

Your choice of spinal sealant matters

## SEAL TO HEAL

Integra® DuraSeal® Exact is the **ONLY** dural sealant approved for use for dural repair in **SPINE** surgery

### *Spine Indication?*

- ☒ Integra® DuraSeal® Exact
- ☐ Adherus® Dural Sealant
- ☐ Tisseel® Fibrin Sealant

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## ORDERING INFORMATION

|           |                                            |             |
|-----------|--------------------------------------------|-------------|
| 202050    | DuraSeal® Dural Sealant System, 5 mL       | 5 units/box |
| 206520    | DuraSeal® Exact Spine Sealant System, 5 mL | 5 units/box |
| 206320    | DuraSeal® Exact Spine Sealant System, 3 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  |

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

**INDICATIONS:** 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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