Your choice of sealant matters

SEAL TO HEAL

Introducing DuraSeal® Exact, the spine sealant that strengthens your repair and supports the body’s natural healing process.
Spine Sealant System

Securing Your Work

DuraSeal® is more effective at preventing CSF leaks than fibrin glue¹

• DuraSeal® Exact is engineered for appropriate strength and optimal duration for the tighter confines and higher pressures of the spine
• Demonstrated superior tissue adherence versus fibrin glue²

ORDERING INFORMATION

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Units/Box</th>
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<tbody>
<tr>
<td>206520</td>
<td>DuraSeal® Exact Spine Sealant System, 5 mL</td>
<td>5 units/box</td>
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<tr>
<td>206320</td>
<td>DuraSeal® Exact Spine Sealant System, 3 mL</td>
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<tr>
<td>205108</td>
<td>Extended Tip Applicator, 8 cm</td>
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<tr>
<td>205115</td>
<td>Extended Tip Applicator, 15 cm</td>
<td>5 units/box</td>
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<tr>
<td>205000D*</td>
<td>MicroMyst™ Applicator</td>
<td>5 units/box</td>
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<tr>
<td>FR6065*</td>
<td>Flow Regulator</td>
<td>1 unit/box</td>
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</tbody>
</table>

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.


INDICATION: The DuraSeal® Exact Spine Sealant System is indicated for use as an adjunct to sutured dural repair during spinal surgery to provide watertight closure. CONTRAINDICATIONS: Do not apply the DuraSeal® Exact hydrogel to confined bony structures where nerves and spinal cord are present since neural compression may result due to hydrogel swelling. The hydrogel may swell up to 12% of its size in any dimension. WARNINGS: In the treatment arm of the DuraSeal® Exact PMA clinical study the rate of post-operative CSF leaks in Chiari malformation procedures was reported as 30.4% (7/23). Of the 30.4%, 8.7% are CSF Fistula, 8.7% are Pseudomeningocele (surgical intervention required), and 13% are Pseudomeningocele (no surgical intervention required). SAFETY RESULTS: In the PMA study of 98 randomized subjects, the overall incidence of protocol defined CSF leaks within 90 days post-procedure was slightly lower in the DuraSeal® Exact arm, but not statistically different within the two groups: DuraSeal® Exact 11.0% vs. Control 12.5%. There were no statistically significant differences between treatments in the incidence of AEs and SAEs between the two treatment groups.

Please see DuraSeal® Exact Instructions for Use for more information.

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DuraSeal® Exact
Spine Sealant System