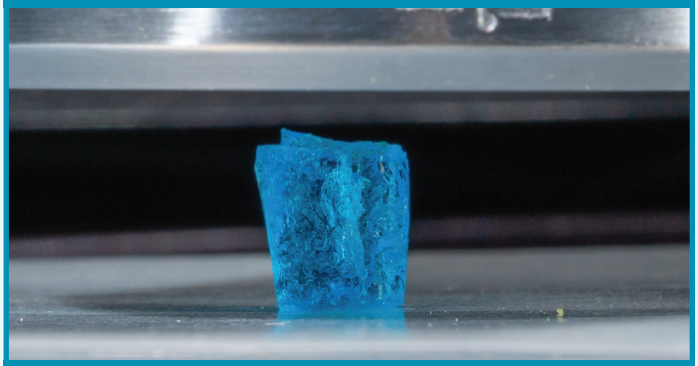
See the Difference

DuraSeal® Dural Sealant vs Adherus® Dural Sealant

A series of flexibility comparison tests were conducted for DuraSeal and Adherus. In order to test the mechanical strength and resilience of hydrogels, 12 samples of DuraSeal and Adherus were compressed by the same constant force to 90% compression.

DuraSeal

DuraSeal Dural Sealant

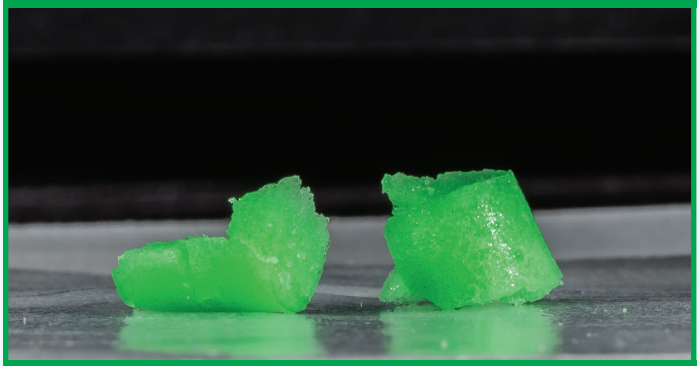


99% Recovery

DuraSeal has a average recovery rate of 99% across all samples tested.[1]

Adherus

Adherus Dural Sealant



0% Recovery

Adherus consistently fractured and fragmented across all samples tested at an average compression of 42.8%.[1]

DURASEAL DEMONSTRATES SIGNIFICANT ELASTICITY AND RECOVERABILITY VS ADHERUS IN BENCHTOP TESTING

DuraSeal®: See the Difference

Measurements of strength and flexibility demonstrate that not all sealants are created equal. DuraSeal and DuraSeal Exact are the first and only dural sealants approved for use in cranial and spinal surgery, respectively. Benchtop tests demonstrated that DuraSeal and DuraSeal Exact provide appropriate strength and flexibility to secure a seal that resists pressure.

Choice Matters.

DuraSeal Dural Sealant System, Extended Tip Applicator

Ordering Information

Reference	Description	Quantity
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 used in conjunction with the Flow Regulator.

REFERENCE: 1. Data on file, Integra LifeSciences Corporation. Correlation between benchtop studies and clinical performance has not been established.

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 intraoperative 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.

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% were CSF fistulas, 8.7% were pseudomeningoceles (surgical intervention required), and 13% were pseudomeningoceles (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.

INTEGRA® LIMIT UNCERTAINTY

DuraSeal®
Dural Sealant System