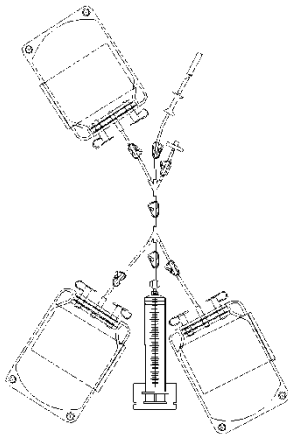


**C3<sup>TM</sup> Closed Cell  
Cryopreservation**  
Patent Pending



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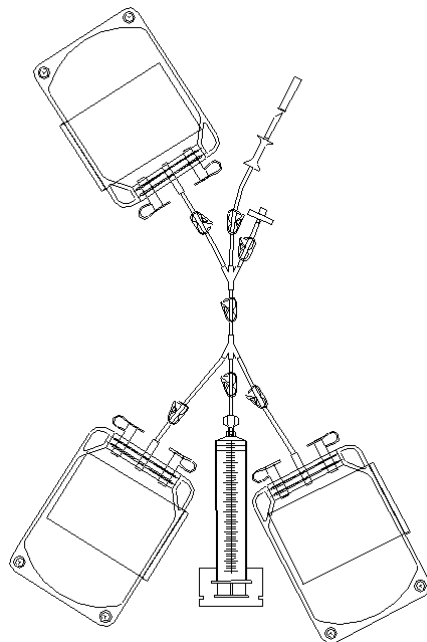
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**NEW**

## Cell Freeze™ Liquid Nitrogen (-196°C) Freezing Bags

- ✓ **NO clean room required** - functionally closed fluid path.
- ✓ Pre-attached **DMSO resistant filter** 0,2 µm
- ✓ Exceptional bag strength and validated product quality
- ✓ Bag sizes fit most racking systems
- ✓ Pre-attached syringe enables sterile sampling
- ✓ Unique non-plasticized film provides excellent bag clarity for pre and post freezing
- ✓ Pre-attached large patient label
- ✓ Individually packaged within a sterile overpouch
- ✓ CE Marked medical device



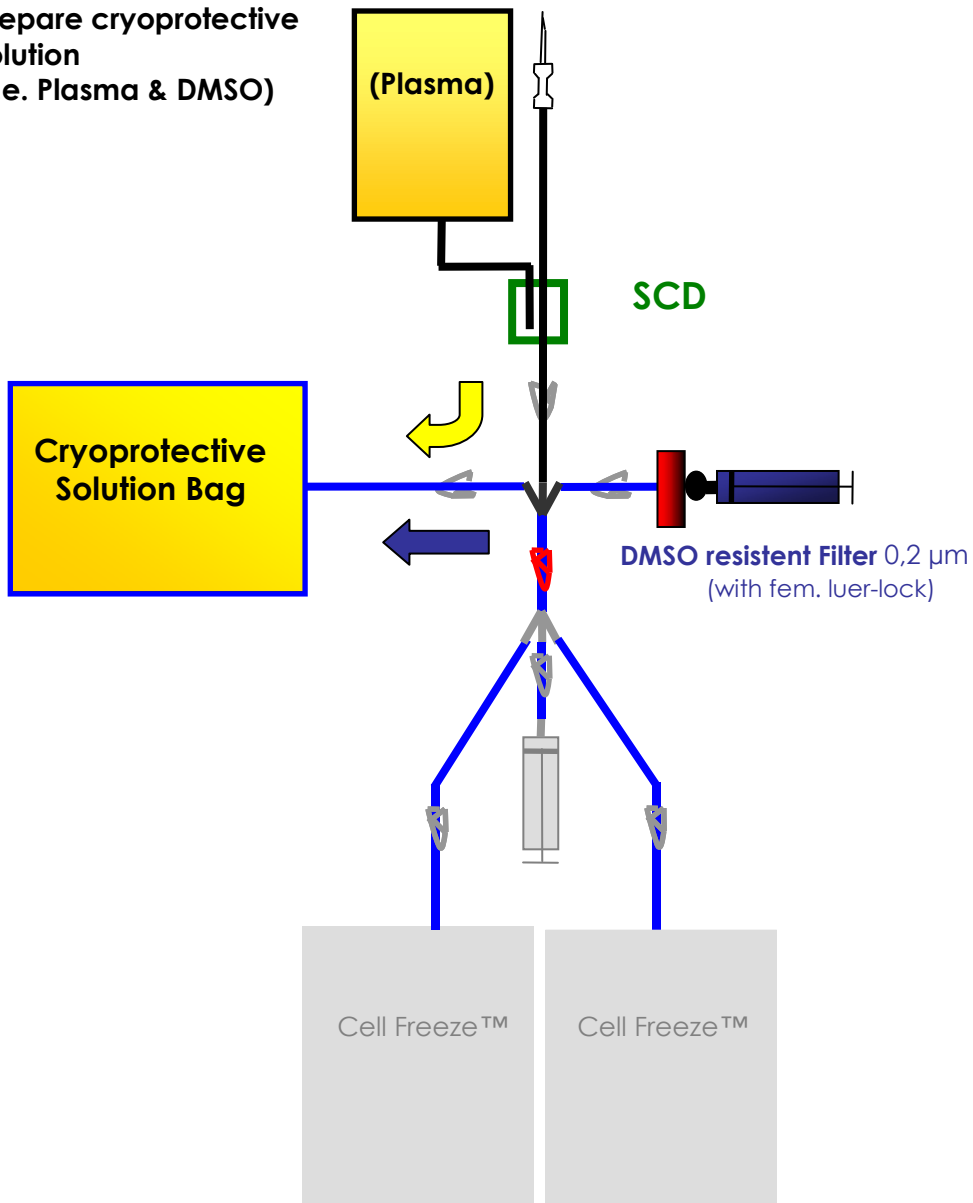
**C3™ Closed Cell  
Cryopreservation**

order #	name	freezing volume	components	#/case
HPF 0601	CF100-C3	70-375 mL	3 CF100 bags, DMSO filter, 60ml syringe	12

**Cell·MAX GmbH**

# Cell preparation

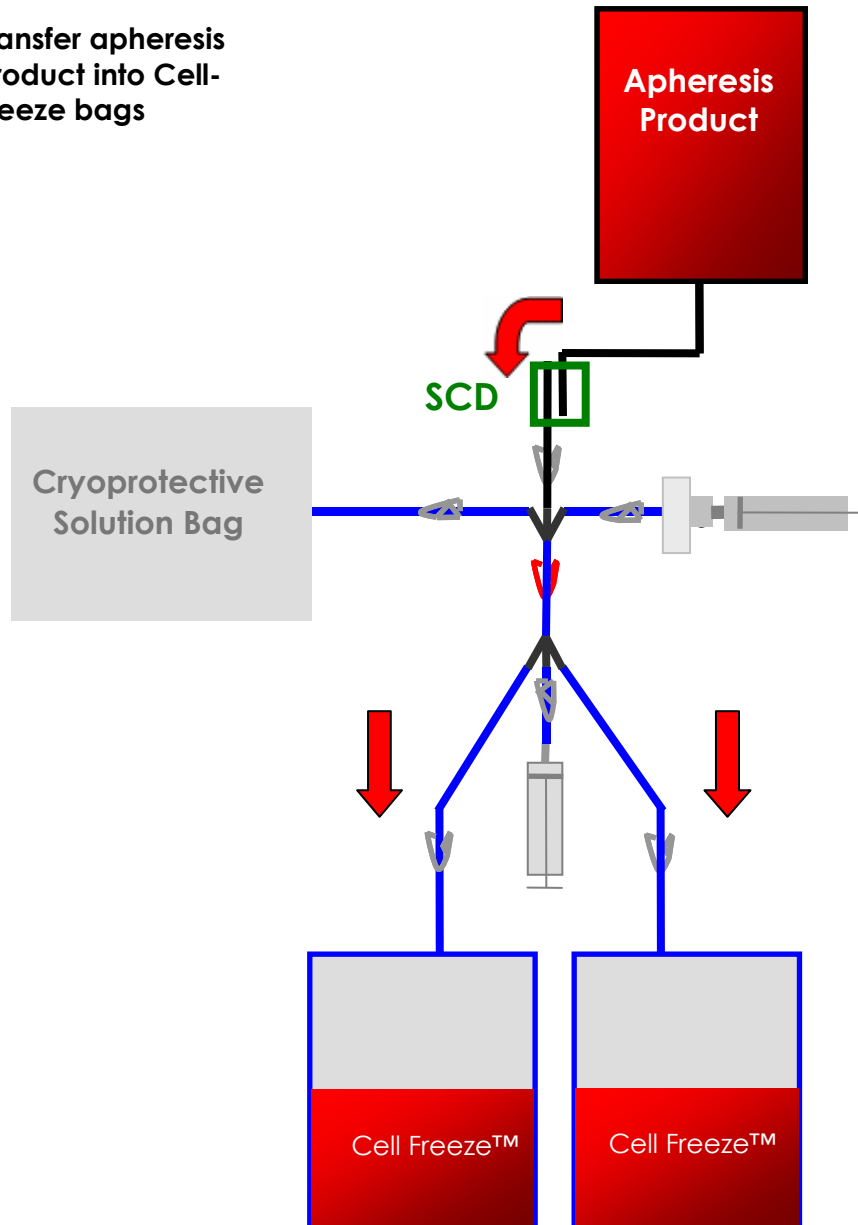
1. Prepare cryoprotective solution (i.e. Plasma & DMSO)



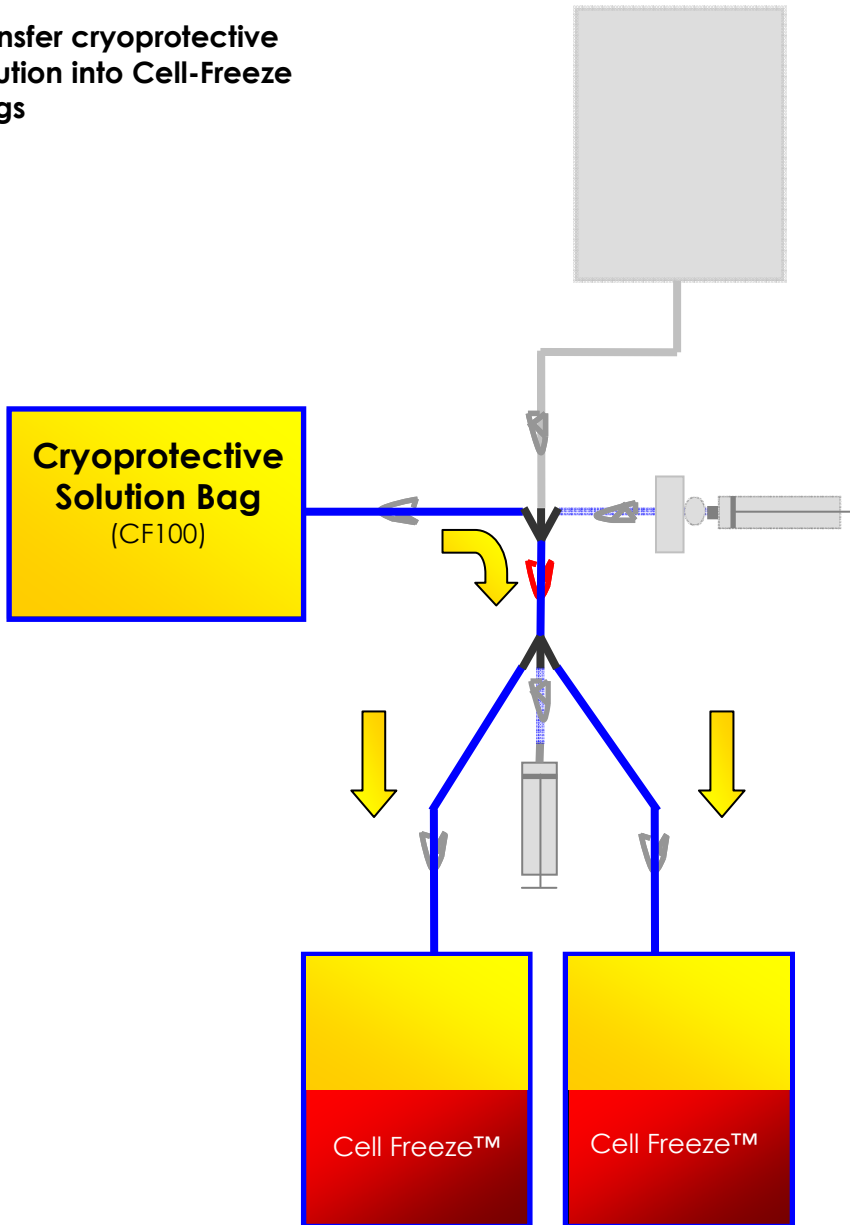
SCD compatible PVC

EVA tubing

**2. Transfer apheresis product into Cell-Freeze bags**



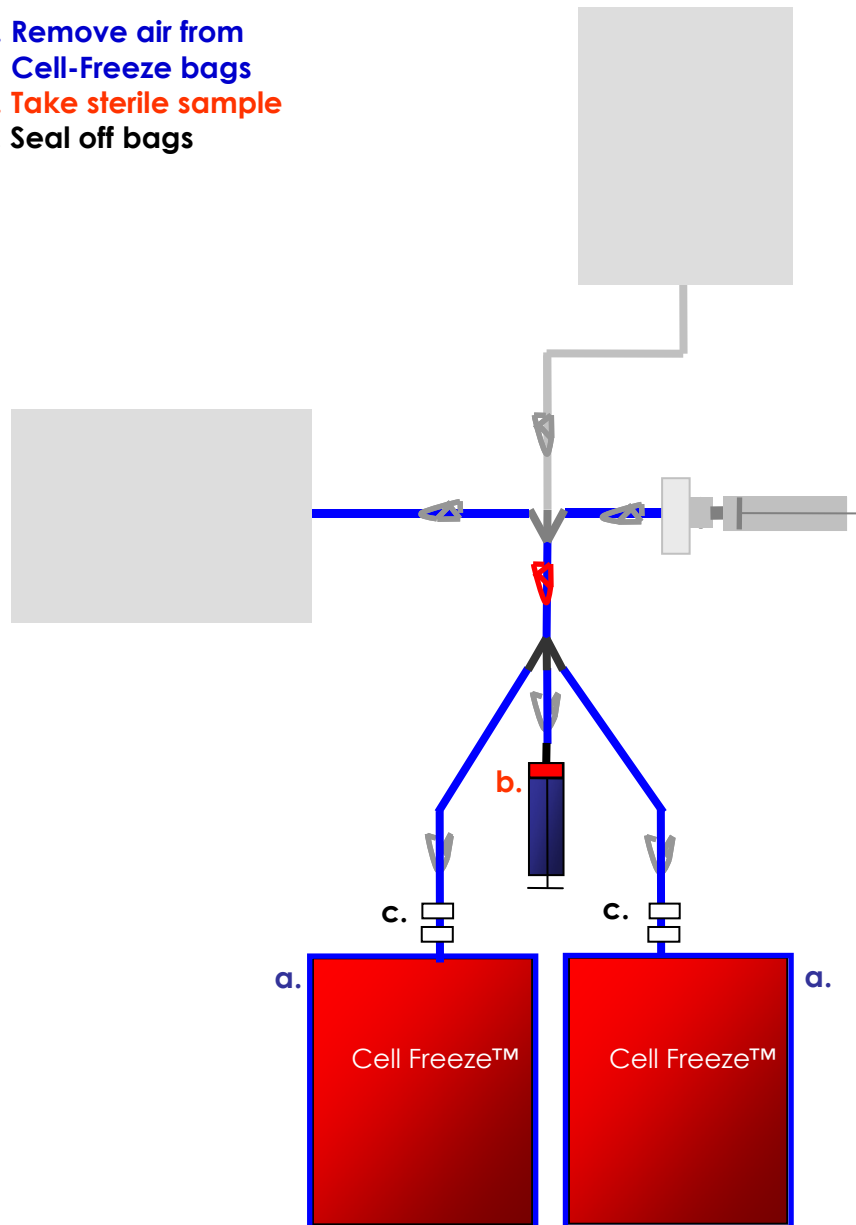
3. Transfer cryoprotective solution into Cell-Freeze bags



— SCD compatible PVC

— EVA tubing

4. **a. Remove air from Cell-Freeze bags**  
**b. Take sterile sample**  
**c. Seal off bags**



## Q&A

### How is DMSO introduced into the C3 set?

- DMSO is drawn into an external syringe. Thereafter, the syringe is attached to the female leur-lock on the filter and injected into the set.
- As you would introduce external solutions such as ACDA or NaCl into a "closed apheresis set", DMSO is introduced into the "closed C3 set" via a pre-attached and validated DMSO 0,2 µm filter.
- Please see the attached graphical description.

### How are additional solutions (i.e. cells & plasma) introduced into the set?

With use of a SCD (Sterile Connect Device), additional solutions are introduced into the set via the PVC tube.

- Please see the attached graphical description.

### What is the minimum and maximum freezing volume for the C3 set?

- The validated freezing volume for each CF100 bag is 70-125 ml. Thus:
- Minimum freezing volume: 70 ml
- Maximum freezing volume: 125 ml x 3 = 375 ml
  - o Please contact us for 3-bag usage suggestions
- We strongly suggest validating your processes.

### How can 4 (or more) Cell-Freeze bags be utilized?

- When freezing 4 (or more) bags, take 2 (or more) sets.
- When using more than one set, we suggest using the sets in parallel to minimize the exposure time of the cells with DMSO.

### How can a sterile sample be taken?

- Each C3 set has a pre-attached syringe. The syringe enables a sterile sample to be taken and sealed off. (see graphical description)



### **Which tube sealers are recommended?**

- The tubes that are directly attached to the Cell-Freeze bags consist of a unique EVA (Ethylene Vinyl Acetate). The high quality material does not incorporate additional PVC mixtures and thus enables a very high degree of freezing and fluid transfer safety.
- Suitable tube sealers (please contact us for quotes):
  - o Impulse sealers
  - o Sebra Model 2380 MINI™ Tube Sealer
- We strongly suggest validating your sealer.

### **How can the pre-attached labels be labeled?**

- Each Cell-Freeze™ bag has a pre-attached label that allows for a large labelling area.
- Information can directly be written on the label with a validated pen.
- Additionally, you can attach a laser-jet adhesive backed label.
- If you use cassettes, it is pertinent that information is appropriately placed so that it can be read through the cassette window.
- Please ask us for:
  - o Pre-formatted Microsoft Word™ label templates and
  - o A summary of excellent long-term customer validated adhesive label experiences and label manufacturer suggestions.

### **What is the regulatory classification?**

- CE marked medical device according to EU directive 93/42/EEC

### **How is the “closed cell cryopreservation” set packaged?**

- The sets are packaged individually within a sterile over-pouch.
- The inner and outer set surfaces are sterile.  
(i.e. There are no holes in the over-pouch.)
- 12 sets per case

