### SEAL TO HEAL WITH DuraSeal®

### Why your choice of sealant matters

**DuraSeal® contributes to shorter length of stay versus fibrin glue.**\(^1\-^3\)**

<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>Length of stay (d)</td>
<td>5 ± 3.6(^\dagger)</td>
<td>6.3 ± 4.3</td>
<td>0.02(^\ddagger)</td>
</tr>
</tbody>
</table>

\(^\dagger\)These data exclude one patient, whose length of stay (42 d) was considered to be an outlier.

\(^\ddagger\)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.\(^1\)

Patients treated with fibrin glue stayed in the hospital on average 1.3 days longer than those treated with DuraSeal®.\(^1\)
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.

**References:**
3. Baird CJ, Ernst FR, Minshall ME. The potential cost impact of using a PEG hydrogel sealant compared with surgical standard of care to prevent cerebrospinal fluid leaks after cranial surgery. Poster presented at: The 2009 Annual Meeting of the Congress of Neurological Surgeons (CNS); October 24-29, 2009; New Orleans, LA.

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

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