

URGENT FIELD SAFETY NOTICE

May 29, 2012

Attention: Purchasing / Materials Manager / Distribution Partner

RE: **Monoject™ Insulin Safety Syringe**

Covidien is conducting a FSCA regarding specific lots of Monoject™ Insulin Safety Syringe with a volume of 3/10 and 1/2 ml. This FSCA is being conducted due to a molding issue that can allow the safety shield to separate from the syringe, exposing the needle, which could potentially result in a needle stick. Covidien is requesting that customers quarantine and return any remaining stock of the lots listed below.

THIS FSCA APPLIES ONLY TO PRODUCT ID AND LOT NUMBERS LISTED BELOW. No other lots or product codes of Monoject™ Insulin Safety Syringe are affected by this FSCA.

Product ID	Description	Lot
8881511144	Monoject™ Insulin Safety Syringe 3/10mL 29 X 1/2"	013816 017007
8881511344	Monoject™ Insulin Safety Syringe 3/10mL 30 X 5/16"	019115
8881511136	Monoject™ Insulin Safety Syringe 1/2mL 29 X 1/2"	Any lot in the series 015806 - 033106
8881511336	Monoject™ Insulin Safety Syringe 1/2mL 30 X 5/16"	015605 034606 019114

The listed product was produced from May 2010 through November 2010. Our records indicate that you may have received some of the listed product. Please examine your inventory and in-use stock to determine if you have any units of the affected product on hand.

Product ID and lot numbers are clearly visible on the unit package and shipping case labels.

Should any of the listed product be found, please remove it from inventory and place in quarantine immediately.

Please refer to the instructions on the following page for product return and replacement.

DIRECT USER CUSTOMERS:

Please complete the attached Monoject™ Insulin Safety Syringe Verification form in entirety, **even if you do not have product to return**. Please return the completed form by fax to [local Fax number], or e-mail at [local email address]

You will be contacted by Customer Services to arrange return of affected products; you will receive credit for returned products.

Please include a copy of the Verification form with the product being returned.

CUSTOMERS WHO HAVE BOUGHT PRODUCT FROM COVIDIEN AUTHORIZED DISTRIBUTORS:

If you are an end-user with affected product purchased from a Covidien authorized distributor, please call that distributor for credit. The Covidien authorized distributor will refund 100% of the purchase price and arrange for replacement.

COVIDIEN AUTHORIZED DISTRIBUTORS:

If you are a Covidien authorized distributor (dealer), we request that you notify your customers of this letter.

Please complete the attached Monoject™ Insulin Safety Syringe Verification Form in entirety, even if you do not have product to return. Please return the completed form by fax to [local fax number], or e-mail at [local email address]

Your customers should notify YOU directly of any product they have on hand, not Covidien.

You will be contacted by Customer Services to arrange return of affected products; you will receive credit for returned products.

If you would like to place a new order to receive new product, please contact your local Sales representative.

Should you have any questions concerning this FSCA, please contact [local contact person].


This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

This action is being conducted with the knowledge of [local Competent Authority].

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We apologize for any inconvenience this action may cause.

Sincerely,


Vice President,
Regulatory Affairs
Medical Supplies

URGENT MEDICAL DEVICE FSCA - Monoject™ Insulin Safety Syringe VERIFICATION FORM

Customer Contact Details	Covidien Contact Details
Hospital Name: Covidien Account Number:	To: <i>[please insert name Covidien commercial office]</i>
Collection Address: Department: Street: City: Postal Code: Contact Person at Point of Collection: Opening Hours:	Address: <i>[please insert Covidien address]</i>
Telephone n°:	Telephone n°: <i>[please insert Covidien telephone number]</i>
Fax n°:	Fax n°: <i>[please insert Covidien 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 stock, please indicate '0'.

Product code	Invoice or Despatch Note	Lot number	Qty EA	Qty CT

Information for the courier:

Number of parcels to collect: _____

Weight: < 45kg > 45kg

Name:
(please print)

Signature:

Date:

- Please fax this form to the fax number referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit for these products.
- Please don't send the goods back before having received the return documentation.