Multi Unite 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 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 Implant products will void any warranty or other obligation, express or implied, of Implant.
The user of Implant products has the duty to determine whether or not any product is suitable for the particular patient and circumstances.
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 Implant products. The user is also obliged to study the latest developments in regard to this Implant product and its applications regularly. In cases of doubt, the user has to contact Implant.
Since the utilization of this product is under the control of the user, it is his/her responsibility. 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 Multi-unit Abutment is made of titanium.
The Multi-unit Abutment is available for use with the SOLVO SLA and SOLVO SLAct 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. Multi-unit Abutment in combination with endosseous implants are indicated for multiple unit reconstructions when screw retained prosthetics is preferred.

Indications:
Multi-unit Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

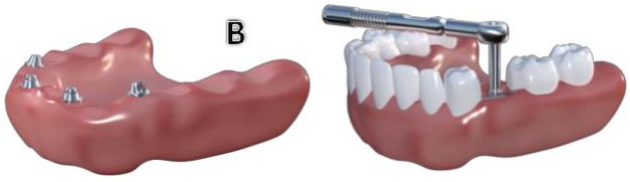
Contraindications:
It is contraindicated to use Multi-unit Abutment in:
– Patients who are medically unfit for an oral surgical procedure.
– Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
– Patients who are allergic or hypersensitive to commercially or Titanium.

Cautions:
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.
It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
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.
Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.
All instruments and tooling used during procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.
Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is recommended to use a rubber dam in order to prevent inhalation of loose parts.
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.
Never exceed the recommended maximum prosthetic tightening torque for the abutment screw (see table 1). Overtightening of abutment may lead to a screw fracture.

Handling instructions:
Clinical procedure:
1. Place appropriate abutment (A). Use plastic holder to facilitate the insertion It is recommended to verify the final abutment seating using radiographic imaging.

A

2. Tighten the abutment using Manual Torque Wrench prosthetic (B).
Caution: Never exceed recommended tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.



Materials:
All Multi Unite Abutments and Abutment Screws: Titanium
Holder for Multi Unite Abutment: Titanium
Coping: Titanium
Cleaning and sterilization instructions:
Multi-unit Abutment is delivered non sterile for single use only prior to the labelled expiration date. Abutment must be sterilized at 121 ˚C for at least 20 minutes by autoclave before using. Abutment can be sterilized again.
Warning: Do not use device if the packaging has been damaged or previously opened.
Caution: Multi-unit Abutment is a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.
Coping Multi-unit Abutment are delivered non-sterile for single use.
Final framework with the Coping Multi-unit Abutment should be cleaned and disinfected, as applicable per manufacturer's instructions, before intraoral use.
Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.
Warning: Consult your doctor if there is a change in the performance of the device
Warning: The Multi-unit Abutment 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 Multi-unit Abutment are 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	NON STERILE	Sterile (121℃-1atm-20Minutes)
8 680671 490687	Barcode		Do not use if packaging is broken

Manufacturer:
SOLVO UK Implants CO. LTD.
60 Millmead Business Center Mill Mead Road
N179QU London, England
E-Mail: info@solvodental.com Web: www.solvodental.com

TF01_2.2-2.2 – 24.09.2018 / Rev.02 / 15.10.2021