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Urgent: Medical Device Recall

Palindrome™ Precision Chronic Hemodialysis Catheters

Palindrome™ Chronic Hemodialysis Catheters

Mahurkar™ Chronic Carbothane Catheters

14 June 2022

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic has initiated a voluntary recall for specific lots of chronic hemodialysis catheters. You are receiving this letter as Medtronic records indicate your facility may have at least one of the chronic hemodialysis catheters identified for recall in **Appendix 1**. Medtronic initiated this action to prevent the usage of potentially affected chronic hemodialysis catheters that may impact patients.

Issue Description:

During the production process, Medtronic has identified a potential leaking condition within the hub of specific chronic hemodialysis catheters. Flushing one extension tube may result in unanticipated fluid return through the adjacent extension tube (in addition to the anticipated flow of fluid through the distal tip of the catheter). The condition is the result of an inter-lumen void formed in the hub component of the catheter during the manufacturing process. During use, this observed condition could translate to cross-communication of the blood circuit.

To date, Medtronic has received one reported complaint and has not received any reports of patient injury or death related to this issue.

Risk to Health:

Utilization of a product with this manufacturing defect could introduce the potential for patient harm(s) including