INDIVIDUAL DEVICE PRODUCT CODES

Product Code	Product Type	French Size	Usable Length	Curl Size
DCF-2-8-55-130	**EPstar** Diagnostic Catheter	2F	130 cm	N/A
DLF-6-10-55-95R	**EPstar** Diagnostic Catheter	6F	95 cm	N/A
DEX-10	Connector Cable	N/A	230 cm	N/A
DEX-14	Connector Cable	N/A	230 cm	Small
TSK0004	**SureFlex**™ Steerable Guiding Sheath	8.5F	63 cm	Medium
TSK0005	**SureFlex**™ Steerable Guiding Sheath	8.5F	63 cm	Large
TSK0006	**SureFlex**™ Steerable Guiding Sheath	8.5F	63 cm	

SOLUTION PRODUCT CODES

Product Code	Includes			
	2F	6F	**SureFlex**™ Steerable Guiding Sheath	Cables
DLFK0001	✓	✓	Small curl	✓
DLFK0003	✓	✓	Medium curl	✓
DLFK0005	✓	✓	Large curl	✓
DLFK0007	✓	✓	Steerable Sheath not included	✓

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

Brief Summary | EPstar Fixed Electrophysiology Catheter with Lumen

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 EPstar Fixed Electrophysiology Catheter with Lumen can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

CONTRAINDICATIONS: The EPstar Fixed Electrophysiology Catheter with Lumen is recommended only for use in cardiac electrophysiological examinations.

WARNINGS: • The EPstar Fixed Electrophysiology Catheter with Lumen is intended for single patient use only. Do not attempt to sterilize and reuse the catheter. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The EPstar Fixed Electrophysiology Catheter with Lumen must be used with the EPstar Electrophysiology Cable (DEX-10/DEX-14). Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Laboratory staff and patients can undergo significant x-ray exposure due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • DO NOT force to push or pull this product in vessels if you feel resistance during insertion of this product [because there is a risk of damaging the blood vessel or heart chamber, and a situation requiring thoracotomy may occur]. • DO NOT use the product in the following patients: • Patients with excessive peripheral vascular diseases that prevent insertion of a sheath in an appropriate size [the vessel may be pierced] • Patients with excessive prolongation of coagulation time contraindicated for antiplatelet therapy and anticoagulation therapy [the antiplatelet therapy and anticoagulation therapy may be required when the product is used] • Patients with a serious allergy to drugs necessary for the procedure such as a contrast medium • Pregnant or possibly pregnant patients • Patients with bacteremia or sepsis • Patients with hypercoagulation or hypocoagulation causing coagulation disorder • Patients not eligible for thoracotomy procedures • Patients with tricuspid replacement if the product needs to pass a cardiac valve • Patients with severe circulation instability or shock • Patients with intracardiac mural thrombus, myocardial and unstable angina

PRECAUTIONS: • Use only for cardiac electrophysiological examinations. • Careful catheter manipulation must be performed to avoid cardiac damage, or tamponade. Catheter advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the catheter. • Do not bend the EPstar Fixed Electrophysiology Catheter with Lumen excessively. Excessive bending or kinking of the catheter shaft may damage the integrity of the catheter and may cause patient injury including the detachment or fall of the catheter tip. Care must be taken when handling the catheter. • In the case that this product is used in combination with a heart stimulator or external pacemaker, pay careful attention to the location so that the electrodes of this product do not contact other leads.

ADVERSE EVENTS: Adverse events that may occur while using the EPstar Fixed Electrophysiology Catheter with Lumen includes: • Air embolism • Difficulty in catheter retraction • Death • Ventricular fibrillation/tachycardia • Sepsis, infections • Arrhythmia with hemodynamic collapse • Cardiac tamponade • Myocardial infarction/ angina attack • Pseudoaneurysm • Access-site complication • Hemorrhagic complication • Bradycardia including atrioventricular block • Thromboembolism • Distal embolization (air, tissue, thrombus) in the lung • Pneumothorax • Subcutaneous hematoma formation • Malfunction of implantable pacemaker/ ICD • Cerebral infarction/ cerebrovascular disorder • Laceration, perforation and dissociation of blood vessel • Cardiac valve damage such as valve insufficiency or valvular incompetence • Hypertension/hypotension • Cell damage

EP-1514904-AA

Brief Summary | EPstar Fixed Electrophysiology Catheter

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 EPstar Fixed Electrophysiology Catheter is intended for electrogram recording and pacing during diagnostic electrophysiology studies.

CONTRAINDICATIONS: The EPstar Fixed Electrophysiology Catheter is recommended only for use in cardiac electrophysiological examinations.

WARNINGS: • The EPstar Fixed Electrophysiology Catheter is intended for single patient use only. Do not attempt to sterilize and reuse the catheter. Reuse can cause the patient injury and/or the transmission of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The EPstar Fixed Electrophysiology Catheter must be used with the BMC EPstar Electrophysiology Cable (DEX-10). Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Laboratory staff and patients can undergo significant x-ray exposure due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • DO NOT use force to push or pull this product in vessels if you feel resistance during insertion of this product [because there is a risk of damaging the blood vessel or heart chamber, and a situation requiring thoracotomy may occur.] • DO NOT use the product in the coronary arteries [it may induce myocardial infarction, arterial perforation, or cardiac tamponade, which may result in death]. • DO NOT use the product in the following patients: • Patients with excessive peripheral vascular diseases that prevent insertion of a sheath in an appropriate size [the vessel may be pierced] • Patients with excessive prolongation of coagulation time contraindicated for antiplatelet therapy and anticoagulation therapy [the antiplatelet therapy and anticoagulation therapy may be required when the product is used] • Patients with a serious allergy to drugs necessary for the procedure such as a contrast medium • Pregnant or possibly pregnant patients • Patients with bacteremia or sepsis • Patients with hypercoagulation or hypocoagulation causing coagulation disorder • Patients not eligible for thoracotomy procedures • Patients with tricuspid replacement if the product needs to pass a cardiac valve • Patients with severe circulation instability or shock • Patients with intracardiac mural thrombus, myocardial and unstable angina.

PRECAUTIONS: • Use only for cardiac electrophysiological examinations and temporary pacing purposes. • Careful catheter manipulation must be performed to avoid cardiac damage, or tamponade. Catheter advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the catheter. • Do not bend the EPstar Fixed Electrophysiology Catheter excessively. Excessive bending or kinking of the catheter shaft may damage the integrity of the catheter and may cause patient injury including the detachment or fall of the catheter tip. Care must be taken when handling the catheter. • Pay full attention to the potential for suppression of pacing or malfunction of an ICD due to stimulation by electrophysiology studies of the heart; deal with the matter by changing the settings. • In the case that this product is used in combination with a heart stimulator or external pacemaker, pay careful attention to the location so that the electrodes of this product do not contact other leads. • Store under stable conditions, avoiding vibration and shock (including during transportation).

ADVERSE EVENTS: Adverse events that may occur while using the EPstar Fixed Electrophysiology Catheter include: • Air embolism • Difficulty in catheter retraction • Death • Cardiac tamponade • Sepsis, infections • Vascular tear, perforation or dissection • Arrhythmia with hemodynamic collapse • Ventricular fibrillation/tachycardia • Myocardial infarction/ angina attack • Cerebral infarction/ cerebrovascular disorder • Thromboembolism • Hemorrhagic complication • Pneumothorax • Pseudoaneurysm • Pacing failure • Puncture-site complication • Skin disorder by defibrillation • Distal embolization (air, tissue, thrombus) in the lung • Malfunction of implantable pacemaker/ICD • Cardiac valve damage such as valve insufficiency or valvular incompetence • Hypertension/hypotension • Subcutaneous hematoma formation • Ecchymoma formation • Bradycardia including atrioventricular block • Laceration, perforation and dissociation of blood vessel • Difficulty in retracting other concurrently- used medical device from product • Excessive bleeding

EP-1515407-AA

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EP-1657608-AA

Boston Scientific
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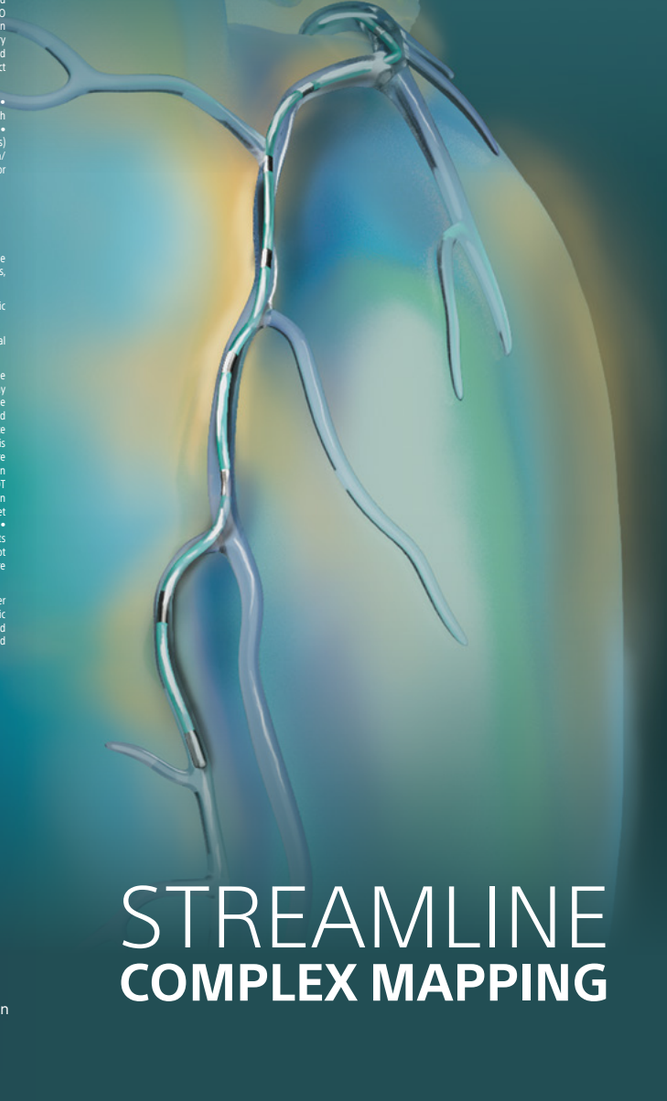
EPstar
Coronary Venous Mapping Solution

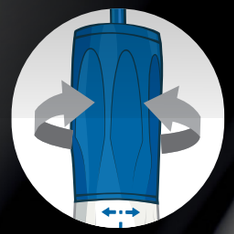


STREAMLINE
COMPLEX MAPPING

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

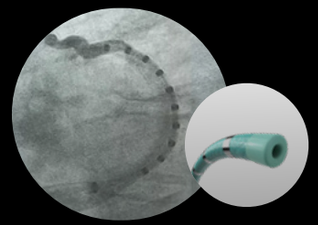
GUIDE

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 5-5-5 spacing



3F LUMEN

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

PINPOINT

EPstar 2F† Microcatheter

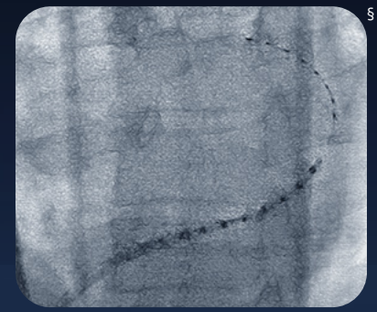
Enable mapping and pacing in distal coronary venous system branches with the octapolar† 2F Microcatheter for deeper diagnostic precision

GO FURTHER. KNOW MORE.

Access areas inaccessible to other catheters

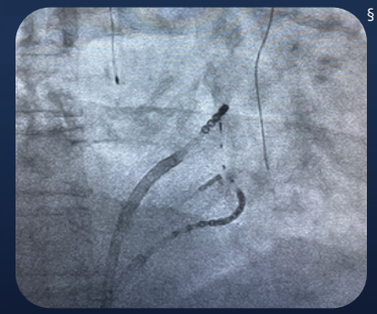
18 TOTAL ELECTRODES

Octapolar 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 PVCs[1-3]
- Complex ATs[4,5]
- Mapping and pacing in VOM[4,6]



Vein of Marshall Mapping

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

1. Komatsu et al., 2018, Circ Arrhythm Electrophysiol – (2F EPstar Fix)
2. Ito et al., 2005, PACE – (2F Pathfinder, Cardima)
3. Pothineni et al., 2021, Heart Rhythm – (2F EPstar Fix)
4. Kawamura et al., 2019, J Interv Card Electrophysiol – (2F EPstar Fix)
5. Yamamoto et al., 2014, Heart Rhythm – (2F EPstar)
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