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BARD MEDICAL DIVISION

TECHNICAL REPORT

BFF20, Bard® Flip-Flo® Catheter Valve Test for Functionality Beyond 7 Days

Background and Purpose:

Bard Medical Division Product BFF20, Bard® Flip-Flo® Catheter Valve, has a labeled use period of 7 days. Based on customer feedback, testing was performed to determine if the product has functional use up to 28 days after exposure to simulated use conditions.

Materials:

- 10 BXBFF valves, Lot NGX10890, with short piece of latex tubing added to the distal end to allow clamping while the valve remains open
- 10 Bard urine drainage bags
- 50L of EN1616 Artificial Urine
- 10 3/16-3/16 plastic connectors Lot 178-1
- 10 latex catheters Lot NGXC1858

Procedural Summary:

- Experiment was designed to simulate repeated use of BFF throughout the day and with connection to a urine drain bag at night.
- The testing was performed over a 4-week period (excluding weekends) for a total of 20 non-consecutive days.
- Artificial urine was used and the test system was maintained at body temp (37°C).
- BFF's were connected to a source such that an aliquot of artificial urine could be drained through the BFF 3 times a day, simulating actual use.
- At night/weekends, the tubing at the tip of the BFF was clamped shut while the valve remained in the open position thus allowing urine to remain in constant contact with the valve.
- Valves were evaluated at four time points throughout the study to determine the amount force required to move the mechanism.
- The amount of fluid that could be drained through the valve in a 20-sec sampling period was measured throughout the study.

Results:

- Other than the initial opening force (when removed from package) being high, there was no notable change in the force to open valve. (Note: The initial force to work the valve is higher, possibly from the prolonged set in one position during storage.)
- No substantial difference was found in flow rate over the duration of the test (4 weeks).
- Force after initial use did not show a clear increasing or decreasing trend.
- During the duration of this test, there was no leakage or other issues noted

Discussion:

This test used minimum sample quantities of artificial urine and does not investigate the possibility of bacterial contamination. Use of artificial urine cannot predict what individual patients might experience and does not account for potential bacterial growth or infection and complications associated with such.