

Seal-In Kit for Steeper Electrodes

Technical Information



Introduction

The Seal-In Kit is designed for use with the high performance ELEC50/ELEC60 Steeper electrodes.

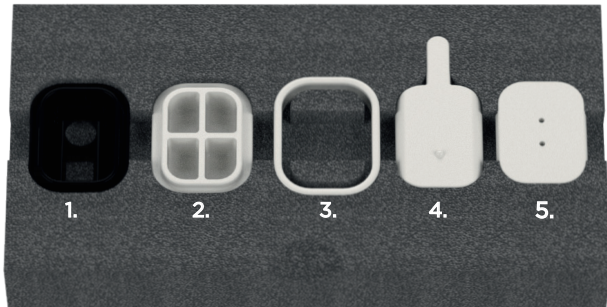
The mounting method stabilises the electrode within the inner socket and allows a seal-in gasket to maintain an air-tight seal. The seal also helps to prevent moisture ingress from the inner socket, reducing the risk of damage to components housed within the prosthesis.

The Seal-In Kit is an accessory for Class I Medical Devices which meet the general safety and performance requirements in MDR 2017/745 Annex I.

The Seal-In Kit must only be prescribed and fitted by a qualified prosthetist in a suitable clinical environment.

Note: The Seal-In Kit is only for use with Steeper electrodes (ELEC50 / ELEC60)

Box Contents

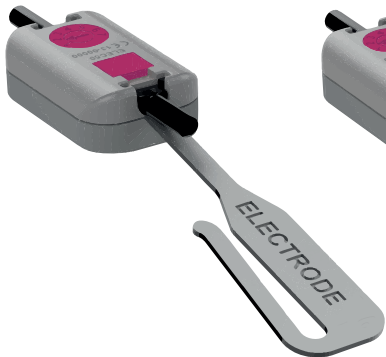


1. ELSK gasket
2. Rolled silicone socket blank
3. Gasket retainer
4. Outer socket blank
5. Thermoplastic inner socket blank

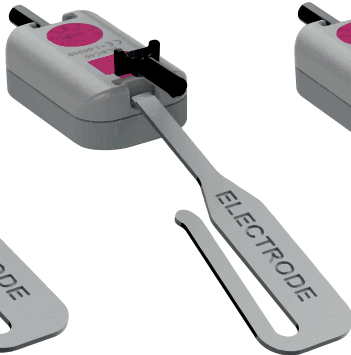
Electrode Suspension Leg Removal

Electrode suspension legs must be removed prior to fitting a Seal-In Kit, as shown in steps 1-3.

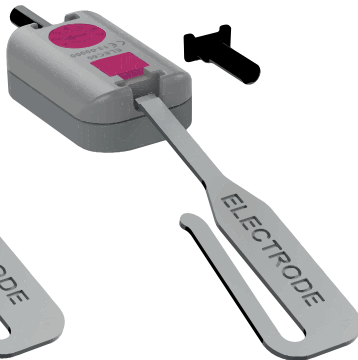
1.



2.



3.



Connecting to the Electrode

First remove the electrode block from the electrode, using the electrode tool, as shown in steps 1-3.

1.



2.



3.



4. Feed the cable through the gasket and insert the cable into the cable block ensuring the cable is fully located into the cable block.



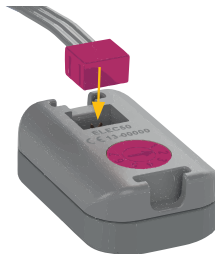
5. Using the electrode tool, apply a small amount of **NLU0010** silicone grease in the cable block recess prior to inserting the cable block.*



⚠ WARNING

Ensure the blue side of the electrode cable (ECA=300, 600 or 1000) is facing towards the electrode.

6. Insert fully until the cable block is flush with the electrode casing.



7. Remove any excess grease from the electrode casing after connection.



*Ensure that each time the cable block is removed from the electrode a small amount of grease is applied.

Slide the electrode cable through the gasket, gently pushing the electrode into the gasket so that it is contained as shown in steps 8, 9 and 10.

8.



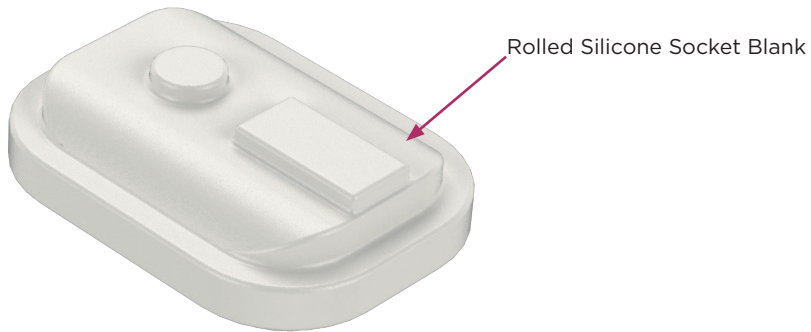
9.



10.

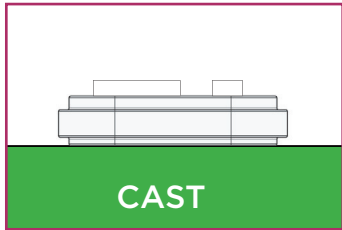


ELSK - Rolled Silicone Inner Socket

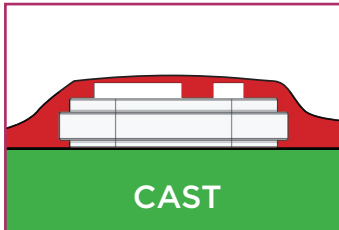


Fabrication Technique

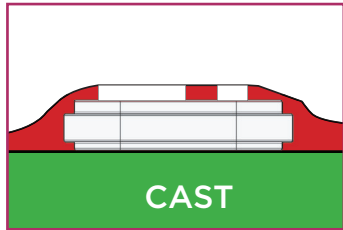
All views show a cross section through the cast



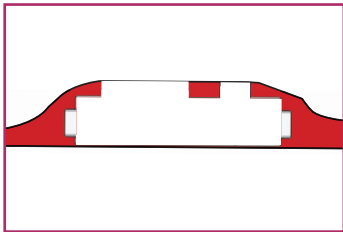
1. Identify the position of the electrode(s) on the cast and check the area is completely flat to ensure a close fit of the blank(s). Place the blank(s) onto the cast and draw its footprint.



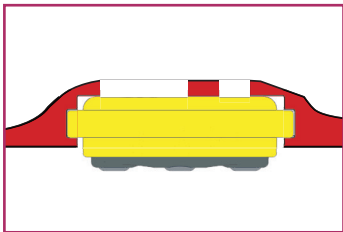
2. Apply a harder shore silicone around and over the blank(s), ensuring it is butted well into the recess. Taper the silicone to form a small skirt. Apply silicone (use normal shore hardness) to remainder of cast in normal way and blend into harder shore silicone around blank(s).



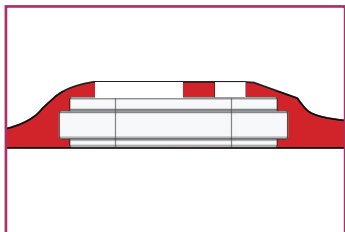
3. Remove excess silicone from the top of the blank(s) to allow the two raised areas on the blank(s) to be completely exposed. The silicone should be no thicker across the rest of the blank(s) than the height of these two surfaces. Finish the job and the curing process in the normal way.



4. Once the silicone is fully cured, remove from the cast and remove the blank(s). Carefully trim away any excess material.

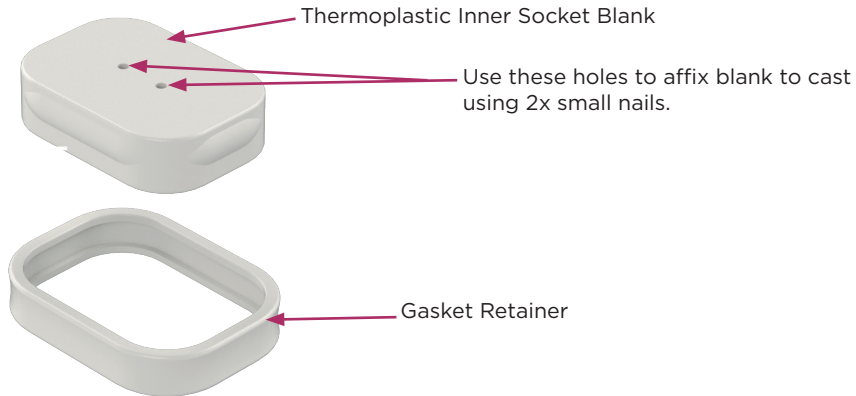


5. Fit the gasket(s) to the liner, making sure to press the rim firmly in place. Thread the electrode cable through the gasket, and press the electrode into the gasket observing the correct orientation. Make sure to press the electrode firmly into the gasket retaining lugs.



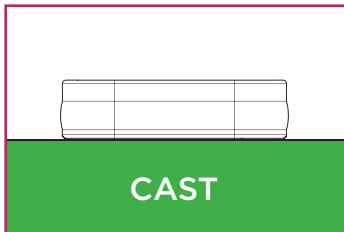
6. The blank can be re-inserted to the silicone liner to cast the patient for the outer socket which can then be fabricated in the usual way. It is not necessary to add any additional build up or blank for the outer socket fabrication.

ELSK - Vacuum Draped Inner Socket

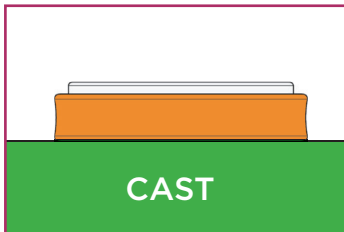


Fabrication Technique

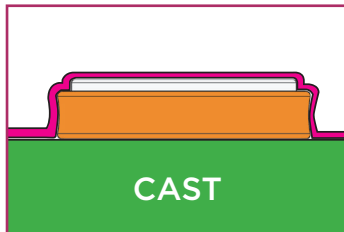
All views show a cross section through the cast



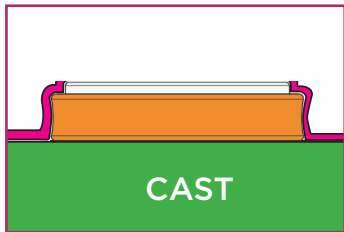
1. Identify the position of the electrode(s) on the cast and check the area is completely flat to ensure a close fit of the blank(s). Apply a nylon wick over the cast then attach each inner socket blank to the cast using 2 small nails.



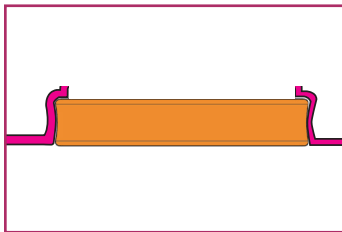
2. Clip the gasket retainer(s) onto the blank(s).



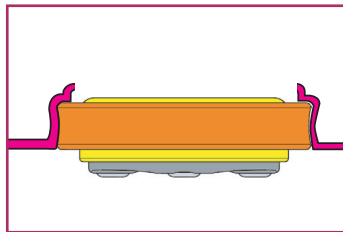
3. The cast is then draped in the desired fashion paying particular attention to getting a good tight seal around the blank(s). This can be encouraged with the use of a blunt tool if required.



4. Once material has cooled remove the excess material as indicated. Only expose the top surface and do not expose the gasket retainer.

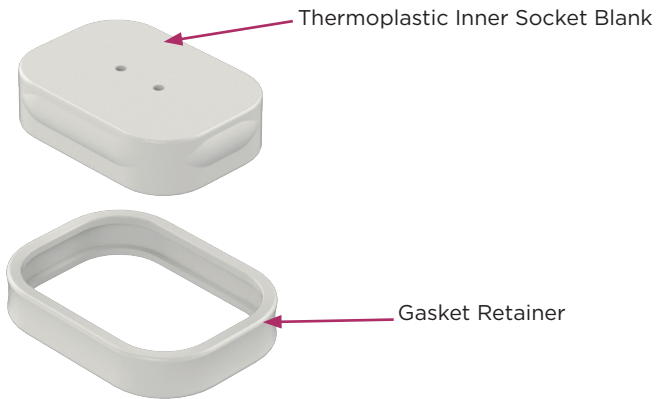


5. If a trial fitting is required, remove the cast and blank(s) leaving the gasket retainer within the socket.



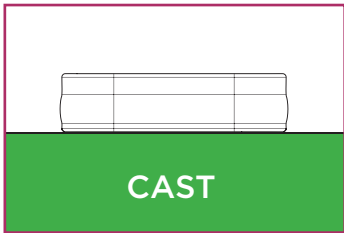
6. Fit the gasket(s) to the gasket retainer(s) making sure to press the rim firmly in place. Thread the electrode cable through the gasket, and press the electrode into the gasket observing the correct orientation. Make sure to press the electrode firmly into the gasket retaining lugs.

ELSK - Laminated Inner Socket

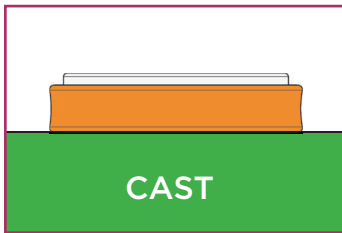


Fabrication Technique

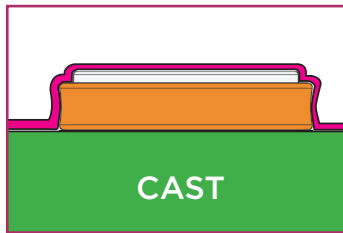
All views show a cross section through the cast



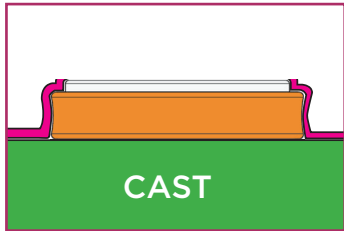
1. Identify the position of the electrode(s) on the cast and check the area is completely flat to ensure a close fit of the blanks, and use tape to attach the blank to the cast, over the PVA bag.



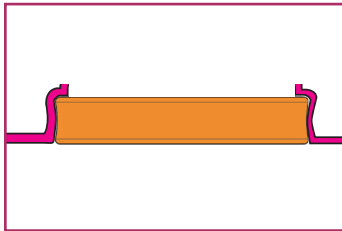
2. Clip the gasket retainer(s) onto the blank(s).



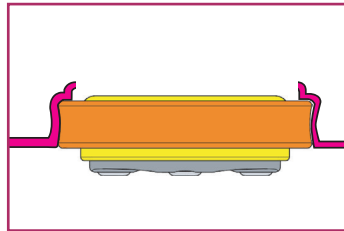
3. Apply layers of material to cast as required, apply outer bag and laminate in the desired fashion. Pay particular attention to working resin around gasket to ensure a good seal.



4. Once the material has cooled remove the excess material as indicated. Only expose the top surface and do not expose the gasket retainer.

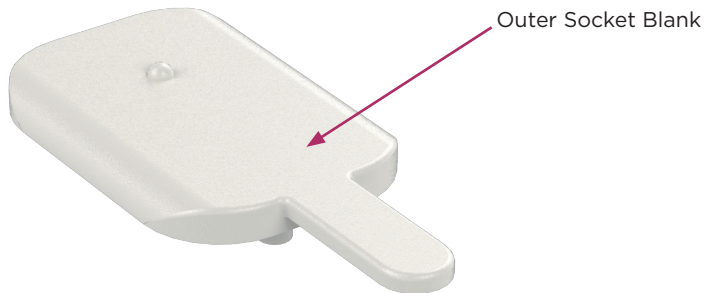


5. If a trial fitting is required, remove the cast and blank(s) leaving the gasket retainer within the socket.



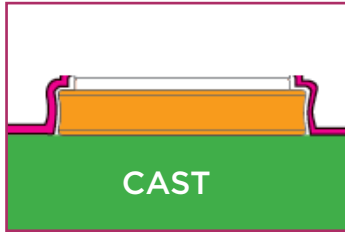
6. Fit the gasket(s) to the gasket retainer(s) making sure to press the rim firmly in place. Thread the electrode cable through the gasket, and press the electrode into the gasket observing the correct orientation. Make sure to press the electrode firmly into the gasket retaining lugs.

ELSK - Thermoplastic/ Laminated Outer Socket

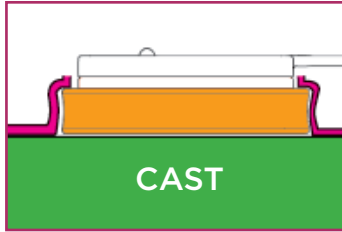


Fabrication Technique

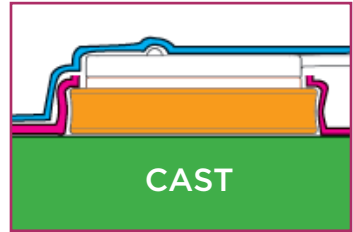
All views show a cross section through the cast



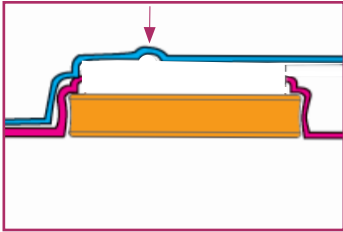
1. If a trial fitting was conducted, refit the original inner socket blank(s) to the gasket retainer. Fill the socket with plaster.



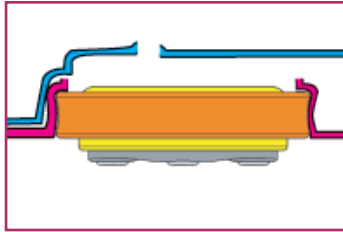
2. Place the outer socket blank(s) on top of the inner socket blank(s), making sure the two lugs sit in the corresponding holes, and the tongue is pointing in the direction of the wrist.



3. The outer socket / forearm is formed in the usual way.



4. The cast and blanks are removed. The hole for the electrode gain adjustment is drilled in the position indicated by the blank, on the socket surface as shown.



5. Fit the gasket(s) to the gasket retainers(s) in the inner socket/liner, pressing the rim firmly into place. Thread the electrode cable through the gasket, and press the electrode into the gasket observing the correct orientation. Ensure the gasket retaining lugs are fully engaged. The inner socket/liner and outer socket can now be assembled in the usual way.

Environment and Operational Conditions

Please note the following environmental operational conditions for the for the Seal-In Kit, which match that of the Steeper electrodes.

Storage, transport and operation	-20°C (-4°F) to +60°C (+140°F)
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Operational	-15°C (+5°F) to +60°C (+140°F)
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Pressure range	700-1060 hPA
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Maximum 95% relative humidity, above non-condensing

Do not expose to EM emissions above 8kV contact, 15kV air

If the Seal-In Kit has been in storage or has been transported, place in an ambient temperature (20° C) for a minimum of 2 hours before use.

Care and Maintenance

The Seal-In Kit is a consumable part, and therefore is not subject to regular maintenance.

To clean the Seal-In Kit use a cloth lightly moistened with soapy water, ensuring the Seal-In Kit is thoroughly air-dried afterwards and no residue remains.

Disposal

Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling.

Please dispose of in accordance with local requirements.

Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

Warranty Terms

The Seal-In Kit is a single use consumable and unless it is received damaged it does not have a warranty.

If the Seal-In Kit is damaged on arrival, picture evidence must be taken prior to opening.

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.

Returns

If items are to be returned for any reason, please contact Steeper Customer Services or your local Steeper distributor to request a RTA - Returns Authorisation Number and 8.2.1 FRM 028 Product Concern Report Form.

Quality Assurance

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-RP605

This device is an accessory for Class I Medical Devices which meet the general safety and performance requirements in MDR 2017/745 Annex I.

Quality Assurance cont.






The 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.






The 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.

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

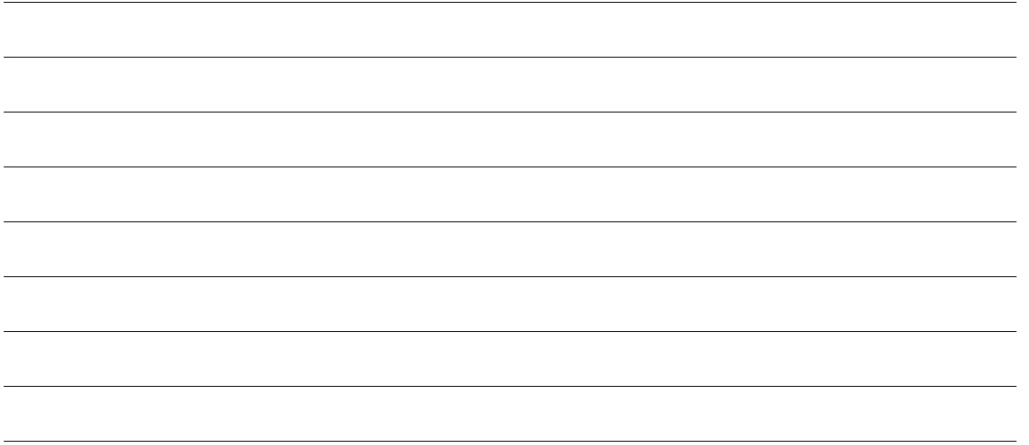
The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. The company, therefore, reserves the right to introduce changes and withdraw products without notice. For the most recent issue of this technical manual, please visit: www.steepergroup.com.

Symbols Used on Product & Packaging

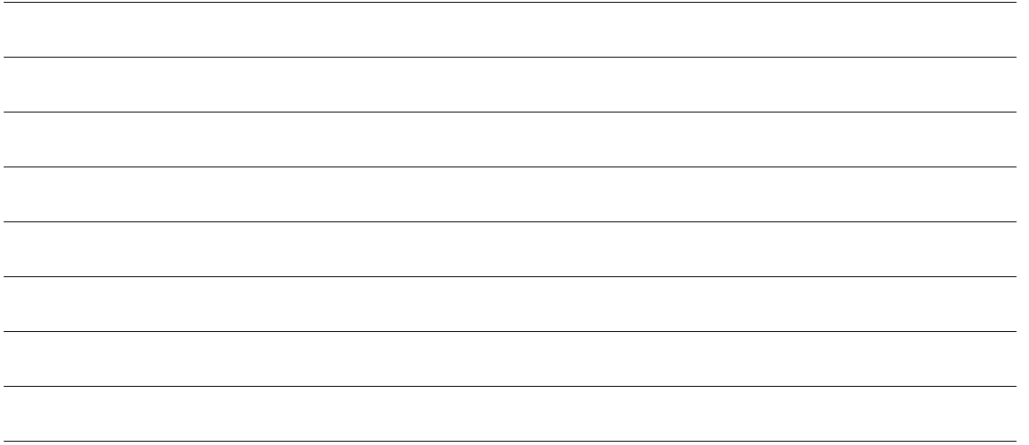
Symbol	Definition	Source
	Indicates the medical device manufacturer.	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)
	Indicates the authorised representative in the European Community/European Union.	ISO 15223-1:2016 Reference no 5.1.2
	Indicates a carrier that contains Unique Device Identifier 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)
	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

	<p>The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Regulations.</p>	<p>https://www.gov.uk/guidance/using-the-ukca-marking</p>
	<p>Single Patient - Multiple use Symbol.</p>	<p>ISO/DIS 15223-1:2020(E) DRAFT Reference no. 5.4.12. (ISO 7000-3706)</p>
	<p>Indicates a medical device that has not been subjected to a sterilisation process.</p>	<p>ISO 15223- 1:2016 Reference no. 5.2.7. (ISO 7000-2609)</p>
	<p>To indicate that the marked item or its material is part of a recovery or recycling process.</p>	<p>ISO 704, ISO/IEC 13251, ISO 10987-1, ISO 9687 (Reference no. ISO 7000 -1135)</p>
	<p>Packaging is covered by the Forest Stewardship Council assurance that it is made with, or contains, forest-based materials from FSC certified forests or reclaimed sources.</p>	<p>FSC Certification</p>

Notes



Notes



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