MEDENTiKA®

A Straumann Group Brand

IPS - Implant Systems

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Chirurgie Bohrer

Surgical Drill

Forets à chirurgie

Frese chirurgiche

Fresa quirúrgica

Hersteller
Manufacturer
Fabricant
Produttore
Fabricante
Fabricante

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MEDENTiKA® Implant Systems
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Instruction for use

Minicone / Microcone / Quattrocone Surgical Drill

CE 0483

1. Indication

The Minicone / Microcone / Quattrocone surgical drills and instruments are used for the preparation and conditioning of the implant bed. If using drill templates, ensure that the drills are not tilted, as this could possibly cause the drill bit to fracture.

2. Material

Stainless steel/ADLC coated

3. Contraindications

Risk to anatomical structures in the region of planned measures.

4. Liability information

The instructions for use must be read before using the Minicone / Microcone / Quattrocone drills and auxiliary components. Minicone / Microcone / Quattrocone drills and instruments are only to be used for medical/dentistry applications along with the Minicone / Microcone / Quattrocone system. Further information can be found in the respective surgical manual. The following descriptions are not sufficient for ensuring proper use if the user lacks experience in implant prosthetic treatment. The user must be familiar with dental surgery and prosthetics, including diagnostic and preoperative planning and/or laboratory procedures. The user is obliged to check to ensure that the products are suitable for the intended use prior to treatment. MEDENTiKA® GmbH liability shall be reduced or eliminated in the event of the user's contributory negligence. This applies in particular if the user fails to comply with the instructions for use or warnings, or in the event of accidental misuse.

5. Safety notice

Any worn or damaged instruments or system components must be immediately removed and replaced with new products. The user information on handling must be followed. The instruments or system components may only be used for the defined purpose. Failure to comply with these safety instructions may lead to injury. Position the patient so that the danger of aspiration of components is minimized. All components that are used intra-orally must be secured to prevent aspiration or swallowing.

6. Application

Treatment procedure/proper use

General instructions for the various surgical techniques are described in the specialist literature. Patients must be informed of the generally applicable safety measures and of what is expected of them prior to the surgical procedure.
It is recommended that computer tomography imaging is used in addition to investment techniques and orthopantomograms to establish the precise position and depth of the drilling. To rule out risk to adjacent structures it is essential to check the area around the application site of the drill. Administer local anaesthetic to the application site of the drills. Incision and preparation of the mucosal tissue and the periosteal region in accordance with the surgical technique.
A round drill ($\circlearrowleft_{opt.}$ 1000 min^{-1} / $\circlearrowleft_{max.}$ 1200 min^{-1}) is used to determine the exact position of the osteotomy site. The pilot drill ($\circlearrowleft_{opt.}$ 1000 min^{-1} / $\circlearrowleft_{max.}$ 1200 min^{-1}) is positioned at the point determined with the round drill. It is used for the initial deep drilling of the intended preparation. The use of a pilot drill is not necessary when using Minicone implants. The initial deep drilling of Minicone implants is performed directly with the standard drill. When using drilling templates, make sure that the instrument does not tilt in order to prevent a possible drill fracture.

The standard drill ($\circlearrowleft_{opt.}$ 300–600 min^{-1}/$\circlearrowleft_{max.}$ 800 min^{-1}) is used to widen the cavity until the final width is achieved. The drill bits are colour coded and matched to the relevant implant diameter. Drilling should be intermittent with continuous external cooling with sterile saline solution. External cooling prevents the bone tissue from overheating and also washes out or rinses away bone splinters. Ensure that the drill is not tilted and locked in position during use (increased risk of fracture). Preparation is carried out with minimal pressure down to the desired depth at a speed of 300–600 min^{-1}. This speed should be observed to prevent drill fracture.
The cortical drill ($\circlearrowleft_{opt.}$ 300–600 min^{-1}/$\circlearrowleft_{max.}$ 800 min^{-1}) is used to widen the cavity where there is hard bone.
The conical reamer ($\circlearrowleft_{opt.}$ 300–600 min^{-1}/$\circlearrowleft_{max.}$ 800 min^{-1}) is for widening the cavity conically when using conical Microcone implants D 4.5/3.5 mm to the maximum definitive width of the conical section.

7. Care and maintenance

All system components mentioned in these instructions are supplied non-sterile. They therefore have to be disinfected and sterilised prior to each use. Please take note of the instructions concerning disposable instruments, where applicable. Prior to first use, prepare the instruments as described below. Only use brushes with metal-free bristles for pre-cleaning ceramic instruments as these do not leave discolorations caused by abrasion.

8. Cleaning and Disinfection

Careful cleaning and disinfection of the instruments and cassette are a precondition for guaranteeing optimal sterilisation conditions. Surgical residues (blood, tissue remnants, secretions) must never dry on the instruments. Gross soiling must be removed from the instruments directly after use with water or disinfectant, if necessary with a soft sponge or cloth, avoiding prolonged exposure to wetting or moisture.

The instruments can be cleaned and disinfected with the aid of a thermo-disinfector (follow the manufacturer's instructions for use) or manually with suitable cleaning and disinfectant solutions.

Please note that titanium and stainless steel instruments must be cleaned and disinfected separately as this leads to an increased risk of contact corrosion.

Contact between the instruments during cleaning, disinfection and sterilisation should be avoided as this may damage them, particularly on the cutting surfaces. Suitable protective clothing should always be worn when cleaning contaminated instruments to ensure personal safety.

Use of an enzymatic cleaning agent with a nearly neutral pH is recommended. Do not use any cleaning agents or disinfectants containing halogens (chlorine, iodine, bromine, fluorine), oxidising agents (H_2O_2), organic solvents, heavy metal salts, aldehydes or aromatic/halogenated hydrocarbons. Never clean with abrasive cleaners such as metal brushes or coarse pot scrubbers.

The following steps are recommended for the automatic cleaning/disinfection process in the thermo-disinfector:

Cleaning:

- Rinse for 1 minute with cold water
- Clean for 5 minutes with a suitable cleaning agent at 55°C (± 2°C) (e.g., neodisher MediClean (0.5%))
- Neutralise for 2 minutes with cold water
- Rinse for 1 minute with cold water

Disinfection:

- Thermal disinfection for 5 minutes at 93°C with demineralised water.

The following steps are recommended for the manual cleaning/disinfection process:

Cleaning:

- Clean the entire surface mechanically, especially cavities, crevices and holes under running water (drinking water, 30 ± 3°C) using a soft brush until no more residues are present (at least 20 seconds per part)
- Clean for 5 minutes in an ultrasonic bath (minimum frequency: 35 kHz) with a suitable cleaning solution (e.g., 2% MediClean ® , Dr. Weigert, in drinking water)
- Rinse off or out the entire surface, especially cavities, crevices and holes under running water (drinking water, 30 ± 3°C) for at least 10 seconds per part. Movable parts must be moved during this.
- Rinse with demineralised water for at least 5 seconds per part

Disinfection:

- Submerge the parts for 30 minutes in disinfectant (e.g., 2% neodisher® SeptoMED, Dr. Weigert, in drinking water at 20 ± 2°C) and move the parts in the solution to remove air bubbles on the surface.
- Rinse off or out the entire surface, especially cavities, crevices and holes under running water (drinking water, 30 ± 3°C) to remove residual disinfectant solution. Movable parts must be moved during this.
- Rinse with demineralised water for at least 5 seconds per part

Prior to sterilisation, the instruments must be examined for cleanliness and damage. Do not use any instruments that are contaminated or damaged.

9. Sterilisation

It is recommended to sterilise instruments in a cassette, which should be packed in the sterilisation bag for sterilising according to manufacturer's instructions. Sterilisation of the cassette with contents was tested and validated only for vacuum sterilisers/vacuum autoclaves.

- Sterilise for 4 minutes at 132°C (270°F), 3x fractionated prevacuum.
- Let the cassette with the instruments dry for 20 minutes.

Please follow the vacuum steriliser or vacuum autoclave manufacturer's instructions. Other sterilisation methods or protocols must be checked and validated by the user.

Note:

Drills can be reused up to ten times (i.e. for 10 implants), provided they receive proper care. Any application beyond this is not permitted. For safety, a drill list should be kept in which the respective use can be recorded.

It is confirmed that the above detailed reprocessing methods are suitable for preparing the above named instrument group to enable their reuse. The operator of medical products is responsible for making sure that reprocessing is carried out byqualified personnel, using the appropriate materials and suited equipment.

To guarantee this, routine controls of the validated mechanical preparation methods are required. Any deviation from the above detailed process must be carefully checked by the operator to ensure effectiveness and to avoid possible adverse consequences.

10. Signs and Symbols

LOT	Batch code
REF	Catalogue number
	Manufacturer
	Consult Instructions for Use
Rx ONLY	Federal law restricts this device to sale by or on the order of a dental professional.
	Non-sterile
CE 0483	CE - marking with 4digit identification number of the Notified Body

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