

# Recommended Reporting Standards for Vena Caval Filter Placement and Patient Follow-Up

The Participants in the Vena Caval Filter Consensus Conference

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THE use of vena caval filters has increased significantly since the introduction of percutaneous placement techniques and the development of reduced-profile devices. The literature contains hundreds of reports of immediate and long-term outcomes for patients who have had these devices placed but the reports do not employ consistent standards, definitions, or techniques, making it difficult to compare outcomes and determine the relative efficacy and safety of the available devices (1-3).

Successful deployment of a vena caval filter fundamentally requires a patent filter, properly positioned within the vena cava in such a manner as to protect against pulmonary embolism. With this premise, the following reporting standards have been developed to assess caval filter placement, function, and other outcome parameters. They are applicable to all FDA-approved vena caval filters, regardless of other reportable aspects: basic de-

sign, manufacturer, the specialty of the clinician placing the device, the indications for which it was placed, and whether it was intended for permanent or temporary use. These data should be evaluated with use of rigorous statistical methods to allow unbiased comparisons that should lead to improved outcomes for patients. Extensive literature citations have been included either to highlight the significance of each standard, or to provide examples of typical reports.

## PATIENT ASSESSMENT

General patient information including age, gender, underlying disease and level of severity, and current use of anticoagulation (type and level) should be noted (4,5). Patient informed consent and Investigational Review Board approval (where appropriate) should be documented. Because outcomes are related to the underlying venous disorder, the presence or absence of venous thromboembolism (pulmonary embolism and/or deep vein thrombosis) should be described, along with extent of deep vein thrombosis involvement for correlation with subsequent status of the limb. Pulmonary embolism should be objectively documented using available imaging studies, including radionuclide ventilation/perfusion scans employing the PLOPED criteria (6), pulmonary angiography, echocardiography, contrast-enhanced spiral computed tomography, or gadolinium-enhanced magnetic resonance (MR) angiography (7-12). The presence of deep vein thrombosis should

be documented by contrast venography, duplex ultrasound, computed tomography (CT), or MR venography (13-15). The proximal extent of thrombus should be identified, as well as the percent of greatest luminal narrowing (Table 1).

The patient's risk factors for venous thrombosis should be identified (Table 2). This is especially important when the filter is placed for prophylaxis in the absence of thromboembolism (16-20).

The indications for filter placement should be identified (Table 3) (21-25). Multiple indications may be present but only the primary one should be used for group analyses (3,26). Normal and abnormal factors related to successful filter placement should be described. These include: (a) the transverse caval diameter at the level of desired placement corrected for magnification, (b) caval anomalies such as duplication or renal vein anomalies, (c) spinal deformities, and (d) the patency of the planned access site (graded according to Table 1).

## DEVICE ASSESSMENT

The manufacturer and type of filter should be recorded, as well as specific information concerning the delivery system, such as the size of the introducer system and use of a guide wire. The reason for device selection should be noted (Table 4). The intended duration of placement, either permanent, temporary (requiring removal), or optional (may be removed) should be indicated.

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**Table 1**  
**Staging Deep Vein Thrombosis**

Extent of Thrombus	Grading of Occlusion
Calf	0 = Clear 1 = Partial Occlusion 2 = Occluded
Popliteal	
Femoral	
Iliac	
Vena cava (inferior or superior)	
Axillary/subclavian	

**Table 2**  
**Classification of Risk Factors for Thromboembolism**

Factors
Previous history of deep vein thrombosis
Immobilization
Postoperative status
Age
Malignancy and tissue type
Cardiac disease
Limb trauma
Prothrombotic state
Hormonal therapy
Pregnancy and postpartum
Obesity

Based on Reference 19.

## PROCEDURAL ASSESSMENT

The training background and specialty of the physician placing the filter should be identified, such as interventional radiologist, surgeon, interventional cardiologist, or pulmonologist, as well as the level of experience characterized as either trainee or staff. The timing of the procedure should be classified as elective, urgent (within 24 hours of decision), or emergent (as soon as possible).

The location in which the procedure was conducted should be identified, such as the operating room, radiology suite, cardiac catheterization laboratory, bedside, or other (27–30). Anesthesia other than local should be indicated.

The method by which the vena cava was evaluated prior to placement of the device should be provided (ie, contrast venography or intravascular ultrasound) (31–34). If venography was used, the type of contrast material and the degree and method of correction

**Table 3**  
**Categorical Indications for Filter Placement**

1. Contraindication to anticoagulation (absolute or relative)
2. Complication of anticoagulation  
Failure: objectively documented extension of existing deep vein thrombosis or new deep vein thrombosis or pulmonary embolism while therapeutically anticoagulated  
Hemorrhage: major or minor  
Thrombocytopenia  
Skin necrosis  
Drug reaction  
Evidence/probability of poor compliance
3. Prophylaxis: no thromboembolic disease (90)
4. Prophylaxis with thromboembolism in addition to anticoagulation
5. Failure of previous device to prevent pulmonary embolism; central extension of thrombus through an existing filter or recurrent pulmonary embolism
6. In association with another procedure: thrombectomy, embolectomy, lytic therapy (91–94)

for magnification should be included (35). Identification of the renal veins should be reported.

The site of insertion should be identified by name and location, such as left or right femoral or jugular vein, an upper extremity vein, the external jugular vein, or by direct vena caval access. This is important because the route of insertion has been shown to affect performance in some cases (36–40). The method of access should be described as being either percutaneous or venotomy. If ultrasound guid-

**Table 4**  
**Justification for Device Selection**

1. Device routinely available at the institution  
Clinician preference  
Clinical research study  
Training  
Cost
2. Specific choice  
Diameter of the vena cava  
Upper extremity access (95)  
To be positioned above the renal vein  
Short period of thromboembolic risk (temporary or optional)  
Ease of deployment  
Access vein problem (tortuosity, thrombosis, compression, etc.)  
Freedom from magnetic susceptibility artifact

**Table 5**  
**Criteria for Successful Placement**

1. The delivery system was advanced to the intended placement level
2. The filter was deployed and fixed at the intended position  
No migration (> 20 mm) or embolization of the filter  
No extravascular penetration of guide wire or device
3. The filter configuration was consistent with protection from pulmonary embolism  
Complete opening (42)  
Adequate distribution of filtering mechanism (no additional device was placed) (96)  
Alignment with the axis of the vena cava (eg, tilting) (record degree)

ance was used to identify the vessel, this should also be reported. The intended site for deployment should be recorded as infrarenal or suprarenal vena cava, iliac vein, or the superior vena cava (41).

## PLACEMENT PROBLEMS

The characteristic steps of successful placement are listed in **Table 5** and should be referred to in reporting placement problems. Problems should be identified by and, in larger series, stratified by these levels or steps, and whether clinical sequelae developed as a result.

## TECHNICAL SUCCESS/FAILURE

Technical success requires proper placement of the filter. Each filter placement that is attempted should be included in the total number of filter placements reported, following the intent-to-treat rule. Failures occur when the filter cannot be placed as intended and a second attempt is made with a different filter (42–47).

Procedural complications are not the same as technical failures but both should be reported. Insertion site thrombosis or hemorrhage, infection, or the development of an A-V fistula or positioning that requires placing an additional filter or correcting the placement of an existing filter are considered to be complications and should be identified as such (39,48,49). Insertion site thrombosis should be graded as being either occlusive or nonocclusive, and the method of diagnosis reported (50–52). Complications that require additional procedures, prolong hospitalization, or result in death are considered to be major. Events that occur within 24 hours are considered to be early as compared to those occurring after that period.

## FOLLOW-UP ASSESSMENT

Patients with permanently implanted devices deserve routine follow-up (53–58). When this follow-up is reported, the number of patients followed should be compared to the total number of filters placed at each institution during the period of the report. Censored patients should be indicated as having been lost to follow-up or dead. The cause of death and method of ascertainment should be identified. The time between filter placement and follow-up should be given as a mean with the standard deviation and median, but in an intermediate or long-term study, success rates should be reported using classic life table or Kaplan Meier plots (59). Clinical success is defined as a technical success without subsequent pulmonary embolism, significant filter migration or malpositioning, symptomatic caval thrombosis, or other complication requiring removal or invasive intervention.

The preferred method for following patients is by clinical examination and

objective testing. The clinical evaluation should include venous duplex examination of the lower extremities for recurrent deep vein thrombosis and/or chronic venous insufficiency (50,52,60–62). Edema, other post-thrombotic skin changes or ulceration, the current use of anticoagulants (63,64), and any complications resulting in discontinuation of anticoagulant therapy should be reported, as well as the occurrence of suspected or proven pulmonary embolism. When pulmonary embolism is reported, the method of diagnosis should be included, as well as the treatment received. Minimum objective testing should include evaluation of the stability and patency of the filter. Patency of the filter and vena cava should be determined by vena cavography, ultrasound, CT, or MR. The findings should be accompanied by statements concerning the adequacy of the examination (65–70). The report should indicate whether there was thrombus within the vena cava, its location, and whether it was occlusive.

The stability of the filter can be documented by orthogonal plain films. From these, the location of the filter relative to its original position at placement in both the horizontal and vertical dimensions should be determined. Change in vertical position can be measured and documented, as well as the direction (proximal vs. distal) (71–77). The diameter at the base of the filter should be measured. A reduction in diameter of the cone-shaped filters may suggest caval stenosis or occlusion, and expansion can be indicative of extracaval extension the anchoring devices; therefore, both should be reported (78). More specific tests such as CT scans, cavography, intravascular ultrasound, or MR studies may be indicated to document penetration and/or impingement on an adjacent organ, or caval occlusion. Finally, any deformation of the filter should be reported, (ie, fracture or collapse) (79–85).

Outcome data should be based on samples of sufficient size to support clinical conclusions. Actual numbers, not just percentages, should be included. A large number of literature reports are based on small case series or even case reports that make it difficult to determine the magnitude of the problem. Data should be obtained

**Table 6**  
**Additional Reporting Criteria for Temporary and Optional Filters**

1. Description of the device including the materials
2. Recommendation for duration of placement
3. Whether used in conjunction with another procedure
4. Whether it was removed and the length of time it was in place
5. Complications related to removal of the device (ie, inability to remove according to directions, infection or trapped embolus within the filter and its fate) (97)
6. How complication was treated
7. Need for a permanent filter

from primary contacts that are less subject to the bias found in chart reviews or telephone contacts.

## TEMPORARY AND OPTIONAL DEVICES

There are no currently approved temporary (must be removed) or optional (may be removed) vena caval filters in the United States. However, there is great interest among many physicians in evaluating the efficacy and safety of these devices (86–89). Clinical studies are currently in progress and we urge that study results be reported according to these recommendations to facilitate fair evaluation. Reports for these devices should include all the information listed above and also those factors particular to these devices (Table 6).

## CONCLUSIONS

These recommendations are based on current practice patterns and are subject to change as our knowledge improves, technology changes, and practice develops. However, adherence to these guidelines, which are summarized in Table 7, will allow the combination of reports from multiple sites and provide a better level of evidence upon which to base future recommendations.

## ADDENDUM

The Participants in the Vena Caval Filter Consensus Conference were: Dr.

**Table 7**  
**Summary of Reporting Standards and Level of Recommendation**

	Required	Highly Recommended	Recommended
<b>Patient Assessment</b>			
Age	X		
Gender	X		
Underlying disease	X		
Anticoagulation use	X		
Deep vein thrombosis (diagnosed)	X		
Pulmonary embolism (diagnosed)	X		
Risk factors		X	
Indications for placement	X		
<b>Filter Placement</b>			
IVC transverse diameter	X		
IVC/renal vein abnormality	X		
Spinal deformity		X	
Access site patency		X	
<b>Device Assessment</b>			
Device identification	X		
Guide wire use	X		
Reason for selection		X	
Intended duration of placement	X		
<b>Procedural Assessment</b>			
Physician specialty		X	
Physician level training		X	
Location of procedure			X
Type anesthesia	X		
Method IVC evaluation	X		
Insertion site	X		
Method of access	X		
Use of ultrasound	X		
Deployment site	X		
Technical success rate	X		
Clinical sequelae	X		
<b>Follow-Up Assessment</b>			
% patients followed	X		
Patient status	X		
Cause of death		X	
Time to death or failure		X	
Venous duplex		X	
Postphlebotic symptoms		X	
Anticoagulation	X		
Complication of anticoagulation	X		
Suspected/proven pulmonary embolism	X		
Diagnosis of pulmonary embolism		X	
Treatment of pulmonary embolism			X
Filter stability	X		
IVC patency	X		
Method of determining patency	X		
Outcomes reported as raw numbers and %	X		
Source of data	X		

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