



INSTRUCTIONS FOR USE

Document No: TF02_2.2-1
Release Date: 20.02.2019
Revision No:01
Revision Date:21.10.2022

DENTAL IMPLANT SURGICAL KIT-DRILL

Below is information about using drills. Please read the following information and explanations carefully before using the product.

1 General Definitions

1.1. Product Information

1.1.1. **Name:** Dental Implant Surgical Set – Drills

1.2. Manufacturer Information

1.2.1. **Name:** SOLVO UK IMPLANTS CO. LTD.

1.2.2. **Address:** 60 Millmead Business Center Mill Mead Road N17 9QU London / England

1.2.3. **Mail:** info@solvodental.com

2 Product Specifications:

2.1. Intended Use: The dental drill is used in dental implant treatment, including the drills required during the dental implant placement process

2.2. Indications: Tooth deficiencies that cannot be treated with other prosthetic and surgical techniques (conditions with insufficient retention of existing teeth or tissue defects). Situations where dental implants are more beneficial than conventional treatment (short edentulous arches, single tooth missing, orthodontic retention). Cases with similar functional results from conventional treatment and implant treatment. In these cases, the decision for implant treatment is made as a result of personal considerations or aesthetic concerns.

2.3. Sterility Information: The product is supplied non-sterile. It is recommended to be sterilized by the user in an autoclave for 20 minutes at 121 °C before use.

2.4. Usage Area: Dental implant surgical set – drills are produced for the use of authorized persons who are professionals in the dental (dental) field.

2.5. Shelf life: Shelf life has not been determined. The product is non-sterile. Sterility, tightness, etc. risks are not applicable. It is fixed that there is no significant change in the mechanical and corrosion properties of stainless steel, which is a critical feature, under 30 years. Based on this, taking into account MEDDEV 2.2/3 rev 3 clause 4.2.c, shelf life is not defined for the products.

2.6. Storage Conditions: Our product does not have any special storage conditions.



EU Authorized Representative:
MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany



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2.7. Reusability: Products can be resterilized under recommended methods and parameters. It can be reused after sterilization. The number of sterilization cycles is not limited, but it is recommended to use a maximum of 10 times. There is a possibility of blunting the tip of the bur with more than 10 uses, which may result in poor performance and reduced clinical success. To ensure that the cutting performance of Solvo UK surgical instruments is not reduced, the following should be considered:

- Avoid contact of the tip of the burs with the surfaces so that it does not become blunt.
- After the surgical application, the blood should be washed immediately before it dries on the instruments.
- Clean the instruments thoroughly with a soft brush after use. All surfaces must be cleaned in disassembled condition.
- Never disinfect, ultrasonically wash, sterilize with hand tools made of different materials.
- Use only with disinfectants and/or cleaning agents suitable for 4116 steel. Perform in accordance with the disinfectant or cleaning agent manufacturer's instructions.
- Rinse the disinfectant and cleaning agent thoroughly with water.
- Never leave instruments damp or wet.

2.8. Safe Usage Information: The product usage speed should be used as 800 rpm and the torque value should be 35 Ncm.

2.9. Information of Devices Used Together: The product should be used with physio dispenser and anguldruva motor.

3 Patient Population

It is suitable for the entire patient population.

4 Device Contraindications

Conditions where there is insufficient bone volume and/or quality. Serious internal medical problems, insufficient wound healing capacity, underdeveloped maxillary and mandibular, inadequate general health status, uncooperative and low motivation patient profile, drug and alcohol addiction, psychosis, weak immune system, uncontrollable endocrine problems, stainless steel allergy.

5 Safety and Warnings

Before using the Dental Implant Surgical Set – Drill, the user should be familiar with its application. The user should learn the operating procedures before using it for the first time.



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Not suitable for use outside of the Solvo SLA-SLAct Implant System.










6 Warnings

It must be re-sterilized before each use. Otherwise, there are risks of biological contamination.
For use by professionals, healthcare professionals.

7 Side Effects

It has no known side effects.

Symbols and Meanings Prepared According to EN 15223-1:2016 Standard

	Reference number	 eIFU Indicator	Consult electronic instructions for use
	Lot number	 NON STERILE	Sterile (121° C- 20 min.)
	Production date	 CE 1984	Notified body number
	Authorized representative in the European Community		Medical Device
	Manufacturer Name/ Manufacturer Address		

