Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

FDA
Food and Drug Administration
PHILIPPINES

**FDA ADVISORY**
No. 2021-1124

21 MAY 2021

**TO:** **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

**SUBJECT:** **Voluntary Recall of Covidien Surgiwand™ II Suction and Irrigation Devices**

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The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of Covidien Surgiwand™ II Suction and Irrigation Devices with FDA registration numbers, MDR-01054, MDR-01055 and MDR-01145, manufactured by Covidien-USA, imported and distributed by Medtronic Philippines, Inc.:

| 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 | P9C1632Y | P9E0016Y | P9K1503Y | P0E1281Y | P0F0872Y |
| | | P9C1634Y | P9E0017Y | P9K1618Y | P0E1313Y | P0G0649Y |
| | | P9C1635Y | P9E1007Y | P0B1134Y | P0E1314Y | P0G0650Y |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Irrigation Device with L-Hook Tip 5 mm | 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 | P0E1384Y | P0K0334Y |
| | | P9D1180Y | P0B1400Y | P0E1383Y | P0G0739Y | |

| **Covidien Best Practices Kits containing Surgiwand™ II Auto Suture™ Suction and Irrigation** | |
|---|---|
| **Affected Kit Parent Code** | **Description** |
| 00C9010 | 00C9010 LAP CHOLE BP KIT |

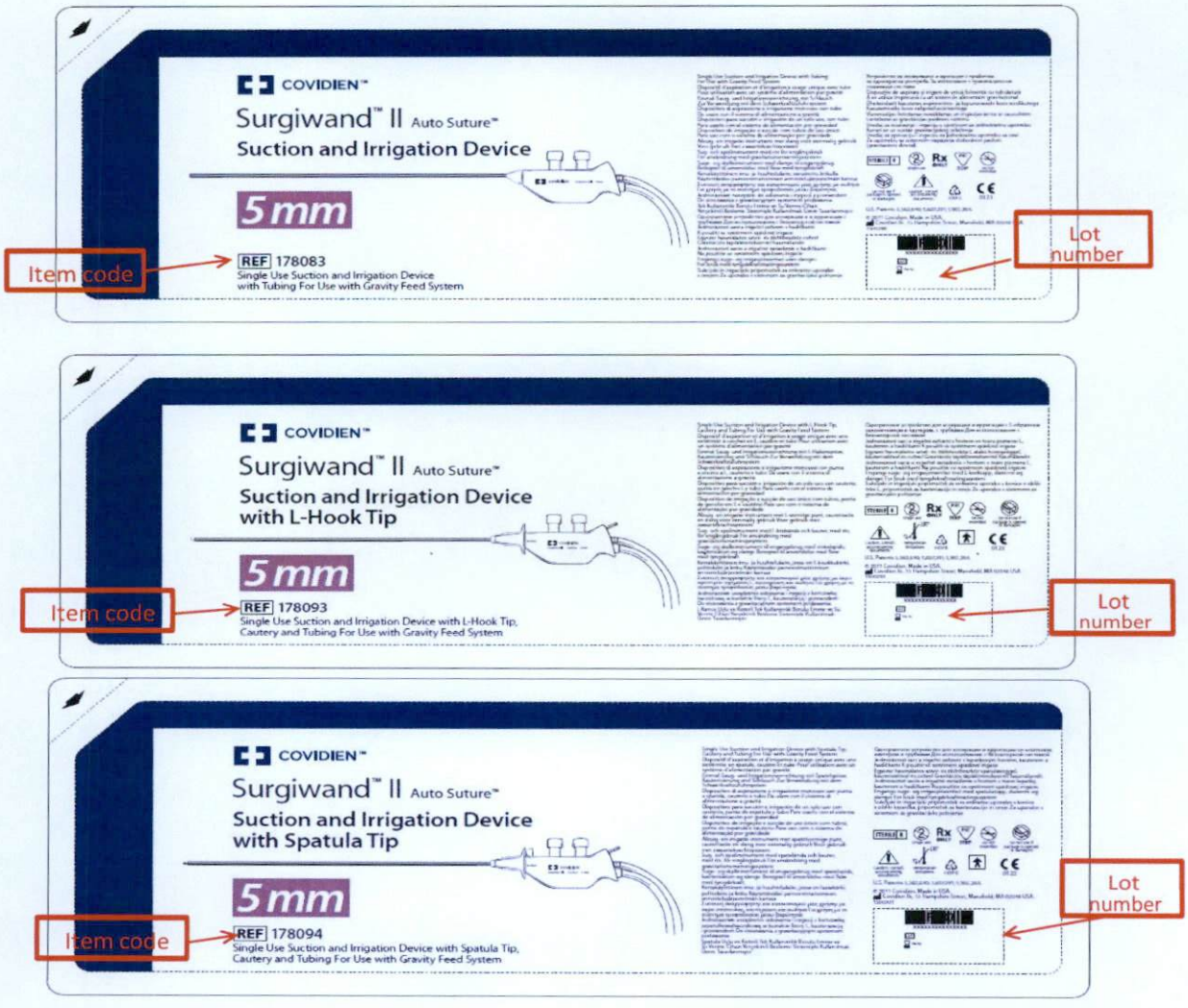


Figure 1. Covidien Surgiwand™ II Suction and Irrigation Devices

Medtronic International, Ltd. initiated the voluntary recall of the above-mentioned specific lots/batches of Covidien Surgiwand™ II Suction and Irrigation Devices after customers reported foreign particles in the device tubing. On their investigation, they 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. Manufacturing process improvement have been implemented to remediate this issue. There have been no reports of serious injury to this issue.

In light of the foregoing, all concerned healthcare professional, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots/batches of Covidien Surgiwand™ II Suction and Irrigation Devices.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 8857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

**ROLANDO ENRIQUE D. DOMINGO, MD**
Director General

DTN 20210419094503