



INSTRUCTIONS FOR USE

Lamination anchor with rotatable adjustment core	A21
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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

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: cast stainless steel EN 1.4301

stainless steel EN 1.4305

screw M5x30 DIN 912

GENERAL SAFETY INSTRUCTIONS

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

ASSEMBLY INSTRUCTIONS

1. Cover the gypsum model with a PVA bag.
2. Apply an adequate amount of the lamination material.
3. Place the A21 lamination anchor in position.
4. Apply lamination material, according to the patient's bodyweight and/or the expected load.
5. Apply an outer PVA bag.
6. Proceed with the lamination using acrylic resin 80:20.
7. After drying, remove the PVA bags.

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

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.