DuraSeal™ Dural Sealant

"IMPORTANT: Please refer to the package insert for complete instructions, indications, contraindications, warnings and precautions."
CSF Leak Manifestation

**Otorrhea** - leakage from the external auditory canal

**Rhinorrhea** - leakage through the nose

**Incisional leakage** - drainage from the surgical wound

**Pseudomeningocele** - extradural fluid collection
The Clinical Need

• Postoperative CSF leaks are “One of the most challenging and potentially dangerous complications of cranial surgery”¹

• CSF leaks lead to meningitis, pseudomeningocele, impaired wound healing, headaches and prolonged hospitalization. ¹

• The incidence of postoperative CSF leaks in cranial procedures performed via the infratentorial and supratentorial approach remains as high as 10% to 27%. ¹
Historical Prevention of CSF Leakage

• If the dura is closed “watertight” during surgery, then postoperative CSF leaks are decreased. ¹

• Needle holes prevent true watertight closures ²
  When pressure tested only 3/61 (5%) of patients in the first DuraSeal™ study had watertight sutured closures ³

• Effectively sealing dural incisions during surgery is therefore important because it may prevent CSF leakage and related complications. ⁴
The Solution: 
DuraSeal™ System

“IMPORTANT: Please refer to the package insert for complete instructions, indications, contraindications, warnings and precautions.”
Proprietary "Reversible" Hydrogel Technology

When mixed, the liquids crosslink to form an absorbable hydrogel

Water Soluble PEG Reactive End Groups

Amino acid with Reactive End Groups

Hydrolyzable Segments

Reaction (~2 sec)

GEL

 (> 90% water)

Segments Hydrolyze

Absorption (4-8 weeks)

Water Soluble PEG cleared by kidneys

Amino acid with Reacted End Groups cleared by kidneys

LIQUID
## DuraSeal™ Biocompatibility

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
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<tbody>
<tr>
<td><strong>Genotoxicity</strong></td>
<td></td>
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<tr>
<td>Ames mutagenicity</td>
<td>Non mutagenic</td>
</tr>
<tr>
<td>Chromosomal aberrations</td>
<td>Non genotoxic</td>
</tr>
<tr>
<td>Mouse Micronucleus test</td>
<td>Non genotoxic</td>
</tr>
<tr>
<td>Mouse Lymphoma</td>
<td>Non mutagenic</td>
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<tr>
<td><strong>Cytotoxicity</strong></td>
<td></td>
</tr>
<tr>
<td>Cytotoxicity</td>
<td>Non cytotoxic</td>
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<tr>
<td><strong>Toxicity (Systemic and Local)</strong></td>
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<tr>
<td>Pyrogenicity</td>
<td>Non pyrogenic</td>
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<tr>
<td>Acute systemic toxicity</td>
<td>Non toxic</td>
</tr>
<tr>
<td>Subchronic toxicity</td>
<td>Non toxic</td>
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<tr>
<td><strong>Irritation, Sensitization, and Local Effects</strong></td>
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<tr>
<td>Acute intracutaneous reactivity</td>
<td>Non reactive</td>
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<tr>
<td>Sensitization</td>
<td>Non sensitizing</td>
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<tr>
<td>Intramuscular implant</td>
<td>Slight Irritant</td>
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<td><strong>Interactions with Blood</strong></td>
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<tr>
<td>Hemolysis</td>
<td>Nonhemolytic</td>
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</tbody>
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DuraSeal™ – Mechanism of Action\textsuperscript{1,2,3}

When applied, DuraSeal:

- Rapidly diffuses into tissue crevices and cross links
- Interlocks within tissue crevices resulting in strong tissue adherence
- Blue colorant allows for visualization of gel coverage and thickness
DuraSeal™ can withstand elevated CSF pressures due to:

- Strong tissue adherence
- High cohesive strength
- Elasticity
DuraSeal™ – Mechanism of Action$^{1,2}$

Post operative attributes:
- Separates dura from the bone flap preserving the tissue plane
- May facilitate subsequent re-operation
DuraSeal™ – Mechanism of Action\textsuperscript{1,2}

**Biocompatible absorption:**
- Water soluble linkages hydrolyze over 4 to 8 weeks
- Water soluble PEG molecules are liberated and cleared via the kidneys
DuraSeal™ Sealant Technology

Characteristics of Ideal Dural Sealant

Effective at forming a strong seal (adherent, strong)\(^1\)

Biocompatible \(^2\)

Not derived from human or animal products

Absorbable

Easy to prepare and use

– Ready within minutes \(^1\)

– Fast polymerization \(^1\)

– Easily visible

– Allows suction and irrigation after application

Cost-effective \(^3\)
DuraSeal™ Sealant Instructions For Use

Indications for Use

Intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure.

1. LCN 80-2005-072 Rev H
Contraindications

Do not apply the DuraSeal™ Surgical Sealant in abdominopelvic surgical procedures for use as a sealant or adhesion barrier.
The safety and effectiveness of the DuraSeal™ hydrogel has not been studied in:
• Patients with severely altered renal or hepatic function.
• Patients who are pregnant or lactating.
• Patients with a known allergy to FD&C #1 Blue dye.

Do not use if an active infection is present at the surgical site.

Do not use as a void filler in the spine as postoperative hydrogel swelling may impinge on surrounding tissues. The surgical sealant may swell up to 50% of its size in any direction.

The DuraSeal™ Surgical Sealant is designed for use in neurosurgical procedures as an adjunct to standard methods of repair or closure and should not be used as a replacement of standard methods of repair or closure.