

Qualität und Funktion

Gebrauchsanweisung *Instruction Manual*

Einzugsmechanik (EM) *Pull-In Mechanism (EM)*



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Please read the IFU carefully before fitting. Only correct usage will warrant the function.

1. Intended Use

The pull-in mechanism is used to secure a liner in the socket of a leg prosthesis.

2. Technical data

Installation height: 20 mm

Casting body weight: 30 g

REF

Order No.	Description	Art. No.
EM	Pull-in mechanism BK- and AK-Prothesis	4 147 000 00 00 001

Material:

Pull-in mechanism:	POM
Perlon cord:	Perlon
Coupling screw:	POM
Cover Perlon cord:	PA
Handle:	Aluminium
Wrap button and rivets:	Steel

2.1 Service parts

Order No.	Description	Art. No.
E-EM01	Lamination body	4 147 009 00 00 001
E-EM02	Perlon cord 1,5 m	4 147 009 00 00 002
E-EM03	Coupling screw with perlon cord	4 147 009 00 00 003
E-EM04	Cover for perlon cord	4 147 009 00 00 004
E-EM05	Clamp for perlon cord	4 147 009 00 00 005
E-EM06	Handle	4 147 009 00 00 006

3. Indication/ Contraindication

Indication:

- Limb amputation
- With pin-connection liners (Locking liners)

Contraindication:

- With non-pin liners (Cushion liners)
- Sensitive distal end of the residual limb

4. Side effects

There are no known side effects.

5. General safety instructions



- This medical device is designed for single patient, multiple use.
- Fitting/service of this medical device is only allowed by a certificated orthopedic professional.
- The professional should instruct the correct use of the device to the user.
- We recommend an installation and function check by a specialist in case of mal-function, abnormalities such as external forces.
- Improper modification or application to the product is not allowed. In case of non-observance, the function of the product may be impaired, so that product liability is excluded.

6. Application information

Place the dummy at the distal end of the positive plaster model and fix with the included nail. Please pay attention to the correct position of cord exit.

Then cut a 15 mm piece of the supplied cover of the perlon cord and put this in the opening hole of the dummy. It should have an overhang of 5 mm. Deep drawing the socket as usual. Pull the thermoforming material firmly into the circumferential groove.

Drill the model on the nail and remove with the help of compressed air.

The fixation nail can be removed. The hose guide is free to be grinded and the dummy can be removed.

Now fix the cord clamp at the desired position on the outside of the socket; pay attention to the correct installation direction of the clamp. Drill two holes of 3.5 mm into the socket and rivet the cord clamp.

Attention: Do not damage the cord clamp during fitting. Defect cord must be replaced immediately.

For better locking attach the winding button on the side of the feeder mechanism, by drilling a 3.5 mm hole in the socket. (fig. 1).

Now shorten the cover of the perlon cord to the desired length and insert the cover distally into the feeding mechanism. Fix the cover of the perlon cord on the socket circularly with tape. Thread perlon cord through feeder mechanism, cover and cord clamp.

Screw in coupling screw with perlon cord hand-tight into the distal M10 thread of the liner.

Before first usage check proper function of the system.

After the liner has been pulled into the socket, the patient must lock the perlon cord in the cord clamp (fig. 2) and secure it at the winding button.

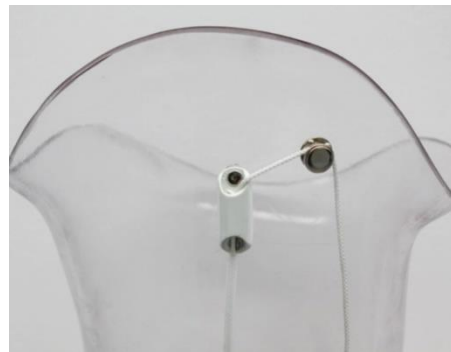


fig.1

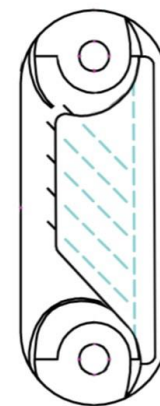


fig.2

7. Maintenance and Cleaning



A 6 months check of the feeding mechanism is recommended.

Cleaning:

- Compressed Air up to 2 bar
- Soap and hand warm water

8. CE-Conformity

The product satisfies the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and bears the CE mark. All major incidents related to the product needs to be informed to Uniprox and the competence European Authority.

9. Warranty and Guarantee

Depending on the degree of usage, the pull-in mechanism can generally be used for 5 years with regular maintenance.

Warranty is provided under the terms of sale and supply of Uniprox GmbH & Co. KG provided that the above conditions are met.

10. Storage and Disposal

This product has no special storage regulations.

The product is disposable with standard household garbage This product has no special storage regulations.

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Please direct any questions to:

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