

MC Hand Wrist Disarticulation

Prosthetist Manual

Special Precautions



Risk Management

To minimize the risk of device damage or injury to the user while maximizing the functions of this device, follow the instructions for installation, and use this device as described in this manual.



The MC ETD is water-resistant, not waterproof

While the Motion Control ETD is water-resistant, the quick disconnect wrist is not. Do not submerge the ETD beyond the wrist.



Flammable Gases

Caution should be used when operating the ETD around flammable gases. The ETD utilizes an electric motor that can ignite volatile gases.



Do not bend fingers

While the MC ETD is robust, body weight represents a great deal of force. Do not apply full body weight on the fingers. Additionally, a fall with the force directed to the fingers could cause damage. If the fingers do become bent or out of alignment, see your prosthetist.



Safety Release

Do not force the ETD fingers opened or closed. This will result in serious damage to the device. The safety release will allow easy opening and closing of the ETD. If the release mechanism does not allow motion, the device requires service by Fillauer Motion Control.



Safety Caution

Use caution when using this device in situations where injury to yourself or others may occur. These include but are not limited to activities such as driving, operating heavy machinery, or any activity where injury may occur. Conditions such as a low or dead battery, loss of electrode contact, or mechanical/electrical malfunction (and others) may cause the device to behave differently than expected.



Repairs or Alterations

Do not attempt to repair or alter any of the mechanical or electronic components of the MC ETD. This will likely cause damage, additional repairs and void the warranty.



Serious Incidents

In the unlikely event a serious incident occurs in relation to the use of the device, users should seek immediate medical help and contact their prosthetist at the earliest possible convenience. Clinicians should contact Motion Control immediately in the event of any device failure.

Figure 1-Configuration

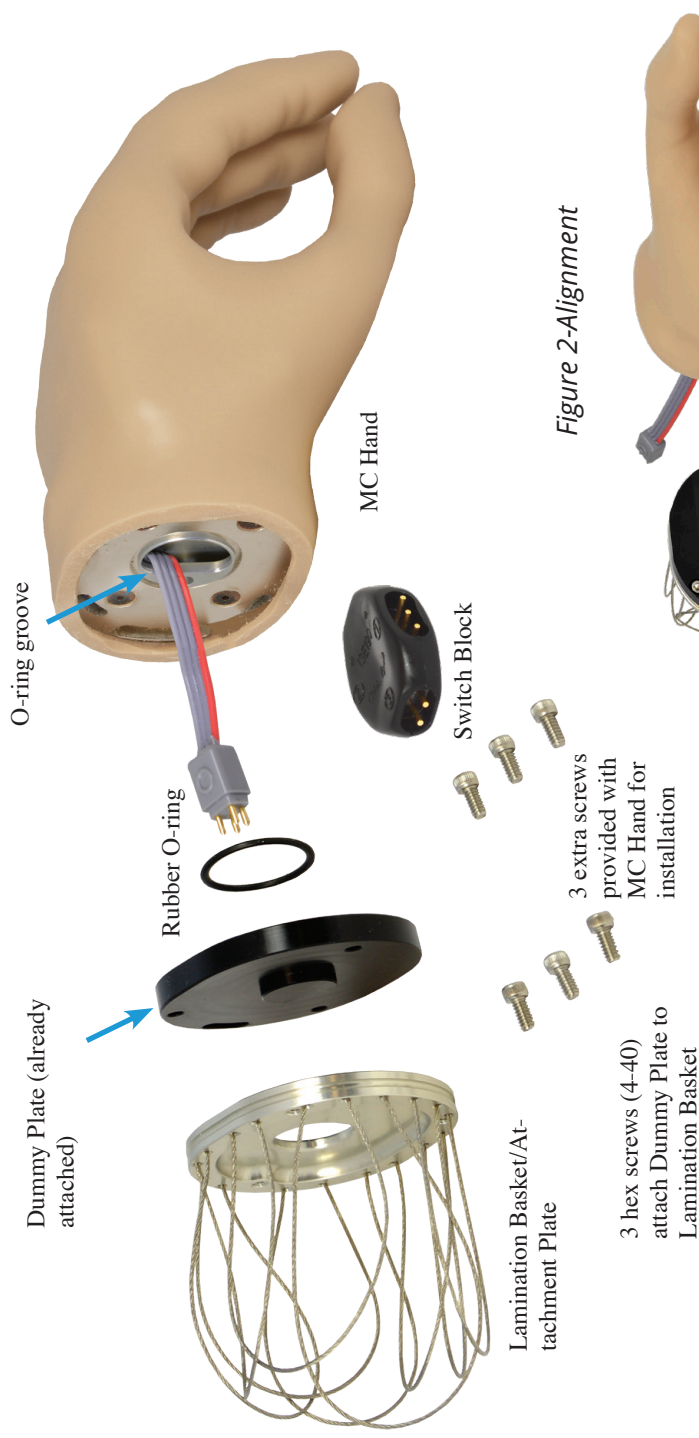
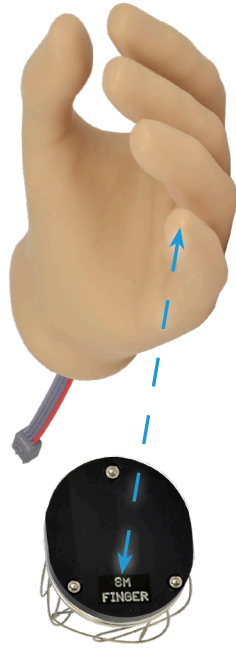


Figure 2-Alignment



Introduction

The Wrist Disarticulation option provides an attachment plate that can be laminated directly to the outer socket of the prosthesis. This minimizes the length of the prosthesis in cases where much of the patient's remnant limb has been saved. While it does allow a slight amount of rotational adjustment, it sacrifices passive rotation and interchangeability of terminal devices for the patient.

Instructions

1. Using foam, plaster of Paris, wax or other preferred material, shape the distal portion of the forearm. Ensure that the inner socket can be removed from the outer socket to allow installation of electrodes, preamps, wires, and internal battery.
2. Establish the mounting surface for the Lamination Basket. This must be at the correct length and wrist angle.
3. If necessary, use a parting agent (such as a PVA bag) between the forearm material and the Lamination Basket. This will allow easy removal of material, and removal of the inner socket from the outer forearm
4. Temporarily attach the Lamination Basket, making sure the **"SM FINGER"** marking on the Lamination Dummy Plate (already installed) is in the direction of the small finger (ulnar direction) of the MC Hand (Figure 2). Otherwise the lamination basket will be off by 180 degrees.
5. In the lay up, make sure at least 2 stockinettes (4 layers) are firmly tied off in the tie-off grove.
6. Remove and add parting agent to each of the 3 hex screws holding the lamination dummy in place.
7. Reinstall the Lamination Dummy Plate and screws.
8. Laminate.
9. Trim the excess lamination away and remove the screws and the lamination dummy. Use care in removing the last piece of plastic to prevent damage to the attachment plate.
10. Slide the O-ring over the connector and into the groove on the MC Hand (Figure 1). A small amount of silicone grease will help hold it in place.
11. With the inner socket removed, feed the wire of the MC Hand through the center slot in the attachment plate.

12. Place a small amount of medium strength threadlocker (Loctite 242, 243 or equivalent) on the 3 hex screws packaged with the MC Hand. Use these screws to attach the MC Hand to the attachment plate. Note that the attachment holes are slotted to allow some rotational adjustment.
13. With a 3/32 in. ball end hex key, firmly hand-tighten the screws.

Other Information

Please see the enclosed MC Hand Prosthetist Manual and User Guide for important Instructions, Cautions, Specifications, Warranty information, etc.

Single Patient Use

Each amputee is unique. The shape of their residual limb, the control signals each generates and the tasks an amputee performs during the day require specialized design and adjustment of the prosthesis. Motion Control products are manufactured to be fit to one individual.

Disposal/Waste Handling

This device, including any associated electronics and batteries should be disposed of in accordance with applicable local laws and regulations. This includes laws and regulations regarding bacterial or infectious agents, if necessary.

Limited Warranty

Seller warrants to Buyer that the equipment delivered hereunder will be free from defects in materials and manufacturing workmanship, that it will be of the kind and quality described and that it will perform as specified in Seller's written quotation. The limited warranties shall apply only to failures to meet said warranties that appear within the effective period of this Agreement. The effective period shall be one year (12 months) from the date of delivery to the fitting center that has purchased the components. Refer to the shipping receipt for the date of shipment.

For more information regarding the Limited Warranty, see the MC FACT SHEET - Limited Warranty.

Return Policy

Returns are accepted for a full refund (not including any repairs that may be required) for up to 30 days from date of shipment. Returns 31-60 days from date of shipment will be accepted, subject to a 10% restocking fee. Returns 61-90 days from date of shipment will be accepted, subject to a 15% restocking fee. Returns must be in re-saleable condition. Beyond 90 days, returns are not accepted.

Technical Specifications

Operating Temperature: -5° to 60° C (23° to 140° F)

Transport & Storage Temperature: -18° to 71° C (0° to 160° F)

Pinch Force: At 7.2 volts nominal: 11 kg (24 lbs, or ~ 107N)

Operating Voltage Range: 6 to 8.2 Vdc - MC Hand

Load Limit: 22 kg / 50 lbs in all directions (+/- 10%)

Declaration of Conformity

The product herewith complies with the Medical Device Directive 93/42/EEC guidelines, and is registered with the United States Food and Drug Administration. (1723997)



Customer Support

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The logo for Fillauer, featuring the brand name in a stylized, blue, cursive script font with a registered trademark symbol.

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