The Sclerosafe and V – Block Procedure:
Office based Vein Therapy

Prof. Ralf R. Kolvenbach MD, PhD, FEBVS
Vascular Centre Catholic Hospital Group – Augusta Krankenhaus
CAT GmbH
Duesseldorf FRG
Conflict of Interest

• None
Non Thermal, Non Tumescent: NTNT

- Mechanical Occlusion Chemically Assisted - ClariVein™
- Cyanoacrylate Adhesive – Venaseal™
- Polidocanol Injectable Microfoam – Varithena™
- V Block™ – VVT Medical
Management of Saphenous Vein Incompetence

- **Chemical Ablation (Foam Sclerotherapy)**
  - No surgical incisions
  - Excellent efficacy in several studies
  - No need for tumescent anesthesia
  - Risk of thrombophlebitis, pulmonary embolism, visual disturbances, stroke
  - Not approved by FDA

Cavezzi et al. Phlebology 2002;17:13-8
Dual Process Syringe - DPS

- Single-hand operated
- Injects and aspirate with a single motion at a 2:1 ratio
- Negative pressure at the tip
- Helps reduce vein volume
- Not dependent on pull-back rate
- Prevents sclerosant/blood dilution (allows for liquid, low concentration substance)
ScleroSafe™ - Procedure kit for treating Shallow Varicosities (Reticular\ below the skin incompetent veins)

Minimal anesthesia – local at micro puncture point. No pain, fast immediate VISIBLE results. No scarring, No discoloration \ matting, No trapped blood clots, minimal to zero Thrombophlebitis.
Sclerosafe
The Sclerosafe and V–Block Procedure

• Percutaneous delivery of a vascular occluding device (V-block Device) into the proximal GSV

• Concomitant liquid sclerotherapy of the GSV using a proprietary dual procedure syringe system
The V-Block Device

- Conical, nitinol frame
- Covered by PTFE membrane
- Parabolically-shaped scaffold at inner base
- Fixation through radial force and nitinol barbed hooks
Technique

Wire 2 – 3 cm from sapheno femoral junction

No tumescence

No sheath or wire exchange

Polidocanol 1% proximal 0.5% distal

Total amount < 10 ml per saphenous Vein (European Consensus meeting on Foam sclerotherapy 2003)

Compression 48 h, take off for showering, during daytime

3 cm from SFJ

Post treatment SFJ
The Sclerosafe and V Block Procedure
Complications

- Phlebitis day 2  
  1 Patient

- Conversion (2 years)  
  1 Patient

Frequency of Any Adverse Events

<table>
<thead>
<tr>
<th>Subject</th>
<th>#</th>
<th>Medical Problem</th>
<th>AE preferred term</th>
<th>MedDRA System class</th>
<th>Onset Date</th>
<th>Date Resolved</th>
<th>Severity</th>
<th>Device Relationship</th>
<th>Treatment Required</th>
<th>Anticipated</th>
<th>Patient outcome to date</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>1</td>
<td>THROMBOPHLEBITIS</td>
<td>Thrombophlebitis</td>
<td>Vascular disorders</td>
<td>10/03/2012</td>
<td>14/03/2012</td>
<td>Mild</td>
<td>Not study device related</td>
<td>Drug Therapy</td>
<td>Anticipated</td>
<td>Recovered-No Residual Effects</td>
</tr>
</tbody>
</table>
Results II

2 Year results
GSV Occlusion rate

No Stent Migration!
Complete Stent Incorporation

No Late Adverse Events

Can be combined with Foam – Acryl-Cyanate
Conclusion I

The Sclerosafe and V-Block Procedure

- No Stent Migration
- No Late Adverse Events
- Can be combined with Foam – Acryl-Cyanate
Conclusion II

The Sclerosafe and V–Block Procedure

- Office based technique
- No tumescent required
- No hardware downpayment
- No Polidocanol related major complications
- Learning curve
The Sclerosafe and V – Block Procedure:
Office based Vein Therapy

Prof. Ralf R. Kolvenbach MD, PhD, FEBVS
Vascular Centre Catholic Hospital Group – Augusta Krankenhaus
CAT GmbH
Duesseldorf FRG