



DATASHEET

STEAM2®

ARTeSYN®

About the steam2® Valve

The steam2® design concept 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 single-use flow path made out of ARTeSIL® molded silicone has a seal-free actuation mechanism making it safe and reliable 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.

The ARTeSYN® 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., ½ in., ¾ in., and 1 in. internal diameter. The liner comes with an integrated flange gasket, thereby minimizing the connection sealing surface.

With a range of sizes, the ARTeSYN® steam2® valves are suitable for use in liquid or gas transfer applications from upstream processing, downstream processing through to formulation and filling. The steam2® 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 316L stainless steel ensuring they meet the highest quality standards.



Features & Benefits

Features

Single-use flowpath

Full bore flow path, 3/8", 1/2", 3/4" or 1" internal diameter

Seal free, reversible actuation

Steam on, steam off functionality

Minimal steam dead leg ($\leq 1,5D$ x internal diameter)

Tool free installation

Hemispherical closure

Liner closure encapsulation

Visual indicator

Benefits

Simplified material validation

Eliminate cross contamination risk, reduce down time

Unrestricted flow throughput

Transfer speed gain, up to 5 fold compared to other devices

Simple reduced risk concept

Process flexibility, multiple actuations possible

Increased sterility assurance

Facilitated sterilization validation

Safe, reliable and simplified processing

Closure resistance and reliability

Suits both pressurized and unpressurized applications

Safe stainless to stainless flange connection

Simple verification of valve position for operators

Applications

Upstream applications



MEDIA AND BUFFER
PREPARATION



CELL
CLARIFICATION/HARVEST



PERFUSION



FILTRATION

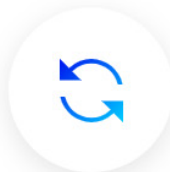


MIXING

Downstream applications



DOWNSTREAM
CHROMATOGRAPHY



DOWNSTREAM BUFFER
EXCHANGE



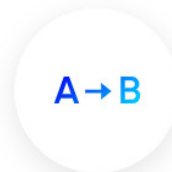
DOWNSTREAM VIRUS
INACTIVATION



DOWNSTREAM
CONCENTRATION



DOWNSTREAM
FRACTIONATION



DOWNSTREAM TRANSFER



DOWNSTREAM 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

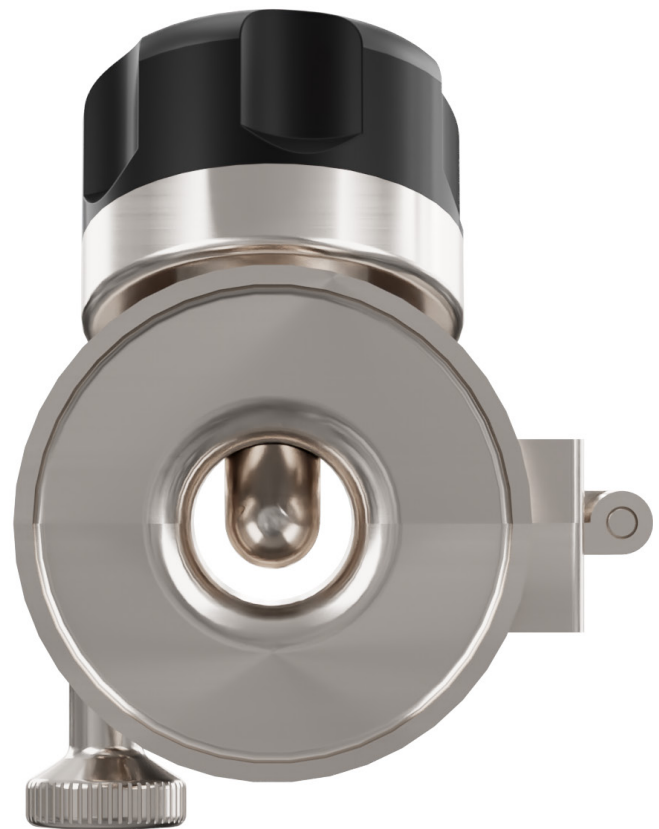
Reduced stress on SU elements

Minimized dead leg

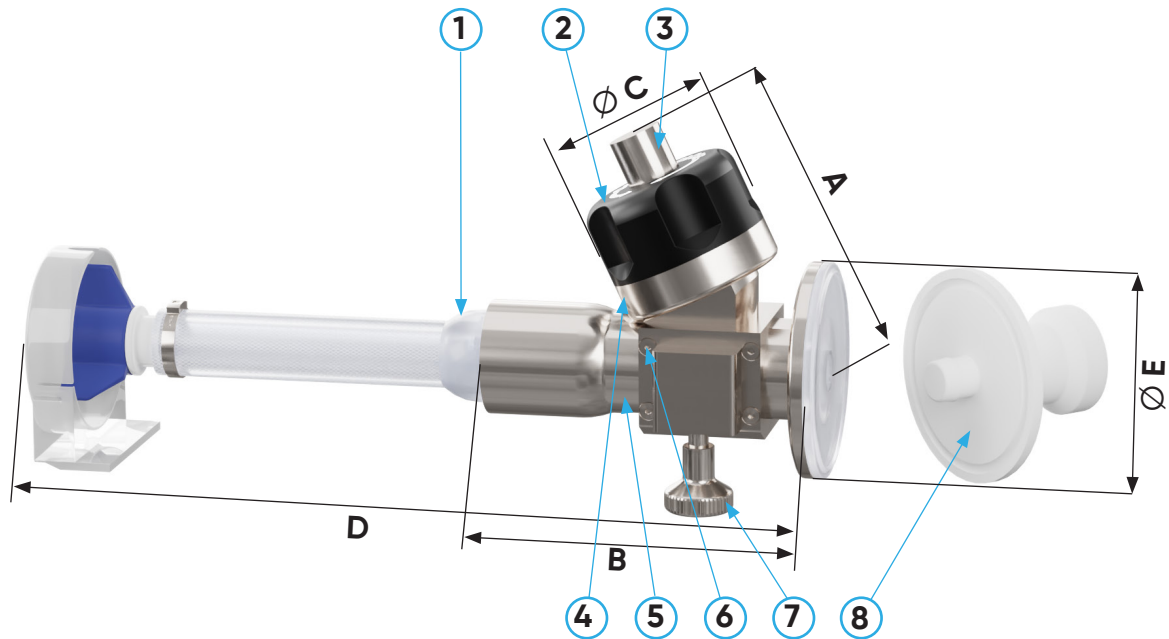
ASME BPE Compliant

Tools not required

Easy to install & 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	2.4 in. (70 mm)	3 in. (76 mm)	(38 mm) 1.5 in.	6.3 in. (160 mm)	2 in. (50 mm)	1.1lb (0.5kg)
	0.5 in. ID	2.8 in. (71 mm)	3.4 in. (84 mm)	(38 mm) 1.5 in.	6.5 in. (163 mm)	2 in. (50 mm)	1.3lb (0.6kg)
	0.75 in. ID	4.1 in. (104 mm)	3.9 in. (100 mm)	2.4 in. (60 mm)	6.89 in. (175 mm)	2 in. (50 mm)	2.2lb (1kg)
	1 in. ID	5.2 in. (132 mm)	5.1 in. (131 mm)	3.0 in. (76 mm)	8.76 in. (223 mm)	2 in. (50 mm)	4.4lb (2kg)

Materials of construction

Item no	Description	Material
1	Liner	Platinum Cured Silicone
2	Upper Handle	Polyetherimide (PEI)
3	Stem	Stainless steel 316L
4	Lower Handle	Stainless steel 316L
5	Valve Body	Stainless steel 316L
6	Body Pins	Stainless steel 316L
7	Lock Knob	Stainless steel 316L
8	Cap	Polypropylene

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, dependant on application.	Downstream: contact factory, dependant on application

NOTE: Max Pressure is only applicable when the inlet hygienic clamp is connected to an ASME BPE stainless steel hygienic clamp and the valve is in the fully closed/shut position.

NOTE: For performance outside of factory guidelines consult an Artesyn representative.

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

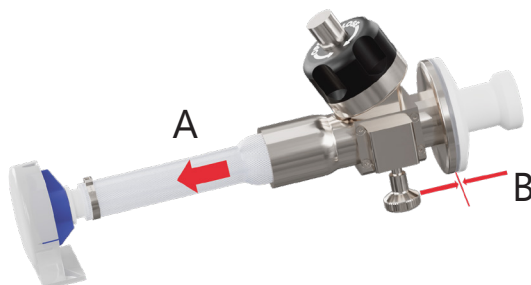
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Easy to use



: 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 & apply steam

Ordering Information

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 ARTeSYN® steam2® solution is integrated as part of a comprehensive single-use systems offering. This allows for closed SU systems including a multitude of adjacent technology.

Hardware				Consumable *	
	Tubing Size	Part Number	Quantity	Part Number	Quantity
1 and 1 ½ in. ASME BPE hygienic clamp	0.375 in. ID	S2AE0375X062516	1 valve per box	S2SBAE0375X0625B	10 liners per box, individually double bagged in larger outer bag
	0.5 in. ID	S2AE0500X087516		S2SBAE0500X0875B	
	0.75 in. ID	S2AE0750X112516		S2SBAE0750X1125B	
	1 in. ID	S2AE1000X140516		S2SBAE1000X1405B	

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

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