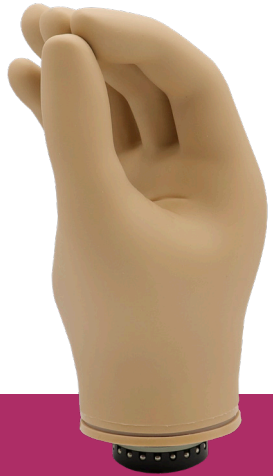
Myo Kinisi
Technical Manual



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Contents

Box Contents

- Myo Kinisi with PVC hand shell
- Technical Manual (for clinician use)
- User Guide (please supply to the end user)

Features of the Myo Kinisi

- Independently controlled opening and closing speed options.
- Integrated function button to turn the hand on/off.
- Grip strength increase pattern allows the user to confidently increase their grip when required.
- Auto-grip feature allows the user to have a secure grasp on unstable objects.
- Compatible with the Steeper Quick Disconnect Wrist, Friction Wrist, and Short Wrist ranges (M12 or ½" x 20 TPI threaded stems).
- Recommended for use with the Steeper S-Charge System - other 6-8.4V power systems are compatible, however these may restrict capacity.
- Independently operated mechanical safety feature.
- Durable PVC hand shell.
- Programmed using the Steeper Configuration Device, which enables the choice between Mode 0-4 for the Myo Kinisi (see the Steeper Configuration Device - Programming Guide for Myo Kinisi).

Steeper Myo Kinisi

The Myo Kinisi is a myo-electrically controlled terminal device designed for external use by those with an upper limb absence. It is suitable for patients at levels equivalent to transradial and more proximally, in both unilateral and bilateral applications. The hand is available in three sizes (7¼", 7¾" and 8¼") and four wrist variations, to suit a broad range of clinical presentations.

The Myo Kinisi offers an easy to control, high-speed grasp, with a strong maximum grip force; promoting bi-manual manipulation and performing daily activities. The device is supplied in Mode 1 'Dual Elec' which provides a standard grip function and the auto-grip feature is enabled. In combination with the Steeper Configuration Device, the Myo Kinisi operational Mode 0-4 can be changed; threshold settings can be manipulated and the auto-grip feature can be enabled or disabled. Dependant on the user's ability, the Steeper Configuration Device can be used to adjust the parameters, including the speed and grip strength.

For optimum performance and extended capacity, it is recommended that the Myo Kinisi is used alongside the Steeper S-Charge System and Steeper Electrodes.

A PVC hand shell encloses the inner mechanism to protect the Myo Kinisi and provide a hand shape. Prior to providing the user with the Myo Kinisi, a Steeper cosmetic glove must be fitted to protect the hand shell. The Elegance Plus reinforced silicone cosmetic glove is recommended and has been designed specifically for use with the Myo Kinisi.

The Steeper Configuration Device

The Steeper Configuration Device offers prosthetists the choice between five modes to suit patient needs. The Myo Kinisi is supplied in Mode 1: 'Dual Elec' the parameters of this mode can be adjusted using the Steeper Configuration Device.

More details about the modes available can be found on page 19.

The Steeper Configuration Device can be ordered using product code MYO-CFG via Steeper Customer Services.

Important Clinician Information

- The Myo Kinisi 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.
- Do not adjust, dismantle, attempt to maintain or modify the Myo Kinisi or its associated components.
- It is important the user inspects their myoelectric hand regularly to ensure early detection of any problems.
- Ensure that the hand is securely fitted to the wrist plate of choice for the hand to function.
- If the Myo Kinisi is not functioning as expected, check the electrode connection/connectors are not damaged.
- The Myo Kinisi is not dirt resistant or waterproof, therefore moisture and/or debris must not enter the hand. If liquid/debris does enter the hand, it must not be operated and should be returned for safety checks and/or repair.
- In the event of device failure, or suspected malfunction, please contact Steeper Customer Services or your local Steeper distributor.
- If a serious incident occurs, in relation to the device, it should be reported to the Manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Unless under clinical supervision, the user must always operate the hand with the inner PVC shell fitted.
- To clean the outer glove or the hand shell, use a damp cloth to gently remove any marks. **Do not use solvents**.
- Do not expose the Myo Kinisi to a naked flame

or excessive heat. Avoid exposing the hand to long periods of direct sunlight.

- Do not expose the Myo Kinisi to any live electrical components.
- Do not subject the hand to any impact, mechanical vibrations, or excessive load.
- Before detaching the Myo Kinisi from the power source, the user must ensure that the Myo Kinisi is switched off, press and hold the function button; as described in 'Location of the Function Button' (p.12) and then check the hand functionality to ensure it is switched off.
- Do not use a combination of batteries with varying voltages to power the hand.
- Ensure the end user is fully informed of the care and operation of this product. A User Guide will be supplied with the hand for their reference.
- This product is intended for use by a single user during daily activities. See warranty terms for further information.
- If this product does not meet your expectations, please contact Steeper Customer Services or your local Steeper distributor.

See **www.steepergroup.com** for the latest version of this Technical Manual.

Warning: Do not modify this equipment.

Important User Information

- If your Myo Kinisi has been fitted with a Quick Disconnect Wrist, the device must be consciously positioned when performing any turning actions to prevent unintentional disconnection of the hand at the wrist.
- When driving, the hand must be turned **off,** and in a position that prevents the permanent connection between the device and the vehicle. Driving with the Myo Kinisi switched on may result in accidental/ unintentional operation of the hand, presenting a significant risk of losing control of the vehicle and injury as a result.
- If exposed to salt water, contact your prosthetist immediately to arrange an inspection, and return to Steeper for repair if required.
- Do not expose the device to a naked flame or excessive heat. Avoid exposing the hand to long periods of direct sunlight.
- The prosthesis must not be worn whilst the batteries are charging.
- Whilst the battery pack is being charged, the hand will not function.
- Do not touch any live electrical equipment with the hand.
- The Myo Kinisi must not be used during extreme sports. Steeper does not accept any responsibility for damage or injury due to improper use.
- Do not store device in fully closed position, always store with fingers and thumb slightly open.
- The maximum carry load for the Myo Kinisi is 12.5kg (27.55lb).

- Before detaching the Myo Kinisi from the prosthesis, you must ensure that the Myo Kinisi is switched off, press and hold the function button; as described in 'Location of the Function Button' (p.12) and then check the hand functionality to ensure it is switched off.
- In the event that the device or prosthesis is exposed to unusual substances or stresses, please stop using the device immediately and contact your prosthetist to arrange an inspection, and return for repair if required.

Please visit **www.steepergroup.com** for the latest version of the User Guide.

Warning: Do not modify this equipment.

Technical Information

Hand sizes*:	7¼”	7¾”	8¼”
Maximum opening width	100mm (3.9”)	100mm (3.9”)	100mm (3.9”)
Maximum length - fingertip to hand base	170mm (6.7”)	170mm (6.7”)	175mm (6.89”)
Maximum speed when closing from fully open	220mm/s	220mm/s	220mm/s
Compatible with wrist sizes	45mm (1.77”)	50mm (1.97”)	54mm (2.16”)
Weight of device with EQD Wrist and hand shell	530g	550g	565g
Grip force	c.90N	c.90N	c.90N

*All figures are for guidance only.

Environmental and operational conditions:

Storage and Transport	-20°C (-4°F) to +50°C (+122°F)
If the hand has been in storage or has been transported, place the device in an ambient temperature (20°C) two hours prior to using.	
Operational	-5°C (+23°F) to +40°C (+104°F)
Pressure Range	700-1060 hPA
Maximum 80% relative humidity, non-condensing	
Do not expose to EM emissions above 8kV contact, 15kV air	

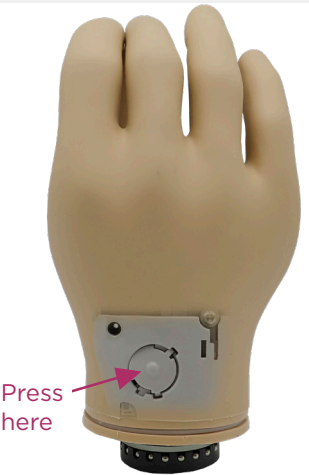
The Function Button

The Myo Kinisi has a low profile function button, located on the back of the hand (as shown in the diagram).

- The Myo Kinisi is on by default after connecting to a power source; initial start up of the device will take between 2-4 seconds after which you can operate the device.
- To switch off the device press and hold the button for 3 seconds, a feedback vibration will indicate that the device is switching off.
- To switch the Myo Kinisi back on, press the function button for for 1 second - a vibration feedback will indicate the device is on.
- When the device is on; the auto-grip function can be activated by pressing and releasing the function button (see p.14 for more details).

Note: The force required to press this button has been designed to avoid accidental operation.

Note: If the Myo Kinisi is not functioning this will likely be because the system is off - press the button firmly to turn it on.



Location of the Function Button. This switches the device ON/OFF and is used to activate the auto-grip feature.

Specific Activity Use

The hand must be turned **off** during an activity that requires it to remain in the same position for long periods of time, or when the user wants to prevent accidental operation of the device - particularly if associated muscle contractions in the residual limb will occur. The function button is used to power the hand off.

If the Myo Kinisi has been fitted with a Quick Disconnect Wrist, the device must be consciously positioned when performing any turning actions to prevent unintentional disconnection of the hand at the wrist.

Whilst using the hand, if the user is intending to drive they **MUST** ensure the device is turned **off**, and in a position which allows them to easily disconnect the hand from the vehicle. Driving with the power on may result in accidental/unintentional operation of the hand, potentially causing loss of vehicle control and injury as a result.

It is the responsibility of each user to ensure they comply with local regulations before operating any motorised vehicle.

Note: Steeper recommends assessment from an authorised/specialist test centre to determine if the user's vehicle requires any adaptations.

Activating the Auto-Grip Feature

The auto-grip feature is designed to give the user greater confidence when grasping objects. When gripping an object, this feature will offer a grip strength that automatically adjusts to accommodate for any slip of the gripped object.

Prosthetists can enable/disable this feature using the Steeper Configuration Device.

Auto-grip utilises the function button; please see page 12 for a diagram of location.

To operate:

- The hand must be in an open position and powered on.
- Press and release the function button to activate auto-grip; a single short burst haptic vibration will indicate that the auto-grip is active.
- Close the hand onto the object until the grip force increases to elicit 1 pulse. Auto-grip is now engaged; ensuring the grip strength applied to the object is maintained.
- Once auto-grip is active, the hand must be engaged in gripping an object within 1 minute; otherwise the auto-grip function will automatically deactivate.
- If the object is removed, the hand will close.
- When engaged, auto-grip is cancelled by a strong open signal, or after 2 minutes if the gripped object does not slip.
- Auto-grip can also be cancelled by pressing the function button a second time before gripping the object (producing a double burst haptic vibration).

Mechanical Safety Release

In the event in that the grip cannot be released, such as a loss of power to the Myo Kinisi, the safety release button can be used to disengage the thumb.

The safety release button is located on the outside of the thumb. Press this firmly and push the top of the thumb open to activate the safety release.

⚠ Important Clinician Information

The safety release function must be demonstrated to the patient prior to leaving the clinic. The patient must be confident in how to safely manoeuvre the safety release back into its correct position. A video guide can be found on the Steeper website www.steepergroup.com.

⚠ **Caution:** This must only be used in the event of loss of power on the

Re-engaging the safety release

- To reset the mechanical safety release, push the button and move the thumb back to its original position, you will then feel it relocate. To check if the thumb has re-engaged ask the user to close the hand - if the thumb moves accordingly, it has been reset correctly.

- The mechanical safety release will work with the hand in either an open or closed position, and will not require recalibration if deployed.

- To ensure the thumb is functioning as expected, the user must grip an object before commencing with further activities.

Additional Safety Feature

When the battery runs low the hand will slow; this is intentional to signal the user to recharge or change their battery.

If the battery fully discharges during use, as a final action, the Myo Kinisi will open and remain in an open position until the battery is recharged or changed.

Maximum Pulses

The grip can be maximised by maintaining or pulsing the close signal after gripping an object. A number of pulses will be felt as the grip increases. This feature incrementally increases grip to the pre-set ‘maximum pulse count’ (1-3). When the ‘maximum pulse count’ is achieved the grip is at a maximum.

Myo Kinisi - Control Parameters

The Myo Kinisi hand offers five mode options. Each mode provides a different variety of characteristics allowing mode selection based on the need of the user. These modes cannot be selected or adjusted without the use of the Steeper Configuration Device. The table adjacent illustrates the key attributes of each of the five modes.

Control Mode	No. of Sites		Compatible Inputs				Control Strategy				Auto Grip
							Opening		Closing		
	Single	Dual	AC/DC Electrode	Force Sensitive Resistor (FSR)	Switch	Linear Transducer	Threshold	Proportional	Threshold	Proportional	
0	•		•	•	•	•	•	•			
1		•	•	•	•	•	•	•	•	•	•
2	•		•	•		•	•	•	•	•	
3	•		•	•	•	•	•	•	•	•	
4	•		•	•	•	•			•	•	

Adjustable Parameters Table

The adjustment parameters available for use with each of the five Myo Kinisi hand modes are illustrated in the table below:

Control Mode	Invert	Flip Electrodes	Auto-Grip	Electrode Mode			Input 1		Input 2		Control Parameters				
				Highest	First	Close priority	ON Level	Max Level *	ON Level	MAX Level*	Max Open Speed	Max Close Speed	Pulse Period	Alt Delay	Max Pulses
0	•						•	•			•	•			•
1		•	•	•	•	•	•	•	•	•	•	•			•
2							•	•			•	•			•
3							•	•			•	•		•	•
4	•						•	•			•	•	•		•

*Only available when using a Proportional mode

Myo Kinisi Mode Overview

Mode 0: 'AUTO CLOSE'
Single Site: Auto Close

A signal rising above the 'ON Level' threshold will open the hand. When the signal drops below the 'ON Level' the hand will close, regardless of the speed at which it is removed.

There is an option to invert the functions in this mode, so that a signal rising above the 'ON Level' threshold will close the hand and when the signal drops below the 'ON Level' the hand will open.

Mode 1: 'DUAL ELEC'
Dual Site: Open/Close Signal - **Default Mode**

This mode uses 2 inputs to provide proportional or threshold control over opening and closing the terminal device.

Default settings are:

- Proportional Control
- Maximum Opening/Closing Speeds
- Highest Electrode Mode
- Auto-Grip enabled
- Maximum Pulses Count of 3

An input signal must pass the 'ON Level' threshold to elicit movement in a respective direction. The method for changing direction of movement is 'Highest' by default, meaning that the largest signal will take priority to determine the direction of the hand. When the 'First Signal' option is selected, the first electrode to increase above its 'ON Level' threshold will determine the direction of travel. If the 'Close Priority' option is selected, a valid close signal will take priority even if the hand is opening. This can be altered by 'Electrode Mode' selection. If the signals from both inputs drop below their independent 'ON Level' thresholds the device will stop moving.

The grip force achieved is determined by the strength and duration of the close signal. The grip can be incrementally increased by maintaining, or pulsing, the close signal above the 'ON Level' threshold to the 'maximum pulse count'. This is set to 3 pulses by default.

Mode 2: 'QUICK OPEN'
Single Site: 2 Channel Signal

A fast-rising input signal will open the hand, and a slow-rising input signal will close the hand.

Mode 3: 'ALTERNATE'
Single Site: Successive Signals

An initial input signal will move the hand when it rises above the 'ON Level' threshold.
Any successive signals from the same input passing the 'ON Level' threshold, after a pre-programmed 'Alt delay' period has elapsed, will move the device in the opposite direction. Within the 'Alt delay' period, all signals passing the 'ON Level' threshold produce movement in the same direction as the initial signal.

Mode 4: 'PULSE'
Single Site: 2 Channel Signal

A short burst input signal will open the terminal device; to close the device the user must provide a long burst signal.

A short burst signal is an input signal that rises to 400% of the 'ON Level' threshold and falls back below the 'ON Level' threshold within a programmable 'Pulse Period'.

A long burst signal is an input signal that is sustained for a longer than usual 'Pulse Period'.

There is an option to invert the functions in this mode, so that a short burst will elicit a full close of

the terminal device, and a sustained burst will allow controlled opening of the hand.

For more information about the mode options for the Myo Kinisi please refer to the Steeper Configuration Device Programming Guide, which can be found at: **www.steepergroup.com.**

Removing the Hand Shell

- Remove the retaining ring from the wrist of the inner hand shell.
- Open the hand slightly and isolate the power supply.
- With the hand firmly and carefully secured in a vertical position, begin to firmly and carefully work the inner hand shell distally on the chassis.
- Ensure the fingers are worked free from the palps throughout the process until the hand shell can be lifted off.
- Some gentle external heating of the inner hand shell can aid the process, however extreme care must be taken not to heat the internal mechanism. **Do not put the hand in the oven.**

Note: The inner hand shell should only be removed if the palps need replacing; avoid removing the inner hand shell at any other point to protect the inner mechanisms of the hand.

Fitting the Hand Shell

If the hand shell requires fitting, the instructions below must be followed:

- Steeper recommend securing the hand firmly and carefully in a vertical position, with the hand in a slightly open position and the power supply isolated.
- **The use of talcum powder is not recommended.**
- The PVC hand shell can be gently heated to aid the donning process; place the hand shell on to a clean flat surface in a fan assisted oven at 110°C (230°F) for 90 seconds.
- When the hand shell is warm and malleable; carefully ease the wrist section over the fingers before pulling over the chassis.
- Once partially donned, the inner hand shell should be pushed down fully into place so that there is no bridging and the finger/thumb tips are fully located.

- The retaining ring should be mounted to secure the hand shell in place.

If in doubt, please contact Steeper Customer Services.

Fitting Replacement Palps

If the palps require replacement due to damage to the hand, please follow the instructions below. If you require any assistance with this process, please contact the Steeper Customer Services team, or your local distributor.

- Remove the cosmetic glove and cosmetic hand shell, as per the instructions within in this manual.
- Gently pull off the damaged palp(s), ensuring unnecessary damage is not inflicted to the fingers or hand.
- The surface must be cleaned with IPA or equivalent prior to the palp being replaced.
- Replacement palps are a push-on fit, but for additional security super glue must be applied sparingly to the thumb or fingertips beforehand.
- Carefully push the palp fully into position so it sits on the shoulder of the distal.
- Refit the Kinisi hand shell, ensuring the hand shell is not damaged prior to fitting.

Donning the Cosmetic Glove

The Elegance Plus glove is designed to be used with the Myo Kinisi, however, a number of alternative gloves may also be applied. For the best results, please see the instructions supplied with the glove you are fitting.

- Ensure the hand shell is fitted to the Myo Kinisi before applying a cosmesis.
- With the myoelectric hand in a slightly open position and the power isolated, firmly secure the hand in a vertical position - taking care not to damage the device or prosthesis.
  PVC only: Gently warm the cosmetic glove, taking care to avoid localised overheating. If applying a silicone glove, no heating is required.
- Pull the glove over the hand, manipulating it carefully to avoid excessive stretching.
- Once the fingertips of the device meet the palm of the glove, carefully push the glove down into position over the fingers and thumb.
- The cosmetic glove should fit closely all over the fingers and the thumb and cover the hand. When extended up the forearm, the glove should not have wrinkles, folds or any bridging.
- The glove can now be trimmed to the desired length for finishing.
  PVC only: Areas of stretch formed during the fitting process can be removed by careful application of gentle local heating.

Note: For a video showing the fitting of the Elegance Plus Glove please see the resources available on the Steeper online learning platform, UpSkill by Steeper **www.upskillbysteeper.com**

Doffing the Cosmetic Glove

- The suggested method to remove the cosmetic outer glove is to slightly open the hand and isolate the power supply.
- Apply a water-based surgical lubricant to the outer glove surface, before inverting the glove and pulling the proximal edge back over the hand distally in a firm action.
- Avoid cutting off the cosmetic glove where possible to prevent risk of damaging the inner hand shell beneath.

Warranty Terms

The warranty for the Myo Kinisi is two years. Warranty covers design and manufacturing issues only.

Where a claim is made under warranty, this claim must be supported by appropriate documentation. Photographs of any failed products must be provided in lieu of the product itself. If applicable, please do not send faulty batteries back to Steeper.

The warranty will be void on all system components if any components have been subject to abuse, modification, neglect, deliberate damage, loads beyond those for which the product was designed, or repair or maintenance by an uncertified person.

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.

The service life of the Myo Kinisi is five years. Outside of this, please contact your local Steeper representaive for possibilities regarding service or repair.

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.

All items must be returned to Steeper with an RTA and completed 8.2.1 FRM 028 Product Concern Report with the product return. The RTA number must be clearly stated on the outside of the packaging prior to return.

The serial number found under the hand shell, close to the wrist (as per photo) must be added to the Serial N° section on the form.

Location of serial Number

Quality Assurance

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°: RP628

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.

Test Certification

The Device and its associated components listed within this document have been tested and certified to the following standard and requirements:

IEC 60601-1:2005, AMD:2012
IEC 60601-1-11:2015
IEC 60601-1-2:2014
RTCA DO – 160G

Includes meeting requirements of ISO 14971:2019.

Disposal

The Myo Kinisi is an electrical device and should not be mixed with general household waste. For proper treatment, recovery and recycling, please take this product(s) to designated collection points.

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 contact your local authority for further details regarding your nearest designated collection point.

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

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

Symbols Used on Product and 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
	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)
	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
	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 5.7.7.
	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)
	This product contains electrical and electronic components that may contain materials which, if disposed of 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 of or recycle this product in accordance with local laws or regulations that apply.	IS EN 50419:2006 Reference no. Fig. 1
	Indicates the medical device may be used multiple times (multiple procedures) on a single patient.	ISO/DIS 15223- 1:2020(E) Reference no. 5.4.12. (ISO 7000-3706)
	Mobius logo indicates 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 the 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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STPPR089 Issue 1 June 2021