

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

| | |
|---|---|
| ----- | X |
| IN RE ETHICON, INC., PELVIC REPAIR | : |
| SYSTEM PRODUCTS LIABILITY | : |
| LITIGATION | : |
| ----- | : |
| | : |
| This Document Applies To All Actions | : |
| ----- | : |
| | X |

PLAINTIFFS' NOTICE OF SUPPLEMENT TO

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR
A FINDING OF SPOLIATION AND FOR SANCTIONS**

for the entire TVT line of products in their official 30b6 response.¹ Despite Mr. Clay's key position related to this litigation, and his selection by Defendants as the most knowledgeable of regulatory personnel, Defendants have produced no custodial file for Mr. Clay at all, and have indicated that none exists.²

- **Kendra Munchel** Global Marketing Manager, 2005-07: Ms. Munchel was also a manager of professional education from 2002-05. She was a member of the "core teams" for professional education for both the TVT-O and Prolift launches. Defendants have inexplicably produced no custodial file at all for Ms. Munchel, and have indicated that none exists.

- **Tom Divilio**, Director, Medical Affairs, from 1997 through 12-31-2009: Though they are undoubtedly only a fraction of the internal correspondence in which he was involved, hundreds of e-mails uncovered in other files establish that Mr. Divilio was heavily involved in TVT projects. Once again, Defendants have produced no custodial file at all for this key executive, and have stated that production of his custodial file is complete, and no responsive documents were identified.³

- **Amy Godwin**, Clinical Development, 2000-recent years: The fact that Ms. Godwin served as the Manager of Clinical Studies, was promoted to Associate Director of Clinical Development in 2004 and ultimately became Director of Clinical Trial Operations in 2007 makes the total of zero documents in her custodial file untenable, especially since a search of her name reveals her involvement in over 4,000 documents indicating she had substantial

¹ February 26, 2013, Response to Topics 1 and 4 (Regulatory Affairs 30(b)(6) notice (Exhibit 1).

² December 17, 2013, Email from William Gage to Bryan Aylstock, et al. Subject: Pelvic Mesh Custodial Production Summaries (Exhibit 2).

³ See Exhibit 2.

involvement in the clinical affairs of the TVT line. Again, Defendants have confirmed that production of her custodial file is complete, yet there is no custodial file for Ms. Godwin.⁴

- **Susan Landgrebe**, 2005-present or recent time: She worked on the matrix materials project and is actually named on the Patent for the TVT-Secur. It is thus implausible that her custodial file, which Defendants claim has been fully produced,⁵ consists of 75 documents totaling 543 pages.

- **Zenobia Walji**, Worldwide Director, Strategic Planning, 2009-12: She has been with Johnson and Johnson since 1988 and worked her way up in the Ethicon/Gynecare franchise to the position of marketing director from 2000 to 2004, where she oversaw the “vision and launch” of a pelvic floor platform in Gynecare (a division of Ethicon), a “\$200M adjacent business.”⁶ Her CV states that she developed short term operational and seven year strategic plans for core businesses.⁷ From 2004 to 2005, she served as Director, Strategic Marketing, and was heavily involved in the global launch of Ethicon’s Prolift product. Defendants’ claim her custodial file has been fully produced.⁸ Perhaps the few hundred documents (including all emails from her numerous years at the company) that appear in that file might not seem quite so suspect were it not for the fact that nearly 7,000 documents produced to date contain her name. Indeed, in her case, there can be no doubt that key documents are clearly missing, including prior and subsequent versions of the Global Launch Plan for Prolift.⁹ Moreover, where are her short term operational or seven year strategic plans for any of the pelvic floor products? Ms. Walji has since moved to the Far East and Ethicon has not produced her for a deposition in the TVT

⁴ See Exhibit 2.

⁵ See Exhibit 2.

⁶ See Zenobia Walji - Summary of Qualifications (CV) (Exhibit 3); Note - TVT-O was launched in 2003 and early 2004

⁷ *Id.*

⁸ See Exhibit 2.

⁹ ETH.MESH.00633750-789 (Exhibit 4).

cases despite a request to do so.¹⁰ Clearly key documents that at one time existed in Ms. Walji's filed have been lost or destroyed by Ethicon despite the litigation hold that was in effect during these key times of her employment with Ethicon/JNJ.

- **Nancy Leclair**, Director, Marketing Services, 2000-11. The fact that she held the highest position in marketing services and has been at the company for upwards of 12 years makes the custodial file of 189 documents totaling 1,633 pages, that Defendants say constitutes full production,¹¹ unacceptable. That is especially true given that she was copied on over a thousand e-mails that appear in other custodial files but not hers.

The spoliation inherent in production of these skeletal custodial files is in addition to the more than a dozen files discussed in Plaintiffs' original memorandum.

2. The sheer magnitude of the spoliation belies any claim that the custodial files can be recreated by Plaintiffs.

Defendants have hinted to Plaintiffs that they may actually argue that the fact that some of these executives' documents have been found in other files means Plaintiffs have no business complaining. Plaintiffs, the argument goes, should have just laid out all the documents, matched names as best they could and put the pieces of each custodial file together like a jigsaw puzzle. This contention is flawed on so many levels. First, this was most certainly not Plaintiffs' burden; it was Defendant's. There is no discovery rule that authorizes Defendants to ignore document requests and merely produce whatever custodial files it can locate. Moreover, given the magnitude of spoliation of documents, with custodians ranging from the President and Vice President of Ethicon, to key clinical, marketing, regulatory, and professional education

¹⁰ June 5, 2013 Email from Mary Ellen Scalera to Jeffrey Grand, et al. Subject: In re Pelvic Mesh – NJ Deposition Scheduling (Exhibit 5).

¹¹ See Exhibit 2.

personnel, the amount of relevant information being withheld from the plaintiffs in this case is nothing short of astounding.

Further, and most importantly, the information is not something that can simply be recreated by finding documents in another custodial file. This is true for multiple reasons. Initially, this method of attempting to “recreate” a custodial file could realistically encompass missing e-mail only. That is, only e-mails or other internal correspondence might appear in other custodial files. Documents that an executive created himself or that weren’t attached to e-mail will not appear in other files. Second, the argument presupposes other custodians whose files were produced were included in the missing e-mails. Thus, e-mails limited to the custodian at issue and third parties or other company personnel whose files were not produced would not show up elsewhere. Finally, but significantly, the argument ignores the huge gaps in multiple custodial files that exist. So many documents are missing from so many files that there are undoubtedly e-mails involving multiple personnel that simply no longer exist (or have been withheld). A custodial file is not like a jigsaw puzzle in that, after piecing together such a file, Plaintiffs have no way of seeing all the pieces that are missing from the middle. For all of the above reasons, and for those set forth in Plaintiff’s original motion, severe and punitive sanctions are clearly warranted in this case.¹²

¹² Compare the abuse here with the conduct that is the subject of Defendants’ motion to dismiss with prejudice the cases of those plaintiffs who were the least bit tardy in filing their plaintiff profile forms where such tardiness visited absolutely no prejudice upon Defendants. In those cases, even when the PPFs were served before Defendants filed their motion to dismiss, Defendants have refused to withdraw its motions or back off its claim for the most severe sanction possible – dismissal with prejudice - against women who claim permanent injury as a result of Defendants’ mesh products. Yet, Defendants’ spoliation has been longstanding, highly prejudicial and the product of at least negligence, if not a deliberate plan.

Dated: December 27, 2013

Respectfully submitted,

/s/ D. Renee Baggett
D. RENEE BAGGETT
BRYAN F. AYLSTOCK
Aylstock, Witkin, Kreis and Overholtz, PLC
17 E. Main Street, Suite 200
Pensacola, FL 32563
P: 850-202-1010
F: 850-916-7449
Rbaggett@awkolaw.com
Baylstock@awkolaw.com

/s/ Thomas P. Cartmell
THOMAS P. CARTMELL
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
P: 816-701-1102
F: 816-531-2372
tcartmell@wcllp.com
<http://www.wagstaffcartmell.com/>

Plaintiffs' Co-Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing memorandum on December 27, 2013, using the Court's CM-ECF filing system, thereby sending of the filing to all counsel of record for this matter.

/s/ D. Renee Baggett

EXHIBIT 1

RESPONSE TO TOPICS 1 AND 4

(Regulatory Affairs 30(b)(6) Notice)

I. Vice President of Regulatory Affairs:

- A. John Paulson (1997-2000)
- B. Catherine Beath (2000-2012)
- C. Lynn Pawelski (2012-2013)

II. Regulatory Affairs Director:

- A. Greg Jones (1996-12/2003)
- B. Cindy Crosby (2004-6/2005)
- C. Jennifer Paine (7/2005-2009)
- D. Brian Lisa (2009-2010)
- E. Brian Kanerviko (2011-2012)

III. Regulatory Affairs Associates with Principal Responsibility for TVT Line:

- A. Peter Cecchini (RA Fellow in 1997 assisted on the 510(k) submission for TVT)
- B. Karen Lessig (Sr. Project Manager, RA, 1999-2003, project leader of TVT-AA and assisted in the submission of 510(k))
- C. Sean O'Bryan (Sr. Project Manager, RA, 2003-3/2005 responsible for TVT-O 510(k) submission)
- D. Patricia Hojnoski (Sr. Project Manager, RA, 3/2005-4/2006 responsible for TVT-Secur 510(k) submission)
- E. John Clay (Manager, RA, 2006-2007)
- F. Kristina Laguna (Manager, RA 2008)
- G. Susan Lin (Manager, RA, 2009-3/2011 responsible for TVT Exact and TVT Abbrevio 510(k) submissions)

H. Laura Vellucci (RA Fellow, 4/2011-current)

EXHIBIT 2

Andrew N. Faes

From: William Gage <William.Gage@butlersnow.com>
Sent: Tuesday, December 17, 2013 1:32 PM
To: 'Bryan Aylstock'; Tom P. Cartmell; Renee Baggett; Daniel Thornburgh (DThornburgh@awkolaw.com); Betsy Williams (BWilliams@awkolaw.com); Andrew N. Faes; Ben Anderson
Cc: Christy Jones; Donna Jacobs; Ben Watson; 'David Thomas'
Subject: Pelvic Mesh Custodial Production Summaries
Attachments: Pelvic Mesh Custodial Production Summaries.pdf

Bryan,

This is in response to Andrew's December 4, 2013, letter regarding custodial files for 16 custodians. It is also in response to your December 2, 2013, e-mail to Ben Watson regarding depositions for two of the custodians identified in Andrew's letter.

For many of the custodians at issue, the questions raised are addressed by charts we previously sent to plaintiffs. I am attaching them for your reference and in response to your inquiry, with respect to the ones not covered, I have asked for an additional chart to be prepared in the same format, which I am also attaching. Together, I believe these charts address all of Andrew's inquiries.

We note that David Stoloff was last collected in January 2013, as he is not a custodian who was designated to be supplemented on a six month cycle pursuant to the list we previously provided to plaintiffs. Please let us know if plaintiffs are now requesting a supplementation of his file. If so, I understand that we will need approximately 45 days to collect and supplement.

As to Bryan's request for depositions of Barbara Schuldt and Christopher Walker, we note that neither of these individuals were on plaintiffs' comprehensive list of depositions circulated earlier this Fall. While I understand that Walther's pelvic mesh documents will be produced later this months, we have only recently obtained Barbara Schuldt's authorization and are in the process of scheduling her collection. It is unlikely that her documents will be produced before the end of January, although I have asked that best efforts be made to collect and produce her documents as quickly as possible, taking into account other production

demands. We suggest that both these depositions be put off until after the Lewis trial and we will work with you to schedule them in due course.

Thanks, William

William M. Gage

Butler Snow LLP
Direct: (601) 985-4561
Fax: (601) 985-4500
William.Gage@butlersnow.com

BUTLER | SNOW

About Butler Snow

Bio

V-Card

P.O. Box 6010
Ridgeland, MS 39158-6010

Suite 1400
1020 Highland Colony Parkway
Ridgeland, MS 39157

CONFIDENTIALITY NOTE: This e-mail and any attachments may be confidential and protected by legal privilege. If you are not the intended recipient, be aware that any disclosure, copying, distribution or use of the e-mail or any attachment is prohibited. If you have received this e-mail in error, please notify us immediately by replying to the sender and deleting this copy and the reply from your system. Thank you for your cooperation.

CIRCULAR 230 DISCLOSURE: Pursuant to Treasury guidelines, any federal tax advice contained in this communication, or any attachment, does not constitute a formal tax opinion. Accordingly, any federal tax advice contained in this communication, or any attachment, is not intended or written to be used, and cannot be used, by you or any other recipient for the purpose of avoiding penalties that may be asserted by the Internal Revenue Service.

**CUSTODIANS IDENTIFIED IN DECEMBER 04
CORRESPONDENCE FROM A. FAES^{*}**

| Custodian | Custodial File Updated as of | Status of Production¹ |
|----------------------|-------------------------------------|---|
| Divilio, Tom | separation | complete ² |
| Harm, Michael | separation | to be completed as of 01/31/14 |
| Librojo, Rey | N/A | to be completed as of 01/31/14 |
| Linsky, Cary | separation | complete ² |
| Riedley, Charles | w/n last 6 mos. | to be completed as of 12/31/13 |
| Schuldt, Barbara | scheduled | to be completed as of 01/31/14 |
| Selley, Nicole | separation | to be completed as of 12/31/13 |
| Stoloff, David | Jan. 2013 | to be completed as of 12/31/13 |
| Thomas, Tiffany | w/n last 6 mos. | to be completed as of 12/31/13 |
| Vasquez, Domingo | w/n last 6 mos. | to be completed as of 12/31/13 |
| Walther, Christopher | w/n last 6 mos. | to be completed as of 12/31/13 |

^{*} Not already identified on the September Depo, Post-September Depo or Other Custodian charts.

¹ "Complete" means that Ethicon is presently not aware of additional responsive documents to be produced. However, as a result of resolution of technical exceptions, possible privilege downgrades, additional filter terms that may be agreed to, and searches described in the hernia mesh stipulation, additional documents may still be produced for these custodians as they become identified.

² No documents were identified.

**OTHER CUSTODIANS IDENTIFIED IN AUGUST 30
CORRESPONDENCE FROM B. AYLSTOCK**

| Custodian | Custodial File Updated as of | Status of Production¹ |
|--------------------|-------------------------------------|---|
| Barendse, Stevan | separation | complete |
| Bennett, Jeffrey | w/n last 6 mos. | complete |
| Busch, Sean | separation | complete |
| Butler, General | w/n last 6 mos. | to be completed as of 09/30 |
| Chaves, Melissa | transfer | complete |
| Clay, John | separation | complete ² |
| Courts, Paul | w/n last 6 mos. | complete |
| Crawford, Richard | transfer | complete |
| Cronan, Juli | w/n last 6 mos. | to be completed by 09/16 |
| D'Aversa, Margaret | Jun. 2011 | complete |
| David, Elizabeth | w/n last 6 mos. | complete |
| Day, Diana | separation | complete |
| Doane, Peter | w/n last 6 mos. | to be completed by 09/30 |
| Dodd, Sheri | separation | complete |
| Duncan, Katherine | separation | complete |
| Dunning, R Scott | w/n last 6 mos. | complete |
| Elbert, Katrin | w/n last 6 mos. | to be completed by 09/30 |
| Esau, Christen | separation | complete |
| Fights, Mark | separation | complete |
| Gallagher, Matthew | separation | complete |
| Globerman, Eric | separation | complete |
| Godwin, Amy | transfer | complete ² |
| Hamby, Jessica | separation | complete |
| Heckman, Brian | separation | complete |
| Heitzmann, Barbara | N/A | newly-identified by plaintiffs |

¹ "Complete" means that Ethicon is presently not aware of additional responsive documents to be produced. However, as a result of resolution of technical exceptions, possible privilege downgrades, additional filter terms that may be agreed to, and searches described in the hernia mesh stipulation, additional documents may still be produced for these custodians as they become identified.

² No documents were identified.

IN RE: PELVIC MESH LITIGATION

| Custodian | Custodial File Updated as of | Status of Production ¹ |
|---------------------|------------------------------|-----------------------------------|
| Hutchinson, Richard | Nov. 2011 | complete |
| Johnson, Kevin | separation | complete |
| Johnson, Matthew | Jul. 2012 | complete |
| Kajy, Mark | w/n last 6 mos. | complete |
| Kelly, Susan | separation | complete |
| Kerl, Brad | w/n last 6 mos. | complete |
| Kisner, Heather | separation | complete |
| Landgrebe, Susanne | w/n last 6 mos. | to be completed by 09/16 |
| Langen, Brian | transfer | complete |
| LeClair, Nancy | separation | to be completed by 09/16 |
| Lisa, Bryan | transfer | complete |
| Martin, Samantha | separation | complete |
| Meyer, Stacy | N/A | newly-identified by plaintiffs |
| Miller, Douglas | separation | complete |
| Mohler, Troy | separation | complete |
| Mooney, Mark | Feb. 2013 | to be completed by 09/30 |
| Munchel, Kendra | separation | complete ² |
| Oldelehr, Marcus | separation | complete |
| Phillips, James | N/A | newly-identified by plaintiffs |
| Pompilio, Sandra | separation | complete |
| Prefer, Scott | Apr. 2012 | complete |
| Remoll, Adam | separation | complete |
| Ricicki, Patricia | Jun. 2012 | complete |
| Sanford, Thomas | Apr. 2012 | complete |
| Schwarz, Chad | separation | complete |
| Shah, David | Apr. 2012 | complete |
| Shellhammer, Jay | separation | complete |
| Shen, Peter | Apr. 2012 | to be completed by 09/16 |
| Smith, Ashley | transfer | to be completed by 09/16 |
| Steele, Joseph | separation | to be completed by 09/30 |
| Storozuk, Thomas | separation | complete |
| Taveroni, Lauren | separation | to be completed by 09/16 |
| Vallecillo, Cesar | separation | complete |

IN RE: PELVIC MESH LITIGATION

| Custodian | Custodial File Updated as of | Status of Production¹ |
|------------------------|-------------------------------------|---|
| Viana, Euzebio ("Zeb") | Jun. 2012 | complete |
| Walji, Zenobia | transfer | complete |
| Warren, Jennifer | transfer | complete |
| Wess, Alyson | w/n last 6 mos. | to be completed by 09/16 |
| Wilson, David | Apr. 2012 | complete |
| Wingard, Michael | separation | complete |
| Wohlert, Stephen | separation | complete |

**CUSTODIANS SCHEDULED FOR DEPOSITION
AFTER SEPTEMBER or NOT YET SCHEDULED**

| Custodian | Custodial File Updated as of | Status of Production¹ |
|----------------------------------|-------------------------------------|---|
| Bagalio, Sheryl | separation | complete ² |
| Barbolt, Thomas | Separation | complete ³ |
| Borkes, Gary | w/n last 6 mos. | complete |
| Cecchini, Peter | w/n last 6 mos. | complete |
| Chen, Meng | w/n last 6 mos. | to be completed by 09/16 |
| DeLacroix, Bruno | N/A | newly-identified by plaintiffs |
| Gauld, Judi | Nov. 2012 | complete |
| Guidry, Cyrus | Feb. 2013 | complete |
| Harm, Michael | N/A | newly-identified by plaintiffs |
| Hinoul, Piet (depo continuation) | w/n last 6 mos. | to be completed by 10/15 |
| Jacobs, Ed | Dec. 2011 | complete |
| Kaminski, Marianne | separation | complete |
| Kammerer, Gene | separation | complete |
| Kirkemo, Aaron | separation | complete |
| Landgrebe, Susan | w/n last 6 mos. | to be completed by 09/16 |
| McCabe, Barbara | w/n last 6 mos. | complete |
| Medina, Marjorie | w/n last 6 mos. | complete |
| Munchel, Kendra | separation | complete ² |
| Patire-Singer, Wanda | N/A | newly-identified by plaintiffs |
| Savidge, Sandy | w/n last 6 mos. | to be completed by 10/15 |
| Schiaparel, Jill | separation | complete ² |
| Smith, Dan (depo continuation) | Nov. 2012 | complete |
| Vazquez, Angel | w/n last 6 mos. | complete |
| Weisman, Harlan | separation | complete |

¹ "Complete" means that Ethicon is presently not aware of additional responsive documents to be produced. However, as a result of resolution of technical exceptions, possible privilege downgrades, additional filter terms that may be agreed to, and searches described in the hernia mesh stipulation, additional documents may still be produced for these custodians as they become identified.

² No documents were identified.

³ Upon his separation, Mr. Barbolt left custodial documents with James Oldham, from whom they were collected.

CUSTODIANS SCHEDULED FOR DEPOSITION IN SEPTEMBER

| Custodian | Custodial File Updated as of | Status of Production ¹ |
|------------------------------------|------------------------------|--|
| Angelini, Laura | w/n last 6 mos. | to be substantially completed on 9/16 ² |
| Arnaud, Axel (depo continuation) | Nov. 2012 | complete |
| Brennan, Carolyn | Aug. 2013 | to be completed on 9/16 ³ |
| Brown, Allison London | separation | complete ⁴ |
| Crosby, Cindy | w/n last 6 mos. | complete |
| Godwin, Amy | transfer | complete ⁴ |
| Hart, James | w/n last 6 mos. | to be substantially completed on 9/16 ² |
| Hellhammer, Brigitte | separation | complete |
| Isenberg, Richard | separation | complete ⁴ |
| Lamont, Dan (depo continuation) | Nov. 2012 | complete |
| Robinson, Dave (depo continuation) | transfer | complete |
| Trzewik, Jurgen | w/n last 6 mos. | complete |

¹ "Complete" means that Ethicon is presently not aware of additional responsive documents to be produced. However, as a result of resolution of technical exceptions, possible privilege downgrades, additional filter terms that may be agreed to, and searches described in the hernia mesh stipulation, additional documents may still be produced for these custodians as they become identified.

² Hard drives were not available for supplemental collection until recently. Responsive documents, if any from these hard drive supplementations are expected to be produced early to mid-October.

³ Ms. Brennan is presently updated and complete through June 2011. Her supplemental collection was conducted in August 2013, shortly after plaintiffs identified her as a deponent.

⁴ No documents were identified.

EXHIBIT 3

ZENOBIA WALJI

Dynamic and proven **Global Healthcare Leader** with extensive medical device and market development experience including new market assessment, strategy, and product development.

GLOBAL BUSINESS • TALENT DEVELOPMENT • GROWTH PLATFORMS • LEADERSHIP

SUMMARY OF QUALIFICATIONS

- Results oriented leader adept at building both U.S. and worldwide businesses.
 - Over 15 years of International market and business development experience in Europe and Asia-Pacific.
 - Upstream and downstream marketing and market development experience.
 - Unique ability to identify and develop talent, having built high performance teams across global markets.
 - Proven ability to build cross functional and cross cultural relationships to create sustainable business value.
-

CAREER ACHIEVEMENTS/SKILLS

- **Broad-based global healthcare experience with strong strategic and tactical expertise in:**
 - **Market Development** – Functional expertise in Marketing, Sales and General Management to build new (\$100 M), mid-sized (\$500 M) and large (\$1 B) medical device businesses.
 - **Product and Business Creation** – Designed, developed, and established growth platforms involving new products, procedures, and business adjacencies for new start-ups, mid-sized, and large medical device businesses within Johnson & Johnson.
 - **Strategic Planning** – Developed short-term operational and seven-year strategic plans for core businesses as well as White Space areas. Strategic assessments included high and low-end competitive disruption, new market and business model innovation as well as scenario planning.
 - **Leadership of cross-functional teams to secure Board-level investments and deliver Growth:**
 - 2011: Predictive view of competitive landscape for building the new Business Transformation plans
 - 2009: Minimally Invasive Surgery Scenario Analysis of market and competitive disruption.
 - 2007: Creation of an emerging market strategy and plan for China and India: 4x growth in 3 years
 - 2006: Vision and launch of an “Asia-Pacific Regional Hub” for Ethicon Endo-Surgery: 3x in 4 years
 - 2003: Vision and launch of a “Pelvic Floor” Platform in GYNECARE: \$200M of adjacent business
 - 1998: Vision and launch of a “Women’s Health” franchise in Australia and New Zealand. \$10+ M
 - 1995: Business re-engineering of the Singapore market to establish corporate account structure.
 - 1990: Partnership with McKinsey & Co. on laparoscopic business assessment for Asia-Pacific.
 - **Achieved world class results as Executive Director-Asia-Pacific** with the creation of an Asia-Pacific Regional Hub that grew from a U.S. \$360 million to \$1 billion business in four years:
 - Built the vision and defined the critical capability for a sustainable \$1 billion business.
 - Partnered with key opinion leaders and leading hospitals to establish world class surgical training and advisory boards.
 - Established clinical sales and marketing training to accelerate the development of Asian talent.
 - **Professional Awards:** Recipient of Johnson & Johnson Standards of Leadership and Encore Awards; ten awards granted from 2002 to 2011 including Asia-Pacific’s “One-To-Win” Award for Business Excellence in 2008 and 2009, and the Medical Device Design Award in 2006.
 - **Multilingual:** Fluent in English, French, Urdu, and Kutchi.
-



PROFESSIONAL EXPERIENCE

THE JOHNSON AND JOHNSON FAMILY OF COMPANIES, MEDICAL DEVICE FRANCHISES

1988 - PRESENT

ETHICON ENDO-SURGERY, INC., CINCINNATI, OHIO

2005-Present

Manufacturer of advanced medical devices for minimally invasive and open surgical procedures.

DIRECTOR, WORLDWIDE STRATEGIC PLANNING

2009-Present

- Excels in business strategy development by facilitating global forums for strategy dialogue and insights; leverage of Disruptive Innovation frameworks and analytics have been foundational for developing predictive views of the market.
- Scenario planning combined with risk-opportunity modeling has helped to direct strategic investments in new business and white space areas.
- Strategic plan development includes seven-year financials with full P&L.

EXECUTIVE DIRECTOR, ASIA-PACIFIC

2005-2009

- Spearheaded the creation and implementation of the "Asia-Pacific Regional Hub" building critical skills, competencies, and processes in support of \$1 billion business; key focus on maximizing new product launch impact and accelerating the growth of emerging markets.
- Led the recruitment and development of the Regional Marketing team supporting the 15 countries of Asia-Pacific; business process and capability development resulted in delivering revenues two years ahead of the strategic plan forecast achieving the highest global growth for four consecutive years.
- Other key initiatives included building a product and talent pipeline for sustainable growth.

GYNECARE WORLDWIDE, SOMERVILLE, NEW JERSEY

2000-2005

A division of Ethicon offering minimally invasive treatment options for a variety of gynecologic conditions.

DIRECTOR, STRATEGIC MARKETING

2004-2005

- Established long term growth initiatives via new technology assessments and market development; lead two due diligence teams to evaluate White Space opportunities in new platform areas.
- Instrumental to the development and global launch of the new Pelvic Floor platform.

DIRECTOR, MARKETING

2000-2004

- Developed and directed new product pipeline and process improvement strategies resulting in the launch of seven new products in four years and double digit annual growth; 41% in 2000 and 2001, 37% in 2002, and 22% in 2003 and named the fastest growth medical device and diagnostics company in 2002.
- Defined marketing capability requirements for the newly established U.S. marketing organization; recruited, trained, and supervised six Product Marketing Managers.

JOHNSON AND JOHNSON MEDICAL, AUSTRALIA AND NEW ZEALAND

1998-2000

GROUP MARKETING MANAGER – WOMEN'S HEALTH, CODMAN, AND MITEK

1999-2000

- Successfully established a Women's Health franchise combining BIOPSYS and GYNECARE; met first year sales goal, and exceeded second year business plan by \$1.0 million which enabled the achievement of break-even in year two.
- Mitek Australia achieved recognition as the second largest Mitek business outside of the U.S.
- Pioneered the integration of consumer marketing into the medical device business.

MARKETING MANAGER, ORTHOPAEDICS

1998-1999

- Orchestrated full integration of DePuy into Johnson & Johnson and achieved 15% growth; managed all sales, marketing, customer service, and logistics functions.

ADDITIONAL EXPERIENCE

- Division Director, Johnson & Johnson Medical, Singapore, 1994-1998.
- Regional Market Development Manager, Johnson & Johnson Medical, Asia-Pacific, 1994-1995.
- Marketing Manager, Ethicon Endo Surgery, Singapore, Indonesia and Malaysia, 1992-1994.
- Sales Manager, Ethicon Suture franchise, Singapore and Brunei, 1989-1992.
- IRDP Management Trainee, Full Line Ethicon Representative, Las Vegas, Nevada, 1988-1989.

EDUCATION

MASTER OF BUSINESS ADMINISTRATION – INTERNATIONAL MARKETING

PETER DRUCKER GRADUATE MANAGEMENT CENTER

Claremont, California

BACHELOR OF ARTS – EUROPEAN STUDIES AND PHILOSOPHY

CLAREMONT MCKENNA COLLEGE

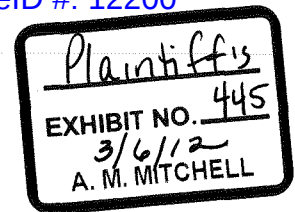
Claremont, California

STUDY ABROAD – THE EXPERIMENT IN INTERNATIONAL LIVING

SCHOOL FOR INTERNATIONAL TRAINING

Toulouse and Paris, France

EXHIBIT 4



From: Mahar, Kevin [ETHUS]
 Sent: Sat, 20 Jun 2009 11:21:52 GMT
 To: Mahar, Kevin [ETHUS] <KMahar@ITS.JNJ.com>
 Subject: FW: Gynecare Prolift: Global launch plan, budget, Gant chart

Importance: High

From: Walji, Zenobia [ETHUS]
 Sent: Friday, September 03, 2004 3:48 PM
 To: Berthier, Ophelie [JNJFR]; Bonet, Giselle [ETHUS]
 Cc: Bell, Steve [ETHIT]; Mahar, Kevin [ETHUS]
 Subject: FW: Gynecare Prolift: Global launch plan, budget, Gant chart
 Importance: High
 Sensitivity: Confidential

Dear Ophelie & Giselle,

This is an excellent first draft! With a desire to get some comments back to you as quickly as possible, I have not tried to "word-smith" anything, but rather focus on the big things. My comments have been made in red in the attached word document for your review. Overall, Ophelie as per our phone conversation, here are some additional points that I think will require additional thought and time:

1) Basis especially where the US is with GYNEMESH PS 2004 sales and with respect to TRUE acceptors of large pieces of mesh for prolaps repair, we have a lot of work to do. Realistically therefore, especially since Pre-launch monies have been allocated, it is important to have a **section of Pre-launch that focuses on WHAT we will do to build more advocates of GYNEMESH PS** - I mean users of large mesh. **This should be separate from the Pre-launch of D'Art.** In reality we need to have both activities to achieve success. This clarity will also help make sure that we have the solid support before we spend too much on D'Art activity pre-maturely....

2) An obvious question that management will be interested in is **HOW we will MEASURE success** of our pre-launch work? Will we have questionnaires? What if only 60% of preceptors who are exposed to D'Art are willing/convinced to start, do we scale back our plans, do we do something different? **Remember you are selling a concept first and then a product. When/How will you know if the market has accepted the concept and is ready for the product?**

3) While there is some cleaning up to do in the overall market model, I think you need to think about a spreadsheet that has units of GYNEMESH PS sold to date, and also separately the number of users of GYNEMESH PS. From there, you should project out how many doctors you must enroll and prepare during Pre-launch and Launch to achieve your forecast numbers...For example, if we are selling @ 500 units a month in August, how much ramp can we expect by year-end, and what will it look like through each month of 2005 for GYNEMESH and separately one line for D'Art... The combined will tell you what forecast **REALISTICALLY** the team is prepared to commit to...Laura has apparently told the Board that US and EU combined for 2005 will be \$3.1-3.5 MM not including GYNEMESH PS. Before there are too many more numbers flying around, the team should agree and be prepared to defend it.

4) Most of my comments are around Positioning and Claims - its important we have a strong and clear statement here.

5) To keep the document crisp, just as you have done with "Clinical Strategy" , you need a title of Regulatory Strategy, Reimbursement Strategy, Communication Strategy (instead of Launch Materials), Promotional Strategy, Convention Strategy (instead of Exhibition strategy) , Manufacturing Strategy (instead of Product Logistics) Ophelie, also a couple items that are missing:

- **Value Proposition** (Physicians, Patients, Payers, Site of Care)... you have Features and Benefits, but it is not the same (I know that work was started on this between Scott and you...)
- **Reimbursement** - Laurent has collected this info, but not sure how complete it is
- **Assumptions** - I have suggested you include that as part of the Forecast section...

I trust this is a good start...I may think of other things and will advise later. Overall, great job and thanks for the solid progress! I'll be in touch to discuss numbers some more once Giselle is back on Tuesday. Tks

Zenobia Walji
Director, Strategic Marketing
GYNECARE WORLDWIDE
Tel - 908-218-2647
Fax - 908-218-3146
e-mail - zwalji2@ethus.jnj.com

-----Original Message-----

From: Berthier, Ophelie [JNJFR]
Sent: Friday, September 03, 2004 10:08 AM
To: Bell, Steve [ETHIT]
Cc: Walji, Zenobia [ETHUS]; Bonet, Giselle [ETHUS]
Subject: Gynecare Prolift: Global launch plan, budget, Gant chart
Sensitivity: Confidential

Steve,

As requested for the conf call of Laura with Et Carino on Monday afternoon, you will find enclosed the drafts of:

Gynecare Prolift Launch Plan

The executive summary needs to be finalized. I prefer to wait for a first feedback before.

Objective-Pelvic Floor Strategy needs to be developed but I preferred to focus on the other items.

Competitive landscape: I will probably develop a part on each key competitor and their products later on. As time was running, I put the info I already knew.

Fastener: as few documents are available on fastener and launch should occur later in 2005, I didn't include the fastener in the plan yet.

Gant chart:

We did a chart with several tab: one for marketing tools, market seeding, Prof Ed, Internal training, Clinicals

Budget:

We built the budget out of the 650K\$ and we will isolate the EU expenses from the US expenses once we have approval on the spendings. We also included 2005 expenses for Global Launch.

A big thank to Giselle who contributed to the realization of all those documents and made me able to send all those drafts today.

Looking forward for your feedback,

Ophélie

Ophélie Berthier
Gynecare Marketing Manager
Phone: (33) 1 55 00 31 99
Mobile (33) 6 64 05 49 13
<mailto:oberthie@inifr.ini.com>

Confidentiality Notice: This e-mail transmission may contain confidential or legally privileged information that is intended only for the individual or entity named in the e-mail address. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or reliance upon the contents of this e-mail is strictly prohibited. If you have received this e-mail transmission in error, please reply to the sender, so that Johnson & Johnson can arrange for proper delivery, and then please delete the message from your Inbox. Thank you.

Confidential Internal Information: Property of Gynecare : Not for Distribution



Global Launch Plan

Draft 2.0 2th September 2004

Contents

| | |
|---|-----------------------------|
| Global Launch Plan | 1 |
| 1. Executive Summary | 3 |
| 2. Objectives and Pelvic Floor Strategy – Gynecare | Erreur ! Signet non défini. |
| 3. Market Overview | 5 |
| 3.1 Market definition | 4 |
| 3.2 Market size | |
| 3.3 Market dynamics | |
| 4. Product overview | |
| 4.1 TVM – Procedural Overview | 8 |
| 4.2 Gynecare Prolift™ Instruments and Implant Overview | 9 |
| 4.3 Key product features and benefits | |
| 5. Product positioning | |
| 6. Targeting | |
| 7. Pricing | |
| 8. Competition Overview | 16 |
| 7.1 Competitive landscape | |
| 7.2 New comers in 2004-2005 | 17 |
| 7.3 AMS rebuttal strategy | |
| 9. Pre launch strategy | |
| 9.1 Customer communication | |
| 9.2 Pre-launch countries involvement and key activities | |
| 9.3 Pre-launch preceptor programme | |
| 10. Launch strategy milestones | |
| 10.1 Product availability | |
| 10.2 Pre-launch/launch activities | |
| 11. Professional Education | 22 |
| 11.1 Internal | |
| 11.2 External | |
| 12. Clinical Strategy | 26 |
| 13. Launch Materials | 26 |
| 14. Exhibition Strategy | 27 |
| 15. Product logistics | |
| 15.1 Inventory | |
| 15.2 Forecasts | |
| 15.3 Samples | |

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

| | |
|------------------------------------|----|
| 15.4 Sales Projections | |
| 16. Budget summary/Resources | 29 |
| 16.1 Global launch team budget | |
| 16.2 2005 Local Launch team budget | |
| Appendix | |
| References | |

Prepared by Ophélie Berthier and Grégoire Bonel, 5th of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

1. Executive Summary

The Pelvic Floor platform opportunity worldwide is \$300MM. (Here you should include what the clinical unmet need is and why Pelvic Floor Repair is so important – i.e. high reoccurrence rates, no standard procedures, poor/inconsistent clinical outcomes as the procedures today are very surgeon skill dependent. Then explain what the opportunity is and why this strategically important for GYNECARE and why GYNECARE is well-placed to lead the market in this area) Moreover, sustained leadership in Incontinence requires significant participation in PF market and GYNECARE is well positioned to leverage learning's & relationships from TVT to drive breakthrough results.

To become the leaders in the Pelvic Floor market, speed to market and a portfolio of products are a must.

Strong synergies with existing customer base for TVT, within the segment: Urogynae, Gynae, Urologist.

Market is changing dramatically, there is rapid entry of competitors in this market (SUI market is now starting to become in some countries a commodity market) and there is a new trend of using meshes to treat vaginal prolapse.

Pelvic floor is a growing market.

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

2. Objectives and strategy for Pelvic Floor Repair

The overall objective is to become the leader and most innovative company in both Incontinence and Pelvic floor procedures.

This means Gynecare is to become the leading company for Pelvic Floor repair offering a broad range of products to meet the customer's needs.

Leadership is defined as:

#1 Unit Market Share

#1 \$ Market Share

The best Quality of professional education, support materials and product

Gynecare is working on a multigenerational product and procedure approach to meet all the needs of the customer.

Today Gynecare provides GYNEMESH PS as a state of the art implant. This allows surgeons to tailor their own personal Graft repair with a shapable inert, soft implant with PROLENE at the core.

Prepared by Ophélie Berthier and Giselle Bonot, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

3. Market Overview

3.1 Market definition

Pelvic organ prolapse is thought to result from a stretching, weakening or tearing of the soft tissue structures that support the pelvic organs.

Risk factors for pelvic organ prolapse include vaginal parity, neuropathy, obesity, excessive, chronic valsalva, connective tissue disorders, prior surgery, estrogen status and advancing age^{iii,iii,iv}. Surgical correction of these problems is a major health care issue for women.

It is estimated that as many as 50% of parous women experience some degree of pelvic organ prolapse during their lifetime. 19MM women in the US and Europe are diagnosed and 1MM (5%) women currently seek treatment.

In addition an analysis of members of a large health maintenance organization estimated the lifetime risk of 11.1% of at least one operation for pelvic organ prolapse and urinary incontinence with a reoperation rate of 29.2%.^v

Non-surgical interventions for prolapse management include pelvic floor exercises and pessary support.

Surgical options are numerous, made more challenging as multiple weakened regions often occur in a patient and incomplete correction of any region may lead to worsening of the other regions. The surgical procedures may involve tightening and reinforcing of weakened tissue, suspension of unsupported structures or a combination of both. The tightening/reinforcing and suspension procedure may utilize several materials including:

- suture alone
- autologous tissue
- cadaveric material
- allograft material
- synthetic permanent mesh.

Worldwide it is estimated over 500,000 procedures are performed for Pelvic Organ Prolapse (POP).

Traditional surgical treatments, with sutures alone are starting to be considered inadequate with published recurrence rates up to 40%. Mesh materials have been used with great success in hernia repair by General surgeons and the Gynaecologic and Urologic communities are starting to utilize them to provide additional support to the pelvic floor where autologous tissues are not adequate, but they do add the risks of erosion and rejection.^{vi} These grafts may be placed using an abdominal or vaginal approach.

Literature reviews describing the outcome and complications associated with pelvic floor repair procedures are inconclusive. In the cases where meshes were used to provide additional support, advantages have been reported. Julian studied patients with multiple recurrence of vaginal prolapse in two groups that differed by mesh use or not. In his study, all grafts were placed using a vaginal approach. He found a decrease in the expected recurrence rate with mesh, but did observe some complications associated with the use of synthetic mesh. The erosion rate was 25%. Overall, he concluded that adding synthetic mesh was effective in these cases.^{vii} Visco reported an overall vaginal mesh erosion rate of 5.5% using an abdominal approach for mesh placement. This rate was considered low when compared to historical data, which shows a 9% erosion rate for abdominal mesh placement.^{viii}

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

The abdominal approach to repair of pelvic organ prolapse uses one of two procedures, the abdominal sacral colpopexy or the abdominal sacral colpoperineopexy. These two procedures have the highest long-term success rates of any surgical procedure for pelvic organ prolapse.^{ix,xv} Both procedures involve enveloping the vaginal vault with a graft material and then attaching the grafts to the anterior longitudinal ligament over the sacrum. These procedures attempt to restore the normal connective tissue support to the vagina by replacing the damaged connective tissue with a graft.

Problems with erosions of permanent mesh placed in the body are not unique to pelvic surgery.^{xii,xiii} Several factors are thought to contribute to mesh erosions including a poor healing environment influenced by nutritional status and blood flow, infections, foreign body reactions, and mesh characteristics such as rigidity and mesh density.

Currently today these procedures are divided between Plication (tissue to tissue suturing) and reinforcement with grafts (cadaveric grafts, autologous grafts, xenografts, animal derived grafts, synthetics). From the surgical procedures standpoint, the market includes:

Cystocele:

Anterior colporrhaphy
Paravaginal repair (vaginal & lap approach)
Graft/mesh procedure

Rectocele

Posterior colporrhaphy
Graft/mesh repair
Vault Suspension
Sacrospinous ligament fixation
Uterosacral ligament fixation
Abdominal sacrocolpopexy
Graft/mesh repair

Enterocele

McCauley culdoplasty

Polypropylene mesh has been the most widely used mesh in gynecologic surgery including many types of pelvic floor repair procedures.^{xiv} Polypropylene meshes include Bard MARLEX Mesh and Ethicon PROLENE Polypropylene Mesh.

To address the market trend to use meshes to repair pelvic organs prolapse, Gynecare introduced in Europe a polypropylene mesh called **GyneMesh** in 1998.

In May 2003, **GYNECARE** introduced in Europe **GyneMesh PS** a second generation of synthetic Mesh indicated for repair or reinforcement and long-term stabilization of the pelvic floor or other defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

GyneMesh PS was launched in the United States in March 2003 as a first generation of synthetic mesh exclusively designed for pelvic floor repair surgery.

GYNECARE GyneMesh Prolene Soft (Polypropylene) Mesh (PSM) is a modified PROLENE Mesh identified as, a reduced density construction PROLENE Polypropylene Mesh. *(need to add data from the 1 year follow up US study)*

Prepared by Ophélie Borthier and Gaëlle Bonnet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

3.2 Market size

US

| Year | 2003 | 2004 | 2005 | 2006 |
|-----------------------|---------|---------|---------|---------|
| Applicable procedures | 242,300 | 252,000 | 262,100 | 272,500 |
| Number grafts sold | 18,500 | 32,300 | 25,700 | 35,400 |
| % Penetration | 7,6% | 12,8% | 9,8% | 12,96% |

These numbers of penetration up and down 2004-2006 need fixing

EU

| Year | 2003 | 2004 | 2005 | 2006 |
|-----------------------|---------|---------|---------|---------|
| Applicable procedures | 208,000 | 216,300 | 225,000 | 234,000 |
| Number grafts sold | 14,600 | 21,600 | 33,300 | 39,800 |
| % Penetration | 7,0% | 10% | 14,8% | 17,0% |

Source: TVM financial model 010701.xls

3.3 Market dynamics

In both the EU and US, techniques for prolapse surgery using meshes have been under development for several years. Key EU countries are at different stages of development with respect to the use of mesh for prolapse repair, but techniques which gain acceptance in one country often spread rapidly to the others.

In the US, the use of synthetic materials for the treatment of prolapse has also been under development for a number of years. KOL opinion's on the use of synthetic materials for prolapse repair are at various stages of development and acceptance. However at this point in time, there are many techniques and products currently being utilized and no clear consensus has been reached on both materials choice and technique.

Current limitations today are high recurrence rates, higher than required erosion rates and non-standardisation of technique making it hard to adopt but the market unmet needs are high.

Gynecare's challenge is to enter the market with a product *and* technique that will allow gynecologists, urogynaecologists, and urologists to perform a quick, efficient, effective (long term reduced recurrence rate, consistent outcomes), safe (low erosion rate) and reproducible procedures for the treatment of these pathologies. It is felt that the GYNECARE Prolift product and technique, supported by the results of the pending clinical study, will address these market needs.

Prepared by Ophélie Herthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

4. Product overview

4.1 TVM – Procedural Overview

The Trans-Vaginal Mesh (called TVM) procedure is the result of the work of a group of 9 french physicians (Dr J. Berrocal, Dr H. Clavé, Dr M. Cosson, Dr P. Debonance, Dr O. Garbin, Pr B. Jacquetin, Dr C. Rosenthal, Dr D. Salet-Lizée, Dr R. Villet) who had extensive experience in pelvic floor repair and the use of mesh through vaginal route, lead by Pr Jacquetin on the initiative of Axel Arnaud. It started in 2000 and every time they were meeting they would go to one of the group members to observe prolapse repair surgery.

It is expected to be the next evolution in POP repair. It utilises a GYNEMESH PS implant that has been developed over 2 years and will adress anterior, vault, posterior and total repairs.

The aim of the procedure is to provide a standardized implant for Grade III and IV POP with a low tissue reaction and soft synthetic implant.

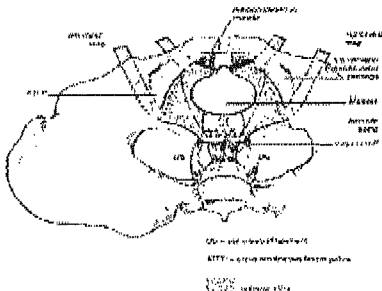
The procedure has been created to be simpler to teach and reproducible in a wide variety of patients while ensuring them consistent outcomes.

It is performed through vaginal route and mesh is held in place by a series of straps to sustain pelvic defects.

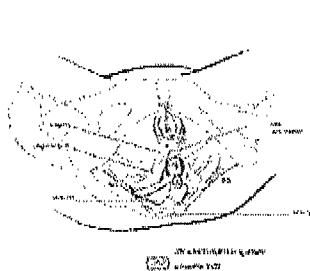
Initial incisions are performed through the anterior and/or posterior walls of the vagina (depending on anterior repair only, posterior repair only or total repair). The tissues planes are dissected and organ prolapses reduced. The correct implant is selected and then placed.

Anterior only, posterior only and total repair techniques are described on the below drawings:

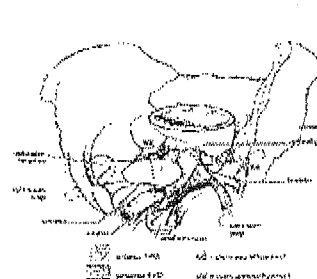
Anterior repair: single anterior mesh, two bilateral arms through the obturator space in the arcus tendineus



Posterior repair: single posterior mesh, one bilateral arm through the sacrospinous ligament



Total repair: posterior and anterior mesh in place



Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

4.2 Gynecare Prolift™ Instruments and Implant Overview

The following components will be part of the kits:

GYNECARE GYNEMESH® PS

GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE®

Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. The mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

Total Mesh Implant

The Total mesh implant is GYNECARE GYNEMESH PS and is shaped for performing a total vaginal repair. The implant has 6 straps: 4 for securing the anterior portion of the implant through the obturator foramen and two for securing the posterior portion of the implant in the sacrospinous ligament via a trans-gluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and the implant can be secured via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends. See Figure 1.

Anterior Mesh Implant

The Anterior mesh implant is GYNECARE GYNEMESH PS and is shaped for repair of anterior vaginal defects. The implant has 4 straps that are secured via a trans-obturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively. See Figure 1.

Posterior Mesh Implant

The Posterior mesh implant is GYNECARE GYNEMESH PS and is shaped for repair of posterior end/or apical vaginal vault defects. The implant has 2 straps that are secured in the sacrospinous ligament via a trans-gluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and the implant can be secured to the sacrospinous ligament via a vaginal approach. The posterior straps have rounded ends. See Figure 1.

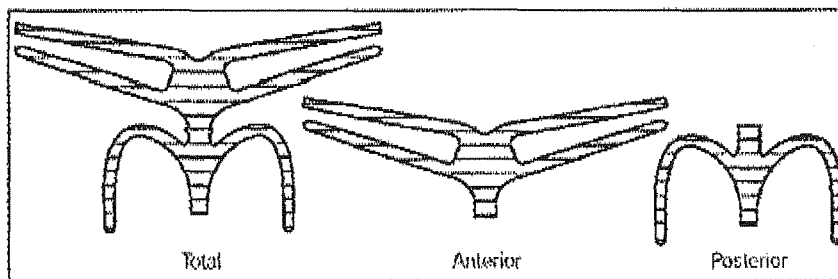


Figure 1 - Mesh Implants (Total, Anterior and Posterior)

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

GYNECARE PROLIFT Guide

The GYNECARE PROLIFT Guide is a single-patient-use instrument designed to create a path to allow placement of the Total, Anterior and Posterior mesh implants and to facilitate the placement of the GYNECARE PROLIFT Cannula. Its length and curvature are specifically designed to allow for the proper placement path for the mesh implant straps. The GYNECARE PROLIFT Guide is suitable for use on both sides of the patient. See *Figure 2*.

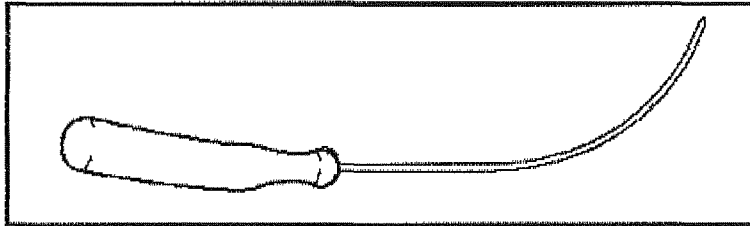


Figure 2 – GYNECARE PROLIFT Guide

GYNECARE PROLIFT Cannula

The GYNECARE PROLIFT Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT Cannula is placed over the GYNECARE PROLIFT Guide prior to passage and remains in place after the GYNECARE PROLIFT Guide is withdrawn. See *Figure 3*.

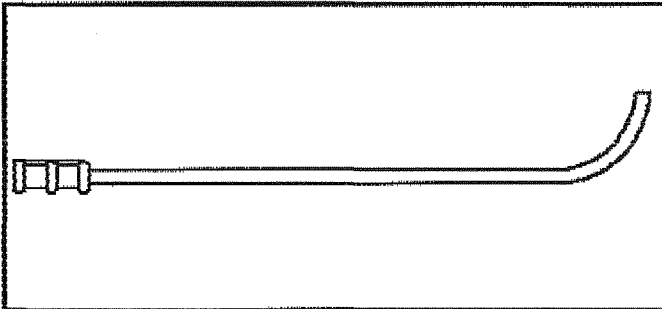


Figure 3 – GYNECARE PROLIFT Cannula

GYNECARE PROLIFT Retrieval Device

The GYNECARE PROLIFT Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps.

The GYNECARE PROLIFT Retrieval Device is passed through the previously positioned GYNECARE PROLIFT Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT Cannula. See *Figure 4*.

Prepared by Ophélie Berthier and Giselle Bonet, 5th of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

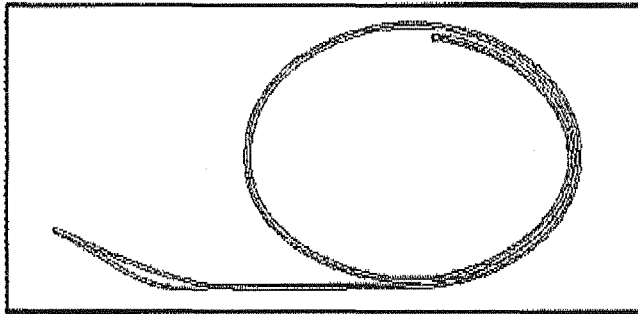


Figure 4 – GYNECARE PROLIFT Retrieval Device

There will be three different kits available for performing TVM

| REPAIR SYSTEM | COMPONENTS | | | |
|---------------|--------------|-------|-------------------|---------|
| | Mesh Implant | Guide | Retrieval Devices | Camulas |
| Total | 1 Total | 1 | 6 | 6 |
| Anterior | 1 Anterior | 1 | 4 | 4 |
| Posterior | 1 Posterior | 1 | 2 | 2 |

Table 1 – GYNECARE PROLIFT Repair System Components

Prepared by Ophelie Hordier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

4.3 Key product features and benefits

| Key Feature | Key Benefits |
|---|---|
| GYNECARE GyneMesh PS Implant | Proven safe material Allows rapid fibrinous fixation and excellent tissue ingrowth AMID type I monofilament mesh which is the preferred implant for pelvic floor surgery (MOT) |
| Standardized procedures | Proven effectiveness (less incidence of recurrence) Easy to perform More anatomically correct repair which should lead to better function Standardized procedure to achieve outcome Lower recurrence rates Shorter OR time compared to complex repairs Practice expansion due to growing patient population |
| Anterior transobturator approach, Posterior approach, total repair approach | Provide the greatest possible flexibility to users Addresses all types of repairs: prophylactic or not |
| Pre formed mesh implant | Optimal repair Reduce time for preparation Ease of placement, use |
| One Guide for all passages | Anatomically designed Facilitate accurate introduction and smooth, continuous passage of the mesh Thin diameter needle to allow atraumatic passage in tissue |
| Retrieval lines | Use in pulling the Mesh Implant fixation straps through the Cannulas Facilitate passage of the straps in the cannulas Easier to grasp than suture |
| Plastic cannulas | Facilitate proper, atraumatic placement of the Mesh Implant fixation straps Reduce tissue tearing |

Prepared by Ophélie Berthier and Ginelle Bémol, 5th of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

5. Product Positioning

GYNECARE *Prolift* kits will be positioned as an innovative, efficient, safe, standardized apical, anterior, and posterior vaginal defect repair procedures for physicians who are looking for an effective, clinically proven standardized prolapse repair procedure with consistent outcomes. It will complement the GyneMesh PS product and as such will contribute to create a Gynecare full range of products for prolapse repair addressing each segment of the market (anterior, vault/apical and posterior repairs).

Most importantly, it will be positioned as fulfilling all the critical success factors needed for a procedure to become a gold standard: (Our strongest position is: The only clinically supported Prolapse repair utilizing a synthetic mesh with 1 year evidence of safety)

- ease of use
- greater efficacy than current procedures performed (presumed not proven – cannot claim)
- short term and long term efficiency (do mean efficacy? Not proven yet. Cannot claim)
- safe and reproducible procedure
- meeting an unmet need (yes. A procedure that supports the critical principles of a good repair: a) good coverage of the defect, b) apical support, c) “tension free” repair with natural attachment that allows restoration to the “normal anatomical position”
- high patient satisfaction (not proven yet, cannot claim)

In addition the following will be our positioning statements:

GyneMesh-PS

Proven Implant because

- Prolene – tried and tested (inert, US GyneMesh study 1 year results)
- Soft – Less erosions (reduced erosions compared to other materials)
- Optimised (Specifically designed) for pelvic floor

TVM (Trans-Vaginal Mesh) procedure

Best Procedure because

- Standardized for reproducible outcomes that have been clinically evaluated
- Anatomically correct
- Flexible (comprehensive offering of solutions – Ant / Post / Total, and flat mesh)
- Tried and tested (clinical data) – safe (& effective – cannot claim yet)
- KOL endorsed

Gynecare Prolift Kit

Best delivery devices because

- Atraumatic delivery system – Sheathed needles
- Unique needles – anatomically designed and tested
- Simplified mesh placement – (no sheaths on mesh to remove – careful with this as a sheath for TVT is good. Let's claim – Simplified & smooth mesh placement – cannula & retrieval system)
- Unique fastener technology – multiple approaches offer physicians flexibility & choice

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare ; Not for Distribution

Best Education

Best training because

- World class Preceptor network – Live trainings
- State of the art training materials
- Advanced training courses – combined procedures with TVT
- Evidence-based medicine to support our innovation & training

GyneMesh PS will continue to be marketed as the “state of the art” implant for the physicians who prefers to perform their “own” technique.

6. Targeting

The targeting and follow-up of the physicians Gynecare want to engage early on as well as the physicians who will be trained once the product is launched will be key critical success factors for future spreading of the technique.

As this procedure is new, Gynecare must make sure to establish the foundations of KOL engagement and advocacy to have the Trans-Vaginal Mesh technique become a gold standard.

Main reasons for physicians to switch to Gynecare Prolift range of product are:

- Efficient restoration of anatomy
- Reproducible procedure: speed and ease of use backed by clinical evidence & experience
- Low complications rates (short term & long term): low erosion rate
- Low long term recurrence rate (cannot claim this)

Anterior repair:

| Phase | Target selection criteria |
|--|--|
| Phase 1: Pre launch Preceptors KOL High volume GyneMesh PS customers | -Gynecare friendly -50% of practice is pelvic floor -has experience in teaching pelvic floor surgery (preceptors) -currently using GyneMesh PS -doing transobturator SUI surgery or knowledge of the anatomical transobturator space |
| Phase 2: Launch | -50% of practice is pelvic floor -currently using grafts (not only mesh) (first target mesh users, secondary target using biologics) -doing transobturator SUI surgery or knowledge of the anatomical transobturator space |

Posterior repair:

| Phase | Target selection criteria |
|----------------------------|---------------------------|
| Phase 1: Pre-launch | -Gynecare friendly |

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

| | |
|---|--|
| Preceptors KOL High volume GyneMesh PS users | -50% of practice is pelvic floor -has experience in teaching pelvic floor surgery (preceptors) -currently using GyneMesh PS -doing sacrospinofixation (sacrospinous fixation) (Richter) -doing or has done IVS posterior |
| Phase 2: Launch | -50% of practice is pelvic floor -currently using mesh (first target, secondary target using biologics) -doing sacrospinofixation (Richter) -doing or has done IVS posterior |

Total repair :

| Phase | Target selection criteria |
|---|--|
| Phase 1: Pre-launch Preceptors KOL High volume GyneMesh PS users | -Gynecare friendly -50% of practice is pelvic floor -has experience in teaching pelvic floor surgery (preceptors) -currently using GyneMesh PS (and comfortable using large graft materials for repair) -doing transobturator SUI surgery or knowledge of the anatomical transobturator space -doing sacrospinofixation (Richter) -doing or has done IVS posterior |
| Phase 2: Launch | -50% of practice is pelvic floor -currently using mesh for anterior and posterior repair (first target, secondary target using biologics) -doing transobturator SUI surgery or knowledge of the anatomical transobturator space -doing sacrospinofixation (Richter) -doing or has done IVS posterior |

7. Pricing

Worldwide pricing of GYNECARE *Prolift* anterior, posterior, total kits has yet to be finalized according to the global pricing process in place.

The pricing of the PROLIFT procedure kits will be based upon the extreme value that this new procedure delivers to the end user as well as what the end user perceived value is. It will also have to take into account the health economic environment of each countries.

A pricing research study done by an external company has been ordered which includes VOC and healthcare environment price constraints. In parallel, the Gynecare Health Economics & Reimbursement department will give its recommendations for US & EU countries.

Prepared by Ophélie Berthier and Ghislaine Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

Based on those findings, the launch team will submit its recommendation to the Global Pricing Committee who will decide on the final products price.

In the financial model, the rational used for the pricing was based on current competitive devices already in the market:

US:

- for the anterior or posterior stand alone repair kits, the reference average selling price was 500\$ (SUI devices average selling price is 600\$)
- for the total repair kits, the reference average selling price was 750\$ (1,5 times the stand alone kits)

EU:

- for the anterior or posterior stand alone repair kits, the reference average selling price was 400\$ (SUI devices average selling price is 400\$)
- for the total repair kits, the reference average selling price was 600\$ (1,5 times the stand alone kits)

Due to health economics reimbursement issues, it is anticipated there will be room for increasing the price in EU which will be most probably unequal among countries and limited while in the US it should be much greater.

8. Competition Overview

Currently the grafts are split between non-synthetic (biologics), hybrid (synthetic coated with collagen) and synthetics material.

Main reasons for using a non synthetic or hybrid material are the presumed benefits of:

- reduce tissue reaction
- tissue rejection
- reduce adhesions

Main reasons for using a synthetic mesh are:

- long term implant
- high tensile strength
- no risk of prion contamination
- consistent, predictable performance of material
- lower cost

8.1 Competitive landscape:

| Biologics | Hybrids | Synthetics |
|-----------|---------------|------------|
| Bard | Bard/Sofradim | EPD |
| AMS | | Gynecare |
| Mentor | | Tyco |
| Boston Sc | | AMS |
| COOK | | Sofradim |

Prepared by Ophélie Berthier and Giselle Bonel, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

US: competitive landscape

| Company | Products Offered | Price | Share | Alpha | Dollars MM | Anticipated Initiatives |
|---------|---|-------------------------|-------|-------|------------|---|
| BARD | Pelvicul | \$600-\$650 | 30% | 5547 | \$4.4 | Clinical data, Expand Prof Ed & launch Pelvicul + synthetic |
| ISE | Repliform | \$990 | 18% | 3326 | \$3.3 | Expand sales force & contracts |
| TYCO | IVS Posterior | \$600 | 16% | 3325 | \$2 | Expand Prof Ed; launch total PPR, sell 2 for 1 with GUI |
| Mentor | Tutoplast | \$1990 | 6% | 1108 | \$2 | Co-sell w/Ostap |
| AMS | Straight-Me IntraMesh IntraXon IntraDerm | \$695 \$800 \$800 | 5% | 924 | \$0.92 | Co-sell with Monarc; Expand offerings |
| COOK | Surgisite | \$250-\$300 | 6% | 1108 | \$0.59 | Co-sell w/Stratafix TF |

EU: competitive landscape

| Company | Products Offered | Price | Countries | Est'd Mkt share (Value) | Anticipated Initiatives |
|--|---|-------------------------------|-------------------|-------------------------|--|
| BARD | Pelvicul | €500-€230 | EU | 25% | Clinical data; launch of a pelvic EUI device end of 2003 |
| TYCO | IVS Posterior Surgisite | €680-€320 €30-€20 | EU | 15% | Prof Ed; launch of a new prolapse repair procedure 2004-2005 |
| SOFRADIM | Ugyflex Partelox | €400-€250 €300-€200 | France Germany | 8% | Leverage with Urtax; clinical data; Launch of a total repair procedure in 2006 |
| Local competitors: COUSIN, Synlog, Angiologic... | IntraMesh Cytosewing... Angiologic mesh | €160-€350 €350 €200 | France Italy | 6% | Aggressive attacks: price discounts; surgeons' incentive Tailored meshes |
| ETHICON | Proline Mereleone Vypro | €50-€80 €70-€80 €70-€80 | EU | 16% | No focus in gynae |
| AMS | IntraXon | €400-€250 | EU | Not significant | Launched in February 2004; leverage with Monarc |
| COOK | Surgisite | €500-€250 | EU | Not significant | Leverage with Stratafix |

Prepared by Ophélie Berthier and Gaelle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

8.2 New comers in 2004-2005

Other competitors companies have recognized the large potential and market need for a standardized prolapse repair procedure product and search for the 'ideal implant'.

Q1-Q2/2004

SOFRADIM/BARD launched the first hybrid implant (synthetic implant coated with collagen) UGYTEX/PELVITEX in Europe and the US. As the graft market is divided into biologic implant users and synthetic implant users, this product was addressing both segments at one time. However, there is at the moment no clinical data published on the use of this prosthesis for prolapse repair.

Main features and benefits claimed by the company's product are:

- reduce erosion rate
- reduce adhesions
- durable implant

Q3-Q4/2004:

AMS recently launched two prolapse repair procedure kits (one for anterior and one for vault repair) available with two different implants materials. They are not only targeting synthetic mesh users but also biologics mesh users bringing more potential customers to their business. However, the long term benefits of biologics are unknown therefore long term efficacy is uncertain.



AMS Perigee Transobturator Anterior
Prolapse Repair System
IntePro, InteXen meshes



AMS Apogee
Vault Suspension System – Synthetic Mesh



Perigee IFU.PDF



Apogee IFU.PDF



perigee.pdf



apogee.pdf

2005:

SOFRADIM (distributed by BARD in many countries including the US) is currently working on a total repair procedural kit with Dr Delorme (T.O.T. inventor) and Dr Eyglin. They are expected to be launching a new product Q3 2005

TYCO is also expected to launch new mesh materials in 2005 and is working on a total repair procedure called T.O.P.P. with Dr Von Theobald (IVS preceptor for EU).

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

In the long future, it is foreseen the quality and outcomes of the implant will become a primary criteria of choice for physicians and make the difference.





8.3 AMS Rebuttal Strategy

They key attack strategy against AMS will be the TVM (Trans Vaginal Mesh) group credibility, robust procedure development and work accomplished since 2000, the differentiation of the technique (transobturator passage of the helical needle of the AMS product), added value of the different Prolift instruments (based on cadaver labs feedbacks) and lack of clinical experience (300 cases, 1 year data versus no data for AMS). This will be coupled with the further reinforcement of the GyneMesh PS implant, through published clinical evidence (AUGS abstract, publication in scientific magazine on 1 year follow up) and all the additional added value benefits offered by a J&J company. An aggressive pre-launch activities plan to engage early on key opinion leaders, high volume Gynemesh PS customers and create awareness will complement it .

9. Pre-launch strategy



9.1 Customer Communication

In an effort to accelerate adoption and create a faster brand awareness and counteract competition new product launches, Gynecare has decided to start a series of pre launch events communicating on the work done with this group of 9 physicians to develop a Trans-Vaginal Mesh technique with GyneMesh PS implant:

| Date | Events | Attendees |
|--------------------------|--|--|
| July 30 th 04 | <p>AUGS- San Diego Gynecare Symposium Speakers: Dr Miller (US investigator), Dr Cosson(FR investigator)</p>  <p>SymposiumProgramDescription.doc</p> | 80 gynec, urogynaec surgeons attended |
| Aug 23 rd 04 | <p>ICS/IUGA GynecareTVM breakfast Speakers: Pr Jacquetin, Dr Cosson (FR investigators)</p>  <p>TVMinvitationletter.doc</p> <p>Feedback form</p>  <p>ICS PELVIC FLOOR MEETING.doc</p> | <p>45 european KOLs</p>  <p>Participants.xls</p> |

Prepared by Ophélie Berthier and Clotilde Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

| | | |
|-----------------|--|---|
| | <p>Live surgery during ICS/AUGA: Pr Pigné's procedure with GyneMesh PS Dr Cosson to perform live a case with TVM procedure</p>  <p>Workshop13 ICS04.doc</p> | <p>200 attendees</p> <p>350 attendees</p> |
| Sept 22nd 04 | <p>Cercle Récamier-Lyon Live surgery with Dr Cosson</p>  <p>ProgrammeRécamier pdf</p> | 150 attendees |
| Oct 20th 04 | <p>Gynecare UK Study day Pr Jacquetin to present TVM technique and results</p> | 100 UK physicians |
| Nov 12th 04 | <p>One day internal training for D4, umbrellas</p> | MM, CM |
| Nov 13th 04 | <p>AAGL symposium Live surgery case performed by Dr Lucente commented/moderated by Dr Miller (US investigators)</p> | 80 physicians expected |

Due to the increase in competitor activity from AMS especially it is critical to have a consistent rebuttal strategy against Perigee and Apogee's products:

Key Questions for surgeons interested in AMS

- What evidence is there on the implant you are leaving in the patient?
- What clinical evidence is there on the procedure proposed? What is the long term follow-up? How many cases have been performed with those procedures?
- Are the devices proposed adapted to the procedure?
- How do they address the posterior repair? Total repair?

GYNECARE's response to Perigee/Apogee

- Acknowledge there is an unmet need for a standardized procedure for anterior, posterior, total repairs
- A current development address's this concern
- A group of nine French physicians who had extensive experience in prolapse repair and use of mesh has been working with Gynecare since 2000 to develop such a procedure
- A multicenter clinical trial is undergoing/underway to prove consistent outcomes (Independent of the physicians-own experience, a prospective trial involving 180 patients is near completion and forms the basis for the launch of the GYNECARE Prolift system
- It will be introduced with the added reassurance of the only 'tried and tested mesh implant and procedure'

Prepared by Ophélie Berthier and Giselle Banol, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

9.2 Pre-launch countries involvement and key activities:

Involving countries prior to launch of the Gynecare Prolift product range will be critical to ensure a successful launch. (Explain upfront that you are recommending a 3-Phase Launch to ensure that the GYNECARE ProLift System is introduced sequentially in countries that have an established mesh market. This will enable 2nd and 3rd Phase markets to strengthen their mesh advocates before launching ProLift)

(Countries were informed of the intended launch via the Global Marketing Council held in Paris on August 22nd, 2004). All countries will be informed on the pre-launch activities that will take place and will have the opportunity to involve surgeons early on. However, key activities will be available for countries where the Gynecare Prolift range of products will be launched during Phase 1 (Soft launch: February and Full launch: April 05).

The Gynecare Prolift product range will be launched in Phase 1 in the US, EU D4 countries, Australia and three umbrellas (Spain, Benelux, Switzerland). As level of mesh penetration is unequal among countries (umbrellas, Asia), the countries with the highest mesh penetration rate will launch in Phase 1 while the other will launch once they have developed the use of GyneMesh PS.

Phase 2 will start in late September and will include: Portugal, South Africa, Scandinavia, Austria, some Asian countries and Canada (waiting this long for Canada may be an issue)

Phase 3 will start in 2006 and will include: ROW, Eastern countries, Latin America...

Pre-launch and soft launch countries activities includes:

Monthly e-newsletter distribution
Symposium (TVM breakfast at ICS/IUGA, Live surgery)
Observe surgery in Lille or Clermont Ferrand
Internal training for MM or CM

9.3 Pre Launch Preceptor Programme (US, D4, Umbrellas phase 1)

| Activities | Date |
|----------------------|-------------------------|
| Preceptor Selection | 17/09/2004 |
| Preceptor Engagement | 9/17/2004 - 10/15/2004 |
| Cadaver Labs US | 10/15/2004 - 12/15/2004 |
| OR Training EU | 9/27/2004 - 12/7/2004 |

Objective

FDA/CE marked Prolift product for human clinical use will not be available until end January 2004/2005, in order to defend any further existing business from either posterior IVS, Perigee, Apogee or any other implants procedures, there will be a Prolift Pre Launch Training Programme to start enrolling future preceptors, KOL, high volume GyneMesh PS customers.

Programme

Prepared by Ophélie Berthier and Glacelle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

- Capacity to take a further 40 surgeons to Lille (mostly) or Clermont Ferrand between Oct-Dec 04
- Average 3-4 surgeons per visit
- Global Launch Leader and local CD/MM to attend sole country visits
- Evening arrival, following day observe and participate to surgery 2/4 procedures in the OR with a presentation of the physicians results
- The aim of the mixed country visit is to give 'extra importance' to the customer exposing them to a European group and to also diffuse the positive experiences
- Countries will still be given the opportunity to reserve one session for their customers only
- The EU training will focus on OR observation (11 sessions) with inventors in France while US training will focus on cadaver lab (1 lab) and few surgery observations (1 session) in EU for 'VIP' only (what about using the US investigators by December for a live surgery program?)

Proposed dates in Lille with Dr Cosson

- | | |
|---------------------------------|--|
| ○ 27/28 th September | Mixed European Visit |
| ○ 5 th October | Umbrella Visit |
| ○ 19 th October | Mixed European Visit |
| ○ 2/3 th November | Mixed European Visit/US |
| ○ 16 th November | Mixed European Visit |
| ○ 23/24 th November | Mixed European Visit |
| ○ 30 th November | Mixed European Visit |
| ○ 7 th December | Mixed European Visit |
| ○ 11 th December | Mini summit cadaver lab in Las Vegas/US and procedure training |

10. Launch strategy milestones

10.1 Product availability

| | |
|--|-------------------------|
| Release of Reusable Guides For First Human Use (Pr Jacquetin, Dr Cosson, Dr Debodinanco) | Mid Oct |
| Design Verification | |
| Packaging complete | Sept 04 |
| IFU complete | Sept 04 |
| Demo product availability | Mid Nov 04 |
| Limited Quantity Release Of Pilot Devices For First Human Use (30 kits) | Mid Dec |
| Design Validation | Dec 04/Jan 05 |
| 510k submission | Mid Nov |
| -Approval (11/1 or 1/1) | |
| IQ/OQ/PQ | Aug 04 – Dec 04 |
| -(Sterilization and all other processes at Medilinc, JEB, & Neuchatel) | |
| CE mark | Jan 29 th 05 |
| PRA Approval For US and EU(Beta Launch) | Jan 29 th 05 |

10.2 Pre-launch/Launch activities

| | |
|-------------------------|------------|
| AUGS symposium | Jul 04 |
| ICS/IUGA breakfast | Aug 04 |
| Cerele Récamier | Sept 04 |
| Train future preceptors | Oct-Dec 04 |
| Gynecare UK study day | Oct 04 |

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

| | |
|--|----------------------|
| AAQL symposium | Nov 04 |
| Pre-training of EU/Umbrella | Nov 12 th |
| Cadaver labs/Mini Summit | Dec 04 |
| Soft Launch | Jan 29 th |
| Full product available/Release to preceptors | Jan 29 th |
| EU Live surgery with preceptors/Train the trainers programme | Feb 05 |
| Soft launch Training US team | NTM |
| Soft launch training EU team | Feb 05 |
| TVT Preceptor Summit | Feb 05 |
| Clinical data availability | March 05 |
| Tools available | March 05 |
| Start Training sessions | March 05 |
| Full launch | Apr 05 |
| (There must be a plan to have a webcast/training for the US sales force in Q4 2004 to share our plans for D'Art, help the DM's/ reps to understand the advantage and positioning of our product, begin looking for the right target doctors and also "rebut" the competitor's products...) | |
| See attached Gantt charts (Appendix 2) | |

11. Professional Education

11.1 Internal Training

As prolapse repair is very complex, it is expected learning the TVM procedure will take more time than for SUI procedures to learn. Therefore, the training will occur in different phases:

EU:

- 1) Exposure to the pelvic floor platform opportunities and future product launches last May 2004 during the umbrella meeting
- 2) Involvement of local management (Marketing Managers and Sales Managers) and training on prolapse repair through a one day pre-training course in November 12th

This will assist the sales team to clearly understand and learn the anatomy, the reason for the use of meshes, the different techniques in prolapse repair and competitors product prior to launch meeting. The content will detail:

- Anatomy
- What is a prolapse?
- Surgical treatments including techniques using grafts or not grafts
- Reasons for the use of meshes, criteria of choice for the implant (Gynemesh PS differentiation)
- Techniques using meshes and competitive products
- Gynecare Prolift procedures
- Pre-launch /launch strategy

- 3) Soft launch for sales force and training on prolapse repair through a 12 hours training during the next European meeting in February. The course will use the content taught in November adapted by local marketers.
- 4) Full launch during local sales meeting in April

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare ; Not for Distribution

US:

- 1) Involvement of sales and marketing management on prolapse and pelvic floor strategy
 - 2) one to two hours training course on anatomy and prolapse repair techniques during US regional meetings in July 04
 - 3) Soft launch and training course on prolapse repair and TVM procedure the next NTM in late January
 - 4) Full launch during local sales meeting
- (There must be a plan to have a webcast/training for the US sales force in Q4 2004 to share our plans for D'Art, help the DM's/ reps to understand the advantage and positioning of our product, begin looking for the right target doctors and also "rebut" the competitor's products. Waiting until January will be too late - this will help to capitalize on the AUGS workshop as we should be following up to get feedback.)

Launch material will be prepared which will cover the following areas. (let's make sure we are not leaving too much for the "local" team to develop - our US resources on the Global project are also the local resources, and Joe will have to support many umbrellas...)

- Background to local market (Local MM to prepare)
- Review of anatomy (Local MM to adapt content given)
- Review of prolapse repair most used techniques locally (Local MM to adapt content given)
- Background to launch of GYNECARE Prolift (Local MM to adapt content given)
- Detailed description of procedure (Local MM to adapt content given)
- Key features and benefits (Local MM to adapt content given)
- Clinical Evidence (Local MM to adapt content given)
- Competition Rebuttals (Local MM to adapt content given)
- Review of literature: on meshes, techniques, competition (Local MM to adapt content given)
- GYNECARE Prolift Positioning & Price (Local MM to adapt content given)
- Promotional Material (Local MM to adapt content given)
- Q&A (Local MM to adapt content given)
- Next steps - Targeting & surgeon Prof Ed & Follow up (Local MM to prepare)

11.2 Surgeon Training

In January 05 when GYNECARE Prolift product range will be available there will have been over 40 surgeons across Europe who will have attended the Pre Launch Preceptor Training in Lille or Clermont Ferrand as well as well as 30 surgeons who will have attended a cadaver lab in Las Vegas and/or gone to Lille for training.

EU:

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

| Activities | Date |
|---------------------------|------------------------|
| Preceptor Selection | 17/09/2004 |
| Preceptor Engagement | 9/17/2004 - 10/15/2004 |
| OR Training EU Pre Launch | 9/27/2004 - 12/7/2004 |
| Preceptor Live surgery | 1/29/05-2/13/05 |
| OR Training EU | 9/27/2004 - 12/7/2004 |

During Soft Launch in February, Gynecare will organize a live surgery event as well as a teaching session on content that will be given to preceptors. This will give the opportunity to bring together the surgeons who have agreed to become Preceptors in order for them to clearly understand the 'cook book' technique in order to then continue to teach the correct procedural steps, which will then create the pyramid of training. They are expected to perform 5-8 procedures in February-early March before they start training in March-April. (To make this a little more exciting, it might be nice to ask the US investigators what they think about starting with M. Cosson operating on a Live Telecast from France and having the US investigators be the local moderator -- we can use Dave Robinson for West Coast, Dennis Miller for Mid-west and Central Region, and Vince Lucente for East Coast)

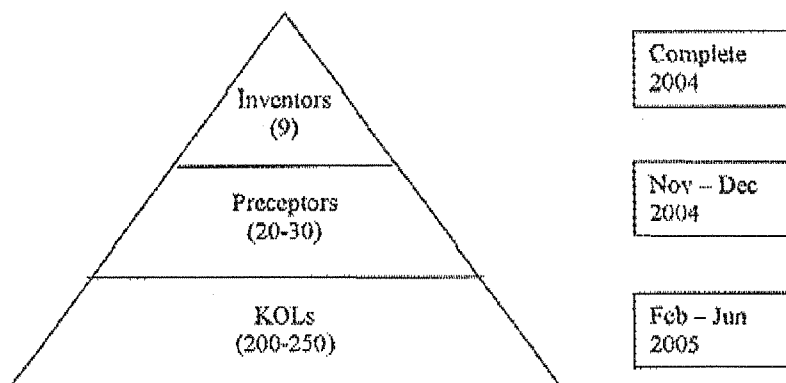
In addition each country will be able to arrange local launch/webcast/symposium and given the opportunity to invite Pr Jacquetin or Dr Cosson (an at least two month notice will be required to ensure inventors availability).

Each market will then be required to execute their own Professional Education with local preceptors (2-3 centers) who had been enrolled on earlier activities (OR observation, live surgery).

Training with 'key' or 'VIP' surgeons being invited to Lille or Clermont Ferrand will still be an option but will be limited due to capacity issues.

A flying program will also be set up to give more flexibility to countries, Dr Debodinance will do most of it (an at least two month notice will be required to ensure inventors availability).

Our aim is to create a preceptor pyramid-training program:



Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

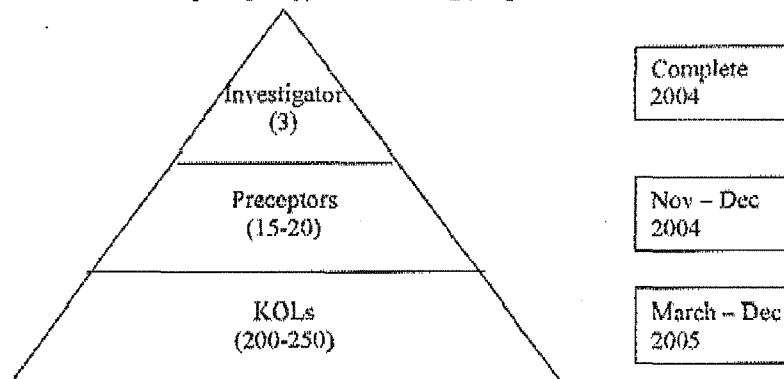
US:

| Activities | Date |
|----------------------|-------------------------|
| Preceptor Selection | 17/09/2004 |
| Preceptor Engagement | 9/17/2004 - 10/15/2004 |
| Cadaver Labs US | 10/15/2004 - 12/15/2004 |
| OR Training EU | 9/27/2004 - 12/7/2004 |
| OR Training US | 3/3/2005 - 15/12/2005 |

From mid January to February, Gynecare will organize for the physicians who attended the cadaver lab (25) in Las Vegas to go observe surgery in one of the 3 US investigators sites. It is expected each physicians will use the product 5-8 times before they feel confident with the technique during February-early March. In addition, a webcast to train future preceptors (10-15) on training content will be set up once tools will be available.

Each preceptor is expected to train 3-4 physicians a month. Complementing OR surgery observation with cadaver lab will be pursued if feedback from surgeons who attended the one organized in Las Vegas shows it brings value to the training.

Our aim is to create a preceptor pyramid-training program:



This will allow us a controlled roll of this complex procedure but create enough users to achieve our first year sales target.

(NB. All users of TVM MUST go through our preceptorship programme in the US and ARE RECOMMENDED to go through our preceptorship programme in EU)

Prepared by Ophelie Hostlier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

12. Clinical Strategy

To date there is now 1 abstract on TVM technique at IUGA/ICS. Dr Debodinance is submitting one article on technique in a French scientific magazine.

Regarding Gynemesh PS publications, many abstracts can be found (AUGS, ICS/IUGA) and one/two scientific papers (one abdominal, one vaginal paper) is under writing for a potential submission in an American scientific magazine in late November.

A prospective multicenter clinical study is undergoing with 3 US investigators (Dr Miller, Dr Lucente, Dr Robinson) and 9 French physicians (Pr Jacquetin, Dr Cosson, Dr Debodinance, Dr Berrocal, Dr Garbin, Dr Clavé, Dr Rosenthal, Dr Villet, Dr Salet-Lizée) on 180 patients with 6 month, 1 year, 3 year and 5 years follow up.

Gynecare aims to launch the TVM procedure with a set of clinical data therefore for the launch of GYNECARE Prolift, the 6 month clinical data will be available as well as a monograph of the technique. Both the above evidence and the monograph by Pr Jacquetin and the TVM group will adequately support safety and efficacy of the procedure. However, further published results will be necessary to support clinical evidence. Dr. Joel Lippman has agreed to meet with the clinical and marketing team in Q4 to flush-out the publication strategy as well as discuss what data can be made used for launch.

As of today, more than 300 cases have been performed by the group of 9 physicians. The group has collated its data and is anticipated to submit it for publication towards end Q4.

Post launch customer initiated research studies have yet to be determined. A need for further clinical study to be undertaken has already been identified and will need to be budgeted for 2005.

13. Launch Materials

The below items are currently in development and are planned to be available for the launch of GYNECARE Prolift:


| Support material | Description | Availability |
|-------------------------------------|---|--------------|
| 4 pages detail aid | Description of tools, presentation of features and benefits of the technique, Gynemesh PS implant characteristics, clinical results and characteristics | Dec 04 |
| High res photo images/Photo library | To be used in brochures, presentation | Dec 04 |
| Key procedure steps | Describe technique and key steps | Dec 04 |
| OR staff sales aid | Describes patient preparation, instruments needed to perform procedure, anesthesia protocols, etc | Feb 05 |
| Development of print adverts | Coming soon teaser and launch advertising campaign | March 05 |
| Interactive CD Rom | Case study style format with videos of procedure, cadaver dissections, 3D anatomy and MRI | March 05 |

Prepared by Ophélie Berthier and Ginella Bonet. 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

| | | |
|-----------------------------------|--|----------|
| TVM technique Monograph | Authored by Pr Jacquetin and the group of 9 physicians To support clinical evidence on the procedure: describes evolution, instruments, procedure, anatomy, clinical data | Feb 04 |
| Preceptors PWP presentation | Presentation to support preceptor training on the technique | Feb 05 |
| Preceptee binders | To be handed out after preceptorships, includes CD, product information, clinicals, monograph | March 05 |
| Competitive matrix for salesforce | One page with all competitors tools and mesh characterization | Dec 04 |
| Prolapse repair training CD rom | 3D CD rom to train on prolapse repair | Dec 04 |
| Launch binder | | |
| Mesh bibliography | Bibliography classified according to competition, complications/themes, date of publication with summary to strengthens argumentation | Dec 04 |
| FAQ for salesforce | Adresses how to handle intraoperative or postoperative complications, patient selection, clinical data | Feb 04 |
| Convention marketing salesaids | Prospecting cards, booth posters, promotional giveaways | March 05 |
| Pelvic models | Models used for enhanced training experience. Not custom made. | Oct 04 |
| Patient leaflets | Build awareness of prolapse, failure rates, mesh benefits, patient options, call to action | March 05 |

14. Exhibition Strategy (from now on)

| Where | When | Presenter | Details |
|-----------------------------|-----------------|--------------------------|--|
| Cercle Récamier/Lyon-France | Sept 04 | Dr Cosson | Live surgery  ProgrammeRécamier.pdf |
| Gynecare UK study day/York | Nov 04 | Pr Jacquetin | Presentation |
| AAGL/San Francisco-US | Nov 13th | Dr Lucente/ Dr Miller | Live surgery |
| JPEG/ Paris | Feb 04 | Pr Jacquetin | GYNECARE Symposium organized on prolapse techniques |
| /Dunkerque-France | 27-28 th Feb 04 | Dr Debodinance/Dr Cosson | Live surgery and round table |
| EAU | March 05 | Dr X | L |
| Austria | March 05 | Dr X | Live transmission |
| ICS 2005 | Date (Canada) | Prof X | What we will present etc |

Prepared by Ophélie Borthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

| | | | |
|-----------|--|--|--|
| IUGA 2005 | | | |
| AUGS 2005 | | | |
| etc | | | |

15. Product logistics*15.1 Inventory*

GYNECARE Prolift will be supplied from Neuchâtel, Switzerland. The team in Gargrave, UK, which is led by Richard Noble, is currently managing the demand planning. Rachel Geiser will continue to be the contact for the purchasing department.

| Product Code | Description | Case Contents |
|--------------|---|---------------|
| PFRA01 | GYNECARE Prolift Anterior Pelvic Floor Repair system | 1 |
| PFEP01 | GYNECARE Prolift Posterior Pelvic Floor Repair system | 1 |
| PFRT01 | GYNECARE Prolift Total Pelvic Floor Repair system | 1 |
| PFRF01 | GYNECARE Profix Fastener system | 1 |

All components will be provided sterile and single use.

15.2 Forecasts

The latest forecasts for GYNECARE Prolift are attached. This includes local markets safety stock, sterile and non sterile samples. The rate of cannibalization of the existing GyneMesh PS needs to be addressed in each of the local markets forecasts.

(It is quite useful to include an assumptions section as it relates to the forecast : example, timing of product availability, advocacy of large pieces of mesh, etc... This is so that if a critical assumption changes, then it will affect the forecast, and people understand that better)
See appendix 3

15.3 Samples

First build reusable guide prototypes anticipated Mid October 04 (3 samples: 1 for Pr Jacquelin, Dr Cosson, Dr Debodinance)

Final product – Non sterile samples for demos or product shooting anticipated Mid November 04

Final product – sterile anticipated mid December 04 (30 kits for US investigators and 9 FR investigators)

Final product – sterile release for sales anticipated January 29th 2005

15.4 Pelvic Floor Sales Projections (WW)

| | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 |
|--------------------------------------|----------|----------|-----------|-----------|-----------|-----------|-----------|
| WW Direct Sales | | | | | | | |
| GyneMesh Net Sales (\$000s) | \$ 3,050 | \$ 3,400 | \$ 4,412 | \$ 5,037 | \$ 5,951 | \$ 6,120 | \$ 6,448 |
| Anterior Prolift Net Sales (\$000s) | \$ - | \$ 1,280 | \$ 3,060 | \$ 4,044 | \$ 6,206 | \$ 6,338 | \$ 6,026 |
| Posterior Prolift Net Sales (\$000s) | \$ - | \$ 1,424 | \$ 4,827 | \$ 6,026 | \$ 11,183 | \$ 12,235 | \$ 13,988 |
| Local Repair Net Sales (\$000s) | \$ - | \$ 1,877 | \$ 4,999 | \$ 8,872 | \$ 17,507 | \$ 23,181 | \$ 30,800 |
| TOTAL Prolift Net Sales | \$ - | \$ 4,581 | \$ 12,437 | \$ 22,715 | \$ 41,948 | \$ 42,702 | \$ 50,814 |
| Total PFR Net Sales | \$ 3,050 | \$ 7,981 | \$ 16,252 | \$ 25,392 | \$ 38,870 | \$ 46,898 | \$ 55,362 |

Confidential Internal Information: Property of Gynecare : Not for Distribution

Source: TVM Financial model 061404. Heed the priors of the model, it's not here sure previous.

See appendix I

16. Budget summary / Resources

16.1 Global Launch team budget:

All materials listed in the promotional items will be funded from the 2004 Pre Launch budget of the Global Launch Team budget and the 2005 Launch budget of the Global Launch team ;

Prepared by Chloé Horthier and Giselle Bonet, 5th of September, Version 1

[illegible]

See Appendix 4

16.1 2005 Local launch team budget:

Local launch budget should include budget for:

Phase 1 and 2 countries: Accelerating Gynecare Prolift adoption

Duplication of Gynecare Prolift tools (CD, brochures, etc)

Publication reprints (Monograph, GyneMesh PS publications, Bibliography articles)

Samples for customers or salesreps

Local launch events (Roadshows, Live surgeries, etc), workshops and exhibition.

Preceptorship for GynMesh PS and Profit

Any other promotional items

Local consulting fees for advisory board (KOLs sponsorship)

Salesforce meeting and training tools

Salesforce incentives

Local post marketing trial

Prepared by Ophélie Herthier and Grégoire Hovet, 3rd of September, Version 1

HIGHLY CONFIDENTIAL *P*
SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

ETH.MESH.00633783

Confidential Internal Information: Property of Gynecare : Not for Distribution

Phase 3 countries: Develop use of GyneMesh PS

Preceptorship for developing use of GyneMesh PS
Duplication of tools for GyneMesh PS (CD, brochures, etc)
Publication reprints (Monograph, GyneMesh PS publications, Bibliography articles)
GyneMesh PS samples for customers or salesreps if needed
Local launch events (Roadshows, Live surgeries, etc), workshops and exhibition to establish
GyneMesh PS brand and create awareness on Gynecare Prolift product
Any other promotional items
Local consulting fees for advisory board (KOLs sponsorship)
Salesforce meeting and training tools on prolapse repair
Salesforce incentives to drive GyneMesh PS sales

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

APPENDIX 1

Financial model 040704.

Financial model 061404. D'art base case scenario.

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

APPENDIX 2

Gantt chart: Marketing tools, key activities, Prof Ed, Clinical, internal training

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare : Not for Distribution

Appendix 3

2005 Forecasts

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

Confidential Internal Information: Property of Gynecare ; Not for Distribution.

APPENDIX 4

Pre launch and launch budget

Prepared by Ophélie Berthier and Ginella Monet, 5th of September, Version 1

HIGHLY CONFIDENTIAL *P*
SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

ETH.MESH.00633788

Confidential Internal Information: Property of Gynecare : Not for Distribution

REFERENCES

- ⁱ Smith ARB, Hosker GL, Warrell DW. The Role of partial denervation of the pelvic floor in the aetiology of genitourinary prolapse and stress incontinence of urine. A neurophysiologic study. Br J Obstet Gynaecol 1989; 96:24-28.
- ⁱⁱ Gilpin SA, Gosling JA, Smith ARB, et al. The pathogenesis of genitourinary prolapse and stress incontinence of urine. A histological and histochemical study. Br J Obstet Gynaecol 1989;96:15-23.
- ⁱⁱⁱ Norton PA, Baker JE, Sharp HC, et al. Genitourinary prolapse and joint hypermobility in women. Obstet Gynecol 1995;85(2):225-228.
- ^{iv} Smith P, Heimer G, Norgen A, et al. Steroid Hormone Receptors in Pelvic Muscles and Ligament in Women. Gynecol Obstet Invest 1990;30:27-30.
- ^v Olsen A, Smith V, et. al. Epidemiology of Surgically Managed Pelvic Organ Prolapse and Urinary Incontinence. Obstet Gynecol 1997;89:501-506.
- ^{vi} Fenner, D. New Surgical Mesh. Clin Obstet Gynecol. 2000;43:650-8.
- ^{vii} Julian M. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. Am J Obstet Gynecol 1996;175:1472-5.
- ^{viii} Visco G, Weidner A, Addison W, et al. Vaginal mesh erosion after abdominal sacral colpopexy. Am J Obstet Gynecol 2001;184:297-302.
- ^{ix} Sze E, Kohli N, Miklos J, Karram M, et al. A retrospective comparison of abdominal sacrocolpopexy with Burch colposuspension versus sacrospinous fixation with transvaginal needle suspension for the management of vault prolapse and coexisting stress incontinence. Int Urogynecol J 1999;10(6):390-3.
- ^x Cundiff GW, Harris RL, Coates K, et al. Abdominal sacral colpoperineopexy: A new approach for correction of posterior compartment defects and perineal descent associated with vaginal prolapse. Am J Obstet Gynecol 1997;177:1345-1355.
- ^{xi} Fischer JR, Hale DS, Benson JT, et al. Combined Rectocele Repair and Abdominal Sacralcolpopexy. A New Method for Repair of Denovillier's Fascia. Presented at the AUGS 18th Annual Scientific Meeting 1997; Tuscon, Arizona.
- ^{xii} Bauer JJ, Harris MT, Kreel I, Gelernt IM. Twelve-year experience with expanded polytetrafluoroethylene in the repair of abdominal wall defects. Mt.Sinai J.Med. 1999;66:20-25.
- ^{xiii} Fernandez LR, Martinez SC, Ortega DP, Fradejas Lopez JM, Marin Lucas FJ, Moreno AM. Colocutaneous fistula due to polypropylene mesh. Hernia. 2001;5:107-09.
- ^{xiv} Fenner D. New Surgical Mesh. Clin Obstet Gynecol. 2000;43:650-8.

Prepared by Ophélie Berthier and Giselle Bonet, 3rd of September, Version 1

EXHIBIT 5

From: Scalera, Mary Ellen [<mailto:MScalera@RIKER.com>]
Sent: Wednesday, June 05, 2013 11:06 AM
To: Jeffrey Grand; 'Adam Slater'; 'Jillian Roman'
Cc: Crawford, Kelly; Kabbash, Maha
Subject: In re Pelvic Mesh - NJ Deposition Scheduling

Jeff,

In furtherance of our conversation and e-mails, the following is the updated deposition scheduling information on the 12 depositions noticed in the NJ litigation:

- a. Chuck Austin – scheduled for June 13-14 in MDL
- b. Dharini Amin – on vacation on the date scheduled and again in July. She is available after August 6. Please note that she was deposed for a full day on TVT issues as she was not involved in pelvic floor. As such, please reconsider if she needs to be re-deposed at all. If so, one day should be sufficient time.
- c. Zenobia Walji – employed by a different company and resides in Singapore. She is not willing to voluntarily appear for a deposition, and her last known address has been provided to you.
- d. Brian Luscombe – offered for July 29 and 30 in the MDL.
- e. Peter Cecchini – offered for August 14 or 15 in the MDL.
- f. Harlan Weisman – former employee who resides outside of NJ. He is unable to appear on July 16-17, but will make himself available on July 17-18 in Princeton.
- g. Ramy Mahmoud – may be available on July 16-17 (as noticed) or 17-18, but we are still waiting for confirmation.
- h. Axel Arnaud – confirmed for July 19-20.
- i. Allison London Brown – tentatively available for July 30-31 (as noticed), but awaiting confirmation.
- j. Cheryl Bogardus – not a current employee, but has agreed to voluntarily appear on August 30.
- k. Amy Goodwin – former employee of Ethicon, whom we have been unsuccessful contacting. We are still attempting to reach her and produce her voluntarily to ask about her availability on August 6-7 (the noticed dates). If she is not willing to appear voluntarily, we will so advise.
- l. Dr. Jim Hart – available on August 7-8, as scheduled in the MDL.

m. Mark Yale – available on August 7-8 (the noticed dates).

Please let me know if you have any questions or would like to discuss.

As you can see, we have made every effort to both coordinate scheduling and keep the noticed dates when possible.

However, although you advised that the noticed dates were coordinated with MDL Plaintiffs' counsel, there may have been some miscommunication as several dates were different than those previously-scheduled with the MDL Plaintiffs' counsel.

I am sending under separate cover letter minor changes to the other proposed CMO paragraphs.

Thanks.

Mary Ellen

<image001.png>

Mary Ellen Scalera | Partner
Riker Danzig Scherer Hyland & Perretti LLP
Headquarters Plaza | One Speedwell Avenue | Morristown, NJ 07962-1981
t: 973.451.8501 | f: 973.451.8722 | MScalera@RIKER.com | www.riker.com

IRS Circular 230 Disclosure: To ensure compliance with requirements imposed by the IRS, we inform you that any U.S. federal tax advice contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, for the purpose of (I) avoiding penalties under the Internal Revenue Code or (II) promoting, marketing or recommending to another party any transaction or matter addressed herein.

Confidentiality Notice: This e-mail contains information that is privileged and confidential and subject to legal restrictions and penalties regarding its unauthorized disclosure or other use. You are prohibited from copying, distributing or otherwise using this information if you are not the intended recipient. If you have received this e-mail in error, please notify us immediately by return e-mail and delete this e-mail and all attachments from your system. Thank You.

<Proposed Gynecare CMO_No 10.doc>