

Supplementary Online Content

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eReferences

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Summary of IVC Filter Types and Models

	No. (%)	
Filter model	Single-Center (N=139)	Multi-Center (N=126)
Permanent	15 (10.8)	21 (16.7)
Simon Nitinol (Bard) (n/N)	6/15	3/21
TrapEase (Cordis) (n/N)	7/15	15/21
Greenfield (Steel/Titanium, Boston Scientific) (n/N)	2/15	3/21
Retrievable	124 (89.2)	105 (83.3)
ALN (ALN) (n/N)	1/124	1/105
Meridian (Bard) (n/N)	None	1/105
Recovery (Bard) (n/N)	None	1/105
Celect (Cook Medical) (n/N)	11/124	2/105
Gunther Tulip (Cook Medical) (n/N)	65/124	56/105
OptEase (Cordis) (n/N)	32/124	35/105
Option (Rex Medical) (n/N)	15/124	9/105

eTable 2. Adjudicated Complications

Variable	No. (%) (95% CI)	
	Single-Center (N=139)	Multi-Center (N=126)
Adjudicated Complications ^a	42/139	23/126
Device related Major Complications ^b	4 (2.9) (0.8, 7.2) ^c p-value=0.001	5 (4.0) (1.3, 9.0) ^c p-value=0.011
Procedure related Major Complications ^b	5 (3.6) (1.2, 8.2)	5 (4.0) (1.3, 9.0)
Filter fracture with embolization	2	0
Filter penetration	1	0
IVC perforation	1	0
Access site hematoma	1	0
IVC injury with extravasation	0	2
Hematoma, major	0	2
Hemorrhage	0	1
Device related Minor Complications ^d	23 (15.8) (10.2, 23.0)	14 (11.1) (6.2, 17.9)
Procedure related Minor Complications ^d	37 (26.6) (19.5, 34.8)	19 (15.1) (9.3, 22.5)
Filter fracture	1	0
Filter fracture with embolization	1	3
IVC injury with extravasation	9	4
IVC perforation	1	0
IVC stenosis	2	0
Pseudoaneurysm	1	0
Small extravasation	1	0
Access site hematoma	3	0
Additional procedures required for filter retrieval due to filter tilt	2	0
Back pain	1	0
Caval narrowing	1	0
Caval thrombus	0	2
Deep vein thrombosis	0	1
Filter fracture with embedded fragments	2	3
Retrieval tool fracture	0	5
Other	12	1
<p>Data are presented as % of subjects with complication (Number of subjects with complication/Total number of subjects), with number of complications and 95% exact confidence limits.</p> <p>^aOne subject (#037) reported multiple complications/SIR grades – Multi-Center.</p> <p>^bMajor Complications include C. Require therapy, minor hospitalization (<48 hours); D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours); E. Permanent adverse sequelae; F. Death.</p> <p>^cP-value is 1-sided for comparison against the safety performance goal of 10%.</p> <p>^dMinor Complications include A. No therapy, no consequence; B. Nominal therapy, no consequence; includes overnight admission for observation only.</p>		

eTable 3. Subgroup Analyses of the Primary Safety Rates

	No. (%) (95% CI)	
Subgroup	Device Related Major Complication Rate for Single-Center (N=139)	Device Related Major Complication Rate for Multi-Center (N=126)
Overall	4 (2.9) (0.8, 7.2)	5 (4.0) (1.3, 9.0)
Age (years)	p = >0.999 ^a	p = >0.999 ^a
<65	3 (2.9) (0.6, 8.2)	4 (4.2) (1.1, 10.3)
≥65	1 (2.9) (0.1, 15.3)	1 (3.3) (0.1, 17.2)
Unknown	0 (0.0) (0.0, 97.5)	NA
Gender	p = 0.6325 ^a	p = 0.6475 ^a
Male	1 (1.7) (0.0, 8.9)	1 (2.0) (0.0, 10.4)
Female	3 (3.8) (0.8, 10.8)	4 (5.3) (1.5, 13.1)
Unknown	0 (0.0) (0.0, 97.5)	NA
Filter Types	p = 0.3700 ^b	p = 0.1936 ^b
Retrievable	3 (2.4) (0.5, 6.9)	3 (2.9) (0.6, 8.1)
Permanent	1 (6.7) (0.2, 31.9)	2 (9.5) (1.2, 30.4)
^a P-value is obtained from Fisher's Exact Test excluding the unidentified subjects in the Unknown group to evaluate the homogeneity of primary safety endpoint for the subgroup.		
^b P-value is obtained from Fisher's Exact Test. to evaluate the homogeneity of primary endpoint for Filter Type		

eTable 4. Subgroup Analyses of the Primary Efficacy Rates

Subgroup	No. (%) (95% CI)	
	Technical Success Rate for Single-Center (N=139)	Technical Success Rate for Multi-Center (N=126)
Overall	133 (95.7) (90.8, 98.4)	120 (95.2) (89.9, 98.2)
Age (years)	p = 0.6361 ^a	p = >0.999 ^a
<65	100 (96.2) (90.4, 98.9)	91 (94.8) (88.3, 98.3)
≥65	32 (94.1) (80.3, 99.3)	29 (96.7) (82.8, 99.9)
Unknown	1 (100.0) (2.5, 100.0)	NA
Gender	p = 0.0853 ^a	p = 0.6854 ^a
Male	55 (91.7) (81.6, 97.2)	48 (94.1) (83.8, 98.8)
Female	77 (98.7) (93.1, 100.0)	72 (96.0) (88.8, 99.2)
Unknown	1 (100.0) (2.5, 100.0)	NA
Filter Types	p = 0.5027 ^b	p = 0.2615 ^b
Retrievable	119 (96.0) (90.8, 98.7)	101 (96.2) (90.5, 99.0)
Permanent	14 (93.3) (68.1, 99.8)	19 (90.5) (69.6, 98.8)
^a P-value is obtained from Fisher's Exact Test excluding the unidentified subjects in the Unknown group to evaluate the homogeneity of primary (technical) success endpoint for the subgroup. ^b P-value is obtained from Fisher's Exact Test.		

eMethods. Target Performance Goals

In order to set performance goals for safety and efficacy, a literature search was conducted to review clinical outcomes from published experiences. A total of eight published studies¹⁻⁸ using laser for IVC filter retrieval were identified and reviewed. A random-effect-model meta-analysis was performed by using Comprehensive Meta-Analysis (CMA) software that combined the results of the multiple studies to estimate the weighted average of treatment effects for safety and efficacy separately. Meta-analytic results were considered to make recommendations for the target safety performance goal (PGs), as well as the target efficacy performance goal (PGe).

The weighted average rate of major complications is 2.2% (95% CL= 0.9% -5.7%) as shown in eTable 5. The articles analyzed did not report device related major complications and only procedure-related major complication rates. Given the variability of reported major complication rate, ranging from 0%-8.3%, the expected device related major complication rate was assumed to be 3.0% which was in alignment with the meta-analysis estimates. The proposed safety performance goal of device related major complications was 10%, which was set at $\Delta = 7\%$ above the expected device related major complication rate.

The weighted average rate of technical success is 96.3% (92.9% - 98.1%) as shown in eTable 6. For sample size purposes, the expected technical success rate for this study was assumed to be 96.4% which was in line with meta-analysis estimate. The proposed efficacy performance goal of technical success was 89.4%, which was set at $\Delta = 7\%$ below the expected technical success rate.

eTable 5. Meta-analysis Estimate for Major Complication Rate of Laser-Assisted IVC Filter Retrieval^a

Study	Device(s) Used for Retrieval	Major Complication (n)/N	Statistics for Each Study			Relative Weight
			Adj. Rate and 95% CL			
Johnston 2014 ¹	Looped wire w/ Endoscopic forceps	0/3	0.125	0.007	0.734	7.41
Tamrazi 2016 ²	laser	1/12	0.083	0.012	0.413	11.60
Kuo 2017 ³	Forceps + Laser	4/251	0.016	0.006	0.042	19.21
Chick 2017 ⁴	Laser	2/33	0.061	0.015	0.212	15.77
Desai 2017 ⁵	Forceps + Laser	3/762	0.004	0.001	0.012	18.07
Holly 2018 ⁶	Snare + Balloon + Forceps + Laser	0/17	0.028	0.002	0.322	7.96
Von Stempel 2019 ⁷	Wire loop + Snare+ Forceps + Laser	0/181	0.003	0.000	0.042	8.09
Desai 2019 ⁸	Sling + laser + Forceps	1/25	0.040	0.006	0.235	11.88
Weighted avg. by Random model			0.022	0.009	0.057	
aComprehensive Meta-Analysis Software (CMA) was applied for the analysis.						

eTable 6. Meta-analysis Estimate for Technical Success Rates of Laser-Assisted IVC Filter Retrieval^a

Study	Device(s) Used for Retrieval	Technical Success(n)/N	Statistics for each study			Relative Weight
			Adj. Rate and 95% CL			
Johnston 2014 ¹	Looped wire w/ Endoscopic forceps	3/3	0.875	0.266	0.993	4.44
Tamrazi 2016 ²	laser	11/12	0.917	0.587	0.988	7.99
Kuo 2017 ³	Forceps + Laser	249/251	0.992	0.969	0.998	13.12
Chick 2017 ⁴	Laser	30/33	0.909	0.753	0.970	15.45
Desai 2017 ⁵	Forceps + Laser	745/762	0.978	0.964	0.986	25.55
Holly 2018 ⁶	Snare + Balloon + Forceps + Laser	17/17	0.972	0.678	0.998	4.86
Von Stempel 2019 ⁷	Wire loop + Snare+ Forceps + Laser	170/181	0.939	0.894	0.966	23.70
Desai 2019 ⁸	Sling + laser + Forceps	25/25	0.981	0.756	0.999	4.89
Weighted avg. by Random model			0.963	0.929	0.981	
aComprehensive Meta-Analysis Software (CMA) was applied for the analysis.						

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