Urgent Field Safety Notice

Trellis 8 Peripheral Infusion System

FSCA Reference: Trellis 8 12/14

December XX, 2014

< <Name >>

<<Address 1>>

<<Address 2>>

<<City>> <<Postcode>>

Dear Trellis Customer:

The purpose of this letter is to advise you that Covidien is conducting a Field Safety Corrective Action, to remove product from certain production lots of four Product Catalogue Numbers of the Trellis 8 Peripheral Infusion System because a manufacturing error resulted in the risk of incorrect proximal and distal balloon inflation port identification on the units.

Two customer complaints have been received identifying incorrect balloon port identification. One complaint was identified during preparation prior to procedural use and the second complaint was identified during the procedure, but prior to treatment.

Based on our internal investigation, we have identified the potential for a discrepancy in the Trellis 8 inflation port identification. That is, during the product manufacturing process units within this population have been identified to have the distal balloon inflation port incorrectly labeled as proximal. (As well as the converse: the proximal balloon port incorrectly labeled as distal.)

Covidien has not received any reports of patient injury resulting from this issue. If a patient under your care has received treatment with a Trellis 8 from the impacted lots, no immediate action is required. Patients should continue to be monitored in accordance with standard of care.

The product catalog numbers affected are:

Model	Description
EVT808015	Trellis 8
EVT808025	Trellis 8
EVT812015	Trellis 8
EVT812025	Trellis 8

The product code and lot number are printed on the primary and secondary package labeling.

Our records indicate that you have received product from the affected lots. Please review your inventory for these specific lot numbers which are listed on the attached verification form.

REQUIRED ACTIONS:

1. **Immediately quarantine and discontinue use of the affected devices.**

2. **Return affected product as follows: Please complete the attached verification form in its entirety. Fax or e-mail the completed form using the contact details stated on the form.** If you do not have any units in your inventory, simply return the Verification Form indicating you have zero (0) units.

3. **Upon receiving your form, Customer Service will contact you to organize the return of your products. You will receive credit for returned products.**

4. **Please forward this letter to all colleagues within your organization who need to be made aware of it, or to any organisations/persons where the potentially affected devices have been transferred.**

Your response is important to our monitoring of the effectiveness of this Field Safety Corrective Action. If you have additional questions regarding returns, replacement stock, credit, or on the product involved in this FSCA, please contact your local Covidien Representative.

To ensure timely removal of the affected product, it is important that we receive the Return Verification form as soon as possible. We appreciate your immediate attention to this matter.

This action is being conducted with the knowledge of the (local regulatory authority). Adverse events experienced with the use of these products should be reported to your local Covidien Representative.

We apologize for this inconvenience and assure you that Covidien has implemented appropriate measures to protect against recurrence of this problem. If you have any questions regarding this request, please contact your local Covidien Representative at [*telephone number*]

Sincerely,

[*Add Local RA Signature and Title Block*]

Attachment: Returns verification form