

Sterisart® NF for Sterility Test (Canister)

Sterility Testing Systems

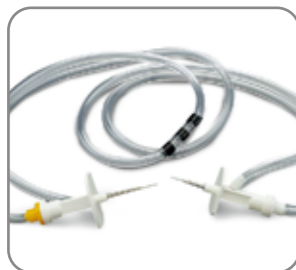


- 제약 제품을 무균 Test하기 위해 사용되는 Closed System
- Membrane Filter 방법을 이용해서 제약 Sample 안에 균의 유무를 확인
- Cross Contamination을 제거하기 위해, 1회용 사용으로 Sterisart Pump에 장착하여 Sample의 이동으로 결과 확인

Technical Specifications

Sterisart® NF

Pore size of the Sartochem® membrane filter	0.45 µm, tested with Serratia marcescens
Filter area	RC : 15.7 cm ² / CA : 14.5 cm ² in each Sterisart container
Flow rate (for water)	500 ml/min at 1 bar approx. 15 psi
Pore size of the air filters	0.2 µm PTFE, validated acc. to HIMA for the retention of B. diminuta
Sample container capacity	120 ml (graduation marks at 50, 75 and 100 ml)
Max. operating pressure	3 bar approx. 44 psi at 20 °C
Max. operating temperature	50 °C
Sterilization	ETO (ethylene oxid gas) or gamma irradiation



Ordering Information

Sterisart® NF alpha Disposable Units for Sterility Testing in Clean Rooms with a Regenerated Cellulose Membrane

Order No.	Description	Type of Sample	Type of Sample Container
16466-ACD	Sterisart® NF alpha with long dual-needle metal spike, sterile-vented	LVPs	Closed glass bottles with septum
16467-ACD	Sterisart® NF alpha with long needle and protective plate, inclusive sterile venting needle	LVPs SVPs	Open containers, i.e. glass ampoules, glass bottles collapsible bags
16467-TCO	Sterisart® NF alpha with long needle, inclusive sterile venting needle bottles, collapsible bags	LVPs SVPs	Open containers, i.e. glass ampoules, glass
16468-ACD	Sterisart® NF alpha with Luer or Luer Lock connector, inclusive long needle and sterile venting needle	Tubing systems and bags with Luer or Luer Lock connectors	Medical devices

Individually, Sterile Packaged, ETO-sterilized, Needles Made of Flame-sterilizable Stainless Steel, 10 Units

Sterisart® NF gamma Disposable Units for Sterility Testing in Isolators with a Regenerated Cellulose Membrane

Order No.	Description	Type of Sample	Type of Sample Container
16466-GBD	Sterisart® NF gamma with long dual-needle metal spike, sterile-vented	LVPs	Closed glass bottles with septum
16476-GBD	Sterisart® NF gamma with short dual-needle metal spike, sterile-vented	SVPs	Closed glass vials with septum
16477-GBD	Sterisart® NF gamma with long needle, (side opening, with solid pointed tip, non-coring), protective plate, inclusive sterile venting needle	LVPs, SVPs, eye drops	Closed plastic containers vials ampoules, plastic containers of Blow-Fill-Seal fillings
16467-GBD	Sterisart® NF gamma with long needle and protective plate, inclusive sterile venting needle	LVPs SVPs	Open containers, (i.e. glass ampoules, glass bottles), collapsible bags
16475-GBD	Sterisart® NF gamma with two dual-needle metal spikes of different length, one is sterile-vented	+Lyophilisates, soluble powders, liquid antibiotics	Closed glass vials with septum
16469-GBD	Sterisart® NF gamma with syringe-adapter and long dual-needle metal spike, sterile-vented	Pre-filled syringes	Syringes with and without needles
16468-GBD	Sterisart® NF gamma with Luer Luer Lock connection, inclusive long needle and sterile venting needle	Medical devices	Tubing systems and bags with Luer or Luer Lock connectors
16478-GBD	Sterisart® NF gamma with female Luer Lock connector	New Medical devices	Containers bags with Luer Lock male connectors

Sterisart® NF gamma Disposable Units for Sterility Testing in Isolators With a Cellulose Acetate Membrane

Order No.	Description	Type of Sample	Type of Sample Container
1646601-GBD	Sterisart® NF gamma with long dual-needle metal spike, sterile-vented	LVPs	Closed glass bottles with septum
1646701-GBD	Sterisart® NF gamma with long LVPs, needle and protective plate, inclusive sterile venting needle	SVPs	Open containers; e.g., glass ampoules, glass bottles, collapsible plastic bags

Individually Sterile, Double-packaged, Gamma Irradiated, Needles Made of Flame-sterilizable Stainless Steel, 10 Units