

STERIS FINN-AQUA®
Pure Steam Generator for
Pharmaceutical Manufacturing



STERIS Corporation has achieved worldwide leadership in the pharmaceutical and biotech industries by understanding customers' requirements and providing the highest quality, most productive systems in the industry.

In 1971, FINN-AQUA water stills were introduced to provide the world's first pharmaceutical grade multiple-effect distillation system. With nearly 3,000 installations worldwide, the original patented Falling Film evaporator has proven reliability. The FINN-AQUA Pure Steam Generator (PSG) was introduced in 1979 in response to market demands for pyrogen-free steam.

What is Pure Steam?

Just because purified water is fed into a steam generator doesn't necessarily mean that the "clean steam" produced is free of endotoxins and other impurities that can threaten your operations. Endotoxins cannot be separated by all technologies that are used in clean steam generators. Pure Steam facilitates the delivery of the highest level of sterility in the manufacture of parenteral or injectable drugs.

Pure Steam Technology.
When clean steam is not enough,
think STERIS.



The term 'Pure Steam' was coined by FINN-AQUA to define this new level of purity as when condensed, it exceeds the requirements of the latest U.S. Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) for Water-for-Injection (WFI) guidelines. The FINN-AQUA PSG's design, manufacturing and performance is in accordance with many global requirements and guidelines, including:

- > ISO 9001:2008
- > ISO 14001:2004
- > OHSAS 18001:2007
- > EN-ISO 3834-2
- > HTM 2010
- > EN 285
- > GAMP 5
- > 21 CFR Part 11
- > EU Annex 11
- > cGMP
- > ASME BPE
- > FDA



Pure Steam Ensures Reliable Sterilization

As the pharmaceutical industry continues to grow and change, STERIS continues to deliver superior-quality products that are manufactured in accordance with current Good Manufacturing Practices (cGMP).

By choosing the FINN-AQUA Pure Steam Generator, you are taking a proactive step in eliminating instances of contamination, thus safeguarding your company and the end-consumer from products that could be potentially harmful.

How does STERIS Deliver the Purest Steam?

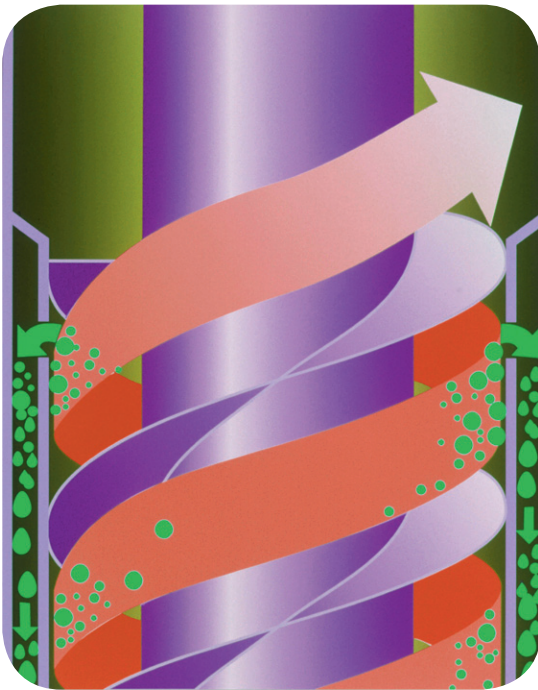
- > Patented three-stage separation
- > Tight pressure control to optimize sterilization performance
- > Fast response time to pure steam demand
- > Patented gas separation method
- > Continuous circulation of non-evaporated feed water
- > Proportional capacity control



Separator Column

Sterilization processes in the pharmaceutical industry require high-quality pure steam with accurate pressure control and fast response times. Additionally, the removal of non-condensable gases is an important challenge for Pure Steam Generators because gas in the feed water causes high conductivity. Dissolved gas in incoming feed water is removed by a patented gas separation method ensuring the highest quality pure steam and fulfilling HTM2010 (EN285) standards during all process conditions and pure steam demands.

The core of the FINN-AQUA Pure Steam Generator is its column – a compact design falling-film evaporator and a separator that removes impurities at high centrifugal velocities at the spiral. The impurities are removed as blowdown is directed away from the pure steam outlet.



FINN-AQUA's patented three-stage separation technology ensures high quality steam free of endotoxins, pyrogens and droplets. Three-stage separation provides:

- > Separation by falling film evaporation
- > Gravity separation by 180-degree flow turn
- > Centrifugal separation





FAT Center, Tuusula, Finland

Testing Saves Time and Money

The unique Factory Acceptance Testing (FAT) center at our factory in Tuusula, Finland, brings together the latest technologies and our experienced team. Our test protocols are structured to give all FINN-AQUA Pure Steam Generators a full evaluation before shipment, ensuring that the design, manufacture and operation are 100 percent as specified.

Test bays fully simulate the customers' specific plant conditions and all test results are precisely documented for smoother and faster on-site verification, thus saving you time and money. Our unique test bay is also equipped with a piping system for in-line CIP and passivation of the whole unit. Endotoxin challenge tests, to prove the high quality of pure steam, are validated LAL tests and ensure the highest purity of steam is generated.

Within our FAT center we can simulate all final installation conditions such as:

- > Plant steam pressure
- > Feed water pressure and temperature (softened water and RO/CDI water available)
- > Cooling water pressure and temperature
- > Pure Steam output demand conditions
- > All global voltage and current combinations

Comprehensive Documentation, Technical Expertise and Global Support

STERIS global field project management together with our factory-based project manager organization is committed to supporting you through the whole project. From design specification submittal to drawing package review to project hand-over, we will oversee your needs from start to finish. STERIS also provides comprehensive documentation in order to assist in validation. Our design, manufacturing testing and documentation processes are all validated and ISO-9001 certified and audited by Lloyd's. Documentation structure, content and format are detailed and cross references are logical and clear. Within our documentation, you will discover that data is easy to locate, thus speeding your validation time. From the time you purchase your FINN AQUA pure steam generator, STERIS's global service is available in close proximity to provide maintenance when you need it.



STERIS Provides Operational Optimization and Positively Impacts Our Environment

FINN-AQUA Pure Steam Generators are designed with our environment in mind. Lower utility consumption means less operating costs for you and saves energy for our environment. FINN-AQUA Pure Steam Generators use:

- > **Less Plant Steam** – The effective falling film evaporation and patented water distribution to the column enables a high performance from the column, optimizing plant steam consumption.
- > **Less Feed Water** – The patented spiral design, which effectively removes endotoxins impurities and droplets, operates proportionally. Less pure steam flow means less blowdown and less feed water rate.
- > **Less Blowdown** – Blowdown rate (typically 5-8% of pure steam produced) is reduced by proportional capacity control operation.
- > **Less Cooling Water** – If reduced blowdown temperature is needed, a heat exchanger is used that consumes much less cooling water than is used in a traditional mixing chamber construction.



With lower utility consumption & optional soft water feed, FINN-AQUA Pure Steam Generators are friendly to the environment and your operating budget!

STERIS Fits Your Needs

At STERIS, we make every effort to accommodate your varying process needs. We offer the FINN-AQUA PSG in a range of sizes and options. Our wide unit portfolio has a solution for every application – ranging from small sizes for the bioprocess industry (available with capacities starting at less than 50 kg/h) up to large units for pharmaceutical sterilization applications with capacities up to nearly 7,000 kg/h.

T-Series	150	250	450	850	1200	1600	2200	2900	4700
Capacity Maximum at 8 bar (116 psig) kg/h / (lb/h)	150/ (3300)	230/ (500)	440/ (970)	800/ (1.760)	1.100/ (2.420)	1.600/ (3.520)	2.050/ (4.510)	2.600/ (5.730)	4.750/ (10.470)

STERIS Offers Options

We offer a variety of standard options to help you maximize operational flexibility and customize the equipment for specific application needs:

- > An additional condensing unit enables simultaneous WFI and Pure Steam production. This capability is ideal for the bioprocess industry where small amounts of WFI are required in addition to Pure Steam.
- > Our Pure Steam Generator can also be fed with softened feed water which helps reduce your total cost of ownership.



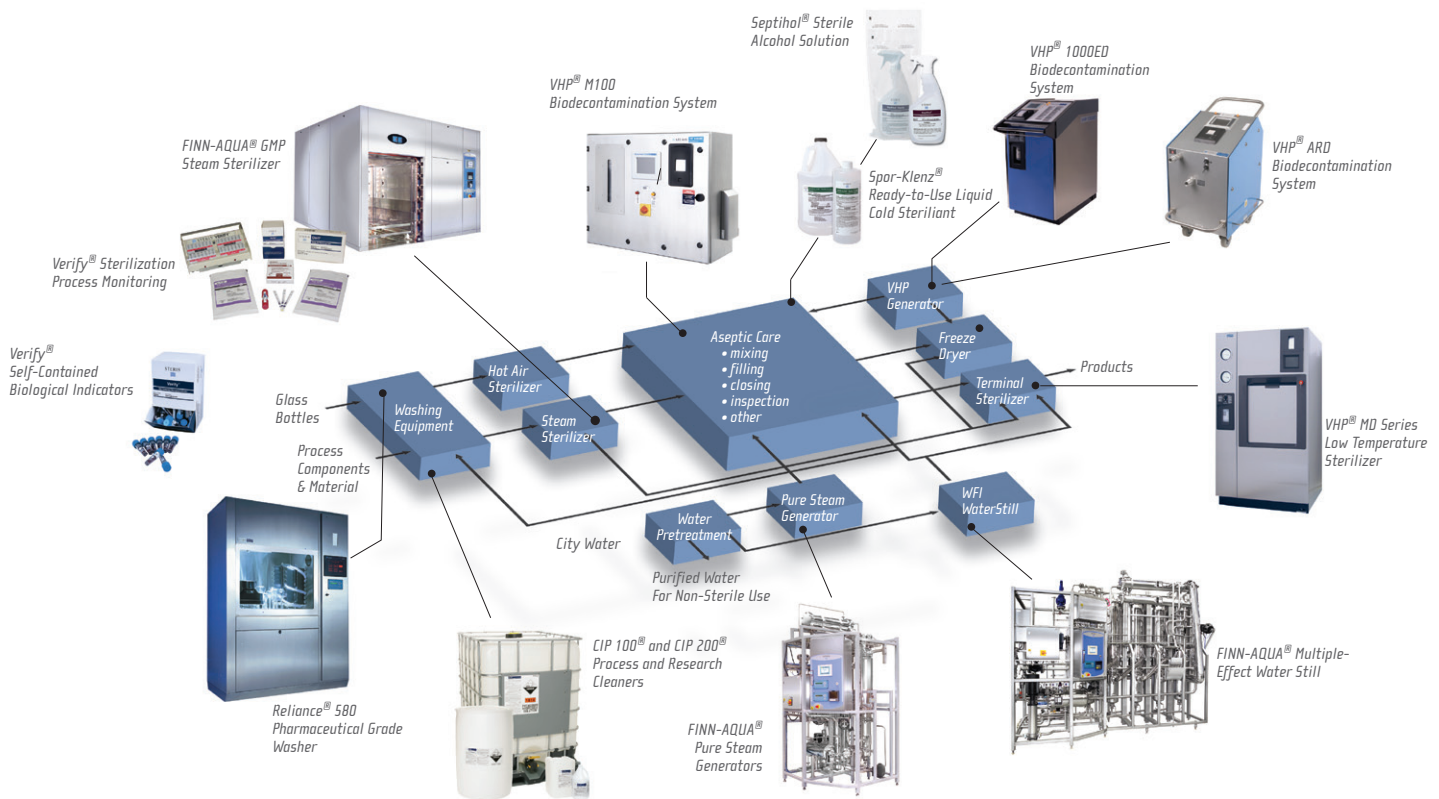
Our Pure Steam Generator includes a user-friendly touchscreen and is available to order with either the latest Siemens or Allen-Bradley control system platform.

The STERIS Difference

STERIS's Life Sciences division provides solutions to help prevent contamination at virtually **every critical point in your manufacturing process**. Our systems are specially designed to answer the contamination challenges associated with regulated pharmaceutical environments, including research laboratories, aseptic processing, and bulk biopharmaceutical manufacturing.

Our expert resources offer integrated solutions to help you achieve faster process validation, more efficient operations, and greater cost control. We also provide onsite training, educational seminars, and technical support to keep your employees current with regulatory compliance issues, product safety and new technologies and protocols. Our support is available when and where you need it through our worldwide manufacturing presence and broad distribution channels.

STERIS Corporation is a leading provider of infection prevention, contamination prevention, microbial reduction, and surgical support systems, products, services, and technologies to healthcare, life sciences, research, food, and industrial customers throughout the world.



Mixed Sources

Product group from well-managed forests, controlled sources and recycled wood or fiber



Printed with Soy based inks and water based coatings on FSC/Green Seal-certified paper.

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