



Field Safety Notice CryoSure-DMSO, WAK-DMSO-70, batch USP23F1

Date: 19.12.2025

Dear Customer,

in this field safety notice in the course of WAK-Chemie Medical GmbH field safety corrective action Dev-5-12/2025 we inform you on an elevated probability of occurrence of vials of CryoSure-DMSO that lack the closure stopper:

1. Information on Affected Products

1. 1. **Product Name and Description:** CryoSure-DMSO, 6 x 70 ml vials
1. 2. **Primary clinical purpose of device:** Cryoprotectant for the cryopreservation of cells or tissues which are destined for transplantation
1. 3. **Product Model/Catalogue/part number:** WAK-DMSO-70
1. 4. **Affected serial or lot number range:** Batch number: USP23F1, Expiry Date: 02/2027

2 Reason for Field Safety Corrective Action

2. 1. **Description of the product problem**
Elevated risk of occurrence of crimped vials without stopper due to a seldom production error.
2. 2. **Hazard giving rise to the Corrective Action**
Content solution of vials without stopper may get contaminated from the outside. Content DMSO may leak from vial via the crimped aluminium seal closure. Sterility might be impaired as the sterile barrier is not intact.
2. 3. **Probability of problem arising**
Approximately 1 – 2 vials per 10.000 CryoSure vials (~ 0,01% - 0,02%). For vials without stopper the probability of detection is very high, as a missing stopper is obvious after removing the blue closure cap, especially when accessing the vial with a syringe needle or a spike for volumetric withdrawal of content
2. 4. **Predicted risk to patient/users**
Even without stopper the vial is closed by the crimped aluminium seal and the blue plastic cap. Therefore and because of the antimicrobial properties of the filling solution DMSO itself, the risk for a clinically relevant microbial contamination is low but not excluded. The purity of DMSO as well as the water content may not comply to specifications as per certificate of analysis. DMSO might leak or might have leaked from the vial. Therefore, the filling volume might be reduced.
DMSO has the characteristic to penetrate via the human skin and then to act systemically. Furthermore, certain alien substances can be carried along across the skin barrier and eventually also act locally or systemically.

3 Action To Be Taken by the User

3.1 Before use, check each vial of batch USP23F1, CryoSure-DMSO 70 ml, for presence of vial stopper

Option 1: As illustrated on **page 2**, **remove the blue flip-cap**. Then inspect the vial for presence of stopper.

Option 2: As illustrated on **page 3**, check by looking from the bottom of the vial if the stopper is in place, **without removing the blue flip-cap**. **Caution: When turning the vial upside down, DMSO may leak from the vial, if the stopper is missing!**

If stopper is missing, do not use the affected vial, but separate and block it and report it to WAK-Chemie Medical GmbH.

3.2 Act according to the Instructions for use (L-09-040-23-2-05 (last revision: 01/2017)), which state:

'Do not use in case package is damaged.'

'CryoSure-DMSO may only be applied by qualified personnel who are accustomed to the use of DMSO as a cryoprotectant. Principally the application of CryoSure-DMSO consists of the following steps:

1. **Withdrawal of DMSO from the sterile container:**

The necessary amount of DMSO for freezing is taken volumetrically from the sterile container. The opening of the sterile container and the withdrawal of DMSO thereof shall be executed under conditions as to minimize the risk of contamination.'

6. General directions to the use of CryoSure-DMSO:

- Penetration of DMSO via the skin:

... Therefore, **it is necessary to wear protective gloves, which are non-permeable to DMSO**, during handling of CryoSure-DMSO and to take care that the DMSO does not get in touch with substances that could be carried via the skin barrier by DMSO and that could consequently have negative effects.



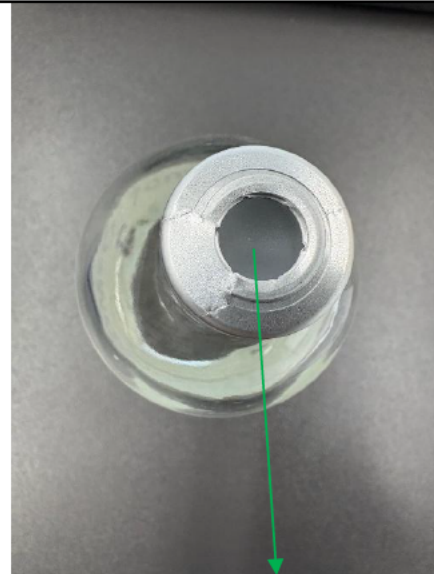
Illustration Option 1



Remove blue vial cap
(flip off)

Stopper is missing

Stopper is in place



Stopper is missing – Do Not Use!

**Stopper is in place
CryoS sure-DMSO vial is suitable to be used
according to instructions for use**

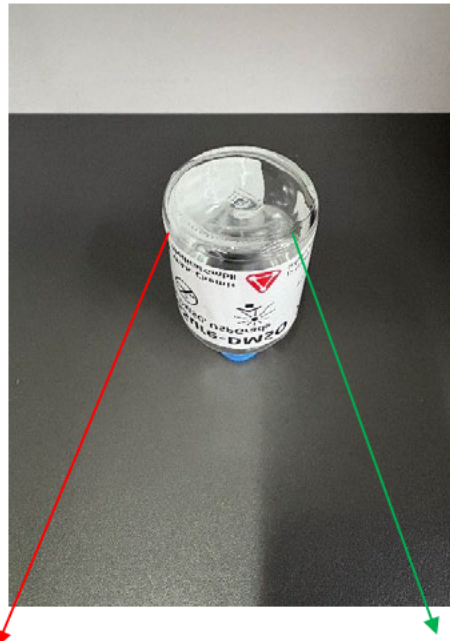
Return affected CryoS sure-DMSO vials to WAK-Chemie Medical GmbH or your reseller from whom you have acquired CryoS sure for further analysis and in order to receive replacement.

Return address for vials without stopper:
WAK-Chemie Medical GmbH, Siemensstr. 9, 61449 Steinbach/Ts, Germany

Communication to: Dr. Florian Pobitschka, Head of Quality Assurance, Tel.: +49 6171 28430, E-Mail: info@wak-chemie.com



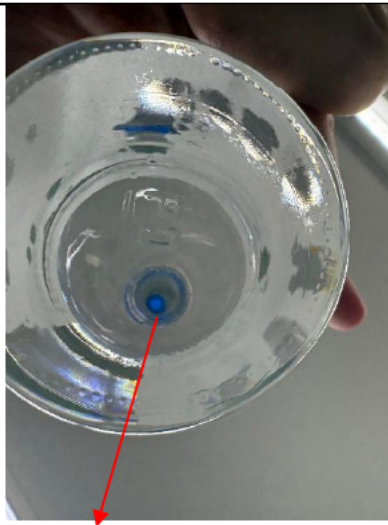
Illustration Option 2



Look via the
bottom of the closed vial
onto the
vial closure

Stopper is missing

Stopper is in place



Blue cap is visible via vial bottom and / or DMSO leaks

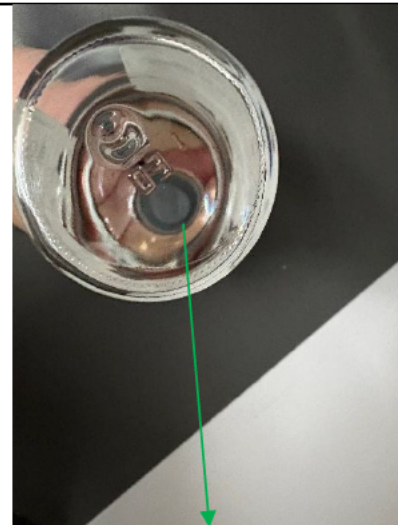
Stopper is missing – Do Not Use!

Return affected CryoSure-DMSO vials to WAK-Chemie Medical GmbH or your reseller from whom you have acquired CryoSure for further analysis and in order to receive replacement.

Return address for vials without stopper:

WAK-Chemie Medical GmbH, Siemensstr. 9, 61449 Steinbach/Ts, Germany

Communication to: Dr. Florian Pobitschka, Head of Quality Assurance, Tel.: +49 6171 28430, E-Mail: info@wak-chemie.com



**Grey Stopper is in place
CryoSure-DMSO vial is suitable to be used
according to instructions for use**

End of Field Safety Notice