

CLINICA

World Medical Technology News

International software standards chaos causes concern to electromeds

Unco-ordinated standards work proposals in the area of software used in the medical environment has provoked an outcry from COCIR, the European association representing the radiological, electromedical and healthcare IT industry.

"There are different instances of proposed international standards on similar matters; we need consistency," Nicole Denjoy, secretary general of COCIR, told *Clinica*. "Otherwise future standards could create problems with regards to those regulations and standards already existing that cover medical devices."

Ms Denjoy is intending to draw the matter to the attention of the chair of the Advisory Board for Health Standards (ABHS) at the European Committee for Standardisation (CEN), Trudy Phelps, although she readily acknowledges that this is an international – not just European – issue, and that the US National Electrical Manufacturers Association (NEMA) also has concerns in this area.

COCIR worries that a new category of "health software" will cause confusion

"Standards organisation committees need to talk to each other before they open the door on a matter that might be under consideration by another," Ms Denjoy said.

Software standards proposal

The proposed new work items are causing concern on two counts: that they contradict existing standards and regulations for medical devices; and that there are work items in the same

area being proposed by (two different) international technical committees.

In particular, proposed new international standards work in the area of "health software" threatens to contradict existing standards for medical devices, Ms Denjoy said, and COCIR is appealing to interested parties to urgently address this global issue.

It has called on its member companies and on national standardisation committees to oppose two new work item proposals (NWIPs) being put forward by International Standardisation Organisation Technical Committee 215 (ISO TC 215) on Guidance on risk evaluation and management in the deployment and use of health software and on the Application of risk management to the manufacture of health software. (ISO TC 215 is responsible for standards in the area of health informatics).

The association is worried that the introduction of a proposed new category of "health software" will cause confusion.

At present, all software is either classified as a medical device and regulated as such along with comprehensive standards being available, or is not classified as a medical device and does not require standards that specify a separate process for the manufacture and testing of such software.

The NWIPs would introduce standards for software that is neither classified as a medical device, nor part of a medical device, but which has a "possible influence" on patient health. **p9 ►**

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Endovascular ablation is heating up varicose veins treatment market

The use of endovascular ablation as a treatment for varicose veins has grown rapidly since its introduction in 1998. The potential US and European market is estimated at \$2bn, with the largest players in this market reporting average annual sales growth of 42% over the last three years. This rapid growth means that it is not just veins that are getting heated: the major treatment providers have been locked in a legal tussle over patent infringement since 2004. In addition, this technology has the potential to move varicose veins treatment away from vascular surgeons and towards interventional radiologists and other clinical groups. This article discusses the current endovascular ablation technology and market, and examines emerging market and technological trends

Heat can have a variety of effects on tissue, including stopping cell replication, coagulating blood vessels, shrinking tissue and causing cell death. In fact, heat is so effective at destroying tissue that the term “ablation” has become largely synonymous with heating in a clinical context. This ability to effectively shrink and ablate tissue means that heat is perfectly suited to treating varicose veins.

Around 10-15% of adult men and 20-25% of adult women suffer from varicose veins in the western world. Although they are visible on the skin’s surface, they are caused by the failure of valves in underlying leg veins.

The chief culprit is the greater saphenous vein, which runs at around 1cm below the surface of the skin down the length of the leg. The failure of valves in these underlying veins leads to pooling of blood and pressure on surface veins that causes them to bulge out in a way that is unsightly, uncomfortable and can eventually lead to serious complications.

Traditionally, treatment has relied upon surgical intervention to remove the underlying cause of the problem by stripping out the incompetent vein. This has significant morbidity and costs associated with it, leading to sufferers avoiding treatment because the cure is worse than the disease. Not only is there a high probability of bruising and other complications, but the need for an operating theatre has a significant cost implication. Even despite the radical surgical intervention, studies suggest that the probability of recurrence is around 20%.

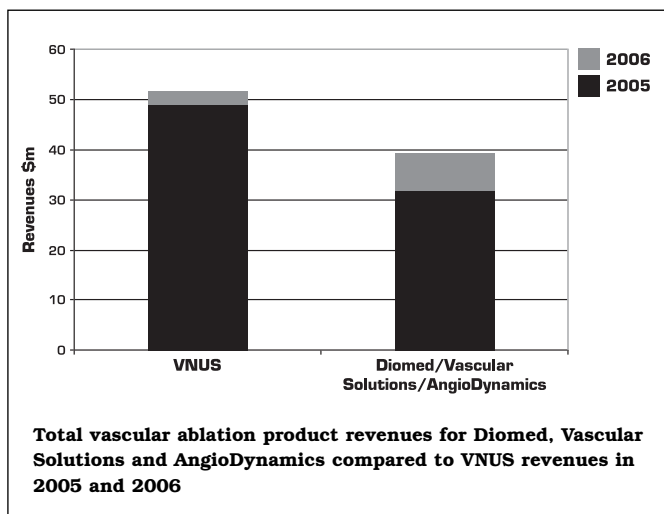
Minimally-invasive techniques are designed to avoid these disadvantages, and vascular ablation has emerged as a front-runner. In vascular ablation a catheter is inserted inside the vein, and radiofrequency (RF) energy or a laser is used to heat the vein from the inside. The damage to the vein wall causes it to occlude, and therefore, like surgical stripping, remove the underlying problem. Clinical studies suggest that morbidity is significantly reduced relative to traditional surgery. The cost is significantly reduced too, with the typical cost of a vein stripping operation in the US estimated at \$14,000, while the cost of minimally-invasive treatment is closer to \$2,000. Perhaps more surprisingly, recurrence rates also appear to be reduced compared to traditional surgery. They are only around 5%, which is a four-fold decrease compared to surgical stripping. While this effect may appear counter-intuitive, it may be that the trauma of surgical stripping leads to a strong repair mechanism and subsequent growth of another incompetent vein. In any event, the advantages of minimally-invasive treatments to the patient over traditional surgery seem clear.

In an endovascular ablation procedure, the ablation device is inserted into the vein to be treated and fed up the vein to the treatment start point. Energy is then applied, and the device is withdrawn, heating the vein as it is pulled back. Although there have been past attempts to occlude veins using RF heating in this way, it is only in the last few years that the market has really taken off. First to market was VNUS Medical Technologies, with its RF-based system, which was launched in Europe in 1998 and the US in 1999. This bi-polar RF system uses a catheter with expanding electrodes at the tip to maintain a temperature of 85 degrees C as the device is withdrawn. Hot on that company’s heels were the laser companies, including Diomed, Dornier Medtech, AngioDynamics, Cooltouch, Vascular Solutions and Total Vein Products. Their devices apply pulses of laser light inside the vein as they are withdrawn.

Company	Product	Modality	Frequency/Wavelength
VNUS	Closure	Radiofrequency	460kHz
Diomed	EVLT	Laser	810nm
Vascular Solutions	Vari-Lase	Laser	810nm
Angio-Dynamics	VenaCure	Laser	980/810nm
Cooltouch	CTEV	Laser	1320nm
Dornier Medtech	SkinPulse S	Laser	940nm

Of the two modalities, laser treatments are faster, with energy being applied for around 5 minutes, compared to a typical RF Closure treatment taking around 15 minutes. Not only is this a competitive disadvantage for RF compared to laser, but the disposable RF catheters are also intrinsically more complex and expensive than laser fibres. This might be expected to lead clinicians to favour laser, but RF also has points in its favour. Firstly, the cost of the laser system is greater than that of a VNUS system. Secondly, clinicians report that patients treated with laser tend to experience more pain than RF. In addition, VNUS recently obtained approval for a faster version of its Closure product. Both treatment modalities, therefore, have advantages and disadvantages, but the lower cost and quick treatment time of laser fibres is a significant driver in

their favour, and this may be reflected in the faster revenue growth of laser products compared to radiofrequency over the last calendar year.



With the very high prevalence of varicose veins, this is clearly a market with plenty of room to grow. The market potential has also been swelled relative to surgical stripping by a new pool of patients who would not have been willing to undergo traditional surgery, but are willing to have these new, more patient-acceptable procedures.

Treatment accessories

This market is not only about selling the treatment catheters themselves, but also the treatment accessories. Access cannulae, drapes, venous illumination devices, devices to keep the skin cool and even ultrasound machines can all be sold along with the device itself, giving a treatment offering that makes life easier for users and increases revenues for the treatment providers.

It is not only vascular surgeons who can perform the treatment – perhaps the most obvious group is interventional radiologists

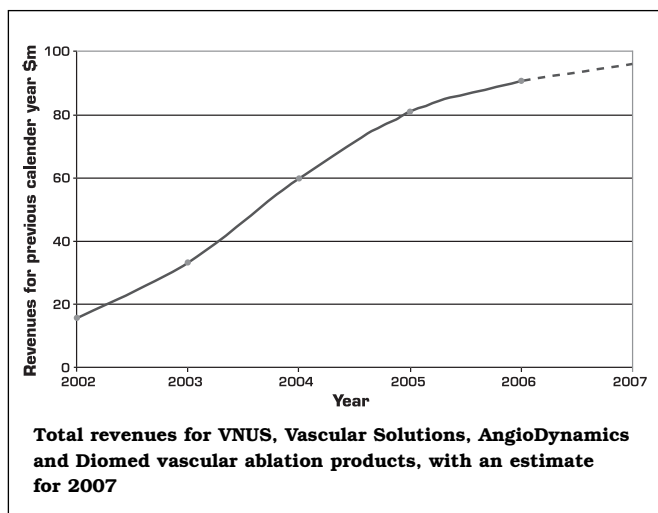
These rising revenues have led to the major laser providers being locked in a legal wrangle since 2004, when Diomed took AngioDynamics, Vascular Solutions and two other competitors to court for alleged patent infringement. And VNUS has been in litigation with Diomed, AngioDynamics, and Vascular Solutions since 2005, too. Both cases of alleged infringement still remain to be resolved, but this technology is also stirring up the clinical community. Since the new treatments do not need to be performed in a surgical setting, it opens the possibility of treating varicose veins in an office environment, with minimal costs. This means that it is not only vascular surgeons who can perform the treatment, but other clinicians too. Perhaps the most obvious group is interventional radiologists, given their skills in image-guided procedures, but even obstetricians and gynaecologists are getting in on the act.

Indeed, VNUS has been promoting its vascular ablation treatment at the American Association of Gynecologic Laparoscopists (AAGL). This may be down to the rising cost of malpractice insurance for US obstetricians, coupled with the high proportion of women with varicose veins, leading to a natural opportunity for gynaecologists to move away from obstetrics and towards vascular intervention.

Conducting treatments in an office environment is also changing the way that the procedure is performed. While varicose vein surgery could only be performed strictly under general anaesthesia, these minimally-invasive techniques allow treatment to be provided using just a local anaesthetic. This has led to the increasing use of tumescent anaesthesia, in which anaesthetic is injected around the vein such that it is effectively completely surrounded by fluid, thus providing the dual function of both numbing the nerve endings and ensuring that the heat is targeted only where it is needed, minimising the chance of unwanted side-effects.

Looking forward, finding ways to minimise the risk of skin and nerve damage is a clear area of interest, as this can be a side-effect from tissue damage extending beyond the vein walls. This could be achieved through more targeted energy delivery along the length of the vein, making this an area that could benefit from robotic treatments on a routine basis in the near future, with automated systems that withdraw the device to give a highly-even treatment, whilst making things easy for clinicians.

There are also factors holding back the market, however. Foremost amongst these is clinician awareness and culture. Vascular surgeons have traditionally treated varicose veins, and have done so using surgical techniques. Getting surgeons to adopt these new methods, or getting patients to be treated



by interventional radiologists, takes time and expense. And indeed, given the huge potential, the revenues to date are surprisingly small.

In addition, the rate of market growth also appears to be slowing. Whilst there is continued pressure on disposable catheter prices from the strong competition in the area, more insidious is the threat of chemical treatments for varicose veins, called sclerotherapy, where sclerosing chemicals are injected into the vein to be occluded. Sclerotherapy offers a significant cost advantage over ablation, but there has been difficulty convincing the market of its safety and efficacy in large vessels. The endovascular ablation market could therefore be prone to attack by a disruptive technology even at this early stage.

There is also the potential for a treatment based on another energy modality, such as microwaves, or even a treatment based on an entirely different technology to emerge.

Whilst it remains to be seen if any particular technology will come to dominate the market, vascular ablation certainly looks set to revolutionise treatment for this very common condition, and a significant number of patients are already reaping the benefits.

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