



THE STERISHIELD DELIVERY SYSTEM

The closed and validated trigger spray system that ensures the integrity of the contents throughout use

The **Ideal Solution** for Cleaning and Disinfection of Critical Areas

FEATURES



An effective cleaning and disinfection programme in controlled areas is critical to maintain product quality and safety in the pharmaceutical manufacturing industry.





Typical delivery solutions such as trigger spray systems and aerosols can compromise various areas of your business, including:

-  **Employee Health and Safety**
-  **Cost of Use / Profitability**
-  **Product Quality**
-  **Regulatory Compliance**

"Disinfectants should be shown to be effective for the duration of their in use shelf-life."

STERISHIELD DELIVERY SYSTEM (SDS)

Specifically designed to address cleaning and disinfection challenges, the SteriShield Delivery System's unique combination of the patented trigger system and integral bag provides a closed system and ensures contamination cannot enter the bottle during use. Unique features of this revolutionary design include:

-  **▲ Closed System**
No air suck back ensures sterility
-  **▲ Validated System**
Sterile in-use shelf life
-  **▲ Variable Spray Pattern**
Ensures optimum surface coverage
-  **▲ Reduced Airborne Particulates**
Safer compared to aerosols



TRIGGER SYSTEMS



- 
- 
- 
- 

Do not form a closed system and are unable to prevent air from being drawn back into the bottle, posing a risk of contaminating the contents of the bottle during use. This is applicable to both bag-in-bottle and standard trigger spray systems. This puts your product quality and compliance at risk due to potential loss of sterility of the contents and increases in-use cost.

AEROSOLS

Can pose a safety risk due to the generation of higher levels of small airborne particulates and may result in an increase in overall cost given their higher disposal costs. Aerosols also lack an adjustable spray pattern that may limit the coverage of surface areas.

- 
- 
- 
- 



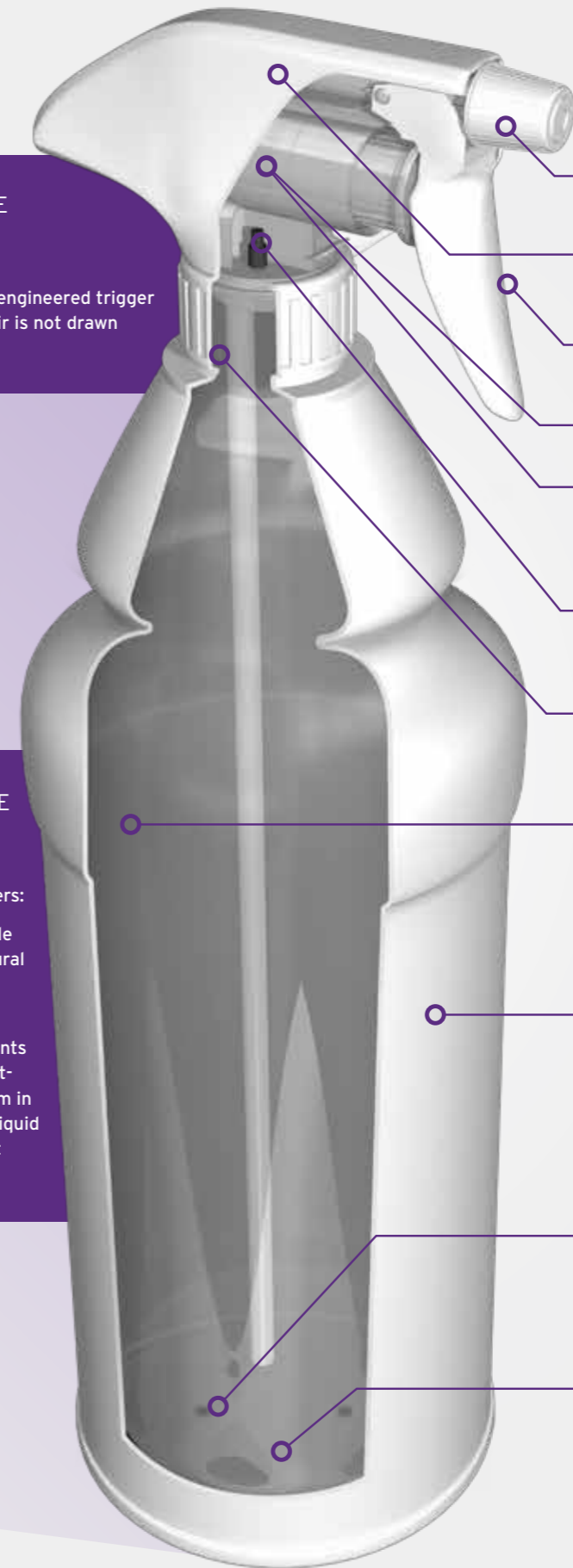
WHAT MAKES THE TRIGGER SO EFFECTIVE?

A patented precision engineered trigger head to ensure that air is not drawn back into the bottle

WHAT MAKES THE BOTTLE SO EFFECTIVE?

A bottle with dual layers:

- ▲ A rigid outer bottle** to provide structural stability
- ▲ An integral bag** protects its contents and creates a post-dispensing vacuum in which remaining liquid is stored and kept sterile



A variable rotating nozzle to deliver the desired spray pattern

A shroud that is smooth, simple and easy to disinfect

An ergonomically designed trigger to provide ease of use and consistency for every operator

Optimum dosing volume

Precision engineered pump system, lubricated with medical grade silicone, to eliminate air ingress around the plungers

A unique venting system, fitted with a 'duck billed valve', to ensure ONLY one way venting during irradiation

An inner bag that is sealed to the outer bottle all around the top of the bottle neck

An inner flexible bag that is co-extruded with the bottle when manufactured

A plastic outer bottle which provides structural rigidity

Two holes drilled into the base of the outer bottle to allow air to move freely into the space between the flexible bag and the outer bottle, enabling the inner bag to collapse around the fluid

An inner bag is sealed to the outer bottle at the centre of the base to allow it to collapse around the dip tube

Why use the Ecolab **SteriShield Delivery System Trigger Spray**?

The SteriShield Delivery System trigger spray delivers the benefits of sterility by preserving the integrity of the product, minimising risk to operators, fulfilling regulatory requirements and providing a cost-effective solution.



HEALTH & SAFETY

- ▲ The variable nozzle allows for a larger spray droplet size to reduce atmospheric concentration of products such as alcohol
- ▲ No pressurised content



COST OF USE

- ▲ Uses the entire volume of product
- ▲ Product can be used for the entire in-use shelf life



PRODUCT QUALITY

- ▲ Closed system eliminating contamination risk
- ▲ Adjustable spray pattern ensuring optimum surface coverage
- ▲ Easy to clean shroud and bottle



REGULATORY COMPLIANCE

- ▲ Validated in-use content sterility and shelf life
- ▲ Validated trigger spray



With the SteriShield Delivery System (SDS), every feature is designed to prevent air return, assuring users of sterile fluid dispensing, every time.

STERILITY ASSURED

The patented and unique trigger head works by forming a complete seal with the bottle, preventing any air from being drawn back inside. This not only eliminates the risk of microbial contamination in critical fill / finish areas but also chemical contaminants, for example where powders or aerosols are present, assuring users of uncompromised, sterile fluid dispensing every time.

EFFICACY ASSURED

The variable nozzle allows the liquid to be dispensed as required and the correct application can be obtained for each procedure enabling thorough wetting of the surface so that all disinfection procedures are effective.

TESTED AND VALIDATED

The SDS has been subjected to a stringent and comprehensive validation testing programme. The system has undergone in-depth validation, including microbiology media broth tests to detect any potential ingress of viable contamination from the external environment.

Additionally, Ecolab has undertaken vacuum and particulate testing to prove without doubt that the trigger and bottle combination creates and maintains a closed system, protecting the sterility of the contents in-use.

OPERATOR SAFETY

The SDS offers improved safety compared to aerosol sprays. The larger droplet size dispensed from the trigger spray reduces the level of atmospheric alcohol created at the time of use, consequently reducing the risk of excessive vapour inhalation by operators, while also reducing false positives in air sampling.

OPTIMUM SURFACE COVERAGE

The fully adjustable trigger spray nozzle allows the liquid to be dispensed in any configuration, from a jet to a wide spray, allowing the user to select the most appropriate method of application.

REDUCED COST OF USE

By providing a closed system, the SDS offers reduced cost by eliminating expensive, pressurised containers with their associated waste disposal requirements and wastage of unused product which cannot be dispensed.

The system also removes the risk of contamination associated with other trigger systems.

From purchase to disposal, the SDS can offer a significant advantage by reducing the total cost of use.

EASY TO USE

The development of our user friendly trigger provides:

- ▲ The same quality product from start to finish
- ▲ An adjustable nozzle
- ▲ Variable spray pattern for specific requirements
- ▲ An easy to clean shroud
- ▲ Negligible wastage
- ▲ Ergonomic design ensuring comfortable use for a range of hand sizes



Always look for the SDS stamp on our packaging - the patented and validated trigger spray system

Validation Studies for the SteriShield Delivery System



Note: The successful validation test results for the SDS are not applicable to any other trigger spray system.

How do you prove the SteriShield System is a closed system?

As part of our development of the SteriShield Delivery System, the system was subjected to rigorous testing to ensure its performance as a closed system.

A combination of vacuum tests, nutrient broth tests and particle tests have been conducted with results summarised below. A full set of data is available for each of these tests.

The results provide the assurance of a fully validated dispensing system which is fitted to our spray products - ensuring long in-use shelf life and peace of mind.

"The combination of Ecolab's unique trigger head and bottle are what makes the SDS a truly closed system."

VACUUM TEST

Identical transparent bottles are tested to ensure a vacuum was maintained by our trigger. Coloured fluid contents are used and 25% of the liquid expelled. These are left to stand for 24 hours and observed for change in fluid level.



Standard Trigger Spray

No vacuum - fluid level drops - system is not closed

25%
Liquid expelled

No vacuum - fluid level drops - system is not closed



SteriShield Delivery System Trigger Spray

Vacuum maintained after 24 hours and thereafter

Vacuum - fluid level maintained - system is closed



The SDS is an "air-tight" closed system

NUTRIENT BROTH TEST

Bottles are filled with microorganism growth promotion media (both FTM and TSB), periodically used (sprayed) over a six month period and the contents regularly tested for continued sterility. In total 90 bottles were tested to ensure robust data.

All test samples showed no growth, indicating sterility



The SDS provides a fully protective environment



A trigger spray without the SDS showed growth with 1/10th of volume usage.

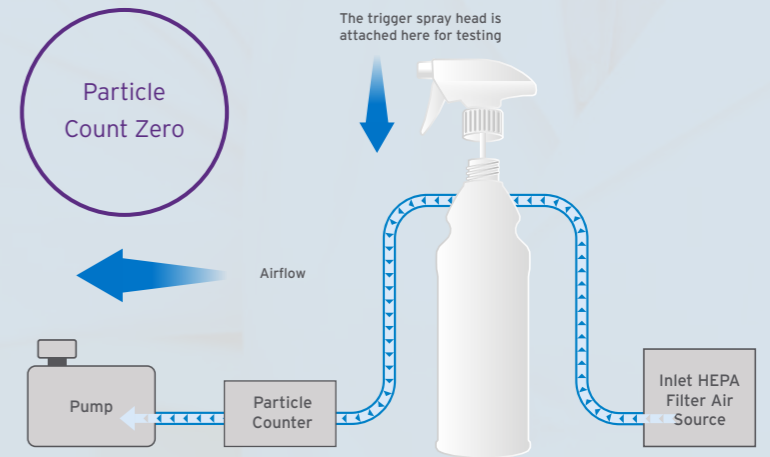
PARTICLE TEST

An empty SDS bottle with a trigger spray is connected to a particle counter and the trigger is 'pumped' multiple times to simulate use.

The system measures 5 and 0.5 micron particles.

Various leading competitor products were subjected to the same particle test and all failed (as shown in the table bottom right).

- ▲ The system was self validating (as 0 was required before each test)
- ▲ The test is a demonstration of real time in-use situations
- ▲ The results highlight the risk of not using the SDS



TRIGGER	> 0.5 microns particles			> 5 microns particles		
	Test 1	Test 2	Test 3	Test 1	Test 2	Test 3
SDS Trigger Spray	0	0	0	0	0	0
Competitor 1	421	15	103	4.2	1.1	0
Competitor 2	249	64	123	0	2.1	2.1
Competitor 3	28	26	74*	4	4	15*
	62	353	56	0	21	8
	189	25	251	21	1	29

*In these two tests it was noted that the trigger and bottle combination were unable to clean up after use. This indicated that the use of the trigger had compromised it permanently. (There was no evidence of any damage to the trigger.)



The SDS maintains an internal sterile environment



ECOLAB KLERCIDE PROGRAMME

Our programme consists of a wide array of products and services that meet your key needs for cleanroom cleaning and disinfection to ensure patient safety, product quality, regulatory compliance, employee health and safety and operational efficiency.

PLEASE SPEAK TO YOUR ECOLAB ACCOUNT MANAGER FOR FURTHER INFORMATION

WORLDWIDE HEADQUARTERS

1 Ecolab Place
St. Paul, MN 55102
USA

www.ecolab.com/lifesciences

EUROPE HEADQUARTERS

Richtistr. 7
8304 Wallisellen
Switzerland

www.ecolablifesciences.com

