NORMADENT s.a.s. of Fantuzzo Saverio & C.
Via Ferrucci, 18 Cesano Maderno - MI
Tel.: (+33) 0362-55.14.11
e-mail info@normadent.com

INSTRUCTIONS FOR USE

The implant material accompanied by the following leaflet should only be used by surgeons, doctors and dentists who have received specific training.
Therefore, the use of such a dental implant cannot only be carried out by following the instructions below, but it is also advisable to undergo appropriate training. This document refers to all NORMADENT S.a.s products.

Insertion of the dental implant produced by NORMADENT sas must be carried out using the components and instruments produced directly by the company, in order to avoid compromising the functionality of the product and the success of the insertion.
If components or instruments not manufactured by NORMADENT sas are used, the warranty shall lapse and any compensation from the manufacturer shall be ruled out.

WARNING!

In intraoral use, it is essential to ensure protection against the risk of aspiration.

1. DESCRIPTION OF IMPLANTS

NORMADENT dental implants are manufactured using medical grade 4 pure titanium (ASTM F67) and have a sandblasted and acid-etched surface.

1.1 DESCRIPTION of the Prosthetic Part

The "prosthetic"
essentially consists of medical devices complementary to the implant. It is divided into abutments, healing screws, cap screws and connecting screws.

- The abutments are mechanical products, NOT STERILE, made of grade 5 titanium, which allows the implant and the tooth built in the laboratory to be joined. They can take different shapes, such as straight, slanted, octagonal and spherical.

- Healing screws are mechanical, NON-STERILE products, always made of grade 5 titanium, which are used during the osseointegration period, i.e. for a defined, long-term period (as defined in Section. 1.1 of Appendix IX), to prevent the gingiva from closing after implant insertion and before abutment insertion. This period varies between 3 and 6 months.

- Cap screws are mechanical, NON-STERILE products, always made of grade 5 titanium, which are used during the osseointegration period, i.e. for a defined, long-term period (as defined in Section. 1.1 of Appendix IX), to prevent the inside of the implant from becoming obstructed by fluids in the mouth (saliva, blood, food).

Unlike healing screws, the gingiva is sutured over the cap screws.

The choice of whether to use a cap screw or a healing screw depends on the practice, experience and method of the individual practitioner, some of whom prefer, in some cases, to suture completely in order to prevent any kind of mechanical stress on the implant which could compromise the osseointegration process, and in others, to suture partially, i.e. using the healing screw. In addition, factors affecting the choice of screws include the morphological nature of the individual patient.

- Connecting screws are mechanical, NON-STERILE products, always made of grade 5 titanium, which are used after the osseointegration period, to permanently join the (inclined) abutment to the implant.

ATTENTION: When using the prosthetic part, it is MANDATORY to meticulously follow the information on the label itself, regarding the **corresponding** implant. Otherwise, a perfect connection between the implant and the abutment is not guaranteed and the life of the implant is compromised. For this behaviour, NORMADENT disclaims all liability for incorrect use of the prosthetic parts.

2. INTENDED USE

The product is intended for dental patients who require the implantation of one or more single or groups of teeth (via dentures). The implant is only used as a support, as a median between the bone-gum site and the prosthesis (the tooth). The prosthetic part is an integral part of an implant, as it allows the implant and the tooth built in the laboratory to be connected. The installation must be carried out in clean and disinfected premises such as medical and minor surgery premises in hospitals, private clinics, and specialist centres.

3. CASES REQUIRING THE USE OF DENTAL IMPLANTS

The use of dental implants is recommended to solve various clinical cases, from total edentulism to partial to single tooth.
While their use was previously intended to solve problems related to the patient's masticatory and joint function, nowadays they are also used to solve aesthetic, phonetic and hygiene issues.

Bug. Rev.12 of 26.04.2021

NORMADENT s.a.s. of Fantuzzo Saverio & C.
Via Ferrucci, 18 Cesano Maderno - MI
Tel.: (+33) 0362-55.14.11
e-mail info@normadent.com

In cases of total edentulism, mobile prostheses created problems of both physical and psychological suffering. With the use of dental implants, if the anatomy of the patient allows it, a fixed and functional dentition like the natural one is obtained.
On the other hand, the use of an implant system in the case of a single tooth replacement does not require the preparation of the adjacent teeth normally required when constructing a bridge, thus leaving them intact and guaranteeing a better aesthetic and functional result.

4. INDICATIONS

As a general rule, it is advisable to always use the implant with the largest diameter.
Particular care must be taken when using small-diameter implants.
In fact, such implants should only be used in the following cases:
- small space between adjacent teeth and limited bone width.
- single tooth prosthetics for lateral incisors in the upper jaw
- Single tooth prosthetics for the lateral and central incisors of the lower jaw

The user must check that the specifications (diameters and lengths) on the label correspond to the needs of the case before using the system.

5. CONTRAINDICATIONS

Before proceeding to the surgical stage and using a dental implant, it is imperative to carry out an assessment of the patient, a pre-surgical diagnosis, and treatment planning, asking the patient in advance if there have been any previous cases of rejection, biological incompatibility, allergies or other information regarding his/her state of health. Incorrect assessment of the situation may result in the loss of the implant.

General Contraindications:
Severe systemic diseases, bone metabolism disorders, uncontrolled bleeding disorders, drug or alcohol use, psychosis, persistent functional disorders, periodic steroid use, untreatable endocrine disorders, titanium allergies, unfavourable anatomy, pregnancy.
Relative Contraindications:
Irradiated bone, diabetes mellitus, treatment with anticoagulant drugs, bruxism, parafunctional habits, unfavourable anatomical bone ratios, tobacco abuse, uncontrolled periodontitis, temporomandibular joint disease, upper or lower jaw disease and treatable mucosal changes, insufficient oral hygiene.
Local Contraindications:
Insufficient bone quantity, inadequate bone quality, local apical remnants.

6. SIDE EFFECTS

There are two types of side effects associated with the use of dental implants.
Short-term ones such as: pain, swelling, phonetic difficulties and gum inflammation.

Long-term ones such as: chronic pain due to implants, permanent paresthesia, dysesthesia, bone loss in the jaw, localised or systemic infections, oroantral or oronasal fistulas, negative effects on adjacent teeth, damage to adjacent teeth, fractures of implants, jaw, bone or dentures, aesthetic problems, nerve damage, exfoliation, hyperplasia.

It is strongly recommended to avoid any activity that requires a high physical load on the body after a dental implant placement.
WARNING
If you become aware of any other side effects not mentioned in this leaflet, please inform the manufacturer.

7. SURGICAL PROCEDURE

Both soft and hard tissues have to be treated with great care in order to achieve an optimal situation for perfect implant integration. For this reason, the implant site must be prepared with the utmost care, observing the following warnings:
- When milling the implant seat, pay attention to the notches indicating the depth to be reached.
- Always use well-sharpened milling tools (no more than 10 applications).
- Avoid thermal trauma that prevents or hinders healing by minimising excessive temperature rise with the following measures: intermittent milling technique, substantial cooling of the drills with cooled sterile saline solution, use of drills with increasing diameter
- Observe the following milling speeds:

Bug. Rev.12 of 26.04.2021

NORMADENT s.a.s. of Fantuzzo Saverio & C.
Via Ferrucci, 18 Cesano Maderno - MI
Tel.: (+33) 0362-55.14.11
e-mail info@normadent.com

MILLING TOOL		IMPLANT
Diameters	Recommended number of turns	
2.2	800	ALFA, OMEGA, KONIC series
2.8	600	ALFA, KONIC series
3	600	OMEGA,
3.5	500	ALFA, KONIC series
3.8	500	KONIC series
4.2	400	ALFA, OMEGA series
4.3	400	KONIC series
5	100	KONIC series
6	100	KONIC series

The primary stability of the implant is a prerequisite for its successful integration.
Pilot and spiral milling tools have an extra apical length (approx. 0.4mm), so bear this in mind when preparing the implant bed. This requirement should be considered when selecting the length of the implant.

Once the implant site has been prepared, proceed as follows:

1. ***Always*** tap the implant site with the appropriate tap for the implant you wish to use.
2. Check the sterility indicator. This indicator is yellow before sterilisation. Therefore, if it has been sterilised correctly, it changes colour and becomes permanently red, otherwise it retains its original colour.
3. Check the integrity of the secondary packaging beforehand.
3.1 Check the expiry date of sterility.
4. Remove the protective film.
5. Open the primary packaging by turning the cap as if to unscrew it.
6. Remove the holder by sliding it out of the ampoule onto a sterile towel.
7. Remove the implant with the suitable key, taking care not to touch it with your hands, and insert it into the previously prepared seat. If necessary, use the ratchet wrench to reach the required depth.
8. Insert the appropriate cap screw or healing screw.
8.1 Tighten by hand or using a torque wrench set to 22 NW.
9. Suture the mucous membrane with atraumatic stitches without excessive tension. Suturing should be done on both sides of the screw so that the edges of the wound are not subject to any traction.

WARNING Before inserting the cap screw or healing screw, or any other prosthetic part, make sure that these parts are only and exclusively the dedicated ones by checking the plate data on the packaging. Otherwise, the connection may be impossible or incorrect.

WARNING Before inserting the healing screw, ensure that it has been previously sterilised in accordance with Section 10.2 of this document.

WARNING Before proceeding with the surgical phase, all personnel must wear suitable clothing (latex gloves, clean gowns, masks, etc.), check that all the instruments to be used are clean and sterile and ensure that the environment in which the activity will take place is clean.

If there is an imperfection or breakage in the secondary packaging or the sterilisation indicator is yellow, we recommend that you DO NOT USE the implant, as its sterility may be compromised. We also advise you to inform NORMADENT s.a.s. of the incident.

WARNING If the implants or prosthetic parts are not to be used immediately, they should be stored in a dry place protected from dust or other contaminants, as specified in Section 13 of this document. Do not place any type of object on top of the packaging that could damage the packaging containing the implant.

8. HEALING STAGE

In the case of good bone quality and sufficient bone quantity, you must wait at least 8 weeks.
In the case of spongy bone and small implant diameters, wait at least 16 weeks.
There is no difference in healing between the lower and upper jaw.
An X-ray check is recommended after 6 to 12 weeks before the prosthetic phase.
WARNING: Temporaries must not be subjected to loads.

Bug. Rev.12 of 26.04.2021

NORMADENT s.a.s. of Fantuzzo Saverio & C.
Via Ferrucci, 18 Cesano Maderno - MI
Tel.: (+33) 0362-55.14.11
e-mail info@normadent.com

9. PACKAGING AND STERILITY

9.1 Each dental implant with its cap screw, manufactured by NORMADENT sas, is supplied in sterile packaging which protects it from external agents and guarantees its sterility during storage until expiry or use. Sterilisation is carried out at a certified external company by means of gamma rays. Implants must not be used after the expiry date shown on the label on the outside of the package. The implants should be stored in their original packaging in a dry place, away from direct sunlight and at room temperature.

The packaging consists of the following:
- hard box (outer packaging)
- protective thermoshrinking film
- primary packaging consisting of a plastic ampoule and a cap (fitted with an o-ring seal) containing a plastic support to which the implant and the cap screw are secured by means of a carrier.

A sticker is applied to the cap in different colours depending on the diameter of the implant:

COLOUR	IMPLANT DIAMETERS [mm].					
	ALFA series		KONIC series			OMEGA
	(1) Alfa CL OCTA(2)	Alfa OCTA (2)	Konic	BETA	2P	
/	/	/	**2.9***	/	/	/
	/	**3.3**	**3.8**	**3.7**	**3.75**	**3.3***
	/	**4.1**	**6**	**4.5**	**4.25**	**4***
	4.8	**4.8**	**5**	**5.2**	**5**	**5***
	/	/	**4.25**	**4**	/	**6***

Note 1: *Wide Neck Implant (WN)*
Note 2: *System with internal octagon connection.*

*** Unidentified caps with coloured sticker**

The packaging of the non-sterile prosthetic part consists simply of a double plastic bag with heat-sealed closure: the first contains the prosthetic part and its label, and the second contains the first bag and the information leaflet. The latter also comes with the same label.

Do not use:
- Implants or prosthetic parts with damaged primary or secondary packaging.
- Previously implanted implants
- Non-sterile implants
- Implants with an expiry date on the label which is before the date of use.

9.2 Sterilisation of prosthetic parts

For sterilisation of the prosthetic part, we recommend using a steam steriliser and performing the treatment using the typical "medical tool cycle" (134°, pressure 2.1 Bar, approx. 5 min.).

WARNINGS:
Although NORMADENT sas suggests using only CE-marked sterilisers and the above cycle, it accepts no liability for the properties and methods adopted by the customer.

WARNINGS:
NORMADENT sas accepts no liability for implants resterilised by itself or by third parties, irrespective of the method used.

WARNINGS:
NORMADENT sas accepts no liability for prosthetic parts sterilised by unauthorised and untrained personnel,
by means of autoclaves that do not comply with the relevant EU directives, and by methods other than those suggested.

WARNINGS:
DO NOT re-use prosthetic parts marked with the symbol 

10. DOCUMENTATION

It is recommended to keep clinical, radiological, photographic and statistical records for each patient. The traceability of each implant and prosthetic part can be done by means of the article code and the batch number which are written on the respective labels inserted in the hard box together with the dental implant. These labels must be attached to the patient file to facilitate traceability.

Bug. Rev.12 of 26.04.2021

NORMADENT s.a.s. of Fantuzzo Saverio & C.
Via Ferrucci, 18 Cesano Maderno - MI
Tel.: (+33) 0362-55.14.11
e-mail info@normadent.com

SYMBOL	MEANING OF SYMBOL	DESCRIPTION OF SYMBOL
	DO NOT REUSE	Indicates that the device is disposable and can therefore only be used once.
	USE BY	This is accompanied by a date expressed with four digits for the year and two digits for the month. Indicates that the device should not be used after the end of the month.
	STERILISATION WITH IONISING RADIATION	Indicates that the device has been sterilised using ionising radiation (in this case gamma rays)
	NOT STERILE	Indicates that the device (prosthetic parts) is NOT supplied in a sterile state
	DO NOT USE IF THE PACKAGING IS DAMAGED	Indicates that if the packaging is damaged, the MD contained therein must not be used for the intended purpose
	BATCH CODE	It is accompanied by the batch number assigned by the manufacturer. In our case it is composed of 2 digits (year of manufacture), 2 letters (IM= installation) and 3 more digits (sequential number)
	SEE ACCOMPANYING DOCUMENTS	Indicates that there is a document accompanying the device which contains all the necessary information for the user.
	WARNING	Indicates that there is a document accompanying the device which contains all the necessary information for the user, and that it may DANGEROUS not to consult it.
	MANUFACTURER	Identifies the MANUFACTURER of the medical device
	KEEP IN A DRY PLACE	Indicates the need to keep the package in a dry place for proper storage
	KEEP OUT OF SUNLIGHT	Indicates the need to keep the package out of sunlight for proper storage
	KEEP AT IDEAL TEMPERATURE	Indicates the need to keep the package at an ideal temperature for proper storage

11 CE marking

Implants and prosthetic parts are medical devices with CE 0068 marking. This marking certifies conformity with the essential requirements of Appendix 1 of the European Community Directive 93/42/EEC Medical Devices, as amended (2007/47/EEC), adopted at the national level with Legislative Decree 46/97, as modified by Legislative Decree 37/10, and is issued by a certification body accredited by the Italian Ministry of Health.

CE **0068**

12 Storage conditions

To ensure that sterility is maintained throughout the storage period, which must not exceed the expiry date on the label, the product must be stored at room temperature, away from direct sunlight and in a dry place.

13 Conditions of disposal

Disposal of dental implant packaging material and prosthetic parts must be carried out in accordance with national, regional and municipal regulations on non-organic waste.