OTNI Osseointegration Femur Prosthesis
Surgical Technique

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OTNI OFP
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Contents

Introduction

OTNI Osseointegration Femur Prosthesis (OTNI OFP) is an intramedullary, femoral and transcutaneous bone fixation system of the lower limb. It is an implantable modular system that can be used to provide a fixed support for the connection of an artificial limb to the residual femoral bone after transfemoral amputation, by means of the *OTNI HELI connector* or by means of the *OPL GV adaptor* or by means of the *OTNI 17 Luci Osseointegrationconnector.*

OTNI Osseointegration Femur Prosthesis (OFP) is a modular bone fixation system comprising of the following components:

- *OTNI Femur Stem equipped with OTNI Proximal Screw*
- *OTNI Healing Plug*
- *OTNI DC Adapter*
- *OTNI Locking Screw*

Figure 1 - The OFP Osseointegrated Femoral Prosthesis
Top to bottom: OTNI Locking Screw, OTNI DC Adapter, OTNI Femur Stem equipped with OTNI Proximal Screw
In parallel: OTNI Healing Plug

Advantages the osteointegrated implants in comparison to conventional socket attachment of prosthetic limbs include significant increase in walking distance with low energy costs, increase in prosthesis wearing time and quality of life, osseoperception and better sitting comfort.(*cit.:* , Van de Meent, ACRM 2013, Al Muderis, Unfallchirurg 2017). The OTNI OFP is a press fit uncemented intramedullary implant made of titanium with titanium plasma sprayed surface facilitating osseointegration into the femur.

Product specialists of OTN Implants B.V. are at your disposal for any further information and/or explanation about the contents of this Surgical Technique.

Please register implantation of this device in your national registry where available.

Intended use

The OTNI OFP is intended to provide a fixed support for the connection of an artificial limb prosthesis to the residual femoral bone after transfemoral amputation, in all those cases of complications after, or contraindications to the use of conventional socket connections. The OTNI OFP is a non-active surgical implant designed for long-term implantation inside the human body. It is intended to be used by (orthopaedic-) surgeons with good knowledge of the specific operative technique, in a standard orthopaedic environment, for skeletally mature patients.

Indications

- Trans-femoral amputation
- Complications after, or contraindications to the use of conventional socket prostheses

Contra-indications

- Inflammatory or septic, acute or chronic, local or systemic processes, also far from the implantation site
- Insufficient bone quality in order to seek appropriate and adequate press-fit anchoring and adequate osseointegration of the intramedullary stem (e.g. severe osteoporosis, osteopenia)
- Vascular, musculoskeletal and neurological disorders
- Bone metabolism disorders
- Long-term cortisone or chemotherapy treatments
- Patients with psychiatric disorders or mental instability or patients who are unwilling or unable to follow the instructions for rehabilitation and aftercare indicated by the doctor
- Smoking, alcohol abuse, drug use
- BMI > 25
- Pregnancy, lactation
- Skeletal immaturity

Two stage surgery

In a first surgery the anatomic shaped, intramedullary OTNI OFP *Femoral Stem* is implanted into the femur diaphysis by retrograde approach. Press-fit interference, bowed profile and proximal winglet stem portion provide a primary stability of the implant. The rough and porous surface structure of the OTNI OFP Femoral Stem facilitates fast and solid osseointegration.
The distal portion of the OTNI OFP Femoral Stem lies outside of the bone, surrounded by soft tissue. The OTNI OFP *Healing Plug* is temporarily applied into the OTNI OFP distal taper to prevent soft tissue ingrowth between surgery one and two.

A second surgery is performed to remove the OTNI OFP Healing Plug and to place the transcutaneous OTNI OFP DC (*dual cone) Adapter*. The OTNI OFP L*ocking Screw* connects the OTNI OFP Femoral Stem with OTNI OFP DC Adapter.
An artificial leg prosthesis may then be connected to the OTNI OFP DC Adapter with the *OTNI HELI connector or* with the *OPL GV adaptor* or with the *OTNI 17 Luci Osseointegrationconnector* (for this read below Post-operative connection to an exoprosthesis). The OTNI OFP DC Adapter can fit the *OTNI HELI connector* or the *OPL GV adaptor* or the *OTNI 17 Luci Osseointegrationconnector,* which can be easy assembled and disassembled.

Implantable components

The OTNI OFP products are supplied in two main packaging configurations which are set to suit the two step surgical approach. Resulting in the availability of the following kits:

Product number	Product name
OTN31101	OTNI Femur Stem Ø15x140 + OTNI Proximal Screw + OTNI Healing Plug
OTN31102	OTNI Femur Stem Ø16x140 +OTNI Proximal Screw + OTNI Healing Plug
OTN31103	OTNI Femur Stem Ø17x140 + OTNI Proximal Screw + OTNI Healing Plug
OTN31104	OTNI Femur Stem Ø18x140 + OTNI Proximal Screw + OTNI Healing Plug
OTN31105	OTNI Femur Stem Ø19x140 + OTNI Proximal Screw + OTNI Healing Plug
OTN31106	OTNI Femur Stem Ø20x140 + OTNI Proximal Screw + OTNI Healing Plug
OTN31107	OTNI Femur Stem Ø21x140 + OTNI Proximal Screw + OTNI Healing Plug
OTN31108	OTNI Femur Stem Ø22x140 + OTNI Proximal Screw + OTNI Healing Plug
OTN31201	OTNI DC Adapter Sz 70 + OTNI Locking Screw
OTN31202	OTNI DC Adapter Sz 80 + OTNI Locking Screw
OTN31203	OTNI DC Adapter Sz 90 + OTNI Locking Screw
OTN31204	OTNI DC Adapter Sz 100 + OTNI Locking Screw
OTN31205	OTNI DC Adapter Sz 110 + OTNI Locking Screw

Table 1, OTNI OFP kits

Recommended surgical instruments

BAAT medical recommends to use the following instrumentation for the surgical implantation of the OTNI OFP:

- OTNI Basic Instruments for Osseointegration Surgery (see document 16013ER180117 OTNI 13 basis-set osseointegratieinstrumenten)

BAAT medical validated the use of these devices in combination with OTNI OFP for its intended use.

BAAT Medical is not legal manufacturer of these surgical instruments.

Requirements of these instruments pertain to OTN Implants BV, Simon Stevinweg 48, 6827 BT Arnhem, The Netherlands. (https://www.otnimplants.nl/)

Post-operative connection devices

The following commercially available devices can fit the OTNI OFP DC adapter and may be used to connect the OTNI OFP to an exoprosthesis:

- OTN Silicon Cap
- OTN HELI connector

or

- OPL GV connector

Or

- OTNI 17 Luci Osseointegrationconnector

BAAT Medical is not legal manufacturer of any devices which connects the OTNI OFP to any exoprosthesis.

Requirements of the devices OTN Silicon Cap, OTN HELI connector pertain to OTNImplants BV, Simon Stevinweg 48, 6827 BT Arnhem, The Netherlands.(https://www.otnimplants.nl/)

Requirements of the device OPL GV connector pertain to Osseointegration International B.V. Spoorstraat 9, 7261 AE Ruurlo, The Netherlands.

Requirements of the device OTNI 17 Luci Osseointegrationconnector pertain to OTN Innovations B.V., Simon Stevinweg 48, 6827 BT Arnhem, The Netherlands (https://otninnovations.com/)

Pre-surgical planning

Calibrated AP X-rays of both legs in standing position are used to calculate the desired femur length in cases with long residual femur length (Figure 2). The knee joint space of the contra-lateral limb is used as reference for the pre-surgical planning. The aim of the pre-surgical planning is to shorten the residual femur in a way that the knee flexion axis of the external prosthesis exactly matches the knee joint space of the sound limb. Finally, the length of the residual femur plus the length of the OTNI OFP DC Adapter plus the length of the OTN HELI

connector or the length of the OPL GV adaptor or the length of the OTNI 17 Luci Osseointegrationconnector with an external prosthesis defines the position of the knee flexion axis of the external prosthesis. In cases with long residual femur length, the femur must be shortened to establish a distance between femur tip and the contra-lateral knee joint space of 140 to 180 mm. The 140 to 180 distance is based on the size of the OTNI OFP DC Adapter. The size of the OTNI OFP DC Adapter is estimated based on the thickness of subcutaneous fat layer. The 70, 80, 90, 100 and 110 mm OTNI OFP DC Adapter lengths match the respectively 140, 150, 160, 170 and 180 mm distance between femur tip and the contra-lateral knee joint space.
Attention should be given to control for the height of femoral heads on the AP X-rays of both legs in standing position. The diameter of the OTNI OFP Femoral Stem is estimated using standard AP femur X-ray with calibration and “agfa” orthopedic pre-surgical planning software.

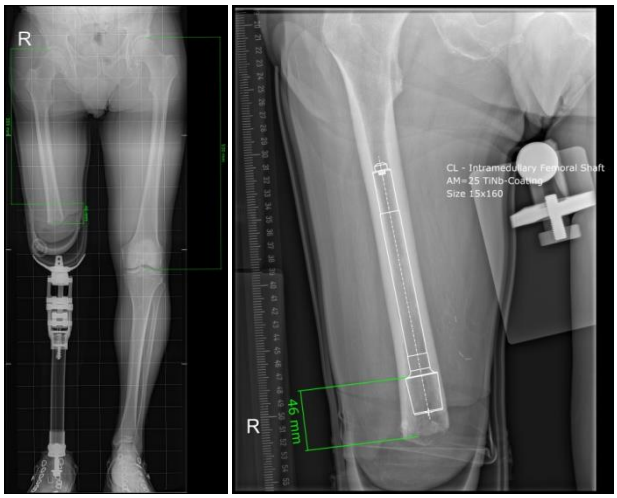

Figure 2, Pre-surgical planning using calibration and specific orthopedic computer software

The full range of OTNI OFP Femoral Stem diameters must be available at the time of surgery in case the pre-surgically estimated diameter does not provide the optimal press fit fixation.

In cases with residual femur shorter than 140 mm between distal femur tip and mid line of the lesser trochanter, a different solution should be pursued (e.g.: custom made OTNI implant and additional fixation with a gamma-type lag screw into the hip head). A standard 140 mm OTNI OFP Femoral Stem may be used in residual femurs shorter than 140 mm between distal femur tip and mid line of the lesser trochanter, however, this may restrict osteosynthesis in case of hip neck fractures and may restrict the possibilities for a modular hip arthroplasty in case of hip osteoarthritis.

Osseointegration surgery is performed under general or spinal anesthesia including prophylactic intravenous antibiotics (e.g. vancomycin (1 g) or cephazolin (2 g) at induction of anesthesia). The patient is placed in supine position on a radiolucent operation table with the 45 degree hip flexion on the amputated side. Draping and prepping is done in a fashion like that used for a standard total hip replacement. The OTNI OFP is implanted in one or two surgeries.

Surgery Stage 1

BAAT Medical recommends to use the instruments as listed in section: Surgical Instruments stage 1 (see below)

1. Open the skin and fascia to exposure of the distal tip of the femur.
2. Release any tethering tissue, identify the sciatic nerve and excise neuroma and shorten the sciatic nerve maximally.
3. Shorten the femur with an oscillating saw according to pre-surgical plan and remove redundant skin and soft tissue.
4. Insert a ball-tipped guide wire into the femoral diaphysis. Ream the medullary canal with standard non cutting flexible reamers under portable X-ray imaging. The last flexible reamer diameter is 1 mm below the predetermined OTNI OFP Femoral Stem diameter.
5. *Rasp the intramedullary canal with the OTNI Curved Rasps*. Use portable lateral X-ray imaging to control for the placement of *the OTNI Curved Rasp* relative to the antecurvation of the femur. Stop rasping at the similar rasp diameter as the predetermined diameter of the OTNI OFP Femoral Stem.
6. *Use the OTNI Tip Rasp* to create a distal femur saw plane exactly perpendicular to the longitudinal axis of the femur. *The size of the OTNI Tip Rasp is chosen according to the created femoral intramedullary diameter.*
7. *Mark the position of the OTNI Curved Rasp relative to the femur by placing the Aiming Device on the tip of the femur. The central tick mark of the OTNI Aiming Device should point exactly to the tick mark on the OTNI Curved Rasp. The position of the OTNI Curved Rasp should exactly match the position of the OTNI OFP Femoral Stem.*
8. Make four 1.25 mm burr holes with K-wire and insert transosseal 4.0 sutures.
9. Tighten the screw at the proximal morse taper of the OTNI OFP Femoral Stem with the *OTNI Hexagonal 4.0mm screw driver (OTNI Hexa 4).*
10. Insert of the OTNI OFP Femoral Stem using the *OTNI M6 femoral stem insertion tool* and hammer. *Ensure that the reference mark on the OTNI OFP Femoral Stem corresponds with the tick mark of the OTNI Aiming Device.* The selected OTNI OFP Femoral Stem diameter must match the last selected *OTNI Curved Rasp* diameter to obtain optimum press fit fixation. Under sizing may lead to non-integration and over sizing may lead to an intra-operative distal femur fissure. *When firm press fit placement is required, e.g. in case of strong cortical bone, the OTNI Taper Installer is used.*
11. Place the OTNI OFP Healing Plug into distal taper of the OTNI OFP Femoral Stem.
12. Rinse the wound.
13. Perform a myodesis by suturing the muscular fascial layers to the bone with the previously applied transosseal sutures.
14. Remove subcutaneous fat of the skin overlying the tip of the femoral stem to a depth of 2 cm.
15. Insertion a catheter for post-surgical local anesthesia near the end of the transected sciatic nerve
16. Close the wound in layers per the surgeon's standard technique.
17. Apply stump pressure bandage.
18. Control for correct OTNI OFP Femoral Stem placement with portable X ray.

Surgery Stage 2 (six to eight weeks after stage 1)

BAAT Medical recommends to use the instruments as listed in section: Surgical instruments stage 2

1. Localize the center of OTNI OFP Healing Plug by palpation and place percutaneously a K-wire into the OTNI OFP Healing Plug.
2. Create a stoma by cutting the skin and soft tissue to the OTNI OFP Healing Plug with the *OTNI Corer* guided over the K-wire.
3. Remove of OTNI OFP Healing Plug and thoroughly rinse the wound and the morse taper interior.
4. Choose the right size of the OTNI OFP DC Adapter based on the thickness of the soft tissue layer. At least 50 mm of the OTNI OFP DC Adapter length must protrude through the skin.
5. Insert the correct OTNI OFP DC Adapter and tighten the OTNI OFP Locking Screw using the *OTNI Retainer and the OTNI Hexa 4 Screw Driver. The OTNI Retainer is an instrument that fits around the OTNI OFP DC Adapter and prevents rotational forces to the stem while tightening the OTNI OFP Locking Screw.*
6. *To create a firm taper connection between the OTNI OFP Femoral Stem and the OTNI OFP DC Adapter, the OTNI OFP DC Adapter is hammered into the OTNI OFP Femur Stem morse taper using the OTNI Punch and hammer. After this, the OTNI OFP Locking Screw is retightened with the OTNI Retainer and OTNI Hexa 4 Screw Driver.*
7. In case the OTNI OFP DC Adapter has to be replaced, the OTNI OFP DC Adapter can be removed from the morse taper with the *OTNI Remover and the OTNI 10mm Cylinders.*

Post-operative connection to an exoprosthesis

The OTNI OFP is intended to provide a fixed support for the connection of an artificial limb prosthesis (exoprosthesis) to the residual femoral bone after transfemoral amputation.

The way the connection of OTNI OFP to an exoprosthesis is performed, does not pertain to the intended use of the device, nevertheless the following commercially available devices can fit in connection and may be used in combination for purposes of:

- OTN Silicon Cap for gauze fixation, when covering the stoma
- OTN HELI connector, when connecting the OTNI OFP DC Adapter with the external prosthesis

Or

- OPL GV adaptor

Or

- OTNI 17 Luci Osseointegrationconnector

Surgical Instruments stage 1

1. *General instrumentation*
   - *Surgical basic instruments for bone surgery*
   - *Power oscillating sawing machine*
   - *Power drilling machine*
   - *Flexible reamer set with ball-tipped guide wire*
   - *Hammer 1 kg*

2. *Recommended instrumentation*
   - *OTNI Tip Rasp size 13-21 (2 mm increments)*
     Ref.OTNI 13 01
     OTNI 13 02
     OTNI 13 03
     OTNI 13 04
     OTNI 13 05

   - *OTNI Curved Rasp size 15-22 (1 mm increments)*
     Ref.OTNI 13 15
     OTNI 13 16
     OTNI 13 17
     OTNI 13 18
     OTNI 13 19
     OTNI 13 20
     OTNI 13 21
     OTNI 13 22

   - *OTNI M6 Installer*
     Ref.OTNI 13 06

   - *OTNI Taper Installer*
     Ref. OTNI 13 07

   - *OTNI Hexa 4 Screw Driver*
     Ref. OTNI 13 08

   - *OTNI Aiming Device*
     Ref. OTNI 13 09

Surgical instruments stage 2

1. *General instrumentation*
   - *K-wire 2mm*
   - *Hammer 1 Kg*

2. *Recommended instrumentation*
   - *OTNI Corer 20mm diameter*
     Ref. OTNI 13 10

   - *OTNI Hexa 4 Screw Driver (= Hexagonal 4.0mm screw driver)*
     Ref. OTNI 13 08

   - *OTNI Punch*
   - *Ref. OTNI 13 11*

   - *OTNI Retainer*
     Ref. OTNI 13 12

   - *OTNI Remover*
     Ref. OTNI 13 13

   - *OTNI 10mm Cylinder*
     Ref.OTNI 13 14

WARNING

Reprocessing implants is not allowed. Reprocessing implants will not ensure adequate safety and performance of the devices.

All instrumentation must be reprocessed in accordance with their own instruction for use.

All details regarding cleaning and sterilization of the recommended surgical instrumentation set OTNI Basic Instruments for Osseointegration Surgery can be found in the instruction of the manufacturer.