

ETHICON LAUNCHES VISTASEAL FIBRIN SEALANT (HUMAN)

TO MANAGE BLEEDING DURING SURGERY

Next Generation Device Simplifies Setup and May Save Valuable Operating Room Time

VISTASEAL is first innovation to emerge from Ethicon's strategic partnership with Grifols, a pioneer in the plasma industry

Somerville, NJ – Dec. 3, 2019 – Many patients today are entering the operating room with multiple factors that can cause disruptive bleeding during surgery, which can be challenging to manage and potentially dangerous. To help address this, Johnson & Johnson Medical Devices Companies* announced today that Ethicon** has launched VISTASEAL Fibrin Sealant (Human) to help surgeons manage bleeding during surgery.

VISTASEAL Fibrin Sealant (Human) contains a combination of fibrinogen and thrombin, clotting proteins found in human plasma. When applied to the bleeding site, it forms a rapid, adherent, and durable clotⁱ and has been demonstrated to sustain hemostasis (stoppage of bleeding), even in high-risk patients.^{i,ii,iii} In three randomized controlled trials, VISTASEAL was associated with a lower overall hemostatic retreatment rate (0.9%-7.8%) compared to standard treatments (8.0%-16.7%).^{iv}

“Surgical patients often present with multiple risk factors such as coagulopathies, uncontrolled diabetes, renal or liver failure or are taking anticoagulants or chronic antiplatelet therapies that may interfere with the body's natural ability to form a clot, which increases the risk of surgical bleeding,” said David Kwon, MD, FACS, Director of Surgical Oncology, Henry Ford Hospital[†]. “VISTASEAL has the potential to offer a rapid, adherent, durable clot even in my most demanding cases.”

VISTASEAL is the first innovation to emerge from Ethicon's strategic partnership with plasma industry leader [Grifols](#), which developed the VISTASEAL Fibrin Sealant (Human) and licensed it to Ethicon. The collaboration combines Ethicon's expertise in developing device technology with Grifols' ability to produce critical plasma-based therapies.

VISTASEAL is the first fibrin sealant exclusively designed to be sprayed without gas in both open and minimally invasive procedures, and it comes in pre-filled syringes. This eliminates some of the steps required for set-up with gas and may save valuable time in the operating room. The VISTASEAL Dual Applicator tip is also uniquely malleable enabling access to difficult anatomy² and enhanced spray control.^{v,vi±}

Throughout a surgical procedure, bleeding must be controlled not only to provide a clear view of the operative site, but also to prevent the adverse clinical outcomes associated with blood loss. An estimated 32 to 68 percent of cases in open surgery procedures experience disruptive bleeding events.^{vii}

VISTASEAL is indicated as an adjunct to hemostasis for mild to moderate bleeding in adults undergoing surgery when control of bleeding by standard surgical techniques (such as suture,

ligature, and cautery) are ineffective or impractical. VISTASEAL is effective in patients treated with heparin (blood thinner).

“VISTASEAL is the latest addition to our broad portfolio of primary and adjunctive hemostat solutions that address the growing and wide-ranging challenges surgeons face in managing bleeding,” said Oray Boston, President, Global Biosurgery, Ethicon. “We will continuously aim to advance the standard of care in surgery to better serve health care professionals and improve outcomes for patients.”

To learn more about VISTASEAL and Ethicon’s portfolio of primary and adjunctive hemostat solutions, visit <https://www.jnjmedicaldevices.com/en-US/product/vistaseal-fibrin-sealant-human>.

About Ethicon

Ethicon, part of Johnson & Johnson Medical Devices Companies, has made significant contributions to surgery for more than 100 years from creating the first sutures, to revolutionizing surgery with minimally invasive procedures. Our continuing dedication to Shape the Future of Surgery is built on our commitment to help address the world's most pressing health care issues and improve and save more lives. Through Ethicon's surgical technologies and solutions including sutures, staplers, energy devices, trocars and hemostats and our commitment to treat serious medical conditions like obesity worldwide, we deliver innovation to make a life-changing impact. For more information, visit www.ethicon.com.

About Johnson & Johnson Medical Devices Companies

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people’s healthcare experiences. In surgery, orthopaedics, vision and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere.

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VISTASEAL™ Fibrin Sealant (Human) IMPORTANT SAFETY INFORMATION

INDICATION

VISTASEAL™ is indicated as an adjunct to hemostasis for mild to moderate bleeding in adults undergoing surgery when control of bleeding by standard surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. VISTASEAL is effective in heparinized patients.

CONTRAINDICATIONS

Do not inject directly into the circulatory system.

Do not use for the treatment of severe or brisk arterial bleeding.

Do not use in patients with history of anaphylaxis or severe systemic reactions to human blood products.

Do not use VISTASEAL for spraying unless the minimum recommended distance from the applicator tip to the bleeding site can be achieved.

WARNINGS AND PRECAUTIONS

Thromboembolic events may occur if VISTASEAL is administered intravascularly.

Only spray VISTASEAL if it is possible to accurately judge the distance from the spray tip to the tissue surface.

Hypersensitivity reactions can occur.

May carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

ADVERSE REACTIONS

The most common adverse reactions (reported in >1% of clinical trial subjects) were nausea and procedural pain.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

For more information and full prescribing information, click [here](#).

* The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopaedics, vision and interventional solutions businesses within Johnson & Johnson's Medical Devices segment.

** Ethicon represents the products and services of Ethicon, Inc., Ethicon Endo-Surgery, LLC and certain of their affiliates. All other trademarks are the property of their respective owners.

***Based on number of set-up steps and thawing time required for VISTASEAL™ Dual Applicator vs competition.

† Dr. Kwon is a paid consultant for Ethicon

‡ Compared to gas- assisted spray

- i Bjelovic M, Ayguasonosa J, Kim RD, et al. A prospective, randomized, phase III study to evaluate the efficacy and safety of fibrin sealant Grifols as an adjunct to hemostasis as compared to cellulose sheets in hepatic surgery resections. *J Gastrointest Surg.* 2018. 22:1939-1949.
- ii Chetter I, Stansby G, Sarralde JA, et al. A prospective, randomized, multicenter clinical trial on the safety and efficacy of a ready-to-use fibrin sealant as an adjunct to hemostasis during vascular surgery. *Ann Vasc Surg.* 2017;45:127-137
- iii Hunt BJ. Bleeding and coagulopathies in critical care. *N Engl J Med.* 2014;370:847-859. 4. VISTASEAL™ Fibrin Sealant (Human).
- iv Danker W, Ferko N, Hogan A. VISTASEAL ISPOR EU cost analysis. June 11, 2019. Ethicon, Inc.
- v Completion Report for Angled Adherence, Study No. 100682576. December 10, 2018. Ethicon, Inc.
- vi Phillips R. VISTASEAL ASA Design Verification Memo for Expression Force and Surface Area. 100675646 Rev 1. December 5, 2018. Ethicon, Inc.
- vii Corral M, Hollmann S, Ferko N, Broder M, Chang E, Sun G. Health and Economic Consequences of Controlled vs Uncontrolled Surgical Bleeding in Patients Treated with Haemostatic Agents: A Retrospective Analysis of the Premier Perspective Database. SABM, 2014.

ⁱ Bjelovic M, Ayguasonosa J, Kim RD, et al. A prospective, randomized, phase III study to evaluate the efficacy and safety of fibrin sealant Grifols as an adjunct to hemostasis as compared to cellulose sheets in hepatic surgery resections. *J Gastrointest Surg.* 2018. 22:1939-1949.

ⁱⁱ Chetter I, Stansby G, Sarralde JA, et al. A prospective, randomized, multicenter clinical trial on the safety and efficacy of a ready-to-use fibrin sealant as an adjunct to hemostasis during vascular surgery. *Ann Vasc Surg.* 2017;45:127-137

ⁱⁱⁱ Hunt BJ. Bleeding and coagulopathies in critical care. *N Engl J Med.* 2014;370:847-859. 4. VISTASEAL™ Fibrin Sealant (Human).

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^{vii} Corral M, Hollmann S, Ferko N, Broder M, Chang E, Sun G. Health and Economic Consequences of Controlled vs Uncontrolled Surgical Bleeding in Patients Treated with Haemostatic Agents: A Retrospective Analysis of the Premier Perspective Database. SABM, 2014.