Manufacturer:
Osseointegration International B.V.
Spoorstraat 9, 7261AE Ruurlo
The Netherlands
frans.verhaegh@Osseointernational.com
+31 (0)6 811 25 124

INSTRUCTION FOR USE GV19 connector

EN

- Please read this document carefully before using the product
- Follow the safety instructions to avoid injuries
- Document is only for general information, please read document "Installation instructions" for full instructions

0. Introduction

Before using the GV19 and accesoiries study the following recommendations, warnings and instructions carefully, as well as the product-specific information (installation manual). The manufacturer does not accept liability in the case of non-compliance with this package insert. This includes but shall not be limited to the following cases;

- assembling this device with components, other than recommended by the manufacturer,
- using instrumentation other than recommended by Osseo Integration staff or appointed distributors.

1. Product Descriptions / Materials

1.0 General

The GV19 Connector serves as a lower limb interface between an osseointegrated intramedullary implant and a standard commercial prosthesis. The device aims to help restore mobility for amputee patients by providing a link of an artificial extension of the patient's amputated limb. Proximally, the connector is attached to the taper sleeve / anti-rotation locking washer construct of the Osseointegrated implant system. Distally, the connector features a standard four threaded holes connection, commonly used in the prosthetic industry, allowing it to be attached to a standard leg prosthesis.

1.1 Indications/contraindications for Use

A. Indications

- This product is to be used solely for lower limb prosthesis fittings in combination with Femur or Tibia osseointegrated intramedullary implants.

B. Contraindications

- Patients weighing more than 110kg.
- Patients doing high impact activities weighing more than 100kg.
- Patient with mental and/or physical restrictions to understand the instructions or lack strength to connect the connector.
- Extreme sports.
- Maximum offset of 60mm between implant and prosthesis.

1.2 Assembly Instructions /Directions for Use

- The fitting of a product to a patient may only be carried out by an orthopaedic technician.
- The fitting of the product may only be carried out after proper instruction.

1.3 Description of the device

Description
OPL-GV19 Connector female
OPL-GV male
Night Cap
Male bush Hexagon
OPL-Connector tool

1.4 Installation and maintance instructions

Please read "installation manual GV19 connector instructions" before placing the connector.

1.5 Regular use

1.5.1 regular placement connector

Patient should be seated while connecting or disconnecting the connector.

A = OPL-GV male
B = OPL-GV19 connector female

Note: Connector "A" should be installed by a orthopaedic technician to ensure safe connection to the implant.
Note: Connector "B" should be installed by an orthopaedic technician to ensure safe connection to the prosthesis.

Connect/Disconnect:

a. Make sure part A and B are clean.
b. Twist the black ring in the direction indicated on the device.
c. While holding the black ring down, place B over A and release the ring.
d. Twist the black ring to lock A & B in place.

1.5.2 Torque safety

The GV19 has a torque safety ring. This ring allows the device to disengage during peak forces in use.

After a safety disengagement, the prosthesis will have to be put back in position. Using enough force to disengage the torque ring in the opposite direction. We recommend to use a rotatable pyramid adapter or tubeclamp, this in order to re-align the connector correctly. Additional we also recommend to use the tool delivered by Osseointegrated International to re-align the connector.

Patients should check rotating ring / activation of the torque ring regularly, typically when GV19 female is connected to GV male.

Manufacturer:
Osseointegration International B.V.
Spoorstraat 9, 7261AE Ruurlo
The Netherlands
frans.verhaegh@Osseointernational.com
+31 (0)6 811 25 124

INSTRUCTION FOR USE GV19 connector

EN

2. Warnings

2.1 Precautions

Avoid subjecting the adaptor to excessive mechanical shocks or vibrations and extreme temperatures. Follow recommended appointments with your orthopaedic technician to ensure proper continued use. Inspect the adaptor prior to use for any signs of excessive wear or damage. If the coupling appears damaged or will not connect to the adaptor, do not use it.

If the adaptor packaging appears damaged or tampered the orthopaedic technician should check the parts of the adaptor and check if they are free of foreign material and are not damaged. If the visual inspection indicates any abnormality, do not use the coupling and return it to the manufacturer.

2.1.1 MRI Safety information

The complete (male, female) device shall not be worn during a MRI scan.

2.2 Adverse Events

In many instances, adverse results may be clinically related rather than device related.

- These devices can break when subjected to the increased loading associated. Loads on the device produced by load bearing, and the patient's activity level, will dictate the prolonged existence of the device.
- Improper alignment can cause a malfunction of the device.

2.3 Cleaning

- Clean the product with a damp cloth.
- Dry the product with a soft cloth.
- Allow to air dry to remove residual moist.

2.4 Environmental conditions

A. Allowable user conditions:

- Temperature range for use: -10 °C to +60 °C.
- Allowable relative humidity 0% till 94%, non-condensing.
- Dust, sand allowable when regularly torque testing is perfomed, according to 2.5 service life.

B. Allowable conditions for transport:

- Temperature: -40 °C to +60 °C.
- Allowable relative humidity: 0% till 94%, non-condensing.

C. Unallowable conditions:

- Mechanical vibrations or impacts.
- Perspiration, urine, salt water, acids, chlorination.

2.5 Service life

- The device service level is 2 years.
- The Torque ring has a service level of 6 months or 3 safety disengagements.*

Inspect the product every 30 days to ensure safe use.

2.6 Disposal

This product may not be disposed of with regular waste.

3. Additional information

3.1 Warranty

The 24-month warranty of the connector commences from the day of the initial fitting. The warranty covers defects that are the result of flaws in the material, production or construction. The warranty shall cover repair, or replacement at no charge, but at the discretion of the manufacturer.

The warranty is only valid were product has been installed by an authorized and trained orthopaedic technician.

* Changing the torque ring should only be done by an authorized orthopaedic technician.

Connector female can be delivered seperately as 2nd connector, male part and other parts can be excluded from delivery.

Products excluding from warranty:

- 1000011 : Protection cover
- 1000013 : Night cap
- 1000031 : Leak cap Black
- 1000171 : Leak cap Transparant
- 1000086 : Torque ring 25 Nm Standaard
- 1000061 : Torque ring 35 Nm Standaard
- 1000087 : Torque ring 50 Nm Standaard
- 1000128 : Torque ring 25 Nm Less Flex
- 1000127 : Torque ring 35 Nm Less Flex
- 1000126 : Torque ring 50 Nm Less Flex

3.1.2. Incident reporting

When a serious incident occurred in relation to the device, please contact Manufacturer, and the competent authority of the member state (EU) where the user/patient is established. See link for relevant competent authority: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human
For determination whether a incident should be reported, see vigilance guidance documentation of the European Union: MEDDEV 2.12/1 rev.8 or link for guidance documents:
https://ec.europa.eu/docsroom/documents/32301
reporting form: https://ec.europa.eu/docsroom/documents/41681

3.2 Symbols used


Symbol for «Manufacturer»


Symbol for «Date of Manufacturing»


Symbol for «Consult instructions for use»


Symbol for «Caution»

Symbol for «Non-Sterile»


Symbol for «Do not use if package is damaged»

Symbol for «Catalogue number»

Symbol for «Batch code»


Symbol for «Use-by date»


Symbol for «Conformity according to the applicable European directive»


Symbol for «single patient, multiple use»

Symbol for «medical device, indicates the item is a medical device»