

# ProConnex® Steam2® Valve

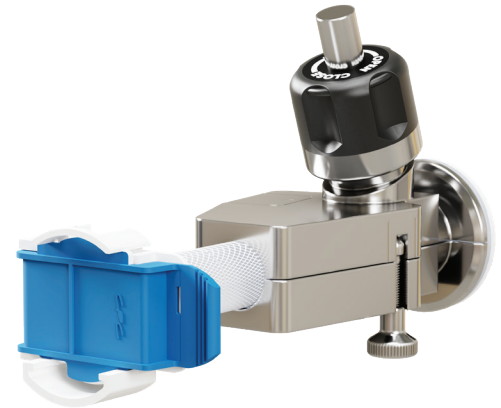
Data Sheet

The ProConnex® Steam2® Valve, powered by Artesyn technology, offers a full bore flow path in open state allowing for fast and unrestricted transfer of fluids. The valve delivers an engineered design with minimized dead leg providing a solution for flexible and safe aseptic fluid transfer at industrial scale. The molded silicone single-use flow path has a seal-free actuation mechanism, ensuring safety and reliability at point of use.

The pre-irradiated liner for the valve features a 3-step fluid contact layer setup. Coupled with the sanitary flange end sterilization by steam in place, the solution provides a convenient method of transfer into pre-sterilized single-use systems. Available with progressive manual actuation in a variety of stainless steel sanitary connection types, it allows for the reliable connection of two stainless steel flange ends.

ProConnex Steam2 Valves are available with hygienic clamp, NA connect and Fastmount flange end connections allowing for seamless connection to a variety of equipment. The single-use tubing end is braided silicone available in 3/8 in., 1/2 in., 3/4 in., and 1 inch internal diameter. The liner comes with an integrated flange gasket, thereby minimizing the connection sealing surface.

With a range of sizes, ProConnex Steam2 Valves are suitable for use in liquid or gas transfer applications from upstream processing, downstream processing through to formulation and filling. The valves are suited to enable aseptic transfers of fluid from traditional to single use process wetted parts. The valve bodies are manufactured from high end 316 L stainless steel ensuring they meet the highest quality standards.



Features	Benefits
Single-use flowpath	Eliminate cross contamination risk, reduce down time
Full bore flow path, 3/8", 1/2", 3/4" or 1" internal diameter	Unrestricted flow throughput
Seal free, reversible actuation	Transfer speed gain, up to 5 fold compared to other devices
Steam on, steam off functionality	Simple reduced risk concept
Minimal steam dead leg (:5 1,5D x internal diameter)	Process flexibility, multiple actuations possible
Tool free installation	Increased sterility assurance
Hemispherical closure	Facilitated sterilization validation
Liner closure encapsulation	Safe, reliable and simplified processing
Visual indicator	Closure resistance and reliability

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## Applications

### Upstream

- Media and Buffer Preparation
- Cell Clarification Harvest
- Perfusion
- Filtration
- Mixing

### Downstream

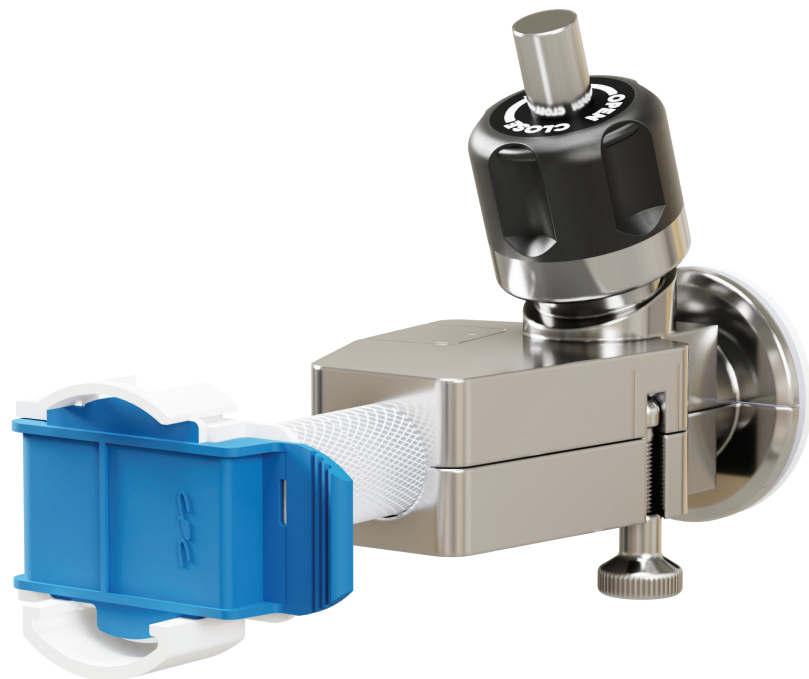
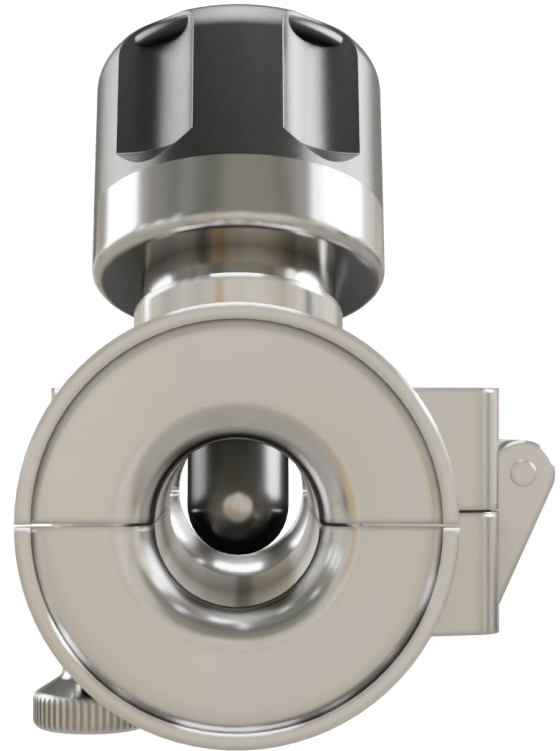
- Chromatography
- Buffer Exchange
- Virus Inactivation
- Concentration
- Fractionation
- Transfer
- Finish Filling

## Closure Principle

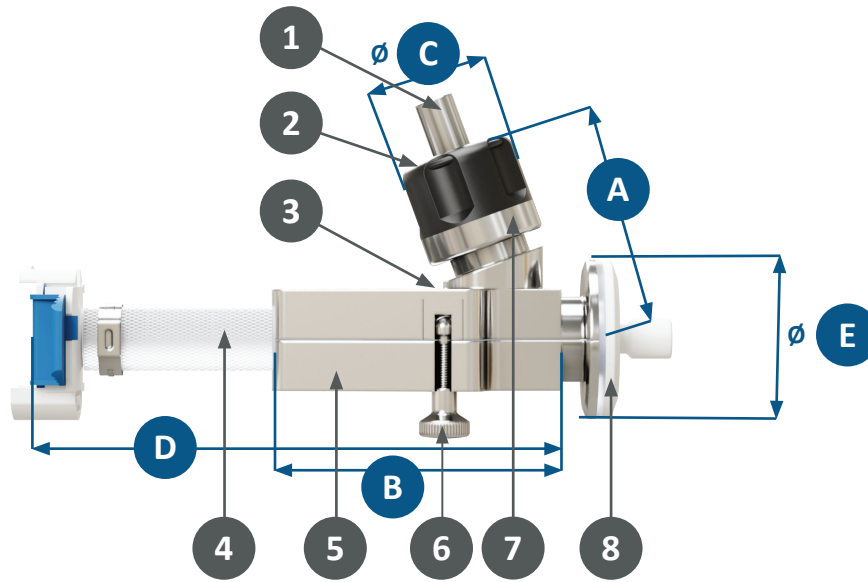
Actuation of the stem on the flexible single-use liner results in a hemispherical closure of the flow path. The manual actuation allows for gradual fluid flow control. The precision designed sized stem to valve seat combination provides a uniform sealing surface ensuring repeatable and high closure resistance preventing leaks while applying minimal material stress and minimal steam dead leg. Over-compression of the liner is avoided by an intrinsic travel stop.

## Performance Benefits

- Leak free design
- Consistent/uniform sealing face
- Reduced stress on single-use elements
- Simple reduced risk concept
- Minimized dead legs
- ASME BPE Compliant
- Tools not required
- Easy to install and operate



Nominal Dimensions

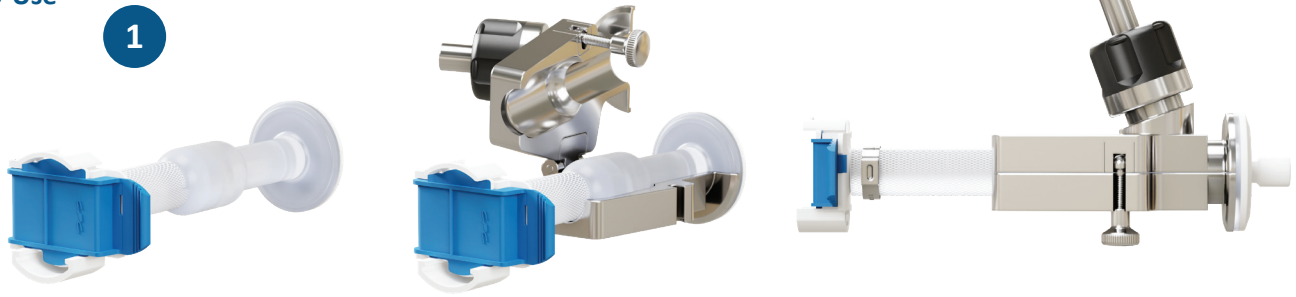


Flange End Type	Liner Internal Dimension	A	B	C	D	E	Weight
Hygienic clamp 1 and 1 ½ in	0.375 in ID	2.9 in (75 mm)	3.8 in (96 mm)	1.5 in (38 mm)	6.8 in (173 mm)	2 in (50 mm)	2.2 lb(1 kg)
	0.5 in ID	3.2 in (81 mm)	4.1 in (103 mm)	1.5 in (38 mm)	7.0 in (178 mm)	2 in (50 mm)	2.2 lb(1 kg)
	0.75 in ID	4.1 in (105 mm)	4.4 in (112 mm)	2.4 in (60 mm)	7.4 in (188 mm)	2 in (50 mm)	3.7 lb (1.7 kg)
	1 in ID	5.8 in (147 mm)	5.6 in (141 mm)	3.0 in (76 mm)	9.5 in (241 mm)	2 in (50 mm)	8.1 lb (3.7 kg)
Hygienic clamp 0.5 and 0.75 in	0.125 in ID	3.0 in (81 mm)	2.3 in (96 mm)	1.5 in (38 mm)	6.4 in (164 mm)	1 in (25.4 mm)	1.7 lb (0.8 kg)
	0.250 in ID	3.0 in (81 mm)	3.2 in (103 mm)	1.5 in (38 mm)	6.5 in (166 mm)	1 in (25.4 mm)	1.9 lb (0.9 kg)
	0.375 in ID	2.9 in (75 mm)	3.8 in (96 mm)	1.5 in (38 mm)	6.8 in (173 mm)	1 in (25.4 mm)	2.2 lb (1 kg)
	0.5 in ID	3.2 in (81 mm)	4.1 in (103 mm)	1.5 in (38 mm)	7.0 in (178 mm)	1 in (25.4 mm)	2.2 lb (1 kg)

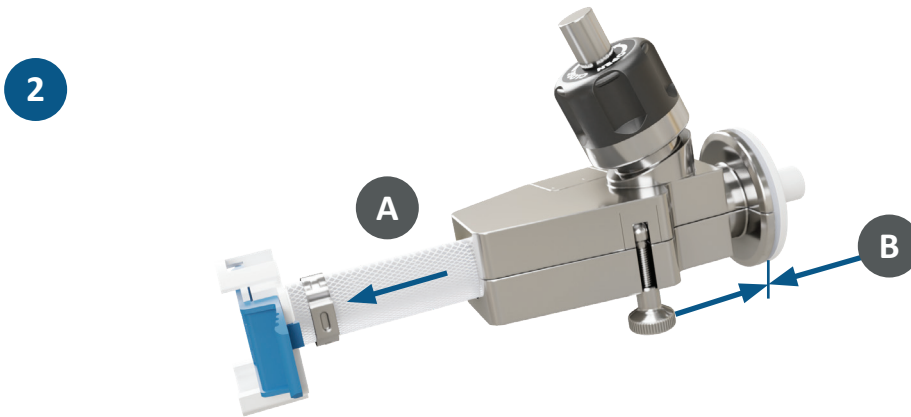
Materials of Construction

Item #	Description	Materials
1	Stem	Stainless Steel 316 L
2	Upper Handle	Polyetherimide (PEI)
3	Body Pins	Stainless steel 316L
4	Liner	Platinum cured silicone
5	Valve Body	Stainless Steel 316 L
6	Lock Knob	Stainless Steel 316 L
7	Low Handle	Stainless Steel 316 L
8	Cap	Polypropylene

Easy-to-Use



Step 1: Unpackage and insert the liner.



Step 2: Pull on the braided tubing in direction A to ensure the silicone TC flange is tight against the stainless BU flange at position B.



Step 3: Close the valve fully.



Step 4: Remove the plastic plug.



Step 5: Attach the valve inlet to the process vessel and apply steam.

## Liner Specifications

### Quality Standards

- Manufacturing in ISO Class 7 cleanroom
- Double-bagged in cleanroom
- Animal derived components free (ADCF) material (including BSE/TSE risk free)

### Operating Conditions

Maximum Pressure	Temperature Range
Max pressure upstream: 6 barg at 60 °C when the valve is closed	From 2 to 130 °C upstream
Max pressure in fluid transfer 4 barg upstream to downstream	
Max pressure downstream: contact factory, dependent on application	Downstream: contact factory, dependent on application

### Extractables

Full BPOG standardized extractables test protocol in progress.

**Note:** A Regulatory Information Guide (RIG) and Validation Summary or Validation Guide are available upon request.

### Bioburden Reduction

Gamma Irradiation	In Situ Steam
Can be gamma-irradiated 25 - 40 kGy	Max 5 cycles of 75-minutes at 130 °C

**Note:** Gamma Irradiation available upon request.

**Note:** Liner can be supplied with closed ends as part of a pre-sterilized single use system. After installation, flange end will be steamed in place before use and, possibly, after use.

### Validation

A Validation Summary or Validation Guide is available upon request.

**Note:** A Regulatory Information Guide (RIG) is available upon request.

### Valves and Liners

The valve can be purchased individually. The liner with cap is also available as a stand-alone item sold per box of 10 pieces. The ProConnex Steam2 solution is integrated as part of a comprehensive single-use systems offering. This allows for closed single-use systems including a multitude of adjacent technology.

### Ordering Information

Clamp Size	Tubing ID	Hardware		Consumable*	
		Part #	Quantity	Part #	Quantity
1/2 in Mini ASME BPE Hygienic Clamp	1/4 in	S2HSAB0250X043716	1 valve per box	S2SBAB0250X0437AQQ	10 liners per box, individually double bagged in larger outer bag
	3/8 in	S2HSAC0375X062516		S2SBAC0375X0625AQQ	
	1/2 in	S2HSAL0500X075016		S2SBAL0500X0750AQQ	
1-1 ½ in Mini ASME BPE Hygienic Clamp	3/8 in	S2HSAN0375X062516		S2SBAN0375X0625AQQ	
	1/2 in	S2HSAK0500X070516		S2SBAK0500X0750AQQ	
	3/4 in	S2HSAF0750X112516		S2SBAF0750X1125AQQ	
	1 in	S2HSAJ1000X137516	S2SBAJ1000X1375AQL		

\* Individual liners with cap are supplied non-sterile only, single-use systems provide a pre-sterilized, ready to use solution.

**Note:** When requesting a quotation from your Repligen representative, please provide details of your stainless steel equipments mating connection type, such as BPE TC, NovAseptic® connector fitting, Fastmount® fitting or other, along with any jacketing geometry or possible surrounding obstructions. Other configurations are also available.

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