

INSTRUCTIONS FOR USE



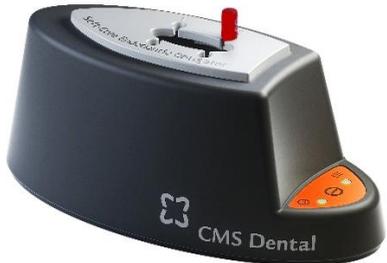
Size Verifier **for Endodontic Obturators**

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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 Size Verifier.

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 Heater see the products instructions for use.

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

The Size Verifier is an accessory to the obturator product. It is a helpful tool for the dentist but not a necessary tool to complete the root canal filling satisfactorily. It is NOT a measuring device.

2.1 Intended purpose

The Size Verifier is intended to verify that there is enough space in the prepared root canal for the obturator to fit in, both in the axial and the vertical directions. The Size Verifier need to have a loose fit and no resistance.

2.2 Device description and specification

The Size Verifier consist of a plastic body with a handle molded in one piece and a length indicator (endo stop) placed on the body. The size is embedded in in device handle.

The Size Verifier has the same dimensions as the corresponding obturator. A size 020 Size Verifier is corresponding to a size 020 obturator.



2.2.1 Sizes

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

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

Product	Size	Packaging
Size Verifier	020	6 pieces
Size Verifier	025	6 pieces
Size Verifier	030	6 pieces
Size Verifier	035	6 pieces
Size Verifier	040	6 pieces
Size Verifier	045	6 pieces
Size Verifier	050	6 pieces
Size Verifier	055	6 pieces
Size Verifier	060	6 pieces

2.2.2 Single-patient use

The Size Verifier is intended for single-patient use due to the risk of cross contamination between patients. In the same treatment of a single patient the Size Verifier can be used multiple times as long as a state-of-the-art hygienic procedure is followed.

2.3 Intended users

The Size Verifier is for professional use only.

The Size Verifier 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

There are no known contra-indications.

2.6 Limitations

The Size Verifier is for professional use only.

The Size Verifier must only be used in a dental clinic or hospital by qualified dental professionals such as general practitioners, endodontists, and dental assistants.

The Size Verifier should only be used in connection with root canal procedures in teeth.

2.7 Side-effects / residual risks

There are no known side-effects.

Take precaution upon usage of the Size Verifier to avoid penetration at the apical end, see section Step-by-step guide, 3.1.1 Preparation.

2.8 Clinical benefits to be expected

Using the Size Verifier offers the possibility of defining the correct obturator dimension/size.

Using the Size Verifier makes the dentist's work easier and reduces discomfort for the patient by eliminating the need for further work on the root canal.

2.9 Precautions

The Size Verifier should only be used as an accessory device when performing root canal procedures in teeth.

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

Contamination risk



To avoid the risk of cross contamination always follow the state-of-the-art rinse protocol after user of the Size Verifier before insertion of the obturator.

Single Patient Use



The Size Verifier is a device for single patient use – Do not reuse.

The material and design have not been tested and approved for long time usage. The device could be damaged if used for numerous patients.



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

Before using the Size Verifier, 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.
- An established working length.

3.1.2 Determine the working length

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

Mark the working length on the Size Verifier by adjusting the endo stop on the Size Verifier body, to the working length measured.

3.1.3 Choose the proper obturator size

Use the Size Verifier to determine the correct obturator size for the root canal treatment. The Size Verifier does not stay in the root canal but is removed before the endodontic obturator is placed.

- Start by testing a Size Verifier in the prepared root canal that corresponds in size to the last file/instrument used.
- 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 the apex.
- If the Size Verifier does not reach the working length, increase the taper of the of the root canal preparation, or use a smaller Size Verifier.
- The correct Size Verifier is the size which fits loosely all the way to the working length.
- Choose the obturator that corresponds to the fitting Size Verifier and discard the Size Verifier.
- After use of the Size Verifier continue to follow the state-of-the-art procedure for root canal fillings.



4 Technical Description

4.1.1 Device classification and conformity route

Region	Classification	Conformity
EU	Medical Device: Class I, rule 5.	European Medical Device Regulation EU 2017/745 (MDR), annex VIII.

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
No special requirements	Store in original packaging. Store out of direct sunlight. Store in a dry place. Temperature +5°C til +40°C.	Use at room temperature

4.1.5 Disposal

The used Size Verifier could be contaminated.

The used product must be handled as required by national law for dental clinics and disposed as required.

4.1.6 Radiopacity

The Size Verifier contains the material Tungsten which makes it possible to take a contrast X-ray of the root canal with the Size Verifier inserted.

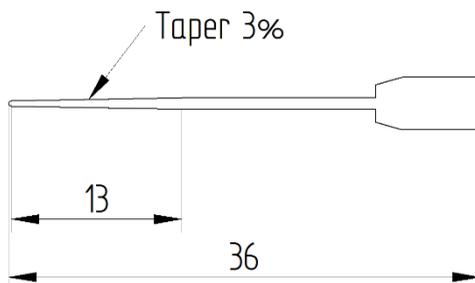
4.1.7 Dimensions, taper, and size

The Size Verifier is dimensioned to correspond the same size endodontic obturator. A size 020 Size Verifier is corresponding to a size 020 Obturator. The mechanical dimensions comply to the definitions in ISO 6877.

The obturator has a uniform taper of 3% over the first 13mm from the tip, therefore this is also the case for the size verifier.

The obturator size 020 has a tip diameter of 0,20mm, therefore the tip diameter of the size verifier, size 020, is also 0,20mm.

The size verifier has an overall length of 36mm.



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 Size Verifier consist of a plastic body with a handle molded in one piece and a length indicator (Endo stop) placed on the body.

Part	Materials
Body/Handle	LCP / Wolfram
Endo stop	Silicone rubber

4.1.9 Parts

Body/Handle– A flexible plastic body

- The tapered plastic carrier is sufficiently flexible to negotiate curved canals.
- The plastic body is radiopaque.

Endo stop

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

4.2 Symbols used

Symbol	Meaning of the symbol	Used on
	Size and taper of the Size Verifier Information's according to ISO 6877.	Label
	Active length of Size Verifier Information 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 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.	Label
	Manufacturer	Label