Instructions for use and reprocessing

Instructions for use and reprocessing for Bone fixation / Bone Augmentation systems

from USTOMED

Attention! IMPORTANT PRODUCT INFORMATION! These instructions must be read carefully before clinical use!

Description
The USTOMED Bone Fixation/ Bone Augmentation System includes screws, pins and plates made of titanium and/or implantable stainless steel, as well as the associated instruments and covered perforated boxes for sterilization and storage of the devices. In these instructions for use, the term "implant" refers to the screws, pins and plates. The implants are intended for single use only, while the instruments are intended for multiple use. All components of the set are supplied non-sterile and must be cleaned and sterilized according to these instructions before use. During surgery, the implants can be easily removed from the screw boxes or the pin box and precisely placed with the corresponding instruments.

The packaging label contains a LOT number (batch code). Be sure to record the LOT number in the patient file. It enables the device to be traced back through the manufacturing process to the raw materials.

Use of the device:
The USTOMED Bone Fixation/ Bone Augmentation System may only be used for its intended purpose by properly trained and qualified personnel. The surgeon is responsible for selecting the appropriate device for each application, correct positioning, proper surgical technique for implantation and use of all instruments and ensuring that all personnel are properly trained and instructed. Each device must be selected based on the bone defect to be treated and the patient's health status.

Incorrect handling and maintenance as well as improper or inappropriate use can affect performance and lead to damaged or broken products. When selecting a product and the appropriate surgical procedure, the surgeon must take into account any concomitant medical conditions of the patient. Further information can be found in the sections "Contraindications", "Warnings" and "Precautions".

The implants are designed for optimal wound and bone healing. Their use requires close attention to the anatomical and biomechanical conditions and precise adherence to well-known standard surgical techniques. Prior to surgery, the surgeon must educate the patient about the expectations of the surgery and ensure that the patient understands the surgeon's instructions regarding appropriate postoperative care and behavior.

Using the wrong implant for a particular procedure can lead to loosening or fracture of the implant and thus affect its performance. The surgeon must inform the patient of the advantages and disadvantages of the specific procedure to be used. The patient must be aware that no pressure should be applied to the implanted area and that and that not complying with this requirement may interfere with proper bone healing.

No description of a surgical procedure can cover all clinical situations or account for all possible risks and complications. The surgeon is responsible for identifying and applying the appropriate surgical techniques for a particular procedure and keeping abreast of relevant scientific publications and other scientific literature. The surgeon must be familiar with the implants and their application before using them. Additional information on the devices can be found in the product catalogs. When evaluating clinical experience or information from the relevant international literature that we make available to you, the patient-specific clinical situation must always be taken into account.

Indications for use
The USTOMED bone fixation/bone augmentation systems consist of screws, pins and/or plates made of titanium or stainless and implantable steel that are intended to stabilize and support bone and/or bone grafts at bony defect sites in the oral cavity. The devices are used during bone regeneration treatment in the oral cavity to stabilize, fixate and/or support bone grafts and bone filling materials. The implants are in direct contact with the body and are intended for long-term use. It is inserted and clinically implanted for more than 30 days, with an expected duration of implantation of three to nine months or until bone regeneration is complete.

Contraindications:
1.) Implants should not be inserted if an active infection is present
2.) Local or systemic pathological processes (e.g. symptoms such as fever, local inflammation, abscesses)
3.) Medical conditions that preclude adequate support of the implant or impede the healing process, such as
    a. Insufficient blood circulation
    b. Insufficient bone quality or quality, including but not limited to osteoporosis
    c. Extreme obesity
4.) Diseases or medication that affect bone metabolism.

Relative contraindications
1.) Incomplete dentoalveolar growth (exception: cases in which no dentoalveolar growth is expected, e.g. ectodermal dysplasia)
2.) The patient is allergic to steel or titanium.
3.) Systemic and/or metabolic diseases or medical treatments that lead to a progressive deterioration in health
4.) Bones (e.g. cortisone, immunosuppressants, bisphosphonates, diabetes, etc.)
5.) Drug and alcohol abuse
6.) Lack of patient compliance
7.) Poor blood circulation
8.) Heavy physical work or active sport
9.) Mental illnesses that preclude participation in the rehabilitation program (Parkinson's disease, alcoholism, drug use, etc.)
10.) Highly atrophied jaw

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Warnings

1.) USTOMED screws, pins and plates are intended for single use only. Even if the implants appear to be reusable after use, they must not be reused due to the risk of product contamination, infection of the patient/user and/or improper function of the implant.
2.) USTOMED screws, pins and plates are NOT intended as permanent implants. They are intended to facilitate the regeneration of a specific oral tissue and must be removed when bone regeneration is complete.
3.) Do not insert implants if an active infection is present. Before insertion, the surgeon should ensure that an active or recent infection has been properly treated.
4.) The screws and pins are very small. Care must be taken to ensure that they are not swallowed or aspirated by the patient during implantation and removal.
5.) After the operation, all activities that expose the body to high physical stress must be avoided.
6.) USTOMED screws, pins and plates are not intended for use under load.
7.) Make sure that screws or pins never penetrate the temporomandibular joint.
8.) Screws, pins and plates have normal contraindications and risks, including gingival recession, pain, swelling, inflammation, superficial or deep infection, loss of crestal bone height, perforation or abscess formation, while osteoporosis, inhibited revascularization and poor bone regeneration can lead to loss of fixation. Depending on the nature and severity of the complication, as assessed by the clinician, removal of the implant or antibiotic therapy may be indicated.
9.) Allergies, tissue and foreign body reactions can occur in the vicinity of the implants.
10.) The insertion of pins can, in very rare cases, lead to benign paroxysmal positional vertigo (BPPV) caused by the tapping procedure. If a patient has previously been affected by BPPV, this risk can be avoided by using screws.
11.) Do not expose a patient who has been clinically implanted to magnetic resonance imaging or magnetic fields. Although the implants are made of antimagnetic stainless steel or corrosion-resistant, non-magnetic titanium, they may migrate or heat up when exposed to magnetic fields during MRI examinations. Further information can be found in the section "Magnetic resonance imaging".
12.) The implants and instruments contained in the USTOMED Bone Fixation Set are manufactured and designed to be used together. The use of instruments from other manufacturers and implant systems together with the products contained in the USTOMED Bone Fixation Set may entail significant and unpredictable risks and/or contamination of the material and mismatching of the implants to the instruments, thereby endangering the patient, the user and/or third parties.
13.) If an instrument is used on a patient who has been diagnosed with Creutzfeldt-Jacob disease or HIV or is suspected of having CJD or HIV, destroy the used device immediately in accordance with approved hospital procedures. Do not reuse!

Precautionary measures

1.) USTOMED micro screws and USTOMED plates are intended to be used together. Do not combine them with products from other manufacturers.
2.) The screws are self-retaining on the screwdriver blade. Before screwing in, ensure that the blade is fully inserted into the screw head in order to achieve correct axial alignment. A secure connection is essential to ensure that the screw holds onto the blade.
3.) Do not use excessive force when inserting a screw, as the screw head could break.
4.) Deformation of the panels before use must be kept to the absolute minimum necessary. The plates must never be bent back and forth. Bending can lead to fatigue, cracks or breakage of the device during or after implantation.
5.) Do not cut the panels to size. They must be used as intended.
6.) Check the device and instruments for damage before use. The use of damaged medical devices poses a serious risk to the safety of the patient and/or the user.
7.) The surgeon should discuss with the patient the expectations of the procedure associated with the use of the device. The patient must be instructed in proper post-operative oral hygiene. Particular attention should be paid to the post-operative discussion and the need for regular medical follow-up as well as the effects of any kind of pressure on the device and/or the implanted area that could affect the healing process of the bone.
8.) Monitor the implants regularly during the healing process. It is known that occasionally implants can become loose or detached. To minimize this possibility, it is important to choose the correct implant size, use the correct surgical technique and ensure that the aftercare is clearly communicated to and understood by the patient. The patient should be advised to inform the surgeon of any unusual changes at the operated site. The surgeon should assess the possibility of subsequent clinical failure and discuss with the patient the need for any measures deemed necessary to aid healing.
9.) The implants must not come into contact with objects, as this can lead to surface damage. They must not be mechanically processed or modified in any way.
10.) Use appropriate personal protective equipment (PPE) in accordance with the Department of Environmental Health and Safety (OSHA) guidelines for bloodborne pathogens when reprocessing implants and instruments.

New devices

Inspect new devices on receipt for any damage that may have occurred during transportation. Return damaged devices to the manufacturer immediately.

New, unused components must be stored in a protected place in their original packaging or in a suitable storage box such as the box for microscrews. See section "Storage" for further information.

Before first use, remove the original packaging and clean and sterilize the device in accordance with these instructions for use. Dispose of the protective shipping packaging in an environmentally friendly manner. The packaging label contains a LOT number (batch code). Make sure to note the LOT number in the patient file. It enables the product to be traced back through the manufacturing process to the raw materials.

Procedure

These instructions for use discuss issues specific to the USTOMED Bone Fixation/Bone Grafting System and its accessories. Please consult the appropriate surgical and restorative manuals and textbooks for treatment planning and medical evaluation information. When using membranes or meshes, refer to the appropriate instructions for use.

It is extremely important that the right implant components are selected. The correct implant type and size must be determined for each individual patient. Using the largest possible implant and positioning it correctly will help prevent bending, fracturing, cracking or loosening of the implant.

Once bone regeneration is complete, the implants can be removed by a minor surgical procedure (second operation), which in many cases can be performed on an outpatient basis.

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Removing the implants from the bone is generally a low-risk procedure. However, as with any surgical procedure, risks and rare complications such as wound infections or bruising cannot be completely ruled out.

In rare cases, it may be found during removal that the bone has not consolidated optimally. In order to stabilize the bone, the implants may need to be left in place for a longer period of time or new implants may need to be placed if the original ones have already been removed.

After removal of the implants, the bone may require additional time to reach the strength required for loading. Always assess the bone condition carefully before loading.

Dispose of all explanted devices properly. Do not reuse!

Preparation for use
To prepare the implants for use, remove the implants from the original packaging and clean and sterilize the devices according to these instructions for use. Clean and sterilize all associated instructions.

If you intend to use devices and instruments that have been previously sterilized and stored in accordance with these instructions for use, check the sterile barrier packaging carefully before use to ensure that the sterile barrier has not been compromised, is not torn or perforated and shows no signs of moisture or tampering. If a rigid sterilization container has been used to sterilize and store the devices, ensure that the plastic safety seals have not been broken or tampered with. If any of these points are present, the contents of the packaging must be considered non-sterile. In this case, repeat the entire cleaning and sterilization process according to these instructions before using the devices.

A sterile field should be maintained throughout the procedure.

Dispose of all implants that have fallen into the oral cavity during insertion.

Micro screws / Schlee umbrella screws
Micro screws can be used for block bone grafts and/or for fixing micro titanium plates. To prevent rotation of a bone block, the use of two microscrews is usually required.
The flat head of the Schlee Umbrella Screw has a diameter of 5 mm and is therefore suitable for tensioning the buccal contour of an alveolus and for protecting the augmented areas against pressure from the lip, tongue or cheek. Depending on the size of the augmented area, several screws can be used at the same time.

Implantation
Prepare the surgical site.

Ensure that the condition of the bone permits proper screw connection.

Buccal placement of the screws is preferred to facilitate screw extraction. However, lingual placement is sometimes necessary, especially when treating large defects.

Select a drill with a diameter that is 0.2 mm smaller than the diameter of the screw to be implanted. Drill a pilot hole that is 0.2 mm-0.3 mm deeper than the length of the screw. When using USTOMED drills for drilling, be sure to follow the instructions in the USTOMED Drill Instructions for Use.

Carefully position the screwdriver blade vertically over the screw in the Micro Screw Box or Schlee Screw Box. Press the screwdriver blade firmly into the screw head and ensure that the blade is fully inserted into the screw head to achieve correct axial alignment.

Insert the screw carefully and slowly for implantation. The screw should turn without resistance and no force should be required. If resistance is encountered, turn the screw back one turn and try insertion again. Repeat the process if you encounter further resistance. Do not apply excessive force when inserting the screw, as the screw head could break off from the screw body.

If additional stabilization of the bone blocks is required during the healing process, a micro-titanium plate can be used. See section "Micro-titanium plates".

Explantation
Expose the surgical site. Remove debris from the screw head by repeated rinsing until the screwdriver blade can be fully inserted into the screw head to ensure an optimal fit between the screwdriver blade and the screw and to achieve correct axial alignment.

Use the screwdriver to unscrew the screw from the bone.

Make sure to remove and properly dispose of all removed screws. The screws must not be reused.

After removal, the explantation site of the screw heals independently by granulation.

Micro titanium plates
Micro-titanium plates are designed to be used in conjunction with micro-screws to provide additional stability and support for blocked bone graft areas and to protect augmented areas from pressure from the lip, tongue and cheek.

Care should be taken to ensure that the micro titanium plate maintains a distance of at least 1 mm from the adjacent teeth.

Deformation of the panels before use must be kept to the absolute minimum necessary. The plates must never be bent back and forth. Bending can lead to fatigue, cracks or breakage of the device during or after implantation.

Do not cut the panels to size. They must be used as intended.

Handle the micro titanium plate with sterile surgical gloves that have been washed with sterile water or with sterile atraumatic forceps.

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Implantation
Place the micro titanium plate over the grafted area and securely fasten it with two or more micro screws according to the micro screw insertion instructions above.

After implantation is complete, check all screws to ensure that the screws and plate are securely connected. Tighten the screws further if necessary.

Explantation
Expose the surgical site. Carefully remove the microscrews according to the microscrew removal instructions. Grasp the micro-titanium plate with tweezers and carefully separate it from the tissue.

After removal, the explantation site of the screw heals independently by granulation.

Make sure to remove all panels and dispose of them properly. Do not reuse the plates.

Pins
The pins can be used to attach PTFE- and titanium-reinforced membranes or meshes up to a thickness of 1 mm. Always consult the membrane and mesh manufacturer's instructions for use when planning the procedure.

Implantation
Make sure that the condition of the bone allows for proper pin attachment.

Buccal placement of the pins is preferable to facilitate insertion and removal of the pins.

Prepare the surgical site.

Prepare the mesh or membrane according to the manufacturer's instructions for use.

Remove a pin from the pin box by positioning the pin applicator vertically over the pin. Press the applicator firmly over the head of the pin and ensure that the pin head is fully inserted into the tip of the applicator to achieve correct axial alignment.

Do not place the pin too close to the edge of a membrane or mesh. Leave at least 1 mm of membrane or mesh material around the pin.

Insert the pin through the membrane or mesh into the bone by gently tapping the pin applicator with a hammer. To achieve satisfactory contact between the pin and the membrane or mesh, the head of the pin must be parallel to the membrane or mesh and the bone surface. Continue tapping gently until the head of the pin is completely flush with the bone and the membrane or mesh. To avoid breaking the pin, it is better to tap gently several times than to try to insert the pin with fewer, more forceful taps.

When the pin is fully inserted, carefully tilt the pin applicator to the side so that it can easily detach from the pin. It is not necessary to pull or apply force. Never use any other instrument to push the pin away from the applicator tip. It is not necessary and the applicator may be irreversibly damaged.

Explantation
Expose the surgical site and use a thin and flat tool, such as a scalpel blade, to detach the head of the pin from the underlying bone and membrane. Remove the membrane or mesh according to the manufacturer's instructions for use.

Make sure to remove all pins and dispose of them properly. Do not reuse the pins.

After removal, the explantation site of the pin heals independently by granulation.

T-Fix membrane screw
The T-Fix membrane screw can be used to attach PTFE and titanium-reinforced membranes up to a thickness of 2 mm. Always follow the membrane manufacturer's instructions for use when planning the procedure.
The T-Fix Membrane Screw is self-tapping and self-drilling. It is not necessary to pre-drill a pilot hole before insertion.

The T-Fix membrane screw can be stored and sterilized in the Micro Screw Box.

Implantation
Ensure that the condition of the bone permits proper screw connection.

Buccal placement of the screws is preferred to facilitate screw removal. However, lingual placement is sometimes necessary, especially when treating large defects.

Prepare the surgical site.

Prepare the mesh or membrane according to the manufacturer's instructions for use.

T-Fix membrane screws are self-retaining on the screwdriver blade. Carefully position the screwdriver blade vertically over the screw in the Micro Screw Box. Press the screwdriver blade firmly into the screw head and ensure that the blade is fully inserted into the screw head to achieve correct axial alignment. A secure connection is essential to ensure that the screw is held onto the blade during insertion.

Do not place the screw too close to the edge of the membrane. Leave at least 1 mm of membrane material around the screw.

Carefully and slowly insert the screw through the membrane into the bone, applying a torque of less than 10 Ncm. The screw should turn without resistance and no effort should be required. If there is resistance when turning the screw, turn the screw back one turn and try inserting it again. Repeat the process if further resistance is encountered. To achieve good contact between the screw and the membrane, the screw head must be parallel to the membrane and the bone surface.

Stop turning the screw when it is fully seated, i.e. completely flush with the bone and the membrane. Do not turn the screw any further! If the screw is turned further after it is fully seated, the screw may loosen and detach from the bone.

Carefully tilt the screwdriver to remove it from the screw.

Explantation
Expose the surgical site. Remove debris from the screw head by repeated rinsing until the screwdriver blade can be fully inserted into the screw head to ensure an optimal fit between the screwdriver blade and the screw and to achieve correct axial alignment.

Use the screwdriver to unscrew the T-Fix membrane screw from the bone.

Make sure to remove and properly dispose of all removed T-Fix membrane screws. The screws must not be reused.

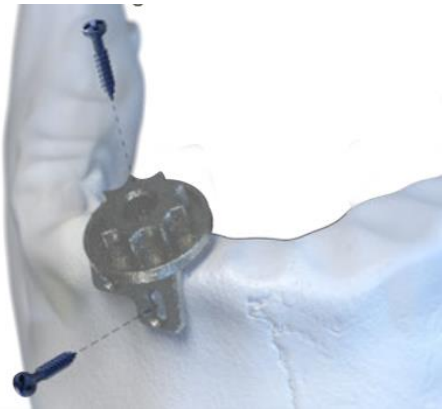
After removal, the explantation site of the screw heals spontaneously by granulation.

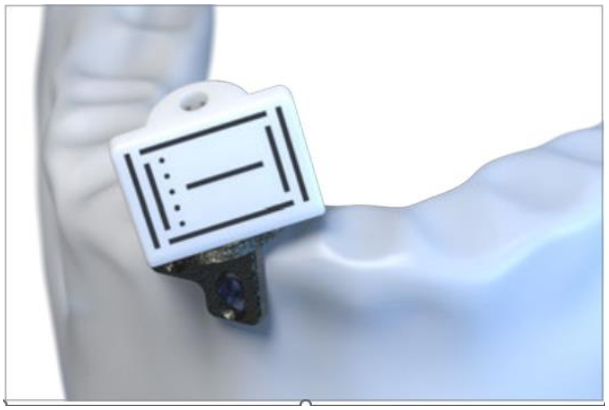
Bone Screws for Straumann® Falcon (FA1710)

The edentulous tray for Straumann®Falcon FA1700 is needed when the chosen workflow requires the localization of the Marker for Straumann® Falcon FA1500 with screws and/or teeth.

The Edentulous Tray for Straumann®Falcon is fixed directly on the jawbone where the implants are planned. To fix the tray it is possible to create an opening on the jaw's gingiva, to reveal the bone. Push the tray through the opening on the jaw so that the spikes present on it can anchor to the bone.

To fix the tray a minimum of 2 screws is required (1 occlusal and 1 vestibular). Guide the screws through the holes present in the tray and secure the screws in the bone. Make sure the tray is stable in the mouth. If the tray is unstable a third screw can be used.





Bone Screws for Straumann® Falcon FA1710 serve as physical landmarks in cases where there are insufficient teeth. They are fixed directly into the jaw prior to CBCT scanning, and during surgery, the screw head is touched with a dedicated probe to establish a reference point for the Falcon system (reference screw-based marker localization). The Straumann® Falcon software requires a maximum of 3 screws, but more can be used if needed"

Implantation
Prepare the surgical site.

Ensure that the condition of the bone permits proper screw connection. Buccal placement of the screws is preferred to facilitate screw extraction.
The Bone Screws for Straumann® Falcon are self-tapping and self-drilling. It is not necessary to pre-drill a pilot hole before insertion.

Carefully position the USTOMED screwdriver (68-740-002) with the blade vertically over the screw in the Micro Screw Box. Press the screwdriver blade firmly into the screw head and ensure that the blade is fully inserted into the screw head to achieve correct axial alignment.

Insert the screw carefully and slowly for implantation. The screw should turn without resistance and no force should be required. If resistance is encountered, turn the screw back one turn and try insertion again. Repeat the process if you encounter further resistance.

⚠ Do not apply excessive force when inserting the screw, as the screw head could break off from the screw body.

Explantation
Expose the surgical site. Remove debris from the screw head by repeated rinsing until the screwdriver blade can be fully inserted into the screw head to ensure an optimal fit between the screwdriver blade and the screw and to achieve correct axial alignment.

Use the screwdriver to unscrew the screw from the bone. Make sure to remove and properly dispose of all removed screws. The screws must not be reused.

After removal, the explantation site of the screw heals independently by granulation.

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Reprocessing instructions - General information
The implants are supplied non-sterile and must be cleaned and sterilized before use. They are intended for single use only. However, if they are not used, they can be reprocessed (cleaned and sterilized) a maximum of two further times in accordance with these instructions for use. Unused implants must be discarded after three reprocessing cycles.

The instruments are supplied non-sterile and can be used several times. The instruments must be cleaned and sterilized before the first use and after each reuse.

Thorough and effective cleaning is essential to ensure effective sterilization.

Minimize or eliminate time delays between processing steps. Delays can create conditions that favor microbial growth or colonization and increase the challenge for each subsequent step.

Follow the instructions and warnings of the suppliers of your cleaning and sterilization equipment.

The following cleaning and sterilization instructions have been validated by the manufacturer as suitable for preparing the implants, Bone Screws for Straumann® Falcon and associated instruments contained in the USTOMED Bone Fixation/Bone Augmentation System for reuse by achieving sterilization to a Sterility Assurance Level (SAL) of 10^{-6} . To ensure safe and effective use of the devices, the user is responsible for ensuring that the reprocessing as actually performed with the devices, materials and personnel in the reprocessing facility achieves the desired results. This requires verification and/or validation as well as routine maintenance and monitoring of the process. All processing steps must be carried out by suitably trained personnel using the appropriate equipment and materials and in strict compliance with the validated parameters.

Observe the nationally applicable guidelines and legal regulations as well as the hygiene regulations of your facility. Any deviation from the reprocessing procedure described in these instructions for use must be validated by the user beforehand.

These reprocessing instructions comply with the requirements of DIN EN ISO 17664-1:2021 Reprocessing of healthcare products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices - Part 1: Critical and semi-critical medical devices.

Restrictions on reprocessing
New/unused implants may be cleaned and sterilized a maximum of three times. Dispose of all implants that remain unused after three cleaning and sterilization cycles.

Reprocessing has little effect on the instruments if the instructions are followed carefully and the instruments are not damaged or contaminated. The instruments can be reprocessed repeatedly until they show one of the end-of-life indicators mentioned in the section "Reusability and product life".

Initial treatment at the place of use
It is recommended to reprocess instruments and unused implants as soon as possible after completion of the surgical procedure.

Do not remove any unused implants from the Micro/Schlee Screw Box or the Pin Box. Wipe the visible part of the unused implants with a disposable cloth or paper towel to remove coarse surface soiling and/or contamination.

Use a disposable cloth or paper towel to remove surface dirt/contamination from the instruments and the outer surfaces of the Micro/Schlee Screw Box and/or Pin Box. Close the lids of the boxes.

If it is not possible to immediately move the devices to the designated cleaning area, keep them wet by immersing them in a container of purified cold water. The closed Micro/Schlee Screw Box and/or Pin Box can be fully immersed in purified cold water.

Optional disinfection of surgical instruments at the point of use
The optional disinfection process is only intended for the protection of hospital staff. Disinfection cannot replace the final sterilization process.

If you choose to disinfect the surgical instruments after use, the disinfectant used must be approved for use with medical devices, compatible with the cleaning agent and suitable for use with stainless steel and titanium surgical instruments.

At the time of use, immerse the surgical instruments completely in a freshly prepared disinfectant solution in accordance with the disinfectant manufacturer's instructions for use. Check that no air bubbles form.

Containment and transportation
Within one hour after completion of the surgical procedure, the implant boxes and all instruments not contained in the boxes must be taken to the designated cleaning area to initiate the cleaning process.

Manual pre-cleaning
During manual pre-cleaning, the water should be kept within a range of 35°C-40°C (95°F-105°F). Temperatures above 105°F (40°C) may cause coagulation of blood proteins and other contaminants and lead to fixation of residues on the device, reducing the effectiveness of the subsequent sterilization cycle. Temperatures below 35°C (95°F) reduce the cleaning effect and also impair the subsequent sterilization cycle.
Do not use wire brushes, steel wool, scalpel blades or abrasive cleaners for cleaning to avoid damaging the appliances.

Implants
Fill several basins with deionized water at 35°C-40°C (95°F-105°F). Remove the implants from the Micro/Schlee Screw Box and/or the Pin Box or from the original packaging if they are to be cleaned and sterilized for the first time. Immerse the pins, plates and each individual screw size or type in a different basin to avoid confusion.

Brush the implants thoroughly with a soft brush for at least two minutes to remove all visible impurities. Pay particular attention to the screw head and thread as well as the plate perforations.

Once the brushing process is complete, check that the appliances are visibly clean.

If there are still visible impurities, repeat the above steps.

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If no soiling remains, continue with the automatic cleaning process.

Instruments
If the instruments can be disassembled, disassemble them before cleaning. Remove the lid and the ruler suitable for comparative measurements from the Micro/Schlee Screw Box. Open the lid of the pin box.

Remove surface dirt and contamination by rinsing the objects under running tap water for 1-2 minutes or until the water runs clear. Pay particular attention to lumens, channels, blind holes, crevices and cracks. Operate all moving parts, such as the lid of the pin box, at least five times during the rinsing process.

Immerse the instruments in a basin of clean tap water at 35°C-40°C (95°F-105°F). Brush the instruments thoroughly with a soft brush for at least two minutes to remove all visible debris. Pay particular attention to lumens, channels, blind holes, crevices, cracks and joints. Operate all moving parts, such as the lid of the pin box, at least five times while fully immersing the device in the cleaning bath.

Remove the instruments from the cleaning bath and rinse them under running tap water for 1-2 minutes. Rinse all lumens, channels, blind holes, crevices and cracks as well as all surfaces of the instruments thoroughly and completely. Operate all moving parts, such as the lid of the pin box, at least five times during the rinsing process. Blow out all channels with air to remove any rinsing water residue.

Check the instruments to ensure that they are visibly clean. If there is still visible contamination, repeat the above steps.

If no soiling remains, continue with the automatic cleaning process.

Automated cleaning and drying
For machine cleaning of implants and instruments, use a cleaning agent that is compatible with titanium, stainless steel and plastics. Ensure that you follow the manufacturer's instructions regarding the water temperature and dilution of the cleaning agent. The cleaning agent must not be diluted too much or too little! USTOMED recommends the use of an enzymatic cleaning agent with the following specifications: pH value 8, density approx. 1.0 g/cm^3 at 68°F/20°C and viscosity <10 mPas at 68°F/20°C.

Rinsing processes are an important part of the automated cleaning process, which can leave chemical residues on the devices if not carried out properly. Residues from cleaning agents can harm patients. Always follow the rinsing instructions exactly. To ensure effective rinsing, make sure that the implants and instruments are placed in suitable trays, inserts, holders, etc. in the washing machine. Do not overload the trays so that the instruments are sufficiently surrounded by the cleaning/rinsing solution during the cleaning process. Larger instruments must be positioned carefully so that they do not prevent other instruments from being thoroughly cleaned and rinsed. Instruments with jaws must be held in an open position. Connect lumen-containing instruments to rinsing connections, if available.

USTOMED recommends the use of a washer that complies with the ISO 15883 series.

Implants and instruments
Place the unused and manually pre-cleaned implants in individual sealable cleaning trays that are available for your cleaning machine. Be sure to place each individual screw size and type, the pins and the plates in separate sealable cleaning trays to avoid mix-ups and cross-contamination of the different materials and to facilitate packaging for sterilization after completion of the automated cleaning process.

Place the Micro/Schlee Screw Box, its lid and the ruler suitable for comparative measurements separately in the washing machine. Make sure that the pin box is open.

Place the instruments in the appropriate instrument trays or baskets and load the washing machine.

Start the program. The following parameters are recommended.

1.) Pre-rinse with cold tap water for 2 minutes.
2.) Drain.
3.) Main cleaning with tap water at 45°C (113°F) for 10 minutes using the enzymatic cleaning agent concentration: 0.5%.
4.) Drain.
5.) Rinse with cold demineralized water for 2 minutes.
6.) Drain.
7.) Rinse with cold demineralized water for 1 minute.
8.) Drain.
9.) Dry the instruments with the drying cycle of the washer-disinfector.

Remove the appliances from the washing machine immediately after completing the program. Repeatedly leaving instruments in a closed appliance can lead to corrosion due to residual moisture.

If the implants or instruments are not completely dry, complete the drying step by air drying them in a clean area or manually with a clean, lint-free cloth if necessary. Use sterile compressed air to dry cavities or hollow spaces on instruments.

Proceed immediately to the appliance check.

Optional thermal disinfection
Low-level thermal decontamination at 93°C (199°F) is often included in automated wash programs after cleaning with detergents. Thermal decontamination is not required as part of these cleaning and sterilization instructions, but may be performed as an additional step to make the devices safe for handling by hospital personnel. Thermal decontamination is compatible with USTOMED implants and instruments.

If you decide to include a thermal decontamination cycle in the automatic washing process, be sure to follow the above instructions for automatic washing with regard to water quality and final drying.

Do not expose the devices to mechanical chemical disinfection.

Checking the device

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After cleaning, the implants and instruments must be thoroughly inspected for residual contamination. If contamination is present, repeat the above steps of manual pre-cleaning and automatic cleaning.

Visually inspect all implants for damage or scratches. Separate all damaged or scratched implants and dispose of them.

Visually inspect the instruments and device boxes for corrosion, cracks, fractures, damaged surfaces, cracks, deformations or porosity. Make sure that the instruments are working properly. Check the burrs for sufficient sharpness.

Dispose of worn, corroded, broken, deformed, blunt, porous or otherwise damaged items immediately. Send repairable instruments to the manufacturer for repair. See section "Repair".

Implants and instruments must not be lubricated.

After successfully inspecting the implants and instruments, reassemble all instruments that were disassembled for cleaning.

Immediately place in the packaging for sterilization.

Packaging

A clean Micro/Schlee Screw Box or Pin Box must always be used to store and protect the implants and the Bone Screws for Straumann® Falcon during sterilization. The Micro/Schlee Screw Box is also equipped with individual compartments for the USTOMED screwdriver, the screwdriver blades, the drills and the ruler.

As all boxes are perforated, approved sterilization packaging must also be used for final sterilization in order to maintain the sterility of the contents.

If one of the USTOMED sterilization containers is to be used for sterilization, it must first be cleaned and prepared for use in accordance with the USTOMED container instructions for use.

1) Sort the cleaned, dry screws and plates by size (length and diameter) and type into the corresponding compartments of the Micro/Schlee Screw Box. Place all instruments in the appropriate compartments of the box to complete the set. Close the lid of the box.

2) Place the cleaned, dry pins in the pin box and close the lid.

3) Sterilization packaging
   - *Sterilization container*
     Place the Micro/Schlee Screw Box or Pin Box and any additional instruments in the USTOMED sterilization container according to the USTOMED container instructions for use. Ensure that the perforations in the lid and base of the Screw Box and the open base of the Pin Box are not covered or blocked by instruments or loading accessories. The perforations must remain clear so that the steam can penetrate sufficiently during the sterilization process. Do not place any objects directly on the Screw Box or Pin Box.

   - *Sterilization bag*
     Wrap the Micro/Schlee Screw Box and the Pin Box individually in disposable sterilization pouches approved for pre-vacuum steam sterilization at 134 °C (273.2°F) for 5 minutes according to the sterilization pouch manufacturer's instructions.

     Any additional instruments not included in the boxes may be individually packaged in single-use sterilization pouches approved for pre-vacuum steam sterilization at 134°C (273.2°F) for 5 minutes according to the sterilization pouch manufacturer's instructions.

4) Label the contents of the packaged instruments with a document-proof marker or another sterilization-compatible labeling system. When using document-proof markers, make sure that you do not label the sterilization pouch on the steam-permeable side, but on the non-steam-permeable side, as the ink of the marker could otherwise penetrate the inside of the sterilization pouch due to the steam. Be sure to note the date of sterilization.

Sterilization
Strictly adhere to the sterilization parameters recommended below, including the drying time. Thorough drying of sterile implants and instruments prior to storage is essential to prevent subsequent growth of water-borne microbes.

Use a validated, properly maintained and calibrated steam sterilizer. Always follow the sterilizer manufacturer's instructions regarding load configuration and device operation. Ensure that there is no rust, dirt or other foreign or corrosive substances in the sterilization system that could contaminate the steam and corrode the instruments, leave surface deposits or cause other damage.

The recommended sterilization process (moist heat) complies with the requirements of the ISO 17665 series.

Steam sterilization parameters for implants and instruments
Place the wrapped appliances in the sterilizer.

Sterilize with the following parameters:
Sterilization method: Steam sterilization
Cycle type: Dynamic air extraction (fractionated pre-vacuum)
Temperature: 134°C (273.2°F)
Exposure time: 5 minutes
Drying time: 20 minutes

Remove the wrapped appliances from the sterilizer.

Check the packaging to ensure that it is dry. Items with wet packaging or containers with a wet filter are considered contaminated.

End-pack, pack and resterilize all devices with moist packaging or a moist filter.

Instructions for use and reprocessing

Storage
Store packaged, sterilized implants and instruments in a designated clean and dry area with limited access, preferably in a closed cabinet that is protected from dust, moisture and temperature fluctuations. If a closed cabinet is not available, ensure that the storage area is clean and dry and offers protection from light, UV radiation, dust, moisture, insects, vermin, extreme temperatures and humidity.

The storage room for new products in their original packaging must also be protected accordingly.

Do not store the products near or in the same room as aggressive substances such as alcohols, acids, bases, solvents or disinfectants.

Reusability and product service life
The implants are intended for single use only. Do not reuse!

Unused implants can be cleaned and sterilized a maximum of three times. Dispose of all unused implants that show signs of damage or scratches. Discard all implants that remain unused after three cleaning and sterilization cycles.

Reprocessing has hardly any effect on the instruments if the instructions are followed carefully and the instruments are not damaged or contaminated.

The service life of the instruments can vary and depends on the frequency of use, care and handling. Improper, ineffective and inadequate reprocessing and maintenance can greatly shorten the service life of the instrument.

The instruments can be used until they show one of the following indicators for the end of their service life:
- Corrosion
- Scratches, dents, splinters, cracks, fractures or deformations
- Blunt cut edges
- Sharp edges, rough surfaces or porosity
- Illegible labeling of the article number and/or batch number

Discontinue use and dispose of the appliance if any of these indicators occur.

Do not use damaged instruments!

Materials and material compatibility
USTOMED implants are manufactured from titanium and stainless steel alloys in compliance with strict quality standards.

Product	Material
Micro screws - Titanium T-Fix membrane screws Pins	Titanium grade 5 alloy 3.7165 (ISO 5832-3)
Micro screws - steel Gluckmann micro screws Schlee Umbrella screws	Stainless steel 1.4441 (ISO 5832-1 or AISI 316LVM)
Micro titanium plate	Titanium grade 2 alloy 3.7035 (ISO 5832-2)
Bone Screws for Straumann® Falcon FA1710	Titanium grade 5 alloy 3.7165 (ISO 5832-3)

The surface of the stainless steel appliances is chemically passivated and the materials are anti-magnetic.

Devices can corrode or be impaired in their function if they come into contact with aggressive substances.

Never expose an implant or instrument to temperatures above 140°C (284°F).

Failure to follow these instructions will invalidate any warranty claims.

Magnetic resonance imaging
This device has not been tested for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifacts in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient implanted with this device may result in injury to the patient.

Repair
Damaged implants cannot be repaired and must be disposed of. Further information can be found in the "Device disposal" section.

Instruments or boxes cannot be repaired by third parties, including repair shops not authorized by the manufacturer, without compromising the integrity of the device.

If an instrument needs to be repaired, clean and sterilize it according to these instructions for use. You can download and print out the USTOMED form for the declaration of decontamination at https://ustomed.de/downloads. Fill out the form, sign it and enclose it with your shipment together with the cleaned and sterilized device.

Leave the product to be repaired in its sterile packaging after reprocessing. For safety reasons, the products will be returned to the sender unprocessed without a fully completed and signed decontamination declaration and intact sterile packaging.

Instructions for use and reprocessing

Return of devices
If errors/malfunctions occur when using USTOMED products, please contact our service department.

Before you return the used or unused device, download the USTOMED decontamination declaration form from https://ustomed.de/downloads and print it out. Complete the form, sign it and enclose it with the return shipment of the device.

Always clean and sterilize all implants or instruments that must be returned to the manufacturer after clinical use in accordance with these instructions for use.

Leave the offending products in their sterile packaging after reprocessing. For safety reasons, the products will be returned to the sender unprocessed without a fully completed and signed declaration of decontamination and intact sterile packaging.

Disposal of appliances
Explanted implants should be handled as dangerous goods in accordance with the hospital/clinic procedures.

Dispose of irreparably damaged instruments and boxes in accordance with the established hospital protocol for the disposal of surgical waste.

Guarantee
The implants are intended for single use only. Reuse is not permitted, even if the devices appear to be suitable for reuse after use. Any warranty expires if an implant is used more than once.

Limitation of liability
Liability for reused implants is excluded. Liability is excluded for implants and/or instruments that have been modified in any way, used for a purpose other than that specified or used or handled improperly.

USTOMED implants and instruments are manufactured from high quality materials and undergo stringent quality control prior to shipment. However, we cannot guarantee the suitability of a device for a particular procedure and/or use in a particular patient. The surgeon is responsible for selecting the appropriate implant or instrument for a particular procedure. USTOMED INSTRUMENTE cannot accept any liability for any damage associated with or resulting from the use of a device or in the event that these instructions for use have demonstrably not been followed.

We accept no responsibility or liability for the re-use of instruments in cases where these instruments are used on patients with Creutzfeldt-Jakob Disease (CJD) or HIV. As stated in the "Precautions" section, if an instrument is used on a patient diagnosed or suspected of having CJD or HIV, we recommend immediate destruction of the device in accordance with approved hospital procedures. The reprocessing and reuse of such instruments is the sole responsibility of the user.

Instructions for use and reprocessing

Graphic symbols / labeling

The symbols available for marking in accordance with DIN EN 980 or DIN EN ISO 15223-1 have the following meanings:

LOT	Batch code
REF	Catalog number
CE 0297	CE marking with identification number of the notified body DQS Medizinprodukte GmbH
	Follow the instructions for use.
	Manufacturer
Rx only	Prescription device (Caution: Federal law restricts this device to sale by or on the order of a physician).
NON STERILE	Non-sterile
	Date of manufacture
	Single use - do not reuse
MR	MR unsafe
MD	Medical Device
	Caution
eIFU Indicator	eIFU: https://www.ustomed.de/downloads/

Manufacturer address:
USTOMED INSTRUMENTE
Ulrich Storz GmbH & Co.KG
Bischof-Sproll-Str. 2
D-78532 Tuttlingen, Germany
Phone: +49 7461/965 85 0
Fax: +49 7461/965 85 65
E-mail: info@ustomed.de
Web: www.ustomed.de

CH Rep:
Dabamed AG
Länggstrasse 17
CH - 8308 ILLNAU
SCHWEIZ
Phone: +41 44 9420101
E-mail:info@dabamed.ch
Web: www.dabamed.ch

UK Rep:
THE DENTAL IMAGING COMPANY
Unit C1, Dolphin Enterprise Centre
West Sussex - Evershed Way
GB - BN43 6QB SHOREHAM-BY-SEA
GREAT BRITAIN
Phone: +44 8456024944
E-mail: office@thedentalimagingcompany.co.uk
Web: www.thedentalimagingcompany.co.uk