



FDA Approves DuraSeal To Prevent CSF Leaks

Ed. Note: The following story is a press release from Confluent Surgical, Inc.

April 7, 2005

Confluent Surgical, Inc. announced today that the U.S Food and Drug Administration (FDA) has approved the DuraSeal™ Dural Sealant System as the first and only product indicated as an adjunct to sutured dural repair during cranial surgery to achieve watertight closure. The FDA has approved the DuraSeal Sealant with a condition to conduct a post-approval study.

The DuraSeal technology is a patented synthetic, absorbable hydrogel delivered by a dual syringe applicator. The device can be stored at room temperature and prepared in less than two minutes. When sprayed on to the dura, a strong, adherent sealing layer is produced and effectively seals the suture line within seconds. A feature unique to the DuraSeal Sealant is the blue colorant that provides the surgeon excellent visualization of coverage and thickness of the material upon application to the dura. Postoperatively, the DuraSeal Sealant continues to seal the suture line as healing progresses under the gel. After several weeks, the hydrogel breaks down into water-soluble molecules that are absorbed and cleared through the kidneys. Clinical results presented to the FDA demonstrated the DuraSeal Sealant was able to achieve watertight closure in 98% of cases, immediate sealing was obtained on the first application in 95% of cases, and 95% of applications were rated as "easy" to "very easy" by neurosurgeons using the product.

"Watertight closure of the dura has to date been an elusive goal. With DuraSeal, it can become a reality. This sealant is easy to apply, really works and has the potential for providing a new paradigm for how the dura is closed following cranial surgery. I'm confident it will have a profound effect on my cranial procedures", said Harry van Loveren, MD, chairman of the Department of Neurosurgery, University of South Florida, and a principal investigator in the pivotal DuraSeal multi-center study.

"We have seen a tremendous reception for DuraSeal internationally and we are looking forward to making it a commercial success in the United States" said Amar Sawhney, Co-Founder, President & CEO of Confluent Surgical.

"This is a remarkable product and as the first and only FDA approved dural sealant product, I look forward to using DuraSeal for achieving a watertight dural closure", said G. Rees Cosgrove, MD, Associate Professor of Surgery, Harvard Medical School, and the Lahey Clinic.

There are approximately 250,000 craniotomies performed in the U.S each year and almost all cases involve a suture repair of the dura. Confluent Surgical has established an extensive and distinguished neurosurgeon focused distribution channel to represent the DuraSeal product in the U.S. market.

Confluent Surgical is a private medical device company that is pioneering the development of in-situ-polymerized biomaterials. The synthetic materials are safe, simple to use, and allow the formation of customized implants at the site of disease. These materials have potentially numerous applications across several surgical disciplines.

For additional information, visit the Confluent Surgical and DuraSeal website at <http://www.confluentsurgical.com/> and <http://www.duralsealant.com/>

[Home](#) | [About Us](#) | [Email](#) | [Donate](#) | [Get Involved](#) | [Privacy Policy](#)

Disclaimer: This publication is intended for informational purposes only and may or may not apply to you. The editor and publisher are not doctors and are not engaged in providing medical advice. Always consult a qualified professional for medical care. This publication does not endorse any doctors, procedures, or products.

© 2003-2020 C&S Patient Education Foundation