Sentinel® Cerebral Protection System

℞Only

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

WARNING Contents supplied STERILE using a radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Claret Medical® representative.

For single patient use only. Do not reuse, reprocess, or re-sterilize as these may compromise the structural integrity of the device and/or lead to device failure, and may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

PRODUCT DESCRIPTION

The Claret Medical **Sentinel® Cerebral Protection System** (Sentinel System) is a percutaneously delivered dual-filter embolic protection device, designed to capture and remove debris dislodged during endovascular procedures. The Sentinel System utilizes an embolic filter delivered to the brachiocephalic artery (Proximal Filter), and a second embolic filter delivered to the left common carotid artery (Distal Filter). At the completion of the procedure, the filters and debris are recaptured into the catheter and removed from the patient.

The Sentinel System consists of a 6 French catheter with deployable Proximal and Distal Filters, an Articulating Sheath, and an integral handle assembly. Table 1 and Table 2 provide information regarding the filter sizes and Sentinel System specifications.

Table 1: Filter-Vessel Sizing Guide

REF (Model) Number for Ordering	Proximal Filter Size (mm)	Target Proximal Vessel Size (mm)	Distal Filter Size (mm)	Target Distal Vessel Size (mm)
CMS15-10C	15	9.0 – 15.0	10	6.5 – 10.0

Table 2: Sentinel System Specifications

Delivery Profile	6F
Working Length	95 cm
Articulating Sheath Length	4 cm
Guidewire Compatibility	0.014" (0.36 mm) diameter floppy tip coronary guidewire, 175 cm minimum length

The Articulating Sheath tip, Proximal Sheath tip, Proximal Filter hoop, Proximal Articulating Sheath Marker, Distal Filter hoop and Distal Filter tip are radiopaque to enable visualization during use. See Figure 3 and Figure 4.

Package contains one (1) Sentinel System

INDICATIONS FOR USE

The Sentinel® Cerebral Protection System is indicated for use as a cerebral protection device to capture and remove embolic material while performing transcatheter aortic valve procedures in order to reduce ischemic injury to the brain peri-procedurally. The diameters of the arteries at the site of filter placement should be between 9 – 15 mm for the brachiocephalic and 6.5 mm – 10 mm in the left common carotid.

CONTRAINDICATIONS FOR USE

- Do not use in patients for whom anticoagulant and antiplatelet therapy is contraindicated.
- Do not use in vessels with excessive tortuosity.
- Do not use in patients with uncorrected bleeding disorders.
- Do not use in patients with compromised blood flow to the right upper extremity.
- Do not use in patients who have arterial stenosis >70% in either the left common carotid artery or the brachiocephalic artery.
- Do not use in patients whose brachiocephalic or left carotid artery reveals significant stenosis, ectasia, dissection, or aneurysm at the aortic ostium or within 3 cm of the aortic ostium.

WARNINGS

- Carefully read all instructions and labeling prior to use. Observe all warnings, cautions, and precautions noted throughout these instructions. Failure to do so may result in complications.
- Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Sentinel System for their intended uses, sizing, warnings, and precautions.
- The appropriate antiplatelet/anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- Prior to use, the packaging and product should be inspected for signs of damage. Never use a damaged product or product from a damaged package.

- Never advance or withdraw the Sentinel System without proper fluoroscopic guidance or against resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- It is recommended that the patency of the right radial or brachial artery be assessed prior to the introduction of the Sentinel System.
- It is recommended that the patient be tested for occlusion of the radial artery prior to device introduction.
- Do not use the device in left radial or left brachial access.
- Do not use the Sentinel System to deliver any type of fluid to the patient e.g. contrast media, heparinized saline, etc. due to risk of air embolization and comprise to device performance.
- Minimize movement of the Sentinel System after initial placement. Excessive movement of filters may lead to embolization of debris, vessel and/or device damage.
- Do not deploy the filters within a previously repaired artery.
- Observe the Sentinel System under fluoroscopy and monitor the patient to verify the filters have not become occluded with debris resulting in slow or no flow. The filters should be recovered if they become occluded or if flow is compromised (See Procedural Use – Retrieval).
- Indwell time of the Sentinel System is not to exceed 90 minutes as occlusion could occur, resulting in slow or no flow.
- Failure to adequately close off the Flush Ports (Front Handle, Rear Handle) may result in air embolism.
- Do not undersize or oversize the filters in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the filters. (Refer to Sizing Guide, Table 1).
- Do not apply excessive force to the Sentinel System. This may lead to distal embolization of debris, and vessel and/or device damage.

PRECAUTIONS

- Do not forcefully bend or reshape the Articulating Sheath of the Sentinel System. This may cause device damage.
- Do not use the product if the packaging sterile barrier has been damaged or compromised.
- Improper bending of the Sentinel System may damage the catheter.
- Do not re-sterilize or reuse on another vessel or patient.

ADVERSE EVENTS

Adverse events associated with transcatheter aortic valve replacement (TAVR) using the Sentinel System with commercially available TAVR devices and TAVR devices alone is presented in Table 3, all events adjudicated.

Table 3: Adverse Events, ≤ 30 Days

	Sentinel System Arms N=244		Control Arm N=119	
Event Type	Total Events	Subjects w/Event(s)	Total Events	Subjects w/Event(s)
Acute kidney injury	7	2.9% (7)	5	2.5% (3)
Vascular complication	21	8.6% (21)	9	7.6% (9)
TAVR Access Site	20	8.2% (20)	9	7.6% (9)
Radial Artery	0	0% (0)	N/A	N/A
Brachial Artery	1	0.4% (1)	N/A	N/A
Stroke	13	5.3% (13)	12	9.2% (11)
Disabling	2	0.8% (2)	1	0.8 (1)
Non-disabling	11	4.5% (11)	9	7.6% (9)
TIA	1	0.4% (1)	1	0.8% (1)
Death	11	4.5% (11)	4	3.4% (4)

Note: AKI includes Class I, II, and III

HOW SUPPLIED

- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible

STORAGE

- Store in cool, dry and dark place.
- Use the device prior to the Expiration Date noted on the box and pouch.

PHYSICIAN TRAINING

The Sentinel System should only be used by physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with endovascular procedures.

SENTINEL CLINICAL STUDIES SUMMARY

Cerebral Protection in Transcatheter Aortic Valve Replacement, The SENTINEL Study

Purpose: To assess the safety and efficacy of the Claret Medical Sentinel Cerebral Protection System used for embolic protection during Transcatheter Aortic Valve Replacement (TAVR) compared to TAVR standard of care (without embolic protection).

Design: A prospective, multi-center, randomized study using the Sentinel System in subjects with severe symptomatic calcified native aortic valve stenosis indicated for TAVR was conducted at 17 sites in the United States and 2 in Germany. The primary safety endpoint was the occurrence of all Major Adverse Cardiac and Cerebrovascular Events (MACCE) at 30 days compared to a historical performance goal, with MACCE defined as all death, all stroke, and all Class 3 Acute Kidney Injury (AKI). The primary efficacy endpoint was the reduction in median total new lesion volume in protected territories between the Imaging Arms (Test and Control) as assessed by DW-MRI at Day 2-7 post-procedure. The observational success criteria was to

demonstrate the true clinical treatment effect by showing the observed ratio of the median total new lesion volumes is ≥ 30% in favor of the Test Arm having a lower median new lesion volume in the protected territories as compared to the Control Arm.

The study population was comprised of patients with severe symptomatic calcified native aortic valve stenosis who meet the commercially approved indications for TAVR and complied with the study inclusion/exclusion criteria. Patients were randomized between the Safety Arm and the Imaging Cohort (Test Arm and Control Arm) on a 1:1:1 basis.

Demographics: The total population consisted of 428 patients. Of these, 65 were training phase non-randomized "Roll-In" subjects that utilized the Sentinel System during TAVR. Of the randomized (n=363) patients, the age ranged from 44 to 99 years with an average age of 82.3 ± 8.31 (mean ±SD) and 47.9% were male. The average STS score was 6.7 ± 3.79, 31.7% of patients had a history of atrial fibrillation, 83.1% of patients had NYHA classification of Class 3 and above, and 5.8% had a previous stroke with permanent deficit.

Methods: Patients randomized into the Safety Arm underwent TAVR with the Sentinel System. Patients enrolled in this arm of the study completed safety assessments post procedure, and again at 30 and 90 days post procedure. In the Imaging Cohort, Test Arm patients underwent TAVR with the Sentinel System and Control Arm patients underwent TAVR only. Patients participating in the Imaging Cohort underwent comparative Magnetic Resonance Imaging (MRI) exams and neurocognitive assessments prior to and following TAVR in addition to the same safety assessments as the Safety Arm. A Clinical Events Committee (CEC) adjudicated all MACCE event endpoints.

Results: The principle safety and efficacy results from patients treated in the SENTINEL Study are provided below. All data presented below is based on the Intent to Treat (ITT) population. For safety, the ITT population consists of all patients with clinical follow-up, for efficacy the ITT population consists of all patients with baseline and follow-up MRI imaging.

Table 4: Primary Safety Endpoint (Non-Inferiority) – 30-Day Adjudicated MACCE Rate

	Total Events	Subjects w/Event(s)	Performance Goal	Upper 95% Confidence Interval[1]	P-value[1]
ITT, with imputation[4]	NA[2]	18/244 (7.4%)	18.3%[3]	10.7%	<.0001

Note: MACCE, Major Adverse Cardiac and Cerebrovascular Events, are defined as All Death, All Stroke, and Acute Kidney Injury (Class 3) at 30 days compared to a historical performance goal.

[1]Upper confidence interval and p-value based on exact one-sided test for alternative hypothesis: rate < PG with 0.05 alpha level

[2]Binary outcome based on imputation analysis, number of events does not apply

[3]Performance Goal of 18.3% was used for testing non-inferiority

[4]Imputation for missing data

Table 5: 30-Day Adjudicated MACCE and Component Rates (Evaluable Subjects)

	Sentinel System Arms	Control Arm	P-value*
Any MACCE	7.3% (17/234) [17] (4.3%,11.4%)	9.9% (11/111) [12] (5.1%,17.0%)	0.4047
Death	1.3% (3/234) [3] (0.3%,3.7%)	1.8% (2/111) [2] (0.2%,6.4%)	0.6584
All Stroke	5.6% (13/231) [13] (3.0%,9.4%)	9.1% (10/110) [10] (4.4%,16.1%)	0.2523
Disabling Stroke	0.9% (2/231) [2] (0.1%,3.1%)	0.9% (1/109) [1] (0.0%,5.0%)	1.0000
Non-disabling Stroke	4.8% (11/231) [11] (2.4%,8.4%)	8.2% (9/110) [9] (3.8%,15.0%)	0.2234
AKI (Class 3)	0.4% (1/231) [1] (0.0%,2.4%)	0% (0.0%,3.3%)	1.0000

Note: Data presented as: % of subjects with event (number of subjects with event/subjects per group evaluable at 30 days or experienced an event, i.e. evaluable) [number of events] (exact 95% CI)

*P-Value based on two-sided Fisher's exact test for Test compared to Control.

Table 6: Deployment and Retrieval

	Sentinel Safety Arm (N=123)	Sentinel Test Arm (N=121)	Control Arm (N=119)	Total (N=363)	p-value[1]
Acute Delivery and Retrieval Success[2]	96.6% (115/119)	92.0% (103/112)	N/A	94.4% (218/231)	0.1570
Distal filter successfully deployed	96.6% (115/119)	92.0% (103/112)	N/A	94.4% (218/231)	0.1570
Proximal filter successfully deployed	100.0% (119/119)	99.1% (111/112)	N/A	99.6% (230/231)	0.4848
Sentinel System retrieved successfully	100.0% (119/119)	100.0% (112/112)	N/A	100.0% (231/231)	N/A
TAVR procedure considered complete[3]	95.8% (114/119)	98.2% (110/112)	N/A	97.0% (224/231)	0.4474

Note: Categorical data presented using % (n/N).
[1] p-values are testing for statistical differences across randomized arms.
[2] Deployment and retrieval of the proximal and distal filters in accessible anatomies. Accessible anatomies are those which are not excessively tortuous or calcified that would prevent cannulation of the device to its position.
[3] Deployment of at least one filter (with either the first or second device) during the TAVR procedure without any incidence of investigational device related MACCE.

Table 7: Treatment Effect Success Criteria - 2-7 Day DW-MRI Median Total New Lesion Volume (Protected Territories)

	Sentinel System Arms	Control Arm	Performance Goal	% Reduction: Sentinel System vs Control (Bootstrapped 95% CI)	95% Confidence Interval[1]
ITT[2], mm[3]	102.8 (36.9, 423.2), n=91 0 min, 5175.9 max	178 (34.3, 482.5), n=98 0 min, 24300 max	30%	42.2 (-10.6, 65.8)	-3.2, 67.6

[1]Calculated using the Price, et al. method
[2]Median Total New DW-MRI Lesion Volume based on Protected Territories

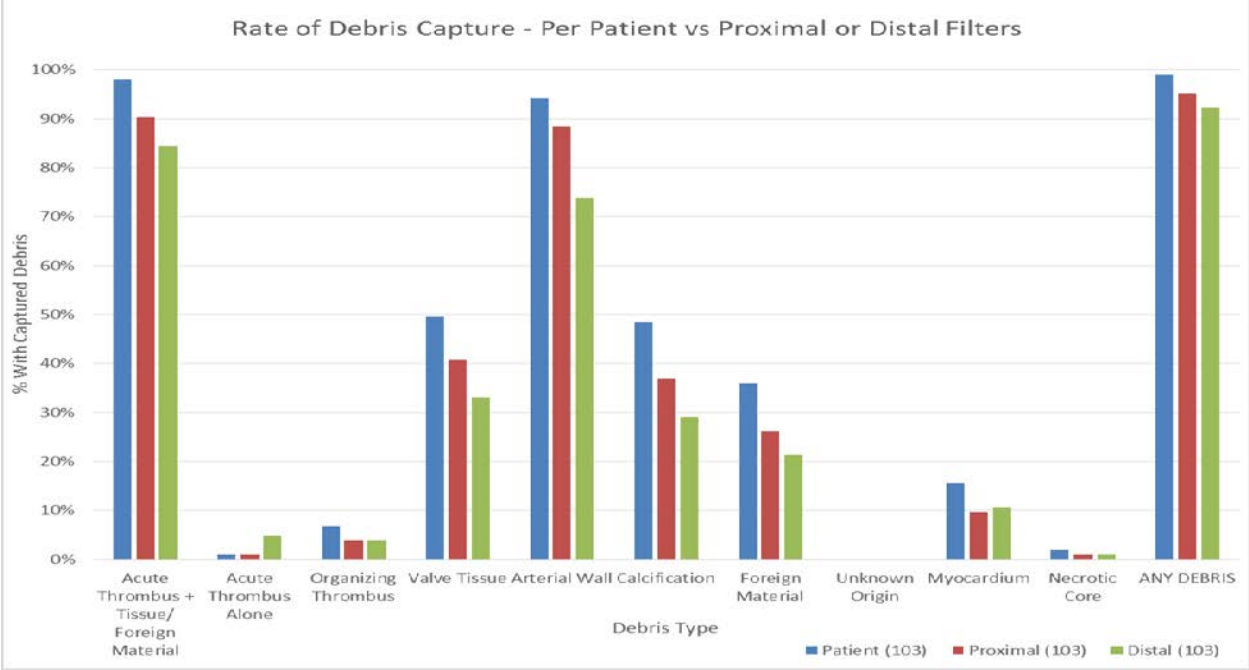

Figure 1: Histopathology Results

Table 8: Primary Efficacy Endpoint - 2-7 Day DW-MRI Median Total New Lesion Volume (Protected Territories)

	Sentinel System Arms	Control Arm	Observed Treatment Difference (test – control)	P-value[1]
ITT[2] with Imputation[3], mm[3]	109.1 (36.9, 379.7), n=121 0 min, 5175.9 max	174 (39.6, 469.3), n=119 0 min, 24300 max	-64.9	0.2354

[1]Based on two-sided Wilcoxon test
[2]Median Total New DW-MRI Lesion Volume based on Protected Territories
[3]Imputation for missing data

A multivariable analysis identified baseline lesion burden (i.e., existing cerebral microvascular disease detected by baseline T2/FLAIR MRI prior to TAVR) as the most significant predictor of new MRI lesion volume following TAVR in these patients. When the interaction of baseline lesion volume, as well as TAVR valve type, are adjusted for there is a statistically significant reduction in new lesion volume and number between the Sentinel System test and control arms, see Table 9.

Table 9: Multivariable Analysis, Least Squares Means and Test of Effects – 2-7 Day DW-MRI (Protected Territories)

Effect	Mean Estimate (95% CI)		% Reduction	p-value
	Test Arm	Control Arm		
New Lesion Volume (mm^3)	83.3 (55.0, 126.1)	162.8 (107.9, 245.5)	49%	0.0248
New Lesion Number (n)	3.2 (2.5, 4.2)	4.7 (3.7, 6.0)	32%	0.0476

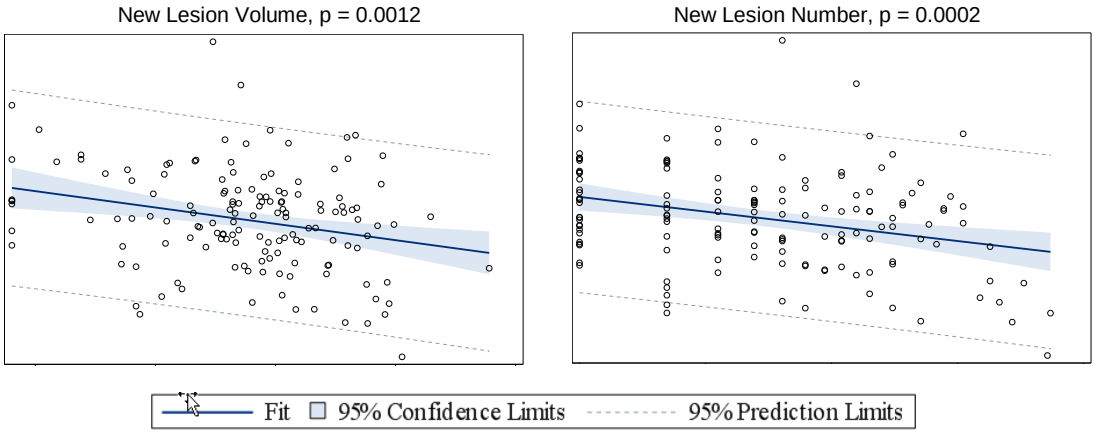

Figure 2: Change in Overall Z-Score Correlated to Volume & Number in All Territories (Follow-up – Baseline)

Conclusions: The SENTINEL trial demonstrated that the Sentinel System is safe and effective. The Sentinel System took less than 10 minutes to deploy in over 90% of patients and did not introduce any additional procedural risk. Sentinel System deployment was achieved in 94.4% of patients and 100% of devices were successfully retrieved. Histopathological analysis showed that a wide range of embolic material/debris was captured in 99% of patients. The trial demonstrated the occurrence of new ischemic embolic brain lesions measured by DW-MRI can be reduced significantly (p=0.0248 and p=0.0476 for volume and number, respectively) through the use of the Sentinel filter-based embolic protection device. The study also demonstrated a strong correlation between volumetric (p=0.0012) and numeric (p=0.0002) lesion burden in all territories of the brain and neurocognitive deterioration in patients.

INSTRUCTIONS FOR USE

Preparing the Sentinel System for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Anticoagulant therapy sufficient to maintain an Activated Clotting Time of at least 250 seconds for the duration of the procedure is recommended.
2. Perform angiogram of the aortic arch.
3. Identify the location within the vessels where the filters will be deployed to ensure appropriate vessel sizing.

WARNING: Do not use the filters in vessels outside the indicated target vessel diameter ranges. This may result in inadequate vessel wall apposition, incomplete deployment of the filters, and/or vessel damage.

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4. Ensure the introducer sheath size will accommodate the Sentinel System.
5. Using sterile techniques remove the Sentinel System from the packaging and place the system in a sterile work area.

CAUTION: Do not use the product if the packaging sterile barriers have been damaged or compromised.

WARNING: Inspect the device for any damage. Never use a damaged product or product from a damaged package.

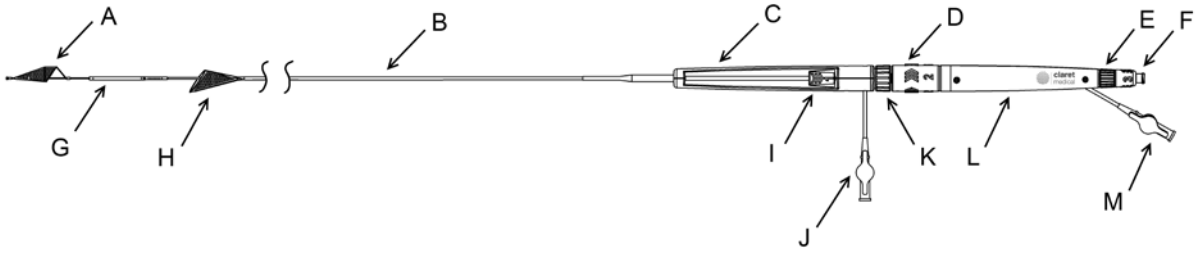

Figure 3: Sentinel Cerebral Protection System

A Distal Filter	**E** Rear Handle Lock	**I** Proximal Filter Slider **(#1)**	**M** Rear Handle Flush Port
B Proximal Sheath	**F** Distal Filter Slider **(#3)**	**J** Front Handle Flush Port	
C Front Handle	**G** Articulating Sheath	**K** Front Handle Lock	
D Articulation Knob **(#2)**	**H** Proximal Filter	**L** Rear Handle	

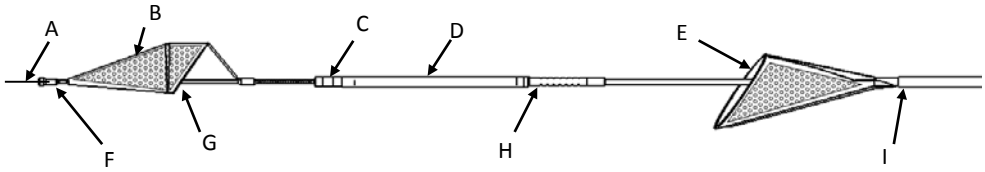

Figure 4: Sentinel Cerebral Protection System – Distal Section

A Guidewire	**D** Articulating Sheath	**G** Radiopaque Distal Filter Hoop
B Distal Filter	**E** Radiopaque Proximal Filter Hoop	**H** Proximal Articulating Sheath Radiopaque Marker
C Radiopaque Articulating Sheath Tip Marker	**F** Radiopaque Distal Filter Tip	**I** Proximal Sheath Radiopaque Marker

Flushing the Sentinel System

CAUTION: Do not prepare the Sentinel System or sheath the Proximal and Distal Filters until immediately prior to use.

Note: The device handle has two handle locks, the Rear Handle Lock, and the Front Handle Lock. Refer to Figure 3. Closing these locks facilitates flushing, prevents back-bleeding, and prevents motion of the device handle components and Distal Filter. The locks should be temporarily opened to facilitate movement of the handle components as required.
Note: The primary controls used to deploy the device, the Proximal Filter Slider **(#1)**, the Articulation Knob **(#2)**, and the Distal Filter Slider **(#3)**, are all marked with the number "1", "2' and "3" indicating the order in which they are used. In this document, these names will be shown with the control number appended to the name.

1. Remove the packaging stylet from the distal guidewire lumen and discard.
2. Ensure that both the Front Handle Lock and the Rear Handle Lock are tightened.
3. Flush through the Flush Port in the Distal Filter Slider **(#3)** with heparinized saline until all air is removed and fluid passes from Distal Filter Tip guidewire lumen. See Figure 3.
4. Flush through the Rear Handle Flush Port with heparinized saline until all air is removed and fluid passes from the tip of the Articulating Sheath. See Figure 3. Ensure that the flush port stopcock is closed following flushing.
5. Flush through the Front Handle Flush Port with heparinized saline until all air is removed and fluid passes from the tip of the Proximal Sheath. See Figure 3. Ensure that the flush port stopcock is closed following flushing.
6. Submerge the distal end of the device in heparinized saline, and loosen the Rear Handle Lock. With the distal tip submerged, slowly retract the Distal Filter by pulling back on the Distal Filter Slider **(#3)** until the filter is fully collapsed into the Articulating Sheath. The submerged filter may be agitated during sheathing in order to facilitate removal of bubbles. Tighten the Rear Handle Lock.
   Note: Flushing and sheathing of the Distal Filter may be repeated to ensure all air has been removed from the system.

CAUTION: Do not over-retract the Distal Filter as damage may occur.

7. Ensure the Articulating Sheath is fully advanced until the Articulation Knob **(#2)** is in contact with the Front Handle Lock to ensure it does not interfere with sheathing the Proximal Filter. Tighten the Front Handle Lock. While submerged, sheath the Proximal Filter by slowly advancing the Proximal Filter Slider **(#1)** relative to the Front Handle until the Proximal Filter is fully sheathed. The submerged filter may be agitated during sheathing in order to facilitate removal of bubbles. See Figure 3 and Figure 10.
   Note: Flushing and sheathing of the Proximal Filter may be repeated to ensure all air has been removed from the system.
8. While submerged, again flush through the Front Handle Flush Port with heparinized saline until all air is removed and fluid passes from the tip of the Proximal Sheath. See Figure 3. Ensure that the flush port stopcock is closed following flushing.

WARNING: Do not use a Sentinel System that has not been properly flushed. Failure to prepare and flush the device before use may introduce air and result in patient injury.

Note: Tighten both the Rear and Front Handle Locks prior to delivering device to prevent inadvertent movement.
Note: Use a minimum of 10cc of heparinized saline to flush through the Front Handle Flush Port to ensure all air has been removed from the system.
Note: Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Sentinel System for their intended uses, sizing, warnings, and precautions.

Procedural Use - Delivery and Deployment

WARNING: Do not use a Sentinel System that has not been properly flushed. Failure to prep and flush the device before use may introduce air and patient injury may result.

WARNING: To prevent damage to the System and/or harm to the patient, never advance, manipulate, or withdraw the Sentinel System without proper fluoroscopic guidance.

WARNING: The Sentinel System is not to be used to deliver any type of fluid to the patient e.g. contrast media, heparinized saline, etc.

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1. Using standard interventional technique, place a 6 French introducer sheath into the radial or brachial artery of the patient's right arm.
2. Backload a floppy tip 0.014" coronary guidewire into the Distal Filter Tip located at the distal end of the Sentinel System until the guidewire tip is located just inside the distal tip of the Sentinel catheter.
3. Introduce the Sentinel System into the introducer sheath.
4. In the patient's right arm, advance the guidewire relative to the Sentinel System until the distal tip of the guidewire is a minimum of 10 cm beyond the distal tip of the Sentinel System using fluoroscopic guidance.
5. Advance the Sheath Dilator distally until it contacts the introducer sheath hemostasis valve. Gently advance the Sheath Dilator until it is fully inserted into the introducer hemostasis valve, and advance the Sentinel System slightly to make sure that it can move easily through the Sheath Dilator.
6. Advance the Sentinel System and the guidewire together using standard interventional technique until the Proximal Filter is in the intended target location in the brachiocephalic artery with the Articulating Sheath section of the catheter extending down the ascending aorta. Should the catheter tip extend down the descending aorta, pull the system back and rotate to advance down the ascending aorta.

WARNING: Do not advance the Sentinel System without a guidewire extending distally past the tip of the catheter a minimum of 10 cm.

WARNING: Do not use excessive force on the Sentinel System while introducing or advancing through the introducer sheath or blood vessels. Excessive force may cause damage to the device and/or patient harm.

Note: The Articulating Sheath will protrude into the aorta during proximal filter deployment.
7. Deploy the Proximal Filter by holding the Front Handle in a fixed position and slowly retracting the Proximal Filter Slider **(#1)** fully.

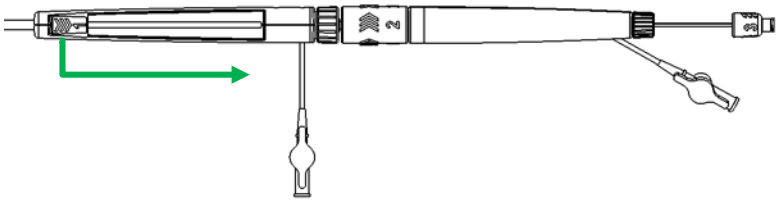

Figure 5: Proximal Filter Deployment

8. Confirm proper Proximal Filter position using fluoroscopy. The Proximal Filter should be positioned in the brachiocephalic artery to prevent any debris from reaching the right carotid artery. See Figure 5 and Figure 6.
9. If the filter position is not optimal, the filter may be retrieved and repositioned up to two times. This may be done by holding the Front Handle in a stationary position and advancing the Proximal Filter Slider **(#1)** until the Proximal Filter is re-sheathed. The Proximal Filter may then be repositioned by advancing or retracting the catheter until optimal positioning is achieved. Finally the Proximal Filter is redeployed by retracting the Proximal Filter Slider **(#1)** while holding the Front Handle in a fixed position.

CAUTION: Repositioning, if required, should only occur during initial placement.

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10. Confirm filter-to-vessel wall apposition using fluoroscopy, and ensure that the Proximal Filter and Proximal Sheath do not move after placement.
11. Withdraw the Sheath Dilator fully from the introducer sheath hemostasis valve to hold the Proximal Sheath stationary relative to the introducer sheath.
12. Withdraw the guidewire until the tip is located just within the distal tip of Sentinel catheter.
13. Loosen the Front Handle Lock to facilitate positioning of the Articulating Sheath.
14. Position the Articulating Sheath by manipulating the Rear Handle relative to the Front Handle in order to position the catheter tip. Rotate the Articulation Knob **(#2)** on the Rear Handle in the direction of the arrows in order to deflect the tip of the Articulating Sheath as necessary toward the left common carotid artery ostium.

CAUTION: Do not move the Front Handle, and thus the Proximal Filter, while manipulating the Rear Handle.

15. Advance the 0.014" guidewire beyond the distal tip of the Articulating Sheath in order to place the guidewire in the left common carotid artery.

CAUTION: Do not to advance the guidewire more than 5 cm into the left common carotid artery.

16. Position the Articulating Sheath so that the curvature matches the Brachiocephalic Artery – Aorta – Left Common Carotid Artery junction and is pulled up to the carina between the two vessels, see .
Note: Ensure that the Articulating Sheath is well apposed to the carina, and does not protrude into the aortic space. See Figure 7 for correct positioning and Figure 9 for incorrect positioning.

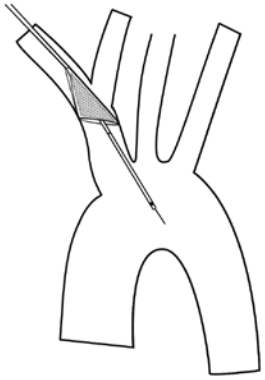

Figure 6

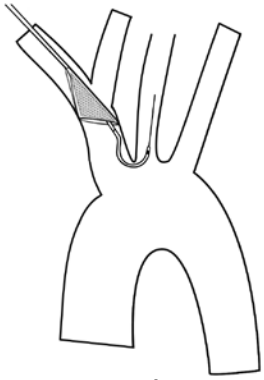

Figure 7

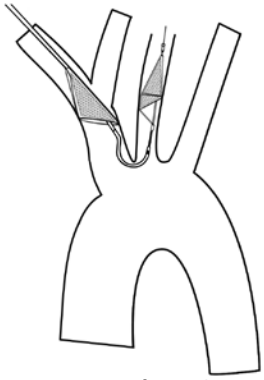

Figure 8

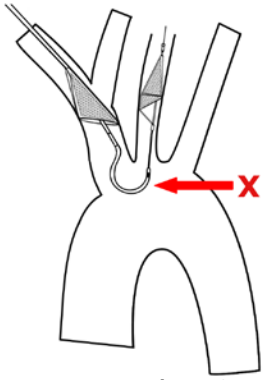

Figure 9

17. Secure the position of the Articulating Sheath by tightening the Front Handle Lock.
18. Loosen the Rear Handle Lock and advance the Distal Filter under fluoroscopy by pushing the Distal Filter Slider **(#3)** forward until the Distal Filter frame is fully expanded and apposed to the vessel wall. The Distal Filter should be positioned just beyond the Articulating Sheath tip and movement should be minimized once it is fully expanded in the vessel. See Figure 8.

WARNING: Minimize movement of the Sentinel System after filter deployment. Excessive movement may lead to embolization of debris, and vessel and/or device damage.

19. Confirm filter-to-vessel wall apposition of the distal filter using fluoroscopy. See Figure 8.
20. Tighten the Rear Handle Lock. See Figure 3.

CAUTION: Verify that the Front Handle Lock and the Rear Handle Lock are tight and secure before any subsequent procedures.

WARNING: The Sentinel System is not to be used to deliver any type of fluid to the patient e.g. contrast media, heparinized saline, etc.

CAUTION: Repositioning, if required, should only occur during initial placement.

21. Cover the exposed portion of the Sentinel System with a drape to prevent movement during subsequent endovascular procedures.

CAUTION: Care must be taken NOT to kink the exposed catheter.

WARNING: Minimize movement of the Sentinel System and its filters after filter deployment. Excessive movement may lead to embolization of debris, and vessel and/or device damage.

WARNING: If gross movement of either the Proximal or Distal Filter is noted, check to ensure filters remain apposed to the vessel walls by fluoroscopy.

WARNING: If the arterial flow is believed to be compromised (slow / no flow), the filters should be retrieved. See Retrieval below.

Procedural Use – Retrieval

WARNING: Do not pull excessively on the Sentinel System to avoid filter membrane tears, filter hoop detachment, system damage or patient harm during use.

WARNING: Never advance or withdraw the Sentinel System without proper fluoroscopic guidance.

WARNING: Never withdraw or move an intravascular device against any resistance until the resistance cause is determined. Advancing or retracting with resistance may lead to embolization of debris, and vessel and / or device damage.

There are two methods for Distal Filter recovery: Partial and Full Enclosure Recovery

1. Loosen the Rear Handle Lock. See Figure 3.
2. Recover the Distal Filter using one of the following two methods:
   a. **Full Enclosure Recovery:** Gently withdraw the Distal Filter Slider **(#3)** relative to the Rear Handle until the radiopaque Distal Filter Tip is flush with the Radiopaque Articulating Sheath Tip Marker as visualized on fluoroscopy. Tighten the Rear Handle Lock. If resistance is felt during Distal Filter recovery, or if it is believed that the Distal Filter is excessively full, follow the Partial Enclosure Recovery method detailed below.
   b. **Partial Enclosure Recovery:** Gently withdraw the Distal Filter Slider **(#3)** relative to the Rear Handle until the Distal Filter Radiopaque Hoop is collapsed inside the Articulating Sheath tip as visualized on fluoroscopy. Tighten the Rear Handle Lock.

WARNING: Exercise caution when using the partial enclosure recovery method. If resistance is felt during catheter withdrawal, advance the Distal Filter and Articulating Sheath together distally and withdraw the Distal Filter more fully into the Articulating Sheath before re-attempting withdrawal of the catheter.

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3. Loosen the Front Handle Lock and withdraw the Articulating Sheath tip from the left common carotid artery by manipulating, straightening, rotating, and advancing or withdrawing the Rear Handle and rotating the Articulation Knob **(#2)** until the Articulating Sheath tip is straight and is within the aorta.
4. Advance the Articulating Sheath completely by advancing the Rear Handle until the Articulation Knob **(#2)** contacts the Front Handle Lock to prevent interference with the Proximal Sheath or Proximal Filter during Proximal Filter retrieval. Tighten the Front Handle Lock. See Figure 3.
5. Advance the Sheath Dilator relative to the Proximal Sheath until it is fully inserted into the introducer sheath hemostasis valve.

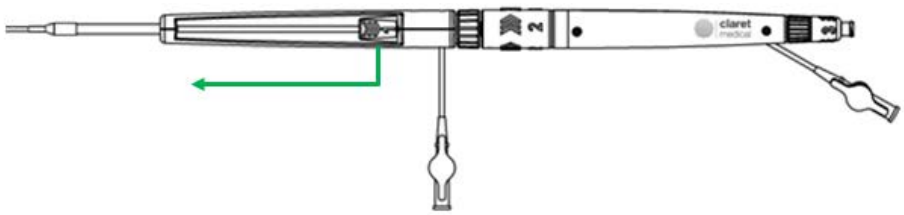

Figure 10: Sentinel Distal Filter Deployment

6. Re-sheath the Proximal Filter by holding the Front Handle in a stationary position and slowly advancing the Proximal Filter Slider **(#1)** until the Proximal Sheath Radiopaque Marker meets the Articulating Sheath as visualized on fluoroscopy. See Figure 10. Minimize retracting or advancing the Front Handle during this step. Vessel damage may occur or debris may be lost should the Proximal Filter be moved when in the deployed state.
7. Fully withdraw the Sheath Dilator from the introducer sheath hemostasis valve.
8. Advance the guidewire prior to withdrawal of the Sentinel System. Withdraw the catheter system while using fluoroscopy.
   Note: If there is any resistance to removing the Sentinel System from the introducer, remove the introducer and the Sentinel System together.

CAUTION: Do not re-sterilize or reuse this device.

Note: After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

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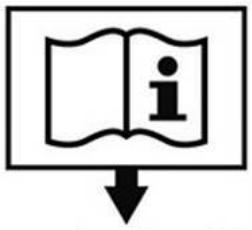

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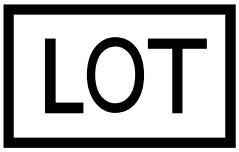
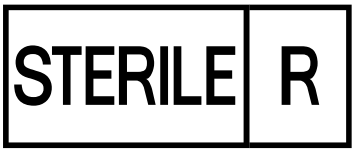


Lot number

Use by Date

Single use



Sterile by Radiation Sterilization

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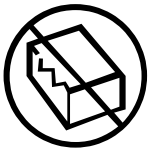
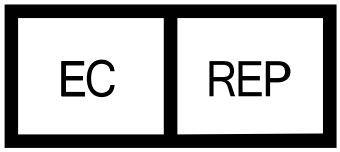


Do not use if packaging is damaged

Do not re-sterilize



Keep dry

Recommended guidewire

Recommended introducer

Non-pyrogenic

U.S Patent Nos. 8,372,108; 8,876,796; 9,055,997; 9,326,843; 9,345,565, and 9,017,364. Other U.S. and Foreign patents pending.