

Consent for CCSVI Interventional Procedure

INTRODUCTION:

Your physician has agreed to perform the following endovascular intervention for your central venous stenosis:

Central Venogram, possible Venoplasty, and possible Stent placement

understand You that any central venograms, venous angioplasty, or venous stents are that are performed to treat symptoms of Multiple Sclerosis is still debated. Relief of MS symptoms with these therapies is still being investigated and has not been proven by in depth medical studies. We are asking you to read and sign this form so that we can be sure you understand the risks and complications potentially associated with this procedure. Please ask questions about anything on this form that you do not understand.

PROCEDURE:

An interventional radiology procedure involves the placement of a needle through your skin and into the vein. Some numbing medicine will be injected in the skin over the site that will be used before the needle is inserted. Intravenous medications may also be given to you to make you more comfortable and relaxed. This is known as conscious sedation.

Following insertion, a catheter will be guided into position using x-rays (fluoroscopy). The veins will be evaluated

by the injection of x-ray contrast material (x-ray dye) into the vein. Any stenosis' within the veins will be treated by venoplasty. This consists of inflating a balloon inside of the vein. On occasion the vein does not stay open after venoplasty. At these times, placement of a stent within the vein may be required to keep the vein open.

At the completion of the procedure, the needle will be removed and pressure will be applied to the insertion site until the bleeding has stopped.

RISKS:

Risks associated with the procedure include:

- Recurrance of your symptoms or restenosis within your vein
- Complications from sedation including aspiration
- Bleeding at the needle site
- Allergic reaction to dye (contrast)
- Injury to a vein resulting in bleeding
- Blood clot formation within the vein
- Misplacement or displacement of venous stents
- Emergency surgery to correct any of the above risks
- The use of thrombolysis to disolve and remove blood clots, which in itself has risks including bleeding and stroke.
- Potential worsening of your condition
- Heart arrhythmias or heart attack
- Stroke
- Death

Pt Initials

(I have read and understand the above risks associated with my procedure)



ALTERNATIVES:

There may be other procedures that can be performed to further evaluate and/or treat your condition. If you are unsure about having an interventional radiology procedure performed, please discuss these other alternatives with your physician.

AGREEMENT:

The information on this form was explained to me by

I understand the information and I have had the opportunity to ask my physician any other questions I might have about the procedure, the reasons it is being performed, the associated risks, and the alternatives to the procedure.

Furthermore, I understand that any improvement in Multiple Sclerosis symptoms from this procedure is still being investigated and outcomes are not guaranteed. In addition, any improvements in my condition may only be temporary and symptoms may recurr requiring additional treatment. The benefits of this procedure and the risk of recurrence is unknown and has not been proven by in depth medical studies.

I have read this agreement, I consent to have the procedure performed, and I accept the risks.

Signature:	Date:
	Patient
Signature:	Date:
	Date: Date: Physician obtaining patient's signature
To be used if the patient is a minor, unconscious, or otherwise lacking decision making capacity.	
I,	, the
of	hereby give consent.
Signature:	Date:
	Relative, Surrogate or Guardian
Signature:	Date:
	Physician
Signature:	Date:
- •	Witness to telephone consent