

Tooling up CGT

Collection
Packaging
Storage
Cold Chain
Thawing

20
24

< LN2
smart
shipper

CQT-
specific
container
design

< 3 mins
thawing —
time

Class-defining solutions for bioproduction workflows

 **Biolife
Solutions**





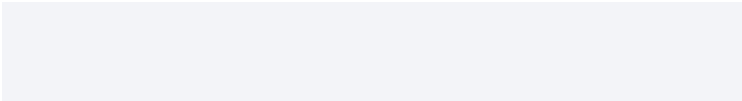
Contents

03/

Biopreservation Best Practices

Fill in the sales inquiry form on our website →
or email:
salesone@biolifesolutions.com

We are revolutionizing bioproduction solutions for the regenerative medicine, biobanking, and biopharmaceutical industries with class-defining technology designed to increase the viability of biologics.



Collection & Processing

04/
06

Gold-standard protection for cell preservation and viability.

Fill & Packaging

07/
09

Automated filling and hermetically sealed vials for process control.

Storage Solutions

10/
12

Long-term, flexible and innovative, refrigerated, frozen and deep frozen storage solutions covering -196°C to +25°C.

Cold Chain Solutions

13/
15

Dry-vapor Smart Shippers with frozen and cryogenic storage temperature capacities.

Thawing Solutions

16/
18

Automated thawing solutions for a controlled and repeatable process.

Cryopreservation Challenges

Cell-based products originate from biological starting material, such as cells from tissue biopsies, blood, and bone marrow, that can be developed and manufactured ex-vivo into a clinical product.

These cells require specialized processes to remain viable and functional throughout their life cycle, including methods to enable short- and long-term storage and transport between manufacturing and clinical sites.

With our leading team of scientists and engineers innovating and evolving alongside the Life Sciences industry, BioLife Solutions provides the experience and knowledge to help customers establish bioproduction best practices. Your success is our success, we will work with you to move your global health initiatives forward.

All challenges discussed in this brochure have been pulled from the PDA Standard 02-2021: Cryopreservation of Cells for Use in Cell Therapies, Gene Therapies, and Regenerative Medicine - An Introduction and Best Practices Approach on How to Prepare, Cryopreserve, and Recover Cells, Cell Lines, and Cell-Based Tissue Products.





Collection & Processing



CryoStor® Freeze Media
HypoThermosol® FRS Media
BloodStor® Media
Cell Thawing Media
Sexton Biotechnologies® nLiven PR™ Platelet Lysate
Sexton Biotechnologies® Stimulate® Platelet Lysate
Sexton Biotechnologies® T-Liven PR™ Platelet Lysate

USP <85>
endotoxin —
testing

Protein-free
Serum-free —

USP
<71>
sterility



Formulate cells to your desired concentration in biopreservation medium

Our CryoStor® and HypoThermosol® solutions are recognized as the gold standard for freeze and storage media, embedded in multiple commercial therapies worldwide.

Our pathogen reduced human platelet lysates (hPL) provide you with a media that reduces risks and improves downstream cell performance.

OUR CELL COLLECTION AND PROCESSING PRODUCTS >

Collection
Packaging
Storage
Cold Chain
Thawing



Cell Collection & Processing Solutions

Featured Products



CryoStor® CS10

CryoStor® Biopreservation Media

CryoStor is a permeating cryopreservation media that helps mitigate damage to biologics like the formation of ice during cryogenic storage.

SOLUTIONS

CryoStor® CSB

An intracellular-like base formulation

CryoStor® CS2

Formulated with DMSO in 2% concentration

CryoStor® CS5

Formulated with DMSO in 5% concentration

CryoStor® CS10

Formulated with DMSO in 10% concentration



nLiven PR™ 500mL & 100mL

nLiven PR™ Human Platelet Lysate

nLiven PR establishes the gold standard for performance and quality of irradiated pooled human platelet lysate. It features a validated pathogen reduction technology.

SOLUTIONS

nLiven PR™ 100mL

Irradiated pooled human lysate

nLiven PR™ 500mL

Irradiated pooled human lysate

Overcome the challenges of cell expansion and product preservation throughout CGT processing.

↓ SOLUTIONS

Collection
Packaging
Storage
Cold Chain
Thawing



Collection & Processing 06

#1

Cryopreservation Media Selection

Independent research demonstrates medium and material used as part of cryopreservation impacts the viability of biologics. Formulation must be consistent and qualified to reduce variability from batch-to-batch.



HypoThermosol® FRS 100mL

#3

Uncompromising Pathogen Reduction

Human and animal derived cell culture supplements often carry a risk of pathogen transmission and sometimes even risk of bovine antigen reactivity. Our irradiation method minimizes the impact of performance while meeting regulatory requirements for risk reduction.



Stemulate® 500mL

#2

Media and Formulation Media Qualification

Cryoprotectant agents should be of the highest quality available and of pharmacopeial grade when possible. Products pre-formulated with USP-grade DMSO are preferred. Across a broad spectrum of cell types, BioLife formulations have proven more effective in reducing post-preservation apoptosis and necrosis than other commercial and home-brew isotonic and extracellular formulations.



CryoStor® CSB



BloodStor® 100

#4

Expansion Serum May Determine Cell Function

Studies have shown that choice of serum for ex-vivo expansion determines in-vivo CAR-T cell function. Select a serum that improves maintenance of less differentiated CAR-T cells and supports in-vitro cytotoxic effect.



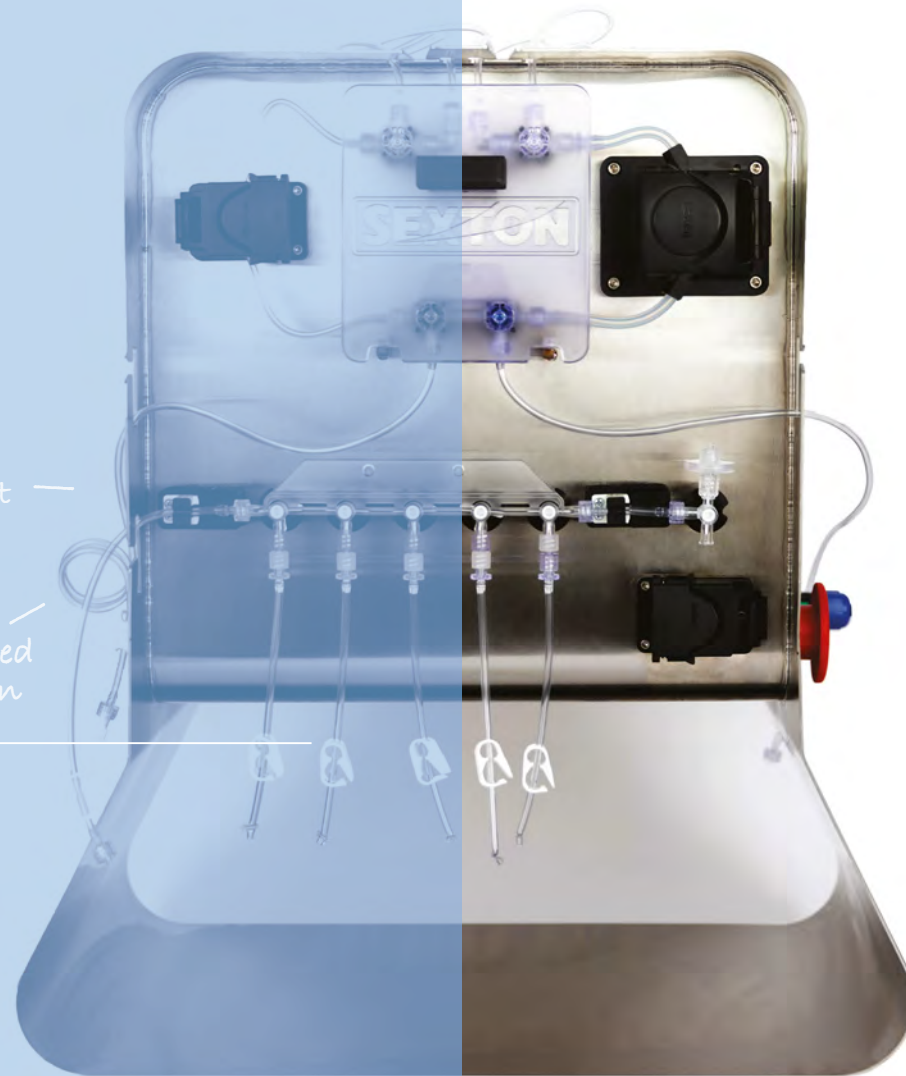
Fill & Packaging



Sexton Biotechnologies® CellSeal® Cryogenic Vials
Sexton Biotechnologies® Signata CT-5™
Closed Fluid Management System
Sexton Biotechnologies® CellSeal® Connect
Sexton Biotechnologies® CellSeal® RF Sealer
Sexton Biotechnologies® CellSeal® AF-500
Automated Fill & Seal

Closed fluid
management
system

Semi-
automated
operation



Select and qualify container closure systems

Selection of a primary and secondary cryogenic container closure system is critical to preserve cell quality during cryostorage and should be suitable for its intended use in a freezer, long-term storage, shipping, and thawing of cryopreserved cells.

Our filling solutions offer flexible automation for early stage success and high-throughput capabilities for late stage manufacturing.

[OUR FILL & PACKAGING PRODUCTS >](#)

Collection
Packaging
Storage
Cold Chain
Thawing





Fill & Packaging Solutions

Featured Products



Signata CT-5™

Sexton Signata CT-5™ Fluid Management System

The Signata platform allows users to incorporate aspects of automation early without eliminating critical flexibility during process development. The Sexton Signata CT-5 brings multiple processes traditionally performed by manual techniques under a higher level of control to protect your products from loss or contamination.

SOLUTIONS

Signata CT-5™
Closed fluid management system



CellSeal® Vials

CellSeal® Cryogenic Vials Secondary Container Systems

CellSeal cryogenic vials are the first purpose-built, rigid containers used in the cell and gene therapy industry. With a full suite of accessories and filling systems, vials can be filled manually, or with high-throughput systems.

SOLUTIONS

CellSeal® Vial Five Set (2mL or 5mL)
Consumable set for CellSeal® cryogenic vials

Custom Bag Five Set
Consumable set with cryobags

Weldable Five Set
Consumable set with weldable pigtails for user-defined consumables

Overcome the challenges of integrating different fill and packaging solutions that were specifically designed for different steps of the CGT manufacturing process.

↓ SOLUTIONS

Collection
Packaging
Storage
Cold Chain
Thawing



#1

Container Selection

Our containers can withstand cryogenic temperatures, provide rigidity and strength to reduce fracture, and optimize downstream product recovery.



CellSeal® AF-500

#3

Container Design for CGT

Choose vials specifically designed for the cell and gene therapy industry. Our CellSeal vials have been qualified as final containers for commercially approved cell therapies around the world.



Signata CT-5™

#2

Manual Through Automated Filling

Select vials that can be filled manually without the need for high capital investment, yet have the ability to scale with your evolving manufacturing needs. We provide flexible fluid management with the Signata CT-5 and high throughput fill with the AF-500.



CellSeal® Connect Vials

#4

Flexible Manufacturing

Utilize tools that are compatible with closed-system manufacturing which allows you to easily integrate other CGT manufacturing equipment and optimizes your fluid management processes.



CellSeal® Cryogenic Vials



Storage Solutions



Ultra-Low
Temperature (ULT)
Sample Transport

Pharmaceutical
pallet storage

Flexible storage conditions:
CRT to -196°C, 40% - 75%
RH stability storage



ISO 9001/ISO 20387

cGMP FDA compliant

FDA registered and inspected since 2011 (CDER and CBER)

Over 86 (SOPs) all modeled after FDA compliance
(21 CFR parts 210 & 211) for pharmaceutical manufacturing

GDP (Good Distribution Practice)

CAP-BAP accredited in U.S. facilities

Reliable Long-Term Storage Extends Shelf Life

Storage criteria should be defined and qualified to maintain sample integrity and viability throughout the duration of storage and transport. Cold storage of products should be monitored with qualified, temperature monitoring devices and best-fit sample systems to optimize sample retrieval. BioLife Solutions offers biostorage services to span the frozen storage range of -196°C to -20°C with added cold chain protection during sample pickup or delivery.

Collection Packaging Storage Cold Chain Thawing

OUR **STORAGE SERVICES** >





SciSafe® Storage Services

Featured Services

SciSafe® Services

World Leader in cGMP Biological
& Pharmaceutical Storage

SciSafe, part of BioLife Solutions, is an established and experienced leader in cold storage. With a tailored approach to client challenges, SciSafe offers flexible, customer-first solutions. From complete, outsourced biostorage to hybrid-sample management models, researchers have quick access to samples while entrusting the highest level of protection possible for their most valued research.

Scale your biostorage program with experience

Scaling an on-campus biostorage program, establishing a mirror bank, or outsourcing biostorage altogether are daunting projects. Choose a biostorage partner that has experience, offers customized storage solutions, charges no hidden fees, has predictable pricing to enhance the program execution and truly partners with you.

Overcome storage scale challenges
with an experienced and trusted biostorage
consulting partner.

↓ SOLUTIONS

Collection
Packaging
Storage
Cold Chain
Thawing



12

Storage
Solutions

#1

Easy Sample Access

If your research requires regular sample access, choose a biostorage partner who includes sample transport as part of their program. Scheduled sample pickups and drop-offs are available.



#3

Equipment Maintenance

Equipment monitoring, validation, calibration and maintenance are all things to consider when selecting storage equipment. Understand how to service the equipment in-house or work with an outsourced vendor to manage the program entirely.



#2

Sample Security

Gated, remote sample monitoring, downloadable sample monitoring reports, and sample tracking from point of storage through delivery are available. Select a partner who offers around-the-clock monitoring, a high security infrastructure, and/or security guards for your project.



#4

Compliance

Most outsourced biostorage partners offer basic compliance packages (i.e. ISO 9001, ISO 20387, cGMP, GDP). Research which partners have the most accreditations and certifications to match your internal Quality and Regulatory requirements, and the list of providers becomes shorter.





Cold Chain Solutions



evo® DV10 Smart Shipper
evo® DI Smart Shipper
ModPak™ Packout Kit
evolS™ Web Application
BioT™ Intra-Campus Transporters

15+ days of
hold time

LN2 smart
shipper



Cold chain management solutions with integrated security and intelligence

Secure transport of biologic material demands shipping solutions with uncompromised thermal integrity and real-time payload visibility. evo® Smart Shippers are easy-to-use, reusable, and provide up to 15 days of cryogenic protection.

[OUR COLD CHAIN PRODUCTS >](#)

Collection
Packaging
Storage
Cold Chain
Thawing



Cold Chain Solutions



Featured Products



ModPak™ Packout Kit

Smart Shippers

Cold Chain Management

evo™ Smart Shippers are efficient, compact and reusable – no more pallets. The integrated sensors and evolS™ platform provide visibility to the status and condition of the shipment for you and your partners, in real-time.

SOLUTIONS

evo® DV10

LN2 shipper with integrated tracking device

evo® DI

Dry ice shipper with integrated tracking device

evolS™ Web Application

Cloud-based software integration that provides visibility into shipment details

ModPak™

Modular Cryogenic Packout Kit designed with versatile shock and liquid absorbing system to secure payload through all phases of transit



BioT™ ULT Mobile Workstation

Intra-Campus Transport

Cold Chain Management

The dry ice-based BioT™ ULT Workstation provides a secure ultra-low temperature (ULT) -75° to -50°C work area for processing or transporting critical frozen samples. The patent-pending DIR™ cooling insert technology ensures that samples are completely immersed in temperatures below -50°C during the operating period.

SOLUTIONS

BioT™ ULT Transporter

-70°C to -50°C Dry ice based temperature stability system

BioT™ ULT Mobile Workstation

-75°C to -50°C Dry ice based mobile temperature stability system

BioT™ LN2 Transporter

-150°C Liquid nitrogen temperature stability system

Overcome the challenges of shipping and transporting products at ultra-low and cryogenic temperatures safely.

↓ SOLUTIONS

Collection
Packaging
Storage
Cold Chain
Thawing



#1

Real-Time Visibility

Real-time tracking of sample location and sample storage conditions must be recorded for complete product traceability. Select a solution with integrated real-time tracking devices.

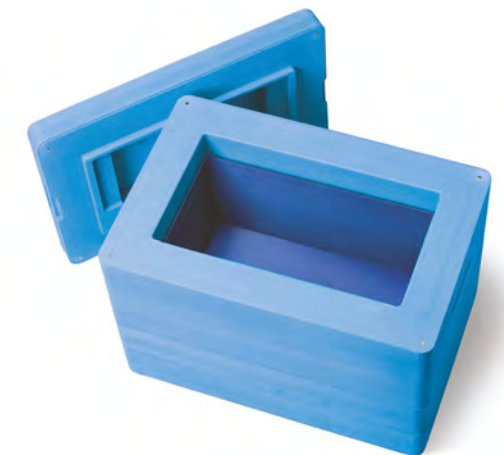


ModPak™ Packout Kit,
Optional Cassettes & Cryobox

#3

Cryogenic Temperatures

Most living cells and biologic materials require ultracold temperatures during transport. Find a shipping solution that protects the payload, but also understands hazardous material handling protocols.



BioT™ LN2 Transporter

#2

Trip Length

Whether it is a two-day or 10-day trip to the far reaches of the globe, the shipping solution must guarantee temperature stability for the entire duration of the trip.



evoIS™ Web Application

#4

Service Partners

The cold chain depends on freight forwarders and airlines to get biologic materials from point A to B. Find a shipping solution that is well connected and approved by all transportation parties to simplify your products' transport.



evo® DV10



Thawing Solutions



< 3 mins
thawing —
time

0.8 – 1.5 mL
fill volume —

Custom
thawing
algorithms

ThawSTAR® CSV2, CSV5
ThawSTAR® AT2, AT6, AT10, AT Transporter
ThawSTAR® CFT1.5, CFT2, CFT Transporter



Your thawing process should be consistent and reproducible

Thawing most cryopreserved products is a critical step that may impact product quality and cell viability. The thawing program must maintain a consistent warming algorithm throughout the sample and be reproducible. Selecting an automated thawing device over a manual water bath, bead bath or thermal block should limit sample variability.

OUR **THAWING** PRODUCTS >

Collection
Packaging
Storage
Cold Chain
Thawing





Thawing Solutions



Featured Products



ThawSTAR® CSV5

ThawSTAR® CSV2 and CSV5

CellSeal® Vial Thawing System

ThawSTAR® CSV2 and CSV5 are water-free thawing systems designed specifically for thawing CellSeal vials. Patent-pending heating technology and real-time, temperature-sensing analytics manage the heat application for a reliable and controlled thaw.

SOLUTIONS

ThawSTAR® CSV2

2mL CellSeal Vial Thawing System

ThawSTAR® CSV5

5mL CellSeal Vial Thawing System



ThawSTAR® CFT1.5

ThawSTAR® AT and CFT

Cell Vial Thawing System

The ThawStar Automated Cell Thawing System replaces unstandardized, manual thawing processes with a controlled, warming profile.

SOLUTIONS

ThawSTAR® AT2 2mL Closed Vial Thawing System

ThawSTAR® AT6 6mL Closed Vial Thawing System

ThawSTAR® AT10 10mL Closed Vial Thawing System

ThawSTAR® AT Transporter

Fits all AT-Closed Vials

ThawSTAR® CFT1.5 Instrument and Transporter
1.5mL Vial Thawing System

ThawSTAR® CFT2 Instrument and Transporter
2mL Vial Thawing System

Overcome the challenges of thawing samples in a manner that is controlled and repeatable.

↓ SOLUTIONS

Collection
Packaging
Storage
Cold Chain
Thawing



18

Thawing
Solutions

#1

Thaw Uniformity

A sample must be consistently and uniformly warmed to avoid weak spots or over-heating within the sample.



ThawSTAR® CB

#3

Reproducible Thaw Program

Controlling a manual thawing program may be difficult. Select an automated thaw instrument that will repeat the same thaw cycle, consistently without human intervention.



ThawSTAR® AT6 Instrument and AT Transporter

#2

Thaw Rate

An optimal thawing rate maximizes cell viability and recovery. Time limits for thawing and post-thaw hold should be established and measured for stability and functionality.



ThawSTAR® CB Barrier Bag

#4

Contamination Avoidance

Using a manual water bath procedure runs the risk of sample contamination. Select a thawing instrument that protects and stabilizes the sample during thaw to eliminate cross-contamination.



ThawSTAR® CFT2 Instrument and Transporter



BioLife Solutions Inc.
3303 Monte Villa Parkway, Suite 310
Bothell, WA 98021 USA
T +1.866.424.6543 or 425.402.1400
F +1.425.402.1433
E info@biolifesolutions.com
BiolifeSolutions.com



Visit
biolifesolutions.com
for more products