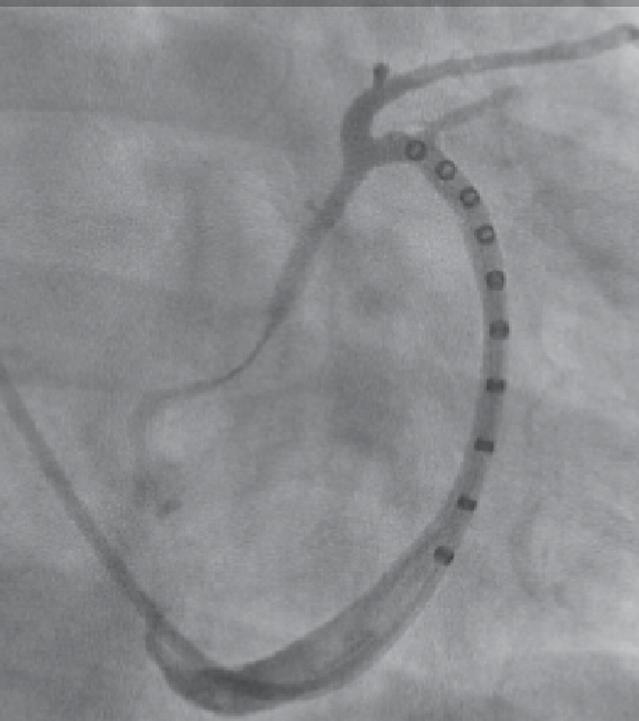


# KNOW MORE

- Large inner lumen size
- Able to flush contrast agent
- Compatible with 2F EPstar Catheters and 0.035" guidewires
- For superior vein access only

Coronary sinus angiography with contrast



## SPECIFICATIONS

Product Name	French Size	Product Code	Electrodes	Electrode Spacing	Electrode size	Usable Length
EPstar Fixed Electrophysiology Catheter with Lumen	6F	DLF-6-10-55-65	10 Decapolar	5-5-5 mm	1.2 mm	65 cm
EPstar Fixed Electrophysiology Catheter with Lumen	6F	DLF-6-10-28-65	10 Decapolar	2-8-2 mm	1.2 mm	65 cm
EPstar Fixed Electrophysiology Catheter	2F	DCF-2-8-55-130	8 Octapolar	5-5-5 mm	1.3 mm, distal tip: 1.5 mm	130 cm
EPstar Electrophysiology Cable (10 pins, resterilizable – 5 uses)	N/A	DEX-10	N/A	N/A	N/A	2.3 m
EPstar Bundle 2F + 6F (555) Virtual Kit	N/A	DLK-2-55-6-55-65	N/A	N/A	N/A	N/A
EPstar Bundle 2F + 6F (282) Virtual Kit	N/A	DLK-2-55-6-28-65	N/A	N/A	N/A	N/A

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Advancing science for life™

Baylis Medical Company Inc.  
5959 Trans-Canada Highway  
Montreal, QC Canada H4T1A1  
[www.baylismedical.com](http://www.baylismedical.com)  
[info@baylismedical.com](mailto:info@baylismedical.com)

General Inquiries  
(514) 488-9801

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EP-1629905-AA

### 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.

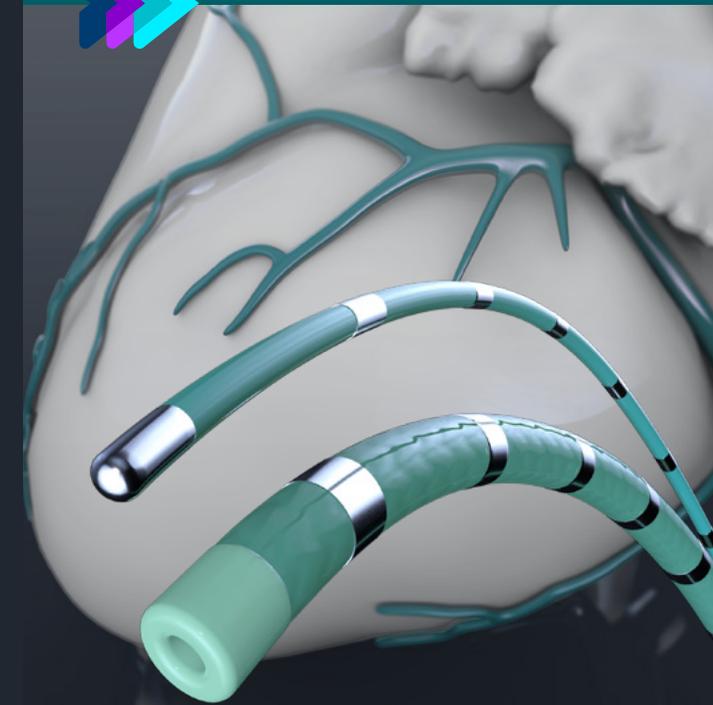
**WARNINGS:** • The EPstar Fixed Electrophysiology Catheter is intended for single patient use only. Do not attempt to sterilize and reuse the catheter. Reuse can cause the patient injury and/or the transmission of infectious disease(s) from one patient to another. Reuse may result in patient complications. • 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 includes: • 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 • Ecthyoma 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

# EPstar Fixed Electrophysiology Catheters



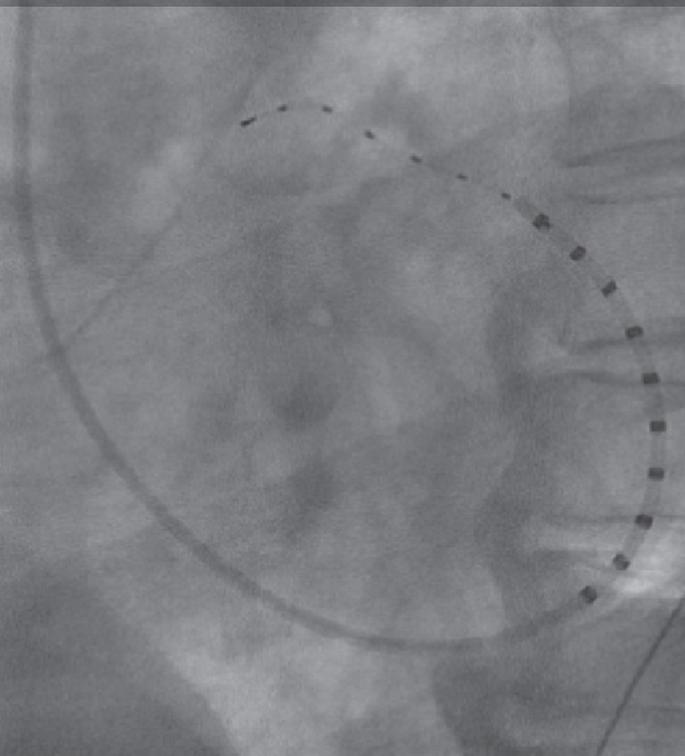
# GO FURTHER KNOW MORE

Deeper diagnostic precision for coronary sinus access and beyond

# GO FURTHER

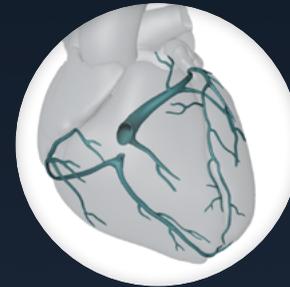
- Reach previously inaccessible areas of the coronary sinus
- Flexible and atraumatic tip
- Pacing even from distal electrode

Distal mapping of coronary sinus



## 6F CHOOSE

Two electrode spacing choices, 2-8-2 or 5-5-5, to tailor your procedure



## 2F EXPLORE

Deeper CS mapping has been used for:

- Idiopathic VTs and PVCs<sup>1-3</sup>
- Complex ATs<sup>4,5</sup>
- Mapping and pacing in vein of Marshall<sup>4,6</sup>

<sup>1</sup> Komatsu et al., 2018, Circ Arrhythm Electrophysiol – (2F EPstar Fix)  
<sup>2</sup> Ito et al., 2005, PACE – (2F Pathfinder, Cardima)  
<sup>3</sup> Pothineni et al., 2021, Heart Rhythm – (2F EPstar Fix)  
<sup>4</sup> Kawamura et al., 2019, J Interv Card Electrophysiol – (2F EPstar Fix)  
<sup>5</sup> Yamamoto et al., 2014, Heart Rhythm – (2F EPstar)  
<sup>6</sup> Fujisawa et al., 2019, Pacing Clin Electrophysiol. – (2F EPstar Fix)



## 2F PACE

Pacing from all electrodes, including the distal electrode



## 2F & 6F BE CONFIDENT

Flexible and atraumatic distal tips facilitate confidence in coronary sinus access



## 6F CONTROL

Fully braided shaft, even under electrodes, allows greater maneuverability