



INSTRUCTIONS FOR USE

Polycentric knee joint with gear drive	S4
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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, Romania

INDICATIONS

Partial or total paralysis of the leg muscles. Orthopedic diseases of the lower limbs.

There are no known contraindications.

DESCRIPTION

This product is intended for the orthotic treatment of the lower limbs. Its use to assemble an orthosis 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 orthosis should only be done with parts or sub-assemblies designated for such purpose.

COMPOSITION

Material: stainless steel EN 1.4305
nut M5 DIN 934

GENERAL SAFETY INSTRUCTIONS

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

ASSEMBLY INSTRUCTIONS

For stability reasons, it is necessary to glue or laminate the bars in the designated areas.

Gluings of the bars:

1. Clean the surfaces with a degreasing cleaning agent.
2. Mix the special adhesive with the hardener.
3. Apply the mixture to the insertion area.
4. Mount the bars in the designated location.
5. Secure the bars.
6. Adjust the correction angle.

Lamination of the bars:

1. Clean the surfaces with a degreasing cleaning agent.
2. Before laminating, secure them in place.
3. Perform the lamination.
4. Clean the ends of the bars.
5. Secure the bars.
6. Adjust the correction angle.

MAINTENANCE

The device and the whole orthosis 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 100 kg.