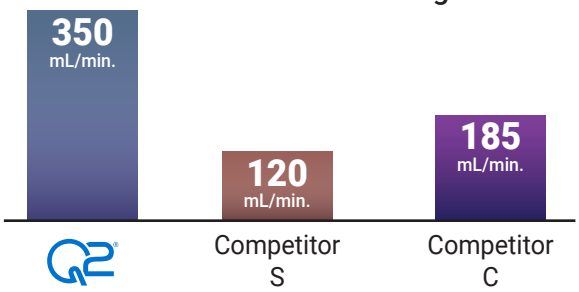
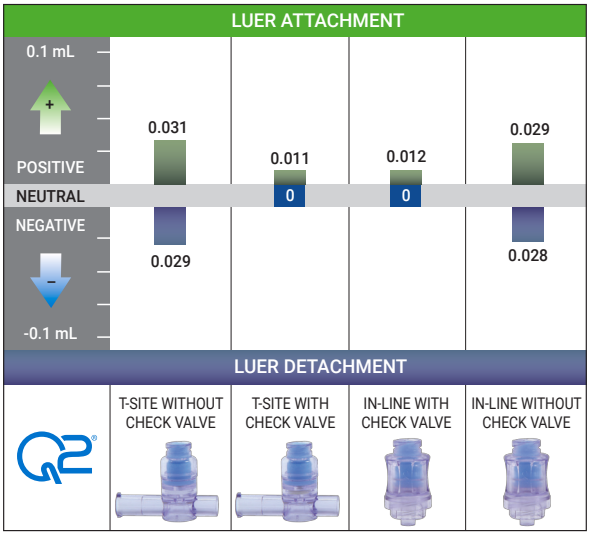
NEEDLE-FREE INJECTION CAP
REFERENCE SHEET

Flow Rate Testing

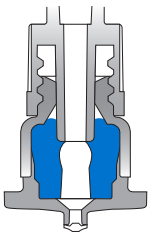


Neutrality Testing



Hemolysis Testing

Non-hemolytic for both blood infusion and withdrawal.



Q2® Injectable Cap
engaged

Q2® Injectable Cap
unrestricted flow path

Sterile Barrier Testing

- Maintains a sterile barrier for up to 7 days.
- Allows more than 100 luer activations.

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Neutrality Verification Study

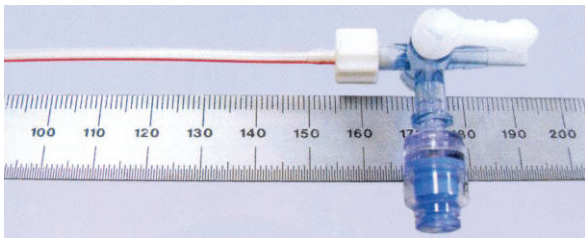
Evaluating fluid displacement

Objective

A desirable characteristic of an injection site is to have zero fluid displacement upon attachment or detachment of a syringe. A "neutral" site is a site which allows zero or minimal fluid displacement. The study objective was to evaluate the volume of fluid displacement created by each model of the Q2® Needle-Free Injection Cap upon attachment and detachment of a male luer-lock syringe. Products evaluated in the study were the Q2 T-Site without check valve, the Q2 T-Site with check valve, the Q2 In-Line without check valve and the Q2 In-Line with check valve.

Experimental Design

Small-bore tubing was attached to a 3-way stopcock as pictured below. The stopcock was positioned so that the injection site and the free port were open and the injection site was primed. The stopcock was repositioned so the injection site and small-bore tubing were open.



A syringe was filled with water and attached to the injection site. Pressure was applied to the syringe until the fluid line was visible in the tubing. The syringe was detached from the injection site. A scale was placed along side the tubing and aligned with the visible fluid line. A syringe was connected to the injection site. The fluid movement was recorded. The scale was repositioned with the new location of the fluid line in the tubing. The syringe was disconnected and the fluid movement was recorded. This process was repeated five times for each of the five test samples for each injection site – equaling 25 attachments and 25 detachments for each injection site.

Results

As can be seen in the Table 1 and illustrated in the figure below, no fluid displacement was measured during detachment from the Q2 T-Site wit check valve or the Q2 In-Line with check valve. Minimal fluid displacement, ~0.03 mL was measured on the T-Site and the In-Line injection caps without check valves.

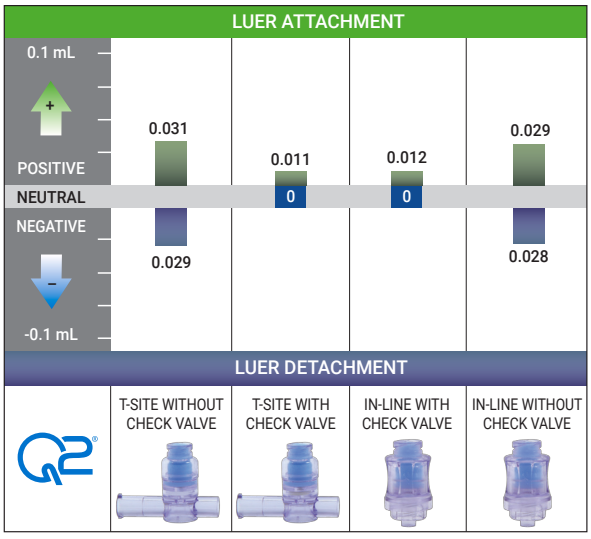
Neutrality Testing

(Details in Table 2)

Table 1

Value N=25	Fluid Displacement Volume mL		Fluid Displacement Volume mL		Fluid Displacement Volume mL		Fluid Displacement Volume mL		Fluid Displacement Volume mL	
	800917		800922 w/check valve		800925 w/check valve		800926		800942 w/check valve	
	Attach	Detach	Attach	Detach	Attach	Detach	Attach	Detach	Attach	Detach
Average	0.031	0.029	0.011	0.000	0.012	0.000	0.029	0.028	0.012	0.000
Maximum	0.043	0.032	0.013	0.000	0.013	0.000	0.032	0.030	0.015	0.000
Minimum	0.028	0.029	0.009	0.000	0.011	0.000	0.028	0.026	0.009	0.000

Table 2



Q2® TECHNOLOGY

7-Day Microbial Barrier Challenge

Evaluating infectious agent growth potential

Objective

The objective of this study was to evaluate the Q2 Injection Cap from an infectious agent barrier standpoint after multiple activations for a period of seven consecutive days.

Experimental Design

Seven (7) Q2 T-Sites were submitted for this testing scenario. Five (5) parts were used for the testing, one as a negative control, and one as a positive control. The five test samples were inoculated daily with Staphylococcus Aureus. A culture of inoculate was prepared each day in a sterile buffer and the concentration was measured each day (minimum concentration of 1700 CFU/0.01 mL of inoculate; average concentration of 2700 CFU/0.01 mL).

Each valve was cleaned with a fresh swab of 70% IPA for a minimum of five seconds. Inoculation occurred at the beginning of the day, each of the seven days, prior to the first activation. The inoculate was distributed (0.01 mL) evenly on the top of the valve. The inoculated valve was left undisturbed for a minimum time of thirty (30) minutes. After thirty minutes, the valve was cleaned using 70% IPA for at least five seconds.

The valve then was actuated fifteen times per day, totaling 105 actuations of each test device and flushed using a separate sterile syringe (10 mL) for each valve.

Validity Criteria

Each test device culture shall show no growth upon testing. The negative control shall show no growth upon testing. The positive control must show growth upon testing.

Results

None of the five inoculated samples exhibited growth.

	Recovered CFU/ Device						
Sample ID	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0
Negative	0	0	0	0	0	0	0
Positive	166	47	744	720	432	430	1128
Media Control	Negative	Negative	Negative	Negative	Negative	Negative	Negative

Conclusion

Based on the test methods outlined herein, the Q2 Injection Cap proved to be an effective barrier to microbial contamination, after repeated activation, when used in conjunction with adequate disinfection procedures.

Staphylococcus Aureus

Hemocompatibility Study

Evaluating blood interaction

Objective

The purpose of this study was to evaluate the hemolytic potential of a Q2 injection cap when subjected to simulated use test conditions.

Experimental Design

Citrated human blood (3.2%) was collected and tested to ensure that the plasma free hemoglobin level was less than 2 mg/mL. The whole blood was then diluted with an appropriate volume of PBS (phosphate buffered saline) to obtain a total blood hemoglobin concentration of 10 mg/mL ± 1 mg/mL.

Group A: The sample blood was loaded into a syringe and 1 mL passed through the device in a normal flow path. The blood was collected into 7 mL of sterile PBS. This process was performed in triplicate.

Group B: The sample blood was drawn in through the device into a syringe in the reverse flow path. The blood was then collected into 7 mL of sterile PBS. This process was performed in triplicate.

A negative control was prepared by passing 7 mL sterile PBS through each device and then 1 mL of diluted blood was added to the collected PBS. A positive control was prepared by diluting 1 mL of blood in 7 mL of sodium carbonate. Three blank replicates were prepared by adding 1 mL diluted blood to 7 mL PBS.

After exposure, the mixtures were centrifuged to remove cellular materials. A cyanmethemoglobin reagent was added to the supernatants and the samples were read at a wavelength of 540 nm on a spectrophotometer.

Validity Criteria

Final evaluation of the validity of the assay was based on the following criteria and scientific judgment. The blood must have a plasma free hemoglobin value less than 2 mg/mL. The negative control should have a hemolytic index less than or equal to 2 and the positive control must have a hemolytic index greater than 8.

Results

The test blood was analyzed for the presence of plasma free hemoglobin prior to the experimental procedures and found to be below the 2 mg/mL criteria. The positive control induced a hemolytic index (%HI) of 11.7%. The plasma free hemoglobin levels of the Q2 Injection Cap test sample were determined to be 0.5 mg/mL, indicating no hemolysis.

Table 1 - Hemolytic Grades

Blank Corrected Hemolytic Index	Result
0-2%	Non-hemolytic
2.1-5.0%	Slightly-hemolytic
Greater than 5.1%	Hemolytic

Table 2 - Results

Group	Absorbance	Average Absorbance	Average Blank Corrected % Hemolysis	Average Blank Corrected % Hemolytic Index
Test Article • Group A	0.000* 0.000* 0.000*	0.000	0	0
Test Article • Group B	0.000* 0.000* 0.000*	0.000	0	0
Blank	0.000* 0.000* 0.000*	0.000	0	0
Negative Control • Group A	0.000* 0.000* 0.000*	0.000	0	0
Negative Control • Group B	0.000* 0.000* 0.000*	0.000	0	0
Positive Control	0.159 0.162 0.161	0.161	93.8	11.7

** Negative values are reported as "0" for the purposes of calculation.*

Conclusion

Based on the test methods outlined herein, the Q2 Injection Caps are considered non-hemolytic for repeated injection and aspiration of medication and other solutions, including blood, when used in conjunction with adequate disinfection procedures and hospital protocol.

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