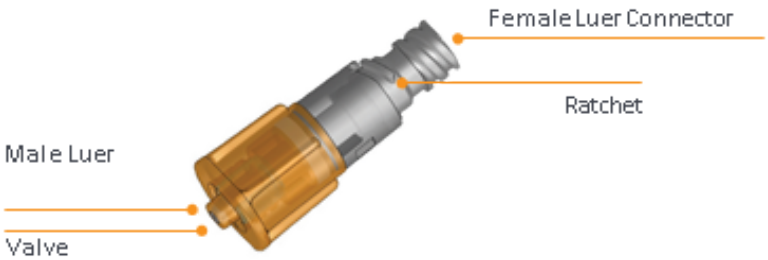
MICROBIAL CHALLENGE EVALUATION

ONCOERA SF 401 CLOSED MALE LUER CONNECTOR

ONCOERA SF 401, a Closed Male Luer Connector, is designed to minimize dripping of liquids and drugs from a male Luer connector that is commonly used in hazardous drugs administration. The device is composed of a normally closed male luer valve from its proximal end that opens upon the connection of the male luer connector to a female luer connector and closes automatically upon disconnection of the two. The male luer tip is level with its valve mechanism ensuring no drug residues remaining on the tip. From its distal end the device includes a female luer connector, allowing it to be connected to many medical devices for fluid administration, e.g. a syringe or infusion set. The female luer connector is designed with a ratchet mechanism that prevents in advertent detachment of the ONCOERA SF 401 from a syringe or infusion set and thereby reduces the risk of hazardous drug spillage.



DATE OF STUDY

2016' FEB

PRODUCT

ONCOERA SF 401
CLOSED MALE LUER CONNECTOR

MANUFACTURER

ERASER MEDİKAL LTD. ŞTİ.

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SUMMARY

Purpose

To evaluate the microbiological barrier-forming performance of ONCOERA SF 401 at worst clinical cases by using 4 types of nosocomial infection organisms.

- Gram positive: Staphylococcus aureus ATCC#6538 and MRSA ATCC#43300.
- Gram negative: Enterobacter aerogenes ATCC#13048 and Pseudomonas aeroginosa ATCC#9027

Method

The testing was conducted in accordance with ISO 11737-1:2006 standard and FDA guidelines for Microbial Ingress Testing. During the study, ONCOERA SF 401 was inoculated with 4 types of bacteria mentioned above. The inoculation suspensions were concentrated at 104-105 CFU. After inoculation, test specimens were left undisturbed for 30 minutes. After which the connector male luer tips were swabbed with 70% Isopropyl Alcohol (IPA) pad, according to common hospital procedures, then followed by a flush of normal saline solution.

The saline solution was then collected and incubated. Following the incubation, CFU enumeration was determined, using pour plate method technique, according to USP <61>. In each test group the bacterial counts were <1 CFU/2mL, demonstrating that the ONCOERA SF 401 can serve as an effective microbial barrier. Two control groups were also tested during the study:

• A Negative Control – went through the same procedure as the test groups, but without microorganisms' inoculation. Test results from this group were also <1 CFU/2mL, negating the possibility that the source of microorganisms was not from the inoculation itself.

• A PositiveControl – went through the same procedure described above but without swab after inoculation (before flush). Test results from this group were <1.0X104 CFU/2mL, demonstrating the effectiveness of the swabbing process.

Conclusion

The ONCOERA SF 401 Closed Male Luer Connector effectively acts as a microbial barrier, minimizing microbial ingress when used during administration or admixture of hazardous medications. The validity of this claim is supported by testing data.

ONCOERA SF 401 Closed Male Luer Connectors have been validated to provide a microbiological barrier.

The study was conducted using a higher concentration of challenge organism then typically found in a hospital environment and a non-typical extended time period.

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