

## **Instructions for Use**

**The PrimeLOC Attachment System** includes: Denture Attachment Housing, Retention Inserts, Ancillary Processing Components (including: block-out spacer and black processing insert).

This document contains the most current Instructions for Use. Please read and retain.

### **DESCRIPTION**

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.

### **INDICATIONS FOR USE**

The PrimeLOC Attachment System is designed 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 10 degrees from vertical. Not appropriate where a totally rigid connection is required.

### **CAUTION**

Federal law in the USA restricts this device to sale only by or on the order of a licensed dentist.

### **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.

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.

## **SINGLE-USE DEVICES**

The PrimeLOC Attachment System components, 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.

## **CLEANING AND STERILIZATION**

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

## **STERILIZATION**

Inserts 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.

## **DISPOSAL**

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

## **PROSTHETIC PROCEDURES**

### Product Compatibility

Inserts and the blockout spacer are compatible with abutments, ancillary components, and tooling for the Locator® attachment system offered by Zest Dental Solutions®.

### Prosthesis Fabrication

- Seat the PrimeLOC Denture Attachment Housings with the black Processing Inserts on each of the abutments.
- Fabricate the prosthesis using standard laboratory techniques.
- When delivering the prosthesis, use the lowest level Retention Insert to begin with and increase the retention level if needed.

### Chair-Side Denture Attachment Housing Pick-Up Technique (Optional)

- Place a Block-Out Spacer around each abutment and press down.
- Seat the PrimeLOC Denture Attachment Housings with the black Processing Inserts in place on each of the Abutments.
- 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.

### Prosthesis Delivery

- Once the fit of the prosthesis is verified, remove the black Processing Inserts from each Denture Attachment Housing using a standard insert tool.
- Replace them with 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.

## 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, thorough 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.