

Fillauer.

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Intended Use

The Model 8, 8X, and 88X are prosthetic terminal devices that are commonly referred to as "canted split hooks" and are used to provide for both fine prehension and gross grasping of objects when controlled through a cable that is operated with body motions. These hooks are a voluntary-opening device and grasping tension is adjusted by the adding of tension bands, rings, or springs (see catalog for additional information). There are also smaller sizes available; see **fillauer.com** for information on other sizes of canted hooks.

Performance Characteristics

	Model 8	Model 8X	Model 88X
Size	Medium Adult	Medium Adult	Medium Adult
Length	4.625 in. (11.7 cm)	4.625 in. (11.7 cm)	4.625 in. (11.7 cm)
Weight	8 oz. (227 g)	7.5 oz. (213 g)	4 oz. (113 g)
Material	Stainless Steel	Stainless Steel	Aluminum
Grip	Serrated Surface	Nitrile Lined	Nitrile Lined

These devices are intended for single patient use only.

Storage and Handling

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

Warnings and Precautions



CAUTION: Nitrile coatings are not intended for use in high temperature applications. Refrain from contact with items that are above 85 °C (185 °F) as damage to the coating may occur.



NOTICE: An upper-limb prosthetic device user's ability to drive should be determined on a case-by-c ase 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 device with fresh water and dry immediately after exposure.



CAUTION: The hook is waterproof to 1 meter. However, if the hook 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)

Installation

The hook may be installed in any Fillauer wrist unit with a %-20 thread. Follow the instructions provided with the wrist unit for best results.

Cabling

The hook "thumb" has been designed with a receiver for a $\frac{4}{2}$ inch ball terminal. A triple swivel with $\frac{4}{2}$ inch ball terminal should be selected with a cable connection that matches the cable used in the prosthesis. Cable routing should ensure a direct line of

pull that minimizes bends in the cable, otherwise excess cable friction or failure could result.

Adding Tension to Hook Grasp

To add more force to the grasp of the hook, additional tension bands may be applied using the E-Z Hook Tension Band Applier (55144) or similar device. Additional bands are included with the hook and are available in beige (53869) or black (53869-BLK). For greater tension, hook rings (57500) or stainless-steel tension springs (55363) may be used. Tension springs are recommended for situations where chemical or heat exposure could cause band or ring failure.

Compatibility

Fillauer hooks have been tested with and are recommended for use with Fillauer wrists that have a %-20 internal thread. They may be used with any equivalent %-20 threaded wrist units; however, damage caused by other manufacturers wrist units is not covered under warranty of this device.

Only Fillauer tension bands, hook rings, and tension springs may be used with Fillauer hooks to adjust the grasping force of the hook.

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 an 18-month warranty against manufacturer defects.

User Instructions

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

Care and Maintenance



CAUTION: Nitrile coatings are not intended for use in high-temperature applications. Refrain from contact with items that are above 85 °C (185 °F) as damage to the coating may occur.



NOTICE: Nitrile coatings are expected to wear under normal use. The coating can be replaced but is not covered under warranty, except for manufacturer defect.



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 device with fresh water and dry immediately after exposure.



CAUTION: The hook is waterproof to 1 meter. However, if the hook 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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