

Urgent Field Safety Notice Covidien Surgiwand™ II suction and irrigation devices Recall

March 2021

Medtronic Reference: FA967

Dear Customer / Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of its **Covidien Surgiwand™ II suction and irrigation devices**.

Issue Description:

This voluntary recall is being conducted after customers reported foreign particles in the device tubing. Our investigation identified an assembly process that could potentially damage the "Y-connector," allowing for small pieces of the connector to move through the device tubing. Use of this device with this issue may result in infection, allergic reaction, or foreign body reaction. Manufacturing process improvements have been implemented to remediate this issue. There have been no reports of serious injury related to this issue.

This voluntary recall affects only the item codes with associated lot numbers listed on Attachment A.

Required Actions:

1. Please immediately quarantine and discontinue use of affected item codes with associated lot numbers listed in Attachment A.
2. Please return affected product as indicated below. All unused products from the affected item codes and associated lot numbers must be returned.
3. If you have distributed the Covidien Surgiwand™ II suction and irrigation devices listed in Attachment A, please promptly forward the information from this letter to those recipients.
4. Complete the Return Verification Form even if you do not have inventory.

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a distributor	Complete all fields on the form and contact your distributor directly to arrange for return of product.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form.

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 at Dima Healthcare

Sincerely,

Zaher Al Moarravi

Surgical Innovations, Chronic & ICU Lead Indirect Markets

Handwritten signature in Arabic script: Zaher Al Moarravi

Attachment A

Item Code	Description	Affected Lot Numbers				
178083	Surgiwand™ II Auto Suture™ Suction and Irrigation Device 5 mm	P9D0020Y	P9F1565Y	P0B1393Y	P0F0332Y	P0G0436Y
		P9D1478Y	P9F1566Y	P0B1394Y	P0F0333Y	P0G0483Y
		P9E1057Y	P9G0718Y	P0C0405Y	P0F0334Y	P0G0484Y
		P9E1058Y	P9G0719Y	P0C0406Y	P0F0335Y	P0G0542Y
		P9E1059Y	P9K1412Y	P0C0413Y	P0F0336Y	P0G0543Y
		P9E1064Y	P9K1444Y	P0C1101Y	P0F0337Y	P0G0544Y
		P9E1065Y	P9D0022Y	P0C1102Y	P0F0646Y	P0G0545Y
		P9E1066Y	P9D0021Y	P0C1554Y	P0F0647Y	P0G0717Y
		P9E1121Y	P9K1493Y	P0C1555Y	P0F0648Y	P0G0718Y
		P9E1122Y	P9K1494Y	P0C1556Y	P0F0649Y	P0H0176Y
		P9E1123Y	P9K1495Y	P0E1077Y	P0F0718Y	P0H0177Y
		P9E1124Y	P9K1496Y	P0E1078Y	P0F0944Y	P0H0213Y
		P9E1197Y	P9K1497Y	P0E1079Y	P0F0945Y	P0H0430Y
		P9E1380Y	P9K1616Y	P0E1086Y	P0F0946Y	P0J0017Y
		P9E1381Y	P9K1615Y	P0E1087Y	P0F0947Y	P0J0627Y
		P9E1382Y	P0A1508Y	P0E1088Y	P0F0948Y	P0K0130Y
		P9E1383Y	P0A1509Y	P0E1177Y	P0G0034Y	P0K0158Y
		P9F1162Y	P0B1130Y	P0E1178Y	P0G0035Y	P0K0373Y
		P9F1163Y	P0B1131Y	P0E1179Y	P0G0036Y	P0L0480
		P9F1280Y	P0A1510Y	P0F0120Y	P0G0037Y	P0L1176
		P9F1281Y	P0B1262Y	P0F0121Y	P0G0038Y	P0L1177
		P9F1563Y	P0B1291Y	P0F0122Y	P0G0059Y	P0L1261
		P9F1564Y	P0B1292Y	P0F0123Y	P0G0060Y	P0L1399
		178093	Surgiwand™ II Auto Suture™ Suction and Irrigation Device with L-Hook Tip 5 mm	P9C1632Y	P9E0016Y	P9K1503Y
P9C1634Y	P9E0017Y			P9K1618Y	P0E1313Y	P0G0649Y
P9C1635Y	P9E1007Y			P0B1134Y	P0E1314Y	P0G0650Y
P9C1636Y	P9E1279Y			P0B1135Y	P0E1393Y	P0H0179Y
P9D1175Y	P9E1325Y			P0B1268Y	P0F0126Y	P0H0180Y
P9D1177Y	P9E1326Y			P0B1399Y	P0F0127Y	P0J0578Y
P9D1176Y	P9E1328Y			P0C0411Y	P0F0440Y	P0J0579Y
P9D1178Y	P9F1164Y			P0C1105Y	P0F0441Y	P0J0629Y
P9D1346Y	P9F1568Y			P0C1557Y	P0F0443Y	P0K0336Y
P9D1347Y	P9K1445Y			P0C1558Y	P0F0651Y	P0L1175
P9D1480Y	P9K1446Y			P0E1180Y	P0F0652Y	P0L1262
P9D1481Y	P9K1501Y			P0E1181Y	P0F0846Y	P0L1304
P9B1359Y	P9K1502Y					
178094	Surgiwand™ II Auto Suture™ Suction and Irrigation Device with Spatula Tip 5 mm			P9D1179Y	P0B1136Y	P0E1173Y
		P9D1180Y	P0B1400Y	P0E1383Y	P0G0739Y	

RETURN VERIFICATION FORM

FA967: Covidien Surgiwand™ II Suction and Irrigation Devices

Please complete this form and return it to Medtronic even if you do not have affected inventory
[Please insert date the form was sent]

Customer Contact Details	Medtronic Contact Details
Hospital Name: Covidien/Medtronic Account Number:	To: <i>[please insert name]</i>
Account Address: Street: Postal Code: City: Department: Contact Person at Point of Collection: Opening Hours: Name of person completing this form:	Address: <i>[please insert Medtronic address]</i>
Telephone:	Telephone: <i>[please insert Medtronic telephone number]</i>
Fax:	Fax: <i>[please insert Medtronic fax number]</i>
E-mail:	E-mail: <i>[please insert contact e-mail address]</i>

Please list the quantity of affected product at your facility, if you have **no** inventory, please tick the box below.

No Inventory (Please tick):

Item Code	Invoice or Despatch Note (if available)	Lot number	Quantity (Eaches or Cases) Please specify

Information for the courier:

Number of parcels to collect: _____

Number of these parcels that weigh more than 45 KG: _____

By signing this form, I confirm that I have read and understand the communication from Medtronic regarding the Covidien Surgiwand™ II suction and irrigation devices dated March 2021.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the Covidien Surgiwand™ II suction and irrigation devices noted in this letter.

Name: (print)

Signature:

Date:

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.