Your choice of sealant matters

SEAL TO HEAL

DuraSeal® is the cranial sealant that strengthens your repair and supports the body's natural healing process.

INTEGRA®
LIMIT UNCERTAINTY

Securing Your Work
DuraSeal®
Dural Sealant System

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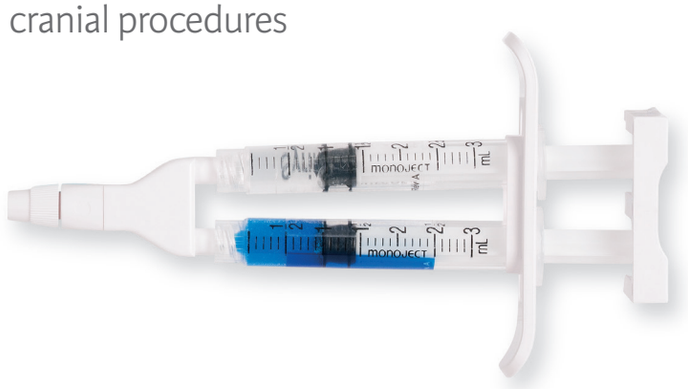
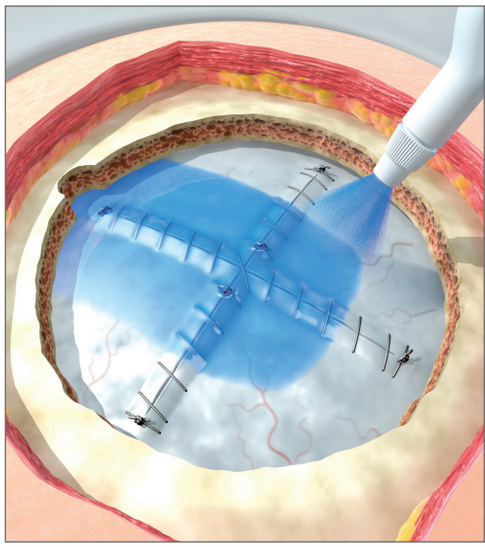
SEAL TO HEAL

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

- Four times fewer incisional CSF leaks versus fibrin glue (*P*=0.03)[1]
- Demonstrated superior tissue adherence versus fibrin glue[2]
- Engineered with appropriate strength and optimal duration for cranial procedures



DuraSeal®, shown with standard tip applicator



ORDERING INFORMATION

202050	DuraSeal® Dural Sealant System, 5 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® 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.

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