

Abutment Straight, Abutment Angled, Healing Abutment, Equator Abutment, Ball Attachment, UCLA Mini Abutment

Instructions for use



Disclaimer of liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions recommendation of Solvo Implant. It is not recommended to use any product which does not included in Solvo SLA/ACT Implant Systems. Non-recommended use of products made by third parties in conjunction with Solvo Implant products will void any warranty or other obligation, express or implied, of Solvo Implant.

The user of Solvo Implant products has the duty to determine whether or not any product is suitable for the particular patient and circumstances.

Solvo Implant disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Solvo Implant products. The user is also obliged to study the latest developments in regard to this Solvo Implant product and its applications regularly. In cases of doubt, the user has to contact Solvo Implant.

Since the utilization of this product is under the control of the user, it is his/her responsibility. Solvo Implant does not assume any liability whatsoever for damage arising thereof.

Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation. **The Straight and Angled Abutment** are made of titanium.

The Straight and Angled Abutment are available for use with the SOLVO SLA and SOLVOACT Implant Systems treatment concept with guided surgery only.

Intended use:

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

The abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructs.

Indications:

Straight and Angled Abutments are pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications:

It is contraindicated to use Multi-unit Abutment in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially or Titanium.

Cautions:

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).

Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Never exceed 15 Ncm prosthetic tightening torque for the abutment screw. Over tightening of abutment may lead to a screw fracture.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Handling instructions:

Modifications of abutments could be performed using copious water irrigation. Extra-oral modification of abutment is recommended.

Clinical procedure:

1. Select appropriate abutment and check occlusal clearance.



2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Abutment Screw with Driver Torque 1,2 and Adjustable Torque Wrench prosthetic.



Materials:

All Straight and Angled Abutments and Abutment Screws: Titanium
Coping: Titanium

Cleaning and sterilization instructions:

Straight and Angled Abutments are delivered non sterile for single use and must be sterilized prior to use. Abutment must be sterilized at 121 °C for at least 20 minutes by autoclave before using. Abutment can be sterilized again.

Warning Use of non-sterile device may lead to infection of tissues or infectious diseases.

Caution: Straight / Angled Abutment is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination. Coping Abutment are delivered non-sterile for single use.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Final framework with the Coping Abutment should be cleaned and disinfected, as applicable per manufacturer's instructions, before intraoral use. **Warning:** Consult your doctor if there is a change in the performance of the device

Warning: The Abutment Implant Systemi 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 Abutment Implant Systemi in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

Caution: Coping Abutment is a single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross contamination.

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:

Devices that come into contact with the patient are treated as medical waste. Disposal of the device shall follow local regulations and environmental requirements taking different contamination levels into account.

CE 1984	Notified body number		Do not re-use
REF	Reference number		Consult instructions for use
LOT	Lot number		Consult accompanying documents
	Date of manufacture		Keep away from sunlight
	Expiration date		Keep dry
	Manufacturer Name/ Manufacturer Address		Sterile (121C-1atm-20Minutes)
	Barcode 8 680671 49		Do not use if packaging is broken



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