P1 mini

Profile® 1

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

DeepNeck, P129, P1Mini, P1Evo

P1 DN

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.

P1 29

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.

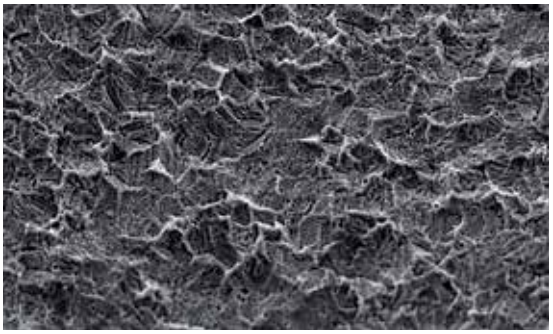
Double acidification

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.

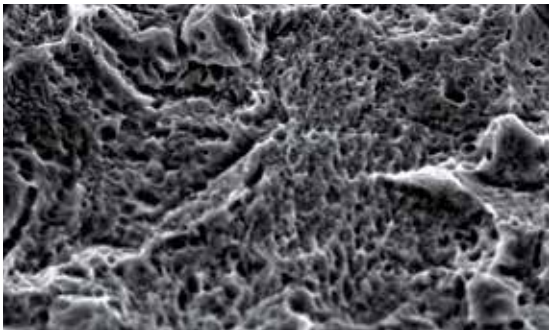
This treatment requires the use of a special apparatus for shot blasting the implant surface with alumina oxide.

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.

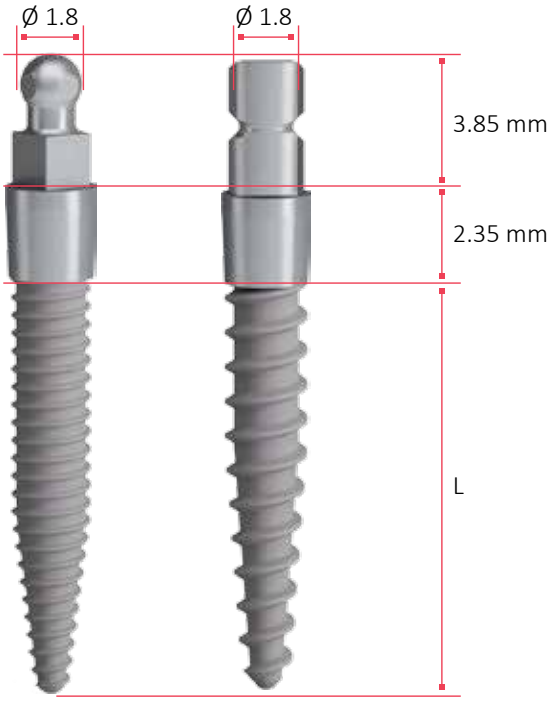
This type of analysis provides information about the qualitative and quantitative chemical composition of the surface material's initial nanometres, or rather the layers that come into the most direct contact with the bone tissue.

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.



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.

The **P1 mini implants** are designed to stabilise mobile prostheses upon insertion, thus ensuring immediate functionality and stability.

Their threads are specifically designed for use with any type of bone tissue. Thanks to its shape, the implant's emergence profile can be used as a support for both titanium components or castable elements. The 1.80 mm ball present on the emerging part of the implant is used as an anchor for mobile prostheses.

The surgical protocol is particularly simple, and only requires the use of a single dedicated bur, with no bone tapping.

code	Ø (mm)	L (mm)
P12010M	2.0	10
P12013M	2.0	13
P12015M	2.0	15

code	Ø (mm)	L (mm)
P12410MW	2.4	10
P12413MW	2.4	13
P12415MW	2.4	15

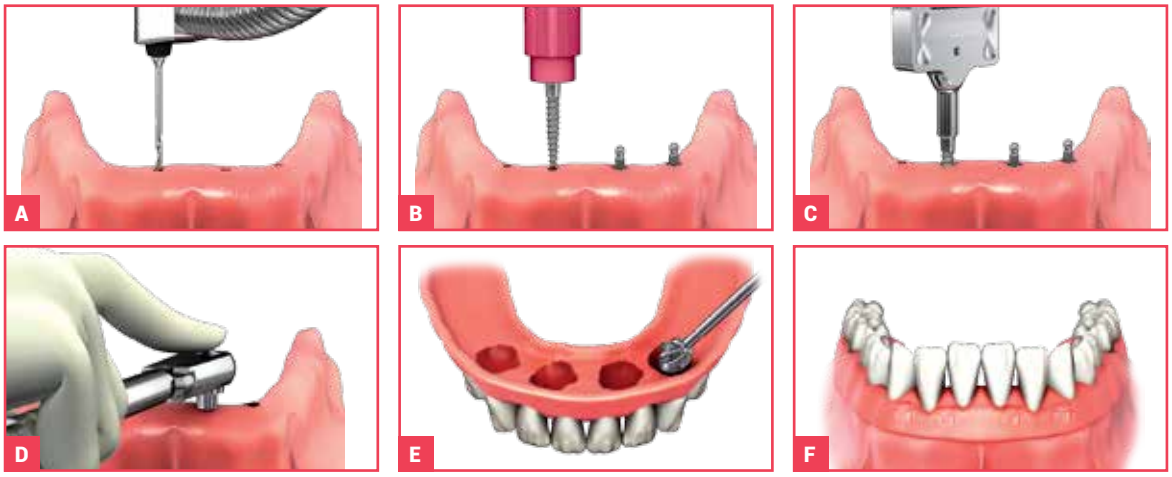
code	Ø (mm)	L (mm)
P12510M	2.5	10
P12513M	2.5	13
P12515M	2.5	15

code	Ø (mm)	L (mm)
P12410MTQW	2.4	10
P12413MTQW	2.4	13
P12415MTQW	2.4	15

code	Ø (mm)	L (mm)
P12510MTQ	2.5	10
P12513MTQ	2.5	13
P12515MTQ	2.5	15

Surgical protocol

Ø 1.50 mm cutter - For implants Ø 2.0 mm (D1-D2 cortical bone) and implants Ø 2.40 mm (D3 cancellous bone)
Ø 2.00 mm cutter - For implants Ø 2.50 mm (D1-D2 cortical bone)
In case of particularly soft or poor quality bone, perforate along roughly 1/3 of the length of the implant and carry out complete insertion on intact tissue.



A. Mark each entry point on the patient's tissue using the 1.5 **pilot cutter** moving it up and down until the cortical plate is penetrated.
B. Move the implant into place with the **plastic mounter** and screw it in until there is bone resistance.
C. Use the **butterfly wrench to insert the implant**. If insertion proves difficult, use the **dynamometric ratchet wrench**.
D. The **dynamometric ratchet wrench** completes the screwing of the implant.
E. Reveal the prosthesis to **house the metal matrices** to be positioned on the implants.
F. **Re-lower the prosthesis** into the patient's mouth with **cold resin**, making him apply pressure with the normal bite in centric occlusion.

KIT chirurgico

DYNAMOMETRIC RATCHET
P1KWD

PREPARATION DRILL
P1SK-M (ø 2)

P1DR20 (ø 2)

BUTTERFLY KEY
P1OSD

DYNAMOMETRIC RATCHET WRENCH
P1KN1L (Long)

P1KN1C (Short)

P1SKM

Prosthetic components

COLLARED ANALOG
P1ANMTS

COLLARED SQUARE HEAD ANALOG
P1ANMTQ

TEMPORARY CAP
P1CPM

TRANSFER CAP
P1ICM

STRAIGHT ABUTMENT
P1DTAM

SQUARE HEAD CAPS
P1CAM

PCV PROTECTION
P1PVCM

LANCEOLATE DRILL
P1DR15

METAL HOUSING

Soft Retention P1ORM-B

Medium Retention P1ORM-M

Hard Retention P1ORM-A

O-RING

Large for soft retention P1ORM-B (5 pieces)

Small for medium/hard retention P1ORM-M (5 pieces)

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.

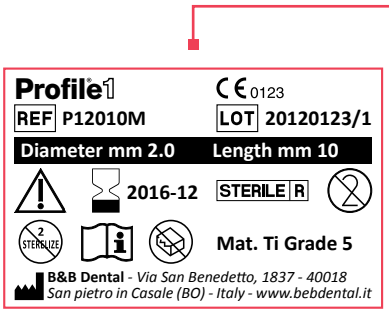
In this manner, if the need should arise, and the patient is unable to contact their dentist, they will nevertheless have access to the information regarding the product and the manufacturer, and will therefore be able to intervene in the most appropriate way.

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:
BCG Technology
Sede Legale: v. Ferrara 17
40018 - San Pietro in Casale - BO
Sede Operativa: v. Due Ponti, 17
40050 - Argelato - Bologna - Italy
T. +39 051 89 78 68
F. +39 051 89 27 91

www.profile1.it

Prodotto da B&B Dental S.r.l. - Via San Benedetto, 1837 - San Pietro in Casale - (BO) Italy