

URGENT FIELD SAFETY NOTICE

SelectSite™ C304-HIS Deflectable Catheter System

Recall

Lot Number(s)					
0010948864	0010958150	0010971148	0011020263	0011025202	0011031177
0010953298	0010961222	0011017539	0011022874	0011028574	

April 2022

Medtronic reference: FA1248

Dear Risk Manager/Health Care Professional,

Medtronic is voluntarily recalling a subset of single-use, disposable SelectSite™ C304-HIS Deflectable Catheter System for a packaging integrity evaluation. The lots being retrieved are listed in the table above. Medtronic records indicate that your facility has purchased one or more of the identified lots listed. No other products or lot numbers are affected.

Medtronic internal processes identified that the packaging in these lots may have an improperly sealed barrier that could potentially compromise sterility. Medtronic is retrieving the above-identified units for additional inspection. No complaints have been received from the field, and there are no reports of patient harm related to the use of these identified catheters.

For identified product that has been used or discarded, no action is necessary.

Customer Actions:

Medtronic is requesting that you take the actions below:

- Please review your inventory for listed product.
- Return all unused affected product in your inventory to Medtronic. Your Medtronic representative can assist you in the return and replacement of affected product as necessary.
- Please complete the enclosed Customer Acknowledgement Form and email to <XXXXXX>.
- Please maintain a copy of this notice in your records and share this notice with all those who need to be aware within your organization or with any organization where the above-listed products have been transferred.

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative at <XXXXXX>.

Sincerely,

Local / OU Manager