

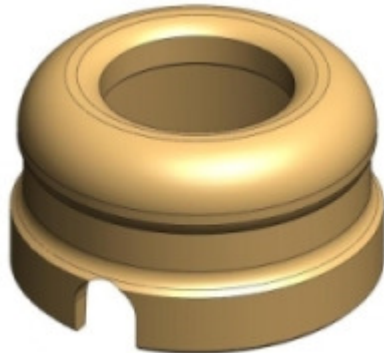


LOCATOR RETROFIT FOR ERA® ROOT ATTACHMENT

Universal hinge, resilient attachment converts worn or damaged standard sized ERA® attachments to new LOCATOR attachment for endodontically treated roots.

#1747 Retrofit Kit includes 2 females, 2 parallel posts, and 2 alignment pins

Locator Retrofit Female



Male Processing Package 8519 or 8540

Parallel Post



Analogue 8516

Weep Hole Alignment Pin



Locator Core Tool 8393



INDICATIONS

The LOCATOR Retrofit for ERA® Root Attachment is designed for use with overdentures or partial dentures, retained in whole or in part, by endodontically treated roots in the mandible or maxilla.

CONTRAINDICATIONS

Not appropriate for Micro sized ERA® attachments or where a totally rigid connection is required.

CAUTION:

Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed dentist.

SINGLE - USE DEVICES

Locator Males: The inadvertent re-use of Locator nylon males could cause loss of retention for the overdenture due to wear from previous use or damage during removal with the Locator Core Tool.

Locator Retrofit Females: The removal of a cemented Locator Retrofit Female post could fracture the patient's root. The inadvertent re-use of a female could contain patient contamination buildup and subsequent wear of the retention bands. This would result in the device to perform with improper fit and function which would result in loss of retention for the prosthesis.

STERILIZATION

All components and instruments are supplied NON-STERILE.

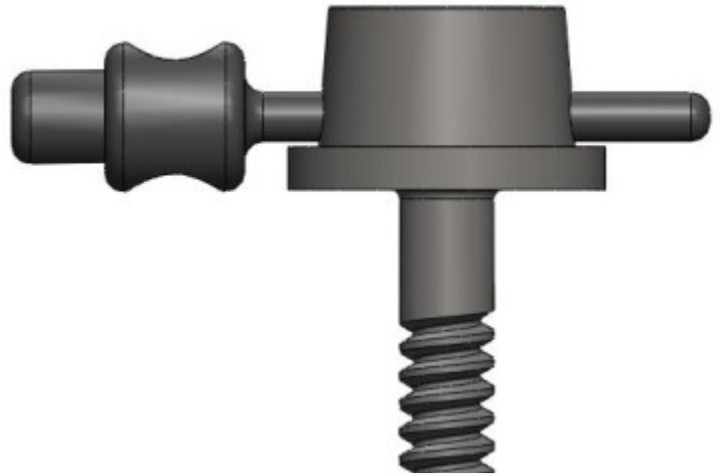
Locator Core Tools (in the disassembled state only) may be sterilized by Autoclave or Dry Heat sterilization using the following parameters:

1. Autoclave sterilize using 121° C (250° F), (15-20 psig at sea level), for 40 minutes minimum.
2. Dry Heat sterilize using 170° C (338° F), for 2 hours minimum.

A. PLACEMENT OF THE LOCATOR RETROFIT FEMALE

1. Place the Weep Hole Alignment Pin (contained in Locator Retrofit Kit #1747) through the two weep holes on the ERA Attachment.

NOTE: The special Weep Hole Alignment Pin is used to align the combined weep holes of the Locator Retrofit Female and the ERA Female, allowing saliva to escape from the socket. The white delrin Weep Hole Alignment Pin comes with a hole in the pin for dental floss. This allows the dentist to have a way to keep this small part from becoming dropped and/or lost and to assist in removal of the pin after cementation.



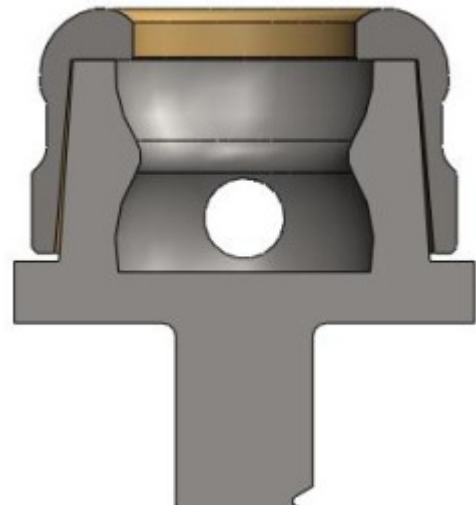
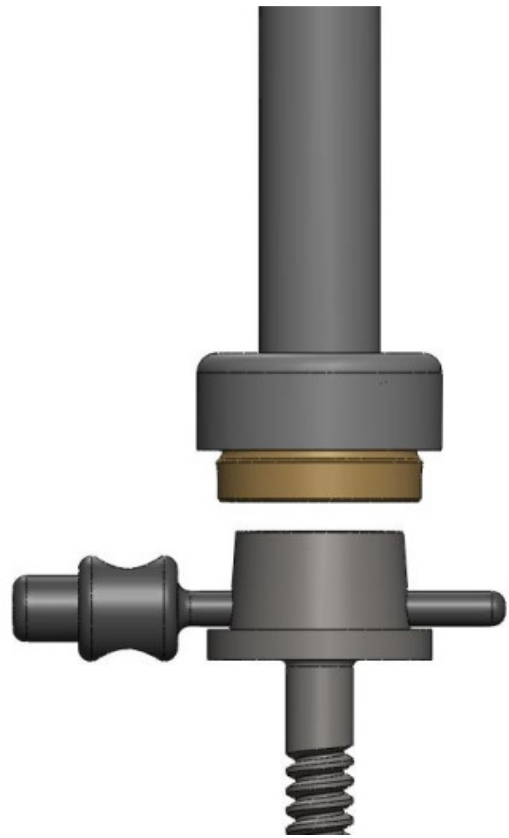
2. Using a Black Parallel Post (contained in Locator Retrofit Kit #1747) as a handle, place a Locator Retrofit Female onto the ERA Attachment to visually approve the proper fit. Make sure the slots on the Locator align with the Weep Hole Alignment Pin.

3. Cement the Locator Retrofit Female in place using crown cement. Apply the cement around the entire circumference of the ERA Attachment. Make sure that the slots on the Locator Retrofit Female line up with the Weep Hole Alignment Pin shaft which has been inserted into the ERA Attachment. Also make sure that the Locator Retrofit Female is fully seated on top of the ERA Attachment.

4. Pull the Weep Hole Alignment Pin out of the assembly using the floss before the cement has fully hardened. Allow the cement to harden somewhat before removing the parallel post as the retention may dislodge the Locator.

5. The bonded Locator Retrofit Female as seen in this sectional view should be tightly seated on the top of the ERA.

Note the small gap at the bottom of the assembly allowing cement to come out around the base. The gap is designed to ensure that the Locator Retrofit Female bottoms out on top of the ERA and not on the base.



B. LOCATOR DENTURE CAP MALE PLACEMENT BY THE DENTIST

1. Cementing of the Locator Retrofit Females and the removal of the entire ERA denture components must be completed before beginning the procedure for the placement of the Locator Denture Cap Processing Male Assembly into the overdenture.

2. Place the White Block-Out Spacer around each cemented Locator Retrofit Female. The spacer is used to block out the remaining exposed surfaces of the root, so that when the denture acrylic is added and cured, it will not come in contact with the root. The space created between the root and the denture base will allow the full resilient function of the pivoting metal denture cap over the Locator Nylon male.



3. Insert a Locator Denture Cap Processing Male Assembly into each cemented Locator Retrofit Female, leaving the White Block-Out Spacer beneath it. The Black Processing Male will maintain the overdenture in the upper limit of its vertical resiliency during the processing procedure.

4. Prepare a recess in the denture to accommodate the denture cap male. There must be no contact between the denture and the titanium cap male. If the denture rests on the metal cap, excess pressure on the root will be the result.



5. Use lightcure acrylic to cure the metal cap into the denture, or use self-curing acrylic and place a small amount in the recess of the denture and around the metal cap of the Processing Male. A lingual escape vent is always recommended.

6. Insert the denture into position in the oral cavity. Guide the patient into occlusion, maintaining a proper relationship with the opposing arch. Maintain the denture in a passive condition, without compression of the soft tissue while the acrylic sets. Excessive occlusal pressure during the setting time may cause tissue recoil against the denture base and could contribute to dislodging and wear of the nylon males.

7. After the acrylic resin has cured, remove the denture and discard the White Block-Out Spacer. Use a bur to remove excess acrylic and polish the denture base before changing to the final male.

8. Use the Locator Male Removal Tool to remove the Black Processing Male from the metal denture cap. The sharp circular edge on the end of the removal tool should be wedged tightly down into the very bottom of the male so that it will catch the inside of the male to pull it at an angle out of the metal housing. To discard the male from the tip on the Core Tool, point the tool down and away from you and tighten the Male Removal Tool clockwise back onto the Core Tool. This will activate the removal pin and dislodge the nylon male from the tip end of the Male Removal Tool.

9. The Locator Male Seating Tool is used to firmly push a Locator Replacement Male into the empty metal denture cap. The replacement male must seat securely into place, level with the rim of the cap. Selection of the nylon replacement male (clear, pink or blue) depends on the appropriate patient's requirement for retention.

NOTE: When using of multiple Locator attachments (3 or more) in the same dental arch, use the Extended Range Males--Green (3.5lbs) #8547, Orange (2.0lbs) #8915, and Red (.05lbs) #8548--for easier removal of the prosthesis by the patient.

NOTE: The Replacement Male will not stay on the tool when it is turned upside down due to the varying sizes of males available. It is best to hold the denture with the base side down and snap the male into the metal denture cap.

10. Instruct the patient in the path of insertion. Have the patient insert and remove the appliance several times.

C. LOCATOR DENTURE CAP MALE PLACEMENT BY THE LABORATORY

In the Operatory:

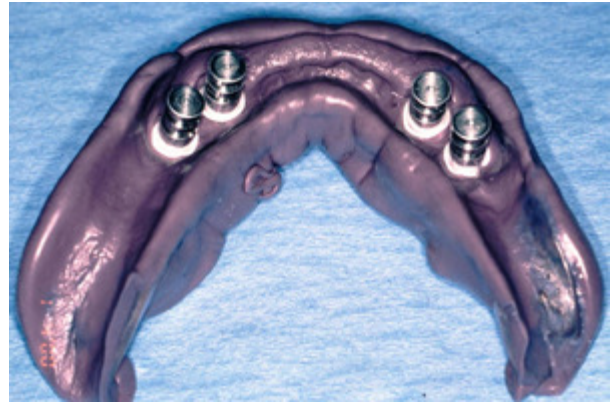
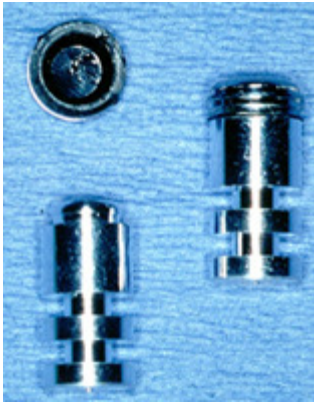
1. Cementing of the Locator Retrofit Females and removal of the entire ERA denture component must be completed before beginning the procedure for placement of the Locator Denture Cap Processing Male Assembly into the overdenture.



2. Insert a Cap Male onto the cemented Locator Retrofit Female. The built-in spacer of the Black Processing Male will maintain the overdenture in its upper limit of vertical resiliency during the processing procedure.

3. Take an impression using a firm body impression material, exercising caution not to compress the soft tissue. When the impression is withdrawn, the Cap Male will remain on the cemented Locator Retrofit Females.

4. Remove the Cap Male from each Locator Retrofit Female and snap it onto a Female Analog #8516. Reposition this assembly back into the impression making sure it is fully seated.

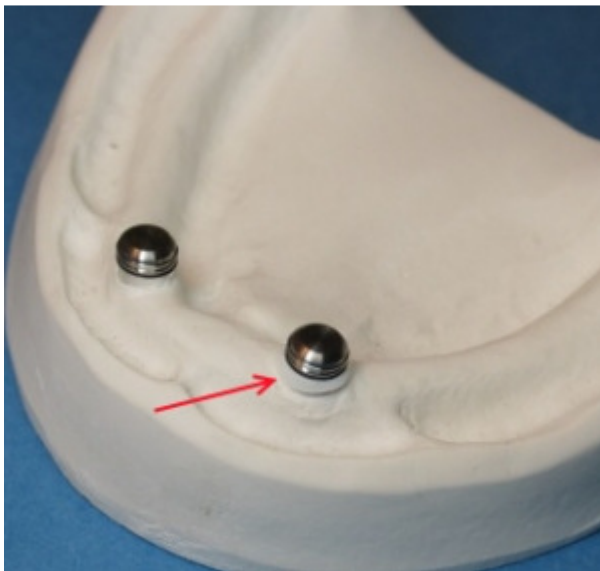


In the Laboratory



5. Pour the master cast. Upon separation, the Analog is a part of the master cast replicating the position of the cemented Locator Retrofit Female in the oral cavity.

6. Before waxing and processing the appliance place a Cap Male into each Analog in the master cast. Make sure the male is fully seated.



7. Set the teeth and wax the appliance. Proceed with the processing technique of your choice through the boil-out step.

8. After the boil-out remove the Cap Male. Place a **White Block-Out Spacer** around each Female Analog. The spacer is used to block out the remaining exposed surfaces of the root, so that the processed acrylic will not come in contact with the root. The space created between the root and the denture base will allow the full resilient function of the pivoting metal denture cap over the nylon male.

9. Re-insert the Cap Male onto each Female Analog, leaving the White Block-Out Spacer beneath it. The Black Processing Male will maintain the overdenture in the upper limit of its vertical resiliency during the processing

procedure.

10. Complete the processing and discard the White Block-Out Spacer. Polish the denture base before changing the replacement nylon male.

11. Use the Male Removal Tool to remove the Black Processing Male from the metal denture cap. The sharp circular edge on the end of the removal tool should be wedged tightly down into the very bottom of the male so that it will catch the inside of the male to pull it at an angle out of the metal housing.

12. The Male Seating Tool is used to firmly push a Replacement Male into the empty metal denture cap. The replacement male must seat securely into place, level with the rim of the cap. Selection of the nylon replacement male (clear, pink or blue; red, orange, or green) depends on the appropriate patient's requirement for retention.

NOTE: When using of multiple Locator attachments (3 or more) in the same dental arch, use the Extended Range Males--Green (3.5lbs) #8547, Orange (2.0lbs) #8915, and Red (.05lbs) #8548--for easier removal of the prosthesis by the patient.

NOTE: The Replacement Male will not stay on the tool when it is turned upside down due to the varying sizes of males available. It is best to hold the denture with the base side down and snap the male into the metal denture cap.

D. HOW TO CHANGE THE LOCATOR MALE

1. The Core Tool contains a Male Removal Tool and Male Seating Tool. It is used to remove the nylon male from the metal denture cap and replace it with another Locator Replacement Male.

2. Use the Male Removal Tool attached to the Core Tool to remove the nylon male from the metal denture cap. The sharp circular edge on the end of the removal tool should be wedged tightly down into the very bottom of the male so that it will catch the inside of the male to pull it at an angle out of the metal housing. To discard the nylon male from the tip on the Core Tool, point the tool down and away from you and tighten the Male Removal Tool clockwise back onto the Core Tool. This will activate the removal pin and dislodge the nylon male from the tip end of the Male Removal Tool.

3. The Male Seating Tool is used to firmly push a Replacement Male into the empty metal denture cap. The replacement male must seat securely into place, level with the rim of the cap. Selection of the nylon replacement male (clear, pink or blue; red, orange, or green) depends on the appropriate patient's requirement for replacement.

NOTE: When using of multiple Locator attachments (3 or more) in the same dental arch, use the Extended Range Males--Green (3.5lbs) #8547, Orange (2.0lbs) #8915, and Red (.05lbs) #8548--for easier removal of the prosthesis by the patient.

NOTE: The Replacement Male will not stay on the tool when it is turned upside down due to the varying sizes of males available. It is best to hold the denture with the base side down and snap the male into the metal denture cap.

E. RELINE AND REBASE

1. Remove each existing nylon male from its metal denture cap following the steps in HOW TO CHANGE THE LOCATOR MALE (Section D). Replace them with Black Processing Males. The built-in spacer of the Black Processing Male will maintain the overdenture in its upper level of vertical resiliency during the reline process.

2. Take a reline impression using the existing overdenture as a tray.

3. The Black Processing Males will engage the Locator Retrofit Females and hold the prosthesis in place while the impression material sets. When the impression is withdrawn, the Black Processing Replacement Males will remain in

the metal denture caps.

4. Snap a Female Analog into each Cap Male in the impression and pour a master model.

5. After processing the reline and polishing the denture base, replace the Black Processing Males with the Nylon Replacement Males.

PATIENT CARE

Good oral hygiene by the patient is vital to attachment success. The Locator Retrofit Females must be thoroughly cleaned each day to prevent wear due to a buildup of abrasive plaque in the socket of the attachment. The use of a soft nylon bristle or end-tufted toothbrush and non-abrasive gel toothpaste to clean the attachment should be taught. An irrigation system is recommended to keep the socket of the Locator Retrofit Female clean.

Patients should maintain a three to four month recall for cleaning and attachment evaluation. The inside of the Locator Retrofit Female and the sulcus area around the attachment are the primary areas of concern. Use plastic instruments for scaling the attachment. Do not use metal instruments that may create scratches on the attachment surface. Examine the cemented Locator Retrofit Female to verify that it is still securely fastened before dismissal of the patient.