

Prosthetic Elbow Joint

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 Prosthetic Elbow Joint is a functional elbow made of Polypropylene, which allows its user to position the elbow in several positions. It is available in one size and 3 colours. Each elbow joint features a wrist unit kit. For the manufacturing of transradial prosthetic devices, the wrist unit kit can be ordered separately.

Intended use

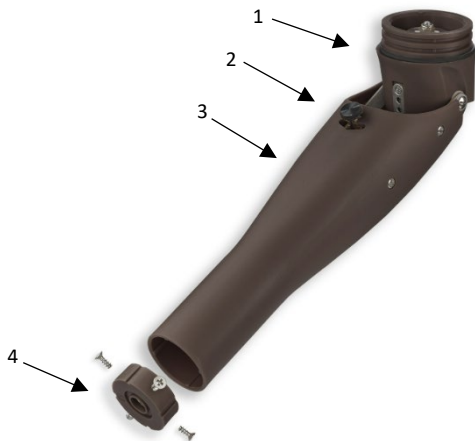
This product is intended for prosthetic fitting on adults and adolescents.

Residual risks, contraindications

n/a

Device specifications

1. Upper arm connector (Polypropylene)
2. Manual lock (Stainless steel + POM)
3. Lower arm (Polypropylene)
4. Wrist adapter M10 (Polypropylene)



Training

Please follow the ICRC manufacturing guidelines for trans-radial or trans-humeral prosthesis:

<https://www.icrc.org/en/doc/assets/files/other/eng-trans-radial.pdf>

<https://www.icrc.org/en/doc/assets/files/other/eng-trans-humeral.pdf>

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

Elbow joint

(Beige : 74-00239 / Olive : 74-00238 / Terra : 74-00237):

- 1x Elbow Joint
- 1x Wrist unit kit (1x wrist unit / 4x screw)

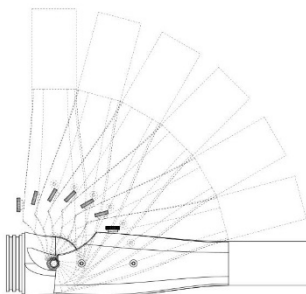
Wrist unit kit:

(Beige : 74-00449 / Olive : 74-00450 / Terra : 74-00451):

- 1x Wrist unit
- 4x Screw 3x10mm

Flexion angle adjustment

The flexion angle can be adjusted in 7 increments from full extension to a bending angle of 90°. The articulation can be blocked in one of these 7 positions or can be left swinging freely.



Assembly instructions

The Elbow Joint is designed to be attached on its proximal end to a custom made upper arm/shoulder socket. A prosthetic hand or a hook can be attached to its distal end.

The Elbow joint can be use in free motion or can be locked in 7 different positions.

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. If the device is used in a corrosive environment or subjected to excessive moisture, this period shall be shortened.

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 3 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 Elbow Joint and the wrist unit is compatible with the Rehab'Impulse passive hand.

- Passive hand, Size L
- Passive hand, Size M

Spare parts

Please contact manufacturer

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. Do not expose the product to environmental conditions other than the one 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".

This product has been tested up to a load of 50N (5kg) applied to the distal end of the forearm in a locked position at any angle or in full extension when it is unlocked.

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
74-00239	Prosthetic Elbow Joint, Beige, Adult
74-00238	Prosthetic Elbow Joint, Olive, Adult
74-00237	Prosthetic Elbow Joint, Terra, Adult
74-00449	Wrist Unit Kit, Beige
74-00450	Wrist Unit Kit, Olive
74-00451	Wrist Unit Kit, Terra

IFU ID and date

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