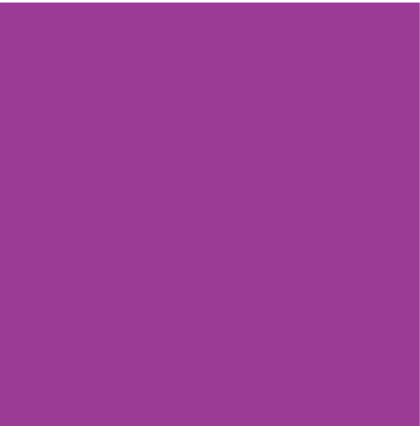


STEAM-THRU® CONNECTIONS



Advantages of Disposable Systems

Increase Productivity

Single-use systems result in increased productivity through the reduction of system downtime associated with cleaning and cleaning validation. Reducing downtime of key processes allows manufacturers to increase output while also decreasing time to market.

Add Flexibility

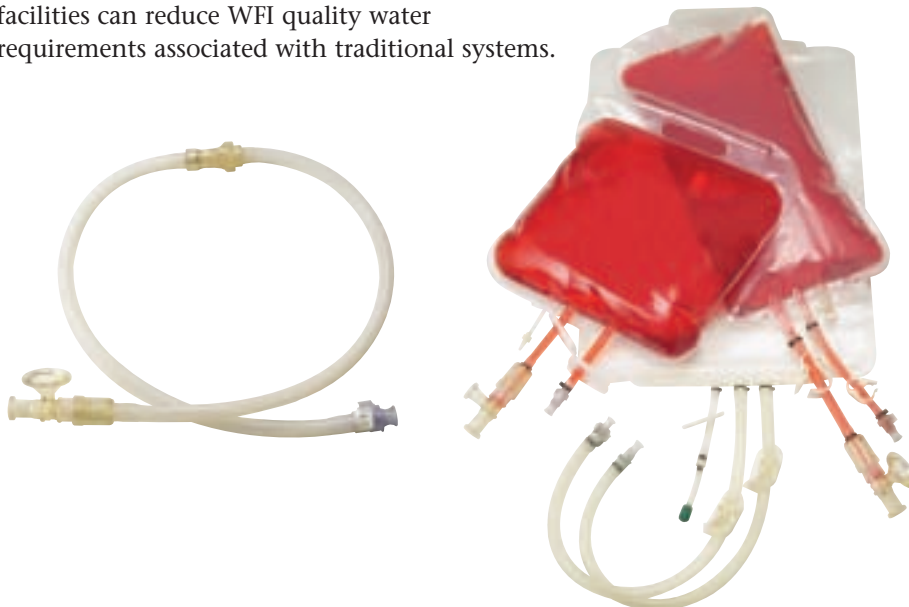
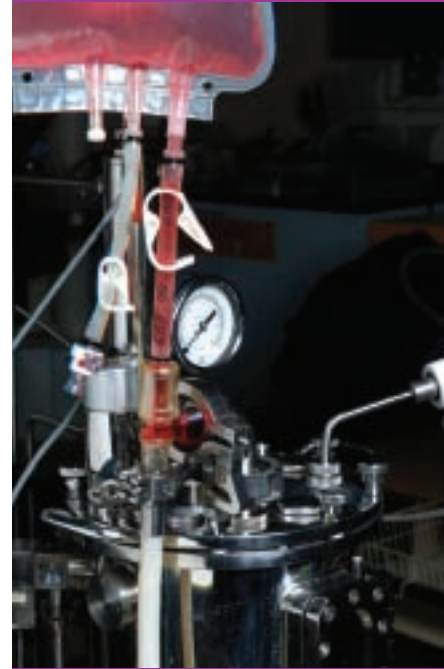
Flexibility is an equally important factor as processors strive to increase productivity and prepare facilities for new drugs. Unlike hard-plumbed piping systems, disposable systems can be easily modified for alternative media handling. For instance, the implementation of single-use technologies can increase production at an existing facility where traditional fixed systems would normally require costly facility expansion.

Minimize Risk

Reducing risks continues to be a fundamental concern in the bioprocessing industry. Media contamination can lead to product quality issues. Subsequently, expensive reprocessing activities are often required to prevent the complete loss of a valuable batch of media. This becomes an even larger concern as companies are now conducting more multi-product manufacturing within single facilities. In addition to having a negative effect on operational efficiency, cross-contamination can negatively impact a company's reputation. The integration of single-use systems can help minimize this possibility.

Reduce Cost

Cost savings include the reduced chemical and utility expenses of cleaning and labor. Capital savings on new construction can be attributed to disposable systems because upfront capital requirements are lowered due to lower equipment and floor space needs. Finally, existing facilities can reduce WFI quality water requirements associated with traditional systems.



Steam-Thru® Connections

Ease The Transition

Colder Products Company advances steam-in-place technology with the introduction of Steam-Thru® Connections. The innovative design allows a quick and easy sterile connection between biopharmaceutical processing equipment and disposable bag and tube assemblies.

The Steam-Thru Connection's patented three-port design allows steam to pass directly through the lower ports to "steam on" to stainless equipment. After the SIP cycle is completed, the connector's valve is actuated, creating a sterile flow path to single-use systems. Media can then be safely transferred without the cleaning and validation concerns associated with reusable components.

The new Steam-Thru II builds upon this proven technology by offering the flexibility of "steam on" and "steam off" functionality. The innovative design allows the valve to be returned to the steam position enabling a second SIP cycle following media transfer. The "steam off" disconnection of disposable systems minimizes cross-contamination risks associated with reusable components.

Today's biopharmaceutical manufacturers are meeting the challenges of increased productivity, reduced costs and decreased time to market with the help of Colder's Steam-Thru Connections.



Applications include:

- Bioreactor feeding
- Cell harvesting
- Product sampling
- Single-use bag systems
- Media transfer lines

FEATURES	BENEFITS
Innovative three-port design	Allows a true steam-through SIP process Eliminates "dead legs" where bacteria can grow Eliminates the need for laminar flow hoods
Steam On	Creates a sterile flow path
Steam Off	Sterilize prior to removal from equipment
Single-use/Disposable	Saves time and money by eliminating unnecessary cleaning procedures Reduces cleaning and validation issues associated with reusable components
Tear-away sleeve/Thumb latch	Provides visual indicator of process stage Secures valve position
Industry standard terminations	Speeds connection to the process equipment Connects to popular sizes of flexible tubing
Medical-grade polysulfone	Meets USP Class VI biocompatibility Animal-free materials Compatible with standard sterilization methods

Steam-Thru® Process

Steam Position

Steam flows from the process equipment through the Steam-Thru to sterilize the connection. With the tear-away sleeve in place, the transfer of fluid to or from the bioreactor is prevented.

Flow Position

When the tear-away sleeve is removed, the Steam-Thru is actuated, the connection to the steam trap is disabled and a sterile flow path is established between the process equipment and the disposable system.

Steam-Thru® II Process

*An audible “click” and the visual indicator of the raised thumb latch provide assurance that the valve is locked in the flow or steam position.

Steam On Position

Steam flows from the process equipment through the Steam-Thru II creating a “steam on” sterile connection.

Flow Position

Once the valve is locked in the flow position a sterile flow path has been created allowing media transfer.

Steam Off Position

Once the valve is locked in the steam position, complete a second SIP cycle to “steam off” the connection.

Transition to Flow

Once the “steam on” cycle is complete and the steam trap has been closed, simply press the thumb latch to allow the valve to be moved down to the flow position.

Thumb latch recessed during valve transition

Transition to Steam

Once media transfer is complete, simply press the thumb latch to allow the valve to be moved back up to the steam position.

Steam-Thru® Specifications

Pressure:

Steam position: Up to 30 psi, 2.07 bar (Steam-Thru);
35 psi, 2.41 bar (Steam-Thru II)

Flow position: Vacuum to 20 psi, 1.38 bar

Temperature:

Steam position: Up to 130° C (266° F) for 60 minutes (Steam-Thru); Up to 135° C (275° F) for 60 minutes (Steam-Thru II)

Flow position: 4° C to 40° C (39° F to 104° F)

Typical Flow Rate: Cv = 4.6 max (Steam-Thru);
Cv = 8.2 max (Steam-Thru II)

Materials:

Connection: Polysulfone, USP Class VI

Seals: Silicone (clear), platinum-cured, USP Class VI

Tear-away sleeve: Polyethylene and polycarbonate (Steam-Thru only)

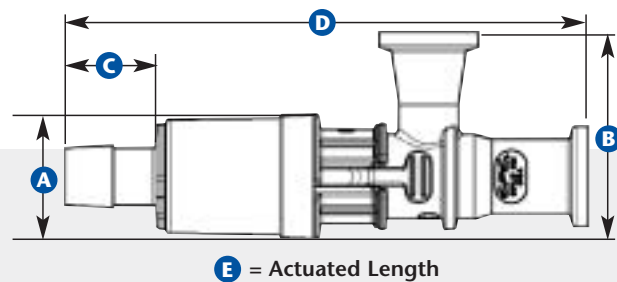
Sterilization:

Gamma: Up to 50 kGy gamma irradiation

Autoclave: At 128° C (265° F) for 30 minutes, up to two cycles (applies only to part numbers STC1700500-
STC1700800)

SIP process: Up to 130° C (266° F) for 60 minutes (Steam-Thru); Up to 135° C (275° F) for 60 minutes (Steam-Thru II)

Tubing sizes: 3/8" and 1/2" ID (Steam-Thru)
9.5mm and 12.7mm ID
1/2" ID (Steam-Thru II)
12.7mm ID



Steam-Thru Configurations

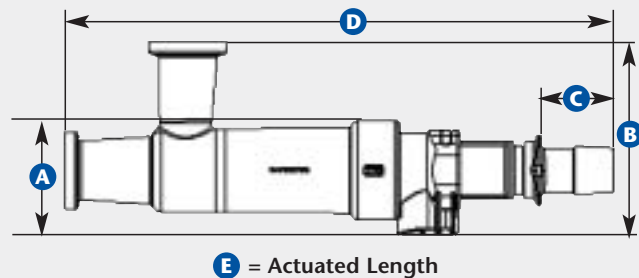
Polysulfone with Polyethylene Sleeve

All measurements are in inches (millimeters).

PART NO.	TERMINATIONS	A	B	C	D	E
STC1700000	3/4" x 3/4" sanitary x 1/2" HB	1.20 (30.5)	2.00 (50.8)	0.89 (22.6)	5.09 (129.3)	4.44 (112.8)
STC1700100	3/4" x 3/4" sanitary x 3/8" HB	1.20 (30.5)	2.00 (50.8)	0.60 (15.2)	4.80 (121.9)	4.15 (105.4)
STC1700200	3/4" x 1-1/2" sanitary x 1/2" HB	1.20 (30.5)	2.00 (50.8)	0.89 (22.6)	5.09 (129.3)	4.44 (112.8)
STC1700300	3/4" x 1-1/2" sanitary x 3/8" HB	1.20 (30.5)	2.00 (50.8)	0.60 (15.2)	4.80 (121.9)	4.15 (105.4)

Polysulfone with Polycarbonate Sleeve

PART NO.	TERMINATIONS	A	B	C	D	E
STC1700500	3/4" x 3/4" sanitary x 1/2" HB	1.20 (30.5)	2.00 (50.8)	0.89 (22.6)	5.09 (129.3)	4.44 (112.8)
STC1700600	3/4" x 3/4" sanitary x 3/8" HB	1.20 (30.5)	2.00 (50.8)	0.60 (15.2)	4.80 (121.9)	4.15 (105.4)
STC1700700	3/4" x 1-1/2" sanitary x 1/2" HB	1.20 (30.5)	2.00 (50.8)	0.89 (22.6)	5.09 (129.3)	4.44 (112.8)
STC1700800	3/4" x 1-1/2" sanitary x 3/8" HB	1.20 (30.5)	2.00 (50.8)	0.60 (15.2)	4.80 (121.9)	4.15 (105.4)



Steam-Thru II Configurations

All measurements are in inches (millimeters).

PART NO.	TERMINATIONS	A	B	C	D	E
STC2020000	3/4" x 3/4" sanitary x 1/2" HB	1.42 (36.1)	2.40 (61.0)	.89 (22.6)	6.84 (173.7)	5.93 (150.6)
STC2020200	3/4" x 1-1/2" sanitary x 1/2" HB	1.42 (36.1)	2.40 (61.0)	.89 (22.6)	6.85 (173.7)	5.93 (150.6)



Colder Products Company®

Quick Couplings & Fittings for Plastic Tubing

Colder Products Company
1001 Westgate Drive
St. Paul, Minnesota 55114
U.S.A.

Phone: 651-645-0091
Fax: 651-645-5404
Toll Free: 800-444-2474

info@colder.com
www.colder.com

Colder Products Company GmbH
Schmalweg 50
D-55252 Mainz-Kastel
Germany

Phone: +49-6134-2878-0
Fax: +49-6134-287828

cpcgmbh@colder.com
www.colder.com

Colder Products Company Limited
Room 1503, 15/F, SBI Center
54 – 58 Des Voeux Road Central
Hong Kong

Phone: 852-2987-5272
Fax: 852-2987-2509

asiapacific@colder.com
www.colder.com

Colder Patent Statement:

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