

# High Security Storage

## Biorepository Concept





# Cryo Bio System High Security Concept

## Introduction

### ***Cryo Bio System Biorepository Concept: High Security Storage***

### ***Cryopreservation with the highest standards for Quality, Safety, Traceability and Storage Space Efficiency.***

The value of a biological sample resides in the combination of quality, safety and traceability. Preservation of initial qualities, safe storage conditions (both for the sample and its environment) and link with information through tamper proof identification, define the value of a sample for scientific and / or medical use.

Cryo Bio System's concept for cryopreservation and biorepositories complies with the highest quality standards.

It ensures the quality of storage and identification for traceability of the sample.

The concept is compatible with all nitrogen freezers, both liquid and vapor, as well as mechanical -80°C and -130°C freezers. It allows for more aliquots to be stored per freezer than in cryogenic vials, boxes and metal racks.

Our parent company IMV Technologies has manufactured for over 40 years instrumentation and consumables for animal reproduction. Twenty years ago, our founder envisioned making the company's expertise in cryopreservation available to scientists in all fields requiring preservation and survival of living organisms. The specific demands of life science combined with the cryopreservation experience resulted in the CBS™ High Security straw storage concept.

In our premises in France - in L'Aigle - Normandy - manufacturing takes place in controlled air rooms. The quality management system includes rigorous selection of raw materials, tests at different stages of production, sterility tests for gamma-radiated products, endotoxin and mouse embryo testing for medical devices. Our equipment is specifically designed for CBS™ High Security straws. Our network of field technicians ensures installation and maintenance service worldwide.

Cryo Bio System is ISO 13485 certified for the development and manufacturing of Medical devices following the Directive 93/42/CE.



***Production site in L'Aigle, Normandy - France***





**ATTESTATION / CERTIFICATE N° 0505 / B5 / 1**  
**Renouvellement de l'attestation du 1<sup>er</sup> janvier 2005**  
*Renewal of the certificate of January 1<sup>st</sup>, 2005*

**Délivrée à Paris le 27 mai 2006**  
*Issued in Paris on May 27<sup>th</sup>, 2006*

**ATTESTATION CE / EC CERTIFICATE**

Approbation du Système d'Assurance Qualité de la Production / Approval of Production Quality Assurance System  
 ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux  
 ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

**Fabricant (nom et adresse)**  
*Manufacturer (name and address)*  
**CRYO BIO SYSTEM – I.M.V. DIVISION**  
**10 rue Clémenceau**  
**61302 L'AIGLE**  
**FRANCE**

**Catégorie du(des) dispositif(s)**  
*Device(s) category*  
**Dispositifs médicaux stériles destinés au recueil d'ovocytes, au recueil de sperme, à la cryoconservation de matériels biologiques, à l'insémination intra-utérine et intra-cervicale.**  
*Sterile medical devices for collection of oocytes, for collection of sperm, for cryogenic preservation of biological materials, for intra-uterine and intra-cervical insemination.*

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé F100028, le système d'assurance qualité pour la production et le contrôle final des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.  
 LNE/G-MED certifies that, on the basis of the results contained in the file referenced F100028, the quality system for manufacturing and final inspection of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.

**Cette attestation est valable jusqu'au : 26 mai 2009 (inclus)**  
*This certificate is valid until : May 26<sup>th</sup> 2009 (included)*



**Pour Le Directeur Général**  
*For General Director*  
**Laurence DAGALLIER**  
 Directeur Certification  
 Certification Director

BS  
 Laboratoire national de métrologie et d'essais • Etablissement agréé à caractère industriel et commercial  
 LNE/G-MED • Organisation notifiée n° 0439  
 1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. 01 40 43 37 00 • Fax 01 40 43 37 37 • www.lne.fr • www.gmed.fr



**CERTIFICAT**  
**CERTIFICATE OF REGISTRATION**  
**N° 0505 / 13485 / 1**

Le LNE certifie que le système de management de la qualité développé par  
 LNE certifies that the quality management system developed by

**CRYO BIO SYSTEM – I.M.V. Division**

pour les activités  
*for the activities*

**Conception, fabrication, commercialisation de dispositifs médicaux stériles, de milieux de culture et de conservation destinés à la procréation médicale assistée, et à la cryoconservation de matériels biologiques.**  
*Design, production and marketing of sterile medical devices, from cells culture and preservation, intended for the medically assisted procreation, and for the cryogenic preservation of biological materials.*

réalisés sur les sites de  
*performed on the locations of*

**10 rue Clémenceau**  
**61302 L'AIGLE - FRANCE**

**49 rue Porte Label**  
**61300 L'AIGLE - FRANCE**

est conforme aux exigences des normes internationales  
*complies with the requirements of the international standards*

**ISO 13485 : 2003**

**Date de délivrance : 18 Juin 2006**  
*Date of issue : June 18<sup>th</sup>, 2006*  
**Date d'échéance de validité : 26 mai 2009**  
*Limit expiry date : May 26<sup>th</sup>, 2009*  
**Renouvellement du certificat du 12 janvier 2005**  
*Renewal of the certificate of January 12<sup>th</sup>, 2005*



**Pour Le Directeur Général**  
*For the general Director*  
**Laurence DAGALLIER**  
 Directeur Certification  
 Certification Director

Le certificat est délivré selon les règles de certification G-MED. (This certificate is issued according to the rules of G-MED certification.)  
 LNE/G-MED Organisation notifiée pour les Dispositifs Médicaux (LNE/G-MED Notified Body for Medical Devices)

BS  
 Laboratoire national de métrologie et d'essais • Etablissement agréé à caractère industriel et commercial  
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**510(k) Premarket Notification Database**

**Device Classification Name** accessory, assisted reproduction  
**510(k) Number** K002595  
**Regulation Number** 21 CFR §884.6120  
**Device Name** CBS STRAW  
 CRYO BIO SYSTEM  
**Regulatory Class** II  
**Classification Product Code** MQG  
**Date Received** 08/21/2000  
**Decision Date** 11/17/2000  
**Decision** substantially equivalent (SE)  
**Classification Advisory Committee** Obstetrics/Gynecology  
**Review Advisory Committee** Obstetrics/Gynecology  
**Statement/Summary/Purged Status** Statement only  
 statement statement

**Underwriters Laboratories Inc.®**

**CERTIFICATE OF COMPLIANCE**

**CERTIFICATE NUMBER:** 240402 - E216951  
**ISSUE DATE:** April 24, 2002 Page 1 of 1

**Issued to:** Cryo Bio System  
 10 Rue Clémenceau • Boite Postale 81  
 F-61302 L'Aigle Cedex France  
**Report Reference:** E216951, December 18, 2001  
**This is to Certify that representative samples of:** Sealing Machines Models SYMS UF250000, UF260000, UF400000 and UF410000

Have been investigated by Underwriters Laboratories Inc.® in accordance with the Standard(s) indicated on this Certificate.

**Standard(s) for Safety:** UL 3101-1 - Electrical Equipment for Laboratory Use; Part I: General Requirements  
 CSA C22.2 No. 310.1-92 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part I: General Requirements

**Additional Information:** Electrical Rating:  
 Models UF410000 and UF260000: 115 Vac, 60 Hz, 2.5 A  
 Models UF400000 and UF250000: 230 Vac, 50-60 Hz, 2 A

Only those products bearing the UL Listing Mark for the US and Canada should be considered as being covered by UL's Listing and Follow-Up Service meeting the appropriate requirements for US and Canada.

The UL Listing Mark for the US and Canada generally include the UL in a circle symbol with "UL" and "UL" identifiers and the word "LISTED", a control number (may be alphanumeric) assigned by UL, and the product category name (product identifier) as indicated in the appropriate UL Directory.

**LOOK FOR THE UL LISTING MARK ON THE PRODUCT**

**Engineer:** Pascal Lemerle - Project Engineer  
 UL International (France) SA  
**Review Engineer:** Yves M. Houdry - Engineering Group Leader  
 UL International (France) SA

Pursuant to the Cooperative Services Agreement between UL International (France) SA and Underwriters Laboratories Inc. ("UL"), UL hereby accepts and issues this Certificate of Compliance. For questions in France, you may call +33 0 1 69 19 88 00.



## CBS™ High Security Straws

Where there is no compromise on **QUALITY** and **SAFETY** for storage of biological samples

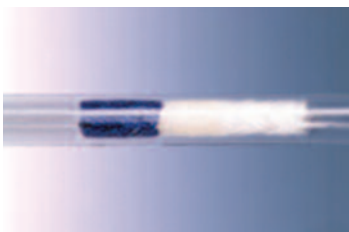
### Material

All Cryo Bio System straws are made from a ionomeric resin that is chemically inert, biocompatible and has physical characteristics resistant to ultra low temperatures and pressures created by expanding liquids and liquid nitrogen. Sealed straws are resistance tested to 150 kg/cm<sup>2</sup> (2133 lb/sq.inch), both the seals and the material should resist in order to have the batch approved.

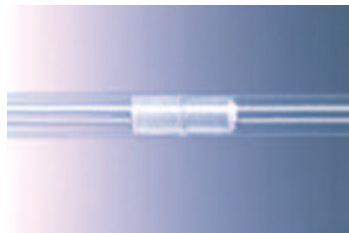
### Plugs

Straws are filled by aspiration through an air permeable plug inside the straw. Two types of plugs are available:

- The factory plug made of two specifically woven polyamide fibers enclosing a polymerizing powder. In the filling procedure the powder polymerizes as soon as the liquid sample comes in contact and blocks the filling. Plugs can come in 6 different colors, for easy identification in the cold environment of a freezer.



- The hydrophobic plug made of a 0.22 µm membrane attached to a hollow stem. This membrane allows air to pass through it but neither liquid nor bacteria.



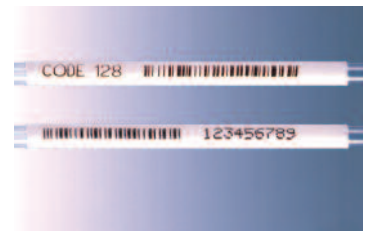
### Seal

Directly after filling, both extremities of the CBS™ High Security straw are thermally sealed with one of our specific machines: SYMS, PACE or MAPI. This makes the straw absolutely leakproof, preventing contamination of the sample and its environment.



### Tamper proof identification

The primary identification of the straw in the cold environment of the freezer is by its color, while its definitive identification is by its alpha-numerical and bar code. The CBS™ High Security straw is identified by tamper proof ink-jet print on a jacket around the straw. The special ink is resistant to liquid nitrogen and to ice crystals as well as plastic materials. Once the straw is sealed, the jacket cannot be removed from the straw unless it is opened.



A second process of identification is available for 0.3 ml straws where a colored identification rod with a label can be inserted inside the straw in the compartment behind the plug. This label can only be taken from the sample when the straw is opened.



CBS™ High Security straws are available in 3 different volumes.

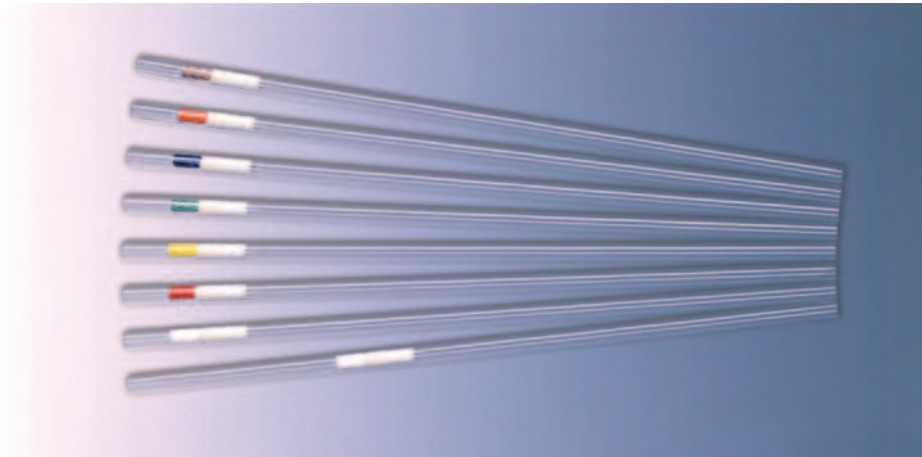
Straw volume	Plug type	Color	Compatibility with equipment
0.5 ml	weave	plug	MAPI, PACE, SYMS
0.3 ml	weave	fixed insert	MAPI, PACE, SYMS
0.3 ml	hydrophobic	plug / insert	SYMS
0.5 ml	hydrophobic	plug	SYMS



# CBS™ High Security Straws

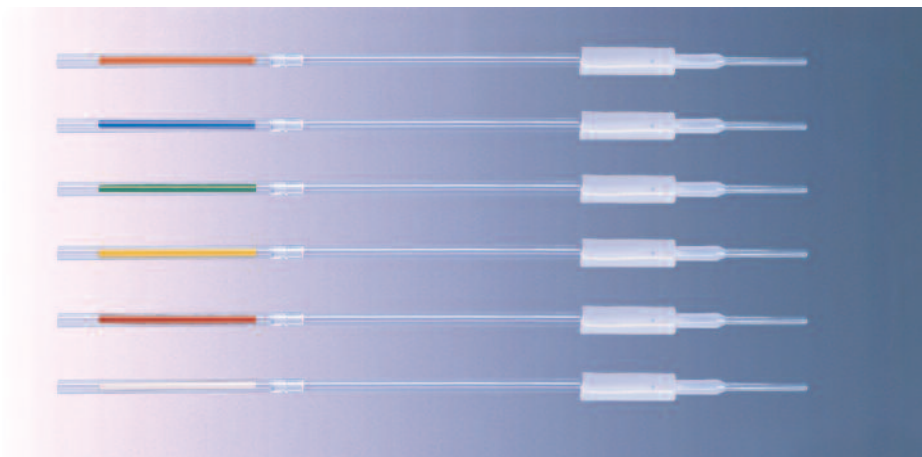
## Storage

For storage, CBS™ High Security straws are placed in colored compartments called visotubes which are available in many colors. These are further placed into colored goblets. Color coding facilitates identification of straws upon retrieval. A Daisy goblet can easily hold 144 straws (12 visotubes).



## Applications

Virtually any liquid sample can be stored in CBS™ High Security straws. Applications include plasma, serum, buffy coat, red blood cells, extracted DNA, urine, mouth wash, cell suspensions, bacterial or viral strains, gametes and embryos.



## Dimensions

- 0.3 ml and 0.5 ml straws
- Length: 130 mm after sealing
- Internal diameter: 2.5 mm

## Accessories

Filling nozzles for manual filling:  
0.3 and, 0.5 ml.  
Syringe connectors.  
Filling nozzles for MAPI and PACE automated filling.



STERILE | R



FDA 510 (k) Clearance  
MEA and LAL tested

# Cryo Bio System High Security Freezer Equipment

## Goblets and Visotubes

Color coded goblets for storage of CBS™ High Security straws.

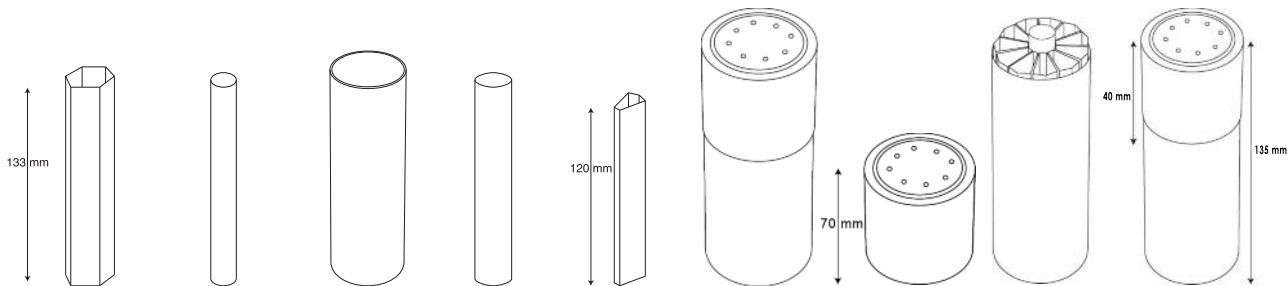
CBS™ High Security straws are placed in goblets for storage in freezers. Goblets come in 8 different colors and their sub-compartments (called visotubes) in 12 different colors.

In the Daisy configuration, goblets hold 12 visotubes of different colors and can easily hold 144 straws of 0.3 ml or 0.5 ml.

The color configuration of each goblet can be customized to the storage protocol. Color becomes an integrated part of the sample identification when it is associated with a sample type, protocol and / or storage level. Material and colors are fully compatible and resistant to long term storage at very low temperatures, including immersion into liquid nitrogen.

Goblets and lids are perforated in order to facilitate the flow of liquid nitrogen or nitrogen vapor into the goblet and around the straws. For storage in liquid nitrogen, the visotubes have not been perforated at their base so as to maintain the liquid nitrogen around the straws even if the goblet is temporarily extracted from the freezer. The goblet and visotubes maintain the sample at a stable low temperature until its decided thawing and use.

The colored plug ends of the straws are visible in all peripheral visotubes and in the clear central round visotube. The central higher visotube protects the straws under the lid when goblets are stacked during storage.



Item Specifications		Hexagonal Visotube 133 mm	Round Visotube ø 13 mm	Goblet ø 35 mm 133 mm	Round Visotube ø 17.5 mm	Triangular Visotube 120 mm	Goblet with pre-attached cover	Cover for Goblet ø 65 mm	Daisy Goblet* (bag of 1) 120 mm	Daisy Goblet* (bag of 5) 120 mm
C O L O R S	Clear	020486	020517	020523	006924	-	021224	006321	015144	015152
	Black	-	-	-	-	018153	-	-	-	-
	Brown	-	-	-	-	018147	-	-	-	-
	Red	020491	020522	-	-	018146	021228	-	015146	015154
	Green	020488	020519	-	-	018145	021226	-	015147	015155
	Blue	020487	020518	-	-	018148	021225	-	015151	015159
	Grey	-	-	-	-	018144	-	-	018141	018142
	Purple	-	-	-	-	018152	021229	-	015150	015158
	Yellow	020489	020520	-	-	018143	021227	-	015148	015156
	Pink	-	-	-	-	018149	-	-	-	-
Orange	020490	020521	-	-	018150	-	-	-	-	
Pistachio	-	-	-	-	018151	-	-	015149	015157	
Packaging		10	10	10	100	100	10	50	1	5
C A P A C I T Y	0.3 & 0.5 ml CBS™ straw	22	8	65	12	12	-	-	144	144

\*Complete goblet containing 11 triangular visotubes and 1 central round visotube, all of different colors and a lid.

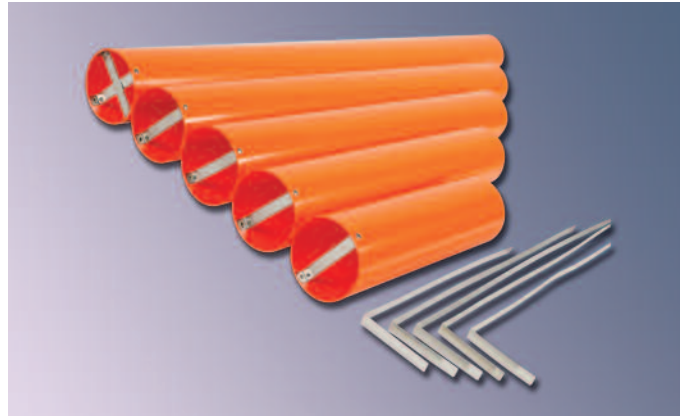




Compatible with all types of liquid nitrogen and vapor freezers but also low-temperature mechanical freezers, Cryo Bio System canisters are the sleeves that hold the goblets.

Five lengths of canisters are available, with a capacity of 2 to 6 goblets stored on top of each other. A colored flag can be placed on the lifter to facilitate retrieval.

Canisters are placed in the nitrogen freezer before filling the container with liquid nitrogen. Goblets are introduced and retrieved one by one with the metal lifter; all manipulation of goblets is in the cold environment of the neck of the nitrogen freezer to ensure the stable low temperature of the samples.



Flags for lifters are available in 9 different colors:

White	007328	Turquoise	015697
Yellow	015693	Orange	015698
Salmon-pink	015694	Purple	015699
Pink	015695	Grey	015706
Green	015696		



References		Levels of goblets	Dimension H x Ø (mm)	Dimension with goblets H x Ø (mm)
Canisters with lifters	008644	2	245 x 70	280 x 70
	008645	3	380 x 70	415 x 70
	008646	4	515 x 70	550 x 70
	007198	5	650 x 70	685 x 70
	007199	6	785 x 70	820 x 70
Lifters			H x W (mm)	
	014762	5 lifter	725 x 65	
	016096	6 lifter	845 x 65	



## PACE

### System for filling and sealing of CBS™ High Security straws

Automation for the packaging in straws of liquid biological samples.

PACE automatically fills and thermally seals a user defined number of straws from a primary sample tube. Both 0.3 ml and 0.5 ml CBS™ straws with weave plug can be used with PACE, either pre-identified or just before ID printing with SIDE (see page 10). Sample is filled into the straw with a disposable filling nozzle (ref 014623) at the open end and an aspiration nozzle (ref 014621) at the plug end of the straw.

Tamper proof ink-jet printed straws packaged in sets of study-specific color combinations are available on request from Cryo Bio System. Filled blank straws can also be printed in the laboratory with a SIDE system.

PACE is the packaging system for laboratories with large aliquoting and storage programs, with fixed or variable numbers of straws. The hopper is designed for distribution until the very last straw, enabling to load the exact number for each color.

The PACE consists of the straw handling system and its control box. The small footprint of the straw handling system can be placed under a laminar flow hood for use in sterile conditions.

Output is dependent on study protocol, more specifically on the number of straws per primary tube.

### Technical specifications

Setup, maintenance and shut-down time are approximately 15 minutes per day.

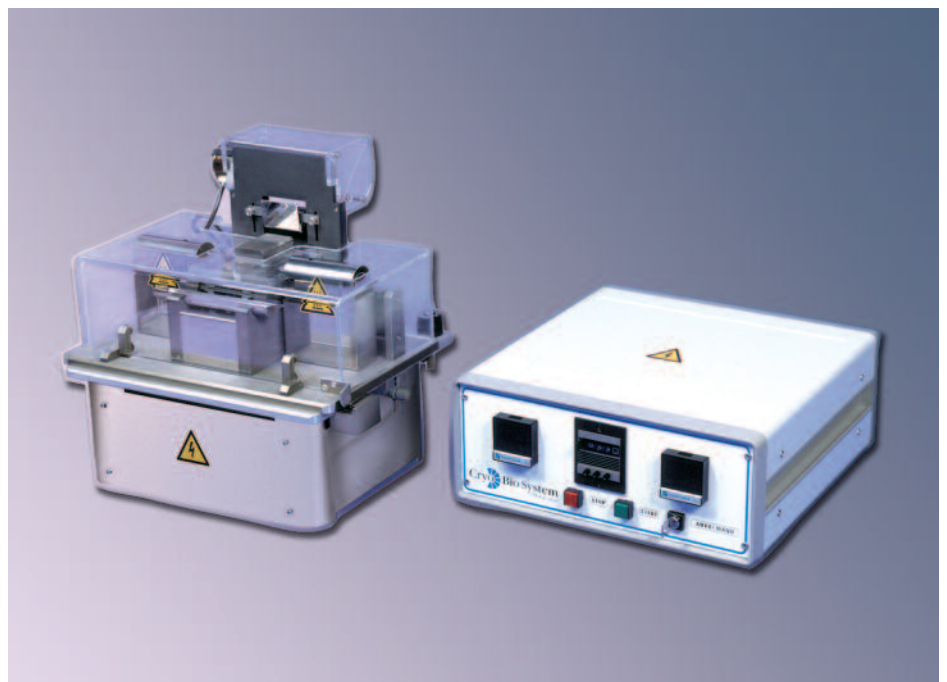
Potentially contaminated parts of the system can be cleaned with ethanol or non-corrosive decontamination fluids.

### Dimensions

- Straw handler  
380 x 300 x 370 mm (L x W x H)  
Weight: 25 kg (55 lb)

- Control box  
410 x 365 x 155 mm  
Weight: 14 kg (31 lb)

Electrical requirements:  
220V/50 Hz or 110V/60 Hz







### System for filling, sealing and identification of CBS™ High Security straws

Automation for the packaging in straws of liquid biological samples including ink-jet identification.

Starting from an open primary sample tube, MAPI fills and thermally seals the programmed number of straws and prints on each of them an identification code. In-line barcode reading validates the identification on each straw and the various steps of the process are checked on-line through several sensors.

MAPI is a flexible system that can handle the different sample aliquoting protocols of a laboratory, different identifications and variable numbers of straws. Straw feeding hoppers with different colors are easily interchangeable.

The MAPI consists of the straw handling system, a control box, a special ink-jet printer and a PC with the MAPI pilot software. A special ergonomical laboratory bench for the unit completes the system.

MAPI is the aliquote packaging system for laboratories with large study projects where important numbers of samples are to be aliquoted in straws. Thanks to its versatility it can be shared resource or technical platform equipment. The in-line printing enables the perfect correspondence of primary tube and aliquot identification numbers.

The MAPI pilot software features barcode reading or keyboard entry of codes to be printed, validation of number of filled and printed straws and export of production files. MAPI can be combined with Cryo Bio System storage management software.

MAPI is compatible with 0.3 ml and 0.5 ml CBS™ straws with weave plugs and white jackets. Sample is filled into the straw with a disposable filling nozzle (ref 014623) at the open end and an aspiration nozzle (ref 014621) at the plug end of the straw.

Output is dependent on study protocol, more specifically on the number of straws per primary tube.

### Technical specifications

Setup, maintenance and shut-down time are approximately 15 minutes per day. Potentially contaminated parts of the system can be cleaned with ethanol or non-corrosive decontamination fluids.

### Dimensions

- MAPI straw system  
760 x 260 x 470 mm (L x W x H)  
Weight: 35 kg (77 lb)
- Support bench  
1200 x 600 x 900 mm  
Height with automate included:  
1260 mm
- Control box  
430 x 380 x 190 mm  
Weight: 14 kg (31 lb)
- Printer control box  
650 x 450 x 375 mm  
Weight: 16 kg (35 lb)

Flexible to printer head: 4 m

Electrical requirements:  
220V/50 Hz or 110V/60 Hz



## SYMS

### Sealer for all types of CBS™ High Security straws

Simply introduce the straw end in the guide and, with one push on the button or foot pedal the thermal pulse seal closes the straw absolutely airtight. Then the opposite end of the straw is sealed, after introduction of an identification rod and / or label OR around the straw a jacket that can be pre-identified or printed on SIDE after sealing. The small footprint of the SYMS makes it easy to place under a laminar flow hood for sterile working conditions. The sealing area can be taken apart and easily decontaminated with ethanol or other non corrosive decontamination liquids.

SYMS is compatible with all CBS™ High Security straws.

The SYMS sealer comes complete with cables, foot pedal and a maintenance kit.

### Technical specifications

Setup, maintenance and down-time are approximately 5 minutes per day. Potentially contaminated parts of the system can be cleaned with ethanol or non-corrosive decontamination fluids.

### Dimensions

- Sealer  
230 x 220 x 170 mm (L x W x H)  
Weight: 6 kg (13 lb)

Electrical requirements:  
220V/50 Hz or 110V/60 Hz



## SIDE

### Straw Identification System

Tamper proof ink-jet printing identification system for open and sealed CBS™ straws.

SIDE is a flexible identification system enabling the laboratory to:

- print exactly the number of requested straws for a sample
- print exactly the same code on the straws as the sample to ensure the link
- print straws after sealing to ensure sterility of the content
- link through data export the sample identifications with storage management software.

SIDE is compatible with 0.3 ml, 0.5 ml and 1 ml straws with white or colored jackets and can print alpha-numerical codes and/or barcodes (Code128). Open straws are distributed from a hopper and printed with a out-put of

60 straws/minute. Sealed straws can be placed manually on the distributor.

SIDE pilot software features bar-code reading or keyboard entry of codes to be printed and export of production files in different formats.

The SIDE system consists of the straw handler, a PC with pilot software and an ink-jet printing system.

### Technical specifications

Setup, maintenance and shut-down time are approximately 15 minutes per day.

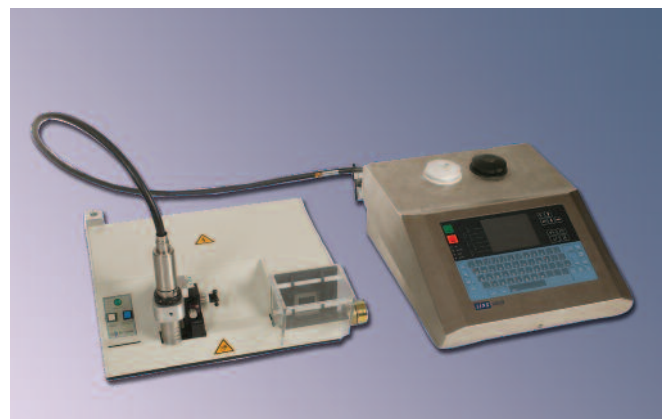
### Dimensions

- Straw handler  
450 x 500 x 190 mm (L x W x H)  
Weight: ≈ 20 kg (44 lb)

- Printer control box  
640 x 460 x 230 mm  
Weight: ≈ 30 kg (66 lb)

Flexible to printer head: 4 m

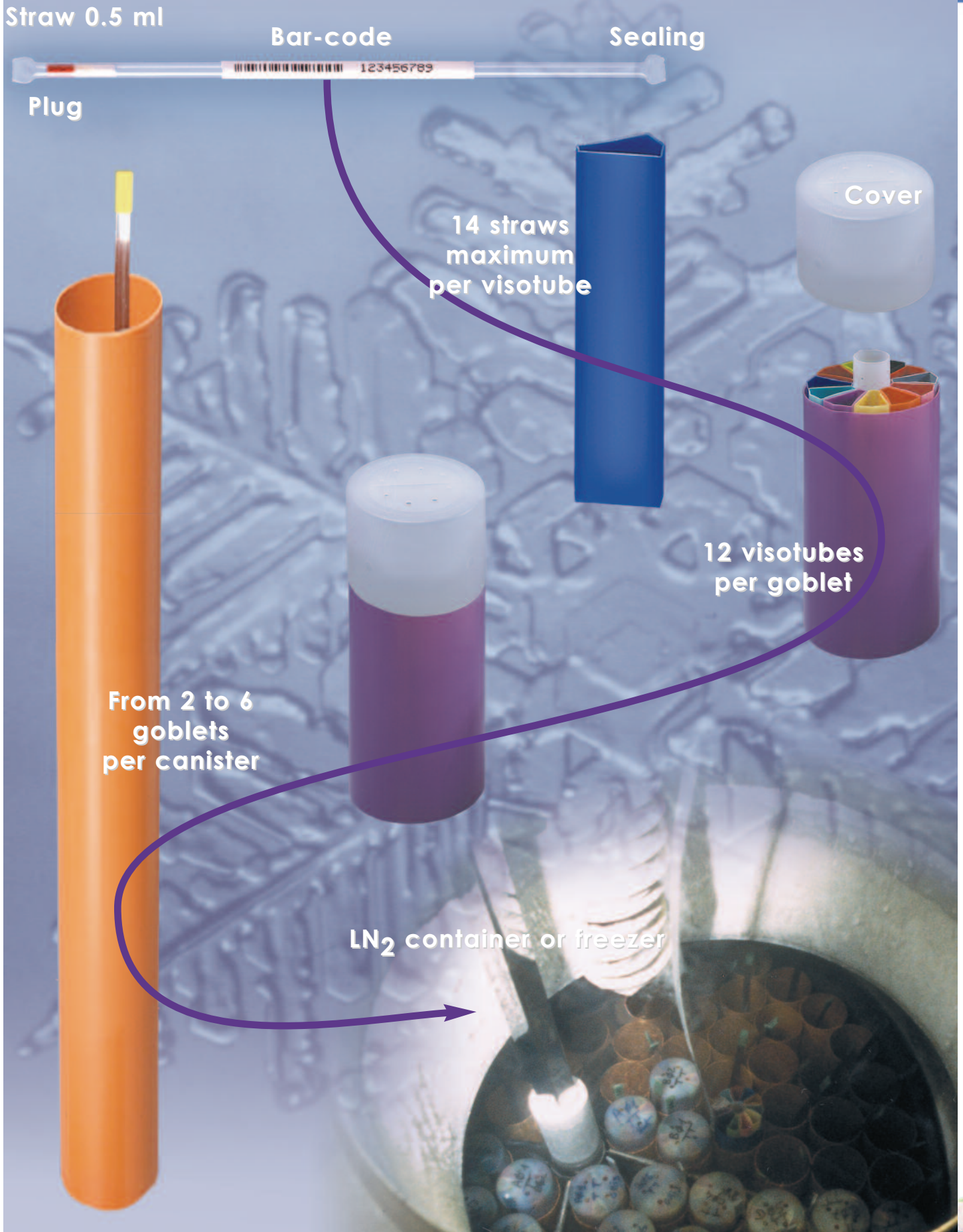
Electrical requirements:  
220V/50 Hz or 110V/60 Hz







# The Cryo Bio System Storage Concept



For more information on our products, please visit our website:

[www.cryobiosystem.com](http://www.cryobiosystem.com)

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75008 PARIS – FRANCE

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For all enquiries, please contact us at:

[contact@cryobiosystem-imv.com](mailto:contact@cryobiosystem-imv.com)

Cryo Bio System has a worldwide network of distributors and subsidiaries in the United States of America, Italy, India and China (representative office).

Your local contact:

non relevant pictures