Instructions for use
stoma® micro-screws

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General information
Read the instructions for use carefully prior to use. The attending doctor, buyer, or user is responsible for selecting the products for the intended application and/or operational use. The attending doctor and all persons involved in the handling of the product are responsible, within their field of activity, for having corresponding product knowledge based on the current state of technology. This enables the correct handling of the products and prevents health or safety risks for the patient, user, or third parties.

Intended use
The stoma® micro-screw is used to fix transplanted bone blocks during the augmentation process.

Indication
stoma® micro screws are developed and manufactured to be used as non-active implants in the field of bone surgery for the treatment of bone fractures. The main field of application for our products is fixing transplanted bone blocks during the augmentation process.
stoma® micro screws are not intended to remain in the body (mandibular or maxillary area) permanently. After they have fulfilled their supportive function such as is the case after healing of a transplant or the fracture, they are to be removed completely. We recommend removing them after 6 months at the latest.

Contraindication
- Inadequate or poor bone substance for anchoring the implant or states of health that impair the healing process, such as osteoporosis, diabetes that has not been optimally compensated, reduced blood supply, insufficient fixation/immobilization of the augmentation material, existing or previous, not fully healed infection.
- Patients with lack of ability and/or willingness to cooperate during the treatment phase.
- When used in conjunction with enossal implants, their contraindications have to be observed in addition.
- Known allergies and sensitivity to foreign bodies. Hypersensitivity against metals after implant surgery with stoma® micro screws has become known in extremely rare cases. In general however, an intolerance to any of the named materials is considered a contraindication.
- The treatment of risk groups is not recommended.
- Combinations with products made of other materials such as titanium and with products of other manufacturers may have a negative influence on the result of the operation and are not permitted.

Possible side effects
- Nerve damages and vascular injuries can be a result of surgical interventions.
- Osteoporosis and bone resorption can lead to loosening or breakage of the screw or premature loss of fixation with the bone.
- Increasing occurrence of fibrous tissue at the implantation site
- Early or late deep and / or surface infection
- Complications by screwing in the screw or tissue / bone injury by imprecise placement of the drill or the screw.

Recommendations and warnings to be respected

⚠ **If these warnings are not respected, this can lead to an increased safety risk.**
- **Only to be used for the intended purpose indicated.**
- **All instructions described here must be absolutely followed.**
- **Use only by specialized personnel!**
- **Small parts, such as bone screws, screwdriver tips or other small products, can be swallowed or aspirated by patients if they fall into the mouth.**

In case of misuse, all liability is excluded.

⚠ **The treating surgeon assumes responsibility for the correct choice of patients, evaluating the indication, the necessary training and the expert knowledge for the choice and positioning of stoma® micro-screws. The stoma® micro-screw has to match the size of the fragment to be fixated, the availability of bone (density, size of the operation site), the degree of activity or potential stress, as well as any accompanying diseases. stoma® micro -screws only serve to support the healing process and do not replace intact tissue and bone material.**
The surgeon has the obligation to inform the patient of the advantages and disadvantages of the stoma® micro-screw.
Prior to turning in the stoma® micro-screws, the use of a drill becomes necessary. Both for the existing jaw bone and the bone block, the drill has to be 0.2 to 0.3 mm smaller than the nominal diameter of the screw. Regardless of the type of screw head (inner square) the connection screw driver / screw head has to be in straight line in order to prevent an increased risk of damage through mechanical impacts for screw and screw driver.
Rotational speed for turning in or off stoma® micro-screws: 5 - 15 rpm (also while using the screwdriver tip for contra-angle piece), with a set torque of maximum 0.030 Nm.
If the bit for mechanical driving is used, a hand-held screwdriver or the handle 13389.00 instead of the attached motor is recommended for the final screwing phase.
After the sensible increase of resistance during the final phase of the turning-in of the stoma® micro-screw, the stoma® micro-screw should be twisted in carefully in order to prevent a damage of the screw or the bone construction through mechanical forces.

Used material
Stainless steels | ASTM F2229-12 Condition B

Products made of stainless steel (corrosion-resistant)
The stoma® micro-screws are made of cobalt- and nickel-poor, nonmagnetic special steel.

⚠ **The stoma® micro-screws have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artefact in the MR environment. The safety of stoma® micro-screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.**

Connections/interfaces
- Screwdriver with gripper
- Screwdriver basic
- Tip for contra-angle piece

Sorting out worn products

⚠ **Verify the identity, completeness, integrity, and function of the products. Immediately after the detection of damage, the products may not be used any longer!**

Delivery state
The stoma® micro-screws are delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to their use (cleaning and disinfecting after removal of the packaging material used for shipping, and sterilization after packing).

Preparation (cleaning, disinfection, sterilization) of stoma® micro-screws

General principles
Effective cleaning and disinfection is an essential prerequisite for effective sterilization.

⚠ **stoma® micro-screws which have already come into contact with a patient, or which have become contaminated must not be re-used under any circumstances.**

Be sure to avoid heavier contamination of the loaded bone screw tray, otherwise separate cleaning/disinfection of the stoma® micro-screws and the corresponding tray will be required.

Within the scope of your responsibility for the sterility of the stoma® micro-screws during use, please note,
- Only adequate, device and product-specific, validated procedures for cleaning/disinfection and sterilization may be used,
- The equipment (cleaning and disinfection device, sterilizer) that is used must be maintained and inspected regularly
- Compliance with the validated parameters is mandatory for every cycle.

Also observe the applicable legal regulations in your country and the hygiene regulations of the medical practice or hospital. This applies in particular to various specifications for the effective deactivation of prions (not applicable for the USA).

Cleaning and disinfection
Basic principles
A mechanical process (cleaning and disinfection device) should be used for cleaning and disinfection if possible. Due to the significantly lower effectiveness and reproducibility, a manual process – including the use of an ultrasound bath – should only be used if a mechanical process is not available.

Pre-treatment
A pre-treatment is not required, since stoma® micro-screws which have already been in contact with a patient, or which have been contaminated, must not be re-used under any circumstances.

Mechanical cleaning/disinfection (cleaning and disinfection device)
In choosing cleaning and disinfection devices, ensure that
- the effectiveness of the cleaning and disinfection device has been tested fundamentally (e.g. DGHM or FDA approval/clearance/registration and/or CE marking according to DIN EN ISO 15883),
- a verified program for disinfection (A0-value> 3000 or – for older equipment – min. 5 minutes at 90 °C/194 °F) is used if possible (with chemical disinfection, there is a risk of disinfectant residues on the stoma® micro-screws),
- that the chosen program is suitable for the stoma® micro-screws and has a sufficient number of rinsing cycles,

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- that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (purified/highly purified water according to the pharmacopoeia) is used for rinsing,
- that the air used for drying is filtered (oil-free, low-germ and low-particle), and
- that the cleaning and disinfection device is maintained and inspected regularly.

In selecting the cleaning agent system that is used, ensure that
- it is fundamentally suitable for cleaning bone screws made of steel,
- if thermal disinfection is not used, a suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration and/or CE marking) is used in addition and that it is compatible with the cleaning agent being used, and
- the chemicals being used are compatible with the stoma® micro-screws (see the section "Material resistance").

⚠ **Complying with the concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and if applicable the disinfectant as well as the instructions for rinsing is mandatory.**

Procedure:
1. Load the stoma® micro-screws into the cleaning and disinfection device. Make sure the stoma® micro-screws do not touch each other.
2. Start the program.
3. Remove the stoma® micro-screws from the cleaning and disinfection device after the program ends.
4. Inspect and package the stoma® micro-screws as promptly as possible after removal (see the sections "Inspection", "Maintenance" and "Packaging", if applicable after subsequent drying in a clean location).

Proof of fundamental suitability of the stoma® micro-screws for effective mechanical cleaning and disinfection was provided by an independent, officially accredited and approved (Section 15 (5) of the Medical Devices Act (MPG)) test laboratory using the cleaning and disinfection device G 7836 GD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent Neodisher mediclean (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account here.

Manual cleaning and disinfection
In selecting the cleaning agents and disinfectants that are used, ensure that,
- they are fundamentally suitable for cleaning/disinfecting stoma® micro-screws made of steel,
- the cleaning agent – if applicable – is suitable for ultrasound cleaning (no foaming),
- a suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration and/or CE marking) is used and that it is compatible with the cleaning agent being used, and
- the chemicals being used are compatible with the stoma® micro-screws (see the section "Material resistance").

⚠ **Using combined cleaning agents/disinfectants should be avoided if possible.**

Complying with the concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent/disinfectant as well as the instructions for rinsing is mandatory. Only use freshly prepared solutions, sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (purified/highly purified water according to the pharmacopoeia).

Procedure: Cleaning
1. Place the stoma® micro-screws into the cleaning bath for the specified exposure time, ensuring that the stoma® micro-screws are adequately covered. Make sure the stoma® micro-screws do not touch each other.
2. Remove the stoma® micro-screws from the cleaning bath and rinse them thoroughly with water at least three times (for at least 1 minute).
3. Inspect the stoma® micro-screws (see the section "Inspection").

Disinfection
1. Place the cleaned and inspected stoma® micro-screws into the disinfection bath for the specified exposure time, ensuring that the stoma® micro-screws are adequately covered. Make sure the stoma® micro-screws do not touch each other.
2. Remove the stoma® micro-screws from the disinfection bath and rinse them thoroughly with water at least five times (for at least 1 minute).
3. Package the stoma® micro-screws as promptly as possible after removal (see the section "Packaging"), if applicable after subsequent drying in a clean location.

Proof of fundamental suitability of the stoma® micro-screws for effective manual cleaning and disinfection was provided by an independent, officially accredited and approved (Section 15 (5) of the Medical Devices Act (MPG)) test laboratory using the cleaning agent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account here.

Inspection
After cleaning or cleaning/disinfection, inspect all stoma® micro-screws for surface damage, chipping, contamination, discolouration and corrosion. Reject stoma® micro-screws that are damaged. stoma® micro -screws that are still dirty have to be cleaned and disinfected again. stoma® micro -screws that are replaced or newly inserted in the trays must be checked for functionality with the screwdriver to be used. The tip of the screwdriver grips the stoma® micro-screw or the gripper of the screwdriver encloses the stoma® micro-screw.
For the maximum number of reuse cycles, see the sections "Reusability".

Packaging
If applicable, sort the cleaned and disinfected stoma® micro-screws into the corresponding sterilization tray (suitable block for screws).
Package the stoma® micro-screws and/or sterilization trays using disposable sterilization packaging (single or double packaging) or sterilization containers that meet the following requirements:
- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature-resistant up to min. 138 °C (280 °F), adequate vapor permeability),
- adequate protection of the stoma® micro-screws and/or sterilization packaging against mechanical damage, and
- regular maintenance according to the instructions of the manufacturer (sterilization containers).

Sterilization
Only the sterilization methods listed below may be used for sterilization; other sterilization methods are not permissible.

Steam sterilization
- fractionated vacuum method (minimum three vacuum steps) or gravitation method[1] (with adequate product drying[2])
- steam sterilizer according to DIN EN 13060/DIN EN 285 and/or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to DIN EN ISO / ANSI AAMI ISO 17665-1 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- sterilization temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO / ANSI AAMI ISO 17665-1)
- sterilization time (exposure time at the sterilization temperature) min. 5 min at 132 °C (270 °F)/134 °C (273 °F)

[1] The use of the less effective gravitation method is only permitted if the fractionated vacuum method is not available. It requires considerably longer sterilization times that must be determined and validated for the specific products, device, process and parameters under the personal responsibility of the user.
[2] The drying time that is actually required depends directly on the parameters that are under the sole responsibility of the user (loading configuration and density, condition of the sterilizer...) and therefore has to be determined by the user. Nevertheless, a minimum drying time must not be less than 20 minutes.

Proof of fundamental suitability of the stoma® micro-screws for effective steam sterilization was provided by an independent, officially accredited and approved (Section 15 (5) of the Medical Devices Act (MPG)) test laboratory using the steam sterilizer EuroSelectomat (MMM Münchener Medizin Mechanik GmbH, Planegg) with the fractionated vacuum method and using the steam sterilizer Varioclav 400 E (Thermo Electron, Oberschleißheim) with the gravitation method. The typical conditions in clinics and medical practices as well as the procedure described above were taken into account.

⚠ **The flash sterilization method is prohibited on principle.**
Also do not use hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

Safekeeping/storage
- Until the first use, it should be stored in the original package at normal room conditions.
- It should not be stored in direct vicinity of any chemicals.

Material resistance
In choosing the cleaning agents and disinfectants, please ensure they do not contain the following substances:
- Organic, mineral and oxidizing acids (maximum allowable pH value 10,5 - neutral/enzymatic cleaning agent recommended)
- concentrated bases
- organic solvents (such as alcohols, ether, ketones, benzine)
- oxidants (such as hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons
- salts from heavy metals

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Never use wire brushes or steel wool to clean any stoma® micro-screws, sterilization trays and sterilization containers.
All stoma® micro-screws, sterilization trays and sterilization containers may only be exposed to temperatures up to a maximum of 138 °C (280 °F)!

Reusability
The stoma® micro-screws are identified as a single-use product
Due to danger of infection and impairment of the technical properties, the stoma® micro-screws may make contact with a patient only one time

Guide values for the number of uses
The stoma® micro-screws that have not been brought into contact with the patient can be sterilized for a maximum of 50 times.

Durability
The stoma® micro-screws should be used within a ten year period from the manufacturing date due to possibly reduced protective properties of the packaging and age related wear.

Documentation and traceability
The packaging material of the stoma® micro-screws includes a label which presents a batch number (LOT); in order to guarantee uninterrupted traceability of the stoma® micro-screw, the doctor is required to include this number in the patient's OP report.

Returns and repairs
The following applies for products already taken out of the original packaging: Returns and complaints are only accepted if the products are declared as "hygienically safe", cleaned, and disinfected, packaged with corresponding proof of decontamination.

Disposal
Defective and obsolete products must be disposed of in accordance with the applicable regulations and national or regional legal provisions.

Liability
The products may only be used according to their intended purpose in the dental area by respectively trained and qualified personnel. Storz am Mark GmbH does not assume any liability for indirect or consequential damages caused by other than intended use, improper use, handling, processing or maintenance and due to failure to observe the instructions for use. The instructions for use were originally prepared in German and translated into the respective national language. The German version takes precedence in case of doubt.

Graphic symbols
The graphic symbols used for identification correspond to the following significations:

	Read the instructions for use		Manufacturer information
	Note the information insert	REF	Article number
	Non-sterile	LOT	Lot number
	Non-reusable		Date of manufacture
CE	CE marking	HIBC 	Health industry barcode

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