CLINICAL EVIDENCE SUMMARY

Preventing Venous Thromboembolism with Intermittent Pneumatic Compression

Welcome

Arjo, has over 40 years' experience as a trusted global leader in venous thromboembolism prevention. Our journey began in the 1970s with the Flowtronaire® device, when clinical VTE studies clearly demonstrated the protective benefit associated with intermittent pneumatic compression (IPC) of the deep veins of the leg. Arjo have been instrumental in developing easy to use, clinically effective IPC systems to support facilities across the globe with their VTE programmes.

Our Flowtron Active Compression System (ACS) range is designed, by prioritising comfort, compliance, affordability and ease of use. The Flowtron Active Compression System with our range of garments is; comfortable for the patient, convenient for the healthcare provider and clinically effective at delivering intermittent pneumatic compression – helping to contribute to improved patient compliance.

We recognise that clinical decision-making is complex and should be based upon the best available clinical evidence. We invite you to review this clinical resource providing examples of some of the key evidence supporting the use of IPC and specifically the *Flowtron* ACS as part of a VTE prevention programme.

What is Venous Thromboembolism (VTE)?

Blood clotting is essential to life but only when it is appropriate, such as sealing a wound or after a cut. However, when the blood clots in the wrong place and/or the wrong time, the results can be life changing and often fatal.

Deep Vein Thrombosis (DVT)

If a blood clot (thrombosis) develops in the deep veins of the leg (less commonly in the arm) it is referred to as a Deep Vein Thrombosis or DVT

Pulmonary Embolism (PE)

If part of the clot becomes dislodged it is referred to as an embolus and can travel through the venous circulation until it reaches the lungs: a pulmonary embolism or PE

Venous Thromboembolism (VTE)

Venous thromboembolism or VTE is the collective term for both DVT and PE (Figure 1)

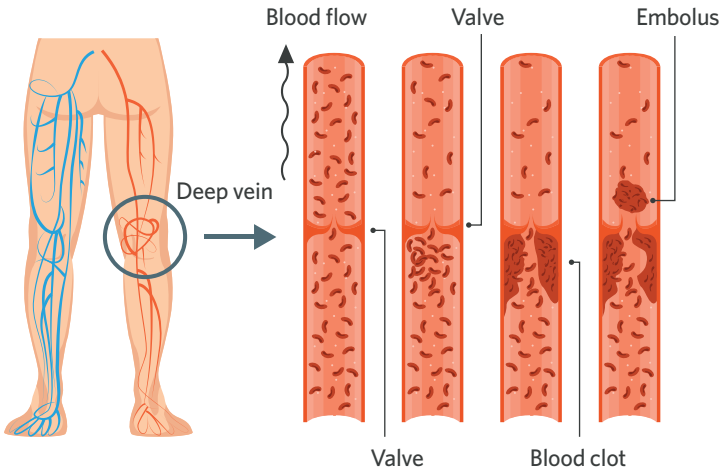
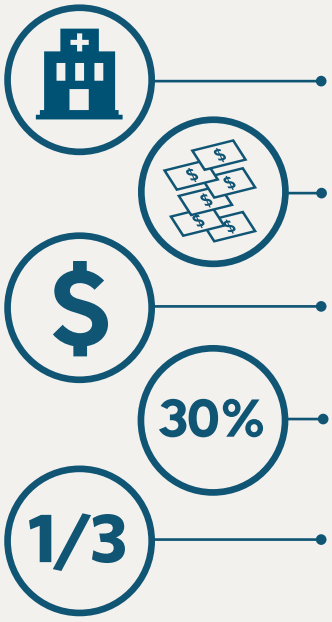


Figure 1: Venous Thromboembolism
10 million people around the world develop VTE each year.[1]

Why is VTE so important?

With healthcare demand at unprecedented levels, and budgets struggling to keep pace, attention is increasingly focussed upon adverse clinical events. Of particular interest are incidents, such as VTE, that are common, have a high economic and humanitarian cost and are largely considered preventable.[2]

Unfortunately, robust economic data is not routinely published, but there is sufficient evidence to show that when VTE does occur, it is frequently fatal and, if not, is often associated with costly and life changing long-term complications. Good enough reason to target prevention.



VTE is the most common cause of preventable death in hospitalised patients[3]

The cost of treating preventable VTE has been estimated to be up to **US$ 14.2 billion per annum**, rising to **US$ 39.3 billion** as cost and incidence rises[2]

Up to **US$ 19.1 billion** is spent each year in the treatment of longterm complications following VTE[2]

Around **30% of patients will die** within 30 days of VTE while **25% of unexpected inpatient deaths** are diagnosed with PE at autopsy[4]

Around 1/3 of patients with DVT develop **Post-thrombotic syndrome** suffering swelling and pain[4] and for 25%,[5] the resultant chronic ulceration is associated with substantial on-going treatment cost[6]

What causes VTE?

The pathophysiology of VTE is complex and the condition is triggered when multiple risk factors, collectively described by **'Virchow's Triad'** (Figure 2), tip the balance of homeostasis leading to clot formation[7]

Venous stasis

Circumstances that cause the blood flow to slow (stasis) in the deep veins will increase the risk of VTE.

- **Immobility**, perhaps due to age, frailty or prescribed bed rest is a clear risk factor.
- **Physical obstruction** of the deep vessels, either due to external forces or pressure from tumours and lymph nodes, is also implicated, as are previous DVTs.

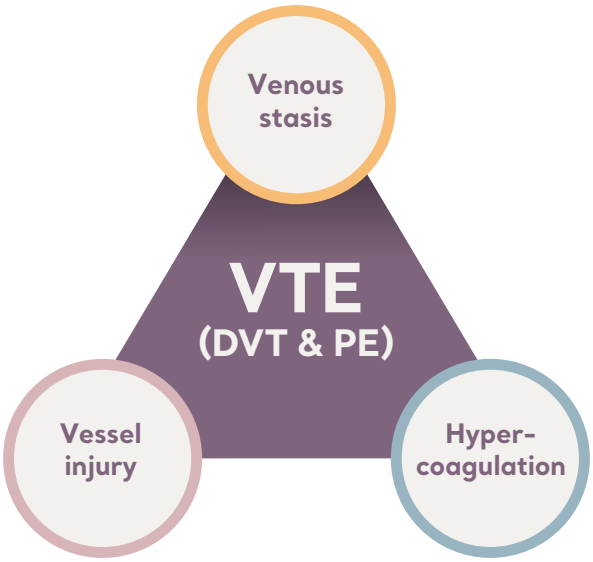
Hypercoagulation

Changes in blood density and chemistry can increase the tendency for the blood to clot. This is associated with conditions such as simple dehydration to hypoxia, malignancy, trauma, hormone therapy, systemic inflammatory disease and genetic predisposition.

Vessel Injury

Injury may occur through accidental trauma or though medical interventions such as surgical or invasive procedures. Even the act of stretching a vessel can trigger the clotting cascade.
Once injury occurs, an orchestrated series of events initiate platelet adhesion and the eventual formation of a blood clot; this protective mechanism seals the damage and begins the healing process: sometimes this process is exaggerated or inappropriate.

Figure 2: Virchow's Triad



Who is at risk of VTE?

> 50% of hospital patients are at risk[8]

< 50% have recommended prophylaxis[8]

When one or more risk factors are present (Figure 3),[9] anybody, from a new mother to a frail elder with reduced mobility, is at risk of VTE.

At particular risk, are surgical inpatients[10] as surgery itself causes the greatest increase in risk, because of the anaesthetic (hypercoagulability), muscle relaxants (stasis) and surgical intervention (vessel damage).

It is now clear that non surgical patients are also at high risk of VTE. Awareness of the need for prophylaxis in high risk groups such as critical care, cancer, obstetrics, bariatrics, stroke and older paediatric patients has been steadily increasing over recent years.

7 fold increase in VTE incidence for patients with malignancy[11]

Figure 3: VTE risk factors[9]

Stasis

- Muscle relaxants used during surgery
- Surgery, trauma, immobility, paresis
- Increasing age
- Pregnancy and postpartum
- Heart or respiratory failure
- Obesity

Vessel injury

- Surgery
- Previous deep vein thrombosis
- Smoking
- Varicose veins
- Central venous catheterisation

Hypercoagulability

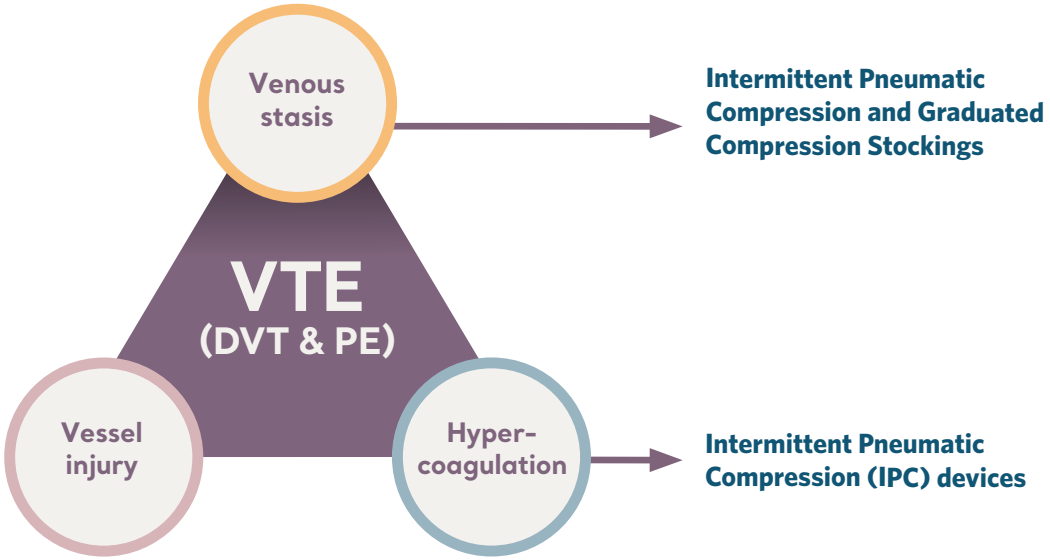
- Increasing age
- Malignancy or cancer therapy
- Oestrogen therapy (contraception or hormone replacement)
- Acute medical illness
- Inflammatory bowel disease
- Nephrotic syndrome
- Myeloproliferative disorders

Preventing VTE

Prevention strategies commonly incorporate the use of pharmacological prophylaxis and mechanical methods including:

- Intermittent Pneumatic Compression (IPC)
- Passive Graduated Compression Stockings (GCS)
- The addition of Inferior Vena Cava (IVC) Filters have also been increasing for a number of patients at very high risk

Figure 4: IPC addresses 2 of the principle causes of DVT formation: Venous Stasis and Hypercoagulation



Some risk factors are difficult or impossible to address, for example, vessel injury arising from trauma, surgery or invasive procedures. These incidental risk factors, along with underlying co-morbidities such as age, obesity, malignancy and genetic thrombophilia, can all trigger hypercoagulation and this is often managed with oral or injected anticoagulation therapy.

Anti-coagulation is not without risk and not all patients are suitable candidates e.g. heightened bleeding risk. Complications, including heparin-induced thrombocytopaenia,[12] dosing error[13] and haemorrhage[14] are not uncommon and anticoagulants do nothing to address stasis in the deep veins where most thrombi develop.

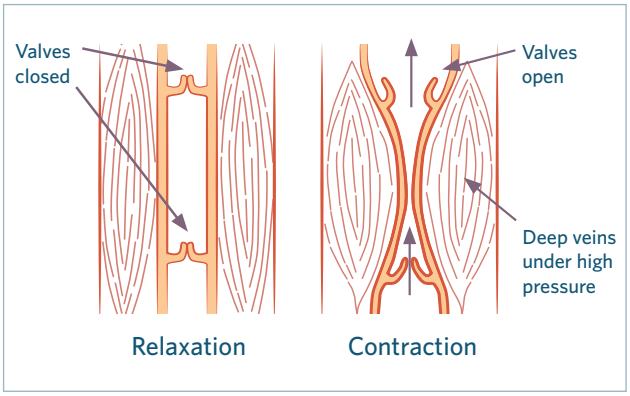
Natural Muscle Pump:

Venous stasis is naturally avoided through the biomechanical action of the calf and foot muscle pump, (Figure 5). Which is why early ambulation is the treatment of choice for patients at lower risk of VTE.[10]

During walking and ankle flexion, the deep veins of the calf are compressed by muscle contraction, while the blood-filled plantar plexus (beneath the sole of the foot) is compressed during weight bearing. Theses bio-pumps eject blood in a proximal direction towards the heart, while venous valves prevent backflow.

When walking is not possible, the benefits of the muscle pump can be simulated by mechanical means.

Figure 5: Natural Muscle Pump



Mechanical prophylaxis

Mechanical prophylaxis is the term used to differentiate VTE prevention strategies from pharmacological methods; it falls into two main categories: passive graduated compression stockings and active intermittent pneumatic compression devices.

Passive graduated Compression Stockings

This is typically achieved through the use of calf-length or thigh-length compression hosiery (Figure 6) commonly designed to apply a graduated pressure decrease, from 18 mmHg at the ankle and gently reducing towards the thigh (8 mmHg).[15] These graduated compression stockings (GCS) are worn throughout the period of immobilisation and often for several weeks after discharge from hospital.

GCS were incorrectly fitted in **29%** of patients[16]

Mode of action

It is thought that by applying pressure to the limb, the diameter of the deep vessels is reduced and the velocity of blood flow may increase.[15]

GCS are often used in combination with other prophylactic measures but, like anticoagulation, their use has been associated with side effects. Incorrect application[16] can lead to a significant increase in complications, some of which (skin ulcers and necrosis) can be serious.[17]

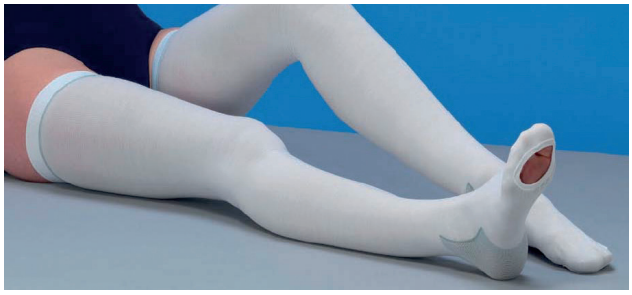


Figure 6: Thigh-length GCS

Intermittent Pneumatic Compression Systems

IPC is a very well established, and proven intervention with a convincing evidence base and few side effects; as such it is indicated for use across a wide range of hospitalised patients at risk of VTE.

As a non-invasive mechanical method of VTE prophylaxis it is effective when used either as a sole prevention modality such as for those patients at high risk of bleeding or is very commonly used in combination with pharmacological prophylaxis for high risk patients.

These powered devices use inflatable calf-length, thigh-length and/or foot compression garments (Figure 7) used to simulate the natural protective mechanism of walking.

Figure 7

All IPC systems have a single common purpose – to propel blood from the deeper veins through the intermittent inflation and deflation of a garment.

Type of compression: sequential & uniform

Active compression comes in many different configurations. There are different garments, compression profiles and cycle times, but all have a common therapeutic purpose – to displace blood from the deep veins and move it in a proximal direction[18] back into the central venous system. How this is achieved may differ, but the end result is the same and no single type of compression can be considered superior in terms of clinical benefit.[18 19]

The most commonly used garments are calf or thigh length and each will deliver either **uniform** compression through a single air bladder in each segment or **sequential** compression (Figure 8), through a series of air bladders, which inflate in a proximal direction. When it is not possible to fit a leg garment, a foot garment can be used instead.

Figure 8a:
Flowtron Uniform Garment

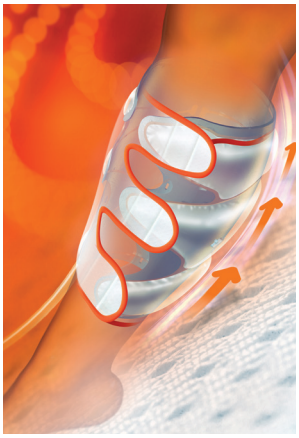


Figure 8b:
Flowtron Sequential Garment

IPC is an effective prophylaxis, irrespective of mode of action[18]

Neither the garment, nor the type of compression (uniform/sequential), makes a significant difference to haematological outcomes[19]

Mode of action

Prior to compression, there is a slow steady flow of blood in the lumen of the deep veins. When compression is applied there is a sudden **increase in blood flow**, which causes distension of the vein and **flushes the valve pockets** where thrombi are thought to originate. There is an overall **decrease in venous hypertension** and **interstitial oedema**.[20] On deflation of the garment, the veins refill and the cycle is repeated.

The compression cycles and cell pressures vary according to the type of application (Table 1), but are designed to be strong enough to propel the blood, frequent enough to maximise the benefit, but with sufficient deflation time to allow the vessels to refill.

The positive effects of Active Intermittent Pneumatic Compression are not limited to the venous system. Improved emptying of the lower extremity veins increases arterial blood flow in patients with arterial disease, without compressing the arteries. This may be due to changes in the arterial-venous (AV) pressure gradient, or hyperaemia caused by the veno-arteriolar reflex or the release of nitric oxide.

The augmented (increased or enhanced) blood flow, induced by the pulsatile compression wave, can be visualised and measured objectively using Doppler ultrasound.

Table 1: Flowtron systems compression profile

	Flowtron Calf & Thigh-Length garments	Flowtron Foot Garments
Cycles per minute	1	2
Inflation: deflation ratio	12 : 48 secs	3 : 27 secs
Compression pressure	40 mmHg	130 mmHg
Inflation rate	Moderate	Fast

Intermittent Pneumatic Compression – a multi modal approach to prophylaxis

Perhaps surprisingly, **Intermittent pneumatic compression** therapy not only reduces **venous stasis,** but also has a measurable **anticoagulant effect.**

So, unlike other methods of prophylaxis, IPC mitigates two of the pathological processes that lead to VTE (Figure 9).

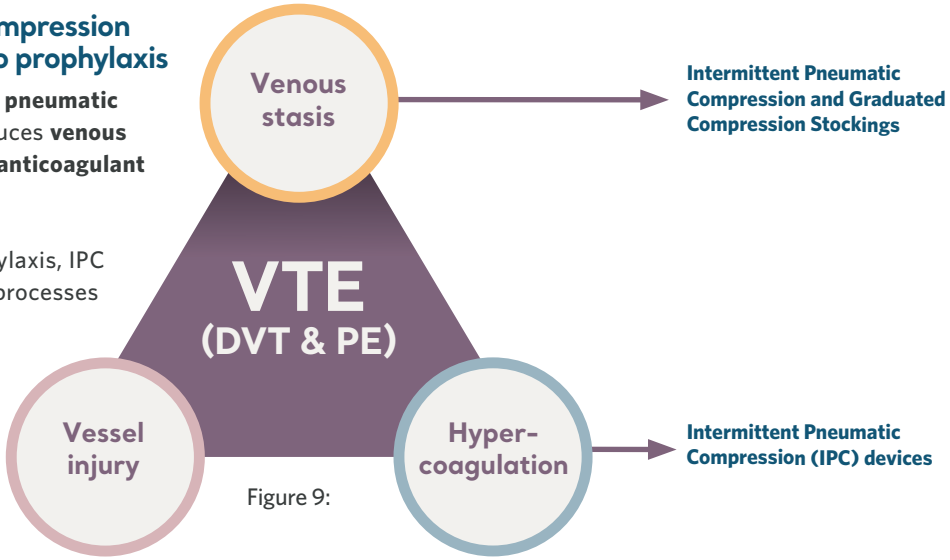
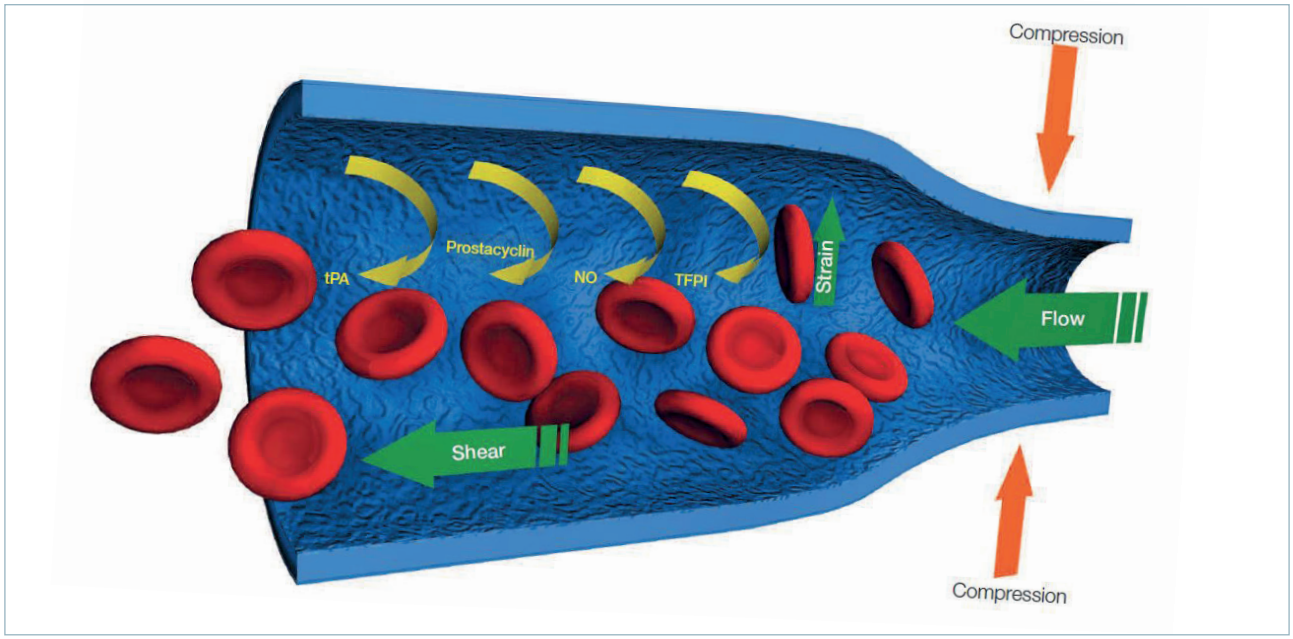


Figure 9:

Figure 10:
Haematological effect of IPC



Haematological Balance

There is a very fine homeostatic balance between the procoagulant ('clot making') and fibrinolytic ('clot breaking') biochemical pathways and IPC has been shown to produce changes that both inhibit clot formation and promote fibrinolysis.[21]

Fibrinolytic effect[22]

- ↑ Tissue plasminogen activator (tPA)[21]
- ↑ Urokinase plasminogen activator (uPA)[23]
- ↓ Plasminogen activator inhibitor[21, 24]

Antithrombotic effect

- ↑ Tissue factor pathway inhibitor (TFPI)[25]
- ↓ Thrombin-Antithrombin Complex (TAT)[26]

Other effects

- ↑ Prostacyclin Platelet disaggregation[21]
- ↑ Nitric oxide vessel dilatation & platelet disaggregation[21, 26]

Haematological effect of IPC

The mechanical effects of IPC in increasing blood flow, not only reduces venous stasis but also has a measurable anticoagulant effect. Figure 10 shows the mechanical force of compression producing shear and strain, which brings about the release of key chemical mediators from the endothelial cells (EC) lining the deep veins.[21]

Safety

Because IPC mimics natural physiological processes, it is one of the safest methods of prophylaxis available. IPC is not associated with the severe complications seen with anticoagulation therapy nor the foot ulcers of GCS.[17] Adverse events are rare and can be avoided by following good clinical practice and the manufacturer's instructions for use.

Flowtron IPC: Clinical Effectiveness

Laboratory studies

Many of the early investigative studies that underpin Intermittent Pneumatic Compression as a generic form of VTE prophylaxis, were conducted using predecessors to the contemporary Flowtron range. Although the technology has been updated, the underlying design principles such as cycle pressure, inflation rate and cycle intervals, remain the same. The following studies demonstrate the antithrombotic and profibrinolytic effect of Flowtron IPC.

The influence of inflation rate on haematological and haemodynamic effects of IPC.

Morris et al 2006[22]

Both fast (comparator) and slow inflation (Flowtron device) reduced procoagulant activity

Only Flowtron significantly increased global fibrinolysis

Haematological Studies Effect of Flowtron IPC on haemostasis and endothelial function in claudicants

Sutkowska et al 2009[26]

Compression increased nitric oxide levels from the endothelium

Flowtron IPC decreased thrombin-antithrombin complex (TAT)

Flowtron IPC reduced platelet activity

Systemic haemostasis after IPC

Giddings et al 2004[23]

Flowtron IPC elicited a beneficial haematological effect, supressing procoagulant activation whilst enhancing fibrinolytic mechanisms

Fibrinolytic effects of IPC in post-thrombotic patients

Comerota et al 1997[24]

Compression was associated with decreased Plasminogen Activator Inhibitor (PAI)

Fibrinolytic activity was significantly increased in both normal (control) and post-thrombotic patients

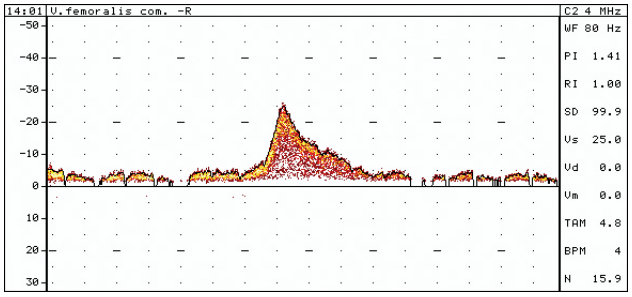
Key Summary:

- IPC reduces pro-coagulant activity (makes clots less likely to form)
- IPC increases inhibition of coagulation activation (increases the suppression of clot formation)
- IPC increases fibrinolytic activity (breaks up clots once they begin to form)

Comparative Blood Flow Studies

The reversal of venous stasis is key to prevention and the Flowtron IPC range has been subject to a number of comparative laboratory tests and consistently demonstrated favourable results [27, 28] (Table 2).

Figure 11: Doppler Ultrasound Machine and Blood Flow Images



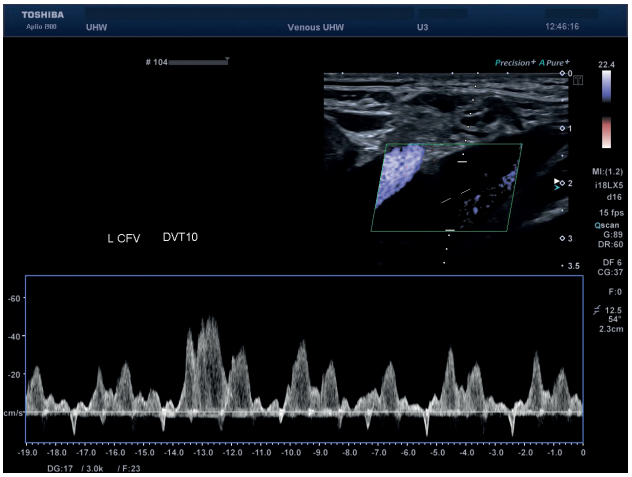


Table 2: Evidence from the laboratory

Author	Study	Design	Key Findings
Woodcock & Morris[29]	Doppler blood flow analysis	**Thigh-Length Compression** • Flowtron [uniform] compression • Sequential compression (other brand)	• The Flowtron system demonstrated venous refill (not observed with sequential compression) and so was considered to be a more efficient device
Flam et al[30]	Prospective randomised cross-over study	**Calf Compression** • Flowtron [uniform] compression • Sequential compression (other brand)	Average flow augmentation • **107% Flowtron IPC (superior)** • 77% Sequential Peak velocity • **39.5 cm/sec Flowtron IPC (significant)** • 34.2 cm/sec Sequential
Flam et al[31]	Comparative femoral blood flow study	**Foot Compression** • Flowtron [FP5000] foot compression • Comparator A • Comparator B • Low-cost comparator C	• All systems except Comparator C device delivered an average of 32% augmentation in supine position • **Flowtron FP5000 delivered 219.5%** in the dependent position compared to Comparator C at 36.5%
Flam et al[32]	Comparative blood flow study	**Thigh-Length Compression** • Flowtron [uniform] compression • Sequential compression (other brand)	• Peak compression velocity was similar • **Flowtron IPC produced significantly higher blood flow augmentation = 23%**
Morris & Woodcock[33]	Bariatric garment evaluation	**Calf Compression (Bariatric)** • The DVT 60 (bariatric) garment	• Blood flow augmentation = 83% to 120% • DVT 60 likely to be equally effective compared to standard fit garments

Clinical Effectiveness

Over the past 30 years, independent specialists have conducted a number of clinical studies. Subjects have been recruited from the highest risk patient populations and across a range of clinical specialities. The results have consistently demonstrated the prophylactic capability of the Flowtron IPC range when used with, or in place of, other methods of prophylaxis (Table 3). Although IPC is now widely accepted as a valid form of prophylaxis,[3] these legacy studies continue to have value.

Table 3: Flowtron Clinical Outcome Studies

Author	Study	Design & Results	Key Findings
Delince et al 2011[34]	149 patients randomised to either Flowtron IPC or Enoxaparin + graduated compression stockings	Flowtron IPC was associated with lower VTE rate (1.2% compared to 2.9%) and fewer post-operative transfusions required	Flowtron IPC considered to be a cost effective and safe option when used as the only means of prophylaxis
Ginzburg et al 2003[35]	442 trauma patients randomised	**Group 1:** Flowtron calf garments ▪ DVT = 0.5% & $6,272 **Group 2:** Low Molecular Weight Heparin ▪ DVT = 2.7% & $73,000	Flowtron IPC provides a low-cost and effective method of prophylaxis for trauma patients
Montgomery & Wolf 2005[36]	344 patient charts reviewed	Patients received either Flowtron thigh-length compression or low molecular weight Heparin VTE rates the same in both groups =1.2%	LMWH group has significant risk of major bleed (p=0.045) for no additional benefit
Brooks et al 2007[37]	Comparative chart review	**Group 1:** Spinal anaesthesia + anticoagulants + Flowtron calf garments **Group 2:** Epidural anaesthesia + *Flowtron* calf	▪ Similar VTE rates ▪ Flowtron IPC provides effective prophylaxis in this very high risk group

Table 4: Flowtron Evidence in Speciality Groups

Author	Study	Design	Key Findings
Kurtoglu et al 2005[38]	Prospective Study. High risk trauma and surgical ICU patients	38 patients with multiple trauma were provided with a Flowtron Excel System. Venous duplex ultrasonography performed on days 3 & 7 and at discharge. Chest radiology conducted to screen for PE	No patient developed a DVT. One patient had a symptomatic PE. IPC safe and effective modality in preventing both DVT and PE in high risk ICU patients. IPC should be used when there is a clear contraindication to chemoprophylaxis
Kurtoglu et al 2004[39]	Prospective RCT. Head and spinal trauma patients	**Group 1:** IPC (Flowtron) **Group 2:** LMWH (Enoxaparin) Daily leg circumference plus Doppler ultrasound on admission and weekly until 1 week post discharge	**Group 1:** 4 patients developed DVT and 2 patients a fatal PE **Group 2:** 3 patients developed a DVT and 4 patients a fatal PE. The VTE results were not statistically significant. IPC group required statistically significant (p=<0.03) fewer blood transfusions compared to the LMWH group
Kamran et al 1998[40]	Retrospective & prospective study in stroke patients	**Three phase study:** **Group 1:** Retrospective review of 233 stroke patients – sub-cutaneous heparin & AES **Group 2:** Prospective study 432 patients. Received same prophylaxis as group 1, plus IPC (calf garments) for non-ambulatory patients **Group 3:** Prospective study 16 patients given same therapy as group 1	Using additional IPC for non-ambulatory stroke patients reduced the incidence of VTE by more than 40 times
Capper et al 1998[41]	Retrospective and prospective audit. Elective hip and knee replacements	Retrospective group: 825 patients received LDH, LMWH or hydroxycholroquine Prospective Group: 375 patients received Flowtron IPC calf garments warn pre-operatively until discharge	Retrospective group: VTE rate = 2.6% Prospective group: VTE rate was 1.06% The benefits of IPC warrant serious consideration
Eskander et al 1997[42]	Randomised control trial: Traumatic Hip Fracture	**Group 1:** IPC (Calf) until 48 hours post-op, then LMWH to day 7 **Group 2:** LMWH from admission to day 7	**Group 1:** VTE = 14% of patients **Group 2:** VTE = 17% of patients IPC avoids the complications associated with pharmacological agents

IPC Evidence from Meta-analysis and Systematic Reviews

As with all preventative interventions, IPC can only be effective if it is used with the right patient at the right time and that means identifying patients at risk *before* a VTE incident occurs.
At the same time, the risk of side effects must be considered, in particular, the risk of haemorrhage associated with the use of anticoagulation. Meta analyses and systematic reviews (Table 5), where multiple evidence sources are combined to determine the overall clinical utility of ACT, are useful sources of information and can guide prescription.
As an extension of the systematic review, the publication of national and international clinical practice guidelines translate robust and contemporary research into discrete recommendations (Table 6): knowledge gaps are filled by international consensus panels. While the wording varies, the recommendations are largely consistent and all accept IPC as an effective and safe intervention.

Table 5: IPC Evidence from Systematic Reviews

Author	Study	Key Findings
Kakkos 2016[43]	Cochrane review: IPC with or without chemical prophylaxis	▪ IPC + pharmacological prophylaxis reduces the risk of VTE ▪ Chemical prophylaxis increases the risk of bleeding, this side effect is not seen for IPC
Eppsteiner 2010[44]	Review of **16 RCTs;** n=c.4,000 subjects	▪ No difference between mechanical prophylaxis & heparin ▪ Significantly increased post-operative bleeding with heparin
Morris & Woodcock[45] **2010**[68]	**10 trials.** Graduated Compression Stockings vs. ACT	▪ Both methods known to be effective but trend in favour of IPC

Nice uk 2018[46]

IPC is indicated:

- For many high risk populations e.g. bariatric, gastrointestinal, cardiac and orthopaedic surgery
- As the modality of choice for patients with a high risk of bleeding
- For stroke patients within 3 days of the event and for up to 30 days or when mobile
- To be worn for as many hours as possible, and in many cases from admission

- Featured systematic reviews reinforce no superiority between uniform or sequential compression and calf or thigh length garments with regards to efficacy
- Choice is influenced by comfort, saftey, intended application and clinical preference

Table 6 – Selected ACCP (9th Edition)
Guideline Recommendations Related to Indications for IPC[47]

Population	Prophylaxis
Orthopaedic Surgery:	
Major Orthopaedic Surgery: Total Hip Arthroplasty Total Knee Arthroplasty, Hip Fracture Surgery	Dual prophylaxis with an antithrombotic agent and IPC during hospital stay
With bleeding risk	IPC
Total Hip or Knee Arthroplasty	Recommend IPC plus pharmacological agent
Hip Fracture Surgery	Recommend IPC plus pharmacological agent
General Surgical Patients (Non Orthopaedic):	
At low risk of VTE	Suggest mechanical prophylaxis preferably with IPC, over no prophylaxis
At moderate risk for VTE, who are not at high risk for major bleeding complications	Pharmacological: LMWH or LDUH over no prophylaxis. Suggest mechanical prophylaxis preferably with IPC over no prophylaxis
At moderate VTE risk who are at high risk for major bleeding complications or those whom the consequences of bleeding are thought to be particularly severe	Mechanical prophylaxis preferably with IPC over no prophylaxis
At high risk for VTE, who are not at high risk for major bleeding complications	Recommended Pharmacological: LMWH or LDUH over no prophylaxis. Suggest that mechanical prophylaxis with elastic stockings or IPC should be added to pharmacologic prophylaxis
At high risk for VTE who are at high risk of major bleeding complications or those in whom the consequences of bleeding are thought to be particularly severe	Suggest use of mechanical compression prophylaxis, preferably with IPC over no prophylaxis, until the risk of bleeding diminishes then pharmacological prophylaxis may be initiated
At high risk for VTE whom both LMWH and unfractionated Heparin are contraindicated or unavailable and who are not at high risk for major bleeding complications	Suggest mechanical prophylaxis preferably with IPC, over no prophylaxis
Medical Patients:	
Acutely ill hospitalised medical patients who are bleeding or at high risk for major bleeding	Optimal use of mechanical thromboprophylaxis with GCS. Suggest IPC rather than no mechanical compression, until bleeding risk decreases. If VTE risk persists suggest that pharmacological thromboprophylaxis be substituted for mechanical thromboprophylaxis
Critical Care Patients:	
Critically ill patients who are bleeding or are at high risk of major bleeding	Mechanical thromboprophylaxis with GCS or IPC until bleeding risk decreases, rather than no mechanical compression. When bleeding risk decreases, suggest that pharmacological thromboprophylaxis be substituted for mechanical thromboprophylaxis
Cardiac surgery:	
Patients with an uncomplicated postoperative course	Mechanical prophylaxis, preferably with optimally applied IPC over no prophylaxis
Prolonged hospital course by one or more non haemorrhagic surgical complications	Add pharmacological prophylaxis with LDUH or LMWH to mechanical prophylaxis

Population	Prophylaxis
Thoracic surgery:	
At moderate risk for VTE who are not at high risk for perioperative bleeding	Pharmacological: LDUH or LMWH over no prophylaxis. Mechanical prophylaxis with optimally applied IPC over no prophylaxis
At high risk for VTE who are not at high risk for perioperative bleeding	Pharmacological: LDUH or LMWH over no prophylaxis Mechanical compression with elastic stockings or IPC should be added to pharmacological prophylaxis, until bleeding diminishes then pharmacological
At high risk for major bleeding	Mechanical prophylaxis preferably with optimally applied IPC over no prophylaxis, until the risk of bleeding diminishes and pharmacological prophylaxis may be initiated
Craniotomy:	
Craniotomy patients	Mechanical prophylaxis, preferably with IPC used over no prophylaxis Mechanical prophylaxis, preferably with IPC used over pharmacological prophylaxis
At very high risk of VTE (e.g. those undergoing craniotomy for malignant disease)	Suggest adding pharnacological prophylaxis to mechanical prophylaxis. Once adequate haemostasis established and bleeding risk decreases
Spinal Surgery:	
Spinal surgery	Mechanical compression preferably with IPC over no prophylaxis Mechanical prophylaxis preferably with IPC over pharmacological LDUH or LMWH
Patients undergoing spinal surgery at high risk for VTE (including those with malignant disease or those undergoing surgery with a combined anterior – posterior approach	Add pharmacological prophylaxis to mechanical prophylaxis. Once adequate haemostasis established and bleeding risk decreases
Major Trauma Patients:	
Major Trauma patients	Pharmacological: LDUH, LMWH over no prophylaxis. Suggest use of mechanical prophylaxis with IPC over no prophylaxis.
When LMWH & LDUH are contraindicated	Mechanical prophylaxis, preferably with IPC over no prophylaxis when not contraindicated by lower extremity injury. Pharmacological when risk of bleeding diminishes or contraindication to heparin resolves
Traumatic brain injury, acute spinal injury and traumatic spine injury	Add mechanical prophylaxis to pharmacologic prophylaxis when not contraindicated by lower limb extremity injury

LDUH = Low Dose Unfractionated Heparin
LMWH = Low Molecular Weight Heparin
IPC = Intermittent Pneumatic Compression
GCS = Graduated Compression Stockings

Note: Table 6 provides only a very limited selection and summarised version of the ACCP (9th edition) guideline recommendations related to the indications for IPC. Please refer to the full ACCP published guidelines for full details not included in this table.

Convenience

As with any method of prophylaxis, IPC is only beneficial when it is correctly administered and tolerated by the patients who use it; comfort and usability are key considerations and concordance can vary.[48] In a busy clinical environment the device benefits from an intuitive user interface and appropriate safety features to minimise the risk of harm. Some of these aspects have been evaluated in usability trials (Table 7) and through independent technology assessments, these feature safety, quality, ease of use in addition to cost-effectiveness.

Table 7: Evidence from Usability Studies

Author	Study	Design	Key Findings
ECRI[49]	Independent Product Evaluation	**Evaluation of IPC devices and garments**	Copies of the most recent report are available on the ECRI website
Van Blerk[50]	Usability and acceptance study	**Calf And Foot Compression** • Flowtron [v0] foot compression • Flowtron [DVT 10] calf compression	• The Flowtron device was quiet, lightweight, with good safety features • Garments were comfortable leading to good compliance and positive outcomes: 30 patients, no VTE
Pagella[51]	Comfort and concordance (wear time)	**Calf Compression** • Flowtron IPC • Sequential compression (other brand)	• Flowtron IPC was associated with greater concordance and patient satisfaction • Lower incidence of VTE after implementing Flowtron IPC across the facility
Proctor[52]	Comparative study: effectiveness, comfort, usability	**Calf Compression** • Flowtron IPC • Four other brands of IPC	• Flowtron IPC with calf garments had ▫ lowest incidence of VTE = 1.1% ▫ highest nurse & patient satisfaction ▫ highest level of concordance (wear time)

Flowtron IPC: Choosing the right solution

Table 8: Key considerations for effective prophylaxis are efficacy and safety

	IPC	Chemical prophylaxis	Graduated compression stockings
Does the device prevent venous stasis?	✓	✗	**Passive**
Does the device reduce coagulation?	✓	✓	✗
Does the device increase fibrinolysis?	✓	✓	✗
Can the method induce serious side effects	**Rare** Rare incidents of skin/ nerve damage avoided by correct application	**Frequent** **Haemorrhage** **Heparin-induced thrombocytopaenia**	**Some** No longer recommended for immobile stroke patients due to increased risk of tissue damage. NOTE: Stroke patients share numerous characteristics with other immobile patients

The latest clinical guidelines now recommend battery-powered, portable devices so that VTE prophylaxis can be continued without interruption[47] (Table 9) and, while the clinical and technical aspects of a device are important, so is **patient acceptability.**

Table 9: ACCP (9th edn.) Recommendations

Recommendation	Flowtron AC900
Portability	✓
Battery-powered	✓
Proper wear-time recording and reporting capability	✓
18 hours of daily compliance	✓

Choice of garment

For convenience, there is a choice of Flowtron garments, with calf or thigh-length versions offering either sequential or uniform compression, available in a range of sizes from small through bariatric. Foot compression is available in regular or large foot size.

It is not clear whether there is any advantage in the use of thigh compression and, irrespective of compression profile,[28] all methods deliver a measurable (and clinically important) pulse of blood flow; the choice of garment depends simply upon clinician preference.

For safety and convenience, Smartsense Auto Garment-Recognition (Figure 12) ensures that the correct therapy is applied.

The pause phase of each cycle is sufficient to refill the deep veins. At Arjo we prefer to keep things simple and cost-effective, only adding features if there is a proven benefit.

Figure 12: Smartsense™ Auto Garment Recognition

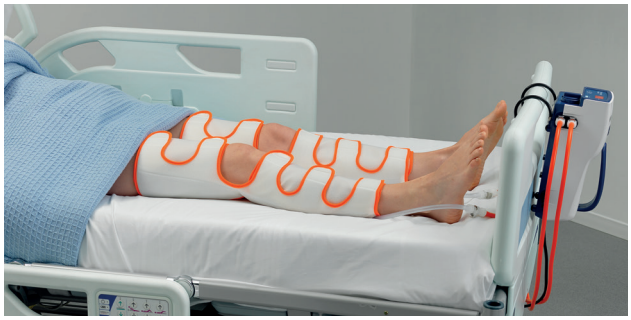
Foot garment

A foot garment might be chosen when access to the calf is not possible and patients may use a combination of leg and foot garments (on different legs).

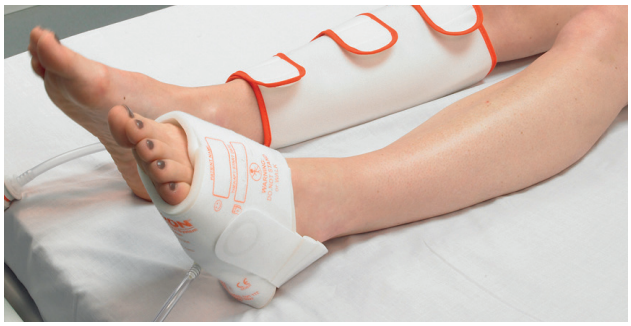
However, given the nature of the smaller plantar reservoir, the pulse required to propel blood through the femoral vein is more abrupt, more frequent and higher pressure is needed. Though producing the necessary blood flow,[18] some patients can find this sensation less comfortable than the 'massage' sensation of leg garments.

Figure 13:

Calf Garment (DVT 10 & DVT 20)
Compress the calf



Calf and Thigh Garment (DVT 30 & DVT 40)
Compress the calf and thigh area



Foot Garment (FG100 FG200)
Compress the arch of the foot. Foot garments can be used in combination with calf and calf and thigh garments.

The Combination therapy

While the 9th ACCP guidelines[47] (Table 6) has found sufficient evidence to recommend IPC in combination with pharmacological prophylaxis in higher risk patients, the same cannot be said for combining mechanical methods. In particular, there is little rationale for adding graduated compression stockings beneath IPC garments. The cost-benefit is not proven and, in the past, this may have been recommended simply to improve comfort when using non-breathable fabrics.

Flowtron IPC delivers active compression and is not dependent on the calf-muscle pump to reverse venous pooling and promote haemostasis.

Single Patient Use

Arjo garments are all indicated for single-patient use.
We don't believe it is safe, hygienic or desirable to ask patients to share garments that are worn for prolonged periods directly against the skin, particularly as the garments will become contaminated with moisture, skin debris and microorganisms, some of which may be drug resistant. Studies have shown that even short wear time increases the bioload to unacceptable levels.[53]

Figure 14: Flowtron garments in use

Comfort and compliance

In order to achieve optimum VTE prevention, continuous use of intermittent pneumatic compression therapy is recommended for a minimum of 72 hours or until the patient is mobile and has been suggested for as long as 10-14 days[47] in patients following major Orthopaedic surgery.

In the latest guideline published by the American College of Chest Physicians (ACCP) in 2012,[47] it is recommended to aim for 18-24 hours of use per day. This can result in the patient wearing the garments for long periods during the day and night; in various climates within the hospital. The condition of the patient can also have an effect on core temperature, which can influence the patient's normothermic state.

This can result in patients perspiring in the lower limb area, leading to discomfort whilst wearing an IPC garment.

Patients are more compliant with therapy when a comfortable VTE prevention garment is used

A randomised trial evaluating patient compliance with IPC therapy demonstrated that a garment, which was more comfortable, was worn for longer periods. The study concluded that "patients are more compliant with a pneumatic compression device that promotes patient comfort when worn".[51]

Specifically in this study, differences in compliance were seen when patients reported that 'the device was hot' (p=0.14) and the 'device made my legs sweat' (p=.029).

Comfort is a critical factor in patient compliance with IPC

Comfortable VTE garments are important in improving the patient experience and therefore concordance with prevention therapy. Better concordance with therapy is linked with reduced VTE event rates as studies reviewing reminder tools have shown.[54]

Improving Patient Comfort

One method of improving patient comfort is to focus on the garments' ability to allow the passage of heat, air or moisture vapour away from the skin through the fabric.

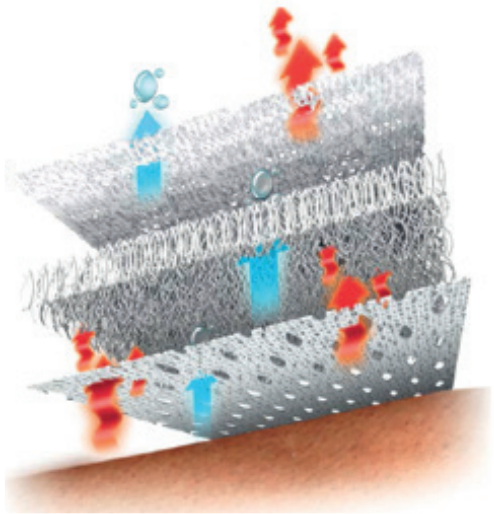


Figure 15: Example of Flowtron TriPulse Garment Fabric Construction

Flowtron Garments have been designed to provide:

- **Low thermal rating (Figure 16)**
- **Heat and moisture vapour transfer through the material (Figure 17)**
- **Quick drying of the fabric (Figure 18)**

In order to demonstrate Flowtron® DVT garments properties, they were tested at an accredited independent laboratory to assess heat, air and water vapour characteristics following recognised test standards.

- Water Vapour Permeability WVP Index BS7209:1990 (1997)
- RET Water Vapour Resistance EN31092
- Thermal Resistance (TOG) BS4745

Example of TriPulse Garment Testing

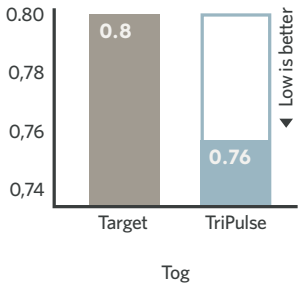


Figure 16: Low Thermal Rating (TOG)

To minimise the risk of perspiration or increased heat production during wear time, VTE prevention garments should be nonthermal – this means that they do not generate additional heat.

A single plate procedure is used to determine the thermal resistance of the fabric.

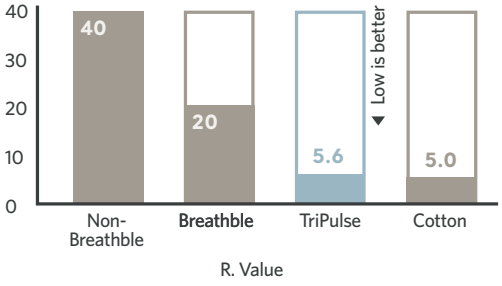


Figure 17: Breathable Fabric (RET)

Resistance Evaporation Permeability (RET) measures the resistance to water vapour transmission through a barrier.

Industry standards (EN31092) state that a fabric which scores > 40 is non breathable, 20-40 is semi-breathable and < 20 is breathable.

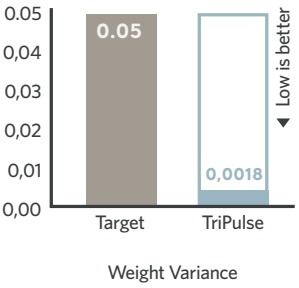


Figure 18: Drying Time

Perspiring is one of the body's methods of thermoregulation. Water can absorb a high amount of heat energy when it evaporates, and this creates a cooling effect. A fast drying time indicates that liquid such as perspiration can evaporate away from a garment quickly. This can help the body cool. A dry vs. wet weight variance of 0.05 over 8 hours shows how quickly fluid has evaporated away from the material.

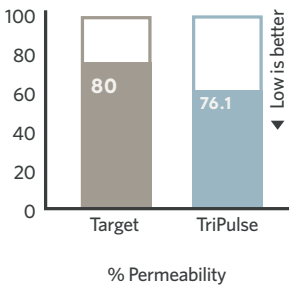


Figure 19: Water Vapour Permeability

The transfer of water vapour away from the patient's skin is a critical factor in patient comfort — this process refers to a fabric's breathability. Water Vapour Permeability (WVP) and RET are 2 measures that are used to evaluate the breathability of a fabric. WVP describes the water vapour permeability of a fabric and therefore the degree of perspiration transported to the outside air.

The higher the value, the more breathable the fabric.

A final thought...

We recognise that you have a choice of provider for your VTE prophylaxis and that IPC devices represents only a small part of your overall VTE prevention strategy. With Arjo's many years of knowledge and experience in VTE prevention. We can support your facility with a range of education, assessment and service solutions to support your VTE prevention strategy.

For further information please visit **www.arjo.com**

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