



Your choice of sealant matters

# SEAL TO HEAL



**DuraSeal®** is the cranial sealant that strengthens your repair and supports the body's natural healing process.

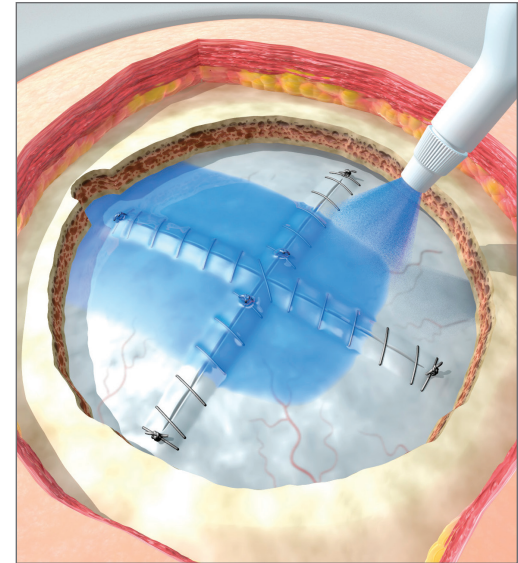
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## DuraSeal® is more effective at preventing CSF leaks than fibrin glue<sup>1</sup>

- Four times fewer incisional CSF leaks versus fibrin glue ( $P=0.03$ )<sup>1</sup>
- Demonstrated superior tissue adherence versus fibrin glue<sup>2</sup>
- Engineered with appropriate strength and optimal duration for cranial procedures



DuraSeal®, shown with standard tip applicator



### ORDERING INFORMATION

|           |                                      |             |
|-----------|--------------------------------------|-------------|
| 202050    | DuraSeal® Dural Sealant System, 5 mL | 5 units/box |
| 205108    | Extended Tip Applicator, 8 cm        | 5 units/box |
| 205115    | Extended Tip Applicator, 15 cm       | 5 units/box |
| 205000DS* | MicroMyst™ Applicator                | 5 units/box |
| FR6065*   | Flow Regulator                       | 1 unit/box  |

For more information or to place an order, please contact:

Integra 311 Enterprise Drive  
Plainsboro, NJ 08536

USA 800-997-4868

Outside USA 609-936-5400

Fax 888-980-7742

\*MicroMyst™ Applicator requires an open air source to operate—used in conjunction with the Flow Regulator.

**References:** 1. Than KD, Baird CJ, Olivi A. Polyethylene glycol hydrogel dural sealant may reduce incisional cerebrospinal fluid leak after posterior fossa surgery. *Neurosurgery* 2008;63(suppl 1):ONS182-ONS186. 2. Data on file, Integra LifeSciences Corporation.

**INDICATION:** The DuraSeal® Dural Sealant System is intended for use as an adjunct to sutured dural repair during cranial surgery to provide watertight closure.

**CONTRAINDICATIONS:** Do not apply the DuraSeal® hydrogel to confined bony structures where nerves are present since neural compression may result due to hydrogel swelling. The hydrogel may swell up to 50% of its size in any direction. **SAFETY RESULTS:** Pre-Market Approval Study: All 111 patients treated with the DuraSeal® Sealant showed no leakage during the intra-operative assessment. 109 of 111 patients (98.2%) met the criteria for primary endpoint success; i.e., intraoperative sealing. The incidence of post-op CSF leaks in this study was 4.5%. Of these leaks, 1.8% were incisional and 2.7% were pseudomeningoceles. Post-Market Approval Study: There were three CSF leaks reported during the course of this study, including one in the DuraSeal® group and two in the Control group (0.8% DuraSeal® vs 1.7% Control,  $p=0.619$ ). The reported leak rate did not show a significant difference between groups. The incidence and nature of adverse events observed in both the pre and post-market study populations are consistent with the type and complexity of the surgery performed and the co-morbid state of the treated patients.

Please see DuraSeal® Instructions for Use for more information.

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