INNOVAL 496 Westminster Ottawa Canada K2A 2V1
Tel: 613-728-8688
Fax: 613-728-0687

Ottawa 7/24/2007

Ms. Inez P. Petersen
[redacted]

Our File No: 103961

By Mail

Dear Ms. Petersen

Thank you for your payment, received on July 23, 2007. A Statement of Account reflecting a nil balance is attached for your records.

As indicated in a June 18, 2007 communication to your legal representative, your implants, explanted by Dr. Melmed on June 5, 2007, are Mammatech round saline inflatable mammary prostheses distributed by Roger Klein of Scarsdale, New York. The implants were probably sold as a paired set under Catalog Number CT 212. Such implants did not enter U.S. commerce until the early seventies. Thus, and given your implant history, these two implants would have been inserted at one of your "redo" surgeries. As medical records were not provided, it is not known if new implants were inserted at the other "redo" surgery of if implants were reused.

Mammatech implants have a history of adverse events which worsen with dwell time. There are also remaining questions about their technology of fabrication and the efficacy of the sterilization process employed by the manufacturer.

Neither of your implants has a ruptured shell. However, both shells are drastically degraded from prolonged in vivo dwell time. The process caused a portion of the silica-reinforced silicone elastomer shell to blister, stiffen and release large quantities of silica-rich material into your surrounding tissue. Implanted or inhaled silica is a recognized substance with long term adverse effects related to chronic inflammation of the tissue it eventually lodges in. Both implants show evidence of gross contamination by viable micro-organisms in organized colonies. Medical journal publications of the early eighties describe adverse events culminating in local and systemic infections surrounding Klein/Mammatech implants.

No capsular tissue was provided. Given the calcified condition of the implant shells, this tissue would have been severely calcified with evidence of chronic inflammation over a large area. Tissue in such a condition would have been recognized as a long term risk and should have been excised by the explanting surgeon. Continuing mammographic follow up (without compression) is recommended.

WITHOUT compression

As requested, a report is provided.

Yours truly,

P. Blais, Ph.D., F.C.I.C.

Attachments

INNOVAL 496 Westminster Ave Ottawa Canada K2A 2V1
TEL: (613) 728-8688
FAX: (613) 728-0687

DATA ENTRY SYSTEM 6000

MODIFIED ID REPORT DATED 7/24/2007 UPDATED

CONFIDENTIAL - PERSONAL INFORMATION

CODE 103961
LAST NAME Petersen (Somerville)
FIRST NAME Inez P.
STREET [redacted]
CITY PROVINCE/STATE [redacted] 98022
DATE FILE OPEN./MAT. REC. June 7, 07

DOB: [redacted]

REPORT REQUESTED BY :
Ms. I.P. Petersen

MATERIAL RECEIVED 2 implants
DATE IMPLANTED 09/23/69 (Dr. W. Scott Brown, Seattle, WA) - see History
DATE EXPLANTED 06/05/07 (Dr. E. Melmed, Dallas, TX) - see History
IMPLANTATION RATIONALE Cosmetic Augmentation

DWELL TIME 38 Years
MULTI-IMPLANTS Yes

IMPLANT SPECIFICATIONS

	LEFT	RIGHT
MFR / TYPE	Same Type, Contemporaneous (not made as a paired set)	Roger Klein Mammatech, Round Saline Inflatable, Peri-Areolar Inverted Center Tube (50-51 mm patch as overlay on 38-39 mm aperture)
STYLE	CT	CT
NOMIN. SIZE	250-350 cc	250-350 cc
PATCH MARK	None	None
SHELL MARK	None	None
CAT. No.	CT 212	CT 212
LOT No.	Unknown	Unknown

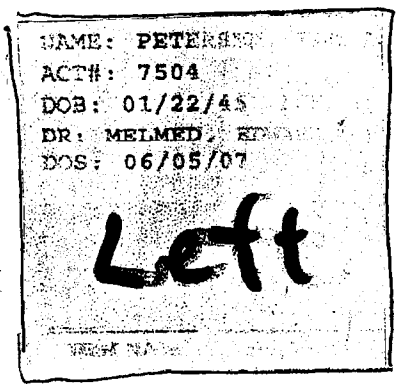
SUMMARY OF FINDINGS

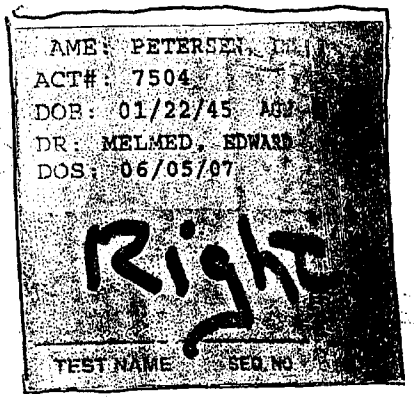
	LEFT	RIGHT
IMPLANT	Not ruptured, overfilled, severe shell degradation (blistering, calcified, spherulitic), white flocculent material in saline (100-200 mg), plug cap in place	Not ruptured, overfilled, severe shell degradation (blistering, calcified, spherulitic), white flocculent material in saline (200-300 mg), plug cap in place
CAPSULE	Not Provided - Grossly calcified (on basis of implant condition)	Not Provided - Grossly calcified (on basis of implant condition)
WEIGHT	357.4 gm	362.3 gm

NOTES

Specimen Reception: Two implants are received in 750 cc press-top plastic conical containers. Clinical labels on the containers provide patient data and side of origin. No capsular tissue is included. The specimens are sent by the patient. Upon completion of the study, the implants are placed in individual self-seal bags and returned to their containers.

Clinical Labels:





July 24/07

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Petersen (Somerville) 103961

Symptoms: left breast infection, flu-like symptoms, recurrent bouts of pneumonia, urinary and respiratory infections, extreme fatigue, fibromyalgia, arthralgias, skin rashes, neurocognitive problems, serologic profile with Herpes, Cytomegalovirus, Mycoplasma and Epstein Barr antibodies

History: (no records provided, info from patient)
09/23/69 - (Dr. W. Scott Brown) - office surgery - augmentation mammoplasty with insertion of mammary prostheses, "old type" with "tube" and a "stopper", obtained from a "foreign country" (*most probably Simaplast saline inflatable with side tube*)
xx/xx/69 - infection, left breast with purulent exudate at incision site - antibiotics prescribed
xx/xx/xx - (Dr. W. Scott Brown) - revision surgery (implant replacement)
xx/xx/xx - (Dr. W. Scott Brown) - revision surgery (possible implant replacement or reuse)
xx/xx/97 - worsening disability, serologic abnormalities (rheumatoid, etc.)
xx/xx/xx - MRI studies (breast and neurological)
06/05/07 - (Dr. E. Melmed) - removal of implants; bilateral mastopexy

Implant Identification: The implants are identified by direct examination as Mammatech round saline inflatables, distributed by Roger Klein Assoc. of Scarsdale, New York. The implants are fitted with a Peri-Areolar Inverted Center Tube intended for anterior *in situ* filling. They are of the large type with a nominal fill rating of 250-350 cc, consistent with Catalog Number CT 212. The principal identification characteristics include a thick molded shell with a clearly visible seam (flashing) on the equator, a prominent filling tube on the anterior side in nearly exact coincidence with the apex. The filling tube is everted internally and a slightly oversize ovoid Teflon plug is inserted as an occluder. This implant design was primarily intended for insertion through a periareolar (nipple periphery) incision. Such implants were sold as empty shells and were intended to be filled intraoperatively with aqueous-based fluids. Both of the provided implants reflect manufacturing techniques employed circa 1971-74. In their original state, and as supplied, the filling tube would have projected externally by about 8-10 cm. It would have been subsequently cut to 10-16 mm after filling with the tube in the externalized condition. The tube would have then been pushed within the shell enclosure and the obturating plug would have been inserted to ensure patency of the saline-containment system. Such implants were provided without valve mechanisms. The "Inverted" fill tube which appears in the product name is the principal identification characteristic of such devices. The implants have a single layer posterior patch of about 50-51 mm applied externally at a shell aperture of 38-39 mm. The patch is featureless and there is a layer of coarsely applied adhesive at its periphery to improve sealing of the poorly-mated lap. Shell dimensions and gravimetric measurements are consistent with the large size implant (Catalog Number CT 212).

MDL 926 Unique Identifier Issues: There is no published MDL 926 Unique Identifier for these mammary prostheses. However, there are distinctive criteria of identification such as the unique filling tubes, valve configurations and patch designs. The commercial history of the product is provided in Appendix A. Catalog excerpts are in Appendix B.

Composition of Constituents Employed in Roger Klein/Mammatech Mammary Prostheses: Mammatech implants did not comprise Dow Corning raw materials in significant quantities. Based on available Lot History records, such implants were mostly made from silicone raw materials obtained from General Electric and other providers of general purpose silicone-based substances. The Dow Corning Settlement does not list Klein, Mammatech or Simaplast implants as eligible products under provisions of Class 7 ("Silicone Materials").

July 24/07

...3

Summary: In 1969, Ms. Petersen was implanted with saline inflatable mammary prostheses. Based on the time of implantation and the patient's description of the implants as "old type" with "tube" and a "stopper", obtained from a "foreign country", the prostheses could only have been early Simaplast products sold in North America by Roger Klein. Complications presented early with the incision failed to heal and evidence of intracapsular infection. Two revision surgeries took place. Medical records were not provided. Based on the identity and type of implants recovered at the explantation of 2007, the original implants inserted in 1969 were replaced at one or both of the intervening surgeries. It is also probable that one or more implants were reused at one of the 'replacement' surgeries. In June 2007, and with longstanding health problems and serologic abnormalities, Ms. Petersen underwent definitive removal of the implants. Bilateral mastopxies were also performed.

The implants removed on June 5, 2007 were received at Innoval on June 7, 2007. The contemporaneous study on the explanted material identified the prostheses as Mammatech round saline inflatables, distributed by Roger Klein Assoc. of Scarsdale, New York. They were of the Peri-Areolar Inverted Center Tube type, with a nominal fill rating of 250-350 cc. The products would have been sold as a paired set under Catalog Number CT 212. Mammatech implants of this kind did not enter U.S. commerce until the seventies. Thus, they are consistent with implants inserted at one of the replcement surgeries.

Such implants were designed to be inserted in a deflated condition and filled in situ, a procedure which unavoidably introduced contaminants such as tissue, blood products and micro-organisms into the saline charge. Details pertinent to the insertion technique are comprised in Appendix B. Based on publications of the early eighties, there is a strong possibility that the interior compartment of the implants was not subjected to appropriate sterilization procedures, resulting in surviving micro-organisms. These organisms would then have used nutrients such as the tissue and blood products. Over time, the interior of the implants would have developed a large population of viable micro-organisms.

Degradation and calcification of the shell material then took place, affecting a large part of the anterior side near the filling tube and the patch. The destructive processes penetrated a large fraction of the shell thickness causing it to become porous, blistered and stiff. Major defects would then have formed and allowed passage of low molecular weight substances. Bypass leakage from the plug/fill tube area resulted from secondary tissue-ingrowth and through shell defects and may have allowed some of the micro-organisms initially captive within the saline compartment to egress into the intracapsular space, giving rise to infective phenomena. With ongoing degradation of the shell material, the shell surface became blistered and brittle causing parts of the surface to detach as fine debris. Large portions of the shell surface eroded, exposing silica particles. Silicone elastomers of the kind used for Ms. Petersen's Mammatech implant shells contained more than 25-30% of the total weight as silica-reinforcing filler. Silica, a potent tissue irritant and fibrotic agent, would have elicited chronic inflammation of the capsular tissue and accelerated formation of fibrous tissue which adhered to the shell surface causing additional degradation through mechanical ingrowth. Calcification of the tissue would have taken place concurrently. These aspects are discussed in Appendix C, as part of problems habitually encountered by saline inflatable implant users. During the late dwell time, osmotic pressure would have increased the amount of aqueous fluid within the implants until the shells stretched, increasing the rate of transport across the degraded shell material. On balance of probability, the degraded shell material would have accelerated the formation of silica-specific antibodies as the stressed and reactive silica-rich surface increased until it reached about 20% of the outer shell surface.

On direct examination, Ms. Petersen's implants showed large quantities of flocculent material including 'biofilm' aggregates, reflecting ongoing micobiological activity of longstanding. Parts of this biomass were strongly colored indicating the presence of multiple types of biological organisms. Some of this material, on detailed examination through the transparent portions of the shell, was consistent with mycobacteria as evidenced by the presence of multi-colored agglomerated hyphae. Such a finding confirmed gross micro-biological colonization of both implants and is consistent with the user's history of chronic infective events. Formation of bacteria within saline-containing implants is a common occurrence and habitually reflects major production and/or intraoperative errors. This issue is further discussed in Appendix D.

July 24/07

...4

SIMAPLAST, KLEIN AND MAMMATECH SALINE-FILLED MAMMARY IMPLANTS

Introduction:
Saline-filled mammary augmentation devices first appeared commercially in France in the early sixties. Production was initiated circa 1965 under Simaplast S.A., a corporation located in the south of France. The first production versions consisted of a simple silicone bag made by joining two half-shells or molded elastomer and forming a filling tube integrally by bonding the projecting strip of elastomer which extended from the perimeter of each half shell. These devices were quasi-spherical in shape and had side tubes employed for filling. Closure was achieved by knotting this seamed side tube or by inserting a solid Teflon™ plug into its lumen.

These early saline designs were credited to H. Arion, a French physician. They were imported to the U.S. by Roger Klein Assoc. which later became the Mammatech Corporation. Distribution of the early Simaplast inflatables in North America was limited to about 1967-71. The original design was superseded by other versions from the same source. A small number of these evolutionary variants were made during the period 1970-76. Most were inserted incidental to unsanctioned clinical investigations. A few entered commerce through conferences and by personal contact with foreign distributors and clinicians. The last variant associated with H. Arion is described in U.S. Patent 3,860,969 which was granted on January 21, 1975. It consisted of a device with a central posterior tube intended to be coiled into a posterior recess. Unlike the earlier versions, the late Arions had shells made from General Electric polycarbonate-silicone copolymer. They were not silicone devices per se.

Later variants produced by Simaplast, specifically for Roger Klein Assoc., copied design elements of the "Jenny" style inflatable implants which were then made commercially in the U.S. by the Heyer-Schulte Corporation, a competing implant firm. These Klein implants were sold under the brand of Mammatech and may have been made in part at U.S. facilities using components manufactured by Simaplast. The Klein product line was later broadened to include other variations of saline and gel implants which are not of Arion design.

Fabrication Aspects:
The fabrication technology of the most widely sold Mammatech inflatables was based on acetoxy catalyzed room temperature vulcanizing silicone (RTV) shell materials. The products were not consistently made and there appears to have been poor control over key processes. Some of the elastomeric shell components incorporated large amounts of mineral fillers. The fillers enhanced the osmotic permeability of the shell and drastically reduced durability causing early ruptures and deflations. General Electric silicones were used almost exclusive for items made after 1970. Dow Corning silicone constituent materials reappeared in items made in the late seventies. Performance of the devices was erratic and shell material frequently calcified or degraded to crumbly substances. Components suffered embrittlement, sometimes with debonding and deflation frequently took place after 3-6 years in situ. Many of the Klein saline devices were explanted after users reported prolonged chronic recurring infections.

Competing corporations copied the Arion concept and introduced modifications to the valve/filling port. Klein and Simaplast products were subsequently overshadowed by the U.S.-based implant makers who had more production capacity. Devices fundamentally similar to the Arion and Mammatech designs appeared in the mid and late-seventies. Dow Corning, 3M/ McGhan, Cox-Uphoff and the Medical Engineering Corporation, as well as foreign corporations entered the inflatable breast implant market. The original makers of saline implants received significant competition, even outside the U.S., with the emergence of PMT Corp, Perouse and Eurosilicone S.A. Still more variations on the original concepts of Arion appeared. Heyer-Schulte cataloged devices credited to Birnbaum, Tabari and Jenny. Valves were re-designed to circumvent patent aspects and to reduce fabrication costs. Valve and shell failures with early deflation were encountered in progressively greater number. Litigation emerged as a significant cost factor in the late-seventies and claims came from physicians as well as patients.

Commercial Aspects of Saline Implants:
By the early eighties, most corporations had discontinued the salines. Klein/Mammatech products, targeted in much of the litigation, were discontinued and the distributor was forced into receivership following publication of papers on fungal infections secondary to the use of Klein products. Some of the other firms continued to market saline inflatables but the products were largely abandoned by the clinical community until the FDA Moratorium on gel-filled prosthetic systems on January 6, 1992.

Fragmentary records and proceedings confirm that residual property from the bankrupt Roger Klein Assoc. was acquired by Bioplasty circa 1986-87. Bioplasty then emerged as yet another maker of breast implants. The Bioplasty line originally consisted of the "Molecular Impact Surface Textured Implant" (MISTI). Such products were made in single shell, multiple shell (double lumen), gel-filled and saline-filled versions. They were supplemented in 1988 by the MISTI GOLD™, a textured single-lumen implant filled with water thickened by a synthetic substance, polyvinylpyrrolidone (PVP). Bioplasty termed these variants of saline inflatables as 'bio-oncotic gel-filled' implants. Commercialization took place in late 1990 under the 510k provisions of the Food and Drug Administration (FDA) Medical Device regulations. Bioplasty's gel and shell material suppliers included Dow Corning (1987-1988), Admiral Materials (1987-1988) and Applied Silicone (1988-1992). The PVP filling material used in the Misti Gold was the same substance which had been withdrawn from commerce shortly after World War II where it had been used as a plasma expander. Adverse effects from intravenous and intramuscular absorption of PVP were widely reported amongst veterans who received the product. Promotional literature from Bioplasty claimed PVP to be quickly eliminated by the kidneys. Claims to the effect that PVP id not cause granulomas in tissue were also made. Bioplasty made further assertions about reduced contracture and the detectability of tumors with their prostheses in situ. The FDA deemed the claims unfounded. The dispute led to seizure of Bioplasty products circa 1991. Bioplasty entered bankruptcy in 1992 and its assets were purchased by NovaMed, another controversial implant maker from Houston, Texas. NovaMed continued to market Bioplasty-like implants under alternate tradenames until about January 2000 until offshore recalls forced discontinuation of some of its products. Thus, Simaplast and Roger Klein continued in part under Bioplasty which, contrary to general beliefs, continues to this day under NovaMed. These corporations were not settling defendants under MDL 926 as all were deemed to be bankrupt.

Improvised Applications of Saline Inflatables as Tissue Expanders:
Saline inflatables with Klein/Simaplast style filling tubes were once employed as tissue expanders. This was done by severing part of the filling tube and coupling the stem to silicone tubes sometimes externalized through an opening for post-operative filling. Hickman-type percutaneous catheters or Port-a-Caths™ designed for percutaneous drug delivery were also used in conjunction with the modified implants. These provided wholly implanted tissue expanders where even the filling port was buried in tissue at sites remote from the implant, specifically the axillae or abdomen.

Results were disappointing and adverse reactions, particularly infective episodes, were encountered in large numbers. Later, tissue expanders were investigated as commercial undertakings by Simaplast/Klein but were not sold in large numbers. Competing corporations such as Heyer-Schulte and Surgitek made copies and dominated the market. These products were based on fundamentally different technologies. They were designed for post-implantation filling using percutaneous injection ports. Tissue expanders with ports that are continuously accessed are virtually impossible to keep sterile, notwithstanding that gross leakage and ruptures occur because of the high injection pressures. The saline filling solution becomes rapidly colonized, reaching septic conditions.

Injury Compensation Under MDL 926 and other U.S. or Canadian Settlements:
Roger Klein Assoc. and the Mammatech corporation are deemed to be under receivership and are not participants in MDL 926. The principal subcontractor for Klein/Mammatech products, Simaplast S.A., a French-based corporation, is also deemed bankrupt. However, its assets were sold to other European-registered corporations circa 1988. Formal dissolution of the Simaplast group was followed by the acquisition of its assets which were consolidated under Poly Implant Prosthèses (PIP). PIP continues as a manufacturer of plastic surgery products in France. Foreign manufacturers of this kind are fluid organizations and extraterritorial claims are difficult to process. There are long-arm statutes which may give U.S.-based plaintiffs jurisdiction over countries that voluntarily do business in the U.S.

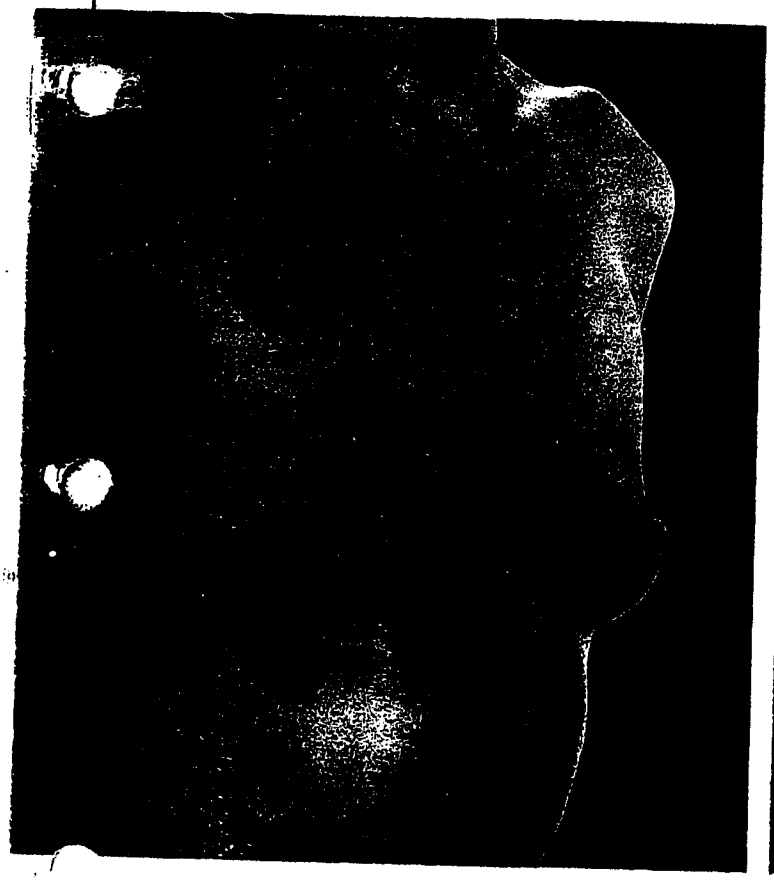
Information originating from the Claims Administrator and committees of MDL 926 suggest that compensation may be possible under special provisions made for Bioplasty Claimants. Bioplasty, a non-solvent defendant, was listed as a Released Party under Exhibit B of early agreements. If so, Roger Klein Assoc., Mammatech and Bioplasty claimants would be deemed eligible for certain benefits. The status of non-U.S. Simaplast, Roger Klein, Mammatech and Bioplasty plaintiffs under the U.S. Revised Breast Implant Settlement Program (1996) and the Canadian-based partial settlements is not specifically addressed.

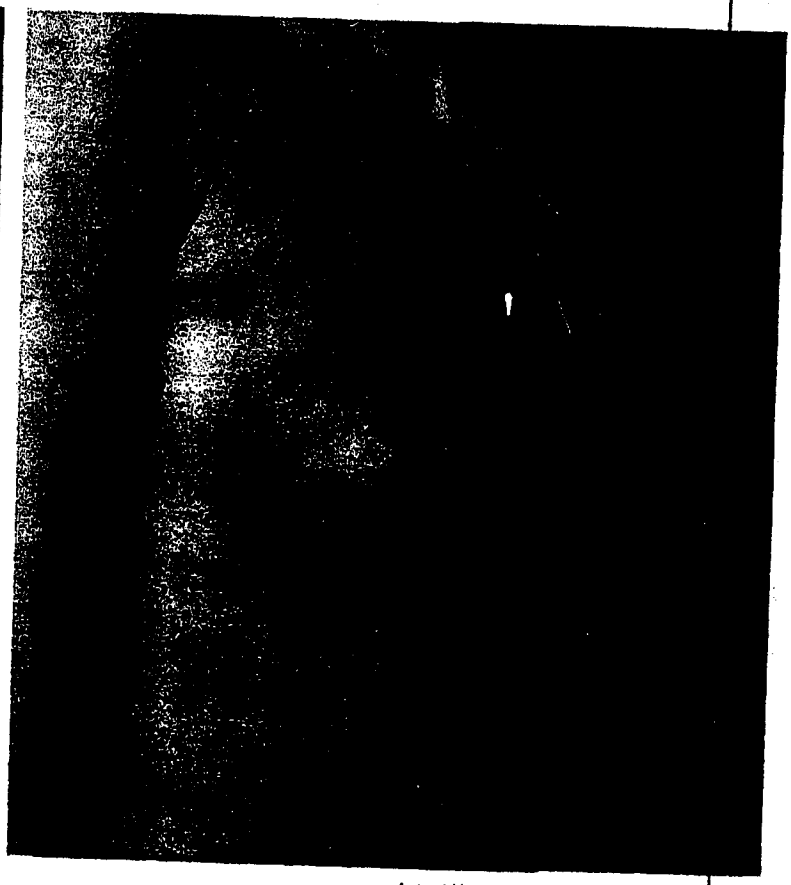
EXCERPT OF CATALOG FOR ROGER KLEIN/MAMMATECH SALINE PROSTHESES

Descriptive technical information extracted from Roger Klein brochure issued circa 1972. Note presence of the Peri-Areolar Inverted Center Tube versions shown as CT212.

MAMMATECH MAMMARY IMPLANT

Inflatable Seamless Sterile





Actual Unretouched Photographs

DESCRIPTION

Mammatech prostheses are available, sterile, in various sizes to accommodate the specific volume of the breast desired. Peri-areolar or infra-mammary approach can be used for subdermal or submuscular[1] implantation.

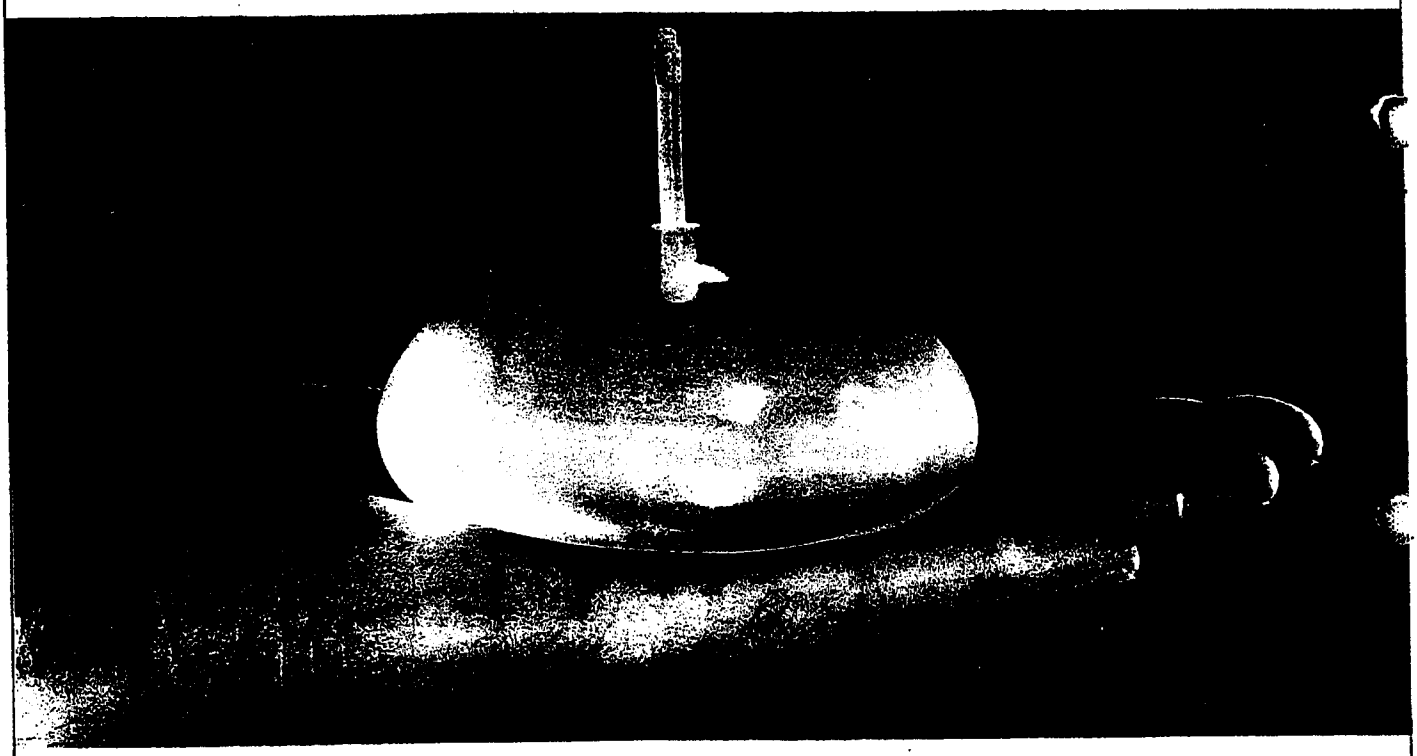
The Mammatech prosthesis consists of an inflatable,[2] thin walled, seamless pouch shaped like a normal breast; made of high tear resistant medical grade silicone elastomer, which is among the most inert implant material available.[3]

A marked advantage is the use of physiological saline as the filling fluid.

INDICATION

For implantation for augmentation of the breast in cases of amastia[4] hypomastia,[4] hypotrophy,[5] hypoplasia,[6] asymmetry, and replacement following subcutaneous or radical mastectomy.[7,8]

CT 210–CT 212
Mammatech Peri-Areolar
Inverted Center Tube



ADVANTAGES

1. Peri-areolar approach: no scar on the mammary fold.
2. Local tissue acceptance with minimal fibrous tissue formation.
3. Harmlessness of the prosthetic liquid.
4. Motion and suppleness comparable to normal breasts.
5. Symmetry of the breasts may be achieved readily.
6. The retractable tube eliminates the risk of abrasion of the sutured site.

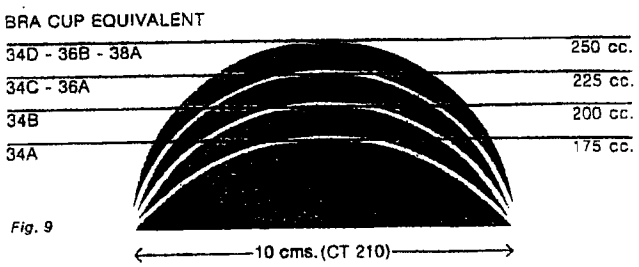


Fig. 9

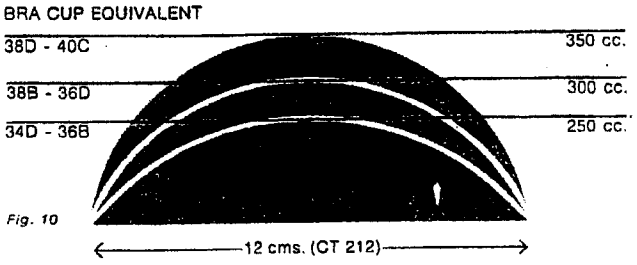


Fig. 10

The amount of physiological saline to be instilled in the protheses ranges from 170 cc. to 350 cc. depending on the size or volume of the breast desired.

OPERATIVE TECHNIQUE

As Performed by Dr. Thomas D. Rees, New York

A one inch incision is made inferiorly following the semicircular line of the areola at the junction of the pigmented and the lighter skin of the breast.

A skin flap is elevated caudally for a distance of about 4 cm. to protect the neurovascular supply to the areola and nipple. The dissection is then turned inward directly through the inferior portion of the parenchyma down to the pectoralis fascia. A pocket is formed by blunt dissection between the gland and the muscle to accommodate the prosthesis. This pocket should have a minimum size of six to seven inches. All bleeders are controlled with cautery or ties.

The prosthesis is conveniently folded around the filling tube and inserted. It is filled in situ with the desired amount of sterile physiological saline solution. After the desired symmetry and size has been achieved, the prosthesis is plugged. (See figure 12)

The wound is closed in layers using 4-0 colorless nylon in the parenchyma and a running subcuticular 5-0 nylon suture in the skin. Steri-strips are applied. An all elastic brassiere of the proper size is used in lieu of dressings. The patient is instructed to wear this brassiere day and night for a period of two weeks.

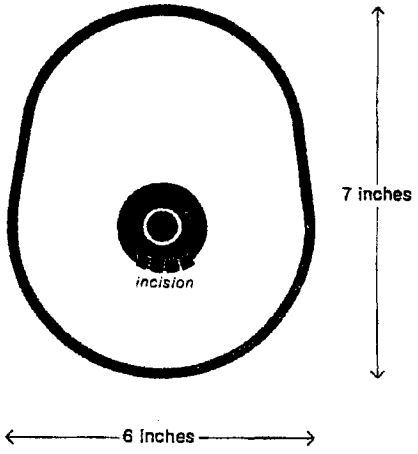


Fig. 11

The extent of undermining for CT 212 (5 inches diam.) should have an average diameter of 6 to 7 inches; slightly smaller for CT 210 (4 inches diam.).

(Photo right) In a controlled atmosphere room, each prosthesis is inspected under magnification for defects. It is then thoroughly tested for leakage by inflation prior to packing, sealing and sterilizing.

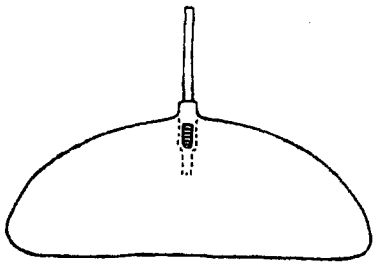


Fig. 12

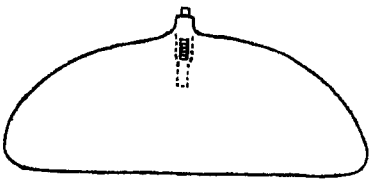


Fig. 13

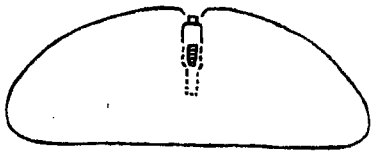
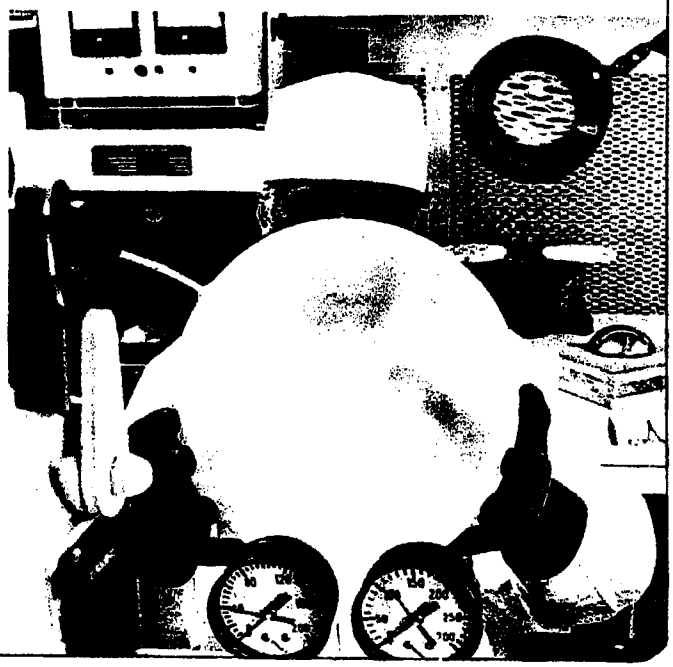


Fig. 14

CLOSING THE PROSTHESIS (After Filling)

1. Place the pierced end of the teflon plug on the tip of the special instrument and push it into the filling tube until it can go no further.
2. Pull gently on the tube until the cuff shows for about one half centimeter (3/16"). Cut the tube close to the cuff being careful not to damage the cuff.
3. The portion of the tube remaining on the prosthesis is pushed inside, using the finger or blunt instrument, until it pops in.



SUGGESTED SURGICAL TECHNIQUE

The surface of the area to be undermined is first marked with a dermographic pencil. This surface should have an average diameter of six inches (15 cm.) to seven inches (18 cm.), the lower part being two inches below the lower edge of the areola where a one inch incision is made.

Retromammary detachment is carried out by blunt dissection between the anterior surface of the fascia and the mammary gland.

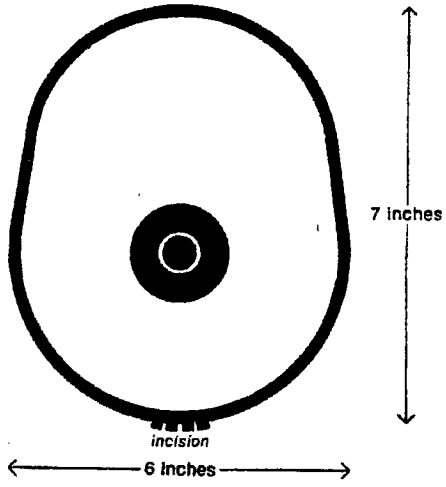


Fig. 16

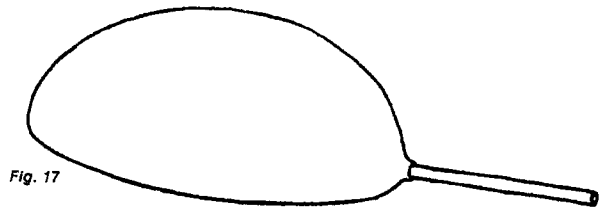


Fig. 17

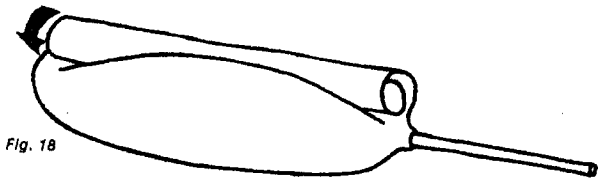


Fig. 18

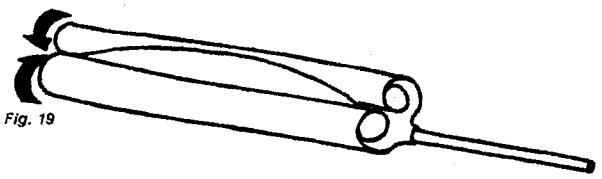


Fig. 19

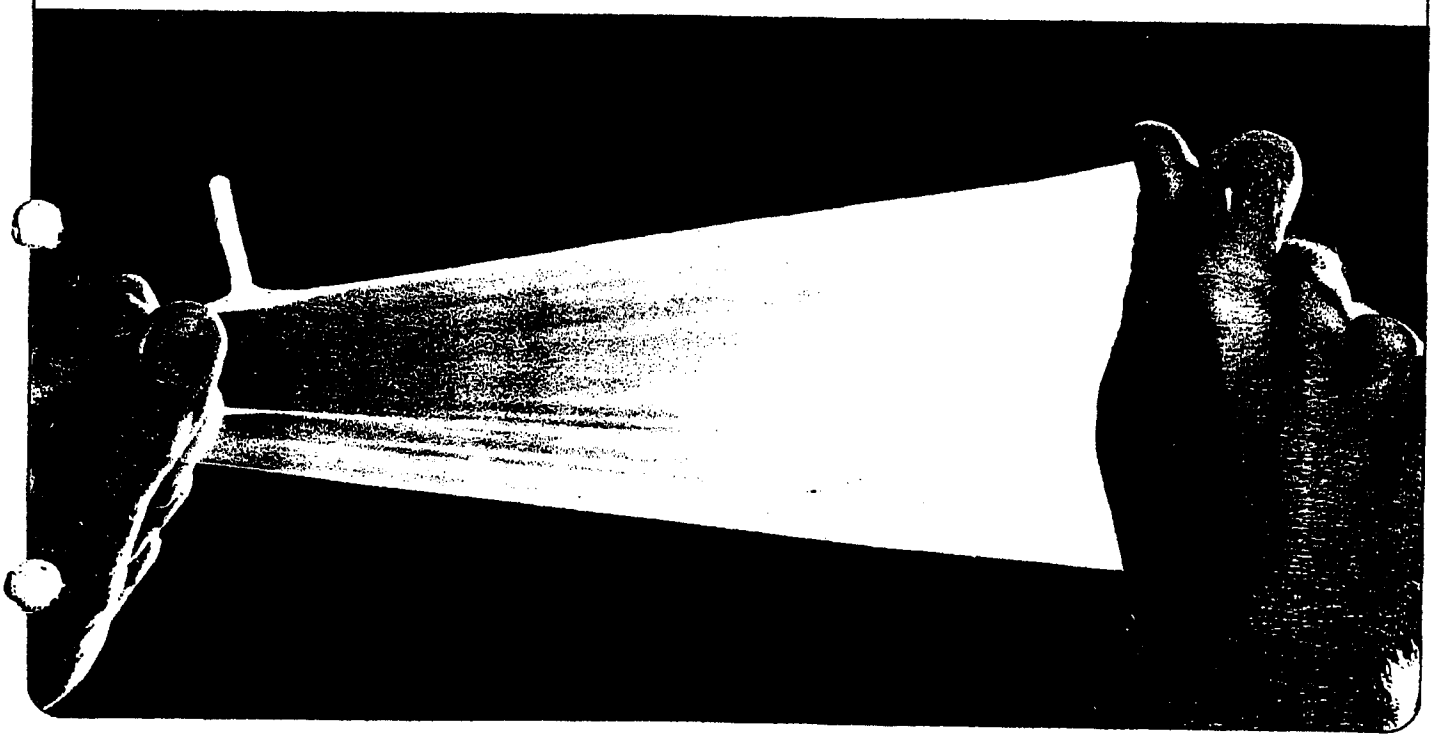
BEFORE INSERTION

To remove the air from the implant, roll each side of the prosthesis toward the middle.

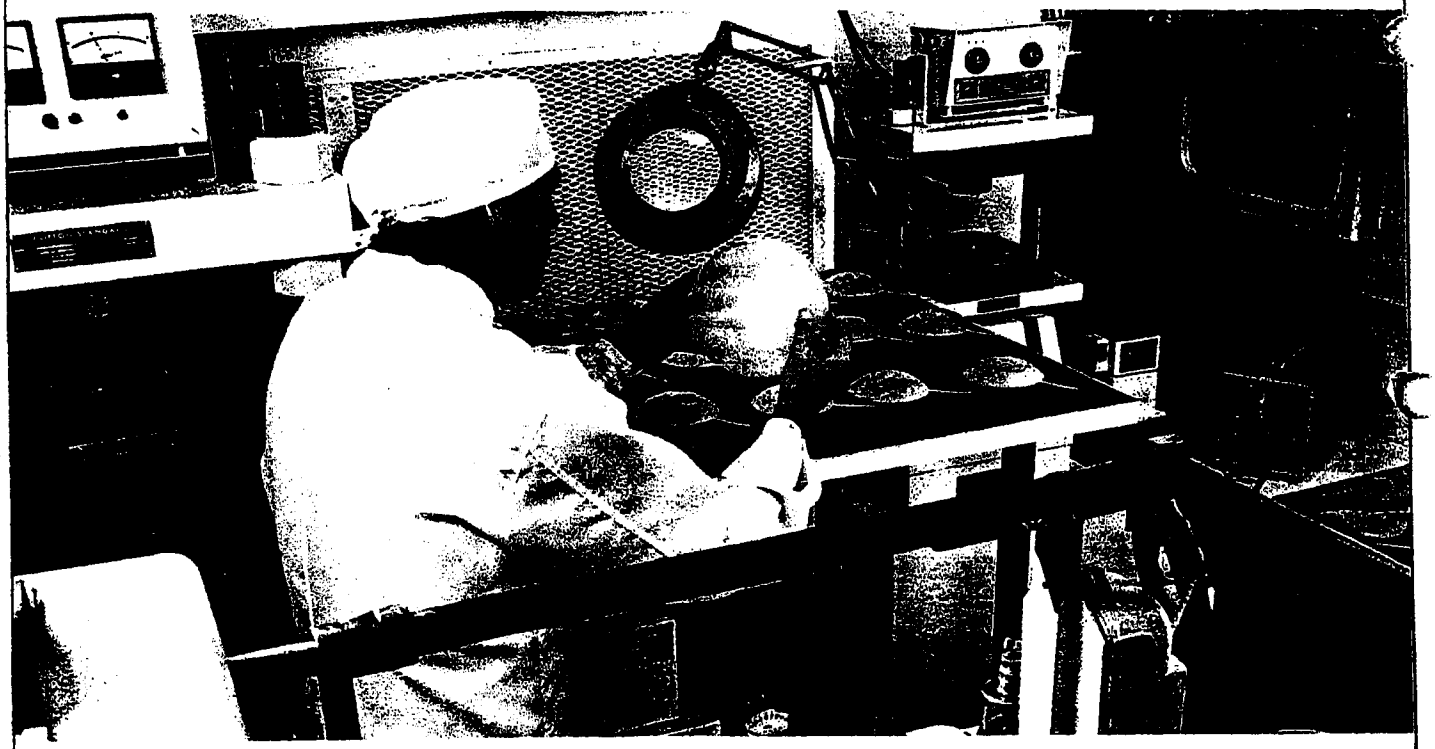
FILLING FLUID

Physiological Saline 230 to 380 cc.

(Photo below) The Silicone employed has: Specific gravity = 1.12; Tensile strength = PSI-850; elongation = 600%; the thickness of the wall = 17 thousandths of an inch; Prosthesis weight 7 grams.



(Photo below) The manufacturing of these implants is performed in controlled atmosphere meeting federal standard 209A-class 100.



CATALOGUE NO.	DESCRIPTION
112 ST	Mammatech Prosthesis — Infra-Mammary, Standard Side Tube small/medium — Diam. 5 inches — 250 cc. to 380 cc. — Sterile
210 CT	Mammatech Prosthesis — Peri-areolar — Inverted Center Tube petite/small — Diam. 4 inches — 170 cc. to 250 cc. — Sterile
212 CT	Mammatech Prosthesis — Peri-areolar — Inverted Center Tube small/medium — Diam. 5 inches — 250 cc. to 380 cc. — Sterile
310 IT	Mammatech Prosthesis — Infra-mammary, Inverted Side Tube petite/small — Diam. 4 inches — 170 cc. to 250 cc — Sterile
312 IT	Mammatech Prosthesis — Inverted Side Tube small/medium — Diam. 5 inches — 250 cc. to 380 cc. — Sterile

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INJURY MECHANISM FROM SALINE INFLATABLE MAMMARY PROSTHESES

The insertion of ill-conceived or defective implants in a disease-prone area has predictable morbidity and a potential for injury which rises with the dwell time of the product. It is well established that implants cause major structural, physiological and biochemical changes in the breast environment. Some undergo degradation of the shell materials and thus further complicate the environment of the prostheses.

The devices also act as time release systems for pharmacologically active compounds. Saline-inflatable devices containing aqueous fluids and valves add additional problems specific to this class of product. It is necessary to review the mechanisms by which such devices can affect the user's health, appearance and comfort in order to understand their risks and their shortcomings. It is also necessary to review the microbiological implications of having an improperly sealed compartment containing water within a tissue pocket for a long dwell time. Devices of this kind perform habitually as reservoirs for decaying proteins and blood products and proliferation of microbiological entities which remain contained only when the shell retains its integrity and if the valve maintains its capacity for an absolute seal. This is not the case as nearly all saline inflatable devices examined to date show significant deficiencies with respect to the integrity of the shell, its ability to contain solutes and micro-organisms. The issue of valve competence is another major problem, in particular for more recent versions of these devices.

Prosthetic injuries in breast implant users can be attributed to at least six major mechanisms:

(1) 'Normal' surgical trauma and surgical misadventures resulting in damage to functional/sensorial parts of the chest and the upper limbs;
(2) Biomechanical effects induced by the presence of large foreign objects that cause compressive trauma, excoriation, distention, atrophy and restrictive adhesion of tissues or compressive/occlusive ischemia of the vasculature within the pectoral-axillary area;
(3) Locally injurious biochemical effects from reactive dispersible substances that induce fibrotic, inflammatory or destructive tissue changes;
(4) Long term tissue remodelling and deviant repair processes leading to hyperplasia, densification, mineralization and dehydration of the implant site;
(5) Implant-capsule adjuvant interactions leading to tissue degeneration or denaturation to produce host tissue-derived antigens that elicit antagonistic host-directed antibodies; devices with degradable materials that revert to silica-rich particles perform in a similar way and are associated with autoimmune disturbances and unusual focal tissue reactions;
(6) Pathologic effects from bacterial, viral or fungal colonization of the capsule space leading to low grade chronic infections and toxic phenomena from microbiological metabolites. Users of saline-filled implants are particularly subject to such problems. Furthermore, many surgeons habitually incorporated pharmaceuticals such as anti-inflammatories and antibiotics with the aqueous solutions of such implants. These compounds degrade to comparatively toxic entities which add their effects to the previously-cited injuries.

For most long term users, all of these effects are present concurrently. Their severity increases over the period of use. However, the early occurrence of intracapsular infection, seromas and hematomas appears to be a strong accelerating and intensifying factor for implant adverse reactions. Atypical infection may be a key factor leading to late systemic effects.

Users of saline inflatable implants are subject to other problems. Contamination and colonization of the saline compartment takes place comparatively rapidly and depend on implantation techniques, valve design and position of the device with reference to the valve mechanism. They also depend on the presence or absence of pre-existing contamination or contamination iatrogenically inserted during the filling procedure or during attempts to access the valve to alter the volume intrasurgically. Many implant users also undergo temporary removal of such implants with refilling of the content and reimplantation. Such procedures, termed 'reuse', have special risks which greatly magnify problems. Filling solutions frequently harbor viable micro-organisms. These may derive from retrograde ingress of micro-organisms from the user or contamination during filling. Viable entitles can also derive from survivors of the original sterilization cycle. These organisms may develop into large colonies and habitually belong to the mycobacteria families.

Leaky valves allow inoculae from the interior to leak into the intracapsular space causing low grade infections. When shells eventually perforate, systemic symptoms generally develop. The event may not be immediately noticeable and the space originally filled with saline solutions will become filled with tissue debris and body fluids. These substances later decay and produce additional infective and immunological phenomena as they incubate over the long term. Movement from the user causes a type of 'pumping' action which leads to back and forth flow of biological fluids and decaying material entrapped within the porous, permeable or perforated shell. Thus, such implants can injure severely without frank rupture of the shell.

Protected intracapsular infections remaining for a substantial period of time have the ability to enhance capsular fibrosis. Such micro-organisms in protected compartments tend to resist antibiotics. Over the long term and with large colonies, the formation of pharmacologically significant quantities of toxins becomes possible. Health effects associated with chronic low grade infections and microbiological metabolites such as toxins may account for the disturbances noted in long term prosthetic users of such implants.

Capsule problems are common in prosthetic patients in general. They are habitually worse for users that show baseline colonization of the capsule with bacterial and fungal entities. Frank infections with overt symptoms promote rapid and thick contractile capsules. There are many reports on cases where incompletely removed capsules containing embedded prosthetic debris led to continuing disease processes even after removal of the implants. Such phenomena are creditable to fluids and microbiological entities as well as prosthetic debris acting in concert within a protected fluid pocket. Such pockets can often be visualized under radiographic conditions, in particular when they become calcified. They can also present a very alarming aspect to radiologists who may mistake the calcification phenomena for a developing malignancy.

It is most probable that the early encapsulation of an implant that can disperse solid, inflammatory debris establishes a condition which creates bioactive mixtures with dispersions of denatured proteins. The site often attracts bacterial contamination. The capsule ensures long term survival of the viable entities even in the presence of systemic antibiotics.

If the infection is allowed to remain within the capsule space, the capsule integrity is eventually lost through lysis or mechanical damage and the material escapes. The number of antibodies directed against such autogenous degraded tissue antigens may rise to the point where it can create degenerative tissue disease symptoms.

Intracapsular and pericapsular mineralization (calcification) is primarily a consequence of tissue necrosis (tissue destruction). It affects more than 50% of implant users with dwell times in excess of 10 years. Some types of implants lead to abundant early calcification. Their compositions (effluents) appear particularly destructive to peripheral tissue. This is a chemically driven process. Calcification of this kind is unlike naturally occurring dystrophic calcification. It is a more severe and injurious phenomenon which culminates in development of sharp, abrasive structures which traumatize the tissue and may cause focal bleeding and the occurrence of small hematomas with their attendant risks.

38 years is even worse.

Calcification causes yet other problems to long term users of saline implants. As the implant ages and the capsule becomes mineralized, the alkalinity of the intracapsular space increases. Silicone elastomers have poor resistance to alkaline environments. The elastomer degrades to a brittle frangible material that is unlike the starting substance. Implants in situ for more than 20 years show the effect dramatically with deeply-ingrown calcific entities that sometimes span the thickness of the shell causing it to become highly permeable to solutes and fine particles. The phenomenon is visible to the eye unaided and often takes the form of well-organized crystals growing within the shell material. Interstitial calcification of the shell marks the end of the useful life for any liquid-containing implant.

RISKS FROM IMPLANTS CONTAINING AQUEOUS FILLING SOLUTIONS

Introduction:
A noteworthy characteristic of saline-inflatable breast implants and tissue expanders filled with aqueous media is their ability to sustain microbiological activity within the saline-containing compartment. Another is their susceptibility to rapidly lose their saline charge because of valve failure and/or shell deterioration culminating in shell perforation. The devices are also radiopaque.

In combination, such characteristics have long term safety implications. On the basis of recovered implants, atypical infections and their sequelae account for a significant part of the morbidity and the public costs associated with the use of this technology. The diagnostic of the condition and the clinical management of such patients presents unrecognized challenges. The area requires additional investigation to establish the extent of the problem and the optimum treatment options. Similar consideration extends to certain classes of trans-cutaneous port drug administration devices such as Hickman-type catheters, inflatable penile implants and porous wall mammary implants. Contrary to claims, the devices are markedly radiopaque. For oncologic purposes, these devices should be considered capable of obscuring underlying tumors.

Overview of Implants:
my breast augmentation Sep 1969
Saline mammary implants were introduced commercially in the mid-sixties. Early models were simple and robust. All were sold non-sterile. They required individual hospital sterilization as well as meticulously clean intraoperative procedures. Many gave excellent service for more than two decades and a few are still in use in original patients.

As demand grew, the quality diminished and many unsatisfactory designs were introduced. Most were promoted on the basis of lower prices, faster surgical implantation and more gratifying immediate appearance. By the late-seventies, the quality and performance had degraded to the point where seasoned clinicians avoided their use. Implants were deflating after several months and most perforated within 1-2 years following implantation.

Worse still, many were being explanted in grossly contaminated states with assorted viable and non-viable entities, sometimes visible to the naked eye. Intraoperative errors, manufacturing problems and inappropriate sterilization procedures were generally credited with the problem but its etiology and clinical significance were not widely recognized.

Nevertheless, many clinicians abandoned the products by 1980. Some successfully sued the manufacturers for loss of wages and damage to their reputation. The products then nearly vanished from commerce until their "renaissance" in the nineties following a successful bid by the U.S. Food and Drug Administration to regulate the popular but problem-plagued gel-filled implants and other abuses surrounding silicone cosmetic surgery implants.

Risk Factors for Saline-Containing Systems:
All devices have been sold as sterile products since the late-seventies. Saline chambers with small amounts of viable micro-organisms occur occasionally. They may be improperly sterilized products. This problem beset the industry for many years and forced the introduction of specialized sterilization technology in the eighties. Because of the closed internal configuration of these devices, the validity of current sterilization techniques is still a contentious issue. Non-sterile compartments also reflect contaminated devices. Contamination can take the form of surgically introduced pathogens during in situ filling as opposed to sterile field filling. Given the non-sterile character of the mammary gland, the introduction of viable entities from contact with extracellular fluids and breast tissue is very probable.

Additional pitfalls include resterilization attempts following unsanctioned device re-use or habitual filling with non-sterile substances. Deviations from established filling recommendations were commonplace in the recent past. Some of these procedures have been published and were once very popular. A few remain in use by some surgeons to this day.

Such procedures typically include filling with non-parenteral grades of electrolytes or colloids and extemporaneously prepared solutions of oral pharmaceuticals such as anti-infectives and anti-inflammatory steroids. The long term fate of these degraded mixtures in a closed environment is also worthy of consideration as "nutrients" to late arriving micro-organisms and in the context of chemically-mediated adverse reactions after shell rupture.

An inoculated prosthesis may remain in a biologically-dormant state until the viable entities are provided with nutrients. If the filling substance contains no nutrient, no biological activity will take place. Alternately, the inocula may die spontaneously.

However, on balance of probability, some proteinaceous matter will eventually enter the compartment through valves, shell defects or late perforations. Paradoxically, very few valve designs demonstrate concern about this issue. Very few are secure even when new and definitive "plugs", cement seals and valve caps are rarely used even when available.

Most valves of the eighties are simply variants of unidirectional flow control devices. They were developed for hydrocephalus drainage shunts. They allow inward flow and can be made to function as pumps that transfer liquid from the capsular space to the fluid compartment by manipulating the prosthesis-capsule assembly. There are therefore no reliable means of preventing nutrients from reaching an inoculum in these systems.

The Prosthesis as a Fermentation Reactor:
Inoculated devices with nutrients may not present an overt risk until the biological processes involve sufficient mass transfer to produce significant amounts of pathogenic material. In the early post-surgical period, the processes may be no more than survival of the most hardy entities and may not be sufficient to cause problems. However, with faulty valves and late perforations, conditions for proliferative colonization of the compartment will be met.

Even if sterile at the onset, leaky saline compartments constitute nearly idealized incubation zones for adventitious pathogens in the capsular space. Adjuvant-like impurities from leaky gel cores further complicate the chemistry of these pockets. They add to the denatured proteins, decaying tissue, fermenting pharmaceuticals and active micro-organisms. Scar tissue also re-form and can act as temporary plugs for the perforations, thus further improving the environment for less competitive micro-organisms such as anaerobes.

The cul-de-sac or "blind pocket" geometry of the area forbids irrigation by physiologic fluids or administered antibiotics. The limited oxygen permeability of the silicone wall favors anaerobic processes. Egress of this contamination eventually takes place in response to movement and pressure applied to the breast area. Dispersion of this material may periodically invade the prosthetic capsular space and may establish secondary colonies outside of the prosthesis. Symptoms of infection should appear at this stage but may resolve temporarily.

Typical Sequence of Events:
The adverse affects in saline solution-filled mammary implants usually take place according to the following sequence: (1) Prostheses containing viable microorganisms within the saline compartment are filled and suffer further contamination of the solution with new organisms and nutrients. (2) Colonization of the interior and the valves of the prostheses by bacteria, mycobacteria and fungi takes place. (3) Pannus tissue grows into the unprotected valve and allows more nutrients into the chamber and some of the colonizing organisms exit. (4) Silent infection takes root in the periprosthetic capsule space. (5) Under stimulus of natural chest movement, breast compression (closed capsulotomy) and/or tissue contracture, the colonizing organisms are redistributed around the prosthesis and secondary colonization takes place. (6) Recurring fleeting episodes of infection, discomfort, fever and swelling are noted; antibiotic medication may be prescribed by treating physicians yet the symptoms recur. (7) Early displacement and "hardening" of the prostheses may take place as the intracapsular colonization progresses to fibrosis and capsular contracture becomes obvious. (8) There may be attempts at breaking the capsule via compression (capsulotomy) but there is only temporary relief. (9) The shell then perforates or ruptures providing pressure relief but fevers and discomfort worsen as the colonized interior is discharged into the intracapsular space. (10) The devices are finally explanted and the site is disinfected as it is the only remaining option.

Clinical Considerations:
Valve and saline compartment (outer lumen) contamination by micro-organisms, scar tissue and decaying proteinaceous debris as well as colonization of the interior of the prostheses by atypical flora is a major long term safety issue for aqueous media filled devices because the durability of the shell is very limited and release of the content is inevitable.

The eventual loss of the fluid containment system because of shell perforation and valve leakage allows contaminated fluids to egress from the prosthesis to the capsule space and thus reach the patient. The very long incubation periods and the unusual growth environment favor the presence of atypical flora and micro-organisms that are not commonly encountered in clinical practice and about which there is limited treatment data.

If secondary colonies become established outside of the periprosthetic space, for example in the proximal lymph nodes, the problems may persist even with the complete removal of the offending devices and their tissue capsules. Additional surgery or systemic treatments may be indicated if the identity of the flora is known or suspected through biopsy or antibody assays.

Research Needs and Clinical Management Strategies:
Patients suffering adverse reactions from saline-filled prostheses present with problems different from individuals affected by direct "inert" oil injections and/or silicone gel implants. The latter lead to systemic dissemination of hydrophobic contaminants. Please note this.

Saline users are not oil-contaminated. Instead, they require novel diagnostic and infection control strategies that address nosocomial pathogens as well as atypical anaerobes, mycobacteria, algae and fungi that thrive in closed environments.

The sequelae of long term infections in closed spaces protected by scar tissue are documented in the early publications. Much of this information is embedded in "unfashionable" trauma and military medicine literature. This information is valuable in the context of implant adverse reactions and ought to be revisited. The sensitivity of these organisms to commercially available antibiotic and the newer systemic anti-infectives must also be reviewed.

Protracted exposure to large amounts of surface-active, silica-containing microparticulate debris of silicones mixed with proteins and microbiological toxins also has predictable but poorly documented adverse effects. Additional concerns come from the nature of the silica-based fillers and their association with immunochemical phenomena, the chemical composition of the complex adjuvant mixtures, their ability to form coacervates which mimic antigens, the inefficient excretion pathways of these materials and their affinity for lipids.

The pharmacologic properties of alkaloid-like metabolites from atypical micro-organisms that thrive in poorly irrigated environments add other concerns. The type and by-products of reactions that take place in contaminated periprosthetic scar tissue, stagnant fluid media within capsule spaces and occluded lymph channels have disturbing immunologic and neurologic implications that have not been evaluated. occluded lymph channels

These issues must be addressed before further usage of these coarse implant technologies can be promoted. The needs are particularly urgent because, unlike classical gel implants, saline-filled prostheses are still widely used and are aggressively promoted in the public media for elective cosmetic surgery. Their history of adverse events, poor workmanship, debatable long term aesthetic efficacy and unpredictable durability further reinforce the recommendations.