1. 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

For U.S. Market only

Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.
This Instructions for Use applies to any SIC CAD/CAM Products described in its label as:

- Bonding Base CAD/CAM
- Milling Blank CAD/CAM
- Crown Base "Safe on Four", CAD/CAM

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

2. Device Description

SIC CAD/CAM Products are suitable for the fabrication of CAD/CAM designed and manufactured implant abutments and single-tooth restorations on SIC implants.

3. Indications for Use

SIC CAD/CAM Products are intended for use with SIC Dental Implants for prosthetic restorations from single tooth replacements to full arch restorations with fixed or removable superstructures. The Bonding Bases consist of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.
All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Bonding Base or Milling Blank are to be sent to an SIC invent validated milling center for manufacture.

4. Intended Users

SIC invent AG devices are intended to be used, handled and managed in a healthcare setting by appropriately trained and qualified dentists, dental clinicians, dental surgeons and personnel. The operator must be familiar with dental surgery and prosthetics, including diagnostics and preoperative planning.

5. Target Population

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

6. Contraindications

- High loads on supra structures with an extra axial force center.
- Non-splinted SIC CAD/CAM Products 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 22.5° 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.

7. 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 CAD/CAM Products 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).

8. MRI Safety Information

SIC Dental Abutments 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

9. Interface Information

SIC CAD/CAM Products with Hexagonal Implant Interface

SICace®, SICmax®, SICtapered	
Implant	Prosthetics
3.4/3.7 mm	3.3 mm
4.0/4.2 mm	
4.5/4.7 mm	4.2 mm
5.0/5.2 mm	

SIC CAD/CAM Products that have a cylindrical hexagonal implant interface are only to be used in connection with SICace, SICmax or SICtapered implants.

SIC CAD/CAM Products with SICvantage Implant Interface

SICvantage® max SICvantage® tapered	
Implant	Prosthetics
3.0 mm	2.2 mm
3.7 mm	2.5 mm
4.2 mm	2.9 mm
4.7 mm	
5.2 mm	

SIC CAD/CAM Products 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 CAD/CAM Products should be vertically screwed in with a defined torque of 20 Ncm using the Fixation Screw provided with the SICvantage CAD/CAM Products or fitted in situ without an SIC Fixation Screw and secured by tapping lightly. During assembly of the final SIC CAD/CAM Products, 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 CAD/CAM Products. The SIC Extractor Tool should then be screwed into the open screw channel of the abutment beyond the stop thus loosening the abutment.

10. Prosthetic Procedure

The SIC CAD/CAM Products 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:

Connection	**Min. wall thickness***	**Min. gingival margin diameter***	**Max. angle correction** (in the abutment)	**Gingival margin height**	**Abutment post height**	**Total abutment height** (post height + gingival height + implant connection height; only for Milling Blanks)
HEX	0.5 mm	**0.2 mm** wider than the implant platform	no angular correction permitted Exception for Milling Blanks: 30°	Min: 0.3 mm Max: 3.0 mm Exception for Milling Blanks: Min.: 0.3 mm	Min: 4.0 mm Max: 7.0 mm	Min: 6.55 mm Max: 12.2 mm
SICvantage	0.5 mm	**1.10 mm** wider than the implant platform	no angular correction permitted Exception for Milling Blanks: 30°	Min: 0.30 mm Max: 3.0 mm Exception for Milling Blanks: Min.: 0.5 mm	Min: 4.0 mm Max: 7.0 mm	Min: 8.8 mm Max: 14.1 mm Exception for Milling Blanks: min.: 8.45 mm
Multi Unit	0.5 mm	**5 mm** for Safe on Four, **4.02 mm** for Mini Multi-Unit	No angular correction permitted for Crown Bases	**0.29 mm** for Safe on Four, **0.25 mm** for Mini Multi-Unit	**5.9 mm** for Safe on Four **5.65 mm** for Mini-Multi-Unit	n/a

* For the wall thickness and gingival margin diameter only the minimal values apply. There are no fixed limits for maximal values as the thicker the individualized abutment becomes, the more stable it gets.

For all SIC CAD/CAM Products, 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.

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 with a torque of 20 Ncm. A fixed prosthetic restoration can be cemented or fixed with an occlusal or horizontal screw. The coping should be bonded to the base by a trained and qualified dentist, clinician or professional personnel.

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, disinfect and sterilize the final restoration (base with cemented superstructure and prosthesis) according to validated cleaning procedures. Check the fit of the final restoration. After removal of the gingiva shaper, insert the final restoration 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 CAD/CAM Products are:

Picture	Name	Description
	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. A coping is prepared with the following parameters: Material: Zirconia, ISO 13356, cleared in K130991 as NexxZr Cement: 3M ESPE RelyX Unicem bonding cement, cleared in K022476 as RelyX RMGIP. Coping angulation for SIC Bonding Base CAD/CAM (for SICace®, SICmax®, SICtapered implants): total maximum angulation of 30° (15° for angled bases and 30° for straight bases). Coping angulation for SICvantage Bonding Base CAD/CAM (for SICvantage® max, SICvantage® tapered implants): 0°. The parameters in section 10 "Prosthetic Procedure" mentioned rules for individualization must be followed.
	Crown Base	SIC Crown Base "Safe on Four", CAD/CAM, 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 Crown Base and adhesive bonded or cemented stress-free on the master model or intraorally. Customized bars are fabricated in the same manner. The in section 10 "Prosthetic Procedure" mentioned rules for individualization must be followed.
	Crown Base	SIC Mini Multi-Unit Crown Base, CAD/CAM, is used in conjunction with 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 Mini Multi-Unit abutments using the SIC Fixation Screw for Mini Multi-Unit. Customized bridge frameworks for occlusal screw retention can be waxed up using the Crown Base and adhesive bonded or cemented stress-free on the master model or intraorally. Customized bars are fabricated in the same manner. The in section 10 "Prosthetic Procedure" mentioned rules for individualization must be followed.
	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. The in section 10 "Prosthetic Procedure" mentioned rules for individualization must be followed.

The design parameters for the CAD/CAM zirconia superstructure to be used on the SIC Bonding Base CAD/CAM abutments and SICvantage Bonding Base CAD/CAM abutments are:

Minimum wall thickness – 0.5 mm
Minimum post height for single-unit restoration – 4.0 mm
Minimum gingival height – 0.3 mm
Maximum gingival height – 4.0 mm
Maximum angulation for SIC Bonding Base CAD/CAM (for SICace®, SICmax®, SICtapered implants) Angled Titanium Bases – superstructure maximum angle – 15° Straight Titanium Bases – superstructure maximum angle – 30°
The maximum angulation of the final abutment – 30°
Maximum angulation for SICvantage Bonding Base CAD/CAM (for SICvantage® max, SICvantage® tapered implants) – 0°
The final abutment is straight only, no angulation.

The design parameters for the CAD/CAM Pre-Milled Blank custom abutment are:

Minimum wall thickness – 0.5 mm
Minimum post height – 4.0 mm
Minimum gingival height (for SICace®, SICmax®, SICtapered implants) – 0.3 mm
Minimum gingival height (for SICvantage® max, SICvantage® Tapered implants) – 0.5 mm
Maximum gingival height – 3.0 mm
Maximum Angulation (for SICace®, SICmax®, SICtapered implants) – 30°
Maximum Angulation (for SICvantage® max, SICvantage® Tapered implants) – 30°

11. Warnings:

When an abutment with a short gingival collar for clinical use with a compatible dental implant near the crestal bone level is the treatment of choice, consider the following clinical considerations:
- Select an appropriate gingival abutment collar height that maintains biologic width (supracrestal attachment) and suits the patient- and site-specific clinical conditions.
- Use careful clinical technique to avoid subgingival peri-implant cement impaction.
- Provide patient education, focusing on oral hygiene instruction and dental implant home care.
- Provide adjuncts to oral hygiene for effective plaque control, as needed.
- Monitor for plaque accumulation, soft tissue inflammation, clinical attachment loss, abutment loosening, and marginal bone loss around the implant during patient maintenance visits.
- Consider increasing the frequency of patient maintenance visits for oral examination and prophylaxis, as needed, to improve implant care and/or to monitor for tissue changes that could affect the long-term success of the implant.

12. Precautions

These Instructions for Use must be read prior to using SIC CAD/CAM Products. 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 torque.
- Small diameter implants with angled abutments are recommended only for use in the anterior region of the mouth.

13. Delivery Conditions

SIC CAD/CAM Products are delivered non-sterile and have to be cleaned and sterilized prior to first use.

SIC CAD/CAM Products 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:

14. 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 CAD/CAM Products 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. Firm debris or 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

- 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

15. Sterilization

Before sterilization, the original packaging should be removed, and the devices should be single-wrapped using a wrap that is FDA cleared for the indicated cycle. SIC invent AG recommends the following sterilization procedures:

Steam Sterilization Procedure	Parameters
Fractionated pre-vacuum method	132°C (270°F) for 4 min. with a drying time of 20 min.

16. Storage

The SIC CAD/CAM Products must be stored in the original packaging at room temperature in a clean and dust-free place and needs to be protected from damage.

SIC CAD/CAM Products must be stored in a dry place.

17. Validated Milling Center (VMC)

The following validated milling center (VMC) is intended to serve as the contract manufacturing location to SIC invent AG for the proposed digitally customized abutments, superstructures, and/or hybrid crowns for the use with SIC Bonding Base and Milling Blank CAD/CAM devices:
Imagine Milling Technologies, LLC,
located at 14220 Sullyfield Circle, Suite B,
Chantilly, VA 20151, +1 888-635-4999,
info@imagineusa.com,
FDA Establishment Registration Number 3009727738.

18. Symbols Glossary

ANSI/AAMI/ ISO 15223-1
Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol	Title of Symbol *(Reference Number)*	Meaning of Symbol
	Date of manufacture *(5.1.3)*	Indicates the date when the medical device was manufactured.
	Manufacturer *(5.1.1)*	Indicates the medical device manufacturer.
REF	Catalogue number *(5.1.6)*	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Batch code *(5.1.5)*	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Consult instructions for use *(5.4.3)*	Indicates the need for the user to consult the instructions for use.
	Caution *(5.4.4)*	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Non-sterile *(5.2.7)*	Indicates a medical device that has not been subjected to a sterilization process
	Do not re-use *(5.4.2)*	Indicates a medical device that is intended for one single use only.
	Keep dry *(5.3.4)*	Indicates a medical device that needs to be protected from moisture.
MR	MR Conditional *(n/a)*	Conditions under which a medical device can safely enter the MR environment

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

CE 0297

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

995071-en-US 1.7 2026-06-09