NORMADENT s.a.s. di Fantuzzo Saverio & C.
Via Ferrucci, 18 Cesano Maderno - MI
Tel./Fax: 0362-55.14.11
e-mail info@normadent.com

Drills and surgical instruments accompanied by the following leaflet must only be used by surgeons, doctors and dentists who have undergone specific training.
This document refers to all devices belonging to the "Drills and Surgical Instruments" category manufactured by Normadent S.a.S.

1. DESCRIPTION OF THE DEVICES

Cortical bur: is intended to create a corticial cavity for subsequent burs.
Pilot drill: used during the preliminary preparation of the implant site to determine depth and inclination;
End drill: used to prepare the implant site. Designed with a cylindrical or conical shape and a vertical cutting edge for better control of the instrument during surgery. Furthermore, the device with three vertical cutting edges allows the collection of coarse bone fragments. ***Neck bur:*** used to prepare the neck to make accommodation of the implant in the cortical more comfortable without creating tension in the implant site.
Tapping: used to prepare the implant site with the same profile as the implant to be inserted, with reduced trauma.
Other instruments: other devices that are part of the surgical instruments such as parallelism indicators, screwdrivers, adapters, inserters, extractors, etc., which are used by the dentist to assist in the preparation and insertion of the implant system.

2. INTENDED USE

Medical devices used in the dental field, designed and manufactured for use by licensed implantologists to prepare patients' bone socket for the insertion of a dental implant. These devices may be used manually (if provided for connection to a ratchet) or electrically (if provided for connection to a micro motor).

3. PRECAUTIONS FOR USE AND SIDE EFFECTS

Medical devices have specific precautions for use, the assessment of which is left to the discretion of the surgeon, who decides whether they are to be considered relative or absolute, such as, for example: Active infections, fevers or leucocytes, obesity, allergies to a metal, mental illness, the patient's discomfort, special patient conditions such as old age, alcoholism, mental disorders and infections.
Incorrect use of the medical device may lead to: pain and painful sensations, infection, foreign body reaction, neurological complication involving possible paralysis, haemorrhage, pseudoarthrosis.

4. MATERIALS

All burs and surgical instruments are made of AISI 630 STAINLESS STEEL, with the exception of the tapping devices made of Grade 5 TITANIUM.

5. WARNINGS AND PRECAUTIONS

- The surgeon is responsible for selecting and using the appropriate instruments to prepare the implant site.
- The manufacturer disclaims all liability arising from incorrect use of the devices.
- Appropriate training is recommended before use.
- Medical devices are supplied in a "NON-STERILE" state.
- Scrupulously follow the instructions given in this document.
- If the device and/or its packaging are visibly damaged, do not use it and contact the manufacturer.
- Always ensure that burs and surgical instruments are cleaned and sterilised before use.
- Do not use burs and surgical instruments that have exceeded 20 uses or 20 sterilisation cycles.
- Never exceed 800 rpm when using the burs.
- Never exceed 30 rpm when using the tapping devices.
- Always check before use that the laser markings on the device are present and clearly visible. If not, refrain from use.
- Visually check that the bur's stem is not damaged from accidental blows and that the rectilinearity between the stem and the cutting part is not disrupted, so as not to oversize the implant site
- Wear appropriate PPE to protect against any ejected particles during surgery.

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- Make sure that there is adequate irrigation of the implant site.
- Incorrect cleaning and/or maintenance can irreversibly damage the device and its cutting properties.
- Stainless steel materials must be cleaned and disinfected in accordance with their instructions for use.
- Substances containing high levels of chlorine or containing oxalic acid should not be used for cleaning and disinfection of devices.
- Use demineralised water to prevent streaks from forming on the surface of the devices.
- Do not exceed 135°C during sterilisation.
- Do not allow residual blood, secretions or other tissues to settle on the device.
- Any encrustations should only be removed with nylon brushes, with special emphasis on the concave parts of the device.
- Do not clean and/or disinfect different materials at the same time.
- During ultrasonic cleaning, avoid contact between various devices, which would lead to their mechanical damage.
- After cleaning, rinse thoroughly with distilled water.
- Do not store devices moistened or immersed in liquids.

6. USE, CLEANING AND STERILISATION

Use any device with extreme care and avoid contact with metal objects that may alter mechanical and cutting properties (if any).
Before use, it is necessary to check the correct insertion of the cutters in the micro motor (or hand ratchet) and the correct direction of rotation.
Great leverage forces must not be applied during use, which could cause the bur, the handpiece or the bone wall to break. Direct injection of saline solution is needed to facilitate cooling of the drill.

Bur diameters	No. of revs recommended
Between 1.8 and 2.5	800
Between 2.8 and 3.0	600
Between 3.5 and 3.8	500
Between 4.0 and 4.5	400
Between 5.0 and 5.5	100

Cleaning can be done using an ultrasonic tank and a suitable cleaning solution for surgical instruments. Refer to the manufacturer's instructions for the duration and concentrations to be used.
In the case of manual cleaning, brush the device under running water and apply the cleaning agent to each of its surfaces. When finished, rinse thoroughly with distilled water.
At the end of the cleaning phase, dry the devices and pack them in the appropriate sterilisation bags.

Sterilisation can be carried out in an autoclave with a 20-minute minimum “surgical instruments cycle”, T between 121°C and 124°C and a 15-minute drying cycle.

7. STORAGE CONDITIONS

Devices must be kept within the sterilisation pouch until they are used. The sterility maintenance time is provided by the supplier of the pouch; do not use the device(s) if the sterilisation pouch is damaged. We recommend preventing damage and storing them in a cool, dry place, away from heat and direct sunlight.

8. DISPOSAL

The device must be disposed of at the end of its life in accordance with the regulations and laws in force.

9. DOCUMENTS AND SYMBOLS

	See Operating Instructions
	Production batch
	Non Sterile
	Warning
	Do not use damaged packaging
	Protect against rain and store in a moisture-free environment
	CE marking of class IIa devices
	CE marking of class I devices