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Figures 1 and 2 (on the preceding page) show the percentage of implanted patients that remain free from revision or explant-related events at various time points post implant. These probabilities are estimated using the Kaplan-Meier statistical method. These estimates are intended to illustrate the probability that a patient will be free from a surgical revision or device explant related event for a given number of years. As an example, a probability percentage of 97% indicates that through the stated follow-up time, the patient had a 3% risk of a surgical revision or device explant since the time of initial implant.

These statistical curves are estimates based on internal quality reporting systems. As our experience accumulates, the accuracy of the estimation improves.

Intraoperative Complications – ADHERE Registry

The ADHERE registry monitors serious adverse events (SAE) during the procedure to place Inspire. Less than a half of a percent of implant procedures result in serious adverse events.

SAE Type ¹	# of Events	% of Patients
Hematoma	2	<0.1%
Infection	1	<0.1%
Failed Implant	1	<0.1%
Pneumothorax	1	<0.1%
Other	3	0.16%
Total	8	0.43%

Postoperative Complications – ADHERE Registry

The ADHERE registry also monitors serious adverse events (SAE) and other complications during the post-implant follow-up period.

SAE Type ¹	# of Events	% of Patients
System explant (2 or more components)	1	<0.1%
System revision (2 or more components)	3	0.16%
Sensor lead revision	13	0.7%
Stimulation lead revision	12	0.64%
IPG Pocket revision	2	0.11%
Other	4	0.16%
Total	35	1.9%

The most frequent complication is therapy-related discomfort which is more commonly observed at the 6 month post-titration visit compared to the 12 month final visit. Of patients with 12 month follow-up data, 19% reported some therapy-related discomfort which most commonly presented as stimulation discomfort, insomnia/arousal or tongue abrasion.

Complication Type ¹	# of Events	% of Patients
Stimulation related discomfort	151	8.2%
Insomnia/Arousal	66	3.6%
Tongue abrasion	63	3.4%
Other non-serious events	69	3.7%
Total	349	18.9%

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