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GuttaCore[®]
Crosslinked Gutta-Percha Core Obturators

Directions for Use



 Dentsply
Sirona
Endodontics



Travel challenging
canals with confidence

DIRECTIONS FOR USE

Prior to using any new product, read all of the manufacturer's instructions. Make sure that you are competent when using the product and technique prior to clinical use. Consider the following directives to ensure successful applications and outcomes.

FOR DENTAL USE ONLY

REF A1703—A1803

DESCRIPTION

GuttaCore® Crosslinked Gutta-Percha Core Obturators are used for filling root canal systems.

INDICATIONS FOR USE

GuttaCore and GuttaCore for WaveOne® Gold Obturators are used to fill the cleaned, shaped and irrigated root canal space.

CONTRAINDICATIONS

None Known.

WARNINGS

None.

PRECAUTIONS

- Select the GuttaCore or GuttaCore for WaveOne Gold Obturator according to the appropriate GuttaCore size verifier that fits the shaped canal passively.
- GuttaCore Obturator cores and/or hand files should not be used as size verifiers.
- Do not remove gutta-percha from the apical section of GuttaCore Obturator prior to filling the root canal space. Removing the gutta-percha may damage the obturator.

ADVERSE REACTIONS:

None.

Step-by-Step Instructions

These instructions are designed to help gain an understanding of the technique and safe application of the product. Practice on plastic blocks and extracted teeth are strongly recommended prior to clinical applications.

Crosslinking

Crosslinking is a well known chemical process of linking polymer chains together. Crosslinking creates the subtle strength needed in a centrally compacting obturator. GuttaCore® Obturators create the hydraulics you expect from Dentsply Sirona obturators with the added benefit of having a gutta-percha core. It is important to note that Crosslinked gutta-percha is not sticky, does not melt and will not dissolve with solvents.

Hydraulics

GuttaCore Obturators move warm gutta-percha 3-dimensionally into the root canal system. Many obturation techniques use lateral or vertical compaction, however the hydraulic force from these techniques generally moves gutta-percha in one or two unequal directions (laterally or apically). GuttaCore uses a crosslinked gutta-percha core for centrally compacting the flowing gutta-percha in the canal. The hydraulic force compacts warm gutta-percha flowing equally in 3-dimensions. Proper cleaning, shaping and irrigation, along with the central compacting hydraulic force facilitates the flow of gutta-percha in the root canal system.

1. Consult the File System Directions For Use

Consult the file system's directions for use when using GuttaCore or GuttaCore for WaveOne Gold Obturators to ensure the proper final shape is created.

2. Flare the Canal

Flare the canal coronally and ensure the GuttaCore® Obturator has sufficient space to enter the root canal along the straight line access by using an orifice shaping instrument as necessary such as Endo Access Kit, or a ProTaper® Gold®, or S1 file.

3. Verify the Shape at Working Length and Passive Fit

Following proper cleaning and shaping, confirm the final working length measurement using a size verifier that reaches the apical constriction passively, with no significant resistance or twisting. It is necessary to use the GuttaCore® size verifier from the obturator package to confirm the shape at working length and passive fit. Verifying the shape at working length and passive fit ensures that the GuttaCore Obturator being used matches the correct apical canal diameter.

The size verifiers included in the GuttaCore package are made of nickel titanium and are fluted, making them excellent for minor apical shaping, if necessary. If the

size verifier is slightly short of your working length, you can use it to enlarge to your working length by rotating it in a clockwise direction while exerting slight apical pressure.

- i. Remove the GuttaCore or GuttaCore for WaveOne® Gold size verifier from the obturator package to confirm a passive fit at working length; set the silicone stopper at your working length using the size verifier's calibration mark. Check passivity by taking the size verifier to working length and confirm by rotating in the canal 180°.
- ii. If the fit is passive, remove a GuttaCore Obturator from the package and proceed to step 5.
- iii. If the fit is not passive, use the size verifier as a finishing file to gently enlarge the canal terminus or select a smaller size verifier. If the smaller size verifier fits passively, remove a GuttaCore Obturator of the same size as the verifier and proceed to step 5.

4. Irrigate the Canal

The cleaning of the shaped root canal system is accomplished primarily through the use of copious irrigation with NaOCl. Irrigants are activated using a cavitation and acoustic streaming device or ultrasonic irrigation needle. The activated irrigants improve debridement and disrupts the smear layer and biofilm inside the canal, promoting deep cleaning and disinfection of lateral canals, fins, webs, isthmuses, anastomoses, and dentinal tubules. Dry the canal thoroughly using absorbent points.

5. Selecting the Obturator and Setting Working Length

When the final shape is a .04 taper, select a GuttaCore Obturator package *one size smaller* than the last file taken to working length. When the final shape is a .06 taper or larger, select a GuttaCore package of the same size as the last file taken to working length.

When using GuttaCore for WaveOne Gold, select the GuttaCore for WaveOne Gold Obturator package of the *same size* as the last WaveOne Gold file taken to working length.

Set the silicone stopper on the GuttaCore Obturator to coincide with the working length established. Place the silicone stop on the calibration ring. Calibration rings are set at the following working lengths (in millimeters): 18, 19, 20, 22, 24, plus 27 and 29 on the obturator handles.

Select a GuttaCore® or GuttaCore for WaveOne® Gold Obturator from the same package as the size verifier used to verify the shape of the working length and passive fit. **Available GuttaCore Obturator sizes include:**

GuttaCore Obturators			
Final Shape .04 Taper	GuttaCore Obturator	Final Shape .06 Taper	GuttaCore Obturator
20/.04	—	20/.06	20
25/.04	20	25/.06	25
30/.04	25	30/.06	30
35/.04	30	35/.06	35
40/.04	35	40/.06	40
45/.04	40	45/.06	45
50/.04	45	50/.06	50
55/.04	50	55/.06	55
60/.04	55	60/.06	60
70+/.04	60	70+/.06	70
80+/.04	70	80+/.06	80
90+/.04	80	90+/.06	90

Final Shape GuttaCore for WaveOne Gold	WaveOne Gold Obturator
Small	Small
Primary	Primary
Medium	Medium
Large	Large

6. Drying the Canal and Applying Sealer

Use a sterile paper point of the same tip and taper as the last file taken to working length. Brush a very light coating of AH Plus® Jet sealer circumferentially to the canal wall with the paper point. To help ensure the obturator reaches working

length, use an additional absorbent point to remove any excess sealer that may have accumulated on the canal walls or pooled in the apex.

If obturating more than one canal in a single tooth, place sealer in all the canals at the same time. This facilitates removal of excess gutta-percha by preventing the gutta-percha from sticking to other orifices or dentin.

7. Heating GuttaCore Obturators in the Obturator Oven

For details on the obturator oven please refer to the ThermaPrep® 2 Obturator Oven Instruction Manual.

8. Placing Obturator in the Canal

After the first signal “beep” of the ThermaPrep® 2 Oven, the obturator is ready for use. Push the obturator holder and guide the holder with your finger. Take the obturator carefully out of the holder by first lifting it up and pulling it toward you. The oven will “beep” every 15 seconds to remind you that the obturator is still in the oven. After 90 seconds, the oven will switch off automatically. Insert GuttaCore Obturator directly into orifice of canal. Avoid touching the walls of the occlusal opening.

Note: If the canal has been properly shaped and the gutta-percha properly heated, the obturator should seat to place without twisting or forcing. To avoid overextension, don't force the GuttaCore® Obturator beyond the working length. You will note a backflow of sealer and gutta-percha resulting in an accumulation at the orifice. This is to be expected, especially in multirooted teeth, because the obturator is designed with excess gutta-percha to accommodate even the most widely flared or anatomically irregular canals.

9. Removing the GuttaCore Obturator Shaft and Handle

Remove the shaft and handle at the orifice by bending to either side of the canal wall. Alternatively, while stabilizing the GuttaCore Obturator with your index finger, use a round bur, or an inverted cone bur in a high-speed handpiece, or use a sharp spoon excavator. Dispose of obturators in an appropriate biohazard container.

10. Compacting Gutta-Percha in Large, Oval or Irregular Shaped Canals.

Insert a small segment of conventional gutta-percha, 4-6 mm long, alongside the shaft of the GuttaCore Obturator with a lubricated plugger and compact. The gutta-percha segment compacts the heat softened gutta-percha and

becomes an integral part of the filling. This will also prevent inadvertent removal of gutta-percha from the orifice with an inadequately lubricated plugger, as well as compensate for the lack of gutta-percha in uncommonly large canals or those with internal resorption defects. Due to the tacky nature of the plasticized gutta-percha, you must use a lubricant such as Glyde File Prep® root canal conditioner, sealer, topical anesthetic, etc., on the plugger.

11. Removing Excess Gutta-Percha

Using a spoon excavator, explorer, etc., remove any excess gutta-percha that may block access to the chamber and other canals. Repeat all of the above steps on each canal of a multi-rooted tooth.

If necessary, protect adjacent canal orifices from debris and guttapercha with tiny cotton pellets or a paper point until time for obturation. Clean the canal chamber and create an occlusal leakage barrier with a composite restorative.

12. Removing GuttaCore Obturation Materials

Creating post space and retreatting are accomplished using traditional methods for removing obturation material. For creating post space, remove the GuttaCore® Obturator by selecting either an appropriately sized post space instrument or Peeso Reamer. When removing the obturation material for retreatment purposes, use the same sized rotary file used for shaping and engage the obturation material (A non-landed rotary file is preferable). Take a radiograph to confirm the removal of all obturation material.

Use a hand file with solvent to soften the gutta-percha on the GuttaCore Obturator if retreatting and encountering intricate anatomy in the apical 1/3 of the canal.












13. Disinfection, Cleaning, and Sterilization

Disinfect the GuttaCore® Obturator in a 5.25 sodium hypochlorite solution (bleach) for one minute. Gently wipe the gutta-percha on the obturator with 70% alcohol. Do not use disinfecting solutions containing Phenol or any products which are not compatible with the treated filling material.

GuttaCore® Obturator is intended for Single use only.
Non sterilizable device.

Asepsis

Disinfect the obturator in a sodium hypochlorite solution (bleach) for one minute. Gently wipe the gutta-percha on the GuttaCore® Obturator with 2" X 2" gauze moistened with alcohol.

Symbols	EN
	Expiry date
	Manufacturer
	Consult Instructions for use
	Non sterilizable
	Single use only
	Batch number
	Gutta-Percha
	Keep away from sunlight and heat
	This product does not contain natural rubber latex
	The upper limit of temperature of use, storage and transportation
	Opened packages are not replaced

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