B BRAUN
SHARING EXPERTISE

CLINICAL
PERFORMANCE
STUDIES

Caresite® Needlefree Connector

CLEAN, CLEAR CONNECTION

CONTENTS

For a full version of any of the studies detailed, please ask your B. Braun Medical Ltd representative

Caresite®: Clean, Clear Connection

MICROBIAL INGRESS STUDY 1

BACKGROUND

It is widely acknowledged that the physical features of the surface of a needlefree connector can influence the effectiveness of decontamination. A flat, sealed, solid access surface is considered superior and the fluid pathway should be simple in design to prevent the risk of bacteria becoming trapped inside the needlefree connector[3,9]. The following microbial ingress studies were undertaken to assess the microbial barrier performance of Caresite after 5 and 7 days.

Casey, A., et al. (2015). An In Vitro Comparison of Microbial Ingress into 8 Different Needleless IV Access Devices[2]

AIMS

To assess the differences between the rates of microbial ingress into 8 different needlefree connectors following contamination with Colony Forming Units (CFU) of Staphylococcus Aureus over 7 days of clinical simulation.

METHODOLOGY

24 of each device were exposed over a period of 7 days to 5 rounds of inoculation with viable Staphylococcus Aureus and decontaminated with a Sani Cloth® wipe (70% Isopropyl alcohol) following either a 5 or 15 second cleaning regime. All flush eluates were collected and incubated for assessment of microbial ingress.

RESULTS

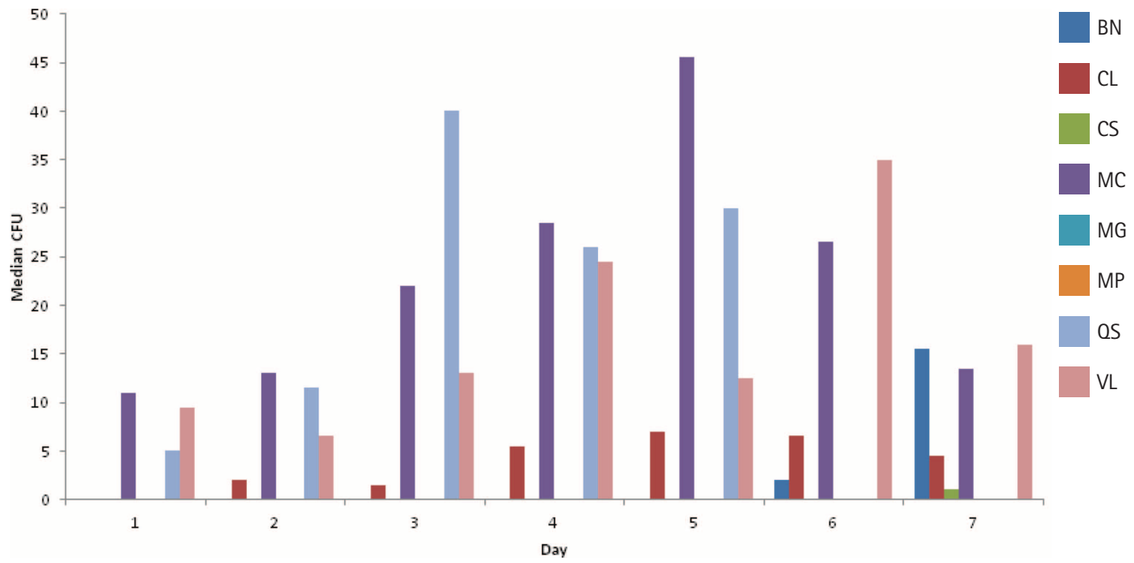
Following 7 days use, and with both cleaning regimes, significantly fewer CFUs were detected in the eluates collected from Caresite:

Days 1 – 6 median CFUs = 0

Day 7 median CFUs = 1

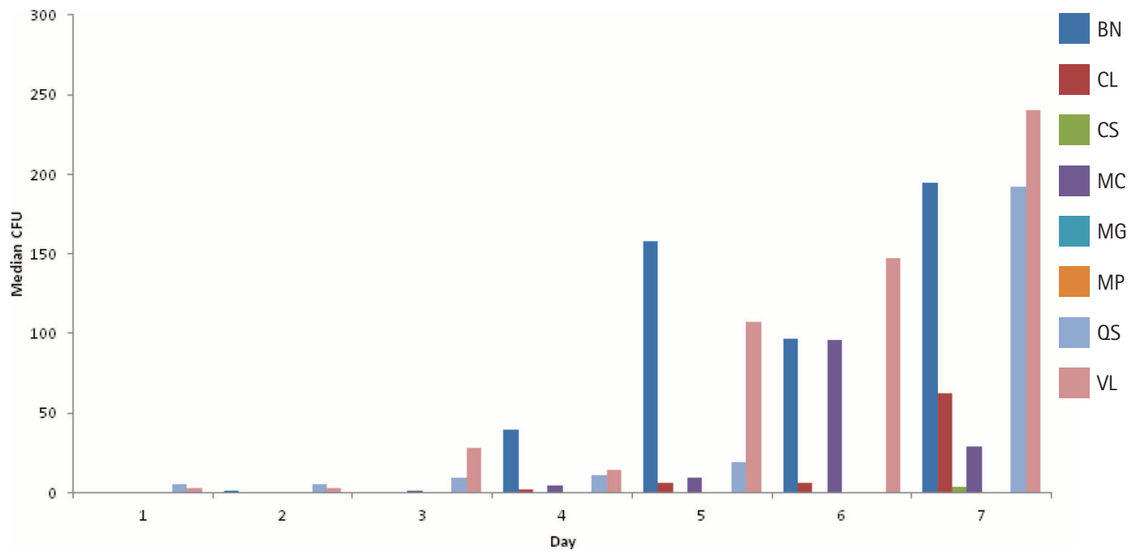
This was attributed to Caresite providing an easy to decontaminate access surface.

5 SECOND CLEANING REGIME



Median CFU of Staphylococcus Aureus recovered from each daily saline eluate of 8 different needleless IV access devices over 7 days of simulated clinical use with a 5 second cleaning regimen (n = 12). Abbreviations: BN, Bionector; CFU, colony forming unit; CL, Clave; CS, CARESITE; IV, intravenous; MC, MicroClave Clear; MG, MaxGuard; MP, MaxPlus Clear; QS, Q-Syte; VL, V-Link.

15 SECOND CLEANING REGIME



Median CFU of Staphylococcus Aureus recovered from each daily saline eluate of 8 different needleless IV access devices over 7 days of simulated clinical use with a 15 second cleaning regimen (n = 12). Abbreviations: BN, Bionector; CFU, colony forming unit; CL, Clave; CS, CARESITE; IV, intravenous; MC, MicroClave Clear; MG, MaxGuard; MP, MaxPlus Clear; QS, Q-Syte; VL, V-Link.

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MICROBIAL INGRESS STUDY 2

B. Braun Medical Inc. (2010). Caresite® Luer Access Device: Microbial Barrier Performance of the Needlefree Connector[10]

AIMS

The aim of this study was to analyse the microbial barrier performance of Caresite when challenged with CFUs of 4 different species of microorganism over 7 days of clinical simulation.

METHODOLOGY

24 of each needlefree device were inoculated daily for 7 days with 4 species of microorganism: Staphylococcus Aureus, Staphylococcus Epidermidis, Pseudomonas Aeruginosa, Escherichia Coli – and decontaminated with a 70% Isopropyl alcohol wipe for 15 to 20 seconds. Devices were accessed every 3 hours and daily flush eluates were collected and incubated for assessment of microbial ingress.

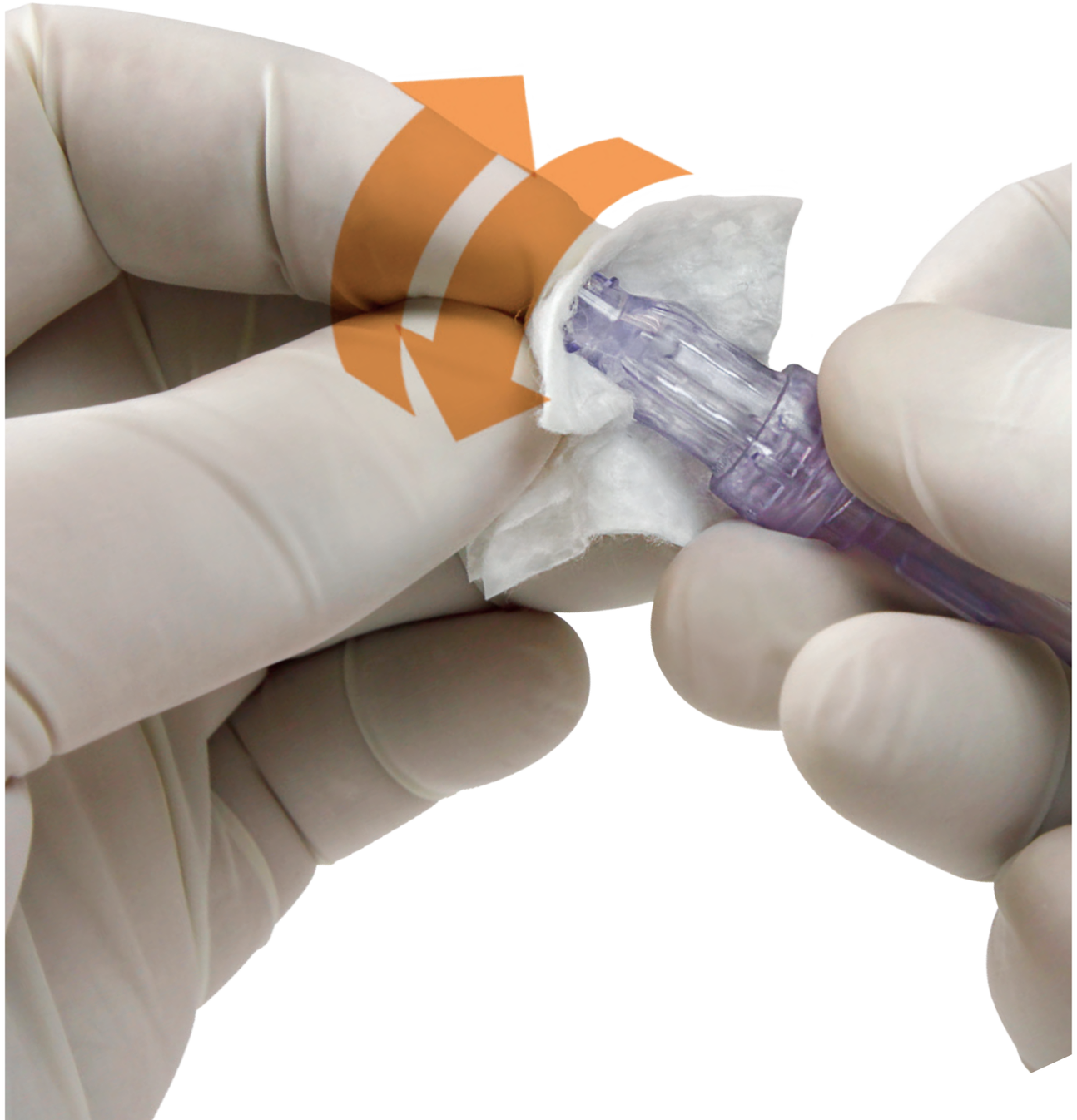
RESULTS

Following 7 days of clinical simulation no clinically significant microorganisms of any of the 4 test species were detected. As such this study further demonstrates that Caresite prevents passage of microorganisms* through the needlefree connector following thorough, well defined cleaning after each use.

Caresite needlefree devices growing greater than 15 CFU of the test species

ORGANISM	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
Staphylococcus Aureus	0	0	0	0	0	0	0
Staphylococcus Epidermidis	0	0	0	0	0	0	0
Pseudomonas Aeruginosa	0	0	0	0	0	0	0
Escherichia Coli	0	0	0	0	0	0	0

*No CFU greater than 15



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MECHANICAL HAEMOLYSIS STUDY

B. Braun Medical Inc. (2010). Caresite® Luer Access Device: Mechanical Haemolysis Test of the Needlefree Connector[12]

BACKGROUND

Haemolysis can lead to unreliable laboratory results or in samples being rejected for coagulation testing resulting in delays to patient care. As such it is important when selecting your needlefree device to ensure that it does not increase the risk of mechanical haemolysis.

AIMS

The aim of this study was to demonstrate that blood sampling and infusion can be performed via the Caresite needlefree connector without increased risk of mechanical haemolysis.

METHODOLOGY

The average rate of haemolysis of 15 Caresite needlefree connectors was measured using citrated whole rabbit blood. Between 1-2 mls of blood were aspirated or injected through each device to facilitate testing.

After the blood samples were collected they were diluted with 0.9% sodium chloride. The samples were centrifuged to separate supernatant from the blood pellet. The supernatant was assessed for absorbance using a spectrophotometer, a method to determine the amount of light absorbed by liquid.

Positive and negative controls determined the absorbance to haemolysis ratio.

RESULTS

The haemolyitic rate for blood aspirations through Caresite was 0.4% for blood aspiration and 0.2% for injection. The haemolysis values were well below the 5% haemolysis limit[13], indicating that the material used and the design of the device does not produce haemolysis.

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SYRINGE ATTACHMENT FORCES STUDY

B. Braun Medical Inc. (2014). Caresite® Luer Access Device: Easy to Connect[14]

BACKGROUND

The use of an extension set between a peripheral catheter and a needlefree connector is recommended to reduce catheter related manipulation and associated complications[6]. To further assist in reducing catheter manipulation, Caresite has been designed to require minimal connection force upon attachment of a Luer connector.

AIMS

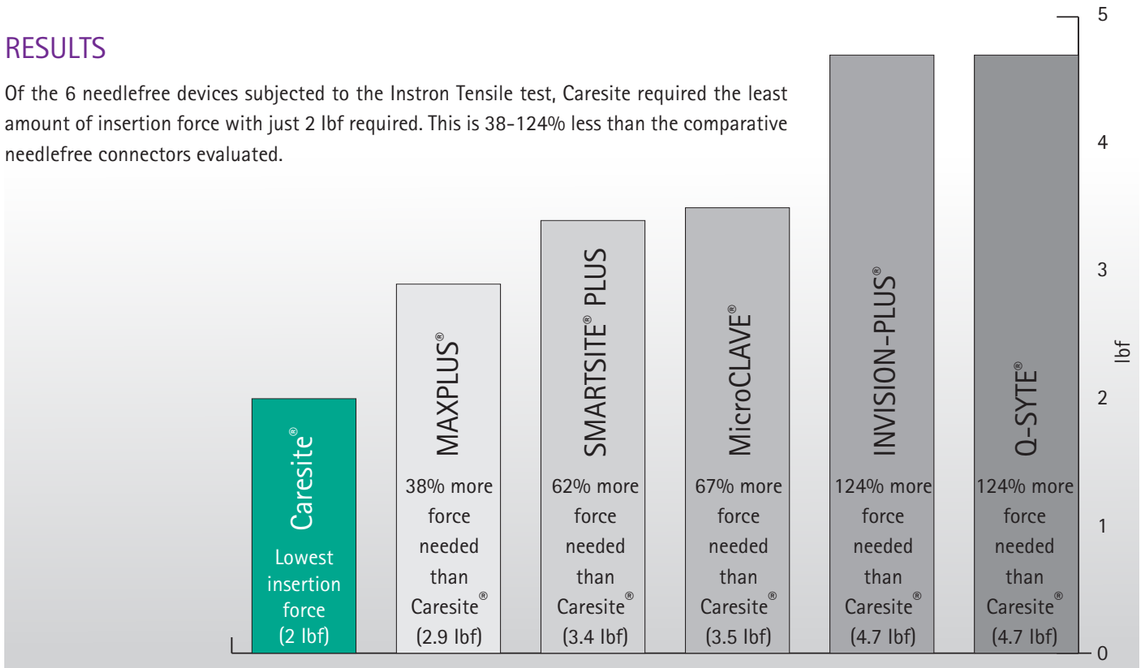
To determine the force required to move the internal mechanism of 6 needlefree valve devices from the closed to the open position.

METHODOLOGY

A male Luer Instron Tensile Tester was used to measure the pounds force (lbf) required to fully open 6 different needlefree connectors. The Intsron Tensile Tester was held in place for 5 seconds maintaining the open position of the needlefree valve. The peak point of the insertion force was recorded for 12 samples of each needlefree device.

RESULTS

Of the 6 needlefree devices subjected to the Instron Tensile test, Caresite required the least amount of insertion force with just 2 lbf required. This is 38-124% less than the comparative needlefree connectors evaluated.



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