

Lynx® S2S and Lynx® ST Connector Tubing Assembly Autoclave Sterilization

Introduction

Lynx® S2S and Lynx® ST connector devices are used in biopharmaceutical processing to perform one-time sterile connections between process steps and vessels. Customers install these connectors into their process by preparing the appropriate tubing, device, and connector assemblies that can be autoclave-sterilized prior to use. The Lynx® S2S connector comprises a female coupling and a male coupling, that when connected together and actuated, create a sterile fluid path connecting two separate process steps. This study was

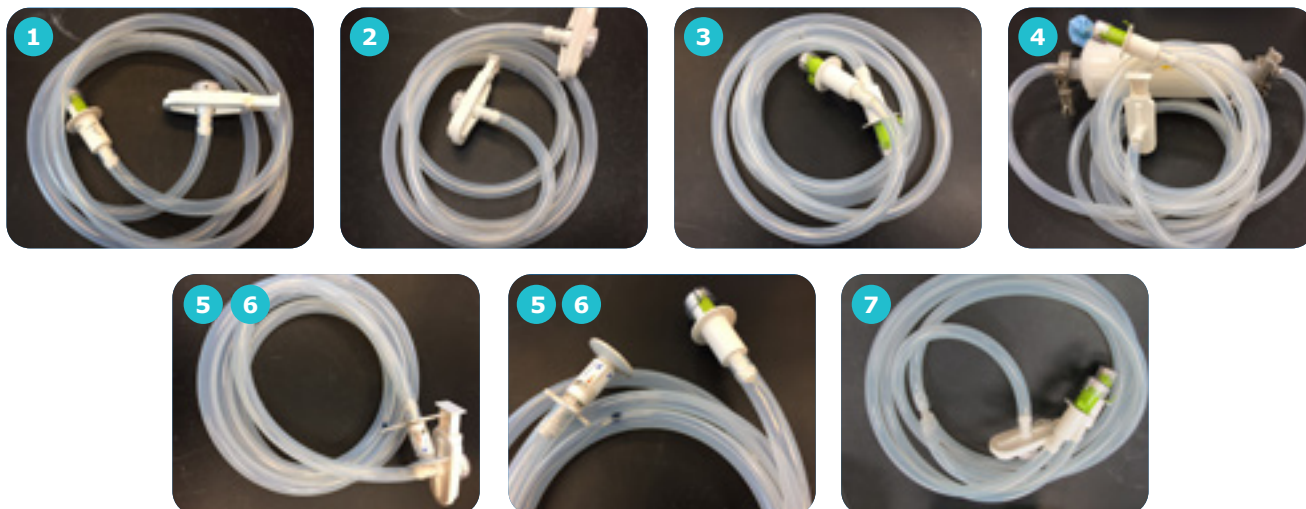
designed to determine the minimum time required to achieve sterilization of different assemblies containing tubing, filters, and Lynx® S2S connectors using both gender couplings and Lynx® ST connectors. To ensure repeatable results, three different lots of male and female Lynx® S2S couplings were used for each assembly type. Sterility was assessed by the absence of growth from biological indicators placed in multiple locations within each assembly.

Sterilization Results

The table below shows the autoclave sterilization time at 121°C required to kill all biological indicator spore threads placed at multiple locations within an assembly. The assemblies comprised 3 m tubing length, using Dow Corning® Pharma 65 tubing (0.5 in. ID x 0.75 in. OD) with various combinations of connector terminations, as well as an assembly containing a 10 in. filter capsule. Assemblies terminated with a Lynx® S2S connector required a maximum 60 min sterilization at 121°C regardless of the coupling gender. For an

assembly containing a 10 in. filter capsule, or an assembly with branched tubing containing multiple male Lynx® S2S connector terminations, 60 min was required to achieve complete sterilization. Assemblies bearing a Lynx® ST connector, with the connector in the open position, were sterilized with a 30 min exposure time, indicating very effective steam penetration. When the same assemblies were autoclaved with the Lynx® ST in the closed position, a minimum sterilization time of 60 min at 121°C was required.

Tubing/Connector Assembly		Time (min) at 121°C	Replicates/lot
1	S2S male - 3 m tubing - S2S female	45	2
2	S2S female - 3 m tubing - S2S female		
3	S2S male - 3 m tubing - S2S male		
4	S2S female - 3 m tubing - 10 in. capsule - 3 m tubing - S2S male	60	3
5	S2S female - 3 m tubing - Lynx ST (open)	30	1
	S2S male - 3 m tubingv - Lynx ST (open)		
6	S2S female - 3 m tubing - Lynx ST (closed)	60	
	S2S male - 3 m tubing - Lynx ST (closed)		
7	S2S male (2) - 1.5 m tubing - Y - connector - 1.5 m tubing - S2S female	60	2



ASSEMBLY

Summary

Tubing assemblies using the Lynx® S2S connector, regardless of gender, and the Lynx® ST connector, can be effectively autoclave-sterilized at 121°C at times ranging from 30 to 60 minutes, depending on the assembly configuration. This study demonstrates the capability of autoclave-sterilization for assemblies containing Lynx® S2S connectors and provides some

general guidelines and recommendations for minimum autoclave-sterilization times of tubing assemblies with different connector terminations. We recommend performing additional studies to validate assembly sterility using your specific assembly, autoclave and conditions. For further information, please refer to the Lynx® S2S connector webpage at [EMDMillipore.com](https://www.emdmillipore.com).

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To place an order or receive technical assistance

Please visit [MerckMillipore.com/contactPS](https://www.MerckMillipore.com/contactPS)

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