

Description:

TotalFill® BC Pellets, TotalFill®, TotalFill® BC, TotalFill® BC 150, TotalFill® ESR BC, and TotalFill® ES-SF BC Gutta Percha are non-resorbable, biocompatible root canal filler used to fill the root canal of a tooth after cleaning and shaping. TotalFill® Gutta Percha and Paper Points contain absorbent paper points used to dry the root canal before using the gutta percha.

Contraindications:

- There is a potential for patients sensitive to latex to have an allergic reaction to Gutta Percha.
- Use a rubber dam to avoid accidental swallowing or aspiration of Gutta Percha which contains barium sulfate and zinc oxide and could cause side effects in patients.
- Do not use Paper Points on patients that may be sensitive to any of its components.

Precautions:



Store below 37°C (99°F)



Keep out of direct sunlight



Single use only



Keep Dry



Do not use after the expiration date

- Closely follow the recommended storage conditions. Failure to do so will cause the Gutta Percha to prematurely harden resulting in procedural delays or requiring re-treatment to remove the Gutta Percha.
- Keep Gutta Percha dry to avoid bacteria growth making the Gutta Percha unusable.
- Gutta Percha and Paper Points cannot be cleaned or sterilized. Cleaning or sterilization may cause the device to become unusable.

Warnings:

- Ensure the canal is completely dried following use of Paper Points. Failure to properly dry the canal could lead to patient sensitivity or procedural delays.
- Do not apply excessive force during lateral condensation to prevent vertical fracture of root.
- Ensure proper site preparation to remove infected tissue/bone/dentin to prevent a biomaterial centered infection (BCI).
- Follow proper aseptic techniques to prevent contamination, which could result in a BCI.
- Ensure the Gutta Percha is not accidentally introduced into the maxillary sinus as this could cause foreign body inflammation or maxillary sinus Aspergillosis.
- Overextrusion of Gutta Percha may cause Parathesia or anesthesia of the alveolar nerve.

- Follow proper obturation techniques to avoid procedural accidents, which could result in persistent apical periodontitis infection.
- Ensure removal of the Paper Point or fibers from the root canal after use. Failure to do so can cause postendodontic periapical inflammation, exuberant granulation of tissue or periapical cysts.
- Do not use distorted or flimsy Paper Points as this could result in poor drying of the canal or procedural delays.
- Do not use bent or distorted Gutta Percha as this could cause procedural delays during placement.
- If the Gutta Percha will not sear at the orifice use an alternate technique to trim the Gutta Percha at the orifice to prevent procedural delays.
- If using a powered heat source (e.g. EndoPro 270) ensure that the temperature control is set correctly to ensure the Gutta Percha melts. An incorrect temperature setting can cause procedural delays or require re-treatment.
- Always check the expiration date of the product to prevent procedural delays or user inconvenience (e.g. Gutta Percha becomes brittle or hardens or Paper Points unroll).
- Carefully read package labeling to ensure use of the appropriate Gutta Percha or Paper Point. Failure to do so may cause procedural delays.

Indications for Use:

Cold Lateral Condensation Technique:

Cold Lateral Condensation is the most popular obturation method used throughout the world.

The following steps summarize this obturation technique:

1. Select the paper point that best matches the last instrument used to shape the canal.
2. Dry the canal by gently inserting paper points to the final working length (apex).
3. Deliver a thin layer of sealer into the canal using any delivery method.
 - a. Instruments used to deliver the sealer include small hand files, paste fillers, gutta percha points and paper points.
 - b. The gutta percha cone itself can also be coated and inserted into the canal for delivery of the sealer.

Note: The layer of sealer should be thin. The goal is to take up as much space in the canal with the dimensionally stable/inert gutta percha and leave only a thin layer of sealer. Sealers typically shrink due to the setting reaction. The most desirable sealer is one that does not shrink.

4. Select the gutta percha that best matches the last instrument used to shape the canal. Slowly insert the gutta percha point to the final working length.
5. Always attempt to insert accessory cones into the canal alongside the master gutta percha cone.
6. Sear off the gutta percha at the orifice and vertically compact as desired.
7. Cap the canal with a restorative material and complete the restoration so your coronal seal is not compromised.

Warm Vertical Condensation Technique:

The following steps summarize this obturation technique:

1. Select the paper point that best matches the last instrument used to shape the canal.
2. Dry the canal by gently inserting paper points to the final working length (apex).
3. Select the master cone corresponding to the canal taper and size of the apical foramen. Adjust for tugback by removing 0.5mm increments from the working length.
4. Select the largest heat plugger that will go to within 5mm of the working length without binding but no closer than 3mm. Confirm and set working length with rubber stopper.
5. Lightly coat the dry canal walls with sealer short of the apical third. Coat the apical third of the fitted master cone with sealer and place into the canal.
6. Sear off excess master cone at the orifice level. Use the larger end of a stainless steel plugger and lightly compact the softened gutta percha at the orifice.
7. Activate and drive the pre-measured heat plugger to within 5mm of the working length, release heat and continue to apply apical pressure for approximately 5-10 seconds. This will minimize the shrinkage of the filling material.
8. Apply a short, 1 second separation burst of heat and withdraw the heat plugger. Select a small hand plugger and gently compact the remaining gutta percha into the apical portion of the canal.
9. At this point, confirm apical obturation radiographically. If you need a post space created you are already done, otherwise, the canal is prepared for backfilling with the warm gutta percha delivery system.
10. Place the warmed applicator needle in the canal and allow the tip to heat the apical plug of gutta percha for approximately 2-5 seconds.
11. Pull the trigger and let the pressure of the gutta percha being extruded push you out of the canal. Do not apply apical pressure and do not pull the needle out of the canal.

Note: In small canals, the expression of gutta percha can be completed in one step, however in larger canals, it is recommended that you express in 3-5mm increments coronally until you reach the canal orifice.

12. Select the flat, larger stainless steel end of a hand plugger and compact the gutta percha to reduce any shrinkage that may occur during cooling, and verify the obturation radiographically.

Note: You may choose to repeat steps 1-3 until the canal is sufficiently filled or enough to create a post space



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Glossary of Symbols

Symbol	Meaning	Standard
	Catalogue Number	ISO 15223-1
	Use-by date	ISO 15223-1
	Batch Code	ISO 15223-1
	Quantity	N/A
	Consult instructions for use	ISO 15223-1
	Caution	ISO 15223-1
	Non-sterile	ISO 15223-1
Rx Only	Caution: Federal law restricts this device 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 device.	FDA 21 CFR Part 801.109 (b)(1)
	Do not re-use	ISO 15223-1
	Keep Dry	ISO 15223-1
	Temperature limit (Max – Min)	ISO 15223-1
	Keep away from sunlight	ISO 15223-1
	Manufacturer/Legal Manufacturer	ISO 15223-1



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