REVOIS® Dental Implantat System
Instruction for Use (IFU) Sterile surgical instruments and tools

1. Product description
These instructions for use apply to the under (11.) listed sterilely provided surgical instruments and tooling for the REVOIS® Dental Implantat System. Product specifics such as size are shown on the packaging labels. The full list of products of the REVOIS® Dental Implantat System, instruction for cleaning, disinfection and sterilization for those instruments that may be used more than one time, service materials and quality certificates can be found at www.revois-dental.com.
Products are made of surgical steel, titanium grades 2, 4, or 5, gold alloy (Ceramicor®, Elitor®).

2. Indication
The REVOIS® Dental Implantat System is indicated for oral implantation into tooth spaces or the edentulous jawbones, serving as a fixation for prostheses (single tooth replacement, fixed or mobile pontics, overdentures or full dentures.
By this, REVOIS® supports the vital denture function and serves as well as base for a functional and highly aesthetic rehabilitation.

3. Field of use
The surgical instruments and prosthetic tools of the REVOIS® Dental Implantat System are used to prepare for insertion, insert, maintain & connect, or remove a REVOIS® implant. For specific indications for REVOIS® implants, please refer to the respective instructions for use that can be found on our website. If you would like to receive a printed copy, please contact our customer service.
Drills and bone taps are use to prepare the cavity for the implant. Use of conical drill and bone taps are mandatory for bone density D I, and optional for D II – IV (after Lekholm & Zarb).
Drill stops may be used with the precision pilot drills, but are not needed with conical drills or bone taps which are rounded at the tip.

4. Contraindications
Any disease questioning elective oral surgery. Further on: childhood (incomplete bone development); diseases and circumstances which may negatively impact the healing and performance of an implant such as insufficient oral hygiene, drug- or nicotine abuse; alcoholism; dysregulated metabolic disorders such as diabetes mellitus affecting bone metabolism or osteoporosis or therapy with bisphosphonates; allergy or hypersensitivity to Titanium; any kind of immune deprivation or deficiency, e.g. during therapy with cortisone or cytostatics; pregnancy or lactation; generalizing diseases of the connective tissue or the bones; rheumatological diseases; increased affinity to develop hemorrhage; mental disorders; diseases of heart, liver, kidney or the blood. Do not use instruments / tools from other implant systems which may not fully fit our products.

5. Side effects and interactions; Complications
As for any surgery, the patient should avoid physical stress after undergoing surgery / insertion of an implant. The Implantologist has to explain to the patient the possible risks, side effects, interactions, precautions and complications associated with the planned oral surgery and implantation.
This includes e.g. transient and –rarely- persistent paresthesia in the areas of lower lip and chin following mandibular surgery, and numbness of the perinasal tissue following maxillary surgery; further on pain, swelling, affection of speech and gingival inflammation.
In addition, bone height may reduce associated with loosening of the implant, local or secondary systemic infections may develop incl. the development of abscesses or fistula; Impairment of surrounding teeth, roots or nerves; fractures of the prostheses, of the implant or of the bone; aesthetic impairment; gingival hyperplasia.
Instruct your patient for a best possible oral hygiene.

6. Warnings and Precautions
General
All surgical and prosthetic components are relevant for osseointegration and implant survival and therefore must only be used by a trained specialist. If you would like to receive information about training opportunities, please contact us.
Each individual patient requires full anamnesis and examination with regards to his radiologic, mental and physical status, including teeth, soft- and hard tissue defects which could impair the result of an implantation. A close collaboration between Implantologist / Surgeon, Dentist and Dental technician is essential for an optimal functional and aesthetic result.
Other precautions
To grant the sterility of the implant make sure the blister is not damaged and the expiry date has not passed.
The trauma to the surrounding tissue and the implant site should be minimized as possible. In particular, overheating, multiple surgical trauma such as unnecessary drilling, and any risk for infections need to be strictly avoided.
Otherwise, the risk for a delayed or incomplete osseointegration and secondary periimplantitis will increase. For the different drills, please follow the recommended U/min (following table):

	U/min	REVOIS® PRO	REVOIS® compact
Gingival punch	25 – 30	X	X
3-sided drill or rose burr	800	X	X
Precision Pilot drills (optional: drill stop)	up to 1000	X	X
Conical drills	300 – 600	X	-
countersink	300-600	-	X
Bone taps	25-30	X	-
Implant insertion	-	Manuelly & torque wrench	Manuelly & torque wrench

Drilling and bone tapping require the use of appropriate, sharp and sterile instruments in combination with sufficient cooling (e.g. isotonic sodium chloride solution). Do not use instruments from other implant systems. Implants should be inserted always aiming for primary stability. All tools and instruments need to be inspected for proper function prior to their use and have to be used in accordance with the instructions for use of the manufacturer to avoid damage to implants, tissue, or other structures.
Due to the small size of the different components take special care that they must not be swallowed or aspirated by the patient. As technically possible, REVOIS® components have a whole to connect with floss that can be held by hand.
After implant insertion the Implantologist needs to decide the time point of first load based on bone quality and primary stability (defined as out-torque resistance of 20 Ncm).

With one or more of the following findings reconsider the risk / benefit ratio of a the intended therapy with a dental implant, and assure the patient also understands such: Osteopenia and insufficient bone quality for any other reason, in relation to intended implant diameter and length; metabolic disease such as diabetes mellitus or disease locally or generally affecting bone metabolism; drug- or nicotine abuse; alcoholism; bruxism; hematologic disease; HIV; autoimmune disease; therapy with a blood-thinning medication; past or planned irradiation therapy of head and neck; incapability of the patient for any reason to maintain the necessary oral hygiene.
The performance of a titanium dental implant may further be impaired by infections, in particular by periodontitis, chronic infections of the maxillary sinuses, untreated nasal airway abnormalities; facial neuralgia; a dehiscence requiring a bone

transplant; further on formation of abscess or fistula; suppuration; perforation of maxillary sinus or the basis of the mandibular jaw, root of tongue or lower alveolar channel; bleedings, hematoma or edema; infections as well as local or systemic allergic reactions; neuralgic pain, paresthesia. In such cases we recommend to complete the therapy and healing process of such conditions first before the treatment with a dental implant.

7. Delivery and Preparation for Use; Reconditioning

Those surgical Instruments delivered non-sterile and the prosthetic tools and accessories of the REVOIS® Dental Implantat System are delivered washed and disinfected. If they are supposed to be used sterile, please follow the instructions below.
Some surgical Instruments are delivered sterile (sterilized after washing and disinfection) and are ready for use.
Sterile instruments indicated for single-use only are labeled with the respective pictograms. They may be used only until the expiry date. reconditioning is not recommended, (re)-sterilization is not possible.
Products delivered as sterile but having a damaged sterile barrier must not be used and have to be discharged.
Products to be sterilized prior to use (*) or to be re-sterilized in case of multiple use (++) are marked under (11.) as beforementioned.
Reconditioning and sterilization has to follow a validated process. All applicable laws have to be followed.
Reconditioning should be performed immediately following use of the instruments. By rinsing in a cleansing fluid such as Komet DC1 you can avoid protein fixation and ease the further cleaning process. It is recommended to use an automated washer for further cleaning and disinfection. For details of the reconditioning process validated for REVOIS please refer to our website www.revois-dental.com.
After disinfection, all instruments and tools must be inspected for proper function and necessary calibration. Products with damage to their coating or cutting edges, deformations or oxidized surfaces and should not be used again, and have to be discharged in accordance with applicable laws.

Choose an appropriate packaging for sterilization. Single instrument packaging: Ensure the sealing is not tense. Set packaging: Put the instruments into a sufficiently large tray. Protect the tray with an appropriate sterilization bag.
Sterilisation: Vacuum steam sterilisation at 134°C in an autoclave with specifications fulfiling DIN EN 13060, following a validated process:

- Fractioned pre-vacuum
- Sterilisation temperatur 134 °C
- Time at temperature: 5 minutes min. (full cycling)
- Drying time: 10 minutes min.

To avoid instrument staining and oxidation, steam must be free of any oxidative substances.
Do not overload autoclave. Follow instructions for use of the manufacturer of the autoclave.

8. Storage

Please store the components of the REVOIS® Dental Implantat System in their original packaging, at room temperature, dry and protected from sunlight.
Any other form of storage may impact the sterile barrier and therefore endanger patient and the success of the procedure.
Use of the sterile product after the expiry date may lead to infections.

9. Product variants and compatibility

The REVOIS® Dental Implantat System consists of three different, and in-between each other not compatible product variants: **REVOIS® Classic, PRO und compact.**
All three product variants are made of Titanium and therefore have an excellent biocompatibility
For the implantation and prosthetic work only use the components of the respective product line chosen. For a complete overview of the various parts please refer to the User Manual available at www.revois-dental.com or contact us to receive your personal copy.

REVOIS® Classic consists of prosthetic accessories and tools for the between 2004 and 2011 commercialized REVOIS® implants.
REVOIS® PRO implants (Titanium grade 4) are delivered as a pre-assembled set consisting of implant, impression post and impression screw (open tray), and cover screw. REVOIS® PRO implants are available in the following sizes:

Length (mm)	Diameter (mm)	Color code
9, 11, 13, 15	3.8	Green
9, 11, 13, 15	4.3	Blue
9, 11, 13, 15	5.0	yellow

REVOIS® PRO implants, accessories, drills and tools are color-coded in accordance with the respective implant diameter. There is a broad range of prosthetic components available allowing the use of REVOIS® PRO for almost every patient.

REVOIS® compact consists of small one-piece implants (Titanium grade 5) delivered as pre-assembled sets consisting of implant, impression post and impression screw (open tray). REVOIS® compact implants are available in the following sizes:

Length (mm)	Diameter (mm)
7	3.0
9	3.0
11	3.0
13	2.2

The 2.2 mm REVOIS® compact implant is designed as a temporary implant where the need for provisional restauration is high but the loading of the final implant site is still not possible. REVOIS® compact is of particular benefit for single tooth replacement with small geometries (e.g. the enosseal replacement of the teeth 12/22/32/31/41/42) as well as for easy fixation of individual or standardized bar systems such as the SFI-BAR®, pontics, or overdentures.

Designed as an open system, the REVOIS Dental Implantat System allows to connect with SFI-Bar®, Dalbo®, Locator®, and CM LOC®, to meet patient needs and implantologists` preferences in almost every situation.
For an overview on all components and their use, please refer to the REVOIS® Dental Implantat System User Manual available at www.revois-dental.com, or contact us for your personal printed copy.

10. Use of Product / Procedure

The tools for the preparation of the implant site, implant cavity, insertion and removal of an implant are the gingival punch, the rose burr or 3-sided drill; the measuring device / open-ended wrench, precision pilot drills with optional drill stops, conical drills and bone taps, hex tool, handle, angle, thumb wheel, removal tool, and a torque wrench (20-70 Ncm).
All recommended REVOIS® drills and tools are designed or selected for their precise fitting to the respective REVOIS®

implants. Please be aware that the use of other tools or drills may impact the intactness of the products and prohibit us to take liability for any resulting functional or material defects.
Tools have to be regularly maintained (and as appropriate calibrated), and in accordance with the instructions of the respective manufacturer, to be cleaned, disinfected and sterilized.
Implants and accessories are for single use, only.

Prior to surgery, the implantologist has to verify through an appropriate method, e.g. radiography, that the bone quality at the intended implant size is sufficient relative to the intended implant size. As control for a correct implant placement, a subsequent radiography is recommended, as well.
If primary stability cannot be achieved, the time required for osseointegration and to the first load of the implant varies between individuals. It is at the discretion of the implantologist to define such time point.
The REVOIS® Dental Implantat System may be used in one-time technique immediately loading the implant after insertion (if primary stability is reached), or staged technique, after osseointegration.

Insertion:
After preparation of the gingiva, roughen the implant site by using the 3-edged drill or the rose burr to ensure the safe use of the precision drills with or without drill stops. With these precision drills –use the ones appropriate for the respective implant size- prepare the cavity in direction and depth.
The REVOIS® precision drills are labeled with marks coding for the drill depth, and carry adapters to be used with the REVOIS® drill stops.
If using REVOIS® PRO, the cavity may then further be prepared in form and width with the conical drills, and subject to the bone density, finally with the bone taps mimicking the form of the implants.
The REVOIS® PRO conical drills and bone taps have a flat tip avoiding the risk of unnecessary depth drilling and subsequent injury of the underlying tissue. Their use is mandatory for hard bone (D I), and optional for D II to D IV. The implant-size specific REVOIS® PRO bone taps are color coded in line with the color code of the implant size.
After preparation of the bone cavity remove the sterile blister from the carton box. Always applying aseptic working procedures, ensure that the Tyvek®-blister is not damaged and expiry date has not passed. Remove the Tyvek®-foil covering the implant-set. Sterility prior to the expiry date is ensured if the sterilization indicator on the Tyvek®-foil is reddish.

REVOIS® PRO: Remove the insert blister by using the recessed grips. Touching the impression screw only, remove the premounted set and insert the implant into the prepared implant cavity screwing manually.
Then remove the impression screw and post (you may keep both for re-use for the open-tray impression procedure later on). Using insertion piece and torque wrench screw (turn right) the implant into its final position not exceeding forces of 30 Ncm. Ensure the insertion piece is fully fitting onto the implant. The typical final position of the REVOIS® PRO implant upper edge is 0.5 - 1 mm below the bone crest level. For the open-tray impression (re-)place impression post and screw onto the finally inserted implant. The impression post functions as impression negative and remains in the impression mass. You may hand over the impression mass together with a laboratory analogue to a dental lab to develop the chosen prosthetic solution. CAD/CAM data are available at www.revois-dental.com.
If for any reason, the implant has to be removed again from the cavity, insert the insertion angle and put on the flipped-over torque wrench to turn out (leftwards) the implant not exceeding forces of 70 Ncm.
When choosing a staged technique (e.g. with bone type D III or IV), do not immediately proceed with the impression procedure, but cover the implant after the insertion into its final position with the cover screw avoing strain on the implant.
After the healing period (osseointegration with or without augmentation) proceed with the impression procedure as explained before.
For alternative impression options (e.g. snap-on wings, titanium posts, multifunctional abutments) please refer to our manual.

Subsequent prosthetic work: With reaching primary stability or osseointegration, respectively, you can start structuring the oral mucosa by using a gingiva former available in different widths and heights.

After impression taking, one of the various straight or angled standard abutments, or the sprue-able gold-ceramic abutment (Ceramicor®) may be placed on the abutment with the fixation screw using the torque wrench at 30 Ncm. Make sure the screw angle is fully and straight placed onto the screw. Afterwards, the prosthesis can be glued using appropriate media.
In the rare case that a fixation screw has to be removed again, place the screw angle and put on the flipped-over torque wrench to turn out (leftwards) the screw not exceeding forces of 40 Ncm.
When using conical abutments make sure to use the appropriate hulls, as well.
When using male/female housing systems such as Dalbo®, Locator®, CM LOC® or CM LOC® Flex, ensure to use the specific tools and accessories, only – all available from AUROSAN.

REVOIS® compact: Remove the insert blister by using the recessed grips. Touching the impression screw only, remove the premounted set and insert the implant into the prepared implant cavity screwing manually.
Then remove the impression screw and post (you may keep both for re-use for the open-tray impression procedure later on). Using insertion piece and torque wrench screw (turn right) the implant into its final position not exceeding forces of 30 Ncm. Ensure the insertion piece is fully fitting onto the implant. Typically, insert the REVOIS® compact implant until the upper end of the thread is just covered by the bone crest. For the open-tray impression (re-)place impression post and screw onto the finally inserted implant. The impression post functions as impression negative and remains in the impression mass. You may hand over the impression mass together with a laboratory analogue to a dental lab to develop the chosen prosthetic solution. CAD/CAM data are available at www.revois-dental.com.
If for any reason, the implant has to be removed again from the cavity, insert the insertion angle and put on the flipped-over torque wrench to turn out (leftwards) the implant not exceeding forces of 70 Ncm.
When choosing a staged technique (e.g. with bone type D III or IV), do not immediately proceed with the impression procedure, but cover the implant after the insertion into its final position with the plastic cap avoing strain on the implant.
After the healing period (osseointegration with or without augmentation) proceed with the impression procedure as explained before.
For alternative closed tray impression options (e.g. titanium or gold jackets) please refer to our manual.

The use of the surgical instruments, tools & accessories is described in detail in the REVOIS® User Manual that can be downloaded at www.revois-dental.com. Please contact us if you like to receive a personal print copy.

11. These Instructions for use apply to the following REVOIS articles. The complete sets of the instructions can be found at www.revois-dental.com. Please contact us if you wish to receive a printed copy.

Ref-No.	Product variant	Article description
MD6000403	Classic	Gingiva former ø 4.6 mm, H5
MD6000460	Classic	Cover screw, universal
MD6001013*	PRO	Mucosa punch ø 3.0 mm
MD6001014*	PRO	Mucosa punch ø 4.0 mm
MD6001211++		Precision pilot drill ø 2.0 mm
MD6001212++		Precision pilot drill ø 2.8 mm
MD6241250++		Precision pilot drill ø 2.5 mm
MD6243450++	compact	countersink
MD6001233++	PRO	Conical drill REVOIS PRO ø 3.8 mm
MD6001234++	PRO	Conical drill REVOIS PRO ø 4.3 mm
MD6001235++	PRO	Conical drill REVOIS PRO ø 5.0 mm
MD6001240++	PRO	Bone tap REVOIS PRO ø 3.8 mm
MD6001241++	PRO	Bone tap REVOIS PRO ø 4.3 mm
MD6001242++	PRO	Bone tap REVOIS PRO ø 5.0 mm
MD6001602	PRO	Gingiva former Ø 4.4 mm, H2
MD6001603	PRO	Gingiva former Ø 4.4 mm, H3
MD6001605	PRO	Gingiva former Ø 4.4 mm, H5
MD6001652	PRO	Gingiva former Ø 5.2 mm, H2
MD6001653	PRO	Gingiva former Ø 5.2 mm, H3
MD6001655	PRO	Gingiva former Ø 5.2 mm, H5
MD6001701	PRO	Cover screw, universal
MD6001702	PRO	Cover screw, sinus lift 5.0 mm
MD6001800*, ++	PRO	Parallelising pin, 0°
MD6001818*, ++	PRO	Parallelising pin, 18°
MD6001825*, ++	PRO	Parallelising pin, 25°

Articles marked with an asterix (*) are delivered non-sterile and must be sterilized prior to use.

Articles marked with a double-plus (++) may be re-used and have to be reconditioned and re-sterilized prior to re-use.

12. Contact details of the manufacturer

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CE 0483

For USA: Federal law permits the sale of this medical device only through or after prescription by a licensed dentist or medical doctor.

Pictogram	Meaning
	Manufacturer
CE 0483	The REVOIS® Dental Implantat System is in conformity with the medical device guideline 93/42 EWG
	Read instructions for use, available at www.revois-dental.com/gba
REF	Catalog number
	Lot number
	Use before
	Sterilised by irradiation
	Single use only
QTY	Quantity
	Keep dry
	Protect from sunlight
Rx only	Prescription only