The implant system shape1, in order to ensure the use of a smaller number of prosthetic components, while not giving up all solutions, supplies on all its lines bn, b, eh and t, one platform suitable for all the different implant diameters (Platform Switching).
For line s1b and s1bn with hexagonal internal connection a range of prosthetic components has been developed with Friction Fit connection, presenting 1° of taper on the walls of the post hexagon. This connection ensures a “cold weld” between implant and post if the retaining screw is tightened at 35 Ncm. This eliminates micromovements and significantly reduces bacterial infiltrations between implant and post.

The connection between implant and post is present on the entire implant line with the configuration to be finished as shown in figure 1 or classic as in figure 2, depending on the diameter of the flaring required, respectively 3.5 mm or 5 mm. An emergence profile is also available, figure 3, which ensures a more rounded connection without sharp corners, creating a greater space for mucosa anchoring.

This profile which guarantees better conditioning of the soft tissues is contemplated on the whole prosthetic range, from healing screws right up to the final posts.
There is extensive scientific literature* on how surface roughness characteristics influence cell behaviour. Compared to a smooth surface, topographical patterns smaller in size than a fibroblast cell (micro and nano topography) orient the arrangement of the cells and stimulate osteoblastic and platelet activity, accelerating the production of extracellular matrix and bone regeneration, and therefore the osseointegration of the dental implant.

The three fundamentals of surface treatment of dental implants from a biological point of view are:
1) control of surface topography to stimulate cellular response in an osteogenic direction;
2) control of the chemical composition of the surface to promote cell colonisation;
3) control of biological contamination from adherent endotoxins so as not to interfere with the natural inflammatory response.

For the surface treatment a sand-blasting process was used followed by a double acid attack. In the images, increasing the magnification, it can be seen how the macroscopic aspects of the screw (spire, cutting edge) are not affected by the treatment and that the surface is free from processing residue. The dual-beam roughness typical of SLA treatment can be clearly observed, which contains large cavities due to large grit blasting on which is superimposed the microroughness due to treatment with acids. The microroughness illustrated in the figures highlights the typical three-dimensional topography, which gives these surfaces “sponge-like” characteristics that are the basis of their excellent clinical performance. In fact, the very short peak-to-peak distance, about 1 micrometer, stimulates both the activity of osteogenic cells and the capillary penetration of the blood in the surface structure, offering very favourable characteristics to stimulate bone regeneration, as described in many articles on this topic. This unique combination of long-range roughness (large grit sand-blasting) and short-range (acid etching) is a substrate favourable to cell regrowth that adequately promotes cell differentiation. The level of roughness is Ra 1.42 ± 0.12.

After the surface treatment, the implants are cleaned to remove processing residues by washing them with solvents and then subjecting them to a process of surface decontamination with cold plasma (Argon). The partially ionised Argon atoms (inert gas) act as an additional atomic sand-blasting that promotes the removal of organic contaminants and activates the ionisation of surface atoms of titanium, improving the wettability of the implant. The treatment conditions adopted on shape1 implants offer the best characteristics considered important, according to the state of current knowledge*, in the processes of implant healing, both in terms of surface morphology and in terms of chemical composition (surface cleaning). Plasma cleaning, packaging in a controlled environment, the absolute respect of “clean” procedures, quality control tests of during the manufacturing process, play a fundamental role in the control of adherent endotoxins (biological cleaning), the main agent of immunological response to implant surfaces.

* Valutazione del rapporto tra costo e qualità della pulizia superficiale di alcuni sistemi implanta- ti in commercio Marco Morra, Clara Cassinelli, Giavanna Cascardo, Daniele Bollati, Nobil Bio Ricerche srl Via Valcastellana 25, 14037, Portacomaro (AT)


surface treatments proposals on body of shape1 implant system

s1b  
Surface treatment on the whole body implant

s1b c  
Surface treatment on the body implant with 1 mm of machined neck

s1eh  
Surface treatment on the body implant with 0.7 mm of machined neck

s1t  
Surface treatment on the body implant with 2.5 mm of machined neck
To preserve its integrity, the dental implant is housed in a vertical position inside a titanium cylinder anchored, by means of the closing cap, to the respective vial made of borosilicate glass for pharmaceutical use, complying with the European Pharmacopoeia in force. This vial really ensures the neutrality of the primary packaging due to the absence of release of contaminants during the sterilisation phase.

It is inserted in a blister of transparent polyglass sealed with heat-sealing lacquer-based Tyvek and packed in a cardboard box that also contains the instructions for use and the labels for the patient records, on which are printed the data that allow product traceability (code and batch number). All the product packaging materials have been tested, approved and certified.

* European Pharmacopoeia, current edition, 3.2.1 Glass containers for pharmaceutical use.

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**gamma sterilization**

**shape1** implants are supplied sterile, in a pack that allows their stability to be guaranteed for 5 years. The sterilisation process is performed with gamma rays respecting the standards in force by qualified suppliers who use automated, safe and reliable systems, with continuous microbiological monitoring of the process.