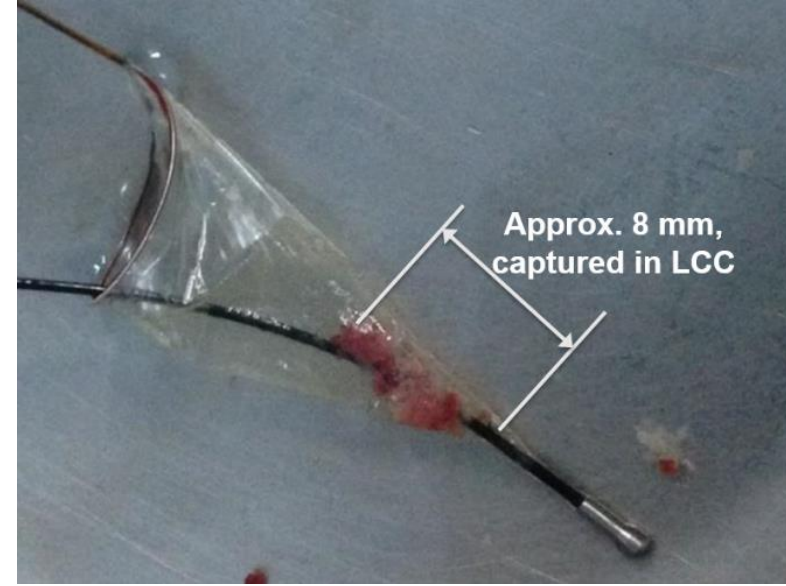


Debris Image Library

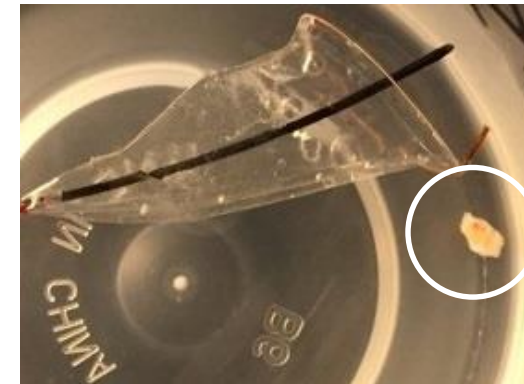
Debris Captured & Removed by SENTINEL CPS



Cedars-Sinai, Los Angeles, CA, USA
SENTINEL IDE Trial 2015

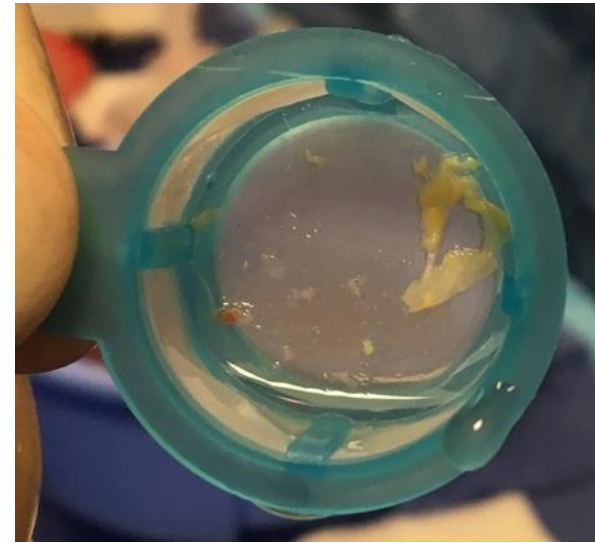
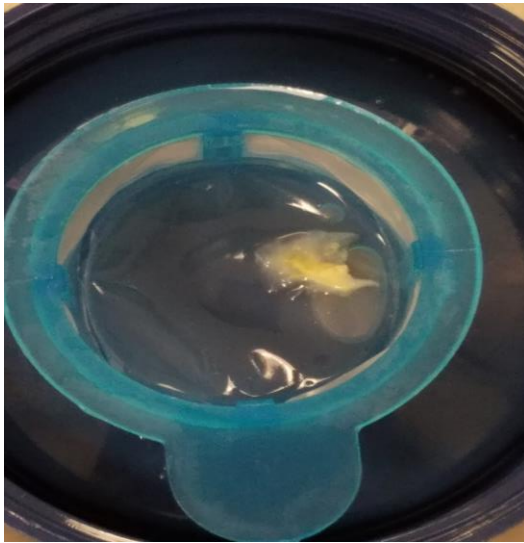
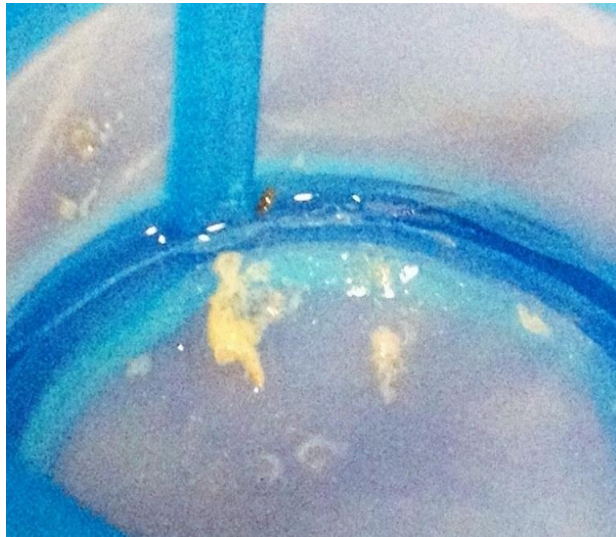
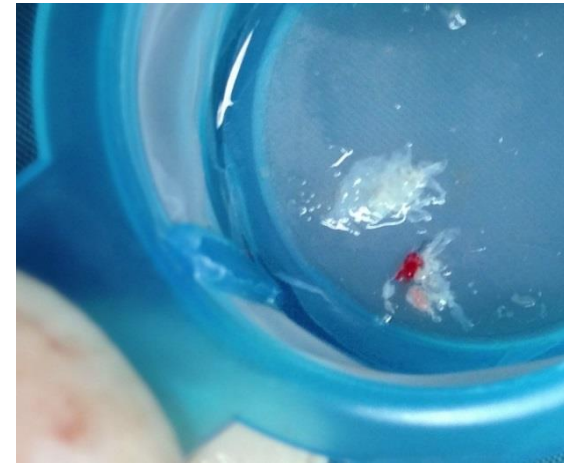
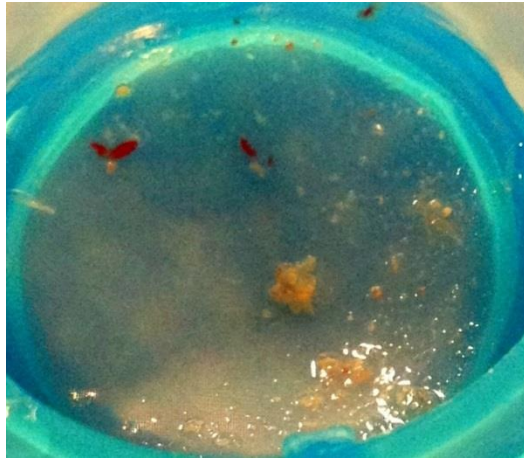
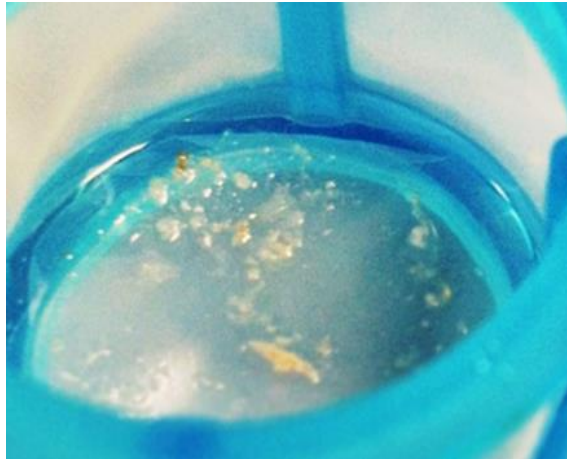


Institute Dante Pazzanese, São Paulo, Brazil
TCT Live Case 2013



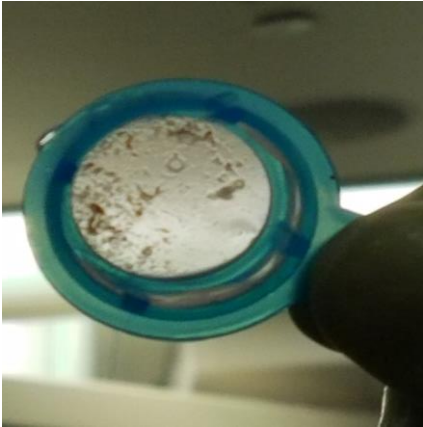
Henry Ford Hospital, Detroit, MI
SENTINEL IDE Trial 2015

Debris Captured & Removed by SENTINEL CPS

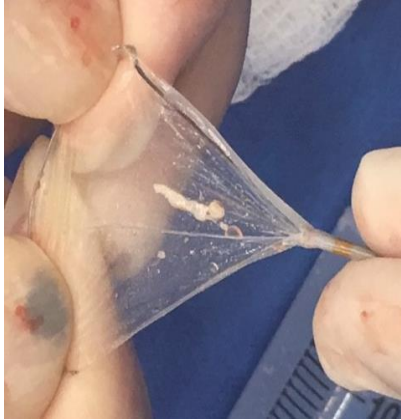


Example images/photos of SENTINEL CPS debris capture - data on file at Boston Scientific

Debris Captured & Removed by SENTINEL CPS – S3 devices



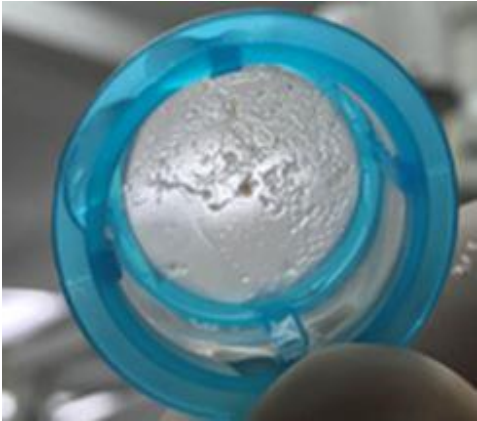
Pinnacle Health
Harrisburg, PA USA
August 2017



WVU-Ruby Memorial Hospital
Morgantown, WV USA
September 2017



Billings Clinic
Billings MT USA
October 2017



Wellspan York Hospital
York, PA USA
November 2017



Kaleida Health
Buffalo, NY USA
December 2017



Prairie Heart Hospital
Springfield, IL USA
December 2017

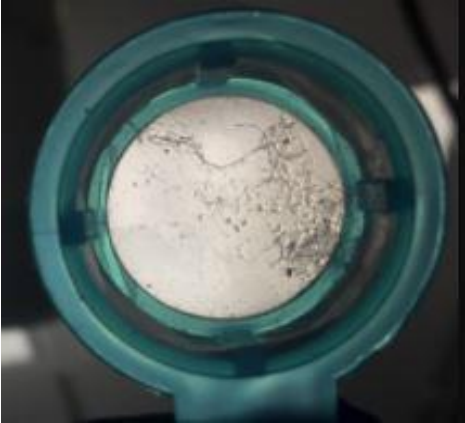


Fairview Southdale
Minneapolis, MN USA
January 2018

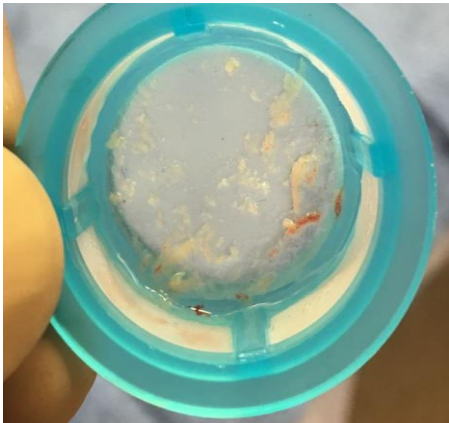


University of Washington Hospital
Seattle, WA
February 2018

Debris Captured & Removed by SENTINEL CPS – S3 devices



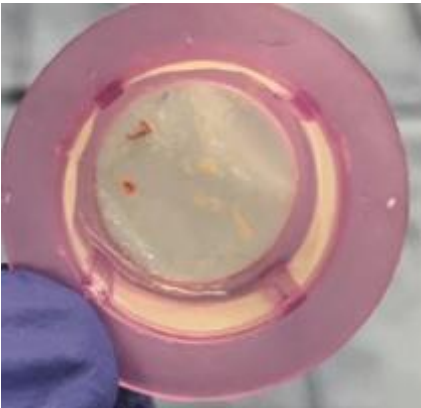
UCSF Hospital
San Francisco, CA USA
Feb 2018



Penn Medicine
Philadelphia, PA USA
March 2018



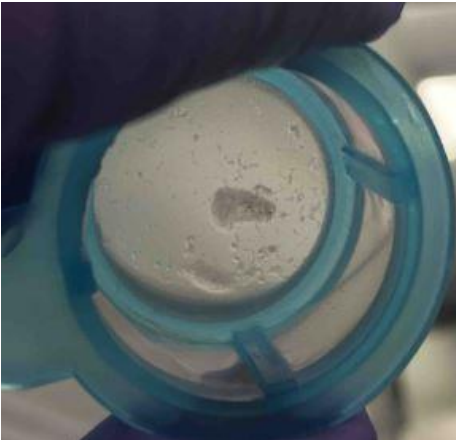
Brigham and Women's Hospital
Boston, MA USA
April 2018



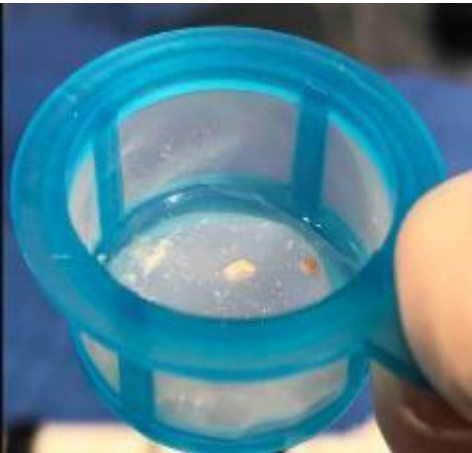
Penn Medicine
Philadelphia PA USA
April 2018



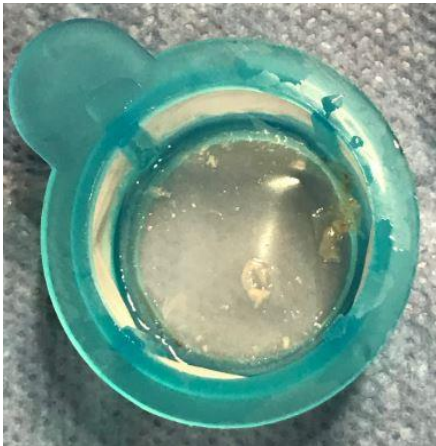
Prince of Wales Hospital
Hong Kong
June 2018



Carolinas Medical Center
Charlotte, NC USA
June 2018



Good Samaritan Hospital
West Islip, NY USA
June 2018



Mercy Hospital of Buffalo
Buffalo, NY USA
June 2018

Debris Captured & Removed by SENTINEL CPS – S3 devices



Wake Forest Baptist
Winston Salem, NC USA
Oct 2018



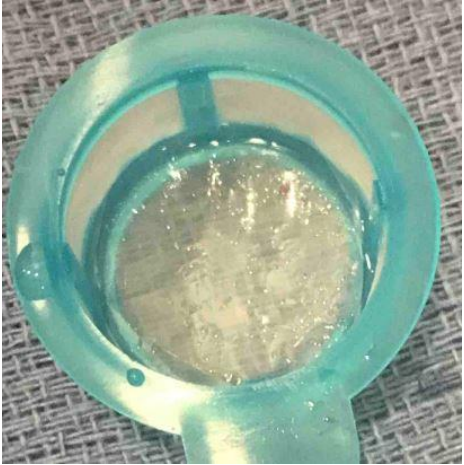
Northeast GA Medical Center
Gainesville, GA USA
Oct 2018



Tulsa Heart Hospital
Tulsa, OK
Oct 2018



Stanford University Med Center
Palo Alto CA USA
Oct 2018



Northshore University Hospital
Manhasset, NY USA
Oct 2018



Memorial Hermann Med Center
Houston, TX USA
Oct 2018



Morristown Medical Center
Morristown, NJ
Oct 2018

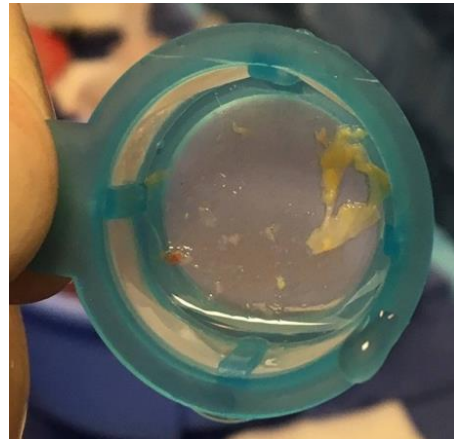


Baptist Medical Center
Jacksonville, FL USA
Oct 2018

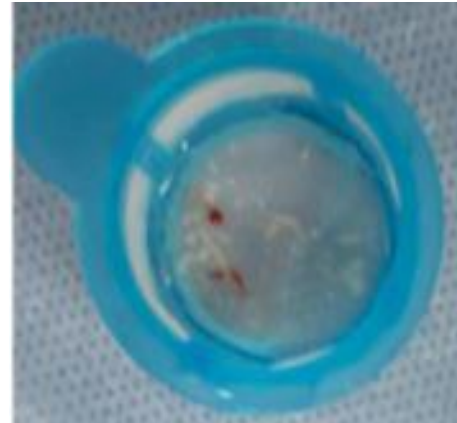
Debris Captured & Removed by SENTINEL CPS– Evolut devices



Cedar Sinai
Los Angeles, CA USA
July 2017



New York-Presbyterian
Weill Cornell, NYC USA
November 2017



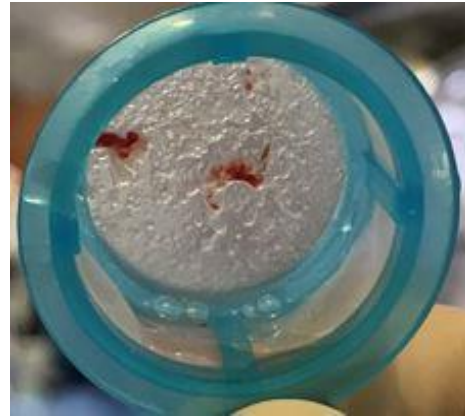
Baylor Scott & White Hospital
Temple, TX USA
December 2017



OLVG Hospital
Greater Amsterdam, Netherlands
January 2018



Piedmont Hospital
Atlanta, GA USA
January 2018



St Louis University Medical Center
St Louis, MO USA
January 2018



Penn Medicine
Philadelphia PA USA
April 2018

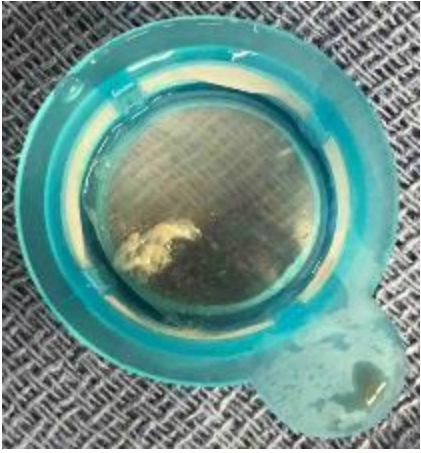


Mercy Hospital of Buffalo
Buffalo, NY USA
May 2018

Debris Captured & Removed by SENTINEL CPS– Evolut devices



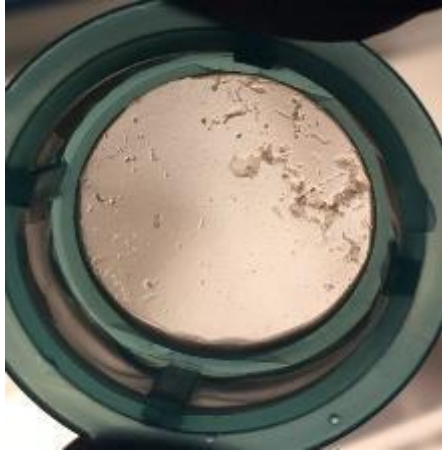
Englewood Medical Center
Englewood, NJ USA
June 2018



Spectrum Health
Grand Rapids, MI USA
June 2018



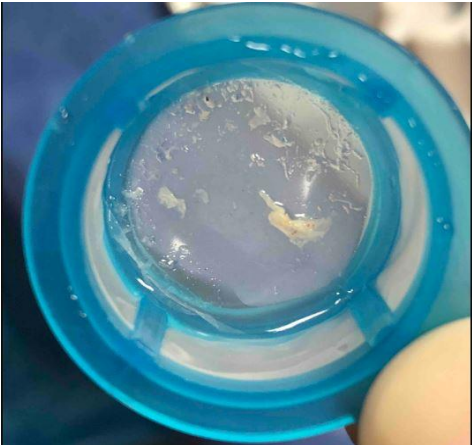
Weill Cornell
New York, NY USA
June 2018



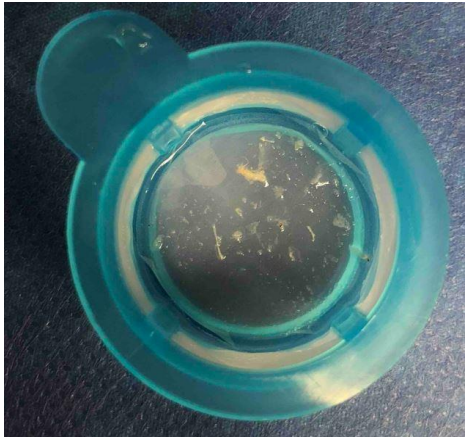
Piedmont Hospital
Atlanta, GA USA
Evolut-Pro, June 2018



Olvg-Oost
Amsterdam Netherlands
July 2018



Johns Hopkins
Baltimore, MD USA
July 2018

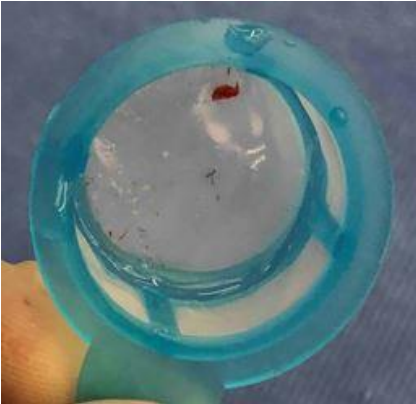


Spectrum Health
Grand Rapids, MI USA
July 2018

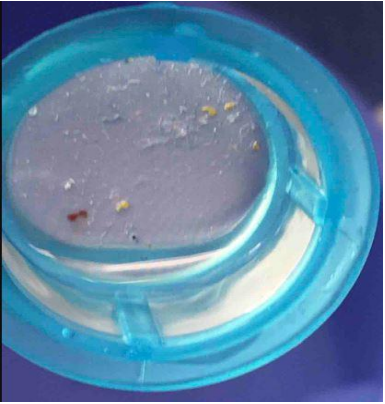


NYU Winthrop
New York, NY USA
Evolut-Pro, July 2018

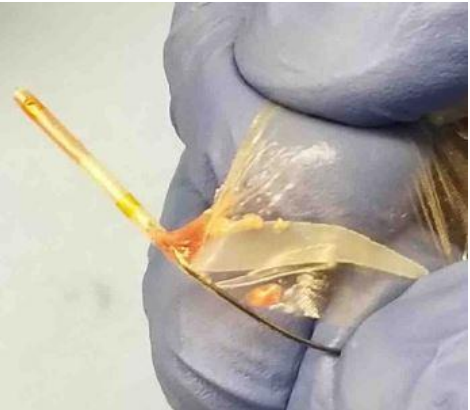
Debris Captured & Removed by SENTINEL CPS– Evolut devices



Lenox Hill
New York, NY USA
Oct 2018



Martin Memorial
Stuart, FL USA
Oct 2018



Lancaster General
Lancaster, PA USA
Oct 2018



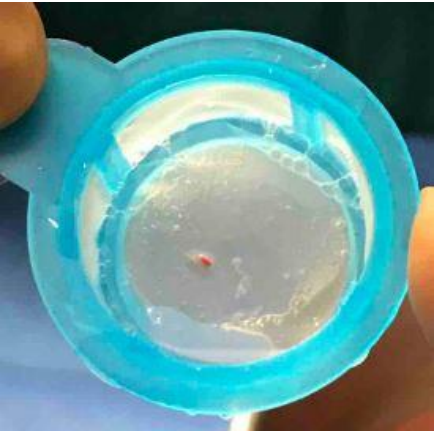
Northshore University Hospital
New York NY USA
Sep 2018



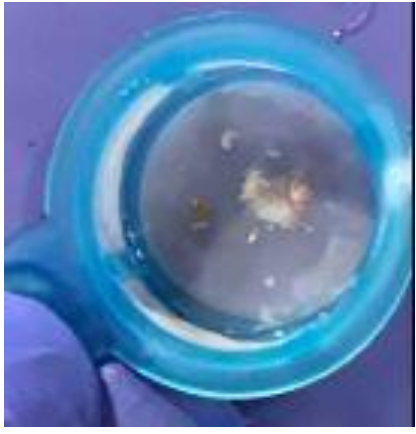
Baylor Scott & White Med Center
Temple, TX USA
Sep 2018



Englewood Hospital & Med Center
Englewood, NJ USA
Aug 2018

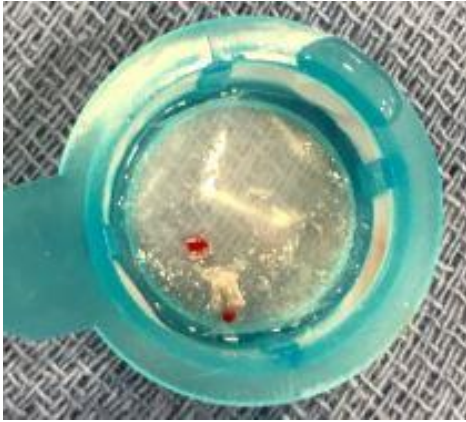


Penn Presbyterian Med Center
Philadelphia, PA USA
Oct 2018

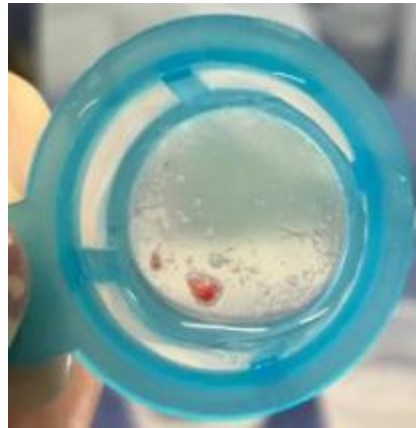


Vermont Medical Center
Burlington, VT USA
Oct 2018

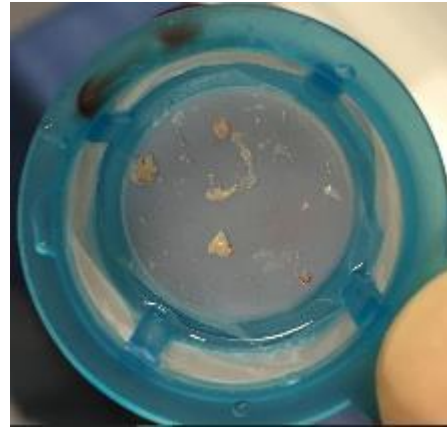
Debris Capture with SENTINEL CPS in Patients with STS Scores ≤ 4



Penn State Medical Center
Hershey, PA
S3, April 2018
STS 1.9



Carolinas Medical Center
Charlotte, NC USA
S3, April 2018
STS 3.5



Weill Cornell
New York, NY USA
S3, April 2018
STS 3.8



Baylor Heart Hospital
Plano, TX USA
Evolut Pro, May 2018
STS 2.6



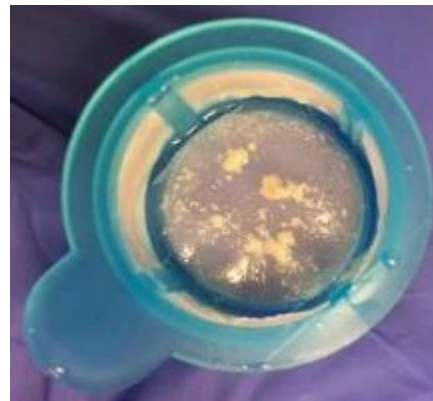
Deborah Heart & Lung Center
Brownsmill, NJ USA
Evolut-Pro, May 2018
STS 3.0



Morton Plant
Clearwater, FL USA
Evolut Pro, June 2018
STS 3.5



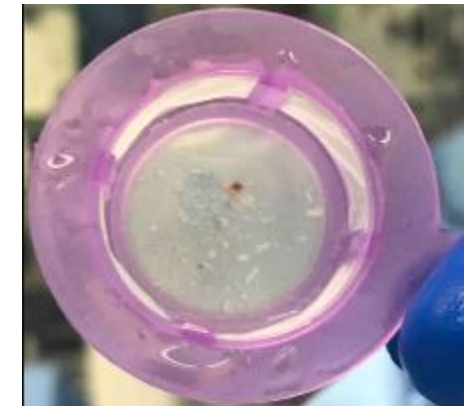
Olvig-Oost
Amsterdam Netherlands
Evolut-Pro, June 2018
STS 1.5



Mount Carmel East Hospital
Columbus, OH USA
S3, June 2018
STS 2.1

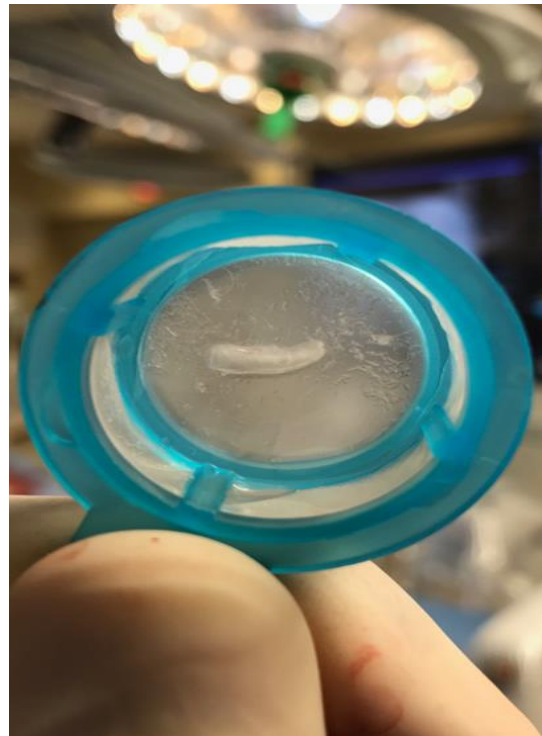


Penn Presbyterian Med Center
Philadelphia, PA USA
S3, June 2018
STS 4.0



Dallas VA Medical Center
Dallas, TX USA
Evolut R, July 2018
STS 1.7

Debris Captured & Removed by SENTINEL CPS – Billings Clinic



Hospital: Billings Clinic (Billings, MT)

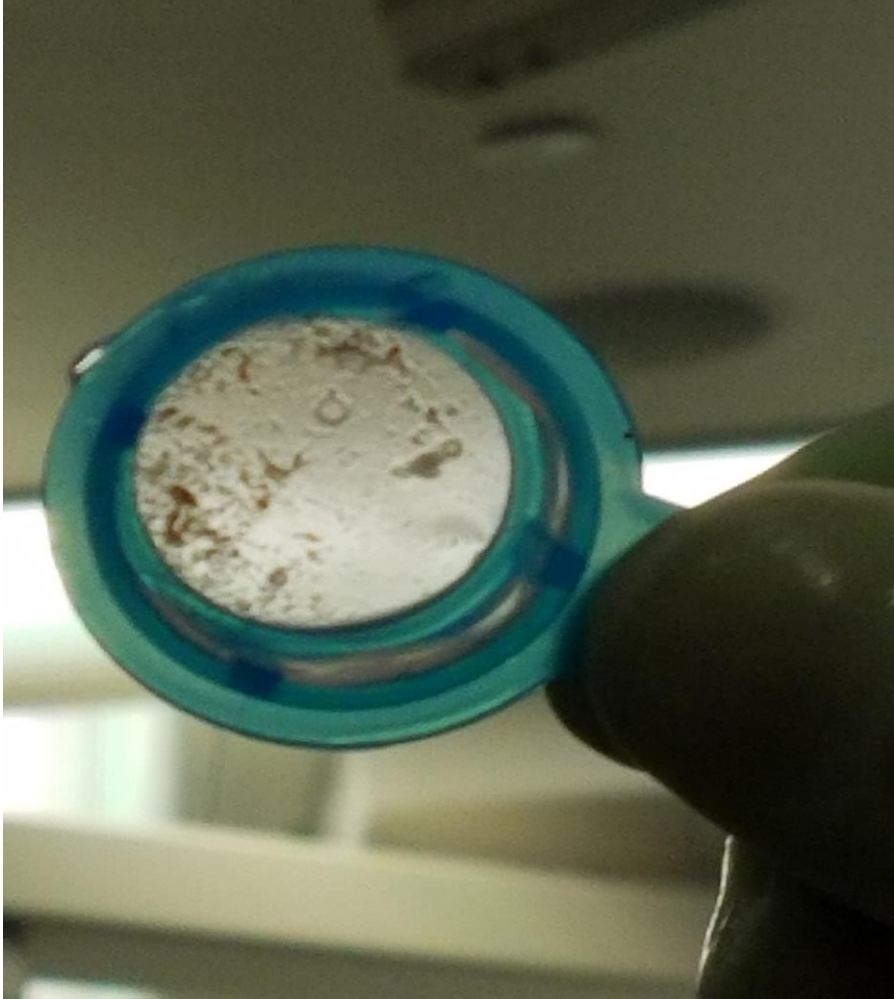
Physician: Per Sommers, MD

Date: 10/04/2017

Valve: S3

Debris: Calcium and fragments of
atherosclerotic plaque

Debris Captured & Removed by SENTINEL CPS – Pinnacle Health



Hospital: Pinnacle Health (Harrisburg, PA, USA)

Physician: Hemal Gada, MD

Date: 8/22/2017

Valve: S3

Notes:

- SENTINEL CPS placed in < 5 min

Debris Captured & Removed by SENTINEL CPS – Ruby Memorial



Hospital: West Virginia University – Ruby Memorial Hospital (Morgantown, WV, USA)

Physician: Bryan Raybuck, MD

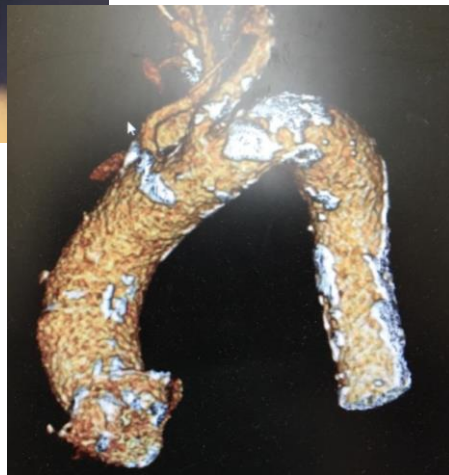
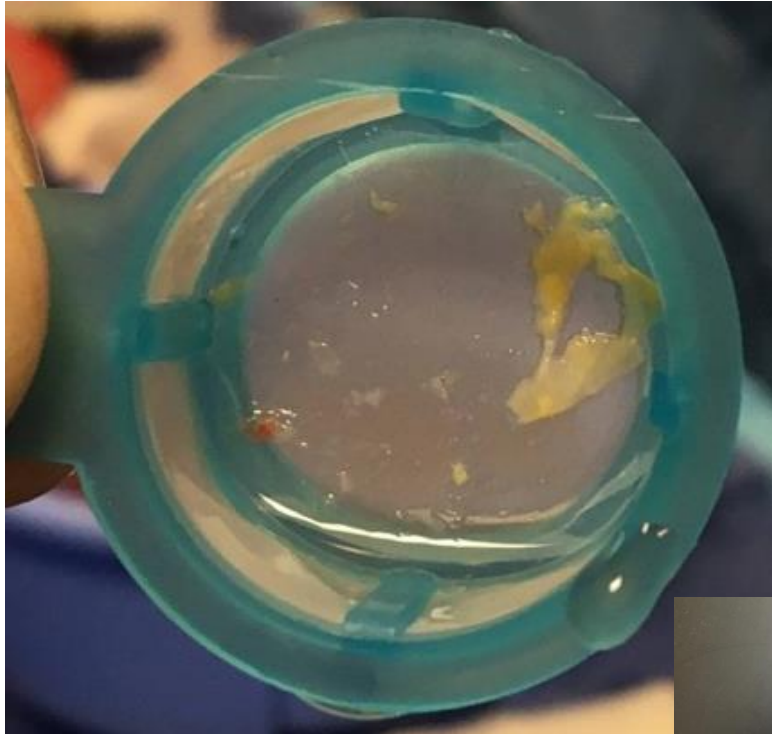
Date: 9/26/2017

Valve: S3 (26 mm)

Notes:

- SENTINEL CPS placed in < 5 min

Debris Captured & Removed by SENTINEL CPS – Weill Cornell



Hospital: NY Presbyterian/Weill Cornell

Physicians: Drs. Chiu Wong, Arash Salemi,
Geoffrey Bergman

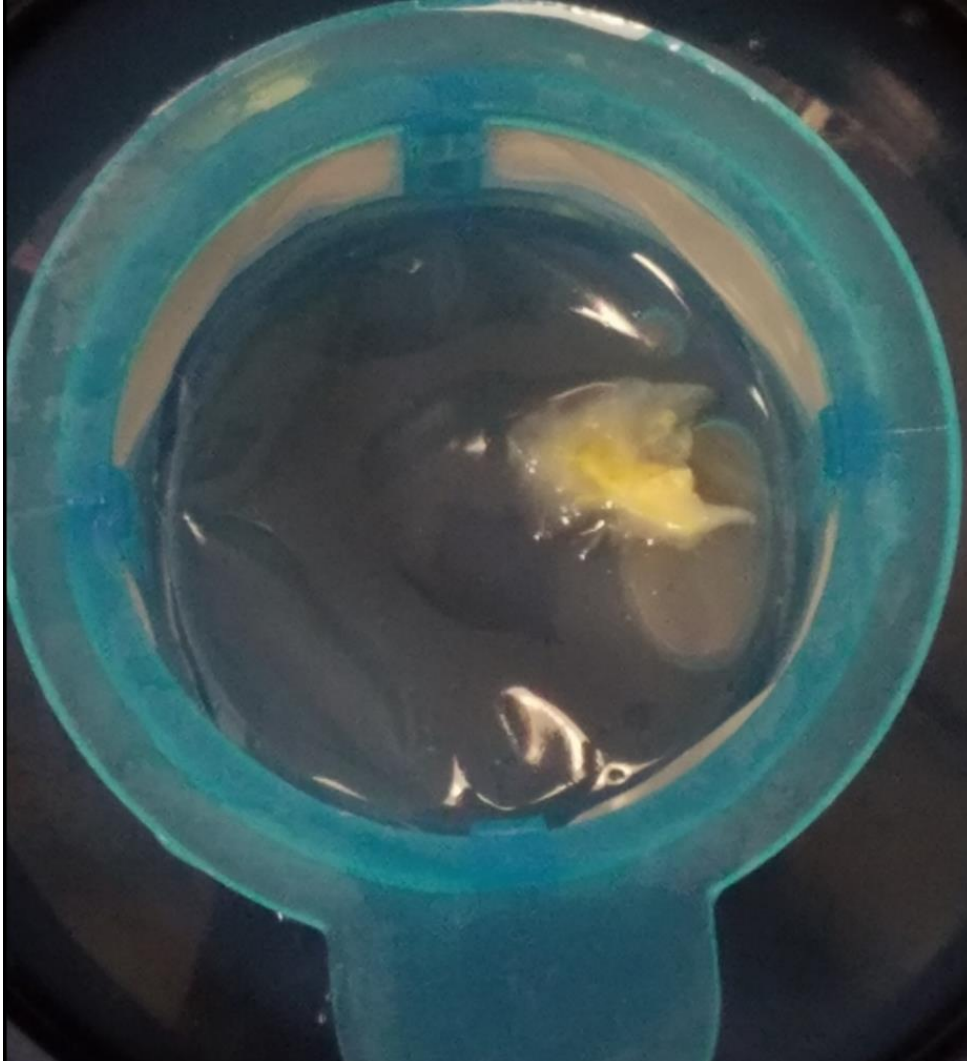
Date: 11/10/2017

Valve: Evolut Pro

Notes:

- High risk TAVR
- SENTINEL CPS placed in <90 seconds
- No pre/post dil
- Difficult Evolut Pro valve delivery

Debris Captured & Removed by SENTINEL CPS



Date: 10/10/2017

Valve: Corevalve EvolutR Pro

Debris: ~7 mm soft tissue material

Notes:

Straightforward deployment of valve no
post-dilatation

Debris Captured & Removed by SENTINEL CPS



Date: 10/17/2017

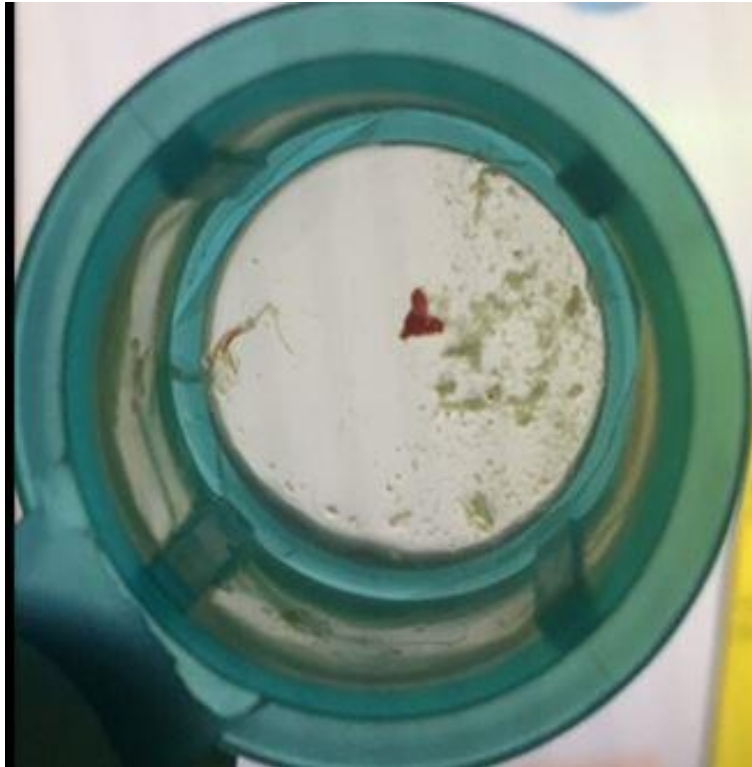
Valve: Evolut-R Pro- 26 mm

Debris: Soft tissue debris, largest piece
~2mm x 4mm

Notes:

- Normal Type I arch, both valve and arch were calcified and post dilatation observed.

Debris Captured & Removed by SENTINEL CPS

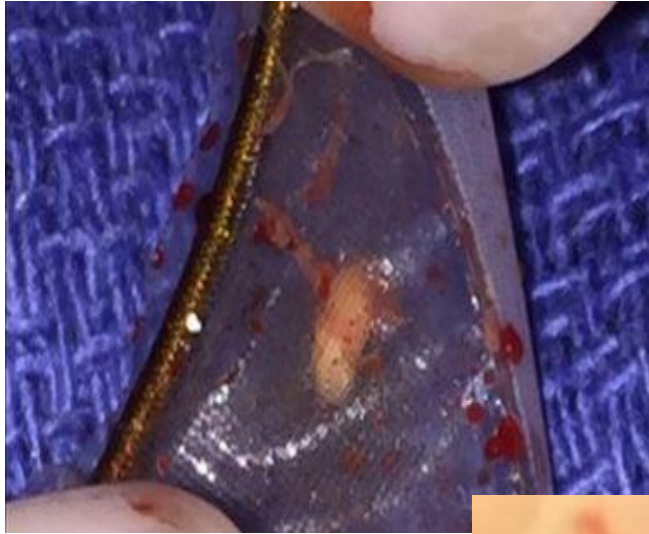


Date: 11/15/2017

Valve: S3

Notes: Type II arch, STS score 2.7

Debris Captured With SENTINEL CPS - Kaleida Health



Hospital: Kaleida Health (Buffalo, NY, USA)

Physicians: Vijay Iyer, MD and William Morris, MD

Date: 12/21/2017

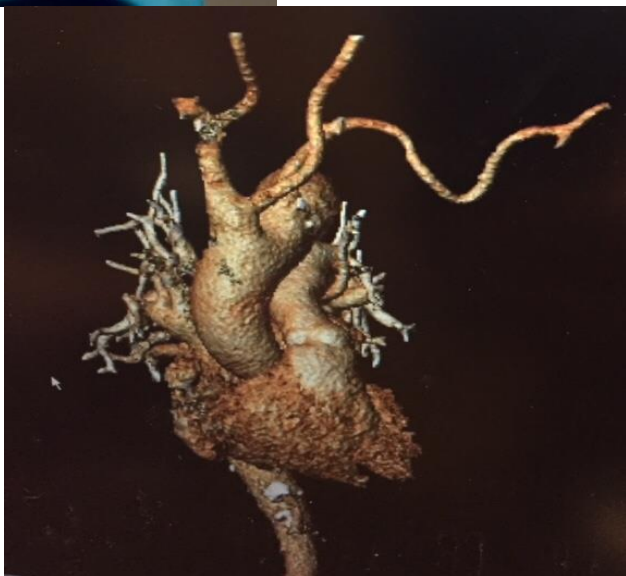
Valve: S3

Debris: ~8 mm piece of debris captured with SENTINEL

Notes:

- SENTINEL CPS placed in < 3 min
- Type I arch

Debris Captured With SENTINEL CPS - Prairie Heart Institute, St John's Hospital



Hospital: Prairie Heart (Springfield, IL USA)

Physician: John B Gill, MD

Date: 12/27/2017

Valve: S3

Notes:

- SENTINEL CPS placed in 2 min
- Type II arch

Debris Captured With SENTINEL CPS - St Louis University Medical Center



Hospital: St Louis University Medical Center
(St Louis, MO USA)

Physician: Tarek Helmy, MD

Date: 01/11/2018

Valve: Evolut R

Notes:

- SENTINEL CPS placed in 5 min
- Type I arch

Debris Captured With SENTINEL CPS - Fairview Southdale Hospital



Hospital: Fairview Southdale (Minneapolis, MN, USA)

Physician: Timinder Biring MD

Date: 01/23/2018

Valve: S3

Debris: Calcium

Notes:

- SENTINEL CPS placed in 8 min
- Type II arch

All trademarks are property of their respective owners

SENTINEL Cerebral Protection System (CPS)

INDICATIONS FOR USE: The Sentinel Cerebral Protection System is indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9 – 15 mm for the brachiocephalic and 6.5 – 10 mm in the left common carotid.

CONTRAINDICATIONS • Do not use in patients for whom anticoagulant and antiplatelet therapy is contraindicated. • Do not use in patients with a known hypersensitivity to nickel-titanium. • 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 safety and effectiveness of the Sentinel System have not been demonstrated with transcatheter aortic valves other than the SAPIEN XT, SAPIEN 3, CoreValve®, and CoreValve® Evolut R®. • 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 or brachial 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 compromise to device performance. • Minimize movement of the Sentinel System after initial placement and stabilize the patient's right arm by their side. 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, an artery that has been used for dialysis purposes, or an AV fistula. • 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 in IFU). • 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. • A guidewire with excessive stiffness may alter the shape of the Articulating Sheath curve and make cannulation of the left common carotid difficult. • Use of a guidewire with an intermediate coil may result in compromised guidewire movement. • Improper bending of the Sentinel System may damage the catheter. • Do not re-sterilize or reuse on another vessel or patient. **ADVERSE EVENTS** Possible adverse events associated with Sentinel System use and application procedure include, but are not limited to, the following: • Access site complications • Angina • Aortic dissection • Arrhythmia • Arteriovenous fistula • Atelectasis • Bleeding, operative or post-operative • Cardiac Tamponade • Cardiogenic Shock • Conduction system injury • Congestive Heart Failure (CHF) • Death • Endocarditis • Embolism, including air • Gastrointestinal (GI) bleed • Hematoma • Ischemia (coronary, limb, carotid) • Infection (local or systemic) • Myocardial Infarction (MI) • Nerve injury • Pericardial effusion • Pneumonia • Pulmonary edema • Pulmonary embolism • Respiratory failure • Respiratory insufficiency • Stroke • Vessel injury (e.g., dissection, rupture, perforation, pseudoaneurysm) Adverse events experienced during clinical studies are presented in the Clinical Study Overview section of the Instructions For Use (IFU). Rx Only, **CAUTION:** The law restricts this device to sale by or on the order of a physician. The SENTINEL Cerebral Protection System may only be used in countries where it is approved for use. Information for use only in countries with applicable health authority product registrations. Information not for use or distribution in France and Japan. Illustrations for informational purposes – not indicative of actual size or clinical outcome.

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