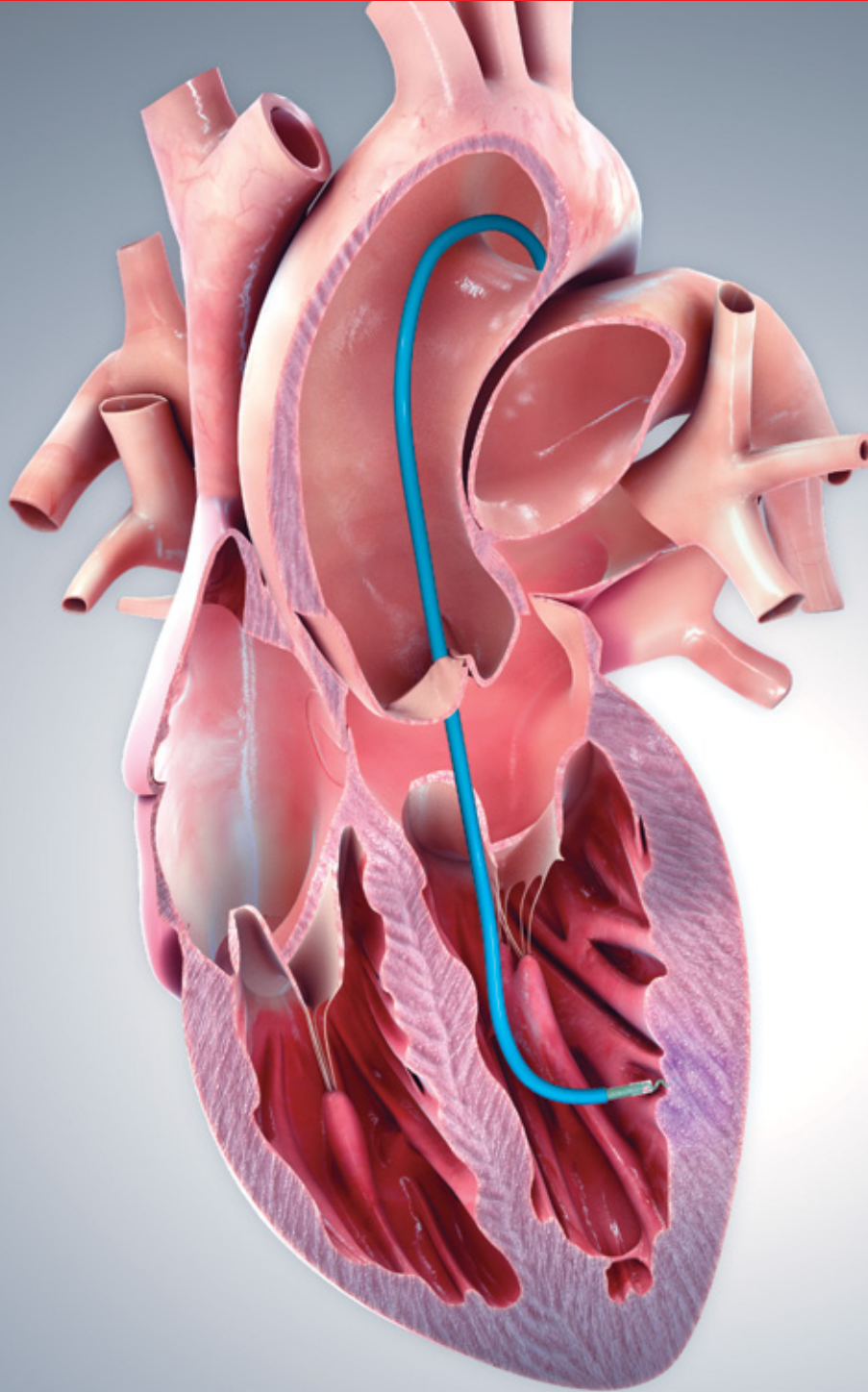


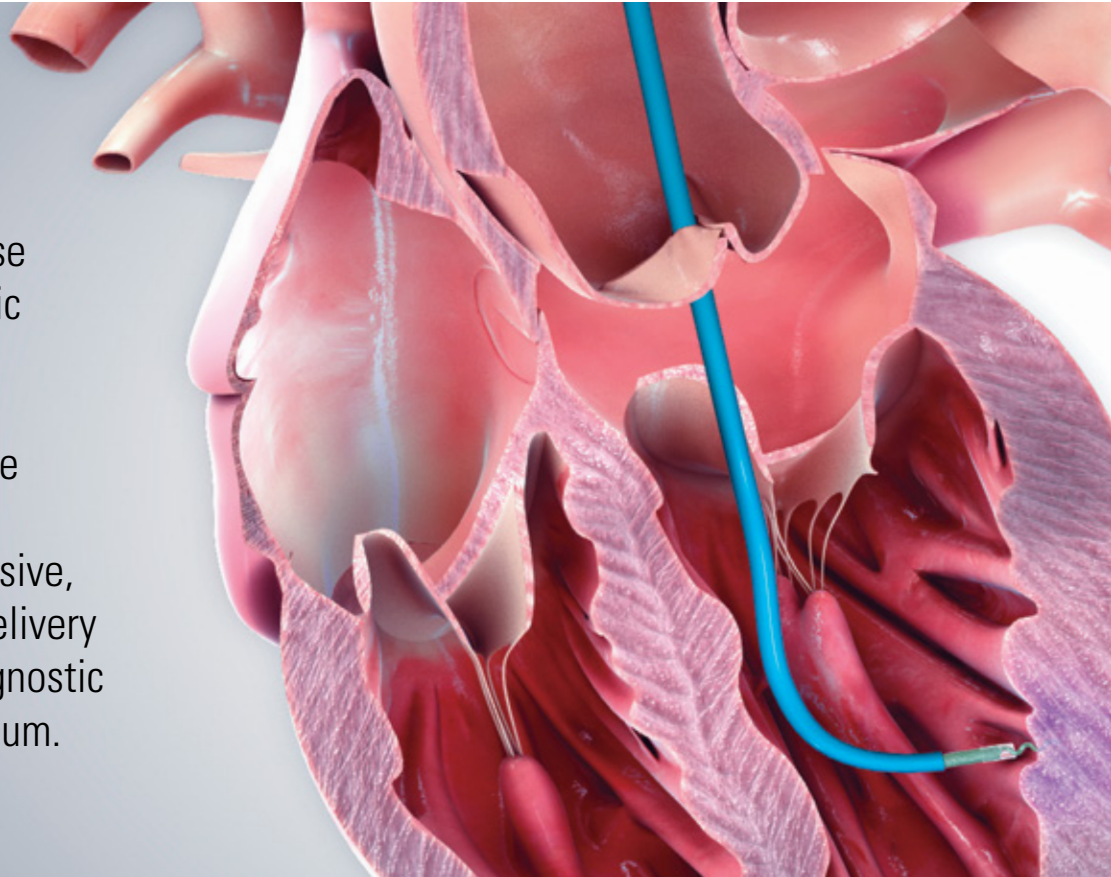
BIOCARDIA[®]

Helical Infusion System[™]



Regenerative Medicine in Cardiology

In cardiology, regenerative medicine holds enormous promise for heart failure, chronic myocardial ischemia, and acute myocardial infarction. Regenerative therapies are enabled through minimally invasive, precise and efficient delivery of therapeutic and diagnostic agents to the myocardium.



Procedure

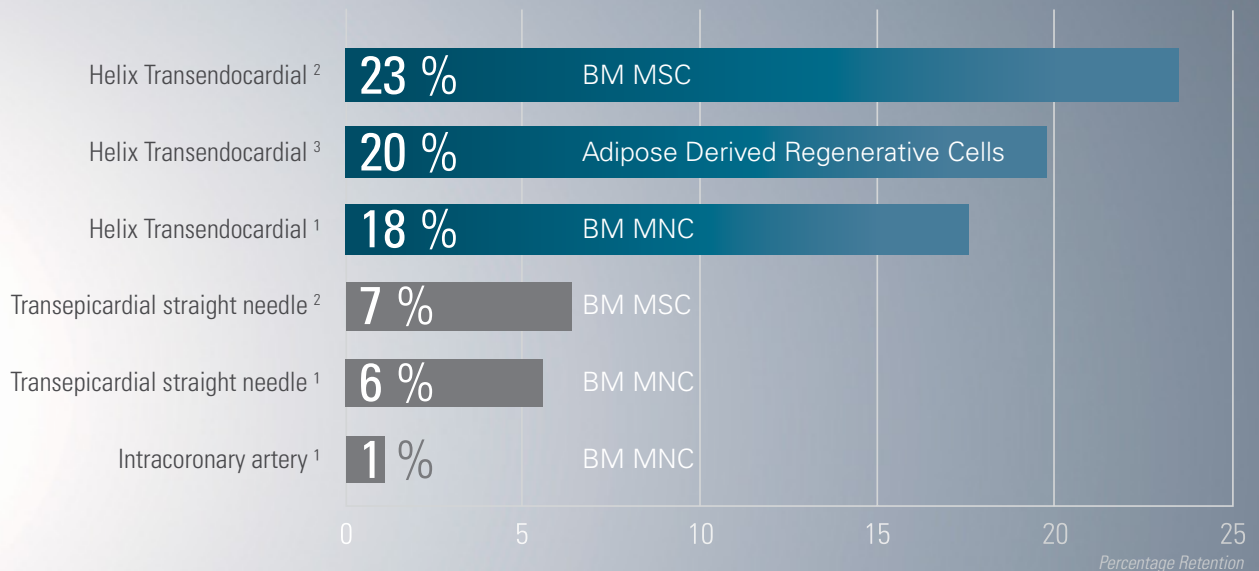
A typical procedure uses available clinical imaging data to define the target sites and a standard pigtail catheter to road map the left ventricle.

The Morph® Universal Deflectable Guiding Catheter is advanced through the aortic valve over a guide wire providing the ability to direct the Helical Infusion Catheter. The Helical Catheter is then advanced from within the Morph Guide until the tip gently touches the target tissue. After rotating into the tissue, engagement is confirmed with a contrast injection at the base of the needle. Once confirmed, a therapeutic agent is delivered through the tip of the helical needle.

Proven Pre-Clinical Performance

Bone Marrow and Adipose Derived Cells % Retention

Expressed in terms of Delivery Route, % Retention and Cell Type



SOURCE

¹ Wong Po Foo C, International Conference on Cell Therapy for Cardiovascular Disease, NYC, January 2013, 18F-FDG labeled cells.

² Cardio3 Biosciences, Report R-C3BS-PC-07-1c Version 1.0, dated December 3, 2007, 18F-FDG labeled cells.

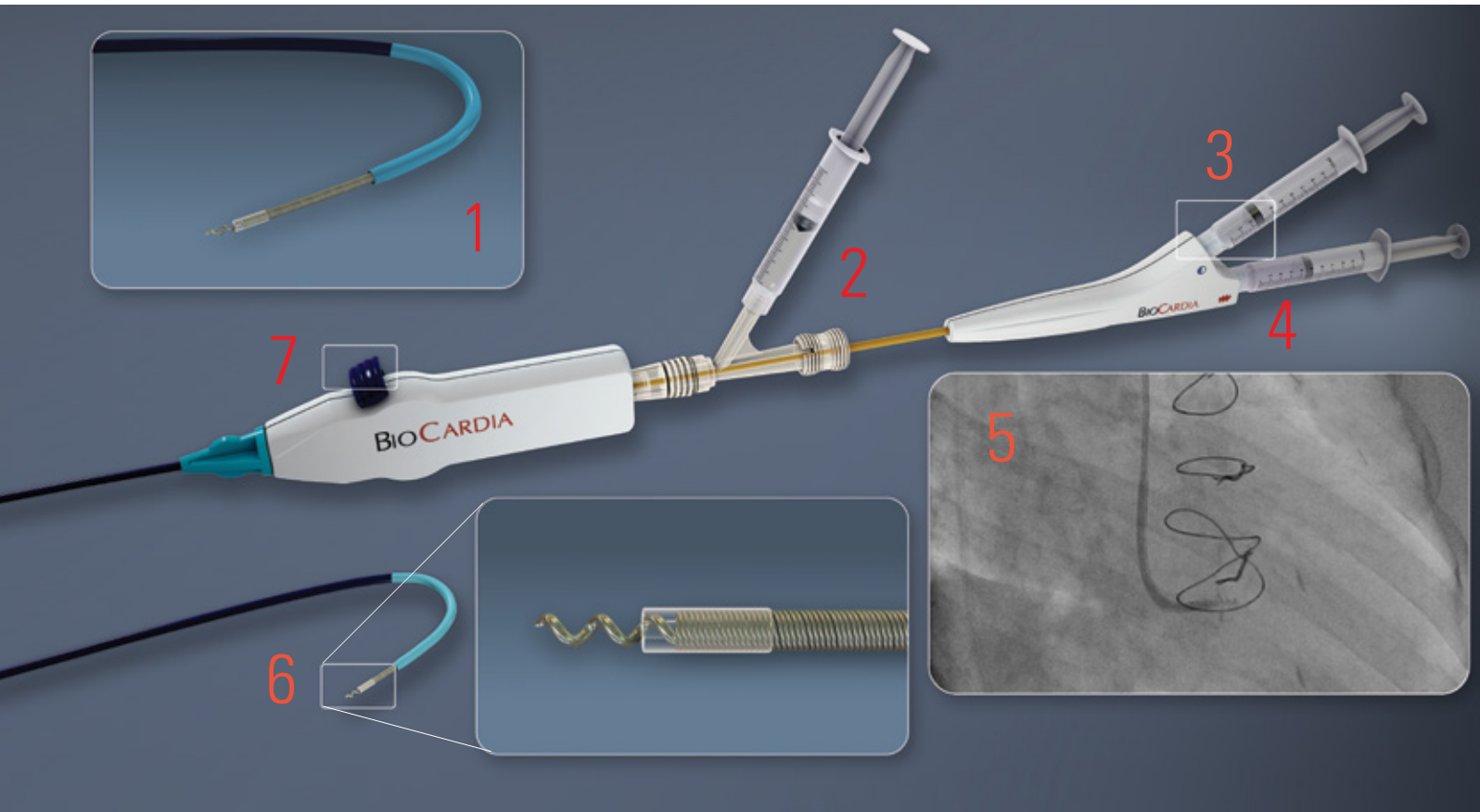
³ Perin E, 10th International Symposium on Cell Therapy and Cardiovascular Innovations, Madrid, Spain, June 2013, Madrid 2013. Biopal labeled cells

The Helical Infusion Catheter appears to have the most efficient delivery of any catheter system currently available. Peer reviewed preclinical swine studies have shown better retention when compared to intracoronary and straight needle transepical delivery. The classic intracoronary artery delivery route may not lead to the best therapeutic efficacy due to poor retention, lack of targeting and the inability to deliver to poorly perfused tissues.

Extensive Clinical Experience

The BioCardia Helical Infusion System has been safely used in hundreds of clinical cases with thousands of intramyocardial deliveries performed in the USA and around the world. For a detailed listing of peer reviewed manuscripts, go to www.biocardia.com.

BioCardia Helical Infusion System



Safety Advantages

- Crosses the aortic valve over a wire
- Use of a Morph Guide enhances navigation within the heart
- Engagement of the Helical needle is confirmed with a contrast injection at the base of the needle
- The stability of engagement within the myocardium provided by the Helical needle is believed to enhance retention of agents in the target tissue

1. Helical Infusion Catheter advanced within Morph Guide Catheter
2. Y-connector for continuous flush
3. Contrast lumen
4. Therapeutic agent lumen
5. Helical tip engaged in myocardium
6. Helical needle with contrast lumen at base of needle
7. Control knob to deflect Morph tip

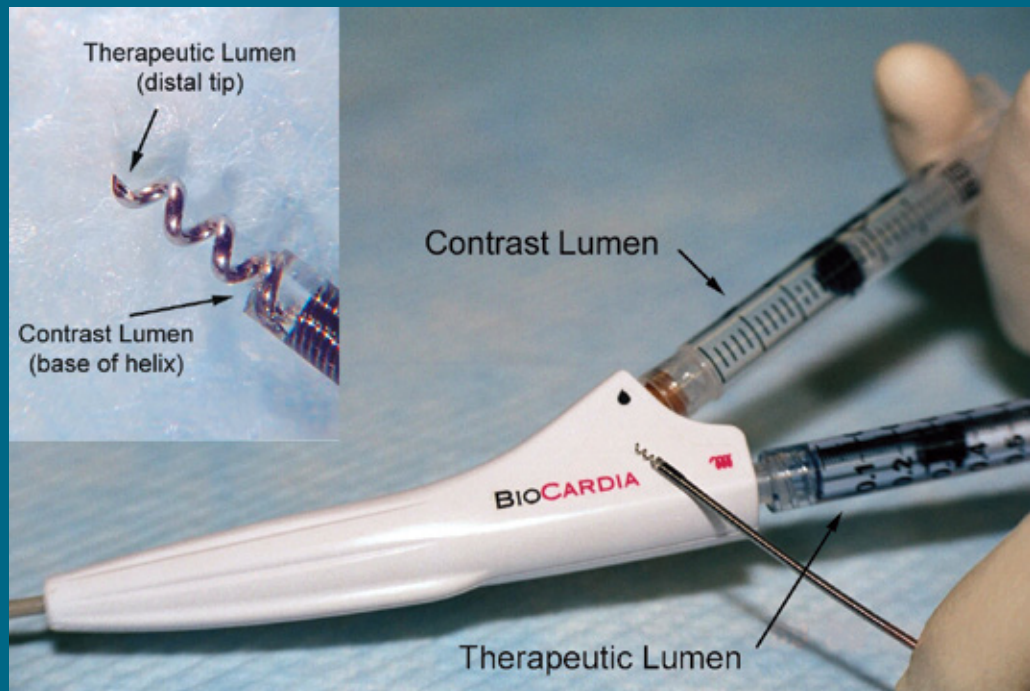
Technical Specifications

Helical Infusion Catheter

- 5.2 Fr O.D. / 136 cm long / dual lumen
- Braided reinforced shaft results in high torque transmission
- Radiopaque for fluoroscopic visibility
- Contrast lumen for anchoring confirmation under fluoroscopy
- CE Mark

Morph Universal Guiding Catheter

- 8 Fr .124 cm long
- Braided shaft for torque response
- PTFE lined inner lumen for lubricity
- Proximal luer fitting for accessories
- Distal soft tip
- Curve reach of 3.0 cm
- CE Mark and FDA 510K cleared



For Inquiries:
+1-800-624-1179

PRODUCT	EU	USA	CATALOG NO.	SIZE	LENGTH
Morph Universal Guide Catheter	CE Mark	510K Cleared	00895	8 Fr	124 cm
Helical Infusion Catheter	CE Mark	Investigational	00953	5.2 Fr	136 cm
Helical Infusion Catheter	Pending	Investigational	00953L	5.2 Fr	138 cm

BioCardia's Helical Infusion Catheter is commercially available in the European Union. CAUTION – Investigational Device. Limited by Federal (or United States) law to investigational use.

BIOCARDIA®

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