

SIC Instruments:

General Information
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Instructions for Use

Implant Systems:	SICace / SICmax / SICtapered		SICVantage max / SICVantage tapered
Ratchet Tools:	Torque Ratchet: 937123		
REF	Screwdrivers: 937117 937118 937120	TR Screwdrivers: 937128 937129 937130	TR Screwdrivers: 937128 937129 937130
	Insertion Tools "direct": 937100 937101	TR Insertion Tools "direct": 937102 937103	SICVantage Insertion Tool: 951612 SICVantage TR Insertion Tool: 951613
	Insertion Tools: 937041 937104 937110	TR Insertion Tool: 937109	
	Adapter for Angle Piece Instruments: 937107		
Angle Piece Instruments:	Screwdrivers: 937031 937032	Insertion Tools: 937112 937113	SICVantage Insertion Tools "direct": 951620 951624 951621 951625 951622 951626 SICVantage Insertion Tools: 951614 951615
REF	SIC LocFix Insertion Tool: 951265	Insertion Tool SICmax onepiece: 937111	
Guided Surgery	GS Insertion Tools: 937114 937115		SICVantage GS Insertion Tools: 951610 951611
REF	GS Drill Keys: 935580 935582 935581 935583		
Tools for manual use	Insertion Tool, manual use: 937042		SICVantage Extractor: 951616 951617 951618 951619 951623
REF			
Other tools	"Easy Screw" designed by Dr. G. Bayer: 935300	Depth Gauge: 935165 935166	Drill extension: 935212
REF	Counter Ratchet with "Easy Handle": 937122		

Device Descriptions

SIC Torque Ratchet

The complete "SIC Torque Ratchet" is made of surgical stainless steel. The head of the ratchet has a holder for various instruments such as screwdrivers and insertion instruments. The ratchet head bends to regulate the pre-set torque on the retention screw – between 0 and 30 Ncm. The torque is produced by a spring in the handle.

Fig. 1

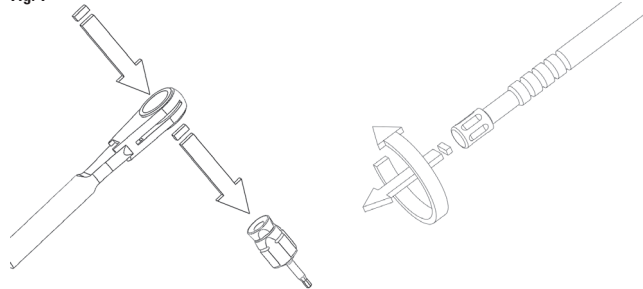


Fig. 2

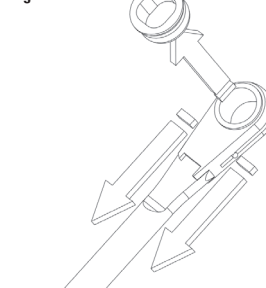


Fig. 3

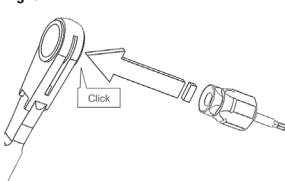
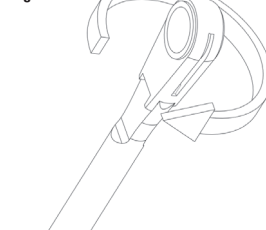


Fig. 4



Tightening Torques:

Gingiva Shaper, Screws for Impression Posts	5 Ncm (hand tight)
All Fixation Screws and Attachments	20 Ncm
SIC Multi-Unit Abutment „Safe on Four“, straight with any SIC insertion tool	30 Ncm

Angle Piece Instruments can be mounted to the Adapters by a gentle push. An instrument can be removed by simply pulling it out of the adapter.

If the Angle Piece Instruments are used in an actual Angle Piece, handle them according to the Instructions for use of the respective manufacturer.

Fig. 5: All SIC Angle Piece Insertion Tools have the high torque HEX connection according to the W&H standard, to apply torques of up to 80 Ncm. Always assure the final setting and the full support of the high torque HEX connection.

Fig. 5



Indications for Use

The intended use of all SIC Instruments is the insertion of one or more dental implants in vivo and all applications during the treatment, clinically and in the lab process, by using exchangeable screwdriver tips and bits.

- **Torque ratchets** are dental torque wrenches for placement and adjustment of dental implants during oral surgery. The scale unit is Ncm.
- **Screwdrivers** are used for the fixation of:
 - All SIC Fixation Screws
 - All SIC Gingiva Shapers
 - All SIC Ball and Socket Attachments
 - All SIC Cover Screws

- **Insertion Tool, manual use** is used for the fixation of SIC Fixation Screws of Transfer Abutments, Open Tray Technique.
- **Insertion Tools "direct"** are used for the insertion of all SICace, SICmax and SICtapered implants without the use of the insertion post.
- **Insertion Tools** are used to tighten the SIC Fixation Post of SIC Bar and Bridge Abutments "Safe on Four" and for the insertion of SICace, SICmax and SICtapered implants with the use of the insertion post.

- **Adapter for Angle Piece Instruments** is used to mount every SIC Angle Piece Instrument to an SIC ratchet. All SIC Angle Piece Insertion Tools have a high torque HEX connection according to the W&H standard (Fig. 5). The corresponding socket is attached to the respective SIC Angle Piece Adapters for the torque ratchet, which allows them to be used to up to 80 Ncm.
- **Insertion Tool for SICmax onepiece** is used for the insertion of SICmax onepiece implants.
- **SIC "Easy Screw" designed by Dr. G. Bayer** is used for the insertion of SICace, SICmax and SICtapered implants with the use of the insertion post and can also be used as an adapter for all Angle Piece Instruments.

- **SICVantage Insertion Tools "direct"** are used for the insertion of SICVantage max and SICVantage tapered implants without the use of the insertion post.
- **SICVantage Insertion Tools** are used for the fixation of "SIC Multi-Unit Abutments "Safe on Four", straight" and the insertion of SICVantage max and SICVantage tapered implants with the use of the insertion post.
- **SICVantage Extractors** are used to remove SICVantage abutments should they need to be extracted. The extractors are handheld and cannot be attached to a ratchet.
- **GS Drill Keys** are used to handle the drills in a guided surgery accurately.
- **GS Insertion Tools** are designed to work as Insertion Tools for SICace, SICmax and SICtapered implants with the use of the insertion post for Guided Surgery.
- **SICVantage GS Insertion Tools** are designed to work as Insertion Tools with the use of the insertion post for SICVantage max and SICVantage tapered implants for Guided Surgery.
- **Drill extension** is used as an extension in case a drill is too short for the required task.
- **Depth Gauge** is used to check the depth and the alignment of drilled holes.

Target Population

The target population for the medical products are individuals that have fully completed their growth phase. All contraindications must be observed.

Intended Users

SIC Instruments are intended to be used, handled and managed in a healthcare setting by appropriately trained and qualified surgeons and personnel. The operator must be familiar with dental surgery and prosthetics, including diagnostics and preoperative planning and/or laboratory procedures. The operator bears the sole responsibility. As SIC invent AG has no control over the use of the products, they are not liable for damage caused by it.



Warning: Improper handling and/or misuse may result in premature wear. All parts of broken instruments must be retrieved immediately following breakage. If ingested broken instrument parts cannot be retrieved, the patient should be referred to a medical opinion.



Precaution: Federal law restricts this tool to sale by or on the order of a licensed Healthcare practitioner.

Contraindications

Do not use the instruments if one or more below reported conditions are present:

- Proven hypersensitivity to one of the metals in the alloy.



Warning: Patients identified as at-risk for Creutzfeld-Jakob disease (CJD) and related infections should be treated with single-use instruments. Therefore, devices that have been in use or suspected of use in patients with CJD after surgery must be disposed of according to current national recommendations.

Warnings, Precautions and Side-Effects

Warnings, precautions and side-effects are listed und preceded by symbol ⚠. Specific warnings, precautions and side-effects are addressed under the appropriate chapter. All the others are listed below:



Precaution: The following precautions are to be met prior to or during treatment:

- SIC Instruments are non-sterile and are intended to be cleaned, disinfected, and sterilized before intraoral use.
- Prior to each procedure, it must be ensured that all necessary components, instruments, and materials are available in the required quantities.
- Do not apply unreasonable force, especially levering and/or over-bending.
- After overloading or if dropped or mishandled in any other way, the device may no longer be used because the correct function can no longer be guaranteed.
- Position the patient such that the danger of aspiration of components is minimized. All components that are used intraorally must be secured to prevent aspiration or swallowing.
- Do not use damaged or blunt instruments. Always inspect instruments before use and assure that they are properly assembled.
- If the laser markings are illegible, the device must be replaced.
- Before the use of SICVantage Extractors, the SIC Fixation Screw must be removed and the screw channel hole must be clean, dust free, and without any cement fragments.

Side-Effects:

- Allergies to metals in the alloy are possible (Al, V) but seldom.
- Systemic side effects caused by metals in the alloy have been claimed in specific cases.
- Mechanical injury the alveolar bone
- Pain

Delivery Conditions

Warning: SIC Instruments are delivered non-sterile and must be sterilized prior to use. This also applies for first-time use after delivery, as well as for single-use devices that are delivered non-sterile and which must be sterilized prior to use. The devices are intended for multiple uses.

Cleaning and Disinfection Procedures

Immediately after use, the SIC Instruments must be fully disassembled and placed in cold water (room temperature). For manual cleaning, rinse the SIC Instruments under cold tap water until all visible soiling is removed. Firmly adhering soiling should be removed with a soft brush. After disinfection and drying, reassemble the instrument(s) and pack them each in a suitable sterile packaging (e.g. Medipeel bags).



- Precaution:**
- Cleaning procedures must begin within 1 hour from surgical application.
 - Do not use warm water or detergent as this may lead to fixation of the residues on the product which can affect the outcome of the subsequent cleaning step.
 - By using automated cleaning and disinfection, avoid direct contact of the instruments to each other
 - For stainless steel instruments, always use solvents especially designed for this material
 - The devices may not be cleaned using hydrogen peroxide or high chlorine content or containing oxalic acid. Disinfection solution should be aldehyde free.
 - Do not apply unreasonable force, especially levering and over-bending
 - Do not mix steel instruments and stainless steel instruments on any cleaning, disinfection and sterilization process

- Manual Pre-Cleaning Procedures

- The products must be placed in cold tap water (room temperature) for 60 minutes.

- Manual Cleaning Procedures

- Rinse the products under cold tap water until all visible soiling is removed. Firmly adhering soiling should be removed with a soft brush
- Place products in an alkaline cleaner (e.g. alkaline cleaner 0.5% neodisher MediClean) for 10 minutes and maximum temperature of 40°C (104° F).
- Rinse the products under cold tap water to remove the detergent
- Manual drying with a lint-free cloth

- Automatic Cleaning Procedures

- Pre-Cleaning for 4 minutes with cold tap water
- Cleaning with an alkaline cleaner (e.g. alkaline cleaner 0.5% neodisher MediClean) for 6 minutes and maximum temperature of 55°C (131°F)
- Neutralization with warm deionized water (>-40°C "104°F") for 3 minutes
- Rinse with warm water (>-40°C "104°F") for 2 minutes

- Manual Disinfection Procedures

- Full immersion of the product in a disinfectant (e.g. Cidex OPA) at 20±2°C (68±3.6°F) for 12 minutes
- Submerge for 1 minute in cold demineralized water
- Extensive flushing with cold demineralized water to remove remaining disinfectants

- Automatic Disinfection Procedures

- Thermal Disinfection with an A0-value of 3000s with 90°C for 5 minutes

Sterilization

SIC Instruments are delivered in a non-sterile condition and must be cleaned, disinfected and sterilized before the initial and each subsequent use. Before sterilization, the original packaging should be removed and the devices should be single-wrapped in sterilization paper. SIC invent AG recommends the following sterilization procedures:

Steam Sterilization Procedure	Parameters
Fractionated pre-vacuum method	135°C for 3 min. with a drying time of 16 min.
Gravitation method	121°C for 90 min. with a drying time of 15 min.



- Warning:**
- Do not sterilize corroded or rusty instruments
 - Check instruments for corrosion after sterilization

Precaution:

- Do not apply temperatures on stainless steel instruments above 135°C on any operation
- Do not mix steel instruments and stainless steel instruments on any cleaning, disinfection and sterilization process!

After sterilization, store the sterile SIC Instruments in a dry, clean and dust-free place, protected from possible damage.

Life Span

SIC Instruments are generally intended for multiple uses unless otherwise stated on the label. The reprocessing cycles have been validated up to 20 times.

Storage

The SIC Instruments must be stored in the original packaging at room temperature in a dry place.



Precaution: Do not use the components if the package is damaged. Before each use, the device must be carefully checked for proper function and damages. In addition to these instructions, please observe the legal regulations valid in your country as well as the hygiene regulations of the dental practice or of the hospital.

Disposal

The products are to be disposed of according to the local laws and regulations.

Adverse event

Should a serious incident (death, relevant deterioration of health or public health threat) relating to the devices occur, the qualified professional should immediately report the event to the manufacturer and to the local competent authority.

Information for patient

Before and after surgery, inform patient about contraindications, possible complications, regular follow-up requirements and dietary, oral hygiene, pre-medication and post-medication instructions. Patients should avoid hot beverages immediately following the implant procedure. Smoking and parafunctional habits can increase the chances of implant failure. Should complications occur, such as bleeding, chronic pain, mobility or postoperative infection and inflammation, the patient should consult a qualified professional. Instruct the patient to immediately report any adverse event to the responsible professional, manufacturer and local competent authority.

Documentation

Each SIC Instruments is traceable using the lot number. The label contains all the corresponding details for transfer to the patient file.

CAUTION: (USA only) U.S. Federal law restricts this device to sale by or on the order of a licensed dentist or physician. This is shown on labels with "Rx only".

Symbol

- Manufacturer
- Article No.
- Lot number
- Consult the Instruction for Use
- Caution, consult accompanying documents
- Federal law restricts this device to sale by or on the order of a licensed Healthcare practitioner
- Non-Sterile
- Date of manufacturing
- Keep dry
- CE-Symbol

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Carefully read these instructions before using SIC Instruments. Keep them in a safe place for future reference.

Precaution:

- These instructions for use must be read prior to using SIC Instruments.
- SIC Instruments may only be used for medical/dental procedures and constructions with the SIC Implant Systems.
- They must only be used for the intended indications in accordance with the general guidelines for dental/surgical procedures and taking into account safety at work/accident prevention regulations.
- If the indication or type of application is unclear, these products must not be used until all issues have been resolved.

Fig. 1: Disassembly: Dismount the current tool out of the ratchet and screw the retention screw out of the screw channel and remove all interior elements.

Fig. 2: To remove the clamping ring, pull the small lever on both sides of the ratchet down and press the ring out of its socket. After all cleaning steps (explained in this Instructions for Use), put the clamping ring back into position by pushing it into the socket. To reassemble the handle, put the torque shell back over the retention shaft, insert the spring and tighten the retention screw until it is back at the correct torque scale.

Fig. 3: Push the driver into the ratchet until there is an audible click. The arrow on the head of the ratchet shows the direction in which the ratchet is functioning.

Fig. 4: To apply torques beyond 30 Ncm, loosen the retention screw until the head can be turned by 90°. In this case, the torque mechanism is blocked and it is possible to apply torques of up to 80 Ncm.