INSTRUCTIONS FOR USE

IFU CODE: 47

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PROSTHETIC

Mechanical Elbow Joint
(HD6)

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INFORMATION

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- Please read this document carefully before using the product.
- Instruct the user in the appropriate and safe use of the product.
- Follow the safety instructions to abstain injuries and damage to the product.
- Please keep this document in a safe place.

Contents

1. HD6

Mechanical Elbow Joint

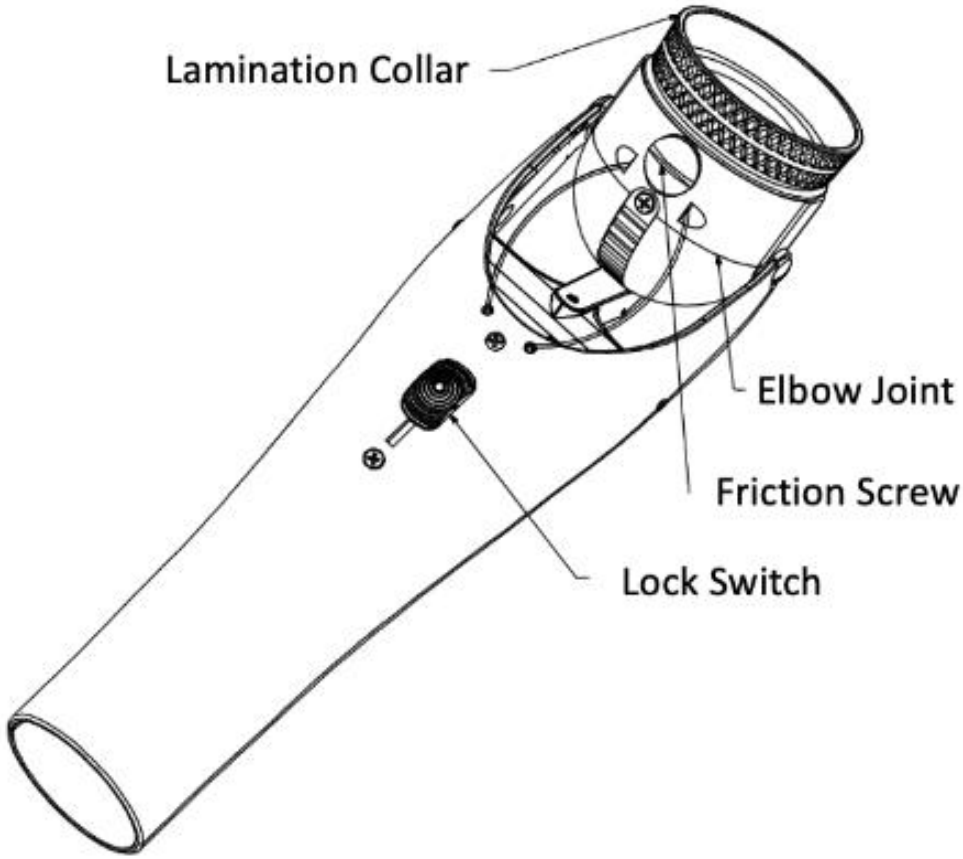
The HD-6 Mechanical Elbow Joint is an advanced engineering solution designed for transhumeral prosthetic users requiring enhanced range of motion, stability, and anatomical mobility. This model features an integrated locking mechanism offering up to 13 different positions for precise arm placement, combined with an upper arm rotation joint that enables natural rotational movement. Utilizing a hybrid construction that combines precision-machined aluminum internal parts with a durable plastic shell, the device achieves a lightweight profile without compromising structural reliability. By facilitating natural mobility patterns, the device significantly reduces mechanical strain on the shoulder girdle and improves the overall ergonomics of the prosthesis.

1.1. Features

Product Name	HD6
Material	Aluminum Parts / Plastic Shell
Locking	Up to 13 Positions
Joint	Upper Arm Rotation Joint
Mechanism	Integrated Locking
Product Weight	355 gr
Distal Diameter (ID/OD)	50.2 mm / 55 mm

2. Operating Instructions

2.1 Assembly



2.2 Lock Operation

The manual locking mechanism provides 13 distinct locking positions, ranging from 5° to 135° of elbow flexion.

Sliding the lock switch downward disengages the mechanism, allowing the user to reposition the forearm to the desired angle. Sliding the lock switch upward engages the mechanism, securely locking the forearm in the selected position.

2.3 Forearm Internal and External Rotation

The forearm allows for 360-degree passive internal and external rotation. The rotational resistance and smoothness can be precisely calibrated by adjusting the integrated friction screw.

3. Environmental Conditions

Acceptable Environmental Conditions
Temperature use range: -5 °C to +45°C
Humidity: Allowable relative humidity 20% to 90% RH, non-condensing

Unsuitable Environmental Conditions
Fresh water, salt water, sweat, urine, acids e.g.
Sand, dust, highly hygroscopic particles (e.g., talcum)
Mechanical vibrations, impacts
Cleaning agents containing solvents

4. Service Life

The service life of the product is about 4 years. This duration depends on the daily activity of the user.

5. General Safety Instructions

CAUTION!

To avoid the risk of injury and product damage, do not use for longer than the service life of the product.

The suitability of the device to the patient and the prosthesis should be evaluated by a healthcare professional. The device must be fitted and adjusted by a healthcare professional.
There is a danger of pinching and injuring your finger or skin. Do not insert your hand into the joint mechanism!
Avoid using this product in unsuitable environmental conditions. If the product has been exposed to unsuitable environmental conditions, check for damage.
Do not use the product that is damaged, has limited functionality or is in doubtful condition. Ensuring that appropriate measures are taken (e.g. control, cleaning, repair, replacement by the authorized workshop or manufacturer).
To prevent mechanical damage, be careful and caution when working the product.
Use the product for a single patient to avoid injuries and product damage.
Products should be used in appropriate combinations. Using the product with unsuitable combinations may result in possible injury.
In case of feeling any space or sound, apply the rehabilitation center who installed the prosthesis.

6. Patient Training and Rehabilitation

1. Following the final fabrication and fitting of the prosthesis, a qualified clinical specialist must guide the patient and demonstrate the correct donning and doffing procedures.

2. The prosthetic service facility must feature a dedicated rehabilitation area equipped with parallel bars/handrails and certified clinical trainers to conduct a structured prosthetic adaptation and functional training program.

3. The duration of the training and rehabilitation period varies for each individual, ranging from one week to several months, depending on the amputation level, patient age, and residual muscle strength.

7. Patient Care and Daily Precautions

1. Strictly adhere to the donning and operating instructions provided by your clinical specialist. Do not alter or modify these instructions under any circumstances.

2. Prosthetic socks or liners must be changed and cleaned daily. (Recommendation: Hand wash and air dry only).

3. The prosthetic socket must be thoroughly wiped down every two days using water or diluted medicinal alcohol.

4. To allow the residual limb to rest, it is highly recommended to doff the prosthesis, liner, and sock for 10 minutes every 4 hours of continuous use.

5. Always carry extra prosthetic socks to manage and adapt to residual limb volume fluctuations during daily activities, work, or travel. Additionally, replace the sock immediately if it becomes damp or wet.

6. If you plan to travel for more than two days, consult your prosthetic service provider beforehand to schedule safety inspections, routine maintenance, and any necessary adjustments.

8. Maintenance

1. After the first 30 days of use, the prosthesis parts should be visually inspected and function checked.
2. Inspect the entire prosthesis for wear during normal consultations.
3. This prosthesis and its components should be checked for function by a prosthetist at regular intervals every six months. If the recommendations are followed properly, there is no risk.

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