URGENT: FIELD SAFETY NOTICE (Removal)

Specific product codes and lots of:

- **Monoject™ Standard Hypodermic Needles**
- **Monoject™ Blunt Cannula**

Event-2019-02170

CardinalHealth

01 May 2019

Attention: Risk Management Director and Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Cardinal Health is voluntarily recalling specific production lots of Monoject™ Standard Hypodermic Needles and Blunt Cannulas. The products were distributed between January 28, 2019 and April 23, 2019**.** This recall is being conducted due to a manufacturing defect that was found for the cartridge component, which could compromise the sterility barrier of the product. The usage of a needle with compromised sterility could result in infection. Cardinal Health is not aware of any reports of patient harm.

This FSCA affects the listed item code and lot listed in Table 1:

Table 1

Item code	Item Description	Lot No.
8881200011	Monoject™ Standard Hypodermic Needle, 14 G x 1-1/2"	904218 904918 906329
8881200029	Monoject™ Standard Hypodermic Needle	904956
8881200037	Monoject™ Standard Hypodermic Needle, 16 G x 1-1/2"	904212 905612 907002
8881200045	Monoject™ Standard Hypodermic Needle, 16 G x 1-1/2"	905613
8881200078	Monoject™ Standard Hypodermic Needle, 18 G x 1-1/2"	907007
8881200508	Monoject™ Standard Hypodermic Needle, 27 G x 1-1/4"	904901
8881200664	Monoject™ Standard Hypodermic Needle, 20 G x 1-1/2" bulk	905657 906327 906341
8881202314	Monoject™ Blunt Cannula, 15 G x 1-1/2" (1.829 mm x 3.8 cm)	905659 905660 906343
8881202322	Monoject™ Blunt Cannula, 16 G x 1-1/2" (1.651 mm x 3.8 cm)	902110 902111
8881202355	Monoject™ Blunt Cannula, 19 G x 1-1/2" (1.067 mm x 3.8 cm)	905617 905618 905619 905620 907004 907005
8881202363	Monoject™ Blunt Cannula, 20 G x 1-1/2" (0.902 mm x 3.8 cm)	907734
8881202389	Monoject™ Blunt Cannula, 22 G x 1-1/2" (0.711 mm x 3.8 cm)	903530

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Cardinal Health's records indicate you may have received product associated with this action. Please ensure the lot of the product code listed below is returned immediately to Cardinal Health and is not used per the instructions outlined in the **Required Actions** section below.

Required Actions:

1) **Check** all storage and usage locations to confirm whether you have any units of the affected product code in your possession. Identify and set aside any units of the affected product code in a manner that ensures the affected product will not be used. **(see Attachment A for examples of product labeling)**
2) **Review, complete, sign and return** the enclosed Acknowledgement Form in accordance with the directions on the form.
3) **Return** all affected product or contact your local sales representative to facilitate return of the affected product. Your sales representative will inform you of the product replacement or credit options.
4) **Share** this letter with others in your facility who need to be made aware of this recall. Contact any other facilities that have been provided with units of affected lot.
5) **Maintain awareness** of this notice until all affected product has been returned to Cardinal Health.
6) **Keep** a copy of this notice with any affected product until returned.

The applicable regulatory agencies are being notified that Cardinal Health is voluntarily taking this action. We request that you contact Cardinal Health if you have experienced quality problems or adverse events. We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your local sales representative or local sales office.

Sincerely,

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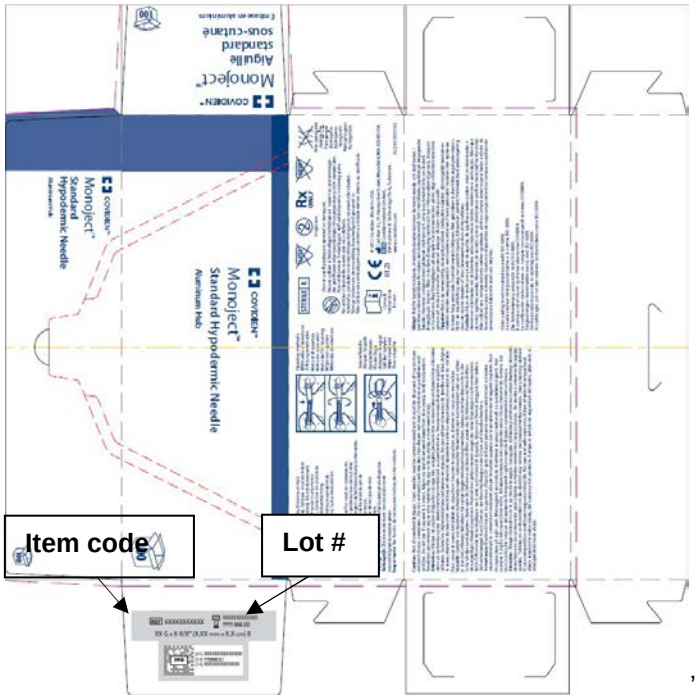
Attachment A

Unit:



Case: