

Mand.ro Cosmetic Hand Instruction for Use



ENGLISH

INTENDED USE

The device is intended to restore the cosmetic appearance of a missing upper limb and to provide limited passive support. The suitability of the device for the individual patient and prosthetic configuration must be assessed by a qualified healthcare professional. The device must be fitted and adjusted by a qualified healthcare professional. The device must only be modified or repaired by Mand.ro or by personnel authorized by Mand.ro.

PRODUCT DESCRIPTION

Mand.ro Cosmetic Hand is a non-powered external upper-limb prosthetic device designed to restore the cosmetic appearance of a missing hand while providing limited passive support during daily use.

The device features a manually positionable 3-degree-of-freedom wrist/forearm unit that supports 360° axial rotation, wrist flexion/extension, and radial/ulnar deviation, allowing the hand to be oriented in multiple positions to better match the user's activity and posture. This enables improved positioning for selected daily tasks and light recreational activities.

Depending on the fitting and user capability, the device may assist with limited passive support or stabilization during activities such as holding lightweight objects, supporting utensils, stabilizing a bicycle handlebar, or handling sports equipment. An optional silicone cover glove in a natural skin tone may be worn over the device to provide a more aesthetic and natural appearance and to enhance the overall cosmetic finish.



The device is intended to enhance appearance and provide passive functional support only. It does not provide powered movement, active finger actuation, or autonomous grasping. Proper fitting, alignment, and user instruction by a qualified healthcare professional are required for safe and effective use.

INDICATIONS FOR USE

- Individuals with upper-limb loss, amputation, or deficiency
 - Individuals with congenital absence or deficiency of the upper limb
 - Users who require a passive prosthetic hand for cosmetic restoration and limited functional support in daily activities
 - Users who may benefit from a prosthetic hand for light stabilization or assistance with selected daily tasks
-

CONTRAINDICATIONS

There are no known absolute contraindications to the use of this device when fitted and used as intended.

SAFETY INSTRUCTIONS

The healthcare professional must inform the patient of all information in this document that is necessary for the safe use of this device. The user is the primary operator of the device and is responsible for its safe and appropriate use. The device is intended for single-patient use only. The device is intended for cosmetic restoration and limited passive support only. It does not provide powered motion, active grasping, or sensory feedback. The device should be removed during prolonged periods of rest, such as sleep, unless otherwise instructed by a qualified healthcare professional. If the device shows visible damage, loosening, loss of intended function, unusual wear, or any condition that may affect safe use, the user must discontinue use and contact a qualified healthcare professional.

Warnings

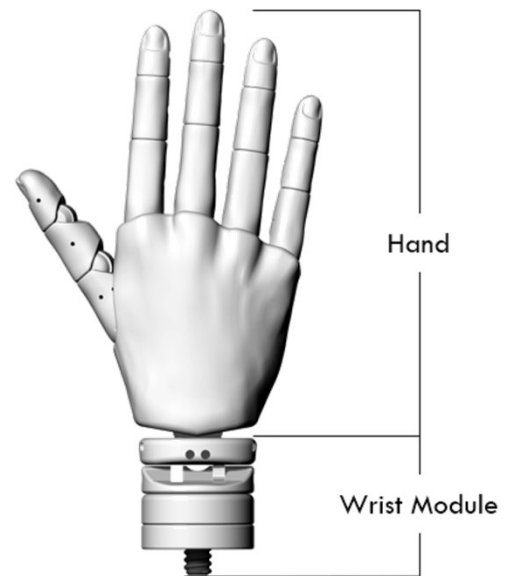
- The device does not provide natural sensation. Heat, pressure, moisture, and surface conditions cannot be perceived through the device.
- The device is intended for everyday, low-to-moderate intensity activities only.
- Do not use the device for heavy lifting, forceful manual tasks, or activities that exceed its intended passive use.
- Do not use the device in high-risk or extreme activities that may expose it to impact, excessive force, or sudden loading.
- Do not use the device near powered tools, moving mechanical parts, or machinery that could cause injury or damage.
- Do not expose the device to excessive heat, open flames, sparks, or other high-temperature sources.
- Do not expose the device to chemicals, solvents, oils, or other substances that may damage silicone, cosmetic surfaces, or structural components.
- Do not wear the device directly over an open wound, irritated skin, or damaged skin.
- Do not attempt to open, disassemble, modify, or repair any part of the device.
- Any modification or repair must be performed only by Mand.ro or personnel authorized by Mand.ro.
- Do not use the device if the cosmetic cover, silicone glove, or external surface is torn, degraded, detached, or otherwise damaged.
- If the device includes a manually positionable wrist/forearm unit, do not force the mechanism beyond its intended range of motion.
- Repeated excessive loading, twisting, bending, or impact may result in damage to the device or loss of function.
- If the device becomes loose, unstable, cracked, torn, or otherwise damaged, stop using it immediately and consult a healthcare professional.

Precautions

- Use the device only with accessories, covers, gloves, and components approved by Mand.ro.
- Any damaged cosmetic glove, cover, or protective element should be replaced by a qualified healthcare professional or authorized service provider.
- All fitting, alignment, adjustment, and maintenance procedures must be carried out only by qualified personnel.
- The device should be inspected regularly for signs of wear, surface damage, deformation, loosening, or reduced stability.
- Only water-based products approved by Mand.ro should be used where applicable. Oil-based lubricants, petroleum-based products, or unapproved care products may damage the device.
- Clean the device only in accordance with the instructions provided in this IFU.
- Avoid prolonged exposure to direct sunlight, excessive humidity, dust, or contaminated environments.
- Avoid applying excessive localized force to the fingertips, sides of the fingers, joints, or wrist mechanism.
- When supporting objects, avoid sudden loading or leverage that may overstress the device structure.
- Users are responsible for following all local laws and safety requirements when operating vehicles, bicycles, or equipment while wearing the device.
- If unusual discomfort, skin irritation, or instability occurs during use, discontinue use and consult a healthcare professional.

SPECIFICATION

Specification	Male	Female	Youth
Type	Left/Right		
Number of Articulated joints	Hand: 15 Wrist: 3		
Wrist Activation	360° axial rotation, flexion/extension, radial/ulnar deviation		
Size(mm)	Hand: 182 Wrist: 58	Hand: 163 Wrist: 58	Hand: 134 Wrist: 58
Weight(g)	Hand: 137 Wrist: 68	Hand: 112 Wrist: 68	Hand: 97 Wrist: 60
Structural Material	Engineered polymers, including TPU and ABS		
Silicone Glove	Natural Skin Colors (Optional)		



CLEANING AND STORAGE

For routine disinfection, the cosmetic cover may be gently cleaned with isopropyl alcohol (IPA) once per week, unless otherwise instructed by your clinician.

Store the device in a clean, dry, and well-ventilated place. Do not store the device while damp or in an airtight container, as trapped moisture may promote bacterial or mold growth.

REPORTING A SERIOUS INCIDENT

Any serious incident related to the device must be reported to Mand.ro and the relevant competent authority.

DISPOSAL

The device, its components, and its packaging must be disposed of in accordance with applicable local or national environmental regulations.

LIABILITY

Mand.ro shall not be liable for improper use or operation of the device, including but not limited to the following circumstances:

- failure to use, clean, store, or maintain the device in accordance with this manual
- use with components, accessories, or modifications not supplied or authorized by Mand.ro
- use outside the intended purpose, recommended conditions of use, or specified environmental limitations.