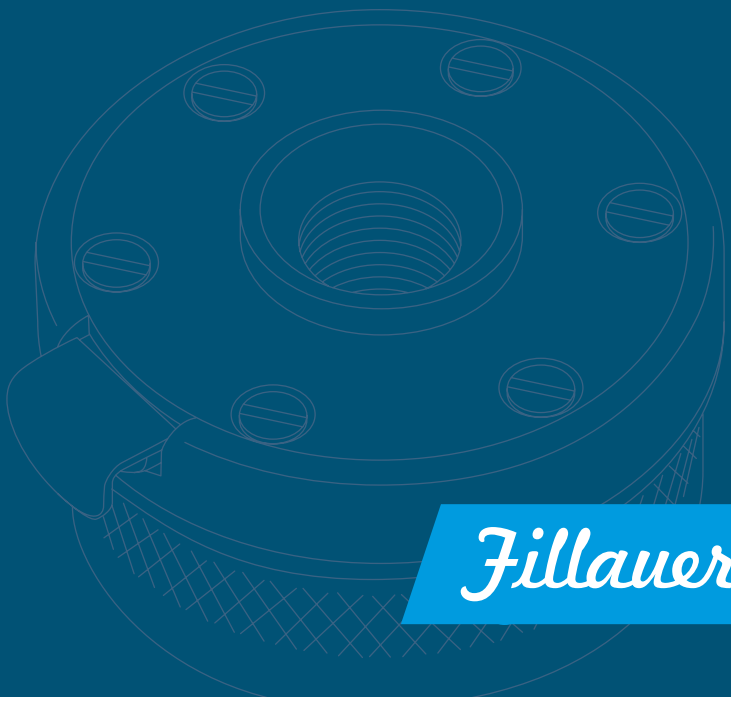
FM Quick Change Wrist

Product Manual



Intended Use

The FM Quick Change Wrist is designed for quick changes of the terminal device and its positions. Light pressure on the button unlocks the wrist and permits free rotation. Heavier pressure on the button allows the terminal device to be detached from the wrist. Pressure on the end of the terminal device will re-seat and lock it into position.

Performance Characteristics

- Quick Disconnect
- Locked Rotation

FM Quick Change Wrist

Material	Diameter	Build Height	Weight	Lamination Ring	Product Number
Al	2.0 in. (51 mm)	0.94 in. (24 mm)	3.2 oz. (92 g)	No	**51043**
SS	2.0 in. (51 mm)	0.94 in. (24 mm)	6.0 oz. (170 g)	No	**51044**
Al	2.0 in. (51 mm)	0.997 in. (25 mm)	4.0 oz. (112 g)	Yes	**58297**
Ti	2.0 in. (51 mm)	1.02 in. (26 mm)	5.9 oz. (166 g)	Yes	**62436**

FM Quick Change Wrist Insert

Material	Thread	Weight	Product Number
SS	½-20	1.0 oz. (29 g)	**51052**
SS	12 mm	1.0 oz. (29 g)	**58229**

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

Storage and Handling

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

Warnings and Precautions

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.

WARNING: Body-powered devices should not rely on cable tension for grasp control if the user has been cleared to drive with the prosthesis. Failure to maintain tension while controlling the steering wheel could cause serious injury or death.

CAUTION: Abnormal or improper environmental conditions will lead to malfunctioning and damage of the prosthesis and are not covered under the warranty of the device. This prosthetic component must not be subjected to dust/debris, liquids other than fresh water, abrasives, vibration, activities which would damage the biological limb, or prolonged extreme temperatures (< -5 °C or > 50 °C). Do not allow debris or liquids to remain in the prosthesis and its components during use. Rinse the wrist with fresh water and dry immediately after exposure.

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

Prosthetic wrists should be aligned to provide the best possible work envelope for the patient's specific goals. Standard alignment begins at 5° of flexion and 5° of radial deviation but should be tailored to the individual patient.

Fabrication Without Lamination Ring

1. Check to make sure that the wrist can be placed on the distal end of the socket such a way that the internal components do not contact the inner socket before the wrist body.
2. The wrist may be laminated by removing the faceplate and internal components from the wrist body that is held in by the screws on the distal face of the wrist unit.
3. Once the internal components and face have been removed, the screws can be replaced to protect the threads during lamination.
4. Place the wrist body on the distal end of the forearm mold (beeswax, foam, plaster, or similar). A PVA bag should be used to separate the wrist body from the forearm mold if foam or plaster are used.
5. Wax the interior surface of the wrist body and the distal face of the body.
6. Pack the wrist body with silicone fitting gel or similar to prevent it from filling with laminate.
7. Mask the body distal to the tie-in groove on the lamination ring to preserve access to any moving components and to keep all laminate clear of the distal end.
8. Laminate with the appropriate materials for durability and finish as desired by the patient, being sure to tie each structural layer into the tie-in grove in the lamination ring.
9. Carbon fiber tape is a good choice for reinforcing the connection to the lamination ring and is commonly used as distal to proximal strips tied in with circumferential wraps.
10. When reattaching the faceplate, be sure to use medium-strength threadlocker on the attachment screws before delivery.

Fabrication With Lamination Ring

1. Place the wrist unit on the distal end of the forearm mold (beeswax, foam, plaster, or similar). Be sure that the internal components do not contact the inner socket.
2. The wrist may be laminated by removing the face assembly and internal components from the lamination ring once its alignment and clearance are confirmed.
3. A PVA bag should be used to separate the lamination ring from the forearm mold if foam or plaster are used.
4. Wax the interior surface of the lamination ring.
5. Pack the lamination ring with silicone fitting gel or similar to prevent it from filling with laminate.
6. Mask the lamination ring distal to the tie-in groove to keep all laminate clear of the distal end and away from any moving components.
7. Laminate with the appropriate materials for durability and finish as desired by the patient, being sure to tie each structural layer into the tie-in groove in the lamination ring.
8. Carbon fiber tape is a good choice for reinforcing the connection to the lamination ring and is commonly used as distal to proximal strips tied in with circumferential wraps.
9. When the lamination is complete clean the lamination ring and remove any packing material. Ensure that no lamination is left distal to the tie-in groove.
10. Slide the nutplate through laminating ring and pull it into place. Keep the engaging bumps proximal.
11. When reattaching the face assembly and/or internal components, be sure to use medium-strength threadlocker on the attachment screws before delivery.
12. Install the face assembly, engaging the nutplate with the #4-40 screws. Tighten the screws.
13. If the orientation of the button/lever needs to be changed, loosen the #4-40 screws approximately 1⁄16 inch (2 mm) and

gently tap the face assembly. To loosen the nutplate, rotate to the proper orientation and re-tighten.

Adjusting the Lamination Ring

1. If the wrist unit has a separate lamination ring, its alignment can be adjusted during the installation of the internal components.
2. To install, slide the nutplate through laminating ring and pull it into place. Keep the engaging bumps proximal.
3. When reattaching the face assembly and/or internal components, be sure to use medium-strength threadlocker on the attachment screws before delivery.
4. Install the face assembly, engaging the nutplate with the #4-40 screws. Tighten the screws.
5. 5. If the orientation of the button/lever needs to be changed, loosen the #4-40 screws approximately 1⁄16 inch (2 mm) and gently tap the face assembly. To loosen the nutplate, rotate to the proper orientation and re-tighten.

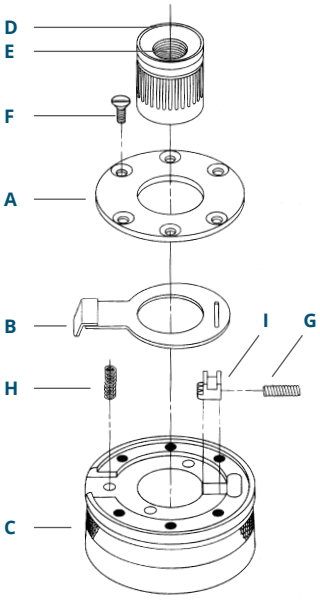
Installation and Replacement of the Quick Change Insert (51052)

The quick-change insert should be installed on the terminal device using medium or high-strength threadlocker. An insert may be replaced by lightly heating the insert to allow the threadlocker to release.

Wrist Assemblies

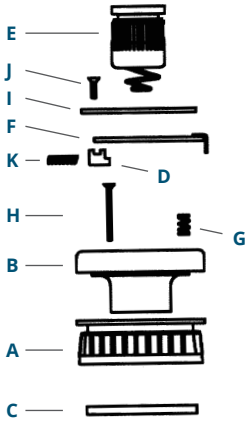
51043 Quick Change Wrist FM-100, Al Body

51044 Quick Change Wrist FM-100S, SS Body



A. 51045 Face Plate
B. 51046 Yoke
C. 51049 Body, Aluminum
51051 Body, Stainless Steel
D. 51052 Insert, Standard ½-20 Thread
58229 Insert, M12 × 1.5 Metric Thread
E. 51055 Insert Spring, for 51052
F. 51057 Screw
G. 51058 Spring
H. 51059 Spring
I. 51060 Gear Rack

58297 Quick Change Wrist with Laminating Ring FM-100LR



A. 59522 Laminating Ring
B. 58299 Body
C. 58287 Nut plate
D. 51060 Gear
E. 51052 Insert, Standard ½-20 Thread
58229 Insert, M12 × 1.5 Metric Thread
F. 51046 Yoke
G. 51059 Spring
H. 58283 Screw #4-40, 4 Each
I. 51045 Plate
J. 51057 Screw #4-40, 6 Each
K. 51058 Spring 58305 Body Assembly

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.

Warranty

This product has a 12-month warranty against manufacturer defects.

User Instructions

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

Warnings and Precautions for the User

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: All maintenance should be performed by the qualified health care professional.

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. Failure to maintain tension while controlling the steering wheel could cause serious injury or death.

CAUTION: Abnormal or improper environmental conditions will lead to malfunctioning and damage of the prosthesis and are not covered under the warranty of the device. This prosthetic component must not be subjected to dust/debris, liquids other than fresh water, abrasives, vibration, activities which would damage the biological limb, or extreme temperatures (< -5 °C or > 50 °C). Do not allow debris or liquids to remain in the prosthesis and its components during use. Rinse the device with fresh water and dry immediately after exposure.

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, local competent authority, and Fillauer at the earliest possible convenience. Clinicians should at any time contact their local Fillauer representative and local competent authority immediately in the event of any device failure.

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Fillauer

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