

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

*BD is issuing an update to the previous recall notification to include two additional affected lots that have been identified. The newly identified lots are bolded.*

Huons Co., Ltd. manufactured bupivacaine ampules were recalled due to quality issues identified during a recent FDA inspection and limited reports of drug ineffectiveness. These ampules are included in BD anesthesia trays. While theoretical risk exists if a compromised injectable were used (e.g., localized infection, inflammatory response or reduced anesthetic effectiveness), no patient harm or product sterility failures have been identified. BD has not received any reported complaints or adverse events associated with this issue.

**List of Affected Product**

| <b>SKU</b> | <b>Kit Description</b>                | <b>BD Finished Good Lot Number</b> |
|------------|---------------------------------------|------------------------------------|
| 400866     | 25GX3.5IN WHIT 5ML GLASPAK BUPI CLEAR | B01V232D                           |
| 400868     | 24GX3.5IN WHIT 20G SPINAL INTRO CLEAR | B01V206D                           |
| 400868     | 24GX3.5IN WHIT 20G SPINAL INTRO CLEAR | B01V220D                           |
| 400868     | 24GX3.5IN WHIT 20G SPINAL INTRO CLEAR | B02V266D                           |
| 405609     | TRAY SPN QNKE22G3.5 L/B-D/E           | B01V212D                           |
| 405609     | TRAY SPN QNKE22G3.5 L/B-D/E           | B01V238D                           |
| 405621     | TRAY SPN QNKE25G3.5 L/B-D/E           | B01V142D                           |
| 405621     | TRAY SPN QNKE25G3.5 L/B-D/E           | B01V176D                           |
| 405632     | TRAY SPN QNKE26G3.5 L/B-D             | B01V231D                           |

|               |                                                    |                 |
|---------------|----------------------------------------------------|-----------------|
| <b>405632</b> | <b>TRAY SPN QNKE26G3.5 L/B-D</b>                   | <b>B02V248D</b> |
| 405637        | TRAY SPN SPT24G3.5 L/B-D/E                         | B01V160D        |
| 405637        | TRAY SPN SPT24G3.5 L/B-D/E                         | B01V241D        |
| 405637        | TRAY SPN SPT24G3.5 L/B-D/E                         | B01V265D        |
| 405637        | TRAY SPN SPT24G3.5 L/B-D/E                         | B02V183D        |
| 405645        | TRAY SPN WHIT22G3.5 L/B-D/E                        | B01V223D        |
| 405652        | TRAY SPN WHIT24G3.5 L/B-D/E                        | B01V353D        |
| 405652        | TRAY SPN WHIT24G3.5 L/B-D/E                        | B02V267D        |
| 405658        | TRAY SPN WHIT25G3.5 B-D/L                          | B01V217D        |
| 405671        | TRAY SPN WHIT25G3.5 L/B-D/E PLAST<br>DRAPE         | B01V275D        |
| <b>405671</b> | <b>TRAY SPN WHIT25G3.5 L/B-D/E PLAST<br/>DRAPE</b> | <b>B01V294D</b> |
| 405672        | TRAY SPN WHIT25G3.5 L/B-D/E BLUE<br>DRAPE          | B03V267D        |
| 405673        | TRAY SPN WHIT25G3.5 L/B-D/E                        | B01V225D        |
| 405673        | TRAY SPN WHIT25G3.5 L/B-D/E                        | B01V281D        |
| 405673        | TRAY SPN WHIT25G3.5 L/B-D/E                        | B02V211D        |
| 405673        | TRAY SPN WHIT25G3.5 L/B-D/E                        | B02V217D        |
| 405674        | TRAY SPN WHIT25G3.5 L/B-D/E W SHRP<br>STIC         | B01V218D        |

|        |                                         |          |
|--------|-----------------------------------------|----------|
| 405675 | TRAY SPN WHIT25G3.5 25G1.5 L/B-D/E      | B01V183D |
| 405675 | TRAY SPN WHIT25G3.5 25G1.5 L/B-D/E      | B01V198D |
| 405707 | TRAY SPN SPT24G3.5 B/L/E                | B02V230D |
| 405709 | TRAY SPN WIT25G3.5B/L/E                 | B02V174D |
| 405709 | TRAY SPN WIT25G3.5B/L/E                 | B02V202D |
| 405721 | TRAY SPN WHIT25G3.5 B-D/L X3611A        | B02V227D |
| 405723 | TRAY SPN WHIT25G3.5 B-D/L X3730         | B01V174D |
| 405723 | TRAY SPN WHIT25G3.5 B-D/L X3730         | B01V189D |
| 405723 | TRAY SPN WHIT25G3.5 B-D/L X3730         | B02V254D |
| 405735 | TRAY SPN QNKE25G3.5 B-D/L/E/P           | B01V149D |
| 405735 | TRAY SPN QNKE25G3.5 B-D/L/E/P           | B01V190D |
| 405741 | TRAY SPN QNKE22G3.5 WHIT25G3.5<br>X3802 | B02V204D |
| 406704 | TRAY SFTY SPN WHIT25G3.5 L/B-D          | B02V246D |