



# CAPP & Shapeable Passive Hand Wrists

Product Manual

*Fillauer*®

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# Intended Use

CAPP and Shapeable Passive Hand Wrists are plastic constant-friction wrist rotation units. Fine friction adjustment can be obtained with exceptionally smooth and constant friction throughout the entire turning arc. These wrist units are lightweight, shapeable wrists for passive, lightweight, and pediatric devices.

## Performance Characteristics

- Constant friction applied with unique friction adjustment collar
- Lightweight and shapeable wrist for passive and lightweight devices
- ½-20 thread

### CAPP Wrist

Material	Diameter	Build Height	Weight	Product Number
Delrin	1.5 in. (38 mm)	0.63 in. (16 mm)	0.6 oz. (16 g)	<b>55108</b>
Delrin	1.75 in. (44 mm)	0.63 in. (16 mm)	0.8 oz. (22 g)	<b>55109</b>
Delrin	2.0 in. (51 mm)	0.63 in. (16 mm)	1.1 oz. (30 g)	<b>55110</b>

### Shapable Passive Hand Wrist

Material	Diameter	Build Height	Weight	Product Number
ABS	1.9 × 1.4 in. 48 × 36 mm	0.68 in. (17 mm)	0.6 oz. (16 g)	<b>62022</b>
ABS	2.2 × 1.5 in. 56 × 38 mm	0.68 in. (17 mm)	0.8 oz. (22 g)	<b>62021</b>
ABS	2.6 × 1.7 in. 66 × 43 mm	0.68 in. (17 mm)	1.1 oz. (30 g)	<b>62020</b>

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:** Do not tighten the friction screw without first inserting a terminal device with a 1/2-20 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.

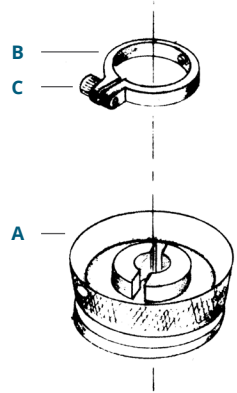
## Lamination Instructions

1. Check to make sure that the wrist can be placed on the distal end of the socket in such a way that the internal components do not contact the inner socket before the wrist body.
2. Cover both flat surfaces of the unit with two layers of masking tape. Plug the adjustment screw hole with beeswax, foam plater, or similar.
3. A PVA bag should be used to separate the wrist housing from the forearm mold if foam or plaster are used.
4. Wax the interior surface of the wrist housing and the distal face of the housing.
5. Pack the wrist housing 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 lamination ring to preserve access to any moving components and to keep all laminate clear of the distal end.
7. The position of the adjustment screw must be well marked before starting lamination.
8. After lamination, cut out the hole for the adjustment screw.
9. Laminate with the appropriate materials for durability and finish as desired by the patient.

# CAPP Wrist Assemblies

55108	CAPP Wrist 1412, 1 ½ in. (3.8 cm) Diameter
55109	CAPP Wrist 1413, 1 ¾ in. (4.4 cm) Diameter
55110	CAPP Wrist 1414, 2 in. (5.1 cm) Diameter

- A.** 55105 Housing, 55108  
55106 Housing, 55109  
52805 Housing, 55110
- B.** 59711 Clamp Assembly
- C.** 56661 Socket Head Screw  
55313 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 1/2-20 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 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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