Patient Information

Femoral Implant Keep Walking™

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1. GENERAL INFORMATION

1.1 Intended purpose and functionality

The Femoral Implant Keep Walking™ is intended to be used in patients who have suffered or are going to suffer an above- knee amputation due to vascular (blood circulation problem), trauma (injury) or tumoral (cancer) causes and are expected to have moderate level of activity after insertion of the implant.

Due to the shape of the Implant Keep Walking™, the stump can withstand direct loads into the prosthetic socket, which will reduce discomfort associated to the use of traditional leg prosthesis.

After an upper leg amputation, no direct load can be given on the end of the stump. If this does happen, the remaining bone of the thigh presses too hard on the muscles and the skin of the end of the stump and sore spots may occur. The fact that no direct load can be given on the end of the stump means that the pressure exerted on the leg during walking should be compensated elsewhere. Often this is solved by making a socket that comes to your seat bones. During the walk, most pressure is placed on the seat bones that can absorb that well. However, there are also a number of drawbacks in this pressure area: when sitting, people often suffer from the prosthetic socket and while walking the skin in the groin can become trapped.

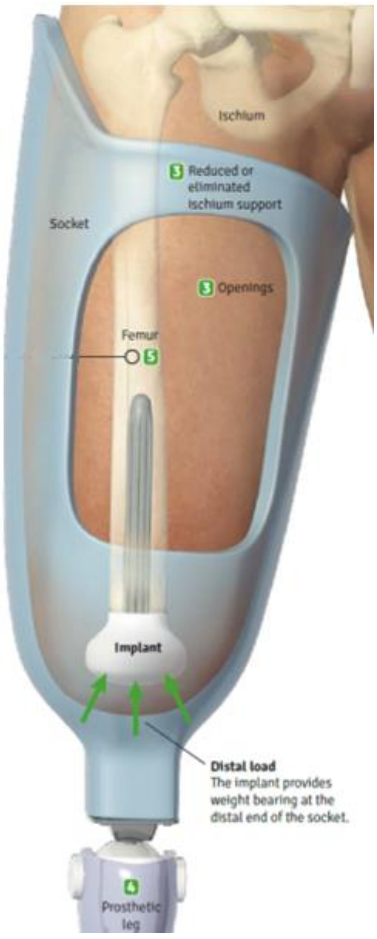


Figure 1. Illustration of Implant Keep Walking™ placed into the femur bone and the stump performing distal load on the socket.

Through this implant you can head the major part of your weight to the end of the femur achieving a high control of your prosthesis.

The implant is fixated into the femur (thigh bone) by means of a metal stem that can be impacted or cemented. If it is impacted into the bone, the surrounding bone tissue will grow and anchor the implant.

You can be a possible candidate for the Femoral Implant Keep Walking™ either if you have had or are going to have an above-knee amputation, as long as your physician recommends it and there is no contraindication.

1.2 Description of femoral implant components

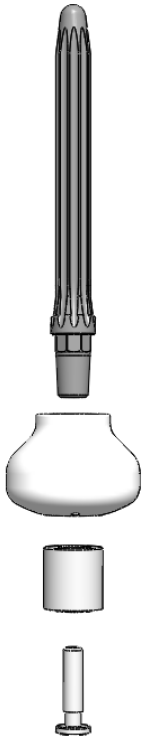
The Femoral Implant Keep Walking™ is composed of 4 components that are assembled and implanted during the surgery:

1. **Femoral stem**
   A metal rod made out of titanium alloy of medical grade[1] that is fixed to the femur. The stem is made of grooved shape with a rough surface in order to allow the fixation of bone.

2. **Spacer**
   A part made out of ultra high density polyethylene[2] that is placed covering the end of the femur.
   It is has a rounded shape in order to create a wide and comfortable surface for distal weight bearing of the stump.

3. **Washer**
   A plug made out of ultra high density polyethylene[2] that is placed into the spacer.

4. **Screw**
   A metal screw made out of titanium alloy of medical grade[1] that will unify all the components by being threaded into the stem.



1.3 Overall treatment procedure

During the surgical intervention, the femoral implant is placed inside the stump and fixed into the femur bone.

After the surgery, you'll be instructed by your rehabilitator physician about some exercises to perform until getting the definitive socket and prosthetic leg.

[1] Ti6Al4V – material composition according to the standard ASTM F136.
[2] UHMWPE – material composition according to the standard ASTM F648.

Between 7 to 10 days after the surgery, you will be instructed to begin gradual loading of the stump, as long as the wound is healed and the pain is bearable. This will prepare your stump for weight-bearing within the socket.

The provisional prosthetic socket will be fitted by your prosthetist between the 4th and 6th week after the surgery. Once the volume of the stump is stabilized, you will be fitted the final socket 12 weeks later.

2. INDICATIONS

The Femoral Implant Keep Walking™ is indicated for:

- Persons who have suffered or are going to suffer an above-knee amputation due to a pathology of vascular, traumatic or tumoral origin;
- Persons who have residual femoral length over to 14cm (5.51 in) if the implant is placed during the amputation surgery or 16 cm (6.30 in) if the implant is placed some time after the amputation.
- Patients expected to have moderate walking ability after having the implant surgery.

3. CONTRAINDICATIONS

The femoral implant Keep Walking™ is not recommended for patients if any of the following is applicable:

- You have an active cancer pathology and/or are receiving chemotherapy treatment;
- You have Immunosuppression (reduction of the activation or efficacy of the immune system);
- You have mental or psychiatric disorders and are not able to follow the rehabilitation instructions;
- You have allergy to any of the materials of the implant (titanium and polyethylene)
- You have alcohol or drug addiction;
- You have a femur too short, i.e. less than 12cm (4.72 in)
- You are pregnant;
- You have an active infection or a generalized body infection (sepsis).
- You have alterations of the Central Nervous System.

Depending on the clinical assessment made by your doctor, the Femoral Implant Keep Walking™ can be used with caution, if any of the following is applicable:

- You have severe osteopenia (thin bones), in which case the stem cannot be impacted into the bone.
- You have had a previous infection of the stump
- You have a flexion deformity in the hip (>30 degrees)
- You have osteoporosis (weak bones)
- You have a residual femoral bone between 12 and 14 cm (4.72 and 5.51 in).

4. RISK/BENEFIT INFORMATION

BENEFITS ASSOCIATED WITH FEMORAL IMPLANT KEEP WAKLKING™

The Implant Keep Walking™ reduces the problems associated to traditional above-knee prosthetic sockets, contributing mainly to the improvement patient's mobility and function.

This is shown by results from patients already treated with the implant Keep Walking™ where was found a significant increase in distance and walking speed, increased prosthesis use, decrease in pain and improved quality of life.

These improvements will help the patient to be more independent while performing daily living activities.

RISKS ASSOCIATED WITH FEMORAL IMPLANT KEEP WAKLKING™

As in all surgical procedures, the treatment with femoral implant Keep Walking™ is associated to certain risks.

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.

The following risks are associated with Femoral Implant Keep Walking™:

- Infection (fever)
- Phlebitis, thrombophlebitis and thromboembolic pathology (inflammation of circulatory system)
- Fracture of the femur during implant placement (depending of quality bone)
- Stem loosening (depending of quality bone)
- Rupture of the stem
- Loosening of the washer
- Cutaneous complications
- Dehiscence of the wound
- Border necrosis or more ample zones of the skin
- Hypertrophic scar
- Neuroma (sciatic nerve inflammation)
- Vessel lesion (surgery)
- Hemorrhage (surgery)
- Hematoma (surgery)
- Fracture of the femur diaphysis (fall or stumble)
- Unspecific pain or phantom limb pain

5. GENERAL WARNINGS AND PRECAUTIONS

WARNINGS

- If you have a history of previous infection on the amputated side, you should communicate this to your treating physician.

- Chemotherapy drugs can affect negatively bone growth onto the femoral stem and cause its loosening.

PRECAUTIONS

- ! It is very important to follow the rehabilitation protocol instructed by your treating physician in order to have the implant correctly anchored into the femur bone.
- ! After surgery, be sure to be in a clean environment that favors wound-healing and to follow instructions of your doctor regarding frequency of wound dressing changes.
- ! Take special care when performing high demanding activities or sports, since implant failure is more likely to occur.
- ! Pay attention to your weight and try it to be below 100 Kg, since implant failure is more probable to occur in overweighed patients.
- ! Before undergoing any imaging techniques as MRI (Magnetic Resonance Imaging) or CAT (Computerized axial tomography) inform your healthcare specialist about having a metal implant.

For the femoral implant Keep Walking™ perform as intended it is very important that you comply with the rehabilitation protocol, take note of warnings and precautions as outlined above, and always follow the indications of your physician, physiotherapist and prosthetist.
It is also very important that you go to all follow-up appointments.

6. WHEN TO CONTACT A HEALTH PROFESSIONAL

For your safety and comfort, and for the correct anchoring/fixation of the implant as well as for the prosthesis function without problem, it is important to follow certain instructions as when to contact a health care professional.

YOU MUST IMMEDIATELY CONTACT YOUR TREATING PHYSICIAN IF:

You experience pain from your leg or increased body temperature (fever).

You must always contact your treating physician if:

- You have pain in your stump and cannot perform weight bearing.
- You have suffered a fall in the implant side.

Contact your physical therapist if you have any questions related to your rehabilitation protocol.

Contact your prosthetist if you have any questions related to your prosthesis.

7. LIFETIME

Femoral Implant Keep Walking™ is estimated to have a useful life that can reach at least 25 years. However, failure to follow the rehabilitation protocol, excessive physical activity and overweight, can cause the replacement of the implant sooner than expected.

It is patient's responsibility to following the indications laid out in this document, while is responsibility of the treating physician to ensure that all indications applicable to femoral implant Keep Walking protocol are followed correctly and are performed by professional only.

Tequir I+D+i is responsible for the Femoral Implant Keep Waling performance only when the device is used in accordance to Instructions For Use and Patient Information.

8. CONTACT INFORMATION

If any serious incident occurs in relation to the device, it should be reported to the following contact information:

MANUFACTURER
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