

General Information

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For U.S.
 Market only

REF This Instructions for Use applies to any SIC Prosthetic Component described in its label as:

Product Groups
Ball and Socket Abutments
Crown Bases
Fixation Post
Fixation Screws
"Flex Star" Cast-to Abutments
Gingiva Shapers
Multi-Unit Abutments
Mini Multi-Unit Abutments
Standard Abutments
Standard Abutments "Safe on Four"
Transfer Abutment
Provisional Abutment

Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

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

Device Description

SIC Prosthetic Components are made out of different materials and with different design/characteristics to provide a range of choices depending on clinical needs. Further descriptions about the SIC Prosthetic Components can be found under section "Prosthetic Procedure".

Indications for Use

SIC Prosthetic Components are intended for use with SIC Dental Implants for prosthetic-restorations from single tooth replacements to full arch restorations with fixed or removable superstructures. SIC Prosthetic Components with a post height less than 4 mm are intended for multi-unit loaded restorations only.

- **SIC Ball and Socket Abutments** are for the retention of implant-retained removable dentures on a minimum of 4 implants. Individualizing is not permitted.
- **SIC Crown Bases** are used for the laboratory fabrication of screw-retained bridges or custom bar restorations.
- **SIC Fixation Post** is used for the fixation of SIC Bar and Bridge Abutment "Safe on Four", straight. Individualizing is not permitted.
- **SIC Fixation Screws** are used for most prosthetic components. The SIC Fixation Screw is used for the retention of single crowns and bridges on standard abutments. Individualizing is not permitted.
- **SIC "Flex Star" Abutment** includes fabrication of custom cast abutments for restorations using cemented or screw-retained single crowns and bridges. The SIC "Flex Star" Abutment for bridgework is especially for restorations using cemented or screw-retained bridges.
- **SIC Gingiva Shapers** are used for forming the gingiva following implant exposure or, alternatively, with transgingival healing.
- **SIC "Safe on Four" Multi-Unit Abutments** are indicated for fixed or removable bridge or full restorations with the stipulation that the distal implants can have a maximum implantation angle of 30°. For complete restorations a minimum of four implants must be placed in the mandible and a minimum of six in the maxilla. The bone quality must be D3 or higher. The implants must exhibit an intraosseous length of at least 9.5 mm and angled implants 11.5 mm. The implant diameter should be as large as possible – minimum: 4.0 mm. The implant should be placed at 16° resp. 30°. Individualizing is not permitted.
- **SIC Mini Multi-Unit Abutments** are indicated for fixed or removable bridge or full restorations with the stipulation that the distal implants can have a maximum implantation angle of 20°. For complete restorations a minimum of four implants must be placed in the mandible and a minimum of six in the maxilla. The bone quality must be D3 or higher. The implants must exhibit an intraosseous length of at least 9.5 mm and angled implants 11.5 mm. The implant diameter should be as large as possible – minimum: 4.0 mm. Individualizing is not permitted.
- **SIC Standard Abutments** are available in various designs for fabricating cemented or screw-retained single crowns and bridges.

- **SIC Transfer Abutment**, reposition or open tray technique are used to copy the individual patient mouth situation into a cast model for the lab work of the dental technician. Individualizing is not permitted.

- **SIC Provisional Abutment** is designed to carry temporary crowns which can be cemented or directly polymerized onto the abutment. It can be shortened adequate to the occlusal space in order to avoid occlusal interference.

Intended Users

SIC invent AG devices 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.

Target Population

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

Contraindications

- High loads on supra structures with an extra axial force center.
- Non-splinted SIC Prosthetic Components with the crown/implant length ratio of more than 1.2. (Cases with higher ratios must be splinted.)
- Non-splinted angled abutments in high load areas on reduced implant diameters.
- A prosthetic angulation greater than 25° to the implant axis on non-splinted abutments.
- Presence of bruxism or other oral para-functional habits in the patient.
- Proven hypersensitivity to one of the metals in the alloy.

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.

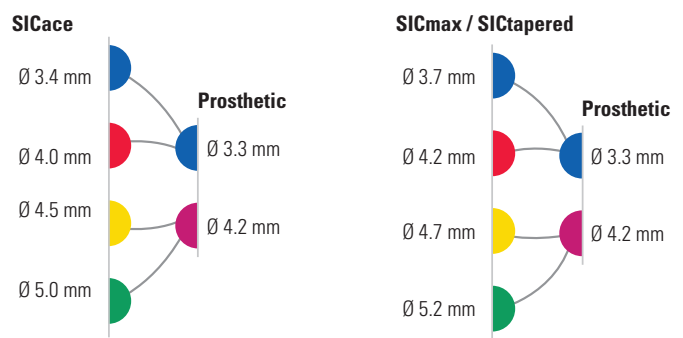
The following complications have arisen occasionally when using prosthetic components and accessories:

- Components used in the patient's mouth have been aspirated and swallowed.
- Due to excessive torque, the SIC Fixation Screw of the abutment has fractured.
- Titanium components have discoloured during sterilization due to residual cleaning agents (no change of mechanical stability or biocompatibility).

INTERFACE INFORMATION

SIC Prosthetic Components with Hexagonal Implant Interface

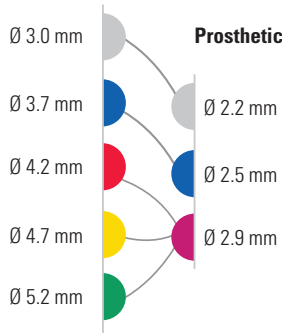
SIC Prosthetic Components that have a cylindrical hexagonal implant interface are only to be used in connection with SICace, SICmax or SICtapered implants.



SIC Prosthetic Components with SICvantage Implant Interface

SIC Prosthetic Components that have a conical SICvantage implant interface are only to be used in connection with SICvantage max or SICvantage tapered implants. The SICvantage implant interface is characterized by a steep-sided and self-locking conical section (Morse Taper), followed by an indexing section with four crossed, parallel-sided grooves – the "Swiss cross".

SICvantage max / SICvantage tapered



SICvantage Abutments should be vertically screwed in with a defined torque of 20 Ncm using the Fixation Screw provided with the SICvantage Abutment or fitted in situ without an SIC Fixation Screw and secured by tapping lightly. During assembly of the final SIC Prosthetic Components, force fitting takes place via the conical section of the interface. The connection is loosened using a special extractor tool. To do this, the SIC Fixation Screw should be removed from the SIC Prosthetic Components. The SIC Extractor Tool should then be screwed into the open screw channel of the abutment beyond the stop thus loosening the abutment.

Prosthetic Procedure

The SIC Prosthetic Components listed below can be customized by trimming and polishing in the laboratory. For an optimal prosthetic restoration, the horizontal and vertical position and the alignment of the implant as well as the thickness of the gingiva have to be taken into account.

The following rules for individualizing must be followed:

SIC Prosthetic Component:	minimum diameter after individualization	minimum length after individualization
Standard Abutment	2.8 mm and min. thickness 0.4 mm	4.0 mm of functional area/post height
Crown Bases	3.5 mm and min. thickness 0.5 mm	6.0 mm of total height
SIC "Flex Star" Abutment	3.5 mm and min. thickness 0.5 mm	4.0 mm of functional area/post height
SIC Gingiva Shapers	2.8 mm	Reduction is not permitted
SIC Fixation Screw	SIC Fixation Screws may never be adapted or shortened under any circumstances!	

For all SIC Prosthetic Components, the surfaces in contact with the implant may not be blasted with abrasives or treated in any other way. The implant connection must remain in its originally delivered state. In addition, no angular correction is permitted for all SIC Prosthetic Components.

The SIC Fixation Screw supplied with the SIC Prosthetic Component should not be used for laboratory use. A separate SIC Fixation Screw should be used during the working steps in the laboratory. The SIC Fixation Screw should only be tightened once. The following torques should be applied:

SIC Prosthetic Component	Tightening Torque
SIC Gingiva Shaper	5 Ncm (hand tight)
All Fixation Screws for Abutments and Attachments	20 Ncm
SIC Fixation Post "Safe on Four" SICvantage Multi-Unit Abutment "Safe on Four", straight	30 Ncm

A fixed prosthetic restoration can be cemented or fixed with an occlusal or horizontal screw. A removable prosthetic restoration can be fixed to the implants by using attachments, telescopes or bars.




When using adhesive or cement, please note the following:





- Use suitable adhesives or cements for the application
- Observe the instructions of the manufacturer of the adhesive or cement
- Keep adhesive or cement clear of the screw channel. Close the screw channel.

Clean and disinfect the superstructure according to validated cleaning procedures. Check the fit of the superstructure. After removal of the gingiva shaper, insert the superstructure into the patient's mouth. Make sure that the prosthetic restoration fits into the implant(s) without a gap or tension and that no soft tissue is caught. Tighten the abutment screw in the implant with the ratchet and the 1.2 mm hex screwdriver to the above defined torque.

Further specific descriptions and prosthetic procedures for SIC Prosthetic Components are:

Picture	Name	Description
	Ball and Socket Abutment	Ball and Socket Abutment is for the retention of implant-retained removable dentures on a minimum of 4 implants. The retention between the ball abutment and matrix is produced either using activating/de-activating gold retention inserts or thermoplastic plastic inserts.
	Crown Base	Crown Base "TITANIUM", for "Safe on Four", is used in conjunction with "Safe on Four" abutments. It is used for the laboratory fabrication of screw-retained bridges or custom bar restorations. The SIC Crown Base is made of Grade 5 titanium and after fitting on the abutment, the base is screw retained with the "Safe on Four" Abutments using the SIC Fixation Screw "Safe on Four". Customized bridge frameworks for occlusal screw retention can be waxed up using the "TITANIUM" Crown Base and adhesive bonded or cemented stress-free on the master model or intraorally. Customized bars are fabricated in the same manner. The above mentioned rules for individualizing must be followed. SIC Crown Base "Safe on Four", residue-free burn-out, is suitable as a "wax-up" base for model fabrication of a metal framework in conjunction with "Safe on Four" Abutments. It is used for the laboratory fabrication of custom screw-retained bridges or bar restorations. It can be used for contouring custom bridge frameworks designed for occlusal screw retention which can be burned residue-free. The crown base is made from PMMA. The screw channel and fit should be checked after casting and corrected if necessary. It must be possible to pass the fixation screw easily through the screw channel and apply it deeply to the screw seating. The above mentioned rules for individualizing must be followed. The SIC Crown Base, castable, is used in conjunction with bar and bridge abutments and SIC "Safe on Four" Abutments. It is used for the laboratory fabrication of screw-retained customized bar or bridges restorations. The Crown Base consists of a prefabricated section which is made from a metal alloy and fits onto the conical head of the abutment. This section is cast-to and is fitted with a burnout plastic sleeve in the region of the screw channel. The Crown Base can be used for contouring and casting customized bar or bridge frameworks, designed for occlusal screw retention. The screw channel and fit should be checked after casting and corrected if necessary. It must be possible to pass the fixation screw easily through the screw channel and apply it deeply to the screw seating. The SIC Crown Base for non-precious alloy is for restoration in a non-precious metal alloy and made from a platinum-iridium alloy. It is fitted with a black burnout plastic sleeve. The SIC Crown Base for high-fusing alloy is made from a high-fusing alloy. It is fitted with a white burnout plastic sleeve. The above mentioned rules for individualizing must be followed.
	Fixation Post	SIC Fixation Post is used for the fixation of SIC "Safe on Four" Abutments straight. Individualizing is not permitted.
	Fixation Screw	There are a variety of SIC Fixation Screws that are used for SIC Prosthetic Components. In the head of the screw is an inner hex - 1.2 mm width across flats - for inserting the screwdriver. The user must assure that the corresponding screw type is used for the prosthetic restoration. The SIC Fixation Screw supplied with the SIC Prosthetic Component should not be used for laboratory use. A separate SIC Fixation Screw should be used during the working steps in the laboratory. The SIC Fixation Screw should only be tightened once to the torques defined in the table above. The SIC Fixation Screw may not be shortened.

Picture	Name	Description
	"Flex Star" Universal Cast-to Abutment	<p>The indication range of the SIC "Flex Star" Abutment includes fabrication of custom cast abutments for restorations using cemented or screw-retained single crowns and bridges. The abutment consists of a prefabricated, metal alloy base which has a cylindrical HEX connection. The SIC "Flex Star" Abutment for bridgework offers a conical connection and is especially used for bridge restorations. SIC "Flex Star" abutments consist of a prefabricated, cast-to metal alloy base which has and a cast-to functional section that allows customized contouring when used with a burnout plastic extension sleeve in the region of the screw channel. The above mentioned rules for individualizing must be followed. The abutment has a gingival emergence profile and can be contoured upwards to an individual abutment emergence profile for aesthetic restorations. This also allows fabrication of directly veneered and occlusal screw-retained restorations. The screw channel and fit should be checked after casting and corrected if necessary. It must be possible to pass the fixation screw easily through the screw channel and apply it deeply to the screw seating.</p> <p>The SIC "Flex Star" Universal Cast-to Abutment, for non-precious alloy is for restoration in a non-precious metal alloy and made from a platinum-iridium alloy. It is fitted with a black burnout plastic sleeve. The SIC "Flex Star" Universal Cast-to Abutment, high-fusing alloy is made from a high-fusing alloy. It is fitted with a white burnout plastic sleeve.</p>
	Gingiva Shaper	<p>SIC Gingiva Shaper is used for forming the gingiva following implant exposure or, alternatively, with transgingival healing. The three designs – cylindrical, concave anterior and concave posterior–cope with the most varied indications. The above mentioned rules for individualizing must be followed. The implant is extended to "supragingival level" in case of transgingival healing. The implant is sealed with a correspondingly shaped SIC Gingiva Shaper directly after implant insertion.</p> <p>Alternatively, after a healing period that must be determined individually but should be not less than 2 months (mandible) or 3 months (maxilla), the implant is exposed conventionally or with a mucosal punch. The cover screw has a central hole for the punch. The healing period should be extended appropriately when augmentation procedures are employed. After removal of the cover screw, the inside of the implant is cleaned and an appropriate SIC Gingiva Shaper is screwed in depending on the mucosal thickness and prosthetic requirements. Further prosthetic restoration should take place only after bland soft tissue healing (minimum 8 – 10 days).</p>
	Multi-Unit Abutment	<p>In the "Safe on Four" system, the Multi-Unit Abutments "Safe on Four" are directly screw-retained with the respective implant. In this way, a fixed transgingival platform is created over which all further prosthetic and laboratory technical measures are completed. The system is indicated for fixed or removable bridge or full restorations with the stipulation that the distal implants can have a maximum implantation angle of 30°. The maximum bone availability is utilized distally by displacement of the most distally placed angled implant.</p> <p>For complete restorations, a minimum of four implants must be placed in the mandible and a minimum of six in the maxilla. The bone quality must be D3 or higher. The implants must exhibit an intraosseous length of at least 9.5 mm and angled implants 11.5 mm. The implant diameter should be as large as possible – minimum: 4.0 mm. The implant should be placed at 16° resp. 30°. In case of immediate placement or immediate loading – to ensure adequate primary stability – the placement torque must be between 30 and 40 Ncm. The secondary parts (crown bases) must be firmly splinted primarily and distal extensions should generally be avoided.</p>

Picture	Name	Description
	Mini-Multi-Unit Abutment	<p>Mini-Multi-Unit Abutment as part of the "Mini-Multi-Unit" system, the Mini-Multi-Unit Abutments are screwed directly onto the respective implant. In this way, a transgingival platform is created through which all further prosthetic and laboratory work steps are carried out. The system is indicated for fixed bridges on at least 2 implants or whole jaw restorations with at least four implants in the lower jaw and at least six in the upper jaw. Bone quality must be at D3 or higher. The implants must have an intraosseous length of at least 9.5 mm. The implant diameter should be as large as possible - at least 4.0 mm and the implants should be placed with an angulation between 0° and 20°.</p> <p>In the case of immediate implantation or immediate loading, the torque must be between 30 Ncm and 40 Ncm to ensure sufficient primary stability. The secondary parts (crown bases) must primarily be rigidly blocked, distal extensions should be avoided in principle. The tightening torque of the Mini-Multi-Unit Abutments is 30 Ncm.</p> <p>The SIC crown base "TITAN", for "Safe on Four" is used in conjunction with "Safe on Four" superstructures. The SIC crown base "TITAN", for "Mini-Multi-Unit" is used in conjunction with "Mini-Multi-Unit" superstructures. It is used for the production of screw retained bridges or restorations with individual webs in the dental laboratory. The SIC crown base is made of titanium (grade 5). After attaching to the superstructure, the base is screwed to the "Safe on Four" or to the "Mini-Multi-Unit" structure with the help of the SIC retaining screw "Safe on Four" or with the "Mini-Multi-Unit" construction. With the help of the crown base "TITAN", individualized bridges for occlusal screw connection can be waxed. They can be tension-free attached to the master model or intraorally with cement or adhesive. Individual webs are made in the same way. The above-mentioned rules for individualization must be adhered to.</p>
	Standard Abutment	<p>SIC Standard Abutments are available in various designs for fabricating cemented or screw-retained single crowns and bridges. The abutment has a convex / concave gingival emergence profile from the implant level to the gingival height (GH) in an anterior (slim) respectively posterior (wide) design. The abutments can be customized by trimming and polishing according to the above mentioned rules for individualizing. Fitting intraorally: Cemented abutments and attachments are permanently fitted using suitable dental cements. Ensure that the abutment is not overfilled with cement. No cement should flow onto the sandblasted and etched transgingival region of the implant. Excess cement should be carefully removed.</p>
	Transfer Abutment	<p>After removal of the gingiva shaper, the SIC Transfer Abutment is screwed into the implant (max. 4-5 Ncm). A custom impression tray is necessary when an open tray technique is employed.</p> <p>It should be ensured (e.g. by X-ray) that the impression post is sitting on the entire surface of the implant interface. After the impression material has set, the fixation screw is loosened and the impression is removed together with the impression post. The implant is then sealed again with the gingiva shaper. A laboratory implant is screwed carefully to the impression post and a model is then made, if possible with a mucosal mask. When a closed impression technique is employed, the corresponding SIC Transfer Abutments are replaced in the impression after removing them from the implant. The impression aids and transfer caps are color-coded according to size.</p>
	Provisional Abutment	<p>The provisional abutment is designed to carry temporary crowns which can be cemented or directly polymerized onto the abutment. It can be shortened adequate to the occlusal space in order to avoid occlusal interference</p>

Precautions

These Instructions for Use must be read prior to using SIC Prosthetic Components. They may only be used for medical/dental procedures and constructions with the SIC Implant Systems. They must only be used for the intended Indications for Use 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. They must be in perfect condition. A visual inspection of the product should be performed before use. In our terms of sale and delivery, we guarantee the perfect quality of our products.

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 we have no control over the use of this product, we are not liable for damage caused by it. The following precautions are to be met prior to or during treatment:

- It is vital to observe a suitable stress distribution of the restoration related to the implant(s) and the bone.
- All implant / abutment connections must have a stress-free passive fit.
- The restoration has to be adjusted to the occlusion of the opposing jaw.
- Prior to each procedure, it must be ensured that all necessary components, instruments and materials are available in the required quantities.
- An equal balance between introduced force and available tissue has to be taken in consideration.
- All products intended for single use must not be reused. Failure to observe this can result in a loss of component precision and the risk of complications such as fractures and implant loss.
- Always wear protective clothing for your own safety.
- 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.
- Observe the specified torques.
- Small diameter implants with angled abutments are recommended only for use in the anterior region of the mouth.


Delivery Conditions

 SIC Prosthetic Components are delivered non-sterile and have to be cleaned and sterilized prior to use.

 SIC Prosthetic Components are intended for single use only. Do not reuse!

Products are delivered in a non-sterile condition. It is necessary to follow the following cleaning procedures before patient use:

Cleaning and Disinfection Procedures

-  Precaution:
- Cleaning procedures must be performed before clinical application and if debris is visible.
 - Do not use warm water.
 - When using automated cleaning and disinfection, avoid direct contact of the instruments to each other.
 - 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.
 - After cleaning and sterilization, SIC Prosthetic Components should be handled only with proper sterile instruments to avoid any contamination.

- 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 debris is removed. Firmly debris. 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.

- 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 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 deionized water (> 40°C "104°F") for 2 minutes

Sterilization

Before sterilization, the original packaging should be removed and the devices should be single- wrapped (e.g.: Brömeda REF: 68170912) in sterilization paper. SIC invent AG recommends the following sterilization procedures:

Steam Sterilization Procedure	Parameters
Fractionated pre-vacuum method	132°C for 4 min. with a drying time of 20 min.

Storage

The SIC Prosthetic Components must be stored in the original packaging at room temperature, dry, clean and dust-free place, and protected from damage.

Disposal

The used products are potentially hazardous to health as they may be contaminated by contact with blood, body fluids, bone or other tissue. Products must be handled and disposed of in accordance with local laws and regulations. Products with sharp or pointed edges must be handled and disposed in such a way that there is no danger to third parties.












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.

Magnetic Resonance Imaging (MRI) Safety Information

SIC Dental Implant System devices are MR Conditional. A person with SIC Dental Abutments may safely be scanned under conditions described in MRI Safety Information available from your local distributor or www.ifu.sic-invent.com

Symbols

-  Manufacturer
-  Manufacturing Date
-  Catalogue Number
-  Batch Code
-  Consult instruction for use
-  Caution, consult accompanying documents
-  Non-Sterile
-  Do not Reuse
-  By Prescription Only
-  Medical device
-  MR Conditional

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