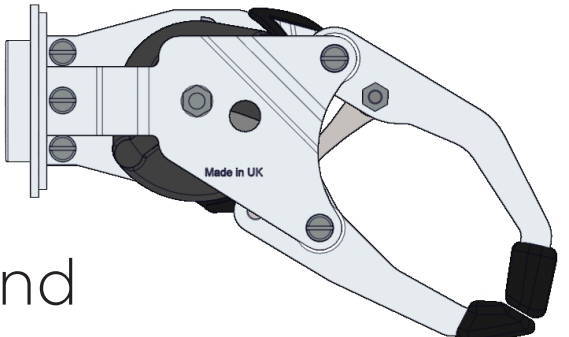


# Mechanical Hand

## Technical Information

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# Introduction

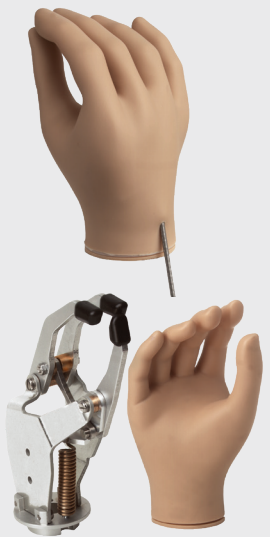
Mechanical Hands are prosthetic devices that connect to the wrist of a forearm and custom socket and provide varying degrees of functionality to cover full hand loss.

The hand chassis and fingers are fabricated from high-grade aluminium alloy. The finger and thumb assemblies are mounted on bronze bushes and attached via a linkage.
The thumb is driven by a second link attached to a spring mounted pulley. This pulley is activated via a pull cable and will positively lock in the fully closed position. The third and fourth fingers are contained within the inner glove.

# Features

Spring and Cable-operated hands provide functional benefits with improved cosmetic appearance. The adult and teenager range is manufactured from high strength aerospace alloy, housed inside a flexible PVC shell and operated by a body-powered cable or manual operation.

- Front pull or back pull voluntary opening
- Plain base or threaded stud
- Full range of hand connection plate options available
- Compatible with the Elegance range of full length silicone and PVC gloves
- Provision made for multiple wrists and cable connection options



**Mechanical Hand:** Important Information

- This device must only be prescribed and fitted by a qualified prosthetist in a suitable clinical environment.
- This device is a Class I Medical Device which meets the general safety and performance requirements in MDR 2017/745 Annex I.
- If a serious incident occurs relating to the device, full details should be reported to the Manufacturer, and the component authority of the Member State in which the user and/or patient is established.

## Hand Plate Fitting Instructions

- Fasten the desired Handplate / wrist attachment (ordered separately) to the hand using the M3.5 screws provided.
- Lock the Handplate into the wrist unit on the prosthesis.

**Note:** If a complete prosthesis is being manufactured for use with this type of hand, it is important to position any external wrist controls so that they do not foul the operating cable when the hand is positioned in its desired range of wrist rotation.

# Setting the operating cord length

With the patient standing and the prosthesis held vertically downward against the side of the body, the operating termination will usually lie against the prosthesis at a point slightly above the wrist unit.

- First select the method of cable attachment, either a loop in the cable locked by a ferrule (UK) or a ball termination crimped onto the cable (USA & Europe).
- With the cable attached to the hand and the position of the prosthesis as previously described, the cable is not quite in tension.
- Slide the protective sheath over the pull cord.
- Crimp the cable into position using the appropriate tool.
- Ask the patient to operate the hand a few times to test the operation of the device.
- When the hand is not normally to be detached from the prosthesis, the cable may be left long so that it can run under the cosmetic glove and terminate with the operating system high on the forearm.
- If the hand is frequently interchanged with functional devices, then a small round hole should be punched into the cosmetic glove at the cable exit from the hand and the cable terminated as previously described.



# Fitting the Elegance Cosmetic glove

The Steeper mechanical hands have been designed exclusively to complement the class-leading Steeper Elegance range of cosmetic gloves. These are available in PVC or silicone with the option of a 'Standard' or 'TrueFinish™'. Use of these cosmetic gloves will guarantee optimal performance of the mechanical hand.

**Note:** Poor fitment of the inner and/or cosmetic glove will result in reduced performance. It is essential that the gloves and cable are situated such that they do not introduce any additional friction within the hand unit.

1. Lightly lubricate the inner glove.
2. Mount the hand vertically in a suitable jig.
3. PVC only - warm the glove for about three minutes, using either a domestic hair dryer, a hot air gun or an oven set on minimum. Take care to avoid localised overheating.
4. With the hand in the closed position pull the glove over the hand manipulating it carefully to avoid excessive stretching.

5. When the tips of the fingers have entered the palm of the glove, the hand should be partially opened. This will allow the glove to be pushed down over the fingers and thumb.
6. The cosmetic glove should fit closely over all fingers and the thumb. It should cover the hand and when fitted to the prosthesis, extend up the forearm without wrinkles, folds or bridging.
7. PVC only - areas of stretch formed during the fitting process can be removed by careful application of local heating. **DO NOT USE A NAKED FLAME.**
8. The glove can now be trimmed to the desired length. Take care not to damage the operating cable.

**Note:** If an exit hole is required for the operating cable, it is important that this is punched cleanly using a sharp hole punch. A ragged hole made by poor piercing or cutting will lead to premature failure.

# Maintenance Instructions

The hand design has been developed to minimise the requirement for any maintenance. However, to maintain performance it may become necessary to lubricate the internal mechanism. This procedure should be performed by a suitably qualified or experienced technician.

**If in doubt, do not attempt to disassemble the unit.**

1. Carefully remove the cosmetic and inner gloves.
2. Remove the retaining nut that secures the pulley axle.
3. Remove the 3 screws that secure the inner chassis plate.
4. Remove the inner chassis plate (the plate that bears the Steeper logo).

**Warning:** The spring/pulley assembly will be under tension - to avoid potential injury take care when dismantling the internal mechanism.

5. Remove the two ‘star-lock’ retaining the link to the pulley.

6. Slide the finger/thumb assembly off the bearing spindles. Before removing the pulley, note the orientation of the wound spring and pulley in the free position.
7. Slide the pulley assembly off the axle.
8. Lightly lubricate/grease the wound spring.
9. Ensure that a thread-lock compound is applied to all threaded fasteners before
10. re-assembling the unit. **The Maximum permissible fastener torque is 3.0 N-m (2.2 lbf-ft).**
11. If the hand performs satisfactorily then the inner glove should be fitted.

The suggested method is to sparingly apply petroleum jelly to the inside of the inner glove. Ensure that the pull cord does not detach from the sprung pulley.



# Adjustment of the Spring Closure Force

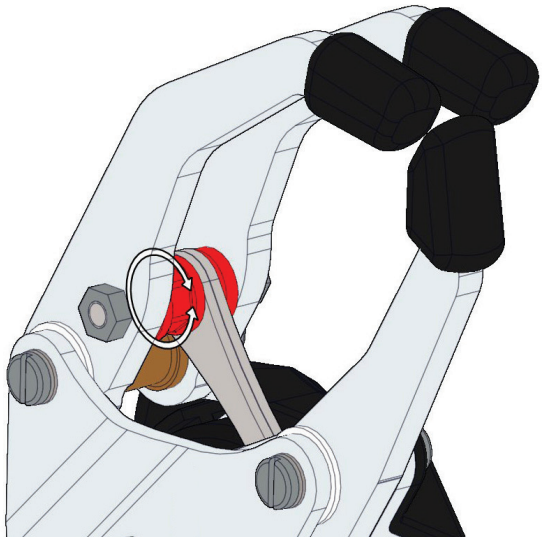
The spring closure force has been factory-set to a pre-determined level deemed suitable to match the requirements of most users. However, in some circumstances it may be necessary to alter the spring closure force.

**Note:** Any change in the spring closure force will result in an equal change to the operating force required upon the pull cord e.g., increased closure force will require increased force (pull) on the cord.

**To adjust the spring closure force:**

- Disassemble the unit as described in the previous section.
- Place the pulley assembly on a bench or suitable work surface with the wound spring upward (facing you).
- Note the orientation of the wound spring in relation to the plastic pulley and carefully slide the spring off the square section bronze bush.
- Dependent upon the desired adjustment, rotate the spring by 90° clockwise or anticlockwise in relation to the pulley and refit it onto the square bush/pulley assembly.
- The unit may now be re-assembled. Ensure that a threadlock compound is applied to all threaded fasteners. **The Maximum permissible fastener torque is 3.0 N-m (2.2 lbf-ft).**

# Adjustment of Finger Spacing



To allow for varying thicknesses of inner and cosmetic gloves, it is possible to adjust the spacing between the fingertips.

Loosen the 6mm Hex Nuts on either side of the fingers and use an 8mm Spanner to rotate the finger spacer until the fingertips are at a suitable distance to allow space for the inner and cosmetic glove.

Tighten the 6mm Hex Nuts, ensuring the finger spacer does not further rotate while doing so.

# Disposal

For safe disposal of this device please contact the Clinic/Hospital/Manufacturer where this device was fitted or supplied who will advise you on the best method of disposal. Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

# Returns

Prior to the Return of any device, the Customer must contact Customer Services for an RA (Returns Authorisation Number) and complete a 8.2.1 FRM 028 Product Concern Report in full and submit with the product return.

# Warranty

The Warranty for this device is 1 year.

The warranty covers design and manufacturing only. Where a claim is made under warranty, this claim must be supported by appropriate documentation. Photographs of any failed devices must be provided in lieu of the product itself. You must state if you wish us to supply a replacement. The warranty will be void on all system components if any components have been subject to abuse, repair or maintenance by an uncertified person, deliberate damage, applied loads beyond those for which the product was designed, or by modification, neglect or actions against those outlined in the important information.

The Service life for this device is 5 Years.

# Environmental and Operational Conditions

| | |
|---|---|
| Storage and Transport | -20˚C (-4˚F) to +50˚C (+122˚F) |
| Operational | -5°C (+23°F) to +40°C (+104°F) |
| Pressure range | 700-1060 hPA |

Maximum 80% relative humidity, above non-condensing.

If the device has been in storage or has been transported, place the device in an ambient temperature (20˚C) two hours prior to use.

# Quality Assurance

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

Continued compliance with the standard is monitored by a program of internal and external audits.

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

This Device is CE marked which indicates that the Device meets EU safety, health and environmental requirements. It also indicates the device's compliance with EU legislation and free movement within the European market.

This Device is UKCA marked which indicates that the Device meets safety, health and environmental requirements. It also indicates the device's compliance with the legislation of Great Britain (England, Wales, Scotland) and free movement within the market of Great Britain.

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.

For the most recent issue of this manual, please visit: **www.steepergroup.com.**

# Symbols used on Product & Packaging

| Symbol | Definition | Source |
|---|---|---|
|  | Indicates the medical device manufacturer. | ISO 15223- 1:2016<br>Reference no. 5.1.1. (ISO 7000-3082) |
|  | Indicates the authorized representative in the European Community/ European Union. | ISO 15223-1:2016<br>Reference no 5.1.2 |
|  | The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Regulations. | 765/2008/EC, 768/2008/EC<br>MDR 2017/745 (Articles 2, 13, 14, 20, 21, 22, 74 and Annex V) |
|  | 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-ukca-marking |
|  | Single Patient - Multiple use Symbol | ISO/DIS 15223- 1:2020(E) DRAFT<br>Reference no. 5.4.12. (ISO 7000-3706) |
|  | Indicates a medical device that has not been subjected to a sterilization process | ISO 15223- 1:2016<br>Reference no. 5.2.7. (ISO 7000-2609) |
|  | Indicates the manufacturer's batch code so that the batch or lot can be identified. | ISO 15223- 1:2016 |

| Symbol | Definition | Source |
|---|---|---|
|  | Indicates a carrier that contains Unique Device Identifier information. | MDR 2017/745 23.2(h)<br>ISO 15223-1:2016 |
|  | To indicate that the marked item or its material is part of a recovery or recycling process. | ISO 704, ISO/IEC 13251, ISO 10987-1, ISO 9687<br>(Reference no. ISO 7000 -1135) |
|  | Packaging is covered by Forest Stewardship Council assurance that it is made with, or contains, forest-based materials from FSC-certified forests or reclaimed sources. | FSC Certification |
|  | Indicates the item is a medical device. | ISO/DIS 15223-1: 2020<br>Reference 5.7.7. |

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