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 Incontinence¹)
- 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 ProACT²:

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balloon Migration</td>
<td>6.5%</td>
</tr>
<tr>
<td>Perforation During Implant</td>
<td>5.3%</td>
</tr>
<tr>
<td>Device Failure, Leakage</td>
<td>4.1%</td>
</tr>
<tr>
<td>Balloon Erosion</td>
<td>3.8%</td>
</tr>
<tr>
<td>Infection</td>
<td>2.2%</td>
</tr>
<tr>
<td>Urinary Retention</td>
<td>1.5%</td>
</tr>
<tr>
<td>Overall revision rate for all causes</td>
<td>22.2%</td>
</tr>
</tbody>
</table>

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.

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¹ "Worsening Incontinence" includes subjective patient-perceived worsening.