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Integra LifeSciences Announces Positive Clinical and Economic Outcomes for Codman[®] Bactiseal[®] EVD Catheter from a Real-World Evidence Study

Data Shows Codman Bactiseal EVD Catheter Reduced Hospital Stay and Costs Associated with Hemorrhagic Stroke Patients

PRINCETON, N.J., July 6, 2023 -- [Integra LifeSciences Holdings Corporation](#) (NASDAQ: IART), a leading global medical technology company, today announced positive clinical and economic outcomes for the use of the Codman[®] Bactiseal[®] External Ventricular Drain (EVD) catheter set in the management of hydrocephalus as a complication of aneurysmal subarachnoid hemorrhage (aSAH) patients. The real-world study was conducted at the University Hospital Gemelli, Rome, Italy thanks to an independent grant by Integra. The study results¹ were recently published by Rina Di Bonaventura, Michele Basile, Alessandro Olivi, Americo Cicchetti, Enrico Marchese in the *Journal of Neurosurgical Sciences (JNSS)* April 2023, a leading journal of neurosurgery in Europe.

aSAH is a hemorrhagic stroke type that is linked with substantial mortality (>30%) for which more than 50% of patients make an incomplete recovery^{2,3}. Acute hydrocephalus is a frequent complication of aSAH, occurring in about 30% of individuals⁴, and it is generally treated by an EVD. Nevertheless, as EVD treatment creates an opening between the environment and the brain, it bears considerable infection risks of up to 22% (average 8-10%)⁵.

The study retrospectively analyzed the data of 100 patients who had randomly received a non-impregnated silicone catheter (NISC) or the Codman Bactiseal EVD catheter. It aimed to determine the cost-effectiveness and budget impact of antibiotic-impregnated silicone catheter (AISC) versus non-impregnated silicon catheters in the management of patients with aSAH related hydrocephalus. The data

¹ Di Bonaventura R, Basile M, Olivi A, Cicchetti A, Marchese E. Antibiotic-impregnated versus standard silicone catheter for external ventricular drainage in acute hydrocephalus associated to aneurysmal subarachnoid hemorrhage: a budget impact analysis from a single center Italian cohort. *J Neurosurg Sci* 2023;67:135-42. DOI: 10.23736/S0390-5616.22.05754-X

² Macdonald RL, Schweizer TA. Spontaneous subarachnoid haemorrhage. *Lancet* 2017;389:655–66

³ Andersen CR, Presseau J, Saigle V, Etmnan N, Vergouwen MDI, English SW; Outcomes in Subarachnoid Haemorrhage Working Group. Core outcomes for subarachnoid haemorrhage. *Lancet Neurol.* 2019 Dec;18(12):1075-1076. doi: 10.1016/S1474-4422(19)30412-0. PMID: 31701889.

⁴ ReKate HL. A contemporary definition and classification of hydrocephalus. *Semin Pediatr Neurol* 2009;16:9–15.

⁵ Lozier AP, Sciacca RR, Romagnoli MF, Connolly ES. Ventriculostomy-related infections: a critical review of the literature. *Neurosurgery.* 2008; 62 (Suppl 2):688-700.

indicated that patients treated with Codman Bactiseal EVD were less likely to have cerebrospinal fluid infections (-25, $p=0.0005$)⁶. The investigators also observed a higher rate of independence amongst patients treated with the Codman Bactiseal EVD catheter (+31%, $p=0.0533$)⁶ set even if patients had a more severe aSAH compared to people treated with NISC.

The investigators projected economic indicators based on the clinical results via a budget impact model. Results of the budget impact analysis indicated that the clinical outcomes for AISC translated into a reduction of the average hospital stay by four days and per patient savings of 5,730 €. This corresponds to savings per patient and hospital admission of 19%. Considering 100 patients are treated with the Codman Bactiseal EVD catheter, it could free up 400 hospital days or generate around half of a million euros of savings for the hospital.

“The prospect of a study on the efficacy, both medical and economic, of the use of antibiotic-impregnated ventricular catheters for external ventricular drainage systems in the treatment of acute hydrocephalus immediately excited us,” said Professor Enrico Marchese, Neurosurgery Department, Fondazione Policlinico Agostino Gemelli IRCCS, Rome, Italy, one the authors of the study. “In fact, every day in clinical practice we are faced with the dilemma of using the tool that allows us to treat the patient in the most effective way. Thanks to the collaboration with Integra and to the completeness of our case studies, we have managed to obtain scientifically valid results, as demonstrated by the publication of our study in one of the most influential neurosurgery journals worldwide.”

The study results provide concrete evidence of the benefit of antibiotic-impregnated catheters to decision makers responsible for improving patient care and defining cost effective treatment. Besides being a lifesaving device, Codman Bactiseal EVD is also a cost-saving device that reduces the economic burden and ensures a safe clinical outcome in patients with aSAH-related hydrocephalus.

“Acute hydrocephalus is one of the most significant and devastating complications of aSAH that leave surgeons and patients with a critical need for effective solutions beyond standard of care,” said Harvinder Singh, president International at Integra. “This recently published clinical data further supports Codman Bactiseal EVD’s clinical and economic value to our customers, providing strong evidence for healthcare

⁶ Absolute risk reduction

professionals to reduce cerebrospinal fluid infection rates as well as costs related to hospital care. This technology will continue to underpin our innovation in advanced catheters.”

Abstract of the study and the full study can be found [here](#)

About Integra LifeSciences:

At Integra LifeSciences, we are driven by our purpose of restoring patients’ lives. We innovate treatment pathways to advance patient outcomes and set new standards of surgical, neurologic and regenerative care. For the latest news and information about Integra and its products, please visit

www.integralife.com

About Codman Bactiseal EVD Catheter:

Please note this product may not be available in all jurisdictions.

The Codman Bactiseal EVD Catheter and Codman Bactiseal Clear EVD Catheter Sets (Bactiseal EVD Catheters) are used for gaining access to the ventricles of the brain and can be used with dimensionally compatible devices for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.

Description

The Bactiseal EVD Catheters are made of silicone tubing and are supplied sterile. Bactiseal EVD Catheters are subjected to a treatment process by which the silicone tubing is impregnated with rifampin and clindamycin hydrochloride. The catheter supplied in the Bactiseal EVD Catheter Set is made of radiopaque (barium sulfate impregnated) silicone. The catheter in the Bactiseal Clear EVD Catheter Set is made of clear silicone with a barium sulfate impregnated stripe. The quantities of rifampin and clindamycin hydrochloride used to impregnate the Bactiseal EVD Catheter are only a fraction of a therapeutic dose of these two antibiotics and have no potential for any systemic therapeutic effect.

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