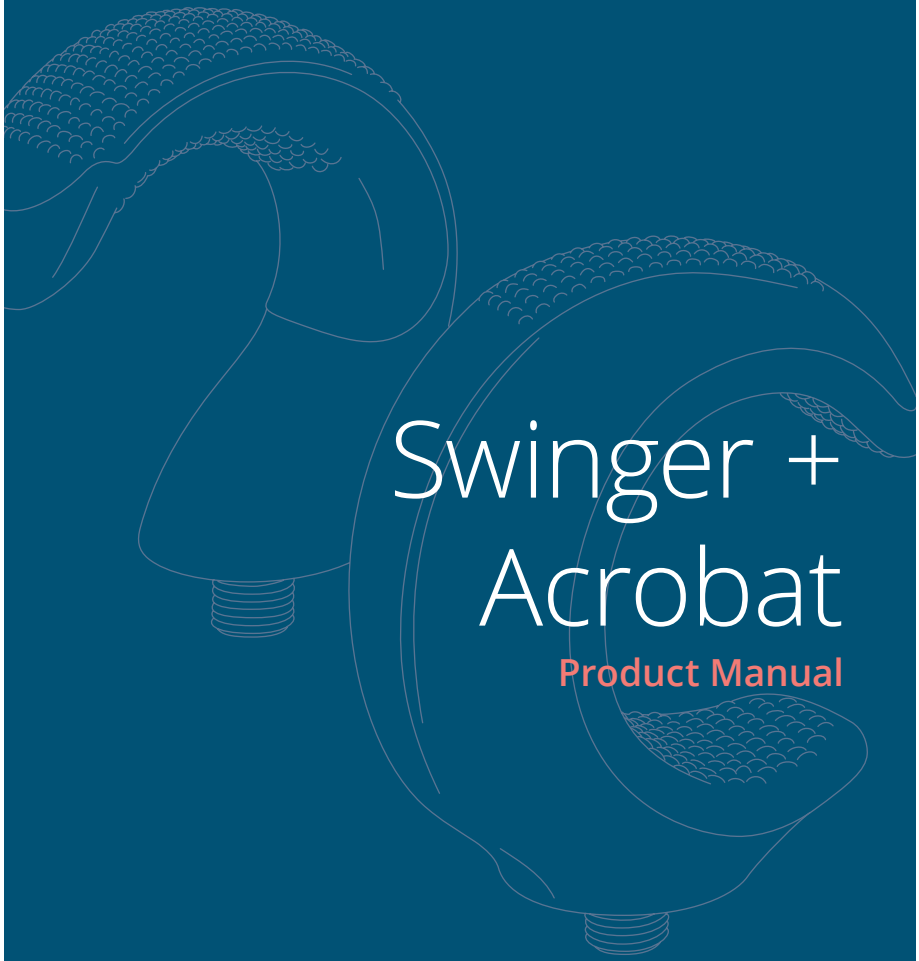

Swinger + Acrobat

Product Manual

Fillauer®

Contents

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Intended Use

These products, terminal devices, were specifically designed for activities that involved supporting the body's weight while hanging and while providing specific other functions and performance features. These products are designed to easily attach to any ½-20 threaded prosthetic wrist. They are waterproof and require little maintenance.

These devices are intended for single user/patient use only.

Indications:Upper Extremity Terminal Devices — End Effectors

Prosthetic devices are tools designed to provide or replicate certain aspects and functions of the human hand including anatomical realism. All these devices have benefits, limitations, ranges of function and liabilities that need to be understood by the user-consumer. The basis for any reliable functional outcome in using these devices is premised upon having a well-designed, reliably suspended, comfortable, functional prosthetic limb, which optimizes the user's remaining physical capabilities, including range of limb motion and strength. The remaining limb itself is a very basic limiter of function and performance. Typically, the longer the limb the more functional capacity over a prosthesis will be achieved, assuming the limb's muscular and skeletal framework are not compromised beyond simply hand absence. Loss of muscle tissue, permanent nerve damage and phantom limb sensations/pain can all impact the user's ability to perform with a prosthesis. In general, a user with a limb absence where less than 25% of the humerus remains, will **not** be a good candidate for using upper extremity prosthetic technology successfully. Additionally, the user's cognitive acuity and capability are important in understanding the ranges of function and the specific limits of function, while controlling such prosthetic tools, to optimize their performance and avoid injury.

Finally, all prosthetic terminal devices, have inherent dangers of entanglement or engagement where release can be compromised because of their physical exterior design, unique unforgiving materials, and inanimate lack of "feel". Wearing an upper extremity prosthesis does involve risk! **Training and therapy are always recommended when using a prosthesis, especially when using new or unique technology or changing prosthetic system operative controls.**

Indications: Weight Bearing/Supporting Activity TDs

This is a smaller class of prosthetic device designed for supporting distal pulling loads for body support while hanging, swinging or any other activity which requires overhead or above shoulder pulling support, such as ladder climbing. The user needs to understand that these devices are structurally very strong in supporting heavy loads but that disengagement from such support requires that the user has the physical

capability to lift their body weight to down-load and release the device from its support. These devices can also be used for carrying heavy loads below the waistline by capturing that load from underneath with a “C” shaped or “L” shaped structure. The activities of swing or climbing with any prosthesis in general create an elevated risk. Climbing can result in severe injury or death if a fall takes place. Outdoor and indoor climbing should always be augmented with overhead protection of special climbing ropes and gear. These devices have no actual “prehension” and therefore “grasp” is not controllable other than that which is created through gravitational forces. Swinging activities can be dangerous if the device prematurely releases from its overhead support resulting in falling. Gymnastic mats or equivalent should always be employed when these devices are used for gymnastic type activities and a “spotter-assistant” is highly recommended. Used properly these devices can last for many years. Regular inspection of the devices is highly recommended before each use. Severely worn surfaces or parts should be replaced as needed by a prosthetics professional. These devices should only be provided to a prosthetic user with an intimate understanding of the liabilities involved in the activity and are not recommended for individuals compromised by low muscle strength, poor range of motion, or cognitive challenges.

Storage and Handling

It is recommended that any Weight Bearing and Supporting Activity TDs (or prosthetic/orthotic components) are stored in a cool, clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

Warnings and Precautions

NOTICE: The ability of an upper limb prosthetic device user 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. Voluntary Opening body-powered devices can rely on cable tension for grasp control if the user has been cleared to drive with the prosthesis.

CAUTION: Abnormal or improper environmental conditions will lead to malfunctioning and damage of the prosthesis and is 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, or activities which would damage the biological limb. 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: Weight Bearing and Supporting Activity TDs are waterproof to 1 meter; however, if submerged, they should be rinsed with fresh water and **dried** immediately to remove salt, chlorine, or debris.

Specifications & Preparations Before Use

	Acrobat	Swinger
Age	**2 – 9 Years**	**9 Years – Adult**
Limb Level	**Transradial**	**Transradial**
Prosthesis	**Capable of self-suspension required**	
Patient Weight	**< 100 lbs. (45 kg)**	**< 200 lbs. (91 kg)**
Length	**3.4 in. (8.6 cm)**	**3.8 in. (9.6 cm.)**
Width	**1.25 in. (3.2 cm)**	**3.3 in. (8.4)**
Product Weight	**3.5 oz. (99 g)**	**8 oz. (227 g)**
Primary Materials	**High strength polyamide polymer structure with replaceable thermoplastic polyurethane grip surface**	

Preparation

Consider the following factors as you determine the most appropriate technology and prosthesis design for your client:

- Does the user understand the function and safety features of the device?
- What other terminal devices will be used with this prosthesis?
- In what types of environments will the device(s) be used?
- In what positions will the person use the device?
- How will the user switch terminal devices? Will quick-disconnect be helpful?
- For what other activities might this device be helpful?
- Will the person benefit from additional training in the use of the device?

Installation

Weight Bearing and Supporting Activity TDs may be installed in any Fillauer TRS Omega Wrist, or Fillauer LLC wrist unit with a ½-20 thread. Follow the instructions provided with the wrist unit for best results.

Cabling

Weight Bearing and Supporting Activity TDs may be installed in any Fillauer TRS Omega Weight Bearing and Supporting Activity TDs do not require any cable systems.

Compatibility

Fillauer TRS Weight Bearing and Supporting Activity TDs have been evaluated with and are recommended for use with Fillauer TRS Omega Wrists, and Fillauer LLC wrists that have a ½-20 internal thread. They may be used with any equivalent ½-20 threaded wrist units; however, damage caused by other manufacturer's wrist units is not covered under warranty of this device.

Care and Maintenance

These devices have no moving parts, so they are extremely simple. They are durable and reliable but should be inspected regularly before each use. These devices are waterproof and can be washed and totally immersed in water. Replaceable grips, if incorporated in the product, are easily replaced by the prosthetist. Since these devices are designed to support a user's total body weight, in critical and potentially dangerous activities, it is important to inspect the connection to the prosthesis, whether it be a screw in type wrist or disconnect wrist to ensure that the device will be securely fastened to the end of the prosthesis and not disconnect prematurely. Should any part or surface of these devices appear compromised, then the device should be returned to a professional prosthetist for inspection, repair, or potential replacement.

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.

Preparation for User

Consider the following factors as you prepare for this device:

- Are you able to don and to doff the device independently?
- Are you able to switch terminal devices independently?
- Are you able to access services from a skilled occupational therapist for additional training if needed?

Warnings and Precautions for the User

NOTICE: The ability of an upper limb prosthetic device user 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.

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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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