Welcome to the MAX

OPERATOR’S MANUAL
Heated Gutta Percha System
The Obtura III MAX 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 823-800 DC 12V, 1.0A
Medical Device Class IIa. Electrical Class II equipment. Type BF Applied Part.

Instructions for cleaning and a product diagram are also included on a separate laminated sheet.

The precision of the indicated value of temperature is ±5°C.

Use accessories manufactured or supplied by Obtura Spartan only.

This equipment contains no electrical parts serviceable by the user.

<table>
<thead>
<tr>
<th>Environmental Conditions</th>
<th>Normal Use</th>
<th>Transport and Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient Temperature</td>
<td>+10°C to +40°C</td>
<td>-5°C to +50°C</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>30% to 75%, non-condensing</td>
<td>30% to 75%</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>860 hPa to 1060 hPa</td>
<td>700 hPa to 1600 hPa</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>🔴</td>
<td>Attention, see accompanying documents</td>
<td>🆕</td>
<td>Type BF applied part</td>
</tr>
<tr>
<td>☑️</td>
<td>Single use, do not re-use</td>
<td>⚠️</td>
<td>Class II Equipment</td>
</tr>
<tr>
<td>🔴</td>
<td>Steam sterilize at temperature indicated</td>
<td>🔄</td>
<td>Use by</td>
</tr>
<tr>
<td>🎯</td>
<td>Batch or Lot code</td>
<td>🔴</td>
<td>Memory preset for temperature</td>
</tr>
<tr>
<td>🔴</td>
<td>Do not dispose of this equipment as unsorted municipal waste, it is to be collected separately. Consult local regulations for disposal.</td>
<td>🔴</td>
<td>Temperature Up/Down represents the acceptable temperature range for transportation of this device. Allow unit to come to room temperature before use.</td>
</tr>
<tr>
<td>🔴</td>
<td>Year of Manufacture</td>
<td>🔴</td>
<td>Serial Number/Part Number</td>
</tr>
<tr>
<td>🔴</td>
<td>Power On/Off</td>
<td>🔴</td>
<td>Temperature Up/Down</td>
</tr>
</tbody>
</table>
Quick Start Guide

1. Insert the handpiece cord connector into the handpiece cord port on the rear of the main control unit. (Follow the cord-label instructions, or you may follow the “Handpiece Attachment/Detachment” instructions on page 9)

2. Insert the power supply connector into the power supply port. Then plug the power supply into the appropriate electrical outlet. (Use the appropriate interchangeable electric adapter. See page 3 for details.)

3. Use the buttons as described in the picture below to operate your new Obtura III MAX System.

More detail on setup and operation is included in this manual. You may also follow the product diagram located on the opposite side of the provided laminated cleaning instruction card.

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Recommended separation distances between portable and mobile RF communications equipment and the Obtura III Max Heated Gutta Percha System

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>d = 1.2 √P</td>
<td>d = 1.2 √P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
<tr>
<td>80 MHz to 800 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>d = 2.3 √P</td>
<td>d = 2.3 √P</td>
</tr>
<tr>
<td>0.23</td>
<td>0.73</td>
</tr>
<tr>
<td>2.3</td>
<td>7.3</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.
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Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Obtura III Max Heated Gutta Percha System is intended for use in the electromagnetic environment specified below. The customer or the user of the Obtura III Max Heated Gutta Percha System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Level</td>
<td>Level</td>
<td></td>
</tr>
<tr>
<td>Conducted RF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>3 Vrms</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Obtura III Max Heated Gutta Percha System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>3 V/m</td>
<td>3 V/m</td>
<td>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol.</td>
</tr>
</tbody>
</table>

Recommended separation distance

- 80 MHz to 2.5 GHz: 1.2 √P
- 80 MHz to 800 MHz: 1.2 √P
- 800 MHz to 2.5 GHz: 2.3 √P

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 meters (m).

NOTE 1 At 80 MHz and 800 MHz, 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.

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 electromagnetic site survey should be considered. If the measured field strength in the location in which the Obtura III Max Heated Gutta Percha System is used exceeds the applicable RF compliance level above, the Obtura III Max Heated Gutta Percha System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Obtura III Max Heated Gutta Percha System.

- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact</td>
<td>± 2, 4, 6 kV contact</td>
<td>Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>± 8 kV air</td>
<td>± 2, 4, 6 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>± 2 kV for power supply lines</td>
<td>± 2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>± 1 kV for input/output lines</td>
<td>± 1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV line(s) to line(s)</td>
<td>± 1 kV line(s) to line(s)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>± 2 kV line(s)</td>
<td>± 2 kV line(s)</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5 % ( U_r ) (&gt;95 % dip in ( U_r )) for 0.5 cycle</td>
<td>100 % dip in ( U_r ) for 0.5 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40 % ( U_r ) (80 % dip in ( U_r )) for 5 cycles</td>
<td>60 % dip in ( U_r ) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td>70 % ( U_r ) (30 % dip in ( U_r )) for 5 cycles</td>
<td>30 % dip in ( U_r ) for 5 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;5 % ( U_r ) (&gt;95 % dip in ( U_r )) for 5 sec</td>
<td>100 % dip in ( U_r ) for 25 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td>3 A/m</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: \( U_r \) is the (AC) mains voltage prior to application of the test level.

TWO-YEAR WARRANTY

Obtura Spartan warrants that all products sold by the company are of high quality materials and workmanship. The Obtura III MAX is warranted against defects in materials and workmanship for two (2) years 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 two (2) full years, excluding consumable items such as plunger seals, needles and cleaning accessories. 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 pre-paid) 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 2 years from date of purchase.

To register for your Obtura III MAX two-year warranty, please take a moment to fill out the registration card included in your clear plastic introductory packet.

SAFETY INFORMATION

1. Please read the operator’s manual in its entirety before using the Obtura III MAX.
2. To avoid explosion hazard, do not use the Obtura III MAX 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 patient 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 supply cable are free from cuts, nicks or other damage.
5. Place the main control unit within sufficient proximity to the patient so as not to disrupt operation by reaching too far with the handpiece.
6. This Obtura system complies with current Electromagnetic Compatibility standards (IEC 60601-1-2). However, the user should ensure that any possible electromagnetic interference does not present an additional risk of interfering with or damaging the device or any other electronic devices in the vicinity. (See pages 15-18).
7. The Obtura System does not use RF energy to function. Therefore, it is not likely to cause any interference in nearby electronic equipment. (See pages 15-18).
8. The Obtura System should only be used with the provided cables and accessories. Use of other cables or accessories has the potential to damage the device or affect compliance to EMC standards.
9. Cables and Accessories:
   - Handpiece Cord - Max length 8’, IEC 60601-1
   - Power Cord - Max length 8’, IEC 60601-1
10. Requirements of cables and accessories:
    - 2-wires unshielded cable - 1.5m, AC/DC Adapter Type: FW7553M/12
    - Obtura Handpiece shielded cable - 2m, Handpiece Attachment/Detachment

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 or intended 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 on your purchase of the Obtura III MAX! Please read the entire manual prior to using this unit. Here are some useful tips that will aid your usage of the Obtura III MAX:

When you are ready to practice with your Obtura III MAX, you should become familiar with its components. After attaching the needle and thermal protector, turn the Obtura III MAX on and set it to operating temperature. It takes the unit 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 (sold separately). Begin by filling the plastic practice blocks with gutta percha per the instructions included. Use condensers to condense the material void free. We recommend the Obtura Spartan S-Kondenser (available in 3 sizes):

• The soft silver applicator needles are designed to conduct heat to insure flow even at the needle tip; however, as the needle tip cools between uses, you should 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, proper needle bending will be easily accomplished. Obtura applicator needles are designed for one use only.

• Do not loosen or remove the blue plastic Heater Nut. The Heater Nut is fastened to the gun with a set-screw; removal of the heater nut 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 (see page 3 for further details).

• The cord to the handpiece can extend 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 (page 3).

• Cleaning the Obtura III MAX is simple but very important; just follow the directions in this manual (page 6) or on the provided laminated cleaning instruction card. If your Obtura III MAX 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.

Thank you for purchasing the Obtura III MAX. 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); we welcome the opportunity to speak with you. Also, visit our website at: www.obtura.com.

System Description

The Obtura III MAX 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 quick and complete obturation of the root canal.

There is a minimum level of understanding and background assumed in the descriptions and instructions found in this manual; if at any time you feel overwhelmed or unsure of how to properly operate your Obtura III MAX unit, immediately cease use and call Obtura Spartan for assistance. We value safety first and foremost.

The Obtura III MAX features an interchangeable plug-in handpiece. Any Obtura III MAX handpiece will work with any Obtura III MAX base unit. However, the Obtura III MAX handpiece cannot be retrofitted to the Obtura III or any other future handpieces.

EMC Table

IEC 60801-1-2:2007 (Ed 3.0)

<table>
<thead>
<tr>
<th>Guidance and Manufacturer’s Declaration – Electromagnetic Emissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Obtura III Max Heated Gutta Percha System is intended for use in the electromagnetic environment specified below. The customer or the user of the Obtura III Max Heated Gutta Percha System should assure that it is used in such an environment.</td>
</tr>
<tr>
<td>Emission test</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>RF emissions</td>
</tr>
<tr>
<td>CISPR 11</td>
</tr>
<tr>
<td>Harmonic emissions</td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions</td>
</tr>
</tbody>
</table>

IEC 61000-3-2 IEC 61000-3-2 class A

Harmonic emissions

CISPR 11 Group 1

CISPR 11 Class B

CISPR 11

RF emissions

IEC 61000-3-2

IEC 61000-3-3

Complies

below. The customer or the user of the Obtura III Max Heated Gutta Percha System should assure that it is used in such an environment.
SECTION VI – Health Hazards
Routes of Entry: Skin and eye contact. Inhalation.
Signs and symptoms of exposure:
- Skin contact: Repeated exposure may cause skin dryness or cracking
- Eye contact: Irritating to eyes
Inhalation and Ingestion: Excessive inhalation of vapors can cause irritation of the respiratory tract, nausea, dizziness, or headache. Product has a low order of acute oral toxicity, but ingestion of large quantities may cause nausea, vomiting, and gastrointestinal irritation. May cause injury if aspirated into lungs.
Medical conditions aggravated by exposure: Persons with pre-existing central nervous system (CNS) disease, neurological conditions, skin disorders, chronic respiratory diseases, or impaired liver or kidney function should avoid exposure.

SECTION VII – Emergency First Aid Procedures
Eyes: Check for and remove contact lenses. If irritation or redness develops, flush eyes with cool, clean, low pressure water for at least 15 minutes. Hold eyelids apart to ensure complete irrigation of the eye and eyelid tissue. Do not use eye ointment. Seek medical attention immediately.
Skin Contact: Remove contaminated shoes and clothing. Clean affected area thoroughly with mild soap and water. Do not use ointments. Seek medical attention if irritation persists.
Inhalation: Immediately move victim to fresh air. If victim is not breathing, immediately begin rescue breathing. If heart has stopped, immediately begin cardiopulmonary resuscitation (CPR). If breathing is difficult, seek medical attention immediately.
Ingestion: DO NOT induce vomiting unless directed to do so by a medical personnel. Never give anything by mouth to an unconscious person. If spontaneous vomiting is about to occur, place victim’s head below knees. If victim is drowsy or unconscious, place on the left side with head down. Do not leave victim unattended. Seek medical attention immediately.

SECTION VIII – Special Precautions, Spill/Leak Procedures, and Transportation
In case of spill: Small Spill and Leak, absorb with an inert material and dispose of properly. For Large spill and leak, secure the area and control access. Dike far ahead of a liquid spill to ensure complete collection. Pick up free liquid for disposal using absorbent pads, sand, or other inert non-combustible absorbent materials. Place into appropriate waste containers for later disposal.
Waste disposal: Waste must be disposed of in accordance with federal, state, and local environmental control regulations.
Handling: DO NOT spray into or around ignition sources. After handling, always wash hands thoroughly with soap and water. Use only with adequate ventilation. Avoid breathing vapors or spray mists.
Storage: Keep container in a cool, well-ventilated area. Avoid all sources of ignition (spark or flame). Store below 120 °F.

SECTION IX – Special Protection Information / Control Measures
Protective wear: Safety glasses and nitrile gloves.
Ventilation: Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.
Respiratory Protection: Use organic vapor cartridge type respirator if ventilation is inadequate.
Work / Hygienic Practices: Wash thoroughly after handling. Have eye-wash facilities immediately available.

***IMPORTANT***
While seller believes that the information contained herein is accurate, such information is offered solely for its customers’ consideration and verification under their specific use conditions. This information is not deemed a warranty or representation of any kind for which seller assumes legal responsibility.

24-Hour Emergency #: (U.S.) (800) 535-5053 • (Outside U.S.) (352) 323-3500
Operation
Operation of the Obtura III MAX has been designed to be intuitive, however, 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 III MAX and an LCD display. The functions of the four switches are: Power On/Off, Temperature Up, Temperature Down and Temperature Memory (as shown in the “Quick Start Guide” section). When the Obtura III MAX is activated, the 3-digit display will indicate the current operating temperature in degrees centigrade, and any memory presets desired. Description of each button follows:

Press the Power On/Off button to activate the Obtura III MAX. 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 the Power button again to toggle off.

With the unit on, press the Temperature Up (+) button to increase the set-point temperature in single degree increments. Press the Temperature Down (-) button to reduce the set-point temperature, also in one degree increments.

The Temperature Memory button retrieves preset memory set-points. A quick press of this button displays the letter “M” and the preset position number. The temperature associated with the memory setting is displayed on the three-digit display. To set the unit to this temperature, no other action is required, and after 5 seconds, it will now be the new set-point temperature and will be indicated on the unit screen. To access another memory position, again press the Temperature Memory button to display the desired memory setting, and again within 5 seconds, the unit will set to the next positioned temperature.

To reset a memory location, press the Temperature Memory button until the preset position number you want 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 more seconds, with no button pressed, the Obtura III MAX display will change from the previously set temperature to the new set-point temperature. Note: preset memories are saved even during power failure.

The Obtura III MAX 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:

<table>
<thead>
<tr>
<th>Memory Number</th>
<th>Factory Preset</th>
<th>New Setting</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>M1</td>
<td>140°C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M2</td>
<td>150°C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M3</td>
<td>170°C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M4</td>
<td>180°C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M5</td>
<td>200°C</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Material Safety Data Sheet

Obtura Cleaning Solution
Catalog Numbers: 822-609, 3069-01, 3069-01A, 823-703, 823-601, 823-600, 823-603, 35-114, 823-803

SECTION I – Manufacturer
Obtura Spartan
2260 Wendt Street
Algonquin, IL 60102
(800) 344-1321

SECTION II – Hazardous Ingredients / Identity

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>% by weight</th>
<th>CASRN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solvent Naphtha, (petroleum)</td>
<td>40 – 60 %</td>
<td>64742-88-7</td>
</tr>
<tr>
<td>medium aliphatic d-limonene</td>
<td>40 - 60 %</td>
<td>5989-27-5</td>
</tr>
</tbody>
</table>

SECTION III – Physical & Chemical Characteristics

Solubility: Less than 0.1%
Boiling Point: 157 °C @ 760 mmHg
Specific Gravity: 0.80 – 0.82 @ 20°C
Densities: 4.8
V.O.C Content: 100%, 810 g/L, 6.75#/gal
Evaporation Rate (Butyl Acetate = 1): 0.15
Appearance / Odor: Colorless Liquid with Orange Aroma

SECTION IV – Fire & Explosion Data
Flash Point: 40 °C (104 °F)
Flash point in Air, % by Volume (Estimated): Lower: 0.7%, Upper: 6%
Extinguishing Media: Dry chemical, water spray, fog, or foam
Auto-ignition Temperature: Not Established
Special Fire Fighting Procedures; Unusual Fire and Explosion Hazards: Small Fire, Use Dry chemical powder. Large Fire, use water spray, fog, or foam. Cool containing vessels with water jet in order to prevent pressure build-up, auto-ignition, or explosions. Firefighters must use full bunker gear including NIOSH-approved positive pressure self-contained breathing apparatus to protect against potential hazardous combustible decomposition products and oxygen deficiencies. Evacuate area and fight fire from a maximum distance or use unmanned hose holders or monitor nozzles.

SECTION V – Physical Hazards (Reactivity Data)
Stability: Stable
Hazardous Polymerization: Will not occur
Hazardous Decomposition Products: Carbon Oxides (carbon monoxide and carbon dioxide) upon combustion.
Conditions and Materials to Avoid: Extremely reactive or incompatible with oxidizing agents.
Installing a Needle

To place the gutta percha where desired in the root canal, choose an applicator needle diameter best suited (20, 23 or 25-gauge). With the Obtura III MAX off and cool, remove the needle nut using the Multi-Tool; the needle nut should remain on the Multi-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 (diagram G). Re-attach the needle nut on to the heater thread using the Multi-Tool, making sure not to cross-thread (diagram H). Tighten until snug (do not over tighten, but do not leave too loose).

Bending the Needle

In most situations, a straight applicator needle will not provide access to the root canal. Using the Multi-Tool, gently bend the needle to provide a shape conducive to the procedure (see diagram I). Be careful not to bend too sharply as kinks will result and gutta percha flow will be blocked. For access to difficult to reach root canals, simply loosen the needle 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 III MAX and wait for the heater to come up to your desired temperature. Press the handpiece release button on the top of the Obtura III MAX handpiece and withdraw the plunger shaft. Insert a gutta percha stick into the chamber via the opening just forward of the release button (see diagram J). Re-insert the plunger shaft until the plunger seal engages the gutta percha pellet. 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 III MAX, but let the gutta percha fill “push” the needle out of the canal. Pulling the needle out may cause voids and require condensation or re-work.
- 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 full operating temperature before attempting to express; material that is too cool will require much more pressure or may be impossible to pass through a small diameter applicator needle.
- Before beginning a procedure, express about 3 cm of gutta percha so that the up-to-temperature material will be at the end of the needle; the warm material will fill space more completely.

Replacement Parts

<table>
<thead>
<tr>
<th>PN</th>
<th>Description</th>
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<th>Description</th>
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<tbody>
<tr>
<td>823-800</td>
<td>Obtura III MAX Complete System</td>
<td>822-609</td>
<td>Obtura Cleaning Kit - Bottle of Cleaning Solution with 2 Brushes</td>
</tr>
<tr>
<td>823-810</td>
<td>Obtura III MAX Handpiece</td>
<td>822-613</td>
<td>Obtura Cleaning Brushes - Pack of 2</td>
</tr>
<tr>
<td>823-711</td>
<td>Obtura Power Supply</td>
<td>825-103</td>
<td>Obtura Heater Reamer Tool</td>
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<tr>
<td>823-815</td>
<td>Obtura III MAX Thermal Protectors - Pack of 4</td>
<td>823-620</td>
<td>Obtura Applicator Needles - 20 Gauge</td>
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<tr>
<td>823-616</td>
<td>Obtura Needle Nuts - Pack of 2</td>
<td>823-623</td>
<td>Obtura Applicator Needles - 23 Gauge</td>
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<tr>
<td>823-618</td>
<td>Obtura Plunger Seal Assembly</td>
<td>823-635</td>
<td>Obtura Applicator Needles - 25 Gauge</td>
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<tr>
<td>823-812</td>
<td>Obtura III MAX Plunger Shaft with Plunger Seal</td>
<td>822-602</td>
<td>Obtura Gutta Percha - Box of 100 Pieces</td>
</tr>
<tr>
<td>823-814</td>
<td>Obtura III MAX Handpiece Bushing</td>
<td>822-604</td>
<td>Obtura Flow 150 Gutta Percha - Box of 100 Pieces</td>
</tr>
<tr>
<td>823-813</td>
<td>Obtura III MAX Multi-Tool</td>
<td></td>
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</tbody>
</table>
Sterilization Instructions
The Obtura Thermal Protectors are designed to provide patient protection from the elevated temperatures of the heating chamber. Patient contact requires that the Thermal Protectors be sterilized between uses to prevent cross-contamination issues.

Thermal Protector Sterilization Instructions
1. Turn off the unit and allow it to cool to room temperature.
2. Using the Obtura Multi-Tool, disengage the tab on the rear of the thermal protector.
3. Pull the Thermal Protector off the front of the handpiece.
4. Place the Thermal Protector in a cassette-style autoclave at 135°C for 10 minutes.
5. After replacing the Applicator Needle, Reinstall the Thermal Protector by pressing it onto the front of the handpiece. Be careful of the Applicator Needle as it is capable of injuring your hand.

By steam sterilizing the Thermal Protector and using a new Applicator Needle every time, you are greatly reducing the chance of any cross-contamination to your patients.

If you have any questions regarding this or any other aspect of using the Obtura System, please call us at 1-800-344-1321.

Thank you,
Obtura Spartan

In the control unit, the data stream from the handpiece is read (and the temperature interpreted) by a microcontroller. This 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.

Power supply voltage never enters the Obtura III MAX, as the 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
Q. How often should the unit be cleaned?
A. The Obtura III MAX should be cleaned at the end of each day or procedural session (see page 6).

Q. How often should the applicator needle be changed?
A. The applicator needle must be changed after each patient operation and when damage is detected or suspected. This is to ensure proper operation and to prevent the spread of infectious diseases.

Q. How often should the plunger seal be changed?
A. Observe seal for wear; replace if seal is torn or missing (see page 8).

Q. Why should I only use one pellet of gutta percha?
A. Critical lengths of the mechanical components of the Obtura III MAX have been designed for a single piece of gutta percha; using more can cause excessive back pressure and damage (see page 5).

Q. Is the Obtura III MAX Handpiece Autoclavable?
A. No, the Obtura III MAX handpiece is not autoclavable. It should be cleaned using a BIREX-type solution. Only the thermal protectors are autoclavable, once removed from the handpiece.

Q. The handpiece trigger is not working, how can I fix it?
A. Incorrect bushing installation can cause the trigger not to work. Make sure the bushing is installed with the small indicator line at the 12 O’Clock position at the back of the handpiece (see page 8).

Q. Can I leave the needle nut loose so that it can be rotated during use?
A. No, the needle nut is not designed to be used in this manner. The needle nut must always be tightened securely before extruding gutta percha (see page 5).

Q. How do I disconnect the Obtura III MAX Handpiece Connector from the base unit?
A. Squeeze the serrated section on the handpiece cord connector (by the triangle) and gently pull back. Connector does not turn (see page 9).

Q. Can I use the Obtura III MAX if the display is showing an Error Code?
A. No, your Obtura III MAX unit should be evaluated and repaired if it is displaying an error code on the screen (see page 9).

Q. Is there any way to reduce the force required to extrude gutta percha?
A. Yes, a few options exist. You may try to increase the operating temperature to improve the flow ability of our standard gutta percha. Obtura Spartan also sells Flow 150 gutta percha and Resinate pellets that may flow more easily than the standard gutta percha.
Error Codes

<table>
<thead>
<tr>
<th>Error Code</th>
<th>Fault</th>
<th>Remedy</th>
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</table>
| S-1        | Handpiece disconnected (communication failure) | 1) Verify firmness of handpiece connector  
2) Remove and replace  
3) Check cable for breaks or damage  
4) Check connector for broken or bent pins  
5) Contact factory for handpiece repair/replace |
| S-2        | Cannot reach Temp. in 250 sec | Heater fault – Contact factory for repair |
| H-1        | Heater Wire open             | Replace handpiece or contact factory for repair guidance |
| H-2        | Heater Wire short            | Replace handpiece or contact factory for repair guidance |
| H-3        | Thermocouple error           | Replace handpiece or contact factory for repair guidance |
| B-1        | Internal control base failure | Not user-serviceable – Contact factory for repair |
| P-1        | Power Supply fault           | Replace power supply or contact factory for repair guidance |

Handpiece Attachment/Detachment

To Attach: Hold the handpiece cord connector at the rear of the main control unit, facing the triangle indicator at the 12 O’Clock position (see diagram N). Plug in to the handpiece cord port when proper alignment is reached.

To Detach: Squeeze the serrated section on the handpiece cord connector (by the triangle) and gently pull back (see diagram O). Connector does not turn.

Theory of Operation

The heating system of the Obtura III MAX 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, and into a digital stream for use by the main 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 handpiece trigger, which pushes the shaft via a spring-loaded pawl, moves the shaft forward. The heater assembly is directly connected to the handpiece shell, providing a straight through path for gutta percha, warming it in the process.

Maintenance

For best results, the Obtura III MAX handpiece should be cleaned daily. This prevents build-up of excess gutta percha within the heating chamber.

Regular Maintenance (Day to Day Cleaning)*

Tools you will need:
- Multi-Tool
- Cleaning brush and Cleaning solution
- Disposable cloth (napkin, gauze, etc.)

1. Prior to cleaning, ensure that your Obtura III MAX unit is turned off, fully cooled and unplugged.
2. Unlatch and remove the thermal protector using the Multi-Tool.
3. A) Use the Multi-Tool to unscrew the needle nut from the heater thread.  
   B) Set aside the needle nut. Dispose of the needle (for optimum performance, Obtura applicator needles should be used only once).
4. Extrude all remaining gutta percha by squeezing the handpiece trigger. The gutta percha will come out in solid pellet form.
5. Push and hold the release button, removing the plunger shaft from the handpiece.
6. A) Inspect the plunger seal for gutta percha.  
   B) If gutta percha is present, dip the cleaning brush into the cleaning solution, fully coating the brush.  
   C) Clean the plunger seal with the cleaning brush in a back and forth motion until all visible gutta percha is cleared.
7. A) Inspect the inside of the handpiece shaft for any visible gutta percha.  
   B) If gutta percha is present, re-dip the cleaning brush into the cleaning solution, fully coating the brush.  
   C) Place the cleaning brush inside the handpiece shaft and clean in a back and forth motion until all visible gutta percha is cleared.
8. A) Reassemble all components in the reverse order from which they were detached.  
   B) Place the handpiece back on its cradle.

WARNING: AT NO POINT SHOULD ANY PART OF THE OBTURA III MAX HANDPIECE BE SUBMERGED INTO THE CLEANING SOLUTION.

NOTE: A) For optimal cleaning, use a Birex®-type solution to aid in disinfecting and deodorizing your Obtura III MAX unit.  
   B) Never spray the disinfectant solution directly on to the unit; always spray into a disposable cloth, then wipe down.

*The above regular maintenance cleaning instructions are also displayed on the provided laminated cleaning instruction card, which contains visual diagrams for your convenience.
Extended Maintenance

As Needed for:

- Repeated plunger seal failure
- The plunger shaft repeatedly gets stuck in handpiece
- The cleaning brush is ineffective in removing excess gutta percha from the handpiece shaft during normal cleaning

Tools you will need:

- Multi-Tool
- Cleaning brush and Cleaning solution
- Disposable cloth (napkin, gauze, etc.)
- Heater Reamer Tool

1. Prior to cleaning, ensure that your Obtura III MAX unit is turned off and fully cooled.

2. Unlatch and remove the thermal protector using the Multi-Tool.

3. Use the Multi-Tool to unscrew the needle nut from the heater thread. Set aside the needle nut. Dispose of the needle (for optimum performance, Obtura applicator needles should be used only once). The needle nut may become filled with gutta percha, which will inhibit complete tightening and thermal transfer from the heater to the applicator needle. The needle nut threads can be cleaned with a 1/4-28 tap, but it's 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 needle nut has been tightened insufficiently. Use the Multi-Tool to assure proper fit.

4. Turn the unit back on and allow it to reach full operating temperature (200˚) in order to loosen residual gutta percha.

5. Once the full operating temperature is reached, turn off the unit and unplug.

6. Immediately extrude all remaining gutta percha into a disposable cloth by squeezing the handpiece trigger. (WARNING: CONTENTS WILL BE EXTREMELY HOT!)

7. Push and hold the release button, removing the plunger shaft from the handpiece. Visually inspect the plunger seal ---(WARNING: CONTENTS WILL BE EXTREMELY HOT!)--- to determine if a replacement is necessary (example: metal threads at the tip of the plunger shaft are exposed or there is other obvious erosion).

8. Using the heater reamer tool, clean the handpiece shaft in a back and forth motion until all excess gutta percha is cleared.

9. Dip the cleaning brush into the cleaning solution, fully coating the brush. Clean the handpiece shaft with the cleaning brush in a back and forth motion until all excess gutta percha is cleared.

10. Reassemble all components in the reverse order from which they were detached. Place the handpiece back on its cradle.

WARNING: AT NO POINT SHOULD ANY PART OF THE OBTURA III MAX HANDPIECE BE SUBMERGED INTO THE CLEANING SOLUTION.

NOTE:

A) For optimal cleaning, use a Biorex®-type solution to aid in disinfecting and deodorizing your Obtura III MAX unit.

B) Never spray the disinfectant solution directly on to the unit; always spray into a disposable cloth, then wipe down.

*The heater reamer tool should only be used as needed.

The Thermal Protectors must sterilized before use.

Handpiece Bushing

Handpiece Bushing is susceptible to wear caused by the bushing misalignment. This causes the trigger pawl to wear at the pawl engagement opening. The bushing should be aligned in the handpiece so that bushing rotation ceases. To install the handpiece bushing, slide it in the opening at the rear of the handpiece (diagram K), 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 a quick and accurate indication of the plunger seal’s condition. If excessive gutta percha passes by the seal, the plunger seal assembly should be replaced. The plunger teeth should be inspected for wear or chipping. The plunger shaft should be replaced if plunger teeth are badly chipped or slipping occurs during testing. The plunger shaft of the Obtura III MAX should be checked for bending; if it will not roll smoothly on a piece of glass or flat tabletop (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 plunger seal assembly, first locate the Multi-Tool’s small hex shape opening (diagram L). Then heat the end of the plunger shaft (a lighter will work; please use precaution) to soften the thread-locker. After the thread-locker softens, carefully insert the plunger seal assembly within the hex shape opening, and unscrew the plunger seal assembly from the plunger shaft (diagram M). To replace the assembly, thoroughly clean the end of the plunger, using extra care to be sure the threads are clean and dry. Re-apply and tighten the plunger seal assembly using the Multi-Tool’s hex utility once again. Do not over-tighten.

Needle Nut

The needle nut may become filled with gutta percha, which will inhibit complete tightening and thermal transfer from the heater to the applicator needle. The needle nut threads can be cleaned with a 1/4-28 tap, but it's 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 needle nut has been tightened insufficiently. Use the Multi-Tool to assure proper fit.

Handpiece Cable Assembly

The handpiece cable should be thoroughly inspected at the handpiece entry point for broken wires and cracks in the cable housing (may be due to the frequent bending in this area). These signs are an intermittent problem where the unit will work fine initially, but when the handpiece cable is bent, the unit stops heating altogether. If these conditions exist, the error codes on the Obtura III MAX display can diagnose them (see error codes chart on page 9).