SIC Drills and Cutting Instruments

Instructions for Use

General Information

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REF

Pilot Drills:
935222
935214

Extension Drills:

935223	935228	935218
935224	935215	935221
935225	935216	935220
935226	935217	

Crestal Drills:

935167	935192
935187	935193

Bone Tap:

935198	935185	935190
935168	935186	

GS Pilot Drills:
935553
935554

GS Extension Drills:

935555	935567	935562
935556	935559	935568
935557	935560	
935558	935561	

GS Countersinks:

935550	935552
935551	935566

GS Bone Tap:

935563	935565
935564	935569

Marking Drill:
935194

GS Gingiva Punches: 935127
935128
935129

Reamers:
Cutter:
935230

Trepan Drills:

935231	935233
935232	935234

HSS Drill:
935235
(HSS Drills are single use items)

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

Device Description

SIC invent AG has a range of drills and cutting instruments with several technical features to support the SIC invent AG dental implants surgical procedures.

Precaution:
- Implantation is a surgical procedure. It must be performed according to the general rules of surgery (informed consent, sterility, postoperative care).
- Atraumatic treatment of the hard and soft tissue is essential for creating optimal conditions for healing.
- Reducing the temperature rise in alveolar bones during dental implant surgery improves the initial recovery of alveolar bones and improves the success rate of implants. Therefore, in order to minimize the bone damage and necrosis, surgeons should consider the influence and relationship between the drilling parameters and choose optimum parameters for their specific clinical case and situations.
- The depth stop guarantees secure friction fit. This is achieved by a clip on the drill depth stop which can simply be attached over the working section of the drill. The cutting and flank geometry, in combination with the "Tri-Spade Design", guarantees that the blades are centered well initially in the bone cavity. It ensures that the direction remains stable, providing unusual good concentricity.

SIC invent Drill System

SIC invent Dental Implants are self-tapping implants. The following summary presents the surgical guideline.

SICace SICmax SICvantage max	Ø 3.0 *	Ø 3.4 * Ø 3.7 * Ø 3.7 *	Ø 4.0 * Ø 4.2 * Ø 4.2 *	Ø 4.5 * Ø 4.7 * Ø 4.7 *	Ø 5.0 * Ø 5.2 * Ø 5.2 *
Length*	9.5 to 14.5	7.5 to 14.5	6.0 to 14.5	6.0 to 14.5	6.0 to 14.5
Pilot drill Ø 2.0	X	X	X	X	X
Extension drill Ø 2.8	X	X	X	X	X
Extension drill Ø 3.1		X			
Extension drill Ø 3.25		((X))	X	X	X
Extension drill Ø 3.75			((X))	X	X
Extension drill Ø 4.25				((X))	X
Extension drill Ø 4.60					((X))
Crestal drill Ø 3.3		X			
Crestal drill Ø 3.75			X		
Crestal drill Ø 4.25				X	
Crestal drill Ø 4.75					X
Bone tap Ø 3.0	(X)				
Bone tap Ø 3.4		(X)			
Bone tap Ø 4.0			(X)		
Bone tap Ø 4.5				(X)	
Bone tap Ø 5.0					(X)

Legend: *Dimensions are in [mm] (X): optional use according the bone quality
((X)): use in very hard bone

Warning:
- When preparing the cavity, the clinician can react gradually to the different bone classes (D1 – D4).
- (X) In the case of hard and compact bone, the corresponding bone tap should be employed. In this case the taping depth is usually 50 – 70% of the implant length
- ((X)) In the case of very hard and compact bone, the use of the next drill of the colour code should be employed.
- The insertion torque of the implant should not exceed 40 Ncm through flexible preparation with the drilling system, crestal drill and bone tap.

Precaution:
- Preparation with the corresponding crestal drill facilitates the initial positioning and insertion and reduces compression at the crestal emergence of the implant bond.
- Consider the bony crestal anatomy
- Measure the radiograph with care and apply the correct magnification factor
- Use true-size computer tomograph where needed
- Allow a 1 to 2 mm safety zone

Indications for Use

SIC invent drills and cutting instruments are used for preparation of the bone bed for dental implant placement. All drills have laser markings corresponding to the SIC implant lengths. The drills can be used with or without the depth stop.

- SIC Marking Drills: are used for the initial definition of the implant position and for centering of the cortical bone. It can be used as a first pilot drill as well.
- SIC Pilot Drills: are used for the first preparation of the bony bed considering the implant length and axial alignment.
- SIC Extension Drills (short): are used for final preparation of the bony bed according to the planned implant diameter.
  The short version is especially suitable for limited anatomical and intermaxillary space. The short drill has laser markings corresponding to the lengths of the implants and may be used with implant lengths up to 11.5 mm.
- SIC GS Extension Drills/Long: are intended for use in template-guided preparation of the implant site in navigated implant surgery. They have standard length markings analogous to the implant lengths. They also have markings with an additional 10 mm for use in conjunction with guide sleeves fixed into the template and the SIC GS Drill Guide. The SIC GS Extension Drill is suitable for use in template-guided preparation up to an implant length of 11.5 mm. For GS application with implant lengths of 13.0 and 14.5 mm, the SIC GS Extension Drills, long must be used.
- SIC Crestal Drills: are used for final preparation of the implant drill hole in the crestal region. They are used at different depths depending on the bone quality. The drill head is fully inserted with D1 and D2 bone quality and to the first laser marking with D3 and D4 bone quality.
- SIC GS Countersinks: are used for final preparation of the implant site in the crestal region centered by the guide sleeve in the template.
- SIC Bone Taps/GS: are used to cut the threads to the bony bed for bone of D1/D2 quality. The GS-Version is used via the shank end into the drill key with "TAP" printed on the side and locked into the contra-angle. During insertion into the guide template, the tip of the bone tap is centered in the bone cavity and the guide sleeve in the template.
- SIC Reamers: are used with SICace 6.0 mm short implants as final drill and replace the last Extension Drill, Crestal Drill and Bone Tap.
- SIC Explantation Trepan Drills: are used when an implant must be explanted.

Recommended drill/milling speeds
Since thermal injury may impede or prevent healing, increases in temperature should be kept as low as possible by the following measures:
- Ø 2.0 mm <800 rpm, Ø 3.1 mm <600 rpm, Ø 4.25 mm <500 rpm, bone tap max. 35 rpm
- Intermittent drilling technique with as little pressure as possible, with the exception of the last drilling
- Sharp drills / burs / cutters (the instrument should be replaced after 20 drilling procedures)
- Abundant external cooling of the tool by chilled sterile saline (NaCl) or Ringer solution

Warning: SIC drills and cutters may only be used for medical/dental procedures with the SIC Implant Systems. They must only be used for the intended indications, 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.

Target Population

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

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.

Warning: Improper handling and/or misuse may result in a premature wear. All parts of broken instruments must be retrieved immediately following breakage. If ingested broken instrument parts cannot be retrieved, the patient should be referred for a medical opinion.

℞ Only Precaution: Federal law restricts this device to sale by or on the order of a licensed Healthcare practitioner.

Contraindications

Do not use the devices if one or more below reported conditions are present:
- Proven hypersensitivity to one of the metals in the alloy
- Contact with both central circulatory system and central nervous system.

Warning: Patients identified as at-risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments. Therefore, devices that have been in use or suspected of use in patients with CJD after surgery must be disposed of according to current national recommendations.

Warnings, Precautions and Side-Effects

Warnings, precautions and side-effects are listed and preceded by symbol ⚠ . Specific warnings, precautions and side-effects are addressed under the appropriate chapter. All the others are listed below:

Warning:
Over penetration might cause the drill drop into neurovascular bundle with consequent nerve and vascular injuries (haemorrhage)
Precaution:
- Non-observance of the contraindications, warnings, precautions and side-effects can lead to injuries of the patient.
- Prior to each procedure, it must be ensured that all necessary components, instruments and materials are available in the required quantities. The following precautions are to be met prior to or during treatment:
  - By using any instrument intraorally, always secure against aspiration or swallowing
  - Position the patient such that the danger of aspiration of components is minimized.
  - If the laser markings are illegible, the device must be replaced
  - Always inspect instruments before use and assure that the instruments are properly assembled
  - Do not use damaged or blunt instruments

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.
- Thermal necrosis due to instruments friction or overheat or compression caused by the implant
- Mechanical injury to alveolar bone
- Pain

Delivery Conditions

NON STERILE SIC invent drills and cutters are delivered non-sterile and have to be cleaned and sterilized prior to first and any subsequent intra oral use. This also applies for first-time use after delivery, as well as for single-use devices that are delivered non-sterile and have to be sterilized prior to use.

SIC Sleeves for Guided Surgery and the SIC HSS Drills are single use items! Do not reuse.

Cleaning and Disinfection Procedures

Immediately after use, the SIC drills and cutters must be fully disassembled, placed in cold water (room temperature) or disinfection solution, avoid any drying on of blood, tissue or any other secretion. For manual cleaning, rinse the instrument under cold tap water until all visible soiling is removed. Firmly adhering soiling should be removed with a soft brush. After disinfection and drying, reassemble the instrument(s) and pack them each in a suitable sterilization paper.

Precaution:
- Cleaning procedures must begin within 1 hour from surgical application
- Do not use warm water or detergent as this may lead to fixation of the residues on the product, which can affect the outcome of the subsequent cleaning step
- By using machined cleaning and disinfection, avoid direct contact of the instruments to each other
- For stainless steel instruments, always use solvents especially designed for this material
- 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
- Do not mix steel instruments and stainless steel instruments on any cleaning, disinfection and sterilization process

- 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 soiling is removed. Firmly adhering 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:

SIC drills and cutters are delivered in a non-sterile condition and must be cleaned, disinfected, and sterilized before the initial and each subsequent use. Before sterilization, the original packaging should be removed and the devices should be single-wrapped 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.

Warning:
- Do not sterilize corroded or rusty instruments.
- Check instruments for corrosion after sterilization.

Precaution:
- Do not apply temperatures on stainless steel instruments above 135°C on any operation.
- Do not mix steel instruments and stainless steel instruments on any cleaning, disinfection and sterilization process!

Life Span

SIC invent drills and cutters are generally intended for multiple uses unless otherwise stated on the label. The reprocessing cycles have been validated up to 20 times.

Storage

The SIC invent drills and cutters must be stored dry in an SIC invent surgical tray or in the original packaging at room temperature, clean and dust-free place, protected from damage.

SIC invent drills and cutters must be stored in a dry place.

Precaution: Before every use, the device has to be carefully checked for proper function and damages. In addition to these instructions, please observe the legal regulations valid in your country as well as the hygiene regulations of the dental practice or of the hospital.

Disposal

The products are to be disposed of according to the local laws and regulations.

Symbol

- Manufacturer
- REF Catalogue Number
- LOT Batch Code
- Consult the Instruction for Use
- Caution, consult accompanying documents
- ℞ Only Federal law restricts this device to sale by or on the order of a licensed Healthcare practitioner
- NON STERILE Non-Sterile
- Do not Reuse
- Keep dry

CE 0297

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