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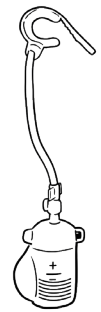
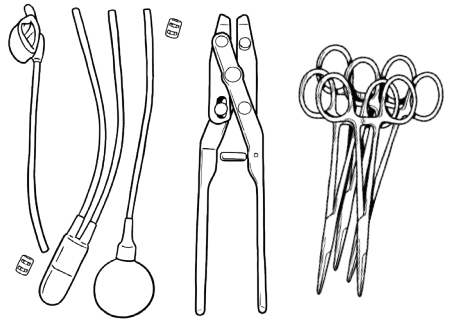
ZSI
Zephyr Surgical Implants

COMPARISON OF ZSI 375 PF AND AMS 800



ZSI 375 PF



AMS 800

I. Comparison of continence rate

Device	Continence rate (%)
ZSI 375 PF	85,10 (77-94)
AMS 800	85,00 (61-95)

ZSI 375 PF :

5 clinical studies[1,2,3,4,6] were selected to assess continence after implantation of the ZSI 375 PF artificial sphincter:

- The average continence rate (social continence and improvement) is 85.10% (depending on the publications and the duration of follow-up, it varied between 77.77% to 94.12%).
- In terms of social continence only, the rate is 79.05% (depending on the publications and the duration of follow-up, it varied between 72% and 94.12%).

AMS 800 :

According to the FDA report[19], "a reasonable degree of continence goes up to 3 pads per day, which represents 82-84% of patients with 10% of patients completely dry".

According to the CNEDiMTS opinion of 21st July 21, 2020[16], in men, *"the average continence rate was 85.5% (depending on the publications and the duration of follow-up, it varied between 61% to 95%) .... These results were confirmed by nine retrospective studies and a prospective study provided in 2010 which reported that the achievement of total continence ranged from 24 to 77%; these studies included a total of 1750 patients and the mean follow-up was 36 months to 6.8 years. Social continence varied from 69 to 100% according to the publications. Revision rates noted ranged from 13% to 66%. Mechanical failures, when identifiable, ranged from 17 to 26% ".*

II. Comparison of adverse events linked to the Cuff and the pump

Device	Erosion (%)	Infection (%)	Mechanical failure (%)
ZSI 375 PF	11,19	4,6	4,69
AMS 800	11,70	4,5	13,80

ZSI 375 PF :
The average complication rates for ZSI 375 are as follows:
- Erosions: 11.19% (2.7 to 18%) [1,2,3,4,6]
- Infections: 4.6% (0 to 8.33%) [1,2,3,4,6]
- Mechanical failures: 4.69% (0 to 7.41%) [1,2,3,4,6]

The 5 studies cover the time to onset of complications:
19.8 months: erosions[7]
29.6 months: atrophies[7]
68.9 months: mechanical problem[7]

AMS 800 :
The CNEDiMTS opinions issued previously in June 2005[20] and May 2010[16] for the AMS 800 device:
- Urethral erosion (11.7%);
- Infection (4.5%);
- Mechanical failures (13.8%).

III. Comparison of adverse events linked to the Pressure Regulating Balloon

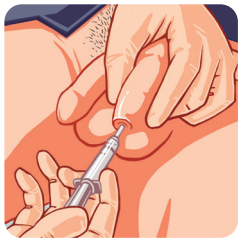
Device	Balloon herniation (%)	Deep thrombosis (%)	Vesical injury (%)	Deep pelvic injury (%)	Bowel injury (%)
ZSI 375 PF	0*	0*	0*	0*	0*
AMS 800	2 à 3,2	1,2	0,6	0,5-1,9	0,5

ZSI 375 PF :
- The implantation of the ZSI 375 PF is subcutaneous, less invasive than the AMS 800.
- ZSI 375 PF has no intra-pelvic or submuscular component. A patient with a ZSI 375 PF will not be able to present with inguinal pain, herniation of the pressure-regulating balloon, deep vein thrombosis, bladder injury, deep pelvic injury, intestinal injury, or any particular problem with anticoagulants.

AMS 800 :
- The herniation of the Pressure Regulating Balloon carries a risk of 2 to 3.2% [21,26,] with the consequence of a drop in pressure in the hydraulic circuit and the return of incontinence requiring a new surgical intervention to reintegrate the balloon into the pelvis to repressurize the cuff [5].
- Deep thrombosis of the iliac or femoral vein secondary to the pressure regulating balloon representing 1.2% [22,23,25].
- The same is true of the risk of implantation of the pressure-regulating balloon of a patient on anticoagulants[24], bladder lesions 0.6% [21], deep pelvic (0.5 to 1.9%) [21], or intestinal wounds (0.5%) [21].

IV. Urethral atrophy is easier to manage with the ZSI 375 PF

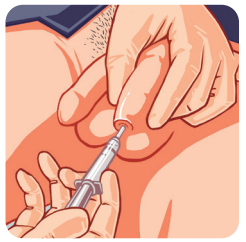
The ZSI 375 PF has an adjustable cuff with adjustable hydraulic volume. In the event of urethral atrophy, the urologist will perform a trans-scrotal injection of physiological serum into the hydraulic circuit at the consulting room to compensate for this atrophy.



For AMS 800, urethral atrophy requires a change of the peri-urethral cuff during surgery under general anaesthesia in the operating room.

V. The pressure increase is easier to manage with the ZSI 375 PF:

With ZSI 375 PF, to increase the pressure, the urologist will perform a trans-scrotal injection of physiological serum in the hydraulic circuit of the consulting room to compensate for this atrophy.



For the AMS 800, an increase in pressure requires a change of the Pressure regulating balloon during surgery under general anaesthesia in the operating room.

VI. There is no evidence of decrease of infection rate with coated sphincters but an increase of price of Hospital

Antibiotic Coating of the Artificial Urinary Sphincter (AMS 800): Is it Worthwhile? Tanja Hüsch, Urology, May 2017 Volume 103, Pages 179–184
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