Espire™ Elbow

Classic Plus, Classic and Basic

User Guide

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WELCOME

Intended Use

The Espire Elbow system is to be purchased, configured and fitted by a qualified prosthetist. These Devices are Class I Medical Devices which meet the general safety and performance requirements in MDR 2017/745 Annex I

The operations contained in this document are intended for the end user.

Intended Use Statement

The Espire Elbow is to be used exclusively for external prosthetic fittings of the upper limbs.

What's Included with Your Device

Espire Elbow System

Welcome to the Espire Elbow system from Steeper Group. The following pages will cover everything you need to know about the elbow operation. If you have any questions, concerns or comments, please contact your prosthetist.

This User Guide covers instructions for 3 types of elbow models:

Espire Classic Plus – Mechanical elbow with manual lock and forearm counterbalance for lift compensation. Body-powered elbow operation. Includes wired connection points at the proximal and distal ends of the elbow for easy connections to input and output devices.

Espire Classic – Mechanical elbow with manual lock and forearm counterbalance for lift compensation. Body-powered only.

Espire Basic – Mechanical elbow with manual lock and forearm spring-assist for lift compensation. Body-powered only.

Features

	Classic Plus	Classic	Basic
Elbow Joint Control	Mechanical	Mechanical	Mechanical
Terminal Device Control	Electronic/ Mechanical	Mechanical	Mechanical
Elbow Lock	Mechanical	Mechanical	Mechanical
Lift Compensation	Counterbalance	Counterbalance	Spring-Assist

Technical Specifications

Specifications	
Weight Limit	25lb/11.3kg
Flexion Angle (preset control)	-5° - 135°

Environmental Use Conditions	
Operating (temperature)	5°C to 40°C (41°F to 104°F)
Storage & Transport (temperature)	-20°C to +60°C (-4°F to 140°F)*
Operating Relative Humidity	15% to 90%

*Note: If storing device above or below operating temperature, allow the device to return to within operating temperature range and leave the device to sit for 15 minutes before using.

IP Rating

IP22	Protected from touch by fingers and objects greater than 12 millimetres. Protected from water spray less than 15° from vertical.

BATTERY

(Classic Plus Only)

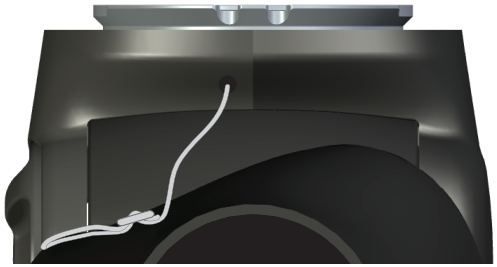
The Espire Classic Plus has a built-in battery compartment which could be used to house a battery. The charging port and switch may be located near this compartment. Your prosthetist can instruct you on how to use it properly.

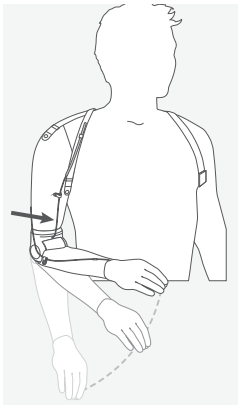
MANUAL LOCK

Manual Lock Overview

The Espire features a mechanical locking mechanism that can be locked or unlocked while under load, with a maximum holding limit of 25lbs/11kg.

The manual lock cable is attached to the upper elbow assembly, near the midline. The lock can be engaged every 10 degrees (13 positions). A strain-relief is included to reduce the likeliness of damage due to excessive pull on the lock cable. The lock cable may or may not be attached to your harness.





Pull on the lock cable to engage/ disengage the lock. Lock response will vary by the amount of force applied.

Standard Lock-Unlock	A strong cable pull (clicking sound) disengages or re-engages the lock.
Temporary Unlock	A light cable pull (no click) unlocks the elbow joint temporarily. Releasing the cable tension re-engages the lock.

Note: When unlocking the elbow, the weight on the elbow may have to be temporarily removed in order for the lock to disengage.

THE COUNTERBALANCE / SPRING-ASSIST

Counterbalance and Spring-assist Overview

Depending on which model you are using, the Espire will include either a counterbalance or spring-assist mechanism:

Espire Model	Lift Compensation Aid
Classic Plus, Classic	Counterbalance
Basic	Spring-assist

Both the counterbalance and spring-assist aid in flexion and extension of the Espire Elbow. Different amounts of tension are necessary based on the elbow's overall length, the weight of the terminal device, and the type of clothing worn.

Adjustment Dial Location

The adjustment dial may be located on either the inside or outside of your elbow. Refer to the arrows on the dial to perform your adjustments. The dial looks identical for both counterbalance and spring-assist; however, these mechanisms adjust in opposite directions (see next page).

ADJUSTMENT DIAL
Example: left arm with inside (medial) adjustment location

Note: Adjustments are easier to make when the forearm is flexed.

Caution: Be aware that if the adjustment dial is at maximum tension and the arm is raised to a horizontal level, the elbow could suddenly flex.

Caution: To prevent injury, users should ensure the elbow is in the maximum flexed position when donning or doffing.

Counterbalance Adjustment

Direction	Adjustment	Result
	Turn the dial posteriorly (backwards) to increase the counterbalance weight. Note: Elbow cannot be over-adjusted in this direction, it will simply reach maximum flexion.	Supports more load on the elbow
	Turn the dial anteriorly (forwards) to decrease the counterbalance weight. Note: Elbow will spring back into flexion according to how much spring lift assist is put into the system if it exceeds the minimum adjustment.	Supports less load on the elbow

Spring-assist Adjustment

Direction	Adjustment	Result
	Turn the dial anteriorly (forwards) to increase the spring-assist weight. Note: Elbow cannot be over-adjusted in this direction, it will simply reach maximum flexion.	Supports more load on the elbow
	Turn the dial posteriorly (backwards) to decrease the spring-assist weight. Note: Elbow will spring back into flexion according to how much spring lift assist is put into the system if it exceeds the minimum adjustment.	Supports less load on the elbow

MAINTENANCE AND TROUBLESHOOTING

Troubleshooting

- Perspiration can diminish the performance of myoelectrodes (Classic Plus only). Remove the prosthesis and wipe down the inside of the socket with a clean, dry cloth, including the electrodes.
- The inside of the socket may be cleaned with mild soap and a damp cloth or isopropyl alcohol. All soapy residue must be removed from the socket.

⚠ Caution: The Espire Elbow should never be serviced while connected to the end-user. Ensure that the device is disconnected and powered off before any service or maintenance is performed. This device should never be serviced while in use. Never let children handle this device unsupervised. Take caution when using this device around pets that may cause damage to the device.

INTENDED USE AND SAFETY

Intended Use Statement

The Espire Elbow is to be used exclusively for external prosthetic fittings of the upper limbs.

Intended Users

The Espire Elbow is intended for use only by the individual being fit with the device. The manufacturer does not approve use by any other person/s. The Espire Elbow system is to be purchased, configured and fitted only by a qualified prosthetist.

Indications for use of the Espire Classic Plus, Classic, or Basic elbow systems include the following:

- Adequate limb length to allow for appropriate socket fit at a level above the elbow. This would include trans-humeral, shoulder disarticulation and fore quarter
- Adequate muscle activity and range of motion of shoulder joint to adequately control a body-powered prosthetic device
- Appropriate sound side limb dexterity or assistive device to position and lock elbow system for use where necessary
- Adequate muscle activity for myoelectric control (Classic Plus only)
- Adequate cognitive ability to master technology and input requirements of device (Classic Plus only)
- The patient is able and willing to participate in training for use of the myoelectric control of the prosthesis (Classic Plus only)
- Access to a qualified prosthetist for fitting and servicing of the elbow system
- Able and willing to charge power source on a daily basis (Classic Plus only)

Contraindications for use of the Espire Classic Plus, Classic, or Basic elbow systems include the following:

- Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear
- Inability to tolerate the weight of the prosthesis
- Inability to produce muscle or body movement necessary for operation of the terminal device(s)
- Significant deformity of remaining limb that would impair the ability to operate body-powered devices
- Specific environmental factors—such as excessive moisture or dust, or inability to clean or maintain the prosthesis

Legend of Symbols

Note: Possible technical damage.

Info: Basic information regarding this product.

Caution: Possible risk of accident or injury.

Warning: Possible risk of severe accident or injury.

Caution: Failure to follow the safety instructions below can lead to damage or malfunction of the product. Follow the safety instructions and stated precautions in this document.

Safety Instructions

Please ensure you are fully aware of all the safety instructions before leaving the clinic.

Info: Disposal

These products may not be disposed of with household waste in some jurisdictions. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the information provided by the responsible authorities in your country regarding return and collection processes.

Caution: Manipulation of system components

Independent changes and/or modifications to system components may lead to faulty control or malfunction of the Espire Elbow, resulting in a risk of injury. No modifications on your Espire Elbow except those described in this information document are authorised. The Espire Elbow and damaged components may only be opened or repaired by certified Steeper Group technicians.

Caution: Penetration of dirt and humidity

The penetration of dirt and humidity may lead to faulty control or malfunction of the Espire Elbow and result in a risk of injury. Ensure that neither solid particles nor liquids can penetrate the Espire Elbow.

Caution: Mechanical overloading

External mechanical influences or loads, such as impacts and vibration, can lead to faulty control or malfunction of the Espire Elbow and result in a risk of injury. The Espire Elbow should not be subjected to mechanical vibrations or impacts.

Caution: Thermal overloading

Extreme temperature conditions can lead to faulty control or malfunction of the Espire Elbow and result in a risk of injury. Avoid areas outside the specified operating temperature range. The operating temperature range must be between 5°C and 40°C (41.0°F and 104.0°F).

Caution: Improper use

Any type of excessive strain, overload or improper use may lead to faulty control or malfunction of the Espire Elbow, resulting in a risk of injury. The Espire Elbow was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports with excessive strain and/or shocks to the wrist joint (pushups, downhill mountain biking, etc.) or extreme sports (free climbing, paragliding, etc.). Do not use when swimming or in wet environments. Careful handling of the prosthesis and its components not only increases their service life but, above all, ensures your personal safety. Should the prosthesis be subjected to unusual stresses (such as a fall), immediately contact a qualified prosthetist and have the prosthesis inspected for any damage.

Caution: holding objects

Do not exceed the maximum holding limit of 11kgs/25lbs.

Caution: Consequences of product deterioration

Wear and tear on system components can lead to malfunction of the Espire Elbow, resulting in a risk of injury. Follow the specified service intervals. The service life of this device is 5 years for device and parts and accessories.

For warranty details please see document STPPR180 Limited Warranty/Elbows.

Caution: Water and humidity

The electrical and mechanical systems of your Espire Elbow are **not** water-resistant. You must prevent water from entering the Espire Elbow. Be careful not to let water run over the top of the prosthetic glove and enter the Espire Elbow as well as the terminal device. If water enters the inside of the prosthesis for any reason, immediately switch off all components and stop using or charging them. A qualified prosthetist must be contacted immediately to assess the device and avoid further damage.

Caution: Risk of accident while operating a vehicle

An upper extremity amputee's ability to drive a vehicle is determined on a case-by-case basis. Factors include the type of fitting (amputation level, unilateral or bilateral, residual limb conditions, design of the prosthesis) and the amputee's abilities. All persons are required to observe their country's national and state driving laws when operating vehicles. For insurance purposes, drivers should have their driving ability examined and approved by an authorised test centre. For maximum safety and convenience, Steeper Group recommends that, at the very least, a specialist evaluate the need for any adaptations to the vehicle. It is indispensable to ensure that the driver can operate the vehicle without any risk with the Espire Elbow turned off. Please check with your doctor or prosthetist before attempting to operate a motor vehicle with this device, otherwise the Espire Elbow is not approved for use whiling driving.

Caution: Risk of pinching where the elbow joint bends

Ensure that fingers and other body parts are not in this area when bending the elbow joint.

Warning: Using with Other Equipment

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. If such use is necessary, any equipment needs to be agreed appropriate with their Prosthetist and/or Steeper.

Warning: Use Only Specified Equipment

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Adverse Incident.

If a serious incident occurs relating to the device, full details must be reported to the Manufacturer and the competent authority of the Member State in which the user and/or patient is established.

QUALITY ASSURANCE

Quality Statement

Steeper/SteeperUSA operate a quality management system that fully complies with the requirements of ISO 13485:2016. This certifies that Steeper/SteeperUSA meet the appropriate international quality standards for the design, manufacture and supply of prosthetic products.

Steeper is registered with both the Medicines and Healthcare Regulatory Authority in the UK, and the Food and Drugs Administration of the United States Government for the manufacture and supply of prosthetic and orthotic products.

MHRA Registration N°: 0000006617
FDA Registration N°: 9612243
Model N°: RP652

This device complies with the requirements of the Medical Device Regulations MDR 2017/745.

The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. The company, therefore, reserves the right to introduce changes and withdraw products without notice.

This device is CE marked to confirm the device is compliant with EU Legislation and meets the EU safety, health or environmental requirements. The CE mark may be applied on packaging, accompanying literature or an enclosure, rather than the product itself.

This device is UKCA marked to confirm the device is compliant with the legislation of Great Britain and meets the health, safety or environmental requirements. The UKCA mark may be applied on packaging, accompanying literature or an enclosure, rather than the product itself.

Complies with Standards

No.		Version
ISO 22523	External limb prostheses and external orthoses – Requirements and test methods	2006

Definitions of symbols used in this device and its packaging

Symbol	Definition	Source
	Consult instructions for use.	BS EN ISO 15223-1: 2012 Reference no. 5.4.3
	Keep dry.	BS EN ISO 15223-1: 2012 Reference no. 5.3.4
	This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.	IS EN 50419:2006 Reference no. Fig. 1
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	USA Code of Federal Regulations 21 CFR Part 801 § 801.109(b)(1)
	Refer to instruction manual/booklet.	IEC TR 60878 Ed. 3.0 b:2015
	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II)
	Temperature limit.	ISO 15223-1 Reference no. 5.3.7
	Storage humidity range.	ISO 15223-1 Reference no. 5.3.8
IP22	Protection against solid foreign objects of 12.5 mm diameter and greater, and protection against vertically falling water drops when tilted up to 15 degrees.	IEC 60601-1, Table D.3, Symbol 2
	Medical device manufacturer.	ISO 15223-1, Clause 5.1.1
	China RoHS Mark I logo. Product does not contain toxic and hazardous substances or elements above the clip level in any material or application including those exempt from the requirements of the EU RoHS Directive.	SJ/T11364-2006
	Subject to recycling under the Waste Disposal Act.	Environmental Protection Administration, R.O.C.(Taiwan)
	Note: Possible technical damage.	
	Info: Basic information regarding this product.	
	Caution: Possible risk of accident or injury.	
	Warning: Possible risk of severe accident or injury.	
MD	Indicates that this item is a medical device	

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MADE IN THE UK

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