

**Urology: Pelvic Sling Material Supply**  
 Phillips Summika - Marlex HGX-030-01 (PP)  
 Boston Scientific

**History**

**2005 – Initial Identification of Supply Interruption**

- Phillips Summika terminates BSC contract for Marlex HGX-030-01, for use in permanent implant device.
- Contract allows last-time buy of 40K lbs.; BSC purchased 4K (10-yr supply)
- BSC Product Affected: Urology Pelvic Sling
- Revenue @ Risk: \$100M Annually

**2006-2010 – Production/PD Activity**

- Initial discussions with new supplier (Borealis) positive
- Increase in forecast and NPD consumes resin at faster rate than planned
- Stock-out date moves in from 2015 to mid-2013
- In late 2010, Borealis reconsiders and will not sell to BSC for use in permanent implant.

**Accomplishments**

- Global Sourcing negotiated with distributor in China to hold additional 30K lbs. until BSC completed initial testing.
- Equivalency testing completed in November; Biocompatibility due February 2012. Team is 90% confident material will be approved.
- Profax (LyondellBasell) has been identified as alternate. Based on Marlex test results, PIB will revisit need to validate an alternate. Currency on HOLD.

**Expect to mitigate potential BO completely**  
 (34K lbs. = 25+ yr. supply)

- Stand-alone BSC Indemnification/Insurance Agreement developed specifically addressing resin manufacturer's concern for use in implants. Additional tool for future negotiations.

**Actions**

- Early 2011, Phillips Summika confirms product line discontinued in 2008 timeframe; and declines request for special BSC run due to issue's with reactor. They eventually close domestic PP plant entirely at year-end.
- Global Sourcing locates potential Marlex sources in China; makes on-site visits; confers with R&D and makes initial 4K purchase of material to test.
- In parallel, R&D continues search for alternate material; works closely with Ludion, the original fiber manufacturer.
- Team from Global Sourcing and Legal initiate discussions on how to mitigate supplier concerns regarding use in implantable devices.

**Lesson's Learned**

- Increased vigilance required in monitoring consumption of last-time buy volumes. This includes the cessation of NPD with identified material - PD/Division/Site Procurement
- Earlier validation of alternate materials required, even when strategic buys are made – PD
- The need to continue engagement directly with resin manufacturer's to build relationships and mitigate supply issue's has become increasingly important, and has been built into Resin Commodity Strategy – Global Sourcing

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