

ONCOERA® SF401 CLOSED MALE LUER CONNECTOR MULTIPLE USE EVALUATION

STUDY INFORMATION

Test Date

17.05.2023-18.05.2023

Report Date

22.05.2023

Test Equipment

- Devotrans DVT VKE 8 Vacuum
- Technoideal P-Test Nine



PURPOSE OF THE STUDY

To evaluate the performance of ONCOERA® SF401 Closed Male Luer Connectors in multiple uses.

ONCOERA® SAFE Needle-Free Syringe Adapters are connectors used for the safe preparation and transport of hazardous drugs.

Syringe Adapters creates a closed system between syringe and vial adapters, as well as infusion sets and needle-free connectors. In this way, it reduces the risk of exposure to hazardous drugs and protects the drug from microbiological contamination.

STUDY PROTOCOL

Experimental Group

In the experimental group, SF401 Closed Male Luer Connector samples were tested. The sealing properties of the samples were tested under a vacuum of 7.25 Psi and compressed air at 5 Psi before multiple use. Then, 100 + 100 (200 in total) syringe activations were applied to the samples, respectively. At the end of 100 activations and after reaching a total of 200 activations, the tests were repeated and visual controls were performed.

Positive Control Group

In addition, damaged SF401 Closed Male Luer Connector specimens were tested as a positive control group. After the silicone part in the samples in this group was damaged with a pointed tool, then the same procedures and tests were performed on the samples of the experimental group.

Pressure Unit Reference Values

1 kPa = 10 hPa = 0,1450376808 Psi



CONCLUSION

Experimental Group

For the samples tested, the following were determined in use up to 200 syringe activations.

- No leakage
- No break in the luer lock
- No drips from connection port.

The performance of the product in multiple uses has been confirmed for the specified number of activations and for the specified criteria.

Positive Control Group

The silicone part of the samples was damaged with a pointed tool, then pre-activation tests were applied to the damaged samples and leakage was detected as expected. For this reason, post-activation tests were not applied to the positive control samples.

The sealing performance of ONCOERA® SF401 Closed Male Luer Connectors has been validated in multiple uses.