INFORMATION ON LASER, ULTRASOUND GUIDED SCLEROTHERAPY, COIL OCCLUSION TREATMENT OF VARICOSE VEINS
(Alternative to Surgery)

This document is an addition to the Varicose Veins advice document and discusses the management of Varicose Veins by non-surgical means.

AIM OF TREATMENT

Ultrasound guided sclerotherapy with **Coil Occlusion or Laser Ablation,** is a further development of standard sclerotherapy (Injection treatment, also known as "Echosclerotherapy" or "Foam Echosclerotherapy") of lower limb varicose veins. This treatment is designed as an alternative to surgery for varicose veins previously only manageable by operation. The aim is to obliterate defective veins inside the leg that are flowing in the wrong direction. The ultrasound machine enables the surgeon to see defective veins and thus guide the treatment. Successful elimination of defective (refluxing) veins results in a decrease in the workload of the remaining normal veins in the limb and a return to a normal state. Because ultrasound guided injections alone are not very successful for long term clearance of varicose veins **Coil and/or Laser** insertion is required for a long lasting result. The largest vein that can be managed by sclerotherapy technology alone is 4mm in diameter. The largest vein that is treatable by the **Coil or Laser** technology is 15-20 mm. Generally veins greater than 15 mm in diameter are still best managed by Surgery.

SCLEROTHERAPY

This treatment was designed many years ago (1930's) and popularised in the United Kingdom in the 1960's. The procedure involves injection of a solution (called a sclerosant) into unwanted varicose veins. The injected veins then go solid and are absorbed by the body. All injection treatments for varicose veins are based on the principle of damaging the lining of the vein to be obliterated. This results in the collapse of the vein followed by solidification. The vein traps blood in the centre of the vessel which makes the vein lumpy after treatment. The body then dissolves the solid vein by creating inflammation around it. This process leads to the redness and tenderness experienced with this treatment. The same process occurs after surgery but inflammation and bruising with injection treatment sometimes takes 6 weeks or more to settle unlike surgery where inflammation settles in 3-4 weeks. Brown staining can occur after any treatment but is more noticeable after laser/sclerotherapy than with surgery. Brown stains from absorbed veins can take up to two years to fade.

LASER ABLATION

To treat larger varicose veins on a more permanent basis heat from a specifically designed Laser destroys the defective veins and is as effective as surgery in achieving elimination of varices. These technologies have been used over the last 10 years with increasing safety and effectiveness. The third generation Laser devices are now offer much less discomfort

afterwards than surgery. This new technology allows for a greater proportion of people with varicose veins to be treated by non surgical means without a hospital stay and with a shorter discomfort period and earlier return to normal activity. The Laser technology is not as suitable as other techniques for recurrent varicose veins. Suitability for Laser treatment is determined by ultrasound scanning.

COIL OCCLUSION

The use of occlusion devices in vascular conditions has been employed for two decades to seal arteries and veins that are abnormal. The extension of this technology to the lower limbs has been undertaken since 1998 and has proved effective in the majority of venous conditions treated. To treat larger varicose veins and large valve leakages in the lower limb this additional treatment is sometimes used. This is known as **"coil occlusion" or "coil embolisation".**

Deployment of an occluding coil into a varicose vein extends the effectiveness and durability of ultrasound guided injections and Laser resulting in a much greater likelihood of long term permanent success. The majority of persons with recurrent varicose veins can now avoid further surgery and about two thirds of patients with primary varicose veins are suitable for this technology as an adjunctive therapy.

SIDE EFFECTS & RISKS:- A sclerosing agent is always used for treatment with Laser or Coils and is of a higher concentratiuon than for the agent used for surface veins and therefore the chances of side effects are greater. The most common side effect is a cough.

<u>SIDE EFFECTS (Transient)</u>:

Pain: Pain occurs, on injection of local anaesthetic and the sclerosant, in the form of a stinging sensation. When the vein wall leaks sclerosant into the tissue this pain can be uncomfortable. Normally this resolves, with no untoward event. Persisting pain usually indicates difficulties with the process and should be reported. For Laser treatments about 5 injections of local anaesthetic is required in the thigh to prevent pain from the heat of the Laser. If treatment is under anaesthesia then no pain occurs.

Swelling: Because the obliteration process involves inflammation, swelling can occur in the limb that has been injected for some period of time (6 weeks).

Cough: A cough may occur with or without a feeling of tightness in the chest and this resolves in 10-15 minutes. This can delay your departure after treatment.

Migraine: A migraine headache, unusual tingling or numbness of a limb or visual aura may occur but also resolves quickly. The sensation of numbness or weakness on one side of the body can last up to 15 minutes. No permanent sequelae have been documented.

Fainting: Either the injection of the vein, stimulating nerve endings in the vein wall, or the agent itself can cause a feeling of faintness associated with what is known as a vaso-vagal response. If severe it will be treated with an injection of Atropine, which, restores your blood pressure and heart rate to normal. You will however notice blurred vision from the injection for about twenty minutes. This reaction is a very common one following any form of painful stimulus or even just the sight of a needle is enough to make some people experience this phenomenon.

MAJOR RISKS: Ulceration, Infection or Deep vein thrombosis are risks of the procedures. An ulcer after this treatment is rare but, if this does occur, it can be large and painful requiring hospitalization and possible skin grafting. Although not seen in this practice it has been reported by other proceduralists. The chance of disabling ulceration is one per 5000 patient treatment sessions. People who have had previous ulcers from their varicose veins seem to be predisposed to this complication.

Deep vein thrombosis requires hospital admission for treatment but the risk is less than 1:5000. Infection requiring treatment has an incidence of 1:3000 treatments. People with ulcers or damaged skin are most likely to suffer this complication and it would require administration of antibiotics. No hospitalization has been required for infection or deep vein thrombosis after Laser in this practice.

The use of occlusion coils for larger vessels has dramatically reduced the incidence of side effects from injection treatment. There is also the additional benefit of reducing the total dose of sclerosing agent as well as reducing the risk of ulceration as a complication.

The risk of coils moving from the original placement site during treatment is considered to be negligible but tangible. Loss of a coil during the actual procedure, however, would require removal of the coil by X-Ray control through a catheter in the vein under local anaesthetic. Surgery to remove an incorrectly placed coil should rarely be required and would consist only of a tiny incision under local anaesthetic performed at the time of the procedure.

Laser treatment can damage the adjacent nerves and cause "neuralgia" which results in numbness and occasional shooting pains. This complication resolves with time and is rarely permanent and is a less common complication than the same risk with surgery.

TREATMENT:- What you need to know.

There are no special requirements beforehand except that you should wear warm clothes loose enough to go over the legs after the application of bandages. Warmth is helpful in dilating the veins so over dress or walk briskly before your visit.

The treatment itself is usually not too uncomfortable with the needle insertions and local anaesthetic injections causing discomfort. Inhalation of an analgesic (Penthrox) is available to lessen discomfort, however, if you use this agent you may **not** drive a vehicle afterwards for 12 hours. If requested a general anaesthetic can be administered but this requires a hospital admission for a few hours.

Usually a fine tube is threaded into the vein to deliver the coil, laser heat and sclerosant. You may be able to feel the tip of the catheter moving inside the leg but this is not a painful sensation.

Once the coils have been placed the sclerosant is introduced and you will feel some stinging in the surface varicose veins as they vanish. Several additional needle insertions are usually required to obliterate remaining veins on the surface. With Laser treatment extra injections of Local Anaesthetic is required in the thigh and some pain may be experienced with the heat. Laser ablation of veins requires a larger amount of local anaesthetic (up to 10 injections) along the course of the vein so "Penthrox" inhalation is useful.

After treatment, with any of the modalities, and following injection of sclerosant, cotton wool balls and adhesive tape are applied at the injection sites. You will then be placed in compression bandages. These cover the cotton wool balls and compress the treated veins. You should leave these bandages intact for at least 8-12 hours.
After treatment you should walk at least two to five hundred metres to help circulate blood through the deeper veins of the limb. This should be repeated a few times over the next few hours.

Bandages: Following application of compression bandages you will be given instructions as to exactly how long to wear them. Normally you will wear the compression bandages until the following morning. You **must** remove the bandages and then shower and remove the cotton wool balls and adhesive tape from the limb. **(Removal of the cotton wool and adhesive tape is essential within 12-24 hours to prevent skin blisters).** Following the shower you should re-apply the bandages to compress the legs (not the thighs) for a further few days. This period may be shorter and you will be advised accordingly. The purpose of the bandages is to try and compress the vein walls together so that there is very little trapped blood. Without compression the veins tend to be big and bulky when solidified and thus they take longer to absorb. Sometimes the thigh bandages tend to unravel rapidly in which case they can be left off but bandages below the knee should be reapplied. If the bandage is too painful (eg at night) then it should be loosened a little or reapplied more comfortably.

AFTER TREATMENT
There will be some tendency for the ankles or legs to swell. Any dramatic increase in swelling should be reported to Mr. Milne. An unusual degree of pain following treatment should also be reported. There is no limitation on your activity following treatment and you should carry on all your normal sporting and work related activities. Discomfort usually settles with analgesia such as Panadeine.
In the weeks following treatment swelling of the ankles will settle, if it has occurred at all. **You will** feel some **hard lumpy** areas where the veins have solidified and these become **tender** as the absorption process gets under way. The veins will become **red and inflamed** as part of the absorption process and simple anti inflammatory agents such as Aspirin, Nurofen, or Naprogesic may be used.
When the veins are completely absorbed (usually within six months) there may be some brown staining left on the surface of the skin. This goes away slowly with time, sometimes as long as 2 years. The coils are virtually impalpable and are not visible except on X-Ray. The veins will disappear as completely as they would with surgical treatment.

THE SCLEROSANT
Over the past ten years several agents have been used as sclerosants The agent that is currently the most satisfactory is known as "Aethoxysklerol" or its generic name "Polidocanol". This agent is a surfactant, which means that it has a soap like action, which leaches the fat from the wall of the vein, resulting in the vein collapsing and going solid. Pregnancy and breast feeding are the only contraindication for treatment with this agent .
Possible side effects are as follows:

Allergy This is very rare and life threatening allergy has not been reported in Australia. A 1:5000 chance of a rash is the only allergic risk.

Local Skin Ulcers

These are very rare and tend to be very small and heal rapidly. Occasionally excision of an ulcer with suturing may be necessary and this will leave a scar.

Deep Vein Thrombosis

This is rare if the correct dosage is followed and the injection is associated with compression bandaging and mobilisation. Walking more than usual is the best means of reducing this risk. Current risk 1:5000 treatments. Being **overweight or a smoker increases the chance of this complication** to a substantial degree. If you have had a deep vein thrombosis in the past or a family history of same we will assess your risk and manage this with post procedure tablets.

THE COILS if used:-

The devices commonly called "coils" are made either of chrome alloy and polyester or platinum and polyester. The devices used for this treatment are T.G.A. approved for use in Australia and have a long documented history of safe deployment. Like surgical clips they are inert after implantation. There is a very small risk of infection (less than 1 in 10,000) with these devices. Infection would require removal of the coil, normally under local anaesthetic. After treatment the coils are visible on plain x-ray and appear very much like surgical clips commonly used for abdominal surgery. They will not trigger a metal detection device such as those commonly used at airports. They are MRI Compatible for MRI scanning. These coils, once implanted, are completely inert with less than 1:10,000 rejection rate.

TREATMENT COMPARISON: The safety of all the treatments is similar with risks of deep vein thrombosis and infection being less than 0.05%. Discolouration, with brown staining, can occur with either surgery, Laser or coil treatment but fades in 6 weeks to 2 years. Mostly fading takes place within 6 months but, injected veins take longer to fade than surgically removed veins. Post procedure visits are at 2-6weeks then 6 months after treatment. "Top up" treatment (sclerotherapy) in the office is available at these visits if required for left over superficial veins.

COMPARISON	Hospital time	Procedure time	Anaesthetic	Discomfort
Surgery	1-2 days	1-2 hrs	General/Spinal	2-6 weeks
Coils/Laser	1-2 hours	20-40 mins	Local	1-2 weeks

Permanence:- Surgery is normally 95% effective in removing large veins for 10 years. Laser treatment appears reliable at 5 years. Small surface veins occur with time after either treatment and can be managed with sclerotherapy in the office. Recurrence of varicose veins in the calf is not uncommon after either surgical or coil treatment and is managed by usually by further injection treatment. Although many patients are permanently free of major varicose veins after surgery it is usual to have some form of recurrence in the future. Most recurrent veins are managed by injection treatment in the office or under ultrasound.
Brown Discolouration:- This occurs after blood is absorbed from destroyed veins and occurs after either surgery or injection/coil treatment. It is more common and more intense after non surgical techniques for veins. Fading time is longer for darker skin than light skin and can take as long as two years. Most fading occurs in 6 months.
Lumps and Bruising:- These occur after any form of treatment but lumpiness redness and bruising can take 6-8 weeks after injection treatment compared to 2-4 weeks for surgery.

Any difficulties with treatment should be reported immediately by phone to this practice, not your local doctor. The result of your treatment, and/or significant complications, must be reviewed by Mr Milne before you can be discharged to your referring medical officer.

COSTS: Out of pocket costs can be substantial if you have no Private Health Cover so please enquire re: same prior to treatment. Estimates are issued by this office for your treatment. Substantial gaps between your fund rebate and the fee charged may occur and is defined with your quote. Rebates vary between Health Funds so your out of pocket cost is fund dependant. Laser treatment is more expensive at present as the rebates from insurers do not reflect costs of the equipment for same. Charges for ultrasound and anaesthetic services are additional to your procedure costs.

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REQUEST FOR TREATMENT OF VARICOSE VEINS BY MEANS OF LASER ABLATION, COIL OCCLUSION, ULTRASOUND SCLEROSIS OF VEINS AND TOPICAL SCLEROTHERAPY WITH "AETHOXYSKLEROL".

I, ... I have read Mr. Milne's information sheets about the sclerosant "Aethoxysklerol" and the information about ultrasound guided sclerotherapy, coil occlusion with Laser ablation of venous trunks.

I fully understand the side effects and possible complications (although rare) of the treatment including ulceration, infection and/or deep vein thrombosis.

I consent to being injected with the above drug and devices under ultrasound control.

Signature: . . . . . .

Witness: . . . . . .

Date: . . . . . .

(c 08/13)