

Gutta-Smart™

Directions for Use



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FOR DENTAL USE ONLY

Introduction

Congratulations on your purchase of the **Gutta-Smart™** cordless obturation system.

These Directions for Use are always kept up to date by Dentsply Sirona to bring them in line with the latest developments. You will find the current version on the website shown on the back cover page of this manual.

In countries where the legal situation enables us to do so, we have decided not to produce a printed version of the Directions for Use, for environmental reasons.

If no printed version is enclosed in your national language and you wish to have a printed one, we will be happy to send you a copy (free of charge within seven calendar days to any address in North America). To order, simply send your request to the contact shown on the back cover page of this manual.

The Directions for Use are available in other languages on request. These Directions for Use have been compiled with the utmost care; nevertheless, it is not always possible to completely rule out the risk of error, despite all efforts to do so. We would appreciate your feedback in this area. If any errors are noted, please contact Dentsply Sirona at the address shown on the back cover page of this manual.

Dentsply Sirona reserves the right to change the information and data contained in the Directions for Use without prior notice.

1 Indications for use

The **Gutta-Smart™** is a cordless obturation system designed for warm vertical obturation. The system contains handpieces that are used for down pack (Pack) and backfill (Flow) techniques to obturate the root canal system.

The Pack handpiece is intended to heat electric heat pluggers for warming and softening gutta-percha master cones and searing off gutta-percha cones. This handpiece is also intended to heat a thermal response tip that subjects a tooth to heat in order to determine pulp vitality.

The Flow handpiece is intended for heating and extruding gutta-percha into the root canal system. The single-use gutta-percha cartridges are designed to place heated gutta-percha into a cleaned and shaped canal.

The **Gutta-Smart™** device can only be used with Dentsply Sirona gutta-percha cartridges, flow heaters, electric heat pluggers and thermal response tips.

2 Contraindications

Read the following contraindications before use.

- This device must not be used in cases where a patient has been fitted with an implanted heart pacemaker (or other electrical equipment) and has been cautioned against the use of small electrical appliances (such as electric shavers, hair dryers, etc.)

3 Warnings

Read the following warnings before use.

- This device is intended to be used for filling a root canal with gutta-percha and provide a heated endodontic plugger for packing the root canal filling material into place and may only be used by trained and qualified dentists.
- Do not use this device for any dental procedure other than root canal obturation.
- Do not use the device in the presence of free oxygen, flammable anesthetic gas mixtures or flammable substances.
- The device can cause radio interference or disrupt the operation of equipment in the vicinity. If this happens, the interference should be reduced by reorienting or repositioning the device or by screening off the immediate environment. The electromagnetic radiations emitted by the device are below the recommended limits specified by the applicable relevant provisions (DIN EN 60601-1-2:2007).

During Treatment

- Gloves and a rubber dam are mandatory during treatment.
- If any irregularities with the device should occur during treatment, turn it off. Contact Dentsply Sirona by phone or online at the contact information shown on the back cover page of this manual, or contact your Dentsply Sirona authorized service partner.
- Thermal hazard risk exists for patients.
- When replacing a gutta-percha cartridge during a procedure, the flow heater sleeve and expended cartridge may be hot to the touch.
- Allow the flow heater to cool before attempting to remove.
- Do not remove a hot gutta-percha cartridge!
- Electric heat plugger tips become hot during use. Turn off unit and allow cooling before exchanging tips.

- The pack handpiece temperature must be set to 90°C when using the thermal response tip to prevent overheating and patient injury.
- Using fingers or any other device other than the cannula bending tool to curve the cannula can result in gutta-percha cartridge rupture or handpiece damage. Repeated bending can damage the cannula.
- Do not stay in the root canal with a heated electric heat plugger tip for more than 4 seconds to prevent thermal injury to the patient.
- Place gutta-percha on the thermal response tip before applying the tip to the patient's tooth. Do not place the tip directly on the tooth!
- Applying excessive downward pressure or not allowing the cannula to back out of the canal may result in a dislocated cannula.
- Gutta-percha cartridges are for single patient use only.
- Gutta-percha cartridges cannot be reheated or reused.
- Do not use gutta-percha cartridges after the expiration date.
- Dispose of gutta-percha cartridges in a sharps receptacle.

Cleaning, Disinfection and Sterilization

- Do not use a disinfection solution for sterilization of gutta-percha cartridges.
- This equipment provides ordinary protection against harmful ingress of liquids. Do not immerse the handpiece in any liquid or spray any fluid directly onto the handpiece.
- Do not immerse gutta-percha cartridges into any liquid.
- Use only the sterilization procedures as instructed in this manual. Other sterilization procedures may not be effective.

Repairs and Defects

- Do not use the device if you suspect damage or a defect.
- There are no serviceable components inside this unit. Do NOT Open!
- Repairs, alterations and modifications to the device are not permitted unless the manufacturer's prior consent has been obtained. Dentsply Sirona cannot be held liable if the device has been altered or modified. If a defect should occur, contact Dentsply Sirona by phone or online at the contact information shown on the back cover page of this manual, or contact your Dentsply Sirona authorized service partner.

Battery and Transport

- The battery charging connections on the handpieces are a proprietary connection. Only use the base station and power adapter supplied with the device to charge the device. Use of non-original chargers jeopardizes the safety of the patient and user.
- Intact devices can be transported by land freight or air freight in the original packaging. The applicable requirements must be met.
- Defective devices can also be transported by air freight or land freight in the original packaging. If the battery is defective, the device must not be transported by air freight under any circumstances.
- For international shipping of lithium-ion batteries, refer to the International Air Transport Association (IATA) guidelines, located at <http://www.iata.org/lithium-batteries>.
- For shipping of lithium-ion batteries within the United States, refer to the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) site at <http://www.phmsa.dot.gov/hazmat/guidance>.

4 Precautions

Read the following precautions before use.

- Place the cannula gently into the canal. Too much pressure will stop the motor from turning.
- Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.
- Follow all local laws and regulations regarding the storage and shipment of lithium-ion batteries.
- Always check to ensure that handpieces have a sufficient battery charge before starting treatment.
- Do not place the handpieces, charging base or gutta-percha cartridges in an autoclave unit or washer-disinfector.
- Chemclaving is not recommended for sterilization and maintenance of the tips as this would cause corrosion.
- If you use a disinfectant in the form of a spray, never spray the devices and accessories directly. Instead, spray a paper towel with the surface disinfectant or use a pre-moistened disinfectant towelette (wipe).
- The front end sealing caps should be used on the handpieces for wipe-down cleaning to prevent moisture from entering the electronics.

5 Step by Step Instructions



Refer to chapters **3 Warnings** and **4 Precautions** to determine any special care to exercise before starting to use the complete device.

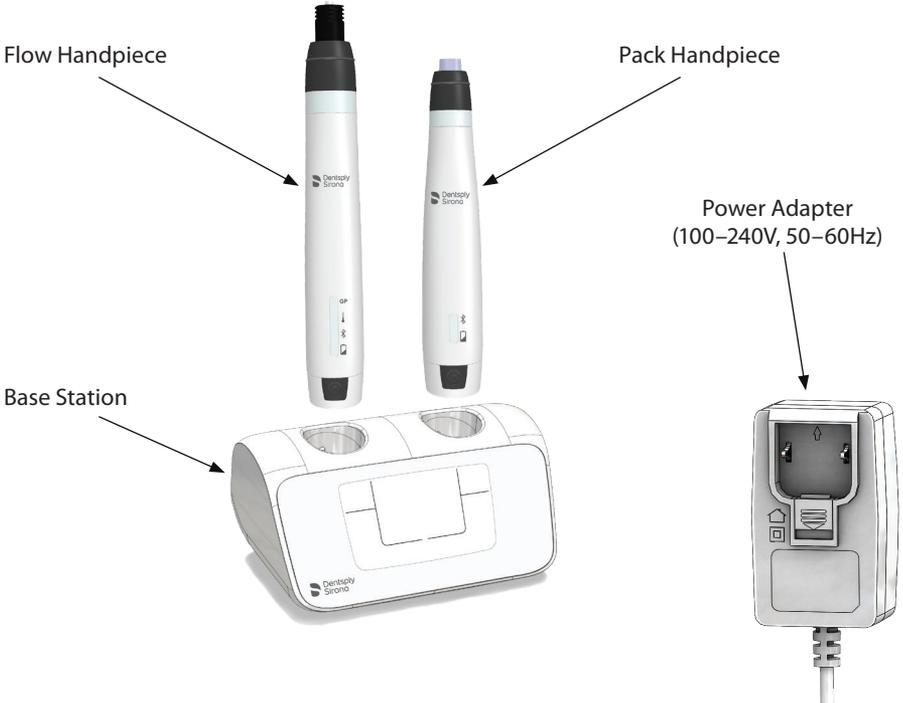
Before use, please check the exact contents of the package. See **5.2 Package Contents**.

5.1 Document Symbols and Abbreviations

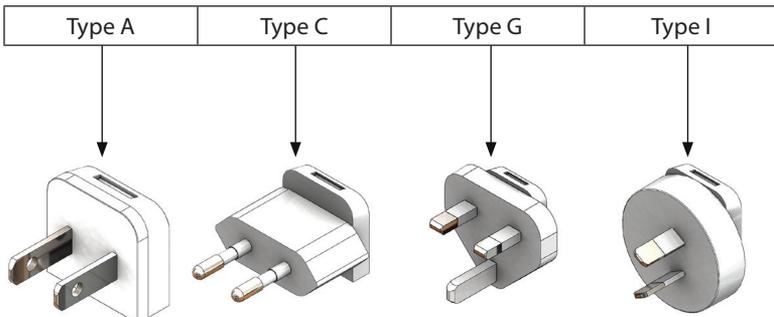
Symbol	Identification
	Consult instructions for use.
	WARNING: Serious injury or death may result if ignored.
	CAUTION: Damage to property or the environment may result if ignored.
	Additional information, explanation on operation and performance.
GP	Gutta-percha
EHP	Electric heat plugger
TRT	Thermal response tip
HTR	Flow heater

5.2 Package Contents

Step	Action
A	Carefully remove the device and the accessories from their packaging and place them on a flat surface.
B	Check that the device is supplied with all the components listed below.



Plug Adapters (used with Power Adapter) IEC Standards:



Flow Heater
(HTR)



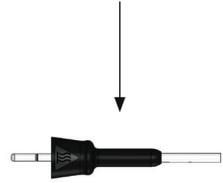
Electric Heat Pluggers (EHP)

Small (black)	Medium (yellow)	Large (blue)
40/0.25	50/0.5	60/0.6



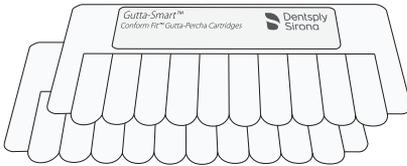
Thermal Response
Tip (TRT)*

*(purchased separately)

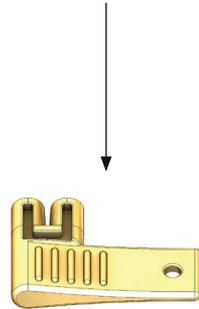


Gutta-Percha (GP)

20 Ga Cartridges (10 pack)
23 Ga Cartridges (10 pack)
25 Ga Cartridges (10 pack)*
*(purchased separately)



Cannula
Bending
Tool



Getting
Started
Guide

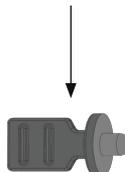


Directions
For
Use



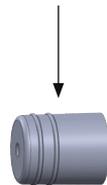
Pack Handpiece
Front-end
Sealing Cap*

*(Save for cleaning
procedure!)



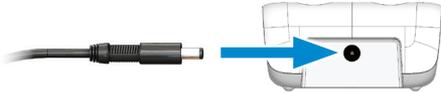
Flow Handpiece
Front-end
Sealing Cap*

*(Save for cleaning
procedure!)



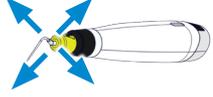
5.3 System Setup

5.3.1 Charging the Handpieces

Step	Action
A	Attach the correct plug adapter for your country onto the power adapter, then plug the power adapter into an electrical outlet.
	
B	Plug the cord from the power adapter into the socket on the back of the base station.
	
C	Place both handpieces into the base station and let them charge until the green LEDs on the handpieces stop flashing, indicating a full charge.
	Either handpiece can be placed into either side of the base station. The left and right base station sockets are interchangeable for charging and programming the pack and flow handpieces.
	
	Time required for a full charge from a very low charge: maximum 5 hours. Handpieces can be routinely stored in the base station with power connected. For long term storage, it is recommended to unplug the power cord or remove the handpieces from the charger in order to conserve energy and prolong battery life.

5.3.2 Attaching Handpiece Instruments

5.3.2.1 Attaching Electric Heat Plugger (EHP) to Pack Handpiece

Step	Action
A	Select one of the three EHPs provided (small, medium or large).
B	Push the EHP into the end of the pack handpiece until it seats firmly.
	
i	EHPs can be installed in any one of 4 orientations.
	
C	To remove the EHP, wait for it to cool down, then pull straight out from handpiece.

5.3.2.2 Attaching Thermal Response Tip (TRT) to Pack Handpiece

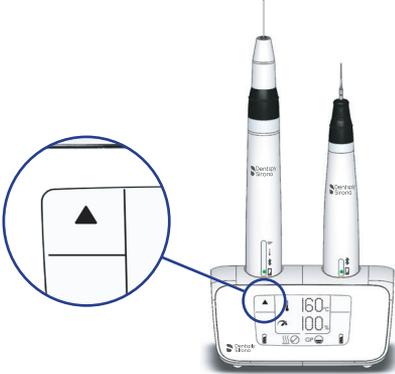
Step	Action
A	Push the TRT into the end of the pack handpiece until it seats firmly.
	
i	TRTs can be installed in any one of 4 orientations.
	
B	To remove the TRT, wait for it to cool down, then pull straight out from handpiece.
	The pack handpiece temperature must be set to 90°C when using the TRT to prevent overheating and patient injury.

5.3.2.3 Attaching Heater (and GP cartridge) to Flow Handpiece

Step	Action
A	Select a GP cartridge (20, 23 or 25 Ga).
B	Insert the GP cartridge through the HTR.
C	Thread the HTR (with the GP cartridge) onto the flow handpiece. Finger tighten only!
D	Bend the cannula to the desired angle using the cannula bending tool.
	Using fingers or any other device other than the cannula bending tool to curve the cannula can result in GP cartridge rupture or handpiece damage. Repeated bending can damage the cannula.
E	To remove the HTR, wait for it to cool down, then unscrew it from the flow handpiece. The GP push-rod will automatically retract.

5.3.3 Programming the Handpieces — General Description

Step	Action
	<p>These descriptions are common to the programming of both handpieces. For programming instructions exclusive to each handpiece, see:</p> <ul style="list-style-type: none"> •5.3.3.1 Programming the Pack Handpiece •5.3.3.2 Programming the Flow Handpiece •5.3.3.1.1 Programming the Pack Handpiece for the Thermal Response Tip (TRT)
	Handpieces must be connected to the base station for programming.

	<p>Either handpiece can be placed into either side of the base station. The left and right base station sockets are interchangeable for programming the pack and flow handpieces.</p>
	<p>The display on the base station is a touch-screen used to program all the settings into the handpieces.</p>
	<p>All settings are stored in the handpieces, not the base station.</p>
	<p>The display back-light will turn off after 20 minutes to save energy. Press the touch-screen to turn back on.</p>
	<p>When two handpieces are connected to the base station, you must press the side of the touch-screen directly below the handpiece you want to program to access the settings for that handpiece. For example, if you want to program the handpiece on the left, press the left side of the touch-screen.</p>
	
	<p>An upward pointing triangle ▲ indicates the handpiece that is currently being programmed.</p>
	

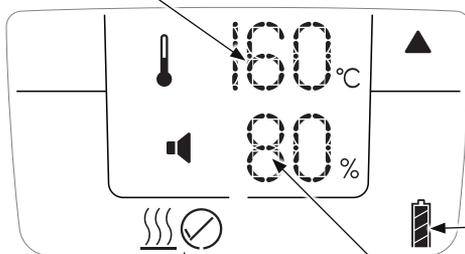
5.3.3.1 Programming the Pack Handpiece

Step	Action
A	Press the segment of the touch-screen directly below the pack handpiece to activate the settings for the pack handpiece.
	For instructional purposes, the pack handpiece is assumed to be on the right side of the base station in the following illustration of the touch-screen.

Pack Handpiece Settings and Indicators

Press here to adjust the pack temperature (100°–400°C) using the ▲▼ buttons that appear. Press here again to exit the adjustment screen.

Setting the temperature to 90°C automatically activates TRT mode. See [5.3.3.1.1 Programming the Pack Handpiece for the Thermal Response Tip \(TRT\)](#).



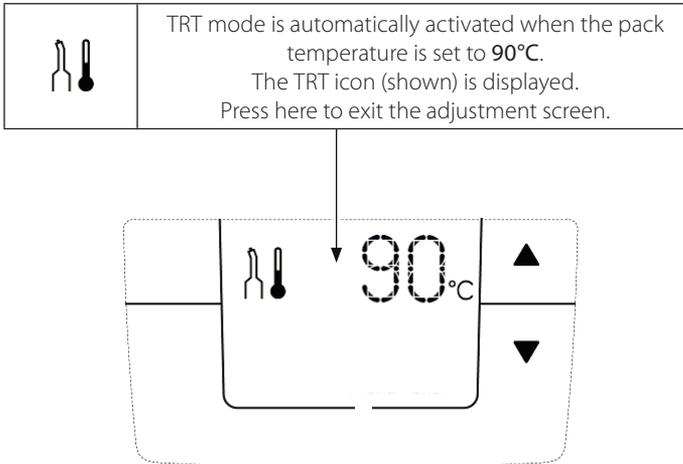
Handpiece Battery Level

If an EHP (or TRT) is installed and working properly, this icon appears:	
If no EHP (or TRT) is installed or not working properly, this icon appears:	

Press here to adjust the tone volume level (0%–100%) using the ▲▼ buttons that appear. Press here again to exit the adjustment screen.

5.3.3.1.1 Programming the Pack Handpiece for the Thermal Response Tip (TRT)

Step	Action
A	Press the segment of the touch-screen directly below the pack handpiece to activate the settings for the pack handpiece.
B	Insert the TRT into the pack handpiece. See 5.3.2.2 Attaching Thermal Response Tip (TRT) to Pack Handpiece .
C	Press the temperature segment of the touch-screen, then use the ▼ button that appears to adjust the temperature to 90°C to activate the TRT mode for the pack handpiece.
	For instructional purposes, the pack handpiece is assumed to be on the right side of the base station in the following illustration of the touch-screen.



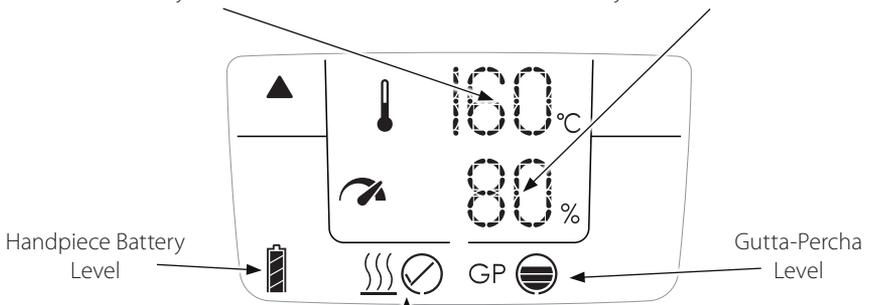
5.3.3.2 Programming the Flow Handpiece

Step	Action
A	Press the segment of the touch-screen directly below the flow handpiece to activate the settings for the flow handpiece.
	The GP level indicator uses the position of the GP push-rod to estimate the GP level remaining in the cartridge.
	For instructional purposes, the flow handpiece is assumed to be on the left side of the base station in the following illustration of the touch-screen.

Flow Handpiece Settings and Indicators

Press here to adjust the GP flow temperature (130°–160°C) using the ▲▼ buttons that appear. Press here again to exit the adjustment screen.

Press here to adjust the GP flow rate (20%–100%) using the ▲▼ buttons that appear. Press here again to exit the adjustment screen.



If a HTR is installed and working properly, this icon appears:	
If no HTR is installed or the HTR is not working properly, this icon appears:	

5.3.4 Pack and Flow Handpieces — Common Features



These features are common to both handpieces. For features exclusive to each handpiece, see [5.3.4.1 Pack Handpiece Features](#) and [5.3.4.2 Flow Handpiece Features](#).

BLUETOOTH INDICATOR	
	Bluetooth reserved for future firmware upgrades
	<i>Flashing blue:</i> Searching for connection
	<i>Blue:</i> Bluetooth connection established
	<i>Flashing yellow:</i> Connection lost

BATTERY LEVEL INDICATOR	
	<i>Green:</i> Battery full
	<i>Flashing green:</i> Battery charging
	<i>Red:</i> Battery low
	<i>Flashing Red:</i> Battery very low. Charge immediately.

POWER BUTTON	
Press to turn on and off the handpiece. Handpieces will automatically turn off after 20 minutes of inactivity.	

ELECTRICAL CONTACTS	
The base of each handpiece contains three electrical contacts. Periodically clean the contacts on the handpieces and the corresponding contacts in the base station with a cotton swab to ensure reliable operation. Handpiece serial numbers are also located on the bases.	

5.3.4.1 Pack Handpiece Features

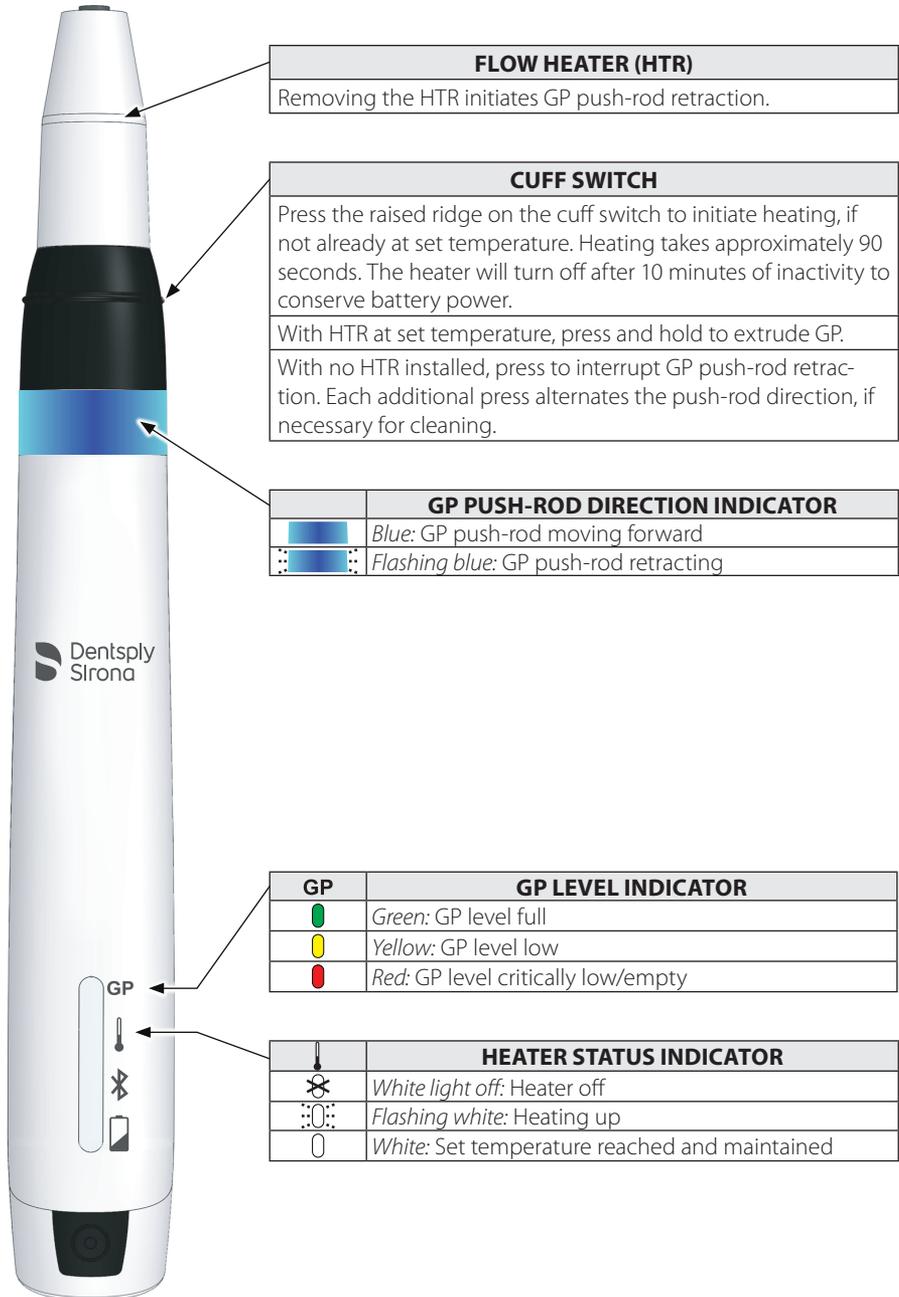
	ELECTRIC HEAT PLUGGER (EHP)
OR	
	THERMAL RESPONSE TIP (TRT)

CUFF SWITCH (EHP MODE)	
	Temperature setting: 100°–400°C.
Press and hold the raised ridge on the cuff switch to heat the EHP. The heater will automatically turn off after 10 seconds of continuous heating. Release and press the cuff switch again to continue heating.	
OR	
CUFF SWITCH (TRT MODE)	
	Temperature setting: 90°C.
Press and hold the raised ridge on the cuff switch to heat the TRT. The heater will automatically turn off after 60 seconds of continuous heating. Release and press the cuff switch again to continue heating.	

HEATER INDICATOR	
	<i>Blue:</i> Heater is on (cuff switch is depressed)

AUDIBLE TONE OPTION	
<i>High-frequency tone:</i> Heating up	
<i>Low-frequency tone:</i> Set temperature reached and maintained	

5.3.4.2 Flow Handpiece Features



FLOW HEATER (HTR)	
	Removing the HTR initiates GP push-rod retraction.

CUFF SWITCH	
	Press the raised ridge on the cuff switch to initiate heating, if not already at set temperature. Heating takes approximately 90 seconds. The heater will turn off after 10 minutes of inactivity to conserve battery power.
	With HTR at set temperature, press and hold to extrude GP.
	With no HTR installed, press to interrupt GP push-rod retraction. Each additional press alternates the push-rod direction, if necessary for cleaning.

GP PUSH-ROD DIRECTION INDICATOR	
	Blue: GP push-rod moving forward
	Flashing blue: GP push-rod retracting

GP	GP LEVEL INDICATOR
	Green: GP level full
	Yellow: GP level low
	Red: GP level critically low/empty

	HEATER STATUS INDICATOR
	White light off: Heater off
	Flashing white: Heating up
	White: Set temperature reached and maintained

5.3.5 Handpiece Operation

Step	Action
A	Fully charge handpieces before starting a procedure.
	Disinfect handpieces and sterilize tips before starting a procedure. See 6 Cleaning, Disinfection and Sterilization .
	Do not sterilize the GP cartridges.
	Handpieces will automatically turn off after 20 minutes of inactivity. Press the power switch on the handpiece to turn back on.

5.3.5.1 Pack Handpiece – Electric Heat Plugger (EHP) Operation

Step	Action
A	Install the desired EHP tip on the pack handpiece.
B	Place the pack handpiece in the base station and set the desired pack temperature (100°-400°C) and audible tone volume (0%-100%)
C	Remove the pack handpiece from the base station and press the power switch on the handpiece to activate, if necessary.
D	Press and hold the cuff switch to heat the EHP tip for a maximum of 10 seconds at a time. You will hear a high-frequency tone while the tip is heating, then a low-frequency tone once the set temperature is reached. Release and press the cuff switch again if the heat cycle times out.
	Do not stay in the root canal with a heated EHP tip for more than 4 seconds to prevent thermal injury to the patient.

5.3.5.2 Pack Handpiece – Thermal Response Tip (TRT) Operation

Step	Action
A	Install the TRT on the pack handpiece.
B	Place the pack handpiece in the base station and set the temperature to 90°C.
C	Remove the pack handpiece from the base station and press the power switch on the handpiece to activate, if necessary.
D	Press and hold the cuff switch to heat the TRT for a maximum of 60 seconds at a time. You will hear a high-frequency tone while the tip is heating, then a low-frequency tone once the set temperature is reached. Release and press the cuff switch again if the heat cycle times out.
	Place GP on the tip of the TRT before applying the TRT to the patient's tooth. Do not place the tip directly on the tooth!

5.3.5.3 Flow Handpiece – Gutta-Percha (GP) Operation

Step	Action
A	Install the desired GP cartridge and the HTR on the flow handpiece.
B	Use the cannula bending tool to place a smooth radius curve on the cannula so it can extend to within 5 mm of the working length of the canal.
C	Place the flow handpiece in the base station and set the desired GP flow temperature (130°-160°C) and desired GP flow rate (20%-100%).
D	Remove the pack handpiece from the base station and press the power switch on the handpiece to activate, if necessary.
E	Press and release the cuff switch to heat the GP cartridge to the set temperature.
F	Once the GP has heated up to the set temperature, press the cuff switch to extrude a small amount of GP from the needle. Wipe the excess GP from the tip before inserting the needle into the canal.
G	Place the heated tip of the cannula against the previously packed GP for 5 seconds.
H	Hold the handpiece lightly when expressing material to allow the device to readily back out of the canal.
	Applying excessive downward pressure or not allowing the cannula to back out of the canal may result in a dislocated cannula.

5.3.5.4 Replacing the Flow Gutta-Percha (GP) Cartridge

Step	Action
	Allow the HTR to cool before attempting to remove.
A	Remove the HTR from the flow handpiece by rotating the HTR in a counter-clockwise direction, as viewed from the end.
	The GP push-rod will automatically retract when the HTR is removed.
B	Remove the spent GP cartridge from the HTR.
C	Insert a new GP cartridge into the HTR.
D	Install the HTR with GP cartridge onto the flow handpiece by rotating the HTR in a clockwise direction, as viewed from the end. Finger tighten only!
E	Use the cannula bending tool to place a smooth radius curve on the cannula so it can extend to within 5 mm of the working length of the canal.

6 Cleaning, Disinfection and Sterilization

6.1 Forward

The components of the **Gutta-Smart™** have not been disinfected or sterilized when they are delivered. Please perform the necessary steps before every treatment.

You are responsible for the sterility of accessories; always ensure that only validated methods of cleaning/disinfection and sterilization are used, that regular maintenance and inspections are performed on the equipment (disinfector, sterilizer) and that the validated parameters are maintained in every cycle.

Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization. Observe the concentration of the cleaning or disinfecting solution stated by the manufacturer.

Failure to adhere to the following instructions or blatant misuse of the device and/or related components will be considered abuse of the device and will void all warranty responsibilities.

6.2 Base Station

Step	Action
A	Clean the exterior of the base station by wiping with a soft cloth moistened with mild non-chlorinated detergent or disinfecting solution.
	Do not immerse the device in any fluid.

6.3 Handpieces

Step	Action
A	Remove the EHP or TRT from the pack handpiece.
B	Insert the front-end sealing cap firmly into the end of the pack handpiece.
C	Remove the HTR from the flow handpiece.
D	Install the front-end sealing cap firmly onto the end of the flow handpiece.

E	Clean the exterior of the handpieces with a soft cloth moistened with a mild non-chlorinated detergent or disinfecting solution.
	Do not spray any liquid directly on the handpieces. Do not allow any moisture to get past the barrier created by the front-end sealing caps and into the handpiece electronics.
	Do not immerse the device in any fluid.

6.4 Electric Heat Pluggers (EHP), Thermal Response Tips (TRT) and Flow Heaters (HTR)

Step	Action
	Each EHP, TRT and HTR must be pre-cleaned and sterilized prior to and following every treatment.
A	PRE-CLEANING: Gently use a soft brush or moist cloth to remove all visible signs of debris from each EHP/TRT/HTR .
	Using a metal probe to clean the HTR or forcefully scraping the HTR may cause damage and void the warranty.
B	<p>STERILIZING: Select one of the three following sterilization methods (1, 2, or 3):</p> <ul style="list-style-type: none"> • 1. Gravity Wrapped: <ul style="list-style-type: none"> • Minimum Temperature - 132°C (270°F). • Full Cycle Time - 20 minutes • Minimum Dry Time - 30 minutes • 2. Gravity Unwrapped “Flash Sterilization”: <ul style="list-style-type: none"> • For Immediate Use Only • Minimum Temperature - 132°C (270°F). • Full Cycle Time - 10 minutes • Minimum Dry Time – No dry time required • 3. Pre-vacuum Wrapped: <ul style="list-style-type: none"> • Preconditioning Pulses - 3 • Minimum Temperature - 132°C (270°F). • Full Cycle Time - 4 minutes • Minimum Dry Time – 30 minutes
C	<p>Inspect EHP/TRT/HTR regularly for damage:</p> <ul style="list-style-type: none"> • Deformed or oxidized EHP/TRT/HTR should be replaced. • All EHP/TRT/HTR will gradually lose their heating efficiency over time. • Use of damaged or contaminated EHP/TRT/HTR is at the user’s own risk. • Dispose of EHP/TRT in a sharps receptacle.

6.5 Gutta-Percha Cartridges (GP)

Step	Action
A	Prior to using a GP cartridge on a patient, wipe the cannula with isopropyl alcohol and allow to dry.
	GP cartridges are for single patient use only.
	Do not immerse GP cartridges into any liquid.
	Do not use GP cartridges after the expiration date.
	Dispose of GP cartridges in a sharps receptacle.
	GP cartridges cannot be reheated or reused.
	Reheating or reusing a GP cartridge can result in the cartridge rupturing, which will permanently damage the handpiece. Reheating GP cartridges is a misuse of the Gutta-Smart™ and voids the device warranty.
	Store GP cartridges at room temperature.

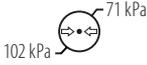
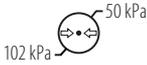
7 Supplies and Accessories

For replacement supplies and accessories, contact Dentsply Sirona by phone or online at the contact information shown on the back cover page of this manual.

Part	Description
	Gutta-percha cartridge 20 gauge
	Gutta-percha cartridge 23 gauge
	Gutta-percha cartridge 25 gauge
	Small electric heat plugger (40/025)
	Medium electric heat plugger (50/05)
	Large electric heat plugger (60/06)
	Thermal response tip
	Flow heater
	Cannula bending tool
	Pack handpiece front-end sealing cap
	Flow handpiece front-end sealing cap

8 Technical Characteristics

Specification	Description
ETL Classified	<p>ETL CLASSIFIED</p> <p>ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14 IEC 80601-2-60(First Edition): 2012</p>
Manufacturer and European representative	<p>Manufacturer</p> <p>Aseptico Inc 8333 216 St SE Woodinville WA 98072 USA</p> <p>Advena Ltd Pure Offices Plato Close Warwick CV34 6WE UK</p>
Model	Gutta-Smart™
Box Dimensions (Length x Height x Width)	237 mm x 147 mm x 133 mm
Weight	1.46 kg (3.22 lb)
Power supply	LiFePO4 Battery, 3.2 V, 1500 mAh
Charger power adapter	100-240 VAC
Frequency	50-60 Hz
Charger current input	0.6 A maximum
Type of protection against electrical shock	Class II and internally powered equipment
Applied part	BF
Safety level in the presence of flammable anesthetic gas mixtures or oxygen	Not suitable for use in the presence of flammable anesthetic gas mixtures or oxygen.

Specification	Description
Operating conditions	<ul style="list-style-type: none"> • Use: in enclosed spaces
	<ul style="list-style-type: none"> • Ambient temperature: 15°C - 35°C; (59°F - 95°F) 
	<ul style="list-style-type: none"> • Relative humidity: < 90%; non- condensing at 0°C (32°F) 
	<ul style="list-style-type: none"> • Altitude -20 m - 3000 m (-66 - 9843 ft) above sea level 
Medical device class	<ul style="list-style-type: none"> • U.S.A.: Class I / regulation: 872.4200 • Europe: Class 2A / rule: 9
Transport and storage conditions	<ul style="list-style-type: none"> • Ambient temperature: -20°C - +50°C (-4°F - 122°F) 
	<ul style="list-style-type: none"> • Relative humidity: 20% - 80%, non-condensing at >40°C (104°F) 
	<ul style="list-style-type: none"> • Altitude: -20 m - 5600 m (-66 - 18373 ft) above sea level 
Bluetooth®	<ul style="list-style-type: none"> • Bluetooth 4.0 low energy Device contains transmitter with: FCC ID: RFRMSR, IC-ID: 4957A-MSR • Working distance: 25 m • Output Power: 0.006 W • Frequency Range: 2402.0 - 2480.0 MHz

Guidance and manufacturer’s declaration electromagnetic emission		
<p>Gutta-Smart™ is intended for use in the electromagnetic environment specified below. The customer or the user of Gutta-Smart™ should assure that it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	<p>Gutta-Smart™ must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</p>
RF emissions CISPR 11	Class A	<p>Gutta-Smart™ is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded.</p> <p>Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating Gutta-Smart™ or shielding the location.</p>
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration electromagnetic immunity			
<p>Gutta-Smart™ is intended for use in the electromagnetic environment specified below. The customer or the user of Gutta-Smart™ should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601	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%.
Electrostatic 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 interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of Gutta-Smart™ requires continued operation during power mains interruptions, it is recommended that Gutta-Smart™ be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field 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: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer’s declaration electromagnetic immunity

Gutta-Smart™ is intended for use in the electromagnetic environment specified below. The customer or the user of **Gutta-Smart™** should assure that it is used in such an environment.

Immunity test	IEC 60601	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	4 V	3 V	Portable and mobile RF communications equipment should be used no closer to any part of Gutta-Smart™ , including cables, than the recommended separation distance calculated from 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 and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	

NOTE 1: 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 radios, 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 **Gutta-Smart™** is used exceeds the applicable RF compliance level above, **Gutta-Smart™** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating **Gutta-Smart™**.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Gutta-Smart™			
<p>Gutta-Smart™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Gutta-Smart™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Gutta-Smart™ as recommended below, according to the maximum output power of the communications equipment</p>			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
<p>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.</p>			
<p>NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p>			
<p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

FCC/Industry Canada compliance statements
<p>This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.</p>
<p>This device complies with Industry Canada’s license-exempt RSSs. Operation is subject to the following two conditions: (1) This device may not cause interference; and (2) This device must accept any interference, including interference that may cause undesired operation of the device.</p>

9 Troubleshooting

Problem	Solution
<p>Electric heat plugger (EHP) or thermal response tip (TRT) doesn't heat up.</p> 	<ul style="list-style-type: none"> Place the pack handpiece (with EHP or TRT installed) into the base station and activate the programming screen by pressing the side of the touch-screen below the pack handpiece. If the heater icon appears with an "X" (see left) the EHP or TRT may be defective. Try reseating the tip or replacing with a different one.
<p>Flow heater (HTR) doesn't heat up.</p> 	<ul style="list-style-type: none"> Place the flow handpiece (with HTR installed) into the base station and activate the programming screen by pressing the side of the touch-screen below the flow handpiece. If the heater icon appears with an "X" (see left) the HTR may be defective. Try reseating the tip or replacing with a different one.
<p>Gutta-percha (GP) doesn't flow.</p>	<ul style="list-style-type: none"> Try increasing the flow temperature and flow rate. GP may have accumulated around the GP push-rod. Follow the instructions for removing GP deposits below.
<p>Gutta-percha (GP) cartridge is stuck inside flow heater (HTR) due to GP deposits around the cartridge. .</p>	<ul style="list-style-type: none"> Break off the cannula at the cartridge by bending it back and forth with your fingers, then use the handle of a wooden cotton swab to push the cartridge out of the HTR. Follow the instructions for removing GP deposits below.
<p>Gutta-percha (GP) deposits on the flow heater (HTR), or the GP push-rod on the handpiece.</p>	<ul style="list-style-type: none"> GP may deposit on or inside the HTR or the GP push-rod if the HTR is removed before it has cooled. Always wait for the HTR to cool before removing. Remove the HTR from the handpiece. The GP push-rod will automatically start retracting. Press the cuff switch once to stop the push-rod. Use a soft brush, or a wooden or plastic probe to gently remove the GP deposits. Using a metal probe or forcefully scraping the HTR will cause damage and void the warranty. Press the cuff switch again to alternate GP push-rod direction to facilitate GP removal.
<p>Pack or flow handpiece is malfunctioning.</p>	<ul style="list-style-type: none"> Turn the handpiece off and then back on again. If the handpiece still appears to be malfunctioning, contact Dentsply Sirona by phone or online at the contact information shown on the back cover page of this manual, or contact your Dentsply Sirona authorized service partner.

10 Warranty

Dentsply Sirona warrants the **Gutta-Smart™** against defects in material and workmanship under normal practices of installation, use, and servicing.

- **Gutta-Smart™** pack and flow handpieces guaranteed for 24 months from date of purchase (see terms and conditions below).
- Dentsply Sirona does not warrant any other products that come along with the device, such as electric heat pluggers or gutta-percha cartridges for example, as they are consumables.
- Never open the device yourself. Opening the device voids the warranty.
- If the product fails within 30 days from the date of purchase, please contact Dentsply Sirona by phone or online at the contact information shown on the back cover page of this manual.

Handpiece Warranty Replacement Fee*	
First Replacement in Year 1	Year 1 & Year 2
\$0**	\$99***

* This chart only refers to the handpieces and not the EHP/TRT/HTR or accessories included with the **Gutta-Smart™**

** \$0 cost for the first return. Additional returns will incur a \$99 service fee.

*** Dentsply Sirona reserves the right to replace 2nd year returns with refurbished equipment.

In the following cases the manufacturer declines all liability:

- Use of **Gutta-Smart™** for purposes and applications that differ from the specific requirements made in these Directions for Use.
- Cleaning, disinfection and sterilization methods contrary to the directions in these Directions for Use.
- Work or repairs performed by unauthorized persons.
- Rights under the warranty or statutory guarantee are rendered void if the device is opened without permission.
- Electrical installations in the room must meet the provisions of IEC 60364-7-710 ("Installation of electrical equipment in rooms used for medical purposes") and the regulations applicable in your country.
- If you have any questions, contact your dealer or Dentsply Sirona by phone or online at the contact information shown on the back cover page of this manual.

11 Disposal of Product

Comply with your national regulations, guidelines and requirements for the disposal of end-of-life electrical equipment and batteries.

Make sure the product or battery is not mixed with other types of waste when it is being disposed of. Prior to disassembly and disposal your device must not be contaminated and must have been completely reprocessed (Cleaning / Disinfection / Sterilization).

12 Identification of Symbols

Symbol	Identification
	WARNING: Serious injury or death may result if ignored.
	CAUTION: Damage to property or the environment may result if ignored.
	Additional information, explanation on operation and performance.
	Consult Instructions for Use
	Electronic Instructions for Use
	Serial number
	Lot number
	Catalog number
	Manufacturer
	Class II equipment, per IEC 60417-5172
	Type BF applied part, per IEC 60417-5333
Rx Only	U.S.A. federal law restricts this device to sale by or on the order of a dentist.
	Do Not Throw Away. This product and all its components must be recycled.
	Sterilizable in a steam sterilizer (autoclave) up to temperature specified
	Opened packages are not replaced
	Alternating current
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Keep away from sunlight
	Keep dry
	Fragile, handle with care

Symbol	Identification
	Direct current (connection for power supply)
	Use by date
	Do not sterilize
	Do not re-use
	Accessory
	Dangerous voltage
	Caution, hot surface
	Cartridge contents: gutta-percha
	Cartridge cannula: silver
	Cartridge capsule: aluminum
	Bluetooth®
	Handpiece temperature
	Thermal response tip mode
	Gutta-percha flow rate
	Battery level (base station)
	Battery level (handpieces)
	Handpiece tip installed and working properly
	Handpiece tip not installed or not working properly
	Gutta-percha level (push-rod position)
	Tone option level
	Active handpiece (when appearing alone)
	Up/down setting adjustment (when appearing together)



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