

## Passive Hand

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### 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 Passive Hand is a cosmetic hand made of soft thermoplastic polyurethane. Besides its natural appearance, it allows passive handling and holding of small objects. It is available in two sizes and four colours. The large size is recommended for men while the medium size is recommended for women and adolescents. Both hand sizes feature an M10 interface.

## Intended use

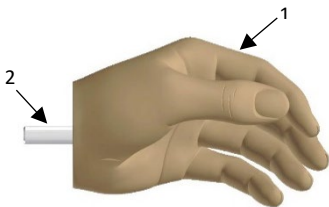
This product is intended for prosthetic fitting on adults and adolescents and is exchangeable with a hook or a working ring.

## Residual risks, contraindications

n/a

## Device specifications

1. Passive Hand (TPU foam)
2. M10 Insert



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

- 1x Passive Hand

## Assembly instructions

Screw the hand into the M10 T-nut of the wrist unit. With the arms resting alongside the torso and hand facing the thigh, ensure that the length is the same as the sound side. Check the functional position of the hand with the elbow at 90 degrees flexion - the hand should be in neutral position (halfway between pronation and supination).

## 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 passive hand is compatible with the Rehab'Impulse wrist unit and the Rehab'Impulse prosthetic elbow.

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

## 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".

## 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

<b>REF</b>	<b>Description English</b>
<b>74-00063</b>	Passive Hand, Beige, Size L, Left
<b>74-00065</b>	Passive Hand, Beige, Size L, Right
<b>74-00067</b>	Passive Hand, Olive, Size L, Left
<b>74-00069</b>	Passive Hand, Olive, Size L, Right
<b>74-00059</b>	Passive Hand, Terra, Size L, Left
<b>74-00061</b>	Passive Hand, Terra, Size L, Right
<b>74-00051</b>	Passive Hand, Dark Beige, Size L, Left
<b>74-00053</b>	Passive Hand, Dark Beige, Size L, Right
<b>74-00071</b>	Passive Hand, Beige, Size M, Left
<b>74-00073</b>	Passive Hand, Beige, Size M, Right
<b>74-00075</b>	Passive Hand, Olive, Size M, Left
<b>74-00077</b>	Passive Hand, Olive, Size M, Right
<b>74-00079</b>	Passive Hand, Terra, Size M, Left
<b>74-00081</b>	Passive Hand, Terra, Size M, Right
<b>74-00055</b>	Passive Hand, Dark Beige, Size M, Left
<b>74-00057</b>	Passive Hand, Dark Beige, Size M, Right

## IFU ID and date

74-02071-IFU-Passive-Hand-EN-V2.0 – 21.03.2023





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