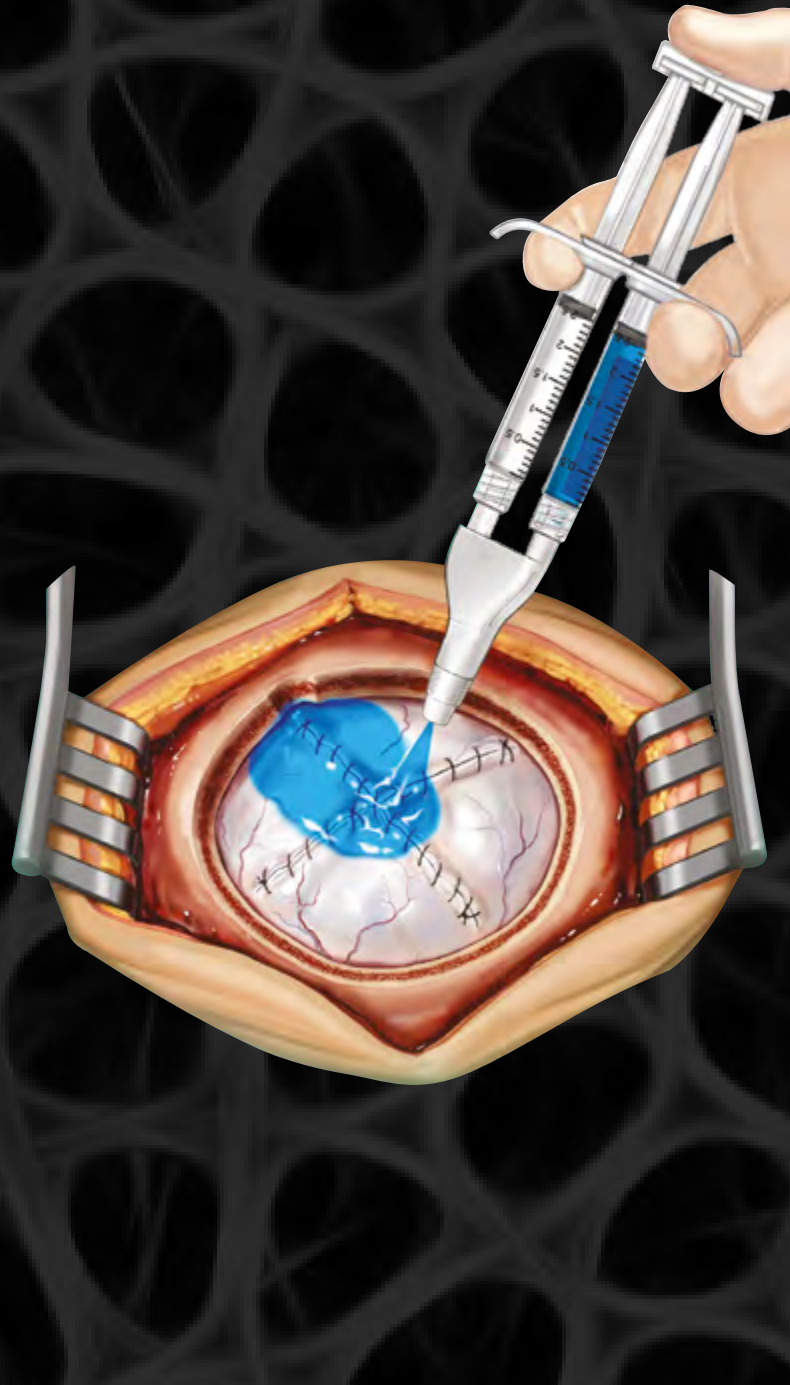


Integra®

DuraSeal® Dural Sealant System
for Cranial Surgery

Limit uncertainty with
DuraSeal® dural sealant
system, hydrogel technology
for watertight closure
during cranial neurosurgery
procedures.



INTEGRA®
LIMIT UNCERTAINTY

Integra®

DuraSeal® Dural Sealant System for cranial surgery

DuraSeal® Dural Sealant System

During neurosurgical procedures, it is essential to prevent the leakage of cerebrospinal fluid (CSF) in order to reduce potential adverse events and ensure positive patient outcomes. DuraSeal® dural sealant system, hydrogel made with a specific polymer technology, provides a quick and effective watertight seal intraoperatively and through the critical healing period.



STRENGTH²

Tissue adherence and cohesive strength to withstand critical pressures.

BIOCOMPATIBILITY^{1,3} VISIBILITY

Biocompatible PEG (polyethylene glycol) hydrogel.

Distinctive blue colorant provides visualization to assess sealant coverage and thickness.

SPEED^{1,4}

Prepared in less than two minutes. When applied, forms a watertight seal in seconds.

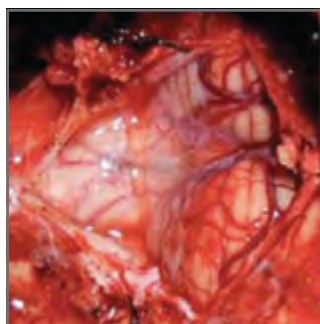
CONVENIENCE

Single kit, stored at room temperature.

Clinical results

DuraSeal® dural sealant system has been studied in two separate, prospective, non-randomized clinical investigations.^{1,5}

In 111 patients treated, the dural sealant demonstrated a total of 100%¹ intraoperative success rate in holding a watertight seal with no overt CSF leakage upon a subsequent Valsalva maneuver.



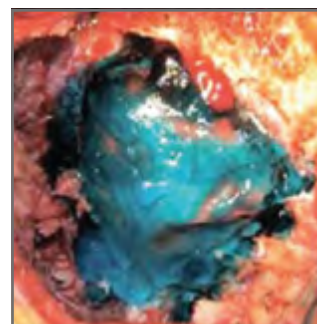
Midline suboccipital craniectomy with dural opening for Chiari Malformation. Cerebellar tonsils below foramen magnum.



Dura closed with bovine pericardial graft using 6-0 Prolene™ suture for duroplasty for treatment of symptomatic Chiari malformation.



Application of DuraSeal® sealant to augment dural closure.



Completion of DuraSeal® dural sealant application of duroplasty for decompression of Chiari malformation.

Watertight closure success rate

| | Patients | Follow-up | Rate of success (no overt CSF leak) |
|------------------------|----------|-----------|-------------------------------------|
| Cosgrove ¹ | 111 | 3 months | 100% |
| Boogaarts ⁵ | 47 | 1 month | 95,3% |

Images: Delashaw J, Coppa N. "Closure Techniques for Common Craniotomies in the Posterior Fossa" (White Paper)

1. Cosgrove GR et al. "Safety and efficacy of a novel polyethylene glycol hydrogel sealant for watertight dural repair". J Neurosurg 106: 52-58, 2007

2. In-vitro Product Comparison Study of Wound Healing Sealants. Report no: R090417B (Cyanta Report)

3. Safety Testing for 4a2okSG-trilysine sealant with BHT. Report no: ER1105, page 2-9

4. Delashaw JB et al. "Reconstruction After Posterior Cranial Fossa Surgery: Application of a Synthetic Tissue Sealant to Augment Dural Closure." Case Report 2009

5. Boogaarts JD et al. "Use of a novel absorbable hydrogel for augmentation of dural repair: results of a preliminary clinical study". Neurosurgery. 57:146-151, 2005

*Trademarks of their respective owners.

Applicators

The DuraSeal® dural sealant system applicators provide extended reach and visibility to the surgical site.

Extended Tip Applicator

The Extended Tip Applicators give DuraSeal® dural sealant system users the versatility of a malleable manual applicator with extended reach and added visibility. Available in 8 cm and 15 cm length.

MicroMyst® Applicator

The flexible air-assisted MicroMyst® applicator delivers precise application through a fine mist spray (14 cm length). Used with the Flow Regulator for the controlled application of two liquids.



The Flow Regulator provides air flow to facilitate a consistent and even spray. Only use the MicroMyst® Applicator with the Flow Regulator.

NOTE: Supplied pressure from N₂ or compressed air source should be set between 50–200 psi (3.45 – 13.8 Bar).

Application Tip

1. Do not prime any Applicator prior to use as plugging may result.
2. Prepare application site by removing all blood clots and fluid.
3. While in the surgical field, spray on gauze briefly prior to moving to the target site.
4. All Applicator tips should be positioned approximately 2–4cm from the target site. When using the MicroMyst® Applicator move tip back and forth during application to improve mixing of solutions.

Extended Tip Applicator:

When attaching a spray tip to the Extended Tip Applicator, gently twist the spray tip onto the applicator so that the treads engage cleanly. Use strong even pressure with non air-assisted applicators.

MicroMyst® Applicator:

When using the MicroMyst® Applicator move tip back and forth during application to improve mixing of solutions.

Integra®

DuraSeal® Dural Sealant System for cranial surgery

Ordering Information

For EUROPE, MIDDLE-EAST and AFRICA

| Reference | Description | Quantity | Availability |
|-----------|---------------------------------------|------------|--|
| DSD5001 | DuraSeal® dural sealant system - 5mL | 1kit/box | All EUROPE, MIDDLE-EAST and AFRICA countries |
| DS-D-5005 | DuraSeal® dural sealant system - 5mL | 5kits/box | |
| 205108 | Extended Tip Applicator - 8cm length | 5kits/box | |
| 205115 | Extended Tip Applicator - 15cm length | 5kits/box | |
| 20-5000** | MicroMyst® Applicator - 14cm length | 5kits/box | |
| FR-6065 | Flow Regulator | 1 unit/box | |

For LATIN AMERICA, ASIA PACIFIC and CANADA

| Reference | Description | Quantity | Availability |
|-----------|--|------------|---|
| DSD5001 | DuraSeal® dural sealant system - 5mL | 1kit/box | LATIN AMERICA and ASIA PACIFIC countries* |
| DS-D-5005 | DuraSeal® dural sealant system - 5mL | 5kits/box | LATIN AMERICA and ASIA PACIFIC countries* |
| 20-2010 | DuraSeal® dural sealant system - 5mL - NOT CE MARKED | 1kit/box | LATIN AMERICA and ASIA PACIFIC countries* |
| 20-2050 | DuraSeal® dural sealant system - 5mL - NOT CE MARKED | 5kits/box | LATIN AMERICA and ASIA PACIFIC countries* |
| 209001 | DuraSeal® dural sealant system - 5mL - NOT CE MARKED | 1kit/box | Canada ONLY |
| 20-9005 | DuraSeal® dural sealant system - 5mL - NOT CE MARKED | 5kits/box | Canada ONLY |
| JDS5001 | DuraSeal® dural sealant system - 5mL - NOT CE MARKED | 1kit/box | Japan ONLY |
| JDS5001 | DuraSeal® dural sealant system - 5mL - NOT CE MARKED | 5kits/box | Japan ONLY |
| 205108 | Extended Tip Applicator - 8cm length | 5kits/box | LATIN AMERICA, ASIA PACIFIC countries* and CANADA |
| 205115 | Extended Tip Applicator - 15cm length | 5kits/box | LATIN AMERICA, ASIA PACIFIC countries* and CANADA |
| 20-5000** | MicroMyst® Applicator - 14cm length | 5kits/box | LATIN AMERICA, ASIA PACIFIC countries* and CANADA |
| FR-6065 | Flow Regulator | 1 unit/box | LATIN AMERICA, ASIA PACIFIC countries* and CANADA |

* Not all products are available in all regions. Please check the specific reorder number to determine which product is available in your region. For all the medical devices specially identified as "NOT CE MARKED", please refer to the appropriate Instruction for use: the indications and contraindications of the product may be different as the ones mentioned on this document for CE MARKED medical devices.

** MicroMyst® Applicator requires an air source to operate – used in conjunction with the Flow Regulator.

Indications:

The **DuraSeal® dural sealant system** is intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure.

The **Extended Tip Applicator** is intended for use in the simultaneous delivery of two non-homogenous solutions onto a surgical site.

The **MicroMyst® Applicator** is intended for use in the delivery of two non-homogenous solutions onto a surgical site.

The **Flow Regulator** is intended to provide pressurized gas (air or nitrogen) to gas-assisted applicators.

Contraindications:

Do not apply the **DuraSeal® Dural Sealant** in abdominopelvic surgical procedures for use as a sealant or adhesion barrier.

Do not use **Extended Tip Applicator**, **MicroMyst® Applicator** and **Flow Regulator** for other indications than ones provided in the instructions for use.

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Contact - Product Ordering

integralife.eu/duraseal-order/

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Please read carefully the instructions for use.
- Non contractual document. Integra reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

Additional information for EMEA Customers only:

Products mentioned in this document are CE class IIa and III devices. Please contact Integra customer service should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED". Integra and the Integra logo are registered trademarks of Integra Lifesciences Corporation in the United States and/or other countries. DuraSeal and MicroMyst are registered trademarks of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries.

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