Medtronic
60 Middletown Avenue
North Haven, CT 06473
www.medtronic.com

Medical Device Correction Notice
Smith & Nephew TruClear™ Sheath 5C

May 24, 2018

Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic received notification from third party manufacturer Smith & Nephew of a field action related to specific production lots of the TruClear™ Sheath 5C. Smith & Nephew has initiated this action due to a manufacturing error. The affected sheaths will not attach to the TruClear™ Hysteroscope 5C. We are passing this information on to you as the affected devices have been shipped to your facility. There have been no reports of injury related to this issue.

Smith & Nephew advises that in the event the issue is not noticed until the procedure, a replacement device can be used or the surgeon may decide to proceed without the sheath. Cases can still be completed without using the sheath if a backup device is not available. This issue affects only the item code and lots listed below.

Item Code	Description	Affected Lots	
72204753	TruClear™ Sheath 5C	1462393	1464460

Required Actions:

1. Please inspect your inventory and complete the attached Medical Device Correction Form.
2. If you have the affected product listed in the table above, please maintain awareness of this notice.

We request that you contact Medtronic if you experienced quality problems or adverse events via email to Medtronic Post Market Vigilance, quality.assurance@covidien.com.

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 representative or Customer Service at 800-962-9888, option 2.

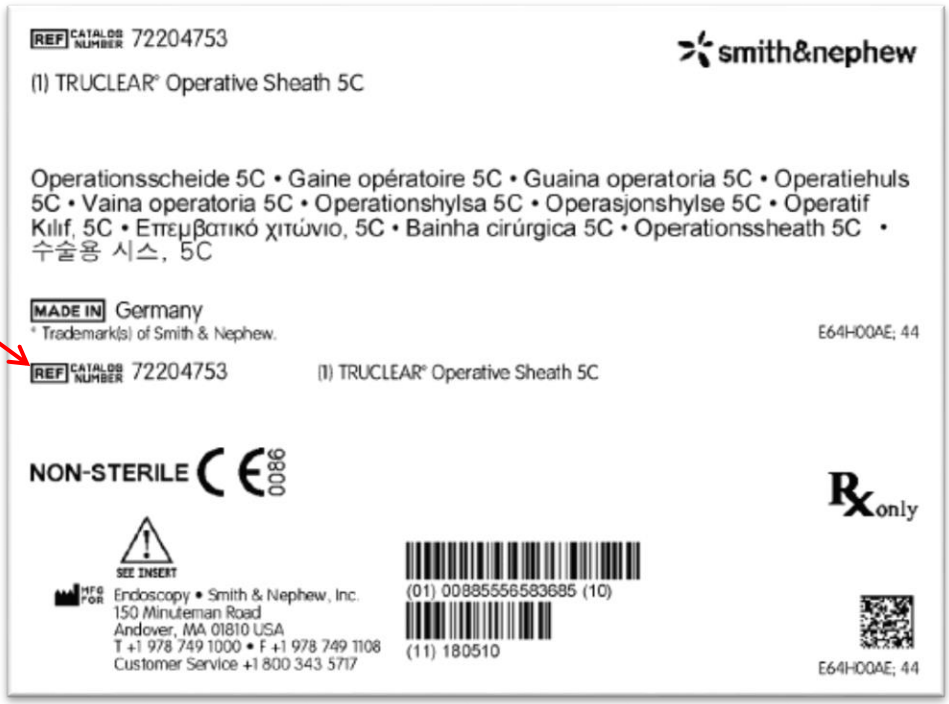
Sincerely,

[redacted]

J. Bryan Dannettell
Vice President, Quality Assurance
Surgical Innovations Medtronic

Attachment A

Item code



MEDICAL DEVICE CORRECTION ACKNOWLEDGEMENT FORM

TruClear™ Sheath 5C C-2017-38

PLEASE COMPLETE THIS FORM

Customers must complete the form even if you do not have inventory.

This is an acknowledgement form; product return is not required

Date:

Name of Person Completing this Form: Title:

Direct Phone #: Email

How did the account purchase this product? (Please complete **ONLY** A or B)

Direct from Medtronic (Complete A): **From a Distributor (Complete B):**

A. Direct Customers:

Account Name:

Primary Account #:

Account Address:

City:

State: Zip Code

B. From a Distributor:

Distributor:

Customer Information:

Customer Name:

Address:

City:

State: Zip:

No Inventory (Please check):

I acknowledge receipt of the TruClear™ Sheath 5C C-2017-38 Medical Device Correction notification dated May XX, 2018, and understand the instructions provided.

(Signature Required)

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO: FCAMITG@Covidien.com or fax it to (203) 492-7719.