Worldwide drug withdrawal puts FDA under scrutiny

Merck faces 300 lawsuits

The worldwide voluntary withdrawal of the painkiller Vioxx (chemical name rofecoxib) in September has not only landed Merck & Co Inc - the drug's manufacturer - with 300 lawsuits, but also cast a dim light on efficiency and stringency at the Federal Drugs Agency (FDA).

Vioxx was withdrawn due to safety concerns of an increased risk of cardiovascular events (including heart attack and stroke) in patients using Vioxx, which had been approved by the FDA for various uses in 1999 (see box).

Results from a most recent trial, called APPROVe (Adenomatous Polyp Prevention on Vioxx), called Merck to withdraw the drug, because this long-term study showed significant adverse cardiovascular events conducted in 2,400 patients at risk of developing recurrent colon polyps. On 27 September Merck contacted the FDA to request a meeting to advise the agency that this study had been halted. The next day, the company informed the FDA of its decision to voluntarily withdraw Vioxx from the market.

In June 2000, the company had submitted the results of a safety study called VIGOR (Vioxx Gastrointestinal Outcomes Research) to the FDA. This study outcome demonstrated an increased risk of serious cardiovascular events in patients taking Vioxx compared with patients taking naproxen, leading to labelling changes being implemented by the FDA in April 2002. Recently other studies have also suggested serious risks in patients taking Vioxx; and the FDA claims to have been in the process of reviewing these results to determine whether further labelling changes were warranted. It has become clear that 25 mg of Vioxx per day significantly increases the risk of serious cardiovascular events (MI and stroke) compared with placebo. The risk only becomes apparent in patients after a period of 18 months, while the exact mechanism for the risk increase is whether it is a platelet effect or related to blood pressure changes - remains unclear.

Shortly after the withdrawal of Vioxx from worldwide markets, the British medical journal The Lancet published results from a cumulative meta-analysis showing that the unacceptable cardiovascular risks of Vioxx were evident as early as 2000. This discovery, made four years before the drug was eventually withdrawn from the market, indicates the manufacturer's failures in internal systems, highlighting the need for example, the services of a European health strategy and of medical care rests solely with the individual Member State. However, many EU policies affect healthcare systems, in particular those concerning the internal market. Consequently, the EU health strategy has always been somewhat incoherent, since one necessary module, namely influence on the healthcare systems per se, didn't exist. Therefore, the EU health policy focused on rather marginal activities such as Europe against cancer or Europe against AIDS. The EU picked single issues, with the result that the health strategy looked more like an incomplete puzzle. Only now there seems to be a widespread acknowledgement that a health strategy cannot neglect the healthcare systems.

At the time that Vioxx and other Cox-2 selective NSAIDs were approved, it was hoped that they would have a lower risk of gastrointestinal ulcers and bleeding than other traditional painkillers such as aspirin, ibuprofen or naproxen. Vioxx is the only NSAID demonstrated to have a lower rate of these side effects. Worldwide sales of Vioxx last year reached US$2.5 billion, following the most impressive sales growth for any drug in 2001.

EU health strategy? In

Details: www.gen.cam.ac.uk/sens

EU health strategy? In...
According to a comment made to national public radio (NPR) by Dr Stuart Sides, Associate director of Washington Hospital Centre, there have been ‘rumblings for the past 2 years’ saying that Vioxx should not be as safe as other drugs in its class. Although the absolute risk for the patient is not that high, it seems to increase the risk of heart attack or stroke 2-3 fold compared with placebo - a significant increase in risk.

Merk is facing at least 300 lawsuits from patients who believe they were harmed by this drug. Investigations by The Wall Street Journal have discovered e-mails that support the belief that Merck’s executives had advanced knowledge of their drug’s adverse effects on the heart and vasculara.

Marketing Invoices from Merck dating back to 1996 was found that included a document intended for its sales representatives (who directly speak to physicians about the drug) labelled ‘Dodge Ball Vioxx’ in which it discussed how to avoid answering questions about the cardiovascular risks of the drug. Was Merck attempting to mislead physicians about apparent risks? Internal company memos seem to imply that Merck has found ways to keep unfavourable safety reports from destroying the commercial prospects of the drug, while trying to design trials that would make the efficacy and side effect profile of the drug look favourable in comparison to older pain killers such as aspirin and naproxen.

The case of Vioxx between the FDA to not live up to its expected role as a strict and effective regulator, for example the pharmaceutical industry and protector of public interests. The pharmaceutical industry is one of the biggest source of funding for the agency, and these interests seem to sometimes override its regulatory function. The Lancet calls the Vioxx story one of blindly aggressive marketing by Merck mixed with regulatory blindness by the drug regulators. Hopefully the drug industry and government regulators will wise up to the fact that over two million patients were knowingly being misled by this drug that has been on the market for 5 years, so better vigilance and pre-cautionary measures can be imple-mented to prevent patients from being endangered by faulty medi-cine due to corporate greed and negligence in the future.
Smoking is in the genes

The Netherlands - The number of cigarettes smoked daily, and a person's level of nicotine dependence, are mainly genetically determined, according to research conducted by Jacqueline Vink for her PhD research. Working at the Department of Biological Psychology, Vrije University, she used data from a large study of over 16,000 twins (and their relatives) from the Dutch Twin Register, and some participants also supplied DNA material for the study. The researcher used this to investigate which genes play a role in this addiction and found that chromosomes 6 and 14 contain regions involved with taking up smoking. A region on chromosome 3 is involved in the number of cigarettes that somebody smokes per day. A region on chromosome 10 plays a role in both the number of cigarettes smoked per day as well as the chance that somebody takes up smoking. Further research is needed to determine exactly which genes are involved. Whether or not a young person starts to smoke largely depends on his/her environment. Smoking friends and family members increase the chance that someone will take up the habit. However, a predisposition for nicotine addiction does not mean that somebody will also become addicted or remain addicted. Smokers who have a genetic disposition can still stop smoking, although they probably belong to the group who finds it hardest to quit, according to the NWO and ZonMw (Netherlands Organisation for Health Research and Development), in its programme Addiction, for which Jacqueline Vink's study was undertaken.

Details: jm.vink@psy.vu.nl

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Acquisition moves firm to ‘big league’

In 2005, Smiths Group is expected to complete its recently announced acquisition of Medex Inc, a leading supplier of infusion equipment for critical care, specialising in intravenous catheters that prevent needle-stick injuries - all high-ly complementary to Smiths own products. Medex also sells to the current management team in the US, with operations in Ohio, Connecticut and Georgia, and plants in Mexico, Germany, Italy and the UK. Medex employs around 2,000 people. Dominick Arena, president & CEO, and the senior management team, have agreed to remain for at least a year after completion. Integration teams will deliver sales, operational and administration synergies quickly, once Medex becomes part of Smiths Group, the latter reports.

For 12 months to 31 December 2004, Medex is expected to achieve sales of $130m, an underlying operating profit of $75m and EBITDA of $100m. For nine months to September, Medex reported underlying operating profit of $59m and pre-tax profit of $39m. The company was formed through an MBO by its current management team in February 2001 from Saint Gobain and was also depressed by a number of non-recurring charges, including $18m relating to one-off acquisition costs. The businesses have, on a pro forma basis, delivered strong underlying sales growth and cash generation over the past three years, Smith's reports.

Two thirds of Medex’s sales are of intravenous catheters. The product range incorporates devices that help prevent accidental injuries caused by ‘sharps’ that remain exposed after use – which align with the Smiths Needle-Pro range of safety devices. Other product lines include pre-packaged trays of single-use products for catheterisation procedures, similar to Smith’s kits for anaesthesia applications. Medex also makes advanced syringe pumps that incorporate medication error detection, while Smiths points out that it supplies ambulatory infusion pumps worldwide.

Smiths Group’s chairman, John Stirling, said, ‘The acquisition of Medex is the next major step in our strategy to increase our presence in the critical care markets. This acquisition fits very well with our core competence of producing high-quality devices that help doctors care for their patients.’

Another Seca launch

seca Vogel & Halke GmbH & Co KG, Hamburg, has launched the seca 709, which the firm describes as ‘...a sturdy column scales, designed for a long service life in professional use. The mechanical column scales (approval class II) displays measured weights up to 200 kg max. in 100 g steps. The catch on the moving beam facilitates speedy weight determination and the results are easy to read, due to high-contrast, screen-printed numbers on the scales. As the moving beam can be attached on both sides, it is possible to position the scales and operating facilities facing a patient or someone standing in front of the scales.’

This new product is identical in construction to the seca 710 but weights are measured in 50 g steps - an indispensable fine graduation when weighing children and dialysis patients.

SECAMAGazine, May 2005
Cross-border sales for IT healthcare systems?

As EU healthcare providers increase their IT spending, Mark Simon outlines the problems and potential market for small to medium sized firms in this field.

Prospects in the healthcare IT sector for small and medium-sized enterprises (SME) have never been better. This is not a widely held view among such companies in Europe, but I believe that the facts speak for themselves.

From the SMEs’ viewpoint, the implementation of IT systems in healthcare cannot just be a matter of research and product development: ‘if we build it, they will buy’. At a national level, competition is significant in all kinds of medical IT applications at a national level. For an ambitious SME, the problem is how to create a genuine Europe-wide market for its innovative healthcare products.

An analysis of the healthcare IT market has seen a shift in the philosophy of the healthcare IT industry, characterised by three specific trends, which will be familiar to observers of IT in other sectors:

- Healthcare providers are rather more interested in integrated IT solutions than they are in separate products.
- More successful SMEs tend to exploit their core capabilities and try to network with other partners or subcontractors who provide complementary competences, and systems integrators are vital to enable the market to mature. They bring their industry-wide expertise in integration to combine existing with next-best-in-breed applications through interface engine and similar systems.
- European healthcare providers, being (at least commercially) non-competitive and non-profit organisations, have well-established low-to-medium margins with little room for IT investments. In addition, the absence of deadline culture turns decision-making into a time-consuming effort, particularly since the state-of-the-art solution may change during the decision process. With this challenging background, SMEs face the following problems - and opportunities -

SMEs frequently develop products that address customer tailored or country specific needs. Having to adapt the application to international practices implies enormous investments, and national language support alone is not enough - and not practical in many cases at the moment - since culture and practice differences can be substantial. However, in the healthcare IT market, SMEs have specialist knowledge with which a multi-national company struggles to compete. Specialist knowledge, as well as knowledge of local practice, is a huge asset that SMEs are uniquely well-placed to provide.

Downsides for healthcare providers in choosing SMEs include the supposed greater commercial risk. Where will the business be in two years’ time? Prospective customers want to know that the SME is well managed, financially strong and can give strong product support. Healthcare providers have the answer in their hands here by ensuring that their SME suppliers are properly motivated and paid as committed for work done, to ensure the perennial issues of cash do not catch a smaller business out.

Healthcare providers looking at potential SME suppliers frequently have the muscle to bring down prices. It is vital that they do not ‘throw the baby out with the bathwater’ by failing to compensate a small company sufficiently to ensure that it remains capable and focused on its project. If properly motivated, an SME is likely to be much more dedicated to the success and ‘referencability’ of the project. That said, do not expect SMEs to do things they cannot do - for larger ‘service managed’ solutions, healthcare providers probably need a systems integrator to ensure the satisfactory service level or management.

Finally, as an SME grows, its success will become apparent and draw the attention of multi-national competitors. However, when bought out by such a larger concern, innovation often diminishes because research and development becomes removed from the local markets. Healthcare SMEs must thrive by embracing standards, systems integration with other systems and focusing on being ‘best of breed’ providers of their specialty application.

Healthcare is very much about people and human diagnosis is rarely done remotely. Software, similarly, is best done at a very human scale - making SMEs (or similar, small groups) the best home for such healthcare innovation.

The UK’s NHS National Programme for Information Technology (NPfIT) is not only the world’s largest IT programme (value: around 9 billion euros), it is also an important opportunity and revenue-generator for SMEs. And there are important deadlines to meet, which makes England an interesting and historically atypical IT environment.

Without a doubt, healthcare is a fantastic market for SMEs to be in. With few exceptions, every European country is in the throes of increasing its spending in healthcare IT. Everyone needs patience - we all need to be winners!

Mark Simon, CEO, UK-owned ComMedica
ComMedica Limited, Hollywood House, Church Street East
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Results may vary. Data on file.
When people lie, different parts of their brains are used than when they tell the truth, and these brain changes can be measured by Functional Magnetic Resonance Imaging (fMRI), according to a study presented today at the annual meeting of the Radiological Society of North America (RSNA). The results suggest that fMRI may one day potentially be used as a lie detector than the polygraph.

‘There may be unique areas in the brain involved in deception that can be measured with fMRI,’ said lead author Professor Scott H Faro MD, vice-chairman of radiology and director of the Functional Brain Imaging Centre and Clinical MRI at Temple University School of Medicine in Philadelphia. ‘We were able to create consistent and robust brain activation related to a real-life deception process.

The researchers created a relevant situation for 10 normal volunteers. Six of the volunteers were asked to shoot a toy gun with blank bullets and then to lie about their participation. The non-shooters were asked to tell the truth about the situation. The researchers examined the individual with fMRI, while simultaneously administering a polygraph exam. The polygraph measured various physiologic responses: respiration, blood pressure and galvanic skin conductance, or the skin’s ability to conduct electricity, which increases when an individual perspires. The volunteers were asked questions pertaining to the situation, along with unrelated control questions. In all cases, the polygraph and fMRI accurately distinguished truthful responses from deceptive ones. During deception, fMRI showed activation in several brain areas: in the frontal (medial inferior and pre-central), temporal (hippocampus and middle temporal), and limbic (anterior and posterior cingulate) lobes. During a truthful response, the fMRI showed activation in the frontal lobe (inferior and medial), temporal lobe (inferior) and cingulate gyrus.

Overall, there were regional differences in activation between deceptive and truthful conditions. Furthermore, there were more areas of the brain active during the deception process compared with the truth-telling situation.

‘This is the first time to use polygraph correlation and a modified version of positive control questions in conjunction with fMRI. It is also the first to involve a real-life stimulus,’ he believes this is a vital approach to understand this very complex type of cognitive behaviour. The real-life stimulus is critical if this technique is to be developed into a practical test of deception,’ he pointed out.

Because physiologic responses can vary among individuals and, in some cases, can be regulated, the polygraph is not considered a wholly reliable means of lie detection.

According to Professor Faro, it is too early to tell if fMRI can be ‘fooled’ in the same way. However, these results are promising in that they suggest a consistency in brain patterns that might provide better control.

‘We have just begun to understand the potential of fMRI in studying deceptive behaviour. We plan to investigate the potential of fMRI both as a stand-alone test and as a complement to the polygraph with the goal of creating the most accurate test for deception,’ he added.

Co-authors: Feroze Mohamed PhD, Nathan Gordon MD, Steve Plunk PhD, Mike Williams MD, and Harris Ahmad MD.

\[Image 43x1061 to 183x1126\]

\[Image 349x63 to 492x83\]

\[Image 351x199 to 491x264\]

\[Image 504x578 to 645x742\]

\[Image 662x931 to 842x1081\]

\[Image 39x1137\]
Results of a study from Australia, published in The Lancet (p. 2038, 4-10 December 2004 issue) offer reassurance as to the safety of repeated ultrasound examination during pregnancy. Ten years ago a randomised trial highlighted how repeated ultrasound exposure, five different times during pregnancy, was associated with growth restrictions among newborn babies compared with children exposed to only one ultrasound examination in utero. The current analysis provides long-term follow-up data on the growth and development of children from the original study. Physical and developmental assessments were done at 1, 2, 3, 5, and 8 years of age on children born without congenital abnormalities and from singleton pregnancies. Follow-up data were available for around 2700 children, half of whom had been exposed to repeated ultrasound, the other half to one ultrasound exposure before birth. Physical sizes of infants were similar in the two groups from one year of age onwards. There were no significant differences indicating deleterious effects of multiple ultrasound studies at any age as measured by standard tests of childhood speech, language, behaviour, and neurological development.

Lead investigator John Newnham (University of Western Australia at King Edward Memorial Hospital, Perth) said: ‘Exposure to multiple prenatal ultrasound examinations from 18 weeks’ gestation onwards might be associated with a small effect on foetal growth but is followed in childhood by growth and measures of developmental outcome similar to those in children who had received a single prenatal scan.’

Details: Professor J P Newnham: jnewnham@obsgyn.uwa.edu.au

No long-term harm from repeated prenatal US

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ICU delirium

By Dr E Wesley Ely MPH, FCCM, of Vanderbilt University Medical Centre, Nashville, Tennessee, and the VA Geriatric Research Education and Clinical Centre (GRECC)

Every day, over 50,000 patients in intensive care units suffer delirium, an acute brain dysfunction - and cases are increasing annually due to our aging population. Yet most doctors, nurses and other health-care providers miss the condition.

Traditionally, the dysfunction is called ‘ICU Psychosis’, and professionals have not thought it clinically significant.

However, using well designed and validated tools in the ICU, researchers have shown this to be an independent predictor of longer stay, a three times higher risk of death within six months of ICU stay, a ten times higher risk of delirium, and validated tools in the ICU, a six times higher risk of worsening long-term cognitive function among survivors. Doctors and nurses can perform a 30-50 second evaluation with the Confusion Assessment Method for the ICU (CAM-ICU) at a patient’s bedside to tell when someone has delirium. The Society of Critical Care Medicine recommends the tool for routine clinical management and thousands of ICUs around the world are now implementing routine monitoring for delirium. The CAM-ICU has been translated into eight languages and all materials are available free, including instruction videos and pocket cards.

Unfortunately, most patients are still not monitored for the condition. There are things which doctors, nurses, and other healthcare providers can do to attempt to prevent or reduce delirium, but they will not be considered on a regular basis unless these health-care providers recognise the problem in the first place, by using some form of monitoring. Some methods to prevent and/or treating delirium include attention to oxygen levels, correction of salts and other metabolic abnormalities, treating infections with antibiotics, giving specific medications for seizures, which treat its underlying pathophysiology, might help (but this needs testing), improving the dosage of sedative and analgesic medications, considering using different/newer sedative techniques/drugs, and even giving antipsychotic medicines, like haloperidol or atypical antipsychotics to treat the delirium. Also, early mobilisation, timely removal from mechanical ventilation, re-orientation, having family present to help re-orient a patient, and helping to restore regular sleep can help.

Ongoing clinical trials are now exploring the safest and most effective ways to prevent and treat ICU delirium in hopes that such treatments will not only reduce delirium but also the high morbidity and mortality associated with it.

Further details: www.icudelirium.org

News

Emergency Care·Perioperative Care·Critical Care·Perinatal Care·Home Care

Newly defined predictor of death can be routinely monitored

By Gregory B. Wells, MPH, MBBS, and Barry B.traub, MD

A newly defined predictor of death in patients with severe sepsis has been identified, and can be routinely monitored.

The predictor, called ‘ICU Psychosis’, has been shown to be an independent predictor of longer stay, a three times higher risk of death within six months of ICU stay, a ten times higher risk of delirium, and validated tools in the ICU, a six times higher risk of worsening long-term cognitive function among survivors. Doctors and nurses can perform a 30-50 second evaluation with the Confusion Assessment Method for the ICU (CAM-ICU) at a patient’s bedside to tell when someone has delirium. The Society of Critical Care Medicine recommends the tool for routine clinical management and thousands of ICUs around the world are now implementing routine monitoring for delirium.

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Further details: www.icudelirium.org

Evolutionizing the Point of Care

Since its introduction in March 2001, the modular platform of the Servo® has continuously been extended with new software functions, the manufacturer Maquet reports. The new version now supports both NIV and suction procedures, and much of the new functionality is also available with the Servo® ventilator. NIV supports ventilation in Pressure Control and Pressure Support modes. NIV is supported with an effective leakage compensation, thus maintaining the pressure set to the patient. Leakage compensation is continuously adaptive, thanks to a high sampling rate and adjustment during breathing rather than after each breath. This highly-responsive NIV function ensures a minimum breathing rate in case of an apnoea and maintains the set Inspiratory pressure and PEEP.

“10 to increase patient comfort when introducing a mask, ventilation can be started either manually or by patient trigger, and any disconnects are detected automatically. In addition, the user can choose to silence a number of alarms, so that patients are not unnecessarily confronted by
ICM researchers awarded

Berlin, Germany - At the 17th Annual Congress of the European Society of Intensive Care Medicine, this October, the Society’s International Sepsis Forum Award was presented to J D Chiche (France), for his poster presentation: ‘Prevalence and consequences of the R753 polymorphism of the toll-like receptor 2 in ICU patients.’

The 2000 euros awards were presented to F M Porta (Switzerland), for the presentation ‘Endotoxamia-induced mitochondrial dysfunction: Effects of dopamine and dobutamine’ and to I Morales (Belgium) for ‘Factors influencing sensitivity and specificity of the surveillance of ICU-acquired infections’.

Free registrations for the ESICM Amsterdam 2005 congress were awarded to the following researchers and their listed presentations:

- S M Lewis (UK), ‘Abnormal expression of adhesion molecules on polymorphonuclear in systemic inflammation’
- S Pedersen (Denmark), ‘Evaluation of pre-hospital triage criteria: A prospective study at Aarhus trauma centre’
- M M G O Garroust-Orgeas (France), ‘ICU admission procedures in patients over 80 years and one-year outcome and quality of life’
- V N Kuklim (Norway), ‘Tezosentan-induced attenuation of lung injury is associated with blockade of protein kinase C’
- B Montag (Germany), ‘Immunoparalysis in severe sepsis resolves after CMC CFS: A double-blind, randomised controlled trial’
- P Wellhoener (Germany), ‘Severe metabolic alterations in adipose tissue during early endotoxemia in humans’

The ESICM is an international non-profit-making association of doctors, nurses, physiotherapists and other allied healthcare professionals, with a membership of about 3000 doctors, nurses, physiotherapists and other related healthcare professionals.

The 18th Annual Congress of the ESICM will take place during 23-28 September 2005, in Amsterdam, The Netherlands. Abstract submission deadline: 15/4/05.

Details: www.esicm.org

13th Winter Symposium on Intensive Care Medicine

Gstaad, Switzerland - Enthusiasm is certainly a characteristic of ICM symposia. ‘A meeting in the snow may seem just like a good opportunity to enjoy some skiing, snowboarding, après-ski ... often with the added benefits of having some financial support from one’s hospital, the industry, etc, and being able to deduct any expenses from income tax!’ say Peter M Suter* and Jean-Louis Vincent* (below), who have organised the meeting for 14 years in leading Swiss and US resorts.

However, sessions will be held between 8.10.30 a.m. and again between 4.30-8.m. presenting, in 6 hours daily, a broad spectrum of intensive care topics, including management of brain injury, the latest sepsis therapies, present and future monitoring techniques, alternative mechanical ventilation modalities, liver and renal support, and delirium and sedation. ‘This meeting will be characterised by short, crisp presentations with plenty of time for discussion, and will also use other formats such as pro/con debates, round table discussions, etc. to make the sessions as lively and interactive as possible,’ they add.

‘It is not cerebrally possible to absorb more than a certain quantity of information per day; breaks are a welcome and necessary part of any meeting,’ the organisers point out. ‘Our conference rooms are full every morning and evening, with some participants even arriving for the evening session with their snow boots still on so that they do not miss any of the first talk!’

Participants come from about 20 countries, including Brazil, Japan, China, Malaysia, South Africa, all European countries, and North America, with the English language used at the sessions.

Early booking is advised, because numbers are limited to 120 annually.

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Heart-lung machines - the future

Leipzig - When over 2,700 cardio and thoracic surgeons met for the 3rd Joint Meeting of the European Association for Cardio-Thoracic Surgeons (EACTS) and the European Society of Thoracic Surgeons (ESTS), the hot topic was the use of drug-eluting stents - considered less invasive than minimally invasive surgery (MIS).

This, and the stagnation of operating theatre figures, is of particular concern to the industry, because there is, says our correspondent Holger Zorn, ‘hardly any money in standard products.’ He recently spoke with Frank Wolff, Director of Sales and Marketing Cardiovascular of the Sorin Group, about this, the firm’s position in the field, and its new products.

The Sorin Group has four divisions: CardioSurgery, Cardiac Rhythm Management, Vascular Therapy and Renal Care. ‘We made some strategic acquisitions recently which strengthened our position and which means that we can offer what the market needs,’ says Frank Wolff, explaining that he firm produces more than the heart-lung machines (HLM) for which it is known worldwide.

H2. Your main competitor for HLMs is Jostra AG, which merged with the Swedish Getinge Group about a year ago, so Jostra can now offer complete operating theatre (OT) solutions. Your company sells single pieces of equipment. Meanwhile, Terumo, another manufacturer in this field, is due to launch another new product in Europe. How do you perceive these challenges?

Frank Wolff: Our company is one of the oldest manufacturers of heart-lung machines. Worldwide, two in three HLMs were made by us. In Germany, the market share is between 70-80%. And obviously we also develop new products. We will present our latest model at the cardio surgeons’ congress in Hamburg in February 2005. Today, the development of HLMs is so advanced that they are extremely reliable and safe, and major technical changes are not necessary. But there is always room for improvement in terms of user-friendliness: handling needs to be more intuitive, the user should be able to program more functions himself. Roll pumps, tried and tested for many years, will have the same fate. A new generation or generation 3 or 4 will be a standard risk de novo lesions. The objective at two-year follow-up was to evaluate the durability of the same, as has shown the substantial trials of anti-restenotic drugs. But scientific began the TAXUS clinical study programme in 1997. Promising results from pre-clinical and clinical studies with Paclitaxel have shown that it reduces restenosis.

At the Transcatheter Cardiovascular Therapeutics (TCT) 2004 meeting, in Washington, the two-year clinical results of TAXUS Stents were reported. UK-based medical journalist David Barrow summarises research.

The incremental benefits of having received the TAXUS stent rather than a bare metal stent continued to increase, with no evidence of late catch-up apparent, said Gregg W Stone MD, Columbia University Medical Centre, New York and Cardiovascular Research Foundation, New York, USA.

Presenting the two-year results of the clinical trials of the TAXUS IV Trial, Dr Stone revealed a MACE rate of 14.7% vs. 24.8% in the control arm of this, the pivotal US study of the slow-rate release polymer-based Paclitaxel-eluting TAXUS stent in patients with De Novo Coronary Lesions. In addition there were 1.8% myocardial infarction, 5.6% target lesion revascularisation, 10.6 target vessel revascularisation, and 14% target vessel failure (Table 1). Reviewing the results, Dr Stone said: ‘When we look at the data, treatment with TAXUS stent markedly reduces clinical restenosis, resulting in reduced rates of bypass graft surgery and repeat percutaneous intervention. These favourable results apply in a wide range of complex patients and lesions, including small vessels, long lesions, and patients with diabetes.’

However, stent thrombosis may rarely occur (after 1 year), possibly in part related to inadequate anti-platelet cover.

H3. TAXUS IV Study Design TAXUS IV is an international trial studying 1,314 patients undergoing elective stenting of single de novo lesions coverable by 1 stent at 73 sites in the USA. Eligible patients had single de novo lesions between 10 and 28 mm covered by one stent in vessels that were, by visual examination, between 2.5 and 3.75 mm in diameter. Patients were randomly assigned before pre-dilatation to either a 1 mg/m2 slow-release Paclitaxel-Express (TAXUS) stent or a bare-metal Express stent (both made by Boston Scientific Corp., Natick, Massachusetts). Patient enrolment was given for six months after the procedures.

Patients excluded from the trial included those with planned or prior PCI or brachytherapy in the target vessel, those in whom there was planned use of an atherectomy or cutting balloon device, those who had failed MI within 72 hours or who had CK-MB levels greater than two times the upper limits of normal on the day of stenting and those with excess tortuosity or calcification of the vessel, total occlusion, probable or definite thrombus, bifurcation lesions, or initial TIMI flow of 0 or 1. The primary end-point was the nine-month rate of ischaemia-driven target vessel revascularisation.

Baseline clinical features and target vessel distribution were well balanced across groups. Importantly, as previous studies have, failed to determine the benefits of drug-eluting stents in this subgroup, 22% of the control group and 23.4% of the study group were diabetic (p=NS), with 8.3% and 7.7%, respectively, requiring insulin therapy. Similarly, baseline angiographic characteristics were similar and restenosis rates excellent in both groups, as expected.

Two-year follow-up results of the TAXUS II Trial were presented for the first time at TCT 2004. The ran-
the Paclitaxel-eluting stent

cular responses after successful treatment with drug-eluting stents. Recent results from matched sub-study patients, Dr Colombo said: ‘The in-stent minimum lumen diameter (MLD) was stable over time (TAXUS SR: 2.32 ± 0.39 at 6 months versus 2.32 ± 0.45 at 2 years; TAXUS MR: 2.34 ± 0.38 at 6 months versus 2.35 ± 0.37 at 2 years). These numbers compare with 1.96 ± 0.47 at 6-months and 2.12 ± 0.44 at two-years (in the control arm).’ Dr Colombo also reported stable late loss in the matched subset overcome and a significant benefit in Percent Volume Obstruction first reported at six-months had been maintained out to two-years. (See Chart 1)

Dr Colombo summarised: This study demonstrates a very durable (stenosis = 50% by ultrasound and angiography) or asymptomatic (stenosis = 80% by ultrasound, 60% by angiogram). The target seg-

ment reference diameter was = 4.00 mm and = 9.00 mm with a lesion length of < 30 mm. The vessel diam-

distal to the target lesion was = 3.5 mm and = 5.5 mm as an optimal Wire landing zone. Patients who were classified as being ‘surgical high-risk’ due to an anatomic risk and/or co-morbid risk were sum-

marised in an accompanying table. Measuring 30 mm in length and manufactured from self-expanding Nitinol, the closed cell rolled sheet designed NexStent was mounted on a 5 F over the wire catheter. It has a self-

tapering tip of 4-9 mm in length. The second device used in the registry is the FilterWire E/EXZ. Suitable for use in vessels 3.5 - 5.5 mm and mounted on a monorail delivery system the filter device is suspended on a radiopaque nitinol loop. It is capable of a 0.014’ guide wire. The filter poor size is 110 microns.

David Barrow also attended the most recent American Heart Association (AHA) meeting, in New Orleans, and here reports on the SIRTAX trial: A randomised comparison of a Sirolimus- with a Paclitaxel-eluting stent for coro-

nary revascularisation. Results of the SIRTAX trial, a head-to-head comparison of two drug-eluting stents, CYpher and TAXUS, show that although there were no significant differences in the individual primary endpoints of cardiac death, myocardial infarc-
tion and target lesion revascularisation at 6-months follow-up, there is a suggestion that there may be a difference in longer-term outcome. Relative to Paclitaxel-eluting stent, treatment with sirolimus-eluting stents resulted in improved out-

comes in terms of cardiac death (0.4% vs. 1.6%), Q-Wave MI (1.4% vs. 2.6%), target lesion revascularisation (3.2% vs. 4.7%) and target vessel revascularisation (3.4% vs. 5.5%).

Presenting the results of this ran-
domised, single-blind, two-centre study (Bern and Zurich, Switzerland), Dr Stephan Windecker noted that only extend-
ed clinical and angiographic fol-

low-up will determine whether there are any differences between the two drug-eluting stents in their ability to prevent restenosis. The objective of the present study was to compare the clinical and angiographic efficacy of SES and PES in a prospective, randomised, two-centre clinical trial funded by an institutional grant. Describing the study, Dr Windecker explained that between March 2003 and April 2004, a total of 1012 patients undergoing PCI were randomly assigned treat-

ment with SES (503 patients) and PES (509 patients). Patients with stable or unstable coronary artery disease and presence of one or more lesions with a diameter steno-
sis>50% and a reference vessel diameter ≥2.25 and ≤3.5 mm which could be covered with one or more stents of 8-13 mm length were eligible for the study. Patients are followed for major adverse car-
diac events (MACE) including car-
diac death, myocardial infarction, and target lesion revascularisation (TLR) at 30 days, six months, one year, 2, 3, 4, and 5 years. Angiographic measures of restenosis are in-lesion and in-segment late luminal loss measured eight months after the index procedure. Both treatment groups were well matched with respect to clinical and angiographic baseline characteristics. Procedural results, in-hospital MACE, and MACE at 30 days and 6-months are summarised in Table 3.

Coronary revascularisation with SES and PES appears safe and effec-
tive. There are no significant differ-

ces between SES and PES with respect to procedural outcome and clinical events up to 6-months. Extended clinical and angiographic follow-up will become available during the upcoming months and scheduled for presentation at ACC 2005 in Orlando, USA.

### Table 2: TAXUS & Two-Year MACC Rates

<table>
<thead>
<tr>
<th></th>
<th>Combined Control</th>
<th>TAXUS SR</th>
<th>TAXUS MR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=264)</td>
<td>(n=127)</td>
<td>(n=127)</td>
</tr>
<tr>
<td>TVR</td>
<td>15.5 (41)</td>
<td>5.5 (7)</td>
<td>3.9 (5)</td>
</tr>
<tr>
<td>TVR, non-TLR</td>
<td>4.9 (13)</td>
<td>3.1 (4)</td>
<td>3.1 (4)</td>
</tr>
<tr>
<td>CABG</td>
<td>3.8 (6)</td>
<td>3.9 (5)</td>
<td>2.4 (3)</td>
</tr>
<tr>
<td>TLR</td>
<td>19.7 (52)</td>
<td>11.8 (15)</td>
<td>9.4 (12)</td>
</tr>
<tr>
<td>Q Wave</td>
<td>11.3 (2)</td>
<td>8.0 (1)</td>
<td>2.4 (3)</td>
</tr>
<tr>
<td>MI</td>
<td>4.5 (12)</td>
<td>3.1 (4)</td>
<td>2.4 (3)</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>1.1 (3)</td>
<td>0.8 (1)</td>
<td>0.8 (1)</td>
</tr>
<tr>
<td>Total MACE</td>
<td>24.6 (65)</td>
<td>14.2 (18)</td>
<td>14.2 (18)</td>
</tr>
<tr>
<td>% patients (absolute numbers)</td>
<td>NS</td>
<td>0.0047</td>
<td>0.0006</td>
</tr>
</tbody>
</table>

### Table 3: SIRTAX trial

<table>
<thead>
<tr>
<th></th>
<th>SES</th>
<th>PES</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>76%</td>
<td>78%</td>
<td>0.3</td>
</tr>
<tr>
<td>Male Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart Rate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In hospital MACE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0%</td>
<td>0%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Q wave MI</td>
<td>0%</td>
<td>0%</td>
<td>1.0%</td>
</tr>
<tr>
<td>NON-WMI</td>
<td>1.0%</td>
<td>1.2%</td>
<td>0.8</td>
</tr>
<tr>
<td>TLR</td>
<td>0.8%</td>
<td>0.6%</td>
<td>0.7</td>
</tr>
<tr>
<td>MACE at 30 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0.2%</td>
<td>0.1%</td>
<td>0.1</td>
</tr>
<tr>
<td>Q wave MI</td>
<td>0.8%</td>
<td>0.6%</td>
<td>0.7</td>
</tr>
<tr>
<td>NON-WMI</td>
<td>1.4%</td>
<td>1.6%</td>
<td>0.8</td>
</tr>
<tr>
<td>TLR</td>
<td>2.2%</td>
<td>1.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>MACE at 6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0.4%</td>
<td>1.6%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Q wave MI</td>
<td>1.2%</td>
<td>0.8%</td>
<td>0.55</td>
</tr>
<tr>
<td>NON-WMI</td>
<td>1.4%</td>
<td>2.6%</td>
<td>0.26</td>
</tr>
<tr>
<td>TLR</td>
<td>3.2%</td>
<td>4.7%</td>
<td>0.20</td>
</tr>
</tbody>
</table>

### Device Performance

<table>
<thead>
<tr>
<th></th>
<th>Success Rate</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful Stent Delivery</td>
<td>99.3%</td>
<td>99.4%</td>
</tr>
<tr>
<td>Device Success</td>
<td>98.0%</td>
<td>98.6%</td>
</tr>
</tbody>
</table>

Data from presentations at ACC 2005 in Orlando, USA.
The International Trade Fair and BioAnalytica Business Conference 5-7 April 2005 Venue: New Munich Trade Fair Centre

Biotechnology is a relatively new branch of industry. According to Ernst & Young’s reports on this industry, covering 2004, the German biotech sector is still in the process of consolidating, after experiencing a boom during the past decade. However, it reported that tensions might not be easing. After the biotech euphoria, the stock-exchange boom and subsequent cleansing of the market, companies now appear more mature and are far more efficient in the market. In part, this, in turn, is creating new trust in the venture-capi-
tal community. According to Ernst & Young, a growing number of new biotech and pharmace-
tica have companies that have begun to manage and consider possible synergies in recent months. Analysts at the auditing and consult-
ing company reported: ‘During the first half of 2004, 141 million euros - 52% of all risk capi-
tal, were invested in biotech and pharmaceutical companies.’ So it comes as no surprise that experts of this sector are forecasting moderate growth for the next few years. BioAnalytica 2005, say the fair’s organis-
ers, will use its exhibition concept to actively promote this upward trend.

This event is also very new. However, in 2003, during the first BioAnalytica, about 5,000 visitors from many countries visited, to gain knowledge of new development and applications in biotechnology and the life sciences, with 270 exhibiting companies originating from 14 countries. Klaus Dittrich, Managing Director of Munich Trade Fairs International, which is organizing the key event for the biotech industry and its suppliers, reports that the event will have three main focal points, to lend structure to the various and diverse growth markets: to illustrate current and future market potential; to explore current and future market potential; to have professional exhibits at the event at affordable prices. The fair will also feature a special exhibition section for startups, technol-
yogy centres, universities and bioregions. The banner for this area will be Minimum invest-
ment - Maximum communication, and it will be set up like a meeting lounge. For 500 euros, companies will be able to book space called ‘demopoint’, where there will be suf-
ficient space for posters, company logo, brochures and presentation equipment. The lounges will also have mailing facilities for dis-
cussions with business associates and cus-
tomers, or for participation in the forum. This new exhibition section has been named BioAnalytica Marketplace - Life Sciences Meet Business. The idea behind this is that posters for posters, a company logo, brochures and pre-
sentation equipment.

To successfully address biosclusters in northern and eastern Germany, but will also address biotech and bio-analysis networks in the new EU member states Austria, Hungary, Slovakia, the Czech Republic and Poland. Networking - Although biotech companies are increasingly moving product-oriented, in many cases, conducting research and development or pro-
siding services.

The fair’s organisers point out, ‘According to the latest Biotechnology Year and Address Book 2004, 141 million euros - 52% of all risk capi-
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...
The Integrating the Healthcare Enterprise project

Setting up an IHE transnational committee

The 22nd International Conference of the European Association for the Picture, Archiving and Communication Systems Association (EuroPACS), combined with the Management in Radiology Conference (MMIR), held in Trieste this September, aimed to discuss and propose innovative and organisational solutions for the integration of the health systems in the enlarged Europe (supporting the approach to the patient). This ranges from beginning in radiology departments, then moving towards the integration of the entire healthcare enterprise. The conference has been partially supported by the Central European Initiative (CEI).

As the conference organiser, and its President, with radiologist Professor Roberto Pozzi Mucelli, I encouraged discussion around some key points and strategies already successfully experimented on in our laboratories at the University of Trieste - thanks to 13 years research work in this field.

The core of our experience is a Data & Picture Archiving and Communication System (DPACS). This was designed in 1995 and implemented, at that time, in the Trieste Province, and is now present as ‘PACS 2004’, an IHE-compliant, Java-based, Open-source Modular System that can store and manage any type of data (radiology, cardiology, clinical laboratory, homecare, etc.), in a citizen-centred vision of health management in the future. Java assures independence from the hardware platform (Unix computer, pc, palm, etc) and from the used operating system; Open-source assures the push and diffusion of e-health both in the industrialised world and in transitional countries, such as European central-eastern countries. Full complicity with the Integrating the Healthcare Enterprise (IHE) project assures interoperability at local, regional and transnational levels.

To work with DPACS 2004, we developed the HTL Dicom Workstation (HDW), which is a modular IHE-based application, written in Java, working as a DICOM and HL7 client, and with some special characteristics, such as management and visualisation of a wide range of DICOM modalities including Structured Reporting and Waveforms for cardiology, neurology, etc.) and wide scale configurability, e.g. referring WS for radiology specialist, reports and images visualisation WS for the general practitioner, anonymous search & visualisation WS for education, etc.

Finally, to allow wide integration of hospitals and territorial bodies at any level, Virtual Integrator of the Electronic Health Record (Vi-HER), based on XML/XSLT technologies, completes the DPACS family: information is collected on demand from different and potentially heterogeneous sources, which perceive the Vi-HER as one of their clients. The physician or the public, are able to select and retrieve part of the data, when and where needed for a particular care, welfare or emergency situation. Access to the Vi-HER is possible in multiple ways, devices and communication means, both fixed and mobile. All necessary concerns for security and protection are considered, and addressed mainly by sets of static and dynamic policies and rules.

Thanks to the experience made with DPACS 2004, we have been able to propose, at the end of a very intensive IHE workshop at the conference, the creation of a European transnational IHE committee, under the umbrella of the Central European Initiative (CEI), with the task of proposing technical, legal and harmonisation solutions for real e-health integration in the enlarged Europe, which is characterised by several languages, different economics and multiple uses and legislations. This European committee is now being set up, with an extension from the 17 CEI countries to the three Baltic countries, Greece and Russia.

Tapping in to e-health

Ministers of the EU member states, acceding and associated countries, as well as the EC and NE regions, met in May 2003, during the eHealth 2003 conference (organised jointly by the European Commission and the Greek Presidency of the Council Ministers). At that meeting the participants expressed their commitment to the development of the national and regional eHealth implementation plans as an integral part of eEurope 2005, and declared their willingness to work together towards best practices in the use of information and communication technologies as tools for enhancing health promotion and health protection, as well as quality, accessibility and efficiency in all aspects of health care delivery.

‘eHealth refers to the use of modern information and communication technologies to meet the needs of citizens, patients, healthcare professionals, healthcare providers and policy makers. European countries devote an increasingly high percentage of their GNP to healthcare (7%-12%). Therefore, efficiency becomes a key issue in healthcare policies: ‘Maximising the output that one gets from given quantities of inputs’.

Our Spanish Correspondent, Dr Eduardo de la Sota, met with Eduardo Susanna, director of Netdoctor.es to discuss the development and aims of this service in Spain.

‘Netdoctor,’ Eduardo Susanna explained, ‘is Europe’s leading, technology-driven, healthcare communications company, which improves health outcomes by breaking down the “medical language barrier” by presenting evidence-based medical information in a clear and understandable way so that the patients are empowered. We have demonstrated that the Netdoctor’s innovative approach to patient awareness can positively impact patient behaviour.

‘We also recognise that this new patient will place more demand on the healthcare system so we are committed to applying our technology and medical expertise to develop programmes to support clinicians, payers and other healthcare organisations in meeting these challenges.’

‘Netdoctor’s philosophy, strength and resultant success is derived from our close collaborators: committed physicians, healthcare professionals, information specialists and patients who believe that best medical practice should be based on quality information and evidence-based medicine. Today, 60 Spanish leading experts and specialists are involved in Netdoctor Spain. Our editorial independence and reliance on professional advice is our single most important asset. There is a clear distinction between the editorial and business staff. As a matter of policy our doctors, writers and editors are not allowed to be influenced or answerable to our sponsors or advertisers. We follow the same standards of practice as the leading medical journals.’

Asked what products are included in Netdoctor, Eduardo Susanna said: ‘Our portals and Communities provide a unique and powerful channel to reach health consumers. They consist of information and tools around diseases states and issues of key interest to healthcare consumers. We also provide patient-focused clinical software tools to help physicians achieve greater efficiency, especially in the area of chronic diseases.

In terms of innovative solutions, Eduardo Susanna said he believed that Netdoctor ‘partners primarily rely on Netdoctor for new ideas in healthcare marketing and healthcare products, such as emerging technology, new insights into, or ways to modify, patient behaviour, or innovative approaches to enhance the efficiency of healthcare delivery. ‘Specifically, Netdoctor intends to deploy new solutions that can impact on disease awareness and diagnosis rates, brand differentiation, retention, and loyalty, and compliance and concordance.’

For the present, he pointed out that Netdoctor recently signed an agreement with the Spanish online newspaper ‘abc’, a publication owned by the leading Spanish communications group Vocento. ‘We are now working together for future developments.’

By Professor Paolo Inchingolo, Director of Higher Education in Clinical Engineering (HECE) at the Health Telematics Laboratory (IHTL), University of Trieste, Italy, and President of EuroPACS-MIR 2004 in the Enlarged Europe.

Eduardo Susanna, Director, Netdoctor.es
Spain

Netdoctor.es

21st Korea International Medical & Hospital Equipment Show
March 17 – 20, 2005
COEX, Seoul, Korea
"KIMES 2005" will be exhibiting a variety of products and services with 20,000 exhibits.

Organizers: Korea E&X Inc., Korea Medical Devices Industrial Coop. Association, Korea Medical Devices Industry Association

Korea E & X Inc. / Tel: +82-2-551-0102 / Fax: +82-2-551-0133
E-mail: Kmkinfo@kimex.coistleadline.com / www.kimex.coistleadline.com
**Footwear inspired by Africa**

Masai Barefoot Technology (MBT), a revolutionary range of footwear, which re-establishes the natural conditions of standing and walking, the manufacturer Swiss Masai reports, adding: ‘This design has some remarkable effects. It improves posture, strengthens the back, in fact MBTs are recommended by orthopaedic and physiotherapy specialists across the world. It tones muscles and constantly works the legs, stomach and buttocks.’

‘All the principles of MBT have been verified by the Human Performance Laboratory at the University of Calgary, one of the world’s leading research centres on the body’s biomechanical movements.’

The footwear imitates the terrain the Masai walk on, turning hard and even surfaces, which we walk on every day, into the soft and natural ground of The Masai Mara, the firm explains. ‘This causes our muscles to work harder and become the natural shock absorbers they were designed to be, thus protecting our back and joints. Instead of a traditional heel, a heel sensor and pivot sole force us to balance and straighten up. With a more upright posture we not only look better but are healthier, and automatically stronger.’

Details: www.swissmasai.com

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**Lighter oxygen cylinders cut injuries**

The range of ultra-lightweight medical gas cylinders produced by Luxfer Medical aims to minimise occupational injuries associated with patient and equipment handling.

‘Risk Management issues in equipment handling remain high priority across Europe resulting in uncontrolled demand from healthcare specialists and managers keen to benefit from the physical and operational advantages associated with Luxfer Medical’s lightweight oxygen cylinders,’ explained Vicky Butler, the firm’s European Marketing Manager who has been liaising with medical managers keen to benefit from the equipment’s added safety and increased freedom and mobility.

‘The range of ultra-lightweight medical gas cylinders produced by Luxfer Medical aims to minimise occupational injuries associated with patient and equipment handling.’

Details: www.luxfercylinders.com

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**Emergency airway access kit**

The Portex Cricothyrotomy Kit (PCK) - which comes complete with all the equipment in compact, robust packaging and contains all items needed to establish emergency airway access - was designed specifically for use by clinicians in civil and combat situations.

Based on an innovative stylus needle design that confirms entry into the trachea and indicates any subsequent contact with the posterior tracheal wall, the firm reports that the device has a femto bore Cricothyrotomy tube that enables spontaneous breathing and a Portex Soft Seal cuff to secure the airway. At MEDICA, Smiths Medical also launched its Deltec Cosmo insulin pump into the German market. (Over 10,000 Deltec Cosmo insulin pumps have been sold beyond this device). This is part of the firm’s CozMore concept, which combines insulin pump therapy, blood glucose monitoring and personalisation of data management in just one system.

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**Safer archiving**

Digital data archiving is now a legal requirement in most countries, so survival of long-term storage is vital - particularly in hospitals.

A data safe manufactured by the German firm Lampertz and shown at MEDICA, had been tested for eight hours in a bush fire, raging at 1,200-1,400 degrees. The firm reported that the data was not damaged.

Details: www.lampertz.de

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**Clear and effective**

Aid to reduce backpain

The Staby, equipment developed by Andrea Burkhardt of S.W.H.C GmbH (www.staby.de) treats back pain by sending blood and oxygen into the injured area, removes waste products and toxins, strengthens the core muscles, and improves the efficiency of the nervous system. While positive results are quick to appear, regular use is recommended if you don’t want to return to your painful state. The experience of German physiotherapists indicates it can take as little as three weeks for problems to begin to reappear. The Staby offers an effective means to maintain a pain-free existence, without the expense of ongoing therapy, the firm pointed out.

‘The equipment looks like a plastic garden cane with rubber pieces attached to the centre and each end. To operate, you shake it forcibly a couple of times until momentum takes over. It then continues vibrating with only minimal movement of the arms needed - the key is keeping the abdominal muscles contracted. Relax these and the bar stops’. The user performs various exercises, against the vibrations, such as squat-thrusts and lunges.

Shock waves from the vibration through the body force it to work harder, the firm explained.

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**Clear and effective**

Binning at a distance of 20 cm, and as a 20 cm wide tube. A symbol clearly indicates in which direction the pouch should be peeled open. Blue Line pouches can be used when sterilising, with steam, formaldehyde, or ethyleneoxide. An indicator for each one of these sterilisation methods is printed on the front of the packaging - in common with the handling advantages of see-through packaging: the sterile goods can be packaged quickly and easily and are always visible.

The packaging is then sealed with the usual continuous sealing devices. When compared directly with packaging in crepe wrapping paper, it quickly becomes obvious that Blue Line is the more efficient and more economical solution. In addition, less space is needed for storage. To ensure easy opening, Blue Line pouches have a specially marked and shaped seal on both sides of the pouch, which can then be peeled apart from the corners - an advantage, particularly when packaging heavy weight objects. A symbol clearly indicates in which direction the pouch should be peeled open. Blue Line pouches can be used when sterilising with steam, ethylene oxide. An indicator for each one of these sterilisation methods is printed on the front of the packaging - of course, outside of the space filled by the object to be sterilised.

Blue Line comes in five different pouch sizes, from 27 x 36 to 57 x 72 cm, and as a 20 cm wide tube.

Details: www.vp-group.de

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**Clear and effective**

Medical Index GmbH, one of Germany’s leading manufacturers of X-ray protection garments, brightened many faces at the MEDICA this November, by launching this new design of non-lead protection material in bright, fresh colours. The garment has a new back support to take weight off the shoulders and prevent back pain, the firm reports, making it more comfortable. It is also light in weight and easy to clean, the manufacturer adds.

Details: www.medical-index.de

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**Clear and effective**

New breakthrough for healthcare hygiene regulations cover the disposal of soiled items in rubbish bins. A product named AutoBin, seen at MEDICA, features an integrated infrared sensor that opens the bin at a distance of 20 cm, ensuring touch-free rubbish disposal.

Details: www.saydameoel.de

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**Clear and effective**

Lighter oxygen cylinders cut injuries

The range of ultra-lightweight medical gas cylinders produced by Luxfer Medical aims to minimise occupational injuries associated with patient and equipment handling.

‘Risk Management issues in equipment handling remain high priority across Europe resulting in uncontrolled demand from healthcare specialists and managers keen to benefit from the physical and operational advantages associated with Luxfer Medical’s lightweight oxygen cylinders,’ explained Vicky Butler, the firm’s European Marketing Manager who has been liaising with medical managers keen to benefit from the equipment’s added safety and increased freedom and mobility.

‘The range of ultra-lightweight medical gas cylinders produced by Luxfer Medical aims to minimise occupational injuries associated with patient and equipment handling.’

Details: www.luxfercylinders.com

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**Clear and effective**

Easier monitor mounting

Ergotron specialists in ergonomically designed workstations and provides desk and wall-mounted TFT monitor mounts and mobile standing combinations. The firm’s new Neo-Flex arm, in silver metallic finish, has a sleek design and refined construction that makes TFT monitor positioning far more flexible and easy. Additional turn and slant functions allow the user to achieve an optimum visual angle, and the swivel function means the monitor can be turned left or right to enable other users to view the screen. The monitor also can be used in either a portrait or landscape position. Additionally, the arm is supplied with an adjustable desk mount so that it can be fixed to a desk to free up workspace.

Price: €129.

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**Clear and effective**

**NEW**

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Details: www.lampertz.de

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**Clear and effective**

**NEW**

Footwear inspired by Africa

‘Masai Barefoot Technology (MBT), is a revolutionary range of footwear, which re-establishes the natural conditions of standing and walking,’ the manufacturer Swiss Masai reports, adding: ‘This design has some remarkable effects. It improves posture, strengthens the back, in fact MBTs are recommended by orthopaedic and physiotherapy specialists across the world. It tones muscles and constantly works the legs, stomach and buttocks.’

‘All the principles of MBT have been verified by the Human Performance Laboratory at the University of Calgary, one of the world’s leading research centres on the body’s biomechanical movements.’

The footwear imitates the terrain the Masai walk on, turning hard and even surfaces, which we walk on every day, into the soft and natural ground of The Masai Mara, the firm explains. ‘This causes our muscles to work harder and become the natural shock absorbers they were designed to be, thus protecting our back and joints. Instead of a traditional heel, a heel sensor and pivot sole force us to balance and straighten up. With a more upright posture we not only look better but are healthier, and automatically stronger.’

Details: www.swissmasai.com
Auto-immunity research honoured

Hungary - Donato Alarcon Segovia, Ian R Mackay and Noel R Rose, notable research pioneers in auto-immune diseases, were rewarded for their life’s work at the opening session of the 4th International Congress on Autoimmunity in November. The German firm Arasku Diagnostics, which donated the Arasku Award for a lifetime’s contribution to autoimmunity, pointed out that studies by these three researchers have formed today’s understanding of the principles of such diseases. Donato Alarcon Segovia, of the National Institute of Medical Sciences and Nutrition, Mexico, could not attend the event. However, his life’s work was presented by congress chairman Yehuda Shoenfeld of Tel Aviv University, who was the world’s first autoimmunologist. In his lecture on ‘The transition from benign to pathogenic autoimmunity: the myasthenia model’, Noel Rose, of the Departments of Pathology and Molecular Immunology, and John Hopkins Medical Institutions, Baltimore, USA, described mechanisms that turn a relatively benign disorder into a life-threatening disease. Dr Rose, and his team at Baltimore, are analysing the transition of auto-immunity to establish the significant field of autoimmunity as an independent research area, and to foster inter-disciplinary co-operation, Arasku said. The company, which continually invests in research and development to create new opportunities to improve diagnosis and therapy of autoimmune diseases, also contributed to the congress scientific programme along with its university research partners. Source: www.arasku.com

Cancer research awards

Germany - Dr Angela Risch, of the Department of Toxicology and Cancer Risk Factors, based in the German Cancer Research Centre (GCR), and Dr Gerald Antoch, of the Institute for Diagnostic and Interventional Radiology, University Hospital Essen, have received the Salzer Awards (each worth 5,000 euros) at a ceremony organised by the GCR in Heidelberg. Biochemist Dr Risch was recognised for her investigation of genetic factors influencing lung cancer risk, and Dr Antoch for establishing and evaluating an improved method to diagnosis cancer.

For research on immune defence Dr Markus Feuerer and Dr Philipp Beckhove, both at the Department of Cellular Immunology, also advised women on the cardiovascular effects of physical activity, and gained new ones, as well as to gather material on medical advances for our readers. Even if, after four days, our feet hurt and some hallucinated when finally back in camp chairs at home, we love the excitement and inspiration of Medical - the world’s biggest medical fair.

Now, of course, we’re looking forward to meeting you there in 2005.

Best wishes to you all
Daniela Zimmermann, Executive Director, and all the European Hospital@MEDICA team

UN award for heart campaign

Switzerland - The 2003 World Heart Day Campaign, devised for the World Health Federation by international public relations agency Cohn & Wolfe Geneva, has won the 2004 United Nations Grand Award for ‘outstanding achievement in public relations’. Jointly sponsored by the Department of Public Information ( DPI) and the International Public Relations Association (IPRA) this annual award recognises excellence in public relations campaigns addressing priority issues before the United Nations.

Launched on St Valentine’s Day, and titled ‘A Heart For Life’, the winning campaign utilised research that indicated love is good for the heart. International press releases, leading up to September’s World Heart Day, also advised women on the cardiovascular effects of physical activity, nutrition and passive smoking. The campaign is said to have reached over 300 million people.

This year, Medica presented itself in a sparkling new outfit: the new metro station made life much easier for thousands of visitors, now able to arrive directly at the North Entrance in the Messe Dusseldorf grounds. EUROPEAN HOSPITAL’s team, at all entrances, welcomed visitors (though not all 136,000 of them, we admit!) and provided our latest 2004/05 publication - a new appreciation and established landmark at the fair. The team also manned our stand, where a multitude of visiting experts dropped by for information. We also fanned out through the halls and meeting areas, to see conference delegates, exhibitors and journalists.

DESIGN in EH - our newest publication, which is now in its second year, proved a strong attraction. We are more than pleased about the interest in hospital architecture and design, as well as equipment design, and the positive reaction to this magazine, because we take this as evidence that the hospital landscape indeed is changing and will alter more, from an outdated and intimidating prospect, to an aesthetically pleasing and emotionally appealing environment.

As in each Medica, the EH team walked miles to meet old friends and to gain new ones, as well as to

EUROPEAN HOSPITAL@MEDICA

Daniela Zimmermann (right) with members of our international team at Medica

AWARDS

EUROPEAN HOSPITAL@MEDICA
KIMES 2005
17-20 March
Venue: COEX Exhibition Centre, Seoul, Korea
21st Annual Korea International Medical & Hospital Equipment Show
promotes the development of the medical-equipment industry in Korea and neighbouring nations, and provides a commercial meeting ground that is expected to attract around 80 medical equipment firms from 30 nations. Some 12,000 medical items, in 500 medical categories, will be demonstrated on 28,748 square metres of three exhibition halls, where over 65,000 visitors from 30 nations are expected, making this the biggest medical exhibition in that country.

Along with diagnostic and therapeutic equipment, plus IT solutions, Oriental medicine will be featured.
First held in June, 1988, this annual event has contributed to the expansion of medical-equipment export and import industries during its 25-year operation, the organizer’s report. Medical conferences and seminars are held concurrently with the show and at the same venue.
Full information relating to the scope and objectives of KIMES, the educational programme, detailed hall plan and list of exhibitors, transport and choice of accommodation during this four-day event is available at www.kimes.info

Reach your audience!
Highlight your congress, conference or trade fair.
Simply contact us for details.
Our readers are leading hospital administrators, medical practitioners and medical manufacturers throughout Europe. GLOBAL EVENTS is a special print edition, published to help our readers keep abreast of future conferences and congresses.

2005
JANUARY
9-13 Helsinki, Finland
‘Medicine’ healthcare exhibition
www.tikki.fi
15-19 Phoenix, USA
34th Congress of the Society of Critical Care Medicine
www.sccm.org
16-21 Fribourg, Switzerland
Ewoc 9 - European Winter Oncology Conference
www.ucc.org
28-30 Stuttgart, Germany
Medicine and rescue meeting
www.stut.de
FEBRUARY
1-4 Paris, France
16th International Congress on Anti-Cancer Treatment
www.ucc.org
5-9 Davos, Switzerland
14th European Urology Winter Forum
www.uroweb.org
10-13 Salzburg, Austria
8th International Symposium on Allergies in Cancer and Human Reproduction
www.kimes.info
12-14 Hyderabad, India
Hospimedica India
www.india.com
12-19 Dubai, United Arab Emirates
Asia Hospital Equipment Show
international trade fair, medical tech and hospital equipment
www.auanet.org
18-19 Dusseldorf, Germany
Diagnostic & Therapeutic Endoscopy 7th International Symposium
www.docguide.com
22-25 Miskolc, Hungary
Boluszmedica medical, laboratory and optics exhibition
www.l.b
MARCH
3-5 Amsterdam, The Netherlands
Targeted Anticancer Therapies 3rd International Conference
www.docguide.com
4-7 Vienna, Austria
European Congress of Radiology (ECR)
www.ucr.org
10-11 Paris, France
ECCC 2005
European Cancer Conferences www.socbe.st
16-17 Glasgow, Scotland
3rd Medical Patients’ Care & Treatment Society
www.docguide.com
16-19 Istanbul, Turkey
EASU 20th Congress of the European Association of Urology www.uroweb.org
17-18 Poznan, Poland
SAUL - Prevention and Health Care, Forum and Exhibition
http://saul.mp.p.kr
17-20 Seoul, South Korea
KIMES 2005
21st Annual Korea International Medical & Hospital Equipment Show
www.kimes.info
27-23 Cambridge, England
British Society for Investigative Dermatology - annual meeting
www.bsids.org
27-29 Bruges, Belgium
International Care & Emergency Medicine 25th ICMC Meeting
www.intresar.org
31 - 5 April New Orleans, USA
SIR 2005
30th Annual Scientific Meeting
www.sirweb.org
APRIL
2-6 London, England
14th Annual Congress of the International Society for Gynaecological Endoscopy Hosted by the British Society for Gynaecological Endoscopy
www.docguide.com
4-7 Hamburg, England
BES 2005: 24th Joint Meeting of the British Urology Societies
www.docguide.com
4 - 6 Edinburgh, Scotland
Molecular Pathogenesis of Virus Infections
www.docguide.com
5-8 Munich, Germany
German Surgical Society 122nd Congress
www.chirurgie2005.de
5-8 Dusseldorf, Germany
Int’l Fair for Telemedicine and Telecare www.medialat.de
5-8 Edinburgh, Scotland
EANO VI - 2nd Quadrennial Meeting of the World Federation of Neuro-oncology www.docguide.com
7-11 Florence, Italy
International World Congress of the Society of Thoracic Radiology www.docguide.com
7-11 Strasbourg, France
Neurochirurgie 2005 (Neurourgy)
www.docguide.com
7-13 Miami Beach, USA
13th Scientific Meeting & Exhibition of the Int’l Society for Magnetic Resonance www.iirmm.org
8 - 11 Lisbon, Portugal
IWCNT - International Conference of Nuclear Cardiology www.ecardio.org
9 - 10 September, Sweden
12th European Congress of Clinical Neurophysiology www.docguide.com
MAY
1-5 Lisbon, Portugal
Cistm - Conference of the International Society of Travel Medicine www.cistm.org
1-7 Berlin, Germany
86th German Radiology Congress www.docguide.com
5-7 Budapest, Hungary
8th Congress of the European Society for Paediatric Dermatology www.docguide.com
5-8 Edinburgh, Scotland
EANO VI - 2nd Quadrennial Meeting of the World Federation of Neuro-oncology www.docguide.com
3-9 Vienna, Austria
19th World Congress of Skin Cancers www.docguide.com
19-21 Kaunas, Lithuania
5th Congress of Baltic Association for Maxillofacial and Plastic Surgery www.balticconference.com/damtp2005
21-26 San Antonio, Texas, USA
3rd Annual Congress of the American Urological Association www.auanet.org
24-30 Vienna, Austria
European Congress of Neurology
www.docguide.com
30-31 Vienna, Austria
EuroAnaesthesiia 2005 www.docguide.com
30-31 June Madrid, Spain
CHIO Cancer Conference: MAP Kinases and Cancer www.ucg.org
3-9 July Dublin, Ireland
ESPR - Congress of the European Society of Paediatric Radiology www.espfr2005.com
JUNE
8-11 Vienna, Austria
EURAL 2005
European Congress of Rheumatology www.eurl2005.com
8-12 Heldnah, Portugal
40th World Conference on Breast Cancer www.docguide.com
25-28 Sydney, Australia
International Congress of the World Federation of Sleep Research Societies www.docguide.com
SEPTEMBER
3-7 Sydney, Australia
International Society of Dermatologists 2005
4-7 Lisbon, Portugal
9th International Conference on Methods and Applications of Fluorescence Spectroscopy, Imaging and Probes www.docguide.com
14-17 San Diego, USA
14th International Congress and Endo Expo 2005
15-21 Rome, Italy
Pan Europe Asia Medical & Legal Conferences www.docguide.com
18-22 Melbourne, Australia
7th World Congress on Inflammation www.docguide.com
18-23 Bhatinda, India
14th International Pigment Cell Conference www.docguide.com
22-26 New Delhi, India
Interim Meeting of World Federation of Sleep Research Societies www.docguide.com
29-30 San Francisco, USA
American Academy of Family Physicians Annual Meeting
www.docguide.com
15-18 Berlin, Germany
1st Congress of the World Association of Sleep Medicine (WASIM)
www.docguide.com
OCTOBER
14-16 Nice, France
16th Annual Meeting of the European Council for Cardiovascular research (ECCR)
www.docguide.com
NOVEMBER
2-8 Toronto, Canada
2005 Annual Meeting of the International Society for Traumatic Stress Studies www.docguide.com
10-13 7th Annual Congress of the American College of Phlebology www.docguide.com
12-15 Bangkok, Thailand
IXth Asian Pacific Congress of the ISBT www.docguide.com
17-20 Havana, Cuba
3rd International Conference on Neuromuscular Disorders www.docguide.com
27-29 Haridwar, India
Psychotherapy, Yoga and Spirituality www.docguide.com