
Urgent Field Safety Notice**Revivent TC Ventricular Enhancement System
Revised Instructions for Use, Precautions**

Date: 22 January, 2018

Attention:

Details on affected devices:

Several important changes have been made to the Instructions for Use to reduce the potential risk to patients being treated with the Revivent TC System. Specifically, the following changes have been made:

1. The Instructions have been modified to identify 3 additional or modified steps as follows.
 - First, the instructions for placement of the anchors has been modified to add the following – “Determine location of incision by placing an instrument under fluoroscopy at the desired location and ensure that the position allows access to the LV apex for placement of the most basal anchor pair.”
 - In addition, the following instruction has been added – “Place a “leash” or tethering mechanism to manipulate the heart. The “leash” consists of a 2-0 double pledgeted, horizontal mattress suture with a tourniquet. The “Leash” should be placed in the epicardial scar tissue of the heart using suture and pledgets appropriately deep in the scar to prevent pulling through the wall of the heart. The site of the leash should be about half way between the lateral scar margin and the LAD at the level of the RV-apical anchor on the LV epicardium. Additional leashes may be placed in the scar as necessary to allow appropriate cardiac manipulation. Leashes should be placed only in scar intended for exclusion.
 - Finally, the following instruction was modified to provide additional clarity – “Advance a pigtail catheter over a guidewire through the 14Fr Introducer (which has crossed the tricuspid valve) to the RV apex and perform an RV ventriculogram to assess the size and morphology of the RV to direct subsequent needle placement.”
2. Two new Precautions have been added as follows:
 - Excessive manipulation (especially twisting) of the anchor delivery catheter during placement of the anchors on the septum must be strictly avoided. Excessive manipulation of the anchor delivery catheter while still attached to the anchor can cause damage to RV structures or unintended release of the anchor.
 - Placement of anchors outside the scar margin may result in immediate erosion of anchors through the heart wall resulting in a ventricular-septal defect (VSD).

Description of the problem:

Two recent adverse events occurred in patients treated with the Revivent System. In one case damage to the RV occurred during placement of the Revivent TC System causing excessive bleeding requiring surgical repair of the RV. In a second patient, during or immediately following anchor placement, the anchors pulled through the septum causing a VSD which also required surgical repair.



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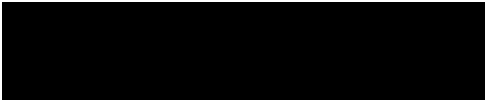
Placement of anchors in the correct position using the correct amount of manipulation is critical. Conversion to open surgery can be very traumatic for these high risk patients who typically have multiple co-morbidities. Therefore, corrective and preventative action is being taken to reduce the risk of recurrence of these events in the future.

This information has been incorporated into the BioVentrix Revivent TC training program. BioVentrix personnel will perform retraining at your institution covering these procedural modifications prior to your next case. If you have any questions or concerns, please contact me at the following address:

Contact reference person:

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The undersign confirms that this notice has been provided to the appropriate Regulatory Agency



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