SGS Dental
Swiss Implant System

US EDITION

INSTRUCTIONS FOR USE

Healing Caps

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About this edition. This US edition adds this cover page for customers in the United States. The 5 pages that follow are the manufacturer's Instructions for Use, reproduced unchanged. Follow them for all clinical steps, torque values, cleaning and sterilization. Dates inside the manufacturer's pages are written year.month.day (for example, 2025.08.13 is 08/13/2025).

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REPORTING A PROBLEM

In the United States, report any serious incident, adverse event or device problem to SGS Dental East Coast at 212-754-6555 or Support@sgseast.com. You can also report it to the FDA through MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

MANUFACTURER

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USING THIS DOCUMENT

Read the full Instructions for Use before use. Keep this document for reference. For the latest version, contact SGS Dental East Coast.

Rx only. U.S. federal law restricts this device to sale by or on the order of a dental professional.

Healing caps



Important – Disclaimer of Liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of S.G.S. International Kft. Non-recommended use of products made by third parties in conjunction with S.G.S. International products will void any warranty or other obligation, express or implied, of S.G.S. International. The user of S.G.S. International products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. S.G.S. international disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of S.G.S. International products. The user is also obliged to study the latest developments in regard to this S.G.S. International product and its applications regularly. In cases of doubt, the user has to contact S.G.S. International. Since the utilization of this product is under the control of the user, they are his/her responsibility. S.G.S. International does not assume any liability whatsoever for damage arising thereof.

Product Description

Healing caps are premanufactured dental implant caps which can be directly connected to the endosseous dental implant to support healing of the surrounding soft tissue.

Healing caps H-3.75, HN-3.75, HW-3.75, HW7-3.75, HW8-3.75 and HA-3.75 are available with an Internal hexagonal connection and are suitable for all implant diameters.

Healing caps HD, HND, HWD, HW7D, HW8D are available with Conical connection and are suitable for all implant diameters.

Healing caps HN-2.1, HWN-2.1, HNN-2.1 are available with a Narrow Conical connection.

Healing caps HW-3.75, HW7-3.75, HW8-3.75, HWD, HW7D, HW8D and HWN feature a wide platform, while HN-3.75, HND-2.1 and HNN-2.1 feature a narrow platform.

Healing caps HA-3.75 are Anatomic Healing caps, which help to support the shaping of the surrounding soft tissue to resemble the natural tooth contour during healing.

The healing caps are available in multiple sizes. For a complete overview of the available sizes, please refer to Table 1.

Table 1. Product range

Connection type	Product code	Diameter	Lengths
Hexagonal	H – 1 mm	Ø 4.7 mm	1 mm
	H-3.75	Ø 4.7 mm	2mm; 3mm; 4mm; 5mm; 6mm
	HW-3.75	Ø 5.8 mm	3mm; 5mm
	HW7-3.75	Ø 7.0 mm	3mm; 5mm
	HW8-3.75	Ø 8.0 mm	3mm; 5mm
	HN-3.75	Ø 3.8 mm	2mm; 3mm; 4mm
	HA-3.75	Ø 5.1 mm	3mm; 4mm; 5mm; 6mm
Conical	HD	Ø 4.7 mm	2mm; 3mm; 4mm; 5mm; 6mm
	HWD	Ø 5.8 mm	3mm; 5mm
	HW7D	Ø 7.0 mm	3mm; 5mm
	HW8D	Ø 8.0 mm	3mm; 5mm
	HND	Ø 3.8 mm	2mm; 3mm; 4mm
Narrow	HN-2.1	Ø 4.5 mm	2mm; 3mm; 4mm
	HWN-2.1	Ø 5.0 mm	2mm; 4mm
	HNN-2.1	Ø 4.0 mm	2mm; 4mm

Materials:

Healing Caps: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium).

Intended Purpose / Intended Use

Intended to be temporarily connected to an endosseous dental implant to support healing/forming of the surrounding soft tissue.

Indications

Healing caps are indicated for use with endosseous dental implants in the maxilla or mandible for supporting single tooth to full arch denture procedures.

Contraindications

It is contraindicated to use healing caps in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V

Intended Users and Patient Groups

Healing caps are to be used by dental health care professionals.

Healing caps are to be used in patients subject to dental implant treatment.

Clinical benefits

Healing caps are a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Residual risks and Undesirable side-effects

Residual risk: The evidence of safety of dental implants and its accessories and their contribution to the well-being of the patient - functionally, aesthetically and psychologically - is clear. The predictability of success is evidently high, and the set goals can be achieved in over 95% of cases. Risks are extremely low; no severe systematic problems are at risk and the majority of severe localized problems are transitory. The summary of benefits compared to the risk indicates a very high ratio of predictable success and patient satisfaction compared to the possible risks. Nevertheless, good professional education and patient selection is indispensable for maintaining low risk, and patient cooperation is also essential for good long term-prognosis of treatment.

Undesirable Side Effects:

The placement of these devices is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. During the placement or removal the pharyngeal reflex (gag reflex) may be triggered in patients with a sensitive gag reflex.

Healing caps are part of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as retained cement, calculus, mucositis, ulcera, soft tissue hyperplasia, soft and/or hard tissue recessions. Some patients may experience discoloration in the mucosal area such as graying.

Where required per the European Medical Device Regulation (MDR; EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) is available for the Healing caps. The SSCP can be obtained at the following website:

https://ec.europa.eu/tools/eudamed 1

Notice regarding serious incidents: For a patient / user / third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

https://sgs-dental.com/contact-us/

Performance Requirements and Limitations

To achieve the desired performance, healing caps must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible S.G.S. International products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with healing caps, check the color coding, dimensions, lengths and connection type. For further information regarding compatibility please refer to Annex I of this Instructions for Use.

Performance characteristics of the device

The healing cap is designed for temporary use during the soft tissue healing/forming phase and must be compatible with the corresponding implant's connection type to ensure a precise fit. It is recommended to be placed using low torque (typically 10–15 N·cm).

Recommended use

Use procedure for Healing Caps:

1.Select appropriate Healing Cap and check occlusal clearance

2.Connect the Healing Cap to implant and hand-tighten using dedicated drivers

See Annex I for compatibility.

Warning: Do not exceed the recommended insertion torques. Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury. Besides the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid damage to nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Caution: One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure. Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants. Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment. It is strongly recommended that S.G.S. implants are used only with dedicated S.G.S. surgical instruments and prosthetic components, as combining components that are not dimensioned for correct mating can lead to mechanical instrumental failure, damage to tissue or unsatisfactory esthetic results. It is strongly recommend that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. S.G.S. International offers a wide range of courses for various levels of knowledge and experience. For more information please visit https://sgs-dental.com/

Before Surgery: Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient. Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy. In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered. With respect to pediatric patients, routine treatment is not recommended until the end of the jaw bone growth phase has been properly documented.

At surgery: All instruments and tooling used during procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components. Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. S.G.S. implants may be tilted up to 45° relative to the occlusal plane. When used with angulations between 30° and 45°, the following applies: The tilted implant must be splinted; a minimum of 4 implants must be used when supporting a fixed prosthesis in a fully edentulous arch.

After the implant installation, the surgeon's evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

Surgical procedure: The company will only take responsibility for the product if the surgeon follows the drilling protocol (See. DR-1101-1) provided and implantation protocol (IMP-1101-1) by the company.

After surgery: To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Facilities and training

It is strongly recommended that both professionals experienced in the application of S.G.S. International products and those who are not familiar with them undergo specialized training before using any new product. S.G.S. International offers a variety of courses tailored to professionals with different levels of knowledge and expertise. Furthermore, all users must possess the necessary basic medical/professional qualifications. It is always the responsibility of the user to ensure that the procedure is carried out in a licensed facility that complies with the regulations in force in the respective country.

Sterility and Reusability Information

Caution: S.G.S. Prosthetic devices are delivered non-sterile and are intended for single use only. Prior to use clean and sterilize the products following the applicable procedure in this Instructions for Use.

Warning: Use of non-sterile device may lead to infection of tissues or infection diseases.

Caution: Healing caps are single use products and must not be reprocessed. Reprocessing could cause loss of machanical, chemical and / or biological characteristics. Reuse could cause local or systemic infection.

Warning: Do not use device if the packaging has been damaged or previously opened as the device's integrity may be compromised.

Sterilisation

Each device must be individually sealed in a sterilization pouch and sterilized.

Note: The devices have been validated to withstand these cleaning and sterilization procedures.

1. Do not assemble multi-piece devices before sterilization.
2. Seal each device in a suitable sterilization pouch.
3. Label the sterilization pouch with the information necessary to identify the device (e.g. the product name with article number and lot/batch number (if applicable)).
4. Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.
5. Sterilize the device using the following recommended parameters (Table 2).

Table 2 Recommended parameters for sterilisation

Temperature	121 °C
Duration	20 minutes
Vacuum cycles	3

Note: Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance to EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Caution: After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place.

Compatibility

Each S.G.S. International dental system has corresponding connection types, parts, and instruments. For proper use of the corresponding parts and instruments, please refer to the Compatibility Table in Annex I of this Instruction for Use.

Magnetic Resonance (MR) Safety Information:

If there is no MR Safety symbol on the product label, the device has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR.

Selection of the appropriate device

The selection of the appropriate size/type is always the responsibility of the attending physician after they have performed or received the preliminary condition assessment data

Disposal:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Storage, Handling and Transportation:

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure. Recommended storage/transportation conditions 0-50ºC/32-122ºF. Federal law restricts this device to sale by or on the order of a dentist or other licensed healthcare practitioner.

Information to be provided to the patient:

Information on contraindications, warnings, precautions, side effects and complications with S.G.S. devices should be provided to the patient.

Manufacturer

S.G.S. International Kft.
Budapest, Károlyi István u. 1-3, 1047

Symbols Glossary:

LOT	Batch code
MD	Medical device
	Manufacturer
UDI	Unique Device Identifier
	Do not re-use
	Do not resterilize
	Caution
	Date of manufacture
#	Model number
℞ Only	U.S. federal law restricts this device to sale by or on the order of a dental professional.
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight
	Temperature limit
CE 1011	CE Marking (Class IIb)

Annex I Compatibility Table for S.G.S. International Healing Caps

Connection type	Healing caps	Implants
Hexagonal	H – 1 mm H-3.75 HW-3.75 HW7-3.75 HW8-3.75 HN-3.75 HA-3.75	P1 P7
Conical	H – 1 mm HD HWD HW7D HW8D HND	P1D P7D P5D P5G
Narrow	HN-2.1 HWN-2.1 HNN-2.1	P7N