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February 27, 2013

URGENT FIELD SAFETY NOTICE / PHYSICIAN ADVISORY

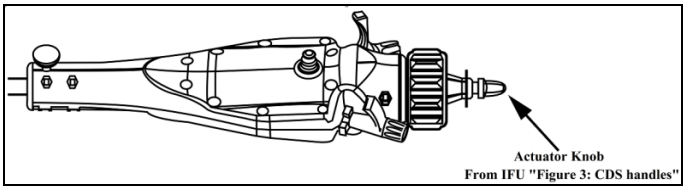
COMMERCIAL NAME: MitraClip Mitral Valve Repair System
FSCA-Identifier: February 27, 2013
Type of Action: Advice regarding the use of the device

Attention: Implanting Physician

Dear Valued Abbott Vascular Customer:

Abbott Vascular is voluntarily issuing this Field Safety Notice for the MitraClip Mitral Valve Repair System, product number MSK02ST. The MitraClip System contains the Clip Delivery System, product number CDS02ST and the Steerable Guide Catheter, product number SGC01ST. Please read this Field Safety Notice thoroughly to understand the issue and ensure continued safe use of the product.

Abbott Vascular has received a total of 4 reports to date (since 2008) where the Actuator Knob of the Clip Delivery System was incorrectly turned in the clockwise direction during Clip deployment. In the event that the Actuator Knob is incorrectly turned, the device may incur damage that prevents the deployment of the clip. This situation may require additional medical intervention or conversion to surgery, which could lead to complications including post-procedural death.



You are advised to consult the approved Instructions for Use that were distributed with each device, which contains important information for the proper Clip deployment steps. Specifically, step 17.2.2 states:

> *"Turn the Actuator knob of the DC approximately 8 turns counterclockwise. If it is difficult to turn the Actuator Knob, confirm that the Arm Positioner moves freely. Retract the Actuator Knob after it is fully unthreaded."*

Subsequent to this step, the following Warning appears:

> *"Failure to stop turning the Actuator Knob when resistance is felt or turning the Actuator Knob in the clockwise direction may result in inability to deploy the Clip."*

Abbott Vascular has completed corrective actions to add a directional arrow on the Actuator Knob of newly manufactured devices to aid in proper Clip deployment. Your

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current inventory of product is acceptable for safe use following the Instruction for Use steps highlighted above. Therefore, there is no need to return any product to Abbott Vascular. Finally, patients that have had Clips successfully implanted are not affected by this action.

The relevant Regulatory Agencies have also been made aware of this action.

Thank you for your attention to this matter, Please provide this FSN to those who need to be aware in your organization and address any questions you may have with your local Abbott Vascular representative.

Sincerely,

Paul Hodge

Country Manager, UK & Nordics

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Effectiveness Check Form

Customer Account # _____

Account Name _____

Address _____

_____

_____

Phone _____

(Information required for regulatory effectiveness check)

I acknowledge receiving and reading the February 27, 2013 MitraClip Physician Advisory Notice

_____ _____

Customer Name/ Title (print) Signature Date

This form is to be returned to Abbott Vascular

- Return this signed form to your Abbott Vascular Representative, or
- Fax this signed form to 0800 328 0868

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