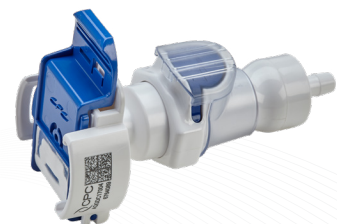


Q&A:

Combination Sterile Connections for Single-Use Applications

What are combination connections and why are they used in single-use bioprocessing?

Combination connections combine two or more specialty connectors to enhance process flexibility while minimizing risk and complexity. Specialty connectors for single-use systems have been integral to the success of single-use processes over the past decade and will continue to be over the next decade. These connectors are designed to meet a single, specific operational need. Examples include sterile connectors, aseptic disconnects (DC), sterile connect with open format connect, and steam-in-place (SIP) connectors. Sterile connectors allow users to connect two pre-sterilized systems in a non-controlled environment. Aseptic disconnects are used to separate two parts of a system in a process without introducing contamination to either part. SIP connectors link pre-sterilized single-use systems with steam-in-place fixed process equipment such as stainless steel bioreactors. In many cases, however, bioprocess engineers may want to combine two of these technologies at the same point in a process. For example, combining a sterile connector and aseptic disconnect creates a combination connection, meeting two critical needs.



Robust all-in-one sterile connect/sterile disconnect for tubing to tubing



Combination SIP/sterile connectors for hybrid systems

How can single-use systems be designed for combination connections?

Until recently, combination connections have been assembled by linking two specialty connectors in series with a flexible tubing junction. For example, several bioprocessors have developed custom assemblies that consist of a SIP connector and a sterile connector with a length of tubing in between. While custom assemblies can address a need for combining connection technology, they do have their disadvantages that include the high cost for custom assemblies and limited security resulting from the addition of a tubing junction. These disadvantages can be minimized with the used of integrated combination connectors.

Are any integrated combination connectors currently available?

Yes, AseptiQuik[®] G DC and AseptiQuik[®] STC, both developed by CPC. AseptiQuik G DC combines sterile connect and aseptic disconnect functionality all in one connector. This is accomplished by joining an AseptiQuik sterile connector directly with a HFC series aseptic disconnect into a single connector. A sterile connection can be made with a standard AseptiQuik connector in a simple, three-step process that allows sterile liquid transfer in a few seconds. After liquid transfer, an aseptic disconnect can be made in a quick, single step. Similarly, AseptiQuik STC combines sterile connect and SIP (steam-in-place) capability that is typically needed in hybrid systems. In this case, a 3/4-inch mini sanitary junction is used to integrate an AseptiQuik connector directly with a Steam-Thru[®] II SIP connector. The sanitary junction provides a more secure connection and reduces the number of potential leak points associated with use of a length of tubing between the connectors.

AseptiQuik STC connectors can be pre-sterilized by either gamma irradiation or autoclaving. The pre-sterilized AseptiQuik STC connector is attached to stainless steel equipment during system preparation and the connection point is sterilized with the system during SIP. The final sterile connection is completed by attaching a standard AseptiQuik connector body any time after the SIP cycle. Genderless connection technology reduces the number of SKU's needed and greatly reduces the risk of operator error.

How would you use an AseptiQuik G DC in a bioprocess?

Applications for AseptiQuik G DC include sterile supply bags, sterile hold bags and inlets/outlets for single-use bioreactors. For these applications it is important to consider process flow when designing your single-use system. For example, when connecting a sterile harvest bag to a single-use bioreactor, the best option is to specify an AseptiQuik G DC on the harvest bag and a standard AseptiQuik connector on the bioreactor harvest line. This configuration is best for ensuring process integrity and sterility.

What applications benefit from utilization of AseptiQuik STC?

Additions to and transfers from stainless steel bioreactors are the most common applications for AseptiQuik STC, especially for time and temperature sensitive materials. Consider transferring inoculum from a single-use, seed bioreactor into a production scale stainless steel bioreactor. In theory, this could be accomplished by specifying a SIP connector as part of a custom single-use bioreactor. However, waiting to complete the SIP cycle for that connection could disrupt process flow. Utilizing the AseptiQuik STC as an adaptor that is steamed-on in advance allows almost immediate inoculum transfer at the proper time.

About CPC

CPC (Colder Products Company) is the leader in single-use connection technology, offering a wide variety of connectors for biopharmaceutical manufacturing. Innovative, flexible designs easily combine multiple components. The company's well-known AseptiQuik® and MicroCNX® connectors provide quick and easy sterile connections even in non-sterile environments. Learn more about these connectors and our entire portfolio at cpcworldwide.com/bio. Connect with confidence with CPC, an operating company within Dover Corporation.

We Inspire Confidence at Every Point of Connection

What applications benefit from the AseptiQuik® S MPC connector?

AseptiQuik S MPC is a combination connector and adapter to enable open format systems to be easily closed. It incorporates an MPC termination with the commonly used AseptiQuik S technology. For any system with an MPC connector on it, easily close that system by installing the AseptiQuik S MPC onto the MPC body or back-to-back connector already installed on the single-use system, and then connect aseptically.

For applications like bag sets that have to be connected in a hood, AseptiQuik S MPC connectors allow users to easily move to the bench top. This is beneficial in the cell-culture scale-up process.



AseptiQuik S with MPC termination connector

About Anoop Gupta

Anoop Gupta is a senior product manager for biopharma at CPC with 20+ years of experience in business development and product management in several different industries. His experience and expertise are helping CPC accelerate the new product development process from ideation through launch and beyond. Anoop holds a Bachelor of Science in Mechanical Engineering from Cornell University, a Masters of Science in Mechanical Engineering from Rensselaer Polytechnic Institute, and an MBA from Indiana University.

