

continuity, electron microscope examination, functional testing, etc., must be discussed and justified.

All data collected from in vitro and animal testing, regarding the useful lifetime or long-term reliability of the device, must be compared to data from clinical studies (prospective and/or retrospective) where the useful lifetime of the device has been determined. This comparison must validate the ability of the in vitro and animal tests to accurately predict the useful lifetime of the implanted device.

If accelerated aging is used to demonstrate device durability and reliability, all processes used should be completely described, and the calculations validating the expected aging should be provided.

All physical, chemical, and functional properties of the device should be completely characterized, and the design specifications must be adequately justified. Chemical characterization should include, where applicable, molecular weight and molecular weight distribution, cross-link density, infrared analysis (free isocyanate content, side reaction products), and differential scanning calorimetry. The physical tests should include, but are not necessarily limited to the tests discussed below.

Testing should include the following specific methods or their equivalents:

(1) American Society for Testing Materials (ASTM) Test Method D412 to measure tensile strength, force to breakage, ultimate elongation, and total energy to rupture of the pad, cuff, pump, reservoir, tubing, and bulk of all elastomeric components (with and without incorporated fold flaws) of the finished, sterilized device; dynamic mechanical analysis and fatigue characterization of all elastomeric components particularly those comprising the cuff of the finished, sterilized device; (2) ASTM Test Method D624 to determine tear and abrasion resistance of all components; an applied force at the rate of 1 Hertz versus number of cycles to failure (AF/N) curve (including the minimum force required to rupture the component under a single stroke of applied load), constructed on the basis of cyclical compression testing of intact sterilized devices; and (3) ASTM Test Method F703 (section 7.2) to determine the force to break of adhered or fused joints. A complete report of the cohesivity and penetration testing of the gel must also be reported for the devices containing silicone gel. The results of each of these tests must be compared to the energy, forces, etc., that the device will encounter in vivo.

Life testing should demonstrate the device is sufficiently durable to withstand the demands of use while maintaining operational characteristics sufficient for urethral compression throughout the expected operational lifetime of the implanted mechanical/hydraulic urinary continence device, as stated in the physician and patient labeling. Life testing should include measurements of all component and material wear and bond strengths after the device is cycled between inflated and deflated conditions. A discussion comparing the rate of cycling performed in each test to the approximate maximum rate of cycling of the device in vivo and to the expected longevity of the implant should be included.

Appropriate "downtimes" at predetermined cyclical intervals should be included in the life tests to evaluate relevant performance characteristics and conformance to design specifications. Material characteristics indicative of material degradation that could induce device malfunction should be completely evaluated. Cyclical testing beyond the expected longevity of the implant and recording of failure mode must also be included as part of the life tests.

Filling agent permeability from the reservoir and body of the device must be evaluated to demonstrate that fluid loss due to osmosis will be acceptable over the expected life of the implanted mechanical/hydraulic urinary continence device.

Component-specific tests are also necessary. Reliability over the expected life of the device, proper operation, and conformance to predetermined operational specifications must be demonstrated for each component. Resistance of each component to abrasion, tear, crazing, fracture, material fatigue (including wear between each component), change of position (e.g., valve seats), and permanent deformation also must be demonstrated.

Pad characterization and testing should include, but not be limited to: Measurement of stiffness and rigidity, including resistance to buckling; uniformity of dimensions (if the device is inflated); and wear characteristics.

Cuff characterization and testing should include, but not be limited to: Maximum pressure and expansion capability; measurement of stiffness, including resistance to buckling; resistance to aneurysms; ability of cuff closure to remain inflated under maximum loads expected in vivo; uniformity of inflated dimensions; inflation and deflation characteristics; and wear characteristics at folds in the cuff.

Pump characterization and testing should include, but not be limited to: The range of volumes displaced per stroke; minimum force required to affect fluid displacement; squeeze force versus fluid displacement; inflation effort, defined as pump force times the number of strokes required for full device activation; and ability of the implanted mechanical/hydraulic urinary continence device to maintain its set pressure after repeated punctures to its pressure adjustment port with both new devices and devices evaluated in the reliability tests.

Valve characterization and testing should include, but not be limited to: Pump output pressure required to affect valve opening for device activation; tactile pressure/force required to affect valve opening, against fully inflated cuffs, for deflation; back pressure required for valve failure; maximum pressure differential across closed valve at full inflation and deflation, and the leakage rates at these pressures; prevention of spontaneous deflation under movements and loads simulating those expected to be sustained by the implanted device in an inflated state; and potential for valve failure which could result in an inability to inflate or deflate the cuff.

Reservoir characteristics should be evaluated and should include, but not be limited to: Volume capacity; pressures generated over the inflation/deflation cycle; rate of maximum fluid outflow and inflow; wear characteristics if a fold in the reservoir envelope occurs; and durability tests demonstrating adequate resistance to fatigue caused by cyclic external compression applied radially to inflated reservoir.

Tubing testing should include, but not be limited to: Tensile characteristics (with and without tubing connectors, if any); tear or rupture resistance; kink resistance; wear characteristics if a fold in the tubing develops; and ability of the tubing to remain intact under loads simulating and exceeding those expected in vivo.

Testing to demonstrate the inflation/deflation characteristics of the device should include, but not be limited to: Amount of pressure generated during inflation of the cuff; amount of pressure drop (deflation) and rise (inflation) per unit time; ability to maintain the inflated cuff dimensions; and time to fully inflate and deflate the cuff from specified starting pressures.

All bonds within the device and between components should undergo appropriate testing including, but not be limited to measurement of bond shear and tensile strength. Bond strength