



RODO Smileloc® Abutment System Instructions for Use

Please read the following Instructions for Use (IFU) before using the RODO Abutments and Components.

Note: RODO “Components” include the Abutment Analog, Impression Coping, Titanium Coping, Lab Sleeve, Abutment Screw to Implant, Healing Cap, Healing Abutment, the shape memory retention sleeve (Smileloc®), Socket Driver, Screw Driver, Smileloc® Seater, Seal Seater, Accessory Screws and Seals. The aforementioned “Components” are used for single and multi-unit prosthesis fabrication and restoration. RODO Abutment System prostheses are removable with the RODO Smilekey® (IFU 0004).

Caution

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

The RODO Abutments and Components are used for restoration of prostheses on implants of different types, diameters, lengths, thread design, surface coatings, and platforms. These instructions are valid for all RODO Abutments and Components.

Indications

The RODO Abutment System is intended to be used in conjunction with compatible implant systems in the maxillary or mandibular arch to provide support for crowns, bridges and full arch prostheses.

Compatible Systems

Implant Line	OEM Platform Size	OEM Body Size
Straumann Bone Level	NC, RC	3.3, 4.1, 4.8
Neodent Drive CM	3.5, 4.3, 5.0	3.5, 4.3, 5.0
Neodent Titamax CM	3.5, 3.75, 4.0, 5.0	3.5, 3.75, 4.0, 5.0
Neodent Alvim CM	3.5, 4.3, 5.0	3.5, 4.3, 5.0
Neodent GM	3.5	3.5, 3.75, 4.0, 4.3, 5.0, 6.0
NobelActive	3.0, NP, RP, WP	3.0, 3.5, 4.3, 5.0, 5.5
NobelReplace Conical	NP, RP	3.5, 4.3, 5.0
NobelReplace Straight	NP, RP, WP	3.5, 4.0, 5.0
NobelReplace Tapered	NP, RP, WP, 6.0	3.5, 4.3, 5.0, 6.0
NobelSpeedy Replace	NP, RP, WP, 6.0	3.5, 4.0, 5.0, 6.0
BioHorizons Tapered Internal	3.0, 3.5, 4.5, 5.7	3.0, 3.4, 3.8, 4.6, 5.8
Biomet 3i Certain Internal	3.4, 4.1, 5.0, 6.0	3.25, 3.4, 4.1, 5.0, 6.0

Compatibility Information

The RODO Abutments and Components are available in a variety of configurations to meet your clinical needs. The label on each product contains information to help you identify the specific implant system with which the RODO product is compatible.

Ensure that you use RODO Abutments and Components with compatible implants as shown on the label for each RODO part.



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Precaution

The RODO Abutments must be used only with compatible implants. Failure to do so may harm the patient and/or result in damage to the implants, abutments, components or instruments.

Contraindications

Allergies or hypersensitivity to chemical ingredients of materials used in the individual RODO product: Nickel (Ni), Nickel Titanium alloy (Nitinol), Titanium (Ti), Titanium alloy (Ti 6Al/4V ELI), PEEK, Silicone.

Sterilization

The RODO Abutment System components are provided non-sterile. Prior to placement in the patient, components must be sterilized using a gravity steam sterilization cycle of 135°C for 10 minutes with a drying time of 30 minutes using an FDA cleared sterilization wrap.

The RODO Abutment System components are to be sterilized individually. The RODO Abutment is provided with the silicone seal pre-mounted and should not be disassembled for sterilization.

Warnings and Precautions

The RODO Smileloc® Abutment System should be used only by operators familiar with the RODO Smileloc® Abutment System and trained in the restoration of dental implants. Placing abutments and related components without proper restorative dental implant training, may lead to failure of the abutment or component. Abutment failure may lead to implant failure and/or removal.

RODO Abutments and Components must be secured to prevent aspiration during intraoral use and insertion into the implant.

Warning: Straight abutments are not intended for placement on implant bodies placed such that the implant body requires angle correction.

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

The minimum post height above the abutment collar when combined with the long coping in a single-unit restoration is 4 mm.

The RODO Regular Abutment Series are straight abutments designed for locations with limited occlusal space and restricted interproximal space.

The RODO Wide Abutment Series are straight abutments designed for use in areas with large interproximal spaces such as molars.



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The RODO Regular Multi-Unit Abutment Series is for multi-unit restorations only.

Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications:

- Infection
- Damage to the implant, abutment or other accessories
- Loosening of the abutment and other accessories
- Improper final restoration or malfunction of the prosthesis
- Impairment of the patient's chewing function
- Failure of the implant
- Removal of the implant

Always place and/or adjust temporary restorations, healing abutments, and healing cap to avoid hyperocclusion.

Do not remove healing cap with rotary movements to prevent abutment loosening.

The healing cap and healing abutment are indicated for temporary use up to 180 days.

Safety and Liability

This product is to be used only with original components and instruments specified in the compatibility section and elsewhere in this IFU. The use of components or instruments other than those specified in these instructions for use will void any warranty or other obligation,

express or implied, of RODO Medical. The proper use and handling of this product is the sole responsibility of the user. RODO Medical accepts no liability for any damage resulting from the improper use of its products.

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

INSTRUCTIONS FOR USE

These instructions contain both clinical and laboratory procedures and are written in a linear flow from placement to final restoration.

A. SINGLE UNIT FOR RODO REGULAR (350-SERIES)
AND SINGLE / BRIDGE WIDE (400-SERIES)
ABUTMENTS

I. Healing Abutment Placement

1. Select a single-use healing abutment with appropriate diameter and gingival height.
2. Hand tighten healing abutment using a Torx T6 Screw Driver.

WARNING: Over-tightening the healing abutment may lead to abutment and/or implant failure.

3. Verify the healing abutment is fully seated with radiograph.

II. Impression Taking

1. Take implant level impression using implant manufacturer's components and procedures to take impression and send to dental lab for abutment selection and crown/bridge fabrication.

III. Lab Procedures

1. Pour implant level impression model using implant manufacturer's components and procedures.
2. Evaluate the gingival height of the specific implant case and choose the RODO abutment with the appropriate gingival height.
3. Seat RODO Abutment on the implant analog, then hand-tighten the abutment screw using a Torx T6 Screw Driver with adapter handle.

WARNING: Ensure Torx T6 Screw Driver is fully seated and perfectly aligned with the long axis of the RODO Abutment Screw, to avoid undesirable stripping of RODO Abutment Screw.

4. FOR Wide (400-series): If making a bridge, use RODO Ti Copings for Bridge and ensure that the non-engaging sides (marked on coping outer surface with "B") are oriented in the direction of implant divergence. Also, verify markings are facing opposite directions as shown.





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NOTE: RODO (350-series) Regular Abutment Bridge Copings not available. Use RODO (300-series) Regular Ti Abutments and reference page 7 for Lab Procedure related to Regular Bridge restorations.

5. Fabricate crown on RODO Ti Coping(s) using standard lab techniques.
6. Seat RODO Ti Coping(s) on model and cement crown. Finish and polish as needed.
2. If using abutment-level impression:
 1. Insert and screw RODO Regular Abutment Analog into RODO Impression Coping and pour impression model.
 2. Fabricate crown on RODO Ti Coping using standard lab techniques.
 3. Seat RODO Ti Coping on model and cement crown. Finish and polish as needed.

IV. Restoration Placement

Helpful Instruments: Loupes, dental mirror, half hollenback, explorer, cotton forceps, and hemostat.

1. If patient is wearing RODO Healing Abutment (implant level impression was taken):
 - a. Remove RODO Healing Abutment using T6 Torx Screw Driver.
2. Ensure that RODO abutment is clean and dry. Use air/water syringe as needed.

3. Seat RODO Abutment on the implant, then torque the abutment screw using a Torx T6 Screw Driver with a torque wrench. Tighten the RODO Abutment Screw to the torque specification by the implant manufacturer. Note you may need an adapter for your particulate torque wrench to fit the Torx T6 Screw Driver.

WARNING: Ensure Torx T6 Screw Driver is fully seated and perfectly aligned with the long axis of the RODO Abutment Screw, to avoid undesirable stripping of RODO Abutment Screw. Torques greater than those recommended by the implant manufacturer may result in the failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

4. Examine RODO Abutment to ensure that abutment seal is seated correctly. If necessary, reseat the seal into the abutment groove. Use care not to damage seal.
5. Test fit restoration WITHOUT Smileloc® if needed. Place the restoration on the abutment(s) and press down to a fully seated position.
6. Check proximal contacts with dental floss, and occlusal contacts with articulating paper. Adjust as necessary.
7. Repeat steps 5 and 6 as needed. If necessary, place on model.
8. It is extremely important that the restoration fits completely on the abutment(s). Evaluate contacts and angle of abutment(s) to make certain you are 100% sure the restoration is fully seated before placing the Smileloc®.



RODO Smileloc[®] Abutment System Instructions for Use

9. Remove a new, single-use RODO Smileloc[®] from packaging and place RODO Smileloc[®] on abutment until it engages the occlusal undercut on the RODO Abutment. The wider end of the Smileloc[®] should be oriented towards the apical end of the implant. Use Smileloc[®] Seater to push into place, touch only the occlusal portion of the Smileloc[®] (avoid touching arms).
10. Check 4 inner arms of Smileloc[®] to make sure they are engaged on abutment. Inspect each Smileloc[®] to ensure they are free of debris. Check 4 outer arms to make sure they are in the ready-to-lock configuration.
11. Dry inside of restoration and Smileloc[®] abutment assembly.
12. Re-examine abutment to ensure that abutment seal is seated correctly.
13. Place restoration on abutment(s) and apply downward pressure to engage restoration with Smileloc[®].
14. Instruct patient to bite down on restoration using a bite stick to ensure final engagement.
15. Verify restoration is fully seated with radiograph.

B. <u>SINGLE UNIT / BRIDGE RESTORATIONS FOR RODO REGULAR TI (300-SERIES) ABUTMENTS</u>

I. Healing Abutment Placement

1. Select a single-use healing abutment with appropriate diameter and gingival height.
2. Hand tighten healing abutment using a Torx T6 Screw Driver.

WARNING: Over-tightening the healing abutment may lead to abutment and/or implant failure.

3. Verify the healing abutment is fully seated with radiograph.

II. Impression Taking

1. If taking implant level impression, use implant manufacturer's components and procedures to take impression and send to dental lab for abutment selection and crown/bridge fabrication.
2. If taking abutment level impression (regular single unit only):
 - a. Select Regular RODO Abutment with appropriate gingival height and tighten to the torque specified by the implant manufacturer using the RODO Socket Driver with a torque wrench. Note that you may need an adaptor for your particular torque wrench to fit the RODO Socket Driver.

WARNING: Ensure that the RODO Socket Driver is fully seated and perfectly aligned with the long axis of the RODO Abutment Screw, to avoid damaging of RODO abutment driver features. Torques greater than those recommended by the implant manufacturer may result in the failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

- b. Seat impression coping on RODO abutment. Hand tighten the accessory screw onto impression coping on RODO abutment using Torx T6 Screw Driver.
- c. Proceed with impression taking procedure. An open tray impression technique is recommended to facilitate removal of accessory screw.
- d. Inspect impression for completeness and accuracy. Ensure that the impression coping is solidly retained within the impression.
- e. If using screw-retained healing cap, seat healing cap on RODO abutment and hand tighten accessory screw. Alternatively, if using Smileloc®-retained healing cap, refer to instructions in Section IV, steps 8-12, to use Smileloc® to secure healing cap on RODO abutment.
- f. Send impression to dental lab for crown/bridge fabrication.

III. Lab Procedures

3. If using implant level impression:
 1. Pour implant level impression model using implant manufacturer's components and procedures.
 2. Evaluate the gingival height of the specific implant case and choose the RODO abutment with the appropriate gingival height.
 3. Seat the apical part of the RODO abutment on the implant analog, then hand-tighten abutment screw using the RODO Socket Driver with adapter handle.

WARNING: Ensure that the RODO Socket Driver is fully seated and perfectly aligned with the long axis of the RODO Abutment Screw, to avoid undesirable stripping of RODO abutment driver features.

4. If making a bridge, use RODO Ti Copings for Bridge and ensure that the non-engaging sides (marked on coping outer surface with "B") are oriented in the direction of implant divergence. Also, verify markings are facing opposite directions as shown.



5. Fabricate crown on RODO Ti Coping(s) using standard lab techniques.
6. Seat RODO Ti Coping(s) on model and cement crown. Finish and polish as needed.
4. If using abutment-level impression:
 1. Insert and screw RODO Regular Abutment Analog into RODO Impression Coping and pour impression model.
 2. Fabricate crown on RODO Ti Coping using standard lab techniques.
 3. Seat RODO Ti Coping on model and cement crown. Finish and polish as needed.

IV. Restoration Placement

Helpful Instruments: Loupes, dental mirror, half hollenback, explorer, cotton forceps, and hemostat.

1. If patient is wearing RODO Healing Abutment (implant level impression was taken):
 - a. Remove RODO Healing Abutment using T6 Torx Screw Driver.
 - b. Ensure that RODO abutment is clean and dry. Use air/water syringe as needed.
 - c. Seat the apical part of the Regular Abutment (300-series) on the implant, then torque the RODO abutment screw using a Socket Driver with a torque wrench. Tighten the RODO abutment screw to the torque specification by the implant manufacturer. Note you may need an adapter for your particulate torque wrench to fit the RODO Socket Driver.
2. If patient is wearing RODO Healing Cap (abutment level impression was taken), remove RODO Healing Cap by using T6 Torx Screw Driver or Smilekey®.
3. Examine RODO Abutment to ensure that abutment seal is seated correctly. If necessary, reseal the seal into the abutment groove. Use care not to damage seal.
4. Test fit restoration WITHOUT Smileloc® if needed. Place the restoration on the abutment(s) and press down to a fully seated position.
5. Check proximal contacts with dental floss, and occlusal contacts with articulating paper. Adjust as necessary.
6. Repeat steps 4 and 5 as needed. If necessary, place on model.
7. It is extremely important that the restoration fits completely on the abutment(s). Evaluate contacts and angle of abutment(s) to make certain you are 100% sure the restoration is fully seated before placing the Smileloc®.
8. Remove a new, single-use RODO Smileloc® from packaging and place RODO Smileloc® on abutment until it engages the occlusal undercut on the RODO Abutment. The wider end of the Smileloc® should be oriented towards the apical end of the implant. Use Smileloc® Seater to push into place, touch only the occlusal portion of the Smileloc® (avoid touching arms).
9. Check 4 inner arms of Smileloc® to make sure they are engaged on abutment. Inspect each Smileloc® to ensure they are free of debris. Check 4 outer arms to make sure they are in the ready-to-lock configuration.
10. Dry inside of restoration and Smileloc® abutment assembly.

WARNING: Ensure RODO Socket Driver is fully seated and perfectly aligned with the long axis of the RODO Abutment Screw, to avoid undesirable stripping of RODO abutment driver features. Torques greater than those recommended by the implant manufacturer may result in the failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.



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11. Re-examine abutment to ensure that abutment seal is seated correctly.
12. Place restoration on abutment(s) and apply downward pressure to engage restoration with Smileloc®.
13. Instruct patient to bite down on restoration using a bite stick to ensure final engagement.
14. Verify restoration is fully seated with radiograph.

C. FULL ARCH RESTORATIONS

I. Impression Taking

NOTE: Abutment level splinted impressions should be taken for RODO full arch restorations.

1. Evaluate the gingival height of each implant and choose the RODO abutment with the appropriate gingival height.
2. If using a RODO Regular Multi-Unit Series straight abutment, torque the RODO abutment using the RODO Socket Driver with a torque wrench. Tighten the RODO abutment to the torque specified by the implant manufacturer. Note that you may need an adaptor for your particular torque wrench to fit the RODO Socket Driver.
3. If using a RODO Regular Multi-Unit 17° or 30° angled abutment, seat the abutment on the implant, then torque the abutment screw using a Torx T6 Screw Driver with a torque wrench. Tighten the RODO abutment screw to the torque specified by the implant manufacturer. Note that you may

need an adaptor for your particular torque wrench to fit the RODO Screw Driver. Once the angled abutment screw is torqued into the implant, unscrew and remove the abutment handle from the abutment and discard.

WARNING: Ensure that the RODO Socket Driver or Torx T6 Screw Driver is fully seated, and perfectly aligned with the long axis of the RODO Abutment Screw to avoid damaging of RODO abutment driver features. Torques greater than those recommended by the implant manufacturer may result in the failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

4. Seat impression copings on abutments. Hand tighten accessory screws on impression copings using Torx T6 Screw Driver to secure impression copings to abutments.
5. Splint impression copings with metal wires, floss, acrylic, and composites.
6. Proceed with impression taking procedure. An open tray impression technique is recommended to facilitate removal of accessory screws.
7. Inspect impression for completeness and accuracy. Ensure that the impression copings are solidly retained within the impression. If impression is acceptable, place healing caps on abutments.



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II. Lab Procedures

1. Insert and screw RODO Abutment Analog into RODO Impression Coping and pour impression model.
2. Place Lab Smileloc® on RODO Abutment Analogs.
3. Place Multi-Unit Tall Ti Copings onto the RODO Abutment Analogs.
4. Process denture prosthesis directly over Multi-Unit Tall Ti Copings.
5. Finish and polish denture.

Note that these procedures can be modified for windowed denture techniques.

III. Prosthesis Placement

1. Remove RODO Healing Caps using Torx T6 Screw Driver.
2. Ensure that abutments are clean and dry. Use air/water syringe as needed.
3. Examine abutments to ensure that abutment seals are seated correctly. If not, realign seals in abutment groove. Use care not to damage seals.
4. Test fit WITHOUT Smileloc® if needed. Test fit the prosthesis by placing the prosthesis on abutments and press into fully engaged position.
5. Adjust prosthesis as necessary for comfort, function, and esthetics.
6. Repeat steps 3-5 as needed.

7. Remove a new, single-use Smileloc® from packaging and place Smileloc® on each abutment until it engages the occlusal undercut on the RODO Abutment. The wider end of the Smileloc® should be oriented towards the apical end of the implant. Use Smileloc® Seater to push into place, touch only the occlusal portion of the Smileloc® (avoid touching arms).
8. Check 4 inner arms of each Smileloc® to make sure they are engaged on abutments. Inspect each Smileloc® to ensure they are free of debris. Check 4 outer arms to make sure they are in the ready-to-lock configuration.
9. Dry inside of prosthesis and Smileloc® abutment assemblies.
10. Place prosthesis on abutments and apply downward pressure to engage Smileloc®. If abutment angulation does not allow straight path of draw with other abutments, rotate the prosthesis over the alignment undercuts caused by the diverging angle. Ensure that the prosthesis is fully seated onto each abutment.
11. Instruct patient to bite down on prosthesis using a bite stick to ensure full engagement of prosthesis. Check occlusion and adjust, as necessary.
12. Verify prosthesis is full seated with radiograph.

EXPLANATION OF SYMBOLS

Important Information – Read and Keep
All symbols are not applicable to all products



Manufacturer
 RODO Medical, Inc.
 2635 N. First St., Suite 218
 San Jose, CA 95134, USA
 Phone: (408) 245-7636
 www.rodomedical.com



Non-sterile



Caution
 See Instructions for Use



Consult Instructions for Use



Use before expiry date



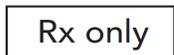
Do not re-use



Article number



Lot/batch number



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

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