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

URGENT: Medical Device Correction

Versatex™ Monofilament Mesh 50 x 50 cm

February 23, 2018

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 Medical Device Correction for its

Covidien Versatex™ Monofilament Mesh 50 X 50 cm

Medtronic is issuing this Medical Device Correction 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 Medical Device Correction is in relation to all lots of the item code listed below.

Item Code	Product Description
VTX5050M	Versatex™ Monofilament Mesh, 50x50 cm

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.

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

Sincerely,

[redacted]

J. Bryan Dannettell
Vice President, Assurance
Surgical Innovations
Minimally Invasive Therapies Group

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Attachment A

Versatex™

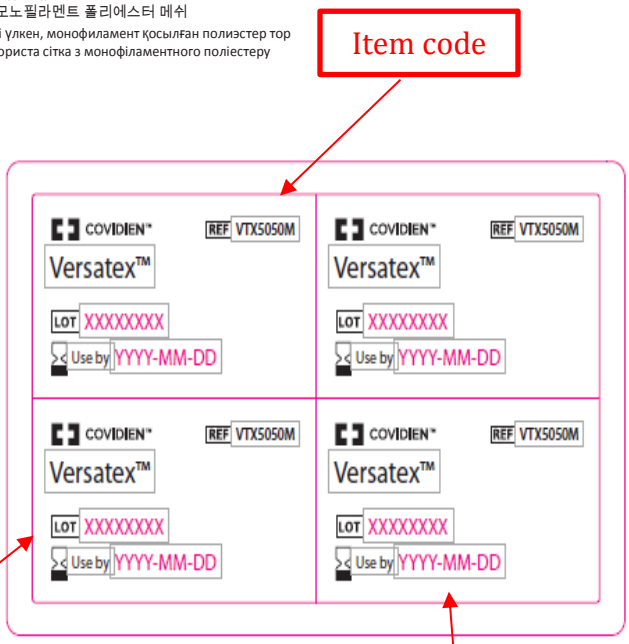
Monofilament Mesh

Macroporous Polyester

Macroporous Monofilament Polyester Mesh
Renfort Macroporeux en Polyester Monofilament
Makroporöses Monofilament-Polyestergewebe
Rete macroporosa in poliestere monofilamento
Malla de poliéster monofilamento macroporosa
Malha de poliéster monofilamentoso macroporosa
Macroporeus monofilament polyester gaas
Makroporöst monofilt polyesternät
Makroporøst, monofilament polyesternet
Makrohuokoinen yksisäikeinen polyesteriverkko
Μακροπορώδες μονόκλωνο πλέγμα πολυεστέρα
Makroporowata monofilamentowa siatka poliestrowa
Makroporöz Monofilament Polyester Ağ
Крупнопористая монофиламентная сетка на основе полиэфира
Makroporézní polyesterová monofilamentní síťka
Makroporózus monofil poliészter háló
Makroporézna monofilová polyesterová sieťka
Makroporøs monofilament polyesternetting
Makroporozna monofilamentna poliestrska mrežica
Макропореста еднонишкова полиестерна мрежа
Meşă macroporoasă din poliester monofilament
Makropoorne monofilamentne polüestervõrk
Viendzīslas poliestera tīkls ar makroporām
Makroporozna jednostruka mrežica od poliestera
Makroporozna mrežica od poliester monofilamenata
Makroporinis vienagijis poliesterio tinklelis
大孔隙单纤维聚脂补片
大孔型單絲聚酯網膜
다공성 모노필라멘트 폴리에스터 메쉬
Тесіктері үлкен, монофиламент қосылған полиэстер тор
Макропориста сітка з монофіламентного поліестеру

STERILE R
Single use
Rx ONLY
Do not resterilize
Do not use if package is opened or damaged
Caution, consult accompanying documents

Sofradim Production, 116, avenue du Formans-01600 Trévoux, France.
1305359



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Medical Device Correction

Versatex™ Monofilament Mesh 50 X 50 cm

Acknowledgement and Receipt Form—Response is required

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

Please complete this form in its entirety.

Date: _____

Name of Person Completing this form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name: _____

Covidien Account Number: _____

Account Address: _____

City: _____ State: _____ Zip Code: _____

I have read and understand the instructions provided and acknowledge receipt of the Medical Device Correction regarding the Versatex™ monofilament mesh 50 X 50 cm dated February 23, 2018, by signing below.

I also agree to further distribute and communicate this important information within my facility as required.

_____	_____	_____
Name: (print)	Signature:	Date:

If you have any questions regarding this Medical Device Correction, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT (Page 3) To:

Quality Compliance FCAMITG@Covidien.com **or fax it to (203) 492-7719**