



## Connectors for Hybrid Single-Use/Reusable Systems



### What is a hybrid system?

A hybrid system in biopharmaceutical manufacturing is one that utilizes both fixed, reusable equipment (such as stainless steel bioreactors) and flexible, single-use equipment.



In essence, a hybrid system is a halfway point between fully reusable and fully single-use. Hybrid systems can be found in a wide range of processing applications, such as:

- Using smaller single-use bioreactors in the beginning of a seed train while using stainless steel bioreactors in the larger volumes of the seed train.
- Using single-use transfer lines between bioreactors or for suite-to-suite transfer.
- Making media additions to stainless steel equipment via single-use bag assemblies.
- Sampling from a stainless steel bioreactor using single-use tube assemblies.

The adoption of hybrid systems can vary site by site, even for the same manufacturer. Some processors employ only a small amount of single-use equipment in their facility, while others may be largely single-use with stainless steel equipment employed just for larger volume processing.



Hybrid systems require connections between single-use assemblies and stainless steel processing equipment. SIP connectors such as CPC's Steam-Thru Connections enable processors to make quick and easy sterile connections between single-use and reusable systems.



### Why use a hybrid system instead of a fully disposable or fully reusable solution?



The classic approach for biopharmaceutical processing facilities has been to utilize only reusable stainless steel equipment—including bioreactors, piping, valves and storage vessels. As single-use technologies advanced and their adoption accelerated, more manufacturers have elected to add single-use systems as a strategy to reduce costs, cross-contamination and downtime. Biopharmaceutical processors are often eager to implement single-use systems, but one of the obstacles to full adoption is the difficulty of implementing single-use throughout an entire existing facility. New construction eliminates these obstacles.

Manufacturers with existing facilities usually need to take small steps toward single-use, a phasing approach that results in hybrid systems. Manufacturers can start by eliminating stainless steel piping and valves in favor of single-use assemblies, while retaining larger stainless steel equipment that can be very difficult to replace. While a hybrid system may not provide the same level of benefits as a fully equipped single-use facility, it does provide improved systems flexibility along with other benefits not available from a fully stainless steel-equipped facility.



### How is a single-use system connected to fixed equipment?



Many suppliers deliver single-use components that are pre-sterilized and ready to use. However, these pre-sterilized single-use systems still need to be connected to the fixed equipment in an aseptic manner. One of the most common ways to do this is with single-use steam-in-place (SIP) connectors, such as Steam-Thru<sup>®</sup> Connections from CPC. The connector attaches to the end of the single-use system and is pre-sterilized along with the rest of the system. When the assembly is received at the bioprocessing facility, the connector can be attached to the stainless steel vessel via a sanitary port (3/4" or 1-1/2"). An SIP cycle can be supplied through this to sterilize the connection without the risk of dead-legs. Once the SIP cycle is complete, a sterile fluid transfer can be done either to the vessel or from the vessel easily by actuating the valve into the flow position.

More and more single-use technology is being used in the industry and this adoption will continue to grow because of the flexibility hybrid systems provide in the transition from stainless steel to single-use. Effective single-use SIP connectors help manufacturers ease the transition.

**Q** What is unique about CPC's Steam-Thru Connections?

**A** The Steam-Thru was recognized by the *BioProcess International* awards in 2012 as the "Technology of the Decade" because of its role in the industry's transition to utilizing more single-use systems. Steam-Thru Connections allow a quick and easy sterile connection between stainless steel bioprocessing equipment and disposable bag and tube assemblies. The valve allows steam to pass through the connector eliminating the risk of dead legs and ensuring an effective sterilization of the connector prior to use. The open flow path of the connector provides high flow rates when transitioned into the flow position, allowing quick transfer of large volumes of product. All materials of the connector are animal-free, USP Class VI and manufactured in CPC's ISO Class 7 cleanroom.



For even greater flexibility in hybrid stainless steel and single-use processing, CPC's AseptiQuik® STC connector combines either a genderless or gendered sterile connector with a Steam-Thru Connection that can be mounted directly to a steel vessel via a sanitary termination.

**About CPC**

CPC (Colder Products Company), the leader in single-use connection technology, offers a wide variety of bioprocessing connection solutions. Our innovative designs offer flexibility to easily combine multiple components and systems including process containers, tubing manifolds, transfer lines, bioreactors and other bioprocess equipment. Sterile fluid connections from CPC are available in a complete range of 1/8- up to 1-inch flow configurations.

**About Todd Andrews**

Todd Andrews is the Bioprocessing Global Sales and Business Development Manager at CPC. He has spent over 10 years in the bioprocessing field with expertise in single-use connection technology. During his tenure with CPC, he has held leadership positions in engineering, marketing, and business development. Todd is an active member with the BPSA, ASME-BPE and ASTM E55 committees. He holds a Bachelor of Science in plastics engineering from the University of Massachusetts – Lowell and a Masters of Business Administration from the University of St. Thomas in St. Paul, Minn.



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