

URGENT MEDICAL DEVICE RECALL

for Devon™ Light Glove

April 16, 2015

Attention: Risk Management

Please forward this communication to all potential users of the product who may include:

- Surgical Units
- Central Sterile Processing
- Biomedical Engineering

Dear Valued Customer:

This letter is to advise you that Medtronic is voluntarily recalling all lots of former Covidien Devon™ Light Gloves and specific sterile kits for which the lot number begins with 508xxxx or lower. This product is a disposable cover used in operating rooms and similar settings to cover the handles of surgical lights. This voluntary recall is being conducted due to the risk that Devon™ Light Gloves of these lots could contain splits or holes. Should the user be unaware that the Light Glove is torn/split, a transfer of microorganisms from the light handle into the patient wound is possible when the clinician touches the handle and then onto the sterile field. Surgical site infections can cause morbidity, prolonged hospitalization, and death. We have received reports where this issue was discovered during a surgical procedure; however, no adverse events have been reported.

The affected product was produced during the time period, March 2012 through March 2015. Our records indicate that you may have received some of the affected product.

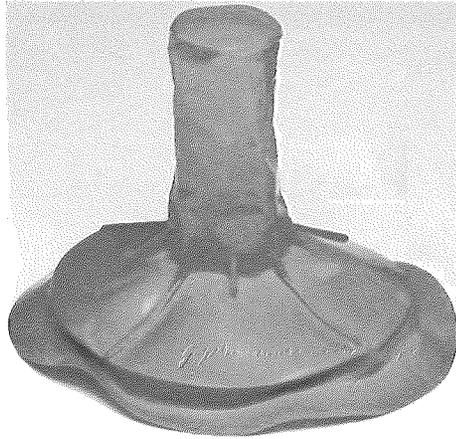
Medtronic is requesting that customers quarantine any remaining stock of the items/lots detailed on the below list for which the lot number begins 508xxxx or lower and follow the appropriate instructions on the attached forms as they pertain to your method of purchase. The list of items below contains both single sterile product as well as sterile procedure kits marketed under the Medtronic brand.

Item Number	Item Description	Item Number	Item Description
31140208	3611 LIGHT GLOVE	31141651	K-1560-S OR Mini Kit
31140216	3613 LIGHT GLOVE	31141669	K-1530-S OR Mini Kit
31140257	3612 LIGHT GLOVE	31141677	K-1200-S OR Mini Kit
31141479	K-1842-S OR Mini Kit	31141784	K-1960-S OR Mini Kit
31141487	K-1560-S3 OR Mini Kit	31141859	K-1615-S3 OR Mini Kit
31141495	K-1530-S3 OR Mini Kit	31141875	K-1940-S3 OR Mini Kit
31141537	K-1940-S OR Mini Kit	31144507	7519 Minor Surgical Kit
31141552	K-1920-S OR Mini Kit	31144895	7614-T4 Single Basin Set Up Kit
31141560	K-1200-S3 OR Mini Kit	31144960	7693-T4 Single Basin Set Up Kit
31141578	K-1840-S OR Mini Kit	31144978	7766 Double Basin Set Up Kit
31141586	K-1660-S OR Mini Kit	31145025	7496-8 MINI-PLUS KIT
31141602	K-1630-S OR Mini Kit	31145215	7896 Double Basin Set Up Kit
31141610	K-1615-S OR Mini Kit	31145231	7897 Double Basin Set Up Kit
31141628	K-1614-S OR Mini Kit	31145249	7897-T8 Double Basin Set Up Kit



Item Number	Item Description	Item Number	Item Description
31145298	7896-T8 Double Basin Set Up Kit	50007698	7698-T4 Single Basin Kit
31145397	7497-8 MINI-PLUS KIT	50007699	7699-T4 Single Basin Kit
31145413	7497-88 Mini-Plus Kit	50007898	7898-T8 Double Basin Kit
31145496	7696-T4 Single Basin Set Up Kit	50007899	7899-T8 Double Basin Kit
31145504	7708 Double Basin Kit	50047403	7496-HCS MINI-PLUS KIT
31145520	7614 Single Basin Set Up Kit	50047405	7496-HES MINI-PLUS KIT
31145546	7693 Single Basin Set Up Kit	52000076E	7339-ES C-SECTION DELUXE PACK
31145629	7696 Single Basin Set Up Kit	52000082E	7335-HUV DELIVERY KIT
31145645	7608 Single Basin KIT	56479	7335-SMC C-Section Kit
31150470	7496-PUP MINI PLUS KIT	573208	7519-DHCG MINOR KIT
31153060	7697-T4 Single Basin Kit	573210	7581-CSD Minor KIT
31153938	7756-KST Surgical Set Up Kit	573326	7497-HLS Surgical Kit
31154266	7656-KST Surgical Set Up Kit	573328	7437-NRF SURGICAL ASC KIT
31175089	7497-8T6 Surgical Kit	573343	7499-88 SURGICAL KIT with Light Gloves
31321097	7697 Surgical Set Up Kit	573346	7499-TLG Surgical Kit with Edge
31324299	7830-HOH Surgical Set Up Kit	573359	7499-HLW Surgical KIT
31404851	7382-OTO2 Delivery Kit	573368	7494-CAB2 SURGICAL KIT
31451092	7600-DNV Surgical Set Up Kit	573509	7696-GSL-VL SINGLE BASIN KIT
31451480	7493-SFW SURGICAL KIT	573558	7665-CPB SINGLE BASIN KIT
31453098	7682-MHP Surgical Set Up Kit	573561	7696-KSC SINGLE BASIN KIT
31460432	7596-SHH Surgical KIT	573732	7620-CWA Augmentation Kit
50000148	K-1920-COE MINI-KIT	573741	7667-HMI Minor Kit
50000511	7516-UNI Universal ASC Kit	573776	7520-BHP SURGICAL KIT
50000512	7557-UNI Universal ASC Kit	573777	7527-BHB SURGICAL KITS
50000515	7667-BRT Breast ASC Kit	573798	7496-8KB Surgical KIT
50000568	7605-SEC Single Basin Kit	573799	7516-UNIKB Surgical SET-UP KIT
50000599	7694-ADA Single Basin Kit	573375A	MINI-PLUS KIT
50000947	7413-CAD Surgical KIT	573830D	MINOR KIT
50001029	7417-PCP Surgical KIT	573831B	MAJOR KIT
50001052	7427-CFS Surgical KIT		

Many of the items in the above list are procedure kits marketed under the Covidien, now part of Medtronic brand. The Light Glove is one of many components included in the kits. The Medtronic Light Gloves can be readily recognized among the kit components by the color and shape (see below).



Please respond to Medtronic using one of the two attached forms. All customers must reply to Medtronic via one of these forms, WHETHER you have affected product at your site OR NOT. Please choose the form that best describes your situation.

Your response is vital to our monitoring of the effectiveness of this recall.

Thank you for your business and continued support. This action is being taken with the knowledge of the FDA and other regulatory authorities. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative or Medtronic Customer Service, Monday through Friday, 8am – 6:30pm ET, at (800) 882-5878.

Adverse reactions or quality problems experienced with the use of this product should be reported to FDA and Medtronic:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail), or
- Call FDA (800) FDA-1088
- Call Medtronic Quality Assurance at (800)-962-9888, option 8, then extension 2500.

We sincerely apologize for any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,



Michael P. Spears
Vice President, Quality Assurance
Medical Supplies

RECALLED PRODUCT RETURN FORM

Devon™ Light Glove – Instructions

Required Actions / Instructions:

Customers who purchased the Devon™ Light Glove from a Distributor as a unique, sterile item:

1. Immediately quarantine and discontinue use of the affected devices.
2. Please complete **all fields** on the form in their entirety and contact your Distributor directly to arrange your return.
3. Please return all affected product to your Distributor
4. Please email the completed form to DevonLightGloveFCA@Covidien.com or fax it to (508) 261-8461.

Customers who purchased the Devon™ Light Glove from a distributor as part of a Medtronic manufactured procedure kit:

1. Immediately quarantine and discontinue use of the affected devices.
2. Please complete **all fields** on the form in their entirety and contact your Distributor directly to arrange your return.
3. Please return all affected product to your Distributor. Please note, you must return the **ENTIRE KIT**.
4. Please email the completed form to DevonLightGloveFCA@Covidien.com or fax it to (508) 261-8461.

Customers who purchased the Devon™ Light Glove but do not have any product to return.

Regardless of whether you purchased the product as a unique, sterile item or part of a Medtronic manufactured kit, or whether you purchased it directly from Medtronic or via Distributor, **if you do not have any product to return, you must complete and return this form.**

1. Please complete **all fields** on the form in their entirety. Please be sure to check the box indicating “no inventory”
2. Please email the completed form to DevonLightGloveFCA@Covidien.com or fax it to (508) 261-8461.



RECALLED PRODUCT RETURN FORM

Devon™ Light Glove

Please use this form if you are returning product that you purchased directly from Medtronic. PLEASE COMPLETE THIS FORM IN ITS ENTIRETY.

Date:

Name of Person Completing this Form: Title:

Direct Phone #: Email:

Account Name: Medtronic Acct #:

Account Address:

City: State: Zip Code:

Return Goods Authorization (RGA) #: (please include once received from Customer Service)

If you have more than 4 items to return please use multiple forms and mark 1 of 2, 2 of 2 etc.

Please complete the following as it pertains to the inventory you will return

Part Number	Lot Number	Qty	Case or Each?

I ACKNOWLEDGE RECEIPT OF THE Devon™ LIGHT GLOVE RECALL NOTIFICATION DATED APRIL 16, 2015 AND UNDERSTAND THE RECALL INSTRUCTIONS PROVIDED.

(Signature Required)

Required Actions / Instructions:

1. Immediately quarantine and discontinue use of the affected product
2. Please complete this form in its entirety and fax it to (800) 895-6140 or email it to feedback.customerservice@Covidien.com.
3. If you have affected units to return, Customer Service will respond with a Return Goods Authorization (RGA) number as well as shipping documents, which will cover shipment pickup and all freight costs associated with the return. Note: If you purchased a Medtronic manufactured kit, please return the ENTIRE KIT to Medtronic.
4. Once the RGA number is received, please enter this number on the completed Devon™ Light Glove Recalled Product Return Form and include the form with your returned product.
5. Please ship affected product(s) with the RGA # provided by Customer Service to:
Medtronic - Attention: Devon™ Light Glove 110 Kendall Park Lane. Atlanta, GA 30336
For questions regarding the RGA / return process, please contact Medtronic Customer Service, M-F, 8am – 6:30pm ET at (800) 882-5878.



RECALLED PRODUCT RETURN FORM

Devon™ Light Glove

Please use this form if you do not have any product to return OR if you will be returning product to a Distributor.

PLEASE COMPLETE THIS FORM IN ITS ENTIRETY

Date:

Name of Person Completing this Form: Title:

Direct Phone #: Email

Direct Customers:

Account Name: Medtronic Acct #:

Account Address:

City: State: Zip Code:

How did the account purchase this product? (Please check)

Direct from Medtronic:

From a Distributor:

Customers of Distributors:

Distributor Name:

Address:

City: State: Zip Code:

No Inventory (Please check):

If you have more than 8 items to return please use multiple forms and mark 1 of 2, 2 of 2 etc.

Please complete the following as it pertains to the inventory you will return to your distributor.

Part Number	Lot Number	Qty	Case or Each

I ACKNOWLEDGE RECEIPT OF THE Devon™ LIGHT GLOVE RECALL NOTIFICATION DATED APRIL 16, 2015 AND UNDERSTAND THE RECALL INSTRUCTIONS PROVIDED.

(Signature Required)