GENERAL ASPECTS

Authorisation: The use of Bioner implants, burs and attachments is restricted to Odontologists, Stomatologists and Maxillofacial Surgeons. The laboratory products and devices may be used by Dental technicians.

Labelling: The labelling of BIONER products uses a series of standard symbols with the following meanings:

	Product reference		Batch number		Refer to the instructions on use
	Date of Manufacture		Manufacturer		Do not reuse Single use only
	Expiry date		Sterilised by gamma radiation		Non-sterile
	Do not use if the packaging is damaged		Health Compliance by NB		Product of self-certification

Storage: Bioner products do not require any special storage conditions even though it is recommended not to expose them to conditions that could affect the product, its packaging or label, such as extreme temperature and humidity, knocks, etc.

Cleaning and disinfection: Bioner products are supplied “non-sterile” with the exception of implants. Before placing the restoration in the patient's mouth, the product should be cleaned, disinfected and sterilised. The recommended procedure is to clean using ultrasounds and adequate cleaning products (bactericide, fungicide, virucide active against HIV-1 and hepatitis B).

Sterilisation and Reuse: Bioner products are supplied “non-sterile” with the exception of implants. All products that are to be used in the mouth must be sterilised. The recommended sterilisation process is in a wet steam autoclave with the following conditions: 121ºC and 15 min (as per the UNE-EN ISO 17665-1 Standard), set the autoclave to a vacuum cycle (drying) after the sterilisation process. The label of some references includes the symbol corresponding to “single use only” indicating that its reuse is absolutely forbidden.

***General* warnings**: Check the dimensional compatibility between the implant and other components of the prosthesis. Make sure that the patient has no intolerance to the material used. Record the products (brand, reference and batch) used on the patient’s medical record. The patient should be warned about the limitations and maintenance requirements of their implant-supported prosthesis (correct hygiene, need for regular check-ups, among others) as well as the convenience of visiting a specialist in the event of any strange symptom. The physician is responsible for the complications associated with inadequate asepsis, inadequate preparation of the area where the operation takes place, and incorrect indications or surgical techniques. In the same way, they are also responsible for providing the patient with correct information; and any possible detriment if these instructions are not followed. Regular check-up visits should be scheduled to verify and maintain the adequate function of Bioner products and, if applicable, the condition of surrounding tissue. Immediately report any complications that occur in relation to any product to Bioner S.A.

Communication with the patient: According to regulations applicable to patient autonomy, rights and obligations regarding clinical information and documentation, prior to surgery, the patient must be informed about the content of the Informed Consent Form for Implantology and be handed a copy for signing.

The patient should also be informed about:

- The limitations and maintenance requirements of their implant-supported prosthesis, explaining about correct mouth, implant and restoration hygiene and care.

- The greater risk of pseudarthrosis among patients who are smokers or frequently consume products containing nicotine.

- The load limitations on implants, especially the predicable effects that non-compliance with the postoperative instructions of the surgeon could have on the results of the operation.

- The convenience of visiting a specialist in the event of any strange symptom.

Handling: When removing the product from the packaging, make sure that there is no damage and that the product corresponds to the description and characteristics on the label. In the event of noting any deviation from the label, please contact Bioner S.A.

DENTAL IMPLANTS

Indications: Bioner implants are indicated for providing an anchor point for intraoral reconstructive prostheses in the jaw or upper maxillary and in cases of partial or total edentulism.

Description: Bioner implants are manufactured from Titanium and biocompatible material. They are presented suspended inside a polyethylene tube and only in contact with a titanium ring inserted inside the tube which, in turn, is contained within a sealed blister to guarantee the sterility of the implant. The implant is held in place by a screw fitted to the cap of the inner tube. Implants are supplied sterile. The sterilisation process is gamma radiation and has been validated.

Traceability: Bioner implants include traceability labels indicating the reference of the product and batch for inclusion on the patient file card.

General precautions: It is necessary to make detailed clinical examination of the patient before any treatment with implants. Radiological studies (CAT, Ortho scan, etc) should also be performed When prescribing therapy with implants it is important to consider such aspects as the degree of motivation and capacity for cooperation of the patient, oral hygiene conditions, addiction or excessive consumption of tobacco, alcohol or drugs, bone quality, the chewing loads the implants must support, etc.

The product is supplied sterilised by Gamma irradiation. In the event of any packaging defect, the product should not be used and the manufacturer notified immediately. All the implants are supplied sterile and designed for a single use only prior to the expiry date indicated on the label. Bioner S.A. accepts no responsibility in the event of re-sterilisation or reuse of the product by the physician.

Implants have specific dimensional characteristics that must remain unaltered for coupling to the future prosthesis. The use of instruments and/or components that do not have the adequate size may cause damage to the implant and the patient's tissue, apart from jeopardising the aesthetic result of the prosthetic reconstruction.

In order to simplify the surgical technique, there is a specific range of devices for Bioner implants. Precautions should be taken during surgery to prevent patients from swallowing or choking on the components.

After placement of the implant, the physician should assess the initial stability to determine the time for applying the prosthetic load. Applying excessive force on the dental implant should be avoided during the healing period. Follow the placement instructions in the surgical protocol for Bioner implants.

Contraindications: No contraindications have been identified to date for Bioner titanium implants and so the contraindications are those defined in general for all oral surgery involving the placement of implants.

The lack of bone structure or insufficient bone quality, inflammation, septicaemia and the osteomyelitis are absolute contraindications.

Other complaints or conditions previous to surgery that could negatively affect the potential benefits of the procedure are: presence of tumours, congenital defects, immunosuppressant diseases, increased sedimentation rate, and increased leukocyte count.

All applications not included in the indications and specialised literature are contraindicated.

Possible complications and adverse reactions: All possible complications or adverse reactions indicated are not specific to Bioner S.A. products but are general to all implants. These complications and adverse reactions include:

- *Loss and integration failure*
- *Stress Shielding: bone loss (dehiscence) requiring a bone graft.*
- *Perforation of the maxillary sinus, lower jaw, lingual cortical plate, palate, lips, inferior alveolar canal and the gums.*
- *Sinus infection of the wound after the operation and tardive infections with possible systemic infection and septicaemia.*
- *Persistent pain, sensation of discomfort or abnormal sensations.*
- *Swelling, hyperplasia, thrombosis and embolism.*
- *Damage to nerves.*
- *Slackening, deformation or fracture of the implant*
- *Displacement or misalignment of the implant with reduction of the range of movement.*
- *Haematoma in the wound and delayed healing of the wound.*
- *Temporary or prolonged functional neurological disorders.*
- *Tissue reactions due to allergy or reaction to foreign bodies as a result of particle detachment.*

Immediately inform Bioner S.A. about any complications that occur in relation to the implants or surgical devices used.

BURS

Presentation: Bioner burs are indicated for perforating bone in the oral implantology procedures. Bioner burs are devices manufactured from surgical stainless steel and designed for use with rotating devices. Bioner burs incorporate marks to guide the physician and indicate the depth of the perforation being performed.

Maintenance: Make sure device is in good condition before use. Repeated use may cause a loss in its characteristics. Sterilise before use using moist heat. Clean and disinfect the product after each use. Check the condition of the cutting edges. Do not store burs that are still moist after of the cleaning process and/or sterilisation. Discard the bur at the first sign of wear. Only use the burs with devices for a type 1 shank as defined in the ISO 1797-1 standard.

Cleaning and sterilisation of burs: Burs should be cleaned using ultrasounds and SPECIAL CLEANING PRODUCTS FOR BURS (bactericide, fungicide, virucide active against HIV-1 and hepatitis B). Burs should be sterilised before use. The preferred sterilisation technique is a wet steam autoclave in accordance with general instructions. Burs may be prepared for sterilisation in sterilisation bags or boxes. Do not use the product after sterilisation if there is any detectable deterioration of the container used.

Possible causes of malfunction: In the event that the bur does not perforate bone smoothly, check the sharpness of the edges. Discard the bur in the event of any deficiency. Check the drill speed. In the event of bur breakage during use, remove any remains from the wound, clean it, and continue with the procedure.

Special recommendations for use in clinical practice: Make sure that the hand pieces, turbines and contra-angles where the bur is connected are in perfect hygienic and working condition. Always make sure the bur is correctly fitted to the contra-angle. Check the correct rotational speed of the bur before use on the patient. Always use irrigation during the drilling process. Any lack of irrigation may cause necrosis of the bone and adjacent tissue due to the heating effect. During of the drilling sequence the rotational speed of the tool should be within the range of 500-1000 rpm, depending on the hardness of the bone and the drilling phase. Obtain a real measurement of the perforation made using calibrated measurement probes.

Drilling sequence: The burs are designed for sequential use to shape a cavity of the appropriate size, both in diameter and depth, for the placement of Bioner implants. All dimensions have been set to meet the objective including the insertion marks corresponding to the heights of Bioner implants. The drilling depth will depend on the height of the implant to be placed and the insertion marks on the burs. Refer to the drilling guide in our catalogue.

Drilling stop marks: Bioner, S.A. offers a range of drill depth stops for burs to ensure the drill depth does not exceed the size of the implants. Before use, make sure the selected stop corresponds to the bur used and the depth of the implant to be placed.

ACCESSORIES

➢ GENERAL ASPECTS

Compatibility: The products should not be used with incompatible components. Before placement, review the components available in the catalogue of Bioner products for a correct selection of the height and diameter. The physician must be sure of size compatibility and design of the implant these elements are to be combined with; Bioner S.A. accepts no responsibility for the use of its products for incompatible implant systems.

Conditions of use: All the attachments produced by Bioner S.A. are supplied clean and appropriately packaged. The cleaning process has been validated. Bioner attachments are not supplied sterile and should be sterilised before use in the mouth. The recommended sterilisation method is wet heat at 121ºC for 15 minutes. The products should be clean before sterilisation. In the event the physician performs the cleaning, it is recommended to use gloves and take the precaution to use non-abrasive disinfectant agents. Products that are not used n the mouth and are restricted to laboratory use do not require sterilisation.

Special instructions: Bioner attachments should not be reused; they are products for single use only. Remove the product from its original packaging and place it in a suitable container before sterilisation.

➢ SPECIFIC ASPECTS

- ***Abutments***: These elements are used for the prosthetic restorations prepared by a dentist in a dental clinic. A prefabricated dental implant abutment connected directly to the dental implant is designed to be an auxiliary transepithelial attachment in screw-retained prosthetic rehabilitation. Its position should be verified using periapical x-rays.

  In the case of straight abutments: place a suitable abutment as per metrology and system. Tighten the abutment to 20-30 Ncm using an appropriate torque wrench. Take an impression using the routine procedure. If a temporary prosthesis is not necessary, put healing plugs in place.

- ***Healing abutments***: A healing abutment is used as an auxiliary transmucosal cylinder. It is placed in the implant before prosthetic restoration to simplify the formation of a soft tissue sulcus. Choose the appropriate height to ensure correct operation and prevent the transmission of chewing forces. Before putting it in place, make sure that the platform of the implant is free of any tissue residue. Use a gentle manual torque.

  Straight and angled abutments are used for prosthetic restorations prepared by dental technicians in the laboratory or by dentists in the dental clinic. Straight and angled abutments form the basis for crowns or provide support for bridges. Make sure that the parts of the attachment are correctly aligned with the retention pieces of the implant and are placed correctly in reference to secondary parts. We recommend a periapical X-ray to check correct adjustment after tightening the screws. Caution: If customisation of the abutment is necessary, do not reduce the walls to less than 0.5 mm. Warning: Any cutting should be performed outside the mouth. If this is not possible, use appropriate suction. Position the patient so that they do not inhale or swallow the filings. Use carbide burs and carborundum disks with water cooling. Before cementing the final restoration, check the torque according to the connection and size of the implant. Use final or provisional cement after sealing the chimney (screw access hole) with Teflon tape or gutta-percha. Clean excess cement from the edge of the crown to prevent peri-implantitis that could lead to implant loss. After cementation remember to check static and dynamic occlusion using the conventional protocol.

- ***Provisional Healing abutments***: A provisional abutment used for prosthetic restorations prepared by the dentist in the clinic and acting as support for provisional screw-retained prosthesis: crowns, bridges and full dentures. Make sure that the attachment parts are correctly aligned with the retention parts of the implant. We recommend a periapical X-ray to check correct adjustment after tightening the screws. Warning: Any cutting should be performed outside the mouth. If this is not possible, use appropriate suction. Position the patient so that they do not inhale or swallow the filings. Before fixing the final restoration in place, check the torque according to the connection and size of the implant. It is important to seal off the chimney (screw access hole). Clean any excess cement close to the platform to prevent peri-implantitis that could lead to implant loss. It is very important to check static and dynamic occlusion avoiding excessive loads that could prolong or prevent osseointegration, especially in the case of immediate load.
- ***Stumps***: Stumps, depending on whether they are machinable (cement- or screw-retained) are metallic elements for mounting prosthetic restorations directly on implants or abutments. It is important to make correct selection of the stump on the model (compatibility, height and angle).
- ***Provisional stumps***: Designed to support a temporary prosthesis or immediate loads, among others. The recommended usage time is 30 days. Once the time prescribed by the physician has elapsed they should be replaced by permanent stumps.

  Titanium Cylinders: Used for the restoration of dental prostheses on implants or abutments using screw- or cement-retained techniques or for the implant of structures created using CAD-CAM. In this last case the use of castable abutments designed to fit over them is recommended with waxing of the prosthesis to ensure good fit.

  Clinical Screws: Screws are used to fix dental prosthesis and auxiliary abutments to the implant or similar. Make sure to choose the screw adapted to the system and metrology used in the reconstruction. For best results, the following conditions must be meticulously applied:
  - Use a suitable wrench model and size to tighten or loosen the screws. If in doubt, check whether a larger size wrench fits the seat. The tip should be placed on the longitudinal axis of the prosthesis/implant assembly. It is essential to use a new screw when placing the prosthesis for the first time, as well as after each review of the prosthesis.
  - In the event of immediate load, tighten the screws manually to prevent excessive torque while holding the implant firmly to prevent any twisting while tightening the screws.
  - When transferring to the patient, do not use the same screw used in the laboratory.
  - Make sure that the screw used is the correct model.
  - If there is any doubt about the adjustment of the screw, ask your local distributor.
  - Place the patient in a safe position to prevent choking in the event the screw falls during handling.
- ***Laboratory Screws***: Screws for exclusive use in the prosthetic laboratory. Not to be used in the mouth. They are used to hold the dental prosthesis during manufacture. Make sure to chose the screw adapted to the system and metrology used in the reconstruction.
- ***Replicas***: Replicas are used to simulate the connection of the dental implant and its position on a plaster model. Before any manipulation, make sure that the anti-rotation and retaining parts are firmly connected. Before tightening, make sure that the replica and the prosthesis coincide in size and connection type. The aim is to obtain a firm connection with passive adjustment. Do not reuse a replica, its connection may be altered and its technical specifications modified.
- ***Impression taking***: Dental impressions are used to transfer the position of the implant out of the mouth for modelling in a dental laboratory. Either an open or closed tray technique may be used. Make sure the connection seat of the implant is clean before taking the impression. Any residue or dirtiness could affect later adjustment of the prosthesis. Check compatibility with the implant model to be connected. Loosen the closure screw, clean the connection with water and dry with air. Prepare the impression considering the connection of the implant and size of the platform. Place it over the implant and check its correct position. Put the screw in place and tighten manually.

- Choose a short screw for the closed tray technique. After tightening, block the hexagon of the screw with wax. After the impression has hardened check its stability before sending it to the laboratory.
- Choose a long screw for the open tray technique. Before mixing the impression material place the tray in the mouth and check access to the screws. After hardening, dismantle all the screws and remove the tray.

❖ ***Casting cylinders***: Casting cylinders are used for prosthetic restorations prepared by dental technicians in the laboratory. For a better connection seal we recommend metal abutments with pre-machined bases. However, when using the cast and cement method, take the following precautions:

- Add sufficient wax to create a layer to compensate for the expansion of the cast cylinder.
- Tighten gradually to prevent deformation.
- Pour the parts of a size and shape that favours filling cavities and prevents the appearance of air bubbles.
- Use high fluidity alloys for complex models.

❖ ***Casting cylinders with Chrome Cobalt base***: A Cr-Co base is used for prosthetic restorations prepared by dental technicians in a laboratory. The abutment is comprised of a chrome cobalt base and a plastic cast cylinder that burns without leaving any residue. The laboratory procedure consists of overcasting: the portion of melted alloy is impregnated over the contact areas. The metallic assembly is obtained by mechanical retention.

Procedure: The abutment should be carefully mounted on the replica and tightened with a laboratory screw. The laboratory screw is exclusively designed for laboratory processing. The clinical screw of the assembly should only be used for final mounting of the restoration after being sterilised.

Cover the space between the cast cylinder and the border of the CrCo base with wax creating an edging of at least 0.3 mm in thickness to prevent cracks in the ceramic.

Before placing the sprues, clean the base with a cotton bud and alcohol. The sprues should possibly be placed on the rotational axis of the abutment to prevent the concentration of pores within the construction.

The facing should pass easily through the chimney (screw access hole).

The components must be placed as far as possible from the thermal centre of the cylinder.

The position of the sprues ensures correct placement of the wax in the cylinder.

The metallic part of the abutment should not be placed too close to the walls or the base of the cylinder to prevent the elimination of heat (cooling vents).

If the base cools too fast defects may appear in the cast.

Make sure the facing is free of all air bubbles. The kiln parameters must be the same as for conventional CrCo bridges to prevent any imperfection in the construction.

Follow the manufacturer's instructions for the facing. In order to guarantee a good connection, the final pre-heating temperature of the crucible furnace should be at least 950°C. Maintain the cylinder at the final temperature for 30 to 60 minutes depending on the cylinder size. Prevent tension in the structure by slow cooling the cylinder to room temperature. Sandblasting may damage the connection surface. Cover the connection with replica to prevent damage when polishing the neck. When working with cement-retained restorations design the crown and bridge structures on the abutments in the same way as for periodontal restorations.

- ***Abutment Scan***: A scanning jig is used for [illegible]sthetic [illegible]s prepared by dental technicians in a laboratory or by a dentist in the clinic [illegible] CAD/CAM processes. It is indicated for obtaining geometric information on the model using a 3[illegible]esktop scanner in the laboratory or for optical impressions using an intraoral 3D [illegible]anner. Befo[illegible]canning, visually check the abutment and replica for surface damage and t[illegible] implant connection for any tissue residue. The flat surface should be placed in the upper [illegible]heric[illegible] part in a palatal/lingual direction for greater scanning precision. Fix the abutment with t[illegible]respo[illegible]ng screw either by hand or at a maximum torque of 10 Ncm. The scanning jig is a pre[illegible]on t[illegible] and over tightening could change its geometry and cause scanning errors [illegible]d discrepanci[illegible] the precision.

  Scanning should be pe[illegible]med as [illegible]r the instructions of the manufacturer of the CAD/CAM system. It is ext[illegible] imp[illegible]nt [illegible] select the correct implant connection in the software. After scanning is co[illegible]pleted, [illegible]ma[illegible]the jig and place it gently in the tray or box. Complete scanning may require [illegible]taining ad[illegible]ional information (for example: silicone bite, gum shape, etc.).

  Sterilisation is [illegible]sential i[illegible]he event of intraoral use.

TOOLS

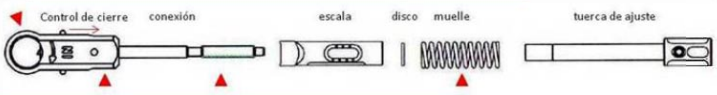
Too[illegible] used for placing and adjusting dentures by the physician in a clinic or the dental technician in [illegible]e la[illegible]atory.

Compatibility: Before using the tool make sure it is the right size and shape and fits the part where it is [illegible]e used. Only use tools that are in good condition. A worn tool may damage the part where it is used.

Intraoral use: All tools must be cleaned and sterilised according to a recommended method before use. When using tips or tools with handles that adapt to ratchets, make sure they are well blocked. When using tools with a handle, the tool should be fastened to the handle with dental floss. Take the necessary precautions not to pinch or injure the patient.

RATCHETS

- **Torque wrench (LCC):**



Use*:* Adjust the screwdriver using the closure control as indicated in the diagram. Adjust the torque strength using the adjustment knob. The degree of adjustment is shown on the scale. For uncontrolled torque, turn the adjustment knob to the ∞ position. When the ratchet reaches the set torque the handle disengages from the head. Applying more force at this point could damage the ratchet. Always store the ratchet adjusted to the minimum.

- **Fixed wrench (LDR)**

Cleaning and maintenance: Always clean after use with a soft disinfection brush using abundant water to eliminate any remains of blood or other residues. Then immerse the ratchet in liquid dental instrument cleaner as per the manufacturer's instructions. Dry the tool after cleaning. Disassemble torque wrenches before cleaning.

▼The areas marked on the drawings should be lubricated with special oil for dental instruments.

Sterilisation: Ratchets should be sterilised before use. The recommended sterilisation is in a wet steam autoclave at 121ºC for 15 min with a final drying cycle. Do not use the product after sterilisation if there is any detectable deterioration in the container used.

Storage: Bioner ratchets do not require any special storage conditions even though it is recommended not to expose them to conditions that could affect the product, its packaging or label, such as extreme temperature and humidity, knocks, etc.

Label: All products are identified by a reference (unique coding), a brief product description, batch number to identify the product and ensure traceability, and the CE mark.

General warnings: Do not use the ratchet if it is defective or damaged. It should be sterilised before use for surgical procedures as described in the corresponding paragraph. Do not clean the ratchet with metal brushes.

DENTAL GRAFT KIT

Description: The Kelt Dental Graft family corresponds to a kit (and its individual replacement components) designed to be used for oral surgery requiring the insertion of autologous, homologous, heterologous or alloplastic mucous grafts, bone and membrane regeneration, as well as to stabilise the edge of a vestibuloplasty. The mounting components may also be used as complements for suturing. The different elements included in the kit can be defined as:

- Support element: Corresponding to the box where the different components are placed.
- Placement elements: Corresponding to the different tools (handles and screwdrivers) designed for placement of the mounting accessories.
- Mounting accessories: Corresponding to products used directly to ensure bonding of the graft during surgery and/or buccal reconstruction.
    - INJ-CHIC *Clip for holding membranes*
    - INJ-MDM *Self-threading DM micro-screw for holding soft tissues*
    - INJ-TO *Screw for Osteosynthesis and fixation of hard tissues*

***Material*:** All mounting accessories are manufactured in Grade 5 Titanium as per the standard (ASTM F-136). All placement elements are manufactured from medical grade stainless steel with the exception of the staple placement tip which is Grade 5 Titanium as per the standard (ASTM F-136).

***Storage*:** The kit and its replacement parts do not require any special storage conditions even though it is recommended not to expose them to conditions that could affect the product, its packaging or label, such as extreme temperature and humidity, knocks, etc.

Preparation of the kit: Remove the cover from the organiser to dispense screws and instruments, placing the different elements in their corresponding place. Locate the placement elements to be required for the operation, once they are clean and dry. Place the number of mounting points required for the operation with planning for any possible incidents and needs. Replace the cover on the box and place the prepared kit in a sterilisation bag of suitable size. Close it and label it with the sterilisation date, patient code and any other routine information.

Sterilisation: The Kelt Dental Graft Kit and its replacement parts are packaged without being sterilised and so should be sterilised before use in the mouth. The products should be clean before sterilisation. In the event the physician performs the cleaning, it is recommended to use gloves and take the precaution to use non-abrasive disinfectant agents. The preferred sterilisation technique is wet steam autoclave in accordance with general instructions.

***Use*:** Remove the kit from the sterilisation bag immediately before use. Remove the cover from the kit. Assemble, if necessary, the handle and the tip making sure the connection is correct and solid.

Make sure all impact elements (clips) are well placed in the tool before use. Only use Bioner, S.A. tools for the placement of mounting accessories (*clips, micro-screws and osteosynthesis screws*)

***Contraindications*:** The use of the Bolt Dental Graft Kit and its mounting accessories is contraindicated in the event of active infection, in patients having previously shown hypersensitivity to titanium, in patients with disorders that could make following the physician's instructions or the limitations of orthodontics difficult. They are not recommended in the event of systemic, bone or metabolic disorders that could alter the result of the reconstitution, as well as in the case of drug or alcohol abuse or medical conditions undergoing treatment with steroids or which affect blood coagulation. The use of osteosynthesis screws is not indicated whenever there is insufficient bone available or it is of unsuitable quality.

***Reuse*:** The box with the tools is replaced and the different placement elements may be reused. *Mounting accessories (clips, micro-screws and osteosynthesis screws)* should not be reused.

Use

- The Dental Graft Kit should be used under sterile or similar environmental conditions.
- Inspect the placement elements before and after each procedure to ensure they are in good working condition. Defective instruments must not be used and should be replaced.
- The fixing elements (clips, micro-screws and osteosynthesis screws) are indicated for temporary mounting and should be removed once the reconstruction has been consolidated.
- The selection of the size of the mounting accessories should be made depending on the operation and the type of graft to be performed.
- Do not use the sterilised kit if there is any defect or breakage of the sterilisation container.
- Make sure to use the correct tool for each type of mounting element.
- Multiple re-sterilisation of the mounting elements may alter their working capacity because of successive changes in temperature.

EC DECLARATION OF CONFORMITY

All medical devices comply with Directive 93/42/EEC relative to healthcare products and its later amendments, as well as its transposition into Spanish legislation in RD 1591/2009 with its corresponding amendments. The Quality System implemented for manufacture follows the directives established in the ISO 9001 and ISO 13485 standards. All class IIa and IIb devices have been certified by the NOTIFIED BODY No. 0051, IMQ, S.P.A. (CERTIFICATE No. 1153/MDD) according to the COMPLETE QUALITY ASSURANCE SYSTEM in accordance with APPENDIX II of the directive.

CE MARK

CE 0051

CE mark for medical devices defined as implants, surgical burs, stumps, healing abutments, abutments, clinical screws, capping screws and mounting accessories (micro-screws, clips and osteosynthesis screws)

CE

CE mark for medical devices defined as tools, casting cylinders, replicas, impressions, laboratory screws, boxes