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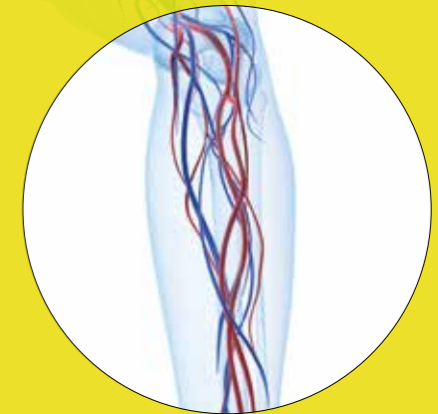
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Deep Vein Thrombosis Patient Information



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Dear patient,

Many people have an increased risk of developing a thrombosis. The risk is particularly high in certain situations, for example following an operation.

Vein thrombosis, as described in this brochure, usually develops in the deep veins of the leg. These can have life-threatening consequences and lead to lasting damage to the leg.

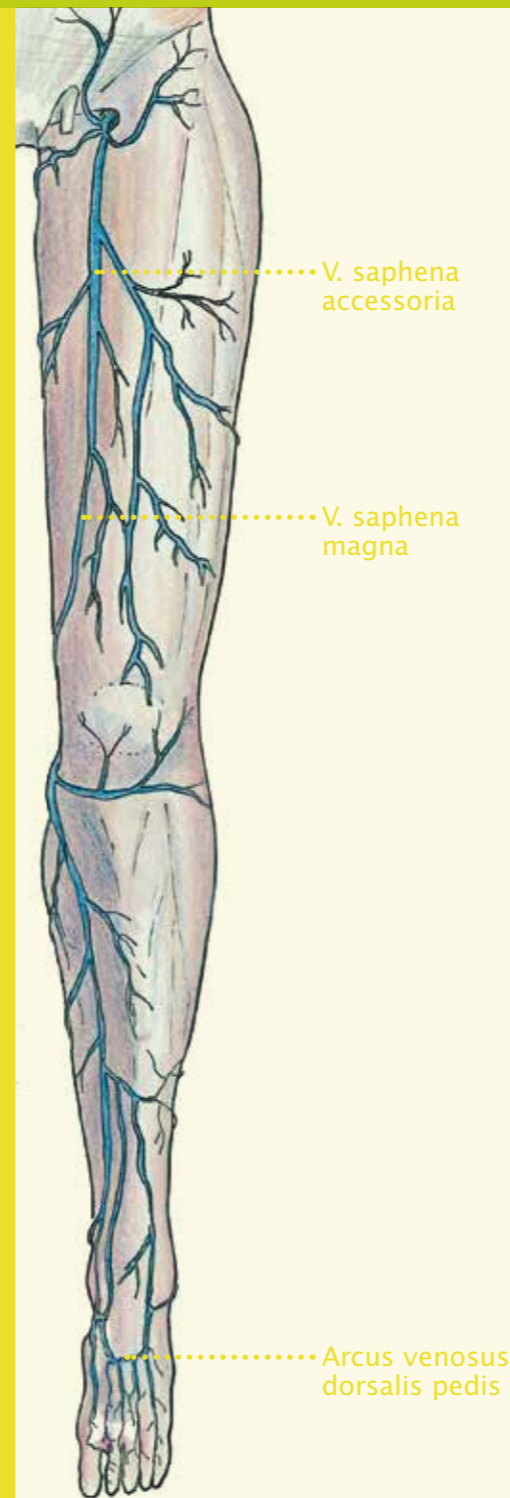
Blood clots are easy to prevent, nowadays. Find out everything you need to know about thromboses here, in a brief and clear overview.



What Is a Deep Vein Thrombosis (DVT)?

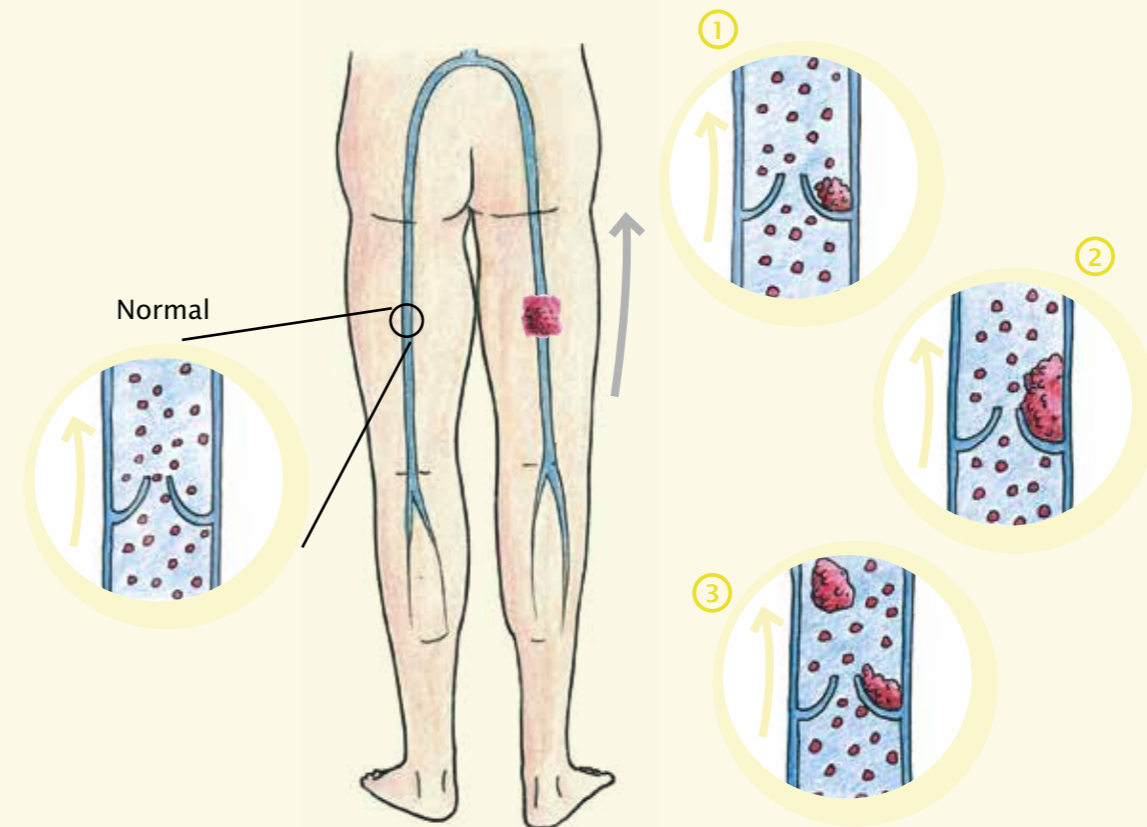
In our body there are blood vessels called veins and arteries carrying the food and oxygen needed to keep us alive. It is essential that these keep circulating to all parts. Within our bodies there are two systems - the clotting system that can form a 'plug' or clot to stop us from bleeding and the fibrinolytic system, that works in the opposite way, keeping the blood flowing.

This clotting mechanism is highly effective and under normal circumstances it stays inactive. When we injure ourselves - a cut to the skin for example - the second function is activated and a clot is formed to protect us from losing blood. But sometimes this function can go wrong and the blood becomes a solid mass within a blood vessel that has not been cut, causing what is known as a thrombosis or clot.



As there are veins and arteries throughout our bodies, a thrombosis can happen in any part of the body. As well as the changes in the blood vessel wall and reduction in the blood flow, a change in the make-up of the blood (sticky

blood) can cause a thrombosis. Sticky blood can be inherited and other factors, such as getting older, not being able to move around much, and pregnancy can make our blood more sticky and at greater risk of venous thrombosis.



1. Should a blood clot develop and adhere to the vessel wall (causes and risks on pages 7-8), it may grow bigger and make blood platelets sticky, and therefore steadily accumulate. This allows a thrombosis to form.

2. This blocks the blood vessel, causing blood flow to progressively slow down until it eventually comes to a standstill, because the blood vessel is completely blocked.

3. This presents a danger when the thrombosis detaches from the vessel wall and travels in the direction of the lungs.

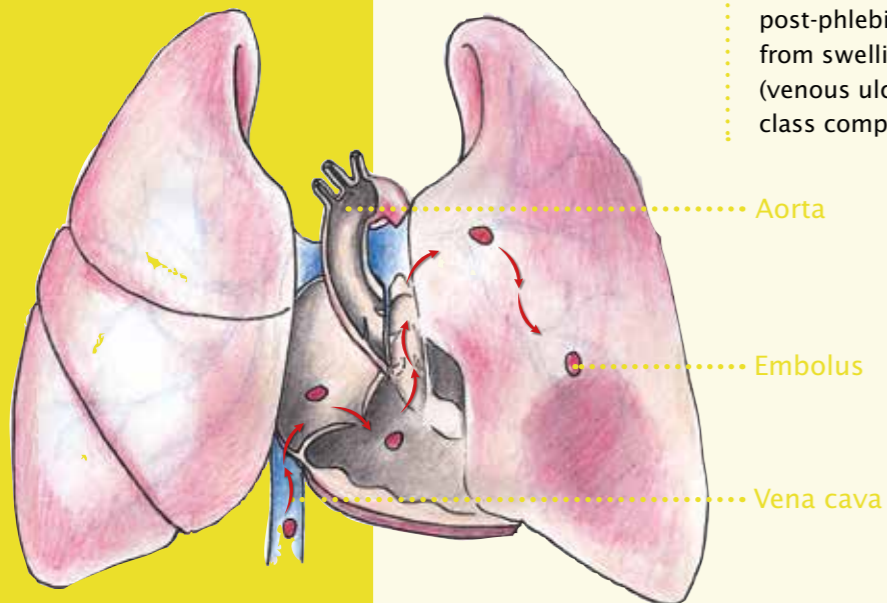
What Is a Pulmonary Embolism? (PE)

An embolism is when part of the clot 'breaks off' and travels around the body, eventually blocking an artery. The most common and dangerous is a pulmonary embolism when part of the clot from a DVT breaks off, moves up the leg, through the heart and lodges in a lung artery or pulmonary artery.

This process is known as pulmonary embolism (PE), and the piece of clot is called an embolus.

PE is the most common cause of death among patients having an orthopaedic procedure.¹

Normally the valves in deep veins prevent blood from travelling back down the leg. Damage to these valves higher in the leg can cause increased pressure in the veins of the lower calf and ankle. This is known as post-phlebotic syndrome (PPS). Patients with PPS suffer from swelling, chronic pain and nonhealing leg ulcers (venous ulcers) which require lifelong wearing of high class compression stockings.

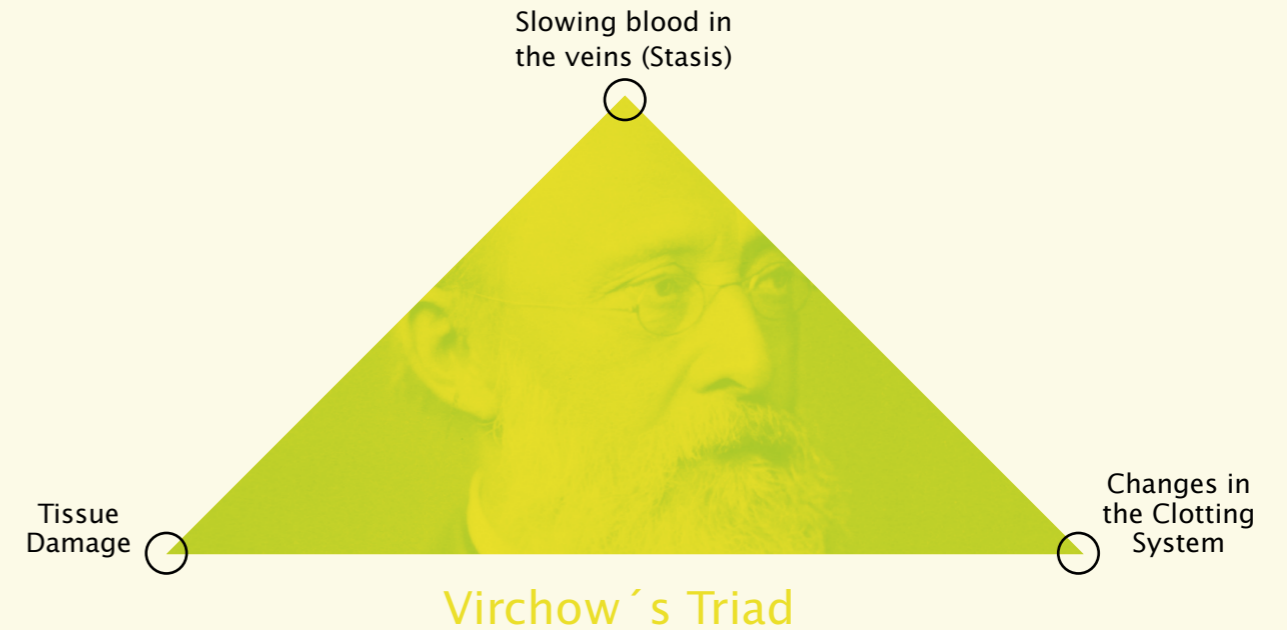


Which Factors Put Me at a Higher Risk of Developing a DVT or PE?

The German Surgeon Rudolph Virchow found out that stasis, changes in the clotting system and vessel tissue damage, which is known as the Virchow's Triad are the main triggers for

DVT formation. All occur during a hospital, surgery, immobilization or ankle fixation putting the patient on an increased risk to develop a DVT.

The Three Triggers for DVT Formation



Cancer surgery increases the risk by 73 times and orthopedic surgery by 138 times compared to other hospital patients. They have the highest risk among all surgery patients. ¹

Surgery is the key risk factor.

Surgery increases the risk to develop a DVT by 44 times compared to other patients in hospital, receiving no surgery.

Other risk factors:

- Previous DVT or PE in history or family
- Genetic factors
- Age over 40
- Previous stroke
- Obesity
- Smoking and contraceptive
- Cancer
- Varicose veins



Immobilisation, such as bed rest or ankle fixation, leads to less blood circulation in the veins and is one major risk factor in developing a DVT. Vessel tissue damage, occurring for example during surgeries or injuries, is another factor which increases the risk. During and after surgery the clotting system is hyperactive, which again boosts the likelihood of a clot forming in the leg veins. Also, the length and kind of surgery is significantly influences the DVT risk. Just one of the above risk factors can already lead to a moderate or even high risk to develop a DVT. ²

On top of that, each patient brings his/her individual risk factors. It is known that a history of DVT or PE significantly increased the risk of a DVT or PE re-occurrence.

Your individual risk will be assessed by your doctor, resulting in a low, moderate or high risk. According to your risk level, there are different measures which have to be taken to protect you from DVTs and PEs (see page 11).

When Does a DVT/PE Occur?

The majority of DVTs form during the surgery or the days after. Therefore an effective prophylaxis is mandatory particularly around and closely after the surgery, as long as you are

not fully weight bearing. Thus is it very important to comply with the DVT preventive measures particularly during this phase until full, normal mobility.

What Are the Symptoms of a DVT?

Many DVTs are silent, meaning they do not cause any symptoms such as pain, swelling or skin erythema. Although they form in the very early phase, they might lead to symptoms or PE after weeks, if ever, or to the PPS after months or years.



What Are the Secondary Diseases of DVTs?

As most DVTs are silent, many of them are not discovered. All DVTs lead to damage of the veins and their functions. As a consequence, the post phlebotic syndrome (PPS) occurs in approximately 50% of the cases of DVTs in history. *2

The most dangerous complication of a deep vein thrombosis is a pulmonary embolism (see page 6). If a small pulmonary artery is blocked, this may only lead to a slight cough. The blockage of a major vessel triggers the build-up of blood in the heart, however, which can be life-threatening in severe cases.



If there are no symptoms, it doesn't mean that there is no DVT!

PPS is characterised by:

- Massive swelling of the leg and ankle
- Chronic pain
- Itchy skin rash
- Prominent veins
- Chronic wounds (venous ulcers)

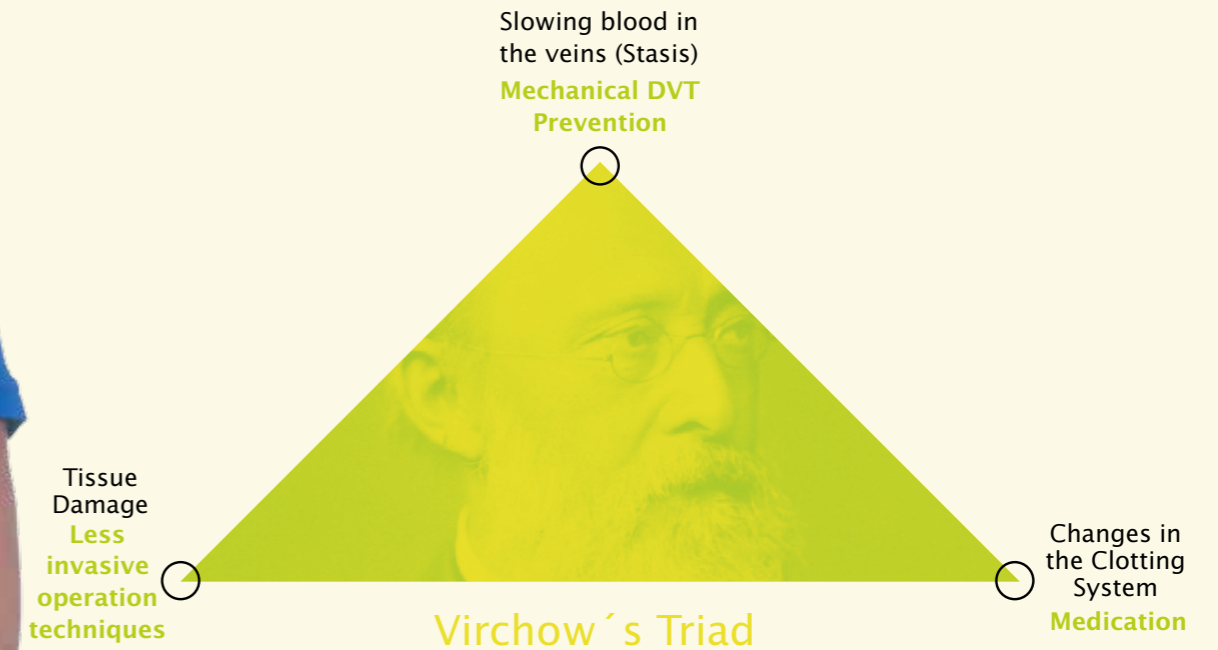


How to Prevent a DVT/PE?

According to general scientific standard, prevention is the only practical approach to these serious and life-threatening medical problems. Hospitalised patients are mainly at moderate and high risk. There are two kinds of preventive methods – mechanical and pharmaceutical prevention (medication).

They address the risk factors of clot forming described on page 7.

The DVT Prevention Methods address the Triggers



With pharmaceutical prevention, injections or drugs are used, which interfere with the clotting system, such as low molecular weight heparines (LMWH) or oral anticoagulants. They address mainly the **changes in the clotting system**. This is an effective and proven method, however the pharmaceutical methods have side effects and close to the surgery they can cause bleeding complications. They must be monitored closely with serial blood tests.

Mechanical methods are proven to be very effective and have no side effects such as bleeding or others. However their application can be disturbing sometimes to the patient. They eliminate the **stasis**, which is one major factor for clot forming, by pushing the blood through the leg veins. At the same time they activate the fibrinolytic system, which works against clot formation.

The **vessel tissue damage** tries to be addressed by short duration and less invasive operation techniques where possible (e.g. micro invasive surgery).

None of the methods, mechanical or pharmaceutical, provide a 100 % safety from DVTs, thus methods have to be combined for the utmost protection, depending on the level of your risk.^{*2}

However, there are different kinds of mechanical methods, which have different effects.

Your physician has chosen for you to use VADOPlex, which is one of the most effective methods to protect you from DVTs.



Mechanical and Pharmaceutical Prevention (Medication)

How Does VADOPlex Work and Why Is It so Effective?

The VADOPlex system works on clinically proven Impulse Technology (FIT). This unique method applies a strong air impulse towards the vein plexus in your foot. This vein plexus is directly connected to the deep leg veins, the place where the most dangerous DVTs occur. In contrary, compression from outside (calf or leg) has to be transferred through the leg tissue to be directly acting on the veins.

The strong impulse creates a fast flush of the blood through the leg veins towards the heart, as while walking with full weight bearing. This so called Impulse Technology is proven to be as effective in preventing DVTs as the most common drug (LMWH) in high risk patients, but without increasing the risk of bleeding or having any other side effects.

The VADOPlex calf application working with impulse technology is proven to be the most efficient method to eliminate stasis among all available devices.^{*3}



Is It a Proven Method?

VADOPlex is safe and a proven method to prevent DVTs particularly in high risk patients. It is recommended in the International Consensus Guidelines for DVT Prevention. Studies have shown similar results in preventing DVTs in high risk patients as pharmaceuticals (LMWH). *4 *5

In addition, patients treated with VADOPlex had less swelling and no bleeding complications in comparison with patients receiving pharmaceuticals for DVT prevention. *4 *5



What Other Effects Does the Use of VADOPlex Have?

It has been shown that VADOPlex is highly effective in reducing swelling, e. g. after ankle or wrist trauma.*6 *7 *8 Due to that, the operation of the fracture can be pulled forward and the patient can leave the hospital approx. 3.6 days earlier. *7 After the operation the VADOPlex system avoids severe complication (such as compartment syndrome and fasciotomy) in these indications. *9

Studies show that the Impulse Technology also increases significantly and long term the arterial blood supply *10, which means it can be also applied when other mechanical methods are contraindicated (such as graduated compression stockings or intermittend pneumatic compression).



Abstracts of Studies reference
A-V Impulse System™

J. Cashman, S. Blagg, M. Bishay
ROYAL UNITED HOSPITAL, BATH, ENGLAND
Injury, International Journal of the Care of Injured; 1998; Vol. 29 Nr. 2

What Kind of Applications and Pads are Available?

- ① Foot Pads for DVT prevention (moderate and high risk) and swelling reduction. To be used with mode 130/1. They can be used in individuals with arterial diseases.
- ② Undercast Pads for application below the VACOPed or cast, for swelling reduction and DVT prevention (moderate and high risk). To be used with mode 130/1. They can be used in individuals with arterial diseases.
- ③ Shorty Pads for „short term“ or intraoperative use. To be used with mode 130/1. They can be used in individuals with arterial diseases.
- ④ Hand Pads for swelling reduction. To be used with mode 80/1. They can be used in patients with arterial diseases.
- ⑤ Calf Pads for DVT prevention (moderate risk). To be used with mode 130/3. They must NOT be used in individuals with arterial diseases.



Glossary

Anticoagulants

Drugs designed to prevent and treat blood clots. Sometimes referred to as 'blood thinners'.

Coagulation cascade

A chain of biomechanical reactions that result in the formation of a clot. Anticoagulants work by blocking or regulating a stage, or stages, of the coagulation cascade.

Deep vein thrombosis (DVT)

A blood clot in a deep vein, usually resulting from damage to the vein or blood flow slowing down or stopping. DVTs are usually found in the leg, but can also be in the arm.

The most common type of DVT are found in the deep veins of the calf and are called Distal DVTs. Proximal DVTs are found in the legs above the calf up to the waist.

Low molecular weight heparin (LMWH)

An anticoagulant used to prevent new clots forming and existing clots from getting larger. It is injected under the skin (subcutaneously).

Morbidity

A diseased condition or state.

Mortality

A fatal outcome of a disease or procedure.

Pulmonary embolism (PE)

A potentially fatal condition caused by a blood clot blocking a vessel in the lung: usually the clot originates from a DVT in the legs. PE can result in permanent lung damage.

Thromboprophylaxis

Preventative treatment to stop a blood clot forming.

Thrombosis

Formation of a clot inside a blood vessel.

Venous thromboembolism (VE)

A disease process beginning with a blood clot occurring within the venous system, including DVT and PE.

Warfarin

An anticoagulant that inhibits multiple steps in the blood clotting process. Administered as a tablet, the dose varies by patient, and regular monitoring and dose adjustment is required. Warfarin and other similar drugs are sometimes also known as Vitamin K antagonists (VKAs).

Glossary content from AntiCoagulation Europe (UK).

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Abstracts of Studies reference A-V Impulse System™

Notes

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