Medical device <<<recall/notice>>>

HeartSine® samaritan® PAD
Pad-Pak-03, -03J, -04, -04J & -07

Customer name: <<merge file>>
Customer #: <<merge file>>
Attn: AED Program Manager/Safety Manager
Recall number: PR 4068245 (FA327)

<<September 2025>>

This medical device voluntary <<<recall/notice>>> is being issued to alert customers with Pad-Paks that have expiry date between April 17, 2025 – August 1, 2029, of a potential bent locator pin issue, and to provide instructions to ensure the Pad-Pak is properly inserted into the SAM PAD device.

Product description

Both the Adult and Pediatric Pad-Pak accessories to the HeartSine samaritan PAD device contain the battery to power the AED, and two electrode pads to provide the electrical connection to the patient's chest for delivery of defibrillation shock.

Product issue

Post-market surveillance has revealed that the Pad-Paks are not always inserted properly into the HeartSine samaritan PAD devices as outlined in the IFU, which can create failure during device use. In the event the device is unable to complete connection, the device will repeatedly prompt "Apply Pads to patient's bare chest". In some cases, the AED device may fail to power on entirely.

Upon investigation, two potential causes of the improper insertion of Pad-Paks include use error and bent locator pins, which may occur during the manufacturing process.

Potential risks

The connection issues that may arise from improper insertion of the Pad-Pak are not always obvious to the user when the Pad-Pak is inserted into the HeartSine samaritan PAD device. If the Pad-Pak is not properly inserted into the HeartSine samaritan PAD device, or if the Pad-Pak locator pins are bent, the device **may** fail to deliver the intended therapy during use, potentially leading to a delay in treatment or no treatment being delivered during use. A delay in treatment or no treatment may result in serious injury or patient expiry.

Complaint information

Since 2018, 120 complaints were reported among more than 1,447,266 Pad-Paks in service worldwide. Of these, there have been **36 adverse events** of which five were confirmed to be caused by bent locator pins, two devices were not returned for investigation and 29 were determined to be related to potential use error.

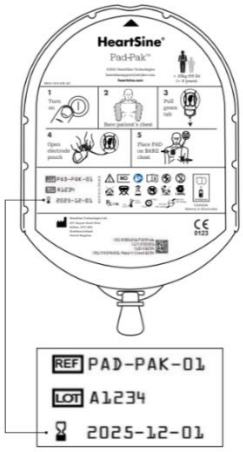
Please continue to next page for customer actions.

Customer actions needed:

To ensure the device works correctly in an emergency, follow the instructions below to ensure that the Pad-Pak is securely and correctly installed. No qualification is required to perform this test.

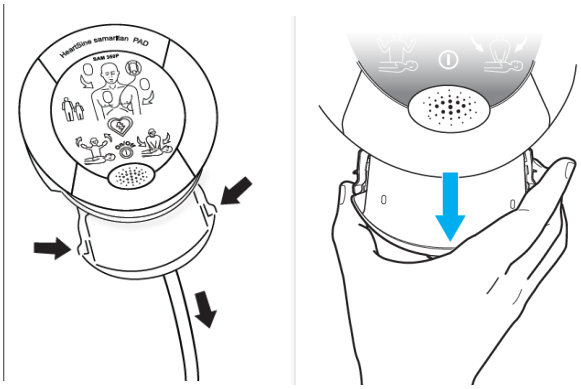
A. **Check the expiry date on your Pad-Pak:**
The expiry date can be found on the rear of the Pad-Pak (see diagram at right or refer to section "Set up your AED" in the IFU).

- If your Pad-Pak expires between April 17, 2025 – August 1, 2029 proceed to ***Step B*** below.

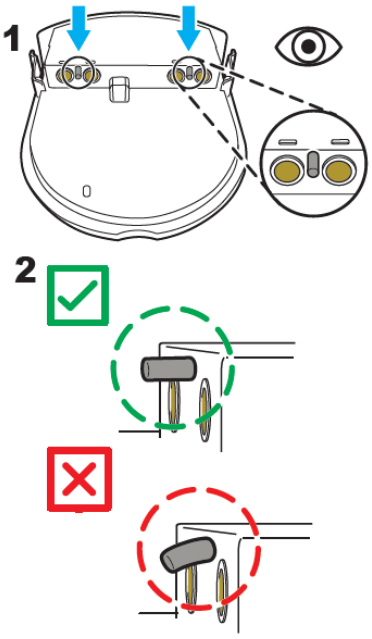


B. **Check for bent locator pins:**

- Place the HeartSine samaritan PAD device face up on a table or other flat surface.
- Squeeze the tab on each side of the Pad-Pak as shown on the right.
- Pull to remove the Pad-Pak from the device.



- Once the Pad-Pak is removed from the device, check the locator pins (blue arrows in Step 1 at the right) to ensure they are straight and not bent, as shown in Step 2 at the right.
  - If locator pins are straight, proceed to ***Step C*** below to follow Pad-Pak insertion instructions.
  - If pins are bent:
    - Remove that Pad-Pak from your device, and set it aside. Pull another Pad-Pak from your inventory, verify locator pins are straight, then proceed to ***Step C*** below, to properly insert the Pad-Pak into the device.
    - If you do not have an additional Pad-Pak in your inventory, remove the device from service and proceed to ***Step D***.



C. **Follow Pad-Pak insertion instructions:**

Illustration 1: Place your HeartSine samaritan PAD device
and the Pad-Pak face up on a table or other flat surface.

Illustration 2: Slide the Pad-Pak into bottom of the AED as shown until you hear the “double click” and
look at both clips to ensure they are correctly engaged.

Illustration 3: Look at both clips to ensure they are correctly engaged.

Illustration 4: Correctly engaged clips will click in and sit snugly/tightly against the AED with no gap as per the green tick. Incorrectly engaged clips will not click and will have a gap as shown in the image with the red x.

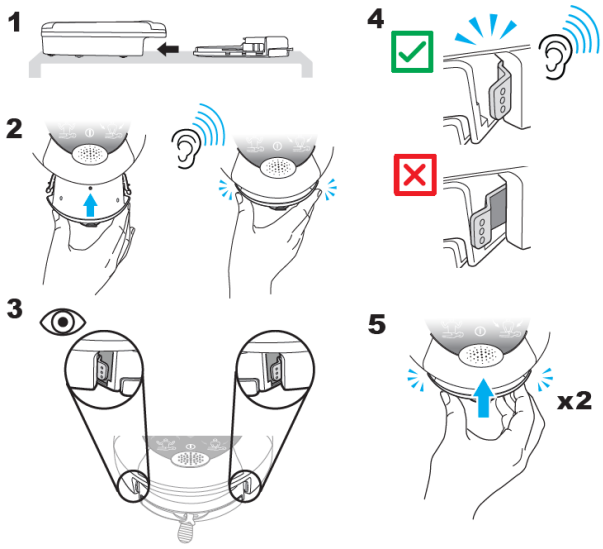


Illustration 5: Push the Pad-Pak in one last time to ensure correct engagement. Once you’ve verified proper insertion, return the device to its storage location for use.

Proceed to ***Step D*** – submit your response.

D. **Submit your response:**

D.1) If you are a Stryker direct End user/Customer:

D.1.1 Submit your response by completing the **Appendix A - Response Form** and submit via email to: <<<enter email address>>>.

D.12. Maintain awareness: Maintain awareness of this communication internally and near the affected unit until all required actions have been completed within your facility.

D.2) If you are a Stryker direct Distributor:

D.2.1. Submit your response by completing the **Appendix A - Response Form** and submit via email to: <<<enter email address>>>.

D.2.2 Maintain awareness: Maintain awareness of this communication internally and near the affected unit until all required actions have been completed within your facility.

D.2.3.If you have further distributed affected product(s), please use the attached Distribution Letter (Attachment 2) to notify the new responsible party or your direct customers and collect all the responses by completing the Appendix A – Response form and email your Stryker representative at <<< address enter email address>>> when you have collected all the responses. Add the quantity and lot number for any Pad-Paks that have been disposed of.

Stryker’s planned action:

Stryker is notifying all customers who have received affected Pad-Paks to perform the actions outlined above by <<DD-MON-YYYY>>. On behalf of Stryker, we thank you sincerely for your response and regret any inconvenience this may have caused.

In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

If you have any questions or concerns, please contact <<<Enter email or appropriate regional/country customer service number>>.

Appendix A

Business Reply Form

HeartSine® samaritan® PAD
Pad-Pak-03, -03J, -04, -04J & -07

Recall/Notice number: PR 4068245 (FA327)
September 2025

Response to this Notification is required. Please complete and sign this form.
Email the completed form to <<<emailaddr>>> by **DD-MON-YYYY**.

Account number: _____
Company name_____
Company address: _____

A. Stryker identified _____number of Pad-Paks distributed to your organization.
B. # of Pad-Paks with bent pins, catalog number and lot: *
_____
_____
_____
C. Total number of Pad-Paks verified and properly inserted into the HeartSine samaritan PAD device:
_____
D. # of Pad-Pak with bent pins disposed, catalog number and lot: *
_____
_____
_____
E. Have you distributed any Pad-Paks outside of your organization?
___ Yes * ___ No

***Follow the instructions from the main letter Step D.2.3.** Stryker will be in contact with you to discuss next steps.

By signing and submitting this form, I acknowledge receipt of the medical device recall letter, agree I have provided accurate information and approve my responses.

Form completed by:

Printed name		**Title**	
Signature		**Phone**	
Date		**Email**	