Laborie

T Clinical Innovations LLC

URGENT FIELD SAFETY NOTICE

Kiwi Complete Vacuum Delivery System (VAC-6000MTE)

Re: Customer Notification regarding the Field Safety Notice of the Kiwi Complete Vacuum Delivery System (with Traction Force Indicator) (V*AC-6000MT*E)

March 11, 2026

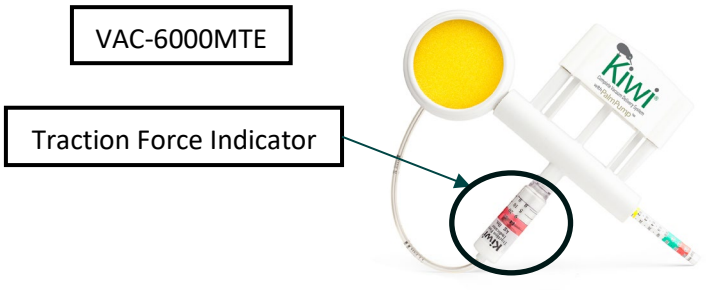
Dear Valued Laborie Customer:

This is to inform you of a voluntary recall of Clinical Innovations' **Kiwi** Complete Vacuum Delivery System (VAC-6000MTE) involving the lots in Table 1 below. The purpose of the field safety notice is to address the potential failure of handle break at the Traction Force Indicator handle joint when angular force is applied to the handle. This field action is being conducted due to a manufacturing issue which can compromise the integrity of the bond between the Traction Force Indicator (TFI) and handle joint when certain use techniques are utilized.

It is important to note that this recall **does not affect the following**:

1) Kiwi VAC-6000MTE manufactured before August 31, 2025
2) Kiwi VAC-6000ME, Kiwi VAC-6000S or VAC-6000C

For clarity, a picture of the **affected** model is shown below*.



The company has received 47 complaints involving this issue out of 94,000 devices sold globally. Four complaints indicated that there may have been an undefined patient injury. Although these events have not been confirmed, the company is currently working with these accounts to obtain additional

information. Based on the company's investigation into this, the issue may occur on units from affected lots when the device is pulled at an angle and/or torque is applied to the joint. We remind users that the Instructions for Use includes a warning "not to twist, torque or use excessive force."

The company's investigation has determined that the breakage is not likely to occur when pulling force is applied in line with the TFI

Risk to Health

Breakage of the device results in complete loss of vacuum which can lead to a delay in the procedure while another mode of delivery is employed or the possible conversion to cesarean section delivery. Delaying a procedure may pose an increased risk of harm when the indication for vacuum assisted delivery is fetal distress. In cases of use in cesarean sections, it is also theoretically possible that fragments could fall into the patient.

Actions to be Taken by Customers and Distributors

Clinical Innovations' (Laborie) records indicate you have received a product that is affected by this action and we are notifying all customers of this recall to confirm that no product (Impacted Lots listed in Table 1 below) remains in distribution channels. Please take the following actions immediately:

1. **Identify and quarantine** all unused inventory of the affected product.
2. **Discontinue distribution** of the affected product.
3. **Return all unused, affected product** to Clinical Innovations (Laborie), regardless of the labeled expiration date.
4. **Complete and return the attached *Recall Acknowledgement and Receipt Form*** within 15 **business days**, even if no inventory remains. Please return the forms via email to recalls@Laborie.com.
5. **If you have product to return,** a company representative will contact you once we receive your Recall Acknowledgement and Receipt Form to issue you an RMA per company policy and arrange for a product return.

Product Return Instructions

- Once we receive your Recall Acknowledgement and Receipt Form, a company representative will contact you and arrange for the return of the product.
    - If you have any questions, call Clinical Innovations (Laborie), at 1-(888)- 268-6222 M-F 8:00 AM- 5:00 PM MT or + (33) 383 22 20 76 M-F 8:00 AM - 5 PM GMT +2 or your Clinical Innovation's (Laborie) service representative.
- Returned product will be **credited to your account**

Communication to Others

Please provide this information to your hospitals. If you have further distributed impacted lots of this product listed in Table 1, please identify your customers and notify them at once of this communication and/or contact Clinical Innovations (Laborie) with contact information so that we can follow up with the owner of the device.

Product and Distribution Information

See Table 1 for a list of affected Kiwi VAC-6000MTE lots.

Action Being Taken by Clinical Innovations

We are working diligently to resolve this issue and to support our customers in minimizing any disruption. Once replacement product of Kiwi VAC-6000MTE becomes available, we will contact you directly.

Clinical Innovations (Laborie) is notifying and working with the appropriate regulatory authorities in each country in accordance with applicable laws.

Please note, Kiwi VAC-6000ME is NOT impacted and remains available for use.

We regret any inconvenience this may cause and appreciate your understanding and partnership. Our priority remains ensuring that every Laborie product meets the high-quality standards you expect and rely on to deliver safe maternal and neonatal care.

If you have any questions regarding this recall, please contact us using the information above.

Sincerely,

Nicole Boser

Executive Vice President, Quality and Regulatory

nboser@laborie.com

Table 1: Lots of *Kiwi Complete Vacuum Delivery System (VAC-6000MTE)* Impacted by this Notice:

Lot	Product Code:
251484	VAC-6000MTE
251485	VAC-6000MTE
251597	VAC-6000MTE
251625	VAC-6000MTE
251626	VAC-6000MTE
251652	VAC-6000MTE
251668	VAC-6000MTE
251676	VAC-6000MTE
251678	VAC-6000MTE
251722	VAC-6000MTE
260004	VAC-6000MTE
260005	VAC-6000MTE
260022	VAC-6000MTE
260029	VAC-6000MTE
260075	VAC-6000MTE
260187	VAC-6000MTE

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MEDICAL DEVICE FIELD SAFETY RETURN RESPONSE

Acknowledgement and Receipt Form

Response is Required

Customer Information:
Customer Name:
Street Address:
Town, State, Zip Code:

Kiwi Complete Vacuum Delivery System (VAC-6000MTE with Traction Force Indicator)

Lot/Serial Numbers:

I have read and understand the recall instructions provided in the March 11, 2026 letter.
Yes _ No_

Any adverse events associated with recalled product? Yes __ No __

If yes, please explain:
_____
_____
_____

Affected Product Information: Include information that is applicable for affected product.

Affected Product Information Table		
Product/Brand Names	Lot/Serial Number/UDI of product in inventory	Quantity in Inventory

Return this form to: Recalls@laborie.com