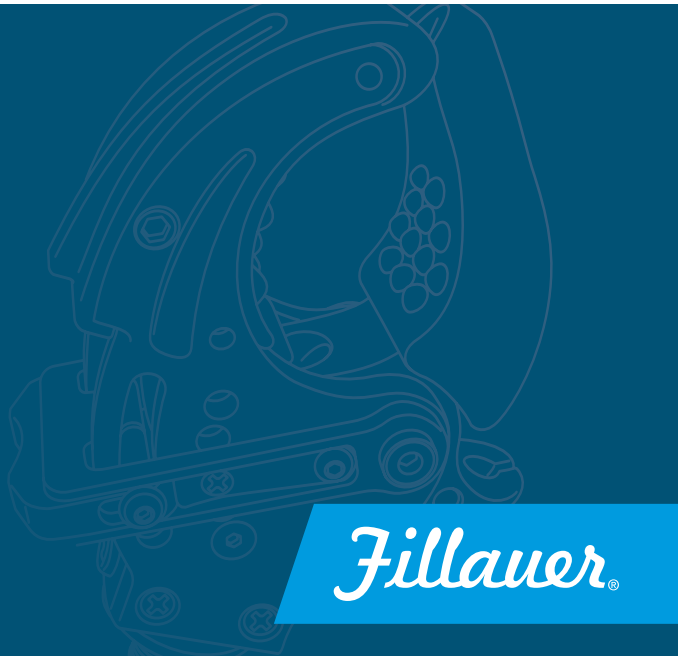
Fillauer TRS Passive Gripping TDs

Product Manual



Intended Use

These terminal devices were all designed to perform in various specific activities or tasks. They are “passive” in the sense that all of the devices, except the Criterium+, SKI 2 and Criterium Pivot models, operate without traditional “mechanical elements” such as hinges-joints, springs, etc. They derive their unique flexible, elastic, movement, performance and function mimicking specific biomechanical motions of the hand, wrist and forearm through the use of flexible polymers instead of basic mechanical linkages. Additionally, their unique materials provide for the capture, storage and release of external energy generated by the user in performing the activity, such as swinging a golf club or a bat, etc. The Criteriums, Eagle, Eagle Flex, Lamprey, Mountain Master, Pinch Hitters, Grand Slam, Power Plays and Ski2 are universal left and right. The Downhill Racer, Golf Devices and Helix have right and left models. All these terminal devices easily mount, connect, to any USA standard prosthetic wrist.

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

Performance Characteristics

Criterium Pivot 70, Criterium Pivot 85, Criterium Pivot Short 70, Criterium Pivot Short 85

These terminal devices, do not require body powered cable operation, were designed primarily to clasp around and control bicycle handle bars for general recreational, street bicycling not off road or rugged terrain bicycling. They have cross-over features in that they are also useful for controlling shopping carts, strollers, etc. or other types of equipment that feature handle bars or cylindrically shaped control handles. Their function comes primarily from the use of elastic polymer frames designed and shaped to snap-on and snap-off cylindrical handles, that are sized like bicycle handlebars. The models 70 and 85 refer to the hardness and therefore the stiffness, elasticity and strength of the materials used with the higher number representing higher performance product. The “pivot” models provide a radial-ulnar range of motion mitigating or eliminating the need for extra compensatory movements of the elbow and shoulders. The “short” models are applicable to individuals, who are younger or with smaller proportions or users that might have a wrist disarticulation, who need to conserve and reduce the length of the overall prosthesis.

Criterium+

This terminal device is primarily designed for grasping and controlling handlebar grips with larger diameters such as used in BMX bicycle racing, however the design accommodates grips for road biking and mountain biking and fits a variety of other types of equipment that use handlebars and or levers for steering control. It snaps on and off (Pushes on and pulls off) grips and never locks-on, for safety reasons. The Criterium+ is built with a solid aircraft aluminum core surrounded by a high strength, polymer body and gripping surfaces. It is energized by two powerful extension springs. The Criterium+ provides a high level of gripping force and control, enhanced by it’s friction adjustable pivoting wrist system. The device operates either right or left and is useable in the water.

Mountain Master

This product has a two-component construction and is designed for controlling handlebars of bicycles and similar two-wheeled recreational vehicles in primarily rough, off-road, terrain and environments. A strong stainless steel and aluminum pedestal with a sphere-shaped, ball top-knob is attached permanently to the handlebars in a normal gripping location. The terminal component is a strong flexible polymer component that fits onto the prosthesis and snaps down onto and pulls off the metal pedestal. This design provides for solid, reliable control over the handlebars, a wide range of motion and still allows the rider to disengage quickly off the handlebars when required. Several other shaped-features on the exterior of the terminal component provide for enhanced function and control over the handlebars or frame for manipulation, carrying the bike, etc. The Mountain Master operates either as a right or left model.

Downhill Racer (DHR)
This activity specific terminal device was initially designed for snow ski racing; slalom, giant slalom and downhill events. It also functions with trekking (hiking poles) and can be used for Nordic type skiing activities. The DHR features a flexible but strong polymer frame that snaps on and off ski poles where the regular grip has been permanently removed. The DHR comes in both left and right versions for safety and function in that the pole always releases laterally away from the body during a pole release. The DHR is designed to hold the pole or trekking pole at a fixed inclined angle to stay clear of the snow or terrain while being used.

Eagle, Eagle Flex, Golf Pro Left, Golf Pro Right
These products were all designed as "activity specific" terminal devices for playing golf, although certain devices have "cross-over" applications for using certain types of long handled garden tools, brooms, etc. They have two to three primary functions and features. They engage onto the grips of golf clubs or similar cylindrical handles and provide the user with the ability to replicate the biomechanical motions-actions and energy capture and return, required for a smooth, controlled and powerful swing. The Eagle, Eagle Flex and Golf Pro Left are all designed to be used on a "leading arm" prosthesis. The Golf Pro Right is designed more specifically for use on a "trailing arm" prosthesis. The Eagle is a one-piece, flexible, synthetic polymer design, The Eagle Flex incorporates aspects of the Eagle but has a replaceable flexible coupling. The Golf Pro Left utilizes a flexible coupling terminating in a special cylindrical connector that fits around the lower golf club shaft then pulls up and lodges firmly onto the grip. This connector can be custom modified to accept and conform to different tapers and sized golf club grips. The Golf Pro Right is almost identical to the "left" model except that it employs a longer and stiffer flexible coupling to more closely mimic the function and biomechanics of a "trailing hand grasp" on the club grip.

Grand Slam, Pinch Hitter, Pinch Hitter HD, Pinch Hitter Flex
These products were all designed as "activity specific" terminal devices for playing baseball, softball and cricket. The Pinch Hitter, Pinch Hitter HD and Pinch Hitter Flex were specifically designed for use on a "leading arm" prosthesis. The Grand Slam was designed specifically for the "trailing arm" prosthesis. All the devices are designed to clasp around standard diameter aluminum baseball bat and similar sized handles. All require a "sound-hand" over grasp to help maintain their connection onto the bat or equivalent equipment and all have the built in capability to replicate the energy storage and flexible biomechanics of the hand, wrist and forearm required for a smooth, controlled and powerful swing. The Pinch Hitter HD is designed to be more robust than the Pinch Hitter for larger, more powerful users. The Pinch Hitter Flex provides for a replaceable flexible coupling instead of a one-piece polymer design body-frame. These devices all operate as either right or left models.

Helix
This product manufactured from strong, flexible, synthetic, polymer rubber comes in both right and left-hand models. Although initially designed for playing hockey and lacrosse the Helix has many "cross-over" applications for tools with handles for gardening, home maintenance, etc. The Helix's unique design provides for quickly engaging and disengaging from handles-shafts and moving up and down repositioning on handles and shafts, yet still grips firmly for solid control. Under load and torque the Helix's "coils" actually constrict tighter around the shaft for improved control. The flexibility and energy storage capacity of the Helix's materials replicate the biomechanics of the hand, wrist and forearm to provide for very natural movement and control.

Lamprey
This product was specifically design for the safe handling and control of long gun type firearms including military "M" type firearms. Originally requested as a product concept, by personnel of Walter Reed Army Hospital, the Lamprey is designed to accurately clasp around the forearm-forends of guns like rifles, carbines and shotguns. A strong but flexible, synthetic polymer rubber "U" shaped cleat snaps up from under the gun's forend to stabilize and control the firearm without interfering with aiming or sighting-scope accessories. The cleat is mounted to a multi-position, lockable, ball and socket mechanism, when precise bench or off-handed shooting is desired. The device is universal right or left. The Lamprey quickly engages or disengages from the firearm and does not mar the gun's surfaces or require any permanent gun modifications. Useful for competitive shooting and recreational hunting activities.

Power Play 85, Power Play 95
These products designed specifically to play hockey are identical except in the materials from which they are made with the 95 model being stronger but less flexible than the 85 model. The Power Play is used only for "end-of-stick" handling and control, "top handed" control. They can be used either right or left. The hockey stick slides into the end of the device to secure it and the flexible body provides for the energy storage and range of motion required to replicate the biomechanics of the hand, wrist and forearm. Additionally the flexible non-rigid, structure provides a "fail-safe" for the anatomical arm inside the prosthesis helping to prevent injury during a collision or fall, with the hockey stick engaged.

Indications/Contraindications

General — Upper Extremity TD End Effectors:

Prosthetic devices are tools designed to provide or replicate certain aspects and functions of the human hand including anatomical realism. All of 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.**

Passive Gripping TDs:

Passive gripping TDs have fairly limited scope and application and are oriented around performing well in very specific activities and applications. They typically provide holding control using mechanical capture mechanisms or synthetic polymers that exhibit good elasticity for clasping around handles and objects with cylindrical features. The devices may or may not provide a level of gripping force that is equivalent to the human hand and they are designed to release during an application of excess force or by specific physical manipulation. An analogy of certain release characteristics might be a modern bicycle pedal release system, where the bicycle footwear in engaged into the pedal until the rider overrides a mechanical linkage, using a particular twisting action of the foot, thereby releasing the shoe from the pedal. These devices provide for good control with a higher margin of safety and risk than other types of TDs that have true locking function or are engaged and disengaged using body powered cable type control. This class and type of device might be a better selection for those individuals with lower levels of functional performance, higher levels of limb absence or more limited cognitive capacity. The devices that are constructed from elastic polymers are subject to deterioration from exposure to severe or caustic chemicals and to long exposure to intense, direct sunlight and heat, outside of normal use.

Storage and Handling

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

Warnings and Precautions

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: Passive Gripping TDs are waterproof to 1 meter; however, if submerged, these 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)

Criterium

	Criterium Pivot	Criterium Pivot Short	Criterium+
Product Number	**CRITERIUM PIVOT 70** **CRITERIUM PIVOT 85**	**PIVOT SHORT 70** **PIVOT SHORT 85**	**CRITERIUM PLUS**
Length	4.0 in. (10.2 cm)	2.9 in. (7.4 cm)	4.1 in. (10.4 cm)
Width	2.5 in. (6.4 cm)	2.4 in. (6.1 cm)	2.3 in. (5.8 cm)
Height	—	—	2.4 in. (6.0 cm)
Weight	7.5 oz. (213 g)	6.0 oz. (170 g)	6.5 oz. (184 g)
Opening	Designed to snap on-off smooth 1.0 in. (2.5 cm) handlebars. Flexible design accommodates larger diameters.		Fits bars up to 1.5 inches (3.8 cm) in diameter
Color	Satin Black	Satin Black	Stealth Black and Silver
Applications	70 Models designed for milder recreational riding. 85 Models are higher performance and are more difficult to engage-disengage from handlebars. Not designed for mountain biking or rough off pavement bicycling.		—
Age	Children through adult	Children and adults with small proportions or longer residual limbs	Youth from 10 years old through adult
Limb Description	Trans-radial & mid/long-length Trans-humeral	Trans-radial & mid/long-length Trans-humeral	Trans-radial and trans-humeral applications

Downhill Racer

	Downhill Racer
Product Number	**SKIRACER LEFT** **SKIRACER RIGHT**
Length	3.3 in. (8.4 cm)
Width	2.5 in. (6.4 cm)
Thickness	1.3 in. (3.3 cm)
Weight	4.0 oz. (114 g)
Opening	Fits ⅝ in. (1.6 cm) diameter Ski Pole
Color	Black (BLK) Blue (BLU) Teal (TL) Violet (V)
Age	Youth through adult
Limb Description	Trans-radial & mid/long-length Trans-humeral

Installation

Passive Gripping 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

The only Passive Gripping TD which can be, but not necessarily operated with a prosthetic control cable is the SKI-2. The “pivoting block” of the SKI-2 has been designed with a receiver for a 9/32” terminal ball or a 3/16” terminal ball. A Binary Swivel, or triple swivel with either a 3/16” or 9/32” terminal ball should be selected with a cable connection that matches the cable used in the prosthesis. Cable routing should assure a direct line of pull that minimizes bends in the cable which could result in excess cable friction or failure.

Compatability

Fillauer TRS Passive Gripping TDs have been tested 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 manufacturers wrist units is not covered under warranty of this device.

Care and Maintenance

Passive Gripping TDs:
These devices require minimal maintenance and care other than keeping them clean and generally inspecting them before using. Polymer rubbers can deteriorate over time so inspection for cracking or "checking" in the material is recommended. Cleaning regularly is recommended. Treat these devices like your hand from a sanitation perspective. If damage is apparent consult with your prosthetic professional for potential replacement of parts or the entire device, as might be needed. These products are highly reliable when treated and cared for properly.

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

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: Passive Gripping TDs are waterproof to 1 meter; however, if submerged, these 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 at the earliest possible convenience. Clinicians should contact their local Fillauer representative immediately in the event of any device failure.

Customer Support

Americas, Oceania, Japan

Fillauer TRS
3090 Sterling Circle, Studio A
Boulder, Colorado 80301
303.444.4720

Europe, Africa, Asia

Fillauer Europe
Kung Hans väg 2
192 68 Sollentuna, Sweden
+46 (0)8 505 332 00

Fillauer®

www.fillauer.com

Fillauer LLC

2710 Amnicola Highway
Chattanooga, TN 37406
423.624.0946

Fillauer Europe

EC REP

Kung Hans väg 2
192 68 Sollentuna, Sweden
+46 (0)8 505 332 00

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