USE INSTRUCTION

Figure 1 FC Regular

Figure 2 FC Short

ATTENTION: The figures are merely illustrative. They do not represent the real dimensions.

This device is intended to a specialized procedure, which shall be made by professionals qualified in Dental Implants. To achieve optimized results, use the product knowing the proper techniques. Always apply them in proper conditions in a surgical environment.

DESCRIPTIVE INFORMATION

INDICATION OF USE

The System of FC Regular and FC Short Implants is intended to be surgically installed on the human upper and lower jawbone, serving as support for prosthetic devices, such as artificial teeth, in order to restore the masticatory function. The DSP Implant System may be used in one- or two-stage procedures, for unit or multiple restorations, enabling performance of immediate loading, when achieving a good primary stability and the proper occlusal loading.

DESCRIPTION OF THE DEVICE

Flexcone REGULAR (FC REGULAR) and Flexcone SHORT (FC SHORT) are dental implants made of commercially pure titanium (Grade 4). Their external surfaces are treated with mechanical attack and chemical attack. FC REGULAR and FC SHORT present a design of conical root type (conical) and an hexagonal coronal portion. They present trapezoidal threads and apex with three land lips to facilitate their installation. They are supplied with a fitter. The implants may be installed with Surgical Motor or Torque Wrench (manual).
They are available according to the table below.

IMPLANT	DIAMETER (mm)	HEIGHT (mm)	PLATFORM (mm)
FC REGULAR	3.8, 4.3, 5.0	8.5, 10, 11.5, 13, 15	4.0
FC SHORT	3.8, 4.3, 5.0	5.5, 6.0, 7.0	4.0

WARNING

The non-recognition of the real lengths in relation to the radiographic measures may result in permanent injury to the nerves and other vital structures. The drilling beyond the depth intended to the surgery of the lower jaw may result in permanent numbness on the lower lip and chin or lead to bleeding on the lower part of the mouth.
Follow the mandatory procedures of any surgery, such as: asepsis during the bone drilling, avoid damages in blood vessels and nerves, using the pre-surgery anatomical and radiographic knowledge.

CONTRAINDICATIONS

This product is contraindicated for patients that present signs of allergy or hypersensitivity to the composition of the material: titanium.
In the presence of acute inflammatory or infectious processes, inadequate bone volume or quality, serious clinical problems, such as: disorders of the bone metabolism, disorders of blood coagulation, inadequate capacity of regeneration, insufficient oral hygiene, incomplete growth of the jaw, non-collaborative and non-motivated patient, undue use of drugs or alcohol, psychosis, extended functional disorders that resist to any treatment with medicines, xerostomia, weakened immune system, diseases requiring the use of steroids, endocrine diseases, pregnancy.

RISKS AND BENEFITS

As any surgery, there is no total guarantee of operation, because achieving a good performance involves several factors, being them usability, clinical conditions of the patient, and the product itself. Non-observance of the indicated limitations of use and work stages may result in failure.

The non-recognition of the real lengths of the risks in relation to the radiographic measures may result in permanent injury to the nerves and other vital structures. The drilling beyond the depth intended to the surgery of the lower jaw may result in permanent numbness on the lower lip and chin or lead to bleeding on the lower part of the mouth.

APPLICATION

FC REGULAR is indicated for surgical intraoral installation in bones with density III and IV, and FC SHORT is indicated for surgical intraoral installation in bones with density I, II, III, and IV according to Lekholm & Zarb classification of maxillary quality (1985). FC Regular and Short implants may be installed immediately after the performance of dental extraction; they are not recommended for correction or angular divergence.
For unit restorations, the FC REGULAR and FC SHORT implants shall be exclusively used with a coping that extends the portion of the level of the tissue at a minimum of 4 mm. For multiple restorations, the FC REGULAR and FC SHORT implants shall be exclusively used with a coping that extends the portion of the level of the tissue at a minimum of 2mm or with the O-ring pillar.

PRECAUTIONS

- Do not use the product if the package is violated.
- Do not use the product if the validity is expired.
- The material to be used during the procedure shall be sterile.
- This product shall be used immediately after the opening of the package, at the surgery time. If it is not used, dispose of it.
- This product is of single use and may not be re-sterilized.
- Reprocessing is Forbidden.
- The reuse of this product may cause adverse biological effects due to microorganisms and/or substances resulting of previous uses and/or reprocessing; changes in the physical, mechanical, and chemical properties of the products, macro- and micro-structural, which may put the function desired at risk.
- The reuse of this product does not guarantee its safety and efficacy and exempts any guarantee of the product.
- Observe the conditions of the intraoral tissue, the bone quality, and the quantity of the bone bed, through radiographic exams and/or tomography. The absence of the pre-surgery assessment may compromise the success of the procedure.
- The inadequate surgical and/or prosthetic planning may compromise the performance of the implant/prosthesis set, resulting in failure in the system, such as loss or fracture of the implant, loosening, or fracture of prosthetic components and/or screws.
- The maximum installation torque suggested is 55 N.cm. The insertion torque higher than the recommended one may make the system inoperative.
- Before each procedure, certify that the parts are duly laid down.
- Certify that the parts are not swallowed or aspirated by the patient.
- Check the passivity and make the occlusal and interproximal adjustments after the installation of the prosthesis, avoiding the impairment of the implant/prosthesis set.
- Before each procedure, check the conditions of DSP Biomedical surgical instruments, always respecting their service life. Replace the instruments if there are damages, marks removed, sharpening compromised, deformation, or wear and tear.
- Always use the sequence of DSP Biomedical products, the use of prosthetic components and/or instruments of other manufacturers does not guarantee the perfect function of the DSP Implant System, and exempts any guarantee of the product.
- It is the professional's responsibility to use the DSP Biomedical products according to the instructions of use.

IMPORTANCE OF THE NEED OF ADHESION TO A CARE REGIME

The products shall be protected against aspiration when handled through intraoral way. The aspiration of products may lead to infection or physical injury not planned. If you want to protect it, use a rubber barrier. If an implant or an instrument is swallowed or aspirated, immediately call a doctor. In addition to the mandatory precautions to each surgery, such as asepsis, during the drilling in the jawbone, it shall be avoided damages to the inferior alveolar nerve and to the facial, deep facial, superior and inferior lip blood vessels. The anatomic knowledge and the pre-surgery medical images (for example, radiographies) shall be referred to.
The non-recognition of the real duration in relation to the radiographic measures may result in permanent injury of the nerves and other vital structures. The drilling beyond the depth intended to the surgery of the lower jaw may potentially result in permanent numbness on the inferior lip and chin or lead to bleeding on the floor of the mouth.
The inadequate use of the products lead to a work poorly performed, and increase of the risk. In particular, the users of manual tools shall take care of gently using them and with attention. The user shall always avoid touching on the instruments and pieces with no protection (sterile protective gloves and aprons shall be used). The thermal bone damages caused by rotary and oscillating tools shall always be avoided (user's training, work at low speed and with sufficient cooling. During the intraoral application, it shall pay attention to the fact that the products are protected against aspiration or dropping on the floor. The rotary instruments need to be fixed as further as possible with their speed set before the application. Do not exceed the recommended drilling speeds, since it may cause bone necrosis or fracture of components of the system. The inadequate cleaning and sterilization of the instruments may result in the patient's infection with harmful bacteria. To avoid damaging the instruments, they shall be individually taken out of the blister package.

Do not use the device if the primary package had been damaged or previously opened.
Do not use damaged or forceful instruments for drilling. The broken land lips of the instruments cause vibrations and high pressure forces, which, on their turn, leads to broken preparation corners and rough surfaces. Instruments that are folded and/or do not work shall be immediately disposed of. Damaged, corroded, or worn devices shall not contact intact instruments to avoid contact corrosion.

OPERATION INSTRUCTION

DRILLING

Under abundant irrigation, perform the drilling with drills in good cutting conditions and rotations between 800-1200 rpm. Select the sequence of drills according to the intended implant according to the table below. The depth of insertion of the drills shall observe the planning of the final position of the implant.

SEQUENCE OF FC REGULAR DRILLS – BONE TYPE III AND IV					
IMPLANT DIAMETER mm	LANCE DRILL Ø2.0mm	CONICAL DRILL Ø2.5mm	CONICAL DRILL Ø3.8mm	CONICAL DRILL Ø4.3mm	CONICAL DRILL Ø5.0mm
Ø3.8	●	●	●		
Ø4.3	●		●	●	
Ø5.0	●		●		●

● Indicated

SEQUENCE OF FC SHORT DRILLS – BONE TYPE I, II, III, AND IV					
IMPLANT DIAMETER mm	LANCE DRILL Ø2.0mm	SHORT CONICAL DRILL Ø3.5mm	SHORT CONICAL DRILL Ø3.8mm	SHORT CONICAL DRILL Ø4.3mm	SHORT CONICAL DRILL Ø5.0mm
Ø3.8	●	●	●	●	●
Ø4.3	●		●		
Ø5.0	●		●		

● Indicated

The drilling depth of the drills, as well as their size, shall be in compliance with the model of implant selected during the planning, considering measures of the implant, installation level, three-dimension spacing.

SEQUENCE OF IMPLANT HANDLING

1. The box of the Implant shall be manually opened, with no sterile gloves.
2. Break the seal of the box and remove the Blister. Open the Blister and put the USB stick on the sterile surgical field.
3. Using sterile surgical gloves, hold the tube with the non-dominant hand, and remove the Badock (cap of the tube) with the dominant hand.
4. For installation using a surgical motor, capture the implant with the proper connection driver. Take the implant to the surgical cavity. In the surgical motor, use maximum torque of 35 Ncm and rotation of 20-30 rpm.
5. Complete the installation of the implant with the torque wrench. The maximum installation torque suggested is 55 N.cm. The indication of application of loads in relation to the torque is described in the table as follows:

IMPLANT	LOAD APPLICATION	MIN. TORQUE (Ncm)	MAX. TORQUE (Ncm)
FC Regular	Delayed Loading	35	45
	Immediate Loading	45	55
FC Short	Delayed Loading	35	45
	Immediate Loading	45	55

PROSTHETIC

To use the FC REGULAR and FC SHORT in two-stage procedures, the prior preparation of the soft tissues may be made using a compatible Protection Cylinder.
For molding procedure, the coping is used properly fitting it on the implant head.

1. Fit the corresponding transfer, assure the proper fitting, and make the molding with proper materials.
2. Prepare the cast model.
3. Prepare the prosthesis using the corresponding coping (temporary metal coping, calcinable coping, definitive coping) being able to be cemented or screwed, or use Abutment Oring, according to the proper laboratory techniques.
4. The tests shall be made on the passivity and the adjustment of the structure of the prosthesis.
5. Cement or screw the final prosthesis on the implant head, use its indexer, and check the perfect fitting between prosthesis and implant.

TRACEABILITY LABEL

This product is accompanied by three labels that allow its traceability and shall be attached to the following documents:

- Patient's records;
- Prosthetic records;
- Document to be delivered to the patient.

The identification and traceability are carried out through the REF and LOT number codes.

PRESENTATION AND STERILIZATION

This product is indicated for single use and is provided sterile by gamma radiation, packed unit by unit in packages that offer quadruple protection: clear tube, capsule, blister, and box.

MAGNETIC RESONANCE (MR) - SAFETY INFORMATION

The DSP Implant System was not assessed for safety and compatibility in the MR environment. Tests were not carried out regarding factors of heating, migration, or image artifact in the MR environment.
The safety of the DSP Implant System in the MR environment is unknown, submit a patient that has this device to magnetic resonance may result in injury to the patient.

STORAGE INSTRUCTIONS

This product shall be stored in its original package, in clean and ventilated place, at maximum temperature of 45°C, and protected against direct sunlight.

INSTRUCTIONS ON HOW TO SAFELY DISPOSE THE DEVICE

Every product and consumable used during the surgery for installation of dental implants may put at risk the health of those who handle them, after the use. Before disposing of them in the environment, it is recommended to observe the effective legislation and adhere thereto.

FURTHER INFORMATION

Instruct the Patient regarding the need of professional medical follow-up after the surgery, and follow the guidelines relative to the precautions, hygiene, and prescription of medicines. Such guidelines are responsibility of the professional in charge.

SERVICE LIFE

This product is of single use; it may not be reused.

EXPIRATION DATE

See package.

ADVERSE EVENTS

The installation of dental implants, as well as any other surgical procedure, may cause a slight discomfort and localized edema. More persistent symptoms may occur, such as: chronic pain related to the dental implant, permanent paresthesia, dysesthesia, maxillary/mandibular bone reabsorption, localized systemic infection, oroantral or oronasal fistula, adjacent teeth unfavorably affected, irreversible damages to the adjacent teeth, fracture of the implant, jaw, bone, or prosthesis, aesthetic problems, injury to the nerves, exfoliation, hyperplasia.
Failure in the osseointegration and loss of the prosthesis during the treatment may be caused by:
Inadequate osteotomy, infections, diseases, or systemic problems, low quality or insufficient volume of bone, absence or failure of irrigation, use of instruments and/or non-specific instruments with no power of cutting, poor oral hygiene, occlusal trauma, lack of prosthetic passivity, and lack of specific training.

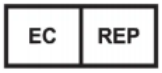
PRODUCT GUARANTEE

DSP Biomedical assures to the owner of this product guarantee against any material or manufacturing defect, the presence of any defect shall be immediately informed to the manufacturer, respecting the legal term. The guarantee of the products manufactured by DSP Biomedical is strictly connected to following the information described in the instruction of use. The inadequate use of the product disregarding the indications releases the manufacturer and/or vendor of any responsibility.
Note: the guarantee does not cover wear and tear from using the product.

ASSISTANCE INFORMATION

If there is need of further information, or the product presents any adverse effect, with potential of risk to the patient, which generates or has potential of injury or threat to public health, or any dissatisfaction of the client, contact DSP through the phone numbers 0800 600 88 66, or send an e-mail to sac@dspbiomedical.com.br.

SYMBOLS

SYMBOLOGY	DESCRIPTION	SYMBOLOGY	DESCRIPTION
	Batch number		Consult instructions for use or consult electronic instructions for use
	Date of manufacture		Do not resterilize
	Manufactured by		Keep dry
	Sterilized using irradiation		Keep away from sunlight
	Product Code		Single sterile barrier system with protective packaging inside
	Model Number		Used by-date
	Do not reuse		Unique Device Identifier
	Limit of temperature		Country of manufacturer
	Authorized representative in the European Community		Do not use if package is damaged and consult instructions for use
	Caution		Humidity limitation
	Importer		Medical device
	Fragile, handle with care		Mandatory medical prescription Notification required by FDA for United States market
	CE Mark		CE marking with number of Notified body; SIQ, number 1304

The SSCP is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI.
Please see Eudamed public website: https://ec.europa.eu/tools/eudamed. BASIC UDI:
7908467800417FCREGEB and 7908467800417FCSHORTGM

REF : **Products**

Device Description	Code
FC REGULAR IMPLANT Ø3.0 X 8.5	17.3808
FC REGULAR IMPLANT Ø3.0 X 10.0	17.3810
FC REGULAR IMPLANT Ø3.0 X 11.5	17.3811
FC REGULAR IMPLANT Ø3.0 X 13.0	17.3813
FC REGULAR IMPLANT Ø3.0 X 15.0	17.3815
FC REGULAR IMPLANT Ø4.3 X 8.5	17.4308
FC REGULAR IMPLANT Ø4.3 X 10.0	17.4310
FC REGULAR IMPLANT Ø4.3 X 11.5	17.4311
FC REGULAR IMPLANT Ø4.3 X 13.0	17.4313
FC REGULAR IMPLANT Ø4.3 X 15.0	17.4315
FC REGULAR IMPLANT Ø5.0 X 8.5	17.5108
FC REGULAR IMPLANT Ø5.0 X 10.0	17.5110
FC REGULAR IMPLANT Ø5.0 X 11.5	17.5111
FC REGULAR IMPLANT Ø5.0 X 13.0	17.5113
FC REGULAR IMPLANT Ø5.0 X 15.0	17.5115
FC SHORT IMPLANT Ø3.8 X 5.0	17.3805
FC SHORT IMPLANT Ø3.8 X 6.0	17.3806
FC SHORT IMPLANT Ø3.8 X 7.0	17.3807
FC SHORT IMPLANT Ø4.3 X 5.0	17.4305
FC SHORT IMPLANT Ø4.3 X 6.0	17.4306
FC SHORT IMPLANT Ø4.3 X 7.0	17.4307
FC SHORT IMPLANT Ø5.0 X 5.0	17.5105
FC SHORT IMPLANT Ø5.0 X 6.0	17.5106
FC SHORT IMPLANT Ø5.0 X 7.0	17.5107

MANUFACTURED BY

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Reference

1-Lekholm U, Zarb G. Patient selection and preparations. Branemark, PI, Zarb,G & Albrektsson, T, eds Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chigado: Quintessence; 1985. p. 233-40.