IPB Inc
INNOVATIVE PRODUCT BRANDS

PrimeLOC

ENG

Instructions for Use

The PrimeLOC Attachment System includes: Denture Attachment Housing, Retention Inserts, Ancillary Processing Components (including: abutment analogs, processing spacer, impression coping, block-out spacer and black and yellow processing inserts), and Tooling (including: Retention Insert Tool and abutment drivers for torque wrenches and latch handpieces).

This document, at the time of distribution, contains the most current Instructions for Use. Please read and retain.

DESCRIPTION AND CLINICAL BENEFITS

The PrimeLOC Attachment System is a universal hinge, resilient attachment for endosseous implants and angled or straight multi-unit abutments in the mandible or maxilla that is designed to restore masticatory function. The attachment system is patient-removable and therefore allows for the prosthesis to be removed and replaced by the patient. The attachment system allows the prosthesis to be secured in the patient's mouth without the use of adhesives or excessive denture material which can minimize the ability to taste and minimize the security of the prothesis.

INDICATIONS FOR USE

The PrimeLOC Attachment System is designed to facilitate patient removal of a dental prosthesis for use with full arch overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.

CONTRAINDICATIONS

Not recommended for use with a single implant with divergence of greater than 20 degrees from vertical. Not appropriate where a totally rigid connection is required unless overdenture bar attachments are secured to a rigid bar structure.

Target Groups and Users

These products are intended to be used in any partially or fully edentulous patient into which endosseous dental implants have been placed. Patients must have the appropriate dexterity or access to assistance to allow for removal, maintenance, and replacement of the overdenture prosthesis secured to dental implant abutments using the PrimeLOC attachment system. The system must be placed by a licensed dental practitioner. Restorations incorporating use of the system must be fabricated by a licensed dental practitioner or dental laboratory. The patient will utilize and maintain the prosthesis which incorporates the attachment system.

CAUTION

Federal law in the USA restricts this device to sale only to or on the order of a licensed dentist through a dental laboratory service provider.

MRI SAFETY INFORMATION

The PrimeLOC Attachment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the PrimeLOC Attachment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

STORAGE AND HANDLING

The PrimeLOC Attachment System in its original, undamaged packaging is not subject to any special considerations for transport, storage and handling.

WARNINGS AND PRECAUTIONS

Product should be inspected for integrity prior to use. Product from damaged packaging should not be used on patients. In the event that the packaging is damaged, the damaged packaging with the product should be returned to the manufacturer and a replacement will be provided only if damage to packaging is caused by product shipment.

A prosthesis restored with the PrimeLOC Attachment System should be carefully placed on the mating abutments and pressed firmly into place. Inaccurate placement can cause premature wear of the denture housing and abutments, and may cause damage to the retention inserts. If damage occurs which causes retention of the prosthesis to be diminished, the patient should schedule a follow-up appointment for replacement of the damaged components. Denture housings do not have a restriction on functional life and will last as long as the prosthesis remains appropriately contoured to the patient's gingival tissue except in the case of premature wear as noted.

Retention inserts can wear and loose retention over time. With proper maintenance, retention inserts are expected to maintain an appropriate level of retention for a minimum of 2 year. Retention force may be affected by foreign material ingress into the retention insert or buildup around the abutment. Daily maintenance of the denture is required. If retention becomes inadequate, the patient should schedule a follow-up appointment for replacement of retention inserts.

As surgical instruments are susceptible to damage and wear, they should be inspected before each use. Under normal use conditions, reusable instruments have a minimum expected useful life of 50 uses. Any reusable instrument should be replaced if damage or wear is present to ensure proper functionality. The number of uses will vary and depends on a variety of factors including but not limited to maximum forces achieved during use, handling, proper cleaning, autoclave exposure, and storage conditions (do not store tools or instruments wet). Over time, repeat sterilization may affect appearance

Patient evaluation including the determination of the general health, oral hygiene habits and status, motivation towards good dental care, and anatomical acceptability prior to the placement of the implant attachments as part of restorative process, is critical. Thorough evaluation of the patient's medical status and health history is mandatory. Treatment planning is vital to the success of the implant and prosthesis.

The use of this attachment system requires that the clinician be thoroughly familiar with the product and the method for its use and application. The clinician must also use reasonable judgment in deciding when and where to use the product.

MATERIALS

The components which remain within the oral cavity are fabricated from titanium alloy (containing approximately 89% titanium, 6% aluminum, and 4% vanadium) and nylon.

SINGLE-USE DEVICES

The PrimeLOC Attachment System components and the abutment retention sleeve are single-use devices and are provided non-sterile. Single-use devices must not be reused or re-sterilized. Reuse of a single-use device may cause harm to the patient in the transfer of blood, tissue or saliva that may contain infectious disease. Single-use devices may not function as intended if re-sterilized and may result in an improper surgical procedure and lead to improper function or failure of the device.

PrimeLOC Retention Inserts: The inadvertent re-use of PrimeLOC nylon Retention Inserts could cause loss of retention of the overdenture due to wear from previous use or damage during removal.

MULTIPLE-USE DEVICES

The tools of the PrimeLOC Attachment System are multi-use devices. Reusable tools and instruments must be cleaned and sterilized prior to reuse on patients.

Tooling: The PrimeLOC Tools are designed for multiple uses and are provided NON-STERILE. Follow the instructions provided here within for proper sterilization of non-sterile components and the instructions for cleaning and resterilization processes of reusable components.

CLEANING AND STERILIZATION

The PrimeLOC Attachment System restorative components and instruments are supplied NON-STERILE and should be sterilized prior to use on patients.

STERILIZATION

Inserts, assemblies which include inserts (such as the denture housing assembly and impression coping), and the blockout spacer are heat sensitive. An FDA approved liquid chemical sterilant is recommended for use with these components to achieve appropriate disinfection/sterilization of these components. These components may be sterilized/disinfected using a liquid chemical sterilant according to the manufacturer's instructions.

Instruments, including drivers and the system tool must be sterilized prior to use on patients. These devices may be sterilized by autoclave sterilization using the following parameters. For gravity cycle, place components in autoclave bag; and for Pre-Vacuum Cycle, wrap the component with autoclave wrap material and secure wrap with autoclave tape. Wrap the components using a wrap that is FDA-cleared for the indicated cycles.

Autoclave Sterilization Parameters are listed below:

Part Description	Cycle Type	Temperature	Exposure Time	Drying Time
PrimeLOC Instruments including System Tool and Abutment Drivers	Gravity	132°C / 270°F	15 Minutes	30 Minutes
	Pre-Vacuum	132°C / 270°F	4 Minutes	20 Minutes

Re-sterilizable instruments should be dried completely and stored in a clean and dry location at normal room temperature. Prior to instrument use, the exterior of any sterilized packaging should be inspected for integrity. Care must be exercised in the handling of wrapped or autoclave bagged instrument kits or instruments to prevent damage to the sterile barrier. If damage to the sterile barrier is observed, resterilization is recommended for reusable devices only. Single Use devices should not be resterilized.

CLEANING

Reusable instruments must be cleaned in between patient uses according to the following instructions.

- Disconnect or disassemble the instruments.
- Soak the instruments in enzymatic cleaning solution mixed according to manufacturer's instructions by completely submerging them for 20 minutes. Scrub the components using a soft-bristled, nylon brush until all soil has been removed.
- Remove the instruments from the enzymatic cleaning solution and rinse in tap water for a minimum of 3 minutes. Make sure to thoroughly flush internal holes/crevices of the instruments that have difficult to reach areas.
- Visually inspect instruments and tools for cleanliness and presence of residual debris. If additional cleaning is needed, place instruments in ultrasonic cleaner with enzymatic cleaning solution prepared according to manufacturer's instructions making sure that they are completely submerged and sonicate for 10 minutes.
- Remove the instruments from the ultrasonic cleaner, and rinse for 3 minutes making sure to thoroughly flush cleaning solution out of the holes/crevices and/or difficult to reach areas.
- Remove excess moisture from the instruments with a clean, absorbent, non-shedding wipe and allow instruments to dry completely.

Prior to use on a patient, sterilize the instruments according to the sterilization instructions above.

DISPOSAL

Dispose of used devices which pose a risk of infection according to facility clinical waste procedures and applicable local and state regulations.

PROSTHETIC PROCEDURES

Product Compatibility

The components are compatible with abutments, ancillary components, and tooling for the LOCATOR® attachment system offered by Zest Dental Solutions®[1].

Impression and Stone Model Fabrication

- With abutments torqued in place (utilizing the abutment drivers and abutment retention sleeve as required), snap the Impression Copings on the abutments until they are seated firmly.
- Proceed with taking an impression
- Remove the tray and snap an Analog into each Impression Coping.
- Capture the abutment position in stone using standard methods for fabricating a laboratory stone model.

Prosthesis Fabrication

- Fabricate the prosthesis using standard laboratory techniques. Create a recessed clearance in the prosthesis which will be large enough to passively accept the Denture Attachment Housing.

Denture Attachment Housing Pick-Up Technique

- Denture Attachment Housing pick-up may be performed on the laboratory stone model or chair-side directly from the patient.
- Place a Block-Out Spacer around the coronal portion of each abutment or abutment analog.
- Seat the PrimeLOC Denture Attachment Housings with the black Processing Inserts on each of the abutments. Where a bar-supported overdenture prosthesis is being fabricated, seat the Denture Attachment Housings with the yellow Processing Inserts on each of the abutments which are secured to the bar.
- Secure the Denture Attachment Housings to the prosthesis using light-cure, auto-polymerizing or composite resin, following the respective material guidelines for each pick-up technique.
- Once curing is complete, remove the prosthesis and verify fit of the prosthesis by engaging it onto the abutments or abutment analogs.

Prosthesis Delivery

- Once the fit of the prosthesis is verified, remove the Processing Inserts from the Denture Attachment Housing utilizing the barbed edge of the System Tool. Remove the barbed end and use this end of the System Tool body to press a Retention Insert into the Denture Attachment Housing. When delivering the prosthesis, use the lowest level Retention Insert to begin with and increase the retention level if needed.
- Firmly snap the prosthesis in place, ensuring that each insert is fully engaged onto each abutment.

Retention Insert Replacement and Prosthesis Fit

- As needed, remove the Retention Inserts from the Denture Attachment Housing utilizing the barbed edge of the System Tool. Remove the barbed end and use this end of the System Tool body to press the desired Retention Insert into the Denture Attachment Housing.
- Firmly snap the prosthesis in place, ensuring that each insert is fully engaged onto each abutment.
- If the fit of the prosthesis must be modified, such as if typical denture reline procedure are employed, new Denture Attachment Housings must be reprocessed into the prosthesis as noted above.

PATIENT CARE

Good oral hygiene is vital to success with the PrimeLOC Attachment System. The patient should be made aware of the following:

- Attachments must be thoroughly cleaned each day to prevent buildup of plaque biofilm. The patient should use a soft nylon bristle or end-tufted toothbrush with a non-abrasive toothpaste to clean the Abutments.
- The coarse particles in abrasive toothpastes may scratch the surfaces of the attachments and cause additional plaque accumulation.
- An irrigation system is recommended to flush out debris from the inside of the PrimeLOC Retention Inserts.

- PrimeLOC Retention Inserts are made of a soft plastic material (nylon) to allow the overdentures to be removed and replaced regularly. Plastic materials are subject to wear as part of normal use and may require replacement.
- Bruxism may reduce the longevity of Retention Inserts.

Patients should be instructed to maintain routine follow-up visits for hygiene and evaluation of attachment function. Should a patient experience any discomfort or loss of overdenture retention, they should consult a dental professional. Follow-up visits are recommended at 6-month intervals.

Inserting and Removing Overdentures

The patient should be instructed on how to properly insert the Overdenture. The patient should make sure they can feel that it is positioned over the Abutments prior to applying pressure. The patient should use both hands and press down on each side and firmly snap the Overdenture into place.

NOTE: The patient must NOT bite their Overdentures into place, as this force will result in improper wear of the Abutments and Retention Inserts. The Overdenture is to be removed by the patient by placing their thumbs under the edges of the Overdenture flanges and pulling each side upward (mandibular denture) or downward (maxillary denture) simultaneously. Use of the tongue may aid in removal. Once removed, through cleaning is recommended.

Cleaning of Implant-Retained Overdentures

Instruct the patient to follow the protocol below to ensure the longevity of their Overdenture.

1. Fill a washing basin with warm water to prevent fracture of the Overdenture. Apply non-abrasive toothpaste onto a soft nylon bristle or end-tufted toothbrush and thoroughly clean every surface of the Overdenture.
2. Each night remove the Overdenture and rinse with plain water.

Additional Information

Traditional restorative protocols should be followed to process the attachments into the patient's Overdenture. Standard Overdenture care and maintenance should be followed in order to ensure the longevity of each restoration.

Any serious incident which may occur in relation to the PrimeLOC Attachment System should be reported to the manufacturer and local regulatory authorities including the competent authority of the Member State in which the user and/or patient is established.

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SYMBOLS USED IN PRODUCT LABELING

Symbol	Symbol Title	Symbol Description	Standard	Standard Section Reference
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1	5.1.1
	Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1	5.1.3
	Batch code	Indicates the manufacturer's batch code wo that the batch or lot can be identified.	ISO 15223-1	5.1.5
	Catalogue number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1	5.1.6
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1	5.2.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use and, where accompanied by in eIFU indicator below the symbol, the location within which the eIFU may be found.	ISO 15223-1	5.4.3
	Prescription only	Indicates a medical devices that may be sold by prescription only.	US CFR Title 21	801.15(c)(1)(i)(F)
	Quantity	Indicates the number of units within the package.	N/A	N/A

[1] LOCATOR® and Zest Dental Solutions® are registered trademarks of Zest Anchors, LLC

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