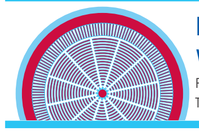
Always the best Solution.

Steritest™ system by Merck Millipore.

Choose your Steritest EZ device ...

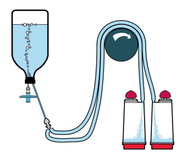
Filtration membranes are thermo-sealed onto the base in all Steritest EZ units, ensuring full integrity of the device, efficient membrane rinsing and eliminating the risk of by-pass.



For antibiotics and products with antimicrobial agents[1]

Red canister base indicates low absorption Durapore® membrane and specific drain design.
This optimizes the rinsing of products that inhibit microbial growth.

Liquids

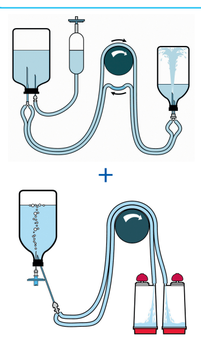


Steritest EZ Device
TZHV AB2 10

- Single needle adapter and connections designed to reduce the risk of antimicrobial residuals
- Separate vent needle

Recommended Accessories
- Sterile vent needles for safe transfer of liquid media TEFG02525

Powders and Superpotent Antibiotics

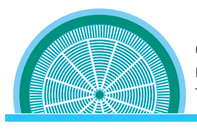


Steridilutor® Device with Expansion Chamber
TZVC 000 10
+ Steritest EZ Device TZHV AB2 10

- Tubing and needle assembly for antibiotics and products containing antimicrobial activity that require dilution or dissolution
- Aseptically connects the diluent or dissolution fluid to the product container for dilution
- Used for pooling superpotent antibiotics to reduce product-membrane contact time when product is then filtered
- Contains vent with expansion chamber for optimized venting
- Diluted product subsequently filtered with Steritest EZ device (TZHV AB2 10).

Recommended Accessories
- Sterile vent needles for safe transfer of liquid media TEFG02525
- Steridilutor vial accessory TA00 000 03

[1]Additional devices are available for products with antimicrobial agents. Please contact your local Merck Millipore representative for more information.

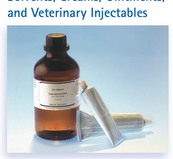


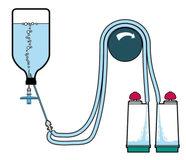
Increased chemical compatiblity

Green canister base indicates low absorption Durapore membrane, specific drain design and polyamide canister polymer.

This optimizes the chemical compatibility of products dissolved in solvents.

Solvents, Creams, Ointments, and Veterinary Injectables





Steritest EZ Device
TZHV SL2 10

- Canister designed for testing products dissolved in solvents such as isopropyl myristate
- Canister connections and reinforced base structure provide better resistance to pressure
- Single needle adapter for products in vials or ampoules
- Separate vent needle

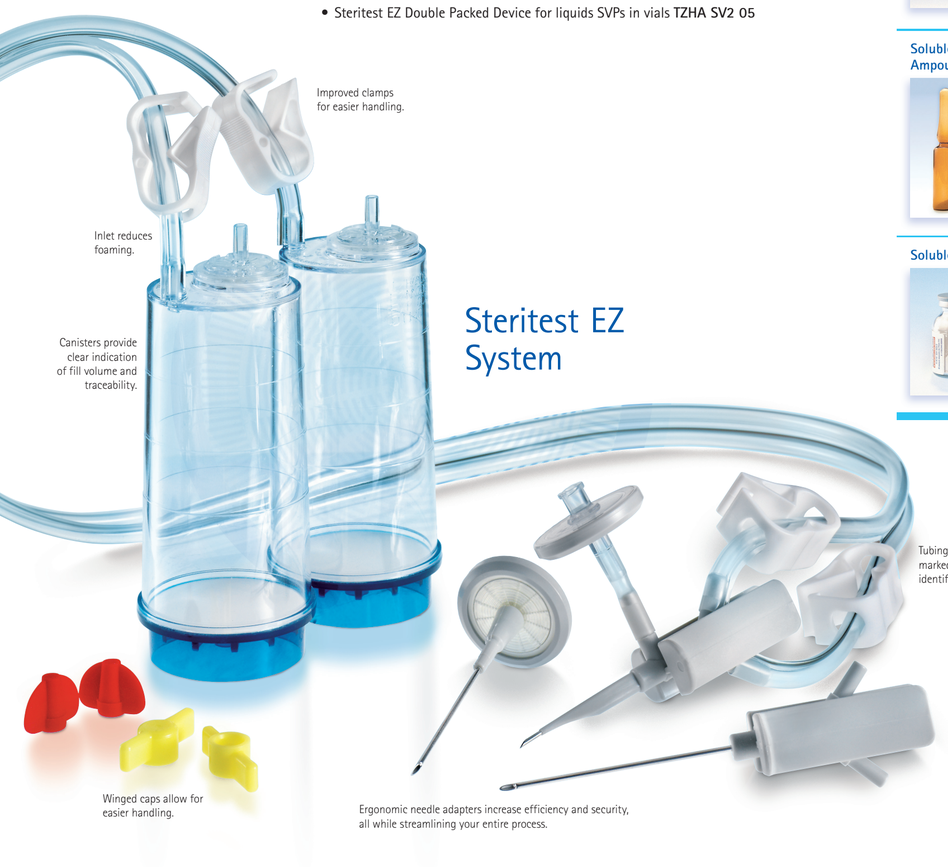
For emulsions or viscous products, different canister types can be used, depending on product properties. Please contact your local Merck Millipore representative for more information and to define which units perfectly fits for your application.

[2]Steritest EZ Double-Packed Devices

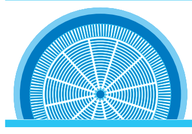
- Gamma sterilized and double packed for quick transfer into sterility testing environments, simplifying decontamination procedures and saving time.
- Sealed bag provides optimum decontamination of the outer bag and easy bag opening.
- Outer packaging materials ensure complete integrity of the bags during transportation, minimizing risk of piercing or damage.
- One box contains two bags, with five devices each.

The following Steritest EZ Devices are available in double packs:

- Steritest EZ Double Packed Device for liquids in ampoules or collapsible bags **TZHA LA2 05**
- Steritest EZ Double Packed Device for liquids in LVPs in glass botttles **TZHAL V2 05**
- Steritest EZ Double Packed Device for liquids SVPs in vials **TZHA SV2 05**



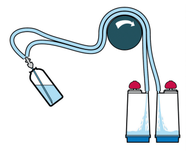
Steritest EZ System



For products without antimicrobial agents

Blue canister base indicates mixed esters of cellulose membrane.
This membrane provides an optimal filtration flow rate for standard products.

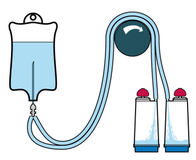
Liquids in Ampoules



Steritest EZ Device
TZHA LA2 10
TZHA LA2 05 (double packed)[2]

- Single needle adapter for easy access to ampoules
- Separate vent needle

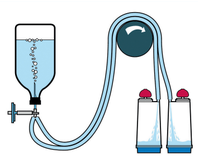
Liquids in Collapsible Bags



Steritest EZ Device
TZHA LA2 10
TZHA LA2 05 (double packed)[2]

- Single needle adapter for easy access to collapsible bags
- Separate vent needle

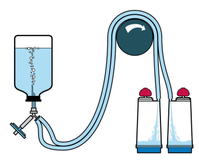
LVP in Glass Bottles



Steritest EZ Device
TZHA LV2 10
TZHA LV2 05 (double packed)[2]

- Vented needle adapter vents and transfers test product from large volume containers with septa to Steritest EZ devices

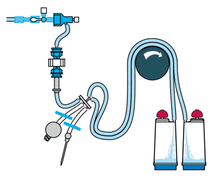
SVP in Vials



Steritest EZ Device
TZHA SV2 10
TZHA SV2 05 (double packed)[2]

- Small diameter double needle adapter for small vials with septa

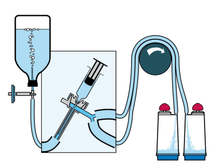
Medical Devices and collapsible bags with Luer connection



Steritest EZ Device
TZHA MD2 10

- Three adapters provided; male Luer, female Luer or single needle allow connection to a variety of test devices
- Separate vent for transfer of culture media or rinse buffer
- Use with NovaSeptum® sterile sampling devices. For additional information, visit www.merckmillipore.com/sterility-testing

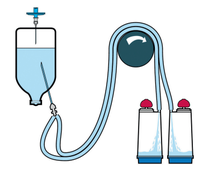
Pre-filled Syringes



Steritest EZ Device
TZHA SY2 10

- Adapter allows for sequential testing of syringe contents and needle surfaces

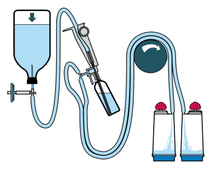
Liquids in Plastic Containers



Steritest EZ Device
TZHA PC2 10

- Non-coring needle adapter with aperture on side of needle minimizes blockage when piercing plastic containers
- Separate vent needle included for transfer of test product, culture media or rinsing buffer

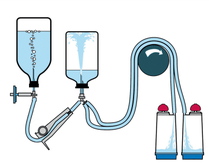
Soluble Powders in Ampoules



Sterisolutest EZ Device
TZHA DA2 10

- Simultaneously dilutes and transfers test products to canister set
- Single needle for transfer into and out of ampoules

Soluble Powders in Vials



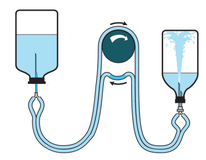
Sterisolutest EZ Device
TZHA DV2 10

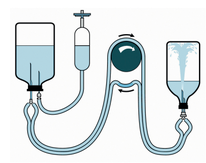
- Simultaneously dissolves/dilutes the sample in sterile diluent and filters the resulting solution
- Small diameter double needle adapter for small vials with septa

Complete your package ...

Accessories

Steridilutor Device For Vials



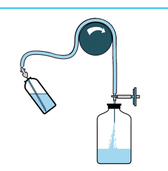


Steridilutor Device without Expansion Chamber
TZV0 000 10

Steridilutor Device with Expansion Chamber
TZVC 000 10

- Tubing and needle assembly to dissolve powders, for dilution and pool products in vials
- To be used for difficult to dissolve powders, dilution and pooling of viscous products in vials as well as antibiotics (to reduce the contact time with the filtration membrane)
- The expansion chamber vents residual vacuum or pressure from the vials without after-drip or contamination risk.
- Small diameter double needle connects test product to diluent
- Diluted product subsequently filtered with suitable Steritest EZ canisters

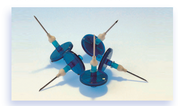
Liquid Transfer



Liquid Transfer Kit
TZA0 000 10

- Tubing and needle assembly for transfer of liquids from ampoules or vials to a diluent vial with septum
- Diluted products subsequently tested with suitable Steritest EZ canister

Sterile Vent Needles



Steritest EZ Vent with Needle
Single needle vented with PTFE 0.22 µm membrane

- For venting glass vials with septa and rigid plastic vials
- For venting of media bottles during the direct inoculation method
- For sterility and growth promotion qualification of media batches

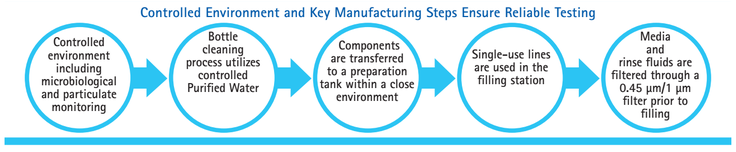
Sterility Test Media and Rinsing fluids

Sterility Test Media, Diluting/Rinsing Fluids

- Manufactured in ISO® 9001 manufacturing centers
- Formulated and tested to meet the requirements of the US, Japanese and European Pharmacopeias
- New rimless screw cap to optimize bottle sanitization steps and eliminate the risks of inhibition from decontamination agent residuals.
- New large septum to facilitate piercing step
- Clear FTM, an alternative formulation for customers who prefer a medium with extra visual clarity
- Validated to meet the performance and quality specifications set forth in the USP, EP, and JP for pH, sterility, percent oxidation, and growth promotion

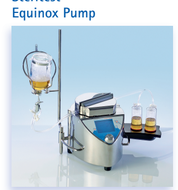
Description	Formulation	Volume	Catalogue No.
Soybean Casein Digest Broth	USP/EP/JP	100 mL	STBM TSB 12
Soybean Casein Digest Broth Double packed			STBMTSB12DP
Fluid Thioglycollate	USP/EP/JP	100 mL	STBM FTM 12
Fluid Thioglycollate double packed			STBMFTM12DP
Clear Fluid Thioglycollate	USP/EP/JP validated	100 mL	STBM CTM 12
Clear Fluid Thioglycollate Double packed			STBMCTM12DP
USP Rinse Fluid A		100 mL	STBM RFA 12
		300 mL	STBM RFA 34
		600 mL	STBMRFA64
		900 mL	STBMRFA94
USP Rinse Fluid D		300 mL	STBM RFD 34
USP Rinse Fluid K		300 mL	STBM RFK 34

Controlled Environment and Key Manufacturing Steps Ensure Reliable Testing



Pumps

Steritest Equinox Pump



Steritest Equinox Pumps

- Software-controlled peristaltic pump with "stop control" ensures uniform transfer of volume sampling.
- Automated mode with on-board standard operating procedures (SOPs). Procedure information is displayed and pump speed and filtration times are pre-set, for repeatability and reliability.
- Automatic pump head makes it easy to load and unload tubings.
- Built-in timer to control the time required for the transfer of product. This improves the accuracy of the volume filtered and is critical for product in opened containers where there is a risk of introducing non-sterile air into the canisters.
- For security and repeatability, a pressure control system constantly monitors the pressure inside Steritest EZ canisters.

Steritest Equinox Pump for Laminar Flow Hoods TQNX LFH 01

- Fits in both horizontal and vertical ClassA/Class100 laminar flow hoods.
- Profile prevents undesirable air turbulences in the area where handling is performed, eliminating the risk of false positives.

Steritest Equinox Pump for Isolators TQNX ISL 01

- Fits in both glove and half suit isolators.
- Profile ensures perfect decontamination inside isolators, eliminating any risk of false positives.
- Unique design makes it easy to connect and disconnect from an isolator work table during maintenance.

Steritest Equinox Isofit Pump for Isolators TQNX ISL 03

- Height of the Steritest Equinox Isofit pump reduced by 10 cm (4 in) compared to the Steritest Equinox pump to improve the ergonomic fit in isolators.
- Designed with smooth edges and constructed of 316L stainless steel for optimal decontamination.
- Standard operating procedures (SOPs) can be developed on a computer and easily loaded onto the Steritest Equinox Isofit pump.

Accessories
Footswitch TQOOFTS01 / Ampoule breaker TNTAC0001 / Drain tray TQOODTR01

Services & Support[3]

Reliable sterility test results with methods development and optimization services.

Test Method Development

- Product filtration protocol following pharmacopeia recommendations
- Recovery assessment performed with the relevant microorganisms
- Complete report generation

Compliant test methods with ready to use validation protocols, on-site IQ/OQ execution and PQ consultancy services.

Steritest Equinox Pump for Laminar Flow Hoods and/or Isolators Validation Protocol European A4 format TQNX A4V P1

- With over 35 years of experience in sterility testing, Merck Millipore offers a successful strategy for validating microbial test methodologies.
- Our protocols include installation (IQ), operational (OQ), and performance qualification (PQ) protocols, which are in compliance with pharmaceutical standards and international pharmacopoeias.
- Ready-to-use protocols, which include complete activity descriptions and result worksheets are ideal for busy QC/QA departments, as it reduces workload and enables workers to focus on other projects.

On-site Validation Services

- Agreements Technical training
- IQ, OQ: Execution of the test methods
- PQ Consultancy: On-site support for implementation of tests

Certified conformity & extended warranty for sterility test hardware renewed yearly with preventative maintenance agreements

Service for Preventive Maintenance of Equinox Pumps

Maintenance of your sterility testing equipment is critical to ensure the repeatability of filtrate volume and its equal splitting. To provide reliable testing required by cGMP® guidelines, the Equinox pump needs to be serviced on a regular basis. Merck Millipore currently offers maintenance agreements for Europe.

Steritest school[3]

Interactive course to provide an in-depth review of the regulatory requirements of sterility testing, its validation and practical implementation. This course will help you to better understand the current requirements of pharmacopoeias and be familiar with good sterility testing procedures from method development / validation through to routine test result interpretation.

An opportunity to:

- Take preventive actions to avoid false positive or false negative test results.
- Develop and optimize sterility testing procedures.
- Understand and identify root causes for common handling issues

[3]For availability of Steritest School and services in your geography, please contact your local Merck Millipore representative.

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