LOCATOR® IMPLANT ATTACHMENT SYSTEM

IMPORTANT: This document contains the most current instructions for use. Please, read and retain.

DESCRIPTION: Universal hinge, resilient attachment for endosseous implants.

ATTACHMENT COMPONENT ORDER NUMBERS
Product numbers of Locator Implant Abutments vary with implant type, implant diameter, and tissue cuff height. It is necessary to have this information available to place your order.

PARTS IDENTIFICATION

<table>
<thead>
<tr>
<th>Implant Abutment</th>
<th>Processing Denture Cap Male/Pkg. No. 8519</th>
<th>Processing Denture Cap Male/Pkg. No. 8540</th>
<th>Block Out Spacer No. 8514</th>
<th>5.0 lb. Repl. Male No. 8524</th>
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<tbody>
<tr>
<td>Titanium alloy with TiN coating</td>
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<tr>
<td>Titanium Cap with black Low Density Polyethylene Male, Block Out Spacer, and Nylon Repl. Males (clear, pink, blue)</td>
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<td>3.0 lb. Light Retention Repl. Male No. 8527</td>
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<td>1.5 lb. Extra Light Retention Repl. Male No. 8529</td>
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<td>4.0 lb Extended Range Repl. Male No. 8547</td>
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<td>1.0 lb Extended Range Extra Light Retention Repl. Male No. 8548</td>
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<td>Nylon (Red)</td>
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<tr>
<td>Locator Zero Retention Replacement Male No. 8558</td>
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<tr>
<td>Impression Coping No. 8505</td>
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<tr>
<td>Female Analog (4mm) No. 8530</td>
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<tr>
<td>Female Analog (5mm) No. 8516</td>
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<td>Processing Spacer No. 8569</td>
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<tr>
<td>Nylon (Gray)</td>
<td>Aluminum housing with black low Density Polyethylene Male</td>
<td>Aluminum</td>
<td>Aluminum</td>
<td>Delrin</td>
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</table>
INDICATIONS
The LOCATOR® Implant Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.

CONTRAINDICATIONS
Not appropriate where a totally rigid connection is required. Use on a single implant with divergence of greater than 20 degrees is not recommended.

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 Abutments: The inadvertent re-use of Locator abutments could contain patient contamination build-up 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.
Titanium abutments 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 20 minutes minimum.
2. Dry Heat sterilize using 170°C (338°F) for 2 hours minimum.

Locator Core-Tools (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.
The nylon males may be sterilized/disinfected using a liquid chemical sterilant. In order to ensure that the nylon males are sterilized/disinfected (all microorganisms including Clostridium sporogenes and Bacillus subtilis spores are eliminated), the nylon males must be soaked for a minimum of 3 hours in the liquid sterilant at room temperature.

**NOTE:** An FDA approved liquid chemical sterilant for critical devices that are heat-sensitive and incompatible with sterilization methods such as steam and gas/vapor/plasma low temperature processes may be used following the manufacturer’s directions for the sterilization (not just high-level disinfection) of the device.

**FEATURES**

1. **LOWEST VERTICAL HEIGHT:** The total height of the Locator Attachment (abutment plus male) is only 3.17mm on an externally hexed implant, and 2.5mm on a non-hexed implant.
2. **LOCATING DESIGN:** Self-locating design allows a patient to easily seat their overdenture without the need for accurate alignment of the attachment components.
3. **RETENTION INSIDE AND OUT:** The patented Dual Retention innovation provides the Locator Attachment with greater retention surface area than ever before available with other attachments. A combination of inside and outside retention ensures the longest lasting performance.
4. **ROTATIONAL PIVOTING ACTION:** The design of the pivoting Locator Male allows a resilient connection for the prosthesis without any resulting loss of retention. The retentive nylon male remains completely in contact with the abutment socket while its titanium denture cap has a full range of rotational movement over the male.
5. **USE WITH NON-PARALLEL IMPLANTS:** The Locator Replacement Males can be used to restore an implant with up to 10 degrees of divergence (20 degrees between implants). The Locator Extended Range Replacement Males can accommodate a divergent implant between 10 and 20 degrees (40 degrees between implants).

**A. PLACEMENT OF THE LOCATOR IMPLANT ABUTMENT**

1. To select the proper Locator Implant Abutment, determine the type of implant and the diameter being used. Then measure the tissue thickness from the apical rim of the implant body to the crest of the gingiva at the highest side of the implant site. Choose the corresponding abutment tissue cuff height that exactly equals the tissue measurement, or is the next closest higher size available. The exact tissue cuff height of Locator abutment will position the proper 1.5mm of working attachment above the surrounding gingival level (which should not be submerged below the tissue).
2. After the secondary gingival healing period is complete, remove the healing cuff according to instructions provided by the manufacturer of the implant system being used.
3. It is imperative that all bone and soft tissue be removed from the superior aspect of the implant body to guarantee complete seating of the Locator Implant Abutment.
4. A special gold plated Abutment Driver (contained in Locator Core Tool, Zest order No. 8393) is designed to engage the inside diameter of the Locator Abutment and thread it into the implant by hand. (Fig. 1) A Locator Abutment Retaining Sleeve (Zest order No. 8394) slips onto the Abutment Driver to hold the Locator Implant Abutment while delivering it to the implant site by hand.
5. Final torque tightening of the Locator Abutment to prevent screw loosening is achieved using the 30N-cm Torque Wrench Kit (Zest order No. 9020, Fig. 2). The 15mm length...
Square Drive Torque Wrench Driver is used when interocclusal space is limited, and the 21mm length is used when interference is caused by an adjacent tooth.

NOTE: Various connection types of Locator Torque Wrench Drivers are available that fit into commonly used implant torque wrenches to allow direct torque tightening of the Locator Implant Abutment. In addition, the use of any Torque Wrench with a .050 (1.25mm) Hex Torque Wrench Driver Tip will fit into the backside of the Locator Abutment Driver. Use your own Torque Wrench with either of these options to achieve 30N-cm that will help prevent screw loosening of the Locator Implant Abutment.

6. For Implant Attachments with ≤ 1.4 mm thread (IDENTIFIED BY “≤ M1.4” SYMBOL ON LABEL), use a calibrated torque wrench and tighten the Locator Abutment to 20 Ncm.

Warning: Use of higher torque values than recommended above could cause a fracture of the LOCATOR® Abutment or Bar Female.

B. ANGLE MEASUREMENT OF A DIVERGENT IMPLANT

1. Choose one of the four threads on the titanium Alignment Pin (Zest order No. 9531) which matches the type of implant being used.

2. Thread the Alignment Pin by hand directly into the divergent implant (or implant analog on a stone model) being careful not to cross-thread the pin. Place the stainless steel Angle Measurement Guide (Zest order No. 9530) behind the Alignment Pin, level with the path of prosthesis insertion, to determine the divergence in degrees. (Fig. 3) An additional Alignment Pin can be placed into an adjacent non-divergent implant to determine the difference in the angle between it and the divergent implant.

WARNING: IF THE ALIGNMENT PIN DOES NOT EASILY THREAD INTO AN IMPLANT, DO NOT FORCE THE INSERTION.

NOTE: An alternative method of determining the angulation of an implant is to first place the Locator abutment into the implant, and then snap a Locator Parallel Post (Zest order No. 8517) onto it. Use the Angle Measurement Guide behind the Parallel Post to determine the angle of the implant.

3. Choose the final Locator nylon male retention liner based upon the determined angle measurement of each implant. If the divergence of an implant is less than 10 degrees, use one of the Locator Replacement Males (clear = 5 lbs., pink = 3 lbs., and blue = 1.5 lbs.). If the divergence of any implant is between 10 degrees and 20 degrees, then use one of the Extended Range Replacement Males (green = 4 lbs., orange = 2 lbs. and red = 1 lbs.) which can accommodate a divergent implant up to 20 degrees (40 degrees between implants).

4. Follow the steps in Section C, LOCATOR DENTURE CAP MALE PLACEMENT BY THE DENTIST for chairside placement of the Locator Male, or the steps in Section D, LOCATOR DENTURE CAP MALE PLACEMENT BY THE LABORATORY for indirect placement of the Locator Male.

C. LOCATOR DENTURE CAP MALE PLACEMENT BY THE DENTIST

1. Insertion of the proper Locator Implant Abutment at tissue level must be completed (see Section A-1) before beginning the procedure for placement of the Locator Denture Cap Processing Male Assembly.

2. Place a White Block-Out Spacer (contained in Zest order No. 8519 Package) over
the head of each Locator Abutment. (Fig. 4) The spacer is used to block out the area immediately surrounding the abutment. The space created will allow the full resilient function of the pivoting metal denture cap over the Locator Black Processing Replacement Male.

NOTE: If the White Block-Out Spacer does not completely fill the space between the tissue and the metal denture cap, it is necessary to block out any remaining undercuts to prevent the added acrylic resin from locking the denture onto the abutment. This can be accomplished by stacking more Block-Out Spacers.

3. Insert a Locator Denture Cap Processing Male Assembly (contained in Zest order No. 8519 Package) onto each Locator Implant Abutment, leaving the White Block-Out Spacer beneath it. (Fig. 5) The Black Processing Replacement 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 protruding Locator Denture Cap Processing Male Assembly. There must be no contact between the denture and the titanium cap. If the denture rests on the metal cap, excess pressure on the implant will result.

5. An autopolymerizing or light cure acrylic resin may be used to pick up the caps. Dry the Denture Caps. Apply a small amount of acrylic around the circumference of each cap. Place acrylic into the relief areas of the denture and seat it over the caps and onto the tissue. Have the patient close into occlusion and hold while the acrylic sets.

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 (attached to the Locator Core Tool, Zest order No. 8393) to remove the Black Processing Replacement 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 and pull it at an angle out of the metal housing. (Fig. 6) 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 Male from the tip end of the Male Removal Tool.

9. The Locator Male Seating Tool (attached to the Locator Core Tool, Zest order No. 8393) is used to firmly push a Locator Replacement Male into the metal denture cap. (Fig. 7) The Replacement Male must seat securely into place, level with the rim of the cap. (Fig. 8)

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.
D. LOCATOR DENTURE CAP MALE PLACEMENT BY THE LABORATORY

In the Operatory:

1. Insertion of the proper Locator Implant Abutment at tissue level must be completed (see Section A-1) before beginning the following impression procedure.

2. Place a Locator Impression Coping with Black Processing Replacement Male (Zest order No. 8505) onto each Locator Abutment. (Fig. 9)

3. **Take an impression using a firm body impression material, exercising caution not to compress the soft tissue.** The Locator Impression Coping is designed with minimum retention to be picked up with the impression material.

4. Snap a Locator Female Analog (Zest order No. 8530 for 4mm or No. 8516 for 5mm) onto each Impression Coping in the impression. The Female Analog must not fall off when turned upside-down with vibration. (Fig. 10)

   **NOTE:** An alternative reline impression technique using the patient’s prosthesis is possible with use of the Locator Denture Cap Processing Male Assembly (contained in Zest order No. 8519 Package). When the impression is withdrawn, the Locator Denture Cap Processing Male Assembly will remain on the abutment. Remove the Locator Denture Cap Processing Male Assembly from each abutment and snap it onto a Locator Female Analog. Reposition this assembly back into the impression making sure it is fully seated.

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

6. Before waxing and processing the appliance, place a Locator Denture Cap Processing Male Assembly onto each Female Analog in the master cast (Fig. 11). Make sure the Denture Cap Processing Male Assembly 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 Locator Denture Cap Processing Male Assembly. Place a White Block-Out Spacer over the head of each Female Analog. The spacer is used to block out the immediate area surrounding the Locator Implant Abutment. The space created will allow the full resilient function of the pivoting metal denture cap over the Locator Nylon Male.

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

   **Note:** If the dentist prefers to do a chairside pick-up of the Locator Denture Cap Processing Male Assembly, use of the Locator Processing Spacer (Zest order No. 8569) will create the exact space needed.

10. Complete the processing and discard the White Block-Out Spacer. Polish the denture base before changing to the appropriate Locator Nylon Replacement Male.

11. Use the Locator Male Removal Tool (attached to the Locator Core Tool, Zest order No. 8393) to remove the Black Processing Replacement 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 and pull it at an angle out of the metal housing. (Fig. 12) 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 Male from the tip end of the Male Removal Tool.
12. The Locator Male Seating Tool (attached to the Locator Core Tool, Zest order No. 8393) is used to firmly push a Locator Replacement Male into the empty metal denture cap. (Fig. 13) The Replacement Male must seat securely into place, level with the rim of the cap. (Fig. 14)

**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. HOW TO CHANGE THE LOCATOR MALE**

1. The Locator Core Tool (Zest order No. 8393), which contains a Locator Male Removal Tool and Locator Male Seating Tool, is used to remove the nylon male from the metal denture cap and replace it with another Locator Replacement Male.
2. Use the Locator Male Removal Tool attached to the Locator 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 and 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 Male from the tip end of the Male Removal Tool.
3. The 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. Use of multiple Locator attachments (3 or more) in the same dental arch may require use of the 1.5 lbs. (extra light retention) blue colored Replacement Male No. 8529, in combination with 0.0 lbs (non-retentive) gray colored Replacement Male No. 8558 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.

**F. 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 E). Replace them with Black Processing Replacement Males (Zest order No. 8515). The built-in spacer of the Black Processing Replacement 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. The Black Processing Replacement Males will engage the Locator Implant Abutments and hold the prosthesis in place while the impression material sets.
3. When the impression is withdrawn, the Black Processing Replacement Males will remain in the metal denture caps.
4. Snap a Locator Female Analog (Zest order No. 8530 for 4mm or No. 8516 for 5mm) onto each Locator Denture Cap Processing Male Assembly in the impression and pour a master model.
5. After processing the reline and polishing the denture base, replace the Black Processing Replacement Males with the appropriate Locator Nylon Replacement Males.
G. PATIENT CARE

Experts recommend that overdenture abutments should be brushed at least once a day with a gel toothpaste to remove plaque and to stimulate gingival tissues, followed by applying a 0.4% Stannous Fluoride gel.

The patient should be instructed to periodically visit their dentist for professional cleanings and attachment evaluation. Use plastic instruments for scaling the attachments. Do not use metal instruments which may create scratches.

Good oral hygiene is vital to attachment success. The Locator Implant Abutments must be thoroughly cleaned each day to prevent wear of the abutments due to buildup of abrasive plaque in the socket of the abutment. The use of a soft nylon bristle or end-tufted toothbrush, and superfloss to polish the abutments should be taught. A non-abrasive gel toothpaste, and an irrigation system is recommended to keep the socket of the Locator Abutment clean.

Patients should maintain a three to four month recall for cleaning and attachment evaluation. The inside socket of the Locator Abutment and the sulcus area around the implant abutment are the primary areas of concern. Use plastic instruments for scaling the abutments. Do not use metal instruments which may create scratches on the abutment surface. Examine patients for signs of inflammation around the implant abutments, and for implant mobility. Use a 30N-cm torque wrench to make sure the Locator Implant Abutment is tight before dismissal.

RETURN POLICY
Check with your Distributor for their policy on returns.

WARRANTY
Zest Anchors, LLC provides a limited warranty for its products, to the original purchaser, to be free from defects in workmanship and materials under normal use for a period of one year from the date of purchase. Zest Anchors, LLC will, at its option, substitute the returned product that proves to be defective with a similar product, free of charge.

Zest Anchors, LLC continually strives to improve its products, and therefore, reserves the right to improve, modify or discontinue products and components at any time without notice or incurring obligation. Purchaser assumes all risks and liability resulting from the use of Zest Anchors, LLC products, whether used separately or in combination with other products not of Zest Anchors, LLC manufacture.