NORMADENT s.a.s. di Fantuzzo Saverio & C.
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INSTRUCTIONS FOR USE

The implant material accompanied by the following package insert must only be used by surgeons, doctors and dentists who have undergone specific training.
Therefore, use of this dental implant cannot be made only by following the instructions below, but it is also advisable to undergo adequate training. This document refers to the use of 2P Ø 3.3 Mini implants by NORMADENT S.a.s.

The 2P Ø 3.3 mini implant manufactured by NORMADENT sas must be inserted using components and instruments manufactured directly by the same company, in order to avoid compromising the functionality of the product and the success of the operation.
If components or instruments not manufactured by NORMADENT sas are used, the warranty will be void and the manufacturer will not be liable for any compensation.

Report any serious incidents involving the device to your competent authority and to the manufacturer.

The Summary of safety and clinical performance is available from NORMADENT sas upon request. It will also be available on EUDAMED (https://ec.europa.eu/tools/eudamed).

CAUTION!

When used intraorally, protection against aspiration risks must be ensured.

1. DESCRIPTION OF THE IMPLANTS

The 2P Ø 3.3 mini implants are manufactured using ASTM F136 grade 5 titanium and have a surface treated by sandblasting and subsequent double acid-etching.

The 2P Ø 3.3 mini implants have the following characteristics:

- External morphology: truncated cone cylinder
- Implant structure designed to promote greater primary stability
- Connection diameter Ø3.3
- Lengths 8, 10, 12 and 14 mm
- Etching of the thread and implant body up to the last thread
- Apical part of the implant polished to 2

mm The 2P Ø 3.3 mini implants are STERILE and

SINGLE-USE.

CAUTION: when using the prosthetic part, it is MANDATORY to strictly follow the information on the label itself, relating to the reference of the **corresponding** implant. Otherwise, the perfect connection between the implant and the abutment is not guaranteed and, as a result, the life of the implant is compromised. NORMADENT accepts no liability for incorrect use of the prosthetic parts as a result of this behaviour.

2. INTENDED USE

The 2P Ø3.3 reduced dental implant is intended for use in dental patients with reduced mandibular or maxillary bone thickness, insufficient to accommodate a larger diameter implant, or as an aid in stabilising dental extensions suitable for the treatment of atrophic maxillae in order to restore normal chewing function. They must always be used in combination with other implants of the same diameter or, if possible, with a larger diameter. The implant is used exclusively as a support, as an intermediary between the bone-gingival site and the prosthesis (the tooth) in order to restore good chewing function. The implant must be performed in clean, disinfected premises such as those used for medical purposes, minor surgery, hospitals, private clinics and specialist centres in the sector, by specialised and duly trained medical personnel.

The 2P Ø3.3 mini implants are suitable for adult patients. The 2P Ø3.3 mini implants are not suitable for children and adolescents (under 18 years of age) or pregnant women.

INDICATIONS AND CLINICAL BENEFITS

The use of 2P Ø3.3 mini implants is recommended for resolving various clinical cases, for rehabilitation of the anterior and posterior maxillary/mandibular region, even in cases where overdentures are required for rehabilitation in edentulous jaws and with bone atrophy.

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The 2P Ø3.3 mini implants are recommended for resolving problems related to patients' chewing and joint functionality, although nowadays they are also used to resolve aesthetic, phonetic and hygienic issues.

With the use of 2P Ø3.3 mini implants in cases of total edentulism, if the patient's anatomical conditions allow for it, it is possible to obtain a fixed and functional set of teeth similar to natural teeth, avoiding the use of removable prostheses, which often cause physical and psychological suffering for patients.

2P Ø3.3 mini implants can be used as an alternative to pre-implant bone reconstruction techniques, thus avoiding more invasive procedures and reducing patient morbidity and treatment time. They also allow for early and immediate loading implant-prosthetic rehabilitation with high long-term success.
Finally, they can be used in clinical cases where the width of the edentulous ridge is insufficient to place conventional implants, both in areas with weak occlusal forces and in the posterior regions of the maxilla/mandible with reduced bone quantity, where the occlusal loads are greater.

3. WARNINGS

Special care must be taken when using small-diameter implants. The clinician must decide on the most suitable diameter to use after performing an x-ray examination and after reviewing the patient's medical history.

Before using the implant, the operator must check that the specifications (diameters and lengths) shown on the label correspond to the requirements of the case in question.
Before proceeding with the surgical phase and using a dental implant, it is mandatory to assess the patient, make a pre-surgical diagnosis and plan the treatment, asking the patient in advance if there have been any previous cases of rejection, biological incompatibility, allergies or other information regarding their health conditions. Incorrect assessment of the situation may result in the loss of the implant.

The 2P Ø3.3 mini implants are designed for situations with reduced bone thickness or as an aid to stabilise dental extensions suitable for the treatment of atrophic maxillae. During placement, care must be taken to avoid vital structures such as nerves, arteries or veins.
The smaller diameter of the implant reduces the contact surface between bone and implant, which is a potential cause of fracture due to reduced mechanical stability, failed osseointegration and risk of implant overload, especially in anatomical areas where occlusal loads are greater. However, it is known that the use of high-strength grade 5 titanium, the rough surface and the design give the mini implants high primary stability.

Before proceeding with surgery and using a mini implant, it is mandatory to assess the patient, make a pre-surgical diagnosis and plan the treatment.

Normadent recommends that all professionals attend theoretical and/or practical courses on the use of implants under the guidance of doctors who are experts in the use of these particular implants.

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4. CONTRAINDICATIONS

2P Ø3.3 mini implants are contraindicated in patients who are clinically unsuitable for oral surgery or if there have been previous cases of rejection. It is advisable to obtain the patient's complete medical and dental history beforehand, with emphasis on the presence of soft and/or hard tissue pathology.

General contraindications:
Ø3.3 implants should not be placed in patients with insufficient bone height and/or thickness or poor bone quality to achieve adequate primary anchorage stability. 2P mini implants must not be placed in patients with maxillary sinus pathologies or in patients with anatomical defects in the maxillary sinus, biological incompatibility or allergies to grade 5 titanium.

Relative contraindications:
Severe systemic diseases, metabolic bone diseases, uncontrolled bleeding disorders, drug or alcohol use, psychosis, persistent functional disorders, untreatable endocrine disorders and pregnancy

Irradiated bone, diabetes mellitus, treatment with anticoagulants and bisphosphonates, periodic use of steroids, bruxism, parafunctional habits, tobacco abuse, uncontrolled periodontitis, temporomandibular joint disorders, disorders of the upper or lower jaw and mucosal changes amenable to treatment, poor oral hygiene.

5. SIDE EFFECTS

There are two types of side effects associated with dental implants.
Temporary side effects: pain, swelling, difficulty speaking, gum inflammation and sinusitis.

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Medium- to long-term problems: chronic pain due to the implant, permanent paraesthesia, dysaesthesia, bone loss in the jaw, localised or systemic infections, oroantral or oronasal fistulas, fractures of implants, jaw, bone or prosthesis, aesthetic problems, nerve damage, exfoliation, hyperplasia.

It is strongly advisable to avoid any activity that requires high physical exertion after undergoing dental implant insertion.

CAUTION
Please inform the manufacturer if you experience any side effects not listed in this package insert.

7. SURGICAL TECHNIQUE

Both soft and hard tissue must be treated with great care to achieve an optimal situation that allows for perfect integration of the implant. For this reason, the implant site must be prepared with the utmost care, observing the following precautions:

- When drilling the implant site, pay attention to the notches indicating the depth to be reached.
- Always use sharp drills (no more than 10 applications).
- Avoid thermal trauma that prevents or hinders healing by minimising excessive temperature increases with the following measures: intermittent drilling technique, thorough cooling of the drills using cooled sterile saline solution, use of drills with increasing diameters.

1 Start preparation of the implant site with a Ø 2 mm drill bit for the length of the chosen implant.
2 Finish preparation of the site with a Ø3.15 mm drill bit for the length of the chosen implant.

Primary implant stability is a fundamental prerequisite for its successful integration. Proceed as follows once the implant site has been prepared:

1. Check that the packaging is intact.
2. Check the sterilisation expiry date.
3. Open the blister pack.
4. Check the sterility indicator on the bottom of the bottle. This indicator is yellow before sterilisation. Therefore, if it has been correctly sterilised, it will change colour to red; otherwise, it will maintain its original colour.
5. Open the primary packaging by unscrewing the cap.
6. Remove the implant with the special inserter, taking care not to touch the implant with your hands, and insert it into the previously prepared site. If necessary, use the ratchet wrench to reach the required depth.
7. Tighten by hand using the appropriate screwdriver or use a torque wrench set to 40 cN.
8. Suture by bringing the edges of the mucosa together with atraumatic sutures, without applying excessive tension. The suture should be made on both sides of the screw so that the edges of the wound are not subject to any traction.

CAUTION: Before proceeding with the surgical phase, all personnel must wear suitable clothing (nitrile gloves, clean gowns, masks, etc.), must check that all the instruments to be used are clean and sterile, and must ensure that the environment where the operation will be carried out is clean.

If there is any damage to the secondary packaging or the sterilisation indicator is yellow, DO NOT USE the implant, as its sterility may have been compromised. It is also advisable to inform NORMADENT s.a.s. of the incident.

CAUTION: If the implants are not used immediately, store them in a dry place protected from dust or other contaminants, in accordance with the specifications in section 13 of this document. Do not place any objects that could damage the implant container on top of the packaging.

8. HEALING PHASE

If the bone quality is good and there is sufficient bone quantity, wait at least 8 weeks. In case of spongy bone and small implant diameters, wait at least 16 weeks.
It is advisable to perform an X-ray check 6 to 12 weeks before the prosthesis phase.
CAUTION: Temporary prostheses must not be subjected to loads.

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To ensure long-term results, it is advisable to have regular follow-up sessions with patients after implant treatment and to inform them about proper oral hygiene.

9. PACKAGING AND STERILITY

9.1 Each dental implant manufactured by NORMADENT sas is supplied in sterile packaging that protects it from outside agents and guarantees its sterility during storage until expiry or use. Sterilisation is carried out by a certified external company using gamma rays. Implants must not be used after the expiry date indicated on the label on the outside of the packaging. The implants must be stored in their original packaging in a dry place, away from dust, moisture, direct sunlight and heat sources.

The packaging consists of:
- Titanium container holding the implant
- Polyester bottle with cap
- Blister pack containing the bottle
- Labelled packaging package containing the Information leaflet and the label to be placed on the patient's medical record

Do not use:
- Implants with damaged primary or secondary packaging
- Implants that have already been implanted
- Non-sterile implants
- Implants with an expiry date on the label that is earlier than the date of use

WARNINGS:
NORMADENT sas accepts no responsibility for implants that have been re-sterilised by the user or by third parties, regardless of the method used.

10. DOCUMENTATION

It is advisable to keep clinical, radiological, photographic and statistical records for each patient. Each implant can be traced using the item code and batch number shown on the corresponding labels included in the hard case together with the dental implant. These labels must be applied to the patient's file to facilitate traceability.

11. SYMBOLS

SYMBOL	MEANING OF SYMBOL	DESCRIPTION OF SYMBOLS
	MEDICAL DEVICE	Indicates that this is a medical device.
	DO NOT REUSE	Indicates that the device is single-use and therefore can only be used once.
	DO NOT RE-STERILISE	Indicates that the device must not be re-sterilised.
	DATE OF MANUFACTURE	Indicates the date that the sterile device was manufactured.
	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 must not be used after the end of the month.

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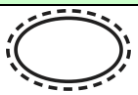
STERILE R	STERILISATION WITH IONISING RADIATION	Indicates that the device has been sterilised with ionising radiation (in this case gamma rays).
SYMBOL	MEANING OF SYMBOL	DESCRIPTION OF SYMBOLS
	SINGLE STERILE BARRIER SYSTEM WITH EXTERNAL PROTECTIVE PACKAGING	The device is contained in a bottle that maintains sterility and is further protected by a blister pack and box.
	DO NOT USE IF PACKAGING IS DAMAGED	This indicates that, if the packaging is damaged, the MD contained therein must not be used for the intended application.
	BATCH CODE	This is accompanied by the batch number assigned by the manufacturer. In our case, it consists of 2 digits (year of manufacture), 2 letters (IM = device) and 3 other digits (serial number).
	SEE ACCOMPANYING DOCUMENTS	Indicates that the device is accompanied by a document containing all the information necessary for the user.
	CAUTION	Indicates that the device is accompanied by a document containing all the information necessary for the user, and that failure to consult this document could be DANGEROUS.
	MANUFACTURER	Identifies the MANUFACTURER of the medical device.
	KEEP IN A DRY PLACE	Indicates that the packaging must be kept in a dry place for proper storage.
	KEEP AWAY FROM SUNLIGHT	Indicates that packaging must be kept away from sunlight for proper storage.
	KEEP AT TEMPERATURE	Indicates that packaging should be kept at a temperature between -5°C and +50°C for proper storage.
	UNIQUE DEVICE IDENTIFICATION	Unique Device Identification (UDI) is a unique alphanumeric code associated with a medical device which allows specific devices placed on the market to be clearly and unambiguously identified and facilitates their traceability.

12 CE marking

Implants are medical devices bearing the **CE 0425** marking. This marking certifies compliance with the general safety and performance requirements of Annex 1 of EU Regulation 745/2017 and is issued by a certification body notified by the Ministry of Health.

CE 0425

13 Storage conditions

To ensure that the product remains sterile during storage, which must not exceed the expiry date indicated on the label, it must be stored at room temperature, away from dust, moisture, direct sunlight and heat sources.

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14 Disposal conditions

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

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