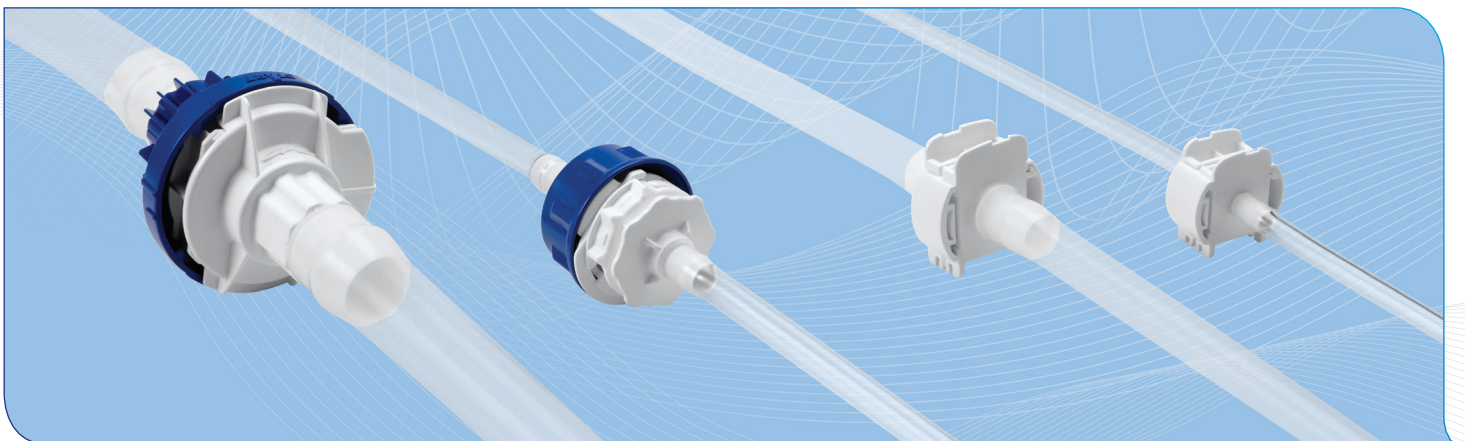


Comparison Guide: Tube Welders and Aseptic Connectors

As we continue, as an industry, to see unprecedented demand in therapies, there is increased demand for efficiencies, speed to market and regulatory transparency. Manufacturers are evaluating all steps in their workflows to determine if improvements can be made; one such area for evaluation should be in your aseptic connections. While tube welders can provide a closed system, review the chart below to determine if your process could be enhanced by aseptic connectors.

FACTOR	STERILE TUBE WELDING	ASEPTIC CONNECTORS
Set-up/Use Time	<p>Move welder into position, obtain and install the correctly sized tubing holder, initialize the welder, load tubing, weld, cure time (~4-7 minutes total)</p> <p>Set up/use time multiplied by hundreds of welds a week affects overall productivity (e.g., 100 welds/week x 4 minutes = 6.67 hours operator time for welding)</p>	<p>Aseptic connectors are sterilized and ready to go in tubing/bag assembly, requiring only seconds to connect and actuate</p>
System Flexibility	<p>Connection can be made at any time or any place in the tubing</p> <p>Welder must be set up for correct tubing size and material</p> <p>Tube holders are gauged to specific sizes (e.g., 3/8" x 5/8")</p> <p>Only the same-size tubing (same ID and OD) can be welded together</p>	<p>Single-use connectors are available that allow for flexibility between different types and sizes of tubing</p> <p>No reducers required</p>
Acquisition/Use Costs	<p>Capital equipment and ancillary equipment costs range from a few thousand dollars to tens of thousands per welder in each clean room</p> <p>Single-use blades cost</p> <p>Staff time for set-up and use or downtime if system jams or locks</p> <p>Back-up welder if needed</p> <p>Maintenance cost</p>	<p>Higher variable costs than blades</p> <p>No capital expense</p>



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Contamination Risks	<p>Nonconformance to manufacturer's recommendations might raise contamination risk due to:</p> <ul style="list-style-type: none"> - Placing tubing with the incorrect diameter in the tube holder. This can cause small pinholes in the weld, due to pinching or squeezing the tubing out of the holder during the weld process - Welding different tubing types together, which can lead to weld failure 	<p>Little to no contamination risk because validated aseptic connectors maintain a sterile boundary between two adjoining single-use systems</p>
Potential for Operator Error	<p>Not following manufacturer's recommendations can lead to the following potential operator errors:</p> <ul style="list-style-type: none"> - Using wrong tube holders for size of tubing - Using incorrect tubing: silicone, mismatched TPE - Using incorrect tubing type setting on the welder - Not using long enough tubing - Putting tension on the tubing - Inserting the blade incorrectly or reusing single-use blades 	<p>Not following manufacturer's recommendations can lead to the following potential operator errors:</p> <ul style="list-style-type: none"> - Using process fluids outside of the connector's chemical compatibility specifications - Not fully attaching connector to tubing - Applying too much side load
Materials Considerations	<p>Minimum tubing lengths might be required to fit tubing into welder</p> <p>Must connect same materials (e.g., C-Flex to C-Flex)</p> <p>Costly C-Flex tubing is often used for welding</p> <p>Silicone can't be welded because the material burns</p> <p>Must know each vendor's type/size of tubing to ensure compatibility of supplies</p>	<p>Any tubing length—no minimums required</p> <p>Connect to any type of tubing, including silicone, and different types of tubing (e.g., silicone to C-Flex)</p> <p>Connect different hose barb sizes (e.g., one side with 3/4" hose barb and the other with a 1/2" hose barb)</p> <p>Genderless connectors eliminate the need to carry male/female components</p> <p>Connectors from the same family can be interconnected</p>
Extractables Package	<p>Very limited package</p> <p>Published studies on the impact of thermal welding process to the flow path of the tubing</p>	<p>Most manufacturers provide a published extractables package to understand potential effects on cell lines.</p>
Level of Validation	<p>New welders require onsite validation but come with a full weld validation package</p> <p>No new product contact material will be introduced into the process</p>	<p>Connectors are ready to use and have been validated for material biocompatibility, extractables, sterility, and leakage</p> <p>New product contact material might need to be introduced and tested if the connector material has not been used elsewhere in the process</p>
FACTOR	STERILE TUBE WELDING	ASEPTIC CONNECTORS
Wet Welding	<p>Weld on a new bag at any time or any place in the tubing line (e.g., during a perfusion process). Sufficient tubing length is required to make the weld</p>	<p>A pre-assembled, sterilized manifold of aseptic connectors facilitates adding additional lines to a process</p>
Operating Conditions	<p>Ensure sufficient room and ample tubing to place welder near the process due to the size of the welder</p>	<p>No extra space, materials or equipment required for connector use</p>
Product Weight	<p>~25 - 35 lbs. for welder</p>	<p>Negligible weight per connector</p>

When properly applied, either sterile tubing welders or single-use sterile connectors can create reliable connections. Therefore, factors such as ease of use, potential for downtime, risk for operator error, cost and supply management take on added importance for system designers and processors. Aseptic connectors—particularly genderless models—deliver the flexibility, ease of use, reliability and cost efficiencies sought by today’s bioprocessors.



About CPC

CPC is a leader in single-use connection technology, offering a wide variety of bioprocessing connection solutions. Innovative designs easily combine multiple components and systems including process containers, tubing manifolds, transfer lines, bioreactors and other bioprocess equipment. Sterile fluid connections from CPC range from 1/8” to 1” flow configurations.



For more information, visit:
cpcworldwide.com/bio

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References:

1. “Friday’s Five Questions for the Biotechnology Community” Survey. Aspen Alert. Issue 2441: 8 June 2017.

Confidence at every point of connection.

