Keep Walking

English

Femoral Implant

Surgical technique

CE 1984

Polígono Industrial el Oliveral, Calle C, S/N
CP 46190 Ribarroja del Turia. Valencia, Spain
Telephone no.: (+34) 96 166 87 95
Fax: (+34) 96 166 88 89
e-mail: info@tequir.com
www.tequir.com

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Medical advisors:
Dr. Rafael Tibau Oliván
Dr. Jesús Alós Villacrosa

Design and illustration:
Fundamentium

Photography:
Fran Martínez Tarazona

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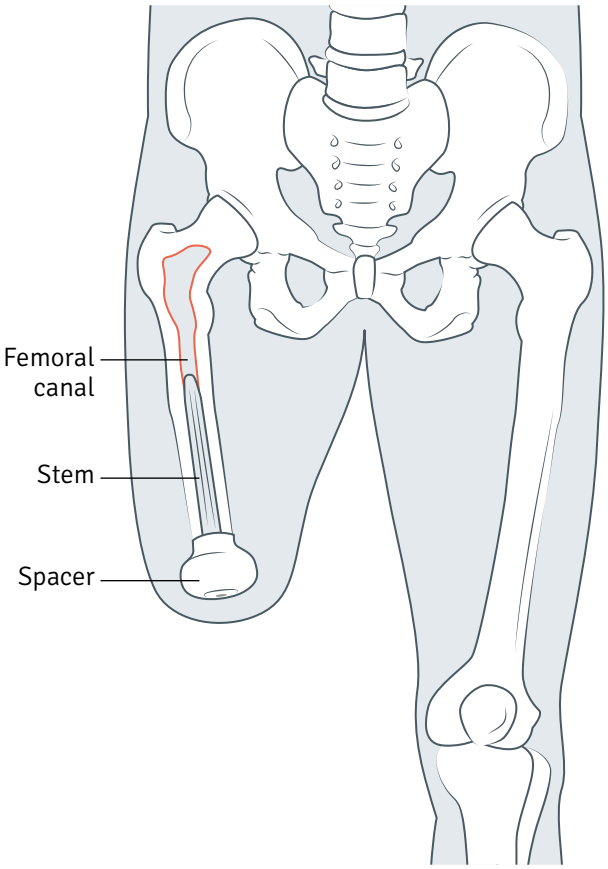
Femoral implant

The Femoral Implant Keep Walking is the solution for those patients who have suffered a lower limb amputation at femoral level who desire to improve their walking capacity, augment their proprioception and prosthesis user's comfort, reducing thereby the usual problems that affect a stump and avoid demineralization that affects the residual femur over time, by permitting the use of a distal charge prosthesis.



Target group

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.

Patients whose residual femoral length is over 14 cm (5.51 in) in early implantation surgery (the amputation and implantation are performed in the same surgery) or 16 cm (6.30 in) in delayed implantation surgery (when the implant is used in already amputated patients), using the greater trochanter as a reference.

Patients whose expected functionality after implantation is a K2-K3 level.

Contraindications

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
- 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 neurological or psiquiatric disorders, incapable to follow the rehabilitation instructions.
- Allergy to any of the components of the implant.

Material

Femoral stem

Reference	Length (mm - in)	Intraoseous lenght (mm - in)	Diameter (mm - in)
TGUI3111212	120 - 4.72	87 - 3.43	12 - 0.47
TGUI3111213	120 - 4.72	87 - 3.43	13 - 0.51
TGUI3111214	120 - 4.72	87 - 3.43	14 - 0.55
TGUI3111215	120 - 4.72	87 - 3.43	15 - 0.59
TGUI3111216	120 - 4.72	87 - 3.43	16 - 0.63
TGUI3111217	120 - 4.72	87 - 3.43	17 - 0.67
TGUI3111218	120 - 4.72	87 - 3.43	18 - 0.71
TGUI3111412	140 - 5.51	107 - 4.21	12 - 0.47
TGUI3111413	140 - 5.51	107 - 4.21	13 - 0.51
TGUI3111414	140 - 5.51	107 - 4.21	14 - 0.55
TGUI3111415	140 - 5.51	107 - 4.21	15 - 0.59
TGUI3111416	140 - 5.51	107 - 4.21	16 - 0.63
TGUI3111417	140 - 5.51	107 - 4.21	17 - 0.67
TGUI3111418	140 - 5.51	107 - 4.21	18 - 0.71
TGUI3111612	160 - 6.30	127 - 5.00	12 - 0.47
TGUI3111613	160 - 6.30	127 - 5.00	13 - 0.51
TGUI3111614	160 - 6.30	127 - 5.00	14 - 0.55
TGUI3111615	160 - 6.30	127 - 5.00	15 - 0.59
TGUI3111616	160 - 6.30	127 - 5.00	16 - 0.63
TGUI3111617	160 - 6.30	127 - 5.00	17 - 0.67
TGUI3111618	160 - 6.30	127 - 5.00	18 - 0.71
TGUI3111812	180 - 7.08	147 - 5.79	12 - 0.47
TGUI3111813	180 - 7.08	147 - 5.79	13 - 0.51
TGUI3111814	180 - 7.08	147 - 5.79	14 - 0.55
TGUI3111815	180 - 7.08	147 - 5.79	15 - 0.59
TGUI3111816	180 - 7.08	147 - 5.79	16 - 0.63
TGUI3111817	180 - 7.08	147 - 5.79	17 - 0.67
TGUI3111818	180 - 7.08	147 - 5.79	18 - 0.71

Spacer

Reference	Size	Diameter (mm - in)
TGUI3120054	Small	54 - 2.13
TGUI3120058	Medium	58 - 2.28
TGUI3120062	Large	62 - 2.44

Screw-Plug assembly

Reference	Size
TGUI3150000	Unique

Associated instruments

Tray A

Reference	Description
TGUI0010000	Depth gauge
TGUI0020200	Trial probe (ø12-18 mm) (ø0.47-0.71 in)
TGUI0030300	Frontal plane burr (2 units)
TGUI0030112	Medullar burr ø12 mm (0.47 in)
TGUI0030113	Medullar burr ø13 mm (0.51 in)
TGUI0030114	Medullar burr ø14 mm (0.55 in)
TGUI0030115	Medullar burr ø15 mm (0.59 in)
TGUI0030116	Medullar burr ø16 mm (0.63 in)
TGUI0030117	Medullar burr ø17 mm (0.67 in)
TGUI0030118	Medullar burr ø18 mm (0.71 in)
TGUI0030200	Conical burr ø12-17 mm (0.47-0.67 in)
TGUI0030201	Conical burr ø18 mm (0.71 in)
TGUI0030231	Conical burr stopper ø12-14mm (0.47-0.55in)
TGUI0030232	Conical burr stopper ø15-17mm (0.59-0.67in)
TGUI0030233	Conical burr stopper ø18mm (0.71in)

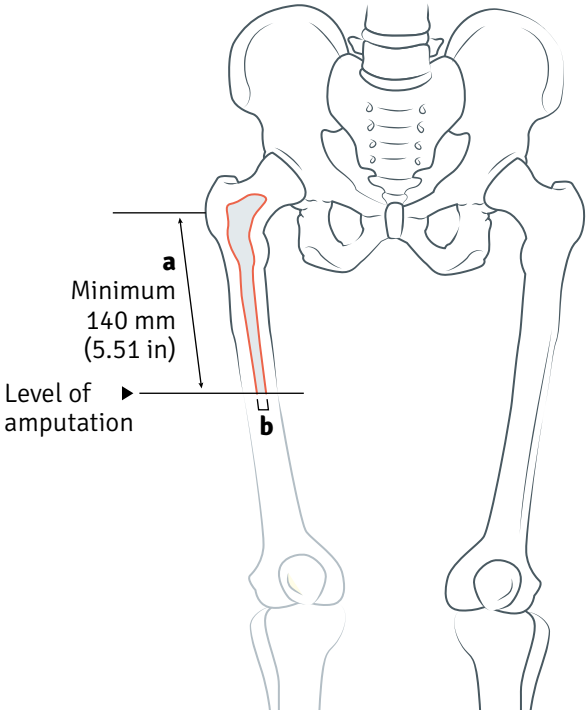
Reference	Description
TGUI0030212	Conical burr guide ø12 mm (0.47 in)
TGUI0030213	Conical burr guide ø13 mm (0.51 in)
TGUI0030214	Conical burr guide ø14 mm (0.55 in)
TGUI0030215	Conical burr guide ø15 mm (0.59 in)
TGUI0030216	Conical burr guide ø16 mm (0.63 in)
TGUI0030217	Conical burr guide ø17 mm (0.67 in)
TGUI0030218	Conical burr guide ø18 mm (0.71in)
TGUI0060000	Hexagonal screwdriver
TGUI0070000	Impactor
TGUI0110000	Plug extractor
TGUI15655HU	Jacobs-Hudson Adaptor
TGUI15680HU	Silicone Hudson handle (2 units)
TGUI15600HU	Dynamometric Hudson T handle

Tray B

Reference	Description
TGUI0050000	Anti-rotation guide
TGUI0121012	Trial stem ø12 mm (0.47 in)
TGUI0121013	Trial stem ø13 mm (0.51 in)
TGUI0121014	Trial stem ø14 mm (0.44 in)
TGUI0121015	Trial stem ø15 mm (0.59 in)
TGUI0121016	Trial stem ø16 mm (0.63 in)
TGUI0121017	Trial stem ø17 mm (0.67 in)
TGUI0121018	Trial stem ø18 mm (0.71 in)
TGUI0100000	Stem extractor
TGUI0040000	Blockage support
TGUI0122062	Trial spacer, large
TGUI0122058	Trial spacer, medium
TGUI0122054	Trial spacer, small

Surgical procedure

The procedure varies and depends on whether it is an early implantation, where the patient receives the implant during the amputation surgery, or a delayed implantation, where the patient has undergone the amputation surgery prior to the implant placement surgery.



1. Presurgical planning

1.A. Early implantation surgery

The pre-surgical planning prior to the amputation offers possibilities to define an adequate femoral length, and depends on the extent of the affection caused by the pathology that has led to the amputation.

The planning of the implant size is performed based on the expected level of amputation. To do this, the compatible dimensions with the technique can be verified on the antero-posterior X-ray of the patient's lower limb, in which the most adequate amputation level with respect to the severity of the affection shall be marked **(a)** and which permits the implant placement both in length and in diameter **(b).**

The planning should pay attention to the length of available skin and to the soft tissue disposition needed for the stump's surgical closure, as well as to the type of incision to be performed which shall be recommended hereafter.

It must be noted that the minimum distance, from the expected amputation level to the greater trochanter **(a)** has to be at least 140 mm (5.51 in).

Besides the length consideration, it is highly important that the state of the cortical bone and the grade of osteoporosis of the femur are evaluated during the planning, and an adequate size of stem, that also fills the diameter of the medullary canal, should be chosen. If an advanced loss of bone mineral density is observed in the affected femur, which limits the cortical section for stem impaction, a cemented technique should be considered.

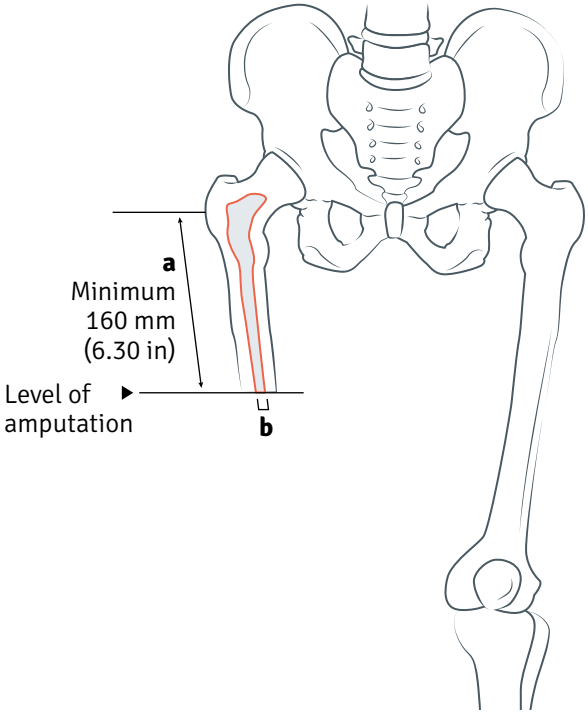
1.B. Delayed Implantation Surgery

The pre-surgical planning in an already amputated patient is performed by a radiographic study, taking into account the diameter of the medullary canal and length of the residual femur.

It should be taken into account that the minimum distance from the level of amputation to the major trochanter **(a)** has to be at least of 160 mm (6.30 in) since these patients will need an additional resection, to level or to even the irregular distal end of the femur. See point **5.B.**

Apart from length considerations, it is important to evaluate the state of the cortical bone and mineral bone loss of the femur and plan a proper stem size for the medullary canal diameter.

Note that years of progression after amputation have a negative influence on the bone quality of the residual femur. A medullary canal wider than the one planned with Rx as well as a thinner cortex can be found. In the event of observing very advanced mineral bone loss, which limits the cortical section for stem impaction, a cemented technique should be considered.



2. Patient positioning

2.A. Early implantation surgery

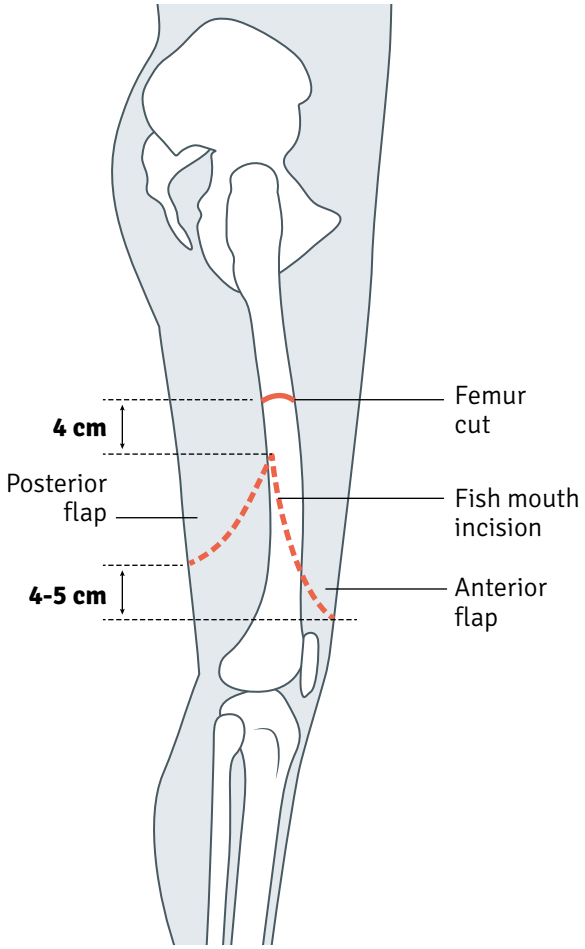
The patient will be positioned in a decubitus supine position. It is recommended to apply a tourniquet to the affected limb, with the consideration of retrieving it before the aponeurotic muscle closure, in order to be able to achieve good hemostasis, to avoid a hematoma and leave the muscle groups free that are necessary for the myoplasty to cover the spacer.

For the work procedure regarding implant placement, it is recommended to use a support below the thigh root, so it stays as flexed as possible. This facilitates the procedure and the preparation of the implant placement zone.

2.B. Delayed Implantation Surgery

The patient will be placed in a decubitus supine position. For implant placement we recommend to use a support below the root of the thigh so it stays as flexed as possible. This facilitates the preparation of the zone for implant placement.

In general the placement of a tourniquet sleeve on a stump is difficult, so in these cases we don't recommend its use. The surgical site should leave the whole extremity free, starting from the inguinal zone.



3. Incision

3.A. Early implantation surgery

The approach can be either a sagital approach, or one in form of a fish mouth, and should consider the consequent closure of the stump.

In the first case the scar stays in the coronal plane. The flaps can be equal, or in case of a fish mouth incision the anterior flap can be longer (4-5 cm / 1.57-1.97 in). This last option, which is recommended, leaves the scar out of the load zone. It is suggested to mark the amputation level on the skin according the performed pre-surgical planning.

The level of bone resection should be 4 cm (1.57 in) above the flap apexes regardless of whether you have chosen a fish mouth incision or a sagital one.

The skin and the subcutaneous muscles are subsequently incised and the saphenous vein is bound and then sectioned.

3.B. Delayed Implantation Surgery

Whenever there is no contraindication, the approach will be done using the existing scar. If that should not be possible, we recommend using a new fish mouth incision. A longitudinal anterior approach is not recommended, although it allows an easier distal femur approach, because it impedes the correct coverage of the spacer and the stump closure.

4. Soft- and vascular tissue

4.A. Early implantation surgery

The section of the aponeurosis and the underlying muscles is performed parallel to the skin incision, taking care to make it oblique from the surface till the depth. It is important to take away as little fascia skin as possible.

As for the muscles, first cut the anterior musculature until you reach the level of the femoral veins (those are tied and sectioned) and of the sciatic nerve (before it is sectioned it will be tractioned to remove it as far away as possible from the scar). Afterwards, using the same criteria, you proceed with the posterior thigh muscles.

4.B. Delayed Implantation Surgery

Try to resect as minimum amount of soft tissue as possible without compromising the correct execution of the technique.

5. Femoral cut

5.A. Early implantation surgery

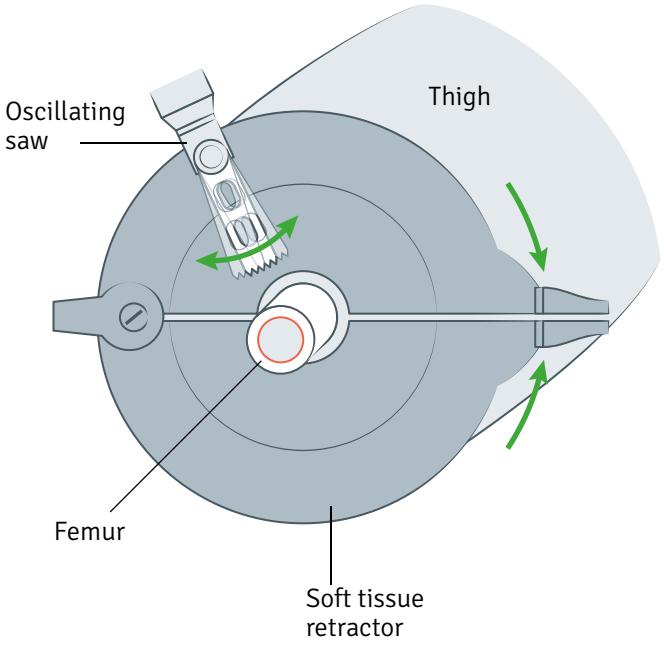
Proceed with the removal of the periosteum of the femur until a level 4 cm (1.57 in) above the flap apex.

Soft tissues should be retracted and separated before you proceed. The femoral cut should be perpendicular to the axis of the diaphysis and is performed with an oscillating saw. Once it has been performed, edges and spurs that might remain should be regularized.

5.B. Delayed Implantation Surgery

Perform an additional resection on the distal part, variable between 2 to 4 cm (0.79-1.57 in), depending on the patient's needs, availability of femoral bone and soft tissue. On the one hand this cut is necessary to regularize the distal end of the femur, frequently with imperfections of bony spikes, and on the other hand to leave space to cover the spacer of the implant and to close the stump correctly. The spacer sticks out of the femoral bone and augments thereby its length.

In stumps with scarce distal soft tissue, the femur should be resected to the established maximum: 4 cm (1.57 in) of distal femur. However, in these cases it is recommended to start with a resection of 2 cm (0.79 in) and, depending of the available tissue for closure, proceed with a mayor length of resection or not.



Diameter measuring tools

Depth gauge

6. Femur length verification

The length of the available femur is measured by means of the depth gauge. It's a graduated rod that is inserted into the medullary canal until it encounters resistance, which will coincide approximately with the level of the greater trochanter.

The depth gauge has marks at 120, 140, 160 and 180 mm (4.72, 5.51, 6.30 and 7.08 in). The last mark that is left in the canal is taken as reference. This mark indicates the maximum stem length to be implanted. It should be introduced at least till the 120 mm (4.72 in) indication, which is the smallest stem length.

7. Diameter verification

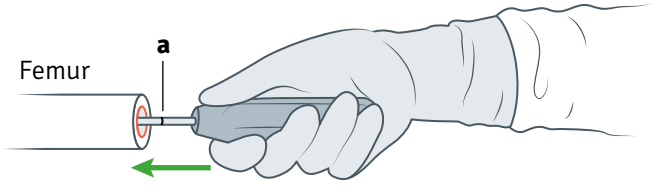
7.A. Early implantation surgery

Introduce the diameter trial probes into the medullary canal one after the other from the minor diameter trial till one of them can't be wholly introduced, leaving the depth mark outside the femur at sight **(a).** This way the correct cortical reaming of the femur is assured.

This will be the diameter of the final reamer and the diameter of the of the stem to be implanted.

7.B. Delayed Implantation Surgery

Note that the progression of the amputation may lead to endosteal reabsorption at the distal femur. Please, take this into account when introducing the femoral trial probe and selecting the final diameter. In this case, the femoral trial probe will give you only information about the possible stem diameter and the definitive diameter should be chosen evaluating this circumstance.



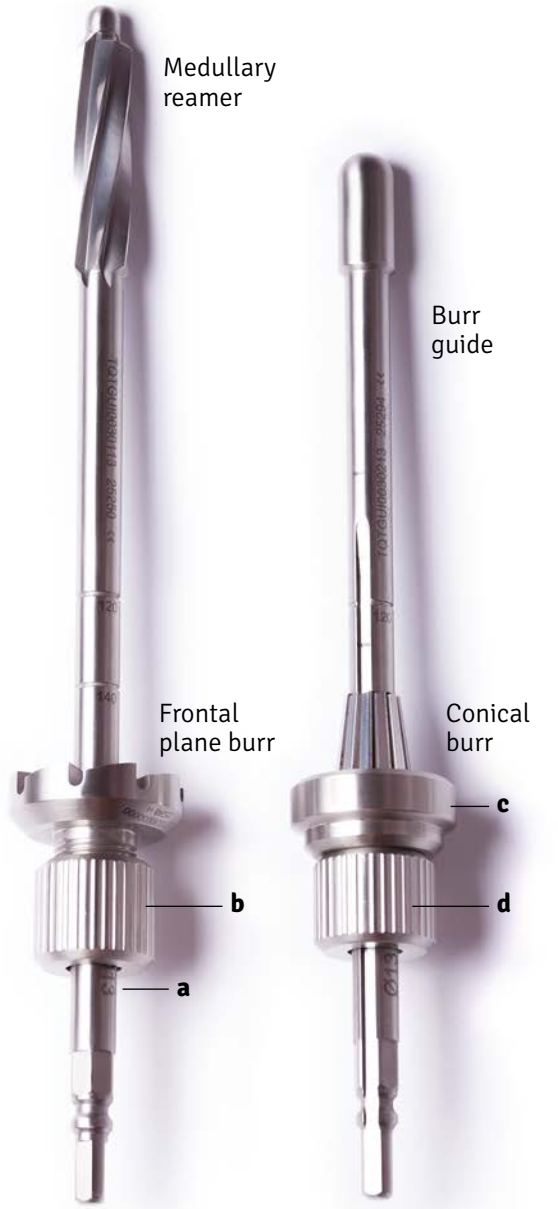
8. Medullary canal reaming

By using the medullary burrs connected to a surgical motor, the interior of the medullary canal is reamed to house the stem.. Start with a lesser diameter reamer and increase the size progressively till you reach the reamer size suitable to the patient.

All the medullary burrs will be used with the frontal plane burr attached and fixed at the foreseen stem length.This limits the depth of the reaming while it resects the distal femur to leave it completely flat.

The frontal plane burr should be connected with every burr used, blocking the mechanism at the foreseen stem length. The number should be seen at the proximal part of the burr **(a).** The blockage is performed manually by turning the nut of the frontal plane burr **(b).** Low revolution reaming is recommended to avoid osteonecrosis.

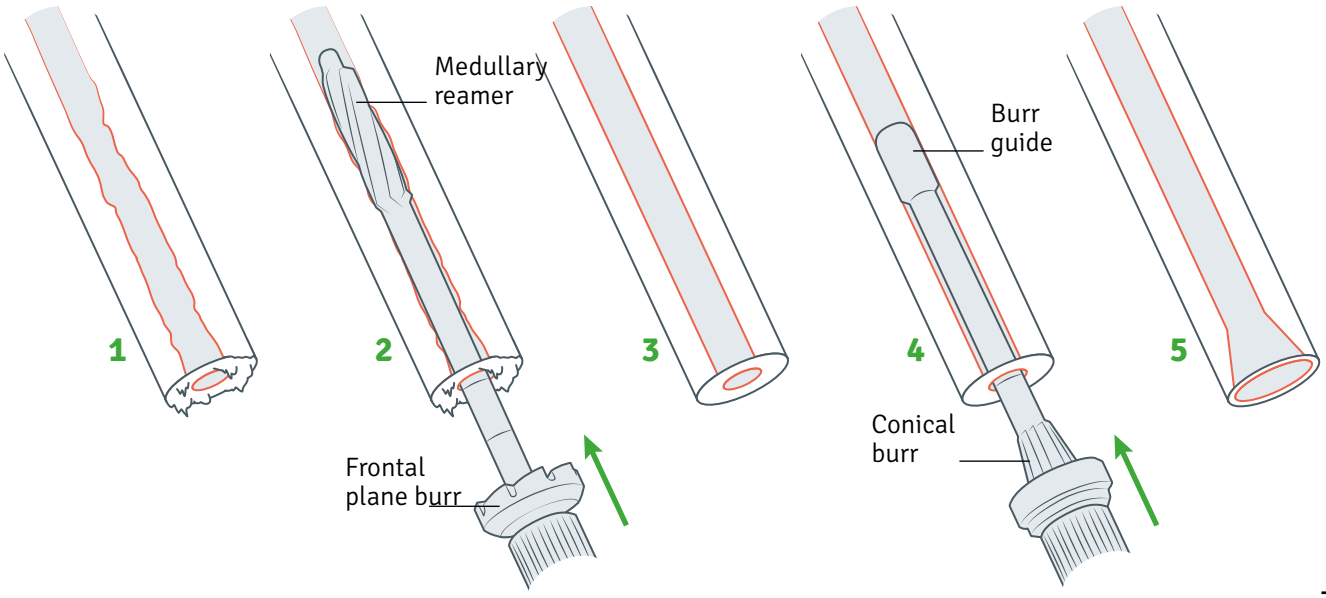
Having finished the medullary reaming, please verify that the transverse surface of the distal extreme of the femur is flat, to assure the support of the spacer.

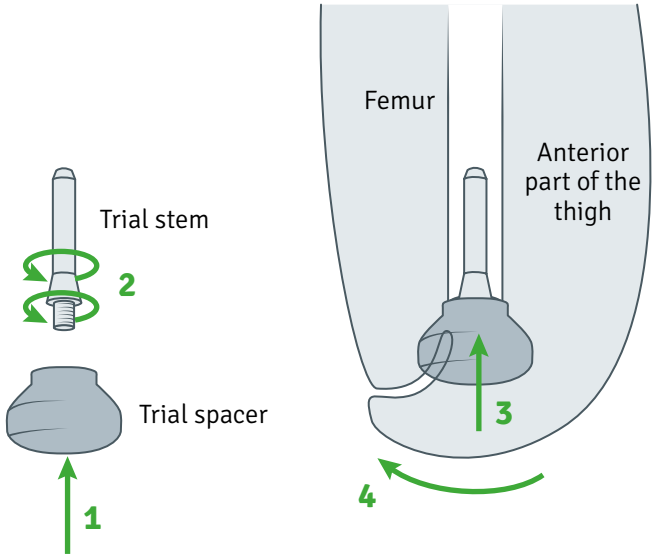


9. Conical reaming of the distal femur

The conical burr should be placed over the burr-guide of the appropriate diameter (same diameter as the last used reamer), blocking the mechanism at the appropriate length and connected to a surgical motor. Previously, the conical burr has to be assembled with the appropriate conical burr stopper **(c).** There are three stoppers for the conical burr, each one marked with the corresponding diameters to be used. Ensure to select the correct burr stopper.

The conical burr should be placed on the burr guide, blocking the mechanism to the appropriate length, which is the one selected in the reaming procedure. Blocking is achieved by manually turning the nut of the conical burr **(d).**





10. Spacer size

Proceed with the selection of the appropriate size of polyethylene spacer. There are three sizes of trial spacers. The largest possible one that still allows a closure without tension, should be selected.

Screw the large spacer on the trial stem of appropriate diameter (defined by the reamed diameter). Then place it in the reamed canal and proceed with the coverage using the surrounding soft tissue. If it covers completely, then the largest size spacer is used. If not, use the middle size and perform the same verification. If that doesn't close either, the smallest size should be used or proceed with an additional bone resection of 1-2cm until the spacer can be completely covered. If this is the case, proceed to ream the canal again, both with the straight and conical reamers.

Spacers

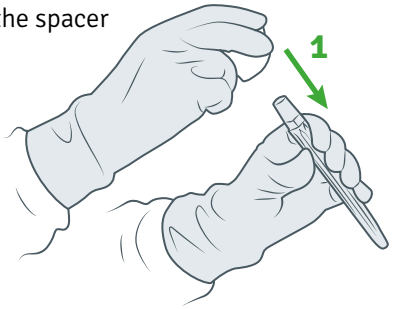
Trial stems

11. Implant preparation

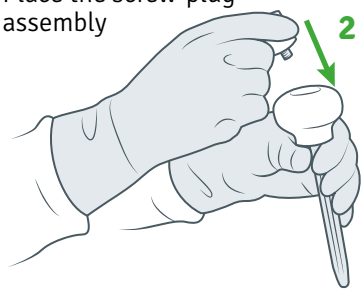
The different components of the implant are previously assembled on a specially designed supporting fixture. The stem and the selected polyethylene are manually mounted assuring that the polyethylene rests perfectly in the stem.

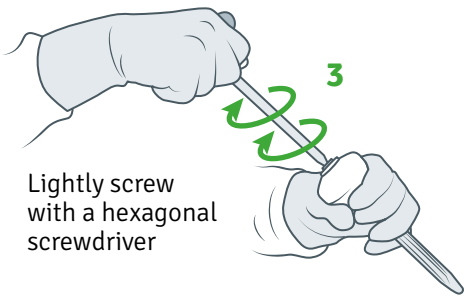
The screw-plug assembly is inserted into the spacer and afterwards is screwed onto the stem. The pre-assembled implant is placed on the support and tightening of the screw is assured with the help of a dynamometric tool and an anti-rotation guide (fixed to the polyethylene with pins in three holes for that purpose). To assure the correct fixation of the screw, the dynamometric key (TGUI15600HU), adjusted for a force of 5 Newton meter, should be used.

Introduce the stem into the spacer

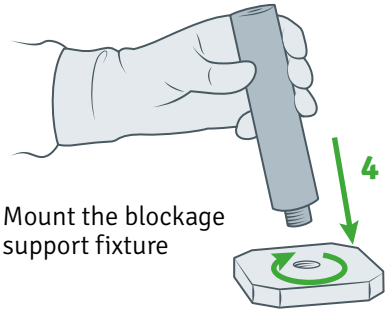


Place the screw-plug assembly

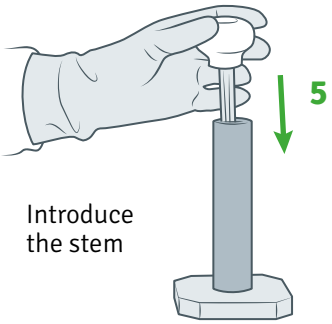




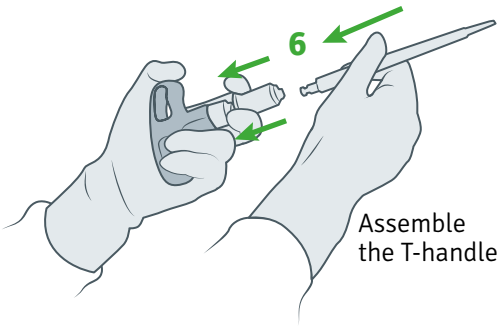
Lightly screw with a hexagonal screwdriver



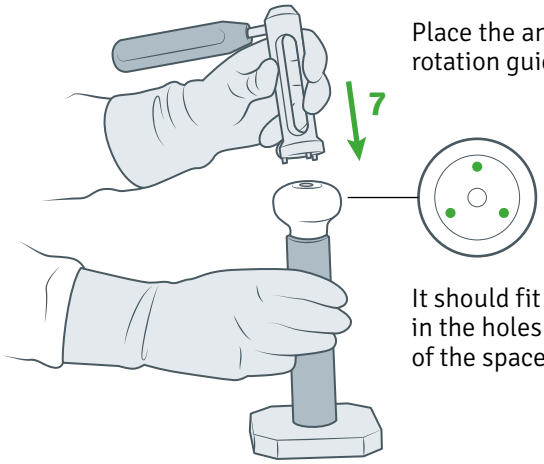
Mount the blockage support fixture



Introduce the stem

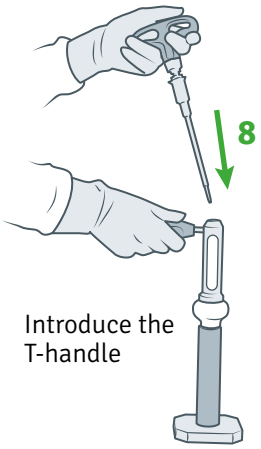


Assemble the T-handle

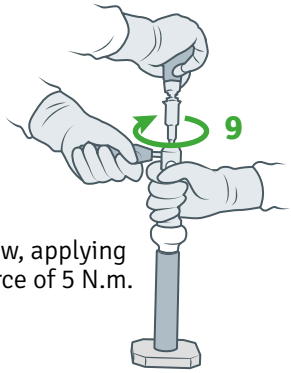


Place the anti-rotation guide

It should fit in the holes of the spacer

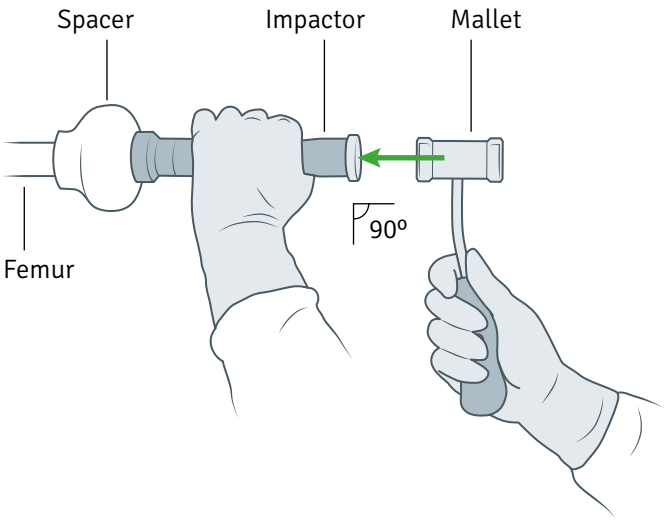


Introduce the T-handle



Screw, applying a force of 5 N.m.

Impactor



12. Implant insertion

12.A. Press-fit technique

The implant is introduced into the medullary canal and is impacted with help of the impactor, hitting it with a mallet, as aligned as possible with the femur diaphysis, until the Spacer contacts the distal surface of the femur.

A cerclage system is recommended in case of any fissure in the femur during the impact phase.

12.B. Cemented technique

If the femur doesn't have the capacity to withstand impaction on the cortical or with a cortical section thinner than 3 mm (0.13 in), a cemented technique is recommended.

Surgical bone cement will be used, according to manufacturer's indications. It's recommended to follow strictly a third generation cementation technique. This technique should be pressurized by using an intramedular cement plug suitable to the size and configuration of the medullary canal, a pulsatile washing system and drying of the medullar canal before placing the cement. The use of a distal centralizer is therefore recommended.

13. Surgical closure

13.A. Early implantation surgery

If you have used an ischemia sleeve we recommend retrieving it before surgical closure, in order to verify, firstly, that no important vessel is bleeding and, secondly, to permit the correct sliding of the muscular planes.

The closure is done by planes. Take into account that the excess of soft tissues will jeopardize the posterior support of the stump into the orthopedic prosthesis socket. In this sense, if there is an excess of muscle you should resect the surplus.

You should try to practice a myoplasty that covers the whole implant. This is done by suturing the quadriceps muscle with the posterior muscles of the thigh.

The cutaneous suture should not stay under tension, but an excess of subcutaneous fat will result in a less consistent stump ("pudding" stump) which will hinder the posterior prosthesis fitting and ulterior prosthesis control.

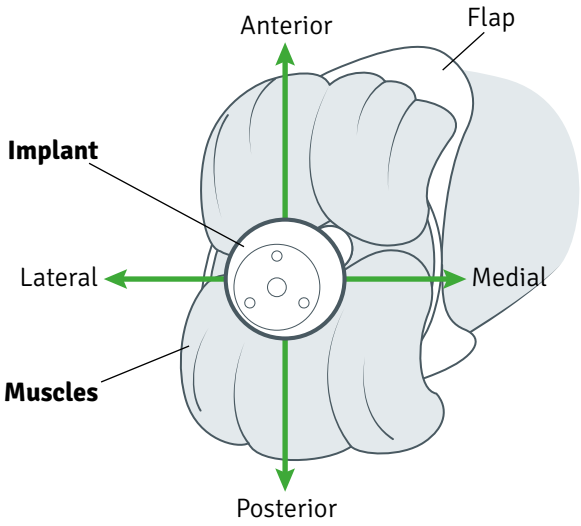
The use of drainage is optional. In case you use it, retrieve it after 48 hours at most.

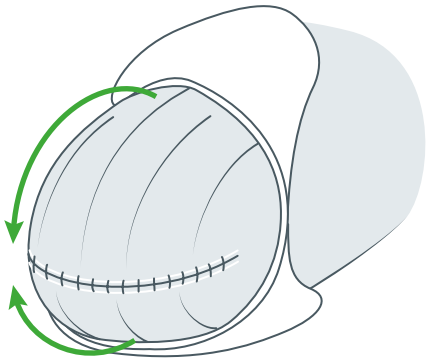
13.B. Delayed Implantation surgery

The closure is done by planes, trying to reconstruct the stump as similar as possible as it was before the surgical procedure. For realization of the myoplasty, suturing and drainage, follow the indications of the anterior paragraph as close as possible.

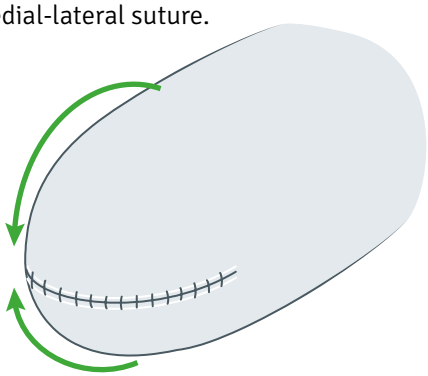
Take advantage of the surgery to correct defects the stump could have, such as irregularities or invaginations.

1 Closure of the musculature, anterior with posterior. Medial-lateral suture.

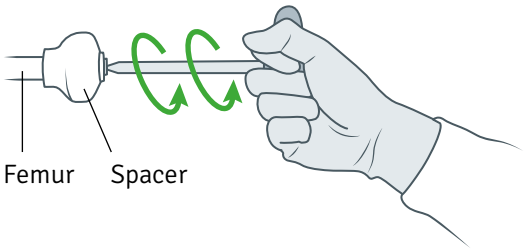




2 The skin and the subcutaneous tissues are sutured, attaching the anterior and posterior flap with a medial-lateral suture.

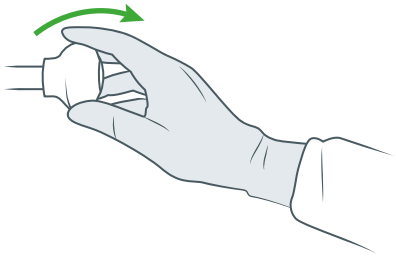


1 Remove the plug with the hexagonal screwdriver.

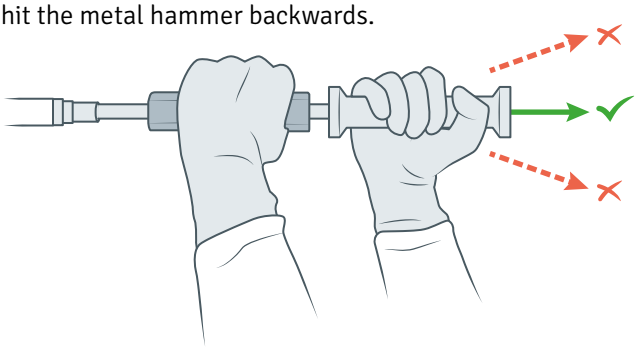


2 If needed, use the plug extractor.

3 Remove the spacer.



4 Screw the extractor to the stem and hit the metal hammer backwards.



14. Implant extraction

In case it is necessary to proceed to the extraction of the implant, the instruments available for that purpose should be used. Provided that there is no contraindication, the approach will be made through the existing scar.

Once the approach is completed the hexagonal screwdriver is used to remove the plug-screw assembly. This way the spacer is released and can be manually pulled out.

Once the spacer is removed, the cone of the femoral stem is visible where the extraction hammer must be screwed in until it stops. Hold the affected limb firmly. The stem is extracted by hitting the hammer linearly backwards with sharp blows until it is completely extracted.

Important: the direction of the extraction force must be aligned with the femoral canal and the implant. Hitting in the wrong direction can cause a bone residue fracture.

The retrieval of the product once used should be done by an authorized hospital waste processing company. An implant that has previously been used on a patient should never be reused.

Notes

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