Gebrauchsanweisung:
SWISS VEL-Ri DENTAL IMPLANT SYSTEM

Bestimmungsgemässer Gebrauch
Swiss Vel-Ri Zahnimplantate werden in den Kieferknochen implantiert. Sie bieten eine Grundlage für den prothetischen Aufbau für den Einzelzahnersatz oder Brückenkonstruktionen. Das Implantat wird in der Einheilzeit teilbelastet oder mit einem temporären Aufbau versorgt

Warnung
Swiss Vel-Ri dental Implantate dürfen ausschliesslich von trainierten und erfahrenen Zahnärzten oder Implantologen eingesetzt warden.
Patienten müssen vor dem Eingriff untersucht warden, ob der mentale udn physische Zustand einen derartigen Eingriff zulässt. Die Untersuchung der Mundhöhle und Zustand der Zähne muss gibt Aufschluss darüber, ob das erwartete Resultat des Eingriffs beinträchtigt werden könnte. A close cooperation between the surgeon, the prosthodontist and laboratory technician is key for a successful procedure. Finally, procedures and a instructions for use have been developed specifically for dental implantologists, oral prosthodontics, and laboratory technicians.

Description:
Swiss Vel-Ri Dental Implants are manufactured from bio compatible titanium and titanium alloy and abutments from titanium or titanium alloy. Swiss Vel-Ri Dental Implants and abutments include various surface treatments and coatings. Other restorative components are manufactured with titanium or titanium alloy, stainless steel and a variety of polymers. For specific product description refer to individual product labels.

Indications for Use:
Swiss Vel-Ri Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or as a terminal or intermediary abutment for fixed or removable
bridgework and to retain over dentures.

Additional Indications:
Swiss Vel-Ri dental abutments and overdenture bars are intended as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. These are intended to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cemented to the abutment.
PEEK Abutment are intended as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. These are intended to support single and multiple unit prostheses in the mandible or maxilla for up to 180 days during end osseous and gingival healing, and are for non occlusal loading of single and multiple unit provision at restorations. The prostheses can be screwed and/or cemented to the abutment. These temporary posts and cylinders require a minimum inter arch space of 6mm and a maximum angulation of 15°. These also allow for occlusal loading of single and multiple unit restorations of integrated implants for guided soft tissue healing. The quick bridge provisional components are intended to be mated with Swiss Vel-Ri abutments for use as an accessory to end osseous dental implants to support a prosthetic device in a partially or fully edentulous patient.

Contraindications:

Contraindications normally associated with elective oral surgery should be observed. When selecting patients. These include, but are not limited to:

Clotting disorders, e.g., anticoagulant therapy, inherited or acquired clotting disorders; Prolonged bone and wound healing periods, e.g., caused by uncontrollable diabetes, metabolic or systemic disorders that affect bone or wound healing; general restrictions on elective surgery apply to smokers and patients suffering from alcohol abuse; Immune-suppressing therapy, e.g., chemotherapy and radiation therapy; Intraoral infection or inflammation e.g., periodontitis; Uncontrollable parafunctional habits, e.g., bruxism ; Inadequate oral hygiene; Patient's being not prepared to undergo further oral rehabilitation; untreatable occlusal/articulation dysfunctions and insufficient inter- arch space; Insufficient height and/or width of bone and insufficient soft tissue volume

Side effects – Complications

Side effects: pain, oedemia or hematoma, speech difficulties, gingivitis, temporary anaesthesia or paraesthesia, temporary mastification problems.

Complication: The following complications have been observed with endosseous implants:

Postoperative bleeding; Necrosis due to inadequate cooling; Infection; Suture dehiscence; Insufficient osseointegration /Implant loss; Periodontal problems due to inadequate width of attached soft tissue; Fixation screw breakage due to over-tightening; Swallowing or aspiration of the small components; In rare cases, implant breakage can occur under extremely unfavorable loading conditions (prosthetic overload, heavy bone resorption). ^

Warnings:
Excessive bone loss or breakage of a dental implant or restorative device may occur when an implant or abutment is loaded beyond its functional capability. Physiological and anatomic conditions may negatively affect the performance of dental implants. The following should be taken into consideration when placing dental implants:
- Poor bone quality
- Poor oral hygiene
- Medical conditions such as blood disorders or uncontrolled hormonal conditions.

It is recommended that small diameter implants not be restored with angled abutments in the molar region.
Mishandling of small components inside the patients mouth carries a risk of aspiration and/or swallowing.
Forcing the implant into the osteotomy deeper than the depth established by the drills can result in: stripping the driver hex interface inside the implant, stripping the driver, cold welding of the mount-driver interface to the implant, or stripping the walls of the osteotomy that may prevent an effective initial implant fixation.

Precautions:
For safe and effective use of Swiss Vel-Ri Dental Implants, abutments and other surgical and restorative dental accessories, these products or devices should only be used by trained professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration.

Sterility:
All dental implants and some abutments are supplied sterile and are sterilized by an appropriate validated method. Refer to individual product labels for sterilization information; all sterile products are labeled "STERILE". All products sold sterile are for single use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave except where instructions to do so are provided on the product label, in the Surgical Manual, in the Restorative Manual or in any additional marketing literature for that product. Products provided non-sterile must be cleaned and sterilized according to the directions found in Surgical Manuals prior to use.

Procedural Precautions, Surgery:
For a detailed explanation of the procedural precautions refer to the Surgical Manual. During the planning phase, it is important to determine the vertical dimension, the actual space available between the alveolar crest and the opposing dentition, in order to confirm that the available space will accommodate the proposed abutment and the final crown restoration.
This information varies with each patient and abutment; therefore it should be carefully evaluated before placing any dental implant. The final prosthesis should be designed prior to the placement of the dental implant. Utilize continuous irrigation with a cool, sterile irrigating solution to avoid excessive damage to the surrounding tissue and to prevent compromising osseointegration. This is mandatory during gall procedures. Avoid excessive pressure during preparation of the bone site. As the drilling speed varies based on the instrument and the surgical procedure, recommendations for speed can be found in the Surgical Manual. Only sharp instruments of the highest quality should be used for any surgical procedure involving bone. Minimizing trauma to the bone and surrounding tissue
enhances the potential for successful osseointegration. In order to eliminate contaminants and other sources of infection, all non-sterile devices should be cleaned and/or sterilized prior to use, per the instructions on the individual product labels.

Procedural Precautions, Restoration:
The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's bone density at the time of the surgical procedure.
Excessive force applied to the dental implant should be avoided during the healing period. Proper occlusion should be evaluated on the implant restoration to avoid excessive force.

Swiss Vel-ri Standard System: abutments, healing abutments, and Instruments

Description of the components

Healing abutment
Allows to shape the gingiva after implant uncovery, is used for transgingival healing.

Straight and angled abutments
Various abutments that are a part of Swiss Vel-ri System allow further orthopedic care following the osseointegration.

Fixation screws for abutments
Fixation screws secure abutments on implants. Transfers for open or closed tray impressions are used to transfer the abutment position to the laboratory models.

Transgingival ring
Transgingival ring is used for gingival forming. It can also be used for provisional orthopedic restoration on straight and angled abutments (maximum period: 30 days).

Abutment placement
Abutments are screwed in with a ratchet (35 N*cm torque). Use of excessive force/torque can lead to the thread or implant damage. When preparing the components, saliva and, if necessary, dust must be removed from the patient’s mouth.

Straight abutment placement
Select an abutment according to the used healing abutment and prosthetic situation. The abutment is screwed in with a rotating key insertion key. Seal-off the abutments inner thread until the superstructure is placed.

Standard angled abutment placement
Select an abutment according to the used healing abutment and prosthetic situation. The abutment is screwed in the implant with the positioning key. Tighten the fixing screw with the hex screwdriver.

Storage and Handling:
Devices should be stored in original package, dry and at room temperature. Refer to individual product labels and the Surgical Manual for special storage or handling conditions.

Cleaning
The components can be mechanically cleansed with a soft brush in a usual solution for dental components.

Autoclaving
Autoclaving to be performed by saturated steam in an autoclave for 18 minutes at 135 °C or for 21 minutes at 121 °C (250 °F).

USED MEDICAL SYMBOLS

	Single-use, disposable, do not use more than once
	See instructions/package information

	Use before this date
LOT	Loading code, serial number
	Radiation-sterilized
	Manufacturer
REF	Item number, order number

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1.1 Lagerung, Reinigung, Sterilisation

Achtung: Suprakonstruktionen und deren Zubehör wird unsteril geliefert und müssen mit den üblichen klinischen Methoden gereinigt, desinfiziert und sterilisiert sein.

1.1.1 Lagerung

Die Komponenten müssen in der Originalverpackung bei Zimmertemperatur und trocken aufbewahrt werden.

1.1.2 Reinigung

Die Komponenten können mit einer weichen Bürste in für Dentalkomponenten üblicher Lösung mechanisch gereinigt werden.

1.1.3 Desinfektion

Desinfektion mit in der Klinik freigegebem Desinfektionsmittel, anschliessend dreimalige Spülung mit Reinstwasser und Trocknen mit einem fuselfreiem Tuch. Das Trocknen von Komponenten/Instrumenten mit Löchern, soll mit einem Luftstrom durchgeführt werden.

1.1.4 Sterilisation

Die in Sterilisationspakete verpackten Komponenten sollen mit dem Datum und Sterilisationsindikatoren versehen werden. Die Sterilisation erfolgt im Autoklav bei 134°C/18min bei Sattdampf oder bei 121°C/20min bei Sattdampf.

1.2 Erläuterungen, der auf der Produkte-Etikette verwendeten Symbole

	nicht wiederverwenden, single use
	Anleitung/Packungsbeilage beachten
	verwendbar bis Datum
LOT	Chargen-Code, Lot-Serialnummer

STERILE R	Steril-Symbol Strahlensterilisation
	Hersteller
REF	Artikelnummer, Bestellnummer

Für weitere Informationen kontaktieren Sie
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