URGENT FIELD SAFETY NOTICE **issued: 7 February, 2017**

Affected products:	model number	lot number
BioCardia Helical Infusion Catheter	00953L	01347, 01362
BioCardia Morph Universal Deflectable Guide Catheter	00895	01309

Notification: BioCardia has revised our Instructions For Use (copy attached) to include clarifying guidelines for medical management of patients who experience an Adverse Event that may be related to the use of the aforementioned products. The following is the existing text related to Potential Adverse Events in the Instructions For Use (IFU) with the changes identified in bold, red text:

Potential Adverse Events, which may result in serious injury or death

- Cardiac perforation leading to pericardial effusion or tamponade
- Vascular perforation
- Air, plaque or thrombo-embolism
- Damage to vessels or cardiac structures, including heart valves
- **Unstable** arrhythmias, including ventricular tachycardia, bradycardia, atrial or ventricular fibrillation or heart block
- Myocardial infarction
- Stroke
- Infection

Subject to clinical assessment of the patient and knowledge of standard of care, it is recommended that the procedure be discontinued if any of the foregoing Potential Adverse Events is suspected of occurring, or if the patient requires medical intervention to correct the condition.

Description of the Problem: We have provided these instructions due to a procedure where a patient experienced three episodes of ventricular tachyarrhythmia- one related to initial guidewire placement in the ventricle and two related to use of the Helical Infusion Catheter with the Morph Guide during positioning within the left ventricle. The second two episodes required external defibrillation to restore sinus rhythm.

The patient was not injured, but the treatment was aborted before all planned injections could be performed.

There are no other changes to the products, and this Notice has not been made in response to any deficiency or malfunction of the products.

While the patient experience was related to one previously identified adverse event, the addition to the IFU relates to all potential adverse events that may occur due to the use of the BioCardia products.

Nothing in these instructions should pre-empt the best clinical judgment of the treating physician regarding current standard of care treatment of the specific patient's medical condition.

Scope: This notification applies to all BioCardia products indicated for use in the chambers of the heart. These guidelines are likely also applicable to any device that is placed into the chambers of the heart that identifies arrhythmia as a potential risk.

Your feedback: We request your feedback regarding these changes and whether they clearly convey the instructions or if we could better communicate this issue to future users of our products.

Required Actions: There is no required action regarding the product that you have ordered for your use. The inventory will be re-worked to contain the updated Instructions For Use by the BioCardia support team who will be present at the time of the next use of the devices as specified in our Clinical Support Agreement.

A BioCardia Clinical Representative may contact before this time you to review this Notice and answer any questions you have.

We request that you confirm receipt of this Notice by filling out the bottom of this page, signing it and returning it by fax or scanned pdf document to the Contacts below.

Contacts: Please contact us if you have any further questions regarding this notification.

Dr. Eric Duckers, MD PhD FESC
Chief Medical Officer
BioCardia, Inc.
125 Shoreway Road, Suite B
San Carlos, CA 94070 USA
Ph: +1 650 226-0120
Fax: +1 650 631-3731
educkers@biocardia.com

Andy Mackenzie
VP Regulatory
BioCardia, Inc.
125 Shoreway Road, Suite B
San Carlos, CA 94070 USA
+1 650 226-0120
Fax: +1 650 631-3731
amackenzie@biocardia.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

…

Andy Mackenzie

****

Confirmation of receipt and replacement of Instructions for Use

Facility:	
Name:	
Signature:	**Date**
Questions or comments:	