

Ideal Implant Incorporated

Dallas, TX

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General and Plastic Surgery Devices Advisory Panel

Day 2 – March 26, 2019



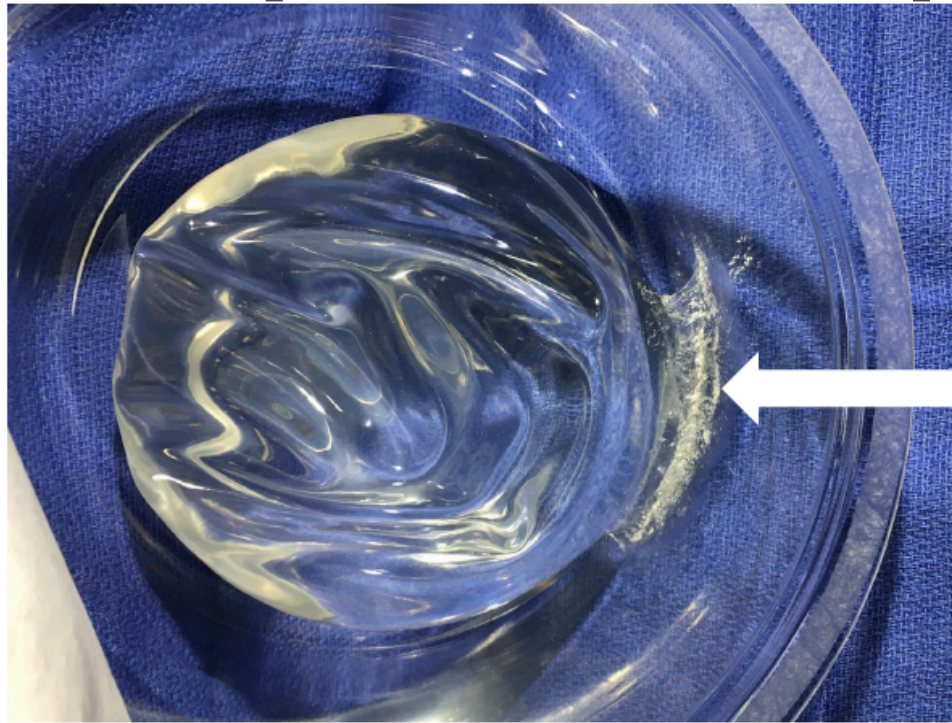
How do Women Feel about Silent Rupture?

- 2017 online randomized survey, independent third party
- 933 women – 45% RNs
- 97% would want to know if their silicone gel implant had silently ruptured
- 95% would want to replace a ruptured silicone gel implant, even if not causing symptoms

Silent Rupture of Silicone Gel Implants

- Intact implants are FDA approved as safe
- Ruptured implants are NOT approved
 - There was no 10-year clinical trial of ruptured implants
- Surgeons and patients have a dilemma:
 - Reassure and leave it in – “silicone gel implants are safe”
 - Remove it – FDA recommendation / women’s preference

A Ruptured Implant is Defective..... Before Implanted or After Implanted



Extent of Silent Rupture Problem

- >150,000 women have ruptured implants and don't know
 - Estimate based on 2007-2017 ASPS & ASAPS procedural statistics
 - Assume 1% rupture per year
 - Assume few get MRIs
- Warranty funds available for replacement (\$3,500 each)
- Patient dilemma – high cost of MRIs to access warranty funds

Is High Resolution Ultrasound an Option?

- Marc Salzman, MD presentation at ASPS
 - Ruptures confirmed in surgery
- Scanner – inexpensive, hand-held, in office
- Ideal started study - 1,000 women, 9 sites
 - Implanted between 2000-2015
 - No symptoms
 - Survey of feelings about silent rupture



Informed Consent - Optimal Process

- Surgeon *listens* to patient's concerns
- Presents all 3 implant options / choices
 - Saline, silicone gel, structured
 - Unbiased and objective information
 - Ethical informed consent process
- Women's implant choices are NOT limited
- Woman chooses implant best for her - with help of surgeon

Informed Consent - Altered by Hospital Bias

- Some hospitals limit number of vendors and implants
 - Disregard technology differences - “structured” is not “saline”
- Some hospitals block companies with physician stockholders
 - HCA, Tenet, Intermountain
 - Response to an HHS policy
- Limits women’s implant choices

Informed Consent - Altered by Surgeon Bias

- Some surgeons dismiss women's concerns
 - Silent rupture / MRIs / health issues
- Some surgeons will only use silicone gel
 - Resist change – “this implant works best for me”
 - Discourage saline-filled options
- Limits women's implant choices

“People Don’t Know What They Want
Until You Show It To Them”

Steve Jobs

CEO, Apple

“Let Me Show You all Your Choices”



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