Espire™ Elbow

Classic Plus and Classic

Technical Manual

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SECTION 1 - SYSTEM OVERVIEW

The Espire Elbow system is to only be purchased, configured and fitted by a qualified prosthetist. This device is intended for use in accordance with the information contained in this document. Instruct the patient on proper use of this device before transferring the device to the patient.

These Devices are Class I Medical Devices which meet the general safety and performance requirements in MDR 2017/745 Annex I

Intended Use Statement

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

1.1 Introduction

In the following document, you will find information on everything from fabrication to maintenance and care of the Espire Elbow system. Read these instructions carefully and educate the end-user on all functions of this product before final delivery.

Thank you for purchasing the Espire Elbow system from Steeper Group. If you have any questions, concerns or comments, please contact our Customer Service team at +44 (0) 870 240 4133 (UK & ROW), (+1) 210 481 4126 (US).

Product Description

Espire Classic Plus – Mechanical elbow with manual lock and forearm counterbalance for lift compensation. Body-powered elbow operation. Includes provisions for myoelectric control of terminal devices.

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

Features

	Classic Plus	Classic
Elbow Joint Control	Mechanical	Mechanical
Terminal Device Control	Electronic/ Mechanical	Mechanical
Elbow Lock	Mechanical	Mechanical
Lift Compensation	Counter-balance	Counter-balance

1.2 Anatomy

1.3 Pre-Installation Checklist

What's in the box:

Hardware

- Espire Elbow
- Lamination Collar and Clamp Ring
- Lamination Dummy
- Forearm Cable Lift Kit (optional extra)

Instruction Manuals

- Espire Elbow Technical Manual – Classic Plus and Classic,
- Espire Elbow User Manual – Classic Plus and Classic
- Espire Elbow Fabrication Instructions
- Note: All manuals are available at steepergroup.com

1.4 Technical Specifications

Specifications

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

Connections (Classic Plus only)

Inputs	4
Outputs	4

IP Rating

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

SECTION 2 - INPUTS (CLASSIC PLUS)

2.1 Input Overview

The Espire Elbow is compatible with many types of inputs, offering versatile control strategies.

Example List of Supported Inputs:

- A/C Remote Electrodes*
- D/C Cased Electrodes
- Linear Transducers
- Touch Pads
- Switches (Single-State, Dual-State, Bump, etc)
- Other Items Not Listed (Contact Steeper Group)

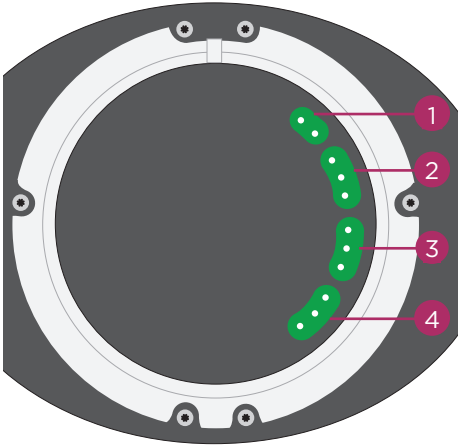
**Not compatible with Steeper A/C Electrodes with TruSignal™*

Note: For an input to be compatible, the shape of the plug connector must match the receptacle on the input board.

2.2 Input Connector Board

There are 4 plug receptacles on the input board. The table below lists the location, the type of input that can be used, and its setup type.

Input Connector Board - Top View



Board Location	Input Option
1	Battery
2	Electrode-Close
3	Electrode-Open
4	Switch

2.3 Connecting Cables to the Input Board

1. Apply silicone grease to the plug connectors before inserting into the board.
2. When attaching cables, note the proper orientation. The connectors are “keyed” or asymmetrical to assure proper alignment. The connector should plug in easily and is held in place with friction.
3. Once the cables are attached, apply more silicone grease on top of the connectors to prevent moisture from entering receptacles.
4. When removing cables, pull close to the connector to avoid pulling on the wires. Wires that become loose could cause intermittent operation.

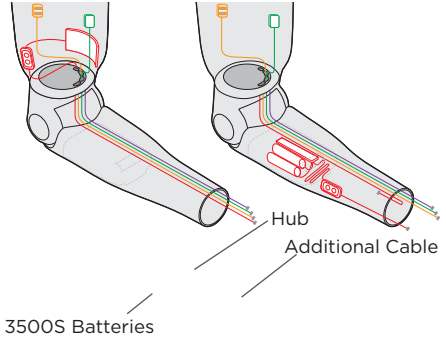
SECTION 3 - BATTERY INSTALLATION (CLASSIC PLUS)

3.1 Battery Installation

Internal Batteries from Steeper

Steeper 3500S batteries can be used to power the hand and wrist. For ordering information, please view the Steeper Upper Limb Catalogue or visit www.steepergroup.com. Batteries may be installed above or below the elbow and must be in conformance with all applicable safety and operational specifications.

Note: Steeper 3500S batteries must be placed within the elbow compartment as shown on the diagram below,



Above Elbow Battery Location

Batteries that are mounted above the elbow can be connected to the top of the input board using the input board of the Classic plus and input wire supplied by the battery manufacturer (see section 2). A pre-installed pathway routes battery power from above the elbow to the distal end of the forearm (see section 4.2).

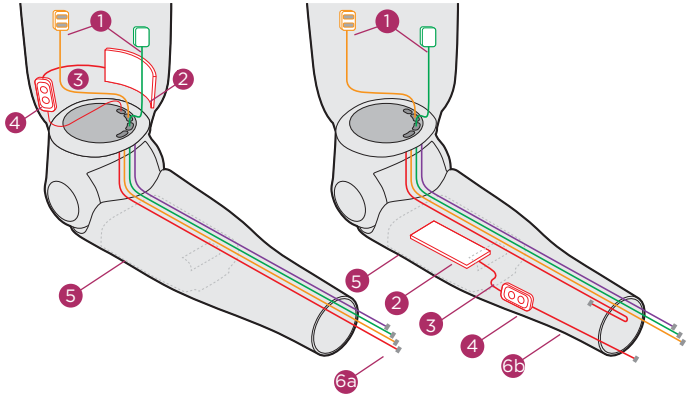
Below Elbow Battery Location

The Espire Classic Plus provides a compartment on the bottom side of the elbow for housing the 3500S batteries and, if needed, other manufacturers' batteries. Other manufacturers' batteries can be installed in this compartment, providing the battery dimensions fit without modifying the arm.

1. Route the battery wire through the hole inside of the compartment into the forearm.
2. Substitute the pre-installed power output wire for one supplied by the battery manufacturer, then route the wire through the forearm.

Example Configurations

Above Elbow Location **Below Elbow Location**

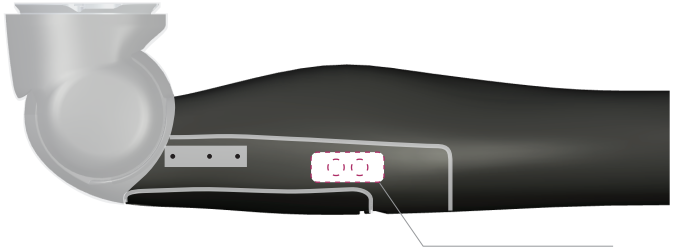


	Component
1	Electrodes
2	Battery
3	Battery Wire
4	Charging Port/Power Button
5	Battery Compartment
6a	Power Output Wire (pre-installed)
6b	Power Output Wire

3.2 Charging Port/Power Button

For below elbow locations, a charging port/power button can be mounted anywhere on the forearm. To prevent damage, avoid the grey shaded areas and seam lines when drilling holes. Attach the unit according to the manufacturer's recommendations.

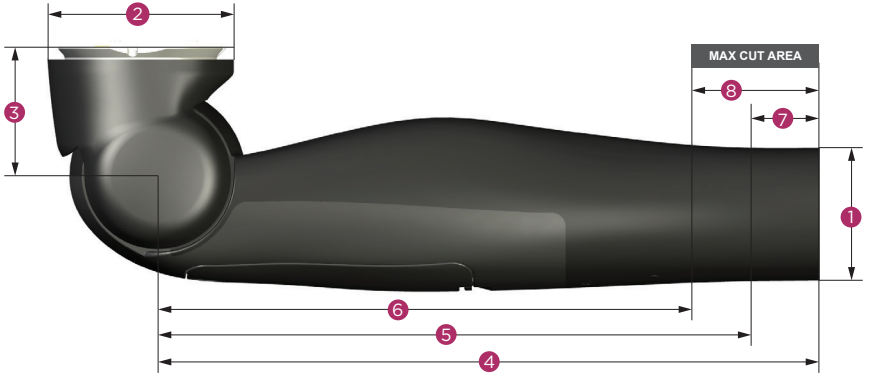
NOTE: Do not drill in grey shaded areas or on grey seam lines



SECTION 4 - MEASURING AND CUTTING FOREARM

4.1 Measuring the Forearm

The Espire Elbow is available in two forearm lengths, Small (45mmØ wrist) and Standard (50mmØ wrist). Forearm measurement can be referenced from the centre of the elbow. A removable sticker is applied to the forearm to reference the maximum cut area.



	Dimension	Measured From	Small	Standard
1	Diameter - Wrist	---	45 mm	50 mm
2	Diameter - Upper Arm Connection	---	70 mm/2.74 in	70 mm/2.74 in
3	Minimum Build Height	Residual Limb to Elbow Centre	48 mm/1.89 in	48 mm/1.89 in
4	Overall Length	Elbow Centre	248 mm/9.75 in	273 mm/10.73 in
5	Minimum Length – w/rotator	Elbow Centre	222 mm/8.75 in	225 mm/8.86 in
6	Minimum Length – w/out rotator	Elbow Centre	200 mm/7.88 in	225 mm/8.86 in
7	Maximum Cut Area – w/rotator	Distal End	25 mm/1.00 in	48 mm/1.875 in
8	Maximum Cut Area – w/out rotator	Distal End	48 mm/1.875 in	48 mm/1.875 in

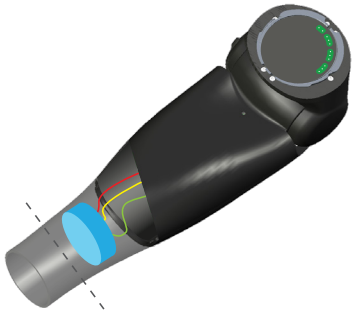
4.2 Protective Foam Insert (Classic Plus)

A foam insert is installed prior to shipping to protect the output wires and to prevent dust or debris from entering the elbow.

Note: Foam insert must be in place prior to cutting the forearm and completing wrist fabrication. Failure to use the insert will damage the Espire Elbow.

4.3 Cutting the Forearm to Length

1. Measure the desired length of the forearm.
2. Cut the forearm, preferably with a bandsaw.
3. Continue with wrist fabrication.



Note: It is important to avoid subjecting the system to excessive vibration such as that caused by a carbide-tip saw blade or a sanding belt/disk.

SECTION 5 - WRIST FABRICATION

5.1 Wrist Options Overview

The Espire Elbow accommodates two wrist sizes. Wrist options are available from multiple manufacturers and the compatible option depends on the Espire model. Refer to the manufacturer's instructions for fabrication and assembly information.

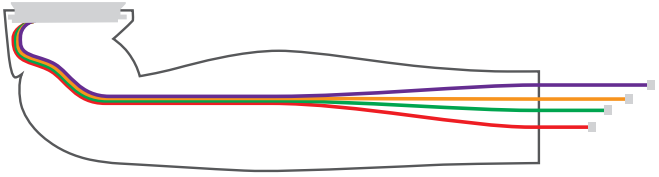
	Small Elbow	Standard Elbow
Wrist Size	45 mm	50 mm

Espire Model	Wrist Option
Classic	Mechanical Wrist, Friction Wrist, Heavy Duty Wrist, Short Wrist, Child's 2-knob Wrist (Small Elbow only)
Classic Plus	Quick Disconnect Wrist, Electronic Wrist Rotator, Friction Wrist, Short Wrist

5.2 Output Wires for Terminal Devices (Classic Plus)

Output wires will already be installed into the circuit board of the Espire Elbow Classic Plus. They can easily be retrieved from inside of the forearm and connected to the desired device. The wires will be colour coded and simply need to be plugged into the appropriate terminal device. Wires that are not needed can be tucked away into the forearm.

Colour	Output Type
● (Red)	Power
● (Orange)	Hand-Open
● (Green)	Hand-Close
● (Purple)	Switch



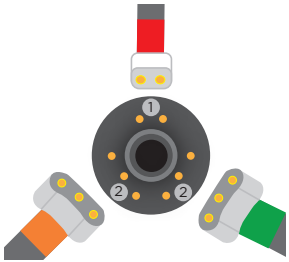
Note: If mounting the battery in the forearm please refer to section 3 for further details.

5.3 Quick Disconnect Wrists (Classic Plus)

Wiring

The hand-open, hand-close, and power output cables will plug into a single coaxial unit which fits through the centre of the quick disconnect wrist.

1. Plug the orange (hand-open) cable into the left plug labeled “2”, then plug the green (hand-close) cable into the right plug labeled “2”.
2. Plug the red (power) output cable into the plug labeled “1”.



Note: If the two 3-socket connectors (hand-open/ hand-close) are attached to the wrong plugs labeled “2”, the open-close functions will operate in reverse.

Note: If fitting with a short wrist or friction housing but still want batteries above elbow, the cable option uses different connector. Therefore, if using power with the Classic version it would require external wiring if power proximal to the elbow joint was needed. If integrated power is desired, the Classic Plus would be advisable.

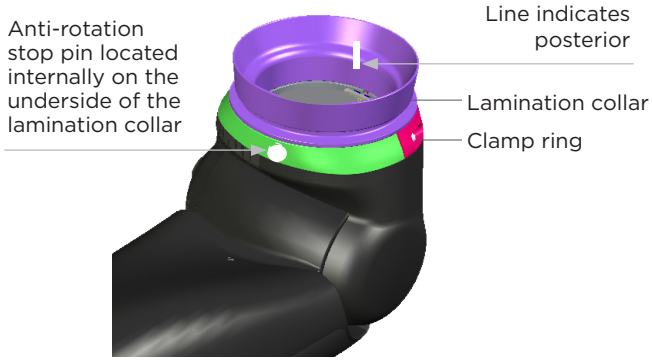
5.4 Electronic Wrist Rotators (Classic Plus)

Electronic wrist rotators require a battery that supplies an additional plug for the wrist power (See section 3.1). To connect a wrist rotator, install the battery in the forearm and use that unique system. The wire should be attached to the battery, run though the distal end of the forearm, and connected to the wrist. Contact the wrist manufacturer for more information.

SECTION 6 - THE LAMINATION COLLAR AND CLAMP RING

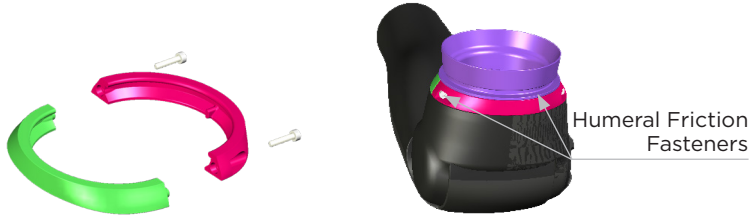
6.1 Orientation of the Lamination Collar and Clamp Ring

The lamination collar must be oriented properly relative to the patient socket to allow for correct internal / external humeral rotation and to protect the wiring of the Espire Elbow.



Colours for representation only.

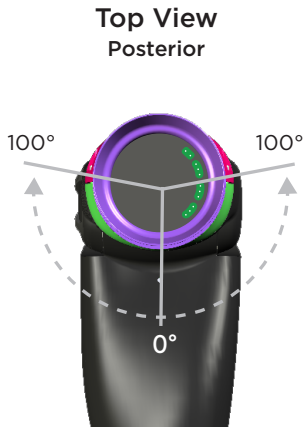
The clamp ring is a two-piece assembly that is uniquely shaped to fit the profile of the Espire Elbow. When assembled to the elbow, the clamp screws will face posterior.



6.2 Internal-External Rotation

The Espire is designed with a humeral anti-rotation stop pin to prevent 360-degree rotation. This feature is to prevent input wires from being twisted and potentially damaged. The anti-rotation stop pin allows for 100° external / 100° internal rotation for a total range of 200°.

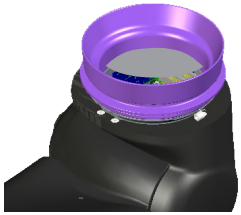
Info: Normal human range of motion is 30° externally and 135° internally.



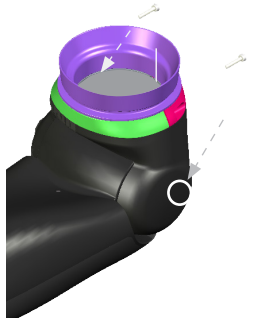
4. With the laminating collar in place, insert Clamp Ring A (green) around both the anterior end of the lamination collar and elbow attachment.
5. Then insert Clamp Ring B (pink) around both the posterior end of the lamination collar and elbow attachment.

6.3 Attaching the Lamination Collar to the Elbow

1. Disassemble the clamp ring by removing the fasteners.
2. Place the lamination collar (or socket with attached collar) near top of the elbow.
3. Plug appropriate cables into the input board (if applicable, see section 2.3).



6. Insert the fasteners and torque, (hand tighten to start and then tighten until appropriate friction is achieved for humeral rotation). Apply equal torque to both fasteners.



6.4 Determining Proper Orientation on Test Socket

The lamination collar attachment to the socket must provide a clinically acceptable measurement from centre axis of shoulder to centre axis of elbow. The appropriate elbow carry angle must also be established, preferably for full extension.

1. Test the collar orientation by placing it under the user's test socket with the orientation line facing posterior. It may be necessary to extend the collar away from the socket to establish the correct elbow position. Mark where the collar contacts the socket or extension material.
2. Remove the clamp ring from the lamination collar and elbow.
3. Temporarily attach the collar to test socket using fibreglass tape, epoxy or other adhesive. Clean any residue from the collar surface at the elbow attachment point.
4. Re-attach the elbow to the lamination collar and test socket. Rotate the forearm clockwise and anti-clockwise and verify the stop positions at 100° from centre (see section 6.2). Rotate the collar accordingly to adjust the amount of internal or external rotation.
5. Temporarily fit the arm to the user, verify that the position, carry angle, and elbow centre are appropriate. Record the data.
6. Create a new mould for the definitive socket. Transfer the measurements and position from the test socket.
7. Fabricate the definitive socket with sensors and applicable prosthetic materials.

Info: For more information on lamination, see Espire Elbow Fabrication Instructions.

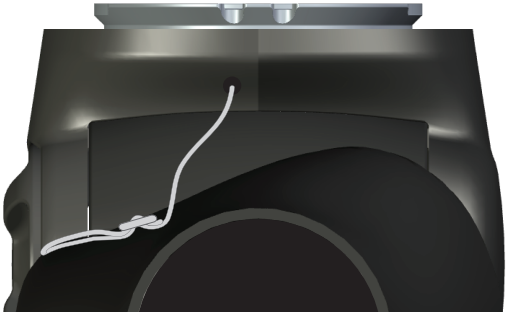
6.5 Final Adjustment with the User

The humeral rotation is adjusted with a 2.5mm hex key that is supplied with the clamp ring. While the user is wearing the prosthesis, adjust the friction until it is most comfortable. This friction can be adjusted as needed.

Note: Over tightening this screw may damage the screw threads. Use small, controlled adjustments until the desired amount of friction is reached.

SECTION 7 - MANUAL LOCK

7.1 Manual Lock Overview



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

The manual lock cable is attached to the upper elbow assembly, near the midline. The lock can be engaged/disengaged every 10° (13 positions). A strain-relief is included to reduce the likeliness of damage due to excessive pull on the lock cable.

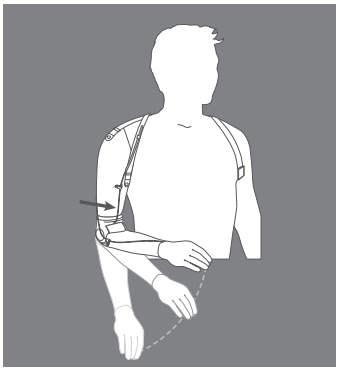
The lock cable can be used with or without the Steeper Harness System. Attach the cable to a harness using your preferred mounting method. The cable may be shortened, but do not remove it completely.

For further details on the Steeper Harness System please view the Steeper Upper Limb Catalogue.

⚠ Caution: Complete removal of the manual lock cable can lead to malfunction and injury to the user.

Note: The manual lock is not removable or field-serviceable. Do not attempt to disassemble or modify the unit.

7.2 Operating Manual Lock



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

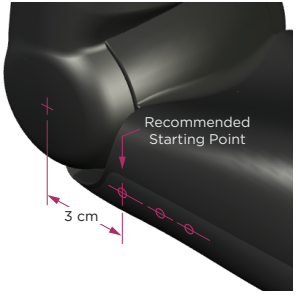
Standard Lock-Unlock	A strong cable pull (clicking sound) disengages or re-engages the lock.
Temporary Unlock	A light cable pull (no click) unlocks the elbow joint temporarily. Relieving the cable tension re-engages the lock.

SECTION 8 - CABLE MOUNTING

8.1 Cable Mounting Overview

Your preferred cable system can be mounted to the forearm to provide elbow flexion and/or prehensile control.

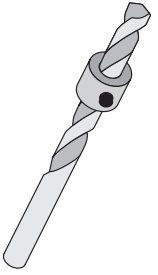
A cable mounting bracket is located internally, (both medially and laterally). Three indentations on the surface of the forearm indicate where a hole may be drilled to attach the cable loop. The recommended starting point is the first hole (closest to elbow centre). The closer to the joint the bracket is located the more force is required to flex the elbow.



8.2 Setting Up the Cable Mounting

Drill Mounting Hole

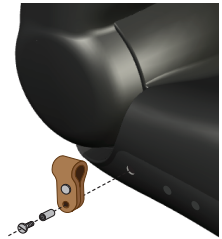
A (17/64in or 6.75mm) drill bit and collar are provided to control the depth of the hole that is drilled. Carefully drill the mounting hole. Do not drill beyond the forearm shell surface or contact the internal mounting bracket.



Attach Cable Loop

(or preferred cable anchor)

1. Fold the leather cable loop and fasten together with the rivet.
2. Align the cable loop to the hole. Attach with a 10-32 fastener and hand tighten.
3. Attach your preferred cable system to the prosthesis.



SECTION 9 - SETTING UP THE COUNTERBALANCE

9.1 Counterbalance Overview

The Classic Plus and Classic models feature a counterbalance mechanism to aid flexion and extension.

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.

Note: The counterbalance mechanism is not removable or field-serviceable. Do not attempt to disassemble or modify the unit.

Adjustment Dial Location

The adjustment dial can be installed on either the medial or lateral side of the elbow and should be specified at the time of ordering. Medial placement is the typical location.

The dial is identical for both models. However, these mechanisms adjust in opposite directions (see sections 9.2 and 9.3).

Adjustment Dial

Example: left arm with 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.

9.2 Counterbalance Adjustment

Direction	Adjustment	Result
	Turn the dial **posteriorly** 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** to decrease the counterbalance weight.	Supports less load on the elbow

Note: The direction of adjustment would be opposite if on the lateral aspect of the elbow. There is a sticker that indicates + or – on the dial to indicate more or less assist to lift.

SECTION 10 - MAINTENANCE AND TROUBLESHOOTING

10.1 Troubleshooting

For troubleshooting connection issues on the Classic Plus, contact your local distributor or Product Manager for support.

⚠ 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.

10.2 Maintenance

The Espire Elbow cannot be maintained in the field, and must be returned for repair/service. For support on maintenance please contact your local distributor or Product Manager.

SECTION 11 - INTENDED USE AND SAFETY

11.1 Intended Use

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

11.2 Indications and Contraindications

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

- Adequate limb length to allow for appropriate socket fit at a level above the elbow. This would include elbow disarticulation, transhumeral, shoulder disarticulation and forequarter
- 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
- 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 or Classic, 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

11.3 Safety

Please ensure that the user is fully aware of all the safety instructions before they leave the clinic,

	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 that follow can lead to damage or malfunction of the product. Follow the safety instructions and stated precautions in this document.
	If serious incident occurs relating to the device, full details should be reported to the Manufacturer and the competent state of authority of the Member State in which the user and/or patient is established.

Safety Instructions

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 of the 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 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 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°F and 104°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.). Not for 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: Consequences of product deterioration

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

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

Caution: Water and Humidity

The electrical and mechanical systems of your Espire Elbow are not water-resistant. Water must be prevented 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 recommends that, at the very least, a specialist evaluate the need for any adaptations to the car. It is indispensable to ensure that the driver can operate the vehicle without any risk with the Espire Elbow turned off. A doctor or prosthetist should be consulted before operating 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.

Caution: Unsupervised Use

It is not recommended for children to operate this device without the supervision of an adult. Use extreme caution around small children and household pets.

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, 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.

Complies with Standards

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

SECTION 12 - QUALITY ASSURANCE

12.1 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.

12.2 Definitions of symbols used in and on this device and 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
℞ Only	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
	Temperature limit.	ISO 15223-1 Reference no. 5.3.7

Symbol	Definition	Source
CE	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)
UK CA	Certification mark that indicates conformity with the applicable requirements for products sold within Great Britain (England, Wales, Scotland)	https://www.gov.uk/guidance/using-the-uk-ca-marking
	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.	

Definitions of symbols used in and on this device and packaging: continued.

Symbol	Definition	Source
	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	

Additional Notes

Additional Notes

steeper
Creating life's turning points, together

Part of the eqwal. family

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