

3/24/99

K983483

0-000029

Appendix A – Summary of Safety and Effectiveness, Continued

- General Provisions**
- The common names used for this device include:
 - Platinum Fibered Coils
 - Microcoils or Minicoils
 - The Vascular Occlusion System consists of the following components:
 - TRUFILL Pushable Coils
 - TRUPUSH Coil Pusher

Predicate Devices The predicate devices are listed in the table below:

Device	Manufacturer	510(k) Number, Concurrency Date	Product Code
Hilal Embolization Microcoil	Cook, Inc.	K901337, 11/9/90	HCG
Helix Shaped Coils with Dacron Fibers	Target Therapeutics	K901721, 1/8/91	HCG
Vascular Occlusion System	Cordis Endovascular Systems, Inc.	K964367, 1/30/97 K972881, 6/4/98	HCG

Classification Class II

Performance Standard The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards.

Intended Use The Vascular Occlusion System may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

Device Description The Vascular Occlusion System consists of straight and shaped TRUFILL Pushable Coils (made from platinum alloy and synthetic fibers) and the TRUPUSH Coil Pusher (with 1 or 2 radiopaque markers). The pushable coils are designed for use under fluoroscopy with microcatheters having a minimum 0.21” inner diameter.

Continued on next page

Appendix A – Summary of Safety and Effectiveness, Continued

Biocompatibility	All applicable biocompatibility testing was successfully performed for the Vascular Occlusion System.
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Summary of Substantial Equivalence	The Vascular Occlusion System is substantially equivalent in design, materials, sterilization, and indications for use as other commercially available occlusion devices. ¹
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¹ A statement of substantial equivalence to another product is required by 21 CFR 807.87, and relates to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, *et seq.* (1977).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 1999

Ms. Martine D. Martino
Sr. Regulatory Affairs Associate
Cordis Endovascular Systems, Inc.
14000 N.W. 57th Court
Miami Lakes, FL 33014

Re: K983483
Vascular Occlusion System
Regulatory Class: III (Three)
Product Code: 84 MCG
Dated: December 21, 1998
Received: December 24, 1998

Dear Ms. Martino:

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

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

Page 2 - Ms. Martine D. Martino

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

0-000033

Appendix C – Indications for Use Statement, Continued

Indications for Use Statement

The Cordis Endovascular Systems, Inc. Vascular Occlusion System may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-the-Counter Use


Robert D. Dwyer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983483

K982483/A'

ORIGINAL



December 18, 2008

FDA CDRH DMC

JAN 08 2009

Received

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Reference: Add to File Letter
Cordis Neurovascular 510(k)s – Transfer of Ownership

Dear Sir or Madam:

The purpose of this letter is to notify FDA that effective December 29, 2008, Cordis Neurovascular Inc., will be merged with and become a business unit with Codman & Shurtleff, Inc. With this transfer, all rights of the attached 510(k)s are transferred to Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham, Massachusetts 02767. Codman acknowledges ownership of these 510(k)s.

Please feel free to contact me at 508-828-3704 or kmahoney@its.jnj.com if you should have any questions regarding this transfer of ownership.

Regards,

Karen F. Mahoney
Worldwide Director of Regulatory

ORIGINAL

K032553/A1



December 18, 2008

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
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Codman has supplied the attached letter acknowledging ownership of the 510(k)s.

Please feel free to contact me at 908-412-3065 or jodonne7@its.inj.com if you should have any questions regarding this transfer of ownership.

Regards,

James P. O'Donnell
Vice President, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
7 Powderhorn Drive
Warren, New Jersey 07059

2 K39

ORIGINAL

510(k) Ownership Transferred to Codman & Shurtleff, Inc.

510(k) #	Description
K925131	9F ENVOY Guiding Catheter
K940187	6F ENVOY Guiding Catheter
K945705	5F ENVOY Guiding Catheter
K951314	TRUFILL PVA Particles
K965174	TRUFILL PVA Particles
K964367	TRUFILL Pushable Coils/ TRUPUSH Coil Pusher
K972881	TRUFILL Pushable Coils/ TRUPUSH Coil Pusher
K983483	Vascular Occlusion System (Peripheral Indication)
K071962	TRUPUSH Coil Pusher Changes
K014041	TRUFILL DCS Detachable Coil System
K082324	TRUFILL DCS Syringe
K030963	TRUFILL DCS ORBIT Detachable Coil System
K032553	TRUFILL DCS ORBIT Detachable Coil System
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K950910	RAPID TRANSIT Infusion Catheter
K952874	TRANSIT Infusion Catheter
K954949	TRANSIT Infusion Catheter
K965181	PROWLER Infusion Catheter
K971306	REGATTA Infusion Catheter
K972518	Infusion Catheters (Guidewire Exchange/Support (not for MASS TRANSIT))
K974222	MASS TRANSIT Infusion Catheter
K983003	MASS TRANSIT Infusion Catheters 50 cm Flex
K993266	PROWLER Plus Infusion Catheter
K003925	PROWLER Infusion Catheters with Pre-Shaped Tips
K020680	PROWLER Select 10 and 14
K021591	PROWLER Select (10, 14 and Plus)
K043538	HYPERTRANSIT Infusion Catheter
K070279	HYPERTRANSIT Infusion Catheter
K984214	Temporary Occlusion Balloon Catheter (Discontinued)
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K943522	PROMPT Guidewires (Obsolete)
K955637	ESSENCE Guidewires
K991646	Agility (.010) Steerable Guidewires
K001033	Agility (.014) Steerable Guidewires
K010511	Agility (.016) Steerable Guidewires



FEB 17 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

James P. O'Donnell
Vice President, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
7 Powderhorn Drive
Warren, New Jersey 07059

Re: See Attached

Dear Mr. O'Donnell:

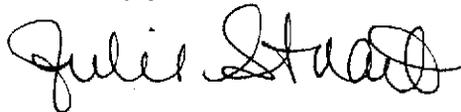
We have reviewed your letter, received January 8, 2009, stating that the rights to the above referenced premarket notification (510(k)) have been transferred. Transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.81(a)(3). Consequently, we cannot change the name of the original 510(k) submitter in our database. Please note, as per 21 CFR 807.85(b), a firm may not both manufacture and distribute a device under their own name without having their own 510(k).

We suggest that information showing the transfer of the 510(k) and its current ownership should be maintained in the company's files for review by an FDA investigator. You may contact the Center for Devices and Radiological Health's Office of Compliance at (240) 276-0100 if you have any questions on what information we expect to be maintained in your files.

"Please note, under 21 CFR 807.81(a)(2) a firm may not both retain and transfer 510(k) marketing rights to another person, e.g., a contract manufacturer, because each person who manufactures and distributes a device must have their own 510(k), if the device is not exempt from the premarket notification requirement. Likewise, distributors need 510(k) clearances before marketing devices when they alter them by doing more than putting their name on the device, because such actions would disqualify them from the 510(k) distributor exemption under 21 CFR 807.85(b)."

If you have any other questions regarding this letter, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,



Julie "Brandl" Stuart
Consumer Safety Officer
Premarket Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

CC: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

ORIGINAL

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K001033	Agility (.014) Steerable Guidewires
K010511	Agility (.016) Steerable Guidewires

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 1-8-09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K983483/A1

To: Division Director: CV/DCD/TF

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

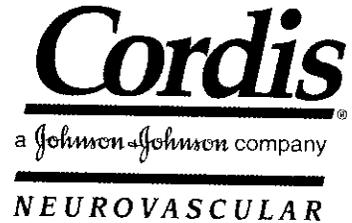
Reviewed by: _____ 2-17-09 ✓

Date: _____

POS

ORIGINAL

K983483/A1



December 18, 2008

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA CDRH DMC
JAN 08 2009
Received

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Regards,

James P. O'Donnell
Vice President, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
7 Powderhorn Drive
Warren, New Jersey 07059

K34 2

ORIGINAL

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3

ORIGINAL

Codman
a Johnson & Johnson company

December 18, 2008

FDA CDRH DMC

JAN 08 2009

Received

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

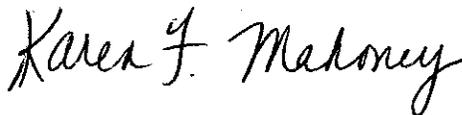
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Regards,



Karen F. Mahoney
Worldwide Director of Regulatory



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 1999

Ms. Martine D. Martino
Sr. Regulatory Affairs Associate
Cordis Endovascular Systems, Inc.
14000 N.W. 57th Court
Miami Lakes, FL 33014

Re: K983483
Vascular Occlusion System
Regulatory Class: III (Three)
Product Code: 84 MCG
Dated: December 21, 1998
Received: December 24, 1998

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Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



0-000033

Appendix C – Indications for Use Statement, Continued

Indications for Use Statement

The Cordis Endovascular Systems, Inc. Vascular Occlusion System may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

Becca D. Dwyer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983483



Memorandum

Reviewer(s) - Name(s) John W. Karanian

Subject: 510(k) Number K983483/S1

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.) YES NO

Is this device subject to Postmarket Surveillance? YES NO

Is this device subject to the Tracking Regulation? YES NO

Was clinical data necessary to support the review of this 510(k)? YES NO

Is this a prescription device? YES NO

Was this 510(k) reviewed by a Third Party? YES NO

Special 510(k)? YES NO

Abbreviated 510(k)? YES NO

This 510(k) contains:

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

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

The required certification and summary for class III devices

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

Material of Biological Origin YES NO

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

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

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

84 HCG, III

Reviewed by: Bette G. Campbell CSPE 15 March 99
(Branch Chief) (Branch Code) (Date)

Final Review: Bette G. Campbell for 15 March 99
(Division Director) (Date)

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

4

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: K 883483
John W. Karanian
 Division/Branch: DCRD/CSPG
 Device Name: Vascular Occlusion System
 Product To Which Compared (510(K) Number If Known): K964367 K972881

	YES	NO	
1. Is Product A Device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
2. Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
3. Same Indication Statement?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If YES = Stop NE
5. Same Technological Characteristics?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Stop NE
9. Accepted Scientific Methods Exist?	<input type="checkbox"/>	<input type="checkbox"/>	If NO = Stop NE
10. Performance Data Available?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Request Data
11. Data Demonstrate Equivalence?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

5

1. Intended Use: *Reduction/blockage of bld. flow in AVMs/AVFs and other lesions in neuro and peripheral vasculature*
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important. *See attached memo*

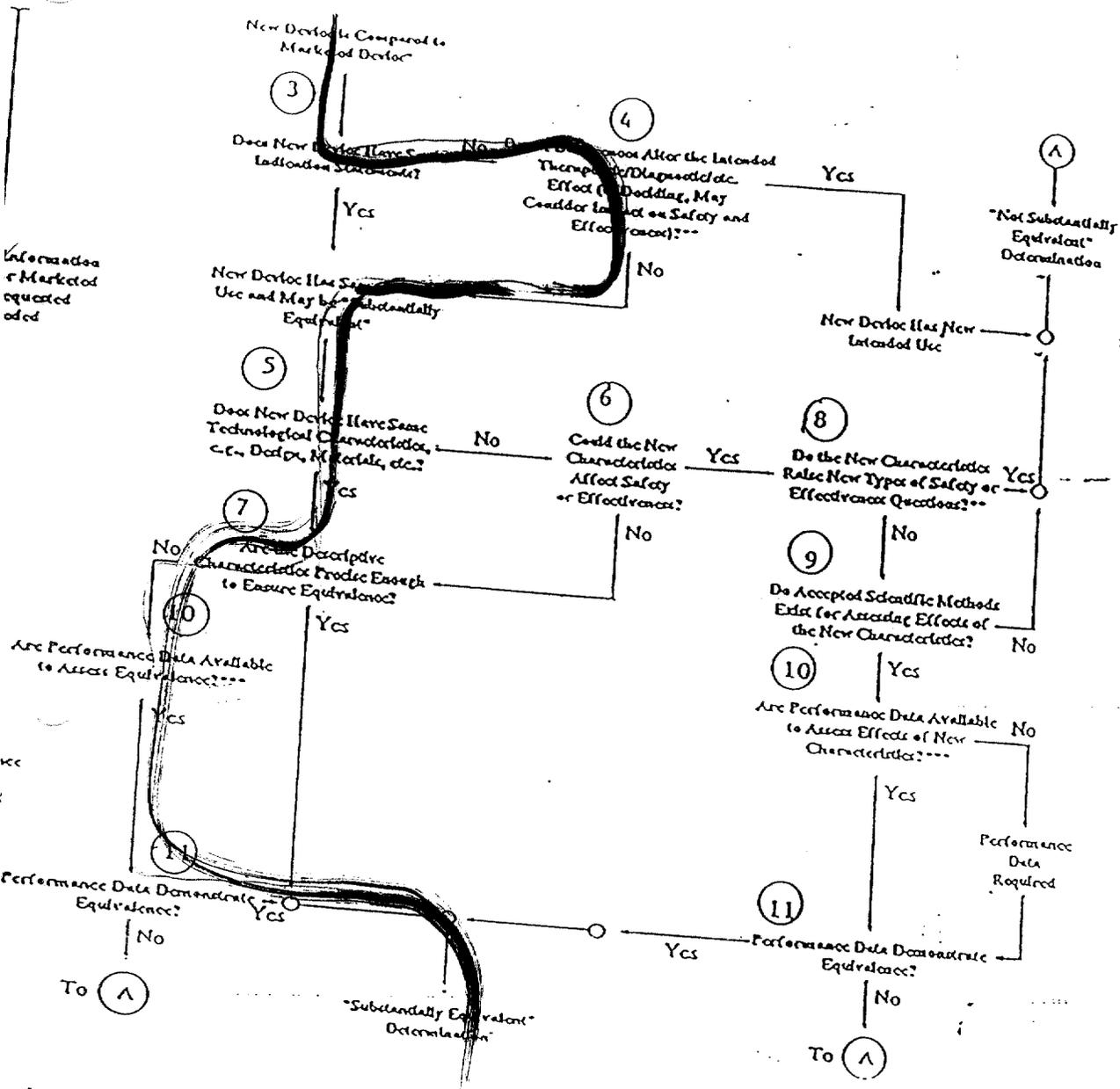
EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication: *(b)(4)*
4. Explain why there is or is not a new effect or safety or effectiveness issue: *Change in intended use requires additional information as provided (see memo)*
5. Describe the new technological characteristics: *NONE*
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are *(b)(4)* precise enough: *(b)(4)* *(see memo)*
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *Performance and comparative information as summarized in attached memo demonstrate SE*

ATTACH ADDITIONAL SUPPORTING INFORMATION

See memo

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



Commissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear. Information is normally based on descriptive information alone, but limited testing information is sometimes required. In the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

DATE: February 21, 1999 JK

FROM: JOHN W. KARANIAN, CDRH, ODE, DCRND, CSPDG

TO: File: K983483
Firm: Cordis Endovascular Systems, Inc.
Device: Vascular Occlusion System
Class: 21CFR 882.5950 Occlusion Coil, Artificial
Embolization Device, Class III, 84 HCG

SUBJECT: Substantially Equivalent

The sponsor was notified by phone (12/16/98) that the document will be placed on hold until the required information is provided. The sponsor has provided a class III summary. The document is complete and considered substantially equivalent to the cited predicates.

Device/Application Summary

The Cordis Vascular Occlusion System is currently cleared for use in neuro vascular indications (K964367 and K972881) and may be considered similar to other occlusion coils cleared for use in the peripheral vasculature. The purpose of the present submission is to expand the indications to include the **peripheral vasculature**. The design, performance, materials, manufacturing and sterilization processes for the subject device remain unchanged from that of the predicate devices. The document may be considered equivalent to the predicate.

The Vascular Occlusion System consists of straight and shaped TRUFILL Pushable Coils and the TRUPUSH Coil Pusher (contains 1-2 radiopaque markers). The coils are made of platinum alloy and synthetic fibers. The pushable coils are designed for use under fluoroscopy with microcatheters which have a minimum 0.21" inner diameter. These coils may also be considered similar to Target's pushable Platinum Occlusion coils (K901721), and the Cook Company Occlusion Coils

-2-

(K901337), cleared for use in both the peripheral and neurovasculature. The delivery method is via a mechanical push rod which has been cleared for use and performed safely in fragile neuro vasculature and cerebral aneurysms during clinical studies. In K961923 the Cordis coil was found to be substantially equivalent to currently marketed Target and Cook coils for use in both neuro and peripheral vasculature. With the provision of adequate comparative and performance data, and existing clinical data (K964367, K972881), the data base supports the expansion of Cordis's indications for use to include peripheral indications.

Submission Contents

1. Descriptive Information

A platinum alloy wire is wound into a primary coil and formed into a secondary helical or curved shape. The coils are designed to be delivered by catheter using a push rod at the target site. The coils are provided loaded on an Introducer for transfer into a delivery catheter. The coils are radiopaque for flouro visualization. The coils are available in four shapes (i.e., straight, c-shaped, complex and flat spiral) and a range of sizes (2-15l x 3-10d).

All component materials, dimensions, features and functional specifications are described in tabular form with drawings (section 3). The intended use for the coil will be expanded to include arterial and venous embolizations of malformations and fistulas in the peripheral vasculature. Indications for use are adequately compared to the predicates (attachment E).

2. Performance

Adequate *in vitro* performance testing has been performed on the subject device for previous submissions (K964367 and K972881) and described in section 7. All test data was summarized: **Functional bench testing** was performed on the Coil and adequately demonstrated the safety, effectiveness and performance integrity. The **forces** required to advance and retract the coil through a catheter were defined

-3-

and established the standard for setting minimum specifications and evaluating the (b)(4) of the Coil. These tests demonstrate that the Coil can be delivered through the selected catheter without consequence using a range of pressures. (b)(4)

(b)(4) testing demonstrated the Coil's ability to perform well with recommended microcatheters. The (b)(4) were well (b)(4) the catheters tested.

Animal testing was not performed for the new indication for use. Given the significant commercial use of these and related coils in the clinical treatment of neuro and peripheral vascular malformations, the lack of animal data may be considered acceptable for this application.

3. Labeling and instructions for use

Labeling and instructions for use were provided (section 4 and attachment D) and adequately compared to the cited predicates for neuro and peripheral use (attachment F and G). The labeling for the Cordis Coil is similar to that of the predicate Coil with the expanded indication for use. The Instructions for Use are complete and clear regarding the intended use and instructions for operation.

4. Comparison Information

In general the information as provided suggest equivalence. The Cordis Coil is considered similar to the predicates for neuro use (K972881) and pushable Platinum Occlusion coils (K901337 and K901721) cleared for use in both the peripheral and neurovasculature (see indications for use comparison chart, section 6, pg 21). The delivery method for the Coil has been cleared for use and performed safely in fragile neuro vasculature and cerebral aneurysms during clinical use (K972881). With the provision of adequate comparative (and performance) data, and existing clinical use the data base supports the expansion of Cordis's indications for use for the Coil to include peripheral indications.

Predicate device labeling was compared and demonstrated equivalence to that of the present submission (with expanded indications). The

physical characteristics of the Coil have not been changed as described in the predicate 510Ks. The anatomical sites for Coil therapy are certain aneurysms and other vascular malformations (i.e., AVMs, AVFs) of the peripheral and neuro vasculature.

The design, materials and available sizes are equivalent to the predicate. Coil composition is identical to that of the predicate(s). Bench testing and biocompatibility testing were summarized for the subject device (section 6). These data clearly establish that the subject Coil is similar to the predicate(s). When used as indicated the Cordis Coil should not raise safety or effectiveness issues which are different from the predicate(s).

5. Biocompatibility

Biocompatibility testing was performed on (b)(4) (b)(4) sterilized coils in accordance with the ISO-10993 (b)(4) for the subject device predicate. The data submitted for the predicate Coil demonstrated that the subject device is nontoxic and biocompatible as summarized in section 6. All (b)(4) data (not provided) were summarized in tabular form and the data referenced in the predicate document (K961923).

6. Sterilization

The coils will be sterilized utilizing a valid (b)(4) Validation and assurance levels are similar to that of the predicate sterilization method. The validation method is based upon the (b)(4) (b)(4) (b)(4). The SAL for all coils was (b)(4). The sterilization methods for the subject Coil have not been changed and are the same as that described for the predicate 510(k)(section 8).

-5-

7. SMDA information

The Sponsor has not submitted a summary of safety and effectiveness for the class III Cordic Coil. The file will be placed on hold until the requested information is provided. A summary of safety and effectiveness this type of device and the literature which the summary is based upon is provided (attachment A).

510(k) Decision Making Documentation

1. Is the product a device? Yes.
2. Is the device subject to 510(k)? Yes.
3. Is the new device compared to a legally marketed device? Yes.

Does the new device have the same indication statement? No.
4. Do the differences alter the intended therapeutic/diagnostic/etc? No.
5. Does the new device have the same technological characteristics (e.g., design, materials, etc.)? Yes.
7. Are the descriptive characteristics precise enough to ensure equivalence. No.
10. Are performance data available to assess equivalence? Yes.
11. Performance data demonstrate equivalence? Yes.

Recommendation: Substantial Equivalence



A handwritten signature in cursive script, followed by the date "2/22/09".

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

December 28, 1998

CORDIS ENDOVASCULAR SYSTEMS, INC. 510(k) Number: K983483
14000 N.W. 57TH CT. Product: VASCULAR
MIAMI LAKES, FL 33014 OCCLUSION SYSTEM
ATTN: MARTINE D. SCHNEIDER

The additional information you have submitted has been received.

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

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

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

Sincerely yours,

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

K983483/S1

FDA/CDRH/OCE/DMD

24 Dec 98 10 17

Cordis

a Johnson & Johnson company

ENDOVASCULAR

December 21, 1998

Dr. John Karanian
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-450)
9200 Corporate Boulevard
Rockville, Maryland 20850

14000 N.W. 57th Court
Miami Lakes, FL 33014
Phone (305) 512-6500
Fax (305) 512-6480

Mailing Address:
P.O. Box 025700
Miami, FL 33102-5700

RECEIVED

Reference: Cordis Endovascular Systems, Inc. Vascular Occlusion System, K983483, dated 10/5/98.

Dear: Dr. Karanian,

Purpose: As per your previous request on December 18th, attached is our Class III Summary and Citation, Bibliography and Class III Certification Statement for K983483 for Cordis Endovascular Vascular Occlusion System for peripheral indication. You can attach the new attachments I and J as part of K983483.

Class III Summary and Citation A Class III Summary and Citation describing the literature search performed to support the peripheral indication for the Vascular Occlusion System is included in the following pages.

Bibliography The bibliography is included in Attachment I.

Class III Certification Statement The Class III Certification Statement is included in Attachment J.

For additional information Thank you in advance for allowing us to submit this information without stopping the review process. If there are any questions, please contact Maritza Celaya at (305) 512-6546, since I'm relocating to Jacksonville, Florida to work for Vistakon, a Johnson and Johnson company. If she is not available, you can contact Alina Caraballo, Regulatory Affairs Manager at (305) 512-6518. The fax number is (305)512-6520.

Sincerely, Martine D. Martino, Sr. Regulatory Affairs Associate

Martine Martino

JK-13

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Class III Summary and Citation

Background Information

The documented use of pushable coils for embolization dates prior to 1976.

- A comprehensive summary of published literature identifying relevant clinical information supporting the use of microcoils to treat neurovascular malformations (lesions) in humans was included with #K964367, concurred 1/30/97.
- A comprehensive summary of published literature identifying relevant clinical information supporting various diseases (lesions) including AVFs that may be successfully treated with pushable coil embolization was included in K972881, concurred 6/4/98. In addition relevant clinical information supporting long term use of pushable coils was included and concurred in K972881.

Introduction and Purpose

Currently, the CES Vascular Occlusion System is cleared for use in the intravascular management of Arteriovenous Malformations (AVMs), Arteriovenous Fistulas (AVF), other vascular lesions in the neurovasculature (brain, spinal cord and spine) and for long term use. The purpose of this summary is to provide a more focused review of the literature to support expanding the indications for use of the product to include :

- Expand the indications for use in the peripheral vasculature

Continued on next page

Class III Summary and Citation, Continued

Use in the Peripheral Vasculature

Included in Attachment H of K983483, submitted on 10/5/98 is a summary of 17 journal articles documenting the successful use of coils to specifically treat arteriovenous malformations, arteriovenous fistulas and other vascular lesions found in the **peripheral vasculature**.

Background

Originally, the CES Vascular Occlusion System was cleared for use in the neurovasculature via 510 (k) K974367 (concurrent 1/30/97). Complications associated with lesions in the peripheral vasculature are similar to those which occur in the neurovasculature. A list of these complications reported in the literature and a benefit/risk analysis is included with K964367 (concurrent 1/30/97). Subsequently the Vascular Occlusion System was cleared for use for AVFs and long term use via K972881 (concurrent 6/4/98).

The individual journal article summaries and the full journal articles are located in Attachment H and the Bibliography in Attachment I. The Class III Certification is located in Attachment J.

Attachment I - Bibliography

Bibliography

This section provides the bibliography for the 17 journal articles documenting the use of pushable coils in the peripheral vasculature included in Attachment H.

1. **Barnwell SL, Halbach VV, Dowd CF, Higashida RT, and Hieshima GB. Endovascular Treatment of Scalp Arteriovenous Fistulas Associated with a Large Varix. Radiology. 173(2): 533-539, 1989.**

2. **Beaujeux R, Saussine C, Al-Fakir A, Boudjema K, Roy, Jacqmin D, and Bourjat P. Superselective Endo-Vascular Treatment of Renal Vascular Lesions. Journal of Urology. 153(1): 14-17, 1994.**

3. **Cikrit DF, Daising MC, Lalka SG, Fiore NF, Sawchuck AP, Ladd AP, and Solooki B. Early Results of Endovascular-Assisted In Situ Saphenous Vein Bypass Grafting. Journal of Vascular Surgery. 19(5): 778-787. 1994.**

4. **Finnegan MF, Tisnado J, Bexirdjian DR, and Cho S-R. Transcatheter Embolotherapy of Massive Bleeding After Surgery for Benign Gynecologic Disorders. Journal De. L'Association Canadienne Des Radiologistes. 39(3): 172-177, 1998.**

5. **Hendrickx P, Orth G, and Grunert G-H. Long-Term Survival After Embolization of Potentially Lethal Bleeding Malignant Pelvic Tumours. The British Journal of Radiology. 68(816): 1336-1343.**

6. **Kuroiwa T, Hasuo K, Mizushima A, Yoshida K, Hirakata R, Komatsu K, Yamaguchi A, and Masuda K. Transcatheter Embolization of Testicular Vein for Varicocele Testis. Acta Radiologica. 32(4): 311-314, 1991.**

7. **McDermott VG, England RE, and Newman GE. Case Report: Bleeding Gastric Varices Secondary to Splenic Vein Thrombosis Successfully Treated by Splenic Artery Embolization. The British Journal of Radiology. 68(812): 928-930, 1985.**

8. **Merimsky E, Papo J, Zaltzman S, and Braf Z. High Ligation or Embolization of Varicocele. Israel Journal of Medical Sciences. 22(12): 877-879, 1986.**

Continued on next page

Attachment I - Bibliography, Continued

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9. Miller RE, Baer KW, Nizin JS, and Pascal RR. Hemorrhagic Pancreatitis: A Complication of Transcatheter Embolization Treated Successfully by Total Pancreatectomy. 149(6): 802-808, 1985.
-
10. Rankin EM, Rubens RD, and Reidy JF. Transcatheter Embolisation to Control Severe Bleeding in Fungating Breast Cancer. European Journal of Surgical Oncology. 14(1): 27-32, 1988.
-
11. Rosenthal D, Herring MB, O'Donovan TG, Cikrit DF, Comerota AJ, and Corson JD. Endovascular Infrainguinal In Situ Saphenous Vein Bypass: A Multicenter Preliminary Report. 16(3): 453-458, 1992.
-
12. Senocak F, Cerkirge S, Senocak ME, Karademir S. Hepatic Artery Aneurysm in a 10-Year Old Boy as a Complication of Infective Endocarditis. Journal of Pediatric Surgery. 31(11): 1570-1572, 1996
-
13. Stambo GW, Hallisey MJ, and Gallaher JJ. Arteriographic Embolization of Visceral Artery Pseudoaneurysms. Annals of Vascular Surgery. 10(5): 476-480, 1996.
-
14. Suzumiya J, Nagano M, Higashihara H, Yoshida T, Hirano M, Go Y, Morloka E, Kimura N, Hisano S, Okazaki M, Kikuchi M, and Okumura M. Hemorrhage of Emergency Abdominal Non-Hodgkins Lymphoma Treated Successfully by Emergency Transcatheter Arterial Embolization. American Journal of Hematology. 52(3): 201-204, 1996.
-
15. Tarazov PG, Polysalov VN, and Ryzhkov VK. Transcatheter Treatment of Splenic Artery Aneurysms (SAA). Journal of Cardiovascular Surgery. 32(1): 128-131, 1991.
-
16. Teitalbaum GP, Halbach VV, Fraser KW, Larsen DW, McDougall CG, Higashida RT, Dowd CF, and Hieshima GB. Direct-Puncture Coil Embolization of Maxillofacial High-Flow Vascular Malformations. Laryngoscope. 104(11 Pt. 1): 1397-1400, 1994.
-

Continued on next page

Attachment I - Bibliography, Continued

-
- 17. Theobald MR, Contractor EM, Kiproff PM, Khoury MB, and Chao SH. Embolization of a Renal Transplant Pseudoaneurysm Following Angiolipoma Resection. *Angiology*. 45(9): 817-821, 1994.**
-

Attachment J – Class III Certification

I certify, in my capacity as a Sr. Regulatory Affairs Associate of Cordis Endovascular Systems, Inc., that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the occlusion coils. I further certify that I am aware of the types of problems to which the occlusion coils are susceptible and that, to the best of my knowledge, the following summary of the types of causes of safety or effectiveness problems about the occlusion coils is complete and accurate.

Martine D. Martino
Martine Martino
Sr. Regulatory Affairs Associate

12/21/98
Date

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

December 21, 1998

CORDIS ENDOVASCULAR SYSTEMS, INC. 510(k) Number: K983483
14000 N.W. 57TH CT. Product: VASCULAR
MIAMI LAKES, FL 33014 OCCLUSION SYSTEM
ATTN: MARTINE D. SCHNEIDER

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

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

Sincerely yours,

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Reviewer(s) - Name(s) John Karanian
Subject: 510(k) Number K 983483

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

- Refused to accept.
- Requires additional information (other than refuse to accept)
- Accepted for review
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

Phone Hold
Bl: 17 Dec 98

- De Novo Classification Candidate? YES NO
- Other (e.g., exempt by regulation, not a device, duplicate, etc.) YES NO
- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? YES NO

- This 510(k) contains:
 - Truthful and Accurate Statement Requested Enclosed (required for originals received 3-14-95 and after)
 - A 510(k) summary OR A 510(k) statement
 - The required certification and summary for class III devices
 - The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

No, Phone Hold

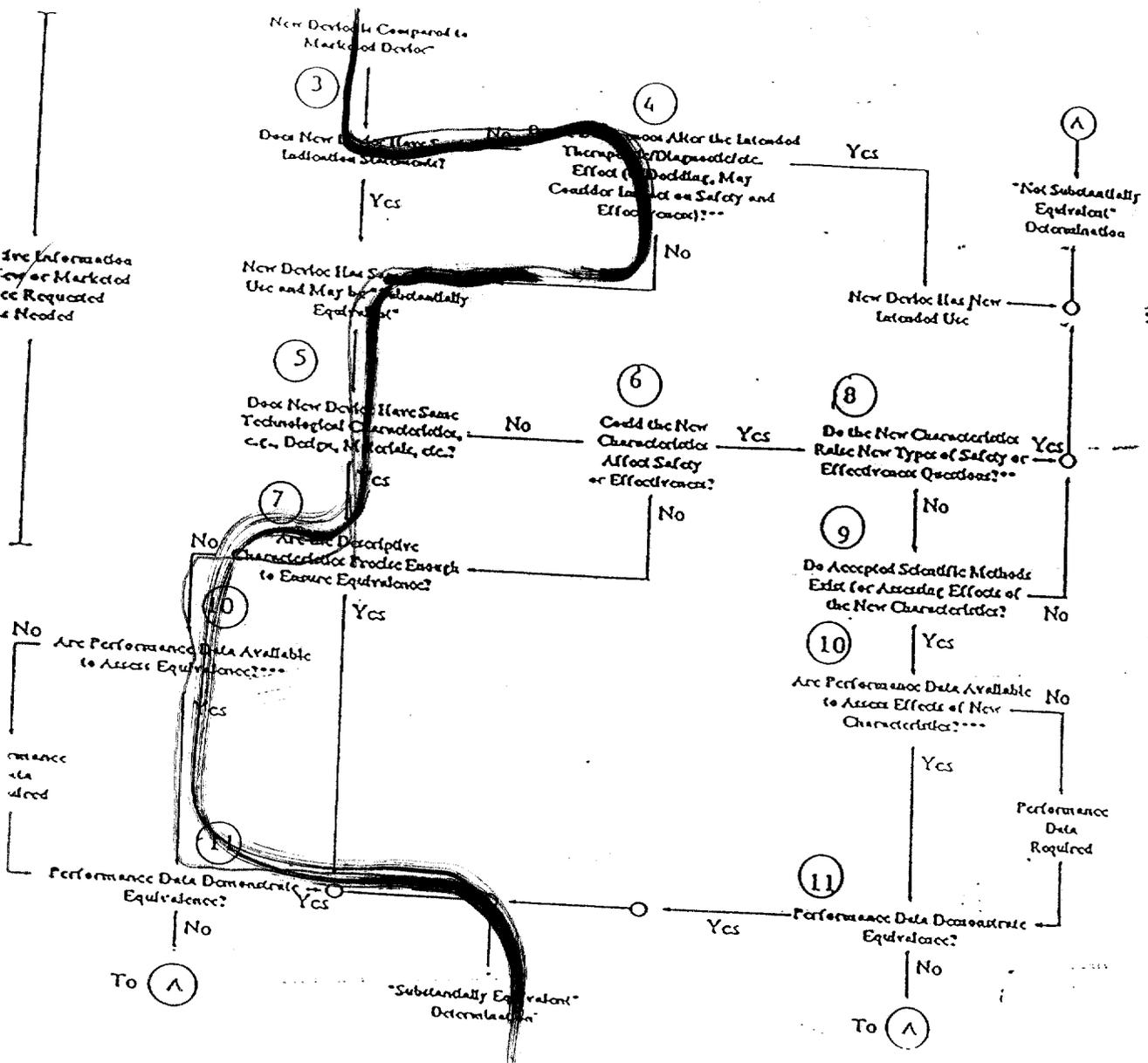
The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Class III, P4 MCG Additional Product Code(s) with panel (optional):

Signature: _____ (Branch Chief)
Signature: _____ (Branch Code) _____ (Date)
Review: _____ Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Signature: _____ (Division Director)

22

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



1) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear. Decision is normally based on descriptive information alone, but limited testing information is sometimes required. may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

DATE: December 11, 1998

FROM: JOHN W. KARANIAN, CDRH, ODE, DCRND, CSPDG

TO: File: K983483
Firm: Cordis Endovascular Systems, Inc.
Device: Vascular Occlusion System
Class: 21CFR 882.5950 Occlusion Coil, Artificial
Embolization Device, Class III, 84 HCG

SUBJECT: Phone hold (Substantially Equivalent)

The sponsor did not provide a class III summary. The sponsor was notified by phone (12/16/98) that the document will be placed on hold until the required information is provided (estimated 1/5/99).

Device/Application Summary

The Cordis Vascular Occlusion System is currently cleared for use in neuro vascular indications (K964367 and K972881) and may be considered similar to other occlusion coils cleared for use in the peripheral vasculature. The purpose of the present submission is to expand the indications to include the **peripheral vasculature**. The design, performance, materials, manufacturing and sterilization processes for the subject device remain unchanged from that of the predicate devices. The document may be considered equivalent to the predicate.

The Vascular Occlusion System consists of straight and shaped TRUFILL Pushable Coils and the TRUPUSH Coil Pusher (contains 1-2 radiopaque markers). The coils are made of platinum alloy and synthetic fibers. The pushable coils are designed for use under flouroscopy with microcatheters which have a minimum 0.21" inner diameter. These coils may also be considered similar to Target's pushable Platinum Occlusion coils (K901721), and the Cook Company Occlusion Coils

-2-

(K901337), cleared for use in both the peripheral and neurovasculature. The delivery method is via a mechanical push rod which has been cleared for use and performed safely in fragile neuro vasculature and cerebral aneurysms during clinical studies. In K961923 the Cordis coil was found to be substantially equivalent to currently marketed Target and Cook coils for use in both neuro and peripheral vasculature. With the provision of adequate comparative and performance data, and existing clinical data (K964367, K972881), the data base supports the expansion of Cordis's indications for use to include peripheral indications.

Submission Contents

1. Descriptive Information

A platinum alloy wire is wound into a primary coil and formed into a secondary helical or curved shape. The coils are designed to be delivered by catheter using a push rod at the target site. The coils are provided loaded on an Introducer for transfer into a delivery catheter. The coils are radiopaque for flouro visualization. The coils are available in four shapes (i.e., straight, c-shaped, complex and flat spiral) and a range of sizes (2-15l x 3-10d).

All component materials, dimensions, features and functional specifications are described in tabular form with drawings (section 3). The intended use for the coil will be expanded to include arterial and venous embolizations of malformations and fistulas in the peripheral vasculature. Indications for use are adequately compared to the predicates (attachment E).

2. Performance

Adequate *in vitro* performance testing has been performed on the subject device for previous submissions (K964367 and K972881) and described in section 7. All test data was summarized: **Functional bench testing** was performed on the Coil and adequately demonstrated the safety, effectiveness and performance integrity. The **forces** required to advance and retract the coil through a catheter were defined

-3-

and established the standard for setting minimum specifications and evaluating the (b)(4) of the Coil. These tests demonstrate that the Coil can be delivered through the selected catheter without consequence using a range of pressures. (b)(4) (b)(4) (b)(4) testing demonstrated the Coil's ability to perform well with recommended microcatheters. The (b)(4) were well (b)(4) the catheters tested.

Animal testing was not performed for the new indication for use. Given the significant commercial use of these and related coils in the clinical treatment of neuro and peripheral vascular malformations, the lack of animal data may be considered acceptable for this application.

3. Labeling and instructions for use

Labeling and instructions for use were provided (section 4 and attachment D) and adequately compared to the cited predicates for neuro and peripheral use (attachment F and G). The labeling for the Cordis Coil is similar to that of the predicate Coil with the expanded indication for use. The Instructions for Use are complete and clear regarding the intended use and instructions for operation.

4. Comparison Information

In general the information as provided suggest equivalence. The Cordis Coil is considered similar to the predicates for neuro use (K972881) and pushable Platinum Occlusion coils (K901337 and K901721) cleared for use in both the peripheral and neurovasculature (see indications for use comparison chart, section 6, pg 21). The delivery method for the Coil has been cleared for use and performed safely in fragile neuro vasculature and cerebral aneurysms during clinical use (K972881). With the provision of adequate comparative (and performance) data, and existing clinical use the data base supports the expansion of Cordis's indications for use for the Coil to include peripheral indications.

Predicate device labeling was compared and demonstrated equivalence to that of the present submission (with expanded indications). The

16

-4-

physical characteristics of the Coil have not been changed as described in the predicate 510Ks. The anatomical sites for Coil therapy are certain aneurysms and other vascular malformations (i.e., AVMs, AVFs) of the peripheral and neuro vasculature.

The design, materials and available sizes are equivalent to the predicate. Coil composition is identical to that of the predicate(s). Bench testing and biocompatibility testing were summarized for the subject device (section 6). These data clearly establish that the subject Coil is similar to the predicate(s). When used as indicated the Cordis Coil should not raise safety or effectiveness issues which are different from the predicate(s).

5. Biocompatibility

Biocompatibility testing was performed on (b)(4) (b)(4) sterilized coils in accordance with the ISO-10993 (b)(4) for the subject device predicate. The data submitted for the predicate Coil demonstrated that the subject device is nontoxic and biocompatible as summarized in section 6. All (b)(4) data (not provided) were summarized in tabular form and the data referenced in the predicate document (K961923).

6. Sterilization

The coils will be sterilized utilizing a valid (b)(4). Validation and assurance levels are similar to that of the predicate sterilization method. The validation method is based upon (b)(4) (b)(4) (b)(4). The SAL for all coils was (b)(4). The sterilization methods for the subject Coil have not been changed and are the same as that described for the predicate 510(k)(section 8).

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-5-

7. SMDA Information

The Sponsor has not submitted a summary of safety and effectiveness for the class III Cordic Coil. The file will be placed on hold until the requested information is provided. A summary of safety and effectiveness this type of device and the literature which the summary is based upon is provided (attachment A).

510(k) Decision Making Documentation

- 1. Is the product a device? Yes.**
- 2. Is the device subject to 510(k)? Yes.**
- 3. Is the new device compared to a legally marketed device? Yes.**
Does the new device have the same indication statement? No.
- 4. Do the differences alter the intended therapeutic/diagnostic/etc? No.**
- 5. Does the new device have the same technological characteristics (e.g., design, materials, etc.)? Yes.**
- 7. Are the descriptive characteristics precise enough to ensure equivalence. No.**
- 10. Are performance data available to assess equivalence? Yes.**
- 11. Performance data demonstrate equivalence? Yes.**

Recommendation: phone hold (Substantial Equivalence)

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name: <i>Vascular Occlusion System</i>					K983483	
Submitter (Company): <i>Cordis Endovascular Systems, Inc.</i>						
Items which should be included (circle missing & needed information)	S P E C I A L	A B B R E V I A T E D		T R A D I T I O N A L		✓ IF ITEM IS NEEDED AND IS MISSING
		YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as:						
a) "Special 510(k): Device Modification"						
b) "Abbreviated 510(k)"						
c) <u>Traditional 510(k)</u>						
GO TO # 2,4		GO TO # 3,4,5		GO TO # 4,5	✓	
2. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE						
a) Name & 510(k) number of legally marketed (unmodified) predicate device						
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*						
* If no - STOP not a special						
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*						
* If no - STOP not a special						
d) Design Control Activities Summary						
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis						
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied						
iii) A declaration of conformity with design controls. The declaration of conformity should include:						
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met						
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.						

→ → → CONTINUE TO SECTION 4 ← ← ←

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

→ → → CONTINUE TO SECTION 4 ← ← ←

4. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							✓ IF ITEM IS NEEDED AND IS MISSING
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, address of manufacturer, device class					✓		
b) OR a statement that the device is not yet classified	FDA - may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				NA		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)					✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)					NA		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:							
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)					✓		
m) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) labeling					✓		
ii) intended use					✓		
iii) physical characteristics					✓		
iv) anatomical sites of use					✓		
v) performance (bench, animal, clinical) testing	NA				✓		
vi) safety characteristics	NA				✓		
n) If kit, kit certification							
5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material					✓		
ii) identify patient-contacting materials					✓		
iii) biocompatibility of final sterilized product					✓		
b) Sterilization and expiration dating information:							
i) sterilization method					✓		
ii) SAL					✓		
iii) packaging					✓		
iv) specify pyrogen free					✓		
v) ETO residues					✓		
vi) radiation dose					✓		
c) Software validation & verification:							
i) hazard analysis					NA		
ii) level of concern							
iii) development documentation							
iv) certification							

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

Passed Screening Yes No
 Date: 11/24/98

Reviewer: Jenna F. Smallwood
 Concurrence by Review Branch: _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

October 05, 1998

CORDIS ENDOVASCULAR SYSTEMS, INC.
14000 N.W. 57TH CT.
MIAMI LAKES, FL 33014
ATTN: MARTINE D. SCHNEIDER

510(k) Number: K983483
Received: 05-OCT-1998
Product: VASCULAR OCCLUSION
SYSTEM

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

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

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

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

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14983483

October 2, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA/CDRH/OCE/DID
5 Oct 98 10
Cordis
a Johnson & Johnson company
ENDOVASCULAR
Cordis Corporation
4000 N.W. 57th Court
Miami Lakes, FL 33014
Phone (305) 512-6500
Fax (305) 512-6480
Mailing Address:
P.O. Box 025700
Miami, FL 33102-5700

RECEIVED

Reference 1 Cordis Endovascular Systems, Inc. Vascular Occlusion System, K964367 concurred 1/30/97
Reference 2 Cordis Endovascular Systems, Inc. Vascular Occlusion System, K972881 concurred 6/4/98

To Whom It May Concern:

Purpose of the submission In accordance with section 510(k) of the Food, Drug and Cosmetic Act, and in compliance with 21 CFR 807.81, Cordis Endovascular Systems, Inc. (Cordis Endovascular), a subsidiary of Cordis Corporation is submitting this Premarket Notification for a modification to the Vascular Occlusion System, that consists of the TRUPUSH Coil Pusher and TRUFILL Pushable Coils. Cordis Endovascular currently markets their Vascular Occlusion System (Reference 1 and 2). No changes have been made to the currently marketed device except the expanded indications for use:
• Cordis Endovascular would like to expand the indications for use to include the peripheral vasculature.

Device Classification Artificial Embolization Devices are Class II Devices that have been classified within the Division of Cardiovascular, Respiratory, and Neurological Devices.

Required Information Required information immediately follows the Premarket Submission Cover Sheet, with supporting documentation such as attachments including the 510(k) Summary of Safety and Effectiveness, and the Truthful and Accurate Statement.

Confidentiality Statement Cordis Endovascular Systems, Inc. considers our intent to market this device as confidential commercial information and requests it to be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market the device. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331 (q).

For additional information Thank you in advance for your kind consideration of our application. If there are any questions, please contact me at (305) 512-6546, or Alina Caraballo, Regulatory Affairs Manager at (305) 512-6518. The fax number is (305) 512-6520.

Sincerely Martine D. Schneider, Sr. Regulatory Affairs Associate *Martine D. Schneider*

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

0-000004

Date of Submission: October 2, 1998

FDA Document Number:

Section A

Type of Submission

- | | | | |
|--|---|--|---|
| <input checked="" type="checkbox"/> 510 (k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510 (k) Add'l Information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement - 30 day |
| | <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement - Panel Track |

Section B1

Reason for Submission - 510(k)s Only

- | | | | |
|-------------------------------------|--|--|--|
| <input type="checkbox"/> New Device | <input checked="" type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials, or manufacturing process | <input type="checkbox"/> Other reason (specify): |
|-------------------------------------|--|--|--|

Section B2

Reason for Submission - PMAs Only

- | | | |
|---|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component, or specifications: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | | |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| | <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Packager |
| | | <input type="checkbox"/> Distributor |
| <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Process Change: | Report submissions: |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Instructions | <input type="checkbox"/> Sterilizer | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Packager | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Shelf Life | <input type="checkbox"/> Response to FDA correspondence (specify below): | <input type="checkbox"/> Device defect |
| <input type="checkbox"/> Trade Name | | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Other (specify below) | | |
| <input type="checkbox"/> Change in ownership | <input type="checkbox"/> Request for applicant hold | |
| <input type="checkbox"/> Change in correspondent | <input type="checkbox"/> Request for removal of applicant hold | |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Request for extension | |
| | <input type="checkbox"/> Request to remove or add manufacturing site | |

Section B3

Reason for Submission - IDEs Only

- | | | |
|--|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion/extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed Consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Deficient investigator report |
| <input type="checkbox"/> Termination of Study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol - other | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Emergency Use: | <input type="checkbox"/> Report Submission: | <input type="checkbox"/> IOL Submissions only: |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator | <input type="checkbox"/> Change in IOL style |
| <input type="checkbox"/> Additional information | <input type="checkbox"/> Annual progress | <input type="checkbox"/> Request for protocol waiver |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |

FDA Document Number: 0-000005

Section C Product Classification

Product Code: 84HCG	CFR Section: 21 CFR 882.5950	Device Class:
Classification Panel: CARDIOVASCULAR, RESPIRATORY, & NEUROLOGICAL DEVICES		<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified

Section D Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: <input checked="" type="checkbox"/> 510 (k) summary attached
1 HCG	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510 (k) Number	Trade or proprietary or model name	Manufacturer
1 K901337	1 Hilal Embolization Coils with Dacron Fibers	1 Cook, Inc.
2 K901721	2 Helix Shaped Coils with Dacron Fibers	2 Target Therapeutics
3 K964367	3 Vascular Occlusion System	3 Cordis Endovascular Systems, Inc.
4 K972881	4 Vascular Occlusion System	4 Cordis Endovascular Systems, Inc.

Section E Product Information - Applicable to All Applications

Common or usual name or classification name: **Artificial Embolization Device**

Trade or proprietary or model name	Model Number
1 Vascular Occlusion System	1 VARIOUS

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

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

Data included in submission: Laboratory Testing Animal Trials Human Trials

Current Indications (from labeling): The Cordis Endovascular Systems, Inc. Vascular Occlusion System is indicated for use to reduce or block the rate of blood flow in vessels of the neurovasculature for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

Proposed Indications: The Cordis Endovascular Systems, Inc. Vascular Occlusion System is indicated for use to reduce or block the rate of blood flow in vessels of the **peripheral and** neurovasculature. They are intended for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

FDA Document Number: 0-000006

Section F Manufacturing/Packaging/Sterilization Sites

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 1058196	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
---	--	--	---

Company/institution name: **CORDIS ENDOVASCULAR SYSTEMS, INC.**

Division name (if applicable): N/A	Phone number (include area code): (305) 512-6546
--	--

Street address: 14000 NW 57th COURT	Fax number (include area code): (305) 512-6520
--	--

City: MIAMI LAKES	State/Province: FL	Country: USA	ZIP/Postal Code: 33014
-----------------------------	------------------------------	------------------------	----------------------------------

Contact Name/Title: **MARTINE D. SCHNEIDER, SR. REGULATORY AFFAIRS ASSOCIATE**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: (b)(4)	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input checked="" type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/ relabeler
---	---	---	---

Company/institution name: **(b)(4)**

Division name (if applicable): N/A	Phone number (include area code): ()
---	--

Street address: (b)(4)	Fax number (include area code): ()
-------------------------------	--

City: (b)(4)	State/Province: (b)	Country: (b)	ZIP/Postal Code: (b)
---------------------	----------------------------	---------------------	-----------------------------

Contact Name: **PLEASE CONTACT SPONSOR FOR INQUIRIES**

Contact Title: **MARTINE D. SCHNEIDER, SR. REGULATORY AFFAIRS ASSOCIATE**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: (b)(4)	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input checked="" type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/ relabeler
---	---	---	---

Company/institution name: **(b)(4)**

Division name (if applicable): N/A	Phone number (include area code): ()
---	--

Street address: (b)(4)	Fax number (include area code): ()
-------------------------------	--

City: (b)(4)	State/Province: (b)	Country: (b)	ZIP/Postal Code: (bb)
---------------------	----------------------------	---------------------	------------------------------

Contact Name: **PLEASE CONTACT SPONSOR FOR INQUIRIES**

Contact Title: **MARTINE D. SCHNEIDER, SR. REGULATORY AFFAIRS ASSOCIATE**

FDA Document Number: 0-000007

Section G Applicant or Sponsor

Company/institution name: **CORDIS ENDOVASCULAR SYSTEMS, INC.** FDA establishment registration number: **1058196**

Division name (if applicable): **N/A** Phone number (include area code): **(305) 512-6546**

Street address: **14000 NW 57TH COURT** Fax number (include area code): **(305) 512-6520**

City: **MIAMI LAKES** State/Province: **FL** Country: **USA** ZIP/Postal Code: **33014**

Signature: *Martine D. Schneider* 10/2/98

Name: **MARTINE SCHNEIDER, SR. REGULATORY AFFAIRS ASSOCIATE**

Section H Submission correspondent (if different from above)

Company/Institution Name:

Division Name(if applicable): Phone number (include area code):

Street address: Fax number (include area code):

City: State/Province: Country: ZIP/Postal Code:

Contact Name:

Contact Title:

Section 1 - General Information

General Information

Trade name The trade name of the Vascular Occlusion System is:

- TRUFILL™ Pushable Coils
- TRUPUSH™ Coil Pusher

Common Name The common names are:

- Platinum Fibered Coils
- Microcoils or Minicoils
- And Coil Pusher
- These are all Artificial Embolization Devices

Site Information The following table lists the manufacturing and sterilization site information.

Site	Address	Establishment Registration Number
Manufacturer: Cordis Endovascular Systems, Inc.	14000 NW 57th Court Miami Lakes, Florida 33014	1058196
Sterilization Site: (b)(4)	(b)(4)	
Alternate Sterilization Site: (b)(4)		

Device class and Appropriate Panel Artificial Embolization Devices have been classified as Class II, 21 CFR 882.5950 (84HCG), which have been classified within the Division of Cardiovascular, Respiratory, and Neurological Devices.

Continued on next page

General Information, Continued

Reason for the Submission

Cordis Endovascular Systems, Inc. (Cordis Endovascular) submits this 510(k) to obtain concurrence from FDA to modify the indications for use of the Vascular Occlusion System. The current indications are:

- The Vascular Occlusion System is indicated for use to reduce or block the rate of blood flow in vessels of the neurovasculature for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

The current indications will be modified to include an indication for use in the **peripheral** vasculature. Therefore, the new indications for use are:

- The Vascular Occlusion System is indicated for use to reduce or block the rate of blood flow in vessels of the **peripheral and** neurovasculature. They are intended for use for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

The design, performance, materials, manufacturing and sterilization processes for the devices submitted herein remain unchanged from those of the currently marketed Vascular Occlusion System.

Predicate Devices

The predicate devices are listed in the table below.

Device	Company	510 (k) Number/ Concurrence Date	Product Code	Predicate for:
Hilal Embolization Microcoil	Cook, Inc.	K901337/ November 9, 1990	84HCG	Indications and Claims
Helix Shaped Coils with Dacron Fibers	Target Therapeutics	K901721/ January 8, 1991	84HCG	Indications and Claims
Vascular Occlusion System	Cordis Endovascular Systems, Inc.	K964367/ January 30, 1997	84HCG	Design, Manufacturing, Sterilization, Packaging
Vascular Occlusion System	Cordis Endovascular Systems, Inc.	K972881/ June 4, 1998	84HCG	Intended Use, Design, Manufacturing, Sterilization, Packaging

Continued on next page

0-000010

General Information, Continued

**Performance
Standards**

There are no performance standards applicable under Section 514 of the Food, Drug and Cosmetic Act for Artificial Embolization Devices.

Section 2 - Summary & Certification

Summary & Certification

**510 (k)
Summary**

The 510 (k) Summary of Safety and Effectiveness is included in **Appendix A.**

**Kit
Certification**

A kit certification is not applicable for the Vascular Occlusion System.

**Truthful and
Accuracy
Statement**

The Truthful and Accuracy Statement is included in **Appendix B.**

**Indications for
Use Statement**

The Indications for Use Statement is included in **Appendix C.**

**Class III
Summary,
Citation and
Certification**

A Class III Summary and Citation is not applicable for Class II Devices.

Section 3 - Device Description

Device Description

Introduction There are no changes being made to the currently marketed Vascular Occlusion System (via K964367 and K972881) design, materials, manufacturing processes, sterilization, and packaging.

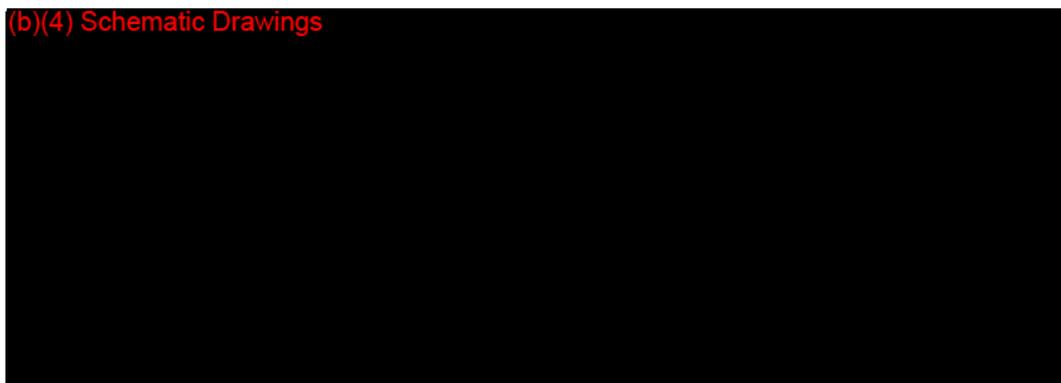
Device Description The following components make up the Vascular Occlusion System:

- TRUFILL Pushable Coils
- TRUPUSH Coil Pusher

Description of TRUFILL Pushable Coils There are no changes being made to the description of the currently marketed Pushable Coils:

- The TRUFILL Pushable Coils consist of straight and complex shaped pushable coils. The TRUFILL Pushable Coils are offered in various sizes and shapes and in standard or extra-fibered configurations.
- These devices consist of a coiled Platinum (b)(4) wire with rounded ends. The coil is securely fitted with (b)(4) fibers in between the windings.
- The diagram below illustrates the straight Pushable Coil configuration.

(b)(4) Schematic Drawings

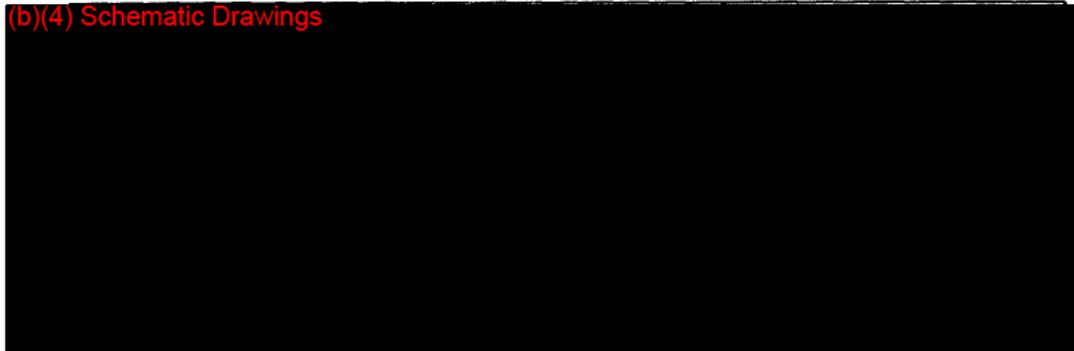


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Device Description, Continued

**TRUFILL
Pushable Coil
Packaging
Description**

There are no changes being made to the currently marketed Pushable Coil packaging. The TRUFILL Pushable Coils are packaged inside an introducer tube and shipped with a (b)(4) stylet as illustrated below.



**TRUFILL
Pushable Coil
Shapes and
Sizes**

There are no changes being made to the currently marketed Pushable Coil shapes and sizes. The TRUFILL Pushable Coils are available in the shapes and sizes listed in the table below.

Shape	Coil Size Range
Straight	2 – 15mm long
C-Shaped	3 – 11mm diameter
Complex	3 – 10mm diameter
Flat Spiral	3 – 10mm diameter

Continued on next page

Device Description, Continued

**Shape
Comparison
Diagram**

There are no changes being made to the currently marketed Pushable Coil shapes. The shapes of the TRUFILL Pushable Coils and the predicate devices manufactured by Cook, Inc. and Target Therapeutics are similar.

**TRUPUSH Coil
Pusher
Description**

There are no changes being made to the currently marketed Coil Pusher.

- The TRUPUSH Coil Pusher consists of a one-piece, (b)(4) corewire with a (b)(4) sleeve shrunk over the length of its taper to provide enhanced lubricity through the microcatheter delivery systems.
 - The distal tip portion of the (b)(4) corewire is sheathed with tapered, (b)(4) coils that overlay a radiopaque platinum marker.
 - The proximal end of the (b)(4) coil and the platinum marker are bonded to the (b)(4) corewire with adhesive.
 - The distal end of the (b)(4) coil is soldered to the (b)(4) corewire.
-

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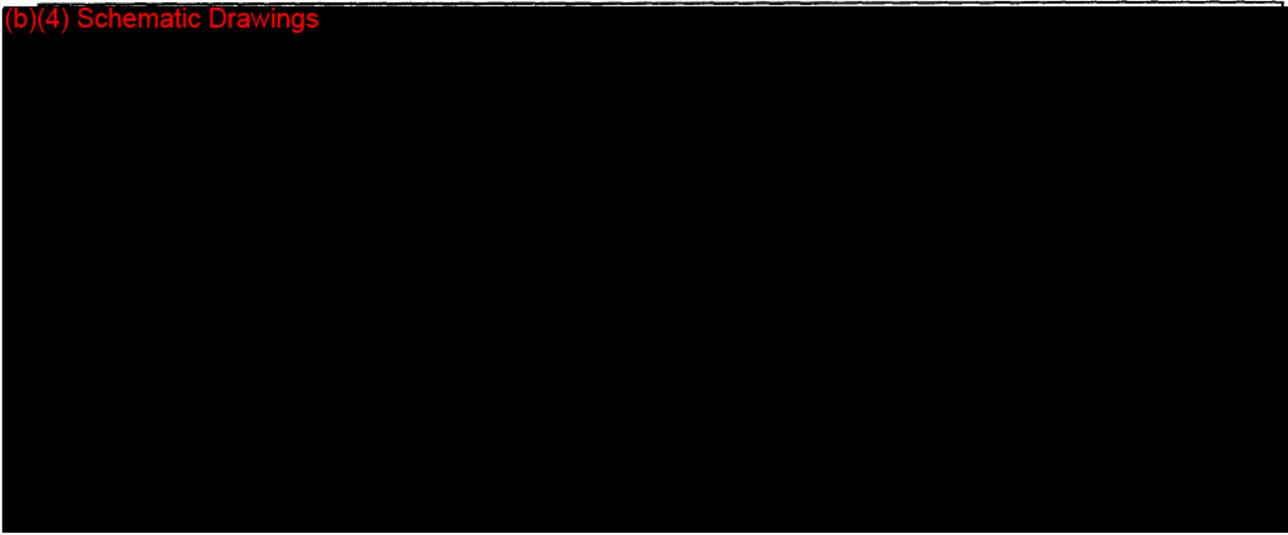
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Device Description, Continued

TRUPUSH Coil Pusher Configurations There are no changes being made to the currently marketed Coil Pusher configurations. The TRUPUSH Coil Pusher is available in both single and dual marker configurations. The dual marker configuration has a second radiopaque marker soldered to the corewire just proximal to the (b)(4) coil and 3cm proximal to the distal tip marker.

- **Single Marker Coil Pusher**

(b)(4) Schematic Drawings

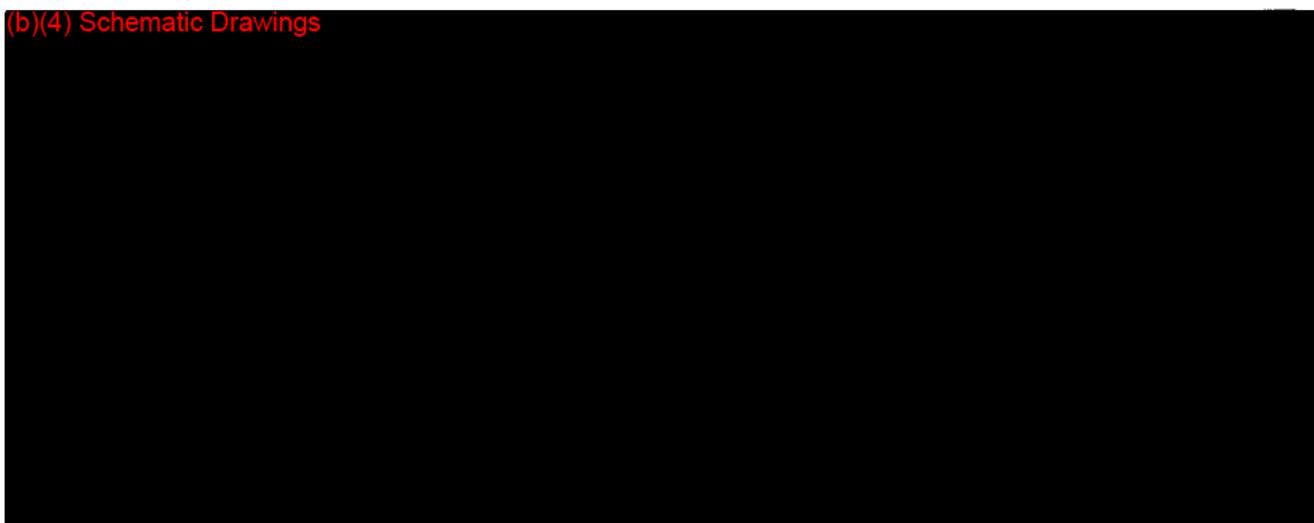


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Device Description, Continued

- **Dual Marker Coil Pusher**

(b)(4) Schematic Drawings



Continued on next page

Device Description, Continued

How the Vascular Occlusion System Works

There are no changes being made to the currently marketed Vascular Occlusion System. The Vascular Occlusion System works as described in the table below:

Step	Action
1	Based on superselective angiograms of the target lesion (indicating vessel size and hemodynamic conditions), select appropriate coil size and configuration to be delivered.
2	Insert the introducer tube tip in the hub of the microcatheter.
3	Introduce the coil slowly in the microcatheter using the stylet.
4	Remove the stylet and discard along with the introducer.
5	Thread the distal (floppy) end of the coil into the microcatheter.
6	Advance the coil with the coil pusher under fluoroscopy. Never advance the coil pusher beyond the microcatheter tip. The diagram below illustrates this process at this point, where the coil is about to exit the microcatheter and be deposited into the desired vessel space
7	Remove (withdraw) the coil pusher after the coil has exited the microcatheter completely and is deposited. Repeat this process to deliver multiple coils.

(b)(4) Schematic Drawings



Biocompatibility

No material changes have been made to the Vascular Occlusion System (TRUFILL Pushable Coils and TRUPUSH Coil Pushers) included in this submission. The materials are identical to materials previously concurred for the Vascular Occlusion System and all applicable biocompatibility testing was successfully performed and included in K964367.

Section 4 - Proposed Labeling

Proposed Labeling

Package Labels	There are no changes being made to the outer box and inner pouch labels previously cleared by FDA for the Vascular Occlusion System (via K972881). Sample copies of representative TRUFILL Pushable Coils and TRUPUSH Coil Pusher labels are located in Appendix D .
Instructions for Use (IFUs)	The Vascular Occlusion System IFUs will be revised to included the peripheral indication as listed in the "Statement of Intended Use" below.
Statement of Intended Use	The Vascular Occlusion System is indicated for use to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for the interventional radiologic management of aneurysms, arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.
Advertisements or Promotional Materials	Product advertisement/promotional materials have not yet been developed.

Section 5 – Predicate Device Information

Predicate Device Information

Vascular Occlusion System

A copy of the Indications for Use Statement and the IFUs for the currently marketed Vascular Occlusion System (via K972881) is included in **Appendix E**.

Target Therapeutics Helix Shaped Coil with Dacron Fibers

A copy of the Instructions for Use (IFUs) and promotional literature for this predicate device is included in **Appendix F**.

Cook, Inc. Hilal Embolization Microcoil

A copy of the IFUs and promotional literature for this predicate device is included in **Appendix G**.

Section 6 – Justification for Expanding Indications for Use

to include the Peripheral Vasculature and Predicate Device Summary

Introduction There are no changes being made to the currently marketed Vascular Occlusion System design, materials, manufacturing processes, sterilization, and packaging. The TRUFILL Pushable Coils were found to be substantially equivalent to the currently marketed Vascular Occlusion System, the Target Therapeutics Fibered Helical Coils, and the Cook, Inc. Hilal Embolization Microcoils in design, materials, manufacturing processes, and intended use.

Purpose The purpose of this section is to provide justification and support for expanding the Vascular Occlusion System indications for use in the peripheral vasculature. Immediately following is supporting information included:

- A comparison of indications for use
- A comparison of physical characteristics
- A summary of similarities and differences
- A justification summary is located at the end of this section.

Physical and Performance Characteristics Cordis Endovascular conducted in-vitro testing on the currently marketed Vascular Occlusion System to compare their performance with that of the predicate devices. The testing results summarized in Section 8 demonstrate that the physical characteristics (b)(4) and performance characteristics (b)(4) were shown to be substantially equivalent. To facilitate review, a table comparing the physical characteristics of the currently marketed Vascular Occlusion System and the predicate devices is included later in this section.

Comparison of Indications and Claims The TRUFILL Pushable Coils have similar indications for use/claims to the predicate devices. A comparison of indications/claims and similarities and differences between these devices is included in the following table.

Continued on next page

Justification for Expanding Indications for Use to include the Peripheral Vasculature and Predicate Device Summary,

Continued

Comparison of Indications and Claims (continued)

Device	Indications/Claims
Vascular Occlusion System (this 510(k) submission)	The Vascular Occlusion System may be used to block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for the interventional radiologic management of arteriovenous malformations (AVMs), arteriovenous fistulas (AVFs), and other vascular lesions of the brain, spinal cord, and spine.
Cook, Inc. Hilal Embolization Microcoil (K901337)	For embolization of selective vessel supply to AVMs and other vascular lesions of the brain, spinal cord, spine, and other small vessel applications.
Target Therapeutics Fibered Helical Coil (K901721)	To obstruct or reduce the rate of blood flow in the peripheral and neurovasculature for the interventional management of AVMs and AVFs when devascularization prior to surgical resections is required.
Vascular Occlusion System (K972881)	The Vascular Occlusion System may be used to block the rate of blood flow in vessels of the neurovasculature for the interventional radiologic management of AVMs, AVFs, and other vascular lesions of the brain, spinal cord, and spine.

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Justification for Expanding Indications for Use to include the Peripheral Vasculature and Predicate Device Summary,

Continued

Comparison of Physical Characteristics The table below compares the physical characteristics of the TRUFILL Pushable Coils with the predicate devices.

Physical Characteristic	TRUFILL Pushable Coils (K972881, K964367)	Target Therapeutics Helical Fibered Coil (K901721)	Cook, Inc. Hilal Embolization Microcoil (K901337)
Labeling Configuration and Sizes	2-15mm Straight 3-11mm C-Shape 3-10mm Complex 3-10mm Flat Spiral	2-5mm Straight 2-4mm Curled 2-10mm Complex Helical	5-15mm Straight 3-10mm Single Curled 3-10mm Multi-Curled
Extended Length (Inside Introducer)	2-100mm	2-100mm	5-70mm
Coil Material	Platinum (b)(4)	Platinum (b)(4)	Platinum (b)(4)
Fiber Material	(b)(4) b	(b)(4) b	(b)(4)
Wire Diameter	.003"	.003"	.004"
Wound Coil Diameter	.014"	.014"	.014"
Distal End	Platinum Round	Platinum Round	Platinum Round
Proximal End	Platinum Round	Platinum Round	Cut Flat Open

Summary of Similarities and Differences

The only difference between the currently marketed TRUFILL Pushable Coils and the predicate devices described in this submission is the additional indication for use for the peripheral vasculature. The design, performance, materials, manufacturing processes, and sterilization remain unchanged.

Supporting Information

Supporting information for adding the peripheral indication is included in **Appendix H**. A summary of published journal articles documenting the successful use of pushable coils in the peripheral vasculature and copies of the journal articles are included in **Appendix H**.

Continued on next page

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Justification for Expanding Indications for Use to include the Peripheral Vasculature and Predicate Device Summary,

Continued

Justification Summary

Based on the supporting information included or referenced previously in this Section, justification for adding use in the peripheral vasculature as an alternate indication is listed below:

- Testing demonstrated that the TRUFILL Pushable Coils performed similar to, or better than, the Target Therapeutics Helix Shaped Coil with Dacron Fibers and the Cook, Inc. Hilal Embolization Microcoils. The physical characteristics (b)(4) and performance characteristics (b)(4) were shown to be substantially equivalent.
- There were no changes made to the currently marketed Vascular Occlusion System (TRUFILL Pushable Coils and TRUPUSH Coil Pusher) design, materials, manufacturing processes, and sterilization since the previous 510(k) submissions (K964367 concurred 1/30/97 and K972881 concurred 6/4/98).
- The peripheral indication is included in the indications for use statement for the predicate devices, the Target Therapeutics Helix Shaped Coils with Dacron Fibers and the Cook, Inc. Hilal Microcoil.
- Review of the published literature included in **Appendix H** documents the extensive use of the predicate devices in the peripheral vasculature specifically for pathologies (lesions).

Conclusion

The proposed additional indication, use in the peripheral vasculature does not pose any additional risks or expose the use of the Vascular Occlusion System to a new patient population previously untreated by the predicate devices. The Vascular Occlusion System indicated for use in the peripheral vasculature is substantially equivalent to the predicate devices.

Section 7 – Performance Testing

Performance Testing

Background

Cordis Endovascular successfully conducted in-vitro performance testing as part of previous Vascular Occlusion System 510(k)s (K964367 concurred 1/30/97 and K972881 concurred 6/4/98). Since there are no changes made to the design, materials, manufacturing, and sterilization, additional performance testing was not repeated for this submission. The in-vitro tests performed for the currently marketed Vascular Occlusion System are summarized in the table below. All Vascular Occlusion System samples passed the tests listed in this table, therefore, are substantially equivalent to the predicate devices:

In-Vitro Test	Description
(b)(4)	

Continued on next page

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Performance Testing, Continued

Background (continued)

In-Vitro Test	Description
(b)(4)	

Results and Conclusion

Testing demonstrated that the TRUFILL Pushable Coils performed similarly to or better than the predicate devices, the Target Therapeutics Helix Shaped Coil with Dacron Fibers (K901721 concurred 11/9/91) and the Cook, Inc Hilal Embolization Microcoils (K901337 concurred 11/13/90). The physical characteristics (b)(4) and performance characteristics (b)(4) were shown to be substantially equivalent based on the in-vitro test results.

Biocompatibility Testing

No material changes have been made to the Vascular Occlusion System (TRUFILL Pushable Coils and TRUPUSH Coil Pushers) included in this submission. The materials are identical to materials previously concurred for the Vascular Occlusion System and all applicable biocompatibility testing was successfully performed and included in K964367.

Section 8 – Sterilization Information

Sterilization Information

Introduction The sterilization processes and specifications for the Vascular Occlusion System remain the same. The sterilization information is outlined below for the reviewer's convenience.

Sterilization Method The sterilization of the product is achieved using (b)(4). Cordis currently uses a specification limit of (b)(4) (b)(4), respectively, in accordance with the 1978 Guidelines for Devices Contacting Blood (Federal Register, Vol. 43, No. 122, Friday, June 23, 1978).

Validation Method The sterilization cycle used to sterilize the device was validated by using the International Standard ANSI/AAMI/ISO (b)(4) (b)(4)

Sterility Assurance Level The sterility assurance level is (b)(4)

Shelf Life The shelf life remains at 3 years.

Pyrogen Test Method The Vascular Occlusion System is labeled "nonpyrogenic" because it has a Pyrogen level of (b)(4) (b)(4). The (b)(4) (b)(4) Pyrogen testing method utilized at Cordis Endovascular Systems is the same method used at Cordis Corporation. The method is conducted on a (b)(4) (b) basis according to the Guidelines on Validation of (b)(4) (b)(4) Test as an (b)(4) Test for (b)(4)

0-000027

Section 9 – Software Validation

Software Validation

Not Applicable Statement This section is not applicable since the Vascular Occlusion System does not utilize any software.

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Appendix A – Summary of Safety and Effectiveness

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K983483
0-000029

Appendix A – Summary of Safety and Effectiveness, Continued

General Provisions

- The common names used for this device include:
- Platinum Fibered Coils
- Microcoils or Minicoils
- The Vascular Occlusion System consists of the following components:
- TRUFILL Pushable Coils
- TRUPUSH Coil Pusher

Predicate Devices

The predicate devices are listed in the table below:

Device	Manufacturer	510(k) Number, Concurrence Date	Product Code
Hilal Embolization Microcoil	Cook, Inc.	K901337, 11/9/90	HCG
Helix Shaped Coils with Dacron Fibers	Target Therapeutics	K901721, 1/8/91	HCG
Vascular Occlusion System	Cordis Endovascular Systems, Inc.	K964367, 1/30/97 K972881, 6/4/98	HCG

Classification

Class II

Performance Standard

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards.

Intended Use

The Vascular Occlusion System may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

Device Description

The Vascular Occlusion System consists of straight and shaped TRUFILL Pushable Coils (made from platinum alloy and synthetic fibers) and the TRUPUSH Coil Pusher (with 1 or 2 radiopaque markers). The pushable coils are designed for use under fluoroscopy with microcatheters having a minimum 0.21" inner diameter.

Continued on next page

Appendix A – Summary of Safety and Effectiveness, Continued

Biocompatibility All applicable biocompatibility testing was successfully performed for the Vascular Occlusion System.

Summary of Substantial Equivalence The Vascular Occlusion System is substantially equivalent in design, materials, sterilization, and indications for use as other commercially available occlusion devices.¹

¹ A statement of substantial equivalence to another product is required by 21 CFR 807.87, and relates to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977).

Appendix B – Truthful and Accuracy Statement

Introduction

The Truthful and Accurate Statement as required by 21 CFR 807.87(j) is included below.

Statement

Pursuant to 21 CFR 807.87(j), I certify that in my capacity as Sr. Regulatory Affairs Associate at Cordis Endovascular Systems, Inc., I believe to the best of my knowledge, that all data and information submitted to me in this Premarket Notification [510(k)] are truthful and accurate and that no material fact has been omitted.

Martine D. Schneider
Martine D. Schneider
Sr. Regulatory Affairs Associate

9/30/98

Date

Cordis Endovascular Systems, Inc.
September 28, 1998

510(k) Number: To be issued

Appendix C – Indications for Use Statement

Appendix C – Indications for Use Statement, Continued

Indications for Use Statement

The Cordis Endovascular Systems, Inc. Vascular Occlusion System may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983483

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

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0-000034

Appendix D – Draft Instructions for Use and Labels

VI. Precautions

- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to "Use By" Date.
- Angiography is necessary for the pre-embolization evaluation, operative control and post-embolization follow up.
- Ensure proper selection of occlusion device size according to vascular territory and measurements taken from a baseline angiogram.
- Required additional items: Appropriate sized Guiding Catheter to facilitate TRANSIT catheter access to the intended vasculature. Continuous flush setup with two (2) rotating hemostatic valves, three (3) bags of appropriate flush, one (1) 3-way stopcock, and one (1) 1-way stopcock.
- CES Occlusion Devices should be delivered through a microcatheter with a minimum I.D. of 0.021 inch (0.5 mm), such as the TRANSIT Infusion Catheter Product Line. The CES Occlusion Devices are designed to be delivered using the CES Coil Pusher. Compatibility of the CES Occlusion Device with other catheters and with other coil delivery devices has not been established.

VII. Complications

Vascular occlusion procedures should not be attempted by physicians unfamiliar with all possible complications. Complications specific to embolization procedures may occur at any time during or after the procedure and may include, but are not limited to, the following:

- Ischemia at an undesired location
- Stroke or cerebral infarction
- Occlusion device migration into normal vessels adjacent to the lesion
- Pulmonary embolism
- Vessel dissection, perforation, rupture and hemorrhage
- Neurological deficits
- Injury to normal vessels or tissue
- Infection
- Allergic reaction
- Vasospasm
- Death

VIII. Preparations for Use**Occlusion Device Size Selection**

Appropriate size selection of the CES Occlusion Device increases the device effectiveness and patient safety. In order to choose the optimum size CES Occlusion Device for any given lesion, examine pre-embolization angiograms. It is important to select the optimum occlusion device based on the appropriate overall length and coil diameter to avoid migration. The appropriate device size should be chosen based on the vessel diameter. It is suggested that the coil diameter be slightly larger than the actual vessel diameter (approximately 25% larger) to prevent inadvertent coil displacement or migration.

Continuous Flush Setup Preparation

In order to achieve optimal performance of Cordis Endovascular Systems (CES) catheters, guidewires, and embolization devices, and to reduce risk of thromboembolic complications, it is critical that a continuous infusion of appropriate flush solution be maintained between (a) the femoral sheath and guiding catheter, (b) the TRANSIT catheter and guiding catheters, and (c) the TRANSIT catheter and CES guidewires or occlusion devices. See Figure 1.

2

1. Attach a rotating hemostatic valve (RHV) to the hub of the guiding catheter. Attach a three-way stopcock to the side arm of the RHV, then connect a line for continuous infusion of the appropriate flush solution (such as 0.9% normal saline heparinized at 1-5 units per cc).
2. Attach a second RHV to the hub of the TRANSIT catheter. Attach a one-way stopcock to the side arm of the RHV then connect a line for continuous flushing of the appropriate solution. One drop from pressure bag every 3-5 seconds or at a rate of 2-5 cc/min is suggested.
3. Check that all fittings are secure so that air is not introduced at any time into the guiding catheter or TRANSIT catheters during continuous flush.

IX. Directions for Use

Carefully catheterize the vasculature to be treated. The access system should include a guiding catheter of sufficient inner diameter (ID) not only to accept a TRANSIT catheter, but also to permit adequate contrast infusion around the TRANSIT catheter for fluoroscopic road mapping. Measure the size of the vessel to be treated and select an appropriately sized CES Occlusion Device.

1. Position catheter for occlusion device deposition using standard techniques, then remove guidewire, if used.
2. Gently infuse introducer with saline to remove air, reduce friction, and aid in occlusion device introduction.
3. Insert occlusion device introducer with pre-loaded occlusion device through the RHV and into the hub of the TRANSIT catheter.
4. Using the stylet provided, slowly advance the occlusion device (in a continuous motion) completely through introducer, RHV, past the catheter hub and into the catheter lumen. If occlusion device does not easily advance into catheter, rotate introducer one half turn while maintaining contact with the TRANSIT catheter hub. Continue advancing occlusion device into catheter hub with the stylet.
5. Once the occlusion device has entered the catheter lumen, remove the introducer and stylet.
6. Insert the stylet through the RHV and into the catheter lumen to further advance the occlusion device.
7. Reinsert the occlusion device introducer through the RHV into the microcatheter hub.
8. Thread the distal (floppy) end of the CES Coil Pusher through the introducer into the TRANSIT catheter to advance the occlusion device under fluoroscopy, and pull back introducer from RHV to enable continuous flush. With the CES Coil Pusher, carefully deposit occlusion device into desired vessel space.
9. Remove the CES Coil Pusher after the occlusion device is placed.

Caution: Never advance the coil pusher past the tip of the microcatheter after the occlusion device has been placed. Advancing the coil pusher after occlusion device placement risks damaging the vessel and displacing the occlusion device.
10. Place additional occlusion devices by repeating steps 2 - 8.

Caution: Replace the TRANSIT microcatheter when deploying multiple occlusion devices if resistance is noted during occlusion device delivery.

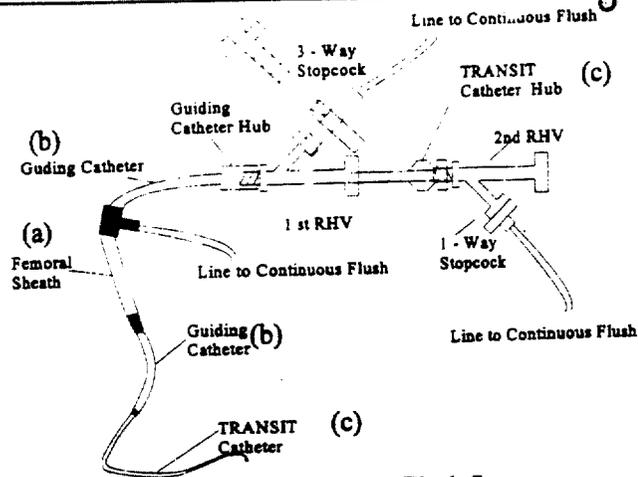


Figure 1. Continuous Flush Setup

X. Additional Precautions and Warnings

- Coil pushers are delicate instruments and should be handled carefully. Prior to use, and when possible during the procedure, inspect the coil pusher for coil separation, bends, or kinks. Do not use a coil pusher that shows signs of damage.
- Never advance the coil pusher past the tip of the microcatheter after the occlusion device has been placed. Advancing the coil pusher after occlusion device placement risks damaging the vessel and displacing the occlusion device.
- Never advance, withdraw, or auger the coil pusher against resistance without first determining the cause of resistance under fluoroscopy. Torquing the coil pusher against resistance may cause damage and/or fracture which may result in separation of the distal tip.
- Advance and retract catheter smoothly, especially in tortuous anatomy. Replace the occlusion device if unusual friction is noted within the TRANSIT catheter. If friction is noted in any successive occlusion device, carefully examine both the occlusion device and the TRANSIT catheter for possible damage. Replace both if necessary.
- Tortuosity or difficult anatomy of the vessels may affect accurate placement of the occlusion device.
- Do not advance the occlusion device with force if the occlusion device becomes lodged within the TRANSIT catheter. Determine the cause of resistance and replace TRANSIT catheter and occlusion device when necessary.
- It is recommended to hold the microcatheter body in place while the occlusion device is deposited to prevent the microcatheter tip from moving from the intended site.
- To date, there have been no reports of adverse events associated with Magnetic Resonance Imaging (MRI) procedures conducted on patients with platinum occlusion devices in their neurovasculature. However, compatibility with MRI has not been established, and the degree of imaging distortion resulting from the occlusion device has not been measured.
- Do not expose to organic solvents.
- The long term effect of this product on extravascular tissues has not been established, so care should be taken to retain this device in the intravascular space.
- Multiple embolization procedures may be required to achieve the desired occlusion of some vessels.
- Prior to use of this product by a trained physician, it is recommended that any available instructional materials be reviewed.

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Cordis Biot Operation
2905, Route des Doignes
06921 Sophia Antipolis cedex
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Facsimile 93-65-4030

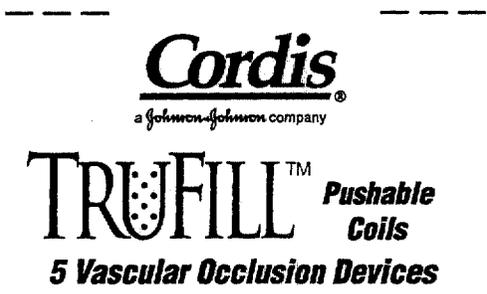
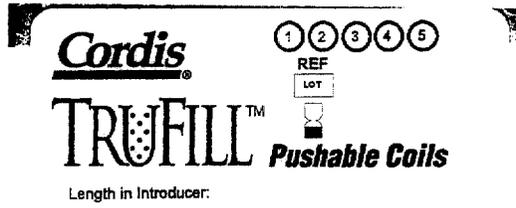
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14740 NW 60th Ave.
Miami Lakes, FL 33014, USA
Telephone 305-824-8600
Facsimile 305-824-8610



RECYCLED
100% Recycled Fibers
Including 20%
Post Consumer Waste

0-000039



REF
Cat.No.

Compatibility:

Length in Introducer:

Contents: 5 pushable coils , 5 introducers, and 5 stylets.

Lot
Lot No.

Use
By

STERILE. Sterilized with ethylene oxide gas. For one use only. Nonpyrogenic. Radiopaque. Do not autoclave. Do not use open or damaged packages. Store in a cool, dark, dry place. **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.



Attention, see instructions for Use.



Cordis Endovascular Systems, Inc.
14740 NW 60th Ave., Miami Lakes, FL 33014, USA
ES02921-2

72

0-000040

Cordis[®]

a Johnson & Johnson company

**TRUFILL[™] Pushable
Coil**

Vascular Occlusion Device

REF

Cat.No.

Compatibility:

Length in Introducer:

Contents: 1 pushable coil , 1 introducer, and 1 stylet.

Lot
Lot No.

Use
By

STERILE. Sterilized with ethylene oxide gas. For one use only. Nonpyrogenic. Radiopaque. Do not autoclave. Do not use open or damaged packages. Store in a cool, dark, dry place. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



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Cordis Endovascular Systems, Inc.
14740 NW 60th Ave., Miami Lakes, FL 33014, USA
ES02920-2

73

0-000041

Cordis

1 2 3 4 5
REF 633-140
LOT XXXXXXXX
XXXX-XX

TRUFILL® Pushable Coils

Length in Introducer: 10 mm
5 mm C

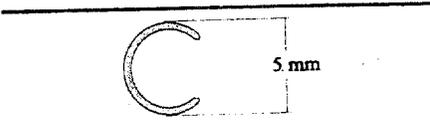
Cordis
a Johnson & Johnson company

TRUFILL® Pushable Coils
5 Vascular Occlusion Devices

REF 633-140
Cat.No.

Compatibility: .021" ID(.53mm) MICROCATHER

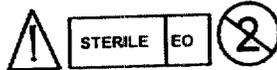
Length in Introducer: 10 mm



Contents: 5 pushable coils, 5 introducers, and 5 stylets.

LOT XXXXXXXX Use By XXXX-XX
Lot No.

STERILE. Sterilized with ethylene oxide gas. For one use only. Nonpyrogenic. Radiopaque. Do not autoclave. Do not use open or damaged packages. Store in a cool, dark, dry place. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



Attention, see instructions for Use.



Cordis Endovascular Systems, Inc.
14740 NW 60th Ave., Miami Lakes, FL 33014, USA
ES02921-2 633GS010-2 / 0005

CE
0084

74

0-000042

Cordis

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TRUFILL® Pushable Coil

Vascular Occlusion Device

REF 633-140

Cat.No.

Compatibility: .021" ID(.53mm) MICROCATHER

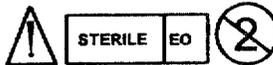
Length in Introducer: 10 mm



Contents: 1 pushable coil, 1 introducer, and 1 stylet.

LOT XXXXXXXX Use By XXXX-XX
Lot No.

STERILE. Sterilized with ethylene oxide gas. For one use only. Nonpyrogenic. Radiopaque. Do not autoclave. Do not use open or damaged packages. Store in a cool, dark, dry place. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



Attention, see Instructions for Use.



CE
0084

Cordis Endovascular Systems, Inc.
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ES02920-2 633GS010-2 / 0005

95

Cordis

Cat.No. **633-010**

TRUFILL™

Lot No. **X0297000**
Use By **2000-02**

Pushable Coils

5 Vascular Occlusion Devices

5mm STRAIGHT

Cordis

a Johnson & Johnson company

TRUFILL™

Pushable Coils

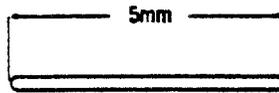
5 Vascular Occlusion Devices

REF **633-010**

Cat.No.

Compatibility: **.021" ID (.53mm) MICROCATETER**

Length in Introducer: **5mm**



Contents: 5 occlusion devices, 5 introducers, and 5 stylets.

LOT **X0297000** Use By **2000-02**

STERILE. Sterilized with ethylene oxide gas. For one use only. Nonpyrogenic. Radiopaque. Do not autoclave. Do not use open or damaged packages. Store in a cool, dark, dry place. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



Attention, see Instructions for Use.



+ H78963301037

Cordis Endovascular Systems, Inc.
14740 NW 60th Ave., Miami Lakes, FL 33014 USA
ES02921-1 **633GS004-1 / 0002**

Cordis Cat.No. **633-140**
 Lot No. **X0297000**
 Use By **2000-02**
TRUFILL™ *Pushable Coils*
5 Vascular Occlusion Devices
5mm C

Cordis
 a Johnson & Johnson company

TRUFILL™ *Pushable Coils*
5 Vascular Occlusion Devices

REF **633-140**
 Cat.No.
 Compatibility: **.021" ID (.53mm) MICROCATHETER**
 Length in Introducer: **10mm**



Contents: 5 occlusion devices, 5 introducers, and 5 stylets.

Lot No. **X0297000** Use By **2000-02**

STERILE. Sterilized with ethylene oxide gas. For one use only. Nonpyrogenic. Radiopaque. Do not autoclave. Do not use open or damaged packages. Store in a cool, dark, dry place. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



Attention, see instructions for Use.



Cordis Endovascular Systems, Inc
 14740 NW 60th Ave., Miami Lakes, FL 33014, USA
 ES02921-1 **633GS010-1 / 0002**

0-000045

Cordis

Cat.No. **633-240**

TRUFILL™

Lot No. **X0297000**
Use By **2000-02**

Pushable Coils

5 Vascular Occlusion Devices

5mm FLAT SPIRAL

Cordis
a Johnson & Johnson company

TRUFILL™

Pushable Coils

5 Vascular Occlusion Devices

REF 633-240

Cat.No.

Compatibility: **.021" ID (.53mm) MICROCATHETER**

Length in Introducer: **31mm**



Contents: 5 occlusion devices, 5 introducers, and 5 stylets.

LOT

Lot No. **X0297000**

Use By

2000-02

STERILE. Sterilized with ethylene oxide gas. For one use only. Nonpyrogenic. Radiopaque. Do not autoclave. Do not use open or damaged packages. Store in a cool, dark, dry place. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



Attention, see instructions for Use.



+ H7396332403C

Cordis Endovascular Systems, Inc
14740 NW 60th Ave., Miami Lakes, FL 33014, USA
ES02921-1 **633GS016-1 / 0002**

78

Cordis

Cat.No. **633-360**

TRUFILL™ Pushable Coils
5 Vascular Occlusion Devices
7mm COMPLEX

Lot No. **X0297000**
Use By **2000-02**

Cordis

a Johnson & Johnson company

TRUFILL™ Pushable Coils
5 Vascular Occlusion Devices

REF **633-360**

Cat.No.

Compatibility: **.021" ID (.53mm) MICROCATHETER**

Length in Introducer: **60mm**



Contents: 5 occlusion devices, 5 introducers, and 5 stylets.

Lot No. **X0297000** Use By **2000-02**

STERILE. Sterilized with ethylene oxide gas. For one use only. Nonpyrogenic. Radiopaque. Do not autoclave. Do not use open or damaged packages. Store in a cool, dark, dry place. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



Attention, see instructions for Use.



+ H7396333603F

Cordis Endovascular Systems, Inc.
14740 NW 60th Ave., Miami Lakes, FL 33011, USA
ES02921-1 **633GS024-1 / 0002**

79

0-000047

Cat. No. 632-774 REF 632-774
 Coil Pusher Diameter 0.017" (.43 mm) Cat. No.
 Usable Length 195cm Lot No. X0197000
 Use By 2000-01

TRUPUSH™

REF
Cat. No.
632-774

Coil Pusher / Poussoir de spirale / Dispositivo di spinta della spirale / Guía posicionadora de coils / コイルプッシャー

Coil Pusher Diameter / Diamètre du poussoir de spirale / Coil Pusher Durchmesser / Diametro del dispositivo di spinta della spirale / Diámetro de la guía posicionadora de coils / コイルプッシャーの直径

.017" (.43 mm)

Usable Length
Longueur utile
Nutzbare Länge
Lunghezza utile
Longitud útil
有効長

195cm

Taper Length
Longueur effilée
Länge der Verjüngung
Lunghezza rastrematura
Longitud Ahusada
テーパの長さ

50cm

Tip Shape
Forme de l'extrémité
Spitzenkonfiguration
Forma della punta
Forma de la punta
先端形状

Straight

Contents: 1 Coil Pusher and 1 Torquing Device
 Contenu: Un poussoir de spirale et un dispositif de torsion
 Inhalt: 1 Coil Pusher und 1 Steuerungshilfe
 Contiene: 1 dispositivo di spinta e 1 dispositivo di torsione
 Contenido: 1 guía posicionadora de coils y 1 dispositivo de torque
 本製品はコイルプッシャー 1本、トルクデバイス 1本

LOT
 Lot No. X0197000

Use By 2000-01



+H7396327743N

Cordis

A Johnson & Johnson company

632GS002-1 / 0002

Cordis Endovascular Systems, Inc.,
14740 NW 60th Ave., Miami Lakes, FL 33014, USA

ES02212-1

80

0-000048



LABELING / COIL PUSHER

SEM-BLANK PRINTING



11 REF
Cat. No. 1

Coil Pusher / Pousoir de spirale / Dispositivo di spinta della spirale / Guia
posicionadora de coils / コイルプッシャー

Coil Pusher Diameter / Diamètre du pousoir de spirale / Coil Pusher Durchmesser / Diámetro del dispositivo
di spinta della spirale / Diámetro de la guía posicionadora de coils / コイルプッシャーの直径

Usable Length
Longueur utile
Nutzbare Länge
Lunghezza utile
Longitud útil
有効長

Tapor Length
Longueur effilée
Länge der Verjüngung
Lunghezza rastrematura
Longitud Ahusgado
テーパの長さ

Tip Shape
Forme de l'extrémité
Spitzenkonfiguration
Forma della punta
Forma de la punta
先端形状

Contents: 1 Coil Pusher and 1 Torquing Device
Contenu: Un pousoir de spirale et un dispositif de torsion
Inhalt: 1 Coil Pusher und 1 Steuerungshilfe
Contiene: 1 dispositivo di spinta e 1 dispositivo di torsione
Contentido: 1 guía posicionadora de coils y 1 dispositivo de torque
内容物: コイルプッシャー 1本、トルクデバイス 1本

Lot: TYMMXXX
Use By: 9

8 6 10

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Cordis Endovascular Systems, Inc.
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14740 NW 60th Ave., Miami Lakes, FL 33014, USA
ES02211-1

Coil Pusher / Pousoir de spirale / Dispositivo di spinta della spirale / Guia
posicionadora de coils / コイルプッシャー

Coil Pusher Diameter / Diamètre du pousoir de spirale / Coil Pusher Durchmesser / Diámetro del dispositivo
di spinta della spirale / Diámetro de la guía posicionadora de coils / コイルプッシャーの直径

Usable Length
Longueur utile
Nutzbare Länge
Lunghezza utile
Longitud útil
有効長

Tapor Length
Longueur effilée
Länge der Verjüngung
Lunghezza rastrematura
Longitud Ahusgado
テーパの長さ

Tip Shape
Forme de l'extrémité
Spitzenkonfiguration
Forma della punta
Forma de la punta
先端形状

Contents: 1 Coil Pusher and 1 Torquing Device
Contenu: Un pousoir de spirale et un dispositif de torsion
Inhalt: 1 Coil Pusher und 1 Steuerungshilfe
Contiene: 1 dispositivo di spinta e 1 dispositivo di torsione
Contentido: 1 guía posicionadora de coils y 1 dispositivo de torque
内容物: コイルプッシャー 1本、トルクデバイス 1本

Lot: []
Use By: []

8 6 10

Appendix E – Indications for Use Statement for Currently Marketed Vascular Occlusion System

✓

510 (k) Number: K972881

0-000050

Indications for Use Statement

CES Pushable Coils may be used to obstruct or reduce the rate of blood flow in vessels of the neurovasculature for the interventional management of arteriovenous malformations, arteriovenous fistulas and other vascular lesions of the brain, spinal cord, and spine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972881

85



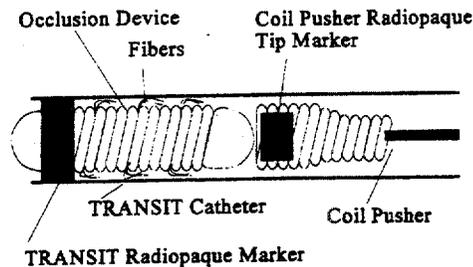
Instructions for Use CES Vascular Management System

STERILE. Sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque. For one use only. Do not autoclave.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

THERE IS NO WARRANTY OR WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE DRAWINGS, ILLUSTRATIONS, AND PHOTOGRAPHS DESCRIBED IN THIS PUBLICATION ARE FOR INFORMATION ONLY AND ARE NOT TO BE USED AS A BASIS FOR ANY DIRECT OR INDIRECT LIABILITY OR DAMAGES. THE USER SHALL BE RESPONSIBLE FOR ANY DIRECT OR INDIRECT DAMAGES. THE USER SHALL BE RESPONSIBLE FOR ANY DIRECT OR INDIRECT DAMAGES. THE USER SHALL BE RESPONSIBLE FOR ANY DIRECT OR INDIRECT DAMAGES. THE USER SHALL BE RESPONSIBLE FOR ANY DIRECT OR INDIRECT DAMAGES.

Descriptions of the illustrations and drawings are for information only and are not to be used as a basis for any direct or indirect liability or damages. The user shall be responsible for any direct or indirect damages.



I. Description

The CES Vascular Management System consists of straight and complex shaped CES Occlusion Devices (made from platinum alloy and synthetic fibers) and the CES Coil Pusher (a device with a radiopaque tip marker). The occlusion devices are designed for use under fluoroscopy with microcatheters having a minimum 0.021" (0.5 mm) I.D., such as the TRANSIT[®] Infusion Catheter, Product Line family ("TRANSIT"), and the CES Coil Pusher. Items sold separately.

II. Packaging

The CES Occlusion Devices are packaged in an introducer cartridge, together with a stylet, inside a sealed protective pouch which will remain sterile unless opened or damaged. The CES Coil Pusher is shipped in a dispenser tube with a torque device and packaged inside a sealed protective pouch that will remain sterile unless opened or damaged. Store in a cool, dark, dry place.

III. Intended Use

CES Occlusion Devices may be used to reduce or block the rate of blood flow in small or tapering vessels. They are indicated for use in the interventional radiologic management of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine, when devascularization prior to definitive surgical resection is desired.

IV. Contraindications

The use of CES Occlusion Devices is contraindicated when any of the following conditions exist:

- When superselective placement is not possible.
- When the arteries supplying the lesion are not large enough to accept emboli.
- When patent extra-to-intracranial anastomoses are present.
- When end arteries lead directly to cranial nerves.
- When the A-V shunt is bigger than the size of the occlusion device.
- When there is severe atheromatous disease.
- When in the presence or likely onset of vasospasm.

V. Warnings

Performing therapeutic embolizations to occlude blood vessels is a high risk procedure. The procedure should be carried out under the direction of personnel with the requisite interventional training and thorough knowledge of angiographic techniques, especially coil embolization techniques. Appropriate facilities should be available for coping with the potential complications of the procedure.

Contaminants found in the angiography room may cause foreign body reactions or infection. The physician must use the utmost caution to avoid introducing contaminants.

Incomplete occlusion of vascular bed or territories may give rise to hemorrhage, ischemia, infarction, development of alternative vascular pathways, or recurrence of symptoms.

Do not reuse. Discard after one procedure. Cordis Endovascular Systems will not be responsible for any direct, incidental, or consequential damages resulting from reuse of this product.

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VI. Precautions

- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to "Use By" Date.
- Angiography is necessary for the pre-embolization evaluation, operative control and post-embolization follow up.
- Ensure proper selection of occlusion device size according to vascular territory and measurements taken from a baseline angiogram.
- Required additional items: Appropriate sized Guiding Catheter to facilitate TRANSIT catheter access to the intended vasculature. Continuous flush setup with two (2) rotating hemostatic valves, three (3) bags of appropriate flush, one (1) 3-way stopcock, and one (1) 1-way stopcock.
- CES Occlusion Devices should be delivered through a microcatheter with a minimum I.D. of 0.021 inch (0.5 mm), such as the TRANSIT Infusion Catheter Product Line. The CES Occlusion Devices are designed to be delivered using the CES Coil Pusher. Compatibility of the CES Occlusion Device with other catheters and with other coil delivery devices has not been established.

VII. Complications

Vascular occlusion procedures should not be attempted by physicians unfamiliar with all possible complications. Complications specific to embolization procedures may occur at any time during or after the procedure and may include, but are not limited to, the following:

- Ischemia at an undesired location
- Stroke or cerebral infarction
- Occlusion device migration into normal vessels adjacent to the lesion
- Pulmonary embolism
- Vessel dissection, perforation, rupture and hemorrhage
- Neurological deficits
- Injury to normal vessels or tissue
- Infection
- Allergic reaction
- Vasospasm
- Death

VIII. Preparations for Use**Occlusion Device Size Selection**

Appropriate size selection of the CES Occlusion Device increases the device effectiveness and patient safety. In order to choose the optimum size CES Occlusion Device for any given lesion, examine pre-embolization angiograms. It is important to select the optimum occlusion device based on the appropriate overall length and coil diameter to avoid migration. The appropriate device size should be chosen based on the vessel diameter. It is suggested that the coil diameter be slightly larger than the actual vessel diameter (approximately 25% larger) to prevent inadvertent coil displacement or migration.

Continuous Flush Setup Preparation

In order to achieve optimal performance of Cordis Endovascular Systems (CES) catheters, guidewires, and embolization devices, and to reduce risk of thromboembolic complications, it is critical that a continuous infusion of appropriate flush solution be maintained between (a) the femoral sheath and guiding catheter, (b) the TRANSIT catheter and guiding catheters, and (c) the TRANSIT catheter and CES guidewires or occlusion devices. See Figure 1.

2

1. Attach a rotating hemostatic valve (RHV) to the hub of the guiding catheter. Attach a three-way stopcock to the side arm of the RHV, then connect a line for continuous infusion of the appropriate flush solution (such as 0.9% normal saline heparinized at 1-5 units per cc).
2. Attach a second RHV to the hub of the TRANSIT catheter. Attach a one-way stopcock to the side arm of the RHV then connect a line for continuous flushing of the appropriate solution. One drop from pressure bag every 3-5 seconds or at a rate of 2-5 cc/min is suggested.
3. Check that all fittings are secure so that air is not introduced at any time into the guiding catheter or TRANSIT catheters during continuous flush.

IX. Directions for Use

Carefully catheterize the vasculature to be treated. The access system should include a guiding catheter of sufficient inner diameter (ID) not only to accept a TRANSIT catheter, but also to permit adequate contrast infusion around the TRANSIT catheter for fluoroscopic road mapping. Measure the size of the vessel to be treated and select an appropriately sized CES Occlusion Device.

1. Position catheter for occlusion device deposition using standard techniques, then remove guidewire, if used.
2. Gently infuse introducer with saline to remove air, reduce friction, and aid in occlusion device introduction.
3. Insert occlusion device introducer with pre-loaded occlusion device through the RHV and into the hub of the TRANSIT catheter.
4. Using the stylet provided, slowly advance the occlusion device (in a continuous motion) completely through introducer, RHV, past the catheter hub and into the catheter lumen. If occlusion device does not easily advance into catheter, rotate introducer one half turn while maintaining contact with the TRANSIT catheter hub. Continue advancing occlusion device into catheter hub with the stylet.
5. Once the occlusion device has entered the catheter lumen, remove the introducer and stylet.
6. Insert the stylet through the RHV and into the catheter lumen to further advance the occlusion device.
7. Reinsert the occlusion device introducer through the RHV into the microcatheter hub.
8. Thread the distal (floppy) end of the CES Coil Pusher through the introducer into the TRANSIT catheter to advance the occlusion device under fluoroscopy, and pull back introducer from RHV to enable continuous flush. With the CES Coil Pusher, carefully deposit occlusion device into desired vessel space.
9. Remove the CES Coil Pusher after the occlusion device is placed.

Caution: Never advance the coil pusher past the tip of the microcatheter after the occlusion device has been placed. Advancing the coil pusher after occlusion device placement risks damaging the vessel and displacing the occlusion device.

10. Place additional occlusion devices by repeating steps 2 - 8.

Caution: Replace the TRANSIT microcatheter when deploying multiple occlusion devices if resistance is noted during occlusion device delivery.

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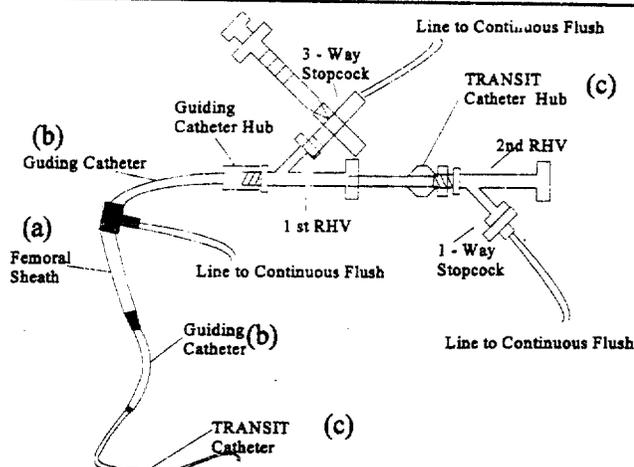


Figure 1. Continuous Flush Setup

X. Additional Precautions and Warnings

- Coil pushers are delicate instruments and should be handled carefully. Prior to use, and when possible during the procedure, inspect the coil pusher for coil separation, bends, or kinks. Do not use a coil pusher that shows signs of damage.
- Never advance the coil pusher past the tip of the microcatheter after the occlusion device has been placed. Advancing the coil pusher after occlusion device placement risks damaging the vessel and displacing the occlusion device.
- Never advance, withdraw, or auger the coil pusher against resistance without first determining the cause of resistance under fluoroscopy. Torquing the coil pusher against resistance may cause damage and/or fracture which may result in separation of the distal tip.
- Advance and retract catheter smoothly, especially in tortuous anatomy. Replace the occlusion device if unusual friction is noted within the TRANSIT catheter. If friction is noted in any successive occlusion device, carefully examine both the occlusion device and the TRANSIT catheter for possible damage. Replace both if necessary.
- Tortuosity or difficult anatomy of the vessels may affect accurate placement of the occlusion device.
- Do not advance the occlusion device with force if the occlusion device becomes lodged within the TRANSIT catheter. Determine the cause of resistance and replace TRANSIT catheter and occlusion device when necessary.
- It is recommended to hold the microcatheter body in place while the occlusion device is deposited to prevent the microcatheter tip from moving from the intended site.
- To date, there have been no reports of adverse events associated with Magnetic Resonance Imaging (MRI) procedures conducted on patients with platinum occlusion devices in their neurovasculature. However, compatibility with MRI has not been established, and the degree of imaging distortion resulting from the occlusion device has not been measured.
- Do not expose to organic solvents.
- The long term effect of this product on extravascular tissues has not been established, so care should be taken to retain this device in the intravascular space.
- Multiple embolization procedures may be required to achieve the desired occlusion of some vessels.
- Prior to use of this product by a trained physician, it is recommended that any available instructional materials be reviewed

86

0-000054

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Facsimile 050-5022100

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Est. Consiglieri Pedrosa N.º 69 - A
Queiz de Baixo
2745 Barcarena
Telephone 351-1-436-87-70/1/2/3/4
Facsimile 351-1-435-48-07

Spain:

Johnson & Johnson S.A.
Paseo de las doce Estrellas 5-7
28042 Madrid
Telephone 34-1-326-45-24
Facsimile 34-1-326-79-84

Sweden:

Johnson & Johnson AB
P.O. Box 6119
S-20011 Malmö
Telephone 46-40-30-05-50
Facsimile 46-40-30-00-22

Switzerland:

Cordis AG
Gaswerkstrasse 48
CH-4900 Langenthal
Telephone 063-22-88-55
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Cordis U.K. Ltd.
Unit 9, The Gate Centre
Syon Gate Way
Brentford, Middlesex TW8 9DD
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Cordis Endovascular Systems, Inc.
14740 NW 60th Ave.
Miami Lakes, FL 33014, USA
Telephone 305-824-8600
Facsimile 305-824-8610

Cordis Operations:

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Cordis Biot Operation
2905, Route des Dolines
06921 Sophia Antipolis cedex
Telephone 93-95-5600
Facsimile 93-65-4030

The Netherlands

Cordis Europa, N.V..
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USA:

Cordis Endovascular Systems, Inc.
14740 NW 60th Ave.
Miami Lakes, FL 33014, USA
Telephone 305-824-8600
Facsimile 305-824-8610



RECYCLED
100% Recycled Fibers
Including 20%
Post Consumer Waste

81

Appendix F – Predicate Device IFUs and Promotional Material (Target Therapeutics)

pp

0-000056



Vascular Occlusion System
Product Information

U.S. patents 4,994,069 and 5,226,911.
Other U.S. and foreign patents pending.

JA



Vascular Occlusion System Product Information

U.S. patents 4,994,069 and 5,226,911. Other U.S. and foreign patents pending.

CAUTION
Federal (USA) Law restricts these devices to use by or on the order of a physician.

These devices are intended for one use only. Do not resterilize and/or reuse these devices. After use, dispose in accordance with hospital, administrative, and/or local government policy. Do not use if sterile packaging has been breached or damaged.

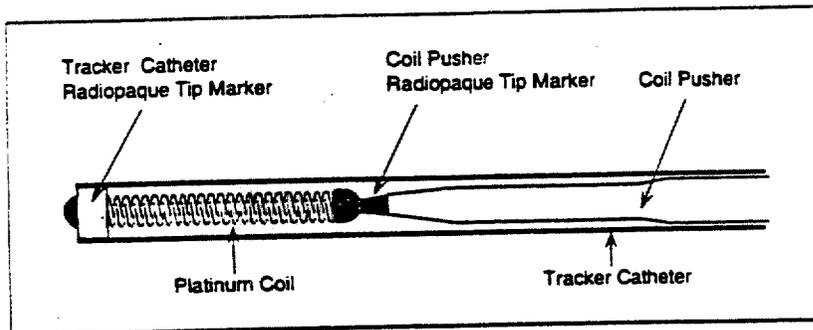


Figure 1
Coil Delivery Set-Up

DEVICE DESCRIPTION

Target Therapeutics Vascular Occlusion System consists of straight or complex helical-shaped platinum coils that are available with or without synthetic fibers¹. Coils are designed to be delivered under fluoroscopy using a Tracker®/FasTRACKER® System Infusion Catheter with a radiopaque tip and a Target Therapeutics Coil Pusher. The Coil Pusher, a guidewire-like device, is used to push the coil through the Tracker catheter. Coils come loaded in an introducer for easy transfer into a catheter (see figure 2).

¹Animal studies indicate that occlusion may occur earlier when fibers are present; however, character or duration of occlusion seems no different at later points in time.

90

0-000058

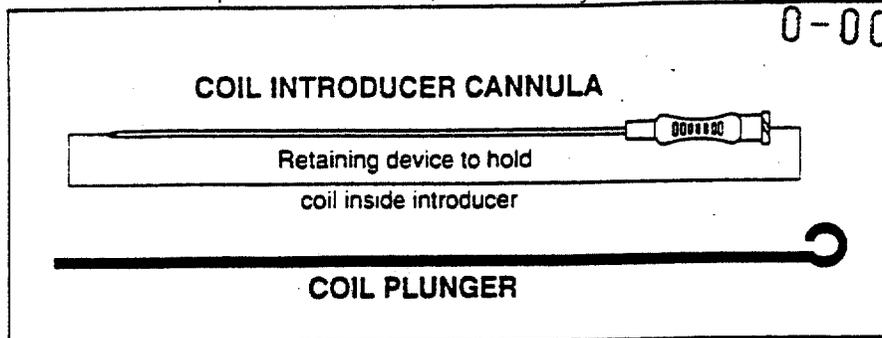


Figure 2
Coil Introducer Cannula

INDICATION FOR USE

Coils are intended to obstruct or reduce blood flow in the peripheral and neurovasculature. They are intended for use in the interventional radiologic management of arteriovenous malformations and arteriovenous fistulas when devascularization prior to definitive surgical resection is desirable.

This device should be used by physicians trained in interventional neuroradiology or interventional radiology.

POTENTIAL COMPLICATIONS

Potential complications include but are not limited to: hematoma at the site of entry, vessel perforation, emboli, hemorrhage, ischemia or vasospasm, neurological deficits including stroke and possibly death.

ADDITIONAL ITEMS

- Continuous flush set-up with two rotating hemostatic valves, appropriate flush, and two stopcocks.

COIL SIZE SELECTION

Correct coil size selection increases occlusion effectiveness and patient safety. Occlusion effectiveness is dependent upon coil compaction, coil mass, and physical obstruction of the vessel which is a direct consequence of proper selection of coil size in relation to vessel diameter. To choose the optimum coil size, examine pre-treatment angiograms. Selection of a coil larger than the vessel may result in a non-compact placement with less effective reduction of blood flow. Selection of a coil smaller than the vessel may result in coil migration.

Only 0.010 inch coils are compatible with the Coil Pusher-10 and Tracker-10/FasTRACKER-10 System Infusion Catheters. Only 0.018 inch coils are compatible with the Coil Pusher-16 and Tracker-18/FasTRACKER-18 System Infusion Catheters.

Precaution: If advanced through a Tracker-18 catheter, 0.010 inch coils could develop an unacceptable level of friction resulting in jamming, stretching, or breaking.

Precaution: Compatibility with catheters other than the Tracker/FasTRACKER System Infusion Catheters has not been established.

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PREPARATIONS FOR USE

0-000059

Prior to use, ensure that sterile packaging is intact. When removing devices from packaging, carefully inspect for evidence of kinks, bends, or other damage. Return the device if sterility appears to have been compromised, or the device itself appears damaged.

Precaution: Do not use catheters, coil pushers or coils that have been damaged in any way.

CONTINUOUS FLUSH SET-UP

In order to achieve optimal performance of the Vascular Occlusion System, and to reduce the risk of thromboembolic complications, it is critical that a continuous flow of appropriate flush solution be maintained between a) the Tracker/FasTRACKER catheter and guiding catheter, and b) the Tracker/FasTRACKER catheter and any intraluminal device. Continuous flushing also reduces retrograde flow of blood into catheter during coil delivery and reduce the potential for contrast crystal formation and/or clotting on both the guidewire and inside the catheter lumen.

1. Attach a rotating hemostatic valve (RHV) to the hub of the guiding catheter. Attach a stopcock to the side arm of the RHV, then connect a line for continuous infusion of appropriate solution.
2. Attach a second RHV to the hub of the Tracker catheter. Attach a stopcock to the side arm of the RHV, then connect a line for continuous flushing of appropriate solution. One drop from pressure bag every 3-5 seconds is suggested.

Precaution: Check that all fittings are secure so that air is not introduced into guiding or Tracker catheters during continuous flush.

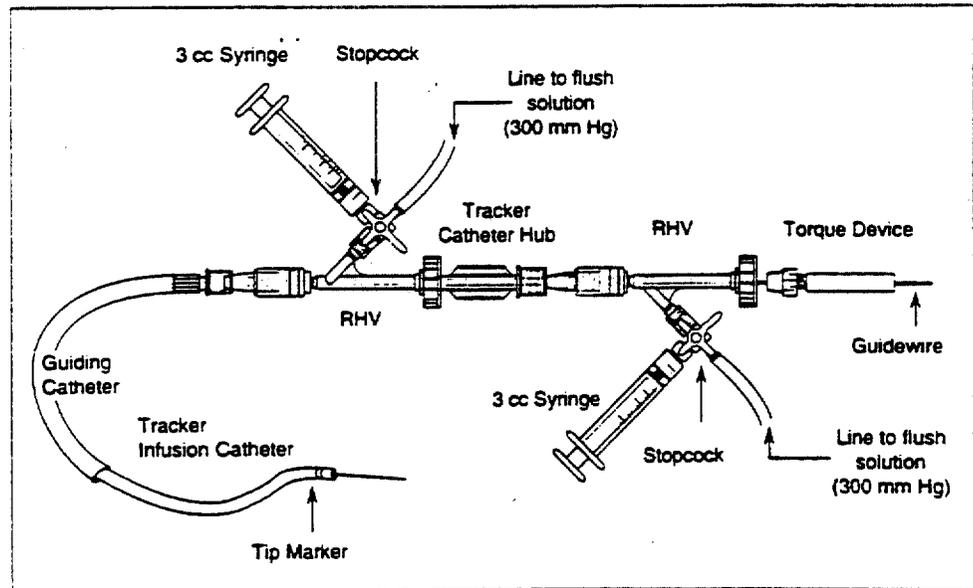


Figure 3
Example of Continuous Flush Set-up

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DIRECTIONS FOR USE

0-000060

PRECAUTION

Verify repeatedly that the distal shaft of the coil delivery catheter is not under stress before coil deployment. Axial compression or tension forces may be stored in the catheter causing the tip to move during coil delivery.

1. Position the Tracker catheter within the vasculature using standard technique according to the Instructions for Use provided with the catheter. If a guidewire has been used to facilitate the placement of the catheter, remove it after placement of the catheter.

Precaution: The use of high quality, digital subtraction fluoroscopic road mapping helps to monitor the catheter position and is a useful tool in the selection of the appropriate delivery site and the corresponding coil size.

2. Remove the retaining wire from the coil introducer (see figure 2) and discard. Gently infuse the introducer with saline to reduce friction and aid in coil introduction.
3. Insert the coil introducer with pre-loaded coil into the RHV of the Tracker catheter.
4. Using the plunger provided, slowly advance the coil completely through the introducer, the RHV, past the catheter hub, and into the catheter lumen.

If the coil does not easily advance into the RHV, rotate the introducer one half turn while maintaining contact with the RHV. With the plunger, continue advancing the coil into the RHV.

5. Once the coil has entered the catheter lumen, remove the introducer and the plunger.
6. Insert the proximal, stainless steel end of the coil pusher into the Tracker RHV and advance the coil approximately one quarter of catheter's total length. **Remove coil pusher.**

Precaution: If resistance is encountered when withdrawing the coil pusher, draw back on the catheter simultaneously until the coil pusher can be removed without resistance.

7. Verify under fluoroscopy that the distal tip of the Tracker catheter has remained at the desired location.

Thread the distal (floppy) end of the coil pusher into the Tracker catheter RHV and continue to advance the coil into the desired position while monitoring via fluoroscopy.

Precaution: Do not advance the coil with force if the coil becomes lodged within the Tracker catheter. Determine the cause of resistance and replace the Tracker catheter and the coil when necessary.

8. Remove coil pusher after the coil is in place.

WARNING

Never advance the coil pusher after the coil has been deposited. Advancing the coil pusher after the coil has been deposited risks damaging the vessel.

Inject contrast medium and assess coil placement and vessel occlusion.

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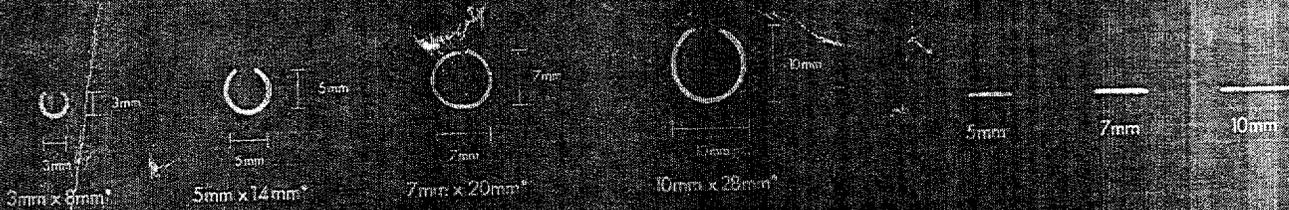
Coil Sizing Chart

Records processed under FOIA Request # 2015-6315; Released by CDRH on 11-18-2015

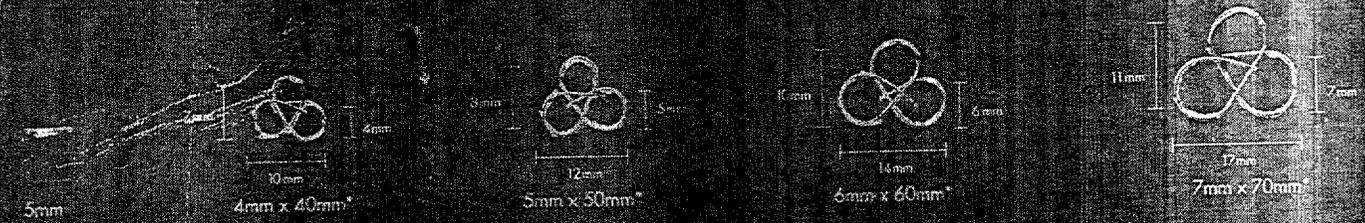
0-00006



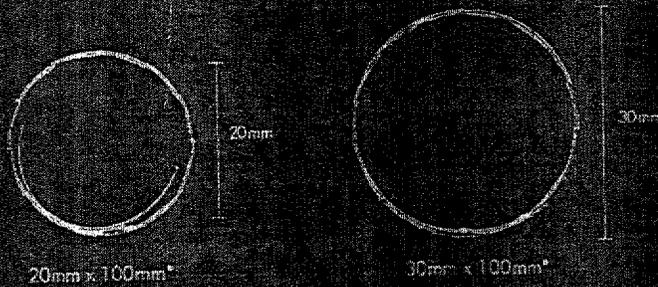
BRAIDED OCCLUSION DEVICE



TRACKER®-3 COILS



TRACKER®-18 VEIN OF GALEN COILS



TRACKER®-10 COILS



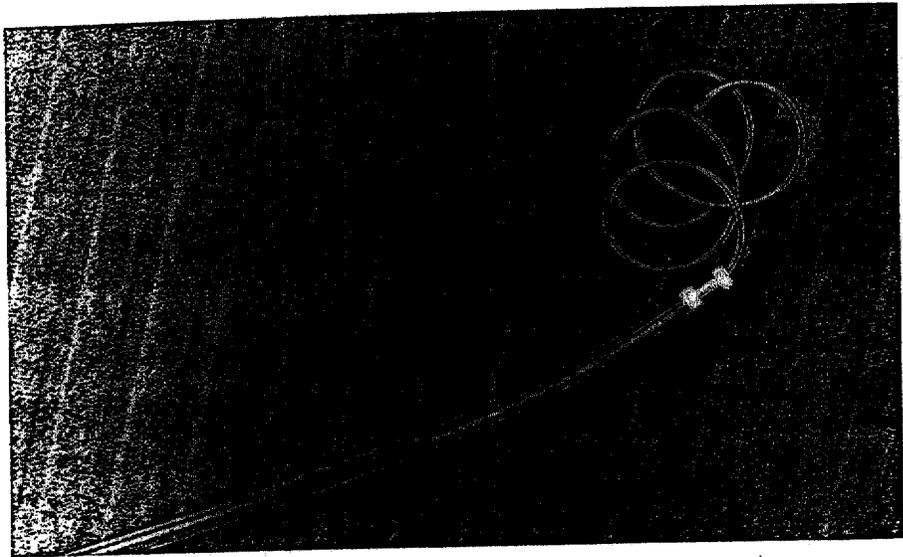
Sizes are defined by Secondary Coil Diameter and Length in Introducer

To select the optimum coil size, examine pre-embolization angiograms and vessel diameter. Compare this to the secondary coil diameter. Selection of a coil larger than the vessel may result in a non-compact placement with less effective reduction of blood flow. Selection of a coil smaller than the vessel may result in coil migration.

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COMPLEX HELICAL
PLATINUM COILS
VASCULAR
OCCCLUSION SYSTEM

0-000062



APPPLICATIONS

- The occlusion system, used in conjunction with a Tracker[®]-18 Catheter, allows selective delivery of Platinum Coils to the smallest vasculature. The Platinum Coils are indicated for preoperative vaso-occlusion and site

specific flow reduction of vascular abnormalities in the central nervous system:

- Arteriovenous malformations
- Arteriovenous fistulas

FEATURES

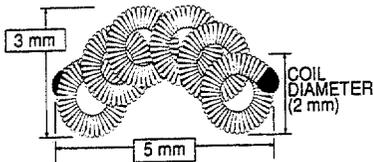
- Platinum Coils are non-ferromagnetic.
- Complex helical design reduces dead space evident in single helical coils.
- Spatial filling of selected vasculature by radiopaque platinum.
- Polished, soft coil tip lessens likelihood of vessel wall trauma.

- Coil Pusher-16 improves control during coil delivery.
- Laminated polymer surface on pusher reduces friction with the Tracker-18.
- Radiopaque gold-tipped marker on Coil Pusher-16 allows fluoroscopic visualization.
- Available in a wide variety of sizes.



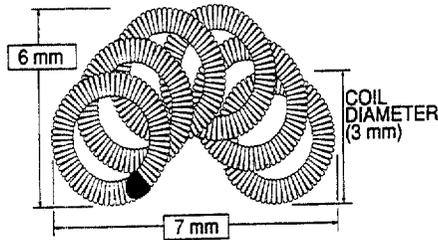
**COMPLEX HELICAL
PLATINUM COILS
VASCULAR
OCCLUSION SYSTEM**

0-000063



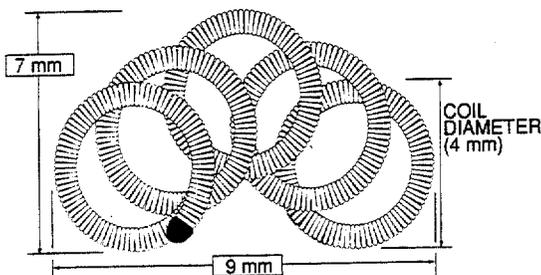
Kit Product Number: 520024

- Coil Diameter: 2 mm
- Length in Introducer*: 40 mm
- In Vitro Diameter/Length (mm): 3 / 5



Kit Product Number: 520036

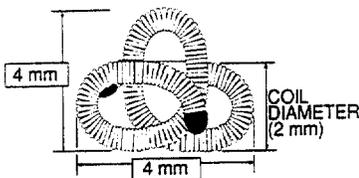
- Coil Diameter: 3 mm
- Length in Introducer*: 60 mm
- In Vitro Diameter/Length (mm): 6 / 7



Kit Product Number: 520046

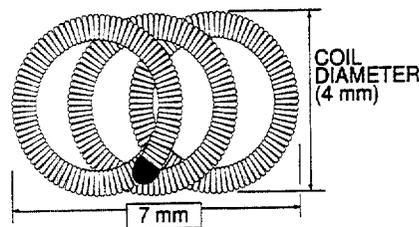
- Coil Diameter: 4 mm
- Length in Introducer*: 60 mm
- In Vitro Diameter/Length (mm): 7 / 9

Shorter Length Coils



Kit Product Number: 520022

- Coil Diameter: 2 mm
- Length in Introducer*: 20 mm
- In Vitro Diameter/Length (mm): 4 / 4



Kit Product Number: 520043

- Coil Diameter: 4 mm
- Length in Introducer*: 30 mm
- In Vitro Diameter/Length (mm): na / 7

The Vascular Occlusion System consists of one box of 5 coils and one Coil Pusher. Coils are each loaded in a introducer cannula and are individually sterile pouched.

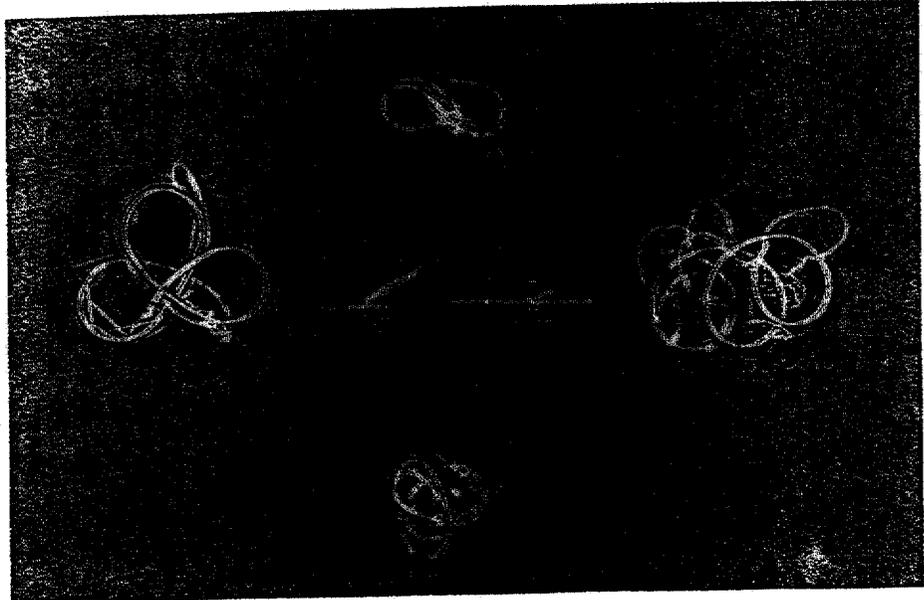
*Straight length of coil in introducer.



OK

FIBERED
PLATINUM COILS
VASCULAR
OCCCLUSION SYSTEM

0-000064



APPPLICATIONS

- The occlusion system, used in conjunction with a Tracker®-18 Catheter, allows selective delivery of Polyester Fibered Coils to the smallest vasculature. The Coils are indicated for preoperative vaso-occlusion and site specific

flow reduction of vascular abnormalities in the central nervous system:

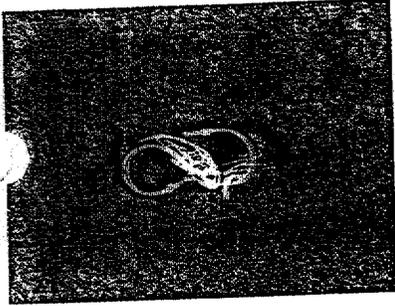
- Arteriovenous malformations
- Arteriovenous fistulas

FEATURES

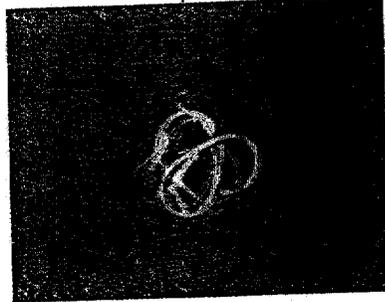
- Polyester Fiber promotes immediate thrombosis.
- Platinum Fibered Coils are non-ferromagnetic.
- Complex helical design reduces dead space evident in single helical coils.
- Unique space filling design.
- Radiopaque for easy visualization.
- Polished, soft coil tip lessens likelihood of vessel wall trauma.
- Secure interwoven fiber attachment.
- Available in a wide variety of sizes and shapes.



97



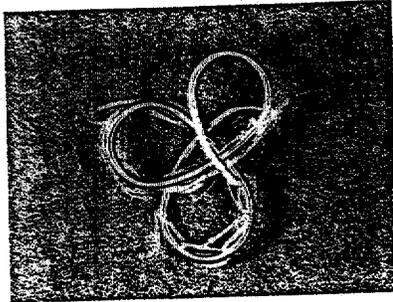
Kit Product Number: 522021
 ○ Coil Diameter: 2 mm
 ○ Length in Introducer: 10 mm



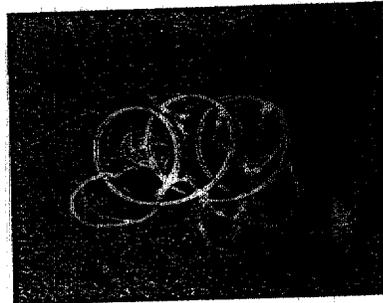
Kit Product Number: 522022
 ○ Coil Diameter: 2 mm
 ○ Length in Introducer: 20 mm



Product Number: 312002
 ○ Coil Diameter: na (Straight)
 ○ Length in Introducer: 2 mm



Kit Product Number: 522033
 ○ Coil Diameter: 3 mm
 ○ Length in Introducer: 30 mm



Kit Product Number: 522043
 ○ Coil Diameter: 4 mm
 ○ Length in Introducer: 30 mm



Product Number: 312005
 ○ Coil Diameter: na (Straight)
 ○ Length in Introducer: 5 mm

SPECIFICATIONS

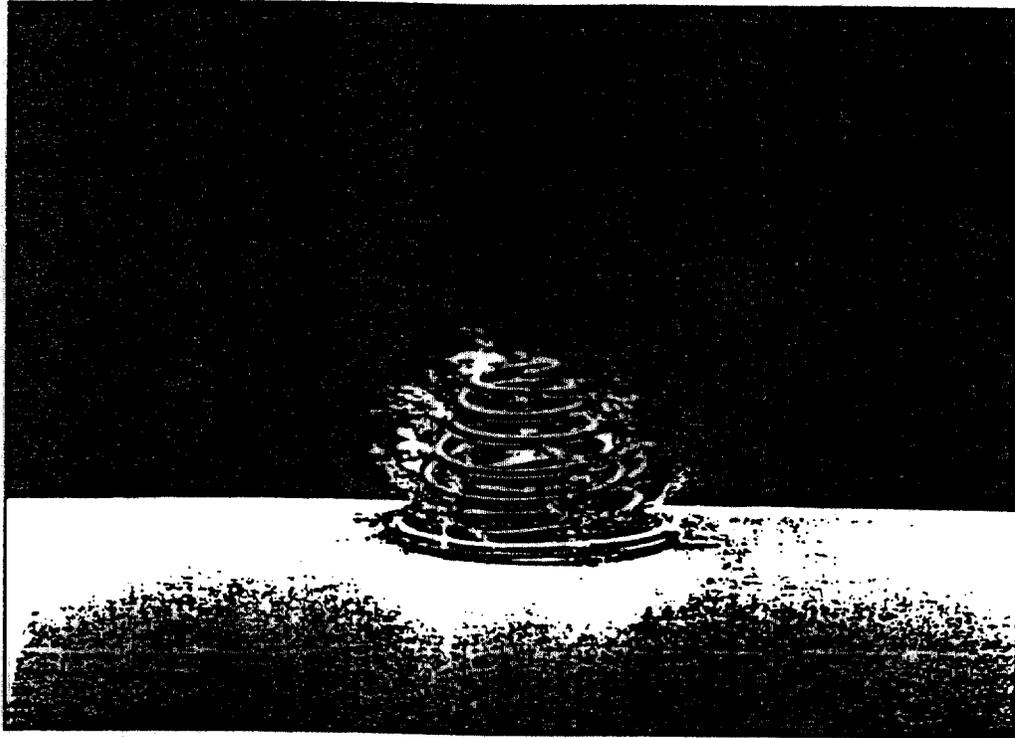
Kit Product No.	Coiled Diameter (mm)	Length in Introducer (mm)	Configuration
522021	2 mm	10 mm	Complex Helical
522022	2 mm	20 mm	Complex Helical
522033	3 mm	30 mm	Complex Helical
522043	4 mm	30 mm	Complex Helical
Vascular Occlusion System (VOS) contains one box of 5 polyester fibered platinum coils and one Coil Pusher.			
312002*	N/A	2 mm	Straight
312005*	N/A	5 mm	Straight

*Not available in kit form. Contains one box of 5 polyester fibered platinum coils.



0-000066

Vascular Occlusion Coil



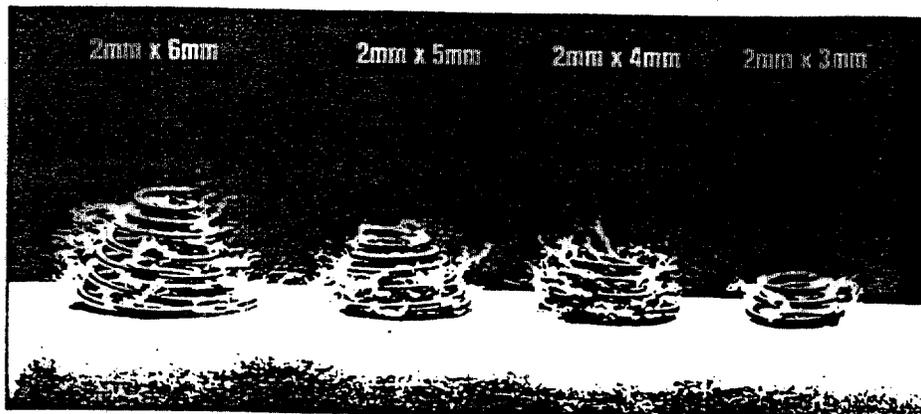
- New *VORTX* shape provides for more compact, complete vessel occlusion
- Soft platinum construction, compatible with Tracker/FasTRACKER[®]-18 and Tracker/FasTRACKER[®]-325 families of micro-catheters
- Range of sizes from 2mm (apex) x 3mm (base) to 2mm x 6mm



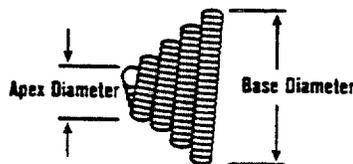


0-000067

Vascular Occlusion Coil



- Apex first deployment • Constructed from radiopaque platinum
- Dense fiber placement promotes thrombogenicity • Rounded coil ends



ORDERING INFORMATION

Product No.	Description	Apex Diameter	Base Diameter	Length of Coil in Introducer	Deployment in Introducer	Recommended Micro-Catheter
381203	VORTX coil - 2mm x 3mm	2mm	3mm	22mm	Apex First	FasTRACKER®-18/325 families
381204	VORTX coil - 2mm x 4mm	2mm	4mm	42mm	Apex First	FasTRACKER-18/325 families
381205	VORTX coil - 2mm x 5mm	2mm	5mm	60mm	Apex First	FasTRACKER-18/325 families
381206	VORTX coil - 2mm x 6mm	2mm	6mm	85mm	Apex First	FasTRACKER-18/325 families



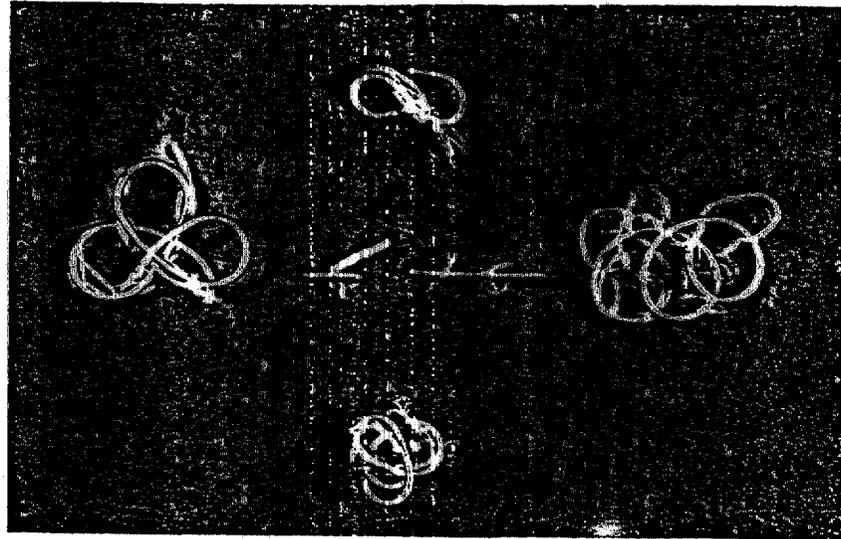
47201 Lakeview Blvd, Fremont, CA 94538 Customer Service; (800) 345-2498

F-224 (2/95)

180

FIBERED
PLATINUM COILS
VASCULAR
OCCLUSION SYSTEM

0-000068



APPPLICATIONS

The occlusion system, used in conjunction with a Tracker®-18 Catheter, allows selective delivery of Polyester Fibered Coils to the smallest vasculature. The Coils are indicated for preoperative vaso-occlusion and site specific

flow reduction of vascular abnormalities in the central nervous system:

- Arteriovenous malformations
- Arteriovenous fistulas

FEATURES

Polyester Fiber promotes immediate thrombosis.

Radiopaque for easy visualization.

Platinum Fibered Coils are non-ferromagnetic.

Polished, soft coil tip lessens likelihood of vessel wall trauma.

Complex helical design reduces dead space evident in single helical coils.

Secure interwoven fiber attachment.

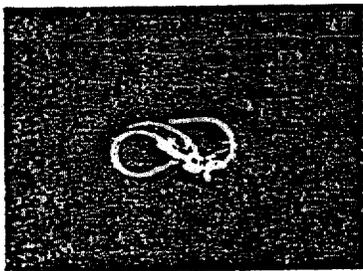
Unique space filling design.

Available in a wide variety of sizes and shapes.

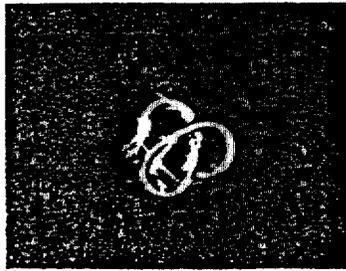


130 Rio Robles San Jose, CA 95134-1806
408-435-7700 800-345-2498 FAX 408-943-0840

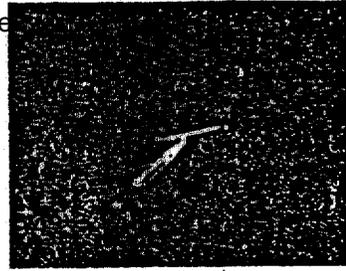
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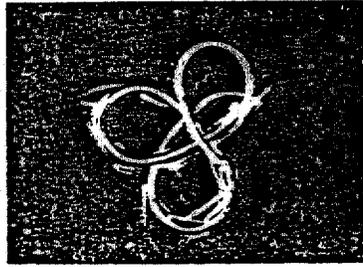
Kit Product Number: 522021
Coil Diameter: 2 mm
Length in Introducer: 10 mm



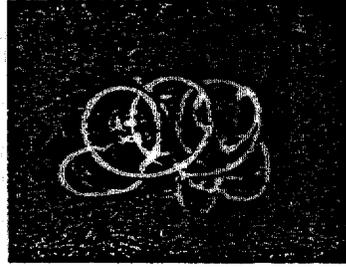
Kit Product Number: 522022
Coil Diameter: 2 mm
Length in Introducer: 20 mm



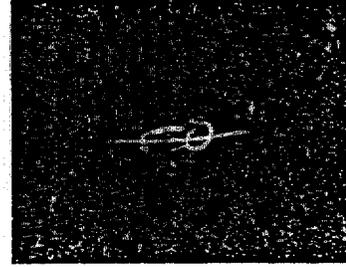
Product Number: 312002
Coil Diameter: na (Straight)
Length in Introducer: 2 mm



Kit Product Number: 522033
Coil Diameter: 3 mm
Length in Introducer: 30 mm



Kit Product Number: 522043
Coil Diameter: 4 mm
Length in Introducer: 30 mm



Product Number: 312005
Coil Diameter: na (Straight)
Length in Introducer: 5 mm

SPECIFICATIONS

Kit Product No.	Coiled Diameter (mm)	Length in Introducer (mm)	Configuration
522021	2 mm	10 mm	Complex Helical
522022	2 mm	20 mm	Complex Helical
522033	3 mm	30 mm	Complex Helical
522043	4 mm	30 mm	Complex Helical

Vascular Occlusion System (VOS) contains one box of 5 polyester fibered platinum coils and one Coil Pusher.

312002*	N/A	2 mm	Straight
312005*	N/A	5 mm	Straight

*Not available in kit form. Contains one box of 5 polyester fibered platinum coils.

FasTRACKER-18 / Tracker-18 System

Records for Classed under FOIA Request # 2011-0357; released by CDRH on 11/18/2015

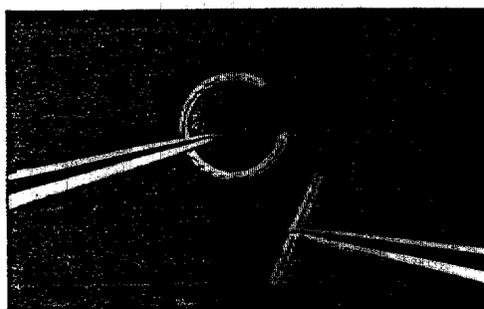
0-000070

FasTRACKER-18 / Tracker-18 System / FasTRACKER-325 BOD: Braided Occlusion Device

Please refer to page 12 of this catalog for a Coil Sizing Chart

Prod. No.	Description	Secondary Coil Diameter/ Length in Introducer	Unrestrained Coil Height/ Unrestrained Coil Length	Configuration
332005	0.018" BOD Coils	Straight / 5mm	Straight / 5mm	Straight
332007	0.018" BOD Coils	Straight / 7mm	Straight / 7mm	Straight
332010	0.018" BOD Coils	Straight / 10mm	Straight / 10mm	Straight
332308	0.018" BOD Coils	3mm / 8mm	3mm / 3mm	C-Shaped
332514	0.018" BOD Coils	5mm / 14mm	5mm / 5mm	C-Shaped
332720	0.018" BOD Coils	7mm / 20mm	7mm / 7mm	C-Shaped
332128	0.018" BOD Coils	10mm / 28mm	10mm / 10mm	C-Shaped

Product is packaged 10 coils per box.



BOD: Braided Occlusion Device



Fibered Coils

FasTRACKER-18 / Tracker-18 / FasTRACKER-325 System Fibered Platinum Coils

Please refer to page 12 of this catalog for a Coil Sizing Chart

Prod. No./Kit No.	Description	Secondary Coil Diameter/ Length in Introducer	Unrestrained Coil Height/ Unrestrained Coil Length	Configuration
312002 / No Kit	0.018" Fibered Coils	Straight / 2mm	Straight / 2mm	Straight
312005 / No Kit	0.018" Fibered Coils	Straight / 5mm	Straight / 5mm	Straight
312021 / 522021	0.018" Fibered Coils	2mm / 10mm	2mm / 5mm	Complex Helical
312022 / 522022	0.018" Fibered Coils	2mm / 20mm	4mm / 4mm	Complex Helical
312033 / 522033	0.018" Fibered Coils	3mm / 30mm	6mm / 6mm	Complex Helical
312043 / 522043	0.018" Fibered Coils	4mm / 30mm	4mm / 7mm	Complex Helical
312044 / 522044	0.018" Fibered Coils	4mm / 40mm	7mm / 10mm	Complex Helical
312055 / 522055	0.018" Fibered Coils	5mm / 50mm	8mm / 12mm	Complex Helical
312066 / 522066	0.018" Fibered Coils	6mm / 60mm	10mm / 14mm	Complex Helical
312077 / 522077	0.018" Fibered Coils	7mm / 70mm	11mm / 17mm	Complex Helical
314210 / No Kit	0.018" Vein of Galen	20mm / 100mm	20mm / 20mm	Helical
314310 / No Kit	0.018" Vein of Galen	30mm / 100mm	30mm / 30mm	Helical

Product packaged 5 Coils per box; Kit includes box of 5 Coils with a Coil Pusher

Prod. No.	Description	Total Length	Catheter Compatibility
4n1216	Coil Pusher-16	175cm	Tracker-18
16	Coil Pusher-16	195cm	Tracker-18

For best performance during coil delivery, we recommend an appropriately sized Coil Pusher

Target Therapeutics • Customer Service: (800) 345-2498 Fax: (510) 440-7680

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FasTRACKER -18 / Tracker -18 System

HYDROLYSE® Coils

• Now for 1998 8-000071

FasTRACKER-18 / Tracker-18 / FasTRACKER-325 System BOD™ (Braided Occlusion Device)

Product is packaged 10 coils per box.

Prod. No.	Description	Secondary Coil Diameter (mm)	Length in Introducer (mm)	Unrestrained Coil (mm)		Configuration	Price Per Unit (US\$)
				Height	Length		
332005	0.018" BOD Coils	Straight	5	Straight	5	Straight	370.00
332007	0.018" BOD Coils	Straight	7	Straight	7	Straight	370.00
332010	0.018" BOD Coils	Straight	10	Straight	10	Straight	370.00
332308	0.018" BOD Coils	3	8	3	3	C-Shaped	420.00
332514	0.018" BOD Coils	5	14	5	5	C-Shaped	420.00
332720	0.018" BOD Coils	7	20	7	7	C-Shaped	420.00
332128	0.018" BOD Coils	10	28	10	10	C-Shaped	420.00

FasTRACKER-18 / Tracker-18 / FasTRACKER-325 System Fibered Platinum Coils

Product packaged 5 coils per box. Kit includes box of 5 coils with a Coil Pusher.

Prod. No. / Kit No.	Description	Secondary Coil Diameter (mm)	Length in Introducer (mm)	Unrestrained Coil (mm)		Configuration	Box of 5 Coils/Kit Price (US\$)
				Height	Length		
312002 / No Kit	0.018" Fibered Coils	Straight	2	Straight	2	Straight	160.00/ No Kit
312005 / No Kit	0.018" Fibered Coils	Straight	5	Straight	5	Straight	160.00/ No Kit
312021/522021	0.018" Fibered Coils	2	10	2	5	Complex Helical	290.00/385.00
312022/522022	0.018" Fibered Coils	2	20	4	4	Complex Helical	290.00/385.00
312033/522033	0.018" Fibered Coils	3	30	6	6	Complex Helical	290.00/385.00
312043/522043	0.018" Fibered Coils	4	30	4	7	Complex Helical	290.00/385.00
312044/522044	0.018" Fibered Coils	4	40	7	10	Complex Helical	315.00/410.00
312055/522055	0.018" Fibered Coils	5	50	8	12	Complex Helical	315.00/410.00
312066/522066	0.018" Fibered Coils	6	60	10	14	Complex Helical	315.00/410.00
312077/522077	0.018" Fibered Coils	7	70	11	17	Complex Helical	315.00/410.00
314210/ No Kit	0.018" Vein of Galen	20	100	20	20	Helical	370.00/ No Kit
314310/ No Kit	0.018" Vein of Galen	30	100	30	30	Helical	370.00/ No Kit

For best performance during coil delivery, we recommend an appropriately sized Coil Pusher.

Prod. No.	Description	Total Length (cm)	Catheter Compatibility	Price Per Unit (US\$)
401216	Coil Pusher-16	175	Tracker-18	95.00
401316	Coil Pusher-16	195	Tracker-18	100.00

Tracker®-18 Hi-Flow System

Target Therapeutics complex helical coils are not compatible with the Tracker-18 Hi-Flow System.

Tracker-18 Hi-Flow Infusion Catheters

Prod. No.	Description	Length (cm)		OD (F)		ID (in)		Rec. Guidewire Diam. (in)	Min. Guiding Catheter ID (in)	Price Per Unit (US\$)
		Total	Distal	Proximal	Distal	Proximal	Distal			
102104	Tracker-18 Hi-Flow	135	12	3.2	2.7	0.026	0.021	0.014	0.042	210.00
102107	Tracker-18 Hi-Flow	150	18	3.2	2.7	0.026	0.021	0.014	0.042	210.00
132101	Tracker-18 Hi-Flow Unibody*	150	20	3.2	2.5	0.026	0.021	0.014	0.042	250.00

Tracker-18 Hi-Flow System Steerable Guidewires (located on page 1).

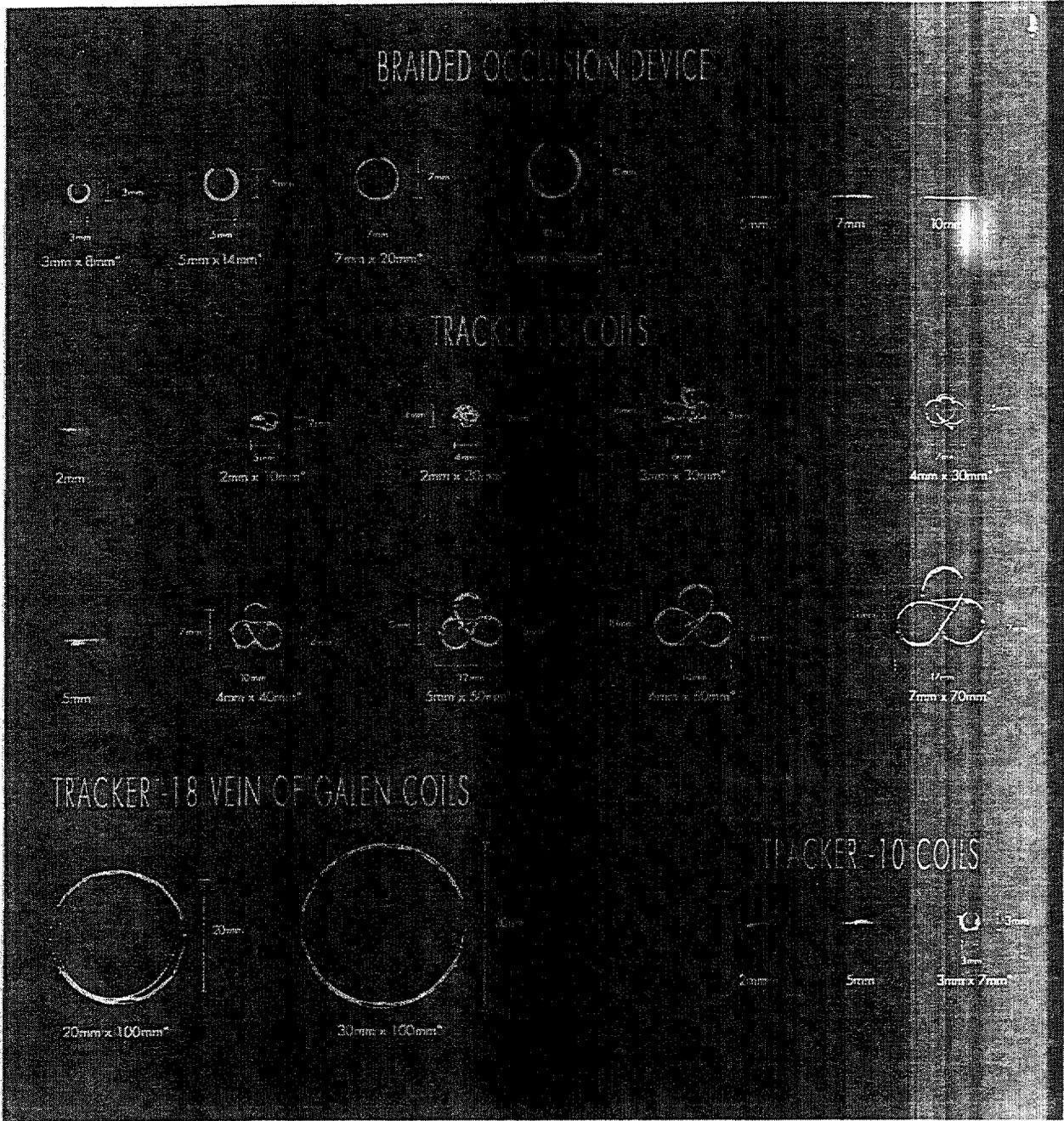
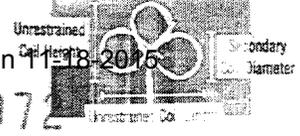
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Coil Sizing Chart

Records processed under FOIA Request # 2015-6315; Released by CDRH on 11-18-2015

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Sizes are defined by Secondary Coil Diameter and Length in Introducer

To select the optimum coil size, examine pre-embolization angiograms and vessel diameter. Compare this to the secondary coil diameter. Selection of a coil larger than the vessel may result in a non-compact placement with less effective reduction of blood flow. Selection of a coil smaller than the vessel may result in coil migration

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0-000073

SCVIR 1997
Please visit us at
Exhibit # 1032

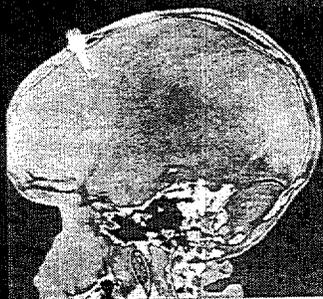
47201 Lakeview Blvd. Fremont, CA 94537

TARGET
THERAPEUTICS®

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New Products from TARGET THERAPEUTICS

NOW AVAILABLE
TurboTracker™ & 60C
For Peripheral Vascular Indications

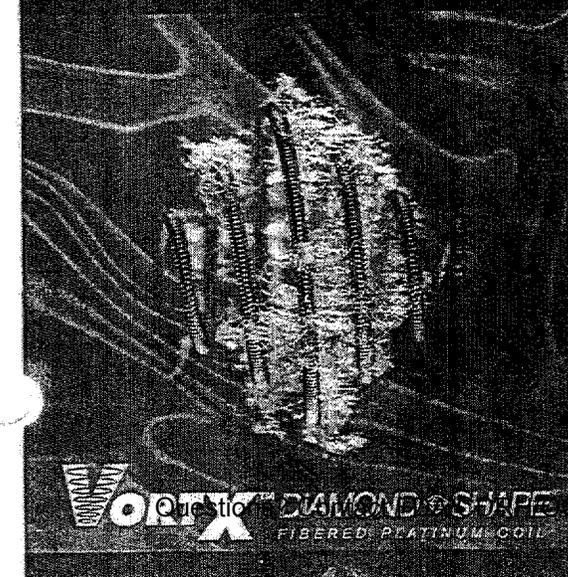
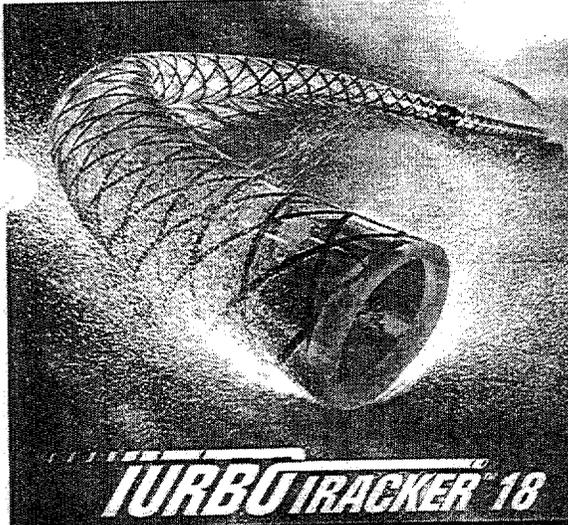


Innovation in
Neurological and Peripheral Intervention

Contact FDA/CDRH/OC [redacted] C.F.A.F.S. [redacted]@da.hhs.gov or 301-796-8118

TARGET
THERAPEUTICS®

1086



0-000074

TurboTracker™

- High performance micro-catheter with revolutionary multilayer NITRACK™ construction.
- Superior pushability, kink and ovalization resistance in tortuous anatomy.

FasDASHER™-14

- Stainless steel .014" micro-guidewire with HYDROLENE®, Target's proprietary hydrophilic coating.
- Excellent combination of trackability, durability and torque response.
- Shapeable distal tip enables customizing for multiple vessel access.

Attracter™-18



- Endovascular retrieval device with microfiber entrapment design and stainless steel guidewire construction.
- Compatible with TurboTracker 18, FaSTRACKER®-18 MX, FaSTRACKER-18 and Tracker®-18.

Vessel Occlusion Coils

Berenstein LIQUID COIL™

- Extremely soft non-fibered platinum coil designed to conform to the space in which it is injected.
- Only embolic coil compatible with flow directed catheters.

Vortyx™ Diamond Shape Coil

- New diamond shape is designed to provide improved coil compaction for a more complete vessel occlusion.
- Double apex design anchors coil in the vessel, minimizing migration and elongation compared with conical and helical shape coils.

Vortyx™-35 Occlusion Coil

- New Vortyx design offers more compact, complete vessel occlusion.
- Longer overall coil length and increased number of fibers, compared to similarly sized .035 helical coils, is designed to provide improved vessel occlusion.

Vortyx™ DIAMOND SHAPE FIBERED PLATINUM COIL

DRH-FOISTATUS@fda.hhs.gov or 301-796-8118 TARGET THERAPEUTICS

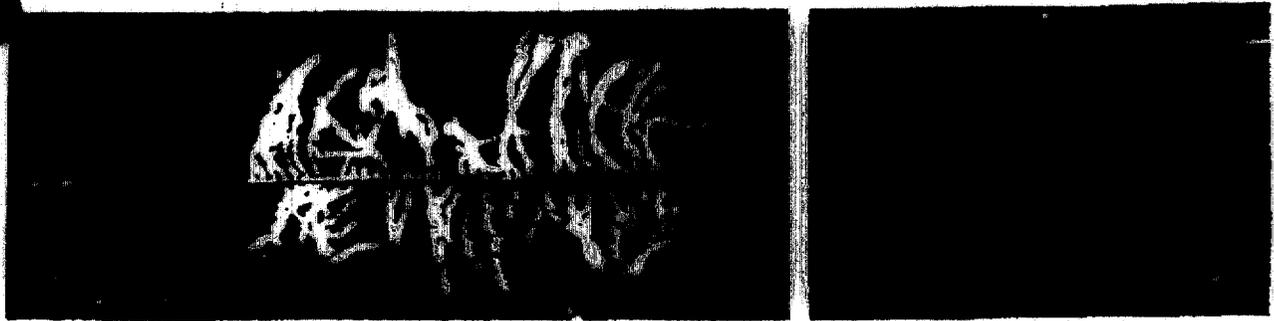
For more information call: 800/345-2498 • 510/440-7792 Fax 800/261-2143 • 520/440-7620

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Appendix G – Predicate Device IFUs and Promotional Material (Cook, Inc.)

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OCCCLUDING SPRING EMBOLUS



OCCCLUDING SPRING EMBOLUS

CATALOG NUMBER	Length	Diameter	Color Code of Cartridge
100-100	4	3	Black
100-101	5	4	Blue
100-102	5	6	Red

WIRE GUIDES FOR USE WITH OCCCLUDING SPRING EMBOLI

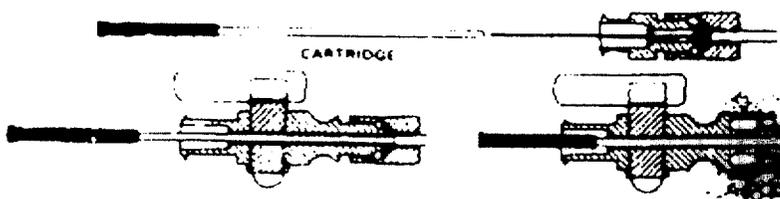
CATALOG NUMBER	Name
NEWTON	
100-103	25 cm Flexible Tip
100-104	20 cm Flexible Tip
LONG FLEXIBLE TIP	
100-105	20 cm Flexible Tip

These occluding spring emboli are designed to be used with 6.5 French COOK TORCON and 5.0M French COOK polyethylene catheters with a tapered tip and without sideports. If a catheter with sideports is used, the embolus may not be able to pass through the sideports other than that intended.

To use the occluding embolus, first insert the cartridge through the stopcock, hub or both until it is seated on the catheter. Then, using the wire guide, insert the embolus into the catheter. Push the embolus into the catheter for a distance of 10 cm using the COOK TORCON wire guide. Remove wire guide and cartridge.

When using any of the wire guides, push the spring embolus through the distal tip of the catheter. The ease with which the embolus can be pushed through the terminal divers of the catheter depends upon the flexibility of the wire guide tip. Flexible tip wire guides, such as the Newton SFNB guide described above, are recommended for most cases. In some instances a more flexible SFNB or SFB guide may be useful for greater flexibility. Teflon coated wire guides have proven to be useful.

Chuang, Wallace and Quattrocchi suggest that the last spring embolus be positioned with particular care. This spring embolus should not be left too close to the inlet of the artery and should be intermeshed with the previous spring emboli if possible. It should be of sufficient size to wedge against the arterial walls. A minimal but sufficient arterial blood flow should remain to hold this spring embolus against the previous spring emboli or other embolic materials until a solid clot insures a permanent fixation. The purpose of these suggestions is to minimize the possibility of a loose spring embolus becoming dislodged and blocking a vital and essential arterial branch.



Reference
 V. P. Chuang, S. Wallace, C. Quattrocchi. A New Improved Coil for Tapered Tip Catheter for Arterial Occlusion. *Neurology* 33 (1980) 507-509

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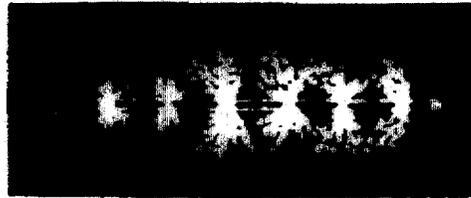
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EMBOLIZATION AND OCCLUSION

HILAL EMBOLIZATION MICROCOILS™
STRAIGHT

Used for embolization of selective vessels, supply to arterio-venous malformations and other vascular regions of the brain, spinal cord and spine. Design of the Microcoils™ permits introduction through small, pre-positioned delivery catheters. The coils are made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum thrombo-genesis. Straight embolizing design facilitates delivery by saline flush after initial advancement through straight segment of catheter using TSEB™ (0.46 mm diameter Teflon® coated tapered core, straight wire guide). Final positioning of Microcoils™ treated a distal but just affect with vessel lumen. Supplied sterile in peel open packages. Intended for one time use.



MICROCOIL™
 Platinum with synthetic fibers

ORDER NUMBER	Length	Configuration	Remarks
MWCE 18-0.5-0-HILAL	5 cm	Straight	
MWCE 18-0.7-0-HILAL	7 cm	Straight	
MWCE 18-1.0-0-HILAL	1.0 cm	Straight	Supplied 2 each per package
MWCE 18-1.5-0-HILAL	1.5 cm	Straight	

*Microcoils™ are recommended for use through catheters designed for use with 0.18 inch (0.46 mm) diameter wire guides and whose inner diameter (ID) does not exceed 0.25 inch (0.64 mm) diameter.

*Recommended wire guides for loading and pre-positioning Microcoils™ into delivery catheter: TSFNA 18 180 TSFNB 18 180

Positioning of Microcoils™ should be done with particular care. Microcoils™ should not be left too close to the inlets of arteries and should be intermeshed with previously placed Microcoils™ if possible. A minimal but sufficient arterial blood flow should remain to hold the Microcoils™ against the previously placed Microcoils™ until a bond does insure permanent fixation. The purpose of these suggestions is to minimize the possibility of loose Microcoils™ becoming dislodged and obstructing a normal and essential arterial channel.

REFERENCES

S. Hail, M.D. Department of Radiology, The Neurological Institute, New York, New York

S. Hail, et al. "Synthetic Fiber Coated Platinum Coils Successfully Used for the Endovascular Treatment of Arterio-Venous Malformations, Aneurysms and Direct Arterio Venous Fistulas of the Central Nervous System." Scientific paper presented at the 26th Annual Meeting of the American Society of Neuro-radiology, Chicago Illinois, May 1988.

V. P. Chuang, S. Wallace, C. Giaturco. "A Improved Coil for Tapered Tip Catheter for Arterial Occlusion." *Radiology* 135 (1980), 507-509.

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 Phone 416 675 1793
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EMBOLIZATION AND OCCLUSION

HILAL EMBOLIZATION MICROCOILS™

STRAIGHT

Used for embolization of selective vessel systems to arterial, venous malformations and arteriovenous malformations of the brain, spinal cord, and other small vessel applications. Design of the Microcoil™ permits introduction through small bore catheters and delivery catheters. Unique coil design and loading design permits delivery into the target vessel by having "push" rather than "pull" advancement through the shaft of the delivery catheter using the wire guide. The coils are made of platinum and are detected radiographically with leaded or thin filters to promote maximum visualization. **NOTE:** Microcoil™ may be used in conjunction with particulate and liquid embolization materials. Final positioning of Microcoil™ creates a "platinum cast" effect within the vessel lumen. Supplied sterile in peel open packages. Intended for one time use.



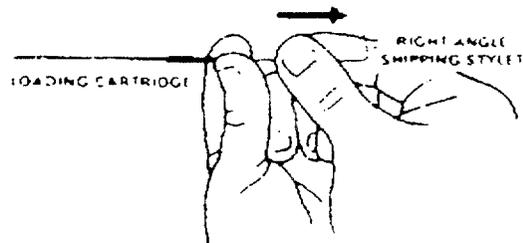
ORDER NUMBER	Length	Configuration	Remarks
MWCE-18-0.5-0-HILAL	5 cm	Straight	
MWCE-18-0.7-0-HILAL	7 cm	Straight	
MWCE-18-1.0-0-HILAL	1.0 cm	Straight	Supplied 2 each in package
MWCE-18-1.5-0-HILAL	1.5 cm	Straight	

*Other coil lengths available upon request

DELIVERY CATHETER AND WIRE GUIDE RECOMMENDATIONS FOR STRAIGHT AND CURLED MICROCOILS™

- Microcoil™ are recommended for use through catheters designed for use with 018 inch (0.46 mm) diameter wire guides and whose inner diameter (ID) does not exceed 027 inch (0.69 mm) diameter. **NOTE:** Coaxial catheters, appropriate for use with non-tapered 13.0 and 13.0S Teflon™ catheters.
- Microcoil™ are not recommended for use with polyurethane or polyvinylchloride catheters.
- Wire guides recommended for loading and positioning Microcoil™ are Teflon™ coated 018 inch (0.46 mm) diameter with shaft diameter of .027 inch (0.69 mm). **NOTE:** Teflon™ Coated Number 1 TSFNA 18 180 TSFNB 18 180

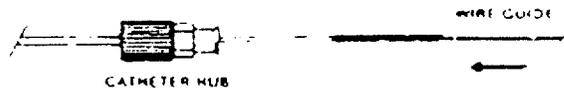
TO LOAD MICROCOIL™ INTO DELIVERY CATHETER



1. Firmly grasp Microcoil™ loading cartridge between thumb and forefinger at point where right angle shipping stylet exits.
2. While maintaining firm finger grip, remove shipping stylet. This will prevent Microcoil™ from exiting cartridge. Verify its position inside cartridge by direct vision.



3. Position loading cartridge into base of hub of catheter.



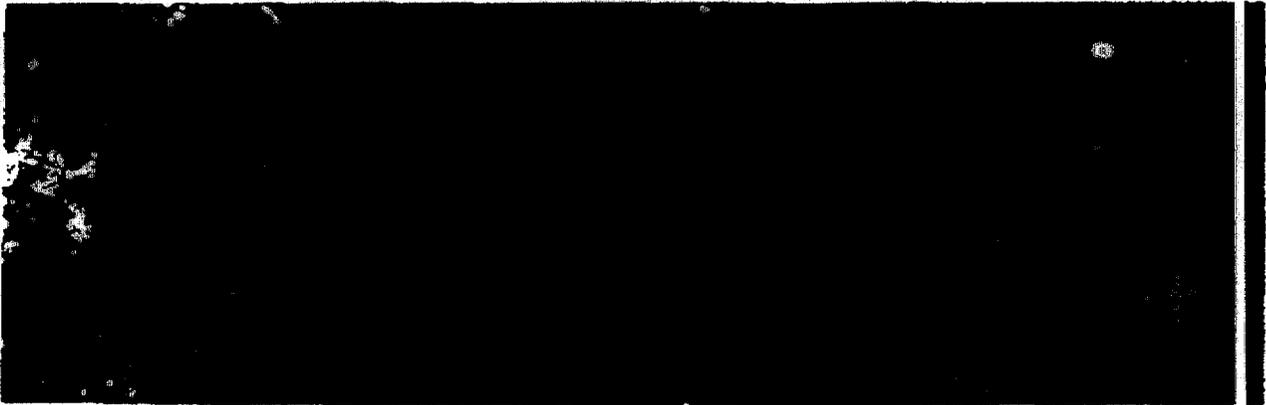
4. Using 018 inch (0.46 mm) diameter wire guide, push Microcoil™ out of loading cartridge into catheter lumen.
5. Remove loading cartridge.

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HILAL EMBOLIZATION MICROCOILS™

CURLED

These coils are made of platinum and are designed for use in the treatment of intracranial aneurysms and arteriovenous malformations. The coils are made of platinum and are designed for use in the treatment of intracranial aneurysms and arteriovenous malformations. The coils are made of platinum and are designed for use in the treatment of intracranial aneurysms and arteriovenous malformations. **NOTE:** Microcoils™ may be used with particulate or liquid embolization materials. Supplied sterile in peel open packages. Intended for one-time use.



ORDER NUMBER	Coiled Diameter	Length	Configuration	Remarks
MWCF 18 10 3 HILAL	3mm	1.0cm	Curled	
MWCF 18 15 5 HILAL	5mm	1.6cm	Curled	
MWCF 18 21 7 HILAL	7mm	2.1cm	Curled	Supplied 2 each per package
MWCF 18 30 10 HILAL	10mm	3.0cm	Curled	

REFERENCES

S. Halal, M.D., Department of Radiology, The Neurological Institute, New York, New York.
 S. Halal et al., Synthetic Fiber Coated Platinum Coils Successfully Used for the Endovascular Treatment of Arterio Venous Malformation, Aneurysms, and Direct Arterio Venous Fistulae of the Central Nervous System. Scientific paper presented at the 26th Annual Meeting of the American Society of Neuroradiology, Chicago, Illinois, 1988.

V. P. Chueng, S. Wallace, C. Giordano, "A New Improved Curled Tapered Tip Catheter for Arterial Occlusion." Radiology: 135 (1980): 507-509.

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HIA EMBOLIZATION MICROCOILS

IDEAL FOR
SMALL VESSEL
EMBOLIZATION

PLATINUM COIL
CONSTRUCTION

STRAIGHT AND
CURVED DESIGNS

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HILAL EMBOLIZATION MICROCOILS™

STRAIGHT

Brain aneurysms and other vascular lesions, due to arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine when surgical resection is indicated or desired. Design of the Microcoils™ permits introduction through small bore post-procedure catheters. Unique straight, non-curling design permits delivery into the target vessel by simple push stroke. Advancement through the steepest segment of the catheter using the wire guide. The coils are made of platinum, easily detected radiographically with spaced synthetic fibers to promote maximum thrombogenicity. Final positioning of Microcoils™ creates a platinum cast™ effect within the vessel lumen. Supplied sterile in periscope packages intended for one-time use.



ORDER INFORMATION

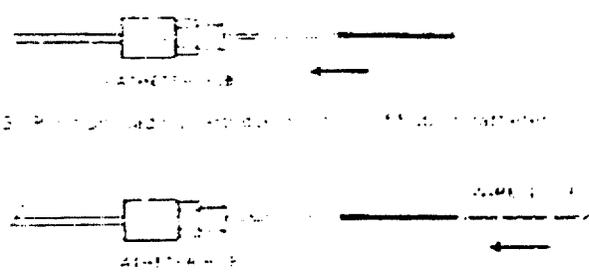
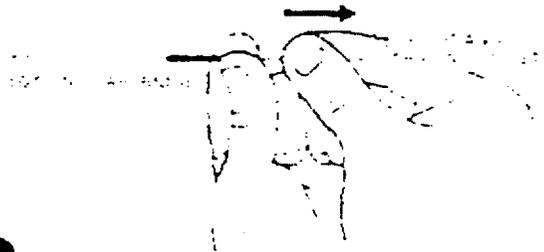
ORDER NUMBER	Length	Coils	Delivery
MADE IN THE USA	1.5m	10	1.5m
MADE IN THE USA	2.0m	10	2.0m
MADE IN THE USA	2.5m	10	2.5m
MADE IN THE USA	3.0m	10	3.0m

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DELIVERY CATHETER AND WIRE GUIDE RECOMMENDATIONS FOR STRAIGHT AND CURLED MICROCOILS™

- Minimum catheter length of 1.5m (5ft) for 1.5m coils, 2.0m (6ft) for 2.0m coils, 2.5m (8ft) for 2.5m coils, and 3.0m (9ft) for 3.0m coils. NOTE: The length of the catheter should be at least 10cm (4in) longer than the coil length.
- Minimum catheter inner diameter of 1.5mm (0.059in) for 1.5m coils, 2.0mm (0.079in) for 2.0m coils, 2.5mm (0.098in) for 2.5m coils, and 3.0mm (0.118in) for 3.0m coils.
- Minimum catheter outer diameter of 4.0mm (0.157in) for 1.5m coils, 4.5mm (0.177in) for 2.0m coils, 5.0mm (0.197in) for 2.5m coils, and 5.5mm (0.217in) for 3.0m coils. NOTE: The length of the catheter should be at least 10cm (4in) longer than the coil length.

TO LOAD MICROCOIL™ INTO DELIVERY CATHETER



1. Insert the wire guide into the catheter.
2. Push the microcoil into the catheter.
3. Push the microcoil into the catheter.
4. Push the microcoil into the catheter.
5. Push the microcoil into the catheter.

EMBOYLIZATION AND COILS

HILAL EMBOLIZATION MICROCOILS™

CURLED

Use for arterial and venous embolization of intracranial aneurysms of the brain, spinal cord and the head and neck. Resection is anticipated or desired. Design of the Microcoils™ permits introduction into the vessel lumen by means of catheters. Deployment of coils into the vessel lumen is accomplished utilizing standard wire guided catheter techniques. They are made of stainless steel and coated with polyurethane. With special surface treatments to make them thromboembolic. Supplied sterile in packaged packages intended for one-time use.



GREEN
CATHETER

Model	Length	Number of Turns	Number of Wires
Model 1015 - Hilal	15 cm	10	10
Model 1025 - Hilal	25 cm	10	10
Model 1035 - Hilal	35 cm	10	10
Model 1045 - Hilal	45 cm	10	10

EST 1968

REFERENCES

1. Green, M.C. Department of Neurology, New York University School of Medicine, New York, New York.

2. Green, M.C., et al. "Surgical Treatment of Intracranial Aneurysms: Use of the Embolic Coil Treatment System for the Management of Intracranial Aneurysms and Direct Arteriovenous Fistulae of the Central Nervous System." Scientific paper presented at the 20th Annual Meeting of the American Society for Neurological Surgery, Chicago, Illinois, May, 1968.

3. Green, M.C., et al. "A New Approach to the Treatment of Intracranial Aneurysms and Direct Arteriovenous Fistulae." *Journal of Neurological Surgery*, 1968, 29: 1-5.

CONFIDENTIAL

SUGGESTED INSTRUCTIONS FOR USING OCCLUDING SPRING EMBOLUS

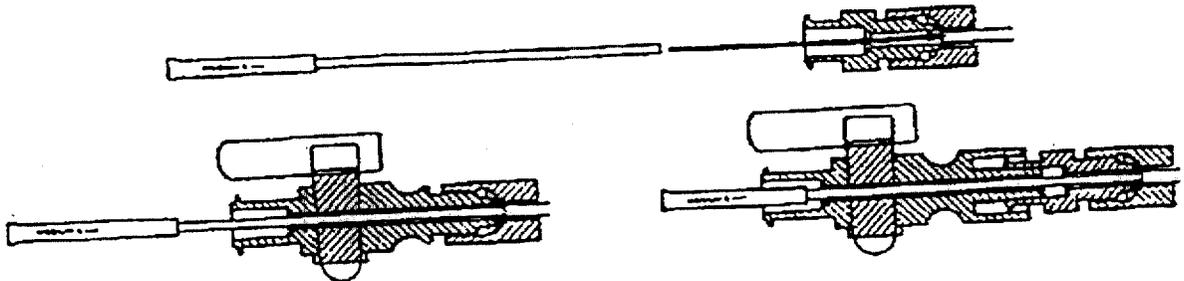
CATALOG NUMBER	Diameter of Coiled Spring Embolus mm	Color Code of Cartridge
MWCE-38-4-3	3	Black
MWCE-38-5-5	5	Blue
MWCE-38-5-8	8	Red

These occluding spring emboli are designed to be used with 6.5 French TORCON and 5.0A1 French (COOK) polyethylene catheters with tips tapered to a .038 inch (0.97 mm) wire guide.

To load the spring embolus into the catheter, insert the cartridge through the stopcock, hub, or both until it is seated on the catheter flare (see figures below). While maintaining the cartridge in this position, push the embolus into the catheter for a distance of 20-30 cm using the stiff end of a .038 inch (0.97 mm) wire guide. Remove the wire guide and cartridge.

With the soft tip of the wire guide, push the coil through the distal tip of the catheter. The ease with which the coil can be pushed through the terminal curve(s) of the catheter depends upon the flexibility of the wire guide tip. The Newton LLT (catalog number SFNB-38-x) is recommended for most cases; SFNC and SLF guides may be useful in some instances of excessive tortuosity of the vessels.

Gianturco, Wallace, and Chuang recommend that the last coil be positioned with particular care. This coil should not be left too close to the inlet of the artery and should be intermeshed with the previous coils if possible. It should be of sufficient size to wedge against the arterial walls. A minimal but sufficient arterial blood flow should remain to hold this coil against the previous coils or other embolic materials until a solid clot insures a permanent fixation. The purpose of these recommendations is to minimize the possibility of a loose coil becoming dislodged and obstructing a normal and essential arterial channel.



NOTICE
 If a catheter with sideports is used, the embolus may jam in the sideport or pass through it into a location other than that intended.

REFERENCE
 V. P. Chuang, S. Wallace, C. Gianturco: "A New Improved Coil for Tapered Tip Catheter for Arterial Occlusion," *Radiology*, 135 (1980), 507-509.

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HILAL EMBOLIZATION MICROCOILS™

- IDEAL FOR
SMALL VESSEL
EMBOLIZATION

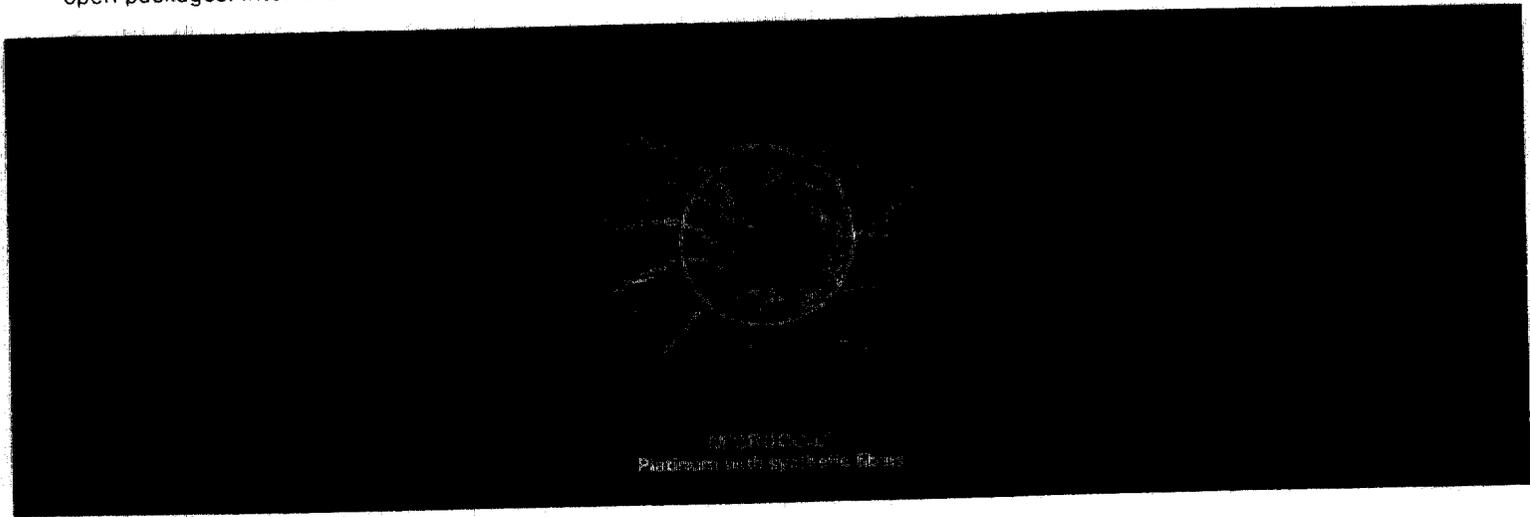
- PLATINUM COIL
CONSTRUCTION

- STRAIGHT AND
CURLLED DESIGNS

HILAL EMBOLIZATION MICROCOILS™

CURLED

Used for arterial and venous embolization procedures. Design of the Microcoils™ permits introduction through small pre-positioned delivery catheters. Deployment of coils into the vessel lumen is accomplished utilizing standard wire guide pusher techniques. The coils are made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum thrombogenicity. **NOTE:** Microcoils™ may be used with particulate or liquid embolization materials. Supplied sterile in peel-open packages. Intended for one-time use.



ORDER NUMBER	Curled Diameter	Length	Configuration	Remarks
MWCE-18-1.0-3-HILAL	3 mm	1.0 cm	Curled	
MWCE-18-1.5-5-HILAL	5 mm	1.5 cm	Curled	Supplied 2 each per package
MWCE-18-2.1-7-HILAL	7 mm	2.1 cm	Curled	
MWCE-18-3.0-10-HILAL	10 mm	3.0 cm	Curled	

REFERENCES

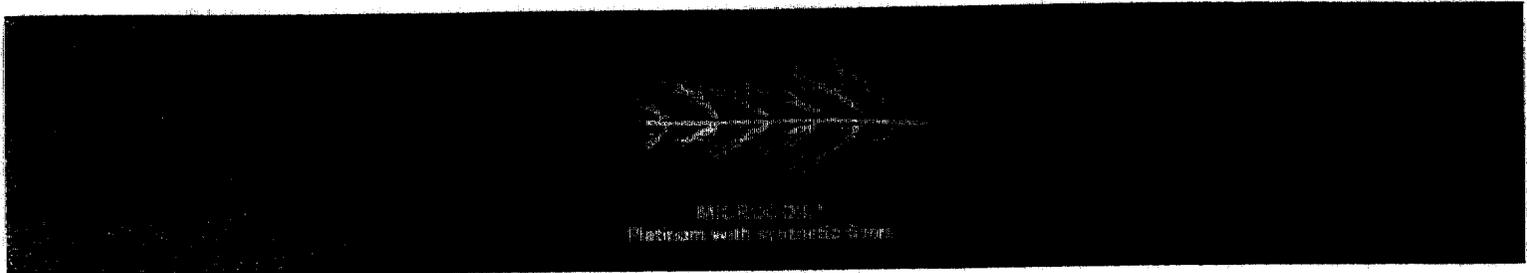
S. Hilal, M.D., Department of Radiology, The Neurological Institute, New York, New York.

S. Hilal, et al: "Synthetic Fiber Coated Platinum Coils Successfully Used for the Endovascular Treatment of Arterio-Venous Malformations, Aneurysms, and Direct Arterio-Venous Fistulae of the Central Nervous System," Scientific paper presented at the 26th Annual Meeting of the American Society of Neuroradiology, Chicago, Illinois, May, 1988.

V. P. Chuang, S. Wallace, C. Gianturco: "A New Improved Coil for Tapered Tip Catheter for Arterial Occlusion," *Radiology*, 135 (1980), 507-509.

**HILAL EMBOLIZATION MICROCOILS™
STRAIGHT**

Used for embolization of selective vessel supply to arterio-venous malformations and other vascular lesions of the brain, spinal cord and spine. Design of the Microcoils™ permits introduction through small, pre-positioned delivery catheters. Unique, straight, non-curling design permits delivery into the target vessel by saline flush after initial advancement through the straightest segment of the catheter using the wire guide. The coils are made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum thrombogenicity. **NOTE:** Microcoils™ may be used in conjunction with particulate or liquid embolization materials. Final positioning of Microcoils™ creates a "platinum cast" effect within the vessel lumen. Supplied sterile in peel-open packages. Intended for one-time use.



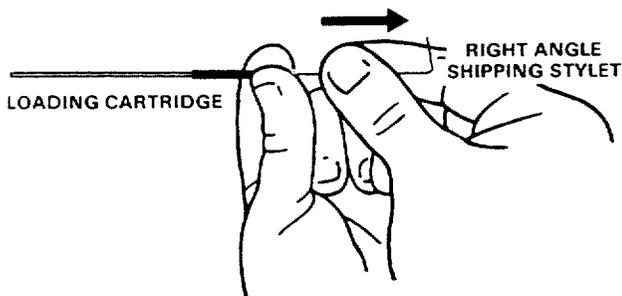
ORDER NUMBER	Length ¹	Configuration	Remarks
MWCE-18-0.5-0-HILAL	.5 cm	Straight	Supplied 2 each per package
MWCE-18-0.7-0-HILAL	.7 cm	Straight	
MWCE-18-1.0-0-HILAL	1.0 cm	Straight	
MWCE-18-1.5-0-HILAL	1.5 cm	Straight	

¹Other coil lengths available upon request

**DELIVERY CATHETER AND WIRE GUIDE
RECOMMENDATIONS FOR STRAIGHT AND CURLED MICROCOILS™**

- Microcoils™ are recommended for use through catheters designed for use with .018 inch (0.46 mm) diameter wire guides and whose inner diameter (ID) does not exceed .027 inch (0.69 mm) diameter. **NOTE:** Cook catheters appropriate for use are non-tapered T3.0 and T3.0S Teflon® catheters.
- Microcoils™ are not recommended for use with polyurethane or polyvinylchloride catheters.
- Wire guides recommended for loading and positioning Microcoils™ are Teflon® coated .018 inch (0.46 mm) diameter with flexible tapered tips. **NOTE:** Cook Order Numbers: **TSFNA-18-180, TSFNB-18-180.**

TO LOAD MICROCOIL™ INTO DELIVERY CATHETER



3. Position loading cartridge into base of hub of catheter.



4. Using .018 inch (0.46 mm) diameter wire guide, push Microcoil™ out of loading cartridge and into catheter lumen.

5. Remove loading cartridge.

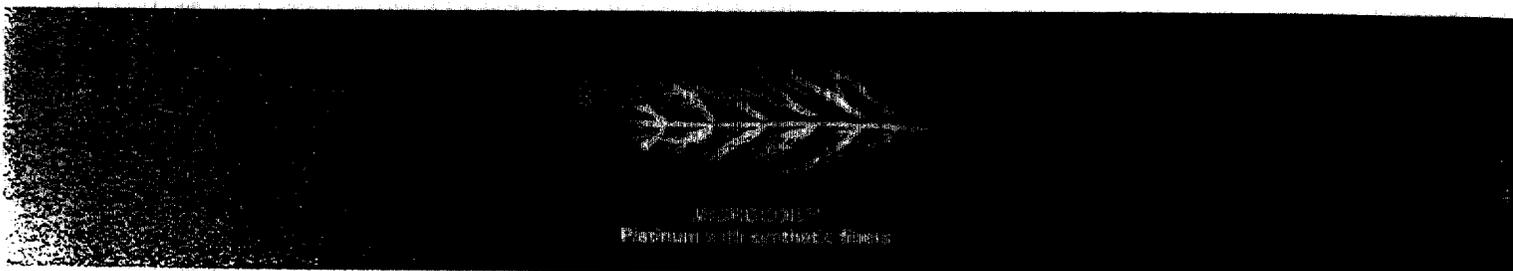
1. Firmly grasp Microcoil™ loading cartridge between thumb and forefinger at point where right angle shipping stylet exits.
2. While maintaining firm finger grip, remove shipping stylet. This will prevent Microcoil™ from exiting cartridge. Verify its position inside cartridge by direct vision.

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HILAL EMBOLIZATION MICROCOILS™

STRAIGHT

Used for embolization of selective vessel supply to arterio-venous malformations and other vascular lesions of the brain, spinal cord and spine. Design of the Microcoils™ permits introduction through small, pre-positioned delivery catheters. Unique, straight, non-curling design permits delivery into the target vessel by saline flush after initial advancement through the straightest segment of the catheter using the wire guide. The coils are made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum thrombogenicity. **NOTE:** Microcoils™ may be used in conjunction with particulate or liquid embolization materials. Final positioning of Microcoils™ creates a "platinum cast" effect within the vessel lumen. Supplied sterile in peel-open packages. Intended for one-time use.



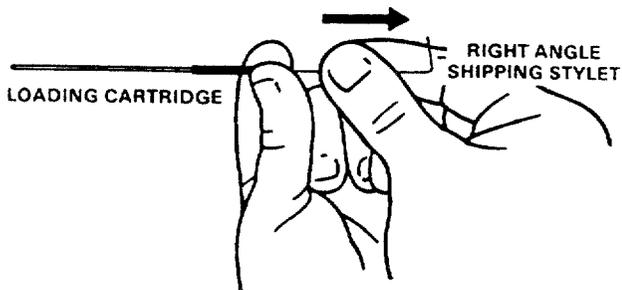
ORDER NUMBER	Length ¹	Configuration	Remarks
MWCE-18-0.5-0-HILAL	.5 cm	Straight	
MWCE-18-0.7-0-HILAL	.7 cm	Straight	
MWCE-18-1.0-0-HILAL	1.0 cm	Straight	Supplied 2 each per package
MWCE-18-1.5-0-HILAL	1.5 cm	Straight	

¹Other coil lengths available upon request

DELIVERY CATHETER AND WIRE GUIDE RECOMMENDATIONS FOR STRAIGHT AND CURLED MICROCOILS™

- Microcoils™ are recommended for use through catheters designed for use with .018 inch (0.46 mm) diameter wire guides and whose inner diameter (ID) does not exceed .027 inch (0.69 mm) diameter. **NOTE:** Cook catheters appropriate for use are non-tapered T3.0 and T3.0S Teflon® catheters.
- Microcoils™ are not recommended for use with polyurethane or polyvinylchloride catheters.
- Wire guides recommended for loading and positioning Microcoils™ are Teflon® coated .018 inch (0.46 mm) diameter with flexible tapered tips. **NOTE:** Cook Order Numbers: **TSFNA-18-180, TSFNB-18-180.**

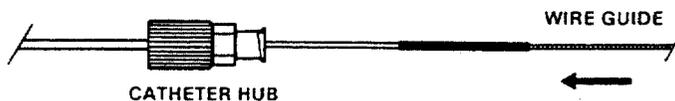
TO LOAD MICROCOIL™ INTO DELIVERY CATHETER



1. Firmly grasp Microcoil™ loading cartridge between thumb and forefinger at point where right angle shipping stylet exits.
2. While maintaining firm finger grip, remove shipping stylet. This will prevent Microcoil™ from exiting cartridge. Verify its position inside cartridge by direct vision.



3. Position loading cartridge into base of hub of catheter.



4. Using .018 inch (0.46 mm) diameter wire guide, push Microcoil™ out of loading cartridge and into catheter lumen.
5. Remove loading cartridge.

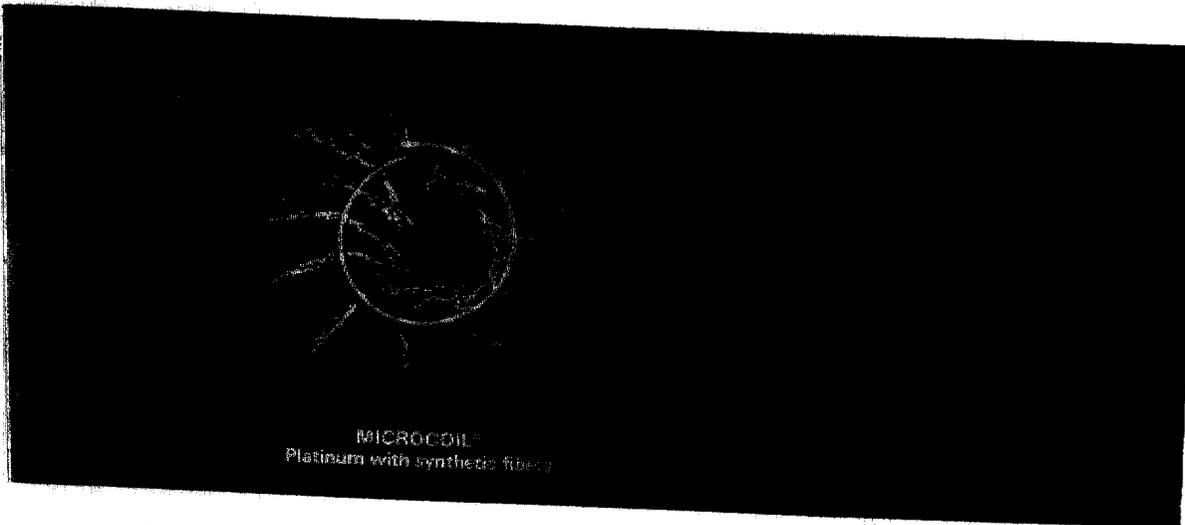
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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0-000089

EMBOLIZATION MICROCOILS™

...olization procedures. Design of the Microcoils™ permits introduction through small pre-
 ...eters. Deployment of coils into the vessel lumen is accomplished utilizing standard wire guide pusher
 ...e made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum
 ...: Microcoils™ may be used with particulate or liquid embolization materials. Supplied sterile in peel-
 ...d for one-time use.



Curled Diameter	Length	Configuration	Remarks
3 mm	1.0 cm	Curled	Supplied 2 each per package
5 mm	1.5 cm	Curled	
7 mm	2.1 cm	Curled	
10 mm	3.0 cm	Curled	

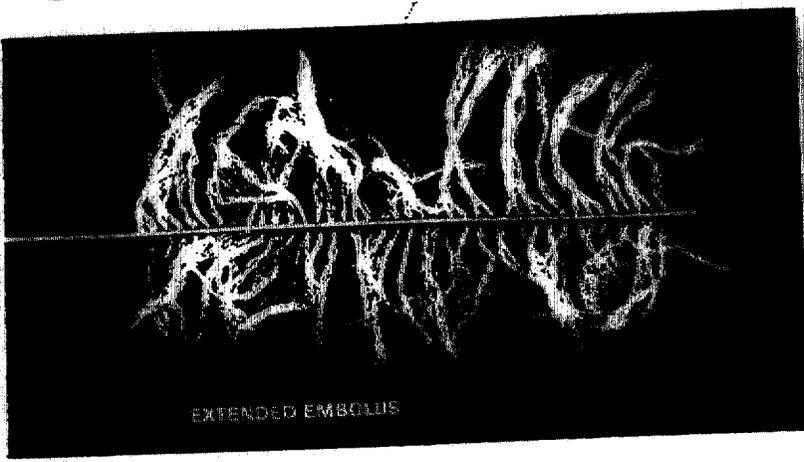
...radiology, The Neurological Insti-
 ...ated Platinum Coils Successfully
 ...ment Arterio-Venous Malfor-
 ...Art Venous Fistulae of the
 ...ific presented at the 26th
 ...an Society of Neuroradiology.

V. P. Chuang, S. Wallace, C. Gianturco: "A New Improved Coil for
 Tapered Tip Catheter for Arterial Occlusion," *Radiology*, 135
 (1980), 507-509.

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MC PRING EMBOLI

Various embolization. Supplied sterile in peel-open packages. Intended for one-time use.



	EXTENDED EMBOLUS		COILED EMBOLUS		Cartridge Color	Remarks
	Diameter	Length	Diameter			
-2	.025 inch (0.64 mm)	1.2 cm	2 mm		Black	MWCE-25 emboli are used with non-tapered T3.0S radiopaque Teflon® catheters. Position with .025 inch (0.64 mm) wire guides.
-2	.025 inch (0.64 mm)	2.5 cm	2 mm		Black	
	.025 inch (0.64 mm)	3 cm	5 mm		Black	
	.025 inch (0.64 mm)	4 cm	3 mm		Black	
	.038 inch (0.97 mm)	2 cm	3 mm		Black	MWCE-38 emboli are used with BPS6.5 French Torcon®, HBP5.5 French High-Flo™ Silver, and 5.0B French polyethylene catheters with tips tapered to .038 inch (0.97 mm) wire guide and without sideports. Position with .038 inch (0.97 mm) wire guides.
	.038 inch (0.97 mm)	4 cm	3 mm		Black	
	.038 inch (0.97 mm)	5 cm	5 mm		Blue	
	.038 inch (0.97 mm)	5 cm	8 mm		Red	MWCE-52 emboli are used with non-tapered BPS8.2 French Torcon® and non-tapered HBP7.0 French High-Flo™ Silver catheters without sideports. Position with .052 inch (1.32 mm) wire guides.
-15	.052 inch (1.32 mm)	10 cm	15 mm		Black	
-15	.052 inch (1.32 mm)	15 cm	15 mm		Black	
-20	.052 inch (1.32 mm)	15 cm	20 mm		Black	

OCE
S. Wallace, C. Gianturco: "A New Improved Coil for Tapered Tip Catheter for Arterial Occlusion," *Radiology*, 135 (1980).

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0-000091

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111 Sandiford Drive
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L4A 7X5 CANADA
Phone: 416 640-7110
Toll Free: 800 668-0300

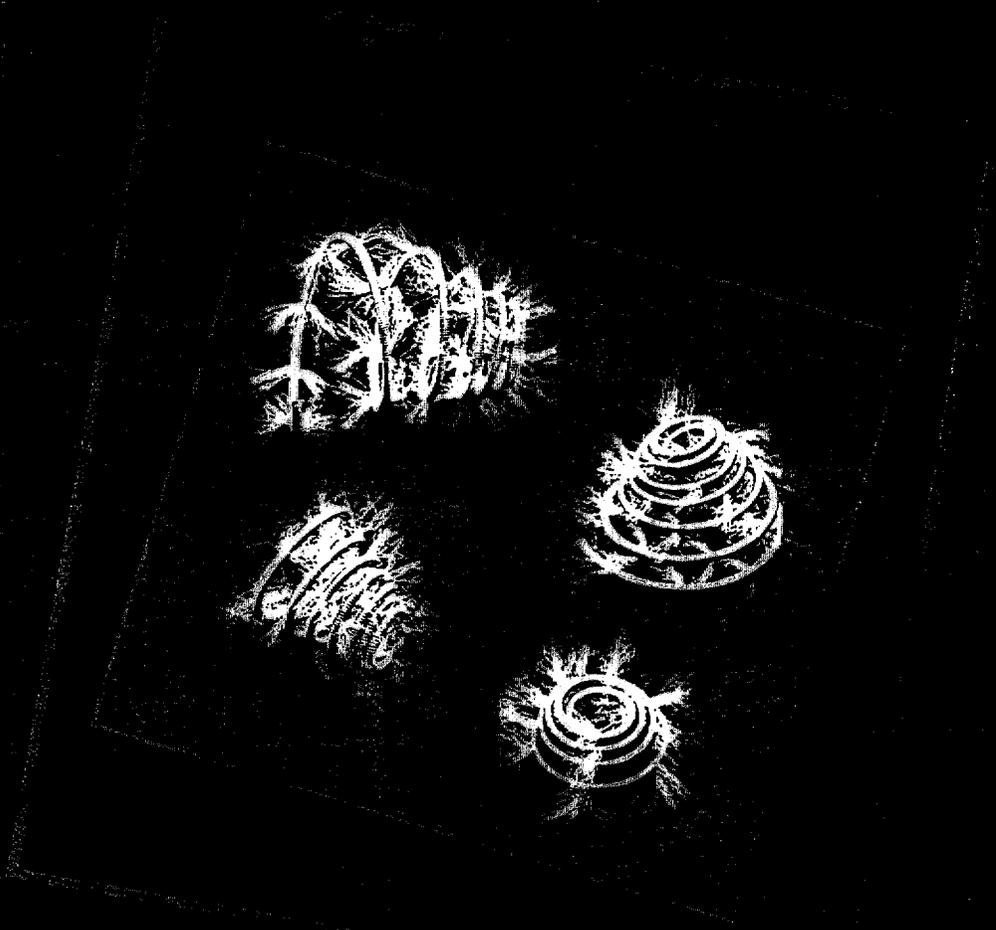
WILLIAM A. COOK AUSTRALIA PTY. LTD.
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Sandet 6 DK-4632
Bjaeverskov, DENMARK
Phone: 45 53-671133

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TORNADO™

EMBOLIZATION MICROCOILS™



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HILAL EMBOLIZATION MICROCOILS™

- IDEAL FOR
SMALL VESSEL
EMBOLIZATION

- PLATINUM COIL
CONSTRUCTION

- STRAIGHT AND
CURLLED DESIGNS

COOK

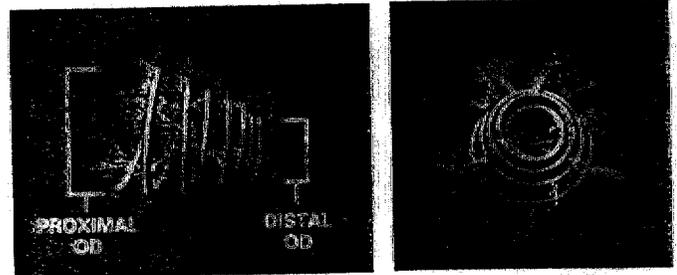
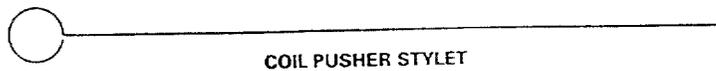
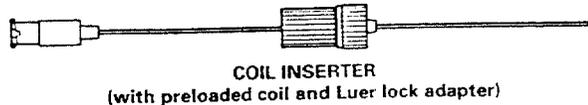
Cook Incorporated

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0-000094

TORNADO™ EMBOLIZATION MICROCOILS™

Used for embolization of selective vessel supply to arterio-venous malformations and other vascular lesions in small vessel anatomy. Longer coil length and tornado-like configuration in deployed state maximizes coil exposure to cross section of lumen for disruption of blood-flow. The Tornado™ coil is also ideally suited for tapering vessel situations. Special platinum coil (**18S** as denoted in the order number) used for construction is soft, easily detected radiographically and features spaced synthetic fibers to maximize thrombogenicity. **Coil design permits delivery into the target vessel by saline flush or by push technique using an appropriately sized wire guide or pusher.** Supplied sterile in peel-open packages. Intended for one-time use.



TORNADO™ EMBOLIZATION MICROCOIL™
Platinum with synthetic fibers

ORDER NUMBER	EXTENDED EMBOLUS		COILED EMBOLUS	TYPE	Remarks
	Diameter	Length	Tapering Diameter		
MWCE-18S-6/2-TORNADO	.018 inch (0.46 mm)	7 cm	6 mm - 2 mm	TORNADO	Supplied 1 each per package
MWCE-18S-5/2-TORNADO	.018 inch (0.46 mm)	5 cm	5 mm - 2 mm	TORNADO	
MWCE-18S-4/2-TORNADO	.018 inch (0.46 mm)	4 cm	4 mm - 2 mm	TORNADO	
MWCE-18S-3/2-TORNADO	.018 inch (0.46 mm)	2 cm	3 mm - 2 mm	TORNADO	

DELIVERY CATHETER AND WIRE GUIDE RECOMMENDATIONS FOR TORNADO™ EMBOLIZATION MICROCOILS™

- Tornado™ Embolization Microcoils™ are recommended for use through catheters that accept .018 inch (0.46 mm) maximum diameter wire guides and whose inner diameter (ID) does not exceed .027 inch (0.69 mm). Examples: 3.0 French nylon catheters with radiopaque tips (N3.0B-RT); COOK MicroFerret™ Superselective Catheter (not available in United States).
- Tornado™ Embolization Microcoils™ are not recommended for use with polyurethane or polyvinylchloride catheters.
- Wire guides recommended for loading and positioning Tornado™ Embolization Microcoils™ are TFE coated .018 inch (0.46 mm) diameter with flexible tapered tips. Examples: TSFNB-18 and TSFNC-18.
- Refer to product insert for suggested instructions for use.

COOK®

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Bjaeverskov, DENMARK
Phone: 45 53-671133



HILAL
MICROCOILS™
PLATINUM

STRAIGHT

SINGLE CURLED

EMBOLIZATION COILS

MULTIPLE CURLED



STANDARD
DESIGNS
STAINLESS STEEL

COOK®

Cook Incorporated

12/08

HILAL EMBOLIZATION MICROCOILS™

STRAIGHT

Used for embolization of selective vessel supply to arterio-venous malformations and other vascular lesions of the brain, spinal cord and spine. Design of the Microcoils™ permits introduction through small, pre-positioned delivery catheters. Coil design permits delivery into the target vessel by saline flush after initial advancement through the straightest segment of the catheter using the wire guide. The coils are made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum thrombogenicity. **NOTE:** Microcoils™ may be used in conjunction with particulate or liquid embolization materials. Final positioning of Microcoils™ creates a "platinum cast" effect within the vessel lumen. Supplied sterile in peel-open packages. Intended for one-time use.



ORDER NUMBER	Length ¹	Configuration	Remarks
MWCE-18-0.5-0-HILAL	.5 cm	Straight	
MWCE-18-0.7-0-HILAL	.7 cm	Straight	Supplied 2 each per package
MWCE-18-1.0-0-HILAL	1.0 cm	Straight	
MWCE-18-1.5-0-HILAL	1.5 cm	Straight	

¹Other coil lengths are available upon request.

DELIVERY CATHETER AND WIRE GUIDE RECOMMENDATIONS FOR STRAIGHT AND CURLED MICROCOILS™

- Microcoils™ are recommended for use through catheters designed for use with .018 inch (0.46 mm) diameter wire guides and whose inner diameter (ID) does not exceed .027 inch (0.69 mm) diameter. **NOTE:** Cook catheters appropriate for use are nontapered N3.OB, T3.0 and T3.0S Teflon® catheters.
- Microcoils™ are not recommended for use with polyurethane or polyvinylchloride catheters.
- Wire guides recommended for loading and positioning Microcoils™ are Teflon® coated .018 inch (0.46 mm) diameter with flexible tapered tips. **NOTE:** Cook Order Numbers: **TSFNA-18-180, TSFNB-18-180.**

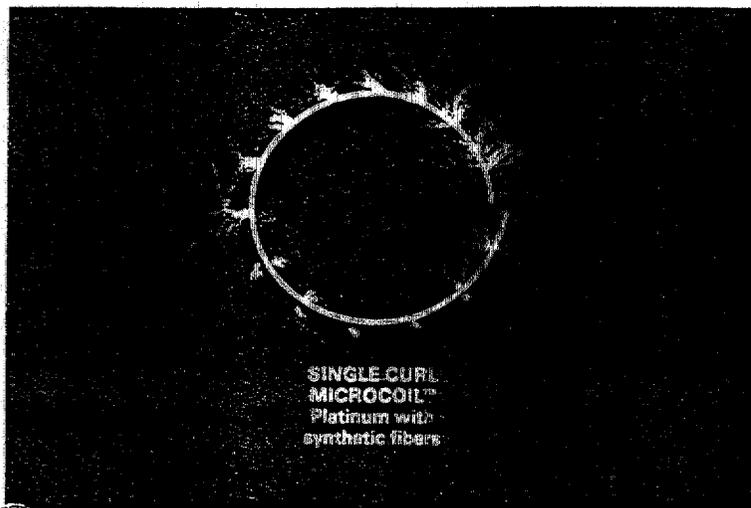
REFER TO PRODUCT INSERT FOR SUGGESTED INSTRUCTIONS FOR USE.

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HILAL EMBOLIZATION MICROCOILS™

SINGLE CURLED AND MULTIPLE CURLED COIL CONFIGURATIONS

Used for embolization of selective vessel supply to arterio venous malformations and other vascular lesions of the brain, spinal cord and spine. Design of the Microcoils™ permits introduction through small, pre-positioned delivery catheters. Coil design permits delivery into the target vessel by saline flush after initial advancement of the straightest segment of the catheter using the wire guide. The coils are made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum thrombogenicity. **NOTE:** Microcoils™ may be used in conjunction with particulate or liquid embolization materials. Final positioning of Microcoils™ creates a "platinum cast" effect within the vessel lumen. Supplied sterile in peel-open packages. Intended for one-time use.



ORDER NUMBER	EXTENDED EMBOLUS		COILED EMBOLUS		
	Diameter	Length	Diameter	Configuration	Remarks
SINGLE CURLED COIL CONFIGURATIONS					
MWCE-18-1.0-3-HILAL	.018 inch (0.46 mm)	1.0 cm	3 mm	Single curl	Supplied 2 each per package
MWCE-18-1.5-5-HILAL	.018 inch (0.46 mm)	1.5 cm	5 mm		
MWCE-18-2.1-7-HILAL	.018 inch (0.46 mm)	2.1 cm	7 mm		
MWCE-18-3.0-10-HILAL	.018 inch (0.46 mm)	3.0 cm	10 mm		
MULTIPLE CURLED COIL CONFIGURATIONS					
MWCE-18-2.0-2-HILAL	.018 inch (0.46 mm)	2.0 cm	2 mm	Multiple curls	Supplied 2 each per package
MWCE-18-2.0-4-HILAL	.018 inch (0.46 mm)	2.0 cm	4 mm		
MWCE-18-3.0-3-HILAL	.018 inch (0.46 mm)	3.0 cm	3 mm		
MWCE-18-3.0-4-HILAL	.018 inch (0.46 mm)	3.0 cm	4 mm		
MWCE-18-4.0-6-HILAL	.018 inch (0.46 mm)	4.0 cm	6 mm		
MWCE-18-4.0-7-HILAL	.018 inch (0.46 mm)	4.0 cm	7 mm		
MWCE-18-6.0-5-HILAL	.018 inch (0.46 mm)	6.0 cm	5 mm		
MWCE-18-6.0-7-HILAL	.018 inch (0.46 mm)	6.0 cm	7 mm		
MWCE-18-6.0-10-HILAL	.018 inch (0.46 mm)	6.0 cm	10 mm		

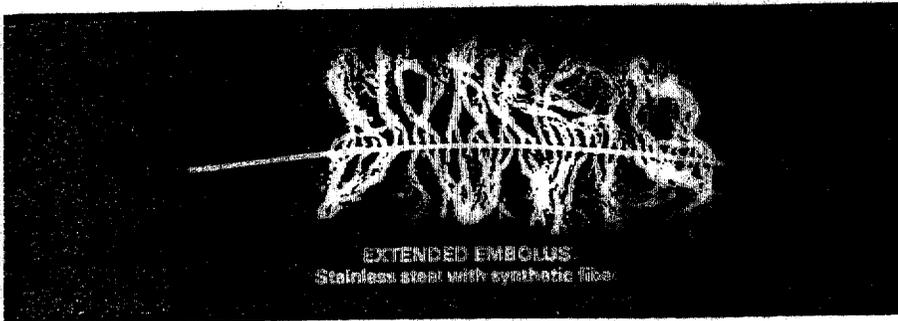
REFER TO PRODUCT INSERT FOR SUGGESTED INSTRUCTIONS FOR USE.

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0-000098

EMBOLIZATION COILS

Used for arterial and venous embolization. Supplied sterile in peel-open packages. Intended for one-time use.



ORDER NUMBER	EXTENDED EMBOLUS		COILED EMBOLUS		Remarks	
	Diameter	Length	Diameter			
MWCE-25-1-2-2	.025 inch (0.64 mm)	1.2 cm	2 mm		MWCE-25 emboli are used with nontapered T3.0S radiopaque Teflon® and N3.0B nylon catheters. Position with .025 inch (0.64 mm) wire guides.	
MWCE-25-2-3	.025 inch (0.64 mm)	2 cm	3 mm			
MWCE-25-2.5-2	.025 inch (0.64 mm)	2.5 cm	2 mm			
MWCE-25-3-2	.025 inch (0.64 mm)	3 cm	2 mm			
MWCE-25-3-3	.025 inch (0.64 mm)	3 cm	3 mm			
MWCE-25-3-5	.025 inch (0.64 mm)	3 cm	5 mm			
MWCE-25-4-3	.025 inch (0.64 mm)	4 cm	3 mm			
MWCE-25-5-5	.025 inch (0.64 mm)	5 cm	5 mm			
MWCE-35-1-2	.035 inch (0.89 mm)	1 cm	2 mm			MWCE-35 emboli are used with BPS6.5 French Torcon®, HBP5.0N French High-Flo™ Silver, HNB5.0 French Torcon NB® Advantage and P5.0 French polyethylene catheters with tips tapered to .035 inch (0.89 mm) wire guide and without sideports. Position with .035 inch (0.89 mm) wire guides.
MWCE-35-1-3	.035 inch (0.89 mm)	1 cm	3 mm			
MWCE-35-2-3	.035 inch (0.89 mm)	2 cm	3 mm			
MWCE-35-3-2	.035 inch (0.89 mm)	3 cm	2 mm			
MWCE-35-3-3	.035 inch (0.89 mm)	3 cm	3 mm			
MWCE-35-3-4	.035 inch (0.89 mm)	3 cm	4 mm			
MWCE-35-3-5	.035 inch (0.89 mm)	3 cm	5 mm			
MWCE-35-4-3	.035 inch (0.89 mm)	4 cm	3 mm			
MWCE-35-5-3	.035 inch (0.89 mm)	5 cm	3 mm			
MWCE-35-5-5	.035 inch (0.89 mm)	5 cm	5 mm			
MWCE-38-1-3	.038 inch (0.97 mm)	1 cm	3 mm		MWCE-38 emboli are used with BPS6.5 French Torcon®, HBP5.5 French High-Flo™ Silver, HNB5.0 French Torcon NB® Advantage and P5.0B French polyethylene catheters with tips tapered to .038 inch (0.97 mm) wire guide and without sideports. Position with .038 inch (0.97 mm) wire guides.	
MWCE-38-1.2-2	.038 inch (0.97 mm)	1.2 cm	2 mm			
MWCE-38-2-3	.038 inch (0.97 mm)	2 cm	3 mm			
MWCE-38-3-2	.038 inch (0.97 mm)	3 cm	2 mm			
MWCE-38-3-5	.038 inch (0.97 mm)	3 cm	5 mm			
MWCE-38-3-8	.038 inch (0.97 mm)	3 cm	8 mm			
MWCE-38-4-3	.038 inch (0.97 mm)	4 cm	3 mm			
MWCE-38-5-3	.038 inch (0.97 mm)	5 cm	3 mm			
MWCE-38-5-5	.038 inch (0.97 mm)	5 cm	5 mm			
MWCE-38-5-8	.038 inch (0.97 mm)	5 cm	8 mm			
MWCE-38-5-10	.038 inch (0.97 mm)	5 cm	10 mm		MWCE-52 emboli are used with nontapered BPS8.2 French Torcon® and nontapered HNB7.0 French Torcon NB® Advantage catheters without sideports. Position with .038 inch (0.97 mm) or .052 inch (1.32 mm) wire guides.	
MWCE-38-5-12	.038 inch (0.97 mm)	5 cm	12 mm			
MWCE-38-5-15	.038 inch (0.97 mm)	5 cm	15 mm			
MWCE-38-8-10	.038 inch (0.97 mm)	8 cm	10 mm			
MWCE-38-8-12	.038 inch (0.97 mm)	8 cm	12 mm			
MWCE-38-8-15	.038 inch (0.97 mm)	8 cm	15 mm			
MWCE-38-15-15	.038 inch (0.97 mm)	15 cm	15 mm			
MWCE-52-10-15	.052 inch (1.32 mm)	10 cm	15 mm			
MWCE-52-15-15	.052 inch (1.32 mm)	15 cm	15 mm			
MWCE-52-15-20	.052 inch (1.32 mm)	15 cm	20 mm			

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POSITIONING EMBOLIZATION COILS

These embolization coils are not recommended for use with polyurethane catheters or catheters with sideports. If a catheter with sideports is used, the embolus may jam in the sideport or pass through it into a location other than that intended. Use of a polyurethane catheter may also result in jamming of the embolus within the catheter.

To load the embolization coil into the catheter, insert the cartridge through the stopcock, hub or both until it is seated on the catheter flare. While maintaining the cartridge in this position, push the coil into the catheter for a distance of 20-30 cm, using the stiff end of a wire guide. Remove the wire guide and the cartridge.

With the flexible tip of the wire guide, push the embolization coil through the distal tip of the catheter. The ease with which the embolization coil can be pushed through the terminal curve(s) of the catheter depends upon the flexibility of the wire guide tip. Flexible tip wire guides, such as the Newton **TSFNB** guide described below, are recommended for most cases; in some instances a more flexible **TSFNC** or **TSLF** guide may be useful. For greater lubricity, Teflon® coated wire guides have proven to be useful.

Gianturco, Wallace and Chuang suggest that the last embolization coil be positioned with particular care. This embolization coil should not be left too close to the inlet of the artery and should be intermeshed with the previous embolization coils if possible; it should be of sufficient size to wedge against the arterial walls. A minimal but sufficient arterial blood flow should remain to hold this embolization coil against the previous embolization coils or other embolic materials until a solid clot insures a permanent fixation. The purpose of these suggestions is to minimize the possibility of a loose embolization coil becoming dislodged and obstructing a normal and essential arterial channel.

WIRE GUIDES FOR POSITIONING EMBOLIZATION COILS

Supplied sterile in peel-open packages. Intended for one-time use.

TO ORDER, FOLLOW THE ARROWS: (Example: **TSFNB-38-145**)



ORDER NUMBER PREFIX	DIAMETER				LENGTH cm	Remarks
	.018 0.46	.025 0.64	.038 0.97	.052 1.32		
Teflon® Coated						
NEWTON CEREBRAL						
TSFNB	18	25	38	52	145	LLT—15 cm flexible tip
TSFNC	18	25	38	52	145	LLLT—20 cm flexible tip
LONG FLEXIBLE TIP						
TSLF	18	25	38	52	145	20 cm flexible tip

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Appendix H – Supporting Information for Peripheral Indication

Individual Article Summaries

This section provides individual summaries for 17 journal articles documenting the use of pushable coils in the peripheral vasculature. Following the summaries are copies of the journal articles.

1. Barnwell SL, Halbach VV, Dowd CF, Higashida RT, and Hieshima GB. Endovascular Treatment of Scalp Arteriovenous Fistulas Associated with a Large Varix. Radiology. 173(2): 533-539, 1989.

- The authors report the successful use of coils, alone or combined with other embolic agents or therapies, to treat 5 patients with scalp AVFs associated with a large varix (cirroid aneurysms or large draining vein). This method has been used recently as an adjunct to surgery (feeding vessel occlusion facilitates surgical excision by reducing blood loss) or as a definitive therapy in scalp aneurysm treatment.
- The coils used for the embolization procedures were the Gianturco coils (Cook) and platinum mini coils (Target Therapeutics). One patient was treated via a femoral transarterial route, 3 patients via direct percutaneous puncture (2 with the combined use of liquid adhesive), and 1 patient via femoral transvenous embolization combined with the use of liquid adhesive.
- After treatment, 4 cases were cured and the 5th exhibited a 50% decrease in flow. No major complications or morbidity resulted and no complications were associated with the coils.
- The authors conclude that embolization should be primary therapy for these types of lesions. Recent microcatheter technology advances facilitated the delivery of embolic materials, both transarterial and transvenous, resulting in a definitive lesion cure with minimal morbidity and no mortality.

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2. Beaujeux R, Saussine C, Al-Fakir A, Boudjema K, Roy, Jacqmin D, and Bourjat P. Superselective Endo-Vascular Treatment of Renal Vascular Lesions. Journal of Urology. 153(1): 14-17, 1994.

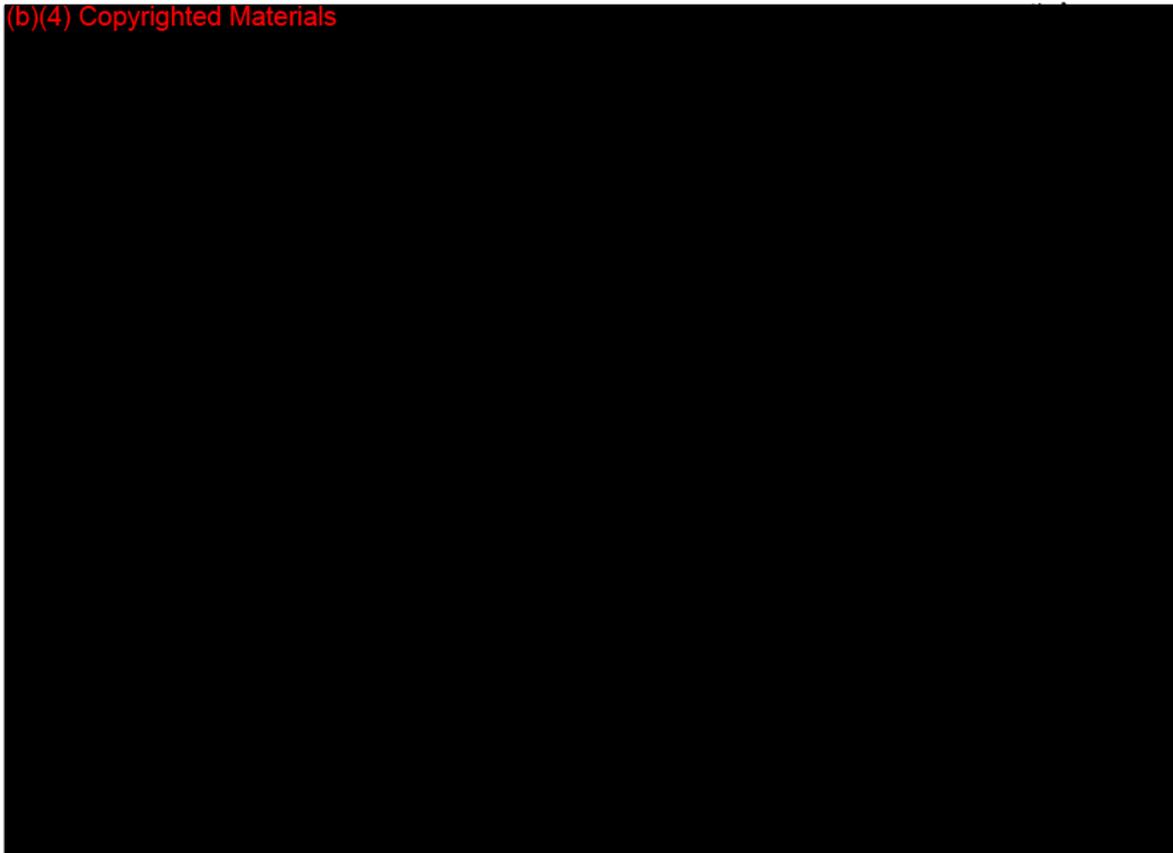
- Beaujeux, et al discuss 6 patients with renal vascular lesions where peripheral selective catheterization with standard angiographic catheters could not be utilized. Instead, embolization with platinum microcoils was chosen. In total, 7 peripheral renal vascular lesions were present (3 AVFs, 2 false aneurysms, 1 direct vascular trauma, and 1 AVM) and all cases were initially treated with complex helical polyester fibered platinum microcoils. Two patients required subsequent glue embolization. The treatments were successful in all cases without complications. Either small peripheral (n=3) or renal parenchyma (n=3) infarctions occurred, which are often found in traditional catheterization techniques.
- In conclusion, embolization is a simple, effective treatment that cures vascular lesions and retains the functional renal parenchyma. The ability to position the microcoils precisely within the artery feeding the AVF or within the shunt results in permanent occlusion.

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Appendix H – Supporting Information for Peripheral Indication, Continued

3. **Cikrit DF, Daising MC, Lalka SG, Fiore NF, Sawchuck AP, Ladd AP, and Solooki B. Early Results of Endovascular-Assisted In Situ Saphenous Vein Bypass Grafting. Journal of Vascular Surgery. 19(5): 778-787, 1994.**

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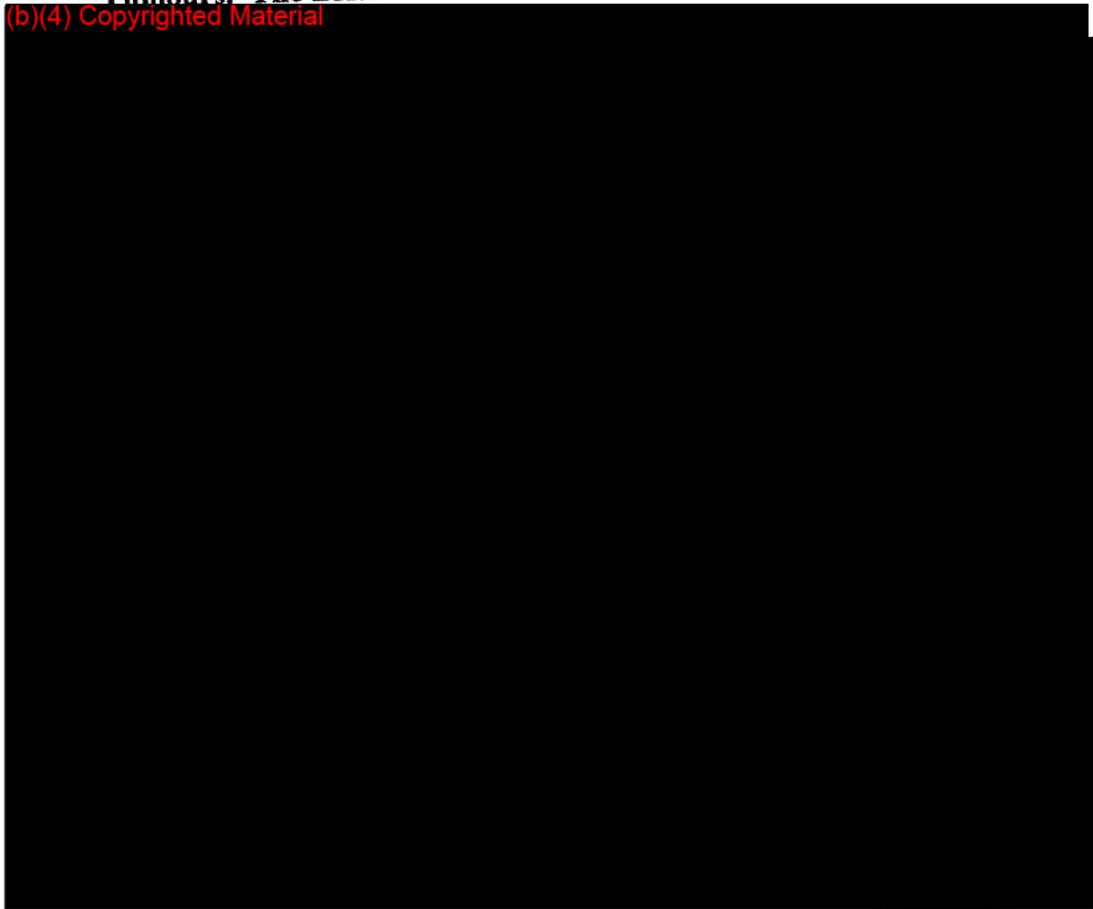


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Appendix H – Supporting Information for Peripheral Indication, Continued

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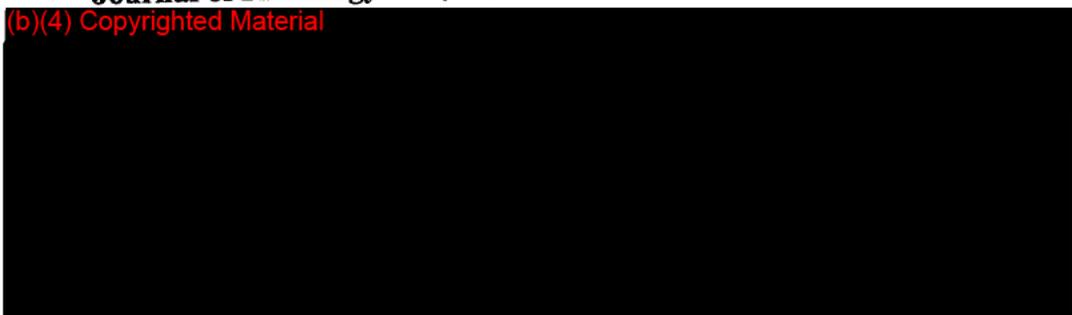
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Appendix H – Supporting Information for Peripheral Indication, Continued

6. Kuroiwa T, Hasuo K, Mizushima A, Yoshida K, Hirakata R, Komatsu K, Yamaguchi A, and Masuda K. **Transcatheter Embolization of Testicular Vein for Varicocele Testis.** *Acta Radiologica.* 32(4): 311-314, 1991.
- Testicular vein percutaneous transcatheter embolization was performed on 28 patients diagnosed with varicocele testis. In 26 cases, only the left vein was embolized and the other 2 had bilateral procedures. All procedures used stainless steel coils. In 23 of the 28 cases (82%), the grade of the varicoceles improved after embolization, but pregnancy was achieved in only 1 case. The simplistic method resulted in no serious complications. However, Kuroiwa, et al note the potential risk of coil dislodgment with left renal vein thrombosis or pulmonary embolus. They conclude that testicular venography and transcatheter embolization for varicoceles with the basilic vein approach are relatively simple procedures with minimal complication risk. Most infertile male patients with clinical diagnosis of varicoceles may benefit from this technique.
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Appendix H – Supporting Information for Peripheral Indication, Continued

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10. Rankin EM, Rubens RD, and Reidy JF. Transcatheter Embolisation to Control Severe Bleeding in Fungating Breast Cancer. *European Journal of Surgical Oncology*. 14(1): 27-32, 1988.

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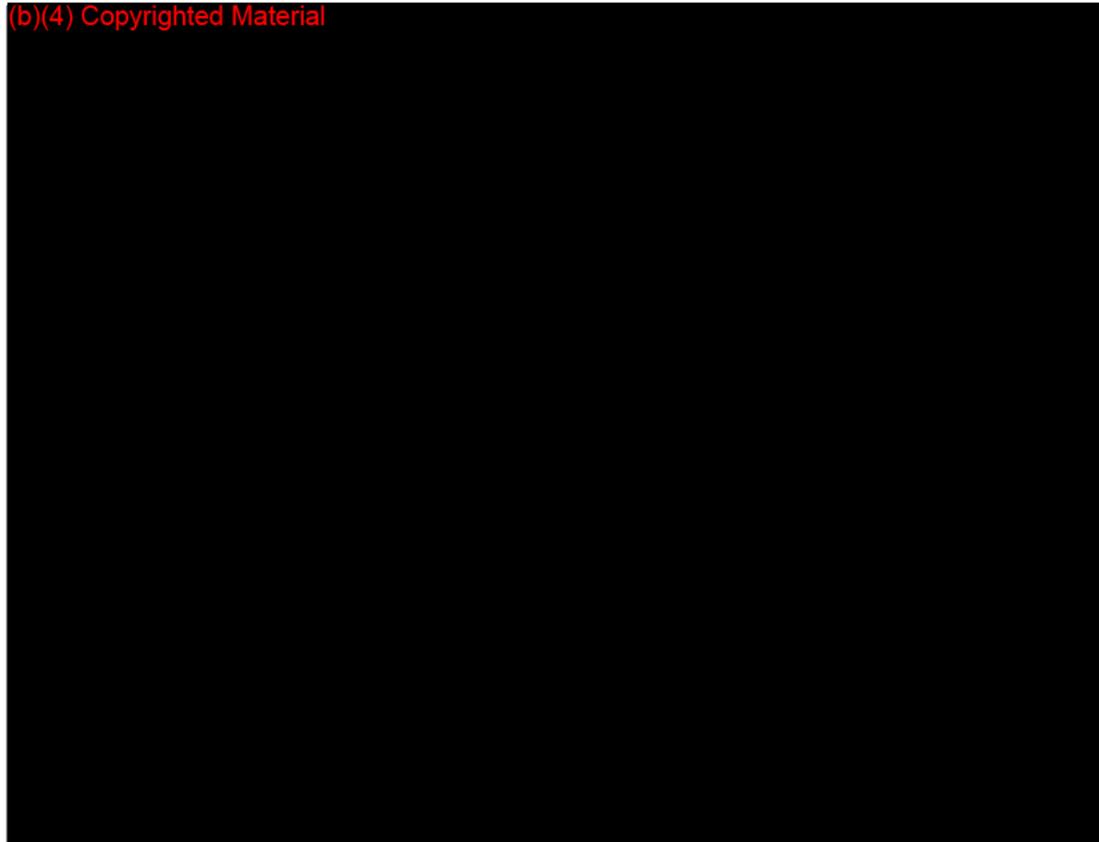
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Appendix H – Supporting Information for Peripheral Indication, Continued

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- 13. Stambo GW, Hallisey MJ, and Gallaher JJ. Arteriographic Embolization of Visceral Artery Pseudoaneurysms. Annals of Vascular Surgery. 10(5): 476-480, 1996.**

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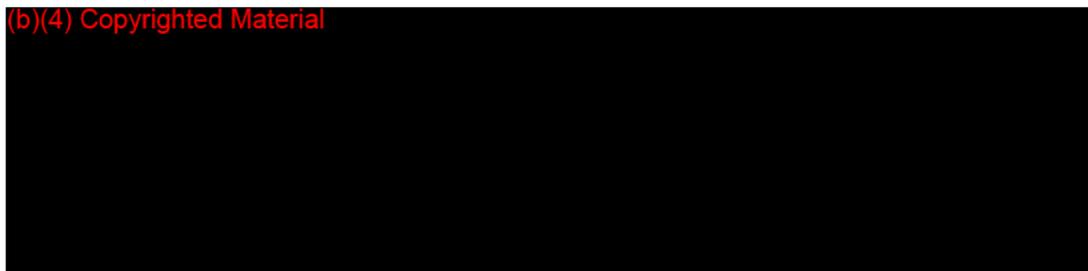
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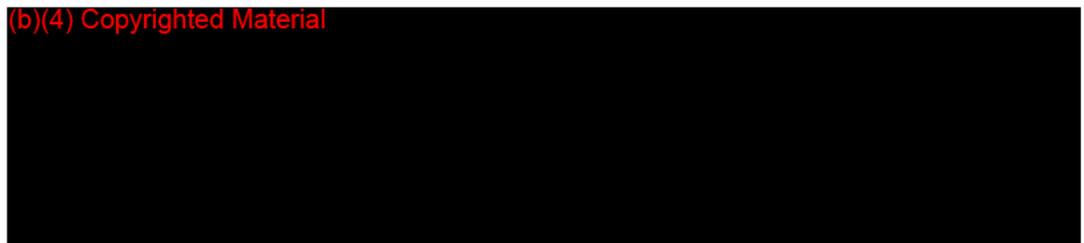
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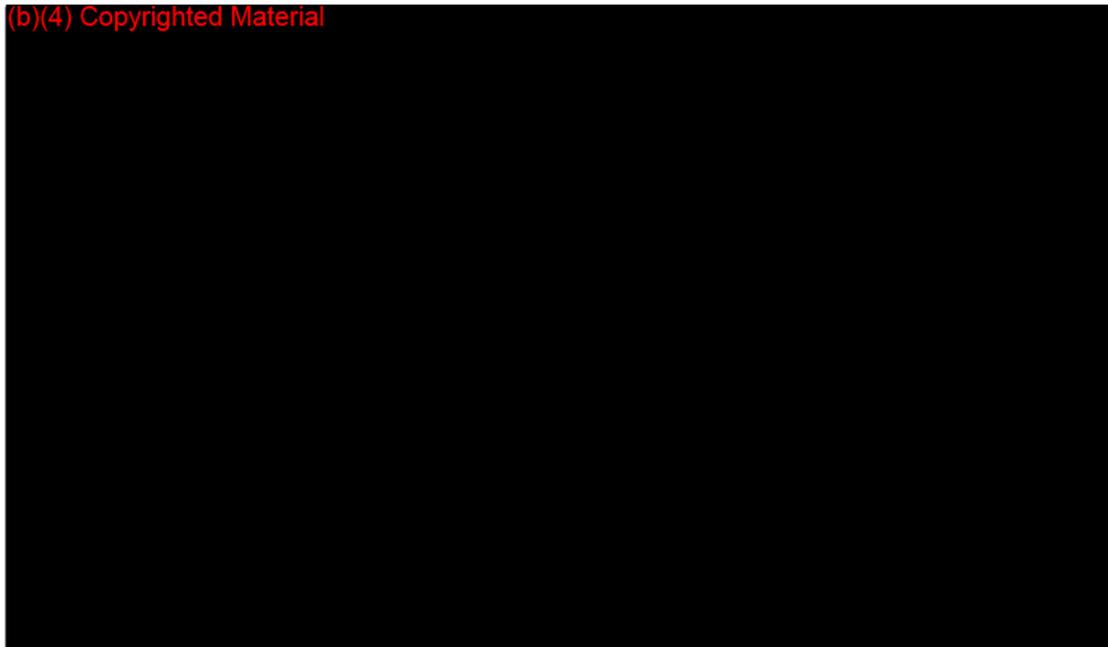
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Appendix H – Supporting Information for Peripheral Indication, Continued

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Stanley L. Barnwell, MD, PhD • Van V. Halbach, MD • Christopher F. Dowd, MD •
Randall T. Higashida, MD • Grant B. Hieshima, MD

Endovascular Treatment of Scalp Arteriovenous Fistulas Associated with a Large Varix¹

Ten patients with scalp arteriovenous fistulas associated with a large varix (cirroid aneurysms) were treated with a combination of interventional neuroradiologic procedures. These procedures included transarterial embolization, transarterial embolization followed by surgical excision, and two new methods of treatment of cirroid aneurysms: transvenous embolization and direct puncture of the fistula for embolization. The embolic materials included liquid adhesive agents, particulate agents, detachable balloons, and wire coils. The embolization was performed to lodge the embolic agents in the fistula or proximal draining vein, not just the feeding vessels. Surgery was performed in two cases to remove a small residual nidus of fistula that could not be completely treated with intravascular embolization. With the use of these forms of treatment, cures were obtained in seven patients, and clinical and angiographic improvement was achieved in three patients. No major morbidity, blood loss, or mortality occurred during the treatment of these patients. The follow-up period ranged from 1 month to 8 years.

Index terms: Arteries, therapeutic blockade, 17.126 • Arteriovenous malformations, 11.494 • Fistula, arteriovenous, 11.494 • Interventional procedures, 11.126 • Veins, therapeutic blockade, 17.126

Radiology 1989; 173:533-539

¹ From the Departments of Radiology, Neurointerventional Section (S.L.B., V.V.H., C.F.D., R.T.H., G.B.H.), and Neurological Surgery (S.L.B., V.V.H., R.T.H., G.B.H.), University of California, San Francisco, 505 Parnassus Ave, San Francisco, CA 94143-0112. Received January 10, 1989; revision requested February 8; revision received May 12; accepted May 23. Address reprint requests to Stanley L. Barnwell, MD, PhD, at CDRH/FOIA, 1380 Mead Dr., Rockville, MD 20855. © RSNA, 1989

CIRROID aneurysms are abnormal arteriovenous communications that most often occur in the scalp (1). The fistulous connection is associated with a large draining vein or varix. The clinical manifestations relate primarily to the size of the fistula. Dilation of vascular channels often results in a deforming cosmetic lesion. Clinically, the patients present with symptoms of loud bruits, hemorrhage, scalp necrosis, pain, and throbbing headaches.

In the past, treatment of scalp arteriovenous fistulas relied primarily on surgical excision or ligation of feeding arteries (2-8). Surgery was necessarily extensive; otherwise, recurrence was predictable. The excision was often associated with excessive blood loss and the need for skin reconstructive procedures. This surgical approach was often ineffective because of the development of collateral supply if the entire malformation was not completely removed.

Transarterial embolization of scalp arteriovenous fistulas has more recently been used as an adjunct to surgery or as definitive therapy (9,10). Occlusion of the feeding vessels facilitates surgical excision by reducing blood loss. However, embolization often occludes vessels proximal to the fistula, and recurrence commonly develops owing to recruitment of collateral supply. Successful occlusion of a scalp arteriovenous fistula by embolization through a draining vein was reported by Clarisse et al (11).

This report evaluates the results of treatment of 10 patients with cirroid aneurysms. Superselective embolization of the fistulous portion of the aneurysm was performed in all cases. Two techniques for lodging embolic material directly at the fistula site are described—embolization of the fistula from the venous side and direct puncture of the cirroid aneurysm with placement of embolic material

directly at the connection site of the fistula.

PATIENTS AND METHODS

Ten patients with arteriovenous fistulas involving the scalp were treated with embolization or embolization in conjunction with surgery. Patient age, location and primary arterial supply of the fistula, treatment, outcome, and follow-up are summarized in the Table. All patients were male except for patient 10. The age range was 12-62 years (median, 36 years). The fistula was in the left parietal scalp in three patients, in the right parietal scalp in two patients, in the left auricular area in three patients, and in the retromandibular and occipital regions in one patient each. The origin of the cirroid aneurysm was traumatic in patients 4, 5, and 9 and was spontaneous in the others. All patients underwent selective angiography to document the location, size, arterial feeders, and venous drainage prior to treatment. The arterial supply to the fistula involved the superficial temporal artery in seven patients, the occipital artery in five patients, the posterior auricular artery in four patients, and the internal maxillary artery in two patients. Six patients had more than one major arterial feeder.

Patients 6 and 8 had previously undergone ligation of feeding arteries or subtotal resection of the lesion in an attempt to treat the fistula. Both patients had subsequent recruitment of collateral supply to the fistula. These previous therapies complicated subsequent management by limiting transvascular access.

The embolic agents used included both liquid and particulate materials and wire coils. The liquid adhesives included isobutyl-2-cyanoacrylate (Ethicon, Norderstedt, Federal Republic of Germany) and N-butyl-2-cyanoacrylate (CRX Medical, Raleigh, NC). Both of these materials were classified as investigational devices, and informed consent from the patient was required for their use. Isobutyl-2-cyanoacrylate is no longer commercially available for intravascular use. Injection volumes of 0.1-0.2 mL were used. The particulate material used was polyvinyl alcohol sponge particles, available in sizes of 200-1000 µm (Medtronic, Pacific

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Summary of 10 Cases of Scalp Arteriovenous Fistulas

Patient No./Age (y)	Location	Primary Arterial Supply*	Treatment†	Outcome	Follow-up
1/30	Left parietal	STA	PVA, balloon	50% decrease	8 y
2/21	Left parietal	STA, OA	Balloons, surgery	Cure	4 y
3/62	Right parietal	STA	Transvenous, IBCA	Cure	2 y
4/29	Left auricular	AA, PA	PVA, balloon	80% decrease	6 mo
5/37	Right occipital	STA, OA	Transvenous, wire coils, direct puncture, NBCA	Cure	6 mo
6/62	Left retromandibular	IMA	Direct puncture, wire coils, NBCA	Cure	3 mo
7/33	Right parietal	MMA, PA, OA	NBCA, PVA, surgery	Cure	1 mo
8/40	Left auricular	STA, PA, OA	Direct puncture, wire coils, NBCA	Cure	1 mo
9/41	Left parietal	STA	Direct puncture, wire coils	Cure	1 mo
10/12	Left auricular	PA, OA, IMA	Wire coils	50% decrease	1 mo

* STA = superficial temporal artery, OA = occipital artery, AA = anterior auricular artery, PA = posterior auricular artery, IMA = internal maxillary artery, MMA = middle meningeal artery.

† Unless transvenous route or direct puncture is indicated, treatment was by transarterial route. PVA = polyvinyl alcohol particles, IBCA = isobutyl-cyanoacrylate liquid adhesive, NBCA = N-butyl-2-cyanoacrylate liquid adhesive.

Medical Industries, La Mesa, Calif). For larger fistulous connections, hand-cut pieces of polyvinyl alcohol were used. The choice of size depended on the estimated size of the fistula, with care being taken not to occlude the feeding arteries proximal to the fistula. A detachable Silastic balloon (Interventional Therapeutic, South San Francisco, Calif) was used in three patients. The balloon was attached to the end of a 2-F catheter and inflated to occlude the artery with slightly hypertonic (200 mg of iodine per milliliter) metrizamide (Amipaque; Winthrop Pharmaceuticals, New York). The wire coils included Gianturco coils (Cook, Bloomington, Ind) of varying widths and lengths and platinum minicoils (Target Therapeutics, Los Angeles).

Embolization of the fistula was performed in all patients. Three approaches were used to access the fistula: femoral transarterial, femoral transvenous, and direct percutaneous catheterization of feeding arteries or draining veins.

The femoral transarterial approach required placement of a 7.5-F sheath in one of the femoral arteries and passage of a 5.0-F catheter over a 0.035-inch Bentson guide wire into the external carotid artery. The 5.0-F catheter was then exchanged over a 260-cm-long 0.035-inch Newton exchange guide wire for a 7.3-F and 5.0-F coaxial polyethylene catheter system. The 7.3-F catheter was advanced into the branch of the external carotid artery to be embolized. Through the 7.3-F catheter, a coaxial catheter system could be advanced to superselect the artery to be embolized. The choice of catheters included a 3.2-F Tracker catheter (Target Therapeutics) over a 0.014-inch platinum-tipped guide wire when smaller particulate embolic agents, wire coils, or liquid adhesives were being used. To deliver balloons, either a 2.0-F and 4.0-F coaxial polyethylene catheter system (Cook) (cases 1, 2) or a 2.7-F Tracker catheter system (case 4) was used.

The femoral transvenous approach required placement of a 7.5-F sheath into one of the femoral veins. Through this sheath, a 7.0-F Berenstein catheter was advanced into the vein draining the fistula. This catheter was exchanged with a 7.3-F and 5.0-F coaxial polyethylene cath-

eter system over a 260-cm-long exchange guide wire. The 7.3-F catheter was advanced into the draining vein. A 3.2-F Tracker catheter was advanced over a 0.016-inch steerable guide wire into the fistula to deliver liquid tissue adhesives or coils.

Direct percutaneous catheterization of the fistula was performed when access through the artery or vein was not possible. This difficulty was encountered when ligation of feeding arteries had been performed and when the venous drainage was so complex as to prohibit catheterization. The site of the fistula was identified with use of digital subtraction angiography and road-mapping technique. Superficial skin markers were helpful in estimating the depth of the fistula. Once the fistula had been accurately located, the skin was cleaned in an aseptic fashion and anesthetized with 1% lidocaine (Elkins-Sinn, Cherry Hill, NJ). The varix was punctured close to the fistula with a 20-gauge Angiocath catheter (Becton-Dickinson, Sandy, Utah). Wire coils were pushed through the catheter with a 0.025-inch guide wire. Particulate embolic agents or liquid tissue adhesives could also be delivered through the catheter.

In two patients the fistula was not completely closed by means of embolization. Surgery was performed to remove the residual nidus and give a more favorable cosmetic result. The embolization greatly decreased the blood supply, and surgery primarily involved removing thrombosed vessels. Blood loss in both cases was minimal.

All patients were followed up at 1-month, 6-month, and yearly intervals. A clinical cure was defined as complete resolution of symptoms and signs attributed to the fistula during the follow-up period. Follow-up angiography was not performed unless there was a recurrence of symptoms.

RESULTS

The 10 patients were divided into four groups according to the forms of therapy they had received: femoral transarterial embolization, femoral transvenous embolization, and

surgery, direct percutaneous puncture of the fistula and embolization, and femoral transvenous embolization.

Femoral Transarterial Embolization

Patients 1, 4, and 10 were treated with embolization alone via the femoral transarterial route. Particulate embolic agents and balloon embolization resulted in a 50% decrease in filling of the fistula in patients 1 and 10 and an 80% reduction in patient 4.

Illustrative case.—Patient 4 was a 29-year-old man who had been hit in the head with a roll of tar paper and within days had noted a purple discoloration at the site of injury. Over the next 9 years this lesion enlarged to form a cosmetically deforming, pulsatile mass behind the left ear. A left external carotid angiogram showed a cirroid aneurysm supplied by branches of the superficial temporal and posterior auricular arteries (Fig 1a). Treatment of this lesion was to be staged, with transarterial embolization to decrease the flow and surgery to remove any residual nidus. The transvenous approach was not feasible because venous drainage was by way of multiple small veins, including perforating veins that traverse the mastoid bone and drain to the sigmoid sinus and inferior petrosal sinus. A branch of the anterior auricular artery supplying the fistula was embolized with a detachable Silastic balloon. A second fistulous connection with the posterior auricular artery was embolized with polyvinyl alcohol sponge particles. A post-embolization angiogram demonstrated 80% reduction in filling of the fistula (Fig 1b). The patient refused any additional therapy aimed at removing the residual nidus. At follow-up 6 months later, his condition was markedly improved.



Figure 1. Case 4. (a) Left distal external carotid angiogram, lateral view, shows arteriovenous fistula supplied by the anterior auricular artery (straight arrow), a branch of the superficial temporal artery (curved arrow). (b) Left external carotid angiogram, lateral view, after embolization of the fistula with detachable balloon and polyvinyl alcohol particles shows complete obliteration of the anterior and posterior auricular (arrow) artery supply.



Figure 2. Case 7. (a) Right external carotid angiogram, lateral projection, shows hypertrophied middle meningeal arterial branches (straight arrows) and occipital artery (curved arrow) branches, which traverse the skull to supply the fistula and then drain to scalp veins. (b) Right external carotid angiogram, lateral projection, obtained after fistula had been embolized with liquid adhesives and particulate agents. Supply from the occipital artery (curved arrow) still remains.

balloon in patient 2 and liquid tissue adhesive and particulate emboli in patient 7. Both patients were cured. There were no complications from the surgery, and blood loss was minimal.

Illustrative case.—Patient 7 was a 33-year-old man who had experienced the spontaneous onset of a pulsatile swelling and severe headaches in the right parietooccipital region. A magnetic resonance image showed a mass composed of multiple large vascular channels. A right external carotid angiogram showed a hypertrophied middle meningeal artery and posterior auricular artery supplying a cirroid aneurysm (Fig 2a). The middle meningeal arterial supply was catheterized and embolized with liquid adhesives. A postembolization angiogram demonstrated 95% occlusion of the scalp arteriovenous fistula (Fig 2b). His headaches were markedly ameliorated after the embolization.

At follow-up 5 months later the patient still noted a palpable mass, although the bruit and thrill were absent and symptoms were minimal.

An angiogram demonstrated that the

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fistula had reformed at about 20% its original size. A right external carotid angiogram demonstrated an arteriovenous fistula in the scalp, which was supplied through the skull by a hypertrophied middle meningeal artery and the posterior auricular and occipital arteries. These arteries were embolized with polyvinyl alcohol particles. There was a small residual nidus remaining after the embolization, which was supplied by the middle meningeal artery. To achieve an improved cosmetic result and remove the remaining fistula, a craniotomy was performed to remove the residual fistula, which was in the dura. Less than 100 mL of blood was lost during the procedure.

Direct Percutaneous Puncture and Embolization

Direct percutaneous catheterization of the fistula or proximal draining varix was performed in patients 6, 8, and 9 to occlude the fistula. A liquid adhesive was used in two cases, and wire coils were used in all three cases. In all three patients the fistula was closed completely.

Illustrative cases.—Patient 6 was a 62-year-old man who had first been treated for a retromandibular arteriovenous fistula in 1945. Over the next 28 years he underwent 12 surgical procedures to remove or treat the lesion, including removal of his ear and ligation of the left external carotid artery and several of its branches. During the 15 years after the last procedure he had frequent episodes of bleeding, and the skin around the ear and mandible was necrotic with purulent drainage. An angiogram demonstrated that the fistula was supplied by branches from the internal maxillary artery. This artery was filled by collateral vessels from the ophthalmic and middle meningeal arteries (Fig 3a, 3b). The venous drainage was circuitous into dilated varices. Because there was no safe transarterial or transvenous passage to the fistula, a direct puncture of the proximal varix was performed. Gianturco coils were delivered into the varix. To further occlude the fistula, liquid adhesive was placed through the varix into the fistula. An angiogram (Fig 3c) obtained on the following day disclosed a residual fistula; therefore, the remaining varix was punctured, and additional coils were placed at the fistula site. A common carotid angiogram (Fig 3d) demonstrated complete occlusion of the fistula. At clinical follow-up 3 months

Femoral Transarterial Embolization and Surgery

Two patients were treated with transarterial embolization and surgery. The embolic agents included a

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later, the patient had no recurrence of the pulsatile mass.

Patient 8 was a 40-year-old man who presented with a pulsatile mass behind his right ear that had been noticed since childhood. He had previously undergone ligation of feeding arteries and proximal occlusion of the external carotid artery with only transient improvement in symptoms. A vertebral angiogram demonstrated an enlarged muscular collateral vessel at the level of C-1 that reconstituted the occipital and posterior auricular arteries in a retrograde fashion (Fig 4a). These arteries filled a scalp arteriovenous fistula behind the right ear. Catheterization via the femoral transvenous route was attempted, but the catheter could not be advanced into the fistulous segment of the aneurysm. Percutaneous puncture of the posterior auricular artery and embolization with polyvinyl alcohol particles were performed. On the following day, the posterior auricular artery was surgically exposed and embolized with steel coils. The small residual fistula from the superficial temporal artery was obliterated with direct puncture and embolization with liquid adhesives. A postembolization vertebral angiogram (Fig 4b) demonstrated complete closure of the fistula. At follow-up at 1 month, the patient had complete resolution of symptoms.

Femoral Transvenous Embolization

The femoral transvenous approach was used to occlude the fistula in patients 3 and 5. Complete obliteration was achieved in both. Liquid adhesive was used in patient 3, and coils and liquid adhesive were used in patient 5.

Illustrative case.—Patient 3 was a 62-year-old man who presented with spontaneous onset of a pulsatile swelling in the right parietal region. The right external carotid angiogram showed an arteriovenous fistula supplied by a tortuous superficial temporal artery that drained into several superficial temporal veins (Fig 5a). The fistula site was reached via a transvenous approach, and liquid adhesives were deposited in the fistula site (Fig 5b, 5c). The postembolization angiogram disclosed complete fistula closure (Fig 5d). Immediately after fistula closure, the scalp became edematous, erythematous, and hyperemic on the ipsilateral side; these changes resolved slowly over the next few hours. This effect was not

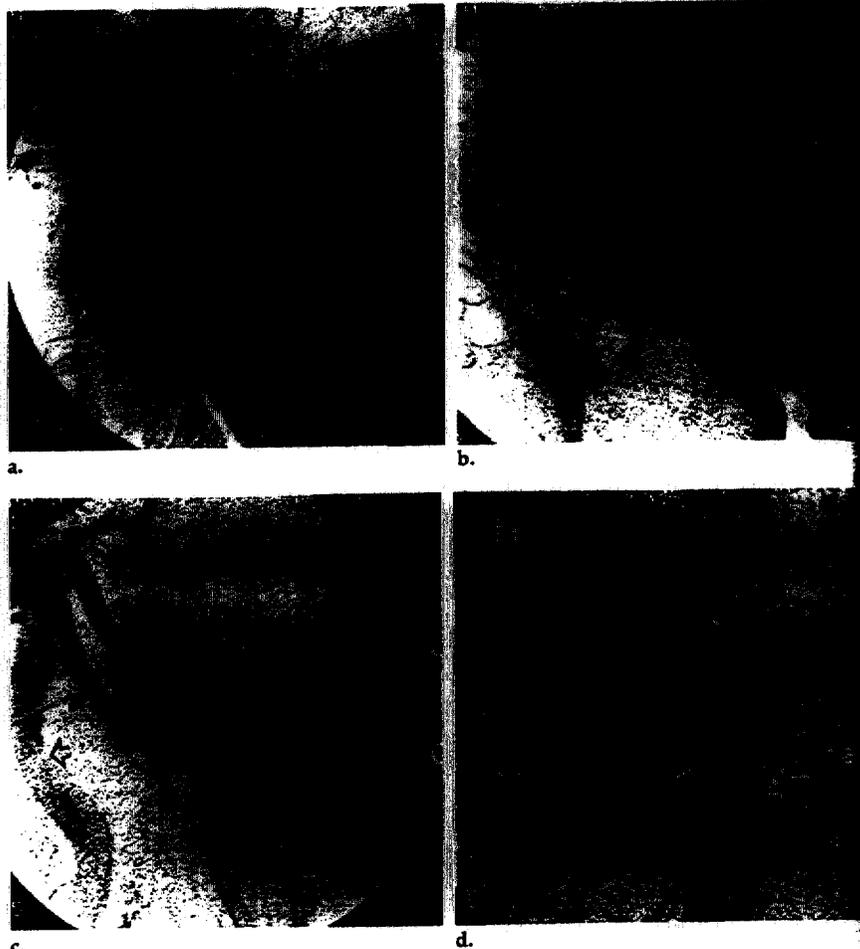


Figure 3. Case 6. (a) Left common carotid angiogram, lateral projection, shows retrograde filling of the middle meningeal artery (solid arrow) and internal maxillary artery (arrow-head) with drainage into the varix (open arrow). The external carotid artery had been ligated. (b) Left common carotid angiogram, left anterior oblique projection, demonstrates fistula site (large curved arrow) supplied by retrograde filling of the internal maxillary artery (small straight arrow) and middle meningeal artery (small curved arrow) from the internal carotid artery (open arrow). (c) Left common carotid angiogram, left anterior oblique projection, after initial embolization with wire coils shows occlusion of the superficial venous compartment by multiple coils (solid straight arrows). The internal carotid artery (open arrow), middle meningeal artery (small curved arrow), and internal maxillary artery (large curved arrow) are depicted. (d) Left common carotid angiogram, left anterior oblique projection, shows complete occlusion of the fistula after placement of additional wire coils.

far removed from the embolization site and presumably was a manifestation of perfusion breakthrough. The patient has been followed up for 2 years and has had no recurrence of the pulsatile mass.

Complications

There were no major complications or morbidity in any of the patients. After embolization, most patients experienced pain at the fistula site; this problem was managed effectively with narcotics and dexamethasone as needed. There were no ischemic complications related to the embolization procedures. Patient 3 may have had a manifestation of perfu-

though the changes resolved over the course of several hours.

DISCUSSION

Soft-tissue arteriovenous fistulas occur most commonly in the scalp. Although only 14% of the body surface area is in the head, 50% of integument arteriovenous fistulas occur in this region (1). When these abnormal fistulas enlarge to a size that is clinically recognizable and there are large, dilated draining veins, the lesions are termed cirroid aneurysms (12).

The nomenclature used to describe these lesions has been complex and inconsistent. Various names applied to these lesions include aneu-

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Figure 4. Case 8. (a) Left vertebral angiogram, lateral projection, demonstrates an enlarged muscular C-1 collateral vessel from the vertebral artery (small curved arrows) reconstituting the occipital artery (open arrows) retrograde to the external carotid artery and then the posterior auricular artery (arrowheads), which ultimately supplies the fistula (large curved arrow). Note the skin markers (small spheres), which were used to measure the depth of the fistula. (b) Left vertebral angiogram, lateral projection, after embolization of the fistula by direct puncture of the posterior auricular artery for coil placement and direct puncture of the varix for placement of the liquid adhesive. The occipital (straight arrow) and posterior auricular (large curved arrow) arteries continue to fill from a C-1 collateral vessel off the vertebral artery (small curved arrows). The fistula has been obliterated.



Figure 5. Case 3. (a) Right external carotid angiogram, lateral projection, shows arteriovenous fistula supplied by a tortuous superficial temporal artery (arrow) draining into superficial temporal veins (arrowheads). (b) A catheter has been navigated by means of a femoral transvenous approach through the superficial temporal vein to the fistula site. (c) After liquid adhesive injection performed after manual compression of the draining vein, liquid adhesive (straight arrow) is depicted refluxing into the feeding artery. Contrast material injected through the venous catheter fills the distal superficial temporal artery (curved arrow). (d) Right external carotid angiogram, postembolization lateral view, confirms complete obliteration of the fistula. Note the cast of liquid adhesive in the fistula site (arrowheads).

described in this report are defined as clinically recognizable arteriovenous fistulas of either congenital or traumatic origin that do not have an intervening capillary bed between the artery and the vein. The lesions have one or more large draining veins, which cause the cosmetic deformity. These lesions are distinguished from hamartomatous vascular malformations with abnormal arteriovenous connections, such as hemangiomas, sinus pericranii tumors, lymphangiomas, aneurysmal bone cysts, and scalp arteriovenous malformations. Some reports in the literature that have described circoid aneurysms lack the distinctive angiographic findings and probably have described arteriovenous malformations (2-4). In other reports, the term arteriovenous malformation is used to describe fistulas (13,14).

The earliest accurate description of an arteriovenous fistula was by William Hunter in 1764 (15). In 1829, Benjamin Brodie performed the first successful treatment of a scalp arteriovenous fistula by circumferential ligation (16).

Scalp arteriovenous fistulas usually begin as small subcutaneous swellings that enlarge to produce a disfiguring, pulsatile mass. Symptoms associated with these fistulas have included bruit, tinnitus, diffuse pain or pain at the site of the fistula, throbbing headaches, stabbing pain, flushed face, bleeding, and epistaxis (6,17,18). The pain can be so severe that patients may be incapacitated (17). One patient committed suicide by lacerating his scalp arteriovenous fistula (13). Large lesions have been associated with scalp necrosis (19,20). Congestive heart failure has been noted with larger fistulas (20). Most of the lesions in this report

angiosarcoma, aneurysma serpentinum, aneurysma racemosum, aneurysm by anastomosis, arteriovenous angioma, arteriovenous fistula, arteriovenous aneurysm, and arteriovenous malformation. The lesions

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had a spontaneous onset. Only two patients clearly related the lesion to trauma. In one case discoloration was noted on the skin before the mass developed. All of our patients had a bruit or thrill associated with the lesion.

Most congenital lesions become symptomatic in the 3rd decade of life (range, 3 months to 59 years of age) (6). However, the congenital lesions have often been noticed for many years before the development of symptoms (6). In one case an angiomatic nevus that had been present since birth became the site of an arteriovenous fistula (6). Sixty percent of affected persons are male (6). Congenital cirroid aneurysms usually have been described as having a more complex vascular pattern than that of acquired lesions, although this complexity may be a function of the longer time it takes for them to develop. Congenital cirroid aneurysms usually are supplied by scalp vessels—rarely the meningeal vessels, as in patient 7 (6,21).

Acquired lesions may be related to fistula formation at the time of blunt or penetrating injuries; the lesions undergo hypertrophy over periods of months to years to become clinically recognizable (5,22). Approximately 1% of all warfare vascular injuries result in an arteriovenous fistula (5,23). Hair transplantation has resulted in the development of fistulas (24,25). Traumatic scalp arteriovenous fistulas have been described in patients as young as 8 years of age and as old as 62 years of age. Sixty-six percent of cases occur in males (6).

Familial arteriovenous fistulas have been described in one kinship, with two siblings affected (26). One case of a cirroid aneurysm associated with plexiform neurofibromatosis has been reported (27).

The location of scalp arteriovenous fistulas is roughly evenly distributed among the frontal, temporal, and parietal regions (6). The superficial temporal artery has frequently been described as involved in traumatic cirroid aneurysms, in part due to its lengthy, unprotected course (22). The superficial temporal artery was involved in 75% of our patients.

The involvement of vessels other than those in the scalp has been most frequently described with congenital lesions (2,12). The one kinship with familial arteriovenous fistulas also had transcranial penetration of the vascular supply (26). The middle meningeal artery has usually been

of cerebral blood vessels has rarely been described and would represent an anomalous communication because of the different embryonic sources of these vessels (6). Involvement of dural vessels may be responsible for the severe headaches that some patients have described. Patient 7, who had headaches and dural supply, was markedly improved after embolization of the dural supply.

Treatment of scalp arteriovenous fistula has included surgical excision, ligation of feeding vessels, transarterial embolization, injection of sclerosing material into the nidus, and electrothrombosis (14,19,28-31). These methods have had varying degrees of success in curing or reducing the size of the lesion.

Ligation of feeding arteries, injection of sclerosing agents, and electrothrombosis have not been effective in treating cirroid aneurysms (17,19,30). Ligation of feeding arteries has been particularly troublesome because of loss of access to the fistula for further embolization and recruitment of collateral supply. The collateral vessels that develop may be impossible to embolize, or parasitization of flow from the brain may develop with ischemic complications (17).

Surgical excision has been the most common method in the past for obliterating scalp arteriovenous fistulas. These procedures were necessarily extensive, and all of the fistula had to be removed to obtain a cure. The use of reconstructive skin flaps was often incorporated in the treatment because of the extensive skin resection required to remove the nidus. Injury to nerves in the face was sometimes a complication of these procedures (17). Some lesions were so large that excision was not possible (31). Incomplete removal of the fistula has nearly always been followed by recurrence, and further surgery was made more difficult by the scarring from previous procedures. Blood loss has been severe during resection of cirroid aneurysms.

Embolization as a form of therapy for scalp arteriovenous fistulas has been recently developed. Lodging of embolic material in proximal feeding vessels lessens the blood supply and has been a helpful adjunct to surgery but rarely is curative (10,29). Collateral supply develops after proximal occlusion and complicates further therapy. The new vessels are often difficult to catheterize for embolization. Complications of proximal oc-

clusion include development of aneurysms at the site of occlusion, probably related to ischemia of the vessel wall (9). In patient 3, proximal occlusion of the feeding artery may have resulted in normal perfusion pressure breakthrough, with hyperemia noted in the scalp distant from the site of the embolization. This finding may have been related to rerouting of large amounts of blood through normal scalp vessels (32).

With use of the methods described in this report, embolization should be the primary therapy for these lesions. Safe and effective embolization necessitates an awareness of the normal collateral vessels and anatomic variants. This knowledge enables access to the fistula and also exclusion of unwanted connections between the external carotid and internal carotid or vertebral circulations. Embolization must be performed so as to close the fistula completely. Surgery should be reserved for cases in which an improved cosmetic result is desired and those in which it is necessary to remove residual fistulas that cannot be embolized.

We found that access to the fistula was facilitated by the use of small, flexible catheters, such as the Tracker catheter, which are capable of being navigated through tortuous vessels. The small size and flexible yet steerable tip of the Tracker catheter make possible delivery of embolic agents on either side of the fistula. The Tracker catheter system has been extensively used for transarterial embolization.

Proximal occlusion was utilized in our cases to reduce the flow to the fistula prior to surgery and to allow more accurate placement of liquid adhesives into the fistula site from another point of access. In patient 8, this technique allowed delivery of liquid adhesive directly into the fistula by means of direct puncture.

The technique described herein for treating these lesions, transvenous embolization, allowed access to the fistula when the arterial route was not available. This method has been described in the past (11). Transvenous embolization was always successful in completely obliterating the fistula when used.

In this study, direct percutaneous puncture of the fistula enabled treatment of the occasional arteriovenous fistula that lacked any arterial or venous access. Catheterization of either the artery leading into the fistula (as in patient 8) or the draining varix (as in patients 5 and 6) could then be

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performed. Exposure of vessels leading into the fistula requires the presence of a surgeon experienced in vascular cutdowns but could be performed in the angiography suite. Percutaneous catheterizations were performed by the radiologist. The arterial vessels supplying the fistula often had very thin walls, and hemorrhage would have been severe if uncontrolled. The primary goal of direct puncture, as for the other techniques, was to allow embolic material to be placed directly at the fistula site.

The follow-up of these patients has relied on the clinical examination. Angiography has not been used routinely for follow-up unless there were signs or symptoms of recurrence. The lesions were benign in nature, and treatment was based on clinical problems.

Scalp arteriovenous fistulas associated with a large varix are the most common arteriovenous shunts involving the scalp and can be associated with disabling symptoms. With use of the variety of techniques described above, including transarterial and transvenous embolization and direct percutaneous puncture, definitive cure of these lesions can be achieved with minimal morbidity and no mortality. ■

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SUPERSELECTIVE ENDO-VASCULAR TREATMENT OF RENAL VASCULAR LESIONS

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ABSTRACT

Embolization with platinum micro-coils delivered through the Tracker-18 micro-catheter was performed in 6 patients when peripheral selective catheterization with standard angiographic catheters was not possible. The patients had a total of 7 peripheral renal vascular lesions (3 arteriovenous fistulas, 2 false aneurysms, 1 direct vascular trauma and 1 arteriovenous malformation). In all patients we initially used platinum micro-coils as the embolic agent. Two patients required repeat embolization with glue. Endo-vascular treatment was technically successful in all cases and no complications were encountered. There was no renal parenchyma infarction in 3 patients and small peripheral infarctions (10 to 15% of the renal parenchyma) occurred in 3. Super selective endo-vascular treatment with a variable stiffness catheter is a safe and useful technique when classical methods of embolization are not possible.

KEY WORDS: arteries; fistula; renal artery; urinary catheterization; embolization, therapeutic

Embolization is a well known endo-vascular treatment of renal vascular lesions. Nevertheless, classical catheterization techniques frequently led to a high rate of renal parenchymal loss. Recent technological improvements in interventional radiology devices have made super selective catheterization and embolization possible. The aim of this endo-vascular treatment was to target the embolization precisely and, consequently, to save most of the renal parenchyma. We report on 6 patients with a vascular abnormality treated by this technique.

MATERIALS AND METHODS

Patients. We retrospectively reviewed the charts of 6 patients evaluated for symptomatic renovascular lesions at our hospital from 1991 to 1994. The 4 men and 2 women ranged from 25 to 60 years old (average age 52). The most common presenting symptom was bleeding in 5 patients: 4 with life-threatening hemorrhage for which blood transfusion became necessary (3 had hematuria and 1 had retroperitoneal hemorrhage) and 1 with limited hemorrhage (subcapsular hematoma) associated with flank pain. One patient with a graft kidney presented clinically with renal failure.

Angiographic evaluation. Initial global injection of contrast medium was followed by selective catheterization of the renal artery. Injections were then performed to assess the site and feeding pedicles, flow pattern and venous drainage of the renal vascular lesion. Angiography was performed with a 5F cobra or sidewinder catheter used with a 0.035-inch angle tip guide wire.

Treatment protocol. All vascular lesions were too peripheral to be catheterized with a standard angiographic catheter. Therefore, a 0.016-inch steerable guide wire was placed into a variable stiffness 2.2F catheter. The catheter and guide wire were inserted into the angiographic catheter through a rotating hemostatic valve. The coaxial system was continuously flushed with saline solution. The catheter and guide wire were guided to the tip of the angiographic catheter. Then, the guide wire was twisted with the torque device

to facilitate directional catheterization through vessel tortuosity. The tip of the guide wire was placed as close as possible to the vascular lesion and the catheter was advanced along the guide wire. Angiography was then performed through the micro-catheter by using contrast medium with hand injection to confirm the catheter position. Then embolization was performed.

In all patients we first used complex helical polyester fibered platinum micro-coils (coil diameter 0.015 inch, the complex helical diameter must be adapted to the lesion size). Each coil was pushed through the micro-catheter with a coil pusher 0.016-inch guide wire. In 2 patients it was necessary to complete embolization with glue (N-butyl-cyanoacrylate mixed with iodized oil (0.5/0.5) and injected through the variable stiffness catheter. Embolizations with glue were performed 1 day later in 1 patient and 1 month later in 1. Patients were followed clinically, biologically and with color Doppler flow sonography at 1, 3 and 6 months after endo-vascular treatment, and then at yearly intervals.

RESULTS

Renovascular lesion. The 6 patients had a total of 7 peripheral renal artery branch diseases: 1 renal allograft post biopsy arteriovenous fistula, 1 fistula associated with a large false aneurysm due to a percutaneous nephrolithotomy tube (staghorn calculus), 1 arterio-caliceal fistula secondary to spontaneous rupture of an arteriovenous malformation located near the caliceal surface, 1 arteriovenous fistula due to a percutaneous nephrostomy tube, 1 arterio-retroperitoneal fistula due to a percutaneous nephrostomy tube and 1 spontaneous false aneurysm within a 5 cm. angiomyolipoma in the upper part of the kidney sinus. The lesion in the latter case was fed by only 1 small artery originating from the superior polar artery.

Angiographic results. Total occlusion of the vascular lesion was achieved immediately with 1 or 2 coils in 4 patients while 2 required the use of glue. One of the 2 patients with consumption coagulopathy syndrome presented with residual hemorrhage and required glue embolization 1 day later while 1 had an arteriovenous malformation in which coil embolization of the feeders stopped the hemorrhage but di-

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occlusion of renal arteries and no renal parenchymal infarction in 3 patients. Small peripheral infarctions occupied approximately 10 to 15% of the renal parenchyma in the remaining 3 patients. One of these limited infarctions was secondary to a post-nephrolithotomy vascular lesion without modification after embolization and 2 were secondary to the use of glue.

Clinical results. Embolization stopped the bleeding completely in all 5 hemorrhagic patients: immediately after coil embolization in 4 with hematuria (fig. 1) and after repeat embolization with glue to occlude the nidus and prevent recurrent bleeding in 1 with an arteriovenous malformation (fig. 2). In the patient with the consumption coagulopathy syndrome the bleeding was dramatically less and the use of glue was necessary to complete occlusion. The patient died of post-radiotherapy rupture of a carotid artery 1 month later. For the remaining 5 patients mean followup was 15 months (range 6 to 24). Bleeding and pain disappeared in the patient with a false aneurysm within the angiomyolipoma. In the allograft kidney patient subsequent biological tests showed significant improvement in renal function (50%). Hemorrhage ceased immediately in the patient with a staghorn calculus treated by percutaneous nephrolithotomy. Three

months later, this patient underwent a conventional operation to remove residual stone. No surgery was performed in the remaining patients. No immediate or delayed complication was encountered with the use of super selective endovascular treatment. Serum creatinine was always in the normal range. No split radionuclide scans were done but in 3 patients excretory urography showed no significant abnormalities and none of them had hypertension.

DISCUSSION

The incidence of a renovascular lesion is reported to range from 4 to 16% after percutaneous renal biopsy (arteriovenous fistula)¹ and from 0.5 to 1% after percutaneous nephrostomy (false aneurysm),² and to be 0.9% after percutaneous nephrolithotomy.³ The incidence of arteriovenous malformation is reported as less than 0.04%.⁴ More than 70% of renovascular lesions heal spontaneously and most of them will be treated conservatively.^{5,6} However, in 4 to 9% of the cases they can persist and lead to complications, such as permanent hematuria, hypertension and ischemic renal failure, which require specific treatment.⁶ The surgical approach to a renovascular lesion is no longer indicated in most circumstances since

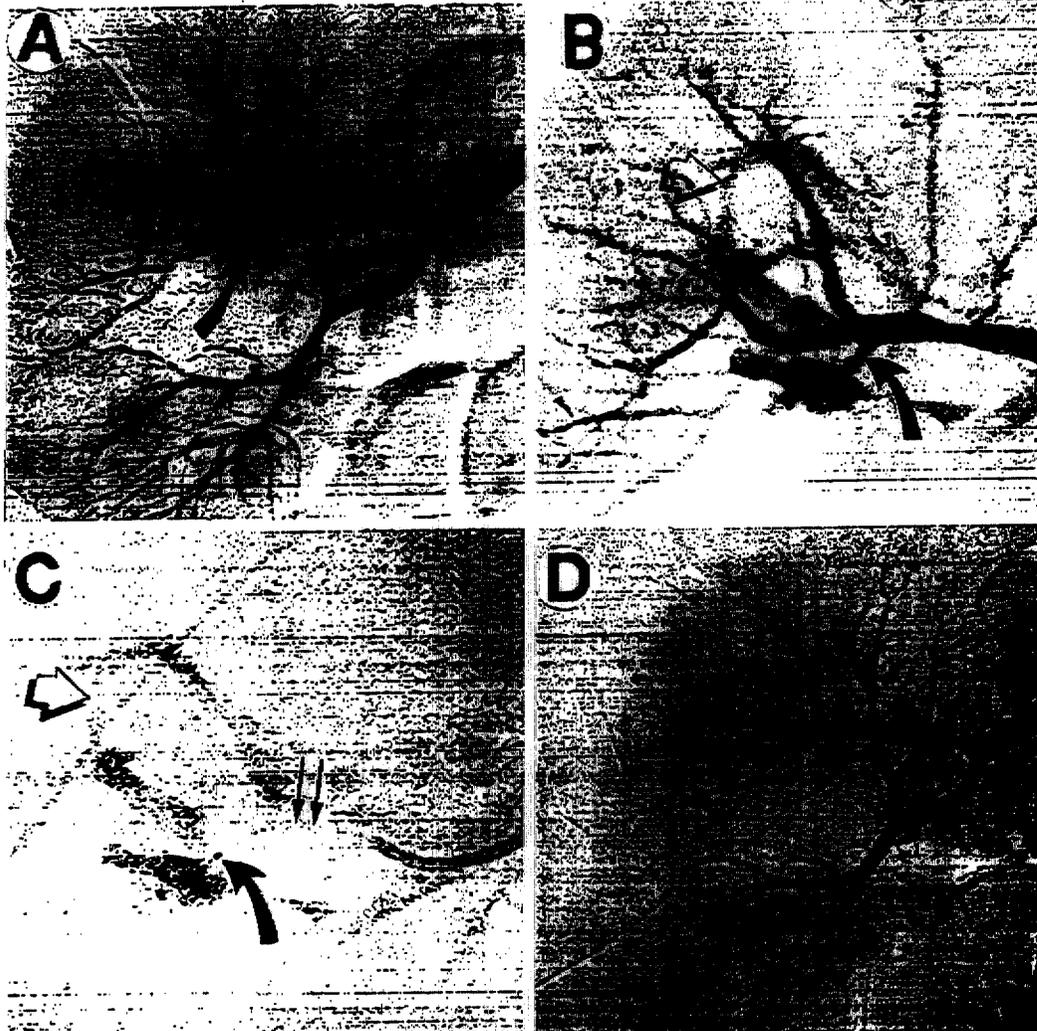


FIG. 1. Right renal arteriography shows arteriovenous fistula (arrow). B, selective catheterization (5F) of polar artery determines type of vascular lesion fed by small artery (black arrow). Note venous drainage (open arrow). C, small artery is catheterized with variable stiffness catheter (double arrows) and tip of micro-catheter (curved arrow) is placed into fistula. Note venous drainage (open arrow). D, early phase of global post-embolization

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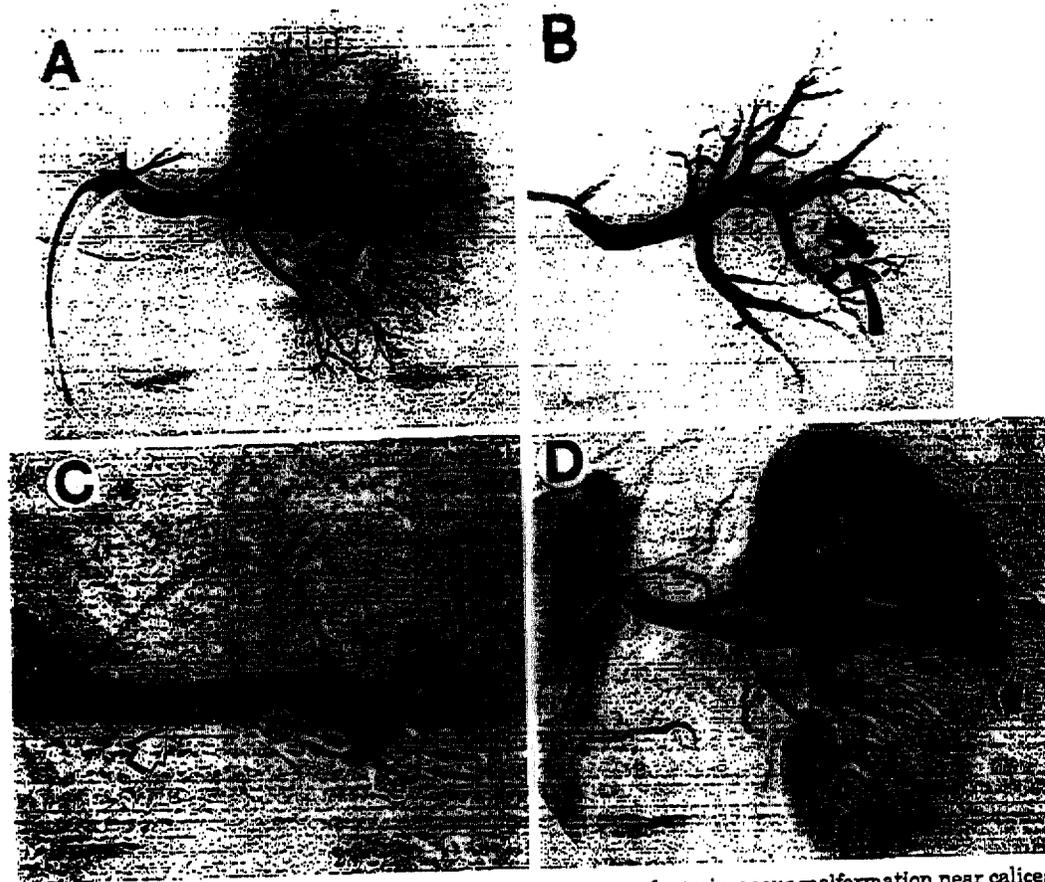


FIG. 2. 32-year-old man with massive hematuria due to spontaneous rupture of arteriovenous malformation near caliceal surface. A, first embolization coils of 2 feeder arteries (white arrows) stopped hemorrhage but did not allow persistent occlusion of nidus (black arrow). Embolization with glue was performed 1 month later to occlude nidus and prevent recurrent bleeding. B, selective catheterization of artery. C, superselective catheterization of nidus (curved arrow) with 5F catheter shows 1 feeder artery of vascular malformation (arrow). Angiography was then performed through micro-catheter by using contrast medium hand injection to verify catheter position. Embolization was then done. Note venous drainage (open arrow). Other feeder was catheterized and embolized with same technique. D, global post-embolization control angiogram. Arteriovenous malformation and small feeder arteries are embolized. There is limited cortical defect (arrow).

classical operations, such as partial or total nephrectomy or arterial ligation, always cause significant parenchymal damage.⁷ Embolization is currently the simplest and most effective treatment, since it definitively eliminates vascular lesions while preserving functional renal parenchyma.^{8, 8}

Successful endo-vascular treatment depends on the catheterization technique and on the material used for embolization. Previous reports on endo-vascular treatment of renovascular malformations advocated the use of transient occlusive agents, such as autologous clot or absorbable gelatin sponge. To minimize the extent of renal damage caused by nonselective embolization,⁷ Benoit et al reported successful selective embolization of an arterio-caliceal fistula using absorbable gelatin sponge but reported a 30% loss of functional parenchyma.⁹ Using the same material to embolize iatrogenic and traumatic arteriovenous malformations, Fisher et al reported less than a 30% loss of renal function in 12 of 15 patients, and a 30 to 50% loss in the remaining 3.¹⁰ Therefore, many radiologists have chosen to abandon absorbable gelatin sponge, whose distribution is difficult to control.^{5, 11} Gianturco coils¹⁰ and detachable balloons¹² allow for successful embolization but can be used only in cases of a proximal vascular lesion.

Technological progress regarding embolization materials and catheters allows for precise catheterization and localization of the lesion. We used a poly-

ethylene coaxial catheter with a stiffer 3F proximal portion and a floppy 2.2F distal portion with a radiopaque marker at the tip. This catheter is compatible with a guiding catheter accepting a 0.038-inch diameter guide wire. Used with long acting or permanent occlusive agents, this technique allows for precise embolization.^{13, 14}

The choice of the embolizing material is important to achieve a good result and depends on the pathological conditions in which it is used. Good results were described with the use of a variable stiffness catheter and polyvinyl alcohol particles.¹⁴ However, use of these irregularly shaped polydextran particles creates many problems, including the significant lack of homogeneity of the particle sizes, which can determine paradoxical embolization with extensive ischemia.¹⁵ Another problem is the aggregation of particles causing catheter obstruction and too proximal embolization of the vascular network.¹⁶

On the other hand, the ready-to-use platinum micro-coils can be placed precisely into the artery feeding the arteriovenous fistula or into the shunt and allow for permanent occlusion.¹⁷ Micro-coils were initially used for interventional neuroradiological procedures in cases of arteriovenous fistula or intracranial aneurysms.¹⁶ Vessel occlusion is obtained by helical platinum micro-coils and polyester fibers, which facilitate thrombosis. There are few reports on the use of platinum micro-coils with a variable stiffness catheter for neuroradiological embolization.^{5, 18-20} Because of the high cost, this material must be reserved for cases in which cl-

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sical techniques and material do not allow for super selective catheterization. This was the case in our patients and the use of platinum micro-coils allowed us to achieve embolization without a cortical defect.

Cyanoacrylate also has been used in these indications¹³ but the aim of embolization with bucrylate varies in accordance with many factors, such as the iodized oil-to-cyanoacrylate ratio, injection rate, local blood flow and a tortuous vascular network. Bucrylate embolization may be dangerous in inexperienced hands and it is better used as a second step. Nevertheless, this embolic material, presently not approved for use in the United States, is useful in cases of arteriovenous malformation to cast the nidus completely and to minimize the chance of a recurrent lesion due to recruitment of collateral vessels distal to the site of coil placement.²⁰

CONCLUSION

The use of a coaxial variable stiffness catheter system allows for precise super selective catheterization. The choice of embolic material must be adapted to the pathological condition, bearing in mind that the micro-coil is an efficient embolic material to target a precise pathological area. Super selective catheterization and good choice of embolic material allow for precise embolization and preservation of most of the renal parenchyma.

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Early results of endovascular-assisted in situ saphenous vein bypass grafting

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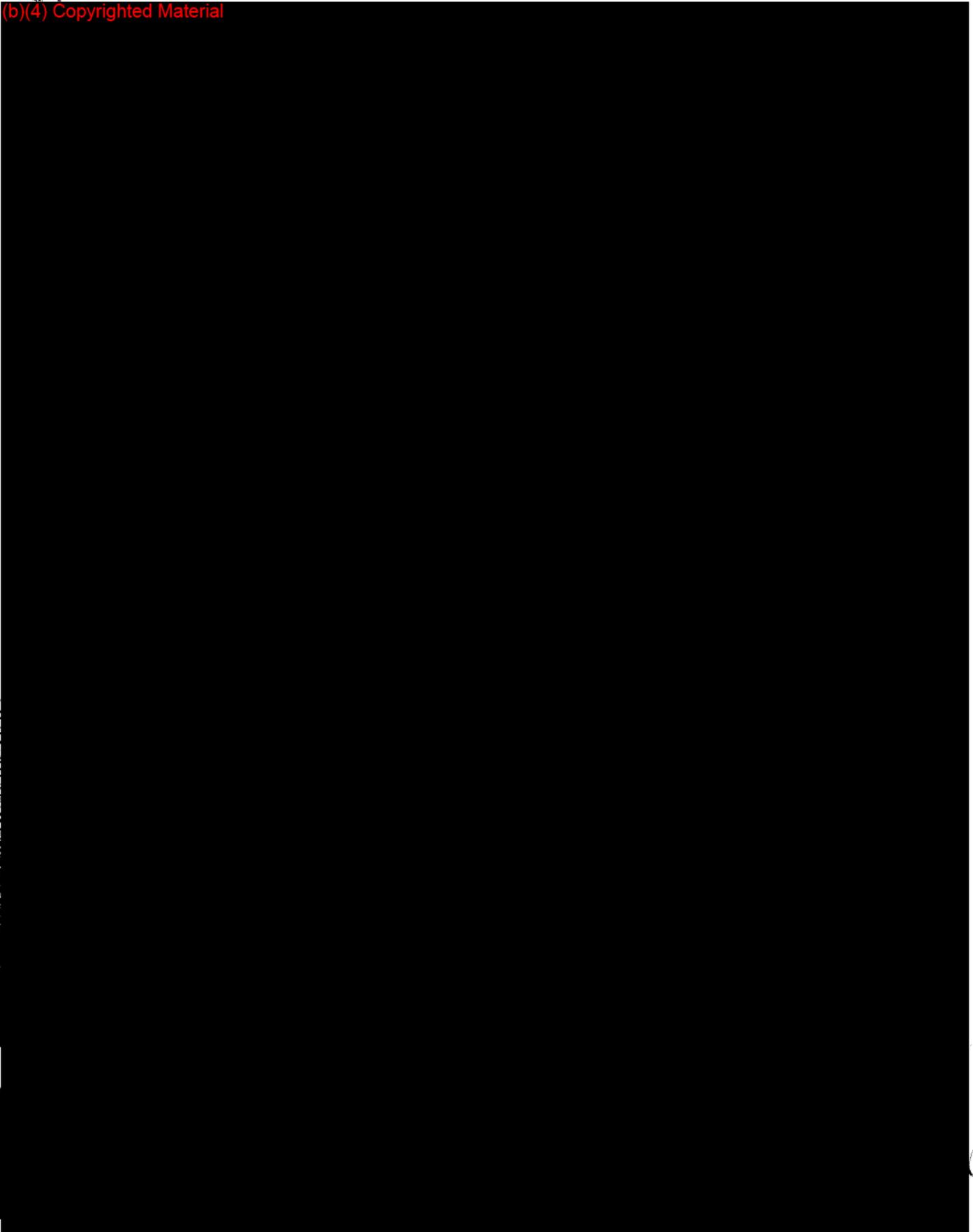
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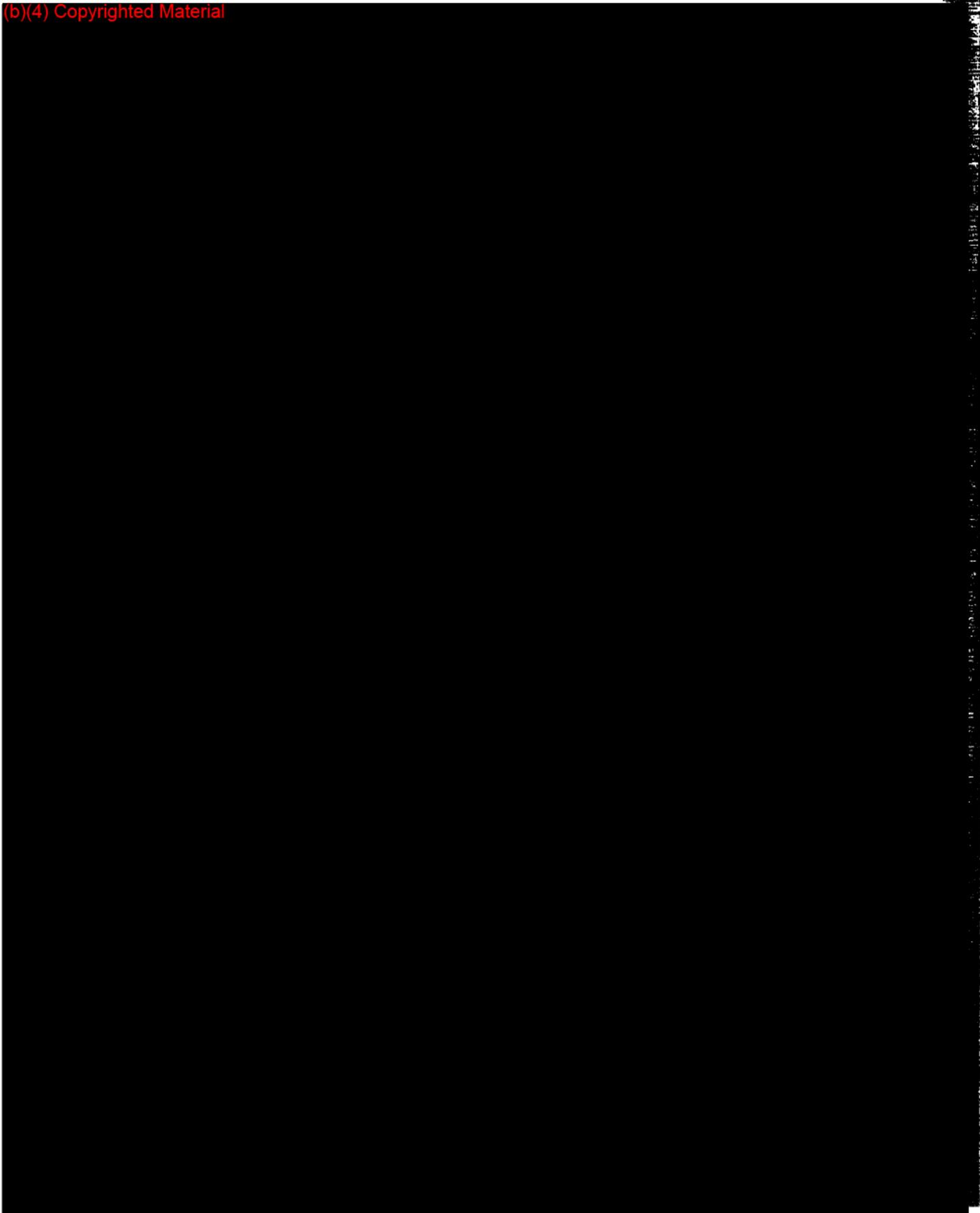


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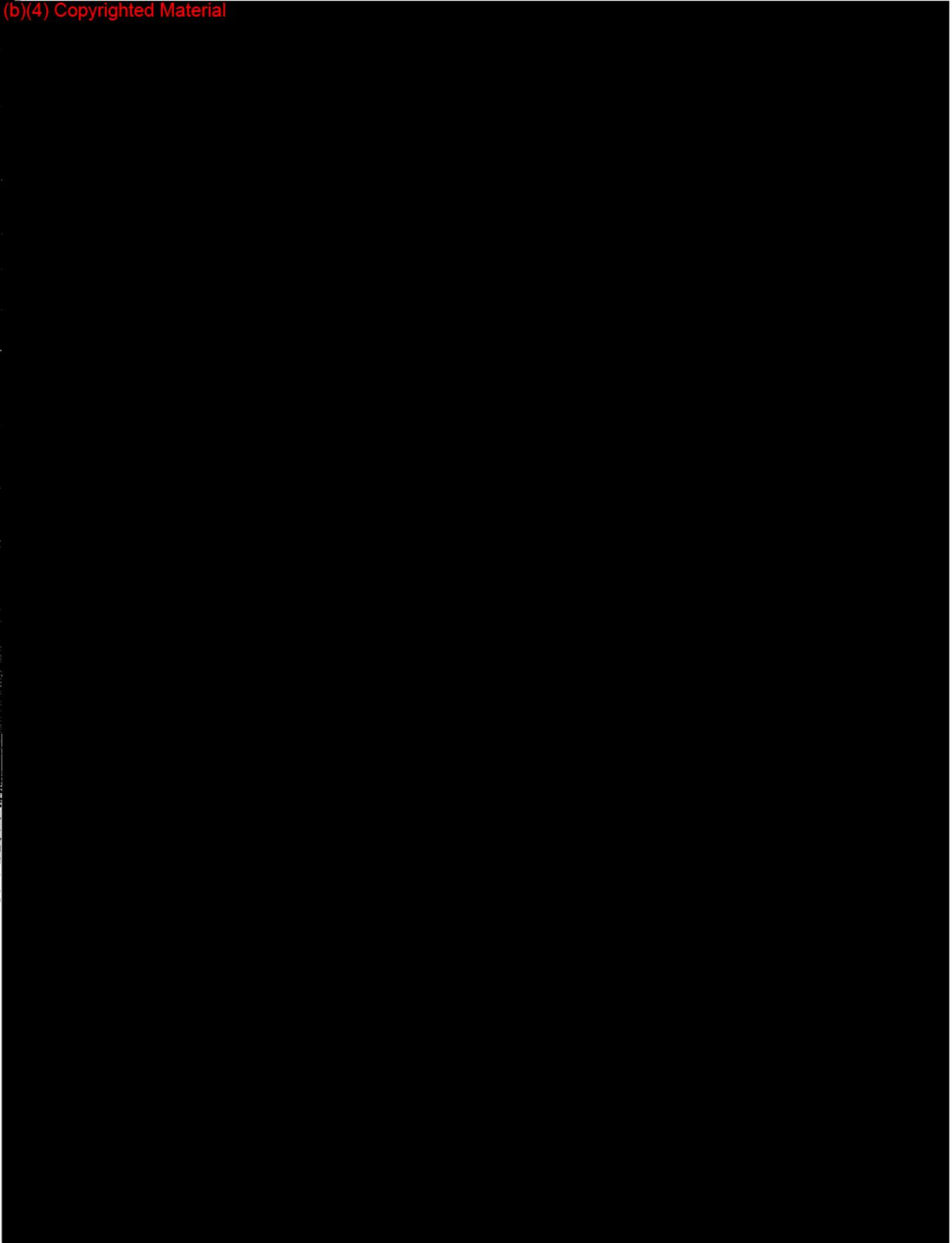
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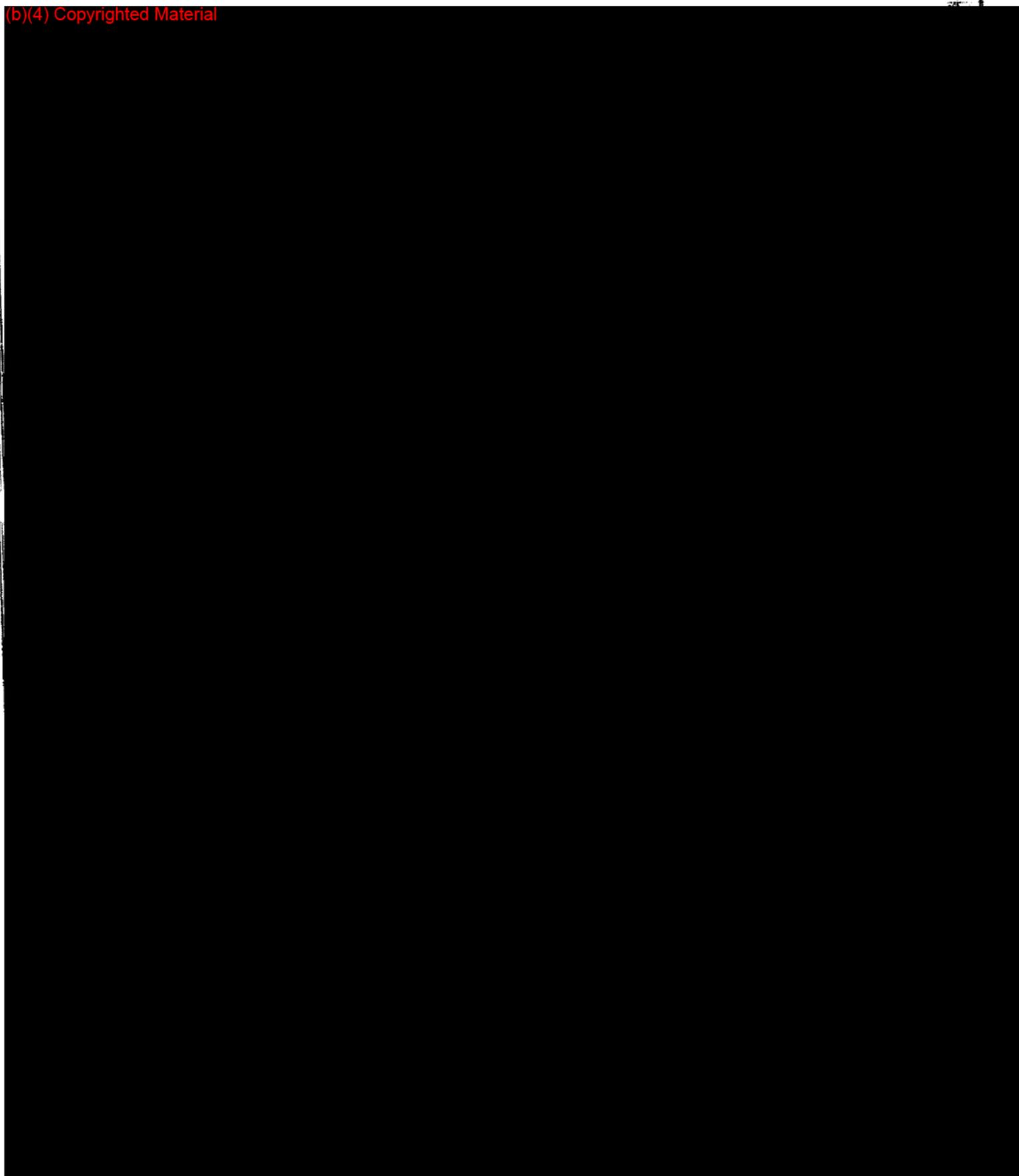
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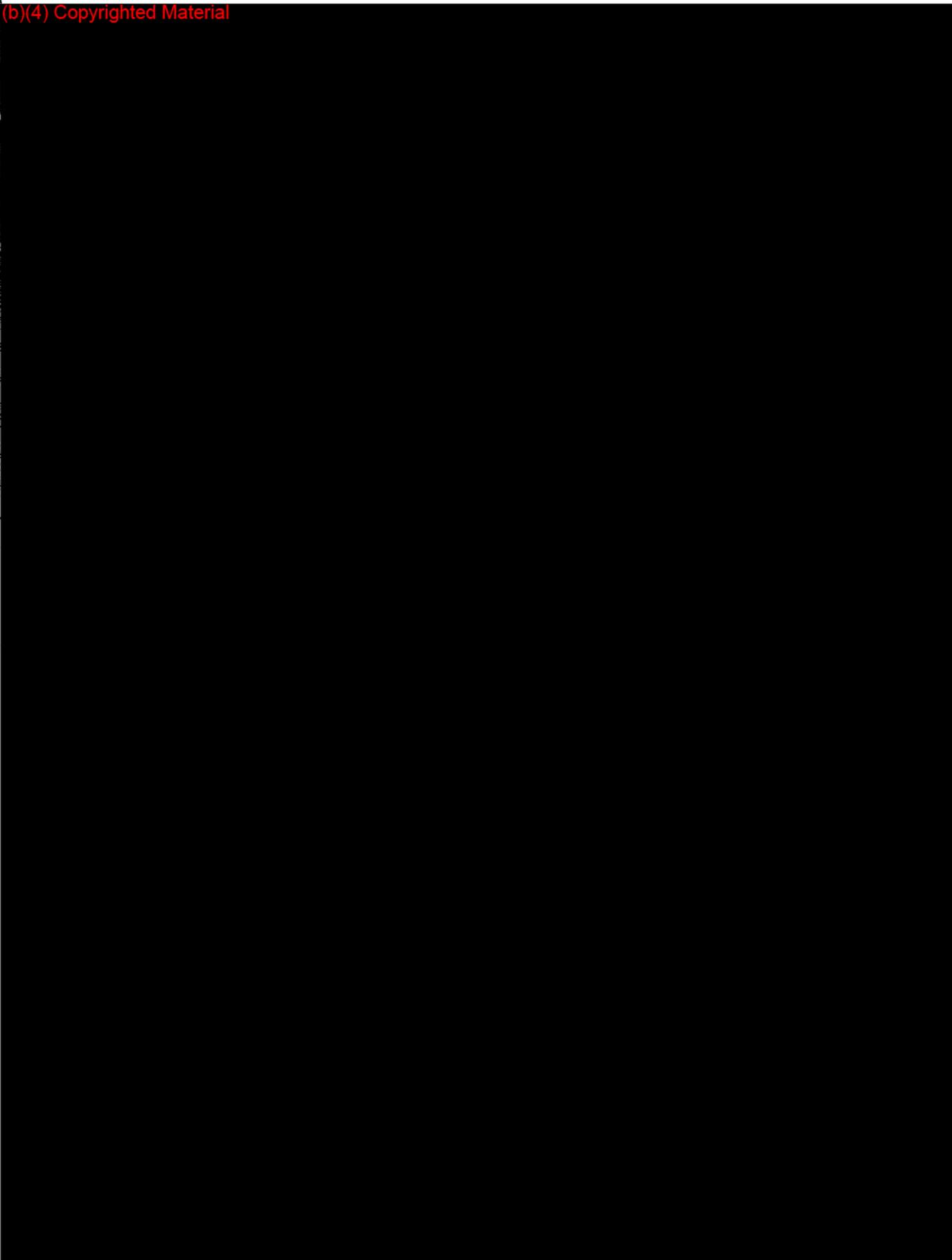


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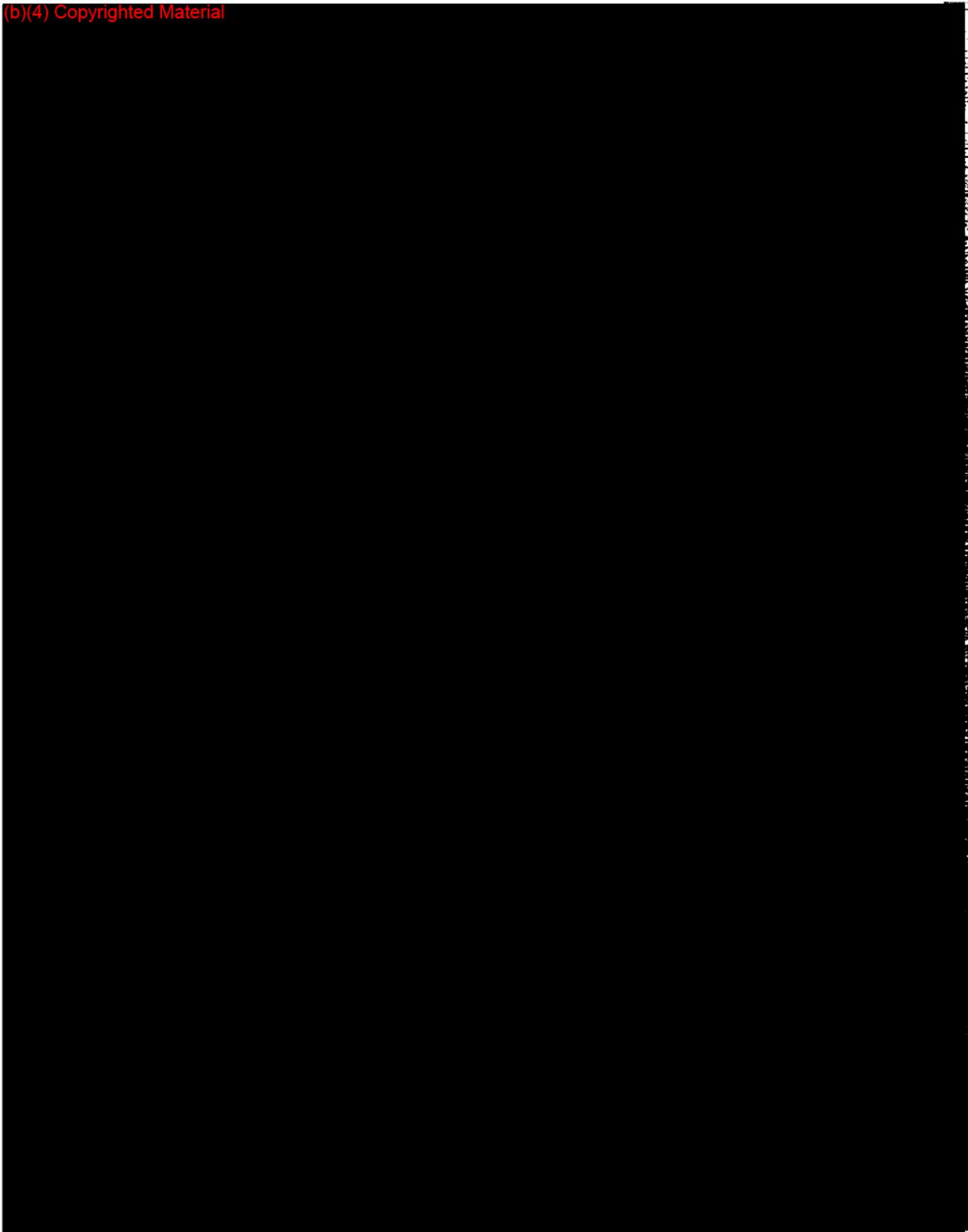
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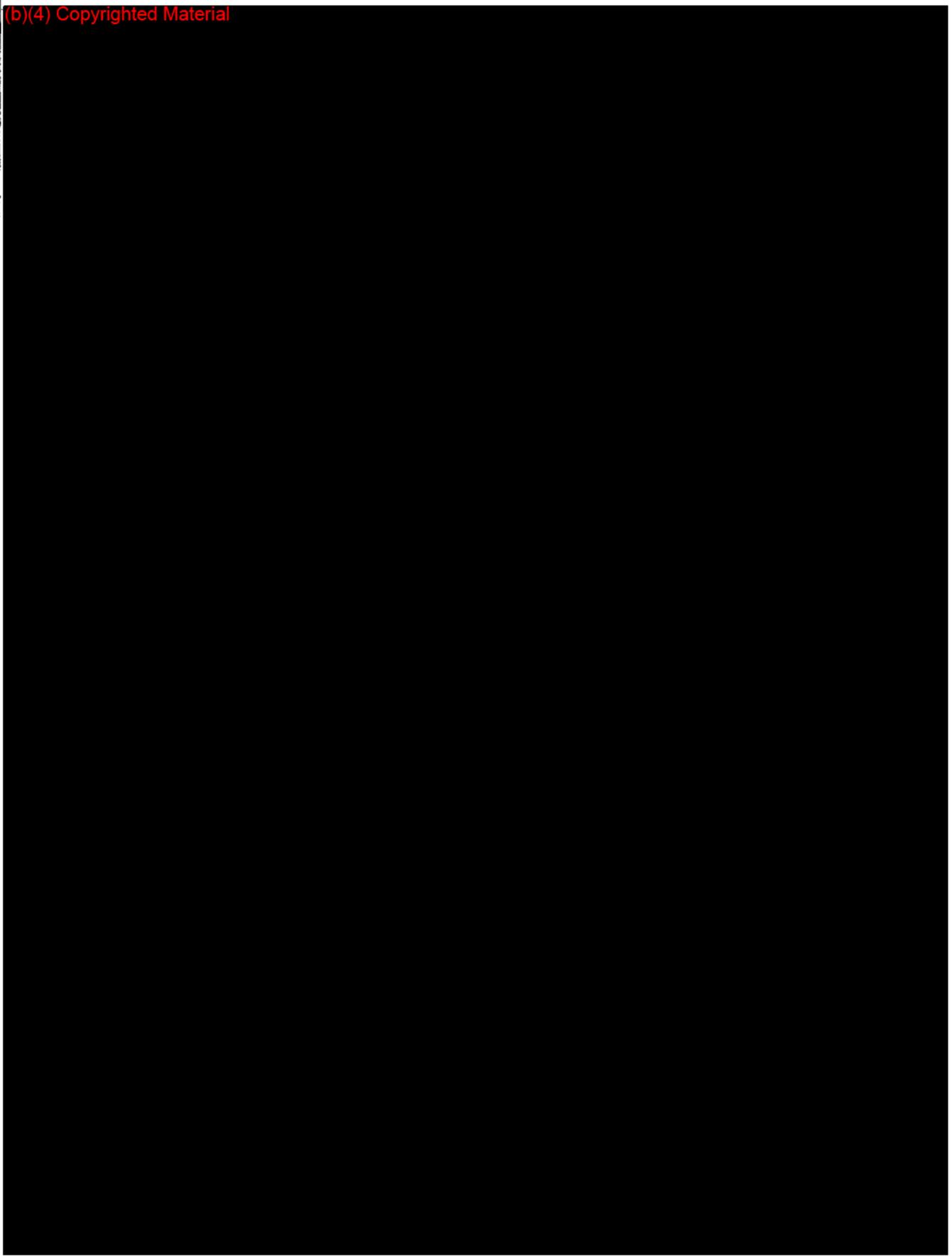
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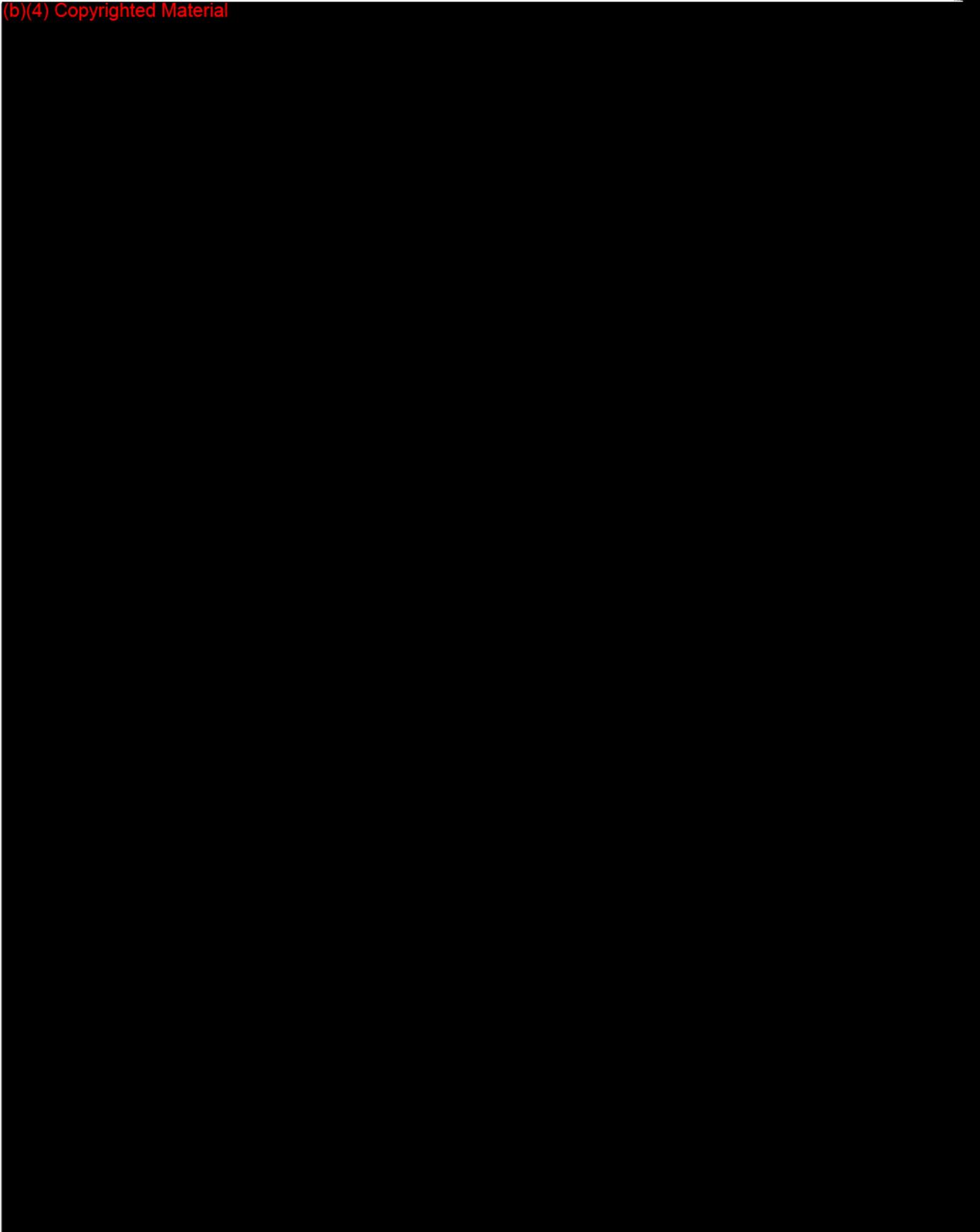
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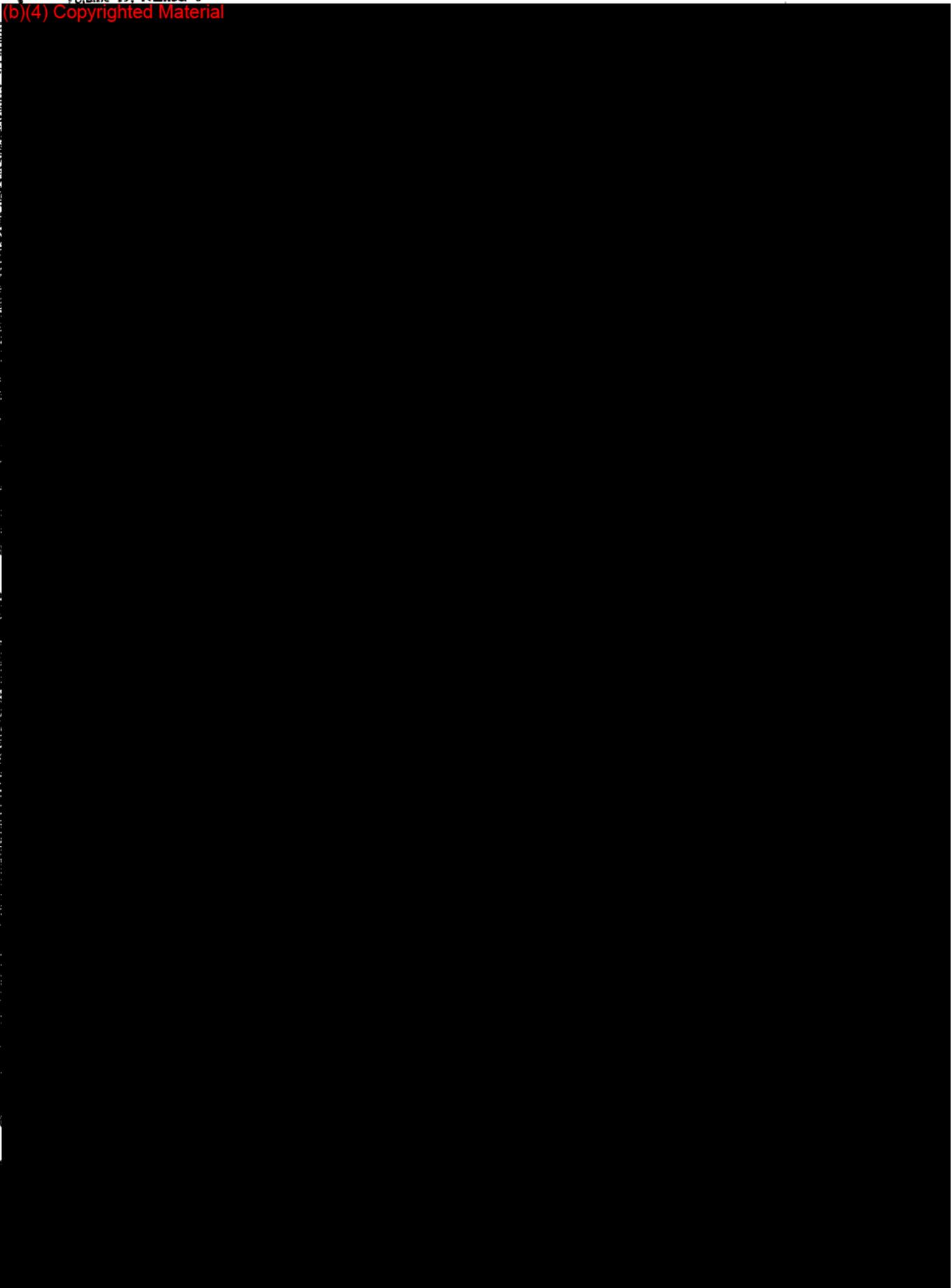
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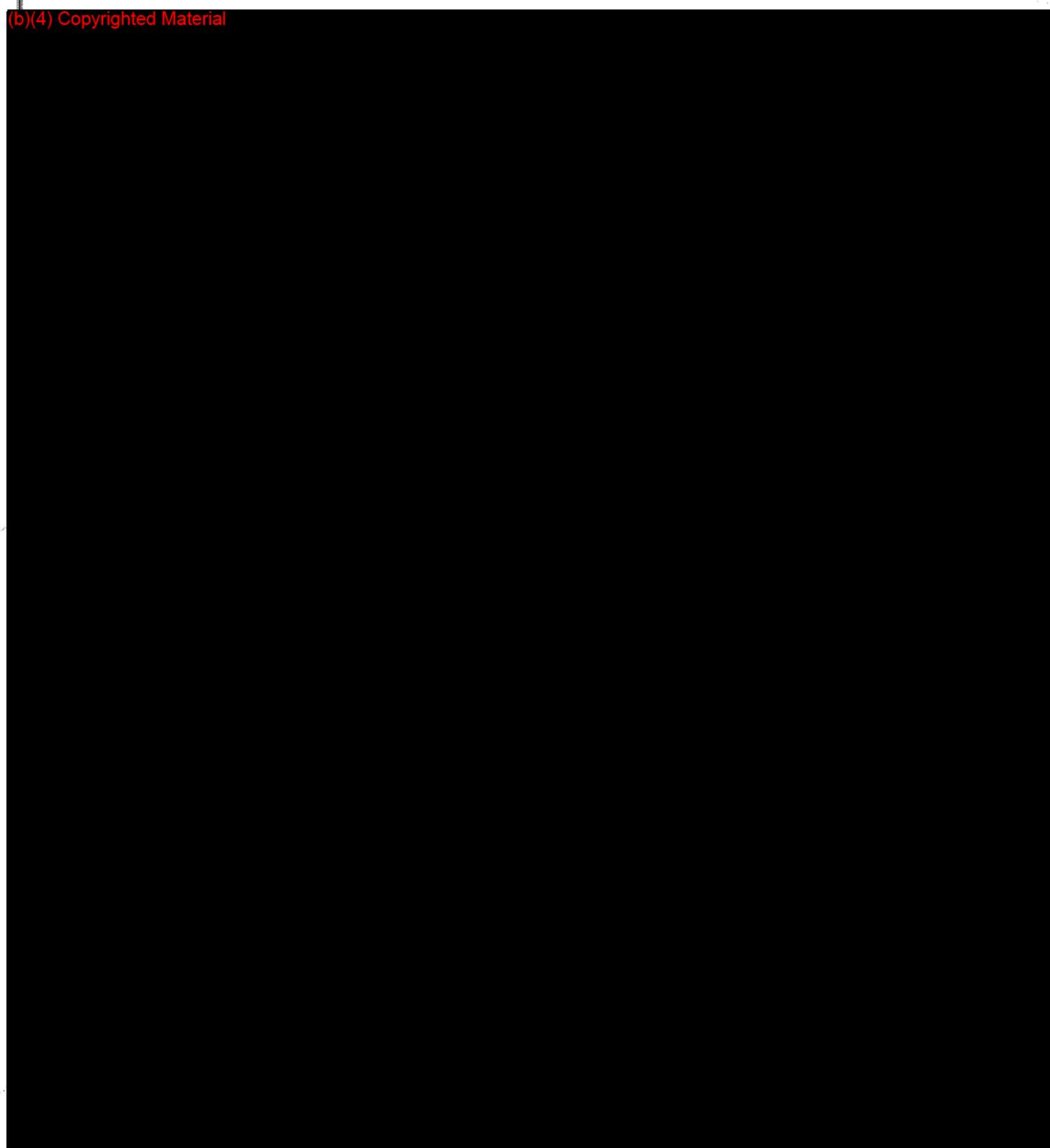


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TRANSCATHETER EMBOLOTHERAPY OF MASSIVE BLEEDING AFTER SURGERY FOR BENIGN GYNECOLOGIC DISORDERS

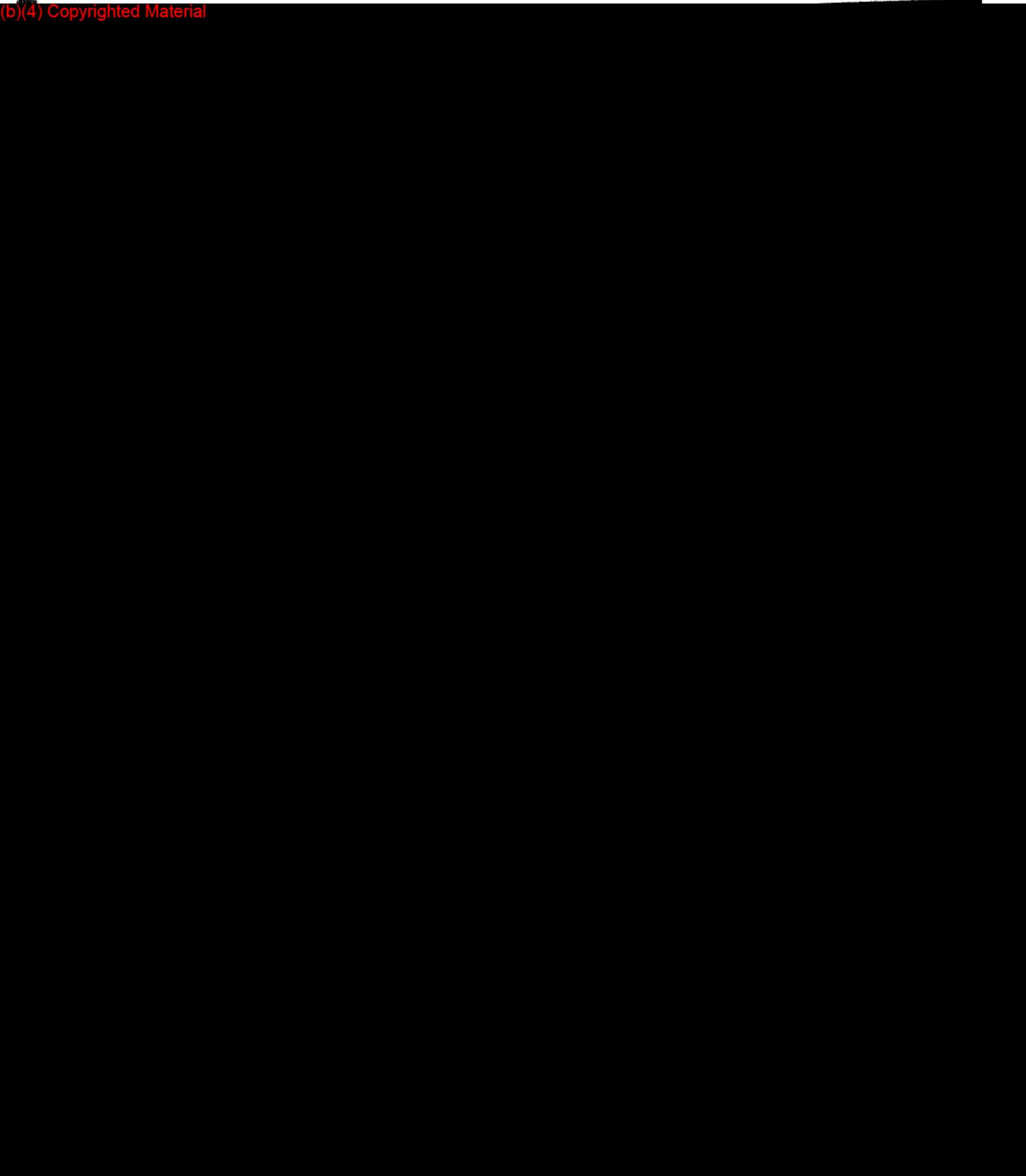
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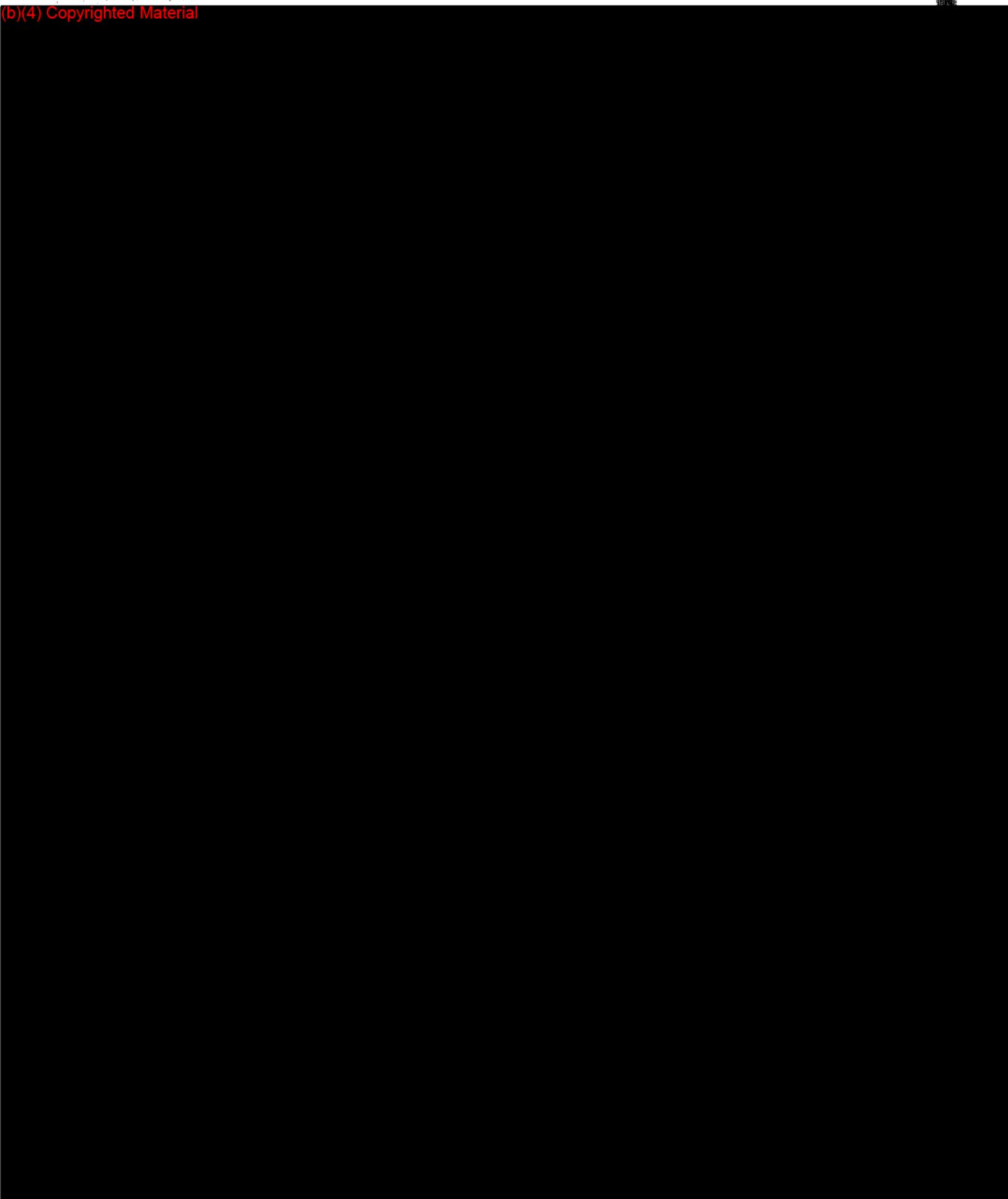
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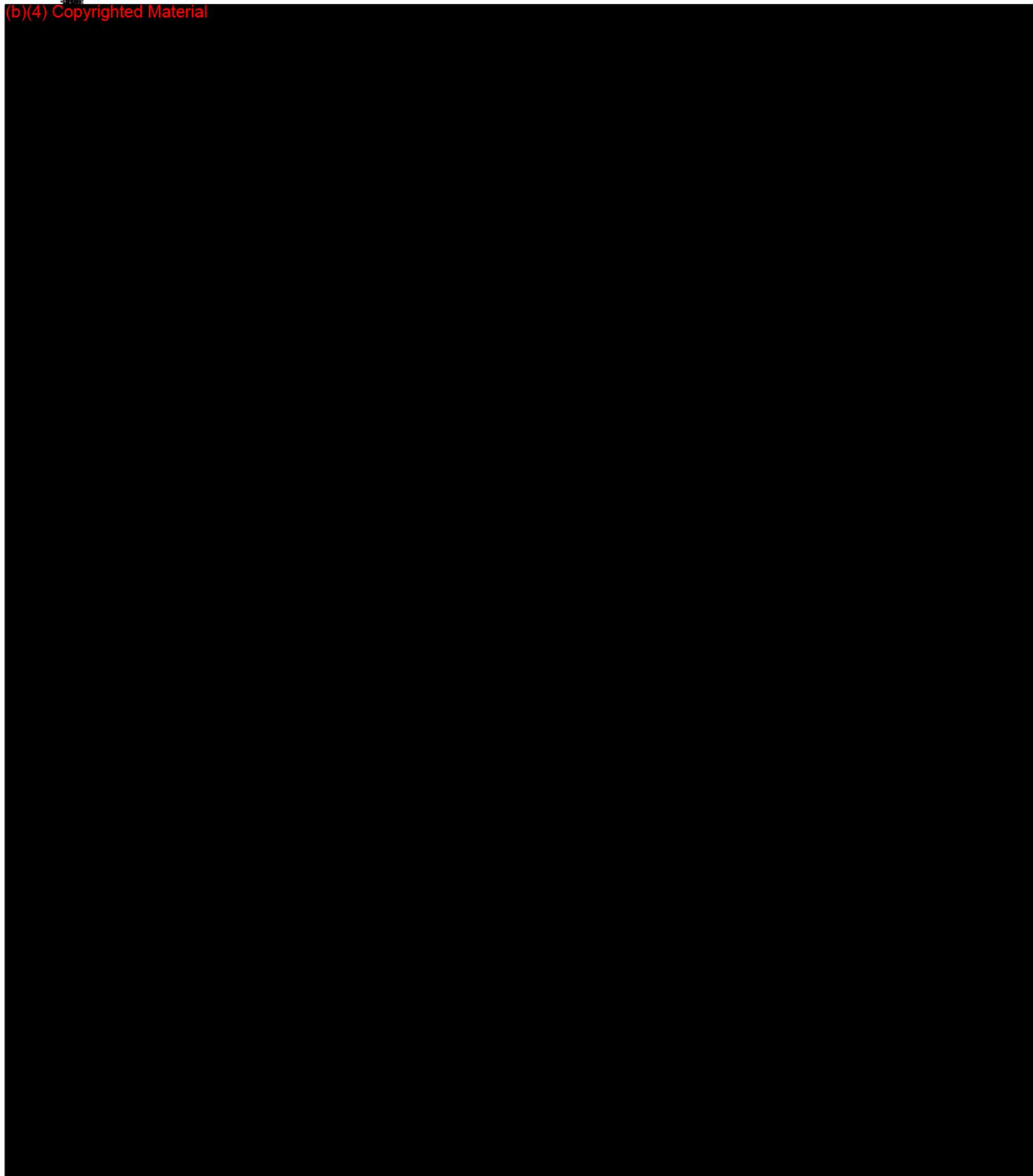
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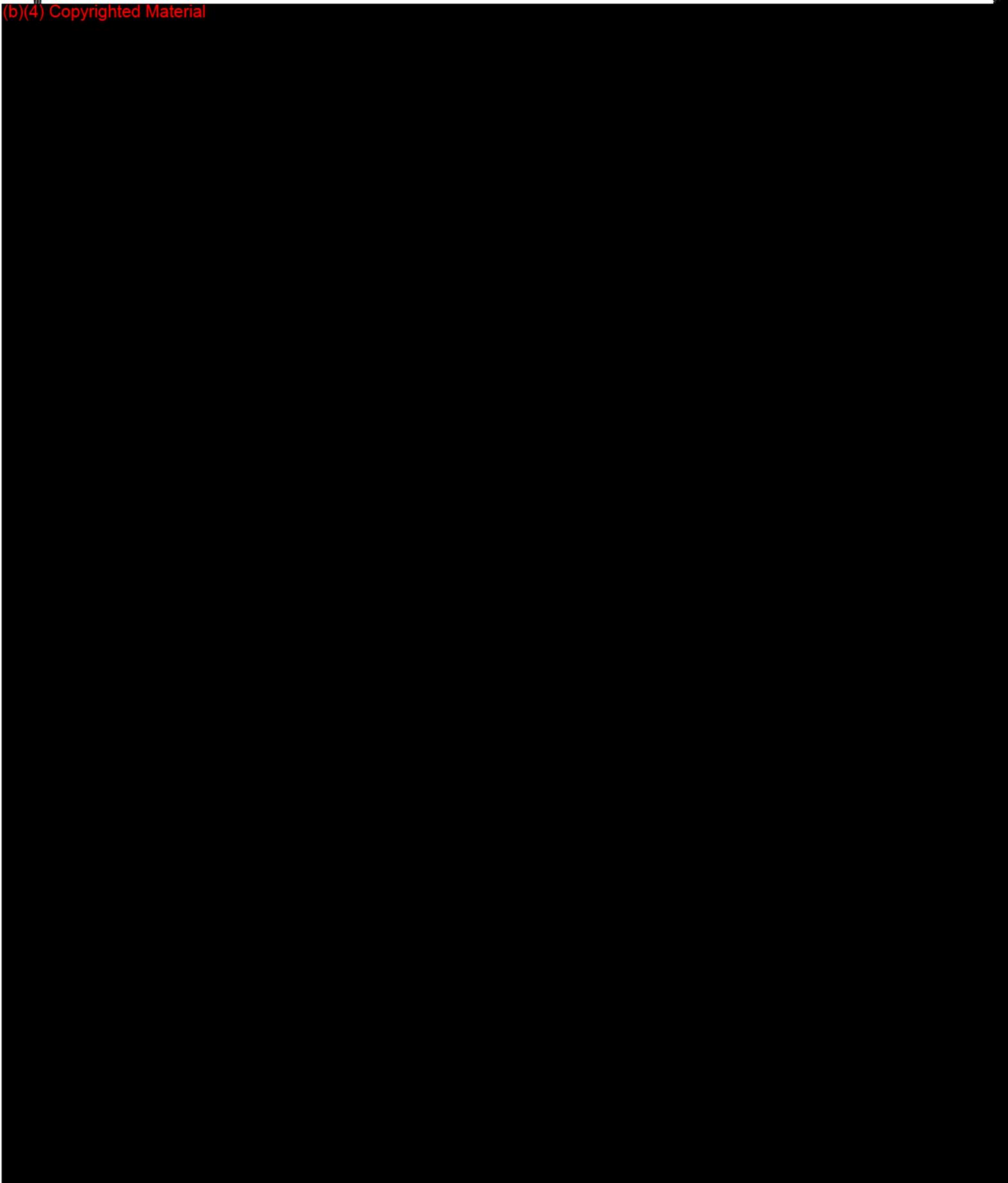


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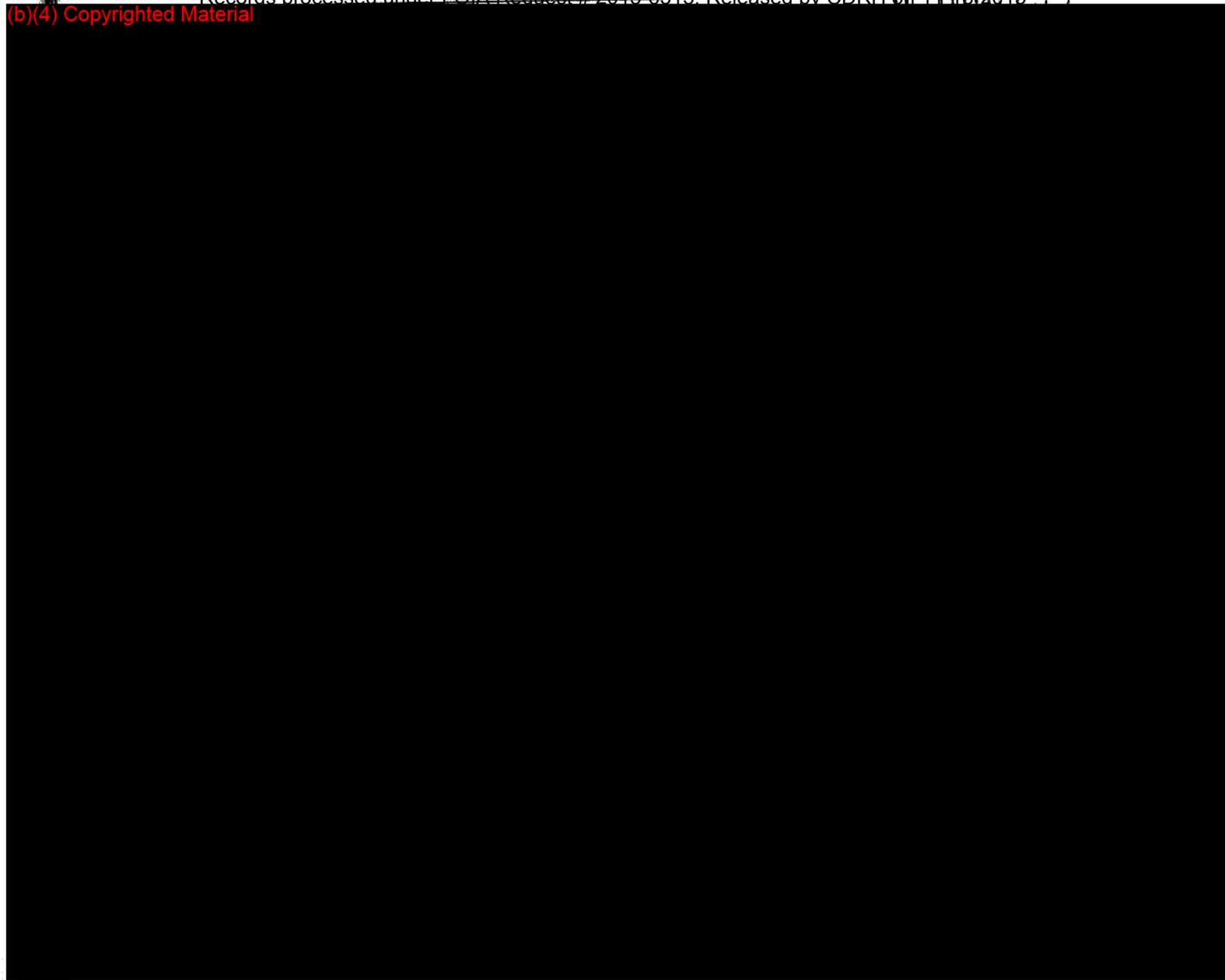
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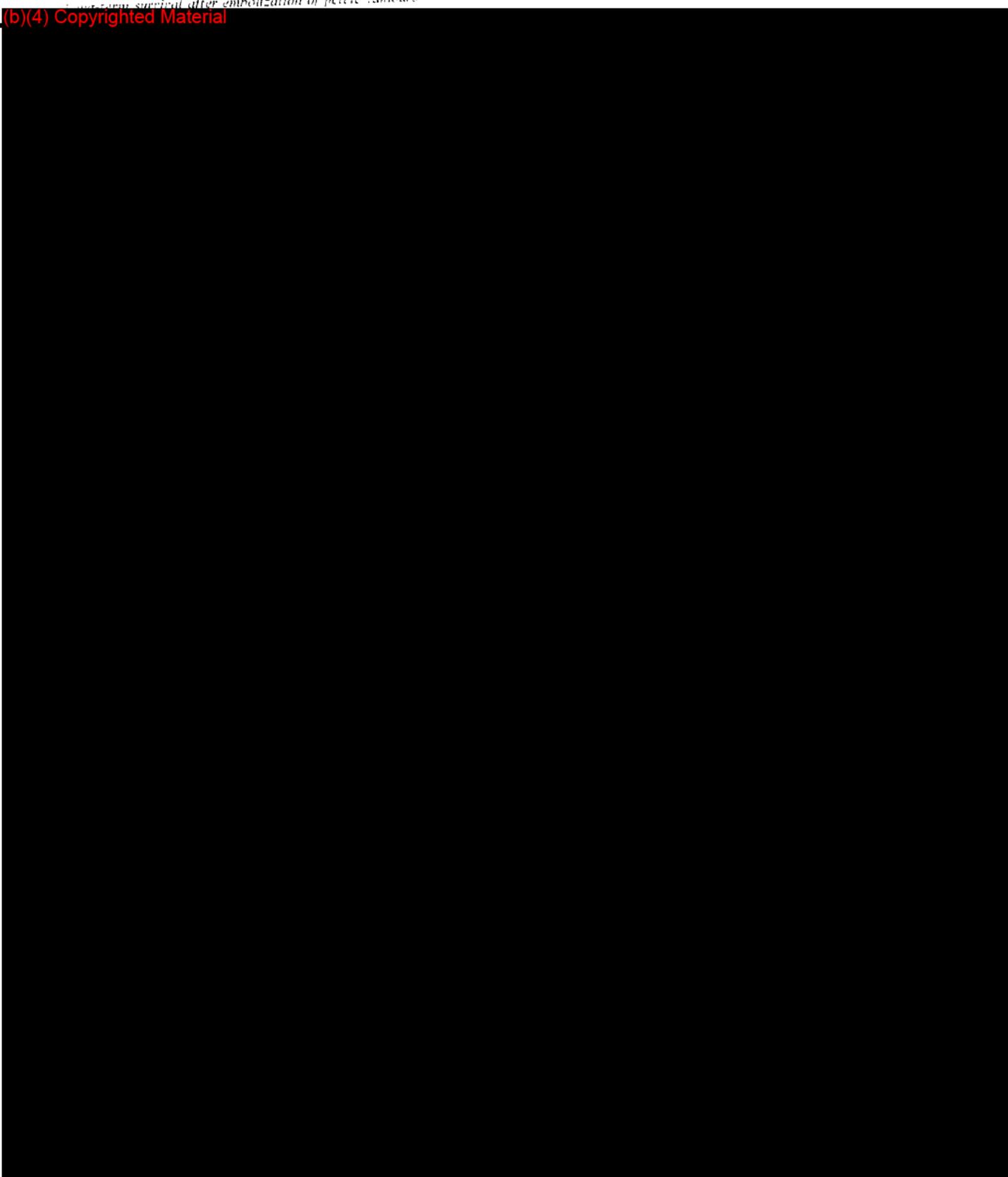
Long-term survival after embolization of potentially lethal bleeding malignant pelvic tumours

Ph HENDRICKX, G ORTH and J-H GRUNERT

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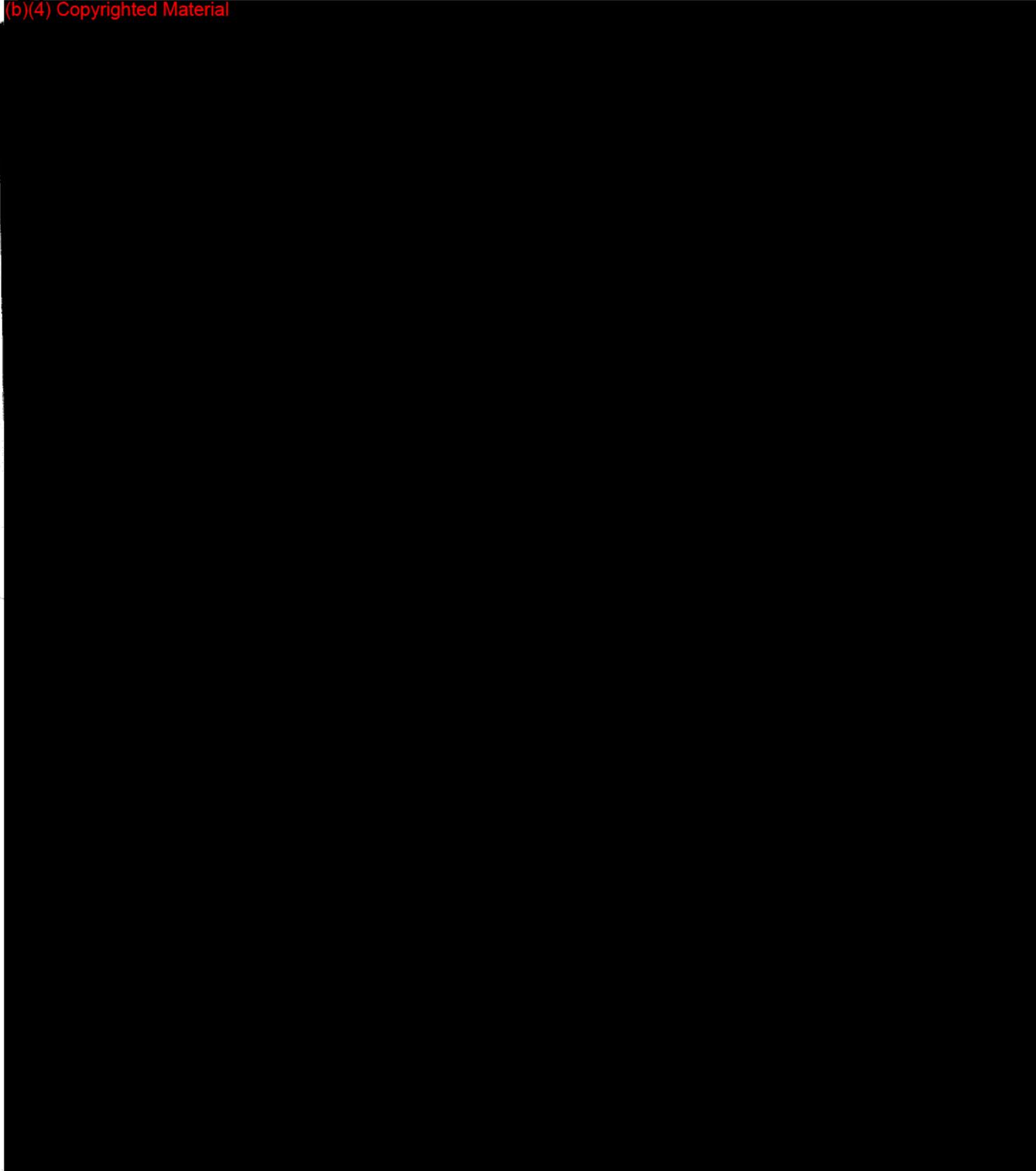
...surgical after embolization of pelvic tumours



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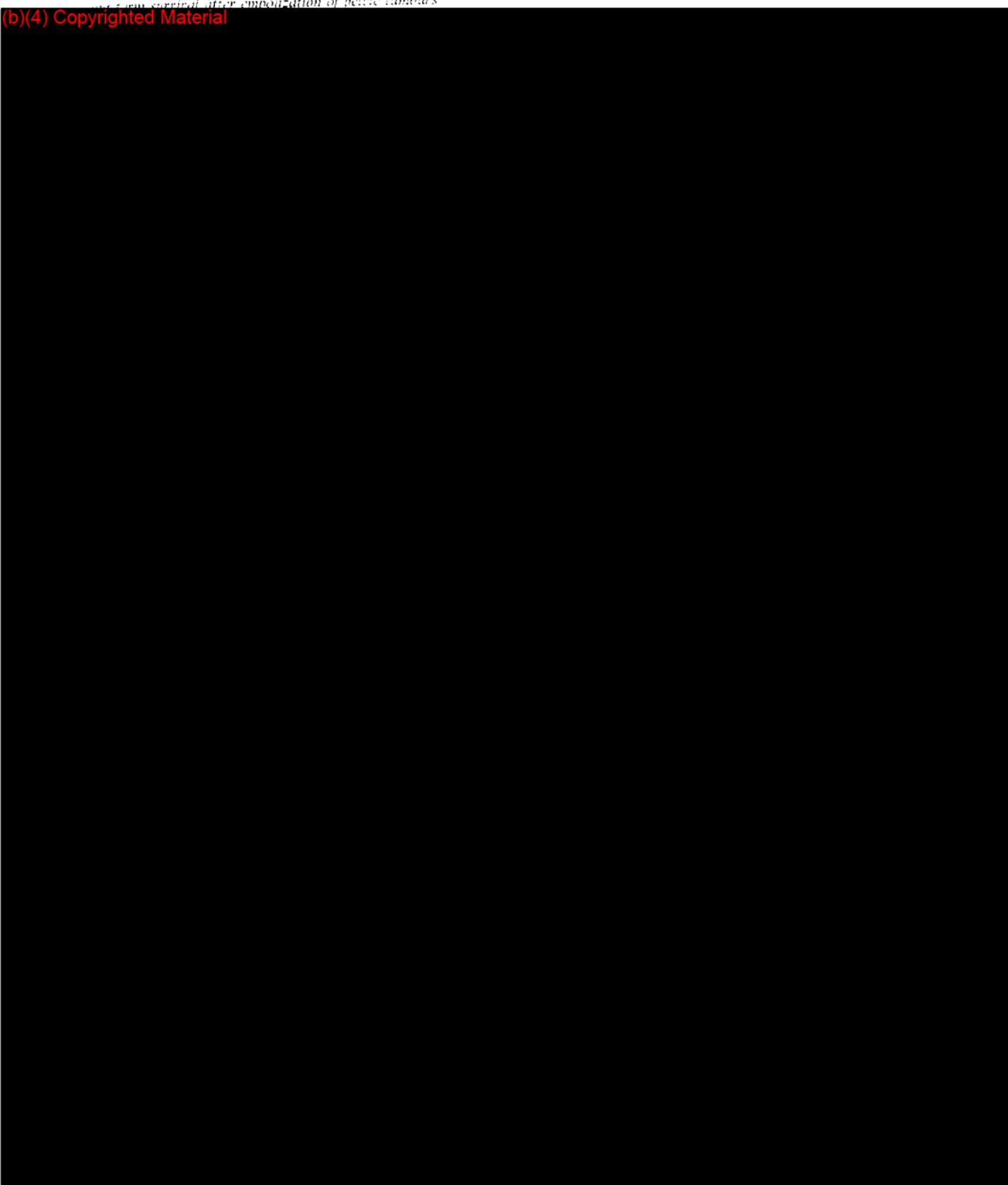
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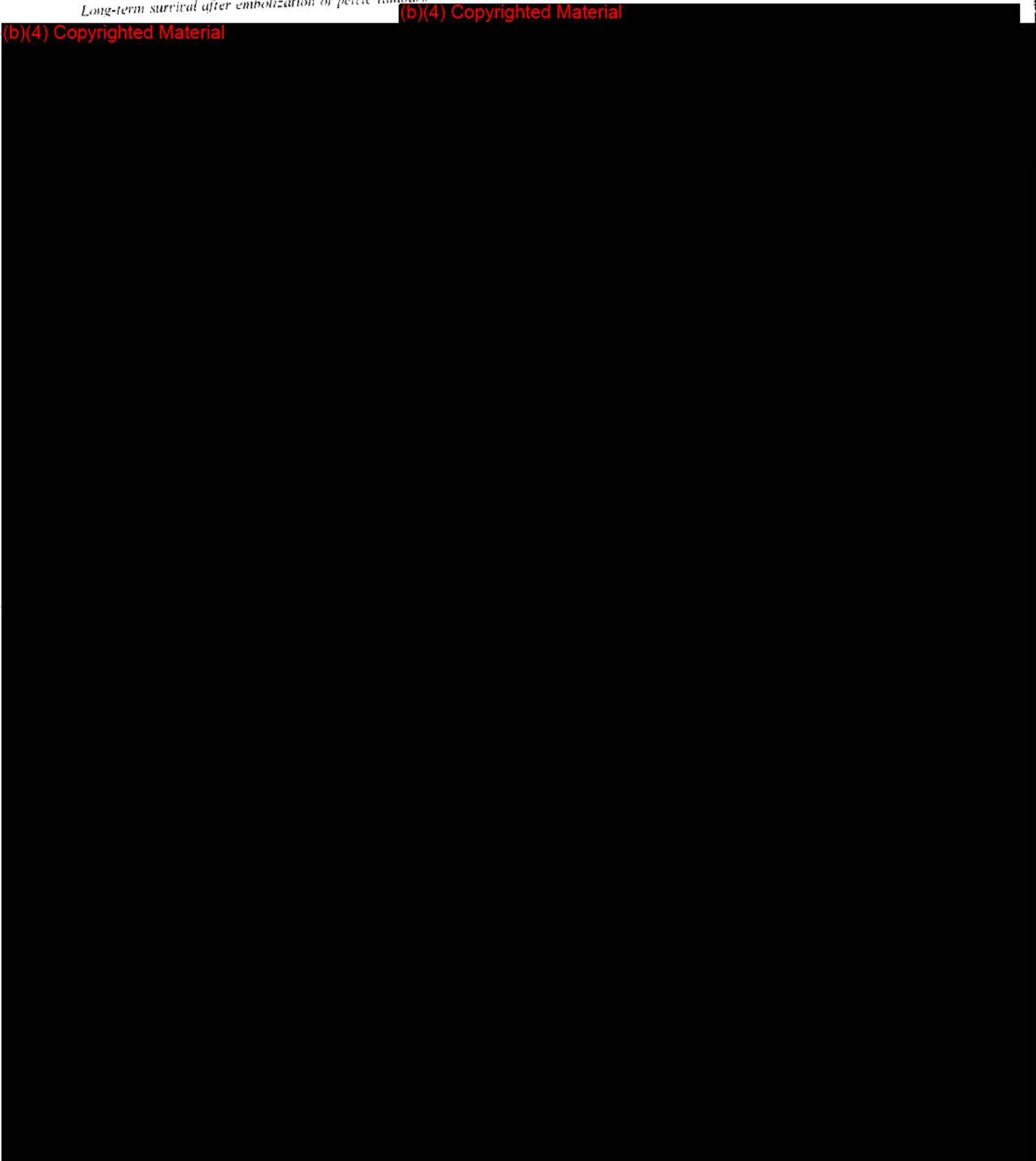
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Long-term survival after embolization of pelvic tumours

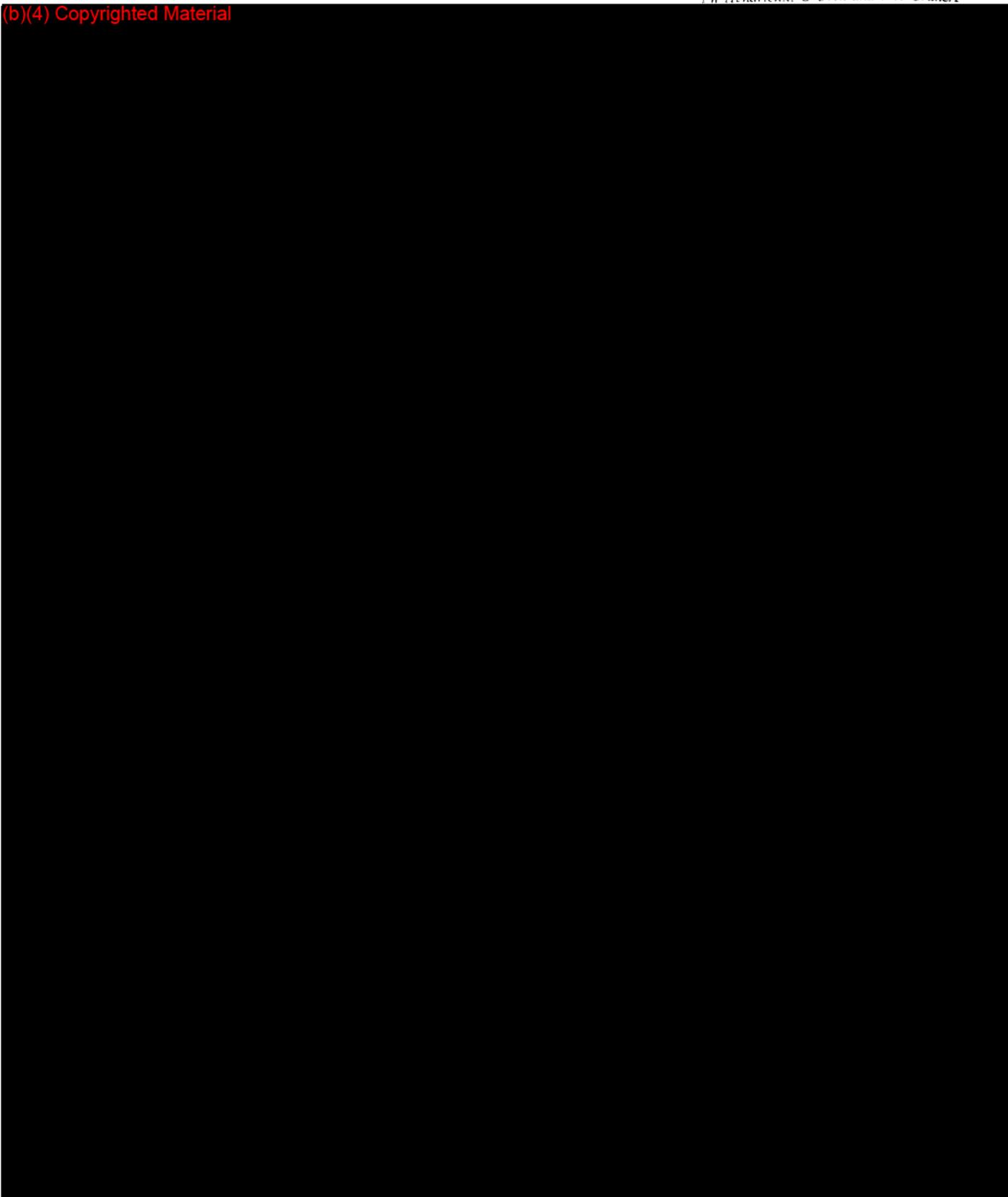
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FROM THE DEPARTMENT OF RADIOLOGY, FACULTY OF MEDICINE, KYUSHU UNIVERSITY, AND THE DEPARTMENT OF UROLOGY, SANSHINKAI HARA HOSPITAL, FUKUOKA, JAPAN.

TRANSCATHETER EMBOLIZATION OF TESTICULAR VEIN FOR VARICOCELE TESTIS

T. KUROIWA, K. HASUO, K. YASUMORI, A. MIZUSHIMA, K. YOSHIDA, R. HIRAKATA, K. KOMATSU, A. YAMAGUCHI and K. MASUDA

Abstract

Percutaneous transcatheter embolization of the testicular vein was performed on 28 patients with angiographically proven varicocele testis. In 2 patients bilateral and in 26 only the left vein was embolized using 3-, 5-, or 8-mm stainless steel coils. All patients had clinically palpable varicoceles and male infertility. The grade of varicoceles improved after embolization in 23 of 28 cases (82%). Effective sperm count increased significantly from 34.5 ± 44.6 to 65.1 ± 71.0 following embolization. However, pregnancy was achieved only in one of 28 cases. Technically, the basilic vein approach was felt to be superior to the femoral vein or jugular vein approach for this procedure.

Key words: Veins, spermatic; —, therapeutic blockade; varicocele; sterility.

Varicocele testis is one cause of male infertility (3). Surgical high ligation of the testicular vein has been performed (2), but recurrence of varicocele or surgical complications have been reported (7, 11). Percutaneous transcatheter embolization using various embolic material for the treatment of varicocele is widely performed (5, 8, 15–17). Here we report our experience with percutaneous transcatheter embolization with stainless steel coils for the treatment of clinically palpable varicocele testis in 28 patients with male infertility.

Material and Methods

Twenty-eight patients, 26 to 44 years old (mean 33 years) with male infertility were clinically diagnosed to have varicocele testis. All patients had either an oligospermia or infertility period of more than 3 years. According to the following grading system, varicocele was classified in 4 groups: V0 = varicocele was not palpable even with the Val-salva maneuver; V1 = varicocele was palpable only with Val-

salva; V2 = varicocele was easily palpable during ordinary respiration; V3 = varicocele was visible on inspection (9, 12). All 28 patients had varicocele on the left side, and in 2 the varicocele was bilateral.

Embolization was performed using Seldinger's technique as follows: A 5F (1.7 mm) catheter was percutaneously inserted into the femoral vein in 11 patients or the basilic vein in 17 patients, through a 5.5F (1.8 mm)-long sheath introducer in most of the cases. After catheterization of the left or right testicular vein, testicular venography was performed. Coils of stainless steel, 3-, 5-, and 8-mm in diameter, were introduced as embolic material into the testicular vein. One to 5 coils were placed in the testicular vein, paying special attention to their position in order to prevent collateral flow. Immediately after the embolization therapy, testicular venography was repeated to confirm disappearance of the varicoceles.

The volume of sperm, sperm motility, and sperm density were analyzed (at least twice) about one month before and about 3 to 6 months after embolization, respectively, in all patients. At the same time, in 24 of 28 patients, various hormone levels, such as luteinizing hormone (LH), follicle-stimulating hormone (FSH), and testosterone, were evaluated. As a rule men treated with embolization therapy were followed up as outpatients, and sperm analysis was continued every 3 to 6 months. The average follow-up period time was 13.9 months (range 4–48 months).

Results

A successful embolization rate was higher with the basilic vein approach than with the femoral approach (Table 1).

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Table 1*Percutaneous embolization in 28 patients*

Approach	Successful embolization rate
Femoral vein	
Left	10/11*
Right	0/1
Basilic vein	
Left	17/17**
Right	1/1

*Embolization impossible because of Nutcracker's syndrome in one case.

**Approach changed from femoral vein to basilic vein in 2 of 17 cases.

Table 2*Changes in grade of 28 varicoceles between pre- and postembolization*

Postembolization	Preembolization			
	V0	V1	V2	V3
V0	2	8	4	
V1	2	6	1	
V2			3	2
V3				

Improvement: 23 (82%)

No change: 5 (18%)

Recurrence: 2 (7%)

Table 3*Spermatic findings in pre- and postembolization (28 cases)*

	Preembolization	Postembolization
Sperm volume (ml)	4.14 ± 1.80	4.21 ± 1.68
Sperm density (× 10 ⁶ /ml)	28.9 ± 36.3	36.7 ± 33.4
Sperm motility (%)	31.5 ± 19.3	39.3 ± 23.1
Effective sperm count*	34.5 ± 44.6	65.1 ± 71.0**

*Effective sperm count =

$$\frac{\text{sperm volume} \times \text{sperm density} \times \text{sperm motility}}{100}$$

**p < 0.05 (Wilcoxon's test).

Table 4*Various hormone levels before and after embolization (24 cases)*

	Before	After
LH (MIU/ml)	13.5 ± 5.92	15.6 ± 6.19
FSH (MIU/ml)	11.4 ± 4.98	12.1 ± 4.52
Testosterone (ng/ml)	5.42 ± 1.71	5.90 ± 1.59

Embolization was accomplished with the basilic vein approach in 2 cases after an unsuccessful attempt from the femoral veins. Extravasation of contrast medium following coil placement occurred in 3 cases (4 sides), but no serious complications resulted.



a

b



c

Fig. 1. Varicocele (V2) was palpable bilaterally in a 39-year-old man. Right (a) and left (b) testicular venography suggest bilateral dilated pampiniform plexus. Radiograph (c) after embolization shows two 3-mm coils and two 5-mm coils in the left, and one 5-mm coil in the right testicular vein.

Table 2 gives the changes in grade of 28 varicoceles before and after embolization treatment. Two varicoceles which could not be treated because of unsuccessful catheterization were excluded. The improvement ratio of varicocele after

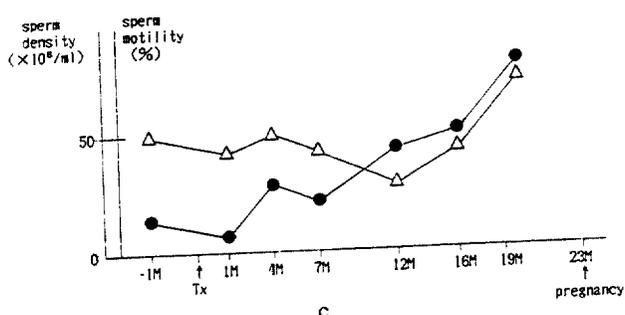


Fig. 2. Palpable varicocele (V3) on the left side in a 30-year-old man. Dilated pampiniform plexus was observed by left testicular venography (a). Embolization was performed using three 8-mm coils (b). About 23 months after embolization, pregnancy was accomplished, and a healthy baby was born. c) Time-course curve of the spermatic findings after embolization. Δ —sperm density, \bullet —sperm motility.

embolization was 82%. In only 18% was the clinical situation unchanged. Two patients who originally improved had recurrent varicoceles 6 months after embolization.

There was significant improvement in effective sperm count after embolization (Table 3). Sperm volume, sperm density, and sperm motility also improved after embolization but the difference was not significant.

Table 4 shows hormone levels before and after embolization in 24 cases. There was no significant difference in LH, FSH, and testosterone between values obtained before and after embolization.

Two representative cases are shown in Figs 1 and 2. The partner of one patient became pregnant 23 months after embolization (Fig. 2). The time-course of the spermatic findings after embolization in this case showed that the sperm density and motility were obviously improved (Fig. 2 c).

Discussion

Femoral vein catheterization is the most common approach for embolization of testicular veins (8, 14, 15, 17). However, the jugular vein approach is performed in some institutes (5, 6, 10, 16). The femoral vein approach was initially attempted, but since we had experienced several difficulties in catheterizing the testicular veins, the basilic vein approach was chosen, usually from the right side. The success rate improved from 91% to 100%. As a consequence, embolization rate improved and the procedure caused less discomfort mainly due to the shorter catheterization time required.

Various embolic materials such as stainless steel coils (1, 5, 10), sclerosing agents (4, 8, 14, 15), detachable balloons (1, 17), and hot contrast material (13, 16) have been used. We performed embolization with coils of various sizes according to the diameter of the testicular vein to be embolized. The method was technically easy, and no serious complications were encountered. However, the risk of coil dislodgement with left renal vein thrombosis or pulmonary embolus cannot be completely eliminated, and passing a catheter through the right atrium also implies a small risk with the basilic vein approach. Consequently, care must be taken with every patient undergoing varicocele therapy involving deliberate catheterization and coil placement for a testicular vein. On the other hand, in recurrent varicoceles after primary embolization therapy, reembolization by stainless steel coil may be difficult because of development of multiple collateral channels. No embolization material may be suitable in these cases.

Although the sperm improved after embolization, pregnancy was accomplished in only one case out of 28. Higher pregnancy rate (24% of 58 cases) after embolization has been reported (9). This difference may depend upon the degree of oligospermia and the length of the infertility period.

Testicular venography and transcatheter embolization for varicoceles with the basilic vein approach are relatively simple procedures carrying no significant risk of complications. They may be indicated in virtually all infertile male patients with clinical diagnosis of varicoceles, not only for confirming the diagnosis but for possible cure of infertility.

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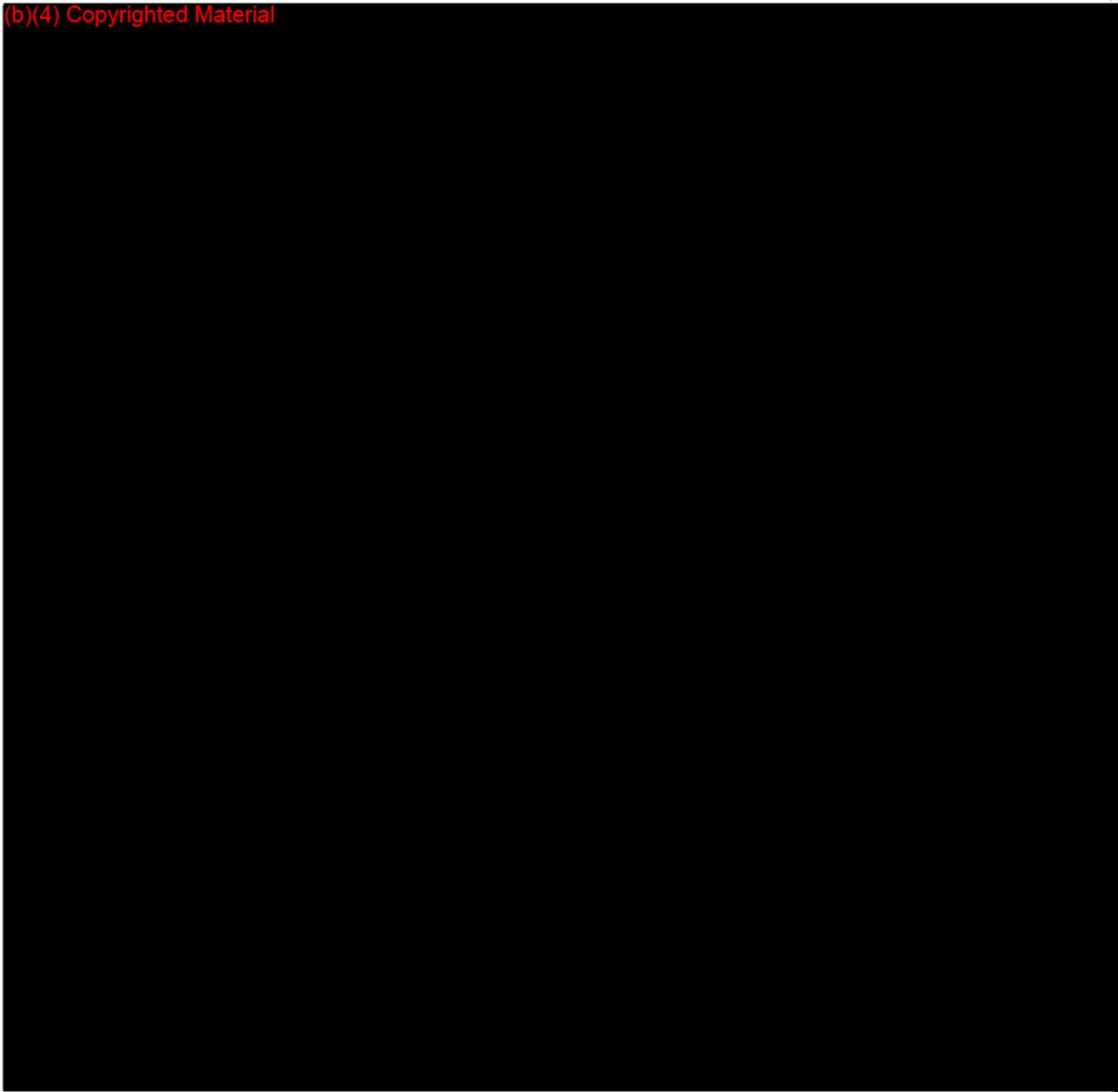
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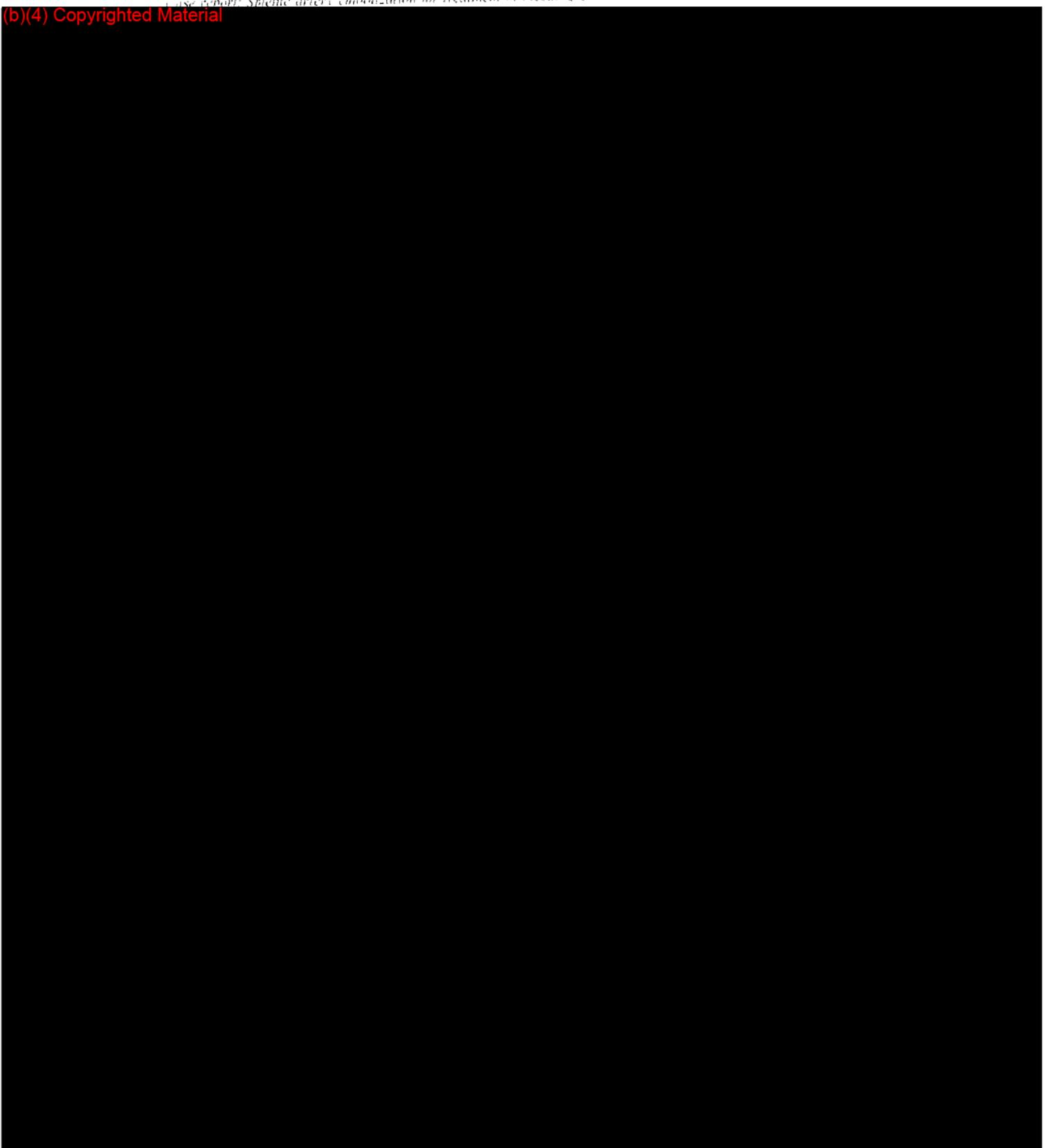
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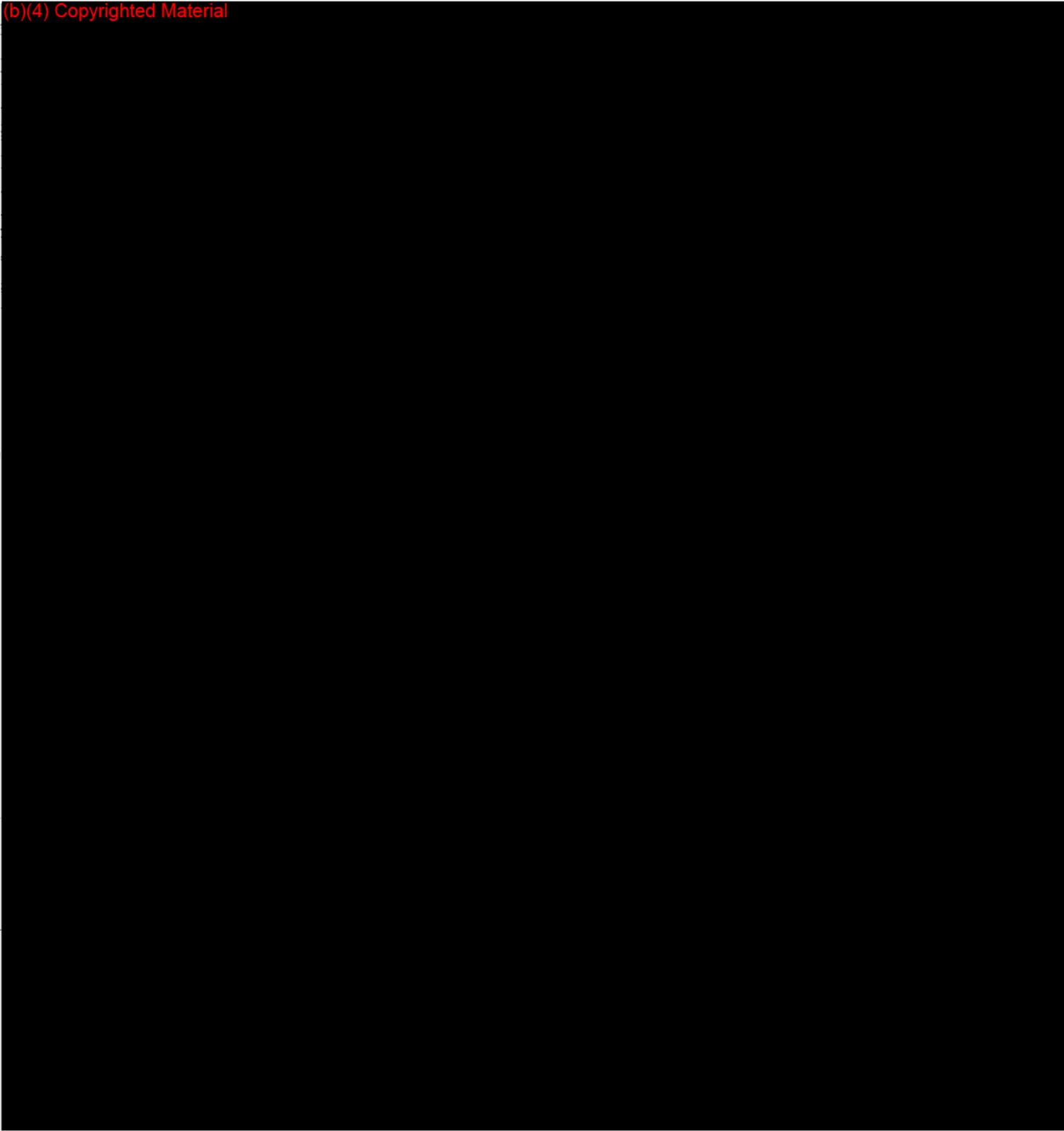
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HIGH LIGATION OR EMBOLIZATION OF VARICOCELE

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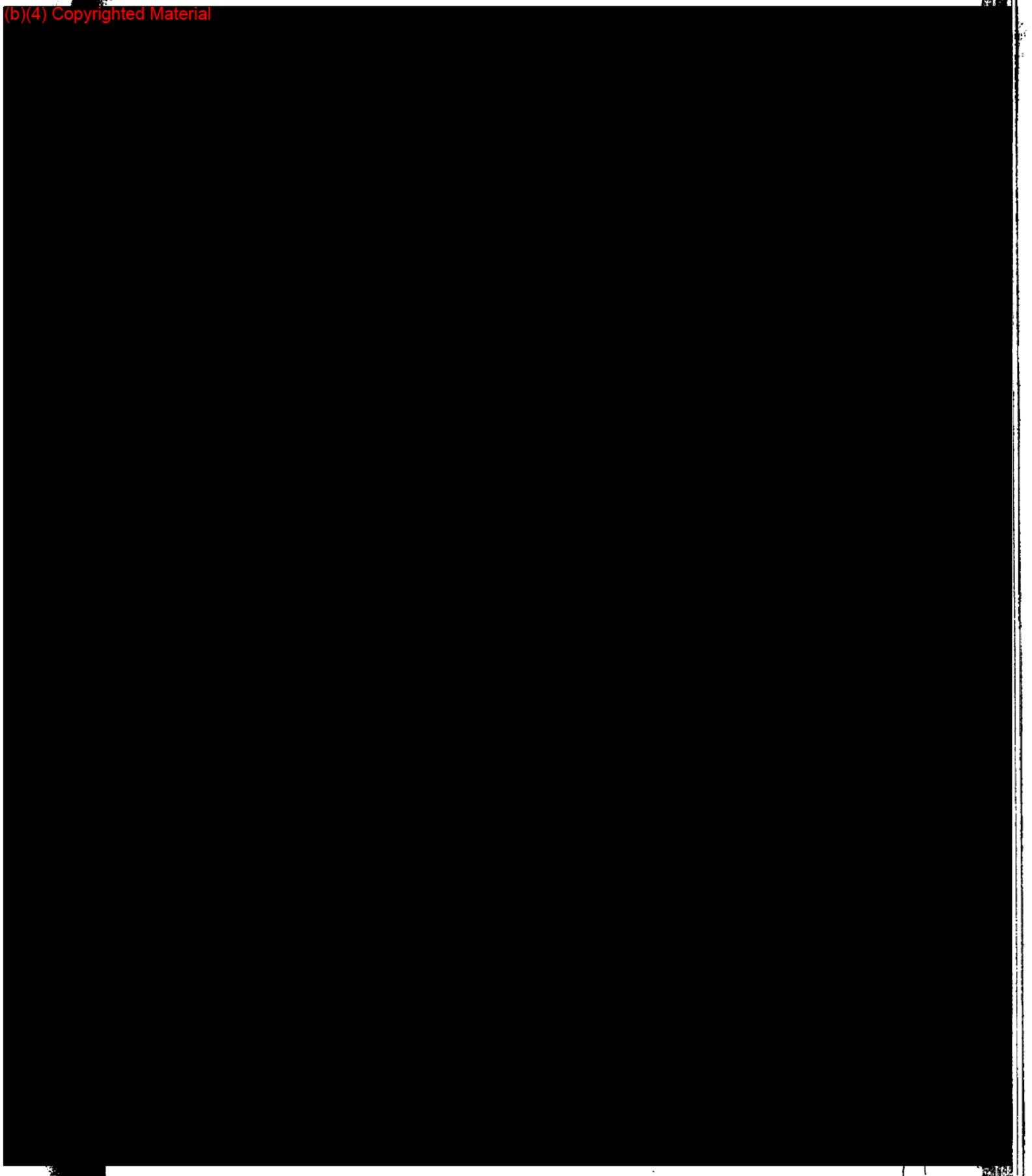


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CASE REPORTS

Hemorrhagic Pancreatitis: A Complication of Transcatheter Embolization Treated Successfully by Total Pancreatectomy

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Joel S. Nizin, MD, New York, New York
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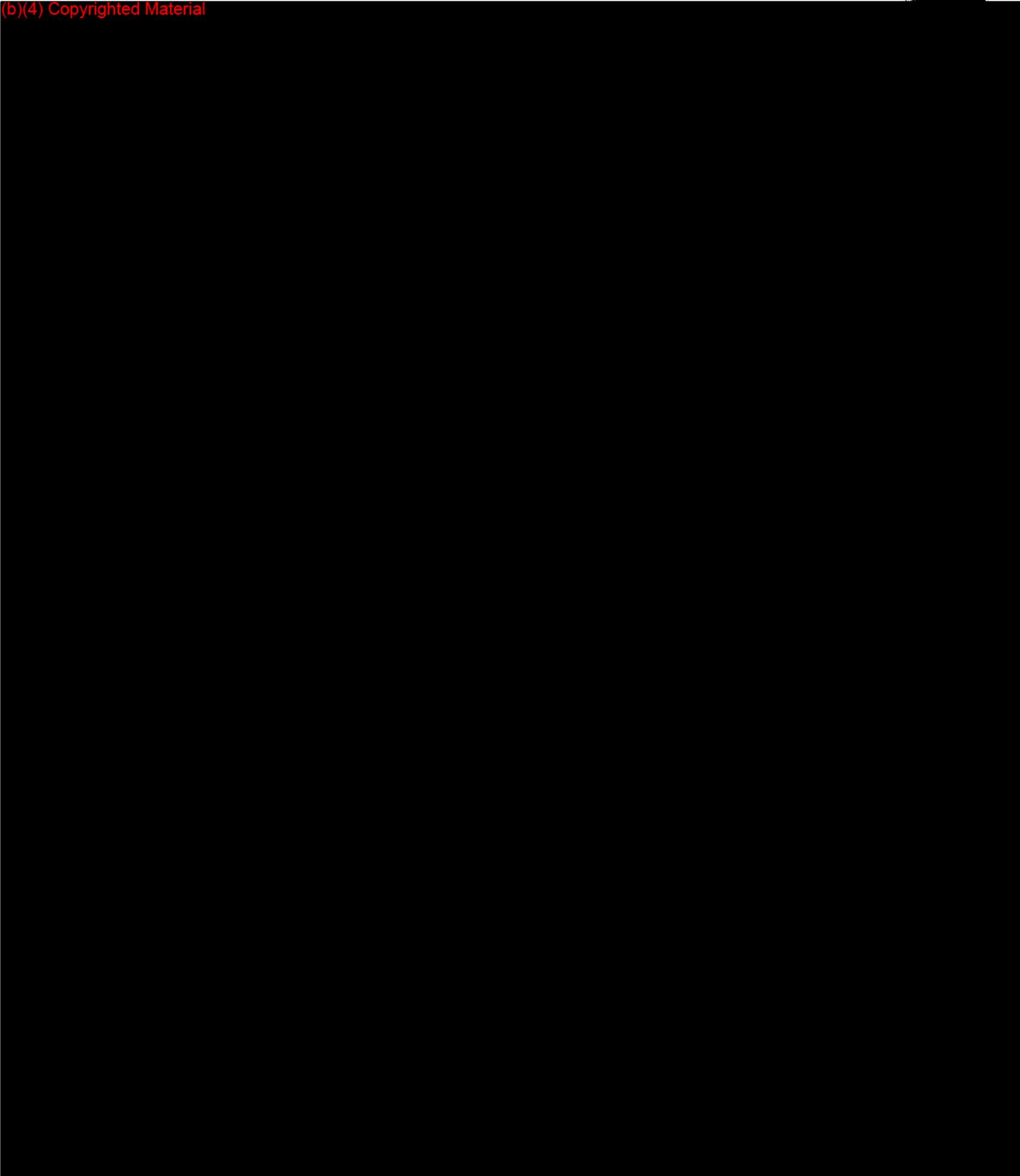
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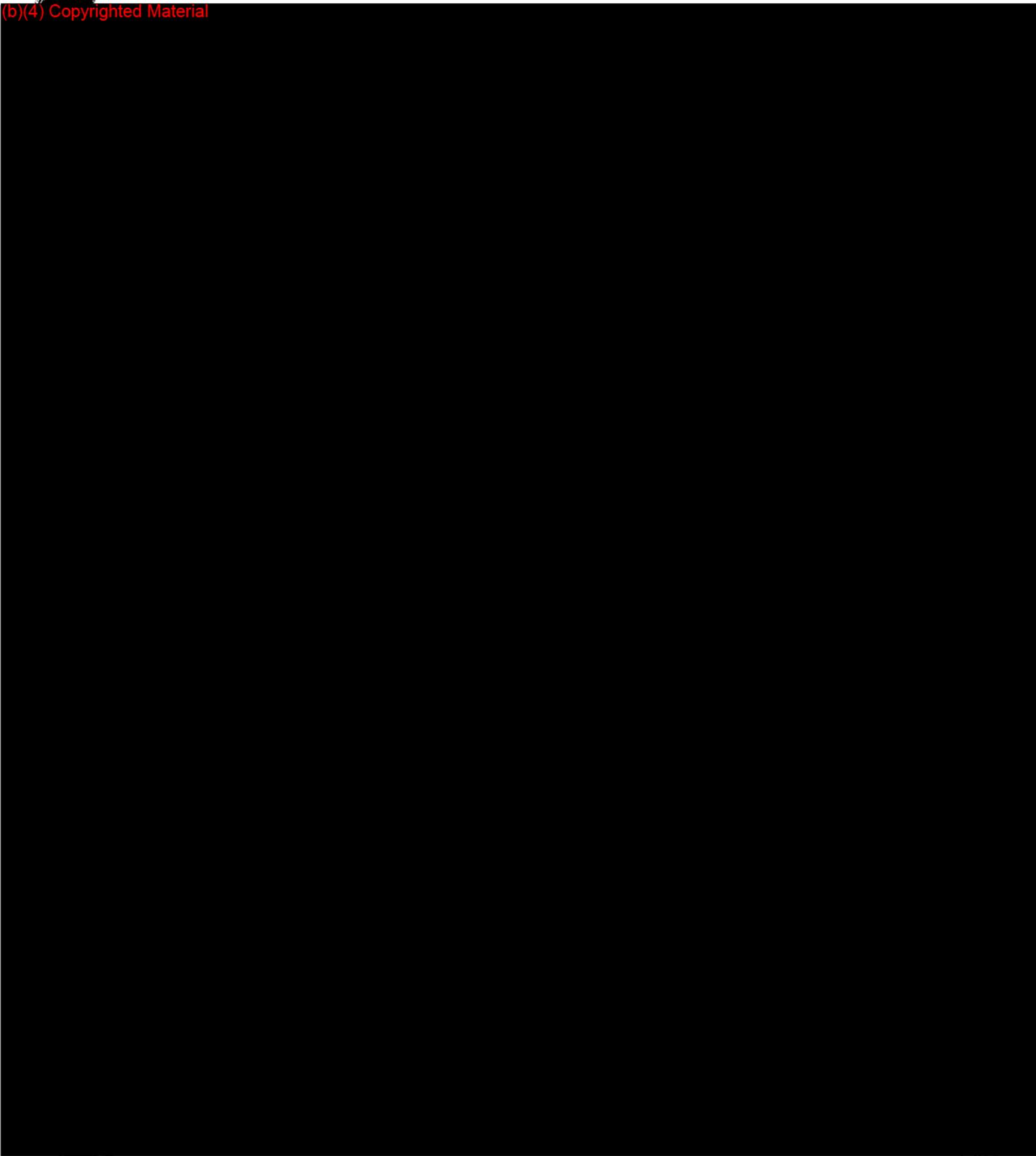
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Hemorrhagic Pancreatitis

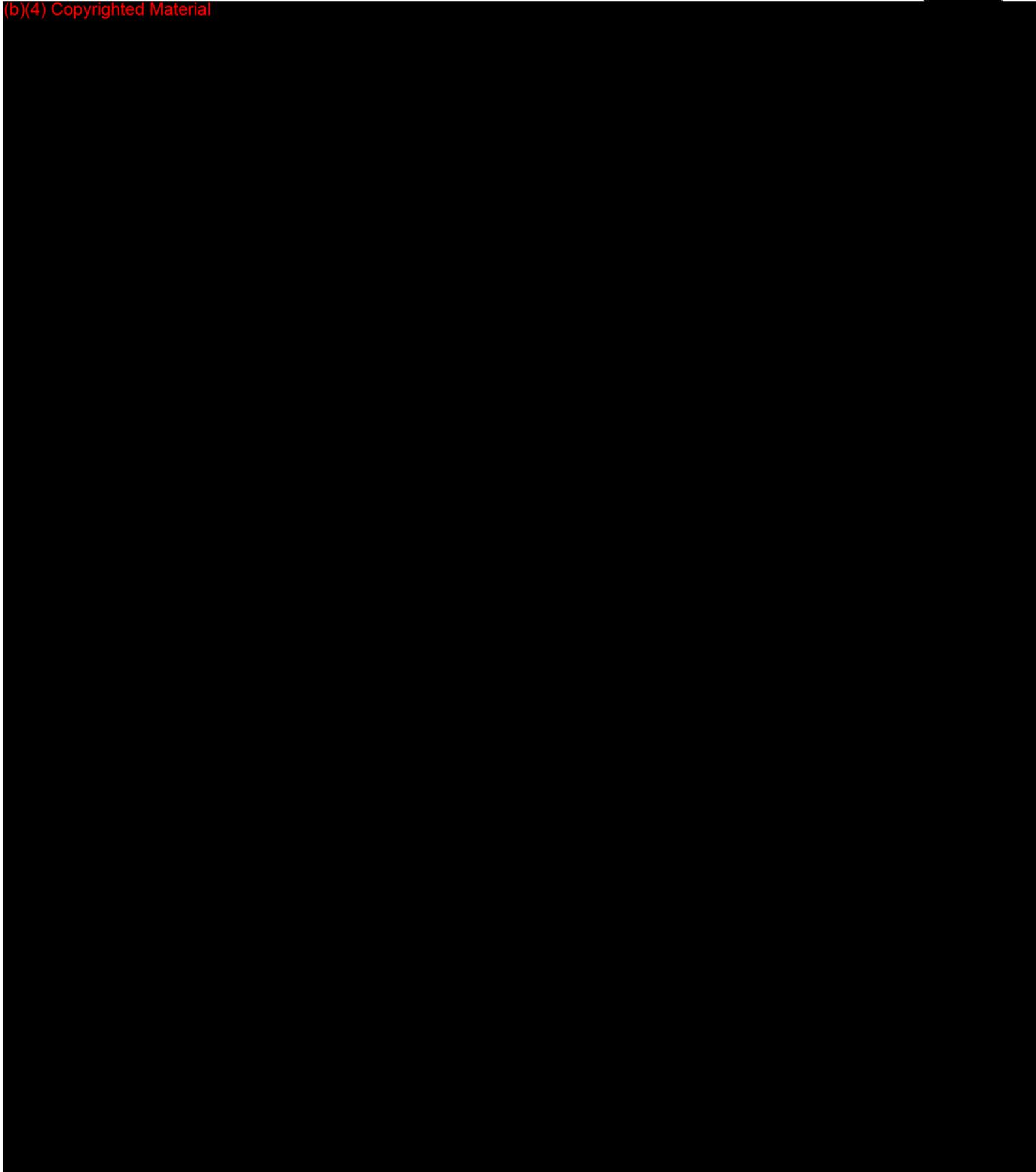
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Miller et al

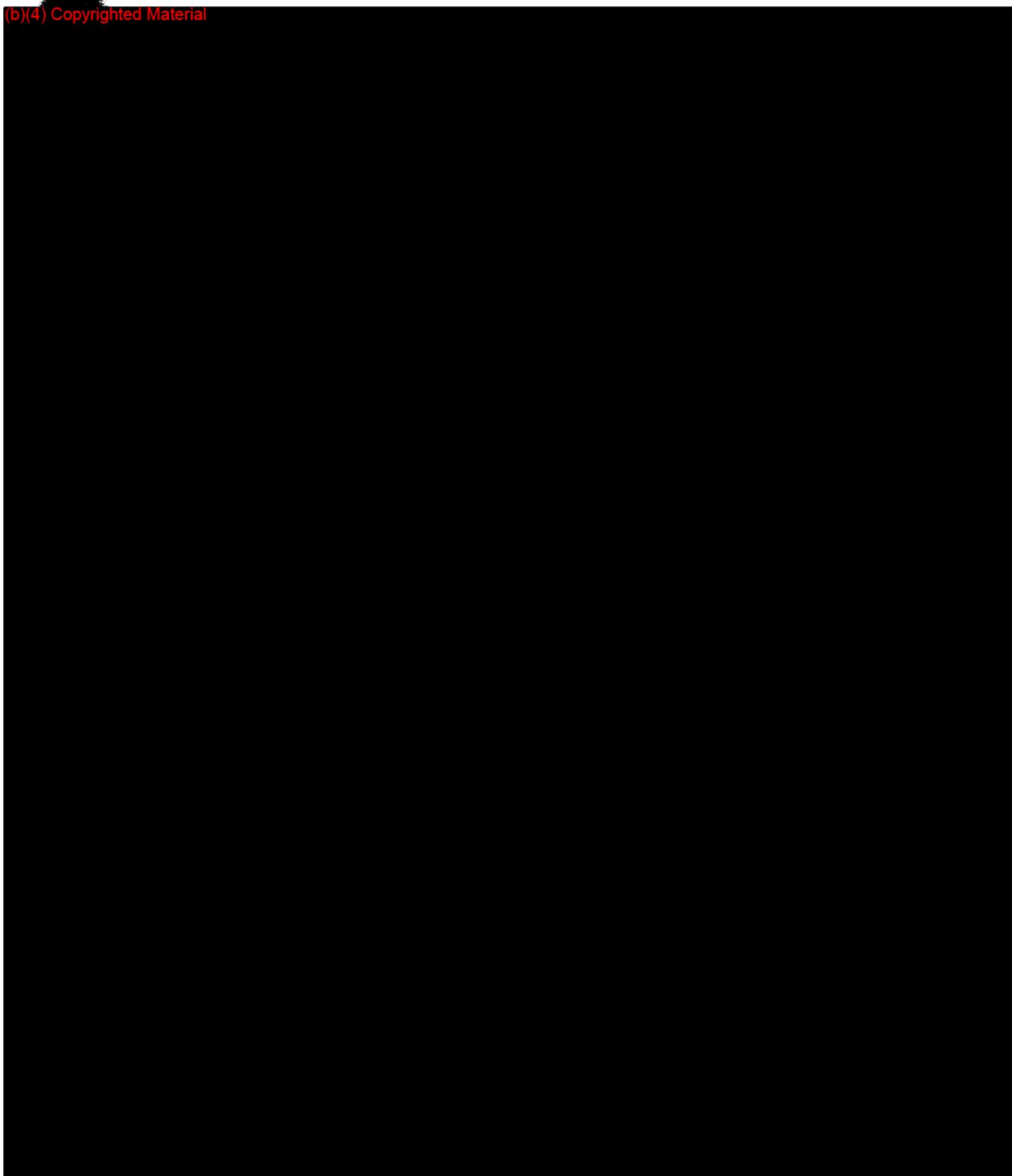
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Hemorrhagic Pancreatitis

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

European Journal of Surgical Oncology 1988; 14: 27-32

Transcatheter embolisation to control severe bleeding in fungating breast cancer

E. M. Rankin,* R. D. Rubens and J. F. Reidy†

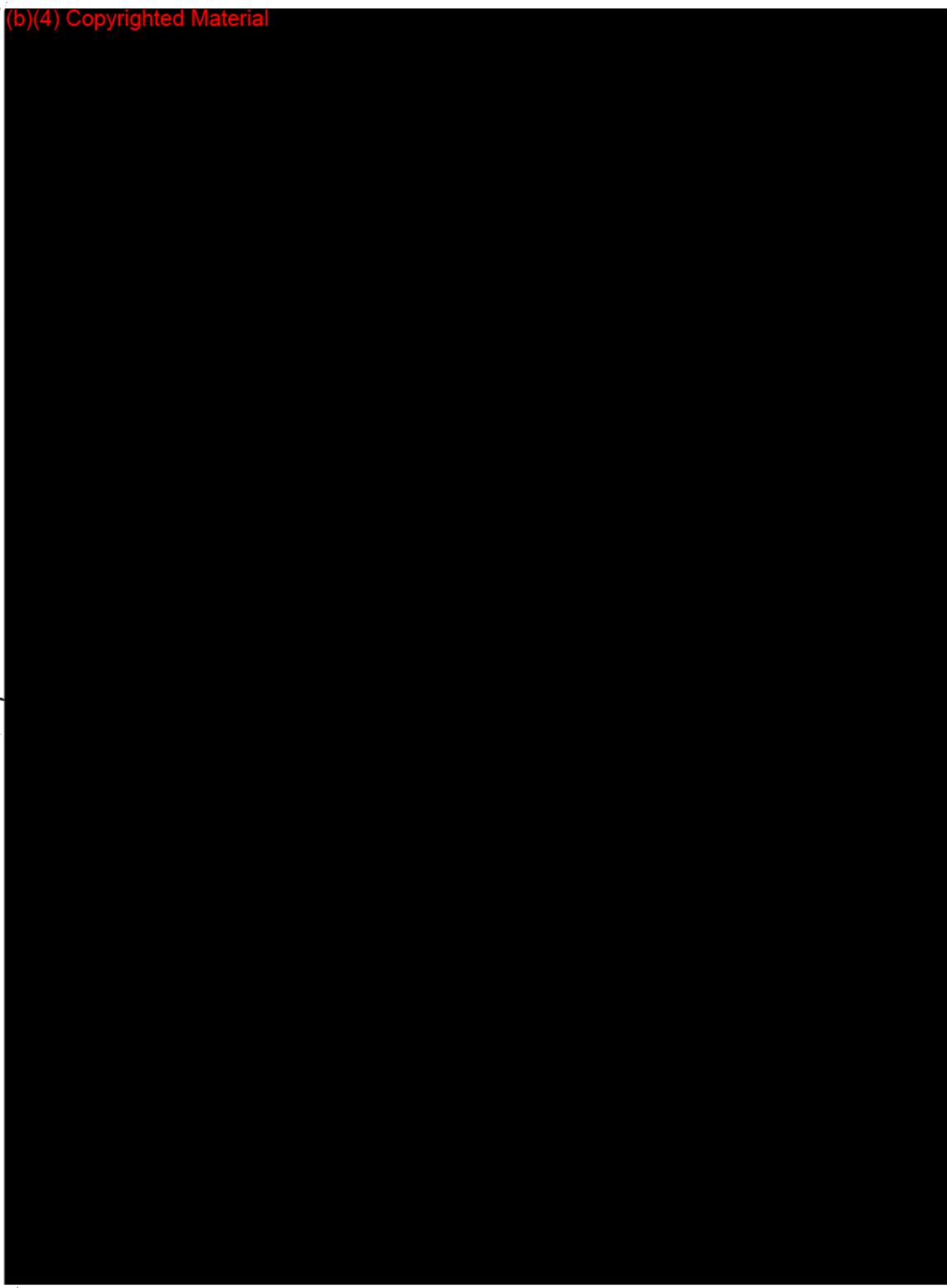
*Imperial Cancer Research Fund, Clinical Oncology Unit, and †Department of Radiology,
Guy's Hospital, London, SE1 9RT, U.K.*

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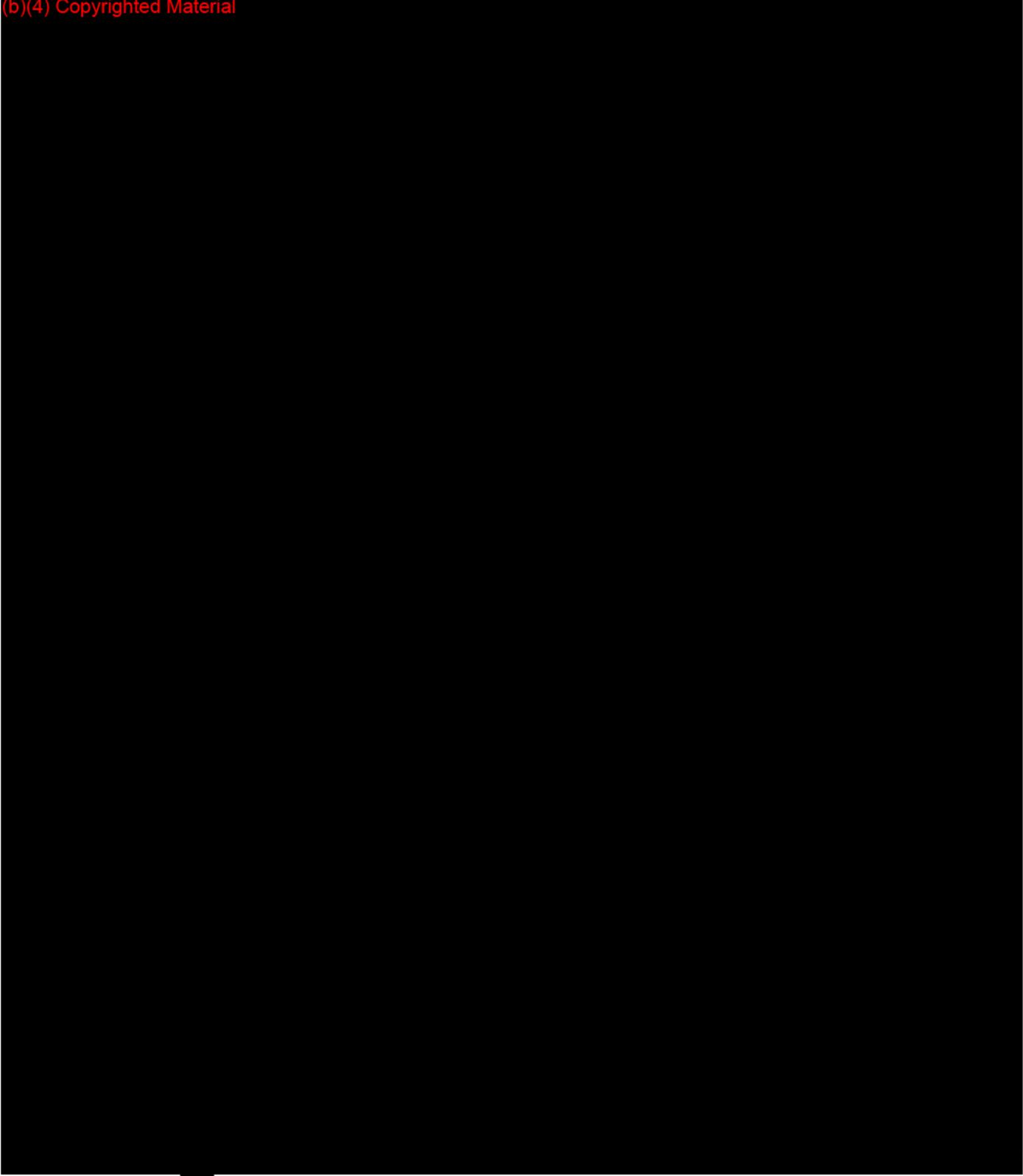
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Severe bleeding in fungating breast cancer

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Endovascular infrainguinal in situ saphenous vein bypass: A multicenter preliminary report

David Rosenthal, MD, Malcolm B. Herring, MD, Terence G. O'Donovan, MD,
Dolores F. Cikrit, MD, Anthony J. Comerota, MD, and John D. Corson, MBChB

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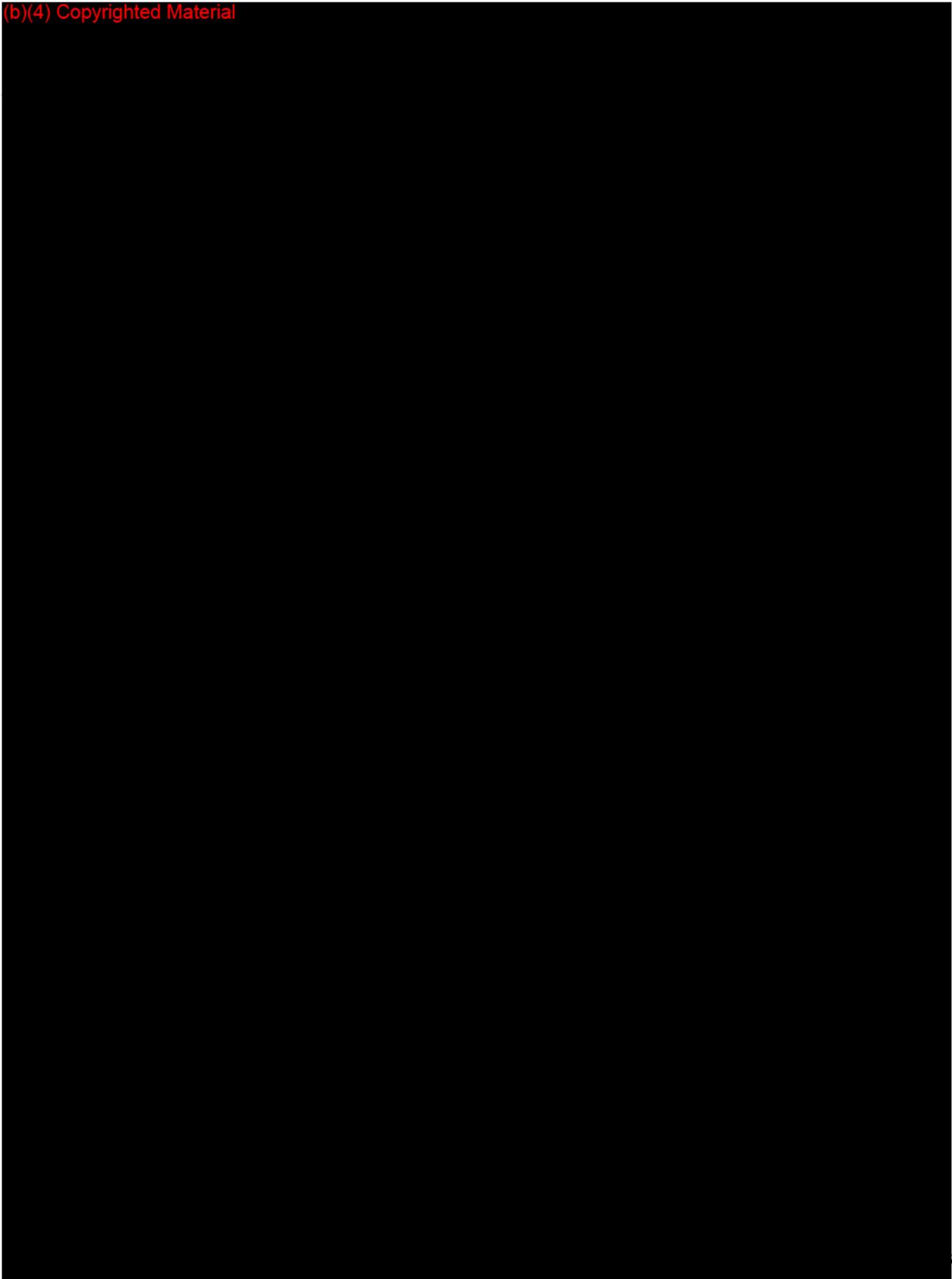
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Volume 16
No. 3
1992

Endovascular in situ infrainguinal bypass 455

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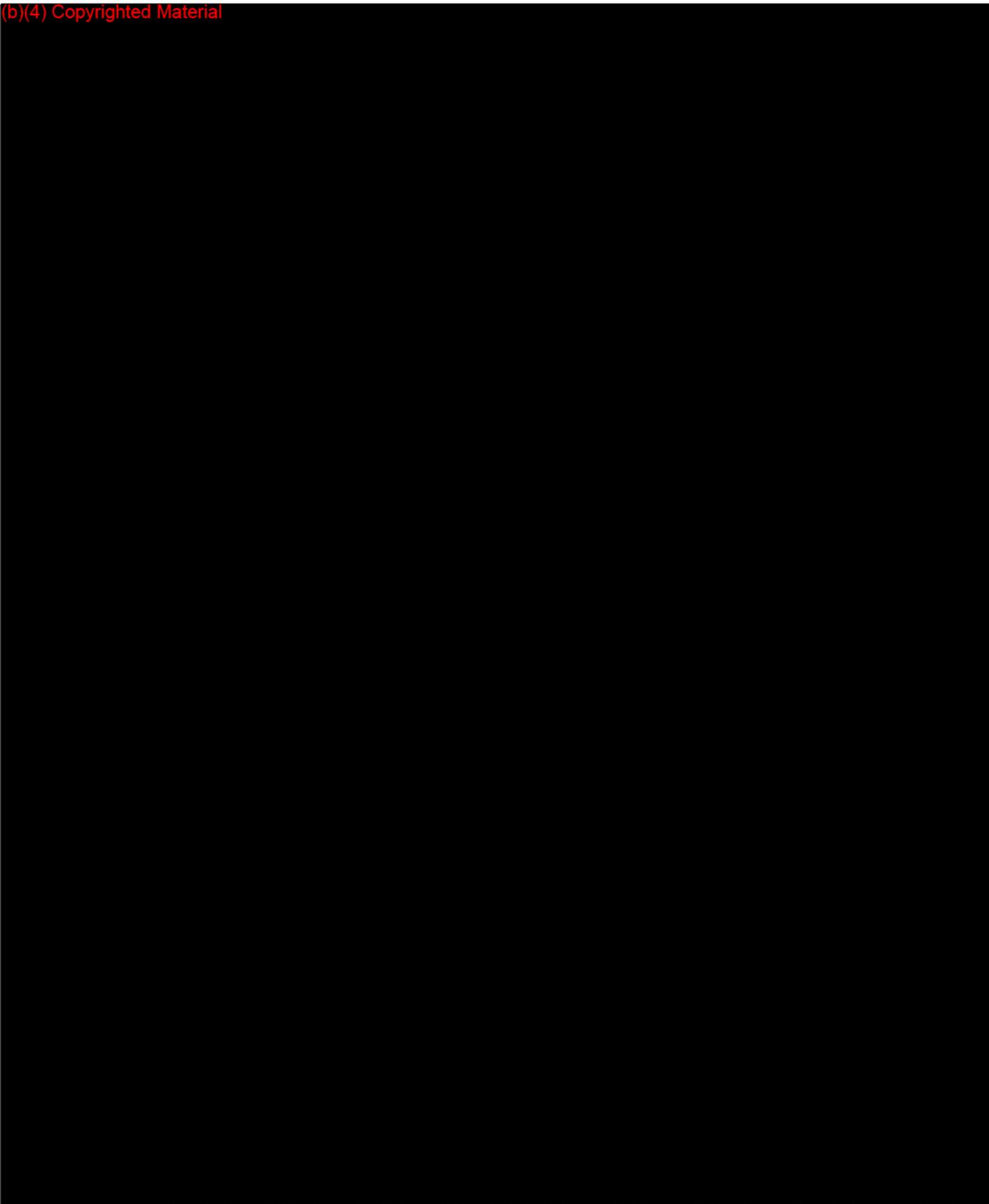
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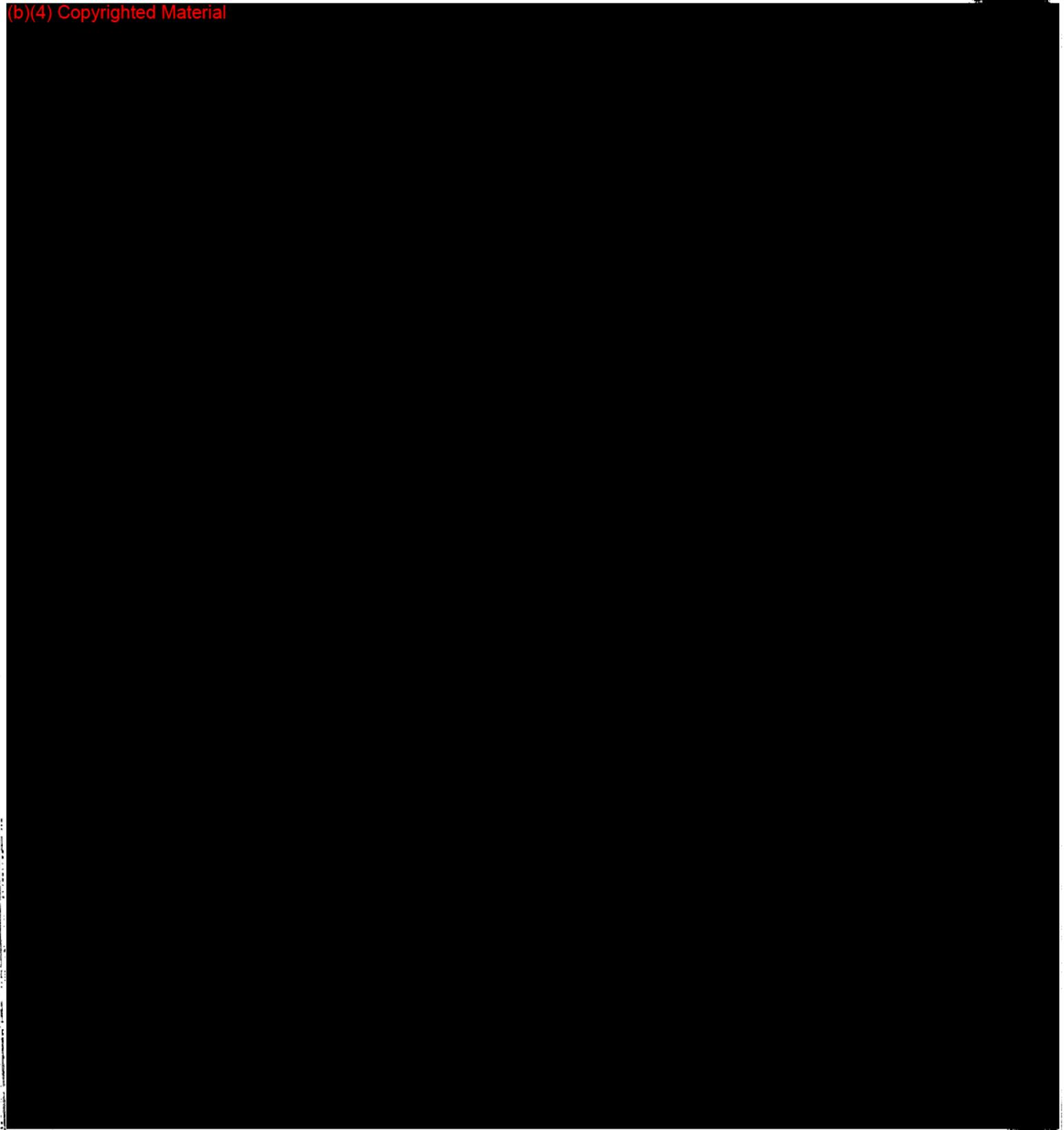
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Hepatic Artery Aneurysm in a 10-Year-Old Boy as a Complication of Infective Endocarditis

By Filiz Şenocak, Saruhan Çekirge, Mehmet Emin Şenocak, and Selmin Karademir
Ankara, Turkey

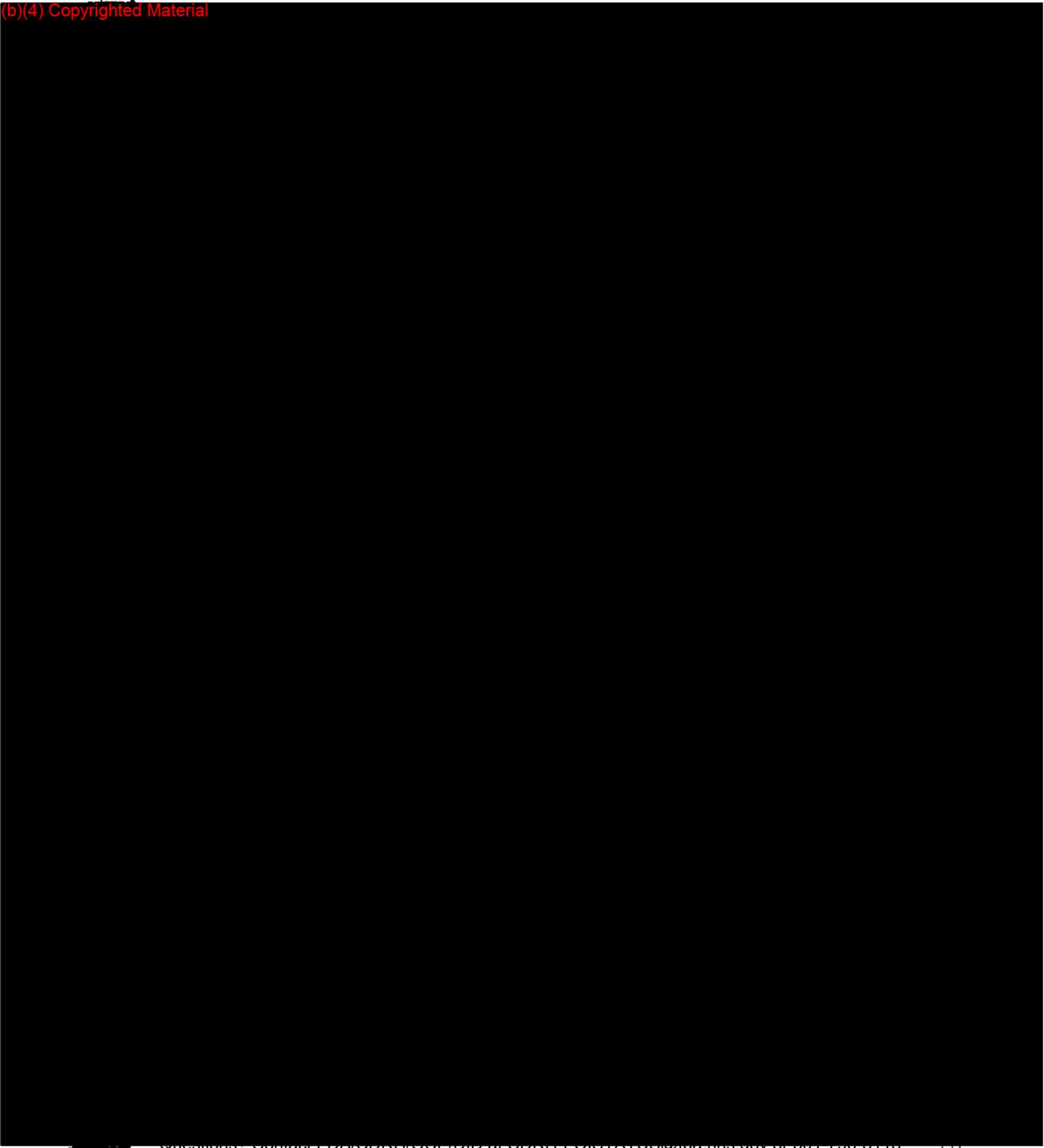
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HEPATIC ARTERY ANEURYSM IN INFECTIVE ENDOCARDITIS

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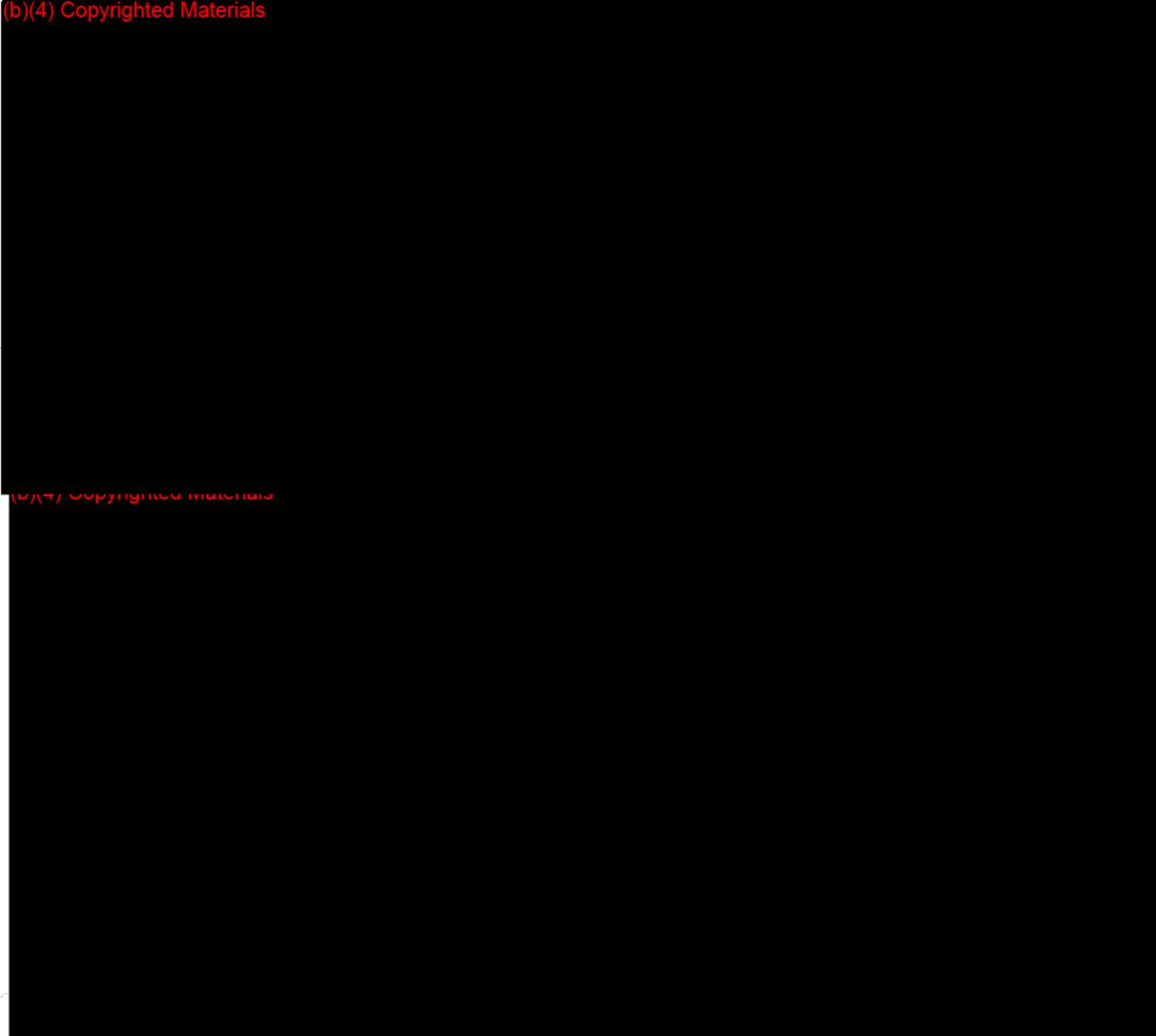
School of Medicine Library, Univ. of Miami

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Arteriographic Embolization of Visceral Artery Pseudoaneurysms

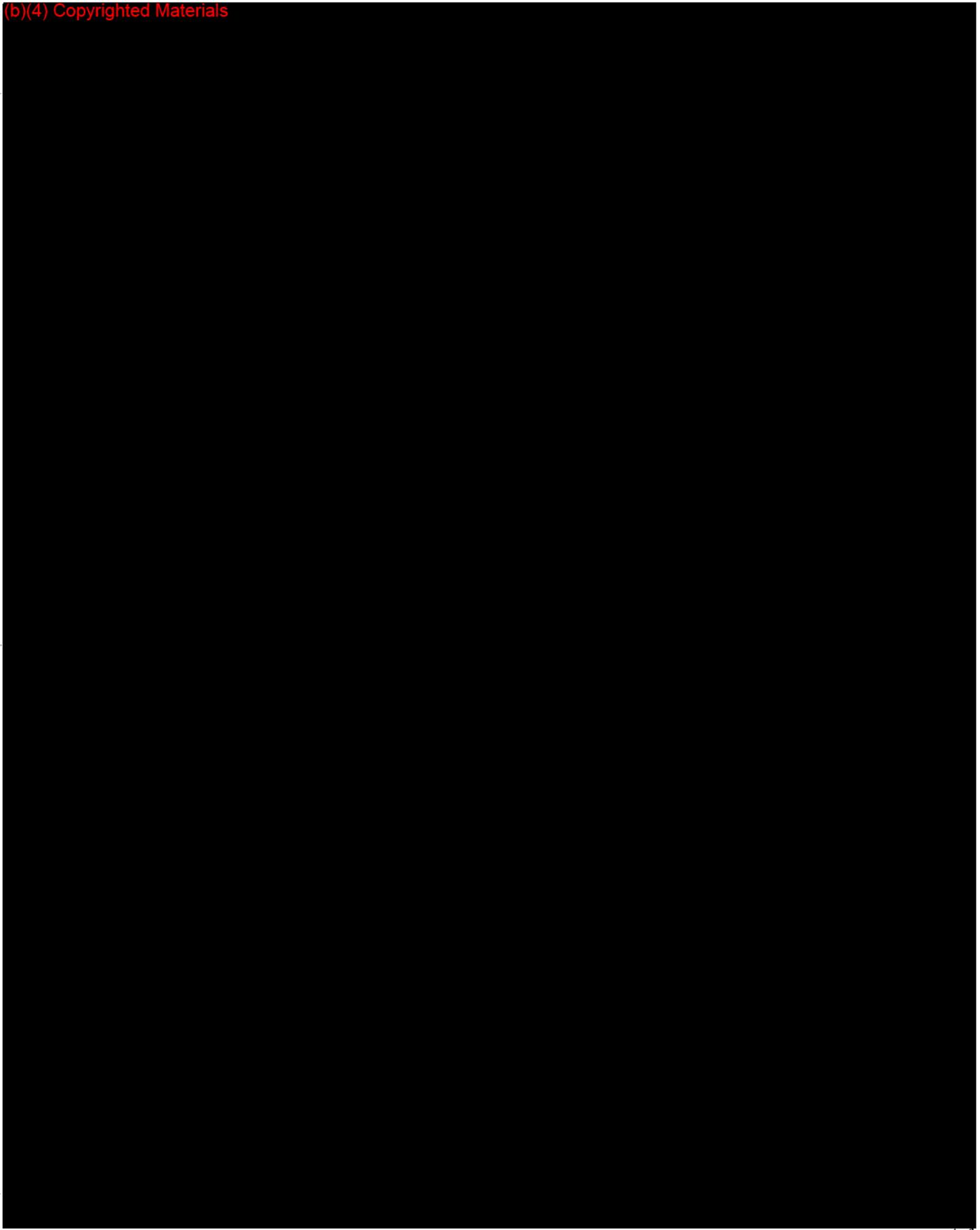
*Glenn W. Stambo, MD, Michael J. Hallisey, MD, and James J. Gallagher, Jr., MD,
Hartford, Connecticut*

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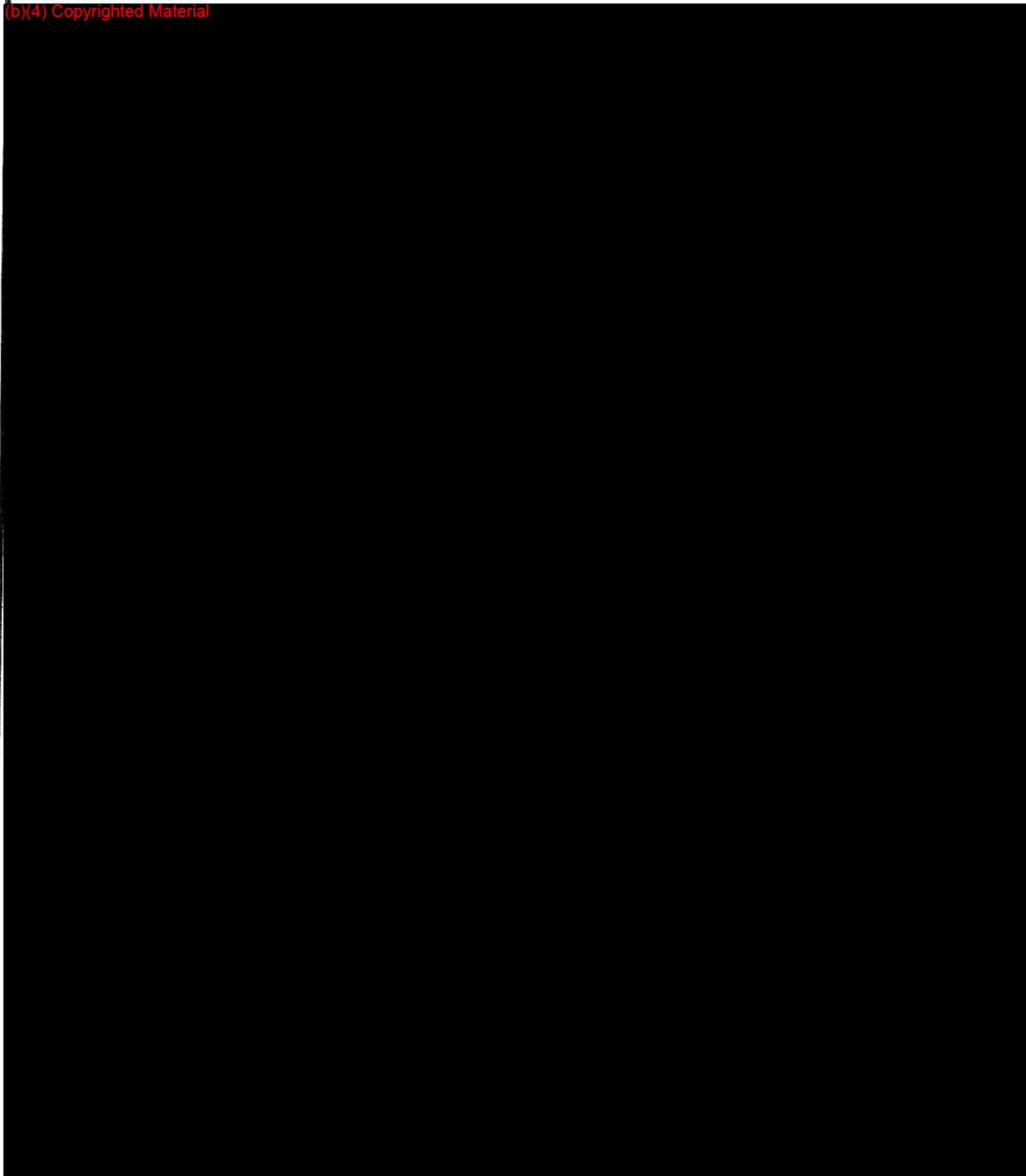
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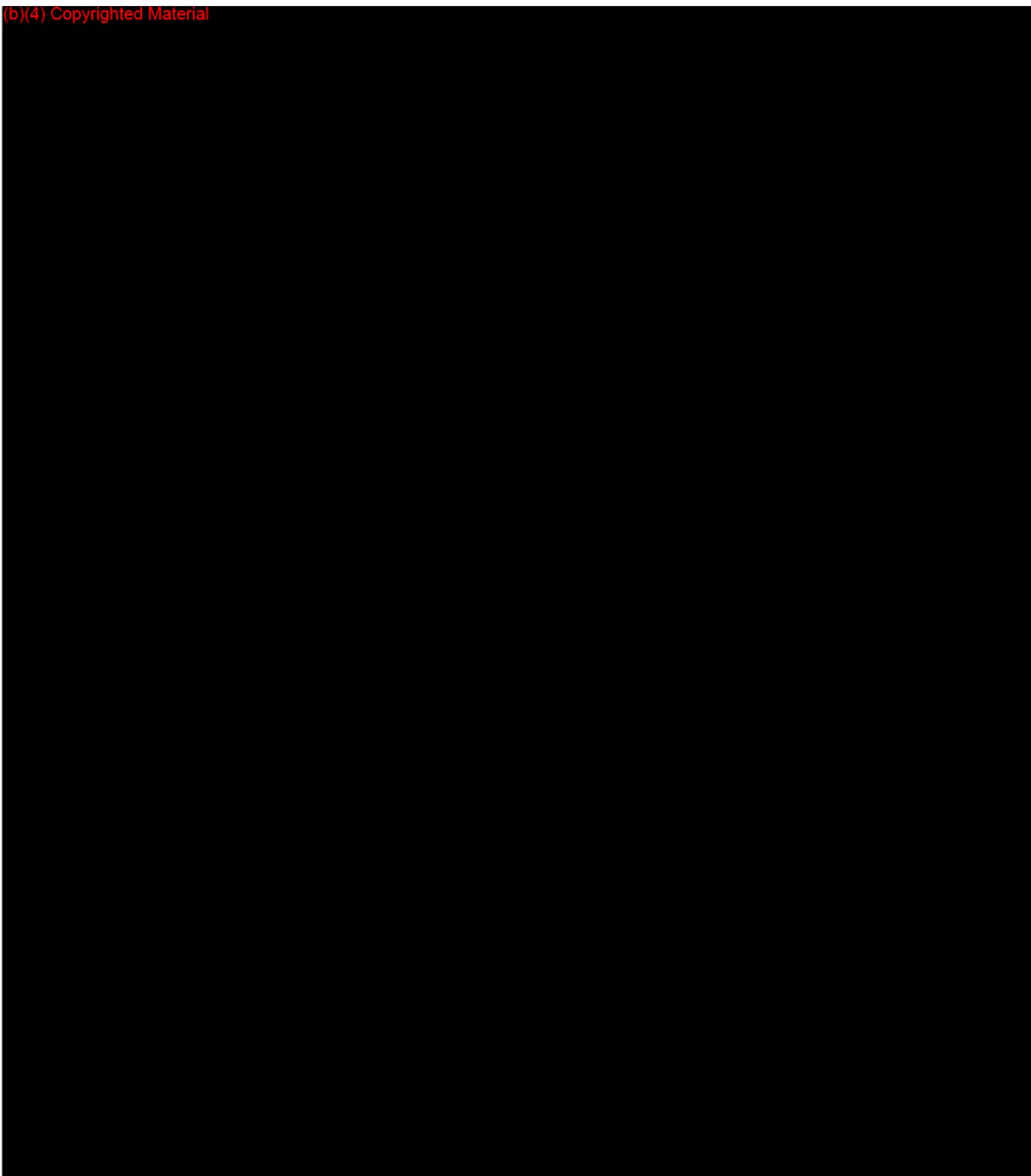
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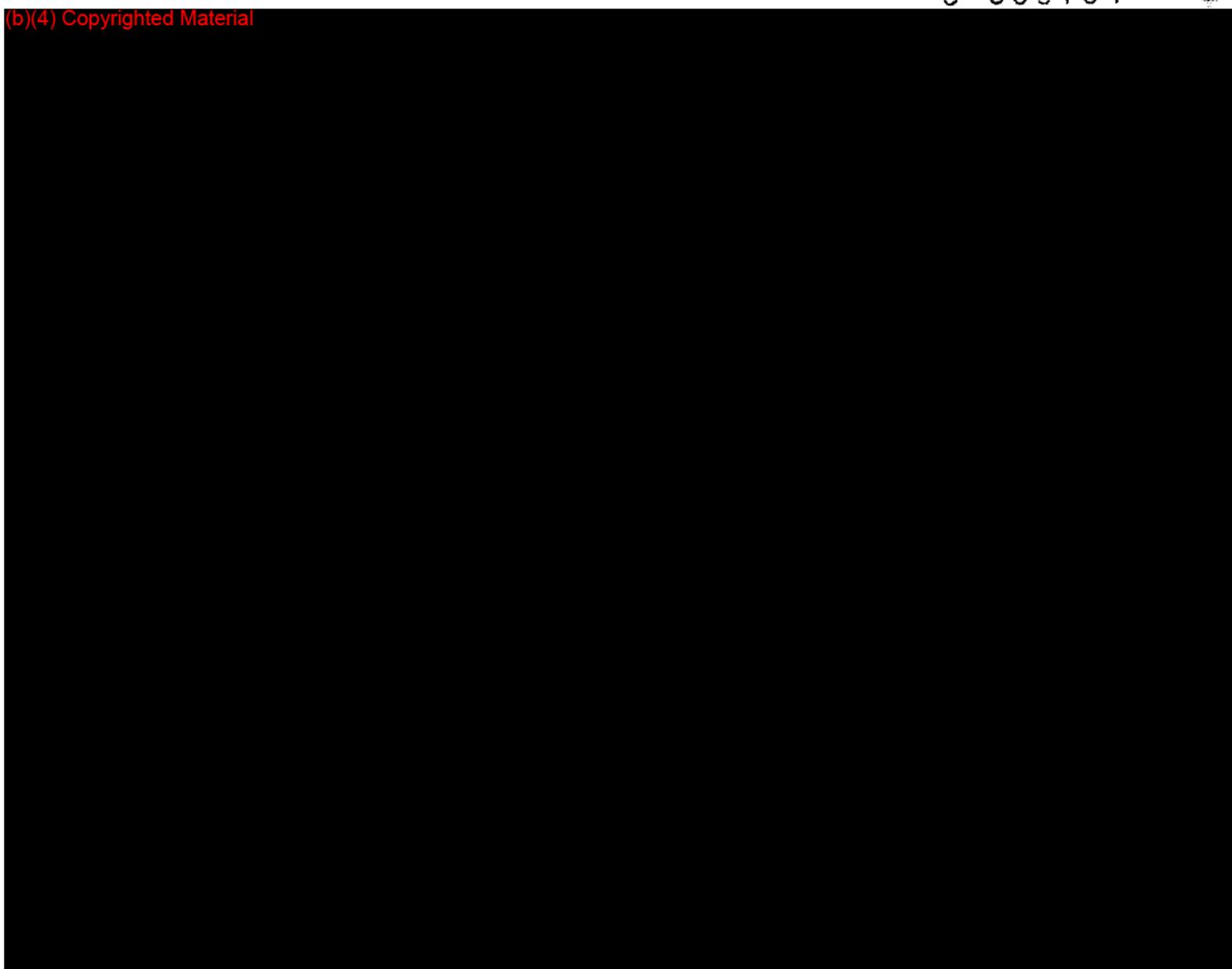
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American Journal of Hematology 52:201-204 (1996)

Hemorrhage From Abdominal Non-Hodgkin's Lymphoma Treated Successfully by Emergency Transcatheter Arterial Embolization

Junji Suzumiya, Mitsuyuki Nagano, Hideyuki Higashihara, Tetsuya Yoshida, Motoi Hirano, Yoshinori Go, Eiji Morloka, Nobuhiro Kimura, Shusuke Hisano, Masatoshi Okazaki, Masahiro Kikuchi, and Makoto Okumura

First Department of Internal Medicine (J.S., M.N., T.Y., M.H., E.M., N.K., S.H., M. Oku.), Department of Radiology (H.H., M. Oka.), and First Department of Pathology (J.S., Y.G., M.K.), School of Medicine, Fukuoka University, Fukuoka, Japan

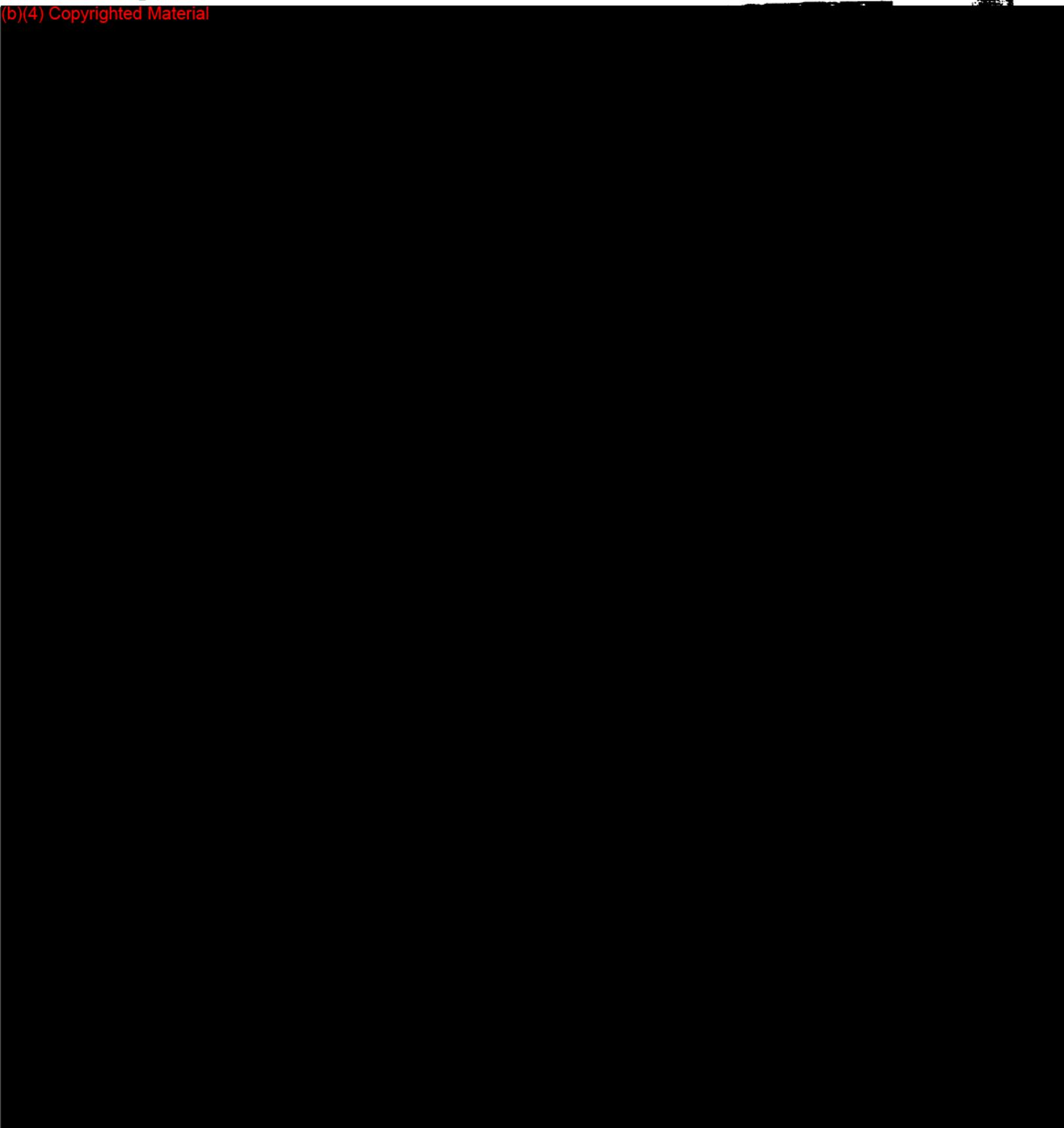
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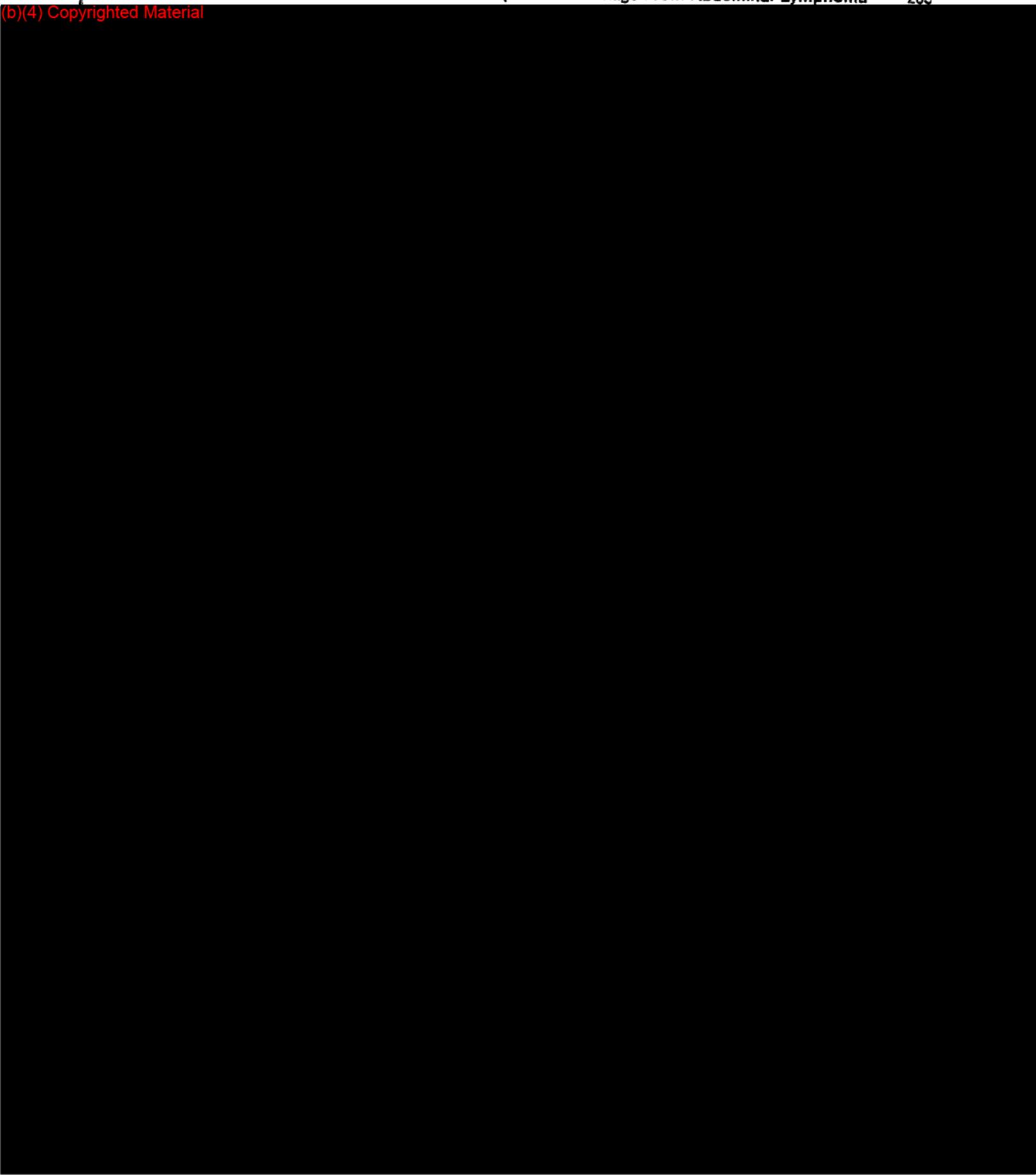


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Case Report: Hemorrhage From Abdominal Lymphoma

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CASE REPORT

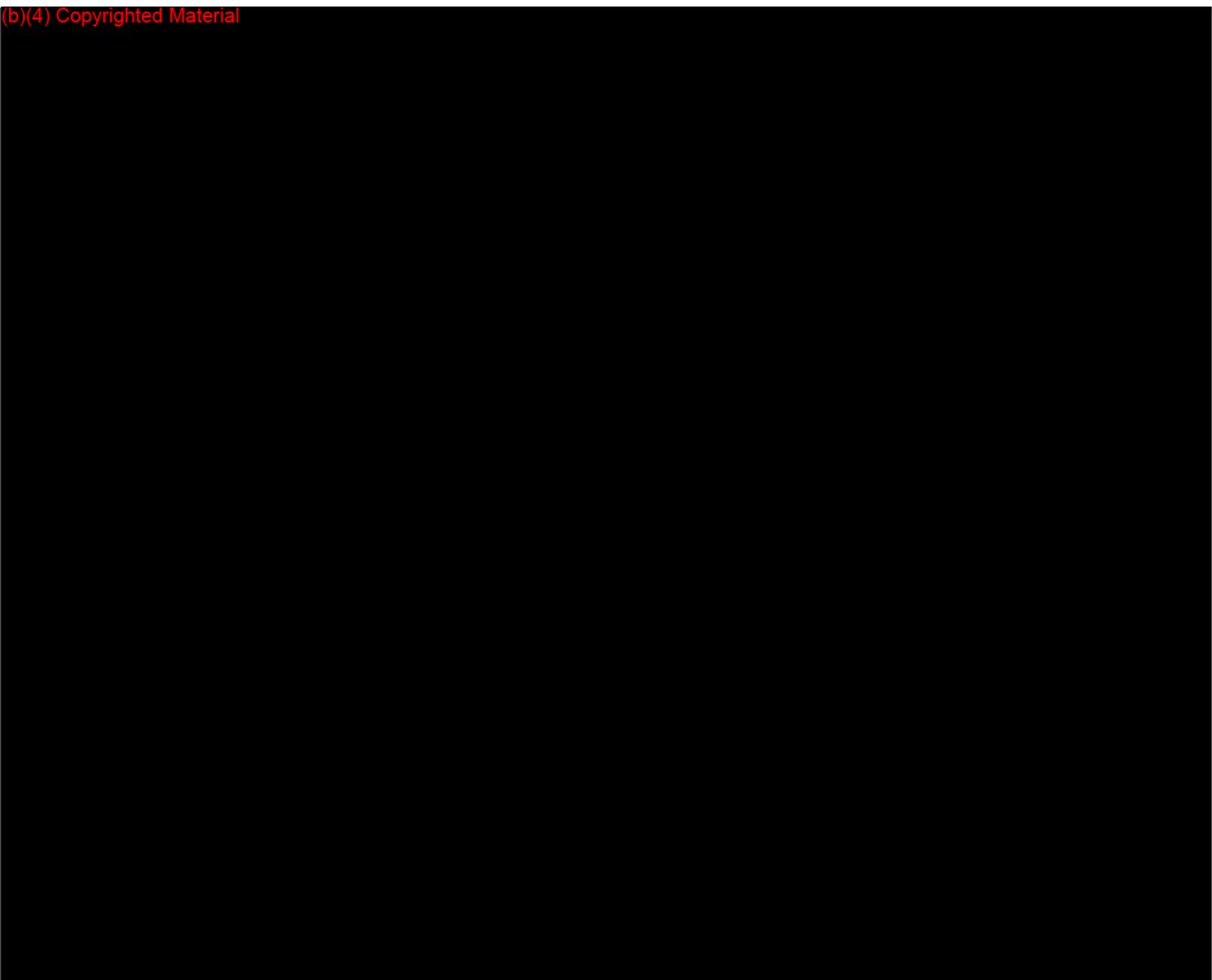
Transcatheter treatment of splenic artery aneurysms (SAA)

Report of two cases

Pavel G. Tarazov, M.D., Vladimir N. Polysalov, M.D., and Vladimir K. Ryzhkov, M.D.

*From the Central Research Institute of Roentgenology and Radiology
of the Ministry of Publical Health, Leningrad, USSR*

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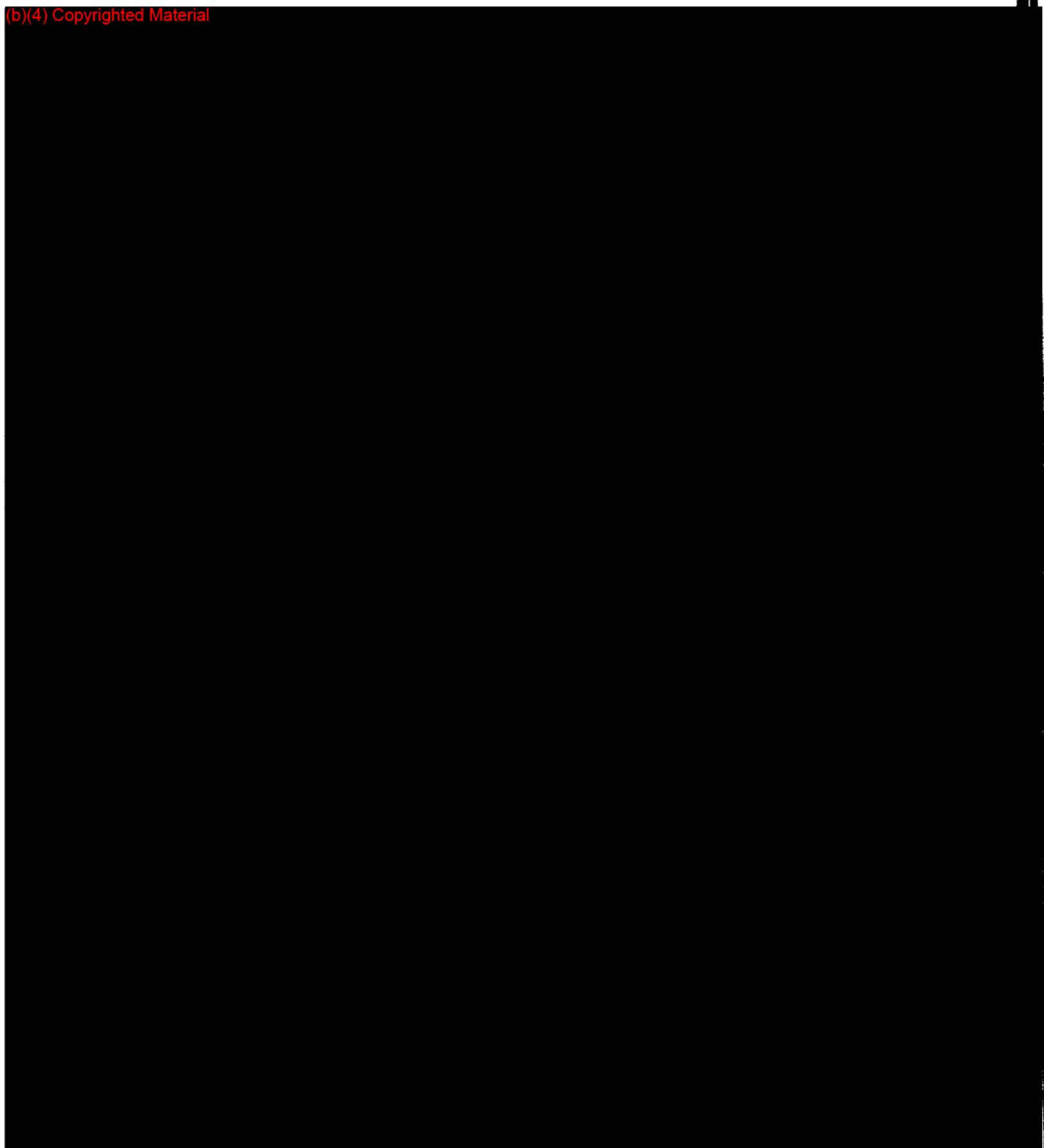


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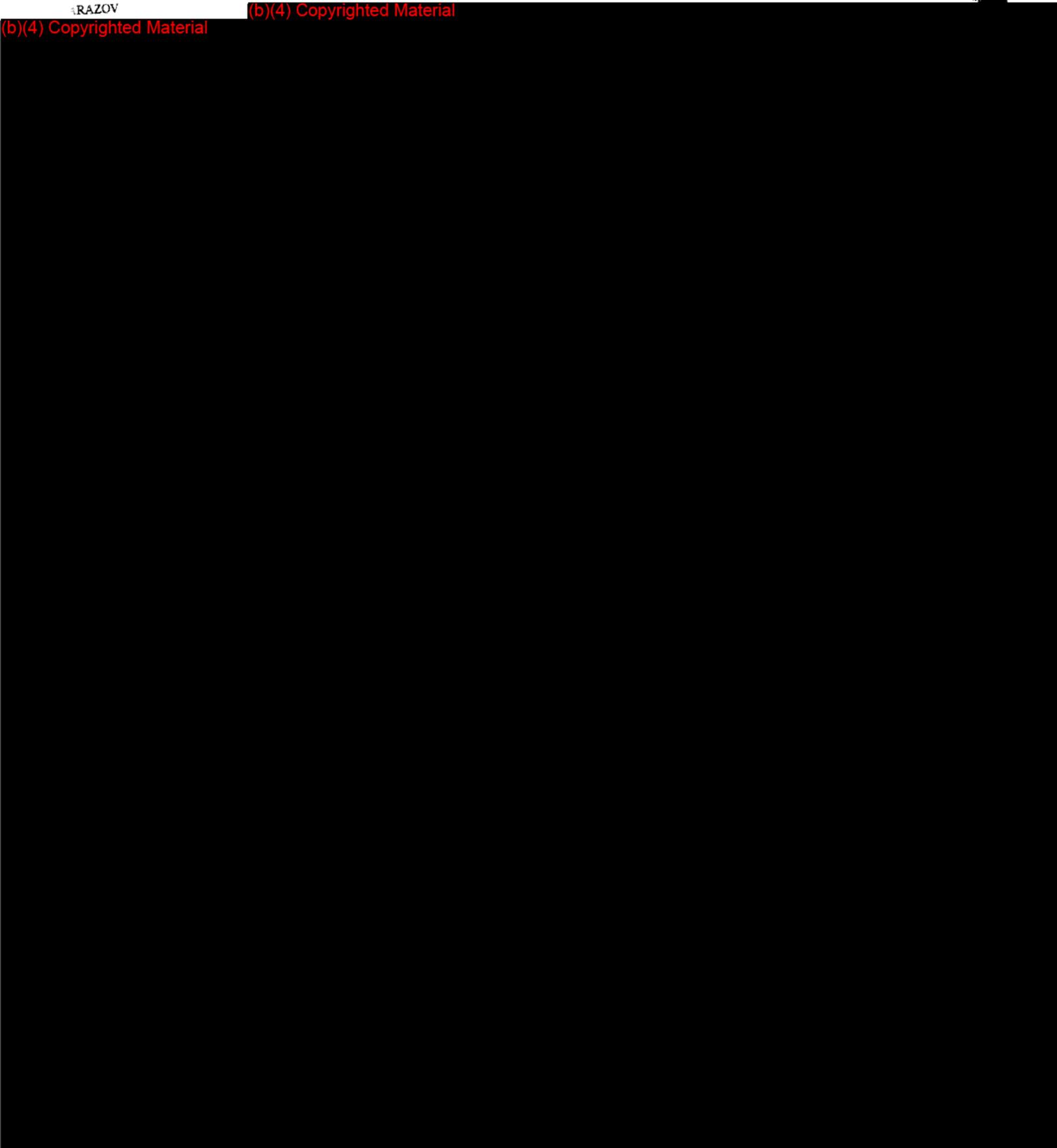


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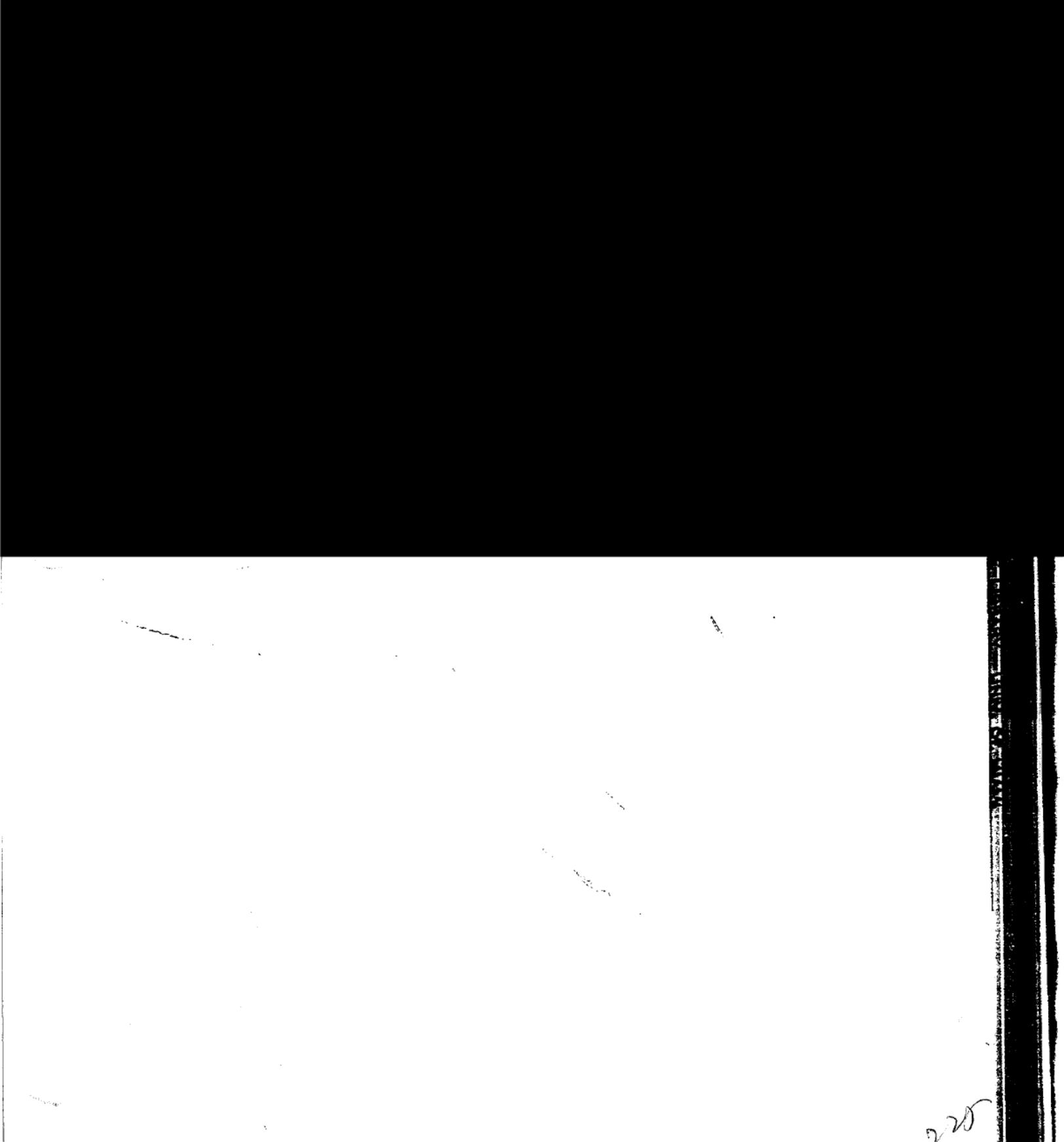


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How I Do It
Head and Neck and Plastic Surgery
A Targeted Problem and Its Solution

Direct-Puncture Coil Embolization of Maxillofacial High-Flow Vascular Malformations

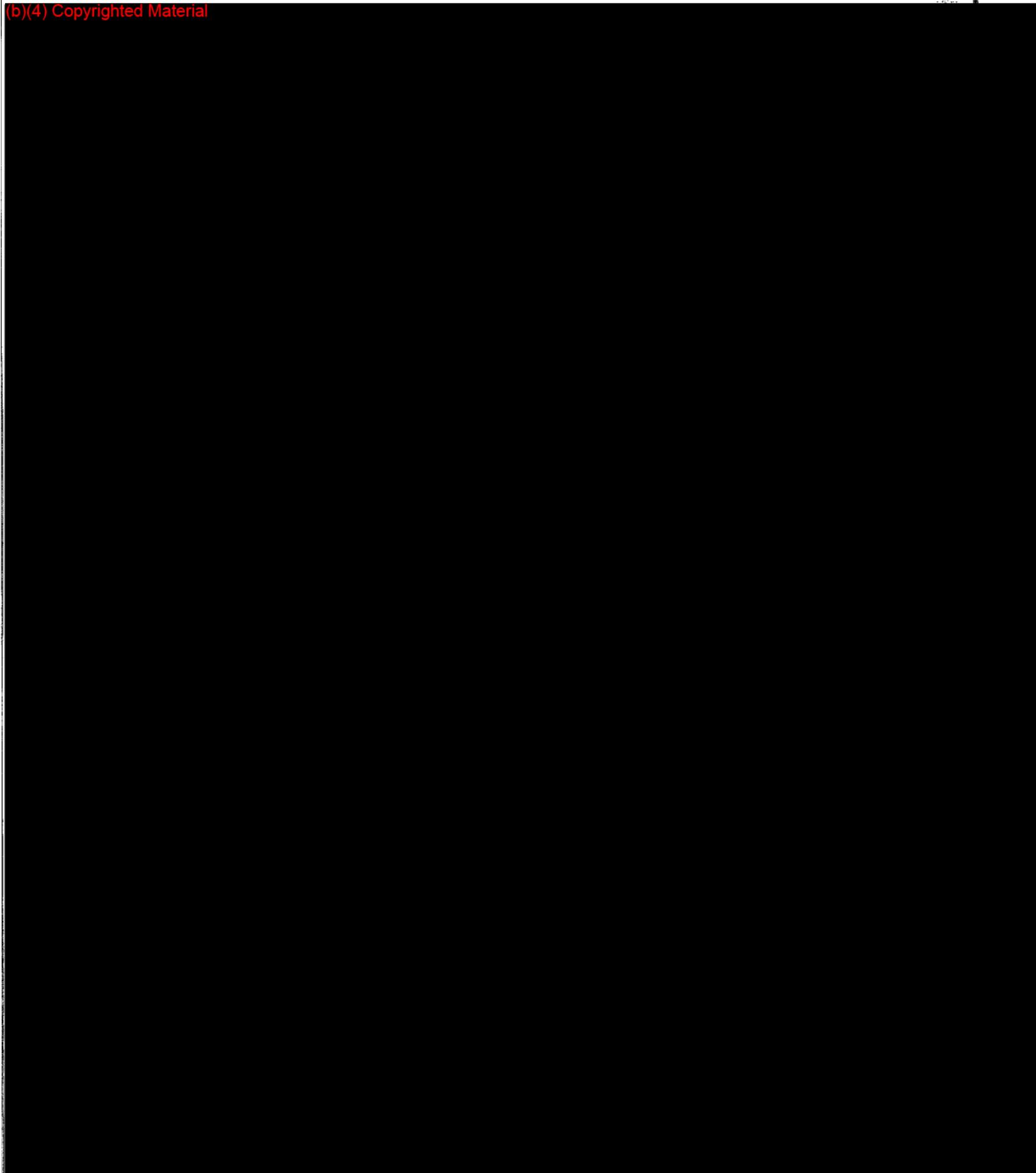
George P. Teitelbaum, MD; Van V. Halbach, MD; Kenneth W. Fraser, MD; Donald W. Larsen, MD; Cameron G. McDougall, MD; Randall T. Higashida, MD; Christopher F. Dowd, MD; Grant B. Hieshima, MD

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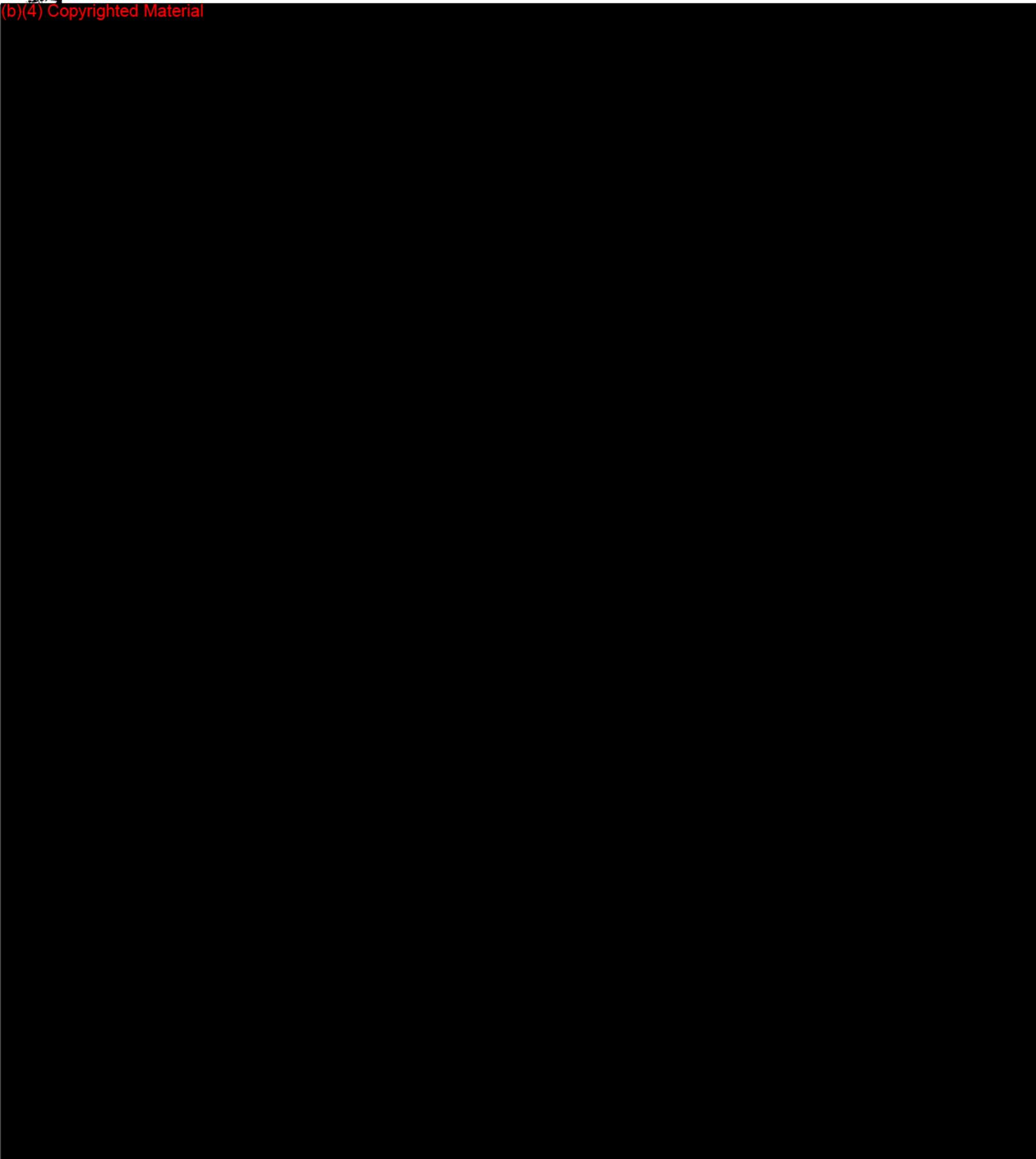
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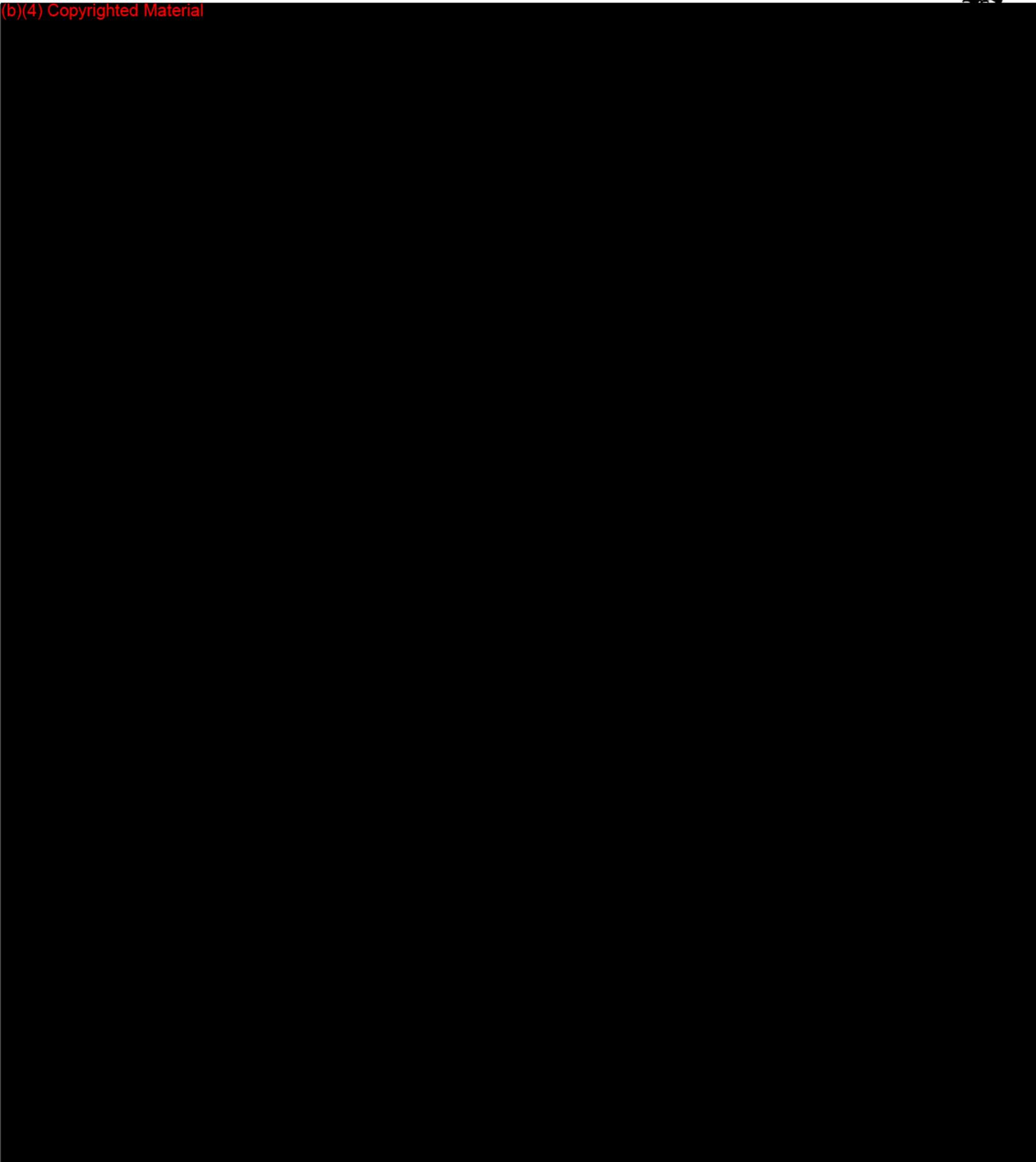
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Angiology

The Journal of Vascular Diseases

VOLUME 45

SEPTEMBER 1994

NUMBER 9

Embolization of a Renal Transplant Pseudoaneurysm Following Angiolipoma Resection

A Case Report

Michael R. Theobald, M.D.
Farhad M. Contractor, M.D.
Paul M. Kiproff, M.D.
Maroon B. Khoury, M.D.
and Stan H. Chao, M.D.*

PITTSBURGH, PENNSYLVANIA

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From the Departments of Diagnostic Radiology and *Surgery, Allegheny General Hospital, Medical College of Pennsylvania, Pittsburgh, Pennsylvania.

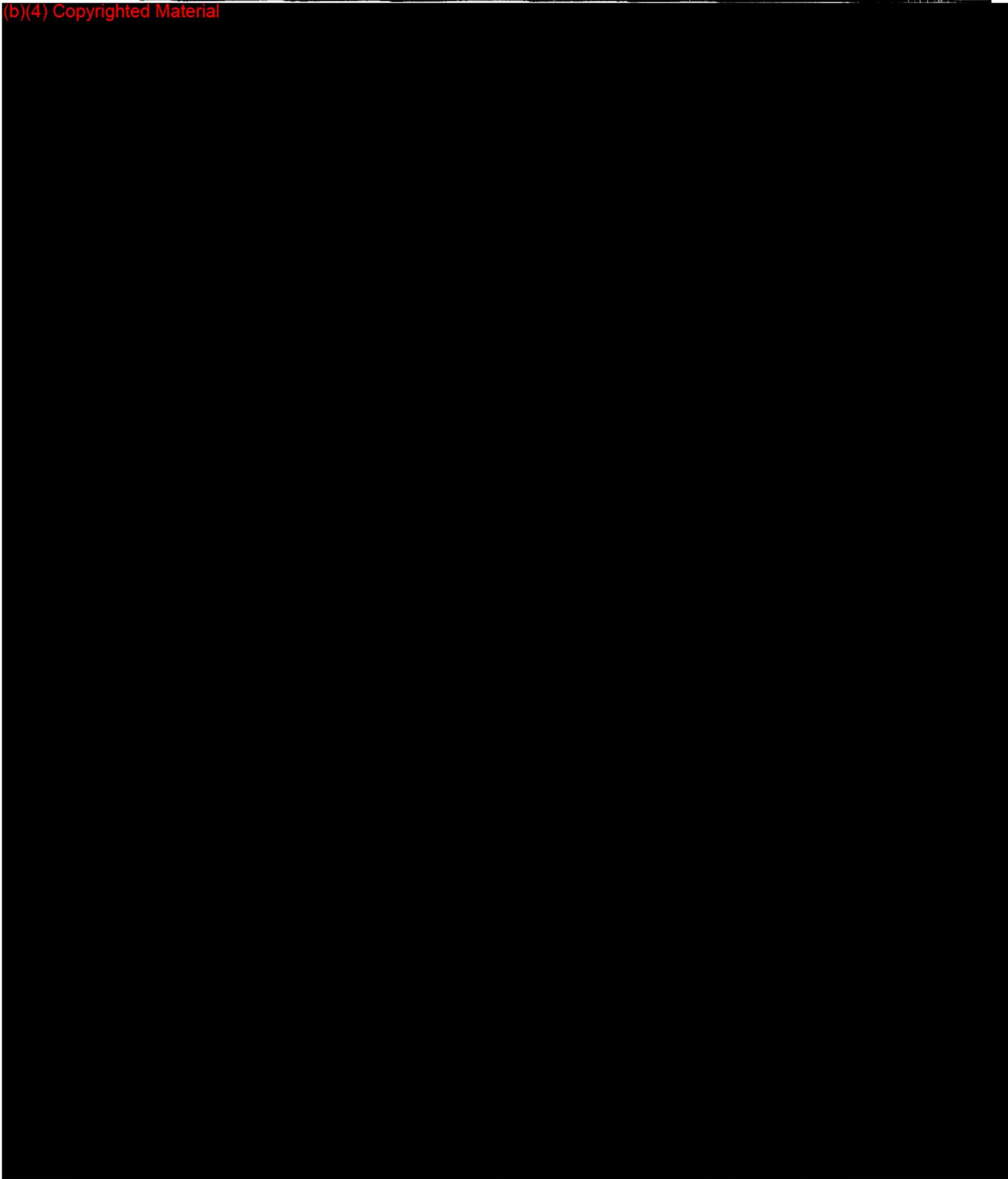
Questions? Contact FDA/CDRH/OCE/DID at CDRH.FO.ISTAFF@fda.hhs.gov or 301-796-8118

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Angiology *The Journal of Vascular Diseases* September 1994

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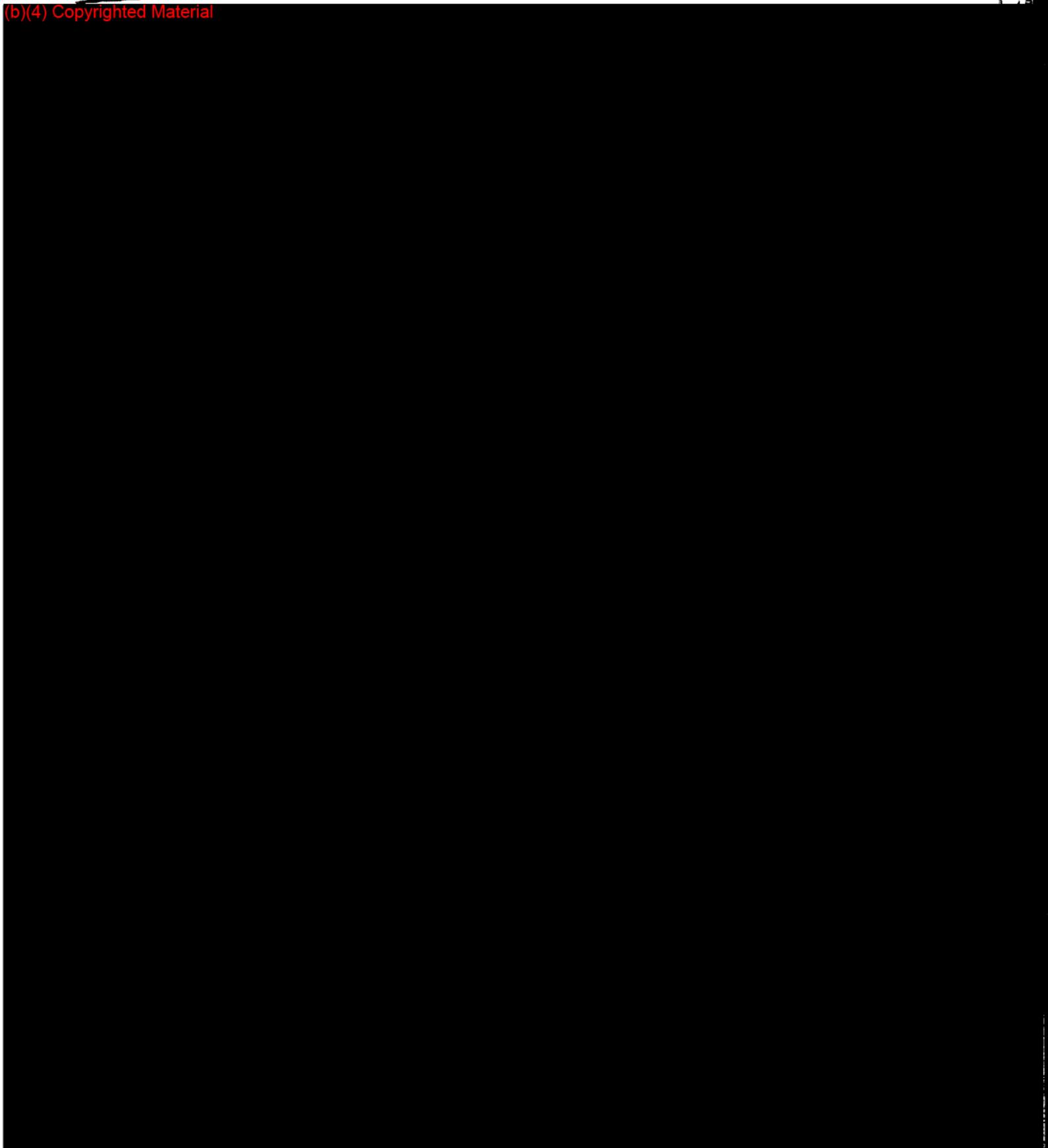


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Theobald *Pseudoaneurysm in Renal Allograft*

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