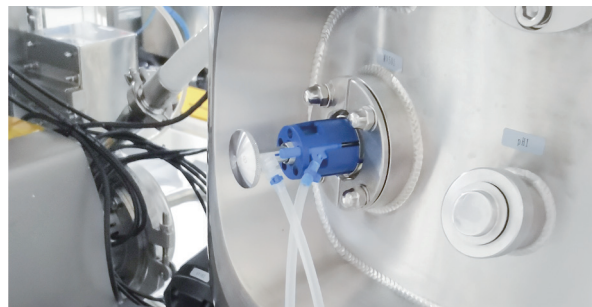


LeCouple® KY Sterile Sampling Systems

During the production of biological products, key parameters in sampling is needed to monitor and adjust the process to achieve desired quality of drug products. Sampling solutions must provide representative samples while minimizing contamination risks. From upstream cell culture, downstream purification to final product filling, LeCouple® KY aseptic sampling system provides a closed, sterile, uniform solution to ensure safe and reliable process monitoring.



Typical applications

Widely used in stainless steel production technology of biological products in the production or storage process of aseptic sampling

- ⦿ Bioreactor seed pot and production
- ⦿ Buffer/culture medium preparation and storage
- ⦿ The storage and preparation of the intermediate/bulk

Advantage

- ⦿ Closed, sterile sampling methods, reduce the risk of cross contamination
- ⦿ Allow online cleaning (CIP) and online sterilization (SIP)
- ⦿ Provide flexible customization services

Quality Standards

- ⦿ LePure factory has passes SGS ISO 9001:2015 and ISO 13485:2016 quality management system certification
- ⦿ Validation tests include:
 - Integrity test
 - Burst test
 - Pull force test
 - Sealing test
 - Bacterial endotoxin
 - Bacterial spore challenge test
 - Irradiation verification
 - Protein adsorption test
- ⦿ The materials of fluid path meet regulatory requirements:

Endotoxin	<2.15EU/unit
Biocompatibility	Biological Reactivity Tests in vivo of Class VI Plastics, USP<87>, USP<88>

Composition of aseptic sampling system

LeCouple® KY sterile sampling systems mainly include sampling kit, holder and sealing cap. The LeCouple® KY sampling kit can be customized according to customer requirements.



Sampling kit

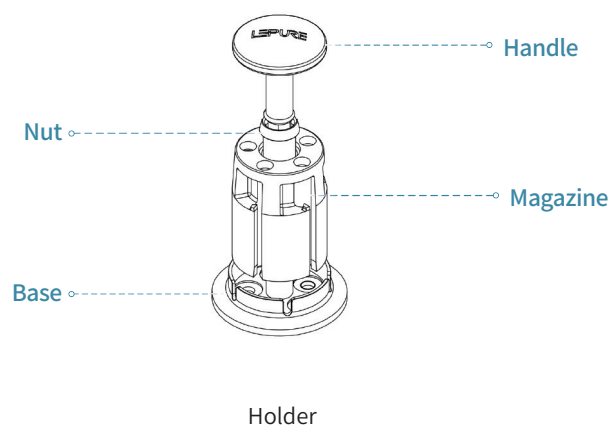
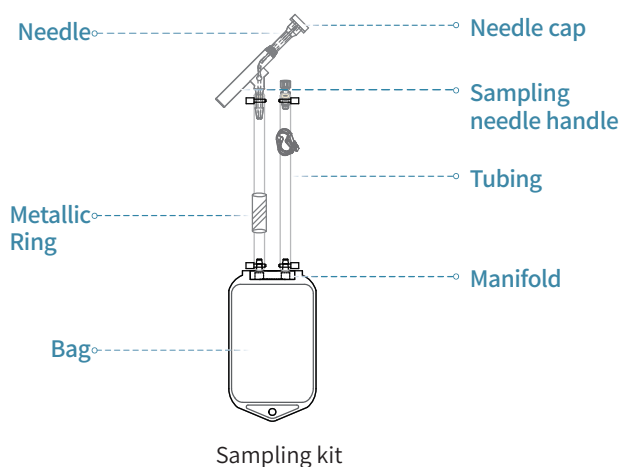


Sealing cap



Holder

Product design



Constituent materials

LeCouple® KY Sampling Kit

Component	Material
Needle cap	Platinum vulcanized silicone rubber
Needle handle	PP
Needle	316L stainless steel
Bag	LeKrius® film
Manifold	PE
Pipeline	TPE
Metal ring	Nickel-plated brass

LeCouple® KY Holder

Component	Material
Nut	316L stainless steel
Base	316L stainless steel
Handle	316L stainless steel
Slide rail	Polymer materials

Sealing cap

Component	Material
Cap	Platinum vulcanized silicone rubber
Washer (fits 2mm needle)	Stainless steel

Specification

LeCouple® KY Sampling Kit

Sterilization method	Gamma: 25-40 kGy
Temperature range	50mL—250mL: -80°C—50°C 1000mL: -20°C—50°C
Operating conditions	Max operation pressure: 0.5bar
Self-life	2 years

LeCouple® KY Holder

Surface Finish	Wetted parts electropolished Ra ≤0.5 μm
Operating conditions	Max operation pressure: 6bar Max temperature: 150°C

Sealing cap

Operating conditions	Max operation pressure: 6bar Max temperature : 180°C
Self-life	5 years

Technical specification

Regulatory compliance

Standard	Test	Result
Internal control standards	Integrity test	Pass
Internal control standards	Burst pressure test	Pass
Internal control standards	Pull force test	Pass
Internal control standards	Sealing test	Pass
Internal control standards	Bacterial challenge test	Pass
USP <665>	Extractable detection	Pass
Internal control standards	protein adsorption	Pass
Internal control standards	Freeze thaw test	Pass
USP790	Visible impurity inspection	Pass
USP<788>	Insoluble particle test	$\geq 10 \mu\text{m} : \leq 10 \text{ pcs/mL}$ $\geq 25 \mu\text{m} : \leq 1 \text{ pcs/mL}$
Internal control standards	Verification of irradiation	Pass

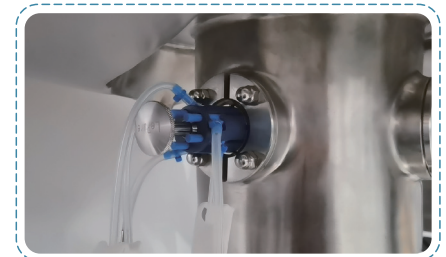
Operation guide



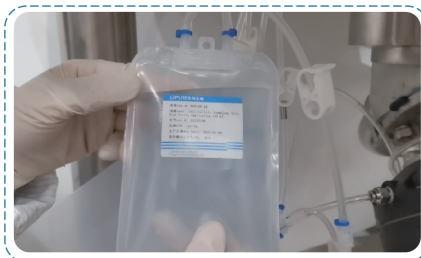
Disassemble the holder, insert the trigger into the holder and turn the trigger so that the collar locks into place. Repeat each trigger installation and make sure all 5 holes are locked. Then assemble the holder and lock it tightly.



To connect the installed holder to the interface of the tank body and tighten it to prevent leakage.



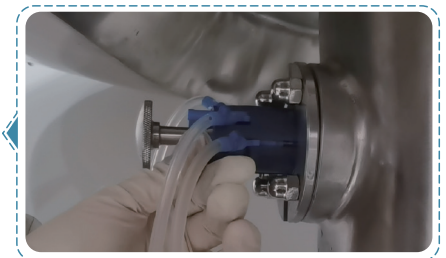
After installing, clean the vessel by Clean-in-place (CIP) and Steam-in-place (SIP) according the standard operating procedures (SOP).



Sampling completion.



Use disconnecting pliers to crimp the pinch pipe on the tubing and separate it from the liquid.



Rotate the sampling needle handle to the slide rail and depress the sampling needle handle to insert into the liquid being sampled. retract the needle from the liquid after completion.

Ordering information

LeCouple® KY Sampling Kit

Part No	Volume (mL)	Description
HS0050-2K	50	Tubing 1: 2/15 "-6/25" Le-Flex thermoplastic tube, 26cm, with metal disconnection ring, end 2mm Y-shaped sampling needle
HS0100-2K	100	
HS0250-2K	250	
HS001-2K	1000	Tubing 2: 2/15"-6/25" Le-Flex thermoplastic tube, 26cm, end female Luer connector + male plug
HS0050-3K	50	Tubing 1: 2/15 "-6/25" Le-Flex thermoplastic tube, 26cm, with metal disconnection ring, end 2mm Y-shaped sampling needle
HS0100-3K	100	
HS0250-3K	250	
HS001-3K	1000	Tubing 2: 2/15"-6/25" Le-Flex thermoplastic tube, 26cm, end female Luer connector + male plug

Sealing cap

Part No.	Fit the inner diameter of the needle (mm)
MNDY1-2	1
MNDY2-2	2

Note: Sealing caps are not sold in sterile form.

Holder

Part No	Fit the inner diamete (mm)	size
HST51/5	1	5 holes TC50.5 holder
HST52/5	2	5 holes TC50.5 holder