

URGENT FIELD SAFETY NOTICE

Covidien Auto Suture™ Structural Balloon Trocar & Auto Suture™ Blunt Tip Trocar Potential for Damage to Seal When Used with Mesh Products

26 August 2026

Medtronic Reference: FA1398

Dear Health Care Professional/Risk Manager,

The purpose of this letter is to advise you that Medtronic is issuing an Urgent Field Safety Notice regarding the potential for damage to the seal structure of the **Covidien Auto Suture™ Structural Balloon Trocar** and **Auto Suture™ Blunt Tip Trocar** when used to introduce hernia mesh products under certain conditions as described below. This safety notice applies to all distributed products with the Customer Facing Numbers (CFNs) listed in Table 1.

Issue Description:

We have received reports of events related to Covidien Auto Suture™ Structural Balloon Trocar and Auto Suture™ Blunt Tip Trocar reporting trocar seal disengagement when using the trocar with certain mesh products. This issue can occur when the trocar is used to deploy the mesh not in accordance with the mesh Instructions for Use (IFU).

Not following the IFU for the mesh and including use of incompatible trocar size, excess force, and not hydrating the mesh and/ or folding of the mesh could result in a seal disengaging into the cavity during mesh insertion in the trocar. The user would not be able to detect these issues prior to use.

It is important to carefully review and adhere to the manufacturer's IFU for both the trocar and mesh. The trocar products are meeting the design and functional intent and are clinically acceptable for use. In addition, the trocar products meet the manufacturing specifications. The Auto Suture™ Structural Balloon Trocar and Auto Suture™ Blunt Tip Trocar devices can continue to be used clinically.

Insertion of mesh products through a trocar without adequate preparation and trocar size selection can result in excessive force during insertion, leading to potential seal disengagement. Similar issues may also occur during insertion or removal of other oversized devices through the trocar. This Field Safety Notice serves to also caution users to adhere to all manufacturer's IFU of devices used in combination with trocars. Specifically, to ensure the size of the trocar is compatible with the device and to avoid excessive force during insertion/removal.

Potential Patient Risk:

Seal disengagement may lead to the potential risk for foreign body in the patient (including radiation exposure for radiographic imaging, and possible allergic reaction of any retained foreign body), delay of treatment, subcutaneous emphysema from CO₂ insufflation leak, tissue injury and/or nerve damage with any sudden loss of pneumoperitoneum.

Up until 25-JUN-2026, Medtronic has received 536 reports from customers globally related to the Covidien™ Auto Suture™ Structural Balloon Trocar and Auto Suture™ Blunt Tip Trocar seal disengagement issue. No serious adverse events have been reported for this issue.

Customer Actions:

Medtronic

1. Inform all surgeons and clinicians who handle the preparation and/ or placement of a Mesh or other devices that utilize the Covidien Auto Suture™ Structural Balloon Trocar and Auto Suture™ Blunt Tip Trocar devices.
2. Prior to using any Mesh device in conjunction with the following Trocars: Covidien Auto Suture™ Structural Balloon Trocar and Auto Suture™ Blunt Tip Trocar, please carefully review and adhere to the mesh manufacturer's Instructions for Use (IFU) on proper insertion techniques.
3. Prior to using devices in conjunction with the following Trocars: Covidien Auto Suture™ Structural Balloon Trocar and Auto Suture™ Blunt Tip Trocar, please carefully review and adhere to the manufacturer's Instructions for Use (IFU) on proper trocar size selection.
4. Please complete and return the Customer Acknowledgement Form enclosed with this letter acknowledging receipt of this information.
5. Please transfer this notice to other organizations on which this action has an impact and maintain a copy of this notice in your records.

Medtronic Additional Actions to be taken for this issue:

Medtronic has updated the Trocars' Instructions for Use (IFU) to bring additional emphasis to the mesh manufacturer's IFU through an additional warning and precaution, supporting proper use of Auto Suture™ Trocar's with mesh products. **Auto Suture™ Structural Balloon Trocar** and **Auto Suture™ Blunt Tip Trocar** products with the updated IFU are currently being manufactured and distributed, while the product with the previous IFU is no longer within Medtronic's immediate distribution network. Affected product with the previous IFU may continue to be used with consideration of this notification.

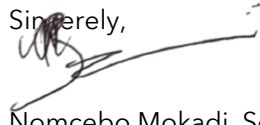
Additional information:

Medtronic has notified the Competent Authority of your country of this action.

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.

Sincerely,



Nomcebo Mokadi, Senior RA Specialist

Enclosed:

- Customer Acknowledgment Form
- Appendix 1: Product Scope

Appendix 1: Product Scope

Product Description	CFN	GTIN	Total
BOX KIT BYPASS	KIT00832R	00763000162559	6
BOX TLH BOX	BOX01922V1	00763000513283	18
PDB1000NT10B PDB1000+10M TROC BLUNT	PDB1000NT10B	10884521619876	5
BOX COLECISTECTOMIA	KIT00528V	00643169858626	888
BOX COLECISTECTOMIA	KIT00528V1	00763000597696	30
BOX INGUNAL BALOON + ONB TROC KIT	INGBALONB1	00763000265236	520
BOX MR CLEMENTS TEP HERNIA	BOX01883V1	00763000508876	20
BOX KIT COLON IZQUIERDO Y RECTO	KIT00678	00643169881174	176
BOX GENERAL SURGERY KIT	BOX02746V1	00763000596545	1116
BOX GENERAL SURGERY KIT	BOX02746V2	00763000927578	28
BOX LAP CHOLE KIT 57757C	KIT57757C	00763000442897	90
BOX LAP CHOLE KIT MR CONDON	PST03575	00763000075323	10
BOX APPENDIXBOXZONDERDUALPCK	BOX01536V3	00763000624996	67
BOX KIT COLE LAP	KIT01033V1	00763000618360	98
BOX KIT COLE LAP	KIT01033	00763000238261	454
BOX KIT GYN DOTT DI FRANCESCO	PST04338	00763000137410	205
BOX KIT COLON IZQUIE	KIT00952V6T	00763000619046	16
BOX APPENDIX BOX	BOX01536V2	00763000536701	200
KITDE0126 HERNIENKIT PANKLINIK KOELN	KITDE0126	10884521657984	117
BOX TROCAR BOX ZONDER DUALPCK	PST00890V2	00763000624972	215
BOX KIT COLECISTECTOMIA	BOX02175V2	00763000589967	426
BOX KIT COLECISTECTOMIA	KIT00680	00643169881198	24
BOX KIT COLECISTECTOMIA	BOX02175V3	00763000603632	160
BOX KIT COLECISTECTOMIA	BOX02175V6	00763000918293	185
BOX HER ING TEPPPDB1	BOX00196V1	00763000325022	148
BOX TROCAR BOX	PST00890	00643169900530	734
BOX TEPP KIT	KITDE0174	00643169997493	255
BOX BOX LAP NIER	PST02523	00643169994232	64
BOX KIT COLON DERECHO	KIT00677	00643169881167	199
BOX KIT APENDICECTOMIA	KIT00681	00643169881204	47
BOX KIT APENDICECTOMIA	KIT00691R	00763000008185	182
BOX KIT APENDICECTOMIA	BOX02176V1	00763000918316	40
K-BE-HER108-008 HERNIA GENERAL 108 X1	K-BE-HER108-008	10884521562028	182
BOX TEP BOX	BOX01500V1	00763000455354	347
KIT-DE-0074V BLUNT TIP KIT AUG KOLN X1	KIT-DE-0074V	10884521584488	351
PDBS2NT10SB PDBS2+10M STRUC BALOON KIT	PDBS2NT10SB	10884521590755	271
BOX PDBS2NT10SB KIT	INGBAL21	00763000266776	184
PDBS2NT10SBNA PDBS2+10M STRUC BALOONX1	PDBS2NT10SBNA	10884521592599	345
KIT57649- COSMOS LAP HERNIA KIT V RENS	KIT57649-	10884521628250	36
BOX LAP CHOL BOX	BOX01451V1	00763000448103	30
BOX LAP CHOLE KIT ST JOHN S	PST01134	00643169900486	142
BOX COLECISTECTOMIA SIN CUCHILLA	KIT00498V	00643169858299	174
BOX KIT COLON DERECHO SIGMA	KIT00910	00763000118709	60
BOX KIT BY PASS	PST05320V3	00763000603670	50
BOX KIT COLON DERECHO LAP	KIT00952V5	00763000597184	30

Product Description	CFN	GTIN	Total
BOX KIT COLON DERECHO LAP	KIT00952V5S	00763000716806	93
BOX KIT COLON DERECHO LAP	KIT00952V5SS	00763000742966	10
BOX KIT COLON DERECHO LAP	KIT00952D2	00763000830106	8
BOX KIT HISTERECTOMIA LAPAROS	PST05327V4	00763000603687	8
BOX KIT DE PROSTATECTOMIA	PST05303V3	00763000639907	36
BOX KIT COLON IZQUIERDO EE28	KIT00952V6	00763000597191	90
BOX KIT COLON IZQUIERDO EE28	KIT00952R	00763000763060	48
BOX COLE TROCAR PTICO 12	BOX02175OPT	00763000651077	88
BOX KIT APENDI LAPARO	PST05321V2	00763000373283	90
BOX KIT COL LAPARO	PST05322V2	00763000373252	328
BOX BASIC LAP SURGERY KIT	PST05206	00763000239725	118
BOX NEW ST JOHNS KIT	GENLAPKIT2016	00643169863170	37
BOX KIT RECTO LAPAROSCOPICO	PST05323V2	00763000375157	29
BOX KIT RECTO LAPAROSCOPICO	PST05323V6	00763000741303	10
BOX KIT RECTO LAPAROSCOPICO	PST05323V7	00763000755089	26
BOX KIT NEFRECTOMIA	BOX04078V1	00763000654504	34
BOX KIT PROSTATE LAPARO	PST05325V2	00763000373306	80
BOX TLH BOX MET L HOOK	BOX01922V2	00763000648541	53
BOX KIT NEFRECTOMIA LAPARO	PST05326V2	00763000375034	43
BOX ZESTAW NEFREKTOMIA	NEFRLIND	00763000500580	17
BOX KIT DE NEFRECTOMIA	PST05304V3	00763000639693	18
BOX KIT COLON T OPTICOS	KIT00589RV2	00643169857865	30
BOX LAP HERNIA KIT MR CONDON	PST03574	00763000075316	10
BOX KIT DE HISTERECTOMIA	PST05301V3	00763000639143	42
BOX KIT PROSTATECTOMIA RADICAL	BOX00385V1	00763000345495	24
BOX KIT DE ANEXECTOMIA	PST05302V3	00763000640392	6
BOX BOX01515V1 KIT COLECISTECTOMÍA	BOX01515V1	00763000458010	374
BOX HERNIABOX	KHER321	00643169931671	197
BOX ADRENALEKTOMIA LAP	LAPPADR	00763000700133	10
BOX KIT COLECISTECMIA	BOX02428VT	00763000687861	18
BOX KIT COLECISTECMIA	BOX02428V1	00763000558659	195
BOX KIT CISTECTOMIA	BOX04076V1	00763000654535	10
BOX TEP KIT KORT	BOX04293V1	00763000699840	2
BOX KIT HIATO T OPTICOS	KIT00590RV2	00643169857872	24
BOX JOHNS ONB KIT	BOX04652V1	00763000724962	114
BOX BASIC LAP ONB	BOX04654V1	00763000724948	122
BOX LAP CHOL FOR OPEN INTROD	BOX01451V3	00763000741433	6
BOX KIT COLECISTECTO	BOX02428V4	00763000742805	8
BOX KIT COLE ONB5 Y ONB12	BOX02175V4	00763000758370	112
BOX KIT NEFRECTOMIA LAPAROSCO	PST05590VV	00763000719609	10
BOX KIT NEFRECTOMIA LAPAROSCO	PST05590VZ	00763000867720	17
BOX KIT NEFRECTOMIA LAPAROSCO	PST05590VT	00763000930547	10
BOX KIT COLE	BOX02428V5	00763000754556	102
BOX PRAWA HEMIKOLE LAP	PHLLAP	00763000700140	10
BOX PRZEDNIA RESEKCJA LAP	PRLLAP2835	00763000700171	20
BOX LAP CHOL BOX OPEN INTROD	BOX01451V8	00763000761325	44
BOX LAP CHOL BOX OPEN INTROD	BOX01451V7	00763000761233	63

Product Description	CFN	GTIN	Total
BOX LAP CHOL BOX OPEN INTROD	BOX01451V6	00763000748876	28
BOX KIT COLECISTECTOMIA LAPAR	PST05322V3	00763000760298	18
BOX HERNIA INGUINAL	BOX00196V2	00763000760465	53
K-BE-HER107-007 HERNIA GENERAL 107 X1	K-BE-HER107-007	10884521562011	4
BOX KIT HERNIE PROF HEIZMANN	BOX05251V1	00763000761332	66
BOX LAP INGUINAL KIT	OMSHSZ21	00643169939677	29
BOX KIT NEFRECTOMIA RADICAL LAP	KIT00898	00763000112400	12
BOX KIT HERNIA LAP TEP	KIT01061	00763000248017	30
BOX KIT CISTECT RADI LAPAR	BOX00531V2	00763000402150	10
KITOPT020- CHOLECYSTECTOMY KIT X1	KITOPT020-	10884521588998	17
BOX NEPHRECTOMY LIGASURE	NEFRLIND1	00763000722517	6
BOX KIT COLE CON 176657	BOX02175V5	00763000864309	301
BOX HERNIA KIT FOR PROF SHEEN	PST034332244	00763000228767	11
BOX KSKS LAP PARTIAL NEFRECTO	BOX06290V1	00763000891152	6
BOX APPENDIXBOX NONB5STF	BOX01536V4	00763000876555	6
BOX KIT VESICULA	KIT01255V	00763000865955	125
BOX NEPHRECTOMY SONICISION	NEFRLIND2	00763000722500	6
BOX TLH BOX L HOOK NONB5STF	BOX01922V3	00763000876548	2
BOX PST00890V3 TROCAR BOX	PST00890V3	00763000949785	104
BOX PST05398V4 LAPCHOL BOX	PST05398V4	00763000949044	37
BOX BOX01478V4 LAP CHOL LARGE	BOX01478V4	00763000949082	12
BOX BOX01536V6 APPENDIX BOX	BOX01536V6	00763000950347	14
BOX LAPCHOL BOX	PST05398V6	00763000962753	10
BOX KIT COLON CON NONB5	BOX02177V3	00763000925321	14
OMS-T10SB TROCAR BALLOON O ARMATURES10	OMS-T10SB	20884521081083	175513
OMS-T10SB TROCAR BALLOON O ARMATURES10	OMS-T10SB	10884521081086	2990
OMST10BTNL 10 BLUNT TIP TROCAR W/O LATEX	OMS-T10BTNL	20884521527383	460473
OMST10BTNL 10 BLUNT TIP TROCAR W/O LATEX	OMS-T10BTNL	10884521527386	2091
TROCAR OMS-T12BTNL BNLT TIP 12MM NOLATEX	OMS-T12BTNL	10884521552449	649
TROCAR OMS-T12BTNL BNLT TIP 12MM NOLATEX	OMS-T12BTNL	20884521552446	59983
OMS-T10BTSNL 10MM BLUNTTIP TROCARW/OLATX	OMS-T10BTSNL	10884521539648	18435
OMS-T10BTSNL 10MM BLUNTTIP TROCARW/OLATX	OMS-T10BTSNL	10884521539648	161
OMS-T12BT TROCAR BLUNT TIP 12 STR UUX5	OMS-T12BT	20884521081090	130437
OMS-T12BT TROCAR BLUNT TIP 12 STR UUX5	OMS-T12BT	10884521081093	5320
OMS-T10BT BLUNT TIP TROCAR 10 X5	OMS-T10BT	20884521080871	219540
OMS-T10BT BLUNT TIP TROCAR 10 X5	OMS-T10BT	10884521080874	18508
OMST10BTS TROCAR BLUNT COURT TIP 10SHRT	OMS-T10BTS	20884521081076	28193
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