

significant risks associated with the use of the implanted mechanical/hydraulic urinary continence device:

#### 1. Erosion of the Implanted Mechanical/Hydraulic Urinary Continence Device

Erosion is the destruction or breakdown of tissue and is the most common cause of failure in the implanted mechanical/hydraulic urinary continence device (Refs. 1 through 5). Cuff erosion into the urethra or bladder neck is a serious complication that has been frequently reported (Refs. 3 and 6 through 15). This type of erosion makes reimplantation difficult and is associated with higher complication rates for reimplantation (Refs. 1 and 16 through 18) of the device. Erosion of the pump through the labia, vagina, scrotum (Refs. 14 and 19 through 21), and the perineum (Refs. 2, 9, and 22) have also been reported.

Erosion often occurs as a result of low grade, nonclinical infection of the prosthesis (Refs. 9, 14, and 23 through 28). Other factors which can contribute to erosion include previous surgery (Ref. 11), poor vascularization (Refs. 27 and 29 through 31), prior pelvic irradiation (Refs. 17, 28, and 32 through 35), improper cuff size (Ref. 30), improper reservoir volume (Ref. 17), surgical injury (Refs. 18 and 24), excessive urethral compression (Ref. 16), and premature activation (Refs. 19 and 27).

#### 2. Infection

Infection, a risk of any surgical implant procedure, is associated with the use of implanted mechanical/hydraulic urinary continence devices (Refs. 7, 10, 12, 33, and 36 through 39). Infection is one of the most serious potential complications of device implantation and usually necessitates removal of the prosthesis (Refs. 7, 40, and 41). As in any implantation procedure, compromised device sterility and/or surgical techniques may be major contributing factors to this risk (Refs. 40 and 42). Additionally, a life-long risk for hematogenously seeded infection possibly exists in these patients and antibacterial prophylaxis for subsequent dental and surgical procedures may be needed (Ref. 40).

#### 3. Mechanical Malfunctions

Fluid leakage is one of the most commonly reported mechanical malfunctions (Refs. 2, 26, 28, 37, 43, and 44) of implanted mechanical/hydraulic urinary continence devices. Fluid can leak from the cuff or pad (Refs. 7, 13, 21, 31, and 45), reservoir (Refs. 7, 13, and 31), or connectors (Ref. 10). Leakage from the cuff has been associated with cuff folding and attendant material wear

(Refs. 31, 36, and 46). This malfunction results in inadequate cuff pressure and incontinence (Ref. 7). Tube kinking is another reported device malfunction (Refs. 7, 12, 26, 28, 34, 37, 43, 44, and 47). Also, disconnection of the tubing from components of the device can occur (Ref. 19). Pump assembly failure is another noted complication (Refs. 2, 19, 36, 37, and 44) of this implant. This can include malfunction of the valves within the hydraulic system (Ref. 45). Finally, balloon herniation has been noted (Ref. 17). Device malfunction usually requires replacement or revision surgery (Refs. 7 and 43).

#### 4. Iatrogenic Disorders

Iatrogenic complications can occur as a result of any medical procedure, including implantation of the implanted mechanical/hydraulic urinary continence device. Improper device handling (including cutting or nicking of the device) can lead to device malfunctions. Inadequate pressure within the system (due to selection of incorrect cuff or reservoir size) results in either incontinence (due to inadequate urethral closing pressure) or outflow obstruction (due to excessive urethral closing pressure), both of which lead to the need for reoperation (Refs. 7, 12, 30, and 34). This may be due to a lack of guidance for determining the appropriate device size for an individual patient (Refs. 2, 9, 25, 31, and 48). Erosion secondary to infection, can be caused by intraoperative field contamination or urethral or vaginal injury (Refs. 26 and 42). Finally, intraoperative and postoperative kinks in the tubing can occur due to incorrect tubing length (Ref. 7) and result in a low urethral closure pressure (Refs. 9, 34, and 48).

#### 5. Hydronephrosis

Hydronephrosis refers to the dilation of the upper urinary tract as a result of chronic obstruction to urine outflow, which can lead to kidney damage. Some authors have reported an elevated incidence of hydronephrosis following implantation of the implanted mechanical/hydraulic urinary continence device (Refs. 49 through 52). This complication has mostly occurred when the device is implanted in patients with myelopathy. It has been theorized that the development of hydronephrosis is due to a combination of slight detrusor hyperreflexia and low bladder capacity (Ref. 49). Other researchers have noted the development of detrusor hypertonicity after implantation, leading to hydronephrosis (Ref. 52). The pathogenesis and

incidence of this risk is unknown and requires further study.

#### 6. Human Carcinogenicity

Carcinogenesis has been widely discussed as a reputed risk secondary to implantation of any material. Evidence from the literature indicates that in animal studies, different forms of silicone have been associated with various types of cancer (Refs. 53 through 57). Cases of several types of cancer in humans have been reported in association with various forms of implanted silicone (Refs. 58 through 61).

#### 7. Human Reproductive and Teratogenic Effects

The effect of certain silicone compounds on the reproductive potential of the male is largely unknown. Le Vier and Jankowiak report that at least one form of organosiloxane, which is known to be present in some silicone gels, mimics estrogens in the male rat, leading to rapid testicular atrophy (Ref. 62).

Teratogenesis includes the origin or mode of production of a malformed fetus and the disturbed growth processes involved in the production of a malformed fetus. Studies using silicone fluid in animals have been minimal, and yield contradictory and inconclusive results (Refs. 63 through 65). Prolonged contact with either silicone elastomer, or silicone gel-filled membrane in devices containing silicone gel, presents a potential risk of teratogenicity in humans. Further study of these risks is necessary.

#### 8. Immune Related Connective Tissue Disorders—Immunological Sensitization

Immunological sensitization may be a serious risk associated with an implanted mechanical/hydraulic urinary continence device. Recent clinical data have shown that silicone elastomers are capable of producing immune responses (Ref. 66). Immune related connective tissue disorders have also been reported in women who have silicone gel-filled devices or who have had silicone injections in augmentation mammoplasty. There are clinical reports of several patients who have undergone augmentation mammoplasty with silicone gel-filled breast prostheses and later presented with connective tissue disease-like syndromes (Ref. 67). Recently, Naim et. al. conducted studies in rats which demonstrated that silicone gel is a potent immunological adjuvant (Ref. 68). Because implanted mechanical/hydraulic urinary continence devices may consist of similar silicone elastomers and gels,