

## **URGENT FIELD SAFETY NOTICE** **Versatex™ Monofilament Mesh 50 x 50 cm**

March, 2018

Medtronic Reference: FA803

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

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is issuing a Field Safety Corrective Action (FSCA) for its

### **Covidien Versatex™ Monofilament Mesh 50 X 50 cm**

Medtronic is issuing this FSCA following receipt of patient reports of abdominal hernia recurrence following hernia repair using Versatex™ monofilament mesh 50 x 50 cm. The majority of these patients have been confirmed to have undergone the Transversus Abdominis Muscle Release (TAR) procedure. Patients who experience hernia recurrence may be asymptomatic or symptomatic. Symptoms of hernia recurrence include pain or discomfort, localized bulging, and possible changes in the overlying skin. There have been twenty-seven (27) reports of patients exhibiting abdominal hernia recurrence following an initial repair with Versatex™ monofilament mesh 50 x 50 cm.

This FSCA is in relation to all lots of the item code listed below.

<b>Item Code</b>	<b>Product Description</b>
VTX5050M	Versatex™ Monofilament Mesh, 50x50 cm

Medtronic recommends continued post-operative monitoring of patients who have the mesh implanted to assess for hernia recurrence.

Additionally, Medtronic is adding the following statement to the Versatex™ monofilament mesh Instructions for Use so that surgeons are aware of the risks involved in using Versatex™ monofilament mesh 50x50 cm in TAR procedures.

*In case of large abdominal wall defects, use of Versatex™ monofilament mesh in posterior component separation techniques with transversus abdominis muscle release may lead to a higher risk of hernia recurrence. Versatex™ monofilament mesh is not recommended for posterior component separation techniques with transversus abdominis muscle release when the mesh is used as a bridging material for the lateral relaxing incisions.*

If you have distributed the Versatex™ monofilament mesh 50 X 50 cm listed above, please promptly forward the information from this letter to those recipients.

This action is being taken with the knowledge of the local Competent Authority. We request that you contact Medtronic if you experienced quality problems or adverse events.

Medtronic is committed to providing you with the most up-to-date and relevant information with respect to the use of our products. If you have any questions, please contact your Medtronic Representative.

Sincerely,

Attachment A

# Versatex™

## Monofilament Mesh

### Macroporous Polyester

Macroporous Monofilament Polyester Mesh  
 Renfort Macroporeux en Polyester Monofilament  
 Makroporöses Monofilament-Polyestergewebe  
 Rete macroporosa in poliester monofilamento  
 Malha de poliéster monofilamento macroporosa  
 Malha de poliéster monofilamento macroporosa  
 Macroporeus monofilament polyester gaas  
 Makroporöst monofilit polyesterinät  
 Makroporöst, monofilament polyesterinet  
 Makrohuokoinen yksisäikeinen polyesteriverkko  
 Μακροπορώδες μονόκλωνο πλέγμα πολυεστέρα  
 Makroporowata monofilamentowa siatka poliestrowa  
 Makroporöz Monofilament Polyester Ağ  
 Крупнопористая монофиламентная сетка на основе полиэфира  
 Makroporézni polyesterová monofilamentní síťka  
 Makroporézna monofilová polyesterová sieťka  
 Makroporözna monofilament polyesteronetting  
 Makroporozna monofilamentna poliestrška mrežica  
 Μακροπορеста εδνονιश्кова πολιεστερνα mreža  
 Meşə macroporosaş dın poliester monofilament  
 Makropoorne monofilamentne poliesterivõrk  
 Viendzīslas poliesterā tīkls ar makroporām

Makroporozna jednostruka mrežica od poliester  
 Makroporozna mrežica od poliester monofilamena  
 Makroporinis viengijis poliesterio tinklelis  
 大孔除单纤维聚酯补片  
 大孔型單絲聚脂網膜  
 다공성 모노필라멘트 폴리에스터 메쉬  
 Тесіктері үлкен, монофиламент қосылған полиестер топ  
 Макропориста сітка з монофіламентного поліестеру



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