

PMDA Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No. 61 March 2022

Failure to Break Separation of Two-chamber Bag Preparations (Bag-type Kit Preparations)

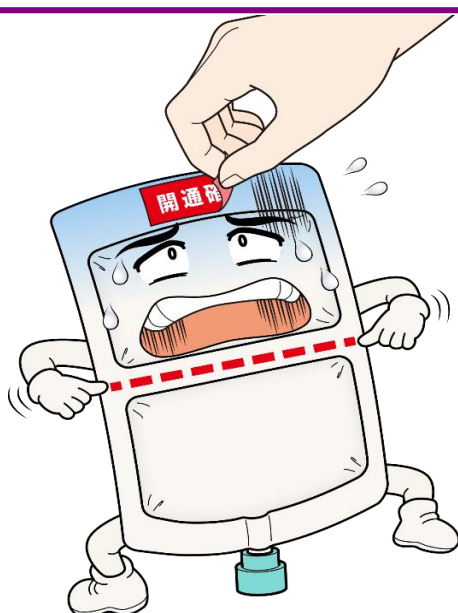
POINT Key points for safe use

1 Failure to break the separation seal of two-chamber bag preparations

- Two-chamber bag preparations require breaking the separation seal before use.
- Do not remove the opening confirmation sticker or tag before confirming that the separation seal is broken.

* In some products which have built-in mechanisms to prevent administration while the separation seal is unopened, there may be no sticker or tag to confirm that the separation seal is broken.

(Case 1) When mixing an infusion preparation, the red opening confirmation tag was unintentionally removed before breaking the separation seal, and the procedure was interrupted for another task. When resuming, the medical staff took it for granted that the separation seal of the preparation had been opened because the confirmation tag had been removed, and it was administered without breaking the separation seal.



Do not peel off the opening confirmation sticker before breaking the separation seal!

The ingredients of the upper and lower chambers are different. If only the lower chamber is administered without breaking the separation seal, the expected ingredients, dose, and concentration cannot be administered! This may cause hyperglycemia/hypoglycemia, etc.

There have been **repeated reports** of administering the preparations **without breaking the separation seal of the two-chamber bag.** Make sure to follow the opening method and the procedures of opening confirmation.



(Case 2) The preparation was administered without breaking the small chambers for the vitamin preparations. When mixing it, there was an assumption that the solution in small chambers for the vitamins would gradually flow out after the start of administration even if they were not opened manually.

Only upper and lower chambers are open

Only one small chamber is open

Completely open

There have been many reports of **unopened small chambers** in preparations where vitamin preparations, etc. are integrated into the bag! Make sure to check if all the chambers are completely open and the **preparation is colored uniformly**.

2 Precautions for reconstitution process

- Make sure of the following points for the reconstitution process.

Points to check during reconstitution process

(1)

Have you removed the breaking confirmation sticker or tag before breaking the separation seals? Remove the sticker and tag only after breaking the separation seals.

(2)

Are the separation seals (including small chambers) completely broken? Check them visually.

(3)

Has it been completely mixed? If so, are the separation seals broken? Make sure that the preparation is completely mixed with the separation seals broken.

(4)

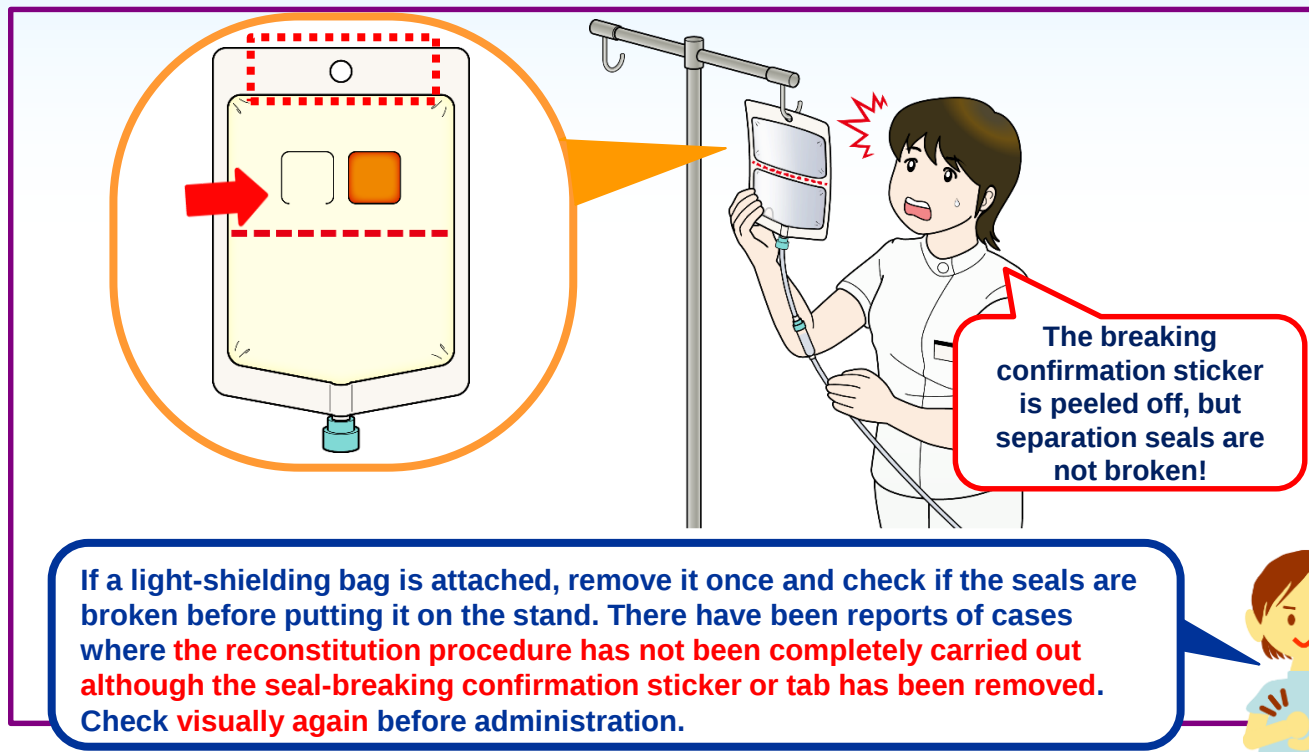
Are the small chambers or the separation seal hidden by an injection label with the patient's name on it, etc.? Make sure that the opening status can always be checked.

The procedures for reconstitution and confirmation differ depending on preparations! Make sure to check the package inserts and other materials prepared by each manufacturer.

3 Precautions before administration

(Case 3) Because the opening confirmation sticker of the infusion preparation had been peeled off, the medical staff took it for granted that the separation seals had been broken, and they administered it without checking visually.

- Before administering, make sure once again that all the separation seals are broken.



The Ministry of Health, Labour and Welfare (MHLW) issued notifications related to PMDA Medical Safety Information No. 61.

- PFSB Notification No. 0602009 dated on June 2, 2004
Reinforcement and Thorough Implementation of Measures for the Prevention of Drug-related Medical Accident
- PFSB Notification No. 0808001 and No. 0808002 dated on August 8, 2005
Preventative Measures against Administration of Two-Chamber Bag Preparations without Breaking Separation Seal

This notification is published on the Pharmaceuticals and Medical Devices Agency website (<https://www.pmda.go.jp/english/index.html>) Home > Post-marketing Safety Measures > Provision of Information regarding Post-marketing Safety > Medical Safety Information

Notice from organizations and groups that are related to this medical safety information is available at the Pharmaceuticals and Medical Devices Information website (only in Japanese).

About this information

- * PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Law on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices.
- * We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.
- * This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.

Access to the most up-to-date safety information is provided via the PMDA Medi-navi service.

