Omega Wrist

Product Manual

Fillauer®

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Intended Use

Omega Wrists utilize a unique, foolproof capture and disconnect insert technology that has tested stronger and more stable than typical bayonet-style disconnect wrist systems. Precision fit between the insert and housing allows an easy change of the terminal device without a loose feel. The easy-to-install Omega disconnect insert and capture mechanism locks in and locks open with an easy, out of the way switch instead of a button that can be inadvertently pressed.

The rotational frictional adjustment design is toolless and easily replaced by the patient as needed. Omega Wrists are CNC machined from surgical quality stainless steel and aircraft aluminum. All parts are machined — no castings. Lamination rings have extra aggressive surfaces for robust fabrication, providing a secure terminal device and laminating foundation.

Round Omega Wrist

	Large	
Diameter	2.04 in. (51.8 mm)	
Height with Laminating Ring	1.03 in. (26.2 mm)	
Weight	3.6 oz. (103 g)	
Thread	½-20 Thread	
Material and Color	Aluminum	Black Aluminum
Product Number	**OMEGA R**	**OMEGA RB**

Oval Omega Wrist

	Medium		Large	
Length × Width	2.0 × 1.5 in. (50 × 38 mm)		2.4 × 1.7 in. (60 × 45 mm)	
Height with Laminating Ring	1.0 in. (25 mm)		1.0 in. (25 mm)	
Weight	3.2 oz. (89 g)		3.9 oz. (111 g)	
Thread	½-20 Thread		½-20 Thread	
Material and Color	Aluminum	Black Aluminum	Aluminum	Black Aluminum
Product Number	**OMEGA M**	**OMEGA MB**	**OMEGA L**	**OMEGA LB**

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, abrasives, 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.

CAUTION: The wrist unit is waterproof. However, if the wrist is submerged, it should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.

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

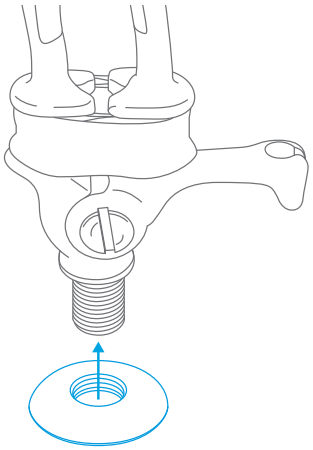
Prosthetic wrists should be aligned to provide the best possible work envelope for the patient's specific goals. Standard alignment begins at 5° of flexion and 5° of radial deviation but should be tailored to the individual patient.

Fabrication

1. Place the wrist unit on the distal end of the forearm mold (beeswax, foam, plaster, or similar). Ensure that the internal components do not make contact with 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. When reattaching the face assembly and/or internal components, be sure to use a medium-strength threadlocker on the attachment screws before delivery.

Hook Adapter

The Omega Hook Adapter is a required component for use with all split-hook TDs and any other TDs that have a narrow base. The Omega Hook Adapter permanently fits onto a split hook over the threaded stud and provides a broader platform necessary for Omega Disconnect Insert frictional adjust function. This Hook Adapter can be left on the TD and will not interfere with its function, except on a flexion style wrist.



Prosthetic Device Installation and Removal

Any non-electric terminal device equipped with an Omega Quick-Disconnect Insert can be installed into the Omega wrist in two ways:

1. Push the Omega Quick-Disconnect Insert into the face plate. The spring-wire-capture mechanics are compliant and will spread apart then snap closed into the precision groove of the Insert, securing the device to the wrist.
2. Alternatively, you can first lock open the wrist by manually sliding the control button to the lock-out position. The ball-spring-plunger mechanism holds the system unlocked, where it will remain until the control button is manually released back into its locking mode.
3. To release and remove a terminal device from the wrist, slide the control button into the unlock position first.

Prosthetic Device Rotational Friction Adjustment

The Omega Wrist is unique in that it allows the user to change the amount of friction that is required to rotate a terminal device on the wrist without the use of any tools. Rotating a terminal device either slightly 10 – 20 degrees or to a greater offset angle may be convenient when manipulating objects, tools, etc.

Note: The friction can be adjusted to be very loose or it can be increased to a point where the terminal device does not rotate at all.

1. The six (6) gear teeth that live on the underside of the quick-disconnect insert that is installed onto the terminal device perfectly mesh with the twelve (12) gear teeth of the gear ring on the face plate.
2. The rubber O-ring is contained and sandwiched between the quick-disconnect insert and the terminal device. As the insert is screwed down onto the terminal device it creates and becomes a simple compressible friction adjustment. The tighter the insert is screwed down the more the O-ring is compressed, increasing the friction and energy that it takes to loosen the quick-disconnect insert.

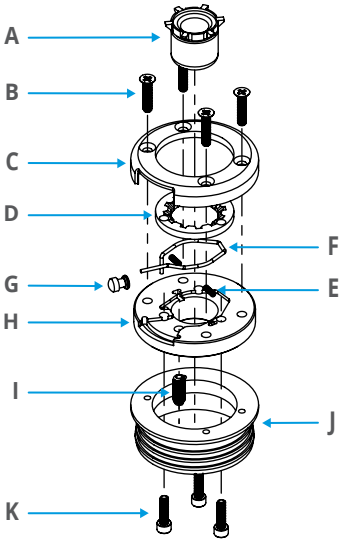
3. With the control button in the unlocked mode, slide the quick-disconnect insert into the wrist and allow the teeth to engage. Clockwise rotation tightens and compresses the O-ring, increasing the friction, while counterclockwise rotation decompresses the O-ring and decreases the friction.

Note: It is possible to permanently lock the Omega Disconnect Insert to a prosthetics device using permanent thread-locking adhesive, but doing this will limit the Omega Wrist and the terminal device to operate in only twelve (12) locking positions, not the unlimited number of positions that using the friction-adjust mechanism provides.

Wrist Assemblies

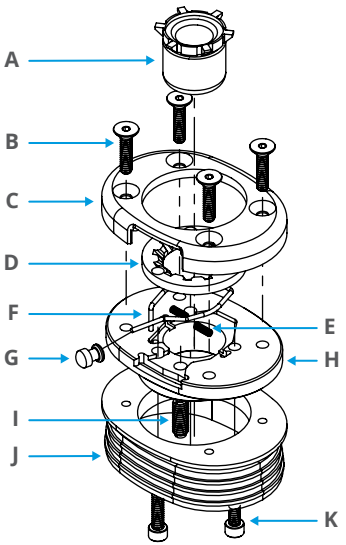
OMEGA R Round Omega Wrist
OMEGA RB Round Omega Wrist, Black

A. OM003 Omega Q/D Insert
B. OM010 Screws, Faceplate, Omega Rnd, 4 Each
C. OMR101 Omega Rnd Faceplate, Clear
OMR101B Omega Rnd Faceplate, Black
D. OM002 Omega Ring Gear
E. OM006 Omega Balance Spring, 2 Each
F. OM001 Omega Wrist Wire Form Spring
G. OM004 Omega Spring Button, Large
H. OMR102 Omega Round Midplate
I. OM009 Ball Plunger, Omega Wrist
J. OMR103 Omega Round Lam Ring
K. OM008 Screws, Omega Ring Gear, 3 Each
HELIX001 Helix Washer, Not Shown
PTA005 Adept O-Ring, 3 Each, Not Shown

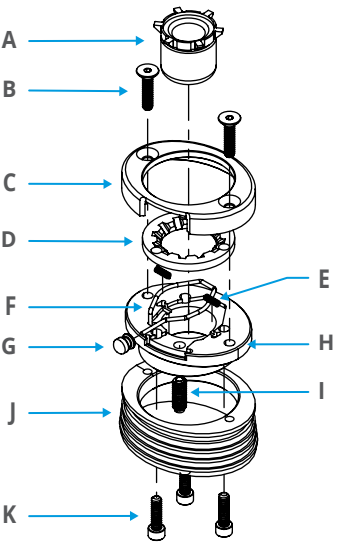


OMEGA L Oval Omega Wrist, Large
OMEGA LB Oval Omega Wrist, Large, Black

A. OM003 Omega Q/D Insert
B. OM007 Screws, Omega Faceplate, 4 Each
C. OML101 Omega Faceplate Lg, Clear
OML101B Omega Faceplate Lg, Black
D. OM002 Omega Ring Gear
E. OM006 Omega Balance Spring, 2 Each
F. OM001 Omega Wrist Wire Form Spring
G. OM004 Omega Spring Button, Large
H. OML102 Omega Midplate Lg
I. OM009 Ball Plunger, Omega Wrist
J. OML103 Omega Lam Ring, Lg
K. OM008 Screws, Omega Ring Gear, 3 Each
Helix001 Helix Washer, Not Shown
PTA005 Adept O-Ring, 3 Each, Not Shown



OMEGA M		Oval Omega Wrist, Medium
OMEGA MB		Oval Omega Wrist, Medium Black
A.	OM003	Omega Q/D Insert
B.	OM007	Screws, Omega Faceplate, 2 Each
C.	OMM101	Omega Faceplate, Med., Clear
	OMM101B	Omega Faceplate, Med., Black
D.	OM002	Omega Ring Gear
E.	OM006	Omega Balance Spring, 2 Each
F.	OM001	Omega Wrist Wire Form Spring
G.	OMM005	Omega Spring Button, Medium
H.	OMM102	Omega Midplate Med
I.	OM009	Ball Plunger, Omega Wrist
J.	OMM103	Omega Lam Ring, Med
K.	OM008	Screws, Omega Ring Gear, 3 Each
	HELIX001	Helix Washer, Not Shown
	PTA005	Adept O-Ring, 3 Each, Not Shown



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.

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CAUTION: The wrist unit is waterproof. However, if the wrist is submerged, it should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.

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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