SIC Prosthetic Components

Instructions for Use

General Information

SIC invent AG, Birmannsgasse 3, 4055 Basel, Switzerland
Tel.: +41 61 260 24 60, Fax: +41 61 261 39 68, Web: www.sic-invent.com
Email: contact.switzerland@sic-invent.com

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:

- Ball and Socket Abutment
- Bar and Bridge Abutment
- Bar Coping
- Bonding Base CAD/CAM
- Cover Screw
- Crown Base
- Fixation Post
- Fixation Screw
- "Flex Star" Universal Cast-to Abutment
- Gingiva Shaper
- Horizontal Screw
- Inner Matrix
- Locator® Attachment
- Milling Blank CAD/CAM
- Multi-Unit Abutment
- O-Ring Attachment
- P2F Abutment
- Retention Cap
- Transfer Abutment
- TempCap
- TempFix
- Wax-Up Abutment
- "White Star" Zirconium Oxide Abutment

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, Matrixes and Retention Caps** are for the retention of implant-retained removable dentures on a minimum of 4 implants. Individualizing is not permitted.
- **SIC Bar and Bridge Abutments** are ideal for fabricating direct screw-retained bar restorations or bridges and when there is limited available space due to their minimal overall height. Individualizing is not permitted.
- **SIC Bar Coping** for bar and bridge abutments Ø 3.3/4.2 mm are used for laboratory fabrication of screw-retained and prefabricated bars.
- **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. Sirona inLab software or Sirona CEREC® Software are to be used to design the prosthesis structure for SIC CAD/CAM Bonding Bases for CEREC. Therefore, the customers are required to use the device models (3D models) and the workflow defined and validated by Sirona through K111421. For all other SIC CAD/CAM products (Bonding Bases, Milling Abutments), the software 3Shape Abutment Designer, cleared under 510(k) K151455, shall be used. Individualizing 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.
- **SIC Horizontal Screws** are used for the horizontal retention of single crowns and bridges on standard abutments. Individualizing is not permitted.
- **Locator® 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 Locator® Attachment includes retention of partial and full dentures on a minimum of 4 implants.
- **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 O-Ring Attachments** are used for retaining a denture in the upper or lower jaw using SICmax onepiece implants. Individualizing is not permitted.
- **SIC P2F Abutments Dr. Galip Gürel** enables fabrication of an immediate restoration and include the fabrication of temporary single restorations or bridges.
- **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 Wax-up Base CAD/CAM** can be used as a wax-up base for laboratory fabrication of the scan pattern. The Wax-Up Base can also be used for fabricating a temporary abutment.
- **SIC Wax-Up Abutment for SICmax onepiece** is suitable for use as a wax-up base for fabricating the pattern of a single crown or metal framework.
- **SIC "White Star" Abutments** are indicated for all-porcelain restorations at bone height. They can be used for fabricating adhesive-retained or cemented all-porcelain crowns. It can also be used for fabricating economical, screw-retained, all-porcelain restorations by firing a compatible facing porcelain directly onto the abutment.

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.

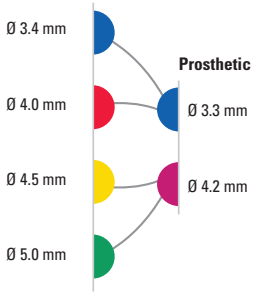
The following complications have arisen occasionally when using prosthetic components and accessories:

- 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).

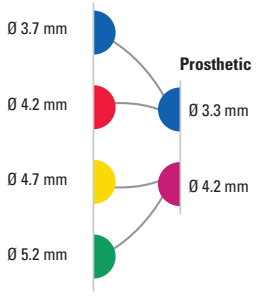
Interface Information

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.

SICace

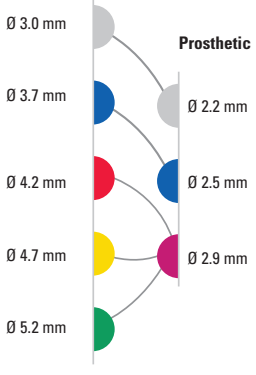


SICmax / SICtapered



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



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.

SIC Prosthetic Components for SICmax onepiece
SIC Prosthetic Components for SICmax onepiece are only to be used in connection with SICmax onepiece implants. The integrated multi-indicative prosthetic connection consists of an initial conical functional section, followed by a rotational lock and a ball abutment for fitting O-ring attachments.

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, SIC "White Star" Abutments SIC Wax-up Bases	2.8 mm and min. thickness 0.4 mm	4.0 mm of functional area/post height
Crown Bases, SIC Bar Coping	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 P2F Abutments	min. thickness 0.4 mm of PEEK part	4.0 mm of PEEK part/post height
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, SIC Horizontal Screw	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" 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. The Retention Cap holds the respective Inner Matrix. After they have been assembled, the Retention Cap is fitted on the ball of the abutment, aligned horizontally and polymerized into the denture.
	Inner Matrix	
	Retention Cap	
	Bar and Bridge Abutment	The SIC Bar and Bridge Abutment is ideal for fabricating direct screw-retained bar restorations or bridges with passive fit. 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 max. 15°. 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.
	Bar Coping	The SIC Bar Coping is used in conjunction with bar and bridge abutments or "Safe on Four" abutments. The bar coping is used for laboratory fabrication of screw-retained, prefabricated bars and is made from a gold-platinum alloy. The respective bars are soldered to the bar copings. A special stainless steel soldering implant is used for fabricating the solder model. The bar coping fits on the conical head of the abutment. The bar coping can be - if required - customized by trimming and polishing according to the above mentioned rules for individualizing.
	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. SIC CAD/CAM Bonding Bases for CEREC are to be used only in connection with Sirona inLab software or Sirona CEREC® Software by a validated laboratory for designing the prosthesis structure. All other SIC CAD/CAM products (Bonding Bases, Milling Abutments), the software 3Shape Abutment Designer shall be used by a validated laboratory for designing the prosthesis structure.
	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.

Picture	Name	Description
	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	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. 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.
	Gingiva Shaper	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. 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).
	Horizontal Screw	SIC Horizontal Screw is used for the retention of single crowns and bridges on standard abutments. It has a screw thread with a diameter of 1.4 mm and is made from Titanium Grade 5. The head of the screw incorporates a hex, key width 1.2 mm, for insertion of the screwdriver. The head of the screw can be shortened by up to 1.0 mm to adapt it to the morphology of the crown.
	Locator® Attachment	The range of applications of the Locator® Attachment includes retention of partial and full dentures on a minimum of 4 implants. The design of the Locator® 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.

Picture	Name	Description
 	Multi-Unit Abutment	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. 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.
	O-Ring Attachment	SIC O-Ring Attachment is used for retaining a denture in the upper or lower jaw using SICmax onepiece implants. The denture should be liberally relieved in the region of the implant. The O-ring attach¬ments are fitted onto the ball abutments and retained in the denture using cold-curing acrylic. When using SIC Retention Attachments, the ball is separated from the SICmax onepiece implant and the abutment is retained using permanent cement. A rubber dam must be carefully placed in the oral cavity before separation. It is essential that the implant is well cooled during separation of the ball. Please note: SIC Retention Attachments are not available for the U.S. market.
	P2F Abutment	SIC P2F Abutment Dr. Galip Gürel enables fabrication of an immediate restoration. Due to subtractive milling or grinding, the operator is in the position to fabricate a temporary single restoration or bridge. The above mentioned rules for individualizing must be followed. The abutment is force fitted onto a SIC CEREC bonding base. A crown can be cemented directly on the P2F abutment base for the final prosthetic restoration. The P2F abutment is retained clinically on the implant using the SIC Standard Fixation Screw.
	Standard Abutment	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. **SIC Standard Abutment for SICmax onepiece:** There is a choice of cementable abutments for single-tooth restorations and for the retention of bars and bridges. 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.
	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.

Picture	Name	Description
	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	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. 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.
	Wax-Up Abutment	SIC Wax-Up Base CAD/CAM can be used as a wax-up base for laboratory fabrication of the scan pattern. The Wax-Up Base can also be used for fabricating a temporary abutment. The SIC Wax-Up Base is fitted on the Lab Implant and retained in position using a screw. The shape of the custom abutment pattern is then fabricated using pattern resin or sculpting wax and the pattern is scanned. The above mentioned rules for individualizing must be followed.
		The SIC Wax-Up Abutment for SICmax onepiece is suitable for use as a wax-up base for fabricating the pattern of a single crown or metal framework. The Wax-Up Abutment is fitted on the Lab Implant. The shape of the customized abutment or framework pattern is then fabricated using pattern resin or sculpting wax and then the customized superstructure is casted. The abutment burns out without residue. Fabrication of a temporary abutment is also possible. The superstructure should be cemented using phosphate cement.
	"White Star" Zirconium Oxide Abutment	SIC "White Star" abutment is indicated for all-porcelain restorations at bone height. The abutment is manufactured from yttrium-reinforced zirconia high-performance ceramic without metal strengtheners and can be used for fabricating adhesive-retained or cemented all-porcelain crowns. It can also be used for fabricating screw-retained, all-porcelain restorations by firing compatible facing porcelain directly onto the abutment. The zirconium oxide abutment can be customized by trimming using water-cooled turbines and sintered diamond rotary instruments as well as by direct application and firing of porcelain. The abutments can be customized by trimming and polishing according to the above mentioned rules for individualizing.

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 first 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 if debris are 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 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.

- 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 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 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.

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.

Symbols for Labels

- Manufacturer
- Manufacturing Date
- REF Catalogue Number
- LOT Batch Code
- Consult the Instruction for Use
- Caution, consult accompanying documents
- Non-Sterile
- Do not Reuse
- Keep dry

CE 0297

Conformity to the essential requirements with notified body number of DQS Medizinprodukte GmbH, Frankfurt, Germany

SIC invent AG - Birmannsgasse 3
4055 Basel, Switzerland
Phone: +41 (0)61 260 24 60
Fax: +41 (0)61 261 39 68
www.sic-invent.com

05/2019 Rev. 1.5 English - International