DENSPLY

Densfil® Thermal Endodontic Obturation System

Manufactured for: DENTSPLY Maillefer DENTSPLY International, Inc. 608 Rolling Hills Drive Johnson City, TN 37604 1-800-924-7393 1-800-924-7399 (fax) www.maillefer.dentsply.com This product contains dry natural rubber.





Rx only

For Dental Use Only

Caution: U.S. federal law restricts this material to the sale by, or on the order of a dentist.

Indications for Use:

For the permanent obturation of root canals of teeth of the secondary dentition in combination with root canal points.

Contraindications:

Hypersensitivity against epoxy resins, amines or other components of the root canal filling material.

Warnings:

- AH Plus® Jet™ contains epoxy resins (paste A) and amines (paste B) which may
 cause sensitization in susceptible persons.
- Avoid eve contact with AH Plus Jet to prevent irritation and possible corneal damage.
- Avoid skin contact with AH Plus Jet to prevent irritation and possible allergic response.
- · Avoid contact of AH Plus Jet with oral soft tissues/mucosa to prevent inflammation.
- . Do not swallow AH Plus Jet or take internally.
- Avoid overfilling the canal with AH Plus Jet.
- · Densfil Thermal Obturators contain dry natural rubber.
- . To prevent fire or electric shock, do not expose the oven to moisture.
 - Do not remove the cover of the oven.
- · Turn off oven and unplug when not in use.
- . This oven is designed for use in a dental office. Do not use in any other environment.

Precautions:

- · When obturating the canal, choose the appropriate size obturator.
- AH Plus Jet is intended to be used only as specifically outlined in the Directions for Use. Any use of AH Plus Jet inconsistent with the directions for use is at the discretion and sole responsibility of the dental practitioner.
- When using AH Plus Jet, wear protective glasses, mask, clothing and gloves. Protective glasses are recommended for patients.
- Under certain storage conditions, AH Plus Paste B may slightly separate. It has been shown that this process does not negatively affect the performance of the mixed product.
- To reduce the risk of electric shock, do not remove oven cover; there are no user-serviceable parts inside.
- The oven is intended for use in heating gutta-percha coated obturators only.
 Do not insert anything other than an obturator into the oven.
- . Turn off and unplug the oven when it is not in use.

Adverse Reactions:

- Patients with latex sensitivity may experience allergic reactions to gutta-percha, which contains dry natural rubber.
- 2. AH Plus Jet may cause allergic contact dermatitis

Step-By-Step Instructions:

Thorough debridement, cleansing and shaping are important to the success of the following techniques and should be completed prior to beginning the application. If you have questions concerning any of the steps described in this technique, please call our Technical Service Department at 1-800-924-7393.

1. Preheat your DensHeat® Oven II.

- Plug the oven into a 110 VAC outlet. Then turn the oven on with the power on/off switch located on the back. The green LED indicator will tell you when the oven is ready for use. If you are utilizing plastic carriers, you must use the oven.
 The DensHeat Oven II is also an ideal controlled heating environment and is recommended for titanium carriers.
- Put both obturator holders in the upper position by pressing the back of the holder (arrow up) and guiding the holder up with your finger.

3. Anesthetize the selected tooth.

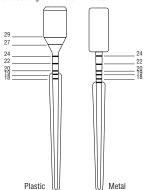
 To avoid any discomfort from apical pressure when you insert the obturator, first administer anesthesia and allow it to act. This will prevent the patient from flinching.

4. Measure the length of the prepared canal.

 Use the largest file that reaches the apical constriction without marked resistance or twisting. Confirm your measurements by taking x-rays from two angles.

5. Choose your obturator.

- The selected obturator size should match the size of the file used in Step #3 above.
 - Small plastic carriers (in graduated sizes #25, #30, #35) are specially tapered.
- All Densfil carriers are pre-calibrated for your convenience. Use the Densfil carrier
 calibrations to adjust the rubber stop for proper working length. Using the
 calibrations on the Densfil carrier, adjust the rubber stop to coincide with the
 working distance length taken from the tooth.



Special Note:

- The calibration rings MUST be used to set the working length distance on the
 Densfil carrier. Working length based upon a measurement from the tip of the
 gutta-percha will be incorrect. Calibrations are set at the following working lengths
 (in millimeters): 18, 19, 20, 22, 24 plus 27 & 29 on the plastic handles. If gutta-percha
 covers the needed measurement ring, trim away the excess with a scalpel blade.
- Accurate working length measurements can only be taken from the calibration rings.
 Use a scalpel blade to trim any gutta-percha covering the necessary measurement right.
- Generally, pre-curving is not necessary when using plastic carriers or titanium carriers smaller than size #35.

6. Disinfect your obturator.

 Use a 5.25% sodium hypochlorite solution, then rinse in 70% alcohol and dry for several seconds

After disinfecting the obturator and setting the rubber stop, place the Densfil Obturator in the left obturator holder.

- Regardless of what working length you have determined, the rubber stop must be under the holder.
- Make sure the obturator is hanging straight, not at an angle. The obturator must clear all sides of the heating chamber.

8. Push the holder down (arrow down) until you hear it click.

9. Push the button which corresponds to the size of the Densfil Obturator you wish to heat.

Then push the "start left" button. The obturator is now being heated.

The heating time varies depending on obturator size and is regulated automatically.

The heating times for each button are as follows:

SIZE	SIGNAL TIME	TOLERANCE
#20 - #25	20 seconds	± 5 seconds
#30 - #60	41 seconds	± 7 seconds
#70 - #140	45 seconds	± 8 seconds

10. Completely dry the canal.

· Dry the canal with sterile paper points.

11. After the first signal "beep," the obturator is ready for use.

Push the obturator holder (arrow up) and guide the holder with your finger. Take
the obturator carefully out of the holder by pulling it toward you, making sure not
to scrape the obturator on any part of the holder.

12. You may leave the obturator in the DensHeat Oven II for up to 90 seconds after the first signal "beep."

- The obturator will remain at the appropriate temperature and ready for use.
- The oven will "beep" every 15 seconds to remind you that the obturator is still in the oven.
- . After 90 seconds, the heating element will switch off automatically.

13. Turn the oven off after you've removed the obturator.

- As an extra safety precaution, switch off the heating element by pushing the start left button again.
- Keep in mind that you won't be able to switch the heating element off during the heating cycle.

14. If you want to heat more obturators, you may alternate using the left and right holders to continue your work efficiently.

- Wait until after the signal "beeps" for the first holder, and then you may immediately start to heat the other one.
- You will be unable to heat both sides at the same time.

15. Using AH Plus Jet Mixing Syringe

- The Jet Mixing Syringe allows direct application of the sealer into the root canal orifices and into the coronal parts of the canals.
 - i. Remove the cap by turning it 90° counter-clockwise and pulling it.
- Note: For AH Plus Jet Mixing Syringe, the syringe filling volumes of pastes A and B vary slightly. To ensure appropriate mixing, bleed the syringe prior to the first use.
 ii. Attach the mixing tip to the syringe, aligning the notch.
 - iii. Turn the tip 90° clockwise and secure the mixing tip in place.
- The intra-oral tip can be rotated and adjusted in angle in order to meet individual
 anatomic conditions and treatment requirements. Use of a DisposaShield®
 Barrier Sheath is recommended for intra-oral use. For application of the sealer,
 carefully apply steady pressure on to the plunger. The two pastes are automatically
 mixed in equal volume units.
- Having finished the sealer application, the mixing tip must be discarded. Remove the mixing tip by turning it 90° counter-clockwise and pulling it. Replace the cap on the syringe head, aligning the notch, then turn it 90° clockwise.
- · Working Time
 - i. The working time is 4 hours at 23°C
- Setting Time
- i. The setting time is 8 hours at 37°C.

16. Completely obturate the canal.

- Carefully remove the Densfil obturator from the DensHeat Oven II and insert it into the prepared canal to the working length. Excess gutta-percha may accumulate at the orifice.
- · Do not over-extend your obturator, because it could penetrate the apex.
- Note: You have approximately 6 to 8 seconds after removing the fully heated obturator from the oven to position it in the canal.

17. Sever the shaft and remove the handle.

- · Plastic and titanium carriers must be stabilized before removal of shaft and handle.
- · When using a plastic carrier:
 - Sever the shaft level with orifice by using a round or sharp inverted cone bur or a hot (not flame-heated) instrument.
- · When using a titanium carrier:
- i. Sever the shaft with a sharp #37 inverted cone bur 1-2.0mm above the orifice.

If access is difficult, pre-notch the titanium shaft 2.0mm above the orifice, then sever the shaft with a fissure-type bur.

18. Compact the thermally plasticized gutta-percha.

Coat the tip of an endodontic plugger with a lubricant such as Vaseline®, topical
anesthetic or alcohol before compacting the gutta-percha. If using Vaseline® or
topical anesthetic, first smooth the coating by passing the plugger tip through a flame.

19. Be sure the chamber is free of excess gutta-percha.

 Use an endo excavator or caries spoon to remove excess gutta-percha so that it does not block access to the chamber of other canals.

20. Temporize or restore

For a multi-rooted tooth, repeat the appropriate steps for each canal. Adjacent
canal orifices should be protected from debris and gutta-percha with paper
points until time for obturation. When obturations are completed and excess
gutta-percha removed, prepare a base for the orifices and chamber floor.
 Temporize or restore, then perform a post-op x-ray.

Cleaning, Disinfection and Sterilization:

To prevent AH Plus Jet Mixing Syringe from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended to avoid package contamination. Repeated disinfection may damage label. Spatulas, mixing slabs and instruments should be cleaned immediately after use with alcohol or acetone.

Dispose all products in accordance with the local regulations.

Clean oven after each use. Any gutta-percha remaining on the holder or in the heating chamber may be effectively removed with Orange Solvent (generic dental solvent) on a cotton pledget.

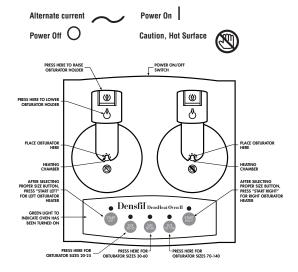
Technical Specifications

Voltage rating: 110 VAC, 50/60 Hertz, range of the supply voltage +/- 10%, Fuse 2 Amps Slow.

Lot Number and Expiration Date (AH Plus Jet)

- 1. Do not use after expiration date. ISO standard is used: "YYYY/MM".
- 2. The following numbers should be quoted in all correspondence:
- Reorder Number
 - · Lot Number
 - · Expiration Date

EXPLANATION OF MARKING SYMBOLS



DENTSPLY Int'l Inc. Made in U.S.A. Manufactured under U.S. Patents # 5,089,183; 5,098,298; 5,118,297; 5,149,268; 5,088,927; 5,624,976 and other U.S. and foreign patents pending. DENSIFU 02/09