

Application Note

Lynx[®] S2S Connector

Low Temperature Compatibility (-80°C)

Introduction

The Lynx[®] S2S connector is a single-use, single-actuation, gamma and autoclave-compatible connector to aseptically connect pre-sterilized fluid paths in biopharmaceutical processes. The Lynx[®] S2S connector facilitates connections between pre-assembled, pre-sterilized filters, tubing, and process containers in classified or non-classified environments.

The Lynx[®] S2S connector consists of a female and male connectors. (See Figure 1). Once these two components are assembled together, the sterile fluid path is enabled.

This technical brief summarizes data concerning the integrity and functionality of Lynx[®] S2S connectors after exposure to low temperature (-80°C).

Quick and easy connectivity

A series of simple steps connects the fluid paths of the Lynx[®] S2S connector by joining the female and male connectors. During the connection process, the male fitting is aligned and snapped into the female fitting. The sealing plugs are positioned into the slider on the female fitting and moved away allowing for the male fitting to be sealed to the female fitting (see Figure 2).

The two previously sterilized flow paths are now one continuous sterile flow path enabled by the design of the Lynx[®] S2S connector. The Lynx[®] S2S connector has been validated to ensure sterile connectivity in non-sterile environments.



Figure 1.
Male and Female Connector of the Lynx[®] S2S connector



Figure 2.
Connected Lynx[®] S2S connector. Once these two components are assembled together, the sterile fluid path is enabled.

Features	Indications
Designed for single actuation	Cannot be disassembled
Male and Female Lynx [®] S2S parts are NOT a valve and do not act as a plug.	Does not stop or control the fluid flow before or after being connected
Must be connected DRY	– Connect before liquid is present or clamp upstream tubing

Test methodology and experimental design

Lynx® S2S female and male connectors were prepared as follows:

- Six male and six female connector fittings were autoclaved at a minimum temperature of 122°C for 30 minutes.
- Six male and six female connector fittings were gamma irradiated at a minimum of 45 kGy.

Compatibility of the Lynx® S2S connectors with low temperatures was demonstrated by:

- Integrity testing of three male and three female Lynx® S2S connector fittings from the autoclave and the gamma sterilized samples. These six devices were tested on the equipment used for product release at the site of manufacture after two freeze and thaw cycles at -80°C.
- Testing the integrity of the frozen and thawed Lynx® S2S connectors via pressurization with water at 70°C.

Integrity of Lynx® S2S female and male connectors after freezing steps

Autoclave and gamma sterilized male and female Lynx® S2S connectors were placed in a deep freezer at -80°C for 24 hours, and then placed at ambient temperature for 8 hours to defrost. The operation was repeated once.

When the device reached ambient temperature after the second freeze-thaw cycle, the female and male connectors were visually inspected. Three sets of male and female Lynx® S2S connectors were integrity tested at the site of manufacture on the test equipment used for the 100% in process integrity test. All six devices met the acceptance criteria.

Functionality of connected Lynx® S2S connectors for the connection functionality

Autoclave and gamma sterilized male and female Lynx® S2S connectors were placed in a deep freezer at -80°C for 24 hours, and then placed at ambient temperature for 8 hours to defrost. The operation was repeated once.

When the device reached ambient temperature after the second freeze-thaw cycle, the female and male connectors were visually inspected. The devices were actuated to create a sterile and leak free flow path.

The connected Lynx® S2S devices were inserted into fluid recirculation test equipment. Hot purified water (average of 70°C) was recirculated to simulate worse case process conditions for 4 hours at 1.5 bar (21.8 psi) in order to stress the connection. The connected Lynx® S2S was cooled for 4 hours at ambient temperature. This operation was repeated once.

Lynx® S2S connection sets were visually inspected and leak tested.

Acceptance Criteria

Male and female fittings must pass the 100% manufacturing integrity test after sterilization and freeze thaw.

Connected Lynx® S2S connector leak tests should not detect any pressure decrease above 35 mbar after 5 minutes at 4.14 bar (60 psi) after exposure to two freeze-thaw cycles, and exposure to hot purified water. Liquid cannot leak from the connected device during each of the 4 hour recirculations.

Results

Integrity after freezing of Lynx® S2S connector

The male and female devices passed the manufacturing integrity test

Gamma Irradiated Lot number	Male connector Air flow rate (ml/min)	Female connector Air flow rate (ml/min)
110907	0.4	n/a
100209	0.3	n/a
100318	0.3	n/a
110127	n/a	3.8
110127	n/a	11.6
110127	n/a	9.0

Functionality of connected Lynx® S2S connector parts

Autoclaved Lot number	Leak test after -80°C exposure (mbar)	Leak test after +70°C exposure (mbar)
101220A/101220A	25.2	23.3
101220A/101220A	22.6	22.3
101220A/101220A	22.3	21.2

Gamma Irradiated Lot number	Leak test after -80°C exposure (mbar)	Leak test after +70°C exposure (mbar)
110218/110127	25.6	21.6
110218/110127	26.8	22.7
110218/110127	22.3	22.7

Following freezing, thawing, and recirculation for two cycles of 4 hours at 70°C (158°F), the stability of all connections were confirmed.

Conclusion

The Lynx® S2S female and male connectors are compatible with temperatures as low as -80°C. All male and female connectors remained integral per the manufacturing release integrity test prior to actuation after being subjected to the two freeze and thaw cycles. The connected devices were shown to be integral after exposure to 70°C hot water pressurization at 1.5 bar per the connected integrity test and by visual inspection. No liquid leaks were observed.

Acknowledgement to Provantage® Lab Services

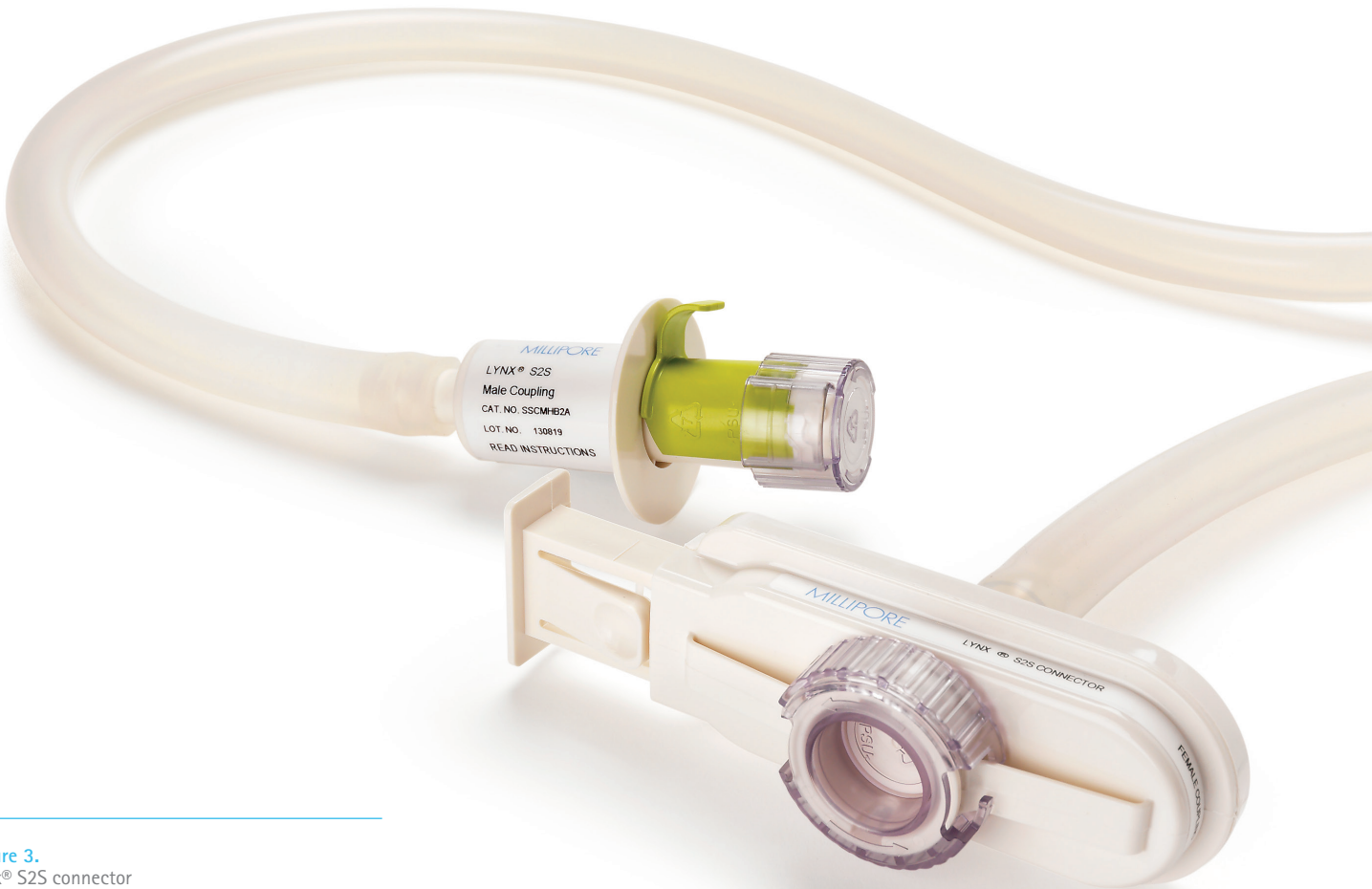


Figure 3.
Lynx® S2S connector

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