



## URGENT: FIELD SAFETY NOTICE (Removal)

EVENT #: 2019-02623

### Specific product codes and lots of:

- **Monoject™ 3mL Syringe with Hypodermic Safety Needle**
- **Monoject™ Hypodermic Safety Needle**
- **Monoject™ Bluntfill with Filter**

15 January 2020

### 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™ Hypodermic Safety Needles and Monoject™ Bluntfill Needles. The products were distributed between August 1, 2015 and November 11, 2019.

### Issue Description

This recall is being conducted due to non-sterile product that was inadvertently shipped to customers. The product is labeled as "NON-STERILR Not For Human Use" (Exhibit A). The usage of a needle that is not sterile could result in infection. Cardinal Health is not aware of any reports of patient harm.

Cardinal Health is initiating this voluntary recall on the following item codes and lot numbers:

Item code	Item Description	Lot Number
11832215	Monoject™ 3mL Syringe with Hypodermic Safety Needle, 22G x 1-1/2"	15072015
1183005	Monoject™ Hypodermic Safety Needle 30G x 1/2"	15063001
1182558	Monoject™ Hypodermic Safety Needle 25G x 5/8"	15063004
11811022F	Monoject™ Bluntfill with Filter, 18G x 1-1/2"	15072024

Cardinal Health's records indicate you may have received product associated with this action. Please follow the directions 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 codes and lot numbers containing the labeling outlined in Exhibit A in your possession. Exhibit A outlines examples of product labeling and how to identify the affected product.
- 2) **Review, complete, sign and return** the enclosed Acknowledgement Form in accordance with the directions on the form.
- 3) **Return** product labeled as in Exhibit A below 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.

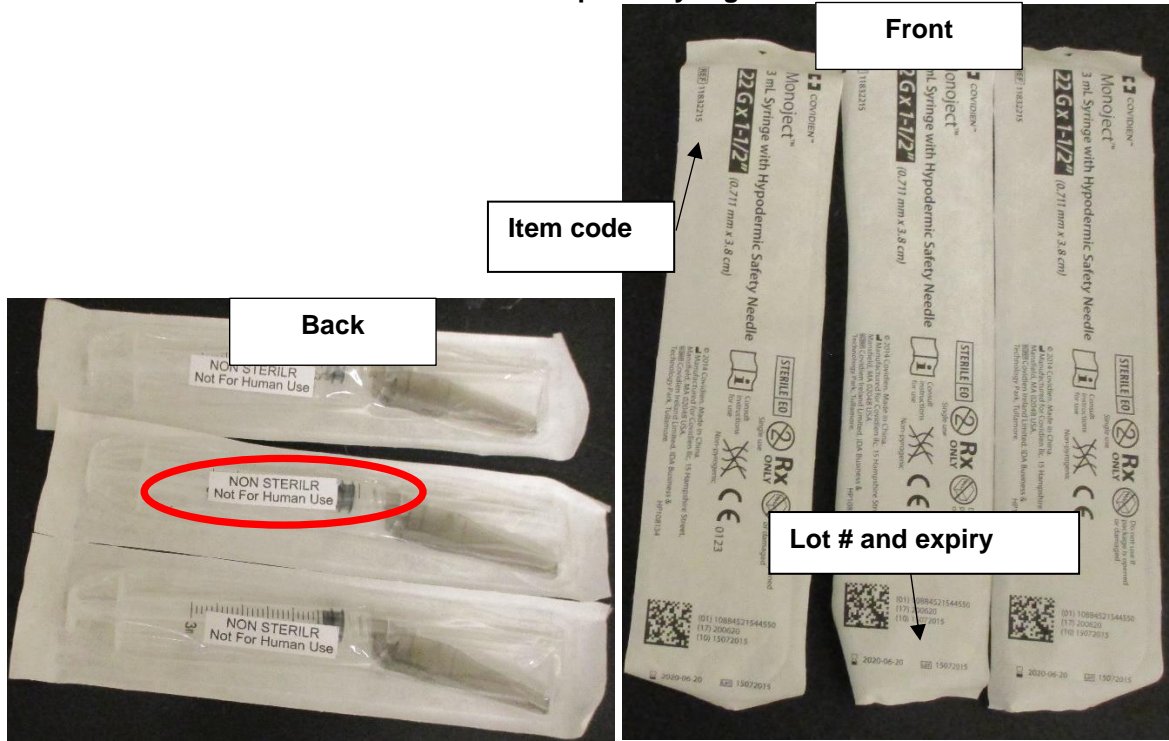
Sincerely,

A handwritten signature in black ink that reads "Moazzam Khan".

Moazzam Khan  
Director, QRA Management

**Exhibit A: Packaging of Affected Product**

**Example of Syringe**



**Carton**

