INSTRUCTIONS FOR USE OF THE FEMORAL IMPLANT

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INSTRUCTIONS FOR USE

NAME OF THE PRODUCT: FEMORAL IMPLANT
CLASSIFICATION: IIb

The CE mark is valid only if it is also printed on the product label.

The safety and effectiveness of the construction has been tested among the products manufactured by Tequir, and they have to be taken as a whole construction. Safety and effectiveness have not been tested in combination with products or components from other manufacturers. If surgeon decides to assemble in this construction and implant or a device not manufactured, or prescribed by Tequir, he does so in reliance on his own clinical judgment and should inform the patient.

IMPORTANT NOTE:

The surgeon should be aware and the patient informed of the following information: patient's weight and activity level will have a significant impact on the useful life of the femoral implant. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities.

Complications and/or failure of the femoral implant are more likely to occur in: (1) patients with unrealistic functional expectations; (2) heavy patients, especially those over 100 kg; (3) small-boned patients; (4) patients who practice physical activities; and (5) patients whose postoperative environment is not suitable for wound healing.

- **INTENDED USE:**

Persons who have suffered or are going to suffer a lower limb amputation at transfemoral level due to a pathology of vascular, traumatic or tumoral origin, whose residual femoral length is over to 14cm (5.51 in) in early implantation surgeries or 16 cm (6.30 in) in delayed implantation surgeries, taking in both cases the greater trochanter as reference. Patients whose expected functionality after the incorporation of the implant is a K2-K3 level.

- **FORESEEN FUNCTIONALITY:**

The foreseen functionality of the implant is permitting the indicated patients the usage of distal weight bearing socket, diminishing in this manner the uncomfortable ischium charge of existing ischium support sockets, permitting to take maximum advantage of the performances of a distal socket without any proximal hindrances. Anchoring or fixation of the implant in the medullar canal of the residual femur will be performed by means of an intra-medullar stem that can be impacted or cemented. In the case of the press-fit technique, stem osseointegration with the surrounding bone tissue will take place.

The femoral implant is composed of 4 assembled pieces:

Femoral stem: component made out of titanium alloy of medical grade Ti6Al4V, according ASTM F136. Its exterior design presents radial slots to improve primary fixation to the cortical bone of the residual femur. There are variations with respect to the diameter (Ø 12-18mm) (Ø 0.47-0.71 in) and length (120-140-160-180 mm) (4.72-5.51-6,30-7.08 in). Any size of the stem is compatible with the three sizes of spacer and the washer-screw assembly.

Spacer: component made out of ultra high density polyethylene, UHMWPE, ASTM F 648. Its external design permits a distal support of the cortical bone to the spacer, while it acts as a support between the femoral stem and the socket of the external prosthesis. Interiorly the design is prepared for assembling to the stem through the washer-screw assembly. There are 3 sizes (large, medium and small).

Washer: component made out of polyethylene of ultra high density, UHMWPE, ASTM F 648. Its design is prepared, both interior as well as exterior, for linkage with the spacer and stem components. It is single size.

Screw: component made out of titanium alloy of medical grade Ti6Al4V, according ASTM F136. The function of the screw is to unify all the components and it is to be threaded in the interior of the stem. It is single size.

The implant is presented in the operating room in three individual packaging, one for the stem, one for the spacer and another one for the washer-screw assembly.

The union of the implant to the bone can be achieved by two modalities described in the surgical technique of the implant, either **impacted** or **cemented**, through the use of surgical cement. It is recommended to follow strictly a third generation cementing technique. This must be pressurized using an intramedullary plug of appropriate size and configuration to the medullary canal, as well as using a distal centralizer. Should be performed an exhaustive washing of the medullary canal, preferably using a pulsatile washing and drying of the canal prior to the introduction of the cement.

The implant has a specific instrument set associated that facilitates its introduction and is comprised of a depth gauge, diameter testers, burrs for creating the right bedding to the implant a prosthesis mounting fixture, an Allen type key and blockage fixture, impacter and extractor. It also has trial spacers.

- **ATTENTION:**

The sizes of the stem and spacer components should be correctly selected according the anatomical characteristics of the patient. It is important to perform a preoperative planning based on radiography of the residual extremity or the extremity that will be amputated in order to preselect the most adequate stem diameter and verify the bone quality of the patient in order to anticipate possible complications during the surgical technique.
It is important to review the surgical technique on behalf of the surgeon who is going to perform the intervention, as well as the involvement of the affected services in the treatment of the amputated patient.

It is important, for the functional success of the implant that the clinical rehabilitator performs the follow up of the patient, according the indications included in the rehabilitation guide.

- **INFORMATION FOR USE:**

Upon opening the packaging of the product for its use, verify that the sterility dot-sticker shows a red color, (gamma ray sterilization) and that the product's shelf life hasn't expired. Inform your supplier of any incidence regarding this.

Once the adequate sizes are selected, the distinct components of the implant are assembled on the surgical table prior to its implantation, using a mounting support designed for that purpose. It is important that the operating room personnel review the surgical technique associated with the implant (TQGUI300000) prior to the commencement.

For implant assembly, the stem and the spacer must be connected. Cover the distal hole of the spacer with the plug and assure it to the stem with a screw.

The implant has to be used only by surgeons, experts in the surgical technique. Must bear in mind the considerations of the multidisciplinary team with respect to the final length of the residual stump, soft tissue remodeling and appropriate spacer size.

For implantation, please use the specific instrument set provided by the manufacturer.

- **PRE-SURGICAL WARNINGS:**

Perform pre-surgical planning based on AP radiological imaging of the inferior limb of the patient, with canal diameter and available femur length data.

Foresee the availability of skin and necessary soft tissue for stump closure around the spacer.

Dispose in the Operating Room of the necessary equipment in case you need to proceed with the cemented technique or the press-fit technique isn't clear during the planning. Its recommended to dispose in the operating room, during the surgery, of the usual tools to solve the problems that may arise during the procedure, for example: bone fissures or lack of bone stock quality.

Carefully read the implants associated surgical technique, TQGUI300000.

- **INTRAOPERATIVE WARNINGS:**

To achieve good results, it is necessary, on behalf of the surgeon, a careful attention and dominion of the surgical technique. Inadequate selection, placement, positioning and fixation of the components can result in a deficient fixation of the implant or can fracture the femur during placement.

Considerations in the surgical technique about the length of the femur, remodeling of soft tissues around the spacer, the availability of skin and surgical wound closure, influence the success of the subsequent prosthetization and therefore on the functionality of the implant, so it is necessary that the leading surgeon take into account these aspects during surgery.

The correct manipulation of the implant is forcefully essential. Before its surgical use, a visual routine inspection of each implant should be performed to verify it has no imperfections. Damages or alterations of the implants can produce abnormal loads and cause defects that can result in a focal point of failure of the implant.

Don't use in case the packaging is damaged.

During femoral canal reaming, take special care with the temperature that can be reached in the interior of the canal to avoid death of bone cells due to heat, for which it is recommended to ream the bone at lower revolutions and with abundant refrigeration.

To minimize the possibility of fractures, it's recommended to initiate the reaming with the smallest diameter burr and progressively increase the reaming diameter until the selected size is reached.

If a fissure appears during impactation of the implant, it can be solved using a surgical cerclage. Cerclage can be used before implant impactation if the bone characteristics make us expect a possible fissure.

- **POSTOPERATIVE WARNINGS:**

The surgeon who performed the operation will do a follow-up of the patient in those aspects related to the surgical act, especially the closure of the surgical wound and the processes related with possible infection and post-surgical pain.

In case a screw loosening occurs with use, it's indicated the replacement of the washer-screw assembly and not the re-tightening thereof.

The clinical rehabilitator must take into account the established protocol in the rehabilitation guide (PRGUI300000), especially regarding the gradual loading of the stump. Following this rehabilitation protocol is important for the correct osseointegration of the implant in the residual femur.

Correct socket adaptation and rehabilitation treatment, have a great influence in the global functionality of the implant. The forces that actuate on the interface implant-stump are an essential part of the adaptation and alignment success of the implant.
The socket should be conformed as much as possible to the spacer in its entire circumference, in the distal part of the socket, to improve control of the prosthesis, as indicated in the Prosthetics Technical Guide (GOGUI300000). In addition, improper fit between the stump and the socket might increase the risk of hygroma occurrence around the implant.

The femoral implant has not been tested for heating or migration in the MR environment unless specified otherwise in the product labelling or respective operative technique. Although not tested, research shows that similar devices are considered safe for post-op evaluation using MRI equipment.

When employing certain imaging techniques (MRI, TAC) artifacts can be produced which can affect the visibility of the implant and surrounding bone.

The implant can cause electromagnetic interference with certain rehabilitation therapy systems based on the emission of high frequency waves.

- **CONTRA-INDICATIONS**

Relative:
- Severe osteopenia (for press-fit technique)
- Previous infection of the stump
- Deformity in hip flexion greater than 30º.
- Osteoporosis.
- Residual length of the femur between 12 and 14 cm (4.72 and 5.51 in), measured from the greater trochanter.

Absolute:
- Active neoplasia pathology
- Chemotherapy treatment
- Immunosuppression
- Psychiatric disorders
- Sepsis or active infection
- Residual length of the femur less than 12 cm (4.72 in) measured from the greater trochanter.
- Pregnancy
- Alcohol or drugs addiction, etc.
- Alterations of the Central Nervous System
- A none-cooperative patient with neurologic or psychiatric disorders, incapable to follow the rehabilitation instructions.
- Allergy to any of the components of the implant.

- **ADVERSE EFFECTS:**

  - Infection
  - Phlebitis, thrombophlebitis and thromboembolic pathology
  - Fracture of the femur during implant placement
  - Stem loosening
  - Rupture of the stem
  - Untightening of the washer-screw assembly
  - Cutaneous complications
  - Dehiscence of the wound
  - Border necrosis or more ample zones of the skin
  - Hypertrophic scar
  - Neuroma
  - Vessel lesion
  - Hemorrhage
  - Hematoma
  - Fracture of the femur diaphysis
  - Unspecific pain or phantom limb pain
  - Shortening of the residual femur
  - Distal bone resorption

- **STERILIZATION**

Product sterilized by Gamma irradiation of 25KGy.
The product is presented in a sterile packaging and in no case should be re-sterilized, because sterility of the product at the moment of placement can't be guaranteed, and could cause infection, cross contamination and implant failure.
It is a single use product. In case of re-use, sterility is not guaranteed.
Inspect the package of any sterile product for structural integrity prior to use. If the seal of either the inner or outer thermoformed cavity is broken or if the cavities are otherwise damaged, the product must be assumed to be non sterile.

- **STORAGE AND MANIPULATION:**

The packaging of the implant should stay intact until the moment of use, verifying that it
has no damage: in case some deterioration is detected, the implant should be considered as none sterile and returned to the manufacturer.

In no case should the implants present damage on its surface or on its form: all deteriorated implants or implants suspicious of being damaged should be returned to the supplier.

An Implant never should be re-used when it has been previously used in a patient. The retrieval of the product once used should be done by an authorized hospital waste processing company.

- The usage of the implant should be done in a properly sanitized operating room.**INFORMATION:**

In case you need any additional information to this prospectus, please contact the company TEQUIR, S.L.

▪ REFERENCES:

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Don't use in case the packaging is damaged.

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SYMBOL	TITLE	DESCRIPTION
REF	Catalogue number	Indicates the manufacturer´s catalogue number so that the medical device can be identified.
LOT	Batch code	Indicates the manufacturer´s batch code so that the batch or lot can be identified.
	Use-by-date	Indicates the date after which the medical device is not be used.
	Date of manufacture	Indicates the date when the medical device was manufactured.
MD	Medical device	Indicates the item is a medical device
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	Do not re- use	Indicates a medical device that is intended for one single use only.
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information.
	Caution	Indication that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
STERILE R	Sterilized using irradiation	Indicated a medical device that has been sterilized using irradiation.
	Do not resterilise	Indicates a medical device that is not to be resterilized.
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damage or opened and that the user should consult the instructions for use for additional information.
	Manufacturer	Indicates the device medical device manufacturer.