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Title: OSCAR 2 Blood Pressure Monitor graded A for both Systolic and Diastolic Blood Pressure when assessed according to the British Hypertension Society protocol

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Body: As mercury sphygmomanometers are phased out there is an increasing need for accurate alternatives which have been validated against well recognised criteria. The OSCAR 2 is a new small and light weight ambulatory blood pressure monitor designed for clinic and home use. We undertook an assessment of the OSCAR 2 according to the British Hypertension Society (BHS) protocol. Having passed the initial phases of the protocol, relating to before and after use calibration and a field assessment, a static device validation was undertaken by three observers who, after a period of appropriate training, achieved a high level of agreement in paired measurement of both systolic and diastolic blood pressure. Blood pressure measurements undertaken by the trained observers were compared to those taken by a third observer using the OSCAR 2. To ensure that 85 subjects stratified for both systolic and diastolic blood pressure were included, a total of 114 adults were studied. 56 subjects were included in both analyses. The subjects had the following characteristics: male sex 47.6%, mean age 54.3 (range 18 - 88) years, mean arm circumference 29.2 (range 21 - 49) cm. There was very close agreement between the trained observers and the OSCAR 2, 0 mmHg for systolic and -1 mmHg for diastolic blood pressure. All readings taken by the trained observers were within 5 mmHg. As > 60% of the OSCAR 2 readings were within 5 mmHg, > 85% were within 10 mmHg and > 95% were within 15 mmHg, the final grade for the static device validation as defined by the BHS

protocol was A for both SBP and DBP. As a result the OSCAR 2 can be recommended for clinical use in adults. The OSCAR 2 is the first instrument to be receive an A grading for both systolic and diastolic blood pressure using the BHS protocol and to have achieved a pass under the international protocol.

Grading criteria for OSCAR 2 - static validation

	Grade	Differences (mmHg)			Mean BP	Mean difference
		≤5	≤10	≤15	mmHg ± SD	mmHg ± SD
Observer 1						
SBP	B	62	84	96	131 ± 29	1 ± 7
DBP	A	70	92	98	83 ± 19	-1 ± 6
Observer 2						
SBP	A	62	87	95	132 ± 29	0 ± 7
DBP	A	67	91	98	83 ± 19	-1 ± 6
Final Grade						
SBP	A	62	87	95	132 ± 29	0 ± 7
DBP	A	70	92	98	83 ± 19	-1 ± 6

Differences are between standard and OSCAR 2

Disclosure:

I HAVE FINANCIAL INTEREST/ARRANGEMENT OR AFFILIATION WITH ONE OR MORE ORGANIZATIONS THAT COULD BE PERCEIVED AS REAL OR APPARENT CONFLICT OF INTEREST IN THE CONTEXT OF THE SUBJECT OF THIS PRESENTATION.

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Name of Organization

SunTech Medical, Inc

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Validation of the OSCAR 2 oscillometric 24-hour ambulatory blood pressure monitor according to the International Protocol for the validation of blood pressure measuring devices

Stephen C. Jones¹, Mary Bilous¹, Sue Winship¹, Paul Finn²
and James Goodwin²

Objectives The accuracy of blood pressure measuring devices is of prime importance and should be validated before devices are used clinically. We carried out an independent evaluation of the OSCAR 2 oscillometric ambulatory blood pressure monitor (SunTech Medical model 222) according to the European Society of Hypertension International Protocol.

Methods Adult subjects were recruited from patients and staff at The James Cook University Hospital, Middlesbrough, UK. Nine sequential same-arm blood pressure measurements were taken alternating between simultaneous readings by two independent, trained observers using mercury sphygmomanometers and the device operated by a third observer. In phase one, 15 subjects participated (five in each of the low, medium and high blood pressure ranges) with 18 subjects participating in phase two. Data from 33 subjects (11 in each of the three blood pressure ranges) were analysed for systolic (19 male, 14 female, mean age 56.0 years) and for diastolic (17 male, 16 female, mean age 51.1 years) blood pressure.

Results The OSCAR 2 passed the first phase of the validation process. In phase 2.1, the OSCAR 2 monitor had 71 readings within 5 mmHg, 86 within 10 mmHg and 94 within 15 mmHg for systolic blood pressure (SBP) and 72

readings within 5 mmHg, 88 within 10 mmHg and 96 within 15 mmHg for diastolic blood pressure (DBP). Mean (\pm SD) differences between observers and device were 0.9 ± 2.3 mmHg for SBP and -0.5 ± 2.3 mmHg for DBP. In phase 2, 24 subjects had at least two of the differences within 5 mmHg and three subjects had no differences within 5 mmHg for SBP while for DBP 25 subjects had at least two of the differences within 5 mmHg and two subjects had no differences within 5 mmHg.

Conclusions The OSCAR 2 passes all requirements for validation by the International Protocol and can be recommended for clinical use in an adult population. *Blood Press Monit* 9:219–223 © 2004 Lippincott Williams & Wilkins.

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Keywords: Blood pressure, oscillometric, European Society of Hypertension, International Protocol for the validation of blood pressure

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Introduction

As mercury sphygmomanometers are phased out the need for alternatives to accurately record blood pressure is rising. We tested the OSCAR 2 oscillometric 24-h ambulatory blood pressure (ABP) monitor—a small lightweight upper arm device designed for office and home use—according to the International Protocol for the validation of blood pressure measuring devices. This method represents a very rigorous assessment of a blood pressure measuring device and was described by O'Brien *et al.*, on behalf of the European Society of Hypertension [1]. The International Protocol is itself a modification of the protocol described by the British Hypertension Society (BHS) [2]. The European Society for Hypertension defined the International Protocol recognising that

other protocols such as that defined by the British Hypertension Society are costly and difficult to undertake. Particular emphasis is placed on the need to maintain the integrity of the previous protocols whilst simplifying the process and reducing the numbers of subjects that are studied. To our knowledge there are no previous reports of a validation of the OSCAR 2 monitor using the International Protocol.

Methods

Subjects

The subjects of this study were recruited from the adult patients and staff of a large teaching hospital in the UK. Ethical approval was obtained from the local ethical committee before the study began and informed consent

was obtained from all subjects who took part. Only adult subjects were approached to take part in the study. The following subjects were excluded: (1) subjects with atrial fibrillation or sustained arrhythmia and (2) those in whom it was not possible to identify clearly all Korotkoff sounds during auscultation.

Blood pressure measurement technique

Blood pressure was measured according to the method described in the International Protocol. Briefly two mercury sphygmomanometers (Baumanometer, WA Baum Co Inc, New York, USA) were calibrated and represented the reference standard. All components of the manometers were carefully checked for serviceability. Blood pressure was checked after at least 10 min rest, with the arm supported at heart level using an appropriately sized cuff and bladder, which would encircle at least 80% of the arm circumference.

Observer training

Three observers were trained according to the standards defined in the International Protocol using the training CD-ROM produced by the BHS. To monitor and minimise inter-observer differences, three 'drift' or interim checks were carried out at the beginning, middle and towards the end of the validation exercise. These checks involved 10 randomly sampled blood pressure readings on each of five patients who were not involved in the main study, giving 50 measurements in total, as detailed in the BHS protocol [2]. Initial training and subsequent drift checks were carried out under the supervision of an expert observer and were satisfactory at all stages of the study. The additional drift checks are not a requirement of the International Protocol but were carried out to ensure that the quality of data obtained was of a consistently high standard.

Familiarisation session

Having successfully completed initial training the observers went through a process of familiarisation using the OSCAR 2 device. Three machines were obtained from the manufacturer, who gave a written declaration that they were standard production models. The familiarisation session enabled the observers to gain experience in using the OSCAR 2 device and to confirm that all three devices were performing well and without idiosyncratic problems. Each observer used the monitor to carry out a minimum of two 24-h ambulatory data collections as part of the familiarisation process. No problems were identified at this stage and one of the machines was selected at random for the formal validation exercise.

Subject selection

Subjects were selected according to the criteria defined in the International Protocol. Subjects were stratified according to their blood pressure described in Table 1 below. Entry blood pressure was defined in three groups:

low, medium and high for both systolic (SBP) and diastolic blood pressure (DBP). Of the 33 subjects required for the systolic and diastolic validation, 15 participated in phase one and 18 in phase two, with 11 out of the 33 subjects falling in each of the three blood pressure bands (as in Table 1). Subjects were not stratified according to arm circumference or age.

Observer measurement

The two observers, under supervision, made measurements simultaneously. Observers were blinded from each other's readings and those recorded by the device. Readings were made using simultaneous same-arm measurement, each observer using a dual head binaural stethoscope and a calibrated mercury sphygmomanometer. Data were recorded independently, to the nearest 2 mmHg and were checked by the supervisor who also operated the device. Observer readings that were more than 4 mmHg apart were repeated until agreement was reached, as required by the International Protocol. At least 30 seconds but no more than 60 seconds was allowed between readings.

Procedure

Having given consent each subject was introduced to the observers. Arm circumference, gender and age were recorded plus the date and time of the session. Care was taken to ensure that the environmental conditions were constant, including the exclusion of extraneous noise. The subject was allowed to relax, in the seated position for a minimum of 10 min in order to reduce arousal levels or any 'white-coat' effect. Subjects with a history of atrial fibrillation or who were found to have an

Table 1 Blood pressure ranges for entry blood pressure

	Systolic blood pressure	Diastolic blood pressure
Low	90–129	40–79
Medium	130–160	80–100
High	160–180	100–130

Systolic and diastolic blood pressure stratification for patients entering the International Protocol.

Table 2 Summary of subject clinical characteristics

	Systolic blood pressure (n=33)	Diastolic blood pressure (n=33)
Sex (M/F)	19/14	17/16
Age (years)		
Mean \pm SD	56.0 \pm 12.1	51.1 \pm 12.9
Range	31–86	22–78
Arm circumference (cm)		
Mean \pm SD	30.9 \pm 4.6	30.4
Range	25.0–49.0	21.0–49.0

Clinical characteristics of subjects taking part in the International Protocol validation of the OSCAR 2 oscillometric 24-h ambulatory blood pressure monitor.

irregular pulse were excluded before blood pressure measurements were undertaken. Nine sequential same-arm readings were taken using standard mercury sphygmomanometers and the device, alternating between the two. The mean of the first readings, taken by the observers using sphygmomanometers, was used as the entry blood pressure. This classified the subject into the low, medium or high range separately for SBP and DBP (Table 1). The first readings taken by the observers and device were not used in the validation. Thus seven readings, four manual readings taken by blinded observers and three readings taken by the device and recorded by the supervisor, were used in the analysis.

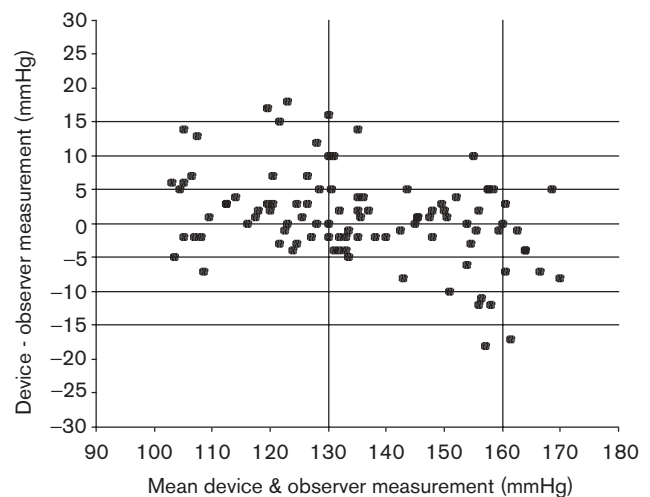
Analysis

Data were analysed and presented according to the method described in the International Protocol. For phase one, subject recruitment was stopped as soon as there were five subjects in each of the three blood pressure ranges (high, medium and low; see Table 1). The data were analysed to determine whether the instrument met the requirements to proceed to phase two. The criteria required to pass this initial phase of the assessment are described in Table 3. Briefly the differences between test readings taken by the device and sphygmomanometer standard readings are classified according to whether they lie within 5 mmHg, 10 mmHg, and 15 mmHg. The grading is based in the number of differences falling into these categories. Phase two of the analysis was then carried out. Phase 2.1 of the analysis compared all of the readings obtained by observers and the device. Phase 2.2 of the analysis considered the readings obtained for individual subjects. To pass the latter part of the analysis no more than three subjects can have all of the blood pressures readings recorded by the device more than 5 mmHg different from that recorded by the observers.

Results

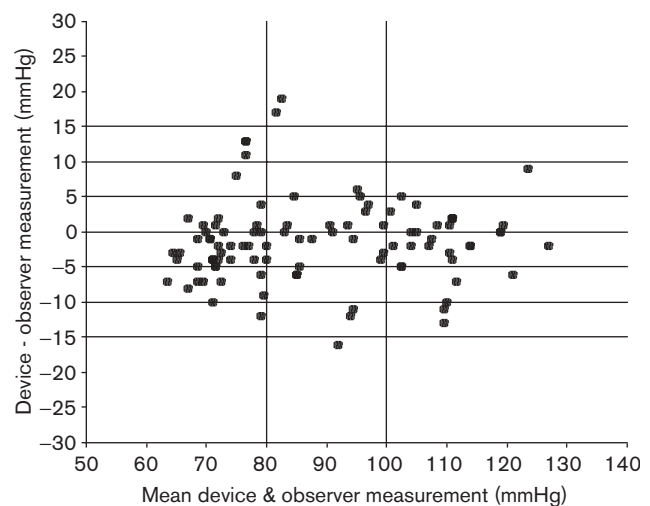
A total of 104 subjects were approached, gave informed consent and underwent at least one initial blood pressure measurement. Forty-six subjects were excluded, as their entry blood pressures did not fit within the ranges needed. Six subjects were excluded because of atrial fibrillation. Three subjects were excluded as a result of difficulties in hearing Korotkoff sounds, and one subject was excluded as the systolic blood pressure readings recorded by the observers varied by more than 20 mmHg according to the protocol variation described by Cuckson *et al.*, [3]. Thus a total of 48 subjects were included in the data collection, their blood pressure ranging from 96 to 180 mmHg for SBP and 63 to 125 mmHg for DBP, respectively. Data on 18 subjects were included in both the systolic and diastolic analyses. The clinical characteristics of the two groups are described in Table 2.

Fig. 1



Scatter plot of systolic blood pressure readings in all subjects ($n=99$). Plot of the mean of device and observer readings on the X-axis against device minus observer readings on the Y-axis for systolic blood pressure.

Fig. 2



Scatter plot of diastolic blood pressure readings in all subjects ($n=99$). Plot of the mean of device and observer readings on the X-axis against device minus observer readings on the Y-axis for diastolic blood pressure.

Observer-device agreement

The blood pressure data are expressed graphically in Figures 1 and 2 below in which the mean of readings taken by the device and the observers is plotted against the difference between the observers and the device. The mean differences between observers and device

Table 3 Device validation phase 1

		Within 5 mmHg	Within 10 mmHg	Within 15 mmHg
Required	At least one of	25	35	40
Achieved	SBP	33	40	44
	DBP	34	41	44

Recommendation: instrument meets requirements to proceed to phase two

Table 4 Device validation phase 2

		Within 5 mmHg	Within 10 mmHg	Within 15 mmHg
Required	Two of	65	80	95
	All of	60	75	90
Achieved	SBP	71	86	94
	DBP	72	88	96

Data (99 comparisons) are analysed to compare the number of comparisons falling within the 5, 10 and 15 mmHg error bands. To pass there must be a minimum of 60, 70 and 90 comparisons falling within 5, 10 and 15 mmHg, respectively. In addition to pass there must be a minimum of either 65 comparisons within 5 mmHg and 80 comparisons within 10 mmHg, or 65 comparisons within 5 mmHg and 95 comparisons within 15 mmHg, or 80 comparisons within 10 mmHg and 95 comparisons within 15 mmHg.

Recommendations for phase 2.1: SBP: Pass DBP: Pass.

Table 5 Device validation phase 2.2

		2/3 within 5 mmHg	0/3 within 5 mmHg
Required		At least 22	At most 3
Achieved	SBP	24	3
	DBP	25	2

Analysis by subject to determine the number of comparisons per subject falling within 5 mmHg. At least 22 of the 33 subjects must have at least two of their three comparisons lying within 5 mmHg. At most three of the 33 subjects can have all of their comparisons over 5 mmHg apart.

Recommendations for phase 2.2: SBP: Pass DBP: Pass.

were 0.9 ± 2.3 mmHg and -0.5 ± 2.2 mmHg for systolic and diastolic blood pressure respectively.

The results of the phase one analysis (15 subjects) are shown in Table 3. For both systolic and diastolic blood pressure the OSCAR 2 passed the first phase of the International Protocol as more than 25, 35 and 40 of the 45 comparisons fell within 5, 10 and 15 mmHg respectively. The data for phase 2.1 are shown in Table 4. For systolic blood pressure the measurements within the three categories were 71, 86 and 94 respectively and for diastolic blood pressure, 72, 88 and 96. Thus both are well within the criteria defined in the protocol. In addition for both systolic and diastolic blood pressure more than 65 comparisons were within 5 mmHg and more than 80 within 10 mmHg fulfilling the second part of phase 2.1 of the analysis.

Data were then analysed with respect to the phase 2.2 of the protocol. The data are presented in Table 5. This final stage of the validation analyses the data per subject.

The OSCAR 2 passed this stage of the International Protocol for both diastolic and systolic blood pressure as at least 22 subjects were within 5 mmHg for two out of the three comparisons. In addition no more than three subjects in each group had all of their readings more than 5 mmHg apart. Thus for systolic blood pressure at least two of the three comparisons were within 5 mmHg for 24 individuals. Only three individuals had all three comparisons more than 5 mmHg apart. For diastolic blood pressure at least two of the three comparisons were within 5 mmHg for 25 individuals and all three comparisons were more than 5 mmHg apart in only two subjects. Thus the OSCAR 2 passed phases 1, 2.1 and 2.2 of the International Protocol for the validation of blood pressure measuring devices.

Discussion

The device was validated across a range of blood pressures from low to severe hypertension. The main difficulty encountered in this study was in identifying patients with low systolic and high diastolic blood pressures who were well enough and able to consent to take part in the study. To complete the analysis of diastolic blood pressures two subjects under the age of 30 with high diastolic blood pressure were included. Although the International Protocol suggests that patients should be aged over 30 we do not believe that the inclusion of the two patients in their twenties is of clinical or physiological significance. Each of these patients was hypertensive, which is the inclusion principle on which the age criterion of 30 appears to be based. One additional subject was excluded as a result of very variable blood pressure values, which varied by more than 20 mmHg between readings, according to the modification described by Cuckson *et al.*, [3].

Subjects in whom high values were recorded in the clinical setting were often found to have much lower blood pressures when studied in the optimal conditions defined by the International Protocol. This explains why a large number of subjects were recruited to complete the diastolic and systolic arms of the International Protocol. This discrepancy between screening measurements in the clinical setting emphasises the need not only for devices that are accurate and precise but also the need to adhere to guidelines for the process of blood pressure measurement in the clinical setting.

The OSCAR 2 oscillometric 24-h ambulatory blood pressure monitor passed the International Protocol for the validation of blood pressure measuring devices for both systolic and diastolic blood pressure. To our knowledge this is the first report of the successful validation of an ambulatory blood pressure device using the International Protocol. As a result the OSCAR 2 can be recommended for use in the adult population.

Acknowledgements

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Validation of the OSCAR 2 oscillometric 24-hour ambulatory blood pressure monitor according to the International Protocol for the validation of blood pressure measuring devices.

Blood Pressure Monitoring. 9(4):219-223, August 2004.

Jones, Stephen C. 1; Bilous, Mary 1; Winship, Sue 1; Finn, Paul 2; Goodwin, James 2

Abstract:

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Study suggests VNS may help patients suffering from epilepsy

A study conducted at Emory University has shown that Cyberonics' vagus nerve stimulation (VNS) therapy may activate many areas of the brain for longer periods, up to months or longer, than previously thought. The researchers measured neuronal activity before, and after, long-term VNS, and found more seizures were reduced when higher levels of stimulation were used. The results were published in the September 2004 issue of the journal, *Epilepsia*.

Using PET scans, ten Emory patients were scanned before receiving stimulation and then again within 20 hours of treatment (immediate-effect study). The scans were repeated three months later (prolonged study). Half of the participants received high levels of stimulation (stimulation on more than off), while the other half received low levels of stimulation (stimulation off more than on). In the immediate-effect study, cerebral blood flow (CBF) changes showed increased synaptic activity in the so-called "sensory strip" of the brain's cortex, which was expected because the patients felt mild sensations during stimulation. VNS also activated the thalamus and other brain areas that are involved in memory such as thinking, alertness, arousal and emotional processing.

In the prolonged study, researchers again found CBF changes were similar between the high and low stimulation groups, but the volumes of significant changes in synaptic activity tended to be larger in the high stimulation group. Participants in each stimulation group showed some sites had significant VNS-induced CBF change, both in the immediate-effect study and prolonged study. However, in general, the volumes of significant VNS-induced CBF change were reduced after three months of VNS versus the volumes of significant CBF change that occurred acutely. During prolonged studies, CBF changes were not observed in any regions that did not have CBF changes during immediate-effect studies. The thalamus, which is considered a major centre of anti-seizure effects of VNS, was activated both in the immediate-effect and the prolonged studies.

Throughout the first three months of VNS, the frequency of seizures decreased by 25 per cent in the entire epilepsy group. Mean seizure frequency decreased by 35 per cent in the high stimulation group and by 15 per cent in the low stimulation group. According to Dr Thomas Henry, Professor of Neurology at Emory, these findings show that CBF changes in various areas of the brain help in reducing seizures when activated by VNS.

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CORPORATE NEWS

St Jude Medical strengthens position in AF market with Irvine Biomedical purchase

St Jude Medical has acquired Irvine Biomedical, a developer of electrophysiology (EP) catheter products that are used by physician specialists to diagnose and treat cardiac rhythm disorders, such as atrial fibrillation (AF). Its products consist of diagnostic and therapeutic EP catheter systems that include its proprietary radio frequency (RF) generator.

EP catheters are used by physician specialists to diagnose and treat a wide range of tachycardias. In placing these catheters inside the heart, physicians can determine the location of the abnormal conductive tissue that often causes arrhythmias. If necessary, an ablation catheter is used to apply RF or other energy to the abnormal tissue, disabling it in a process similar to cauterisation. By destroying the abnormal tissue, physician specialists can often cure a patient for life, eliminating the need for medication or other therapies.

The acquisition broadens St Jude Medical's EP catheter product line consistent with the company's "Surround AF" strategy, offering cardiologists and surgeons devices and catheter systems to diagnose, suppress and cure AF. St Jude Medical pacemaker and ICD systems incorporate the company's AF Suppression algorithm, the first clinically-proven technology to suppress AF. The company also offers a range of advanced catheter systems for use by clinicians in the clinical management of patients with AF.

In recent months the company has moved to solidify its position in the AF market. In June 2004, St Jude Medical completed the acquisition of Epicor Medical, a developer of high intensity focused ultrasound devices for the surgical ablation of cardiac tissue, further strengthening its position in the treatment of cardiac arrhythmias. In July 2004, the company announced the formation of an Atrial Fibrillation Division to focus on medical technology and services to help cure AF as well as address the broad field of electrophysiology. Finally, in September 2004, St Jude Medical signed a definitive agreement to acquire Endocardial Solutions, a developer, manufacturer and marketer of the EnSite system used for the navigation and localisation of diagnostic and therapeutic catheters used in AF ablation and other electrophysiology catheterisation procedures.

Trafalgar Ventures and Cyberkinetics complete merger

Trafalgar Ventures has completed a merger with privately-held Cyberkinetics, a neurotechnology company headquartered in Foxborough, MA. The new company has been renamed Cyberkinetics Neurotechnology Systems.

The transaction was completed by the merger of a wholly-owned subsidiary of Trafalgar with, and into, Cyberkinetics, with the latter as the surviving corporation and a wholly-owned operating subsidiary of Trafalgar. In consideration for their shares of Cyberkinetics' capital stock, the Cyberkinetics stockholders collectively received approximately 92 per cent of Trafalgar's equity after giving effect to the transaction. The officers and directors of Cyberkinetics replaced all of the officers and directors of Trafalgar, which ceased all of its existing business operations and has adopted and implemented Cyberkinetics' business plan upon completion of the merger.

In connection with the merger, Trafalgar Ventures has re-incorporated from Nevada to Delaware. According to the terms of the merger, each share of Trafalgar's outstanding common stock has automatically converted into one share of common stock of Cyberkinetics Neurotechnology Systems. As a result, the company now has outstanding approximately 13.63 million shares of common stock.

The new company's lead product, the BrainGate neural interface system, is currently undergoing a pilot clinical trial to evaluate the safety and effectiveness of providing a quadriplegic person with the ability to control computers and other devices, with thought alone. The BrainGate system is based on a technology platform that may also be utilised in the future to develop and commercialise medical devices for the monitoring, diagnosis and treatment of many neurological disorders, such as epilepsy and depression.

(Cyberkinetics reports data from pilot study of neural interface system - see R&D News Section)

Andromed restructures its operations and ponders long-term future

Andromed has released details of a major restructuring plan aimed at rapidly raising the company's technological and strategic value with a view to completing a possible merger or the partial or complete sale of the company.

The four-part plan will involve Andromed focusing on projects that offer the most potential value and, in particular, on the development of the applications of its Androsonix platform: Androflo and Androgram. The company will complete clinical trials under way for Androflo, a device used to measure respiratory rate based on sounds from the trachea, with a view to obtaining FDA approval in 2005. It will also carry out clinical trials on Androgram, a system that estimates pulmonary artery pressure based on heart sounds. These trials will begin in the last quarter of 2004 and should lead to submission to the FDA in the second half of 2005.

Andromed plans a major cut in its personnel and operating costs associated with other activities, with two-thirds of its staff losing their jobs and monthly operating costs lowered by 34 per cent to C\$185,000. The company will also divest its other activities, including its line of Androscope electronic stethoscopes, the Androfact system and other technologies, in the short term.

In a further shift in strategy, Andromed has appointed Sage Group, a US company specialising in strategic and transactional services to companies in the healthcare sector, to identify the best merger and acquisition opportunities and to carry out any related transactions.

To provide Andromed with the financial resources needed to implement this plan, four major shareholders, namely SGF Santé, Theratechnologies, SIPAR (Société d'Investissements en Participations) and Natcan Investment Management, have subscribed for 7,222,222 shares of the company, representing total value of C\$1.3 million. In addition, Andromed will proceed with a rights issue and private placement worth around C\$2.2 million. The company intends to use the proceeds from the investments for the clinical development of targeted applications derived from its Androsonix technological platform with a view to the merger or the partial or complete sale of the company.

Cedara Software closes eMed Technologies purchase

Cedara Software has completed the acquisition of eMed Technologies, a privately-held provider of PACS and web-based medical imaging radiology solutions for US\$48 million. Cedara financed the net cash disbursement of approximately US\$29 million to complete the transaction with approximately US\$14.5 million from its own cash reserves and approximately US\$14.5 million from its new credit facility with the Royal Bank of Canada.

As a wholly-owned subsidiary of Cedara, eMed's installed base of hospital and imaging centres across the US will provide opportunities for the eMed salesforce to promote Cedara's clinical applications and image management technologies. At the same time, Cedara will use its extensive global channel to promote eMed solutions worldwide.

eMed recently introduced its Matrix PACS solution, the only such solution built with the Microsoft .NET smart client architecture. The client technology of Matrix maximises the power of the PC for easy deployment, effortless maintenance and improved client performance. For the year ended 31st December 2003, eMed posted approximately US\$24 million in revenue, US\$3 million in net income and US\$5 million in cashflow from operating activities. On closing, eMed's balance sheet included cash of approximately US\$19 million and no debt.

A new report from Espicom

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- ▶▶ **What technologies are being developed?**
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- ▶▶ **What are the problems facing the sector?**

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CORPORATE NEWS IN BRIEF

NanoSignal has failed in its attempt to acquire **Haverhill Technology Group** for restricted stock. The majority shareholder of NanoSignal, Gary W Walters, and the company were unsuccessful in receiving all approvals from the creditors and did not receive approval by all necessary authorities in the transactions. NanoSignal said it will explore additional opportunities to strengthen its balance sheet and produce sales for the medical community.

Global Med Technologies has entered into a common stock purchase agreement with **Fusion Capital Fund II**, a US-based institutional investor, whereby Fusion Capital has agreed to purchase up to US\$8.0 million of common stock over a 32-month period. This new financing will provide Global Med with a value-added partner and a flexible source of capital to help redeem preferred stock and pay down debt obligations, as well as to help fund expansion. Global Med provides information management software products and services to the healthcare industry.

Medtronic has announced plans to appeal against a US District Court ruling that its **Medtronic Sofarmor Danek** (MSD) unit must pay **Dr Gary K Michelson** and **Karlin Technology** punitive damages of US\$400 million. The dispute centres upon technology agreements between

MSD and Michelson and his company, Karlin. The court also stated that the agreements between MSD and Michelson/Karlin remain in effect. In September 2004, the same court, the US District Court in Memphis, TN, awarded Michelson/Karlin US\$110 million in damages after concluding that MSD breached certain provisions of its technology agreements. In addition, the jury found that certain products infringed Michelson's patents and that MSD may be required to pay additional amounts on those products. The same jury has reached the decision that punitive damages are applicable in this case.

Roche Diagnostics has filed complaints for patent and trademark infringement and unfair competition in the US District Court, Southern District of Indiana against **Winsur Wholesale**. The latter sells lancets, under the Softlet II name, which are specifically advertised for use in Roche's Accu-Chek Softclix lancing device. According to Roche, these sales infringe its legal rights.

Refocus Group has successfully completed an interim financing programme which enables the company to continue its Phase II clinical trial evaluating the Scleral Spacing Procedure for the surgical treatment of presbyopia. The funds will also be used to support its other operations for a period of time. The interim financing is designed to bridge the company's operations until the close of a subsequent private placement, strategic alliance or other financing alternative. Those financing efforts are currently being pursued by the company.

AGREEMENT NEWS

MD Anderson installs Siemens SPECT-CT technology

The University of Texas MD Anderson Cancer Center is to acquire five Symbia systems, incorporating TruePoint SPECT-CT technology from Siemens Medical Solutions. MD Anderson plans to install the new systems in early 2005 in one of its latest facilities, the Ambulatory Care Building.

Siemens TruePoint SPECT-CT, which made its worldwide debut in June 2004 at the annual meeting of the Society of Nuclear Medicine, represents a new concept in hybrid imaging. This technology combines the functional sensitivity of SPECT with the anatomical detail of diagnostic multi-slice CT, providing clinicians with true imaging clarity and diagnostic confidence.

According to Siemens, TruePoint SPECT-CT has the potential to revolutionise diagnosis and treatment for cancer. With a single scan, this imaging technology quickly captures comprehensive, accurate diagnostic information both on the molecular and anatomical levels, and will enable physicians at MD Anderson to detect changes in molecular activity even before structural changes become visible. With earlier and more accurate diagnosis, physicians will be able to plan treatment even more effectively and provide feedback on treatment efficacy, as well as avoid unnecessary invasive surgery and reduce the risks of necessary surgery.

Symbia's ability to perform three different scans - SPECT, diagnostic CT, and SPECT-CT - in a single, automated procedure also enhances therapy planning, speeds exam time, and increases comfort and convenience for the patient. The system's integration of syngo, Siemens' multi-modality platform, offers a common, intuitive user interface and enables access to patient data. The syngo software also includes fully automated and integrated workflows, so that SPECT and CT datasets can be acquired and processed on one single workstation.

Pall secures Japanese marketing partner for enhanced bacterial detection system

Pall Corporation has finalised an agreement for Kawasumi Laboratories to become the exclusive provider of the Pall eBDS (enhanced Bacterial Detection System) in Japan. Bacterial contamination of platelets is the number one infectious cause of morbidity and mortality from a blood transfusion. According to Pall, the number of platelet collections in Japan is about 780,000 annually.

This agreement is the latest in a ten-year long relationship between the two companies. Kawasumi, a provider of medical devices and pharmaceuticals for blood banking, uses only Pall leukocyte (white blood cell) reduction filters in its blood collection and transfusion systems and is Pall's exclusive route to market for these filters in such systems in Japan.

Under the new agreement, Pall is also receiving milestone payments to correspond with providing Kawasumi scientific and technical support to help it bring the technology to market in Japan. Kawasumi will submit the product to the Japanese regulatory authority. The FDA cleared the Pall eBDS for marketing in January 2004, and the system is already approved in Canada and in Europe.

The eBDS can detect bacteria in all platelets, whether derived from single donor (apheresis) or random donor (whole blood) collection procedures. It allows blood banks to accurately detect the lowest levels of bacterial contamination so that viable and valuable platelets are not discarded or wasted. A rapid read system provides pass/fail results in approximately 30 seconds thus improving availability of blood for transfusion by allowing faster access to platelets found to be bacteria free prior to becoming outdated.

Ortec and Hapto to pursue development of peptide-based biomaterial

Ortec International has formed a joint-venture partnership with Hapto Biotech for the purpose of further developing promising product leads identified through a research collaboration established in September 2002.

The partnership will seek to optimise the combination of peptides found in Hapto's Haptide technology with the properties of Ortec's proprietary collagen biomaterial. The joint-venture will evaluate the safety and efficacy of a non-cellular peptide-based collagen biomaterial in promoting the attraction and attachment of healthy cells within the patient's body in regenerating new tissue or repairing wounds. It is believed that this advanced biomaterial may also be applied to the cosmetic, reconstructive orthopaedic and dental markets.

The joint-venture's initial objective will be to produce a GMP grade product that will be used in biosafety and toxicology studies and clinical evaluation of efficacy at a pilot level. Concurrent with the further development and evaluation of the product, the companies expect to seek licensing opportunities with companies interested in co-developing and commercialising the product for specific indications.

Ortec's current focus is the application of its OrCel (Bilayered Cellular Matrix) to heal chronic and acute wounds. OrCel is composed of a collagen sponge seeded with allogeneic epidermal and dermal cells. These cells secrete growth factors and cytokines normally found in acute human wounds and are believed to have a beneficial role in promoting tissue repair. In addition to having received FDA approvals for the treatment of Epidermolysis Bullosa and donor sites in burn patients, a pivotal clinical trial has been completed for venous ulcers and a PMA has been filed. In addition, the FDA has granted Ortec approval to initiate a pivotal trial in diabetic foot ulcers. Ortec believes that its platform technology may extend to the regeneration of other human tissue such as tendons, ligaments, cartilage, bone, muscle and blood vessels.

Spectranetics and Elana sign business development agreement

Spectranetics has entered into a series of agreements with Elana, a privately-held company based in the Netherlands, concerning the supply of Spectranetics laser systems and the development of catheters. A cross-licensing arrangement of the respective companies' selected intellectual property rights also forms part of the agreements. The products subject to these agreements will be marketed by Elana for use in bypass surgery, initially focused on neurovascular applications.

The Elana (Excimer Laser-Assisted Non-occlusive Anastomosis) technique enables surgeons to create a bypass without occluding the recipient vessel, ensuring continued blood supply during an operation. To make the anastomosis, a platinum implant is attached onto the outside wall of the recipient vessel and the end of the bypass graft is stitched to the wall of the recipient vessel, using the implant as a guide. A specialised laser catheter is inserted through the bypass graft to the wall of the recipient vessel. Laser ablation is used to create a hole in the artery wall and the laser catheter removes the disc, enabling bloodflow to the recipient vessel.

Clinical research for the Elana technique is currently being performed at five European sites that are accumulating more than 250 cases. Additional clinics are expected to be added soon, including sites in the US. The technique will be commercialised by Elana and is currently used for patients with a giant aneurysm or a skull base tumour and insufficient collateral circulation. The technique has been used to successfully treat patients at risk of haemodynamic stroke and, should pilot studies corroborate these results, further research could result in a considerable expansion in the number of Elana operations. Additionally, in the future, the suture-less technique could be used with an anastomosis device developed by Elana to increase the safety and simplicity of the traditional bypass operation and may expand use of the Elana technique beyond neurovascular applications.

Revenue to Spectranetics associated with these agreements will consist of laser sales and rental revenue, service revenue and catheter revenue. Revenue during the first 12 months of the agreements is estimated to be in the range of US\$150,000 to US\$200,000, and increases from this level will be dependent on clinical results from the Elana technique and the success of commercialisation efforts.

AGREEMENT NEWS IN BRIEF

TriPath Imaging has been awarded a five-year contract to supply Cheshire and Merseyside Strategic Health Authority, in the UK, with its SurePath liquid-based Pap test. The pap test is expected to be utilised in excess of 90 per cent of the organisation's total annual cervical cancer screening requirements. The SurePath solution will be supplied by **Medical Solutions**, a cancer and pathology services group that serves as TriPath's licensed distributor in the UK. No further details were made available.

Premier Purchasing Partners, a US group purchasing organisation, has awarded 21 multi-source contracts to 13 suppliers for hypodermic and sharps products in seven product categories. The awarded suppliers include; **B Braun**, for passive safety IV catheters; **Becton Dickinson**, for IV site management products, standard and safety hypodermic products, safety IV catheters, blunt cannula access devices, and safety blades and scalpels; **DeRoyal** for safety blades and scalpels as well as surgical and specialty blade products; **Hypoguard**, for safety blades and scalpel products; **LSL**, for IV site management products; **Medex**, for safety IV catheters; **Medical Action Industries**, for IV site management products; **Personna Medical**, for safety blades and scalpel products; **Retractable Technologies**, for safety hypodermic products; **Smiths Medical**, for safety hypodermic products; and **Tyco Healthcare**, for standard and safety hypodermics, as well as blunt cannula access devices.

Quill Medical and **Surgical Specialties** have entered into an exclusive manufacturing and distribution alliance in the field of aesthetic surgery. The agreement coincided with the announcement that FDA clearance had been obtained for the first product from the alliance, Contour Thread, a minimally-invasive product for lifting skin based on Quill's patented self-anchoring suture technology. Under the alliance, Surgical Specialties will manufacture and market worldwide Quill's suture technology for aesthetic surgery under the Contour Thread trade name. Quill is providing licenses to its patent portfolio, along with technology for manufacturing and optimised product design. The two companies will also collaborate to develop new products for aesthetic surgery applications. Financial terms of the alliance were not disclosed.

MED-TEC has reached an agreement to produce patient position systems under **Varian Medical Systems'** US Patent No. 5,806,116. The licensing agreement covers the full range of indexing systems produced by MED-TEC. As part of a previous partnership, MED-TEC manufactured Indexed Immobilisation accessories for VMS' Exact couch, which enables clinicians to position patients precisely and reproducibly for radiation therapy. Under this new arrangement, MED-TEC will continue to serve as a preferred, licensed vendor of the Exact and Indexed Immobilisation positioning technologies, including Exact-compatible inserts for CT and PET/CT systems. The two companies also plan to explore further collaboration possibilities for developing new patient positioning solutions and bringing them to the market.

Lifeline Cell Technology, a private early-stage company, has signed an agreement to exclusively license certain embryonic stem cell technology from Advanced Cell Technology (ACT) for the production of retinal cells for therapeutic research use. Previous studies have shown that retinal cells have the potential to benefit patients suffering from blinding diseases, including macular degeneration and retinitis pigmentosa.

Novation, the supply company of **VHA** and the **University HealthSystem Consortium** (UHC) have signed an agreement with **R2 Technology** that will enable VHA and UHC members to save money on purchases of the R2 ImageChecker computer-aided detection (CAD) system for mammography and the ImageChecker CT system for lung nodule detection on multi-detector CT (MDCT) exams. The three-year contract comes into effect on 1st November 2004. The ImageChecker CAD system is intended to detect findings that might otherwise be overlooked during

the review process, thus improving cancer detection capabilities. Clinical trials have shown that use of the ImageChecker system could result in earlier detection of up to 23.4 per cent of the cancers currently detected with screening mammography. Research studies demonstrate that CAD has comparable capabilities (26 per cent) to reduce the number of potentially cancerous solid lung nodules missed during a Chest CT exam.

Agfa has signed an agreement with **Queensland Health** for the supply and implementation of a statewide radiology information system (RIS) software, incorporating over 30 Queensland Health hospitals. This project, the largest and most geographically dispersed in Australia, will see the implementation of the full suite of Agfa RIS modules including patient registration as well as the new MediWeb results distribution system, implemented in most major public hospitals across the state of Queensland. The total value of the five year deal is estimated at EUR 5.8 million, including a large proportion of Agfa professional services revenues. The going-live date for the project is set for second quarter of 2005 at The Townsville Hospital and Ingham Hospital.

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FINANCIAL NEWS

Company Name	Period	To	Total Revenue			Net Income		EPS	
			2003	2004	% chge	2004	% chge	2003	2004
Alltracel Pharmaceuticals (EUR m)	3 mths	30/09/04	0.1	2.7	4,400.00	n/a	n/m	n/a	n/a
AngioDynamics	3 mths	28/08/04	10.6	13.1	23.28	0.8	147.08	0.03	0.07
E-Z-EM	3 mths	28/08/04	33.1	36.9	11.53	1.3	n/m	-0.03	0.12
GE	3 mths	30/09/04	33,394.0	38,272.0	14.61	4,051.0	11.02	0.40	0.38
	9 mths	30/09/04	97,223.0	108,657.0	11.76	11,215.0	7.40	1.10	1.08
Johnson & Johnson	3 mths	30/09/04	10,455.0	11,553.0	10.50	2,341.0	12.98	0.69	0.78
	9 mths	30/09/04	30,608.0	34,596.0	13.03	7,292.0	36.25	1.78	2.43
Philips (EUR m)	3 mths	30/09/04	6,989.0	7,229.0	3.43	1,172.0	845.16	0.10	0.92
	9 mths	30/09/04	20,020.0	21,140.0	5.59	2,338.0	2,310.31	0.08	1.83
Vasomedical	3 mths	31/08/04	5.4	4.8	-11.17	-0.9	-246.07	0.00	-0.02

Note:

All figures in US\$ million, unless otherwise stated.
 All EPS figures given by US companies are the "basic" measure.
 All net income/EPS figures include any applicable exceptional charges.
 Companies in **bold** feature in subsequent articles.

E-Z-EM reports strong performance for AngioDynamics unit ahead of spin-off

E-Z-EM has reported that its revenue in the first quarter of 2005 increased by 11.5 per cent to US\$37 million, with sales from AngioDynamics up by 23.3 per cent to US\$13.1 million and revenue from company's core business rising by 6 per cent to US\$13.1 million. Growth in the core business was driven by demand for CT products, including the Smoothie line of oral contrast agents, CT injectors and syringes. Products for the virtual colonoscopy market also continued to grow in the quarter.

AngioDynamics' results were driven by strong growth from the company's latest product lines, along with continued market share gains across its entire product portfolio. VenaCure, AngioDynamics' laser system for the treatment of severe varicose veins, continued to sell well under its new brand name, while the VenaCure procedure kit and haemodialysis and vascular access products were also strong contributors to the first quarter results.

E-Z-EM's net earnings for the first quarter of 2005 rose to US\$1.3 million compared with a net loss of US\$299,000 for the prior-year quarter. The E-Z-EM segment posted an operating loss of US\$94,000, which included plant closing and restructuring costs of US\$601,000, compared with an operating loss of US\$936,000 for the prior-year quarter, including restructuring costs of US\$572,000. AngioDynamics' operating profit rose by 35 per cent to US\$1.3 million, while the division's net earnings grew by 147 per cent to US\$761,000. In addition, E-Z-EM's other income amounted to US\$700,000 in the quarter, largely due to a gain from a sale of a non-core equity security.

Cordis' US sales affected by competition in the drug-eluting stent market

Johnson & Johnson has announced a 10.5 per cent increase in sales for the third quarter of 2004, to US\$11.6 billion, representing operational growth of 7.7 per cent and a positive currency impact of 2.8 per cent. For the nine-month period, the company's revenue rose by 13 per cent to US\$34.6 billion and net income grew by 17.5 per cent to US\$7.3 billion.

Within the Medical Devices and Diagnostics segment, revenue rose by 7 per cent to US\$4 billion in the third quarter, with operational growth of 3.6 per cent and a positive impact from currency of 3.4 per cent. In the quarter, US sales declined by 3.4 per cent to US\$2.1 billion, although this was offset by 20.6 per cent growth in international revenue, to US\$2 billion, with 12.8 per cent of the increase from operations and 7.8 per cent from currency.

Primary contributors to the quarterly growth were a 16 per cent sales increase for LifeScan's blood glucose monitoring products; higher demand for Vistakon's disposable contact lenses, leading to 15 per cent sales growth for the Vision Care segment; Ethicon Endo-Surgery's minimally-invasive surgical products; DePuy's orthopaedic joint reconstruction and spinal products; and 51 per cent international sales growth for Cordis, lead by strong demand for the Cypher Sirolimus-eluting coronary stent. However, US sales of Cypher were adversely impacted by competition and Cordis' US revenue declined by 26 per cent, leading Cordis' total sales to fall by 4 per cent in the quarter.

In the nine-month period, the Medical Devices and Diagnostics segment achieved 13.6 per cent sales growth to US\$12.2 billion, with 4.5 per cent of the increase due to positive currency effects. The growth was driven by 19.2 per cent increase in international sales to US\$5.9 billion, while US revenue rose by 8.8 per cent to US\$6.3 billion in the period.

In the nine months, Cordis' revenue rose by 27 per cent to US\$2.3 billion, DePuy's sales grew by 12 per cent to US\$2.5 billion, Ethicon's revenue increased by 7 per cent to US\$2.1 billion, Ethicon Endo-Surgery reported sales growth of 8 per cent to US\$2 billion, LifeScan's sales were up by 19 per cent to US\$1.2 billion and Vision Care revenue increased by 17 per cent to US\$1.1 billion.

Philips announces strong earnings growth; Medical Systems suffers from volatile exchange rates

Philips has recorded net income of EUR 1.2 billion for the third quarter of fiscal 2004, compared with net income of EUR 124 million in the same period last year. In the nine-month period, Philips reported net income of EUR 2.3 billion, compared with EUR 97 million in the same period last year. The company generated income from operations of EUR 1.6 billion in the nine months compared with a loss of EUR 120 million in the 2003 period, helped by a non-taxable gain of EUR 635 million from an initial public offering for Navteq, an insurance settlement related to the Semiconductors unit, and a decline in restructuring and impairment charges.

Third-quarter sales rose by 3.4 per cent to EUR 7.2 billion, despite the negative impact from the weaker US dollar and dollar-related currencies, which reduced revenue by 5 per cent. In the nine-month period, Philips' revenue grew by 6 per cent to EUR 21.1 billion, with the weaker US dollar and dollar-related currencies reducing sales by a 5 per cent.

Philips' revenue grew in all areas except for North America in the first nine months of 2004, where sales declined by 6.2 per cent to EUR 5.3 billion as the weaker US dollar had a negative effect on revenue. In the US, sales fell by 6.8 per cent to EUR 5 billion during the period. In Latin America, sales rose by 23.7 per cent to EUR 1 billion.

In Europe and Africa, revenue increased by 4.4 per cent to EUR 9 billion in the nine months, with sales from customers in the Netherlands up by 0.4 per cent to EUR 814 million, revenue from Germany rising by 8.7 per cent to EUR 1.7 billion, sales to France up by 1.5 per cent to EUR 1.3 billion and UK revenue up by 0.7 per cent to EUR 825 million. In the Asia-Pacific region, revenue rose by 18.1 per cent to EUR 5.8 billion in the nine-month period, driven by strong sales from China, which increased by 14.2 per cent to EUR 2.2 billion.

Philips Medical Systems' income from operations increased by 18.8 per cent to EUR 164 million in the third quarter of 2004 and by 7.5 per cent to EUR 388 million for the nine-month period as a result of higher sales volumes and improved margins. However, the

division's quarterly sales were virtually level with those of the same period of last year, at EUR 1.4 billion, and revenue for the year-to-date period declined by 2.2 per cent to EUR 4.1 billion. The decline was mainly due to exchange rate effects, without which sales grew by 5 per cent in the quarter, driven by double-digit growth for CT, MRI and X-ray products. All regions contributed to the comparable sales growth, particularly Latin America, the Asia-Pacific region and Europe, the Middle East and Africa. The order book also remained strong and, on a comparable basis, order intake increased by 29 per cent in the third quarter of the year.

Based on strong orders for new products and cost control measures, Philips believes the Medical Systems unit remains on track to reach 14 per cent EBITA as a percentage of sales for 2004, representing 12.2 per cent of income from operations. Philips has still not been able to complete its goodwill impairment test of its MedQuist investment as investigations into allegations of potential improper billing practices are continuing.

GE Healthcare reports 43 per cent sales growth in third quarter

GE has reported strong sales and earnings growth for the first nine months of fiscal 2004, with revenue up by 15 per cent to US\$38.3 billion in the third quarter and by 12 per cent to US\$108.7 billion for the year-to-date period. The company's net income grew by 11 per cent to US\$4.1 billion and by 7 per cent to US\$11.2 billion in the two periods, respectively. As a result of the strong operating results, GE has narrowed its EPS target for 2004 to US\$1.57 to US\$1.60, the high end of its previous forecast. The company also remains confident it will achieve 10 to 15 per cent EPS growth in 2005.

GE Healthcare reported the strongest growth of any GE business in the quarter, with sales up by 43 per cent to US\$3.3 billion and operating profit rising by 31 per cent to US\$503 million, driven by the acquisition of Amersham and solid demand for the company's imaging products. Total orders rose by 42 per cent to US\$3.4 billion in the quarter while, excluding Amersham, orders grew by 15 per cent to US\$2.8 billion, driven by 41 per cent growth in PET orders and 7 per cent service growth. GE Healthcare also reported strong results for the nine-month period, with revenue up by 34 per cent to US\$9.2 billion and operating profit rising by 26 per cent to US\$1.4 billion.

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PRODUCT NEWS

Canamet gets FDA clearance for blood pressure monitoring system

Canamet, a start-up business spun out of the research arm of Canada's Department of National Defence (DND) has obtained FDA approval for its first product, the Piesometer Mk-1 automated ambulatory blood pressure monitoring system. In addition, the company has also announced new sales to distributors in Taiwan and China worth US\$255,000.

Canamet's core technology was developed by its CEO, Dr Stergios Stergiopoulos, while he was a defence scientist at Defence Research & Development Canada (DRDC) Toronto. The Canadian government holds the patent rights for these technologies, and Canamet was created to commercialise the inventions.

The Piesometer Mk-1 is a part of a range of products that provide a portable kit that is intended to saving lives, and prevent or relieve health emergencies. Other products in its development pipeline include: Vital Signs 7 in 1; a device which samples and reports signals from the body and external environment with a graphic user interface and telemedicine functionality that allows for records to be transmitted over land or wireless phones or to be monitored over internet; MC-CAT software, which converts an old CT scanner into an advanced CT with the equivalent cardiac and 3D imaging capabilities as a multi-slice CT scanner; digital, portable 2D and 3D ultrasound systems that use aperture and adaptive beam-forming techniques to provide improved image resolution; and an intracranial ultrasound system that provides monitoring of brain density variations and the early diagnosis of stroke, brain haemorrhage, oedema and head injuries.

Toshiba offers Opart upgrade packages

Toshiba America Medical Systems (TAMS) has launched Version 5.0, a combined software plus central processing unit (CPU) upgrade program for the Opart mid-field (0.35T) open-MRI system. Available for all Opart system configurations, the new upgrades expand the system's pulse sequence capabilities and provide significant improvement in image processing speed. The Opart Version 5.0 software upgrades have been packaged into four categories to meet the imaging requirements of various imaging facility types.

The basic package includes basic pulse sequences with FASE (Fast Advanced Spin Echo) and 3D Swirl Encoding for imaging flow artefact, and the MR Angiography (MRA) Package includes 3D TOF (time-of-flight) MRA, providing a new Sliding Slab option, 2D/3D TOF MRA with Flow Averaging, and Segmented and Gated 2D TOF for carotid artery or peripheral vessel imaging.

The Orthopaedic Package includes the new Water Fat Separation options of Duo and Tri-enabling users to either gain signal-to-noise ratio or reduce the acquisition time, Extended Fast Spin Echo sequences for high-resolution imaging and SST2 (Steady State T2) for heavily weighted T2 images. The fourth package, the Advanced Neurological Package, includes brain imaging enhancements with improved Spin-Echo (SE) diffusion and perfusion imaging, Apparent Diffusion Coefficient (ADC) mapping and new Line Scan Diffusion, which provides more robust imaging against undesired patient movements than conventional SE DWI (Spin-Echo Diffusion-Weighted Imaging). It also includes new SSFP (Steady State Free Precession) for cerebrospinal fluid contrast spine imaging with high signal-to-noise ratio.

Toshiba is also offering a wide selection of radiofrequency (RF) coils to complement each software package. The new high-performance CPU upgrade of the Toshiba Opart claim to improve the speed of important routine imaging functions; image reconstruction, display and postprocessing, and multitasking functionality.

Iridex gets FDA clearance for dual wavelength laser; FDA clears new system to simplify MIP procedure

Iridex has received 510(k) clearance for its VariLite dual wavelength laser to be used in 19 specific dermatology indications, including the treatment of vascular lesions, leg veins, benign pigmented lesions, cutaneous lesions, hair removal and moderate inflammatory acne vulgaris. According to the company, the VariLite offers 532nm and 940nm wavelengths in a small and reliable platform.

The VariLite system features ergonomic dual wavelength handpieces that allow immediate switching between the two wavelengths for added convenience when treating a wide variety of dermatological indications. The 532nm wavelength is the standard of care for purpura-free treatment of facial vessels and pigmented lesions, and complements the 940nm wavelength which penetrates more deeply into tissue allowing treatment of larger vessels, such as leg veins. Treatment usually takes a few minutes and normally yields immediate outcomes without bruising, allowing patients to quickly resume normal activities with little risk of side effects.

Iridex plans to introduce the product at the American Society of Plastic Surgery (ASPS) annual meeting in Philadelphia, PA, in October 2004, and internationally at the 13th Congress of the European Academy of Dermatology and Venereology (EADV) in November 2004, in Florence, Italy.

Separately, Iridex has gained FDA approval for its solid-state Iris Medical IQ 810 infrared diode laser photocoagulator for the treatment of retinal disorders and glaucoma. The is designed to perform traditional and Minimum Intensity Photocoagulation (MIP) procedures in the office and operating room settings. In addition, the IQ 810 incorporates SmartWare interactive software with customisable settings, advanced waveform capability and FiberCheck Slit Lamp Adapter (SLA) delivery device.

The IQ 810 features SmartWare interactive software for intuitive set up and operation of the laser, customisation of laser output and settings, and integrated system diagnostics. SmartWare enables quick access to CW-Pulse (continuous wave), MicroPulse and LongPulse operating modes as well as advanced pulse modalities, Group and PowerStep, for precise control and laser energy output customisation with developing protocols.

The IQ 810 is compatible with a variety of Iris Medical delivery devices, including the Laser Indirect Ophthalmoscope, G-Probe, DioPexy Probe and a range of EndoProbe handpieces to maximise clinical versatility. The FiberCheck feature for the SLA allows the doctor to verify the integrity of the fibre before treatment, which is increasingly important with the adoption of MIP procedures where endpoints are not visible.

Philips begins shipments of Gemini PET/CT scanner model

Philips has begun commercial shipments of its Gemini PET/CT scanner with Brilliance 16 Power CT technology. The Gemini PET/CT is designed for maximum imaging flexibility, ease-of-use and patient comfort. The latest release in this product line, Gemini 16 Power configuration, acquires functional and anatomical images of "exceptional" quality in one procedure, supporting high patient throughput.

Philips unveiled this advanced scanner configuration in December 2003 and completed installation of the first clinical test sites in June 2004. The company installed its first commercial Gemini system in August 2003 and has now received more than 75 orders for the product. The Gemini 16 Power is available in a mobile configuration, which was introduced in June 2004 and enables patients to be processed at multiple customer locations. Gemini is also available in a dual-slice Mx8000 CT configuration, which Philips released in August 2003.

According to Dr Medhat M Osman, assistant professor at the Department of Internal Medicine and director of PET, Division of Nuclear Medicine at St Louis University in St Louis, MO, image acquisition on the Gemini PET/CT 16 Power scanner is more flexible, with the timeframe shortened with CT attenuation correction without compromising imaging quality. Osman also found that the open design of the PET/CT enabled effective imaging for patients with claustrophobia, and the ability to do a true whole body scan. Recent studies conducted by St Louis University have shown that 8 per cent of metastatic lesions were outside the limited whole

body field imaged by other scanners and, therefore, missed in the process. The Gemini 16 Power scanner tackles this problem by enabling clinicians to image the whole body length, up to 190cm, in a single scan. This total body scan includes the skull, brain, upper arms and lower extremities. Saint Louis University was one of the test sites for the technology.

The Gemini PET/CT provides comprehensive clinical applications for oncology, cardiology and neurology, and also enables seamless workflow between radiology and radiation oncology. The system can also be integrated within Philips' Pinnacle radiation therapy planning system.

Masimo plans to release new specialty sensors at NANN conference

Masimo is to introduce two low noise optical probe (LNOP) specialty sensors at the NANN conference in October 2004 in Orlando, FL. The new LNOP specialty sensors were designed to give clinicians maximum accuracy and reliability in difficult-to-monitor paediatric and neonatal situations, particularly in applications involving emergency, trauma, and newborn delivery and resuscitation monitoring.

The Masimo LNOP Blue sensor is designed for cyanotic babies and children with congenital heart defects. Cyanotic babies' oxygen saturation is usually around 60 to 80 per cent compared with the normal 90 to 95 per cent. According to Masimo, pulse oximeters in the past have had poor accuracy and precision in this patient population. In contrast, the LNOP Blue sensor has been designed to improve the accuracy in monitoring cyanotic patients.

The Masimo LNOP Hi-Fi Trauma sensor was specifically designed for trauma situations, including accurate tracking through newborn resuscitation. To improve clinicians' efficiency in extreme situations, the LNOP Hi-Fi sensors automatically reconfigure Masimo SET oximeters to the fastest-response and highest sensitivity modes, so clinicians do not have to spend precious seconds reconfiguring the oximeter.

European approval for Mentor's combination tissue expander

Mentor has gained the CE mark for its Contour Profile Becker 35 expander/implant, a shaped-combination tissue expander and long-term implant that can be temporarily over-expanded postoperatively.

Traditional breast reconstruction involves the initial placement of a tissue expander which is inflated over time to create a pocket under the skin. Once the pocket has been formed, the tissue expander is removed and replaced by a breast implant in a second surgery. Mentor claims the Contour Profile Becker 35 is the only shaped expander/implant that is designed for use as both a tissue expander and a long-term breast implant in one device, thereby minimising the need for the second surgery.

The Contour Profile Becker 35 is filled with saline via a removable tube through a remote injection dome. The fill tube and dome can be left in place for up to six months. By removing the fill tube and dome, the patented valve system of the tissue expander is safely sealed, turning the device into a long-term implant. The device is a combination silicone and saline expander/implant used in breast reconstruction as well as augmentation. The outer lumen, approximately 35 per cent of the volume of the implant, is comprised of Memory Gel, a cohesive silicone gel. The inner lumen, the remaining 65 per cent of the volume, is filled with saline. The saline lumen can be temporarily over-expanded postoperatively, allowing surgeons to optimise results in the breast reconstruction process.

As with all of Mentor silicone gel filled breast implants, Memory Gel is a proprietary cohesive silicone gel filler formulation, used in the Contour Profile Becker 35. The latter is shaped to imitate the contour of the breast, a feature which is particularly important for breast reconstruction. By varying the components of the gel, the company is able to produce a wide selection of products ranging from a very soft to a very firm consistency.

Biosil seeks partners for CE-marked prosthetic anal sphincter device

Biosil has obtained the CE mark for its prosthetic anal sphincter (PAS) device for the treatment of severe faecal incontinence in men and women.

The new device represents an alternative to existing treatments for faecal incontinence, including a colostomy. The company says its CE-marked device is a major advancement in the field as previous attempts to develop and introduce other artificial sphincters have been limited in their success, mainly due to complications including tissue ischaemia, infection and erosion of the bowel caused by high pressures within the device.

Designed and developed in conjunction with Ian Finlay, a consultant colorectal surgeon at Glasgow Royal Infirmary in the UK, the PAS is a patented silicone device that reflects the normal action and function of the anal sphincter and pelvic floor muscles by reproducing the normal physiology of the ano-rectum by flattening and angulating the bowel without causing crenation. With a patient group between 21 and 70 years of age, and follow-up of over eight years, the PAS has shown its efficacy and performance by successfully achieving/restoring continence without the complications of erosion and damage to local bowel blood supply as experienced with other artificial sphincters.

Biosil is currently planning a training programme that will introduce prospective surgeons to the design and development of the PAS, along with in-theatre experience and recommended operative techniques to support their focused introduction to market. The company also aims to drive growth in the market by seeking commercial partners with specialised and focused sales and marketing structure.

Integra LifeSciences launches IDRT-TS in Europe and the US; new wound dressing released in the US

Integra LifeSciences has received approval by authorities in Europe and the US to sell the terminally sterilised version of its currently-marketed Integra Dermal Regeneration Template-Terminally Sterilized (IDRT-TS) in their respective regions. Integra introduced the IDRT-TS at the American Society of Plastic Surgeon's 2004 Annual Meeting in Philadelphia, PA, and plans to launch the product in Europe shortly. Integra will sell IDRT-TS through its Plastic and Reconstructive Surgery salesforce in the US, through its direct salesforces in Germany, UK and France, and through distributors in the remainder of Europe.

Integra Dermal Regeneration Template is a two-layer skin regeneration system. The inner layer, which is placed in contact with the excised wound, is constructed of a complex matrix of cross-linked fibres. This porous material acts as a scaffold for regenerating dermal skin cells, which enables the re-growth of a functional dermal layer of skin. The outer layer is a thin silicone film that protects the wound from infection and controls both heat and moisture loss. Once dermal skin has regenerated, the silicone outer layer is removed and replaced with a thin epidermal skin graft, leaving the patient with flexible, growing skin.

IDRT-TS is functionally the same as the Integra Dermal Regeneration Template. However, the packaging configuration and storage requirements of IDRT-TS offer certain benefits over the original product, such as no longer requiring refrigeration and its ability to be stored flat. These attributes simplify the preparation and handling of the Integra product in the operating room. In addition, IDRT-TS requires a significantly shorter rinse time prior to application than does the Integra Dermal Regeneration Template.

In a separate development, the company has introduced the Integra Matrix wound dressing, a single layer version of its woundcare product line that can be used for the management of partial and full-thickness soft tissue wounds.

The Integra Matrix is a single layer tissue engineered matrix, part of a range of products that includes the Integra Dermal Regeneration Template and the Integra Bilyer Matrix wound dressing. The device is constructed of a complex biodegradable matrix of cross-linked collagen and glycosaminoglycan, which provides a scaffold for cellular invasion and capillary growth. The scaffold is eventually remodelled as the patient's cells rebuild the damaged site.

The new wound dressing is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The product will be available in four sizes: 2"x2", 4"x5", 4"x10" and 8"x10".

Laser-ANAP represents alternative treatment for periodontal disease

Millennium Dental Technologies has received FDA clearance for a laser-based periodontal disease treatment protocol which uses its digital dental laser, the PerioLase MVP-7. The FDA cleared the Laser-ANAP (Laser Assisted New Attachment Procedure) with a specific claim for, "cementum-mediated new periodontal ligament attachment to the root surface in the absence of long junctional epithelium."

FDA clearance for the Laser-ANAP, using the PerioLase MVP-7 variable pulsed Nd:YAG dental laser, follows three years of research at Louisiana State University, School of Dentistry, New Orleans, by Principal Investigator, Professor Raymond A Yukna, and co-ordinator of postgraduate periodontics. Yukna led a controlled, blinded, clinical and human histology study that showed new root surface coating (cementum) and new connective tissue (periodontal ligament) formation (collagen) on teeth following the use of the PerioLase MVP and Laser-ANAP protocol.

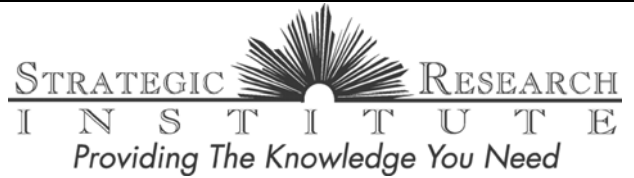
According to Yukna, the data shows that, microscopically, specialists in the field can form a new root coating (cementum) and a new connective tissue attachment (collagen). The results, which show that all LANAP-treated teeth showed a positive result, suggest that the best possible type of healing can be obtained using the specific Laser-ANAP protocol and represents a "wonderful" alternative to traditional surgery.

Researchers validate SunTech's ABP monitor

SunTech Medical has welcomed news that its Oscar 2 oscillometric 24-hour ambulatory blood pressure monitor (ABPM) has become the first device of its kind to pass the new blood pressure monitor standard established by the European Society of Hypertension's Working Group on Blood Pressure Monitoring.

The Oscar 2 is a lightweight instrument that provides a solution for monitoring patient blood pressure outside the clinical environment. The monitor is the core of two other SunTech products - the Oscar PowerPack, which includes additional accessories and ABP report generation software; and the Oscar Express system, a trans-telephonic device for ABPM particularly effective for clinical research and telemedicine applications.

The independent evaluation was conducted in the UK by Dr Stephen C Jones, a physician with James Cook University Hospital, and Dr James Goodwin. Subjects involved in the study had blood pressure values ranging from moderate hypotension (low blood pressure) to severe hypertension. Results of the study show the Oscar 2 passed for both systolic and diastolic pressures.



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Viking unveils 3D visualisation system for MIS applications

Viking Systems has released its new EndoSite 3Di visualisation system at the American College of Surgeons (ACS) 90th Annual Clinical Congress. Designed for use in minimally-invasive surgery (MIS) procedures, this new system delivers advancements in 3D visualisation capabilities, freedom of movement and comfort during MIS procedures, and on-demand access to secondary clinical information.

According to the company, the EndoSite 3Di system provides 3D stereoscopic vision, enabling enhanced depth perception and surgical precision, while at the same time allowing surgeons to remain engaged with their patient. Using the patented Head Mounted Display (HMD), each member of the surgical team can have high-resolution, stereoscopic images delivered directly to their natural line of sight. The system creates an immersive surgical environment, providing MIS surgeons with the vision quality and the sense of open surgery.

In addition, the EndoSite 3Di system provides real-time, critical information to the surgeon through Infomatix, the system's digital information platform, which allows voice-activated, picture-in-picture presentation of existing diagnostic images and live secondary video. Access to this information, without the need to divert attention from the surgical field, equips surgeons to perform accurately and quickly while also facilitating an informed decision-making process during surgery.

Mobile phone technology provides help to heart attack victims

Medical Intelligence of Canada has introduced a 12-lead ECG derivation VPS (Vital Positioning System) unit that is intended to considerably reduce detection time during a heart attack. The VPS automatically detects a cardiac problem occurring away from the hospital environment and alerts emergency services, through a cellular phone network, as to the condition and exact location of the victim. The French telecommunications company, Orange, is contributing to the VPS project by providing materials and allowing access to its GPRS network throughout the pilot application process.

The VPS is a belt that integrates a cellular modem, a digital ECG (electrocardiograph) and artificial intelligence to detect the very first signs of an acute heart attack or cardiac arrhythmia developing outside the hospital environment. The system alerts the emergency services, in totally automated fashion, about the condition and the location of the victim. Medical Intelligence introduced a derivation prototype in Montreal, Canada, in November 2003, following exhaustive research in collaboration with a team of cardiologists. The company elected to implement the product in France because of its highly developed mobile phone network.

The new cardiac alert system has been conclusively tested in Paris during summer 2004. The tests, conducted among 50 patients, showed that the VPS has the potential to detect the early signs of an acute myocardium infarctus, as well as most cardiac arrhythmia dysfunction.

The VPS enables doctors to remotely and directly receive the ECG signals from the person that is ill, thereby allowing them to conduct a routine follow-up, ensure that there is home care and, if need be, swiftly dispatch emergency attendants to the proper place. This can be done even if the person wearing the VPS is alone or is unconscious. The pilot application was conducted in collaboration with Orange and the UMDT (Unité Mobile pour la Douleur Thoracique), based at the Clinique Turin de Paris, under the supervision of cardiologist, Dr Abderrahmane Ameer.

Current plans call for the VPS to be assembled and marketed in France in 2005. There may be two different models, one of which is linked to a portable telephone that communicates with the VPS through Bluetooth, while the other is connected to a modem inside the belt.

Siemens unveils biplane angiography/neuroradiology system

Siemens Medical Solutions has released Axiom Artis dBA, a flat panel detector-based neurointerventional biplane system. The fully-digital system was introduced at the LINC Course, in Houston, TX. Developed by the Baylor College of Medicine and sponsored by Siemens, the LINC course is designed for neuroradiologists, neurosurgeons, neurologists and cardiologists.

The Artis dBA biplane angiography system is used for simultaneous digital imaging techniques and is designed to overcome the challenges of modern angiography and interventional procedures in neuroradiology and universal angiography. The gantry system for the dBA unit is equipped with both floor and ceiling-mounted C-arm stands, allowing for flexible positioning and quick, programmable movements.

Representing the latest member of Siemens' Axiom Artis range of systems, the dBA offers image quality, easy handling, maximum radiation protection and optimal network connectivity. With syngo, Siemens' standard user interface, all patient data can be seamlessly shared and physicians are able to create a patient report during the exam. Additionally, the system is compatible with the Axiom Sensis electrophysiology and haemodynamic recording system, which improves workflow by providing accurate calculations of data obtained during the procedure. The dBA also incorporates CARE (Combined Applications to Reduce Exposure), to reduce radiation exposure for the patient and clinician.

(MD Anderson installs Siemens SPECT-CT technology - see Agreement News Section)

PRODUCT NEWS IN BRIEF

Criticare Systems has received FDA approval to market a cardiac monitor with magnetic resonance (MR) compatibility. The company claims the approval is part of a strategy to participate in highly-technical niche markets with significant growth potential and represents a planned departure from traditional patient monitoring products that are sold into commodity environments.

Chad Therapeutics has received clearance from the FDA to market its Lotus electronic oxygen conserver. The product offers several significant enhancements to its existing Oxymatic 400 series platform, including the option of an audible and visual low battery alarm. These features offer homecare providers and their patients with a wide range of home oxygen choices to suit individual needs, preferences and disease conditions.

LuMend has launched the Outback re-entry catheter, which combines with the Frontrunner XP CTO catheter, to provide the first system solution that addresses the two major challenges associated with facilitating treatment of CTOs in peripheral arteries: lesion crossing and sub-intimal re-entry. The Outback re-entry catheter is designed to provide a simple and safe re-entry process that quickly redirects a guidewire from the false lumen back into the true lumen of the artery. Once this is achieved, the interventional procedure can continue. The company claims that the Outback catheter represents an outgrowth of the corporate strategy by creating a pathway of re-entry to the true lumen, and giving physicians the ability to consider catheter-based treatment options for an expanded set of patients suffering from debilitating peripheral vascular conditions.

Evo Medical Solutions has initiated commercial sale of **Aerogen's** Aeroneb Go nebuliser in Japan. The Aeroneb Go is a simple-to-use nebuliser developed for patients who require respiratory therapy in and away from home. The Aeroneb Go was designed to eliminate many of the problems associated with current methods of medication delivery when using nebulisers. Unlike many compressor, ultrasonic or mesh-based nebulisers, the Aeroneb Go allows patients to complete their treatments quickly, with minimal wasted medication, and delivers a high-quality respirable aerosol. The product incorporates Aerogen's OnQ Aerosol Generator.

The FDA has approved **Novo Nordisk's** Norditropin NordiFlex (somatotropin [rDNA] injection), the first premixed, prefilled, multi-dose, disposable growth hormone formulation (hGH) pen. The pen is indicated for the long-term treatment of children with growth failure due to inadequate secretion of endogenous growth hormone. Norditropin NordiFlex is a fully-integrated delivery system for hGH based on Novo Nordisk's insulin delivery systems. The new disposable Norditropin NordiFlex is prefilled so there is no loading of cartridges. Fine dosing increments are available in a 5mg/1.5mL pen that delivers doses from 0.025 to 1.50mg, and a 15mg/1.5mL pen that delivers doses from 0.075 to 4.5mg. Between these two delivery systems, a total of 100 different dosing options are available.

Diagnostic Ultrasound has released its bladder assessment kit to help primary care physicians identify common bladder conditions that, until recently, have been under diagnosed. The kit can assist physicians in creating pharmacological treatment plans for minor urinary complaints, while ensuring that patients with more serious conditions are referred to a urologist. The bladder assessment kit allows primary care physicians to make assessment of bladder function an integral part of the office visit. The kit provides the essential tools and knowledge base, including a BladderScan bladder volume instrument for non-invasive measurement of residual urine, a FloPoint Uroflowmeter for diagnosis of obstructed or abnormal urinary flow patterns, patient questionnaires to encourage the disclosure of bladder problems in a discreet manner and additional services, including reimbursement assistance and focused, clinical training in urology for primary care. A nurse or technician can perform both the BladderScan and FloPoint tests in a few minutes, allowing physicians to discuss potential treatment options with patients at the time of their initial office visit.

Medline Industries has introduced a new endotracheal tube that enables the clinician to rapidly and safely adjust the tip of the tube into position for a variety of difficult airway situations. Called EndoFlex, the endotracheal tube will be officially launched by Medline at the American Society of Anesthesiologists annual meeting in Las Vegas, NV, in late October 2004. The device, developed and manufactured by **Merlyn Associates**, is exclusively distributed in the US by Medline.

Vasamed has received 510(k) clearance to market its SensiLase PAD 3000 skin perfusion pressure (SPP) system in the US. Following approval, the company has begun worldwide shipments of the system, the first and only fully automated, commercial system for non-invasive quantitative evaluation of microcirculatory perfusion. The SensiLase is a fully automated, PC-based diagnostic instrument designed to provide critical information about the health of the micro circulatory system. As a result it has gained recognition in the woundcare market for assessing healing potential and to monitor interventional therapy. Additionally, it may also be a diagnostic tool for the early identification of peripheral arterial disease (PAD). With broad usage of SPP and the SensiLase at the early stages of the disease, Vasamed believes that treatment costs could be reduced due to earlier detection and disease management. The company speculates that this could expand the market for SensiLase from the US\$30 million wound healing assessment market to the US\$200 million PAD screening market.

Boston Scientific has received 510(k) clearance to market its new coronary IQ guidewire in the US, designed to provide physicians with control in a variety of situations. The company also announced the availability of the IQ Marker guidewire, which features two 5mm markers. Both the IQ and the IQ Marker guidewires are available in 185c, and 300cm lengths, and in both straight and J-tip configurations. The IQ guidewire complements Boston Scientific's PT2 guidewire, which is designed for use in more difficult cases such as tight lesions or multi-vessel disease.

R&D NEWS

21CM awarded grant to develop heart preservation device

21st Century Medicine (21CM) has received a Phase II grant of US\$900,000 from the Small Business Innovation Research programme of the National Institutes of Health. The grant will enable the company to develop solutions and processes for preserving hearts that is expected to dramatically improve the transplantation of human hearts.

This grant follows the successful completion of a previous Phase II grant of US\$150,000 in which a device designed and built by 21CM was successfully used at the University of Rochester, NY, to preserve dog hearts for 24 hours by simple storage on ice. When transplanted, the hearts performed similarly to hearts preserved for only four hours using a currently available heart cold storage solution. 21CM's technology, developed with the co-operation of the University of Rochester, should extend that time limit to 24 hours or even longer. This allows transcontinental and perhaps even international, transportation of human hearts to those who need them.

The company and its research partners plan to pursue results obtained at the University of Rochester showing that dog hearts can be preserved for at least 49 hours with no reduction in functionality or viability. The new NIH grant will be used primarily to show that the results obtained with the canine model in New York can be applied successfully to human hearts. The company plans to obtain human hearts from around the US and show they retain the ability to perform to a clinically appropriate standard after a total of 24 hours of simple cold storage using a new preservation solution known as UR solution. In addition, the company will refine its device design to enable it to attempt even longer preservation periods of two days or more in future research. Human hearts will be evaluated using a new machine that will circulate human blood through the hearts and measure the function of the hearts. The company will show that hearts preserved with its methods are functional before attempting any transplants into human recipients.

Benephit infusion system helps provide effective delivery of fenoldopam to kidneys

Direct intra-renal drug delivery using the Benephit infusion system can increase the beneficial effects of fenoldopam on the kidneys, while minimising systemic side effects in patients undergoing coronary procedures, according to important new clinical data reported at the Transcatheter Cardiovascular Therapeutics (TCT), in Washington, DC. Presented by Dr Hooman Madyoon, the data resulted from a physician-sponsored clinical study of the Benephit infusion system developed by FlowMedica, a medical device company developing targeted renal therapy.

Madyoon reported the results of a randomised, placebo-controlled trial conducted at St Joseph's Medical Center in Stockton, CA, and Scripps Clinic in La Jolla, CA, under Dr Paul Teirstein. The trial was designed to evaluate the Benephit infusion system for its ability to deliver fenoldopam directly to the renal arteries, thereby preventing certain changes in kidney physiology associated with radiocontrast nephropathy (RCN), a common cause of acute kidney failure among patients undergoing interventional and diagnostic cardiovascular procedures. Although fenoldopam can increase bloodflow to the kidneys and improve kidney function, its systemic use to prevent RCN is limited since doses high enough to be effective are associated with significant blood pressure lowering, or hypotension.

The investigators found that fenoldopam delivered intra-renal via the Benephit infusion system significantly improved kidney function. In contrast, the intravenous (systemic) administration of fenoldopam at the same dose improved kidney function only minimally. Kidney function was measured using the gold standard test for glomerular filtration rate, inulin clearance. At the same time, systemic drug levels were significantly less following intra-renal delivery of fenoldopam vs intravenous treatment. Correspondingly, blood pressure reduction was significantly less following intra-renal delivery. In addition, the beneficial effects on kidney function lasted at least two hours following intra-renal treatment, according to preliminary results. Trial subjects included 27 patients with abnormal kidney function scheduled for cardiac catheterisation or peripheral angiography that were randomised to fenoldopam or placebo (no drug and no device).

The Benephit infusion system is a proprietary, selective infusion catheter system capable of delivering therapeutic agents directly to the renal arteries through a dedicated infusion catheter while enabling concurrent cardiovascular procedures through a single-vessel access site. The system consists of a proprietary Bifurcated infusion catheter and an introducer sheath. In January 2004, FlowMedica received 510(k) clearance for the system to be used for the infusion of physician-specified agents to the renal arteries.

MicroMed, World Heart and Thoratec see positives from VAD reimbursement decision

MicroMed Technology has welcomed the announcement by the Centers for Medicare and Medicaid Services (CMS), which increased reimbursement for all ventricular assist devices (VADs) implanted for destination therapy (DT). Dallas Anderson, President and CEO of MicroMed, said the decision was "excellent" news for the VAD sector, adding that the company will benefit from this increase in reimbursement as the device moves through its clinical trials.

In January 2004, the FDA approved MicroMed's request to supplement its IDE-approved DT clinical trial, changing the patient randomisation scheme to a 2:1 ratio of MicroMed DeBakey VAD implants to Thoratec's HeartMate XVE implants. MicroMed is approved for a multi-centre pivotal trial for VAD use as a bridge-to-transplant and DT in up to 40 clinical sites across the US. The trial, known as DELTA (Destination Evaluation Long-Term Assist), will use the International Center for Health Outcomes and Innovation Research as its clinical data-gathering/reporting platform. The principal investigator for the DELTA clinical trial is Dr Eric Rose, Surgeon-in-Chief and Chairman of the Department of Surgery at Columbia Presbyterian Medical Center in New York.

Designed in collaboration with NASA, the Baylor College of Medicine and Drs Michael DeBakey and George Noon for long-term use, the DeBakey VAD is intended for end-stage heart failure patients who can no longer provide necessary blood flow with their native heart. The DeBakey VAD system has been awarded the CE mark for bridge-to-transplant, DT and paediatric use in Europe.

World Heart has also welcomed the significant increase in reimbursement and the implications for its Novacor LVAS.

Specifically, the Novacor LVAS, when used as a bridge-to-transplantation or for DT in the RELIANT (Randomized Evaluation of the Novacor LVAS In A Non-Transplant Population) trial, is now reimbursed under this higher paying DRG in either case. In the US, World Heart is currently conducting the landmark clinical trial, RELIANT, which will evaluate the Novacor LVAS for DT use in patients suffering from irreversible late-stage congestive heart failure who are not candidates for transplantation. Without LVAS support, these patients have a life expectancy of less than two years. Patients will be randomly assigned to receive either the Novacor LVAS or the HeartMate XVE LVAS, which was approved by the FDA in 2002 for a DT indication. Data from this trial is expected to support a PMA supplement that will request approval for use of the Novacor LVAS by non-transplant eligible patients (DT).

The company said the recent increases in payment by CMS will facilitate the industry moving forward with assist devices for DT patients who have very few options and it is hoped that these increases in CMS payment for implantation of VADs will significantly benefit enrolment in the RELIANT trial.

Another company to pass comment on the CMS decision, Thoratec, said that effective Medicare reimbursement rates for all VADs (Ventricular Assist Devices) implanted for DT represents an increase of approximately 40 per cent.

In August 2004, the CMS filed a notice in the Federal Register that all VADs implanted for DT would be reimbursed under DRG (diagnosis-related group) 103, the highest paying DRG, which covers heart transplantation procedures, for the Federal government's fiscal year.

Using the newly-published payment rates, the average Medicare payment to CMS-certified LVAD centres has increased to approximately US\$136,000 from approximately US\$96,000. This latest reimbursement increase follows, by a year, a reimbursement increase of approximately 25 per cent that occurred when CMS issued its National Coverage Decision for DT in October 2004.

Thoratec anticipates that adoption of DT will occur over time and that this new level of reimbursement will help eliminate an important initial barrier, enabling the 69 centres that are currently DT-certified by CMS to begin building and maintaining successful DT programmes. In addition to the increased reimbursement for DT, CMS is now also reimbursing the use of the HeartMate LVAS and the Thoratec Implantable VAD when used as a bridge-to-heart transplantation under DRG 103, section 376.

MIV completes porcine coronary HAp-coated stent trials

MIV Therapeutics has completed the first *in vivo* pilot coronary arteries implantation studies on its proprietary, biocompatible Hydroxyapatite (HAp) nano-film coating, designated for passive application on cardiovascular stents and other implantable medical devices.

After the 28-day angiographic transvascular coronary implant, HAp-coated stents performed successfully and displayed little in-stent neointima by angiography and intravascular ultrasound (IVUS). Furthermore, prescreening of pathology specimens by low vacuum scanning electron microscopy suggested favourable healing, with complete endothelialisation and a stable neointima. Complete pathology evaluation is being finalised and the final report of this study will be published in November 2004.

HAp-coated stainless steel coronary stents were evaluated through *in vivo* tests in pig coronary arteries to determine implant safety and tissue response. Stents were examined by angiography and IVUS at implantation and after 28 days to determine changes in the coronary luminal diameter. The arteries were carefully explanted and histopathological studies made. Longitudinal cuts along the stented area, using low-vacuum scanning and light microscopy enabled microscopic evaluation of the lumen, the neointimal lining and amount of tissue response and cellular growth.

The animal trial was conducted at the Methodist DeBakey Heart Center and Baylor College of Medicine, Houston, TX, by Dr G Kaluza. The ongoing histologic evaluation is being conducted by Dr Fred J Clubb, Director of the Cardiovascular Pathology Research Laboratory, Texas Heart Institute, Houston.

MIV's ultra-thin coating formulation is primarily designed to protect surrounding tissue from the chemical interaction of metal stents. The company has progressed to the next development stage, which is expected to finalise the drug-eluting R&D programme.

Medtronic unveils MAVERIC I and II carotid stenting clinical trial results

Dr Stephen R Ramee, the co-principal investigator of the Medtronic AVE Self-Expandable Carotid Stent System with Distal Protection In the Treatment of Carotid Stenosis (MAVERIC) trial, has presented positive preliminary 30-day data from the MAVERIC II trial and one year data from the MAVERIC I trial. The MAVERIC I and II clinical studies, which comprise a total of 498 patients, are designed to evaluate the short- and long-term safety and efficacy of Medtronic's Exponent carotid stent system and the GuardWire balloon occlusion device in reducing the incidence of stroke and death in patients with carotid artery disease.

The MAVERIC II trial is a 399-patient pivotal trial designed to study the safety and efficacy of the self-expanding Exponent carotid stent with the GuardWire balloon occlusion and Aspiration system for the treatment of carotid stenosis. The preliminary 30-day results showed a Major Adverse Event (MAE) rate of 5.3 per cent. MAE includes any stroke, myocardial infarction (MI) and/or death. The MAE rate for MAVERIC II included an MI rate of 2 per cent, a death rate of 1 per cent and stroke rate of 3.3 per cent. The study also assessed lesion, device and procedural success, with both the Exponent stent and GuardWire system performing well in the study. The MAVERIC II trial completed enrolment in August 2003 and is being performed at 34 centres in the US. Patients in the MAVERIC II trial will be followed up to one year after their procedure. Medtronic anticipates that final patient follow up will occur in the third quarter of 2004.

The MAVERIC I trial was a 99-patient feasibility study designed to demonstrate the safety of the self-expanding Exponent carotid stent with the GuardWire temporary occlusion and Aspiration system for the treatment of carotid stenosis. At one year, the study found MAE rate of 5.1 per cent, which was unchanged from the 30-day results. The study also demonstrated positive device, lesion and procedural success. The study completed enrolment in December 2002 and was performed at 16 centres in the US. Medtronic intends to conduct the MAVERIC III trial in the US, beginning in the third quarter of 2004, to study the safety and efficacy of the Exponent carotid stent system, with the Interceptor Plus filter system, in reducing the incidence of stroke and death in patients with carotid artery disease.

The Medtronic Exponent carotid stent system is designed to push the atherosclerotic material back against the carotid artery wall, and the GuardWire device is designed to block and remove dislodged particles. The GuardWire device is deployed prior to the carotid stent and also serves as a guidewire for stent delivery. Once in place, the balloon at the tip of the device is inflated to occlude blood flow and block any material dislodged from the wall of the vessel during placement of a stent. The blocked material is then withdrawn through an aspiration catheter before the balloon is deflated and bloodflow through this artery is restored.

The Exponent stent system is an investigational device and is not available for commercial distribution in the US, whilst the GuardWire system, the first FDA-cleared embolic protection device, has been available for use in US markets since June 2001 for treating diseased saphenous vein grafts.

Positive data from BrachySil trial released

Interim data analysis from pSivida's Phase IIa trial at Singapore General Hospital (SGH) has confirmed expectations that BrachySil (32-P BioSilicon) is safe and effective at tumour regression. The interim results enable pSivida to prepare for BrachySil dose-optimisation studies for increased tumour regression and multi-centre Phase IIb studies, to commence in 2005.

The first four inoperable liver cancer patients have shown no product-related adverse side effects and up to 60 per cent regression of tumours, three months after administration. All eight patients required for the approved trial have received BrachySil treatment at SGH. The primary objective of the trial was to assess the safety profile of BrachySil and the delivery method, which uses a fine-gauge needle injected directly into tumours. The secondary objective was to provide efficacy data on tumour regression.

The trial will continue to conclusion to encompass three- and six-month reviews of all patients for the purpose of regulatory approval. BrachySil is expected to be on the market worldwide during 2007, initially for liver cancer, and thereafter for the treatment of a wider variety of cancers, involving solid tumours, following regulatory approvals. Current brachytherapy-style products typically involve localised radioactive treatment of tumours and are limited to liver and prostate tumours by virtue of their manner of delivery. BrachySil has the potential to significantly expand the current market size through application to other cancers as a result of the successful fine-gauge direct needle delivery procedure. The procedure is undertaken without surgery under local anaesthetic and patients are discharged the following day.

A key finding of the study is that the radioactive 32P-BioSilicon nanostructured microparticles remain in the tumour with no or insignificant detectable radioactive leakage. pSivida owns the worldwide intellectual property rights to BioSilicon, royalty-free for use in or on humans and animals.

Access provides OraDisc technology update

Access Pharmaceuticals has provided an update on the OraDisc technology development, the commercialisation strategy, and the impact of the recently announced FDA approval of OraDisc A on this programme.

The company says that the successful development and FDA approval of OraDisc A is an important milestone which supports the development of the OraDisc range of products. To achieve OraDisc A approval, in addition to performing the necessary clinical studies to prove efficacy, Access conducted an irritation study, a 28-day safety study and drug distribution studies.

Additionally, Access demonstrated safety in patients down to 12 years of age. Patients in the 700-patient clinical study and 28-day safety study completed a survey which produced very positive results with regard to perceived effectiveness, ease of application, ability of the disc to remain in place and purchase intent. The company says these data give strong support to its overall development programme. The survey data confirms market research studies which indicate a strong patient acceptance of the delivery device.

Now that OraDisc A is approved as a prescription product, Access intends to move this product to market as rapidly as possible. Initially, the company plans to embark on a dental campaign to gain professional endorsement for this product. Ultimately, it is Access' objective to move this product from prescription status to an OTC consumer product. To accomplish these commercialisation objectives, Access intends to out-license OraDisc A. In addition to royalty payments, it is anticipated that a licensing agreement would include a substantial upfront licensing payment and future significant payments on the achievement of milestones. The company says there has been a strong interest expressed by numerous corporate partners with advanced discussions ongoing.

The company also plans to gain regulatory approval for OraDisc A in all the major global markets. In Western Europe, the OraDisc A product has been licensed and Access is in the process of extending its licensing coverage to cover all major global markets.

Projections received from Access' European licensing partners indicate a sales potential of US\$50 to US\$60 million annually in Europe. This estimate, together with market research that has been conducted, would indicate that OraDisc A and Aphthasol together have a global market potential of up to US\$150 million annually. Agreements signed to date give Access a royalty in the range of 10 to 15 per cent of net sales. Product revenues from OraDisc A and Aphthasol are anticipated to start increasing in 2005 when it is projected that one or both of these products will be marketed throughout the US, Europe and Canada.

Cyberkinetics reports data from pilot study of neural interface system

Initial results of Cyberkinetics Neurotechnology Systems' BrainGate neural interface system pilot clinical study have been presented at the annual meeting of the American Academy of Physical Medicine and Rehabilitation in Phoenix, AZ. The preliminary results represent the first demonstration of a quadriplegic person controlling a computer using thoughts and the BrainGate system. The latter is being evaluated by Cyberkinetics in an ongoing pilot study under an IDE programme approved by the FDA.

The poster presentation of these initial results from the pilot (feasibility) study was made by Dr Jon Mukand, of Sargent Rehabilitation Center. The ultimate goal of the BrainGate development programme is to create a safe, effective and unobtrusive universal operating system which will allow physically disabled people to quickly

and reliably control a wide range of devices using their thoughts, including computers, assistive technologies and medical devices. The results have so far demonstrated that a person unable to move their arms, hands and legs can quickly gain control of a system which uses thoughts to control a computer and perform meaningful tasks.

The poster entitled, "Feasibility Study of a Neural Interface System for Quadriplegic Patients," includes preliminary data from one patient with a three-year-old spinal cord injury. The reported results were recorded over a two-month period in approximately 20 study sessions. The surgery to implant the BrainGate sensor was performed in June 2004 at Rhode Island Hospital, Providence, RI, by Dr Gerhard M Friehs, Director of Functional Neurosurgery, and Associate Professor of Clinical Neurosciences at Brown Medical School.

The signal processing function of the BrainGate system was confirmed by its ability to detect, transmit and analyse brain signals. The first patient was able to immediately modulate their neural output in a controllable and meaningful fashion in response to directional commands. A computer interface was successfully developed using the patient's thoughts, thus enabling the patient to perform tasks and operate basic computer functions repeatedly. The patient's control of the cursor was immediate and intuitive, and the patient was able to perform multiple tasks at the same time, without disruption.

These results are preliminary and represent the early outcomes from a single patient. While the first patient will continue in the study, Cyberkinetics plans to expand the pilot study to additional clinical sites and will enrol additional patients. Cyberkinetics expects to announce additional preliminary results and scientific observations from the pilot study at the forthcoming annual meeting of the Society for Neuroscience in San Diego, CA.

The ongoing study will enrol up to five quadriplegic individuals between the ages of 18 and 60 who meet the study's selection criteria, which include that the patient be able to verbally communicate. The two primary goals of the pilot clinical study are to characterise the safety profile of the device and to evaluate the quality, type and usefulness of neural output control that patients can achieve using thoughts. Participants will undergo surgery to implant the sensor portion of the BrainGate neural interface on the area of the brain responsible for movement. During the study, they will perform tasks with the device such as attempting to control the movement of a cursor on a screen toward a specific target with their thoughts. The study is expected to last for about 13 months for each patient. At the end of the study, each participant will undergo further surgery to have the device removed or may have the option to participate in future studies.

The BrainGate neural interface system is a proprietary, investigational brain-computer interface device that consists of an internal neural signal sensor and external processors that convert neural signals into an output signal under the person's own control.

The sensor consists of a tiny chip about the size of a baby aspirin, with 100 electrode sensors each thinner than a hair that detect brain cell electrical activity. The sensor is implanted on the surface of the area of the brain responsible for movement, the primary motor cortex. The sensor is connected by a small wire to a pedestal which is mounted on the skull, extending through the scalp. The pedestal is in turn connected by a cable to a cart containing computers, signal processors and monitors which enable the study operators to determine how well a study participant can control their neural output.

DCRI to evaluate Recom Model 100 12-Lead ECG system

Recom Managed Systems has entered into a sponsored research agreement with Duke University's Clinical Research Institute (DCRI) to evaluate the performance of the Recom Model 100 ambulatory ECG monitoring system. This market preference testing will evaluate the Model 100's performance against currently marketed ECG monitoring devices.

Under the terms of the agreement, Recom will provide financial support for DCRI's costs to perform the study, which the parties anticipate will commence within the next two months. With regard to the study, the DCRI's responsibilities will include: strategy development; protocol development; study planning; interim analysis; a Clintrial database; and final study report. As a condition to the agreement, DCRI is entitled to publish its findings for its own teaching, research, education and clinical purposes.

The Recom ECG monitor system utilises the company's patented signal technology that produces a high-fidelity ECG signal in the presence of ambient noise. This research is intended to demonstrate that a Recom 12-lead ambulatory recording can produce ECG data on a par with other 12-lead modalities such as resting ECG and exercise stress testing.

AMIHOT data supports use of new device for reducing infarct size

TherOx has released data that indicates their investigational device to treat heart attacks, the DownStream system, significantly reduces the size of a heart attack when used in conjunction with the standard of care (angioplasty and stenting) for the treatment of Acute MI. Drs William W O'Neill and Jack L Martin, presented results from the Acute Myocardial Infarction Hyperoxemic Therapy (AMIHOT) 269-patient trial on behalf of the investigators, at the recently-convened Transcatheter Therapeutics (TCT) conference in Washington, DC.

The TherOx DownStream system incorporates a proprietary process dissolving oxygen in saline to create an AO solution and mixes it with the patient's blood. The system then delivers the highly oxygen-enriched blood to oxygen-deprived areas of the heart following heart attack. AO is the first recent adjunctive therapy to reduce the endpoint of infarct size in STEMI. TherOx' DownStream system includes portable hardware that

infuses AO into blood, and disposable devices for the local delivery of this hyperoxemic blood to targeted regions of the cardiovascular system.

The AMIHOT study was conducted at 23 sites in the US and Europe. All patients enrolled in the study were administered urgent PCI with stents; for patients who were treated with PCI within six hours of symptom onset, significant reductions in infarct size as measured by SPECT imaging and regional wall motion score as measured by contrast 2D ECHO, were observed in the AO therapy group, as compared with controls. O'Neill and Martin, also presented results for anterior AMI patients treated within 24 hours of symptom onset, showing significant improvement in both wall motion score and ST-Elevation reduction in the AO therapy group.

The study is the first AMI adjunctive device study to demonstrate significance in the multiple endpoints of ST-Elevation reduction, Sestamibi perfusion scan, and Regional Wall Motion Score Index. The data revealed that hyperoxemic reperfusion with AO appears safe and well-tolerated after primary PCI for AMI; Infarct size (as determined by Sestamibi Scan) showed a favourable trend in the entire cohort with a significant reduction in infarct size in patients treated within six hours of symptom onset; early indication of relief of myocardial ischaemia (ST-Segment resolution) leads to later functional recovery (RWMSI improvement at three months); and ST-Segment resolution is significantly better in the anterior MI group with a favourable trend in the entire cohort.

The results also showed a statistically significant reduction in infarct size versus the control group for patients who received the AO therapy within six hours from symptom onset. The majority of heart attack victims arrive at the hospital and are treated within this six-hour window, therefore, the investigators claim, AO therapy will benefit the majority of patients.

TherOx received the CE mark in 2002 and is currently commercialising the DownStream system in Europe. The system is currently under investigational use in the US, pending FDA approval.

Study demonstrates efficacy of ON-Q PainBuster following robotic radical prostatectomy

I-Flow has announced that a study led by urologist, Dr Vipul Patel, shows the use of ON-Q PainBuster pain relief system following radical prostatectomy surgery performed with a robotic minimally-invasive technique, effectively treats pain while minimising or eliminating the need for narcotics, the current standard of care. The data was presented by Patel at the American College of Surgeons 90th Annual Clinical Congress. The results of the study, which included 300 patients and was conducted at St Vincent's Hospital in Birmingham, AL, and the Urology Centers of Alabama, showed that patients got back to their normal lives faster.

Results of the study show that 77 per cent of patients who were given ON-Q PainBuster to relieve their pain following robotic radical prostatectomy required no narcotics during their postsurgical recovery. The remaining patients required significantly less narcotics than normal. Furthermore, ON-Q patients returned to normal activities more than a full day earlier following this procedure.

Narcotics are still the current standard of care for pain relief following surgery. However, use of narcotics carry side effects which include nausea, drowsiness, constipation, difficulty breathing and potential addiction. As seen from this study, reducing narcotics intake allows patients to spend less time in the hospital, thus returning them to normal faster. The ON-Q PainBuster consists of a small balloon pump that holds a local anaesthetic and delivers it through a catheter directly into the surgical site. The proprietary ON-Q Soaker Catheter is designed to provide more even distribution of local anaesthetic over a wider area, as compared with other catheters, because of its patented wicking capabilities. ON-Q is now labelled to significantly reduce pain and narcotics intake after surgery.

CPV Intraject trial demonstrates successful performance and "excellent" reliability

Aradigm has announced positive results from the Clinical Performance Verification (CPV) trial of its Intraject needlefree delivery system. Results from the trial showed that the study met its primary endpoint of demonstration of successful injection performance with Intraject with an "excellent" reliability profile.

The trial demonstrated acceptable performance and delivery consistency of the selected configuration in 194 healthy subjects who were each given multiple injections of saline via Intraject. In total, there were 1,152 injections with no occurrence of injection-related adverse events and no reliability issues such as glass breakage or malfunctions. Subjects rated their injections as causing little or no pain sensation, a result in line with numerous other studies previously conducted with Intraject. In addition, the majority of subjects responded that they preferred the use of the Intraject device to a standard needle injection.

This trial was the final stage of technical development for Intraject and Dr Bryan Lawlis, President and CEO, believes that it demonstrates that the technological and design issues that faced the system prior to Aradigm's acquisition of the Intraject technology have been fully addressed. The company expects to complete and announce the selection of the drug by the end of 2004, with the objective of commencing pivotal trials for regulatory submissions in the second half of 2005.

IDMC backs further testing of Northfield's blood substitute product

An independent data monitoring committee (IDMC) has recommended that Northfield Laboratories' pivotal Phase III trial with PolyHeme continue without modification, following the second planned interim analysis of the study.

According to the IDMC, there are no concerns to alter the protocol after a review of blinded data on mortality and serious adverse events in the first 120 patients enrolled in the study. Northfield believes this is the first time a blood substitute has successfully passed this patient evaluation milestone in a Phase III trial in the high-risk trauma population.

The pivotal Phase III study is designed to evaluate the safety and efficacy of PolyHeme, Northfield's human haemoglobin-based oxygen carrier, when administered to patients in haemorrhagic shock following traumatic injury. It is the first study in the US in which treatment with a blood substitute begins at the scene of injury. Patients are currently being enrolled at Level I trauma centres throughout the US, with a target enrolment of 720 patients. The primary endpoint is 30 days survival.

The IDMC is a group of experts, not associated with Northfield, responsible for periodically evaluating the safety data from the study and making recommendations relating to the continuation or modification of the study to minimise any identified risks to patients. These "interim looks" are defined in the study protocol and take place after 60, 120, 250 and 500 patients are enrolled and followed for a 30-day period to assess survival. The IDMC will review all safety data as the study proceeds, focusing on mortality and serious adverse events. Northfield will receive a recommendation from the IDMC after each review, but does not have access to the actual data or the deliberations of the IDMC, and will remain shielded from the data until the study is complete. Patients continue to be enrolled in the study while the IDMC conducts its reviews of interim data.

Magnesium-based compound could eliminate screws/plates in surgery

In clinical testing at Ohio State University, a magnesium-based, bio-absorbable adhesive compound has been successfully tested against leading products in the orthopaedic cement/filler markets. Bone Solutions, the company involved in the trial, claims its products provided "significantly superior strength" and could potentially eliminate the need for screws, plates and other traditional tools used widely in orthopaedic surgery.

Bone Solutions believes the material has the potential of "revolutionising" certain orthopaedic surgical procedures, starting with the ACL market, and that of extremities, since the material reduces the time it takes for hand, shoulder or ankle injuries to heal. The company's inorganic compound not only has powerful adhesive qualities and is bio-absorbable and non-toxic, but is also injectable. As the compound is magnesium-based, it also overcomes many of the limitations of calcium-based cements and fillers.

The results showed adhesive properties exceeding 1,000 newtons, which could be sufficient to contain even fracture fragments in comminuted fracture repair. The compound is sufficiently strong to significantly support, or potentially be used independently, in ACL reconstruction.

Third patient reaches one-year milestone after receiving the CardioPass CABG

CardioTech International has revealed that a third patient has reached the one year milestone and is living a normal life, after receiving a CardioPass synthetic coronary artery bypass graft (CABG) at the Institute for Cardiology, Porto Alegre, Brazil, in October 2003.

The CardioPass is used for no-option patients, who have used all available veins and arteries and have no other option but to use a synthetic artery. During CABG surgery, a surgeon takes a segment of a healthy vein or artery from another part of the body and uses it to create a detour or bypass around the blocked portion of the diseased coronary artery. A patient may undergo one, two, three or more bypasses, depending upon how many coronary arteries are blocked. According to protocol, the triple bypass was performed using the CardioPass to bypass the circumflex artery; the left internal mammary artery was used to bypass the left anterior descending, and a radial artery was used to bypass a diagonal artery. CardioTech believes it is the only company in the world in clinical trials with a synthetic coronary artery bypass graft. This technology addresses a potential market of US\$1.5 billion annually.

CardioTech intends to expand the Brazilian trials to include an additional 25 patients in ten different hospitals and is also preparing for a clinical trial in Europe recruiting 30 to 50 patients to be followed for one year with its CABG technology in early 2005.

Study suggests new procedure helps treat OA in lumbar facet joints

A clinical study, published in the October 2004 issue of the Journal of Minimally Invasive Spinal Technology, has shown that Trimedyn's Holmium laser can be effectively used to treat osteoarthritis (OA) in lumbar facet joints in the spine, a common cause of low back pain.

A total of 20 patients with arthritis of the facet joint were treated on an out-patient basis by Dr Sri Kantha, of the Metropolitan Neurology and Spine Institute, Fort Lee, NJ. All of the patients were discharged the same day, with pain medication, muscle relaxants and no restrictions on physical activity. After one-year, 75 per cent of the patients reported significant or partial relief of their lower back pain, with 25 per cent reporting their back pain was the same as before the procedure. Older patients did not respond as well as younger patients. According to Kantha, at least one million people in the US who suffer from lower back facet joint pain could be successfully treated with the new laser procedure, called laser lumbar facet rhizotomy.

Trimedyn plans to submit this clinical study to the FDA for review, along with an application for clearance to market its Holmium laser and disposable laser needles for this use. These devices will not be available for sale for the treatment of arthritis in lumbar facet joints in the US until such approval has been received for the treatment of this condition.

Study finds FzioMed's Oxiplex/AP Gel reduces postsurgical adhesions

FzioMed is set to present positive clinical results of its Oxiplex/AP Gel, an adhesion barrier for laparoscopic gynaecological surgery, at the 13th Annual Congress of the European Society of Gynaecological Endoscopy, being held between 14th and 17th October 2004 in Cagliari, Italy.

The majority of patients undergoing gynaecological surgery will develop postoperative adhesions: abnormal bands of scar tissue that can form inside the body after surgery. Postsurgical adhesions can cause infertility and/or chronic pelvic pain. Oxiplex/AP Gel is an absorbable, synthetic gel that coats tissues and acts as a barrier to adhesion formation.

The oral presentation entitled, "Reduction of Adhesions Following Laparoscopy with Oxiplex/AP Gel" will include clinical data from a randomised, blinded, parallel-group postmarket study of Oxiplex/AP Gel conducted in four hospitals in Europe. Study objectives were designed to evaluate the performance of Oxiplex/AP Gel in patients undergoing laparoscopic gynaecological surgery. The results of the study demonstrated that Oxiplex/AP Gel was well tolerated by patients and easy to apply by laparoscopy. Patients with and without endometriosis who received Oxiplex/AP Gel during surgery had reduced adhesion formation, compared with patients who did not receive the gel, as demonstrated by statistically significant reduction in American Fertility Society adhesion scores.

FzioMed's Oxiplex adhesion barrier technology is approved in the EU for spinal, gynaecological and abdominal surgery. FzioMed began selling Oxiplex/SP Gel for spine surgery in the EU in 2002, and has plans to launch the product for gynaecological and abdominal surgery.

Interactive breathing device helps lower high systolic blood pressure

Details of a multi-centre, randomised controlled study of InterCure's interactive breathing device, RESPeRATE, have been published in the October 2004 edition of the Journal of Clinical Hypertension.

The study, which involved a total of 149 patients and was led by Dr William J Elliott of Rush University Medical Center, demonstrated that as little as 45 minutes of weekly self-treatment with the RESPeRATE device significantly reduces systolic blood pressure in both medicated and non-medicated patients. The reductions were significantly greater than those observed in patients in the control group. Patients in both groups self-monitored their blood pressure with data-logging digital blood pressure monitors.

The company says it is confident that this validation from a large US-based study, together with the successful results from six previous European RESPeRATE clinical trials, will expedite the integration of RESPeRATE into the standard of care for hypertension.

AB5000 gives surgical team time to save patient

The first European patient to have his heart supported by Abiomed's AB5000 circulatory support system has recovered from acute fulminant myocarditis. The AB5000 provides temporary support for one or both sides of the native heart in circumstances where the heart has failed, giving the patient's heart the opportunity to rest and potentially recover, and giving surgeons the therapeutic flexibility necessary to determine the best endpoint for treatment.

The patient was admitted to University Hospital Lund, in Sweden, suffering from a cardiac arrest. The patient was treated for cardiogenic shock and was considered to have close to 100 per cent risk of mortality. Over a period of two days, the patient's situation deteriorated, culminating in a severe shock requiring CPR and stabilisation with the heart lung machine. He was immediately placed on the Abiomed BVS5000 circulatory support system to support both sides of his heart, which helped improve his stability and bloodflow. After four days, he was switched to the AB5000 system to prepare him for a longer duration of support and to allow him improved mobility.

Dr Bansi Koul noted that the patient, who during the treatment developed heparin-induced thrombocytopenia, was managed with an alternative regimen of anti-coagulation without any clots forming. After 20 days of total support, it was determined that the patient's native heart had fully-recovered and was once again able to sustain his circulation. The AB5000 was successfully explanted and the patient is due to be discharged from the hospital. According to Koul, by stabilising the patient on the BVS 5000 and then converting to the AB5000, the clinical team had adequate time to assess the patient and determine the best course for treatment. Receiving bi-ventricular support on the AB5000 allowed the patient's heart to recover. Furthermore, the ability to switch from the BVS5000 to the AB5000 without re-opening the chest also helps with recovery, as there is a greatly reduced possibility of infection or bleeding.

Intraop plans US IORT lung study

Dr Subir Nag, Director of Intraoperative Radiation Therapy and Brachytherapy at the Arthur James Cancer Hospital at The Ohio State University in Columbus, has agreed to be the principal investigator in a protocol that will use intra-operative radiation therapy (IORT) for the treatment of advanced lung cancer. In addition to The Arthur James Cancer Center, several other US centres with dedicated IORT capability are expected to participate in this study. In addition, a similar study has been initiated for European IORT centres. The study will be funded in part by Intraop Medical, which has developed the Mobetron system for IORT treatment of cancer.

The protocol is based on a pilot study of about 100 patients treated with IORT at the University of Navarre in Pamplona, Spain. In this pilot study, patients were transported from the surgical theatre to the radiation department in the middle of the surgery to give the IORT

treatment using a conventional electron linear accelerator. After the IORT treatment, the patients were transported back to the operating room for the completion of the surgery. This pilot study showed significant improvement in both local control and survival (about 40 per cent five-year survival) compared with conventional treatment for advanced lung cancer (about 15 per cent five-year survival).

Studies in the US and China showed similar results, but because of the difficulty of delivering IORT for lung cancer patients through patient transportation, it has been difficult to establish IORT as an important component of advanced lung cancer treatment.

Study suggests weight loss surgery helps to improve obesity-related health conditions

Details of a new study have been published in the October 2004 issue of The Journal of the American Medical Association (JAMA), which indicate that weight loss surgery improved or eliminated diabetes, hypertension, sleep apnea and high cholesterol in the vast majority of morbidly obese patients. The study was sponsored by Ethicon Endo-Surgery, a Johnson & Johnson company.

Using a process known as a meta-analysis, researchers for the first time systematically reviewed over 130 studies that included more than 22,000 weight loss surgery patients and reported on the impact weight loss surgery had on these four obesity-related conditions. According to Dr Henry Buchwald, Department of Surgery of the University of Minnesota, weight loss surgery appears to be one of the most effective treatments for diabetes, hypertension, obstructive sleep apnoea and high cholesterol in morbidly obese patients.

According to the study, diabetes was eliminated in 76.8 per cent of patients, while 86 per cent eliminated or improved their condition. Hypertension was eliminated in 61.7 per cent patients and resolved or improved in 78.5 per cent. Obstructive sleep apnoea or sleep-disordered breathing was eliminated in 85.7 per cent of patients and high cholesterol levels or hyperlipidemia decreased in more than 70 per cent of patients. The mean percentage of excess weight loss was 61.2 per cent for all patients.

New system could produce real benefits for breast cancer research

Researchers at the Tom Baker Cancer Center and University of Calgary are using VivoMetrics' LifeShirt system in combination with the Mindfulness Based Stress Reduction (MBSR) programme to help identify how stress reducing activities can affect symptoms of fatigue, sleep and autonomic parameters in breast cancer patients. A better understanding of how psychological and physiological factors combine to affect distressing symptoms associated with breast cancer is expected to lead to behavioural treatments aimed at reducing these symptoms, improving quality of life and restoring balance among bodily systems.

This study, the first non-intrusive research of its kind, is using the LifeShirt to continuously monitor respiratory and cardiac function to determine sleep disruption, fatigue and anxiety in ten patients that previously underwent an eight-week MBSR programme, teaching mindfulness meditation, relaxation and yoga techniques. The study is funded by the Canadian Breast Cancer Research Alliance and was made possible by its Developmental and Exploratory Grants programme. Results of the study will be announced in 2005.

The LifeShirt system is a non-invasive, ambulatory monitoring system that continuously collects, records and analyses a broad range of cardiopulmonary parameters. Users wear a lightweight, machine washable garment with embedded sensors that collect pulmonary, cardiac, posture and activity signals. Data collected by integrated peripheral devices measure blood pressure, blood oxygen saturation, EEG/EOG, periodic leg movement, temperature, end tidal CO2 and cough. An electronic diary captures subjective user input and all physiologic and subject data are correlated over time.

US patent for VISICU's remote patient monitoring system

VISICU has been granted US Patent No. 6,804,656 by the USPTO relating to its eICU technology, entitled, "System and method for providing continuous, expert network critical care services from a remote location(s)."

The eICU solution features a centrally located, remote monitoring system equipped with high-fidelity telemedicine and proprietary early warning and intervention software. This patented technology, which is currently operational in 13 major health systems around the US, will be monitoring over 1,500 critical care beds by the end of 2004. VISICU believes it is the first company to receive such US patent protection and

the first to bring remote critical care (eICU centres) to the marketplace.

eICU technology enables hospitals to meet stringent patient care safety standards and supports key changes in hospital critical care. The solution connects the patient to the doctor continuously and allows hospitals to use their intensivists resources to care for large numbers of patients simultaneously. This new care delivery model enables optimal use of scarce healthcare resources while simultaneously improving patient outcomes and financial results for health systems.

R&D NEWS IN BRIEF

Ossur's partnership with the R&D company, **Victrom Human Bionics**, has led to the development of a bionic prosthetic for lower extremity amputees that will move rapidly into premarket tests in selected markets, including North America. A full-scale market launch for the product is expected to take place during 2005.

Cambridge Consultants and **TeraView** are working together with a team of international surgeons to establish the best market entry strategy for TeraView's advanced imaging technology for breast cancer. TeraView is currently conducting a series of studies with Addenbrooke's Hospital, in Cambridge, UK, which involve imaging healthy and cancerous tissues. By utilising the technology, it is hoped that significant healthcare savings could be made worldwide by reducing the need for repeat surgery. TeraView's core technology centres around the use of Terahertz radiation, which lies between microwave and infrared and represents the last unexplored region of the electromagnetic spectrum. Terahertz radiation is able to image in 3D, provide spectroscopic information and can distinguish between diseased and normal tissue. The potential benefits of the system include improved detection rates of unhealthy tissue during surgery, leading to a decrease in repeat surgery and morbidity.

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