Johnson&Johnson MedTech

Ethicon

URGENT: FIELD SAFETY NOTICE

ENDOPATH ECHELON™ Vascular White Reload for Advanced Placement Tip (35 mm, 4 Row)

– Voluntary Field Safety Corrective Action (Notification) –

[Date]

IMPORTANT INFORMATION REGARDING INADVERTENT INSTRUMENT LOCKOUT

Product Name	Product Code	UDI
ENDOPATH ECHELON™ Vascular White Reload for Advanced Placement Tip (35 mm, 4 Row)	VASECR35	10705036014591

Dear Operating Room Supervisors, Recall Coordinator, and Director of Materials Management:

PLEASE DISTRIBUTE THIS INFORMATION WITHIN YOUR FACILITY TO ALL STAFF WHO USE ENDOPATH ECHELON™ VASCULAR WHITE RELOAD FOR ADVANCED PLACEMENT TIP (35 MM, 4 ROW).

Purpose of this Letter

The intent of this letter is to communicate important information regarding ENDOPATH ECHELON™ Vascular White Reload for Advanced Placement Tip (35 mm, 4 Row), product code VASECR35, **distributed since May 30, 2024 and with expiration dates starting from August 31, 2026** to help ensure safe and effective use.

This letter is a **notification only and is not a product removal.**

Reason for the Voluntary Correction (Notification)

Ethicon Endo-Surgery, LLC has received an increase in reports regarding inadvertent instrument lockout during surgical procedures involving ENDOPATH ECHELON™ Vascular White Reload for Advanced Placement Tip (35 mm, 4 Row), product code VASECR35. This reload is used exclusively with the ECHELON™ Flex Powered Vascular Stapler, product code PVE35A. The instrument's lockout feature is designed to prevent a used or improperly installed reload from being fired, or an instrument from being fired without a reload.

If a user encounters this issue the device will momentarily activate but will not cut or staple tissue and additional steps will be required to open it and remove it from tissue. This communication includes reinforcement of mitigating instructions for addressing lockouts, which can be found in the current Instructions for Use (IFU) for the ECHELON™ Flex Powered Vascular Stapler, product code PVE35A.

Risk to Health

The device has been designed such that an instrument lockout event should not lead to patient harm. In the event of lockout, the knife does not advance far enough to cut and staples will remain below the tissue contact surface. However, if the user is unable or unsure how to complete the necessary actions to remove the device from tissue, then potential harms may include additional surgical delay, bleeding/hemorrhage, life threatening hemorrhage/hemorrhagic shock, and conversion to open surgery.

During the period where an increase in inadvertent lockout complaints has been observed, Ethicon Endo-Surgery, LLC has received two adverse events, including one patient death, where the user experienced an inadvertent lockout and had difficulties opening the device which may have contributed to the negative patient outcomes. Both devices were returned for analysis, and no issues were noted with device opening when the appropriate steps for use were followed.

The issue would be identified intraoperatively, and health care practitioners who have treated patients using ENDOPATH ECHELON™ Vascular White Reload for Advanced Placement Tip (35 mm, 4 Row), product code VASECR35, should follow those patients post-operatively in the usual manner with no additional action required.

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Actions Required –

1. Share this notification with all users of ENDOPATH ECHELON™ Vascular White Reload for Advanced Placement Tip (35 mm, 4 Row), product code VASECR35.
2. Confirm that personnel using ENDOPATH ECHELON™ Vascular White Reload for Advanced Placement Tip (35 mm, 4 Row), product code VASECR35, understand the Instructions for Use (IFU) for the ECHELON™ Flex Powered Vascular Stapler (product code PVE35A) and this notification.
3. Post a copy of this communication.
4. If any subject product has been forwarded to another facility, contact that facility to share this information. Please share a copy of this notification when communicating.
5. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and fax or email to [Enter Affiliate Information] within three (3) business days. **Please return the BRF even if you do not have product subject to this Field Safety Corrective Action**.

Other Information

At Ethicon, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize Field Safety Corrective Action may be disruptive to your facility and we appreciate your assistance in this matter.

If you have additional questions, please contact [Enter Affiliate Information].

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to Ethicon, or your National Health Authority. If you have any further questions related to this notice or if you need any additional communications, please contact your local Sales Representative.

ATTACHMENTS:

Attachment 1: Instrument Lockout Instructions

Attachment 2: Business Reply Form (BRF)

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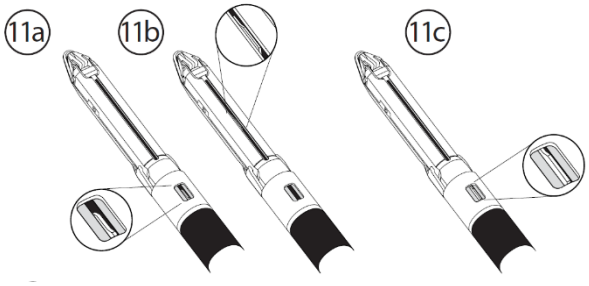
Attachment 1: Instrument Lockout Instructions

Stapler Lockout

The ECHELON FLEX™ Powered Vascular Stapler is designed to prevent firing in certain circumstances, including if there is no cartridge, an incorrect cartridge or a used cartridge.

NOTE: A lockout condition can be verified by viewing the position of the knife in the knife lockout window (Illustration 11c). First, ensure provision of proximal and distal control prior to attempting to follow these steps. If the device is not operating as expected and the knife is not visible as illustrated, this may be indication of a different issue. Consult the Instructions for Use.



The knife can be retracted by pushing the "Reverse" button forward on the device.

1. Reverse: Slide the knife reverse switch forward in the direction of the shaft. DO NOT push inward into the handle.

NOTE: When returning the knife from the lockout position, the motor will only run for a brief period of time. The knife returning to the home position can be verified by viewing the position of the knife in the knife lockout window (if visible). (See Illustration 11a above.)

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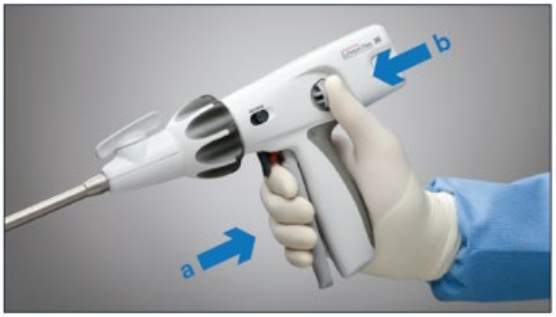
After the knife has been retracted, open the device following these directions:



1. Ensure knife is in the home position. (Jaws will not open if knife is not in the home position.)
2. To open the jaws, a) first squeeze the closing trigger, then b) simultaneously push the anvil release button on the side of the device.

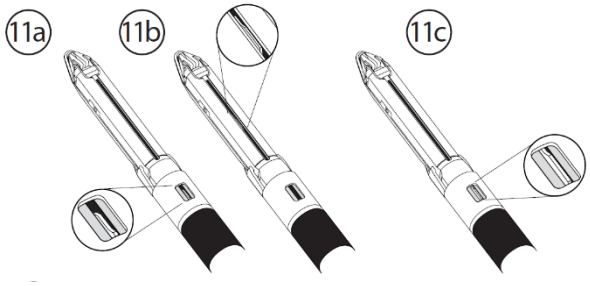
3. Maintaining pressure on the anvil release button, slowly release the closing trigger.

If the knife reverse switch does not return the knife to home position (see Illustration 11b or 11c below) and the jaws will not open:

a. **First, ensure the battery pack is securely installed and the instrument has power; then, try the knife reverse switch again.**

1. Battery pack securely installed

If the knife still does not return (see Illustration 11a below), use the manual override. This can be verified by viewing the position of the knife in the knife lockout window (if visible).



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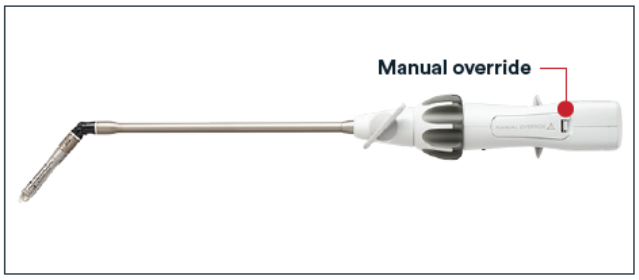
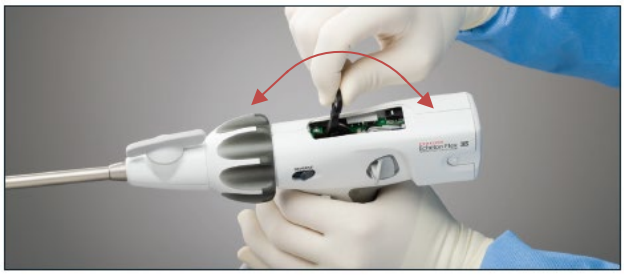
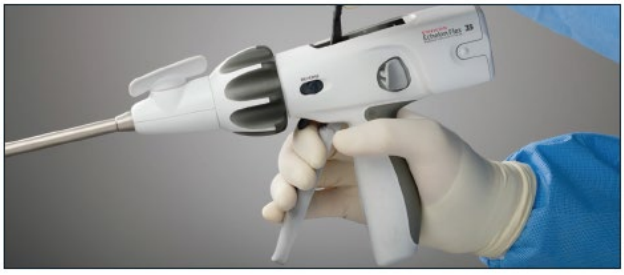


1. **To use the manual override, remove the access panel labeled "Manual Override" on the top of the instrument handle.**

2. **The manual override lever will be exposed.**



3. **Apply force to completely move the lever forward and backward repeatedly until it can no longer be moved.**



4. **Open the device following the instructions on the previous page.**

   Caution: After the manual override system is used, the instrument is disabled and cannot be used for any subsequent firings.

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Attachment 2: Business Reply Form (BRF)

Business Reply Form (BRF)

Your timely response to this recall notification is requested. Please complete this form and fax or email it to [Enter Affiliate Information] or e-mail the form to [Enter Affiliate Information] **within 3 business days, even if you do not have product subject to this recall to return.**

[Account Name]
[Account Address]

Your Name and Title:	Date:
Email Address:	Telephone Number:
J&J Account Number: [Account Number]	
Signature*: **Your signature provides confirmation that you have received and understood this notification and completed the required actions.*	

Have you notified all appropriate hospital staff of this notification?
□ Yes □ No

Are you replying for addresses beyond the address listed above?
□ Yes □ No

If yes, please add additional addresses and J&J Account Number(s) here:

Account Name, Address, and J&J Account Number: