Agenda

• Anatomy of Venous System
• Venous Thromboembolism
• DJO Product Offering
  – VenaFlow Elite
  – VenaPure
• Key Clinical Aspects for Combined Prophylaxis
• Venous Disease
• Compression Therapy
• DJO Product Offering
  – Veinax
# Vascular Continuum of Care

<table>
<thead>
<tr>
<th>Prevent</th>
<th>Treat</th>
<th>Maintain</th>
</tr>
</thead>
<tbody>
<tr>
<td>• VenaPure/VenaFlow</td>
<td>• Veinax Compression Hosiery</td>
<td>• Dr Comfort therapeutic footwear</td>
</tr>
<tr>
<td>• Prevent venous</td>
<td>• For the treatment of</td>
<td>• For the long term care of</td>
</tr>
<tr>
<td>thromboembolism</td>
<td>venous disorders</td>
<td>venous disorders associated with</td>
</tr>
<tr>
<td>(DVT and PE)</td>
<td>• For the mobile patient</td>
<td>the foot</td>
</tr>
<tr>
<td>• For the immobile</td>
<td>• Available in the community</td>
<td>• Available in the community</td>
</tr>
<tr>
<td>patient</td>
<td>• Prescription primarily</td>
<td>• Reimbursed &amp; patient pay</td>
</tr>
<tr>
<td>• Primarily for use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>in hospitals</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Anatomy of the Vascular System
Anatomy

• The Heart
• Arterial & Venous System
• Veins
• Venous Return
The Heart

- Maintains constant circulation of blood through body
- Right side moves blood to lungs, CO₂ removed and O₂ added
- Oxygenated blood returned from lungs to left side of heart and then to rest of body
- Blood flows from heart via arteries and returns to heart in veins
The Circulatory System
Venous Network

- **Deep venous system:**
  - 90% total venous network.
  - Enclosed in muscle and fascia.
  - Acts to drain away from the muscles and deep tissue.

- **Superficial venous network**
  - Directly under the skin, above the muscle layer.
  - 10% of total venous system.
  - Function to drain the skin and tissues.
  - When abnormal swelling occurs here, varicose veins are formed.

- **Perforator veins:**
  - Cross the fascia to link deep veins with superficial veins.
What are Veins?

- Veins differ from arteries in their structure and their function.
- Veins (and venules) thinner, less muscular walls and can dilate to accommodate 80% of the total blood volume if necessary.
  - Venous blood pressure affected by gravity and changes in the body position.
  - Standing pressure in deep veins is 90mmHg - depending height of individual.
  - Recumbent pressure 10mmHg.
  - Any vein that distends over 20% will result in micro tears in the endothelium.
- Feature of leg veins - presence of one-way valves.
  - Semi lunar folds of smooth endothelium.
  - Once valves are damaged, they never repair themselves.
Venous Return

- Venous return is the rate of blood flow *towards* the heart.

- Blood returns to the heart from the legs via deep & superficial venous system & through action of:
  
  1. **Contraction of calf muscle pump** (gastrocnemius/soleus) and effect on deep venous system
  2. Presence of valves along within the veins
  3. Venous system in foot (plantar)
  4. **Variations in intra-abdominal & intra-thoracic pressures caused by breathing**
1) Calf Muscle Pump

- Often called the second heart
- Pump action caused by intramuscular pressure exerted at the calf
- Pressure > 200 mm Hg at the time of muscular contraction.
2) Venous Valves

- Ensure blood moves in one direction only - preventing reflux.
- Found along the veins.
- Semi-lunar folds of smooth endothelium
- Valves can be found every 4 to 5 mm
3) Foot Pump / Walking

- Cardiac pump alone is not enough to overcome gravity and allow the blood to return.

- Plantar venous pump consists of plantar veins located deep between plantar muscle which compress during walking.
3) The Effect of Walking

- The impulse provided by the plantar step is followed by the calf muscle pump.
- Venous return continues.
- Valves oppose gravity and prohibit the reflux of blood.
4) Effect of Breathing

- Venous system works with breathing, creating diaphragmatic aspiration.
- At each breath in:
  - Diaphragm descends.
  - Intra-abdominal pressure rises.
  - Blood flow slows down.
- At each breath out:
  - Abdominal pressure reduces.
  - Blood flow increases.
Venous Thromboembolism

What is it and why is it important?
Definition of Terms

- **Thrombus/thrombi/thrombosis**: blood clot
- **Deep Vein Thrombosis (DVT)**: a blood clot that forms in a vein deep in the body. Most deep vein clots occur in the calf or thigh.
- **Embolus/emboli/embolism**: clot that is moving or has moved
- **Coagulation**: natural process of creating a clot
- **Fibrinolytics/fibrinolysis**: breakdown of clots
- **Pulmonary Embolism (PE)**: If a clot in a vein breaks loose from the wall of the vein and travels to the lungs, blocking the pulmonary artery. This blocks the blood flow from the heart and is life threatening.
- **Venous Thromboembolism (VTE)**: Disease that involves blood clots – covers both DVT and PE
So How Big is The Problem?

• Asia
  – Korea: Annual incidence of VTE shown to be 13.8 per 100,000 4
  – Singapore: Acute DVT found in 15.8 per 10,000 5, total deaths to PE at 1.8% 17
  – Thailand: In a large study of non-surgical hospital patients, 0.59% VTE with mortality of 26% 18
  – India: 17.46 per 10,000 hospitalised admissions & separately 14% DVT rate in surgical patients 15,16
  – Incidence of DVT in 7 Asian countries was 41% post major orthopaedic surgery 8

• UK
  – 25,000 people die from VTE each year 1

• Europe
  – 543,454 estimated VTE deaths per annum 2
  – Around 140,000 cases of VTE treated in France each year, with mortality at 10%

• US
  – 200,000 VTE related deaths per annum

• Australia
  – 5,000 VTE related deaths per annum 3

VTE is still a major cause of preventable deaths globally
Under-diagnosed - Under-prophylaxed!

• PROVE registry compared VTE events in Europe/Australia with those in Asia⁹:
  – Asian patients younger
  – More proximal DVTs
  – Fewer patients received prophylaxis
• Piovella and his review work from 2005 showed⁷:
  – Using Venography, incidence of DVT following orthopaedic surgery was higher than in Western populations
  – Lack of awareness in Asian countries – slow to adopt new techniques
• Multinational study involving 32 countries proved that high percentage of hospitalised patients were at risk of VTE but too few received appropriate prophylaxis²²:
  – Surgical patients: 64.4% at risk – only 58.5% received correct prophylaxis
  – Medical patients: 41.5% at risk – only 39.5% received correct prophylaxis

Low rate of thromboprophylaxis in Asian population despite their high risk of VTE.
Why is there still VTE?

- Hospital versus Community acquired
  - 10% of patients will develop VTE in hospital, with 0.5% developing immediately post-discharge!
  - 74% of VTE present in outpatients \(^{10}\)
    - 42% of VTE outpatients have had hospital admissions
    - Only 40% received prophylaxis in hospital
  - 2/3 of VTE deaths occur post-discharge
- Lack of clinical studies in certain areas
  - Highest risk groups: Obs & Gyn, Medical, Oncology
- National differences not recognised
  - Health systems
  - Income growth & distribution
- Varying levels of VTE awareness
- Underestimate risk
  - No risk assessment at admission or prior to surgery
  - 72.9% patients demonstrate 1 or more risk factors for DVT \(^{17}\)
  - Patients readmitted into other departments – lost in system
- Lack of acceptance of guidelines

Risk assessment is critical for all patients not just to assess risk of VTE but to identify other possible co-morbidities.
Why VTE Prophylaxis?

• Personal Health Cost
  – 30% greater cumulative risk of recurrent VTE after 1st case
  – Sequelae of post-thrombotic syndrome, PE, PAH
  – Loss of work, social mobility, lack of confidence

• Financial Burden
  – Cost of treating VTE
    • Hospitalisation
    • Drugs
    • Care givers
    • Long term sequelae

• National pressures for effective VTE management
  – Public reporting
  – Accountability
  – #1 potentially preventable death in hospitalised patients
  – VTE management rated #1 most effective safety policy in US hospitals
  – Health systems may stop paying for hospital induced VTE

Prophylaxis works: Reduced risk of VTE from 1.8 to 1.1! 19
## DVT Prevalence Rates

<table>
<thead>
<tr>
<th>Condition</th>
<th>Prevalence Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal Cord Injury</td>
<td>60 - 80%</td>
</tr>
<tr>
<td>Hip/Knee Surgery</td>
<td>40 - 60%</td>
</tr>
<tr>
<td>Major Trauma</td>
<td>40 - 80%</td>
</tr>
<tr>
<td>General Surgery</td>
<td>15 - 40%</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>15 - 40%</td>
</tr>
<tr>
<td>Major urology surgery</td>
<td>15 – 40%</td>
</tr>
<tr>
<td>Stroke</td>
<td>20 – 50%</td>
</tr>
</tbody>
</table>

Based on objective diagnostic screening for asymptomatic DVT in patients not receiving thromboprophylaxis. 

ACCP, 2008
General Risk Factors for DVT

• Age > 60 years
• Obesity (BMI >30kg/m²)
• Oestrogen-containing contraceptive therapy
• Pregnancy
• Use of HRT (Hormone Replacement Therapy)
• Critical care admission
• Travel for extended periods of time (plane, train, truck, car)
• Personal history or first degree relative with history of VTE
• Active cancer or cancer treatment
• Severe asthma
• One or more significant medical comorbidities (eg. Heart disease, metabolic, endocrine or respiratory pathologies, acute infectious diseases, inflammatory conditions)
• Varicose veins with phlebitis
• Known thrombophilias
## Hospital Specific Risk Factors

### Medical

- If mobility significantly reduced for $\geq 30$ days
- If expected to have ongoing reduced mobility relative to normal state

### Surgical

- If total anaesthetic + surgical time $> 90$ mins
- If surgery involves pelvis or lower limb + total anaesthetic + surgical time $> 90$ mins
- If acute surgical admission with inflammatory or intra-abdominal condition
- If expected to have significant reduction in mobility
Cause of VTE: Virchow’s Triad

The presence of at least two of the above factors will cause a DVT/PE to form.

1856
Clinical signs and symptoms of VTE

• DVT is often asymptomatic, however if symptoms do exist:
  – Calf pain or tenderness, or both
  – Swelling with pitting oedema
  – Swelling below knee in distal DVT and up to groin in proximal DVT
  – Increased skin temperature
  – Superficial venous dilatation
  – Cyanosis can occur with severe obstruction
  – Coughing and/or chest pain

• The Silent Killer
  – The clinical signs can be unreliable especially in early thrombosis. In up to 50% of cases, there are few or no significant signs and symptoms. *(Turner & Turner 1982)*
  – Only 25% of patients with DVT display clinical signs *(O’Meara 1990)*
So who is at risk?

- What caused it?
  - 2 recent surgeries on her foot in March 2011
  - Later complained of pain in her leg
  - DVT & PE!

- Why was it missed?
  - Slower heart rate – increased risk of stasis
  - Misdiagnosis
**Consequences of VTE**

Even if D.V.T. does not cause mortality (death), it can cause long-term morbidity (disease).

**Irreversible Valve Damage**

When a clot forms, the valve is damaged. Damage results in an incompetent valve. When the valves are incompetent, there is a reflux of blood in the veins. (Valves never repair)

**Postphlebitic Syndrome**

*Around 50% of patients following VTE develop post-thrombotic syndrome*

The patient can experience chronic pain, swelling and venous ulcers, due to irreversible damage of the venous valves, promoting venous pooling in the deep veins and consequently, venous hypertension.
Thrombi Development

- Where clots form
- When clots form
- Methods of prevention
- Anti coagulants
Where Do Clots Form?

- Embolus develops as a result of faulty valves in veins
  - Typically in deep venous system
  - Majority of valves in Great Saphenous (10-20)
  - Popliteal has 4 valves & Femoral 3 valves
- According to data:
  - 80-90% of DVT occur in the operative limb of orthopaedic patients
  - Pulmonary emboli generally arise from proximal thrombosis, femoral DVTs are responsible for 75% of fatal PEs
  - Proximal thrombi can form without association to distal thrombi

O’Meara PM & Kaufmann Orthopedics 1990
When Do Clots Form?

• During long period of immobility
• During surgical manipulation of limbs
• High percentage form intra-operatively
  – 50% begin intraoperatively or within the first 24 hours post-surgery (O’Meara, 1990)
  – 74% develop within the first 48 hours post-operatively (O’Meara, 1990)
  – 23% of patients following major surgery were free from DVT on discharge, but developed DVT within 6 weeks (Scurr, 1992)
Methods of diagnosis VTE

Venography
Impedance Plethysmography
Colour Doppler Ultrasound
MRI Scanning
Perfusion Lung Scan (non-invasive)
Methods of Preventing DVT

A. Prevention of Stasis and Endothelial Damage (Mechanical)
   - Leg elevation and early ambulation
   - Graduated elastic compression
   - Intermittent pneumatic compression
   - Plantar foot compression

B. Prevention of Hypercoaguable State (Pharmaceutical)
   - Oral anticoagulants
   - Low dose Subcutaneous Heparin
   - Low Molecular Weight Heparin (LMWH)
   - Pentasaccharides- Fondaparinux
   - Oral LMWH

C. Combination of Methods from A and B
Pharmaceutical Prophylaxis

- Use of drugs to prevent VTE by affecting the ability of the blood to clot
  - Vitamin K antagonists (warfarin/coumadin) long term, now mostly used for treatment (oral use)
    - Block synthesis of vitamin K-dependent coagulation factors
  - Heparins
    - Unfractionated heparin (UFH) injections short term
  - Low molecular weight heparins (LMWH), such as Clexane/Lovenox (enoxaparin & dalteparin) indicated for VTE prophylaxis in medical & surgical patients. Injection only.
  - Fondaparinux – synthetic sugar (pentassacharide) that binds to Factor Xa.
  - New synthetic oral anticoagulants:
    - Pradaxa (dabigatran) launched March 2009 – direct thrombin inhibitor, IIa
    - Xarelto (rivaroxaban) and Eliquis (apixaban) – Factor Xa
# Pros & Cons Pharmaceuticals

<table>
<thead>
<tr>
<th></th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharmacological:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| LMWH | Longer ½ life  
Improved efficacy  
Wide indications  
Cost effective  
Widely studied/clinically proven | Injection only – trained healthcare professionals  
Ongoing lab monitoring  
Poor compliance post-discharge  
Increased bleeding risk  
Poor reversibility (Protamine)  
Variable effect in renal failure, obesity  
Regimen commences post-surgery  
Epidural haematoma - Black box warning  
Porcine based  
Risk of HIT (heparin induced thrombocytopenia) |
| Novel oral anticoagulants | Oral formulation - ideal for home use  
No monitoring required  
Similar efficacy to LMWH  
Shorter ½ life (5-9 hrs  
Rivaroxaban, 12-17 dabigatran)  
Synthetic drugs | Very limited indications  
Bleeding risks resulting in some deaths  
Increased risk with renal insufficiency, elderly, obese  
Therapy commences post-op  
No antidote |
External pressure has the effect of:

- Reducing the diameter of the superficial and deep veins.
- Reestablishing the functionality of the valves by narrowing vein diameter.
- Retaining the interstitial fluid in the vessels.
- Improve lymphatic microcirculation.
- Increase circulation at the level of the skin.
Why different levels of compression?

• Recumbent/immobile
  – Patients laying in bed require low levels of pressure (>10mmHg) to control venous stasis
  – This is sufficient to prevent thrombus formation
  – Pressures in excess of 30 mmHg do not have beneficial effect if patient is laying down

• Ambulatory/standing
  – Far higher levels of pressure required to influence blood flow
  – Pressure during walking fluctuates between 20-100mmHg
  – Working pressures of 40-50mmHg are required to influence this
Why different levels of compression?

• Recumbent/immobile
  – Patients laying in bed require low levels of pressure (>10mmHg) to control venous stasis
  – This is sufficient to prevent thrombus formation
  – Pressures in excess of 30 mmHg do not have beneficial effect if patient is laying down

• Ambulatory/standing
  – Far higher levels of pressure required to influence blood flow
  – Pressure during walking fluctuates between 20-100mmHg
  – Working pressures of 40-50mmHg are required to influence this
DJO Global Vascular Therapies
Dynamic and Static Compression
VenaFlow Elite
Definition of Terms

- **IPC**: Intermittent pneumatic compression
- **Rapid inflation**: cuffs inflate immediately and apply a quick squeeze to the muscle
- **Duplex aircell**: dual aircell design; the proximal aircell overlaps the distal in calf
- **Sequential compression**: cuff squeezes distal portion of calf first and then proximal
- **Graduated compression**: there is more pressure in one chamber than the other; distal pressure is slightly higher than proximal pressure
- **Asymmetric compression**: cuff does not compression equally around the circumference of the calf, but applies focused compression on specific areas of the calf
- **Integrated Sequential Flow System (IGSF)**: single tube system integrated into the duplex (dual) aircell
# Mechanism of Action

<table>
<thead>
<tr>
<th>Rapid Inflation</th>
<th>Turbulent Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Increases peak blood flow through the veins by:</td>
<td>• Induces turbulent flow deep in the venous pockets where stagnant flow can cause stasis</td>
</tr>
<tr>
<td>– Sequentially compressing the leg applying graduated compression levels to milk blood proximally</td>
<td>• Directly influences the fibrinolytic effect of the blood to form and subsequently break down clots</td>
</tr>
<tr>
<td>– Rapid inflation to replicate the mechanism of walking</td>
<td>– Promotes release of nitric oxide, which in turn inhibits platelet aggregation and leukocyte adhesion to the endothelium (clots)</td>
</tr>
<tr>
<td>– Rapid inflation with high compression ensures maximum venous velocity</td>
<td>• Turbulent flow less likely in slow inflating devices since not enough momentum achieved to accelerate flow</td>
</tr>
</tbody>
</table>
Rapid Inflation

- The pressure curve below shows how the distal and proximal curves start out at different times and different pressures, then as time progresses, then the pressures synchronize.
- Important is the graduated, sequential nature of the peak pressures. The initial rapid inflow of the distal aircell first and then the proximal second is the key to increasing venous velocity.
How to Read a Doppler

- A Doppler provides information about the speed and direction of blood flow through the vein which also indicates how well a compression device moves blood and thus prevents clots.

  - **Baseline velocity:** blood flow velocity at rest when no ambulation or inflation is occurring
  - **Peak Velocity:** the speed of blood flow at the point when the VenaFlow cuff is inflating. This is what blood flow looks like when a person is flexing their foot or walking.
  - **% Increase over baseline:** When comparing Dopplers between competitive devices, it is best to look at the percentage above baseline. This shows true blood flow achieved from just the device apart from normal flow. Studies show that the higher the peak velocity, the lower the DVT rates.
Asymmetric Compression

VenaFlow Elite provides asymmetric compression to the leg
VenaFlow Doppler Comparisons

- **Standard VenaFlow System**
  110% increase in venous velocity over baseline

- **VenaFlow Elite System**
  112% increase in venous velocity over baseline

- **Plantar/dorsiflexion**
  111% increase in venous velocity over baseline
Competitive Dopplers

**VenaFlow Elite System**
112% increase in venous velocity over baseline

**Slow inflation, SCD device**
50% increase in venous velocity over baseline

**Slow inflation, uniform compression device**
33% increase in venous velocity over baseline
Without VenaFlow.

Vein During Rest
- Clots can form behind valve cusps

With VenaFlow.

Vein with Compression
- Turbulence (reduces clot formation)
VenaFlow Elite Features

- Bed hanger release button
- Telescoping bed hanger
- Graphical display
- Single/Dual Leg Operation
- Pump indicator lights (green = on, flashing red = alarm)
- Patient compliance meter
- On/Off/Reset Button
All-In-One System (Foot, Calf, Thigh)

- Digital display with Alarm prompts
- Green/Red lights seen from any angle
- Alarm volume can be adjusted from high to normal
- Telescoping bed hook (up to 9cm)
- Mains only or Mains/Battery models
  - Battery runs approximately 2 hours
  - Takes 4 hours to charge
- Pressures are preset
- Cycle is preset
- Auto detects cuff type
- Microprocessors monitor and prevent overinflation
- 4 lengths of tubing available
Rapid Inflation

- **Leg Cuffs**
  - Seamless duplex cells
    - Distal inflation at 73 mmHg (+/- 15)
    - Proximal inflation at 63 mmHg (+/- 15)
    - Holds at 45 mmHg
  - The distal aircell inflates first within 0.5 seconds. Then at a certain pressure or “pinch” point the air flows into the proximal aircell.
    - Total cycle time 6 seconds
    - After 54 secs, cycle recommences
  - Alternate legs

- **Foot cuffs**
  - One cell
    - 130 mmHg for 0.5 secs
    - Holds at 45 mmHg
  - Cycle 6 secs, after 54 secs cycle recommences
  - Alternate feet
Cuffs and Tubing

• Cool, lightweight, breathable sleeves
  – Durable fabric
  – Brushed nylon & polyester
• 3 sizes of calf cuff and 1 size for thigh
  – Minimal inventory required
  – Can be trimmed to size
• Bariatric calf cuff available (up to 76cm)
  – Bariatric doppler results unchanged
• Cuffs are Single Patient Use
• Aircells can be placed anterior, posterior, medial, lateral on leg
  – Does not affect performance
• Safe connectors, durable tubing, anti-kinking
• Can be applied with or without anti-embolism stockings
  – Medical decision
Pump Set Up and Action
VenaFlow Elite Function

Pump Set Up

- Hang pump from bed frame, rest on floor or table
- Press release button at back to operate the telescopic bed hanger. Gently pull out to required width

Tubing Connection

- Insert the tubing into the connectors
- Ensure they lock into place
- There is no specified left or right
- Plug the device into power (if using mains)
**Cuff Application**

- Apply calf or thigh cuff with aircell centred on back of leg with tube pointed towards foot
- Apply foot cuff with aircell centred on sole of foot and tube pointed to left

**Tubing to Cuff**

- Attach the tubing to the cuffs selected
- Snap into place and ensure they are locked
• For varied patient sizes, trim calf and thigh cuffs as required for improved patient fit
• The cuffs should fit snugly but not tight (2 fingers between leg and cuff)
To turn pump on, press Φ
- The display will illuminate
- Once on, system will enter cuff detection mode. Display will read: DETECTING CUFF and %
- Once it reaches 100%, transitions to normal screen
- To turn device off, press Φ
Single Leg Operation

- Automatic default is 2 legs/feet
- If Single Leg is required:
  - Within 3 minutes of start up, press the single leg operation button
  - The single leg icon will appear in top right hand corner
  - Device inflates 6 seconds every minute
  - Either port may be used
Patient Compliance Meter and Alarm Reset

- **Alarm Reset**
  - Once an alarm goes off, it must be reset
  - Press the Φ and resolve the issue
  - The pump will go through the same procedure as before

- **Patient compliance commences once the machine is switched on and continues until the Reset button is pressed**
  - To reset, press the button for 1 second and release
  - The hours, mins and sec reset
Alarms

- Tubing – kinked or leaking Sounds after 4-6 mins
- Single/Dual Leg Operation Sounds after 4 mins
- Compliance – if cuffs not attached Sounds after 15 mins
- Call for Service If one of the critical components not working
- Low Battery With 15 mins of charge, beeps every 3 mins. Less than 5 mins of charge, constant beeping
In Service Recommendations

• Sleeves or Foot cuffs should be worn throughout the immobilsation period, **pre-op, intra-op and post-op**
• Cuffs should be kept on for **24 hours** and for as many days as prescribed until the patient is fully mobile
• At sleep – device should not be disconnected – risk of DVT forming if no prophylaxis used
• Remove daily and inspect skin for signs of pressure damage
• Become familiar with the fault alarms both visual and audible with corresponding coding.
# Product Selection & Measurement

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Qty</th>
<th>Max Calf Circumference</th>
<th>Max Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>3040</td>
<td>VenaFlow Elite Calf Cuff</td>
<td>Pair</td>
<td>48.26cm (19”)</td>
<td>29.5cm (11.5”)</td>
</tr>
<tr>
<td>3041</td>
<td>VenaFlow Elite Sterile Calf Cuff</td>
<td>Each</td>
<td>48.26cm (19”)</td>
<td>29.5cm (11.5”)</td>
</tr>
<tr>
<td>3042</td>
<td>VenaFlow Elite XL Calf Cuff</td>
<td>Pair</td>
<td>55.88cm (22”)</td>
<td>29.5cm (11.5”)</td>
</tr>
<tr>
<td>3043</td>
<td>VenaFlow Elite Bariatric Calf Cuff</td>
<td>Pair</td>
<td>76.2cm (30”)</td>
<td>29.5cm (11.5”)</td>
</tr>
<tr>
<td>3044</td>
<td>VenaFlow Elite Sterile XL Calf Cuff</td>
<td>Each</td>
<td>55.88cm (22”)</td>
<td>29.5cm (11.5”)</td>
</tr>
<tr>
<td>3050</td>
<td>VenaFlow Elite Foam Calf Cuff</td>
<td>Pair</td>
<td>48.26cm (19”)</td>
<td>Max Thigh Circumference</td>
</tr>
<tr>
<td>3045</td>
<td>VenaFlow Elite Thigh Cuff</td>
<td>Pair</td>
<td>74cm (29”)</td>
<td>53.5cm (21”)</td>
</tr>
<tr>
<td>3046</td>
<td>VenaFlow Elite Foot Cuff</td>
<td>Pair</td>
<td>One size, 41cm (16”)</td>
<td>23cm (9”)</td>
</tr>
</tbody>
</table>
Clinical Indications

• Prophylaxis for deep vein thrombosis (DVT) and pulmonary embolism (PE)

• Designed to mimic/replace the ineffective calf muscle pump, which for reasons of immobility is not working effectively to move blood
Contra-Indications

Leg Sleeves
1. Any local leg condition in which the sleeves may interfere, such as: (a) dermatitis, (b) vein ligation [immediate postoperative], (c) gangrene, or (d) recent skin graft.
2. Severe arteriosclerosis or other ischemic vascular disease.
3. Massive oedema of the legs or pulmonary oedema from congestive heart failure.
4. Extreme deformity of the leg.
5. Suspected pre-existing deep venous thrombosis.

Foot Compression
1. Conditions where an increase of fluid to the heart may be detrimental.
2. Congestive heart failure.
3. Pre-existing deep vein thrombosis, thrombophlebitis or pulmonary embolism.

Use with caution on the infected or insensitive extremity.
Frequently Asked Questions

• Can you use IPC in patients following heart failure
  – Venous return in these patients tends to be lower and the use of IPC addresses the possible issues with stasis. The pressure parameters used and frequency of cycle are not enough to overload the heart, unless the heart disease is significant. If there are any concerns, then do not use

• When would you use a single leg?
  – Under certain operating conditions, it might be advisable to use the cuffs on only one leg, e.g. Knee or hip surgery

• When should I start using IPC
  – Ideally IPC should commence as soon as the patient becomes immobile – this will typically be in the pre-op phase, will continue peri-op, post-op and until the patient is normally ambulatory

• Can I stop the IPC during the night
  – The IPC should remain connected and functioning for as long as the patient is immobile. If the patient is concerned about sleeping, then the device can be switched off, but must be reconnected as soon as the patient is awake

• Can I use the cuffs on other patients
  – These devices are single patient use, that means that they can be used on the same patient, as long as the integrity of the material is not compromised. They can be wiped down with mild disinfectant
# Intermittent Pneumatic Pump Competitor Overview

<table>
<thead>
<tr>
<th>Features</th>
<th>VenaFlow Elite DJO</th>
<th>SCD Express Covidien</th>
<th>SCD 700 Covidien</th>
<th>AV Impulse Covidien</th>
<th>Flowtron Universal ArjoHuntleigh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression</td>
<td>Rapid – 0.5 secs</td>
<td>Slow – 11 secs</td>
<td>Slow – 11 secs</td>
<td>Rapid – 0.4 sec</td>
<td>Slow – 12 secs</td>
</tr>
<tr>
<td>Sequential</td>
<td>2 aircells (leg) 1</td>
<td>3 aircells</td>
<td>3 aircells</td>
<td>No - Single</td>
<td>No - Uniform</td>
</tr>
<tr>
<td></td>
<td>aircell (foot)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gradient (distal to proximal)</td>
<td>73-63-45 mmHg (leg)</td>
<td>45-40-30 mmHg</td>
<td>45-40-30 mmHg</td>
<td>130 mmHg</td>
<td>40 mmHg</td>
</tr>
<tr>
<td></td>
<td>130 – 45 mmHg (foot)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Battery</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Single leg operation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Range of sleeves</td>
<td>Knee, Thigh, Bariatric, Sterile, Foot</td>
<td>Knee, Thigh, Bariatric, Sterile, Foot</td>
<td>Knee, Thigh, Bariatric, Sterile, Foot</td>
<td>Foot only (inc sterile)</td>
<td>Knee, Bariatric, Large, Thigh, Foot x 2, Sterile</td>
</tr>
<tr>
<td>All in one</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Adjustable Bed hanger</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Clinical data</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Other</td>
<td>Offer VenaPure AES in conjunction with VenaFlow</td>
<td>Offer TED AES in conjunction with IPC</td>
<td></td>
<td>Licensed for Swelling reduction &amp; circulation enhancement</td>
<td></td>
</tr>
</tbody>
</table>
Covidien (Kendall)

SCD 700

• New ergonomic design for better visuals and easier cleaning
• 3.2 inch color LCD screen using larger icons for easier visuals
• Animated icons displaying leg detection, type of alarm and how to remedy
• Adjustable bed hanger
• Smooth, grooveless surface and slim profile
• Easy to clean - Compatible with most cleaning agents
• USB port for easier software updates
• Mains/battery operation
• Reduced noise via vibration dampeners and soft overmolding
• Pump is compatible with new Comfort sleeves as well as the cuffs from SCD Express
• Vascular Refill Detection

SCD Express

• Clinically Proven
• Sequential, gradient, circumferential
• Slow compression
• Vascular Refill Detection
• Battery/mains operation
• Anatomical shape of sleeves
• Range of sleeves available, inc Kambia
• Foot cuff
• All in one system
Covidien A-V Impulse System

- Plantar compression
  - 0.4 second rapid inflation
  - 130 mmHg pressure
  - 3 second hold time
  - 20 second cycle time
- 3 pre-set parameter settings
  - Adjustable pressure, inflation-cycle & hold times
  - Left or right foot
- Inflate on sole of foot
- ImPad Foot Covers
  - Rigid sole
  - Dorsum wrap
  - Extended bladder
  - Left or Right foot
  - Sterile option
ArjoHuntleigh Flowtron Systems
## Flowtron® Excel

- **Controller**
  - Uniform (40 - 45mmHg recommended)
    - Range from 30 – 60 mmHg
  - 12 Sec Comp w/ 48 Sec Vent
  - Microprocessor (no auto adjust)
  - No Sleeve Cooling
  - No battery operation

- **Sleeve**
  - Posterior & Uniform compression
  - PVC bladder
  - Foam liner
  - Popliteal inflation

## Flowtron Universal

- **Compression**
  - Calf or thigh sleeve: 40 mmHg
  - Foot cuff: 130 mmHg
  - 12 second compression time

- **Cuff Bladder**
  - Single PVC bladder
  - Available in 3 calf sizes, 2 thigh, 2 foot, sterile in thigh, foot and calf

- **Controller**
  - All in one controller
  - New design
  - Battery optional
  - Unique “Smartsense™” recognition.
VenaPure Anti-Embolism Stockings
# Mechanism of Action

<table>
<thead>
<tr>
<th>Minimise Venous Dilation</th>
<th>Increase Blood Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Specially constructed (knitted) stocking will prevent the veins from dilating and thus reduce risk of endothelial damage</td>
<td>• Use of clinically proven graduated compression levels have been shown to increase blood flow in the deep veins</td>
</tr>
</tbody>
</table>
Compression Profile

8 mmHg
10 mmHg
8 mmHg
14 mmHg
18 mmHg
Inspection Toe Opening
Popliteal Break
Interrupted Silicone Band
Pressure Relieving Panel
Defined Heel Pocket
Colour Size Identifiers
Range of Styles

Knee Range
12 sizes available in Regular and Long lengths

Thigh Without Belt Range
15 sizes available in Small, Regular and Long lengths

Thigh With Belt Range
15 sizes available in Small, Regular and Long lengths
In-Service Recommendations

- Stockings should be worn throughout immobilisation period, pre-operatively, intra-operatively, and post-operatively.
- Stockings should be kept on for 24 hours and should not be left off for more than 30 minutes when bathing etc.
- Ensure the proper fit. Re-measure if decrease/increase in oedema and reapply correct size
- It is recommended that stockings continue to be worn for at least 6 weeks post surgery
- Do not pull or tug stockings into place as this can cause shear and friction
- Do not allow stockings to roll down
- Washing Instructions:
  - Wash every 2-3 days at 40-60°C
  - Dry at room temperature or tumble dry at a low-moderate heat.
  - Do not use ointments containing lanolin.
  - With correct care, stockings last 2-3 months (approximately 30 washes)
If measuring for a **thigh** length product (with or without belt):

1) The widest circumference of the thigh
2) The widest circumference of the calf
3) The length of the leg from the buttock fold to the floor

If measuring for a **knee** length product:

2) The widest circumference of the calf
3) The length of the leg from behind the knee to the floor

An incorrectly fitting stocking can result in:

- Inadequate compression, tissue damage & pain
- This could lead to DVT formation and lack of patient compliance
Application of Stockings

1. Insert hand into the stocking, locating the upper palm into the heel pocket

2. Grab heel pocket with hand and start to pull stocking inside out

3. Roll the stocking inside out, whilst holding the heel pocket
4. Whilst holding the heel pocket, place the foot into the stocking and pull over the foot.

5. Continue to roll the stocking up the leg, ensuring that this is done carefully. Make sure that you are working with the patient’s leg and not against.

6. The stocking is applied correctly, when the heel socket is located properly and there are not wrinkles along the leg.
Packaging

**Polybag**

One pair of stockings.

**Dispenser Box**

The polybags are contained within a Dispenser Box (sales unit).

Knee Product – 12 pairs per box
Thigh Product – 6 pairs per box
Dispenser Box Labels
Denote the Style (Knee, Thigh or Thigh with Belt), the Size, the Colour Coding and the EAN numbers.

Tape Measures
Every dispenser contains the same number of tape measures as pairs of stockings, either 6 or 12.
Frequently Asked Questions

- Do the stockings contain latex
  - Our VenaPure stockings do not contain any latex
- Can you provide these stockings in pairs or singly?
  - No, VenaPure is only available in dispensers of 6 or 12 pairs – we have completed packaging tests on the dispenser and can guarantee the integrity of this level of packaging
- When should I start using the stockings
  - Ideally VenaPure should be applied as soon as the patient enters the hospital – they can continue to be worn through the majority of surgical procedures and can be worn by medical patients throughout their stay in hospital. The stockings should only be removed permanently when the patient is normally ambulatory
- Can I use the stockings on other patients
  - These devices are single patient use, that means that they can be used on the same patient, as long as the integrity of the material is not compromised. They can be washed up to 30 times without compromising the compression profile.
## Anti-Embolism Stocking Competitive Overview

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>VenaPure™</th>
<th>T.E.D.™</th>
<th>Mediven® Thrombexin® 18 &amp; 21</th>
<th>Comprinet® Pro</th>
<th>Brevet® tx</th>
<th>Preventex®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>DJO Aircast</td>
<td>Covidien Kendall</td>
<td>Medi</td>
<td>BSN</td>
<td>Mölnlycke</td>
<td>Urgo Medical</td>
</tr>
<tr>
<td>Graduated compression profile (mmHg)</td>
<td>18-14-8-10-8</td>
<td>18-14-8-10-8</td>
<td>18 (ankle) – 8 (upper thigh)</td>
<td>18</td>
<td>None specified</td>
<td>18 at ankle</td>
</tr>
<tr>
<td>Popliteal break</td>
<td>Yes, noticeable change in knit</td>
<td>Yes, noticeable change in knit</td>
<td>Yes, noticeable change in knit</td>
<td>No</td>
<td>Yes</td>
<td>Yes, noticeable change in knit</td>
</tr>
<tr>
<td>Pressure relieving panel (thigh)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Inspection toe opening</td>
<td>On top of foot</td>
<td>Underneath foot</td>
<td>Underneath foot</td>
<td>On top of foot</td>
<td>Underneath foot</td>
<td>Underneath foot</td>
</tr>
<tr>
<td>Styles &amp; Sizes:</td>
<td>- Knee - Thigh - Thigh with Belt</td>
<td>- Knee - Thigh - Thigh with Belt</td>
<td>- Knee - Thigh - Thigh with Belt</td>
<td>- Knee - Thigh - Thigh with Belt</td>
<td>- Knee - Thigh - Thigh with Belt</td>
<td>- Knee - Thigh - Thigh with Belt</td>
</tr>
<tr>
<td></td>
<td>- 12 - 15 - 15</td>
<td>- 12 - 18 - 10</td>
<td>- 6 - 9 - 4</td>
<td>- 4 - 8 - 0</td>
<td>- 5 - 5 - 5</td>
<td>- 8 - 12 - 8</td>
</tr>
<tr>
<td>Other</td>
<td>-Antibacterial toe -3D fleecy soft heel</td>
<td>Reinforced heel pocket</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical compression available</td>
<td>Yes, VenaFlow® Elite: Graduated, Sequential, Rapid inflation</td>
<td>Yes, SCD Express™ &amp; SCD 700: Graduated, sequential, circumferential, slow compression</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
Covidien (Kendall) T.E.D Stockings

- Original Sigel clinical work (1975) on TED
- Clinically proven over 35 years
- Inspection hole on bottom of foot
- Developed extensive training & support programme
- Generic term for anti‐embolism stockings
Medi Thrombexin 18 & 21

• Claim to meet Sigel profile
• Offer 2 compression levels of AES:
  – 18mmHg at ankle
  – 21mmHg at ankle
• Inspection toe underneath foot
• No pressure relieving panel
• Specially designed top band
• Antibacterial toe section
• Colour coded, softer heel
BSN Comprinet

• Limited range of sizes offered:
  – 4 knee
  – 8 thigh without belt
• Claim to meet Sigel profile
• No pressure relieving panel in thigh
Urgo - Preventex

- No pressure relieving panel
- Inspection toe underneath foot

Mölnlycke – Brevet TX

- Only 5 sizes per style
- Inspection toe underneath
- No pressure relieving panel
Marketing & Clinical Support
## Marketing Support

<table>
<thead>
<tr>
<th>Vascular Therapies</th>
<th>VenaFlow Elite</th>
<th>VenaPure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aircast Vascular Catalogue</td>
<td>Launch binder</td>
<td>Launch binder</td>
</tr>
<tr>
<td></td>
<td>Nurse User Guide</td>
<td>Ward Poster</td>
</tr>
<tr>
<td></td>
<td>Doppler DVD</td>
<td>Patient prescription pad</td>
</tr>
<tr>
<td></td>
<td>In-service DVD</td>
<td></td>
</tr>
</tbody>
</table>

*Images of Aircast Vascular Catalogue and VenaFlow Elite.*
Where Do We Fit In?

VenaFlow
VenaPure

VenaFlow

VenaPure

Modalities
Mechanism of Action: VenaPure & VenaFlow

- **VenaPure**
  - Reduce venous dilation preventing endothelial damage
  - Graduated compression profile increases blood flow velocity (138.4%) Sigel 1975

- **VenaFlow**
  - Increases venous velocity by 112% above baseline, empties veins bringing vein walls into opposition

- Turbulent flow releases tissue factor pathway inhibitors & tissue plasminogen activators – released by body in response to vessel damage
VenaFlow Elite

• Only device to truly replicate normal ambulation and the mechanism of action of the calf muscle pump
  – Demonstrated by the Doppler comparisons
• Very easy to set up device
• Compliance meter is standard
  – Essential to ensure that the correct therapy is being administered
• Integrated Sequential Flow System ensures that the minimal amount of tubing is used to administer maximum benefit
  – Reduces the risk of pressure points on leg
• Clinically proven with recent studies to reduce DVTs
• Clinically proven to be more effective than competitors in reducing DVT
  – Lachiewicz 2004
• One device for all situations
  – Delivers the same clinically proven compression profile
**VenaPure**

- Design and manufacture has been based on the market leader (TED)
- Uses the same clinically proven compression profile that has demonstrated a reduction in the rate of DVTs
- Construction ensures venous dilation is minimised, therefore limiting endothelial damage
- Clinically proven to prevent VTE both as mono-therapy and as an adjuvant
- Inspection toe on top of the stocking facilitates nurse observations
  - Less risk of the patient picking up dirt etc from the ward floor
- Range of sizes available ensure the majority of the population are covered
- All the dispenser boxes contain tape measures – enough for every patient
  - No need to reuse tape measure and risk cross infection
## The Good News!

<table>
<thead>
<tr>
<th>Author</th>
<th>Patient pop</th>
<th>Control Group</th>
<th>Treatment Group</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eisele 2007</td>
<td>Orthopaedic</td>
<td>LMWH</td>
<td>LMWH &amp; VenaFlow</td>
<td>0.4% Yes</td>
</tr>
<tr>
<td>Westrich 2006</td>
<td>TKA</td>
<td>VenaFlow &amp; Aspirin</td>
<td>VenaFlow &amp; Enoxaparin</td>
<td>14.1% No</td>
</tr>
<tr>
<td>Silbersack 2004</td>
<td>THR/TKR</td>
<td>LMWH &amp; Comprinet</td>
<td>LMWH &amp; VenaFlow</td>
<td>0% Yes</td>
</tr>
<tr>
<td>Roderick Review 2005</td>
<td>125 trials, surgical &amp; medical</td>
<td>Control</td>
<td>GCS IPC</td>
<td>8.6% 10.1% 66% risk reduction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>Pharmcinet</td>
<td>18.1% Pharma</td>
</tr>
<tr>
<td>Kakkos, Cochrane Review 2009</td>
<td>7,000 patients from 11 RCTs</td>
<td>Mechanical compression</td>
<td>Mechanical plus pharmacological</td>
<td>DVT 1% Sympt PE 1% NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pharmacological</td>
<td>Pharmacological plus Mechanical</td>
<td>DVT 0.65% NA</td>
</tr>
</tbody>
</table>
When Mechanical is Enough!

• High risk patients:
  – Bleeding
  – Wound hematoma
  – Renal insufficiency
  – HIT
• Type of surgery
  – High risk orthopaedic procedures
  – CABG
  – Spinal
  – Neurosurgery
• Type of anaesthesia
  – Neuraxial, spinal or epidural risk of haematoma
• Virchow Triad
  – All 3 factors covered
Review

• DVT is real and lethal!!
• Hospital based disease.
• Preventable cause of death.
• Massively under diagnosed.
• Under treated.
• Multimodal treatments efficient.
Let’s Keep the Blood Flowing!
Compression Therapy

DJO Capabilities
Venous Diseases – What are they?

- Affects blood vessels of circulatory system
- Various terms used
  - Post-thrombotic syndrome
  - Chronic venous insufficiency
  - Chronic venous disease
- Can be as a result of:
  - DVT / PE
  - Phlebitis (inflammation of the vein)
  - Higher than normal blood pressure in the veins leading to damage to the valves (incompetent valves)
  - Family history of varicose veins
  - Environmental/behavioural factors
    - Prolonged standing or sitting
  - Personal factors
    - Overweight
    - Pregnancy
    - Smoking
    - Lack of exercise
Symptoms

- Swelling at the ankles
- Calves feel tight
- Legs may feel heavy, tight, restless or achy
- May be painful to walk
- Discolouration of the skin
- Varicose veins
- Itchiness of skin
Venous Circulation

• In venous disease, large veins become incompetent
• Blood refluxes back towards feet instead of passing smoothly towards heart
• Blood oscillates between damaged segments of valves
• Leads to gradual rise in pressure in venous circulation
  – Walking no longer effective at reducing pressure
  – Changes occur in microcirculation
    • Oedema formation
    • Tissue changes (lipodermatosclerosis)
    • Possibly ulceration
Pressure Variation Caused by Chronic Venous Insufficiency

In a normal human, pressure measured at the ankle:
- Standing 80-90 mmHg
- Sitting 45 mmHg
- Laying down 10 mmHg

Takes around 1 minute for blood to completely circulate the body
Stages of Venous Insufficiency

- **1st Stage**
  - Venous dilation without oedema
  - Legs feel heavy, pain in calf, night cramps, skin feels hot and burning

- **2nd Stage**
  - Venous dilation with oedema in feet and ankles, especially at night, during warm weather and then eventually permanently

- **3rd Stage**
  - Complications of chronic venous insufficiency (CVI)
  - Varicose eczema, skin pigmentation, hyperdermatitis, leg ulcers
Venous Disease Progression

- Swelling
- Venous Reflux
- Venous Insufficiency
- CVI
- Venous Stasis
- Venous Ulcer
Sequelae of Venous Insufficiency

- Skin discolouration
- Swollen legs
- Phlebitis
- Leg ulcers
Varicose Veins

Photo courtesy of Rajabrata Sarkar, MD, PhD
So What is the Fuss?

- Prevalence of varicose veins estimated at between 5 – 30% of adults:
  - Female : Male 3:1
- CVI been estimated in:
  - 21.2% of men >50yrs
  - 12.0% of women >50yrs
- Estimated prevalence of venous ulcers of ≈ 0.3%
- US estimates that ≈ 2.5m have CVI
  - Of which 20% will develop venous ulcers
- > 50% of venous ulcers require prolonged therapy lasting >1yr

The effects of varicose veins and CVI are devastating both for the patient, but also the family and the healthcare system.
Treatment Options

• Conservative:
  – Exercise
  – Compression therapy
    • Stockings
    • Layered bandages
    • Garments
  – Wound and skin care
  – Pharmacological therapy

• Interventional:
  – Sclerotherapy
  – Ablative therapy with endovenous radiofrequency and laser
  – Endovascular therapy

• Surgical:
  – Ligation and stripping
  – Subfascial endoscopic perforator surgery
  – Valve reconstruction
External pressure has the effect of:

- Reducing the diameter of the superficial and deep veins.
- Reestablishing the functionality of the valves by narrowing vein diameter.
- Retaining the interstitial fluid in the vessels.
- Improve lymphatic microcirculation.
- Increase circulation at the level of the skin.
Why different levels of compression?

• Recumbent/immobile
  – Patients laying in bed require low levels of pressure (>10mmHg) to control venous stasis
  – This is sufficient to prevent thrombus formation
  – Pressures in excess of 30 mmHg do not have beneficial effect if patient is laying down

• Ambulatory/standing
  – Far higher levels of pressure required to influence blood flow
  – Pressure during walking fluctuates between 20-100mmHg
  – Working pressures of 40-50mmHg are required to influence this
Why different levels of compression?

• Recumbent/immobile
  – Patients laying in bed require low levels of pressure (>10mmHg) to control venous stasis
  – This is sufficient to prevent thrombus formation
  – Pressures in excess of 30 mmHg do not have beneficial effect if patient is laying down

• Ambulatory/standing
  – Far higher levels of pressure required to influence blood flow
  – Pressure during walking fluctuates between 20-100mmHg
  – Working pressures of 40-50mmHg are required to influence this
Compression therapy is the application of controlled graduated external pressure to the limb to reduce venous pressure within the limb. It is strongest at the ankle, decreasing proximally.
## Classifications of Medical Compression Hosiery

<table>
<thead>
<tr>
<th>Class</th>
<th>UK BSI 40</th>
<th>German RAL-GZ 387/1 DIN58133</th>
<th>French FD CEN/TR 15831</th>
<th>Indications</th>
</tr>
</thead>
</table>
| Class 1 | 14-17 mmHg | 18-21 mmHg | 10-15 mmHg | • Varicose veins during pregnancy  

  • Superficial or early varices. |
| Class 2 | 18-24 mmHg | 23-32 mmHg | 15-20 mmHg | • Varices of medium severity.  

  • Ulcer treatment and prevention of recurrent ulcers.  

  • Mild oedema varicose during pregnancy.  

  • Superficial phlebitis |
| Class 3 | 25-35 mmHg | 34-46 mmHg | 20-36 mmHg | • Gross varices.  

  • Post thrombotic venous insufficiency.  

  • Gross oedema.  

  • Ulcer treatment and prevention of recurrent ulcers |
| Class 4 | N/A | 49 mmHg & higher | | • Made to measure stockings  

  • Lymphoedema Stage III |
CEAP Classification

This classification has been adopted worldwide to classify various forms of venous diseases.

It covers:
- All clinical abnormalities (those visible)
- All symptomatic disorders (patient-driven) of chronic venous disorders of the lower leg.

C0s  No visible or palpable sign of venous disease

C1s  Varicose veins (or telangiect stases) or reticular veins (diameter > 3 mm)

C2  Varicose veins (diameter > 3 mm)

C3  Venous oedema

C4a  Pigmentation (or other dermitis) and/or eczema

C4b  Hypodermatitis or lipodermatosclerosis (inflammation of the subcutaneous tissue), atrophie blanche

C5  Healed venous ulcer

C6  Active venous ulcer
Range of Stockings

• Knee
  – Below knee style
  – Worn by men and women
• Hold Ups
  – Self fixing normally with a silicone non-slip band at the top
  – Can be worn by women and men
• Tights
  – Sometimes called panty hose
  – Normally only worn by women
Range of Stocking Types

• Open Toe
  – Arthritic or clawed toes
  – When foot size does not correspond to girth measurements of leg
  – When patient prefers to wear sock over the top
  – When patient is wearing 2 layers of hosiery, one layer should be open toe to avoid excessive constriction
  – To enable the use of specific hosiery aids
  – If patient has problem with fungal infections

• Made to Measure Hosiery
  – Patient has unusual shaped limb or if any measurements are proportionately large or small
  – Measurement around the malleoli is particularly wide
  – Flat bed knit is required for lymphodema
Asheboro Capabilities
DJO Veinax Medical Compression Hosiery

Manufactured according to the French standard
Supplied fully packaged
Currently only sold into France and some French speaking territories
## Where does Veinax Fit in?

<table>
<thead>
<tr>
<th>CEAP Classification</th>
<th>C₀ No visible or palpable sign of venous disease</th>
<th>C₁ Telangiectasies or reticular veins</th>
<th>C₂ Varicose veins (diameter of &gt;3mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Veinax Positioning</td>
<td>Microtrans Class I</td>
<td>Microtrans Class II Transparent Class II Fantaisie Class II Cotton Class II</td>
<td>Microtrans Class II Transparent Class II Fantaisie Class II Cotton Class II Transparent Class III</td>
</tr>
<tr>
<td>C\text{\textsubscript{3}} Oedema</td>
<td>C\text{\textsubscript{4}} Changes in skin and subcutaneous tissue: ( C\text{\textsubscript{4a}} ) Pigmentation or eczema ( C\text{\textsubscript{4b}} ) Lipodermatosclerosis or atrophie blanche</td>
<td>C\text{\textsubscript{5}} Healed venous ulcer</td>
<td>C\text{\textsubscript{6}} Active venous ulcer</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------------------------------</td>
<td>---------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><img src="image1.jpg" alt="Image" /></td>
<td><img src="image2.jpg" alt="Image" /></td>
<td><img src="image3.jpg" alt="Image" /></td>
<td><img src="image4.jpg" alt="Image" /></td>
</tr>
</tbody>
</table>

| Transparent Class III | Microtrans Class III | Superposition: Microtrans Class I + Transparent Class III | Superposition: Microtrans Class I + Transparent Class III |
Subjective Aspects

- Quality of manufacture
- Softness of yarn
- Softness on skin
- Easy to don
- Robust yarn but softness maintained
- Modern, attractive packaging
Veinax

Objective Aspects

- Extra flat seams:
  - Toe box
  - Self fixating band
- Extendable toe box which adapts to all morphologies.
- Reinforced section at level of toe.
- Reinforced sole.
- Reinforced heel.
- Wide hem for knee high.
- Panty area of the tights provides additional support without extra compression.
- Unequalled transparency.
- Edge to edge stitching on the top band.
Veinax Features
Reinforced sole
Reinforced Heel
Extra Flat Seams
Wider Toe Box
Extra Wide Topband
Pretty Floral Motif
Extra Flat Seam to Seam Stitching
Soft and Strong Silicone Band
Microtrans/Microfibre

**Class 1**
- Knee, Hold Ups, Tights
- Black

**Class 2**
- Knee, Hold Ups, Tights
- Black
- Beige
- Mocha
- Island Beige
- Knee, Open Toe
- Island Beige
- Hold Ups, Open Toe
- Beige

**Class 3**
- Knee, Hold Ups, Tights
- Black
- Beige
Fantaisie / Diamond Pattern (Microfibre)

Class 2

Knee, Hold Ups, Tights

Small Diamond  Large Diamond
New Colour: Smokey Grey to be launched in Sept
Cotton

- May be worn by men or women
  - Unisex

Class 2

- Socks: Black, Grey, Brown, Navy Blue
- Hold Ups: Black
Sizing for Compression Hosiery

- The sizing for compression hosiery is very specific and takes into account a number of measuring points:
  - Ankle circumference (point A).
  - Calf circumference (point B).
  - Circumference at midpoint of thigh (point C).
  - Length from floor to popliteal (point D)
  - Length from floor to buttock fold (point E)
# Veinax Size Chart

<table>
<thead>
<tr>
<th>Sizing in cm</th>
<th>Microtrans, Transparent, Fantaisie</th>
<th>Cotton</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ankle</td>
<td>Calf</td>
</tr>
<tr>
<td>Size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>18-20</td>
<td>29-32</td>
</tr>
<tr>
<td>2</td>
<td>20-23</td>
<td>32-36</td>
</tr>
<tr>
<td>3</td>
<td>23-26</td>
<td>36-40</td>
</tr>
<tr>
<td>4</td>
<td>26-29</td>
<td>40-44</td>
</tr>
</tbody>
</table>

## Length

<table>
<thead>
<tr>
<th>Knee</th>
<th>Thigh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium</td>
<td>Long</td>
</tr>
<tr>
<td>&lt;40</td>
<td>&gt;40</td>
</tr>
<tr>
<td>Medium</td>
<td>Long</td>
</tr>
<tr>
<td>&lt;72</td>
<td>&gt;72</td>
</tr>
</tbody>
</table>

## Shoe Size

One Size
Modern Packaging

Available in English & French:
- Box
- IFU
Challenges with Compression Hosiery

• Medical compliance
  – Incorrect size
  – Incorrect compression profile
  – Monitoring
• Patient compliance
  – Difficult to don and doff
  – Too painful to wear
  – Appearance
  – Warming effect, especially in warmer climates
• Negatively affects daily life
• Skin sensitivity
• Incorrect sizing will lead to increased problems
Risks Associated with Hosiery

- If they don’t fit properly:
  - Reduce blood flow and tissue oxygenation (tourniquet effect)
  - Pressure ulcers
  - Arterial occlusion
  - Thrombosis
  - Gangrene
## Compression Hosiery French Spec Competitor Overview

<table>
<thead>
<tr>
<th>Features</th>
<th>Veinax (DJO)</th>
<th>Varisma (Innothera)</th>
<th>Mediven (Medi)</th>
<th>Venotrain (Bauerfeind)</th>
<th>Jobst (BSN)</th>
<th>Sigvaris</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Country of Origin</strong></td>
<td>USA</td>
<td>France</td>
<td>Germany</td>
<td>Germany</td>
<td>USA/Germany</td>
<td>Switzerland</td>
</tr>
<tr>
<td><strong>Compression Standard</strong></td>
<td>French</td>
<td>French</td>
<td>German RAL, UK BSI</td>
<td>German RAL</td>
<td>RAL, French</td>
<td>UK BSI, RAL</td>
</tr>
<tr>
<td><strong>Ranges</strong></td>
<td>Transparent, Cotton, Microfibre, Pattern</td>
<td>Seduction, Comfort, Transparence, Zen, Cotton</td>
<td>Elegance, Plus, Comfort, Men, Forte, Duomed</td>
<td>Shine, Micro, Soft, Business, Sport, Impuls, Ultrasheer, Opaque, Classic,</td>
<td>UlcerCare</td>
<td>Diaphane, Eclat, Opalis, bamboo, Cotton, Magic, Comfort, Traditional</td>
</tr>
<tr>
<td><strong>Sizes</strong></td>
<td>4 sizes, 2 lengths</td>
<td>4 sizes, 2 lengths</td>
<td>8 sizes, 2 lengths</td>
<td>9 sizes, 2 lengths</td>
<td>Ca 10 sizes</td>
<td>Up to 24 sizes</td>
</tr>
<tr>
<td><strong>Made to Measure</strong></td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Flat Knit</strong></td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Delight</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Ulcer Kit</strong></td>
<td>No</td>
<td>No</td>
<td>Ulcer kit – silver impregnated</td>
<td>Ulcertec – overstocking &amp; liner</td>
<td>UlcerCare</td>
<td>UlcerX</td>
</tr>
<tr>
<td><strong>Lymphodema</strong></td>
<td>Not under Veinax range</td>
<td>Sensoo, Mondi, Esprit, Thorax</td>
<td>Curaflow-custom</td>
<td>E Ivarex, Bellevar</td>
<td>Advance</td>
<td></td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td>Wide variety of styles available. Amazing colour selection. Swarovski elements</td>
<td>Skin care component in Micro Balance. Perfect Fit system – choice from standard range</td>
<td></td>
<td>SensiNova new silicone band</td>
</tr>
<tr>
<td><strong>Accessories</strong></td>
<td>Donning device</td>
<td>Medi Butler</td>
<td>Glider</td>
<td>Donning glove</td>
<td>Donning device, glove</td>
<td></td>
</tr>
<tr>
<td><strong>Clinical data</strong></td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
• Medi - Mediven