

URGENT FIELD SAFETY NOTICE

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April 28, 2009

Subject: Product Recall Action

CAH Catalog # 2D73PB55, 2D73PB60, 2D73P865, 2D73PB70, 2D73PB75, 2D73PB80, 2D73PB85, 2D73PB90

Description: ESTEEM® BLUE with NEU-THERA™ Polyisoprene Surgeon Gloves

Lot Number: ALL LOTS NUMBERS starting with TS0409XXXX to TS09020495

Dear Customers,

Cardinal Health has recently identified through customer feedback that the Esteem® Blue with Neu-Thera™ Polyisoprene Surgeons Glove has experienced increased issues of cuff tears. As a result of this feedback, we have decided to initiate a **voluntary recall** for the above referenced product.

Due to its unique manufacturing process, **only Esteem Blue with Neu-Thera™ is affected by the here above mentioned issues.** The rest of the Esteem® range of products: Esteem® SMT, Esteem® with Neu-Thera™ and Esteem® Micro are consequently not affected.

This notice has been provided to the appropriate regulatory agencies.

Cardinal Health has completed its investigation of this notice and our records indicate that you have been shipped product affected by this recall action.

Consequently, please follow the below recall process:

- Immediately take the appropriate measures to cease further distribution and ultimately, usage of the product (i.e. Place the remaining products on hold in your warehouse, remove product from supply and storage areas, etc.).
- Complete the enclosed Customer Acknowledgment Form and return it to us by fax at the following number: **XXXXXXXXXX**. Cardinal Health is obliged to collect the exact amount of Esteem® Blue with Neu-Thera™ still in your possession.
- Even if no affected product is in your possession, please check the appropriate box and return the form. The receipt of this form will verify that all affected parties have received this notification.
- Cardinal Health will contact you within 48 hours to provide further guidance. This includes, but is not limited to, providing you with **suitable alternative temporary solutions** to replace Esteem® Blue with Neu-Thera™ (see the list hereafter) while the product is not available.

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

We sincerely apologize for any inconvenience this notice may have caused you and your staff. Should you have any questions or desire special assistance relating to this recall, please feel free to contact your local Cardinal Health contact at the following number: **XXXXXXXXXX**

Sincerely,

Country QA/RA and/or Customer Services
Full country address

CARDINAL HEALTH CUSTOMER ACKNOWLEDGMENT FORM
Esteem[®] Blue with Neu-Thera[™] Surgical Gloves Recall
 Recall Notice date : 28/04/2009

Dear QA/RA Dept. and Customer Services,

This is to acknowledge that we have received your communication, concerning the above referenced action. We have reviewed the documentation and are providing you with the following checked information:

INVENTORY SECTION		
WE HAVE AFFECTED INVENTORY WITHIN OUR POSSESSION*		
<i>Product REF</i>	<i>Quantity of Product Captured</i>	<i>Lot Numbers</i>
-		
-		
-		
-		
-		
WE DO NOT HAVE AFFECTED INVENTORY WITHIN OUR POSSESSION*		

* **Select your situation and cross the grey square**

INSTITUTION INFORMATION SECTION	
<i>Name of the person completing the form</i>	
<i>Name of the Institution</i>	
<i>Full address of the Institution</i>	
<i>Email address</i>	
<i>Phone number</i>	
<i>Fax number</i>	
<i>If your Institution is part of a group, please mention</i>	

Please, return this form via fax at the following number: **XXXXXXXXXX**

Cardinal Health thank you for your time & support.
 With our best regards.

NAME & SIGNATURE

ESTEEM® BLUE with NEU-THERA™ Substitution List

1st Choice – Latex Free Option.

Comment: Offers a good donnability, sensitivity & tactility – No blue colour.

2D73PB55 - Esteem® Blue with Neu-Thera™ - Size 5,5	2D73TE55 - Esteem® with Neu-Thera™ - Size 5,5
2D73PB60 - Esteem® Blue with Neu-Thera™ - Size 6,0	2D73TE60 - Esteem® with Neu-Thera™ - Size 6,0
2D73PB65 - Esteem® Blue with Neu-Thera™ - Size 6,5	2D73TE65 - Esteem® with Neu-Thera™ - Size 6,5
2D73PB70 - Esteem® Blue with Neu-Thera™ - Size 7,0	2D73TE70 - Esteem® with Neu-Thera™ - Size 7,0
2D73PB75 - Esteem® Blue with Neu-Thera™ - Size 7,5	2D73TE75 - Esteem® with Neu-Thera™ - Size 7,5
2D73PB80 - Esteem® Blue with Neu-Thera™ - Size 8,0	2D73TE80 - Esteem® with Neu-Thera™ - Size 8,0
2D73PB85 - Esteem® Blue with Neu-Thera™ - Size 8,5	2D73TE85 - Esteem® with Neu-Thera™ - Size 8,5
2D73PB90 - Esteem® Blue with Neu-Thera™ - Size 9,0	2D73TE90 - Esteem® with Neu-Thera™ - Size 9,0

2nd Choice – Latex Free Option.

Comment: Offers a reasonable donnability and excellent sensitivity & tactility – No blue colour.

2D73PB55 - Esteem® Blue with Neu-Thera™ - Size 5,5	2D73PM55 - Esteem® Micro - Size 5,5
2D73PB60 - Esteem® Blue with Neu-Thera™ - Size 6,0	2D73PM60 - Esteem® Micro - Size 6,0
2D73PB65 - Esteem® Blue with Neu-Thera™ - Size 6,5	2D73PM65 - Esteem® Micro - Size 6,5
2D73PB70 - Esteem® Blue with Neu-Thera™ - Size 7,0	2D73PM70 - Esteem® Micro - Size 7,0
2D73PB75 - Esteem® Blue with Neu-Thera™ - Size 7,5	2D73PM75 - Esteem® Micro - Size 7,5
2D73PB80 - Esteem® Blue with Neu-Thera™ - Size 8,0	2D73PM80 - Esteem® Micro - Size 8,0
2D73PB85 - Esteem® Blue with Neu-Thera™ - Size 8,5	2D73PM85 - Esteem® Micro - Size 8,5
2D73PB90 - Esteem® Blue with Neu-Thera™ - Size 9,0	2D73PM90 - Esteem® Micro - Size 9,0

3rd Choice – Latex Free Option.

Comment: Offers a good donability and a good tactility. No blue colour but a light brown.

2D73PB55 - Esteem® Blue with Neu-Thera™ - Size 5,5	2D72PN55 - Duraprene® SMT - Size 5,5
2D73PB60 - Esteem® Blue with Neu-Thera™ - Size 6,0	2D72PN 60 - Duraprene® SMT - Size 6,0
2D73PB65 - Esteem® Blue with Neu-Thera™ - Size 6,5	2D72PN 65 - Duraprene® SMT - Size 6,5
2D73PB70 - Esteem® Blue with Neu-Thera™ - Size 7,0	2D72PN 70 - Duraprene® SMT - Size 7,0
2D73PB75 - Esteem® Blue with Neu-Thera™ - Size 7,5	2D72PN 75 - Duraprene® SMT - Size 7,5
2D73PB80 - Esteem® Blue with Neu-Thera™ - Size 8,0	2D72PN 80 - Duraprene® SMT - Size 8,0
2D73PB85 - Esteem® Blue with Neu-Thera™ - Size 8,5	2D72PN 85 - Duraprene® SMT - Size 8,5
2D73PB90 - Esteem® Blue with Neu-Thera™ - Size 9,0	2D72PN 90 - Duraprene® SMT - Size 9,0

4th Choice – **WARNING: Non Latex Free Option.**

Comment: Offers excellent donability and tactility with the blue colour... but only for latex free allergy customers/patients.

2D73PB55 - Esteem® Blue with Neu-Thera™ - Size 5,5	2D73NU55 - Protegrity® Blue with Neu-Thera™ - Size 5,5
2D73PB60 - Esteem® Blue with Neu-Thera™ - Size 6,0	2D73NU60 - Protegrity® Blue with Neu-Thera™ - Size 6,0
2D73PB65 - Esteem® Blue with Neu-Thera™ - Size 6,5	2D73NU65 - Protegrity® Blue with Neu-Thera™ - Size 6,5
2D73PB70 - Esteem® Blue with Neu-Thera™ - Size 7,0	2D73NU70 - Protegrity® Blue with Neu-Thera™ - Size 7,0
2D73PB75 - Esteem® Blue with Neu-Thera™ - Size 7,5	2D73NU75 - Protegrity® Blue with Neu-Thera™ - Size 7,5
2D73PB80 - Esteem® Blue with Neu-Thera™ - Size 8,0	2D73NU80 - Protegrity® Blue with Neu-Thera™ - Size 8,0
2D73PB85 - Esteem® Blue with Neu-Thera™ - Size 8,5	2D73NU85 - Protegrity® Blue with Neu-Thera™ - Size 8,5
2D73PB90 - Esteem® Blue with Neu-Thera™ - Size 9,0	2D73NU90 - Protegrity® Blue with Neu-Thera™ - Size 9,0