TOPIC 705

Genderless Sterile Connectors for Single-Use Applications

What is a genderless connection?

Historically, single-use connections involved a male and a female half. These were two distinctly different parts that mated with each other. Connections like these are considered gendered. Genderless connections are those in which the connector halves are identical in design, thus eliminating the need for different male and female halves to make the connection.

What are the benefits of having a genderless connector?

There are multiple benefits to incorporating genderless connections into your single-use system, including:

Ability to connect any two connector halves – Genderless connectors eliminate the possibility that two connectors you need to link cannot be mated. This attribute is especially important if you are using single-use systems from multiple OEM suppliers. Trying to manage which supplier provides the male half and which supplier provides the female half adds unnecessary complexity and it creates the risk of being supplied two systems with the same gendered half at the end. Unfortunately, this situation tends not to be noted until the time of use.

Fewer SKUs – Genderless connections allow you to inventory fewer components. This applies not only to the components themselves, but also to complete single-use systems. Fewer SKUs results in a simpler ordering process, reduces inventory needs and minimizes the risk of specifying or ordering the wrong components or assemblies. To illustrate the benefit of reduced SKUs at the assembly level, consider a basic tube set with a sterile connector on each end of the tubing. With a gendered connector, there are three possibilities:

- A female connector on each end
- A male connector on each end
- A male connector on one end and a female connector on the other end

With a genderless connector, there is only one possibility for a tube set – a genderless connector on each end.

Supply chain benefits – The ability to inventory fewer components can increase your opportunities for streamlining your supply chain.

What other features should I take into consideration when evaluating genderless connectors?

While genderless interchangeability is a significant advantage, it is not the only feature to consider. You need to ensure that the connector will have the overall functionality to ensure a reliable, repeatable and secure connection. Important connector attributes to consider are:

Ease of use – Connectors should be as intuitive to use as possible with a minimal number of actuation steps. The more actuation steps required in a connection, the higher the risk of operator error. Simpler is better.

Robustness – Connectors need to be able to withstand intended use as well as unintended abuse. One of the issues common with some connectors is the inability to withstand side-loading. Side-loading is difficult to avoid when dealing with tube and bag assemblies, so the connector you choose needs to be able to handle situations that are less than perfect.

Secondary equipment – Ideally, connectors do not require additional equipment (such as tri-clover clamps, fixtures or assembly aids) to ensure a solid connection. If additional equipment is needed, this may indicate that the connector on its own is not as robust as you need. Another concern is that operators can fail to use components not integral to the connector, and these usage errors could make the connector non-functional.

Seal design – The seal design is your last line of defense against leaking or microbial ingress into the connector, so it is important to understand what is providing the final seal within the connector. When evaluating connectors, you will want to look inside each option to see the seal design and how it functions. A great seal design ensures the seal will stay in place throughout the actuation steps and that the connector will withstand side-load and tensile forces.

What is the current market perception of genderless connectors?

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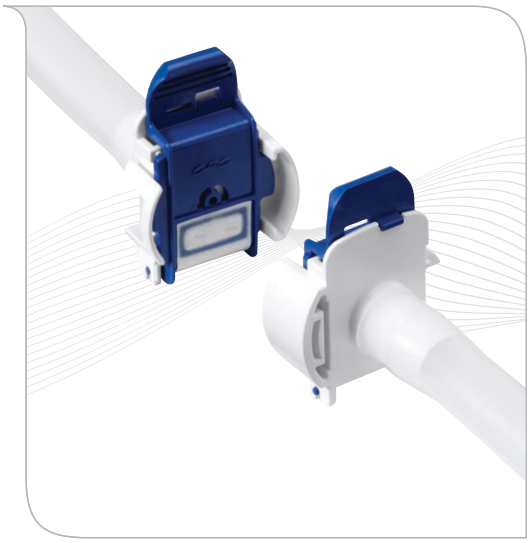
It is next to impossible to attend a conference on single-use without hearing about standardization. While standardization can cover several items, one of the most common discussion topics is connector compatibility (e.g., interchangeability). Research conducted in "*BioPlan Associates, Inc., April 2014, Biotechnology Industry Council™ Analysis of Single Use Connectivity*" showed that 88% of respondents viewed standardizing connector compatibility as important. This same study reported a 73% preference for genderless connectors over gendered connectors. End users are identifying easy-to-use, robust, genderless connectors as an answer for both standardizing single-use systems and eliminating many of the headaches experienced at facilities using single-use technology.



Genderless AseptiQuik G connectors provide interchangeable 1/4" - 3/4" sterile connections.

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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