STERELYNX INC.

Advanced RTU Sterile Packaging & Drug Delivery Systems

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ABOUT US

STERELYNX Inc. delivers Ready-To-Use (RTU) sterile primary packaging systems and advanced drug delivery platforms for injectables, biologics, vaccines, and specialty pharmaceuticals. Our operations are supported by tightly integrated, globally compliant manufacturing capabilities, ensuring regulatory alignment, consistent quality, and cost efficiency across the supply chain.

Designed to meet the needs of both emerging biotech innovators and established pharmaceutical organizations, our solutions enable accelerated scale-up while minimizing operational complexity and regulatory risk.

OUR VISION

To become a globally trusted supplier of Ready-To-Use sterile packaging and advanced drug delivery systems, enabling safe, scalable, and compliant injectable therapies worldwide.

OUR MISSION

- Deliver US FDA-aligned primary packaging and device solutions
- Support pharmaceutical innovation through reliable, future-ready platforms
- Build long-term partnerships through quality, transparency, and supply assurance

REGULATORY ALIGNMENT

PRODUCTION

ISO 9001 and ISO 15378 certified facilities operating at GMP standards, ensuring safe, reliable production under strictly controlled temperature and humidity conditions.

LICENSES & CERTIFICATIONS

STERELYNX Inc. have products that are internationally accepted under regulatory approvals, including:

- ISO 15378 – Primary Packaging for Medicinal Products
- ISO 9001 – Quality Management Systems
- GMP-compliant manufacturing facilities
- DMF support & regulatory documentation readiness for US FDA submissions

READY-TO-USE STERILE PACKAGING SYSTEMS

"RTU, Engineered for Confidence"

Fully automated production takes place in a GMP-certified cleanroom (Class C + Class A).

With 100% visual and AI inspection, micron-level precision ensures complete sealing safety for highly sensitive drugs throughout the entire process.

Sterile packaging delivers a more attractive appearance, superior mechanical performance, and fewer processing steps - reducing downtime and failure risks.

Through rigorous sterilization and particle control, the product supports "Ready-to-Fill" operations right out of the box. This eliminates the need for costly equipment investments such as washing machines, water systems, and tunnel ovens - saving floor space and maintenance costs. It helps manufacturer reduce capital expenditure, minimize factory footprint, and cut overall costs by up to 80%.

WHY CHOOSE RTU PACKAGING

Sterelynx Ready-to-Use (RTU) vials and cartridges are developed to meet the highest global pharmaceutical packaging standards.

Material Excellence

Type I borosilicate glass offering superior chemical resistance and mechanical strength.

Fill-Ready Convenience

Pre-washed, depyrogenated, and terminally sterilized—ready for direct aseptic filling.

Zero-Contact Protection

Validated nest-and-tub system prevents glass-to-glass contact, reducing breakage and contamination.

Cleanroom Processing

Manufactured and packaged in controlled cleanroom environments for particle-free handling.

Regulatory Compliance

Fully compliant with ISO, USP, and GMP standards for global pharmaceutical markets.

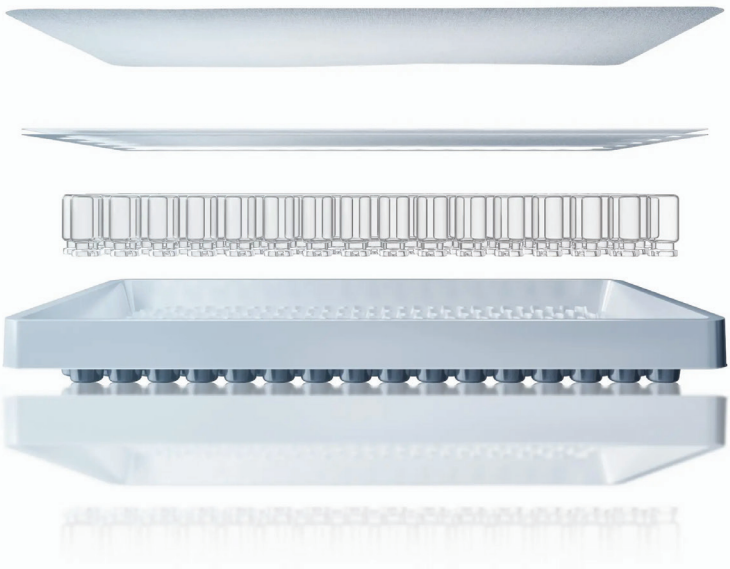
Operational Efficiency

Designed for seamless compatibility with automated filling lines.

Flexible Configurations

Available in multiple sizes and formats for injectables, biologics, and laboratory use.

STERELYNX RTU VIALS PACKAGING OVERVIEW



“Eliminating preparation steps, Accelerating production”

Key Features

- Individual container positioning within molded nests
- Secure tubs with validated sterile barriers
- Reduced glass-to-glass contact, minimizing cosmetic defects
- Optimized for robotic pick-and-place systems

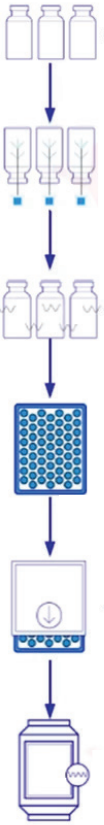
Benefits for US Biotech & Pharma

- Eliminates in-house washing, depyrogenation, and sterilization
- Reduces cleanroom footprint and operational complexity
- Improves batch-to-batch consistency
- Lowers risk of particulate contamination

Tub Materials & Sterile Barrier Systems

- Medical-grade polymer tubs
- Tyvek or equivalent breathable sterile barrier lids
- Gamma or ETO sterilization compatibility
- Designed to maintain sterility through transport and storage

STERELYNX RTU PACKAGING ASEPTIC PROCESS



Type I neutral borosilicate tubular glass vials

Vials are 100% inspected in ISO 7-class clean room.

Type I neutral borosilicate tubular glass vials

Vials are washed with WFI (water for injection)

Depyrogenation

Vials are depyrogenated in a tunnel drying cabinet according to the Pharmacopea requirements.

Tray loading

Vials are placed into the nest tray or tub by automatic manipulator in ISO 4.8-class clean room.

Tyvek sealing & sterile bag bagging

One Tyvek paper is put on the vial top and the tub is sealed by Tyvek paper in ISO 4.8-class clean room.

The tub is put into the Tyvek bag in the ISO 7-class clean room.

Sterilization

Sterilization is made through ETO (Ethylene Oxide) according to ISO 11135

Components	Material Description	Regulations & Standard Compliance
Glass injection Vials	Type 1 Borosilicate glass	ISO 8362-1, YBB00292005-2-2015
Nest	Polypropylene (PP)	ISO 10993 USP
Tub	High-impact polystyrene (HIPS)	EN71-3:2013+A1:2014+ A2:2017 +A3:2018+ A4:2019 21 CFR 1771640
Tyvek® inlay	TyvekR: PE-HD fiber	ISO 10993-5
Tyvek® seal	TyvekR: PE-HD fiber and hot melt adhesive	ISO 10993-5
Sterilized bags	Double bag: low-density polyethylene (LDPE) and TyvekR	ISO10993-5
Sterilization method	ETO	ISO11135

NEST & TUB PACKAGING DESIGN

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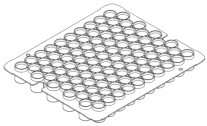
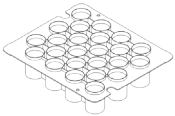
Advanced RTU Sterile Packaging & Drug Delivery Systems



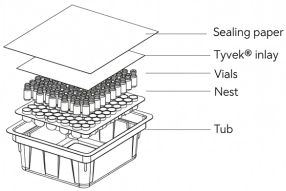
2R/2ml: 100pcs

6R/10R 6ml 10ml 48 pcs



20R/20ml 24 pcs

230 x 198 mm



Nest and Tub

Packing Method

Carton Size:800*245*530MM

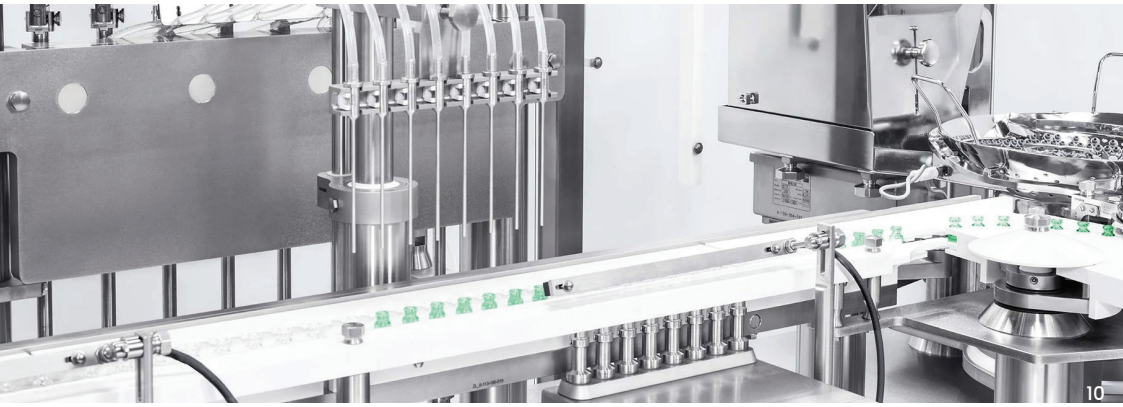
Vial Size	Pc/Nest	Nest/CT	Total Pcs/CT	Dimension	GW/Kg
2R/2 ml	100	15	1500	780*245*535	15.7
2R/2 ml	228	10	2280	780*245*280	15.2
6R/6ml	48	15	720	780*245*535	14.6
6R/6ml	96	8	768	780*245*280	10.4
10R/10ml	48	15	720	780*245*535	15.6
10R/10ml	96	8	768	780*245*280	11.6
20R/20ml	24	15	360	780*245*535	15.0
20R/20ml	60	8	480	780*245*280	12.6

INJECTABLE APPLICATIONS

"Designed for high-value injectable applications."

STERELYNX INC.
Advanced RTU Sterile Packaging & Drug Delivery Systems

- **Injectable Pharmaceuticals**
  Small-molecule and parenteral drug products
- **Biologics & Biosimilars**
  Proteins, peptides, and complex formulations
- **Vaccines**
  Liquid and lyophilized vaccine applications
- **Specialty & High-Value Drugs**
  Oncology, orphan drugs, and critical care products
- **Clinical Trial & R&D Use**
  Development, stability, and compatibility studies
- **Hospital & Institutional Use**
  Ready-to-fill sterile applications



QUALITY AND COMPLIANCE ALIGNMENT

STERELYNX RTU packaging systems are designed to support:

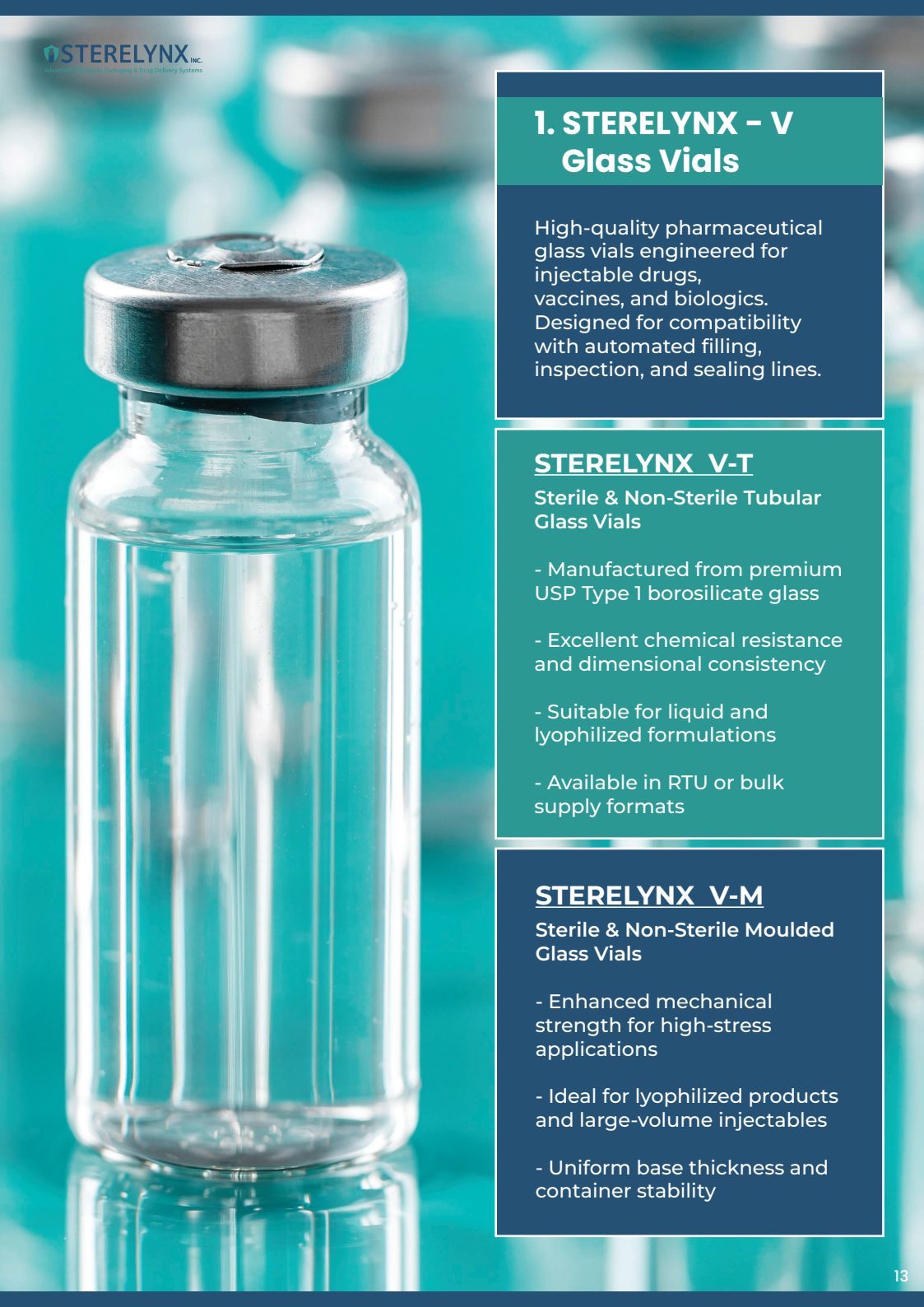
- US FDA aseptic processing expectations
- EU GMP Annex 1 principles
- Container Closure Integrity (CCI) requirements
- Extractables & Leachables study compatibility

Each RTU configuration is supplied with:

- Sterilization validation support
- Batch traceability documentation
- Regulatory documentation for DMF support

STERELYNX PRODUCT PORTFOLIO

PRODUCT LINE	PRODUCT CATEGORY
1. STERELYNX – V	Glass Vials
2. STERELYNX – C	Glass Cartridges
3. STERELYNX – P	Closures & Seals
4. STERELYNX – D	Drug Delivery Devices



1. STERELYNX – V Glass Vials

High-quality pharmaceutical glass vials engineered for injectable drugs, vaccines, and biologics. Designed for compatibility with automated filling, inspection, and sealing lines.

STERELYNX V-T

Sterile & Non-Sterile Tubular Glass Vials

- Manufactured from premium USP Type 1 borosilicate glass

- Excellent chemical resistance and dimensional consistency

- Suitable for liquid and lyophilized formulations

- Available in RTU or bulk supply formats

STERELYNX V-M

Sterile & Non-Sterile Moulded Glass Vials

- Enhanced mechanical strength for high-stress applications

- Ideal for lyophilized products and large-volume injectables

- Uniform base thickness and container stability

2. STERELYNX – C Glass Cartridges

Precision-engineered cartridges for pen injectors and advanced drug delivery systems, ensuring accurate dosing and container integrity.

STERELYNX C-3

3 mL Sterile Glass Cartridge – Individual Packing

- Individually packed to ensure maximum sterility assurance
- Ready for direct integration into aseptic filling lines
- Suitable for biologics and chronic therapies

STERELYNX C-DC

4 mL Double-Chamber Glass Cartridge (Sterile)

- Designed for dual-component drug formulations
- Enables separation and reconstitution at point of use
- Ideal for complex injectable therapies

STERELYNX C-NS

Non-Sterile Glass Cartridges (1.5 / 1.8 / 3 mL)

- For customers with in-house washing and sterilization
- Consistent dimensions for device compatibility

3. STERELYNX – P Closures & Seals

Critical elastomeric and aluminum components designed to ensure container closure integrity (CCI) and drug compatibility.

STERELYNX P-RS

Sterile & Non-Sterile Rubber Stoppers

- Low extractables and leachables profile
- Suitable for liquid and lyophilized injectables
- Compatible with standard vial and cartridge systems

STERELYNX P-FO

Sterile & Non-Sterile Flip-Off Caps

- Secure aluminum crimp seals
- Tamper-evident and reliable sealing performance
- Available in multiple color options

4. STERELYNX – D Drug Delivery Devices

Patient-centric drug delivery solutions designed for ease of use, dosing accuracy, and regulatory compliance.

STERELYNX D-PEN

Injection Pens – Disposable & Reusable

- Medical-grade plastic and metal construction
- Suitable for insulin, GLP-1, and biologics
- Designed for scalability and customization

Future-Ready Platforms:

- Autoinjectors
- Wearable drug delivery systems

WHY CHOOSE US?

Faster clinical and commercial scale-up

Lower operational risk

Reduced capital expenditure on washing/sterilization lines

Strong fit for emerging biotech and CDMO workflows

Customized RTU configurations

Dedicated after-sales technical support

Flexible supply and delivery models

Reliable long-term partnership

CONNECT WITH US

STERELYNX INC.
Advanced RTU Sterile Packaging & Drug Delivery Systems

Request Product Samples.

Experience STERELYNX Quality, Sterility, and Consistency.

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