URGENT MEDICAL DEVICE SAFETY NOTICE

COMMERCIAL NAME: **Absolute Pro LL** Peripheral Self-Expanding Stent System

Date: May 23, 2022
FSCA – Identifier: **Absolute Pro LL** May 23, 2022
Manufacturer: Abbott Vascular Santa Clara, CA USA , SRN: BE-AR-000002043
Type of Action: Advisory Regarding the Use of the Device

Attention: Healthcare Professional, Implanting Physician

Dear Valued Abbott Customer:

Abbott is issuing this important Field Safety Notice for the **Absolute Pro LL** Peripheral Self-Expanding Stent System (PSESS). Abbott has confirmed reports of mechanical locking, stent deployment and partial stent deployment failures, resulting from unintended excessive force used to deploy the stent. To reduce occurrences of deployment failures and associated outcomes, Abbott is notifying all users of the potential causes and risks.

This action does not affect patients having successfully undergone procedures using these devices.

The **Absolute Pro LL** PSESS includes a self-expanding stent that is pre-mounted on an over-the-wire Delivery System. The **Absolute Pro LL** PSESS is intended for the stenting of peripheral arteries as an adjunct to percutaneous transluminal angioplasty (PTA) and for the palliation of malignant strictures in the biliary tree. Relevant model numbers are attached.

Deployment related issues are occurring at a rate of 0.27%. Investigation of these events has identified particular use conditions that can increase the likelihood of a stent deployment failure or potentially worsen the outcomes should a partial stent deployment occur. In the event the stent is partially deployed, the inability to fully release or capture the stent has led to surgery or additional intervention. Potential patient effects include dissection / tissue damage, foreign body in the patient, and occlusion. In one case following a procedure, a series of cascading events that included surgery resulted in a patient's death.

<u>What action is Abbott asking you to take?</u>

- Read through this Safety Notice
- Share this information with other personnel associated with **Absolute Pro LL** procedures in your organization
- If you have further distributed/transferred these products, notify those customers
- Sign the provided Effectiveness Check Form
- Report any occurrence of product performance issues or patient adverse events to Abbott

<u>What is Abbott doing?</u>

- This communication provides information on practices and use conditions (refer to the attached materials) for use with current inventory of **Absolute Pro LL** PSESS. The information explains actions required to reduce the potential for deployment issues and associated outcomes.
- This information will be emphasized in, or added to, the **Absolute Pro LL** PSESS Instructions for Use (IFU) as appropriate.

Additional Considerations

Your current inventory of product is acceptable for safe use following the practices and use conditions described in the attached materials. 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. If you have any questions, please do not hesitate to contact your local Abbott Representative or Customer Service department at <insert regional phone number>.

Sincerely,

<signature of country manager>

<printed name>

<title>

Absolute Pro LL Peripheral Self-Expanding Stent System Model Numbers:

Canada

Reference Number	GTIN/UDI	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1012082-120	08717648184840	5.0	120	80
1012082-150	08717648184857	5.0	150	80
1012083-120	08717648184864	6.0	120	80
1012083-150	08717648184871	6.0	150	80
1012084-120	08717648184888	7.0	120	80
1012084-150	08717648184895	7.0	150	80
1012085-120	08717648184901	8.0	120	80
1012085-150	08717648184918	8.0	150	80
1012086-120	08717648184925	5.0	120	135
1012086-150	08717648184932	5.0	150	135
1012087-120	08717648184949	6.0	120	135
1012087-150	08717648184956	6.0	150	135
1012088-120	08717648184963	7.0	120	135
1012088-150	08717648184970	7.0	150	135
1012089-120	08717648184987	8.0	120	135
1012089-150	08717648184994	8.0	150	135

China & Thailand

Reference Number	GTIN/UDI	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1013011-120	08717648191480	5.0	120	80
1013011-150	08717648191497	5.0	150	80
1013012-120	08717648191503	6.0	120	80
1013012-150	08717648191510	6.0	150	80
1013013-120	08717648191527	7.0	120	80
1013013-150	08717648191534	7.0	150	80
1013014-120	08717648191541	8.0	120	80
1013014-150	08717648191558	8.0	150	80
1013015-120	08717648191565	5.0	120	135
1013015-150	08717648191572	5.0	150	135
1013016-120	08717648191589	6.0	120	135
1013016-150	08717648191596	6.0	150	135
1013017-120	08717648191602	7.0	120	135
1013017-150	08717648191619	7.0	150	135
1013018-120	08717648191626	8.0	120	135
1013018-150	08717648191633	8.0	150	135

Rest of World – CE (MDD)

Reference Number	GTIN/UDI	Stent Diameter (mm)	Stent Length (mm)	Catheter Length (cm)
1012008-120	08717648121265	5.0	120	80
1012008-150	08717648130168	5.0	150	80
1012009-120	08717648121333	6.0	120	80
1012009-150	08717648130175	6.0	150	80
1012010-120	08717648121401	7.0	120	80
1012010-150	08717648130182	7.0	150	80
1012011-120	08717648121470	8.0	120	80
1012011-150	08717648130199	8.0	150	80
1012014-120	08717648121661	5.0	120	135
1012014-150	08717648130205	5.0	150	135
1012015-120	08717648121739	6.0	120	135
1012015-150	08717648130212	6.0	150	135
1012016-120	08717648121807	7.0	120	135
1012016-150	08717648130229	7.0	150	135
1012017-120	08717648121876	8.0	120	135
1012017-150	08717648130236	8.0	150	135

PRACTICES TO PREVENT EXCESSIVE RESISTANCE / FORCE

Why? Excessive resistance in the catheter system can prevent movement of the retractable sheath that allows the pre-mounted stent to deploy. Excessive resistance in the catheter system can also increase the force on the deployment mechanisms in the handle to the point that device damage occurs preventing the ability to fully deploy the stent. In either scenario, this may result in difficulty to deploy the stent, or a partial stent deployment. If the stent is only partially deployed, there is a greater potential for patient harm.

Best Practice / Use Condition	Discussion
Use **only 0.035"** guide wire.	Use of smaller diameter guide wires can result in greater interaction and resistance between internal device components. Use of an undersized guide wire, with insufficient support, may cause kinking in the Stent Delivery System and / or lead to deployment failures, including partial deployment.
Cross-over or contralateral access approach in highly angulated / acute or tortuous aorto-iliac bifurcations may lead to deployment failures, including partial deployment.	Tight bends around the aorto-iliac bifurcation can significantly increase resistance.
If sudden or unusual resistance is felt at any time during: • lesion access • initial rotation of the thumbwheel Discontinue use & remove system with introducer sheath / guiding catheter **as a single unit**.	Continued use, despite observed resistance, can result in partial stent deployment. In turn, the risk of damage to, or separation of, the stent or delivery system components is increased.

Additional practices to prevent excessive resistance / force:

- Appropriate assessment of the patient's arteries should be employed in determining the best treatment plan in all situations: the location(s) of disease, arterial access, length of stenoses and occlusions, calcium content, presence of thrombus, and quality of the runoff vessels as well as other anatomic factors all play key roles in the choice between this and other treatment options.
- As detailed in the Instructions for Use:
  - Check the catheter for kinks or signs of damage prior to use.
  - If detachable outer jacket is not engaged in the introducer sheath, manually stabilize prior to deployment to help ensure accurate stent delivery. Do not restrict retracting sheath during stent deployment.
  - Do not use if thumbwheel moves prior to removing the lock.
  - Do not remove the lock from the handle prior to positioning the stent at the intended location.
  - Do not use if thumbwheel moves freely in both directions after removing the lock.

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PRACTICES TO LIMIT IMPACT OF A PARTIAL STENT DEPLOYMENT

Why? Should a partial stent deployment occur, consideration should be made for surgical intervention. However, if an attempt is made to retract the stent and delivery system, extreme care must be used to ensure that the vessel is not damaged.

Best Practice / Use Condition	Discussion
Do not attempt to retract the stent back into the delivery system.	The **Absolute Pro LL** stent design does not re-collapse. The stent can elongate and/or separate, or the catheter can separate and remain in the body.
Do not attempt to remove the stent or delivery system into the introducer sheath / guide catheter with a partially deployed stent.	
If the decision is made to remove the delivery system and stent, remove the entire system (including the introducer sheath / guide catheter) **as a single unit**.	Removal as a single unit limits the likelihood of damage to, or separation of, the stent or delivery system components and additional complications.

Additional practices to limit impact of a partial stent deployment:

- When removing the delivery system as a single unit:
  - Do not retract the delivery system into the sheath or guiding catheter.
  - Tighten the rotating hemostatic valve (if applicable) to secure the delivery system to the sheath / guiding catheter, and then remove as a single unit.
  - An attempt to maintain guidewire position may be made.

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Effectiveness Check Form

Customer Account # _____

Account Name _____

Address _____

_____

(Information required for regulatory effectiveness check)

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

By signing below, I acknowledge:

I have read and understood the May 23, 2022 Absolute Pro LL Peripheral Self-Expanding Stent System Safety Notice.

And, I have shared this information with other personnel associated with Absolute Pro LL procedures in my organization and any customers to whom we may have further distributed / transferred these products.

_____	_____	_____	_____
Physician Name (print)	***Title (print)***	***Signature***	***Date***

This form is to be returned to Abbott
Scan and email this form to <insert regional email> or fax to <insert regional fax number>