

23 March 2026

URGENT FIELD SAFETY NOTICE (FSN)
FSN Reference No.: FSN-2026-2303

Kiwi Complete Vacuum Delivery System (VAC-6000MTE)

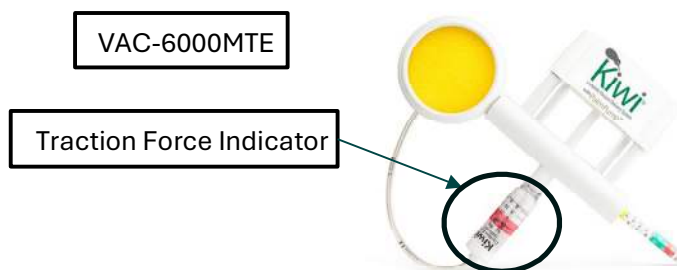
Re: **Customer Notification regarding the Field Safety Notice of the Kiwi Complete Vacuum Delivery System with Traction Force Indicator - VAC-6000MTE.**

Dear Valued 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 risk of handle breakage at the Traction Force Indicator (TFI) 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. 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." Investigation has determined that the breakage is not likely to occur when pulling force is applied in line with the TFI.

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



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 caesarean section delivery. Delaying a procedure may pose an increased risk of harm when the indication for vacuum assisted delivery is foetal distress. In cases of use in caesarean sections, it is also theoretically possible that fragments could fall into the patient.

Actions to be Taken

Jamesco Trading Ltd 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 stock at your warehouse
2. **Discontinue distribution** of the affected product.
3. **Inventory Collection** Instruct end users to return any affected inventory currently in their possession back to you.
4. **Returns** Once you have collected the affected units, please contact us to coordinate the return
5. **Complete and return the attached *Recall Acknowledgement and Receipt Form*** even if no inventory remains.
6. **Please return the completed form via email.**
7. **This notice must be shared with all relevant personnel within your organisation.**

Product and Distribution Information

According to our records you have received **150 units** of one of the lots affected ie.Lot **251484** in January.

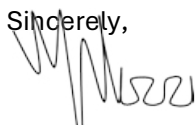
Action Being Taken

We are actively working to resolve this issue and to support you in minimising any disruption to your operations. Replacement product for the Kiwi VAC-6000MTE will be made available as soon as possible, and we will contact you accordingly.

We sincerely regret any inconvenience caused and appreciate your cooperation in this matter. Jamesco Trading Ltd remains fully committed to ensuring the safety, quality, and reliability of all products supplied.

For any urgent matter in relation to this FSN, please contact Mariella Mizzi (MDRP) on 99995265 / mariella.mizzi@jamescotrading.com

Sincerely,



Mariella Mizzi

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
251652	VAC-6000MTE
251722	VAC-6000MTE
260004	VAC-6000MTE
260005	VAC-6000MTE
260022	VAC-6000MTE
260029	VAC-6000MTE
260187	VAC-6000MTE

MEDICAL DEVICE FIELD SAFETY RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

CENTRAL PROCUREMENT & SUPPLIES UNIT
MINISTRY FOR HEALTH
UB002, Industrial Estate, San Gwann, SGN3000.
Tel: (+356) 2540 4000 E-mail: info.cpsu@gov.mt

Product: **Kiwi Complete Vacuum Delivery System with Traction Force Indicator - VAC-6000MTE**

Lot/Serial Numbers: _____

I have read and understand the recall instructions provided in the March 23, 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	Lot/Serial Number	Quantity (pieces)
Kiwi Complete Vacuum Delivery System VAC-6000MTE		

Name : _____

Signature : _____

Date : _____