

Consent for Inferior vena Cava (IVC) Filter Placement

INTRODUCTION:

You have been diagnosed as having a deep vein thrombosis (small blood clots in your legs) and/or a pulmonary embolism (blood clot in your lungs). To reduce the risk of blood clots breaking off from veins in your legs or pelvis and traveling to your lungs, a filter will be placed into the main vein in your abdomen, the inferior vena cava (IVC). This filter is designed to trap any blood clots traveling in your venous system before they reach your lungs. Blood clots that reach your lungs may be fatal. We are asking you to read and sign this form so that we can be sure you understand the procedure and potential benefits, along with the associated potential risks, complications, alternatives, the likelihood of achieving the goals, and the recuperative process. Please ask questions about anything on this form that you do not understand.

PROCEDURE:

Placement of an IVC filter involves the insertion of a plastic tube (catheter) into a vein in either your leg or your neck. Some numbing medicine will be injected in the skin over the vein before the catheter is inserted. Intravenous medications may also be given to you to make you more comfortable and relaxed. This is known as moderate sedation. Once the catheter has been placed into the vein, it will be advanced through the blood vessels and into the IVC. During this time, x-ray contrast material (x-ray dye) will be injected through the catheter and x-ray pictures taken. You may be asked to hold your breath for several seconds as these pictures are taken. During the injection of x-ray contrast material, you may experience a warm feeling or a strange taste in your mouth. Both of these sensations are temporary and will go away soon. A series of x-ray pictures will be obtained of the IVC. Once the catheter is placed into the IVC, the filter will be inserted through the catheter. During the placement procedure, positioning of the filter will be monitored with x-ray pictures. At the completion of the procedure the catheter will be removed and pressure will be applied to the insertion site until the bleeding has stopped. To help prevent bleeding, it will be very important for you to lie flat in bed without moving your leg for up to four hours.

RISKS:

Risks associated with the procedure include, but are not limited to, pain or discomfort at the catheter insertion site, bleeding at the site, injury to a blood vessel, and infection which may result in an infection of the blood stream. It is possible that the IVC will become blocked after the placement of the filter. Blockage of the IVC is a gradual process and usually does not cause any symptoms. You will develop veins around the blocked area and these veins will allow blood flow from your lower body. However, this results in the risk of a clot passing through these veins, bypassing the filter, and reaching your lungs. It is also possible that, after placement, the filter may shift in position. If your femoral vein (located in your leg) was used for the procedure, there is the possibility that the vein may become blocked. This may result in leg swelling and may require intravenous blood thinners or the use of blood clot dissolving drugs given into the IVC. Even with an IVC filter, it is possible to experience a recurrent pulmonary embolism due to clot material passing through the small openings in the filter. Risks associated with the x-ray contrast material include an allergic reaction and reduced kidney function. The medications used for the moderate sedation are associated with the risks of aspiration (inhaling food or liquid into your lungs) or respiratory depression. In addition to these potential risks associated with the procedure, the x-ray contrast material, and the moderate sedation medications, there may be other unpredictable risks including death.

(Complete this paragraph if applicable or document "NA")
Due to your additional medical history of _____,

added risks for you include but are not limited to: _____

_____.

ALTERNATIVES:

There may be other methods to treat your deep vein thrombosis and/or pulmonary embolism, including medical management and surgery. If you are unsure about undergoing placement of an IVC filter, please discuss these other alternatives with your physician.



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AGREEMENT:

The information on this form was explained to me by _____. I understand the information and I have had the opportunity to ask any other questions I might have about the procedure, the reasons it is being performed, the associated risks, and the alternatives to the procedure. I agree to undergo the procedure to be performed by an authorized member of the Division of Vascular and Interventional Radiology and his/her associates, assistants, and appropriate hospital personnel, and accept the risks. I also agree that fellows, residents and surgical assistants may participate in significant tasks that are part of the procedure. In addition, I agree to have any other appropriate personnel present for the procedure.

I assign to the University of Pennsylvania Health System (“Health System”) all rights to any tissues, organs, cells, body parts, and/or body fluids that may be removed during this procedure and I authorize the Health System to use or dispose of such specimens according to its standard practices.

The University of Pennsylvania Health System routinely suspends all resuscitative aspects of living wills and Do Not Attempt Resuscitation orders during the pre-procedure, procedural and post-procedural period, unless you specifically tell us otherwise. This applies to all invasive and operative procedures.

Signature: _____ Date: _____ Time _____
Patient

Signature: _____ Date: _____ Time _____
Authorized Healthcare Professional obtaining
and witnessing patient's signature

Signature: _____ Date: _____ Time _____
Attending physician (if applicable)

To be used if the patient is a minor, unconscious, or otherwise lacking decision making capacity.

I, _____, the _____
Relationship to patient
of _____ hereby give consent.

Signature: _____ Date: _____ Time _____
Legally Authorized Representative

Signature: _____ Date: _____ Time _____
Authorized Healthcare Professional obtaining
and witnessing representative's signature

Signature: _____ Date: _____ Time _____
Attending physician (if applicable)

Signature: _____ Date: _____ Time _____
Witness to telephone consent

