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«Hospital_Name»
«Users_Name»- «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Reference: 92378480 -FA 29 April 2019

Urgent Field Safety Notice (for Distributor) - Medical Device Withdrawal

Xenform™ Soft Tissue Repair Matrix
Uphold™ Lite with Capio SLIM Vaginal Support System
Polyform™ Synthetic Mesh
Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior

Dear «Users_Name»,

Boston Scientific is implementing a withdrawal of the following products indicated for transvaginal placement of pelvic organ prolapse:

- Xenform™ Soft Tissue Repair Matrix
- Uphold™ LITE with Capio SLIM Vaginal Support System
- Polyform™ Synthetic Mesh
- Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior

On Tuesday, April 16, 2019, the United States Food and Drug Administration (FDA) ordered all manufacturers of surgical mesh for transvaginal repair of pelvic organ prolapse to stop selling products immediately and withdraw all products from the US market. FDA does not believe sufficient clinical evidence is available to assure the benefits of these devices outweigh their probable risks; for the US market this withdrawal was specific to only Xenform™ Soft Tissue Repair Matrix and Uphold™ LITE with Capio SLIM Vaginal Support System

Based on this FDA decision and the global regulatory environment regarding transvaginal mesh for this indication, BSC has now made the decision to voluntarily withdraw from inventory, all products listed above from the rest of the world, which are indicated for the transvaginal repair of pelvic organ prolapse.

Clinical Recommendations

Boston Scientific recommends that patients who have had transvaginal mesh placed for the surgical repair of pelvic organ prolapse should continue with their annual, other routine check-ups, and follow-up care. There is no need to take any additional action if patients are satisfied with their surgery and are not having any complications or symptoms.

Next Steps
Following is a list of affected products in scope of this action, all batches of which are to be withdrawn. No other BSC products are impacted by this withdrawal.

Attached to this letter is a specific listing of products which we have record of shipping to your facility. Please segregate the product immediately and return it to Boston Scientific in accordance with the enclosed instructions.

AFFECTED PRODUCT LISTING

UPN	Description	GTIN	Batch
M0068302410	Xenform™ Tissue Repair Matrix - 2cm X 7cm	8714729775133	All batches
M0068302430	Xenform™ Tissue Repair Matrix - 4cm X 7cm	8714729774464	
M0068302450	Xenform™ Tissue Repair Matrix 6cm X 10cm	8714729773764	
M0068302470	Xenform™ Tissue Repair Matrix 8cm x 12cm	8714729774198	
M0068318170	Uphold™ LITE with Capio SLIM Vaginal Support System	8714729839200	
M0068402400	Polyform™ Synthetic Mesh, 10cm x 15cm, box 1	08714729121305	
M0068402410	Polyform™ Synthetic Mesh, 15cm x 20cm, box 1	08714729767015	
M0068318150	Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior	08714729854548	

Further distribution or use of any remaining product affected by this action should cease immediately.

INSTRUCTIONS:

1- **Check your Inventory for the products affected by this Field safety Notice**.

2- **Please segregate and do not distribute any of the affected products found in your inventory.**

3- **Please notify all your customers that have received affected product of this Field Safety Notice.** To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this recall to the medical facility level.

4- **Have all affected product returned to your facility** and held in quarantine for reconciliation

5- **Please complete the attached Verification Form**, even if you do not have any product to return.

6- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **15 May 2019**.

7- **If you have products to return,** please package them in an appropriate shipping box and **contact** «Customer_Service_Tel» **of your local Boston Scientific office,** to arrange return.

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the high-quality standards that you expect from Boston Scientific.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

«Hospital_Name»
«Users_Name»- «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Referenca: 92378480 -FA 29. april 2019

Nujno varnostno obvestilo (za distributerja) - **Nujni odpoklic medicinskega pripomočka**
Matrica za popravilo mehkega tkiva Xenform™
Uphold™ Lite z vaginalnim podpornim sistemom Capio SLIM
Sintetična mrežica Polyform™
Pribor za popravilo posteriornega medeničnega dna Pinnacle™ LITE

Spoštovani «Users_Name»,

družba Boston Scientific umika naslednje izdelke, ki so indicirani za transvaginalno namestitev pri prolapsu medeničnega organa:

- Matrica za popravilo mehkega tkiva Xenform™
- Uphold™ LITE z vaginalnim podpornim sistemom Capio SLIM
- Sintetična mrežica Polyform™
- Pribor za popravilo posteriornega medeničnega dna Pinnacle™ LITE

V torek, 16. aprila 2019, je ameriška zvezna agencija za hrano in zdravila (FDA) vsem proizvajalcem kirurške mrežice za transvaginalno popravilo prolapsa medeničnega organa odredila takojšnjo zaustavitev prodaje izdelkov in umik vseh izdelkov z ameriškega trga. Agencija FDA ne meni, da je na voljo dovolj kliničnih dokazov, ki bi zagotavljali, da so koristi teh pripomočkov večje od njihovih morebitnih tveganj; za ameriški trg umik velja samo za matrico za popravilo mehkega tkiva Xenform™ in Uphold™ LITE z vaginalnim podpornim sistemom Capio SLIM.

Na podlagi te odločitve agencije FDA in globalnega regulativnega okolja glede transvaginalnih mrežic za to indikacijo se je družba BSC odločila, da iz svojega inventarja iz preostalih delov sveta prostovoljno umakne vse izdelke, ki so navedeni zgoraj in indicirani za transvaginalno popravilo prolapsa medeničnega organa.

Klinična priporočila

Družba Boston Scientific priporoča, da bolniki z nameščeno transvaginalno mrežico za kirurško popravilo prolapsa medeničnega organa nadaljujejo z letnimi in drugimi rutinskimi pregledi ter kontrolno nego. Če so bolniki zadovoljni s svojo operacijo in niso prisotni nobeni zapleti ali simptomi, potem ni potrebe po dodatnih ukrepih.

Naslednji koraki
Spodaj je seznam izdelkov, ki so vključeni v ta ukrep, in vse serije, ki jih je treba umakniti. Ta umik ne vpliva na noben drug izdelek družbe BSC.

Temu pismu je priložen podroben seznam izdelkov, ki so bili glede na naše evidence poslani v vašo ustanovo. Prosimo, da takoj izločite izdelek in ga v skladu s priloženimi navodili vrnete družbi Boston Scientific.

SEZNAM ZADEVNIH IZDELKOV

UPN	Opis	GTIN	Serija
M0068302410	Matrica za popravilo tkiva Xenform™ - 2 cm X 7 cm	8714729775133	Vse serije
M0068302430	Matrica za popravilo tkiva Xenform™ - 4 cm X 7 cm	8714729774464	
M0068302450	Matrica za popravilo tkiva Xenform™ - 6 cm X 10 cm	8714729773764	
M0068302470	Matrica za popravilo tkiva Xenform™ - 8 cm X 12 cm	8714729774198	
M0068318170	Uphold™ LITE z vaginalnim podpornim sistemom Capio SLIM	8714729839200	
M0068402400	Sintetična mrežica Polyform™, 10 cm x 15 cm, škatla 1	08714729121305	
M0068402410	Sintetična mrežica Polyform™, 15 cm x 20 cm, škatla 1	08714729767015	
M0068318150	Pribor za popravilo posteriornega medeničnega dna Pinnacle™ LITE	08714729854548	

Takoj prekinite z nadaljnjo distribucijo ali uporabo preostalih izdelkov, na katere se nanaša ta ukrep.

NAVODILA:

1- **Preglejte vašo zalogo izdelkov, na katere se nanaša to Varnostno obvestilo.**

1- **Prosimo, da vse prizadete izdelke iz vaše zaloge takoj izločite in jih ne posredujete dalje.**

2- **Prosimo, da o tem obvestilu obvestite vse vaše stranke, ki so prejele v to Varnostno obvestilo vključene izdelke.** Za učinkovito obvladovanje tega Varnostnega obvestila naj vaše stranke komunicirajo neposredno z vami in ne z družbo Boston Scientific. Če je katera od vaših strank distributer, jo obvestite, da mora obvestilo o tem odpoklicu posredovati na nivo zdravstvenih ustanov.

3- **Poskrbite, da so vsi prizadeti izdelki vrnjeni v vašo ustanovo** in jih do razrešitve zadeve dajte v karanteno.

4- Prosimo, da priloženi **Obrazec za preverjanje izpolnite**, tudi če nimate nobenega izdelka za vračilo.

5- **Izpolnjeni Obrazec za preverjanje vrnite vašemu lokalnemu uradu družbe Boston Scientific** za: najkasneje do **15. maj 2019**.

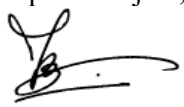
6- **Če imate izdelke pripravljene za vračilo,** jih zapakirajte v ustrezno embalažo in **se povežite z vašim lokalnim uradom družbe Boston Scientific,** da se dogovorite za vračilo.

Vaš Pristojni organ je obveščen o tem Varnostnem obvestilu (velja za države ES).

Opravičujemo se za morebitne nevšečnosti, nastale zaradi teh ukrepov, in se vam zahvaljujemo za razumevanje, saj smo se za ta ukrep odločili zaradi zagotavljanja varnosti bolnikov in zadovoljstva strank. Zavezani smo k nadaljnji ponudbi izdelkov, skladnimi z najvišjimi standardi kakovosti, ki jih pričakujete od družbe Boston Scientific.

Če imate v zvezi s tem Varnostnim obvestilom kakršnokoli vprašanje ali potrebujete pomoč, vas prosimo, da se obrnete na vašega lokalnega prodajnega predstavnika.

S spoštovanjem,



Marie Pierre Barlangua
Oddelek za zagotavljanje kakovosti
Boston Scientific International S.A.

Priloga: Obrazec za preverjanje