

K864492

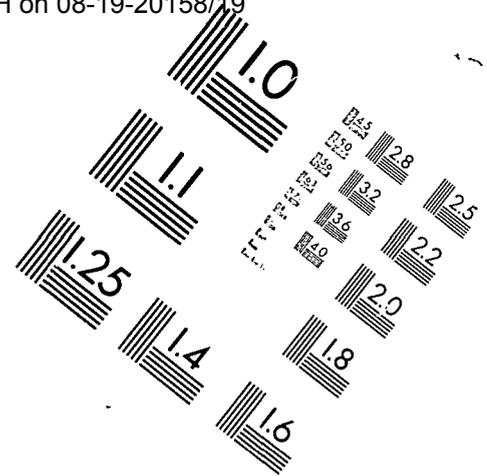
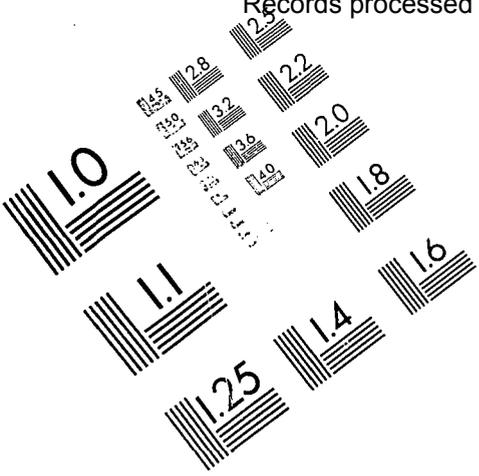
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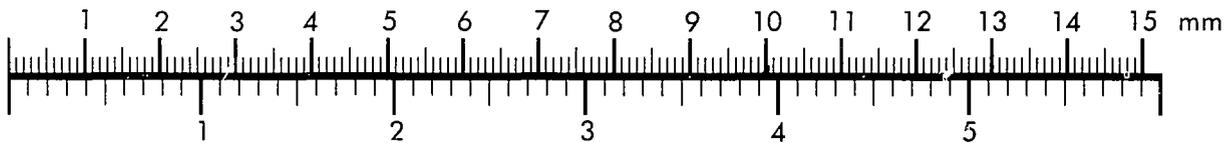


Association for Information and Image Management

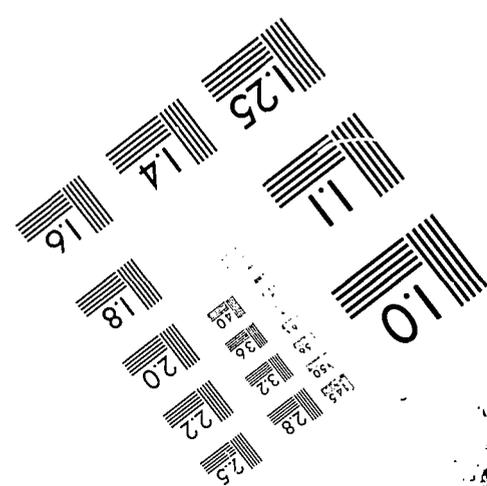
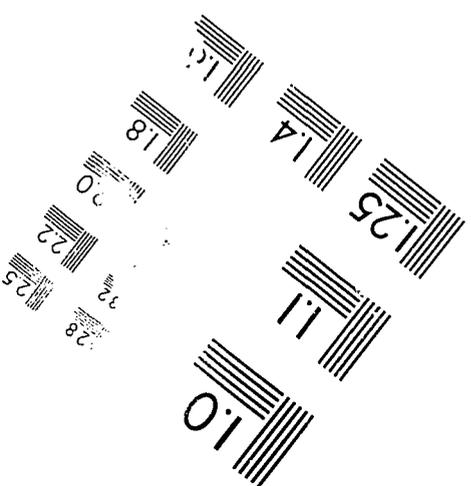
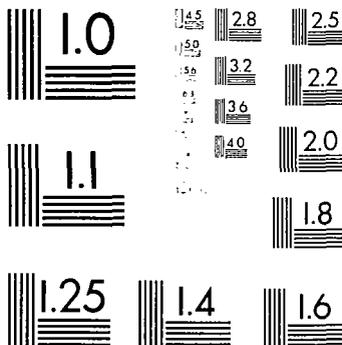
MS303-1980



Centimeter



Inches



K864492





Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

15

Mr. Anthony J. Lentz
Group Leader
Polymer Orthopaedics R&D
Dow Corning Wright
P.O. Box 100
Arlington, Tennessee 38002

Re: K864492
Swanson Titanium Great
Toe Implant
Dated: February 3, 1987
Received: February 4, 1987

Dear Mr. Lentz:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

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

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

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

Sincerely yours,

Carl A. Larson
Carl A. Larson, Ph.D.
Director
Division of Surgical and
Rehabilitation Devices
Center for Devices and
Radiological Health

10/95

1



Memorandum

Date April 10, 1987
From REVIEWER(S) - NAME(S) Sharon Staronics
Subject 510(k) NOTIFICATION K864492/A
To THE RECORD

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

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

Additional Comments:

SE (Without Classification)
(Refer to memo dated 4/10/87).

S.S.
4/10/87

The submitter requests:

- No Confidentiality
- Confidentiality for 90 days *
* Engineering drawings only
- Continued Confidentiality exceeding 90 days

Class Code w/Panel:

87 KWD
*Prosthesis, Toe,
Hemi-, Phalangeal*

REVIEW: T. J. Alban 4/14/87
(BRANCH CHIEF) (DATE)

FINAL REVIEW: Carl A Larson 4/14/87
(DIVISION DIRECTOR) (DATE)

April 10, 1987

FROM: Records processed under FOIA Request # 2015-3685; Released by CDRH on 08-19-2015/19
Sharon StarowiczOFFICE
ODE

TO: File

DIVISION
DSRD/OR

SUBJECT: K864488- Swanson Titanium Condylar Implant

SUMMARY
K864489- Swanson Titanium Trapezium Implant
K864490- Swanson Titanium Carpal Scaphoid Implant
K864491- Swanson Titanium Carpal Lunate Implant
K864492- Swanson Titanium Great Toe Implant
(Dow Corning Wright)Background

The five submissions listed above are related. They represent a series of Swanson titanium finger, hand, and toe joint prostheses that were originally manufactured from Dow Corning medical grade high performance silicone elastomer (SILASTIC[®]), as preamendment devices. Each device is intended to be used without bone cement and will be fabricated from commercially pure titanium (ASTM F67- Unalloyed Titanium for Surgical Implant Applications). Each device is described below in further detail:

K864488- Swanson Titanium Condylar Implant

The Swanson Titanium Condylar Implant is claimed to be substantially equivalent to the SILASTIC[®] Condylar Implant H.P. (Convex) Swanson Design. Each implant is a one-piece device that consists of a single intramedullary stem and a joint spacer. The stem is inserted into the proximal end of the first metacarpal and the joint spacer replaces the surface articulating against the trapezium. The device is designed to replace the trapezium in an attempt to preserve the anatomical relationships of the basal joints of the thumb after resection arthroplasty by acting as a space filler. In terms of specific design differences between the two devices; the (b)(4)

(b)(4)

K864489- Swanson Titanium Trapezium Implant

The Swanson Titanium Trapezium Implant is claimed to be substantially equivalent to the SILASTIC[®] Trapezium Implant H.P. Swanson Design. Both implants are one-piece devices consisting of a single intramedullary stem and a joint spacer. The stem is inserted into the proximal end of the first metacarpal and the joint spacer replaces the trapezium articulating against the scaphoid. The stem has a triangular cross section to improve rotational stability and the head of the implant has a slightly concave surface to provide a better fit with the articular surface of

1

SIGNATURE

Sharon Starowicz

DOCUMENT NO.

FROM: Sharon Starowicz Records processed under FOIA Request # 2015-3685; Released by CDRH on 08/19/2015/19	OFFICE CDRH
TO: File	DIVISION DSRD/OR
SUBJECT:	
SUMMARY	

the scaphoid. (b)(4)

K864490- Swanson Titanium Carpal Scaphoid Implant

The Swanson Titanium Carpal Scaphoid Implant is claimed to be substantially equivalent to the SILASTIC[®] Carpal Scaphoid Implant H.P. (Convex) Swanson Design. Both implants are one-piece devices designed to act as joint spacers and maintain the relationship of the adjacent carpal bones after excision of the scaphoid. The titanium implant's features differ slightly from the silicone implant. The silicone implant has an

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

K864491- Swanson Titanium Carpal Lunate Implant

The Swanson Titanium Carpal Lunate Implant is claimed to be substantially equivalent to the SILASTIC[®] Carpal Lunate Implant H.P. Swanson Design. Both implants are one-piece devices designed to act as joint spacers and maintain the relationship of the adjacent carpal bones after excision of the lunate. Both devices have essentially the same anatomical configuration as the lunate bones, the concavities being more pronounced to provide for greater stability. The predominant design difference between the silicone and titanium versions of the device is the

(b)(4)

K864492- Swanson Titanium Great Toe Implant

The Swanson Titanium Great Toe Implant is claimed to be substantially equivalent to the SILASTIC[®] Great Toe Implant H.P. Swanson Design. Both implants are one-piece devices consisting of a single intramedullary stem and a joint spacer. They are designed to supplement resection arthroplasty of the first metatarsophalangeal joint. The stem of the implant fits into the intramedullary canal of the proximal phalanx with the implant head replacing the proximal third of the proximal phalanx. Both devices are similar in design, except

SIGNATURE <i>Sharon Starowicz</i>	DOCUMENT NO.
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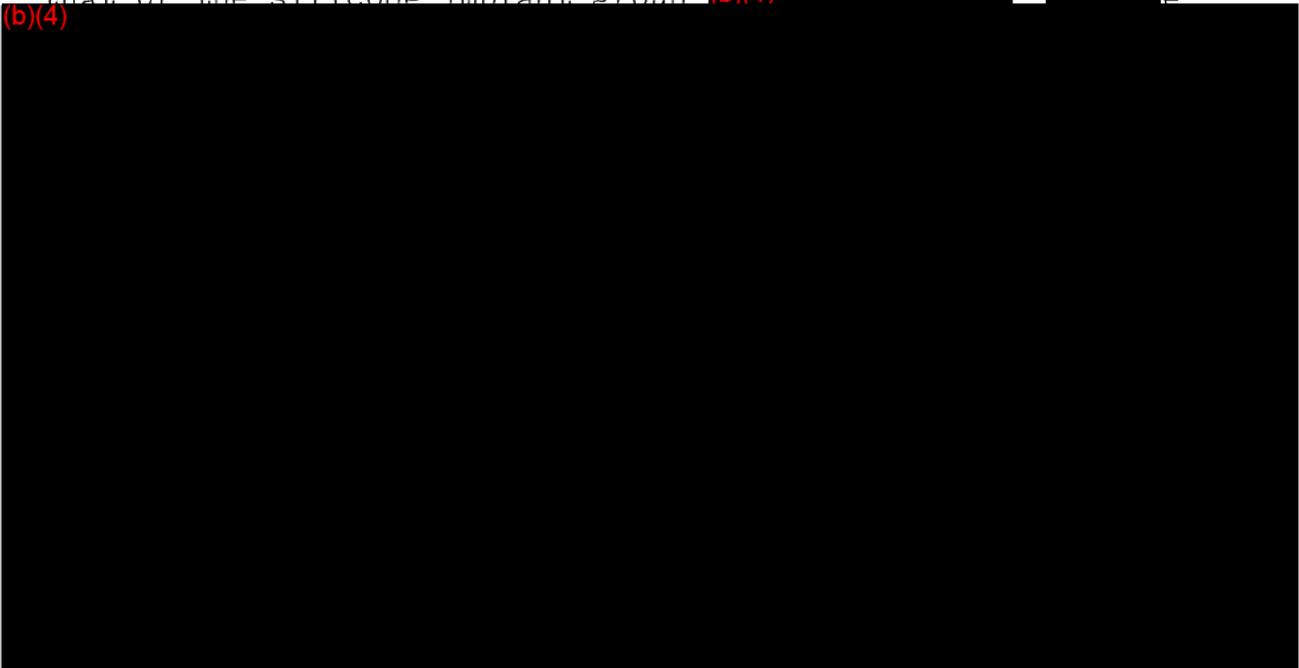
FROM:	Records processed under FOIA Request # 2015-3685; Released by CDRH on 08-19-2015/19 Sharon Starowicz	CODE
TO:	File	DIVISION DSRD/OR
SUBJECT:		

SUMMARY

that the (b)(4)

Basis for Substantial Equivalence

In addition to the description of design, materials, and surgical technique, the manufacturer has included some limited clinical data on the implantation of these five titanium implants. Unfortunately, this data is not complete and the length of follow-up is too short when compared with that of the silicone implant group (b)(4)

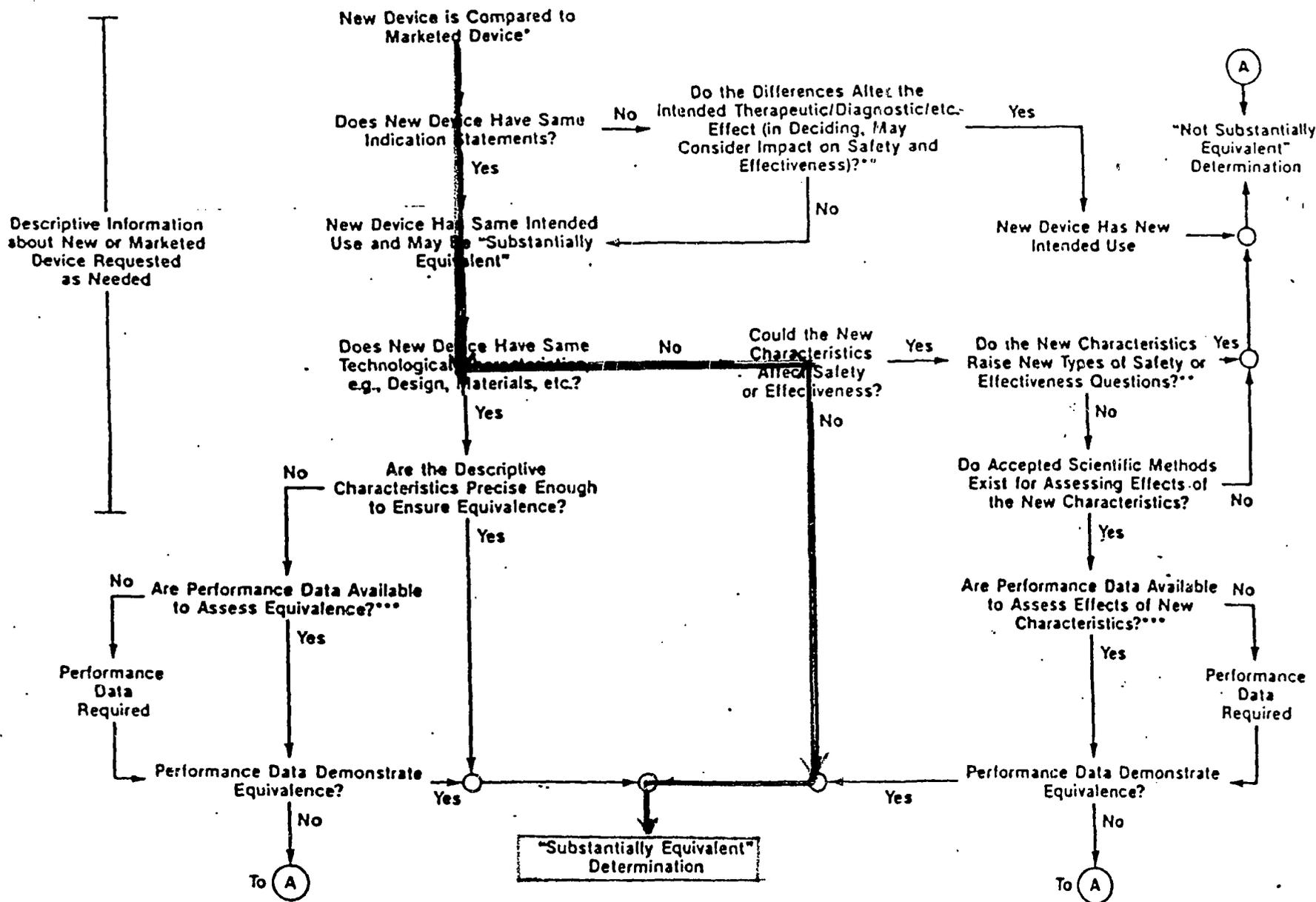


safety or effectiveness. For this reason, I recommend that the Swanson titanium implants be found substantially equivalent to the predicate silicone implants.

SIGNATURE	DOCUMENT NO.
<i>Sharon Starowicz</i>	

THIS IS A NON-RECORD PAGE AND HAS BEEN
INSERTED FOR FICHE FORMATTING PURPOSES ONLY

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



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predecessor" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

DOW CORNING
WRIGHT
P.O. BOX 100 • ARLINGTON, TN 38002

April 1, 1987

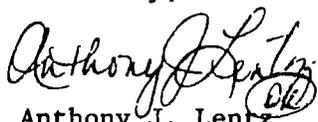
Food and Drug Administration
Office of Device Evaluation
Mail Station HFZ-410
8757 Georgia Avenue
Silver Spring, MD 20910

ATTN: Sharon Starowicz

Dear Sharon:

Attached is the information you requested to supplement the 510(k) notifications for the Swanson titanium implants. Please contact me at 901-867-9971 if you have any additional questions.

Sincerely,



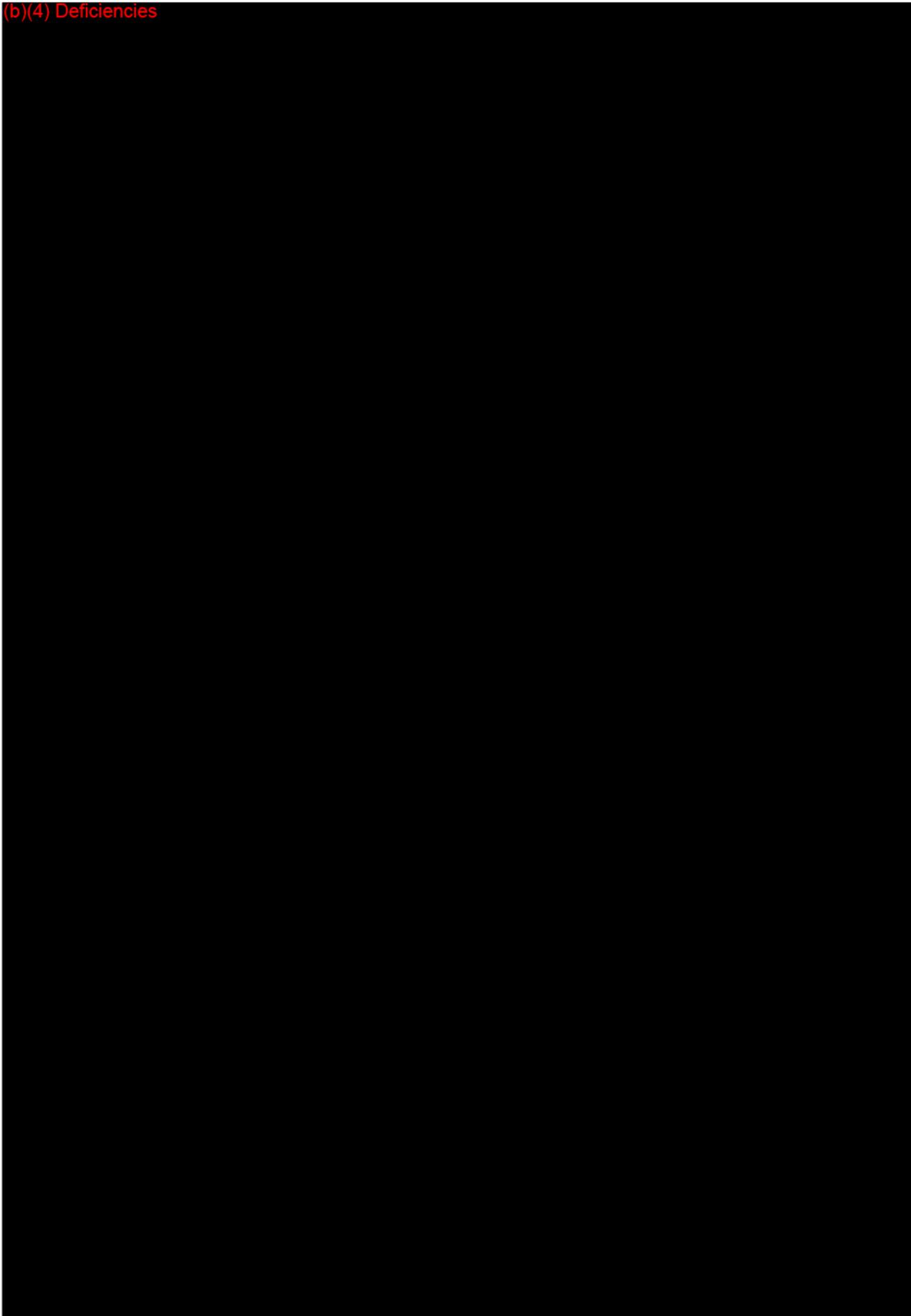
Anthony J. Lentz
Group Leader
Polymer Orthopaedics R&D

AJL/dwk

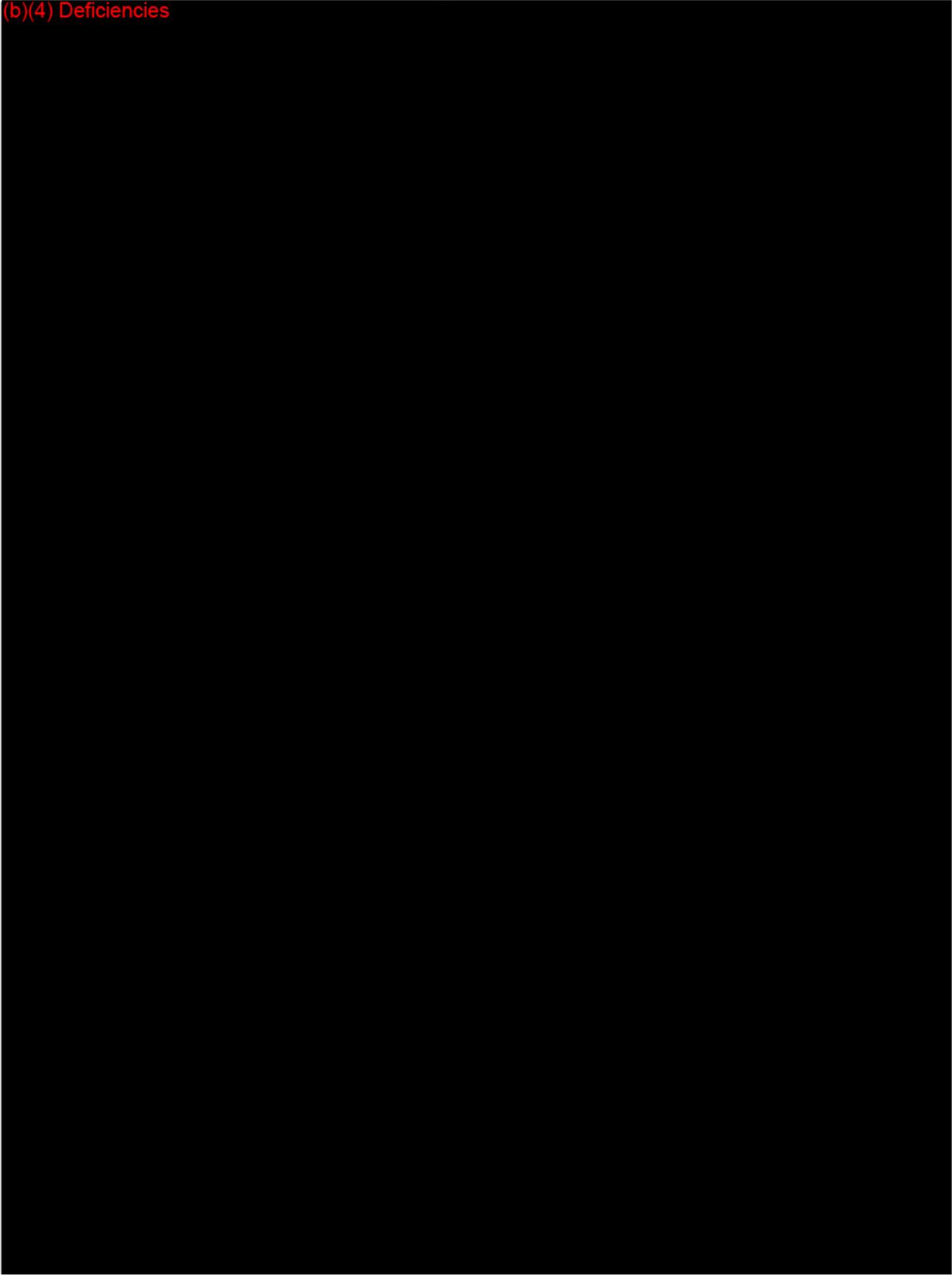
(The first three questions are related to the incident of (b)(4)

(b)(4)

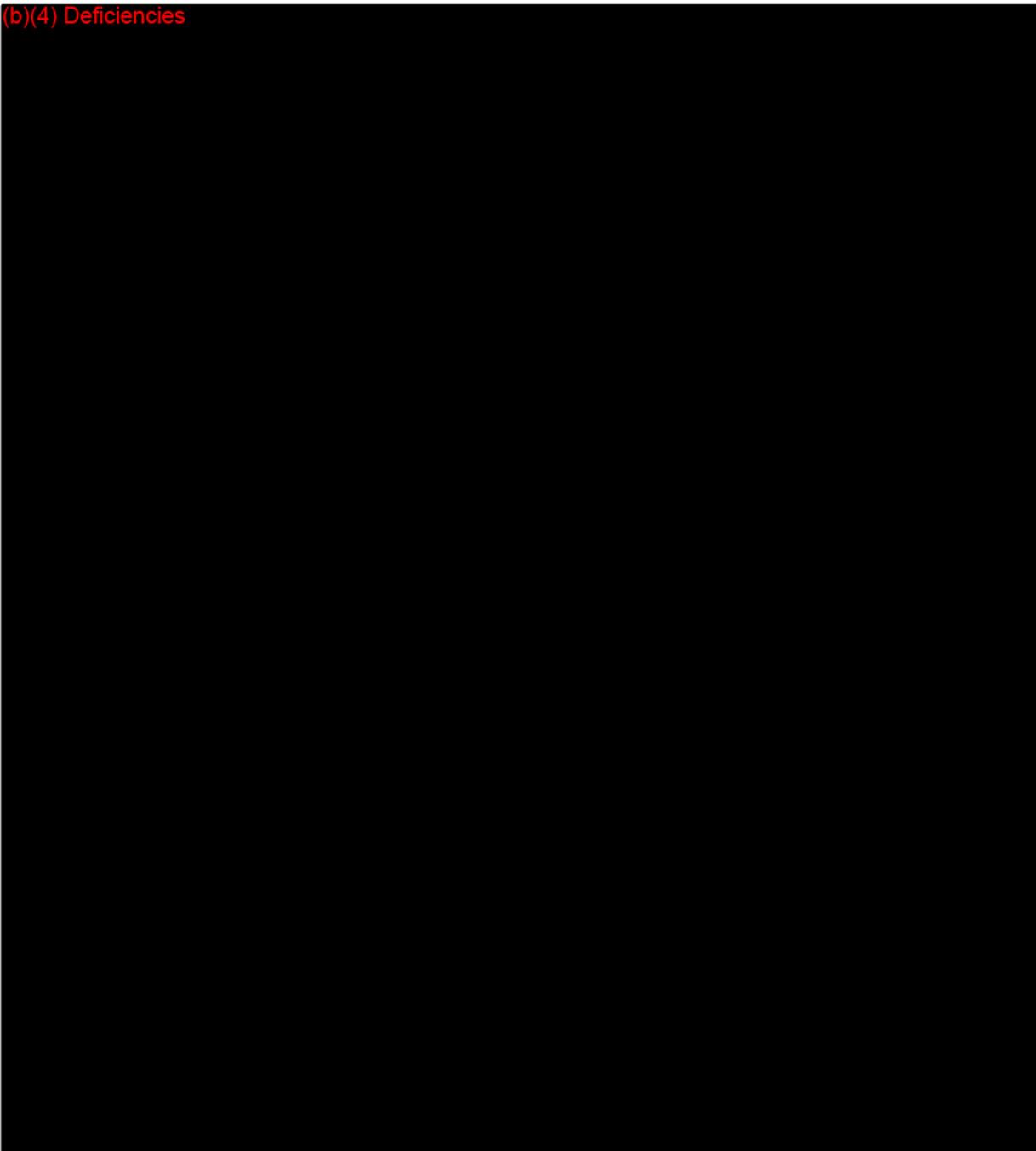
(b)(4) Deficiencies



(b)(4) Deficiencies

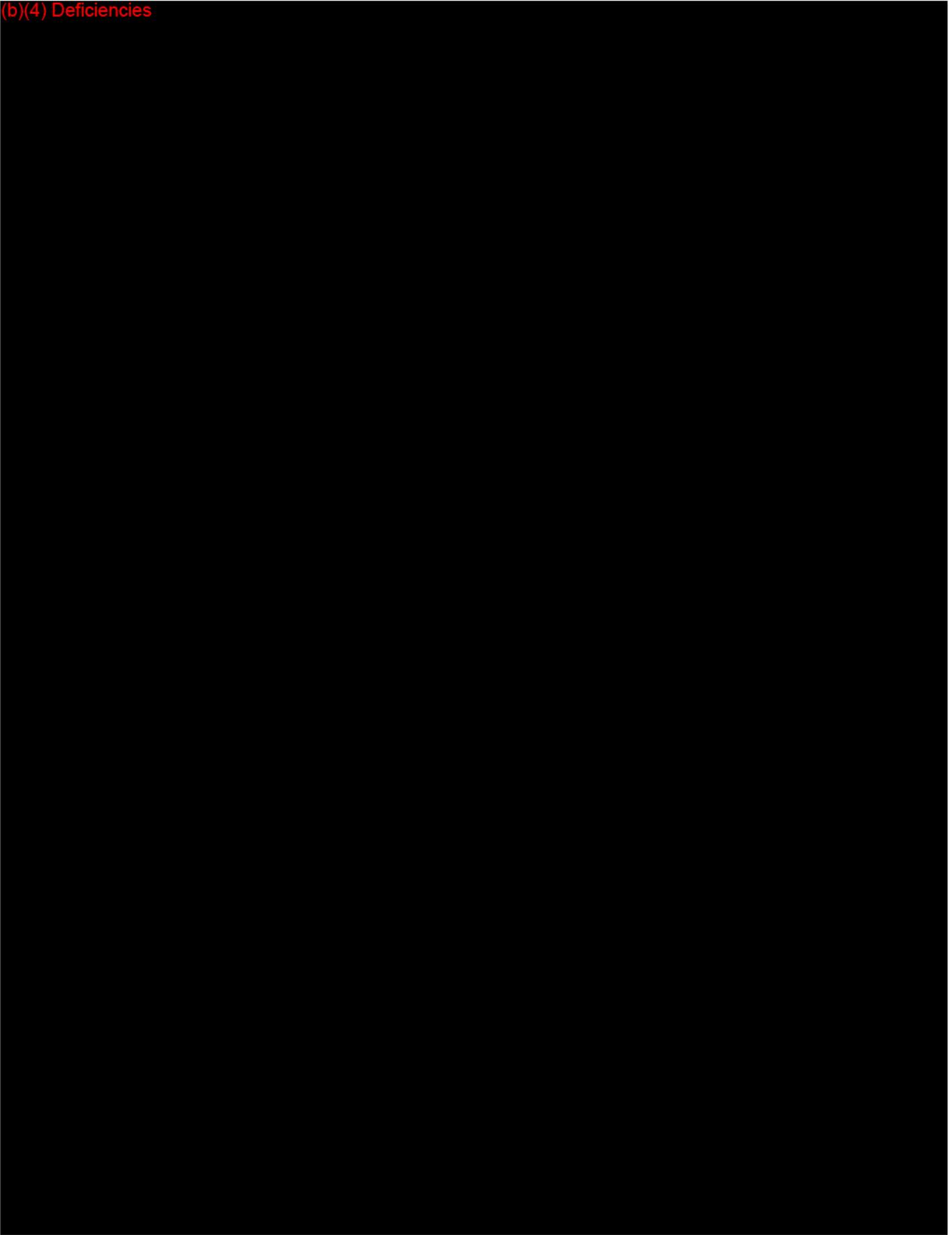


(b)(4) Deficiencies



APPENDIX

(b)(4) Deficiencies



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November 24, 1986

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

ATTN: Robert I. Chissler

Dear Mr. Chissler:

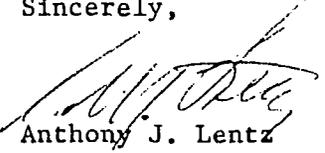
In reviewing the five 510(k) documents that I sent to the FDA recently,

- D.C. Number K864488 Swanson Titanium Condylar Implant
- D.C. Number K864489 Swanson Titanium Trapezium Implant
- D.C. Number K864490 Swanson Titanium Carpal Scaphoid Implant
- D.C. Number K864491 Swanson Titanium Carpal Lunate Implant
- D.C. Number K864492 Swanson Titanium Great Toe Implant

I noticed that there is no telephone number for our company listed on the letterhead. Please find enclosed several of my business cards which can be attached to the 510(k) documents if anyone should need to contact me with questions.

Thank you.

Sincerely,



Anthony J. Lentz
Group Leader
Polymer Orthopaedics R & D

AJL:ds

TL0037

ANTHONY J. LENTZ
Group Leader
Polymer Orthopaedics R&D

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(901) 867-9971

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

FEBRUARY 4, 1987

DOW CORNING WRIGHT
ATTN: ANTHONY J. LENTZ
P.O. BOX 100
ARLINGTON, TN 38002

D.C. Number : K864492
Received : 02-04-87
Product : SWANSON TITANIUM
GREAT TOW IMPLANT

The additional information you have submitted has been received.

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

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

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

Sincerely yours,

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

K864492/A

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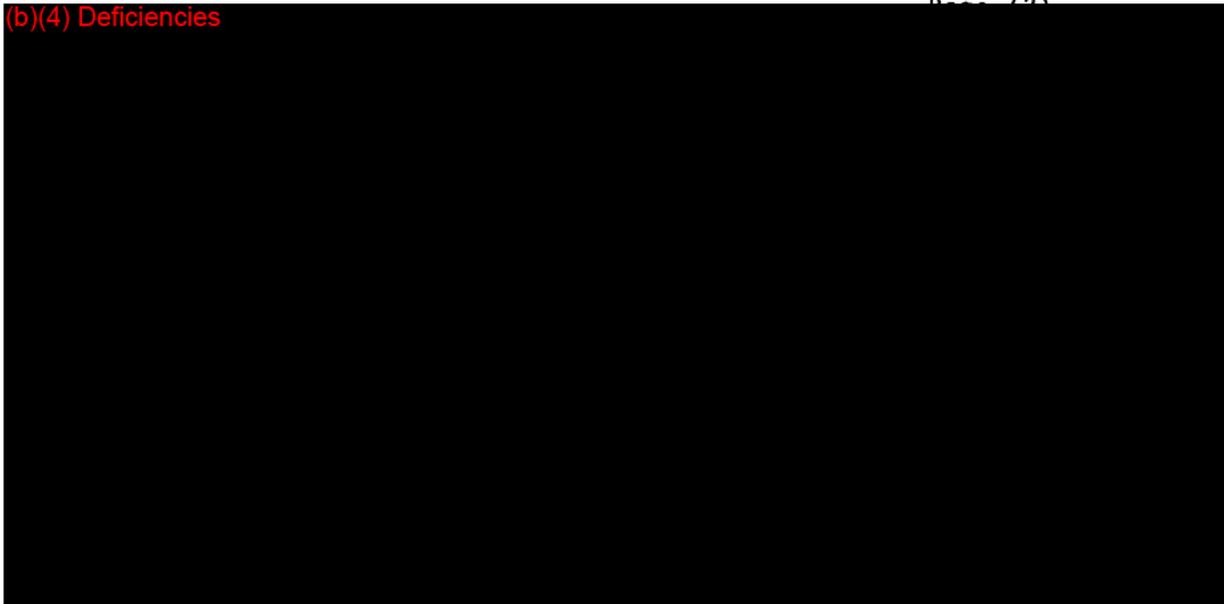
SUBJ: Amendment to 510(k) Notification
REF: K864492, Swanson Titanium Great Toe Implant

Dow Corning Wright hereby submits an amendment to the above-referenced Premarket Notification (510(k)) in response to a request by the Office of Device Evaluation for additional information. Six subject areas were addressed, as indicated below. For clarity, each subject or question posed by the Office of Device Evaluation is underlined, immediately followed by the appropriate information.

(b)(4) Deficiencies

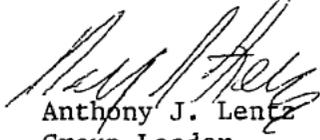


(b)(4) Deficiencies



We are forwarding this amendment herewith in duplicate. (The cover letter is included in triplicate pursuant to 21 CFR 806.90(c).) Your prompt attention to this matter is appreciated.

Very truly yours,



Anthony J. Lentz
Group Leader
Polymer Orthopaedics R & D

cc

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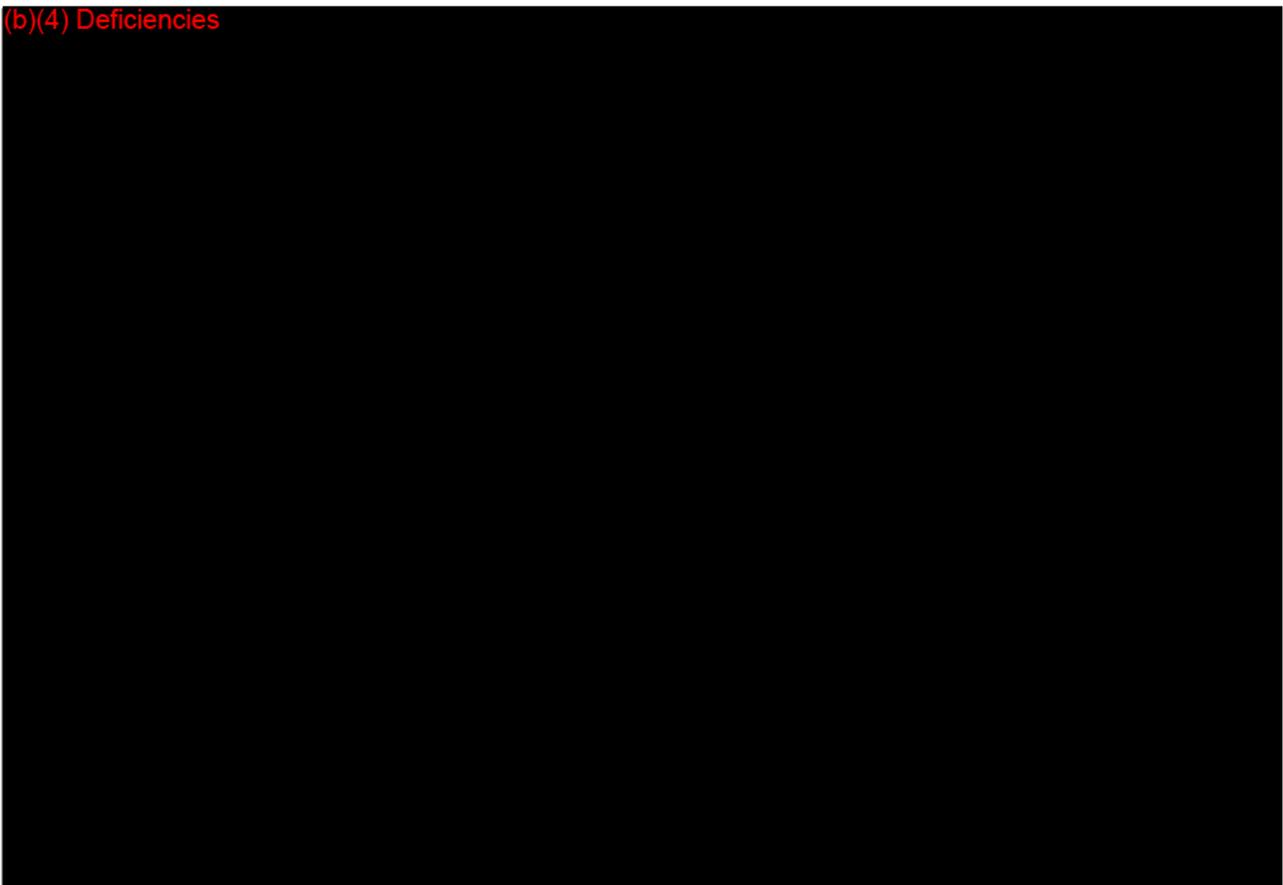
February 3, 1987

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

SUBJ: Amendment to 510(k) Notification
REF: K864492, Swanson Titanium Great Toe Implant

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(b)(4) Deficiencies

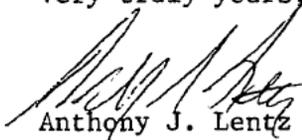


(b)(4) Deficiencies



We are forwarding this amendment herewith in duplicate. (The cover letter is included in triplicate pursuant to 21 CFR 806.90(c).) Your prompt attention to this matter is appreciated.

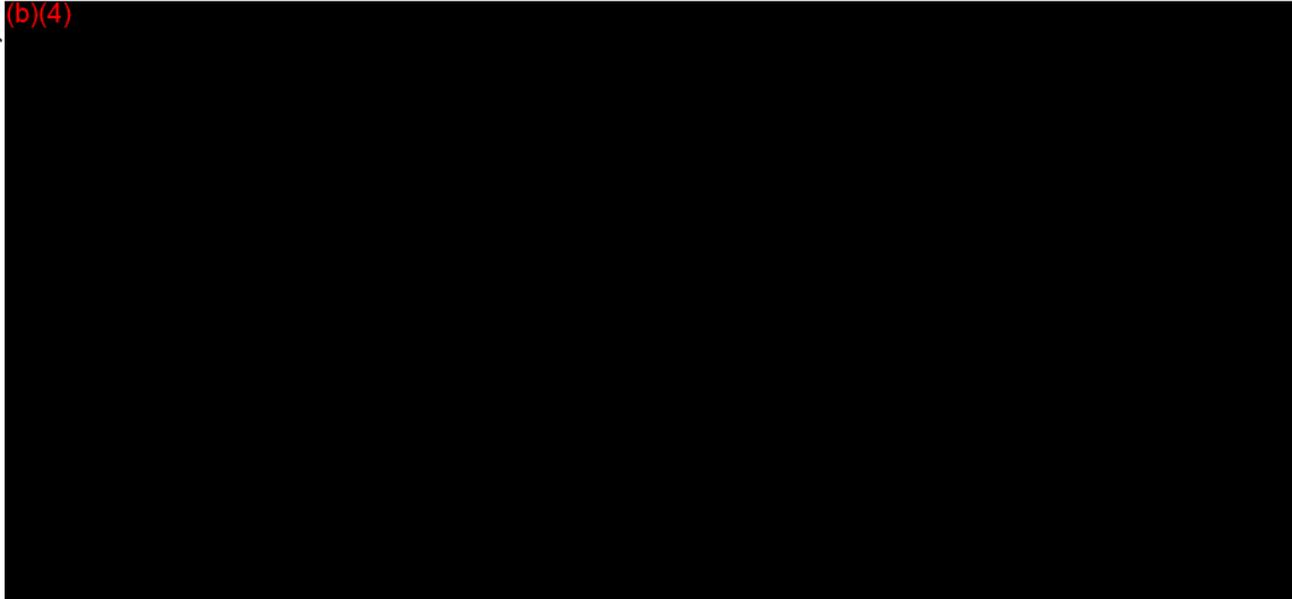
Very truly yours,



Anthony J. Lentz
Group Leader
Polymer Orthopaedics R & D

cc

TABLE 1
MEAN FOLLOW-UP TIMES FOR TITANIUM IMPLANTS

IMPLANT	N	MEAN	RANGE
<p>(b)(4)</p> 			

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

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

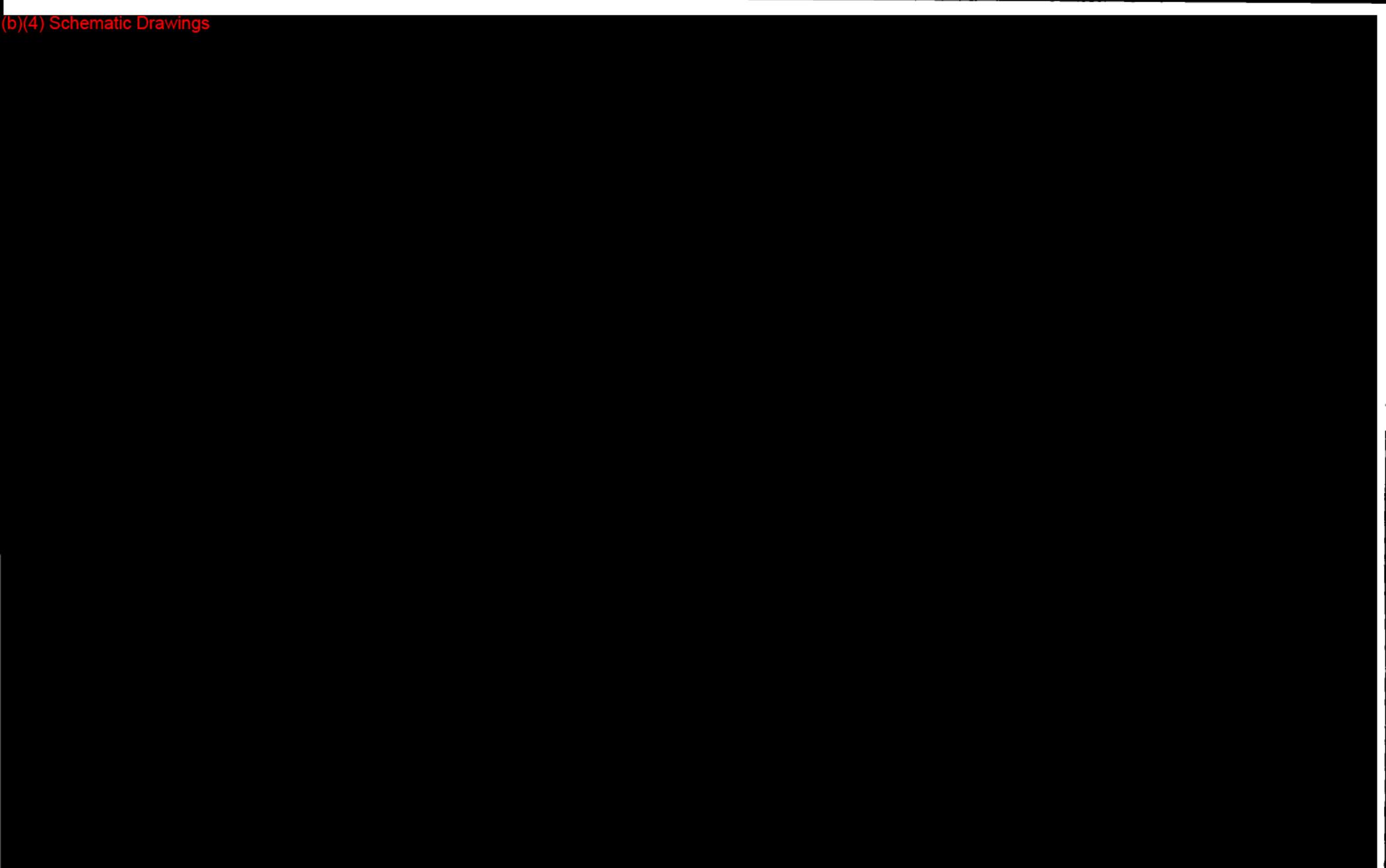
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President of Dow Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

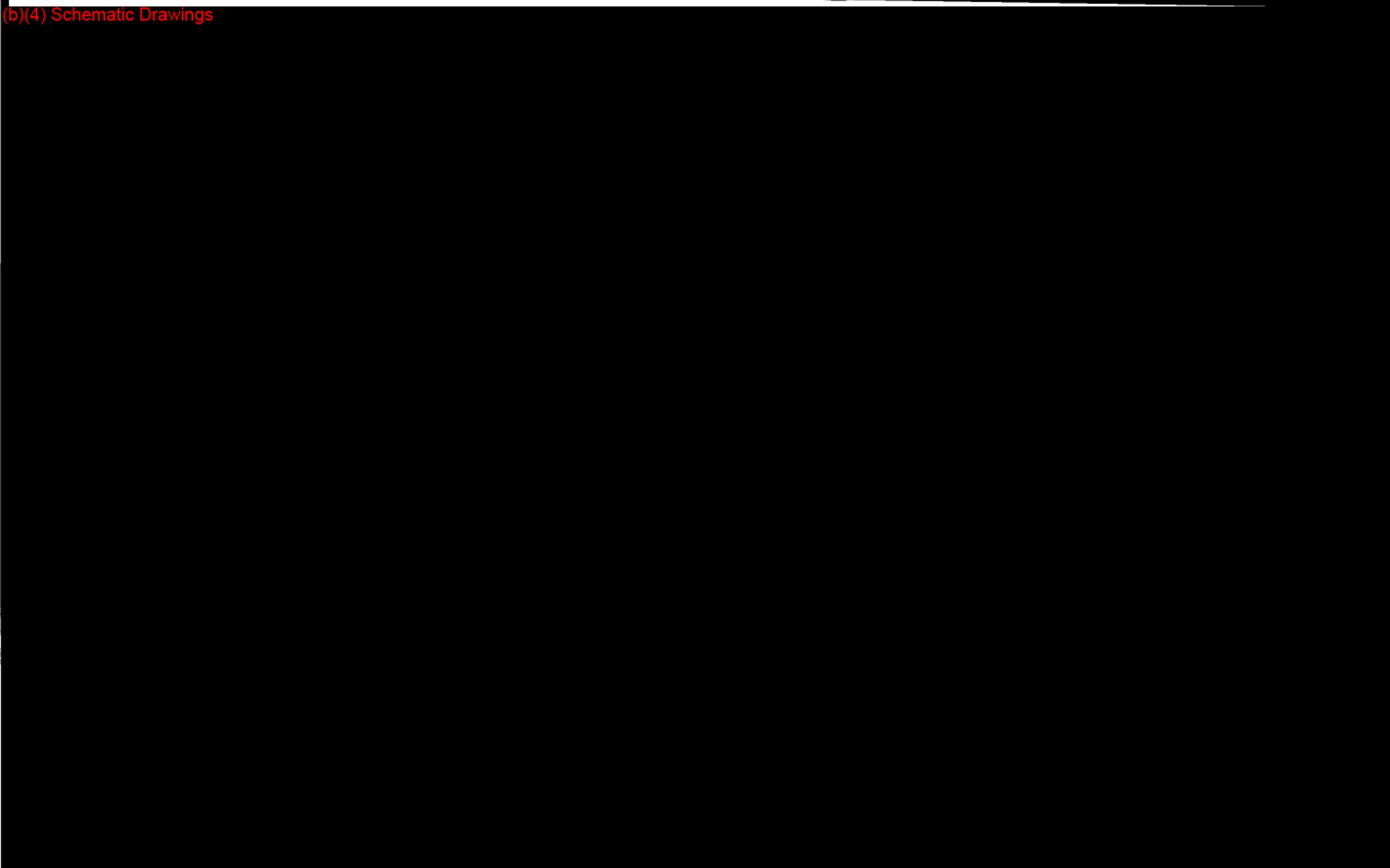
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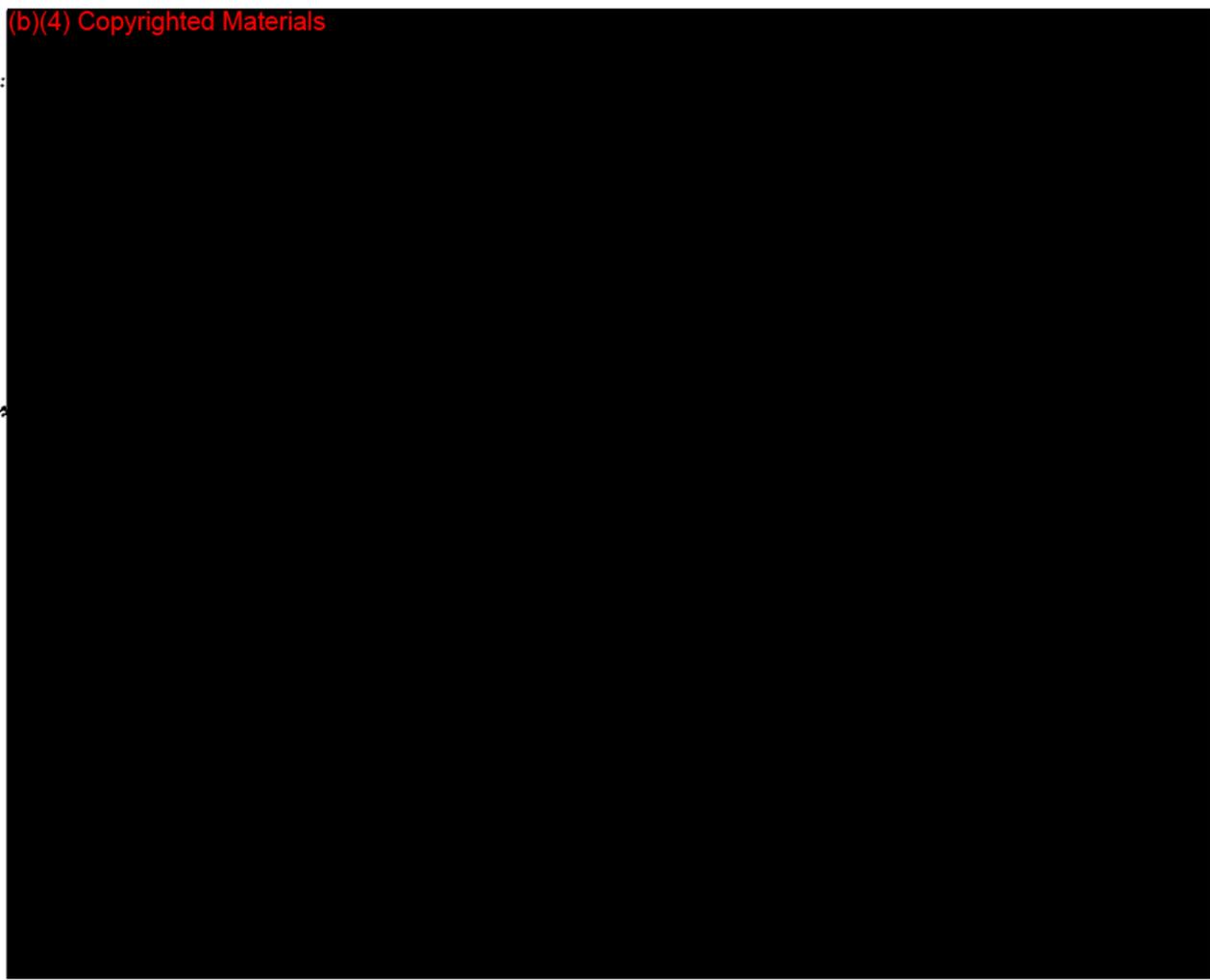
PROPRIETARY

Silicone Implant Arthroplasty of the Great Toe

A Review of Single Stem and
Flexible Hinge Implants*

ALFRED B. SWANSON, M.D.,** ROBERT M. LUMSDEN, II, M.D.
AND GENEVIEVE deGROOT SWANSON, M.D.

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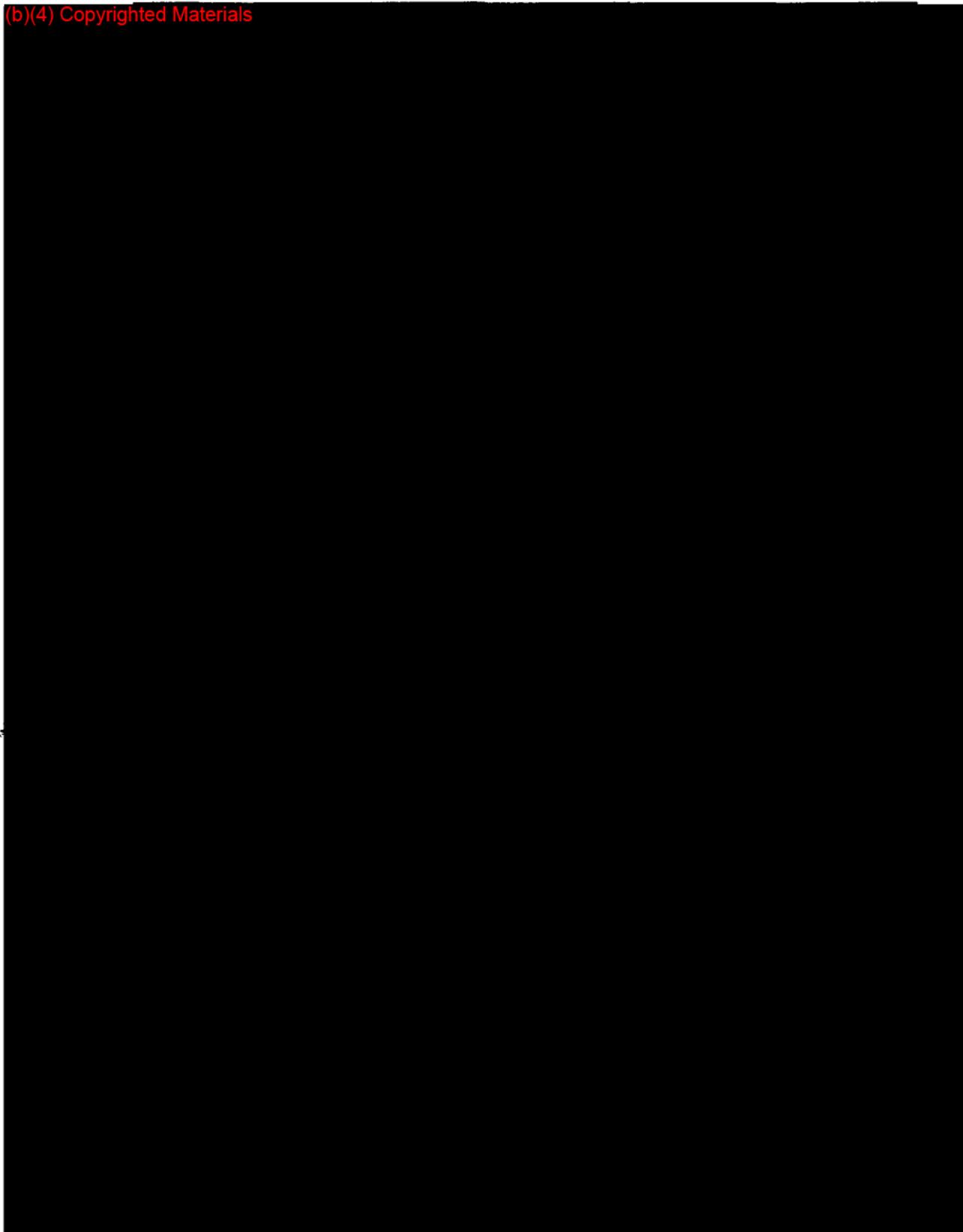


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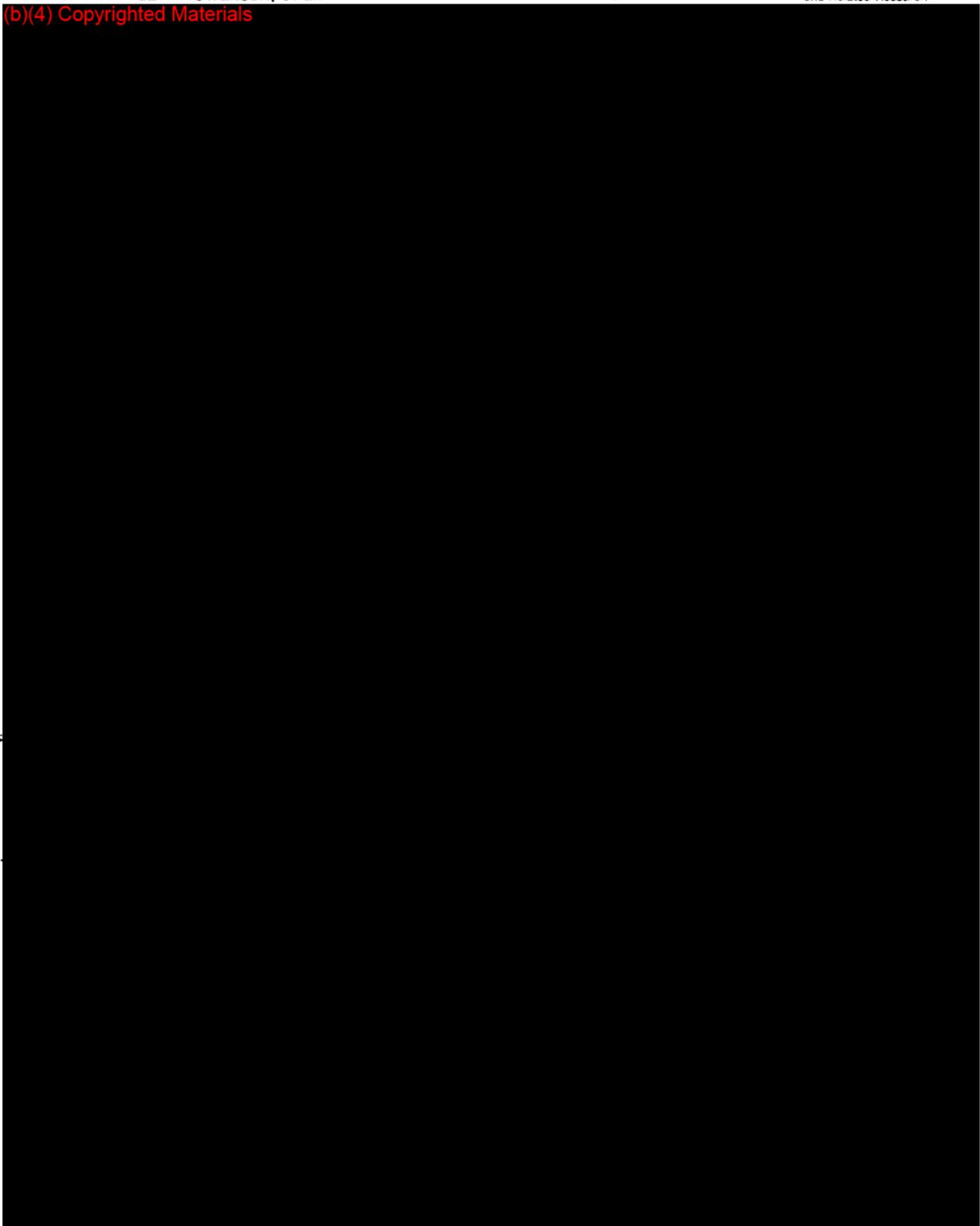
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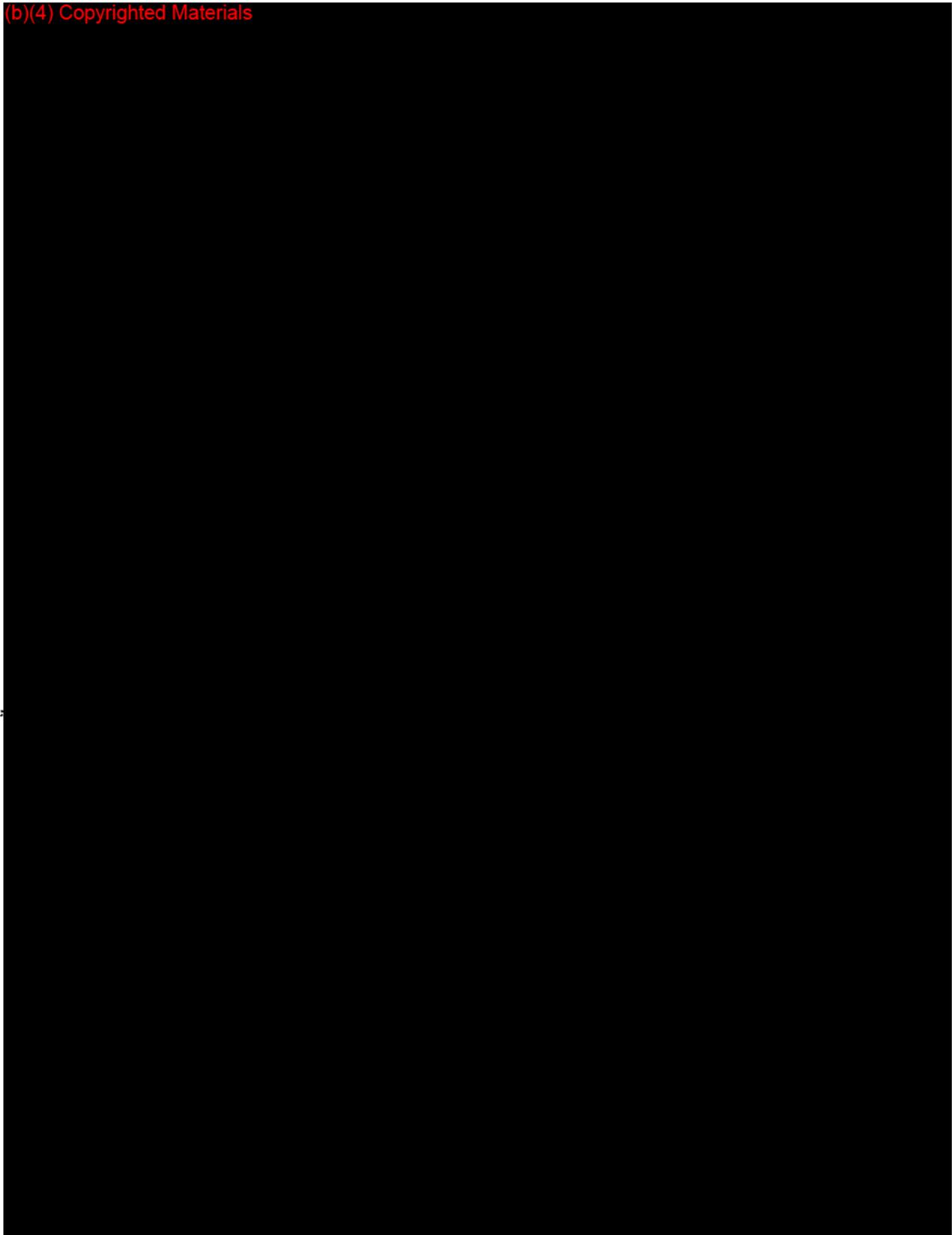


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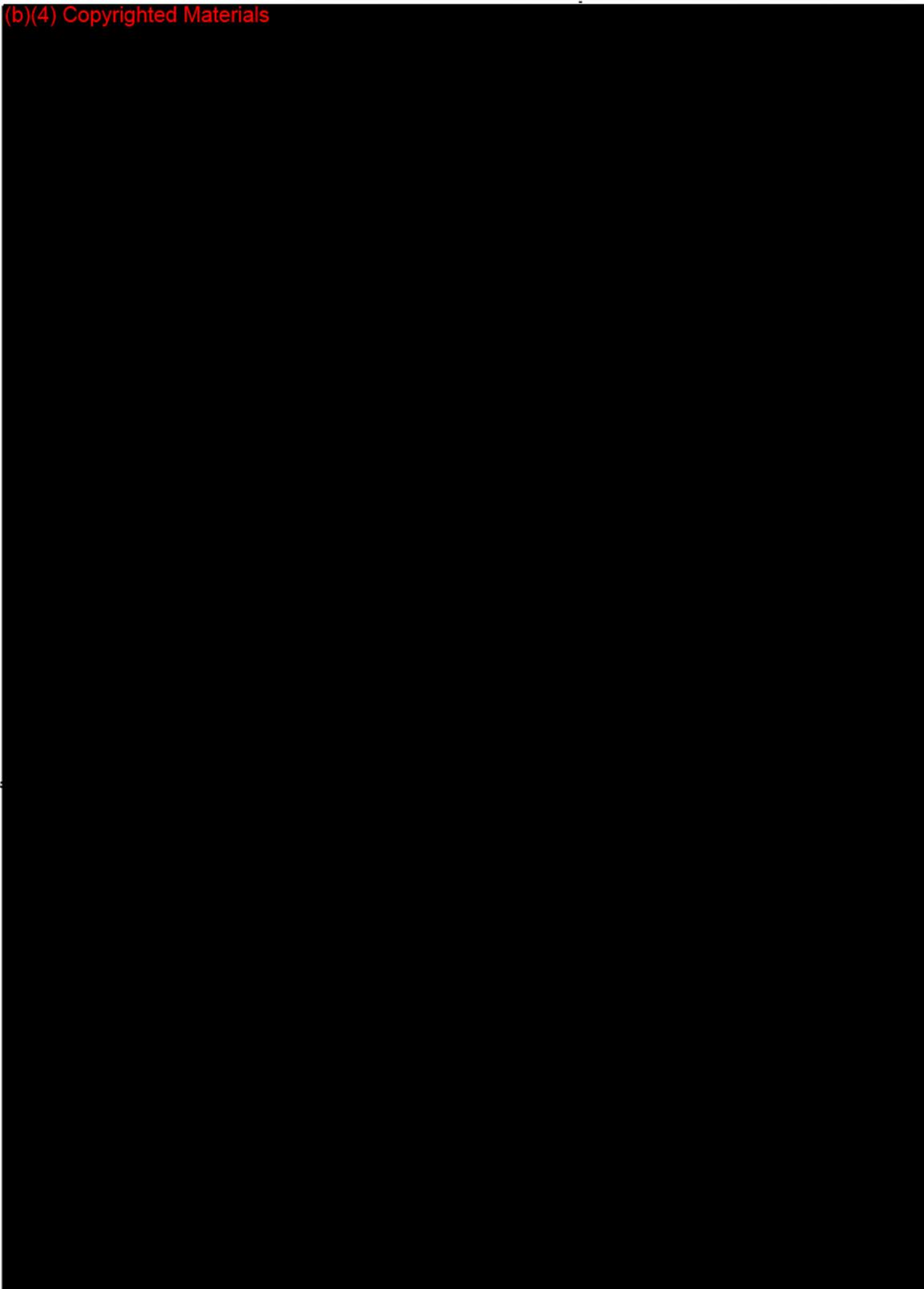


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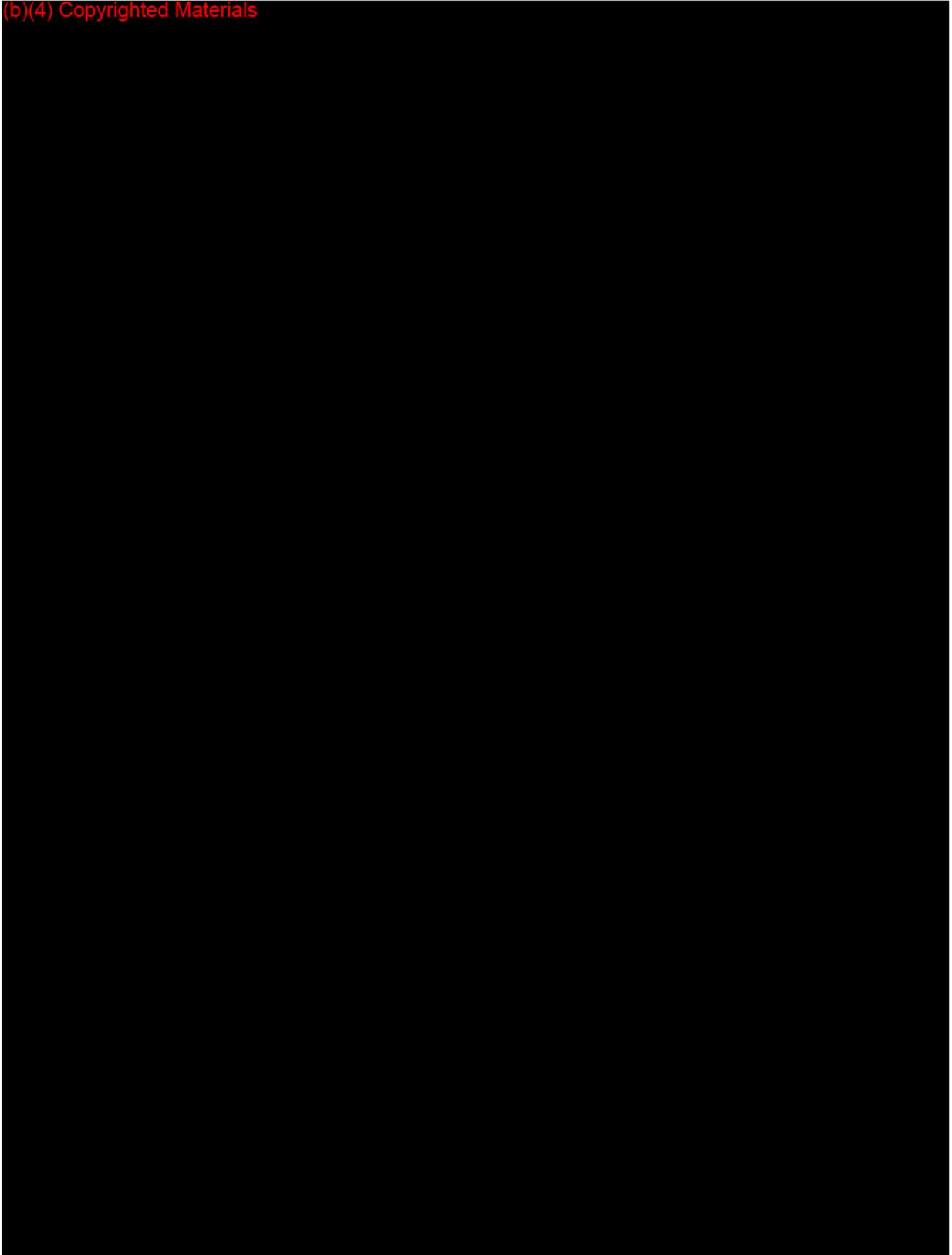
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Number 142
July-August, 1979

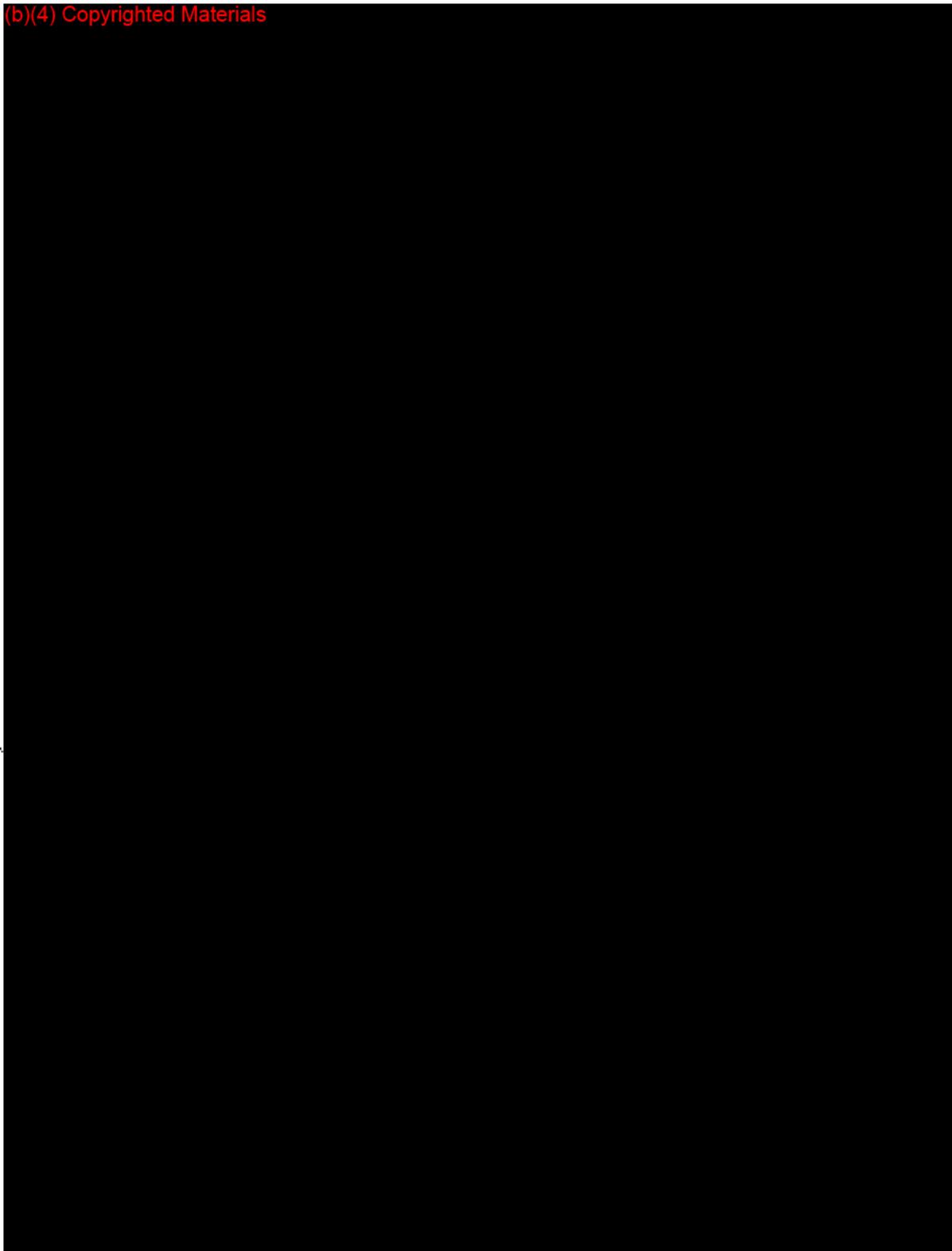
Implant Arthroplasty of the Great Toe 35

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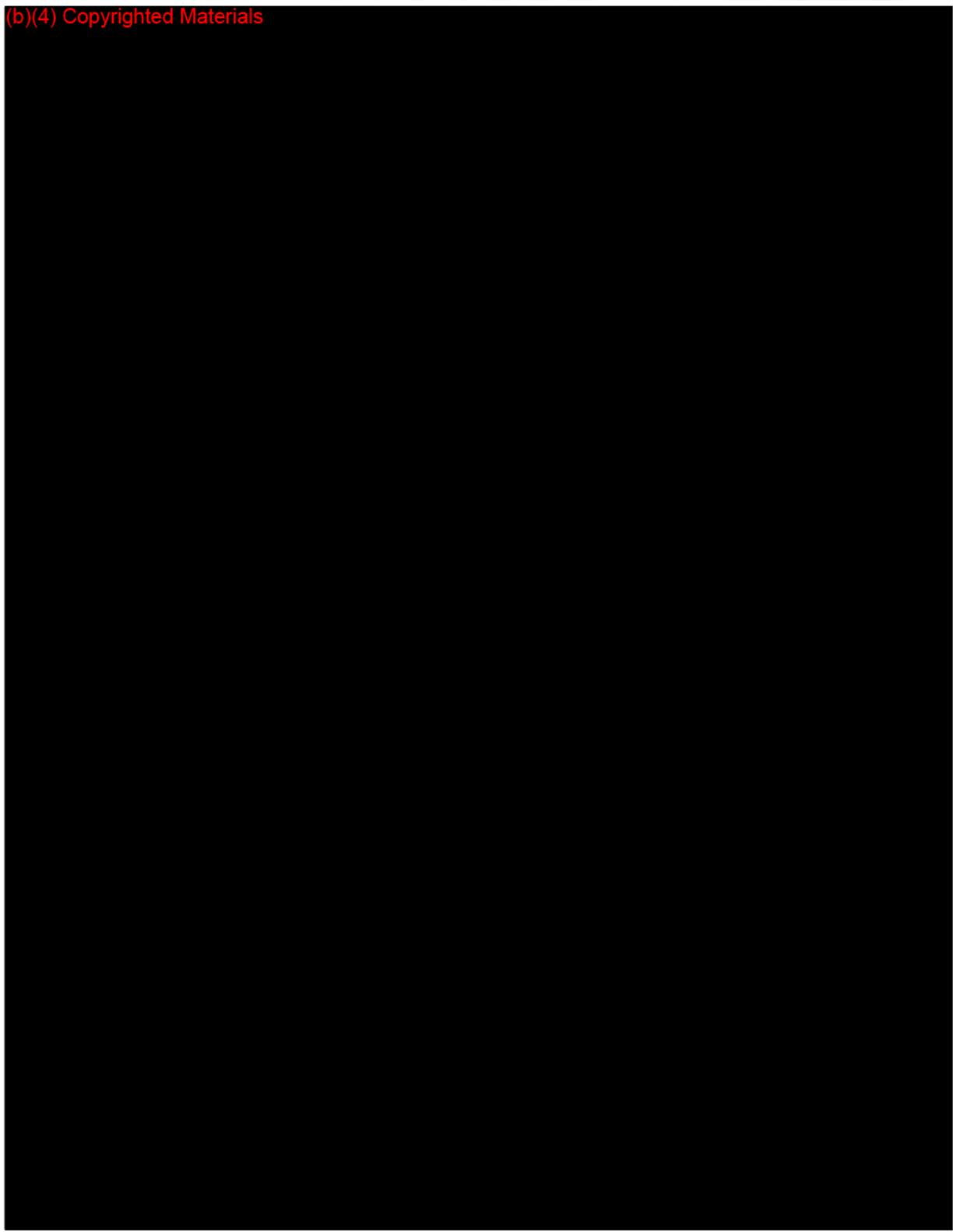
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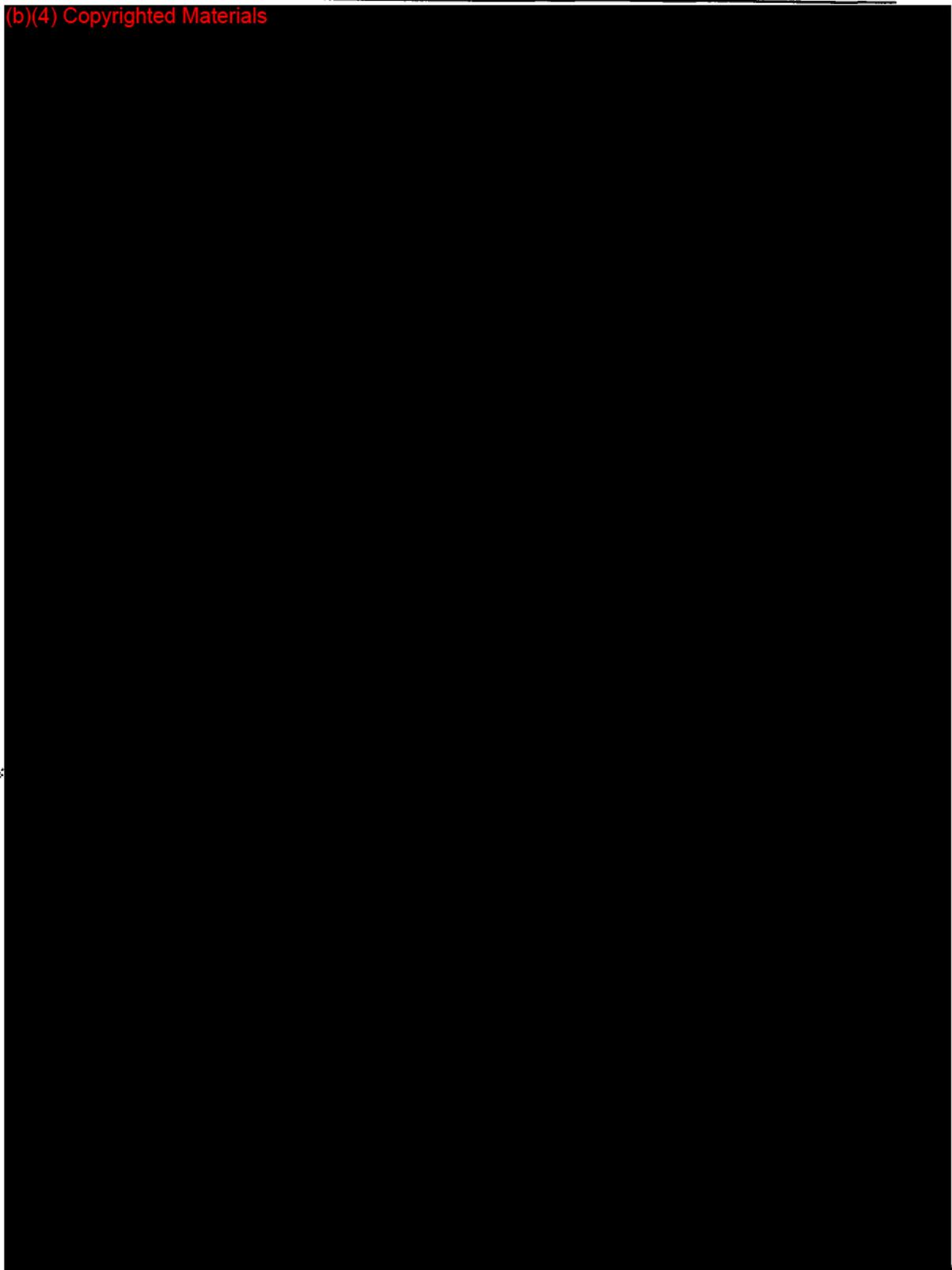
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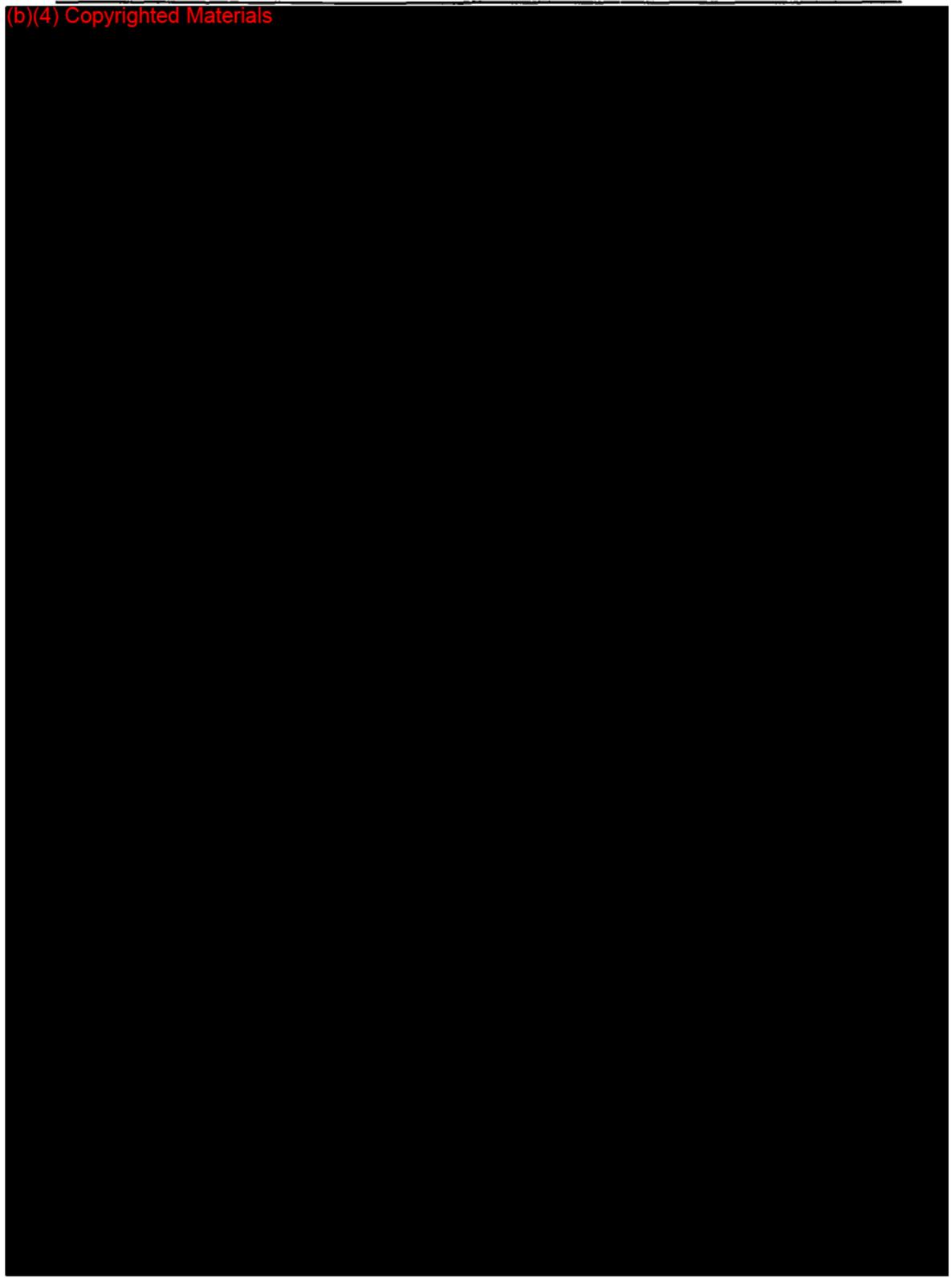


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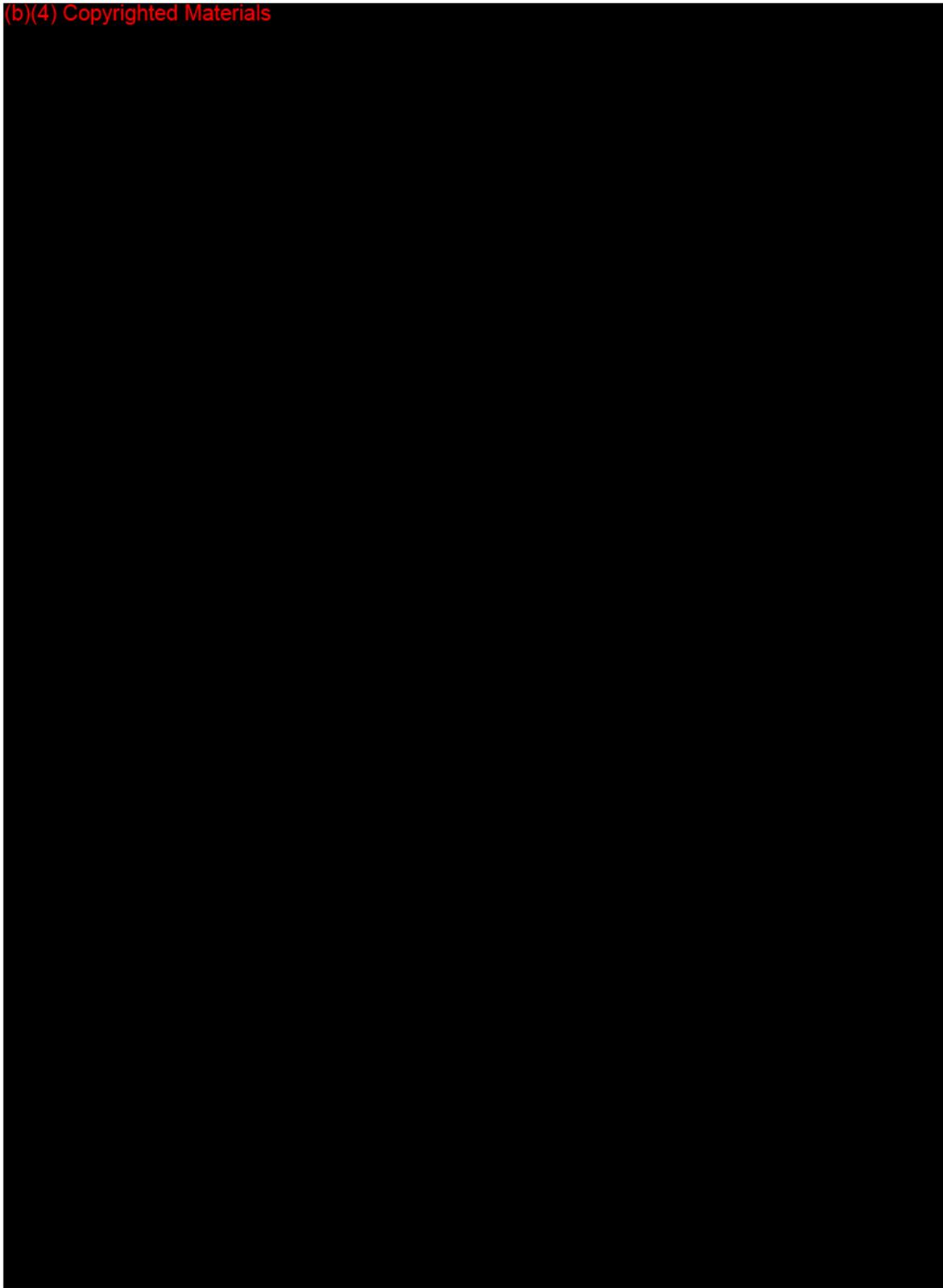


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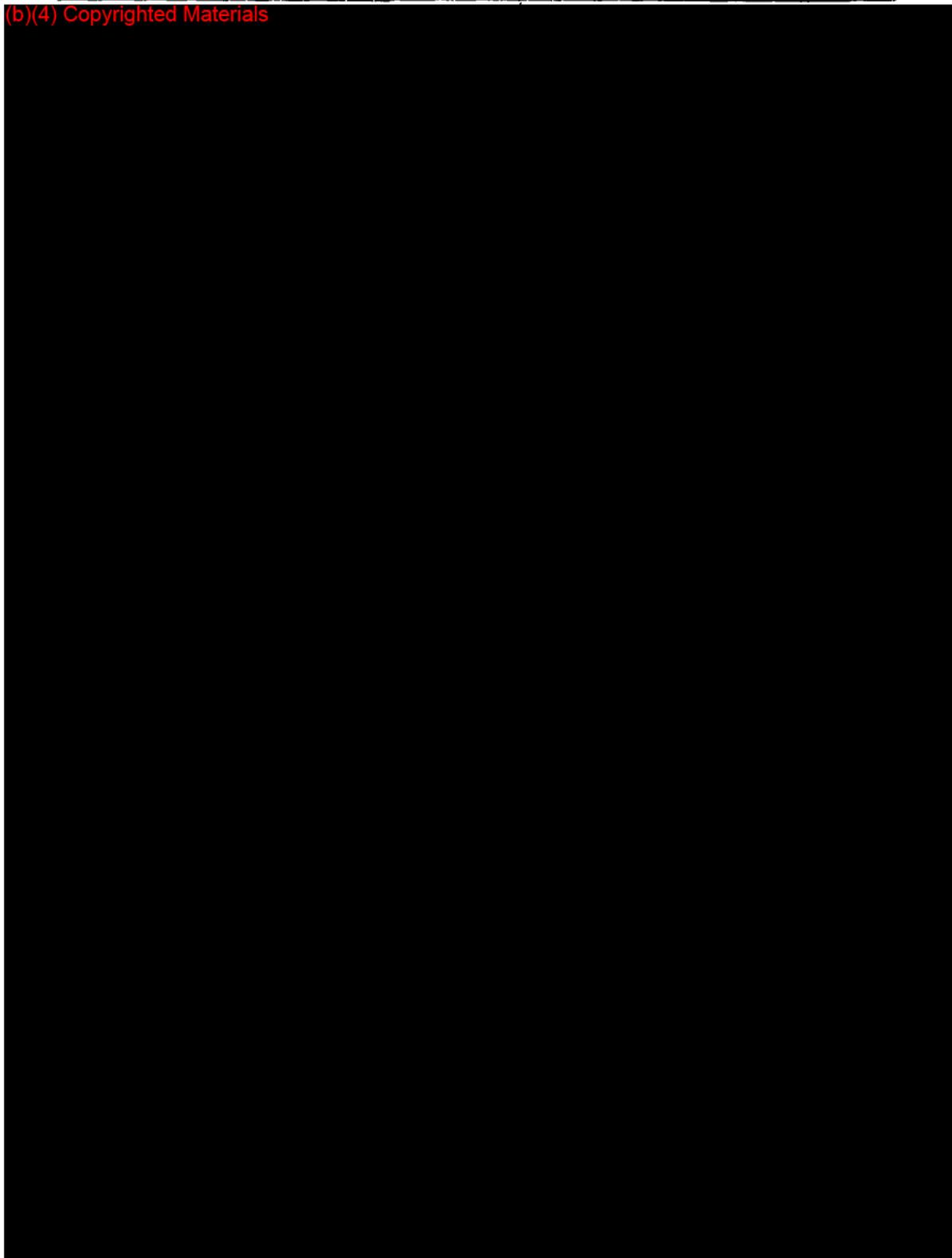


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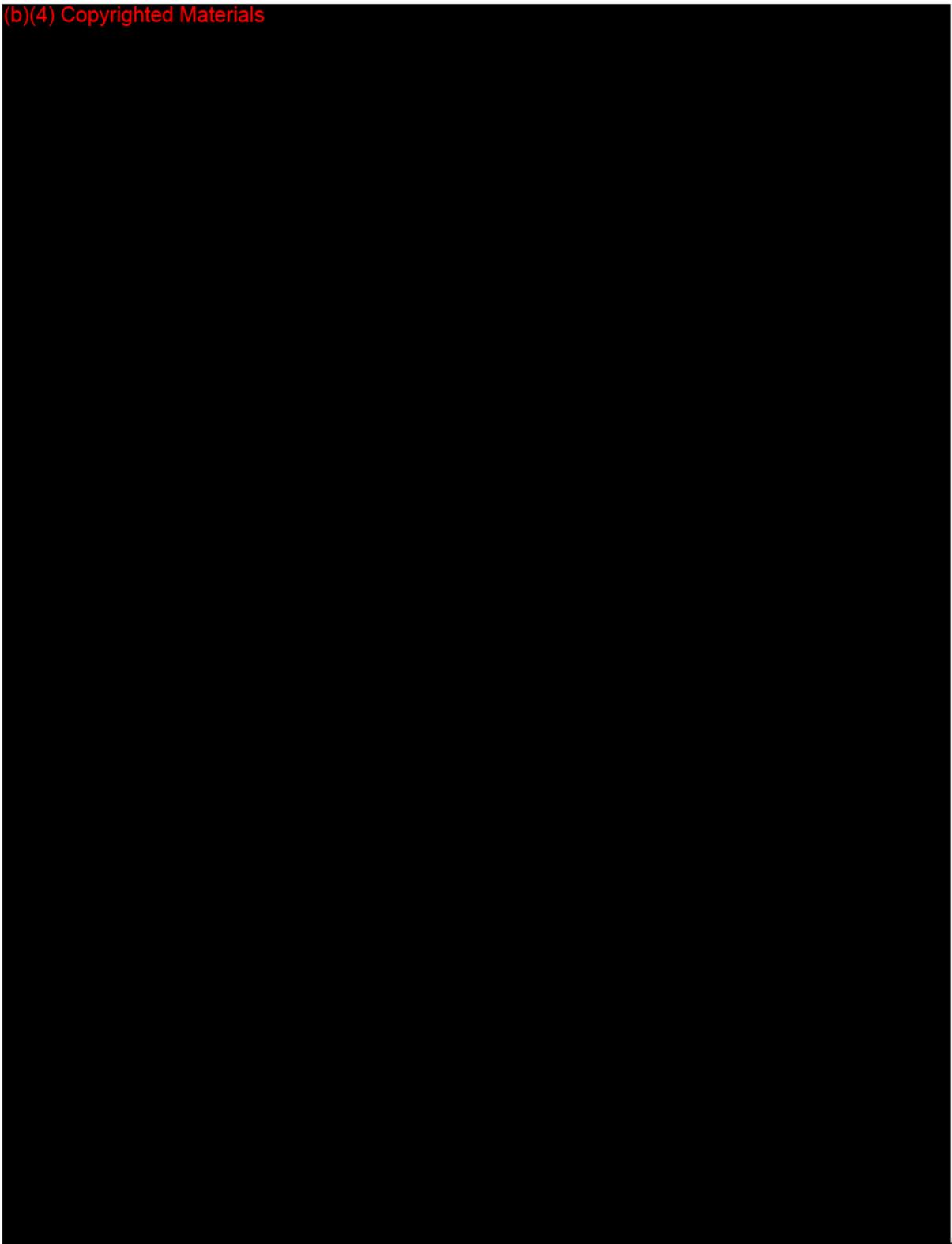


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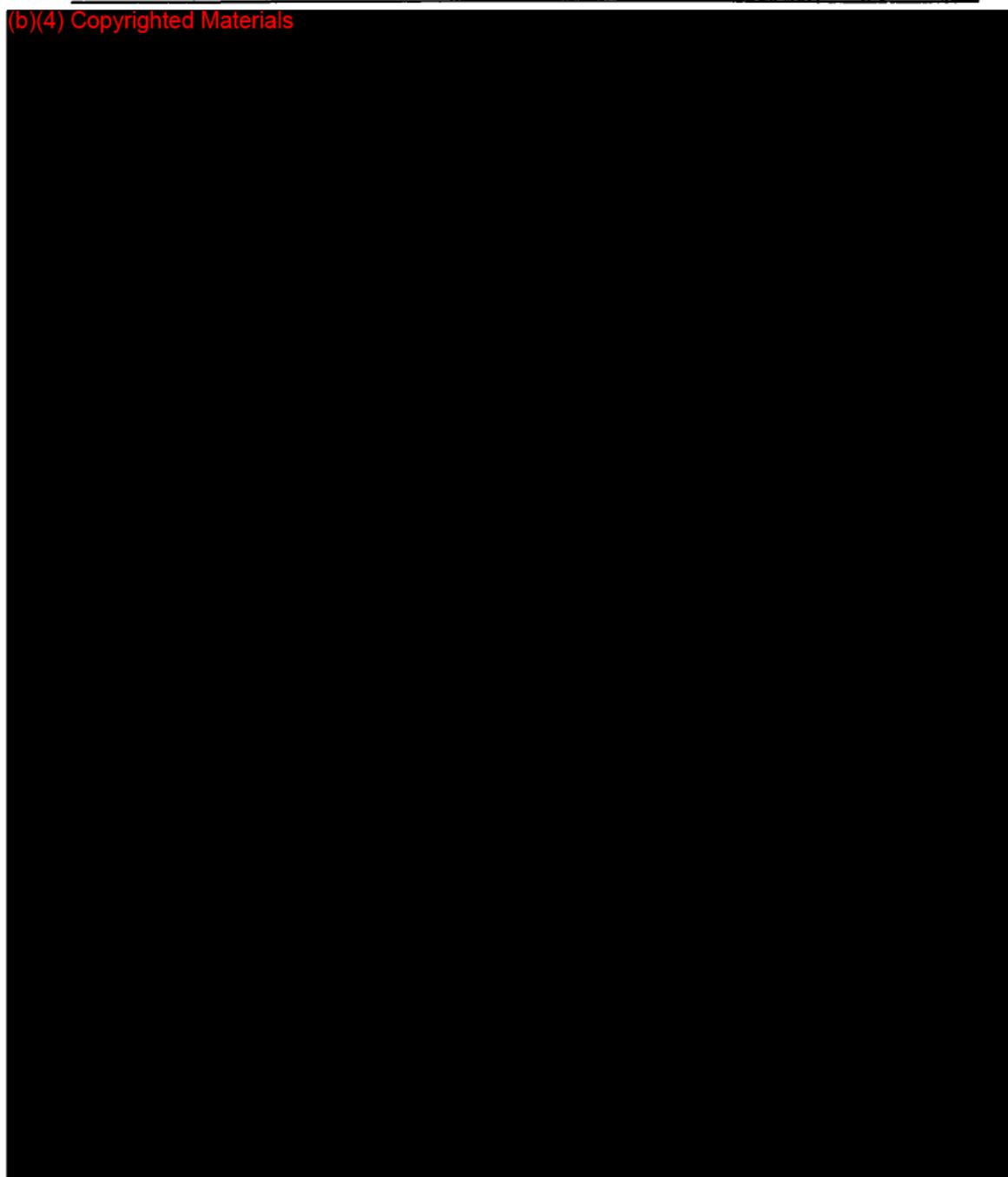
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

JANUARY 16, 1987

DOW CORNING WRIGHT
ATTN: ANTHONY J. LENTZ
P.O. BOX 100
ARLINGTON, TN 38002

Ref : K864492
Product : SWANSON TITANIUM
GREAT TOW IMPLANT

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

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

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

If after 30 days the requested information is not received, we will stop reviewing your submission. 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 the 90-day time period will begin again.

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

Sincerely yours,

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

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-86-4492

1/16/87

FROM: DOW CORNING WRIGHT ATTN: ANTHONY J. LENTZ P.O. BOX 100 ARLINGTON, TN 38002		LETTER DATE 11/10/86	LOGIN DATE 11/13/86	DUE DATE 02/11/87
		TYPE OF DOCUMENT: 510 (k)		CONTROL # K864492
TO: ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : OR PAN/PROD CODE(S): OR/ / /			
SUBJECT: SWANSON TITANIUM GREAT TOW IMPLANT				
DECISION: DECISION DATE: / /	RQST INFO DATE: 01/16/87 DATE: / / DATE: / /	INFO DUE DATE: 02/15/87 DATE: / / DATE: / /		



Memorandum

January 8, 1987

From

REVIEWER(S) - NAME(S)

Sharon A. Stasowicz

Subject

510(k) NOTIFICATION

K264492

To

THE RECORD

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

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

Additional Comments:

*Request for Additional Information / Hold
(Refer to memo dated 1/8/87)*

*S.S.
1/8/87*

The submitter requests:

Class Code w/Panel:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

*87 FFF
(original code -
87 KWD Prosthesis, Toe,
Hemi-, Phalangeal.
(material changed from
silicone to metal)*

REVIEW:

(BRANCH CHIEF)

(DATE)

FINAL REVIEW:

(DIVISION DIRECTOR)

(DATE)

MEMO RECORD

AVOID ERRORS

DATE

Records processed under FOIA Request # 2015-3085; Released by CDRH on 08/19/2015

January 8, 1987

OFFICE

OCE

DIVISION

DARD/OR

FROM:

J. Staronig

TO:

File

SUBJECT:

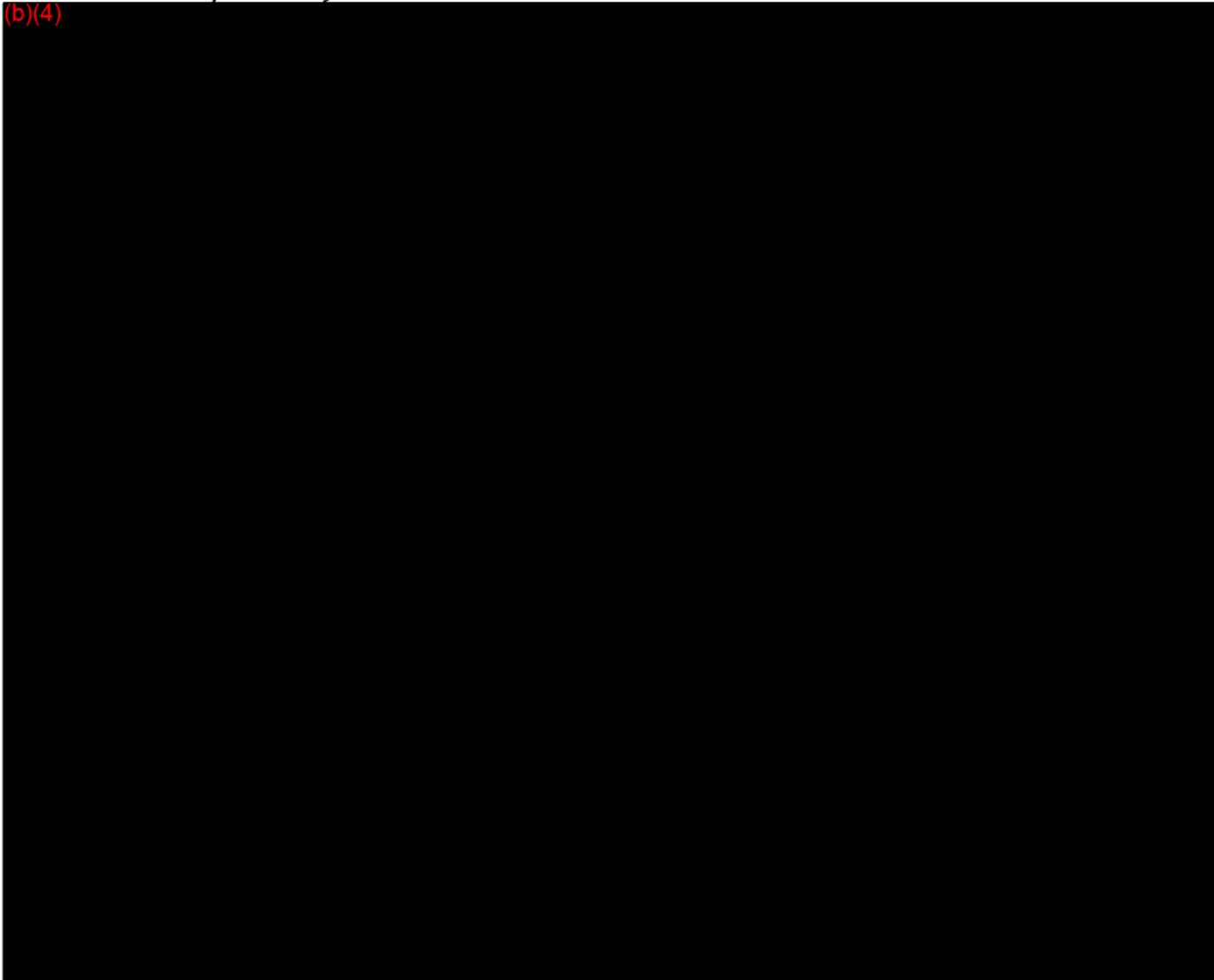
Request for Additional Information:

SUMMARY

- Re: K864488 - Swanson Titanium Condylar Implant
- K864489 - Swanson Titanium Trapezium Implant
- K864490 - Swanson Titanium Carpal Scaphoid Implant
- K864491 - Swanson Titanium Carpal Lunate Implant
- K864492 - Swanson Titanium Great Toe Implant

The following information was requested
 in a telecon of 1/8/87 with Anthony Lentz of Louis
 Corning Wright:

(b)(4)



SIGNATURE

J. Staronig

DOCUMENT NO.

K864488 - K864492

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

NOVEMBER 14, 1986

DOW CORNING WRIGHT
ATTN: ANTHONY J. LENTZ
P.O. BOX 100
ARLINGTON, TN 38002

D.C. Number : K864492
Received : 11-13-86
Product : SWANSON TITANIUM
GREAT TOW IMPLANT

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

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

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

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

Sincerely yours,

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

K864492



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1986 NOV 13 AM 11: 24
DOCUMENT CONTROL
CENTER

November 10, 1986

Food and Drug Administration
Office of Device Evaluation
Document Mail Center HFZ-401
8757 Georgia Avenue
Silver Spring, MD 20910

RE: 510(k) Notification

Dear Sirs:

Dow Corning Wright hereby submits a notification pursuant to section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act), and the regulations thereunder (21 CFR 807). The purpose of this filing is to notify the agency of our intent to market a great toe implant which is substantially equivalent (as that phrase is used in Section 513(f) of the Act) to another which was in commercial distribution before May 28, 1976.

1. Device Name:

Dow Corning Wright Swanson Titanium Great Toe Implant

2. Establishment Registration Number: 1043534

3. Classification under Section 513 of The Act:

This category of devices has not yet been classified as of this date.

4. Performance Standards:

No performance standards have as yet been developed. The American Society for Testing of Materials (ASTM) has developed a voluntary standard from the F-4 Committee on Medical and Surgical Materials and Devices.

ASTM F67 - Unalloyed Titanium for Surgical Implant Applications

A copy of this specification is included as Attachment I.

5. Representative Samples of Labels and Labeling:

Representative samples of proposed labels and labeling describing the device, its intended use, and the directions for its use are included in Attachment II.

Food and Drug Administration
November 10, 1986
Page 2

6. Substantial Equivalence:

The Dow Corning Wright Swanson Titanium Great Toe Implant is substantially equivalent to the SILASTIC® Great Toe Implant H.P. Swanson Design, which has been commercially distributed since prior to May 28, 1976. Product literature for the SILASTIC® Great Toe Implant is included as Attachment III (refer to page 4 of the first brochure and pages 8-10 of the second brochure).

The Titanium Great Toe Implant has the same design as the SILASTIC® Great Toe Implant. Both implants are one-piece devices consisting of a single intramedullary stem and a joint spacer. Further, both implants are used in the same manner. The stem is inserted into the proximal end of the proximal phalanx of the first toe and the joint spacer replaces the surface articulating against the distal end of the first metatarsal. A chart which compares the indications and instructions for use of both implants is included as Attachment IV.

The Titanium Great Toe Implant differs from the SILASTIC® Great Toe Implant primarily in the material of construction. (b)(4) has a long history of successful clinical application and is considered safe for use as an implant material in contact with bone. An example of such use is the (b)(4) (b)(4)

Additional documentation to illustrate that the Titanium Great Toe Implant is substantially equivalent to the SILASTIC® Great Toe Implant is provided in Attachment VI. A clinical summary was assembled to compare the results achieved using a group of (b)(4) (b)(4)

Table 1 presents a generalized overview of the number and kind of implants studied.

Figures 1-3 profile the patient population and distribution of implant types to show that the silicone group and metal groups are comparable.

Figures 4-6 and Table 2 present the postoperative results.

An examination of these data will demonstrate that similar results were achieved in both groups. Clinical data for the silicone implants were extracted from published studies; the literature references are cited at the end of Attachment VI.

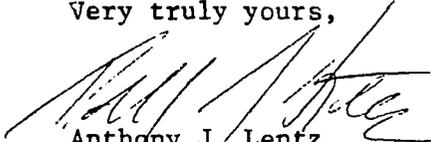
Food and Drug Administration
November 10, 1986
Page 3

Attachment VII lists two references which describe the historical use of metal as an implant material for small joint replacement.

Based upon a review of the labelling for this and the substantially equivalent device, plus the aforementioned documentation, we firmly believe that it is readily apparent that the Dow Corning Wright Swanson Titanium Great Toe Implant is substantially equivalent to products sold prior to enactment of the Medical Device Amendments of 1976.

We are forwarding this submission herewith in duplicate. (The cover letter is included in triplicate pursuant to 21 CFR 806.90(c).) Your prompt attention to this matter is appreciated.

Very truly yours,


Anthony J. Lentz
Group Leader
Polymer Orthopaedics R&D

AJL/smd

Enclosure

Attachment

I



Designation: F 67 - 83

Standard Specification for UNALLOYED TITANIUM FOR SURGICAL IMPLANT APPLICATIONS¹

This standard is issued under the fixed designation F 67; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for four grades of unalloyed titanium in mill product forms used for the manufacture of surgical implants.

NOTE—The values stated in inch-pound units are to be regarded as the standard.

2. Applicable Documents

2.1 ASTM Standards:

B 265 Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate²

B 348 Specification for Titanium and Titanium Alloy Bars and Billets²

B 381 Specification for Titanium and Titanium Alloy Forgings²

E 8 Methods of Tension Testing of Metallic Materials³

E 16 Method of Free Bend Test for Ductility of Welds⁴

E 120 Methods for Chemical Analysis of Titanium and Titanium Alloys⁵

E 190 Method for Guided Bend Test for Ductility of Welds³

E 290 Method for Semi-Guided Bend Test for Ductility of Metallic Materials³

2.2 American Society for Quality Control (ASQC) Standard:

C1-1968 Specifications of General Requirements for a Quality Program⁶

3. General Requirements for Delivery

3.1 Material furnished to this specification shall conform to the requirements of the latest issues of Specifications B 265, B 348, and B 381.

3.2 In the case where a conflict exists between this specification and those listed in 3.1, this specification shall take precedence.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces).

4.1.2 Grade (1, 2, 3, or 4).

4.1.3 ASTM designation.

4.1.4 Form (sheet, strip, plate, bar, billet or forging).

4.1.5 Condition (5.1).

4.1.6 Mechanical properties (if applicable, for special conditions).

4.1.7 Finish (5.2).

4.1.8 Applicable dimensions including size, thickness, width, and length (exact, random, multiples) or print number.

4.1.9 Special tests, and

4.1.10 Special requirements.

5. Manufacture

5.1 *Condition*—Material shall be furnished to the implant manufacture in the hot-rolled, cold-finished, forged, or annealed, condition.

5.2 *Finish*—Mill products shall be finished as descaled or pickled, sandblasted, ground, or combinations of these operations.

¹ This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.20 on Resources.

Current edition approved Nov. 28, 1983. Published January 1984. Originally published as F 67-66. Last previous edition F 67-77.

² Annual Book of ASTM Standards, Vol 02.04.

³ Annual Book of ASTM Standards, Vol 03.01.

⁴ Discontinued; see 1977 Annual Book of ASTM Standards, Part 10.

⁵ Annual Book of ASTM Standards, Vol 03.05.

⁶ Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.



6. Chemical Requirements

6.1 The heat analysis shall conform to the requirements as to chemical composition prescribed in Table 1. Ingot analysis may be used for reporting all chemical requirements except hydrogen, samples of which shall be taken from the finished product.

6.2 The chemical composition of samples taken for product analysis shall conform to the product tolerances prescribed in Table 2.

6.3 For referee purposes, Methods E 120 shall apply.

6.3.1 Samples for chemical analysis shall be representative of the material being tested. Extreme care must be taken in sampling titanium for chemical analysis because of its affinity for elements such as oxygen, nitrogen, and hydrogen. Therefore, when cutting samples for analysis, the operation should be carried out in a dust-free atmosphere, if possible. Chips should be collected from clean metal. Cutting tools should be clean and sharp. Samples for analysis should be stored in suitable containers.

7. Mechanical Requirements

7.1 The material shall conform to the appropriate requirements as to mechanical properties prescribed in Table 3. Grades 3 and 4 may be ordered to higher minimum strength levels in the cold-rolled condition as agreed upon between the supplier and the implant manufacturer.

7.2 Bend Test:

7.2.1 The purpose of this test is to measure the cleanliness or ductility, or both, of the metals.

7.2.2 Perform bend tests for all strip,

sheet, and plate in accordance with Method E 190 (for plate) or Method E 16 (for sheet and strip). The welds mentioned in these methods are not necessary.

7.2.3 Specimens shall withstand being bent cold through an angle of 105° with no cracking or surface separation on the outside of the bent portion. The bend shall be made on a diameter equal to that shown in Table 3.

7.3 Tension Test—Perform tension testing in accordance with Method E 8. Determine tensile properties using a strain rate of 0.003 to 0.007 in./in. (mm/mm)·min through the specified yield strength, and then increased so as to produce failure in approximately one additional minute.

7.4 Any other special requirements shall be specified on the implant manufacturer's purchase order.

8. Certification

8.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification together with a report of the test results shall be furnished to the implant manufacturer at the time of shipment.

9. Quality Program Requirements

9.1 The producer shall maintain a quality program, such as, for example, is defined in ASQC C1-1968.

9.2 The manufacturer of surgical implants or medical appliances shall be assured of the producer's quality program for conformance to the intent of ASQC C1-1968, or other recognized program.

TABLE 1 Chemical Requirements

Element	Composition, %							
	Grade 1		Grade 2		Grade 3		Grade 4	
	Flat Prod- uct	Bar and Bil- let	Flat Prod- uct	Bar and Bil- let	Flat Prod- uct	Bar and Bil- let	Flat Prod- uct	Bar and Billet
Nitrogen, max	0.03	0.03	0.03	0.03	0.05	0.05	0.05	0.05
Carbon, max	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
Hydrogen, max	0.015	0.0125 ^a						
Iron, max	0.20	0.20	0.30	0.30	0.30	0.30	0.50	0.50
Oxygen, max	0.18	0.18	0.25	0.25	0.35	0.35	0.40	0.40
Titanium	balance	balance	balance	balance	balance	balance	balance	balance

^a Bar only; max hydrogen content for billet is 0.0100 %.



F 67

TABLE 2 Permissible Variation in Product Analysis

Element	Product Analysis Limits, max or range, %	Permissible Variation in Product Analysis, under min or over max, %
Nitrogen	0.05	0.02
Carbon	0.10	0.02
Hydrogen	0.02	0.002
Iron	0.50	0.15
Oxygen	0.30 to 0.40	0.04

TABLE 3 Mechanical Requirements

NOTE—These mechanical properties also apply to forgings having a maximum cross section not greater than 1 in. (25.4 mm); properties of larger forgings shall be negotiated.

Grade	Ultimate Tensile Strength, ^d min		Yield Strength ^d (0.2 % off-set), min		Elongation in 2 in. or 50 mm, % min	Reduction of Area, % min ^e	Bend Test ^c	
	psi	MPa	psi	MPa			Under 0.70 in. (17.8 mm) Thickness	Over 0.70 in. (17.8 mm) Thickness
1	35 000	240	25 000	170	24	30	3T	4T
2	50 000	345	40 000	275	20	30	4T	5T
3	65 000	450	55 000	380	18	30	4T	5T
4	80 000	550	70 000	485	15	25	5T	6T

^d Tensile and yield requirements apply to tests taken both longitudinally and transversely to the direction of rolling.

^e Apply to bar, billet, and forging products.

^c Bend test applicable to sheet and strip products; T = thickness of the bend specimen in reference to diameter of bend.

APPENDIX

(Nonmandatory Information)

X1. Rationale

X1.1 The primary reason for this standard is to characterize composition and properties to assure consistency in the starting material used in the manufacture of medical devices.

X1.2 The material compositions specified herein

have been shown to produce a well-characterized level of biological response following long term clinical use.

X1.3 The choice of composition and mechanical properties is dependent upon the design and application of the medical device.

The American Society for Testing and Materials takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, 1916 Race St., Philadelphia, Pa. 19103.

Attachment

II

ATTACHMENT 11

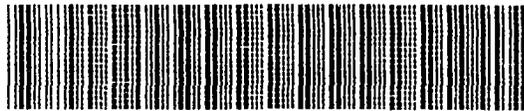
DOW CORNING 5677 Airline Rd.
WRIGHT Arlington, TN 38002

CAT NO. 0000-0000
LOT NO. N/A

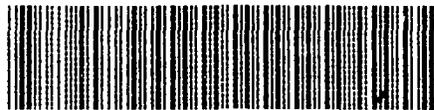
TITANIUM
GREAT TOE IMPLANT

ATTACH TO PATIENT RECORD

DOW CORNING WRIGHT 5677 Airline Rd., Arlington, TN 38002	
CAT. NO. 0000-0000	LOT N/A
SIZE # 3	QTY. 1 EACH
TITANIUM GREAT TOE IMPLANT	
STERILE	
<small>CAUTION: Federal (United States) law limits this device to sale by or on the order of a physician.</small>	



* +H4270000000 N *



* +N/A NL *

SILASTIC® H.P. SWANSON GREAT TOE IMPLANT
AND
DOW CORNING WRIGHT SWANSON TITANIUM GREAT TOE IMPLANT

Description

The SILASTIC® H.P. Great Toe Implant and the Titanium Great Toe Implant are one-piece, intramedullary-stemmed implants developed to overcome the disadvantages of shortening, occasional instability, or painful stiffening which may follow standard arthroplasty procedures of the great toe.

The Great Toe Implant is designed to supplement resection arthroplasty of the first metatarsophalangeal joint. The stem of the implant fits into the intramedullary canal of the proximal phalanx with the implant head replacing the proximal third of the proximal phalanx. It serves to provide a smooth articulating surface for the first metatarsal head, helps restore and maintain motion without loss of stability, and preserves good cosmetic appearance. Biologically and mechanically well tolerated, the implant is surrounded by a fibrous supporting capsule which helps preserve joint space relationship and stability, resulting in early pain-free rehabilitation.

The SILASTIC® H.P. Great Toe Implant is fabricated from medical-grade high performance silicone elastomer, and is available in five anatomical sizes of regular or small stems to adequately meet various operative requirements. The Swanson Titanium Great Toe Implant is fabricated from unalloyed titanium for surgical application (ASTM F67). Blue sizing sets, supplied nonsterile and not suitable for implantation, are available for proper size determination during surgery.

Specific Advantages

- ° Minimal irritation to bone and surrounding soft tissue.
- ° Extensive testing has demonstrated high durability.
- ° Fixation in the intramedullary canal is not necessary.
- ° Available in five sizes of regular or smaller stems to adequately meet the various operative requirements.
- ° Visible on x-ray evaluation.
- ° The implant is provided sterile.

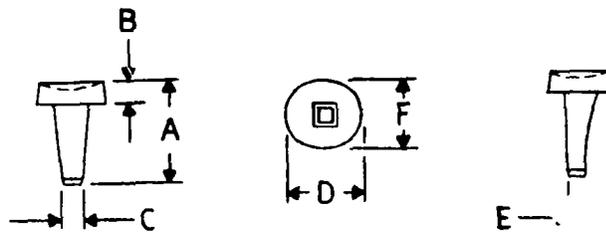
Clinical Advantages

- ° Improves toe dynamics: provides stability, mobility, pain relief and maintains toe length. The increased flexion power transfer of the great toe assists in normal gait pattern.
- ° Provides a smooth articular surface for the first metatarsal head.
- ° Acts as a space filler: maintains joint space and allows capsule/ligament reconstruction to correct the deformities.
- ° Improves cosmetic appearance.
- ° Facilitates postoperative rehabilitation. Excessive postoperative fixation that could compromise the range of useful motion is not required.

Typical Dimensions

SIZE	OS	0	1S	1	2S	2	3S	3	4S	4
A	.605 (15.4)	.70 (17.8)	.725 (18.4)	.92 (23.4)	.825 (21.0)	1.02 (25.5)	.855 (21.7)	1.16 (29.5)	.895 (22.7)	1.26 (32.0)
B	.14 (3.6)	.14 (3.6)	.19 (4.8)	.19 (4.8)	.22 (5.6)	.22 (5.6)	.22 (5.6)	.22 (5.6)	.23 (5.8)	.23 (5.8)
C	.136 (3.5)	.17 (4.3)	.146 (3.7)	.21 (5.3)	.156 (4.0)	.22 (5.6)	.166 (4.2)	.22 (5.6)	.176 (4.5)	.22 (5.6)
D	.52 (13.2)	.52 (13.2)	.59 (15.0)	.59 (15.0)	.66 (16.8)	.66 (16.8)	.74 (18.8)	.74 (18.8)	.79 (20.0)	.79 (20.0)
E	.096 (2.4)	.12 (3.0)	.100 (2.5)	.12 (3.0)	.104 (2.6)	.14 (3.6)	.108 (2.7)	.13 (3.3)	.112 (2.8)	.14 (3.6)
F	.44 (11.2)	.44 (11.2)	.52 (13.2)	.52 (13.2)	.57 (14.5)	.57 (14.5)	.63 (16.0)	.63 (16.0)	.68 (17.3)	.68 (17.3)

Dimension: Inches (Millimeters)



SILASTIC® H.P. SWANSON GREAT TOE IMPLANT
AND
DOW CORNING WRIGHT SWANSON TITANIUM GREAT TOE IMPLANT

GENERAL INDICATIONS

Any joint implant arthroplasty requires consideration of the following general indications:

- ° Good condition of the patient.
- ° A good neurovascular status.
- ° An adequate skin coverage.
- ° The possibility of a functional musculotendinous system.
- ° Adequate bone stock to receive implant.
- ° Availability of postoperative therapy.
- ° A cooperative patient.

CLINICAL INDICATIONS

Use of the SILASTIC® H.P. Great Toe Implant or Titanium Great Toe Implant may be considered for patients with good, normal density bone stock who exhibit the following clinical conditions.

1. Hallux valgus (Figure 1A and B): mild to moderate only.
2. Hallux rigidus.
3. Unstable or painfully stiff MP joint following Keller-type bunionectomy (Figure 2A and B).

Only the SILASTIC® H.P. Great Toe Implant should be considered for use in patients with osteoporotic bone, such as in some elderly or rheumatoid patients.

NOTE: For severe hallux valgus as seen in rheumatoid arthritis or in the senile bunion or following a failed Mayo-type resection, the double-stemmed SILASTIC® Flexible Hinge Toe Implant H.P. (Swanson Design) is recommended.

CONTRAINDICATIONS

- ° Physiologically or psychologically inadequate patient.
- ° Inadequate skin, bone and/or neurovascular status.
- ° Irreparable tendon system.

How Supplied

The SILASTIC® H.P. Swanson Great Toe Implant has been sterilized and packaged as follows:

Regular Stem		
Quantity	Description	Catalog Number
1 box	1 each, Size 0	2483-0010
1 box	1 each, Size 1	2483-0001
1 box	1 each, Size 2	2483-0002
1 box	1 each, Size 3	2483-0003
1 box	1 each, Size 4	2483-0004
1 sizing set	1 each, 5 sizes, numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	2493-0000

Small Stem		
Quantity	Description	Catalog Number
1 box	1 each, Size 0S	2483-0110
1 box	1 each, Size 1S	2483-0101
1 box	1 each, Size 2S	2483-0102
1 box	1 each, Size 3S	2483-0103
1 box	1 each, Size 4S	2483-0104
1 sizing set (smaller stem)	1 each, 5 sizes, numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	2493-0100

The Dow Corning Wright Swanson Titanium Great Toe Implant has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	1 each, size 0	(To be assigned)
1 box	1 each, size 1	(To be assigned)
1 box	1 each, size 2	(To be assigned)
1 box	1 each, size 3	(To be assigned)
1 box	1 each, size 4	(To be assigned)

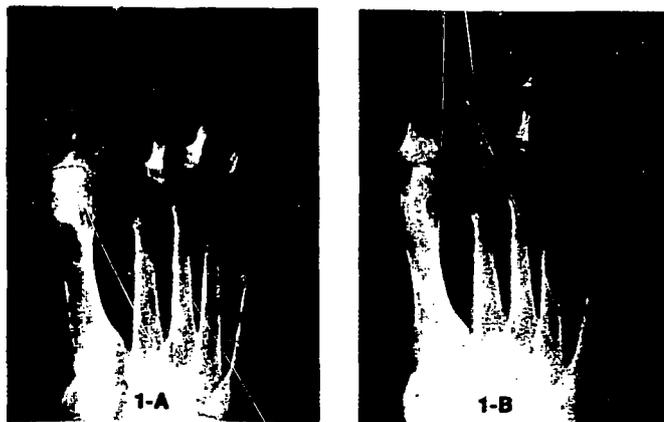


Fig. 1A: Shows a hallus valgus deformity with disabling pain in the metatarsophalangeal joint.

Fig. 1B: Post-operative roentgenogram: The implant is well tolerated by the bone and soft tissue. This patient has a pain free toe with good functional and cosmetic result.

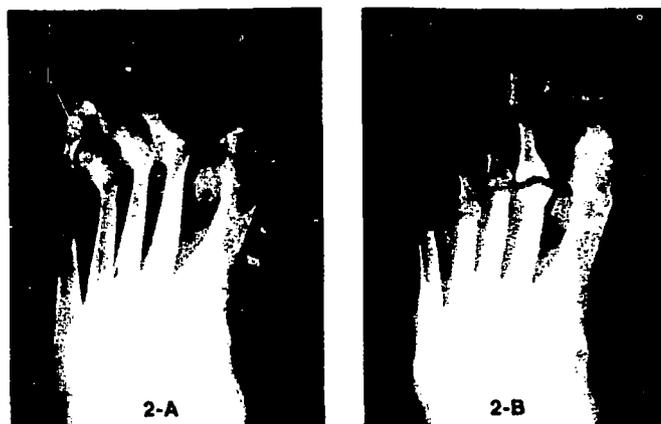


Fig. 2A: Pre-operative roentgenogram shows rheumatoid arthritic foot with painful pseudoarthrosis following resection arthroplasty of great toe and dislocation of MP joints in 2, 3, 4, 5 toes.

Fig. 2B: Post-operative roentgenogram shows MP of great toe with implant. Heads of metatarsals 2, 3, 4, 5 have been resected. The patient has a pain free, functional foot.

INSTRUCTIONS FOR USE

SURGICAL PROCEDURE

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Alfred B. Swanson. Each surgeon must evaluate the appropriateness of the procedure based on his or her own medical training and experience.

INCISION AND EXPOSURE

A slightly curved longitudinal skin incision is made along the dorsomedial aspect of the metatarsophalangeal joint (Fig. 3A). Care must be taken to avoid injury to the small dorsal sensory nerves and veins in the area. The fascia and the medial capsule are dissected making a proximally-based medial fascial capsular flap. This flap is reflected for later resuture. If a bursa is present, it is excised and the metatarsophalangeal joint opened.

BONE PREPARATION

The proximal third of the basal phalanx is carefully resected with drill holes and an osteotome, or with air drill or motor saw (Fig. 3B). The exostoses of the metatarsal head are removed on both lateral and plantar surfaces so that a smooth rounded metatarsal head is presented. The head of the metatarsal may be reshaped but not shortened if it is too rough or too long to allow correction of the deformity. Its surface should be carefully smoothed with a rongeur or bur and air drill. The sesamoid bones are rarely excised. Using a drill, rasp, broach or curette, the canal of the proximal phalanx is shaped to accept the implant stem.

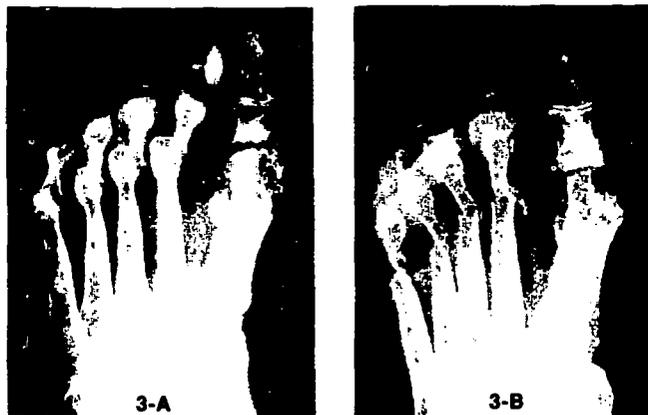


Fig. 3A: A dorso-medial approach through a slightly curved longitudinal incision along the medial aspect of the metatarsophalangeal joint is used when only surgery of the great toe is indicated.

Fig. 3B: The proximal third of the basal phalanx is resected, exostoses on lateral and plantar surfaces are removed presenting a smooth, rounded metatarsal head. Using curette, broach or drill, the proximal phalangeal canal is shaped to accept the implant stem.

IMPLANT INSERTION

The implant stem should fit snugly into the canal with the collar of the implant fitting firmly against the proximal cut surface of the phalanx. The curved portion of the stem should be placed plantarward (Fig. 4). Proper implant choice from the five available sizes in either SILASTIC® or titanium will assure correct fit. The stem of the SILASTIC® implant may be cut to appropriate length, if necessary. No trimming should be done

elsewhere on the implant. The toe should then be easily brought over into the corrected position. The implant should be handled with blunt instruments to avoid traumatizing its surface or contamination with foreign bodies.

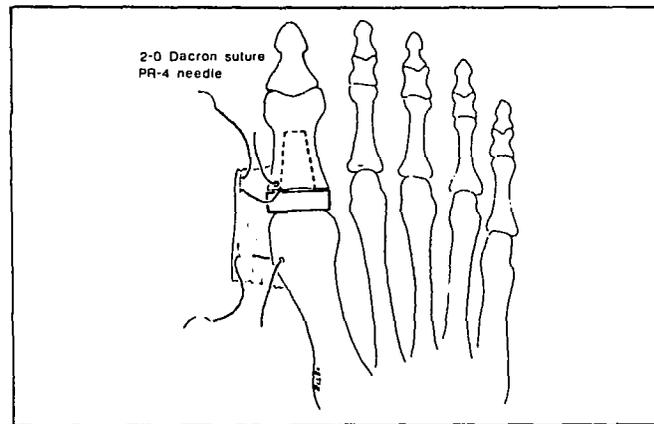


Fig. 4: Implant stem should fit snugly in the canal with collar of implant fitting firmly against cut proximal surface of phalanx. The curved portion of the stem should be placed plantarward. Firm reattachment to bone of a loose medial capsule either proximally or distally is of absolute importance for correction of valgus deformity.

NOTE: A reusable sizing set containing one of each size implant is available to assist proper size determination. Numerically marked and blue in color for easy identification, the sizing set is supplied non-sterile and is not suitable for implantation. For use, follow instructions under section, "Sterilization."

SOFT TISSUE RELEASE, REEFING AND CLOSURE

Further release of the lateral capsule, adductor muscle attachments or rerouting or lengthening of the long extensor may be indicated. The usual practice is to cut the short extensor tendon and lengthen the long extensor tendon distal to the metatarsophalangeal joint in a manner similar to a Z-plasty. There should be a good and unrestricted range of motion of the toe before closure. With the toe in the correct position, the medial fascial-capsular flap is firmly sutured to the bone through small drill holes. A 3-0 Dacron suture is passed through the hole in the base of the proximal phalanx. Using buried knot technique, the capsule is held to the medial aspect of the proximal phalanx in the corrected position. The aponeurosis of the long extensor tendon which may have been released on its lateral aspect is sutured medially to the medial capsule using 4-0 Dacron sutures with a buried knot technique. The skin is closed and a small SILASTIC® Incision Drain is placed in the wound. A voluminous conforming dressing is applied to the foot including a simple longitudinal splint to support the toe in position.

POSTOPERATIVE CARE

After 3 to 15 days the initial dressing is removed and a dynamic splint* is applied to maintain the alignment of the toe while allowing early and active flexion-extension exercises (Fig. 5). An exercise program is prescribed. The dynamic splint is either attached to a cast, or a removable type splint may be used.



Fig. 5: Appearance of the dynamic toe splint worn with the wooden-soled shoe. The shoe is fitted with a 1/2 inch-thick foam rubber inner sole extending to the distal metatarsal level to allow flexion exercises.

It is worn continuously for 3 to 4 weeks and then used as a night splint for approximately 3 to 6 weeks. The patient may walk on his heel or on a wooden-soled shoe in a week. The use of a 1/2 inch thick foam rubber inner sole extending to the distal metatarsal level is important to allow flexion exercises. Exercises over a step or other solid objects are prescribed to encourage flexion. Guarded weight bearing is encouraged 3 weeks post-operatively. Appropriate nonconstrictive shoe wear is prescribed. It is also important to avoid extraneous movements of pins extending through the skin against the shoe on walking.

IMPORTANT POINTS TO OBSERVE

1. Using the blue sizing set as a guide, select the largest implant that the bone can accommodate, as the same time being very careful that the implant is well seated.
2. Rinse the implant thoroughly with saline solution before insertion.
3. Handle the implant with a blunt instrument to avoid traumatization of the implant and contamination by other foreign bodies.
4. Shortening the end of the stem of SILASTIC® implants is permissible, although reshaping of the implant elsewhere should be avoided because modification might create structural weakness.

Attachment

III

ATTACHMENT III

DOW CORNING WRIGHT

**SILASTIC[®]
ORTHOPAEDIC
IMPLANTS H.P.**



FOR THE FOOT



SILASTIC®

This registered trademark is the brand name for Dow Corning's silicone elastomer products and materials. Only Dow Corning may identify its products with the trademark SILASTIC®. The word is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's material. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

HIGH PERFORMANCE SILICONE ELASTOMER

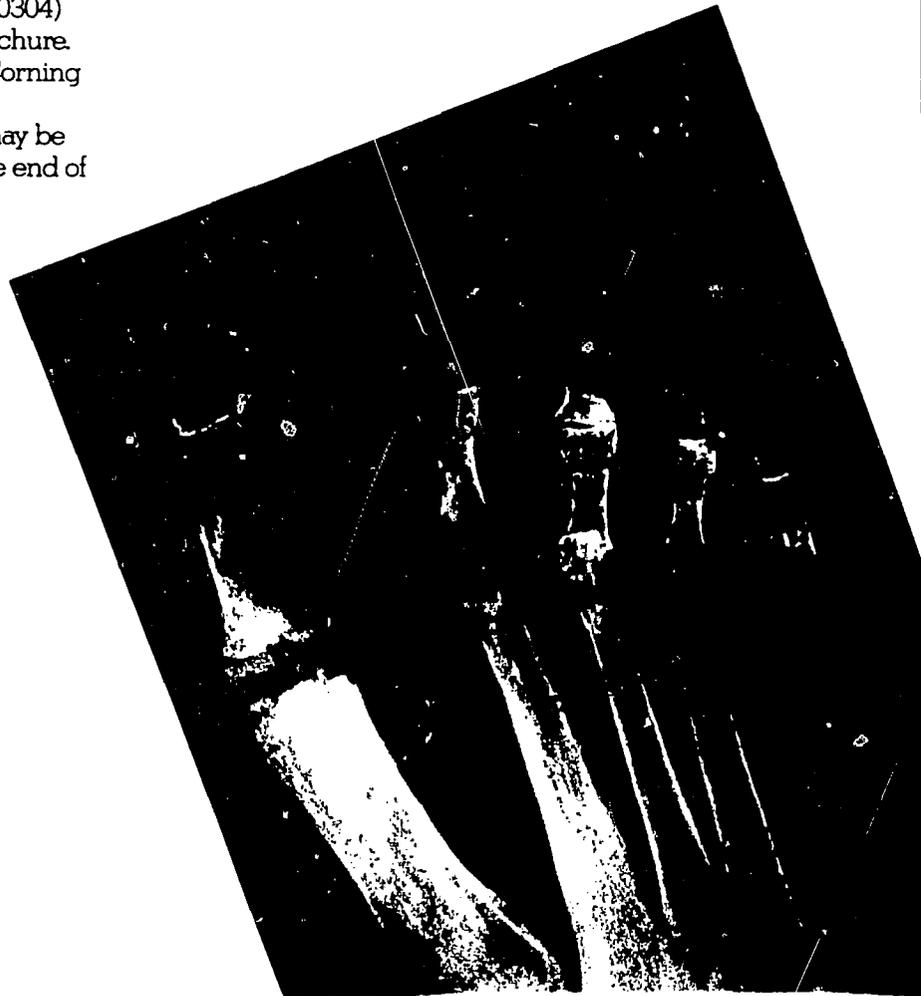
The letters H.P. in the product nomenclature indicate the implant is fabricated from medical-grade high performance silicone elastomer. This elastomer shows greater resistance to tear propagation than conventional silicone elastomer. Its flexural durability and resistance to cut and tear propagation are derived from excellent physical properties: typical tensile strength of 1400 psi (ASTM D412), elongation of 600% (ASTM D412), tear propagation strength of 300 ppi (ASTM D624), and fatigue crack growth of only 0.1 inch per million cycles (ASTM D813). In addition this elastomer has excellent bi durability and biocompatibility.

Dow Corning Wright strongly urges each surgeon to read our booklet SILASTIC® Orthopaedic Implants for the Foot—Surgical Procedures (form no. L083-0304) before using the products illustrated in this brochure. This booklet is available from your local Dow Corning Wright representative.

Footnotes indicated in the following pages may be referenced in the bibliography published at the end of that booklet.

CAUTION:

In some patients, wear particles from silicone elastomer implants used in bone and joint reconstruction may participate in, or exacerbate synovitis or bone cyst complications in contiguous bone. These complications have been reported to occur primarily with scaphoid and lunate replacement implants, and to a lesser degree with trapezium or other articulating implants. Contributing factors have been reported to include the use of implants in young, physically active patients, associated preoperative pathology such as cysts and degenerative changes, intraoperative temporary stabilization with K-wires, and postoperative conditions such as instability and residual or recurrent deformity. Synovitis and bone cyst complications seldom occur with flexible hinge implants such as the finger, wrist, hammertoe, and flexible hinge toe implants.



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SILASTIC® FLEXIBLE HINGE TOE IMPLANT H.P. (SWANSON DESIGN)



*This product now
available in HP 100.
Please refer to the
new data sheet.*

in cases of dislocation and extension contracture of the metatarsophalangeal joint, in cases of bony destruction of one or both joint surfaces as in rheumatoid arthritis, and in cases with dislocation resulting from resection of the base of one or both joint surfaces as in rheumatoid arthritis, and in cases with dislocation resulting from resection of the base of the proximal phalanx, the metatarsal head, or both. The SILASTIC® Flexible Hinge Toe Implant H.P. is made of medical grade high performance silicone elastomer. The design of this implant is based on that of the well proven, load distributing, flexible hinge finger joint implant. The mid-section, however, is thicker and wider to meet the anatomical and physiological requirements of the metatarsophalangeal joint. The proximal (longer) stem of the implant fits into the intramedullary canal of the metatarsal and the distal (shorter) stem into the proximal phalanx. The flexural concavity or open portion of the hinge is placed superiorly or dorsally to allow greater range of dorsiflexion of the toe. The proximal and distal stems have a rectangular cross-section to aid in providing rotational stability in the intramedullary canals.

The SILASTIC® Flexible Hinge Toe Implant H.P. is available in two stem styles, standard and small. Sizes 0 through 7 (standard design) and 0S through 5S (small stem design) will adequately meet most operative requirements in the first metatarsophalangeal joint. Sizes 7-0 through 0 are usually

preferred in the lateral toe joints. In the small stem design, the hinge portion is identical to the standard implant but the stems are proportionately smaller for use in those cases in which less reaming of the intramedullary canal is required to insert an implant. Three separate, nonsterile sizing sets corresponding to sizes 0 through 7 for use in the first toe, sizes 0S through 5S for use in the first toe, and sizes 7-0 through 0 for use in the lateral toes are available for proper size determination during surgery.

SPECIFIC ADVANTAGES OF THE IMPLANT

- Good bone and soft tissue tolerance. Appropriate fibroblastic activity develops around the implant itself.
- Extensive testing has demonstrated high durability. Permanent fixation in the intramedullary canal is not necessary.
- Available in twenty sizes to adequately meet most operative requirements.
- Visible on x-ray evaluation.
- The SILASTIC® Flexible Hinge Toe Implant H.P. has been sterilized.

CLINICAL ADVANTAGES OF THE PROCEDURE

- Improves toe dynamics and helps to relieve pain and maintain stability, mobility, and toe length. The increased flexion power transfer of the toe helps to produce a more normal gait pattern.
- Offers improved stability for maintenance of alignment in reconstruction of the severely deformed metatarsophalangeal joint.
- Acts as a space filler; maintains joint space and allows capsule/ligament reconstruction to correct the deformities.
- Improves cosmetic appearance.
- Facilitates postoperative rehabilitation. Excessive postoperative fixation that could compromise the expected result is not required.

U.S. Patent Nos. 3,462,765 and 3,875,594

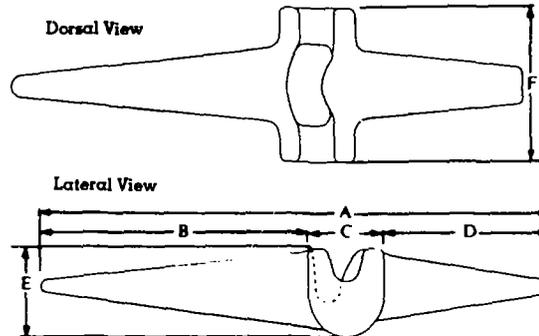
HOW SUPPLIED

The **SILASTIC®** Flexible Hinge Toe Implant H.P. (Swanson Design) has been sterilized and packaged as follows:

REGULAR STEM		
Quantity	Description	Catalog Number
1 box	1 each, size 7-0	1426-0070
1 box	1 each, size 6-0	1426-0060
1 box	1 each, size 5-0	1426-0050
1 box	1 each, size 4-0	1426-0040
1 box	1 each, size 3-0	1426-0030
1 box	1 each, size 2-0	1426-0020
1 box	1 each, size 0	1426-0010
1 box	1 each, size 1	1426-0001
1 box	1 each, size 2	1426-0002
1 box	1 each, size 3	1426-0003
1 box	1 each, size 4	1426-0004
1 box	1 each, size 5	1426-0005
1 box	1 each, size 6	1426-0006
1 box	1 each, size 7	1426-0007
1 sizing set	1 each, sizes 0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0 for Lateral Toes. Numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	1436-0002
1 sizing set	1 each, sizes 0, 1, 2, 3, 4, 5, 6, 7, for the Great Toe. Numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	1436-0001

SMALLER STEM		
Quantity	Description	Catalog Number
1 box	1 each, size 0S	1426-0110
1 box	1 each, size 1S	1426-0101
1 box	1 each, size 2S	1426-0102
1 box	1 each, size 3S	1426-0103
1 box	1 each, size 4S	1426-0104
1 box	1 each, size 5S	1426-0105
1 sizing set	1 each, sizes 0S, 1S, 2S, 3S, 4S, 5S for the Great Toe. Numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	1436-0100

NOTE: Sizes 0 through 7-0 are most often used for the lateral metatarsophalangeal joints and sizes 0S through 5S and 0 through 7 for the Great Toe.



TYPICAL DIMENSIONS

SIZE	A	B	C	D	E	F
7-0	1.105	.560	.155	.390	.185	.334
6-0	1.244	.630	.174	.440	.210	.379
5-0	1.372	.697	.190	.485	.237	.422
4-0	1.507	.765	.207	.535	.265	.465
3-0	1.640	.835	.225	.580	.280	.505
2-0	1.787	.910	.243	.634	.305	.553
0S	1.482	.750	.260	.470	.325	.625
0	1.915	.935	.260	.720	.325	.625
1S	1.584	.824	.285	.487	.350	.652
1	2.055	1.025	.285	.745	.350	.652
2S	1.693	.892	.305	.508	.370	.675
2	2.195	1.115	.305	.775	.370	.675
3S	1.794	.954	.325	.526	.400	.710
3	2.320	1.202	.325	.793	.400	.710
4S	1.906	1.072	.352	.544	.418	.735
4	2.435	1.257	.352	.826	.418	.735
5S	2.017	1.190	.380	.562	.435	.770
5	2.580	1.340	.380	.860	.435	.770
6	2.730	1.420	.395	.915	.455	.800
7	2.867	1.515	.420	.930	.480	.835

All measurements are in inches.

57A

NOT AVAILABLE COPY

SILASTIC® GREAT TOE IMPLANT H.P. (SWANSON DESIGN)



DESCRIPTION

The SILASTIC® Great Toe Implant H.P. (Swanson Design) is a pliable, one-piece, intramedullary-stemmed implant developed to overcome the disadvantages of shortening, occasional instability, or painful stiffening which may follow standard arthroplasty procedures of the great toe.^{2,9,26,30,42,43,51}

The SILASTIC® Great Toe Implant H.P. (Swanson Design) is designed to supplement resection arthroplasty of the first metatarsophalangeal joint. The stem of the implant fits into the intramedullary canal of the proximal phalanx with the implant head replacing the proximal third of the proximal phalanx. It serves to provide a smooth articulating surface for the first metatarsal head, helps restore and maintain motion without loss of stability, and preserves good cosmetic appearance. Biologically and mechanically well tolerated, the implant is surrounded by a fibrous supporting capsule which helps preserve joint space relationship and stability, resulting in early pain-free rehabilitation.³⁹

The SILASTIC® Great Toe Implant H.P. is fabricated from medical-grade high performance silicone elastomer, and is available in five anatomical sizes of regular or smaller stems to adequately meet various operative requirements. Blue sizing sets, supplied non-sterile and not suitable for implantation, are available for proper size determination during surgery.

SPECIFIC ADVANTAGES

- Minimal irritation to bone and surrounding soft tissue.^{3,4,5,36}
- Pliable medical-grade silicone elastomer, (softer than bone) unlikely to cause necrosis or bony resorption.¹⁷
- Extensive testing has demonstrated high durability.
- Fixation in the intramedullary canal is not necessary.
- Available in five sizes of regular or smaller stems to adequately meet the various operative requirements.
- Visible on x-ray evaluation.
- The SILASTIC® Great Toe Implant H.P. has been sterilized.

CLINICAL ADVANTAGES

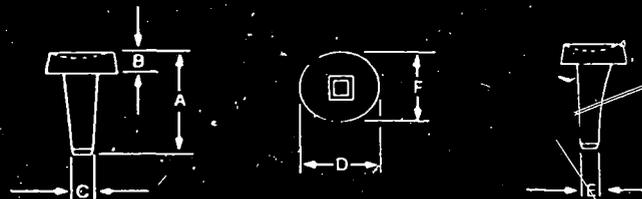
- Improves toe dynamics: provides stability, mobility, pain relief and maintains toe length. The increased flexion power transfer of the great toe assists in normal gait pattern.

- Provides a smooth articular surface for the first metatarsal head.
- Acts as a space filler: maintains joint space and allows capsule/ligament reconstruction to correct the deformities.
- Improves cosmetic appearance.
- Facilitates postoperative rehabilitation. Excessive postoperative fixation that could compromise the range of useful motion is not required.

TYPICAL DIMENSIONS

SIZE	0S	0	1S	1	2S	2	3S	3	4S	4
A	.605 (15.4)	.70 (17.8)	.725 (18.4)	.92 (23.4)	.825 (21.0)	1.02 (25.5)	.855 (21.7)	1.16 (29.5)	.895 (22.7)	1.26 (32.0)
B	.14 (3.6)	.14 (3.6)	.19 (4.8)	.19 (4.8)	.22 (5.6)	.22 (5.6)	.22 (5.6)	.22 (5.6)	.23 (5.8)	.23 (5.8)
C	.136 (3.5)	.17 (4.3)	.146 (3.7)	.21 (5.3)	.156 (4.0)	.22 (5.6)	.166 (4.2)	.22 (5.6)	.176 (4.5)	.22 (5.6)
D	.52 (13.2)	.52 (13.2)	.59 (15.0)	.59 (15.0)	.66 (16.8)	.66 (16.8)	.74 (18.8)	.74 (18.8)	.79 (20.0)	.79 (20.0)
E	.096 (2.4)	.12 (3.0)	.100 (2.5)	.12 (3.0)	.104 (2.6)	.14 (3.6)	.108 (2.7)	.13 (3.3)	.112 (2.8)	.14 (3.6)
F	.44 (11.2)	.44 (11.2)	.52 (13.2)	.52 (13.2)	.57 (14.5)	.57 (14.5)	.63 (16.0)	.63 (16.0)	.68 (17.3)	.68 (17.3)

Dimensions: Inches (Millimeters)



HOW SUPPLIED

The SILASTIC® Great Toe Implant H.P. (Swanson Design) has been sterilized and packaged as follows:

REGULAR STEM		
Quantity	Description	Catalog Number
1 box	1 each, Size 0	2483-0010
1 box	1 each, Size 1	2483-0001
1 box	1 each, Size 2	2483-0002
1 box	1 each, Size 3	2483-0003
1 box	1 each, Size 4	2483-0004
1 sizing set	1 each, 5 sizes, numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	2493-0000

SMALLER STEM		
Quantity	Description	Catalog Number
1 box	1 each, Size 0S	2483-0110
1 box	1 each, Size 1S	2483-0101
1 box	1 each, Size 2S	2483-0102
1 box	1 each, Size 3S	2483-0103
1 box	1 each, Size 4S	2483-0104
1 sizing set (smaller stem)	1 each, 5 sizes, numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	2493-0100

SILASTIC® ANGLED GREAT TOE IMPLANT H.P. (SWANSON DESIGN) WEIL MODIFICATION



DESCRIPTION

The SILASTIC® Angled Great Toe Implant H.P. (Swanson Design) Weil Modification is a pliable, single-stemmed implant designed to replace the base of the proximal phalanx with a smooth, angled, silicone elastomer spacer. This implant was specifically designed for those patients who have angular remodeling of the metatarsal head secondary to hallux valgus.^{1,2,9,25,44,26,27,30,32,39,42,43,45,48,51,53}

The SILASTIC® Angled Great Toe Implant H.P. (Swanson Design) Weil Modification, made of medical-grade high performance silicone elastomer, is designed to supplement resection arthroplasty of the first metatarsophalangeal joint. The stem of the implant fits into the intramedullary canal of the proximal phalanx with the implant head replacing the proximal one-third of the proximal phalanx. The thicker side of the angled implant is placed to the lateral aspect of the metatarsal head to provide improved articulation and stability with the remodeled metatarsal head. This implant provides a smooth articulating surface for the first metatarsal head, helps restore and maintain motion without loss of stability, and preserves a good cosmetic appearance. Biologically and mechanically well tolerated, the implant is surrounded by a fibrous supporting capsule which helps preserve the joint space relationship and can result in early pain-free rehabilitation.^{1,14,26,39,41,44}

The SILASTIC® Angled Great Toe Implant H.P. has been sterilized and is available in three anatomical sizes to adequately meet various operative requirements. A blue sizing set, supplied non-sterile and not suitable for implantation, is available for proper size determination during surgery.

CLINICAL ADVANTAGES

- Improves toe dynamics: The implant provides stability, mobility, pain relief and maintains toe length. The increased flexion power transfer of the great toe assists in normal gait pattern.
- Restores a smooth balanced articulating surface at the base of the proximal phalanx to match the functionally remodeled metatarsal head.

- Acts as a space filler: maintains joint space and allows capsule/ligament reconstruction to correct the deformities.
- Improves cosmetic appearance.
- Facilitates postoperative rehabilitation, since excessive postoperative fixation that could compromise the range of useful motion is not required.

SPECIFIC ADVANTAGES

- Minimal irritation to bone and surrounding soft tissue.
- Articulating surface is angled to fit the remodeled metatarsal head, thus allowing the medial-lateral forces to be balanced.
- Flexible medical-grade silicone elastomer (softer than bone) is unlikely to cause necrosis or bony resorption.³¹
- Available in three sizes to satisfy the operative requirements with most patients.
- Fixation in the intramedullary canal is not necessary.
- Visible on X-ray examination.
- The SILASTIC® Angled Great Toe Implant H.P. has been sterilized.

TYPICAL DIMENSIONS (Inches)

SIZE	A	B	C	D	E	F
1	.585	.516	.150	.467	.242	.165
2	.638	.570	.170	.550	.270	.190
3	.706	.625	.190	.668	.292	.212



HOW SUPPLIED

The SILASTIC® Angled Great Toe Implant H.P. (Swanson Design) Weil Modification has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	1 each size 1	2430 0001
1 box	1 each size 2	2430 0002
1 box	1 each size 3	2430 0003
1 sizing set	1 each sizes 1, 2, 3. Numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	2440 0000

3 58 A

SILASTIC® CONDYLAR IMPLANT H.P. (CONVEX) SWANSON DESIGN



DESCRIPTION

The SILASTIC® Condylar Implant H.P. (Convex) Swanson Design is a flexible one-piece intramedullary-stemmed implant developed to help restore function to smaller joints disabled by rheumatoid arthritis, degenerative arthritis, or posttraumatic arthritis. The implant is designed to replace the convex condylar portion of diseased or destroyed joints as an adjunct to resection arthroplasty. The Condylar Implant H.P. has proven useful for reconstruction of the trapeziometacarpal joint in cases of severe destructive or absorptive changes about the thumb basal joints, as seen in rheumatoid arthritis; for reconstruction of the distal interphalangeal joints of the fingers; and as an adjunct to resection arthroplasty of the metatarsophalangeal joints of the lateral toes, as seen in the Hoffman procedure.

The SILASTIC® Condylar Implant H.P. (Convex) is fabricated from medical-grade high performance silicone elastomer and is available in 13 anatomical sizes. The intramedullary stems are anatomically sized and designed to resist rotation of the implant. The smooth convex articulating surface helps restore and maintain motion and maintain the joint space.

A blue sizing set, supplied non-sterile and not suitable for implantation, is available for proper size determination during surgery.

SPECIFIC ADVANTAGES

- Minimal irritation to bone and surrounding soft tissue.^{3,4,5,36}
- Pliable silicone elastomer (softer than bone) is unlikely to cause tissue necrosis or bony resorption.³⁵
- Fixation in the intramedullary canal is not required.
- Extensive testing has demonstrated high durability.^{46,50}
- The implant is available in 13 sizes to adequately meet

TYPICAL DIMENSIONS (Inches)

SIZE	1	2	3	4	5	6	7	8	9	10	11	12	13
A	.322	.385	.447	.506	.563	.618	.672	.737	.794	.853	.914	.977	1.043
B	.242	.292	.340	.386	.430	.472	.512	.564	.608	.654	.702	.752	.804
C	.174	.213	.252	.291	.330	.369	.408	.447	.486	.525	.564	.603	.642
D	.243	.283	.323	.363	.403	.443	.483	.523	.563	.603	.643	.683	.723

- the various operative requirements.
- Visible on x-ray evaluation.
- The SILASTIC® Condylar Implant H.P. has been sterilized. The blue sizing set is supplied non-sterile.

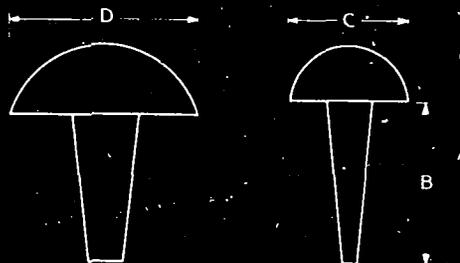
CLINICAL ADVANTAGES

- Acts as a spacer to preserve joint relationship and allow appropriate capsuloligamentous reconstruction to correct deformities.
- Provides improved stability and range of motion and relief of pain.
- Facilitates postoperative rehabilitation, since excessive postoperative fixation that could compromise the range of useful motion is not required.
- Improves cosmetic results.

HOW SUPPLIED

The SILASTIC® Condylar Implant H.P. (Convex) Swanson Design has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	One each, Size 1	2428-0001
1 box	One each, Size 2	2428-0002
1 box	One each, Size 3	2428-0003
1 box	One each, Size 4	2428-0004
1 box	One each, Size 5	2428-0005
1 box	One each, Size 6	2428-0006
1 box	One each, Size 7	2428-0007
1 box	One each, Size 8	2428-0008
1 box	One each, Size 9	2428-0009
1 box	One each, Size 10	2428-0010
1 box	One each, Size 11	2428-0011
1 box	One each, Size 12	2428-0012
1 box	One each, Size 13	2428-0013
1 sizing set	One each, Sizes 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13 Numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION	2438-0000



SILASTIC® HAMMERTOE IMPLANT H.P. (SWANSON TYPE) WEIL DESIGN

DESCRIPTION

The SILASTIC® Hammertoe Implant H.P. (Swanson Type) Weil Design is a double stemmed flexible implant specifically designed for the proximal interphalangeal joint of the lateral toes. It is used as an adjunct to resection arthroplasty in cases of moderate to severe hammer toe deformities of toes 2 through 5.

The SILASTIC® Hammertoe Implant H.P. is made of medical-grade high performance silicone elastomer. It is constructed in a rod shaped design with a thicker mid-section spacer or collar. The implant is symmetrical; therefore, there are no proximal/distal nor lateral/medial designations. Implants are available in 7 sizes with 2 stem sizes, 6 mid-section lengths, and 2 mid-section diameters to adequately satisfy sizing requirements with most patients. Stem and mid-section size should be selected to fit bone. Mid-section diameter should be large enough to adequately maintain cortical bone contact. Mid-section length should be adequate to fill the void formed by resection arthroplasty and thus maintain the desired toe length. During the healing phase, the implant is encapsulated by a functionally oriented fibrous capsule providing stability which can assist in the prevention of the "floppy toe" result, lateral angulation deformities, or recurrence of the original deformity. In addition, the possible complications of arthrodesis (e.g., poor positioning, incomplete fusion, etc.) as well as the postoperative fixation required for arthrodesis are avoided.

The blue sizing set supplied non-sterile and not suitable for implantation is available for proper size determination during surgery. In addition, an instrument set which includes a hand reamer and a hand compactor is available in two sizes from Dow Corning Wright, Arlington, TN, U.S.A. 38002. The reamer is used to drill the medullary canal, while the compactor is used to shape the canal to match the stem of the implant. The size "1" reamer/compactor set should be used with the size 1S, 1, 1L and 1W implants. Similarly the size "2" reamer/compactor should be used with the size 2S, 2 and 2L implants.

CLINICAL ADVANTAGES

- Provides stability, pain relief, and maintains toe length and alignment.
- Acts as a space filler and maintains joint space; also

allows capsule/ligament reconstruction to correct deformities.

- Improves cosmetic appearance.
- Facilitates rehabilitation. Excessive postoperative fixation that could compromise the expected result is not required.
- Toe purchase can be achieved due to flexibility of the implant.

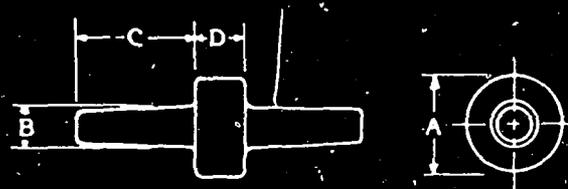
SPECIFIC ADVANTAGES

- Minimal irritation to bone and surrounding soft tissue.
- Pliable medical-grade silicone elastomer (softer than bone) unlikely to cause necrosis or bone resorption.
- Extensive testing has demonstrated high durability.
- Fixation in the intramedullary canal is not necessary.
- Available in seven sizes to adequately meet most operative requirements.
- Visible on X-ray evaluation.
- The SILASTIC® Hammertoe Implant H.P. has been sterilized.

HOW SUPPLIED

The SILASTIC® Hammertoe Implant H.P. (Swanson Type) Weil Design has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	One each, size 1S	1431-0009
1 box	One each, size 1	1431-0010
1 box	One each, size 1L	1431-0011
1 box	One each, size 1W	1431-0012
1 box	One each, size 2S	1431-0019
1 box	One each, size 2	1431-0020
1 box	One each, size 2L	1431-0021
1 sizing set	One each, sizes 1S, 1, 1L, 1W, 2S, 2, 2L, Numerically marked, color blue (non-sterile)	1441-0000
NOT FOR IMPLANTATION		



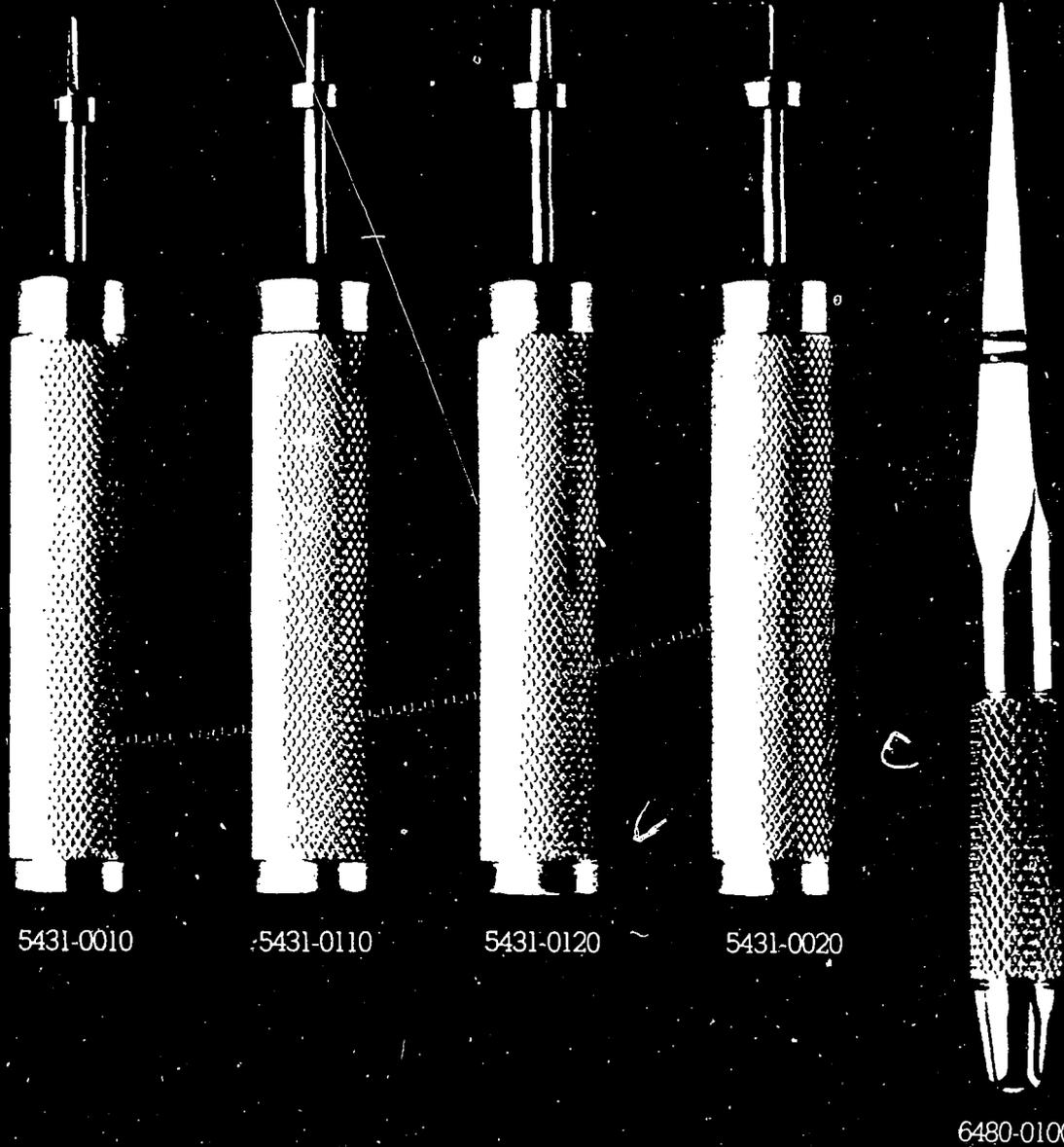
TYPICAL DIMENSIONS

SIZE	A	B	C	D
1S	.25 (6.4)	.10 (2.5)	.36 (9.1)	.078 (2.0)
1	.25 (6.4)	.10 (2.5)	.36 (9.1)	.13 (3.3)
1L	.25 (6.4)	.10 (2.5)	.33 (8.4)	.18 (4.6)
1W	.30 (7.6)	.10 (2.5)	.36 (9.1)	.15 (3.8)
2S	.30 (7.6)	.12 (3.0)	.36 (9.1)	.09 (2.3)
2	.30 (7.6)	.12 (3.0)	.36 (9.1)	.15 (3.8)
2L	.30 (7.6)	.12 (3.0)	.33 (8.4)	.21 (5.3)

Dimensions: Inches (Millimeters)

59A

**INSTRUMENTATION
(NON-STERILE)**



INSTRUMENTATION (NON-STERILE)

Quantity	Description	Catalog Number
1 reamer	One each, size 1 for size 1S,1,1L,W implant	5431-0010
1 compactor	One each, size 1 for size 1S,1,1L,1W implant	5431-0110
1 reamer	One each, size 2 for size 2S,2,2L implant	5431-0020
1 compactor	One each, size 2 for size 2S,2,2L implant	5431-0120
1 broach	One each, intramedullary broach, small	6480-0100

DOW CORNING
DOW CORNING **WRIGHT**

60A

DOW CORNING

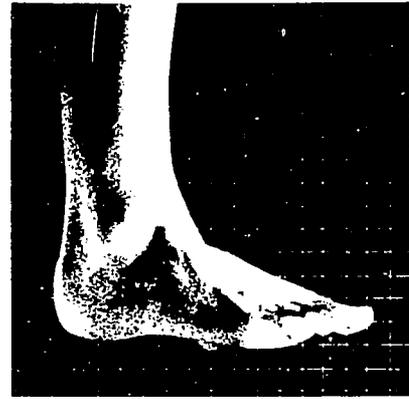
DOW CORNING



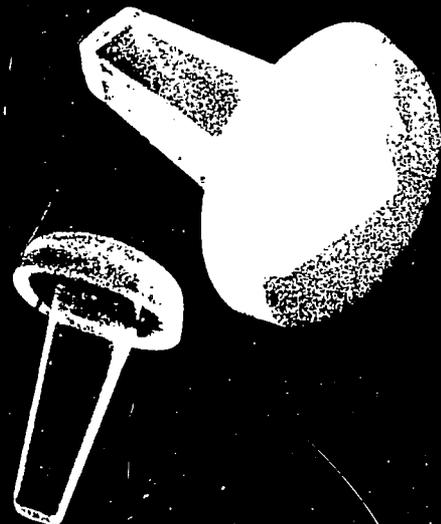
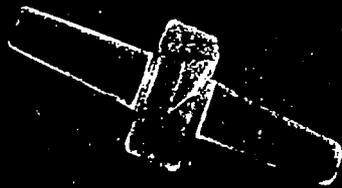
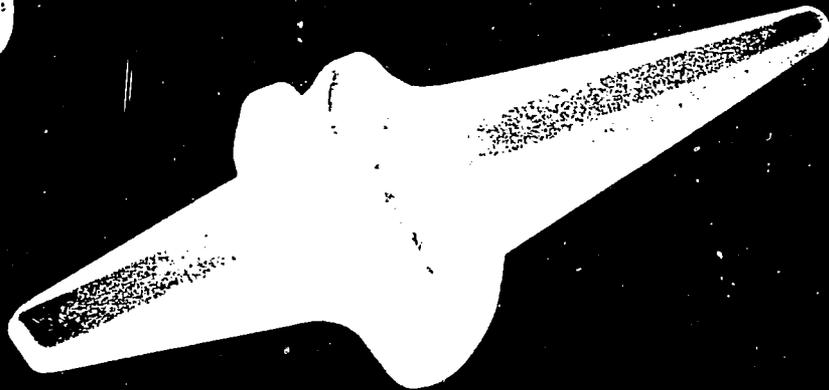
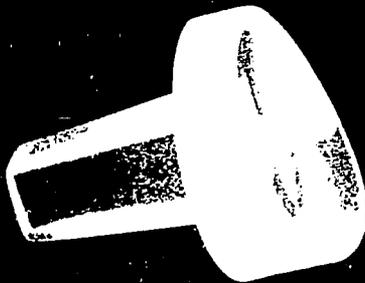
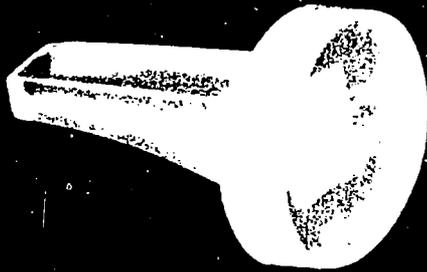
WRIGHT

5677 Airline Rd. Arlington, TN 38002
901-867-9971

SILASTIC[®] ORTHOPAEDIC IMPLANTS H.P.



**FOR THE FOOT
SURGICAL PROCEDURES**



SILASTIC®

This registered trademark is the brand name for Dow Corning's silicone elastomer products, materials and related products. Only Dow Corning may identify its products with the trademark SILASTIC.® The word is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's material. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

High Performance Silicone Elastomer

The letters H.P. in the product nomenclature indicate the implant is fabricated from medical-grade high performance silicone elastomer. This elastomer shows greater resistance to tear propagation than conventional silicone elastomer. Its flexural durability and resistance to cut and tear propagation are derived from excellent physical properties: typical tensile strength of 1400 psi (ASTM D412) elongation of 600% (ASTM D412), tear propagation strength of 300 pli (ASTM D624), and fatigue crack growth of only 0.1 inch per million cycles (ASTM D813). In addition this elastomer has excellent bi durability and biocompatibility.

Caution:

In some patients, wear particles from silicone elastomer implants used in bone and joint reconstruction may participate in, or exacerbate synovitis or bone cyst complications in contiguous bone. These complications have been reported to occur primarily with scaphoid and lunate replacement implants, and to a lesser degree with trapezium or other articulating implants. Contributing factors have been reported to include the use of implants in young, physically active patients, associated preoperative pathology such as cysts and degenerative changes, intraoperative temporary stabilization with K-wires, and postoperative conditions such as instability and residual or recurrent deformity. Synovitis and bone cyst complications seldom occur with flexible hinge implants such as the finger, wrist, hammertoe, and flexible hinge toe implants.

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Form No. L083-0304 Rev. 8/85

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SILASTIC® Flexible Hinge Toe Implant H.P. Swanson Design

†U.S. Patent Nos. 3,462,765 and 3,875,594.

This product now available in HP 100. Please refer to the new data sheet.

Clinical Indications

The use of the SILASTIC® Flexible Hinge Toe Implant H.P. is recommended in the following situations, (Figures 1A, 1B, 9A, 9B):

- (1). In cases of rheumatoid arthritis presenting a moderate to severe hallux valgus deformity, lateral toes involvement, radiographic evidence of erosion, cyst formation and narrowing of the first metatarsophalangeal joint and contractural deformities.
- (2). In cases of severe senile hallux valgus deformity, care must be taken to preserve part of the head to prevent shift of the weight bearing to the second toe.
- (3). For revision of previous procedures when there is evidence of bony destruction involving both sides of the joint.
- (4). In cases of rheumatoid arthritis of the lateral toes presenting a moderate to severe dorsal dislocation of the proximal phalanx with an accompanying extension contracture, radiographic evidence of erosion, cyst formation, and narrowing of the metatarsophalangeal joint.
- (5). In cases presenting unstable or painfully stiff metatarsophalangeal joints with associated unstable, stiff, or painful distal joints.

Contraindications

- Physiologically or psychologically inadequate patient.
- Inadequate skin, bone and/or neurovascular status.
- Irreparable tendon system.
- Presence of infection.

Instructions For Use

Surgical Procedures

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Alfred B. Swanson. Each surgeon must evaluate the appropriateness of the procedure based on his or her own medical training and experience.*

*A. B. Swanson, M.D., FACS, Chief Orthopaedic Training Program
Blodgett-Butterworth Hospitals, Chief, Orthopaedic Research
Blodgett Memorial Medical Center, Grand Rapids Clinical Professor
Surgery, Michigan State University



Fig. 1A: This radiograph shows the foot of a 64-year-old active man who has a painful, disabling arthritic hallux valgus and severe hammer toe deformities of the second and third toes.



Fig. 1B: This radiograph shows postoperative condition at one year following resection arthroplasty with the double-stemmed flexible hinge toe implant. The patient also had resection arthroplasty for the second and third toes. He has a pain free, mobile and stable arthroplasty which has an excellent functional and cosmetic result. The patient is an avid golfer who walks 18 holes 5 out to five times a week without symptoms.

First Metatarsophalangeal Joint Implant Arthroplasty Incision and Exposure

The joint is exposed through a slightly curved, longitudinal incision made over the dorsomedial aspect of the first metatarsophalangeal joint (Fig. 2). Additional longitudinal incisions are used when resection of the heads of the lateral toes is indicated as frequently needed in a rheumatoid foot. A great toe implant arthroplasty is then carried out at the same time as a

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1

typical Hoffman or Clayton procedure on the lateral toes. Care must be taken to avoid injury to the small dorsal sensory nerves and veins in the area. The fascia and medial capsule of the joint are dissected and incised in such a fashion as to prepare a distally based flap on the proximal phalanx for later closure and correction of the deviation deformity. If the anatomical attachments appear weakened these can be reinforced with a suture through the bone. If a bursa is present, it is resected and the metatarsophalangeal joint is entered.

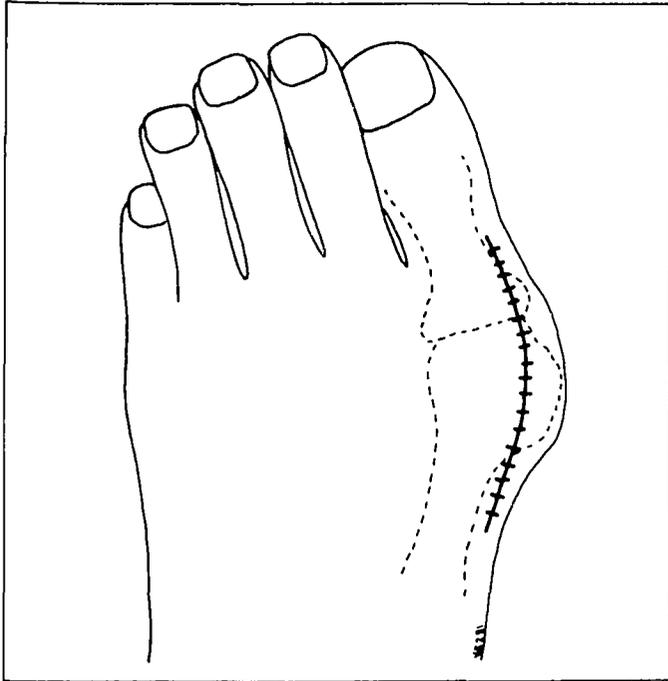


Fig. 2: A dorsomedial approach through a slightly curved longitudinal incision along the medial aspect of the metatarsophalangeal joint is used when only surgery of the great toe is indicated.

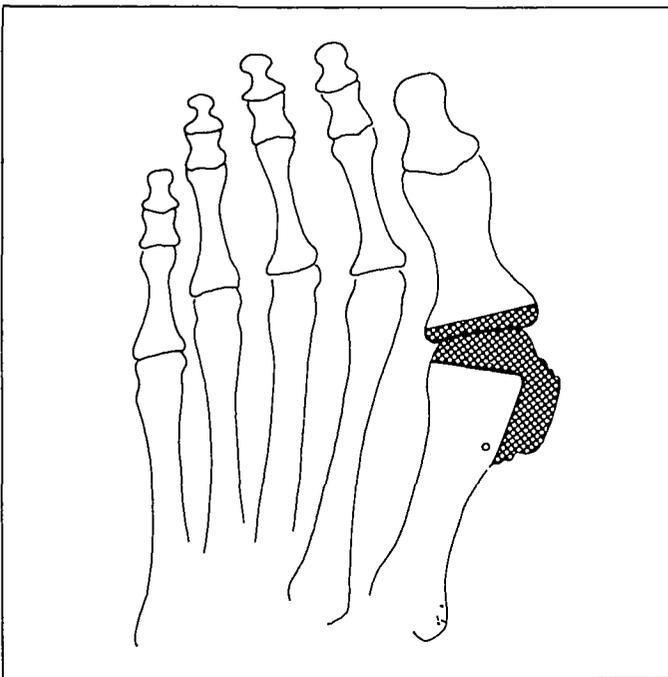


Fig. 3: The metatarsal head is excised distal to the metaphyseal flare at the largest diameter of the head with a 10 degree valgus angle. The base of the proximal phalanx may be removed to provide a wider joint space.

Bone Preparation

The head of the first metatarsal is excised distal to the metaphyseal flare at the largest diameter of the metatarsal head (Fig. 3). A sagittal saw or other power equipment is used to resect this portion of the head in 10 degrees valgus to conform to normal valgus. This way the implant will not be pinched by the lateral bone edge. The intramedullary canal is shaped to accept the implant. An air drill, broach, curette, or rasp may be used. A portion of the base of the proximal phalanx is removed to provide a wider joint space. All bone edges which contact the implant are left smooth. Two 1mm drill holes are made in the medial portion of the metatarsal and proximal phalanx neck and 2-0 Dacron suture with PR-4 needle is passed through the hole in preparation for capsular closure (Fig. 4).

Note: A non-sterile set of blue sizing units in either the standard or small stem design is available to assist in size determination during surgery.

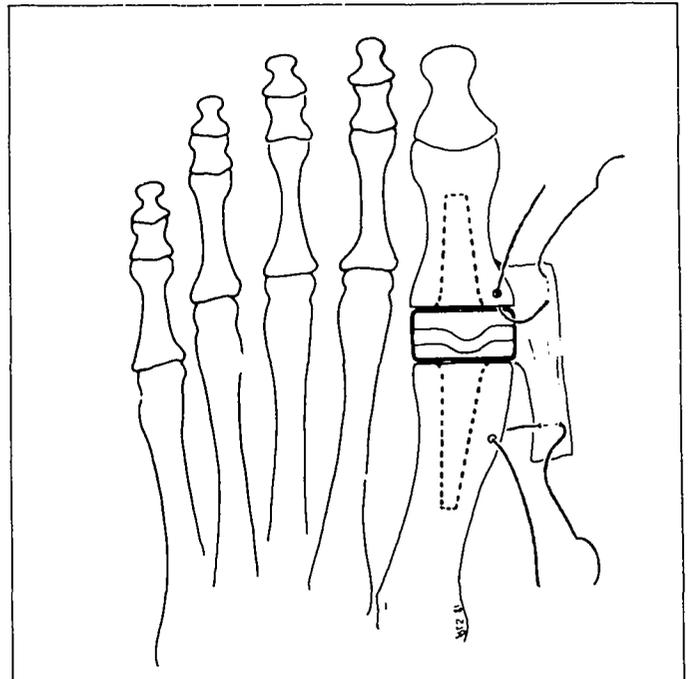


Fig. 4: A distally based flap on the proximal phalanx is prepared from the fascia and medial capsule of the joint. It is later sutured with a 2-0 Dacron suture with PR-4 needle to the medial portion of the metatarsal neck and proximal phalanx through a 1 mm drill hole. Firm reattachment to bone of a loose medial capsule either proximally or distally is of absolute importance for correction of valgus deformity.

Implant Insertion

The proximal (longer) stem of the implant is inserted in the intramedullary canal of the first metatarsal with the open portion of the hinge positioned dorsally. The toe is then flexed and the distal (shorter) stem is inserted into the proximal phalanx. The proper size implant is determined by the width of the remaining metatarsal head and the size of the intramedullary canal. The distal stem may be shortened if it abuts the distal end of the intramedullary canal of the proximal phalanx. Avoid other reshaping of the implant.

Tissue Release and Associated Procedures

The surgical details of the procedure and attention to the complete release of contractures, realignment of the toe and correction of the deformities of the lateral toes are of great importance to obtain the desired results. The extensor hallucis longus is now lengthened in cases that present a moderate to severe valgus angle and/or claw toe deformity. The adductor tendon, the lateral

capsule and the short extensor tendon should also be released. If cut, care must be taken to reattach the short flexor to the medial inferior aspect of the cut proximal phalanx through a drill hole to obtain flexion of the metatarsophalangeal joint. In milder cases of claw toe deformity, the interphalangeal joint should be pinned with a Kirschner wire for 3 to 4 weeks. In cases of moderate to severe claw deformity or pronation deformity, the interphalangeal joint may require fusion. In cases of severe hallux valgus deformity, the correct alignment can be maintained in the early postoperative period by placing a .045" Kirschner wire across the toe ray in the intramedullary canals dorsal to the implant. With the implant in position, the wire is inserted in a retrograde fashion first through the intramedullary canals of the proximal and distal phalanges and then through the first metatarsal. The end of the wire extrudes 1 cm from the toe and is removed after 10 days.

Tissue Reefing and Closure

With the toe held in proper alignment, including rotation, the medial fascial-capsular flap is firmly sutured to a drill hole in the metatarsal neck by means of 2-0 Dacron suture and a buried knot technique. The aponeurosis of the long extensor tendon, which may be released on its lateral aspect, is sutured to the medial capsule with 4-0 Dacron sutures and a buried knot technique.

The cutaneous incision is closed and a SILASTIC® Incision Drain H.P. placed in the wound. A voluminous conforming dressing is applied to the foot. Dressings are placed between the toes, great care being taken not to place them deeply into the webs to avoid embarrassing the circulation postoperatively. Cotton or Dacron batting is used for padding. A longitudinal splint such as a tongue blade, may be incorporated in the medial aspect of the dressing to support the toe in position. A posterior molded plaster splint and a conforming bandage such as a Kling are then applied. The foot is elevated with the patient at bed rest for 2 to 5 days to decrease postoperative swelling.

Postoperative Care

After 3 to 5 days the initial dressing is removed and a dynamic splint** is applied to maintain the alignment of the toe while allowing early and active flexion-extension exercises (Fig. 5). An exercise program is prescribed. The dynamic splint is either attached to a cast, or a removable type splint may be used. It is worn continuously for 3 to 4 weeks and then used as a night splint for approximately 3 to 6 weeks. The patient may walk on his heel or on a wooden-soled shoe in a week. The use of a 1/2 inch thick foam rubber inner sole extending to the distal metatarsal level is important to allow flexion exercises. Exercises over a step or other solid objects are prescribed to encourage flexion. Guarded weight bearing is encouraged 3 weeks post operatively. Appropriate nonconstrictive shoe wear is prescribed. It is also important to avoid extraneous movements of pins extending through the skin against the shoe on walking.

Lateral Metatarsophalangeal Joint Implant Arthroplasty Incision and Exposure

Flexible implant arthroplasty of the lateral metatarsophalangeal joints can be carried out at the same time as the reconstruction of the great toe. The metatarsal heads are exposed through separate longitudinal incisions over the dorsal

**Pope Brace Co., P.O. Box 368, Greenwood, South Carolina 29648.



Fig. 5: Appearance of the dynamic toe splint worn with the wooden-soled shoe. The shoe is fitted with a 1/2 inch thick foam rubber inner sole extending to the distal metatarsal level to allow flexion exercises.

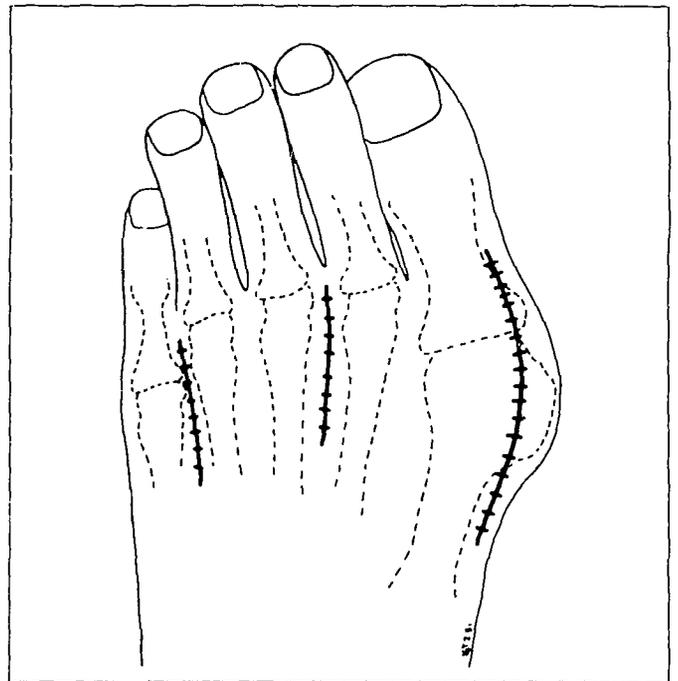


Fig. 6: The metatarsal heads are exposed through separate longitudinal incisions over the dorsal aspect of the metatarsophalangeal joint.

aspect of the metatarsophalangeal joint (Fig. 6). Care must be taken to avoid injury to the small dorsal sensory nerves and veins in this area. Appropriate extensor tendon release is performed and the dorsal capsule is incised.

Bone Preparation

The head of the metatarsal is resected at the metaphyseal flare with sagittal saw or other power equipment to obtain a smooth transverse osteotomy (Fig. 7). The intramedullary canal of the metatarsal is prepared to receive the implant stem, using a hand broach or the air drill with a small leader point burr to avoid per-

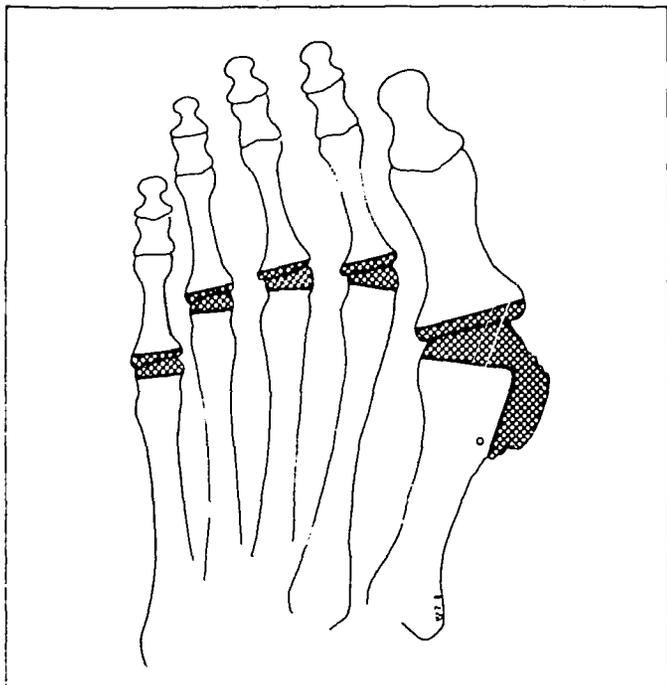


Fig. 7: The head of the metatarsal is resected at the metaphyseal flare



Fig. 9A: Right foot preoperative radiograph of 61 year old rheumatoid arthritis patient shows severe hallux valgus deformity with erosive arthritic changes at metatarsophalangeal joint. The lateral toes show dislocation of metatarsophalangeal joints with reasonably adequate bone stock.

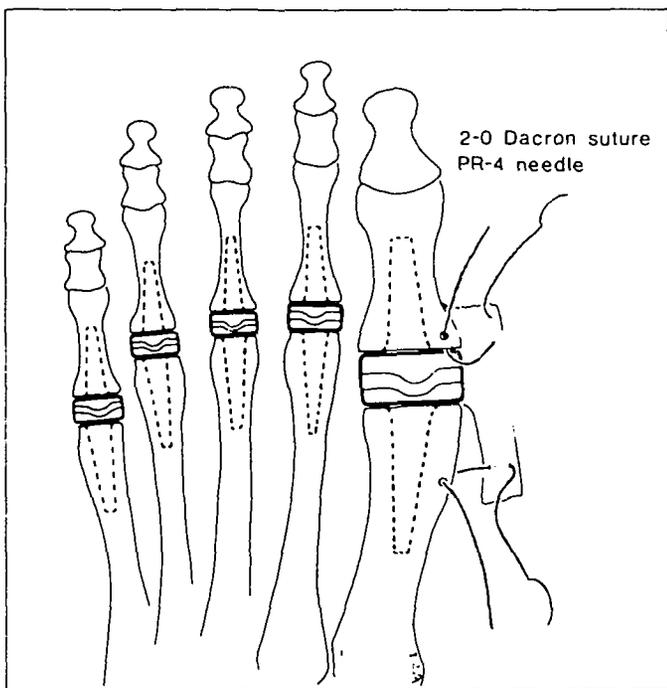


Fig. 8: The appropriate size implant is selected to obtain a snug fit of the stems in the intramedullary canals and to maintain the appropriate joint space. Firm re-attachment to bone of a loose medial capsule either proximally or distally is of absolute importance for correction of valgus deformity.



Fig. 9B: Postoperative radiograph shows correction of deformities of the great toe and the lateral toes following flexible hinged (silicone) implant resection arthroplasty.

rotation of the canal wall. A portion of the base of the proximal phalanx is removed to provide a wider joint space. The amount of bone removed is dependent upon the degree of contracture preoperatively. All bone edges which contact the implant are left smooth. The appropriate size implant is selected to obtain a snug fit of the stems in the intramedullary canals and to maintain the appropriate joint space (Fig. 8).

NOTE: A non-sterile set of sizing units is available to assist in size determination during surgery.

Implant Insertion

The wound is irrigated with saline to remove debris and bony fragments. As in the first metatarsophalangeal joint, the proximal (longer) stem of the implant is inserted into the intramedullary canal of the metatarsal; with the open portion of the hinge positioned dorsally; the toe is then flexed and the distal (shorter) stem is inserted into the proximal phalanx. The

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stems of the implant may be shortened, however this is usually not necessary. Other reshaping of the implant should be avoided.

Associated Procedures and Closing

In patients who present severe claw toe deformities and soft tissue contractures, the toe ray must be temporarily pinned in the corrected position. With the implant in position, a .045" Kirschner wire is inserted in a retrograde fashion first through the intramedullary canals of the proximal and distal phalanges and through the tip of the toe. The wire is then driven back across the top of the implant into the metatarsal canal. The end of the wire extrudes 1cm from the toe end.

The skin incisions are closed with interrupted 5-0 nylon sutures and SILASTIC® Incision Drains H.P. are inserted subcutaneously. A voluminous, conforming foot dressing is applied and the foot is maintained in an elevated position in

the post operative course. The wires which have been left extruding from the tip of the toe are removed in about 10 days; no weight bearing walking is allowed while the wires are in position. The usual postoperative regimen is then instituted for these patients. Exercises over a step or other solid objects are prescribed to encourage flexion. Guarded weight bearing is encouraged three weeks post operatively in appropriate non-constrictive shoe wear.

Important Points to Observe

1. Using the blue sizing set as a guide, select the largest implant that the bone can accommodate, at the same time being very careful that the implant is well seated.
2. Rinse the implant thoroughly with saline solution before insertion.
3. Blunt instruments should be used with a "no touch technique" when inserting SILASTIC® Flexible Hinge Toe implants H.P. to avoid traumatization of the implant and contamination by foreign bodies.
4. Shortening of the end of the stems is permissible, however, reshaping of the implant should be avoided because modification might create structural weakness.

SILASTIC® Hammertoe Implant H.P. Swanson Type Weil Design

General Indications

Any joint implant reconstruction requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive the implant
- Availability of postoperative therapy
- Cooperative patient

Clinical Indications

The use of the SILASTIC® Hammertoe Implant H.P. is recommended in the following situations:

- 1) Semi-rigid or rigid hammertoe deformity associated with degenerative arthritis.
- 2) Semi-rigid or rigid hammertoe deformity associated with rheumatoid arthritis.
- 3) Revision of a failed arthroplasty or arthrodesis.

Contraindications

- Recent fracture in the involved hammertoe
- Inadequate circulatory status of the forefoot and digits
- Physiologically or psychologically inadequate patients
- Inadequate skin, bone, and/or neurovascular status
- Presence of infection

Instructions For Use Surgical Procedure

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Lowell Scott Weil. Each surgeon must evaluate the appropriateness of the procedure based on his or her own medical training and experience.

Incision and Exposure

Surgery may be performed under local anesthesia utilizing a digital block at the base of the involved digit. A total of 2cc of lidocaine hydrochloride 2% is sufficient to give adequate anesthesia. Two semi-elliptical incisions are made over the proximal interphalangeal joint of the hammertoe. The width of the semi-elliptical tissue removed corresponds to the severity of the hammertoe; the greater the deformity, the more tissue removed. The incision is carried to the extensor apparatus. Careful preservation of vascular supply is undertaken. The wedge of tissue is then excised in total. The joint capsule is opened by a transverse incision made over the dorsal aspect of the head of the proximal phalanx. The extensor tendon and apparatus is then dissected free from the head and shaft of the proximal phalanx, approximately 1cm. The collateral ligaments of the proximal interphalangeal joint are then severed exposing the head of the proximal phalanx.

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SILASTIC® Condylar Implant H.P. (Convex) Swanson Design

Indications

General Indications

Any joint implant arthroplasty requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- An adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive and support the implant
- Availability of postoperative therapy
- A cooperative patient

Clinical Indications

Lesser Metatarsophalangeal Joint Implant Arthroplasty

- a. Unstable or painfully stiff MTP joint
- b. X-ray evidence of joint destruction or subluxation
- c. In rheumatoid arthritis, as an adjunct to the Hoffman procedure
- d. Associated unstable, stiff, or painful distal joints

Contraindications

1. Physiologically or psychologically inadequate patient
2. Inadequate skin, bone, and/or neurovascular status
3. Irreparable tendon system
4. Presence of infection

Instructions For Use

Surgical Procedure

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Alfred B. Swanson. Each surgeon must evaluate the appropriateness of the procedure based on his or her own medical training and experience.

Lesser Metatarsophalangeal Joint Implant Arthroplasty

Rationale:

Small convex condylar implants may be used to resurface the amputated ends of the lesser metatarsals following resection arthroplasty as seen in the Hoffman procedure for the rheumatoid foot.¹⁸ This method helps maintain the length and shape of the amputated bone end and helps prevent the severe bone remodeling phenomena sometimes seen in these cases. The use of these implants can improve the results of resection arthroplasty of the lateral toes.



Pre-op: Dislocation of the metatarsal phalangeal joints of the lateral toes on a 63 year old woman

Post-op: Resection arthroplasty of the metatarsal phalangeal joints of toes 2, 3 and 4 using convex condylar implants. Two year follow up on patient shows a pain free mobile arthroplasty and good bone tolerance

Technique:

This procedure can be carried out at the same time as the reconstruction of the great toe. The metatarsal heads are exposed through separate longitudinal incisions; after appropriate release of the extensor tendons and the dorsal capsule, the metatarsal head is resected at the metaphyseal flare with a sagittal saw or other power equipment to obtain a smooth transverse osteotomy. The intramedullary canals of the metatarsals are prepared to receive the implant stem, using a hand broach or the air drill with a smooth leader point burr to avoid perforation of the lateral cortical wall. The appropriate size implant is selected from the 13 available sizes to obtain a snug fit of the stem in the intramedullary canal. After irrigation of the wound with saline to remove all debris and bony fragments, the implants are inserted.

In patients who present severe claw toe deformities and soft tissue contractures, the toe ray must be temporarily pinned in the corrected position. A .045 Kirschner wire is introduced in a retrograde fashion first through the base of the proximal phalanx and through the tip of the toe; it is then driven back through the center of the implant into the metatarsal intramedullary canal; great care must be taken to avoid lacerating the implant; this can be done by exposing 5 mm. of wire at the end of the proximal phalanx and then manually skewering the implant over the wire; the wire can then be easily driven in the intramedullary canal with the implant in position.

The skin incisions are closed with interrupted 5-0 Nylon sutures and SILASTIC® Incision Drains H.P. are inserted subcutaneously. A voluminous conforming foot dressing is applied, and the foot is maintained in an elevated position in the post-operative course. The wires which have been left extruding approximately 1 cm. from the tip of the toe are removed in about 10 days; no weight-bearing walking is allowed while the wires are in position. The usual postoperative regimen is then instituted for these patients.

Important Points to Observe

1. Using the sizing set as a guide, select the largest implant that the bone can accommodate, at the same time being very careful that the implant is well seated.
2. Rinse the implant thoroughly with saline solution before insertion.
3. Handle the implant with a blunt instrument to avoid traumatization of the implant and contamination by foreign bodies.
4. Shortening the end of the stem is permissible, although reshaping of the implant should be avoided because modification might create structural weakness.

SILASTIC® Great Toe Implant H.P. Swanson Design

General Indications

Any joint implant arthroplasty requires consideration of the following general indications:

- Good condition of the patient.
- A good neurovascular status.
- An adequate skin coverage.
- The possibility of a functional musculotendinous system.
- Adequate bone stock to receive implant.
- Availability of postoperative therapy.
- A cooperative patient.

Clinical Indications

Use of the SILASTIC® Great Toe Implant H.P. may be considered for the following clinical conditions:

1. Hallux valgus (Figure 1A and B): mild to moderate only.
2. Hallux rigidus.
3. Unstable or painfully stiff MP joint following Keller-type bunionectomy (Figure 2A and B).

NOTE: For severe hallux valgus as seen in rheumatoid arthritis or in the senile bunion or following a failed Mayo-type resection, the double-stemmed Silastic® Flexible Hinge Toe Implant H.P. (Swanson Design) is recommended.

Contraindications

- Physiologically or psychologically inadequate patient.
- Inadequate skin, bone and/or neurovascular status.
- Irreparable tendon system.

Instructions For Use Surgical Procedure

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Alfred B. Swanson. Each surgeon must evaluate the appropriateness of the procedure based on his or her own medical training and experience.



Fig. 1A: Shows a hallux valgus deformity with disabling pain in the metatarsophalangeal joint.



Fig. 1B: Post-operative roentgenogram: The implant is well tolerated by the bone and soft tissue. This patient has a pain free toe with good functional and cosmetic result.



Fig. 2A: Pre-operative roentgenogram shows rheumatoid arthritic foot with painful pseudoarthrosis following resection arthroplasty of great toe and dislocation of MP joints in 2, 3, 4, 5 toes.



Fig. 2B: Post-operative roentgenogram shows MP of great toe with implant. Heads of metatarsals 2, 3, 4, 5 have been resected. The patient has a pain free, functional foot.

Incision and Exposure

A slightly curved longitudinal skin incision is made along the dorsomedial aspect of the metatarsophalangeal joint (Figure 3A). Care must be taken to avoid injury to the small dorsal sensory nerves and veins in the area. The fascia and the medial capsule are dissected making a proximally-based medial fascial capsular flap. This flap is reflected for later resuture. If a bursa is present, it is excised and the metatarsophalangeal joint opened.

Bone Preparation

The proximal third of the basal phalanx is carefully resected with drill holes and an osteotome, or with air drill or motor saw (Figure 3B). The exostoses of the metatarsal head are removed on both lateral and plantar surfaces so that a smooth rounded metatarsal head is presented. The head of the metatarsal may be reshaped but not shortened if it is too rough or too long to allow correction of the deformity. Its surface should be carefully smoothed with a rongeur or bur and air drill. The sesamoid bones are rarely excised. Using a drill, broach or curette, the canal of the proximal phalanx is shaped to accept the implant stem.

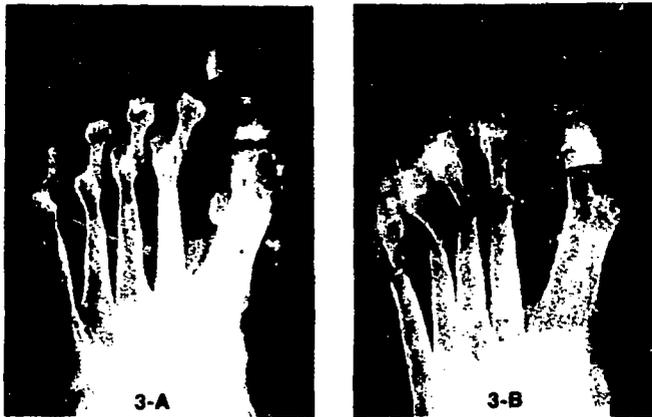


Fig. 3A: A dorso-medial approach through a slightly curved longitudinal incision along the medial aspect of the metatarsophalangeal joint is used when only surgery of the great toe is indicated.

Fig. 3B: The proximal third of the basal phalanx is resected, exostoses on lateral and plantar surfaces are removed presenting a smoothed, rounded metatarsal head. Using curette, broach or drill, the proximal phalangeal canal is shaped to accept the implant stem.

Implant Insertion

The implant stem should fit snugly into the canal with the collar of the implant fitting firmly against the proximal cut surface of the phalanx. The curved portion of the stem should be placed plantarward (Figure 4). Proper implant choice from the five available sizes will assure correct fit. The stem of the implant may be cut to appropriate length. No trimming should be done elsewhere on the implant. The toe should then be easily brought over into the corrected position. The implant should be handled with blunt instruments to avoid traumatizing its surface or contamination with foreign bodies.

NOTE: A reusable sizing set containing one of each size implant is available to assist proper size determination. Numerically marked and blue in color for easy identification, the sizing set is supplied non-sterile and is not suitable for implantation. For use, follow instructions under section, "Sterilization."

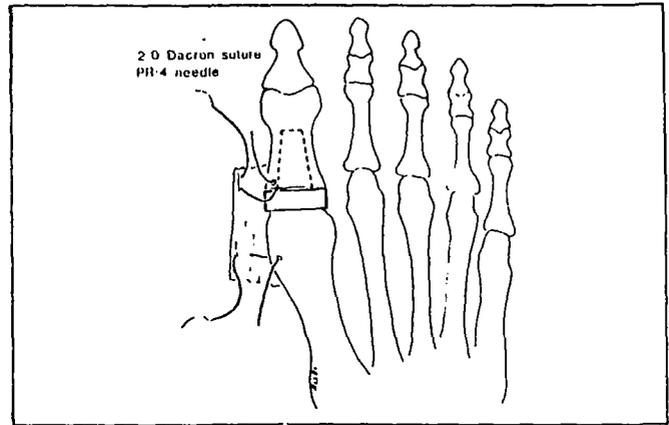


Fig 4: Implant stem should fit snugly in the canal with collar of implant fitting firmly against cut proximal surface of phalanx. The curved portion of the stem should be placed plantarward. Firm reattachment to bone of a loose medial capsule either proximally or distally is of absolute importance for correction of valgus deformity.

Soft Tissue Release, Reefing and Closure

Further release of the lateral capsule, adductor muscle attachments or rerouting or lengthening of the long extensor may be indicated. The usual practice is to cut the short extensor tendon and lengthen the long extensor tendon distal to the metatarsophalangeal joint in a manner similar to a Z-plasty. There should be a good and unrestricted range of motion of the toe before closure. With the toe in the correct position, the medial fascial-capsular flap is firmly sutured to the bone through small drill holes. A 3-0 Dacron suture is passed through the hole in the base of the proximal phalanx. Using buried knot technique, the capsule is held to the medial aspect of the proximal phalanx in the corrected position. The aponeurosis of the long extensor tendon which may have been released on its lateral aspect is sutured medially to the medial capsule using 4-0 Dacron sutures with a buried knot technique. The skin is closed and a small SILASTIC® Incision Drain is placed in the wound. A voluminous conforming dressing is applied to the foot including a simple longitudinal splint to support the toe in position.

Postoperative Care

After 3 to 15 days the initial dressing is removed and a dynamic splint* is applied to maintain the alignment of the toe while allowing early and active flexion-extension exercises (Fig. 5). An exercise program is prescribed. The dynamic splint is either attached to a cast, or a removable type splint may be used.

It is worn continuously for 3 to 4 weeks and then used as a night splint for approximately 3 to 6 weeks. The patient may walk on his heel or on a wooden-soled shoe in a week. The use of a 1/2 inch thick foam rubber inner sole extending to the distal metatarsal level is important to allow flexion exercises. Exercises over a step or other solid objects are prescribed to encourage flexion. Guarded weight bearing is encouraged 3 weeks post operatively. Appropriate nonconstrictive shoe wear is prescribed. It is also important to avoid extraneous movements of pins extending through the skin against the shoe on walking.

*Pope Brace Co., P.O. Box 368, Greenwood, South Carolina 29648



Fig. 5: Appearance of the dynamic toe splint worn with the wooden-soled shoe. The shoe is fitted with a 1/2 inch-thick foam rubber inner sole extending to the distal metatarsal level to allow flexion exercises.

Important Points To Observe

1. Using the blue sizing set as a guide, select the largest implant that the bone can accommodate, at the same time being very careful that the implant is well seated.
2. Rinse the implant thoroughly with saline solution before insertion.
3. Handle the implant with a blunt instrument to avoid traumatization of the implant and contamination by other foreign bodies.
4. Shortening the end of the stem is permissible, although reshaping of the implant should be avoided because modification might create structural weakness.

SILASTIC® Angled Great Toe Implant H.P. Swanson Design Weil Modification

General Indications

Implant resection arthroplasty requires consideration of the following general indications:

- Good condition of the patient
- A good neurovascular status
- Adequate skin coverage
- The possibility of a functional musculotendonous system
- Adequate bone stock to receive the implant
- Availability of post operative therapy
- A cooperative patient

Clinical Indications

Use of the SILASTIC® Angled Great Toe Implant H.P. may be considered when there is an increased proximal articular set angle on the metatarsal head, in combination with the following:

- 1) Hallux Valgus
- 2) Hallux Limitus
- 3) Rheumatoid arthritis, combined with a Hoffman or Clayton type procedure.^{6,18}
- 4) Unstable or painfully stiff MP joint following Keller or Mayo-type bunionectomy.^{21,25}

NOTE: For severe hallux valgus as seen in rheumatoid arthritis or in the senile bunion or following a failed Mayo-type or extensive Keller-type resection, the double-stemmed SILASTIC® Flexible Hinge Toe Implant H.P. (Swanson Design) is recommended.

Contraindications

- 1) Infection
- 2) Physiologically or psychologically inadequate patient
- 3) Inadequate skin, bone, and/or neurovascular status
- 4) Irreparable tendon system

Instructions For Use

Surgical Procedure

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only, a technique used by Lowell Scott Weil, D.P.M. Each surgeon must evaluate the appropriateness of the procedure based on his or her own medical training and experience.

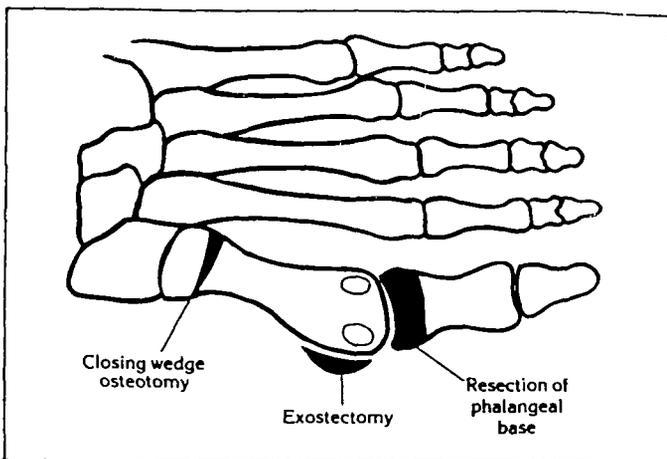
Incision and Exposure

A curvilinear incision, 6cm. in length, is made along the medial plantar aspect of the first metatarsophalangeal joint. The incision is deepened, exposing the superficial vein and nerve which are retracted. Minimal subcutaneous dissection is essential distal to the metatarsophalangeal joint in order to preserve adequate tissue for closure in the area of the phalangeal base. Following complete exposure of the first metatarsophalangeal joint, a lenticular capsular incision is made, utilizing two semi-elliptical incisions. The first of these incisions is made approximately 1cm. medial to the course of the extensor hallucis longus, 3cm. in length, and terminating at the metatarsophalangeal joint. A second capsular incision, parallel to and converging with the first capsular incision, is made approximately 5-10mm plantarward. Thus, a wedge of capsule 3cm. in length and 5-10mm in width, is removed from the medial dorsal aspect of the 1st metatarsal head. The capsular incision is then carried deep from its distal aspect along the medial dorsal aspect of the proximal phalanx about 2cm. It is important that this incision is carried to the bone so that the periosteum and thin capsular tissue around the base of the phalanx and subcutaneous tissue can all be dissected as one, in order to preserve good coverage of the phalangeal base.

Bone Preparation

Utilizing a #67 Beaver blade, the capsular structures are then dissected free from the medial, dorsal and plantar aspects of the 1st metatarsal head, as well as the proximal $\frac{1}{3}$ of the phalangeal base. The medial eminence of the 1st metatarsal head is then resected and rough edges smoothed. The base of the proximal phalanx is then resected perpendicular to its long axis. The amount of base resected will vary from 1 to 2 cm. (in cases of limited range of motion or where the great toe is longer than the 2nd toe, more base is resected). Utilizing a small egg shaped bur, a pilot hole is made in the intramedullary canal of the phalangeal shaft. Utilizing a Weil Angled Toe broach or other instrumentation, a rectangular canal is formed in the proximal phalanx. Since the head of the implant is not symmetrical, appropriate care must be taken in preparing the intramedullary canal so that rotation of the implant will be prevented. A trial fitting is then made, utilizing the blue sizers to determine correct implant size.

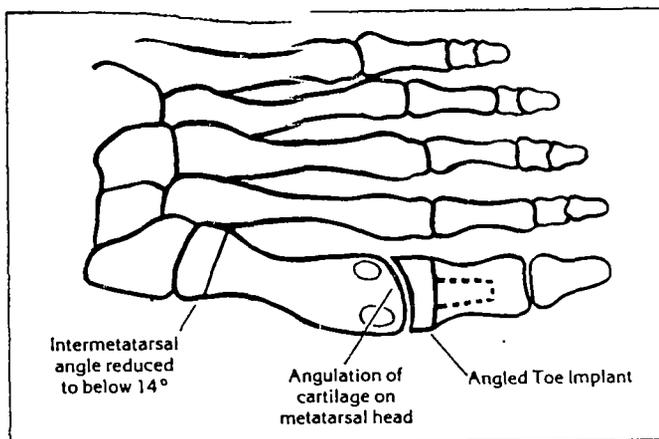
Following a trial fitting of the angled toe, the hallux is plantar flexed and the flexor hallucis longus tendon is easily identified. Utilizing a large cutting needle and a 2-0 non-absorbable suture, 2 sutures are placed into the flexor hallucis longus and into the inferior surface of the proximal phalanx, thereby tenodesing the flexor hallucis longus to the most proximal portion of the proximal phalangeal shaft. This method is preferred over suturing the short flexor apparatus into the proximal phalanx and will help stabilize the proximal phalanx.



Implant Insertion

A final trial fitting is then made with the appropriate blue sizer. The first metatarsophalangeal joint is then put through a range of motion, insuring that there are not any restrictions. The extensor hallucis longus tendon is centralized and lengthened if necessary. The SILASTIC® Angled Great Toe Implant H.Pis then placed into position, using a "no-touch" technique. The implant should be handled with blunt instruments to avoid traumatizing its surface or contamination with foreign bodies. A capsuloplasty is performed as follows. Utilizing a synthetic absorbable suture of 2-0 size, a suture is placed in the most distal aspect of the capsule and secured at the midpoint of the proximal phalanx on the plantar aspect. A second suture is similarly placed on the dorsal aspect. With the toe held in correct alignment, a pulley suture is placed from plantar distal to dorsal proximal at approximate 30° angle. This single suture should be placed to hold the hallux in the correct alignment. The remainder of the capsule is then approximated and maintained with multiple sutures utilizing 2-0 synthetic absorbable sutures. A final 2-0 suture is placed through the capsule and implant collar to prevent lateral slippage of implant. The skin is then approximated and maintained utilizing the

closure of the surgeon's choice. A large fluff dressing is then applied.



Postoperative Care

The initial dressing is removed after 24 hours, after which the wound is inspected for hematoma and a small dressing applied. Subsequent dressing changes are made weekly for three weeks holding the great toe in the correct alignment. A Jacoby Bunion splint is used for an additional six weeks. Three weeks postoperatively, the patient is permitted to wear a closed shoe (usually a jogging shoe with a wide toe box or a soft casual shoe). This shoe is worn as tolerated until the patients can resume their preferred shoes. Active and passive ranges of motion are begun the third postoperative day and continued throughout the postoperative period.

Important Points to Observe:

1. Using the blue sizing set as a guide, select the largest implant that the bone can accommodate, at the same time being very careful that the implant is well seated.
2. Handle the implant with a blunt instrument to avoid traumatization of the implant and contamination by other foreign bodies.
3. The thicker portion of the implant head is placed on the lateral aspect of the metatarsal head.
4. Shortening the end of the stem is permissible, although rarely necessary with the Angled Toe Implant. Reshaping of the implant should be avoided because modification might create structural weakness.
5. If the first intermetatarsal angle is in excess of 13°, it is recommended that this be reduced by an appropriate osteotomy procedure to reduce the possibility of lateral implant dislocation.

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Sterilization

SILASTIC® Implants have been sterilized. The blue sizing set is supplied non-sterile. The following sequential steps are recommended to clean and sterilize the blue sizing set or to resterilize implants:

1. Scrub thoroughly with a clean, soft-bristled brush in a hot water-soap solution to remove possible surface contaminants. Use a non-oily mild soap such as Ivory Flakes or Ivory bar soap. Do not use synthetic detergents or oil based soaps, as these may be absorbed and subsequently leached out to cause a tissue reaction.
2. Rinse thoroughly with distilled water.
3. Wrap in a lint-free cloth or place on a clean open tray, and autoclave by one of the following methods:
 - a. High speed instrument sterilizer—10 minutes at 270°F (132°C).
 - b. Standard gravity sterilizer—30 minutes at 250°F (121°C).
 - c. Prevacuum high temperature sterilizer—either 10 minutes at 270°F (132°C), or 30 minutes at 250°F (121°C).

Note:

Evidence suggests that repeated sterilization may affect the physical characteristics of the implant. Accordingly, resterilization in excess of three times is contraindicated.

The foregoing statement does not apply to the blue sizers where ultimate physical properties are medically irrelevant.

Gas sterilization is not recommended for silicone elastomers. Should this be the only available method of sterilization, it is essential to avoid inserting these implants within 10 days of the gas sterilization; otherwise severe tissue reaction might ensue from the in vivo release of the ethylene oxide.

Caution:

Federal (United States) law limits this device to sale by or on the order of a physician.

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

Attachment

IV

ATTACHMENT IV

COMPARISON CHART OF INSTRUCTIONS
FOR USE OF
SILICONE AND METAL SWANSON GREAT TOE IMPLANTS

	SILICONE	METAL
CLINICAL INDICATIONS	The implant is used in patients with:	
	° Normal density bone stock or	° Same
	° Osteoporotic bone	° N/A
	Who exhibit:	
	1. Hallux valgus, mild to moderate only	1. Same
	2. Hallux rigidus	2. Same
	3. Unstable or painfully stiff MP joint following Keller-type bunionectomy	3. Same
CONTRAINDICATIONS	1. Physiologically or psychologically inadequate patient	1. Same
	2. Inadequate skin, bone, and/or neurovascular status	2. Same
	3. Irreparable tendon system	3. Same
SURGICAL TECHNIQUE	1. Incision	1. Same
	2. Bone resection	2. Same
	3. Canal preparation	3. Same
	4. Selection of implant size	4. Same
		except stems can't be trimmed
	5. Soft tissue reconstruction	5. Same
	6. Closure	6. Same
7. Wound dressing	7. Same	
POSTOPERATIVE CARE	1. Wound care	1. Same
	2. Cast application	2. Same
	3. Physical therapy	3. Same

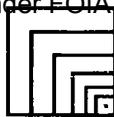
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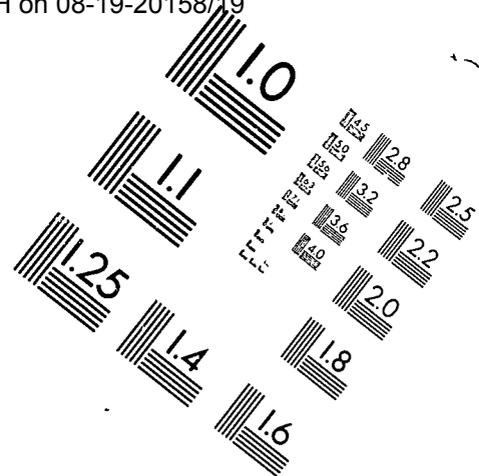
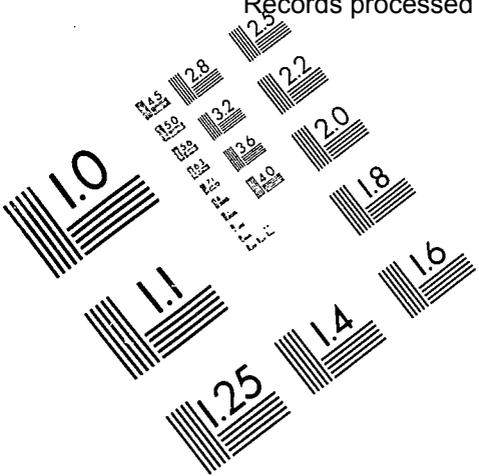
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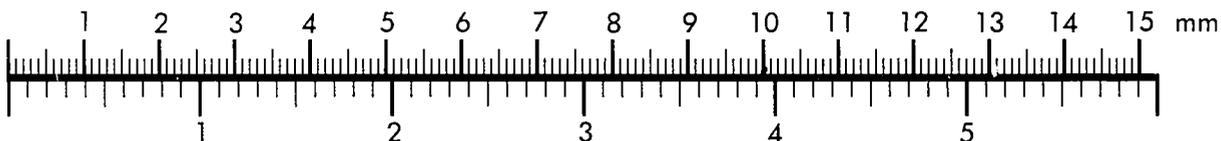


Association for Information and Image Management

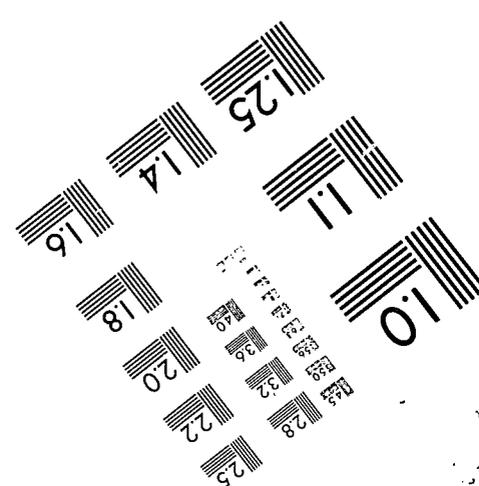
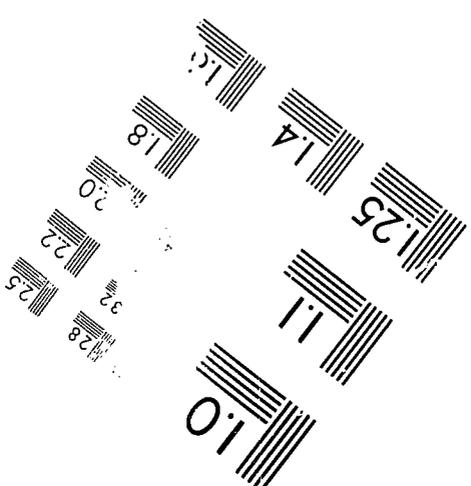
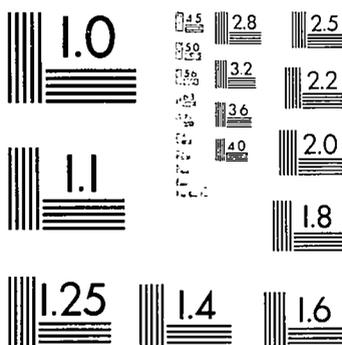
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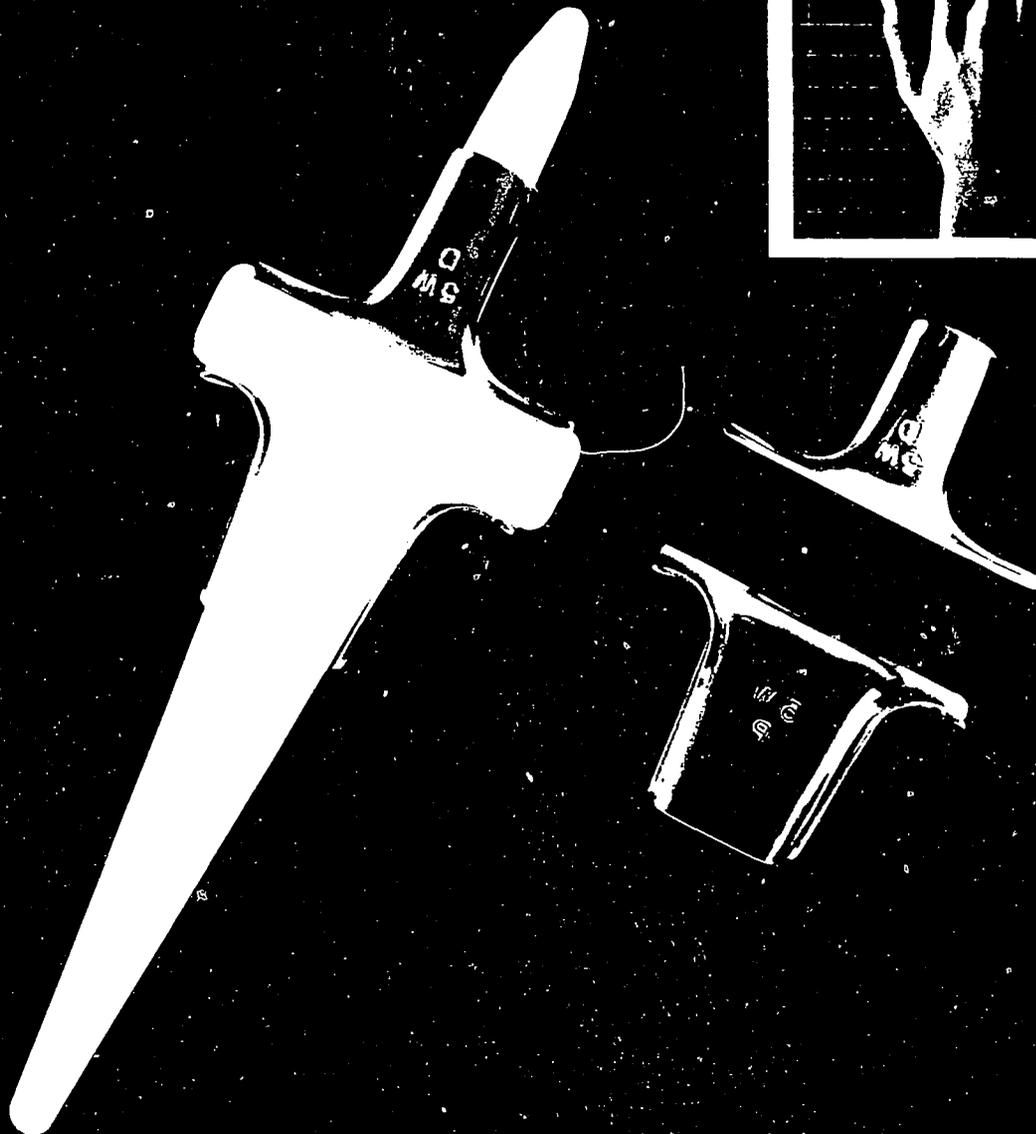
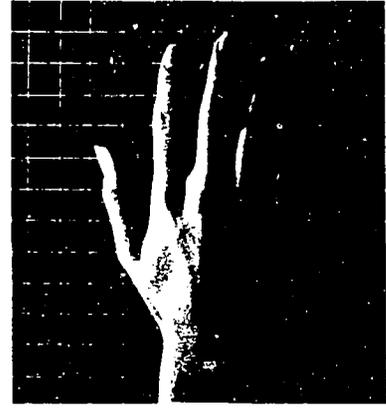
ATTACHMENT V

SILASTIC® HP 100

Swanson Wrist
Joint Implant

AND

Dow Corning Wright
Swanson Wrist
Joint Grommet



SILASTIC®

This registered trademark is the brand name for Dow Corning's silicone elastomer products, materials and related products. Only Dow Corning may identify its products with the trade-mark SILASTIC®. The word is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's material. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

HP 100 SILICONE ELASTOMER

SILASTIC® *HP 100* implants are fabricated from medical grade *HP 100* silicone elastomer, a high performance (HP) elastomer optimized to resist flexion-fatigue-induced-cut-growth (flaw propagation) in flexible hinges. The typical flexion fatigue-cut-growth in *HP 100* test specimens flexed 10^6 cycles by ASTM D813 is 0.010 inch (.25mm). Typical flexion-fatigue-cut-growth in test specimens of the original high performance elastomer, tested identically, is 0.1 inch (2.5mm), ten times greater.

In accelerated flex-life tests, these SILASTIC® *HP 100* Swanson Wrist Joint Implants (size 3) were preflawed with a cut in the center of the hinge 0.220 inch (5.5mm) deep and 0.051 inch (1.28mm) wide. Grommets were installed in the test fixture with two of the implants. After 27,739,000 90° flexion cycles (45° Flex. to 45° Ext.), the average flaw growth was 0.001 inch (0.025mm). In similar implants fabricated from original H.P. elastomer, one with grommets and tested identically, average flaw growth was 0.021 inch (0.53mm), 21 times greater than in *HP 100*.

HP 100 elastomer has excellent tensile strength, elongation, tear propagation strength, bi durability, and biocompatibility.

DOW CORNING
WRIGHT

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DESCRIPTION

Flexible Implant

The **SILASTIC® HP 100 Swanson Wrist Joint Implant*** is a one-piece intramedullary stemmed implant fabricated from medical-grade HP 100 silicone elastomer. It is designed for use in implant resection arthroplasty of the radiocarpal joint. The midsection of the implant contains an interpositional layer of polyethylene terephthalate fabric reinforcement to increase axial stability and resistance to rotary torque.

The Swanson Wrist Joint Implant is available in five sizes to satisfy most anatomical requirements. It has a wide midsection to match the width of the radius. The shorter distal stem extends through the carpus into the base of the third metacarpal. The stems usually do not require shortening. This implant design was previously known as "Wide with Shortened Distal Stem". The former "Regular" and "Wide" designs (both with long distal stems) have been discontinued.

The size of each implant is identified by a number 1 through 5 followed by the letters "WS" indicating wide midsection and short distal stem. A blue sizing set supplied nonsterile and not suitable for implantation is available for proper size determination during surgery.

Grommet

The **Dow Corning Wright Swanson Wrist Joint Grommet**** is a thin, titanium shield designed to modify the Swanson Wrist Joint Implant in selected cases. It is contoured to conform to the shape of the midsection of the flexible implant (wide designs only) and is fabricated from unalloyed, titanium for surgical application. The distal grommet is normally used on the dorsal surface, and the proximal grommet on the palmar surface to protect the implant from the shearing forces of sharp bone edges. Use of the grommet-modified implant is indicated in patients where cutting or abrasion of the flexible implant from contact with resected bone is likely to occur. Patients with severe rheumatoid arthritis or with thin, atrophied bone are particularly good candidates for the grommet-modified implant.

Each package of the Swanson Wrist Joint Grommet contains matching proximal and distal pairs. Grommets are available in five sizes corresponding to the five sizes of the Swanson Wrist Joint Implant. The outer surface of each grommet is marked with a numeral, indicating the size of wide wrist joint implant it fits, as well as the letter "P" or "D", indicating whether it is a proximal or a distal grommet. Swanson Wrist Joint Grommets are designed for use only with Swanson Wrist Joint Implants with wide midsection. They will not fit the original narrower ("Regular") Swanson-designed implant.

*U.S. Patent Nos. 3,462,765

**U.S. Patent Nos. 4,158,893; 4,198,713

RATIONALE

Flexible Implant

Stability of the wrist is important for normal function of the extrinsic muscles of the fingers. Reconstruction of a disabled wrist should provide reasonable stability and strength with enough mobility to assist in hand adaptations. Such a result can be achieved with the flexible implant resection arthroplasty procedure in the arthritic patient.

Swanson Wrist Joint Implant has been used as an adjunct to resection arthroplasty of the wrist in patients who have demonstrated marked instability of the wrist joint with absorptive changes of the proximal carpal row and subluxation of the radiocarpal joint. The purpose of the implants is to maintain an adequate joint space and alignment while supporting the development of a new capsuloligamentous system. It allows vertical and lateral movements through its flexible midsection and stems. The implant is used with a proximal row resection that includes resection of the base of the capitate. The distal implant stem is directed through the capitate into the third metacarpal and the proximal stem into the intramedullary canal of the radius. This positions the implant well in respect to the normal flexural area. It has been demonstrated that the axis of motion of the wrist is at the level of the head of the capitate bone. However, most of these wrists are severely diseased, and the normal radiocarpal and intercarpal articular movements have been altered. The flexible hinge implant, because of its flexibility, can adjust to the required axis of rotation with little resistance. Because the stems are not fixed, this is further facilitated as demonstrated on cinefluoroscopy studies. Furthermore, this procedure is essentially retrievable. If necessary, the implant is easily replaced, and if fusion becomes indicated, it can easily be done with a bone graft.

The degree of stability and mobility obtained with this technique to date has been most encouraging. It would appear that a properly done implant resection arthroplasty of the wrist, including a proper capsuloligamentous reconstruction around the implant and balancing of the muscle power to obtain adequate active movements in all planes, is superior to arthrodesis, pseudarthrodesis, or other simple arthroplasty procedures for the arthritic.

Grommet

The function of the grommet modification to the flexible Swanson Wrist Joint Implant is to provide an unattached, smooth and durable metallic shield between the silicone elastomer implant and contiguous bone. Typically, grommets are placed on the dorsal surface of the distal stem and palmarward on the proximal stem to protect the implant from sharp bone in areas where wear, abrasion, and cutting are most likely to occur. The grommet modification does not alter the function of the implant, patient indications and contraindications, nor reduce the need for careful attention to the arthroplasty technique.

SPECIFIC ADVANTAGES OF THE IMPLANTS

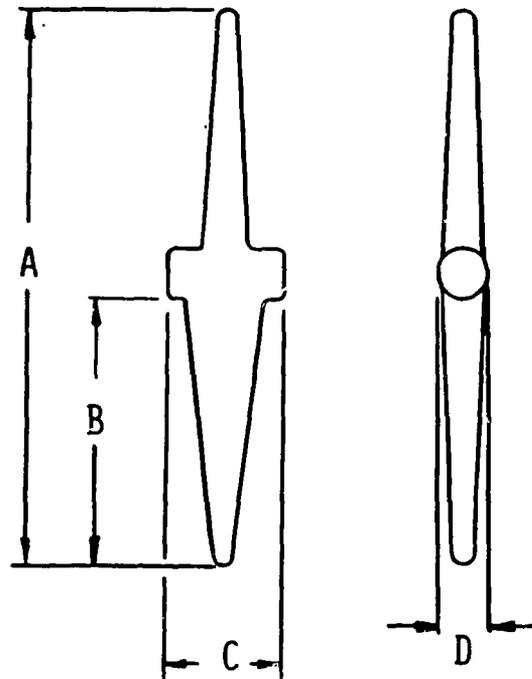
- Both H.P. 100 elastomer and unalloyed titanium have excellent biocompatibility.
- The Swanson Wrist Joint Implant and Swanson Wrist Joint Grommet have been sterilized.
- Accelerated fatigue flex testing has demonstrated high flexural durability of SILASTIC® HP 100 Wrist Joint Implants (average growth of through-and-through flaw in hinge is 0.001 inch (0.025 mm) per 10⁶ 90° flexion cycles).
- Anatomical sizing (length, height, width) available in five sizes to meet various operative requirements.
- The Swanson grommet is durable and abrasion resistant to shield the implant from sharp bone.
- Pliable medical grade silicone elastomer with low-elastic modulus (softer than bone) dampens force-loading and minimizes potential for necrosis or bone resorption. Cortical bone density typically increases postoperatively. These benefits are retained with grommet-modified implants.
- Neither the flexible implant nor the grommet requires artificial fixation to bone. Micro-pistoning of the flexible implant intramedullary stems results in less stress to bone and the implant; allows joint to find its own axis for center of rotation.
- Both flexible implant and grommet are visible on X-ray evaluation.
- Design characteristics of load-distributing hinges include: intramedullary-stemmed, flexible one-piece hinge-like construction of homogeneous material with stiffness/flexibility balance of implant material, and proper compression-tension force distribution in midsection.
- The flexible implant orients and supports joint encapsulation.
- The flexible implant makes results of arthroplasty more predictable, reproducible, and durable.

HOW SUPPLIED

The Swanson® Wrist Joint Implant (Radiocarpal) has been sterilized and packaged as follows:

WIDE WITH SHORTENED DISTAL STEM

Quantity	Description	Catalog Number
1 box	One each, size 1WS	488-0201
1 box	One each, size 2WS	488-0202
1 box	One each, size 3WS	488-0203
1 box	One each, size 4WS	488-0204
1 box	One each, size 5WS	488-0205
1 sizing set	One each, sizes 1WS, 2WS, 3WS, 4WS, 5WS. Numerically marked, color blue, (non-sterile), NOT FOR IMPLANTATION	498-0200



CLINICAL ADVANTAGES OF THE PROCEDURE

- Allows reconstruction and rebalance of musculotendinous structures.
- Good pain relief.
- Provides a reasonably stable wrist.
- Provides adequate wrist motion in all planes, especially extension.
- Maintains AP and lateral relationship of the carpus and radius, joint space, and alignment.
- Facilitates postoperative rehabilitation.
- Essentially a salvageable procedure.
- Does not interfere with later fusion of the wrist if the implant arthroplasty does not meet functional requirements.

TYPICAL DIMENSIONS FOR WIDE IMPLANT WITH SHORTENED DISTAL STEM

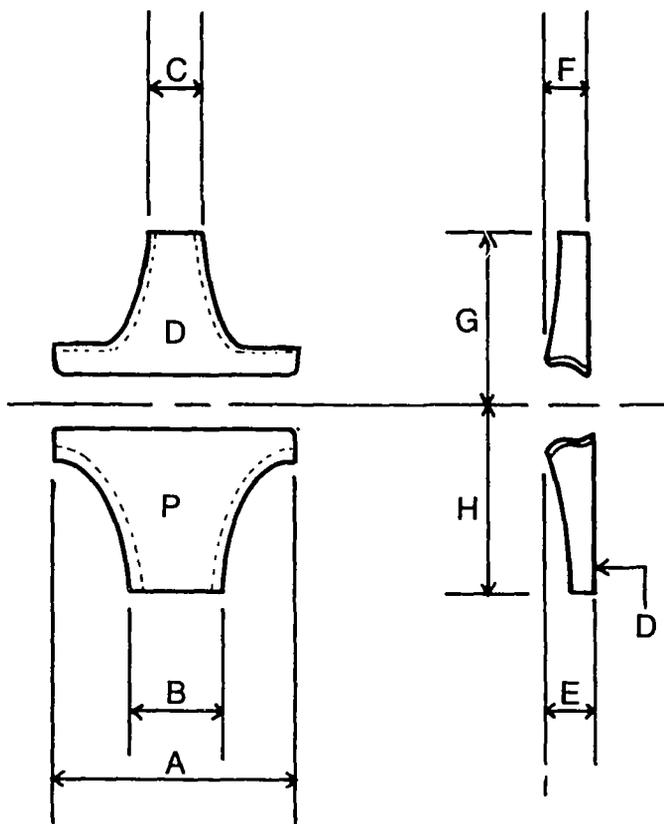
	1WS	2WS	3WS	4WS	5WS
A	63.1	72.1	84.6	96.8	109.4
B	36.3	43.2	50.8	58.9	66.9
C	19.5	22.9	26.7	30.7	35.3
D	6.9	7.2	8.0	9.1	10.2

Millimeters

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The Swanson Wrist Joint Grommet has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	Proximal and Distal Grommets, Pair, one each Size 1W	488-501W
1 box	Proximal and Distal Grommets, Pair, one each Size 2W	488-502W
1 box	Proximal and Distal Grommets, Pair, one each Size 3W	488-503W
1 box	Proximal and Distal Grommets, Pair, one each Size 4W	488-504W
1 box	Proximal and Distal Grommets, Pair, one each Size 5W	488-505W



TYPICAL DIMENSIONS

	1W	2W	3W	4W	5W
A	17.7	20.2	24.1	27.5	31.3
B	9.9	10.5	12.2	13.6	13.6
C	6.9	7.6	7.8	8.6	8.8
D	.5	.8	.8	.8	.8
E	6.0	5.6	6.2	6.2	6.4
F	5.9	5.7	5.7	7.0	6.3
G	12.8	14.2	15.6	18.9	21.8
H	13.8	16.0	18.5	21.2	24.0

Millimeters

INDICATIONS

General Indications

Any joint implant reconstruction requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive implant
- Availability of postoperative therapy
- Cooperative patient

Clinical Indications

Rheumatoid arthritic changes in the radiocarpal joint are frequent and are especially disabling when associated digit deformities are present. 20, 25, 28, 31, 69, 73, 81, 106, 110, 129, 130, 134, 136, 140, 141, 149, 159

They may affect the soft tissues and the joints of the wrist including the radiocarpal, intercarpal and radio-ulnar, singly or in combination. Associated ruptures of the extensor tendons are common. 42, 62, 108, 129, 130, 134, 136, 140, 141, 149, 158, 160

Flexible wrist implant resection arthroplasty is indicated in cases of arthritic or traumatic disability resulting in: 129, 130, 134, 136, 140, 141, 149

- (1) instability of the wrist due to subluxation or dislocation of the radiocarpal joint.
- (2) severe deviation of the wrist causing musculotendinous imbalance of the digits.
- (3) stiffness or fusion of the wrist in a non-functional position.
- (4) stiffness of the wrist where movement is a requirement for hand function.

Reconstruction of the wrist should be performed before surgery of the finger joints unless there are extensor tendon ruptures.

The use of a Swanson Wrist Joint Grommet is indicated in selected patients to prevent cutting of the implant by sharp bone edges. Grommets can be used both distally and proximally to protect the surfaces of the flexible implant. The proximal grommet is placed palmarly and the distal grommet dorsally. Patients with severe rheumatoid arthritis or patients with thin and atrophied bone are particularly good candidates for this implant procedure.

Contraindications

- Young patients with open epiphyses
- Physiologically or psychologically inadequate patients
- Inadequate skin, bone and/or neurovascular status
- Irreparable tendon system
- Patients who plan heavy manual work
- Presence of infection

CAUTION: In some patients, wear particles from silicone elastomer implants used in bone and joint reconstruction may participate in, or exacerbate, synovitis or bone cyst complications in contiguous bone. These complications have been reported to occur primarily with scaphoid and lunate replacement implants, and to a lesser

degree with trapezium or other articulating implants. Contributing factors have been reported to include the use of implants in young, physically active patients, associated preoperative pathology such as cysts and degenerative changes, intraoperative temporary stabilization with K-wires, and postoperative conditions such as instability and residual or recurrent deformity. Synovitis and bone cyst complications seldom occur with flexible hinge implants such as the finger, wrist, hammertoe, and flexible hinge toe implants.

INSTRUCTIONS FOR USE

Surgical Technique (Figs. 1, 2, 3 and 4)

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Alfred B. Swanson.* Each surgeon must evaluate the appropriateness of the procedure based on his or her own medical training and expertise.

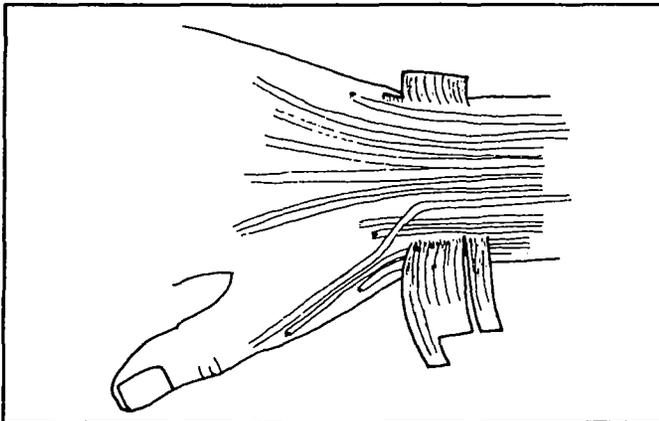


Figure 1A

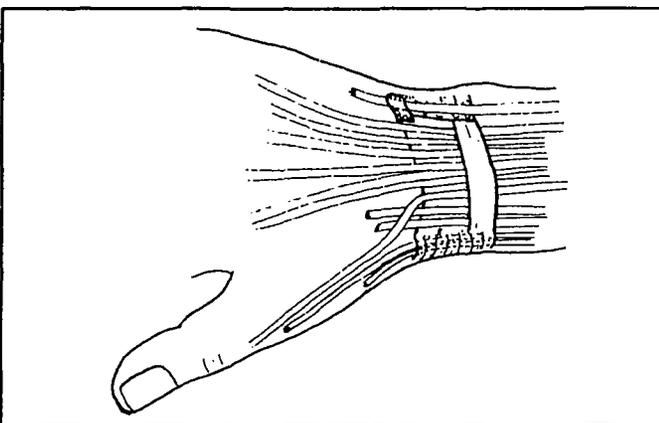


Figure 1B

A straight, longitudinal incision is made over the dorsal wrist, taking care to preserve the superficial sensory nerves. The extensor retinaculum is incised as to prepare a radially-based flap between the first and second dorsal compartments (Figs. 1A, 1B). A narrow proximal flap is prepared for later resuture over the extensor tendons to prevent bowstringing. Another retinacular liga-

ment flap can be prepared to relocate the extensor carpi ulnaris tendon in associated implant reconstructions of the ulnar head.^{118, 128} Synovectomy of the extensor compartments is performed taking care to remove the synovium only. The dorsal capsuloligamentous structures are carefully preserved for later resuture, reflecting them from the radius leaving a distally based flap (Fig. 1C).

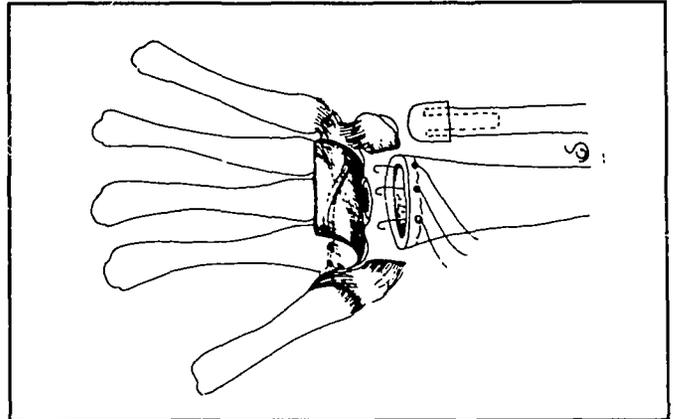


Figure 1C

A part of the proximal carpal row is usually absorbed, and the remnants are displaced palmarward on the radius. Resection of the remaining lunate is carefully done with a rongeur. Part of the distal scaphoid, capitate, and triquetrum can be retained in some cases. Injury to the underlying tendons and neurovascular structures should be avoided. The end of the radius is squared off to fit against the distal carpal row. The distal row of carpal bones should be left intact because of their importance in maintaining the stability of the metacarpal bases. The radiocarpal subluxation should be completely reduced (Figs. 2A and 2B).

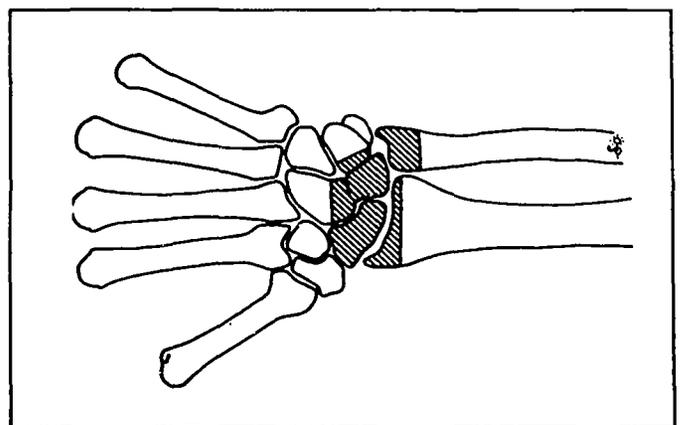


Figure 2A

The intramedullary canal of the radius is prepared with a broach, curette, or air drill to receive the proximal stem of the implant. If there has been a marked radiocarpal dislocation with subsequent soft tissue contraction, it is preferable to shorten the distal radius rather than remove more of the carpal bones.

*A.B. Swanson, M.D., F.A.C.S., Director of Orthopaedic Training Program, Grand Rapids Hospitals, Chief of Orthopaedic Research and Hand Surgery Fellowship, Blodgett Memorial Hospital, Grand Rapids, Michigan, Professor of Surgery, Michigan State University.

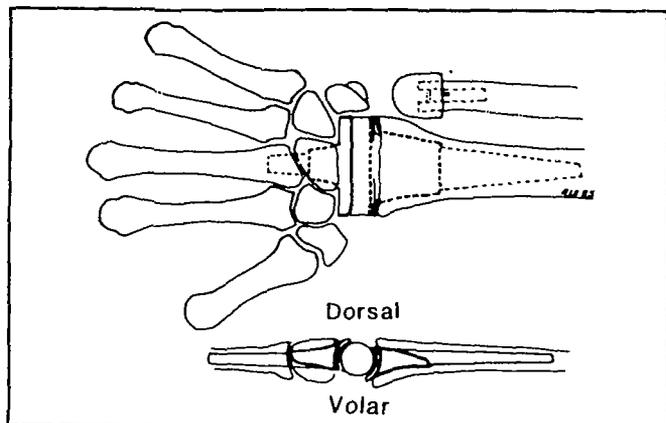


Figure 2B

The distal stem of the implant fits through the capitate bone into the intramedullary canal of the third metacarpal which is carefully prepared by passing a wire or very thin broach through the capitate bone and the base of the third metacarpal. A Kirschner wire can be passed into the base of the metacarpal and out through its head to verify the intramedullary orientation. The bones are usually very soft and this preparation is performed quite easily. An air drill may be used for the final reaming procedure. The distal stem should not be distal to the metaphysis of the third metacarpal in most cases and should be shortened accordingly. When an implant with short distal stem is used, it usually needs no modification (Fig. 2B). Sizers are used as the canals are being prepared and to determine correct implant size.

The distal ulna is trimmed back to about one centimeter from the distal end of the radius and capped with a Swanson Ulnar Head Implant.^{117, 118, 129, 130, 136} The hand is then centralized over the radius. Enough bone should have been removed so that 30° extension and 30° flexion of the wrist can be obtained on passive manipulation. Usually 1.0 to 1.5 cm of separation between the radius and carpus is adequate.

In patients selected to receive Swanson Wrist Joint Grommets, the sizer is removed and the bone canals are prepared to allow a press-fit of the appropriate sized grommet. The resected surfaces of the radius and capitate are shaped so that the grommet fits well into bone and the curvilinear profile of the grommet is covered by bone so that contact with overlying soft tissues is avoided. The distal grommet is normally used on the dorsal surface, and the proximal grommet on the palmar surface to protect the implant from the shearing forces of sharp bone edges (Fig. 3). The grommet sizing corresponds to implant sizing. Final seating of the grommet is done by gentle pressure or tapping against a curved instrument held against the exposed surface of the grommet. This is done with care to avoid bending or distorting the grommet. The grommet shoulders are seated directly against resected bone and inspected to assure the grommet does not protrude. If too loose, the next larger size is selected. When necessary, using a grommet one size larger than the flexible implant is permissible but a grommet smaller than the implant is never used. With grommets in place, the sizer is inserted and joint space and flexion-extension assessed. If the joint space is too small the proximal grommet is removed and it is resealed more deeply to create a larger joint space. The wound is thoroughly irrigated with triple antibiotic solution. The proximal stem of the wrist joint implant is inserted into the intramedullary canal of the radius first, and the distal

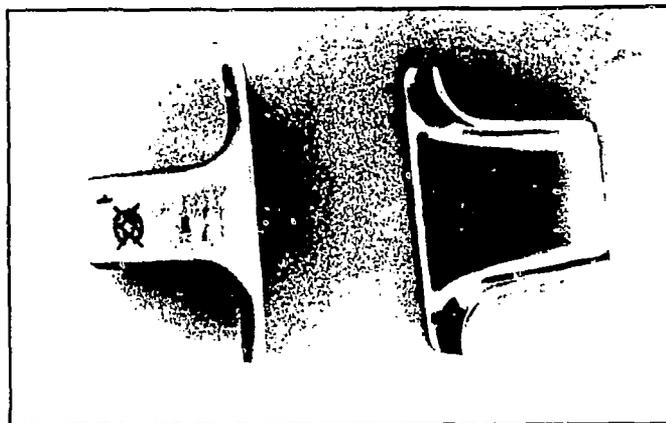


Figure 3A

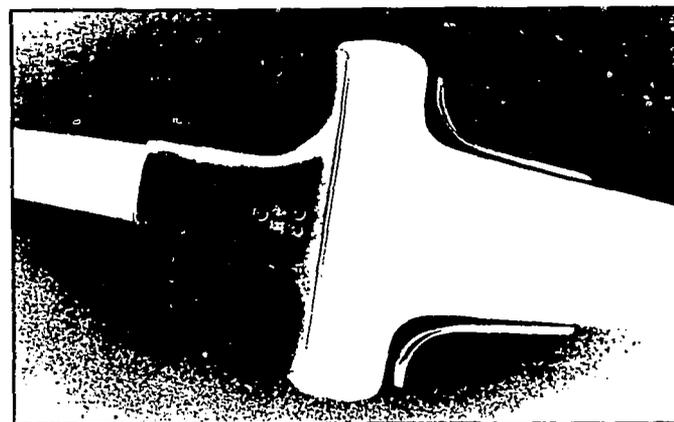


Figure 3B

stem is then introduced through the capitate and into the intramedullary canal of the third metacarpal.

Repair of both the palmar and dorsal capsuloligamentous structures around the implant is critical to obtain an adequate result. The palmar ligaments are reefed proximally or distally or both, according to where they are loose (Figs. 4A and 4B). The proximal palmar reefing is done by passing 2.0 Dacron sutures on a PR-4 needle through two small drill holes made in the palmar distal edge of the cut end of the radius. The distal palmar reefing is done by passing a 2.0 Dacron suture through a small drill hole made in the cut end of the capitate bone. The dorsal carpal ligament must also be firmly sutured over the implant with 2.0 Dacron sutures on a PR-4 needle passed through three small drill holes made in the dorsal cortex of the radius (Fig. 4C). The sutures are placed prior to implant insertion. After implant insertion and closure, the repair should be tested so that approximately 30° of extension and flexion and 10° of ulnar and radial deviation are possible on passive manipulation. More than 30° postoperative extension or flexion may increase the potential for implant failure and does not improve wrist function significantly. In patients with significant bone loss or loose ligaments who may have excessive extension, radial or ulnar deviation after implant arthroplasty, it may be necessary to add sutures to the palmar, radial and ulnar cortex of the radius to tighten the capsule in these areas. Adequate ligamentous repair is very important to proper function and durability with this type of arthroplasty.

The previously prepared extensor retinaculum flap is brought down over the wrist joint under the extensor

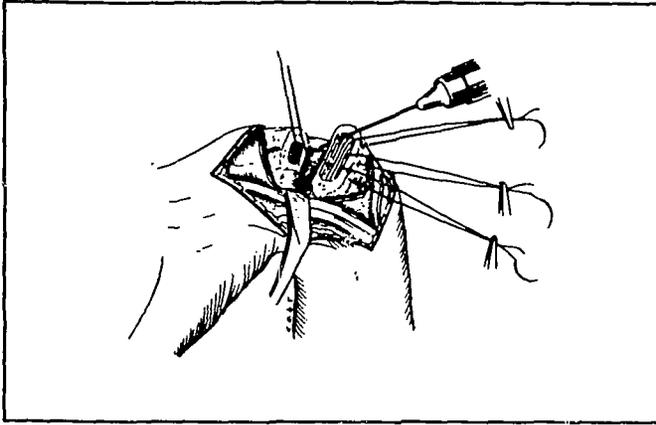


Figure 4A

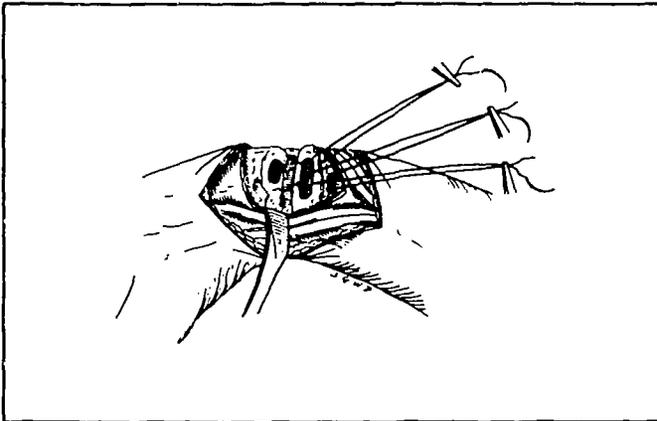


Figure 4B

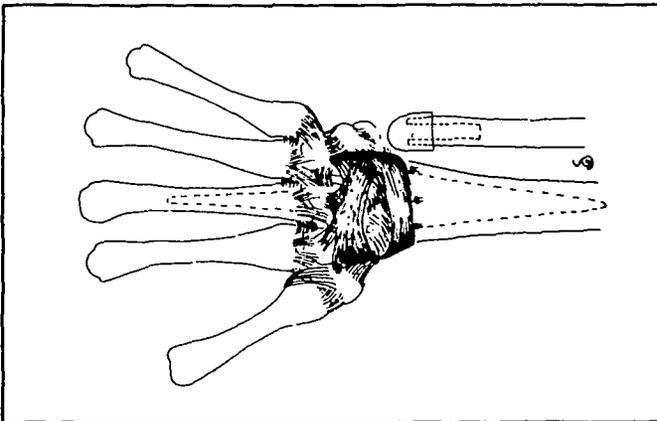


Figure 4C

tendon and sutured in place to provide further capsular support. The pull of the extensor tendons of the wrist joint are then evaluated, and they are shortened or transferred as required to obtain wrist extension without lateral deviation. The extensor carpi radialis longus may be transferred under the brevis to attach to the third metacarpal by a suture through the bone or interwoven into the brevis tendon distal attachment. The extensor tendons of the digits are repaired if necessary. We frequently may use one of the flexor superficialis muscles as a tendon transfer to reconstruct ruptured extensor digitorum communis tendons. If isolated extensor tendons are ruptured, side-to-side suture can be performed. Ruptures of the extensor pollicis longus tendon can be repaired by transferring the extensor indicis proprius tendon. The small proximal flap is placed over the extensor tendons to prevent bowstringing (Fig. 1B). The

reconstruction of the distal radio-ulnar joint is completed by using a retinacular flap from the sixth dorsal compartment to relocate dorsally the extensor carpi ulnaris tendon.

POSTOPERATIVE CARE

The wound is closed in layers, and a Swanson Incision Drain is inserted subcutaneously. Extreme care must be taken to protect the wound from hematoma and the skin from necrosis. A straight line incision, careful tissue handling, proper wound drainage, a supportive, conforming, noncompressive dressing, elevation of the extremity, and proper wound care are essential. The usual voluminous conforming hand dressing is applied, including a plaster splint with the wrist in neutral position. This is worn for three to ten days. The extremity is maintained in an elevated position for three to ten days with an arm sling, the patient being at bed rest. A short arm cast, with the wrist in neutral position, is then applied and fitted with outriggers to hold rubber band slings to keep the fingers in extension if the tendons have been repaired. This is worn as desired for four to six weeks. If necessary, a dorsal window is made in the cast for wound inspection and/or protection. Adequate immobilization is essential to allow firm capsulo-ligamentous healing to occur in proper wrist position. We desire a good ratio of stability and mobility. A joint that is too loose may be unstable. We attempt to obtain 50% to 60% of normal flexion/extension movements as the ideal goal. The patient should be started on an exercise program following cast removal to obtain active flexion and extension. Postoperative therapy includes strength building of the forearm musculature, especially of the wrist extensors. The patient should be restricted from excessive and abusive activity. If there is a tendency for tightness, some active and passive stretching exercises are prescribed.

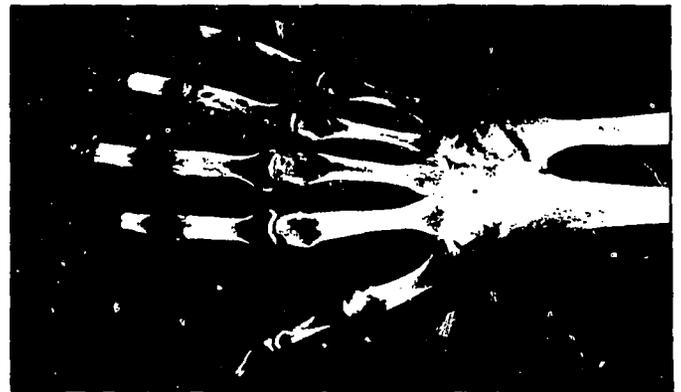


Figure 5A



Figure 5B

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STERILIZATION

The Swanson Wrist Joint Implant and Swanson Wrist Joint Grommet have been sterilized. The blue sizing set is supplied nonsterile.

The following sequential steps are recommended to clean and sterilize the blue sizing set or to resterilize implants or grommets:

1. Scrub thoroughly with a clean, soft bristled brush in a hot water-soap solution to remove possible surface contaminants. Use a non-oily mild soap such as Ivory Flakes or Ivory bar soap. Do not use synthetic detergents or oil-based soaps, as these soaps may be absorbed and subsequently leach out to cause a tissue reaction.
2. Rinse thoroughly with distilled water.
3. Wrap in a lint-free cloth or place on a clean open tray, and autoclave by one of the following methods:
 - a. High speed instrument sterilizer—10 minutes at 270°F (132°C).
 - b. Standard gravity sterilizer—30 minutes at 250°F (121°C).
 - c. Prevacuum, high temperature sterilizer, either 10 minutes at 270°F (132°C), or 30 minutes at 250°F (121°C).

NOTE:

Evidence suggests that repeated sterilization may affect the physical characteristics of the implant. Accordingly, resterilization in excess of three times is contraindicated.

The foregoing statement does not apply to the blue sizers where ultimate physical properties are medically irrelevant.

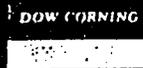
The properties of the titanium grommet are not changed by repeated autoclave sterilization.

Gas sterilization is not recommended for silicone elastomers. Should this be the only available method of sterilization, it is essential to avoid inserting these implants within 10 days of the gas sterilization; otherwise severe tissue reaction might ensue from the in vivo release of ethylene oxide.

CAUTION:

Federal (United States) law restricts this device to sale by or on the order of a physician.

DOW CORNING
WRIGHT



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...@rdm.mhsig
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REFERENCE

D. F. Williams, "Titanium as a Metal for Implantation: Part 2: Biological Properties and Clinical Applications", Journal of Medical Engineering and Technology, September, (1977)

Attachment

VI

TABLE 1
SURGICAL AND POSTOPERATIVE PROFILE
OF
(b)(4) AND (b)(4) IMPLANT SERIES

(b)(4)

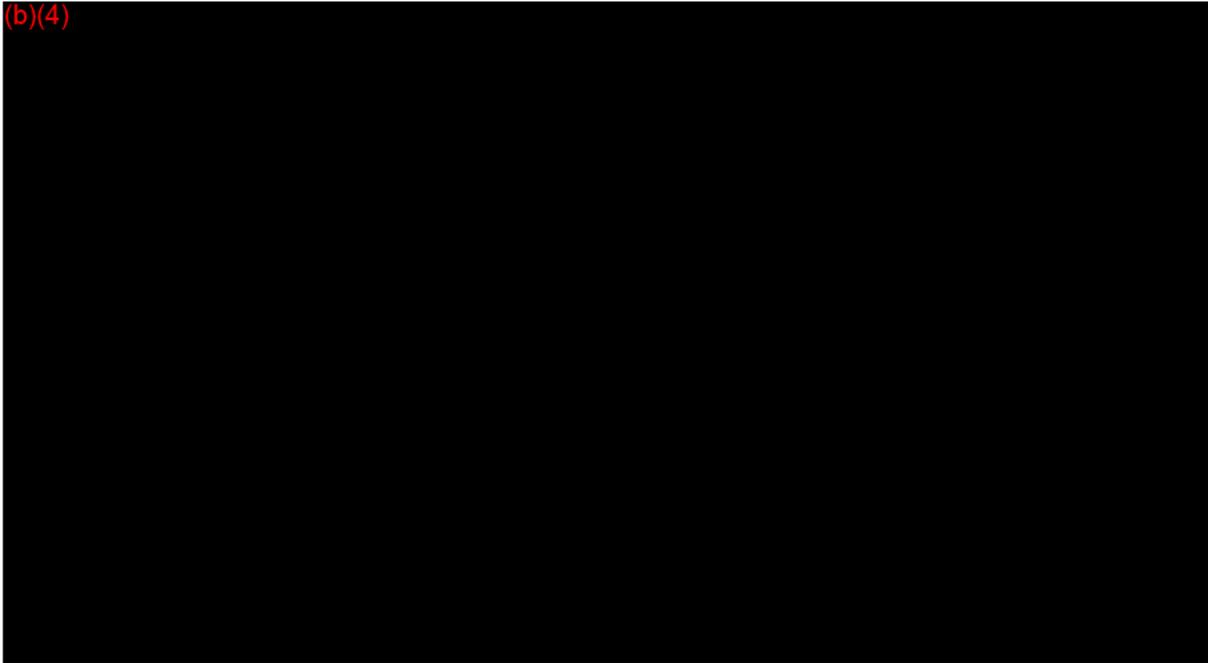


FIGURE 1
DISTRIBUTION OF *MALES AND FEMALES*

(b)(4)

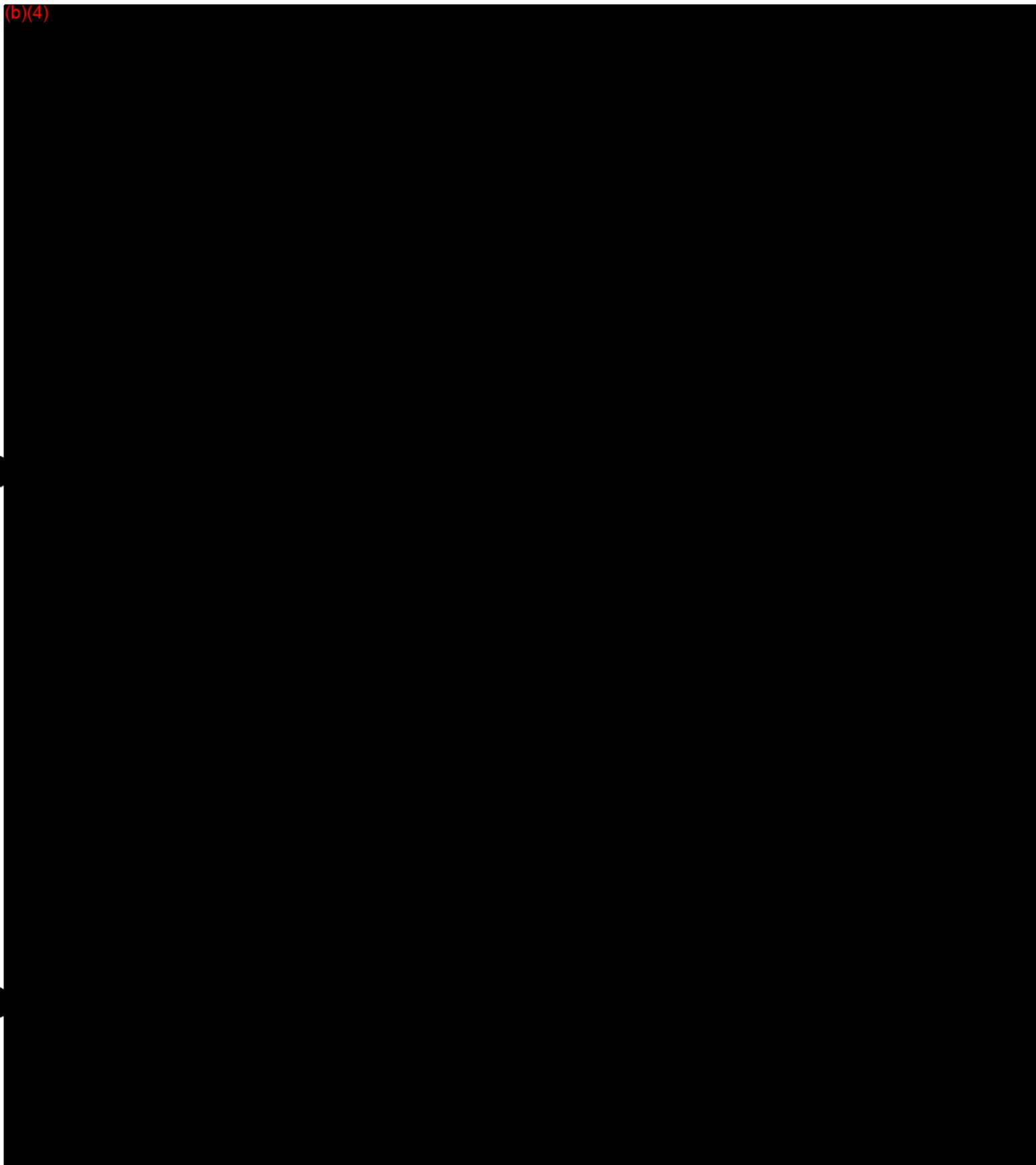
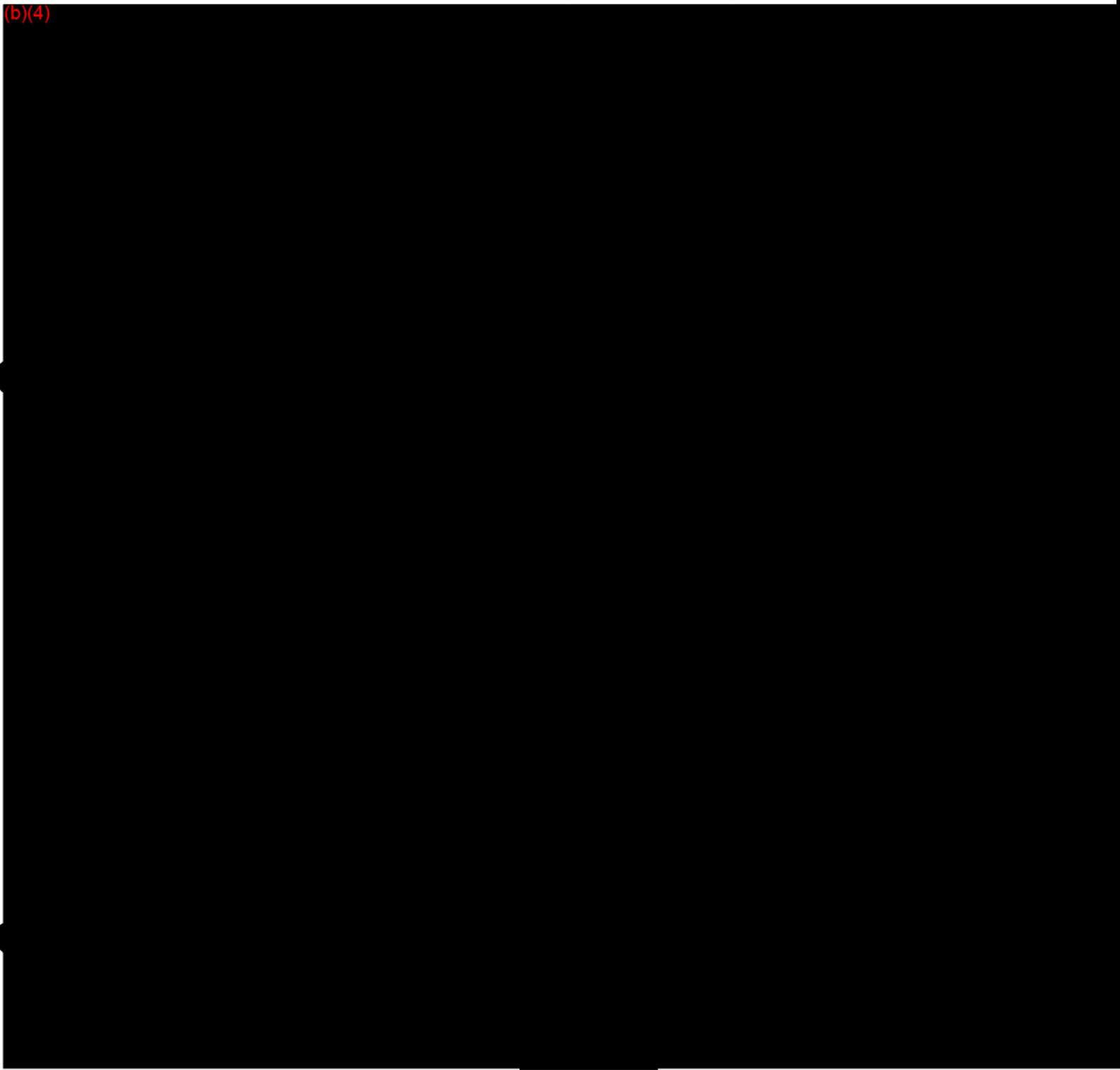


FIGURE 2
DISTRIBUTION OF SILICONE AND METAL
IMPLANT SERIES
BY *IMPLANT TYPE*

(b)(4)



KEY TO FIGURE 3

OA: OSTEOARTHRITIS
RA: RHEUMATOID ARTHRITIS
TA: POST-TRAUMATIC ARTHRITIS
JRA: JUVENILE RHEUMATOID ARTHRITIS
TAVN: TRAUMATIC AVASCULAR NECROSIS
OTHER: HALLUX VALGUS; HALLUX RIGIDUS; NONUNION; LUPUS;
FAILED RESECTION

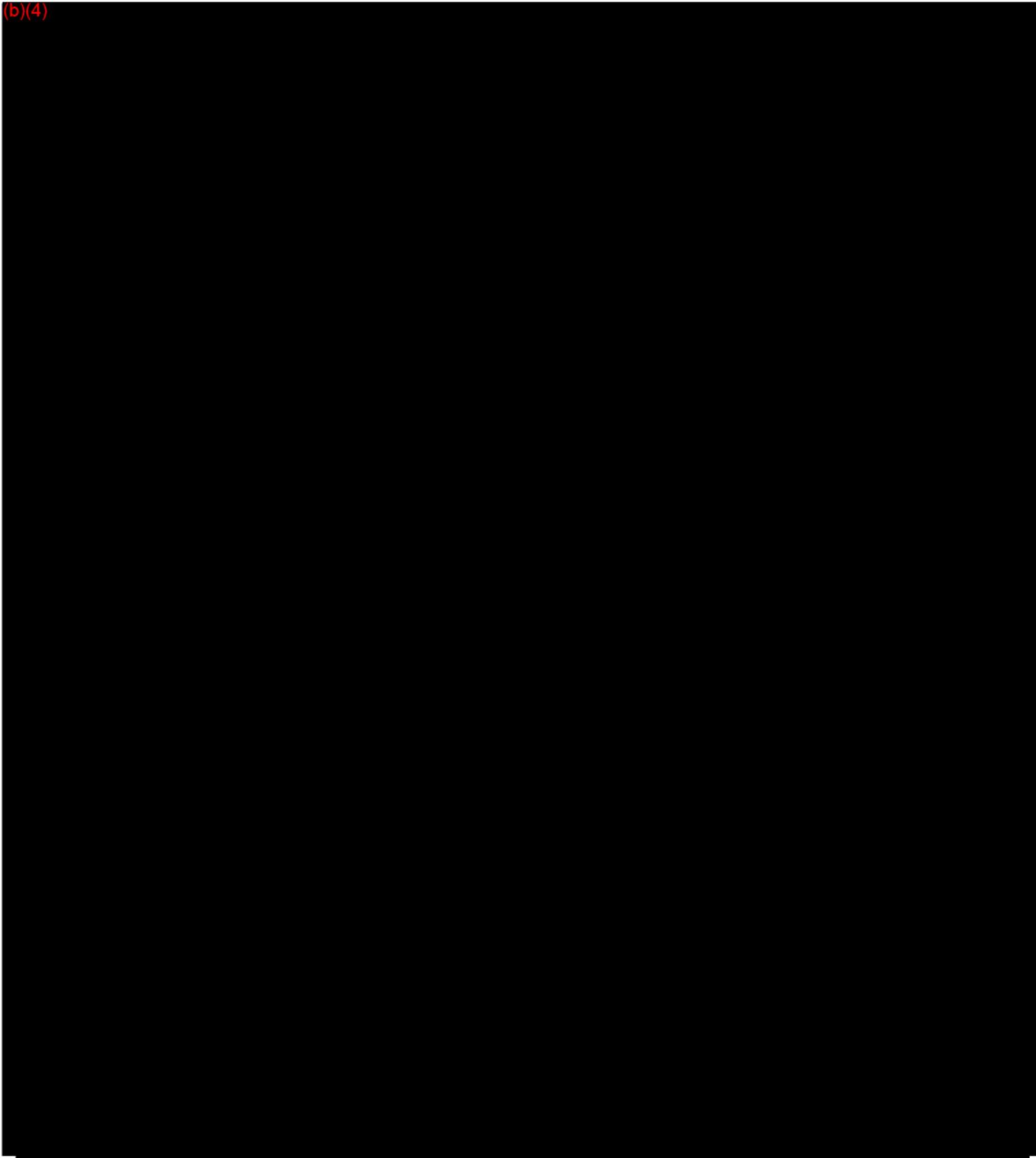
FIGURE 3
PRIMARY DIAGNOSES
OF PATIENTS IN SILICONE AND METAL
IMPLANT SERIES

(b)(4)



FIGURE 4
INCIDENCE OF *POSTOPERATIVE PAIN*

(b)(4)



KEY TO FIGURE 5

NORMAL: NORMAL BONE RESPONSE OR NO CHANGE FROM
PREOPERATIVE STATUS

MINIMAL:
MODERATE: DEGREE OF CYSTIC CHANGE FROM PREOPERATIVE STATUS
SEVERE:

Handwritten scribble

FIGURE 5
BONE TOLERANCE TO SPACER IMPLANTS

(b)(4)

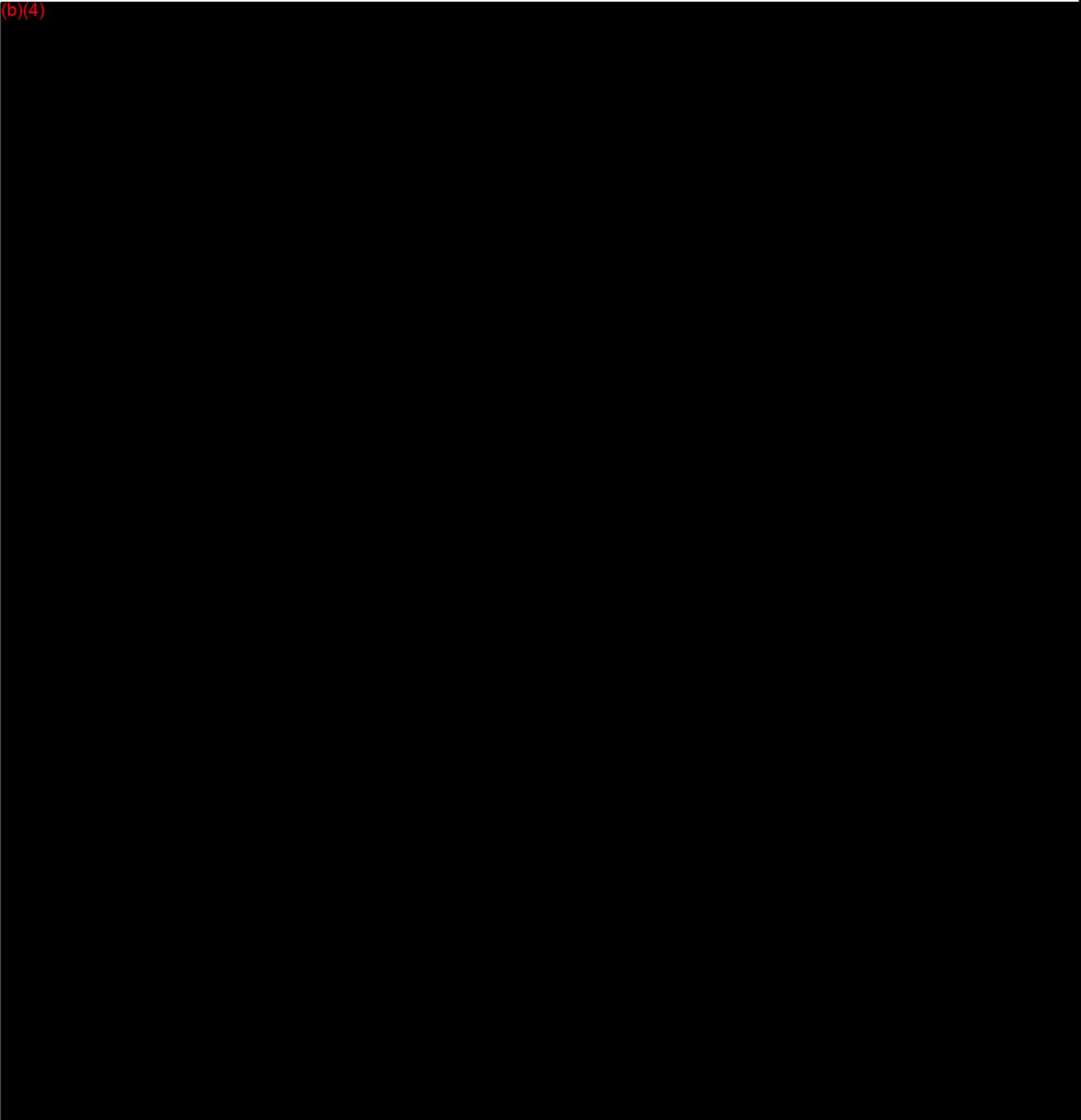


FIGURE 6
RADIOGRAPHIC EVALUATION OF
IMPLANT POSITION

(b)(4)

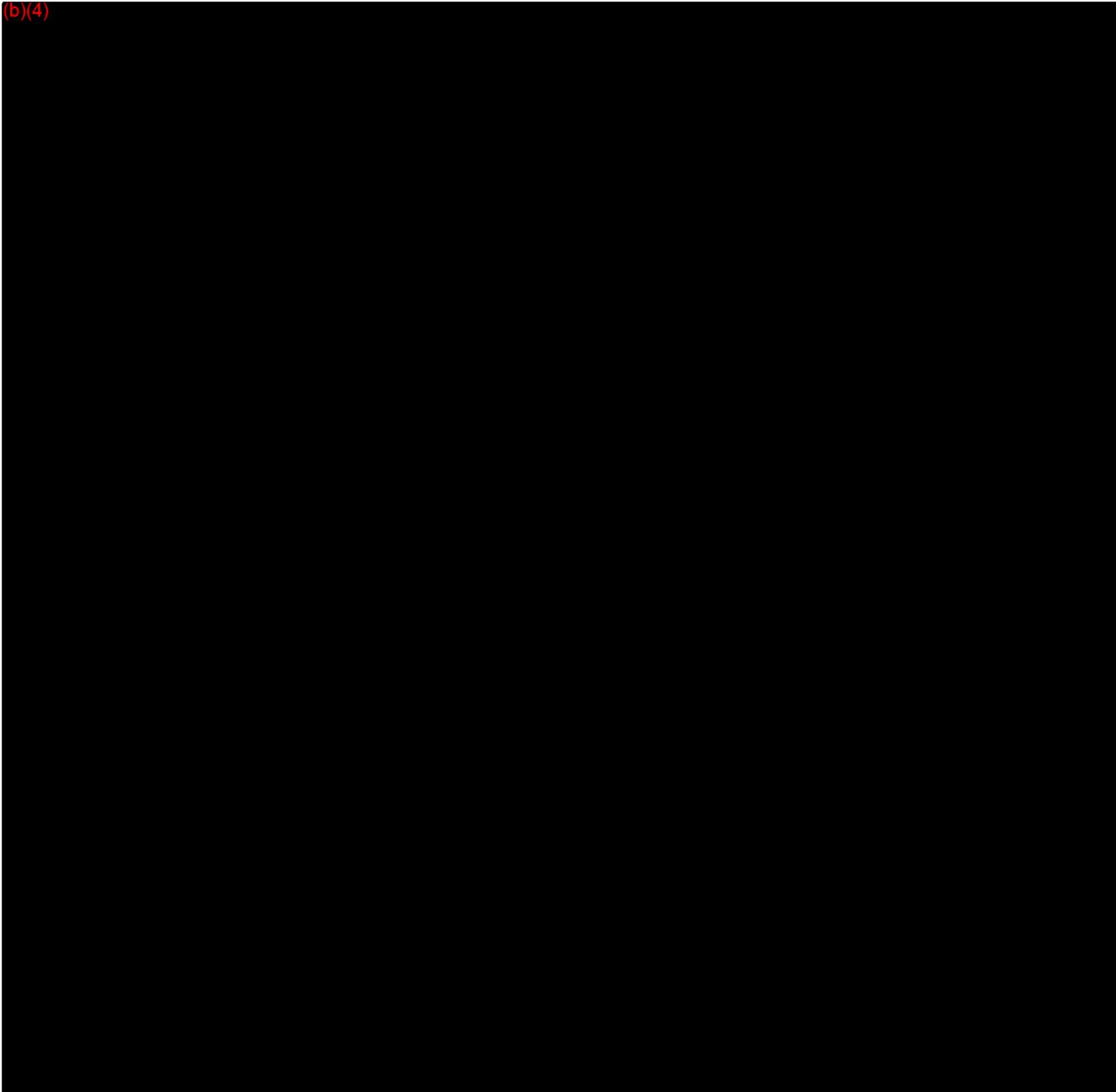
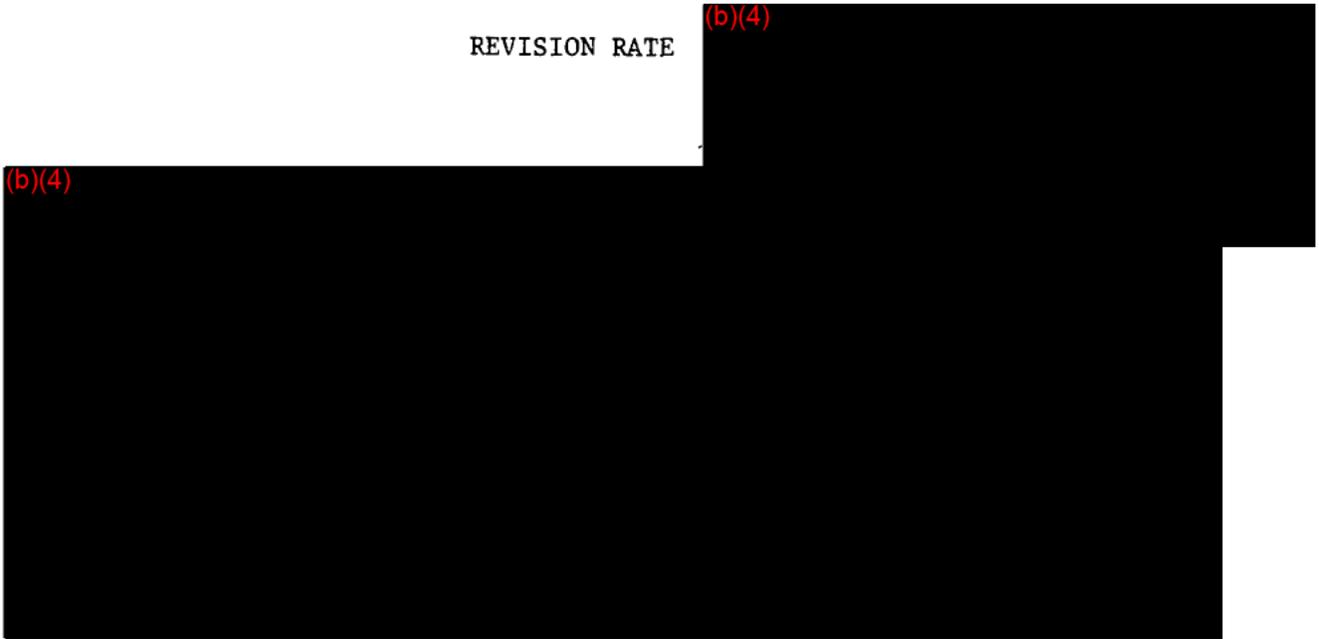


TABLE 2
REVISION RATE

(b)(4)

(b)(4)



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1. A. B. Swanson, G. de Groot Swanson, and J. J. Watermeier, "Trapezium Implant Arthroplasty: Long-Term Evaluation of 150 Cases", The Journal of Hand Surgery, 6:2, pp 125-141 (1981)
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Attachment

VII

ATTACHMENT VII

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1. R. L. Waugh, and L. Reuling, "Ununited Fractures of the Carpal Scaphoid: Preliminary Report on the Use of Vitallium Replicas as Replacements After Excision", American Journal of Surgery, 67, pp 184-200 (1945)
2. K. Speed, "Ferrule Caps for the Head of the Radius", Surgery, Gynecology and Obstetrics, 73, pp 845-850 (1941)