

Urology: Pelvic Sling Material Supply

Phillips-Sumika: Marlex HGX-030-01 (PP)

November 2011 Update

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. Currently 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 Luxilon, 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