ROBERTSITE

NEEDLE FREE VALVE

Solmed Pty Ltd

Robertsite Needle Free Valve

Halkey-Roberts new swabable luer valves were developed as needle free injection ports in IV applications. They are designed to aspirate or inject fluids on demand. The valves allow multiple usages and require no cap. Valve stems and bodies will mate securely with all standard luer syringes and luer connectors.

All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and latex-free. The Straight valves are polycarbonate for easy bonding.

Produced under GMP: Halkey-Roberts is an ISO 9001-2000, ISO 13485-2003 and FDA registered manufacturing facility. Luer fittings are compatible with American National Standards for luer and taper fittings under ANSI/HIMA MD 70.1-83 and ISO 594.

The valve used on Multigate sets has the highest flow rates in the industry and is the preferred standard world wide for non-positive pressure valves that are swab able needle free.

STRAIGHT

Y PORT

STRAIGHT VALVE - SPECS

Performance characteristics

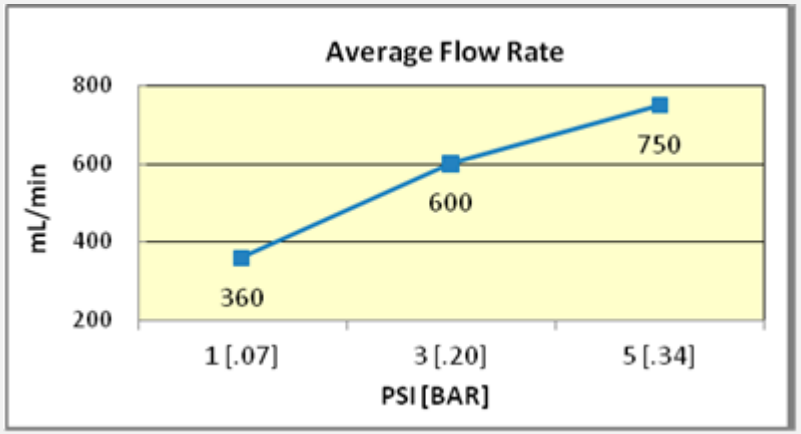
- Priming volume: 0.09ml

Flow rate averages

- Flow rate @ 1 psi: 360ml / minute (21,000ml/hr @ 30 inch height)
- Flow rate @ 3 psi: 600ml / minute
- Flow rate @ 5 psi: 750ml / minute

Materials

- Swabable stem: blue silicone
- Swabable body: clear polycarbonate
- DEHP [di(2-ethylhexyl)phthalate] & latex free, lipid resistant
- Sterilization method: EO (Ethylene Oxide)



Y-PORT- SPECS

Performance characteristics

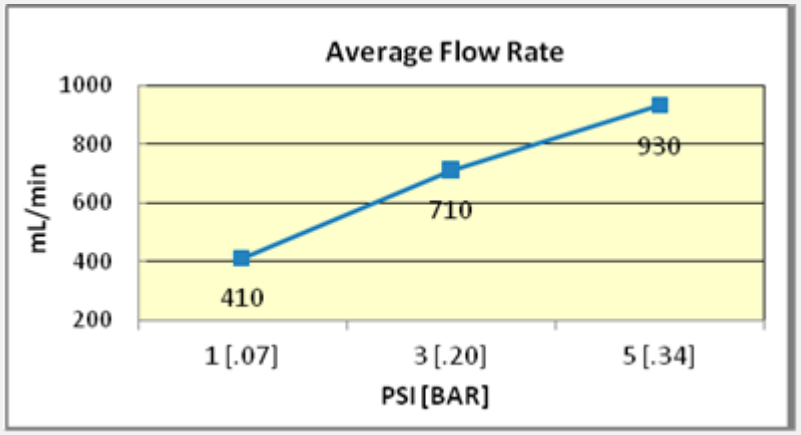
- Priming volume (without tubing): 0.19ml

Flow rate averages

- Flow rate @ 1 psi: 410ml / minute (24,600ml/hr @ 30 inch height)
- Flow rate @ 3 psi: 710ml / minute
- Flow rate @ 5 psi: 930ml / minute

Materials

- Swabable stem: blue silicone
- Swabable body: clear polycarbonate
- DEHP [di(2-ethylhexyl)phthalate] & latex free, lipid resistant
- Sterilization method: EO (Ethylene Oxide)



OPERATION OF VALVE

In the closed position the valve guarantees the complete sealing of the infusion system up to 35psi. This means that the valve does not allow any solution to exit unless a pressure higher than 35psi is created.

When connected with a standard luer, the valve opens for flow. Silicone stem provides a hermetic seal between the luer and the valve. The valve has no obstructions in the flow path so hemolysis is minimal and flow rate is maximized.

Features:

- Minimal back flow upon syringe removal (only – 0.02ml). Which can be completely eliminated using one of the following 2 simple techniques:
  - Close the clamp between the valve and the catheter before disconnection.
  - Keep the syringe plunger slightly under pressure during the disconnection.
- High flow
- Easy access with either slip luer or luer lock syringes
- Low priming volume
- Straight through design for unimpeded flow
- Low priming volume (0.09ml)
- Easy to disinfect
- Tested up to 200 usages or 7 days whichever is sooner

TECHNICAL INFORMATION

CHARACTERISTICS	SPECIFICATION	TYPICAL / TESTED
Back Pressure	>30 PSIG	40 PSIG
Activation Force	< 4 LB	1.9 LB
Priming Volume	< 0.20 ml	0.09 ml
Residual Volume	N/A	0.11 ml
Flow		
@ 1 PSIG head pressure	> 50 ml/ min	360 ml/ min
@ 3 PSIG	N/A	600 ml/ min
@ 5 PSIG	N/A	750 ml/ min
Leak During Use		
@ 1 PSIG	None	None
@ 5 PSIG	None	None
@30PSIG	None	None
Multiple Use	Leak Free after 100 activations, >30 PSIG	36 PSIG
Extended Use	Leak Free after 24 Hrs engagement, >30 PSIG	37 PSIG
Microbial Barrier	Passes Microbial Challenge for repeated access using 70% IPA as a surface disinfectant and Staphylococcus aureus ATCC #6538 as a challenge organism	PASS (12 activations in 3 days interval) PASS (140 activations in 7 days interval)
Sterilization	Sterilize by ETO	PASS

SUMMARY OF BIOCOMPATIBILITY TEST RESULTS ISO 10993-1 STANDARD TESTING PROCEDURES

Test performed	Interpretation	510(k) FDA
Cytotoxicity	The test article is considered non-cytotoxic	K002689
Acute Systemic Toxicity	The test article extracts would not be considered systemically toxic	K002689
Acute Intracutaneous Reactivity	No evidence of significant irritation or toxicity from the extracts injected intracutaneously into rabbits	K002689
Hemolysis (direct contact and chemical)	The test article was determined to be nonhemolytic (less than 5%)	K002689
Pyrogen Study – Material Mediated	The test article extract was judged as non-pyrogenic	K002689
Guinea Pig Maximization	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig	K002689

VALVE COMPARISON

Product	Robertsite®	Clearlink®	Q-SyteTM	MicroClave® Clear	Smartsite®
Product Image					
Supplier	MDevices	Baxter	BD	Hospira / ICU Medical	Alaris
Type of Access	Split Septum	Luer Activated	Split Septum	Split Septum	Luer Activated
Clear Housing	Yes	Yes	Yes	Yes	Yes (partly)
Housing Material	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate
Access Material	Silicone	Silicone	Silicone	Silicone	Silicone
Straight Fluid Pathway	Yes	No	Yes	Yes	Yes
Luer Lock and Luer Slip	Yes	Yes	n/a[1]	Luer Lock only	Yes
Flow Rate[2]	550 ml/min	122 ml/min	533 ml/min	165 ml/min[3]	148 ml/min
Priming Volume	0.09 ml	0.25 ml	0.10 ml	0.049 ml	0.11 ml
Cytotoxic Drugs Compatibility	Yes	Yes	Yes	Yes	Yes
Lipid Compatibility	Yes	Yes	Yes	Yes	Yes
Blood Compatibility	Yes	Yes	Yes	Yes	Yes
MRI Compatibility	Yes	Yes	Yes	Yes	Yes
DEHP Free	Yes	Yes	Yes	Yes	Yes
Latex Free	Yes	Yes	Yes	Yes	Yes

Sources:
Halkey Roberts Corp. data
Published company data

[1] Data not available
[2] Tested according to ISO10555.1 - Annex E
[3] Tested at gravity

TEST 1 - 7 DAY MICROBIAL CHALLENGE EVALUATION

The inoculated sites were allowed to sit undisturbed for thirty minutes. Valves were then swabbed as described above with 70% IPA followed by drying for a minimum of one (1) minute. After drying, each valve was accessed using a new, sterile syringe and flushed with 10 ml of sterile saline. The saline was collected and filtered through a 0.45-micron membrane filter. The filter was placed on TSA and incubated at 30 – 35 C for 48 hours. Following the incubation period, the CFU's for each valve filtrate were enumerated.

Purpose: To demonstrate the integrity of the Robertsite Luer Activated Injection Site (valve) microbial barrier properties after seven days (168 hours) of simulated worst case clinical use (140 activations) using a common nosocomial infection organism, Staphylococcus aureus.

Protocol Summary: AppTec Laboratory Services,Marietta,GA, performed all laboratory testing. Each of 20 devices was accessed 20 times per day for seven days (140 total activations) Each sample was challenged daily after repeated activations using approximately 1.0 x 103 colony forming units (CFU)/ 0.01ml of the challenge organism (Staphylococcus aureus). After routine disinfection of the device, 10 ml of sterile saline was injected through it and passed through a .45µ membrane filter. The filters were incubated on Tryptic Soy Agar (TSA) at 30 - 35ºC. for 48 ± 4 hours and the colony forming units (CFUs) enumerated. The study included two positive, two negative and three sterility control samples. Each of the test samples and positive controls were challenged using the simulated clinical use model. They were swabbed and accessed 20 times each day. Inoculation and CFU determinations were done after the last activation for the day, as well as the first activation on Day 1. Prior to each access the injection site of each valve was swabbed with a fresh sterile 70% isopropyl alcohol (IPA) pad folded once for 25 – 30 seconds followed by drying for a minimum of one (1) minute. After drying, each valve was accessed using a new, sterile syringe and flushed with 10 ml of sterile saline.

Inoculum: A fresh culture of Staphylococcus aureus was used each day. A suspension was prepared and diluted to approximately 1.0 x 103 Colony Forming Units (CFU)/0.01 ml for use as an inoculant and stored at 2-8°C. The inoculum population during the seven day test period ranged from 9.3 x 102 to 5.4 x 103 CFU/0.01 ml. Prior to inoculation of test samples and positive controls, each seal was swabbed as described above and was allowed to dry for a minimum of one (1) minute. 0.01 ml of inoculum was placed directly on the top of bed and accessed twenty times each day as described above. After the last access of the day, the saline was collected and filtered through a 0.45-micron membrane filter. The filter was placed on TSA and incubated at 30 – 35 C for 48 hours. Following the incubation period, the CFU's for each valve were counted. The sterility controls (sterilized devices) were placed in 30 ml tubes of tryptic soy broth and incubated at 30 – 35 C for seven days.

Results: During the seven days and 140 accesses of the test study using the method described above, the Robertsite valve test samples and the challenge organism, positive controls exhibited growth typical of the challenge organism. The recovery ranged from 5 x 100 to 9.4 x 102 CFU with a mean count of 1.86 x 102CFU. Sterility controls demonstrated absence of growth after seven days of incubation.

Conclusion: The Robertsite Luer Activated Valve, when used with an adequate disinfection procedure, maintains its microbial barrier properties after 140 activations over a 7-day period. The study was conducted using a higher concentration of challenge organism than typically found in a hospital environment and a non-typical extended time period.

TEST 2 - FLUSHING STUDY

Purpose: To demonstrate the flushing efficiency of Robertsite Swabable valves. Tested samples were: Halkey-Roberts Robertsite® "Swabable Straight Valve"

Protocol Summary: AppTec Laboratory Services,St. Paul,MN, performed all laboratory testing. Three (3) Halkey-Roberts Robertsite® "Swabable Straight Valves" were tested. 5 mL of human blood was aspirated through each valve. The valves were exposed to the blood for 10 minutes at room temperature. The blood was removed by the attached syringe immediately prior to initiation of flushing. Each valve was flushed with 1mL deionized water. The flushing was repeated five times. The eluates were collected into sample tubes and analyzed for total hemoglobin concentration and flushing efficiency (% clearance).

Method: The study included positive and negative controls. The positive controls were filled with a solution of 5.0 mL of sterile water mixed with 0.35 mL of whole blood. The negative controls were filled with water only. Test samples: 5 mL of blood was aspirated through each sample valve and left for 10 minutes at room temperature. The syringe was then removed immediately prior to flushing. The valve tip was blotted, and a new syringe with flushing fluid was attached. Each valve was flushed with 1 mL of deionized water and the flush was collected into labeled tubes. The flush was repeated five times. The hemoglobin concentration in the samples was determined using Drabkin's reagent at 1:1 ratio. After a 15 minute incubation at room temperature, the absorbance of each sample was read using a spectrophotometer at a wavelength of 545 nm. Controls were tested concurrently. The total hemoglobin concentration and % clearance were determined for each flush separately.

Results: 100 % clearance was achieved by the 3rd flush for the Halkey-Roberts Robertsite® "Swabable Straight Valve"

Conclusion: The Robertsite valve has demonstrated that it can be effectively flushed using the methods performed in this study.

TEST 3 - MULTIPLE USE EVALUATION

Purpose: To demonstrate Robertsite Luer Activated Injection Site integrity after 200 activations.

Background: Robertsite valves were tested for sealing performance before and after 200 activations.

Results: Assembled Robertsite valves passed back pressure sealing performance testing after 100 activations and after 200 activations. The mean back pressure range was 46 to 48 psig. The -3 values ranged from 37 to 42 psig. All samples fell within a +/-3 distribution.

Conclusion: The Robertsite valves were assembled per HRC procedures and accessed by a standard luer (ISO594-1/-2) connector. After 200 accesses, all Robertsite devices passed the HRC specification for back pressure seal performance (30 psig minimum).

SOLMED PTY LTD

- 02-47210371
- sales@solmed.com.au
- www.solmed.com.au