Project to Collect Medical Near-Miss/Adverse Event Information

# Medical Safety Information

September 2023 No.202

To mark the WHO World Patient Safety Day (September 17), we have selected orange as this month's theme color.

World Patient Safety Day 17 September

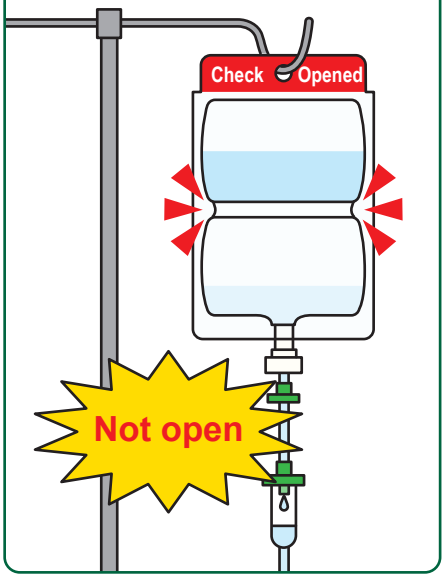
Ministry of Health, Labour and Welfare page on WPSD

# Failure to Open the Central Seal of a Dual Chamber Infusion Bag

## Cases have been reported in which a preparation packaged in a dual chamber infusion bag was administered to a patient without opening the central seal.

Twenty-six such cases were reported between January 1, 2020 and July 31, 2023. This information was compiled on the basis of the content featured in the Details of Events section of the 72nd Quarterly Report.

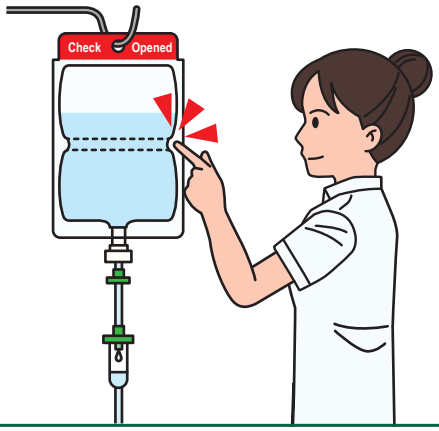
### Image of case 1




### Key points on using dual chamber infusion bags

**<Point 1>**
Press down on the lower chamber with both hands to open the central seal before removing the "Check Opened" sticker or cover.

**<Point 2>**
Check that the central seal is open when administering the preparation to the patient.




### Main Background Factors

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|---|
| -The nurse assumed that no further preparation work was required after removing the outer packaging of the dual chamber infusion bag kit, and forgot to open the central seal. |
| -After removing the dual chamber infusion bag kit from the outer packaging, the nurse intended to open the seal immediately before administering the preparation, but forgot to do so. |
| -The nurse removed the "Check Opened" cover before opening the seal and subsequently broke off from their task. When they resumed the task, the nurse assumed they had already opened the seal. |
| -The nurse opened the seal between the upper and lower chamber and mixed them, but did not check that the small chambers* were open. |

*The small chambers are the sub-chambers in a dual chamber infusion bag that contain solutions of vitamins, trace elements, and the like.

# Failure to Open the Central Seal of a Dual Chamber Infusion Bag

**Case 1**

Day Nurse A removed Bfluid Injection from its outer packaging and removed the “Check Opened” cover without opening the seal. Another patient pressed their nurse call button, so Day Nurse A broke off from the task. Day Nurse A then resumed the preparation of the infusion and mixed Aspara Potassium Injection 10 mEq into the Bfluid Injection. Assuming that the seal was open, because the “Check Opened” cover had been removed, Day Nurse A began administration of the prepared infusion. Night Nurse B noticed that the central seal of the Bfluid Injection bag had not been opened.

**Case 2**

When preparing Meropenem for I.V. Infusion Bag 1 g, Nurse A peeled off the “Check Opened” sticker along with the upper chamber’s cover sheet. Assuming that no further preparation work was required after peeling off the cover sheet and sticker, Nurse A did not open the central seal. Nurse A then began administration of the prepared drug. Nurse B subsequently noticed that the central seal of the Meropenem for I.V. Infusion Bag 1 g had not been opened.

## Preventive measures taken at the medical institutions in which the events occurred

**-Open the central seal before removing the “Check Opened” sticker or cover.**
**-Press down on the upper and lower chambers of the infusion bag in turn to check the two components are mixed.**
**-Check that the central seal is open when administering the preparation to the patient.**
**-Teach staff members why the preparation has a central seal.**

The measures above are examples. Please consider initiatives suitable for your own facility.

The Pharmaceuticals and Medical Devices Agency published PMDA Medical Safety Information No. 61 March 2022 “Failure to Break Separation of Two-chamber Bag Preparations (Bag-type Kit Preparations)” on this topic.
https://www.pmda.go.jp/files/000245528.pdf

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of the “Comprehensive Evaluation Panel” to prevent the occurrence and recurrence of medical adverse events. See the Project website for details.
https://www.med-safe.jp/
* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.
* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

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