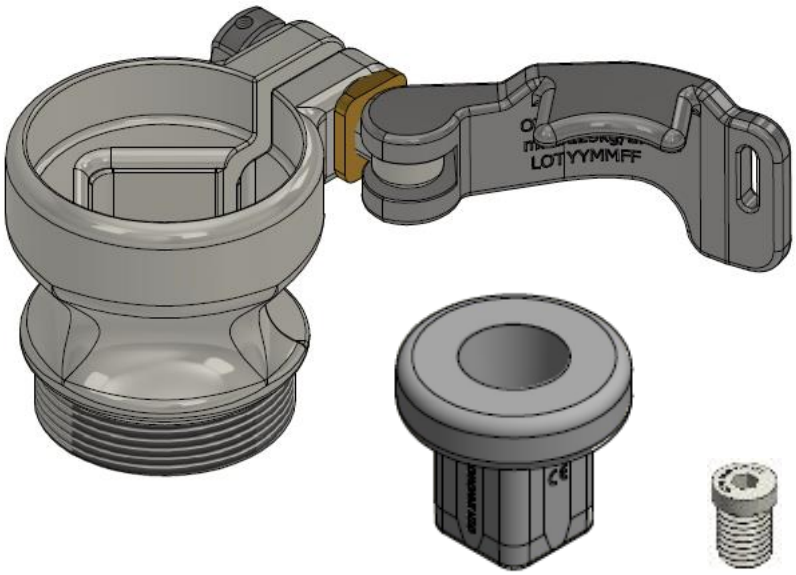
Product information

OTNI 17 LUCI BADAL X connector CE

OTN Innovations BV, Simon Stevinweg 48, 6827 BT Arnhem, the Netherlands

www.otninnovations.com



Notes regarding the document with last update
Additions and rectifications:

WARNING

- Please read this document carefully before using the product.
- Follow the safety instructions to avoid injuries and damage to the product.
- 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 have to be used for the assembly of the BADAL X prosthesis.
- Instruct the user in the proper and safe use and maintenance of the product.
- This document and the product are intended exclusively for the assembly of the BADAL X prosthesis by a certified orthopedic technicians with knowledge of lower limb prosthetic fittings.
- Please store this document in a safe place.

1. General information

1.1 Company

OTN Innovations B.V.
Simon Stevinweg 48
6827 BT Arnhem
Gelderland, the Netherlands

1.2 Explanation of warning symbols

⚠ **CAUTION**	Warning regarding possible risks of accident or injury.
NOTICE	Warning regarding possible technical damage.

2. Product description

The product OTNI 17 Luci connector is a quick attach and release device that consists of a male part (OTNI 1708), a female part (OTNI 1701, OTNI 1702, OTNI 1703, OTNI 1704, OTNI 1705, OTNI 1706, OTNI 1707), an M14 screw (OTNI 1423) and an offsetplate component (OTNI 1700 - OTNI 1760K).

3. Intended use

3.1 Indications for use

The product OTNI 17 Luci connector is intended to be used as part of the compatible bone anchoring device systems for lower limb amputees. The OTNI 17 Luci connector is intended to be used to quickly attach and release the exo-prosthesis of the suitable and compatible bone anchoring devices for lower limb amputees.

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

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

⚠ **CAUTION**	The manufacturer is unable to control all requirements regarding combination possibilities of the exo-prosthesis or bone anchored device components apart from the BADAL X system. Incorrect combinations could lead to injuries, malfunction or product damage. Contact the manufacturer to discuss and inform about the combination possibilities

- Based on the instructions for use of all prosthetic components used, verify that they may be combined with each other and are approved for the patient's field of application
- Contact the manufacturer with questions: OTN Innovations BV; Arnhem, the Netherlands

- The OTNI Luci connector can only be combined with current 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 BV. Functionality with components of other manufacturers that have compatible modular connectors have not been tested and is not recommended.

3.4 Environmental conditions

Do not expose the product to unallowable environmental conditions (see the table "Unallowable environmental conditions" in this section). If the product was exposed to unallowable environmental conditions, take suitable steps (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop etc.)

Allowable environmental conditions
Temperature range: -10°C to +60°C
Sauna (max +90°C) and cold baths: allowed with precautions
Use – relative humidity: 0 % to 90 %, non-condensing Storage/transportation – relative humidity: 20 % 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

Unallowable environmental conditions
Storage/transportation: high vibrations, impacts
Cleaning agents containing solvents

3.5 Service life

⚠ **CAUTION** Ensure that the service life recommendation defined in this section are properly observed.

This product has been tested by the manufacturer according to ISO 10328. Depending on the patient's activity level, this corresponds to a service life of 2 to 3 years.
Service life also depends on proper maintenance and periodical check-ups.

4. General safety instructions

⚠ **CAUTION** Mechanical damage to the product could lead to injuries due to change in or loss of functionality.

- Use caution when working with the product
- Inspect the connector prior to installation on function and compatibility with the other prosthetic components
- Do not use the product if damaged
- In case of changes in or loss of functionality, do not continue using the product and take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service, etc.)

MRI safety is guaranteed under 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 male part (OTNI 1708), M12 screw (OTNI 1422) and M14 screw (OTNI 1423) are MRI-safe. We advise to leave the assembled female part, offsetplate and other components out of the MRI. In all cases, the Health Care Professional is responsible for MR Conditions, MR Imaging quality and patient safety. Any safety issues or major image artefacts should be reported.

5. Scope of delivery

This package contains the OTNI 17 Luci connector consisting of a male part (OTNI 1708), a female part (OTNI 1701, OTNI 1702, OTNI 1703, OTNI 1704, OTNI 1705, OTNI 1706, OTNI 1707), a M14 screw (OTNI 1423), to be combined with an offsetplate component (OTNI 1700 to OTNI 1760K – not included). Components with reference numbers of the OTNI 17 Luci connector can be ordered separately.

6. 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*
Mobility grade:	K1-K4
Allow. body weight:	125 kg/275 lbs
Connector weight:	238 grams

*When exchanging the OTNI 14 Heli connector, an extension of the prosthesis is required

7. Preparation for use

Required tools:

- Allen key 1.5mm(tuning), 4.0mm, 5.0mm & 6.0mm
- Torque wrench <25 Nm
- Key 16 & 20mm
- OTNI Puller (disassembly)

Other: Alcohol, paper towel, marker, Loctite 221 & 222

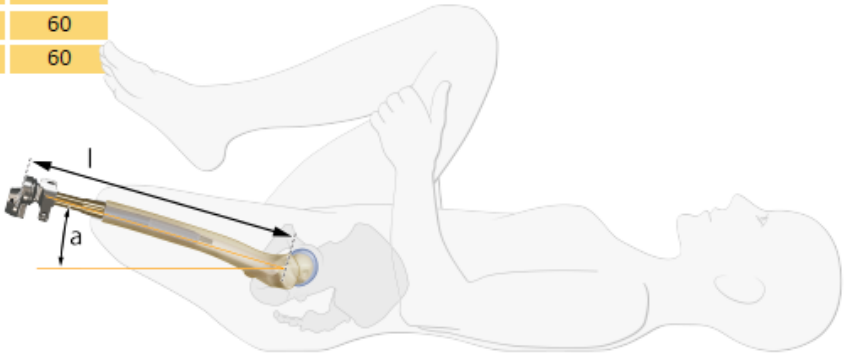
Information on installation and alignment

Using the OTNI 17 Luci Connector, the patient can adapt the prosthesis to various fields of application by quickly changing the lower section. It is important to complete the bench alignment, optimization of the static alignment and optimization during the dynamic trial fitting for each application.

7.1 Determining the size offsetplate

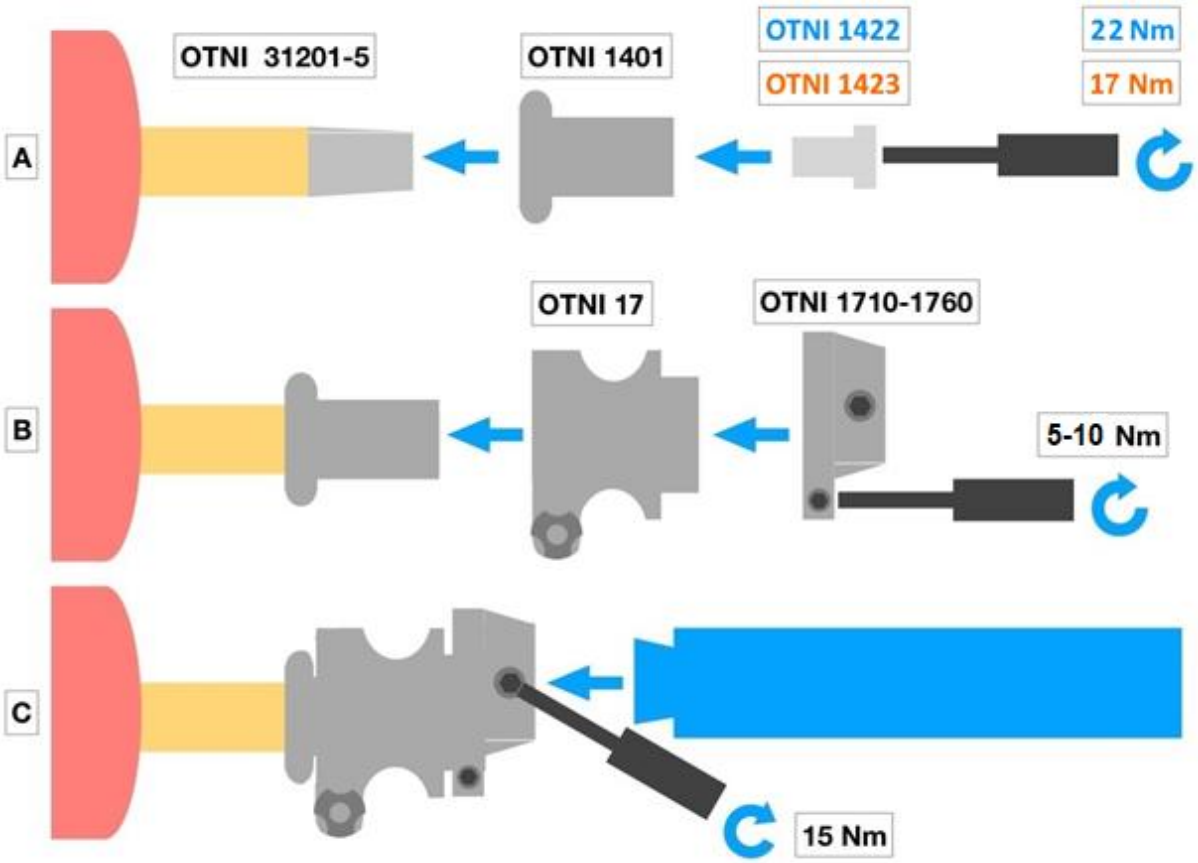
The size in offsetplate can be determined by performing the Thomas-test (next page) and use of the following table:

Offset plate size table				
	Hip flexion angle a (degrees)			
L	0	5	10	20
150	0	10	20	60
200	0	20	40	60
250	0	20	40	60
300	0	20	40	60
350	0	40	60	60



7.2 Bench alignment of the prosthesis

⚠ **CAUTION** Improper assembly of the screw connections could increase the risk of injury due to breakage or loosening of the screw connections.



Installation of the Luci connector

- **A.** Clean the OTN Implants 31201-5 (or OTNI CM 3-4) distal taper and install the OTNI 1708 male part by tightening the M14 screw (OTNI 1423) with (at least) 17 Nm torque **OR** the M12 screw (OTNI 1422) with (at least) 22 Nm torque and Loctite only when necessary. For extra stabilisation of the OTNI 1708 male part, the OTNI 16 Puller can be used by removing the

spiral. Make sure the marking on the OTNI 1708 male part is pointing forward in the walking direction.

- **B.** Apply the assembled OTNI 1701 Female part so such that the fitting corresponds to the OTNI 1708 male part. Clamp the female part onto the male part by closing the OTNI 1702 Lip. Close the OTNI 1702 Lip until it makes contact with the OTNI 1701 Female part. Adjust the OTNI 1703 Locknut by unscrewing the M3 screws and adjust the locknut until it firmly closes with little effort. After choosing the correct tightening make sure to secure the M3 screws with 3 Nm. Use Loctite 221 (fine thread locker) only if necessary. Screw the offset component (OTNI 1700 to OTNI 1760K) onto the M36 thread of the female part. For patients with a tibia bone anchored system it is sufficient to use 0 mm offset using the OTNI 1700 0mm/OTNI 1710 10mm/OTNI 1720 20mm offset component. For patients with a femur bone anchored system, the hip flexion contracture degree will depend on the degree of flexion contracture. An offset of 20/40/60mm corresponds respectively to the OTNI 1720, 1740 and 1760 parts. It is recommended to use the offsetplate table in 7.1 and evaluate in the dynamic pass session whether the patient needs a larger offset.
  When a prosthetic knee with electronic flexion extension protection is used, a small difference can always be compensated with a 0, 10 or 20mm offset. The difference in offsetplates also has consequences for walking. The smaller the offset, the less energy it takes for the patient to flex the knee at the end of the standing phase. With tibial bone anchored systems, the offset can also be used to correct the position of the prosthesis in the frontal plane to medial or lateral. The prosthesis can be adjusted by rotating the prosthesis with the rotation of the OTNI 1700 to 1760K offset plate relative to OTNI 1701 Female part. Once the correct rotation has been determined, the clamping screw of the OTNI offsetplate can be tightened according to table 7.2B:

Body wight	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**
130	6 Nm	7 Nm	8 Nm	**9 Nm**	**9 Nm**

  In this way the connection between the OTNI 17 Luci connector and offsetplate will rotate in case of high rotational forces. When the soft tissue touches the 1701 Female part while standing or walking, it is possible to rotate the female part 90, 180 or 270 degrees. The ability to install the connector backwards is possible.
- **C.** Attach the prosthesis with the universal pyramid connection to the pyramid receiver on the OTNI offsetplate and adjust the position by tightening the M8 set screws of the offsetplate. Patients with a femoral bone anchored system are advised to apply a physiological angle of 7 degrees valgus. For patients with a tibia bone anchored system, the valgus / varus position can be used to load the medial or lateral tibia plateau. The M8 set screws in the offsetplates need to be tightened with 15 Nm torque.

⚠ **CAUTION**

Observe the specified tightening torques: The M12 screw is tightened with 22 Nm, the M14 screw with 17Nm, the M5 clamping screw of the offset component with at least 5 Nm (based on level of activity and the M8 set screws of the pyramid receiver of the offset component with 15 Nm and apply a thread lock.

7.3 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.
- For patients with transfemoral bone anchored systems, set 7^{o} valgus with the pyramid receiver adjustment screws between the OTNI offset component and the rest of the prosthesis.
- For patients with transtibial bone anchored systems, adjust varus / valgus with the pyramid receiver set screws if necessary.
- For patients with transfemoral bone anchored systems, use the various OTNI offset components or OTNI 1700 (0mm), OTNI 1710 (10mm), OTNI 1720 (20mm), OTNI 1740 (40mm) or OTNI 1760 (60mm) depending on the degree of hip flexion contracture. OTNI offset components can also be used for patients with transtibial bone anchored systems to apply a translation in a certain direction.

7.4 Optimising during dynamic trail fitting

- During the dynamic trial fitting, test and optimise the prosthesis with its various distal prosthetic components.

7.5 Attaching the cosmetic cover

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

7.6 Finishing the prosthesis

- To finish the prosthesis, all screw connections have to be tightened according to the prescribed specifications with regard to Nm and the use of thread lock if prescribed. The correct functioning of the prosthesis has to be tested with its various distal prosthetic components. Thread lock is only used for the OTNI 17 Luci connector M12, M14 and M8 screws.

8. Use

⚠ **CAUTION**

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

- Check the product for damage prior to each use.
- Do not use the product if its functionality has been impaired.
- Take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service, etc.)
- The end user should be advised, in case of a technical failure, not to disassemble or repair the Luci connector themself

8.1 Locking the OTNI 17 Luci connector

⚠ **CAUTION**

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 Lip makes contact with the OTNI 1701 Female part

8.2 Available accessories

OTNI 25	Luci night cap for bathing, sleeping and protection after doffing the prosthesis
OTNI 90	Toolbox (not necessary) for instalment, alignment, tuning and maintenance.
OTNI ORBIS	Silicon cover to protect the stump

9. Cleaning

Use of unsuitable cleaning agents or disinfectants or insufficient cleaning could lead to functional limitations and damage. Clean the product only according to the instructions given in this section and observe the cleaning instructions for all prosthetic components

- Clean the product daily with a damp, soft cloth.
- Dry the product with a soft cloth
- Inspect the product daily for sand and dust in the Female part and remove it carefully with water if necessary and dry with a soft cloth.
- After contact with salt or dirty water: rinse the product with clean, fresh water and clean with a soft, dry cloth.

10. Maintenance

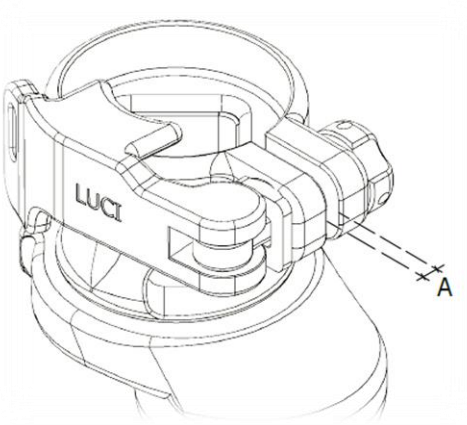
⚠ **CAUTION** Failure to follow maintenance instructions will cause injuries due to changes in or loss of functionality and damage to the product. Observe the following maintenance instructions carefully.

- A visual inspection and functional test of the prosthetic component should be performed after the first 30 days of use by a certified prosthetist
- Inspect the entire prosthesis for wear during normal consultations
- Conduct annual safety inspections. Check for wearing, loss of function, screw connections and sound

10.1 Tuning the clamping mechanism

During every periodic check-up the clamping mechanism of the Luci connector must be checked and tuned if necessary:

1) Doff the exo-prostheses and close the connector without the 1708 male part
2) Measure distance **A** shown in the image right using a calliper, a sufficient clamping is measured between 2.30 and 2.40mm
3) Tune the clamping if distance A is more than 2.40mm or when closing the connector takes little effort by adjusting the 1703 locknut:
   a) Unscrew the three M3 screws locating on the 1703 Locknut using the 1.5mm Allen key
   b) Adjust the 1703 locknut clockwise to tighten the clamping
   c) Adjust the locknut anti-clockwise if closing the connector is too hard for the end user
   d) Tighten the M3 screws with 1Nm, use Loctite 221 to prevent loosening or losing the M3 screws



10.1 Maintenance and periodic check-up

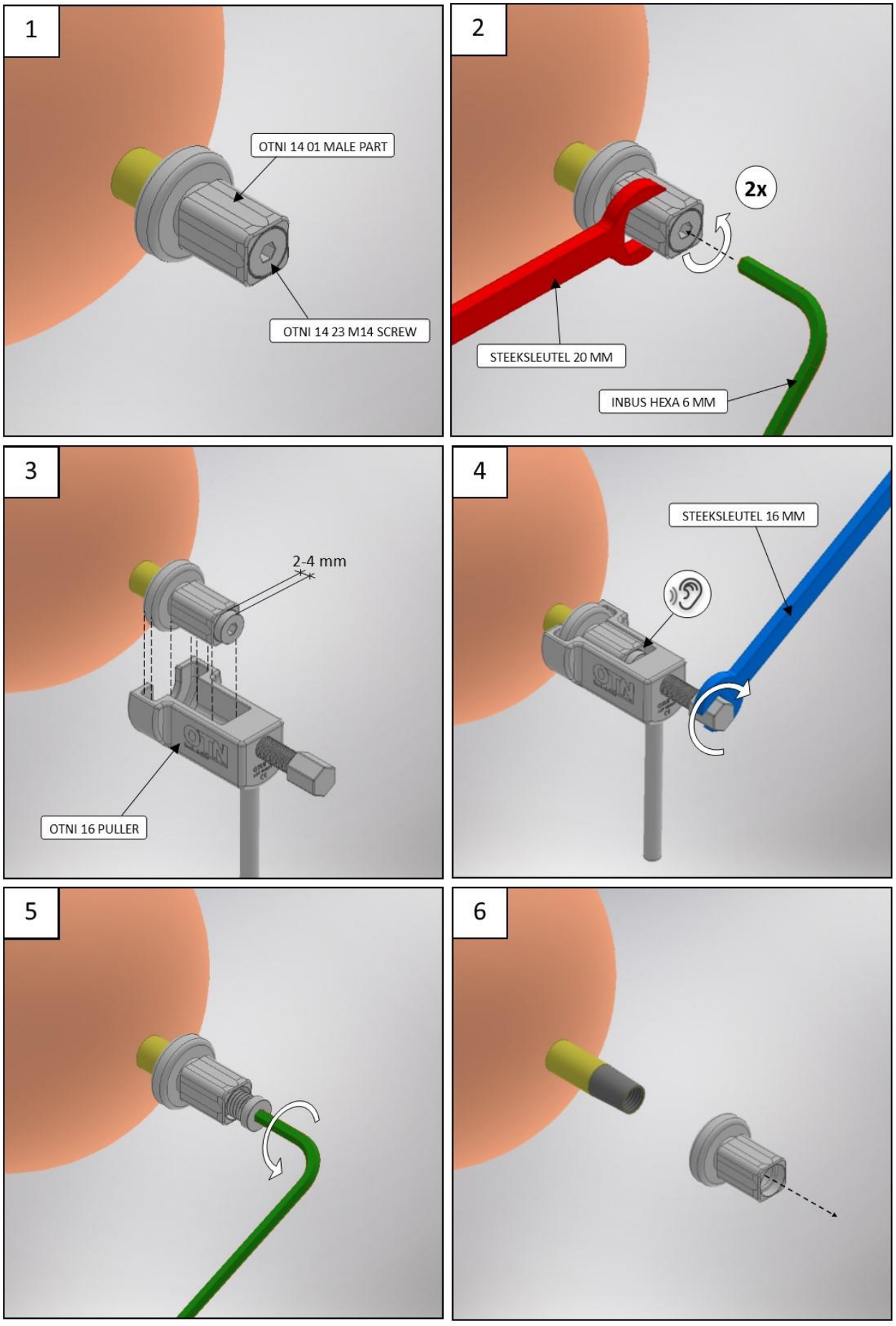
The OTNI 17 Luci connector is part of the aftercare protocol (*BADAL X aftercare* and *Exo-prosthesis installation and alignment* by OTN Implants BV the Netherlands).

	Preoperative	implantation	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			• 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	• Instructing the user • maintenance • Evaluation dynamic alignment	• Exchange of the Luci connector • Cleaning DCA • Instructing the user • maintenance • Evaluation dynamic alignment

Instruction	About maintaining and cleaning of the system Explain where necessary
Check-up	Check for damages, rotations and functionality, retighten where necessary. Check the tuning of the clamping mechanism (black dust may be an indication of inappropriate clamping of the female part)
Evaluation alignment	Flexion contraction (re-evaluate size offsetplate) Hip abduction Hip exorotation Valgus/varus Advise and change (if necessary) prosthetic parts and components based on activity level – change if necessary the torque on the M5 screw in the offsetplate (see table 7.1B)
X-ray	AP, total leg, standing with prosthesis

Disassembling male part

- PTO


1
OTNI 14 01 MALE PART
OTNI 14 23 M14 SCREW
2
2x
STEEKSLEUTEL 20 MM
INBUS HEXA 6 MM
3
2-4 mm
OTNI 16 PULLER
4
STEEKSLEUTEL 16 MM
5
6

11. Disposal

This product may not be disposed of with domestic waste in all jurisdictions. Follow the regulations for disposing in the country where the product is used. 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

The manufacturer will only consider liability if the product is used in accordance with the descriptions and instructions provided in this document *'Instructions For Use LUCI – V7.pdf'*. The manufacturer 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 function of the product that are the result of errors in material, production and construction, provided the Luci connector is used as intended and under regular conditions. Normal wear, tear and play are excluded from warranty. Play caused by failure in the function of the products due to fault's in material, production and construction are also covered by the warranty, to be determined at the discretion of OTN Innovations BV.
In case of excessive activity, warranty is to be determined on discretion of OTN Innovations BV (the extended warranty (OTNI 17=3Y) to 3 years is yet possible exclusively in the Netherlands).
If, in case of installation, it turns out that the included offsetplate is not suitable, OTN Innovations BV offers a free of charge return policy within 14 days after installation for an exchange with the correct offsetplate, provided the initial offsetplate is returned.

12.2 CE conformity

This product meets the requirements of the MDR:2017/745 for medical devices. This product has been classified as a class I device according to the classification criteria outlined from Annex IX to Annex XI of the directive. The declaration of conformity was therefore created by the manufacturer with sole responsibility according to Annex VII of the directive.

13. Service

At OTN Innovations BV, 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 BV strives to resolve the issue free of charge within 2 to 5 working days (provided that they match the warranty conditions and delivery time not included). At OTN Innovations BV, various spare parts are available in stock.
If the complaint or problem cannot be resolved within an acceptable term, OTN Innovations BV offers the possibility to exchange the connector (or parts) within the specified period (2 to 5 working days) so that the end user experiences minimal inconvenience. After exchange, OTN innovations BV attempts to resolve the problems of the original connector or parts within 20 working days.

This document is also available in:

Nederlands

English

Deutsch

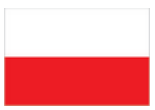
Français

Italiano

Español

Magyar

Português



Polski

Svenska