P1 29

Profile®1

The Profile1® System is characterised by 4 types of implant:

DeepNeck, P129, P1Mini, P1Evo

P1DN

DeepNeck

The line consists of a series of Biphasic implants that are designed to remedy aesthetic problems owing to reduced gum thickness and/or the excessive inclination of the inserted implants. Such implants are also indispensable when one wants to make an immediate temporary screwed implant.

P129

P129

Designed to have the same features of stability and load as larger implants, all contained in a diameter of just 2.90 mm. With a very simple surgical procedure, it is the ideal implant with which to familiarise yourself safely with the Profile1® family.

P1 mini

P1Mini

The Profile1® Mini line consists of a series of monoblock implants of extremely small diameters (2 mm, 2.4 mm and 2.5 mm) for immediate loading (preferably temporary), which can be used as supports for mobile prostheses.

P1 Evo

P1Evo

A line of standard-sized monoblock implants (from 3.00 mm to 5.00 mm) that has been designed with a "switch platform" type of rising shape. These implants have a prosthetic abutment that can be adjusted, with in situ milling, according to the various aesthetic needs. They can be immediately cemented or used as electro-soldered prostheses.

CE 0123

Surface treatment

The procedure for cleaning the surfaces of the implants is rather delicate. Despite being extremely pure, the detergents utilised can leave traces on the underlying surfaces. It is possible for the few impurities present, or "the molecules of the detergent itself", to combine with the constituents of the surface, above all in the case of reactive materials like metals. Therefore, while the cleaning tool should not be capable of chemically reacting with the device's material, it must nevertheless be effective in eliminating any contaminants that may be present. Plasma of Argon has been found to meet these requirements.

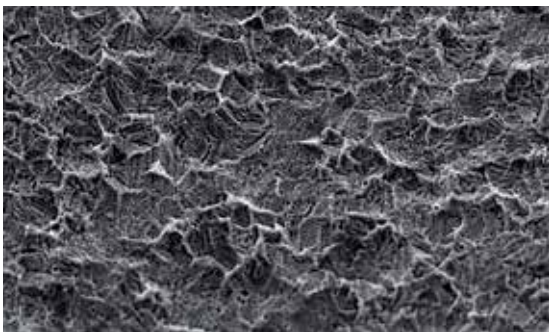
Double acidification

By engaging the services of international researchers with proven experience in implant surface treatment processes, Profile1® has developed a unique treatment that is capable of obtaining a surface with a controlled morphology.

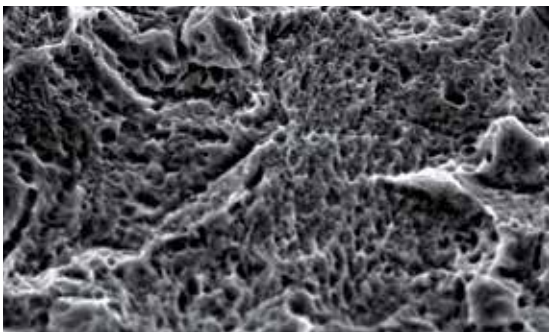
This treatment requires the use of a special apparatus for shot blasting the implant surface with alumina oxide.

At the end of this process, the implants are inspected in order to verify the uniformity of the treatment, and are subsequently subjected to acidification (double acid etching) in order to perfectly clean the implant surface.

This subtraction treatment is designed to obtain an implant surface with a controlled micro-roughness that favours the initial cell anchorage of the osteoblasts and the subsequent integration with the bone tissue, thus decreasing the osseointegration time.



Magnification images 600x 20µm



Magnification images 2400x 5µm

The plasma of argon treatment

Plasma of Argon has been identified as the ideal cleaning tool, since it does not chemically react with the device's material, but is nevertheless extremely effective in eliminating the contaminants present on the implant's surfaces.

In particular, the Argon gas is introduced into a reactor located in a class ISO6 clean room in order to avoid any possible environmental pollution, and is subsequently transformed into plasma. This consists of heavy gas ions, which are bombarded onto the surface of the implant, and the cleaning effect is obtained from the impact energy of its particles with any organic contaminants present. This allows for any contact with solvents to be avoided.

In order to verify the effectiveness of the process, advanced analysis techniques specifically designed for the surfaces of implant screws are utilised. In particular, an X-ray photoelectron spectroscopy (XPS or ESCA) is carried out, which is especially suitable for rough surfaces.

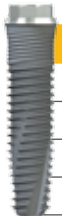
This type of analysis provides information about the qualitative and quantitative chemical composition of the surface material's initial nanometres, or rather the layers that come into the most direct contact with the bone tissue.

Surface topography evaluation of Profile1® implants using the “BioActive” technique

The purpose of this job was to evaluate the surface morphology obtained following the treatment of Profile1® implants using a double acid treatment process.

Materials and methods

The surface morphology of the Profile1® implants was assessed using a scanning electron microscope (SEM). The quantitative evaluation of the roughness was performed using a roughness gauge equipped with data processing software that allows the conventional SEM image to be transformed into a three-dimensional image.



code	Ø (mm)	L (mm)
P1RT30080	2.9	8
P1RT30100	2.9	10
P1RT30120	2.9	12
P1RT30140	2.9	14

TEMPORARY ABUTMENT MOUNTER

P1M29

SURGICAL SCREWS

P1HA29

HEALING SCREWS

P1HA29-30
H 3.0 mm

P1HA29-45
H 4.5 mm

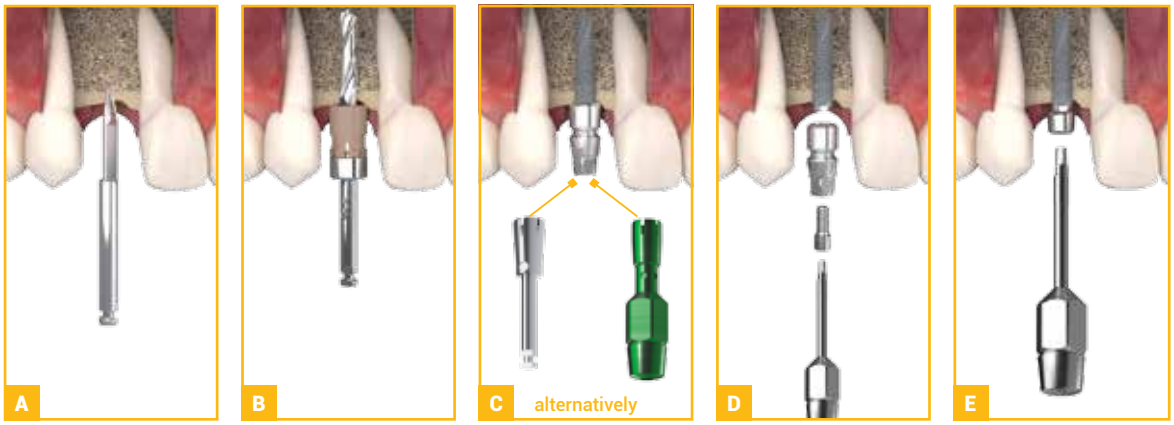
Designed with the aim of fulfilling, with its extremely reduced diameter, all prosthetic requirements in total safety and with the same level of reliability as larger implants. To obtain this level of performance, we have produced **P129** with a grade 5 titanium alloy which is significantly more resistant than the grade 4 titanium usually used in the production of dental implants. We have also created the prosthetic connection on the exterior, an octagonal element that will not weaken the inner core.

The **P129 implant** is equipped with a mounter screwed in with through screws. This mounter that supports the implant, is inserted by friction in the in Peek container, inside the sterile package. This assembly Device, produced in grade 5 titanium, can also be used as a re-positionable twist transfer and as a prosthetic abutment.

The prosthetic components making up this product, which can truly be defined as a Mini-System, are able to resolve most of the implant projects, both fixed and mobile. As well as the temporary abutment/mounter (included in the pack), there are castable elements for rotating parts and for mono-implants, a pre-angled abutment (that can be milled) for disparallelism from 10° to 30°, Donut® connections with metallic matrices and caps with different hardnesses. The peculiarity of all these components is their implant-supporting geometry, conometric to 40° to improve stability and prevent unscrewing.

The extremely simple surgical protocol, as well as the use of a rounger (first surgical step), also foresees the use of a single calibrated cutter, while the use of a tapper is not required. Screwing can be carried out using either a dental implant wrench or dynamometric ratchet wrench (calibrated between 35 and 50 Ncm).

Surgical protocol



A. After opening the surgical flap, proceed with the incision of the cortex using the dedicated bur (Code P1OSD).
B. In order to **perforate the bone tissue**, a single calibrated bur equipped (Code P1PD) with a depth stop is utilised, which can be found in the surgical kit.
C. After taking the implant out of its housing (Peek Holder) present inside the package, the **P129 is screwed** in using the handpiece wrench (Code P1KC) or torque ratchet (Code P1KMC1). It is recommended to screwing stabilizing the system with a maximum torque of 50 Ncm.
D. After completing the screwing operation at the implant site, release the mounting fixture* using the appropriate tool (Code P1PDSA).
E. **Screw in the surgical closure screw** using the same tool (Code P1PDSA). If a transmucosal use of the P129 is desired, 4.5 mm high healing caps are available, which can be used as an alternative to **the surgical screw included in the package**.

**Spanner fork available upon request (Code P1KM) for mounter removal.*

Surgical KIT

DYNAMOMETRIC RATCHET

P1KWD

BONE DRILL

P1OSD

GUIDING DRILL

P1PD

DYNAMOMETRIC RATCHET WRENCH

P1KMC1

IMPLANT TORQUE WRENCH

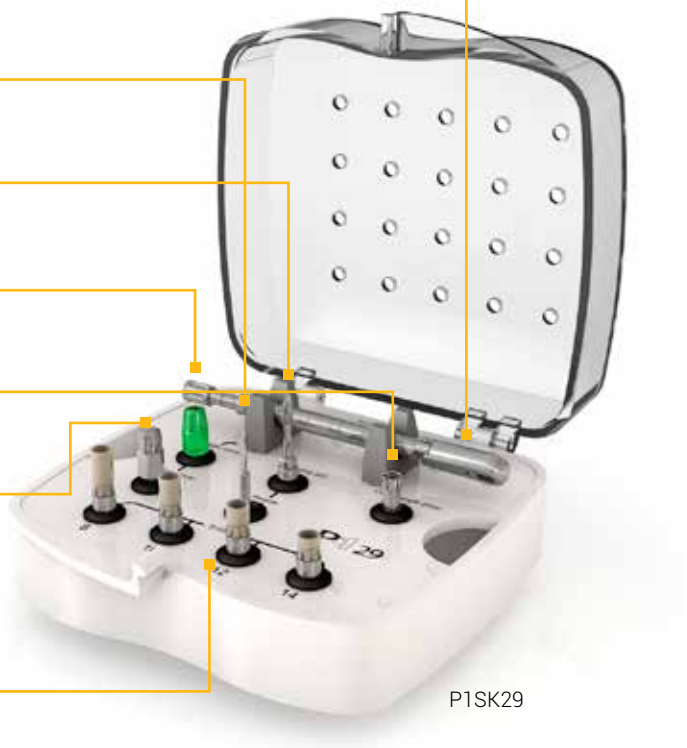
P1KC

SHORT WRENCH

P1CSK1

IN PEEK STOPPER

P1DRST08 P1DRST10 P1DRST12 P1DRST14



Prosthetic components

ANALOGUE DONUT ABUTMENT

P1ANOD29

ABUTMENT FOR MOBILE DONUT

tighten to 25 Ncm with key P1CSK1

P1OD29-15
H 1.5 mm

P1OD29-30
H 3.0 mm

P1OD29-45
H 4.5 mm

METAL MATRIX FOR PLASTIC CAPS

P1CA29T

PLASTIC MATRIX Strong

P1OR29-A

PLASTIC MATRIX Medium

P1OR29-M

PLASTIC MATRIX Soft

P1OR29-B

SHORT THROUGH SCREW

tighten to 25 Ncm with key P1CSK1

P1PS29S

CASTABLE ELEMENT FOR ROTATING PART

P1CPXC29

CASTABLE ELEMENT FOR SINGLE IMPLANT

P1CPXI29

INCLINED MINI-ABUTMENT

P1A29

OPEN TRAY TECHNIQUE

CLOSED TRAY TECHNIQUE

ANALOGUE IMPLANT

P1AN29

TRANSFER

P1TRA29

LONG THROUGH SCREW FOR TRANSFER AND LABORATORY

P1PS29L

TWIST TRANSFER ABUTMENT

P1M29
con vite P1PS29S

TRANSFER CAP

P1M29

Implant passport

The Profile1® Implant Passport is a certify the originality of our implants and prosthetic elements. It is a patient protection tool that is useful for obtaining assistance whenever required, all over the world. After having completed it with the reference codes (REF) and lot numbers (LOT) of the implanted Devices, the Implant Passport should be issued to the patient after surgery in order to allow the devices themselves to be uniquely identified.

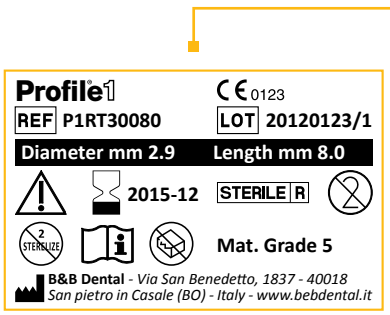
In this manner, if the need should arise, and the patient is unable to contact their dentist, they will nevertheless have access to the information regarding the product and the manufacturer, and will therefore be able to intervene in the most appropriate way.

Packaging and sterilisation

All of the implants, accessories, prostheses and instruments making up the Profile1 system are thoroughly treated with a certified decontamination process and are packed inside a class ISO 6 white chamber. All Profile1 implants are supplied in sterile packaging. The integral packaging protects the implant, sterilised through ionised radiation, from external elements and ensures sterility up to the expiry date cited on the label. The colour change indicator applied to the blister pack signals exposure to rays if it is red.

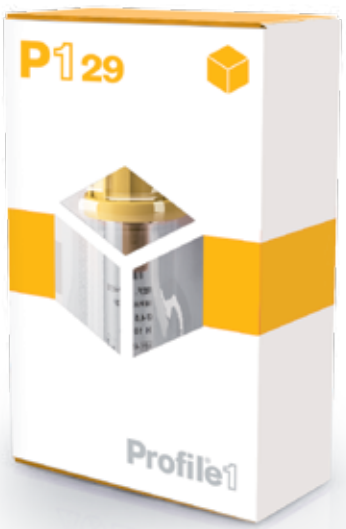
SYMBOL names

LOT	Lot Code
REF	Catalogue Number
	Manufacturer
	Consult the instruction for use
	Non-reusable
STERILE R	Sterilised with ionised radiation
	Do not use if the package is damaged
	Attention
	Use by
2 STERILIZE	Do not resterilise



All Profile1 are electronically managed and can be identified in real time, using a database that ensures the traceability of all phases of the production process through the production lot.

At the end of the operation, we recommend that you note the code and traceability of the implanted Medical Devices on the implant passport.



Note

Profile®1

Profile1 è un marchio di:
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