Dental Instruments by

stoma®

With passion for perfection

stoma® IFU – individual instruments

MADE IN GERMANY

Instructions for use
Crown removing forceps with exchangeable plastic jaws

Article attribution: 5451.01

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
This crown removing forceps with exchangeable plastic jaws is used for provisionally inserted (i.e. not yet cemented) and very lightly cemented ceramic and cast crowns in the upper and lower jaw both in the anterior and posterior areas.

Indication
The plastic jaws prevent damage to the surface of crowns and bridges. The jaws can be exchanged and sterilized.

Contraindication
An improper use can lead to damages to the tissue, to premature wear, to the destruction of the instrument and dangers for the patient, the user or third parties.

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!**

In case of misuse, all liability is excluded.

Guiding values for the frequency of use
For information on the product lifespan, please refer to point 7 of our preparation instructions WAA_0001.

Used material
Stainless steels | DIN EN ISO 7153-1
Synthetic materials, plastics

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Sorting out worn products

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

Delivery state
The product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

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.

Return
For products which have already been retrieved from the original packaging, the following holds: any returns and complaints can only be accepted if the products have been declared as „hygienically harmless“, been cleaned and disinfected and safely packaged with the associated decontamination evidence.

Disposal
Defects and obsolete products must be disposed of professionally according to the provisions/the national or regional legal rules.

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 improper use, handling, processing or maintenance and by disrespect of the instructions for use. The instructions for use have been produced in German in the original version and translated into the respective national languages. In case of doubt, the German version prevails.

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	Non-sterile	LOT	Lot number
CE	CE marking	HIBC	Health Industry Bar Code

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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CE

IFU no. & name **Date of issue:** 10.01.2019
GA_0007_en_ Crown removing forceps with exchangeable plastic jaws
(translation 22/10/2020 [en])

Instructions for use
Titanium bone screws

Article attribution: 23051.06 – 23051.14; 23052.08 – 23052.14; 23053.04 – 23053.14

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 titanium bone screw is used to fix transplanted bone blocks during the augmentation process.

Indication
Titanium bone 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.
Titanium bone 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 titanium bone 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 steel 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 titanium bone screws. The titanium bone 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. Titanium bone 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 titanium bone screw.
Prior to turning in the titanium bone 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 (cross slot) 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 titanium bone screws: 5 - 15 rpm (also while using the screwdriver tip for contra-angle piece), with a set torque of maximum 0.080 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 titanium bone screw, the titanium bone screw should be twisted in carefully in order to prevent a damage of the screw or the bone construction through mechanical forces.

Used material
Titanium: ISO 5832-3 | ASTM F136

Products made of titanium wrought alloy
The titanium wrought alloy used for production, with a very low proportion of interstitial dissolved elements, exhibits good ductility, even at low temperatures. Furthermore, the biocompatibility of this material is good and it rarely causes allergic reactions.

⚠ **The titanium bone 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 the titanium bone screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.**

Connections/interfaces
- Screw driver (self-retaining)
- Tip for contra-angle piece
- Tip for hand 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 titanium bone 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 titanium bone screws

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

⚠ **Titanium bone 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 titanium bone screws and the corresponding tray will be required.

Within the scope of your responsibility for the sterility of the titanium bone 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 titanium bone 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),

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GA_0026_en_ Titanium bone screws (translation 29/07/2020 [en])

- 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 titanium bone screws),
- that the chosen program is suitable for the titanium bone screws and has a sufficient number of rinsing cycles,
- 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 titanium,
- 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 titanium bone 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 titanium bone screws into the cleaning and disinfection device. Make sure the titanium bone screws do not touch each other.
2. Start the program.
3. Remove the titanium bone screws from the cleaning and disinfection device after the program ends.
4. Inspect and package the titanium bone 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 titanium bone 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 bone screws made of titanium,
- 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 titanium bone 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 titanium bone screws into the cleaning bath for the specified exposure time, ensuring that the titanium bone screws are adequately covered. Make sure the titanium bone screws do not touch each other.
2. Remove the titanium bone screws from the cleaning bath and rinse them thoroughly with water at least three times (for at least 1 minute).
3. Inspect the titanium bone screws (see the section “Inspection”).

Disinfection
1. Place the cleaned and inspected titanium bone screws into the disinfection bath for the specified exposure time, ensuring that the titanium bone screws are adequately covered. Make sure the titanium bone screws do not touch each other.
2. Remove the titanium bone screws from the disinfection bath and rinse them thoroughly with water at least five times (for at least 1 minute).
3. Package the titanium bone 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 titanium bone 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 titanium bone screws for surface damage, chipping, contamination, discolouration and corrosion. Reject titanium bone screws that are damaged. Titanium bone screws that are still dirty have to be cleaned and disinfected again. Titanium bone 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 titanium bone screw. For the maximum number of reuse cycles, see the sections “Reusability”.

Packaging
If applicable, sort the cleaned and disinfected titanium bone screws into the corresponding sterilization tray (suitable block for screws).
Package the titanium bone 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 titanium bone 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 titanium bone 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

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

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

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

Durability
The titanium bone 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 titanium bone screws includes a label which presents a batch number (LOT); in order to guarantee uninterrupted traceability of the titanium bone 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	Non-sterile	LOT	Lot number
	Non-reusable		Date of manufacture
CE	CE marking	HIBC	Health industry barcode

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CE 0297

Instructions for use
Tissue punches Dr. Ady Palti

Article attribution: 13388.03 – 13388.06

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/ Indication
The tissue punches according to Dr. Ady Palti are used for the targeted minimally invasive removal of gums in the field of oral implantology or periodontology.

Contraindication
An improper use can lead to damages to the tissue, to premature wear, to the destruction of the instrument and dangers for the patient, the user or third parties.
To avoid any harm to adjacent structures like the tooth root, mouth base, maxillary sinus or nerve channel, the environment of the extraction site must be precisely examined.
The indicated rotational speed must be respected as well as permanent external cooling under low pressure during the punch procedure. The pressure must be adapted to the condition of the extraction site, like the tissue quality of the patients. Too high rotational speeds and pressing forces close to the tooth pulp jeopardize its vitality, the same holds for insufficient cooling technology.
Do not exercise any leveraging movements, otherwise, the tissue punch might slip off the intended extraction site thus causing injuries.
To avoid infections, the procedure must be kept absolutely sterile.

Possible side effects
During the use of the tissue punches heat might be produced, which can cause necrosis, undesired tissue preparation, soft tissue injuries, tissue degradation, nerve injuries and infections.
The materials used can lead to allergic reactions, e.g. in patients reacting allergically to chrome.

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!
In case of misuse, all liability is excluded.

Used material
Stainless steels | DIN EN ISO 7153-1

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Application/handing
The tissue punches can be used in conjunction with an angle piece or manually. The shaft connections are designed according to DIN EN ISO 1797-1 and to be used with a hand or angle piece corresponding to the applicable norms. Before use, it must be checked if the correct fit in the angle piece is guaranteed.
Before approaching the object, the instruments must be brought up to the right rotational speed. The preparation is carried out under low pressure down to the desired depth with the rotational speed recommended below.

Recommended rotation speed
For the use of the tissue punches in connection with an angle piece, we recommend a low rotation speed of c. 800 to 1000 rpm.

⚠ **If the admitted rotation speed is not respected, this leads to an increased safety risk.**
If the recommended rotation speed is not respected, this can lead to unfavorable work results

Pressing forces
Excessive contact pressures have to be avoided. With cutting instruments, they can cause damage of the working part and rupturing of the blade. Heat development increases as well.

Cooling
The tissue punches should be cooled by sprinkling with an isotonic saline solution.

⚠ **Insufficient water cooling can lead to excessive heating and, in the worst case, to irreversible damage to the bone and the adjacent tissue (thermal necrosis). In addition, the lifespan of the instruments is reduced.**

Guide values for the frequency of use
Instruments made of non-corroding stainless steel can be used ca. 4 times, but this value can deviate from the actual standing times depending on the type of use and/or the material treated. Sometimes, the instruments can even be used longer as long as no wear is visible.

Sorting out worn products
- Chipped and deformed cutting edges cause vibrations leading to uneven preparation edges and coarse surfaces.
- Blunt instruments tend to lead to higher pressing forces and thus increase the working temperature. This can damage the pulp.

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

Delivery state
The product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

Safekeeping/storage
- Until the first use, it should be stored in the original package at normal room conditions.
- Rotating instruments must be kept and stored in hygienically maintained racks, bowls or other suitable containers. The same analogously also applies to sterilized instruments.
- It should not be stored in direct vicinity of any chemicals.

Return
For products which have already been retrieved from the original packaging, the following holds: any returns and complaints can only be accepted if the products have been declared as „hygienically harmless“, been cleaned and disinfected and safely packaged with the associated decontamination evidence.

Disposal
Defects and obsolete products must be disposed of professionally according to the provisions/the national or regional legal rules.

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 improper use, handling, processing or maintenance and by disrespect of the instructions for use. The instructions for use have been produced in German in the original version and translated into the respective national languages. In case of doubt, the German version prevails.

Graphic symbols
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NON STERILE	Non-sterile	LOT	Lot number
opt.	Optimal rotaion speed	max.	maximum rotation speed
CE	CE marking	HIBC	Health Industry Bar Code

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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IFU no. & name **Date of issue:** 13.04.2018
GA_0029_en_ Tissue punches Dr. Ady Palti (translation: 22.10.2020 [en])

Instructions for use
Screwdriver for cross-slot screws, self-retaining

Article attribution: 23048.00

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 screwdriver is only used to screw in and screw out titanium cross-slot bone screws.

Indication
The screwdriver is used to screw in and screw out cross-slot screws. It ensures an easy screw pick up and a secure holding of the screws thanks to the self-retaining mechanism.

Contraindication
- An improper use can lead to damages to the tissue, to premature wear, to the destruction of the product and dangers for the patient, the user or third parties.
- The materials used can lead to allergic reactions, e.g. in patients reacting allergically to chrome.

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!
In case of misuse, all liability is excluded.

⚠ **The screwdriver may only be used in conjunction with bone screws that have been placed on the market by Stoma. Before use, it must be checked that the attachment is correctly seated in the hexagon.**

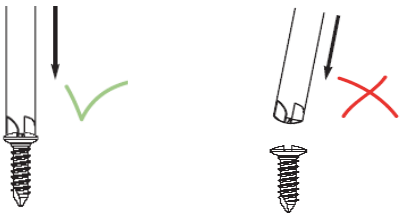
Used material
Stainless steels | DIN EN ISO 7153-1

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Components of the screwdriver
It consists of a handle and a screwdriver tip that must be installed before use.

Mounting/Dismounting
Inserting and removing the screwdriver tip

1. Pull back the small ring on the handle and hold it in this position.
2. Insert the tip an
3. turn it slightly in the direction of the arrow until it engages in the hexagon.
4. When the tip is correctly inserted / removed, the ring snaps back into its original position.
5. Pick up the screw



Place the tip of the screwdriver vertically, the screw is fixed.

Sorting out worn products

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

Delivery state
The product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

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.

Return
For products which have already been retrieved from the original packaging, the following holds: any returns and complaints can only be accepted if the products have been declared as „hygienically harmless“, been cleaned and disinfected and safely packaged with the associated decontamination evidence.

Disposal
Defects and obsolete products must be disposed of professionally according to the provisions/the national or regional legal rules.

Liability
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NON STERILE	Non-sterile	LOT	Lot number
CE	CE marking	HIBC	Health Industry Bar Code

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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CE

IFU no. & name **Date of issue:** 21.09.2020
GA_0031_en_ Screwdriver for cross-slot screws, self-retaining (translation: 22.10.2020 [en])

Instructions for use
Application instrument with pusher

Article attribution: 14634.00, 14635.00

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 application instrument with slide serves the uptake and application of bone material with one hand.

Indication
The open bone applicator with slide (piston) offers the advantage of a simple uptake and the application of bone material with one hand. The bone material is taken up through the opening on the upper side and applied with the piston guide controlled by the finger. The level tamper on the other working edge allows to compress and adapt the bone material at the desired position of the defect.

Contraindication
An improper use can lead to damages to the tissue, to premature wear, to the destruction of the instrument and dangers for the patient, the user or third parties.

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!**

In case of misuse, all liability is excluded.

Used material
Stainless steels | DIN EN ISO 7153-1

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Composition
<u>14634.00 straight</u>

Illustration 1

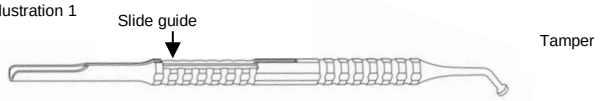
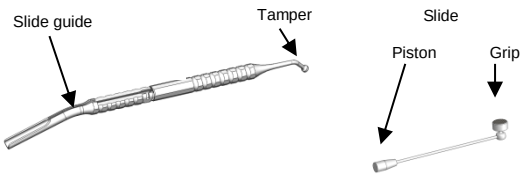


Illustration 2

<u>14635.00 curved</u>

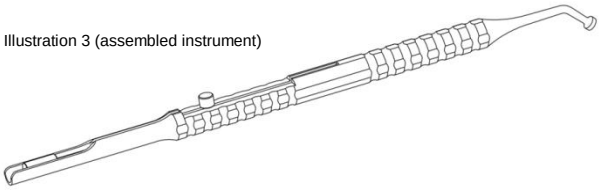


The application instrument consists of two parts:
- a continuous instrument with an opening and slide guide on one working edge and a tamper on the opposed working edge.
- a loose slide with piston and grip.

Assembly/Disassembly
<u>14634.00 straight</u>

1. Assembly: Insert the piston (figure 2) with the slide grip upwards into the slide guide of the instrument (figure 1).
2. In order to check the function, the slide is moved into the direction of the tamper end to the opposite stop.

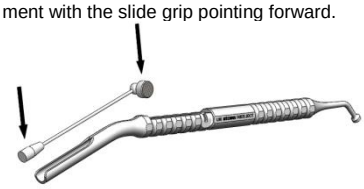
Illustration 3 (assembled instrument)



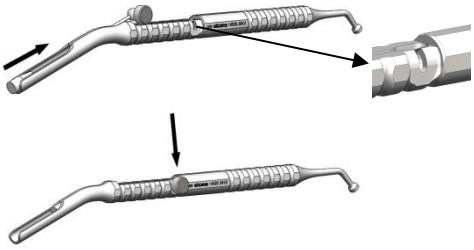
3. Disassembly: Push the slide piston as far as it will go into the direction of the intake edge (fig. 1, left page), slightly lift the grip and push it out entirely.

<u>14635.00 curved</u>

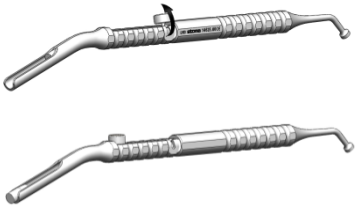
1. Assembly: Insert the slide (as illustrated) into the slide guide of the instrument with the slide grip pointing forward.



2. Move the slide (as illustrated) into the direction of the tamper until the opposite stop and push it down into the provided incision on the grip.



3. Turn the slide grip upwards in the slide guide.
To check the function, move the slide to and fro in this position.



4. Disassembly: Position 1 to 3 in reverse order

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 product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

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.

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.

IFU no. & name **Date of issue:** 09.05.2018
GA_0032_en_ Application instrument with pusher (translation: 03.07.2018 [en])

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		Article number
	Non-sterile		Lot number
	CE marking		Health industry barcode

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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Instructions for use
Contra-angle piece for screwdriver

Article attribution: 23040.00, 23049.30

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
For easier and faster screwing in and screwing out of bone screws in the context of implantological interventions, we have developed inserts for use with the handpiece / contra-angle of the dental unit for use by experienced implantologists.

Indication
The screwdriver insert is used to screw in and screw out cross-slot screws and square head screws.

Contraindication
- An improper use can lead to damages to the tissue, to premature wear, to the destruction of the product and dangers for the patient, the user or third parties.
- The materials used can lead to allergic reactions, e.g. in patients reacting allergically to chrome.

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 screwdriver inserts are only designed for the cross-head screws and square screws placed on the market by Stoma and may only be used in this combination.**

⚠ **Prior to turning in the bone screws, the use of a drill becomes necessary.**
It is up to the surgeon to decide on the use of the insert for mechanically screwing in or out screws during augmentation. The supplied insert can also be used manually in conjunction with our handle (Article No. 13389.00).
The screw driver insert has to be in straight line to the screw in order to prevent an increased risk of damage through mechanical impacts for the screw.
If the insert is used for mechanical screwing in, a hand-held screwdriver or the handle 13389.00 is recommended for the final screwing phase.
After the sensible increase of resistance during the final phase of the turning-in of the Stoma bone screw, the bone screw should be twisted in carefully in order to prevent a damage of the screw or the bone construction through mechanical forces.

Recommended rotation speed
We recommend a speed of 5-15 rpm.
We recommend using a manual screwdriver or the handle (13389.00) for the final screwing phase.

⚠ **If the admitted rotation speed is not respected, this leads to an increased safety risk.**
If the recommended rotation speed is not respected, this can lead to unfavourable work results.

Used material
Stainless steels | DIN EN ISO 7153-1

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Application/handing
The shaft connections are designed according to DIN EN ISO 1797-1 and to be used with a hand or angle piece corresponding to the applicable norms. Before use, it must be checked if the correct fit in the angle piece is guaranteed. The instructions for use of these devices must be respected. The instruments should not be fixed more deeply than necessary.

Sorting out worn products

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

Delivery state
The product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

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.

Return
For products which have already been retrieved from the original packaging, the following holds: any returns and complaints can only be accepted if the products have been declared as „hygienically harmless“, been cleaned and disinfected and safely packaged with the associated decontamination evidence.

Disposal
Defects and obsolete products must be disposed of professionally according to the provisions/the national or regional legal rules.

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 improper use, handling, processing or maintenance and by disrespect of the instructions for use. The instructions for use have been produced in German in the original version and translated into the respective national languages. In case of doubt, the German version prevails.

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	Non-sterile	LOT	Lot number
opt.	Optimal rotation speed	max.	Maximum rotation speed
CE	CE marking	HIBC	Health Industry Bar Code

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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CE 0297

IFU no. & name **Date of issue:** 28.01.2019
GA_0033_en_ Contra-angle piece for screwdriver (translation 22.10.2020 [en])

Instructions for use
stoma p.i.c.®-container & permanent filter

Article attribution: 6700.04 – 6700.13, 6621.40, 6708.00

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
Indication
stoma® p.i.c.®-containers are intended to be loaded with medical devices for sterilization. The sterilization and storage of the encased products are enabled and insured until the next use. The container systems are optimally suitable for steam sterilization (fractionated vacuum process).

A permanent filter serves as germ barrier for the steam sterilization of instruments and is a reusable product that can be correctly inserted into sterile containers.

Contraindication
- Improper use can lead to damages to the container and the permanent filter.
- The use of aggressive detergents can lead to discolorations/staining and even damages to the container and the permanent filter.

⚠ **Do not use for any other than the above-mentioned sterilization methods!**

⚠ **The processing of medical devices must be complied with the national regulations and standards.**
In case of patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or any kind of variations of this disease, the currently relevant national regulations must be applied concerning the processing.

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!
In case of misuse, all liability is excluded.

Used material
stoma® p.i.c.®-container: aluminum alloy | DIN EN ISO 868-8
Permanent filter: PTFE (teflon)

The stoma® p.i.c.®-containers are made of aluminum alloy with an anodized oxide surface which prevents corrosion. Abrasive cleaners, metal brushes or abrasive cleaning pads can cause permanent damage to the container surface and therefore must not be used. Warranty exclusions will be the result in case these instructions are not followed.

Use/handling
Sterilization containers must be used only by qualified or trained and experienced personnel, in order to prevent damage to the containers, closing devices, gaskets and sterile filters. Colored identification tags provide information about the content and location for their use. The closing device can be provided with a security seal, which has to be broken when opening. Only an intact security seal ensures that the sterilization container has not been opened without permission.

Permanent filters must be used only by qualified or trained and experienced personnel. Taking the correct size attribution into account, permanent filters can be inserted into the containers provided for that. The permanent filter is to be checked before each and every sterilization cycle for damage. Permanent filters must have the correct measurements to cover the perforation completely in the container lid.
After the permanent filter is inserted into the filter holder, the filter holder must be depressed so that it can be heard that it clicks into place. Number of sterilization cycles in case of an intact filter: 1200

No adhesives may be applied to the permanent filters (e.g. to document cycles), since adhesives destroy the germ barrier. Only in case of gross contamination, the filter can be removed and then carefully cleaned manually.

An independent and accredited testing laboratory carried out tests and examinations as to the suitability of the permanent filters. The results are as follows:
The used Stoma-PTFE permanent filters are suitable to prevent bacterial growth according to the requirements of DIN 58953 Part 6, Chapter 2.14.

⚠ **To guarantee flawless functioning of the permanent filters, please pay attention to the following information:**
- Respect the specifications for loading the used containers.
- Never puncture the sterile filters.
- Prevent the penetration of bacteria through:
  - the spilling of dirt, cleaning or disinfection solutions
  - Penetration of contaminated external condensate (for example through the space between the stack of hot containers)
  - Rubbing of dust and dirt in the filter by wiping the containers
  - Long term storage

Use in combination with other products
Security seals are attached to the closures outside by guiding the seal through the opening of the spring lock system and joining the seal. The seal will break by opening/flipping the latches.

The supplied indicator of indicator labels changes its color during steam sterilization at 134° C.

Paper filters are intended for one use only. Paper filters are produced according to ISO 11607-1. The paper filters must have the correct measurements to cover the perforation completely in the container lid.

Warranty services can only be provided in case of the exclusive use of original Stoma products or, if applicable, fitting Ermis products. (see point „General Information“).

⚠ **Combine only original Stoma component parts such as lids, bottoms, filters, gaskets and filter holders with each other in order to avoid putting at risk the leak tightness and germ barrier.**
All filters or joints from other manufacturers (excluding the above-mentioned manufacturer) must be accepted by Stoma before they can be used, otherwise Stoma does not assume any warranty.

Implementing of a new/unused container
- The container must be thoroughly cleaned before it is used for the first time.
- The container must be pre-processed in a validated cleaning/washing machine and disinfection process.
- A neutral cleaning agent (pH value 7) should be used for this purpose in the machine.
- Once the pre-processing in the cleaning and disinfection device is completed the products must be steam sterilized at 134° C in a fractionated steam sterilization process.
- Furthermore, all movable parts on the container must be treated regularly with approved instrument maintenance oil.
- A suitable new filter will have to be inserted after the cleaning process (see „Changing of filter”).

Preparation for cleaning
1. Separate the container bottom and lid
2. Remove the contents of the container (tray, instruments, etc.)
3. When using a disposable filter:
   a. Remove the filter holders from the inside of the lid and if applicable from the bottom part (in the case of containers with perforated bottom)
   b. Dispose the disposable filter.
4. When using a permanent filter:
   a. Machine cleaning can be done without removing the filter, but the filter, if necessary, can also be cleaned separately in the cleaning and disinfection device.
   b. Manual cleaning is only done in case of severe contamination of the filter. The filter is removed from the container and cleaned carefully with an appropriate detergent with tested effectiveness (e. g. VAH or FDA approval/CE-labeling).
5. Remove the disposable seals and indicator labels.

⚠ **All paper filters are disposable filters and must be replaced after each use of the container.**

Cleaning and disinfection

⚠ **Improper washing and disinfection may lead to corrosion and stress fractures. For that reason, the specifications of the washing/ disinfection product manufacturer must be considered. The cleaning agent must be free of sodium, alkaline and carbonate and it must have a neutral pH value and/or approved for the treatment of anodized aluminum by the chemical's manufacturer.**

Only demineralized water (quality according to EN 285 Enclosure B) is recommended for the preparation of the containers.
- The container must be washed and disinfected before the first use.
- Containers used for disposal must be cleaned and disinfected after every use.

Manual cleaning/disinfection
- Mild, neutral cleaning agents should be used for the stoma® p.i.c.®-containers and lids which are specifically approved also for the treatment of aluminum containers by the manufacturer. A soft sponge should be used.
- After washing, a thoroughly rinsing with suitable low-salt water (such as demineralized water) and sufficient drying is necessary.

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GA_0034_en_ stoma p.i.c.®-container & permanent filter
(translation: 03.07.2018 [en])

- Do not use any metal brushes or abrasive cleanser.
- Finally, disinfection is to accomplish according to the respective hygiene requirements.
- Manual cleaning of the permanent filter is only done in case of a severe contamination of the filter. The filter is removed from the container and carefully cleaned with an appropriate detergent with tested effectiveness (e. g. VAH or FDA approval / CE labeling).

Mechanical cleaning
Contaminations that cannot be removed in the usual cleaning procedure, irrespective of the method (sticking labels, indicator strips, markings), can be removed with Eloxal detergent. After this special treatment, the containers must be cleaned as usual.

- Neutral or other suitable cleaning and disinfection solutions are to be used which are explicitly approved for the treatment of aluminum products. If necessary, the products must be checked for the suitability for the relevant procedure.
- Only use neutral cleaning agent for the stoma p.i.c.®-containers, which are specifically approved for the washing of aluminum containers by the manufacturer. For the proper dosing please refer also to the manufacturer's specifications. These products are also suitable for cleaning surgical instruments by optimizing the program.
- If using neutralization agent the products must be checked for the suitability for aluminum.
- Low-salt water should necessarily be used for the final rinsing.
- The cleaning devices and inserts must be suitable for the processing of containers and lids. This applies particularly for the correct positioning in the loading inserts to allow adequate and unobstructed rinsing of media flow and the drying of all containers and lids.
- Containers and lids may not be cleaned and disinfected in a closed/assembled state.
- Attention must be paid when loading the machine to ensure a sufficient media flow during the process.
- The container bottom must be placed into the washing machine with the opening downward in order to prevent the accumulation of water and to ensure that the used media flows off adequately.
- The container lid must be washed with the inside facing downward and the latches/closures folded outward.
- The containers and their accessories, without any visible residues, will be removed from the media after completing the mechanical cleaning and disinfection process.
- Should there be still any residues detected then the position of the containers and accessories in the device should be rechecked and possibly changed.
- Machine cleaning of the permanent filter can be done without removing the filter, but the filter, if necessary, can also be washed separately in the cleaning and disinfection device.

Recommended cleaning procedure
We recommend the following validated cleaning procedure:

- 1 minute pre-cleaning with cold (<40°C) water
- 3 minutes cleaning with Mediclean 0,5 % (Dr. Weigert) at 45 °C
- Neutralization with demineralized water

Inspection, maintenance and testing
The sterilization containers rnust be inspected for their functionality before each use. Damages on the closures, gaskets, filter holders and filters as well as bent or dented parts indicate for the need of repair of the sterilization containers and may not be used. Do not use defective sterilization containers.

- The durability of the gasket is up to 500 sterilization cycles. After that, the gaskets will have to be checked out.
- All movable parts on the container must be treated with approved instrument maintenance oil.
- If there are any damages detected on the gaskets, then they have to be replaced immediately.
- The gaskets should not be treated with spray, oil or solvents. It is enough for cleaning and maintenance to wipe occasionally with a moist cloth.
- If there are any damages detected on the sterilization containers then they have to be inspected, repaired or replaced if necessary.
- The sterilization containers may be maintained and repaired only by qualified persons. Do not try to repair yourself the gaskets or attachments in order not to compromise the safe use of the container.
- The sterilization containers may be returned for maintenance or repair to Stoma.
- Spare parts such as filter holders, disposable paper filters, PTFE permanent filters, colored marking labels and plastic security seals can be obtained at Stoma.

Changing of filter
After changing the filter, the filter holder has to be placed by pressing into its correct position with an audible snap. Stoma lids may only be used with Stoma filter holders.

- Disposable paper filters must be reinserted before every re-sterilization.
- PTFE filters have been tested for usage duration of 1200 cycles and must be replaced afterwards.

Recommended sterilization process
stoma p.i.c.®-containers have been validated with the following sterilization parameters:

Method:	3 x pre-vacuum steam sterilization
Temperature:	134 °C (273 °F)
Holding time:	5 minutes
Drying time:	10 minutes
Loading:	Standard medical instruments (scissors, clamps, forceps) and textiles

⚠ **Use with gas sterilization is not appropriate because it is done with formaldehyde or ethylene oxide.**
The stoma p.i.c.®-containers are not prepared for that.

Loading of the container
The total weight of the load of a container should not exceed the following loading size. Otherwise a satisfying sterilization result cannot be ensured.

Model	Ref.no.	dimensions in mm	max. recommended loading in kg	
			instruments	textiles
dental container	6700.04	ca. 310x190x40	0,6	0,5
	6700.06 resp. 6622.00	ca. 310x190x65	0,9	0,7
	6700.10 resp. 6623.00	ca. 310x190x100	1,4	1,0
	6700.13 resp. 6624.00	ca. 310x190x130	1,8	1,4

In case of loading with textiles, please pay attention that the pieces of laundry or folded textiles are in vertical position. It should still be easily possible to slide an open hand between the pieces of laundry by a fully loaded container.

⚠ **The sterilization of various container loadings and the configurations must be determined by the responsible personnel. Endoscopes, instruments with lumina, compressed air or mains-powered units and instruments with cannulas must be prepared for the sterilization according to the specifications of the manufacturer. Small baskets, trays or other accessories, especially the ones with lids or flaps, should only be used together with sterilization container systems, if these were specifically designed and tested for this purpose.**

⚠ **Using water resistant inserts (such as plastic/silicone inserts) may cause remaining condensate inside of the container. Instead please use moisture-absorbing mats. Check the integrity of the inserted filter and the proper sealing of the filter holder. Always use the locking mechanism to attach the container lid to the bottom before placing the container into the sterilizer. Otherwise, the container content becomes unsterile as soon the sterilizer door is opened.**

Position in sterilizer
The stoma p.i.c.®-containers are designed so that they can be used in any commercially available large sterilizer for the sterilization with moist heat. Keep in mind that heavy containers are to be positioned at the bottom of the sterilization chamber. The containers can be stacked easily and safely on top of each other due to their design, without slipping during the sterilization procedure. Stacking is only recommended for sterilization cycles operating with a fractionated vacuum system. The maximum stacking height should not exceed 46 cm in order to ensure an effective air removal and steam penetration. The instructions of the manufacturer of the sterilizer must be followed.

⚠ **Pay attention to the following during sterilization:**
Never wrap the container in an additional outer packaging. Never cover the perforation fields in the lid and bottom with foil packaging or something similar because this prevents the air and steam flow in the container. As a result, there would be a container deformation caused by vacuum due to insufficient pressure compensation and the sterility of the loading cannot be guaranteed. Always carry the sterile container by the carrying handles and never by the lid during loading and/or unloading the sterilizer as well as during transport.

Sequence control

- Operate the loaded sterilizer for the selected sterilizer cycle according to the specifications of the sterilizer manufacturer (referring to temperature and sterilization time). The validation results are in the process to be considered.
- The container should cool down completely on the sterilization cart to avoid condensation in the container.
- The sterile goods must be evaluated and approved after each sterilization according to internal directives and validation results. This is consequently conducted by employees with special knowledge, qualification level 1.

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GA_0034_en_ stoma p.i.c.®-container & permanent filter
(translation: 03.07.2018 [en])

Storage of sterile goods
Under normal clinical conditions, sterile materials remain sterile between several weeks and six months (in closed sterile containers and with undamaged sterile filters). The storage time generally depends on the storage conditions and must be determined by the responsible hygiene specialists. In case of extremely high requirements for asepsis or deviations on the specified storage conditions are shorter storage periods or additional packaging to be used.
Recommended storage conditions:
- Temperature: 15-26 °C
- Humidity: 30-50 %
- Air pressure: normal atmospheric pressure

Different container loadings, storage periods and storage conditions are the responsibility of the hygiene specialists. stoma p.i.c.®-containers have been tested for a storage period of 6 months by applying of Bacillus subtilis – spore suspension. Therefore, we stipulate a storage period of 6 weeks on open shelves and 6 months, if stored under protected circumstances (such as in closed cabinets).

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 product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

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.

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.

Standards applied
The following standards were considered to ensure the safety of the sterilization containers during manufacturing and handling:

DIN EN 868-2	Packaging for medical devices to be sterilized in the final packaging - Part 2: Sterilization wrap - Requirements and test methods
DIN EN 868-8	Packaging for medical devices to be sterilized in the final packaging - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
DIN EN ISO 11607-1	Packaging for medical devices to be sterilized in the final packaging - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN 58952-2	Sterilization; Packaging for sterile goods, sterilizing baskets made of metal
DIN 58952-3	Sterilization; Packaging for sterile goods, sterilizing trays made of metal
DIN 58953-9	Sterilization - Sterile goods supply - Part 9: Application technology of sterilization containers
DIN EN ISO 14937	Sterilization of health care products - General requirements for the characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 11134	Sterilization of health care products; Requirements for validation and routine monitoring; Industrial hot steam sterilization
DIN EN ISO 17665-1	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and control of the application of a sterilization process for medical devices
DIN EN 285	Sterilization – Steam sterilizers – Large sterilizers

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
HIBC	Health industry barcode	LOT	Lot number
CE	CE marking		

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CE

IFU no. & name **Date of issue:** 09.05.2018
GA_0034_en_ stoma p.i.c.®-container & permanent filter
(translation: 03.07.2018 [en])

Instructions for use
Disposable paper filter for containers

Article attribution: 6707.00

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
A paper filter serves as a germ barrier and is to be used only once.

Indication
The disposable Stoma paper filter is only intended for one single use. The paper filter is manufactured according to ISO 11607-1. The paper filter must be dimensioned in such a way that the perforation in the container cap is completely covered.

Contraindication
The disposable paper filter may only be used for its intended use in dental medicine (container accessories) by suitably trained qualified personnel.

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!**

In case of misuse, all liability is excluded.

Used material
Sterilization paper | ISO 11607-1

Steam indicator color
The steam indicator color is printed on the filters and changes its color as soon as they are exposed to the sterilization cycle. The color changes from pink to brown.

Use/handling
Put one disposable paper filter over the perforated area on the inner side of the cap of the sterilization container. Make sure that the indicator points towards the interior of the container. Once the filter is in position (and the indicator is visible), fix the indicator with the retaining plate. Nothing may be stuck on the paper filter (e.g. to document the passages) because the glue may contain pollutants, besides, the lamination would destroy the germ barrier.

⚠ **Please respect the following indications to guarantee a flawless function of the disposable paper filter:**
- Respect the specifications for loading the used containers.
- Never pierce the sterile filters.
- Avoid the intrusion of germs by:
  - the spilling of pain, cleaning or disinfection solutions
  - the intrusion of contaminated external condensate (e.g. through gaps when stacking hot containers)
  - intrusion of dust and dirt into the filter by rubbing when wiping the container
  - long-term storage

Sorting out damaged 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 product is delivered in a non-sterile state.

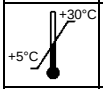
Safekeeping/storage
Should be stored the original package in dry conditions (30-35 % RH, 5-30 °C).
In case of correct storage, the lifetime of the filters is c. 5 years after the date of manufacture.

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		Article number
	Non-reusable		Lot number
	CE marking		Health industry barcode
	Temperature limit		Use by
	Date of manufacture		

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IFU no. & name **Date of issue:** 09.05.2018
GA_0036_en_ Disposable paper filter for containers (translation: 03.07.2018 [en])

Gebrauchsanweisung

Instruction for use

PROTOKOLLKÄRTCHEN MIT INDIKATOR

LOG CARDS WITH INDICATOR

Sie erhalten mit dem Erwerb der Stoma Einmal-Protokollkärtchen mit Indikator ein hochwertiges Produkt, das für alle Stoma Sterilcontainer anwendbar und in Zusammenhang mit einer Dampfsterilisation einsetzbar ist.

1. Artikelnummer und Bezeichnung
6625.00 Protokollkärtchen mit Indikator (100 Stück)

2. Anwendung:
Stecken Sie das Protokollkärtchen in den Schlitz des Sterilisationscontainers.

3. Dampfindikatorfarbe:
Die Indikatorfarbe ist auf das Kärtchen aufgedruckt und ändert ihre Farbe von rosa nach braun wenn sie dem Dampfsterilisationszyklus ausgesetzt war. Der Farbwechsel ist jedoch keine Bestätigung für eine erfolgreiche Sterilisation der Gesamtbeladung.
Als abziehbare Selbstklebeetiketten können die Protokollkärtchen anschließend direkt in Ihre Sterilisationsdokumentation mit übernommen werden.

4. Lagerung:
Die Lagerung sollte in der Originalverpackung und unter trockenen Bedingungen erfolgen (35-50% RH, 5-30 °C). Bei korrekter Lagerung beträgt die Haltbarkeit der Protokollkärtchen ca. 5 Jahre nach Herstellungsdatum.

5. Entsorgung:
Nach dem Gebrauch können die Einmal-Protokollkärtchen der üblichen Entsorgung zugeführt werden.

On purchase of this disposable log cards with indicator you will receive a product of high quality, compatible to all STOMA sterilisation containers and usable for steam sterilisation.

1. Article number and description:
6625.00 Log cards with indicator (100 pieces)

2. Handling:
Put the log card into the slit of the sterilisation container.

3. Steam indicator ink:
The indicator ink printed on the log card changes the colour from pink to brown when exposed to the steam sterilisation cycle. This change of colour is, however, no confirmation of a successful sterilisation of the complete container load.
Being designed as peelable adhesive labels the log cards can be transferred into your sterilisation documentation directly afterwards.

4. Storage
The product shall be stored in its original packaging in dry conditions (35-50% RH, 5-30 °C). When stored correctly the shelf life of the product is approx. 5 years from the date of manufacturing.

5. Disposal
After use you can dispose the log card in accordance with local custom.

Graphische Symbole
Die zur Kennzeichnung verwendeten Symbole gemäß DIN EN 980:2008 entsprechen folgender Bedeutung:

Graphic symbols
The significance of the symbols used for identification purposes according to DIN EN 980:2008 corresponds to the following:

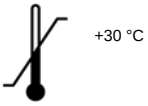
"Gebrauchsanweisung beachten"
"Follow instructions for use"

"Chargenbezeichnung"

„Lot description"

"Artikelnummer"
„Catalogue number"

"Nicht zur Wiederverwendung"
„Do not re-use"



"Temperaturbegrenzung"
"Temperature Margin"

"Herstellungsdatum"
„Manufacturing date"

"Verwendbar bis"
„use by"

Instructions for use
stoma® micro-screws

Article attribution: 23060.04 – 23060.14; 23061.04 – 23061.14

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,

IFU no. & name **Date of issue:** 16.09.2020
GA_0038_en_ stoma® micro-screws (translation 29/07/2020 [en])

- 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

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	Non-sterile	LOT	Lot number
	Non-reusable		Date of manufacture
CE	CE marking	HIBC	Health industry barcode

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IFU no. & name **Date of issue:** 16.09.2020
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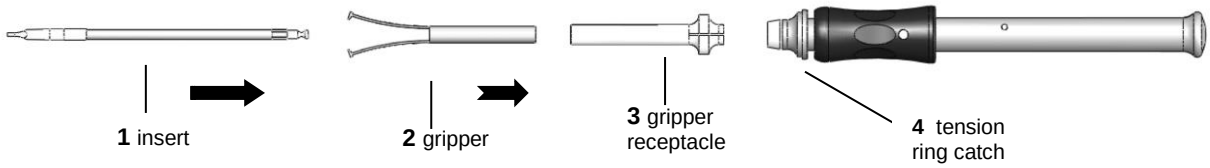
Instructions for use

micro-screw SCREWDRIVER WITH GRIPPER



The screw driver serves to implement the STOMA micro-screws (to screw in or out). The gripper embraces the micro-screw and thus guarantees a secure hold and effortless application.

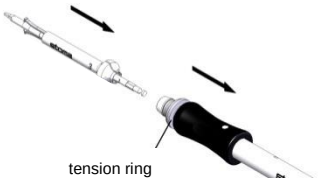
It consists of a handle (see assembly instructions below) into which the gripper and its receptacle with the insert may be placed in the following sequence:

Mounting/Dismounting

1. Introduce the insert with square key (1) into the gripper (2) from the front.

2. Insert the gripper with square key again from the front into the receptacle (3).

3. Pull the tension ring (4) back and insert the mounted gripper device into the designated opening.



4. Release the tension ring and trigger the catch by slightly turning the gripper.

5. Check the unit for a firm fit.
6. To dismount: repeat 1 to 3 in reverse order.

Warnings and Precautions

To be used by dental professionals only! The STOMA screw-driver must be used in combination with STOMA micro-screws only!

For optimal power transfer and to prevent damage to screws the screw-driver must be oriented to the screw in a straight line always.

Follow the user instructions.

Preparation (Cleaning, Disinfecting and Sterilization) of the attachment

General Principles

STOMA-screw drivers are shipped in non-sterile condition and must be cleaned, disinfected and sterilised prior to their use (cleaning and disinfection are done after removing the piece from its protective packaging, while sterilisation occurs after packaging).

For this purpose the screw-driver must always be disassembled into all its individual components (see description above). The individual components must be cleaned and prepared separately. Effective cleaning and disinfection are indispensable prerequisites for effective sterilization.

As a matter of principle within the framework of your responsibilities, in order to ensure the sterile condition of the applied medical devices destined for use, please assure that only sufficiently validated, equipment- and product-specific procedures for the cleaning/disinfection and sterilization are applied, that the devices used (such as the disinfecting and sterilization equipment) are regularly serviced and inspected, and that the validated parameters are adhered to in each respective cycle.

Furthermore, the legal requirements which are at work in your particular country, as well as all of the hygiene requirements applicable to medical practices and hospitals must be observed. This is of particular importance for the varying specifications issued with respect to effective prionic deactivation.

Cleaning and Disinfection

Principles

In general, cleaning and disinfection should take place immediately after use of the products to prevent drying of blood residues which will be much more difficult to clean later. Blood residues may be carriers of pathogenic agents such as found in Creutzfeld-Jakob disease.
If possible, machine based methods (disinfecting equipment) shall be used to carry out cleaning and disinfecting procedures. Due to obviously lower effectiveness and reproduceability, manual procedures – even those using ultrasonic baths – should only be applied if machine-based procedures are not available.

Pre-Treatment

Place of application: Unclean surfaces must be removed with a disposable (single use) towel/paper towel.

Machine Based Cleaning/Disinfection (Disinfector/RDG)

When selecting disinfection equipment please consider:

- that the disinfector has principally been tested for effectiveness (i.e. VAH- or FDA approved or CE marking according to DIN EN ISO 15883).
- that, if possible, a tested programme for thermic disinfection is used (at 93˚C Ao value > 3000 for a minimum of 10 minutes). Chemical disinfection procedures bear the risk of leaving disinfectant residues on the devices,
- that the applied programme is suitable for the device and that it includes enough rinsing cycles,
- that after-rinse cycles are carried out using sterile or low-germ (max. 10 germs/ml) and low endotoxin water (i.e. purified water/highly purified water),
- that the air applied in the drying process is filtered and
- that the disinfector unit is regularly serviced and inspected.

When selecting cleaning agents please consider:

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CE

Instructions for use

micro-screw SCREWDRIVER WITH GRIPPER

- that, as a matter of principle, it is suitable for cleaning products made of metal, plastic or synthetic materials (finger placement screw-driver handle).
- that, insofar as no means of thermal disinfection is used, an additional, suitable disinfectant with tested efficacy (ex: VAH or FDA approved, or with CE approval) is used and that this agent must be compatible with the cleaning agent used, and
- that the chemicals applied are compatible with the products (see Chapter on “material stability”).

Manufacturer recommended cleaning agents and/or disinfectants and listed concentration must be followed at all times.

Procedure:
1. Dismount with screw-driver as described under the paragraph for Mounting/Dismounting.
2. Place the individual components into the disinfectant unit, taking care that they do not touch any other products.
3. Start the programme.
4. Remove the products from the disinfectant unit after completion of the programme.
5. Check and package the products immediately after removal (see Chapters on “Inspection” and “Packaging”, possibly after additional drying in a clean location).

Manual Cleaning and Disinfection
When selecting the cleaning agents and disinfectants, please consider:
- that, as a matter or principle, these are suitable for cleaning and/or disinfecting products made of metal, plastic or synthetic materials (finger placement screw-driver handle).
- that the cleaning agent is suitable for use with ultrasound cleaning (non foaming)
- that a disinfectant with tested efficacy (i.e. VAH or FDA Approval or CE approval) is used and that this is compatible with the cleaning agent used and
- that the chemicals used are compatible with the products (see chapter on “Material Consistency”).

Combined cleaning agents/disinfectants should not be used.

The instructions for concentration levels and application times as provided by the manufacturer of the cleaning agents and disinfectants must be adhered to at all times.
Only use freshly prepared solutions, sterile or low-germ (max. 10 germs/ml) and low endotoxin water (max. 0.25 endotoxin units/ml) such as purified water/highly purified water. For the drying process, use filtered air only.

Process:
Cleaning
1. After dismounting place the components of the screw driver into the ultrasound bath, sufficiently covered, for the recommended cleaning time, taking care that they do not touch any other products.
2. Remove the products from the ultrasound bath and rinse thoroughly with water at minimum three times.
3. Control the parts (see chapter on “Control”)

Disinfection
4. For the prescribed period of time, place the cleaned and controlled products into the disinfectant bath and make sure that they are sufficiently covered. Take care that they do not touch each other.
5. Remove the products from the disinfectant cycle and rinse them at least three times thoroughly with water.
6. Package the products immediately if possible, after removal (see Chapter on “Packaging”, possibly after additional drying in a clean location).

Control
After cleaning or cleaning/disinfecting Inspect all components. Check for corrosion, surface damage, shavings, splinters and impurities. Select and remove any damaged parts. Any still contaminated or unclean parts must be cleaned and disinfected again.

Packaging
Sort the cleaned and disinfected products into their pertinent sterilisation tray.

Please package the attachments, or the sterilization trays, respectively in disposable (one-time use) sterilization packaging (single or double packaging), and/or sterilization containers which meet the following requirements:
- corresponding to DIN EN 868/ANSI AAMI ISO 11607
- must be suitable for vapour sterilization (temperature resistant up to at least 141˚C (286˚F), sufficient vapour permeability).
- sufficient protection of the products or the sterilisation packaging, respectively, from mechanical damage.
- regular maintenance (service) according to the manufacturer’s specifications (sterilization container)

Sterilization
Only the following sterilization procedures must be applied. Other sterilization procedures are not admissible.

Vapour sterilization
- fractionated vacuum process or gravitational process[1] (with sufficient product drying time)
- vapour sterilizer unit according to DIN EN 13060 or DIN EN 285
- validated according to DIN EN ISO / ANSI AAMI ISO 17665-1 (valid commissioning and product-specific performance evaluation)
- maximum sterilization temperature of 138˚C (280˚F; plus tolerance according to DIN EN ISO / ANSI AAMI ISO 17665-1)
- sterilization time (exposure time at the sterilization temperature): a miminum of 5 minutes at 132˚C (270˚F), 134˚C (273 ˚F)

[1] The use of the less effective gravitational process is only admissible when the fractionated vacuum process is not available.

As a general rule, the quick sterilization process is not admissible at all.

Furthermore, do not apply hot air sterilization, radiation sterilization, formaldehyde- or ethylene oxide sterilization, or plasma sterilization.

Storage and Inspection
Storage of the products must not occur in the direct vicinity of chemicals. For optimal storage the products should be stored dry, clean and dust-free at a room temperature of approximately 15 – 35 °C.

Material Consistency
When selecting cleaning agents and disinfectants be sure that they do not contain the following elements:
- organic, mineral and oxidizing acids (maximum admissible pH value is 10.5 – neutral/enzymatic or weak alkaline cleaning agents are recommended)
- strong bases
- organic solvents (such as alcohol, ether, ketone or benzenes)
- oxidants (such as hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons
- salts from heavy metals

NEVER clean screw-driver components or any instruments, sterilisation trays and/or sterilisation containers with metal brushes or steel wool, as a matter of principle.

All instruments, sterilization trays and sterilization containers must be exposed to temperatures BELOW 141 °C (286 °F) ONLY!

Reusability
Our instruments are shipped in non-sterile condition and must therefore be subjected to the complete preparation cycle prior to first use, and after each use.
Frequent reprocessing causes light effect on this product. The end of the product life is normally conditioned by the wear and tear as well as damage during use. Please refer to chapter „Control“.

Graphic Symbols
The symbols used for identification purposes are in accordance to DIN EN ISO 15223-1:2013-02:

„Reference number“

“Batch number”


“Follow instructions for use”

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CE

Instructions for use
Pilot drill

Article assignment: 23070.10 – 23072.08

General information
The pilot drills may only be used as intended in the specialised medical fields by qualified personnel with corresponding training. Selecting the drills for specific applications or use in operations, adequate training, information and sufficient experience for handling are the responsibility of the attending doctor. Storz am Mark GmbH as the producer and seller of the product assumes no liability for direct or consequential damages caused by improper use, handling, preparation or sterilisation. The products must be inspected for damage prior to each use.

Intended use
The pilot drill is intended as a starter for implants. It is used for pre-drilling autologous bone blocks prior to implantation for their fixation in the augmentation process by means of a bone screw.

Indications
To establish the position, direction and depth of the implant bed. Pre-drilling in bones in order to subsequently secure bone transplants with osteosynthesis screws for various augmentation techniques. Generally applicable precautionary measures and rules of conduct have to be explained to the patients prior to surgery. In order to determine the exact position and depth of the bore hole, computer tomography examinations are recommended in addition to taking a bite impression and orthopantomogram. The area surrounding the instrument usage site must be examined in detail to exclude hazards to adjacent structures. Apply local anaesthetic at the instrument usage site. Position the incision and prepare the mucous membrane and periosteum according to the surgical procedure for the augmentation. The pilot drill is applied at the established location. It is used for initial drilling in the planned procedure.
- The instruments should not be clamped deeper than necessary.
- The instruments must be brought up to the rotational speed before they are applied to the object.
- Wearing safety goggles is recommended depending on the application.
- Unprotected contact with the instruments by the user must be avoided (wear protective gloves).
- Thermal damage due to rotating instruments must be avoided under all circumstances (work at low speed and with adequate cooling, see the section “Cooling”).

Make sure that the drill does not cant or jam during use (increased risk of breakage). Use low pressure and the recommended rotational speed below for drilling to the desired depth. Complying with the rotational speed prevents instrument fractures.

Contraindications
Improper application can cause tissue damage, premature wear, destruction of the instruments and hazards for the user, patient or third parties. Danger to anatomical structures in the region of the planned measure. The materials used can cause allergic reactions, for example in patients with a chrome allergy.
Rotating and oscillating medical instruments may only be used by doctors or qualified personnel with the education and experience required to be intimately familiar with the safe handling of these instruments.

Possible side effects
Using the instruments can produce heat with resulting necrosis, unwanted tissue dissection, soft tissue injuries, weakening of tissue, nerve injuries and infections.

Recommendations and warnings

Recommended rotational speed
- We recommend an optimum rotational speed of 1,000 min^{-1} for implant pilot drills; the maximum rotational speed of 6,000 min^{-1} must not be exceeded.
- Using the instrument-specific recommended rotational speed $\circlearrowright_{opt.}$ leads to the best work results.
- Long and pointed instruments tend towards forced resonance vibrations in the area of the tip that can destroy the instrument when the maximum allowable rotational speed $\circlearrowright_{max.}$ is exceeded.

⚠ **Failure to comply with the maximum allowable rotational speed leads to an increased safety risk.**
Failure to comply with the recommended rotational speed can lead to unfavourable work results.
Only axial loads may be applied to the pilot drills!

Connections/interfaces
The shaft connections are designed according to DIN EN ISO 1797-1 and intended for use in suitable standardised handpieces and contra-angle pieces.

Contact pressures
Excessive contact pressures have to be avoided. With cutting instruments, they can cause damage of the working part and rupturing of the blade. Heat development increases as well.

Cooling
Drilling should be carried out intermittently and under continuous exterior cooling with sterile physiological saline solution. Exterior cooling prevents excessive heating of the bone tissue and also dissipates or flushes away the bone fragments.

⚠ **Insufficient water cooling can cause the pilot drill to become clogged with chips, leading to increased heat development and, in the worst case, irreversible damage to the bone and surrounding tissue (thermal necrosis). The service life of the instruments is reduced as well.**

Guiding values for the frequency of use
Instruments made of stainless steel can be used approximately 4 times. This guiding value may deviate from the actual service life depending on the application and/or the material being processed. In some cases the instruments can be used longer if there is no apparent wear.

Material used
Stainless steel: DIN EN ISO 7153-1

Stainless steel products
The stainless steel used for manufacturing forms specific passive layers as a protective layer due to the alloy. The steel is only conditionally resistant to attacks by chloride ions and aggressive water.

Rejecting worn instruments
- Broken and deformed blades cause vibrations and high contact pressures, leading to broken incision edges and rough surfaces.
- Instruments that are bent or do not run smoothly should be rejected promptly.

⚠ **Dull or broken instruments induce excessive contact pressures and therefore increase the working temperature. This can cause damage to the dental pulp. Therefore, damaged instruments have to be rejected promptly.**

Storage
- Storage in the original packaging at room temperature, protected against dust and moisture, is recommended until initial use.
- Rotating instruments should be stored in hygienically maintained stands, cups or other suitable containers. This applies correspondingly to sterilised instruments and instruments in sterile goods packaging.
- Protect instruments against sunlight and heat.
- Aluminium stands and boxes can be attacked and damaged by chemicals. Therefore, only suitable disinfectants and cleaners should be used for disinfection and cleaning.
- Contact with H_2O_2 (hydrogen peroxide) has to be avoided. Hard metal working parts are attacked and damaged, reducing the service life.
- Temperatures in excess of 180 °C must be avoided. Exceeding this leads to a loss of working part hardness and therefore reduces the service life.

⚠ **Compliance with the preceding handling instructions is mandatory. The pilot drills may only be used as intended. Failure to comply with these safety instructions can lead to injuries.**

Disposal
The pilot drills are disposed of in the manner commonly accepted in hospitals/practices.

Liability
The user is obligated to inspect the products prior to use and has sole responsibility for determining suitability for the intended applications. In case of damage, contributory negligence of the user alleviates or excludes the liability of Storz am Mark GmbH. This is the case in particular if the user fails to observe the instructions for use or warnings, or in case of inadvertent misuse by the user.

IFU no. & name **Date of issue:** 12.12.2016 [de]
GA_0042_en_ Pilot drill (translation: 20.07.2017 [en])

Graphical symbols
The graphical symbols used for identification have the following meanings:

	Read the instructions for use		Manufacturer information
	Note the information insert		Article number
	Non-sterile		Lot number
	Optimum rotational speed		Maximum rotational speed
	CE marking		Health industry barcode

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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CE
0297

Instructions for use
Amalgam carrier

Article attribution: 2280.25

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 amalgam carrier serves the introduction of plastic amalgam.

Indication
Use on the correctly prepared tooth according to the used filling material.

Contraindication
- An improper use can lead to damages to the tissue, to premature wear, to the destruction of the instrument and dangers for the patient, the user or third parties.
- Materials used for application can cause intolerances. The user is responsible for an appropriate selection.

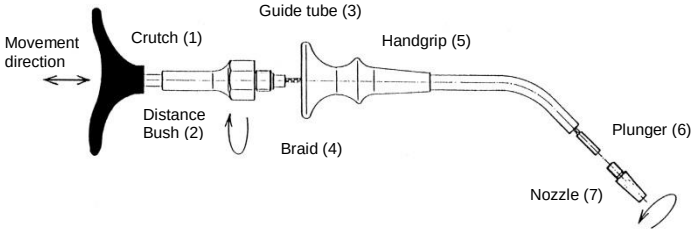
Recommendations and warnings to be respected

⚠ **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!
In case of misuse, all liability is excluded.

Used material
Stainless steels | DIN EN ISO 7153-1

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Disassembly
1. Push crutch (1) completely forward and screw off the nozzle (7).
2. Disconnect the distance bush (2) from the handgrip (5) by turning anti-clockwise.



Assembly
1. Carefully thread braid wire (4) into the handgrip (5).
2. Carefully connect the distance bush (2) with the handgrip (5) by turning clockwise with soft pressure.
3. Push crutch (1) entirely forward and unscrew the nozzle (7) by turning clockwise.

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 product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

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.

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	Non-sterile	LOT	Lot number
CE	CE marking	HIBC	Health industry barcode

For information on reconditioning the products, please see our preparation instructions WAA_0001.

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CE

IFU no. & name **Date of issue:** 09.05.2018
GA_0043_en_ Amalgam carrier (translation: 03.07.2018 [en])

Instructions for use
Swiveling scalpel blade holder

Article attribution: 14512.00

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
By its swivel head, the STOMA swivel head-blade holder serves to hold scalpel blades and to facilitate interventions at places that are difficult to access.

Indication
The STOMA swivel head-blade holder has been developed to make a surgical intervention at a hardly accessible place possible. The head of the blade holder can be swiveled in all directions and thus also be used for all surgical interventions at hardly accessible locations.

Contraindication
An improper use can lead to damages to the tissue, to premature wear, to the destruction of the instrument and dangers for the patient, the user or third parties.

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!
In case of misuse, all liability is excluded.

Used material
Stainless steels | DIN EN ISO 7153-1

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Connections/interfaces
All normed standard scalpel blades available from Stoma.

Assembly/Disassembly
- The standard scalpel blades are taken out of the sterile packaging by means of sterile pliers, pushed from behind forward into the rotatable metal head and fixed with an Allen key.
- Now, the rear part of the blade is broken off and disposed of.
- The positioning and fixing of the blade head is done by means of a metal spindle inside the round grip.

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 product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

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.

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	Non-sterile	LOT	Lot number
CE	CE marking	HIBC	Health industry barcode

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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IFU no. & name **Date of issue:** 09.05.2018
GA_0044_en_ Swiveling scalpel blade holder (translation: 03.07.2018 [en])

Instructions for use
Back Surface mouth mirrors

Article attribution: 483[X].00, 485[X].00, 493[X].00, 495[X].00, 4970.08

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-Back Surface mouth mirror with reflecting layer on the back of the mirror glass serves to examine the mouth cavity and the teeth and to keep away the cheeks.

Indication
The STOMA-Back Surface mouth mirror is a diagnostic instrument for dentists, which is used by the dentist to examine the mouth cavity and the teeth and to keep away the cheeks.

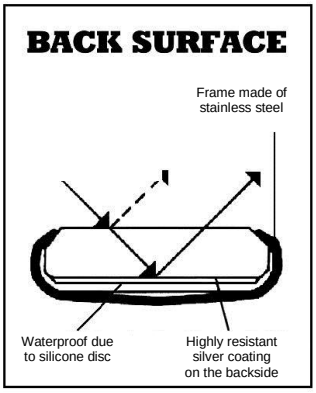
Contraindication
An improper use can lead to damages to the tissue, to premature wear, to the destruction of the instrument and dangers for the patient, the user or third parties.

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!**

In case of misuse, all liability is excluded.

Used material
Stainless steels | DIN EN ISO 7153-1
Glass



Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Connections/interfaces
All handgrips with M 2.5 threads.

Assembly/Disassembly
The STOMA-Back Surface mouth mirror is screwed upon the fitting STOMA-hy-grip, the Stomaform grip or a STOMA-color-stick grip.

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 product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

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.

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	Non-sterile	LOT	Lot number
CE	CE marking	HIBC	Health industry barcode

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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IFU no. & name **Date of issue:** 09.05.2018
GA_0047_en_ Back Surface mouth mirrors (translation: 03.07.2018 [en])

Instructions for use
Front Surface mouth mirrors

Article attribution: 4924.00, 4944.00, 4945.00, 4964.00

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-Front Surface mouth mirror with reflecting layer on the upper side of the mirror glass serves to examine the mouth cavity and the teeth and to keep away the cheeks.

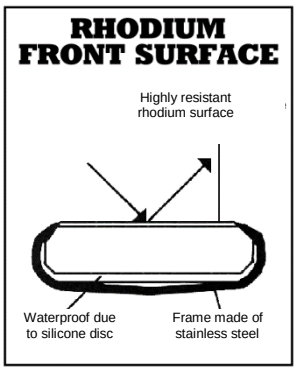
Indication
The STOMA-Front Surface mouth mirror is a diagnostic instrument for dentists, which is used by the dentist to examine the mouth cavity and the teeth and to keep away the cheeks. The Front Surface mouth mirrors have a service life of 60 sterilization cycles (1 month).

Contraindication
An improper use can lead to damages to the tissue, to premature wear, to the destruction of the instrument and dangers for the patient, the user or third parties.

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!
In case of misuse, all liability is excluded.

Used material
Stainless steels | DIN EN ISO 7153-1
Glass, rhodium



Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Connections/interfaces
All handgrips with M 2,5 threads.

Assembly/Disassembly
The STOMA-Back Surface mouth mirror is screwed upon the fitting STOMA-hy-grip, the Stomaform grip or a STOMA-color-stick grip.

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 product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

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.

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	Non-sterile	LOT	Lot number
CE	CE marking	HIBC	Health industry barcode

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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IFU no. & name **Date of issue:** 09.05.2018
GA_0048_en_ Front Surface mouth mirrors (translation: 03.07.2018 [en])

Instructions for use
Trephine drills with internal cooling

Article attribution: 22349.02 – 22349.09

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
Trephine drills are intended for removing endosseous implants or for taking bone implants from suitable donor areas in the mouth area. They are operated with the hand/angle piece of the dentist unit. They are operated with the hand/angle piece of the dentist unit.

Indication
Trephine burs are used to take out autologous bone material within an implanto-logical, periodontal or oral-surgical treatment. The trephine burs can effectuate a targeted removal of drill cores, e.g. at the chin or in the jaw crest, and transplant them to places where a bone defect must be compensated for or generally there is a targeted removal of bones, e.g. for examination purposes.

Contraindication
An improper use can lead to damages to the tissue, to premature wear, to the destruction of the instrument and dangers for the patient, the user or third parties.
To avoid any harm to adjacent structures like the tooth root, mouth base, maxillary sinus or nerve channel, the environment of the extraction site must be precisely examined.
The indicated rotational speed must be respected as well as permanent external cooling under low pressure during the drilling procedure. The pressure must be adapted to the condition of the extraction site, like the bone quality of the patients. Too high rotational speeds and pressing forces close to the tooth pulp jeopardize its vitality, the same holds for insufficient cooling technology.
Do not exercise any leveraging movements, otherwise, the trephine drill might slip off the intended extraction site thus causing injuries.
To avoid infections, the procedure must be kept absolutely sterile.

Possible side effects
During the use of the drill, heat might be produced, which can cause necrosis, undesired tissue preparation, soft tissue injuries, tissue degradation, nerve injuries and infections.
The materials used can lead to allergic reactions, e.g. in patients reacting allergically to chromium.
When removing implants with a trephine drill that are not worth preserving, care must be taken not to impair neighboring tooth structures and to prevent possible bone trauma.

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!
In case of misuse, all liability is excluded.

Used material
Stainless steels | DIN EN ISO 7153-1

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Application/handing
The STOMA trephine drills are designed according to DIN EN ISO 1797-1 and to be used with a hand or angle piece corresponding to the applicable norms. The trephine drills have an inner bore for cooling, which means that handpieces / contra-angles with external and internal cooling can be used. Before use, it must be checked if the correct fit in the angle piece is guaranteed. The instructions for use of these devices must be respected. The instruments should not be fixed more deeply than necessary.
Before approaching the object, the instruments must be brought up to the right rotational speed.
Please make sure that the trephine drill does not jam and get stuck (increased danger of breakage). The preparation is carried out under low pressure down to the desired depth with the rotational speed recommended below. To avoid instrument breakage, the rotational speed should be respected.
User-friendly application:
laser-etched depth mark at 2-4-6-8 mm

Recommended rotation speed
We recommend a speed of 800 rpm for the use of the trephine drill in connection with a contra-angle handpiece. The maximum permissible speed is 1000 rpm.

⚠ **If the admitted rotation speed is not respected, this leads to an increased safety risk.**
If the recommended rotation speed is not respected, this can lead to unfavorable work results.

Pressing forces
As a guideline, we recommend a maximum contact pressure of 2N. Blocking due to excessive contact pressure as well as tilting and levering must be avoided.
Even chip formation during the operating procedure can serve as a guideline. The pressure must be adapted to the condition of the removal site and to the patient's bone quality.

Cooling
The trephine drills should be cooled by sprinkling them with sterile physiological saline solution. The cooling prevents the bone tissue from heating up too much. The cooling can take place by internal and / or external cooling. The cooling must take place continuously.

⚠ **Insufficient water cooling can lead to excessive heating and, in the worst case, to irreversible damage to the bone and the adjacent tissue (thermal necrosis). In addition, the lifespan of the instruments is reduced.**

Guide values for the frequency of use
Instruments made of non-corroding stainless steel can be used ca. 4 times, but this value can deviate from the actual standing times depending on the type of use and/or the material treated. Sometimes, the instruments can even be used longer as long as no wear is visible.

Sorting out worn products
- Chipped and deformed cutting edges cause vibrations leading to uneven preparation edges and coarse surfaces.
- Blunt instruments tend to lead to higher pressing forces and thus increase the working temperature. This can damage the pulp.
  Therefore, damaged instruments must be sorted out immediately.

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

Delivery state
The product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

Safekeeping/storage
- Until the first use, it should be stored in the original package at normal room conditions.
- Rotating instruments must be kept and stored in hygienically maintained racks, bowls or other suitable containers. The same analogously also applies to sterilized instruments.
- Any contact with chemicals, in particular H_2O_2 (hydrogen peroxide), must be avoided. Working parts made of hard metal are degraded and damaged, which reduces standing time.

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.

IFU no. & name **Date of issue:** 10.07.2019
GA_0049_en_ Trephine drills with internal cooling (translation: 15.10.2020 [en])

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

	Read the instructions for use		Manufacturer information
	Note the information insert		Article number
	Non-sterile		Lot number
	CE marking		Health industry barcode

For information on reconditioning the instruments, please see our preparation instructions WAA_0001.

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CE 0297

Instructions for use
Crown remover kit

Article attribution: 5319.00

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 crown removal kit serves to remove crowns and bridges.

Indication
Due to its different extensions, the crown and bridge remover can be flexibly used and allows for an individual dosage of the impulse. Especially for bridge elements, the loop head extension offers special advantages because the force is distributed over the contact surface of the loop thus reducing/preventing damages.

Contraindication
An improper use can lead to damages to the tissue, to premature wear, to the destruction of the instrument and dangers for the patient, the user or third parties.

Recommendations and warnings to be respected

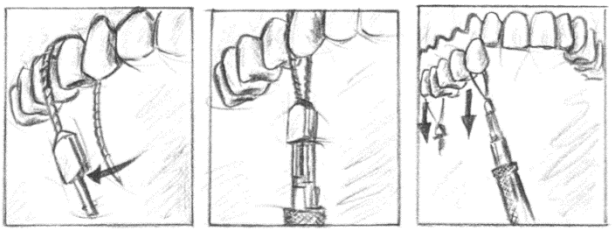
⚠ **If these warnings are not respected, this can lead to an increased safety risk.**
- Only to be used for the intended purpose indicated.
- All instructions described here must be absolutely followed.
- Use only by specialized personnel!
In case of misuse, all liability is excluded.

Used material
Stainless steels | DIN EN ISO 7153-1

Products made of stainless steels (corrosion-resistant)
Due to their alloying, the stainless steels used for production form specific passive layers as a protective coating. The steels are only conditionally resistant against aggressive chloride ions and aggressive waters.

Connections/interfaces
Inserts suitable for crown removers with M 4 threads.

Use/handling
1. Screw the adapter into the crown remover.
2. Pass the wire loop under the bridge segment and hook it into the slot on the loop head.
3. Fix the loop head in the bayonet socket.
4. Quickly move the weight downwards with momentum.
5. In order to prevent straining and bending in larger bridgework, it is recommended to attach a loop head to each abutment crown, and to change back and forth between the two ends several times with the crown remover. Depending on the size of the bridge, you may need to use more loop heads.
6. Please note that the wire will always adapt in an axial direction, parallel to the tooth axis, when the weight is released.
7. Post and core constructions can also be removed with this technique. To facilitate this drill a 1 mm hole from the labial to palatal and pull the wire loop through. Now it's possible to exert a traction force in axial direction of the root.
8. A Post or Richmond crown can be removed using the same technique.



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
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IFU no. & name **Date of issue:** 09.05.2018
GA_0058_en_ Crown remover kit (translation: 03.07.2018 [en])

Dental Instruments by

stoma®

With passion for perfection

For more details about our products and services please contact our customer service team on 1800 776 326.

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MADE IN GERMANY