

# Retrograde administration of ultrasound-guided endovenous microfoam chemical ablation for the treatment of superficial venous insufficiency

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## Patients

**Symptomatic patients with C2-C6 chronic venous insufficiency  
(n= 250; single center, community practice)**

## Objectives

Evaluate treatment outcomes among symptomatic patients with superficial chronic venous insufficiency using Varithena<sup>®</sup>:

- Efficacy – Elimination of symptoms/pathological reflux; closure; wound healing
- Safety – Incidence of adverse events (e.g. DVT, SVT)

## Methods

- All patients were treated with Varithena<sup>®</sup>, then followed for 16±7 months.
- Sixteen of the 250 patients (6.4%) had skin ulcers, and 56 (22.4%) were treated previously with thermal ablation or surgery.
- Patients underwent a duplex ultrasound (DUS) to map perforators/veins to be treated.
- The GSV was accessed with a micropuncture needle distal to the mid-thigh perforator.
- The leg was elevated 45° for 10 minutes before closing the incompetent GSV with Varithena<sup>®</sup> under DUS guidance.
- A second injection was administered through the same catheter directing the microfoam to flow in a retrograde fashion through the incompetent venous valves to the ankle.

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**FDA APPROVED INDICATIONS:** Varithena<sup>®</sup> (polidocanol injectable foam) is a sclerosing agent indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein (GSV) system above and below the knee. Varithena<sup>®</sup> improves the symptoms of superficial venous incompetence and the appearance of visible varicosities. Instructions for Use, including warnings, precautions, potential complications, and contraindications can be found at [www.btg-im.com/en-US/Varithena](http://www.btg-im.com/en-US/Varithena).  
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## KEY RESULTS

- Complete elimination of venous valvular reflux, vein closure, and symptom improvement was documented in 94.4% of patients.
- Minor adverse events included asymptomatic DVT in two patients (<1%) and superficial venous thrombi in four patients (2%).
- Of the 16 patients with skin ulcers, 80% of the wounds were closed within 4 weeks of treatment.



GSV Reflux 1.8 seconds  
GSV Diameter 16.1 mm



Two weeks post-treatment,  
8.1 mL total treatment volume

## CONCLUSION

Ablation of incompetent GSVs using Varithena®, in patients with C2 to C6 disease, is safe and effective with 94.4% of patients experiencing elimination of reflux. Improvements were documented for >1 year post-treatment.

These data demonstrate the efficacy and durability of Varithena® treatment in a community practice.

### INDICATIONS

Varithena® (polidocanol injectable foam) is indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein (GSV) system above and below the knee. Varithena® improves the symptoms of superficial venous incompetence and the appearance of visible varicosities.

### IMPORTANT SAFETY INFORMATION

The use of Varithena® is contraindicated in patients with known allergy to polidocanol and those with acute thromboembolic disease.

Severe allergic reactions have been reported following administration of liquid polidocanol, including anaphylactic reactions, some of them fatal. Observe patients for at least 10 minutes following injection and be prepared to treat anaphylaxis appropriately.

Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Patients with underlying arterial disease may be at increased risk for tissue ischemia. If intra-arterial injection of polidocanol occurs, consult a vascular surgeon immediately.

Varithena® can cause venous thrombosis. Follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization, or pregnancy are at increased risk for developing thrombosis.

The most common adverse events observed were pain/discomfort in extremity, retained coagulum, injection site hematoma or pain, common femoral vein thrombus extension, superficial thrombophlebitis, and deep vein thrombosis.

Physicians administering Varithena® must be experienced with venous procedures, possess a detailed working knowledge of the use of the duplex ultrasound in venous disease and be trained in the administration of Varithena®.

See Full Prescribing Information for Varithena®.

Instructions for Use, including warnings, precautions, potential complications, and contraindications can be found at [www.btg-im.com/en-US/Varithena](http://www.btg-im.com/en-US/Varithena).