

# **DuraSeal™**

## **Post-Approval Study Update**

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# DuraSeal™

- P040034
- Pre-Market Study Protocol
  - Prospective, multi-center, non-randomized single arm study
  - 11 sites
  - Primary endpoint was success rate of intraoperative CSF leak repair following device use
  - Safety endpoints were CSF leak, including post-operative pseudomeningocele, and infection

# Pre-Market Study Results

- 111 subjects enrolled
- Primary endpoint success = 98.2%
  - Two patients tested improperly
- Incidence of post-op CSF leak = 4.5%
  - Incisional Leak = 1.8%
  - Pseudomeningocele = 2.7%
- Infection rate = 8.1%
  - Deep Infection 7.2%

# Advisory Panel Summary

- November 30, 2004
- Concerns discussed
  - Infection rate
  - Lack of concurrent control
- Vote of 7 to 2 for approval
- Panel recommended
  - PAS to investigate infection rate
  - Sponsor should provide MRI/CT data
  - Proposed labeling

# Approval Information

- Date of Approval – April 7<sup>th</sup>, 2005
- Indications for Use Statement
  - The DuraSeal Dural Sealant System is intended for use as an adjunct to sutured dural repair during cranial surgery to provide watertight closure. DuraSeal should only be used with autologous duraplasty material.

# PAS Protocol Summary

- Objectives
  - to evaluate the infection rate and CSF leak rates
- Trial Design
  - Prospective, randomized, single-blind, double-arm, multi-center study
  - Patients randomized to receive DuraSeal or Standard of Care
- Patients scheduled for clean elective cranial surgeries with primary dural closure or closure with autograft
- Inclusion of only patients with intraoperative CSF leak

# PAS Protocol Summary (cont.)

- Primary Endpoint
  - Incidence of neurosurgical complications related to unplanned intervention or return to OR
- Secondary Endpoints
  - Surgical site infection rates
  - CSF leak rates
- 250 patients and 25 sites

# PAS Protocol Summary (cont.)

- Patients will be followed for 30 days after treatment
- Estimated duration of study = 24 months

# Enrollment Status

- First patient enrolled on September 12<sup>th</sup>, 2005
- Number of Sites: 16
- Patients Enrolled: 101 (50 DuraSeal, 51 Control)
- 39 patients in each group completed 30-day follow-up

# Summary of PAS interim results

<b>Complication</b>	<b>DuraSeal (n=39)</b>	<b>Control (n=39)</b>
CSF Leak	0	2
Surgical Site Infection	1	1
Poor wound healing	1	0
Return to OR	1	0



# Post-approval MDRs

- Five (5) reports from MAUDE database since PMA approval
  - One case of infection following use of DuraSeal
  - One case of possible device swelling (used with non-autologous duraplasty)
  - One case of device use in spine
  - Two cases of adverse reaction when applied near facial nerve

# Major Literature Review

- PubMed search with keyword “DuraSeal”
- 1 Relevant study (Kacher, et al.)
  - Characterization of DuraSeal in Canine model using MRI and CT
  - 3 days to 10 weeks
  - Hydrogel apparent up to 6 weeks post-op
  - Able to discern hydrogel from CSF pseudomeningocele using some MRI sequences

Kacher DF, et al. DuraSeal magnetic resonance and computed tomography imaging: Evaluation in a canine craniotomy model. *Neurosurgery* 58(S1):140-7,2006.