MEDICAL DEVICE DAILY™

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ANGIOPLASTY BALLON TECHNOLOGY

Mixed data fogs crystal ball for Bard's Lutonix 035 DCB

By Amanda Pedersen, Senior Staff Writer

The first drug-coated angioplasty balloon approved by the FDA showed superior primary patency over standard balloons at 12 months, but some industry analysts are skeptical about longer-term data. According to 12-month results published in *The New England Journal of Medicine*, the Lutonix 035 drug-coated balloon percutaneous transluminal angioplasty (PTA) catheter from **C. R. Bard** (Murray Hill, New Jersey) demonstrated superior primary patency over standard PTA in the LEVANT 2 study. LEVANT 2 was a single-blind randomized multicenter trial.

The 12-month primary patency rate was 65.2% for the Lutonix and 52.6% for a standard PTA balloon (P=0.02 for superiority), and the rate of freedom from primary

See Bard, page 4

LATIN AMERICA

Big step: Brazil's CDTN registers first domestic radiopharmaceutical

By Sergio Held, Staff Writer

BOGOTA, Colombia — A research center has completed registration of Brazil's first domestically developed and produced radiopharmaceutical, a giant step for nuclear medicine in the country.

Making the event even more significant,

See Latin America, page 5

CATARACT SURGERY PROCEDURES

Calhoun's new vision resonates with patients and investors

By Omar Ford, Staff Writer

Privately owned **Calhoun Vision** (Pasadena, Calif.) is hoping to add more accuracy to cataract surgery procedures through its light adjustable intraocular lens (LAL) technology. The company is vying to get the technology approved and has built up a considerable war chest in the process. Earlier this month, Calhoun revealed that

See Calhoun, page 6

INSIDE THE BELTWAY

FDA targets management at AG Industries; HeartWare provides updates HVAD recall

By Richie Crider, Contributing Writer

FDA rejected several attempts by **AG Industries** (St. Louis) to foist the blame on its employees for not following proper procedures for medical device reporting (MDR) and for meeting other quality system (QS) requirements. Instead, the agency said, inadequate management oversight is the root cause of all the regulatory deficiencies at the company.

During a March 26 to April 13 inspection, FDA investigators uncovered a host of alleged QS failures, such as failure to report a complaint of a serious injury and failure to follow written procedures for conducting corrective and preventive action (CAPA) reviews. In an April 24 response to the FDA form 483, the company blamed most of the violations on employee negligence and inadequate employee training. However,

See Beltway, page 7

IN THIS ISSUE

PATENT HIGHLIGHTS

Medical Device Daily presents Patent Highlights, an excerpt of the most important med-tech patents from this week's Cortellis Patents Gazette. See the attachment at the end of this edition.

NEUROLOGY EXTRA

Staff Writers Robert Kimball and Shyama Ghosh on one of med-tech's key sectors

Read this week's Monday Special

WORLD IN REVIEW

IBA to install three of its Proteus ONE systems in UK

IBA (Ion Beam Applications, Louvain-La-Neuve, Belgium), a provider of proton therapy solutions for the treatment of cancer, has signed three separate binding term sheets with **Proton Partners International** (PPI; Spokane, Wash.) to install three of IBA's Proteus ONE compact proton therapy systems in private clinics in the UK.

Each term sheet covers delivery of the Proteus ONE equipment, including Pencil Beam Scanning and Cone Beam CT capabilities, and a ten-year maintenance agreement. The typical end-user price for a Proteus ONE system with such a maintenance contract is between €35 million and €40 million. These three centers will be the eighth, ninth and tenth installations of IBA's compact single-room proton therapy solution and are expected to treat the first patients in 2017.

The proton therapy center in Newport will treat patients from Wales, the south-west of England and the Midlands, and the center in Newcastle will treat patients from the North of England. The location of the third center will be announced at a later date.

These three projects follow the framework agreement that IBA and Philips signed in September 2014 to advance the diagnosis and treatment of cancer and demonstrate the efficiency of the collaboration between the two organizations.

IBA said that more than half of all proton therapy clinical facilities worldwide are equipped with IBA systems. This includes 18 proton therapy centers currently in operation and 19 additional centers under development. **//**

PEOPLE IN PLACES

• **EndoGastric Solutions** (Redmond, Wash.), a maker of incisionless procedural therapy for gastroesophageal reflux disease (GERD), reported three new appointments to its executive team: Mike Zagger – VP, sales and marketing; Philip Macdonald – VP of healthcare economics, policy & reimbursement; and Adrian Lobontiu, MD – medical director. Prior to joining EGS, Zagger was a senior VP/GM with St. Jude Medical. Mcdonald previously was VP of healthcare economics, policy & reimbursement at Given Imaging. Lobontiu rejoins EGS as its medical director, a position he held for nine years. EndoGastric Solutions makes the EsophyX device which is inserted through the patient's mouth with visual guidance from an endoscope.

• **Orthofix International** (Lewisville, Tex.) has named Lilly Marks to its board. With more than three decades of major healthcare system provider experience, she serves as the VP for Health Affairs for the University of Colorado and has led the University of Colorado Anschutz Medical Campus. Orthofix develops reconstructive and regenerative orthopedic and spine products.

PRODUCT BRIEFS

• **Caldera Medical** (Agoura Hills, Calif.), a company developing products for pelvic organ prolapse, reported the release of an improved Vertessa Lite mesh for sacrocolpopexy procedures. The new Vertessa Lite will be offered in configurations including Y-mesh, flat mesh sheets and mesh strips.

MEDICAL DEVICE DAILY

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CONTACT US

medicaldevicedaily.newsdesk@medicaldevicedaily.com

Donald R. Johnston, (770) 810 3118 // Holland Johnson, (770) 810-3122 // Amanda Pedersen, (912) 660-2282 // Omar Ford, (770) 810-3125 // Robert Kimball, (770) 810-3127 // Mark McCarty, (703) 361-2519 // Sarah Cross, (770) 810-3138// Penney Holland (770) 810-3047 // Tracie Webb, (770) 810-3130 // Lynn Yoffee, (770) 810-3123

OUR NEWSROOM

Lynn Yoffee (News Director), Holland Johnson (Executive Editor), Robert Kimball (Senior Production Editor), Mark McCarty (Regulatory Editor), Omar Ford & Amanda Pedersen (Staff Writers)

PRACTICAL INFORMATION

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BUSINESS OFFICE

Donald R. Johnston (Senior Director, Editorial), Sarah Cross (Marketing Director), Penney Holland (Web Production Manager), Tracie Webb (Customer Service Manager)

10 BIGGEST U.S. WINNERS FOR THE WEEK

By Percent		By Dollars	
Merge Healthcare	15.26	Edwards Lifesciences	12.50
Zeltiq Aesthetics	12.37	Teleflex	5.85
Biolase	12.12	Baxter International	3.66
Echo Therapeutics	11.61	Zeltiq Aesthetics	3.48
Bovie Medical	11.28	Hill-Rom Holdings	3.47
Mazor Robotics	9.76	Inogen	3.35
Edwards Lifesciences	9.36	Henry Schein	3.29
Cynosure	8.22	Abiomed	3.10
Inogen	8.17	C.R. Bard	3.03
Hill-Rom	6.61	Cynosure	2.98

10 BIGGEST U.S. LOSERS FOR THE WEEK

By Percent		By Dollars	
Idexx Laboratories	-50.87	Idexx Laboratories	-65.94
Imris	-50.00	Athenahealth	-2.06
CheckCap	-25.89	Spectranetics	-1.18
Mela Sciences	-23.57	Tornier	-1.15
Delcath Systems	-12.93	NuVasive, .	-0.97
Dehaier Medical Systems	-11.59	CheckCap	-0.95
iCAD	-8.51	3M	-0.95
TransEnterix	-6.29	Haemonetics	-0.84
Iridex	-5.15	Cardiovascular Systems	-0.74
HeartWare	-5.08	Tornier	-0.84

MDD STOCK REPORT FOR PUBLIC MED-TECH COMPANIES

COMPANY	SYMBOL	CLOSE 6/19	CLOSE 6/26	%CHANGE WK	%CHANGE YTD	VOL (000)
3M	MMM	158.04	157.09	-0.60%	-4.40%	11020
Abbott Laboratories	ABT	48.67	49.97	2.67%	11.00%	21729
Abiomed	ABMD	63.65	66.75	4.87%	75.38%	2059
Accuray	ARAY	7.07	6.83	-3.39%	-9.54%	3785
Affymetrix	AFFX	11.63	11.05	-4.99%	11.96%	4856
Agilent Technologies	A	39.84	40.02	0.45%	-2.25%	19524
Alere	ALR	50.88	52.27	2.73%	37.55%	1875
Align Technology	ALGN	63.02	62.63	-0.62%	12.02%	3586
Allscripts Healthcare	MDRX	14.15	14.15	0.00%	10.81%	11531
Athenahealth Inc	ATHN	117.74	115.68	-1.75%	-20.60%	1629
Bacterin Internat	BONE	3.8	4	5.26%	32.01%	297
Baxter Internat	BAX	68.26	71.92	5.36%	-1.87%	44816
BD	BDX	139.6	142.09	1.78%	2.11%	4619
Biolase	BIOL	1.65	1.85	12.12%	-29.66%	260
Boston Scientific	BSX	17.56	18.09	3.02%	36.53%	42692
Bovie Medical	BVX	2.66	2.96	11.28%	-19.57%	119
C.R. Bard	BCR	170.51	173.54	1.78%	4.15%	1527
Cantel Medical	CMN	51.93	53.91	3.81%	24.62%	522
Cardiovascular Syst	CSII	29.13	28.39	-2.54%	-5.62%	1316
CheckCap	CHEK	3.67	2.72	-25.89%	-52.78%	19
Conmed	CNMD	56.22	59.11	5.14%	31.47%	539
Cyberonics	CYBX	61.43	61.5	0.11%	10.45%	1160
Cynosure	CYNO	36.24	39.22	8.22%	43.03%	1169
Dehaier Medical Syst	DHRM	3.02	2.67	-11.59%	-2.55%	98
Delcath Systems	DCTH	1.16	1.01	-12.93%	-16.53%	692
Dentsply Internat	XRAY	52.11	52.33	0.42%	-1.76%	4228
Echo Therapeutics	ECTE	1.55	1.73	11.61%	28.15%	87
Edwards Lifesciences	EW	133.58	146.08	9.36%	14.68%	5210
Fluidigm	FLDM	24.55	25.4	3.46%	-24.70%	1535
Haemonetics	HAE	42.84	42	-1.96%	12.24%	1424
Hansen Medical	HNSN	0.92	0.9	-2.17%	60.71%	4202
HeartWare Internat	HTWR	73.95	75.6	2.23%	2.96%	553
Henry Schein	HSIC	142.16	145.45	2.31%	6.83%	1878
Hill-Rom Holdings	HRC	52.48	55.95	6.61%	22.64%	2263
Hologic	HOLX	37.3	38.25	2.55%	43.04%	9499
iCAD	ICAD	3.88	3.55	-8.51%	-61.29%	332
ICU Medical	ICUI	95.41	95.8	0.41%	16.97%	504
Idexx Laboratories	IDXX	129.63	63.69	-50.87%	-57.04%	3407
Imris	IMRS	0.02	0.01	-50.00%	-98.81%	628
Inogen	INGN	40.99	44.34	8.17%	41.35%	1548
Intersect ENT	XENT	29.03	28.65	-1.31%	54.45%	
Intuitive Surgical	ISRG	495.66	497.15	0.30%	-6.01%	1021
Iridex	IRIX	8.61	8.4	-2.44%	-1.52%	74
Johnson & Johnson	JNJ	98.31	99.64	1.35%	-4.71%	32429
Kips Bay Medical	KIPS	0.03	0.03	0.00%	-80.00%	284
LabCorp	LH	119.88	121.62	1.45%	12.72%	4485
Masimo	MASI	38.84	39.46	1.60%	49.81%	1351
Mazor Robotics	MZOR	13.11	14.39	9.76%	15.95%	279
Medtronic	MDT	75.52	75.16	-0.48%	4.10%	23060
Mela Sciences	MELA	1.57	1.2	-23.57%	0.00%	3360
Merge Healthcare	MRGE	4.26	4.91	15.26%	37.92%	3277
Meridian Bioscience	VIVO	18.42	18.75	1.79%	13.91%	855
NuVasive, Inc.	NUVA	49.99	49.02	-1.94%	3.94%	1442
NxStage Medical	NXTM	15.56	14.77	-5.08%	-17.62%	3089
Orthofix Internat	OFIX	33.97	33.26	-2.09%	10.65%	545
Pall	PLL	124.66	124.59	-0.06%	23.10%	4141
Quest Diagnostics	DGX	73.04	72.75	-0.40%	8.48%	6377
Quidel	QDEL	22.9	23.07	0.74%	-20.23%	1112
RTI Surgical	RTIX	6.57	6.5	-1.07%	25.00%	1594
Smith & Nephew	SNN	34.13	34.65	1.52%	-5.69%	3927
Spectranetics	SPNC	26.5	25.32	-4.45%	-26.78%	3024
St. Jude Medical	STJ	74.34	74.38	0.05%	14.38%	3768
Stryker	SYK	95.67	97.34	1.75%	3.19%	4817
TearLab	TEAR	2.26	2.23	-1.33%	-15.85%	468
Teleflex	TFX	130.91	136.76	4.47%	19.11%	1600
The Cooper Companies	COO	177.47	178.88	0.79%	10.36%	1336
Thermo Fisher	TMO	130.02	132.21	1.68%	5.52%	7614
Thermogenesis	KOOL	0.83	0.79	-4.82%	-22.55%	411
Thoratec	THOR	45.35	44.98	-0.82%	38.57%	1381
Titan Medical	TITXF	1.36	1.29	-5.15%	7.50%	498
Tornier NV	TRNX	26.72	25.57	-4.30%	0.27%	712
TransEnterix	TRXC	3.02	2.83	-6.29%	-2.75%	4715
Varian Medical	VAR	85.78	85.29	-0.57%	-1.41%	3086
Vascular Solutions	VASC	32.65	34.76	6.46%	27.98%	477
Wright Medical	WMGI	27.65	27.2	-1.63%	1.23%	2709
Zeltiq Aesthetics	ZLTQ	28.14	31.62	12.37%	13.29%	2057
Zimmer Holdings	ZMH	112.2	113.56	1.21%	0.12%	8170

NOTES

Trading volumes for Nasdaq, Amex and NYSE are recorded as the total number of shares traded (in thousands) on a weekly basis (cumulative Monday through Friday); the weekly and YTD % changes are from IPO completion, where applicable.

Average Percent Change Week: -0.87%

Range: -50.87% to +15.26%; Number Of Companies: 77
(does not include LSE or TSX; not market weighted)

Average Percent Change YTD: +4.95%

Range: -98.81% to +75.38%; Number Of Companies: 77
(does not include LSE or TSX; not market weighted)

Bard

Continued from page 1

safety end points was 83.9% and 79.0%, respectively (P=0.005 for noninferiority).

The study authors noted that while the 12-month findings are encouraging, long-term follow-up will be important to determine whether the patency benefit of the device is sustained over time. Interim 24-month data that was included in the company's FDA briefing documents for the advisory committee meeting last year showed a diminished treatment effect at 24 months, although that was in a much smaller sample of the initial cohort.

John DeFord, senior VP of science, technology and clinical affairs at C. R. Bard, said the published 12-month results should provide additional confidence to clinicians looking to use a DCB in treating peripheral artery disease (PAD) in the femoropopliteal arteries. DeFord told *Medical Device Daily* that the interim 24-month data that the FDA saw was relatively limited but that the investigators shared a summary of the final 24-month data earlier this month at the annual Society for Vascular Surgery (SVS) meeting.

The primary patency at two years in the complete data dropped from 65.2% at one year to 58.6% at two years in the Lutonix group, which DeFord said is still positive. He said the re-intervention rate was also positive, although not statistically significant, with 12% re-intervention at one year and 18% at two years. As for safety, he said the Lutonix was "almost superior" over the standard device at two years, even though the study was never powered to evaluate that.

Larry Biegelsen, senior analyst of medical supplies and devices at Wells Fargo Securities, noted in a report ahead of the SVS meeting that based on the interim 24-month data in the FDA briefing document, the final 24-month data is likely to disappoint clinicians. The interim 24-month data in the FDA document includes follow-up on more than 50% of patients and shows that the primary patency rate for Lutonix was 31.8% compared to 20.0% for the control device, with a p value of 0.047, which is borderline significant.

Biegelsen did note, however, that the final 24-month data for the Lutonix balloon was expected to look somewhat better than the interim data. That's because the interim data captured patients who had shown up in the clinic as failures whereas the patients who were doing well had not come back yet for their 24-month visit.

"However, we continue to believe that the final data will be disappointing to clinicians. Physicians have indicated that a primary patency rate for Lutonix below 50% would be viewed as disappointing."

Another point Biegelsen made in his report is that if the difference between Lutonix and the control is no longer statistically significant in the final data that would also be viewed as disappointing by doctors.

Freedom from clinically driven target lesion revascularization (TLR) was not statistically significant between the Lutonix and control group at either 12 or 24 months, the difference between the two arms increased from 3.1% at 12 months to 5.8% at 24 months. The authors noted that the 476-patient trial was not sufficiently powered for TLR.

The Lutonix 035 DCB was the first DCB approved by the FDA in October 2014. The approval followed a unanimous favorable recommendation from the FDA's Circulatory Systems Devices Advisory Panel, which voted 9 to 0 on each element of safety, efficacy, and benefit vs. risk. The LEVANT 2 study enrolled patients at a total of 54 sites, 42 in the U.S. and 12 in Europe.

Kenneth Rosenfield, section head of vascular medicine and intervention in the Division of Cardiology and Fireman Vascular Center at Massachusetts General Hospital, served as principal investigator for the study. According to Rosenfield, LEVANT 2 followed a rigorous blinding protocol, which was designed to reduce bias in the results. In addition to superiority in primary patency, he said the Lutonix balloon, which is coated with the drug paclitaxel, demonstrated sustained improvements in Rutherford category from baseline to 12 months, and improved patient-reported walking distance scores.

DeFord said a global real-world registry of 460 patients showed a primary patency of 91% for the Lutonix balloon and freedom from re-intervention was 92%. That registry included data from outside the U.S. as well as within the U.S., he said.

DeFord told *MDD* the LEVANT 2 study was a very uniquely designed and rigorous study that used a different blinding strategy. "That's a lot of the explanation for some of the results that were a little bit less than we saw in the global registry," he said.

The Lutonix 035 DCB faces competition from **Medtronic**'s (Dublin) Admiral DCB, a device that is coated with the same active ingredient as the Lutonix (paclitaxel) but DeFord said the primary difference between the two balloons is the way they are coated. He said the Lutonix is coated with a little more than half the drug that the Medtronic Admiral balloon is coated with.

Biegelsen noted in his report that Medtronic is expected to present 24-month data with its Admiral DCB from the IN.PACT 1 and 2 trial in October. He said Medtronic is expected to garner more than 60% share in this market. //

Latin America

Continued from page 1

the **Brazilian Center of Nuclear Technology Development** (CDTN for its acronym in Portuguese; Belo Horizonte, Brazil) became the first company to register a radiopharmaceutical under a set of 2009 regulations, creating a regulatory precedent and pathway that could open the door for a spike in such registrations.

CDTN registered Radioglic, a fludeoxyglucose (18F) radiopharmaceutical it has been working on since 2008. Radiologic is used in PET and PET-CT scans. 18F is a radioactive analogue of glucose that accumulates in all cells using glucose as its primary energy source. It is the most commonly used radiopharmaceutical to obtain PET images.

"The brand Radioglic came into existence on June 22, 2015, a historic date for nuclear medicine in the country," Juliana Batista da Silva, who heads the Research and Production Unit of Radiopharmaceuticals of the CDTN, told *Medical Device Daily*. "In 2008, when we started our activities, a specific standard over Radiopharmaceuticals registration did not exist, and a permission to commercialize without registration was granted. Until that moment on, we based the production on standards that existed for common drugs, following most cited rules on them," Batista explained.

Radioglic is the first radiopharmaceutical registered in Brazil under RDC [64 of 2009], a resolution by Anvisa, Brazil's health surveillance agency, that outlines the guidelines and minimum requirements for the registration of radiopharmaceuticals to assure quality safety and efficacy.

The CDTN started working on 18F before Anvisa had issued the new guidelines. That product went on to become Radioglic and the first domestic product registered under the 2009 guidelines.

The path to registration was a long one.

"The process began in 2008 with obtaining a Permit of Health [to operate] issued by the health surveillance authority," Batista explained. "Then (Anvisa) granted the authorization for the company [to operate] and in 2013 Anvisa issued the Good Manufacturing Practice certificate."

It wasn't until April 2014 that CDTN filed to register Radioglic and it took another 14 months for Anvisa to grant a permit.

"The long period required to register [Radioglic] is particularly linked to the fact that this is the first radiopharmaceutical to be registered," said Batista.

The 2009 regulation established two-year registration terms for the importers and producers of radiopharmaceuticals to register their products. It also opens the door for five-year registration terms for domestically produced radiopharmaceuticals.

However, while Anvisa adjusted its internal procedures for the registration of radiopharma products, it had to extend twice the deadline for radiopharma producers to register their products. In 2011, the deadline was extended to Dec. 2014, and last year the deadline was set on June, 2015.

Between 2008 and 2014 Anvisa authorized all producers to market the FDG without registration, but they were told to work to comply with certifies such as the GMP.

The precedent that CDTN set now opens the door for other companies to register similar products.

"It is expected for all radiopharmaceuticals that are on sale in the country to file for sanitary registration," said Anvisa in a press release. "The Agency will continue the process of regulation of this class of drugs, creating a positive scenario for the entry of new products."

For Batista, the registration of Radioglic is a key step for other similar products.

"The country had little experience in regards to the requirements and conditions for preparing the dossier," she said. "Today, after this long journey, we believe that everyone involved in the process is already in a position to register a new product in a much shorter period, keeping all the necessary requirements."

"Thus, it will be possible to have better nuclear medicine, closer to people's needs."

Under RDC 64 sanitary registrations of radiopharmaceuticals are granted for five years.

Radioglic was approved by Anvisa in its 10 injectable solution presentations, to be administered through IV.

"Radioglic is intended only for use in diagnostic radiology in nuclear medicine services and aimed at tomography positron emission tomography (PET and PET- CT) in the areas of oncology, cardiology and neurology," explained Anvisa.

CDTN declined to comment on the Brazilian market´s perspectives for Radioglic. In 2013 the Brazilian Society of Nuclear Medicine reported that there were 84 PET-CT devices in the country, which has a population of 202.6 million.

In a 2011 article in the *Journal of Nuclear Medicine Technology*, Ralph Santos-Oliveira and Leila Jorge Antunes highlighted the importance and potential of the Brazilian market for the radiopharma production.

"In terms of sales, Brazil is a major player in the radiopharmaceutical market despite considerable barriers to production and reimbursement," the authors wrote.

In 2009, sales of 18F-FDG reached around $35 million, compared with sales of $522 million. At the time, Brazil had just two PET radiopharmaceutical production facilities, compared to more than 30 in the U.S.

In 2014, there were a total of 10 international and domestic FDG producers in Brazil. //

Calhoun

Continued from page 1

it had completed $52 million in new financing with an additional $17 million in debt conversion (*Medical Device Daily*, June 5, 2015). It marks the first time the company has received funding from institutional investors. In the past the company has relied on raising capital from angel investors and individual investors.

Calhoun Vision's CEO, Rick Heinick credits the successful raise with investors understanding the need that the LAL can help meet. Institutional investor Longitude Capital led the round, along with co-investors H.I.G. BioVentures, Balance Point Capital Partners, and RA Capital Management.

Heinick is no stranger to the space, prior to taking the helm Calhoun's CEO, he served as an executive at **Bausch + Lomb** (Rochester, N.Y.) where he helped transform the company, which led to its eventual sale to **Valeant Pharmaceuticals** (Laval, Quebec) for just under $9 billion (*MDD*, May 29, 2013).

"We are using the money now to support the company through its FDA submission process, to make advancements in our product pipeline and to execute on our commercial strategy," Heinick told *Medical Device Daily*.

The company is right in the middle of a 600-patient Phase III study of the light adjustable intraocular lens. Patents will be followed for one year post-surgery.

Although cataract surgery is remarkably safe and regarded as highly efficacious, various surveys have shown that about 40% of cataract patients are dissatisfied with their results. Specifically, it has been demonstrated in many studies that about 50% of patients have a 0.5 diopters shortfall from the targeted refractive goal. This may result in the need for glasses or secondary laser enhancement surgery to achieve the targeted refraction correction.

That's where Calhoun Vision says that it comes in.

Calhoun's LAL system employs a combination of Calhoun's biocompatible, photosensitive materials called macromers and a customized digital light source. The photosensitive silicone LAL is quite similar to a standard monofocal introcular lens (IOL) and is implanted using standard cataract surgery techniques.

When the patient returns for their follow-up visit, typically 17 to 21 days later, the physician assesses the refractive correction and if it is not exactly as intended pre-surgically, the lens is exposed to Calhoun's proprietary light source for 40 to 150 seconds. This causes the macromers to react, changing the shape and therefore the power of the IOL. The LAL is an intraocular lens that can be modified post-cataract surgery, with one to two visits, with the goal of tailoring the refractive correction precisely to the patient's individual visual requirements.

"The LAL is implanted just like any normal IOL is implanted, using standard surgical techniques," he said. "It allows the ophthalmologist to deliver the visual acuity that they are looking for and that the patient is looking for."

Traditional implanted lenses have a fixed focusing power forcing surgeons to predict the power of the lens that the patient will need.

Heinick said that it wasn't aware of any companies that have a similar solution to the LAL, but noted that the IOL market was a rapidly growing space occupied by numerous companies.

Other companies with a similar approach include: Privately owned, venture capital-backed **Wavetec Vision** (Aliso Viejo, Calif.), which has developed its ORA brand in excess of 300 systems. Its extensive clinical data, which has been presented at several ophthalmic meetings in the recent past, demonstrates that this technology improves visual outcomes.

Clarity Medical Systems (Pleasanton, Calif.) has developed a system called HOLOS IntraOp wavefront aberrometer. The device displays qualitative and quantitative refractive data in real time, providing immediate feedback on how adjustments affect refraction during cataract surgery.

The number of Americans with cataracts is expected to double to nearly 50 million by 2050, with more than three million cataract surgeries performed each year, mirroring increases in Europe.

"We feel very good about the market and its potential," he said. "There are approximately three million cataract cases performed annually in the U.S. today."

The company wasn't always in a good place. The LAL concept was first conceived over a decade ago, but Calhoun struggled with a plethora of technical challenges and the product development had taken much longer than initially predicted, according to a report from **Haimovitch Medical Technology Consultants** (Mill Valley, Calif.).

"I'm here to transform this company," Heinick said. "I think this is one of the most novel technologies of any medical device. This company now is entering a new chapter and we're revamping the strategy and raising the game on becoming a high performance company."

Heinick said that the recent additions to Calhoun's team will only aid in this transformation.

The company recently elected Ron Kurtz, and Eric Weinberg to the positions of COO and CCO, respectively.

Kurtz most recently co-founded **LenSx Lasers**, a developer of femtosecond lasers for cataract removal, and served as the company's president/CEO until its August 2010 acquisition by **Alcon** (Hünenberg, Switzerland) when he became general manager of Alcon LenSx. Eric Weinberg was also a co-founder of LenSx Lasers, and served as its CCO until the acquisition of LenSx.

"We're excited to get that kind of caliber of talent to this company, and we will continue to hire top talent," he said. "I believe from a leadership standpoint that it is all about the people and we're going to build a high performance company."

He added, "we're going to think big; start small and think fast." //

Beltway

Continued from page 1

in a June 12 warning letter, the agency fired back offering a point-by-point rebuttal that cited poor management oversight as the real problem at the company.

For example, in response to allegations in the 483 that it failed to file an MDR for an event where a child was shocked while using one of its nebulizers, the company said it considered the event to be non life threatening. According to the warning letter, the shock ran through the child's body to the opposite hand, turning that hand black. The company allegedly reported the event to the supplier but failed to follow up to determine reporting responsibility. In its response, the company said employees lacked sufficient training on compliance with MDR requirements and on internal procedures for handling product returns and customer complaints.

FDA rejected the response, saying the lack of compliance "may involve more than just inadequate procedures and lack of employee training, and may involve ineffective management oversight."

The company also tried to hold its employees liable for failing to adequately validate various pieces of equipment, as well as the process of adding reground material to fresh resin to manufacture plastic components for its devices. The agency did not buy into that explanation.

"These are significant non-compliances for their root cause to be merely employee oversight," FDA said in the letter. "Management should be reviewing documentation to ensure that [installation qualification] is reviewed, [operation qualification] is conducted, appropriate sampling plans are followed, and all production run data is documented accurately."

AG Industries continued to site employee negligence as the root cause in its response to allegations that it failed to adequately establish procedures for finished device acceptance. According to the company, its employees failed to follow the established sampling plans and the established QS. However, FDA said the company's quality procedure is not adequately written and that the response does not address the lack of effective management oversight in ensuring employees follow written procedures.

The agency also challenged the firm's assertion that failure to adequately maintain complaint files was due to poor employee training. According to the letter, 15 of the approximately 119 complaints the firm received since Jan. 1, 2013, are still open. FDA again rejected the firm's response blaming its employees, saying that the lack of effective management oversight and the firm's lack of follow through on complaint forms is to blame.

The agency also rejected the company's response to allegations that its established procedures for the disposition of non-conforming product is inadequate. According to the letter, AG industries has no documentation to demonstrate that non-conforming parts or products are reviewed and dispositioned. Despite internal procedures requiring staff document nonconformances and place a rejection tag on non-conforming parts or products, the agency alleges in the letter that the company either reworks or throws out rejected product without investigating the nonconformance.

In its response letter, AG Industries again faulted its employees for not following written procedures and blamed the quality control inspector for not enforcing compliance with those procedures. However, the agency deemed the response inadequate, saying it stops short of addressing the lack of effective management oversight to ensure all employees are following written protocol. FDA also encouraged the firm to update its procedures for handling non-conforming parts and products to ensure full regulatory compliance. The company did not return calls from *Medical Device Daily* requesting comment.

HEARTWARE PROVIDES AN UPDATE ON CLASS 1 RECALL

HeartWare (Miami Lakes, Fla.) updated the class I recall of its ventricular assist system (VAD), citing three additional reasons for the recall. The June 16 updated recall of all HeartWare VADs (HVADs) now includes complaints that the device has damaged alignment guides and connections pins that may cause the pump to stop, resulting in serious injury or death.

According to the company, the alignment guides in the power supply connector ports may wear down over time and cause the connection pins to become twisted or bent, and eventually prevent patients from connecting the device controller to their HVAD. HeartWare has received 33 reports of this malfunction and one serious injury report related to this defect.

The company also updated the recall to include a warning about the battery that powers the alarm in the controller for the HVAD failing and preventing the alarm from sounding when both external power sources for the device are disconnected. The company has received four complaints, including three injuries and one death.

"The internal battery is the final mitigation in a cascade of power management risk controls, which include labeling, patient training and alarms related to external battery charge," the company said in a press release announcing the recall. "A failure of the internal controller battery has no impact on normal functionality of the controller and is unlikely to have a clinical impact, provided patients follow the patient manual and never disconnect from both power sources at the same time."

The company said it is developing a software upgrade to improve how the controller manages a transient loss of communication between the controller and HVAD batteries. The software upgrade is expected out later this year. The company also plans to replace the controllers by the end of June 2016.

See Beltway, page 8

BRIEFLY NOTED

SEBELIUS, THOMPSON TO CHAIR ASPEN STRATEGY GROUP

The **Aspen Institute** (Aspen, Colo.) has formed the Aspen Health Strategy Group, a new forum of health care leaders, corporate CEOs, nonprofit executives, and other leaders committed to applying nonpartisan rigor to tackle some of the most pressing issues in health. The group will officially launch June 26, 2015, at Spotlight Health, the opening forum of the Aspen Ideas Festival.

Kathleen Sebelius and Tommy Thompson, both former secretaries of the U.S. Department of Health and Human Services and former governors, will co-chair the Aspen Health Strategy Group. The group's first-year efforts will focus on end-of-life care.

Each year, the group says it will examine a single topic in depth, identify action-oriented steps, and push their ideas into policies and practices. The launch choice of end-of-life care highlights the group's determination to make a difference where it matters most.

CORINDUS ADDED TO RUSSELL 2000 INDEX

Corindus Vascular Robotics (Waltham, Mass.), a maker of precision vascular robotics, said the company has been added to the Russell Global and Russell 2000 Indexes. This inclusion will become effective upon the close of trading on June 26 when the Russell Investment Group reconstitutes its comprehensive set of U.S. and global indexes, according to a preliminary list of additions recently posted.

Corindus's FDA-cleared CorPath system offers interventional cardiologists PCI procedure control from a radiation protective interventional cockpit.

TISSUE REGENIX GETS MEDICARE BENEFICIARIES

Tissue Regenix Group (York, UK), the regenerative medical devices company, has secured approval from the Noridian Healthcare Solutions and Palmetto GBA Medicare administrators for DermaPure reimbursement.

The approval means that the product is now available to 20.7 million Medicare beneficiaries across 30 states and follows previously announced approvals from the Novitas Solutions and CGS Administrators jurisdictions in 2015.

TELEFLEX RECALLS HUDSON RCI VENTILATOR

Teleflex Medical (Plymouth, Minn.) is in the process of recalling 9,333 units of its Hudson RCI manual ventilator for emergency resuscitation because "the intake port may be blocked which can cause the bag to fail to fill," according to the FDA's recall database.

It's designated as a Class 1 recall, meaning the agency believes there is a reasonable probability that the use of or exposure to the violative units "will cause serious adverse health consequences or death."

According to the FDA, Teleflex sent customers a recall notification letter on May 14, 2015, asking them to suspend distribution and quarantine the affected units.

The Biotech Primer: An insider's guide to the science driving the biotech and pharma industries

The devices are distributed throughout the U.S. as well as Australia, the Bahamas, Canada, Guatemala and Mexico.

On the product website, Teleflex says the Hudson RCI meets ISO resuscitation bag standards. The device has variations for use on adults, pediatrics or neonates.

AGREEMENTS/CONTRACTS

Veracyte to become part of Aetna's network

Veracyte (South San Francisco, Calif.), a molecular diagnostics company pioneering the field of molecular cytology, has signed an agreement to become part of **Aetna**'s (Hartford, Conn.) laboratory network, effective July 1, 2015.

Veracyte administers the Afirma Thyroid FNA analysis, a gene expression classifier test. The test is used as part of thyroid cancer diagnosis when it is medically necessary to identify benign thyroid nodules among those deemed indeterminate by cytopathology, potentially enabling patients to avoid an unnecessary surgery.

According to the **American Cancer Society** (Atlanta), thyroid cancer is the fastest-increasing cancer in the U.S., with more than 62,000 new cases expected in 2015. //

Beltway

Continued from page 7

Finally, HeartWare expanded the recall to include the risk of the driveline connector becoming damaged, leading to electrical issues and causing the pump to stop working. The company said the damage occurs over time if the driveline is pulled too often with too much force. The company has received three reports of this problem, including one serious injury and two deaths. //

NEUROLOGY EXTRA

Keeping you up to date on recent developments in neurology

By Robert Kimball, Staff Writer

By Shyama Ghosh, PhD, Incidence & Prevalence Database Writer, and Robert Kimball, Staff Writer

Neurological aspects of Lyme disease

Epidemiology (U.S.): Lyme disease (LD) is caused by *Borrelia burgdorferi*, a bacterium transmitted through the bite of infected Ixodes species ticks. Besides rash, fever, and fatigue, neurological symptoms may appear weeks, months or even years after infection, when the patients experience inflammation of the membranes surrounding the brain (meningitis) and even temporary paralysis of one side of the face (Bell's palsy).

Nearly 30,000 confirmed cases were reported to the Centers for Disease Control and Prevention in 2008, ranking LD among the 10 most commonly reported nationally notifiable diseases in the United States. LD testing is common and costly, with most testing in accordance with diagnostic recommendations. A 2014 US study cited in the Incidence and Prevalence Database (IPD) reported on a survey regarding LD testing performed by large commercial laboratories. Collaborators included investigators participating in the TickNET program, a network of public health partners created in 2007 to foster collaboration on surveillance, research, education, and prevention for tick-borne diseases. Representatives from 7 large commercial laboratories were asked to participate. These laboratories accounted for more than 76% of LD tests reported to health departments in 4 U.S. endemic states, in 2008. The authors also included the laboratories known to provide alternative methods of LD testing. In 2008, approximately 3.4 million LD tests were conducted by participating laboratories on 2.4 million specimens. When multiplied by the estimated percentage of true infections (12%), this yielded 288,000 infected source patients in the United States, approximately 10 times higher than the number of cases reported to the CDC in 2008. Underreporting is a common feature of routine surveillance, and the values here are consistent with what has been previously reported for LD.

U.S. Hospital Inpatients: For selected years, US hospital inpatients data for Lyme disease were reported as follows: First-listed diagnosis (year 2005, 3395 patients; year 2006, 3334 patients; year 2007, 2990 patients; year 2008, 1243 patients; year 2009, 3703 patients; 2010, 4123 patients); all-listed diagnoses (year 2005, 5648 patients; year 2006, 6063 patients; year 2007, 8568 patients; year 2008, 4230 patients; year 2009, 7075 patients; 2010, 9400 patients); average stay in days (year 2005, 6.4 days; year 2006, 4.2 days; year 2007, 4.3 days; year 2008, 2.6 days; year 2009, 3.3 days; 2010, 3.8 days).

U.S. Physician Office Visits: For selected years, US physician office visits for Lyme disease were reported as follows: Primary diagnosis (year 2005, 64291 patients; year 2006, 52760 patients; year 2007, 226806 patients; year 2008, 127737 patients; year 2009, 47811 patients; 2010, 188818 patients); all listed diagnosis (year 2005, 64291 patients; year 2006, 144751 patients; year 2007, 350156 patients; year 2008, 251087 patients; year 2009, 171161 patients; 2010, 227896 patients) (**see Overview Reports, Lyme disease, IPD)**.

Kansas Center uses ClearPoint for SLAH procedure

MRI Interventions (Irvine, Calif.), a maker of platforms for performing minimally invasive surgical procedures in the brain, said the neurological surgical team at **University of Kansas Medical Center** (Kansas City) performed the first stereotactic laser ablation of the hippocampus (SLAH) procedure in their MRI suite last week, using the ClearPoint Neuro Navigation system.

"We performed a successful stereotactic laser ablation on a 22 year old presenting with medically intractable seizures," said Paul Camarata, Associate Professor and Chairman of Vascular and Skull Base Neurosurgery. "Utilizing the ClearPoint System for this amygdalohippocampectomy allowed us to precisely, with sub-millimetric accuracy, provide this life changing treatment to our patient and improve her quality of life. The patient is still seizure free at 3 months," he said.

The ClearPoint system is a technology that enables minimally-invasive neurosurgery under continuous MRI guidance, offering surgeons real-time direction and a direct view of the inside of a patient's brain during a procedure.

Tests could analyze Alzheimer's symptoms much earlier

A new **study** suggests that errors on memory and thinking tests may signal Alzheimer's disease (AD) up to 18 years before the disease can be diagnosed. The research is published in the June 24, 2015, online issue of *Neurology*.

For the study, 2,125 people from Chicago with an average age of 73 without AD were given tests of memory and thinking skills every three years for 18 years. Twenty-three percent of African-Americans and 17% of European-Americans developed AD during the study.

Those who scored lower overall on the memory and thinking

Continues on next page

NEUROLOGY EXTRA

Continued from previous page

tests had an increased risk of developing the disease. During the first year of the study, people with lower test scores were about 10 times more likely to be diagnosed with AD than people with higher scores, with the odds increasing by 10 for every standard deviation that the score was lower than the average. Based on tests completed 13 to 18 years before the final assessments took place, one unit lower in performance of the standardized cognitive test score was associated with an 85% greater risk of future dementia.

Cefaly study examines migraine physiology

Cefaly Technology (Darien, Conn.), makers of an FDA-approved transcutaneous electrical nerve stimulation device, specifically authorized for use prior to the onset of migraine pain, has published a **study** from a new electromyography clinical trial on chronic migraine patients that shows the Cefaly device reduces tension in the neck and head. The study is published in *Neurological Science*s. The company cites the significant data for migraine sufferers who often indicate their pain begins in the back of the neck and works its way up to the head.

Electromyography (EMG) is a diagnostic procedure used to assess the health of muscles and the motor neurons (the nerve cells that control them). These motor neurons transmit electrical signals that cause muscles to contract. By measuring these contractions, Cefaly was able to track its effect on these hyper-specific areas. The results show that on average, the frontalis muscle in the head and the trapezius muscle in the neck experienced a decrease. Additionally, the results confirm that neurostimulation of the first branch of the trigeminal nerve can also activate peripherical muscles that are far from the area of the electrical stimulation. This is a promising finding since it indicates relief may have a ripple-like effect from the entry source of the neurostimulation to other parts of a patient's aching head.

OhioHealth to open comprehensive Neuroscience facility

On July 6, 2015, **OhioHealth** (Columbus) will open its doors to the new OhioHealth Neuroscience Center on Riverside Methodist Hospital's campus.

The $300 million ten-story, 409,000 square foot tower, which consists of 224 private rooms, is now the tallest building on the Riverside Methodist campus.

Neuroscience deals with the diagnosis and treatment of diseases of the nervous system, which includes the brain, the spinal cord, and the peripheral nerves. Patients with neurologic disorders face unique challenges, and therefore require unique care. Neuro patients face conditions including multiple sclerosis, epilepsy, strokes, Parkinson's disease, and Alzheimer's, and they can also experience brain tumors, aneurysms, hydrocephalus, and all kinds of common spinal conditions – all of which can be treated and cared for at the new center.

MEDICAL DEVICE DAILY'S PATENT HIGHLIGHTS

FROM CORTELLIS' PATENTS GAZETTE WEEK 24

DEVICES AND EQUIPMENT

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THOMSON REUTERS™

US20150168270-A1: “Stent holder having a reduced profile.”

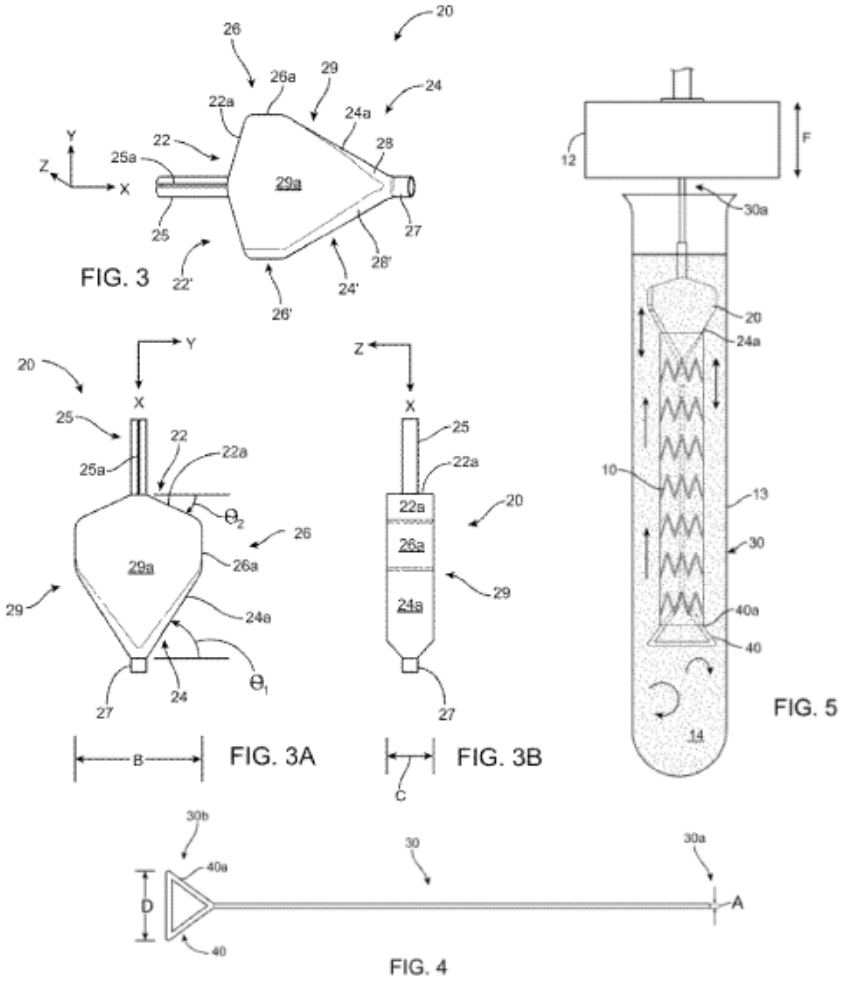
Assignee: Abbott Cardiovascular Systems Inc

Inventors: Haghighat-Khansari, Kiarash; Kamberi, Marika; Pinson, David

IPC Codes: G01M 99/00

Publication Date: 18-Jun-2015

Earliest Priority Details: US2013133321, 18-Dec-2013



Stent holder comprising a retainer with a collar having a forward end and rear end, a forward sloping surface proximal to the rear end, and a rearward sloping surface proximal to the forward end. Useful for securely holding a drug eluting stent (DES) during a real-time or an accelerated in-vitro drug release test of a therapeutic substance contained in the stent. For a previous filing from Abbott Cardiovascular Systems on stents, see WO2015038875.

With reference to the above figures, figure 3 is a perspective view of a retainer of the stent holder, whilst 3A and 3B are side and top views, respectively, of said retainer. Figure 4 provides a side view of a core wire or wire of the stent holder, and figure 5 shows a stent being held by the stent holder during a dipping process in a release medium.

In October 2014, Abbott received US FDA approval for its XIENCE Alpine™ everolimus eluting coronary stent system. At the time of its launch, XIENCE Alpine™ was reportedly the only DES on the US market with an indication to treat chronic total occlusions.

WO2015089106-A1: “Medical adhesives, accelerants, delivery systems, and related methods.”

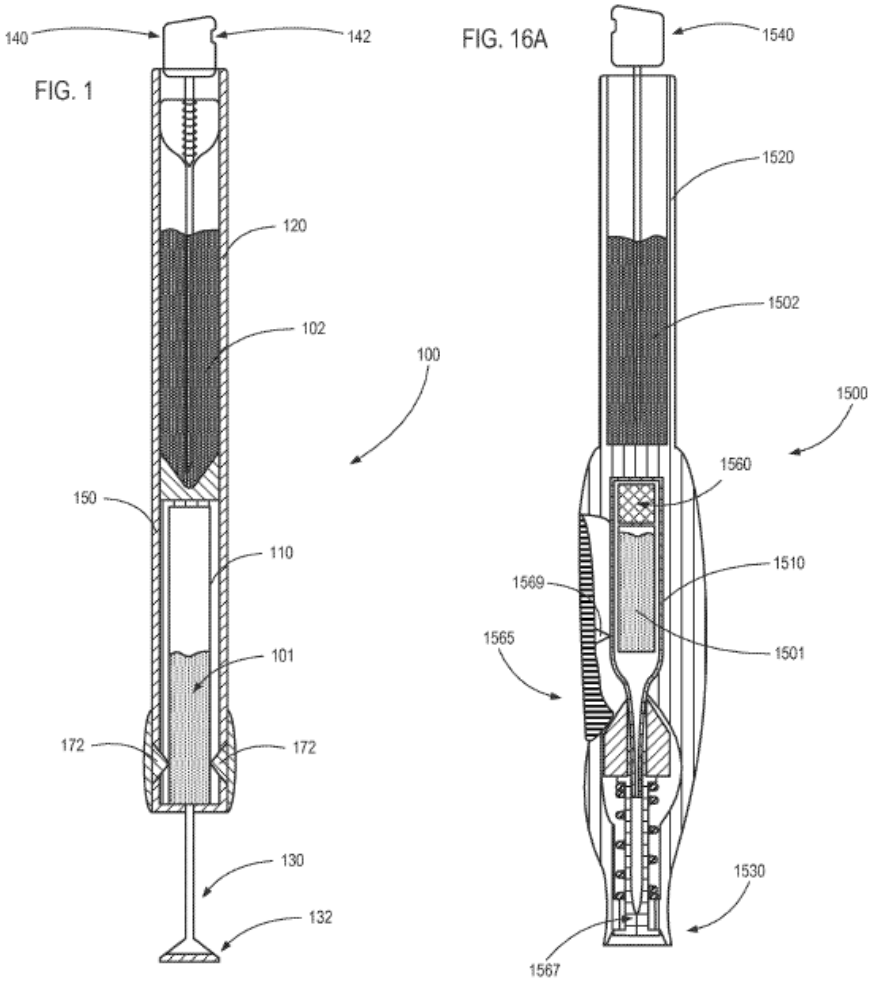
Assignee: Accelefx

Inventors: Butte, Jeffery Brandon

IPC Codes: A61B 17/03

Publication Date: 18-Jun-2015

Earliest Priority Details: US2013913549, 09-Dec-2013



Medical adhesive delivery system comprising a first vessel for containing an adhesive, a first delivery port for dispensing the adhesive, a second vessel containing a biocompatible material that accelerates the polymerization of the adhesive and a second delivery port configured for dispensing the biocompatible material. The biocompatible accelerant (eg sodium bicarbonate) reduces the cure time of medical- or surgical-grade adhesives that are applied to wounds or incisions for closure.

Figure 1 a cross-sectional side view of a medical adhesive delivery system for the delivery of a medical adhesive and an accelerant. Figure 16A is a cross-sectional side view of a medical adhesive delivery system for pressure-assisted delivery of an adhesive and delivery of an accelerant via a pump atomizer.

Represents the first patenting to have been published in the name of Accelefx, and in June 2015 the inventor Brandon Butte, could be seen to be a practicing general surgeon in Worland, Wyoming, specializing in the treatment of varicose veins, hernia repair, gall bladder surgeries and breast biopsies.

US20150165096-A1: “Absorbable polymeric blend compositions based on copolymers prepared from mono- and di-functional polymerization initiators, processing methods, and medical devices therefrom.”

Assignee: Ethicon Inc

Inventors: Andjelic, Sasa; Defelice, Christopher; Jamiolkowski, Dennis D.; Kelly, Brian M.; Steiger, Daniel

IPC Codes: A61L 31/04; A61L 31/14; C08L 67/00

Publication Date: 18-Jun-2015

Earliest Priority Details: US2013917525, 18-Dec-2013

FIG. 1

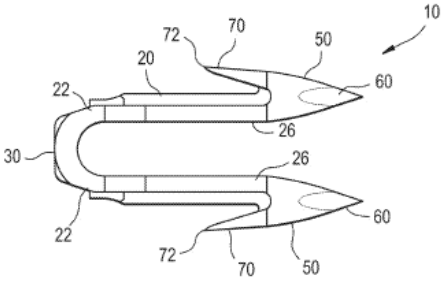


FIG. 3

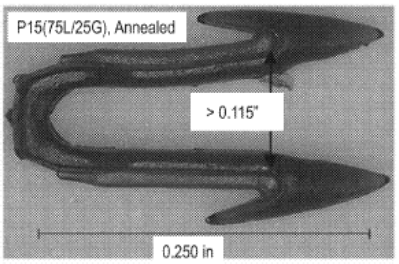


FIG. 2

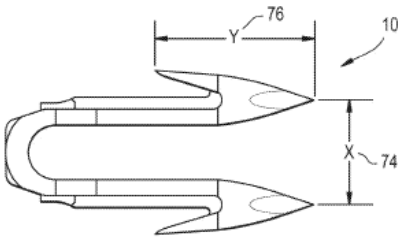
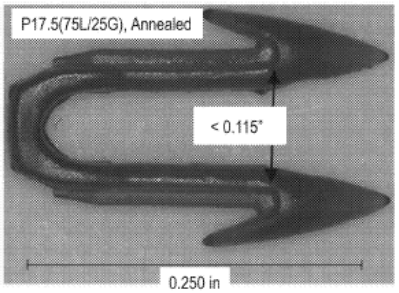


FIG. 4



Absorbable polymeric blend compositions and medical devices. It is disclosed that examples of such devices may include meshes, sutures, and staples, where the properties of both the absorbable and nonabsorbable polymers are advantageous. It is also disclosed how further components, additives or agents may be present to provide additional effects to the polymer blends and medical devices including antimicrobial characteristics, controlled drug elution, radio-opacification, and osseointegration. Follows on from US20150159011.

Figure 1 is a drawing of an implantable staple or tack demonstrating the present invention, and shows a device with a small cross-sectional area. The material of this device must be inherently stiff if the tack is to function properly for the intended application. The article chosen for evaluation was a 5 mm laparoscopic device for hernia repair; it was in the form of a staple or strap with legs and tissue holding means to the end of the legs. The device is illustrated in figure 2. Figure 4 a depiction of an injection molded tack based on the design shown in figure 1, prior to annealing, and made from a polymer composition of the present invention that displays acceptable warping after annealing (unlike the unacceptable warping seen in figure 3, where the tack was made from a polymer blend outside of the invention’s scope).

In January 2015, it was reported how a study published in the October 8 2014 issue of Surgical Endoscopy concluded that an absorbable "strap" device, such as the ETHICON SECURESTRAP® Fixation Device provides greater mesh-tissue fixation strength at acute deployment angles compared to an absorbable blunt-tip hollow screw-fastener device. This was said to add to the growing body of evidence that ETHICON SECURESTRAP® Fixation Device, an absorbable "strap" device, provides superior holding strength, as the study found that the absorbable blunt-tip hollow screw-fastener device at a 30-degree deployment angle is associated with an increased occurrence of immediate tack failure.

WO2015087927-A1: “Patch with cover member and patch kit with cover member.”

Assignee: Hisamitsu Pharmaceutical Co Inc

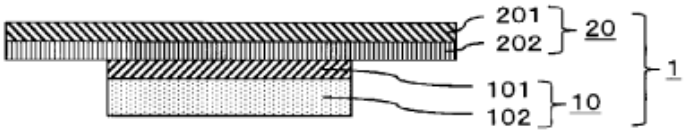
Inventors: Shinoda Tomohiro; Michinaka Yasunari

IPC Codes: A61P 25/28; A61K 9/70; A61K 47/32; A61K 47/34; A61K 31/27

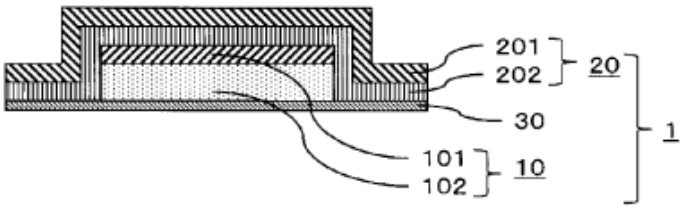
Publication Date: 18-Jun-2015

Earliest Priority Details: JP2013257427, 12-Dec-2013

[図1]



[図2]



Transdermal patch comprises a patch member and a cover member. Whilst a great number of drugs are contemplated within the disclosure, just 3 are named within the claims, ie rivastigmine, terbinafine, and emedastine. The disclosure states that the patch has long-term sticking capabilities, provides sustained release, enhanced skin permeation, and maintains constant drug concentrations in the blood over long periods due to addition of its cover member. Published alongside WO2015087755 describing a patch comprising clonidine, and WO2015087926 describing a patch comprising rivastigmine. For prior patenting from Hisamitsu subsidiary Noven, describing transdermal delivery systems (TDS) for tertiary amine drugs such as rivastigmine, fentanyl or rotigotin, see WO2014151492.

In February 2013, Noven filed an ANDA under Paragraph IV certification to market generic versions of rivastigmine-containing Exelon TDS, but in April 2013 Novartis filed a suit against Noven for alleged infringement of patents US6335031 and US6316023. In October 2014, the USPTO's patent appeal board opted to institute inter partes reviews of the two Novartis patents, finding petitioner Noven had shown a reasonable likelihood of prevailing on its challenged claims.

A phase III study in the US of Hisamitsu's transdermal patch formulation of terbinafine hydrochloride (HTU-520) for treating tinea unguium had been planned for 2013, despite it having observed negative results from a phase III study in Japan in April 2012. By June 2015, this Phase III US trial did not appear to have been conducted.

In June 2015, neither Hisamitsu nor Noven could be seen to have been particularly developing an emedastine-containing patch outside of its patenting; see WO2012144405 describing adhesive patches comprising a basic drug selected from emedastine, setiptiline, and oxybutynin.

US20150164414-A1: “Recursive real-time determination of glucose forcing in a diabetic patient for use in a closed loop insulin delivery system.”

Assignee: Matthews, Grant

Inventors: Matthews, Grant

IPC Codes: A61B 5/00; A61B 5/145

Publication Date: 18-Jun-2015

Earliest Priority Details: US2013913962, 10-Dec-2013

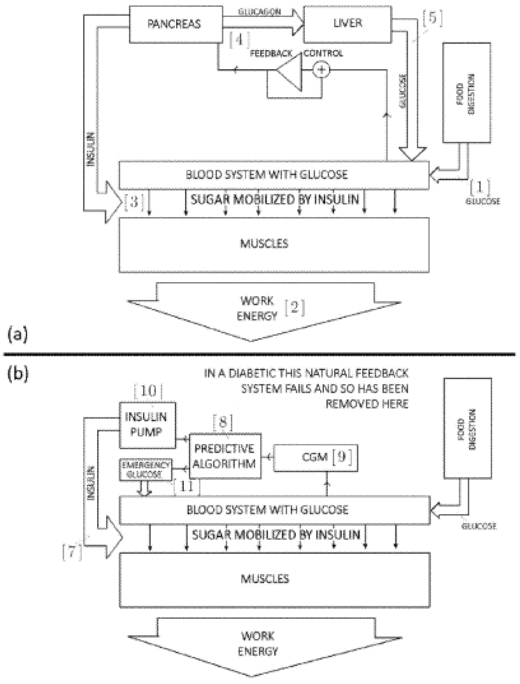


FIG. 1 (a) Natural Feedback system in human body where pancreas controls blood sugar during eating and exercise. (b) Closed loop insulin delivery system in diabetic using a control algorithm[8] (developed herein), CGM[9], insulin pump[10] and emergency glucose supply[11].

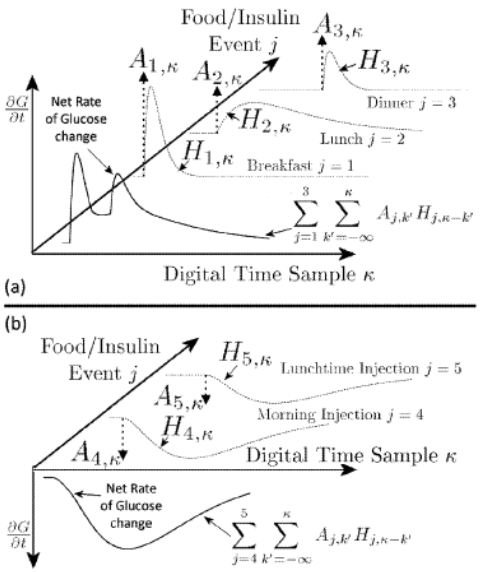


FIG. 3 (a) 2D landscape visualization of blood glucose change rate for three food events of fast carbohydrate at breakfast and dinner($j=1$ & 3) and slow carbohydrate at lunch ($j=2$). (b) 2D landscape visualization of two insulin events caused by breakfast and lunch-time injections ($j=4$ & 5).

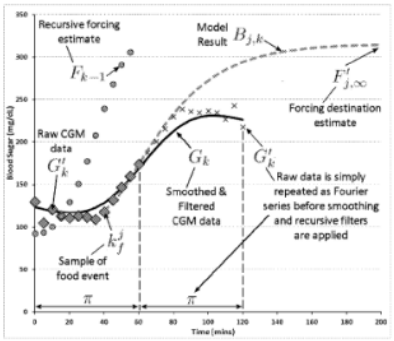


FIG. 4 Example CGM data and model fit after a food event.

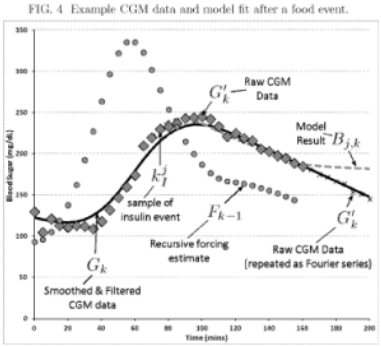


FIG. 5 Example CGM data and model fit after an insulin event.

Recursive real-time determination of glucose forcing in a diabetic patient, for use in a closed loop insulin delivery system comprising a continuous glucose monitoring device transmitting blood glucose measurements as digital data and a blood glucose predictor algorithm.

Appears to be new area of interest for the inventor with regards his prior patenting. In June 2015, Grant Matthews could be seen to be the President of Zedika Solutions LLC that develops algorithms for licensing to a variety of industries from the biomedical to geospatial sectors. This particular patent application can be seen to be describing its glucose prediction algorithm that it says can predict a diabetic’s glucose level up to an hour in advance, which would be a key step in the development of an effective artificial pancreas.

Zedika’s other areas of strategic focus include a solution for climate data model validation and the design of instruments and data methods that use the moon as an absolute calibration target.

WO2015085381-A2: “Pulmonary trunk perfusion system.”

Assignee: Edmo Atique, Gabriel

Inventors: Edmo Atique, Gabriel

IPC Codes: A61M 1/10; A61M 16/20

Publication Date: 18-Jun-2015

Earliest Priority Details: BR201331950, 12-Dec-2013

A device for facilitating blood flow to the lung during cardiac surgery, comprising is claimed. It is useful for preventing ischemia and lung damage during cardiopulmonary bypass.

This appears to be the first patent application from the inventor, who is a cardiovascular surgeon and the director of Clinica Medica Atique Gabriel. He also appears to be associated with the Department of Cardiovascular Surgery at the University Nove de Julho (Uninove), São Paulo. In February 2012, he co-authored an article in the Brazilian Journal of Cardiovascular Surgery, with the title “On-pump coronary artery bypass graft surgery: biochemical, hormonal and cellular features”.

WO2015088793-A2: “Multiple chamber, expandable therapeutic delivery device.”

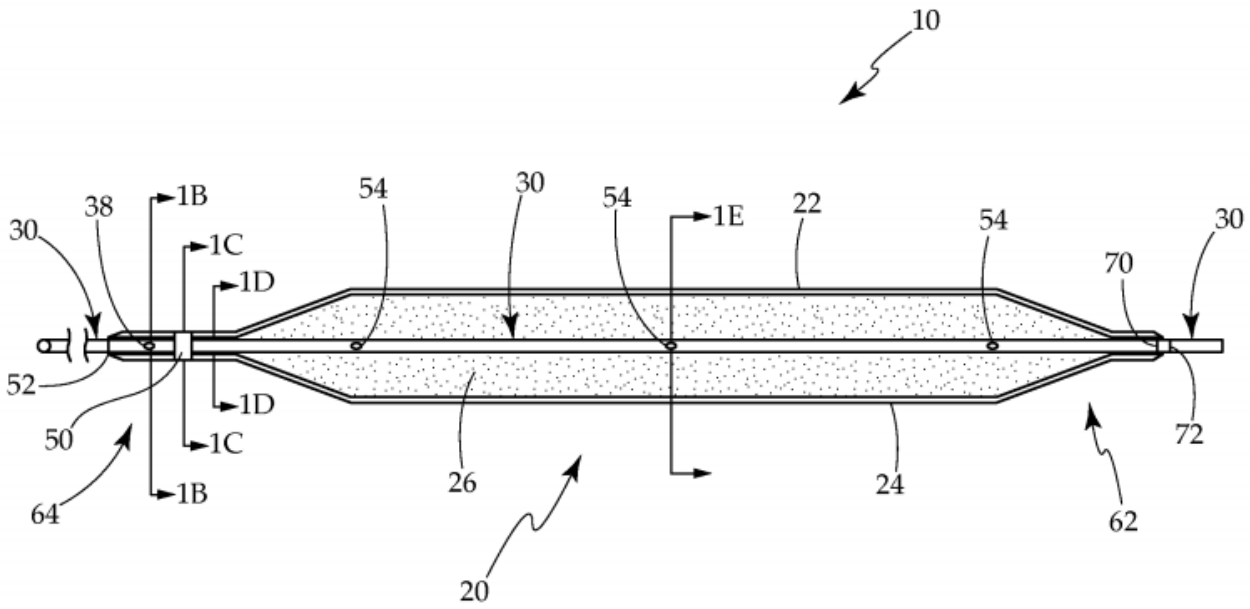
Assignee: Mirizzi, Michael, S.

Inventors: Mirizzi, Michael, S.

IPC Codes: A61M 25/10; A61M 25/00

Publication Date: 18-Jun-2015 (also published as US20150165169-A1)

Earliest Priority Details: US2013915134, 12-Dec-2013



A device for targeted delivery of a therapeutic agent comprising an elongated catheter body comprising an inflation lumen and at least one therapeutic agent delivery lumen, is claimed. Using inner and outer sheets, the inflation lumen is in fluid communication with the inflation chamber, the delivery lumen is in fluid communication with a delivery chamber, but the delivery chamber is not in fluid communication with the inflation chamber.

The device is disclosed to overcome various disadvantages associated with drug eluting balloons and direct injection devices.

Mirizzi appears to be Vice President of R&D at Qool Therapeutics, which is described as developing a noninvasive system to rapidly induce therapeutic hypothermia through the inhalation of frozen saline. In September 2014, Qool was in receipt of the inaugural Transcatheter Cardiovascular Therapeutics (TCT) Innovation Award, designed to promote promising new cardiovascular technologies.

This application appears to pick up from WO2007002304, claiming methods and apparatus for introducing tumescent fluid such as saline to a body tissue. This case is assigned to Vnus Medical Technologies, which markets a “Closure” system for treatment of venous diseases.

US20150165182-A1: “Autonomous fluid instillation system and method with tissue site pressure monitoring.”

Assignee: KCL Licensing Inc

Inventors: Pratt, Benjamin Andrew; Locke, Christopher Brian

IPC Codes: A61M 35/00; A61M 37/00; A61M 39/22

Publication Date: 18-Jun-2015

Earliest Priority Details: US2013917773, 18-Dec-2013

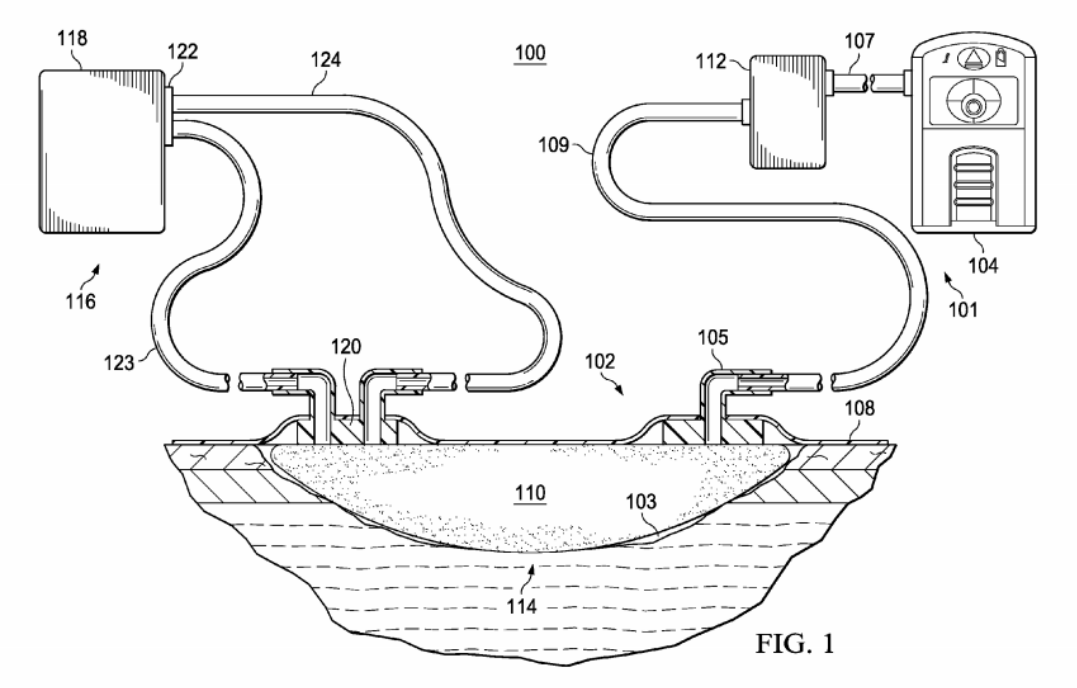


FIG. 1

A system and method for providing instillation therapy to a tissue site comprising an installation therapy system fluidly coupled to a tissue site, is claimed. Pressure supplied to the tissue site by a reduced-pressure source is monitored over a period of time and fluid is supplied to the tissue site with the installation therapy system in response to the pressure.

The system and method are disclosed to be useful for delivering medicinal fluids, such as saline, antibiotics, antifungal agents, antiseptics, and analgesics, and to improve on prior art reduced pressure therapy. This application picks up from WO2014151107, claiming wound healing compositions.

The company website lists several products to which this application may refer e.g the V.A.C.Ultra™ Negative Pressure Wound Therapy System, ABThera™ OA Negative Pressure Therapy Unit and the Prevena™ Incision Management System.

US20150168339-A1: “Hand-held test meter multi-event control solution measurement reminder.”

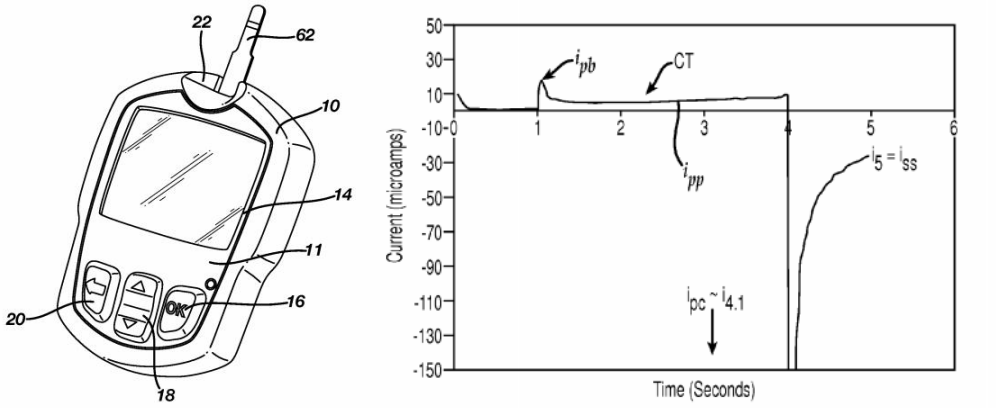
Assignee: LifeScan Scotland Ltd

Inventors: Guthrie, Brian

IPC Codes: G01N 27/237

Publication Date: 18-Jun-2015

Earliest Priority Details: US2013132994, 18-Dec-2013



A hand-held test meter comprising a microprocessor block, a display module, a test counter module, an accelerometer module, a meter measurement timing block, a battery change detection block, a voltage monitor block and a memory block, is claimed. Used for monitoring levels of an analyte in a body fluid, particularly blood glucose levels, in the management of diabetes mellitus.

The concurrently published US20150169837 claims an externally powered test meter firmware upgrade, and both applications continue the theme of US20150083609 which claims an analytical test strip with an integrated battery.

Presumably these applications refer to the range of OneTouch range of products listed on the company website eg the “OneTouch UltraMini®” and “OneTouch® Delica®” glucometers.

US20150164853-A1: “Prostacyclin compositions for regulation of fracture repair and bone formation.”

Assignee: Mayo Foundation

Inventors: Ryan, Zachary, C.; Westendorf, Jennifer J.; Craig, Theodore A.; Kumar, Rajiv

IPC Codes: A61K 45/06; A61K 31/343; A61L 31/10; A61L 31/16

Publication Date: 18-Jun-2015

Earliest Priority Details: US2013915116, 12-Dec-2013

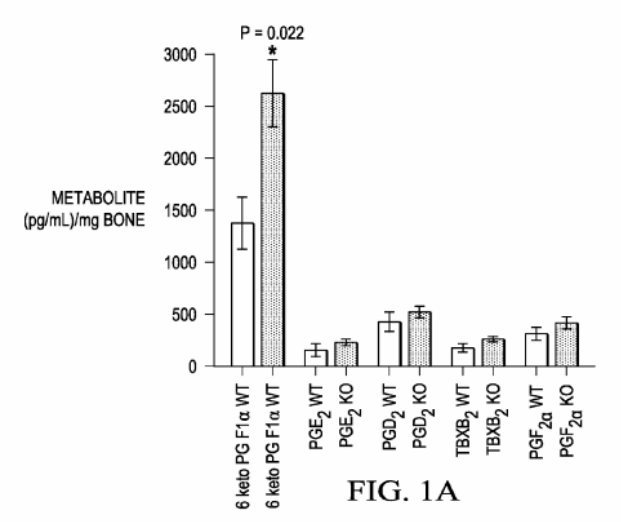


FIG. 1A

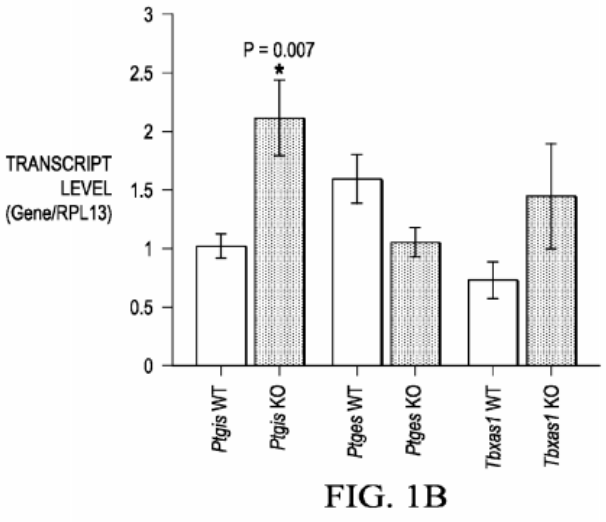


FIG. 1B

A method for treating and enhancing fracture repair and bone formation comprising contacting the two bone segments in need of repair with an implant having a prostacyclin coating, is claimed. The implant may comprise a variety of shapes, eg a cage, wire, staple, plate and/or screw, and provides extended release of the prostacyclin over an extended period of time, preferably up to six months.

This application appears to represent a new interest for the inventors, though US6913762, from a different team at Mayo, claims an implantable medical device (preferably a stent), seeded with cells which express particular peptides, including prostacyclin synthase.

All the inventors on the current application co-authored an article in Biochemical and Biophysical Research Communications in May 2014, titled “Enhanced prostacyclin formation and Wnt signalling in sclerostin deficient osteocytes and bone”. The abstract states that prostacyclin production is increased in bone and osteocytes from sclerostin knockout mice which have greatly increased bone mass.

US20150164323-A1 (one of three co-published applications): “Secure communications between elements in a wireless network.”

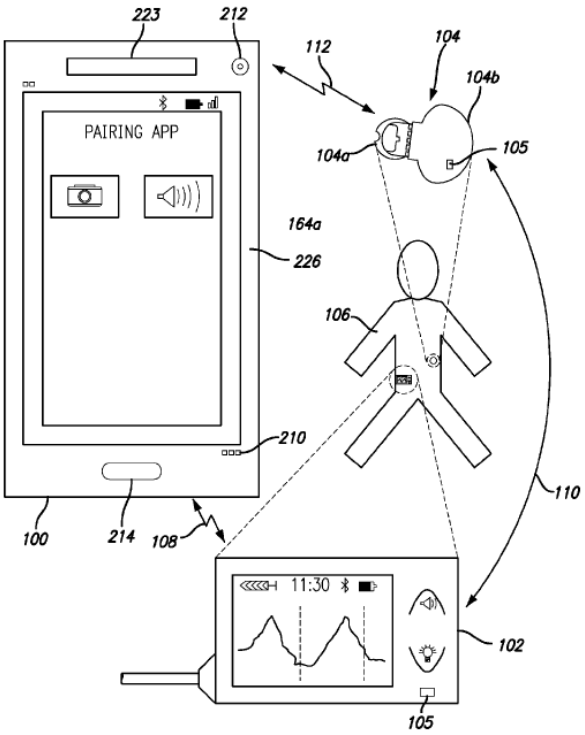
Assignee: Medtronic Minimed Inc

Inventors: Holtzclaw, Kris R

IPC Codes: A61B 5/00; H04Q 9/00; A61B 5/145; A61M 5/172

Publication Date: 18-Jun-2015

Earliest Priority Details: US2013107872, 16-Dec-2103



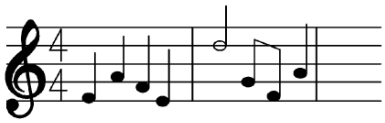


FIG. 7C

FIG. 7D

A series of three co-published applications describe different methods for the improvement of the security of radio transmission between an insulin pump and its controller where control is maintained via a radio signal.

US20150169857 describes a fingerprint enhanced authentication system where the pump requests fingerprint authentication from the user via the controller

US20150172921 where the pump requests a security check from the controller if the signal received from the controller is not of the expected strength

US20150164323 which describes the use of machine-parsable codes to enable the pairing of the pump with the controller. The illustrations have been taken from this application and show a representative system with examples of machine-parsable codes.

These applications continue from WO2011005633 from a different team and describing the coordination of control commands in such systems and include the possibility of fingerprint recognition. Some of the present applications may be in support of the company's Paradigm Revel insulin pump, Enlite sensor or the Contour Next Link meter.

US20150164382-A1 (one of four co-published applications): “Use of electrochemical impedance spectroscopy (EIS) in continuous glucose monitoring.”

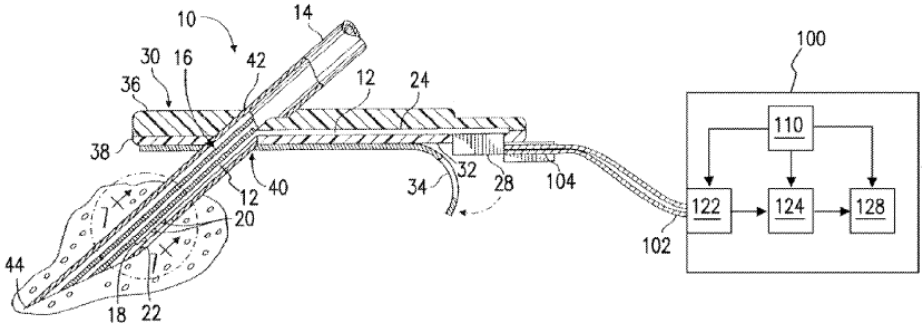
Assignee: Medtronic Minimed Inc

Inventors: Varsavsky, Andrea; Yu, Fei; Miller, Michael E; Liang, Bradley C.; Yang, Ning

IPC Codes: A61B 5/1473; A61B 5/053; A61B 5/145; A61B 5/1495

Publication Date: 18-Jun-2015

Earliest Priority Details: US 2013916637, 16-Dec-2013



Four co-published filings resulting from the same provisional application describe various aspects of electrochemical impedance spectroscopy (EIS) used in conjunction with continuous glucose monitors to enable in vivo sensor calibration, gross (sensor) failure analysis and sensor diagnostics/ fault detection.

US20150164371 describes diagnostics on the sensor to determine if the sensor has lost sensitivity

US20150164386 describing a method for the real time self-calibration of the sensor

US20150164387 describes methods for determining the age of a sensor

US20150164382 describes methods for real-time self-calibration, performing diagnostics on a sensor, determining the age of a sensor and differentiating between different glucose sensors

The applications are disclosed to relate to the company's Enlite sensors.

US20150165213-A1 (one of two co-published applications): “Method and apparatus for monitoring of patient medication compliance.”

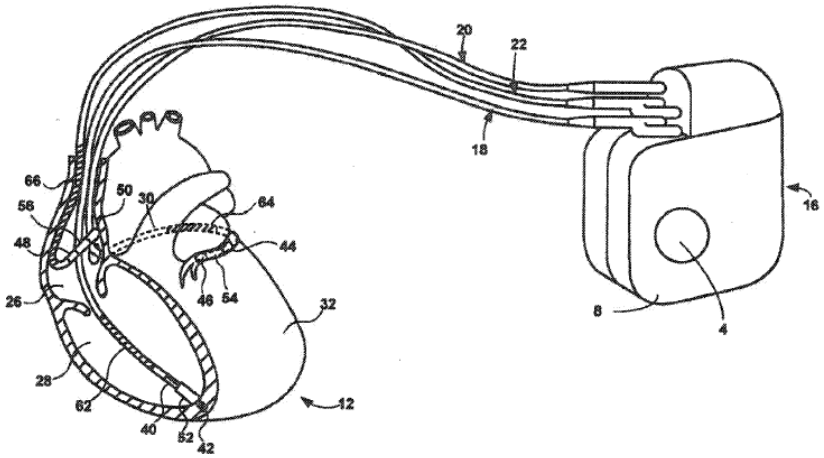
Assignee: Medtronic, Inc

Inventors: Ebert, Michael J; Thompson-Nauman, Amy; Grenz, Nathan A; Mcvenes, Rick D

IPC Codes: A61N 1/37

Publication Date: 18-Jun-2015

Earliest Priority Details: US 2013105306, 13-Dec-2013



Two co-published applications describe medical devices for monitoring patient medication compliance. Both devices have electrodes to deliver pacing therapy and both can determine a pacing threshold in response to the pacing therapy

US20150165213 the device determines if there is a change in pacing threshold and then determines patient medication compliance from this change. In this case patient medication may be amiodarone or corticosteroid

US20150165214 the device determines if there is a change in pacing threshold, if that change is sustained and then determines patient medication compliance from this change. In this case patient medication may be a diuretic or an ace inhibitor

Both applications appear to be in support of the company's LINQ insertable cardiac monitor.

WO2015087029-A1: “Tracheal tubes.”

Assignee: Smiths Group PLC

Inventors: Jeffrey, Andrew, Thomas

IPC Codes: A61M 16/04

Publication Date: 18-Jun-2015

Earliest Priority Details: GB201321877, 11-Dec-2013

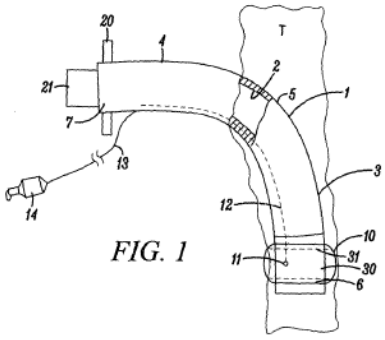


FIG. 1

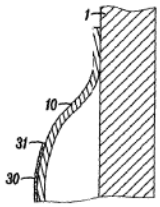


FIG. 2

Tracheal tube comprising a sealing member adapted to provide a seal with the tracheal wall, and has an outside surface region to contact the tracheal wall, wherein the surface region is coated with an active substance such as an anti-proliferative or immunosuppressant agent (eg rapamycin) to reduce damage to the trachea. For prior patenting from Smiths Medical on its tracheostomy tubes technologies, see WO2015075412 that was published 20 days earlier.

Figure 1 above provides a side elevation view of a tracheostomy tube, and figure 2 is an enlarged cross-sectional view through a part of the sealing cuff of the tube. The sealing member may include an expansible sealing member such as an inflatable cuff.

In June 2015, Smiths Medical’s range of tracheostomy tubes and kits included its Portex™ and Bivona® tracheostomy products for both surgical and percutaneous procedures. It launched its Portex® Bivona® FlexTend™ TTS™ tracheostomy tubes in Europe in June 2014. The Bivona® FlexTend™ TTS™ neonatal and pediatric tubes feature a proximal shaft extension helping to keep connections away from the neck, chin, and stoma, intended to enhance patient comfort which could prevent pressure ulcers. The Bivona® FlexTend™ TTS™ tracheostomy tubes are intended to be gentle on the sensitive tissues of neonatal and pediatric patients who require intermittent or temporary cuff use. An inflatable cuff integrated into the outer wall of the tube’s shaft can be filled with sterile water to secure the tube in the patient’s trachea and create a seal between the tube and trachea that directs incoming and outgoing breaths through the inner lumen. This helps to optimize respiration for ventilated patients and for patients who perform lung expanding breathing therapies. When a seal is no longer needed, the cuff can be deflated and it will rest tight-to-shaft, reducing the risk of trauma to the trachea and allowing airflow around the tube supporting the ability to speak.

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