Medtronic, Plc.
4600 Nathan Lane
Plymouth, MN 55442
www.medtronic.com

URGENT FIELD SAFETY NOTIFICATION

Trellis™ 8 Peripheral Infusion Systems

Xx March, 2015

Dear Trellis Customer:

The purpose of this letter is to advise you that Medtronic is conducting a Field Safety Corrective Action (FSCA) of all former Covidien Trellis™ 8 Peripheral Infusion Systems due to potential for a sterility breach of the outer packaging or pouch material. A breach of the outer pouch may compromise the outside surface sterility of the inner pouch and does not directly affect the sterility of the device components within the inner pouch. **Through March 17, 2015, Medtronic has received no complaints and is not aware of any patient injury or death related to this issue.**

This potential for a sterile breach in the outer pouch material was discovered during standard internal packaging tests. The breach in the pouch barrier is likely not detectable by visual inspection of the product. Medtronic has identified possible causes for the pouch damage and has taken actions to prevent distribution of product that may be affected by this issue.

While the device components within the inner pouch are not directly affected by this issue, the introduction of a non-sterile inner pouch (outer surface of the inner pouch contaminated) could potentially contaminate the sterile field and sterile personnel, thereby creating a possible indirect pathway for microbes to come in contact with the patient which may cause an infection. **If a patient under your care has received treatment with a Trellis 8 device, no action is required and patients should continue to be monitored in accordance with standard of care.**

All Trellis 8 product is at risk of this issue and includes the following model numbers:

Model	Description		Model	Description
EVT808015	**Trellis 8**		**EUT808015**	**Trellis 8**
EVT808025	**Trellis 8**		**EUT808030**	**Trellis 8**
EVT812015	**Trellis 8**		**EUT812015**	**Trellis 8**
EVT812025	**Trellis 8**		**EUT812030**	**Trellis 8**

The model number is printed on the primary and secondary package labeling.
Our records indicate that you have received one or more Trellis 8 Peripheral Infusion Systems. Please review your inventory for these specific models which are also listed on the attached returns verification form and perform the following:

REQUIRED ACTIONS:

- Immediately quarantine and do not use listed product.
- Please complete the attached returns verification form in its entirety and return it to Medtronic, even if you have no affected inventory:
- Email the completed form to, or fax it to XXX-XXXXX for the attention of [**Insert Local RA contacts name**].
- Upon receiving your form, Customer Service will contact you to organize the return of your products.

To ensure timely removal of the Trellis 8 product, it is important that we receive the returns verification form and unused product as soon as possible. Your response is important to our monitoring the effectiveness of this FSCA.

Replacement product is not available at this time and Medtronic will be issuing you credit for the returned unused and unexpired device(s).

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Please share this notification with others in your organization as appropriate. If any product within scope of this issue has been sent to another facility, please notify that facility of this issue and facilitate the retrieval of this product. Medtronic is informing regulatory agencies of this action as required.

If you have any questions regarding this FSCA, please contact **<your Representative at XXXXX XXXXXX.>**

We appreciate your cooperation and apologize for the inconvenience that this issue may cause. Please be assured that patient safety and product quality remain our primary concern.

Sincerely,

Add local Signature