COOK®
MEDICAL

Lunderquist® Extra Stiff Wire Guides

Instructions for Use

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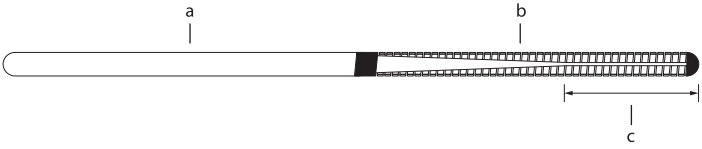
464-01EN

ENGLISH

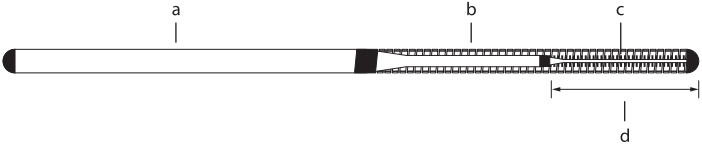
TABLE OF CONTENTS



1a

Straight Lunderquist® Wire Guide

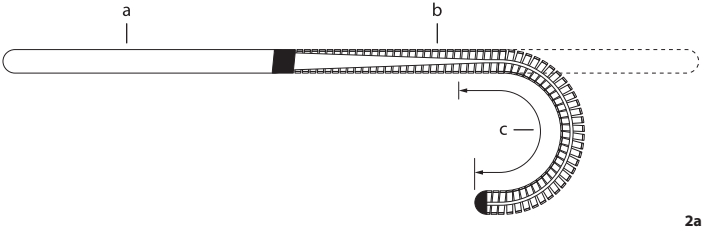
a. PTFE coated mandril
b. PTFE coated coil
c. Flexible tip



1b

Straight Lunderquist® Wire Guide

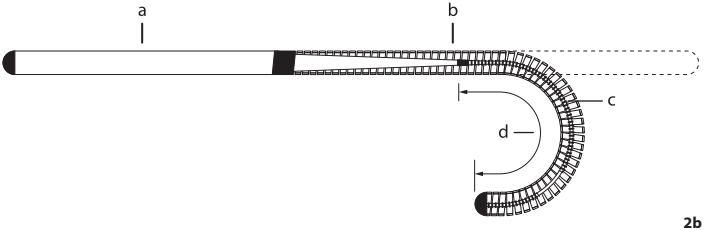
a. PTFE coated mandril
b. PTFE coated coil
c. Gold coil
d. Flexible tip



2a

Curved Lunderquist® Wire Guide

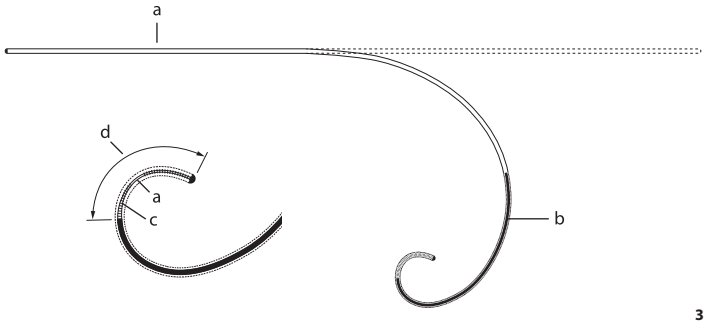
a. PTFE coated mandril
b. PTFE coated coil
c. Flexible tip



2b

Curved Lunderquist® Wire Guide

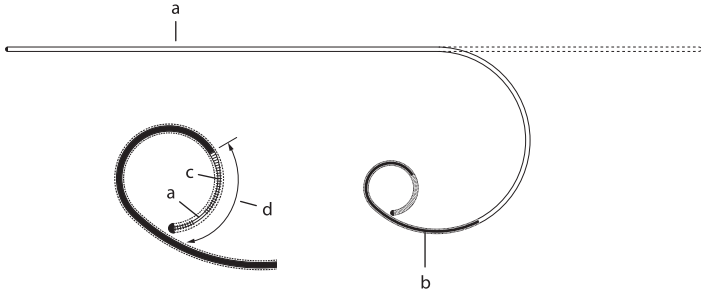
a. PTFE coated mandril
b. PTFE coated coil
c. Gold coil
d. Flexible tip



3

Double Curved Lunderquist® Wire Guide

a. PTFE coated mandril
b. PTFE coated coil
c. Gold coil
d. Flexible tip



4

Extended Double Curved Lunderquist® Wire Guide

a. PTFE coated mandril
b. PTFE coated coil
c. Gold coil
d. Flexible tip

LUNDERQUIST® EXTRA STIFF WIRE GUIDES

Read all instructions carefully. Failure to properly follow the information provided may lead to the device not performing as intended or injury to the patient.

STERILE – DO NOT RESTERILIZE – SINGLE USE ONLY.

CAUTION: US federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

1. DEVICE DESCRIPTION

1.1 Construction of Device

The Lunderquist® Extra Stiff Wire Guides (hereinafter referred to as the Lunderquist wire guides) are 0.035 inch PTFE coated stainless steel wire guides consisting of a mandril and a 15 cm long coil. The mandril has a tapered end with a length of 11 cm and an additional 4 or 7 cm flexible tip. The Lunderquist wire guides are available in the following configurations:

Straight Lunderquist wire guides (TSMG-/-LES) are available in lengths of 90, 145, 180, 260, and 300 cm and either a 4 cm or 7 cm flexible tip. For the 260 cm and 300 cm lengths, the flexible tip includes an inner gold coil. (**Fig. 1a** and **1b**)

Curved Lunderquist wire guides (TSCMG-/-LES) are available in lengths of 90, 145, 180, 260, and 300 cm and either a 4 cm or 7 cm flexible tip. For the 260 cm and 300 cm lengths, the flexible tip includes an inner gold coil. The J-curve radius for the curved wire guides is either 3 mm or 7 mm. (**Fig. 2a** and **2b**)

Double Curved Lunderquist wire guides (TSCMG-/-LESDC) are available in lengths of 260 and 300 cm with a 4 cm flexible tip that includes an inner gold coil. The Double Curved Lunderquist wire guides have a large curve/J-curve radius of 75/15 mm. (**Fig. 3**)

Extended Double Curved Lunderquist wire guides (TSCMG-/-E-LESDC) are available in lengths of 260 and 300 cm with a 4 cm flexible tip that includes an inner gold coil. The Extended Double Curved Lunderquist wire guides have an extended large curve/J-curve radius of 55/15 mm. (**Fig. 4**)

1.2 Performance Characteristics

The Lunderquist wire guides are long and stiff making them suitable for facilitating endovascular procedures in the aorta, including its access vessels and major adjacent vessels. The extra stiff design of the Lunderquist wire guides provides support for placing large devices such as aortic stent grafts through access sheaths, as they have the body and stiffness needed to control over-the-wire devices. The different device configurations available provide the choice of shape, body length, and flexible tip length to facilitate the wire guide to seat or anchor itself in the target anatomy as required. The distal tip is very flexible to prevent damage to the vessel wall.

The Lunderquist wire guides are PTFE coated to ensure a smooth surface of the device, reduce friction, and provide better trackability. The 260/300 cm configurations of the Lunderquist wire guides incorporate an inner gold coil for enhanced visibility under fluoroscopy.

1.3 Specifications

The specifications for the different Lunderquist wire guide configurations are shown in **Table 1**.

Table 1 – Lunderquist Wire Guide Configurations

Lunderquist Wire Guide Configurations				
Prefix/Suffix	**TSMG-/-LES**	**TSCMG-/-LES**	**TSCMG-/-LESDC**	**TSCMG-/-E-LESDC**
Straight/Curved	Straight	Curved	Double Curved	Extended Double Curved
Lengths	90, 145, 180, 260, and 300 cm	90, 145, 180, 260, and 300 cm	260 and 300 cm	260 and 300 cm
Flexible Tip Lengths	4 or 7 cm	4 or 7 cm	4 cm	4 cm
Mandril Tapered Length	11 cm	11 cm	11 cm	11 cm
PTFE Coated Coil Length	15 or 18 cm	15 or 18 cm	15 cm	15 cm
Curve and Radius	N/A	J-curved, 3 or 7 mm	Large curve 75 mm, J-curve 15 mm	Large curve 55 mm, J-curve 15 mm
Gold Coil	For lengths 260 and 300 cm	For lengths 260 and 300 cm	Yes	Yes

1.4 Device Compatibility

The Lunderquist wire guides can be used with medical devices which are compatible with a 0.035 inch wire guide e.g., sheath, catheter, stent, or stent graft.

1.5 Patient Population

The Lunderquist wire guides are auxiliary devices used as part of an endovascular procedure facilitating vascular access and delivery of over-the-wire medical devices to the target site. Hence, the Lunderquist wire guides are not primary interventional devices themselves.

The indications are to facilitate vascular access and/or delivery of over-the-wire medical devices during endovascular procedures in adult patients (18 years and older). The indication depends on the underlying medical condition for which the endovascular procedure is intended, thus not limiting the target population to a particular group of adult patients.

1.6 Intended User

The Lunderquist wire guides are intended for use by physicians trained and experienced in vascular interventional techniques.

1.7 Contact with Body Tissue

The Lunderquist wire guides are externally communicating medical devices, which are in direct contact with circulating blood for a limited contact duration (≤24 hours).

1.8 Operating Principle

The Lunderquist wire guides are used both to assist in vascular access and to support the delivery of medical devices. The wire guide is introduced into the target vessel using the Seldinger technique; other devices, such as a sheath, catheter, stent, or stent graft can then be passed over the wire guide to be positioned or manipulated within the vascular system.

For introduction of the wire guide into the target position, fluoroscopy should be used to confirm proper placement of the wire guide and to observe all wire guide movement in the vessel.

2. INTENDED USE

The Lunderquist Extra Stiff Wire Guides are intended to facilitate catheterization and/or placement of devices during vascular interventional procedures.

The Lunderquist Extra Stiff Wire Guides are intended for use in the aorta, including its access vessels and major adjacent vessels.

3. INDICATIONS FOR USE

The Lunderquist Extra Stiff Wire Guides are auxiliary devices and hence not primary interventional devices themselves. Instead, they are intended to facilitate vascular access and/or delivery of over-the-wire medical devices during endovascular procedures, including TEVAR/EVAR procedures.

The Lunderquist Extra Stiff Wire Guides are both

long and stiff; features that make them suitable for facilitating endovascular procedures that involve placement of large devices e.g., stent grafts in the aorta. The wire guides are not intended for coronary or neurovascular use.

4. CONTRAINDICATIONS

- Not intended for coronary or neurovascular use.

5. WARNINGS

5.1 General Warnings

- The safety and performance of the Lunderquist wire guides have not been evaluated in a pediatric population.
- Using the wire guide in vessels with extensive thrombus may increase the risk of emboli.
- Minimize handling of the device during preparation and insertion to decrease the risk of contamination.

5.2 Sterile and Single Use

- Do not use the device if the sterile packaging is damaged or unintentionally opened before use. If a contaminated device is introduced to the bloodstream, it may cause an infection and lead to severe harm.
- This single-use device is not designed for reuse. If the device is reused it could pose risks of cross contamination with microbiological agents. Attempts to reprocess (resterilize) and/or reuse may lead to device failure and/or transmission of disease.

5.3 Malfunctions/Changes in Performance

- If resistance is encountered tactilely or visually during fluoroscopy, determine the cause, and take appropriate steps to relieve the resistance to avoid the risk of vessel perforation. Excessive force should not be exerted.
- Do not insert the wire guide from the rigid proximal end as this may cause damage to the tissue, the wire guide, or the associated medical devices. Insert the wire guide from the flexible distal end.

6. PRECAUTIONS

6.1 General Precautions

- Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.
- Ensure that the patient does not have impaired tolerance to general, regional, or local anesthesia to avoid adverse reactions associated with the anesthetic procedure.
- Prior to choosing an access vessel, assess the vessel for size, anatomy, disease state, calcifications, tortuosity, and thrombus.
- Fluoroscopy/imaging is required for successful wire guide placement and hence the risk of harms due to radiation exposure should be considered and discussed with the patient. Furthermore, the risk of radiation exposure to developing tissue should be discussed with women who are or suspect they are pregnant.
- If contrast media is used during the procedure, there may be a risk of contrast-induced harms.
- End-hole size and length of the medical device e.g., access catheter, must be taken into consideration to ensure proper fit between the wire guide and the medical device.
- Exercise caution when manipulating the wire guide in close proximity to the heart to avoid inducing arrhythmia or cardiac events.
- Exercise caution during manipulation of catheters, wires, and sheaths within the vessels. Significant disturbances may dislodge fragments of thrombus or plaque, which may cause distal or cerebral embolization or cause vessel damage.
- If a less stiff wire guide is needed, consider using the Amplatz Ultra Stiff Wire Guide.
- Failure to store the device correctly may result in material degradation and/or damage to the device.

6.2 Malfunctions/Changes in Performance

- Altering the tip configuration of the wire guide may result in damage or breakage of the device.
- Withdrawal or manipulation of the wire guide through a needle tip may result in damage or breakage of the device.
- Exercise caution during wire guide manipulation to minimize the risk of entanglement/entrapment with other devices.

6.3 CMR 1A/1B and/or Endocrine Disrupting Substances

- This symbol on the label indicates that the wire guide contains cobalt (Co) at a level above 0.1% w/w. Cobalt is a substance that is toxic to reproduction and carcinogenic (Category 1B). However, the wire guide contains cobalt as part of a stainless steel alloy at a very low concentration (up to 0.4% w/w), it has limited direct exposure (≤24 hours) and does not release cobalt at levels which cause an increased risk of cancer or adverse reproductive effect to the patient.

6.4 Allergic Reaction

- Possible allergic reactions to cobalt, nickel, and chromium in the stainless steel alloy should be considered.

6.5 Training Requirements for User

The physician shall be trained and experienced in vascular interventional procedures.

6.6 Requirements for Facilities

The Lunderquist wire guides are intended for use in hospital operating rooms. Users must wear standard operating room personal protective equipment (PPE; gloves, face mask, sterile gown, etc.) and follow local guidelines for sterile procedures.

7. POTENTIAL ADVERSE EVENTS

- Access site injury
- Allergic reaction
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Arrhythmia
- Cardiac damage (e.g., perforation, pseudoaneurysm, tamponade)
- Cardiac infarction
- Death
- Embolism (e.g., air, blood clots, calcifications, fragments of coating)
- Harms associated with wire guide fragmentation/ separation
- Hematoma
- Hemorrhage
- Infection (e.g., abscess, sepsis)
- Organ injury
- Prenatal radiation exposure
- Radiation exposure
- Stroke and other neurological events
- Valvular/retrograde regurgitation and acute hypotension
- Vascular thrombus/thromboembolism
- Vessel injury (e.g., dissection, perforation, rupture, pseudoaneurysm)
- Vessel spasm

8. STERILIZATION

All devices are sterilized using ethylene oxide (EO) gas.

9. HOW SUPPLIED

Keep the device dry and away from sunlight. Do not use after the expiration date printed on the label.

10. INSPECTION OF DEVICE

Inspect the device thoroughly including all levels of the packaging to verify that there is no damage prior to use. Inspect and confirm that the sterile barrier has not been compromised in any way. Inspect and confirm that the device corresponds to the label and the IFU.

Do not use the device if the sterile packaging is damaged or unintentionally opened before use.

11. DEVICE PREPARATION

11.1 Device Selection

The physician must choose the suitable configuration for the intended procedure.

12. INSTRUCTIONS FOR USE

12.1 Patient Preparation

The physician should follow institutional protocols and local guidelines. Carefully evaluate the vessel size, anatomy, and disease state including if vessels are significantly calcified, occluded, tortuous, or thrombus lined before the procedure.

12.2 Step-by-Step Guide

1. Using aseptic technique, remove the wire guide holder containing the wire guide from the Tyvek® pouch and place it in the sterile field.
2. Attach a syringe with heparinized saline solution or sterile water to the male Luer lock or fitting of the wire guide holder.
3. Inject enough solution to fill the wire guide holder and bathe the wire guide in solution to ease the removal of the wire guide from the wire guide holder.

   NOTE: Excessive force should not be exerted when removing the wire guide from the wire guide holder.
4. Carefully insert the distal tip of the wire guide in the vascular access catheter. The inserter may be used for easier insertion.
5. Under fluoroscopy, maintain the position of the vascular access catheter and advance the wire guide to the target site.

   NOTE: Under fluoroscopy, observe all wire guide movement in the vessel. Do not advance the wire guide if the tip cannot be visualized using fluoroscopy.

   NOTE: If resistance is encountered tactilely or visually under fluoroscopy, determine the cause, and take the necessary action to relieve the tension to avoid the risk of potential adverse events e.g., vessel injury. Be sure to advance and withdraw the wire guide slowly and carefully. Excessive force should not be exerted during the procedure.

6. With the wire guide secured in place, advance the therapeutic device to the target site.

13. REQUIRED EQUIPMENT AND ACCESSORIES

13.1 Materials Required

- Fluoroscope with digital angiography capabilities (C-arm or fixed unit)
- Compatible catheter, introducer sheath, or vascular access device
- Syringe
- Heparinized saline solution or sterile water

14. DISPOSAL OF DEVICE

After the procedure, this device may be contaminated with potentially infectious substances of human origin and should be disposed of in accordance with institutional guidelines.

15. REFERENCES

These instructions for use are based on experience from physicians and/or their published literature. Refer to your local Cook Medical sales representative for information on available literature.

16. PATIENT COUNSELING

Please inform the patient as necessary of the relevant warnings, precautions, contraindications, measures to be taken and limitations of use that the patient should be aware of.

Furthermore, the patient should be informed about the residual risks when treated with this device and the potential adverse events related to the use of this device.

16.1 Symptoms

The physician must advise the patient to contact their healthcare provider if he/she experiences changes in their medical condition or in case of concern.

16.2 Follow-Up Information for the Patient

Follow-up will be individual, so the physician must advise the patient on the recommended follow-up.

17. SERIOUS INCIDENT REPORTING

If any serious incident has occurred in relation to the device, this should be reported to Cook Medical, and the competent authority and/or regulatory authority of the country where the device was used.

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