Elegance Plus Silicone Gloves
Technical Information

steeper
Creating life's turning points, together

steeper USA
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Product Details

These enhanced gloves are designed to fit the Steeper Myo Kinisi myoelectric hand, Steeper cable operated hands and functional hands from other manufacturers.

Crafted using multiple layers of advanced silicone material and constructed with an integrated, reinforced inner mesh layer, these gloves are highly tear-resistant. The Elegance Plus Gloves feature an enhanced cosmetic finish and are especially suitable for higher activity patients. The addition of an easy-glide coating allows clothing to be donned and doffed easily.

High-Definition Nails

Silicone gloves have nails painted by hand following the manufacturing process. If desired, you can apply a silicone adhesive to the nails to create a flexible nail bed to allow the nail beds to accept nail varnishes and re-colouring. We do not recommend the use of polystyrene nails attached with Cyano-acrylic glue as attempts to remove nails bonded with this adhesive will permanently damage the glove.

Note: Steeper accepts no responsibility for damage resulting from the application of inks, varnishes or artificial nails.

Care and Cleaning

Take care when fitting and using silicone cosmetic gloves. Silicone is a soft, flexible material susceptible to punctures, cuts and abrasions. The material used will resist most staining media. The reinforced inner mesh is designed to reduce the level of tearing and to provide increased durability, however care must be taken not to cause damage to the outer silicone.

General soiling can be removed with a soft damp cloth and PH neutral hand soap. After cleaning remove all traces of the cleaner, wipe the surface dry, and leave to air dry.

The easy-glide coating is a temporary finish and will degrade with usage over time.

Do not use alcohol-based sanitisers, lubricants or cleaning products as these will degrade the Elegance Plus coating and finish. Only use water-based soaps and sanitisers for cleaning purposes.

Swatch Information

E24655 - TrueFinish™ Glove Colours
E24658 - TrueFinish™ Glove Colours (US Swatches)

Elegance Plus Gloves: Important Information

- The gloves must only be prescribed by a qualified prosthetist and fitted in a suitable clinical environment.
- The glove is not designed to be waterproof, small holes will allow ingress of moisture that may cause damage to components in the prosthetic structure. The user is asked to guard against this and inspect the glove carefully for damage on a regular basis, particularly if they are using it in environments where exposure to moisture is likely to occur.
- The glove will become slippery when wet. For any activity where moisture is present, extra care is needed when handling/holding items with the glove fitted.
- Do not expose to naked flames or excessive heat.
- Avoid prolonged exposure to direct sunlight.
- Do not use alcohol based lubricants, cleaning or sanitising products with the glove.
- If a serious incident occurs relating to the product, full details should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- TrueFinish™ Elegance Plus Silicone Cosmetic Gloves are Accessories for Class I Medical Devices which meet the general safety and performance requirements in MDR 2017/745 Annex I.

Fitting Instructions

Providing all of the instructions detailed in this document are followed, there are no specific qualifications required to fit this device.

1. Check that you have a suitable replacement glove.
2. Remove the existing glove by cutting along its length using blunt-nosed scissors. Be careful not to cut cables or internal cosmesis. It may be necessary to cut digits off individually.
3. Inspect the prosthesis. If water ingress, corrosion or other damage is evident, contact Steeper customer services or your local distributor.
4. Wipe the prosthesis clean and dry carefully.
5. Fit the glove at room temperature - warming this type of glove will not alter its properties.
6. If fitting to a myoelectric hand, partially close it and turn the power off.
7. Slide the glove firmly on to the prosthesis and work the digits into place (no lubricant or talc required).

For more details and video donning instructions, please visit the resources page on the online learning platform UpSkill by Steeper **www.upskillbysteeper.com**.

Environment and Operational Conditions

Please note the following recommended environmental operational conditions for the Elegance Plus gloves.

Storage, transport and operation	-20°C (-4°F) to +50°C (+122°F)
Operational	+5°C (+41°F) to +40°C (+104°F)
Pressure range	700-1060 hPA
Maximum 80% relative humidity, above non-condensing	

Disposal

For safe disposal, the user should return the prosthesis to their prosthetic clinic. Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

Returns

Prior to the return of any product, 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 Terms

The supplied product does not have a warranty period. The supplied RSLLIT372 Polymer Production QC Inspection Card should be retained and provided in the event of product return. Failure to provide this information could delay processing the return.

Quality Assurance

Steeper/SteeperUSA operate a UKAS approved quality management system and fully complies with the requirements of BS EN ISO 9001:2015. 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°: STP-RP455

Continued compliance with the standard is monitored by a program of internal and external audits. Applied Standards:
ISO 9001:2015 (QMS)
ISO 14971:2019

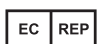
The Elegance Plus gloves are an Accessory for Class I Medical Devices which meet the general safety and performance requirements in MDR 2017/745 Annex I.

The gloves are 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.

The gloves are 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 technical manual, please visit: **www.steepergroup.com**.

Symbols Used on Product & Packaging

Symbol	Definition	Source
	Indicates the medical device manufacturer.	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)
	Indicates the authorised representative in the European Community/ European Union.	ISO 15223-1:2016 Reference no 5.1.2
	Indicates a carrier that contains Unique Device Identifier information.	MDR 2017/745 23.2(h) ISO 15223-1:2016
	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223- 1:2016 Reference no. 5.1.5. (ISO 7000-2492)
	Indicates the item is a medical device.	ISO/DIS 15223-1:2020 Reference no. 5.7.7

	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
	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Regulations.	765/2008/EC, 768/2008/EC MDR 2017/745 (Articles 2, 13, 14, 20, 21, 22, 74 and Annex V)
	Single Patient - Multiple Use Symbol.	ISO/DIS 15223- 1:2020(E) Reference no. 5.4.12. (ISO 7000-3706)
	Indicates a medical device that has not been subjected to a sterilisation process.	ISO 15223- 1:2016 Reference no. 5.2.7. (ISO 7000-2609)
	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 (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

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