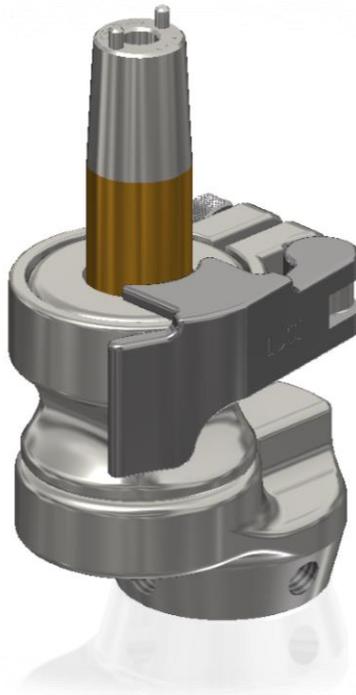


Last update: November 4, 2020

Product information OTNI 17 LUCI Osseointegration connector

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1 Notes regarding the document with last update

Additions and rectifications:

- V4 (August 28, 2020)
 - Addition: 7: required tools
 - Modification 6: net system height
- V5 (November 4, 2020)
 - Rectification: 12.1: Liability and warranty

INFORMATION

- 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 fabrication of the prosthesis.
- Instruct the user in the proper and safe use of the product.
- This document and the product are intended exclusively for the fabrication of a prosthesis by orthopaedic technicians with technical knowledge of lower limb prosthetic fittings.
- Please keep this document in a safe place.

1.1 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 consists of a male part (OTNI 14 01), a female part (OTNI 17 01), a M14 screw (OTNI 14 23) **OR** M12 screw (OTNI 14 22) and an offset component (OTNI 14 00-60/OTNI 17 00-60).

3. Intended use

3.1 Indications for use



CAUTION

The product is to be used solely as part of the OTN Implants osseointegrationsystem for lower limbs. The Luci is to be used to connect the prosthetic leg to the OTN Implants osseointegrationsystem.

3.2 Area of application

Only use the product according to its allowable field of application:

- Allowable amputation types: Transtibial amputation, Transfemororal amputation
- Allowable field of application: Everyday prosthesis, Bathing prosthesis, Sport prosthesis
- Allowable body weight: max 125 kg/275 lbs
- Recommended mobility grade: K1-K4
- Positioning in the prosthesis: Only according to the sections and illustrations in the instructions for use

3.3 Combination possibilities



CAUTION

Failure to observe the manufacturer requirements regarding combination possibilities or unallowable combinations of prosthesis components could lead to injuries, malfunction or product damage.

- 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 may only be combined with the OTN Implants Osseointegrationsystem and the offset component (OTNI 1400-OTNI 1460/OTNI 1710-OTNI 1760) through the M36 junction from OTN Innovations BV. Functionality with components of other manufacturers that have compatible modular connectors has not been tested and is dissuaded.
- The OTNI 17 LUCI Connector is not direct compatible with the Ottobock. 360 degree Lotus Adapter.

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
Use – Relative humidity: 0 % to 90 %
Storage/transportation – Relative humidity: 20 % to 90 %
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: Mechanical vibrations, impacts
Cleaning agents containing solvents

3.5 Service life



Exceeding the service life

Fall due to change in or loss of functionality and damage to the product. Ensure that the service life defined in this section is not exceeded.

This product has been tested by the manufacturer with 3 million load cycles according to ISO 10328. Depending on the patient's activity level, this corresponds to a service life of 2 to 3 years.

4. General safety instructions



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

- Use caution when working with the product
- If the product is damaged, check it for proper function and readiness for use
- In case of changes in or loss of functionality, do not continue using the product (change in the positioning of the prosthetic components relative to each other and by the development of noises)
- Take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service, etc.)

5. Scope of delivery

This package contains the OTNI 17 Luci connector consisting of a male part (ref. no. 14 01), a female part (ref. no. 17 01) an Offset component (ref. no. 14 00 to 14 60 or 17 10 to 17 60) and a M14 screw (ref. no. 14 23) OR M12 screw (ref. no. 14 22). 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 overlap 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 & 6.0mm
- Torque wrench >25 Nm
- Key 16 & 20mm
- OTNI Puller (disassembly)

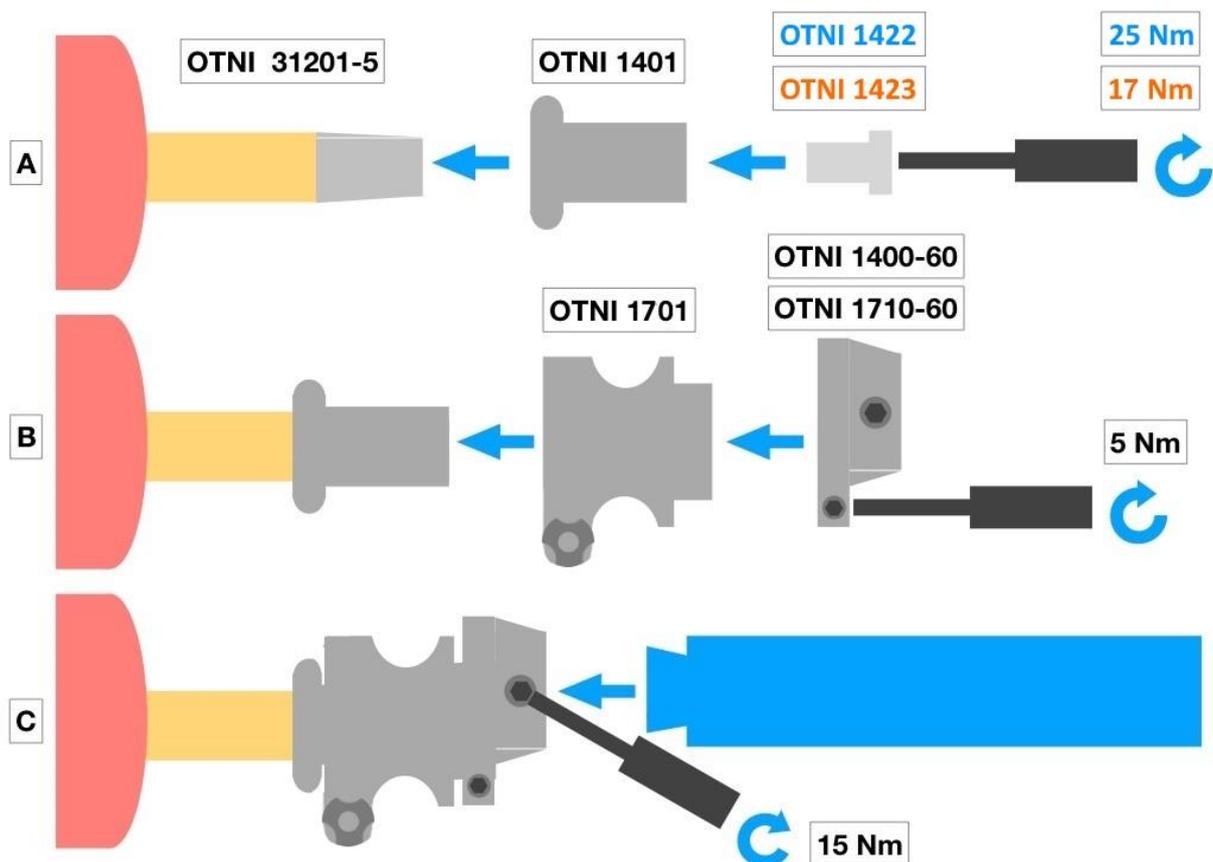
Other: Alcohol, paper towel, marker, Loctite 222

7.1 Information on fabrication of a prosthesis

Using the OTNI 17 Luci Connector, the patient can adapt the prosthesis to various field 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.

7.2 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 1401 male part by tightening the OTNI 1423 M14 screw with (at least) 17 Nm torque **OR** the OTNI 1422 M12 screw with (at least) 25 Nm torque and Loctite when necessary. For extra stabilization of the OTNI 1401 male part, the OTNI 16 Puller can be used by removing the spiral. Make sure the marking on the 1401 male part is pointing forward in the walking direction.

- **B.** Apply the OTNI 1701 Female part so that the fitting corresponds to the OTNI 1401 Male part. Clamp the OTNI 1701 onto the OTNI 1401 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 1400 to OTNI 1460/OTNI 1710 to OTNI 1760) onto the M36 thread of the OTNI 1701 female part. The OTNI 1701 Female part is standard supplied with the OTNI 1720 offsetplate. For patients with a tibia osseointegration system it is sufficient to use 0 mm offset using the OTNI 1400 0mm/OTNI 1710 10mm/OTNI 1720 20mm offset component. For patients with a femur osseointegration 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 start with OTNI 1720 offset 20mm and evaluate in the dynamic pass session whether the patient needs a larger offset of 40 or 60mm. 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 has also 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 osseointegration 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 1400-1460 offset plate relative to OTNI 1701 Female part. Once the correct rotation has been determined, the clamping screw of the OTNI 1400-60/1710-60 offset plate can be tightened with 5 Nm. When the soft tissue touches the 1701 Female part when standing or walking, it is possible to rotate the female part 90, 180 or 270 degrees. Ability to install the connector backwards is possible.
- **C.** Attach the prosthesis with the universal pyramid connection to the pyramid receiver on the OTNI 1400-60/OTNI 1710-60 offsetplate and adjust the position by tightening the M8 set screws of OTNI 1400-60/OTNI 1710-60. Patients with a femoral osseointegration system are advised to apply a physiological angle of 7 degrees valgus. For patients with a tibia osseointegration system, the valgus / varus position can be used to load the medial or lateral tibia plateau. The M8 set screws in the OTNI 1400-60/OTNI 1710-60 offsetplates need to be tightened with 15 Nm torque.



Observe the specified tightening torques: The M14 screw is tightened with 17 Nm, the M5 clamping screw of the offset component with 5 Nm 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 osseointegration systems, set 7° valgus with the pyramid receiver adjustment screws between the OTNI offset component and the rest of the prosthesis.
- For patients with transtibial osseointegration systems, adjust varus / valgus with the pyramid receiver set screws if necessary.
- For patients with transfemoral osseointegration systems, use the various OTNI offset components or OTNI 1400 (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 osseointegration 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 quick change function can be operated reliably.

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.

7.7 Grit plate

- The 1707 Grit plate is intended for users who (e.g.) have little strength in their wrist or fingers, suffer from rheumatism, acquired hand abnormalities, missing fingers, and suchlike. The 1707 grit plate is placed between the 1701 Luci female part and 1702 Luci lip and ensures a smooth and easy closure of the connector. A too high closing moment can lead to a breakage of the grit plate.

8. Use



CAUTION

Mechanical overload could lead to falling due to breakage of loadbearing 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.)

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

9. Cleaning



CAUTION

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 OTNI 1701 Female part and remove it carefully with water if necessary and dry with a soft cloth.
- After contact with salt water or contaminated fresh water: rinse the product with clean, fresh water and clean with a soft, dry cloth.

10. Maintenance

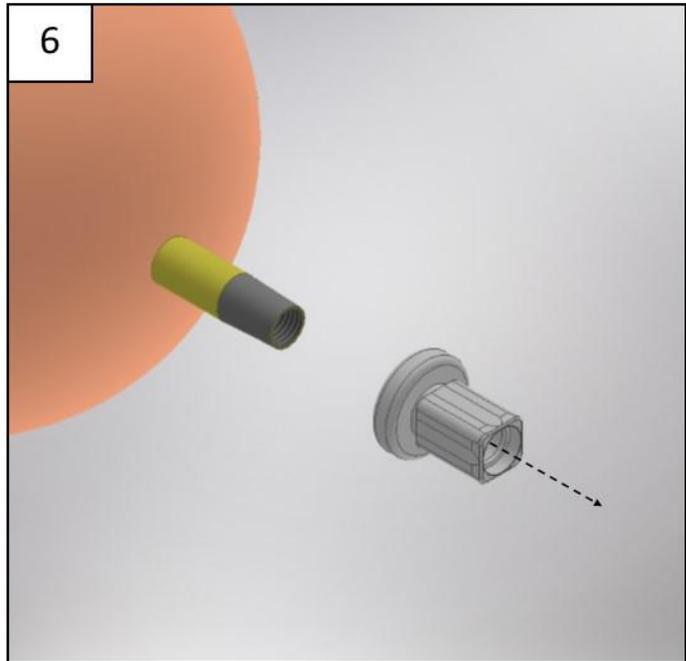
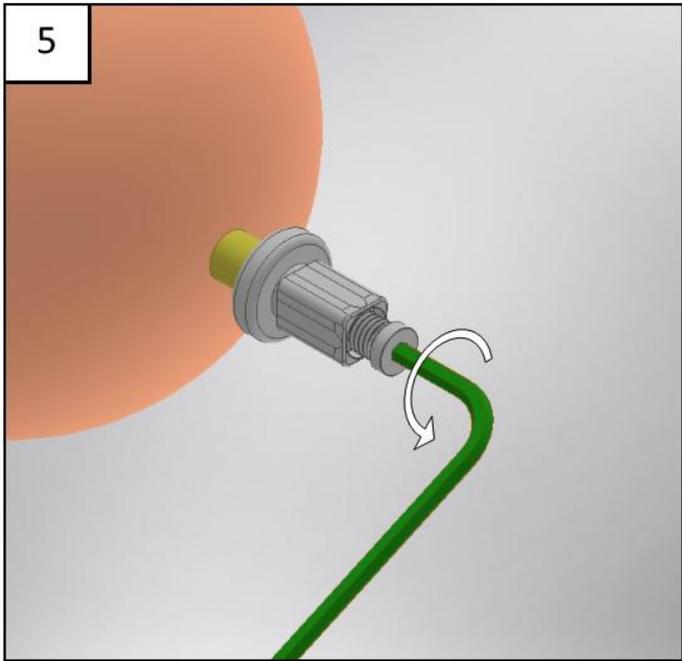
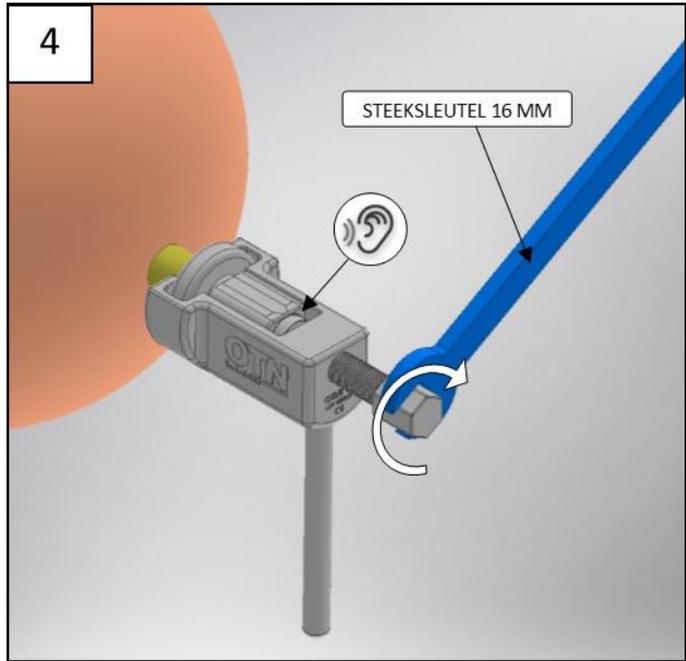
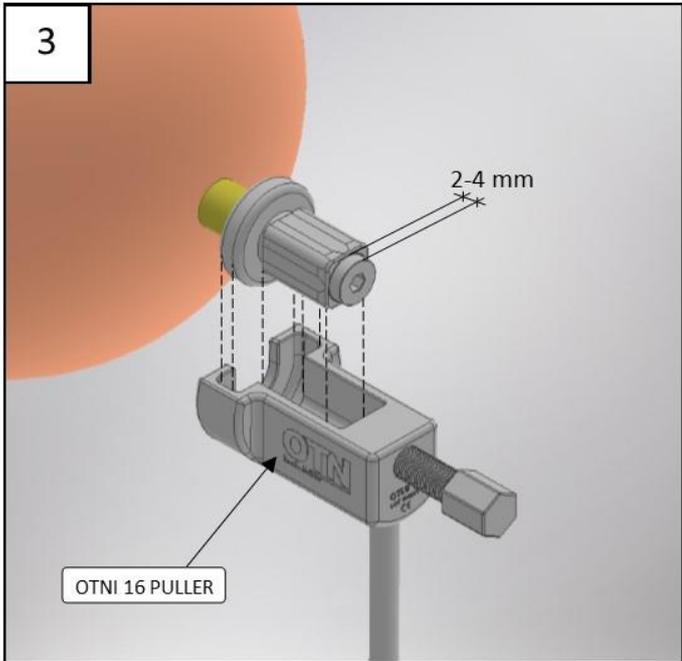
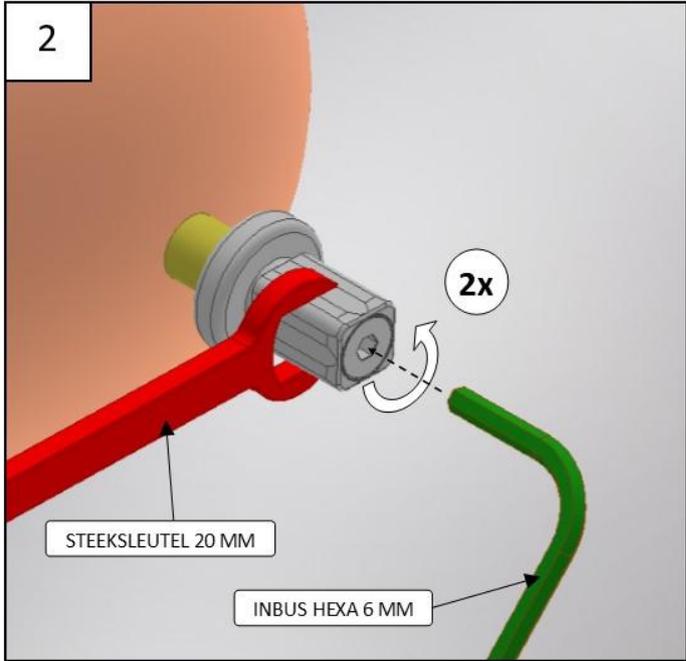
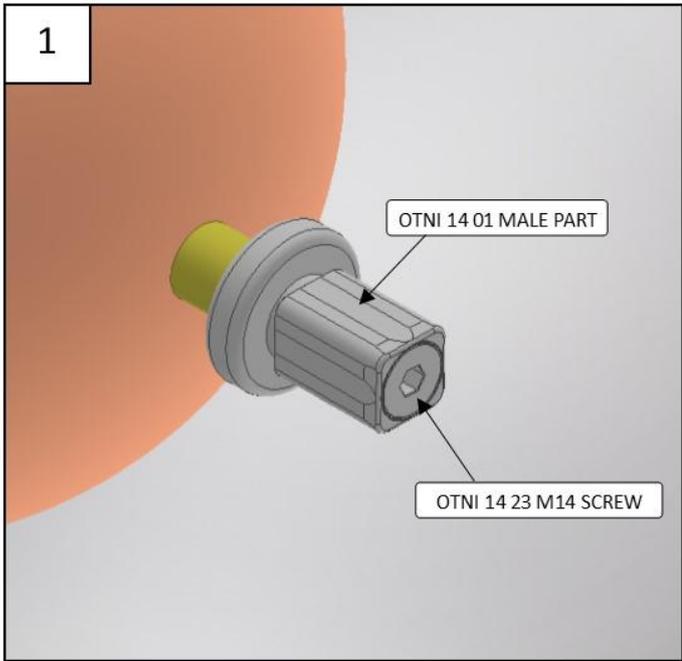


Failure to follow maintenance instructions will cause injuries due to changes in or loss of functionality and damage to the product. Observe the following maintenance instructions carefully.

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

Disassemblage male part

- PTO



11. Disposal

This product may not be disposed of with domestic waste in all jurisdictions. Disposal that is not in accordance with the regulations of the country where the product is used may have a detrimental impact on health and the environment. 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 assume liability if the product is used in accordance with the descriptions and instructions provided in this document '*Instructions For Use LUCI - V5.pdf*'. The manufacturer will not assume liability for damage 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. 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 offset plate 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 offset plate is returned.

12.2 CE conformity

This product meets the requirements of the European Directive 93/42/EEC for medical devices. This product has been classified as a class I device according to the classification criteria outlined in Annex IX 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 connector (and associated accessories) are tested manually before delivery and checked for defects and completeness. If the carrier of the Luci connector encounters complaints or problems, OTN Innovations strives to resolve them 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 parts are in stock that immediately available.

If the complaint or problem cannot be resolved immediately, OTN Innovations BV offers the possibility to exchange the connector (or parts) within the specified period (2 to 5 working days) so that the wearer experiences minimal disruption. After exchange, OTN innovations attempts to resolve the problems of the original connector or parts within 20 working days.