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

URGENT Field Safety Notice

VenaSeal™ Closure System
Model SP-101

April, 2015

Dear VenaSeal Customer:

The purpose of this letter is to advise you that Medtronic is conducting a Field Safety Corrective Action (FSCA) of all former Sapheon (Covidien) VenaSeal™ Closure Systems due to potential for a sterility breach of the outer packaging (pouch) material. A breach of the outer pouch may compromise the outside surface sterility of the sealed inner tray and does not directly affect the sterility of the device components.

Through 23 April 2015, Medtronic has received one (1) complaint potentially related to this issue resulting in an occurrence rate of .0253%. This one complaint is associated with a serious patient injury; however it is unclear if this injury is device related. There have been no reports of death related to this issue. This FSCA is not being triggered by a regulatory agency or field complaint.

This potential for a sterile breach in the outer pouch material was discovered during standard internal packaging tests. The breach in the pouch barrier may not be 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 sealed inner tray are not directly affected by this issue, the introduction of a non-sterile inner tray (outer surface of the inner tray 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 VenaSeal Closure System, no action is required and patients should continue to be monitored in accordance with standard of care.**

All manufactured lots of VenaSeal Closure Systems model SP-101 are at risk of this issue. The model number is printed on the primary and secondary package labeling. Our records indicate that you have received one or more affected VenaSeal Closure Systems.

Please review your inventory for this product model which is also listed on the attached returns verification form and perform the following:

REQUIRED ACTIONS:

- Immediately quarantine and do not use this product.
- Please complete the VenaSeal Closure Systems Returns Verification Form and fax it to xxx-xxxxx for the attention of [Insert Local RA contacts name]. Alternatively you can email the completed form to your local Medtronic representative [INSERT LOCAL EMAIL ADDRESS]. If you do not have any units to return, simply return the form indicting you have zero (0) units.
- Upon receiving your form, Customer Service will contact you to organize the return of your products.
- If you purchased this product from a distributor please contact them directly for direction on returning product. A completed returns verification form should be faxed or e-mailed to your local Medtronic representative using the contacted details outlined above. All affected product must be returned through the Distributor with a copy of the completed form.

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To ensure timely removal of the VenaSeal product, it is important that we receive the returns verification form 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). Medtronic remains highly committed to resolving this issue and is working to implement an effective solution as soon as possible.

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. **<Insert geography specific language for distributors here if relevant>**

Medtronic is informing regulatory agencies of this action as required.

If you have any questions regarding this FSCA, please contact your Medtronic Representative **<or insert local contact xxx-xxx-xxxx.>**

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,

<Insert local Medtronic signature>