Cleaning, Disinfecting and Sterilization Resistance of 3M™ Medical Assembly Vinyl Tape 471 Solution for Reusable Medical Devices

Technical Bulletin **January, 2013**

Introduction:
With the development of reusable medical devices, sterilization between uses has become an important consideration in the development of medical devices. In May 2011, the FDA published a Draft Guidance for Industry and FDA staff entitled *Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.* When finalized, medical device manufacturers will need to include validated labeling instructions for reprocessing reusable medical devices in premarket submissions.

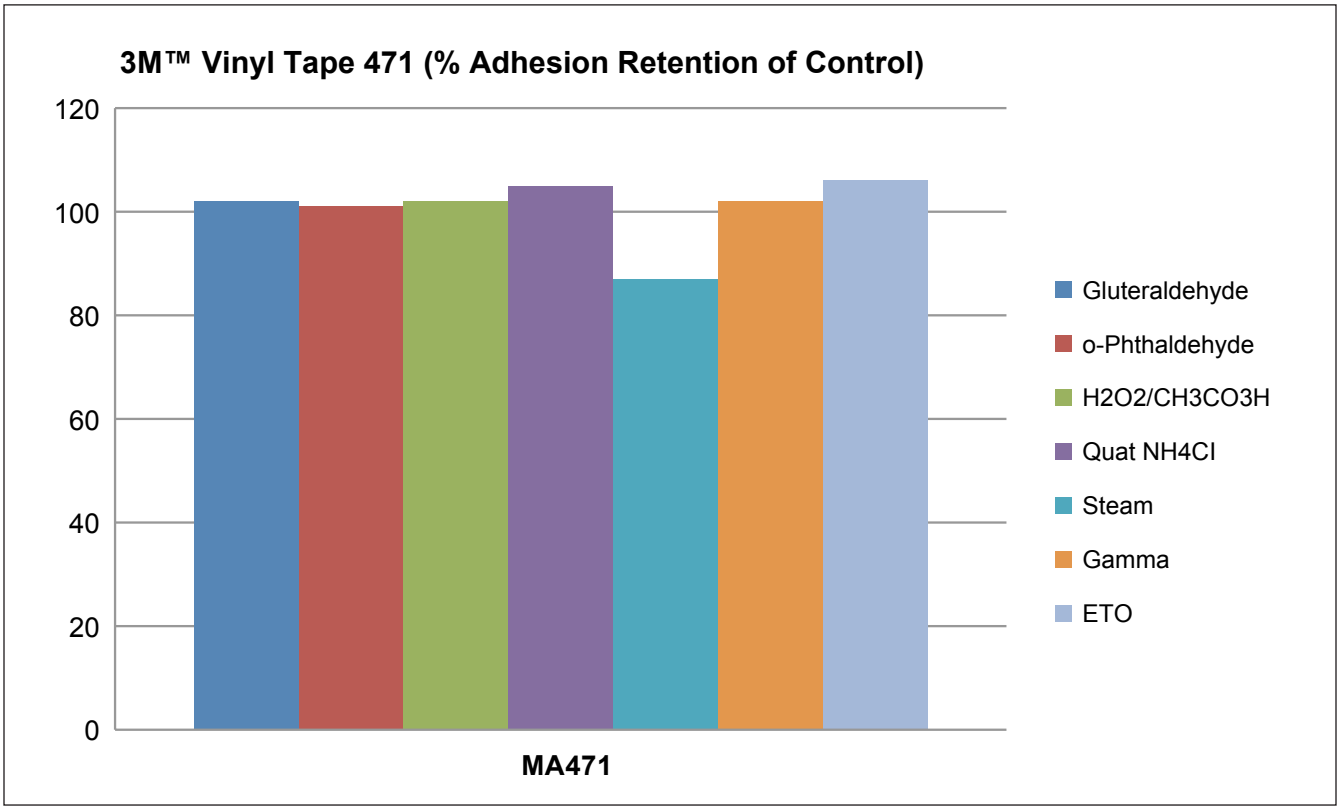
3M™ Vinyl Tape 471 is used in the manufacture of medical devices. This tape is "colored throughout" which resists scrapes, chipping and cracking through repeated sterilization cycles as well as cleaning and disinfecting solutions. It is easily applied color coding, to help organize and track surgical instruments. It is a transparent pressure sensitive synthetic rubber adhesive for high initial adhesion. With the shift to reusable medical devices, these devices must be able to withstand the specified sterilization methods outlined by industry requirements. 3M has tested the integrity of our product by conducting evaluations to several industry protocols.

Protocol Description:
To meet the requirements of various types of medical devices different cleaning, disinfecting, and sterilization techniques were tested including heat, radiation and chemical immersion. The tests conducted were 90° Angle Peel Adhesion tests based on ASTM D3330 on stainless steel panels. Upon completion of the test methods, the samples were visually inspected after each cycle for edge lift and buckling. All tests were conducted on the exposed samples after a minimum of 24 hours at ambient temperature. The different protocols used are described below:

Sterilization Method	Description	Protocol	Visual Inspection
Chemical Disinfecting Solutions	• 3.4% Gluteraldehyde Solution • 0.55% o-Phthaldehyde Solution • 1% Hydrogen Peroxide and 0.8% Peracetic Acid Solution.	For each solution, samples were immersed in the solution for 1 hour for 5 cycles, followed by a rinse with distilled water.	All Pass
	• Quaternary Ammonium Chloride Solution	Immersed for 1 minute for 5 cycles, followed by a rinse with distilled water.	Pass
Steam Autoclave	• Steam under pressure • Temperatures between 100-135°C	Exposed to 3 cycles @ 250°F (121°C) for 20 minutes under 25 psi (172 kPa) pressure.	Pass
Gamma	• Gamma rays • Cobalt 60 radiation source • Ambient temperature	Sample was exposed to 1 cycle 25.0-45.0 kGy	Pass
Ethylene Oxide	**Gas Exposure** • Temperature range between 86°F (30°C) and 140°F (60°C) • Gas concentration between 200 and 800 mg/l	Sample was exposed to 1 cycle at 131°F (55°C) for 60 minutes	Pass

Note: The following technical information and data should be considered representative or typical only and should not be used for specification purposes.

Results:
For the vinyl tape product, the results for all cycles were averaged. The mean value was compared to the corresponding control value and the percent difference is presented below:



In these evaluations, performance of the tape was not negatively affected by exposure to the various sterilization methods. The product performed similar to the control sample, with all samples maintaining at least 85% of the strength of the control.

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