

# SIC Prosthetic Components

## General Information

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## Instructions for Use

IFU is not  
designated for  
the U.S. market

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

Product Groups	Product Availability	
	Non-sterile	Sterile
Ball and Socket Abutments	+	+
Bonding Bases CAD/CAM	+	+
Cover Screws	+	-
Crown Bases	+	+
Fixation Post	+	+
Fixation Screws	+	+
"Flex Star" Cast-to Abutments	+	-
Gingiva Shapers	+	+
LocFix Attachments	+	+
Milling Blanks CAD/CAM	+	-
Multi-Unit Abutments	+	+
Mini-Multi-Unit Abutments	+	+
Provisional Abutments	+	-
Scan Posts and Scan Adapters	+	-
Standard Abutments	+	-
Standard Abutments 'Safe on Four'	+	+
TempCap	+	+
Temp Fix	+	+
Transfer Abutments	+	-
Transfer Caps	+	-

 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 Ball and Socket Abutments** are for the retention of implant-retained removable dentures on a minimum of 4 implants. Individualizing is not permitted.
- **SIC Bonding Bases and Milling Blank CAD/CAM** are suitable for the fabrication of CAD/CAM designed and manufactured implant abutments and single-tooth restorations on SIC implants. Individualization of the SIC CAD/CAM Bonding Bases is not permitted.
- **SIC Cover Screw "Augmentation Plus"** can be used in conjunction with augmentation measures that require the fixation of membranes or meshes. 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 Fixation Screw "Bone Ring"** can be used in conjunction with an augmentation technique for the fixation of circular bone rings of auto- or allografts. 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.

- **LocFix Attachments** are designed for use with overdentures or partial dentures, retained in whole or in part by endosseous implants in the mandible or maxilla. The range of applications of the LocFix Attachment includes retention of partial and full dentures on a minimum of 4 implants. Individualizing is not permitted.

- **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.

- **SICvantage TempCap Gingiva Shapers** assist the process of efficient supragingival healing. Directly after implant insertion, the cap is clicked onto the insertion post. It is suitable for a durability of 180 days. Individualizing is not permitted.

- **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.

- **SICvantage TempFix** is clicked onto the insertion post and facilitates an immediate restoration with a customized temporary. It also offers the possibility to contour a customized gingiva shaper. Furthermore, the TempFix is suitable for direct impression taking. The TempFix Abutment can be clicked cement-free onto the insertion post. It is suitable for a durability of 180 days.

- **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.

## 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.

## 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).

## Intended Clinical Benefit

The Intended Clinical Benefits of SIC invent Dental Implant System are:

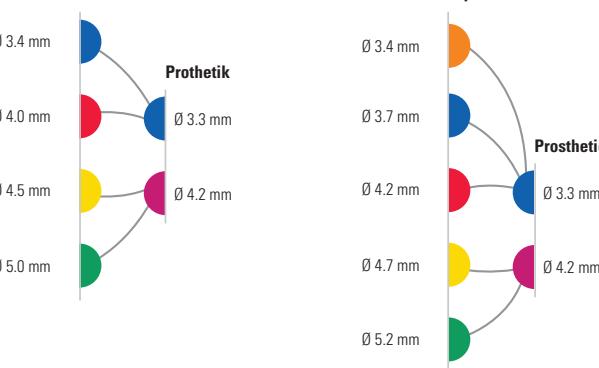
- Replaces the root of a tooth and thus acts as an anchor/a pillar for prosthetic restorations
- Helps to prevent jawbone loss after tooth loss
- Preserves the health of the surrounding bone and soft tissue
- Helps to keep adjacent (nearby) teeth stable and unharmed
- Promotes the preservation of hard and soft tissue shapes and thus supports oro-facial aesthetic appearance
- Psychologically positive benefits by allowing a natural smile for the patient with confidence and quality of life
- Helps restoring speaking and chewing functions
- Represents a form of care for missing teeth with high longevity
- Allows a reliable fit and retention of most types of prosthetic restorations

## 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.

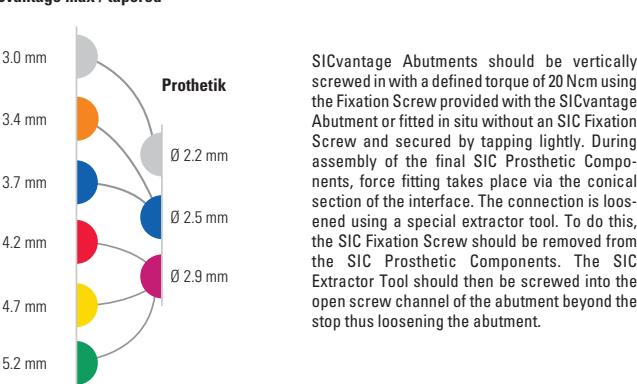
#### SICace



### 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 / tapered



## 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
SICvantage TempFix	min. thickness 0.4 mm of PEEK part	4.0 mm of PEEK part/post height
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)
SIC Impression Post	5 Ncm (hand tight)
All Fixation Screws for Abutments and Attachments	20 Ncm
SIC Fixation Post "Safe on Four"	30 Ncm
SICvantage Multi-Unit Abutment "Safe on Four", straight	
SIC Mini Multi-Unit Abutment	

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.
Bonding Base CAD/CAM		SIC Bonding Base CAD/CAM is suitable for the fabrication of CAD/CAM designed and manufactured implant restorations on SIC implants, which are adhesively retained on the titanium base using a conventional technique.
Cover Screw		SIC Cover Screw "Augmentation Plus" can be used in conjunction with augmentation measures that require the fixation of membranes or meshes. The head of the cover screw has an additional integrated thread, into which a fixation screw can be inserted for retaining a membrane or mesh. SIC Fixation Screw "Bone Ring" can be used in conjunction with an augmentation technique for the fixation of circular bone rings of auto- or allografts in combination with the base of the SIC Cover Screw "Augmentation Plus". Individualizing is not permitted.
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.
Crown Base		SIC Mini Multi-Unit Crown Base is used in conjunction with SIC Mini-Multi-Unit 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 SIC Mini-Multi-Unit Abutment using the SIC Fixation Screw for Mini Multi-Unit. Customized bridge frameworks for occlusal screw retention can be waxed up using the SIC Mini Multi-Unit 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.
Crown Base		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.

Picture	Name	Description
	Crown Base	<p>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.</p> <p>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.</p>
	Fixation Post	SIC Fixation Post is used for the fixation of SIC "Safe on Four" Abutments straight. Individualizing is not permitted.
	Fixation Screw	<p>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.</p> <p>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.</p>
	"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.</p> <p>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>

Picture	Name	Description
	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.</p> <p>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>
	LocFix Attachment	The range of applications of the LocFix Attachment includes retention of partial and full dentures on a minimum of 4 implants. The design of the allows use when implants have extremely divergent axes - up to 40° - and very limited occlusal space.
	Milling Blank CAD/CAM	The indication for use of the SIC Milling Blank CAD/CAM is the same as the SIC Bonding Base CAD/CAM with the difference that the milling blank is individualized by CAD/CAM Technology.
	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	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.</p> <p>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>		TempFix	SICvantage TempFix is clicked onto the insertion post and facilitates an immediate customized temporary restoration. The above mentioned rules for individualizing must be followed. It also offers the possibility to contour a customized gingiva shaper. Furthermore, the TempFix is suitable for direct impression taking. The TempFix Abutment can be clicked cement-free onto the insertion post. It is suitable for a durability of 180 days.
				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 <b>open tray technique</b> is employed. 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 <b>closed impression technique</b> 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	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
	Standard Abutment	<p>SIC Standard Abutments are available in various designs for fabricating cemented or screw-retained single crowns and bridges.</p> <p>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.</p> <p>The abutments can be customized by trimming and polishing according to the above mentioned rules for individualizing.</p> <p>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>			<p><b>Precautions</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>• It is vital to observe a suitable stress distribution of the restoration related to the implant(s) and the bone.</li> <li>• All implant / abutment connections must have a stress-free passive fit.</li> <li>• The restoration has to be adjusted to the occlusion of the opposing jaw.</li> <li>• Prior to each procedure, it must be ensured that all necessary components, instruments and materials are available in the required quantities.</li> <li>• An equal balance between introduced force and available tissue has to be taken in consideration.</li> <li>• 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.</li> <li>• Always wear protective clothing for your own safety.</li> <li>• 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.</li> <li>• Observe the specified torques.</li> <li>• Small diameter implants with angled abutments are recommended only for use in the anterior region of the mouth.</li> </ul>
	TempCap	The SICvantage TempCap Gingiva Shaper assists the process of efficient supragingival healing. Directly after implant insertion, the cap is clicked onto the insertion post. Care must be taken to ensure that there is no functional loading on the implant. It is suitable for a durability of 180 days.			

## Delivery Conditions

 **SIC Prosthetic Components** that are delivered sterile must be handled with care and are not to be contaminated before and during insertion procedure.  
If sterile prosthetic components need to be readjusted during treatment, the cleaning and sterilization procedure must be followed as described below.

 **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!

For products in non-sterile condition, it is necessary to follow the following cleaning procedures before patient use:

## Cleaning and Disinfection Procedures

### Precaution:

- Cleaning and disinfection procedures must be performed before clinical application.
- 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.
- Avoid contact between devices
- Should never be stored without complete drying

### Warning:

- Check devices for damage or distortion after cleaning and sterilization
- Do not sterilize damaged devices

### - 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.
Gravitation method	121°C for 90 min. with a drying time of 15 min.

## Reuse

If devices are intended for single use, reuse is not permitted. Reuse may lead to infection, inflammation, irritation, sensitization and possible unpredictable side effects in the patient, premature loss of the implant or the product may not fulfill its intended use.

## Storage

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

**SIC Prosthetic Components** must be stored in a dry place.

## 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

Non-clinical testing and MRI simulations were performed to evaluate the **SIC Dental Abutments** demonstrating that these 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](http://www.ifu.sic-invent.com)

## Symbols

	Manufacturer
	Date of manufacture
	Reference number
	Lot number
	Consult instruction for use
	Caution
	Non-Sterile
	Single use
	By Prescription Only
	Medical device
	Expiration Date
	Authorized Representative in the European Community/European Union
	Sterilized using irradiation
	Single sterile barrier system with protective packaging outside
	Do not resterilize
	Do not use if the product sterile barrier system or its packaging is compromised
	Keep away from sunlight
	Keep dry
	MR Conditional



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