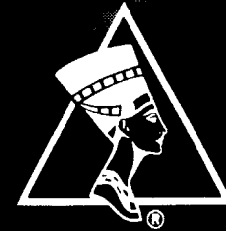




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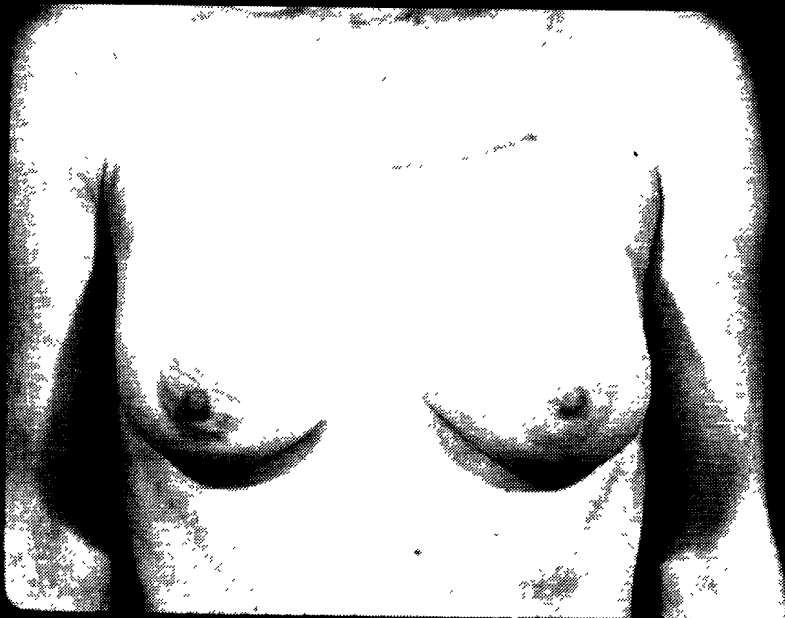
***The Silicone Breast Implant***  
***Education Symposium***

***FDA Patient Education Brochures, Informed Consent***

**ASPS/PSEF – ASAPS**

***Roxanne J. Guy, MD, FACS***

Hospital consult – 58 YOWF, enlarged  
mediastinal nodes, pericardial effusion and  
shortness of breath. Initial augmentation in  
1973, replaced in 1978. Consult date 1-5-94.



Roxanne Guy, MD - DRAFT

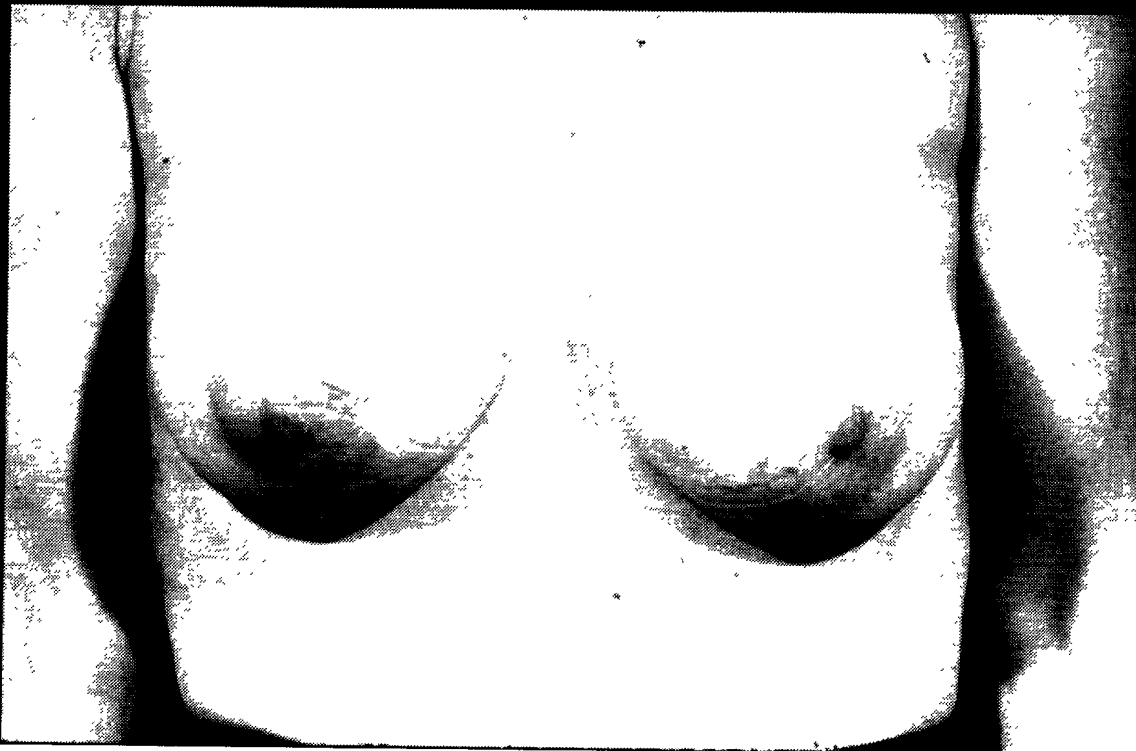


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Surgery 2-9-94 – Total capsulectomy,  
removed/replaced bilateral ruptured silicone  
implants in same subglandular pocket with  
larger, textured saline implants. Insisted on  
some sort of implant.



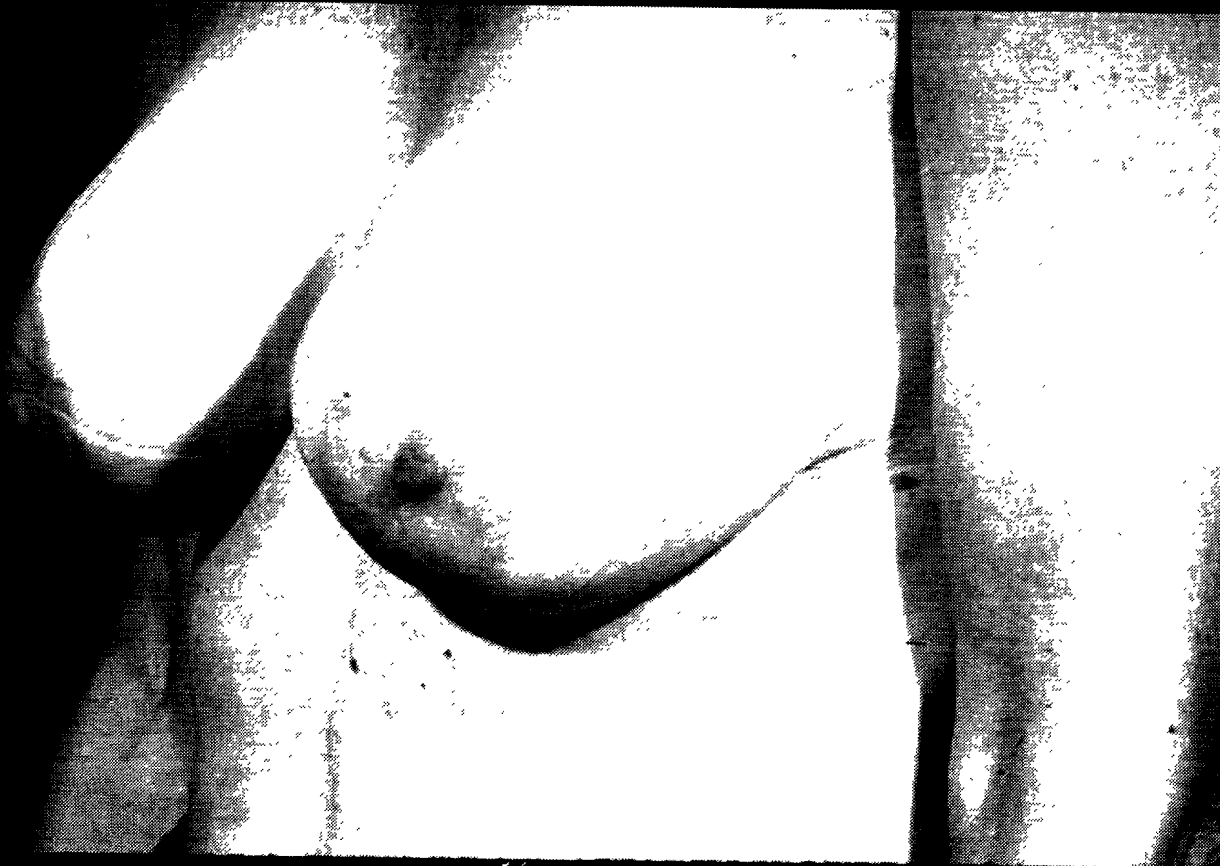


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Post op – tissue thinning, superior  
rippling and increased ptosis  
bilaterally

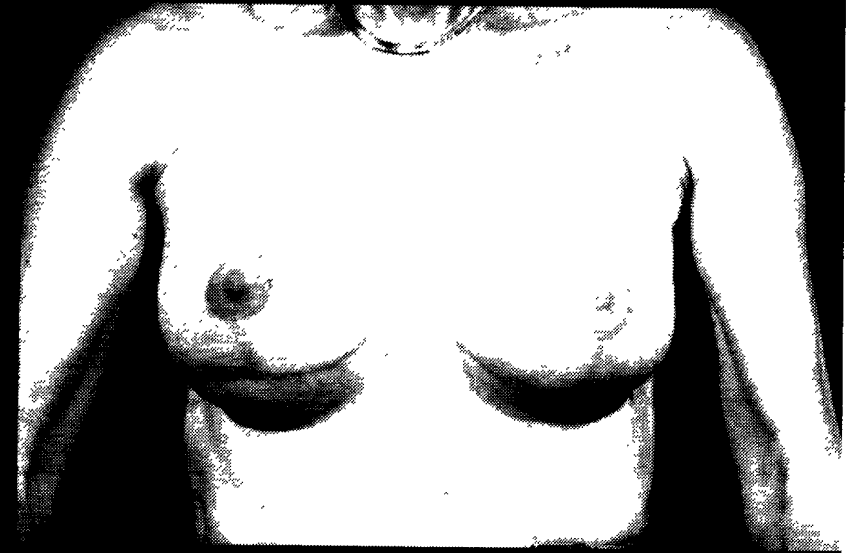
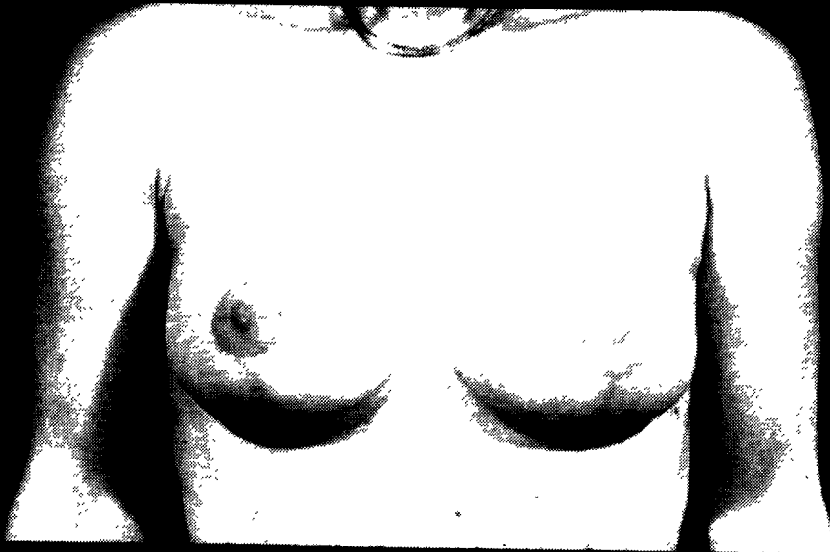




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RELEASED TO THE PUBLIC

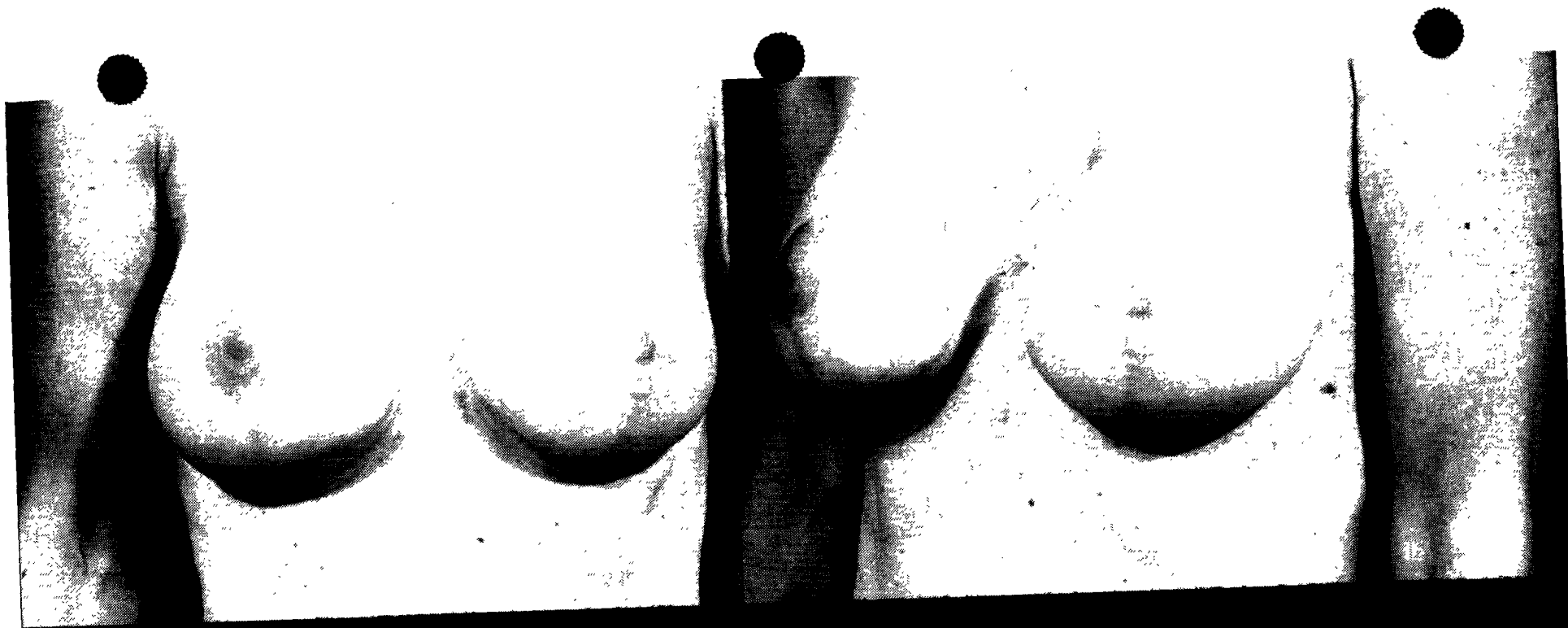


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10-4-94: Removal of textured subglandular saline implants and replacement with partial subpectoral smooth saline implants and bilateral mastopexies. Muscle distortion on pectoralis flexion

Roxanne Guy, MD - DRAFT



1-15-96: Post operative photographs 15 months  
after submuscular conversion and mastopexies

Roxanne Guy, MD - DRAFT

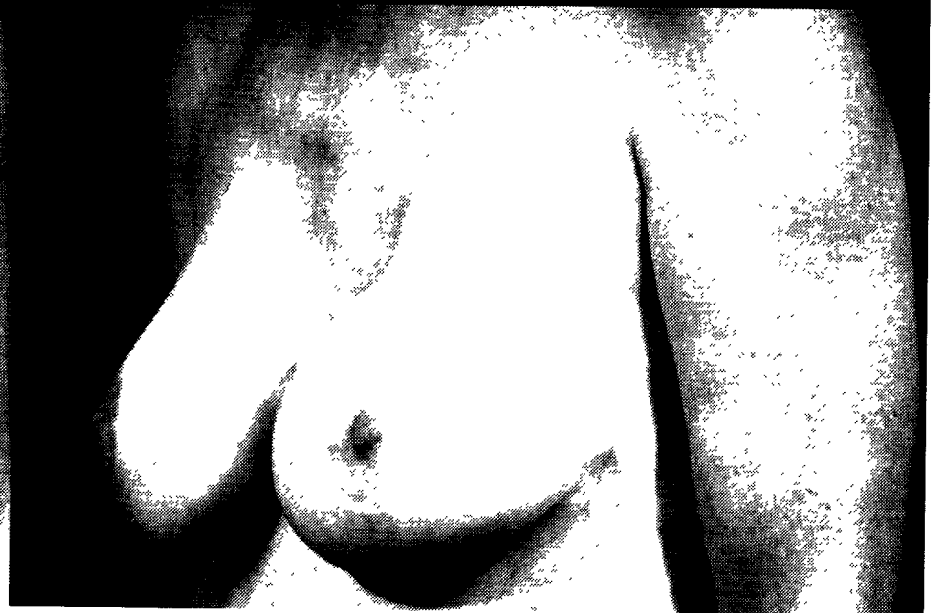
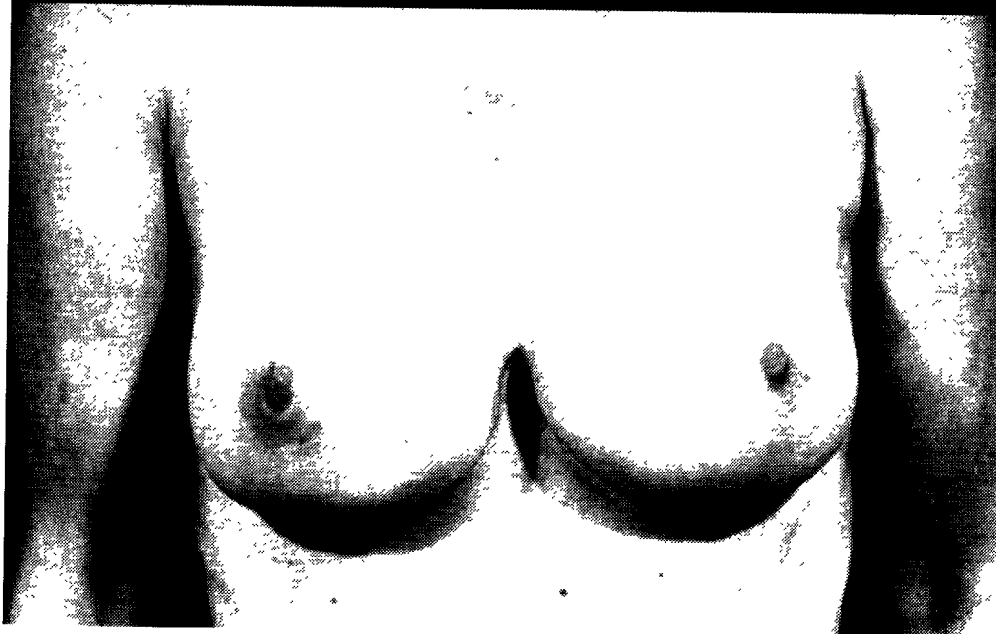


INTERNATIONAL BOARD OF STANDARDS AND PRACTICES FOR CERTIFIED PLASTIC SURGEONS



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**5-10-96: Patient now 60 years old. After second opinion, removed submuscular saline implants and replaced larger, smooth saline implants in the subglandular space. Capsulorrhaphies along inframammary folds.**





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# *Informed Consent* *Criticisms*

Roxanne Guy, MD - DRAFT

8





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# FDA Information Booklet



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## For Women



### *Breast Implants*

An Information Update

- Updated in 2000
- ASPS provided FDA with input and copy edits
- FDA earlier versions in 1998 and 1996
- 84 pages
- MO state law requires MDs give this to women
- [www.fda.gov/cdrh/breastimplants/](http://www.fda.gov/cdrh/breastimplants/)

Guy, MD ~~DRAFT~~

# FDA Brochure On Breast Implant Risks

- Companion brochure to FDA Breast Implant Update booklet
- Itemizes issues of concern
- Includes patient photos of complications
- Online Oct. 2000
- [www.fda.gov/cdrh/breastimplants/](http://www.fda.gov/cdrh/breastimplants/)



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*2/11/2003 FDA CDRH Guidance for  
Saline, Silicone Gel, and Alternative  
Breast Implants: 10.5 Patient  
Information*



- *Device names, styles, etc*
- *Brief device description with material information*
- *Indications for use*
- *Relevant contraindications, warnings, and precautions*



*2/11/2003 FDA CDRH Guidance for*  
*Saline, Silicone Gel, and Alternative*  
*Breast Implants: 10.5 Patient*  
*Information*



- *Potential complications, including the possible methods of resolution*
- *Anticipated benefits*
- *Surgical alternatives, including no treatment or no implants and the benefits and risks of each*
- *Postoperative care, including what to expect after surgery, symptoms to tell doctor about immediately, length of recovery, physical limitations, etc*



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*2/11/2003 FDA CDRH Guidance for  
Saline, Silicone Gel, and Alternative  
Breast Implants: 10.5 Patient  
Information*



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- *Factors to consider in the decision whether or not to get implants (e.g., may not be “lifetime” implant or one-time surgery, many of the changes to your breast following implantation are irreversible, breast implants may affect your ability to breast feed, routine screening mammography will be more difficult, health insurance coverage issues)*
- *Other factors to consider (e.g., choosing a surgeon, implant size and shape, surface texturing, palpability, implant placement, incision sites)*

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2/11/2003 FDA CDRH Guidance for

Saline, Silicone Gel, and Alternative

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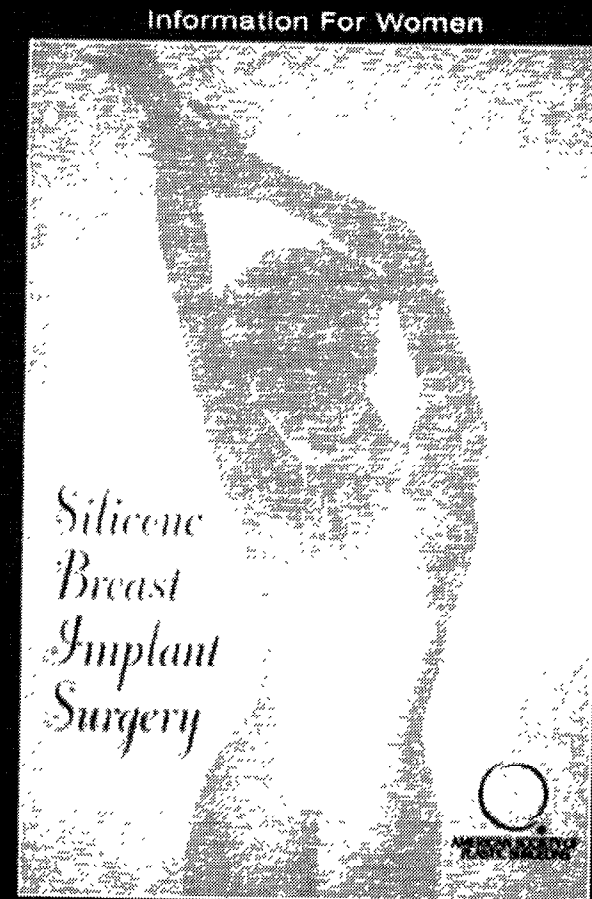


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- *Additional information related to the device such as lifetime replacement and reimbursement policy information, including estimated cost for replacement, costs not covered, etc*
- *Study safety and effectiveness results*

## Information For Women

- Focus on Silicone Gel-Filled Breast Implants
- Online patient education booklet
- Includes patient photos of complications
- Completed Sept. 2003
- Developed by Breast Implant Task Force
- [www.plasticsurgery.org](http://www.plasticsurgery.org) and [www.surgery.org](http://www.surgery.org)



# ASPS Statement Of Principle On Informed Consent

- Shared decision-making: the heart of the physician-patient relationship
- Based on ethical principles of respect for individual autonomy and dignity
- A process of communication and dialogue
- Physician provides information
- Patient makes individual choice



## *On Informed Consent (cont.)*

- Proper informed consent may include
  - Nature of surgery or treatment
  - Indications for the operation
  - Expected benefits
  - Consequences and side effects of operation



# *ASPS Statement Of Principle*



## *On Informed Consent (cont.)*

- Potential risks and adverse outcomes
- Alternatives and their benefits, risks and consequences
- Outcome anticipated

Patient signs written consent before surgery performed

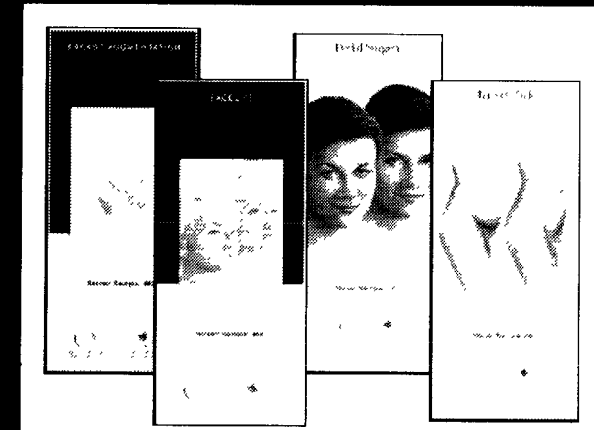
*(2004 ASPS Membership Roster and  
[www.plasticsurgery.org/psf](http://www.plasticsurgery.org/psf))*

## *What To Use?*

- Societies' brochures
- Societies' videotapes
- Manufacturer's package inserts
- Patient self tests
- Other vendors' materials
- Other sources: patients, books, web sites, FDA, etc

# *Informed Consent:* *A Process, Not a Document*

- Initial Telephone Contact
- Mail Patient Education Brochures
- Office Visit – Introductory Videotape
- Staff Interview
- Physician Consultation and Exam
- Informed Consent Document
- Show Pre and Post op Photos
- Additional Information





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# ASPS: Patient Consultation Resource Guide

## The Plastic Surgery Resource For Informed

### Consent



- More than 30 examples of PS informed consent documents
- Help patients understand benefits, risks and alternatives

Guy, MD - DRAFT



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