INSTRUCTIONS FOR USE

IFU CODE: 46

İB-ER PROSTHETIC

Modular Shoulder Elbow Component Kit (HD5)

CE

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. HD5

Modular Elbow Component Kit

The HD5 Mechanical Elbow Joint is a specialized prosthetic solution engineered specifically for Shoulder Disarticulation patients. This model features a reliable passive elbow lock mechanism with 7 different locking positions, providing the user with stable and predictable control over the arm angle. Constructed with a durable aluminum body, it balances the necessary structural strength for high-level amputations with a lightweight design of 375 gr.

1.1. Features

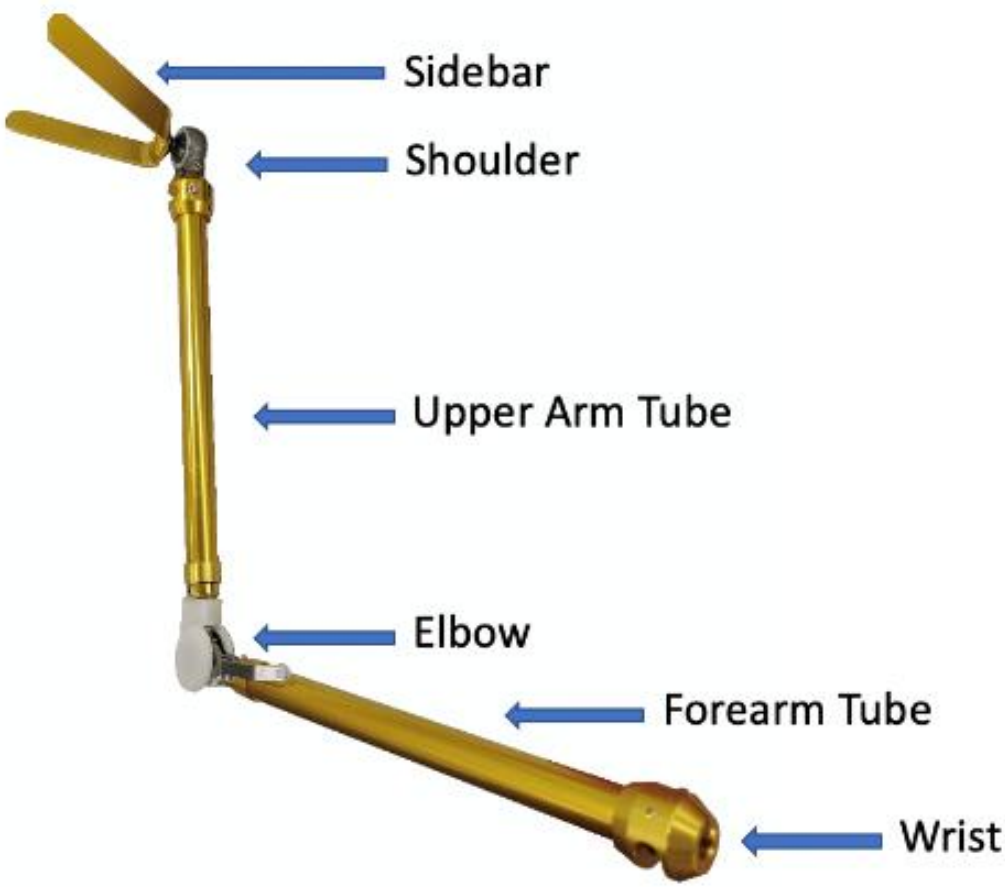
Product Name	HD5-L HD5-R
Body Material	High-Grade Aluminum
Product Weight	375 gr
Connector Thread	M12 x 1.5
Locking	Passive, 7 Position

2. Assembly & Setting Instructions

2.1 Assembly

Please contour and fix the sidebar of the HD-5 to the shoulder disarticulation socket, cut the upper arm and forearm tubes to the desired lengths, and then screw-in the preferred prosthetic hand to the wrist (M12x1.5 thread) in order to finish the whole prosthetic arm assembly. Make sure all screws or nuts of each individual component are tightened properly before patient use.

⚠ WARNING: This elbow mechanism is NOT designed for heavy lifting or carrying heavy items.

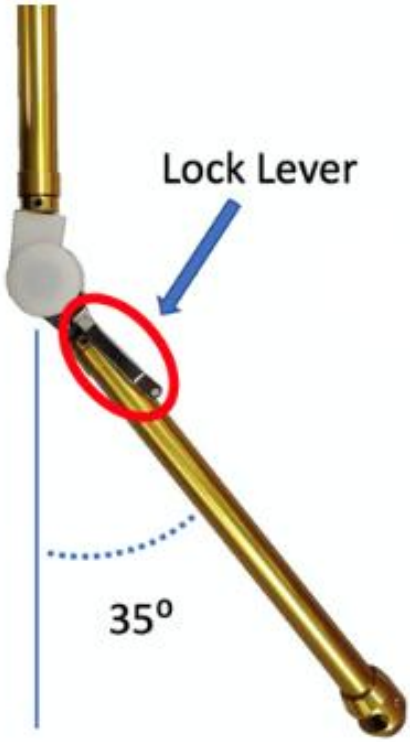


2.2 Friction adjustment of the Shoulder Movement

The ball-and-socket shoulder joint can be passively adjusted to any desired angle. The movement friction and resistance can be calibrated using the integrated set screw.

2.3 Manual Lock Operation

The prosthetic elbow joint features seven distinct locking positions to accommodate various elbow flexion angles: 15°, 35°, 55°, 75°, 95°, 115°, and 135°. These positions can be securely fixed using the integrated manual lock mechanism. To engage the lock, adjust the elbow to your preferred position and slide the lever anteriorly to hold it in place (Fig. B). To release the mechanism and allow free movement, simply slide the lock lever posteriorly (Fig. B).

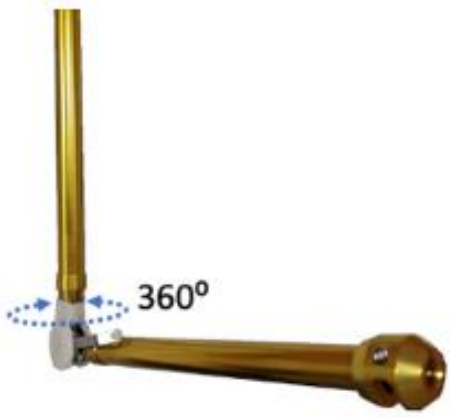
Figure A:	Figure B:
The elbow joint secured at a 35-degree flexion angle.	Directional adjustment of the lock lever to engage or disengage the elbow mechanism.
	

2.4 Forearm Pronation and Supination

The forearm features 360-degree passive pronation and supinational rotation. The rotational friction resistance can be precisely adjusted using the designated set screw.

2.4 Forearm Internal and External Rotation

The forearm features 360-degree passive internal and external rotation. The rotational friction resistance can be precisely adjusted using the designated set 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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