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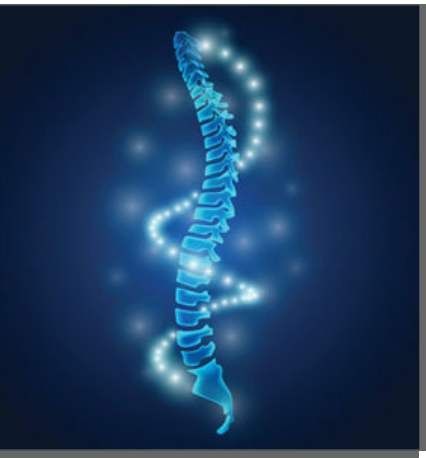

Minimally invasive spine system

Zimmer Biomet scores FDA nod for Rosa One

By Liz Hollis, Staff Writer

Warsaw, Ind.-based Zimmer Biomet Holdings Inc. won clearance from the U.S. FDA for its Rosa One spine system for robotically assisted minimally invasive and complex spine surgeries.

"The clearance is meaningful as it further rounds out [Zimmer Biomet's] portfolio ahead of its full commercial launch in [the second half of 2019]," wrote Wells Fargo's Larry Biegelsen. He added that this latest application could serve as a big boost for the company, potentially contributing up to $15 million this year.

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Inside

Cardiofocus wins CE mark for third-gen endoscopic ablation system Heartlight X3

By Stacy Lawrence, Staff Writer

Cardiofocus Inc. has gained a CE mark for its Heartlight X3 system, the latest iteration of a system that first won a regulatory nod in Europe in 2009. The European launch of this version of the visualization-inclusive, catheter-based ablation technology is slated to start now, with the technology available as an upgrade to existing customers.

The X3 is designed to provide fast, uninterrupted creation of a lesion around the circumference of a vein; the new system requires as little as three

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Chopin composing knowledge web to better understand, organize medical data

By David Godkin, Staff Writer

TORONTO – University of Toronto engineers have launched a startup targeting mid-sized hospitals with small budgets that limit their ability to analyze complex medical data. Toronto-based Chopin Inc. arose from the development by Carolina Gomes and Daniel Zhang of the After Data system which enables hospitals to better understand and organize clinical and public health care data.

"There is a lack of visibility about what exactly is going on at an operational level within health

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Brexit extension approved, but chaos expected to continue

By Nuala Moran, Staff Writer

LONDON – The industry must continue with contingency planning and preparations for a crash-out Brexit, according to an agreement on Friday to postpone the March 29 departure date in a bid to stop the U.K. leaving without a deal.

"I expect the chaos to continue," said Steve Bates, chief executive of the U.K. Bioindustry Association (BIA), in his monthly Brexit briefing. "Keep going on the basis we still need to work on all contingencies," he said.

Having twice lost a vote in parliament on the withdrawal agreement she negotiated, prime minister Theresa May has been desperately

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Robocath prepares for European launch of R-One robotic system for treating cardiovascular disease

By Bernard Banga, Staff Writer

PARIS – Robocath SAS, of Rouen, France, recently obtained CE marking for its R-One robotic device for treating cardiovascular disease. R-One is

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BioWorld MedTech's Cardiology Extra

Staff Writer Liz Hollis on one of med-tech's key sectors

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the first European robotic solution to obtain the CE mark in the field of interventional cardiology. The robot assists interventional cardiologists in stenting by enabling precision technologies that complement existing methods, in order to improve procedures and the working environment. To achieve its objectives, Robocath is planning a new fundraising campaign, with the support of its historical shareholders, for the commercialization of its device over the next few years.

"Our entry into the market for interventional vascular robotics represents a substantial opportunity for growth," said Philippe Bencteux, chairman and founder of Robocath. "There is the potential for the R-One solution to be installed in more than 3,000 procedure rooms, performing around 1.6 million interventions each year in Europe alone."

A PCI every 30 seconds

Today, coronary heart disease causes the death of 7.4 million people a year, according to the World Health Organization. This condition is usually treated using interventional cardiology. More than 3 million percutaneous coronary intervention procedures (PCI) are performed globally, a procedure every 30 seconds. Here, a stent is placed at the relevant lesion using a catheter guide and guidewires to restore normal circulation to the arteries.

However, it has been found that, one year following angioplasty, 66 percent of stents were placed incorrectly, a longitudinal geographic miss (LGM). "Furthermore, interventional cardiology carries significant risk for the operators: X-rays increase the risk to medical staff of developing certain cancers by a factor of eight, and the risk of developing cataracts by nine," Bencteux told *BioWorld MedTech*. Medical staff must wear a lead apron to achieve an acceptable level of protection. This weighs around 10 kilograms and can lead to musculoskeletal disorders in up to 55 percent of hospital staff.

"Robocath came about after I heard about Operation Lindbergh, one of the very first remote robot-assisted procedures, performed by surgeons in the United States on a patient located in France. I realized how important this new technology was going to be for the vascular system," said Bencteux. Over the last three years, his company, formed in 2009, has poured $3.4 million annually into R&D. His team developed a new robotic platform protected by 22 patent families, some of which were filed in conjunction with two French engineering schools: Esigelec (the French graduate school of electrical engineering) and INSA (the French national institute for applied sciences). The Robocath robotic system also utilizes proprietary algorithms.

The R-One robotic assisted platform is a plug and play system comprising two key elements – a mobile radiation protection control station and a telemanipulating robotic unit. The integrated control includes a command unit (joysticks and HD monitors), and a mobile radiation protection screen to protect medical staff from X-rays. The robotic unit consists of a robot weighing 12 kilograms, and an articulated support arm weighing 40 kilograms. This articulated arm carries a consumables kit with guidewire and catheter guide.

How does it work?

The cardiologist can use this control console to move the robot remotely, enabling the guidewire and the catheter guide to be inserted with precision. The guidewire and catheter guide are both inserted into the robot and enter the vascular

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R-One robotic device for treating cardiovascular disease; Robocath SAS

Robocath

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system by means of remotely controlled movement made by the cardiologist from the integrated control station. The joysticks are used to control and secure the progress of these instruments within the vascular system until they reach the lesion.

The innovative aspect of the Robocath technology rests in the algorithms used in its anthropomorphic system. "Our platform replicates movement of the hand precisely, such as rotation and independent, simultaneous translation and navigation accurate to the millimeter," said Bencteux. Furthermore, the Robocath robotic system ensures that instruments remain perfectly still throughout the procedure, avoiding access to the lesion being lost.

Robocath's place among its competitors

Robocath obtained CE marking for its R-One system last month, having carried out its first in vivo tests on the robotic platform in 2013 and having designed its industrial prototype in 2015. The med-tech from Rouen is in direct competition with two American manufacturers of medical robots used in the cardiovascular field: Corindus Vascular Robotics Inc. with its Corpath system and Hansen Medical Inc. with its Magellan robotic system. Hansen was acquired by Auris Surgical Robotics Inc. in July 2017, which was itself acquired on Feb. 13, 2019, by Johnson & Johnson for around $3.4 billion in cash.

According to Bencteux, the main competitive advantage with Robocath lies in the robotic accuracy and enhanced movement from its anthropomorphic technology, which "enables both rotational and other movement simultaneously." R-One uses open architecture, making it compatible with other devices (catheter guides, balloons, stents). "Its design means it can be adapted to any cath lab," said Bencteux.

The company is targeting a market of nearly 4 million angioplasty procedures performed each year in the world's 16,000 cath labs – 900,000 in the U.S. and 2.2 million elsewhere. "Our market entry into interventional vascular robotics represents substantial growth potential." said Bencteux. In fact, cardiology is currently one area in which medical robotics are least prevalent, accounting for just 0.4 percent of the total market. In other words, $200 million in medical robotics for cardiology, compared with $48 billion total market for medical devices. Robocath, is positioning itself in two other markets. These are the remote treatment of peripheral arteries and vessels in the brain, and care of patients during vascular emergencies (infarction and stroke).

The company receives substantial funding from Normandy regional investment funds (NCI, Normandy Participations, GO Capital), national investment funds in France (M Capital, Supernova Invest) and the French banks (Caisse d'Epargne, BNP Paribas, Crédit Agricole). Thanks to these past investors, Robocath was able to raise $12.5 million from two series A rounds in 2013 and 2015, amounting to $2 million each, and a series B round of $8 million in 2017. "We have started working on a preliminary commercial launch in France, Germany and Benelux, prior to rolling out sales across the whole European Union and Middle East," said Bencteux. He is planning commercialization on the American market by 2022. Additionally, Robocath is getting ready for a series C round of $11 million to pursue commercial development. ♦

Financings

San Diego-based **Reva Medical Inc.** has secured a letter of commitment for up to $3 million of debt financing to fund operations on an interim basis. The funding will be made available by existing lenders to the company; it is subject to the negotiation and execution of definitive agreements and a further announcement will be made once those agreements are executed. The funding is to address the company's immediate financial needs on an interim basis, but it remains in discussions about a broader restructure to address its outstanding indebtedness and capital structure moving forward. While those discussions are ongoing, Reva said it considers that it is appropriate for its securities to remain voluntarily suspended from trading and this announcement is not intended to lift its voluntary suspension. At this stage, the company expects that the voluntary suspension will continue until plans for a broader restructure are finalized and the company is in a position to make an announcement to the ASX, which the company currently expects will occur by June 30, 2019. At this time, Reggie Groves has stepped down as CEO and as a member of the board to pursue new opportunities. Jeff Anderson has been promoted to the role of president from that of senior VP, clinical and regulatory affairs. Anderson has been with Reva for 12 years. Additionally, Stephen Oesterle will assume the role of strategic advisor to the company and resign from the board due to long-standing commitments.

Product briefs

Brightwater Medical Inc., of Temecula, Calif., said the U.S. FDA has cleared the company's Convertx biliary stent system for treatment of biliary obstructions. The Convertx system enables stent release in less than one minute during an in-office visit or at bedside without the need for sedation or repeated drain insertions.

Elekta AB, of Stockholm, reported its Elekta Unity magnetic resonance radiation therapy (MR/RT) system received a medical device license from Health Canada, clearing the technology for commercial sales in Canada. Elekta Unity combines a high-field 1.5T Philips MRI scanner with a linear accelerator and real-time dose replanning software that are fully integrated to enable online adaptive radiotherapy and real-time target monitoring. It provides the ability to reshape the dose based on daily changes in shape, size and position of the tumor and surrounding healthy anatomy and then enables accurate dose delivery with real-time visualization of the tumor.