

The logo consists of the word "SAFE2" in white, bold, sans-serif font, centered within a red rectangular box. This box is flanked by two black brackets, one on the left and one on the right. A registered trademark symbol (®) is located to the upper right of the right bracket.

SAFE2®

The logo features the word "STEMCHOICE" in white, sans-serif font. The letter "S" is stylized with a red outline. A red horizontal line runs through the middle of the letters "T", "E", "M", and "C". A registered trademark symbol (®) is located to the upper right of the "E".

STEMCHOICE®

# STEMCHOICE®

*Choice of Innovation and Quality!*

STEMCHOICE® is a product line of **SAFE2** Freezing Bags designed for storage and preservation of stem cells and other biological materials in liquid nitrogen, vapor phase or low temperature storage.

## Innovation

SAFE2® Freezing Bags kit consists of a freezing bag with an integrally attached tubing set and an overwrap bag. Each individual component is part of a unique bag concept that makes the product user-friendly and in line with several cycles of freezing and thawing. Moreover, the bag special design perfectly fits the majority of the existing cassettes and storage systems, thus maximizing storage capacity and protect sample integrity.

## Safety

All SAFE2® Freezing Bags are subjected to different testing methods, both in pre and post production phases. A quality label is applied on the final product as guarantee of its conformity to the testing results and compliance with internal and external standards. Every production batch is released with a Certificate of Conformance (CoC) and a Production Control Report.

## Quality

The material has the most innovative formulation of Ethylene-vinyl acetate (EVA), which retains their flexibility even at lowest temperatures and have a high puncture resistance. The welding is performed with the most advanced technologies. The proven performance of all its components avoids gas and liquid permeation and allows a flexible bag's manipulation, thus preserving all safety conditions and minimizing the risk of contamination.

## Handiness

The blister is made of medical grade paper and disinfectable plastic film, containing the bag and its overwrap. This simplifies and improves working in sterile conditions.

## Flexibility

We can provide you with custom-made solutions that suits all your needs!

SAFE2® Freezing Bags are available in different sizes, depending on the clinical applications and customers' requests.

(1) Except SH-25B and SH-6B models that have different connecting sets

(2) Or clamps in case of SH-6B models

## 1 The freezing bag

The bags are made with an highly biocompatible material, **EVA (Ethyl Vinyl Acetate)**, whose formulation makes them flexible and resistant to low operating temperatures (range from -196°C to +37°C).

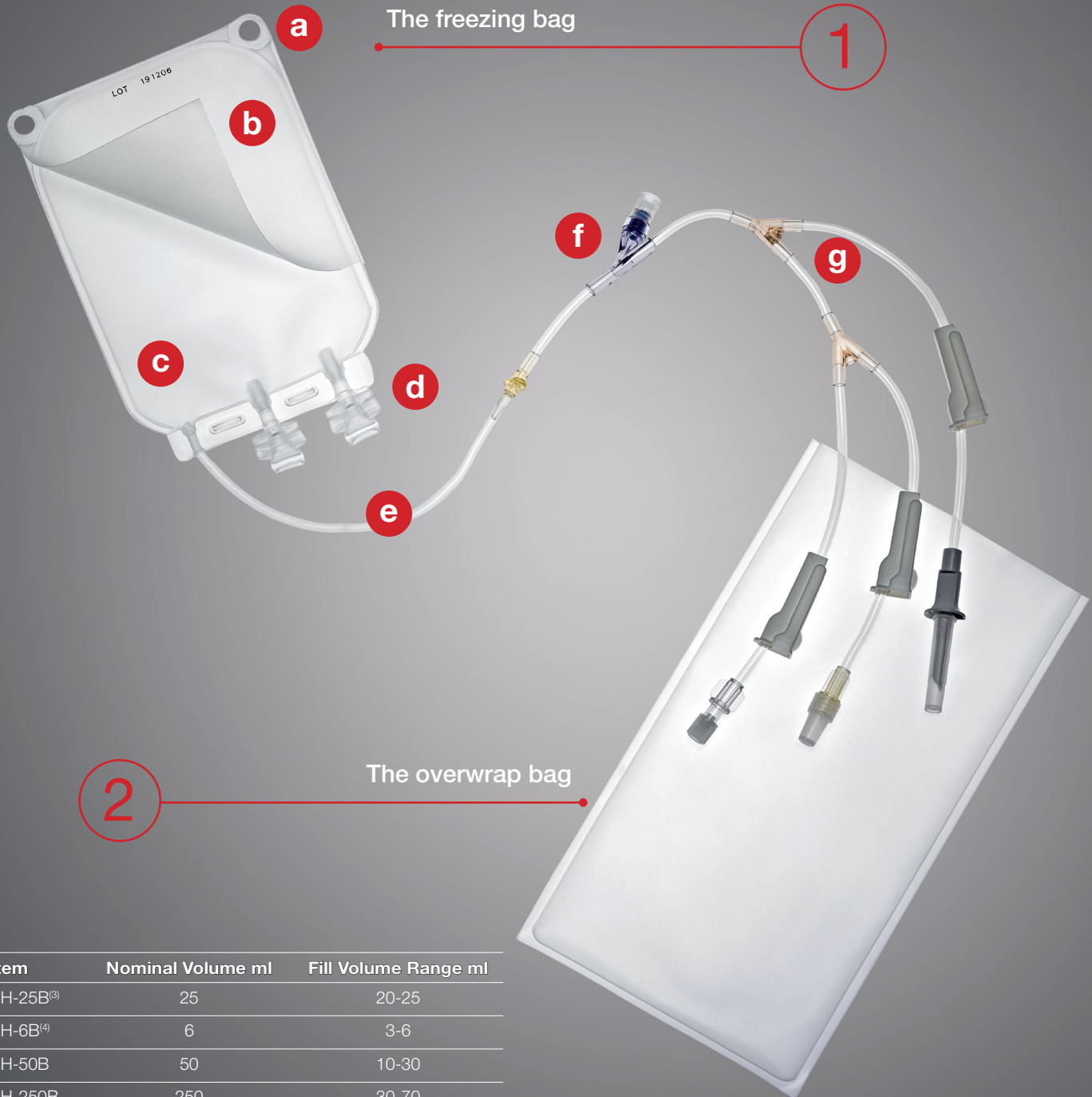
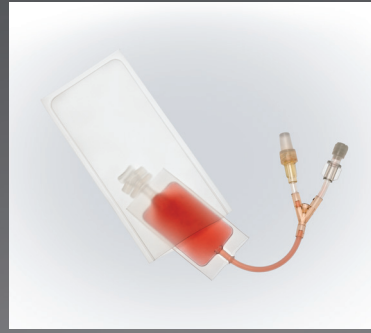
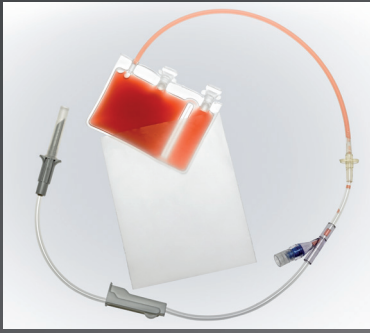
- a. The bag is equipped with two reinforced **hanger holes**, to ensure a stable anchorage during the bag manipulation.
- b. An additional **layer (lemb)** is placed at the bottom of the bag. It allows the application of a label, containing all the information required by law (ISBT128) and prevents the risk of contamination of potential adhesive components, as the glue, inside the bag.
- c. The **round shaped edges** make the full drainage of the bag easier, thus minimizing the cellular loss.
- d. The two **secured spike ports** are designed for the removal of the thawed cell product. The spike ports are realized in EVA and are secured with twist-off protective caps, thus ensuring the sterility during all bag manipulation and penetration phases. The inner part of the spike ports has a slit that enables the complete bag drainage.
- e. The **injection tube** is made of the same material of the bag (EVA) and is positioned close to the taking ports, in order to enable a faster and easier welding. In addition, it is possible to obtain contiguous segments of the tube as sample-filled tubing sections (aliquots) for routine tests.
- f. The **needle-free connector** guarantees the safety of the operator and reduces the risks of needle sticks and contamination. It allows the connection between the luer lock syringe and the port, with a swabable valve that provides a hermetic bond between the syringe luer tip and the valve. This structure ensures a closed system and sterility of the samples, even after syringe removal.
- g. The **integrated filling assembly set**, in PVC material, consists of one spike, one female luer-lock, one male luer-lock and one needle-free connector (1). Each tube is provided with roller clamps (2) and a protective cap.

## 2 The overwrap bag

Safe and practical, the overwrap bag is a double protection for the samples and the freezing bag. It ensures a safe cryopreservation and prevents the risk of cross-contamination. Each bag is provided with an overwrap. The material has the same performance of the primary bag and guarantees a resistant final welding.

- Same resistant ethylene vinyl acetate (EVA) as the freezing bag;
- Included in every bag kit;
- Space saving and flexible shape.

In addition, it is possible to realize a double welding, obtaining a "pocket" for the testing samples (aliquots).



The freezing bag

1

The overwrap bag

2

Item	Nominal Volume ml	Fill Volume Range ml
SH-25B <sup>(3)</sup>	25	20-25
SH-6B <sup>(4)</sup>	6	3-6
SH-50B	50	10-30
SH-250B	250	30-70
SH-500B	500	55-100
SH-750B	750	80-180

The **SH-25B model** is also available in a special product line, which allows a better distribution of the samples, ensuring a more homogeneous freezing.

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(3) available as single compartment, double compartment or 4- compartment bag both in standard and special line.  
 (4) available as single bag and as multiple bags connected to one filling set (x3, x4, x6, ...)

The entire manufacturing process is in conformity with ISO 13485:2016 certified quality system.



ADVATIS® is a contractual joint venture between Medigas Italia S.r.l. and Haemopharm Healthcare. The combination of the experience and know how of both companies makes quality and reliability the foundation of all product design at ADVATIS®. Medigas Italia S.r.l. provides its customers with a wide range of products and services in the home healthcare, cryobiology and medical gases. Haemopharm Healthcare, as part of Paolo Gobbi Frattini Group, develops and manufactures flexible bags and medical devices for a broad spectrum of pharmaceutical and medical applications.

SAFE2® Freezing Bags have been developed thanks to the expertise of these two high-potential companies. This product line is manufactured by Haemopharm Healthcare and marketed by Medigas Italia S.r.l. worldwide.

ADVATIS® portfolio provides innovative and proved solutions in the cryopreservation and cell therapy field. We offer a wide range of products intended for different stages of collection and manipulation of stem cells and tissues. Thanks to our R&D Team's support and flexibility throughout all the manufacturing process, ADVATIS® can offer custom-made solutions to meet customers' needs.

Partnership between:



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