Safety Information Summary

The risks associated with this procedure include:

- Allergic Response
- Anesthetic risks
- Device Leakage
- Erosion of the device at the bladder, perineum, rectum, scrotum, or urethra
- Perforation during procedure (e.g. bladder, rectum, urethra)
- Pain or Discomfort
- Procedure/adjustment not able to be completed
- Prosthetic Infection
- Prosthetic Migration
- Urinary Complications (e.g. Urinary Difficulty, Frequency, or Urgency, Worsening Incontinence[1])
- Urinary Retention
- Urinary Tract Infection
- Vascular Complications (e.g. Bleeding, Bruising, Swelling)
- Wound Infection

A systematic review of nineteen studies, which included data on 1,264 patients and 4,517 patient-years of follow-up data (mean follow-up time: 3.6 years), determined estimates of the frequency by patient of the most common adverse events for ProACT[2]:

Adverse Event	Estimate
Balloon Migration	6.5%
Perforation During Implant	5.3%
Device Failure, Leakage	4.1%
Balloon Erosion	3.8%
Infection	2.2%
Urinary Retention	1.5%
Overall revision rate for all causes	22.2%

Most device-related adverse events are resolved with explant of the device in a short, office procedure. Implantation of ProACT or another anti-incontinence procedure can be performed six weeks after explant.

Review the ProACT Instructions for Use supplied with each device for complete indications, contraindications, warnings, precautions, and risk information.

1 “Worsening Incontinence” includes subjective patient-perceived worsening.
2 Larson T, Jhaveri H, Yeung LL. Adjustable continence therapy (ProACT) for the treatment of male stress urinary incontinence: A systematic review and meta-analysis. Neurourol Urodyn. 2019; 38(8):2051-59.

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