

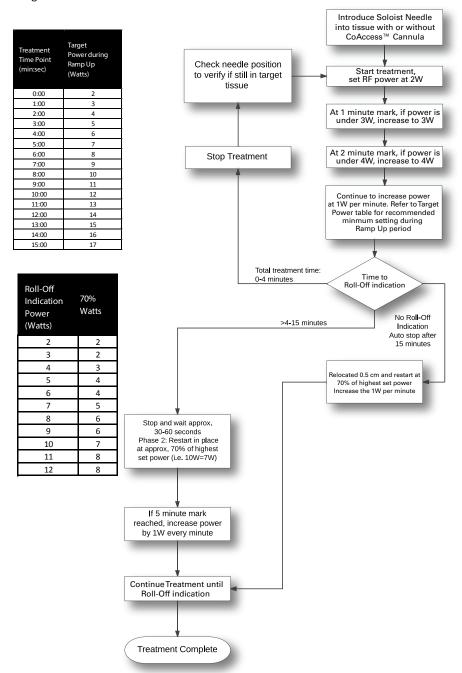
Radiofrequency Ablation



Algorithm Cards

Soloist™

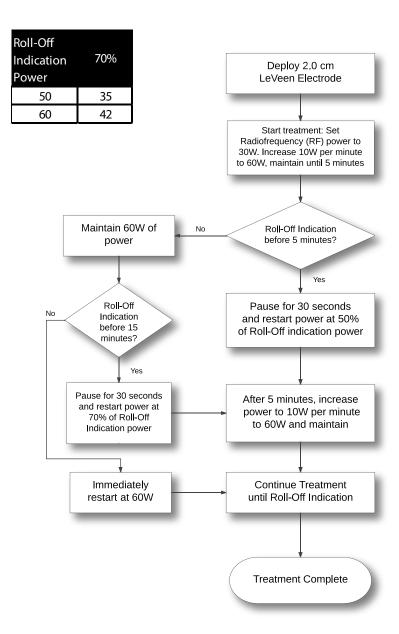
Single Needle Electrode



Soloist™ Single Needle Electrode (16.5ga)

UPN	Order Number	Active Electrode Length (cm)	Cannula Length (cm)
M001 26250 0	26-250	0.9	18.0

LeVeen™ Electrode 2.0 cm



LeVeen™ SuperSlim™ Needle Electrode System

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001 26227 0	26-227	2.0	25.0
M001 26226 0	26-226	2.0	15.0

LeVeen[™] Electrode 3.0 cm

Roll-Off		1		
Indication	70%			
Power				
50	35			Deploy 3.0 cm
60	42			LeVeen Electrode
70	49			
80	56			
90	63			
100	70			V
110	77			Start treatment: Set Radiofrequency (RF) power to 40W. Increase 10W per
120	84			30 seconds to 80W, maintain until 5 minutes
130	91			o ministro
140	98			
150	105			
	No F	Roll-Off Indication before 15 minutes? Yes Pause for 30 seconds and restart power at 70% of Roll-Off Indication power	No	Pause for 30 seconds and restart power at 50% of Roll-Off indication power After 5 minutes, increase power to 10W per 30 seconds to 150W and maintain
		Immediately restart at 150W	,	Continue Treatment until Roll-Off Indication Treatment Complete

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001 26204 0	26-204	3.0	12.0
M001 26205 0	26-205	3.0	15.0

LeVeen SuperSlim™ Needle Electrode System

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001 26229 0	26-229	3.0	25.0
M001 26228 0	26-228	3.0	15.0

LeVeen CoAccess™ Needle Electrode System

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001 26222 0	26-222	3.0	15.0

LeVeen[™] Electrode 3.5 cm

Roll-Off Indication Power	70%			
50	35			
60	42			Deploy 3.5 cm
70	49			LeVeen Electrode
80	56			
90	63			
100	70			
110	77			
120	84			Start treatment: Set Radiofrequency
130	91			(RF) power to 50W. Increase 10W per 30 seconds to 90W, maintain until
140	98			5 minutes
150	105			
160	112			
170	119			
180	126			
	No [Roll-Off Indication before 15 minutes? Yes Pause for 30 seconds and restart power at 70% of Roll-Off Indication power	No	Pause for 30 seconds and restart power at 50% of Roll-Off indication power After 5 minutes, increase power to 10W per 30 seconds to 180W and maintain
		Immediately restart at 180W		Continue Treatment until Roll-Off Indication Treatment Complete

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001 26202 0	26-202	3.5	12.0
M001 26203 0	26-203	3.5	15.0
M001 26215 0	26-215	3.5	25.0

LeVeen CoAccess™ Needle Electrode System

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001 26223 0	26-223	3.5	15.0

LeVeen[™] Electrode 4.0 cm

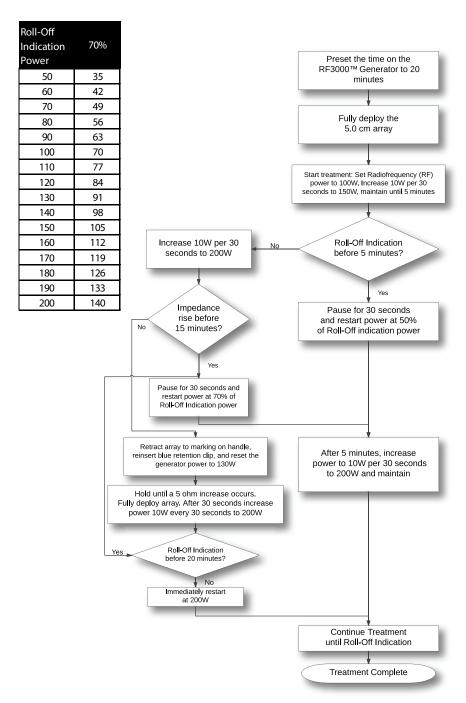
Roll-Off	70%		
Indication Power	7070		
50	35		
60	42		
70	49		Deploy 4.0 cm
80	56		LeVeen Electrode
90	63		
100	70		
110	77		
120	84		
130	91		Start treatment: Set Radiofrequency
140	98		(RF) power to 80W. Increase 10W per 30 seconds to 130W, maintain
150	105		until 5 minutes
160	112		
170	119		
180	126		
190	133		
		Roll-Off Indication before 15 minutes? Pause for 30 seconds and restart power at 70% of Roll-Off Indication power	Pause for 30 seconds and restart power at 50% of Roll-Off indication power After 5 minutes, increase power to 10W per 30 seconds to 190W and maintain
		Immediately restart at 190W	Continue Treatment until Roll-Off Indication Treatment Complete

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001 26213 0	26-213	4.0	15.0
M001 26231 0	26-231	4.0	25.0

LeVeen CoAccess™ Needle Electrode System

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001 26224 0	26-224	4.0	15.0

LeVeen[™] Electrode 5.0 cm



UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001 26216 0	26-216	5.0	15.0
M001 26217 0	26-217	5.0	25.0

The LeVeen Needle Electrode Family

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Prior to use, please see the complete "Directions for Use" for more information on Indications, contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Indications for Use: The LeVeen™, SuperSlim™, and Soloist™ Needle Electrode Families are intended to be used in conjunction with the RF 3000™ Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.

Contraindications for Use: None Known

Warning: Do not use in main biliary ducts, gallbladder or during pregnancy. Do not use in MR Suite. Use of the electrode without the colored insulated cannula may result in serious burns to the patient and./or user. Damage to the insulation of the introducer may result in serious burns to the patient and/or user.

Precautions: The LeVeen, SuperSlim, and Soloist Needle Electrode Families must be used in conjunction with the Boston scientific RF 3000 Generator.

Potential Complications: Potential complications include, but are not limited to:
Abscess, ARDS, Ascites, Arterial Fibrillation, Biloma, Bowel Perforation, Burn, Death, Delayed hemorrhage into ablated tissue, Diarrhea, Electric Shock, Fistula including biliary fistual, Hematoma, Hemorrhage, Infection, Liver Failure, Liver Insufficiency, Pain, Peritonitis, Persistent Fever >39°C, Pleural Effusion, Pneumothorax, Renal Failure, Tumor recurrence, Tumor Seeding, Ventricular Fibrillation.

Prior to use, please consult device DFU for full indications, contraindications, warnings, precautions, adverse events and operating instructions.

RF 3000, LeVeen, SuperSlim, CoAccess and Soloist are registered or unregistered trademarks of Boston Scientific Corporation or its affiliates.



Peripheral Interventions

One Boston Scientific Place Natick, MA 01760-1537 USA

www.bostonscientific.com

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