OLAV™ Closed Male Luer Connector Microbial Challenge

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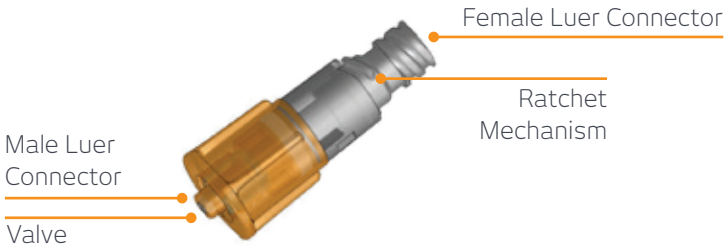
Introduction

Antineoplastic drugs are toxic not only to cancerous tissue but to healthy organs as well. Long-term contact with such drugs was shown to have mutagenic and even cancer-promoting effects[1,2]; therefore, a number of devices have become available to enhance healthcare worker safety in handling such drugs. These devices, not only need to minimize hazardous drugs exposure but also must perform as a microbial barrier, minimizing the likelihood of microbial ingress into the drug administration system and ultimately to the patient. Guidance for demonstrating such microbial barrier is provided by both ISO Standard 11737[3] and the FDA[4]. The following summary will show that the OLAV™ Closed Male Luer Connector device minimizes microbial ingress from the environment and provides the necessary microbial barrier.

System, Description & Performance

OLAV™, 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 inadvertent detachment of the OLAV™ from a syringe or infusion set and thereby reduces the risk of hazardous drug spillage.



Prevention of Microbial Ingress

The effectiveness of OLAV™ design in preventing bacterial ingress was demonstrated in a definitive third-party study[5] supported by Elcam Medical ACAL. In this study, the device was challenged by high concentrations of four bacteria type suspensions simulating extreme case scenarios. The testing was conducted in accordance with ISO 11737-1:2006 standard3 and FDA guidelines for Microbial Ingress Testing[4]. During the study, OLAV™ was inoculated with 4 types of bacteria, which are common nosocomial infection microorganisms:

Gram positive:

- Staphylococcus aureus ATCC#6538
- MRSA ATCC#43300

Gram negative:

- Enterobacter aerogenes ATCC#13048
- Pseudomonas eroginosa ATCC#9027

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Since the staphylococcus family is smaller in size in comparison to other microorganisms, it is also the biggest challenge for the barrier provided by OLAV™. Two types of microorganisms where chosen from this family. The inoculation suspensions were concentrated at 10^4-10^5 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>[6]. In each test group the bacterial counts were <1 CFU/2ml, demonstrating that the OLAV™ 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. The reason for this test was to ensure the absence of microorganism growth and to ensure that the microorganisms are not derived from the product itself, the swab, the syringe or the saline solution. 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 Positive Control –** went through the same procedure described above but without swab after inoculation (before flush). The reason for choosing this group was to ensure that the microorganism exhibit growth that is typical to the microorganism, that they did not die on their own while being in the device or harmed by the physical stresses they were exposed to during removal. Test results from this group were <1.0X10^4 CFU/2ml, demonstrating the effectiveness of the swabbing process.

Conclusion

The OLAV™ 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.

References

1. S. Burgaz et al., Human Toxicol., 1988, 7, 557
2. T. Skov et al., Br. J. Ind. Med., 1992, 49, 855
3. ISO 11737-1:2006 – "Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products".
4. FDA guidance "guidance for Industry and FDA staff, Intravascular Administration sets premarket Notification Submission [510(k)], July 11, 2008, section 8: Microbial ingress testing".
5. Institute for Food Microbiology & Consumer Goods, Nesher Israel, CMC VV Test Report for Microbial Challenge Protocol No. EL1 Rev.1, Issue date 14.06.2011
6. USP <61> 2009: Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests

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