

# High Purity Systems and Products

for the biopharmaceutical industry



**spirax**  
**/sarco**

# Your Perfect Partner for high purity systems

The design of high purity steam systems can be a complex and highly involved discipline. To ensure that your system is designed to current good manufacturing practice (cGMP), you need a partner who understands your process and can support you through the life of your project.

With over 100 years experience in system design, a global network of dedicated technical specialists and one of the broadest range of equipment in the industry, Spirax Sarco is the natural partner to help design and provide solutions and components for your high purity system.

- Support and advice on high purity system design
- Clean steam generation
- Sanitary pressure control and instrumentation
- Pure and clean steam trapping
- Sanitary ancillary products – including ball valves, steam separators, sight glasses and sample coolers
- Steam quality testing and system validation



## Dedicated Service Support

Having invested in your high purity system by bringing it up to its best operating efficiency, it makes economic sense to maintain it at that level, making life simpler and safer for you and your team. This is where outsourcing the maintenance and service work offers the most cost effective solution.

Spirax Sarco engineers can help you to put together a tailored service agreement that balances your maintenance and service requirements with your budget. This may help to avoid costly delays, and reduce risk. You also have the reassurance that all Spirax products come with a warranty and are supported by a global network of highly trained and experienced service engineers.

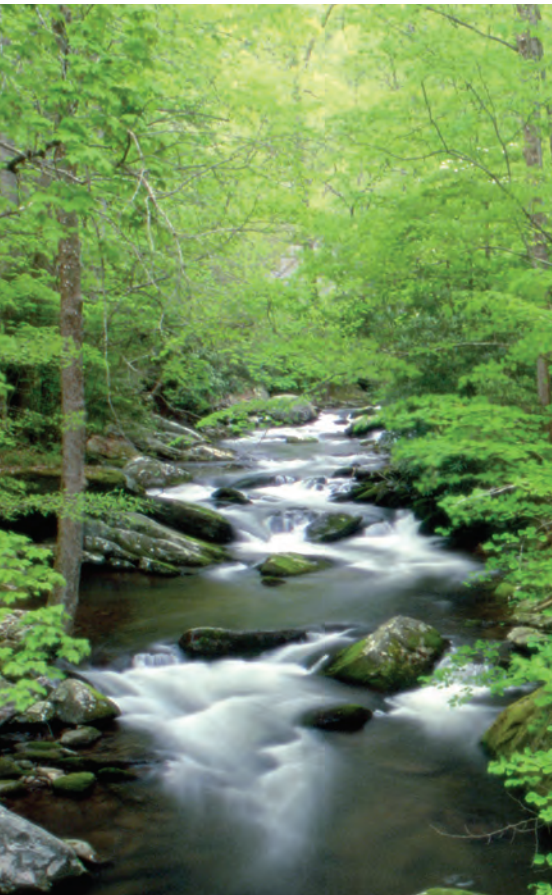


## Validation and compliance

To meet the growing needs of the FDA and other governing bodies, each high purity product we manufacture has been designed in accordance to the relevant industry standard and is available with the required certification.

As you would expect from a world-class manufacturing company, we maintain an ISO 9001 certified quality system. Spirax Sarco is an active participant with key standards such as ASME BPE, ISPE, 3A's, EHEDG, EN 285 and HTM 2031. Other performance validation initiatives include:

- Material test certification
- FDA / USP class VI approved material certification
- Surface finish certification
- Welding procedures and qualifications



## Impact on the environment

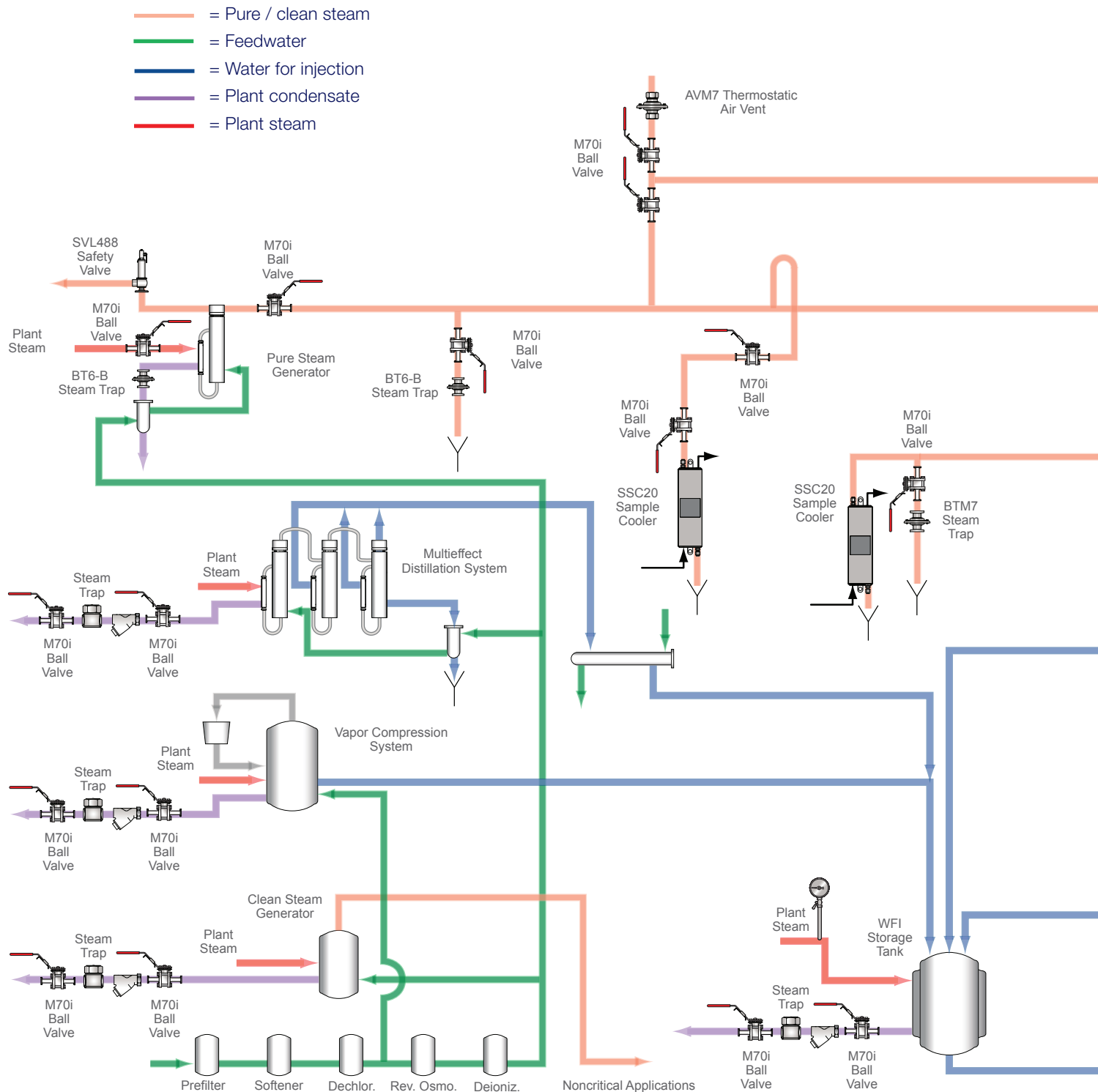
Our aim is to provide a solution that helps you achieve operational improvement through enhanced production capability, usually in the form of reduced energy usage, improved product quality, lower emissions and greater production throughout. Reducing emissions, carbon footprint, and your company's impact on the environment is Spirax Sarco's goal. Not only will this have a strong social and environmental impact but also a positive economic impact today and well into the future.

Although your processes and steam systems may be highly efficient, our experience demonstrates that there is always room for improvement. Spirax Sarco surveys hundreds of systems annually in the USA and has identified the actions required to modernize plants, using the latest best practices, technologies and products. The results for plants like yours are reductions in millions of dollars in energy losses and hundreds of thousands of tons of carbon dioxide emissions pumped into the atmosphere. With Spirax Sarco services, the savings to both your bottom line and the environment are just waiting to be realized.

# High Purity Distribution Systems

Spirax Sarco's range of high purity products are designed and manufactured to suit the demanding process and manufacturing requirements of the high purity industry. All components are designed to ASME-BPE and incorporate cGMP requirements. Product contact parts are universally 316L stainless steel with certified surface finishes applicable to process needs. All elastomers conform to FDA requirements. Each product range is available in connection options ranging from plain butt-weld ends suitable for orbital welding to sanitary Tri-Clamp ferrule connections.

All items are available with supporting documentation for material traceability, elastomer FDA compliance and USP Class VI conformance for relevant chapters, surface finish and certificate of conformance. For in-depth details of products please consult Spirax Sarco's product manual.



# Fabrication and Packages

Spirax Sarco manufactures custom hygienic engineered system packages for the food, dairy, beverage, pharmaceutical, and personal care industries. We meet the demanding needs of today's high purity installers and end users. Complete with all the capabilities of a high purity fabrication facility, we are able to quickly provide a wide variety of complex custom fabrications that meet the strict requirements of today's high purity industry.

## *Pharmaceutical Steam*

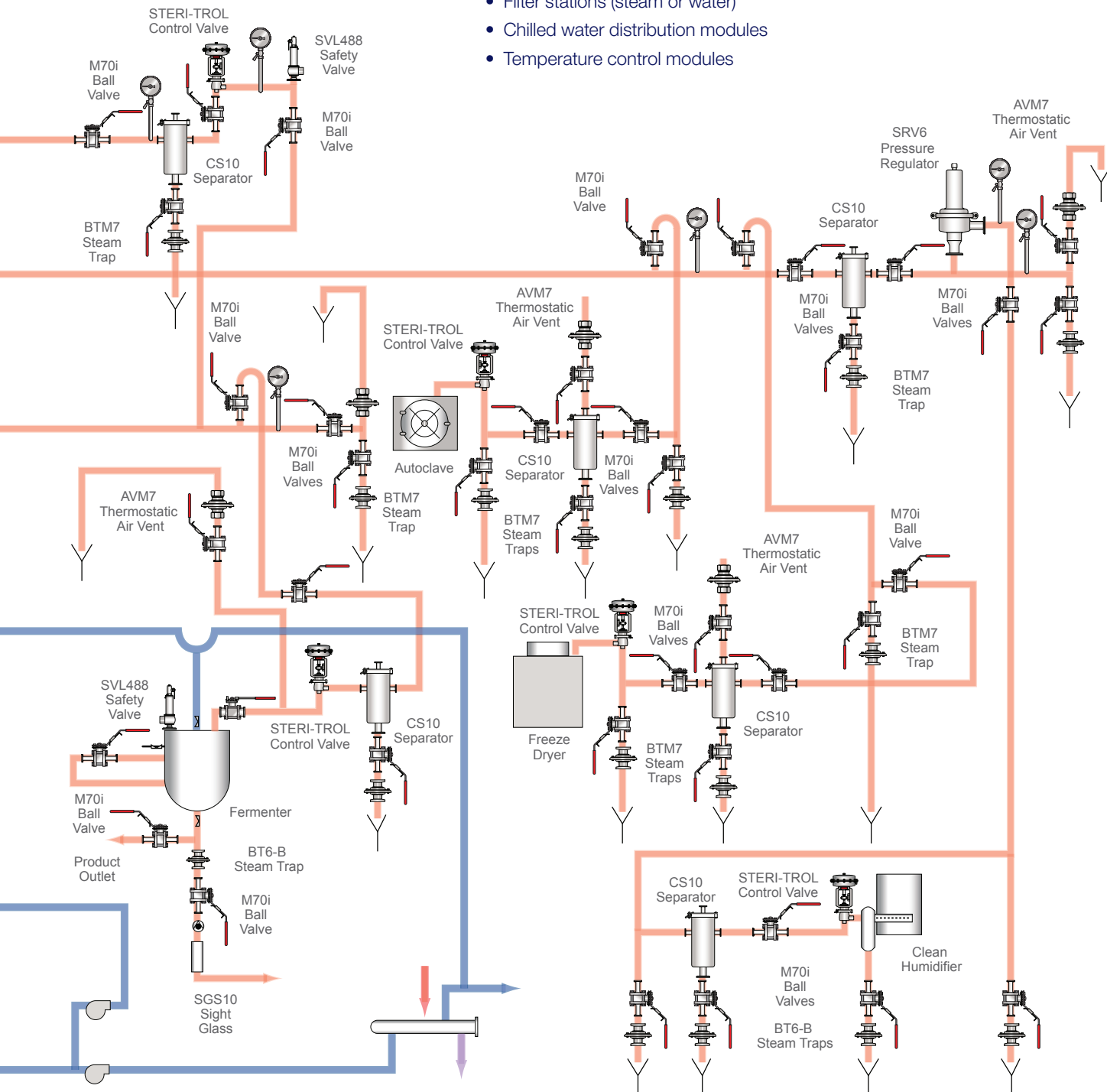
- Sample coolers & assemblies
- HTM 2010 sampling fittings
- Headers and valve manifolds
- Drip trap assemblies
- SIP/CIP trap assemblies
- Pressure reducing stations

## *Central & Critical Utilities*

- Hot water system skids – process & utility
- Steam headers
- Steam pressure reducing stations
- Condensate pump modules & trap assemblies
- Filter stations (steam or water)
- Chilled water distribution modules
- Temperature control modules

## *High Purity Water Distribution Systems*

- Storage & distribution system skids
- Sizes from 1" – 4"
- Available water usage from 10 to 300 gpm
- Many different system configurations available
- Fully automated



# Sanitary Control and Instrumentation

Accurate control is essential for the successful operation of your process. Spirax Sarco offers a wide range of electrically and pneumatically actuated control valves as well as direct acting pressure regulators.

## Clean Service Safety Relief Valves

The 48X Series of spring-loaded safety relief valves was developed in close cooperation with plant engineers and service specialists to protect sensitive processes and installations against overpressure without putting hygienic requirements at risk.

These valves are designed and manufactured to highest standards and fulfill ASME (Sec. VIII, Div.1), FDA and BPE (Bioprocessing Equipment - 2002) requirements, as well as the European standard EN 1672-2 and those of many other countries.

### Features and Benefits

The 48X Series safety valves are available in a wide variety of types, materials and options.

#### *Scope of design*

- Valve sizes are 0.394 in. to 3.622 in.
- Nine orifice sizes from 0.5 x D through P
- Materials: 1.4404 / 316L, 1.4435 / 316L stainless steel as a standard
- Standard soft seat for tight shut-off
- Packed knob, packed lifting lever, gastight cap or pneumatic lifting device

#### *Pryogen-counteractive design*

- Minimum dead space and flushmounting capability
- Wetted-part surfaces in compliance with European Hygienic Pipes Standard DIN 11866 and ASME BPE 2002, part SD table SF-5 and SF-6
- Gap and crevice-free design of internals

- Standard elastomer bellows for protection of the hard-to-clean parts
- Self-draining body avoids residues and reduces corrosion
- Standards-compliant elastomers

#### *Productivity enhancements*

- Optional pneumatic lifting device for cleaning in place (CIP) or sterilizing in place (SIP)
- Optional proximity switch to indicate the operating condition of the valve
- Self-draining body design and aseptic O-ring disc with bellows (HyTight Assembly) ensure effective outlet cleanability



#### *Application versatility*

- Variety of capacities and versions
- Multiple sanitary connection options
- Single trim for steam, gas and liquid for fewer spare parts and easier maintenance



## SRV6 Pressure Regulators

The SRV6 regulator controls supply to bioreactors, centrifuges, freeze dryers (lyophilizers), sterilizers, humidifiers and culinary equipment. Its diaphragm design prevents excessive movement and lengthens

### Key Features

- All wetted parts 316/316L stainless steel mechanically polished to 20 µm. Ra and electropolished.
- All external parts electropolished
- Self-draining angle pattern design
- Tri-Clamp compatible connections

# Steri -Trol Clean Service Control Values

STERI-TROL pneumatically operated control valves offer the very best in valve performance and design. Available in two-port and three-port configurations, these units are designed for mixing/diverting fluids (three-port only), and for on/off and modulating control of clean steam, pure steam and process fluids.

## Key Features

- Crevice free and self draining
- High performance stem sealing
- All industry standard connections
- Standard and customer-defined center face dimensions
- Quick release body and bonnet
- Long life actuator design
- Industry standard control interface devices, including stainless steel positioner
- Modulating and on/off control



## Range and Options

STERI-TROL Model	Body pattern	Sizes	Flow type	Construction	Maximum Operating Pressure	Maximum Operating Temperature	Options
SA	Angle pattern	½" to 4" (DN15 to DN100)	Equal %, Linear or Fast opening	316L Stainless Steel 16 µin Ra	232 psig @ 248°F	338°F @ 206 psig	Reduced flow and micro-flow Class VI soft seal Surface finishes
SH	Horizontal pattern						
SQ	Three way	¾" to 4" (DN20 to DN100)	Linear				

s, autoclaves, process tanks, production suites, maintenance cycles.

- Valve travel stops prevent diaphragm overextension
- Diaphragm includes integral valve stem seal with restraint
- PTFE-faced viton diaphragm

## Range and Options

Sizes	Construction	Maximum Operating Pressure	Maximum Operating Temperature	Maximum Cv	Downstream Pressure Range	Options
1" to 2" (DN25 to DN50)	316/316L Stainless steel 20 µin Ra then electropolished.	116 psig (8 barg)	347°F (190°C)	1" : 5.5 1½" : 13.5 2" : 27	7-75psi (.5 - 5 barg)	Soft seat (SRV6G)



# Pure and Clean Steam Trapping

Spirax Sarco offers a comprehensive range of thermodynamic and thermostatic steam traps developed specifically for clean and pure steam applications. The line includes traps that minimize condensate back-up for critical steam-in-place applications.

## BTD52L Clean Steam Thermo-Dynamic® Traps

Thermo-Dynamic® traps are more suited to constant pressure applications, where small amounts of uncontaminated condensate are present, such as in steam main drainage and in-line filter sterilization applications.

The compact BTD52L Thermo-Dynamic® steam trap is available in a wide range of sizes with screwed, Tri-Clamp® compatible or extended tube end connections. Clean, tight shut-off at steam saturation temperature without a water seal eliminates waste of valuable clean steam. Actual material certification is available as standard for the BTD52L tube end and Tri-Clamp® compatible versions.



### Range and options

Sizes	Construction	Maximum Operating Pressure	Maximum Operating Temperature	Options
1/4" to 1/2"	316L Stainless steel	150 psig (10 barg)	850°F (450°C)	Other connections available upon request



## BTM7/BTS7 Thermostatic Steam Traps

Thermostatic traps are most widely used in process applications, as they can be designed to be free draining and operate close to steam temperature at any given pressure. A large orifice helps eliminate the possibility of fouling in the presence of contaminated condensate or cleaning solutions, while minimal condensate retention and excellent air venting capabilities associated with thermostatic traps ensure rapid heat-up and optimum sterilization.

The BTM7 (maintainable) and BTS7 (sealed) are constructed of 316L stainless steel in a lightweight, compact design allowing easy installation at low initial cost. The BTM7 and BTS7 are available with screwed, extended tube end, or Tri Clamp® compatible end connections for use in either tubing or piping systems. Typical applications include sterilizers, autoclaves, and block and bleed systems.

### Range and options

Sizes	Construction	Maximum Operating Pressure	Maximum Operating Temperature	Options
1/4" to 1" (DN8 to DN25)	316L Stainless steel	102 psig (7 barg)	Saturated steam temperature	Fixed bleed, Other connections are available upon request



## BT6-B Balanced Pressure Thermostatic Steam Trap

The Spirax Sarco BT6-B is a high-performance, sanitary balanced pressure thermostatic steam trap that has been developed specifically to remove condensate with the minimum of condensate retention. The standard element is extremely sensitive to changes in condensate temperature and is designed to open with a minimum of sub-cooling, typically less than 3.6°F (2°C) from steam saturation temperature at pressures below 36 psig (2.5 bar g). Its unique design, with enhanced features, ensures the BT6-B is effective and economical and exceeds the capabilities of other models currently available on the market.

### Key features and benefits

Key features	Key benefits
Stainless steel with high-quality surface finish and FDA and USP class VI compliant seal.	Minimal risk of microbiological growth and high degree of corrosion resistance.
High capacity	The BT6-BL is suitable for main drainage applications with low condensate loads. The BT6-BH is a high capacity trap with high condensate and cold-water handling capacities. This ensures minimum back-up at start-up.
Improved 'near-to-steam' performance	Superior capsule performance means that condensate is discharged at temperatures approaching steam saturation temperature. This means cooling leg height can be kept to a minimum.
Safety clamp for body as standard	The trap can not easily be disassembled by accident; this is an important safety feature to protect operators.
Self-draining design incorporating steep 15° angle towards orifice which exceeds the current ASME BPE 2007 recommendations.	Ensures the product is fully self-draining, which reduces the risk of microbiological growth.



### Range and options

BT6-B Model	Sizes	Construction	Maximum Operating Pressure	Maximum Operating Temperature	Options
BT6-BL Low Capacity	½" to 1½" (DN15 to DN40)	Body and capsule element 316L stainless steel	87 psig (8 barg)	329°F @ 87 psig (165°C @ 8 barg)	PTFE encapsulated viton seal
BT6-BH High Capacity		Body clamp 316 stainless steel  15 µin Ra			

# Sanitary Ancillary Products

To complete your high purity system, Spirax Sarco offers a broad range of ancillary products, including sanitary ball valves, sample coolers and steam separators. Other products (not shown) include hygienic pressure gauges and sanitary sight glasses. Visit our website for more information.

## M70i and M80i Sanitary Ball Valves

Spirax Sarco's range of sanitary ball valves form part of a comprehensive product range for high purity applications, where system integrity, product quality and documentation are paramount.

All of these 316L stainless steel ball valves have been designed in accordance with ASME BPE for the pharmaceutical, bio-processing, food and beverage, and other high purity industries, where bacteria and media deposits can put product quality at risk.

### Key Features

- True port design
- Fully traceable high integrity material
- Designed with orbital welding in mind
- FDA and USP Class VI Seals
- ISO 5211 mounting pads as standard
- Superior sealing
- Lockane handles



### Range and Options

Sanitary ball valve model	Sizes	Construction	Maximum Operating Pressure	Maximum Operating Temperature	Options
M70i	½" to 2" (DN15 to DN50)	Forged 316L - 20 µin Ra	100 psig (7 barg)	390° F @ 0° psig (200°C @ 0 barg)	15 µin Ra Extended Stem
M80i	2½" to 4" (DN65 to DN100)	Investment cast 316L - 15 µin Ra			

Actuation note: Spirax Sarco's type BVA200 series pneumatic actuators and LSB type limit switches can be supplied fitted to the M70i and M80i where actuation is required. Contact Spirax Sarco for further details.

## CS10 Stainless Steel Clean Steam Separator

Moisture is the enemy of any clean steam system. Wet steam damages and degrades the performance of components, especially control valves. What's more, moisture usually results in substandard quality clean steam. The Spirax Sarco CS10 is your best guardian of clean steam reliability and quality. The CS10 is a unique design from Spirax Sarco which has been developed to overcome the related problems associated with wet steam, including control valve damage and failure to comply to steam sterilization standards EN 285 and HTM 2010.

### Key Features

- Designed to exceed the steam dryness value of 95% as per standards EN 285 and HTM 2010.
- Unique, patent pending design with removable baffle plate design to facilitate periodic de-rouging and inspection.
- Designed in accordance with the ASME BPE guide for the biopharmaceutical industry.
- Fully traceable 316L stainless steel material throughout to ensure system integrity.
- All elastomers compliant to FDA regulation CFR 21, part 177, section 2600. USP class VI elastomers are only available in ½", ¾" and 1" (DN15, DN20 and DN25) sizes.

### Range and Options

CS10 Model	Sizes	Construction	Maximum Operating Pressure	Maximum Operating Temperature	Options
CS10 - 1	½" - 2" (DN15 - DN50)	316 L Stainless Steel 20 µin Ra (20 µin.)	110 psig (7.6 barg)	482°F @ 99 psig (250°C @ 6.8 barg)	Electropolishing
CS10 - 2	½" - 2" (DN15 - DN50)	316 L Stainless Steel 30 µin Ra (30 µin.)			-



# SSC20 Sample Cooler

The SSC20 takes samples from clean high purity steam and water systems. Its design prevents “flashing-off” or high temperatures which can be dangerous and could result in an inaccurate sample. Its 316L stainless steel construction and counter current flow path provides accurate, contamination free samples. The compact, maintenance-free design makes it ideal for either permanent or mobile installation.

## Key Features

- Continuous coil minimizes risk of sample contaminations.
- Tube and Tri-Clamp® compatible connection options for simplified installation
- Compact design ideal for mobile installations
- All 316L stainless steel construction for optimum system integrity

## Range and Options

Sizes	Construction	Maximum Operating Pressure	Maximum Operating Temperature	Options
1/2"	316L stainless steel 20 microinch Ra	Coil: 464 psi Body: 145 psi	Coil: 572°F Body: 212°F	Polished Shell



# Pharmaceutical Steam Sampling

The PS-series of steam sampling products is engineered and fabricated with safety, efficiency, and operability as our focus. The highest regard is given to maintaining the integrity of your quality samples.

The PS-series is a complete and comprehensive package available to the industry for pure or clean system services. From the detailed engineering and submittal package, to the turnover documentation, we have meticulously engineered every component and every detail.

Critical steam parameters typically measured include total organic carbon (TOC), conductivity, microbial levels, and endotoxin.

Whether mobile or stationary, we have a product for your critical application.

- Two (2) models available: 0 - 45 psig and 0 - 70 psig (0 - 3 barg and 0 - 5 barg)
  - Multiple heat transfer areas available: .75 sq ft. - 4.19 sq ft. (697 - 3893 sq. cm)
  - All stainless steel, sanitary design
- Sample temperature indication
  - Isolation valves and pressure safety valve
  - Use chilled water, cooling tower water, city water, etc.



# Direct Injection Humidifier

Spirax Sarco offers you a complete package for clean and safe humidification in your facility. Typical applications include those where contaminants such as boiler feedwater chemicals, scale and corrosion particles make plant steam unsuited for your process. The **HygroMATIK** Direct Injection Humidifier, with its constant temperature lance system, provides precise humidity control. The lightweight separating chamber allows only dry steam to flow through the stainless steel steam jacketed manifold while removing condensation with the in-line maintainable BTM7 Thermostatic Clean Steam Trap. The dry steam is regulated with our stainless steel STERI-TROL control valve. You benefit from quality design and materials, efficiency and all around value.







In our century-long commitment to sustainable energy use in buildings and industry, we dedicate our innovative expertise, products, services and business efforts to conserve our valued natural resources, and will actively guide our customers in attaining these same goals:

- Energy - Minimize energy demand, carbon footprint, emissions and maintenance;
- Balance - Apply energy precisely, recovering and reapplying low-grade energy, conserving wherever possible for future use;
- Flow - Precisely regulate fluid flow to optimize energy consumption, for consistent interior comfort and process control accuracy.

## Regional sales offices

### Northeast

Spirax Sarco, Inc.  
7760 Olentangy River Road  
Suite 120  
Columbus, OH 43235  
Phone: (614) 436-8055  
Fax: (614) 436-8478

### Mid Atlantic

Spirax Sarco, Inc.  
4647 Saucon Creek Road  
Suite 102  
Center Valley, PA 18034  
Phone: (800) 251-7676  
Fax: (800) 996-3232

### Southeast

Spirax Sarco, Inc.  
400 Northeast Drive, Unit O  
2021 Business Center  
Columbia, SC 29203  
Phone: (803) 714-2131  
FAX: (803) 786-7050

### Midwest

Spirax Sarco, Inc.  
1500 Eisenhower Lane  
Suite 600  
Lisle, IL 60532  
Phone: (630) 493-4525  
Fax: (630) 724-9176

### Southwest

Spirax Sarco, Inc.  
203 Georgia Avenue  
Deer Park, TX 77536  
Phone: (281) 478-4002  
Fax: (281) 478-4615

### West

Spirax Sarco, Inc.  
8141 E. Kaiser Blvd.  
Suite 311  
Anaheim Hills, CA 92808  
Phone: (800) 883-4411  
Fax: (714) 940-0183

SPIRAX SARCO, INC.  
1150 NORTHPOINT BLVD.  
BLYTHEWOOD, SC 29016  
t: 800.883.4411  
or: 803.714.2000  
f: 803.714.2222  
[www.spiraxsarco.com/us](http://www.spiraxsarco.com/us)

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