







Surgical Procedure Prosthetic Procedure

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Dental Implant

GENERAL INFORMATION

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Read this manual carefully before starting the treatment.

This manual must be used as a reference guide by the doctor so as to optimise the use of the implants, surgical instruments, and the prosthetic components of the system.

The design of JDentalCare® implant system JDIcon® products allows the safe insertion of implants into the mandibular or maxillary bone, fully or partially edentulous, to affix a removable or permanent prosthesis. The JDentalCare® implant system JDIcon® uses proven surgical processes for the affixing of implants in bone tissue, with optimal osseointegration.

The prosthetic procedures described in this manual represent the latest advancement in the field, ensuring the best esthetics and functionality.

The success of an implant system, however, depends on the correct use of its instruments and components. This manual is merely complementary to the training and experience of the professional. Before starting with a new treatment method it is recommended to inform oneself thoroughly on the techniques and procedures to use. To this end, our company offers a consulting service by our experts, who are available at your disposal, as well as a large variety of training courses for all levels. For further information please visit: **www.jdentalcare.com**

INDICATIONS FOR USE

JDentalCare® implant system JDIcon® is intended to replace missing masticatory functional units (teeth) within the maxilla or mandible. JDentalCare® implant system JDIcon® is comprised of dental implant fixtures and prosthetic devices. It 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. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla. JDentalCare® implant system 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.

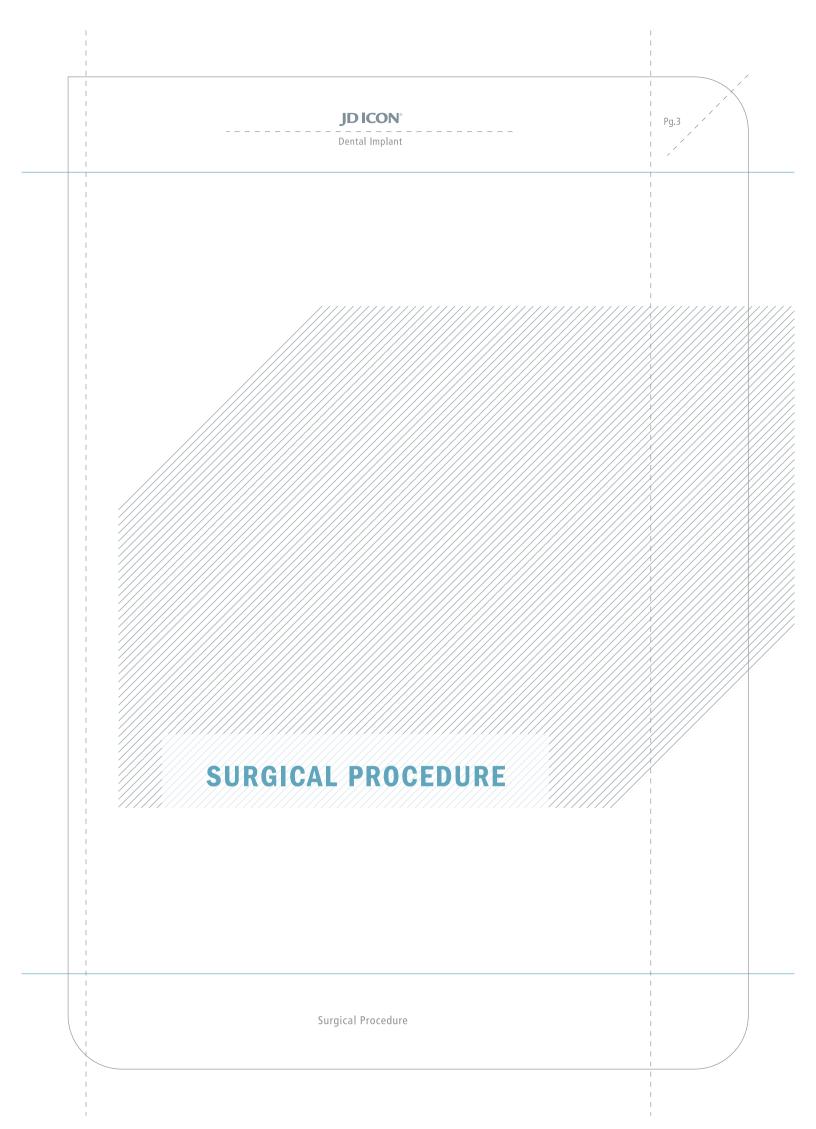
JDentalCare® implant system JDicon® 2.75mm Dental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors for single-stage or two-stage procedures. It is for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

Federal law restricts this device to sale by or on the order of a licensed dentist or physician.

The JDentalCare® implant system JDIcon® has not been evaluated for safety and compatibility in the MR environment. It has not been test for heating, migration or image artifact in the MR environment. The safety of JDentalCare® implant system JDIcon® in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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General Information





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EXAMINATION AND TREATMENT PLANNING

Before beginning the treatment a detailed examination will be necessary of the general health conditions of the patient as well as a careful evaluation of his/her motivation and expectations. It is also necessary to consider key factors such as oral hygiene, occlusion type and habits such as smoking. must rule out the presence of soft tissue pathologies and must consider whether the patient's bone condition is ideal for the insertion of the implant.

Quality of the bone

Generally, dense bone gives the implant a good primary stability, while soft bone requires "under-preparation" of the implant bed to be able to guarantee an adequate primary stability.

Vertical bone quantity

The quantity of available bone for the insertion of the implant varies in function of the anatomy. The JDentalCare® implant system JDIcon® design allows the affixing and stabilisation of the implant in only three millimetres of bone. The available bone may be situated in the most apical section of the implant, as it happens in a post-extraction sites, or at the neck section of the implant, as in cases of maxillary sinus elevation procedure.

Horizontal bone thickness

After placement of the implant the thickness of the residual bone needs to be at least one millimeter, in both lingual-

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

You can use the flapless technique when there is an optimal quantity of bone and soft tissue. Use flap technique when it is necessary to examine the alveolar bone and the adjacent anatomical structures, and when executing ridge augmentation procedures.

Important: an objective 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 the quality of the available bone.





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IMPLANT DIAMETERS AND LENGTHS

To ease treatment planning and the clinical procedures, JDentalCare® implant system JDIcon® are available in various easily identifiable diameters and lengths using colour coding. JDentalCare® implant system JDIcon® products are distinguished by their unique prosthetic connection, in which the abutment platform is the same for all implant diameters. Available lengths for each diameter are indicated in the following table.











Ø 2.75 Ø 3

Ø 4.3

Ø 5.0

IMPLANT DIAMETER	TIP DIAMETER	ABUTMENT INTERFACE	PLATFORM DIAMETER	LENGTH	
Ø 2.75	2.0	2.3	2.75	10 11.5 13 15	-
Ø 3,9	2.9	3.4	3.9	8 10 11.5 13 15	
Ø 4,3	3.2	3.4	4.0	8 10 11,5 13 15	
Ø 5	3.6	3.4	4.7	8 10 11,5 13 15	_

Note: All dimensions are expressed in millimeters.

All implants L8mm are available only fully treated.

WARNING:

Small diameter implants and angled abutment are not recommended for the posterior region

Surgical Procedure

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Dental Implant

DRILLING SEQUENCE

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The drills provided with the surgical kit must be used with external irrigation to prevent excessive heating of the bone tissue. Drilling must be interrupted if it is not possible to verify irrigation.

Drill with an in and out pumping motion without excessive force. When doing this movement, you will have to take out the drill completely to check that irrigation is taking place correctly.

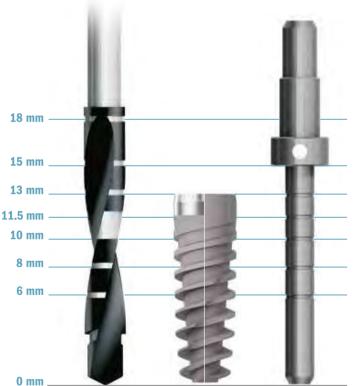
Drills are characterised by their inclined wedges allowing the homogeneous distribution of the cooling physiological solution, as well as the conservation of cortical bone shavings resulting from the drilling process after the preparation.

If the sharpness of the drill diminishes, the latter must be pulled out of the handle for cleaning. Proceed until you are able to take the drill to the desired depth.

Should there be adjacent natural teeth interfering with the head of the contra-angle, the drill extension must be used. It is advisable to use surgical motors with adjustable speed and torque.

Important: The initial drill head is of the precision type.

Drill heads must be substituted approximately every 20 osteotomies, or when their cutting efficiency diminishes.



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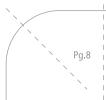
Dental Implant

Drilling sequence

It is recommended to adhere to the indications of the following drilling sequence to ensure optimal primary stability of the implant.

IMPLANT DIAMETER	SOFT BONE TYPE IV	MEDIUM BONE TYPE II-III	DENSE BONE TYPE I
Ø 2,75	1,5 2,0	2,0 2,4	2,0 2,4 2,8*
Ø 3,9	2.0 2.4 (2.8)	2.0 2.4 2.8 (3.2)	2.0 2.4 2.8 3.2 (3.6)
Ø 4,3	2.0 2.4 2.8	2.0 2.4 2.8 3.2 (3.6)	2.0 2.4 2.8 3.2 3.6 (4.0)
Ø 5	2.0 2.4 2.8 3.2	2.0 2.4 2.8 3.2 3.6 (4.0)	2.0 2.4 2.8 3.2 3.6 4.0 (4.4)

Note: All dimensions are expressed in millimeters.



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Drill Stop procedure

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

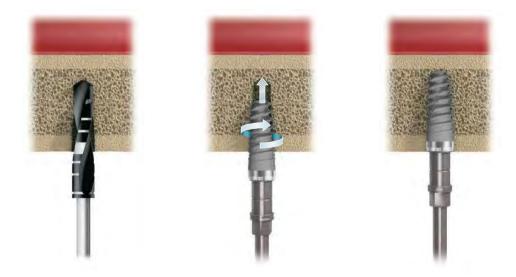


Possibility of "osseus infra-preparation" (infra-drilling) to obtain greater primary stability in soft bone.

In soft bone, the self-threading capacity of the JDentalCare® implant system JDIcon® also make it possible to insert them with a high degree of infra-preparation given that bone condensing in the apical region considerably increases the primary stability of the implant. If it is desired to use this characteristic of the implant it is necessary to drill the bone up to 2 to 4 mm less than the total length of the implant.

Insert the implant in the drilled cavity. Once the drilling depth is reached the implant will have osteotomous effect, condensing 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.



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CLINICAL PROCEDURE STEP BY STEP

The illustrations show the drilling sequence for a JDentalCare® implant system JDIcon® 4.3 x 13 mm implant in medium bone. The drilling protocol for all diameters and bone qualities must be consulted in the preceding table.

If the technique of surgery with flap is used for a better visualisation of the bone anatomy, it will be necessary, as a preliminary operation, to make an incision along all the thickness of the soft tissue, and lift the gum edge to access the bone crest.



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

Initial precision drilling

Drill a hole on the crest with the ø 1.5 mm precision drill. The initial precision drill features an aggressive cutting angle that is efficent even in dense bone.

Make sure that you do not drill with the precision drill to a depth greater than that of the selected implant.

The maximum drilling speed with the precision drill must be 800 rpm.





Note: When operating flapless, always measure the thickness of soft tissue with a probe, for a correct preparation of the osteotomy to the desired depth.



Only if you use flapless surgery:

Tissue punch

Insert the direction guide for the tissue punch corresponding to the diameter of the selected implant in the ø 1.5 hole. Connect the tissue punch to the contra-angle and position it on the guide. Incise into tissue until reaching the osseous crest.

JD ICON°

Dental Implant

The speed must not exceed 800 rpm.



With the use of a normal or small surgical blade incise perpendicularly along the outline of the soft tissue so as to free it and remove it from the top of the crest.

Ø 2 drill

To continue preparing the osteotomy use the ø 2.0 drill. Maximum speed must be 800 rpm.



Direction indicator

You can control the direction of the drilling at all times using the direction indicator. 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 in the sequence.





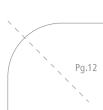


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Ø 2.4/2.8 drilling FLAPLESS WITH FLAP To continue with the preparation use the \emptyset 2.4/2.8 drill head. Maximum drilling speed is to be 800 rpm. \emptyset 3.2/3.6 drilling FLAPLESS WITH FLAP To continue with the preparation use the \emptyset 3.2/3.6 drill head. Maximum drilling speed is to be 800 rpm. Control the depth of the drilling and integrity of the cortical walls in the prepared cavity using a probe. Insertion of the implant The printed label on the exterior of the package contains information on the dimensions of the implant: the diameter, associated with a colour code and the length. Open the package in a sterile environment and remove the plastic protection to access the implant.



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The final placement of the JDentalCare® implant system JDIcon® depending on the clinical situation, can be carried out with one of the following methods:

1. The JDTorque® dynamometric key

2. The surgical engine



Important: An excessive torque on the implant may compromise the integrity of the internal connection and put excessive pressure on the surrounding bone, negatively affecting bone integration. The implant insertion torque cannot exceed 80 Ncm.

Use of 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.

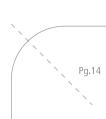


Surgical Driv

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Dental Implant





Dental Implant

Use of the surgical driver

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

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

Insert the implant in the osteotomy previously carried out.

Surgical Procedure

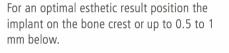
FLAPLESS

Dental Implant

Final positioning

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

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

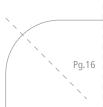




Implants with a machined collar must be placed so that the machined collar is in the gingival area. Pg.15



Important: 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-threading 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.



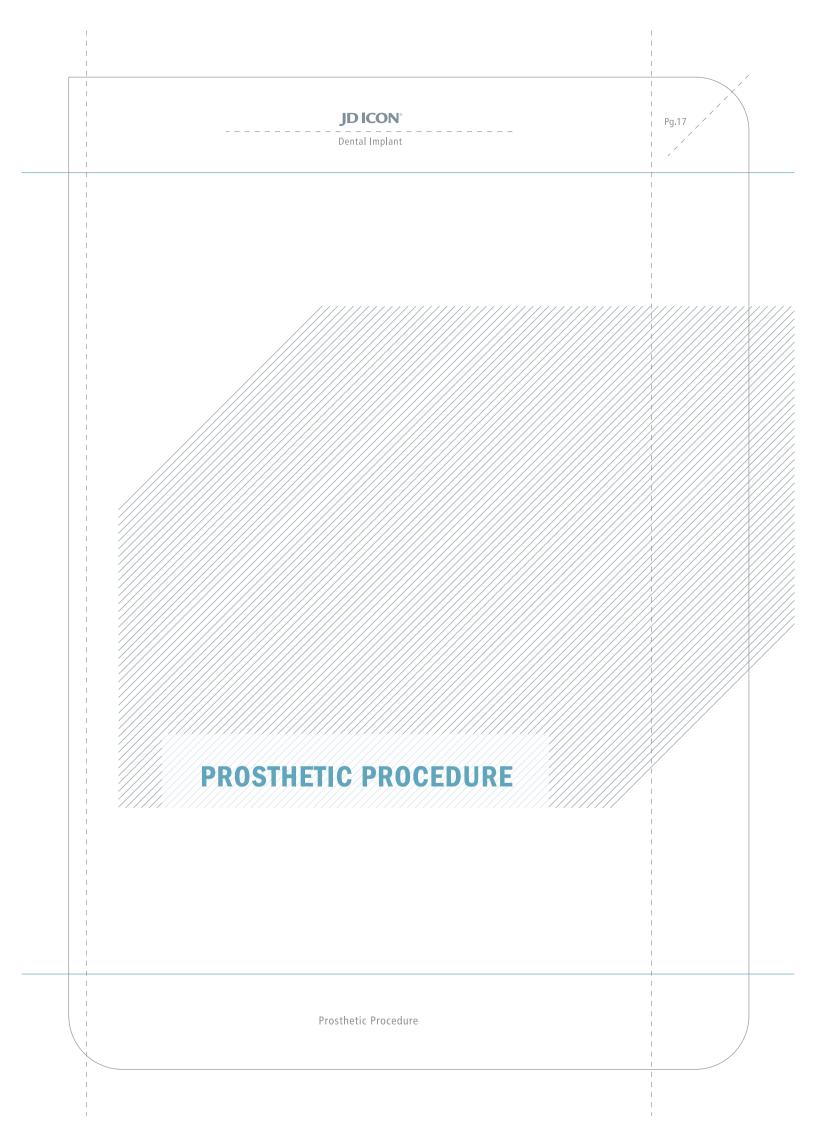
Dental Implant

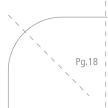
Orientation of the implant

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. In this way the hexagonal shape of the internal connection makes it possible to position and orient the prosthetic abutment in an optimal manner.

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).



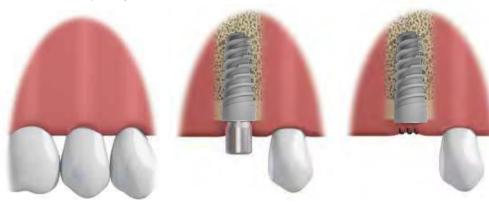




Dental Implant

FINALISATION OF THE IMPLANT SURGERY

There are three options for the finalisation of the implant surgery intervention using JDentalCare® implant system JDIcon®.



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 aforementioned procedures).

NON-SUBMERGED HEALING

Screw into the implant a healing abutment, adapt soft tissue and suture.

SUBMERGED HEALING

Screw a cover screw into the implant and suture with preferred technique.

Bone Mill

If bone above the implant platform interferes with complete seating of any components (healing abutment, impression coping, abutment), the Bone Mill with its guide are used either manually or at low speed in the handpiece to clear the path of insertion.



Dental Implant

Depending on the clinical situation and the choice of the surgeon, there are three options to anchor prosthetic components of the JDentalCare® implant system JDIcon®:

1. Using the JDTorque[®] dynamometric key: connect the JDTorque[®] dynamometric key to the prosthetic adapter and using the screw driver proceed to screw in the prosthetic component.

2. Using a surgical engine connected to a machine screw driver.

3. Using a manual screw driver. Connect the JDTorque[®] prosthetic adapter to the machine screw driver and manually screw in the prosthetic component.

Healing Abutment

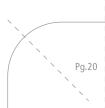
Indications: closing of the implant connection for non-submerged healing.

Connect the healing abutment of the correct diameter and height .

Adapt the soft tissues and suture them around the healing abutment.



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Dental Implant

Implant level Impression

Transfer the position of the implant in the mouth of the patient to a master model so as to select a prosthetic abutment that is adequate for the treated clinical case and for the dentist's requirements.

Abutment level impression

The abutment is selected, positioned, and placed by the dentist. To transfer the position of the abutment in the mouth of the patient to the prosthetic model it is necessary to use an impression coping specific for the selected abutment. The prosthetic restoration will be undertaken in a way adaptable to the abutment.



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Conventional impression

This technique is used when the dentist selects and modifies a definitive abutment to cement a single or multiple unit restorations (crown and bridge technique).

The abutment is fixed to the implant, modified using conventional preparation methods directly in the mouth, using high speed handpiece with abundant irrigation.

Perform a conventional impression of the abutment or abutments previously prepared in the mouth (it is recommended to use a retraction cord).





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TEMPORARY SOLUTIONS FOR THE DENTAL LABORATORY

Temporary Abutment



Indications: screwed-in temporary of single implant cases and cemented temporaries of multiple implant cases





Indications: screwed-in temporaries of multiple implant cases

For cemented crowns and bridges

Pour and make a master model using the corresponding replica.

Position, and fix to the replica, the temporary engaging abutment.

Modify the temporary abutment in function of the existing situation in the mouth of the patient, verifying the necessary occlusal space for the covering materials (do not reduce the abutment to less than 4 mm in height and do not modify wall thickness, diameter and angulation).

Make the crown or bridge to be cemented using conventional processes.

Position the temporary abutment on the implant and screw in manually or with the JDTorque®

dynamometric key, with a torque set between 15 and 35 Ncm. Cover the head of the screw with cotton and temporarily seal the screw channel.

Fill the inside of the crown or the bridge with temporary cement, and place it on the prepared temporary abutment(s).

For screwed-in crowns and bridges

Pour and make a master model using the corresponding replica.

Position and fix the temporary abutment to the replica.

Modify the temporary abutment in function of the existing situation in the mouth of the patient, checking the necessary occlusal space for the covering materials (do not reduce the abutment to less than 4mm in height).

Temporarily seal the screw channel (with cotton, for example) and make a screwed-in crown or bridge with conventional procedures.

Position the temporary abutment on the implant and screw in manually or using the JDTorque® dynamometric key with a torque ranging between 15 and 35 Ncm.

Cover the screw channel with cotton and seal it temporarily with a temporary filling material (composite for example).

Note: To verify the correct adaptation of the abutment to the implant it is necessary to make an X-ray control.

Dental Implant

CHAIR-SIDE TEMPORARY RESTORATIONS

GP Abutment



Indications: cemented temporary restorations of single and multiple implants.

Place the abutment onto the implant and screw it.

Verify the direction and the length of the GP abutment in respect of the adjacent teeth/implants and the necessary occlusal space for the covering materials.

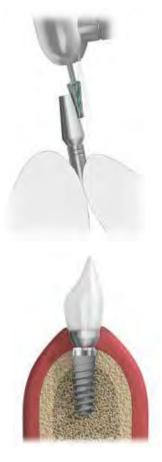
Unscrew the abutment, push it onto an implant replica and modify it in function of the existing situation (do not reduce the abutment to less than 4 mm in height and do not modify wall thickness, diameter and angulation).

Place the modified GP abutment onto the implant and screw it in with a torque of 20 Ncm using the JDTorque[®] dynamometric key or a surgical motor connected to the machine screwdriver.

Note: to verify the correct adaptation of the abutment to the implant it is advisable to make an X-ray control.

A provisional restoration can be relined with acrylic resin directly in the mouth, refined, polished and cemented with temporary cement.

The GP abutment can be used also as a definitive abutment. After tissue healing it is possible to perform a conventional impression of the abutment (it is recommended to use the retraction cord) to make the definitive prosthesis.



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Dental Implant

ABUTMENT SELECTION

Selection of the final abutment is decisive for the final result of the prosthesis to comply with the functional and esthetic requirements of the dentist and the patient. The dentist can choose the abutment and subsequently send to the laboratory an impression taken at the abutment level, or can take a direct implant level impression and later communicate to the dental technician which abutment to use.

For the selection of the final abutment it is necessary to consider certain aspects:

Prosthesis type

Cemented prosthesis

Cemented prosthesis are placed using the same conventional protocols that are used in the techniques of cemented crowns and bridges over natural teeth. The abutments are screwed in to the implants and the prosthesis is cemented on top of them.

Screwed-in prosthesis

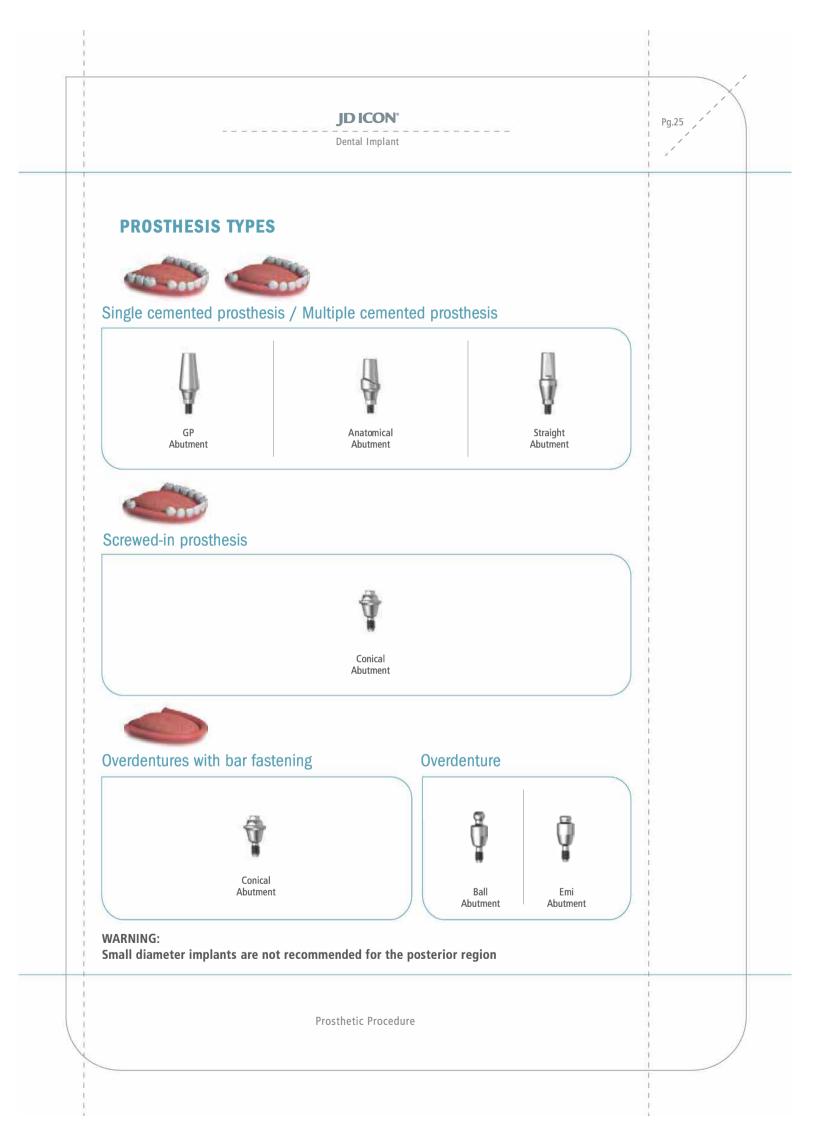
A screwed-in prosthesis is affixed with screws through the occlusal part of the prosthesis. The screw goes through the crown and goes into the abutment or into the implant. The prosthesis may be unscrewed at any time by the dentist.

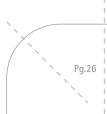
Soft tissues height

To determine the correct height of the soft tissue, measure with a probe the depth of the latter around the implant. The selection of the abutment transgingival height will depend on the hygienic and the esthetic considerations of the dentist.

Interdental space and emergence profile

Available interdental space and emergence profile requirements are key to abutment selection.





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CEMENTED PROSTHESIS

Straight Abutment



Indications: single or multiple unit cemented prosthesis

The laboratory receives an impression at the implant level with a replica of the implant. Pour and make a master model.

Select the titanium abutment that is suitable in function of the height of the soft tissues and affix it to the implant replica with a laboratory screw.

Do not reduce the abutment to less than 4 mm in height and do not modify wall thickness, diameter and angulation. Fabricate the prosthesis in the lab using all the steps conventionally required to fabricate a crown or a bridge on implant abutments with analog (lost-wax casting process) or digital procedures.



Indications: single or multiple unit cemented prosthesis

The anatomical abutment has been designed with an anatomical festoon preparation of the cervical margin . This ensures lesser need of abutment preparation and a better adaptation to the natural profile of soft tissues, given that it is available with different heights.

- The laboratory receives an impression at the implant level with an implant replica.
- Pour and make a master model.
- · Select the anatomical abutment and fix it to the replica of the implant with a lab screw.
- Do not reduce the abutment to less than 4 mm in height and do not modify wall thickness, diameter and angulation. Fabricate the prosthesis in the lab using all the steps conventionally required to fabricate a crown or a bridge on implant abutments with analog (lost-wax casting process) or digital procedures.

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SCREWED-IN PROSTHESIS

Conical Abutment





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Indications: screwed-in prosthesis

The conical abutments are intended only for multi-unit restorations, with no angulation corrections.

Connection of the straight conical abutment Screw in the conical abutment onto the head of the implant in the correct position using the plastic transporter

that comes assembled. If height is insufficient the transporter can be cut. Once in position the plastic transporter can be manually detached from the abutment.

To verify the correct adaptation of the abutment to the implant it is recommended to make an X-ray control. Screw in the abutment at 35 Ncm using the dynamometric key JDTorque[®] or the surgical motor/engine connected to the screw driver.





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Closed tray impression for conical abutment

Place the impression copings on the conical

abutment replicas to the impression copings.

copings and inside the impression tray.

into the cast.

abutments,

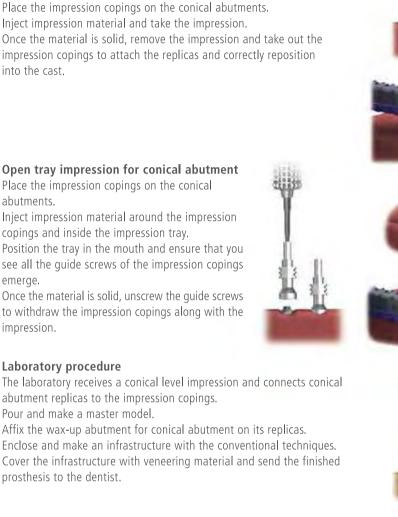
emerge.

impression.

Laboratory procedure

prosthesis to the dentist.

Pour and make a master model.



Note: it is possible to make a provisional prosthesis on the conical abutments using the temporary cylinder for conical abutment.

Connection of the final prosthesis

Connect the prosthesis to the conical abutment with the prosthetic screws. Starting from the central zone, adjust the other screws, alternating the left with the right side.

Screw in the prosthetic screw at 15 Ncm using the JDTorque[®] dynamometric key or the surgical engine connected to the screw driver.

Cover the access channels of the screws with cotton and seal them with a temporary filling material (composite for example).







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OVERDENTURE

Ball Abutment



Indications: overdentures

Emi Abutment



Indications: overdentures with emi anchoring.

with ball anchoring.

Connection and impression

Screw in the ball abutment or the emi abutment to the head of the implant with the screwdriver.

To check the correct adaptation of the abutment to the implant it is advisable to take an X-ray control.

Take the impression in the conventional way. When the material is solid you can take out the cast and connect the ball abutment or the emi abutment replicas.



Laboratory procedures

The laboratory receives an impression at the abutment level with positioned replicas of the ball abutments or the emi abutment.

Pour and obtain a master model.

Block the abutment replicas and prepare an occlusal rim.

Send to the dentist for interocclusal records.

Prepare a teeth set up using the conventional technique.

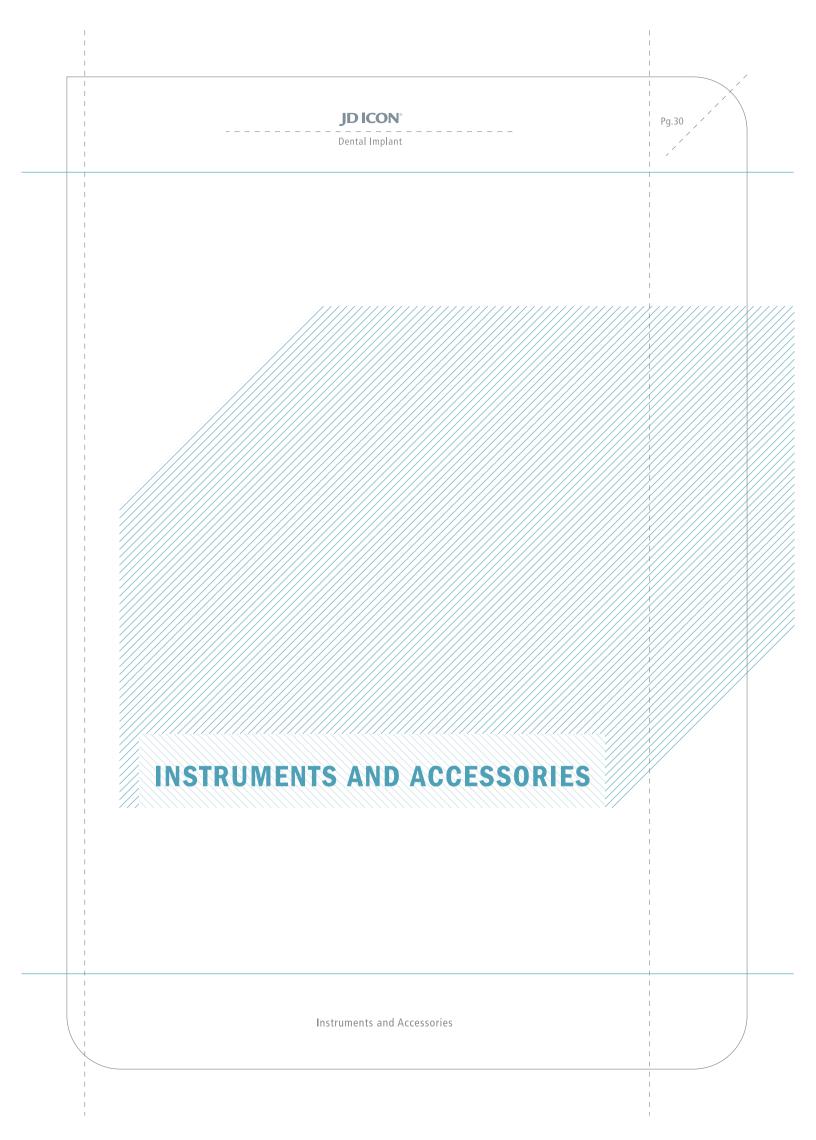
Position the metal female pieces in the replicas of the ball abutments or the emi abutment so that they are parallel to each other with respect to the horizontal and vertical planes.

Block the space between the female piece and the replica.

Cure and finish the prosthesis using the conventional technique.

Send to dentist for delivery.





Dental Implant

MANUAL CLEANING, DISINFECTION AND DRYING

The following instructions should be used for cleaning multiple-use medical devices supplied by JDentalCare including drills, surgical kits, temporary and final prosthetic components such as abutments and screws.

1.Remove debris in lukewarm water and soak devices in cleaning solution.

Remove residual tissue or bone debris by immersing the used instruments in lukewarm water (<40°C /104°F). Do not use fixation agents or hot water (>40°C/104°F) as this could influence subsequent cleaning results. Instruments should be kept in wet environment until next step is initiated. Soak the instruments in a cleaning solution prepared with lukewarm tap water. Soaking time not less than specified in the detergent manufacturer's instructions.

2.Scrub devices with soft bristled nylon brush.

Scrub the instruments with a soft bristled nylon brush until all visible soil and/or debris is removed. Pay particular attention to features that may be shielded from the brushing action.

3.Soak in ultrasonic bath.

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Prepare an ultrasonic bath with cleaning solution at the concentration and temperature specified in the detergent manufacturer's instructions.

Immerse the device completely and activate the bath for at least the time specified in the detergent manufacturer's instructions.

4. Rinse with purified or sterile water.

Rinse for at least 1 minute with freshly prepared purified water or sterile water until traces of cleaning solution are removed.

5.Soak in disinfection solution.

Prepare a bath with a disinfection solution at the concentration and temperature specified in the detergent manufacturer's instruction.

Immerse the device completely for at least the time specified in the detergent manufacturer's instructions.

6.Rinse with purified or sterile water.

Rinse for at least 1 minute with freshly prepared purified water or sterile water until traces of cleaning solution are removed.

7.Dry with compressed air or wipes.

Dry the devices using medical compressed air and clean lint-free single-use wipes.

Instruments and Accessories

Rev. 05 of 11/05/

