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Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

By email to Community.Affairs.Sen@aph.gov.au

Senate Community Affairs Committee Inquiry: The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants.

Device Technologies welcomes the opportunity to provide a submission to the Senate Community Affairs Committee Inquiry.

Device Technologies Australia
Device Technologies has been a major supplier of innovative medical equipment and consumables to hospitals and healthcare professionals for over 20 years and is Australia's largest independent distributor of these products. Device Technologies is one of the TGA approved suppliers of polyurethane foam covered breast implants and also supplies smooth and textured surfaced implants to the market.

Summary
Device Technologies has noted the reporting to the Inquiry by the TGA and others concerning the relatively high complication rates of breast implant surgery and the consequent need for revision surgery. The most common complication involves the hardening of the patient's membrane tissue around the implants, known as capsular contracture. As the FDA core study of smooth and textured surfaced implants shows, this is even more common following secondary surgery. Device Technologies feels the Senate Inquiry should be aware that this high complication rate is not inevitable.

Device Technologies believes that patients should be made aware of the options, particularly PIP patients who may be undergoing replacement surgery and who face the increased risk of capsular contraction.

Capsular Contracture Facts
Polyurethane implants have been used since the 1960's and numerous papers have been published since, confirming the low capsular contracture rate associated with polyurethane implants in comparison to smooth and textured implants. There have been no papers published showing the opposite to be true.

Recent FDA core study data shows that capsular contracture is the leading complication in breast augmentation surgery when smooth and textured implants are used and the risk continues to grow with every year they remain implanted.

FDA Update on the Safety of Silicone Gel-Filled Breast Implants – June 2011

	ALLERGAN	
Complication or Outcome by Study Cohort	**4-year FU Rate (%)**	**10-year FU Rate (%)**
Capsular Contracture		
Primary Augmentation	13.2	19.1
Revision Augmentation	17.0	27.5
Primary Reconstruction	14.1	24.6
Revision Reconstruction	6.7	6.7
Re-operation		
Primary Augmentation	23.5	36.1
Revision Augmentation	35.3	46.0
Primary Reconstruction	40.9	71.9
Revision Reconstruction	33.3	46.7

	MENTOR	
Complication or Outcome by Study Cohort	**3-year FU Rate (%)**	**8-year FU Rate (%)**
Capsular Contracture		
Primary Augmentation	8.1	10.9
Revision Augmentation	18.9	24.1
Primary Reconstruction	8.3	15.3
Revision Reconstruction	16.3	23.1
Re-operation		
Primary Augmentation	15.4	20.1
Revision Augmentation	28.0	37.8
Primary Reconstruction	27.0	38.8
Revision Reconstruction	29.1	40.8

Studies on polyurethane implants have shown that after 18 years the capsular contracture rate remains low between 1-4% for breast augmentation.

"Currently, given our wide experience with the use of polyurethane-coated silicone gel implants, we may state they are the best option for augmentation mammoplasty, and have the lowest incidence of fibrous contraction (1%)."

Vázquez G. Pellón A. Polyurethane-coasted silicone gel breast implants used for 18 years. Aesthetic Plast. Surg.31:4, p.330-6, 2007.

"The longer implants are in place, the greater the cumulative risk for developing contracture."

"Polyurethane foam-covered implants are associated with a dramatic reduced rate of contracture…"

Handel, N. Condray, T., et al. A long-term study of outcomes, complications, and patient satisfaction with breast implants. Plastic and Reconstructive Surgery. Vol 117: 757-767. 2006

"Polyurethane implants have measurable advantages over smooth and mechanically textured gel-filled prostheses and do not appear to be associated with an increased risk of complications or morbidity."

Handel N. Long-term safety and efficacy of polyurethane foam-covered breast implants. Aesthetic Surg J 2006; 26: 265-274

"During the span of this author's practice, he has never been able to match the number and quality of superior results exemplified by these patients when using other devices."

Hester T. R. Tebbetts J. Maxwell G.P.The Polyurethane-covered mammary prosthesis: Facts and fiction (II). A look back and a "peek" ahead. Clinics in Plastic Surgery 2001; 28:3 579-585

Benefits of polyurethane implants have also been shown in reconstruction, where rates with textured and smooth implants have always been shown to be high. Particularly when it comes to combining cancer treatment with radiotherapy.

"In this study, severe capsular contracture was reported in 21.7% of cases with textured prosthesis and in 6.3% with polyurethane implants in patients receiving RT."

"As of today, no case of a clinically noticeable capsular contracture was seen in non-radiated patients receiving breast reconstruction with polyurethane-coasted implants…. However, in patients with textured implants, capsular contracture occurred in 8.3% of patients."

Pompei, S., Arelli, F., Labardi, L., et al. Breast reconstruction with polyurethane implants: preliminary report. Eur J Plast Surg. 2011

Device Technologies Australia trusts this submission will provide the Senate Community Affairs Committee with useful information and referenced facts and will contribute to a truly representative outcome.

We would be pleased to offer further details if required, or to attend a meeting at the Committee's convenience.

Yours sincerely

Kevin Ryan
Managing Director
Device Technologies Australia