

Instructions for use – V8a

OTNI 17 Luci Connector C€

OTN Innovations B.V., Griftdijk 105, 6515AE Nijmegen, the Netherlands

www.otninnovations.com



Notes regarding the document's last update

Additions and rectifications:

- Added the new address of the manufacturer
- Added and revised several notices and cautions
- Added 2.1, 3.6, 4.2, 7.3, 10.2, 12.3
- Revised 3.5, 7.2, 7.4, 9, 10, 12.1
- General text corrections

WARNING

- Please read this document carefully before using the product.
- Follow the safety, cleaning, and maintenance instructions and execute periodic checkups to avoid injuries and damage to the product.
- Instruct the user at installation and check-ups (see 10.3).
- The prosthetic components and prosthesis shown in the illustrations are used as examples to illustrate the general process. The instructions for use of the prosthetic component selected for the patient contain detailed information and must be followed for assembling the BADAL X system.
- This document and the product are intended exclusively for assembling the BADAL X system by a certified prosthetist with knowledge of lower limb prosthetic fittings.
- Please store this document in a safe place and consult it during periodic checkups. The latest version of this document and translations can be found via the QR code on the last page or at www.otninnovations.com/accessoires.

1. General information

1.1 Company

OTN Innovations B.V.

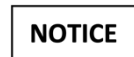
Griftdijk 105, 6515AE Nijmegen, Gelderland, The Netherlands

info@otninnovations.com, +31 6 22 20 47 26

1.2 Explanation of warning symbols



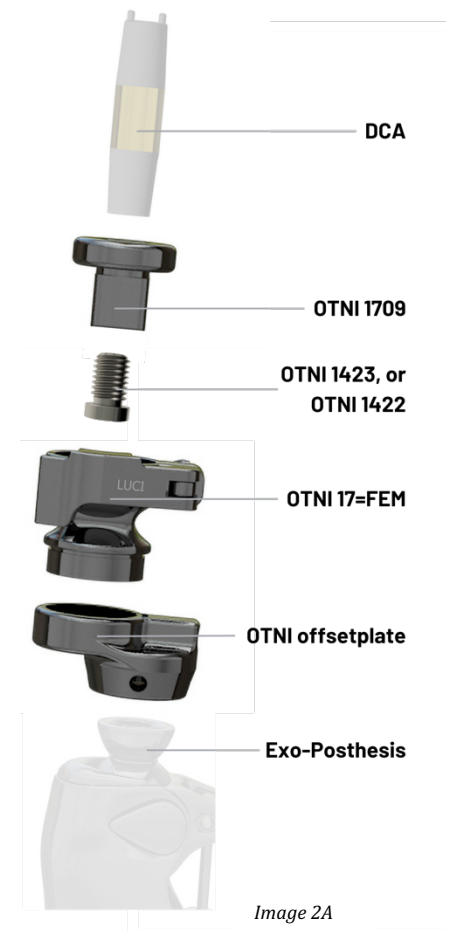
Warning regarding possible risks of accident or injury.



Warning regarding possible technical damage.

2. Product description

The OTNI 17 Luci Connector is a product to quickly attach-and-release bone-anchored prosthetics. It contains an OTNI 1709 Luci Male Part, an OTNI 17=FEM Luci Female Set (consisting of OTNI 1701 Female Part, OTNI 1702 Luci Lip, OTNI 1703 Luci Locknut, OTNI 1704 Luci M6 Shaft Screw, OTNI 1705 Luci Axis, OTNI 1706 Luci Locking Screw (3x M3 screw), OTNI 1707 Luci Grit Plate). The OTNI 17 Luci Connector needs to be combined with an OTNI 1423 M14 Abutment Screw or OTNI 1422 M12 Abutment Screw and an OTNI Offsetplate (OTNI 1700 - OTNI 1760K) (not included, see image 2A). Components with individual reference numbers can be ordered separately.



2.1 Available offsetplates (see 7.1 for determining offset)

OTNI 1700	0 mm	OTNI 1740K	40 mm kink 12°
OTNI 1710	10 mm	OTNI 1750	50 mm
OTNI 1720	20 mm	OTNI 1750K	50 mm kink 15°
OTNI 1730K	30 mm kink 5°	OTNI 1760	60 mm
OTNI 1740	40 mm	OTNI 1760K	60 mm kink 15°

2.2 Available accessories

OTNI 25	Luci Nightcap for bathing, sleeping, and protection after doffing the prosthesis.
OTNI 90	Toolbox for installation, alignment, and maintenance (not necessary).
OTNI ORBIS	Silicon cover to protect the stoma (manufactured by OTN Implants).

3. Intended use

3.1 Indications for use

The OTNI 17 Luci Connector is intended to be used as part of compatible bone anchoring systems for lower limb amputees. By using the OTNI 17 Luci Connector, the user can adapt the prosthesis to various fields of application by quickly changing the lower section.

3.2 Area of application

Only use the product according to its intended use:

- Allowable amputation types: Transtibial amputation, Transfemoral amputation
- Allowable field of application: all daily activities, including bathing and sports
- Allowable body weight: max 125 kg/275 lbs
- Recommended mobility grade: K1-K4
- Non-sterile device, not meant for re-use

Contraindications:

- Activities that may cause high-impact forces on the product (such as skiing, weight lifting, contact sports, and risk of high falls)
- Patients with mental and/or physical restrictions to use the connector

3.3 Combination possibilities



Incorrect combinations could lead to injury, malfunction, or product damage. Consult OTN Innovations B.V. about combination possibilities if they are unclear.

- Based on the instructions for use of all prosthetic components used, verify that they may be combined and are approved for the patient's field of application.
- The product can safely be used with all other components of the BADAL X system. If you are uncertain whether the user is equipped with this system, check the REF or medical file or contact OTN Innovations B.V.
- The OTNI 17 Luci Connector can only be combined with currently available bone-anchored devices provided with a 16/18mm taper connection and the offset component (OTNI 1700 - OTNI 1760K) through the M36 junction from OTN Innovations B.V.. Functionality with components of other manufacturers that have compatible modular connectors has not been tested and is not recommended.
- Contact OTN Innovations B.V. with questions about combination possibilities.

3.4 Environmental conditions

Do not expose the product to unallowable environmental conditions (see Table 3.4B). If it was exposed to unallowable environmental conditions, take suitable steps (e.g., cleaning, repair, replacement, inspection by OTN Innovations B.V.).

Table 3.4A: Allowable environmental conditions	
Use	Temperature: -10°C to +90°C (Sauna (max +90°C) and cold baths are allowed with precautions)
	Relative humidity: 0 % to 90 %, non-condensing
	Air pressure: 250 – 1100 mbar
	Fresh water, rain, salt water, urine, dust, sand – cleaning required after contact with salt-laden air, particles of foam cosmetics
Storage/transportation	Temperature: -10°C to +60°C
	Relative humidity: 20 % to 90 %, non-condensing

Table 3.4B: Unallowable environmental conditions	
Use	High vibrations, cleaning agents containing solvents
Storage/transportation	high vibrations, impacts

3.5 Service life



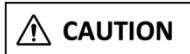
Not meeting the instructions for use may result in a shorter service life.

- OTN Innovations B.V. has tested this product according to ISO 10328 for 125 kg and 3,0x10⁶ cycles (about 2700 steps a day). Depending on the patient's activity level and the offset, this corresponds to a service life of 3 years.
- Wear and service life depend on the quality of cleaning (see Chapter 9), the quality of maintenance (see Chapter 10), and timely troubleshooting. During the service life, the connector can be subject to light wear within normal use but high offset.

3.6 Qualification requirements and responsibility

This product is only to be handled by certified professionals. The certified prosthetist is responsible for all products within the BADAL X system that are produced by OTN Innovations B.V.. This involves the M14 or M12 abutment screw, the Luci Connector, and the offsetplates. This document only describes the responsibility for these products. For requirements and responsibility for the implant, dual cone adapter (DCA), M6 locking screw, and other products from OTN Implants, check the documentation provided by OTN Implants B.V.. For components of other manufacturers, consult their documentation.

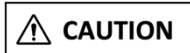
4. General safety instructions



Mechanical damage to the product could lead to injuries due to changes in or loss of functionality.

- Use caution when working with the product.
- Inspect the connector prior to installation for function and compatibility with the other prosthetic components.
- Do not use the product if it is damaged or if the seal on the box is broken.
- If functionality changes or is lost, do not continue using the product and take any necessary measures (see Chapter 8).

4.1 MRI safety



Failure to follow MRI instructions may result in injury.

Safety is guaranteed under the following conditions:

- Static magnetic field of 3-Tesla or less.
- Maximal spatial gradient magnetic field of 720-Gauss/cm (a higher value for the spatial gradient magnetic field may apply if properly calculated).
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (per pulse sequence).
- The OTNI 1709 Luci Male Part, OTNI 1422 M12 Abutment Screw, and OTNI 1423 M14 Abutment Screw are MRI-safe. We advise leaving the assembled OTNI 17=FEM Female Set, offsetplate (OTNI 1700 - OTNI 1760K), and other components out of the MRI.
- In all cases, the healthcare professional is responsible for MR Conditions, MR Imaging quality, and patient safety. Any safety issues or major image artifacts should be reported.

4.2 Safety mechanisms of the BADAL X system



Adhere to the instructions for use to prevent injury. Using the correct torque and thread lock instructions for all parts is vital for proper functioning of the safety mechanisms (see 7.2 and 7.3).

The BADAL X system consists of three safety mechanisms (see image 4.2A):

- 1) The first safety mechanism involves a slip coupling in the M36 threaded connection between the female part and the offsetplate. This safety feature allows rotation in case of high forces and activates between 45 Nm and 75 Nm, depending on the user's weight and alignment. Make sure to save two millimeters between the flange of the Luci Connector and the offsetplate to enable rotation in both directions. The activation point can be adjusted by adapting the torque on the M5 adjustment screw in the offset plate (always between 5-10 Nm). See 7.2 step B for instructions. Upon activation of the safety mechanism, the offsetplate will rotate relative to the female part. After activation, the prosthetist must check the system for damage and reset the mechanism according to this document. Exchanging the M5 screw is necessary. Add 1 or 2 Nm to a maximum of 10 Nm if early rotation occurs.
- 2) The second safety mechanism entails the capability of the male part to rotate around the DCA at approximately 80 Nm.
- 3) The third safety mechanism entails two weak points in the DCA's connection to the implant.

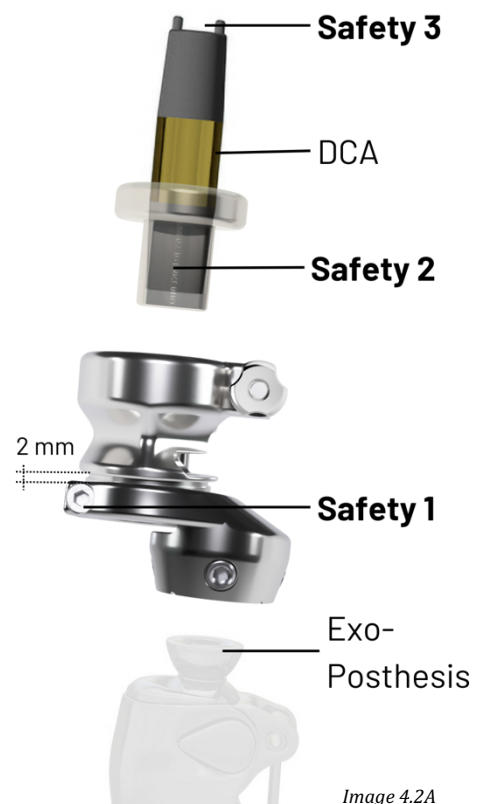


Image 4.2A

5. Scope of delivery

The sets include the following parts:

- The OTNI 17 Luci Connector: OTNI 1709 Luci Male Part, OTNI 17=FEM Luci Female Set, OTNI 1423 M14 Abutment Screw, Allen key 1,5 mm, two spare OTNI 1707 Luci Grit Plate and two spare OTNI 1706 Luci Locking Screw (2 sets of three screws).
- The OTNI 17=FEM Luci Female Set: OTNI 17=FEM Luci Female Set, Allen key 1,5 mm, two spare OTNI 1707 Grit Plate, and two spare OTNI 1706 Luci Locking Screw (2 sets of three screws).

6. Technical data

Table 6A: Technical data	
System height	67 mm (of which 25 mm overlaps with the distal cone from OTN Implants and 12 mm overlaps with the male pyramid).
System height (net)	30 mm
Connector weight	238 grams (excl. tools and spare parts)

7. Preparation for use



Finish all steps in this chapter before dynamic trial to prevent injury.

- Required tools: OTNI 92 DCA Retainer, Allen key 1.5 mm (included in box), Torque wrench <25 Nm with 4.0 mm and 6.0 mm bits, Inbus key 16 mm & 20 mm, or adjustable wrench, OTNI 16 Puller (for disassembly).
- Other supplies: Alcohol, paper towel, marker, Loctite 221 & 222, inclinometer, tape measure.
- All required tools are included in the OTNI 90 Toolbox, which can be purchased through our distributors.

7.1 Determining the size of the offsetplate

The appropriate offset can be determined by performing the Thomas test and using Table 7.1A. The choice of offset may have consequences for static and dynamic alignment.

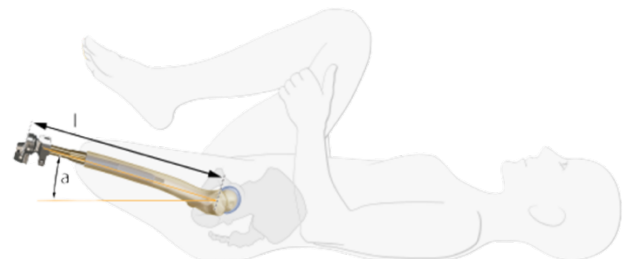


Image 7.1A

Please consider the following:

- A smaller offset reduces the energy required for knee flexion at the end of the standing phase.
- When using a prosthetic knee with electronic flexion-extension control, minor differences in offset can be compensated with a 0, 10, or 20 mm offsetplate.
- In tibial bone-anchored systems, an offsetplate (0, 10 or 20 mm) can be used to correct the position of the prosthesis in the frontal plane, either medial or lateral.

Table 7.1A: Offset plate size table				
length l (mm)	Hip flexion angle a (degrees)			
	0	5	10	20
150	0	10	20	50
200	0	20	30	50
250	0	20	40	50
300	0	30	50	60
350	0	40	60	60

7.2 Bench alignment of the prosthesis

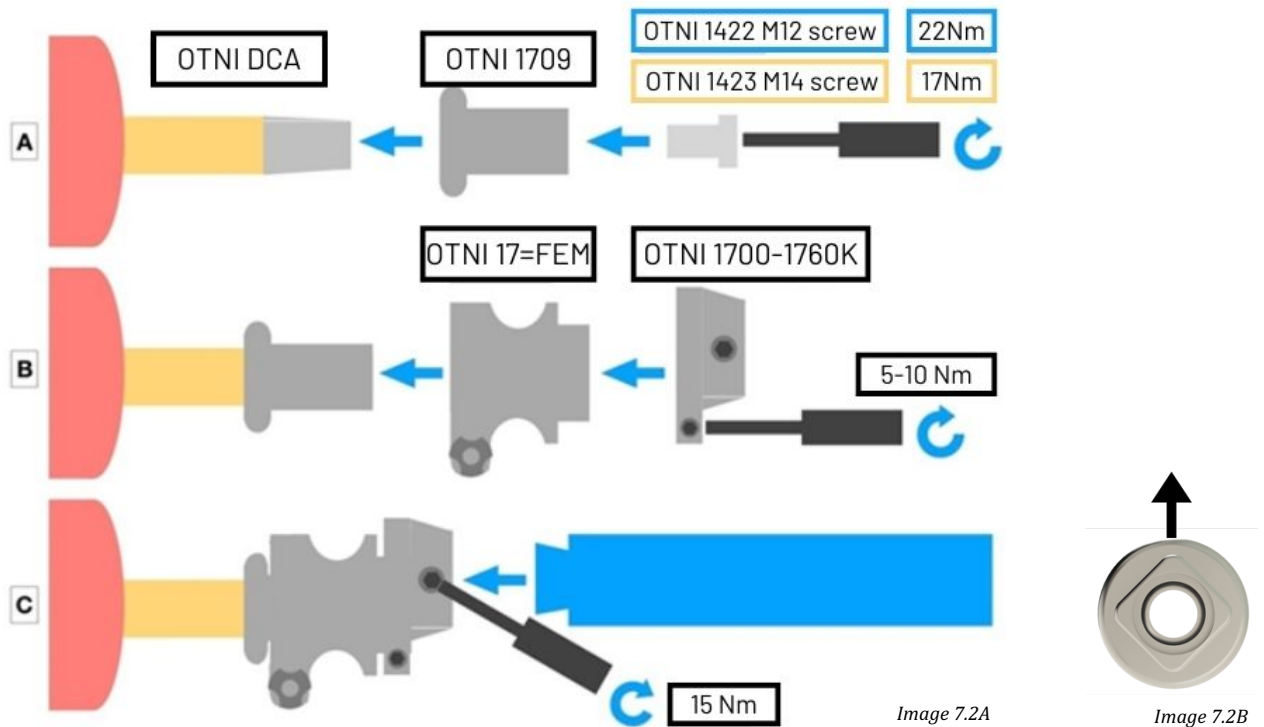


Adhere to the instructions to prevent injury. Improper assembly of the screw connections could lead to injury. Observe the specified settings in 7.3.



Overtightening of the Abutment Screw (OTNI 1423 or OTNI 1422) may lead to a cold weld between the male part and DCA, resulting in malfunction of safety 2.

Consult this document and the aftercare documentation of the implant manufacturer before installation and check-ups.



Installation of the Luci Connector (see image 7.2A)

- **Step A:** Clean the DCA distal taper and install the OTNI 1709 Luci Male Part by tightening the OTNI 1423 M14 Abutment Screw or the OTNI 1422 M12 Abutment Screw with the proper settings (see 7.3). Stabilise the OTNI 1709 Luci Male Part with a 20 mm key. For optimal clamping, place one of the corners of the square of the male part in walking direction (see image 7.2B).
- **Step B:** Apply the pre-adjusted OTNI 17=FEM Luci Female Set so that the fitting corresponds to the OTNI 1709 Luci Male Part. Clamp the female part onto the male part by closing the OTNI 1702 Luci Lip until it makes contact with the OTNI 1701 Luci Female Part. Do not retune the clamping mechanism unless clamping is insufficient. If needed, re-tune according to the instructions in paragraph 10.1.

Screw the offsetplate (OTNI 1700 to OTNI 1760K) onto the M36 thread of the OTNI 1701 Luci Female Part (no thread lock is used to enable rotation in safety 1, see 4.2). For patients with a tibia bone-anchored system, it is sufficient to use 0 mm offset using the OTNI 1700, OTNI 1710, or OTNI 1720. For patients with a femur bone anchored system, the hip flexion contracture degree will depend on the degree of flexion contracture. An offset of 0/10/20/30/40/50/60mm can be used. It is recommended to use Table 7.1A and evaluate in the dynamic pass session whether the patient needs a larger offset. The prosthesis can be adjusted by rotating the offsetplate relative to the OTNI 1701 Luci Female Part.

Table 7.2B: Torque settings M5					
Body weight	MOB 1	MOB 2	MOB 3	MOB 4	MOB 4+
50	5 Nm	5 Nm	6 Nm	7 Nm	7 Nm
55	5 Nm	5 Nm	6 Nm	7 Nm	7 Nm
60	5 Nm	5 Nm	6 Nm	7 Nm	7 Nm
65	5 Nm	5 Nm	6 Nm	7 Nm	7 Nm
70	5 Nm	5 Nm	6 Nm	7 Nm	7 Nm
75	5 Nm	6 Nm	6 Nm	7 Nm	7 Nm
80	5 Nm	6 Nm	6 Nm	7 Nm	8 Nm
85	5 Nm	6 Nm	6 Nm	8 Nm	8 Nm
90	5 Nm	6 Nm	6 Nm	8 Nm	8 Nm
95	6 Nm	6 Nm	7 Nm	8 Nm	8 Nm
100	6 Nm	6 Nm	7 Nm	8 Nm	8 Nm
105	6 Nm	6 Nm	7 Nm	8 Nm	9 Nm
110	6 Nm	6 Nm	7 Nm	8 Nm	9 Nm
115	6 Nm	6 Nm	7 Nm	8 Nm	9 Nm
120	6 Nm	7 Nm	7 Nm	9 Nm	9 Nm
125	6 Nm	7 Nm	8 Nm	9 Nm	9 Nm

Make sure to save two millimeters between the flange of the OTNI 1701 Luci Female Part and the offsetplate to enable rotation in both directions (see safety 1 in 4.2). Once the correct rotation has been determined, the M5 adjusting screws in the offsetplate can be tightened between 5 and 10 Nm; Table 7.2B provides an indication. Offset size can influence the needed torque. Add 1 or 2 Nm to a maximum of 10 Nm if early rotation occurs.

When the soft tissue touches the 1701 Luci Female Part while standing or walking, it can be rotated 90, 180, or 270 degrees. The connector can also be installed backward.

- **Step C:** Attach the prosthesis with the universal pyramid connection to the pyramid receiver on the offsetplate. Adjust the position by tightening the M8 set screws according to 7.4 to optimise the static alignment. Check if all settings are applied correctly (see 7.3). The correct functioning of the prosthesis must be tested with its various distal prosthetic components.

7.3 Screw connection specifications

screw connections must be tightened according to the prescribed specifications in Table 7.3A.

Table 7.3A: screw connection specifications		
	Torque	Thread lock
OTNI 1423 M14 Abutment Screw	17 Nm	thread lock when necessary
OTNI 1422 M12 Abutment Screw	22 Nm	thread lock when necessary
OTNI 1706 Luci Locking Screw	1 Nm	apply thread lock
M5 adjusting screws in the offsetplate	5-10 Nm (see Table 7.2B for indication and instructions)	no thread lock
M8 set screws of the pyramid receiver	15 Nm	apply thread lock

7.4 Optimising the static alignment

- Optimise the static alignment of the prosthesis with its various distal prosthetic components according to the values in the instructions for use of the products that are used.
- Alignment possibilities:
 - 0-60mm anterior-posterior translation and medial-lateral translation with offsetplates.
 - Rotation possibility: 360 degrees relative to DCA, 360 degrees relative to the prosthesis (if the offset is 30mm or higher).
 - Flexion/extension/valgus/varus: standard 7 degrees with female pyramid connection adapter. Optional extra degrees with higher offset (30mm = 5 degrees extra flexion, 40mm = 12 degrees extra flexion, 50/60mm = 15 degrees extra flexion).
- For patients with transfemoral bone-anchored systems, set 7° valgus with the pyramid receiver adjustment screws between the offsetplate and the rest of the prosthesis.
- For patients with transtibial bone-anchored systems, adjust varus / valgus with the pyramid receiver set screws plateau.
- For patients with transfemoral bone-anchored systems, use one of the various offsetplates (see 2.1 for an overview) depending on the degree of hip flexion contracture. OTNI offsetplates 0, 10, and 20 mm can also be used for patients with transtibial bone-anchored systems to apply a translation in a certain direction.

7.5 Optimising during dynamic trial fitting

Test and optimise the prosthesis with its various distal prosthetic components during the dynamic trial fitting.

7.6 Attaching the cosmetic cover

Fabricate the cosmetic cover so that the Luci clamp mechanism can be operated easily and reliably.

8. Use



Mechanical overload or improper use could lead to injury due to breakage of load-bearing components or impaired functionality due to mechanical damage.

- Instruct the user to check the product for damage prior to each use and not to use the product if its functionality has been impaired.
- Instruct the user to contact the certified prosthetist in case of impaired function.
- Take any necessary measures (e.g. repair, replacement, or inspection by the customer service of OTN Innovations B.V.).
- Contact OTN Innovations B.V. if needed.

8.1 Locking the OTNI 17 Luci Connector



Using the product without properly closing the lip could lead to injury due to prosthetic components coming loose.

- Check, before using the prosthesis, whether the OTNI 1702 Luci Lip makes contact with the OTNI 1701 Luci Female Part.

9. Cleaning



Instruct the user to clean the connector regularly according to the instructions to prevent damage to and wear of the product. Use of unsuitable cleaning agents or disinfectants could lead to functional limitations and damage.

Instruct the user

- to daily inspect the product for contamination.
- to daily clean the product with water and a damp, soft cloth, then dry the product with a dry, soft cloth. OTN Innovations B.V. recommends cleaning every time before going to bed to increase the product's service life.
- if needed, to clean the inside of the connector with soap, but not to apply soap to the lip joint and screws.
- to rinse the product with fresh water and clean it with a soft, dry cloth after contact with salt or dirty water.

The appearance of a little black residue is normal with a larger offset, but excessive black residue can be a sign of insufficient clamping. If the connector parts cannot be cleaned according to the instructions above, the prosthetist can use a 320-grit abrasive fleece during the check-up to carefully clean the male and female parts. In case of excessive residue, check if the clamping is sufficient (see 10.1).

10. Maintenance



Failure to follow maintenance instructions can cause injuries due to changes in or loss of functionality and damage to the product.



Excessive retightening of screw connections, including the OTNI 1703 Luci Locknut, can lead to damage to the product.

- Conduct a visual inspection and functional test of the prosthetic component after the first 30 days of use (see 10.3).
- Conduct annual safety inspections (see 10.3).
- Consult this document and the aftercare documentation of the implant manufacturer before installation and check-ups.
- Inspect the entire prosthesis for wear during check-ups.

- Replace parts if they are damaged or worn out (see 10.2). Parts can be ordered separately through our distributors. Some spare parts are included in the packaging and available at OTN Innovations B.V. on request.
- Please contact OTN Innovations B.V. for advice if needed.

10.1 Tuning the clamping mechanism

NOTICE Persisting improper clamping can lead to wear.

The clamping mechanism of the Luci Connector is preset at delivery. OTN Innovations advises only to retune it if the clamping is insufficient or in case of excessive wear.

During every periodic check-up, the clamping mechanism must be checked (and tuned only if necessary). Signs of improper clamping are wear on the parts (excessive black residue), sound, play between the parts, the Lip opening easily, and the locknut being able to rotate. In case of improper clamping:

- 1) Doff the exo-prostheses and close the connector without the OTNI 1709 Luci Male Part
- 2) Measure clamping distance (A) shown in image 10.1A (without the OTNI 1709 Luci Male Part and with a closed lip) using a calliper. Set clamping distance (A) between 2.20 and 2.30mm.
- 3) If the clamping is improper at these settings, tighten further until proper clamping, but no further than the point that the user can still close the lip with one hand:
 - a) Unscrew the OTNI 1706 Luci Locking Screw located on the OTNI 1703 Luci Locknut using the 1.5mm Allen key.
 - b) If not already done, apply a thread lock to the thread of the OTNI 1704 Luci M6 Shaft Screw.
 - c) Adjust the OTNI 1703 Luci Locknut clockwise using a Bacho wrench to tighten the clamping.
 - d) Adjust the locknut anticlockwise if closing the connector is too hard for the end user.
 - e) Tighten the OTNI 1706 Luci Locking screw according to the specifications in 7.3.
- 4) If this still results in improper clamping, the connector may be worn out. Contact OTN Innovations B.V. for help.

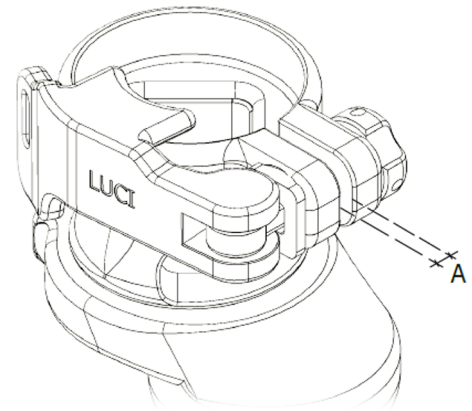


Image 10.1A

10.2 Replacing consumables

NOTICE Periodic replacement of consumables is required to meet the service life.

- The OTNI 17 Luci Connector consists of two spare OTNI 1707 Grit Plate. Replace the grit plate yearly to prevent improper clamping.
- The OTNI 17 Luci Connector consists of two spare OTNI 1706 Luci locking screw (two sets of three screws). Replace the screws when tuning the clamping mechanism to prevent stripping.
- The offsetplates consist of one or two spare M5 screws. Replace the M5 screws when retightening.

10.3 Maintenance and periodic check-up

NOTICE

Users with an offset of 30 mm or higher, high body weight, high level of intensity, or poor maintenance may require more check-ups than prescribed to prevent damage. They also require a release of the OTNI 1709 Luci Male Part at least every two years to prevent a cold weld with the DCA.

- Use Tables 10.3A and 10.3B at check-ups.

Table 10.3A: Periodic check planning							
	Preoperative		6 weeks post implantation	3 months post implantation	12 months post impl.	24 months post impl.	36 months post impl.
By Healthcare institute	•CT scan •Input surgeon on implant design •Cleaning of the DCA	implantation		•Retightening M6 locking screw (15Nm); can be done by prosthetist	•X-ray •Follow-up	•X-ray •Follow-up	•X-ray •Follow-up
By prosthetist	•Input on built-in height, use of componentry and choice in prosthetic foot		•Cleaning of the DCA •Determine offset (e.g. Thomas technique) •Instalment of the connector •Instructing the user	•Retightening M6 locking screw (15Nm) •Instructing the user •maintenance •Evaluation dynamic alignment	•Instructing the user •maintenance •Evaluation dynamic alignment •Replace OTNI 1707 gritplate (see 10.2)	•Instructing the user •maintenance •Evaluation dynamic alignment •Replace OTNI 1707 gritplate (see 10.2)	•Exchange of the Luci connector •Cleaning DCA •Instructing the user •maintenance •Evaluation dynamic alignment

Table 10.3A: Checklist for check-ups	
Instruction	Instruct the user about - Safety (chapter 4) - Use (chapter 8) - Cleaning (chapter 9) - Environmental conditions (paragraph 3.4) - The importance of meeting the periodic check-ups Explain where necessary
Check-up / maintenance	Check for damages, rotations and functionality, retighten where necessary. Check the tuning of the clamping mechanism (see 10.1) Check all torque moments (see 7.3) Check if the connector is maintained properly Replace consumables if advised or needed (see 10.2) Clean male and female part with abrasive fleece if needed (see chapter 9) Release the male part from the DCA if needed (see 10.4)
Evaluation alignment	Flexion contraction (re-evaluate size offsetplate) Hip abduction Hip exorotation Valgus/varus If necessary, advise and change prosthetic parts and components based on activity level – if necessary change the torque on the M5 screw in the offsetplate (see table 7.1B)
X-ray	AP, total leg, standing with prosthesis

10.4 Disassembling the OTNI 1709 Luci Male Part

 **CAUTION** Failing to adhere to the instructions can lead to injury.

- See image 10.4A for visual instruction.
- Stabilise the OTNI 1709 Luci Male Part with a 20 mm key while loosening the OTNI 1423 M14 Abutment Screw or OTNI 1422 M12 Abutment Screw.
- Let the user stabilise the puller handles when removing the male part.
- Contact OTN Innovations B.V. if the male part remains stuck to the Dual Cone Adapter.

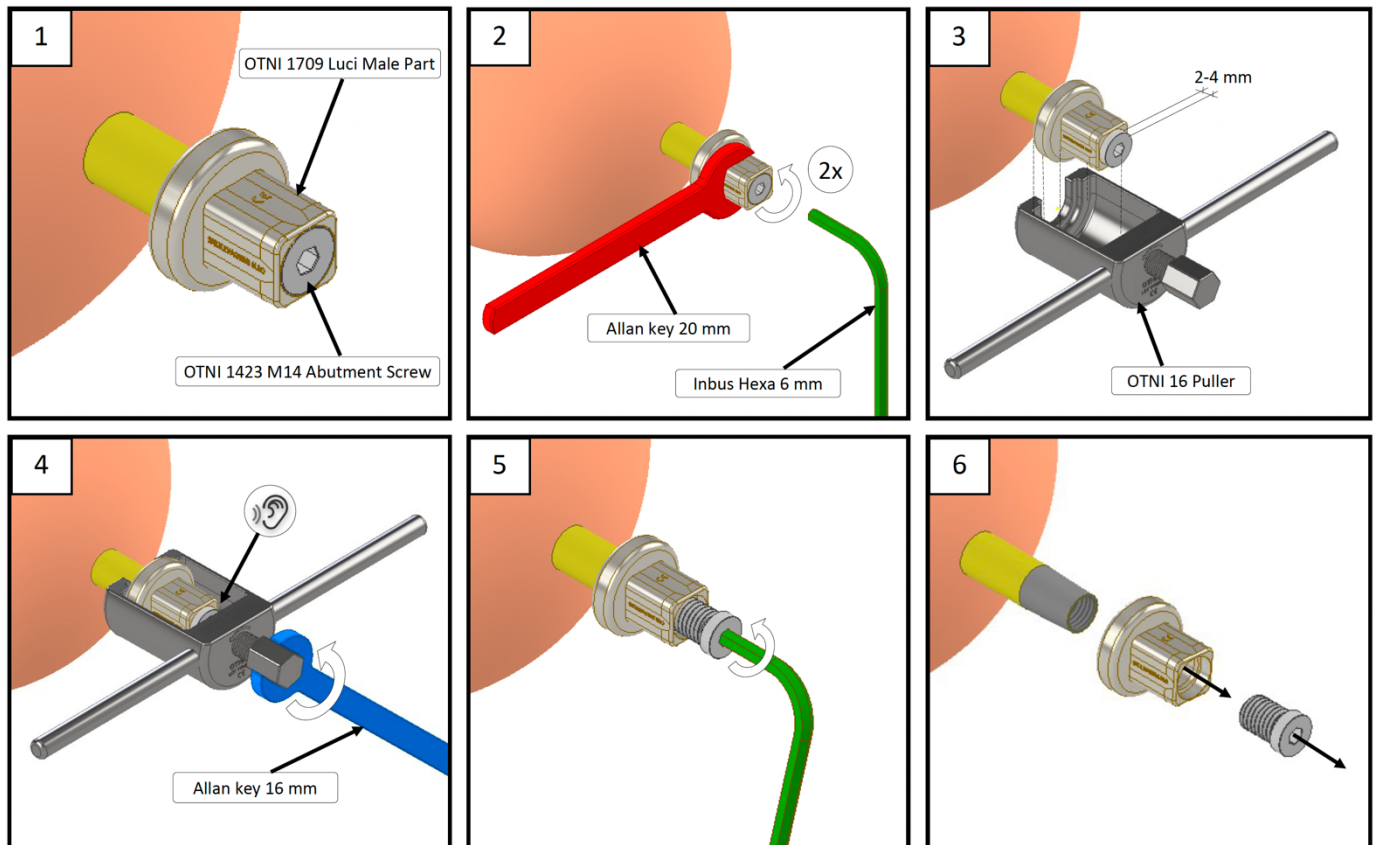


Image 10.4A

11. Disposal

This product may not be disposed of with domestic waste in all jurisdictions. Follow the regulations for disposing of the country where the product is disposed of. Please observe the information provided by the responsible authorities in the country of use regarding return, collection, and disposal procedures.

12. Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

12.1 Liability and warranty

OTN Innovations B.V. will only consider liability if the product is used in accordance with the descriptions and instructions provided in this document *'Instructions For Use Luci – V8a.pdf'*. OTN Innovations B.V. is not liable for damage or injury caused by disregarding the information in this document, particularly due to improper use or unauthorized modification of the product.

The warranty on the OTNI 17 Luci Connector as part of the BADAL X system is 24 months. This warranty covers failures of the product's function that result from errors in material, production, and construction, provided the OTNI 17 Luci Connector is used as intended and under regular conditions. To maintain the warranty, all check-ups must be performed, and the OTNI 1707 Grit Plate must be replaced annually. Normal wear, tear, and play are excluded from the warranty.

In case of excessive activity, warranty is to be determined on discretion of OTN Innovations B.V. (the extended warranty (OTNI 17=3Y) to 3 years is yet possible exclusively in the Netherlands).

If the ordered offsetplate turns out to be unsuitable at installation, OTN Innovations B.V. offers a free-of-charge return policy within 60 days after the shipment date, provided the initial offsetplate is only used for alignment and returned in the original package.

12.2 CE conformity

This product meets the requirements of the Medical Device Regulation (MDR) (EU 2017/745). According to the classification criteria outlined from Annex IX to Annex XI of the directive, it has been classified as a class I device. Therefore, according to Annex VII of the directive, OTN Innovations B.V. created the declaration of conformity with sole responsibility.

12.3 Incidents and feedback

Feedback, concerns, and incidents are requested to be reported to OTN Innovations B.V.. Serious incidents regarding our products must be reported to OTN Innovations B.V. via email and to the appropriate authorities in your country.

13. Service

At OTN Innovations B.V., all connectors (and associated accessories) are tested on functionality before delivery and checked for defects and completeness. If the carrier of the Luci Connector encounters complaints or problems, OTN Innovations B.V. strives to resolve the issue within 2 to 5 working days (provided that they match the warranty conditions and delivery time not included). At OTN Innovations B.V., various spare parts are available in stock.

If the complaint or problem cannot be resolved within an acceptable term, OTN Innovations B.V. offers the possibility to exchange the connector (or parts) for loan parts within 2 to 5 working days so that the end user experiences minimal inconvenience. After exchange, OTN Innovations B.V. attempts to resolve the problems of the original connector or parts within 20 working days after the product is received.

14. This document is available in:



Nederlands



Español



English



Magyar



Deutsch



Português



Français



Polski



Italiano



Svenska



QR to webpage with translations and the latest version.