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Major Article

Evaluation of one-way valves used in medical devices for prevention of cross-contamination

Poulomi Nandy PhD [1], Megan Young PhD [1], Shanil P. Haugen PhD, Kristy Katzenmeyer-Pleuss PhD [2], Edward A. Gordon AA, Stephen M. Retta MSE, MS, Steven C. Wood PhD, Anne D. Lucas PhD *

U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluation or Office of Science and Engineering Laboratories, Silver Spring, MD

Key Words:
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Background: One-way valves used in day use devices (used on multiple patients throughout a day without reprocessing between patients) are intended to reduce the potential for cross-contamination between patients resulting from the backflow of patient fluids. One-way valves are typically designed to withstand high levels of back pressure before failure; however, they may not be explicitly designed as a means of infection control as used in medical device applications.

Methods: Five different medical grade one-way valves were placed in low pressure configurations. After flushing in the intended direction of flow, bacteriophage, bacteria, or dye was placed patient side for 24 hours. The upstream device side of the valve was then evaluated for microbial growth or presence of visible dye.

Results: Leakage (ie, backflow) of the microorganisms occurred with a variety of one-way valve designs across a range of fluid properties tested.

Conclusions: This study describes testing of the one-way valves (component-level testing) for the potential of cross-contamination. Although day use medical device systems may use numerous other factors to prevent patient cross-contamination, this work demonstrates that one-way valves themselves may not prevent leakage of contaminated fluid if the fluid is able to reach the upstream side of the one-way valve.

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There are a wide variety of reusable medical devices that are used on >1 patient (eg, surgical instruments, endoscopes). To prevent cross-contamination of microorganisms between patients, reusable medical devices are reprocessed between uses, which may involve cleaning, disinfection, and sterilization, to render the device fit for a subsequent reuse.[1]

There is a subset of medical devices in which a component or components not in direct contact with a patient would be reused on multiple patients throughout an entire day (eg, 24 hours) without reprocessing between patient uses. These day use[2-4] devices (also referred to as 24-hour use devices) are typically discarded after the end of the day.

Because day use devices have a component that only makes indirect patient contact (eg, tubing sets used with various types of irrigation-fluid systems), they are typically connected to a device that makes direct patient contact, and are typically either (1) used on a single patient and then discarded (single patient use) or (2) appropriately reprocessed between patient uses. Some measures are necessary to prevent cross-contamination between patients in these types of day use devices. One design measure often incorporated into day use devices is a one-way valve which combats the risk of backflow of potentially contaminated patient fluids.

The use of day use devices cuts health care costs, and is particularly attractive when infusing expensive drugs or when health care

* Address correspondence to Anne D. Lucas, PhD, FDA, CDRH, OSEL, DBCMS, Bldg 64, Room 4010, 10903 New Hampshire Ave, Silver Spring, MD 20993.
E-mail address: anne.lucas@fda.hhs.gov (A.D. Lucas).

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[1]Authors contributed equally to the work.

[2]Current address: North American Science Associates, Inc, Berlin, Germany.

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workers must limit their exposure to certain solutions (eg, radioisotopes). However, there have been reports of infection outbreaks in dialysis patients where one-way valves were implicated,[5-9] demonstrating that one-way valves may not prevent cross-contamination between patients.

Currently, there are no established methods to evaluate the performance of one-way valves in terms of infection control. The test parameters that could impact the one-way valve performance include pressure magnitude and fluctuation, duration of use, flow rates, and fluid properties. Differing performance of one-way valves reported in the literature is likely caused by the different experimental conditions. Previous work by Ellger et al[2] simulated the clinically relevant pressure and flow parameters of an infusion system. Those authors observed a failure to prevent contamination in a test system that monitored increasing back pressure. Notable in the results was that there was a difference depending on the fluid used. Propofol was more likely to fail than 0.9% NaCl. Radke et al[3] conducted studies to show using 2 check valves in the system can prevent contamination in a day use system specific to a piggyback intravenous setup. The recognition that test parameters are device system dependent led us to develop a simplified evaluation test method which focuses on the functionality of the one-way valve as component of a system to prevent backflow of fluids contaminated with simulated pathogens (eg, dyes, bacteria, viruses).

MATERIALS AND METHODS

Test valves and additional hardware

Figure 1 depicts the five one-way valves that were chosen for testing, denoted A, B, C, D, and E. The valves all use a flexible diaphragm-type mechanism, which is common in medical devices. The valve design varies slightly between the 5 models and may be designed with a free-floating disk guided by the valve housing (valve C), or a diaphragm attached in some way to either the inflow side (valve E) or outflow side (valves A, B, and D) of the valve. The inflow side, or upstream side, is the side of the valve receiving flow from the device (eg, pump, gravity bag). The outflow side, or downstream side, is the side of the valve

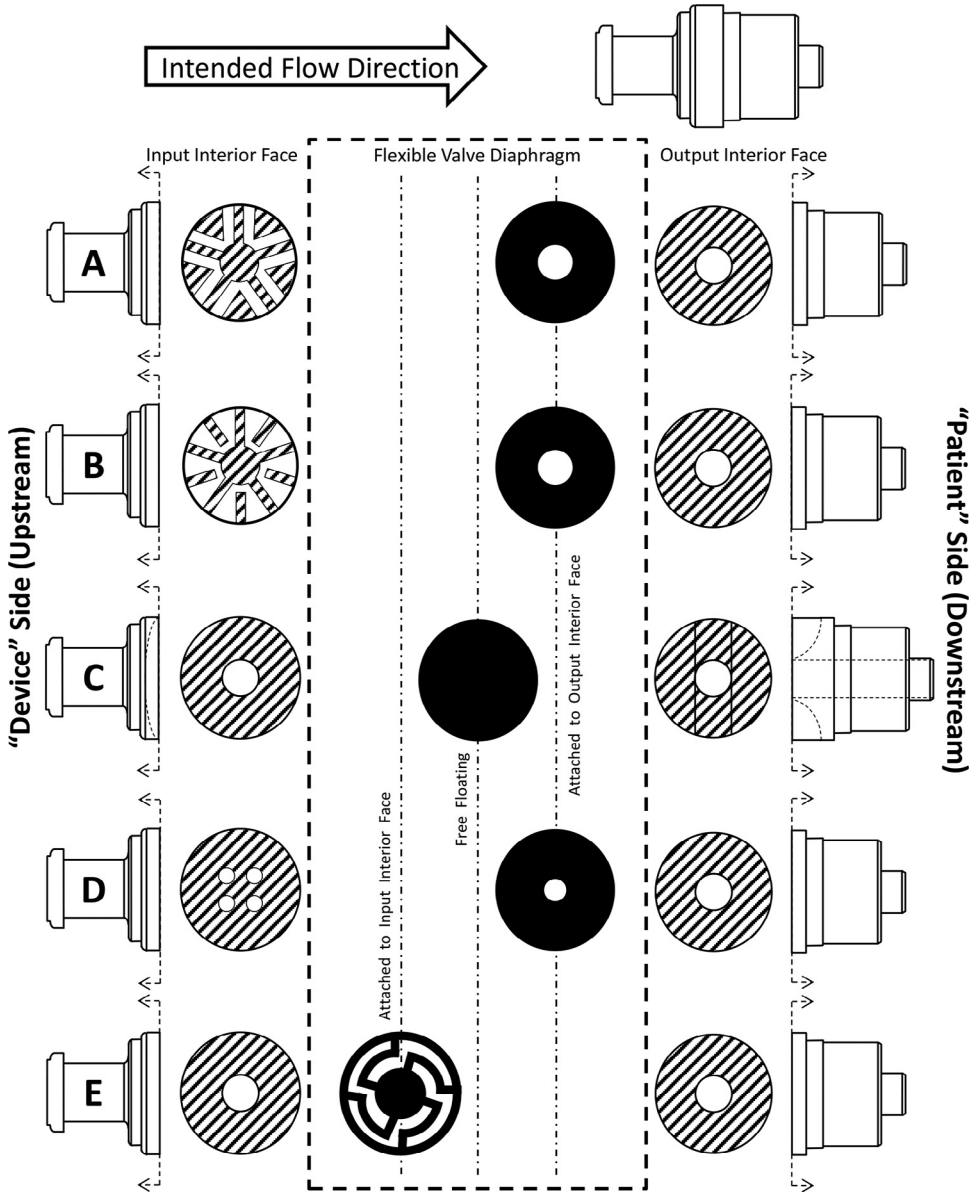

Fig 1. Depiction of the 5 different types of valves used in this study.