

URGENT NOTICE – FIELD SAFETY NOTICE

April 10, 2015

**Hansen Medical Inc.'s Magellan Robotic System, model number 11139:  
FSCA-identifier 2015-04-10**

Dear Sir/Madam:

Purpose: The purpose of this letter is to inform you that Hansen Medical, Inc. has initiated a voluntary field safety correction of the Magellan Robotic System. Installed Magellan Robotic Systems are the subject of this field correction. No catheters or accessories are included. This field safety correction consists of notifying and re-training the Magellan physician-operator to the information contained herein.

Event Description: Hansen Medical has recently become aware of an incident, which occurred during a peripheral vascular case, during the catheter installation steps performed at the beginning of the procedure. A Magellan Robotic Catheter 6Fr was manually inserted a short distance into the patient's femoral artery, as required. However, during the subsequent catheter installation steps, system buttons were simultaneously pressed while removing, then reinstalling the guide wire support, which is a variation from the IFU instructions. During this unusual sequence of steps, the user pressed a button to retract the catheter, installed the guide wire support, then released the button. The catheter did not stop retracting as expected when the button was released. Instead, the system fully retracted the catheter, removing the introducer and patient patch along with the catheter, and vascular access was lost.

Potential Related Adverse Events: If the system continues retracting the catheter, the sequence of events noted above may occur, resulting in a loss of vascular access and hematoma. Conversely, if the system continues inserting the catheter, there is a risk of partial dissection or perforation.

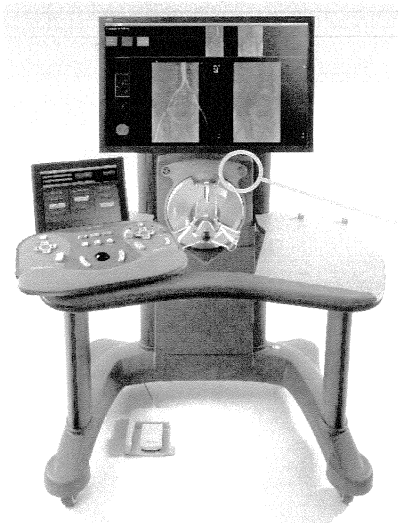
Frequency: The clinical event noted above is the only clinical event received to date relating to the unintended movement.

Actual Adverse Event: None, we have not received a report of an adverse clinical sequela resulting from the identified issue described above.

Action: If this situation should occur, press the Emergency Stop button as described in the Magellan Robotic System IFU.

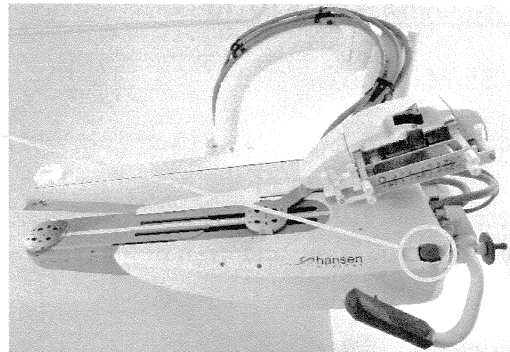
**Instructions for Use Reminder**

The Emergency-Stop button on the Workstation or Remote Catheter Manipulator (RCM) can be pressed at any time to stop Magellan Catheter motion. The Magellan Catheter will relax and the Magellan System will be placed in a safe, idle state.



Workstation

Emergency  
Stop Buttons



Remote Catheter Manipulator (RCM)

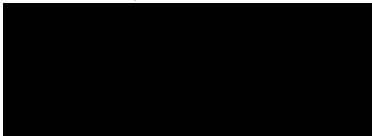
#### **Actions for User**

We request that you review the information in pages 1 and 2 with Hansen Medical personnel and acknowledge your understanding by signing the Field Safety Notice Training Form on page 3.

If you need any further information regarding this issue, please do not hesitate to contact your local Hansen Medical representative at +44 207 393 1900 or me via telephone at +1 650-404-2784 or via email at [elisa\\_aldridge@hansenmedical.com](mailto:elisa_aldridge@hansenmedical.com).

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

Sincerely,



Elisa Aldridge  
Regulatory Affairs  
Hansen Medical, Inc.

**Hansen Medical Magellan Robotic System**  
**Field Safety Notice Training Form**

Hospital Name \_\_\_\_\_

Trainer Signature \_\_\_\_\_

Print Name \_\_\_\_\_

Signature/Date \_\_\_\_\_

Title \_\_\_\_\_

I have read and understood the content of this Field Safety Notice.

Physician Signature \_\_\_\_\_

Print Name \_\_\_\_\_

Signature/Date \_\_\_\_\_

Title \_\_\_\_\_