

INSTRUCTIONS FOR USE





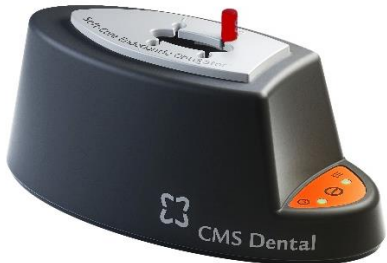
Soft-Core® Endodontic Obturator

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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 Soft-Core® Endodontic Obturator.

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 Size Verifier and the Heater see the products instructions for use.

- TD 234-25 IFU Size Verifier
- TD 212-25 IFU Heater

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 Soft-Core® Endodontic Obturator

The Soft-Core® Endodontic Obturator is a carrier of biocompatible plastic coated with thermoplastic gutta percha.

A single Obturator is all that is needed to fully obturate a root canal. The result should always be a perfectly placed and tight root canal filling with a tight apical seal.

2.1 Intended purpose

The Obturator is used for a permanent sealing and filling (obturation) of an endodontically shaped, cleaned, and irrigated root canal. The Obturator is used after initial sealing of the dentinal wall.

2.2 Device description and specification

The Obturator consists of a handle, a central plastic carrier covered with a thermoplastic gutta percha layer and the endo stop length indicator.

The Obturator handle is color coded corresponding to the Obturator size.

The Obturator is heated to soften the gutta percha.

The Obturator is inserted into the root canal. Verification that the Obturator reaches the apex is done by radiograph. Excess plastic carrier and gutta percha is removed.



2.2.1 Sizes

The Obturator is available in several sizes with differentiated tip diameters. Tip diameters vary from 0.20mm to 0.60mm.

The Obturator has a taper of 3% over the first 13mm from the tip.

Product	Size	Packaging
Soft-Core® Endodontic Obturator	020	6 pieces
Soft-Core® Endodontic Obturator	025	6 pieces
Soft-Core® Endodontic Obturator	030	6 pieces
Soft-Core® Endodontic Obturator	035	6 pieces
Soft-Core® Endodontic Obturator	040	6 pieces
Soft-Core® Endodontic Obturator	045	6 pieces
Soft-Core® Endodontic Obturator	050	6 pieces
Soft-Core® Endodontic Obturator	055	6 pieces
Soft-Core® Endodontic Obturator	060	6 pieces

2.2.2 Single Use

The Obturator is a single use device - **Do not reuse.**

If an attempt to place the heated Obturator in a root canal has been made, the gutta percha layer will be displaced and deformed. It is not possible to reuse the device.

2.3 Intended users

The Obturator is for professional use only. The Obturator are 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

The medical condition treated is endodontic treatment.

Patients are people in all ages needing dental treatment within endodontic procedures.

2.5 Contra-indications

Allergic reaction: Soft-Core® Endodontic Obturators shall not be used on patients with known allergies to Latex. This product may contain traces of dry natural rubber.

There are no other known contra-indications.

2.6 Limitations

The Obturator is for professional use only.

The Obturator are 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.

The Obturator should only be used for root canal procedures in teeth.

All patients deemed suitable for root canal treatment can receive treatment with the Soft-Core® Endodontic Obturator. It is the clinical professional that make this judgement.

There are no limitations.

2.7 Side-effects / residual risks

The Obturator is implanted in an endodontically prepared tooth. When a tooth is obturated the nerve of the tooth and then the tooth as such is by definition dead. Since the Obturator is inserted inside the tooth there is no contact to living tissue.

A possible side effect of a root canal treatment is that the patient obtains a local infection after a root canal treatment is finished. This encounters for all the root filling techniques available at the market and is not specific for this device.

The reason is known to be imperfect preparation of the root canal before obturation, residues of dead tissue and lack of cleaning the canal properly.

In case of a local infection the patient will feel discomfort shortly after the procedure has been conducted and a control consultation will reveal the need for further interaction.

2.8 Clinical benefits to be expected

The alternative to performing an endodontic root canal filling is to remove the tooth entirely. When a patient needs a root canal filling it is because they have a toothache, a bacterial growth in or around the tooth. A toothache is very painful for the patient. Having a bacterial infection in the tooth is a hazard to the general health in the human body.

Performing the endodontic root canal procedure will remove the bacteria and preserve the natural tooth in the patient's mouth. After the procedure, the patient is without pain and has obtained normal function of the tooth for chewing.

2.9 Precautions



- The Soft-Core® Endodontic Obturators must have an appearance as in this product picture.
 - The gutta percha must be intact and plastic carrier must be straight.
 - A deformed or defective product visible to the eye should never be used but should be discarded.
- If the Obturator is contaminated in any way, it shall be discarded.
- The Obturators shall not to be sterilized.
- For your own safety, wear personal protective equipment (gloves, glasses, mask).
- Use a rubber dam system during the endodontic procedure.
- Taking a confirming radiograph is good clinical practice and should always be done.
 - If the radiograph is not satisfactory, take another radiograph from a different angle.
 - If the filling still cannot be satisfactorily documented, remove the Obturator.

2.10 Liability

The Obturator is for professional use only.

The Obturator are 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.

The Obturator should only be used for root canal procedures in teeth.

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

Single use



The Obturator is a single use device.

If an attempt to place the heated Obturator in a root canal has been made, the gutta percha layer will be displaced and deformed. It is not possible to reuse the device.

Hot material



After heating, the gutta percha is hot. Avoid any direct contact between the Obturator and skin or mucous membranes.

Contamination risk



The Obturator should be inserted directly into the root canal. If the Obturator touches any tissue before insertion, it should be discarded.

Preparation



Do not heat the Soft-Core® Endodontic Obturator in other devices than the Soft-Core® Heater. The heater is specifically designed to soften the gutta percha layer of the Obturator.



Do not use the device if packaging has been damaged, unintentionally opened or exposed to environmental conditions outside limits specified on the enclosure.

The device could be compromised and damaged as well.



Do not use after expiry date.

The material composition could change or be less flexible. Not suitable for insertion into the root canal.

3 Step-by-step guide

3.1.1 Preparation

To ensure a proper root filling and to prevent contamination follow state of the art procedure for root canal fillings. Including use of a rubber dam system during the endodontic procedure.

Before using the Obturator, assure that you have achieved the following:

- A coronally flared canal ensuring Obturator has sufficient space to enter the root canal by using an orifice shaping instrument as necessary.
- A dry root canal.
- An established working length.

Tips & Tricks:

The Obturator plastic carrier is flexible enough to negotiate curved canals. Utilize any technique which provides a smooth tapered form and coronal access wide enough to give room for the instruments and Obturator. It is highly advised that rotary files with a higher conicity are utilized to create a sufficient taper for the Obturator.

When using files with a conicity less than 3%, it is advised to combine them with a procedure using Orifice Shaping Instruments, Gates Glidden Drills or similar instruments which can be used to create a sufficient opening in the coronal part of the canal. The use of Size Verifiers is recommended.

3.1.2 Determine the working length

Determine the working length by use of an electronic apex finder. It is recommended to measure the working length from the edge of the cusp to the apex.

Mark the working length on the Obturator by adjusting the endo stop, on the Obturator carrier, to the working length measured.

3.1.3 Choose the proper Obturator size

To determine the size of the Obturator which will be used for the filling, a Size Verifier corresponding in size to the last file/instrument used up to the working length is placed to verify the size of the root canal.

Select the Obturator corresponding to the Size Verifier which fits loosely to the working length.

Tips & Tricks:

For very narrow or highly calcified canals, it may be useful to select one size smaller than the last file used at apex.

3.1.4 Verification of Obturator using a Size Verifier

Mark the working length on the Size Verifier by adjusting the Endo stop on the Size Verifier carrier, to the working length measured.

Place the Size Verifier manually in the root canal while keeping a grip at the handle with a locking tweezers, or fingertips to secure holding it in place.



The Size Verifier must easily slide into the root canal to the working length without force and resistance, it must go all the way to apex. If the Size Verifier does not reach the working length, increase the taper of the preparation, or use a smaller Size Verifier.

For detailed information see the Size Verifier instructions for use.

Tips & Tricks:

If you do not use rotary files with a taper of 4% or more, you should always verify the size of the cleaned root canal with a Size Verifier before inserting the Obturator.

3.1.5 Heating of the Obturator

Use the Heater to soften the Obturators gutta-percha layer before usage.

Disinfect the obturator according to the state-of-the-art endo procedure.



Transfer the working length measurement to the Obturator plastic carrier. The depth references should be used to determine the working length.

Use the working length marked by the endo stop on the Size Verifier and move the endo stop of the obturator to the same location. Or mark the working length determined with the apex finder on the obturator.

Place the Obturator in the Heater and activate it. The Obturator is ready for insertion when the Heater gives a signal.

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

If the Obturator is left unused and the product is completely cooled off, it can be safely removed from the Heater. The Obturator can be reheated and used accordingly.

For detailed information see the Heater instructions for use.

3.1.6 Drying of root canal and application of sealer

Prepare any heat-resistant sealer* with a long working time according to the Sealer instructions for use.

Make sure that the shaped and cleaned root canal is completely dried using sterile absorbent paper points of matching size.

Endodontic sealer shall be applied following its instructions for Use. Any excess sealer that may have accumulated on the canal walls or pooled in the apex shall be removed. The carrier based gutta percha technique involves the use of small quantities of sealer, to prevent the risk of overfilling of sealer.

Utilize a paper point or a Size Verifier to apply a thin layer of sealer on the dentinal walls,

a few mm shorter than established working length. When obturating multiple canals, apply sealer in all canals at once.

Tips & Tricks:

As with any other root filling technique, when using the Soft-Core® Endodontic Obturator system, always apply sealer in the canal first. However, there is a significant difference when using carrier-based obturators. Only apply a very small amount using a Size Verifier or a paper point.

** The Soft-Core® Endodontic Obturator can be used in combination with any heat-resistant sealer that complies to; ISO 6876:2012 Dentistry – Root canal sealing materials. We refer to the instructions for use of the chosen product.*

3.1.7 Insertion of the Obturator into the canal

When the Heater indicates that the Obturator is ready for use, the Obturator is removed from the Heater.

Without twisting the handle, immediately insert the Obturator into the canal to the working length with a slow, firm, and continuous movement in the apical direction. Maintain the pressure a few seconds after the apex has been reached.



3.1.8 Confirming radiograph

Confirm your root canal treatment by a confirming radiograph.

If the root canal filling is not perfectly filled and with a tight apical seal, then the obturation process must be redone.

3.1.9 Removal of excess central carrier and gutta percha

When the gutta percha has hardened, after 2-3 minutes, remove the handle in one of two ways.

1. Lean the handle and metal insertion pin sharply to one side to break off the excess, while keeping the Obturator in place fixating it with an instrument.
2. Stabilize the plastic carrier with an instrument or your index finger and remove the handle and excess plastic carrier using a small inverted cone bur in a turbine without spray.



Then trim away the extra gutta percha using an endo excavator or similar instrument.

The obturation is now complete and the required tooth restoration can be initiated.



Tips & Tricks: Post space preparation

Remove the handle/metal insertion pin by twisting the handle. Stabilize the plastic carrier with a cotton plier while the handle/metal insertion pin is twisted out.

Post space creation is accomplished by removing the coronal portion of the obturation. Since the coronal 6 mm of the plastic carrier is hollow, this procedure should be easier with the Soft-Core® Endodontic Obturator than with other obturation systems.

Use a Post Space Burs or Thermo-Cut Burs. We refer to the instructions for use of the chosen product.

Tips & Tricks: Obturating multi-rooted cases

There will almost always be more than enough gutta percha on each Obturator. When obturating the canal, the excess gutta percha and sealer will backfill to the coronal part of the tooth, possibly blocking the adjacent opening. However, you can avoid this:

- *Obturate the shortest canal first.*
- *Place paper points or Size Verifiers in the other canals prior to obturation to prevent the following root canals in being blocked by gutta percha. Remove paper points or Size Verifiers as each canal is obturated.*
- *While there is sufficient gutta percha on each Obturator to fill even extremely long canals, wide canals or internally resorbed canals, it may be too much in some cases. If it is obvious that there will be an excess of gutta percha to fill the canal, use a sharp blade to trim some of the material from the coronal end of the central carrier prior to heating.*
- *In some cases, it can be beneficial to remove the handle/metal insertion pin from the actual plastic carrier before insertion, especially in multi-rooted teeth where the extra space will make it easier placing the following Obturators in the second and third canal.*

Tips & Tricks: Retreatment of an obturated root canal

Removal of the Obturator is relatively simple prior to the gutta percha cooling. Simply grasp the excess carrier with cotton pliers and remove it.

Once the gutta percha has cooled, or for retreatment at a later appointment, removal is easiest achieved by using a Peeso bur, Gates Glidden, ProTaper for root canal treatment or similar. Please refer to the instructions for use of the Manufacturer.

Place the bur between the canal wall and the plastic carrier, so that the rotational direction will be counterclockwise. Use the instrument at very low speeds (250-400 rpm) and work slowly around the plastic carrier until you feel resistance. The instrument will grasp between the plastic carrier and the canal wall. The plastic carrier will be coiled out of the canal after a short time.

If necessary, a small Hedstrom hand file can be worked down apically along the plastic carrier.

When the plastic carrier has been pulled out of the canal, the gutta percha is removed by traditional means.

4 Technical Description

4.1.1 Device Classification and conformity route

Region	Classification	Conformity
EU	Medical Device: Class IIa, rule 8.	European Medical Device Regulation EU 2017/745 (MDR), annex VIII.
USA	Dentistry - Root-canal obturating points	FDA 510(K) Exempt

4.1.2 Standard compliance

ISO 6877 Dentistry – Endodontic obturating materials
ISO 10993-1 Biological evaluation of medical devices

4.1.3 Declaration of shelf life

Shelf life	Expiry
5 years	Designated on product label

4.1.4 Environmental Conditions

Transport	Storage	Use
Keep away from sunlight.	Store in original packaging. Store out of direct sunlight. Store in a dry place.	Use at room temperature.
Temperature 0°C to +50°C	Temperature +5°C to +30°C	Temperature +5°C to +40°C
Humidity 10-80% RH	Humidity 30-75% RH	Humidity 10-80% RH

4.1.5 Disposal

Residuals from standard treatment: As part of standard obturation procedure, the excess obturation material is cut off and removed in the finishing state of the treatment. This will create some waste material. The removed materials must be handled as required by national law for dental clinics and disposed as required.

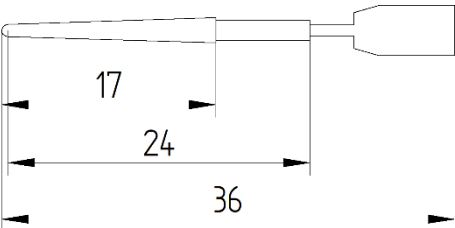
4.1.6 Radiopacity

The Soft-Core® Endodontic Obturator complies to radiopacity requirements in ISO 6877 Dentistry – Endodontic obturating materials.

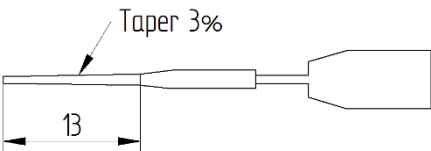
Requirement	Result
The material from which polymeric points are made shall have a radiopacity equivalent to at least 3 mm aluminum.	Radiopacity is equivalent to 6,7 mm aluminum.

4.1.7 Dimensions, taper, and size

The Soft-Core® Endodontic Obturator has an overall length of 36mm. The length of the carrier is 24 mm. The coronal 6 mm of the carrier is hollow to accommodate the metal insertion pin. The gutta percha layer covers 17mm of the carrier. These measurements comply to ISO 6877.



The Soft-Core® Endodontic Obturator is defined as a carrier-based obturation material according to ISO 6877. The standard defines Soft-Core® Endodontic Obturator as having a variable taper, however Soft-Core® Endodontic Obturator has a uniform taper of 3% over the first 13 mm from the tip. For carrier-based devices the dimension requirements in the standard applies to the Obturator carrier. The drawing and dimensions below refer to the Obturator carrier.



Device dimensions for size and taper designation follow the standard, ISO 6877, and have the dimensions shown in the table.

Size designation	Taper (0-13mm)	D tip (mm)	d13 (mm)
020	03	0,20	0,59
025	03	0,25	0,64
030	03	0,30	0,69
035	03	0,35	0,74
040	03	0,40	0,79
045	03	0,45	0,84
050	03	0,50	0,89
055	03	0,55	0,94
060	03	0,60	0,99

4.1.8 Materials

The Obturator consists of a handle, a central plastic carrier covered with a thermoplastic gutta percha layer and a length indicator (Endo stop).

Part	Materials
Handle	ABS / stainless steel
Carrier	PSU /LCP / Wolfram
Gutta Percha	Raw gutta percha / Titanium oxide / Barium sulphate
Endo stop	Silicone rubber

4.1.9 Parts

Handle – A plastic handle with a metal insertion pin.

The plastic handle is color-coded according to the size of the Soft-Core® Endodontic Obturator.

- Color coding according to ISO6877.
- The stainless-steel insertion pin is 9 mm long and is permanently attached to the plastic handle.
- The metal insertion pin is placed 6 mm down in the plastic carrier.
When the metal insertion pin is removed it will leave a hollow part of 6 mm in the plastic carrier.

Carrier– A flexible plastic carrier

- The tapered plastic carrier is sufficiently flexible to negotiate curved canals.
- The plastic carrier is slightly tapered. This insures adequate back flow of the heated gutta percha.
- The length of the carrier is 24 mm. The coronal 6 mm of the carrier is hollow to accommodate the metal insertion pin.
- The plastic carrier is radiopaque.














Gutta Percha – An outer layer of thermoplastic gutta percha.

- The gutta percha is reversible thermoplastic. This means that it becomes soft and highly adhesive when heated to temperatures above approximately 100°C. When cooled, it returns to a firm, rigid state.
- Reheating will once again make the gutta percha soft and adhesive.

Endo stop

- An endo stop is provided to mark the working distance measurement already defined by an apex finder.

4.2 Symbols used

Symbol	Meaning of the symbol	Used on
	Size and taper of the Obturator Information's according to ISO 6877.	Label
	Active length of Obturator Information's according to ISO 6877.	Label
PCS	Pieces Number of items in the box or packaging.	Label
	Catalogue number	Label
	LOT / Batch code	Label
	Use-by date Indicates the date after which the device is not to be used.	Label
	Unique device identifier	Label
	Medical device Medical device according to EU 2017/745 regulation on medical devices (MDR).	Label
	Caution Be aware to follow instructions for use to avoid undesirable consequences.	Label
	Do not re-use This medical device is intended for one single use only.	Label
	Keep away from sunlight	Label
	Temperature limits	Label
	European conformity The sold product is in conformity with European health, safety, and environmental protection standards. Notified Body authorization number.	Label
	Manufacturer	Label