DIRECTIONS AND INDICATIONS FOR USE

The obturator has three components: the carrier, the stop, and the gutta percha.
The carrier has a color-coded handle as a quality tool to visually verify the obturators size. The size is stamped on the carrier and identifies the diameter and taper of the obturator.
During a root canal procedure, an endodontist or clinician removes pulp from the pulp chamber of the tooth and shapes the canal. The canal is disinfected and the wall of the canal is sealed. The depth and diameter of the canal is gauged using a verifier. When the proper dimensions are determined, the proper obturator size is identified. The red silicone stop is used to give the endodontist a reference of the canal depth. The obturator is then heated until the gutta percha becomes malleable and is pressed into the tooth canal. When cool, the excess matter is removed. A crown or other restoration procedure is completed.

Contraindications

•None Known

Warnings

•None Known

Adverse Reactions:

• Patients who have known latex sensitivity may experience allergic reactions to gutta percha.

Precautions for Use

• Select the EdgeCore™ Obturator that matches the Size Verifier that fits passively to the working length. Do not use EdgeCore™ Obturator cores as size verifiers.
• Do not remove gutta-percha from the EdgeCore™ Obturator prior to placing it into the canal or you may damage the obturator.
• EdgeCore™ Obturators are single use devices. Do not reuse.
• Note: EdgeCore™ does not need to be precurved. Precurving may damage the obturator.

Shaping and cleaning

Successful endodontic treatment requires proper straight-line access, canal debridement, shaping, cleaning and obturation of the root canal. While EdgeCore™ is an easier obturation method and decreases the time to obturate the root canal, it is imperative to properly prepare the canal before obturation.

Obturator Selection

After proper shaping, cleaning, and disinfecting is complete and the working length is confirmed by radiograph and/or apex locator, the proper obturator is selected by using the Size Verifiers.
Select the EdgeCore™ Obturator the same size as the Size Verifier that fits passively to the working length. Use the millimeter markings on the Size Verifiers to ensure it is at the appropriate length. In most cases the Size Verifier will match the largest file taken to the working length. But occasionally it may be found that the Size Verifier that fits best to the working length is a size smaller or larger than the largest file taken to the working length. You should choose the obturator that matches the Size Verifier that fits best to the working length.

Disinfection

Disinfect the obturator in 5.25% sodium hypochlorite solution (bleach) for one minute. Rinse the obturator in 70% sterilized isopropyl alcohol. Dry the obturator for about 10 seconds on a clean surface to allow the alcohol to evaporate.

Sealer

Use a noneugenol-type sealer like AH26.

Drying the Canal and Applying Sealer

Use sterile paper points to completely dry the canal before you apply the sealer. With the canal dry, coat the new dry paper point or file with sealer and brush a very light layer of sealer onto the canal walls to the working length. Then dry the canal with another new dry paper point to remove excess sealer. EdgeCore™ will obturate the root canal space with a dense, homogeneous, three-dimensional filling: therefore excessive sealer is not needed or desirable.

Obturating the Canals

Place the EdgeCore™ Obturator in your any and all Tulsa Dental ThermaFil ovens or SoftCore ovens. Start the oven, select the button that matches the obturator, wait, then after the first beep", remove the carrier from the oven and insert the carrier directly into the canal with a smooth, slow motion. Fill one canal at a time. Note: If you use a GuttaCore oven you need to let it beep twice before removing it.

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Removing the EdgeCore™ Shaft and Handle

Stabilize the carrier with your fingers then use a blunt instrument like spoon excavator or plugger and push the instrument against the shaft at the orifice. The shaft is designed to separate as it is brittle at that point. Use a plugger to compact the obturator in the coronal orifice. Discard the handles and shaft in an appropriate biohazard container.

Removing Excess Gutta-Percha

Use a spoon excavator to remove any excess gutta-percha in the chamber or other canals. Repeat all of the above steps on each canal of a multi-rooted tooth.

Storage

Store at room temperature of 10℃~37.8℃, away from any sunlight.

Creating Easy Post Space

Post space is made using traditional methods as if standard gutta percha were in the canal by using Gates Glidden bur, your favorite post space bur, or the bur you normally use to create post space.

Removing EdgeCore™ Obturation Materials

Like making post space, retreating is accomplished using traditional methods for removing obturation material. When removing the obturation material for retreatment purposes, remove the coronal 1/3 of material with a Gates-Glidden bur or other coronal shapers. Then in the presence of solvent, use rotary files in a crown-down method to slowly remove the obturation material. Rinse with solvent after each instrument. In the apical 1/3 of the canal use hand instruments with solvent to soften and remove the obturation material.

Symbol	Meaning (Standard, If Applicable
	Manufacturer/Legal Manufacturer (ISO 15223-1)
	Authorized Representative in the European Community. (ISO 15223-1)
	Used-by Date (ISO 15223-1)
	Keep away from Sunlight (ISO 15223-1)
	Do Not Re-use (ISO 15223-1)
	Do not use if package is damaged (ISO 15223-1)
	Consult instructions for use (ISO 15223-1)
Rx Only	Caution: Federal law restricts this deivse to sale by or on the order of a “dentist/Physician” licensed by the law of the State in which he/she practices to use or order the use of the devise. (FDA 21 CFR[1] Part 801.109 (b) (1))
	Non-sterile. (ISO 15223-1)
	Caution. Indicates the need for the user to consult the instructions for use. (ISO 15223-1)
	Temperature Limit (ISO 15223-1)
	Indicates conformity with the provisions of Council Directive 93/42/EEC. (Council Directive 93/42/EEC)
REF	Indicates the manufacturer’s catalog number so that the medical device can be identified. NOTE: Synonyms for “catalogue number” are “reference number” and “reorder number”. (ISO 15223-1)
LOT	Indicates the manufacturer’s batch code so that the batch or lot can be identified. NOTE: Synonyms for “batch code” are “lot number” and “batch number”. (ISO 15223-1)
GTIN	Global Trade Item Number (GS1)
	Indicates that opened packages are not replaced. (ISO 7000)

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