Why your choice of sealant matters

DuraSeal®’s watertight seal gives the dura more time to heal compared to fibrin glue.¹*

Clinical results show fibrin glue leaks much earlier than DuraSeal®

<table>
<thead>
<tr>
<th>Clinical outcome</th>
<th>DuraSeal® (n=100)</th>
<th>Fibrin glue (n=100)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to leak (d)</td>
<td>28 ± 14</td>
<td>9.1 ± 5.3</td>
<td>0.005†</td>
</tr>
</tbody>
</table>

†Statistically significant, P<0.05

Results from a two-arm clinical study at Johns Hopkins University School of Medicine evaluating the efficacy of DuraSeal® versus fibrin glue in 200 patients who underwent posterior fossa surgery.¹

During the critical post-operative period, when most dural repair complications occur,² Than et al. found that patients treated with fibrin glue experienced CSF leak considerably sooner.¹
**DuraSeal® strengthens your repair and supports the body’s natural healing process.**

- Demonstrated to last longer than fibrin glue\(^3\,^4\)*

- Engineered for appropriate strength and optimal duration, even in high-pressure areas

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**References:**


**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.

*Fibrin glue has not been FDA approved for use as a dural sealant. However, it was considered a standard of care modality in the control group of the DuraSeal Post-Approval Study.

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