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

URGENT <MEDICAL DEVICE RECALL>

Trellis™ 6 and Trellis™ 8 Peripheral Infusion Systems

March, 2015

Dear Trellis Customer:

The purpose of this letter is to advise you that Medtronic is conducting a voluntary recall of all former Covidien Trellis™ 6 and 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 16, 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 6 or Trellis 8 device, no action is required and patients should continue to be monitored in accordance with standard of care.**

All Trellis 6 and Trellis 8 product is at risk of this issue and includes the following model numbers:

Model	Description		Model	Description		Model	Description
BVT608010V01	**Trellis 6**		**CVT808015**	**Trellis 8**		**BVT808015**	**Trellis 8**
BVT608030V01	**Trellis 6**		**CVT808025**	**Trellis 8**		**BVT808030**	**Trellis 8**
BVT612010V01	**Trellis 6**		**CVT812015**	**Trellis 8**		**BVT812015**	**Trellis 8**
BVT612030V01	**Trellis 6**		**CVT812025**	**Trellis 8**		**BVT812030**	**Trellis 8**
			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 6 or Trellis 8 Peripheral Infusion Systems. Please review your inventory for these specific models which are also listed on the attached customer confirmation certificate and perform the following:

REQUIRED ACTIONS:

- Immediately quarantine and do not use listed product.
- **<Please complete the attached customer confirmation certificate in its entirety and return it to Medtronic, even if you have no affected inventory:**
  - **Email the certificate to RS.CFQFCA@Medtronic.com, or fax to Medtronic at 651-367-0612 to the attention of Customer Focused Quality.**
- **Return all unused Trellis 6 and Trellis 8 product as follows if you have product in inventory:**
  - **Provide that product to your Medtronic Sales Representative directly; or**
  - **Contact Medtronic Service at 1-800-716-6700 to arrange for product return.>**

To ensure timely removal of the Trellis 6 and Trellis 8 product, it is important that we receive the customer confirmation certificate and unused product as soon as possible. Your response is important to our monitoring the effectiveness of this recall.

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

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

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 recall, please contact **<your Medtronic Sales Representative or Customer Service at 1-800-716-6700.>**

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,

Jonathan Morris
Vice President Quality
Aortic & Peripheral Vascular
Medtronic Plc

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

Customer Confirmation Certificate

Urgent Medical Device Recall

Trellis™ 6 and Trellis™ 8 Peripheral Infusion Systems – Packaging Issue

Model Numbers:

Model	Description		Model	Description		Model	Description
BVT608010V01	**Trellis 6**		**CVT808015**	**Trellis 8**		**BVT808015**	**Trellis 8**
BVT608030V01	**Trellis 6**		**CVT808025**	**Trellis 8**		**BVT808030**	**Trellis 8**
BVT612010V01	**Trellis 6**		**CVT812015**	**Trellis 8**		**BVT812015**	**Trellis 8**
BVT612030V01	**Trellis 6**		**CVT812025**	**Trellis 8**		**BVT812030**	**Trellis 8**
			EVT808015	**Trellis 8**		**EUT808015**	**Trellis 8**
			EVT808025	**Trellis 8**		**EUT808030**	**Trellis 8**
			EVT812015	**Trellis 8**		**EUT812015**	**Trellis 8**
			EVT812025	**Trellis 8**		**EUT812030**	**Trellis 8**

March, 2015

Account Number:
Account Name
Address
City, State, Zip
Sales Representative: *Rep Name*
Representative Phone: *Rep phone number*

For completion by Medtronic Customers Only – Please complete all fields below

By signing this form I confirm that I have read and understand the Urgent Medical Device Recall Notification Letter from Medtronic regarding Trellis™ 6 and Trellis™ 8 Peripheral Infusion Systems packaging issue dated March, 2015 and I have taken one of the following actions:

1. **I have returned all unused Trellis 6 and Trellis 8 Peripheral Infusion Systems product affected by this packaging issue located in my inventory to Medtronic.** *Please note product affected by this issue includes all lots manufactured with the model numbers listed in the heading of this certificate.*
   –OR–
2. **I confirm that all Trellis 6 and Trellis 8 Peripheral Infusion Systems product affected by this packaging issue (see models above) were either used or unable to be located in my inventory.**

Required Actions:

- <Contact Customer Service at 1-800-716-6700 to initiate a return and credit of product.
- <Please complete the attached customer confirmation certificate in its entirety and return it to Medtronic, even if you have no affected inventory:
  - Email the certificate to RS.CFQFCA@Medtronic.com, or fax to Medtronic at 651-367-0612 to the attention of Customer Focused Quality.
- Return unused listed product as follows if you have product in inventory:
  - Provide that product to your Medtronic Sales Representative directly; or
  - Contact Medtronic Service at 1-800-716-6700 to arrange for product return.>

<Product Return Address:
Medtronic
Attn: Field Returns
60 Middletown Ave
North Haven CT, 06473>

Customer Name (Print): _____

Customer Title (Print): _____

Customer Signature: _____ Date: _____

Telephone: _____

Please send this completed form via email to RS.CFQFCA@Medtronic.com or via fax to 651-367-0612 to the attention of Customer Focused Quality.
For questions, contact your Medtronic (formerly Covidien) Field Representative.