

ELECTRONIC INSTRUCTIONS FOR USE

EdgeFill™ Endodontic Thermal Plastic Obturators are single use medical devices used to fill root canal systems. The obturator is placed within the canal and remains in the patients' tooth canal long term. The devices are provided non-sterile and are intended for disinfection by the user. They are not intended to be reused and/or reprocessed.

EdgeVerify™ Endodontic Verifiers (sold separately) are single use medical devices used to temporarily gauge canal size during root canal obturation. The devices are provided non-sterile, intended for disinfection by the user. They are not intended to be reused and/or reprocessed.

TYPE/MODEL: EdgeFill™ for EdgeEndo®, EdgeFill™ for EdgeTaper™, EdgeFill™ for EdgeOne™ and EdgeVerify™

SPECIFICATIONS: Tip sizes - 20 (Small/F1), 25 (Primary/F2), 30 (F3), 35 (Medium), 40 (F4), 45 (Large), 50 (F5)

INDICATIONS FOR USE

The thermal plastic carrier-based obturators are indicated for the obturation of a tooth root following root canal therapy for patients experiencing dental disease.

EdgeVerify Verifiers (sold separately) are indicated to gauge canal size during root canal obturation following root canal therapy for patients experiencing dental disease.

INTENDED USE

The thermal carrier-based obturators are intended to be used to fill the tooth root following endodontic pulpectomy.

EdgeVerify verifiers (sold separately) are intended to be used before obturation of a tooth to gauge canal size for obturator selection.

INTENDED PATIENT POPULATION

The device is intended for use in patients experiencing dental disease, who have received an endodontic pulpectomy.

INTENDED USERS

The device is intended to be used by endodontic professionals.

INTENDED USE ENVIRONMENT

The device is intended for use in the dental operative environment.

CONTRAINDICATION

None

WARNINGS

- Single-use products shall not be reused.
- This product is used by professional dentists only.
- Do not use this product for any purpose other than dental treatment or service.
- Follow dental practice, to use rubber dams during operation.



• This product can expose you to chemicals including methanol and toluene, which are known to the State of California to cause cancer, and tetrahydrofuran, cumene, and ethylbenzene, which are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

PRECAUTIONS

- Select the EdgeFill obturator that matches the size verifier that fits passively to the working length. Do not use EdgeFill obturators as size verifiers.
- Do not remove gutta-percha from the EdgeFill obturator prior to placing it into the canal or you may damage the obturator.
- EdgeFill does not need to be precurved. Precurving may damage the obturator.

STRUCTURE

- The EdgeFill obturator has three components: the plasticized carrier, the silicone stopper, and the gutta percha.
- EdgeVerify verifier has two components: the carrier and the silicone stopper.

STORAGE CONDITIONS

- Handle with care during transportation and storage; do not stack to avoid damage.
- Avoid storing in areas with high temperature (37.8°F / 100°F), or direct sunlight.

SHELF LIFE

- Obturators: 4 years from the date of manufacture (refer to packaging label) when stored under the recommended conditions.
- Verifiers: No expiration date

DISINFECTION

- It is recommended to disinfect the verifier prior to use and EdgeFill obturator prior to final placement.
- Disinfect the selected verifier/obturator by placing it in 5.25% sodium hypochlorite solution (bleach) for one minute. Rinse the verifier/obturator in 70% sterilized isopropyl alcohol. Dry the verifier/obturator for about 10 seconds on a clean surface to allow the alcohol to evaporate.

STEP-BY-STEP INSTRUCTIONS

1. **Shaping and Cleaning:** 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.
2. **Selection:** Select the EdgeFill obturator the same size as the size verifier that fits passively to the working length.
 - a. Use the millimeter markings on the size verifiers to ensure it is at the appropriate length.
 - b. 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.
3. **Sealer:** Canal should be prepared by first applying sealer of choice. It is recommended to use a bioceramic sealer.
 - a. Apply a very light layer of sealer onto the canal walls to the working length. Use a paper point to remove any excess sealer. EdgeFill will obturate the root canal space with a dense, homogeneous, three-dimensional filling; therefore excessive sealer is not needed nor desirable.
4. **Placement:** Place disinfected EdgeFill obturator in any obturator oven. 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.
5. **Removing 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.
6. **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.
7. **Creating Post Space (when necessary):** 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.

RETREATMENT AND REMOVAL OF EDGEFILL OBTURATION MATERIALS

Like making post space, retreatment 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.

SERIOUS INCIDENT REPORTING

Any serious incident in relation to his product should be reported to the manufacturer and the competent authority according to local regulations.

DISPOSAL

Discard used verifiers as well as all dissected obturator handles and shafts in an appropriate biohazard container.

SYMBOLS GLOSSARY

Symbols	EN	Symbols	EN
	Manufacturer		Batch code
	Date of Manufacture		Quantity
	Use-by-date		Consult Instruction for Use
	Caution		Do not use if package is damaged and consult instructions for use
	Non-Sterile		Do not reuse
	Catalogue number		Indicates opened packages are not replaced
	Unique Device Identifier		Keep away from sunlight
	Packaging unit		Upper limit of temperature
Rx Only	Federal law restricts this device to sale by or on the order of a dentist.		

HOW TO ORDER A FREE PAPER COPY OF THIS ELECTRONIC INSTRUCTIONS FOR USE (eIFU)

By Phone: To order a free paper copy, you need access to a telephone.

1) Call 855.985.3636 and follow the operator instructions.

2) Request paper copy of the Instructions for use for "EdgeFill" and provide the address you would like to receive the paper copy of the Instructions for Use. The paper copy will be delivered to the indicated address within seven (7) calendar days without additional cost.