On-line Table 1: Nonserious adverse events within 1 month of surgery

No. of Patients	CF (*n* = 57)	IBTF (*n* = 55)
With adverse events within 1 month[a]	12	11
Ear and labyrinth disorders		
Vertigo	0	1
Gastrointestinal disorders		
Abdominal pain	1	0
Constipation	0	1
Diarrhea	0	1
Gastritis	1	0
Vomiting	2[b]	0
General disorders		
Adverse drug reaction	1	0
Infections		
Helicobacter gastritis	0	1
Urinary tract infection	0	1
Injury, procedural complications		
Incision site pain	1	0
Hematoma	0	1[c]
Procedural pain	0	1
Musculoskeletal disorders		
Arthralgia	1[d]	0
Back pain	1	2
Musculoskeletal pain	0	1
Pain in extremity	1	0
Nervous system disorders		
Confusion postoperatively	2[e]	0
Headache	2	1[f]
Psychiatric disorders	1	1
Vascular disorders		
Hypertension	0	1

Note:—MedDRA indicates the Medical Dictionary for Regulatory Activities.

[a] Patients may have had multiple adverse events; all MedDRA categories and lower level terms are listed for adverse events occurring within 1 month.

[b] One event was considered possibly anesthesia-related.

[c] Event was considered possibly related to device.

[d] Event was not serious and considered possibly anesthesia-related.

[e] Both were not serious and possibly related to anesthesia.

[f] One event was not serious and possibly anesthesia-related.

On-line Table 2: Serious adverse events within 1 month of surgery

No. of Patients	CF (*n* = 57)	IBTF (*n* = 55)
With serious adverse events within 1 month[a]	5	8
Cardiac disorders		
Atrial fibrillation	1	0
Gastrointestinal disorders		
Abdominal pain	0	1
Infections		
Diverticulitis	0	1
Lung infection	0	1[b]
Pneumonia	1[b]	0
Septic shock	1[b]	0
Urinary tract infection	0	1
Musculoskeletal disorders		
Back pain	0	2
Symptomatic vertebral fracture	1	1
Neoplasms		
Spinal meningioma benign	0	1
Psychiatric disorders		
Psychiatric decompensation	1	0
Reproductive disorders		
Benign prostatic hyperplasia	0	1

Note:—MedDRA indicates the Medical Dictionary for Regulatory Activities.

[a] Patients may have had multiple serious adverse events. All MedDRA categories and lower level terms are listed for adverse events occurring within 1 month; an adverse event was serious if it resulted in death, life-threatening injury, or permanent impairment or if it required extended hospital stay or intervention to prevent impairment. No serious adverse events were related to device or procedure.

[b] Event resulted in death.