Soft-Core®
Endodontic Obturator

MANUAL

English
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Classification
The Soft-Core® Endodontic Obturator is a medical device; class IIA, in compliance with MDD (Medical Devices Directive) section IX. The obturators must only be used by dentists.

*Read and follow the instructions carefully!*

General precautions

Please note that:

- The product should only be used by dentists.

- The product should only be used for root canal procedures in teeth.

- A deformed or defective product should never be used, but should be discarded.

- The manufacturer disclaims all responsibility and liability for injury or damage to persons or property caused by faulty and/or inappropriate use. For information on the correct use of the product, please see the step-by-step guide, section 2.

- The product should be stored in the original packing.

Warning - obturator

- After heating, the gutta percha is hot. Avoid any direct contact between the obturator and skin or mucous membranes. The obturator should be inserted directly into the root canal.

- It is always recommended to take a control x-ray. If the x-ray is not satisfactory, take another x-ray from a different angle. If the filling still cannot be satisfactorily documented, remove the obturator.
1. Description of the Soft-Core® Endodontic Obturator

A Soft-Core® Endodontic Obturator is a core of biocompatible plastic, sized according to ISO standards sizes 20 to 100, coated with thermoplastic gutta percha. The obturator sizes correspond to the ISO standards of root canal files. A single obturator is all that is needed to totally obturate a root canal. The result will always be a perfectly placed root canal filling with a tight apical seal.

A Soft-Core® Endodontic Obturator consists of three parts:

1. Plastic handle with a metal insertion pin
   The injection molded plastic handle is color-coded according to the size of the obturator. The stainless steel insertion pin is 9 mm long, and is permanently attached to the plastic handle. The hollow portion of the plastic core surrounds 6 mm of the pin.

2. Outer layer of thermoplastic Natural GP™ gutta percha
   The gutta percha is reversible thermoplastic. This means that it becomes soft and highly adhesive when heated to temperatures above approx. 100°C. When cooled, it returns to a firm, rigid state. Another heating will once again make the gutta percha soft and adhesive.

3. Plastic core with endo stop
   The tapered plastic core is sufficiently flexible to negotiate curved canals.

   The Soft-Core® plastic core is slightly oval-shaped. This secures adequate backflow of the heated gutta percha. The length of the core is 24 mm. The coronal 6 mm of the core is hollow to accommodate the metal insertion pin. A rubber endo stop is provided to indicate the working distance measurement. The plastic core and gutta percha are radiopaque.


Before using the Soft-Core® Endodontic Obturator, assure that you have achieved the following:
A. A properly cleaned and shaped canal – the key to any successful root canal filling. Utilize any technique which provides a smooth tapered form, and provides you with a coronal opening wide enough to give room for the instruments.

B. A dry root canal.

C. An established working length. The plastic core is flexible enough to negotiate curved canals. It is highly advised that rotary files with a higher conicity are utilized to create a sufficient taper for the obturator core. When using files with a conicity of .02, it is advised to combine them with a procedure using Gates Glidden Drills or other files which can be used to create a sufficient opening in the coronal part of the canal. The use of size verifiers is recommended.

**STEP 1: Determine the working length and choose the proper obturator size**
The working length is measured all the way to the apex. We recommend measuring the working length from the edge of the cusp. The working length can advantageously be measured by use of both x-ray, file and electronic apex locator. Generally, the appropriate size Soft-Core® Endodontic Obturator will be the same size as the last file used at the apex of the canal. TIP: For very narrow and/or highly calcified canals, it may be useful to select one size smaller than the last file used at apex. If you do not use rotary files with a taper of 4 % or more, you should always verify the size of the cleaned root canal with a size verifier before inserting the obturator.

**Mark your working length on your Soft-Core® obturator**
When the size verifier has a slightly loose fit in the apical third, the rubber stop is placed at the working length. Afterwards, the working length is transferred to the obturator.

**STEP 2: Heating of the obturator**
Place the selected obturator in the Soft-Core® oven and activate it. For more information on how to use the oven, please consult the applying oven manual.

**STEP 3: Application of sealer**
While the obturator is heating, mix any heat resistant sealer (usually a non-eugenol sealer) with long working time. Make sure that the root canal is completely dry, before applying sealer.

Place a very thin coating of sealer on the wall of the canal. Too much sealer is neither desirable nor necessary. Utilize a paper point or a Soft-Core® Size...
Verifier to apply a thin layer of sealer on the canal walls. When obturating more canals, apply sealer in all canals at once.

**STEP 4: Insertion of the obturator into the canal**  
When the oven indicates that the obturator is ready for use, the obturator is removed from the oven. For further information on how the oven works, please consult the applying oven manual. Without twisting the handle, immediately insert the obturator into the canal to the working distance using a firm and steady pressure.

**STEP 5: Removal of excess central core and gutta percha**  
When the gutta percha has hardened (after 3-4 min.) remove the handle in one of two ways.

1. Twist the handle and plastic core to one side to break off the excess.

2. Stabilize the plastic core with a finger, and cut away the handle and excess plastic core with a small inverted cone bur.

Be careful to prevent vertical movement of the core to minimize the chance of disturbing the apical seal. Trim away the extra gutta percha using an endo excavator or simular.

**STEP 6: Confirming radiograph**  
Confirm your root canal treatment by taking radiographs.

### 3. Technique tips

It is very easy to use the Soft-Core® system. Feed-back from experienced Soft-Core, however will hopefully make it even easier for you to get started:

**Obturating multi-rooted cases**  
There will almost always be more than enough gutta percha on each obturator. When obturating the canal, the gutta percha and sealer will therefore be transported to the coronal part of the tooth, and in this way block the opening. Especially in multi-rooted cases, this will be an inconvenience; however, you can avoid it:

1. Obtrurate the shortest canal first.
2. Place paper points or size verifiers in the other canals prior to obturation to prevent them being covered by gutta percha. Remove them as each canal is obturated.

3. While there is sufficient gutta percha on each obturator to fill even the most severe internally resorbed canal, it may be too much in some cases. If it is obvious that there will be an excess of gutta percha for the canal, use a sharp blade to trim some of the material from the coronal end of the central core prior to heating.

Applying sealer
As with any other root filling technique, when using the Soft-Core® system, always apply sealer in the canal first. However, there is a significant different; when using Soft-Core® only apply a very small amount. We recommend that you apply the sealer in the root canal using a size verifier or a paper point. A root spiral should not be utilized when using obturators, as there is a tendency to add to much sealer to the canal. Remember; only apply a very thin layer of sealer on the canal walls.

4. Post space preparation

Post space creation is accomplished by removing the coronal portion of the obturation. Since the coronal 6 mm of the plastic core is hollow, this procedure should be easier with the Soft-Core® Endodontic Obturator than with other obturation systems.

Core Remover
The Soft-Core® Core Remover is a tapered, pointed, non-cutting instrument. The Core Remover is developed specifically to ensure safe and fast removal of the plastic core and gutta percha in the coronal portion of the canal.

The Core Remover is manufactured in two lengths - 25 and 30 mm. Each package contains 6 pieces, and is available in three different packages: 6 pcs. of either 25 or 30 mm, or 3 pcs. of each length. Core Remover burs can be autoclaved.

Using Core Remover:

1. The Core Remover should be used in a high-speed hand piece with or without water coolant.

2. Choose the Core Remover length most suitable for the canal. Place the tip in the center of the hollow core. Activate the high-speed hand piece at
full speed, and drill out the desired depth of the obturator core, using an intermittently pulsing technique. Start the bur - press it down - stop - pull the bur back etc., in this way the Core Remover melts and removes the plastic core. You could start this procedure by making a center mark with a small cone bur.

The Core Remover burs should only be used in the top coronal part of the filling till just below the canal opening. When using the Core Remover bur, the obturator core and gutta percha will, due to the friction heat, melt and be coiled out of the canal. However, the plastic core will only melt to the point where the Core Remover is placed.

3. When the desired depth has been reached using the Core Remover, use your usual post space bur. Choose a bur dimension that fits the post system and complete the post preparation.

Other cutting burs may be used, but care should be taken to prevent perforation or displacement of the apical portion of the obturator core.

5. Retreatment of an obturated root canal

Removal of the obturator is relatively simple prior to the gutta percha cooling. Simply grasp the excess core with cotton pliers and remove it. Once the gutta percha has cooled, or for retreatment at a later appointment, removal is easiest achieved by using a Peeso bur, Gates, Profile or similar.

1. Place the bur between the canal wall and the plastic core, so that the rotational direction will be counter clockwise. Use the instrument at very low speeds (250-400 rpm), and work slowly until you feel resistance. The instrument will grasp between the plastic core and the canal wall. The plastic core will be coiled out of the canal after a short time.

2. If necessary, a small dimension hand file can be worked down apically along the plastic core.

3. When the plastic core has been pulled out of the canal, the gutta percha is removed by traditional means.

6. Soft-Core® packaging

Soft-Core® Regular is packed individually in a sealed plastic box. One box consists of 2 x 6-pcs. boxes, each having its own label, making it possible to
divide the boxes into two separate identical boxes if needed. The Soft-Core® Size Verifier is packed in the same way. All products are gamma irradiated after packaging.

7. Labeling

⚠️ See instruction manual

⚠️ Single use

⚠️ Expiry date

⚠️ Lot number

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8. Your Soft-Core® distributor

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