

SIC Tools and Titanium Ratchet (TR):

Instructions for Use

Device Descriptions

General Information

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Implant Systems:	SICace / SICmax		SICvantage max
Ratchet Tools: REF	Torque Ratchet: 937123	Torque Ratchet, Titanium: 937127	Torque Ratchet, Titanium: 937127
	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 Steco Insertion Tool for Magnetic Abutments: 935099	TR Insertion Tool: 937109	
Angle Piece Instruments: REF	Adapter for Angle Piece Instruments: 937107	TR Adapter for Angle Piece Instruments: 937108	TR Adapter for Angle Piece Instruments: 937108
	Screwdrivers: 937031 937032	Insertion Tools: 937112 937113	SICvantage Insertion Tools "direct": 951620 951621 951622
	SIC LocFix Insertion Tool: 951265	Insertion Tool SICmax onepiece: 937111	SICvantage Insertion Tools: 951614 951615
Guided Surgery REF	GS Insertion Tools: 937114 937115		SICvantage GS Insertion Tools: 951610 951611
	GS Drill Keys: 935580 935582 935581 935583		
Tools for manual use REF	Insertion Tool, manual use: 937042		SICvantage Extractor: 951616 951617 951618 951619 951623
	Activator/Deactivator for Inner Matrix "gold": 937040		
Other tools REF	"Easy Screw" designed by Dr. G. Bayer: 935300		Torque Ratchet, 4 Ncm. Matrix: 936006
	Counter Ratchet with "Easy Handle": 937122		Drill extension: 935212
			Paralleling Tool: 936015

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

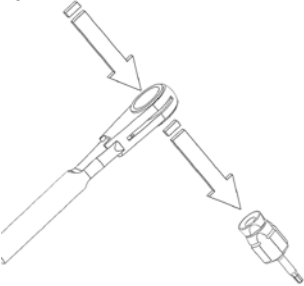


Fig. 2

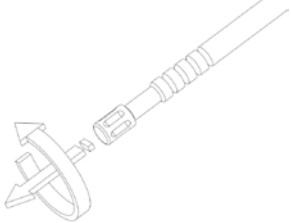
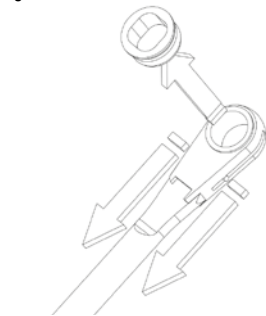


Fig. 3

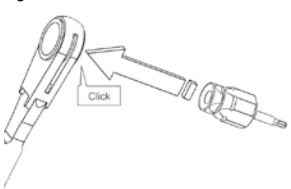



Fig. 4



- 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.

 Carefully read these instructions before using SIC invent AG ratchets or tools. Keep them in a safe place for future reference.

Precaution:

- These instructions for use must be read prior to using SIC tools and ratchets.
- SIC tools and ratchets 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.

SIC Torque Ratchet, Titanium:

The "SIC Torque Ratchet, Titanium" (TR) has a one-piece ratchet body made of a titanium alloy and a snap-on ratchet head made of stainless steel.

For checking torque, the ergonomically designed handle has an individually calibrated and scaled cam follower which is employed at torques of up to 45 Ncm. When used as a surgical ratchet, without torque control, operation without the cam follower allows transmission of a maximum torque of 80 Ncm.

Fig. 5

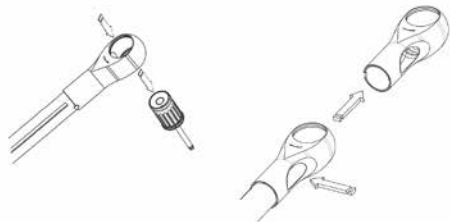


Fig. 6

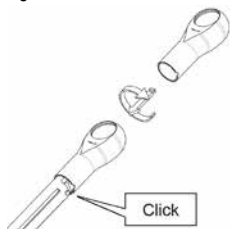


Fig. 7



Fig. 8



Fig. 5: Disassembly: Press the screwdriver to remove it from the head of the wrench and remove the head by pressing a finger into the recess and gently pulling the head. The three separated parts are now ready for cleaning according to the procedures explained in these Instructions for Use.

Fig. 6: After cleaning, attach the head of the wrench to the body by pushing the components together and turning them in opposite directions until there is an audible click.

Fig. 7: Push the driver into the wrench until there is an audible click. The arrow on the head of the wrench shows the direction in which the wrench is functioning.

Fig. 8: Turn the wrench in the direction of the arrow until the desired torque is achieved, N.B.: Before each use, make sure that the functionalities are intact and that the first line on the scale aligns with the arrow. The arm of the torque wrench must not go beyond the end of the scale, as this could result in inaccurate torque readings. If the torque wrench is used as an ordinary wrench, without using the torque scale, then it may not be subjected to a load of more than 80 Ncm.

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. 9: 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. 9



Indications for Use

The intended use of all SIC surgical tray tools 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.
- **Torque ratchet, 4 Ncm, Matrix** is used for the fixation of inner Matrices for the SIC Ball and Socket Attachments.
- **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 and SICmax 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 and SICmax 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 titanium ratchet. All SIC Angle Piece Insertion Tools have a high torque HEX connection according to the W&H standard (Fig. 9). The corresponding socket is attached to the respective SIC Angle Piece Adapters for both of the torque ratchets, which allows them to be used 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 and SICmax 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 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 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 and SICmax 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 implants for Guided Surgery.
- **Activator/Deactivator for Inner Matrix "gold"** is used to activate or deactivate the Inner Matrix "gold" (REF 936002).
- **Steco Insertion Tool for Magnetic Abutments** is used for the fixation of magnetic Abutments in combination with the SIC torque ratchet (REF 937123).
- **Drill extension** is used as an extension in case a drill is too short for the required task.
- **Paralleling Tool** is used to align the Ball and Socket Attachments.
- **Depth Gauge** is used to check the depth and the alignment of drilled holes.

Intended Users

SIC invent AG tools and ratchets 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 tools 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 tools and ratchets 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 the tools 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

 SIC tools and ratchets 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 tools and ratchets must be fully disassembled and placed in cold water (room temperature). For manual cleaning, rinse the SIC tools and ratchets 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 enzymatic 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 enzymatic 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 tools and ratchets 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 tools and ratchet in a dry, clean and dust-free place, protected from possible damage.

Life Span

SIC invent tools and ratchets 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 tools and ratchets 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.

Documentation

Each SIC tool or ratchet 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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