SURGICAL AND PROSTHETIC PROCEDURES

Surgical procedures

Disclaimer

- The selling of S1 Implants, components and instruments are exclusively intended for professionals experienced in dental implant techniques.
- We suggest attending specific courses in order to reach a high level of knowledge and practice in the use of implants.
- We suggest reading carefully the following manual, for a good comprehension of surgical procedures with S1 implant system.
- It is necessary to pay close attention during the surgical procedure to anatomical structures (inferior alveolar nerve, mental nerve, maxillary sinus, and paranasal sinuses) to avoid potential lesions.

Indications

S1 Implant are indicated in the treatment of the following conditions:
• Single-tooth edentulism, partial edentulism, total edentulism
• Two-stage surgical procedures
• Immediate loading

1 - SITE PREPARATION

Flapless Tecnique

This technique can be performed when working on “safe” sites, or previous specific radiographic exam (CT Scan) thus allowing for an accurate evaluation of bone morphology and, sometimes, bone density to confirm correct and safe positioning.

Flap Technique

This technique is used because it allows greater visibility of the operative field and easier management of possible intra-operative complications.
It is especially shown in surgeries “at risk”, where the proximity of anatomical structures such as sinuses, paranasal sinuses and inferior alveolar nerve may be critical, or in cases of insufficient bone quantity in both height and thickness.

2 - FIXTURE SELECTION

S1 dental implants are available in the following dimensions:

fixture **Ø 3,25**	**L 10**	**L 12**	**L 15**
fixture **Ø 4**	**L 10**	**L 12**	**L 15**
fixture **Ø 5**	**L 10**	**L 12**	**L 15**

to select the suitable size for the different cases, follow these steps:

Amount of vertical bone available

Assessing bone quantity available through clinical trials (inspection of edentulous areas or bone crest in the area to be implanted and palpation of site) and radiographic (OPT for an overview and TC Dentascan to evaluate bone thickness); in case of insufficient thickness and/or bone height, it will be possible to provide for a graft before the implant procedure, using the techniques of autologous bone or bone graft homologous. The cylinders S1 for surgical templates are radiopaque, therefore it is advisable to use during the X-ray examinations, for pre-clinical evaluations.

Bone thickness

In order to achieve optimal recovery, it is recommended to maintain a bone thickness of at least 1.5 mm vestibular and palatal/lingual around the implant.

Bone Quality

The bone quality must be taken into account, because a more cortical bone, as the mandibular, offers a major primary stability compared to a more spongy bone like the maxillary especially in the tuberous area, where compensation due to lower primary stability may be needed, improving the contact area between implant and bone. To recognize the patient's bone quality it is recommended to perform a through examination and 3 D Cat Scan to guarantee a successful placement

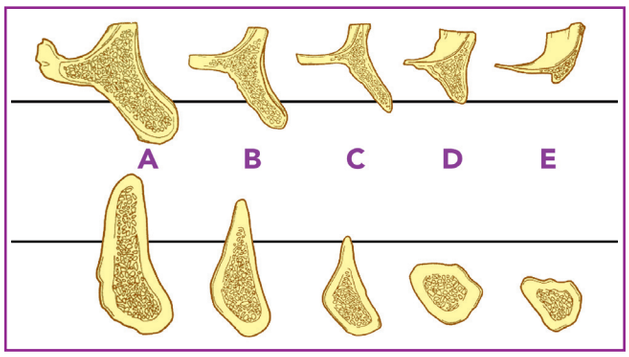
Anamnesis and Objective examination of the patient

Follow the normal procedures to exclude pre-existing contraindications to surgery.

CLASSIFICATION OF BONE MORPHOLOGY Lekholm U. & Zarb G.A.
["Patient selection and preparation" – 1985]

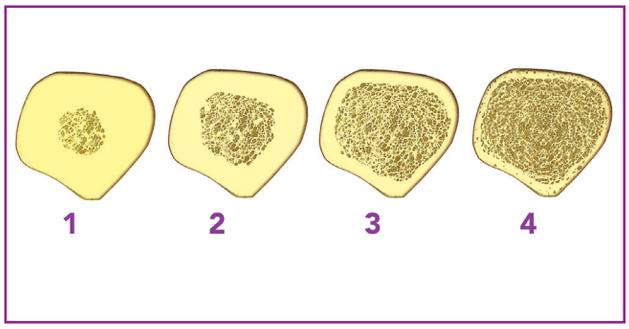
Classification of residual bone morphology, cross section of 5 groups

- **A** Post Extraction Alveoli;
- **B** Bone with enough width and height to accept an implant;
- **C** Acceptable height but unacceptable width (Knife blade crest);
- **D** Bone with unacceptable height and width:
- **E** Alveolar bone total resorbed, only Basal bone is left;



Classification of maxillary bone quality in 4 groups

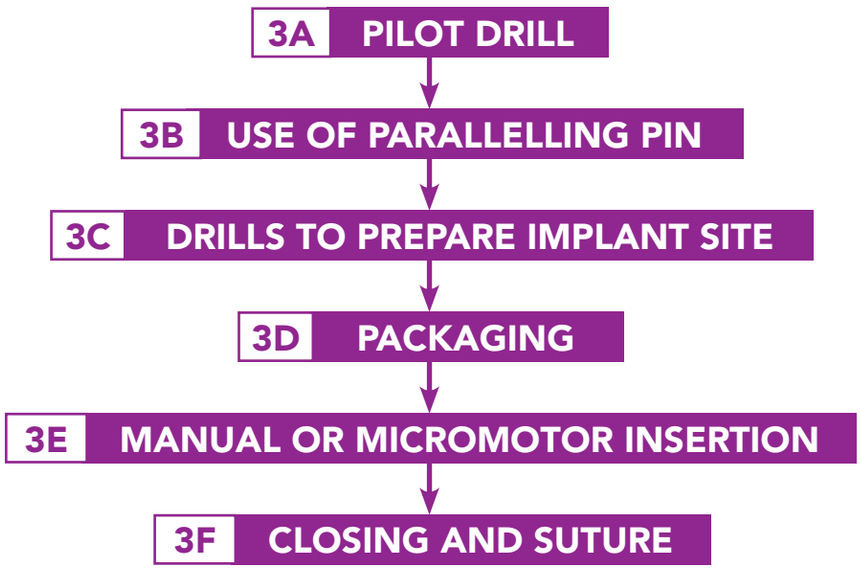
- **D1** Dense Cortical Bone.
- **D2** Dense cortical bone and wide internal reticular formation;
- **D3** Thin cortical bone crest and fine internal reticular formation;
- **D4** Thin reticular formation occupies the entire area.



2 - CLEANING AND STERILIZATION

Cleaning and sterilization procedures have the purpose of safeguards the health of patients and of all operators working in study and laboratory.
Cleaning: practicable manually with warm water and an apposite neutral non-corrosive detergent, using plastic or nylon brushes (never steel wool or metal brushes) to remove eventual residues. Hand washing is efficacious if performed with maximal care. Cleaning can be carried more quickly and safely with ultrasonic tanks, totally immersing the devices in washing liquids and e accorded to the times recommended by the manufacturer. Replace the wash solution to the time limits recommended by the manufacturer. After ultrasonic cleaning rinse thoroughly to remove the wash solution. Immediately after rinsing, before the sterilization, inspect and dry.
Sterilization: Sterilization does not replace the cleaning, but is a process that kills all microorganisms and should be undertaken with great care after cleaning. The most common methods of sterilization are: autoclave, chemical vapor, dry heat sterilization. For the specific methods, always follow the manufacturer's equipment suitable for the procedure.

3 - INSERTION OF IMPLANT



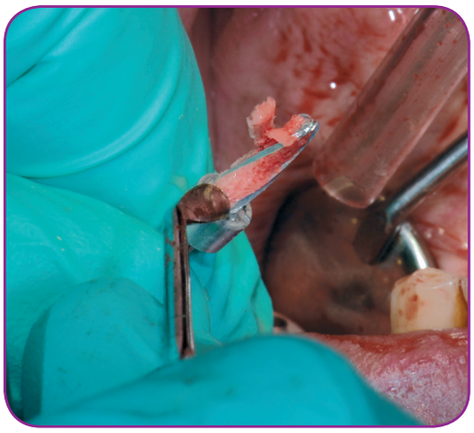
3A - **pilot drill:** use the pilot drill to mark cortical surface of the bone, thus simplifying subsequent drill's passage. The shape of S1 pilot drill allows for easy insertion into very narrow crestal areas. We recommend the use of surgical cylinders for templates S1, for a control of the axis of insertion. The 3 mm diameter cylinder S1 fits perfectly with the final diameter of the pilot drill (equal to 2.9 mm). Therefore, if the drill touches the cylinder before it is fully inserted, it will be necessary to fix the axis of insertion.

3B - **use of parallelling pins:** use the pin to control the correct parallelism. If objectionable proceed to correct the parallelism.

3C - **drills to prepare implant site:** choose the drill diameter 3.25mm -already equipped with stop, which borders both the depth and the diameter of the site, including the different lengths: 10 mm, 12 mm and 15 mm, depending on the desired preparation.

Seen the characteristic of S1 to be a self-screwing implant, we suggest the following steps of drills:

Impianto	h 10	h 12	h 15
Ø 3,25	3.25x10 **cod.054.01**	3.25x12 **cod. 054.02**	3.25x12 **cod. 054.03**
Ø 4	3.25x10 **cod.054.01** 4x10 **cod. 053.01**	3.25x12 **cod. 054.02** 4x12 **cod. 053.02**	3.25x15 **cod. 054.03** 4x15 **cod. 053.03**
Ø 5	3.25x10 **cod.054.01** 4x10 **cod. 053.01** 5x10 **cod. 055.01**	3.25x12 **cod. 054.02** 4x12 **cod. 053.02** 5x12 **cod. 055.02**	3.25x15 **cod. 054.03** 4x15 **cod. 053.03** 5x15 **cod. 055.03**



Insert the drill on a handpiece for implantology, at max speed 400 rpm, torque between 10 and 30 n/cm2 (depending on bone quality).
Apply a to-and-fro movement, to allow the release of bone residues during treatment, with adequate irrigation with cooled bi distilled solution.
To prepare sites for 4 and 5 mm diameter, follow the same procedures and, in progressive sequence, use drills until the necessary diameter and length have been reached.

Please note that it is not necessary measure with other instruments the height of the prepared site, seen that S1 drills are already equipped with stops.

3D - packaging: every implant is packed: in a sterile container which comprehends blister, instructions of use, additional sticker. Push out the implant of the blister with a slight pressure, withdraw it of the box with the driver rachet or handpiece ratchet key and place immediately into the prepared site. Avoid any contact with any non-sterile object.

3E - seating the implant manually or with handpiece

• Manual seating
Extraction of the implant from the blister by means of the driver rachet. Screw the implant in the prepared site using the rachet. Do not apply excessive torque during the screwing.

• Handpiece seating
Mount the tool for handpiece into handpiece, engage with the internal geometrical figure of the implant applying light pressure.
Initial seating of the implant into the implant site without irrigation. Max torque 30 n/cm2. Should the rachet wrench be utilized for latest loops.

3F - closing and suture: completed the surgical procedure, screw the closing screw contained into the blister and proceed with suture.
In the case of semi-submerged implant placement, use the healing screw of height 1 mm or 3 mm, depending on case and proceed to the suture.

Overdenture implant and Miniscrew for provvisional

In case of insertion of S1 Overdenture Implants or S1Miniscrews for Provisional, it is recommended to follow the instruction 4a and 4b in the paragraph of implant seating.
Overdenture Implants and Miniscrews for Provisional are intended to improve total removable dentures retention, but from biomechanical point of view can not and should not bear all the functional stress.
To lighten the load at most, the prosthesis should be given according to the concepts of removable dentures, respecting the criteria for support and stabilization.
S1 Overdenture Implant uses replacement retention caps. Sphere diameter 1,8 mm.

4 - FINALIZATION

With S1 System, immediate loadings are possible, through one or two phases. Indications on choice of the methods, are widely documented in the literature.
For any advice, please contact Safe & Simple customer service.

5 - TAKING IMPRESSION

Position the straight abutment/transfer on implants, taking care of the right connection of geometrical figures. S1 is suitable for all the usual techniques of Impression.
Take the impression and send it to the laboratory for the development.

6 - PROSTHESIC CONNECTION

S1 Implant has a tapered connection with geometric design having four square and smooth corners.
Position the abutment into fixture, to let the two figures coincide, then lock them through the passing screw until it stops. S1 prosthetic connection is designed with Platform Switching, approved technique that promotes the formation and regeneration of tissue between The emergence profile of the implant and the abutment, avoiding bacteria infiltration and consequent inflammatory reactions reducing cervical bone resorption. Do not exceed 20N.
It is important to understand that the conical design of the implant and abutment connection offers a great stability, the screw simply works as a stabilizing device and not as a retentive one.
In case of necessity: whenever necessary to extract abutment from fixture for further verification, S1 methodic is equipped with extractor.

7 - POST-SURGICAL MANTEINANCE

Post-surgical maintenance is an important phase of S1 treatment and has to be considered as integrative part of all surgical therapy.
It is important in order to obtain the health of alveolar bone around the fixture, and also of the peri-implant complex, formed by soft tissues and designed prosthetic manufactured.
As for the periodontium around the natural tooth, also for the peri-implant periodontium tissue, it is fundamental the oral hygiene and the compliance of patient to the daily operations of proper clearing.
Accumulation of plaque in peri-implant tissue, in fact, determines an inflammatory state na-

med "peri-implantitis" that, similarly to periodontitis of the supporting tissue around the natural tooth, and it can conduct to the failure of implant therapy.
Patient's oral hygiene assumes a fundamental rule for the peri-implant bone stability and for the long-term implant endurance.
It is necessary that the patient is adequately informed and motivated to the correct maneuvers of oral hygiene to be executed. For this reason we suggest a post-surgical follow-up of almost 6 months, to evaluate patient's compliance.
It is necessary also contemplate sufficient spaces on "mucosis-prosthesic manufactured" interface, to facilitate oral hygiene to the patient.

Operational phases of the protocol maintenance
Hygiene home care instructions for the patient: the patient has to be carefully instructed of appropriate oral hygiene procedures especially around the implant. Pads revealing plaque motivate the patient to a major cleaning of implant site; removal of plaque with medium-bristle toothbrush using normal brushing techniques; use dental floss in proximity of prosthesic-implant margins and underpontic areas of prosthesis; use of interdental brushes suitable for the spaces; chlorhexidine mouthwash concentration 0,2% thanks to its bactericidal and bacteriostatic action, when necessary.

Phase of monthly follow-up: control of surgical site and evaluation of plaque index, bleeding index and probing depth. A high index of plaque shows a bad cleansing by the patient who has to be called to shorter time intervals, for the professional hygiene maneuvres and for a major motivation to a more careful and meticulous oral hygiene. A high bleeding index denotes a peri-implant inflammatory state.
We therefore recommend a professional hygienic cleaning, followed by treatment with chlorhexidine mouthwash concentration of 0.2% for 7 days and a major motivation on oral hygiene; in case of a generalized gingival inflammation, besides professional hygienic cleaning, it is opportune the systemic administration of rovamicina (3mln UI, 1 tablet each 12 hours for 5 days).

Phase of radiographic follow-up: 6 months after implant setting, a periapical radiography highlights the state of bone health around the fixture, allowing an evaluation for successful osseointegration. A radio-transparent halo around the implant denotes the non-osseointegration and the fixture has to be removed. The lack of osseointegration, however rare, is often to be attributed to poor oral hygiene, with often important accumulations of plaque, and consequent bacterial peri-implantitis. In these patients it is not recommended to repeat the surgical procedure of implant insertion, until patient hygene's habits have been corrected.

Prosthetic Procedures

S1 prosthetic components offer optimal solutions to answer to the whole casuistry. Base of our designs has been making interchangeable elements of the prosthesis, also ensuring a simplification of the prosthetic part, using the shortest possible time, low financial commitment.
The closure of all S1 abutment uses the principle of SWITCHING-PLATE, affirmed technique that promotes the formation and regeneration of tissues between The emergence profile of the implant and the abutment, avoiding bacteria infiltration and consequent inflammatory reactions, reducing cervical bone resorption.
S1 Components and prosthetic techniques have benefited from the contribution in the design and testing of Mr. Valentino Facciani, technician in Cesenatico (Italy).

Straight Abutment/Transfert

Transfert/ Direct abutment in Titanium 5, suitable for immediate loads and direct abutment where conditions permit. Equipped with geometrical figure as reference.

Universal Abutment

Suitable when big dimensions abutments are requested or angles to compensate different degrees of divergence. In Titanium 5. Easy to mill with burrs for titanium, both manually and with miller. Optimal roughing with abrasive wheel and finish with burrs for titanium.

Casting Abutment

Optimal workability of Plexiglas, dimensions allow the production of all abutments, optimal adhesion wax-Plexiglas, equip with apposite S1pin save-hole. The dimensions of S1 castable abutments permit the compensation of different degrees of divergence and do not need particular procedures in casting. Maximal versatility, adaptable to every height of mucosis, without necessity of transmucosal collars. It doesn't leave residues of casting. To get the internal screw into the abutment, the range offer S1 taps, designed for a perfect adaptation with the extractor. It is recommended the using of rectify drill S1..

Spherical abutments

Titanium 5 screw on fixture, it allows anchor for dentures and uses replaceable retentions caps, sphere measure 1,8 mm.

Aesthetical Abutment

Alumina, designed and manufactured directly by the dental technician according to a manual technique which accomplish aesthetics, ergonomic and biocompatibility.
The aesthetical abutment keeps the advantage of titanium/titanium connection between the implant and the abutment itself, offering at the same time the optimization on all the sectors of the emergence profile and the camouflage effect.

Choise of prosthetic components:

	* Transfert	Universal Abutment	Casting Abutment	Aesthetical Abutment	Spherical abutments
Impianto singolo	X	X	X	X	
Ponte su impianti	X	X	X	X	
Ponte misto su impianti	X	X	X	X	
Toronto	X	X	X		
Overdenture con perni	X	X	X		
Overdenture con barra			X		
Overdenture con sfere					X

** moncone dritto / transfert*

Important:
S1 dental implants are in accordance with directive 93/42/CE.

Warning: Planning of treatment and positioning of dental implants need special considerations than those from general dentistry. We suggest to attend courses of practical application to learn the correct techniques, Biomechanical requirements and radiographic evaluations. Incorrect Techniques of positioning or prosthetic can causes the implant fracture and bone loss around. Please contact Safe&Simple srl to receive training programs.

Technical advice on Safe&Simple products is verbal, written, through electronic media and/or demonstration Technical advices respect the state of science and technique at the moment of the product marketing. Information not constitute the user from the required to personally verify the suitability of the product for its intended use, indications and techniques. The processing and application of the product beyond the control of the manufacturer and fall within the responsibility of the user. It is excluded every responsibility for damage caused by this kind of processing and application.

Read carefully surgical and prosthetic procedures as well as use instructions of every component of S1 system before use. All procedures and indications not specifically mentioned in procedures and instructions of Safe&Simple products are contraindications.

For technical questions, or additional information on product, please contact the manufacturer.

Rev. 3 of 18/06/2010

List of symbols

Ref.	Ref. Product code
Ø mm	Diameter in millimeters
l. mm	Lenght in millimeters
Mat.	Material
LOT	Lot number
	Expired date (YEAR-MONTH)
	Do not reuse
	Read instruction od use
STERILE EO	Steryle. Sterilized with ethylene oxide
CE 0476	

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