

# Heavy Duty Outside Locking Hinges

Product Manual

Fillauer®

## Intended Use

Heavy Duty Outside Locking Hinges are used to replace the natural elbow joint for patients with elbow disarticulations and long transhumeral amputations. The joints lock and unlock by cable pull, which allows the carrying of objects and activation of the terminal device. Each pair includes one locking and one non-locking hinge. The locking joint hinge has five individual locking positions throughout the flexion range. This joint is intended for heavy-duty use and will support higher loads than standard joint sets.

### Performance Characteristics

Part Number	53883 / 50950
Locking Positions	5
Housing Length to Joint Center	2.03 in. (51.6 mm)
Housing Width	1.406 in. (35.7 mm)
Thickness	0.37 in. (9.4 mm)
Weight	15.5 oz. (434 g)
Primary Materials	Stainless Steel, Tool Steel, and Aluminum

The device is intended for single user/patient use only.

### Storage and Handling

It is recommended that prosthetic hinges be stored in a cool, clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

## Warnings and Precautions



**CAUTION:** Lubricate moving parts with only Lubriplate® 630-AA or equivalent.



**CAUTION:** Prolonged exposure to liquids will result in corrosion and failure of the device.



**CAUTION:** Body-powered devices should not rely on cable tension for grasp control if the user has been cleared to drive with the prosthesis.



**NOTICE:** Abnormal or improper environmental conditions will lead to malfunctioning and damage of this device and are not covered under the warranty. This prosthetic component must not be subjected to dust/debris, harsh chemicals, liquids, abrasives, vibration, activities which would damage the biological limb, or prolonged extreme temperatures (< -5 °C or > 50 °C).



**NOTICE:** The ability of an upper limb prosthetic device user to drive should be determined on a case-by-case basis by a specialist. Contact your local governing authorities regarding any driving restrictions or limitations. Body-powered devices should not rely on cable tension for grasp control if the user has been cleared to drive with the prosthesis.

## Qualified Provider

Attachment, adjustment, alignment, and delivery of this device must be performed by or under the direct supervision of a qualified prosthetist. Unless stated in this manual, any such activities should not be attempted by the user and will potentially void the device warranty.

## Specifications and Preparations Before Use (Risk Management for Installation and Calibration)

### Alignment

The hinges are most easily aligned in a test fitting by temporarily attaching a single hinge (typically the locking hinge) to the socket and the temporary forearm. With a single hinge in place, the forearm portion of the prosthesis may be aligned by bending the proximal and distal straps to achieve proper hanging angle both in full extension and as the forearm is flexed toward the midline. During fabrication, the alignment of the single joint may be translated to the opposite side joint using the Elbow Hinge Spacer Kit (PN 50188). For final lamination, the anchor straps should be bent over the end of the socket for strength and maintaining alignment, or they may be removed if not needed.

## Installation

Be cautious when disassembling the locking joint. Always disassemble in a clean area and over a tray that can catch any small pieces that may fall out. Always disassemble slowly with the joint straps on top so that the internal parts do not fall out. Tape a small piece of clear plastic or other small flat surface over the internal pieces to keep the assembly together while disassembled. A piece of clear plastic assists installation by making the parts visible to allow a check of function before reinstalling. If the joint no longer functions after installation, ensure that the pieces have been reinstalled as shown in Figure 1.

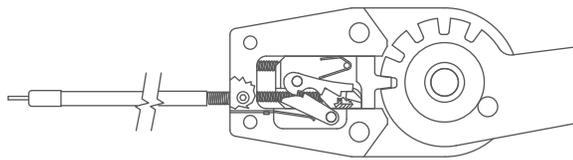


Figure 1

## Cable Housing

The cable housing length can be adjusted by removing the set screw on the side of the joint housing and trimming to the proper length. Reinstall the set screw with a small amount of threadlocker on the threads of the set screw only. Be sure to route the cable directly into the lock housing using cable housing anchor(s). Minimize turns in the cable housing to prevent excess friction on the lock cable which may result in poor function.

## Disposal / Waste Handling

The product must be disposed of in accordance with applicable local laws and regulations. If the product has been exposed to bacteria or other infectious agents, it must be disposed of in accordance with applicable laws and regulations for the handling of contaminated material.

All metal components may be removed and recycled at the appropriate recycling facility.

## User Instructions

The providing health care professional must review the following information directly with the user.

### Care and Maintenance



**NOTICE:** The user should monitor their prosthesis daily and contact their health care professional if they experience changes in device performance or if it begins to make noise.



**CAUTION:** The joint should not be disassembled or lubricated by the user. All maintenance should be performed by a qualified health care professional.



**CAUTION:** Abnormal or improper environmental conditions will lead to malfunctioning and damage of this device and are not covered under the warranty. This prosthetic component must not be subjected to dust/debris, harsh chemicals, liquids, abrasives, vibration, activities which would damage the biological limb, or prolonged extreme temperatures (< -5 °C or > 50 °C). If the joint is exposed to any dust, debris, or liquids, it should be promptly rinsed with fresh water and dried to prevent corrosion.



**NOTICE:** An upper-limb prosthetic device user's ability to drive should be determined on a case-by-case basis by a specialist. Contact your local governing authorities regarding any driving restrictions or limitations.



**CAUTION:** Body-powered devices should not rely on cable tension for grasp control if the user has been cleared to drive with the prosthesis.

## Serious incidents

In the unlikely event of a device failure resulting in injury, seek immediate medical help and contact your prosthetist at the earliest possible convenience. Clinicians should contact their local Fillauer representative immediately in the event of any device failure.

## Warranty

This product has a 12 month warranty against manufacturer defects.



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