

DOMINIQUE DUTSCHER SAS

Sterisart® BD Media and Fluids

One-Stop Shopping for Sterility Testing

Simplifying Progress

SARTORIUS



DOMINIQUE BESSCHER SAS

Sterisart® Products Are Ideal for Use in Isolators

The pump is installed countersunk in the work area and the packaging of the consumables facilitates the transfer from a non-sterile into the sterile area of the isolator.

Description	Order No.
Sterisart® Universal pump, upgraded version	16420
Sterisart® NF gamma for closed containers, dual-needle metal spike, sterile vented, double-packaged, pack size 10	16466--------GBD
Sterisart® BD Medium, Type FTM (Fluid Thioglycollate Medium), acc. to EP/USP, 100 mL, pack size 44	BD-257097

Sterisart® – Increasing Safety And Reliability

Pharmaceuticals, biologicals, medical devices and any material claiming to be sterile must be tested for sterility according to the procedures described in the International Pharmacopoeia. Manufacturers of sterile products are required to supply proof of the sterility of the final product batch.

The preferred method for sterility testing is the membrane filtration method using the closed disposable system Sterisart® NF. Virtually all pharmaceutical containers and product types can be tested thanks to the wide variety of Sterisart® NF units featuring different adapter types, which Sartorius Stedim Biotech offers.



Sterisart® BD Media and Fluids

In order to complete the product range of the disposable, ready-to-use, closed sterility testing system, Sartorius now offers prepared bottled Nutrient Media and Rinsing Fluids according to International Pharmacopoeia. As manufacturer, we chose BD as one of the well respected and best known media for producing quality. Sterisart® BD Media and Fluids are available in a variety of formulations, bottles and closure types, as well as filling volumes. Only the highest quality BBL and Difco brand dehydrated culture media are used for preparation.

Certified Quality

As all Sterisart® products, Sterisart® BD Media and Fluids are also manufactured in Germany. Every aspect of the production process – from raw materials to media manufacture, from R & D to QA | QC, from start to finish – is under manufacturer's supervision and control.

The manufacturing process for Sterisart® BD Media and Fluids is fully validated. The manufacturing facilities are registered with FDA and are in compliance with DIN/EN/ISO 9001:2000, 13485:2003 and cGMP-21CFR820 standards and guidelines. The products comply with the IVD Directive 98/79/EC and EP/USP Pharmacopoeia.

DOMINIQUE DUTSCHER SAS

Sterisart® BD Media and Fluids Complete Our Product Line for Sterility Testing Providing One Source for All Your Needs

Sterisart® BD Media and Fluids are sterilized by autoclaving in their final primary bottles. They are used on clean benches or in clean rooms. Special packaging types are ideal for transferring media from non-sterile areas into sterile areas such as isolators.

Features and Benefits

- Transparent labels allow a clear view of media and cultures.
- Labels resist alcohol and chlorine treatment.
- Color-coded caps and labeling for the nutrient media allow easy product identification.
- Specially developed clear FTM for much easier growth detection.
- Growth performance test conforms to EP and USP requirements.
- Extensive Certificates of Analysis showing microbial recovery of all microorganisms listed in EP and USP.

Multi-Packaged, ETO-Sterile

The autoclaved filled bottles are packaged into a polypropylene box which is then sealed into a Stericlin® bag and sterilized by ethylene oxide (ETO). This treatment provides a sterile outer surface of the bottles and the packaging. The multiple-packaging allows the transfer of the bottles into clean rooms from a non-sterile into a sterile area.

- Sterile outer surface of the bottles eliminating the need for spraying down bottles before transferring them into clean rooms or isolators.
- Polypropylene boxes reduce shedding of particles to a minimum.
- Compact packaging saves working space.
- Optimal for small clean room areas such as isolators due to clever waste management



Individually Double-Packaged, Sterile

The filled bottles are packaged into two Stericlin® bags prior to autoclaving. This unique manufacturing process results in a bottle exterior that is free from microbial contaminants.

- Double-packaging ensures that the area under the cap remains sterile, therefore reducing the risk of false positive results.
- Sterisart® BD Media and Fluids are validated at a sterility assurance level (SAL) of 10-6.
- Sterisart® BD Media and Fluids comply with the requirements set forth in the International Pharmacopoeia such as EP and USP.
- Optimal for all clean room areas including isolators due to easy and reliable transfer into the sterile area



DOMINIQUE DUTSCHER



Nutrient Media Types

FTM – Fluid Thioglycollate Medium according to USP | EP
Liquid nutrient medium for the sterility testing of biologics and for the enrichment and cultivation of anaerobes, aerobes, and microaerophiles acc. to USP and EP.

In order to avoid secondary contamination, the Sterisart® BD Media Type FMT is not under vacuum, but the headspace of the FTM is gassed with a stream of nitrogen to maintain anaerobiosis.

Sterisart® BD Media Type FTM contains a special quality of agar, resulting in a high clarity of the prepared medium.

Color code: red

TSB – Tryptic Soy Broth according to USP | EP
A general purpose liquid nutrient medium used in sterility testing for the detection, isolation, and cultivation of fastidious and non fastidious microorganisms acc. to USP and EP.

Sterisart® BD Media Type TSB is a nutritious medium that will support the growth of a wide variety of microorganisms, including common aerobic and facultatively anaerobic bacteria and fungi.

Color code: blue

Rinsing and Diluting Fluids

Fluid A and Fluid D according to USP
Three different steps are required by the compendia depending on the condition of the sample:

- Rinsing: Sterile devices or materials are rinsed in order to release adhered microorganisms. After filtration of the sample, the Pharmacopoeia also require rinsing steps to be performed on the entire Sterisart® NF unit.
- Diluting: Small volumes or viscous liquids are diluted for better filterability
- Dissolving: Solid samples or ointments are dissolved for better filterability

Fluid A (peptone water)
Fluid A is used for diluting, dissolving and rinsing of all types of samples.

Fluid D (Fluid A with 0.1% polysorbate 80)
Fluid D is peptone water with 0.1% polysorbate 80 (TWEEN® 80). It is used for those samples types which contain lecithin or oil.

Another application is to rinse articles and devices with bacteriostatic or fungistatic activity. Polysorbate 80 may act as an inactivator of microbicides present in or on a testing sample.

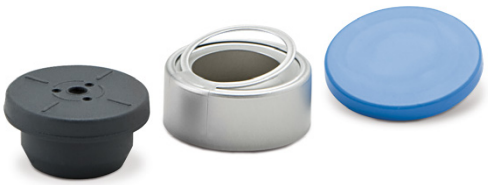
The use of Sterisart® BD Fluid A and Fluid D does not affect the viability of microorganisms. Both Sterisart® BD Fluid Types, Fluid A and Fluid D, are according to the specifications of the United States Pharmacopoeia (USP).

DOMINIQUE DUTSCHER SAS

Closure Types

Flip tear-off seal stopper
The cap is easy to remove by a pull-ring

Typ 1



Typ 2

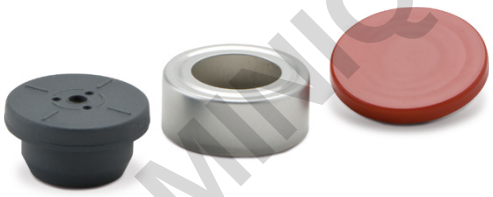


Typ 3



Crimp cap stopper
The stopper is fixed by a crimp cap

Typ 4



Screw cap with septum
The cap can be easily pierced or untwisted

Typ 5



Screw cap
The cap is easy to remove by untwisting

Typ 6



Twist-off
The lid is easy to remove by untwisting

Typ 7



DOMINIQUE DUTSCHER SAS

Ordering Information

Media and Fluids for the Membrane Filtration Method

Multi-Packaged, ETO-Sterile

Sterisart® BD Media and Fluids, sterile bottled, sterile multi-packaged in a PP box and in a Stericlin® bag (sterile outer surface of the bottles), optimal for sterility testing in isolators due to clever waste management

Medium Type	Filling Volume	Closure	Ø Cap	Acc. to	Pack Size	Order No.
FTM (Fluid Thioglycollate Medium)	100 mL in 125 mL infusion bottle	Type 2	32 mm	EP/USP	44	BD-257097
TSB (Tryptic Soy Broth)	100 mL in 125 mL infusion bottle	Type 1	32 mm	EP/USP	44	BD-257307
Fluid A (peptone water)	100 mL in 125 mL sirup bottle	Type 5	28 mm	USP	20	BD-257549

Individually Double-Packaged, Sterile

Sterisart® BD Media and Fluids, sterile bottled, sterile individually double-packaged in two Stericlin® bags (sterile outer surface of the bottles), optimal for sterility testing in clean rooms and isolators

Medium Type	Filling Volume	Closure	Ø Cap	Acc. to	Pack Size	Order No.
FTM (Fluid Thioglycollate Medium)	100 mL in 125 mL infusion bottle	Type 2	32 mm	EP/USP	10	BD-257217
TSB (Tryptic Soy Broth)	100 mL in 125 mL infusion bottle	Type 1	32 mm	EP/USP	10	BD-257213
Fluid A (peptone water)	300 mL in 500 mL infusion bottle	Type 4	32 mm	USP	10	BD-257263
Fluid A (peptone water)	650 mL in 1,000 mL infusion bottle	Type 2	32 mm	USP	4	BD-257222
Fluid D (peptone water with polysorbate 80)	650 mL in 1,000 mL infusion bottle	Type 2	32 mm	USP	4	BD-257223

Standard-Packaged, Sterile

Sterisart® BD Media for sterility testing, sterile bottled, packaged in a cardboard box

Medium Type	Filling Volume	Closure	Ø Cap	Acc. to	Pack Size	Order No.
FTM (Fluid Thioglycollate Medium)	100 mL in 125 mL infusion bottle	Type 2	32 mm	EP/USP	25	BD-257246
TSB (Tryptic Soy Broth)	100 mL in 125 mL infusion bottle	Type 1	32 mm	EP/USP	25	BD-257247
Fluid A Difco™ (peptone water)	100 mL in 100 mL serum bottle	Type 1	20 mm	USP	10	BD-290821
Fluid A (peptone water)	300 mL in 500 mL infusion bottle	Type 2	32 mm	USP	10	BD-254979
Fluid A (peptone water)	650 mL in 1,000 mL infusion bottle	Type 3	32 mm	USP	4	BD-257096
Fluid D Difco™ (peptone water with polysorbate 80)	100 mL in 100 mL serum bottle	Type 2	20 mm	USP	10	BD-290831
Fluid D (peptone water with polysorbate 80)	300 mL in 500 mL infusion bottle	Type 2	32 mm	USP	10	BD-257241

DOMINIQUE DUTSCHER SAS

More information about Sterisart® NF units is available foc in the brochure Sterisart-NF-Brochure-en-L-Sartorius

Media for Direct Inoculation

Multi-Packaged, ETO-Sterile

Sterisart® BD Media, sterile bottled, sterile multi-packaged in a PP box and in a Stericlin® bag (sterile outer surface of the bottles), optimal for sterility testing in isolators due to clever waste management

Medium Type	Filling Volume	Closure	Ø Opening Bottle	Acc. to	Pack Size	Order No.
FTM (Fluid Thioglycollate Medium)	100 mL in 125 mL sirup bottle	Type 5	20 mm	EP/USP	20	BD-257544
TSB (Tryptic Soy Broth)	100 mL in 125 mL sirup bottle	Type 5	20 mm	EP/USP	20	BD-257543

Individually Double-Packaged, Sterile

Sterisart® BD Media, sterile bottled, sterile individually double-packaged in two Stericlin® bags (sterile outer surface of the bottles), optimal for sterility testing in clean rooms and isolators

Medium Type	Filling Volume	Closure	Ø Opening Bottle	Acc. to	Pack Size	Order No.
FTM (Fluid Thioglycollate Medium)	100 mL in 245 mL wide mouth bottle	Type 7	45 mm	EP/USP	10	BD-257293
TSB (Tryptic Soy Broth)	100 mL in 245 mL wide mouth bottle	Type 7	45 mm	EP/USP	10	BD-257293

Standard-Packaged, Sterile

Sterisart® BD Media for sterility testing, sterile bottled, packaged in a cardboard box

Medium Type	Filling Volume	Closure	Ø Opening Bottle	Acc. to	Pack Size	Order No.
FTM (Fluid Thioglycollate Medium)	100 ml in 125 ml sirup bottle	Type 6	20 mm	EP/USP	25	BD-257249
TSB (Tryptic Soy Broth)	0 ml in 125 ml sirup bottle	Type 6	20 mm	EP/USP	25	BD-257228

DOMINIQUE DUTSCHER SAS

Germany
Sartorius Lab Instruments GmbH & Co. KG
Otto-Brenner-Strasse 20
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Corporation
565 Johnson Avenue
Bohemia, NY 11716
Phone +1 631 254 4249
Toll-free +1 800 635 2906

For further information, visit
www.sartorius.com

Specifications subject to change without notice.
Copyright Sartorius Lab Instruments GmbH & Co. KG.
Status: 07 | 2022