Instructions for use

Multiple Use Drills

Description
Neoss® Limited manufactures dental drills and surgical instruments in stainless steel.

Indications
Neoss drills and surgical instruments are used for sole placement of Neoss implants.

Contraindications
Treatment is contraindicated where the patient has a preexisting allergy to the used parts. Use of drills and instruments with other than Neoss products is contraindicated.

Procedures
This Instructions For Use (IFU) is for multiple use drills, including short drills. For detailed information on the other specific Neoss Implant System products you are using, please consult general Instructions For Use (10538), Neoss Implant System Guidelines (10501) and translated versions.

The surgical procedure may entail a range of procedures including minimally invasive surgery and raising a full thickness flap, exposing the bone in the proposed site. A series of increasing diameter drills are used to enlarge the osteotomy for implant placement – this may involve the use of countersinks and screw taps depending on individual preferences and/or the bone quality.

The positions of the implant sites are determined using a round bur, lance drill or 2.2 mm twist drill. Incremental site preparation is carried out as recommended in the Neoss Implant System Drilling Guides in the Neoss Implant System Guidelines (10501). All preparation of the bone tissue is carried out under profuse irrigation with saline and using an intermittently drilling technique. This prevents overheating bone and creates a pumping effect for efficient removal of bone debris.

Recommended speed for drills is 800–2000 rpm using lower speed for larger drills, 800 rpm for countersinks and 20 rpm for screw tapping.

Please note the short multiple use drills are NOT compatible with Neoss Drill Stops and Neoss Guide Kit.

Drill Depth Guide
This guide shows an 11 mm implant in relation to a twist drill and depth guide. Please note actual distance to drill tip is 0.8 mm longer than the reference line.

Note: The 3 mm tip cannot be used for depth purposes in conjunction with the Twist Drill, Tapered Ø3.0.

Sterility
The drills are delivered in a sterile condition for immediate use.

Cleaning and Disinfection
Pre-cleaning and disinfection – Drills are pre-cleaned immediately after surgery with a brush under running water and/or washer/disinfector and suitable detergent (cleaning and disinfectant solution). They are then rinsed clean (a dishwasher may be used – please follow manufacturer’s recommendations). If not cleaned immediately, soak the components in suitable disinfectant and follow manufacturer’s instructions.

Cleaning, disinfection and drying – The drills are placed into a glass beaker with a suitable surgical detergent (cleaning and disinfectant solution) and are cleaned in an ultrasonic bath for minimum of five minutes. After ultrasonic cleaning all drills are rinsed under running water then dried immediately.

Note: During entire handling the drills are placed in an appropriate manner to avoid damage. Drills are checked for damage after each procedure and damaged components are removed.

Packaging and Sterilization
The drills are packaged with the Clinical Organizer in the Neoss System Tray. Before clinical use non-sterile parts are recommended to be sterilized. The following heat sterilization method and process parameters are validated in accordance with EN ISO 17665 and recommended by Neoss Ltd. The components are packaged in a sterilization bag and autoclaved in a prevacuum cycle at 134°C/273°F, exposure time of minimum 3 min. and up to 18 min. (US specific: 135°C/275°F, exposure time 3 min.)

According to EN ISO 17664, it is the user’s and processor’s responsibility to ensure that the recommended process parameters above are validated and controlled.

Note: Never store drills while they are still moist or wet. Check all drills visually. Damaged or blunt drills should not be used. Multiple use drills are disposed after 10 sterilization cycles.

Storage
Sterilized bags are stored in dry environment at room temperature.

General Precautions
Surgical products used to achieve and maintain osseointegration should be utilized by persons trained in this method. Such training is offered at a number of centers.

Please contact the manufacturer for information. Pre-operative hard tissue or soft tissue deficits may result in a compromised esthetic outcome or unfavorable implant angulation. Pre-operative patient evaluation and close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for success.

Handling of hazardous material according to established procedures at the hospital/clinic.

Procedural Precautions
Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

Adverse Effects
Implant techniques have normal contraindications and risks. These are extensively documented in the dental literature. Incorrect clinical placement or loading resulting in loss of implant anchorage or loss of the prosthesis are possible events after surgery. Lack of bone quantity or quality, infections, poor patient hygiene or cooperation, and general diseases are some potential causes for loss of anchorage and function.

Caution
Federal (USA) law restricts the sale of this device to or on the order of a licensed physician or dentist.