DuraSeal® cranial sealant and DuraSeal® Xact spinal sealant strengthen your repair and support the body’s natural healing process.
**SEAL TO HEAL**

**DuraSeal® cranial sealant** is more effective at preventing CSF leaks than fibrin glue after posterior fossa surgery

- Significantly less incisional CSF leaks versus fibrin glue ($P=0.03^*$)\(^1\)
- Length of hospital stay: shorter by more than a day, on average ($P=0.02^*$)
- Longer mean time to leak ($P=0.005^*$)

*Statistically significant, $P<0.05$.


**OBJECTIVE OF THE CLINICAL STUDY**: Determine whether the use of a new polyethylene glycol (PEG) dural sealant product (DuraSeal\(^\circledR\)) is effective at preventing incisional CSF leak after posterior fossa surgery. **DESIGN**: Two-arm study: 200 patients: PEG hydrogel ($n=100$), prospective observation and fibrin glue ($n=100$), retrospective review. **RESULTS**: PEG group: 2 of 100 (2%) patients developed an incisional CSF leak postoperatively vs. 10 of 100 (10%) patients in the fibrin glue group, with a $P$ value of 0.03 (statistically significant). There were no significant difference in the rates of pseudomeningocele, meningitis, or other postoperative interventions. **CONCLUSION**: The application of PEG dural sealant to the closed dural edges may be effective at reducing incisional CSF leak after posterior fossa surgery.
CONCLUSION:

There were no significant difference in the rates of pseudomeningocele, meningitis, or other postoperative interventions.

RESULTS:

PEG group: 2 of 100 (2%) patients developed an incisional CSF leak postoperatively vs. 10 of 100 (10%) patients in the fibrin glue group, with a P value of 0.03.

DESIGN:

Two-arm study. 200 patients: PEG hydrogel (n=100), prospective observation and fibrin glue (n=100), retrospective review.

OBJECTIVE OF THE CLINICAL STUDY:

Assess the efficacy and the safety of a polyethylene glycol (PEG) hydrogel spinal sealant (DuraSeal® Spinal Sealant) as an adjunct to sutured dural repair in the spine. Spine 2011; 36(Number 23):1906-1912.


OBJECTIVE OF THE CLINICAL STUDY: Assess the efficacy and the safety of a polyethylene glycol (PEG) hydrogel spinal sealant (DuraSeal® Spinal Sealant) as an adjunct to sutured dural repair compared with standard of care methods (control) to obtain a watertight dural closure in patients undergoing an intentional durotomy during spinal surgery. DESIGN: Prospective, multicenter, randomized, two-arm, single-blind, investigational device exemption pivotal study. RESULTS: Patients treated with the PEG hydrogel spinal sealant had a significantly higher rate of watertight closure than the control (100% vs. 64.3%, P < 0.001). No statistical differences were seen in postoperative cerebrospinal fluid leak, infection, and wound healing. No neurologic deficits were seen attributable to the sealant. CONCLUSION: The PEG hydrogel spinal sealant evaluated in this study is safe and effective for providing watertight closure when used as an adjunct to sutured dural repair during spinal surgery.

Your choice of cranial sealant matters

DuraSeal® Cranial Sealant System – 5mL 1kit/box

DuraSeal® Cranial Sealant System – 5 mL 5kits/box

Reference Description Quantity

203001 DuraSeal® Xact – Spinal Sealant System – 3mL 1kit/box

204003 DuraSeal® Xact – Spinal Sealant System – 3 mL 5kits/box


CONCLUSION:

The PEG hydrogel spinal sealant had a significantly higher rate of watertight closure than the control (100% vs. 64.3%, P < 0.001). No statistical differences were seen in

watertight dural closure (P<0.001)

Fewer applications required to achieve watertight closures compared to the Standard of Care

100% success rate in achieving an intra-operative watertight dural closure (P<0.001)

DuraSeal® Cranial Sealant

DuraSeal® Xact Spinal Sealant

shown with Extended Tip applicator
Your choice of sealant matters

SEAL TO HEAL

Improve Access in Tight Spaces with Extended Tip Applicators*

- Enhance your approach in hard-to-reach areas of the spine and brain
- Offer flexibility that extends access, through your surgical approach, with a 60° bendable shaft
- Pause and resume application of DuraSeal® and DuraSeal® Xact cranial and spinal sealant systems intra-operatively

<table>
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<tr>
<th>Reference</th>
<th>Description</th>
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<tbody>
<tr>
<td>205108</td>
<td>Extended Tip Applicator, 8 cm</td>
<td>5kits/box</td>
</tr>
<tr>
<td>205115</td>
<td>Extended Tip Applicator, 15 cm</td>
<td>5kits/box</td>
</tr>
</tbody>
</table>

Indications:
The DuraSeal® Dural Sealant System is intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure.
The DuraSeal® Xact Sealant System is indicated for use during spine procedures as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure.
The Extended Tip Applicator is intended for use in the simultaneous delivery of two non-homogenous solutions onto a surgical site.

Contraindications:
Do not apply the DuraSeal® Dural Sealant/ DuraSeal® Xact in abdominopelvic surgical procedures for use as a sealant or adhesion barrier.
Do not use Extended Tip Applicator for other indications than ones provided in the instructions for use.

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