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NEW DATA ON FLOSEAL SURGICAL HEMOSTAT QUANTIFIES CLINICAL AND HEALTHCARE RESOURCE OUTCOMES IN SPINE SURGERY CASES

- *A retrospective study reports that cases with billed charges for **Floseal** in spine surgery were associated with 46 percent fewer blood transfusions and 38 percent lower blood-related complications than cases with charges for **Floseal** and Gelfoam/Thrombin.¹*
- ***Floseal**-only cases were also associated with nearly a half day shorter hospital stay, and 39 minute shorter surgical procedures.¹*
- *A separate cost-consequence model concluded that the decreased hospital resources (e.g., shorter hospital stays and lower hemostat use) could potentially save a medium-volume U.S. hospital \$2,445 per spinal procedure.²*
- *Detailed explanations of the studies' methodologies, results and limitations are available in each respective publication.^{1, 2}*

LOS ANGELES, SEPTEMBER 27, 2018 – Baxter International Inc. (NYSE:BAX), a global leader in advancing surgical innovation, announced the publication of two new analyses of real-world data regarding the use of **Floseal Hemostatic Matrix** in spinal surgeries. The retrospective studies observed better clinical and resource use outcomes in cases with billed charges for **Floseal**, when compared to cases with charges for **Floseal** in addition to certain non-flowable hemostatic agents. The studies were highlighted alongside Baxter's Advanced Surgery portfolio innovation at the North American Spine Society meeting being held September 26-29.

Addressing bleeding effectively and quickly during surgery is critical to avoiding major and minor complications for patients. Surgeons may use flowable hemostatic agents like **Floseal** in conjunction with non-flowable agents like gelatin sponges (Gelfoam) and thrombin when bleeding is not adequately controlled through suture, cautery, ligature or other conventional methods.

“This data suggests that the use of **Floseal** as a primary adjunctive hemostat during spine surgery correlates with measurable improvements for hospital administrators and surgeons such as length of stay and blood loss. This reinforces my belief that the choice of proper adjunctive hemostatic agent is a key component to driving down costs and complications for my patients,” said Nitin Khanna, M.D., minimally invasive orthopedic spine surgeon from Orthopedic Specialists of Northwest Indiana and co-author on the study published in *Hospital Practice*.

“Our retrospective analysis of a nationally representative hospital database observed favorable clinical and resource use outcomes in cases in which **Floseal** was the sole hemostat billed. While the inherent limitations of the study prevent us from assigning a causal relationship between **Floseal**-only use and improved outcomes, the real-world data nonetheless provide compelling support for the cost-effective use of **Floseal** from the start of intraoperative bleeding,” said Manuel G. Ramirez, M.D., MSc, the lead author on both publications and associate director of Health Economics and Outcomes Research for Baxter’s Advanced Surgery business.

In the first study published in *Hospital Practice*¹, researchers studied retrospective data on 15,105 propensity-matched pairs of spinal surgeries from a large U.S. hospital billing database and found that cases with charges for **Floseal**, as the sole hemostat used in the case, were associated with 46 percent fewer blood transfusions and 38 percent lower blood-related complications than cases with charges for **Floseal** and other hemostats (gelatin sponges and thrombin).¹ **Floseal**-only cases were also associated with nearly a half day shorter hospital stay, and 39-minute shorter surgical procedures.¹ Limitations of the study included the retrospective database design and certain exceptions in the propensity score matching.

Researchers then developed a cost consequence model to calculate the potential cost savings associated with the improved clinical outcomes and lower resource use observed in the first study with the **Floseal**-only cases. The model concluded that the decreased resources, including shorter hospital stays and lower hemostat use, could potentially save medium volume U.S. hospitals \$2,445 per spinal procedure.² The results were [published](#) last month in the *Journal of Medical Economics*.

The studies include assessments of many cases with data extracted from Premier’s United States (U.S.) Perspective Database, which contains more than 490 million hospital encounters and



captures approximately 25 percent of U.S. hospital discharges. Detailed explanations of the methodologies and study limitations are available in each respective publication.

Baxter shared the recently published data at the North American Spine Society annual meeting taking place this week in Los Angeles, Calif. Attendees can visit Baxter's booth (#1915) to find out more about the studies and new enhancements coming soon to **Floseal**. Attendees can also learn more about the company's [expanding osteobiologics portfolio](#) in the booth.

About Baxter's Surgery Portfolio

Baxter is committed to partnering with clinicians to make a meaningful impact on patient care in operating rooms (OR) in nearly 60 countries. Surgeons rely on our hemostats to stop bleeding during surgery, our sealants to close wounds, and our repair patches and biologics to promote healing. We are focused on pioneering innovative and dependable surgical tools and programs that help to improve clinical outcomes while reducing the total cost of care.

About Baxter

Every day, millions of patients and caregivers rely on Baxter's leading portfolio of critical care, nutrition, renal, hospital and surgical products. For more than 85 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

About FLOSEAL

Important Safety Information

FLOSEAL Matrix is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedure is ineffective or impractical.

Important Risk Information for FLOSEAL Matrix

Do not inject or compress FLOSEAL Matrix into blood vessels. Do not apply FLOSEAL Matrix in the absence of active blood flow, e.g., while the vessel is clamped or bypassed, as extensive intravascular clotting and even death may result.

Do not use FLOSEAL Matrix in patients with known allergies to materials of bovine origin. Do not use FLOSEAL Matrix in the closure of skin incisions because it may interfere with the healing of the skin edges.

FLOSEAL Matrix contains Thrombin made from human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

FLOSEAL Matrix is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis.

Excess FLOSEAL Matrix (material not incorporated in the hemostatic clot) should always be removed by gentle irrigation from the site of application.

FLOSEAL Matrix swells by approximately 10% to 20% after product is applied. Maximum swell volume is achieved within about 10 minutes.

The safety and effectiveness of FLOSEAL Matrix has not been established in children under 2 years of age and pregnant women.

Do not use air to remove residual FLOSEAL Matrix from Applicator tip. The Applicator tips should not be cut. Do not use FLOSEAL Matrix on bone surfaces where adhesives, such as methylmethacrylate or other acrylic adhesives, will be required to attach a prosthetic device.

Rx Only. For safe and proper use of this device, refer to the full Instructions for Use.

*This release includes forward-looking statements concerning **Floseal**, including potential benefits associated with its use. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*

Baxter and **Floseal** are registered trademarks of Baxter International Inc.

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¹ Manuel G. Ramirez, Harel Deutsch, Nitin Khanna, Donald Cheatem, Dongyan Yang & Erik Kuntze (2018) Floseal only versus in combination in spine surgery: a comparative, retrospective hospital database evaluation of clinical and healthcare resource outcomes, Hospital Practice, DOI: 10.1080/21548331.2018.1498279

² Cost-consequence analysis of a hemostatic matrix alone or in combination for spine surgery patients. Manuel G. Ramirez, Xiaoli Niu, Josh Epstein & Dongyan Yang. Received 10 Jul 2017, Accepted 13 Aug 2018, Accepted author version posted online: 16 Aug 2018, Published online: 30 Aug 2018. <https://doi.org/10.1080/13696998.2018.1513261>