Date: 26 April 2019

Urgent Field Safety Notice
WiSE CRT Electrode-Catheter Model 1000

For Attention of: Name of Physician(s) that implant the WiSE CRT System's Electrode

The attached Field Safety Notice is being issued to alert you to the release of an updated Instructions For Use (IFU) for the WiSE CRT System's Electrode-Catheter Model 1000. This updated IFU is being released to address issues associated with detachment of the Electrode from the Catheter. The updated IFU will allow you to identify and address the issue.

EBR Systems received six complaints related to detachment of the Electrode from the Catheter. Four of these were related to inability to confirm detachment after it had occurred; two of these were related to inability to detach the electrode from the catheter despite activating the release mechanism.

The anticipated risk to patients is considered low. If this issue is experienced it will likely result in prolonging procedure time by approximately 15-minutes.

All physicians who implant the WiSE CRT System should refer to the attached updated IFU. Additional training will be provided by an EBR Technical field representative prior to your next implant. The enclosed Acknowledgement Form will need to be completed and returned via email to: cchung-thornton@ebrsystemsinc.com.

Contact Details of:

Manufacturer
EBR Systems, Inc
E-mail: support@ebrsystemsinc.com
Telephone: +1 408.720.1906

Local Representative
Name:
E-mail:
Telephone:

Urgent Field Safety Notice (FSN)
WiSE CRT Electrode-Catheter Model 1000
Receiver Electrode Detachment Issue

1. Information on Affected Devices	
1.	**1. Device Type(s)**
	The Electrode-Catheter Model 1000 is an 8-French catheter with an Electrode preloaded on to the distal end. The Electrode-Catheter is provided sterile and is a single use device.
1.	**2. Commercial name(s)**
	WiSE CRT Electrode-Catheter Model 1000
1.	**3. Unique Device Identifier(s) (UDI-DI)**
	UDI: 00859244007043
1.	**4. Primary clinical purpose of device(s)**
	The Electrode-Catheter Model 1000, along with the Sheath Model 2000, forms part of the delivery system to advance the Electrode-Catheter into the left ventricle and to anchor the Electrode into the heart tissue. The Electrode is an ultrasound energy receiver and energy converter implanted on the endocardium to pace the left ventricle.
1.	**5. Device Model/Catalogue/part number(s)**
	Model 1000
1.	**6. Affected serial or lot number range**
	Refer to Appendix A for the list of affected Model 1000 products in your hospital's inventory that were manufactured prior to November 2018. These are from lots that may exhibit detach indicator issue (complaint rate 3.1%). All product manufactured from December 2018 onwards have new indicator stickers applied. All Model 1000 product manufactured to date have the potential issue for increased friction in the handle assembly and ball assembly failure.

2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	EBR Systems received six complaints associated with detachment issues of the Electrode on the Electrode-Catheter Model 1000. The implanters were not able to readily confirm detachment of the Electrode and/or experienced difficulty getting the Electrode to release and/or experienced partial detachment of the Electrode during the release steps with the Model 1000 catheter.
2.	**2. Hazard giving rise to the FSCA**

	The following hazards have been observed by users related to the Model 1000 detachment issues: • An adhesive failure of the detach indicator inside the handle (i.e. the color remains green even if Electrode has detached), • Increased friction between components of the handle assembly preventing the Electrode from detaching from the catheter, and • Increased friction between components of the handle assembly resulting in the Electrode partially detaching from the catheter. Although not observed, the above hazards could potentially lead to the following patient risk: • Device embolization could occur if a cascade of events occurs. First, friction within the catheter prevents full electrode detachment which then leads to a handle that does not indicate that it is detached and then the end user pulls the sheath away from the wall, exposing the un-anchored electrode which can then become an embolus. The severity of this harm is, worst case, death due to device embolization. By following guidance within the updated IFU, potential hazards are expected to be reduced to: • Prolonged procedure time associated with having to remove defective device, inserting and positioning replacement device. The additional time is estimated as 15 minutes. The severity of this harm is potential for patient or user annoyance, does not result in any patient injury. • Prolonged procedure time associated with performing the manual release of the Electrode. The additional time is estimated as 5 minutes. The severity of this harm is potential for patient or user annoyance, does not result in any patient injury.
2.	**3. Probability of problem arising**
	The likelihood that the problems will occur, based on current complaint data, is approximately 2.5%. Three (3) detach indicator problems have been reported out of 131 uses and 3 friction-related problems have been reported out of 131 uses.
2.	**4. Predicted risk to patient/users**
	The anticipated risk to the patient for Electrode detachment problems is Low Risk.

3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) The amended IFU provided as Appendix B, should be reviewed by all implanters. Additional training will be provided by EBR technical field representatives prior to the next implant to ensure the implanters understanding, and to answer any questions or concerns.

3.	2. By when should the action be completed?	Ahead of next scheduled device implant
3.	**3. Is customer Reply Required?**	Yes (see Appendix C)

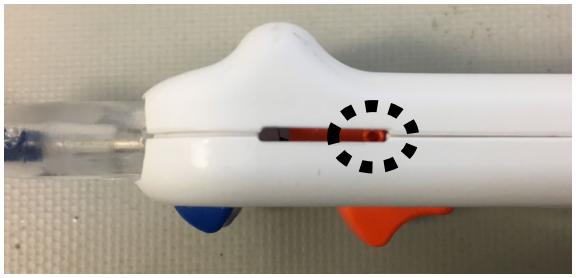
3. **Action Being Taken by the Manufacturer**

☒ IFU or labelling change

☒ Other: Additional Training

The following actions are currently in place to address the device problem:

- An EBR technical field representative will provide training to all implanters ahead of their next implant, and
- An EBR technical field representative will be present at every procedure to provide support to the implanter, and
- There are additional real-time indicators during the procedure to aid in the assessment of electrode detachment such as EGM signal and the position of the circle of the orange indicator on the side of the handle (described below). This orange indicator may also be referred to as “boss”. This is the same sliding part that contains the detach indicator.
    - If the user is uncertain whether or not the electrode was successfully detached, the EBR technical field representative will advise the user to look on the slot on the side of the handle to confirm electrode detachment. Electrode detachment is confirmed when the circle of the orange indicator is positioned on the proximal side of the handle (see below figure, where indicator is shown in the dashed-circle).
    - In the scenario where it is unknown if the Electrode has completely detached, a manual completion of the electrode detachment procedure step can be performed, as detailed in Appendix B.



Short term implementation of the above actions is to provide the required details in Appendix B of this Field Safety Notice so that the user is aware of and understands the potential Model 1000 detachment problems and the appropriate steps to evaluate and resolve the issues.

The long term implementation is to distribute the amended Instructions for Use document to users once the Notified Body has completed their review of the amended information.

3	4. By when should the action be completed?	Ahead of next scheduled implant
3.	5. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	4. List of attachments/appendices:	**Appendix A:** List of Devices from Manufacturing Lots Associated with Detach Indicator Issue **Appendix B:** Amended Electrode Delivery System Instructions for Use **Appendix C:** Acknowledgment Form
4.	5. Name/Signature	Brandi Johnson VP of Clinical, Quality and Compliance
		

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Appendix A: List of Devices from Manufacturing Lots Associated with Detach Indicator Issue (complaint rate = 3.1%)

Location	Serial Number(s)	# of Units
NAME	SERIAL NUMBER(S)	QTY

Appendix B: Amended Electrode Delivery System Instructions for Use

WiSE CRT System Electrode Delivery System Instructions for Use (IFU)

After the procedural step of selecting a suitable endocardial LV implant site (per *section 2.11 Evaluation a Site in the Left Ventricle), section 2.12 Anchoring, Detaching and Releasing the Electrode* provides the instructions to anchor the electrode in the tissue.

The IFU advises that there is a potential for embolization of the electrode, which could cause serious patient harm or death. The specific warning statement is provided below:

> **WARNING –** Electrodes that do not anchor to the heart wall will embolize causing serious patient harm or death. If after anchoring the Electrode to the tissue, the appearance of the Electrode and the Electrode Delivery System on x-ray fluoroscopy indicate that the Electrode is not stable and securely anchored to the heart wall, do not detach the Electrode, do not attempt to reposition or to insert the Electrode into the tissue – the Electrode Delivery System with the Electrode must be cautiously removed from the body.

Additionally, section 2.12 provides the below key safety mitigation steps to follow to ensure the safe and effective implant of the Electrode.

> ***IMPORTANT!*** Maintain the Sheath position throughout the anchoring, detaching, and release process. Maintain torque being held on the shaft of the Sheath at the introducer until the Electrode has been released from the Sheath.
>
> ***IMPORTANT!*** It is important to maintain the position of the Electrode within the Sheath throughout the anchoring process. Do not extend the body of the Electrode more than 50% past the end of the Sheath during anchoring.
>
> ***IMPORTANT!*** If it is necessary to remove the Catheter from the Sheath, carefully extract the Insertion Tool with the Catheter still inside. The Insertion Tool opens the stasis valve in the Sheath. Extracting the Catheter from the Insertion Tool will lose stasis of the Sheath.
>
> ***IMPORTANT!*** If it is necessary to remove the Catheter from the Sheath, ensure that the Electrode does not remain behind in the Sheath; that it is still attached to the Catheter after it is removed. After extracting the Catheter from the Sheath, push the Catheter forward beyond the Insertion Tool and inspect the end of the Catheter to confirm that the Electrode is present.
>
> ***IMPORTANT!*** If it is necessary to remove the Electrode Delivery System with the Electrode still attached to the Catheter or with the Electrode unattached but still within the Sheath, remove the entire system with the following considerations:
>
> - Ensure that the Electrode is in the Sheath. If necessary carefully pull the Catheter and advance the Sheath to ensure the Electrode is captured.
> - Do not flush or inject fluid or dye as this may eject the Electrode from the Sheath. Turn off the positive pressure drip lines.

- If the Electrode is not attached to the Catheter, pull very slightly on the Catheter to create a vacuum in the distal end to assist with holding the Electrode in place. This action may have the desirable effect of drawing the Electrode further into the Sheath.
- After the system is past the aortic valve into the aorta, deflate the balloon by opening the stop cock and pulling back on the 3 cc syringe plunger. It will take several seconds for the balloon to deflate. The balloon must be deflated prior to completely removing the system through the introducer. If significant resistance is felt while removing the Sheath, check that the balloon has deflated.
- Remove the entire Electrode Delivery System by pulling the Sheath back through the introducer. Do not pull the Catheter back through the Sheath.
- Withdraw the Electrode Delivery System completely through the introducer using fluoroscopic guidance.

However, in the event that, after following the required IFU step of pushing the detach button (orange button) forward, there is no indication of detachment (viewing port color did not change from green to orange) and it is uncertain whether or not the Electrode has successfully detached, you may either:

- **Follow the steps in the IFU to remove the Electrode Delivery System; or**
- **Complete the following sequence of steps to visually assess detachment, and if indicated, perform a manual Electrode detachment.**

1. Visual Assessment: On the catheter handle, examine the side port and determine the position of the orange circle (also referred to as "boss"). If it is fully proximal, as shown below in Figure 1, indicating that the Electrode is detached, proceed to release the electrode from the sheath per the IFU. If the "boss" is not proximal (as shown in **Figure 2**), indicating that the Electrode is not detached, proceed to step 2 below, Manual Detach

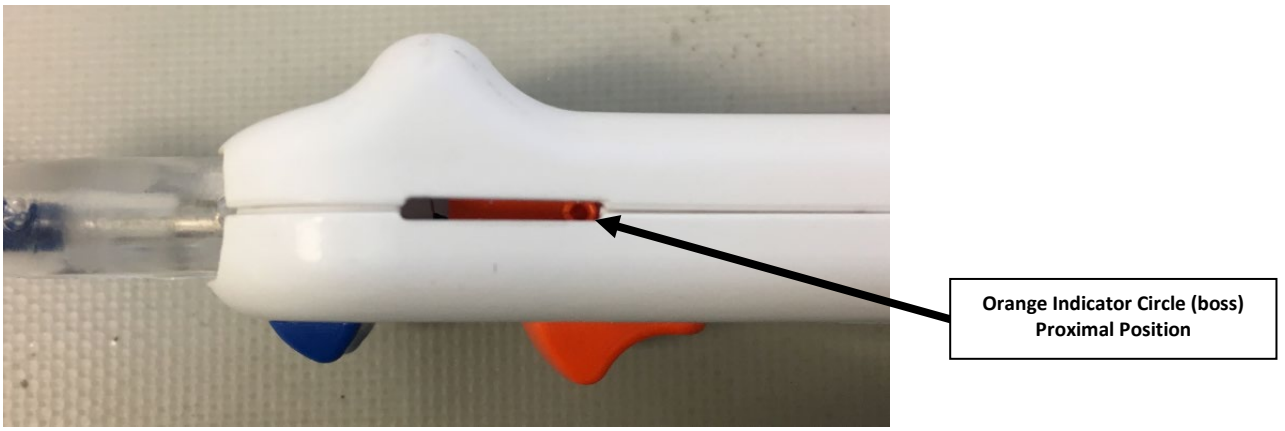


Figure 1: Electrode Detached - Orange Indicator Circle (boss) at Proximal Side of Handle

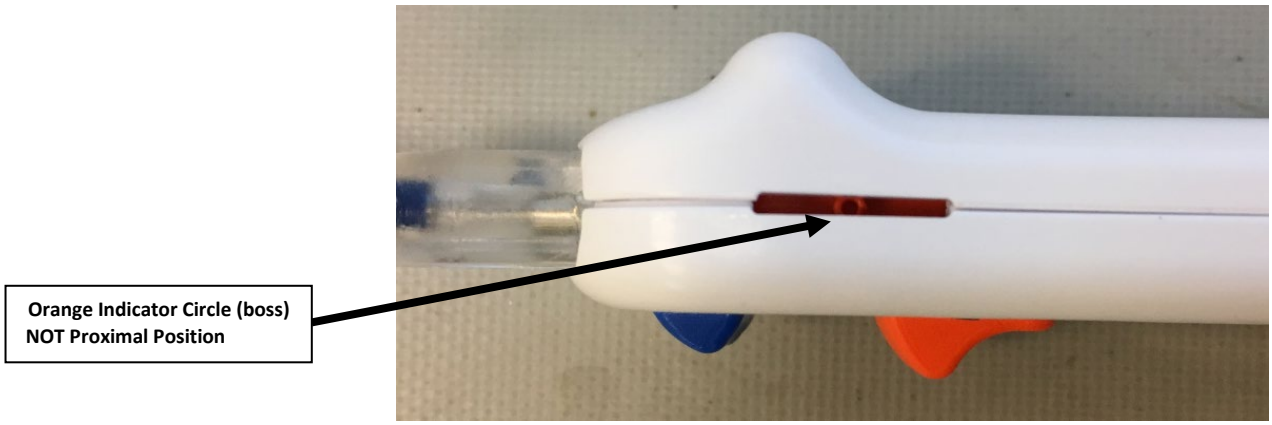


Figure 2: Electrode not Detached - Orange Indicator Circle (boss) NOT at Proximal Side of Handle

2. Manual Detach: While maintaining the position of the Electrode and Delivery Sheath, as shown below in **Figure 3**, push and hold the orange detach button forward and at the same time insert a tool like a forceps or similar into the side port to engage the "boss" (orange circle), and slide the "boss" proximal. The distal tip of the tool should be approximately 1mm diameter and 7mm long to engage the boss feature. Afterwards, release detach button and verify the orange circle (boss) remains fully proximal. If proximal (as shown above in Figure 1), proceed to release the electrode from the sheath per the IFU. If the Orange Indicator Boss is not proximal (as shown in Figure 2**, follow the steps in the IFU to remove the Electrode Delivery System.**

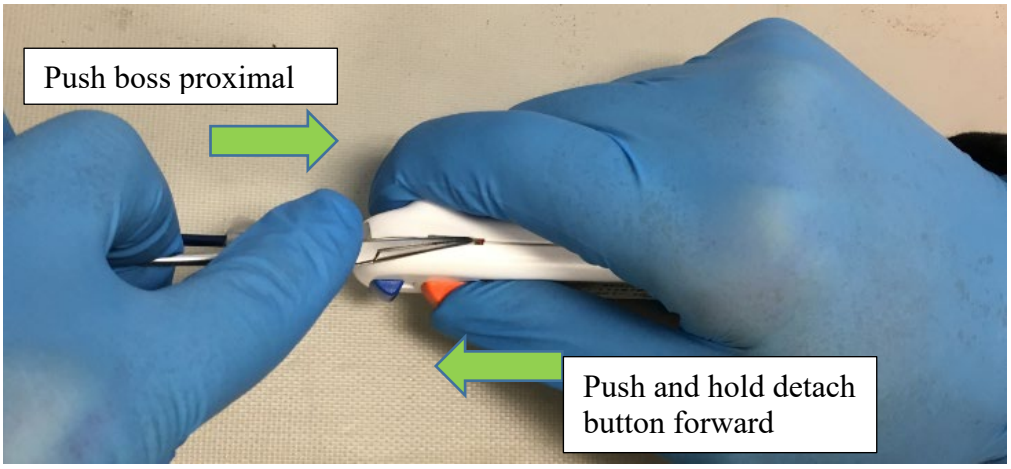


Figure 3: Electrode Manual Release

Appendix C: Acknowledgement Form

Complete this Acknowledgement Form and return to Chi Chung-Thornton, Director of Regulatory Affairs / Regulatory Compliance via email:
cchung-thornton@ebrsystemsinc.com

- We confirm that we have received, read and understood information contained within the Field Safety Notice.
- We confirm that we will take into advisement the actions defined in the Field Safety Notice.

Form completed by:

NAME	TITLE / ROLE
SIGNATURE	**DATE**
HOSPITAL NAME	