





Encircle Medical Devices (Encircle) is an innovative medical textiles programme established by The Merino Company (TMC) in 2007. TMC is the largest vertically integrated company in Australasia incorporating merino wool growing, yarn spinning, textile processing, manufacturing and retail. TMC is a family owned business with over 150 years commitment to the development of merino; a natural renewable fibre with unique moisture absorbent, antibacterial, antimicrobial, odour-inhibiting properties.

TMC has relationships with leading merino growers in New Zealand, Australia, South Africa, North America and South America, which guarantees the supply of the highest quality superfine pure merino fibre from farm to pharmacy.

Encircles goal is to significantly advance patient care through the application of intelligent and natural fibre textiles, specialist medicine and user centred design. Encircle has harnessed the naturally occurring medicinal properties in merino to create a brand of medical (pre and post operative) and over-the-counter (OTC) therapeutic products, that have been clinically proven to improve vein blood flow to help in safely preventing a broad range of health conditions associated with inadequate circulation and venous insufficiencies when encircled around your body.

Contents

Encircle Compression Therapy

Encircle Benefits

2

Product Overview

3

Product System

4

Application & Care

5

Encircle Technology

6

Symptoms & Treatments

7

Specifying Encircle

8

Specification System

9





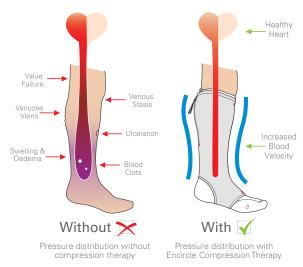
Encircle Compression Therapy

Pathology of Venous Insufficiencies

Venous insufficiency is a condition in which the veins in the human body have problems sending deoxygenated blood from the extremities' back to the heart. Inadequate blood flow increases hydrostatic pressure in the veins, which increases venous hypertension or elevated blood pressure and the onset of Venous Stasis, where a large volume of blood accumulates in the lower extremities.

If this increased hydrostatic pressure is not treated it can cause swelling, oedema, and lymphedema, hyperpigmentation and discolouration of the skin, venous eczema, varicose veins, thrombosis and Deep Vein Thrombosis (DVT), Pulmonary Embolisms (PE) and venous ulcers.

Venous insufficiency and hydrostatic pressure within the venous system can be prevented safely with the application of external compression. Compression therapy is a recommended treatment for providing relief to those that suffer from venous insufficiencies by the World Health Organisation (WHO), the National Health Service (NHS) in the UK, and Ministry of Health in New Zealand (MoH).



Prevalence of CVD

Venous insufficiencies and Chronic Venous Disease (CVD) of the lower extremity affects an estimated 40% of the population aged 45 years and older (Sullivan, 2008). CVD is one of the fastest growing chronic diseases, at a cost of over \$10.3 billion annually to the Australian Health Care system (RACS, 2009). In the U.S, CVD accounts for 4.6 million lost working days every year (Sullivan, 2008), with an average cost of US\$9,337.00 per admission (Radiology, 2009).

Hospitals are striving to control these costs through early discharges, and by aggressively adopting the preventative treatment of 'compression therapy'.

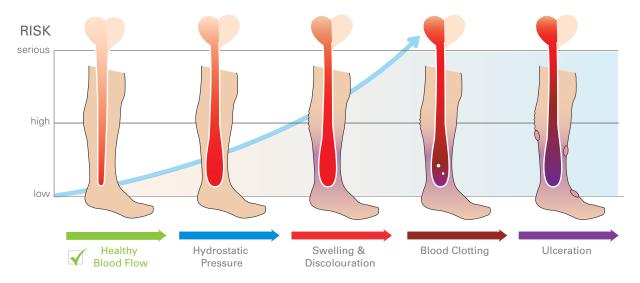
Encircle Compression Therapy (Encircle) is a non-invasive clinically proven method to help prevent circulatory problems and poor venous blood flow. Encircle works by creating a controlled micro-environment for healing, forming a graduated level of pressure around the skin and veins; naturally increasing and maintaining blood velocity at a healthy level. The daily build-up of pressure is managed by the textiles ability to stretch and manage the skin environment, so incompetent venous valves are supported, the diameter of veins are reduced, venous return is accelerated, and fibrinolytic activity of the venous wall is increased.

User research identified that existing compression products are uncomfortable, hot,

and difficult to apply creating greater levels of non-conformance where the therapy is prescribed; thereby reducing its efficacy for the patient.

Encircle differs greatly from standard products in several key areas. The next to skin merino component provides increased long term comfort, the two layer system enables self application by the patient, and the pressure release mechanism enables the patient to temporarily relieve the total level of pressure when wearing for long periods. And critically, for the effective specification, sale and education of the customer, Encircle has a specification system intrinsically linked to the physical embodiment of the product to streamline diagnosis.

Common Conditions & Risk Factors Associated with Poor Venous Blood Flow



Clinical Claims

Encircle has been clinically proven to improve vein blood flow to help prevent lower limb venous disorders; including venous hypertension and venous stasis, swelling, oedema, lymphedema, varicose veins, deep vein thrombosis (DVT), pulmonary embolism (PE) and post-thrombotic syndrome.

Clinically proven to improve venous blood flow by 24%

Increases mean flow velocity and total blood volume flow by 14%

Reduces vein diameter, swelling and oedema

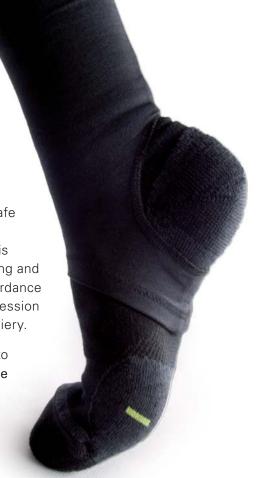
Creates a merino micro-environment for healing

Easy to apply and comfortable

Regulatory Certifications

Encircle is being registered with The Therapeutic Goods
Administration (TGA) in Australia and the Ministry of Health Medsafe
in New Zealand (MoH). Encircle is classified as a Class 1 nonmeasuring non-sterile medical device. Registration for conformity is
also being processed with Communauté Européenne for CE marking and
the FDA in the United States. Encircle has been developed in accordance
with international standards for compression BS 6612:1985 compression
hosiery and BS 7563:1999 non-prescriptive graduated support hosiery.

All of the materials (fibres) used within Encircle have been tested to the highest standards and are certified to the Oeko-Tex Eco-textile Standard.100HKB 20073 TESTEX Environmental Standards for textiles, approving the human ecological safety of the textiles and certifying the product is free of harmful substances. All packaging, user instructions and supporting product documentation is produced using sustainable and certified paper stock.



Encircle Benefits

Encircle makes compression therapy easier to specify, apply, and manage during use while lowering the overall cost of treatment. This has been made possible through the following five design and clinical breakthroughs:

Traditional Therapies

Encircle Benefits

Constructed from synthetic materials - which result in discomfort through overheating and excessive perspiration.

Lack of systemised care existing therapies provide one set level of care.

Difficult to apply - patients find compression very difficult to apply and remove.

Pressure builds up - from prolonged application resulting in non-compliance.

Difficult to specify - Nurses and clinicians find it difficult to specify the correct compression therapy.

An innovative bi-component textile - that creates a 'skin micro-environment' for effective healing of advanced CVD, which also increases fibrinolytic activity in the vein wall. Encircle also provides exception thermo-physiological comfort, remaining warm in winter and cool in summer.

A two layer system - that allows patients to 'build up' the level of care to safely managing internal haemodynamics;

A new method of application - with specific visual indicators and mechanical aids integrated into the textile to enable application as prescribed, without clinical assistance;

A pressure adjustment mechanism - built into the garment that allows the patient to temporarily release pressure once applied, without removing the product.

A method of specification - linked to the product that streamlines diagnosis, making prescription easier & accurate, ensuring the correct delivery of the intended care.









Encircle Product System

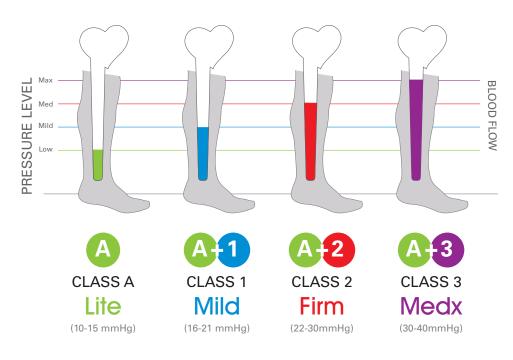
Encircle Compression Therapy is a range of natural and non-invasive pre and post operative medical grade compression, and non-prescription therapeutic compression for over-the-counter sale. Because blood in the lower limb and foot has the longest distance to travel back to the heart, we have developed a range of knee high garments which can be chosen to meet your individual needs. Encircle Compression Therapy is measured by a class system related to pressure applied (in mmHg) to the limb.

This class system provides a range of treatment options using the same inner layer, with an outer layer chosen and applied directly over the inner to increase the level of care when required by the wearer. When applied in this way the two layers systematically create a pressure gradient within the venous system. This pressure gradient internally influences systolic blood velocity and the flow volume of blood, whilst increasing the fibrinolytic activity of proteolytic enzymes in the vein wall to dissolves the fibrin in blood clots to facilitate wound healing.

The two cumulative layers of compression allow patients to also 'build-up' the level of care starting at Lite (10-15mmHg), then Mild

(16-21mmHg), up to Firm (21-30mmHg) and coming in 2012, medical grade compression (30-40mmHg). Each layer includes a series of visual and mechanical aids integrated into the product to allow a patient to apply and use the product without clinical assistance. In some cases this means patients suffering from chronic conditions may no longer need to visit a hospital or outpatient clinic every time they need to have compression reapplied.

The outer layer also has a unique zipper and elasticised bridge detail, which in use, provides two predetermined levels of compression. In the first configuration, when the zipper is closed the garment provides full pressure. In a second configuration, the zipper can be opened to provide a lower level of pressure. This is particularly important because it offers the wearer a pressure release mechanism; and is a first for any compression system. Our research identified that the build-up of sustained pressure for prolong periods is a large contributor to the high level of noncompliance with existing devices. Wearers are often required to wear compression bandages or garments for a long period of time. This feature provides for some relief through temporary and partial release of the pressure without removing the garment.



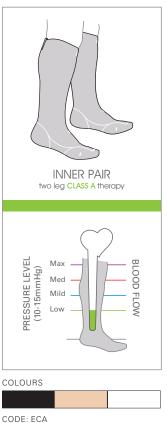
CLASS A Lite (10-15mmHg)

Left & Right Leg Inners DVT flight socks

Encircle Class A (ECA) inner layer garments provide a lite level of graduated pressure, 10-15mmHg at the ankle decreasing up the limb, and functions as a next-to-skin barrier. Encircle Class A is ideal for the prevention of DVT during air travel, providing relief to swollen limbs, and helping to preventing skin issues and blood pooling in the veins and to safeguard against developing a clot (embolism). This product ensures optimal acceleration of vein blood flow and venous return.

Recommended Applications:
Swelling & odema
Skin discolouration
Hypertension
Low blood pressure
Pregnancy
Preventing blood clots
Enlarged veins & mild varicose Veins
Travel & flight to prevent DVT

Specifications & Features:
Inner layer only
Merino micro-environment
Anti-microbial & odour free
Indicator markings
Graduated compression 10-15mmHg
Variable sizing chart & band indicator
Self application without clinical intervention
Bi-component textile: 45% Merino, 40% Elastane, 15% Nylon



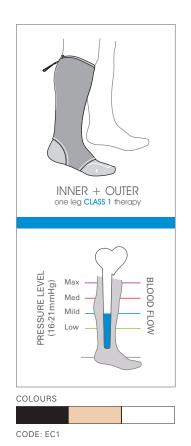
CLASS 41 Mild (16-21mmHg)

Inner + Outer Single Leg Kit

Encircle Class 1 (EC1) provides a mild or mid level of compression (16-21mmHg). Class 1 is a two layer compression garment system, which includes an inner layer next-to-skin garment which provides an effective merino mirco-environment, as well as outer garment that is worn over top of the inner layer to increase compressive support and blood velocity. Encircle Class 1 is ideal for:

Recommended Applications:
Swelling & odema
Lymphedema
Hypertension & venous stasis
Venous eczema
Preventing blood clots
Varicose veins
Deep vein thrombosis

Inner + outer layer Merino micro-environment Anti-microbial & odour free Indicator markings Graduated compression 16-21mmHg Pressure release zipper Self application without clinical intervention Bi-component textile: 45% merino, 46% MediCool, 9% elastane



CLASS A:2 Firm (22-30mmHg)

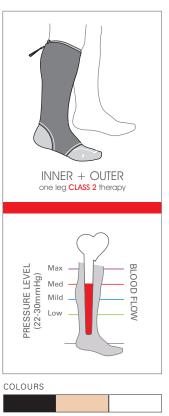
Inner + Outer Single Leg Kit

Encircle Class 2 (EC2) provides firm pressure for a higher level of care (22-30mmHg). Class 2 is a two layer compression garment system, which includes a inner layer next-to-skin garment which provides an effective merino mirco-environment, as well a firm outer garment that is worn over top of the inner layer to increase compressive support and blood velocity.

Encircle Class 2 is ideal for:

Recommended Applications:
Swelling & odema
Lymphedema
Hypertension & venous stasis
Varicose veins
Deep vein thrombosis
Ulceration

Specifications & Features:
Inner + outer layer
Merino micro-environment
Anti-microbial & odour free
Indicator markings
Graduated compression 22-30mmHg
Pressure release zipper
Self application without clinical intervention
Bi-component textile: 45% merino, 46% MediCool, 9% elastane





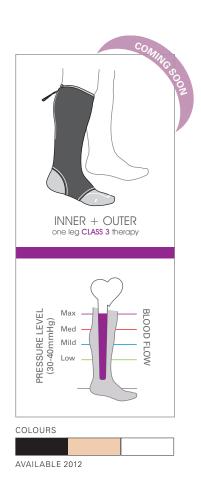
CLASS A Medx (30-40mmHg)

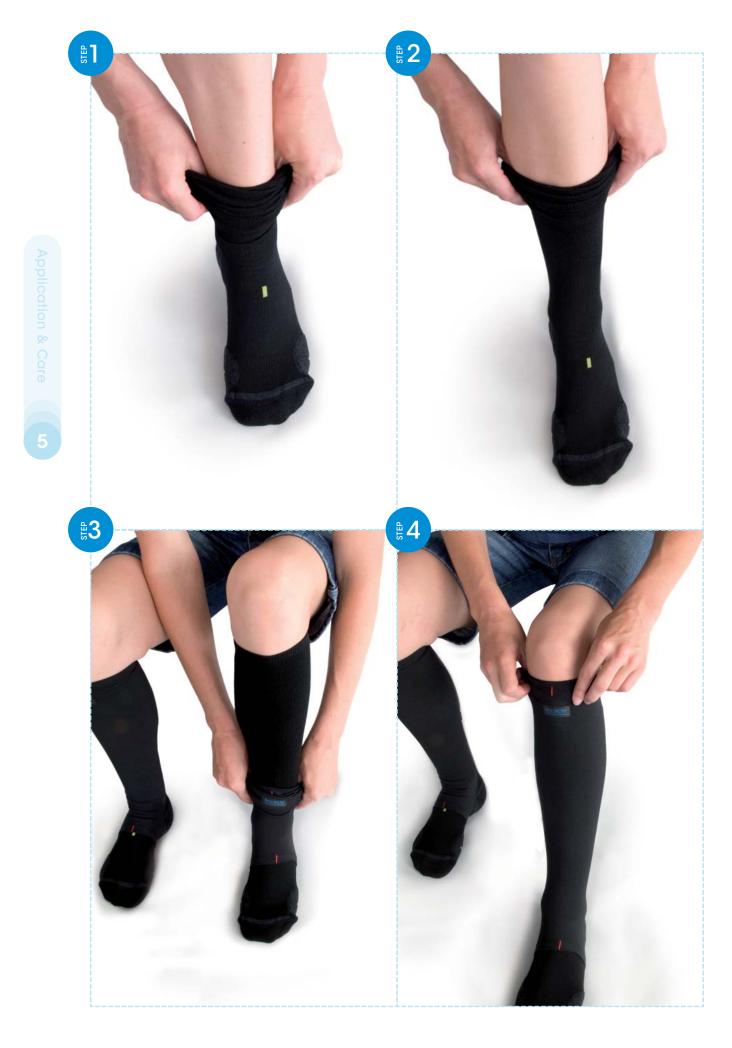
Inner + Outer Single Leg Kit

Encircle Class 3 (EC3) provides firm pressure for a higher level of care (30-40mmHg). Class 3 is a two layer compression garment system, which includes a inner layer next-to-skin garment which provides an effective merino mirco-environment, as well a firm outer garment that is worn over top of the inner layer to increase compressive support and blood velocity. Class 3 is for severe and chronic cases of CVD.

Recommended Varicose veins Ulceration & wound care support







Layering

Class A

Apply class A easily by sliding it over your foot and heal, aligning the small green indicator markers with your limb so it is positioned correctly relative to your body. Then pull it up your legs and align the top marker so it is centred on the front of your leg. Remove any folds and wrinkles.

Class 1 & Class 2

Unzip zipper and slide the outer over your foot while wearing your inner layer Class A garment. Position the garment relative to your limb using the indicator markings. Pull it up the leg and remove any wrinkles. For added support close the zipper. Hold down the small tab below the zip while pulling on the zipper. This helps straighten the zipper so it closes easily.

If the pressure becomes uncomfortable open the zipper to temporarily release pressure.

align indicator markings relatibve to your foot Indicator markings CLASS A Life

Easy Care

Washing Instructions

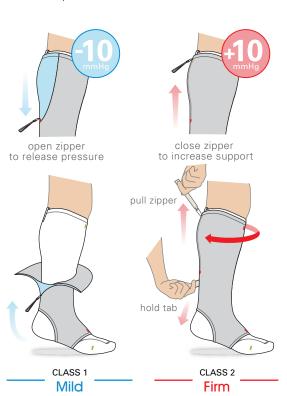
Unlike 100% synthetic compression garments, Encircle naturally breathes better staying fresher for longer. Encircle regulates the skin environment, trapping odours and creating an inhospitable environment to microbial growth, which means it's more comfortable and you can wear it for three times longer without laundering. These properties are advantageous when wound healing is a factor.

Washing will aid in returning your garment to its original size adding longer lasting compression.

Encircle Compression Therapy will give you the recommended levels of compression for up to 50+ washes.

Washing Instructions:

Do not tumble dry
Normal machine cycle with like colours
Do not use fabric softener/bleach
Dry flat or on clothes line
Do not dry clean





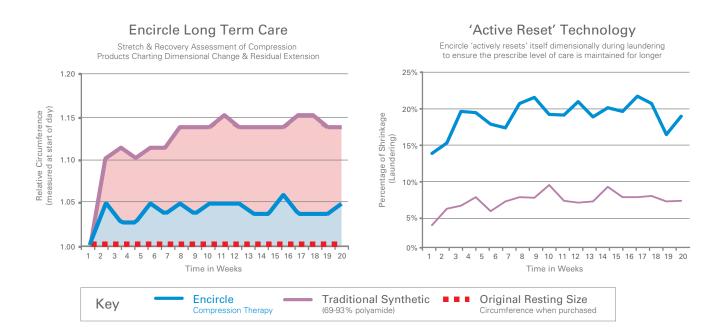
Encircle Technology

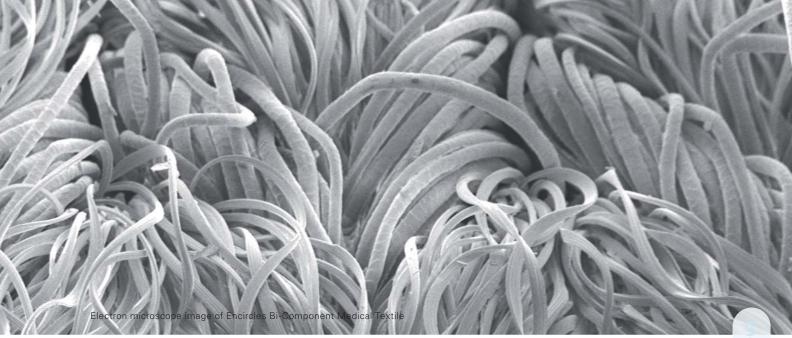
Why Merino

Encircle is the first compression therapy system to utilize the medicinal properties of merino. Merino is a natural protein fibre comprised of keratin – a fibrous protein also found in the outer layer of human skin, hair and nails which makes it ideal for second skin applications. Merino is moisture absorbent, antibacterial, antimicrobial, with odour-inhibiting properties, which helps to provide a healthy skin environment underneath the stocking. Because the fibre is hygroscopic, it is capable of absorbing moisture vapour

into the fibres hydrophilic interior where it is released (desorbed, or diffused) to the external environment.

Merino wool fibres have a smaller diameter than most other fibres with an average fibre diameter ~23 μm and lower, along with a natural crimp or waviness that gives the fibre resilience and softness unparalleled to any synthetic fibre. Merino is incredibly soft and comfortable and it helps to minimize irritation.





Merino Micro-environment

Encircle has harnessed these natural occurring properties of merino to create a bi-component textile that actively forms a micro-environment for skin development and healing when encircled around the body. This merino-micro-environment is advantageous in the advancement of patient care by leading clinicians because the most important goal for any compression system is to reduce the chances of ulceration being caused through infection of the skin and tissue.

Merino is weft-knitted into a new fabric structure whereby it is placed on the inside for next-to-skin comfort, with a flat channelled fibre (with a hydrophilic surface which can transport liquid moisture by capillary action) placed on the outside, and an elastomeric fibre inserted to lie inside the plane of the fabric where it is concealed. The differing moisture absorbency and wicking behaviours of these fibres creates a textile with a moisture gradient that actively absorbs moisture vapour and liquid moisture in a wearer's skin environment, and transports it by capillary action towards the exterior of the garment where it is released.

The knit structure of Encircles bi-component textile naturally absorbs and traps odours, providing an inhospitable environment for microbial growth (this is unique because other textiles need to be modified with antimicrobial chemical agents).

Innovative Bi-component Medical Textile

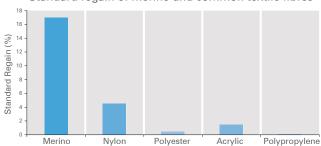


merino next-to-skin

medicool exterior

The other novel attribute of this textile is that it 'actively resets' itself dimensionally during laundering due to the natural shrinking behaviour of merino. This technology has resulted in a product that maintains the prescribe size and therapy for longer with little residual extension, unlike products made of 100% polyamide which creep over time leading to non-compliant care).

Standard regain of merino and common textile fibres



Symptoms & Treatments

Oedema & Lymphedema

Oedema refers to the abnormal accumulation of fluid beneath the skin or in one or more cavities of the body. Lymphedema is a condition of localized fluid retention and tissue swelling caused by a compromised lymphatic system. Compression therapy can improve the diminished subfascial lymph transport, and reduce lymph formation and encourage lymph drainage.

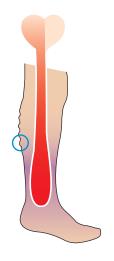
Venous Stasis

Venous stasis occurs when blood flow slows down or completely stops. Immobility associated with prolonged bed rest, general anaesthesia, or extended travel may slow the repetitive muscular contractions that help to pump blood through the veins and return it to the lungs. As the stagnant blood pools in the veins, clotting factors accumulate and a clot forms. Stasis dermatitis refers to the skin changes that occur in the leg as a result of this 'stasis' which is commonly caused from varicose veins or varicose eczema. Compression therapy can increase venous blood flow velocity or venous return and support the capillaries and venous valves.

Varicose Veins

Varicose and spider veins are the enlarged veins whose valves no longer meet properly.



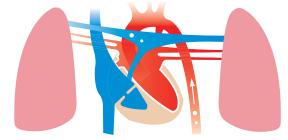


Varicose Veins

As a result the blood collects in the veins resulting in further vein enlargement and valve incompetence. A common cause of valve failure is the increase in hydrostatic pressure and clotting of the blood (Thrombosis), which can cause permanent damage to the valves.

The development of varicose veins usually occurs in the superficial venous system of the lower limbs, especially in the long saphenous veins (LSVs) and their tributaries. The short saphenous veins (SSVs) and their tributaries can also become varicose, but this occurs less often. Varicose veins can lead to thrombophlebitis (due to inflammation or blockage of the vein) and subsequent bleeding of the swollen veins near the skin surface. Other complications, such as oedema, skin pigmentation, varicose eczema, and venous ulceration, are mainly a result of venous hypertension.

Compression therapy can help in preventing Varicose veins by reducing the diameter of the veins so the valves are well supported and can function effectively. Compression can also help increase the total volume flow of blood within the veins.



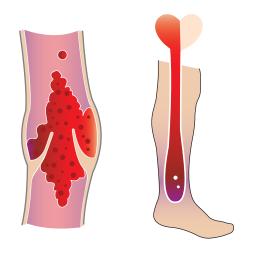
Pulmonary Embolism

Thrombosis, DVT & Pulmonary Embolism

Thrombosis is the formation of a clot or thrombus inside a blood vessel, which obstructs the flow of blood through the circulatory system. Thromboembolism is a general term used to describe both thrombosis and its main complication which is embolisation. A thrombus in a large blood vessel will decrease blood flow through that

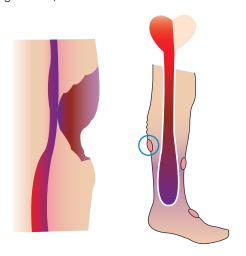
vessel. If a thrombus dislodges and becomes free-floating, it is an embolus. Embolisation occurs when an object (the embolus, plural emboli) migrates from one part of the body (through circulation) and causes a blockage (occlusion) of a blood vessel in another part of the body. Deep Vein Thrombosis (DVT) happens when a blood clot forms in a deep vein, mainly the result of prolonged immobility. DVT most commonly happens in the deep veins of the lower leg and can spread up to the deep veins in the thigh. Pulmonary embolism (PE) is a blockage of the pulmonary artery (or one of its branches), usually when a venous thrombus becomes dislodged from its site of formation and embolises to the arterial blood supply of one of the lungs.

Post-thrombotic Syndrome happens if DVT damages the valves in the deep veins, so that instead of flowing upwards, the blood pools in the lower leg. This can eventually lead to long-term pain, swelling, and in severe cases, ulcers on the leg. Post-thrombotic syndrome refers to the long-term effects that can occur after venous thrombosis. It is characterized by chronic pain, swelling, heaviness and other signs in the affected limb and in severe cases, venous ulcers may develop. It is the most common complication of deep vein thrombosis. Other complications may include purpura, eczematoid reaction, dermatitis, pruritis and ulceration.



Deep Vein Thrombosis

Compression therapy can help in preventing Thrombosis and DVT's by preventing the formulation of clots when circulation slows, and increasing fibrinolytic activity in the vein wall, wherein a fibrin clot, the product of coagulation, is broken down.



Venous Ulcers

Venous Ulcers

Ulcers are wounds that develop on the skin, mucous membranes, or superficial veins. Although they have many causes, they are generally marked by loss of integrity of the area, secondary infection of the site by bacteria, generalized weakness of the patient, fungus or virus, or delayed healing. Venous ulcers in particular, are wounds that occur due to improper functioning of valves in the veins. Compression therapy can help in preventing ulceration by increasing circulation and the flow of blood in and around the wound, and protecting against further infection.

Diabetes

Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar, starches and other food into energy needed for daily life. Compression therapy can enhance venous circulation for diabetics. Compression should not however be worn by diabetics that suffer from peripheral artery disease (PAD) or obstruction or narrowing of large arteries.

Please consult your doctor if you have any of these conditions to see if this product is right for you.



Specifying Encircle

Encircle Compression Therapy is selected based on specific health requirements and sizing information. Encircle can be specified safety by healthcare professionals, or by using the Encircle Specification System. In non-prescription applications, Encircle can be selected simply by choosing your shoe size from the sizing table provided.

The Encircle Specification System streamlines diagnosis, making prescription easier and accurate, ensuring the correct delivery of the intended care. This comprehensive system has been developed to actively and intuitively assist clinicians, healthcare workers, pharmacists and patients by providing clear guidelines for when and how the product should be used. These guidelines provided in the form of checklists have been developed to help provide a framework to ensure the correct level of care is prescribed. This tool enables patients to self assess themselves in low risk situations, freeing up time and costs for healthcare workers. This tool engages the patient and makes the process much for informative and reassuring for users.

Specifying the correctly sized product has always been an issue for healthcare workers and an uncomfortable experience for the patient. Encircle has developed a simple self use tear off measuring strip which allows patients to measure their own limb, with the measuring strip defining the correctly sized compression garment for their situation.

Please consult a physician for advice if you have or experience:

Skin infections

Weeping dermatoses

Incompatibility to fabric

Insensitivity of the limb

Immobility

When to use encircle:

Encircle Compression Therapy provides preventative care for all individuals that have:

Poor or limited blood flow

Limited mobility & effective limb support;

Varicose veins;

Swelling of the ankles and oedema

Skin discoloration

Pre and post-operative surgery

Diabetes

DVT & PE prevention

Pregnant women

Travellers to prevent developing DVT



When not to use encircle:

If you have serious circulatory problems such as active arterial or venous disease, or if you are suffering from, or have suffered from a blood clot, heart or circulatory problems, diabetes, severe varicose veins, cancer, reduced mobility or if you have recently undergone major surgery or are pregnant, please consult a healthcare professional about the suitability of this product for you.

Encircle Compression Therapy should not be worn if you have:

Ischemia or advance arterial disease

Untreated septic phlebitis

Uncontrolled congestive heart failure

Phlegmasia coerulea dolens

Arterioscierosis

Peripheral neuropathy

Ankle Brachial Pressure (ABPI < 0.8

Severe Limb Cellulitis

Specification System Checklist

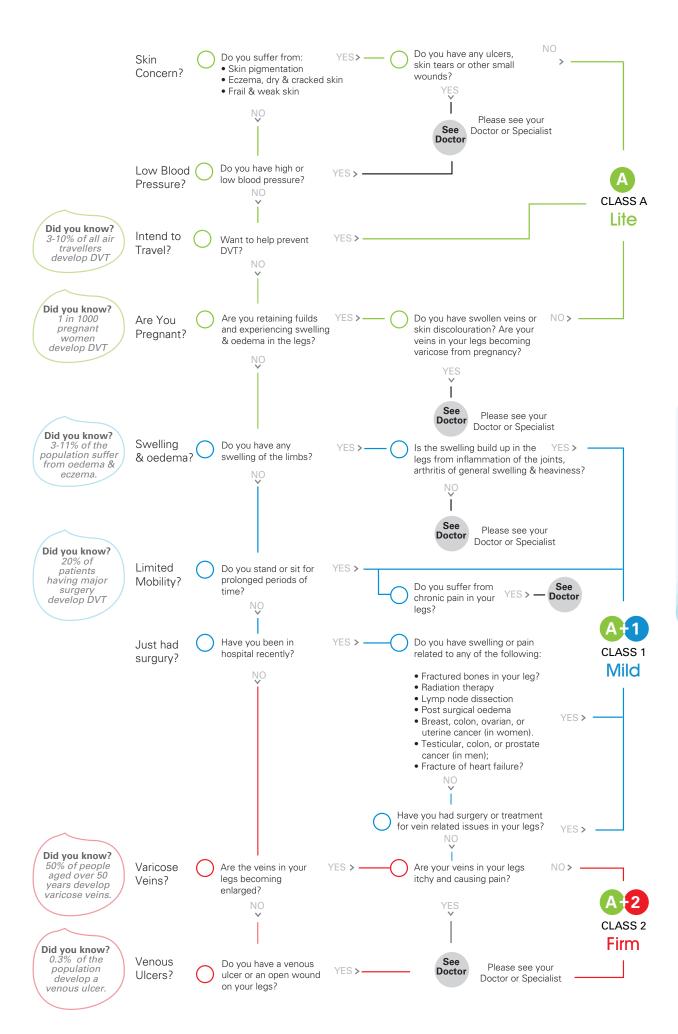
Please measure your limb	Limb Reference	Small	Medium	Large
cC	сС	36 - 41cm	38 - 44cm	40 - 46cm
	сВ	22 - 27cm	24 - 29cm	26 - 31cm
	sS	22 - 24cm	24 - 27cm	27 - 30cm
	Womens	5 - 8	8 - 11	
-cB	Mens	3 - 6	6 - 9	9 - 12
	EU	35 - 39	39 - 43	42.5 - 47
	US	3 - 7.5	6.5 - 10.5	9.5 - 14

Please note:

Your doctor may recommend a specific therapy for your needs. If your wounds or ulcers taking a long time to heal Encircle Class 2 or Ulcer care therapy can be used.

For all other concerns please consult your doctor. For further information please visit: www.encirclemedicaldevices.com





transforming the preventative care of chronic venous disease. naturally

- "a natural fibre is a better option to enclose someone's limbs, especially in summer" (Nurses, 2008)
- "Encircle's approach to creating a natural anti-bacterial micro-environment that effectively promotes skin development and regulation is the most important goal for medical products applied to the skin" (Roake, 2007)
- Nice and warm and feels like a good quality product in comparison to other products I have used. Reinforced toes are great for longevity of the sock (Clinical Trial, 2010)
- Ilssues with applying a tight stocking to a patient with limited physical capability. Getting the stocking over the heel is the hardest part. Two easy to apply layers that are applied loose could make application easier. II (Golden Pond Rest Home 2008)
- Sizing strip and specification tools are very interesting. Many places don't do a good job at specifying products and for those that do, it's an inconvenience. Getting patients to measure at home so the sizing strip and having the products indicate what level of compression is being applied in the garment is good. (Roake, 2007)

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