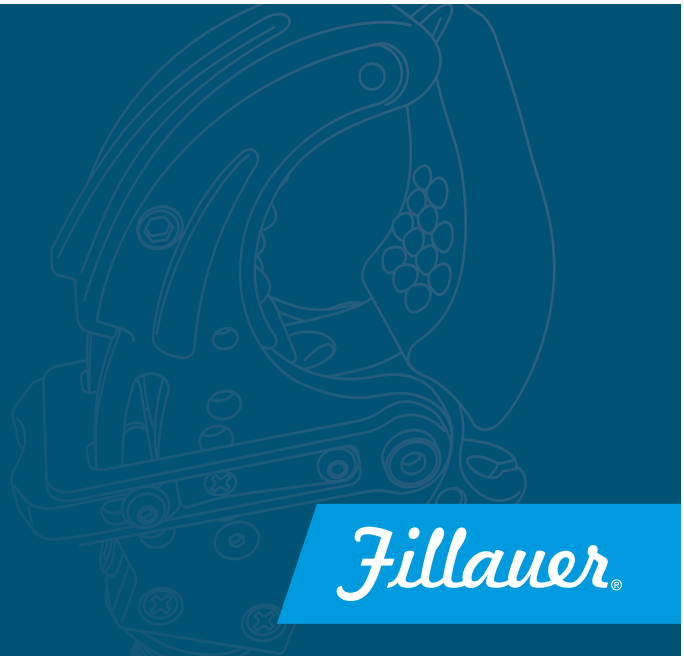
JAWS

Product Manual



Intended Use

JAWS is a heavy-duty, voluntary-opening (VO), body-powered, terminal device, which operates universally as either left- or right-handed. JAWS models are waterproof and are truly a “crossover” type of prosthetic device capable of enhancing control over tools, handles, and equipment, as well as very functional for control of work and recreational vehicles such as fork lifts, tractors, ATVs, snowmobiles, motorbikes and cycles, and jet ski type watercraft. JAWS is a perfect, functional compliment to users of VO split hook technology providing a range of performance and control not possible with that type of technology. JAWS mounts easily to any USA standard prosthetic wrist.

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

	JAWS Medium	JAWS Large / JAWS XFS*
Product Number	**JAWSM**	**JAWS TD / JAWS XFS**
Length	4.8 in. (12.2 cm)	5.0 in. (12.7 cm)
Width	1.6 in. (4.0 cm)	2.1 in. (5.3 cm)
Height	3.7 in. (9.4 cm)	3.9 in. (9.9 cm)
Weight	11.7 oz. (332 g)	15.5 oz. (440 g)
Color	Aluminum and Black	
Age	10-year old youth through adult	Older Teenagers and Adults
Limb Description	Trans-radial and mid-length – long transhumeral	

***JAWS XFS is only intended for users who need extremely strong gripping forces. JAWS XFS should be used with extreme caution, especially in the highest force position, because “releasing the grip” has an extremely high threshold. Additionally, if operating the JAWS XFS with a traditional cable system it may cause premature wear and possible failure of the cable system, due to the extra force required to operate the TD**

Performance Characteristics

JAWS can be operated in three ways: cable operation, manual “pull open” using a built-in “trigger” feature, or push-on/pull-off (snap on/off). For safety, the JAWS line does not have a lock system. JAWS has a manual shift mechanism providing either 3 or 4 gripping force levels. JAWS is equipped with large, compliant-but-tough synthetic rubber gripping surfaces for optimum control over handles and cylindrical objects. JAWS has a manual friction adjustable pivoting wrist system that provides the user with greater range of motion control over objects, reducing elbow and shoulder joint movement and compensation.

Indications/Contraindications

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 control 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.**

Body-powered prosthetic devices using a shoulder harness and cable for operation require a certain level of physical coordination and strength. Additionally, use of such devices requires a sound cognitive basis that provides the user with the understanding of the values of the technology, how it operates, and its limitations and the potential for both performance and self-injury. Body-powered prosthetic devices require practice. More practice will provide better functional outcomes in performance. Certain devices have capabilities beyond that of the human hand regarding their ability to withstand impact, withstand load, and resist environmental elements such as severe heat, fire, freezing cold temperatures and caustic chemicals. Other devices are inferior to the human hand regarding such exposures. The user must understand and take advantage of the aspects of each type of technology they choose to use.

Storage and Handling

It is recommended that JAWS (or prosthetic/orthotic components) is 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 control or external spring/elastic band tension for grasp control, even 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: JAWS is waterproof to 1 meter; however, if JAWS is submerged, it should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris. For JAWS Medium and XFS, the mainspring is coated to prevent corrosion. It should be checked regularly and replaced if there are signs of rust.

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

JAWS may be installed in any Fillauer wrist unit with a ½-20 thread. Follow the instructions provided with the wrist unit for best results.

Cabling

The "thumb" has been designed to be compatible with both a 9⁄32 in. terminal ball and a 3⁄16 in. terminal ball. A **Binary Swivel**, or triple swivel with either a 3⁄16 or 9⁄32 in. 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.

Tension of the JAWS gripping force is adjusted by a manual shift mechanism, providing multiple gripping force levels.

Compatibility

Important clinical notes and features about all body-powered VO and VC terminal devices:

Body-powered terminal devices develop control through the biomechanical manipulation of body forces that are captured through a shoulder harness system and transmitted through a cable to the terminal device. The function, operation, ease-of-use, and optimization of body power in a cable-powered terminal device can be improved by the addition of an "in-line" cable modulation and cable locking system, such as the Fillauer **SURE-LOK** technology. Such technology allows the prosthetic user to grasp objects, then reduce or totally relieve tension on the cable system. This function increases the range of object control motion available to the user and reduces fatigue, while combatting the development of "over-use" syndrome.

JAWS has been tested with and is recommended for use with Fillauer 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

Prosthetic devices should be used and treated as quality tools and regularly inspected for damage, deterioration, and/or excessive wear. The devices are waterproof and/or highly water resistant and constructed of materials that will not rust or corrode or are resistant to such exposure. They can be immersed in water and washed. They should be dried as thoroughly as possible and light lubricants can be applied to moving mechanical linkages as needed. Soap and water cleansing or rinsing are recommended, especially after operation in environments with a lot of dirt, dust, grit, oils, or solvents. If used in salt water, cleaning as soon as possible in fresh water is highly recommended with all devices. Long term exposure in intense direct sunlight or heat outside of normal use will damage prosthetic devices that incorporate synthetic rubber in their construction or coverings.

These devices all employ certain mechanics for their operation. Regular daily cleaning and washing is reasonable and recommended. Treat these devices as if they were your hand from a sanitation perspective. Use a light lubricant, as might be required, on moving parts and linkages. Do not use heavier viscous oils or lubricants. Dry film lubricants with silicone are fine as well. Regularly inspect these types of devices for wear, loose fasteners or fittings, or other aspects of deterioration. If damage or wear is observed, then have a qualified prosthetic technician complete the repair, replace parts, etc. to ensure that the device performs optimally and safely.

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

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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 at the earliest possible convenience. Clinicians should contact their local Fillauer representative immediately in the event of any device failure.

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M107/08-02-22/Rev.1