



General Information for Osseointegration surgery with BADAL X

Author: H. Van de Meent
Version 1
Sept 24, 2026

OTN Implants BV | Griftdijk 105 | 6515 AE Nijmegen | The Netherlands
+31 (0)26 7370371 | www.otnimplants.nl

Osseointegration surgery with BADAL X; General Information:

1. Required assessments prior to OI surgery

1.1 Physical examination with emphasize on the inclusion and exclusion criteria.

Inclusion Criteria:

Above and/or below knee amputation; uni- and bilateral
Difficulties with the socket attached prosthesis
Fit for general anesthesia

Exclusion Criteria:

Atypical femur/tibia anatomy (eg deformity, dysplasia) or nearby hip-, knee joint dysfunction
Radiation therapy at target limb or chemotherapy within past 18 months
Peripheral vascular disease with local critical ischemia (TcPO₂<40mmHg)
Diabetic mellitus with polyneuropathy
Local skin infection or systemic inflammatory disease
Immunocompromised or immunosuppressive drug use
Cardiorespiratory conditions that limit current and future potential for walking
Cognitive impairment with problems to adhere to medical instructions
Somatically unexplained pain or physical condition(s)
Active smoking
Bodyweight>125 kg

1.2. X-Ray: Total leg and CT scan

CT Protocol: Lower extremity CT without contrast

Region of scan: Femoral head to distal femur tip Tibia: Tibia plateau to distal tibia tip

Slice thickness: 0,5mm (120kV 130mAs). Reconstruct axial slices 0,5mm

Filming: Standard bone kernel (FC30) and soft tissue kernel (FC07).

Patient positioning: supine, feet first, toes pointing straight up.

If contralateral knee has implant, elevate that knee to mitigate artifact.

Recommended field of view: 25 x 25 cm for unilateral scan, 32 x 32 cm for bilateral scan.

Peripheral soft tissues can be cut off.

1.3. Laboratory examination

1.3.1. Complete Blood Count (CBC)

Hemoglobin (Hb) & Hematocrit (Hct)

White Blood Cells (WBC)

Platelets

1.3.2. Kidney Function & Electrolytes

Creatinine & BUN (with eGFR)

Sodium & Potassium:

1.3.3. Coagulation Profile (Strolling Tests)

PT / INR and aPTT

1.3.4. Blood Glucose and fasting Glucose or HbA1c:

1.3.5. Blood Type & Antibody Screen:

1.3.6. C-Reactive Protein (CRP) / ESR

2 Treatment plan

BADAL X™ can be installed preferably in a single surgical procedure under spinal or general anesthesia. First the Stem is installed into the diaphysis of the bone remnant of the lower limb by retrograde approach. The installation of Implant is press-fit to provide a primary stability for osseointegration. The surface of the Stem is a rough titanium plasma spray to facilitate fast and solid “bone ingrowth” osseointegration. Then a cutaneous stoma is created and the Adapter component of BADAL X™ is attached to the Implant with the M6 Locking Screw. After the surgery the LUCI Connector is attached to the Adapter with a M14 Abutment Screw to allow a quick-attach-and-release connection of BADAL X™ with an artificial limb.

Surgical technique: see <https://otnimplants.com/badal-x-surgical-technique/>

3 Postoperative monitoring

Plan post surgery	Check	Act
48 hours	Surgical wound with regard to persistent bleeding through wound or stoma. PO X ray regarding proper implant/locking screws position	In case of persistent bleeding apply pressure bandage for another 48 hours or perform explorative surgery to stop the bleeding. Consider redo in case of mal position of implant/locking screws Instruct patient regarding proper stoma cleaning with water and soap twice daily
2-3 weeks	surgical wound with regard to wound healing, infection	Remove sutures Check if stoma care instructions are well understood by patient. If not repeat instructions In case of infection, reevaluate progression after 10 days to check CRP in case of progression and prescribe of oral antibiotics only in case of CRP>15 Instruct patient regarding implant loading and refer to CPO for prosthetic fitting and refer to rehabilitation clinic/physical therapist for gait training (see https://otnimplants.com/wp-content/uploads/2024/02/AftercareGuidelines_DEF.pdf)
3-6 months	Stoma, implant loading capacity, gait pattern/prosthetic alignment and connector maintenance	Retighten M6 internal locking screw with hexa 4 screw driver and retainer (or refer patient to prosthetist with these instructions) Check if stoma care instructions are well understood by patient. If not repeat instructions In case of infection, reevaluate progression after 10 days to check CRP in case of progression and prescribe of oral antibiotics only in case of CRP>15 Refer to either prosthetist or physiotherapist in case of poor prosthetic alignment/ walking pattern/connector maintenance
1-2 years	Stoma, implant loading capacity, gait pattern/prosthetic alignment and connector maintenance Consider follow up X-ray	Check if stoma care instructions are well understood by patient. If not repeat instructions Refer to either prosthetist or physiotherapist in case of poor prosthetic alignment/ walking pattern/connector maintenance

4 Algorithm for action in the event of complications.

Triage level/ complication	Immediate Action&Clinical; Rationale	Referral timeframe	Target Healthcare Facility
Red: Emergency Major Hemorrhage/ Shock	Syncope and arterial pulses indicate hemorrhage/shock	Immediate (<1hour)	Emergency Department (ED) / Level 1 Trauma Center with on-call orthopedics.
Orange: Urgent - Acute Infection - Periprosthetic fracture - Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE)	- High fever, erythema, >3–5 days post-op indicates acute Infection. consider debridement, Antibiotics - Pain during stress testing on the implant and unusual implant position/motion indicates fracture and requires immediate Xray and eventual surgery - Contra-lateral calf swelling or acute shortness of breath requires immediate duplex ultrasound or CT-angiography.	Within 12 to 24 hours	Orthopedic Surgical Ward or the specialized facility where the index surgery was performed.
Green: subacute - Late/Chronic Infection (A)septic Loosening - Skin infection in the skin penetration area	- Gradual onset of pain after months of normal function indicates chronic infection or aseptic loosening. - These require diagnostic workups (X-ray, CT, ESR/CRP labs, or ahead of a planned revision surgery. - Skin infection (cellulitis) requires intensive stoma cleaning measures and in case of raised CRP; oral antibiotics	Within 1 to 2 weeks	Outpatient Orthopedic Clinic via an expedited consultation.