Relax. It's sealed with Exact.



DuraSeal® Exact

SPINE SEALANT SYSTEM

Proven more watertight[1]

1. Wright NM, Park J, Tew JM, et al. Spinal sealant system provides better intraoperative watertight closure than standard of care during spinal surgery: a prospective, multicenter, randomized controlled study. *Spine (Phila Pa 1976)*. 2015;40(8):505-513.

INTEGRA®
LIMIT UNCERTAINTY

DuraSeal® Exact is engineered for minimal swelling* and appropriate strength for the tighter confines and higher pressures of the spine

Health Canada has authorized this device for sale as a dural sealant

Proven more watertight in a peer-reviewed clinical study[1]



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

*DuraSeal® Exact may swell up to 12% in any one dimension.
†MicroMyst™ Applicator requires an open air source to operate—used in conjunction with the Flow Regulator.

1. Wright NM, Park J, Tew JM, et al. Spinal sealant system provides better intraoperative watertight closure than standard of care during spinal surgery: a prospective, multicenter, randomized controlled study. *Spine (Phila Pa 1976).* 2015;40(8):505-513.

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:** There were no deaths or treatment related adverse events observed in the study. The incidence of protocol defined CSF leaks within 90 days post-procedure was slightly lower in the DuraSeal® Exact Spine Sealant arm, but not statistically different within the two groups: DuraSeal® Exact Spinal Sealant 11.0% vs Control 12.5% (P=1.000). The distributions of time to first CSF leak were also comparable between the two treatment groups (P=0.719 from the log rank test). The incidence of surgical site infections (DuraSeal® Exact Spinal Sealant 6.8% vs Control 12.5%; P=0.404) and the distributions of time to first SSI were also comparable between the two treatment groups (P=0.356 from the log rank test).

PLEASE SEE DURASEAL® EXACT INSTRUCTIONS FOR USE FOR MORE INFORMATION

For more information or to place an order, please contact:

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