





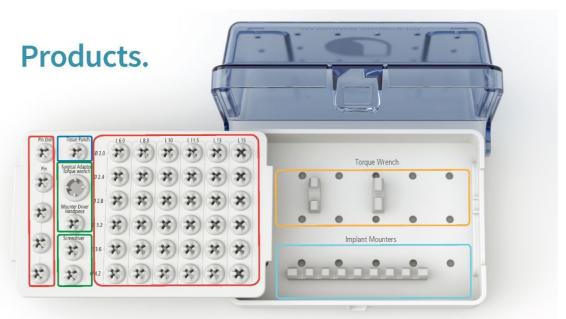


JD Guided Surgery Kit Instruction for use.

JD Guided Surgery Kit.



The JD Guided Surgery Kit is simple and equipped with all instruments needed to place all JD implant lines from $\emptyset 2.75$ to $\emptyset 5.00$ mm. Its new design has been improved with more guided drills. The JD Guided Surgery Kit includes N36 guided drills with a new shape for better surgery. Important: in order to perform a correct osteotomy, the first drill that must be used is the $\emptyset 2.4$ mm L 6.0 mm.



JD Torque®



Implant and Prosthetic Drivers



Tissue Punch



Implant Mounters



Guided Drills



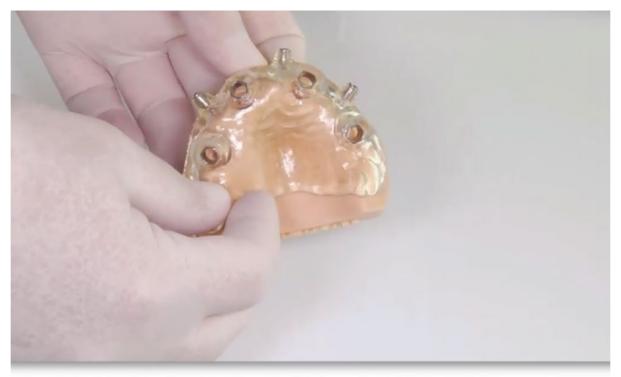


Guided Drills





Instruction for use.



In the surgical guide are inserted the sleeves of 5.05 mm of diameter.







The surgical guide was fixed with the pins in the correct position.







Use it in order to cut the tissue.



In order to perform a correct osteotomy, the first drill that must be used is the drill Ø2.4 mm L 6.0 mm.





The drill insertion is perfectly guided thanks to the precision of the sleeves and to the perfect match between the sleeves and the drills.



Choose the final length of the drill according to the length of the implant to be inserted.





The length of the drill is 9 mm longer than the length of the implant to be inserted.



For example, in this case that an implant length of 11.5 mm is to be inserted, the length of the drill will be 20.5 mm.



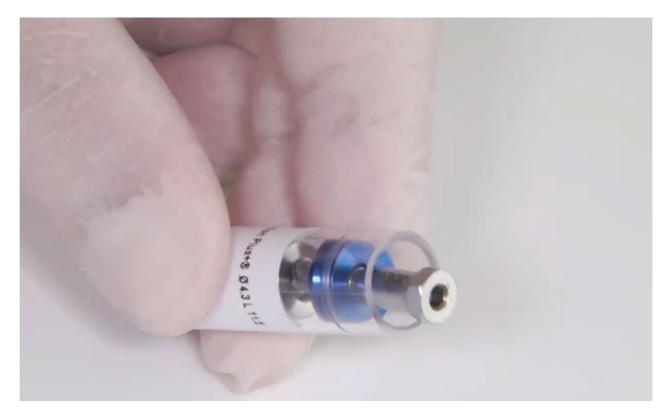


All JD Guided Drills have a new design, non cylindrical and with two lateral cuts which allows a less friction on the sleeves, avoiding overheating and a better external irrigation during the implant site preparation.



Open the packaging and fix the proper implant mounter to the implant with the screwdriver. In this case, it is placed a JDEvolution Plus+ implant.







Take the Implant Driver handpiece and connect it to the implant mounter.



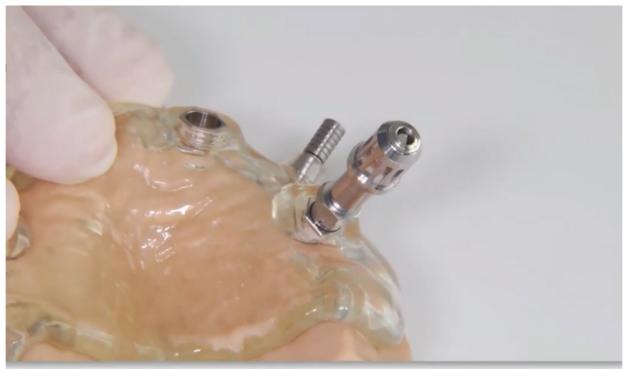


The dental implant is fixed on the implant mounter.



Insert the first JD implant using the proper implant mounter in order to perform a guided implant insertion.





When the implant motor arrives at 45 Ncm, reach the final implant position using the Torque wrench.



Align the side of the hexagon of the implant mounter to the hexagon of the sleeve.







Insert all JD implants using the proper implant mounter.





All JD implants are correctly inserted.







The surgery is completed.



Storage and sterilization information.

Intended use:

JDentalCare dental instruments are intended to allow the preparation of the JDentalCare dental implants site and their insertion into the mandibular or maxillary bone.

The dental instruments are used for surgical intervention in the mandibular bone to allow the dental implant to be placed and screwed in the bone. They are commercialized non-sterile, are packed in single cases and have to undergo a vapor sterilization cycle before use.

Contraindications:

Use of JDentalCare Dental Instrument may be precluded by patient's conditions that are contraindications for surgery.

Absolute contraindications: allergy to titanium, recent myocardial infarction, valvular prostheses, severe kidney disorders, severe liver disorders, treatment resistant diabetes, recent high-dose radiotherapy, severe chronic alcoholism, drug use, terminal illness and tumors.

Relative contraindications: chemotherapy, minor kidney disorders, minor lever disorders, endocrine disorders, psychological and psychic disorders, lack of understanding and motivation, AIDS, HIV positive cases, prolonged use of corticosteroids, disorders of the calcium/phosphorous metabolism, erythropoietic disorders, severe nicotine poisoning. JDentalCare Dental Instruments should not be used on patients where the remaining jaw bone is too diminished or quality bone is



poor to provide an adequate primary stability for the implants.

Warnings:

It is recommended that clinicians, new as well experienced implant users, are updated on JDentalCare dental products' features and their surgical applications.

For detailed information about method of use of JDentalCare dental implants and abutments please consult the surgical manuals.

Excessive bone loss or breakage of implant may occur when implant is loaded beyond its functional capability.

Physiological and anatomic conditions may negatively affect the performance of dental instruments and implants. This should be taken into consideration when operating on patients with the following conditions:

- poor quality bone
- poor oral hygiene*
- medical conditions such as blood disorders or uncontrolled hormonal conditions
- * Periodic checks for plaque on the zone of the implants through close-up recall sessions (every 4-6 months) in order to prevent the formation of periimplantitis, are indispensable.

The JDentalCare implant system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of JDentalCare implant system in the MR environment is unknown.



Precautions:

The JDentalCare Guided Surgery System simplifies the surgical techniques required to place dental implants, but the clinician must attend a specific training beyond the supervision of expert implantologists about this technique. Improper technique can lead implant failure or loss of supporting bone or inadequate primary stability or other adverse effects.

Thorough screening of implants candidates should be performed included an evaluation of patient capacity to maintain a correct oral hygiene, the patient motivation, the presence of parafunctional habits. Visual inspection as well as periapical radiographs is essential to determine anatomical landmarks, occlusal conditions, periodontal status and adequacy of bone. It is strongly suggested TAC dentascan to provide a real evaluation of dimensions and quality of bone.

Sterility:

All JDentalCare surgical kits and instruments are supplied non-sterile and must be steam sterilized before use. Use of non-sterile device may lead to infection of tissues or infectious diseases.

For steam sterilization of the components and the surgical kit of the JDentalCare® implant system, sterilize at 132°C/270°F, for 4 minutes (Autoclave Type: Pre-Vacuum - Drying time: 20 minutes -Wrap type: packaging with sealed containment device). Do not re-sterilize the same component more than 30 times.



Potential adverse events:

Potential adverse events associated with the use of dental implants may include:

- 1. Failure of osseointegration
- 2.Loss of osseointegration
- 3. Dehiscence requiring bone grafting
- 4. Perforation of the maxillary sinus
- 5.Lesion of inferior alveolar nerve
- 6. Persistent pain, numbness, paresthesia
- 7.Inflammation or infection
- 8. Excessive bone loss requiring intervention
- 9.Implant breakage

Storage and Handling:

Devices should be stored at room temperature away from sources of light or heat.

Caution:

Sale of this device is restricted to or on the order of a licensed dentist or physician.





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