Instructions for use



Dental Implant, Accessories, T-L Components Valid only in United States

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PARTS IDENTIFICATION

T-L Component Set (Titanium Cap)

No. TLC-CST(6)



Titanium Cap Black LDPE Male, Nylon Replace Males (blue,pink,clear) and Block out Spacer

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T-I	Titanium	Can

T-L Block Out Spacer White

No. TLC-TC5423

No. TLC-OS56W





Ti-6Al-4V ELI

Silicon

T-L Black Processing Replacement Male 1.5 lb T-L Retention Replacement Male

3.0 lb T-L Retention Replacement Male

5.0 lb T-L Retention Replacement Male

No. TLC-PRM56K

No. TLC-RRM47B

No. TLC-RRM47P

No. TLC-RRM47T









LDPE(Black)

Nylon(Blue)

Nylon(Pink)

Nylon(Clear)

INDICATIONS

T-L Components are laboratory pieces used for fabrication of dental prosthetics.

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.

MRI SAFETY INFORMATION

The T-L Component 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 T-L Component in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

SINGLE-USE DEVICES

T-L Components: The inadvertent re-use of T-L nylon males could cause loss of retention for the overdenture due to wear from previous use or damage during removal.

STERILIZATION

All components and instruments are supplied NON-STERILE.

PROSTHETIC PROCEDURE

RETENTION MALE PLACEMENT BY THE DENTIST

- Place a Block Out Spacer White (No. TLC-OS56W also contained in No. TLC-ST(6)
 Package) over the head of each TruAbutment DS T-L. 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 T-L titanium cap over the T-L Black
 Processing Replacement Male.
 - **NOTE:** If the Block Out Spacer White 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.
- Insert a Ti Cap with Black Processing Replacement Male (No. TLC-PRM56K also contained in No. TLC-CST(6) Package) onto each T-L, leaving the Block Out Spacer White beneath it. The Black Processing Replacement Male will maintain the overdenture in the upper limit of its vertical resiliency during the processing procedure.
- Prepare a recess in the denture to accommodate the protruding T-L Male. There must be no contact between the denture and the T-L cap. If the denture rests on the T-L Cap, excess pressure on the implant will result.
- 4. Use a Chairside Lightcure Acrylic Resin Syringe Kit to light cure bond the T-L Denture Cap Processing Male into the denture, or mix a permanent self-curing acrylic and place a small amount in the recess of the denture and around the T-L Cap of the T-L Denture Cap Processing Male.
- 5. 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.
- After the acrylic resin has cured, remove the denture and discard the Block Out Spacer White. Use a bur to remove excess acrylic, and polish the denture base before changing to the final male.
- 7. Remove the Black Processing Replacement Male from the T-L cap.
- 8. The Replacement Male must seat securely into place, level with the rim of the cap.

T-L CAP MALE PLACEMENT BY THE LABORATORY

- Insertion of the proper Truabutment DS T-L at tissue level must be completed before beginning the following impression procedure.
- 2. Pour the master cast.
- 3. Before waxing and processing the appliance, place a T-L Black Processing Cap

- Male onto each abutment in the master cast. Make sure the Cap Processing Male Assembly is fully seated.
- Set the teeth and wax the appliance. Proceed with the processing technique of your choice through the boil-out step.
- 5. After the boil-out, remove the T-L Cap and Black Processing Cap Male. Place a Block Out Spacer White over the head of each Truabutment DS T-L. The spacer is used to block out the immediate area surrounding the Truabutment DS T-L. The space created will allow the full resilient function of the pivoting metal denture cap over the T-L Nylon Male.
- 6. Re-insert the T-L Cap and Black Processing Cap Male onto each Truabutment DS T-L, leaving the Block Out Spacer White beneath it. The Black Processing Replacement Male will maintain the overdenture in the upper limit of its vertical resiliency during the processing procedure.
- Complete the processing and discard the Block Out Spacer White. Avoid damage
 to the final male by polishing the denture base before changing to the final T-L
 Nylon Replacement Male.

HOW TO CHANGE THE T-L MALE

- 1. Remove the nylon male from the T-L cap.
- Firmly push a T-L Replacement Male into the empty T-L cap. The
 Replacement Male must seat securely into place, level with the rim of the cap.
 Use of multiple T-Ls (3 or more) in the same dental arch may require use of a
 combination of various retention Male Replacements for easier removal of the
 prosthesis by the patient.

PATIENT CARE

Good oral hygiene is vital to attachment success. The TruAbutment DS T-L 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 T-L clean.

Patients should maintain a three to four month recall for cleaning evaluation of abutment and male attachment. Replace male attachment if worn. The inside socket of the T-L 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 Truabutment DS T-L is tight before dismissal.

CAUTION

THE PATIENT MUST NOT BITE their Overdentures into place as this force will result in improper wear of the Abutments, including the Replacement Males in the Overdenture. Remove the Overdenture by placing the thumbs under the edges of the Overdenture flanges and pulling each side upward/downward simultaneously. Use of the tongue may aid in removal. Once removed, a thorough cleaning is recommended.

Cleaning your Implant Retained Denture

Instruct the patient to follow the protocol below to ensure the longevity of their Overdenture. Fill a washing basin with some warm water to prevent fracture of the Overdenture. Apply non-abrasive toothpaste onto the soft bristle toothbrush and thoroughly clean every surface of the Overdenture. Each night, remove Overdenture and immerse in a cup of plain water.

Further 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 the restoration.



LABELING SYMBOLS

Symbols may be used on some international package labeling for easy identification.

(8)	Do not reuse
LOT	Batch code
\mathbb{M}	Date of manufacture
REF	Catalogue number
MON STERRE	Non-Sterile
Rx Only	Prescription only
\triangle	Caution, consult accompanying documents
<u></u>	Manufacturer
$\square i$	Consult instructions for use
	Do not use if package is damaged



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