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Universal CMF and Mandible Implants

Instructions for Use

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1. Indications/Intended Use

1.1. Universal CMF and Universal 2.0 Mini Plating System

The Stryker Leibinger Universal CMF and Universal 2.0 Mini Plating Systems are cranio-maxillofacial (CMF) plate and screw systems intended for osteotomy, stabilization and rigid fixation of CMF fractures and reconstruction.

1.2. Universal Mandible System

The Stryker Leibinger New Generation / Universal Mandible System is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction.

All of these instructions for use must be read carefully prior to clinical use.

2. Contraindications

- Non-reducible and unstable fractures (except reconstruction plates).
- Fractures of a severely atrophic mandible.
- Patients with active infections.
- Patients with metal allergies and foreign body sensitivity.
- Severely non-compliant patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions.
- Patients with limited blood supply or insufficient quality or quantity of bone.
- Patients with unstable physical and/or mental health conditions.
- Reconstruction of the mandible with Universal CMF implants.
- Secondary reconstructions with Universal primary recon plates (gold colored).

3. Possible System Adverse Effects

In many instances, adverse results may be clinically related rather than implant related.

- Loosening of the implant as a result of insecure tightening.
- Severe bending and fracture of an implant.
- Bony necrosis, osteoporosis, inhibited revascularization, bone resorption and poor bone formation can cause loosening, bending, cracking or fracturing of the device or premature loss of fixation with the bone, leading to non-union.
- Delayed union, malunion or non-union of the fracture site resulting from improper alignment may lead to breakage of the implant.
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
- Early or late infection, both deep and/or superficial.
- Nerve damage may occur as a result of the surgical trauma.
- Metal sensitivity reactions in patients following surgical implant have rarely been reported, and their significance awaits further clinical evaluation.

WARNINGS AND PRECAUTIONS

General warnings and precautions

- For single use only. Single use devices cannot be reused, as they are not designed to perform as intended after the first usage in surgery. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use, cleaning and resterilization may compromise the integrity of the design and/or materials leading to diminished safety, performance and/or compliance with compendial specifications. Please refer to the device label to identify single or multiple use and/or cleaning and resterilization release.
- Responsibility for proper selection of patients, adequate training, experience in the choice and placement of implants and the decision to leave or remove implants postoperatively, rests with the surgeon.
- In all but mandibular bridging plate applications and for medical attention of arthrodesis, the implants are designed to function only until bony healing (usually 6-10 weeks). Delayed healing, non-union or subsequent bone resorption or trauma may lead to excessive stress on the implant(s) and result in loosening, bending, cracking or fracturing. Post-operative care consisting of a soft food diet must be followed.
- The surgeon should discuss the expectations of surgery inherent in the use of the product with the patient. Particular attention should be given to a discussion postoperatively, proper post-operative diet consisting of soft foods, and the necessity for periodic medical follow-up.
- The correct selection of the product is extremely important. The product should be used in the correct anatomic location, consistent with accepted standards for internal fixation. Failure to use the appropriate product for the application may result in a premature clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, or fracturing of the product and/or bone.
- Careful handling and storage of the product is required. Scratching or damage to the component can significantly reduce the strength and fatigue resistance of the product.
- Once applied, the product should never be reused. Although it may appear undamaged, previous stresses may have created imperfections that could reduce its service life.
- All implants should be inspected prior to each clinical use.
- The patient should be advised to report any unusual changes of the operated site to their surgeon. The patient should be closely monitored if a change at the fixation site has been detected. The surgeon should evaluate the possibility of subsequent clinical failure, and discuss with the patient the need for any measures deemed necessary to aid healing.

- Selection of the screw length for bi-cortical use is not recommended without confirming the depth through the use of the depth measuring gauge.
- Templates are not authorized under any circumstance for implantation.
- Fracture fixation: a minimum of 2 screws (2.0 mm or 2.3 mm) should be rigidly fixated within the plate on each side of the fracture. Bi-cortical and/or mono-cortical fixation may be used as deemed appropriate by the surgeon. Additional fixation may also be necessary as deemed appropriate by the surgeon.
- Primary reconstruction fixation: a minimum of 3 screws (2.0 mm or 2.3 mm) should be rigidly fixated within the plate bi-cortically on each side of the resection. Additional fixation may be necessary as deemed appropriate by the surgeon.
- Secondary reconstruction fixation: a minimum of 3 x 2.3 mm screws or 6 x 2.0 mm screws should be rigidly fixated within the plate bi-cortically on each side of the segmental gap. Additional fixation may be necessary as deemed appropriate by the surgeon.
- Further specifications regarding condylar implants, refer to the instructions for use provided with the condylar implants.
- Do not use titanium ligature wires for ongoing wire fastening in the intermaxilliary field.

Risk due to the use of products from damaged packaging
Products may not be sterile if the package is damaged. The use of non-sterile products may lead to patient harm.
- Inspect each package before use.
- Make sure the package has not been opened inadvertently.
- Check the shelf life expiration date.
- Visually inspect the sterile barrier for flaws before opening.
- If the package is damaged, was inadvertently opened, or is expired, the product must be assumed to be non-sterile. If the product is not damaged, reprocess the product as recommended in this document.

MRI Information
- The Universal CMF and Mandible Implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the implants in the MR environment is unknown.

Plate warnings and precautions
- Because titanium hardness increases and ductility (bendability) decreases due to cold working during the bending process, it is essential to ensure that the desired shape of the implant is reached in as few bends as possible. Excessive bending can lead to postoperative plate fracture. Plates that have been severely bent and re-bent should be discarded.
- Acute angles together with small bending radii must be avoided because of the potential risk for postoperative breakage. As a result, straight plates may not be used and contoured for use around the mandibular angle.
- Excessively aggressive use of bending instruments can cause recognizable macroscopic damage to the implant (indentations, elongated screw holes, etc.). In such cases, the implant must be exchanged for a new, more carefully bent one.
- Deformed plate holes signify not only an increased risk of breakage in these areas but also impair the accurate fit of the screw head to the plate. Plates should be bent with care.
- A cut bone plate segment to be implanted may require deburring to prevent soft tissue injuries or irritations.
- Plates should be contoured anatomically to bone as closely as possible. Gaps between plate and bone should be avoided.
- Do not use any plates besides reconstruction plates to bridge bony gaps in cases of unreducible, unstable comminution or reconstruction. Application of such may lead to premature implant failure.
- Upper-Face malleable plates are color coded blue and should only be used with the 1.2 mm self-tapping or self-drilling screws from their respective modules. Do not fixate with locking screws.
- Mid-Face malleable plates are color coded blue and should only be used with the 1.7 mm self-tapping or self-drilling screws from their respective modules. Do not fixate with locking screws.

- Upper-Face Standard plates are color coded gold and should only be used with the 1.2 mm self-tapping or self-drilling screws from their respective modules. Do not fixate with locking screws.
- Mid-Face Standard plates are color coded gold and should only be used with the 1.7 mm self-tapping or self-drilling screws from their respective modules. Do not fixate with locking screws.
- Mid-Face Locking plates are color coded grey and can be used with 1.7 mm self-drilling, self-tapping or locking screws.
- 2.0 MP Plates are color coded mint and should only be used with the self-tapping or self-drilling 2.0 mm MP Screws from the 2.0 MP Mini Plating System. Do not fixate with locking screws.
- Malleable Mid Face 2.0 MP Plates are color coded blue and should only be used with the self-tapping or self-drilling 2.0 mm MP Screws from the 2.0 MP Mini Plating System. Do not fixate with locking screws.
- Mid-Face Locking plates may be implanted with either side facing upwards.
- Graduated stability plates are marked with a “G”. These are plates that are part of a series where the smallest plate is the most malleable and the largest is the most rigid. Do not fixate with locking screws.
- The Compression plates are marked with “2.0 C” or a “2.3 C” to indicate which screw diameter should be used with the plate. Compression plates may be used ONLY with bone screws. The use of a locking screw in conjunction with a compression plate may lead to premature implant failure.
- For compression an eccentric drill hole is required pulling the plate with the bone fragment fixed on the other side of the plate toward the eccentric screw. Therefore the use of the eccentric drill guide is recommended
- Mandible Mini Plates and 3D plates are color coded blue and may be used with 2.0 mm, 2.3 mm and 2.7 mm bone screws or locking screws from their respective modules.
- Mandible Mini Plates and 3D plates may be implanted with either side facing upwards.
- Mandible Fracture Plates are color coded gold and may be used 2.0 mm, 2.3 mm and 2.7 mm bone screws or locking screws from their respective modules.
- Mandible Fractures Plates should be implanted such that the laser-marked lines are facing upwards.
- Primary Reconstruction (gold color) plates are not intended for use in secondary reconstruction applications. Use of such may result in excessive plate loading and premature failure.
- Universal primary recon plates (gold color) and reconstruction plates (silver color) should be implanted such that the laser-marked lines are facing upwards.
- The Orbital Reconstruction plate is color coded grey and should only be used with 1.7 mm bone screws or locking screws. It may be implanted with either side facing upwards.
- The Mid-Face Reconstruction plates are color coded gold and should only be used with 2.0 mm or 2.3 mm bone screws or locking screws. Mid-Face Reconstruction plates may be implanted with either side facing upwards.
- The Inclined Screw Insertion (ISI) plate is intended for use for intraoral treatment of mandibular angle fractures. The screw holes for insertion are not perpendicular to the plate surface, but at an angle of 60° in both proximal and distal segments. The angle of the screw holes and the orientation of the plate are laser-marked. E.g. “L60°” for a left plate with screw holes at an angle of 60° or “R60°” for a right plate with screw holes at an angle of 60°! For fixation of the ISI-plate the dedicated Inclined Screw Insertion Combined Instrument must be used. Only use screws from the 2.0 mm MP System. It is advised to use short screws for monocortical fixation, to prevent nerve damage. Explantation of the ISI-plate is only allowed by surgeons who are familiar with and skilled in this special system and technique.

Screw warnings and precautions

- The self drilling screws are not recommended in very small and thin bone fragments because the fragments may be displaced by the axial pressure of insertion.
- If not otherwise expressly noted, bone screws are self-tapping, obviating the use of a tap before bone screw insertion. Exceptions include (but are not limited to) when
  - Bone screws are inserted close to a discontinuity, in which cases tapping may be necessary.

  - In the final phase of screw insertion, the underside of the screw head contacts either the bone or the screw head recess of a bone plate and a steep rise in resistance is clearly perceptible. Sensitive tightening of the screw must be exercised to reduce the risk of mechanical damage to the screw, screwdriver, or bony hole. Tapping should however precede screw implantation in areas of dense cortical bone and insertion close to a discontinuity.
- For Lag screws pilot holes must be tapped prior to screw implantation. They cannot be used for self-tapping applications.
- Placement of all locking screws requires the use of a drill guide to insure proper screw placement. If a drill guide is not used properly the screw may not lock into the plate.
- When using locking screws the first initial placement should be inserted into the plate but not locked until a second screw is inserted and locked into the plate.
- 1.2 mm and 1.7 mm Self-Tapping, Self-Drilling, and Locking Screws utilize the same screwdriver blade. This blade is marked with a yellow and orange band around the blade.
- 2.0 mm, 2.3 mm, and 2.7 mm Bone Screws and Locking Screws utilize the same screwdriver blade. This blade is marked with a red and blue band around the blade.
- 2.0 MP screws utilize a screwdriver blade that is marked with a red and green band around the blade.
- Screws should not be over-tightened during insertion. Excessive over-tightening will compromise the integrity of the screw head, result in possible screw breakage and lead to loss of friction fit performance.
- Excessive screw tightening may lead to stripping of the threads. In the event that a screw thread strips out, an emergency screw should be used.
- Tightness of each bone and/or locking screw should be verified upon completion of implantation to verify a rigid connection between the screw and plate.
- When engaging the screw, axial pressure of the screwdriver into the screw head must be adequately applied to ensure that the blade is fully inserted into the screw head. This results in proper axial alignment and full contact between driver and screw, minimizing the risk of round-out. Otherwise there will be an increased risk of mechanical damage to the implant or the screwdriver blade.
- Prior to implant explantation, the screw head recess should be cleaned of debris by means of a scalpel or other instrument to provide an optimal fit between blade and screw.

Self-drilling screw warnings and precautions

It is recommended that shorter screws (≤4 mm) be used in bone that is known to be dense (e.g. cranial bone) in order to avoid excessive axial forces and torque. Should the screws be difficult to start in bone, a pilot hole should be drilled to facilitate insertion, especially by use of screws with a length of more than 4 mm. Application of a constant downward / axial force on the screwdriver handle and exact screwdriver / screw alignment are recommended during screw insertion to ensure that the blade-to-screw head interface is maintained. In the final phase of screw insertion, the underside of the screw head contacts the countersink recess of a bone plate, evidenced by a clearly perceptible increase in resistance. Insertion into dense bone requires high axial force and torque. This increase in resistance might not be clearly perceived during final tightening. Extra care should be applied in tightening the screw to reduce the risk of mechanical damage to the screw, screwdriver or placement site.

4. Use of Original Products

Implants and instruments are produced and designed to be used together. The use of products from other manufacturers along with Stryker products can involve incalculable risks and/or contamination of the material and misalignments of implant to instrument, thereby endangering the patient, user or third parties. At no time should resorbables and titanium implants be used together (resorbable plate with titanium screws).

5. Material Information

Stryker bone plates and bone screws may be made of commercially pure (CP) titanium or Ti6AI4V alloy (acc. to ASTM F67, ASTM F136/ISO 5832-3). Both materials are biocompatible, corrosion-resistant and non-toxic in the biological environment, and produce negligible artifacts by X-ray and CT.

- It is the responsibility of the user facility to make sure that appropriate cleaning and disinfecting methods are used where Stryker recommendations are not followed.
- Exact compliance with the equipment manufacturer's user instructions and recommendations for chemical detergents is required.
- Contaminated implants have to be disposed of properly.
- Contamination by non-conventional transmissible agents, e.g. vCJD, in accordance with the system indications for use, particularly through contact with lymphatic tissue, is possible. Stryker recommends to incinerate any product that is suspected to have been contaminated by non-conventional transmissible agents.
- New products must be carefully cleaned before initial sterilization. Trained personnel must perform cleaning along with maintenance and mechanical inspection prior to initial sterilization. Implants should be cleaned in accordance with the following decontamination and cleaning specifications:

6.1. Preparation of washing and rinsing agents

– Avoid contact between devices (movement during washing could cause damage and washing action could be obstructed). Washing machines should not be over-loaded.

– In accordance with the manufacturer´s instructions, add the necessary amount of washing and rinsing agent into the washing machine. Stryker recommends only the use of neutral pH cleaning and disinfecting agents.

6.2. Manual precleaning process (if applicable)

For Precleaning use suitable cleaning agent, brushes or cleaning wires. Clean the medical device thoroughly, paying particular attention to rough surfaces and features where soil may be shielded from the brushing. Manual precleaning temperature should not exceed 50°C (122 °F).

6.3. Automated cleaning process

In accordance with EN ISO 15883, the following phases should be adhered to:

- Cleaning according to recommended procedure of washer/disinfector, cleaning and disinfection agent manufacturer.
- Approved thermal disinfection program (A0 value > 3000 or – in case of older devices – application of at least 5 min at 90 °C (194 °F). Do not add any additional agents).
- Rinsing Phase: Rinse implants and implant module(s) successively with Purified Water/ Highly Purified Water to remove any excess cleaning agents.

6.4. Drying process

- Remove the implant module(s) upon completion of the cleaning process.
- If the decontamination-cleaning process does not include a drying cycle, thoroughly dry the implants in an oven at a temperature below 110 °C (230 °F).

6.5. Sterilization

If not expressly specified as sterile, the product is supplied non-sterile.

- Exact compliance is required with the manufacturers´ user instructions for sterilizers.
- It is the responsibility of the user facility to make sure that appropriate sterilization methods are used where Stryker recommendations are not followed to account for potential differences in sterilization chambers, wrapping methods and load configurations.
- Direct contact between templates (if provided in the plating system) and bone plates during sterilization must be avoided.
- All non-sterile products are sterilizable by steam sterilization (autoclaving). For initial sterilization and resterilization, the following parameters can be used:

	6 min. PreVac (see "caution" below)	**3 min. PreVac UK Steam Cycle**	**270°F Gravity**	**Flash Gravity (see "caution" below)**
Sterilizer Type	Pre-vacuumed sterilizer	Pre-vacuumed sterilizer	Gravity displacement sterilizer	Gravity displacement sterilizer
Exposure Time	6 min.	3 min.	40 min.	10 min.
Temperature	270°F (132°C)	274°F (134°C)	270°F (132°C)	270°F (132°C)
Drying Time	35 min.	35 min.	35 min.	≤ 35 min.
Wrapping	Wrapped in the Universal System container	Wrapped in the Universal System container	Wrapped in the Universal System container	Unwrapped in an instrument tray

Container is wrapped using the AAMI (Association for the Advancement of Medical Instrumentation) CSR double wrapping technique. This cycle was validated with only one system in the chamber and using the middle shelf.

CAUTION

Use a legally marketed hospital sterilizer that has been FDA-cleared with a validated prevacuum cycle of 6 minutes at 270 °F (132 °C). Use legally marketed accessories, including biological indicators, sterilization wraps and pouches and sterilization trays that have been FDA-cleared for use in a prevacuum cycle of 6 minutes at
270 °F (132 °C).

The "Flash-Sterilization-Process" is only allowed for use in the USA! The respective individual laws, standards, directives and instructions of each country must be followed and have priority over the specified sterilization-procedures in the table! It remains the responsibility of the user to consider this and to obtain the corresponding information!

If the complete storage container of the system is made subject to steam sterilization (pre-vacuum), it needs to be ensured that it is exposed to saturated steam at 270°F (132°C) for a minimum of 6 minutes as to assure a sterilization level of SAL 10-6. If implants are sterilized individually, they can be sterilized pre-vacuumed at 270°F (132°C) with a 4-minute cycle.

Locking screws and locking plates in conjunction with licensing agreement with Prof. D. Wolter, Hamburg, Germany. US Patent: 6,322,562. German Patent: DE 43 43 117.

7. Symbol Definitions

The following tables define the symbols used in this document, on the product and on the product label.

EN ISO 7010 Graphical symbols – Safety colors and safety signs – Registered safety signs

Symbol	Name: Definition
 W001	**General warning sign:** To signify a general warning.

EN ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied - Part 1 General requirements

Symbol/number	Name: Definition
 5.1.1	**Manufacturer:** indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
 5.1.3	**Date of manufacture:** Indicates the date when the medical device was manufactured.
 5.1.4	**Use-by date:** Indicates the date after which the medical device is not to be used.
 5.1.5	**Batch code:** indicates the manufacturer's batch code so that the batch or lot can be identified.
 5.1.6	**Catalog number:** indicates the manufacturer's catalog number so that the medical device can be identified.
 5.2.4	**Sterilized using irradiation:** Indicates a medical device that has been sterilized using irradiation.
 5.2.7	**Non-Sterile:** indicates a medical device that has not been subjected to a sterilization process.
 5.2.8	**Do not use if package is damaged:** Indicates a medical device that should not be used if the package has been damaged or opened.
 5.4.2	**Do not re-use:** indicates a medical device that is intended for 1 use, or for use on a single patient during a single procedure.
 5.4.3	**Consult instructions for use:** indicates the need for the use to consult the instructions for use.

Product-Specific Symbols

Symbol	Name: Definition
QTY	**Quantity:** Indicates the number of medical devices in the packaging.
	**Note symbol:** it is used to supplement or clarify information.
GTIN	Global Trade Item Number

21 Code of Federal Regulations (CFR), section 801.109(b)(1)

Symbol	Name: Definition
Rx Only	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Regulatory marks and logos

Symbol	Definition
CE	Conformity with Annex I of Medical Device Directive 93/42/EEC for Class I.
CE 0197	Conformity with Annex I of Medical Device Directive 93/42/EEC for Class Is, Im, IIa, IIb and III.

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