SOLVO SLA – SLAct Implant

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 recomended 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.
Implant: SOLVO Implant is an endosseous threaded dental implant made of titanium with SLA or SLA – Active surface.
Cover Screw: A screw placed on the superior part of a dental implant immediately after it is placed in the bone, completely covering the top of the implant and sealing it off from the bone and other debris during the healing and integration period. The screw is removed at the beginning of the next phase of the implant process. The single use screw is for one patient for one treatment only and is delivered sterile with the implant package.
Healing Abutment: Used to tissue opening for establish proper profile.
Abutment and Abutment Screw: A dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation. They are made of titanium.

Intended use:
SOLVO Implants are dental implants intended to be used in the upper or lower jaw bone anchoring or supporting tooth replacements to restore chewing function.

Indications:
SOLVO Implant System is designed for use in dental implant surgery. It replaces the natural tooth root surgically inserted into the upper or lower alveolar bone. The Implant can restore the injured tooth by connecting abutment after osseointegration with the alveolar bone.

Contraindications:
SOLVO Implants should not be placed in patients discovered to be medically unfit for the intended treatment. Prior to clinical intervention, prospective patients must be thoroughly evaluated for all known risk factors and conditions related to oral surgical procedures and subsequent healing.
Contraindications include but are not limited to:
-Patient not prepared to undergo total oral rehabilitation -Vascular conditions
-Uncontrolled diabetes
-Clotting disorders
-Anticoagulant therapy
-Metabolic bone disease
-Chemotherapy or radiation therapy
-Chronic periodontal inflammation
-Insufficient soft tissue coverage
-Metabolic or systemic disorders associated with wound and/or bone healing -Use of pharmaceuticals that inhibit or alter natural bone remodelling
-Any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene e.g. bruxism
-Uncontrolled parafunctional habits
-Insufficient height and/or width of bone
-Insufficient interarch space
-Treatment of children is not recommended until growth is finished and epiphyseal closure has occurred.
-Patients who are allergic or hypersensitive to titanium.

Warnings:
The following instructions are not sufficient to allow inexperienced clinicians to administer professional prosthetic dentistry. SOLVO Implants, surgical instruments, and prosthetic components must only be used by dentists and surgeons with training/experience with oral surgery, prosthetic and biomechanical requirements, as well as diagnosis and preoperative planning.
The implant site should be inspected for adequate bone by radiographs, palpations and visual examination.
Determine the location of nerves and other vital structures and their proximity to the implant site before any drilling to avoid potential injury, such as permanent numbness to the lower lip and chin.
Absolute success cannot be guaranteed. Factors such as infection, disease, and inadequate bone quality and/or quantity can result in osseointegration failures following surgery or initial osseointegration.
Dental implants must not be altered in any way. Implant mobility, bone loss or chronic infection may indicate implant failure. Do not reuse the implants. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection. Implant cannot be re-sterilized.
The SOLVO SLA-SLAct 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 SOLVO SLA-SLAc Implant Systemi in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

Cautions:
Procedural Precautions, Surgery: All efforts must be made to minimize damage to the host tissue, paying special attention to thermal and surgical trauma and to the elimination of contaminants and sources of infection. The surgical procedure requires a high degree of precision and care, and the limits for acceptable tissue handling are must narrower than in general oral surgery. Any divergence from the principle of least possible trauma at implant installation increases the risk of failure to establish osseointegration.
All drilling procedures should be performed at approximately 800~1500 rpm. Pre-tapping (threading of the bone) and implant placement should be accomplished at very low speed (25~30 rpm) or manually. All drilling and pretapping procedures require the use of dedicated, sharp instruments under constant and profuse irrigation for cooling. Implants are ideally installed in a stable manner; however, excessive insertion torque (greater than 40-50 Ncm) to overcome bone resistance may lead to damage to the implant; fracture or necrosis of the bone site (see appropriate clinical manuals). All instruments used in surgery must be

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Procedural Precautions, Prosthetics: Especially important is proper stress distribution: passive adaptation and fitting of the bridge to the implant abutments; adjusting occlusion to the opposing jaw; avoiding excessive transverse loading forces, particularly in immediate loading cases. If the prosthesis metal substructure is made of gold ally, this should have a high gold content. Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.
Caution for Patient: To keep completely the oral hygiene. Do not apply too much bite force until final prosthetic placement.

Surgical Procedure:
1. During drilling procedures bone quality should be considered (please see table)
Recommended drill sequences based on bone quality. Drill data are stated in mm and the drill diameters listed within brackets denote widening of cortex only.

Bone Type	Final Drill				
	Ø 3,0 Fixture	Ø 3,5 Fixture	Ø 4,0 Fixture	Ø 4,5 Fixture	Ø 5,0 Fixture
Soft	Ø 3,0 Twist Drill	Ø 3,0 Twist Drill	Ø 3.5 Stopper Taper Drill	Ø 4.0 Stopper Taper Drill	Ø 4.5 Stopper Taper Drill
Normal	Ø 3,0 Twist Drill	Ø 3.5 Stopper Taper Drill	Ø 4.0 Stopper Taper Drill	Ø 4.5 Stopper Taper Drill	Ø 5.0 Stopper Taper Drill
Hard	Ø 3,0 Twist Drill	Ø 3,5 Hard Taper Cortical Drill	Ø 4,0 Hard Taper Cortical Drill	Ø 4,5 Hard Taper Cortical Drill	Ø 5,0 Hard Taper Cortical Drill

Drilling must proceed at high speed (max. 2000 rpm) under constant and profuse external irrigation by sterile saline at room temperature.

Depth measurement system: the depth gauge has a true depth measurement system. L=15 mm drills are marked to prepare the site to the correct depth and obtain a secure and predictable position.
Caution: Twist Drills and Stopper Taper Drills extend up to 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures (please see image for drill reference lines).

Image shows Twist Drills and Stopper Taper Drills 7–15 mm and implant 13 mm.

Note: The marks on Twist Drills and Stopper Taper Drills indicate actual millimeter length and correspond to the implant collar. Final vertical positioning depends on several parameters, including esthetics, tissue thickness and available vertical space.

2. Prepare implant site. When using a flapless approach add-on soft tissue height to drill depth.
3. Measure the final depth of implant site for applicable implant length using depth probe with same measurements as Twist Drills and Stopper Taper Drills.
4. Open the implant package and pick up the implant from inner casing by applying light pressure on the implant driver and carefully turn the implant sleeve counter clockwise until implant driver is fully seated. SOLVO implants are ideally installed with low speed, max 25 rpm, using drilling device or by hand using surgical driver.

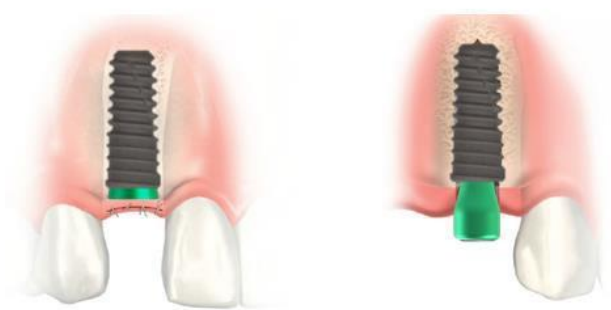
5. Place and tighten the implant. For SOLVO Implant 3.0 use maximum 45 Ncm installation torque and for SOLVO 3.5, 4.0, 4.5 and 5.0 use maximum 70 Ncm installation torque.

Caution: Never exceed insertion torque of 45 Ncm for a SOLVO 3.0 implant and 70 Ncm for SOLVO 3.5, 4.3, 5.0 and 5.5 implants. Due to the narrow implant diameter and narrow implant abutment connection the maximum insertion torque for SOLVO 3.0 differs from the entire SOLVO assortment. Overtightening an implant may lead to damage of the implant, fracture or necrosis of the bone site. If a Mount Driver is used to insert the implant, special care needs to be taken to avoid over tightening.

– Place screw tap into prepared implant site using low speed (25 rpm).
– Apply firm pressure and begin rotating the screw tap slowly. When the threads engage, allow screw tap to feed without pressure to defined depth.
– Switch the drill device with handpiece to reverse mode and back the screw tap out

Continue with implant installation until desired position is achieved using max 45 Ncm installation torque for SOLVO 3.0 implant or max 70 Ncm for SOLVO 3.5, 4.0, 4.5 and 5.0 implants.

6. For Immediate Function, the implant should be able to withstand a final torque of 35–45 Ncm for SOLVO 3.0 implant and 35–70 Ncm for SOLVO 3.5, 4.0, 4.5, and 5.0 implants.
7. Depending on surgical protocol of choice, place a cover screw or healing abutment or abutment and suture.



Materials:
SOLVO implant: titanium
Cover Screw: titanium
Twist Drills, Stopper Taper Drills, and Hard Taper Drills stainless steel.

Cleaning and sterilization instructions:
SOLVO Implants are delivered sterile for single use only prior to the labelled expiration date.
Warning: Do not use device if the packaging has been damaged or previously opened.
Caution: Implants are single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

All Drills are delivered non sterile and intended for re-use. Prior to re-use, clean, disinfect and seal the product in a pouch and steam sterilize using the recommended parameters.
Warning: Consult your doctor if there is a change in the performance of the device
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		Do not re-sterilize
LOT	Lot number		Consult accompanying documents
	Date of manufacture		Keep away from sunlight
	Expiration date		Keep dry
	Manufacturer Name/ Manufacturer Address	STERILE R	Radiation Sterilized
	Barcode		Do not use if packaging is broken
	Consult instructions for use		

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