

LeCouple® KY Aseptic Sampling System

Fully Enclosed and Aseptic Sampling Workflow, Safeguarding Sample Safety

In biopharmaceutical manufacturing, aseptic sampling is a critical step for quality control, process monitoring and batch release, requiring three core attributes: representative sampling, enclosed aseptic operation and low contamination risk. The LeCouple® KY Aseptic Enclosed Sampling System is specifically designed for stainless steel bioreactors, fermenters and buffer/media preparation tanks. It delivers a fully enclosed, aseptic and leak-tight sampling path, effectively mitigating contamination risks from open sampling, and in turn ensuring sample integrity and process safety.

Needle sampling bags are available with 1 mm and 2 mm Sampling needles:

For routine buffers, media and clarified solutions and high-viscosity and high-density cell suspensions, respectively.

Applications

Ideal for aseptic sampling during production or storage of biologic products manufactured with stainless steel infrastructure:

- Stainless steel seed and production bioreactors
- Stainless steel preparation and storage tanks for buffers and culture media
- Storage and preparation tanks for process intermediates and semi-finished products

Advantages

Needle-puncture sealed design eliminates open exposure, significantly reducing microbial contamination risk

- **Pre-sterilized & ready-to-use:**
Gamma irradiation sterilized (25–40 kGy), supplied in sterile packaging
- **Representative sampling:**
Zero dead volume, no residual fluid, delivers true process samples
- **Low endotoxin:**
≤ 2.15 EU/unit, meets high-purity pharmaceutical requirements
- **Compatible with high-viscosity fluids:**
2 mm large-bore needle for high-density cell suspensions
- **Flexible customization:**
Manifold sampling, custom volumes and tailored connectors available



Features

- System components: Needled sampling bags, Sampling port bracket and Seal caps
- Multiple specifications: Sampling needle sizes: 1 mm, 2 mm; Standard bag volumes: 50 mL, 100 mL, 250 mL, 500 mL, 1000 mL; Sampling port bracket : TC50 (5-port), TC65 (9-port)
- Customizable options available
- Comprehensive validation documentation available
- Material safety: Product contact components comply with USP <87> and USP <88> Class VI plastics biocompatibility requirements
- Wide temperature tolerance: -80 °C to + 50 °C
- Long shelf life: 3 years for sampling bags; 5 years for Seal caps

Product Composition

The LeCouple® KY Aseptic Sampling System primarily includes: Needle sampling bag, Sampling port bracket, Assembly and Seal cap.



Needle Sampling Bag

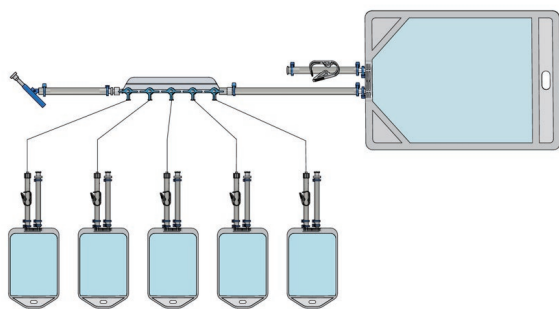


Sampling Port Bracket

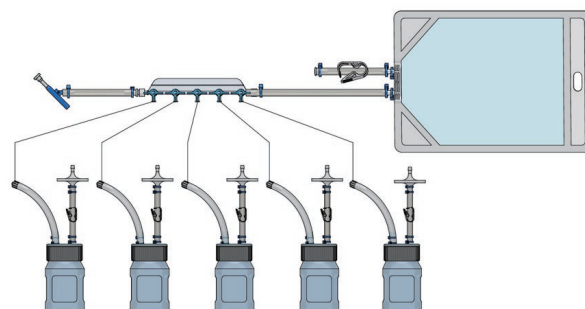


Seal Cap

To further meet diverse customer needs, LePure also offers manifold sampling bags and manifold sampling bottles, delivering highly flexible customized solutions for specific application scenarios.

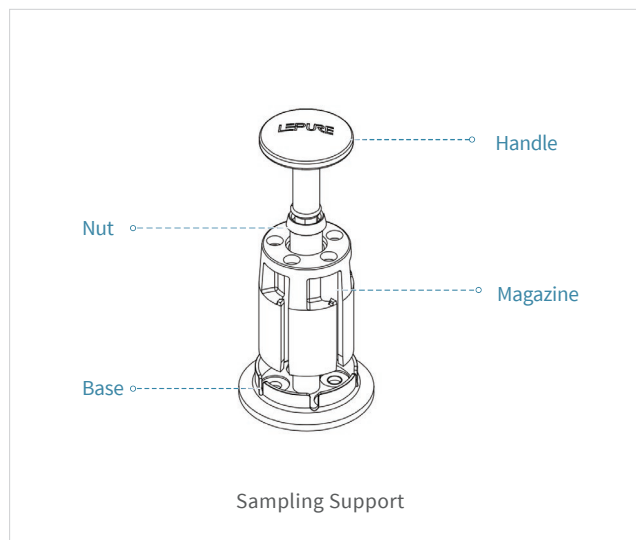
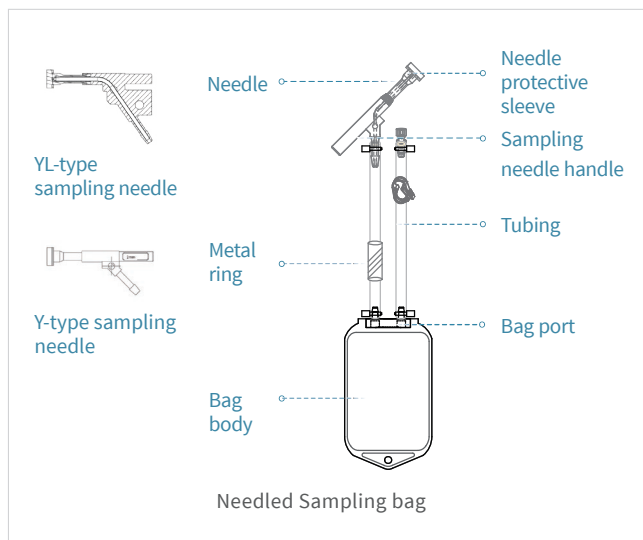


Multi-port Sampling Bags



Multi-port Sampling Bottles

Product Structure



Operating Guide



Assembly: Insert the sampling needle into the support magazine and lock it in place; Assemble the support with the handle and lock it



Docking: Seal and fasten the sampling support to the tank TC interface



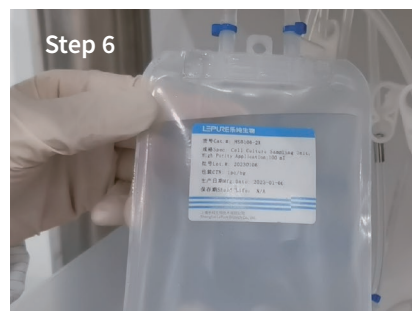
Sterilization: Perform CIP and SIP in accordance with standard operating procedures



Sampling: Rotate the handle and press down the puncture Seal cap to collect the sample; Reset the lock after completion



Disconnection: Cut the metal break ring to separate the sampling bag



Sampling completed

Product material

Product	Components	Material	Material Properties
LeCouple® KY needled sampling bag	Needle protective sleeve	Platinum vulcanized silicone rubber	Sterile seal, puncture-resistant
	Sampling needle handle	Polypropylene (PP)	Good chemical stability and resistance to acids and alkalis
	Needle	316 L stainless steel	Corrosion-resistant, resistant to high-pressure sterilization
	Bag body (LeKrius® membrane material)	Ultra-low density polyethylene (ULDPE)	Low Extractables, low-temperature resistance, excellent flexibility
	Bag opening	Polyethylene (PE)	Flexible, low-temperature resistant, easy to seal
	Tubing	Thermoplastic elastomer (TPE)	Good flexibility, bending resistance, low adhesion
	Metal ring	Nickel-plated brass	Easy to cut, no residue, corrosion-resistant
LeCouple® KY sampling support	Nut/base/handle	316 L stainless steel	Corrosion-resistant, high strength, heat-resistant to sterilization
	Magazine	Polymer materials	Lightweight, impact-resistant, and insulating
LeCouple® KY sealing cap	Sealing cap	Platinum vulcanized silicone rubber	Sterile seal, puncture-resistant, high and low temperature resistant
	Gasket (compatible with 2 mm sampling needle)	Stainless steel	Corrosion-resistant

Quality Specifications

All components that come into contact with the sample liquid meet regulatory requirements

Endotoxin	< 2.15 EU/ unit
Biocompatibility	Compliant with USP <87> and USP <88> Class VI plastic biocompatibility requirements

Regulatory Compliance

Test Items	Standards	Test Results
Extractables	USP <665>	Compliant
Visible foreign object	USP <790>	Compliant
Insoluble particles	USP <788>	Compliant
Endotoxin	USP <85>	Compliant

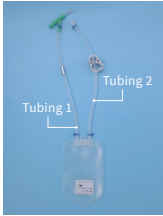
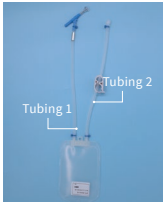
In addition, the integrity test, burst test, pull-off force test, seal test, bacterial challenge test, protein adsorption test, cryogenic storage test and other indicators are all in line with the company's internal control standards, verified by the company's strict content standards

Specification Parameters

LeCouple® KY Needle Sampling Bag	
Sterilization methods	Gamma irradiation: 25-40 kGy
Temperature range	50 mL-250 mL: (-80 °C) - (+50 °C) 1000 mL: (-20 °C) - (+50 °C)
Operating conditions	Maximum operating pressure: 0.5 bar
Validity period	3 years
LeCouple® KY Sampling Support	
Surface roughness	Contact surface with feed liquid: Ra ≤ 0.4 μm
Operating conditions	Maximum operating pressure: 6 bar Maximum operating temperature: 150 °C
LeCouple® KY Sealing Cap	
Operating conditions	Maximum operating pressure: 6 bar Maximum operating temperature: 180 °C
Expiry date	5 years

Order Information

LeCouple® KY Needle Sampling Bag

Product Image	Product Number	Sample Bag Volume (mL)	Inner Diameter of The Sampling Needle (mm)	Description
	HS0050-3K	50	1	Tubing 1: 2/15"x 6/25" Le-Flex® thermoplastic tube (26 cm) with metal break ring and 1 mm Y-type sampling needle at the end
	HS0100-3K	100	1	
	HS0250-3K	250	1	Tubing 2: 2/15"x 6/25" Le-Flex® thermoplastic tubing (26 cm), end with Lure female connector + male plug
	HS0500-3K	500	1	
	HS001-3K	1000	1	
	HS0050-2K	50	2	Tubing 1: 2/15"x 6/25" Le-Flex® thermoplastic tube (26 cm) with a metal break ring and a 2 mm Y-shaped sampling needle at the end
	HS0100-2K	100	2	
	HS0250-2K	250	2	Tubing 2: 2/15"x 6/25" Le-Flex® thermoplastic tubing (26 cm), end with Lure female connector + male plug
	HS0500-2K	500	2	
	HS001-2K	1000	2	

LeCouple® KY Sampling Support

Product Image	Item Number	Compatible Sampling Needle Inner Diameter (mm)	Number of Sampling Ports	TC Interface Size
	HST51-5	1	5	TC50
	HST52-5	2	5	TC50
	HST62-9	2	9	TC65

LeCouple® KY Sealing Cap

Product Image	Item Number	Compatible Sampling Needle Inner Diameter (mm)
	MNDY1-2	1
	MNDY2-2	2

Sealed caps are not delivered aseptically and should be sterilized before use. If you need to purchase or customize, please contact the dedicated sales of LePure Biotech for process compliant and customized solutions.

