Air/Water/Suction Valve Study[10]

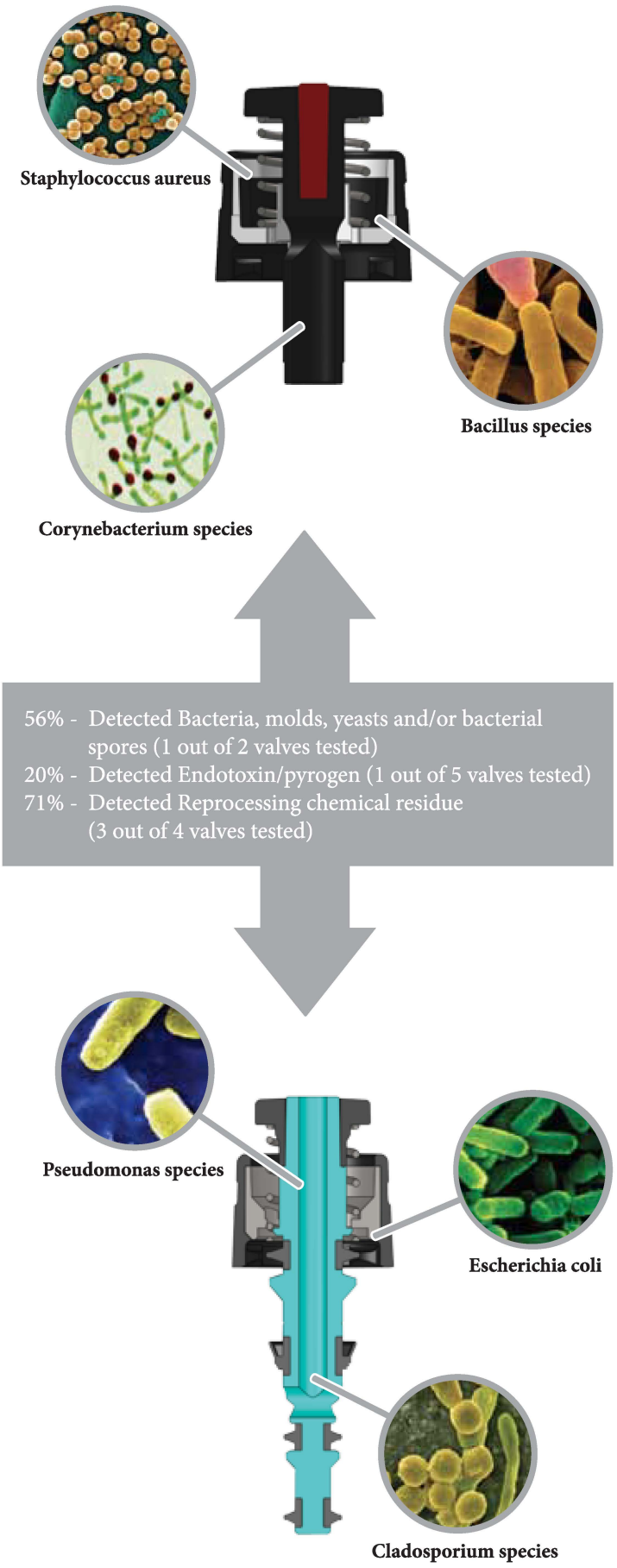
Methods and Materials

Reprocessed and patient-ready endoscope valves were submitted to Nova Biologicals, Inc. for laboratory testing. Endoscopy facilities located in 20 states throughout the United States sent reprocessed, patient ready valves directly to Nova for testing. 64 air/water valves and 64 suction valves were submitted and tested. Included in this total were air/water and suction valves manufactured by Olympus, Pentax and Fujinon.

Study Results

Study results indicate that a significant number of reprocessed valves were not reprocessed according to recommended practices for high-level disinfection as described by the U.S. Food and Drug Administration (FDA) and the American Society for Gastrointestinal Endoscopy (ASGE).[(1)(4)] Additionally, study results show that a significant number of reprocessed and patient-ready valves were not reprocessed according to the guidelines and procedures published and distributed by endoscope manufacturers i.e. Olympus, Fujinon, and Pentax. [(5)(8)(9)]

Pathogenic and objectionable microorganisms detected on the reprocessed valves included: Staphylococcus aureus, Staphylococcus species (not aureus), Escherichia coli, Bacillus species, Corynebacterium species, Pseudomonas species (not aeruginosa), Cladosporium species (mold), and Alternaria species (mold).



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Position Statements

- The FDA reports the presence of pathogenic and objectionable microorganisms indicates improper reprocessing and/or improper environmental controls. (4)
- Detection of objectionable microorganisms reinforces the need for endoscopy facilities to strenuously and effectively pursue The Association of Professionals in Infection Control and Epidemiology's (APIC) focus on preventing and controlling infections in flexible endoscopy. (2)
- According to the Center for Disease Control and Prevention (CDC), the presence of reprocessing chemical residues is a direct indication of inadequate reprocessing i.e. inadequate washing and rinsing of the used valves. (7)

Discussion

Test results demonstrate that a high percentage of the valves tested failed to meet CDC and FDA criteria for high level disinfection.(6) Failure to comply with accepted guidelines for the reprocessing of air/water and suction valves results in the use of microbiologically contaminated equipment for patient care. The use of such equipment establishes a known pathway for the transfer of potentially pathogenic microorganisms from one patient to another with the distinct possibility of initiating an infectious disease in an otherwise healthy patient. (3)

Conclusion

Test results demonstrate that the majority of patient-ready, reusable endoscope air/water and suction valves do not meet the high-level disinfection criteria for semi-critical medical devices as established by the CDC and the FDA.

Given the intrinsic complexity of endoscope air/water and suction valves and the demonstrated difficulties associated with reprocessing the valves it is prudent and in the best interest of the patient to use single-use/ disposable air/water and suction valves.

* *White Paper available upon request.*

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