CMS Dental
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INSTRUCTIONS FOR USE

Heater

for Endodontic Obturators

The Soft-Core® Obturator system

The One-Step Obturator system

CE

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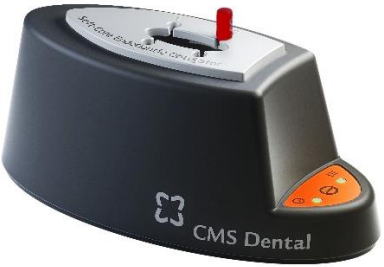
1 The Obturator System

The system consists of the Soft-Core® Endodontic Obturator, the Size Verifier and the Heater. This instructions for use contain information on how to handle and use the Heater.

Part	Description	Picture
Obturator	An endodontic obturator is used for root filling of a prepared tooth. The endodontic obturator is a biocompatible flexible gracile plastic carrier covered with thermoplastic guttapercha.	
Size Verifier	A Size Verifier is used to select the correct size obturator. The Size Verifier confirms if there is enough space in the prepared root canal for the selected obturator size.	
Heater	The Heater is an oven designed to heat and soften the guttapercha that covers the plastic carrier of the obturator.	

Read the instructions for use carefully before using the device. Instructions for use is also available on the company web shop after login, https://www.cmsdentalshop.dk.

Save the instructions for use for later use.

For information on how to use the Endodontic Obturator and the Size Verifier see the products instructions for use.

- TD 208-25 IFU Soft-Core
- TD 234-25 IFU Size Verifier

1.1 Reporting serious incidents

Any serious incident that may occur because of the use of the device must be reported to the manufacturer and the relevant authority in the country where the incident occurs. In Denmark, the competent authority is the Danish Medicines Agency.

For further questions about the device please contact the manufacturer:

CMS Dental A/S
Elmevej 8, 7870 Roslev, Denmark
+45 3257 3000 info@cmsdental.dk
www.cmsdental.com

2 Heater

The Heater must only be used with the described endodontic obturator systems. The Heater is for professional use only. As a safety precaution, keep Heater out of patient reach.

2.1 Intended purpose

The intended purpose of the Heater is to soften the endodontic obturator material prior to usage.

2.2 Device description and specification

The Heater consists of a plastic cabinet with a heat chamber where the obturator can be placed during heating. Up to 4 obturators can be heated in the same heating cycle.
The Heater has a heat chamber that consists of 5 printed circuit boards with cobber lanes. By applying power to the cobber lanes heat is generated.
The Heater is driven by an external power supply.

2.3 Intended users

The Heater is for professional use only.
The Heater is to be used only in a dental clinic or hospital environment by qualified dental professionals such as general practitioners as well as endo specialists and dental assistants.

2.4 Intended patient population

Patients who have an endodontic condition that requires a root canal treatment.
Patients are people of all ages who need dental treatment in endodontic procedures.

2.5 Contra-indications

There are no known contra-indications.

2.6 Limitations

The Heater is for professional use only.
The Heater must only be used in a dental clinic or hospital by qualified dental professionals such as general practitioners, endodontists, and dental assistants.
The Heater should only be used for heating of the Soft-Core and One-Step Endodontic Obturator systems.

2.7 Side-effects / residual risks

There are no known side-effects / residual risks.

2.8 Clinical benefits to be expected

The Heater is a device to soften the endodontic obturator material prior to usage.

2.9 Precautions

The Heater should only be used for softening of Endodontic Obturators.

2.10 Liability

The manufacturer disclaims all responsibility and liability for injury or damage to persons or property caused by faulty and/or inappropriate use.

2.11 Warnings

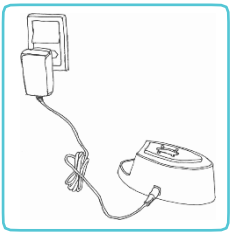
The Heater surface may be hot to touch.

Do not touch the inside of the heat chamber before the oven is completely cooled off.

3 Step-by-step guide

3.1.1 Preparation

Connect the power supply to the DC inlet of the heater and the mains and switch on power.



3.1.2 Preheating

Heat indicator (A) emits a red light while the heater preheats. Pre-heating takes 3-7 minutes depending on surrounding temperature.

When the Heater is ready, the heat indicator emits a green light, and the Heater makes a long beep.

Tips & Tricks: The Heater can be left on the entire day.

3.1.3 Obturator heating

When the Heater is ready for use place the desired number of obturators in the obturator slots marked 1 to 4.
Up to four obturators can be heated in the same heating cycle.

Activate the heating cycle by pressing the ON icon. The Heater will emit a short beep.

Time indicator (B) emits a red light during the heating cycle. The heating cycle last 60 seconds.

When the heating cycle is finished, and the obturator is ready for usage the time indicator changes to a green light and the Heater emits a long beep.

The obturator can be left hanging, ready for use, in the Heater for 15 minutes.

The Heater can be turned off by pressing the ON button for 2 seconds. 3 short beeps indicate that the Heater is turned off. The Heater can be reactivated by pressing the ON button for 2 seconds, by during so a long beep is emitted.

Tips & Tricks: Place the obturator to be used first in slot 1, the second in slot 2 etc. It is recommended to begin with the smallest size obturator.

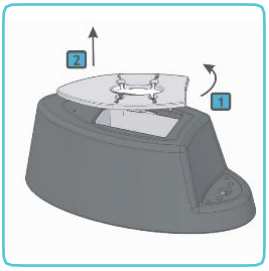
Tips & Tricks: You do not have to turn off the Heater after finished treatment, the Heater can be left on standby all day.

3.1.4 Indication - light and sound

	Time 	Heat 	Sound 
Preheating			-
Ready			Long beep
Activation			Short beep
Obturator ready			Long beep
Turn off			3 x short beep
Power on			Long beep
Auto turn off	-	-	Long beep

3.1.5 Cleaning

When the Heater has cooled completely, residues of gutta percha may easily be removed. To clean the obturator fixture, it can be removed by turning the fixture counterclockwise and lifting it upwards.



The Heater's outer casing can be wiped down with a slightly damp cloth using standard cleaning agents and surface disinfectants.
The gutta percha residues can be removed from the heating chamber using a blunt plastic instrument.

3.1.6 Sterilization guide for removable obturator fixture

The detached obturator fixture may be washed in a dishwasher and/or autoclaved. The gutta percha residues can be removed from the fixture using a blunt plastic instrument.

INSTRUCTIONS	
Dishwasher	Follow dishwasher instructions.
Sterilization in autoclave (maximum 250 cycles)	Vacuum autoclave, minimum 18 minutes at 134ºC, pressure 2.2 bar. Do not exceed 134ºC.
Manual cleaning	Rinse excess residues from top. Use a brush or suitable instrument, apply detergent solution to all surfaces. Rinse under clear running water.
Maintenance, inspection and testing	Discharge damaged products

4 Technical Description

4.1.1 Device Classification and conformity route

Region	Classification	Conformity
EU	Electrical Equipment for Laboratory use.	IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.

4.1.2 Standard compliance

Electrical Equipment for Laboratory use.	IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
Electromagnetic compatibility (EMC)	IEC 61326-1:2021 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
Restriction of Hazardous Substances (RoHS)	RoHS Directive 2011/65/EU Restriction of the use of certain hazardous substances in electrical and electronic equipment.

4.1.3 Environmental Conditions

Transport	Normal transport conditions.	Temperature range -40°C to +60°C Humidity range 10-80% RH
Storage	Store in original packaging. Store out of direct sunlight. Store in a dry place.	Temperature range +5°C to +40°C Humidity range 30-80% RH
Use	Use environment	Indoor use
	Altitude	Up to 2000m
	Temperature	+10°C to +40°C
	Humidity	Maximum 80% RH for temperatures up to 31°C decreasing linearly to 50% RH at 40°C.
	Mains supply fluctuations	+10% of nominal voltage
	Installation category	Defines level of transient overvoltage which the instrument is designed to withstand safely. Overvoltage Category II: 2500V for 230V supply and 1500V for 120V supply.
	Pollution degree	Describes the amount of conductive pollution present in the operation environment. Pollution degree 2: Only nonconductive pollution, such as dust, occurs with the exception of occasional conductivity caused by condensation.

4.1.4 Declaration of shelf life

The Heater consists of solid plastic parts and rigid electronics. Product lifetime is designed to be 15 years. Product warranty is 2 years. For laboratory electronic equipment there is no requirement to place a shelf time on the product. The product has no shelf time as this term is not applicable.

4.1.5 Disposal

Heater is an electrical device	Dispose electrical device to local recycling central.

4.1.6 Technical specifications

POWER SUPPLY	
Input power	100-240V AC, 50/60Hz
Output power	9V DC, 1,7A
SAFETY	
Auto turn off	The Heater turns off automatically after 9 hours.
Overheat protection	The Heater is protected from overheating by two independent circuits.

4.1.7 Materials

The Heater consists of a plastic cabinet, top and bottom, and a removable plastic part.

Part	**Materials**
Heater top Heater bottom	Polybutylene terephthalate (PBT)
Plastic part (obturator fixture)	Polybutylene terephthalate (PBT)

4.2 Symbols used

Symbol	Meaning of the symbol	Used on
	Catalogue number	Label
	Serial number	Label
	Date of manufacturing	Box and label
	Global Trade Identification Number	Label
	Temperature Limits	Box and label
	Humidity Limits	Box and label
	Keep out of sunlight	Box
	Keep dry	Box
	Consult instructions for use	Box and label
	Electrical double insulation Class II according to Medical Electrical Equipment Directive, DS/EN 60601-1.	Label
	Restriction of Hazardous Substances according to RoHS Directive 2011/65/EU. Restriction of the use of certain hazardous substances in electrical and electronic equipment.	Label
	Waste handling according to Waste Electrical and Electronic Equipment Directive, WEEE Directive 2002/96/EC.	Label
	European conformity The sold product is in conformity with European health, safety, and environmental protection standards.	Box and label
	Manufacturer	Label