SIC Prosthetic Components – Multi Unit System "Universal 4.8"

Instructions for Use

General Information

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

REF This Instruction for Use applies to any SIC device listed in the following tables.

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

Device Description

The SIC Multi Unit System "Universal 4.8" consists of prosthetic components – abutments, crown bases, and retention screws – as well as impression and transfer components, instruments for planning, positioning, and tightening. Laboratory implants can be used for model fabrication, indicated for fixed or removable bar and bridge or full restorations.

PROSTHETIC COMPONENTS

Products	EU CE mark
SIC Multi Unit Abutment (MUA) "Universal 4.8", straight[1]	CE 0297
SIC Multi Unit Abutment (MUA) "Universal 4.8", 17° / 30° angle[2]	
SICvantage Multi Unit Abutment (MUA) "Universal 4.8" straight[1]	
SICvantage Multi Unit Abutment (MUA) "Universal 4.8", 17° / 30° angle[2]	
SIC Gingiva Shaper "Universal 4.8" cylindrical	
SIC Crown Base "Universal 4.8", CAD/CAM[3]	
SIC Crown Base "Universal 4.8", Titanium, short/long[3]	
SIC Crown Bases "Universal 4.8", residue-free-burn-out[3]	
SIC Fixation Screw "Universal 4.8" (M 1.4 mm)	
SIC Fixation Screw short (for angled MUA abutments)	
SICvantage Fixation Screw short (for angled MUA abutments)	

[1] incl. Carrier for MUA straight
[2] incl. Handlingtool for MUA angled
[3] incl. SIC Fixation Screw "Universal 4.8"

Indications for Use

SIC Prosthetic Components are intended for use with SIC Dental Implants for prosthetic restorations.

- **SIC Multi Unit Abutments and SICvantage Multi Unit Abutments** "Universal 4.8" are indicated for fixed or removable bar and 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 4 implants must be placed in the mandible and a minimum of 6 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 (HEX) and 3.7 mm (vantage). The distal implant should be placed at 17° 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.
  - Individualizing is not permitted.
- **SIC Crown Bases, short and long**, "Universal 4.8" Titanium are used for the laboratory fabrication of screw-retained bridges or custom bar restorations.
- **SIC Crown Bases** "Universal 4.8", residue free burn out are used for the laboratory fabrication based on casting technique of screw-retained bridges or custom bar restorations.
- **SIC Crown Bases** "Universal 4.8", CAD/CAM are used for the CAD/CAM based fabrication of screw-retained bridges or custom bar restorations.
- **SIC Fixation Posts/Screws** are used for the retention of the abutments to the implant and the fixation of the restoration to the abutment. Individualizing is not permitted.
- **SIC Gingiva Shapers** "Universal 4.8", assist the process of efficient supragingival healing. They are attached to the Multi Unit Abutment and used for forming the gingiva during healing.

IMPRESSION COMPONENTS

Products	EU CE mark
SIC Transfer Abutment "Universal 4.8", reposition (incl. SIC Transfer Cap with Click)	CE
SIC Transfer Abutment "Universal 4.8", Open Tray Technique (incl. SIC Fixation Screw 16.0 mm)	
SIC Scan Adapter for SIC "Universal 4.8"	

Indications for Use

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 Transfer Abutments** "Universal 4.8", type 'reposition' or type 'open tray' technique, are used to copy the individual patient's mouth situation into a cast model for the lab work of the dental technician. Individualizing is not permitted.
- **SIC Scan Adapter** "Universal 4.8" is to be used for digital impression (scanning) on abutment level.

INSTRUMENTS

Products	EU CE mark
SIC Planning Guide for SIC "Universal 4.8"	CE
SIC Positioning Aid for SIC "Universal 4.8" and "Safe on Four"	
SIC Screwdriver Hex 1.2 mm (for angle piece and wrench)	
SIC Screwdriver "Universal 4.8" (for angle piece and wrench)	
SICvantage Extractor Tools	

Indications for Use

The intended use of all SIC Instruments is the insertion of one or more dental implants in vivo and all applications during the treatment, clinically and in the lab process, by using exchangeable screwdriver tips and bits.

- **SIC Planning Guide** for the "Universal 4.8" is a template that is used intraorally to help place the implants at the correct angle.
- **SIC Positioning Aids** "Universal 4.8" and "Save on Four" are attached to the implant's insertion post during the final insertion step (precise alignment) for the angled placed implants. They are used to check the tilt and rotational alignment of the insert- ed implants to each other and to align the insertion axis of the superstructure parallel.
- **SIC Screwdriver** HEX 1.2 mm is used for all Fixation Screws
- **SIC Screwdriver** "Universal 4.8" is used to tight the Multi Unit Abutments, straight
- **SICvantage Extractor Tools** are used for the SICvantage connection, to remove the angled MUA's

IMPLANT ANALOG

Products	EU CE mark
SIC Lab Implant "Universal 4.8"	None

Description

SIC Lab Implant "Universal 4.8" is designed to reproduce the abutment and its position in the mouth in the correct position on the model.

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.

Patient 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.

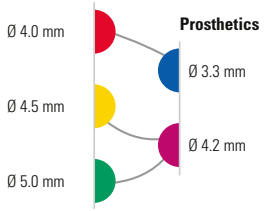
The following complications have arisen occasionally when using prosthetic components and accessories:
- Components used in the patient's mouth have been aspirated and swallowed.
- Due to excessive torque, the SIC Fixation Screw of the abutment has fractured.
- Titanium components have discoloured during 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 orofacial 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

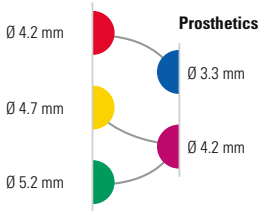
INTERFACE INFORMATION

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



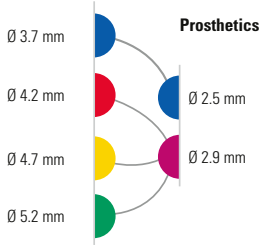
SICmax / SICtapered



SIC Multi Unit Abutments "Universal 4.8", straight, twopiece, should be vertically screwed in with a defined torque of 30 Ncm and Multi Unit Abutments, 17° and 30° should be vertically screwed in with a defined torque of 20 Ncm using the Fixation Screws.
Screws are provided with the Multi Unit Abutment "Universal 4.8".

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 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 tapered



SICvantage Multi Unit Abutments "Universal 4.8", straight, onepiece, should be vertically screwed in with a defined torque of 30 Ncm and MUA 17° and 30° should be vertically screwed in with a defined torque of 20 Ncm using the Fixation Screws.
Screws are provided with the Multi Unit Abutments "Universal 4.8"

During assembly of the final SIC vantage prosthetic components, force fitting takes place via the conical section of the interface. For the angled MUA's, the connection is loosened using the SICvantage Extractor Tool. To do this, the SIC Fixation Screw should be removed from the angled MUA's. 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 must be considered. The following rules for individualization must be followed:

SIC Prosthetic Component	minimum diameter after individualization	minimum length after individualization
SIC Crown Bases	Reduction is not permitted	6.0 mm of total height
SIC Gingiva Shapers	Reduction is not permitted	Reduction is not permitted
SIC Fixation Posts/Screws	SIC Fixation devices 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)
SIC Fixation Screws	20 Ncm
SIC Multi-Unit Abutment "Universal 4.8", straight (post)	30 Ncm
SICvantage Multi-Unit Abutment "Universal 4.8", straight (onepiece)	30 Ncm
SIC Multi-Unit Abutment "Universal 4.8", 17° and 30° (SIC Fixation Screw, short / SICvantage Fixation Screw, short)	20 Ncm
SIC Fixation Screw "Universal 4.8" (M 1.4 mm)	15 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 screwdriver provided for this purpose to the above defined torque.

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

Picture	Name	Description
	Multi Unit Abutments	**SIC Multi Unit Abutments "Universal 4.8" are directly screw-retained with the respective SIC implant.**
		SIC Hexagonal Implant Interface: SIC Multi Unit Abutments "Universal 4.8", straight, twopiece, are fixed with the correspondingly supplied Fixation Posts to a torque of 30 Ncm
		SICvantage Implant Interface: SICvantage Multi Unit Abutments "Universal 4.8", straight, onepiece, are fixed with a torque of 30 Ncm
		The angled abutments in versions, 17° and 30°, are fixed with the SIC Fixation Screws 'short' to a torque of 20 Ncm. (The Fixation Posts and Screws are supplied with the abutments.)
		In this way, a fixed transgingival platform is created, upon which all further prosthetic and laboratory technical measures are completed.
		The straight abutments come with a Carrier, clicked onto the abutment, to enable easier handling and positioning of the abutment.
		The angled abutments come with a Handling Tool, to enable easier handling while positioning the abutment in the implant and placing the fixation screw. The Handling Tool is unscrewed and removed from the abutment after the placement.
	**Crown Bases**	The SIC Crown Base "TITANIUM", short/long "Universal 4.8", is used in conjunction with SIC Multi Unit Abutments and SICvantage Multi Unit Abutment "Universal 4.8". It is used for the laboratory fabrication of screw-retained bridges or custom bar restorations. The SIC Crown Base is made of Titanium Grade 5 and after fitting on the abutment, the base is screw retained with the Abutments using the SIC Fixation Screw M1.4 mm. Customized bars and bridges 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. The above mentioned rules for individualizing must be followed. The SIC Crown Base "Universal 4.8" 'residue free burn out', is suitable as a "wax-up" base for model fabrication of a metal framework in conjunction with the Multi Unit Abutments "Universal 4.8". 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
	**Fixation Screws**	There are different SIC Fixation Screws that are used for SIC Multi Unit Abutment "Universal 4.8". They are supplied in the packaging with the SIC Prosthetic Components. For the angled versions, 17° and 30°, the SIC Fixation Screw 'short' is to be used. In the head of this screw is an inner hex - 1.2 mm width across flats - for inserting the SIC screwdrivers. The above fixation screws must be used to a torque of 20 Ncm. For the Hexagonal Implant Interface straight version, 0°, the Fixation Post, that is supplied with abutment, must be used to a torque of 30 Ncm. It is to be fixed with the SIC screwdriver "Universal 4.8" (fitting the outer hex diameter of 2.0 mm) For the fixation of the prosthetic restoration to the abutment the SIC Fixation Screw "Universal 4.8" (M1.4) has to be used to a torque of 15 Ncm The SIC Fixation Screws 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 user must assure that the corresponding screw type is used for the prosthetic restoration. All Fixation components must not be individualized!
	**Gingiva Shaper**	The SIC Gingiva Shaper (Healing Cap) "Universal 4.8", cylindrical, assists the process of efficient supragingival healing. Directly after implant insertion, it is screwed (internal screw) hand-tight (max. 5 Ncm) onto the Multi Unit Abutment to remain there during the healing period.
	**Scan Adapter**	The SIC Scan Adapter "Universal 4.8" is used for digital impression (scanning) on Multi Unit Abutment level. Prior to scanning they are screwed to the Multi Unit Abutment hand tight. It should be ensured that the impression post is sitting on the entire surface of the prosthetic interface. They are removed after scanning.
	**Transfer Abutments „Open Tray Technique"**	The SIC Transfer Abutments "Universal 4.8", Open Tray Technique is screwed onto the Multi Unit Abutments "Universal 4.8" with the SIC Fixation Screw is supplied and recommended hand tighten to max. torque of 5 Ncm. When the open tray technique is employed a custom impression tray is necessary. It should be ensured that the impression post is sitting on the entire surface of the prosthetic interface. After the impression material has set, the fixation screw is loosened, and the impression is removed together with the impression post. A laboratory implant is screwed carefully to the impression post and a model is then made, if possible, with a mucosal mask.
	**Transfer Abutments „Closed Tray Technique**	The SIC Transfer Abutment "Universal 4.8", reposition, is screwed onto the Multi Unit Abutments "Universal 4.8", is supplied and recommended to hand tighten to max. torque of 5 Ncm. It should be ensured that the impression post is sitting on the entire surface of the prosthetic interface. When a closed impression technique is employed, the Transfer Abutments are replaced in the impression after removing them from the implant. The SIC 'Transfer Cap with Click', supplied with the Transfer abutments, engages with a click. Attention should be paid to this to ensure a perfect fit.

Picture	Name	Description
	**Lab Implant**	The SIC Lab Implant "Universal 4.8" is designed to reproduce the abutment and its position in the mouth in the correct position on the model. It can be used with conventional workflow by fixing it to the transfer abutments in the impression and pouring the model or with digital workflow by inserting it into a printed model.
	**Planning Guide**	The SIC Planning Guide for SIC "Universal 4.8" is a template that is used intraorally to help place the implants at the correct angle. The planning template is inserted with the central pin into an additional central anterior alveolar ridge drill hole (diameter 2 mm). The implant cavities can then be drilled at the correct angle by visually comparing the direction of the drill with the indicated angulations on the template. (0°, 17°, 30°) After the drilling procedure, the template is removed, and the bony guide hole is left to heal.
	**Position-ing Aids**	They are attached to the implant's insertion post during the final insertion step (precise alignment) for the angled placed implants. They are used to check the tilt and rotational alignment of the inserted implants to each other and to align the insertion axis of the superstructure parallel. The SIC Positioning Aid for SIC "Universal 4.8" and "Safe on Four" are offered for the use on SIC implants with insertion post and on SIC Implants "mountless".
	**SIC Screw driver "Universal 4.8"**	The SIC Screwdriver "Universal 4.8" is used to tight the Multi Unit Abutments, straight

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 devices must not be used until all issues have been resolved. They must be in perfect condition. A visual inspection of the device should be performed before use. In our terms of sale and delivery, we guarantee the perfect quality of our devices. 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 devices 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- 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
Gravitation method	121°C for 90 min. with a drying time of 15 min.

The instructions for above have been validated by SIC as suitable for preparing the devices. The reprocessor is responsible for ensuring that the reprocessing (cleaning, disinfection, sterilization) carried out achieves the desired results with the equipment, materials and personnel used in the reprocessing facility.
This usually requires validation and routine monitoring of the process and the used equipment.

Reuse and Limitations
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.

On instruments the reprocessing is limited to 20 cycles.

Storage
The SIC devices 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

Symbols

	Manufacturer
	Date of manufacture
REF	Reference number
LOT	Lot number
	Consult instruction for use
	Caution
	Non-Sterile
	Single use
Rx Only	By Prescription Only
MD	Medical device
EC REP	Authorized Representative in the European Community/European Union
	Do not use if the product sterile barrier system or its packaging is compromised
	Keep away from sunlight
	Keep dry
	MR Conditional

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

EC REP **SIC invent Deutschland GmbH**
Burkheimer Str. 3
79111 Freiburg, Germany

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