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URGENT FIELD SAFETY NOTICE

**Edwards Lifesciences LLC
Ascendra 2 Delivery System – Loader Assembly
Model Numbers 9320AS23 and 9320AS26**

Ref: AT-GEN-0000039

January 07, 2011

ATTENTION: All Edwards Lifesciences Ascendra Users

Details of affected device:

This field safety notice applies to all lots of the Ascendra 2 Delivery System (Model Numbers 9320AS23 and 9320AS26)

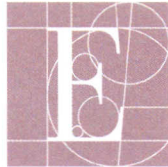
Description of problem:

Edwards Lifesciences is announcing a Field Safety Notice on all loader assemblies contained within the Ascendra 2 Delivery Systems. Edwards has received reports where, during the transapical procedure, the loader assembly de-airing mechanism has become partially unseated thereby creating an insufficient seal around the pusher and resulting in the leakage of blood. Edwards has not seen this issue during product development and validation process testing or from clinical experience gained from the PREVAIL TA clinical trial. This issue is a rare and easily correctable situation. Testing performed by Edwards has shown that hemostasis can be achieved with the current loader assembly by following the steps outlined below.

Edwards is issuing this Field Safety Notice to increase clinician awareness and diligence. As this Field Safety Notice does not pertain to, or relate to, the valve implant in any way, patient notification is not necessary.

Advice on action to be taken by user:

To prevent further occurrences of leakage from the loader assembly de-airing mechanism, Edwards is requesting that all Ascendra 2 users review the following information regarding device preparation and take action as described and illustrated below:

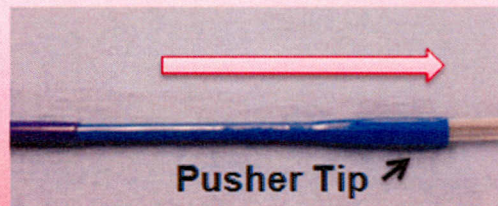
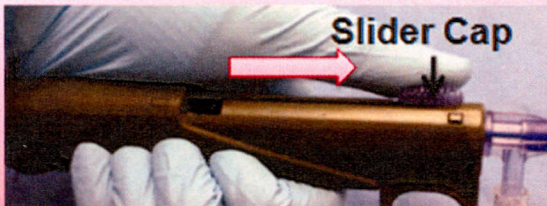


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1. When inserting the Ascendra 2 delivery system into the proximal end of the loader, ensure that the delivery system is coaxial with the loader. Do not insert the delivery system into the loader at an angle.

7. Slide delivery system into loader

- Advance slider cap distally and lock so pusher tip prevents kinking of balloon



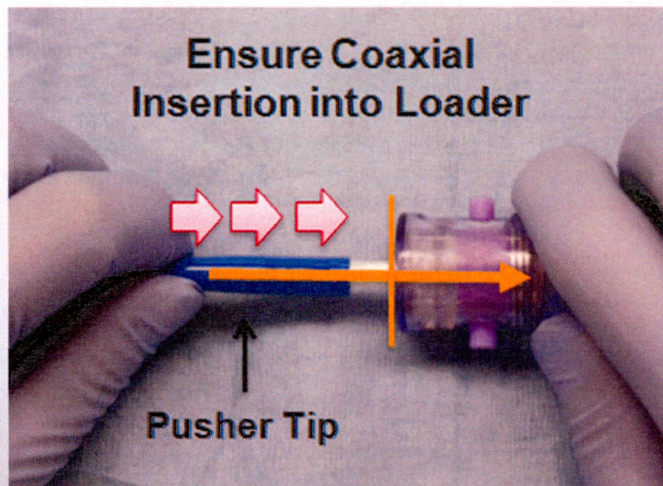
- Slide delivery system into loader until loader is completely proximal

NOTE:

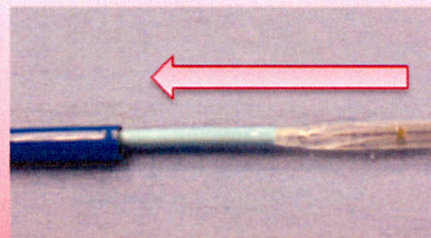
Hold the delivery system at the pusher tip while slowly pushing the delivery system into the loader coaxially and with short movements

NOTE:

Do not insert the delivery system into the loader at an angle

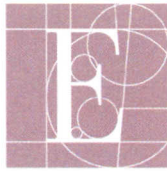


- Retract slider cap proximally and lock so pusher tip moves back to packaged position



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- Following the instructions for use, flush the loader from the distal hub of the delivery system. If the button valves on the loader have become partially dislodged, fluid will be seen leaking from around one or both of the button valves. If this happens press both button valves several times to reseat the seal and then repeat the flushing procedure as per the instructions for use.

8. Maintain hydration of THV prior to implantation by injecting sterile physiologic saline into distal hub of delivery system

- Retract slider cap proximally to the edge of the blue balloon shaft so that the pusher tip sits off of the balloon



 **NOTE:**

Maintain position of the loader and THV on the delivery system while retracting the pusher tip by holding onto both tip of the loader and the delivery system at the same time

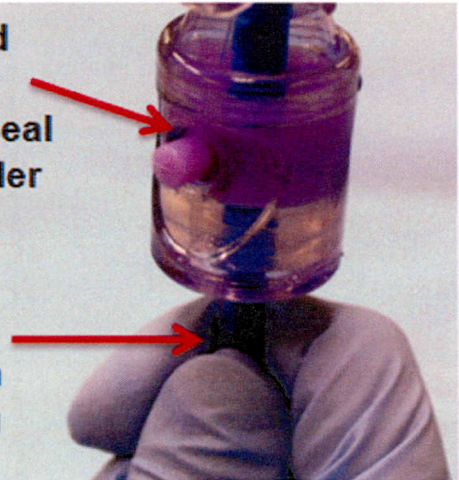
- Flush through the distal hub while applying pressure completely around the outer sheath tubing to force sterile physiologic saline through the pusher and into the loader

 **NOTE:**

If fluid appears to be leaking from the button valves, press both button valves a few times to re-align the button valve seal to the loader and **reflush** again according to the steps above.

**Aligned
Button
Valve Seal
to Loader**

**Outer
Sheath
Tubing**

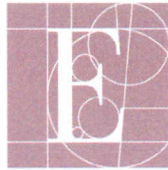


- Once the THV is hydrated, re-advance slider cap distally while maintaining position of loader and THV on delivery system and lock to align pusher tip with proximal end of crimped THV again

 **CAUTION:**

THV should not remain fully crimped and/or in the loader tube for over 30 minutes





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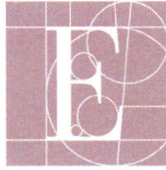
Please pass this Field Safety Notice onto all those who need to be aware within your organization or onto any organization where potentially affected devices may have been transferred.

Please acknowledge that you have reviewed this Field Safety Notification by signing and dating the form below.

If you have any questions or concerns regarding this Field Safety Notification, please do not hesitate to contact your Clinical Specialist.

Yours sincerely,

Momchil Blagoev
Regional Manager Regulatory Affairs
Europe, Middle East, Africa
Edwards Lifesciences



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Edwards has communicated this Field Safety Notice to all appropriate regulatory authorities.

.....
I have reviewed and understand the information contained in the above Field Safety Notification regarding the loader assembly of the Ascendra 2 Delivery System (Model Numbers 9320AS23 and 9320AS26) dated January 05 2011:

Ascendra User Signature

Date

Center

I have reviewed the information above with

Name of Ascendra User

Edwards Representative Signature

Date

*****PLEASE FAX SIGNED FORM TO +41 22 787 4348, ATT: SUZY BAMBARA*****