



## **Aesculap, Inc. proGAV® Gravitational Shunt System Used in Study that Concludes Gravitational Valves Reduce Overdrainage Complications**

*SVASONA study investigates the safety and efficacy of gravitational shunt valves in patients with idiopathic normal pressure hydrocephalus (iNPH)*

**Center Valley, PA (July 8, 2013)** – Aesculap, Inc., a leader in neurosurgery and surgical technology instruments is pleased to announce its participation in a clinical study focused on the benefits of gravitational valve usage. The Aesculap-Miethke proGAV Gravitational Shunt System was featured in the ground breaking study.

The SVASONA study states that gravitational valves will reduce over-drainage complications in shunted iNPH patients by a ratio of 1/3. *“Implanting a gravitational valve rather than another type of valve will avoid one additional over-drainage complication in about every third patient undergoing VP shunting for iNPH.”*<sup>1</sup>

Published in the Journal of Neurology, Neurosurgery and Psychiatry in March 2013, the objective of the SVASONA study was to investigate whether gravitational valve systems reduce the risks of over-drainage complications compared to programmable systems without gravitational valves in patients with idiopathic normal pressure hydrocephalus (iNPH).

The SVASONA study was a large, randomized, pragmatic, open label, multi center trial. 145 patients were enrolled in the study in 7 Hospital Centers in Europe. Some key study findings were:

- Relative risk of symptomatic subdural effusions was reduced by 90% 6 months after randomization.
- Relative risk of over-drainage symptoms (headache, nausea and vomiting) was reduced by 62%.
- Patients without Gravitational Valves had a 40.8% complication rate directly linked to over-drainage as compared to a 6.8% complication rate with gravitational valves.

*“The key finding of this multi-center trial is that, if shunt surgery is considered the treatment option of choice for patients with confirmed iNPH, it should be performed using a gravitational valve.”*<sup>1</sup>

In addition to reducing the risk of over-drainage complications, the SVASONA study also suggests an advantage of gravitational valves in the “mental domains of health related quality of life”.<sup>1</sup> Increased patient comfort and improved quality of life are the primary drivers that fuel the research and development team at Miethke to create breakthrough products such as ShuntAssistant™, proGAV® and the new proSA™ valve that was launched in the United States earlier this year.

“These exciting results not only support our mission to improve the quality of a patient’s life, but represent a cornerstone for the future of iNPH treatment,” stated Chuck DiNardo, President of Aesculap, Inc.

The SVASONA study is available for free as an Open Access article on the JNNP website. Articles may be found using the following link or by searching for SVASONA on the journal’s website.

<http://jnnp.bmj.com/content/early/2013/02/28/jnnp-2012-303936.abstract>,  
<http://www.jnnp.bmj.com>



For additional information on the SVASONA study or Aesculap's shunt valve product offering, please contact your local sales representative or visit [www.aesculapusa.com](http://www.aesculapusa.com).

<sup>1</sup> Lemcke J, Meier U, Müller C, et al. J Neurol Neurosurg Psychiatry Published Online First:1, March 2013 doi:10.1136/jnnp-2012-303936

**About Aesculap, Inc.**

Aesculap, Inc., a B. Braun company, founded in 1867 in Tuttlingen, Germany, is the world's largest and one of the most respected manufacturers of surgical instruments and sterilization container systems. Aesculap is a leading privately-owned manufacturing company, passionately committed to providing high-quality, innovative products and services to all surgical disciplines, with particular focus in the fields of General, Neuro, Spine and Orthopaedics. For more information, contact Aesculap Customer Service at 1-800-282-9000 or visit [www.aesculapusa.com](http://www.aesculapusa.com).

**About B. Braun**

B. Braun Medical Inc. (B.Braun), a leader in infusion therapy and pain management, develops, manufactures, and markets innovative medical products and services to the healthcare industry. The Company is committed to eliminating preventable treatment errors and enhancing patient, clinician and environmental safety. Guided by its "Sharing Expertise®" philosophy, B.Braun continuously exchanges knowledge with customers, partners and clinicians to address the critical issues of improving care and lowering costs.

The B.Braun group of companies includes B.Braun, Aesculap® and CAPS®. B.Braun's U.S. headquarters is located in Bethlehem, Pennsylvania, with its global headquarters based in Melsungen, Germany. It employs more than 44,000 employees in more than 50 countries throughout the world. To learn more about B.Braun visit [www.bbraunusa.com](http://www.bbraunusa.com).

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