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Advisory Notice

For BD syringes that are included in ArcRoyal procedure packs
FSN15J001

06 Oct 2015

Dear Valued Customer,

ArcRoyal has been informed of a potential risk with the use of the BD Hypodermic syringes. ArcRoyal place these syringes into CPT's (custom procedure trays) that may be in your inventory.

Description of Risk

There may be a decrease of potency when drugs are compounded or repackaged and stored in BD syringes. The decreased drug potency is dependent on the application and on the specific drug. To date the drugs reported are fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium and remifentanyl.

Please note: Decreased Potency has only been reported when drugs are stored in these syringes; if the syringes are used for general purpose fluid aspiration or injection they are cleared for use and are not at risk.

Root Cause

The reported decreased potency is caused by an interaction with the rubber stopper.

Details of affected devices

ArcRoyal supply customers with four codes of the affected syringes (see table below).

BD Code	ArcRoyal Code	Description
301073	10-000044	Bulk non sterile syringe
301027	10-000045	Bulk non sterile syringe
300220	10-000085	Bulk non sterile Eccentric Tip syringe
300228	10-000123	Bulk non sterile Catheter Tip syringe

Advice

If you are using the syringes for compounding or storage of drugs, mentioned above, please be aware that there is a potential that the drug potency will be decreased. For this reason we are advising all customers to use the BD syringes for medical fluid aspiration / injection only.

BD continue to manufacture and distribute syringes with the affected stoppers. If you have any concerns please inform your ArcRoyal representative.



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Transmission of this Advisory

We are committed to patient safety and would appreciate your immediate attention and cooperation to this matter. Please immediately forward this information to all departments within your organisation.

We sincerely apologize for any inconvenience that this may cause and thank you for your business and continued support. If you have any questions or concerns, please do not hesitate to contact your ArcRoyal representative.

Yours Sincerely,

A handwritten signature in blue ink that reads "Declan Mulvin".

Declan Mulvin
Head of Quality

A handwritten signature in blue ink that reads "Irene Armstrong" followed by the date "28 Oct 2015".

Irene Armstrong
Quality Compliance Engineer