Plastic & Reconstructive Surgery Registrars Conference

March 2009

DEVICE TECHNOLOGIES

First Choice

Creating a difference in healthcare

Premium Partners in Excellence

Welcome

"Understanding the Technological Advances of Breast Implants"

Presented by Joan Hatfield, Business Manager, Device Technologies

- Conference envelopes
- Breast implant evolution, manufacturing and quality control, & standards.
- Product choices in The Allergan Collection with published clinical papers.

Our special Guest Speaker Dr Niamh Corduff, current president of the Australasian Society of Aesthetic Plastic Surgeons (ASAPS)

- Dr Corduff will take you through, with case studies ,breast augmentation & reconstruction including clinical indications, planning involved in selection & clinical outcomes.

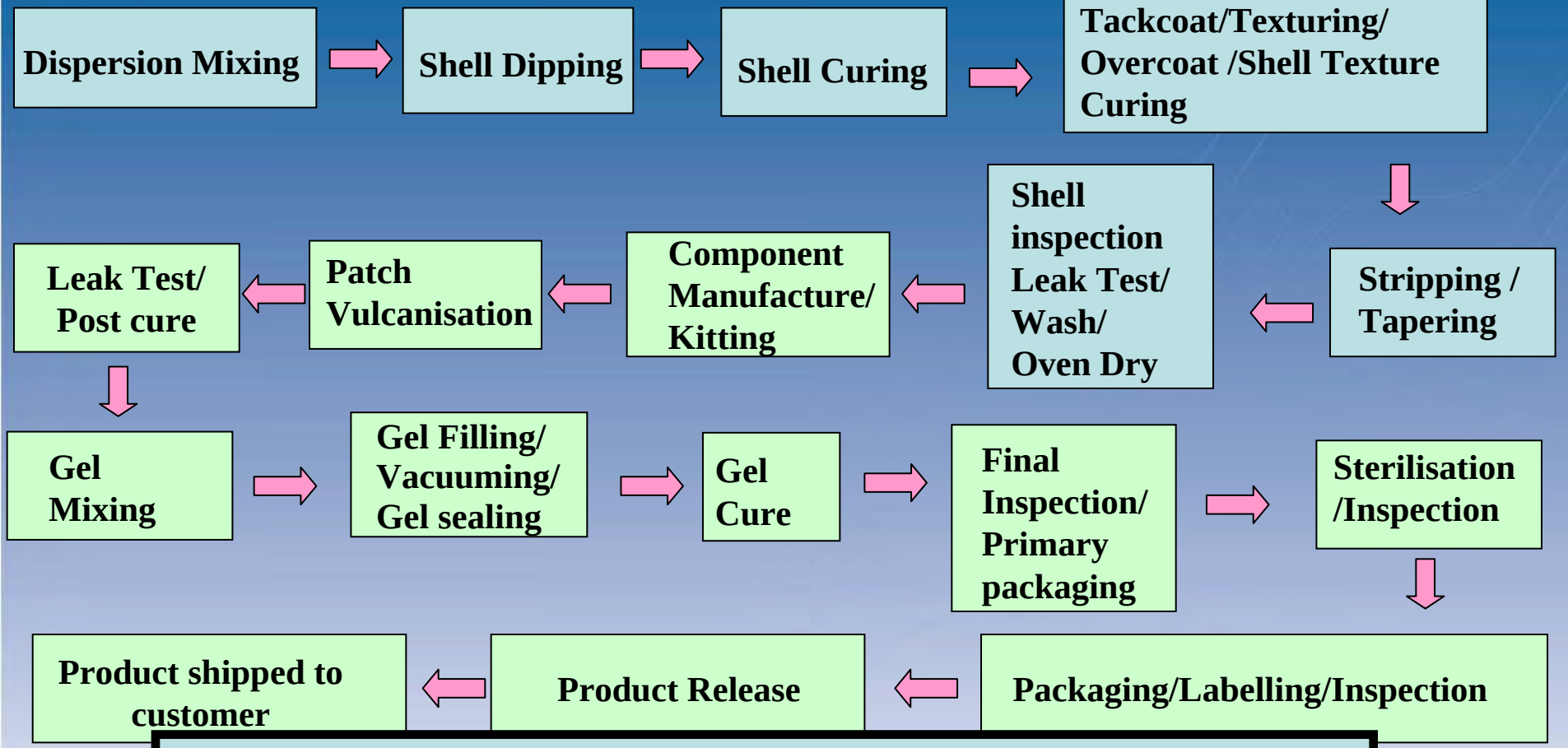
Device Technologies

- Privately owned Australian company
- Offices in VIC, QLD, NSW, SA, WA & NZ
- Diversified range of innovative products
- 10 Years Plastic Surgery Devices
- Exclusive distributor for Allergan implants
- Dedicated Plastic Surgery product team
- In-house Marketing Services
- Clinical Education
- Technical Service
- Full time Regulatory Affairs team
- Project and Systems Planning

Evolution of silicone breast implants

- **First Generation (1962-1970)** - thick shell, smooth, Dacron fixation,anatomical,viscous silicone gel
- **Second Generation (1970-1982)** – thin slightly permeable shell, smooth, no fixation, round less viscous gel
- **Third Generation (1982-1992)** – Thick,strong,low bleed shell (INTRASHIEL™) smooth, round , more viscous gel
- **Fourth Generation (1993-present)** – Thick, strong, low-bleed shell, smooth &textured, round & anatomical,more viscous(cohesive) gel
- **Fifth Generation (1993-present)** Thick, strong, low-bleed shell, smooth and textured surfaces, round and diverse anatomical shapes, enhanced cohesive gel and form-stable silicone gel.

Summary of Breast Implant Manufacturing Process at Allergan



Every Allergan Operator must train for **6 months**
BEFORE they can commence in active manufacturing

Manufacture of an Allergan Breast Implant = 7 - 10 Days

Quality at every stage….

- 146 Quality Procedures
  - Material Inspection
  - Product Inspection
  - Testing
- 123 Manufacturing Procedures
  - Sub component manufacturing / assembly
  - Implant assembly

There are over 140 Checks on EVERY Breast Implant manufactured at Allergan

“Silicone Gel” and The Allergan Collection

- All silicone gels are cross linked to maintain a gel consistency, and thus all silicone gel has cohesive properties. As the cross-linking is increased, the consistency or firmness of the “liquid-feeling” gel changes to that of soft cheese. This refers to the implant maintaining its shape in all positions (shape maintenance). These implants are designed in various anatomic dimensions in addition to round shapes and are collectively referred to as “cohesive silicone gel implants” These FORM –STABLE implants are currently popular world wide and are undergoing FDA- approved clinical trials.
- Unique 360 degree INTRASHIEL™ barrier layer to deplete gel diffusion.

* *Maxwell & Gabriel Possible Future Development of Implants and Breast Augmentation Clinic. Plastic Surg (2009)*

“Silicone Gel” and The Allergan Collection

RESPONSIVE GEL The softest cohesive gel	SOFTEST	INSPIRA™ Textured TRM/TRF/TRX INSPIRA™ Smooth SRM/SRF/SRX Style 110/120, Style MLP/MHP Style SLD/SHD, Style 40/45
SOFT-TOUCH™ GEL A slightly firmer cohesive gel offering shape control with natural movement and feeling	SOFT	INSPIRA™ Textured TSM/TSF/TSX INSPIRA™ Smooth SSM/SSF/SSX Style 410ST
COHESIVE GEL A higher cohesive gel for the ultimate shape and control	FIRM	Style 410 Style CML/CMH Style 510 Dual Gel
FIRM COHESIVE GEL Used exclusively in the tip of the Style 510	FIRMEST	Style 410 Style CML/CMH Style 510 Dual Gel

“Texture” and The Allergan Collection

Biocell™ Texture

- An aggressive open-pore textured silicone surface composed of irregular pores with average density of 3.1 pores/mm2 with a mean pore size of 289um
- For Tissue expanders Biocell texturing promotes adherence to surrounding tissue.
- For Breast Implants adherence may not occur around the entire surface; however there is a high friction coefficient around the devices, making them relatively immobile.
- Biocell has a significantly lower incident of capsular contracture than do their smooth counterparts.

**The Evolution of Breast implants Maxwell and Gabriel, Clin. Plastic Surgery 36 (2009)*

The Allergan Collection with over 400 implant selections

The most widely published breast implants on the market today including long term safety and clinical outcomes..

Breast Augmentation Devices

- INSPIRA™ **Round** matrix selection (new)
- Style 410 matrix **Anatomical**
- Style 510 Dual Gel **Anatomical**

Breast Reconstruction Devices

- Style 410 matrix **Anatomical**
- Style 510 Dual Gel **Anatomical**
- Style 133 (and 133 XP) Tissue expanders
- Style 150 expander-implant

ALLERGAN

"Every women's body is unique so choose the best fit"

The Allergan Collection - ***NEW*** INSPIRA™ Round

NEW INSPIRA™ range of **Round** implants with over 250 combinations .

- 4 profiles: Low, Moderate, Full and Extra-Full
- 2 gel choices: Responsive and *SOFT-TOUCH*™ with *a* higher % Gel fill
- More Base Diameter choices than ever before
- Both Textured and Smooth finishes

ALLERGAN

"Every women's body is unique so choose the best fit"

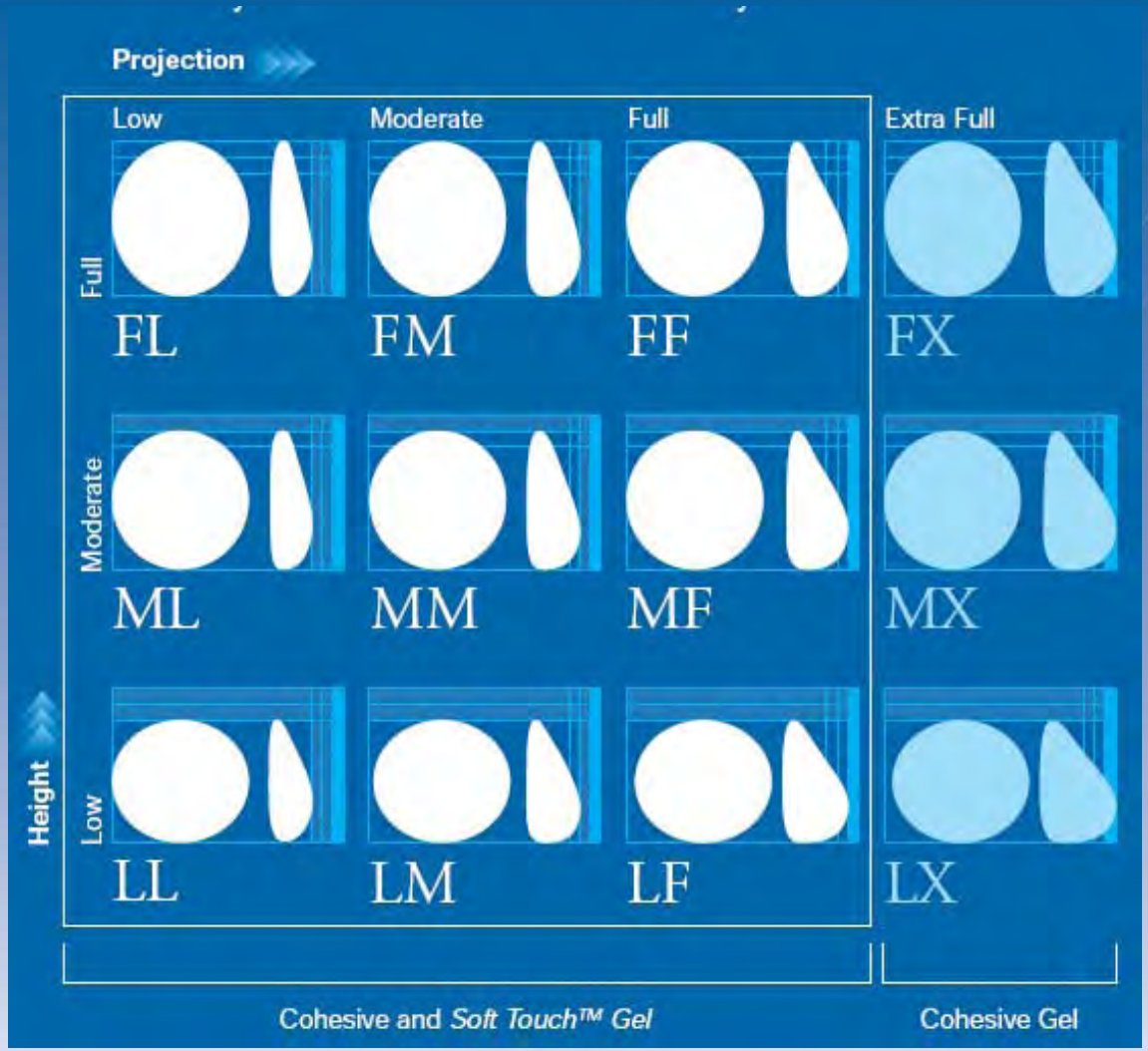
The Allergan Collection - Anatomical

- The **Style 410** Matrix is firmly established as the world's leading, most widely used and clinically proven anatomical implant. 12 years in Australia and New Zealand.

- The **Style 510**, an advancement in devices for breast reconstruction, and augmentation incorporates cohesive gel in the posterior of the implant while the implant anterior is made of a unique firmer cohesive gel; the posterior in concave and implants edges are tapered.

- The **Style 510** provides superior support and projection, emphasising the nipple areola area of the implant. It can be used for both augmentation and reconstruction surgery. It has 100% interface with chest wall avoiding lift off superiorly and medially.2 years in Australia.

BIO-Dimensional™ Matrix



ALLERGAN

"Every women's body is unique so choose the best fit"

The Allergan Collection - Anatomical

Selection of Style 410 and Style 510 Dual Gel implants based on:

- Desired base diameter first
- Implant height second (sternal notch to nipple)
- Desired projection third
- Patients' desire for a natural sloping upper pole.

For stabilisation of the implant

- Implant must snugly fit surgical pocket and is supported by plush texture.
- Post operative support is beneficial for tissue in-growth into the Biocell textured surface. (stabilizers ISBX or compression bra BNRZ)

Clinical indications when implant must shape the breast not just add volume

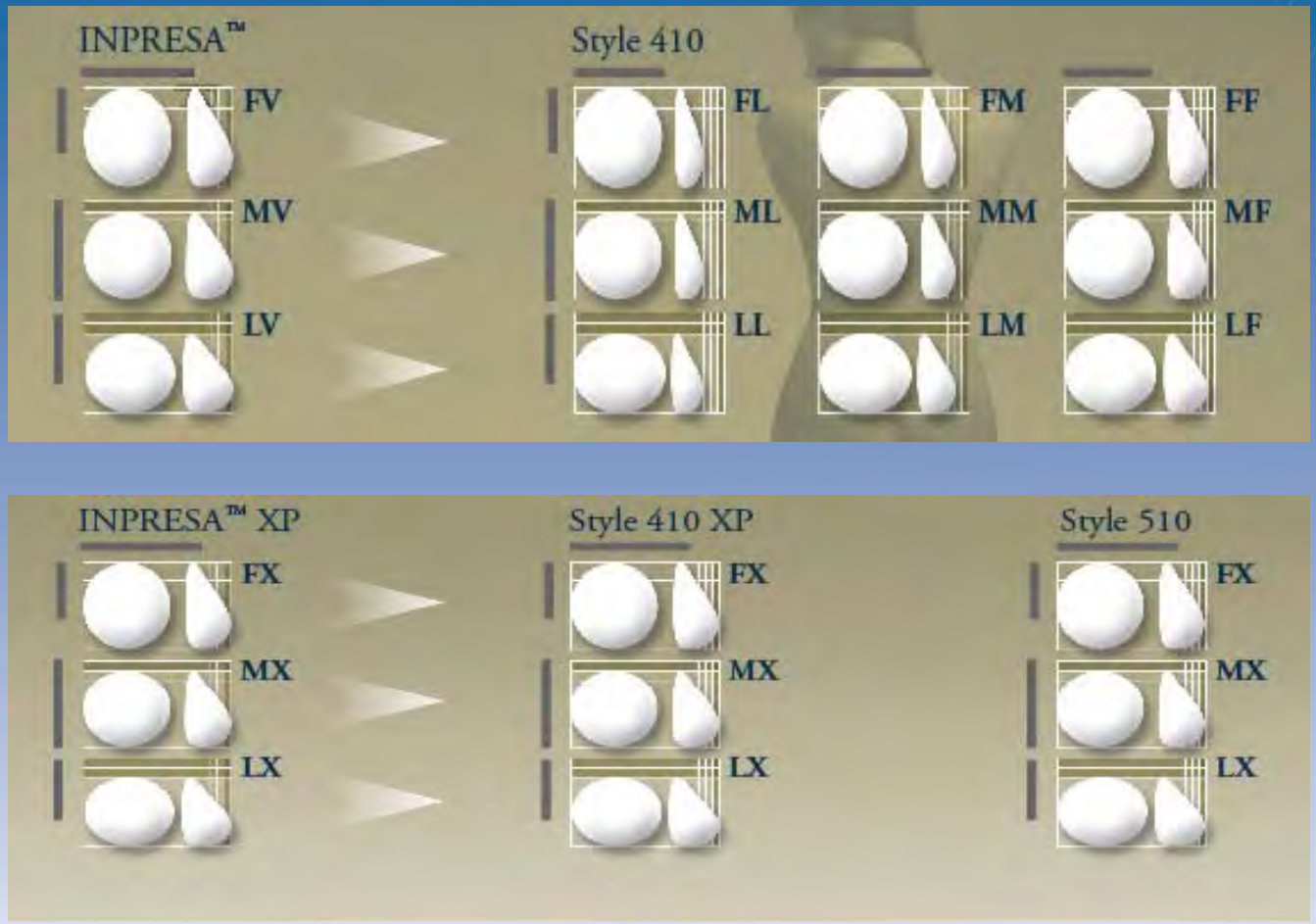
- Thin patients
- Post mastectomy reconstruction/ Asymmetry/ Tuberous breasts
- Polands syndrome

Publications :

- Style 410 is backed by clinical results in 10 years plus of implantation ; rupture and capsular contracture offer better long term results that past round implants along with decreased rippling and wrinkling

The Allergan Collection – Tissue Expanders

Style 133 and 133XP Tissue expander - 2 stage breast reconstruction



"Every women's body is unique so choose the best fit"

The Allergan Collection - Tissue Expanders

Style 133 and 133XP Tissue expanders- 2 stage breast reconstruction

- Style 133 **Full, Moderate** and **Low** height variable projection
- Style 133XP **Full, Moderate** and **Short** height extra-full projection
- Selection by base width and height matching contra lateral breast (with the use of templates)
- Projection based on contra lateral breast and desired result
- Biocell texture diminishes capsule allowing comfortable expansion and keeps expander stable- must be supported in initial post-op period
- Supplied sterile with magna-finder for detecting integrated port for inflation at surgery and postoperatively. Detects up to 6 cms of tissue
- 6 month warrantee
- Volume…can be overfilled 10 % plus and under filled if needed
- Rapid inflation desired, insitu 4-6 months
- Contra indicated for MRIs
- Most popular definitive implants are Style 410 full and extra-full projections and Style 510 Dual Gel extra projection

The Allergan Collection : Tissue Expander - Implant

Style 150 expander-implant- 1 stage reconstruction

- Full height and short height
- Selection by base width and height matching contra lateral breast with the use of templates
- Biocell texture diminishes capsule allowing comfortable expansion and keeps expander stable- must be supported in initial post-op period
- Remote injection site port allowing for long term adjustability
- Optional to remove port and seal tubing with a Fill Tube Plug Kit
- For patients desiring only one operation, best results in medium build patients. Re fashioning of IMF may be necessary.

Relevant Clinical Papers

Recent Published Clinical Papers

- **Expert Review of Medical Devices**; SL Spear & P Heden 4(5), 699 to 708 (2007)
- **Style 410 Cohesive Silicone Breast Implants: Safety & Effectiveness 5-9 years after implantation;** PRS 2006
- **Possible Future Development of Implants and Breast Augmentation;** P Maxwell & A Gabriel Clin Plastic Surg 36 (2009) 167 – 172
- **The Evolution of Breast Implants;** P Maxwell & A Gabriel Clin Plastic Surg 36 (2009) 1 – 13
- **Form –Stable Silicone Gel Breast Implants;** Mark Jewel Clin Plastic Surg 36 (2009) 75 – 89
- **The Anatomy of Revisions after Primary Breast Augmentation: One Surgeon's Perspective** SL Spear Clin Plastic Surg 36 (2009) 157 – 165
- **History of Breast Implants and the Food and Drug Administration** S Spear Clin Plastic Surg 36 (2009) 15 – 21
- **Mastopexy Augmentation with Form Stable Breast Implants**; P Heden Clin Plastic Surg 36 (2009) 91-104
- **Style 410 Highly Cohesive Silicone Breast Implant core study results at 3 years;** B Bengtson PRS June, 2007
- **Capsular Contraction; What is it? What Causes it? How can it be prevented and managed?** William P Adams Clin Plastic Surg 36 (2009) 119-126
- **Comparative Study of Breast Implant Rupture using Mammography, Sonography, and Magnetic Resonance Imaging; correlation with surgical findings.** Di Benetetto The Breast Journal Vol 14 Nov 2008 532-537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