



Universal Medicap Ltd.

Solutions for Pharma Parenteral Packaging



We are committed to providing a  
**safe and hygienic** environment for everyone.

## Many Issues; One Solution

UNISAFE is one answer to multiple problems viz.,

- Clumping / clogging of the stopper during autoclave sterilization.
- Sticking of vials to the shelves in lyophilization chambers, when applied to the top of the stopper flange.
- Complex-shaped closures, commonly used in dry powder and lyophilized applications, can cause issues during the molding process.
- Lyophilization closures with UML UNISAFE film are available in a single-vent design that is proven effective in eliminating mechanical twinning: the problem of interlocking of double-vented stoppers during processing.

## Integrated Containment and Aseptic Barrier Technology:

With UML UNISAFE, you are 100% safe.

- UNISAFE uses integrated containment and aseptic barrier technology.
- Effectively provides a strong barrier against organic and inorganic extractables, achieving
- strong properties in moisture, oxygen, and water-vapor.
- The drug and closure interaction is minimized.
- Maintains container closure integrity.
- The fluoropolymer film effectively reduces drug product absorption and adsorption, ensuring enhanced strength and extended shelf life.
- UNISAFE is with combined or vaporized silicon coating, providing low surface energy, thereby preventing particulate contamination.
- Better flex-crack and puncture resistance.

- Improved package appearance and sustainability.
- Higher yield and lighter weight.
- Low permeation and absorption characteristics.
- Exhibits superior barrier properties and inertness.
- Designed to deliver effective chemical resistance and low absorption rates, exhibiting low reactivity with the medical-grade chemical contents.
- As a result, barrier film-based packaging is more durable and resistant.

As a result, Barrier film-based packaging is more durable and resistant to shop-worn appearance, unlike foil-based packaging.

**Ideal for potent, cytotoxic, hormonal and biological products, as well as special purpose application drugs**

## UNISAFE: Globally Acclaimed Packaging Products:

UNISAFE Stoppers, designed with barrier film laminate, offer superior protection against physical, chemical, and microbial invasions, while preserving their inherent properties for extended shelf life.

UNISAFE Stoppers and Plungers undergo rigorous quality testing to ensure they fully comply with FDA's international cGMP standards in respect of quality packaging, safe use, and accurate ingredients and strength in manufacturing, processing, and packing drug products.

UNISAFE RFU: UNISAFE Ready-For-use is a fully validated, cGMP conforming product for use in injections, and plungers, final-rinsed with treated water, sterilized by steam or gamma irradiation, and packed in an ISO Class 5 clean room.

UNISAFE RFS: UNISAFE RFS is a Ready-For-Sterilization product ideal for direct sterilization, ensuring consistent component preparation with minimal variability in sterile operations.

UNISAFE RFU and RFS process allows freedom from the process of wash, rinse and sterilization in component preparation and ensures seamless operations to pharmaceutical units.



Serum  
Closures

# SOLUTIONS in SVP



ALL PRODUCTS ALSO AVAILABLE AS  
**UNISURE-RFS**  
(READY FOR STERILIZATION) and  
**UNISTAR-RFU**  
(READY FOR USE)



Code No.: 107 20mm



Code No.: 164 13mm



Code No.: 158 13mm

Creativity and innovation are at the heart of UML's core values. Collaborative R&D efforts have led to new application development. Design of Serum Stoppers suitable for High Speed filling lines and Fluoro-Laminated Stopper (inert barrier coating) for sensitive drug applications again reflect our innovative expertise.

UML's serum closures are designed and manufactured with physical, chemical and biological attributes to ensure product safety, integrity and efficacy.

- Serum Stopper complying to ISO 8362-2 & ISO - 8871
- Latex, Zinc, 2MBT & Nitrosamine free Formulations
- Low Extractables and Leachables
- Silicone RTV Coating
- Customized Design and Formulation Option
- Stopper suitable for high speed filling lines - 600 vials/min.

Our Serum Closure Range offers widest variety and blends in RFS (Ready for Sterilization) and RFU (Ready for Use) formats.

Products Registered with Type III US DMF (Drug Master File), USA

Products complying to ISO Standards: ISO-8871, ISO-8536-2, ISO-8362-2 and ISO-8362-5 and ISO-15378.



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Lyophilization  
Closures

# SOLUTIONS in SVP



Code No.: 114 20mm



Code No.: 155 13mm



Code No.: 159 13mm



Code No.: 141 20mm

ALL PRODUCTS ALSO AVAILABLE AS  
**UNISURE-RFS**  
(READY FOR STERILIZATION) and  
**UNISTAR-RFU**  
(READY FOR USE)

UML offers quality solutions in closures for Lyophilized applications with universal elastomeric formulations that guarantee packaging integrity, safety, and efficacy. Our Lyophilized Stoppers ensure minimum dead volume and <0.1% Moisture Content. Available in a spectrum of designs, these stoppers exhibit properties of self sealing and good resistance to coring.

- Lyophilized Stoppers complying to ISO 8362-5 & ISO 8871
- Latex, Zinc, 2MBT & Nitrosamine free Formulations
- Clean Room complying to ISO 14644
- Customized Design and Formulation Options
- Minimum dead volume after reconstitution
- Residual moisture content <0.1%

Our Lyophilization Closure Range offers widest variety and blends in RFS (Ready for Sterilization) and RFU (Ready for Use) formats.

Products Registered with Type III US DMF (Drug Master File), USA

Products complying to ISO Standards: ISO-8871, ISO-8536-2, ISO-8362-2 and ISO-8362-5 and ISO-15378.



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Infusion  
Stoppers

# SOLUTIONS in LVP



Code No.: 176

32mm



Code No.: 211

30mm



Code No.: 182

32mm

ALL PRODUCTS ALSO AVAILABLE AS  
**UNISURE-RFS**  
(READY FOR STERILIZATION) and  
**UNISTAR-RFU**  
(READY FOR USE)

UML's R&D team have developed versatile elastomeric formulations for LVP's which can be used for globally marketed pharmaceutical products, which passes all major Pharmacopoeia like USP, EP and JP in many common configurations.

- Low Piercing Force
- Good Spike Retention and Zero Leakage
- Superior Sealing Properties
- Good Resistance to Coring
- Infusion Stoppers complying to ISO 8536-2
- Customized Design and Formulation Options
- RFS and RFU Formats available.
- Latex, Zinc, 2MBT & Nitrosamine free Formulations

Our Infusion Stoppers Range offers widest variety and blends in RFS (Ready for Sterilization) and RFU (Ready for Use) formats.

Products Registered with Type III US DMF (Drug Master File), USA

Products complying to ISO Standards: ISO-8871, ISO-8536-2, ISO-8362-2 and ISO-8362-5 and ISO-15378.



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# UNISAFE

ETFE Fluoro Coated Stoppers

## Preserving Drugs, Protecting Lives



UML UNISAFE range of products are offered in  
**RFS** (READY FOR STERILIZATION) &  
**RFU** (READY FOR USE)



Serum Stoppers

13 mm, 20 mm  
and 32 mm



Lyophilization  
Stoppers

13 mm and 20 mm  
Igloo- 20 mm and  
32 mm



Plungers for  
Cartridge/Prefilled  
Syringes

1 ml standard



**Universal Medicap Ltd.**

Solutions for Pharma Parenteral Packaging

We take care to preserve the sanctity and integrity of drugs.

While continuing our rich legacy, we are proud to introduce a new range of high-quality barrier-protected laminated component packaging products that will enhance the efficiency and efficacy of high-value drugs. The ETFE fluoropolymer barrier film is applied to the plug area and flange top surface. These are:

**Lyophilization and Serum Stoppers:** Our UNISAFE lyophilization and serum fluoro coated stoppers are protected with a barrier film. Our RFU and RFS processing help reduce absorption and adsorption of the drug safe product.

**Cartridge / Prefilled Syringe Plungers:** Our plungers with UNISAFE barrier film ensure minimal drug-product interactions.

Universal Medicap Limited (UML) also provides packaging component quality enhancement services, including films, coatings, washes, and sterilization processes, to minimize contamination and compatibility risks. Our eco-friendly packaging solutions ensure product protection, quality, patient comfort, and security while preserving dosage quality, preventing damage, and safeguarding pharmaceutical components.

### Why Choose UML UNISAFE Range of Stoppers and Plungers?

- Reduction of particulates—visible and subvisible
- Extended duration and enhanced shelf life of the packaged components
- Minimal interaction of extractables from the rubber
- Lower leachables in the drug formulation

Customized Packaging Solutions are also available.

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**UNISAFE**  
**ETFE** Fluoro Laminated  
Stoppers

# Plunger Stoppers for Pre-filled Syringes & Cartridges



Plungers for Pre-filled Syringes & Cartridges

Laminated



0.50ml



1ml



1ml



1ml Cartridge



2ml



2ml



3ml Cartridge



3ml Cartridge

Non Laminated



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