SOLUTION PRODUCT CODES

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Cables</th>
<th>SureFlex™ Steerable Guiding Sheath</th>
</tr>
</thead>
<tbody>
<tr>
<td>DLFK0003</td>
<td></td>
<td>Medium curl</td>
</tr>
<tr>
<td>DLFK0005</td>
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<td>Large curl</td>
</tr>
<tr>
<td>DLFK0007</td>
<td></td>
<td>Small curl</td>
</tr>
<tr>
<td>DLK0001</td>
<td></td>
<td>Steerable Guiding Sheath</td>
</tr>
<tr>
<td>DLK0003</td>
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<td>Steerable Guiding Sheath</td>
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<tr>
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</tr>
<tr>
<td>DLK0007</td>
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<td>Steerable Guiding Sheath</td>
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</tbody>
</table>

INDIVIDUAL DEVICE PRODUCT CODES

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Size</th>
<th>French Size</th>
<th>Usable Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPstar Fixed Electrophysiology Catheter</td>
<td>2F</td>
<td>N/A</td>
<td>315 cm</td>
</tr>
<tr>
<td>EPstar Fixed Electrophysiology Catheter</td>
<td>6F</td>
<td>N/A</td>
<td>95 cm</td>
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<td>EPstar Diagnostic Catheter</td>
<td>8.5F</td>
<td>N/A</td>
<td>75 cm</td>
</tr>
<tr>
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<td>8.5F</td>
<td>N/A</td>
<td>29 cm</td>
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<tr>
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<td>N/A</td>
<td>63 cm</td>
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<tr>
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<td>8.5F</td>
<td>N/A</td>
<td>63 cm</td>
</tr>
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<td>EPstar Diagnostic Catheter</td>
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<td>N/A</td>
<td>63 cm</td>
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<td>8.5F</td>
<td>N/A</td>
<td>63 cm</td>
</tr>
<tr>
<td>EPstar Diagnostic Catheter</td>
<td>8.5F</td>
<td>N/A</td>
<td>63 cm</td>
</tr>
</tbody>
</table>

TELESCOPE

your devices to achieve deeper coronary venous mapping with the EPstar Coronary Venous Mapping Solution

Kit includes:

- **EPstar 2F Microcatheter†**
  - Eight electrodes at distal end with 5-5-5 spacing

- **EPstar 6F Fixed†**
  - Electrophysiology Catheter
  - Ten 1.2 mm electrodes at distal end with 5-5-5 spacing

- **SureFlex™ Steerable Guiding Sheath**
  - Available in Large, Medium, and Small curls
  - *Cables also included*

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Brief Summary | EPstar Fixed Electrophysiology Catheter with Lumen

**INDICATIONS FOR USE:**
- The EPstar Fixed Electrophysiology Catheter with Lumen is recommended only for use in cardiac electrophysiological examinations.
- The EPstar Fixed Electrophysiology Catheter with Lumen is intended for use in the coronary arteries (it may induce myocardial infarction, arterial perforation, or cardiac tamponade, which may result in death). DO NOT use the product if the following problem exists: Patients with systemic or regional vasodilation that may cause a decrease of arterial pressure because there is a risk of damaging the blood vessel or heart chamber, and a situation requiring thoracotomy may occur. DO NOT use excessive force to advance or withdraw the EPstar Fixed Electrophysiology Catheter. Prior to use, please see the Operator’s Instructions for more information on indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

**PRECAUTIONS:**
- The EPstar Fixed Electrophysiology Catheter with Lumen is intended for use in cardiac electrophysiological examinations. **Cardiac catheterization should only be conducted by trained personnel.** All necessary precautionary functions of the EPstar Fixed Electrophysiology Catheter with Lumen should be properly conducted to ensure patient safety. All necessary precautionary functions of the EPstar Fixed Electrophysiology Catheter with Lumen should be properly conducted to ensure patient safety. The EPstar Fixed Electrophysiology Catheter is intended foruse in the coronary arteries. **Prior to use, please see the Operator’s Instructions for more information on indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.**

**WARNINGS:**
- The EPstar Fixed Electrophysiology Catheter with Lumen is intended for use in cardiac electrophysiological examinations. **Cardiac catheterization should only be conducted by trained personnel.** All necessary precautionary functions of the EPstar Fixed Electrophysiology Catheter with Lumen should be properly conducted to ensure patient safety. All necessary precautionary functions of the EPstar Fixed Electrophysiology Catheter with Lumen should be properly conducted to ensure patient safety. The EPstar Fixed Electrophysiology Catheter is intended foruse in the coronary arteries. **Prior to use, please see the Operator’s Instructions for more information on indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.**

**PRODUCT CODES:**
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Streamline Complex Mapping

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EP-US6760-A4
CANNULATE

**SureFlex™ Steerable Guiding Sheath**

Cannulate the coronary sinus with the 8.5F **SureFlex™ Steerable Guiding Sheath**

Large and Medium curl options available for smooth cannulation of the coronary sinus.

**TruGlide™ HANDLING**

High precision steering to confidently cannulate the coronary sinus with ease.

GUIDE

**EPstar 6F Fixed Catheter with Lumen†**

Navigate the coronary venous system using the decapolar 6F diagnostic catheter with lumen.

**Electrodes**

Ten 1.2 mm electrodes in 3-5-5 spacing.

**3F Lumen**

3F Lumen allows for flushing and aspiration of fluids, and is compatible with devices up to 0.035” diameter.

**GO FURTHER. KNOW MORE.**

Access areas inaccessible to other catheters.

PINPOINT

**EPstar 2F† Microcatheter**

Enable mapping and pacing in distal coronary venous system branches with the octapolar 2F Microcatheter for deeper diagnostic precision.

**18 TOTAL ELECTRODES**

Octopolar 2F and decapolar 6F catheters create a wide activation field in the coronary venous system.

**Deeper coronary venous mapping has been used for:**

- Idiopathic VTs and PVCs1-3
- Complex ATs4,5
- Mapping and pacing in VOM4,6

**Vein of Marshall Mapping**

High precision steering to confidently cannulate the coronary sinus with ease.

**Brief Summary | SureFlex™ Steerable Guiding Sheath**

**CAUTION:**

Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

**INDICATIONS FOR USE:**

The SureFlex™ Steerable Guiding Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

**CONTRAINDICATIONS:**

There are no known contraindications for this device.

**WARNINGS:**

- Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of interventional imaging. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended.
- The SureFlex™ Steerable Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the SureFlex™ Steerable Guiding Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. Air in the sheath may cause injury to the patient or the operator.
- Maintain continuous hemodynamic monitoring throughout procedure.
- Provide continuous heparinized saline infusion while the introducer remains in vessel.
- DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury.

**PRECAUTIONS:**

- Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.
- Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur.
- Do not attempt to use the guidewire with electrocautery tools.
- Do not reshape distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating, leading to patient injury.

**ADVERSE EVENTS:**

Adverse events that may occur while using the SureFlex™ Steerable Guiding Sheath include:

- Infection
- Air embolus
- Local nerve damage
- Vasovagal reaction
- Dissection
- Vessel spasm
- AV fistula formation
- Atrial septal defect
- Pseudoaneurysm
- Aortic puncture
- Arrhythmias
- Perforation and/or tamponade
- Hematoma
- Hemorrhage
- Catheter entrapment
- Embolic events
- Stroke
- Valve damage
- Myocardial infarction
- Pericardial/pleural effusion
- Pacemaker/defibrillator lead displacement
- Pulmonary edema
- Coronary artery spasm and/or damage
- Vessel trauma

1. Komatsu et al., 2018, Circ Arrhythm Electrophysiol – (2F EPstar Fix)
2. Su et al., 2005, PACE – (2F Pathfinder, Cardima)
3. Pothineni et al., 2021, Heart Rhythm – (2F EPstar Fix)
6. Fujisawa et al., 2019, Pacing Clin Electrophysiol. – (2F EPstar Fix)

† EPstar 2F Fixed Electrophysiology Catheter
‡ EPstar 6F Fixed Electrophysiology Catheter with Lumen
§ Images provided courtesy of Venkat N. Tholakanahalli, MD

For more resources on complex EP procedures, please read our clinical dossiers or reach out to your local rep for more info.