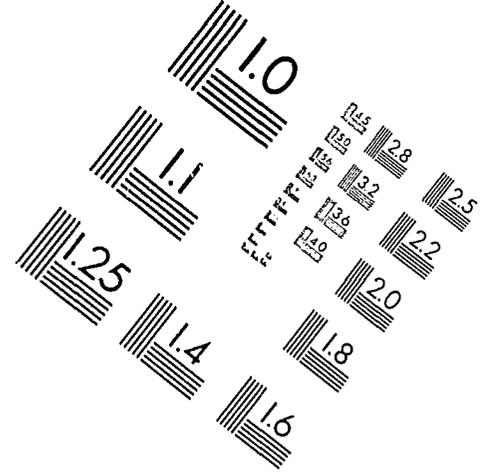
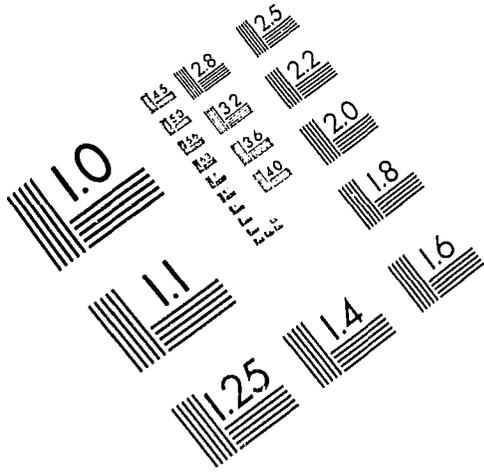
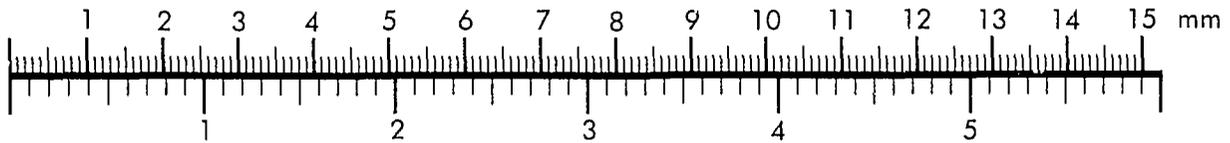


**Association for
Information and Image
Management**

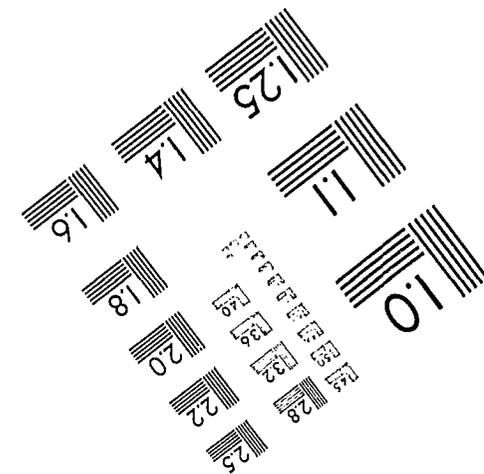
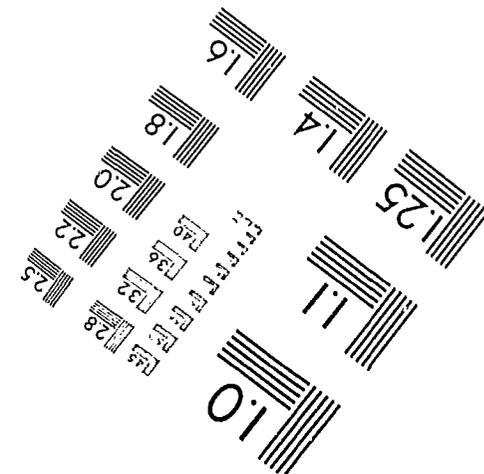
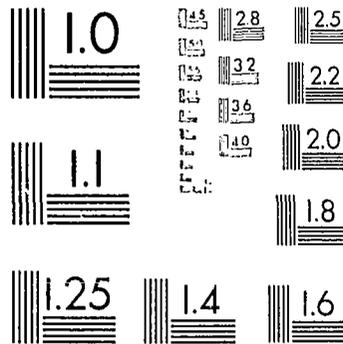
MS303-1980



Centimeter



Inches



K845036



JUN 26 1985

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Mr. Alfred A. Iverson
President
Progress Mankind Technology
Box 464
Hopkins, Minnesota 55343

Re: K845036
Model 3600 Tissue Expanders for
Reconstructive Surgery

Dated: June 3, 1985
Received: June 14, 1985

Dear Mr. Iverson:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-375), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Robert G. Britain
Director
Office of Device Evaluation
Center for Devices and Radiological Health

BEST AVAILABLE



Memorandum

Date

June 24, 1985

From

REVIEWER(S) - NAME(S)

P. Tilton

Subject

510(k) NOTIFICATION

K845036/B

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

PMT's Model 3600 Tissue Expander is substantially equivalent, in terms of intended use, materials, design, & function to several other marketed tissue expanders, i.e. Neger Schulte's Subcutaneous tissue expander (K79 0842), Radovan (K77 1224), McShan (K843704).

PT

The submitter requests:

Class Code w/Panel:

No Confidentiality

79 LCT

Confidentiality for 90 days

skin expander, inflatable

Continued Confidentiality exceeding 90 days

REVIEW:

Richard S. Sternbach / T.J. Callahan
(BRANCH CHIEF)

6-24-85
(DATE)

FINAL REVIEW:

Carl A. Larson
(DIVISION DIRECTOR)

6/25/85
(DATE)



CONFIDENTIAL

PMT, Inc. • BOX 464, HOPKINS, MINNESOTA 55343 • (612) 933-1118

June 3, 1985

KS45036/B

Mr. Paul Tilton
Office of Device Evaluation
Federal Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFC-401)
8757 Georgia Ave.
Silver Spring, MD 20910

RE: Additional information for 510K-845036

Dear Mr. Tilton:

Please find enclosed with this letter the following information that you requested in regards to the 510K of the PMT model 3600 tissue expanders; 1) Tensel strength pounds per inch squared, 2) elongation percentage of silicone rubber material, 3) PMT engineering print of injection dome (classified confidential), 4) maximum volume of each tissue expander model, 5) statement of nonsterile product. We believe this information satisfies your most recent request for information in regards to the tissue expanders. We consider the above technical and engineering information confidential, and should not be released to the public. Information that you requested in this unusual 510K request falls into the scope of trade secret information of the PMT corporation. Please contact me at your earliest convenience if you have any additional questions in this regard. The PMT Corporation is a small manufacturer and we have now documentation which proves we have been financially affected by this unusually long registration period. I thank you in advance for your attention in this matter.

Sincerely yours,

Alfred A. Iverson
President

AI/mag

Enc;

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COPY

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Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

MAY 31 1985

Progress Mankind Technology, Incorporated
Attn: Alfred A. Iversen
Box 464
Hopkins, MN 55343

Ref: K845036/A - Model 3600 Tissue
Expanders for Reconstructive
Surgery

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information should be submitted in duplicate to:

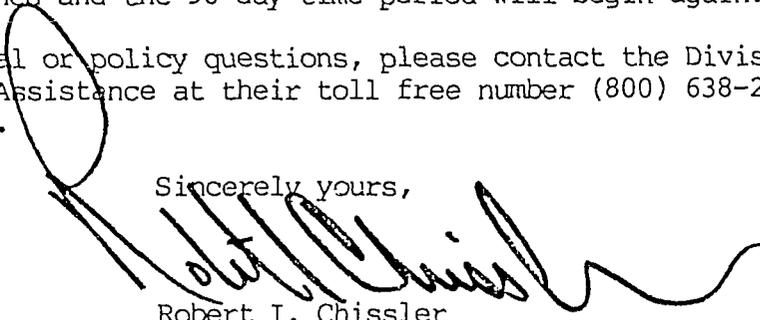
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

When your additional information is received by the Office of Device Evaluation the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and return it to you. Pursuant to 21 CFR 20.29, one copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or me at (301) 427-8162.

Sincerely yours,


Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

BEST AVAILABLE
COPY



Memorandum

Date

May 30, 1985

From

REVIEWER(S) - NAME(S) T. J. Allchin

Subject

510(k) NOTIFICATION

K845036/A

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments: Mr. Iverson did not respond to items #2, 3 & 4 of my memo dtd 4/31/85. In telecon on 5/30/85, I reiterated these points. Mr. Iverson requested that I be more specific in each of these items. I therefore requested the following:

1. tensile ^{strength} + elongation specifications of the elastomer + maximum inflation volume of each model of implant.
2. Engineering diagram of the injection dome. ^{marketed}
3. Statement of the differences between this + other tissue expanders.
4. Modified label to reflect the NONSTERILE finished product.

Note: Mr. Iverson stated that his device is made wholly of Silastic ^{Medical-Grade} Elastomers. The submitter requests: Class Code w/Panel: MDX-4-4515 # MDX-4-4516.

- No Confidentiality
 - Confidentiality for 90 days
 - Continued Confidentiality exceeding 90 days
- 79LCJ
SKin expander, inflatable 5/30

REVIEW:

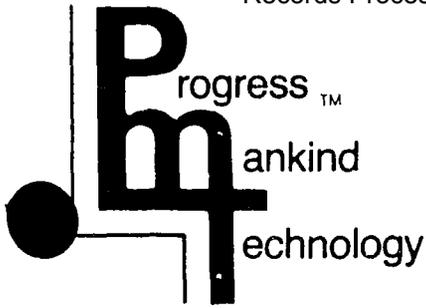
T. J. Allchin 5/30
(BRANCH CHIEF) (DATE)

FINAL REVIEW:

(DIVISION DIRECTOR) (DATE)

BEST AVAILABLE COPY

K845036/A



PMT, Inc. • BOX 464, HOPKINS, MINNESOTA 55343 • (612) 933-1118

March 15, 1985

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices & Radiological Health
Document Mail Center HFC-401
8757 Georgia Ave.
Silverspring, MD 20910

RE: Additional information for 510K K845036.

Dear Sir,

Please find enclosed the requested information in regards to the 510K application;

1. Biocompatibility testing information on silicone rubber.
2. Manual and instructions for use information.

Please contact the PMT Corporation at year earliest attention if we may be of additional assistance. I will look forward to hearing from you.

Sincerely yours,

Alfred A. Iversen
President

AAI/bam

Enc.

RECEIVED
MAR 16 1985
CDRH

BEST AVAILABLE
COPY



Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB 13 1985

Progress Mankind Technology
ATTN: Alfred A. Iversen
Box 464
Hopkins, MN 55343

Ref: K845036-Model 3600 Tissue Expanders
For Reconstructive Surgery

Extended Until: 3/13/84

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

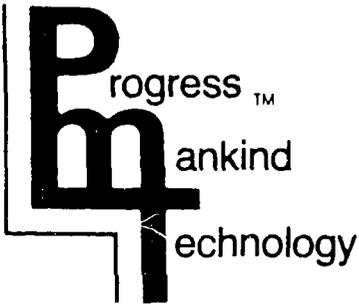
If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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*Please do not give us additional
30 days.
Thanks
Bob C
2/13/85*



PMT, Inc. • BOX 464, HOPKINS, MINNESOTA 55343 • (612) 933-1118

February 7, 1985

Mr. Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and Radiological Health
Food & Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

RECEIVED
FEB 13 1985
12:11:12

RE: Document No. K845035 and K845036-per 510(K) notifications.

Dear Mr. Chissler,

Thank you for your letter dated January 22, 1985 in regards to the previous 510K notifications. The PMT Corporation is processing the additional requested information and will have this information to you as soon as possible. It may require more than the 30 days that you specified in your January 22, 1985 letter, but we will diligently and expeditiously send to you the information you desired as soon as possible.

I thank you for your attention in this matter.

Sincerely yours,

Alfred A. Iversen
President

AI/bam

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB 4 1985

Progress Mankind Technology
ATTN: Alfred A. Iversen
Box 464
Hopkins, MN 55343

Ref: K845036-Model 3600 Tissue Expanders for
Reconstructive Surgery

30 days

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information should be submitted in duplicate to:

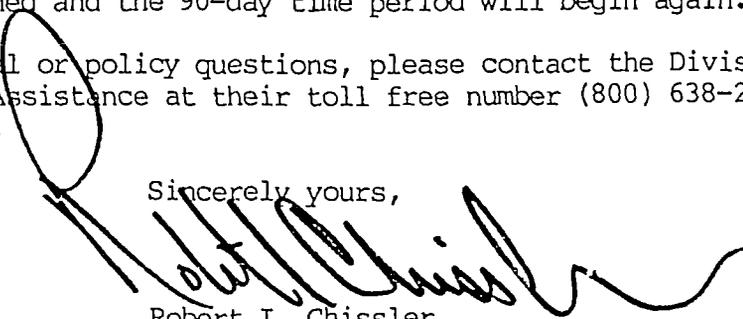
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

When your additional information is received by the Office of Device Evaluation the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and return it to you. Pursuant to 21 CFR 20.29, one copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or me at (301) 427-8162.

Sincerely yours,


Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

BEST AVAILABLE
COPY



Memorandum

Date

1/31/85

From

REVIEWER(S) - NAME(S)

P. Tilton

Subject

510(k) NOTIFICATION

K845036

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments: *Telecon: Al Iverson on 1/31/85 requested:*

- 1. *Data covering biocompatibility profile.*
 - 2. *Finished product specs of std. PMT Model 3600 expanders.*
 - 3. *Mechanism + design of injection dome.*
 - 4. *Similarities / differences between PMT product + preattachment devices.*
 - 5. *Modified labeling to include the following sections: INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, COMPLICATIONS, CLEANING PROCEDURE, STERILIZATION PROC., FILLING THE EXPANDER, POST-OP PERCUTANEOUS FILLING OF DEVICE.*
- Ⓢ to include fluid, needle size, prevention of over-inflation, etc.*

PT

The submitter requests:

Class Code w/Panel:

No Confidentiality

79LCJ

Confidentiality for 90 days

Skin, expander, inflatable.

Continued Confidentiality exceeding 90 days

REVIEW:

(BRANCH CHIEF)

(DATE)

FINAL REVIEW:

(DIVISION DIRECTOR)

(DATE)

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Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JAN 2 1985

Progress Mankind Technology
Attn: Alfred A. Iversen
Box 464
Hopkins, MN 55343

D.C. Number : See Attached List
Received : 12/27/84
Product :

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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JAN 2 1985

D.C. Number

Product

K845035

Model 2111 Electrode
for Neurological Surgery

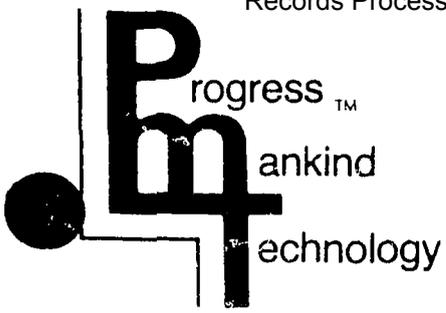
K845036

Model 3600 Tissue
Expanders for Reconstructive
Surgery

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- CONFIDENTIAL -

K845036



PMT, Inc. • BOX 464, HOPKINS, MINNESOTA 55343 • (612) 933-1118

December 10, 1984

Food & Drug Administration
Bureau of Medical Devices
FHK-20 8757 Georgia Ave.
Silver Spring, MD 20910

Re: 510 (K) Notification Sets-510 (K) Notification-Manufacturer NO. 2182979

Dear Sirs,

This letter is written to inform you of our intent to market the model 3600 Tissue Expanders for reconstructive surgery.

A complete discription of these units is enclosed and presently marketed equivalent product literature. Samples of proposed labels and literature are also enclosed.

We will look forward to hearing from you at your earliest convenience. Please feel free to call me at any time.

Sincerely yours,

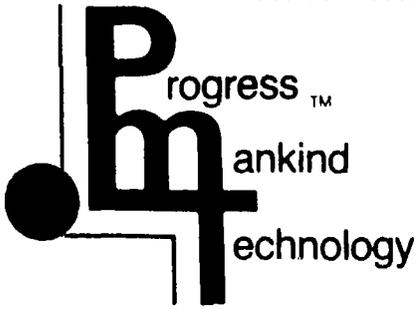
Alfred A. Iversen
President

AI/bam

Enc.

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- CONFIDENTIAL -



PMT, Inc. • BOX 464, HOPKINS, MINNESOTA 55343 • (612) 933-1118

December 10, 1984

Food & Drug Administration
Bureau of Medical Devices
FHK-20 8757 Georgia Ave.
Silver Spring, MD 20910

Re: 510 (K) Notification Sets-510 (K) Notification-Manufacturer NO. 2182979

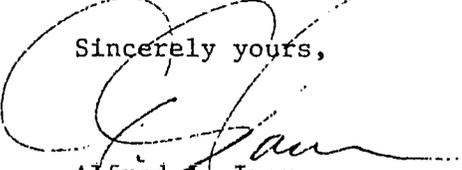
Dear Sirs,

This letter is written to inform you of our intent to market the model 3600 Tissue Expanders for reconstructive surgery.

A complete discription of these units is enclosed and presently marketed equivalent product literature. Samples of proposed labels and literature are also enclosed.

We will look forward to hearing from you at your earliest convenience. Please feel free to call me at any time.

Sincerely yours,


Alfred A. Iversen
President

AI/bam

Enc.

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MODEL 3600 TISSUE EXPANDERS

I. DESCRIPTION AND INTRODUCTION

The Model 3600 Tissue Expanders are used for the expansion of tissue prior to reconstructive surgery. The Model 3600 series tissue expanders come in a range of sizes from approximately 2cm cross sectional diameter to 12cm cross sectional diameter. The Model 3600 series tissue expanders are manufactured out of bio-medical grade silicone rubber. They are primarily composed of a chamber blister type expansion completely manufactured of silicone rubber connected by a silicone rubber tubing to an injection port also manufactured out of silicone rubber.

The unit is manufactured for single use only and temporary use.

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II. EQUIVALENT PRODUCTS

The Model 3600 series tissue expanders are used in reconstructive and plastic surgery. Equivalent or near equivalent products are manufactured by the following companies;

1. Mentor Corporation
2. Mcgahn Medical
3. Cox-Uphoff International
4. Dow Corning Wright

Copies of the manufacturers literature of the above named companies follow this section.

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III. CLASSIFICATION AND PERFORMANCE STANDARDS

Model 3600 Tissue Expanders

(b) (4)

To our knowledge there are no known performance standards available at this time.

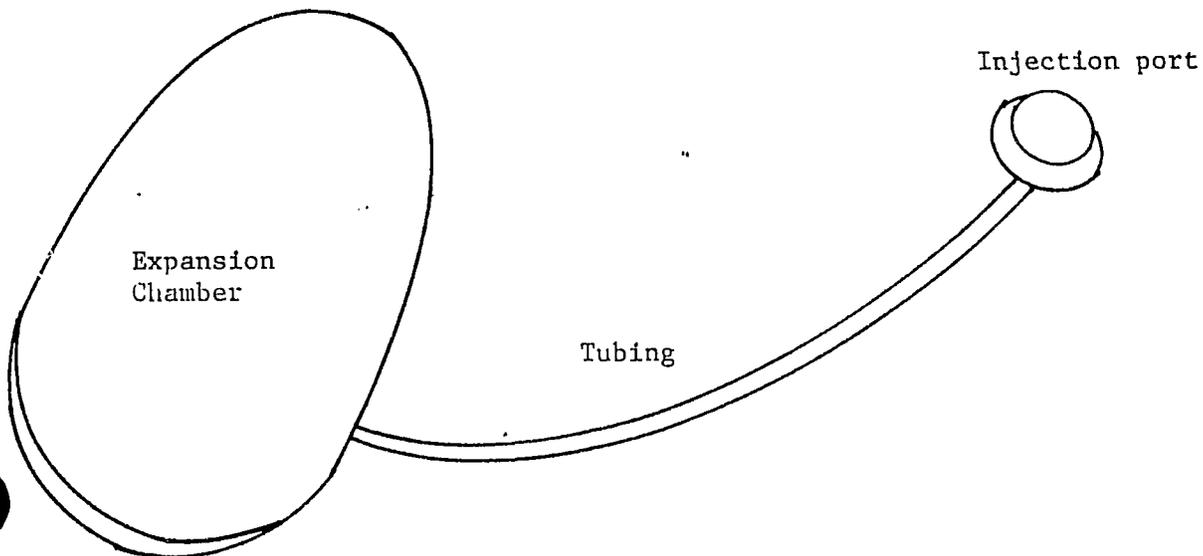
When performance standards are developed for these products, will manufacture accordingly.

(b) (4)

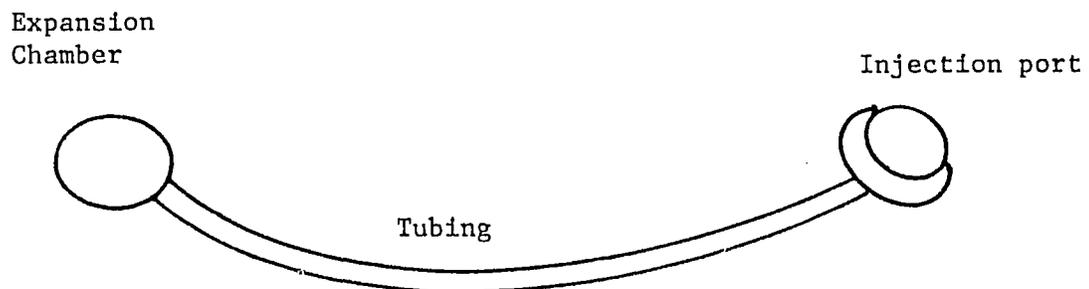
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IV. MODEL 3600 SERIES TISSUE EXPANDERS

A. Model 3602 elongated tissue expanders

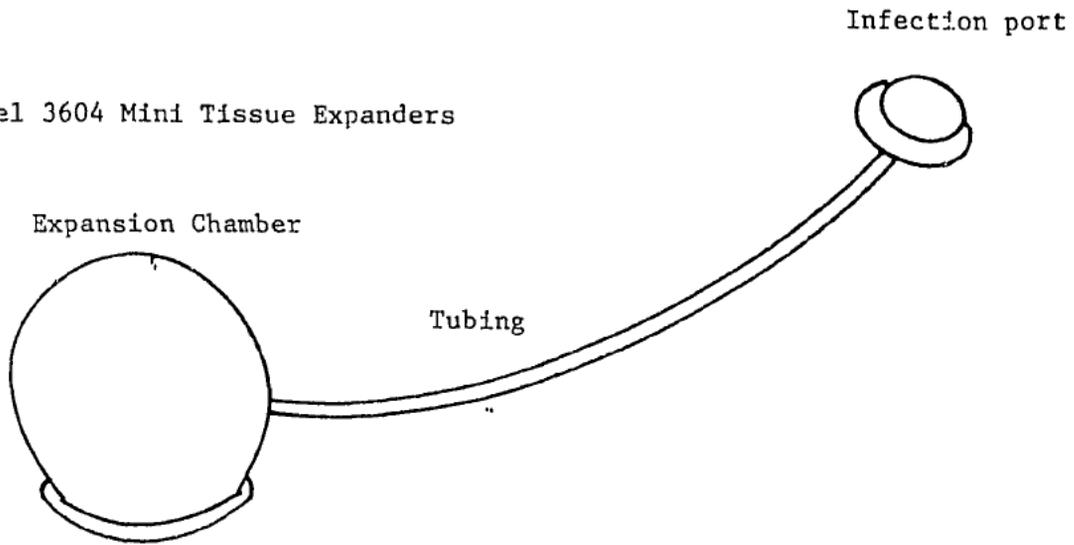


B. Model 3603 micro tissue expanders

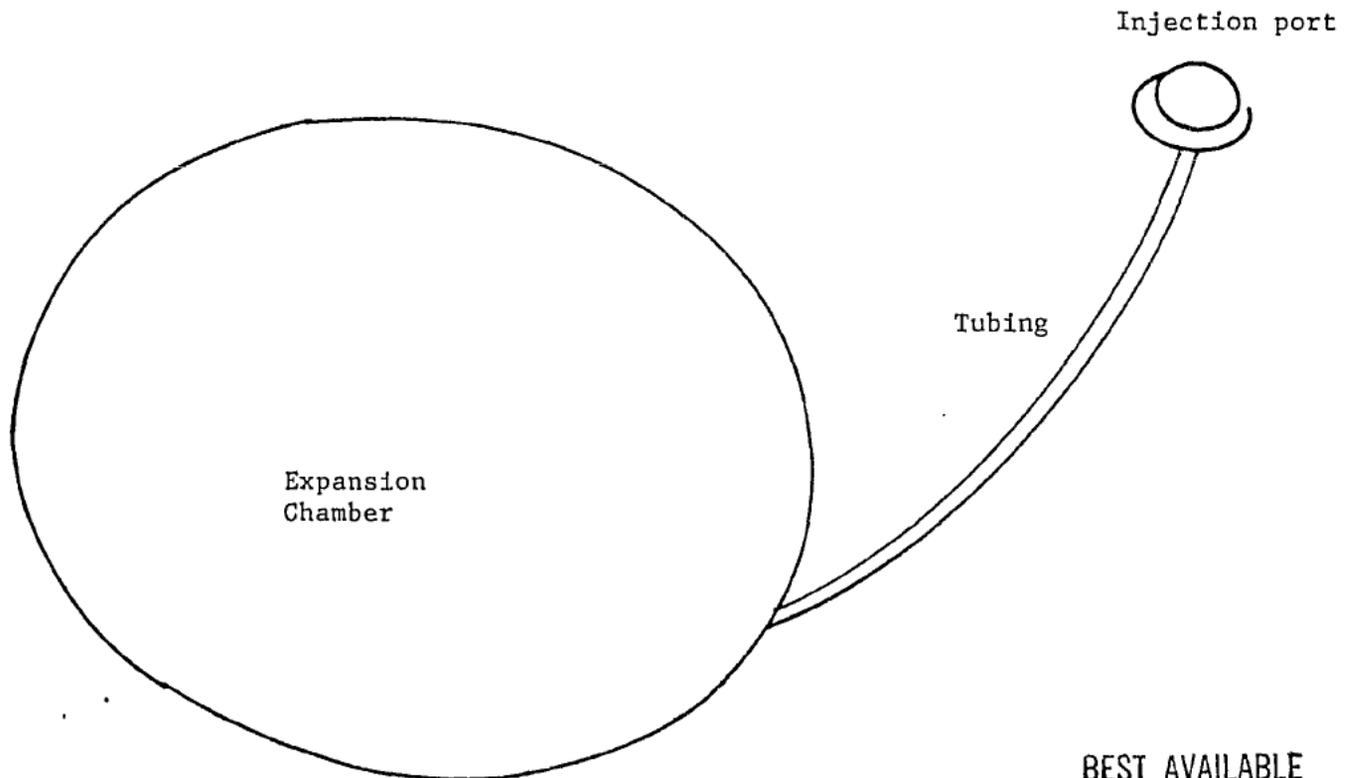


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C. Model 3604 Mini Tissue Expanders



D. Model 3605 Standard Tissue Expanders



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Proposed Labels

PMT^R DuroformTM
"
Tissue Expanders

- Model 3602 Elongated Tissue Expanders
- Model 3603 Micro-Tissue Expanders
- Model 3604 Mini -Tissue Expanders
- Model 3605 Standard Tissue Expanders

Single Use Only

PMT^R Corporation
1630 South Fifth St.
P O Box 464
Hopkins, MN 55343 (U.S.A.)

Caution: Federal Law (USA) restricts this device to the sale
on or by the order of a physician.

**BEST AVAILABLE
COPY**



PMT, Inc. • BOX 464, HOPKINS, MINNESOTA 55343 • (612) 933-1118

DUROFORM™

TISSUE EXPANDERS

Note: This product is recommended for single use only.

I. Description

The Model 3600 series Tissue Expanders were developed for the expansion and transfer of tissue in reconstructive surgery. The PMT Corporation manufactures these items out of top quality medical grade silicone materials. The Model 3600 series Tissue Expanders are available in four primary sizes;

- A. Model 3602 ELONGATED TISSUE EXPANDERS
- B. Model 3603 MICRO TISSUE EXPANDERS
- C. Model 3604 MINI TISSUE EXPANDERS
- D. Model 3605 STANDARD TISSUE EXPANDERS.

The PMT Corporation also provides Tissue Expanders on a custom basis and will ship upon the specifications of the physician. Due to the range of different shapes and sizes in regards to Tissue Expanders, the PMT Corporation thus provides four general type Tissue Expanders and also provides custom design per the particular tissue type and anatomical area.

It is recommended that these units be used by personnel experienced in the technology of tissue expansion and transfer.

II. How supplied.

These products must be cleaned and sterilized prior to use. It is recommended that these products be ethylene oxide sterilized and that each institution establish the efficacy of its sterilization procedure by a method which includes the sterilization of an intentionally contaminated product. These products are recommended for single use only. These products are not recommended for long term (exceeding 90 days) implantation.

CAUTION: (FEDERAL LAW U.S.A) RESTRICTS THIS DEVICE TO THE SALE BY OR ON THE ORDER OF A PHYSICIAN.

III. Instructions for Use

The Model 3600 Series Tissue Expanders should only be used by experienced personnel in the field of plastic and reconstructive surgery. The PMT Corporation manufactures these items out of quality bio-medical grade silicone

materials and even though these materials are quite strong and rugged, caution should be taken in regards to the handling of these items prior to their implant. If any flaws or defects are discovered during the inspection of the unit prior to implantation, please contact PMT Corporation or consult your local PMT representative.

The Model 3600 Tissue Expander should be completely deflated prior to the entry into the body cavity for tissue expansion. All voids containing air should be removed from the Tissue Expander prior to implantation. This may be accomplished by the use of the injection port and a syringe pushing through the unit and extracting the air out of the injection port holding the injection port above the tissue expansion section. This is recommended since air will rise up to the injection port and it may be easily removed by the injection port. After the implantation of the primary tissue expander, the physician may inflate the unit to the desired shape. Continuous monitoring of the area should be accomplished in order to reduce any circulation discontinuity. It is recommended that each institution review its procedures routinely to establish the expansion efficacy that it desires in regards to the end results necessary for final tissue transfer.

IV. WARNINGS

THESE PRODUCTS HAVE BEEN DEVELOPED WITH CARE AND CONSISTANCY BY THE PMT CORPORATION. DUE TO THE VARIATION OF TISSUE EXPANSION SITES AND TECHNIQUES AVAILABLE BY THE MEDICAL STAFF, THE PMT CORPORATION DOES NOT GUARANTEE IN ANY MANNER THE END RESULT OF THE TISSUE EXPANSION AND/OR THE SUCCESS THEREOF OF THE TISSUE EXPANSION TECHNIQUE. THE DECISION TO PERFORM THESE TISSUE EXPANSION TECHNIQUES AND THE USE OF THIS PARTICULAR PRODUCT IS LEFT SOLELY UP TO THE PHYSICIAN AND MEDICAL STAFF.

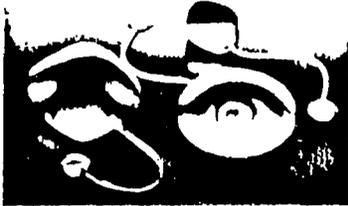
V. Warranty and Disclaimer

PMT Corporation warrants that reasonable care was used in the choice of materials and the manufacture of this product. PMT Corporation shall not be liable for any incidental or consequential loss, damage and expense or injury directly or indirectly arising from the use of this product, other than the replacement of it should PMT, Corporations investigation show the product was defective at the time of the shipment by PMT. The foregoing warranties, as conditioned and limited are in lieu of and exclude all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including but not limited to, any implied warranties of MERCHANTABILITY OR FITNESS FOR-USE. PMT Corporation neither assumes nor authorizes any other person to assume for it, any other or ADDITIONAL LIABILITY OR RESPONSIBILITY in connection with this product.

5 reasons to use the original:

1. Low profile injection dome to minimize erosion.
2. Inflation bag with reinforced base to ensure forward expansion.
3. Stainless steel connector and adjustable tubing to allow patient-specific placement of injection dome.
4. Six standard sizes and over forty custom designs to choose from.
5. Eight years of tissue expander design and manufacturing to support your needs.

THE RADOVAN™ TISSUE EXPANDER



MENTOR

HEYER-
SCHULTE

PRODUCTS

 MENTOR

Phone: 800-235-5731

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

BEST AVAILABLE

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THE PROBLEM:

How to find enough tissue to revise or reconstruct. Especially in those difficult cases where there's never enough, or where secondary site grafts or flaps are a problem.

*"We feel that tissue can be expanded... sometimes dealing with patients in the operating room, you really think that there is no limit to which you could expand tissues."*¹

THE SOLUTION:

The Radovan™ Tissue Expander is for gradual skin expansion at the primary site. The concept of skin expansion has always been with us. (Just think about pregnancy, obesity or normal growth...)

The Radovan allows controlled skin expansion right where you need it — at the site.

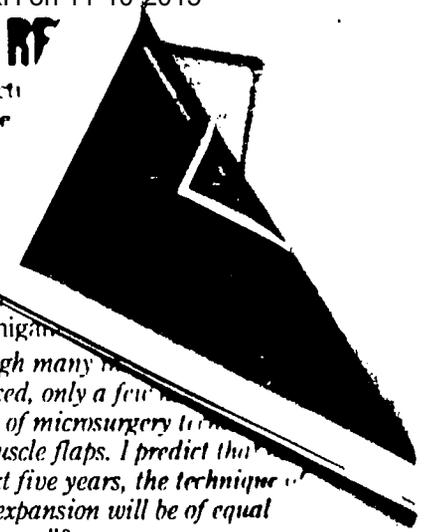
*"It's surprising that such an obvious physical property as tissue expansion, which is at least as old as man himself, has waited so long to come into our surgical armamentarium."*²

THE RE

The pict
And the
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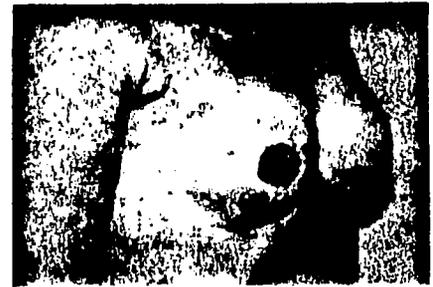
*"Although many have advanced, only a few have recognized the impact of microsurgery on the use of skin and muscle flaps. I predict that in the next five years, the technique of tissue expansion will be of equal importance."*³



Patient with bilateral post-mastectomy deformities.



Each breast was expanded up to 650cc.



The expander was replaced by smaller 450cc implants.



Patient with large hemangioma of the face.



Expander was inserted and adjacent flap doubled in size. After excision, the flap was advanced without tension.



The patient, 6 months post-op.



Open wound of the injured right leg with exposed non-union fracture and osteomyelitis.



Wound was covered with expanded adjacent flap of the calf. Doubled in size, the flap was advanced over the defect.



And the leg was reconstructed without tension.

For more information about the Radovan, including a summary transcript of case histories presented at the Michigan meeting, contact your Mentor Heyer-Schulte representative or call 800-235-5731. Internationally contact your Mentor Heyer-Schulte dealer.

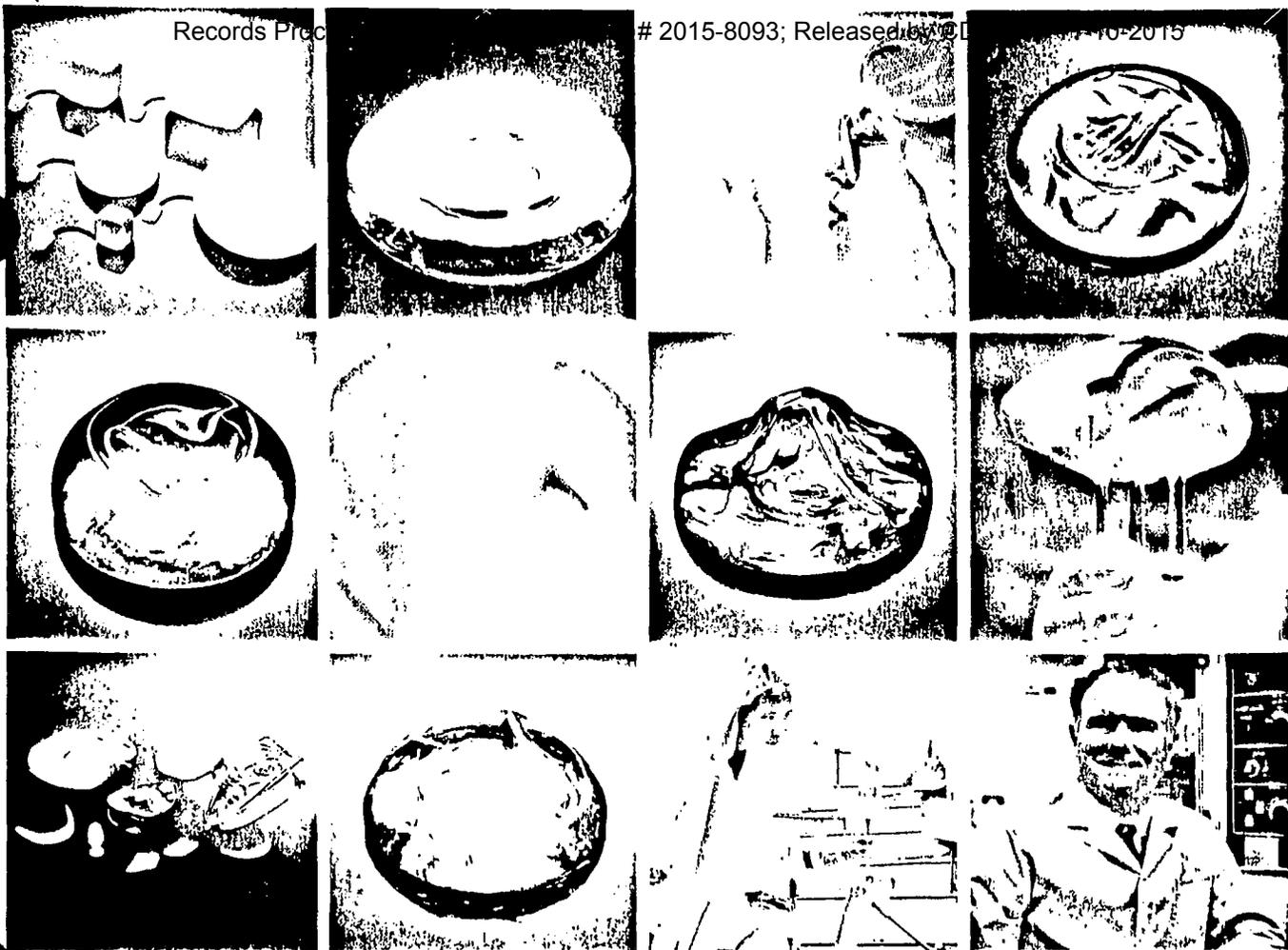
Mentor Corporation, 600 Pine Avenue, Goleta, CA USA 93117.

¹ Argenta, Louis C. *Ibid.*

² Gibney, John. *Ibid.*

³ Grabb, William C. Discussion of "Breast Reconstruction After Mastectomy Using The Temporary Expander." *Plastic & Reconstructive Surgery*, February 1982, p. 207.

Photographs courtesy of Chedmir Radovan, M.D.

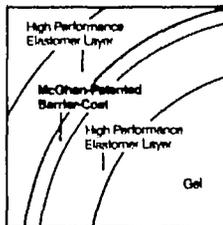


Fact: The *new* McGhan Medical continues their commitment to the goals of the Plastic Surgeon

McGhan Medical has been instrumental in developing the modern mammary implant.

When the plastic surgery profession asked for refined implant styles, McGhan Medical provided technological leadership to produce such innovations as soft, cohesive gel implants, uniform shell thickness, increased sizes and styles, and individual serial numbers and patient chart labels for traceability.

Among other developments pioneered by McGhan Medical are high profile sub-muscular gel implants, and tri-lumen reconstructive implants as well as Natrashiel® (silica free barrier-coat) and Intrashiel® (first low-bleed, barrier-coat implants).



McGhan Medical technology is licensed to other mammary implant manufacturers.

When McGhan Medical introduced Intrashiel in 1979, it was the first effective low gel bleed barrier-coat implant. All barrier-coat implants on the market today are licensed by McGhan Medical Patent No. U.S. 4,455,691.

High performance silicone elastomers and gels are manufactured from raw materials to finished product allowing complete product control. This technology is licensed to other medical device manufacturers.

McGhan Medical's product development is committed to the goals of the plastic surgeon.

We continue to search for new and improved biomaterials to enhance and improve host response and to allow the surgeon new solutions to demanding needs. We continue to develop new products that improve aesthetic results including subcutaneous tissue expanders in a broad range of standard sizes and shapes.

McGhan Medical's biomedical specialists are dedicated to the unusual cases not served by stan-

dard products; and in this custom design development have set precedents in many surgical products.

For further information or to receive the new, factual McGhan brochure, call or write McGhan Medical Corporation, 700 Ward Drive, Santa Barbara, CA 93111, (805) 683-6761, Toll Free (800) 235-6911 or 235-6913, (800) 228-8967 inside California, Telex: 853269 MCGHAN MED SB.

McGhan's Promise

"We will continue to implement concepts suggested by individual surgeons or groups of surgeons. And we will continue to provide a quality product that, when combined with proper surgical techniques, will optimize the percentage of ideal aesthetic results. We are committed to the profession."

Don K McGhan
President, Chairman of the Board



McGhan

The Service Company

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The Challenge: Burn Scars.

The Answer: Cox-Uphoff tissue expanders.

Choose from standard or custom shapes and sizes for every reconstructive need. Patented* posterior flat-fill valve allows for rapid filling at time of surgery. For added convenience and safety, unique self-sealing injection dome permits post-operative injection without repuncturing the tense flap area. All CUI tissue expanders are packaged and supplied sterile.

For further information contact your CUI representative or call direct.

*U.S. Patent Number 4,178,643
Photographs courtesy John Gibney, M.D.



Patient at 1 month after insertion of tissue expander. Initial fill: 150cc's. (Tissue expansion in use to eradicate hypertrophic scar without tension on residual scar.)

Pre-operative, approximately 1 year after unsuccessful serial excision and 3 years after burn. Hypertrophic burn scar was not amenable to successful treatment by total or serial excision.



Intra-operative view demonstrating area of resection of the hypertrophic scar: expander filled to 400 cc's. Interim result: a truly free flap creating excess tissue.



Patient at 9 months after removal of the expander, excision of the scar and advancement of the flap. The final result was a fine line scar of the same color, texture and hair bearing capacity skin with no donor-site defect.



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**From the innovators in tissue expansion,
a shape and size for every reconstructive need.**

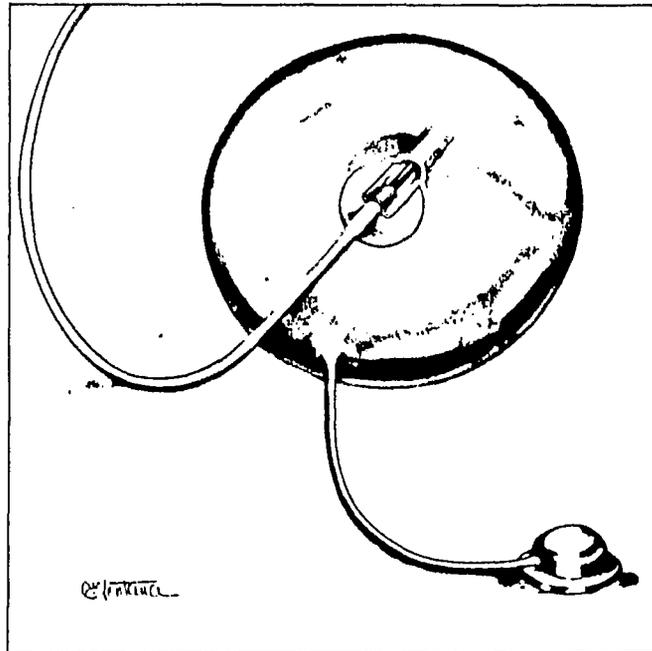
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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THESE IMPROVED SKIN AND TISSUE EXPANDERS ARE PACKAGED STERILE.

NEW FROM CUI.



Create excess skin and tissue. The new, clear silicone elastomer skin and tissue expander creates excess skin and tissue by gradual stretching. Tissue thus developed may be used as a corrective flap; or expanded pocket volume may better accommodate a prosthetic implant.

Seven sizes for breast reconstruction. Although CUI skin and tissue expanders are available for use in numerous body locations, an ideal application is in restorative prosthetic mammoplasty following mastectomy. Use of a CUI expander permits more natural restoration and lessens the need for reduction on the surviving breast.

Self-sealing fill valves for convenience and safety. A patented,* posterior flat-fill valve allows for rapid fill-

ing at time of surgery. No need to make a time consuming tubing connection. A uniquely-designed self-sealing injection dome, connected by a reliable one piece tube to the perimeter of the device, may be injected percutaneously to gradually fill the expander postoperatively. The remote valve avoids having to puncture the tense flap area.

Wide variety of custom shapes and sizes. In addition to seven convenient standard sizes in the ideal round shape for breast reconstruction, the CUI Custom Prosthetic Implant Department will design and fabricate skin and tissue expanders for use in virtually any body area. For more information on standard and custom devices, just contact your CUI representative or call direct.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-STAT @ fda.hhs.gov or 301-796-8116
*U.S. Patent Number 4,178,643

AC 100-121-80-3, Release by DOJ on 11-11-2015

CUI skin expanders.

If one of our standard sizes doesn't fit, we'll design one for you.

For the breast, head, ear, chest, shoulder, arm, thigh and leg. Whatever area of the body, our Custom Implant Department will design and fabricate CUI skin and tissue expanders specifically for your needs.

Or, you can choose from a wide variety of standard shapes and sizes, available in sterile packaging, if desired.

For added convenience and safety, our patented "posterior fill" valve allows for rapid filling at time of surgery. A unique self-sealing injection dome permits post-operative injection without re-puncturing the tense flap area.

Take advantage of our considerable experience. We're pleased to consult and work with you for more information on our products and services. Contact your CUI representative or write to:

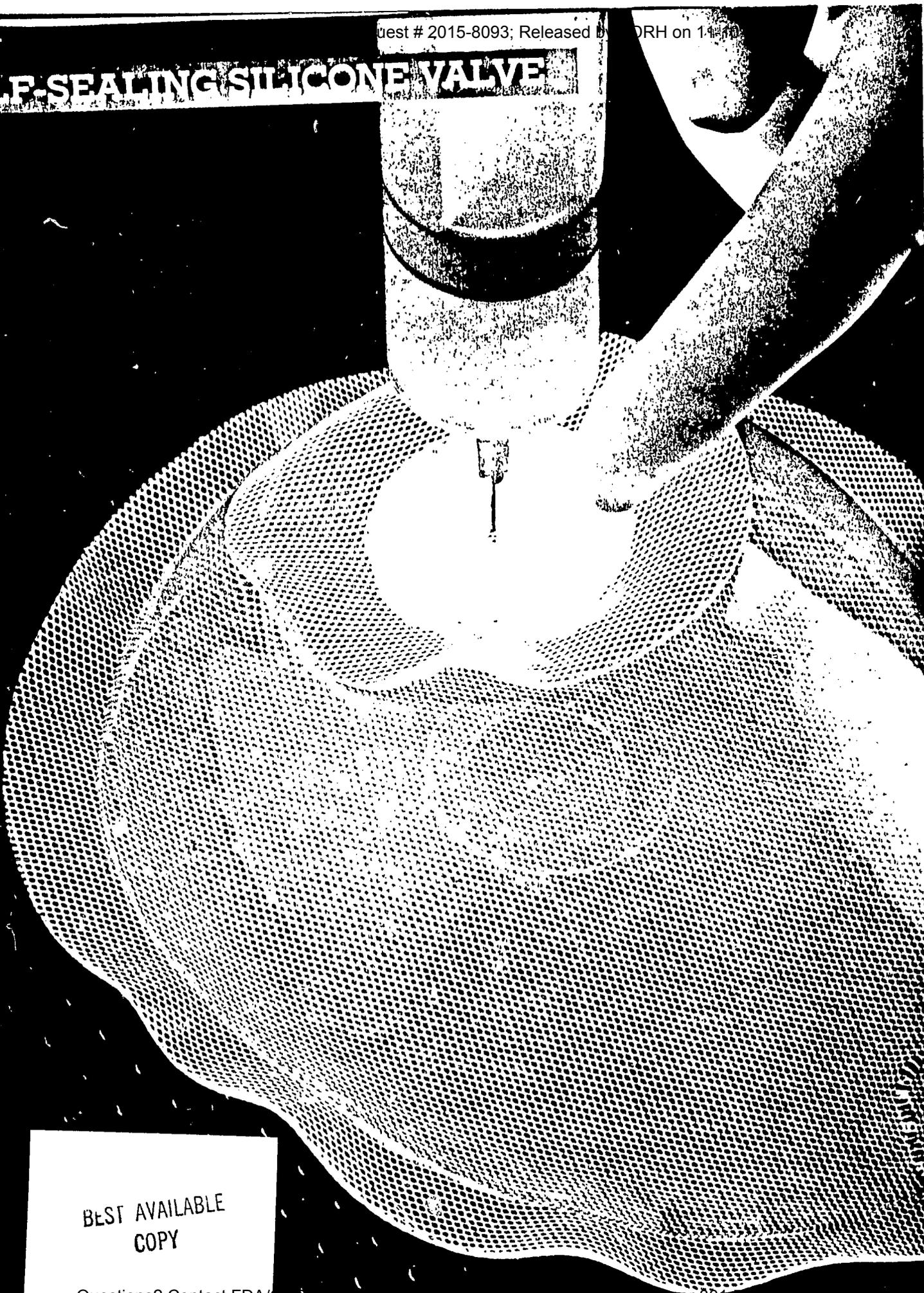
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SELF-SEALING SILICONE VALVE



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SILASTIC® H.P. ELASTOMER

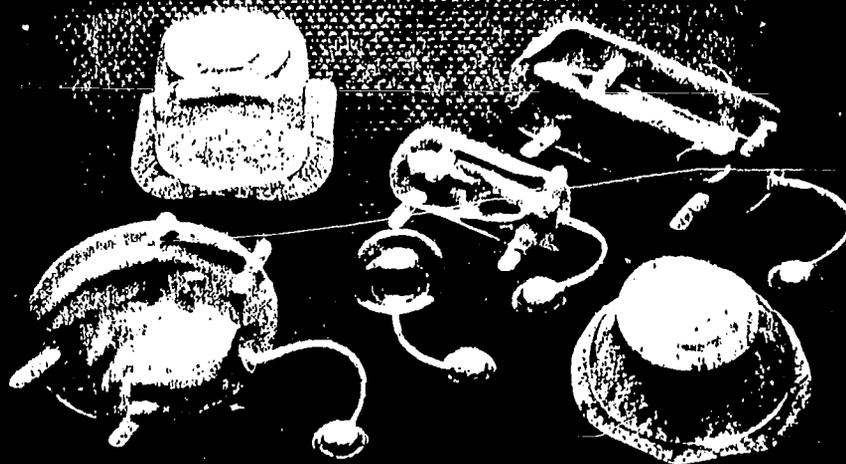
Dow Corning Wright, the long-time leader and innovator in plastic surgery products, utilizing the exclusive H.P. medical-grade formulation, provides another major technological advance with our new sterile SILASTIC® Tissue Expander with self-contained valve. Dow Corning Wright, through expertise in silicone technology, has developed and patented* a unique, self-contained tissue expander which features a metal-backed valve.

Further improvements in the SILASTIC® Tissue Expander include a palpation ring which acts as a guide to target the injection site and a metal-backed needle stop to provide the surgeon with tactile feedback for unambiguous positioning within the valve. The stainless steel needle stop also prevents inadvertent puncturing of the prosthesis.

The SILASTIC® Tissue Expander's self-contained valve eliminates tubing with its tendency to kink, prevents added surgical trauma created by remote placement and removal, avoids the need for aseptic assembly, has no valve connector with its tendency to come off and prevents valve "flip over." The convenient valve collar prevents prosthesis fold over at low fill levels and gives the surgeon a suture option.

This superior valve design and the strength of our H.P. material make us leaders and innovators in Tissue Expansion. The Dow Corning Wright SILASTIC® Tissue Expander is the product you need to provide your patients the safe, pleasing results you want them to have.

For further information, contact your local Dow Corning Wright representative. Ask him also about our custom capability which provides tissue expanders in the shape and size you need for specific cases.



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*U.S. Patent No. 4,428,364

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