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URGENT FIELD SAFETY NOTICE/ MITRACLIP®XTR PHYSICIAN ADVISORY

COMMERCIAL NAME: MitraClip® XTR Clip Delivery System
UDI: 08717648226366

FSCA – Identifier: MitraClip® XTR May 1, 2019
Type of Action: Advisory Regarding the Use of the Device

Attention: Implanting Physician

cc: Chairman Medical Board and relevant Head of Departments

Dear Valued Abbott Customer:

Abbott is voluntarily issuing this Field Safety Notice for the MitraClip® XTR Clip Delivery System, product numbers CDS0601-XTR and CDS0602-XTR. The MitraClip® XTR Clip Delivery System is a Class III implantable mitral valve repair system which employs a transcatheter percutaneous edge-to-edge approach. The MitraClip® XTR Clip Delivery System is intended for reconstruction of an insufficient mitral valve through tissue approximation.

Abbott has confirmed reports of XTR Clips unexpectedly opening and becoming nonfunctional, resulting from unintended excessive force applied to the Clip during implantation. Once the Clip becomes nonfunctional, the inability to close and remove the device has led to surgery or additional intervention. Abbott calculates these events to be occurring at a rate of less than 0.16%. There have been incidents (0.02%) where post-procedure patient death was reported following complications associated with surgery and/or patient comorbidities.

Investigation of these events determined that under normal use conditions, this failure mode will not occur. To prevent unintended excessive force from being applied to the Clip, revised instructions for performing the steps “Establish Final Arm Angle” and “Invert the Clip Arms” were developed and provided herein. The revised instructions will be applied to the shared MitraClip® XTR and NTR Clip Delivery System Instructions for Use (IFU). Unintentional excessive force applied to the MitraClip® NTR Clip Delivery System during “Establish Final Arm Angle” can result in unexpected movement of Clip arms; however, unlike XTR, the NTR Clip does not become damaged and remains functional. Adhering to the revised IFU sections for both product platforms will ensure consistency of use.

Patients who have previously had Clips implanted are not affected by this action.

What action is Abbott asking you to take?

- Read through this Field Safety Notice
- Review the revised Instructions for Use steps with your Abbott representative
- Sign the provided Effectiveness Check Form
- Share this information with other personnel associated with MitraClip® procedures in your organization

What is Abbott doing?

- This communication provides revised IFU steps (refer to page 2) for use with current inventory of MitraClip® XTR/NTR Clip Delivery Systems. The instructions explain the changes to the steps for use and emphasizes the importance of preventing unintended excessive force to the Clip.
- The revised instruction steps provided in this communication will be updated in MitraClip® XTR/NTR Clip Delivery System IFU and included in associated training.

MitraClip® XTR Clip Delivery System Field Safety Notice, May 1, 2019



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Revised Instruction for Use Steps:

TERM	DEFINITION AND RELATED TECHNIQUE
<i>Establish Final Arm Angle</i>	Verification step to confirm that the pre-deployment <i>Clip Arm Angle</i> will reflect the <i>Clip Arm Angle</i> post-deployment. With the Lock Lever fully advanced, and the <i>Arm Positioner</i> to <i>Neutral</i> (note the orientation of the blue line on the Arm Positioner), turn the Arm Positioner 1 turn in the “Open” direction (confirm blue line has returned to the original orientation). The Clip Arms may open slightly (~ 5°) and then remain in a stable position. NOTE: If continued opening of the Clip Arms is noted, reconfirm that the Lock Lever is completely advanced. Close the Clip Arms, and <i>Establish Final Arm Angle</i>. WARNING: DO NOT turn the Arm Positioner more than one turn in the “Open” direction from neutral. Failure to stop turning the Arm Positioner at one turn in the “Open” direction past neutral may result in clip opening or device damage which could cause the clip to become non-functional and lead to embolization and/or conversion to surgical intervention.
<i>Invert the Clip Arms</i>	1. Confirm the Clip is unlocked. 2. Turn the Arm Positioner 1/2 turn in the “Close” direction. 3. Turn the Arm Positioner in the “Open” direction until a Clip Arm angle of 180° is observed under fluoroscopic guidance. Note the orientation of the blue line on the Arm Positioner. 4. Continue turning the Arm Positioner in the “Open” direction until the Clip Arms invert, no more than 1 full turn from 180°. DO NOT over-invert the Clip Arms. DO NOT turn arm positioner more than 1 full turn past a Clip arm angle of 180° or past when resistance is first noted. WARNING: Turning the arm positioner in the “Open” direction more than 1 full turn past a Clip Arm angle of 180° or turning past when resistance is first noted may result device damage which could cause the clip to become non-functional and lead to embolization, and/ or conversion to surgical intervention.

The revised steps, which are identified within the boxed text, provide clarified instructions for establishing final arm angle and inverting the clip arms.



Clip Arms at 180°



Clip Arms Inverted



Clip Arms Fully Inverted



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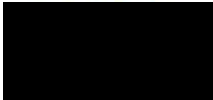
Additional Considerations

Your current inventory of product is acceptable for safe use following the revised IFU steps described above. There is no need to return any product to Abbott.

The appropriate regulatory agencies have been notified of this action.

Thank you for your attention to this matter. Abbott 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 representative.

Sincerely,



Peter Peh

Country Manager
Southeast Asia



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COMMERCIAL NAME: MitraClip® XTR Clip Delivery System

Date: May 1, 2019

Type of Action: Advisory Regarding the Use of the Device

Effectiveness Check Form

Customer Account # _____

Account Name _____

Address _____

Phone _____

(Information required for regulatory effectiveness check)

After reviewing the Field Safety Notice with your Abbott Representative, complete and return this form to Abbott per the instructions below.

Check Both Boxes:

☐

I acknowledge receiving and reading the May 1, 2019 MitraClip® XTR Clip Delivery System Field Safety Notice.

☐

I have completed a review of the revised Instructions for Use steps with my Abbott Representative.

Physician Name/ Title (print)

Signature

Date

Abbott Representative Name (print)

Signature

Date

This form is to be returned to Abbott

- Return this signed form to your Abbott local representative