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- **Abstract MP 40-02**: 5 years of Food and Drug Administration (FDA) Alternative Summary Reporting (ASR) of adverse events associated with the Artificial Urinary Sphincter.

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- **Introduction**: The AUS has been considered the gold standard for treatment of male SUI. The ASR published by the FDA offers new insight into the rate of device-related complications.
- **Materials and Methods**: We reviewed the ASR Program adverse events related the AUS from 2014 to 2018. The 5-year study period was analyzed with respect to Device Problem Codes (DPC) and patient impact.

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- **Results**: A total of 16,989 AUS device issues were included. The most common adverse event was ‘fluid leak’ which was noted in 17.9% of the total cohort.

- **Conclusion**: The variety and number of AUS device reports found in the ASR Program from 2014 to 2018 appears consistent with the types of device malfunctions described in urologic literature with fluid leak being the most common device-related complication. The availability of post-market surveillance data can offer insight into potential risk factors.