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.

INTEGRA®
LIMIT UNCERTAINTY

Securing Your Work

DuraSeal® Exact

Spine Sealant System

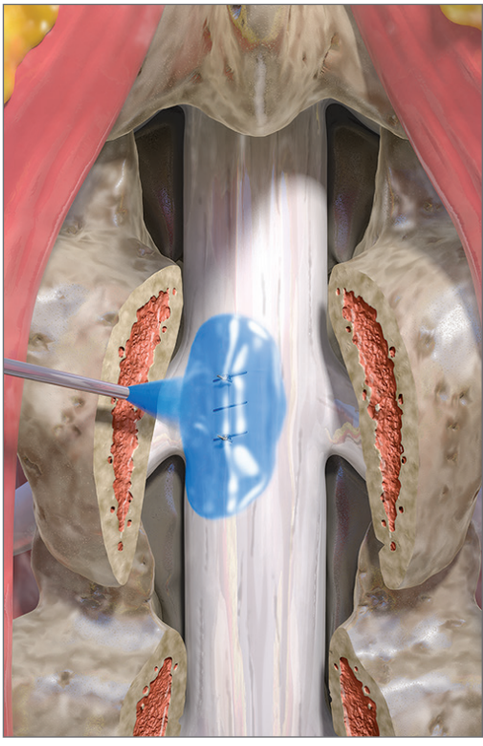
Your choice of spinal sealant matters

SEAL TO HEAL

DuraSeal® is more effective at preventing CSF leaks than fibrin glue[1]

- 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 glue[2]

DuraSeal® Exact, 206520 shown with 8 cm Extended Tip Applicator, 205108



MicroMyst™ Applicator shown

ORDERING INFORMATION

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

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.

References: 1. Than KD, Baird CJ, Olivi A. Polyethylene glycol hydrogel dural sealant may reduce incisional cerebrospinal fluid leak after posterior fossa surgery. *Neurosurgery* 2008;63(suppl 1):ONS182-ONS186. **2.** Data on file, Integra LifeSciences Corporation.

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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