



Note: These directions should be read and understood before using the device. Always follow your institution's protocol.

Intended Use: OriGen DMSO and DMSO formulations are intended for preservation of stem cells and blood components in a frozen state.

USA & Canada: For Research Use Only.

Device Description: Dimethyl Sulfoxide (C₂H₆OS - DMSO) is clear, essentially odorless, hygroscopic, water-miscible liquid. Cryoprotectant Mechanism: DMSO freely permeates the cell wall and displaces water inside the cell, depressing the freezing point of the water remaining inside the cell. As the temperature decreases during the freezing cycle, expansion of ice crystals is inhibited, and the cell is protected from bursting. DMSO has been used to preserve a variety of cell types, including human bone marrow², ovarian tissue³, pancreatic and platelet cells⁴, and hematopoietic stem cells⁵.

Prefix	Meaning
CP-XXXX	> 99.9% Pure DMSO filled into a Vial
SP-XXXX	> 99.9% Pure DMSO filled into a Syringe
CD-XXXX	DMSO/Dextran mixture in WFI filled into a Vial
SD-XXXX	DMSO/Dextran mixture in WFI filled into a Syringe
CDS-XXXX	DMSO/Dextran mixture in saline filled into a Vial
SDS-XXXX	DMSO/Dextran mixture in saline filled into a Syringe

Product volume can be identified by the numbers in place of the XXXX in the product code.



Warnings:



- **Single use only:** Multiple draws may be made from vial using the OriGen VSV adapter. Do not reuse DMSO after exposure to cells or tissue.



- Do not re-sterilize: Re-sterilization may damage product.



- Do not use if packaging is damaged.



- Do not use after expiration date.

- **Toxic:** Heat is generated when pure DMSO is mixed with water. **Do not add pure DMSO directly to cell product.**
- **Aggressive:** DMSO is a highly polar organic solvent and is aggressive against many common plastics (ABS, PVC, PC, etc). Degradation of your bag and tubing may occur, and unwanted byproducts may be released into the sample.
- **Exterior of syringe or vial is not sterile.** Wipe down syringe before use.
- **Not for Injection or IV use**
- DMSO should be removed from cell product prior to administration to patient.
- Dose-dependent adverse effects including nausea, vomiting, flushing, fever, chills, dyspnea, cardiac symptoms, transient hypertension or hypotension, anaphylaxis, encephalopathy and seizures have been reported with the infusion of DMSO-cryopreserved hematopoietic stem cells⁷. DMSO may amplify or change the effect of anticoagulants, steroids, beta-blockers and sedatives⁸.

Directions for Use:

Vials

1. Vials are closed with "Flip off / Tear off" cap.
2. Remove the cap and leave aluminum crimp in place when drawing by needle into syringe.
3. If using needle-free vial spike (VSV), see instructions for use for VSV .
4. To pour DMSO, remove plastic cap, aluminum crimp seal, and stopper.

Syringes

1. Remove all parts from packaging. For Aseptic use, transfer syringe to sterile field.

Note: Graduation marks are for reference only. Do not use in place of calibrated volumetric tools

2. Sterile weld to attached tubing and connect to transfer set or equipment (follow your machine's instructions for use).
3. Open stopcock on syringe and add cryoprotectant.

Freezing

1. Dilute pure DMSO, cool to below 37°C, and add to cells.
Note: DMSO may be toxic to cells if used in high concentrations and if cells are exposed to DMSO for prolonged periods. Stem cells are usually cryopreserved in a solution containing 1.6 molal (10% v/v) DMSO. Concentrations above or below this have been reported to have lower cell viability¹.
2. Allow DMSO solutions at least 20 minutes to penetrate cells⁶.
3. Start cooling within 30 minutes after DMSO has been added.

Thawing

1. Wash DMSO solutions from cell product as soon as it thaws.
Note: Some cells are sensitive at this stage of the procedure, and it may be advisable to dilute DMSO stepwise to minimize osmotic stress imposed upon cells when DMSO is washed out.
2. Begin to infuse cell product as soon as possible after thawing.

Sterilization: Sterilized by aseptic filtration.

STERILE A

Packaging: CryoPur solutions are packaged in syringes or vials. Syringes are packed individually or in a set of two in a plastic container, and then packed into a carton. Vials are packed into cartons.

Storage:



- Store in a dark well-ventilated area

DMSO: Freezes (solidifies) at 18°C. Recommended storage at 20-30°C.



DMSO/Dextran: Store refrigerated: +2 to +8°C



Complaints: Any user/customer who has a complaint or is dissatisfied with the quality, identification, reliability, safety, efficacy, and/or performance of the product should notify OriGen Biomedical or its authorized distributor. In the event of an incident or risk of a serious incident liable to result in, or to have resulted in, the death or serious deterioration in the health condition of a patient or user, OriGen Biomedical or its authorized distributor should be immediately warned by telephone, fax or letter. All complaints should be accompanied by the name(s), reference(s), and batch number(s) of the component(s) and the name and address of the claimant, the nature of the complaint with as much details as possible and the indication of a requested response.

Disclaimer of Warranties

OriGen Biomedical warrants that reasonable care has been used in the manufacture of this device and that it was free from defects in workmanship or materials at the time of shipment from OriGen. OriGen's sole obligation shall be to repair or replace any device which it determines was defective at the time of shipment. The buyer assumes all liability resulting from misuse, re-use, or any use other than as intended, including re-sterilization of this product. OriGen shall not be liable for incidental or consequential loss, damage or expense resulting from the use of this product. THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER IMPLIED, EXPRESS, ORAL OR WRITTEN.

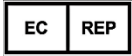
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 2. Stiff, P.; Murgo, A.; Zaroulis, C.; Derisi, M.; Clarkson, B. *Cryobiology*, 20 (1983) pp.17-24.
 3. Hovatta, O.; Silya, R.; Krausz, T.; Abir, R.; Margara, R.; Trew, G.; Lass, A. Winston, M. *Human Reproduction*, 11, no.6 (1996) pp.1268-1272.
 4. Improved Viability of Previously Frozen Platelets, *Blood*, 1972 40: 509-513
 5. Cryopreservation of Hematopoietic Stem/Progenitor Cells for Therapeutic Use
Watt, SM, et al., *Methods in Molecular Biology*, 368, Jun 2007, p 237-259
 6. Effect of DMSO exposure without cryopreservation on hematopoietic progenitor cells. *Bone Marrow Transplant*. 1993 May;11(5):389-93.
 7. Junior AM, et al; Neurotoxicity associated with DMSO-preserved hematopoietic progenitor cell infusion. *Bone Marrow Transplantation* (2008) 41, 95-96

8. American Cancer Society website



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Symbol Glossary at www.origen.com/symbolglossary

Other ISO 15223-1:2016 Harmonized Symbols:

REF - Catalogue Number/Product Code

LOT - Batch/Lot Number

Non-harmonized Symbols:

	Quantity	Indicates the number of units in the associated packaging.
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