Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-18-2015

K002488

JAN - 5 2001

Attachment 3

Summary of Safety and Efficacy Summary of Kelo-cote™ Topical Gel

Manufacturer:	Advanced Bio-Technologies, Inc. PO Box 3099, Silverdale, WA 98383
Regulatory Affairs Contact:	David Bryant
Telephone:	011 44 1477 549392
Date Summary Prepared:	August 8, 2000
Device Trade Name:	Kelo-cote™ Topical Gel
Common or Usual Name:	Silicone Gel
Classification:	Currently unclassified by FDA.
Description:	Kelo-cote™ topical gel is a self drying, topical gel made from medical grade silicone. The primary function of the dressing is to aid in the management of both existing and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds The Advanced Bio-Technologies Inc, Kelo-cote™ topical gel comes in a 15 gram tube for easy application. The gel is supplied non-sterile.
Intended Use:	Kelo-cote™ topical gel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds. Discontinue use if any infection of the wound is suspected and seek guidance from a health care professional. Not for use on third degree burns. Not to be used on open wounds. Not for patients with dermatological conditions which disrupt the integrity of the skin in areas of coverage.
Substantial Equivalence:	Substantial equivalence was provided in 510(k)'s Spenco Silicone Gel Sheet,Spenco Medical Corp and Novagel® Silicone Gel Sheeting, Brennen Medical Inc.
Testing Summary:	.All tests performed in accordance with ISO10993-1 show the product to be non toxic and harmless for its intended application.

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

Advanced Bio-Technologies, Inc.
c/o Mr. David Bryant
Cranage HealthCare International
53 Needham Drive, Suite 5
Cranage
Cheshire, United Kingdom
CW4 8FB

Re: K002488
Trade Name: Kelo-cote™ Topical Gel
Regulatory Class: Unclassified
Product Code: MDA
Dated: November 15, 2000
Received: November 22, 2000

Dear Mr. Bryant:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

Celia M. Witten, Ph.D., M.D. for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 01-19-2015

K002488

510(k) Number (if known): K002488

Device name: Kelo-cote™ Topical Gel

Indications For Use:

Kelo-cote™ topical gel is intended for OTC use for the management of:

Old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR Over The Counter Use** ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost for C. Witten
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002488

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

Advanced Bio-Technologies, Inc.
c/o Mr. David Bryant
Cranage HealthCare International
53 Needham Drive, Suite 5
Cranage
Cheshire, United Kingdom
CW4 8FB

Re: K002488
Trade Name: Kelo-cote™ Topical Gel
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Dated: November 15, 2000
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Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

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Sincerely yours,

Miriam C. Provost

Celia M. Witten, Ph.D., M.D. for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 04-18-2015

K002488

510(k) Number (if known): K002488

Device name: Kelo-cote™ Topical Gel

Indications For Use:

Kelo-cote™ topical gel is intended for OTC use for the management of:

Old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ _____
(Per 21 CFR 801.109)

OR Over The Counter Use ✓

(Optional Format 1-2-96)

Miriam C. Provost for
(Division Sign-Off) C. Witten
Division of General Restorative Devices
510(k) Number K002488

3

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

DATE 12-20-2000

Memorandum

From: Reviewer(s) - Name(s) KEITH FRY

Subject: 510(k) Number K002488-S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device? OTC	☐ YES	☑ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices NA

☑ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: MDA Elastomer, Silicone, For Scar Management

Additional Product Code(s) with panel (optional): Unclassified

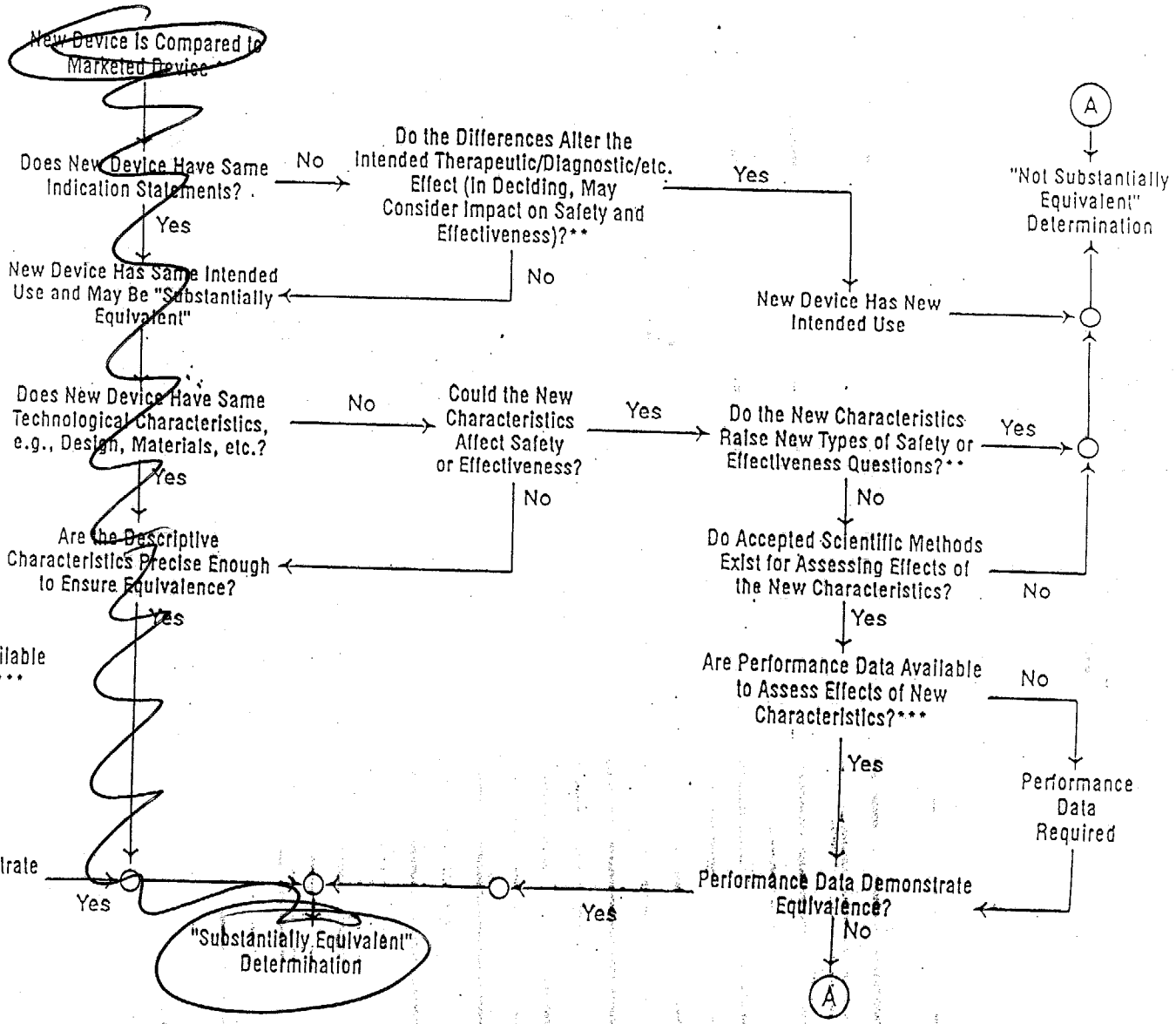
Review: Stephen Rhodes (Branch Chief) PRSB (Branch) 12/28/00 (Date) 4

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

Final Review: Miriam C. Provost, Acting Dep. Director DGRND 1/3/01

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



0(k) Submissions Compare New Devices to Marketed Devices. FDA Requests
ditional Info n if the Relationship Between Marketed and "Predicate"
re-Amendm eclas Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone; But Limited Testing Information Sometimes Required.
*** Data from the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

olive Information New or Marketed ce Requested es Needed

rformance Data Required

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

5

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

K002488S1

Reviewer: Keith Foy, MS
Materials/Mechanical Engineer

Division/Branch: DGRD/PRSB
(HFZ-410)

Proprietary Trade Name: Kelo-cote™ Silicone Gel Scar Management Dressing
Common Name: Silicone Gel for Scar Management
Product to which compared:
(K973572) – Kelo-cote Scar Gel – for management of H & K scars and associated erythema secondary to any trauma causing scars…(also includes laser gel).
(K981902) – Spenco Silicone Gel Sheet
(K963128) – NOVAGEL Silicone Gel sheeting
(K991630) – Advanced Medical Solutions Silicone Gel – supports indications

Applicant: Advanced Bio-Technologies, Inc.
PO Box 3099
Silverdale, WA 98383
Contact: Al Berlat, CEO
Phone: (360) 698-2266 **FAX:** (360) 698-2195
Consultant: David Bryant, Consultant
Phone: 011-44-147-754-9392 **FAX:** 011-44-147-754-9391

	YES	NO
· Is the device life-supporting or life sustaining?	___	X
· Is the device implanted (short-term or long-term)? Permanent	Long term	
· Does the device design use software?	___	X
· Is the device sterile?	___	X
· Is the device single use?	X	___
· Is the device home use?	X	___
· Is the device for prescription? **OTC requested**	X	___
· Does the device contain a drug or biological product as a component?	___	X
· Is this device a kit?	___	X

Indications for Use
The Kelo-cote™ topical gel is intended for OTC use for the management of:
Old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

- While we have been trying to avoid allowing these claims, the sponsor was able to support "…burns, general surgical procedures and trauma wounds" under 510(k) K991630, Advanced Medical Solutions Silicone Gel. Therefore, this is now allowable.

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Device Description

The Kelo-cote™ gel is a self drying, topical gel made from medical grade silicone. The gel is supplied non-sterile, as 15grams, in a plastic tube.

Literature Articles

Silicone gel in scar treatment, Karen J. Quinn, Burns (1967), 13, 533-540.

(b)(4)

[redacted]

Silicon gel: a new treatment for burn scars and contractures, K. Perkins, R.B. Davey and K.A. Wallis, Burns, 9, 201-204.

42 patients with healed thermal burns were treated with the silicone gel and in some cases Jobst garments or pressure inserts. Patient age and scar age and severity varied. The article stated that all 42 patients showed significant improvement, virtually pain free. However, success in this study was based the patients range of motion and/or need for surgical intervention.

Topical Silicone Gel for the Prevention and Treatment of Hypertrophic Scar, Tae Ahn, M.D., William W. Monafo, M.D., Thomas A. Mustoe, M.D.

(b)(4) (b)(4)

[redacted]

Earlier deficiencies and the company response.

(b)(4)

[redacted]

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

(b)(4) Deficiencies

[redacted]

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

(b)(4) Deficiencies

[redacted]

K002488S1

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Substantial Equivalence (SE) Decision Making Documentation

	YES	NO	
1. IS PRODUCT A DEVICE?	X		IF NO, STOP
2. DEVICE SUBJECT TO 510(k)?	X		IF NO, STOP
3. SAME INDICATION STATEMENT?	X		IF YES, GO TO 5
5. SAME TECHNOLOGICAL CHARACTERISTICS?	X		IF YES, GO TO 7
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	X		IF YES, STOP -> **SE**

Reviewer Recommendation: SE

ProCode: MDA Occlusive sheeting for scar management
Class: Unclassified
CFR: §878.4020

Keith Foy, MS
Materials Engineer, PRSB

Date

Keith Foy

Concur
MCP 1/3/01

K002488S1

ID

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Foy, Keith

From: CRANAGEHEALTH@cs.com
Sent: Wednesday, December 20, 2000 6:23 AM
To: KXF@CDRH.FDA.GOV
Subject: Re: K002488

Dear Mr Foy,

Please find attached the response to your e-mail of yesterday

David Bryant

Ph: 011 44 1477 549392

Fax: 011 44 1477 549391

follow up letter to fda III.do...

11

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Suite 6
53 Needham Dr
Cranage
Cheshire, UK
CW4 8FB

Telephone: (44) 1477 549392
Fax: (44) 1477 549931
e-mail: cranagehealth@compuserve.com

Ref:K002488

Mr Keith Foy
Food and Drug Administration
Centre for Devices and Radiological Health
Office of Evaluation (510k)
Document Control Centre HFZ-401
9200 Corporate Boulevard
Rockville , Maryland 20850

20 December 2000

Dear Mr Foy,

Following your e-mail of 19th of December, I have listed below our response to your query.

(b)(4)

[redacted]

12

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

Reconsidered processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

(b)(4)

[redacted]

I hope this is now sufficient to approve the 510k on the above mentioned device.

Yours Sincerely

David Bryant

13

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Foy, Keith
To: CRANAGEHEALTH@cs.com
Subject: RE: K002488

Mr. Bryant,
(b) (4) Deficiencies (b) (4) Deficiencies [redacted]

Please email me your decision/comments as soon as possible.

Keith Foy

-----Original Message-----
From: CRANAGEHEALTH@cs.com [SMTP:CRANAGEHEALTH@cs.com]
Sent: Monday, December 18, 2000 5:12 PM
To: KXF@CDRH.FDA.GOV
Subject: Ref: K002488

Mr Foy

With reference to the above mentioned 510k application, can you please tell me when we should expect the written approval. We are obviously keen to have something before the Christmas vacation.

I await your reply

David Bryant

Ph: 011 44 1477 549392
Fax: 011 44 1477 549391

14

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 24, 2000

ADVANCED BIO-TECHNOLOGIES, INC.
C/O CRANAGE HEALTHCARE INTERNATIONA
53 NEEDHAM DRIVE
SUITE 5, CW4 8FB
CRANAGE, CHESHIRE,
UNITED KINGDOM
ATTN: DAVID BRYANT

510(k) Number: K002488
Product: KELO-COTE TOPICAL GEL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

15

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

K002488-31

Cranage HealthCare International

Suite 5
53 Needham Dr
Cranage
Cheshire, UK
CW4 8FB

Telephone: (44) 1477 549392
Fax: (44) 1477 549931
e-mail: cranagehealth@compuserve.com

RECEIVED
NOV 22 4 03 PM '00
FDA/CDRH/ODE/DMC

Ref:K002488

SK-42

Mr Keith Foy
Food and Drug Administration
Centre for Devices and Radiological Health
Office of Evaluation (510k)
Document Control Centre HFZ-401
9200 Corporate Boulevard
Rockville , Maryland 20850

15 November 2000

Dear Mr Foy,

Following your fax of the 8th of November, I have attached a response, which I hope will clarify our position.

(b) (4) Deficiencies

[redacted]

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

(b) (4) Deficiencies

[redacted]

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Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

(b) (4) Deficiencies

[redacted]

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Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Attachment 3

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Attachment 4
Summary of Biocompatability Testing

(b) (4)

[redacted]

20

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

(b) (4) Third Party Manufacturing Information

(b) (4) Third Party Manufacturing Information

(b) (4) Third Party Manufacturing Information

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(b) (4) Third Party Manufacturing Information

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(b) (4) Third Party Manufacturing Information

Nov-08-00 03:26P
Records processed under FOIA Request # 2015-6975

US005741509A

United States Patent [19]

Kushner

[11] Patent Number: 5,741,509

[45] Date of Patent: Apr. 21, 1998

[54] SILICONE WOUND DRESSING

[75] Inventor: Jack Kushner, Paso Robles, Calif.

[73] Assignee: Alvin S. Berlat, Silverdale, Wash.

[21] Appl. No.: 703,324

[22] Filed: Aug. 26, 1996

[51] Int. Cl.[6] A61F 13/00

[52] U.S. Cl. 424/443; 424/445; 514/944; 514/969

[58] Field of Search 424/448, 449, 424/445, 443; 514/944, 969

[56] References Cited

U.S. PATENT DOCUMENTS

4,865,920	9/1989	Sweet	428/447
4,954,344	9/1990	Gale	424/448
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[57] ABSTRACT

A wound dressing is provided which comprises a blend of silicone fluid and fumed silica having the consistency of a stiff cream prepared in the presence of a volatile diluent that reduces the consistency of the silicon fluid-fumed silica blend to that of a spreadable cream or grease which can applied to a wound without producing further injury or undue discomfort. After the blend is in place on the wound, evaporation of the volatile diluent restores the consistency of the silicone fluid silica blend to its undiluted state, thereby allowing the advantages of increased wound adhesion and "smear proofing" to be achieved without producing further damage to the wound or undue pain and discomfort during application. The consistency of any particular blend of silicone fluid and fumed silica may be adjusted by varying the quantity of volatile diluent, thereby allowing the physician to vary the thickness of the film to help control the loss of water from the protected area.

14 Claims, No Drawings

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SILICONE WOUND DRESSING

BACKGROUND OF THE INVENTION

This invention deals with the field of wound dressings and especially dressings designed for the treatment or prevention of scars resulting from injury or surgery.

Damage to the skin produced by injury or surgery often produces scars instead of the regeneration of the original tissue. While such scars on parts of the body that are ordinarily visible are undesirable as they may create obvious, embarrassing cosmetic problems, they are also very undesirable even on parts of the body which are normally covered. Such scar tissue lacks the functionality of normal skin. For example, the sense of touch may be diminished or completely lost and weak spots are created at locations where such scars join uninjured tissue.

Surgeons and doctors have historically sought and developed procedures, treatments, aftercare coverings, oils and a variety of wound dressings including synthetic skin to lessen the formation of scars. In addition, various procedures and treatments have been tried by the medical profession to ameliorate existing scars.

None of these previous treatments has proven to be totally successful and even the very best of these, such as water bearing plastic films or hydrogels have serious shortcomings. Since such hydrogel dressings do not conform well to the changing topography of the body they press harder at some points than at other points and may not completely cover all injured areas. As the water content of such hydrogel dressings will vary with atmospheric humidity, thus altering their effectiveness and lifetime, a covering or topcoat over the hydrogel sheet is often necessary. The complete hydrogel dressing is heavy, awkward and very difficult to maintain in proper position. Such dressings often require professional attention for proper maintenance. Once released from professional nursing care it is very doubtful that the patient alone or the patient's family can continue the process of maintaining the hydrogel dressing effectively.

A wound dressing designed for the treatment or prevention of scars resulting from injury or surgery should permit easy application to an injured or scarred area without causing undue pain or further damage to the injured tissue. Such a dressing should provide a permeable film over the injured area that would permit the natural transpiration of water vapor and other gases from the underlying tissue. In addition, the permeable film should be nearly weightless and should substantially completely cover any desired area with a thin, uniform, compliant film. Such a wound dressing film should also be generally waterproof or hydrophobic so that as a consequence of such hydrophobicity the film would resist the penetration of pathogenic organisms that require a water pathway to get past the film to the tissue beneath.

Furthermore, the wound dressing film should be made of materials that do not support the growth of pathogens. The wound dressing film must also remain intact when the underlying surface wrinkles, stretches or flexes and should not resist such changes in the underlying surface. The materials from which such a wound dressing is formed must be inert in contact with the wound surface and the surrounding tissue and must not exhibit any harmful effect when used correctly for its intended purpose. The wound dressing film should also have sufficient adhesion to the underlying surface that it protects so that a deliberate effort is required to remove it completely. Ideally, the material comprising such a film would be adjustable in consistency so that the thickness of the film can be varied as needed by the physician to help control loss of water from the protected area.

Many of the above requirements may be met with medical grade silicone oils, also known as siloxanes. Although such oils meet the biological properties required for this application and in addition have a very good record of compatibility with human tissue, they do not have the physical consistency which would make them suitable for use as wound dressings. Generally these materials are too fluid and oily for use as a wound dressing. Generally the consistency of a stiff cream or grease is desirable for the wound dressing when it is in place on the wound. Therefore, physical properties of silicone oils, such as viscosity, must be altered to achieve such a consistency. The desired consistency can be obtained by blending a relatively viscous silicone oil with fumed silica. Typically a silicone oil having a viscosity of at least about 5000 centistokes or higher can be blended with fumed silica to obtain the consistency of a stiff cream or grease. Such blends have been known for a long time and are well documented as a means of converting most oils to the consistency of a grease.

For example, a blend of a silicone fluid having a viscosity of 30,000 centistokes (manufactured by Dow-Corning Inc. and others) with fumed silica having from about 2% to about 3% by weight of fumed silica produces a suitable wound dressing. Although such a blend provides a vast improvement in consistency over the unblended silicone fluid, a much more viscous blend than this composition is desirable to improve adhesion to the wound and to prevent the dressing from smearing (i.e. "smear-proofing"). However, blends having the consistency to provide improved adhesion and "smear-proofing" are too difficult to apply to injured skin without causing further injury and pain. As a result, a compromise must be made in which a wound dressing having a more fluid consistency than would be ideal for a wound covering is used in order to avoid further injury and pain during application. This compromise in consistency has severely limited the use of such silicone based wound dressings in some situations.

There is a need for a silicone based wound dressing having high viscosity and thereby increased wound adhesion that can be used on wounds to prevent scarring without causing undue pain or further injury when it is applied. There is a further need for a silicone wound dressing that does not easily smear. Yet another need is for a method of applying high viscosity wound dressings to a wounded area without causing further injury or undue pain. A still further need is for a silicone wound dressing that can conveniently provide coatings of varying thickness to control water loss from the wound.

BRIEF DESCRIPTION OF THE INVENTION

The present invention is directed to meeting the foregoing needs by providing a wound dressing composition comprising silicone oils, fumed silica and a volatile diluent. Blends of non-volatile silicone fluid and fumed silica having the consistency of a stiff cream are prepared with a volatile diluent that reduces the consistency of the silicon fluid fumed silica blend to that of a spreadable cream or grease which can be applied to a wound without producing further injury or undue discomfort. After the blend is in place on the wound, evaporation of the volatile diluent restores the consistency of the silicone fluid silica blend to its undiluted state, thereby allowing the advantages of increased wound adhesion and "smear proofing" to be achieved without producing further damage to the wound or undue pain and discomfort during application. The consistency of any particular blend of silicone fluid and fumed silica may be adjusted by varying the quantity of volatile diluent, thereby

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allowing the physician to vary the thickness of the film to help control the loss of water from the protected area.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The wound dressing of the present invention comprises a blend of non-volatile silicone oil and fumed silica having the consistency of a stiff cream or grease, and a volatile diluent which in combination with the non-volatile silicone oil and fumed silica blend forms a composition having the consistency of an oil or a light grease. The blend of silicone oil, fumed silica and volatile diluent is coated on an injured area of the body so that a film or coating is formed that covers the injured area. The volatile diluent rapidly evaporates from the film formed by the mixture of silicone oil, silica and volatile diluent leaving a flexible, protective film or coating over the injured area, the film or coating comprising a blend of non-volatile silicone oil and silica having the consistency of a stiff cream or a grease.

The non-volatile silicone oil component forms the base for the wound dressing and provides the chemical properties of the barrier between the injured tissue and the environment. Any silicone oil having a viscosity of at least about 5000 centistokes to about 200,000 centistokes or higher can be used for the wound dressings of the present invention, depending on the properties desired. The higher the viscosity of the silicone oil component, the more durable and removal resistant is the ultimate residual film covering the injured area. The lower the viscosity of the silicone oil component, the more easily can the wound dressing be applied to the injured area and the more easily can it be removed when required. By using the full range of silicone oil viscosities, the wound dressing can be tailored to the unique needs of each case. Silicone fluids having viscosities of about 30,000 centistokes are preferred as they provide a balance of residual film durability and ease of applicability. Most preferred is silicone fluid SF 200 having a viscosity of about 30,000 centistokes produced by Dow-Corning Inc. (Midland, Mich.) or any other generally equivalent silicone fluid produced by other silicone oil manufacturers.

The amorphous fumed silica provides a micro-skeletal structure when dispersed in the silicone oil that interacts with the silicone oil component and forms a gel. The viscosity of the original silicone oil is dramatically increased when blended with suitable quantities of fumed silica to that of a non-fluid grease-like gel. Any amorphous fumed silica that suitably thickens the silicone oil component may be used. Such fumed silicas include both untreated types and types that have been chemically treated to alter the fumed silica surface. Examples of suitable fumed silicas include but are not limited to Aerosil® 90, 130, 150, 200, 300, 380, R202, R805, R812, R972, R974 (Degussa Corporation, Ridgefield Park, N.J.) and CAB-O-SIL® TS-720 and M-5 (Cabot Corporation, Tuscola, Ill.). Generally, Aerosil® 200, Aerosil® R974, CAB-O-SIL® TS-720 and any other generally equivalent products from other manufacturers of fumed silicas are preferred as they suitably thicken silicone oils. The larger the quantity of fumed silica in the blend, the firmer is the resultant gel.

Compositions containing from about 0.5% to about 12% fumed silica based on the weight of the silicone oil component are preferred as they provide consistencies that make useful wound dressings. More preferred are compositions containing from about 1% to about 4% fumed silica based on the weight of the silicone oil component as they provide a balance of thickness and workability.

The volatile component provides a vehicle for loosening or reducing the viscosity of a silicone oil blend that is too thick to spread on an injured area, without causing further pain or injury, to a level which makes it readily spreadable or applicable by other means such as spraying. Within minutes of application, the volatile component evaporates from the loosened reduced viscosity blend leaving a protective wound dressing film residue having the consistency of a stiff cream in place on the wounded area. The properties of the residual silicone oil-silica blend are unaltered after evaporation of the volatile component. In some cases, such as extremely viscous silicone oil-silica blends, traces of volatile component may remain in the composition after application, but they are eventually driven off by body heat. The volatile component may be any suitable fluid that can dissolve or disperse a silicone oil-fumed silica mixture and that is also volatile at or around room temperature. Volatile silicone fluids are preferred as they are generally most compatible with silicone oils. Examples of suitable volatile silicone fluids are Dow-Corning 244 which comprises the cyclomethicone octamethylcyclotetrasiloxane and Dow-Corning 245 which comprises the cyclomethicone decamethylcyclopentasiloxane and other similar silicone fluids produced by other manufacturers. Mixtures of volatile silicone fluids may also be used to alter the rate of volatilization if desired. The volatile component can be added to the silicone oil-fumed silica blend in any proportion required to reduce the viscosity to an easy to apply oil or light grease. At very high dilution, for example 1 part of silicone oil-fumed silica blend to 1000 parts of volatile component, the product can be applied as a mobile fluid with a suitable applicator or even as a spray from a spray bottle. At the other extreme, as little as 1% of the volatile fluid can be added to the more fluid silicone oil-silica blends to assist in their application. The useful range of the volatile component therefore is from about 1% to about 99.9% by weight of the final mixture of silicone oil, fumed silica and volatile component.

The wound dressings of the present invention may be prepared by stirrers, blenders, mills and the like, and any other means known in the art for blending silicone oils and fumed silica. In addition pressure vessels, condensing systems and other means known in the art and commonly used to retain a volatile component in a mixture may be employed in the preparation of the wound dressings of the present invention. Generally, the silicone oil-fumed silica blend is first prepared and then admixed with the volatile diluent. However, in some cases the components comprising, silicone oil, fumed silica and volatile diluent may be combined in one stage to form the wound dressings of the present invention. For wound dressings tailored to specific needs, the method of blending previously prepared silicone oil-fumed silica blends to a desired consistency with the volatile diluent is most convenient.

Use of a volatile diluent provides enormous flexibility in the preparation of silicone based wound dressings since the non-volatile residue can be made to any desired viscosity and protective resistance to smearing or inadvertent removal by simply increasing or decreasing the proportion of silica, and yet still be applied without causing further injury or undue pain.

The flexibility offered by the practice of the present invention permits a complete range of physical properties to be obtained that are appropriate to the stage at which the wound dressing is used. A very fluid consistency may be obtained for the purpose of easy application to an injured skin area without pain, while the residual film left after

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evaporation can have the physical properties ideally suited for good adhesion to and protection of the wound or scar area. As the residual film may have a high viscosity, a sufficient thickness of wound dressing may be built up over the wound or scar area, which will generally remain in place over the wounded area, to control water vapor loss from the injured area. Without the addition of volatile oil, the viscosity of the residual evaporated film and consequently, the properties useful in a wound dressing that are associated with it, could not be adjusted through a broad range suitable for treatment of a wide variety of skin wounds and scars.

Although the present invention has been described in considerable detail with reference to certain preferred versions thereof, other versions are possible. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred versions contained herein.

What is claimed is:

1. A wound dressing comprising a mixture of:

a blend of silicone fluid and about 0.5% to about 12% fumed silica based on the weight of the silicone fluid, with the blend having a first consistency, with the first consistency being the consistency of a stiff cream, and

about 1% to about 99.9% of a volatile diluent based on the weight of the final mixture, with the mixture having a second consistency, and with the second consistency being the consistency of a spreadable cream,

so that the mixture can be easily applied to a wound, and a protective covering comprising the blend of silicone fluid and fumed silica having the first consistency, will remain on the wound upon evaporation of the volatile diluent.

2. The wound dressing of claim 1 in which the blend of silicone fluid and fumed silica contains about 1% to about 4% fumed silica.

3. The wound dressing of claim 1 in which the volatile diluent comprises a volatile silicone fluid.

4. A wound dressing for the treatment of scars and wounds to the skin prepared in steps comprising:

a) forming a blend comprising silicone fluid and about 0.5% to about 12% fumed silica based on the weight of the silicone fluid, the blend having a first consistency, with the first consistency being the consistency of a stiff cream;

b) mixing the blend of step a) with about 1% to about 99.9% of a volatile diluent based on the weight of the final mixture, to form a mixture of silicone fluid, fumed silica and volatile diluent, with the mixture having a second consistency, and with the second consistency being the consistency of a spreadable cream.

5. The wound dressing of claim 4 in which the first consistency is the consistency of a grease, and the second consistency is the consistency of an oil.

6. The wound dressing of claim 4 in which the volatile diluent comprises a volatile silicone fluid.

7. A process for forming a protective coating of viscous silicone grease on a wound comprising the steps of:

a) forming a viscous grease from a silicone fluid and about 0.5% to about 12% fumed silica based on the weight of the silicone fluid;

b) mixing the viscous grease formed in to about 99.9% of a volatile diluent based on the weight of the final mixture, to form a mobile fluid;

c) applying the mobile fluid formed in step b) to the wound so that the mobile fluid coats the wound;

d) allowing the volatile diluent to volatilize from the mobile fluid applied to the wound in step c) thereby forming a residual coating comprising the viscous grease formed in step a) that protects the wound.

8. The process of claim 7 in which the viscous grease formed in step a) is a gel.

9. The process of claim 7 in which the volatile diluent of step b) comprises a volatile silicone fluid.

10. The process of claim 7 in which step c) comprises spraying the mobile fluid formed in step b) on the wound so that the mobile fluid coats the wound.

11. The wound dressing of claim 3 in which the volatile diluent comprises a volatile silicone fluid selected from the group consisting of octamethylcyclotetrasiloxane, decamethylcyclotetrasiloxane and mixtures thereof.

12. The wound dressing of claim 6 in which the volatile diluent comprises a volatile silicone fluid selected from the group consisting of octamethylcyclotetrasiloxane, decamethylcyclotetrasiloxane and mixtures thereof.

13. The process of claim 9 in which the volatile diluent comprises a volatile silicone fluid selected from the group consisting of octamethylcyclotetrasiloxane, decamethylcyclotetrasiloxane and mixtures thereof.

14. The wound dressing of claim 2 in which the blend of silicone fluid and fumed silica comprises a silicone fluid having a viscosity of about 30,000 centistokes.

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1. Silicone gel in scar treatment
Karen J Quinn: Burns (1987) 13, S33-S40

2. Topical silicone gel: A new treatment for hypertrophic scars
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Burns (1987) 13, S33–S40 Printed in Great Britain

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Silicone gel in scar treatment

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Topical silicone gel: A new treatment for hypertrophic scars

Sang Tae Ahn, MD, William W. Monafo, MD, and Thomas A. Mustoe, MD, St. Louis, Mo., and Seoul, S. Korea

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Burns, 9, 201–204 *Printed in Great Britain*

Silicone gel: a new treatment for burn scars and contractures

K. Perkins, R. B. Davey and K. A. Wallis
The Burns Unit, The Adelaide Children's Hospital, South Australia

Summary
A new method of treatment for burn scar management is outlined using silicone gel sheets (Spenco Corporation MD-3071). The method has been applied to 42 patients with burns of varying degree and maturity. The results have been successful in all cases. The mode of action of the gel is unknown, but it does not rely on pressure. The method can easily be tailored to the individual needs of the scar and the patient. Individual initiative and a flexible approach to its use are advocated.

THE degree of scarring left by a thermal injury depends on the depth, extent and site of the burn and the age of the patient. Burn scar management aims at preventing scars from interfering with function and making them cosmetically acceptable: the aims to be achieved as comfortably, quickly and inexpensively as possible.

For many years the method used to achieve these aims has been by the application of pressure such as Jobst anti-burn scar garments. However, effective pressure is difficult and somtimes impossible to apply to scars located in anatomical depressions, over flexures or during movement, unless a variety of pads, pressure inserts or splinting is added to the regimen.

Whilst searching for a medium that would comfortably and effectively convey uniform pressure to any scar in any position or during any movement, a technique was tried that appeared to do that and more. The medium was silicone gel sheets (Spenco Medical Corporation MD–3071), a chemically inert, transparent, flexibile gel supplied as 4 × 4 in (10 × 10 cm) sheets.

PATIENTS AND METHODS

Since February 1981, silicone gel sheets have been applied to 42 patients with healed thermal injuries at The Adelaide Children's Hospital Burns Unit. The children ranged in age from 4 months to 16 years. The injuries ranged from newly healed burns to mature scars up to 12 years old and varied in severity from minor to major.

Silicone gel was first used on a patient with no flexion in the metarcophalangeal joints of his right hand. Within 30 min he was able to move these joints actively through to full flexion (*Fig.* 1).

Twenty of the 42 patients were already receiving pressure treatment with Jobst garments or other methods when silicone gel sheets were introduced, so that pressure remained the main component of their treatment programme before the full value of silicone gel was recognized.

Eleven of these 20 patients also had pressure inserts of either Silastic foam dressing (382 medical grade Silastic elastomer), polycushion or washable sheepskin. These inserts were then alternated with gel until the optimum contact time for the gel was established, and the use of pressure garments reduced accordingly. The gel appeared to relax and soften the scars, allowing the inserts and pressure garments to hasten their levelling effect on the hypertrophied area.

The remaining 9 patients had gel inserts added to their regimen in view of the success with the above 11. Two of the 42 patients had fully matured scars thought to require surgical release. Following the application of silicone sheets for several weeks, one patient no longer required the release, while the other required only minimal surgery. The last 20 patients had

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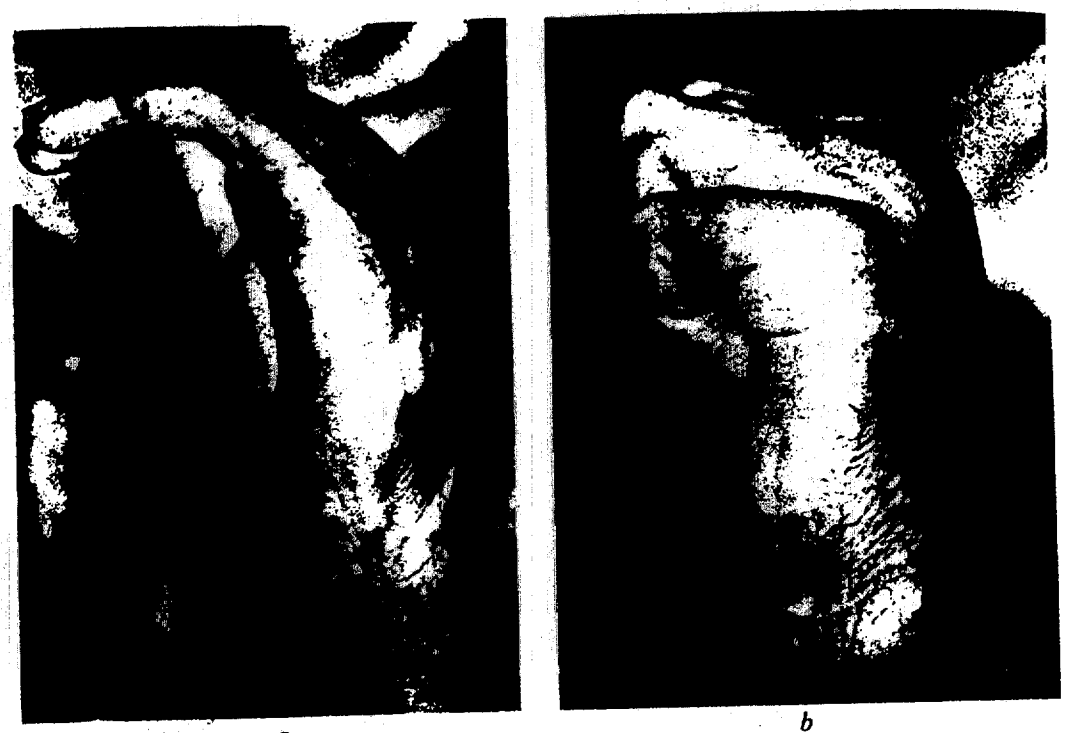

a *b*

Fig. 1. *a*, Before the application of silicone gel sheets; *b*, 30 min after application of gel.

silicone sheets only as the main component of treatment.

All 42 patients showed not only significant improvement, but also pronounced the treatment virtually pain free.

CASE REPORT

A 7-year-old girl sustained 50 per cent full-thickness flame burns to her face, trunk, both axillae, both arms and both thighs (*Fig.* 2). The whole area was treated by excision and split skin grafting. Silicone sheets were applied to each area as it healed and, except for bathing, creaming and swimming, continuous gel contact was maintained until scar maturity. Nine months after injury she has a full range of movement of all joints, no contractures and requires no releases, with all scarring pale, soft and supple. It is expected that all treatment will be discontinued within 12 months of injury. She has worn garments that exerted pressure sufficient only to keep the silicone sheets in position. Other treatment included a full exercise programme, the use of a double abduction frame for 3 months (possibly unnecessary with hindsight), creaming twice daily and regular swimming. With 50 per cent of her body covered in silicone sheets, she still participated in all normal activities at school and at home. Before the advent of silicone gel she would almost certainly have required bilateral axillary releases at a minimum.

MANAGEMENT

Silicone gel sheets were originally designed as inserts in sporting footwear etc. to prevent friction. No data were available for use in the treatment of burns scars and contractures, so the method of application has been by trial and error. A single method cannot be defiined as no two burns are the same. Some principles of management can, however, be outlined.

The sheets are used in two ways: either directly applied to the healed burn or indirectly in a lint envelope. Silicone sheets are applied as soon as there is skin coverage. They not only adhere and mould to any body contour but can be safely and painlessly applied to and removed from newly healed burns or skin grafts. They are applied for increasing periods until the longest possible direct contact time is established. If applied for too long the area will become red or itchy or exhibit 'a heat rash reaction'. They are not used on open areas due to excessive moisture.

Areas healed by grafting and mature scars will tolerate silicone gel sheets continuously within 1–2 weeks. Partial-thickness burns allowed to heal spontaneously will tolerate silicone gel

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a

c

b

Fig. 2. *a*, Three days after injury; *b*, 2 months after grafting; *c*, 10 months after application of silicone gel sheets.

sheets up to 8–10 h daily. Used in this way, the gel does not rely on pressure.

When the gel is not being used directly on the healed area it is enclosed in a lint envelope. It then becomes a 'Jelly bag' making a comfortable pad for the area either to convey pressure or to protect from friction. It is kept in place by an appropriate garment made of cotton–Lycra or Powernet depending on the degree of pressure used in the treatment.

The cotton–Lycra garments are made in the physiotherapy department and as this fabric has a high cotton content, the lighter weight, cooler garments are well suited to South Australia's hot climate. The material can also be styled into clothing that is fashionable, thus reducing the psychological impact of the injury and the treatment on each child, family and general public.

An important factor in the treatment is that the silicone sheets are used on a regular basis.

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Once the regimen is established, the silicone sheet should be used accordingly, until the scar is pale, mature and acceptable, usually within 9 months of injury. Under the influene of silicone gel, split skin grafts refrain from shrinking, whilst the area around and partial-thickness burns healed by epithelization refrain from hypertrophying with their usual exuberance. All of the treated areas fade more rapidly than similar untreated areas. The early application of gel will define areas with hypertrophy potential, allowing therapy to be concentrated on these areas

Because of its anti-frictional qualities, gel is an excellent lining for splints, which can thus be applied at a very early stage to prevent anticipated contractures, the gel being either in direct contact with skin or covered with lint to give a friction-free comfortable splint.

CONCLUSION

The cautious optimism regarding the potential of silicone gel sheets (Spenco Corporation MD–3071) in the treatment of burns scars and contractures has been more than realized. They can be used as a simple, comfortable and effective method of pressure treatment, but they can also be used in the following situations without the need for pressure:

1. Over joints where movement is restricted by tight painful scars, silicone gel sheets will allow pain-free movement in a matter of minutes.
2. Over healed skin grafts, they prevent shrinkage or contracture of the graft.
3. Applied to healed partial-thickness burns, the area with hypertrophy potential will declare itself well before the usual 6–8 weeks.
4. When applied to advanced hypertrophied scar tissue the area will soften, thus allowing it to be more easily controlled by pressure.
5. The use of silicone sheets alone or in conjunction with accepted pressure and pressure insert techniques allows treatment to be tailored to a patient's needs, allowing for a more flexible approach in burn scar management.

Why or how silicone sheets work is unknown, but unlike other methods it does not rely on pressure. Spenco silicone sheets are indeed a most useful medium, a medium that will help to prevent scarring from interfering with function and help to make it cosmetically acceptable regardless of degree, site or age, these results being achieved concurrently, comfortably, quickly and inexpensively.

The full potential of gel is probably no yet realized as newer uses are continually being developed.

Paper accepted 27 April 1982.

Correspondence should be addressed to: Mrs K. Perkins, Physiotherapy Department, The Adelaide Children's Hospital, North Adelaide, South Australia 5006.

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PROPRIETARY.

ɔpical Silicone Gel for the Prevention ıd Treatment of Hypertrophic Scar

Tae Ahn, MD; William W. Monafo, MD; Thomas A. Mustoe, MD

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Cica-Care gel sheeting in the management of hypertrophic scarring

S. A. Carney[1], C. G. Cason[2], J. P. Gowar[2], J. H. Stevenson[3], J. McNee[3], A. R. Groves[4], S. S. Thomas[4], N. B. Hart[5] and P. Auclair[6]

[1]Burns Research Group and [2]West Midlands Regional Burns Unit, Birmingham Accident Hospital, [3]Dundee Royal Infirmary, [4]The Manor Hospital, Nuneaton, [5]Kingston General Hospital, Hull and [6]Dow Corning Healthcare Europe, Valbonne, France

A prospective, controlled clinical trial was undertaken to assess the efficacy and safety of two types of silicone gel, Silastic Gel Sheeting (SGS) and Cica-Care (CC), in the management of hypertrophic scars. Forty-two patients were randomly assigned to SGS and CC groups and their hypertrophic scars were divided into treated and control areas. Extensometric measurements were made at monthly intervals for 6 months and significant improvement of the treated areas relative to the control areas was observed. The two gels were not significantly different in efficacy or safety, but CC, being more adhesive and more conformable than SGS, has advantages in ease of use and patient acceptability.

Introduction

Injuries which penetrate the deep dermis often result in the formation of scar tissue. Scars may follow a normal course of maturation and resolve to an acceptable state with patience rather than active intervention, but hypertrophic scarring is still a widespread problem with a particularly high incidence in burn-injured children under the age of 5 years[1]. The aim of treatment is to minimize the amount of permanent disability and/or disfigurement, as a scar is permanent visible evidence of a significant event in a person's life, and may be a permanent reminder of a very bad experience.[2].

The clinically significant features of hypertrophic scars have been described and defined by Muir[3] and Peacock[4], and the extensive biochemical and histological investigations which have been carried out on scar tissue have been reviewed by Cohen and McCoy[5], and Kischer et al.[6] Forms of treatment currently in use are more empirically based, but nevertheless are constantly subject to efforts at improvement. Silicone gels fall into this category, and this paper describes a study aimed at comparing the efficacy and safety of Silastic Gel Sheeting (Dow Corning) with Cica-Care, a modified gel designed for greater ease of use.

Methods

The study took the form of an open, controlled trial comparing two types of silicone gel, both produced by Dow Corning, one being the standard Silastic Gel Sheeting (SGS) and the other a development product with geater flexibility and adhesive properties, Cica-Care (CC).

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0305-4179/94/020163-05

The patients were recruited at Birmingham Accident Hospital, Dundee Royal Infirmary, Kingston General Hospital and the Manor Hospital, Nuneaton. Entry criteria required hypertrophic scars which could be divided into treated and control areas, or two adjacent and comparable areas of scarring. Each control or treated area had to be large enough to permit extensibility measurements with the extensometer described by Quinn[7], which has a span of 4 cm. Patients between the ages of 2 and 65 years were eligible, provided they or their parents were prepared to give informed consent, were capable of following the treatment schedule and keeping simple records, and were prepared to return for assessment as requested. Patients who had received other treatment aimed at reducing scarring were not admitted to the trial until 1 month had elapsed after cessation of such treatment.

Patients entering the study were given detailed instructions in applying and washing the gel, and were initially encouraged to wear it for as many hours per day as possible. Hours of wear were recorded daily by the patient or parent. The gel was washed in warm soapy water at least daily and dried gently on paper before reapplication. New gel was used when the piece in use became fragmented or difficult to handle. If irritation occurred gel use was discontinued until the problem resolved. Contraindications requiring gel treatment to be discontinued were severe irritation, flaking, weeping or blistering of the skin.

Patients were required to attend a review clinic monthly during 6 months of gel treatment, and then 3 months and 6 months after it was discontinued. At each visit the scar was photographed and the appearance of the treated and untreated areas assessed for state and colour on the scale published by Leung et al[8]. Irritation as described by the patient was rated on a scale of 0–5. The extensibility of each area of the scar was measured as described by Quinn[9]. A standard assessment form was completed at the 2-month and 6-month visits, recording colour, texture, general condition of the scars, and the patient's opinion of the comfort of the scarred area. At the 2-month assessment each treated or control area was rated in one of four categories as: worse, stable, improved or much improved compared with the condition at the commencement of treatment. At the 6-month assessment a comparison was made with the state of the scar areas after 2 months of treatment.

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Results

Forty-two patients were enrolled in the trial, with a total of [illegible] scars. The demographic data obtained at the initial visit were used to compare the homogeneity of the two groups. Significant differences between the groups were demonstrated in respect of age, racial origin, smoking habits, cause of scarring, scar location and the colour and extensibility of the scar at the time of entry into the trial. There was a preponderance of males in the CC group, but it is unlikely that this had a bearing on the outcome of treatment.

The average age of the patients studied was 23.2 years, with a range of 2–60 years; 37 per cent of the scars were on limbs and 13 per cent on hand or foot. Scars of the neck and face accounted for 20 per cent, axilla or shoulder 17 per cent, and chest 13 per cent of scars studied. The vast majority (92 per cent) were the result of burns or scalds. After 2 months of treatment 93 per cent of scar areas treated with CC and 86 per cent treated with SGS were rated as improved, compared with only 12 per cent of untreated areas. Comparable figures at 6 months were 93 per cent, 100 per cent and 38 per cent.

The results specifically relating the colour and texture of the scars after 2 months (28 patients) and 6 months (21 patients) are given in *Tables I* and *II*. The results obtained from extensometry are shown in *Figure 1*.

At 2 months and 6 months from the commencement of treatment the extensibility of the areas treated with SGS or CC was significantly greater than that of the untreated areas, the increases being comparable with those reported by other authors[10]. The initial extensibility of hypertrophic scars ranged from 0 to 8 per cent, while extensibility of normal skin measured by the method used in this study averaged 14 per cent. There was no evidence of regression after suspension of the treatment in patients successfully treated who returned for assessment at 9 and 12 months.

Table I. Effects of SGS and CC on colour and texture of scar areas after 2 months of treatment

	% of areas worse or stable	*% of areas improved*
Blanching		
Untreated	88.0	12.0
SGS	30.8	69.9
CC	33.3	66.7
CC vs. untreated, $P=0.008$		
SGS vs. untreated, $P=0.005$		
Softening		
Untreated	86.0	14.0
SGS	15.4	84.6
CC	6.6	93.4
CC vs. untreated, $P<0.001$		
SGS vs. untreated, $P<0.001$		

Table II. Effects of SGS and CC on colour and texture of scar areas after 6 months of treatment

	% of areas worse or stable	*% of areas improved*
Blanching		
Untreated	47.6	52.4
SGS	11.1	88.9
CC	0	100.0
CC vs. untreated, $P=0.007$		
Softening		
Untreated	62.0	38.0
SGS	0	100.0
CC	0	100.0
CC vs. untreated, $P=0.002$		
SGS vs. untreated, $P=0.012$		

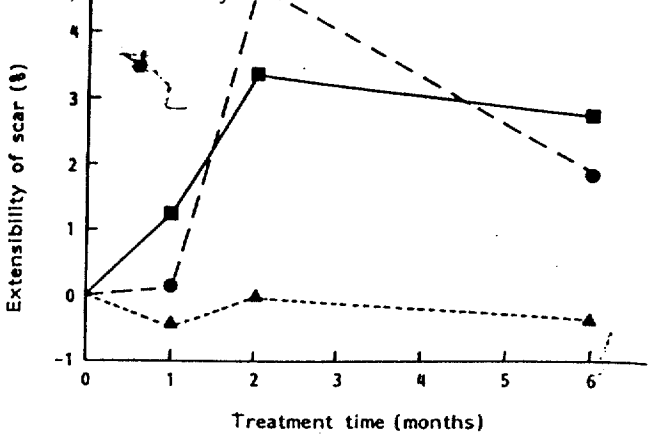

Figure 1. Percentage extensibility of untreated hypertrophic scars, hypertrophic scars treated with Silastic Gel Sheeting and hypertrophic scars treated with Cica-Care. ▲----▲, Untreated scars; ●—●, scars treated with Silastic Gel Sheeting; ■—■, scars treated with Cica-Care. The extensibility of scars treated with Silastic Gel Sheeting was significantly greater than that of untreated scars after 2 and 6 months of therapy ($P<0.0001$, $P<0.03$). The extensibility of scars treated with Cica-Care was significantly greater than that of untreated scars after 1, 2 and 6 months of therapy ($P<0.03$, $P<0.001$, $P<0.04$).

The gels were well tolerated in general, and a phased build-up in the length of time for which the gels were worn per day helped in this respect. Not all adverse events reported could be causally related to the use of the gels, although pruritus was commonly reported. This is often a feature of hypertrophic scars and 48 per cent of patients enrolled in the study reported it before treatment commenced. Irritation at the beginning of the treatment sometimes occurred. Experience suggests that such problems were minimized by use of the gel for a few hours a day initially, with gradual build-up to continuous wear if this could be achieved. There was no significant difference between the groups in the number of hours per day (17.4/18.5) that the gel was worn on the scar. All of the SGS-treated group reported fragmentation of the gel as opposed to 33 per cent of the CC-treated groups.

The adhesive properties of the CC were of considerable advantage in positioning and fixing the gel. On some sites such as the face the gel was used alone and additional fixation was not needed. The average lifetime of this material (6.8 days) was also greater than that of SGS (4.5 days).

Case reports

A male patient aged 27 years received a steam scald to his upper arm in an industrial accident resulting in hypertrophic scar formation. He found that a pressure garment was inconvenient to wear at work and was treated with SGS, with satisfactory results (*Figures 2, 3*). There was no recurrence of hypertrophy 6 months after treatment ceased.

A 2-year-old girl developed scattered areas of hypertrophic

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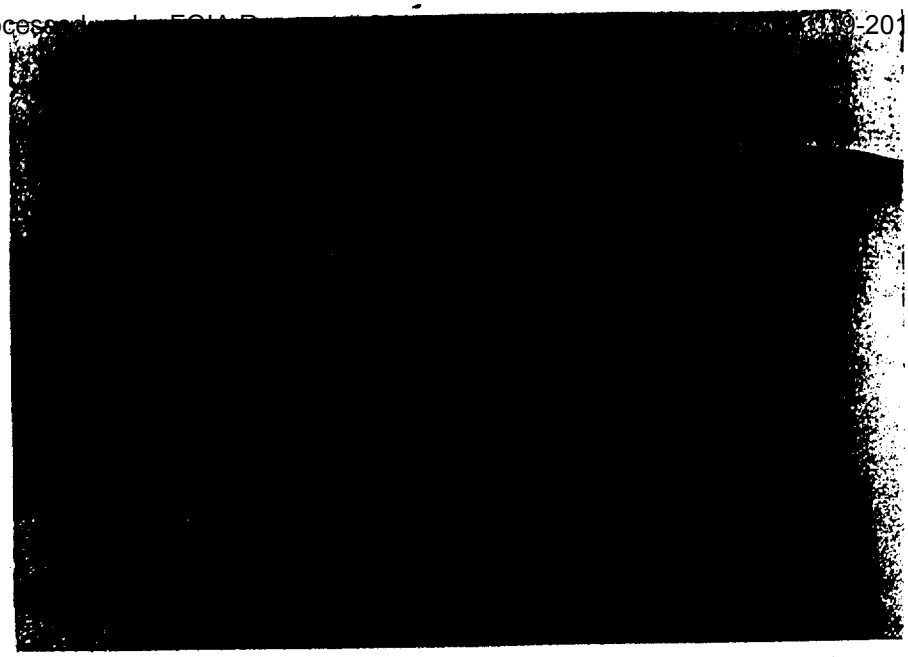

Figure 2. Hypertrophic scar on the arm of a 27-year-old male patient at the time SGS treatment commenced on the distal half of the scar.

Figure 3. Hypertrophic scar on patient in *Figure 2* after 5 months. SGS treatment to the distal half of the scar.

scarring from scalds resulting from hot water spillage. CC was used for 6 months with good results (*Figures 4, 5*).

Discussion

Studies of hypertrophic scarring, particularly those attempting to assess the effects of treatment, are complicated by many variables, it is therefore desirable that an acceptable indicator of scar maturation and resolution should be measured at regular intervals. Measurements of extensibility, as described by Quinn[7], were used in this study to enable quantitative comparisons to be made. In addition, blanching and softening of the scars was recorded. These assessments were necessarily less objective than the extensometric measurements, but sources of variation were reduced by maintaining the same investigator once a patient had entered the trial and by careful recording of the examination findings. Comparisons of the colour of the scars were assisted by photography under standardized conditions. The data obtained substantiated previous reports[7,9–15] of the efficacy of SGS in the management of hypertrophic scars. Untreated areas of scarring showed decreasing extensibility with time, the extent varying with the location. Gel treatment produced improvement at all locations, but least

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Figure 4. Hypertrophic scar on 2-year-old female patient at commencement of CC treatment to shoulder scar only.

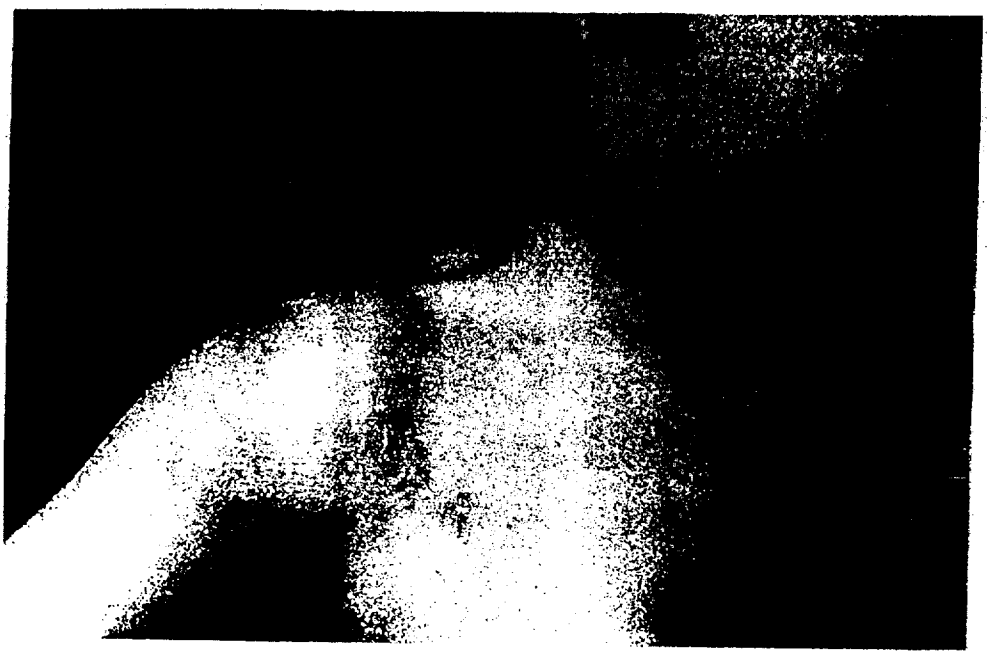

Figure 5. Hypertrophic scar on patient in *Figure 4* after shoulder scar had received 5 months' treatment with CC.

effect was obtained at sites such as the neck or face, where prognosis is known to be poor.

Patient motivation is a vital factor in maintaining continuity of treatment with gels, where fitting, washing and replacing the material is the patient's own responsibility on a day-to-day basis. A careful and detailed explanation was always given when treatment commenced, an instruction sheet written in simple direct terms (Appendix) was also supplied and a contact telephone number given. Patients who mastered the gel application technique sufficiently to attend for assessment over the first 2 months usually completed the 6 months of treatment.

Where fixation of the gel was required, i.e. for Silastic Gel Sheeting or Cica-Care on difficult sites, adhesive tape was used, or a soft tubular bandage (Tubifast, Seaton) which was not tight enough to apply pressure.

A direct comparison between the efficacy of the gels and that of pressure garments has not been attempted, but it appears that scar improvement from gel treatment equals that produced by pressure garments with the advantages of more rapid effect, and efficacy in older scars which do not respond to pressure therapy.

No major adverse effects were recorded. A tendency increased irritation, when not directly attributable to p

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hygiene, could be minimized by gradually increasing the hours per day for which the gel was worn, rather than attempting maximum use from day one. Both SGS and CC produced statistically significant increases in scar extensibility after 2 months and 6 months of use, and were effective on old scars and scars unsuccessfully treated with pressure garments. CC had advantages over SGS in ease of use, its adhesive properties making additional fixation unnecessary in some cases. Because of its greater flexibility and reduced tendency to splitting, greater conformability to the scar surface was possible with this gel and patient acceptability was increased. This is a promising method for the treatment of hypertrophic scars and warrants further study.

Acknowledgements

Thanks are due to Miss R. Lester and Mr P. Levick for permission to include their patients in this study, and to the Occupational Therapists at Birmingham Accident Hospital for their valuable advice and cooperation.

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Appendix: Patient Instruction Sheet

Treatment of scars with Silastic Gel Sheeting

1. Application

Cut the gel sheeting to fit the part of the scar to be treated and apply it with the shiny surface in contact with the skin. (The shiny surface is uppermost when the gel is in the tray.) Hold the gel in place with the tubular bandage and/or the adhesive tape supplied.

2. Care

The scar should be washed at least once a day, and more often if this is necessary for comfort and hygiene. The gel should also be washed and dried (blotting with kitchen paper is the easiest). The same piece can then be used again. It only needs to be replaced when it breaks up or becomes too difficult to clean.

3. Records and reactions

Wear the gel for as many hours per day as it is comfortable to do so. If increased itching, dryness or wetness occur, or a rash appears, leave the gel off for a few hours and try again later, until you find out what routine suits you best. If a rash persists leave the gel off completely and contact Mr Gowar, or his registrar, or the Burns Research Group (Dr Carney or Mrs Cason) (phone number given). Please try to keep a record of the number of hours per day you are able to wear the gel, and note any changes that you see in the scar.

A similar information sheet was devised for patients using Cica-Care.

Paper accepted 5 September 1993.

Correspondence should be addressed to: Dr S. A. Carney, 190 West Heath Road, West Heath, Birmingham B31 3HB, UK.

SYMPOSIUM ON PLASTIC SURGERY AND BURNS WITH INTERNATIONAL PARTICIPATION AND NURSING SECTION

Brno, Czech Republic, 25th - 27th May 1994

in parallel with Applied Skin Culture Meeting, organized by the European Tissue Culture Society.

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Non-pressure treatment of hypertrophic scars*

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Static-Electric Field Induction by a Silicone Cushion for the Treatment of Hypertrophic and Keloid Scars

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Haifa, Israel

Silicone gel and silicone occlusive sheeting are widely used at present for the treatment of hypertrophic and keloid scars, without any scientific explanation as to their mode of action.

In a recent paper the possibility was raised that static electricity generated by friction-activated silicone sheeting could be the reason for this effect, and that it can, with time, cause involution of hypertrophic and keloid scars.

The objective of this study was to test this hypothesis and to observe whether a continuous and also an increased negatively charged static-electric field will shorten the treatment period. A device to implement these requirements gradually evolved over a 5-year period. A number of prototypes were tested until the final product was attained. Some of the patients in this study were treated initially with a silicone sponge inserted in the cushion. Later this version was changed to the final design described herein.

A silicone cushion was developed with the purpose of increasing a negative static-electric charge to accelerate the regression process. The cushion is custom-made using a silicone occlusive sheeting envelope of 0.75-mm thickness, which does not deteriorate with use, and is partially filled with high viscosity silicone oil. Its edges are sealed, and its size is designed to extend a little beyond the scarred area. Static electricity readings, generated by activating the cushion by pumping action with the fingers, stretching or deforming the cushion, are invariably much higher when compared with those obtained with silicone occlusive sheeting and silicone gel sheeting. The interaction between the negatively charged ions of the cushion and the ionic charges of the tissue fluids may be the critical factor in achieving hypertrophic and keloid scars involution.

Of the 30 patients enrolled in the study, 3 patients dropped out. Treatment with the silicone cushions yielded 63.3 percent cessation of itching and burning followed by pallor and flattening of the scar, some markedly so, over a few weeks to 6-month period. An additional 26.6 percent had their scars resolved in up to 12 months of treatment. Good contact of the cushion over the scar has been shown to be important in this clinical trial, and much creativity is needed for making elastic strap bindings that ensure this contact. The clinical trials extended over a 12-month period.

Ten patients (33.3 percent) who had recalcitrant scars with little response to the use of the silicone cushion were given intralesional corticosteroid injections, in addition to the continued use of the cushion, resulting in a fairly rapid resolution of these scars over a period of months to a year. (*Plast. Reconstr. Surg.* 101: 1173, 1998.)

There are histopathologic differences between hypertrophic scars and keloids[1]; however, from a clinical standpoint the treatment of both is virtually identical.

In a previous paper recording the results of a study using silicone occlusive sheeting in the management of hypertrophic and keloid scars,[2] it was hypothesized that the negatively charged silicone gel and silicone occlusive sheeting that act on hypertrophic and keloid scars induce polarization in the scar tissue. When this takes place over a prolonged period of time, it could result in the involution of these scars.

That clinical trial lasted approximately 18 months, and it showed satisfactory results in 88 percent of 32 hypertrophic and keloid scars treated by applying silicone occlusive sheeting

From the Technion Israel Institute of Technology, Lady Davis Carmel Hospital, and Maccabi Sick Fund. Received for publication March 5, 1997; revised May 30, 1997.

Dr. Har-Shai, Prof. Hirshowitz, and Prof. Lindenbaum have stock options in Life Medical Sciences, Inc., the company that funded this research project. The patent for this device was filed by Life Medical Sciences, and the rights to it belong to that company. The Technion Israel Institute of Technology will receive royalties from sales of the device should it be marketed, and the authors mentioned will receive a share of these royalties as well.

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over them. These results compared more than favorably with some other modalities of scar treatment, such as the application of cortisone creams and ointments, intralesional injection of corticosteroids, and pressure garments, which had previously been used in some of these patients. However, considering the discomfort and even distress that many of these patients were suffering until scar involution, it was decided to try and reduce this time lag.

If the assumption is correct that static electricity helps in causing involution of hypertrophic and keloid scars, then an increased static-electric field would hasten the involution of these scars. A device would have to be created that would generate higher levels of static electricity than silicone sheeting does. To satisfy clinical needs it should be of simple design, comfortable when applied to the scar surface, and relatively inexpensive. Ideally, the static-electric field should be self-perpetuating in the sense that the device should be readily recharged by friction of the investing clothes and bodily movements.

A silicone cushion has been designed that generates an increased negatively charged static-electric field and that fulfills these requirements. It is partially filled with high-viscosity silicone oil (Silicaid°F, 30,000 centipoise) enclosed within a silicone envelope of 0.75-mm thickness medical grade silicone occlusive sheeting and is air free. Prolonged use does not cause deterioration of the silicone envelope. The overall thickness of the silicone oil–filled cushion is 4 to 5 mm. It is easily compressed, and this ability imparts to it a soft and pliable consistency. It conforms well to the frequently irregular contours of the underlying scar, enabling nonfocal pressure to be evenly distributed over the scar. The oil is displaced where the scar is elevated and accumulates in areas of depression. The edges of the silicone occlusive sheeting envelope are sealed with clear RTV adhesive sealant (Permatex 66B). In these custom-made cushions the sealed edges can be covered with hypoallergenic self-adhesive fabric for comfort (Fixomull Stretch, Beiersdorf AG., Germany). Friction or deformation by stretching, rubbing, or pumping action with a finger on the cushion may elicit readings of up to 3 to 5 kV/inch of negatively charged static electricity, when ambient conditions are favorable. These readings are taken with a static fieldmeter (Fig. 1) (Charleswater W. Newton Co., Boston, Mass.) with the cushion suspended in the air.

FIG. 1. A photograph of the static fieldmeter placed on a silicone cushion registering −2.95 Kv/inch of static electricity.

When conditions are dry with low humidity, the silicone cushion produces a high static-electric field. Conversely when the weather is hot with high humidity, these readings are lower. It has been noted that cushions with larger surface area give higher readings.

A random comparison of static fieldmeter readings of silicone gel, silicone occlusive sheeting, and silicone cushion was made. All were applied to the skin of the arm. Fixation was by means of elastic netting, and readings were taken by lifting up the end of the sheeting or cushion together with the overlying netting.

These readings show variability; however, it is clear that the cushion produces a far higher static-electric field than the other two sheetings (Table I). We consider that the difference is the dynamic movement of the semifluid, highly viscous silicone oil, enclosed within two layers

TABLE I

Comparison of Static-Electric Fieldmeter Readings (kilovolts/inch) at 25°C and 65% Humidity

Device	Time (min)							
	0	15	30	45	60	75	90	Mean ± SD
Silicone occlusive sheeting	2.80	2.00	1.00	0.28	1.10	1.65	1.24	1.44 ± 0.75
Silicone gel	1.54	1.05	1.70	0.20	0.42	0.32	0.27	0.78 ± 0.59
Oil-filled silicone cushion	3.25	4.10	5.25	3.30	4.41	3.02	3.80	3.88 ± 0.73

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of occlusive sheeting, which continuously causes deformation and stretching, inducing regeneration of the static-electric field. This induction is in contrast to the immobile silicone sheeting in which the static-electric field is intermittently generated by friction of overlying garments and by the limited amount of body movements.

Materials and Methods

Thirty patients with hypertrophic and keloid scars of diverse cause were included in this study, three of whom were lost to follow-up. The trial extended over a 12-month period. All scars that had been present for 4 to 6 months or more were included. Informed consent was obtained from every patient as well as approval of the Institutional Review Board (Helsinki Committee) for research in human subjects.

No controls were used in this study because long-standing scarring before the onset of treatment and refractoriness to other modes of treatment served here as a form of control.

As in the previous trial,[2] the three parameters of hardness, elevation, and color were examined. Also assessed were subjective complaints such as pain, itching, and discomfort (Table II).

Good contact of the silicone cushion on the scar surface is important. To ensure this contact, two procedures are necessary: (1) overlapping the scar edges by the silicone cushion; (2) use of elastic strap bindings, which are passed through loops located on the outer surface of the cushion, ensures a tight anchoring of the cushion to the scar surface (Fig. 2).

The average size of the silicone cushions ranges from 20 to 200 square cm, and they were custom made to fit the variety of scar sizes. Personal hygiene was impressed on our patients, who were required to swab the cushion daily with 95% alcohol and thoroughly dry both the scar area and the cushion. A good

TABLE II

Comparison of Results of Silicone Cushion and SOS* Treatments[2]

Improvement Rate	SOS Team Evaluation No. (%)	Silicone Cushion Team Evaluation No. (%)
None	4 (12.5)	2 (6.6)
Slight	5 (15.6)	5 (16.6)
Moderate	12 (37.5)	12 (40.0)
Excellent	11 (34.4)	11 (36.6)

* SOS, silicone occlusive sheeting.

FIG. 2. A photograph showing the elastic strap bindir passing through fixation loops anchoring the silicone cus ion over the sternomanubrial region. The back strap is a justable with Velcro.

deal of skin irritation occurs when ointmen and creams are applied under the cushion, an their concomitant use with the cushion shoul be avoided.

Patients were encouraged to use the cusl ions for most of the day and night, and possible the cushions should be removed on for cleansing. No adhesive or micropore tap were used for fixing the silicone cushions, b cause they invariably led to skin hypersensiti ity.

Not all patients were able to tolerate tl cushion for more than a few hours stretc because of an unpleasant feeling under tl cushion. In our experience, this feeling w also encountered with the silicone occlusi sheeting.

Results

Table III presents scar location and age scar of the 30 patients of the trial, the results treatment, and the length of time to invol tion. What is evident is that all patients remai ing in the study showed improvement of sym tomatology within a 6 months period, with 63 percent of patients registering definite allevi tion of their symptoms, as well as flattening ar pallor of the scars. The remaining 24 perce had their scars resolved within 1 year. In patients a rapid relief of symptoms, associat with flattening and softening of the scars, co menced within 2 to 3 weeks after the cushic was applied.

However, the rate of improvement was n uniform, some scars responded rapidly ar others more slowly. One reason for the variab ity could be related to scar location, for exar ple, over a bony surface, such as the sternur

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TABLE III

Hypertrophic and Keloid Scar Management Using a Silicone Cushion*

Patient Initials	Redness		Elevation		Hardness		Itching		Tenderness/ Pain		Site	Age of Scar	Cortisone Injection	Time for Scar Improvement (Months)
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post				
Y.M.	3	1	3	0–1	2	0–1	2	0	1	0	Right knee	4mo	Yes	4
M.N.	2	0	2	0–1	2	0	1	0	1	0	Sternum	1 yr	No	4
V.B.	2	0–1	2	0–1	2	0	1	0	1	0	Breast	10mo	No	3
I.B.	2	0	2	0	2	0	1	0	0	0	Sternum	7 yr	Yes	3
K.D.	2	1	2	1	2	1	0	0	0	0	Face	3–4 yr	Yes	12
S.G.	3	1	3	1	2	1	1	0	0	0	Left arm, thorax	10mo	No	9
Z.E.	2	0	1	0	2	0	2	0	2	0	Chest	6mo	Yes	3
S.M.	2	0	1	0	2	0	1	0	1	0	Breast	6 yr	No	1
O.M.	2	0	2	0	2	0	1	0	1	0	Breast	12 yr	No	5
J.A.	2	0–1	2	0–1	2	0	2	0	2	0	Trunk	5 yr	Yes	10
S.B.	1	1	3	3	3	3	1	1	1	1	Sternum	7 yr	Dropped out	
R.A.	2	1	3	1	2	1	3	1	3	1	Sternum	1 yr	No	9
Y.Z.	2		1		3		1		1			Dropped out		
I.G.	2	1	2	0	2	0	2	0	1	0	Breast	1 yr	No	6
K.Z.	2	2	2	2	2	1–2	1	0–1	1	0–1	Shoulder	1 yr	Yes	12
N.L.	2	1	3	1	3	1	2	0–1	1	0–1	Buttocks	5mo	Yes	12
J.G.	2	0	2	1	2	0	3	0	2	0	Sternum	5 yr	Yes	3
S.D.	2	1	1	0	1	0	3	1	3	1	Epigastrium	4mo	No	4
L.S.	3	1	3	1	3	1	2	1	3	1	Sternum	1 yr	No	4
A.G.	2	0–1	2	0–1	2	0–1	2	0–1	1	0–1	Wrist	4mo	No	2
H.M.	2		1		2		0		0			Dropped out		
Y.K.	3	1	2	0	2	0	2	0	3	0	Left arm, forearm	38 yr	No	2
S.Z.	3	2	2	1	2	1	2	1	2	0	Left arm	2.5 yr	No	12
E.A.	2	2	1	1	2	2	1	1	1	0–1	Shoulder, sternum	4 yr	Yes	3
G.L.	3	1	3	0–1	2	1	1	0	2	1	Sternum	1 yr	No	2
E.D.	3	1	3	1	3	2	2	1	2	1	Thigh	9mo	No	1–2
N.B.	3	2	1	0	2	0	1	0	1	0	Left knee region	5mo	No	7
V.G.	2	0	1	1	2	0	1	0	2	0	Sternum	4mo	Yes	1.5
H.W.	2	1	1	0	2	0	0	0	1	0	Sternum	15 yr	No	0.5
N.D.	3	2	2	1	2	1	2	1	1	0	Sternum	20 yr	No	5.0

* Redness: 3, severe redness; 2, redness disappears with pressure; 1, no redness, but alteration in skin tone; 0, normal skin color. Elevation: 3, over 8 mm in height above surrounding skin; 2, 4–8 mm; 1, 1–4 mm; 0, flat or depressed scar. Hardness: 3, very hard, like cartilage; 2, rubbery hard; 1, partially soft; 0, soft (like normal skin). Itching: 3, severe itching sensation or constant itch with signs of scratching; 2, occasional itchy sensation, moderate and tolerable; 1, sometimes itchy; 0, no itchy sensation. Tenderness and Pain: 3, severe irritable pain; 2, moderately irritable pain; 1, sometimes painful; 0, without pain. Pre, before treatment; Post, after treatment.

the response was generally good. Eight patients with sternal scars improved, whereas one was regarded as recalcitrant. Good compression on the scar because of the underlying bone, is important. However, in four cases the scar location was on the breast, and all improved within 6 months. In one patient (Y.K.) a 38-year-old keloid scar in the axillary-arm region rapidly responded within a few weeks after commencement of treatment (Fig. 5, *below*).

Long-standing scars of many years duration and also dense scars of hard consistency responded more slowly to treatment. Patient compliance and readiness to use the cushion for most hours of the day was also a factor that affected the results of treatment.

Before the realization that a well-fitted compression binding over the cushion was mandatory, there had been refractoriness of hypertrophic and keloid scars in six patients. After the use of such a binding, ensuring good contact of the cushion with the scar, a real impetus was given to the involution of the same scars.

There were 10 patients (33.3 percent) whose recalcitrant scars were injected with intralesional corticosteroids. This combination of treatment seemed to definitely accelerate the involution of the scars. Four of these patients had, prior to the use of the cushion, received intralesional corticosteroid injections with no appreciable improvement.

Our overall 81 percent involution rate with silicone cushions, including 27 percent who had intralesional corticosteroid injections, usually within a relatively short time of weeks to 6 months after commencement of therapy is encouraging, especially because the cushion was used in some patients only during part of the day. Patients whose scars were on exposed parts of the body, such as the face, neck, and chest tended to wear the cushions only at night.

In two female patients, after softening and

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flattening of their scars [one woman with a scar over the upper sternum (H.W.) and the other with scars of her breast after mastoplasty (I.G.)], some persistent redness of their scarring was still present when treatment with the silicone cushion was discontinued. The cushions were reapplied for a few more weeks and blanching of the scars ensued. In three patients with long-standing keloid scars, reversibility of the scars was noted. When the silicone cushion was used regularly, the scars flattened somewhat and symptoms improved; whereas, if the cushion was not in use for 2 to 3 days, there was a recurrence of the scars. We have no satisfactory explanation for this observation.

In five patients, the response was minimal; perhaps patient compliance was somewhat lacking because of difficulties with wearing the compression binding and the underlying cushion in hot, humid conditions. Two young women with multiple keloid scars over the upper back and shoulder regions had difficulty in continuing with treatment because of the above reasons.

In one patient who was particularly sensitive to the wearing of synthetic fabrics, a silicone cushion was placed on a fresh vertical hypertrophic scar of the midline of lower abdomen, after a hysterectomy. The patient complained of a burning sensation and severe itchiness after wearing the cushion for 2 days, and she was forced to discontinue its use. Although this was the only such case encountered in our series of 30 patients, the explanation we can offer is that, because the silicone sheeting is a synthetic material, it could not be tolerated by this patient who had skin sensitivity to all synthetic fabrics. (This patient was not included in Table III.)

Case 1

A boy (M.N.) aged 3 years sustained, 14 months previously, second-degree burns on his neck, chest, and left arm from very hot water. Healing was uneventful apart from residual hypertrophic scarring over the upper sternum and the inner aspect of the arm. He was fitted with a pressure garment. A layer of silicone occlusive sheeting was also used over each of the scars. After 9 months of this treatment no appreciable improvement of the sternum scar was noted (Fig. 3, *above*), although the arm scar flattened appreciably and became paler. Five months ago he was provided with a silicone cushion over the sternum scar, which was used in conjunction with the compression binding. After 4 months there was satisfactory involution of the scar (Fig. 3, *below*).

Case 2

Six years ago, a 16-year-old girl (A.B.) had a nevus surgically removed from the upper sternal area. Within a few months a keloid scar measuring 4 × 3 cm developed. It was hard, raised, and reddish in color, slightly itchy and without pain. She was given a layer of silicone occlusive sheeting to wear over the scar. The patient had four intralesional corticosteroid injections, given over a period of 3 years with some slight softening of the scar.

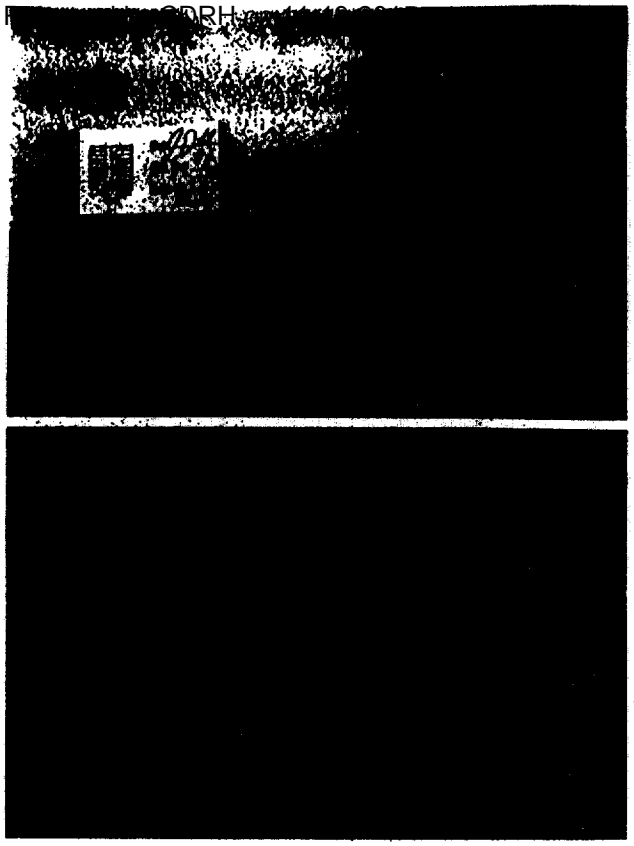

FIG. 3. (*Above*) A postburn hypertrophic scar over the upper sternum in a 3-year-old child who wore compression binding together with silicone occlusive sheeting for 9 months, with minimal improvement of the scar. (*Below*) The hypertrophic scar has almost completely flattened 4 months after replacing the silicone occlusive sheeting layer with a silicone cushion. The pressure garment continued to be worn.

Seven months ago she was provided with a silicone cushion that she wore fairly continuously during the day. After 3 months there was no improvement of the scar (Fig. 4, *above*). The scar was then injected intralesionally with corticosteroids, and the silicone cushion continued to be worn thereafter. The effect was quite dramatic and the scar became flat, pale (Fig. 4, *below*), and symptomless.

Case 3

A 63-year-old man (Y.K.) sustained multiple shrapnel wounds 38 years ago. He developed keloid scarring of the inner aspect of the left arm, bordering on the axilla (Fig. 5, *above*), as well as over the left upper abdomen and back. He underwent all available treatment modalities throughout the intervening years, and he continued to suffer a good deal of pain, itchiness, and discomfort, particularly from the scar of the arm. He was referred for silicone cushion therapy, which was used over the arm scar 4 months ago. Within 3 to 4 weeks there was a definite improvement of the scar, which consid-

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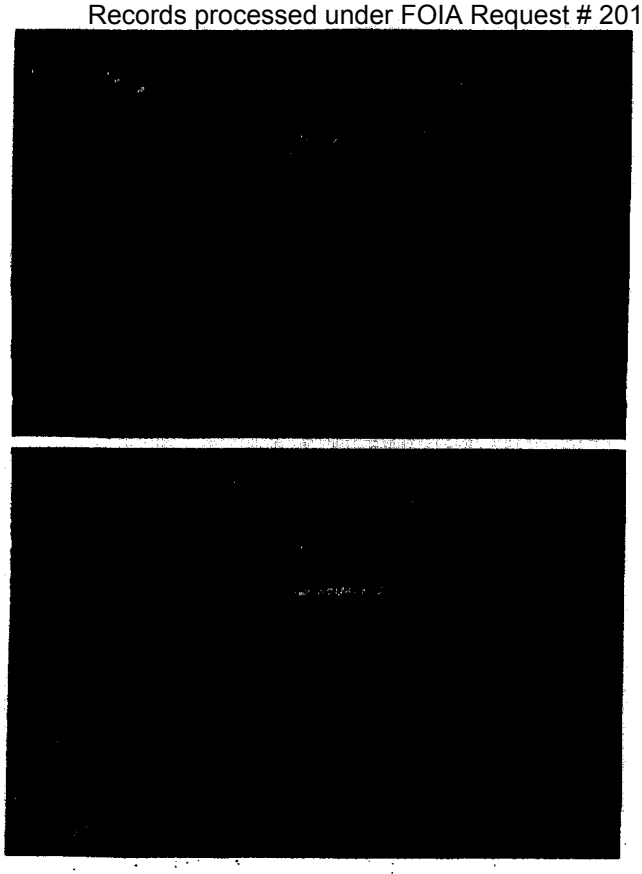

FIG. 4. (*Above*) Surgical intervention 6 years ago on this 16-year-old girl produced a 4 × 3 cm keloid scar over the sternum, which was treated with silicone occlusive sheeting and intralesional corticosteroid injections with some improvement of the scar. Seven months ago she was provided with a silicone cushion, with minimal improvement. After 3 months, an intralesional corticosteroid injection was given in addition to the cushion. (*Below*) Almost complete flattening of the scar is observed 2 months later.

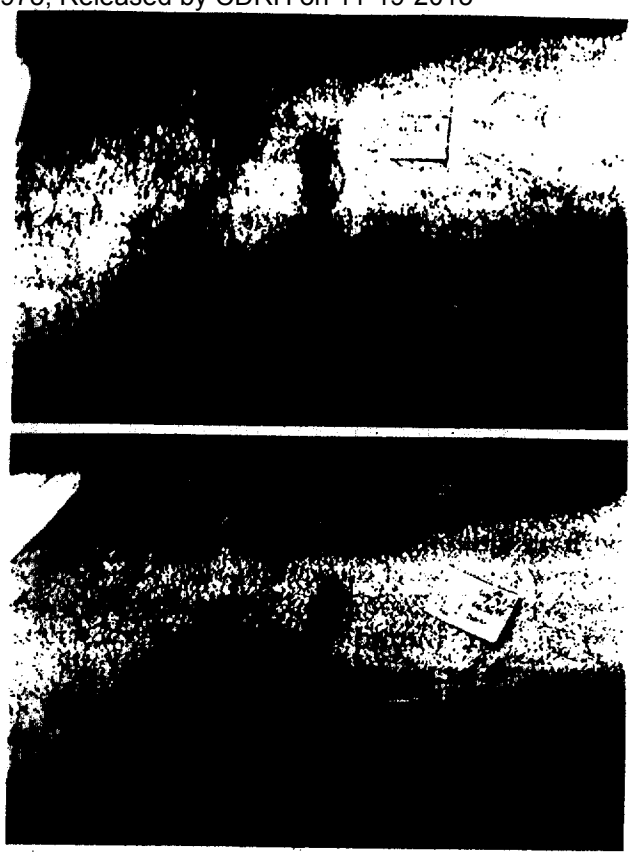

FIG. 5. (*Above*) A 63-year-old patient developed keloid scars on various parts of the body from shrapnel wounds 38 years ago. One such scar on the inner aspect of the arm, bordering the axilla, caused a good deal of discomfort notwithstanding all available treatment modalities throughout the intervening years. (*Below*) He was provided with a silicone cushion, which after 3 to 4 weeks resulted in almost total involution of the scar.

ering its long duration, was unexpected. It is now soft, flat (Fig. 5, *below*), and the patient has almost no discomfort.

Case 4

L.S., a woman aged 70 years, underwent open heart surgery for ischemic heart disease 1 year previously. After the scar became painful, irritable, and raised, she started therapy with a silicone cushion (Fig. 6, *above*). The involution of the scar was observed 4 to 6 weeks after commencement of treatment, and the present appearance of the scar, 3 months later, is seen in Fig. 6, *below*, with the scar flatter, paler, and with far less discomfort.

Case 5

Y.M., a man aged 72 years, had a prosthetic replacement of the right knee performed 10 months ago. The vertical scar became hypertrophic 3 months after surgery, and the prominent scar was tender and irritable (Fig. 7, *above*). Six months ago he began using the silicone cushion, and initial results after 6 weeks were encouraging with some flattening of the scar, which became somewhat paler (Fig. 7, *below*). Two intralesional corticosteroid injections were given with an interval of 2 months between them, with the silicone cushion being used continuously. The scar is now flat, soft, and not irritable (Fig. 7, *below*).

Case 6

A 21-year-old man (E.D.) suffered third-degree burns of the medial surface of both upper thighs, 12 months previously. These areas were skin grafted a with partial take, and he was left with a prominent hypertrophic scar on the right thigh (Fig. 8, *above*). The scar was hyperirritable and was aggravated by walking. He was fitted with a pressure garment together with silicone occlusive sheeting with no appreciable improvement.

Three months ago he was provided with a silicone cushion, and there was quite a dramatic response with flattening of the scar (Fig. 8, *below*) and alleviation of symptoms.

DISCUSSION

Static electricity is an entity that is generally considered to be of a nuisance value. Dry atmospheric conditions favor its production. Its presence on the body is evidenced by a crackling sensation when hair is combed or when synthetic clothing tends to cling to the wearer.

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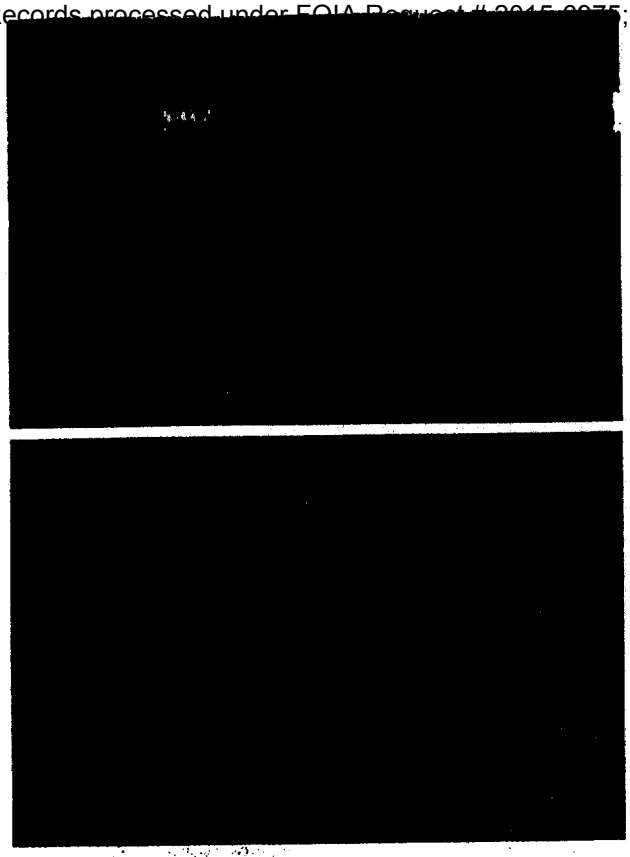

FIG. 6. (*Above*) A keloid scar developed after open heart surgery in a 70-year-old woman. The scar was red, raised, hard, and very sensitive. (*Below*) Three months after the use of the silicone cushion, the scar is flatter, paler, and with much less discomfort.

FIG. 7. (*Above*) A 72-year-old man developed a tender prominent hypertrophic scar over the knee after prosth replacement of the joint 10 months previously. He was vided with a silicone pillow with slight initial improvem Thereafter, there was some regression of the scar. (*Below*) intralesional corticosteroid injection was given. Th months later most of the scar had flattened. The silic pillow was worn continuously.

In motor cars it can cause sparking when the body of the vehicle is touched; to avoid such unpleasant effects, some cars have grounding rods that trail onto the road surface, preventing the accumulation of static electricity. Some plastic bags in food stores are difficult to open because of adherence of the layers due to static electricity. The presence of static electricity on an object can be ascertained by the way dust is attracted to the surface of the object. In industry, static-electric fields of considerable intensity, reaching millions of volts per square inch, can be generated in various situations and can be hazardous to life. An example of this is when grain is poured from chutes into sacks. Great efforts are made to contain such dangers. Lightning flashes are an extreme example of static-electricity discharge.

Amber is a translucent, brittle, pale yellow (sometimes reddish or brownish) fossil resin of pine trees, found in Northern Europe and Africa. It contains 5% succinic acid and becomes negatively static electrified by friction. It is widely used as ornaments. In ancient tin amber necklaces were worn to treat thyr gland pathologic conditions.

In the operating room, when flamma gases such as ether were used for anesthe sparking due to friction by moving a tro could result in an explosion; because of hazard, antistatic materials are used on flo ing and on wheels to avoid this eventually.

The electrostatic readings of the body face as recorded by the static fieldmeter positive. The critical element in the involut process of hypertrophic and keloid scars wo seem to be the interaction between the ne tive static-electric field of the silicone cush and the charged components of the tissue ids.

The skin of a scar is thinner than non skin and has no skin appendages; by provid less insulation, the interaction between charged surface of the cushion and

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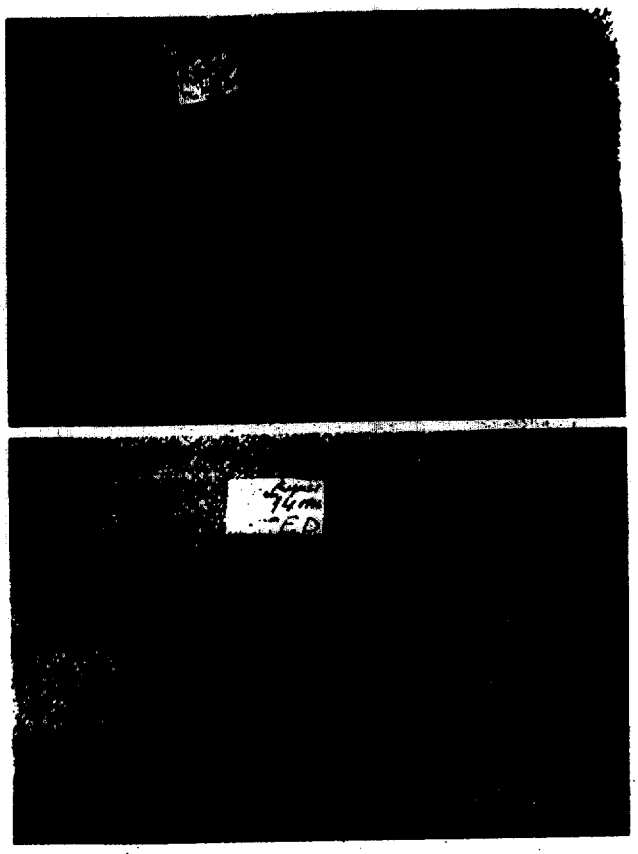

FIG. 8. (*Above*) A hypertrophic scar of the medial aspect of the thigh, after a deep burn is shown before the use of the silicone cushion. (*Below*) The appearance of the scar 3 months after treatment by the use of a silicone cushion demonstrates flattening, softening, and blanching.

charged components circulating in the tissue fluids, in the scar tissue matrix, may be facilitated.

Could some people accumulate more static electricity on their body surface than others, and could this account for the somewhat unpredictable response to treatment when silicone sheeting or cushions are used for the treatment of hypertrophic or keloid scars? This difference may be a variable that can affect the outcome of treatment with the silicone sheeting or silicone cushion.

Comparison of the results of this study with those that were previously reported[2] are revealing. Table II indicates the similarity in results of the treatment with the two modalities, the silicone occlusive sheeting and the silicone cushion. However, what is striking is the difference in the speed of improvement. The majority of patients using the silicone cushion showed improvement within weeks (Fig. 9), whereas those who used the silicone occlusive sheeting demonstrated scar involution generally after many months.

When a silicone cushion is immersed in water, because of the hydrophobic nature of the oil, no water is able to pass into the cushion through the silicone occlusive sheeting envelope. This impermeability is important, we believe, in ensuring the continued regeneration of a static electricity field by the cushion. Moisture vapor, which may accumulate between the cushion and the skin, especially in humid conditions, could cause the rapid decay of the static-electric field. The presence of some "dampness" on the scarred area under the cushion should theoretically cause decay of the static-electric field because water vapor is a conductor. However, static-electric field measurements on the under surface of the cushion range in value from 3 to 5 kV/inch (Table I),

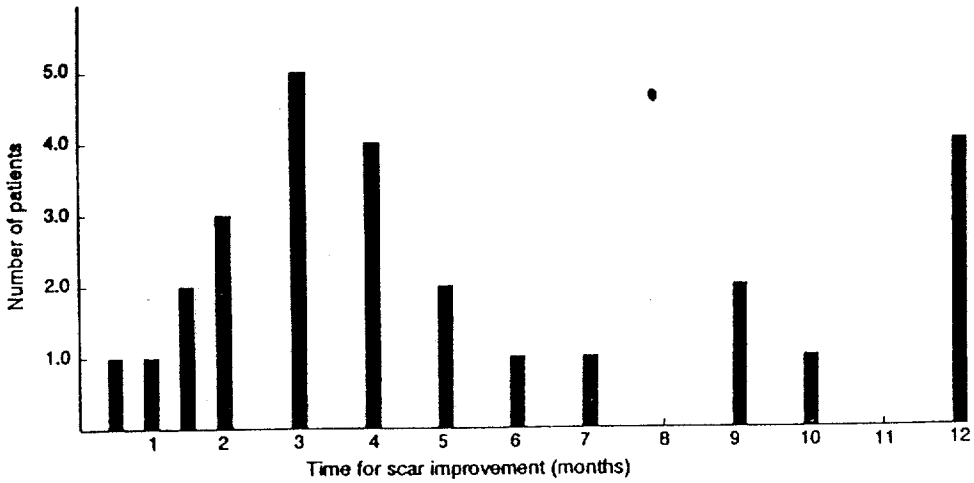

FIG. 9. Histogram of time for scar improvement after silicone cushion treatment. Note that a majority of the patients (22) were improved within a 6-month period.

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long period. This consistent charge is sufficient to produce the desired scar involution.

During the development of the silicone cushion, a 6- to 11-mm-thick silicone sponge provided the initial insert. These sponge-filled cushions did give a good deal higher static-electric reading than silicone occlusive sheeting under favorable climatic conditions. But, during the hot, humid summer months, it soon became apparent, especially in patients who had a high propensity to perspire, that the passage of water vapor into the cushion prevented the regeneration of the static-electric field. The silicone sheeting is semipermeable to water vapor, and its presence in the cushion interfered with the effectiveness of the cushion. Whereas, with the silicone-oil–filled cushion, unfavorable climatic conditions with high humidity did not adversely affect the efficacy.

Electrostatic measurements comparing the silicone-oil–filled cushion with that filled with other oils such as olive oil show lower readings with the latter, as well as a more rapid decay.

In their paper, Sawada and Sone[3] applied silicone oil in the form of a cream over the scarred area without any noticeable improvement of the scars so treated. The authors showed that only after an occlusive dressing (ultralucent plastic film) was placed over the silicone cream and scar, did substantial improvement take place. The authors concluded that the silicone cream combined with an occlusive dressing simulates silicone gel sheeting therapy. We would like to raise the possibility that this above combination of silicone oil and one layer of synthetic sheeting generates a negatively charged static-electric field, as do our silicone cushions, and with it the salutory effect on scar involution.

That electrical currents and negatively or positively charged ions affect tissues is well known. Mustoe et al. have investigated the enhancement of wound healing by application of positive electrical stimulation.[4] Kloth et al. have shown that wound healing is accelerated with high-voltage monophasic pulse current.[5] Krukowski et al. have used negatively charged resins and beads to induce bone formation.[6–8] Chitosan, which is a positively charged polyglycosamine derived from crab exoskeleton, has generated a good deal of interest over the last decade, and it has been intensively investigated by Diegelman et al.[9] and Taravel et al.[10] for its effect on wound healing. Weiss et al. have used exogenous electrical current to reduce the formation of hypertrophic scars and also to stimulate wound healing.[11,12]

It is questionable however, from studies on the use of positive or negatively charged electrical stimulation, whether a common denominator exists between their findings and ours, which are concerned only with a negatively charged static-electric field and not with any form of electrical current.

The static electricity of various synthetic polymer sheeting may register positive readings. Should such a positively charged sheeting be used in conjunction with the cushion, e.g., for fixation purposes, it will tend to neutralize the negative charge of the cushion, and its use would be contraindicated.

To our knowledge, the effects of static electricity on the body function has not been studied. Using silicone occlusive sheeting or silicone cushion, it is difficult to harness static electricity of consistent readings to examine its role in the body, if any. The physiologic response of static electricity on the microenvironment, blood flow, and cell metabolism due to specific attraction or repulsion of charged components in the circulating body fluids, is still unknown. Providing our hypothesis is valid, this study may indicate one avenue in which static electricity can be harnessed for clinical use and that use is to induce involution of hypertrophic and keloid scars.

Patients with hypertrophic and keloid scars are known to have increased plasma histamine levels and elevated mast-cell numbers in the scars, compared with normal individuals.[13,14] These patients also have a significantly increased tendency for allergic reactions.[15] An increase in plasma mast cells is frequently associated with histamine reactions of which hypersensitivity and itchiness are prominent symptoms. The release of histamine from blood-borne mast cells is activated by a complex of antigen and immunoglobulin E antibody. What role immunoglobulin E plays in hypertrophic and keloid scars is still not clear. It is assumed that the changes of softening and pallor of the scar, which are associated with a concomitant reduction of itchiness and discomfort, result from a decrease in the scar blood circulation and in the number of mast cells, and the lowering of the plasma histamine levels. The mean mast cell density of untreated keloids is significantly greater than that of steroid-treated keloid scars.[15] Whether there is an

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interrelationship between the tissue polarization and the presence of mast cell in the scar tissue remains to be elucidated.

In 10 of the treated scars, the combination of intralesional corticosteroids together with the application of the silicone cushions was unexpectedly gratifying.[16] Corticosteroids cause degradation of keloid and hypertrophic scars by the activation of endogenous collagenase, which helps to dissolve collagen fibers. It is postulated that the breaking down of the collagen mass by the steroid injection, augments tissue polarization by the negatively charged static-electric field on the silicone cushion.

One clinical observation that we have encountered in our study is that some patients have found that the mere application of the silicone cushion on a hypertrophic and keloid scars provides some measure of relief from the itchiness and discomfort of the scar, whereas the wearing of coarse fabric over the scar seems to aggravate these symptoms. There may be a direct correlation between friction of the scar by such fabric and the excretion of histamine-like substances from the mast cells. The smooth surface of the silicone cushion seems to minimize this effect.

Small-sized scars when treated with silicone occlusive sheeting usually have the sheeting attached to the scar site by adhesives, which frequently cause skin irritation. In this study even the small scars had the overlying silicone cushions kept in place by an appropriately fitted elastic strap binding, thus avoiding the use of all adhesives. The latter method enhanced the allergic response in patients with hypertrophic and keloid scars and is an additional reason to avoid skin adhesives.

Conclusions

By comparing the results of this trial using silicone cushions for the treatment of hypertrophic and keloid scars with those obtained using silicone gel or occlusive sheeting, a much faster response was demonstrated.

Two different categories of results seem to have emerged from the study: (1) involution within the first weeks to 6 months using only the cushion and investing fixation (13 patients) and involution within 12 months (4 patients); (2) involution after intralesional corticosteroid injections combined with the continued use of the cushion, within the first weeks to 6 months (six patients), and involution within 12 months (four patients).

The hypothesis that a negatively charged silicone surface causes polarization of the charged components of the scar tissue has been elaborated on and further applied. The favorable results of this clinical trial, using a silicone cushion with a potentiated static-electric field would seem to lend support to this concept that static electricity can cause involution of hypertrophic and keloid scars. The constant regeneration of the negatively charged static-electric field on the under surface of the cushion, although small, is sufficient with the passage of time to cause in most patients treated comparatively rapid involution of the hypertrophic and keloid scars.

Bernard Hirshowitz, F.R.C.S.
Technion, P.O. Box 9649
Haifa, 31096 Israel

Acknowledgments

We are grateful for the research grant provided by Life Medical Sciences, Inc., of Edison, N.J. We thank Ms. Liat Dobrin for her patience in typing the manuscript.

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[redacted]

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 09, 2000

ADVANCED BIO-TECHNOLOGIES, INC.
C/O CRANAGE HEALTHCARE INTERNATIONA
53 NEEDHAM DRIVE
SUITE 5, CW4 8FB
CRANAGE, CHESHIRE,
UNITED KINGDOM
ATTN: DAVID BRYANT

510(k) Number: K002488
Product: KELO-COTE TOPICAL GEL

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. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a 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 your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

DATE 11/8/2000

Memorandum

From: Reviewer(s) - Name(s) Keith Fog

Subject: 510(k) Number K002455

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept). Phone Hold
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device? OTC	☐ YES	☒ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices NA

☒ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: _____ (Branch Chief) (Branch Code) (Date)

Final Review: _____ (Division Director) (Date)

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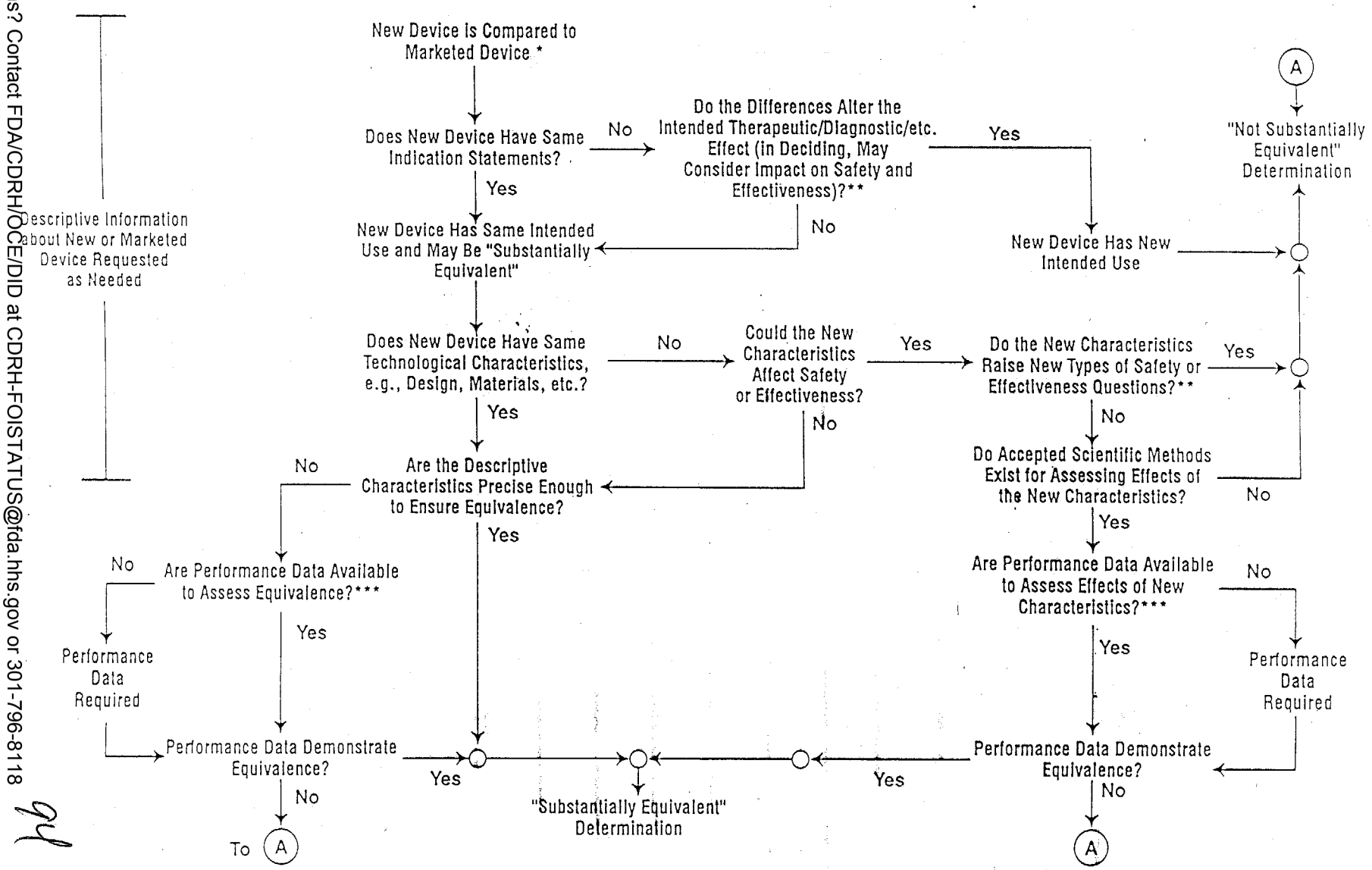
Revised:8/17//99

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

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(missions Compare New Devices to Marketed Devices. FDA Requests Add format the Relationship Between Marketed and "Predicate" (Pre ments c lassified Post-Amendments) Devices Is Unclear.

** ecision is Normally Based on Descriptive Information Alone, But Testing Information is Sometimes Required.

*** May Be In 10(k), Other 510(k)s, The Center's Classification Files, or the Literature.

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

K002488

Reviewer: Keith Foy, MS
Materials/Mechanical Engineer

Division/Branch: DGRD/PRSB
(HFZ-410)

Proprietary Trade Name: Kelo-cote™ Silicone Gel Scar Management Dressing
Common Name: Silicone Gel for Scar Management
Product to which compared:
(K973572) – Kelo-cote Scar Gel – for management of H & K scars and associated erythema secondary to any trauma causing scars…(also includes laser gel).
(K981902) – Spenco Silicone Gel Sheet
(K963128) – NOVAGEL Silicone Gel sheeting

Applicant: Advanced Bio-Technologies, Inc.
PO Box 3099
Silverdale, WA 98383
Contact: Al Berlat, CEO
Phone: (360) 698-2266 **FAX:** (360) 698-2195
Consultant: David Bryant, Consultant
Phone: 011-44-147-754-9392 **FAX:** 011-44-147-754-9391

Indications for Use
The Kelo-cote™ topical gel is intended for OTC use for the management of:
Old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

(b) (4)
[redacted]

	YES	NO
· Is the device life-supporting or life sustaining?	___	X
· Is the device implanted (short-term or long-term)? Permanent	Long term	
· Does the device design use software?	___	X
· Is the device sterile?	X	___
· Is the device single use?	X	___
· Is the device home use?	___	X
· Is the device for prescription?	X	___
· Does the device contain a drug or biological product as a component?	___	X
· Is this device a kit?	___	X

Device Description
The Kelo-cote™ gel is a self drying, topical gel made from medical grade silicone.
The gel is supplied non-sterile.

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

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(b) (4) Deficiencies

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K002488

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

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(b) (4) Deficiencies

[redacted]

Review Analysis/Correspondence record (b) (4) Deficiencies

(b) (4) Deficiencies

[redacted]

Reviewer Recommendation: Phone Hold

ProCode: MDA Occlusive sheeting for scar management
Class: Unclassified
CFR: §878.4020

Keith Foy, MS Keith Foy Date November 8, 2000
Materials Engineer, PRSB

K002488

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

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****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	0570
CONNECTION TEL	9011441477549391
SUBADDRESS	
CONNECTION ID	
ST. TIME	11/08 11:16
USAGE T	01'48
PGS. SENT	2
RESULT	OK

Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Fax

To: Al Berlat, CEO **From:** Keith E. Foy

David Bryant, Consultant

Fax: (360) 698-2195 **Pages:** 2

011-44-147-754-9391

Phone: (360) 698-2266 **Date:** 8 November 2000

011-44-147-754-9392

Re: K002488 Kelo-cote™ Silicone Gel Scar Management Dressing

☐ **Urgent** ☒ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments:**

Mr. Berlat, Mr. Bryant,

Please respond the following list of deficiencies. If you have any questions concerning any of the issues addressed below, please call or email me at the number/email address below.

Deficiencies

(b) (4) Deficiencies

[redacted]

98

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	0569
CONNECTION TEL	913606982195
SUBADDRESS	
CONNECTION ID	
ST. TIME	11/08 11:14
USAGE T	01'20
PGS. SENT	2
RESULT	OK

Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Fax

To: Al Berlat, CEO **From:** Keith E. Foy

David Bryant, Consultant

Fax: (360) 698-2195 **Pages:** 2

011-44-147-754-9391

Phone: (360) 698-2266 **Date:** 8 November 2000

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Re: K002488 Kelo-cote™ Silicone Gel Scar Management Dressing

☐ **Urgent** ☒ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments:**

Mr. Berlat, Mr. Bryant,

Please respond the following list of deficiencies. If you have any questions concerning any of the issues addressed below, please call or email me at the number/email address below.

Deficiencies

(b) (4) Deficiencies

[redacted]

99

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Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Fax

To: Al Berlat, CEO
David Bryant, Consultant

From: Keith E. Foy

Fax: (360) 698-2195
011-44-147-754-9391

Pages: 3

Phone: (360) 698-2266
011-44-147-754-9392

Date: 8 November 2000

Re: K002488 Kelo-cote™ Silicone Gel Scar Management Dressing

☐ **Urgent** ☒ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

- **Comments:**

Mr. Berlat, Mr. Bryant,

Please respond the following list of deficiencies. If you have any questions concerning any of the issues addressed below, please call or email me at the number/email address below.

Deficiencies

(b) (4) Deficiencies

[redacted]

100

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

November 8, 2000

(b) (4) Deficiencies

[redacted]

Your document has been placed on hold. Once you submit a hard copy of your responses to FDA, the document will be reactivated and reviewed.

Keith Foy
(301) 594-3090 x132
KXF@CDRH.FDA.GOV

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: Kelo-Cote Topical Gel | K002488

Submitter (Company): Advanced Bio-Tech. Inc

Items which should be included (circle missing & needed information)	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO		
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class							
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA						
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer							
f) Truthful and Accurate Statement							
g) Indications for Use enclosure							
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*							
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals							
k) Proposed Labeling:						✓	
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:						✓	
i) Labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR*			* If no - STOP not a special				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

inapplicable requirements or deviations noted below					
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed					
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device					
v) A specification of any deviations from each applicable standard that were applied					
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference					
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations					
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards					

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening _____**Yes**_____**No** **Reviewer:** Kath 7g

Date:_____ **Concurrence by Review Branch:**_____

Items were provided but inadequate

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 14, 2000

ADVANCED BIO-TECHNOLOGIES, INC.
C/O CRANAGE HEALTHCARE INTERNATIONA
53 NEEDHAM DRIVE
SUITE 5, CW4 8FB
CRANAGE, CHESHIRE,
UNITED KINGDOM
ATTN: DAVID BRYANT

510(k) Number: K002488
Received: 14-AUG-2000
Product: KELO-COTE TOPICAL GEL

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer

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

Record Clarified by CDRH on 11-19-2015

K002418

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: August 8th, 2000 | FDA Document Number:

Section A — Type of Submission

- ☒ 510 (k)
- ☐ 510 (k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission -- 510(k)s Only

- ☒ New device
- ☐ Additional or expanded indications
- ☐ Change in technology, design, materials, or manufacturing process
- ☐ other reason (specify)

Section B2 — Reason for Submission -- PMAs Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Colour Additive
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify)

FDA/CDRH/OCE/DID
14 AUG 00 11 55
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Section B3 — Reason for Submission --- IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol - feasibility
  - ☐ protocol - other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ IOL submissions only:
  - ☐ change in IOL style
  - ☐ Request for protocol waiver

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8113

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DECLASSIFIED 23

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

☐ Other reason (specify)

FDA Document Number:

Section C — Product Classification

Product code: MDA

C.F.R. Section:

Device class: ☐ Class I ☐ Class II ☐ Class III ☒ Unclassified

Classification panel: General & Plastic Surgery

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 MDA	2	3	4
5	6	7	8

Summary of, or statement concerning safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(K) Number	Trade or proprietary or model name	manufacturer
1 K981902	1 Spenco Silicone Gel Sheet	1 Spenco Medical Corp
2 K963128	2 NOVAGEL Silicone Gel Sheeting	2 Brennen Medical Inc
3	3	3
4	4	4
5	5	5
6	8	8

Section E — Product Information - Applicable to All Applications

Common or usual name or classification name:
Elastomer, Silicone for scar management

Trade or proprietary or model name	Model number
1 Kelo-cote™ Topical Gel	1
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Humans trials

Indications (from labeling):

Kelo-cote™ topical gel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.
Discontinue use if any infection of the wound is suspected and seek guidance from a health care professional.

Not for use on third degree burns.

Not to be used on open wounds.

Not for patients with dermatological conditions which disrupt the integrity of the skin in areas of coverage.

Discontinue use if any infection of the wound is suspected and seek guidance from a health care professional.

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

FDA Document Number:

Section F — Manufacturing / Packaging / Sterilisation Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number:	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: Advanced Bio-Technologies, Inc			
Division name (if applicable) N/A		Phone number (include area code): 1- 360-698-2266	
Street address: 3100 Bucklin Hill Rd, Suite 220		FAX number (include area code): 1-360-698-2195	
City: Silverdale	State / Province: Washington	Country: USA	ZIP / Postal Code: 98383
Contact name: Mr Al Berlat			
Contact title: CEO			
☒ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☒ Contract Manufacturer	☐ Contract sterilizer ☐ Repackager / relaber

(b) (4)

[redacted]

Contact title:			
☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 11710	☐ Manufacturer ☒ Contract Manufacturer	☐ Contract sterilizer ☐ Repackager / relaber

(b) (4)

[redacted]

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Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

	FDA Document Number:

Section G	Applicant or Sponsor		
Company / Institution name: Advanced Bio-Technologies Inc,		FDA establishment registration number:	
Division name (if applicable) N/A		Phone number (include area code): 1-360-698-2266	
Street address: 3100 Buckiln Hill Rd, Suite 220		FAX number (include area code): 1-360-698-2195	
City: Silverdale	State / Province: WA	Country: USA	ZIP / Postal Code 98383
Signature:			
Name: David Bryant			
Tile: Consultant			

Section H	Submission correspondent (if different from above)		
Company / Institution name: Cranage HealthCare International			
Division name (if applicable)		Phone number (include area code): 011 44 1477 549392	
Street address: Suite 5, 53 Needham Dr		FAX number (include area code): 011 44 1477 549391	
City: Cranage	State / Province: Cheshire	Country: UK	ZIP / Postal Code CW4 8FB
Contact name: David Bryant			
Contact title: Managing Director			

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Centre for Devices and Radiological Health process your submission more efficiently. The information you provide should apply only to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

510(k) Number (if known):_____

Device name: Kelo-cote™ Topical Gel

Indications For Use:

Kelo-cote™ topical gel is intended for OTC use for the management of:

Old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109)**

OR Over The Counter Use ✓

(Optional Format 1-2-96)

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Tuesday, August 08, 2000

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(k)]
Document Control Center HFZ-401
9200 Corporate Boulevard
Rockville, Maryland 20850

Subject: **510(k) Premarket Notification for Advanced Bio-Technologies, Inc Kelo-cote ™ Silicone Gel Scar Management Dressing**

Dear Sir/Madam:

In compliance with the Federal Food, Drug and Cosmetic Act, Advanced Bio-Technologies, Inc, as the manufacturer, submits the enclosed 510(k) Premarket Notification for Advanced Medical Solutions Silicone Gel Scar Management Sheet. This notification contains information required under Title 21, Code of Federal Regulations, Sections 807.87(a) through 807.87(k).

In compliance with the Safe Medical Devices Act of 1990, a summary of the safety and effectiveness of the subject device is made available to the Center.

Sincerely,

David Bryant,
Advanced Bio-Technologies, Inc,
PO Box 3099,
Silverdale,
WA 98383

FDA/CDRH/ODE/DHC
14 AUG 00 11 55
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

510(k) PREMARKET NOTIFICATION

for

Advanced Bio-Technologies, Inc
Kelo-cote ™ Silicone Scar Management Gel Dressing

August 8, 2000

Advanced Bio-Technologies, Inc Contact :

David Bryant,
Advanced Bio-Technologies, Inc
PO BOX 3099,
Silverdale,
WA 98383

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

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

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FOREWORD

This Premarket Notification concerns the product Kelo-cote ™ Silicone Scar Management Dressing product manufactured by Advanced Bio-Technologies Inc.This is a new submission and is based upon substantial equivalence to:

Spenco Silicone Gel Sheet	K981902
NOVAGEL® Silicone Gel Sheeting	K963128

On the basis of substantial equivalence presented in the above 510(k)'s both cleared by the Food and Drug Administration for marketing within the United States of America, Advanced Biotechnologies requests clearance based on substantial equivalence.

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

510(k) Premarket Notification for
Advanced Bio-Technologies, Inc Kelo-cote ™ Silicone Scar Management Dressing

August 8, 2000

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[21 CFR 807.87(J)]

I certify that in my capacity as consultant to, Advanced Bio-Technologies Inc, I believe to the best of my knowledge, that all data and information submitted in this Premarket Notification are truthful and accurate and that no material fact has been omitted.

D Bryant
(Signature)

8th Aug 00
(Date)

David Bryant,
Advanced Bio-Technologies Inc,
PO Box 3099,
Silverdale,
WA 98383
Telephone: 44 1606 545611
Fax: 44 1606 86 3600

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

A. THE DEVICE NAME, INCLUDING BOTH THE TRADE OR PROPRIETARY NAME AND THE COMMON OR USUAL NAME OR CLASSIFICATION NAME OF THE DEVICE.

The name of the device is Kelo-cote™ Topical Gel

Common/Usual Name: Silicone Gel Sheeting
MDA Elastomer, Silicone, for Scar Management.

B. THE ESTABLISHMENT REGISTRATION NUMBER, IF APPLICABLE, OF THE OWNER OR OPERATOR SUBMITTING THE PREMARKET NOTIFICATION SUBMISSION.

This 510(k) Premarket Notification is being submitted by the manufacturer:

Advanced Bio-Technologies Inc,
PO Box 3099,
Silverdale,
WA 98383

Establishment Registration Number xxxxxx

Packaged goods are supplied in the non-sterile form.

C. THE CLASS IN WHICH THE DEVICE IS CLASSIFIED UNDER SECTION 513 OF THE ACT AND, IF KNOWN, ITS APPROPRIATE CLASSIFICATION PANEL; OR, IF THE OWNER OR OPERATOR DETERMINES THAT THE DEVICE HAS NOT BEEN CLASSIFIED UNDER SUCH SECTION, A STATEMENT OF THAT DETERMINATION AND THE BASIS FOR THE [OWNER OR OPERATOR]'S DETERMINATION THAT THE DEVICE IS NOT SO CLASSIFIED.

This device is currently unclassified by FDA.

D. ACTION TAKEN BY THE [OWNER OR OPERATOR] TO COMPLY WITH THE REQUIREMENTS OF THE ACT UNDER SECTION 514 FOR PERFORMANCE STANDARDS.

This device is not subject to the requirement for performance standards under section 514 of the Federal Food, Drug, and Cosmetic Act.

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

E. PROPOSED LABELS, LABELING, AND ADVERTISEMENTS SUFFICIENT TO DESCRIBE THE DEVICE, ITS INTENDED USE, AND THE DIRECTIONS FOR ITS USE. WHERE APPLICABLE, PHOTOGRAPHS OR ENGINEERING DRAWINGS SHOULD BE SUPPLIED.

DESCRIPTION

Kelo-cote™ topical gel is a self drying, topical gel made from medical grade silicone.
The primary function of the dressing is to aid in the management of both existing and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds

The Advanced Bio-Technologies Inc, Kelo-cote™ topical gel comes in a 15 gram tube for easy application.

The gel is supplied non-sterile.

INTENDED USE AND DIRECTIONS FOR USE

Kelo-cote™ topical gel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

Discontinue use if any infection of the wound is suspected and seek guidance from a health care professional.

Not for use on third degree burns.

Not to be used on open wounds.

Not for patients with dermatological conditions which disrupt the integrity of the skin in areas of coverage.

LABELS AND PRODUCT LABELING

Package labeling is presented in Attachment 1.

F. A STATEMENT INDICATING THE DEVICE IS SIMILAR TO AND/OR DIFFERENT FROM OTHER PRODUCTS OF COMPARABLE TYPE IN COMMERCIAL DISTRIBUTION, ACCOMPANIED BY DATA TO SUPPORT THE STATEMENT. THIS INFORMATION MAY INCLUDE AN IDENTIFICATION OF SIMILAR PRODUCTS, MATERIALS, DESIGN CONSIDERATIONS, ENERGY EXPECTED TO BE USED OR DELIVERED BY THE DEVICE, AND A DESCRIPTION OF THE OPERATIONAL PRINCIPLES OF THE DEVICE.

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

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Kelo-cote™ is essentially similar to other devices approved by the FDA under the device classification, Elastomer, Silicone for scar management. Predictive devices include Spenco Silicone Gel Sheet 510(k) K981902, Spenco Medical Corp, approved June 25 1998 and NOVAGEL® Silicone Gel Sheeting 510(k) K963128, Brennen Medical Inc. approved 1996.

Kelo-cote™ topical gel poses no significant challenges to the safety and effectiveness when compared against previously approved predictive devices.

Kelo-cote™ topical gel has the same indications for use and product characteristics as those predictive devices already having received premarket clearance prior to this submission.

Product Comparisons are as follows:

Product	Novagel®	Spenco®	Kelo-cote™
Safety Testing			
(b) (4)			

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

G. WHERE [THE OWNER OR OPERATOR] INTENDS TO INTRODUCE INTO COMMERCIAL DISTRIBUTION A DEVICE THAT HAS UNDERGONE A SIGNIFICANT CHANGE OR MODIFICATION THAT COULD SIGNIFICANTLY AFFECT THE SAFETY OR EFFECTIVENESS OF THE DEVICE, OR THE DEVICE IS TO BE MARKETED FOR A NEW OR DIFFERENT INDICATION FOR USE, THE PREMARKET NOTIFICATION SUBMISSION MUST INCLUDE APPROPRIATE SUPPORTING DATA TO SHOW THAT THE MANUFACTURER HAS CONSIDERED WHAT CONSEQUENCES AND EFFECTS THE CHANGE OR MODIFICATION OR NEW USE MIGHT HAVE ON THE SAFETY AND EFFECTIVENESS OF THE DEVICE.

Components

The components used to manufacture the device are similar to those already in use in predictive devices approved by the FDA, a summary of biocompatability testing performed is included as Attachment 4 to this submission.

Product Design

The product design was undertaken in accordance to QSR CFR 820.30

H. A 510(K) SUMMARY AS DESCRIBED IN [SECTION] 807.92 OR A 510(K) STATEMENT AS DESCRIBED IN [SECTION] 807.93.

A summary of safety and effectiveness of the subject device is included as Attachment 3 to this submission.

I. A SUMMARY OF THE TYPES OF SAFETY AND EFFECTIVENESS PROBLEMS ASSOCIATED WITH THE CLASS III DEVICES BEING COMPARED AND A CERTIFICATION THAT A REASONABLE SEARCH OF ALL INFORMATION KNOWN OR OTHERWISE AVAILABLE HAS BEEN CONDUCTED (CLASS III CERTIFICATION) AS DESCRIBED IN [SECTION] 807.94.

Not applicable to this 510(k) application.

J. A STATEMENT, TO THE BEST AVAILABLE KNOWLEDGE, THAT ALL DATA AND INFORMATION SUBMITTED IN THE PREMARKET NOTIFICATION ARE TRUTHFUL AND ACCURATE AND THAT NO MATERIAL FACT HAS BEEN OMITTED.

A Truthful and Accurate Statement is included at the beginning of the document.

K. ANY ADDITIONAL INFORMATION REGARDING THE DEVICE REQUESTED BY THE COMMISSIONER THAT IS NECESSARY FOR THE COMMISSIONER TO MAKE A FINDING AS TO WHETHER OR NOT THE DEVICE IS SUBSTANTIALLY EQUIVALENT TO A DEVICE IN COMMERCIAL DISTRIBUTION.

If additional information is required for FDA to make a determination of substantial equivalence for this device, please contact David Bryant , 011 44 1477 549392

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

If additional information is required for FDA to make a determination of substantial equivalence for this device, please contact David Bryant , 011 44 1477 549392

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Instructions for Use
Advanced Biotechnologies Silicone Scar Management Gel

KELO-COTE™ TOPICAL GEL

DIRECTIONS FOR USE:

Evenly apply a small amount daily to affected area. **DO NOT RUB.** Allow to air-dry for ten minutes. Reapply once every 24 hours in the same manner. Discontinue use if irritation occurs. For external use only. Kelo-cote™ may be worn under cosmetics.

ADVANCED BIO-TECHNOLOGIES, INC.

3100 Bucklin Hill Road • Silverdale, WA 98383 • 800-240-8227

Patent Protected

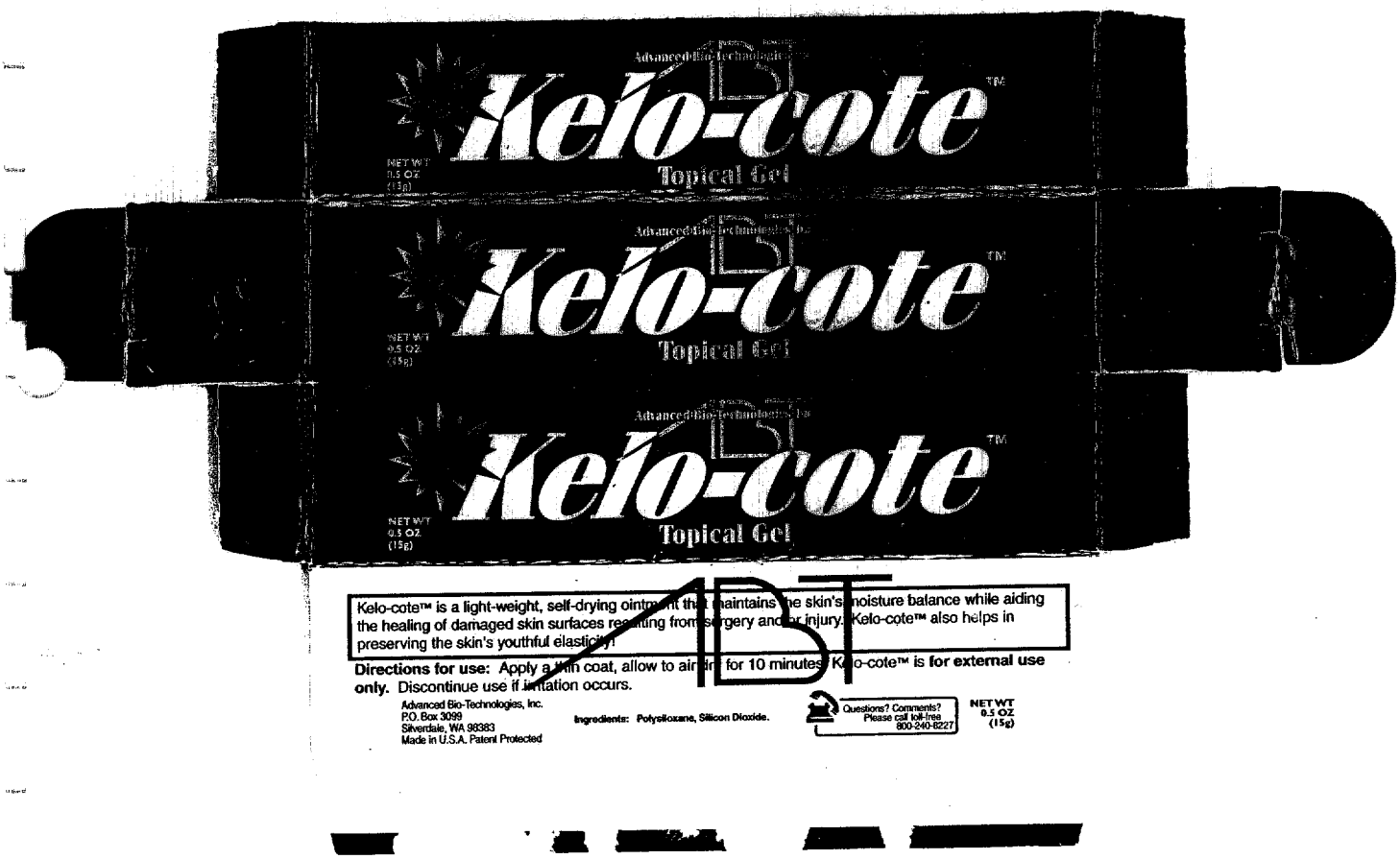
Visit our Web Site at: http://www.kelocote.com

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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Attachment 1

Outer Carton
Kelo-cote ™ Topical Gel



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

Records processed under FOIA Request # 2015-6975; Released by CDRH on 11-19-2015

Attachment 2

Summary of Safety and Efficacy Summary of Kelo-cote™ Topical Gel

Manufacturer:	Advanced Bio-Technologies, Inc. PO Box 3099, Silverdale, WA 98383
Regulatory Affairs Contact:	David Bryant
Telephone:	011 44 1477 549392
Date Summary Prepared:	August 8, 2000
Device Trade Name:	Kelo-cote™ Topical Gel
Common or Usual Name:	Silicone Gel
Classification:	Currently unclassified by FDA.
Description:	Kelo-cote™ topical gel is a self drying, topical gel made from medical grade silicone. The primary function of the dressing is to aid in the management of both existing and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds The Advanced Bio-Technologies Inc, Kelo-cote™ topical gel comes in a 15 gram tube for easy application. The gel is supplied non-sterile.
Intended Use:	Kelo-cote™ topical gel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds. Discontinue use if any infection of the wound is suspected and seek guidance from a health care professional. Not for use on third degree burns. Not to be used on open wounds. Not for patients with dermatological conditions which disrupt the integrity of the skin in areas of coverage.
Substantial Equivalence:	Substantial equivalence was provided in 510(k)'s Spenco Silicone Gel Sheet,Spenco Medical Corp

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