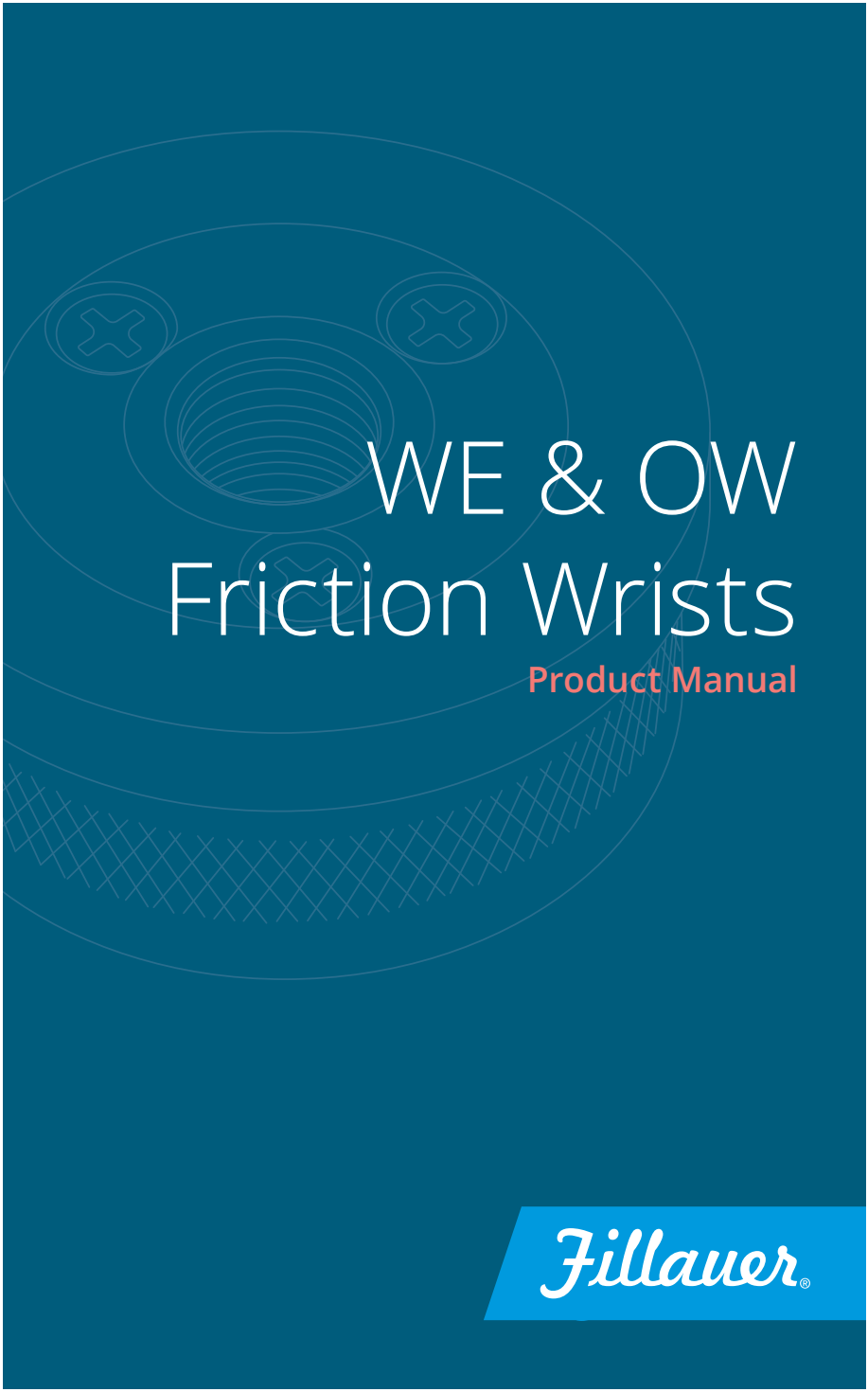

WE & OW Friction Wrists

Product Manual

Fillauer®

Contents

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Intended Use

The WE and OW Friction Wrists permit the terminal device to be rotated to any position and come with a removable, replaceable friction insert. The WE Infant Friction Wrist is designed for pediatric patients and has a pressed-in, non-removable insert.

Product Features

- Permits terminal device to be rotated to any position
- Friction is easily adjusted by a set screw in the body of the wrist
- The friction insert has stainless steel lead threads and is replaceable (except the WE-100N Infant)
- Oval design option for long transradial and passive hands

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.).

Performance Characteristics

Description	Diameter	Weight	Thread	Product Number
WE-200N Child Size	**1 ½ in. (38 mm)**	**1.5 oz. (42 g)**	**½-20**	**52147**
WE-300N Medium	**1 ¾ in. (44 mm)**	**2.0 oz. (57 g)**	**½-20**	**52156**
WE-500N Adult	**2 in. (51 mm)**	**2.6 oz. (74 g)**	**½-20**	**52160**
Friction Wrist Insert Only		**1.1 oz. (30 g)**	**½-20**	**52151**
Description	**Length × Width**	**Weight**	**Thread**	**Product Number**
OW Oval Friction Wrist	**2 × 1 ½ in. (50 × 38 mm)**	**2.0 oz. (57 g)**	**½-20**	**51618**
OW Oval Friction Wrist	**2 ¼ × 1 ⅝ in. (56 × 41 mm)**	**2.5 oz. (71 g)**	**½-20**	**51623**
Friction Wrist Insert Only		**1.1 oz. (30 g)**	**½-20**	**52151**
Description	**Diameter**	**Weight**	**Thread**	**Product Number**
WE-100N Infant Size	**1 ¼ in. (32 mm)**	**1.0 oz. (28 g)**	**½-20**	**52142**

Material: Aluminum, Stainless Steel, Nylon

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

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: Do not tighten the friction screw without first inserting a terminal device with a ½-20 thread.

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.

CAUTION: The wrist unit is waterproof to 1 meter. 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.

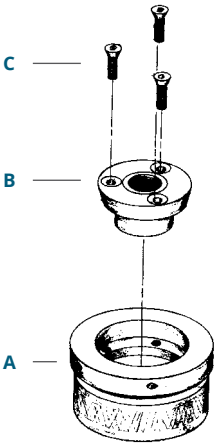
Lamination Instructions

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 friction components from the wrist body.
3. A PVA bag should be used to separate the wrist from the forearm mold if foam or plaster are used.
4. Wax the interior surface of the wrist and the distal face of the wrist body.
5. Pack the wrist with silicone fitting gel or similar to prevent it from filling with laminate.
6. Mask the housing distal to the tie-in groove on the body to preserve access to any moving components and to keep all laminate clear of the distal end.
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 body.
8. Carbon fiber tape is a good choice for reinforcing the connection to the body and is commonly used for distal to proximal strips tied in with circumferential wraps.
9. When reattaching the internal components, use medium-strength threadlocker on the attachment screws before delivery.

WE Wrist Assemblies

52147		WE-200N Child Size
52156		WE-300N Medium Size
52160		WE-500N Adult Size

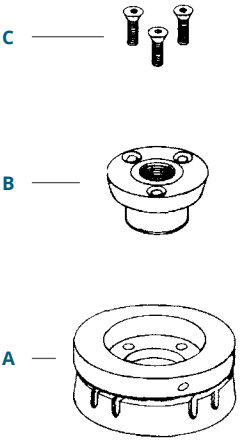
A.	52166	Body, WE-500N
	52157	Body, WE-300N
	52148	Body, WE-200N
B.	52151	Insert Assembly, WE-500, 300N, and 200N
C.	52152	Screw, WE-500, 300 and 200N
	52154	Allen Wrench (Not Shown)
	52155	Set Screw (Not Shown)



OW Wrist Assemblies

51618		OW-75N Medium-Small Size
51623		OW-100N Adult Size

A.	51627	Body, OW-100N
	51621	Body, OW-75N
B.	52151	Insert, Includes 52155
C.	52152	Face Screw
	52155	Set Screw, 52151 (Not Shown)
	52154	Allen Wrench, (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.

CAUTION: Do not tighten the friction set screw without first inserting a terminal device with a ½-20 thread.

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.

CAUTION: The wrist unit is waterproof to 1 meter. 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 of a serious incident, seek immediate medical help and contact your prosthetist at your earliest possible convenience. Clinicians should contact their local Fillauer representative immediately in the event of any device failure.

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