) • 55/08 (824-715) • 55/10 (824-716) • 60/12 (824-717)
- Spreader/S (824-720) • Spreader/N (824-719)
- Thermal Tester (824-718)

SPECIFICATIONS

Charging Base Dimensions: 81mm X 137mm X 36mm

Charging Base Weight: 207g

Heating Unit Dimensions: 12.5mm X 150.5mm X 21.5mm

Heating Unit Weight: 63g

TECHNICAL DATA

Battery: Li-Ion 3.7V Sanyo 18500F

Source: 100~240V / 50~60Hz, DC 12 V \equiv , 850mA

Operating Temperature: 0°C to 45°C, Storage Temperature: -20°C to 60°C

STANDARD SYMBOLS



Class I
Equipment



Type BF
Applied Part



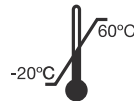
Autoclave
Symbol



Consult
Instructions
For Use



Keep Dry



Temperature
Limitation



Date of
Manufacture



Serial
Number



Authorized
Representative



CE Mark



Manufacturer



Sterilized
autoclave

Certification, Compliance, & Compatibility

REF 824-700 12V DC, 850mA

Electrical Class II equipment. Type B applied part.

The Maxpack satisfies the electrical safety requirements of AAMI ES60601-1, IEC 60601-1 and CSA C22.2#60601-1.

The Maxpack has demonstrated EMC compliance to current standards (IEC 60601-1-2). These limits are designed to provide reasonable protection against harmful interference; however, there is no guarantee that interference will not occur in every particular installation. If turning this equipment on or off causes harmful interference, please relocate the equipment to a different outlet and increase the distance between the equipment and any other electronic devices. Similarly, if other electronic devices compromise the functionality of this equipment, please consult the safety information for those devices. Maxpack must not be used if the patient and/or the operator have a cardiac stimulator or any other active implant such as a cochlear implant. The device is not designed to withstand the shocks delivered by an electric defibrillator.

To maintain safety, do not modify the equipment and use only the power supply included or supplied by Obtura Spartan directly, **REF** 824-704.

Electromagnetic Compatibility

Interactions:

- The Maxpack must not be used if the patient and/or the operator have a cardiac stimulator or any other active implant (e.g. a cochlear implant).
- The device complies with applicable electromagnetic compatibility standards. Nevertheless, the user should ensure that any potential (presence of radio frequency emitters, electronic devices, etc.).
- The device is not designed to withstand shocks delivered by an electric defibrillator.

EMC Table

IEC 60601-1-2:2007 (Ed 3.0)

Guidance and manufacturer's declaration – electromagnetic emissions		
The model Maxpack is intended for use in the electromagnetic environment specified below. The customer or the user of the model Maxpack should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model Maxpack uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The model Maxpack is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity


The model Maxpack is intended for use in the electromagnetic environment specified below. The customer or the user of the model Maxpack should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption, and voltage variations on power supply input lines IEC 60601-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Maxpack requires continued operation during power mains interruptions, it is recommended that the model Maxpack be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note : U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The model Maxpack is intended for use in the electromagnetic environment specified below. The customer or the user of model Maxpack should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the model Maxpack, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d=[3.5/V1] \sqrt{P}$ $d=[3.5/E1] \sqrt{P}$ 80MHz to 800MHz $d=[7/E1] \sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range .b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m 80MHz to 2.5 GHz	

Note 1 At 80MHz and 800MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electro-magnetic site survey should be considered. If the measured field strength in the location in which the model Maxpack is used exceeds the applicable RF compliance level above, the model Maxpack should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orient-ing or relocating the model Maxpack.

b) Over the frequency range 150kHz to 80MHz, field strengths should be less than $[V1] \text{ V/m}$.

Recommended separation distances between portable and mobile RF communications equipment and the Maxpack

The Maxpack is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Maxpack can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Maxpack as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.366	0.366	0.736
1	1.16	1.16	2.33
10	3.66	3.66	7.36
100	11.6	11.6	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

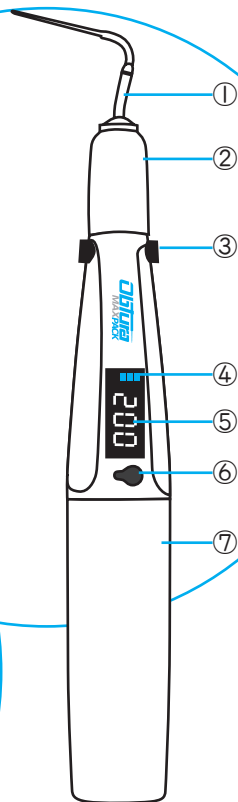
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Product Description

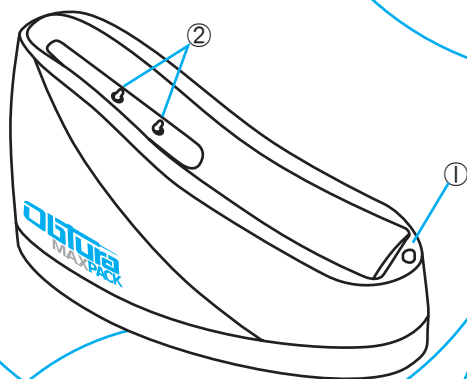
HEATING UNIT

- ① Plugger
- ② Plugger Attachment Cap
- ③ Heater Switches
- ④ Battery Level Indicator
- ⑤ Temperature Display
- ⑥ Power "ON/OFF" Switch / Temperature Selection
Powers the unit on and off, and changes the temperature setting
- ⑦ Battery Casing

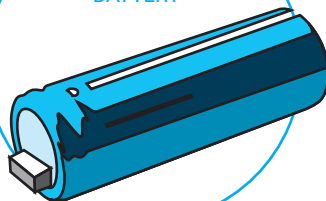


CHARGING BASE

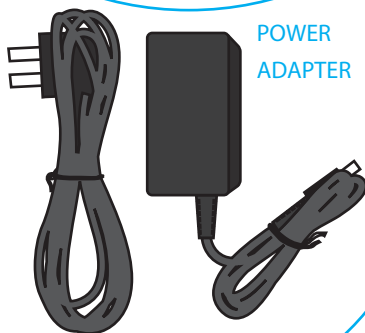
- ① Charging Status Indicator
- ② Charging Contact Terminals



BATTERY

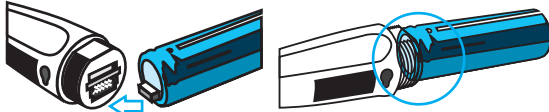


POWER ADAPTER



How to Install/Change the Battery Pack

- ① Insert the Battery Pack into the Heating Unit as shown in the pictures.
- ② Attach the battery connector into the indentation of the heating unit.
- ③ When replacing the battery, turn the Battery Casing counterclockwise. Separate the Battery from the connector of the Heating Unit. See ① and ② above for installation instructions.



Caution: Ensure threads are aligned and avoid excessive forces when threading the battery casing onto the heating unit.

Caution: When inserting the battery, make sure the connector is properly set. When replacing the battery, use B&L batteries only. The replacement should be conducted sequentially as described in the manual. Replace the battery if there is apparent damage or deformity to the battery

Attaching Pluggers to the Heating Unit

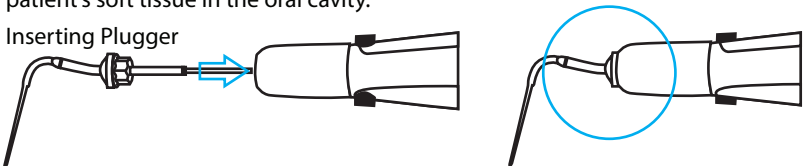
- ① Press the Power "ON/OFF" Switch button. If lights do not display, check the Battery connection. If the display window shows 'oPn', this indicates that the Pluggers are not connected properly. When the pluggers are connected properly, the default temperature of 200°C or the last temperature setting will appear.
- ② To change the temperature setting, press the Power "ON/OFF" Switch until reaching the setting you desire. Pressing the switch will rotate temperature settings in the following order; 150°C -> 180°C -> 200°C -> 230°C -> 150°C.



Recommended Temperatures: Gutta-percha : 200°C Resilon® : 150°C

Caution: Pluggers are extremely hot during use. Avoid direct contact with the patient's soft tissue in the oral cavity.

Inserting Pluggers



Note: The mouth of the Heating Unit has 6 different slots for inserting the Pluggers. Select the appropriate one based on your preferred orientation of the Heater Switches in relation to the Pluggers tip.

Heating the Plugger

- ① Once the Plugger is properly connected to the Heating Unit, press the Power “ON/OFF” Switch to turn on the unit. When the power is on and the Plugger has been properly installed, the temperature will be displayed on the screen.
- ② Change the temperature if necessary.
- ③ Heating the Plugger occurs by pressing (and holding) either one of the two Heater Switches. Releasing the Heater Switch allows the Plugger to return to room temperature. During normal operation, a beeping noise will indicate that the Plugger is hot. Do not touch the Plugger until it has a chance to return to room temperature.

Caution During the Usage of this Device

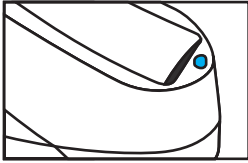
- ① The MaxPack Heating Unit is designed to turn-off automatically if the battery should begin to overheat. While the chance of this occurring is rare, if it occurs please allow the Heating Unit sufficient time to cool. Then, recharge the Heating Unit by placing it on the Charger Base for at least 30 seconds before attempting to use again.
- ② Heat activation of the Plugger inside the canal should not exceed more than 5 seconds.
- ③ This device shuts off automatically if not used for more than 10 minutes. Press the Power “ON/OFF” Switch to turn on the unit.
- ④ The tip of the Plugger is very hot during use. Please perform all endodontic procedures with a rubber dam.
- ⑤ For safety purposes, place the tip of the Plugger at the orifice of the root canal before activating the Heater Switches. Use caution to avoid contact to the soft tissue of the oral cavity while the Plugger is hot.
- ⑥ When replacing the Plugger, turn the power off and ensure the Plugger has cooled down sufficiently.
- ⑦ Plugger Tips must be sterilized before first use and between patient uses. For sterilization of tip, temperature must not exceed more than 132°C in the autoclave.
- ⑧ Be careful: the cap connected to a Plugger also becomes hot during use.



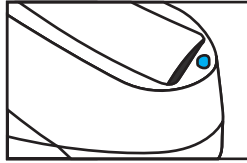
NOTE: This device is only intended for use during root canal therapy. Use extreme caution with the Heating Unit so as not to burn the patient or oneself. Be careful not to get injured from the tip of pluggers.

Charging the Battery

Keep the Heating Unit on the Charging Base while the unit is not in use. The Device is ready for use when the LED charging status indicator displays a green light. Once a red light on the Battery Indicator of the Heating Unit starts to flash, the unit needs to be recharged by carefully positioning the Heating Unit on the Charging Base ensuring the proper contact is made. Once the battery is fully charged, the LED charging status indicator will turn green.



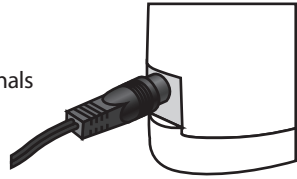
Charging (Amber)



Fully charged (Green)

on the Charging Base ensuring the proper contact is made. Once the battery is fully charged, the LED charging status indicator will turn green.

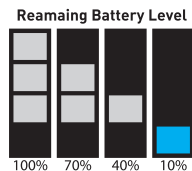
- ① Connect the Power Adapter to the Charging Base.
- ② Position the Heating Unit on the Charging Base correctly so that the Battery Charging Contact Terminals on the bottom of the Heating Unit align with the two Charging Contact Terminals on the Charging Base with the temperature display window facing upwards.
- ③ If the correct connection is made, the LED charging status will display an amber light during charging. Once the battery is fully charged, the LED charging status indicator will turn green.



Note: If the LED is neither amber or green, the charging terminals are not properly connected. Re-align the Heating Unit on the Charging Base and also check that you are getting power to the Charging Base.

Pluggers should be removed while charging. Please keep the pluggers disconnected from the unit after each treatment.

- ④ To confirm whether the battery is fully charged, separate the unit from the Charging Base and turn on the Heater Switch. If there are 3 levels of the green LED displayed, the unit is fully charged.



Note: If the unit has not been in use for more than a month, it may not function cor-rectly due to natural discharge of the battery. Monthly recharging is recommended even when the unit has been fully charged but is not in use.

Technique Overview

STEP 1: CONE FIT

Select a cone that fits snugly to Working Length (WL). Trim 0.5mm from the tip. Note: Do not use sealer for this step.

STEP 2: PLUGGER FIT

Choose the Obtura Spartan Plugger which most closely matches the taper of the prepared canal. Place the Plugger into the canal until it binds.

Note: Plugger tip should be approximately 4 to 7 mm short of WL. Move the rubber stop to indicate the maximum depth of penetration.

STEP 3: CONDENSE CONE WITH HAND PLUGGER

Coat the cone (fitted in step 1) with sealer and push it as far into the canal as possible. Note: Tip should be approximately 0.5mm from WL. Use the MaxPack to sear off excess cone material at the canal orifice. Use a hand plugger to condense the cone.

STEP 4: CONDENSE CONE WITH OBTURA SPARTAN PLUGGER

Activate the button to bring the Obtura Spartan Plugger to the desired temperature. Note: 150°C for Resilon and 200°C for GP is recommended. Advance the Plugger apically until reaching the depth indicated by the rubber stop (set in step 2). Release the button to allow the Plugger to begin cooling, while at the same time holding continuous apical pressure, hold for 5 seconds. Remove the Plugger from the canal. Note: if there is a tendency for the cone to come out with the Plugger – activate the button to heat the Plugger again (allow it time to reach set temperature) before trying to remove the Plugger from the canal.

STEP 5: CONDENSE SHORTENED CONE WITH HAND PLUGGER. BACKFILL

Use a small hand plugger to condense the remaining cone apically. Set the rubber stop (same depth as Step 2) and condense the remaining material. Backfill to the orifice with the Obtura III MAX Heated Gutta Percha System (contact Obtura Spartan Endodontics for details : 800-344-1321 or www.obtura.com).

Technique Tips

- ① It is important to select the appropriate Plugger size and taper. The Plugger's Tip should meet resistance within 4 to 7 mm of the Working Length.
- ② Do not advance the gutta-percha beyond the binding point. If the gutta-percha is advanced beyond the binding point, there will be no pressure applied to the gutta-percha while it is cooling. Therefore, use a hand Plugger and apply direct pressure.
- ③ If the temperature exceeds 200°C, the gutta-percha may become soft and could be ineffective during compression.
- ④ If a large amount of gutta-percha is used, raise the temperature setting to 230°C.
- ⑤ After "sustained push", let the Plugger cool before the removal from the canal. This reduces the chance of pulling the filling back out with the Plugger.

Troubleshooting

Code	Description or possible causes	Recommended action for the user
Er0	Defective Microprocessor	If this error code is displayed on the screen please contact Obtura Spartan's customer service department.
oPn	This message will be displayed on the screen if the Pluggger is not correctly connected to the unit and if the heating mechanism is not working properly.	Separate the Pluggger from the unit and re-connect the Pluggger. If proper temperature setting is displayed, it indicates normal state. If the same message is displayed, replace with a new Pluggger and check to see if same problem occurs. If same problem occurs, please contact Obtura Spartan's customer service department.
SHR	Desired temperature not reached in 200 seconds: defective pluggger or low battery power.	Recharge the battery or replace the pluggger. If the code does not disappear, return the unit to Obtura Spartan for replacement.
HD1	Temperature does not change within 5 seconds after activation: Defective pluggger.	Replace the pluggger. If the code does not disappear, return the unit to Obtura Spartan for replacement.
	Power turns off while in use and power does not turn on again.	A. This may result from the Device overheating. Let the unit cool and retry. B. Recharge. C. If the same problems occur after recharging, change the battery.

* See page 10 for contact information

Sterilization & Maintenance

Keep this device at room temperature away from external shock or direct sunlight.

Heating Unit and Charging Base – Clean the exterior of the Heating Unit and Charging Base by using a soft cloth moistened with a mild detergent or rubbing alcohol. The surfaces should be sheathed with plastic barrier to prevent contamination and discoloration. The use of non-recommended cleaning agents could result in damage to the outer surface of the MaxPack Device.

DO NOT use strong disinfectants or those that contain Bleach or Ammonium Chloride to clean the device.

DO NOT autoclave the Heating Unit or Charging Base.

After each patient use, the pluggger tips should be sterilized by autoclave for 4 minutes at minimum of 132°C (269.6°F).



Notice: If the unit is not used for an extended period of time (more than once per month), it may not work because of battery discharge. Periodical (once per month) recharge is recommended even if the Device is not used. It is recommended to change the battery every 6 months. Please contact Obtura Spartan Endodontics to purchase a replacement battery.

Warranty

Obtura Spartan Endodontics warrants the MaxPack against defects in material and workmanship for 12 months from the date of purchase with proper usage. During that twelve-month period, the manufacturer will repair or replace a defective unit. Defects caused by misuse, neglect, accident or abuse are not covered by this warranty. The manufacturer assumes no liability resulting from improper use, damage or breakage due to misuse of the MaxPack Obturation Device by the purchaser.

The manufacturer is not responsible for breakage of any component of the MaxPack Obturation Device, including the Plugger, resulting from forceful compaction of gutta-percha or Resilon® or use of the Plugger outside of the methods noted in this Instruction for Use.

The battery and Pluggers in the MaxPack Obturation Device are replaceable. New batteries and Pluggers can be ordered from Obtura Spartan Endodontics.

The manufacturer assumes no liability for damage to the MaxPack Obturation Device, injuries to patients or users or other problems resulting from use of accessories or other materials not supplied by the manufacturer.

For Sales Orders and Product Information Contact:
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Algonquin, IL 60102
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www.obtura.com



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