

LOCATOR[®] Implant Attachment System for XiVE[®], FRIALIT[®] and ANKYLOS[®] Implants

CLASSIFICATION

Universal hinge, resilient attachment for endosseous implants

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.

WARNINGS

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed dentist or physician.

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

Please read the instructions for use prior to using the LOCATOR[®] IMPLANT ATTACHMENT SYSTEM. The LOCATOR[®] IMPLANT ATTACHMENT SYSTEM may only be used for its intended purpose according to the general rules for dental/surgical treatment, occupational safety and accident prevention. The LOCATOR[®] IMPLANT ATTACHMENT SYSTEM should only be used if it is in excellent condition. If the indication or use is unclear, treatment should be suspended until these points have been clarified. Friadent GmbH is not liable for damages resulting from treatment outside of our control.

The following instructions are not adequate enough for inexperienced users to provide professional implant-prosthetic treatment. We recommend that an experienced user provide proper use instructions.

The LOCATOR[®] Implant Attachment System for XiVE[®], FRIALIT[®] and ANKYLOS[®] Implants should only be used by dental technicians, dentists and surgeons that are trained and experienced in oral surgery as well as diagnosis and pre-operative planning. Prior to the clinical procedure, ensure that all necessary components, instruments and materials are adequate, complete and functional. All components and instruments that are used clinically must be secured to prevent aspiration or swallowing. Friadent GmbH is not liable for damage resulting from treatment outside of our control. The responsibility rests with the provider.

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.

PRECAUTIONS

The following precautions are to be met prior to or during treatment:

1. Prior to each procedure it must be ensured that all necessary components, instruments and materials are available in the required quantities.
2. Always wear protective clothing for your own safety.
3. Position the patient so that the danger of aspiration of components is minimized. All components that are used intra-orally must be secured to prevent aspiration or swallowing.

ADVERSE REACTIONS

None known

APPLICATION

A. PLACEMENT OF THE LOCATOR® IMPLANT ABUTMENT



Fig. A1

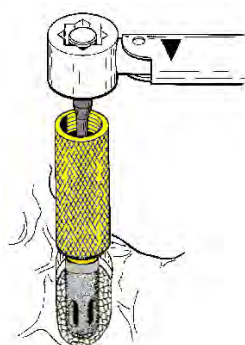


Fig. A2

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. **The following is applicable only to XIVE® and FRIALIT® but not to ANKYLOS® abutments:** 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 the 3-piece LOCATOR® Core Tool) is designed to engage the inside diameter of the LOCATOR® Abutment and thread it into the implant (Fig. A1). A LOCATOR® Abutment Holder Sleeve slips onto the Abutment Driver to hold the LOCATOR® Implant Abutment while delivering it to the implant site.
5. Final torque tightening of the LOCATOR® Abutment to prevent screw loosening is achieved using the FRIADENT® Prosthetic Ratchet with a special torque limited LOCATOR® ratchet insert.

NOTE:

In addition, instead of a special LOCATOR® Insert for the ratchet any Torque Ratchet with a .050 (1.22mm) Hex Driver Tip can be used. The Hex Driver Tip will fit into the backside of the LOCATOR® Abutment Driver. Minimum seating force is 30Ncm. (Fig. A2)

B. ANGLE MEASUREMENT OF A DIVERGENT IMPLANT

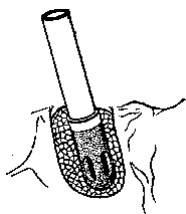


Fig. B1

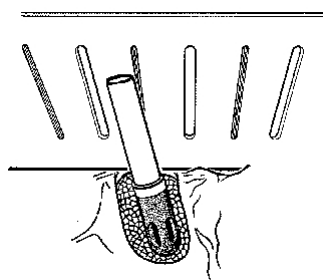









Fig. B2

1. Place the LOCATOR® abutment into the implant, and then snap a LOCATOR® Parallel Post onto it.
2. Place the stainless steel Angle Measurement Guide behind the Parallel Post, level with the path of prosthesis insertion, to determine the divergence in degrees. (Fig. B2). An additional Parallel Post can be placed into an adjacent non-divergent implant to determine the difference in the angle between it and the divergent implant.
3. Choose the final LOCATOR® nylon Male Retention liner based upon the determined angle measurement of each implant.

Divergence of an Implant	Replacement Males	Color / Retention Value
0° - 10°	LOCATOR® Replacement Males	 (clear) 5lbs / 2268g  (pink) 3lbs / 1361g  (blue) 1.5lbs / 680g
10° - 20° (maximum of 40° between implants)	LOCATOR® Extended Range Replacement Males	 (green) 4lbs / 1814g  (orange) 2lbs / 907g  (red) 1lbs / 454g
0° - 20°	LOCATOR® Zero Retention Replacement Male	 (gray) 0lbs / 0g

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

C. LOCATOR® DENTURE CAP MALE PLACEMENT BY THE DENTIST

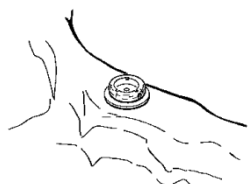


Fig. C1

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 over the head of each LOCATOR® Abutment. (Fig. C1) 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.

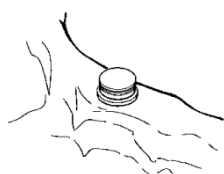


Fig. C2

3. Insert a LOCATOR® Denture Cap Processing Male Assembly onto each LOCATOR® Implant Abutment, leaving the White Block-Out Spacer beneath it. (Fig. C2) 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. Use a viscous, cold-curing acrylic (e.g. Dentsply DeTrey Selectaplast) which is free of bubbles to cure bond the LOCATOR® Denture Cap Male into the denture. Place a small amount in the recess of the denture and around the metal cap of the LOCATOR® Denture Cap Processing Male Assembly.
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.

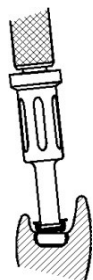


Fig. C3

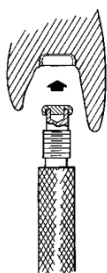


Fig. C4

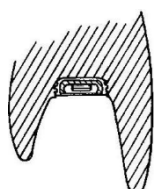


Fig. C5

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 Retention Male.
8. Use the LOCATOR® Male Removal Tool (attached to the LOCATOR® Core Tool) 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. C3) To discard the Male from the tip on the LOCATOR® 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® CoreTool) is used to firmly push a LOCATOR® Replacement Male into the metal denture cap. (Fig. C4) The Replacement Male must seat securely into place, level with the rim of the cap. (Fig. C5)

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

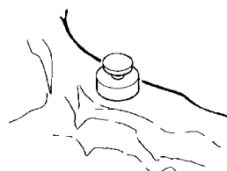


Fig. D1

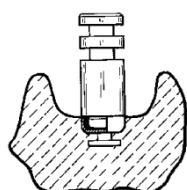


Fig. D2

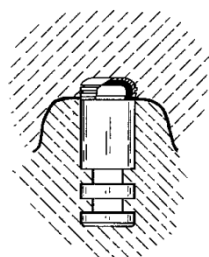


Fig. D3

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 onto each LOCATOR® Abutment. (Fig. D1)
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 (4mm or 5mm) onto each Impression Coping in the impression. The Female Analog must not fall off when turned upside-down with vibration. (Fig. D2)
NOTE: An alternative reline impression technique using the patient's prosthesis is possible with use of the LOCATOR® Denture Cap Processing Male Assembly. 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. D3). 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 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 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 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. D4). 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 Removal Tool.

12. The LOCATOR® Male Seating Tool (attached to the LOCATOR® Core Tool) is used to firmly push a LOCATOR® Replacement Male into the empty metal denture cap. (Fig. D5) The Replacement Male must seat securely into place, level with the rim of the cap (Fig. D6).

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.

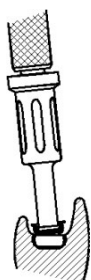


Fig. D4

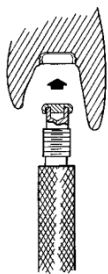


Fig. D5

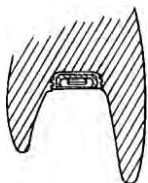


Fig. D6

E. HOW TO CHANGE THE LOCATOR[®] MALE

1. The LOCATOR[®] Core Tool, 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 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./ 680 g (extra light retention) blue colored Replacement Male in combination with 0.0 lbs. / 0 g (non-retentive) gray colored Replacement Male 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 inserts available. It is best to hold the denture with the base side down and snap the insert 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. 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 (4mm or 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 final LOCATOR[®] Nylon Replacement Males.

PATIENT CARE

Good oral hygiene is vital to attachment success. The LOCATOR[®] Implant Abutments must be thoroughly cleaned daily. 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 30Ncm torque wrench to make sure the LOCATOR[®] Implant Abutment is tight before dismissal.

DELIVERY – STORAGE – STERILIZATION

The LOCATOR[®] IMPLANT ATTACHMENT SYSTEM for XiVE[®], FRIALIT[®] and ANKYLOS[®] Implants is composed of components and instruments. All components and instruments are supplied **non-sterile**. Some of the components are **reusable** while others marked  are intended for **single use** only. For correct identification, please refer to the product label.

Store the components in the original packaging at room temperature under conditions normal for dental practices. Do not expose to direct sunlight.

IMPORTANT: Prior to clinical use, all components and instruments delivered non-sterile must be cleaned, disinfected and sterilized according to a validated method.

Sterilization

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 (in the disassembled state only) may be sterilized by Autoclave or Dry Heat sterilize 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.


Minimum hold-time, running times are longer and may vary from unit to unit.

Storage: Store sterilized components dry and dust-free at room temperature.





PARTS IDENTIFICATION



LOCATOR® IMPLANT ABUTMENTS


Order No. XiVE®	Order No. FRIALIT®	Diameter	Gingival Height	
26-3301	45-3301	3.4mm	1.0mm	
26-3302	45-3302		2.0mm	
26-3303	45-3303		3.0mm	
26-3304	45-3304		4.0mm	
26-3305	45-3305		5.0mm	
26-3311	45-3311	3.8mm	1.0mm	
26-3312	45-3312		2.0mm	
26-3313	45-3313		3.0mm	
26-3314	45-3314		4.0mm	
26-3315	45-3315		5.0mm	
26-3321	45-3321	4.5mm	1.0mm	
26-3322	45-3322		2.0mm	
26-3323	45-3323		3.0mm	
26-3324	45-3324		4.0mm	
26-3325	45-3325		5.0mm	
26-3331	45-3331	5.5mm	1.3mm	
26-3332	45-3332		2.0mm	
26-3333	45-3333		3.0mm	
26-3334	45-3334		4.0mm	
26-3335	45-3335		5.0mm	








Order No. ANKYLOS® C/X	Gingival Height	
3102 2610	2.0mm	
3102 2612	3.0mm	
3102 2614	4.0mm	
3102 2616	5.0mm	
3102 2618	6.0mm	






LOCATOR® ACCESSORIES

Order No.	TOOLS AND DRIVERS	
45-3340	LOCATOR® Core Tool	
45-3341	LOCATOR® Abutment Holder Sleeve	
45-3344	FRIADENT® LOCATOR® Insert for Prosthetic Ratchet	
3103 3635	ANKYLOS® Insert for Prosthetic Ratchet for LOCATOR®	












Order No.	ANGLE MEASUREMENT	
45-3345	LOCATOR® Angle Measurement Guide	
45-3346	LOCATOR® Parallel Post (4 Pack)	

Order No.	MALE PROCESSING PACKAGES	
45-3347	LOCATOR® Male Processing Package (Titanium)	
45-3348	LOCATOR® Male Processing Package (Stainless Steel)	

Order No.	REPLACEMENT MALES	
45-3349	LOCATOR® Strong Retention Replacement Male (clear), 4 pcs.	 5.0lbs / 2268g
45-3350	LOCATOR® Light Retention Replacement Male (pink), 4 pcs.	 3.0lbs / 1361g
45-3351	LOCATOR® Extra Light Retention Replacement Male (blue), 4 pcs.	 1.5lbs / 680g
45-3360	LOCATOR® Zero Retention Replacement Male (gray), 4 pcs.	 0.0lbs / 0g
45-3352	LOCATOR® Strong Retention Extended Range Replacement Male (green), 4 pcs.	 4.0lbs / 1814g
45-3353	LOCATOR® Light Retention Extended Range Replacement Male (orange), 4 pcs.	 2.0lbs / 907g
45-3354	LOCATOR® Extra Light Retention Extended Range Replacement Male (red), 4 pcs.	 1.0lbs / 454g

Order No.	PROCESSING COMPONENTS	
45-3355	LOCATOR® Impression Coping, 4 pcs.	
45-3356	LOCATOR® Female Analog 4mm diam., 4 pcs.	
45-3357	LOCATOR® Female Analog 5mm diam., 4 pcs.	
45-3358	LOCATOR® Black Processing Replacement Male, 4 pcs.	
45-3359	LOCATOR® Block-Out Spacer, 20 pcs.	
45-3361	LOCATOR® Processing Spacer	

MATERIALS

Implant Abutment	 <p>XiVE® FRIALIT®</p> <p>ANKYLOS®</p>	Titanium alloy with TiN coating
Processing Denture Cap		Titanium Cap with black Low Density Polyethylene Male
Block Out Spacer		Silicone rubber (white)
Processing Spacer		Delrin
LOCATOR® Angle Measurement Guide	 <p>ZEST ANCHORS INC. 800-262-2310</p> <p>25° 20° 15° 10° 0° 10° 15° 20° 25°</p>	Stainless steel
Impression Coping		Aluminum housing with black Low Density Polyethylene Male
Female Analog		Aluminum
Parallel Post		Low Density Polyethylene
Replacement Males		Nylon (Polyamide 66)
Extended Range (up to 40° divergence between two implants) Replacement Males		Nylon (Polyamide 66)
LOCATOR® Core Tool		Stainless steel with gold plating

RETURN POLICY

For all returns the terms and conditions of Friadent GmbH apply.

WARRANTY

For terms and conditions please refer to Friadent GmbH.

PRODUCT MODIFICATION AND DISCONTINUATION

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LOCATOR® U.S. Patent Nos. 6,030,219 and 6,299,447.

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XiVE®, FRIALIT® and ANKYLOS® are registered trademarks of Friadent GmbH.

Other languages are available upon request

Not all products are available in all countries.

EXPLANATION OF SYMBOLS

For relevant symbols refer to product label.



Batch code



Order number



Manufacturer



Non-sterile



Consult instructions for use



Do not re-use



Prescription only (U.S.)



Class I medical devices in accordance with Directive 93/42/EEC



Classes IIa, IIb, III medical devices in accordance with Directive 93/42/EEC

MANUFACTURER:



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