LEARN THE FACTS ABOUT USING DURASEAL™ DURAL SEALANT WITH NON-AUTOLOGOUS COLLAGEN DURAPLASTY.

The DuraSeal™ sealant is a fully synthetic absorbable material designed to assist surgeons in creating an intra-operative watertight seal when used as an adjunct to sutures for dural closure.

Preclinical and clinical testing of DuraSeal™ sealant used with collagen duraplasty materials has been completed. The use of DuraSeal™ sealant with non-autologous collagen based duraplasty was granted by the FDA in December, 2006.

NON-AUTOLOGOUS, COLLAGEN DURAPLASTY MATERIALS

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<td>Integra LifeSciences</td>
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<td>DuraForm™ Dural Graft Implant</td>
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* DuraSeal™ dural sealant may also be used with autologous duraplasty.
**PRECLINICAL RESULTS**
Application of Hydrogel Sealant Improves Watertight Closures of Duraplasty Onlay Grafts in a Canine Craniotomy Model

- 100% improvement in intraoperative sealing success (vs. collagen duraplasty alone)\(^1,2\)
- 83.3% reduction in postoperative CSF leaks (vs. collagen duraplasty alone)\(^1,2\)
- At reoperation, decreased dura mater bone flap adhesion formation was documented\(^1,2\)
- DuraSeal™ sealant over the collagen duraplasty was not associated with neurotoxicity, delayed healing, degenerative changes, increased dural brain adhesions, or impaired neodura formation\(^2\)

**CLINICAL RESULTS**
The Safety and Effectiveness of a Dural Sealant for Use with Collagen Duraplasty Materials

- A retrospective 66 patient study of DuraSeal™ sealant in conjunction with collagen based duraplasty vs. 50 patients receiving DuraSeal™ sealant in conjunction with autologous duraplasty from the pivotal trial\(^1,3\)
- Safety based upon incidence of neurosurgical complications (ie. post-op CSF leak, surgical site infection and meningitis)\(^1,3\)
- Post operative CSF leak rate of 7.4% in the retrospective DuraSeal™ sealant/collagen based duraplasty group (vs. 6% in the DuraSeal™ sealant/autologous duraplasty pivotal trial group)\(^1,3\)
- There were no surgical site infections in the retrospective population. No serious device-related adverse events or unanticipated adverse device effects noted in the DuraSeal™ sealant/collagen based duraplasty group, or in the pivotal control group \(^1,3\)

1. DuraSeal™ sealant IFU