CE

INSTRUCTIONS FOR USE

Single-axis knee joint	GEN40

This product meets the technical requirements specified in Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, and it meets the requirements provided in Annex I – General safety and performance requirements, and in Annex VIII – Classification rules. The conformity is declared based on Article 52(7), Annex II, and Annex III of Regulation (EU) 2017/745.

INFORMATION

Date of issue: 2025-01-01
Date of last update: 2025-03-12
Please read this document carefully before using the product and observe the safety notices.
Report each serious incident related to the product to the manufacturer and to the relevant authority in your country.
Name of manufacturer: Elitex Prodexim SRL
Address of manufacturer: Ceuașu de Câmpie, str. Principală 7B, Mureș county, Romamia

INDICATIONS

The loss, amputation, or deficiencies of the lower limbs.
There are no known contraindications.

DESCRIPTION

This product is intended for the construction of modular prostheses. Its use to assemble a prosthesis should be carried out in a specialized and approved facility by accordingly qualified personnel.
Combining the product with other parts in order to construct a prosthesis should only be done with parts or sub-assemblies designated for such purpose.

COMPOSITION

Material: aluminium ENAW 2017
stainless steel EN 1.4305
case-hardening steel
spring steel wire OLC55-A
high-density polyethylene
double sealed radial ball bearing 61900-2RS
screw M5x8 ISO 7380-2, screw M4x12 ISO 7380-2
screw M5x20 DIN 912
screw M3x2x4.5 DIN 923
threaded stud M4x6 DIN 913, threaded stud M8x8 DIN 913
polyurethane
polyamid tube 4x2 mm DIN 73378
steel cable OLC55

GENERAL SAFETY INSTRUCTIONS

The medical personnel should provide the patient all the necessary information for the safe use of the device.

ASSEMBLY INSTRUCTIONS

Assembly of the opening mechanism:

1. Open the knee joint, and pull the cable to the desired side.
2. Slide the cable through the guiding tube and the handle.
3. Shorten the cable to the desired length.
4. Attach it to the lateral part of the prosthesis with the screw.

ALIGNMENT INSTRUCTIONS

The alignment reference line for the alignment has to:

- pass through the center of the socket at the ischial tuberosity
- pass through the center line of the knee joint (i.e. the adjustment core on the top)
- be roughly at the 1/3 marking of the foot, measured from the heel

1. Position the foot in a way that the reference line falls on the 1/3 marking on the inner side. Take into consideration the external rotation of the foot.
2. Use the tube adapter to connect the knee joint to the foot and establish the correct height for the center of the knee.
3. Position the knee in a way that the reference line passes through its center line.
4. Position the socket in a way that the reference line intersects its center line at the level of the ischial tuberosity.
5. Set the flexion of the socket to 5° in excess compared to the current position and adjust the total height of the prosthesis.
6. Use the suitable adapters to connect the knee joint to the lamination anchor.

Warning: For a secure fastening use a medium strength thread-locking adhesive (e.g. Loctite 243) and apply a torque of 10 Nm.

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MAINTENANCE

The device and the whole prosthesis should be examined by a medical professional. The exam frequency should be determined based on the physical activity level of the patient.

CLEANING AND CARE

Clean with a wet cloth and mild soap. Dry with a cloth after washing.

WARNING

The weakening of the threaded assembly can lead to accidents. The maximum allowed bodyweight is 125 kg.