



Operator's Manual



Heated Gutta Percha Obturation System

www.obtura.com



Heated Gutta Percha System

The Obtura is intended to be used by professionally qualified dentists, endodontists, and dental clinicians for specialty procedures in root canal and restorative dentistry.

This equipment conforms to the requirements of the Medical Devices 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.

This equipment is not suitable for use in the presence of flammable anesthetics.

Model 823-700 DC 12V, 1.0A
 Medical Device Class IIa. Electrical Class II equipment. Type BF Applied Part.

Instructions for cleaning and disinfecting are included on a separate sheet.

The precision of the indicated value of temperature is +/- 5°C.

Use only accessories manufactured or supplied by Obtura Spartan.

This equipment contains no electrical parts serviceable by the user, except for fuses in the control unit, which must be replaced by exact equivalents for continued safety protection.

Environmental Conditions	Normal Use	Transport and Storage
Ambient Temperature	+ 10°C to + 40°C	- 5°C to + 50°C
Relative humidity	30% to 75%, non-condensing	30% to 75%
Atmospheric pressure	860 hPa to 1060 hPa	700 hPa to 1600 hPa










Symbol	Description	Symbol	Description
	Attention, see accompanying documents		Power On-Off
	Single Use, do not re-use		Type BF Applied Part
	Steam Sterilize at temperature indicated		Class II Equipment
	Year of Manufacture		Use By
	Batch or Lot Code	SN	Serial Number
		PN	Part Number
M	Memory preset for temperature	-	Temperature Down
		+	Temperature Up

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ONE-YEAR WARRANTY

Obtura Spartan warrants that all products sold by it are of high quality materials and workmanship. The Obtura is warranted against defects in materials and workmanship for one (1) year from date of purchase. Obtura Spartan's liability and customer's sole remedy in the event of any claimed defect shall be limited to repair or replacement of the item at Obtura Spartan's option. All parts or components are warranted for one (1) full year, excluding consumable items. This warranty does not cover damage caused by misuse or abuse of the item. All consequential damages are excluded. This warranty is given in lieu of any other warranties, expressed or implied, including any warranty of manufacturability or fitness for use. Failure to clean the instrument according to the instructions in this manual may void the warranty.

To obtain warranty service, the customer must return the instrument, shipping charges prepaid, to the factory or an authorized service center with a written explanation of the claim. To obtain warranty service, the instrument must be received within 1 year from date of purchase.



IMPORTANT SAFETY INFORMATION

1. Please read the entire manual before using the Obtura.
2. To avoid explosion hazard, do not use the Obtura in the presence of flammable materials.
3. Do not allow heated parts to come in contact with soft tissue. All handpiece components attached to the heating chamber are hot and may cause burns if used improperly. During normal use, the handpiece is not intended to contact the patient. Always use a thermal protector for added protection in the event of accidental contact. In addition, the use of a rubber dam will increase protection.
4. Do not abuse the handpiece cable. Ensure that the handpiece cable and power cord are free from cuts, nicks or other damage.
5. If attempting to change the fuses, ensure the power cord is disconnected before attempting to remove the control unit cover.
6. Place the control unit sufficiently close to the patient so it will not be pulled off the counter by reaching too far with the handpiece.

Disclaimer: Obtura Spartan does not assume any responsibility or liability for incorrect diagnosis or failed procedures due to operator error or equipment malfunction. Clinicians who are not familiar with the techniques and uses of this product should attend courses and receive training on the subject prior to use.

To ensure continued compliance with EC Directives and safety, use only the power supply included with this product or supplied by Obtura Spartan, PN 823-711.

Overview

Congratulations! You have purchased an instrument that will improve your productivity and provide you and your patients with quality health care. Please read the entire manual prior to using the instrument. Here are some useful tips that you may find advantageous:

When you are ready to practice with your Obtura, you should become familiar with its components. After attaching the needle and thermal protector, turn the Obtura on and set to operating temperature. It takes the Obtura approximately 120-seconds to reach the highest operating temperature of 200°C. The high temperature setting will improve gutta percha flow, especially when used in the cold practice block. Begin by filling the plastic practice blocks with gutta percha per the instructions included. Use condensers to condense the material void free.

- The soft silver needles are designed to conduct heat to insure flow even at the needle tip; however as the needle tip cools between uses, you will want to express 3 cm of gutta percha to pre-heat the tip just prior to use. The needles are bendable to fit the tooth; however they may break if they are repeatedly bent or if they are bent at the needle attachment point. Always use the multi-tool to bend the needle. Do not kink the needle, as any restriction will impede flow. After a few practice sessions needle bending will be easily accomplished.
- Do not loosen or remove the dark blue plastic heater nut. The heater nut is fastened to the gun with a set-screw; therefore removal will cause damage. The heater nut must be kept tightly fastened in order to secure the heater to the handpiece when expressing gutta percha.
- The stand for the handpiece may be positioned by itself or it may be attached to the bottom of the control unit. The stand can be attached to either side of the control unit with four Phillips-head screws that are fastened to the bottom of the stand.
- The cord to the handpiece can exit from the front or rear of the unit. If a front exit is desired, gently press the handpiece cable into the tracks on the bottom of the unit, to exit either on the "left-front" or the "right-front".
- Cleaning the Obtura is easy and very important; just follow the directions in this manual. If your Obtura is cleaned on a regular basis it will provide years of reliable service. If you do not clean your unit, it may become clogged and difficult to move the plunger due to a buildup of old, hardened gutta percha. Hardened gutta percha can be removed with the heater-reaming tool.

Thank you for purchasing the Obtura. We believe it is a beneficial instrument that will enhance your practice. We are continually striving to improve our products, and services. If you have any questions or suggestions, we would appreciate hearing from you. We are also interested in seeing any x-rays you may have of interesting cases. Feel free to contact us at 1-800-344-1321 (or 1-877-485-3556 in Canada) at any time; we welcome the opportunity to speak to you. Or, visit our website: www.obtura.com

System Description

The Obtura is intended for use by professionally qualified dentists, endodontists and dental clinicians to heat gutta percha and to place it into the previously prepared root canals of human teeth, in order to provide a quick and complete obturation of the canal.

There is a minimum level of understanding and background assumed in the writing of this manual; if, at any time the reader feels overwhelmed or unsure, please cease use and call Obtura Spartan for assistance. We value safety **first and foremost**.

New with the Obtura is the interchangeable, plug-in handpiece. Any Obtura handpiece can be used with any Obtura control unit. The advantages to the user are many, including the “hot spare” concept (one in use while another is being cleaned). The new handpiece **cannot** be retrofit to the Obtura II or any previous model.

Also new is push-button digital temperature control for more accurate, reproducible settings and a memory function that stores up to 5 user-selectable temperature settings for your convenience.

Unpacking and Assembling

Check all packaging for signs of damage, report any found immediately with the shipper so that claims will be honored in a timely way.

Remove the top layer of shipping material from the container and set aside. Save all packing materials in the event of an instrument move or shipping at a later date.

Remove the main unit, the handpiece(s), handpiece stand complete with stand attachment spacer and screws, power supply, instructions, supplies and accessory box. Check for loose items.

Unwrap the main unit and place on a flat surface. Locate the unit so that by extending the cord you will not pull the unit off of the surface! The handpiece cable length is approximately 224 cm (88 in.).

Locate the handpiece stand and place it next to the main unit. The stand provided for the handpiece can be attached to the Obtura by the following means. After determining which side, simply remove the 2 screws in the bottom of the stand. Remove the 2 screws holding the attachment plate to the bottom of the stand and reattach to correct side so it hangs off the side as shown. Attach stand and bracket to control unit using two remaining screws.



Plug the handpiece connector into the rear of the control unit, note the alignment of the “red dot” (12 o'clock position), and the “click” to signify complete insertion. Should the user require the cord to exit the front of the unit, invert the Obtura on a smooth, soft surface and gently press the cable into the tracks provided leaving a small loop of cable from the connector to the beginning of the track. The cable can exit on the left-front or the right-front; or, without use of the cable tracks, from the rear.



Open the box and remove the power supply and receptacle blades. Choose the correct blade to fit your mains supply and slide on to the power supply. Plug the connector into the rear of the unit. Plug the power supply into the mains. The unit display will momentarily indicate the version of installed firmware and then go off. *This only occurs when first connecting to the mains.*



Operation

Operation of the Obtura has been designed to be intuitive, but to fully realize the extent of the instrument and its many features, please read this entire section.

There are four (4) tactile switches on the front of the Obtura and an LCD display. The functions of the four switches are: Power On/Off, Temperature Up, Temperature Down and Memory. The 3-digit display indicates the operating temperature in degrees centigrade and the memory presets, when activated. Description of each button follows.

Press the Power on/off button to activate the unit, the display will show the last used set-point temperature. After 5-seconds, the actual heater temperature will be displayed, heating up to the set-point. Press again to toggle the power off.

With the unit “on”, press the *Temperature Up* button to increase the set-point temperature of the Obtura heater, in single degree increments. The *Temperature Down* button reduces the set-point temperature, also one degree at a time. If either of these two buttons are pressed and held (separately), the temperature setting will increment / decrement at a rate of approximately 2°C per second.

The *Memory* button retrieves preset memory set-points. A quick press displays the letter “M” and the preset position number. The temperature associated with the memory is displayed on the three-digit display. To set the unit to this temperature, no other action is required, as after 5 seconds it will be the new set-point and the actual heater temperature will again be displayed. To access another memory position, press the memory button to display the current memory location, and again within 5-seconds to advance to the next memory position.

To reset a memory location, press the memory button, as required, until the memory number to modify is shown. Then, within 5-seconds, adjust the preset temperature with the Temperature-Up and Temperature-Down buttons. The memory and the display are now set to the new temperature. After 5 seconds with no button press, the Obtura will change the set-point to the new temperature, displaying the actual heater temperature until the new set point is reached. Preset memories are saved even during power failure, as is the last operating temperature (even if it is not a “memory” preset).



The Obtura requires (approximately) 120-seconds to heat from ambient (room temperature of about 25°C) to maximum operating temperature of 200°C.

For your convenience, the table below can be used as a reference.

Memory Number	Factory Preset	New Setting	Date
M1	140°C		
M2	150°C		
M3	170°C		
M4	180°C		
M5	200°C		

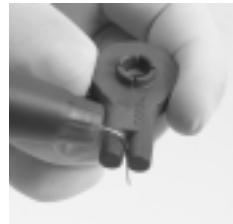
Installing a Needle

To place the gutta percha where desired in the canal, choose the needle diameter best suited (20, 23 or 25-gauge). With the Obtura cool, remove the needle nut using the multi-tool; the nut should remain on the tool when unscrewed. Place the appropriate needle in the rear of the needle nut, so that the length of the needle protrudes through and forward. Reattach the needle nut on to the heater, taking care not to cross-thread. Tighten with the multi-tool until snug. Do not over tighten, but do not leave too loose.



Bending the Needle

In most situations, a straight needle will not provide access to the canal. Using the multi-tool, gently bend the needle to provide a shape conducive to the procedure. Be careful not to bend too sharply, as kinks will result and block gutta percha flow. For access to difficult to reach canals, simply loosen the needle lock nut, rotate the needle to desired position and then re-tighten.



Loading Gutta Percha



Warning: Using more than one stick of gutta percha at a time may damage the seal. **Do Not** use more than one piece at a time.

Power on the Obtura and wait for the heater to come up to your desired temperature. Press the plunger release button on the top of the Obtura handpiece and withdraw the plunger shaft. Insert a gutta percha stick into the chamber via the opening just forward of the release button. Reinsert the plunger shaft until the pawl engages the plunger shaft. Some resistance will be felt as the gutta percha is pushed forward to the heating chamber.



Expressing Gutta Percha

Specifics to technique will not be addressed here, but a few reminders and hints follow.

- When expressing gutta percha, do not “withdraw” the Obtura, but let the gutta percha “push” the needle out of the canal. Pulling the needle out may cause voids and require condensation or rework.
- Take care when bending needles, as a kink will make it all but impossible to express material. Also, repeated bending will cause needle weakening and subsequent breakage.
- Wait for the gutta percha to come up to temperature before attempting to express; material that is too cool will require much more pressure or be impossible to pass through a small diameter needle.
- Before beginning a procedure, express about 3 cm of gutta percha to move the up-to-temperature material to the “end” of the needle; the warm material will fill space more completely.

Maintenance

For best results, the Obtura handpiece should be cleaned daily. This prevents build-up of excess gutta percha within the heating chamber. Follow these steps to clean the unit.



SAFETY NOTE: SAFETY GLASSES SHOULD BE WORN AT ALL TIMES WHILE WORKING ON THE OBTURA AND ITS RELATED COMPONENTS.

SAFETY NOTE: BEFORE BEGINNING TO WORK ON THE HANDPIECE BE SURE THAT THE POWER CORD IS DISCONNECTED FROM UNIT.

Caution: The needle nut and plunger shaft will be hot; use the multi-tool and be careful not to directly contact the metal parts.

1. Turn the unit on and allow it to reach full temperature of 200°C. Express all gutta percha and remove needle and needle nut using the multi-tool. Place the handpiece in the handpiece base, depress plunger release button and remove plunger shaft. **Turn unit off.** Next use a clean towel or a gauze pad to remove any gutta percha from the plunger seal and shaft. Dipping seal assembly into cleaning solution will make cleaning easier. Inspect plunger seal for tearing or cracking. If damaged, replace as described in the Plunger Seal Assembly paragraph of this manual.
2. Hold the gun over cleaning solution bottle, insert the cleaning brush from the back of the handpiece through the handpiece bushing and into the cleaning solution so brush absorbs solution and scrub back and forth. **Do not immerse heater into cleaning solution. Do not insert the brush through the top gutta percha loading slot.**



3. After cleaning, remove all residual gutta percha from the threaded end of the heating chamber to ensure leak-proof seal when installing applicator needles. Be careful not to damage the tip of the heating chamber.
4. Insure that the plunger seal is securely attached to the plunger shaft. It is recommended to visually inspect the inside of the heater to be sure all foreign matter has been removed. Test cleanliness by inserting the plunger. The plunger should insert easily into the full depth of the heater chamber without using the trigger to force it into position. If there is excess resistance during plunger insertion, use the heater reamer tool to remove accumulated gutta percha from the heating chamber. Dipping the reamer tool into the cleaning solution will make cleaning easier. Slowly insert the reamer into the handpiece bushing while turning the reamer clockwise until it bottoms out against the handpiece bushing. Slowly remove the reamer while continuing to turn it clockwise. Clean the handpiece with the brush and solution again to remove any residue that could have been left inside the heating chamber by the reamer tool. If needed, additional leverage can be gained by using the multi-tool as a handle on the reamer. Place the "flats" of the reamer tool into the needle nut socket on the multi-tool and gently turn.
Regular cleaning should make the need for using the reamer tool limited and extend the life of your seal assembly and heater.
5. Make sure the applicator needle nut is clean and free from residual gutta percha. If necessary, immerse the needle nut and let soak for a few minutes to soften any gutta percha and scrub with cleaning brush. Use an explorer tool to remove any excess gutta percha from the threads. If the threads become coated with gutta percha it will act as an insulator, which will not allow enough heat to reach the tip.

Handpiece Bushing

This part is susceptible to wear that is caused by the bushing being out of alignment and this allows the trigger pawl to cause wear at the pawl engagement opening. The handpiece bushing should be aligned in the handpiece so that the bushing rotation ceases. To install the handpiece bushing, slide in and turn clockwise until resistance is felt. The handpiece bushing should be cleaned or replaced as needed.

Plunger Shaft Assembly

Areas of inspection consist of the plunger seal and the plunger teeth. The plunger seal should be inspected for wear or breakage. Gutta percha expressed through the handpiece will give an indication of seal's condition both quickly and accurately. If excessive gutta percha passes by the seals, the plunger seal assembly should be replaced. The plunger teeth should be inspected for wear or chipping. The plunger shaft should be replaced if teeth are badly chipped or slipping is encountered during testing. The plunger shaft of the Obtura should be checked for bending; if it will not roll smoothly on a piece of glass or a flat table-top (indicating a bow or bend), it should be replaced as the use of a bent shaft may cause damage to the heater bore.

Plunger Seal Assembly

To remove the seal assembly, locate the multi-tool as it has the hex for the retainer screw machined-in. Heat the end of the shaft (a lighter will work) to soften the thread-locker, and carefully remove the screw and seal assembly. To replace the assembly, thoroughly clean the end of the plunger, using extra care to be sure the threads are clean and dry. Tighten using the multi-tool. Do not over-tighten.

Needle Nut

The needle nut may become filled with gutta percha and this will inhibit complete tightening and thermal transfer from the heater to the needle. The needle nut threads can be cleaned with a 1/4-28 tap but it is usually more efficient to replace it. The needle nuts can be collected and cleaned thoroughly at a later date for re-use. If the needle nut does become filled with gutta percha it may indicate that the nut has been tightened insufficiently or by hand. Use the multi-tool to assure proper fit.

Handpiece Cable Assembly

The cable should be inspected very thoroughly at the handpiece entry point for broken wires and cracks in the cable housing due to the frequent bending in this area. The signs that this has occurred are an intermittent problem where the unit will work fine and then when the cable is bent the unit stops heating altogether. If these conditions exist the "Er1", "Er2" or "Er3" error code on the Obtura display can diagnose them.

Error Code	Probable Cause	Remedy
Er1	Handpiece disconnected	Verify fitment of connector. Remove & replace. Check cable for breaks or damage: Check connector for broken or bent pins. Contact factory for handpiece replacement.
Er2	Thermocouple wires broken Handpiece cable is bad or damaged; Handpiece internal error	Replace handpiece or contact factory for repair guidance.
Er3	Heater wires open; Handpiece cable is bad or damaged; Heater is bad	Replace handpiece or contact factory for repair guidance.
Er4	Heater wires shorted; Handpiece cable crushed and/or shorted; Bent pins on connector.	Replace handpiece or contact factory for repair guidance.
Er5	Temperature cannot be reached in 255 seconds	Heater Fault – Contact factory for repair.
Er6–Er9	Internal Errors	Not user serviceable – Contact factory for repair.

Fuse Replacement



Warning:
Static Electricity can damage many of the parts used in this equipment. Use ESD precautions when components are exposed.

Other than fuses, there are no user serviceable parts within the base enclosure.

To replace the fuses, first verify that power is not connected, then follow the instructions for disassembly as described below. Replace fuses **ONLY** with size and rating as specified on the main printed circuit board. Verify that all fuses are the correct size, rating, and are in the correct holder(s). Fuse F1 (near the middle of the printed-circuit board) is ½-amp. F2 (towards the rear of the unit) is a 1.00-amp. After fuse replacement, follow instructions for reassembly. Occasionally, the fuse holders will loosen during replacement; simply squeeze the clips together slightly and verify that it is a snug fit for proper contact.

Disassembly of the Chassis

Power off the Obtura. Unplug the power supply from the mains power. Remove the handpiece and power connectors from the rear of the unit. Remove the handpiece cable from the tracks on the bottom (if so fitted). Place the unit inverted (upside down) on a soft, clean surface. Remove the handpiece bracket (if it is in place) by removing two #4-40 screws on the handpiece mounting bracket plate. Remove the three #4-40 case retaining screws, but do not open the case.

Holding the case together, re-invert the unit (place it upside up). Carefully lift the top of the case, starting at the rounded corner and finishing with the straight (front) edge. Lay the top of the case next to the base, with the straight (front) edges next to each other. Unplug the ribbon cables to the display and touch panel.

Reassembly of the Chassis

Reassembly is done in the reverse order of disassembly, with minor exceptions. Locate the base and cover assemblies together with the front edge of the base butting up to the front edge of the cover assembly. Press the display ribbon cable connector on to J4, taking care with the alignment of the pins. Press the touch panel ribbon cable connector on to J5, also taking care with the alignment of the pins. Carefully place the cover on to the base while bending the ribbon cables. Replace the handpiece stand bracket, if previously fitted, and replace the cable into the tracks, as desired.

Theory of Operation

The heating system of the Obtura is a closed-loop design to ensure consistent temperatures and uniform gutta percha flow. This means that the temperature of the heater is read several hundred times per second and corrected (as necessary) to insure accurate and consistent heating.

In the **handpiece**, the temperature of the heating chamber is detected by a thermocouple integrated into the heating element and encapsulated with epoxy. The output from the thermocouple is converted, by an analogue to digital converter, into a digital stream for use by the control unit.

The handpiece is composed of a two-piece heat resistant composite body that encapsulates the trigger assembly, heater system and plunger.

Gutta percha is placed into the top of the handpiece shell and expressed via the plunger shaft assembly. Pressing the trigger, which pushes the shaft via a spring-loaded pawl, moves the shaft. The heater assembly is directly connected to the shell providing a straight through path for the gutta percha, warming it in the process.

In the control unit, the data stream from the handpiece is read and the temperature interpreted by a micro controller, which builds display data for the LCD and reads the touch-panel. The processor also turns the heating element on and off several hundred times per second to maintain constant temperature. A watchdog processor performs “self-diagnostics” for the system.

Mains voltage never enters the Obtura, as the mains voltage is converted to 12-volts DC via an external switch-mode power supply. Selection and installation of the appropriate plug blade is all that is necessary to configure the unit. Low-voltage enters the control unit case via a “standard” power supply connector.

Frequently Asked Questions (and Answers)

Q. How often should unit be cleaned?

A. The Obtura should be cleaned at the end of each day or procedural session.

Q. How often should the needle changed?

A. It is recommended that the needle be changed after each patient and when damage is detected or suspected.

Q. How often should the plunger seal be changed?

A. Observe seal for wear, replace if seal is torn or missing.

Q. Why use only one piece of gutta percha?

A. Critical lengths of the mechanical components of the Obtura have been designed for a single piece of gutta percha, and using more can cause excessive back pressure and damage.

Factory Repair

Factory Service at Obtura Spartan is available on a time-and-materials basis. Contact information:


Obtura Spartan
1663 Fenton Business Park Court
Fenton, MO 63026
 (636) 343-8733
 (800) 344-1321
 (636) 343-5794 - fax
 www.obtura.com

Some problems can be diagnosed and repaired via telephone - call first before sending in your unit.

If you have spoken to the repair department and it is determined that the unit must be returned to the factory, please be sure to pack carefully and appropriately. Use the original box and packaging (if possible) or a minimum of 8 cm. (3 in.) impact absorbing insulation and double boxed. Obtura Spartan will not be responsible for damage due to improper packing or shipping. Insurance is optional but recommended.

Note: Unauthorized repair or attempted repair voids all warranties.

Replacement Parts

Item Number	Description	Item Number	Description
823-700	Obtura Complete System	822-602	Obtura Gutta Percha, Box of 100 Pieces
823-710	Obtura Handpiece	822-604	Flow 150 Gutta Percha, Box of 100 Pieces
823-711	Obtura AC Adapter	823-713	Obtura Multi Tool
823-715	Obtura Thermal Protectors, Pack of 10	822-609	Cleaning Kit, Bottle of Cleaning Solution with 2 Brushes
823-616	Obtura Needle Nuts, Pack of 2	822-613	Cleaning Brushes, 2 Pack
823-618	Obtura Plunger Seal Assembly	825-103	Heater Reamer Tool
823-712	Obtura Plunger Shaft Assembly with 823-618 Seal		
823-714	Obtura Handpiece Bushing		
823-620	Applicator Needles, 20 Gauge, Pack of 6		
823-623	Applicator Needles, 23 Gauge, Pack of 6		
823-635	Applicator Needles, 25 Gauge, Pack of 6		



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