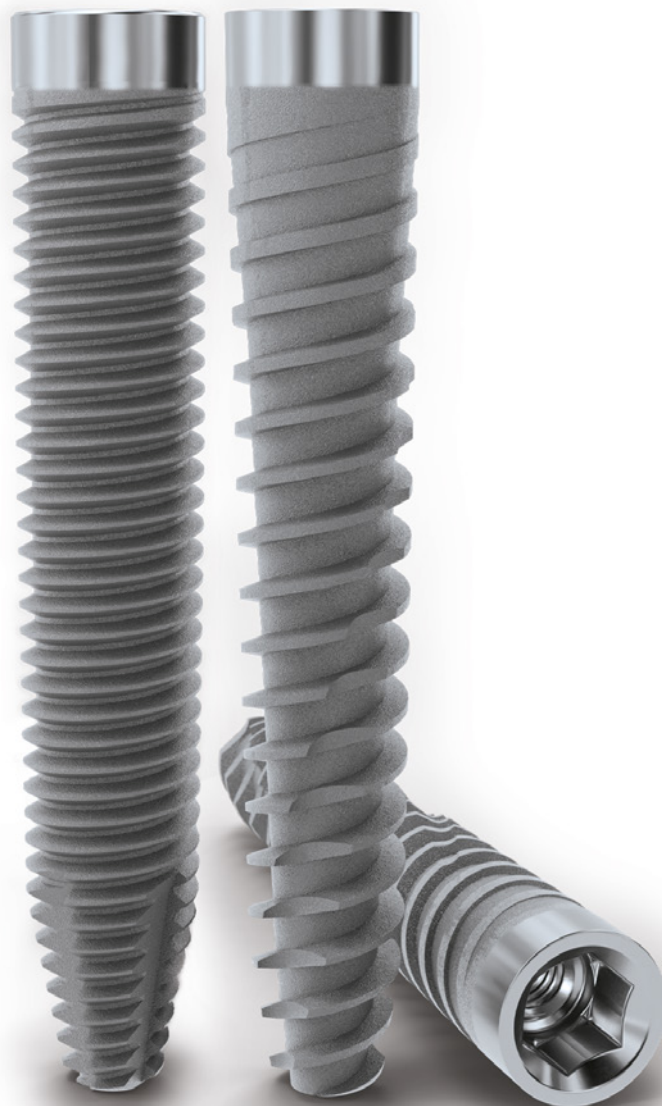




JDENTALCARE
just smile

JDEVOLUTION PLUS L JDEVOLUTION PLUS LE

Surgical Manual



GENERAL INFORMATION

Read this manual carefully before starting the treatment. This manual must be used as a reference guide by the doctor so as to optimize the use of the implants, surgical instruments, and prosthetic components of the system.

Please refer to the Instructions for Use, including Indications for use, Contraindications, Warnings and Cautions before using the products. Instructions for Use are available at ifu.jdentalcare.com.

The success of the treatment of patients is strictly connected to a proper planning of the surgery and to an appropriate choice of the type of dental implant to be used, based on the specific clinical case. JDentalCare offers a series of solutions to a wide range of indications, to allow the clinicians to perform the oral surgeries in order to obtain efficient results in terms of clinical outcomes and patient satisfaction.

This manual contains the main stages of the surgical procedure and has been prepared with the aim to be used as a reference guide by dental implant specialists to optimize the use of JDentalCare implants, surgical instruments, and prosthetic components. Anyway, it can't be used as a substitute for professional training and experience.

Before starting a new treatment, it is strongly recommended to the clinicians to inform and, if necessary, update themselves about the most suitable techniques and procedures to use.

For this purpose, our company offers a consulting service by our experts, who are at your disposal, and a wide variety of training courses for dentists at all experience levels.

For further information please visit: www.jdentalcare.com. Federal law restricts this device to sale by or on the order of a licensed dentist or physician.

INDICATIONS FOR USE

JDEvolution Plus L and JDEvolution Plus LE implant system is intended for surgical placement in the upper jaw.

JDEvolution Plus L and JDEvolution Plus LE implant system provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures.

JDEvolution Plus L and JDEvolution Plus LE is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

JDEvolution Plus L and JDEvolution Plus LE implants with lengths of 18, 20, 22, 24, 26 mm are only indicated for multiple unit restorations in splinted applications with at least two implants when placed in the maxilla.

Contraindications

The use of JDentalCare dental implants and prosthetic components may be precluded in the following cases:

- Patients with conditions that constitute a contraindication for surgery.
- Patients who are allergic or hypersensitive to the materials of which implants, prosthetic components and instruments are made. For information about the material of surgical instruments, refer to the IFU related, available at ifu.jdentalcare.com
- Patients with poor bone quality and/or an insufficient amount of bone, who cannot be subjected to bone grafting.
- Patients in whom, after an appropriate assessment of the case, is not possible to achieve a safe stability and the overall functionality with the devices of the implant lines considered in this surgical manual, even if are available the adequate sizes of implants and prosthetic components

Warnings

Incorrect planning of surgical protocol and/or a wrong choice of the size of the devices can result in: permanent nerve injuries, permanent damages to the gums, bones and blood vessels. An incorrect execution of the treatment may lead to patient related issues, such as permanent numbness to the lower lip and chin or to a hemorrhage in the floor of the mouth.

The longer length implants (i.e. implant lengths ≥ 18 mm) are not intended for any specialized surgical technique or anatomic placements outside of the alveolar arches. The longer length implants should be restored using multiple-unit restorations with at least two (2) splinted implants.

Besides the mandatory precautions for any surgery such as asepsis, during drilling in the jawbone, one must avoid damage to nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

The implants are available in the sizes shown in the tables below.

PATIENT EVALUATION AND PREOPERATIVE PLANNING

JDentalCare dental implants are intended for adult patients subject to dental implant treatment. An appropriate planning of every aspect of the oral surgery is essential for the long-term success of a prosthesis.

The preoperative planning should be made based on the expected aesthetic and functional restorative results.

The choice of unsuitable sizes of the devices and the malposition of the implant may lead to complications, undesirable effects and to the failure of treatment.

To avoid this, a detailed examination through clinical and radiographic analysis of the patient general health condition and current medical status, and an evaluation of patient motivations and expectations are necessary.

Moreover, factors such as cigarette smoking, masticatory function and alcohol consumption are to be considered. Dental casts can be used to define the position and angulation of implants.

The dentist will develop the plan after gathering all the required data, because they provide important information and make possible a backward planning, with the aim to improve the safety and the results of the surgical procedure.

QUALITY AND QUANTITY OF THE BONE

The implant diameter, type and position are all factors that should be selected in each single case, based on the oral anatomy of the patient and taking into account of all the above-mentioned considerations about patient's psychological and physiological condition.

One of the main factors to consider for the definition of the protocol for the preparation of the implant site is the evaluation of the density, the volume and the thickness of the bone, which are features that differ from patient to patient and in a single individual from one area of the mouth to another. Usually, dense cortical bone provides higher primary stability, while soft bone requires "under-preparation" of the implant bed.

The choice of the length of the implant to use is influenced by the height of the available vertical bone. The amount of bone is not the same in all the sites.

The available bone may be situated in the most apical section of the implant, as it happens in a post-extraction site, or at the neck section of the implant, as in cases of maxillary sinus elevation procedure.

After placement of the implant the thickness of the residual bone needs to be at least 1.5 mm, in both lingual-palatal and vestibular direction, in order to avoid the risk of gingival margin recession.

The special reduction in the coronal section of the implant makes it ideal for cases with thin alveolar ridges. The

flapless technique can be used when there is an optimal quantity of bone and soft tissue.

In some cases, the mass of the jaw is not suitable to insert a dental implant and an intervention of bone augmentation may be necessary.

Moreover, JDentalCare provides narrow diameter implants, that can be used as a minimally invasive alternative to bone augmentation and as an evaluable solution in patients with insufficient bone ridge thickness or restricted mesiodistal anatomy.

Important: examination and a radiological study are essential elements to determine anatomical conformation, occlusion, periodontal status and bone thickness.

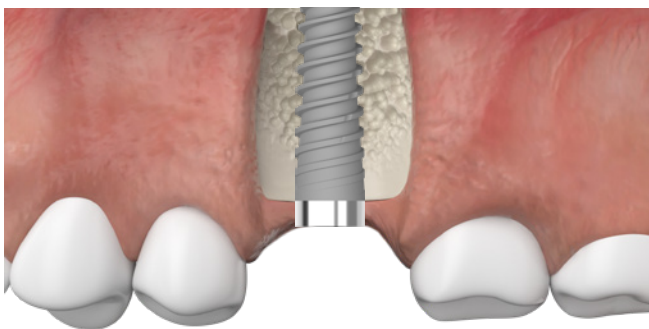
A "Cone Beam CT" radiological study is recommended to obtain a more precise evaluation of the dimension and quality of the available bone.

IMPLANT DIAMETERS AND LENGTHS

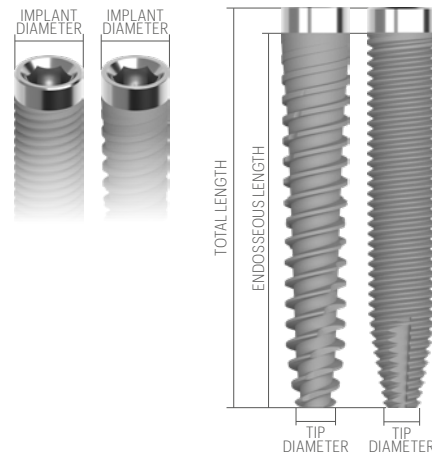
Available lengths for the 4.0 mm implant diameter are indicated in the following table.

IMPLANT DIAMETER	TIP DIAMETER	ABUTMENT INTERFACE	PLATFORM DIAMETER	ENDOSSEOUS LENGTH					TOTAL LENGTH					
				16.5	18.5	20.5	22.5	24.5	18	20	22	24	26	
Ø 4,0	2,4	3,4	4,1											

Note: all measurements in mm



IMPLANTS WITH AN UNTHREATED MACHINED COLLAR MUST BE PLACED SO THAT THE UNTHREATED MACHINED COLLAR IS IN THE GINGIVAL AREA



DRILLING SEQUENCE

JDentalCare offers a set of drills that have been designed in order to perform the flapless and the conventional flapless dental implant surgery.

Caution: All instruments and tooling used during procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Drilling in the bone should be performed at a maximum of 1200 rpm.

Before starting, verify that the drill is engaged/retained in the handpiece, in order to avoid accidental detachment during the surgery. To prevent damages to hard and soft tissues and to prevent the overheating of the bone an intermittent drilling technique with pumping motion and a plentiful irrigation with sterile water or saline solution are required. It's recommended during the procedure to take out the drill completely from the site, to check that irrigation is taking place correctly. Stop drilling if there is no irrigation.

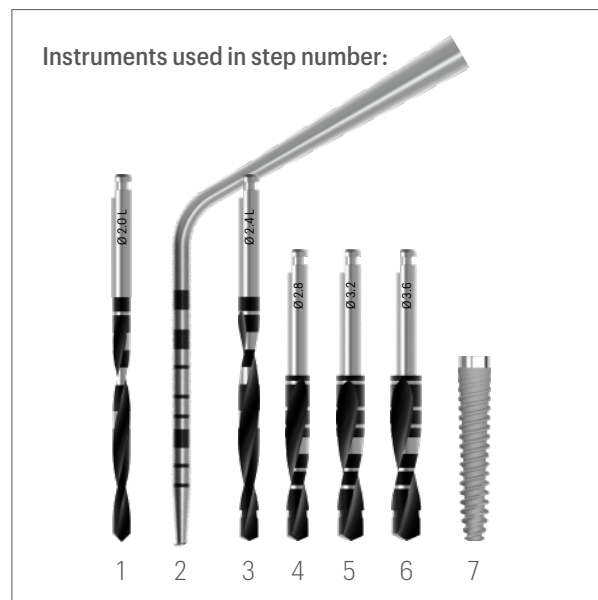
When pulling out the drill, don't stop the motor, in order to allow the irrigation to remove debris.

On the drill there are laser marks that serve as a reference of the depth of the hole to be executed, hence stop drilling when the desired depth is reached. If there are adjacent natural teeth interfering with the head of the contra-angle, the drill extension shall be used.

It is advisable to use surgical motors with adjustable speed and torque.

They can be used for a maximum of 30 times, or should be substituted before if the cutting efficiency degrades significantly. It is recommended to adhere to the indication of the drilling sequence related to the quality of bone and implant diameter 4.0 mm, in order to achieve a good primary stability of the implant. Pay attention to not overprepare the osteotomy with a depth greater than that defined in the planning stage.

For JDEvolution Plus L and JDEvolution Plus LE implants refer to the drilling sequence below to ensure optimal primary stability:



Warning: During drilling when using JDEvolution Plus L and JDEvolution Plus LE implants with lengths of 18, 20, 22, 24, 26 mm pay special attention to bone volume availability, vital structures such as vessels, nerves and sinuses. It is recommended to maintain 1.5 mm of bone surrounding each implant and a minimal distance of 2 mm from critical anatomical structures including nerves.

CLINICAL PROCEDURE STEP BY STEP

Procedure with flap should be performed when it is necessary to observe the underlying alveolar bone and adjacent anatomical structures.

Flapless procedure should be performed when there is sufficient quantity and quality of alveolar bone and soft tissue and it is not necessary to raise a flap to safely direct drilling procedure in relation to the anatomy.

1. Initial drilling

Once the gingiva has been opened, the implantation site shall be prepared. For this purpose, follow the drilling sequence below:

- **Step 1:** Use the Ø 2.0 mm long drill (JDDR20L) to penetrate the cortical bone.

The maximum speed for the Ø 2.0 mm long drill must be 1200 rpm.

Note: Be careful not to drill for a depth greater than that of the selected implants

- **Step 2:** Use the 26mm depth probe (JDNPR) to verify the depth of the site, in order to support the clinician in the choice of the implant with the appropriate length.

- **Step 3:** Drill to final depth with the Ø 2.4 mm long drill (JDDR24L).

The maximum speed for the Ø 2.4 mm long drill must be 1200 rpm.

- **Step 4:** Continue the osteotomy with the Ø 2.8 mm twist drill (JDDR28) at the entrance for 6 mm.

The maximum speed for the Ø 2.8 mm twist drill must be 1200 rpm.

- **Step 5:** Continue the osteotomy with the Ø 3.2 mm twist drill (JDDR32) at the entrance for 6 mm.

The maximum speed for the Ø 3.2 mm twist drill must be 1200 rpm.

- **Step 6:** Complete the osteotomy with the Ø 3.6 mm twist drill (JDDR36) at the entrance for 6 mm.

The maximum speed for the Ø 3.6 mm twist drill must be 1200 rpm.

2. Check of drilling direction

You can control the direction of the drilling at any time, using the direction indicator. The direction indicators are provided of notches to measure the depth of the implant site.

You may need a radiological examination to verify parallelism with other pieces or adjacent implants.

If necessary, correct the direction of the drilling.

When placing multiple implants, proceed with the same drill for all the osteotomies before moving to the next drill planned in the sequence.

3. Drill Stop

The drill stop enables dentists to control the depth of the implant site, during the drilling procedure.

For a safe and accurate drilling procedure, mount the Drill Stop on the drill.



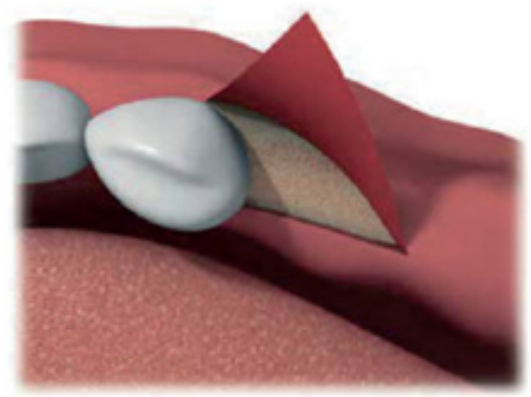
4. Possibility of “osseus infra-preparation” (infra-drilling) to obtain greater primary stability in soft bone.

In soft bone, the self-cutting property of the JDentalCare implants makes it possible the insertion of them with a high degree of infra-preparation, given that bone condensing in the apical region considerably increases the primary stability of the implant. Drill the bone up to 2 to 4 mm less than the total length of the implant and insert the implant in the drilled cavity.

Once the drilling depth is reached, the implant will have osteotomous effect, considering the bone and increasing primary stability until reaching optimal stability at the desired depth.

It is advisable to use the infra-drilling in suboptimal bone quality.

If the flapless technique is used (minimally invasive) it is necessary to remove gum tissue with a circular scalpel.



IMPLANT PLACEMENT

Unpacking of the implant

The fixtures of JDentalCare dental implants are subjected to sterilization by gamma irradiation and are single-use devices. The fixtures are packaged in polystyrene vial, placed into a rigid thermoformed blister sealed with a Tyvek paper. An adhesive label is affixed to the blister of all JDentalCare implants and it reports the main information related to the device. The intact sterile packaging protects the sterilized implant from outside influences and, if stored correctly, ensures the sterility of the device up to the expiration date.

Before the use, check the integrity of the sterile barrier, check that the seal and the welds are intact, that the Tyvek paper is not damaged and/or cut and that there are not detachment points from the blister.

On the blister of implants there is a red sticker, which is a gamma sterilization indicator. It confirms that the device has been subjected to sterilization by gamma radiation.

Warning: Do not re-use the devices (both implants and prosthetic components). If they are reused on another patient, there is a risk of cross-contamination and loss of the performance and functional characteristics of the device.

Warning: Do not use sterile devices after the expiration date.

Warning: Do not use the product if the gamma sterilization indicator is colored differently from red. Previously used or non-sterile implants must not be used under any circumstances.

Warnings: Implants must not be cleaned, disinfected and/or re-sterilized by the users prior to use, since otherwise the main material and design features may be compromised, leading to device failure.

Warning: Don't use the devices (both implants and prosthetic components) if the package has been damaged or previously opened.



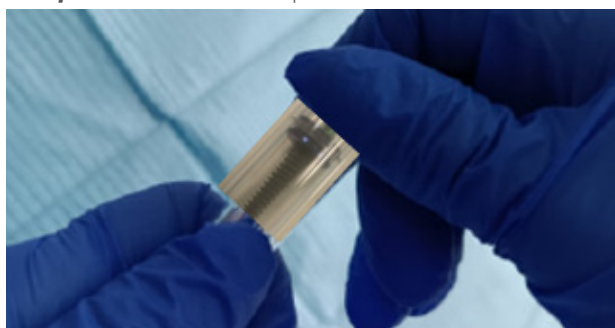
- **Step 1:** Remove the blister with the vial from the box



- **Step 2:** Open the blister: Open by pulling the peel tab located on the lower left corner of the blister. The sterile blister must be opened only at the moment it has to be used during the surgery. The vial must be handled with sterile gloves.



- **Step 3:** Remove the vial cap



Insertion of the implant

JDEvolution Plus L and JDEvolution Plus LE implants may be tilted up to 30° to the occlusal plane. When used with angulations at 30°, pay attention to the following:

- The tilted implant must be splinted; a minimum of 4 implants must be used when supporting a fixed prosthesis in a fully edentulous arch

Tilting of JDEvolution Plus L and JDEvolution Plus LE is a technique to achieve the following:

- Extend the Anterior – Posterior spread (to reduce cantilever lengths)
- Allow for placement of a longer implant

A well established prosthodontics procedure that utilizes the tilting described above in the maxilla is the Full Arch on 4 concept.

The implant shall be inserted slowly into the previously prepared site.

Warning: During insertion, do not exceed the maximum torque values indicated below:

- Insertion torque between 25 Ncm and 80 Ncm

• Step 1: Pick up the implant

The final placement of the dental implant, depending on the clinical situation, can be carried out using one of the following tools:

1. The JDTorque dynamometric key
2. The handpiece
3. The surgical driver

Caution: Pick up the implant taking care to extract it upright, avoiding any contact of it with other components of the vial (i.e blows and rubbing), because this may compromise the integrity of the implant.

Implant placement with JDTorque dynamometric key

Attach the surgical adapter to the JDTorque dynamometric key. Connect the implant driver to the JDTorque dynamometric key with the mounted surgical adapter.



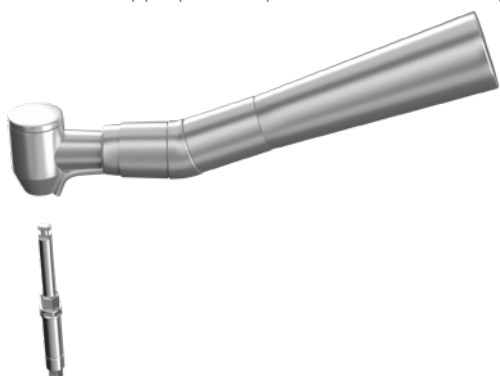
To connect the implant put light pressure on the driver.



Insert the implant in the previously made osteotomy. Move the implant into its final position turning it clockwise.

Implant placement with Handpiece

Connect the appropriate implant driver to the handpiece.



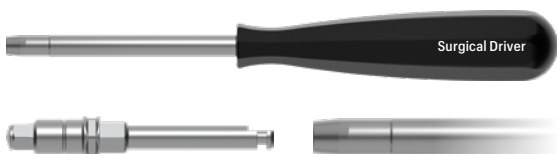
To connect the implant, apply light pressure on the driver.



Slowly insert the implant in the previously made osteotomy (25 rpm for JDEvolution Plus L and JDEvolution Plus LE implants)

Implant placement with the surgical driver

It is also possible to use the surgical driver to position the implant. Connect the implant driver to the surgical driver.



To connect the implant, apply light pressure on the drive.



Insert the implant in the osteotomy previously carried out.

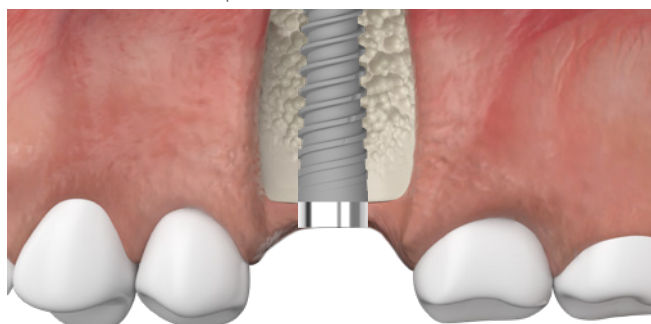
• Step 4: Final positioning

Connect the JD Torque dynamometric key with the JD Torque surgical adapter mounted on the driver of the implant and seat the implant to its final depth.

Note: Available abutment margin height needs to be considered during the planning of implant placement to assure appropriate seating depth of the implant relative to the available soft tissue thickness and the planned emergence of the restoration.

To carry out immediate load protocols, the implant should be inserted with a final insertion torque of 35-45 Ncm but without exceeding in any case 80 Ncm. You can withdraw the driver by extracting it with vertical movement.

Note: Final vertical positioning depends on several clinical parameters, including esthetics, tissue thickness and available vertical space. Pay attention to the "Unthreaded machined collar" implant version positioning: the implant body "unthreaded machined collar version" must be placed so that the unthreaded machined collar is in the gingival area.



IMPLANTS WITH AN UNTHREADED MACHINED COLLAR
MUST BE PLACED SO THAT THE UNTHREADED MACHINED
COLLAR IS IN THE GINGIVAL AREA

Caution: Avoid excessive force when inserting the implant with the dynamometric key given that inadequate pressure on the bone could cause necrosis and compromise integration with the bone.

If you observe excessive torque (of approximately 80 Ncm) at any stage of the insertion, rotate the implant in the counter-clockwise direction two or three turns in order to take advantage of its self-tapping capacity and continue with the insertion.

However, if you still encounter too much resistance, pull out the implant and carry out a more extensive osteotomy.

Implant orientation

At the time of the final placement of the implant, when the desired depth has been reached, it is necessary to align the reference points in the driver with the vestibular wall.

The profile of the internal connections of JDentalCare dental implants makes it possible to place and to orient the implant using implant drivers.



The implant driver has a 3 mm mark to facilitate the vertical positioning of the implant platform in accordance to soft tissue thickness (applicable in flapless surgery).



Cleaning the surgical site

After the placement of the implant, the site shall be irrigated with sterile water or saline solution in order to remove any residual of bone and tissue debris and/or blood.

This procedure is preparatory to the following insertion of the prosthetic components.

Post-operative care

Patient should be informed on the need for regular oral hygiene.

It is important that regular check-up is carried out in order to complete in the best way the planned implant-prosthetic treatment.

IMMEDIATE LOADING

If the implant is inserted with high primary stability it is possible to fix a provisional prosthesis using the JDentalCare provisional components or definitive abutments (consult the compatibility information paragraph below).

When placing implants in soft bone aiming for an immediate loading the following choices can improve the situation:

- Splinting in a multi-unit restoration
- Maximizing implant to bone contact area using long implants

JDEvolution Plus L and JDEvolution Plus LE implants with length of 18, 20, 22, 24 and 26 mm allow the surgeons to take advantage of long implants, which may be combined with other options listed above.

COMPATIBILITY INFORMATION

JDEvolution Plus L and JDEvolution Plus LE implant platform is compatible for use only with JDEvolution Plus prosthetic components manufactured by JDentalCare. Please consult the Prosthetic procedure available at www.jdentalcare.com to select the appropriate prosthetic component.



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Caution: Federal (US) law restricts this device to sale by or on the order of a licensed dentist.

See Instructions for Use for more information such as indications, warnings, precautions and contraindications.

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