

Pyramid Adapter, For Knee Joint Adult

Instructions for Use

Please read this document carefully and follow the safety instructions.

Item codes: see bottom of document



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Functions and benefits

The Rehab'Impulse Pyramid Adapter, Knee Joint, Adult, is part of the Rehab'Impulse modular system and is designed to provide compatibility of the Rehab'Impulse Prosthetic Knee Joints, Adult with standard modular tube clamp adapters used as interface with common modular hip joints.

Intended use

This product is intended for prosthetic fitting on adults. This product is not intended for excessive physical activities. It is approved for a body weight of up to 80 kg (ISO 10328 – P4).

Residual risks, contraindications

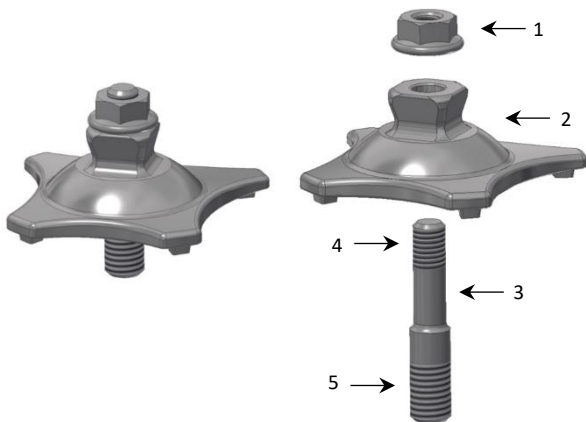
This product is not compatible with the Rehab'Impulse Monocentric Knee Joint, Child.

Device specifications

Material: Stainless steel

Connector Thread: M10

1. Nut M8
2. Pyramid
3. Stud bolt
4. Thread M8
5. Thread M10



Training

n/a

Storage/handling

- Store product in dry conditions
- Store at room temperature (ideally between 15°C and 25°C)
- Keep out of direct sunlight or other sources of light with a high UV content
- Take precautionary measures against sparking and fire
- Keep in original packaging before use

Environmental conditions

Recommended environmental conditions:

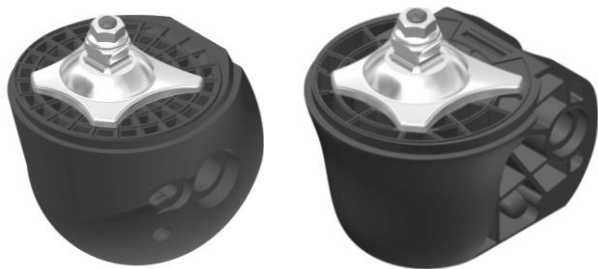
- Temperature range for use : -10°C to 60°C (14°F to 140°F)
- Relative humidity 0% to 90%, no condensing situation
- Avoid exposure to dust, sand, salt water, acids and urine

Included in delivery

- 1x Nut M8
- 1x Pyramid
- 1x Stud bolt M10/M8

Assembly instructions

- Screw the stud bolt into the knee shell insert M10
- Slide pyramid over stud bolt; ensure that the 4 pins under the pyramid fit with the 4 corresponding positions in the PP Shell of the prosthetic knee joint
- Tighten M8 Nut (recommended torque: 20Nm)
- Both, M8 and M10 stud bolt threads must be glued before tightening (recommended product: Loctite® Threadlock 243)



Maintenance

This device is designed for low maintenance. The prosthetic component should be inspected after the first 30 days of use. After this period, it is recommended to inspect the device at least every six months for signs of unusual wear.

Cleaning and care

This device can be cleaned using mild soap or solvent followed by rinsing with water. Allow device to dry completely before use. Avoid strong acid (pH=4 or less) and oxidizing agents.

This device has been engineered for a service life of three to five years depending on user's activity level. Scheduling of regular maintenance lies within the discretion of the service provider. The user shall discontinue use and report to the service provider in the event of any breakage, failure, change in function or any unusual wear.

Disposal

Users are advised to return defective or worn out products to their clinician.

Please note that disposal of this product with regular domestic waste may not be permitted in all countries of use. Not following the disposal regulations of the responsible authorities may have a detrimental impact on health and environment.

Reusability

This device is intended for single-use only.

Compatibilities

The Rehab'Impulse Pyramid Adapter, Knee Joint, Adult is compatible with the Rehab'Impulse Monocentric Knee Joint, Adult and with the Rehab'Impulse Polycentric Knee Joint, Adult. It is furthermore compatible standard modular tube clamp adapters.

- 74-00243 Monocentric Knee Joint, Beige, Adult
- 74-00244 Monocentric Knee Joint, Olive, Adult
- 74-00245 Monocentric Knee Joint, Terra, Adult
- 74-00246 Polycentric Knee Joint, Beige, Adult
- 74-00247 Polycentric Knee Joint, Olive, Adult
- 74-00248 Polycentric Knee Joint, Terra, Adult

Warnings, precautions

Using the product without following these instructions for use may cause injury or harm to the user and/or damage the product. This device shall be fitted by trained prosthetists only. Ensure that the approved service life of 3 million cycles is not exceeded. Do not expose the product to environmental conditions other than the ones specified in this instruction. If damage is apparent or in case of doubt, do not continue using the product. Take suitable measures as required (e.g. cleaning, repair, replacement by trained P&O personal). In case of contact with salt water, acid, abrasive substances or any substance identified above, promptly clean the product in accordance with the chapter "Cleaning and Care".

Compliance

This device has been tested according to the ISO 10328 standard to 3 million load cycles and is approved for a body weight of 80kg (P4).

Depending on the user's activity level, this corresponds to a service life of three to five years. It is recommended to carry out regular safety checks.

CE Conformity

This product meets the requirements of the EU MDR 2017-745 guidelines for medical products. It has been classified as a Class I product according to the classification criteria outlined in Appendix VIII of the guidelines.

Item codes

| REF | Description English |
|-----------------|---------------------------------------|
| 74-00337 | Pyramid Adapter, For Knee Joint Adult |

IFU ID and date

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