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INSTRUCTIONS FOR USE

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One-Step Endodontic Obturator

- Transaktion 09222115557531040409 Signeret LR

MD CE 2460

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1 The Obturator System

The system consists of the One-Step Endodontic Obturator, the Size Verifier and the Heater. This instructions for use contain information on how to handle and use the One-Step 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 gutta percha.	
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 gutta percha 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 234-25-01 IFU Size Verifier
- TD 212-25-01 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

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2 One-Step Endodontic Obturator

The One-Step 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 central plastic carrier with length indicators. The apical part of the plastic carrier is coated with a thermoplastic gutta percha layer.
The Obturator is characterized by NOT having an attached handle. Instead, self-locking tweezers are used to insert the obturator into the root canal.

The apical part of the plastic carrier is uniformly tapered to be sufficiently strong and flexible to negotiate curved canals. The proximal shaft has indentations for use as reference points to properly place the tweezers. The indentations also make it easy to break off the excess shaft after filling.
Both the plastic carrier and the gutta percha are radiopaque.

The Obturator is heated to soften the gutta percha.
The Obturator is inserted into the root canal. Verification whether the Obturator reaches the determined working length 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
One-Step Endodontic Obturator	020	20 pieces
One-Step Endodontic Obturator	025	20 pieces
One-Step Endodontic Obturator	030	20 pieces
One-Step Endodontic Obturator	035	20 pieces
One-Step Endodontic Obturator	040	20 pieces
One-Step Endodontic Obturator	050	20 pieces
One-Step Endodontic Obturator	060	20 pieces

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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: One-Step 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 One-Step 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 the root canal treatment is finished. This encounters all the root filling techniques available on 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.

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2.9 Precautions

- The One-Step 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 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.
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 One-Step Endodontic Obturator in other devices than the One-Step 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.

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3 Step-by-step guide

3.1.1 Preparation

To ensure a prober 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.

3.1.3 Preset working length onto the One-Step Obturator tweezers

Hold the lower part of the One-Step Obturator packaging with one hand. Turn the packaging upright. Use the other hand to turn the upper part of the One-Step packaging to an opening. Next to the opening there is a printed length indicator.
Lock the One-Step Obturator tweezers at the predetermined working length on the shaft, so that the edge of the head of tweezers is placed at your reference point for your working length. The edge of the tweezers' head is used as a traditional rubber stop.

Tips & Tricks:
It can be useful to mark the working length on the plastic carrier with a small amount of sealer before placement of the One-Step Obturator tweezers, this mark will then act as your reference point.

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3.1.4 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.

3.1.5 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.

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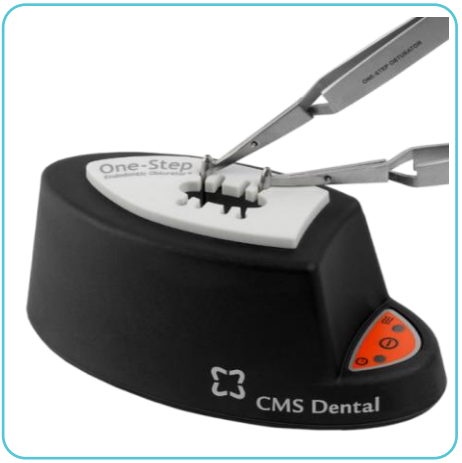
3.1.6 Heating of the Obturator

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 as described in 3.1.3.
The working length should be determined by the use of an electronic apex finder.

Place the One-Step Obturator tweezers, with the One-Step Obturator fixated at the predetermined working length, in the Heater. Use one of the 4 slots to hold the tweezers. Activate the Heater. 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.

3.1.7 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 One-Step 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 One-Step 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.*

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3.1.8 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.

Insert the Obturator immediately into the root canal to the working length with a slow, firm, and continuous movement in the apical direction. Use the tweezers to handle the Obturator placement.
Maintain the pressure a few seconds after the apex has been reached.

3.1.9 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.

3.1.10 Removal of excess central carrier and gutta percha

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

1. Grasp the shaft with the tweezers at the point where you want the shaft to break. Twist the tweezers from side to side and break off the shaft.

2. Stabilize the plastic carrier with an instrument or your index finger and remove the 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
Post space creation is accomplished by removing the coronal portion of the obturation. Use a Post Space Burs or Therma-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.*

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- *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.*

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.

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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	Medical Device: Class I, 872.3850 Gutta-Percha 510(K) Exempt	Code of Federal Regulations CFR 21 800-898 Medical Devices

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 One-Step 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 6,3 mm aluminum.

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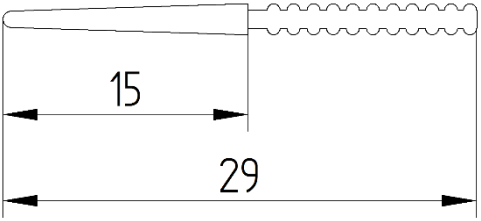
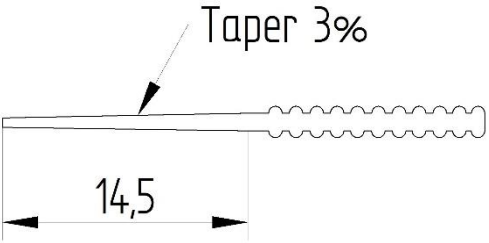
4.1.7 Dimensions, taper, and size

The One-Step Endodontic Obturator has an overall length of 29mm.
The gutta percha layer covers 15mm of the carrier.
These measurements comply to ISO 6877.



The One-Step Endodontic obturator is defined as a carrier-based obturation material according to ISO 6877:2021. The standard defines One-Step as having a variable taper; however, One-Step has a uniform taper of 3% over the first 14,5mm from the tip. For carrier-based devices the dimension requirements in the standard applies to the 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 (0-14,5mm)	D tip (mm)	$d_{14,5}$ (mm)
020	03	0,20	0,64
025	03	0,25	0,69
030	03	0,30	0,74
035	03	0,35	0,79
040	03	0,40	0,84
050	03	0,50	0,94
060	03	0,60	1,04

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4.1.8 Materials

The obturator consists of a central plastic carrier with length indicators. The apical part of the plastic carrier is coated with a thermoplastic gutta percha layer.

Part	Materials
Carrier	PSU /LCP / Wolfram
Gutta Percha	Raw gutta percha / Barium sulphate / Titanium oxide

4.1.9 Parts

Carrier– A flexible plastic carrier

- The tapered plastic carrier is sufficiently flexible to negotiate curved canals.
- The plastic carrier is slightly tapered. This ensures adequate back flow of the heated gutta percha.
- The length of the carrier is 29 mm.
- 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.
- The gutta percha is radiopaque.

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4.2 Symbols used

Symbol	Meaning of the symbol	Used on
020 03	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
REF	Catalogue number	Label
LOT	LOT / Batch code	Label
	Use-by date Indicates the date after which the device is not to be used.	Label
UDI	Unique device identifier	Label
MD	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
CE 2460	European conformity The sold product is in conformity with European health, safety, and environmental protection standards. Notified Body authorization number.	Label
	Manufacturer	Label

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Verifikation

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Dokument

TD-208-25-01-02 IFU One-Step v.17 EN 2024-11-05
Hoveddokument
15 sider
Påbegyndt 2024-11-05 14:41:47 CET (+0100) af Mads Sælland (MS)
Færdiggjort 2024-11-05 17:01:37 CET (+0100)

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