URGENT FIELD SAFETY NOTICE/ MITRACLIP/ PHYSICIAN ADVISORY

COMMERCIAL NAME: MitraClip Clip Delivery System
FS CA-Identifier: February 4, 2016
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 Clip Delivery System, product number MSK02ST. The MitraClip System contains the Clip Delivery System, product number CDS02ST, and the Steerable Guide Catheter, product number SGC01ST.

Abbott Vascular has recently received nine reports of cases on Clip Delivery System devices that contain the One-Way Actuator Knob (Lot number 50714U1 and greater) where a user attempted implanting a MitraClip, but the Clip could not be detached from the delivery system due to a mandrel fracture. These cases resulted in surgical interventions and, in one case, the patient expired post-operatively due to severe comorbidities.

How does the issue occur?
The mandrel is an internal component of the Clip Delivery System that is integral to Clip function and deployment. Abbott Vascular's investigation determined that a mandrel fracture may occur if tension is present on the mandrel when turning the Actuator Knob to deploy the Clip. Tension is present if the Arm Positioner is on the "Closed" side of Neutral, as opposed to being in the Neutral position during Clip deployment.

What is Abbott Vascular doing?
While the current Instructions for Use (IFU) require the Arm Positioner to be in a Neutral position prior to turning the Actuator Knob to deploy the Clip, Abbott Vascular is revising the MitraClip IFU Clip deployment sequence to provide additional assurance that tension is completely eliminated prior to deploying the Clip. Abbott Vascular will train all MitraClip implanters on the revised instructions.

The following contains the revised instructions. It delineates what is changing and explains the step's importance in eliminating tension. Two figures accompany the table; Figure 1 annotates the relevant components, and Figure 2 provides a visual cue that demonstrates system tension is relieved.

What action is Abbott Vascular asking you to take?

- Read through this Field Safety Notice with the revised instructions carefully
- Participate in training with your Abbott Vascular representative
- Sign the provided Training Form
- Share this notification with other relevant personnel in your organization

IFU Step

12.0 CLIP DEPLOYMENT

12.1 Deployment Step 1: Lock Line Removal

12.1.1 Remove the Lock Lever Cap and "O" ring. Unwrap the two ends of the Lock Line. Remove the plastic cover from the lines so that no twists or knots are present.

12.1.2 Grasp one of the free ends of the Lock Line, confirm the line moves freely, and slowly remove the Lock Line. Pull the Lock Line coaxial to the Lock Lever. If resistance is noted, stop and pull on the other free end to remove the Lock Line.

12.1.3 *Establish Final Arm Angle.*

Note: The Clip Arms may open slightly before remaining in a stable position. If Arms open more than slightly, close the Clip to the desired Arm position and re-*Establish Final Arm Angle*.

12.1.4 Turn the *Arm Positioner* to *Neutral.*

12.2 Deployment Step 2: Delivery Catheter Shaft Detachment

12.2.1 Confirm that the Arm Positioner is Neutral and that the two ends of the Gripper Line have been unwrapped from under the cap and are not twisted or knotted. Remove the Release Pin from the DC Handle.

12.2.2 Turn the Arm Positioner in the "Open" direction until the Release Pin groove is fully exposed.

Note: After the Release Pin is removed, turning the Arm Positioner in the "Open" direction will not open the Clip Arms.

12.2.3 Turn the Actuator Knob of the Delivery Catheter (DC) approximately 8 turns counterclockwise.

If it is difficult to turn the Actuator Knob, STOP and confirm that the Arm Positioner has been turned in the "Open" direction, such that the Release Pin groove is fully exposed.

Warning: 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. Inability to deploy the Clip may result in worsening mitral regurgitation, cardiac injury, a single leaflet device attachment (SLDA), and/or conversion to surgical intervention.

12.2.4 Release the DC Fastener then retract the Actuator Knob after it is fully unthreaded.

12.2.5 Retract the DC Handle such that the Clip has separated at least 1 cm from the DC tip.

12.2.6 Secure the DC Fastener.

12.2.7 Allow several minutes after catheter shaft detachment before proceeding to the final Clip deployment step. Use echocardiographic imaging to verify valve function, satisfactory coaptation, and insertion of both leaflets by observation of:

- Leaflet immobilization
- Single or multiple valve orifice(s)
- Limited leaflet mobility relative to the tips of both Clip Arms
- Adequate MR reduction.

WARNING: If Clip placement and/or MR reduction is not satisfactory after Deployment Step 2: Delivery Catheter Shaft Detachment, DO NOT proceed to Deployment Step 3: Gripper Line Removal. Intervention may be required to remove the Clip.

Existing Text

Requires that the Arm Positioner be turned to Neutral, which resolves system tension.

Revised Section

The revisions, which are identifiable within the boxed text, ensure tension is fully removed from the system before deploying the Clip from the Delivery Catheter. They also provide a visual cue (exposed Release Pin groove in Figure 2) to verify the device is not storing tension.

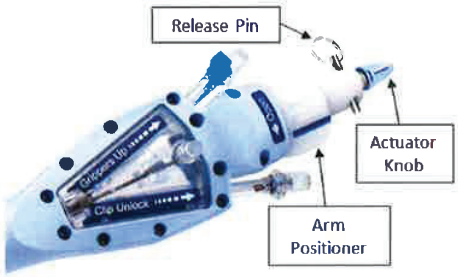

Figure 1, DC Handle

Figure 2, Release Pin Groove

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Additional Considerations
Your current inventory of product is acceptable for safe use following the revised IFU steps described 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 IFU is being revised concurrently to incorporate the revised procedural steps. The appropriate National Competent Authorities, local Regulatory Agencies, and US Food and Drug Administration (FDA) have been made aware of this action.

Thank you for your attention to this matter. Abbott Vascular is committed to providing high quality products and partnering with you to ensure the safety of each patient. Please address any questions you may have with your local Abbott Vascular representative.

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Training Form / Effectiveness Check

Customer Account #_____
Account Name _____
Address _____
_____
Phone _____
(Information required for regulatory effectiveness check)

I acknowledge receiving and reading the February 4, 2016 MitraClip Field Safety Notice.

I have completed training on the revised Instructions for Use steps with my Abbott Vascular Representative.

Customer Name/ Title (print)	***Signature***	***Date***

AV Representative Name (print)	***Signature***	***Date***

This form is to be returned to Abbott Vascular

- Return this signed form to your Abbott Vascular Representative, or
- Scan and email this signed form to simon.bain@abbott.com

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