Instructions for Use

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Description:

The product is a dental supra structure for Single- or Multiple implants for removable or fixed prosthetics.

Intended use:

The product is a dental supra structure for Single- or Multiple implants for removable or fixed prosthetics. The product attaches directly to the endosseous dental implants with clinical screws and provides a basis for restoration. The Supra Solutions dental supra structure for Single- or Multiple implants for removable or fixed prosthetics are designed and made individually to fit the individual requirements for each patient. The products are placed intra-orally and could be in contact with the mucosal membranes. Duration of use can be multiple years.

Indications:

The dental supra structure for Single- or Multiple implants is indicated for use as a fixed or removable prosthetic solution that attaches to implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function or any other dental function.

Contraindications:

– Cases with lengths or dimensions that exceed the maximum limits *(Note: this is a relative contraindication for which the user could decide that the product still is beneficial for the patient despite the risks. Supra Solutions 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 judgement or practice).*

– Bruxism.

Note:

Please refer to the original implant manufacturer's instruction for use, with regards to the implants contraindication as well as tooling and torque when restoring.

Cautions:

General:

– Products made from Titanium alloy Ti6AL4V-ELI may impact patients who are allergic or hypersensitive to Titanium alloy Ti6AL4V-ELI.
– Products made from Cobalt-Chromium alloy may impact patients who are allergic or hypersensitive to Cobalt-Chromium.

It is a must that clinical screws are used when securing the restoration into the patient's mouth. Please refer to the original implant manufacturer's instruction for use, for which compatible clinical screw to use including tooling and torque when restoring the implant.

It is recommended, that no modifications are made to the implant bar or its seating area as this may affect/hinder its strength or fit.

Side Effects

During normal use of the dental supra structure for Single- or Multiple implants for removable or fixed prosthetics, its function towards the prosthetic solution may decrease by wear. In this case counterparts or spare parts might be available for recovering the products original function again.

Instruction for clinician:

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Working the first time with a colleague, experienced with the new device/ treatment method, avoids eventual complications.

Procedural precautions:

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment. Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

Impression implant or abutment level open tray technique:

A custom-made open impression tray is essential for an accurate impression and for access to the impression coping guide pins. A wax lid can cover the opening.

Clinical procedure:

Obtaining impression (work instructions below may vary by clinician's insights):
– Use a custom made rigid impression tray with occlusal screw access holes following an open tray impression protocol.
– Syringe an elastomeric impression material around the impression copings intraorally and take an impression.
– After complete setting of the impression material unscrew the impression coping screws and remove the impression tray.
– In addition, take preliminary interocclusal records.
– Inspect the impression for discrepancies and send to the laboratory.

Laboratory procedure:

Fabricating definitive cast, registration records:
Upon receiving impression* (work instructions below may vary by technician's insights):
– Confirm the position of the implant level impression coping and carefully screw the implant replica onto the implant impression coping.
– Pour the impression with low expansion dental stone and fabricate a master model with soft tissue mask. Allow proper curing time of the model to ensure no dimensional changes.
– The soft tissue preferrably must be at least 2 mm thick so that the implant replicas stick up at least 2 mm from the plaster model.
– Confirm all implant replicas are set firmly in the model (no movement).

* Note that Supra Solutions products are manufactured to very accurate tolerances. It is critical that the proper impression copings, impression materials and laboratory components are used.

Optional: Fabricate model verification jig:

– Make an acrylic framework using non-engaging temporary abutment(s).
– Send to clinician to place in patient mouth to verify model.
– Use an acrylic resin base (optional: integrate provisional abutment cylinders) and fabricate a wax-rim for interocclusal records to properly orient the models in the articulator.

Clinical procedure (if applicable):

Model verification:
– Place the verification jig into the patient's mouth to verify fit.

Intraoral jaw relation records:

– Use the wax-rims and (optionally a facebow) for jaw relation records.

Laboratory procedure:

Fabricating set-up:
Upon receiving back the verification jig and wax bite-rim:
– If available, articulate models using wax bite-rim (and facebow).
– Make a diagnostic tooth set-up on the definitive cast and send it to the clinician for try-in and verification.

Clinical procedure:

Intraoral try-in of set-up:
– Try-in the diagnostic tooth set-up to verify functional and esthetic parameters.

Laboratory procedure:

A) Laboratory procedure (in the workflow of in-lab scanning):
Design of the desired dental supra structure:
– Select and carefully mount the appropriate model scanbody or scanbodies onto the definitive cast to facilitate the capturing of the correct depth and orientation of the implant into the front-end software, prior to designing the implant bar.
– Scan the diagnostic tooth setup (if available) & definitive cast with pre-mounted model scanbody or scanbodies using, according to the tutorial found within the software.
– Once scanned, open the relevant CAD software and design the supra structure according to the patient's clinical needs (only applicable if laboratory designs by itself).
– Send scan data or design data file to Supra Solutions.
– Upon return check for precision of fit on the definitive cast.

Recommendations:

– Regularly check scanbodies for damage/imperfections under a loupe or microscope.
– Clean scanbodies and replicas and remove any foreign material (e.g. CAD spray, finger oils, stone chips/dust).

B) Laboratory procedure (centralized scanning):
When sending your implant bar case to Supra Solutions for centralized scanning or design, it is necessary to complete the appropriate order form, and carefully wrap and ship the required materials. For further information and forms visit: www.supra-solutions.com

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

Manufacturer: Supra Solutions B.V., Mandenmakerstraat 130, 3194DG Hoogvliet, The Netherlands

Canada license exemption: Please note that no products have been licensed in accordance with Canadian law.
Prescription device: Rx only
Caution: Federal law restricts this device for sale by or on the order of a licensed healthcare practitioner.

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