



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (mac)
FOLDER: K965156 - 109 pages
COMPANY: JOHNSON & JOHNSON PROFESSIONALS, INC. (JOHNJOHNPROF)
PRODUCT: PROSTHESIS, HIP, HEMI-, FEMORAL, METAL (KWL)
SUMMARY: Product: ULTIMA*UNIPOLAR HEAD AND ADAPTER SLEEVES

DATE REQUESTED: Jun 10, 2011

DATE PRINTED: Jun 10, 2011

Note: Printed



Summary of Safety & Effectiveness Data for the ULTIMA* Unipolar Head and Adapter Sleeves

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

R 965156

JAN 24 1997

1. **Contact Person**

Johanna Newman, Assoc. Regulatory Affairs Specialist, (508) 828-3268.

2. **Device Name**

Proprietary Name: ULTIMA* Unipolar Head and Adapter Sleeves
Common Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Classification Name: Prosthesis, Hip
Regulatory Class: Class II by 21 CFR § 888.3360
Product Code: 87 JDG
Owner/ Operator # 9001269

3. **Device Classification**

Classification for ULTIMA* Unipolar Head and Adapter Sleeves has been placed in Class II by 21 CFR § 888.3360

4. **Statement of Substantial Equivalence**

The safety and effectiveness of the ULTIMA* Unipolar Head and Adapter Sleeves is substantially equivalent in terms of function to the Johnson & Johnson ULTIMA* Unipolar Modular Head and the Howmedica Unitrax Unipolar System. Furthermore, analysis results demonstrate that the ULTIMA* Unipolar Head and Adapter Sleeves meets the set criteria for the establishment of "substantial equivalence".

5. **Indications for Use**

The ULTIMA* Unipolar Head is indicated for use in conjunction with a modular femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to:

1. femoral neck fracture,
2. avascular necrosis of the femoral head,
3. osteoarthritis,
4. abnormalities where:
 - the major pathology affects the femoral head,
 - the acetabular cavity is normal and not deformed or weakened,
 - acetabular replacement is not required or desirable.

6. Physical Description

The ULTIMA* Unipolar Head is provided in a size range of 38mm to 63mm (outer diameter), in 1mm increments. Sizes from 44mm through 63mm are manufactured as a two-piece assembly. The two pieces are made of cast cobalt-chromium-molybdenum alloy conforming to ASTM F75. Both pieces are treated with hot isostatic pressing and solution annealing. The two cast pieces are machined and then joined permanently by electron beam welding to form a hollow unipolar head. Sizes from 38mm through 43mm are cast from cobalt-chromium-molybdenum alloy as a solid head, and are isostatic pressed and solution annealed before machining. Both of these size ranges are finish machined to the outer diameter size. The outer diameter is highly polished for articulation with the implant recipient's natural acetabulum.

The ULTIMA* Unipolar Head has a tapered bore which can receive a variety of Adapter Sleeves. The adapter sleeves can be tapered on the outside to mate with the unipolar head, and tapered on the inside to mate with the appropriate femoral stem trunnion. The adapter sleeves are available in a 10/12 taper, in size increments for -3mm, +0mm, +5mm, and +10mm neck lengths; in a 11/13 taper, in size increments for +0mm, +6mm, and +12mm neck lengths; and in a 12/14 taper, in size increments for +0mm, +3.5mm, and +7mm neck lengths. The adapter sleeves are machined from cobalt-chromium-molybdenum alloy in wrought bar form conforming ASTM F799.

Table 1. Similarities and Differences Matrix

	ULTIMA* Unipolar Head and Adapter Sleeves	ULTIMA* Unipolar Modular Head	Howmedica Unitrax Unipolar System
	K902365	K901190	K902365
DESIGN			
Range of sizes	38mm-63mm (1mm increments)	38mm-65mm (1mm increments)	38mm-63mm (1mm increments)
Adapter sleeve for increased neck length	Yes	No	Yes
Number neck length sizes	10/12 taper: -3mm, +0mm, +5mm, +10mm 11/13 taper: +0mm, +6mm, +12mm 12/14 taper: +0mm, +3.5mm, +7mm	+0mm, +5mm	-4mm, +0mm, +5mm, +10mm
Morse-taper locking mechanism to modular femoral stem	Yes	Yes	Yes
INTENDED USE			
Partial hip replacement	Yes	Yes	Yes
MATERIALS			
Manufactured from Co-Cr-Mo	Yes	Yes	Yes



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 1997

Ms. Sally Maher
Director, Regulatory Affairs
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K965156
ULTIMA* Unipolar Head and Adapter Sleeves
Regulatory Class: II
Product Code: KWL and LZY
Dated: December 19, 1996
Received: December 23, 1996

Dear Ms. Maher:

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

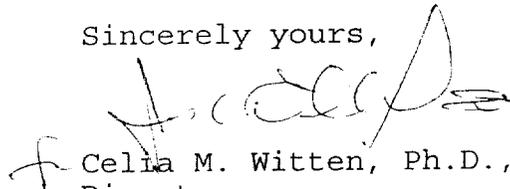
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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. Sally Maher

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) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,


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

Enclosure

2

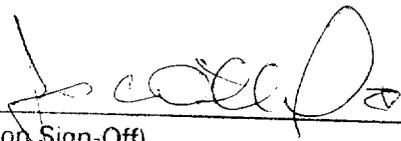
**Indications for Use
for the ULTIMA* Unipolar Head and Adapter Sleeves**

**Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350**

Indications for Use _____

The ULTIMA* Unipolar Head is indicated for use in conjunction with a modular femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to:

1. femoral neck fracture,
2. avascular necrosis of the femoral head,
3. osteoarthritis,
4. abnormalities where:
 - the major pathology affects the femoral head,
 - the acetabular cavity is normal and not deformed or weakened, acetabular replacement is not required or desirable.



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

12965156

Prescription Use X
(Per 21 CFR 801.109)

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TKS

510(K) ROUTE SLIP

510(k) NUMBER K965156 PANEL OR DIVISION DGRD BRANCH

TRADE NAME ULTIMA*UNIPOLAR HEAD AND ADAPTER SLEEVES

COMMON NAME HIP JOINT FEMORAL (HEMI-HIP) METALLIC CEMENTED OR UNCEMENT

PRODUCT CODE ~~206~~

APPLICANT JOHNSON & JOHNSON PROFESSIONALS, INC.

SHORT NAME JOHNJOHNPROF

CONTACT SALLY MAHER

DIVISION _____

ADDRESS 325 PARAMOUNT DRIVE

RAYNHAM, MA 027670350

PHONE NO. (508) 880-8100 FAX NO. (508) 828-3212

MANUFACTURER JOHNSON & JOHNSON PROFESSIONAL REGISTRATION NO.

ISOTRON

DATE ON SUBMISSION 20-DEC-96 DATE DUE TO 510(K) STAFF 08-MAR-97

DATE RECEIVED IN ODE 23-DEC-96 DATE DECISION DUE 23-MAR-97

DECISION DECISION DATE _____

Is this 510(k) identified as a Class III device YES NO DS

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

EdK
1/22/97

Memorandum

From: Reviewer(s) - Name(s) Theodore R. Stevens

Subject: 510(k) Number K965132

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.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? YES NO

Is this device subject to the Tracking Regulation? YES NO

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

Is this a prescription device? YES NO

Was this 510(k) reviewed by a Third Party? 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) ✓

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

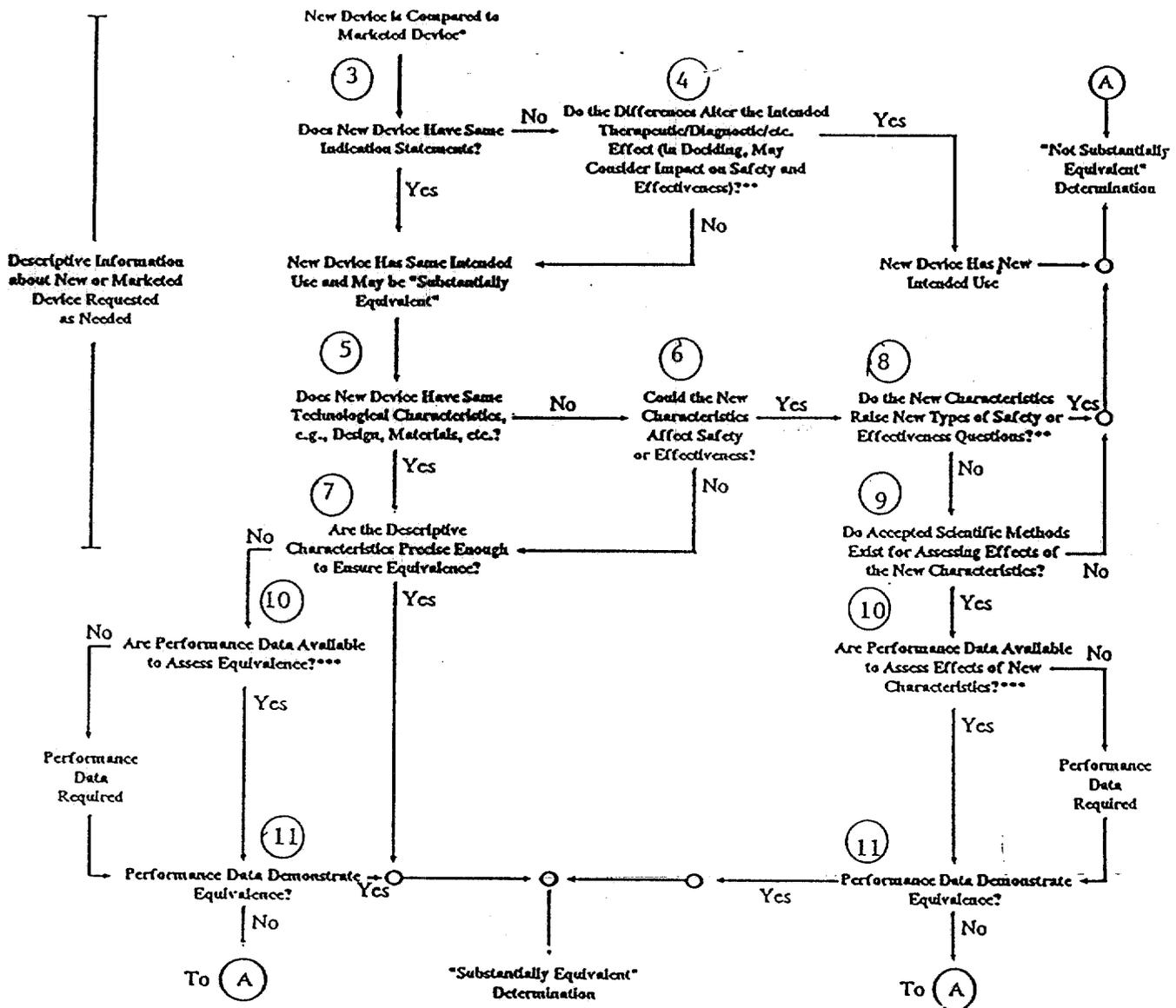
87 (OR)
~~87~~ class II KWL LZY class II

Review: Mark N. Melker ORDB 1/22/97
(Branch Chief) (Branch Code) (Date)

Final Review: J. Cole 1/27/97
(Division Director) (Date)

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



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

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: Theodore R. Stevens
 Division/Branch: DG RD / ORDB
 Device Name: J+S Ultima Unipolar Head and Adapter Screws
 Product To Which Compared (510(K) Number If Known): K902365, K9440190

	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 checked="" type="checkbox"/>	<input 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 type="checkbox"/>	If YES = Stop NE
5. Same Technological Characteristics?	<input checked="" type="checkbox"/>	<input 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 checked="" type="checkbox"/>	<input 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 type="checkbox"/>	<input type="checkbox"/>	If NO = Request Data
11. Data Demonstrate Equivalence?	<input 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.

ELK
1/22/97

MEMO RECORD

DATE: January 21, 1997

FROM: Theodore R. Stevens, Biomedical Engineer, HFZ-410

TO: The Record, K965156

SUBJECT: Johnson & Johnson Ultima® Unipolar Head and Adapter Sleeves

Common Name: Femoral Hemi Hip Prosthesis

Trade Names: Ultima® Unipolar Head and Adapter Sleeves

Classification: 21 CFR 888.3360

Class: II

Product Codes: KWL

- A 510(k) statement
- Truth/accuracy statement
- Indications for Use Statement

Contact Person/Telephone Number: Sally Maher (508)880-8100

Summary: This 510(k) original was reviewed for a SE or NSE recommendation.

Recommendation: I recommend that the subject device be found S.E. to legally marketed predicate devices: Howmedica's Unitrax Unipolar System (K902365), J&J's ULTIMA Unipolar Modular Head (K940190).

Basis of Recommendation:

LABELING: Adequate Samples Provided -

The package labeling includes information on the specific stems for which each adapter sleeve is intended, as well as appropriate indications, contraindications, warnings, adverse effects and sterility information. The devices have prescription labeling.

Intended Use: The included indication states: "The ULTIMA Unipolar Head is indicated for use in conjunction with a modular femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to: 1) femoral neck fracture; 2) avascular necrosis of the femoral head; 3) osteoarthritis; 4) abnormalities where: the major pathology affects the femoral head, the acetabular cavity is normal and not deformed or weakened, acetabular replacement is not required or desirable."

Device Description: The ULTIMA Unipolar heads are manufactured from cast ASTM F-75 cobalt-chromium-molybdenum alloy. Sizes 38mm to 43mm in diameter are solid, sizes 44mm through 63mm are formed from two cast pieces electron-beam welded to make a hollow head.

All sizes are HIPed and solution annealed before machining. The heads have a tapered bore to receive a variety of adapter sleeves which mate on the outside with the modular head, and on the inside with the appropriate taper for the modular head trunnions of J&J's various hips. The modular sleeve adapters are machined from ASTM F-799 wrought Co-Cr-Mo alloy. The adapters are available as follows:

10/12 taper: -3mm, +0mm, +5mm, +10mm (PFC and Ultima Stems)

11/13 taper: +0mm, +6mm, +12mm (S-ROM, Omega stems)

12/14 taper: +0mm, +3.5mm, +7mm (PFC)

The subject device is essentially identical to the currently marketed Ultima Unipolar heads, with the addition of adapter sleeves for neck length adjustment and attachment to various stem tapers. Similar sleeves are a feature of Howmedica's Unitrax Unipolar System (K902365).

Other devices: The adapter sleeves and unipolar head are used with previously cleared Johnson & Johnson femoral stems.

Mechanical Testing: J&J has provided an analysis of the mechanical integrity of their hollow and solid heads. The hollow heads are very similar to those already cleared under K940190. The sponsor has also modeled the heads under the loading conditions of ISO 7206:5. Peak resultant stresses for both the smallest (44mm) and largest (63mm) hollow heads are far below the maximum allowable stress (Goodman criteria).

Sterilization: Components are sterilized with 25 kGy gamma radiation (⁶⁰Co source). Sterilization validation is by AAMI/ISO 1137, and results in a minimum SAL of 10⁻⁶

RECOMMENDATION: I recommend the Johnson and Johnson ULTIMA* Unipolar Head and Adapter Sleeves be found substantially equivalent to: 87 KWL, Hip Joint Femoral (Hemi-Hip) Metallic cemented or Uncemented Prosthesis, 21 CFR §888.3360



Theodore R. Stevens

1. Intended Use:
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 product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

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:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
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:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K 965156 Device Name unpol. head w/ adapter
 Division/Branch ODRD / OR
 Administrative Reviewer Signature Michael Cowley Date 12/30/96
 Supervisory Signature _____ Date _____

Did the firm request expedited review? Yes No _____

Did we grant expedited review? Yes No _____

Truthful and accurate statement enclosed? Yes _____ No _____
 (If Not Enclosed, Must Be A Refuse To Accept Letter)
 Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed? YES _____ No _____
 (Required for Original 510(k)s received 1/1/96 and after --
 must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? Yes _____ No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? -- If so, a new ODE review is not required, please forward to POS.
 Yes No _____

X
Accepted

Refuse To
Accept

11

I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C. Is Device Subject To Review By CDRH?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
(ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	<input type="checkbox"/>	<input type="checkbox"/>
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer. (ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1. Device Trade Or Proprietary Name	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Device Common Or Usual Name Or Classification Name	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Action Taken To Comply With Section 514 Of The Act	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	<input type="checkbox"/>	<input type="checkbox"/>
9. For Class III Devices Only, A Class III Certification And A Class III Summary	<input type="checkbox"/>	<input type="checkbox"/>
10. Photographs Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
11. Engineering Drawings For The Device With Dimensions And Tolerances	<input type="checkbox"/>	<input type="checkbox"/>
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
14. Data To Show Consequences And Effects Of A Modified Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
15. Truthful And Accurate Statement	<input type="checkbox"/>	<input type="checkbox"/>
II. Additional Information That <u>Is</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
A. Submitter's Name And Address	<input type="checkbox"/>	<input type="checkbox"/>
B. Contact Person, Telephone Number And Fax Number	<input type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant If Applicable	<input type="checkbox"/>	<input type="checkbox"/>
D. Table Of Contents With Pagination	<input type="checkbox"/>	<input type="checkbox"/>
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	<input type="checkbox"/>	<input type="checkbox"/>
III. Additional Information That <u>May Be</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
A. Comparison Table Of The New Device To The Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
B. Action Taken To Comply With Voluntary Standards	<input type="checkbox"/>	<input type="checkbox"/>
C. Performance Data	<input type="checkbox"/>	<input type="checkbox"/>
MARKETED DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
NEW DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>

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Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
D. Sterilization Information	<input type="checkbox"/>	<input type="checkbox"/>
E. Software Information	<input type="checkbox"/>	<input type="checkbox"/>
F. Hardware Information	<input type="checkbox"/>	<input type="checkbox"/>
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	<input type="checkbox"/>	<input type="checkbox"/>
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	<input type="checkbox"/>	<input type="checkbox"/>
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	<input type="checkbox"/>	<input type="checkbox"/>
I. Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>

4

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 26, 1996

JOHNSON & JOHNSON PROFESSIONALS, IN 510(k) Number: K965156
325 PARAMOUNT DRIVE Received: 23-DEC-96
RAYNHAM, MA 02767 Product: ULTIMA*UNIPOLAR HEAD
ATTN: SALLY MAHER AND ADAPTER SLEEVES

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 DSMO@FDADR.CDRH.FDA.GOV or me at (301) 594-1190.

Sincerely yours,

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



K965156

Johnson & Johnson
PROFESSIONAL, INC.

JOHANNA NEWMAN
ASSOC. REGULATORY AFFAIRS SPECIALIST

PHONE: (508) 828-3268
FAX: (508) 828-3212

December 19, 1996

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

RECEIVED
23 DEC 96 10 42
FDA/CDRH/ODE/DNO

SUBJECT: 510(k) Premarket Notification
ULTIMA* Unipolar Head and Adapter Sleeves

Dear Sir/Madam:

Enclosed please find three copies of a 510(k) premarket notification for the ULTIMA* Unipolar Head and Adapter Sleeves which is substantially equivalent to other Class II medical devices currently marketed in the United States.

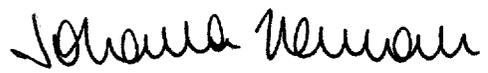
In accordance with 21 CFR §807.87 (j), I believe to the best of my knowledge, that all the data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

We consider technical information stamped "**CONFIDENTIAL**" to be trade secret and confidential commercial information, not available for disclosure under 21 CFR Part 20.

Johnson & Johnson Professional, Inc. acknowledges that the introduction of this device into domestic commercial distribution will be contingent upon written clearance of the 510(k) by the Food and Drug Administration. The statement of substantial equivalence is for FDA marketing clearance only. It in no way reflects upon the patentability of the device.

If you have any questions regarding this submission, please do not hesitate to contact me at (508) 828-3268 or Sally Maher at (508) 828-8128.

Regards,



Johanna Newman
Assoc. Regulatory Affairs Specialist



Sally Maher
Director Regulatory Affairs

Sk-27

OR
IF

**Indications for Use
for the ULTIMA* Unipolar Head and Adapter Sleeves**

**Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350**

Indications for Use _____

The ULTIMA* Unipolar Head is indicated for use in conjunction with a modular femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to:

1. femoral neck fracture,
2. avascular necrosis of the femoral head,
3. osteoarthritis,
4. abnormalities where:
 - the major pathology affects the femoral head,
 - the acetabular cavity is normal and not deformed or weakened, acetabular replacement is not required or desirable.

Q

**PREMARKET NOTIFICATION {510(K)} CHECKLIST FOR ACCEPTANCE DECISION AND
REQUIRED INFORMATION**

I. CRITICAL ELEMENTS

- a. Pursuant to 21 CFR §807 Subpart E, the following notification of the intent of Johnson & Johnson Professional, Inc. to introduce the **ULTIMA* Unipolar Head and Adapter Sleeves** into commercial distribution.
- b. Has the device been the subject of a previous NSE decision? **no**

II. REQUIRED INFORMATION

Under sections 510(k), 512(i) of the Act, and subpart E of part 807 in Title 21 of the Code of Federal Regulations:

- a. Device, trade, or proprietary name: **ULTIMA* Unipolar Head and Adapter Sleeves**
- b. Device common or usual name,
or classification name **Hip Joint Metal/Polymer Semi-Constrained**
- c. Establishment Registration Number **1219655**
Owner/Operator Number **9001269**
- d. Class into which the device is classified **Class 2**
under 21 CFR parts 862 through 892 **§ 888.3360**
- e. Classification Panel **Orthopaedics**
- f. Action taken to comply with Section
514 of the Act **No Standard(s) presently exist for this device.**
- g. Proposed labels, labeling, instructions for use,
and advertisements (if available) that describe
the device, its intended use, and direction for use **Exhibit II, pages 13-23**
- h. 510(k) Safety and Effectiveness Information **Exhibit I, pages 10-12**
- i. Photographs of device **Exhibit III**
- j. Engineering drawing for the device **Exhibit III**
- k. The marketed device(s) to which equivalence is
claimed including labeling and description of device **Exhibit V, pages 67-70**
- l. Statement of similarities and/or differences
with the marketed device(s) **Section VI, pages 6-7**
- m. Data to show consequences and effects of modified device **NA**

III. ADDITIONAL INFORMATION that is necessary under 21 CFR 807.87(h)

- a. Submitter's name and address Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767
- b. Contact Person Johanna Newman
Assoc. Regulatory Affairs Specialist
Telephone number (508) 828-3268
Fax number (508) 828-3212
- c. Representative/Consultant Not Applicable
- d. Table of Contents i
- e. Sterilization sites Section V, page 4

IV. ADDITIONAL INFORMATION that *may be* necessary under 21 CFR 807.87(h)

- a. Comparison table of the new device to
the marketed device(s) Section VI, page 9
- b. Action taken to comply with voluntary standards ASTM F-75
ASTM F-799
- c. Performance Data Exhibit IV, pages 39-66
Marketed Device
 Bench Testing Not Necessary
 Animal Testing Not necessary
 Clinical Testing Not necessary
New Device
 Performance Analysis Not necessary
 Animal Testing Not necessary
 Clinical Testing Not necessary
- d. Sterilization Information Section V, page 4
- e. Software Information NA
- f. Hardware Information NA
- g. Is the device subject to issues that have been addressed
in specific guidance documents? No

V. ADDITIONAL INFORMATION that is necessary under 21 CFR 807.87(j)

- a. 510(k) Certification Statement Included in cover letter

ULTIMA* Unipolar Head and Adapter Sleeves

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ULTIMA* Unipolar Head and Adapter Sleeves

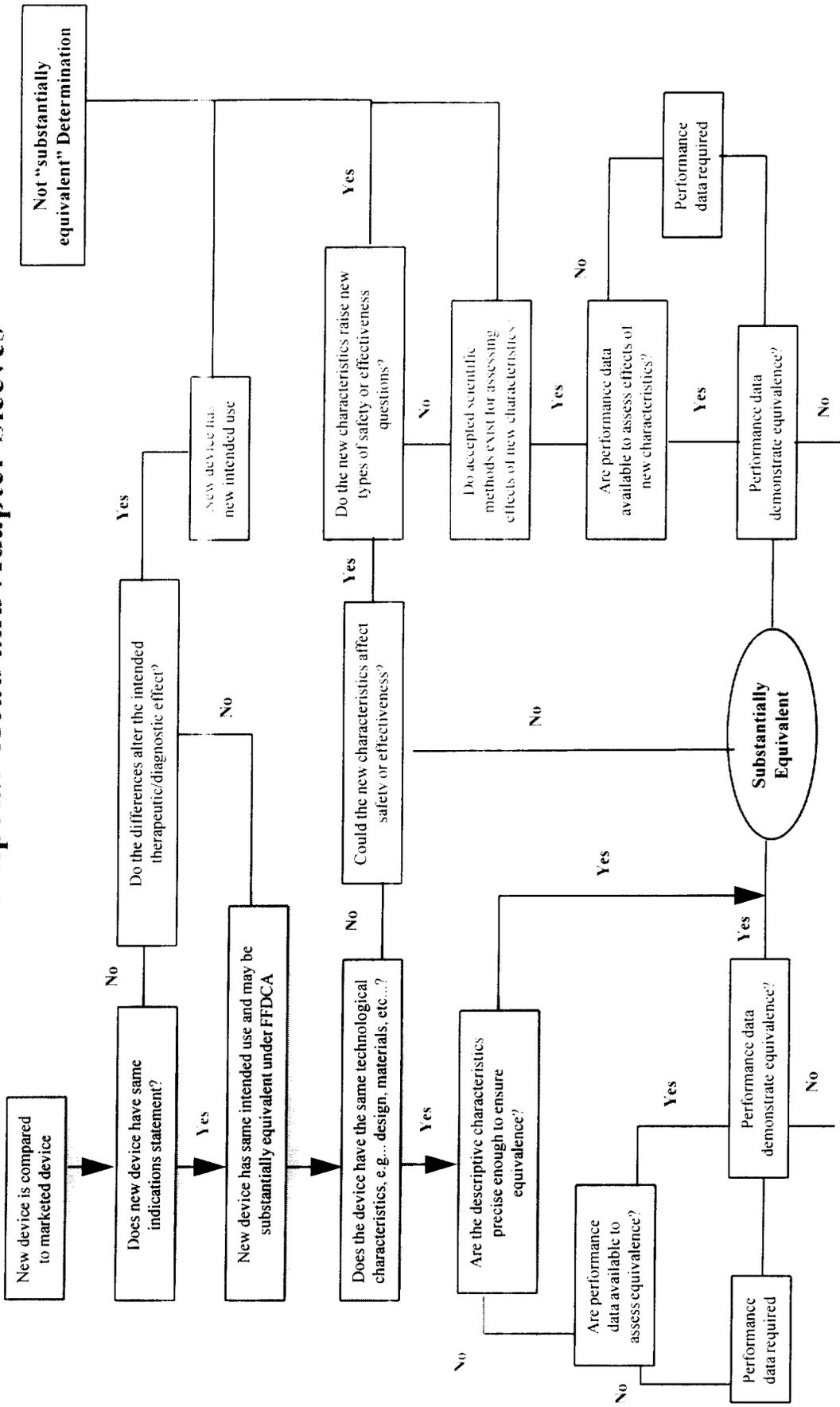
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510(k) "Substantial Equivalence" Decision Making Process for the ULTIMA* Unipolar Head and Adapter Sleeves



Not substantially equivalent

Not substantially equivalent

[Handwritten signature]

Johnson & Johnson
PROFESSIONAL, INC.

November 20, 1996

Document Mail Center
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Subject: **510(k) Premarket Notification**
ULTIMA* Unipolar Head and Adapter Sleeves

Dear Sir/Madam,

Pursuant to 21 CFR Subpart E, the following is a notification of the intent of Johnson & Johnson Professional, Inc. to introduce the ULTIMA* Unipolar Head and Adapter Sleeves into commercial distribution.

I. Device Name

Proprietary Name: ULTIMA* Unipolar Head and Adapter Sleeves
Common Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Classification Name: Prosthesis, Hip
Regulatory Class: Class II by 21 CFR § 888.3360
Product Code: 87 JDG
Owner/ Operator # 9001269

II. Summary of Safety and Effectiveness

The Summary of Safety and Effectiveness is provided in **EXHIBIT I**.

III. Proposed Labels/Labeling/Promotional Materials

Proposed Labels / Labeling / Promotional Materials	Location in Submission
Draft Product Labeling	EXHIBIT II
Draft Product Insert	EXHIBIT II

Claims which Johnson & Johnson Professional, Inc. intends to make for this device include:

1. Unipolar Head is manufactured from cobalt-chromium-molybdenum alloy complying with ASTM F75.
2. Device is used with an adapter sleeve, to allow for neck length options. It is available in a wide range of head diameters ranging from 38mm to 63mm, increasing in 1mm increments.
3. The choice of various neck length options facilitates the restoration of the patient's leg length and offset.
4. The Unipolar Head bore mates the adapter sleeve for use with any femoral stem distributed by Johnson & Johnson Professional, Inc., with a taper matching the taper of the sleeve adapter.
5. Unipolar Head has a single metal to metal locking interface between the femoral head bore and the adapter sleeve, and another at the interface between the adapter sleeve and the femoral stem trunnion. Additional femoral neck sleeves provide neck length options.
6. Revision of the endoprosthesis (Unipolar Head and femoral component) does not require removal of the femoral stem for conversion to a total hip system.
7. Unlike a unitized endoprosthesis where the choice of head and stem sizes is interdependent, the Johnson & Johnson system enables the surgeon to choose the Unipolar Head independent of the femoral component size.

IV. Device Description

A. Intended Use

The ULTIMA* Unipolar Head is indicated for use in conjunction with a modular femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to:

1. femoral neck fracture,
2. avascular necrosis of the femoral head,
3. osteoarthritis.
4. abnormalities where:
 - the major pathology affects the femoral head,
 - the acetabular cavity is normal and not deformed or weakened,
 - acetabular replacement is not required or desirable.

B. Design

The ULTIMA* Unipolar Head is provided in a size range of 38mm to 63mm (outer diameter), in 1mm increments. Sizes from 44mm through 63mm are manufactured as a two-piece assembly. The two pieces are made of cast cobalt-chromium-molybdenum alloy conforming to ASTM F75. Both pieces are treated with hot isostatic pressing and solution annealing. The two cast pieces are machined and then joined permanently by electron beam welding to form a hollow unipolar head. Sizes from 38mm through 43mm are cast from cobalt-chromium-molybdenum alloy as a solid head, and are isostatic pressed and solution annealed before machining. Both of these size ranges are machine finished to the outer diameter size. The outer diameter is highly polished for articulation with the implant recipient's natural acetabulum.

The ULTIMA* Unipolar Head has a tapered bore which can receive a variety of Adapter Sleeves. The adapter sleeves are tapered on the outside to mate with the unipolar head, and tapered on the inside to mate with the appropriate femoral stem trunnion. The adapter sleeves are available in a 10/12 taper, in size increments for -3mm, +0mm, -5mm and +10mm neck lengths; in a 11/13 taper, in size increments for +0mm, +6mm, and +12mm neck lengths; and in a 12/14 taper, in size increments for +0mm, +3.5mm, and +7mm neck lengths. The adapter sleeves are machined from cobalt-chromium-molybdenum alloy in wrought bar form conforming ASTM F799.

Historical Information	The head Johnson & Johnson intends to market is a modification and substantially equivalent to the existing ULTIMA* Unipolar Modular Head which was cleared for marketing via 510(k) K940190 on September 29, 1994. Additionally, a detailed comparison will be made with another representative head:
Predicate Devices	<ol style="list-style-type: none">1. the Johnson & Johnson ULTIMA* Unipolar Modular Head2. the Howmedica Unitrax Unipolar System
Scientific Articles	Scientific articles detailing unipolar head systems can be found in EXHIBIT VI.
Engineering Drawings	Representative engineering drawings and photographs of the ULTIMA* Unipolar Head and Adapter Sleeves are provided in EXHIBIT III.

C. Materials

- The ULTIMA* Unipolar Head is made from a Cobalt-Chromium-Molybdenum (Co-Cr-Mo) alloy for surgical implant applications per ASTM F75.
- The adapter sleeves are made from a Cobalt-Chromium-Molybdenum (Co-Cr-Mo) alloy for surgical implant applications per ASTM F799.

V. Sterilization

A. Method

^{60}Co gamma irradiation.

B. Dose

Minimum of 25 Kgy.

C. Sterility Assurance Level (SAL)

Minimum SAL of 1×10^{-6} .

D. Validation Method

Sterilization validation is conducted per AAMI/ISO 1137 Sterilization of Health Care Products - Requirements for validation and Routine Control - Radiation Sterilization. The method for sterilization is validated by a study used to confirm the distribution of the absorbed dose, (categorized according to density), across selected device products. The results are used to establish the parameters that are then defined in process specifications. During routine sterilization, the categories validated above are not combined.

Dosimeters are located in predetermined positions to monitor the maximum and minimum dose positions across the loaded irradiation carrier. The loaded carriers are processed through the irradiation plant after which the dosimeters are recovered and the absorbed dose at each position is calculated. The relationship between maximum, minimum, and routine dosimeter readings is determined and an acceptable range for routine dosimeter readings is then established. The dose is confirmed with Harwell Red 4034 PerspexTM dosimeters.

E. Packaging Information

The product will be packaged as a single unit in double (inner and outer) peel pouch pack. The inner pack is sealed under a 75mbar vacuum to evacuate the air from the pack to help minimize the movement of the product within the pouch. The pouch is sealed with a double heat seal, to provide additional safeguard to the sterility of the product. The pre-sealed and heat sealed ends of the inner pouch are folded and the pouched product inserted into the outer pouch, which is double heat sealed under a partial vacuum of 350mBar. The pouched product is then placed in an individual cardboard carton and shrink-wrapped. The cartons are packed in a transit outer cardboard box to a specified weight limit (7.1kg-10.4kg.) prior to sterilization by gamma irradiation. Before release of the packed product, there is a 100% visual inspection of every seal for continuity, color change and foreign bodies in seal surface. The packaging system described is routinely used for Johnson & Johnson Professional, Inc. sterile joint replacements

F. Pyrogenicity

No claim of non-pyrogenicity is made.

G. Manufacturer

Johnson & Johnson Professional, Inc.
Queensway Stem Lane
New Milton
Hampshire BH25 5NN
England

First Importer:

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767

H. Sterilization Site

(b) (4)



VI. 510(k) Statement of Substantial Equivalence

The ULTIMA* Unipolar Head and Adapter Sleeves is substantially equivalent to the **Johnson & Johnson** ULTIMA* Unipolar Modular Head (K940190) and the **Howmedica** Unitrax Unipolar System (K902365).

EXHIBIT V contains:

- a current copy of Howmedica's catalog depicting the Unitrax Unipolar System.

Does the device have same indications statements? YES

The ULTIMA* Unipolar Head and Adapter Sleeves is indicated for use in conjunction with a modular femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to:

1. femoral neck fracture,
2. avascular necrosis of the femoral head,
3. osteoarthritis,
4. abnormalities where:
 - the major pathology affects the femoral head,
 - the acetabular cavity is normal and not deformed or weakened,
 - acetabular replacement is not required or desirable.

The Johnson & Johnson ULTIMA* Unipolar Head and Adapter Sleeves is basically intended for the same indications as the Johnson & Johnson ULTIMA* Unipolar Modular Head and the Howmedica Unitrax Unipolar System.

Does the device have the same technological characteristics (e.g. design, materials, etc.)? YES

The ULTIMA* Unipolar Head has similar technological characteristics to the Johnson & Johnson ULTIMA* Unipolar Modular Head and the Howmedica Unitrax Unipolar System.

All three competitive Unipolar Heads are manufactured from Co-Cr-Mo alloy. The ULTIMA* Unipolar Head and Adapter Sleeves is used in conjunction with Johnson & Johnson Professional, Inc. porous coated titanium or Co-Cr-Mo alloy femoral stem components. The Howmedica Unitrax Unipolar System is compatible with all Howmedica 10/12 taper femoral stem components

Are the descriptive characteristics precise enough to ensure equivalence?..... YES

The description provided above demonstrates substantial equivalence to the currently marketed devices. The intended use is the same. The technological characteristics are the same.

Substantially Equivalent? YES

The safety and effectiveness of the ULTIMA* Unipolar Head and Adapter Sleeves is substantiated by similarity in its intended use, materials, manufacturing processes, and function to the Johnson & Johnson ULTIMA* Unipolar Modular Head and the Howmedica Unitrax Unipolar System. Furthermore, analysis results demonstrate that the ULTIMA* Unipolar Head meets the set criteria for the establishment of "substantial equivalence".

510(k) "Substantial Equivalence" Decision Making Process for the ULTIMA* Unipolar Head and Adapter Sleeves

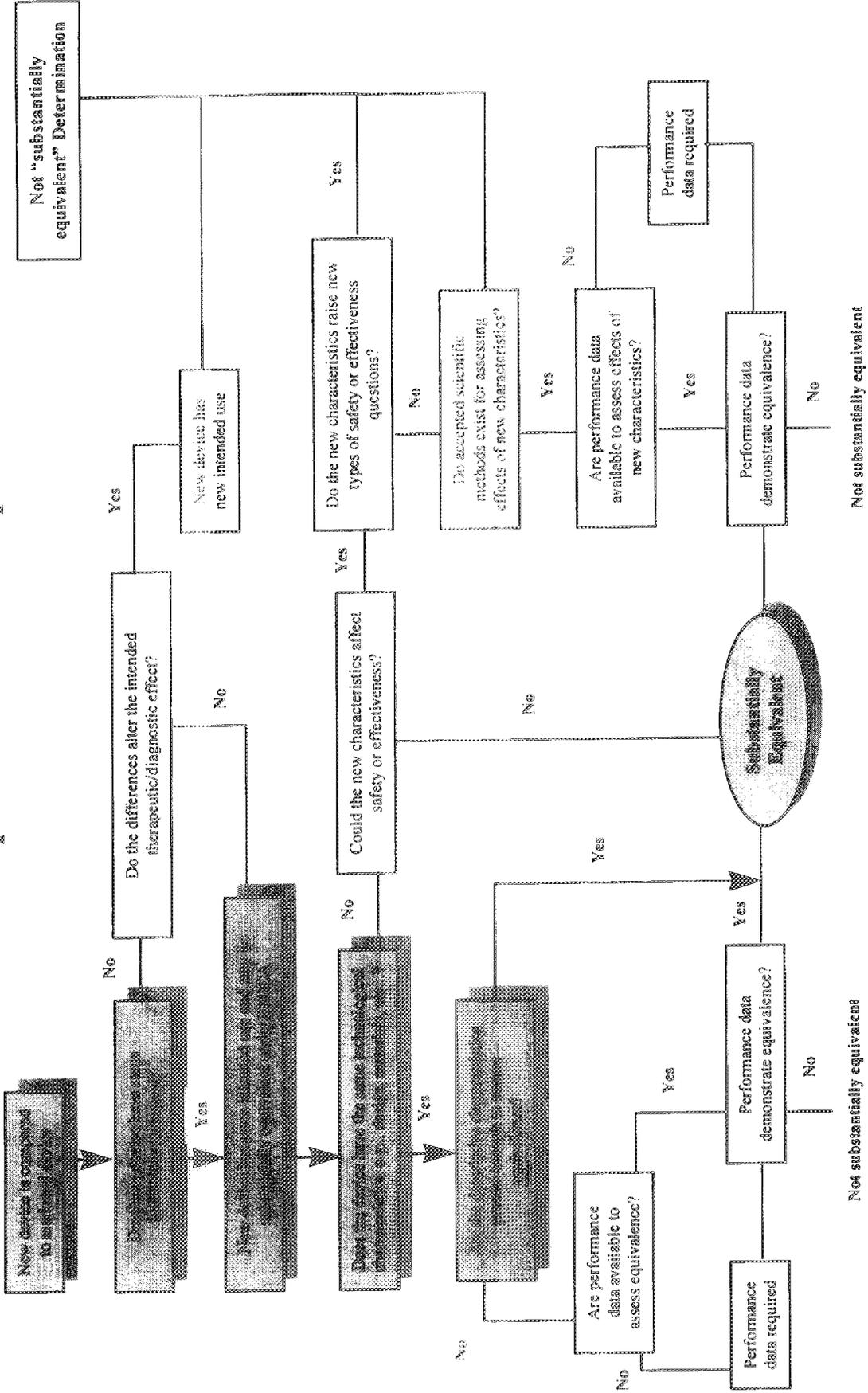


Table 1. Similarities and Differences Matrix

	ULTIMA* Unipolar Head and Adapter Sleeves	ULTIMA* Unipolar Modular Head	Howmedica Unitrax Unipolar System
	Subject Device	K940190	K902365
DESIGN			
Range of sizes	38mm-63mm (1mm increments)	38mm-65mm (1mm increments)	38mm-63mm (1mm increments)
Adapter sleeve for increased neck length	Yes	No	Yes
Number neck length sizes	10/12 taper: -3mm, +0mm, +5mm, +10mm 11/13 taper: +0mm, +6mm, +12mm 12/14 taper: +0mm, +3.5mm, +7mm	+0mm, +5mm	-4mm, +0mm, +5mm, +10mm
Morse-taper locking mechanism to modular femoral stem	Yes	Yes	Yes
INTENDED USE			
Partial hip replacement	Yes	Yes	Yes
MATERIALS			
Manufactured from Co-Cr-Mo	Yes	Yes	Yes

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EXHIBIT I

Summary of Safety and Effectiveness

Summary of Safety & Effectiveness Data for the ULTIMA* Unipolar Head and Adapter Sleeves

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

1. Contact Person

Johanna Newman, Assoc. Regulatory Affairs Specialist, (508) 828-3268.

2. Device Name

Proprietary Name: ULTIMA* Unipolar Head and Adapter Sleeves
Common Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Classification Name: Prosthesis, Hip
Regulatory Class: Class II by 21 CFR § 888.3360
Product Code: 87 JDG
Owner/ Operator # 9001269

3. Device Classification

Classification for ULTIMA* Unipolar Head and Adapter Sleeves has been placed in Class II by 21 CFR § 888.3360

4. Statement of Substantial Equivalence

The safety and effectiveness of the ULTIMA* Unipolar Head and Adapter Sleeves is substantially equivalent in terms of function to the Johnson & Johnson ULTIMA* Unipolar Modular Head and the Howmedica Unitrax Unipolar System. Furthermore, analysis results demonstrate that the ULTIMA* Unipolar Head and Adapter Sleeves meets the set criteria for the establishment of “substantial equivalence”.

5. Indications for Use

The ULTIMA* Unipolar Head is indicated for use in conjunction with a modular femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to:

1. femoral neck fracture,
2. avascular necrosis of the femoral head,
3. osteoarthritis,
4. abnormalities where:
 - the major pathology affects the femoral head.
 - the acetabular cavity is normal and not deformed or weakened,
 - acetabular replacement is not required or desirable.

6. Physical Description

The ULTIMA* Unipolar Head is provided in a size range of 38mm to 63mm (outer diameter), in 1mm increments. Sizes from 44mm through 63mm are manufactured as a two-piece assembly. The two pieces are made of cast cobalt-chromium-molybdenum alloy conforming to ASTM F75. Both pieces are treated with hot isostatic pressing and solution annealing. The two cast pieces are machined and then joined permanently by electron beam welding to form a hollow unipolar head. Sizes from 38mm through 43mm are cast from cobalt-chromium-molybdenum alloy as a solid head, and are isostatic pressed and solution annealed before machining. Both of these size ranges are finish machined to the outer diameter size. The outer diameter is highly polished for articulation with the implant recipient's natural acetabulum.

The ULTIMA* Unipolar Head has a tapered bore which can receive a variety of Adapter Sleeves. The adapter sleeves can be tapered on the outside to mate with the unipolar head, and tapered on the inside to mate with the appropriate femoral stem trunnion. The adapter sleeves are available in a 10/12 taper, in size increments for -3mm, +0mm, +5mm, and +10mm neck lengths; in a 11/13 taper, in size increments for +0mm, +6mm, and +12mm neck lengths; and in a 12/14 taper, in size increments for +0mm, +3.5mm, and +7mm neck lengths. The adapter sleeves are machined from cobalt-chromium-molybdenum alloy in wrought bar form conforming ASTM F799

Table 1. Similarities and Differences Matrix

	ULTIMA* Unipolar Head and Adapter Sleeves	ULTIMA* Unipolar Modular Head	Howmedica Unitrax Unipolar System
DESIGN			
Range of sizes	38mm-63mm (1mm increments)	38mm-65mm (1mm increments)	38mm-63mm (1mm increments)
Adapter sleeve for increased neck length	Yes	No	Yes
Number neck length sizes	10/12 taper: -3mm, +0mm, +5mm, +10mm 11/13 taper: +0mm, +6mm, +12mm 12/14 taper: +0mm, +3.5mm, +7mm	+0mm, +5mm	-4mm, +0mm, +5mm, +10mm
Morse-taper locking mechanism to modular femoral stem	Yes	Yes	Yes
INTENDED USE			
Partial hip replacement	Yes	Yes	Yes
MATERIALS			
Manufactured from Co-Cr-Mo	Yes	Yes	Yes

EXHIBIT II

Draft Product Labeling and Inserts

Draft Product Labeling

031110

Product Code XX-XXXX

Johnson & Johnson Orthopaedics

ULTIMA® Total Hip System
Unipolar Head Sleeve Adapter 10/12 Taper

Size: XX

CoCrMo Alloy
Lot # XXXXX

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

Use only with ULTIMA® Unipolar Head and P.F.C.®/ULTIMA® Femoral Stems 10/12 taper

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767

Made in UK

031110

371

030017

Product Code XX-XXXX

Johnson & Johnson Orthopaedics

ULTIMA® Total Hip System
Unipolar Head Sleeve Adapter 11/13 Taper

Size XX

CoCrMo Alloy
Lot # XXXXX

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

Use only with ULTIMA® Unipolar Head and S-ROM® and OMEGA® Femoral Stems 11/13 taper

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767

Made in UK

030017

Product Code XX-XXXX

Johnson & Johnson Orthopaedics

ULTIMA[®] Total Hip System
Unipolar Head Sleeve Adapter 12/14 Taper

Size XX

CoCrMo Alloy
Lot # XXXXX

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

Use only with ULTIMA[®] Unipolar Head and P.F.C.[®]/ULTIMA[®] Femoral Stems 12/14 taper

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767

Made in UK

000018



Draft Product Insert

ULTIMA® Unipolar Head and ULTIMA Unipolar Head Sleeve Adapter

Manufactured by

JJO Logo

Johnson & Johnson Medical Ltd.
London Road, Bracknell, Berkshire RG12 2AT
United Kingdom
(01344) 864050

Distributed in USA by

JJO Logo

Johnson & Johnson Professional Inc.
325 Paramount Drive
Raynham, MA 02767-0350, USA

For Product Information: 1-800-526-2459
To Reorder: 1-800-255-2500

050510

English

000001

ULTIMA Unipolar Head and ULTIMA Unipolar Head Sleeve Adapter

For Single Use Only

STERILE R

Description

The ULTIMA Unipolar Head is composed of cobalt-chromium alloy (Co-Cr-Mo) and is designed to be used with an ULTIMA Unipolar Head Sleeve Adapter and any femoral stem, distributed by Johnson & Johnson, with a taper matching the taper of the sleeve adapter

The surface of the ULTIMA Unipolar Head is highly polished and is provided in a range of outer diameters. The ULTIMA Unipolar Head must be used with an ULTIMA Unipolar Head Sleeve Adapter. The Adapter Sleeve is composed of Co-Cr-Mo and must be used with an ULTIMA Unipolar Head. It is tapered on the outside to mate with the ULTIMA Unipolar Head and provide a variety of neck length options. It is tapered on the inside with a 10/12, 11/13 or 12/14 taper to mate with a femoral stem, distributed by Johnson & Johnson, with a matching taper

Primary articulation occurs between the polished ULTIMA Unipolar Head and the patient's acetabular cavity.

Indications and Usage

The ULTIMA Unipolar Head and ULTIMA Unipolar Head Sleeve Adapter are indicated for use in conjunction with a modular hip femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to femoral fractures, avascular necrosis of the femoral head, osteoarthritis, or other abnormalities, where major pathology affects the femoral head, where the acetabular cavity is normal and not deformed or weakened, and where acetabular replacement is not required or desirable.

Information for Use

An instrumentation system, as well as a system of trial components, is available to assure proper fit and alignment of the prosthesis. Correct fit and alignment will reduce stresses at interface surfaces to enhance implant fixation. The surgeon should refer to the appropriate surgical technique manual for details on the use of the instrument system and implantation of the prosthesis. This surgical technique manual is available from your Johnson & Johnson sales representative or distributor.

The ULTIMA Unipolar Head Sleeve Adapter 10/12 taper must only be used with the ULTIMA Unipolar Head and P.F.C.[®]/ ULTIMA Femoral Stems 10/12 taper distributed by Johnson & Johnson.

The ULTIMA Unipolar Head Sleeve Adapter 11/13 taper must only be used with the ULTIMA Unipolar Head and S-ROM[®]/OMEGA[®] Femoral Stems 11/13 taper distributed by Johnson & Johnson.

The ULTIMA Unipolar Head Sleeve Adapter 12/14 taper must only be used with the ULTIMA Unipolar Head and P.F.C./ ULTIMA Femoral Stems 12/14 taper distributed by Johnson & Johnson.

Contraindications

Use is contraindicated in cases with active or recent joint sepsis, insufficient bone stock, marked artrophy

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or deformity of the upper femur, skeletal immaturity, or where loss of musculature or neuromuscular disease would render the procedure unjustifiable.

Warnings

Improper prosthesis selection or alignment, use where contraindicated, or in patients where medical, physical, mental or occupational conditions will likely result in extreme stresses to the implant, may result in premature failure due to loosening, fracture, wear, or dislocation. Postoperative care is extremely important. The patient should be instructed on the limitations of the device and should be cautioned regarding load bearing, ranges of motion, and activity levels permissible. Early motion and load bearing should be carefully controlled.

Use of other manufacturers' components with this implant is not advised. Use of components other than those recommended could lead to loosening, wear, fracture during assembly, and premature failure.

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

Precautions

An implant should never be reused. Any implant, once used, should be discarded, even though it may appear undamaged. Likewise, a new implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

The highly polished head should not come into contact with abrasive surfaces, as this may damage the head and affect performance. In addition, all mating surfaces must be clean before assembly to ensure proper seating. If the head is not properly seated on the sleeve adapter and femoral stem, it may become loose and/or may not achieve correct neck length.

Use trials to determine proper head size.

Adverse Effects

Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacements. Subclinical nerve damage has also been reported more frequently, often associated with surgical trauma. Dislocation and subluxation resulting from improper positioning and/or muscle and fibrous tissue laxity also may occur, as erosion and/or *protrusio* have been reported following use of hip endoprosthesis, often associated with improper head size selection.

Histological reactions have been reported as an apparent response to exposure to foreign material. The actual clinical significance of these reactions is unknown.

Serious adverse effects may necessitate surgical intervention.

Sterility and Handling

The ULTIMA Unipolar Head and ULTIMA Unipolar Head Sleeve Adapter components are supplied presterilized by a minimum of 25 kGy of gamma irradiation.

Johnson & Johnson Medical Ltd guarantees the sterility of presterile components unless the package is damaged or opened.

DO NOT RESTERILIZE.

Handle Carefully -- Protect from Damage and Contamination

Components should not be resterilised by the hospital because of the possibility of damaging the articulating or interfacing surface of the implant.

The operating staff should be conservative in component selection since opened packages will not be accepted for credit.

How Supplied

The ULTIMA Unipolar Heads and ULTIMA Unipolar Head Sleeve Adapters are supplied in a range of sizes. Please refer to the current price list for product codes and sizes available.

Symbols for:

For single use only

Use by

Sterilized by gamma irradiation

Batch Code

Reorder Code

See Instructions for Use

Lift

Date of manufacture

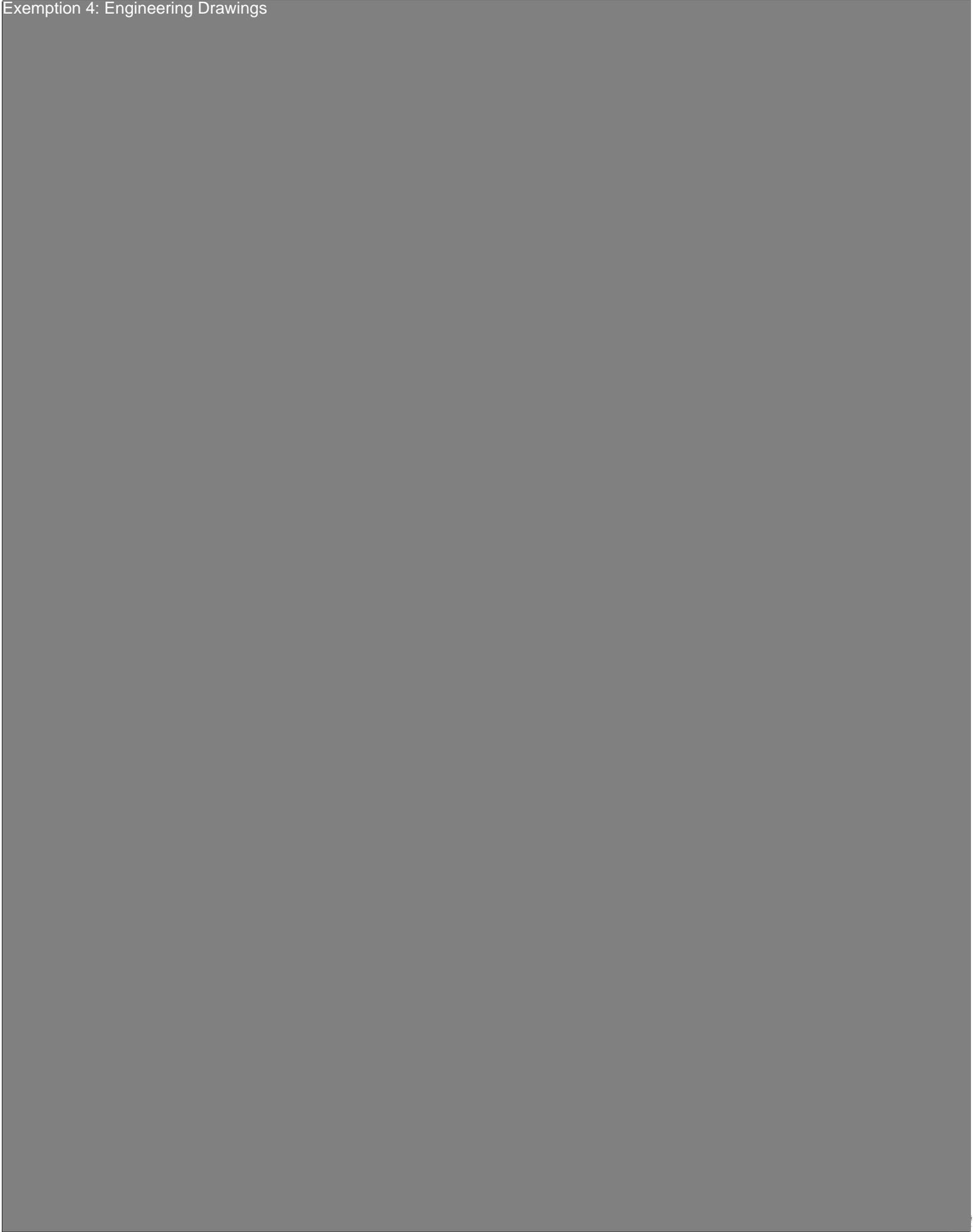
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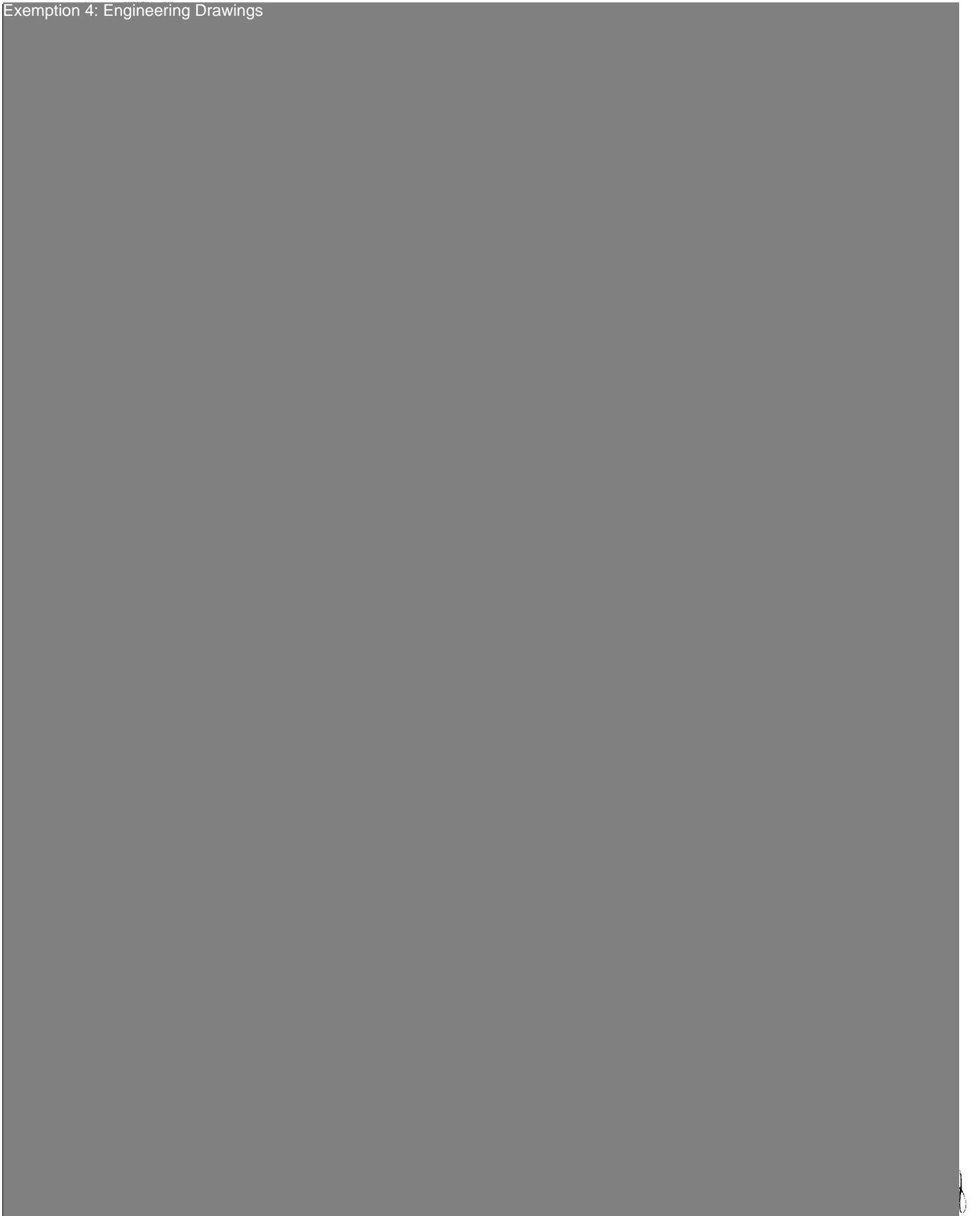
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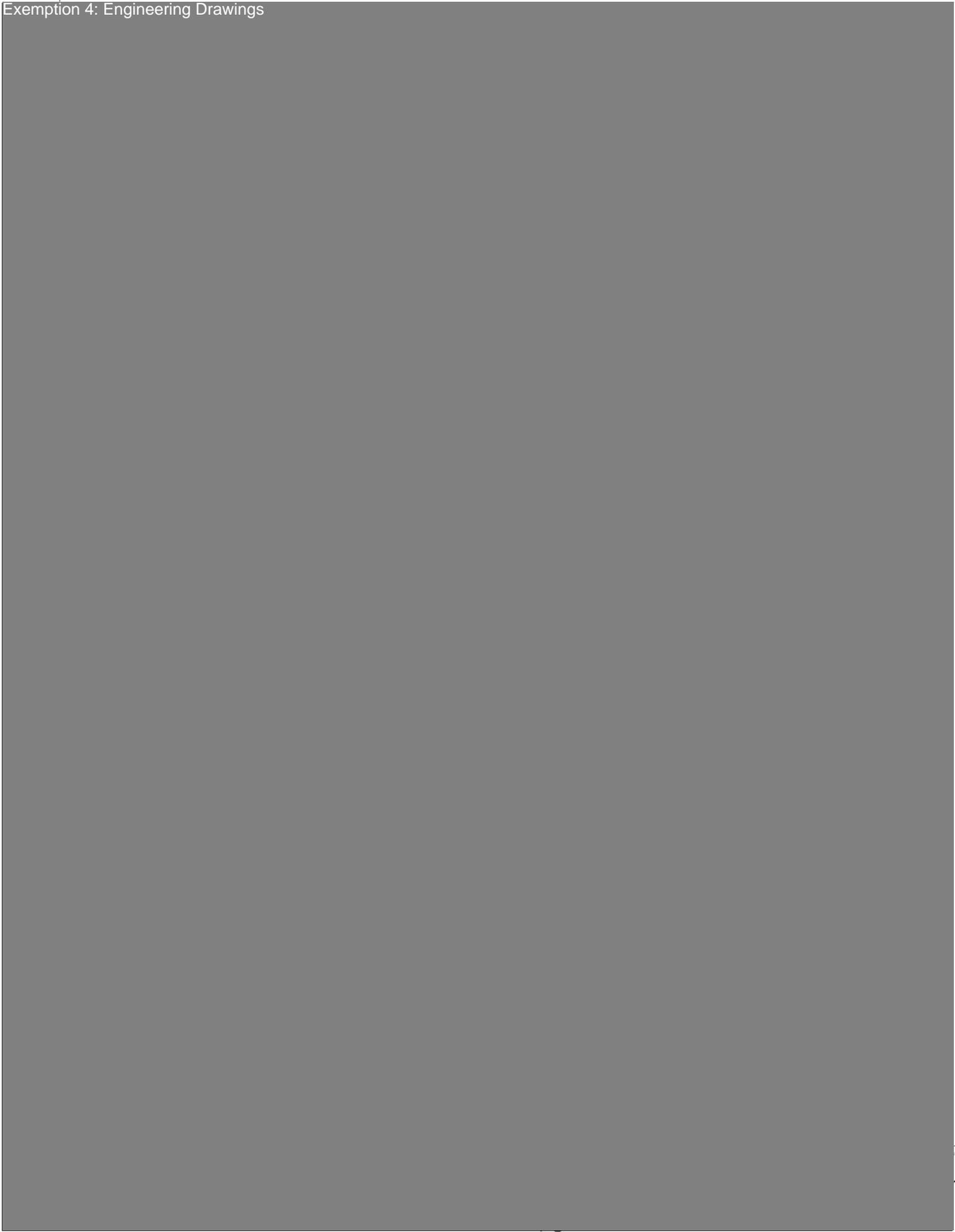
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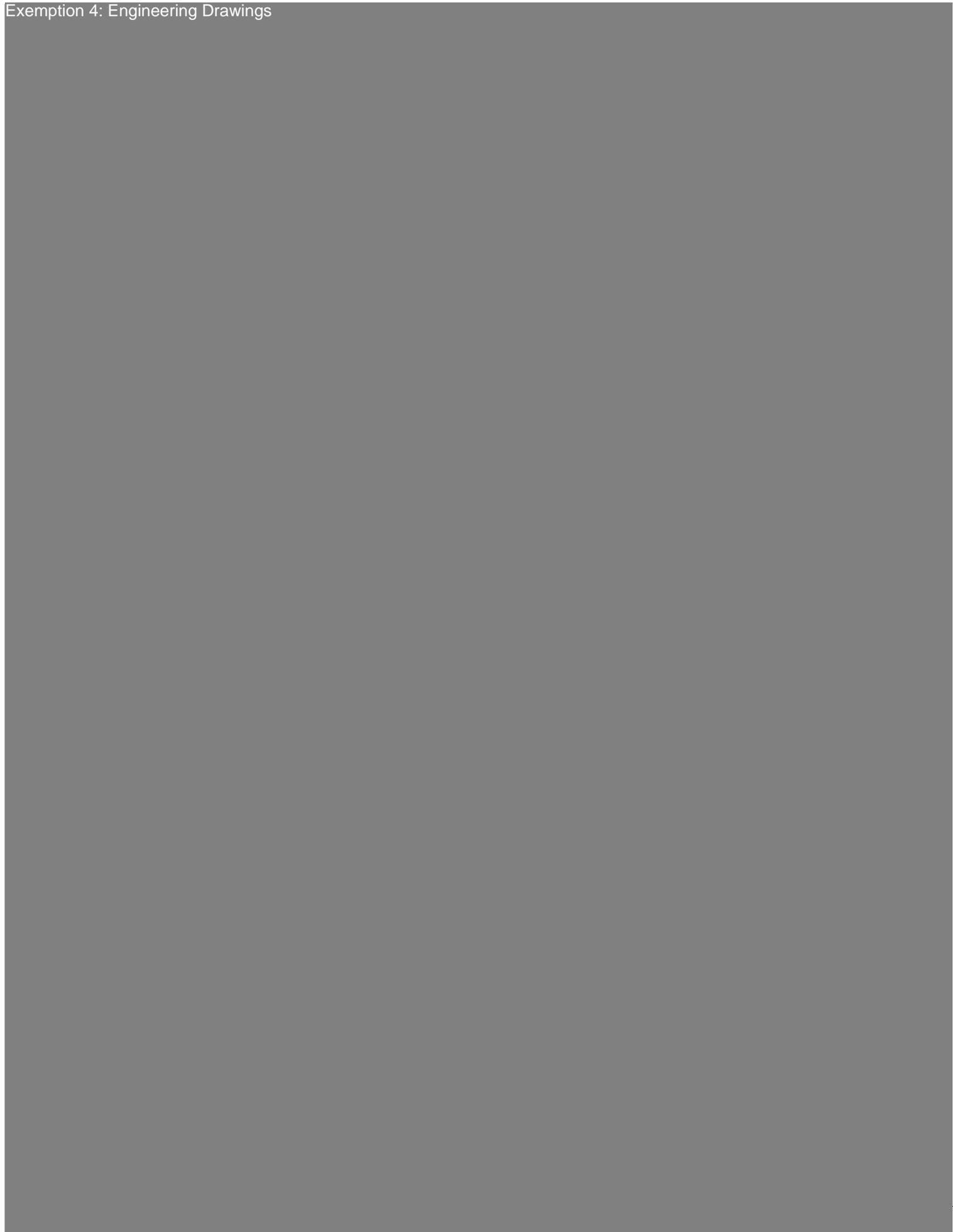
Engineering Drawings and Photographs



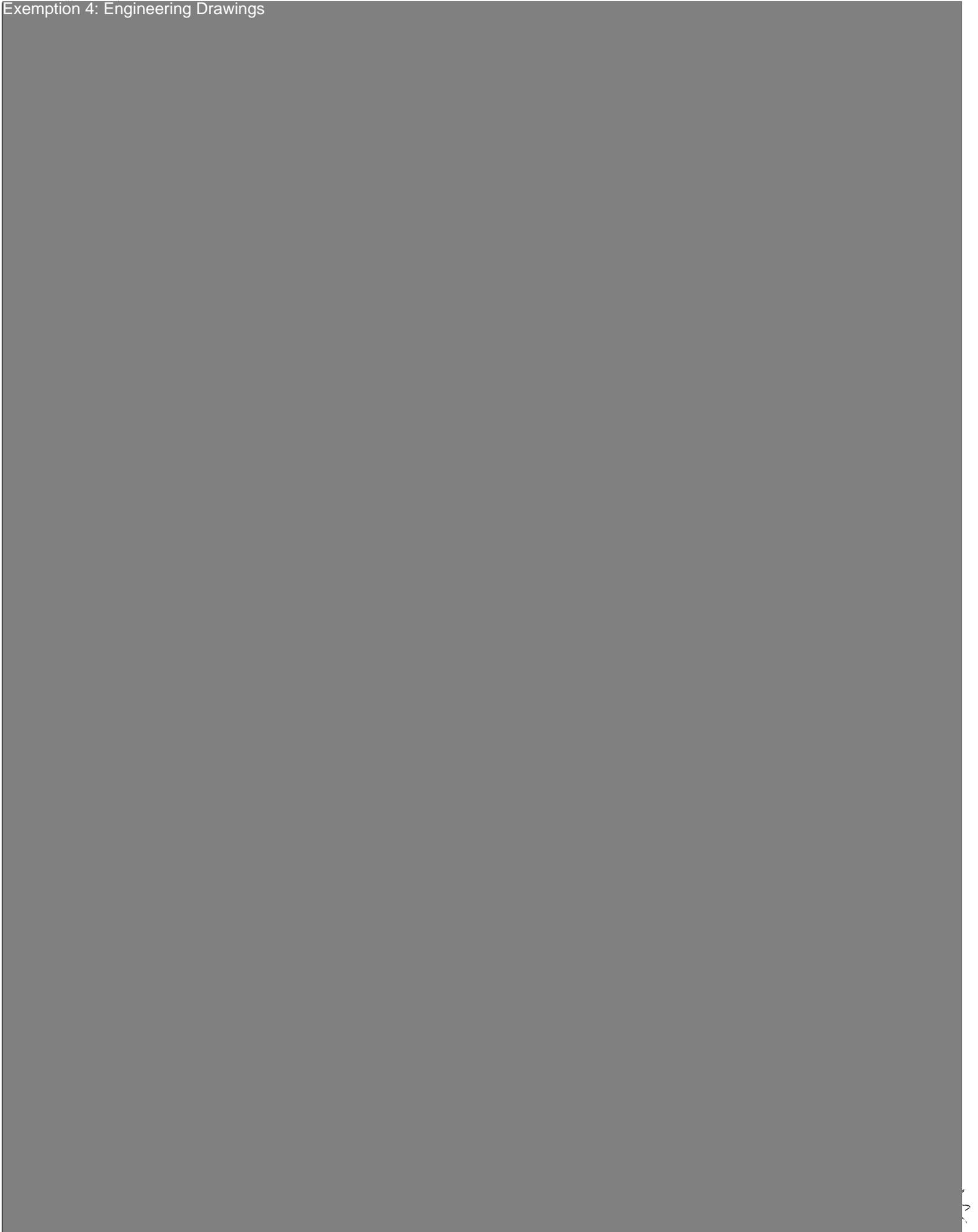


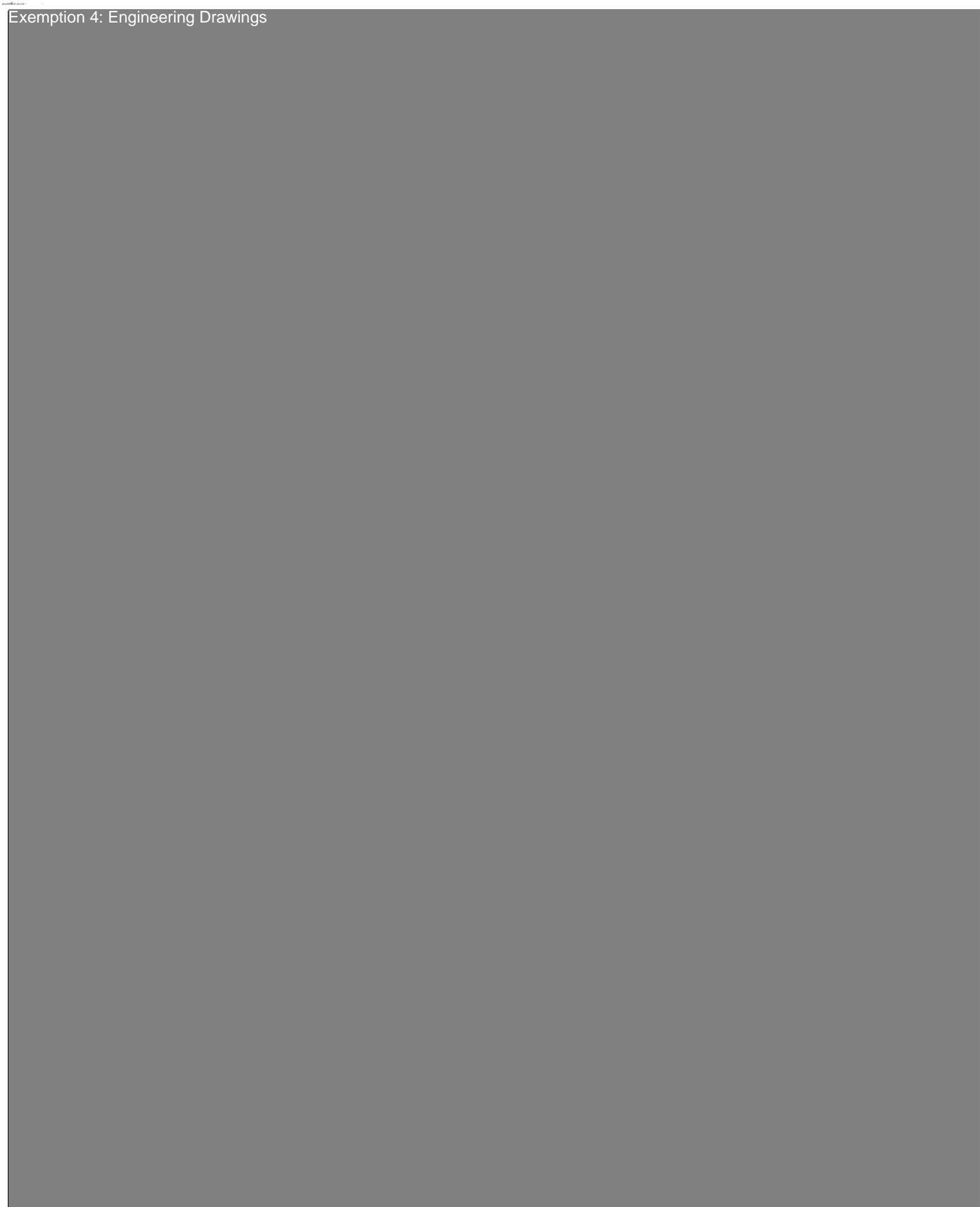


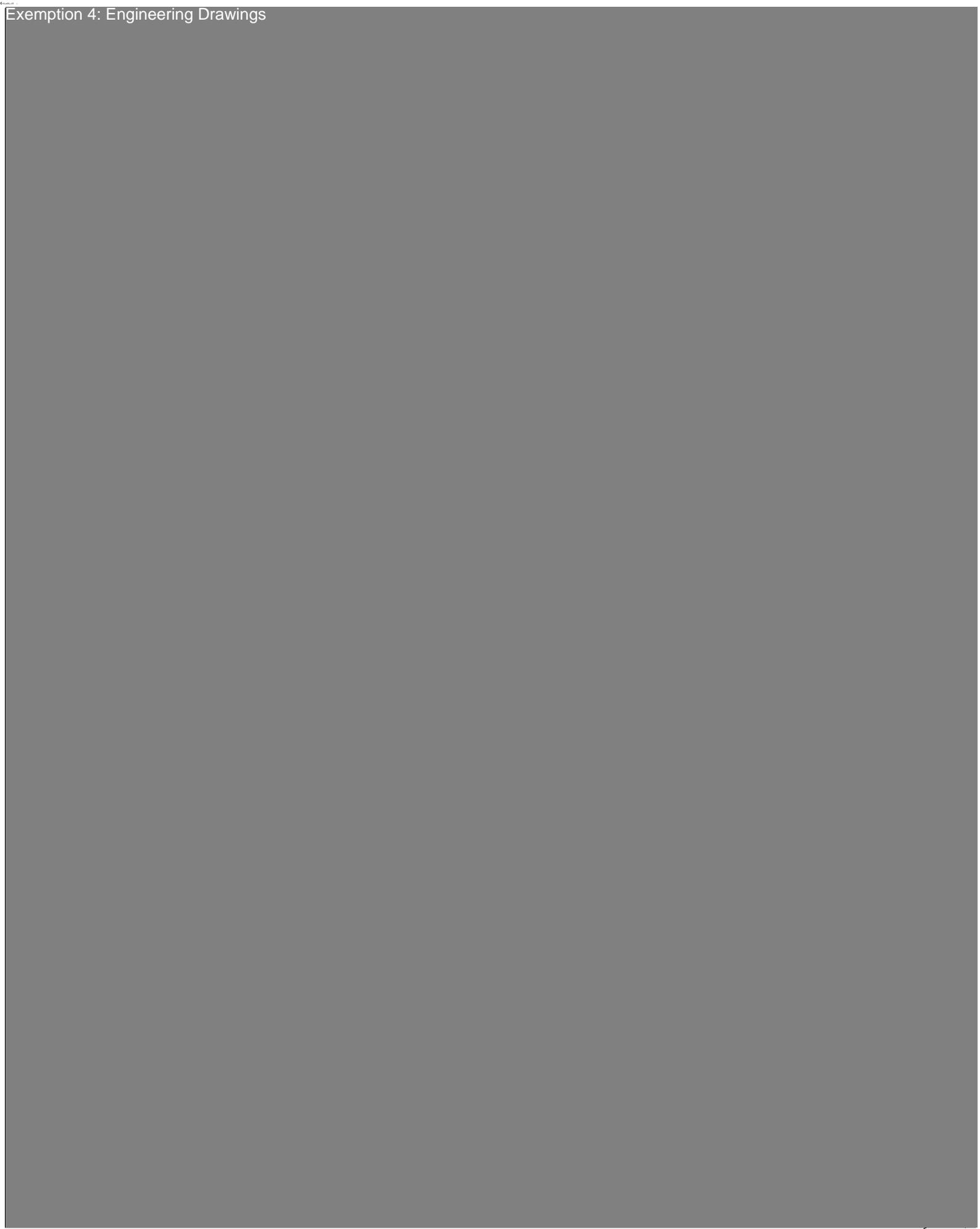


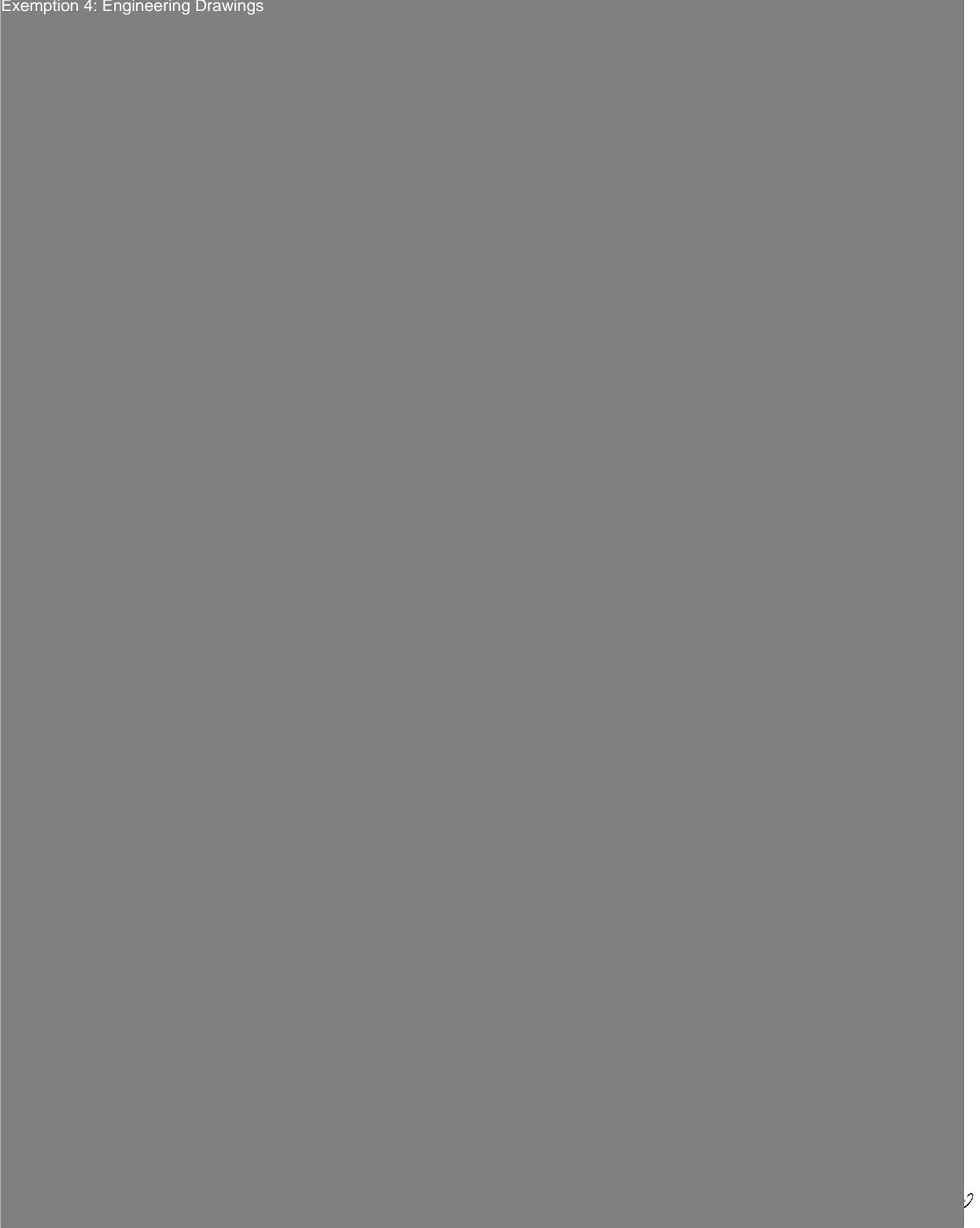


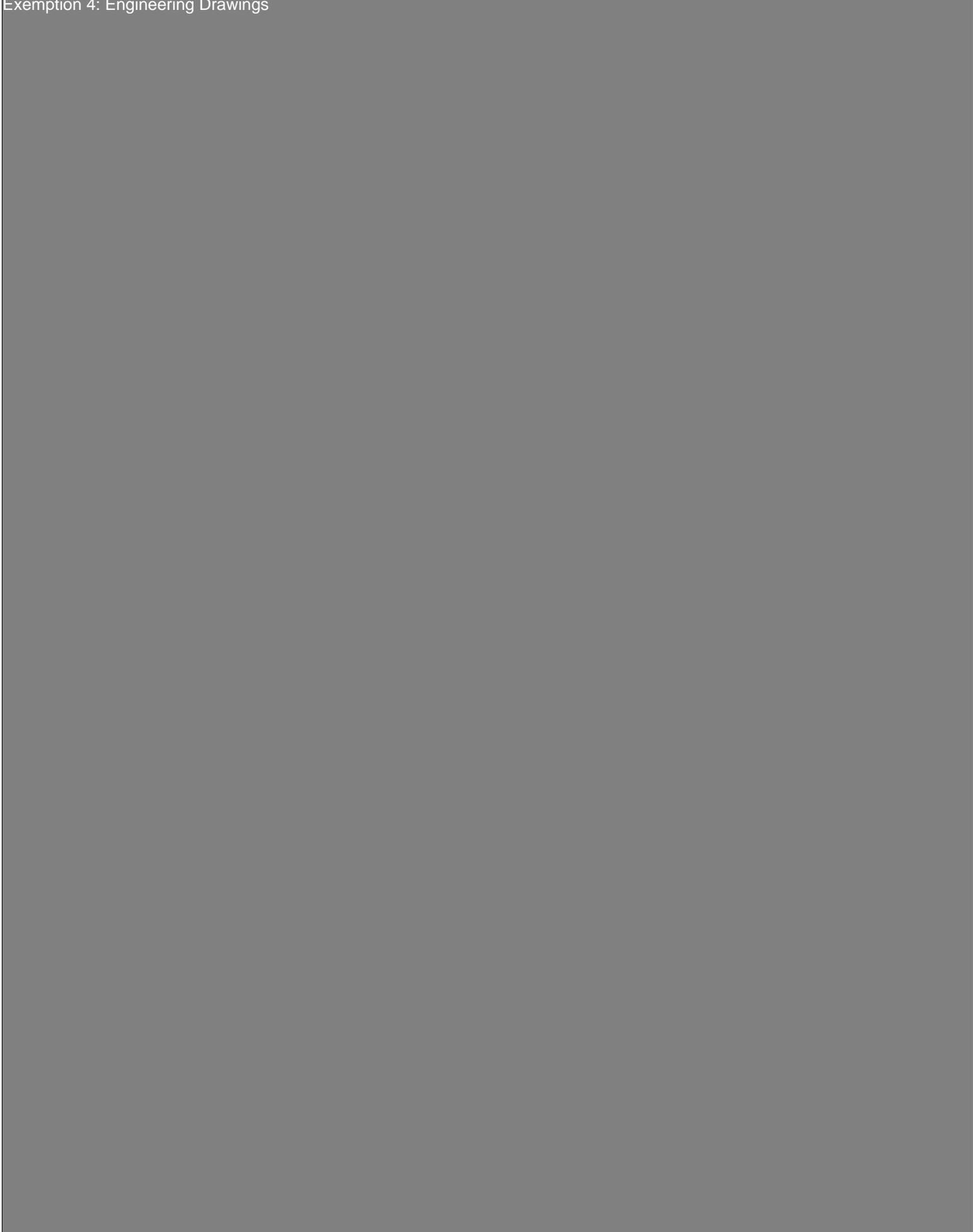


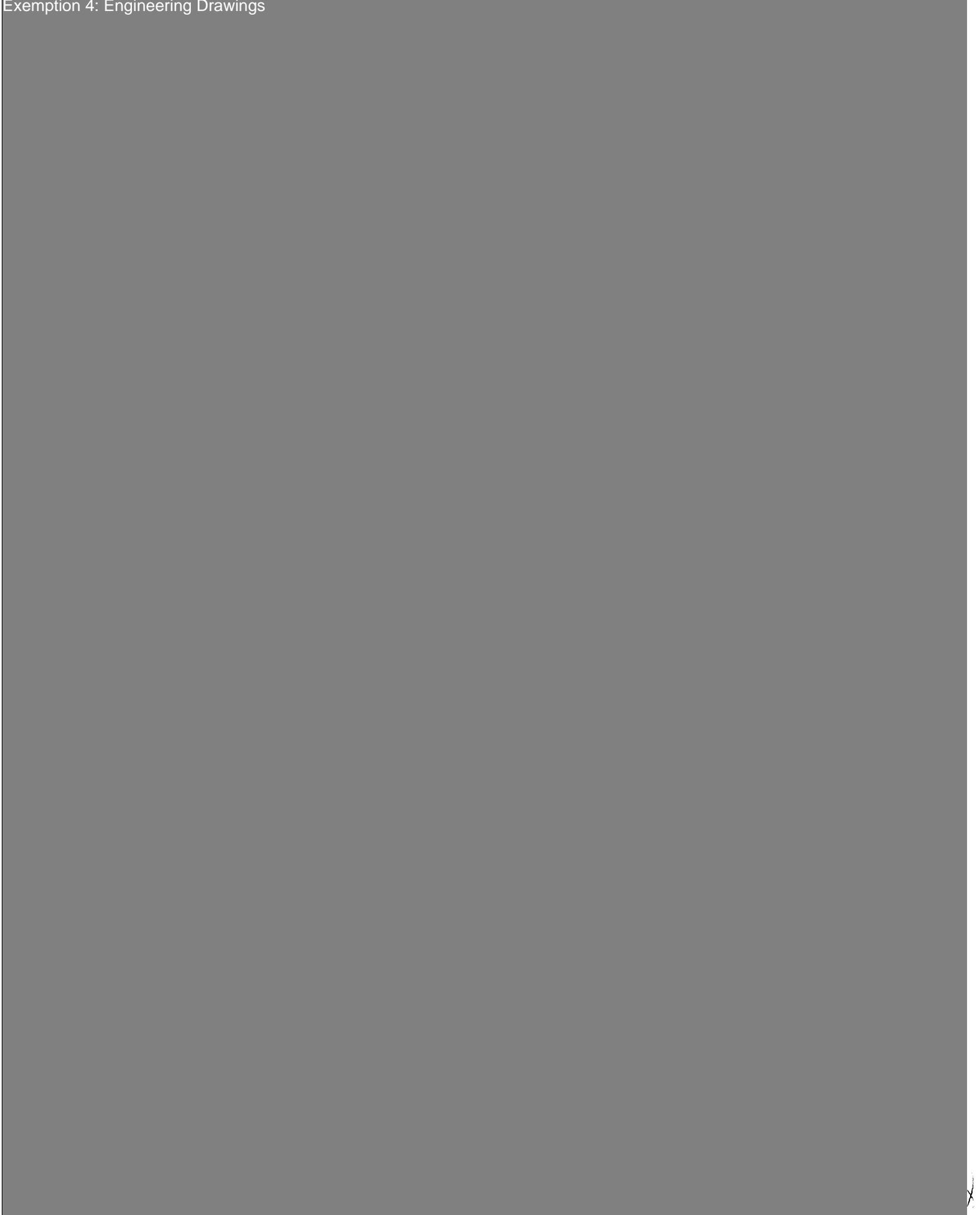




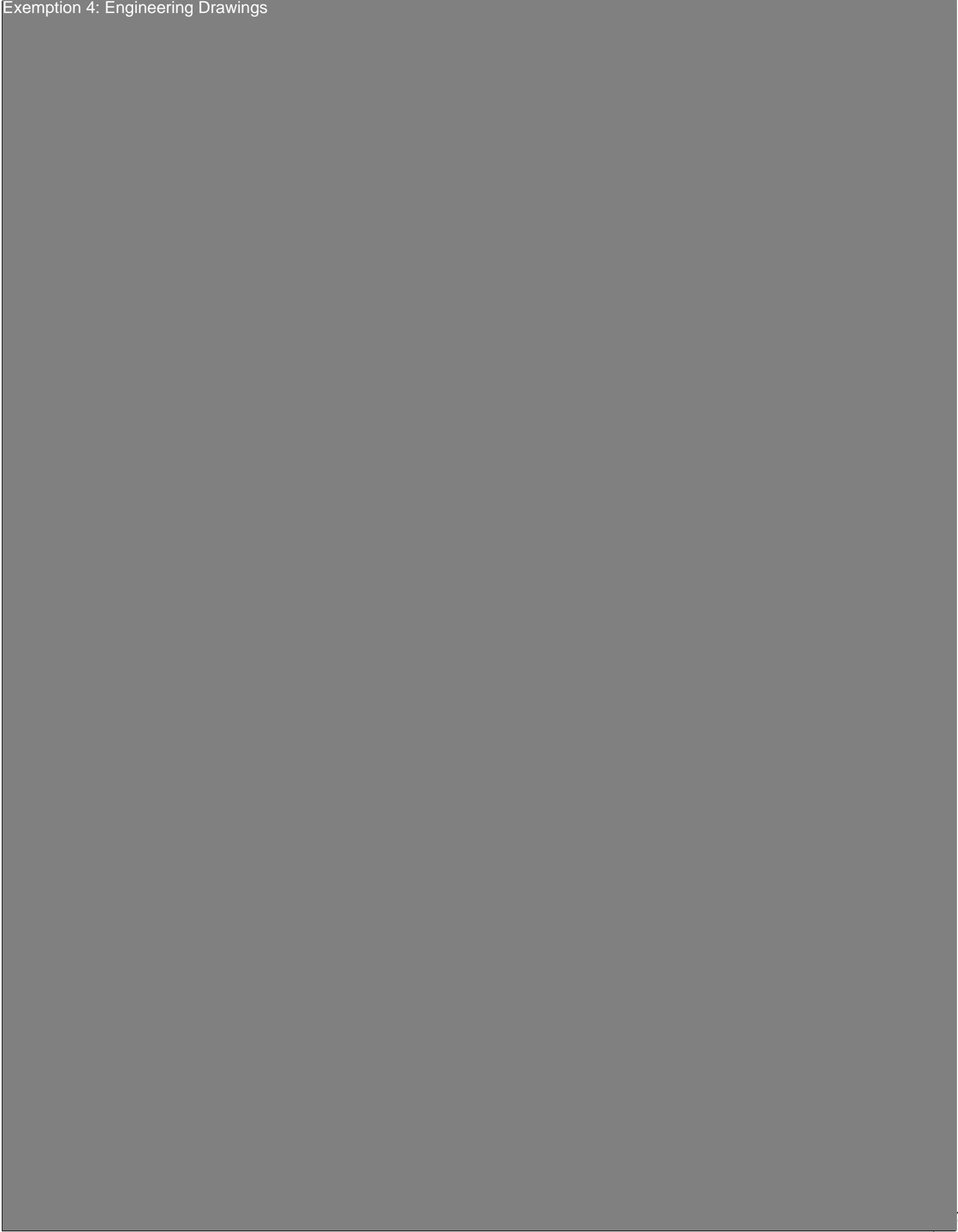




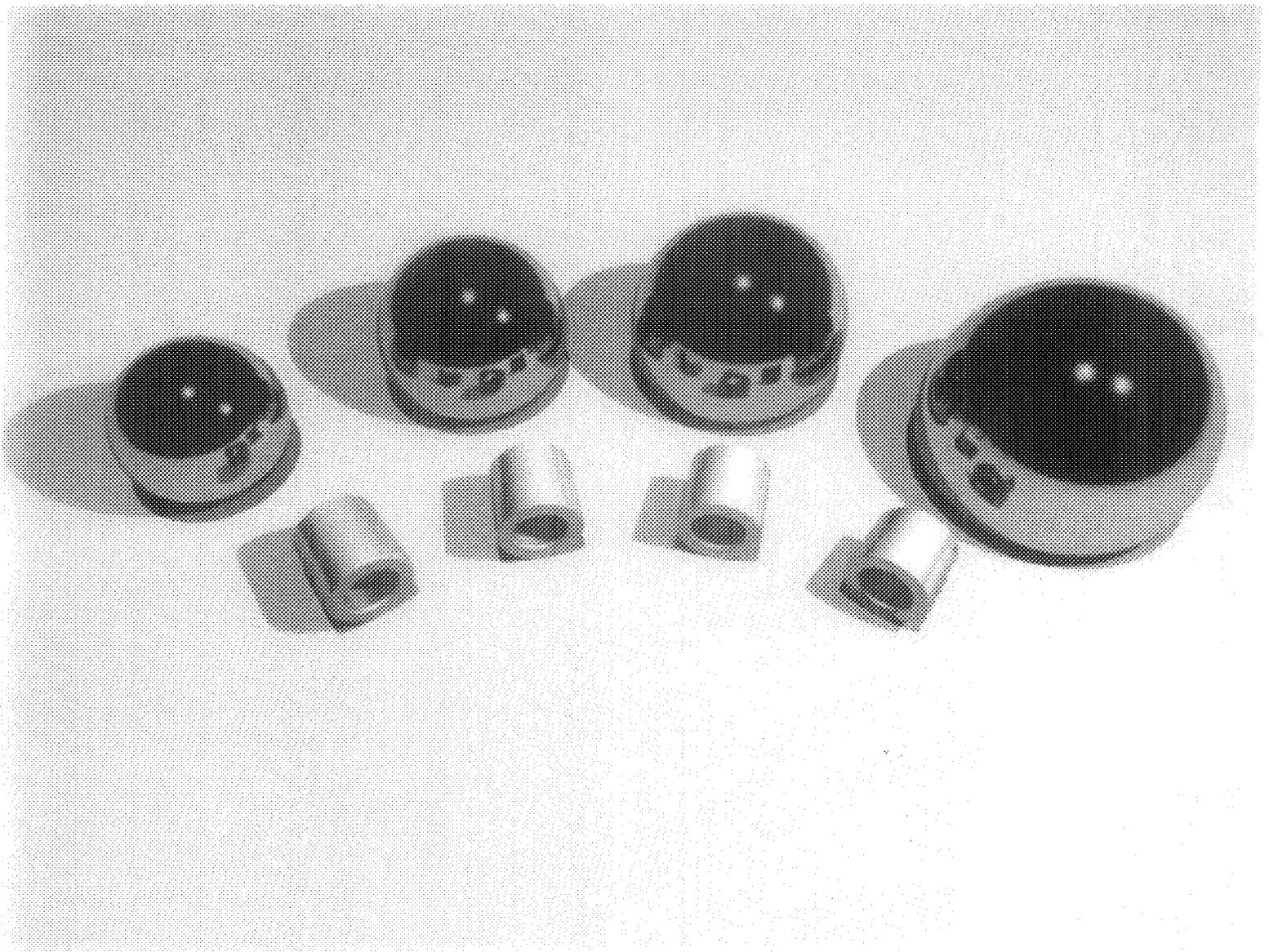




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EXHIBIT IV

Engineering Justification and Structural Analysis on the ULTIMA* Unipolar Head and Adapter Sleeves

Engineering Justification on the ULTIMA* Unipolar Head and Adapter Sleeves



ENGINEERING JUSTIFICATION:

ULTIMA Unipolar Head and Adapter Sleeves

OUTLINE

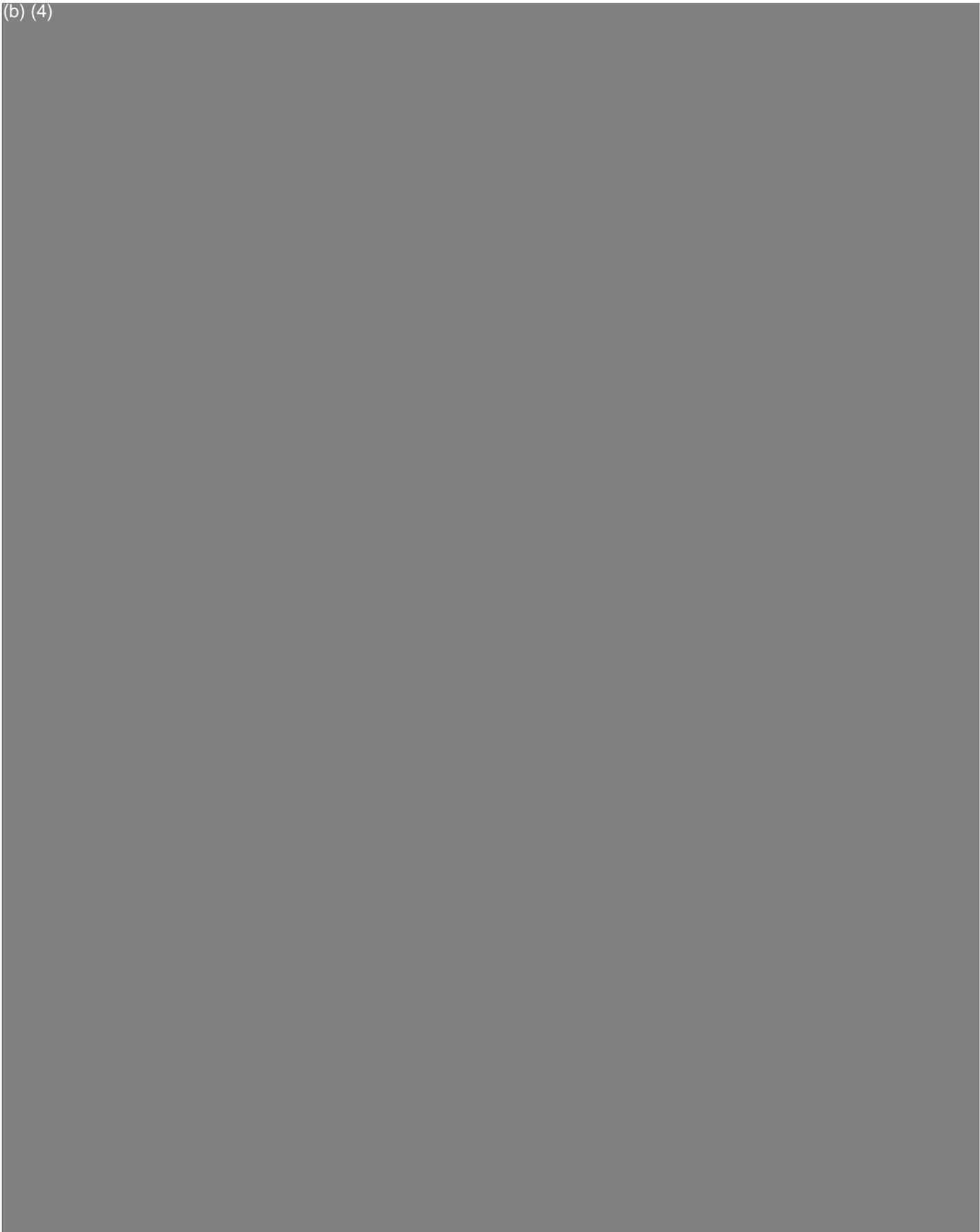
- I. Mechanical integrity of hollow heads ($\text{\O}44\text{mm}$ - $\text{\O}63\text{mm}$)
- II. Mechanical integrity of solid heads ($\text{\O}38\text{mm}$ - $\text{\O}43\text{mm}$)
- III. Mechanical integrity of adapter sleeves
- IV. Pull-off strength
- V. Fretting and Corrosion

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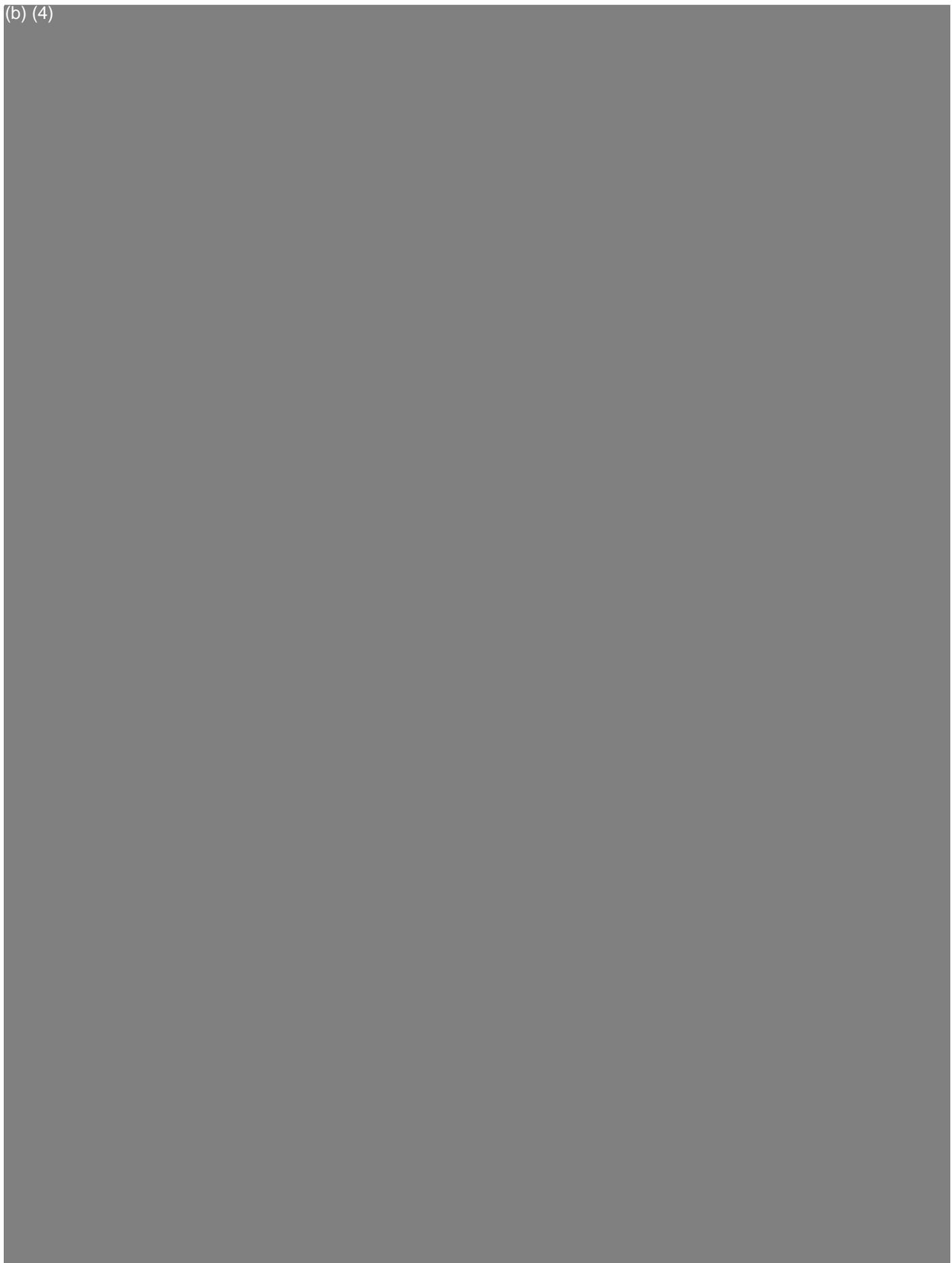
I. Mechanical integrity of hollow heads (Ø44mm - Ø63mm)

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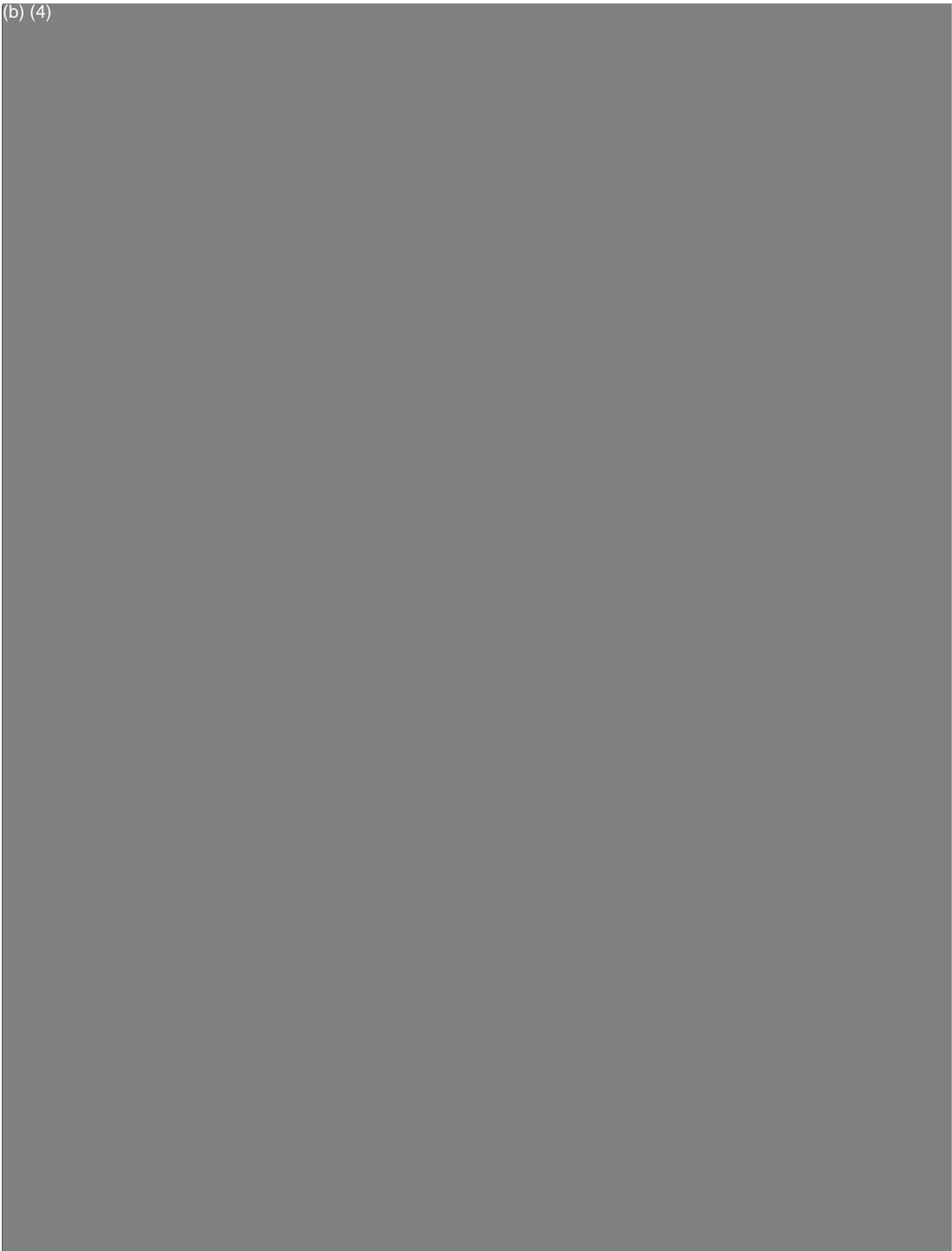
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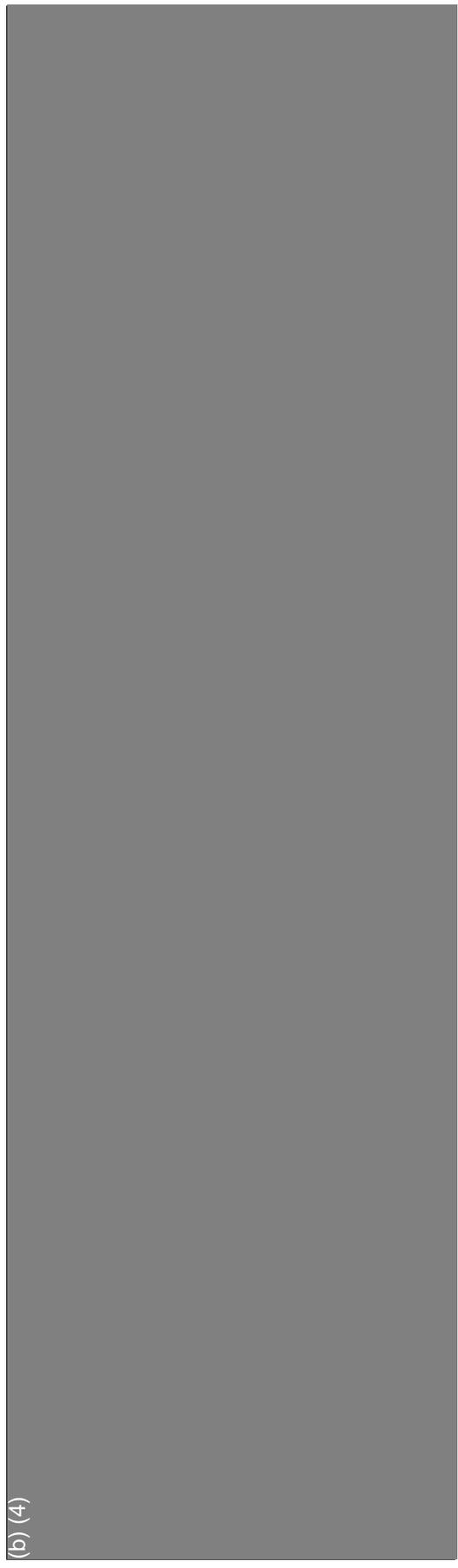
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FIG. 2: 10/12 TAPER ADAPTER SLEEVES AND FEMORAL NECK TRUNIONS ASSEMBLED

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FIG. 3: 11/13 TAPER ADAPTER SLEEVES
AND FEMORAL NECK TRUNION ASSEMBLED

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FIG. 4: 12/14 TAPER ADAPTER SLEEVES
AND FEMORAL NECK TRUNION ASSEMBLED

FIG. 4

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**ULTIMA* Unipolar Head and Adapter Sleeves
Structural Analysis Report**

Head Size - 44mm Diameter

CONFIDENTIAL

Johnson & Johnson

ORTHOPAEDICS

STRUCTURAL ANALYSIS REPORT

Title: Analysis of Ultima Modular UniPolar Head Size 44mm DIA. subject to ISO7206:5 Static Loading.

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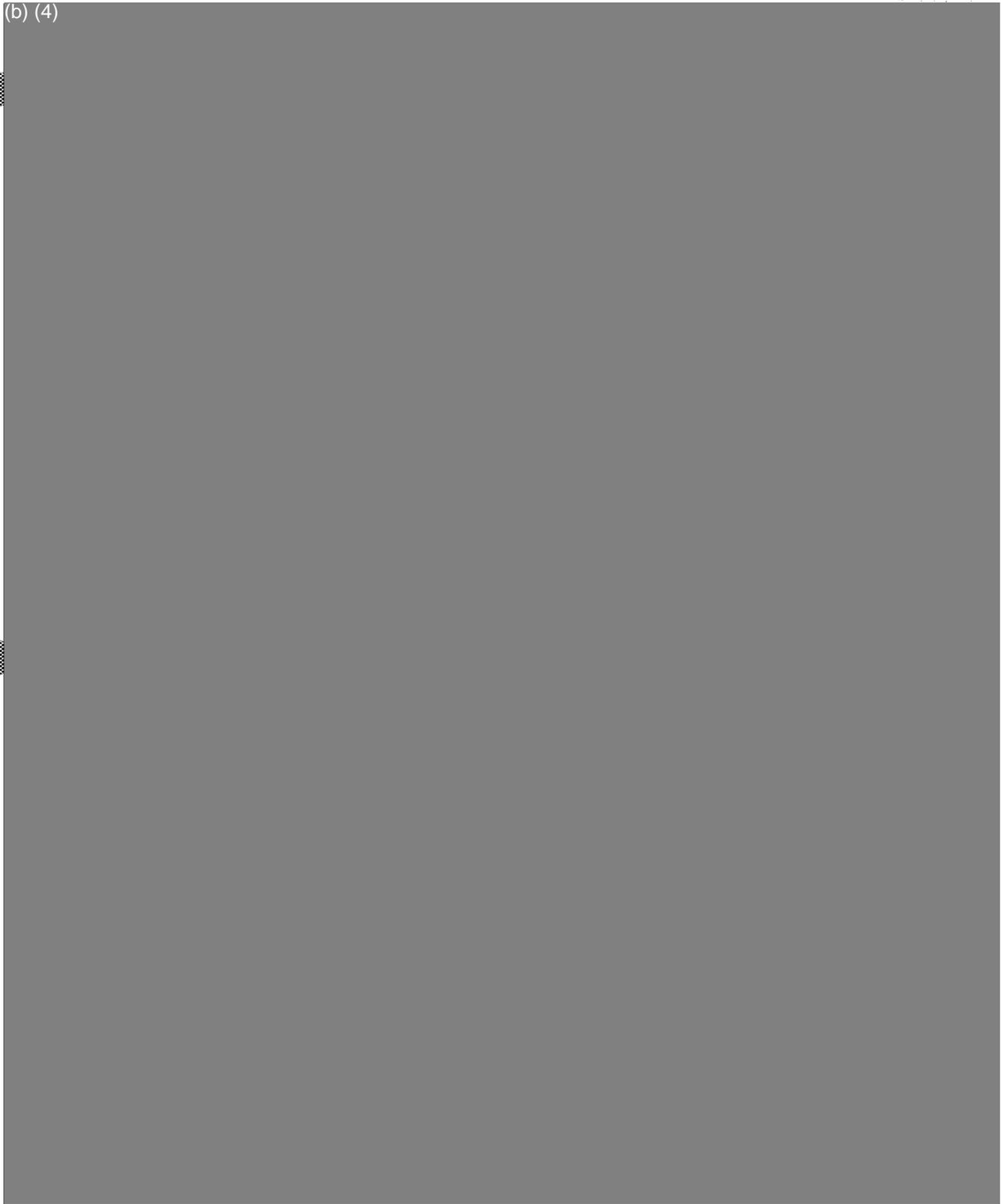
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**ULTIMA* Unipolar Head and Adapter Sleeves
Structural Analysis Report**

Head Size - 63mm Diameter

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Johnson & Johnson ORTHOPAEDICS

STRUCTURAL ANALYSIS REPORT

Title: **Analysis of Ultima Modular UniPolar Head Size 63mm DIA, subject to ISO7206:5 Static Loading.**

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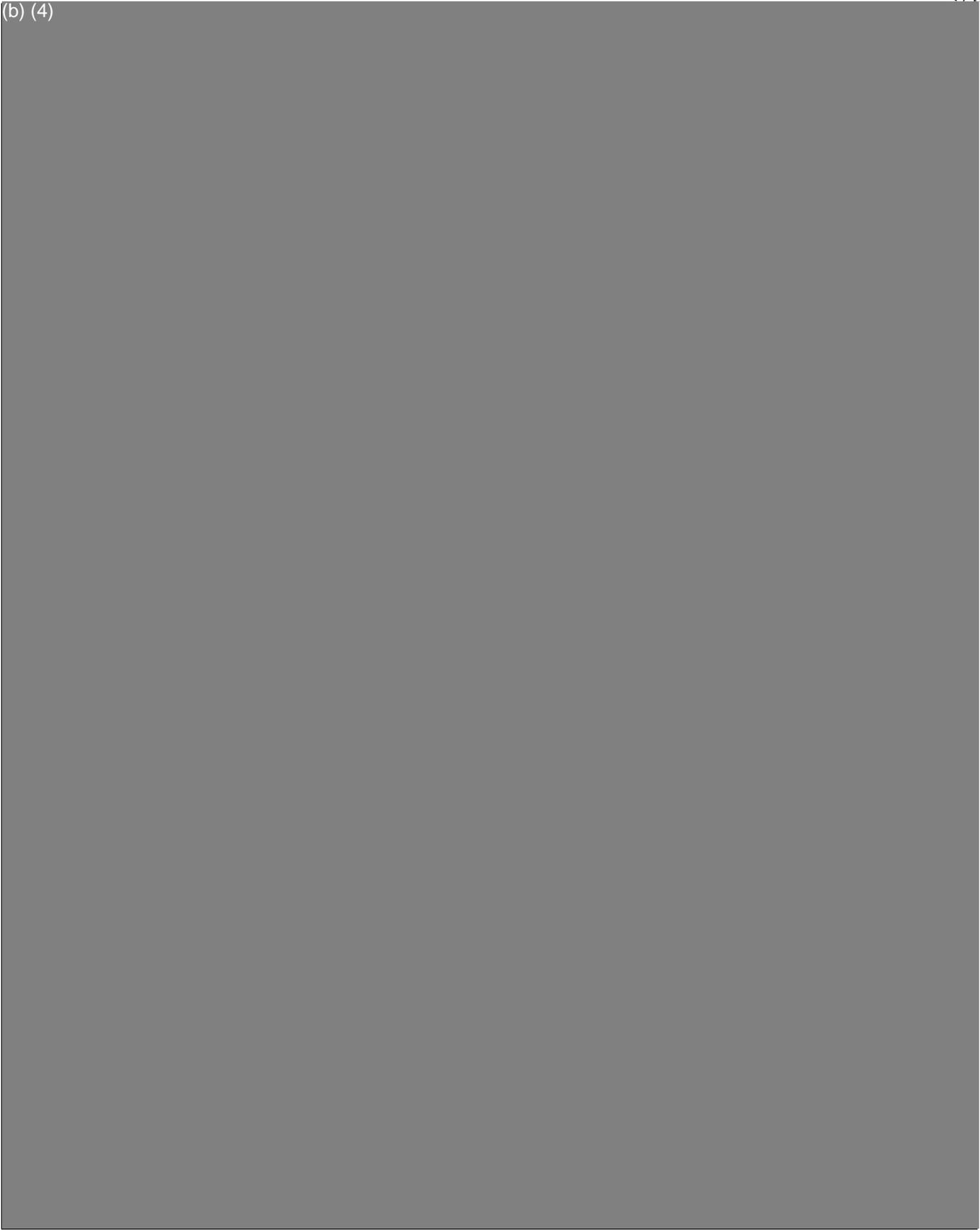


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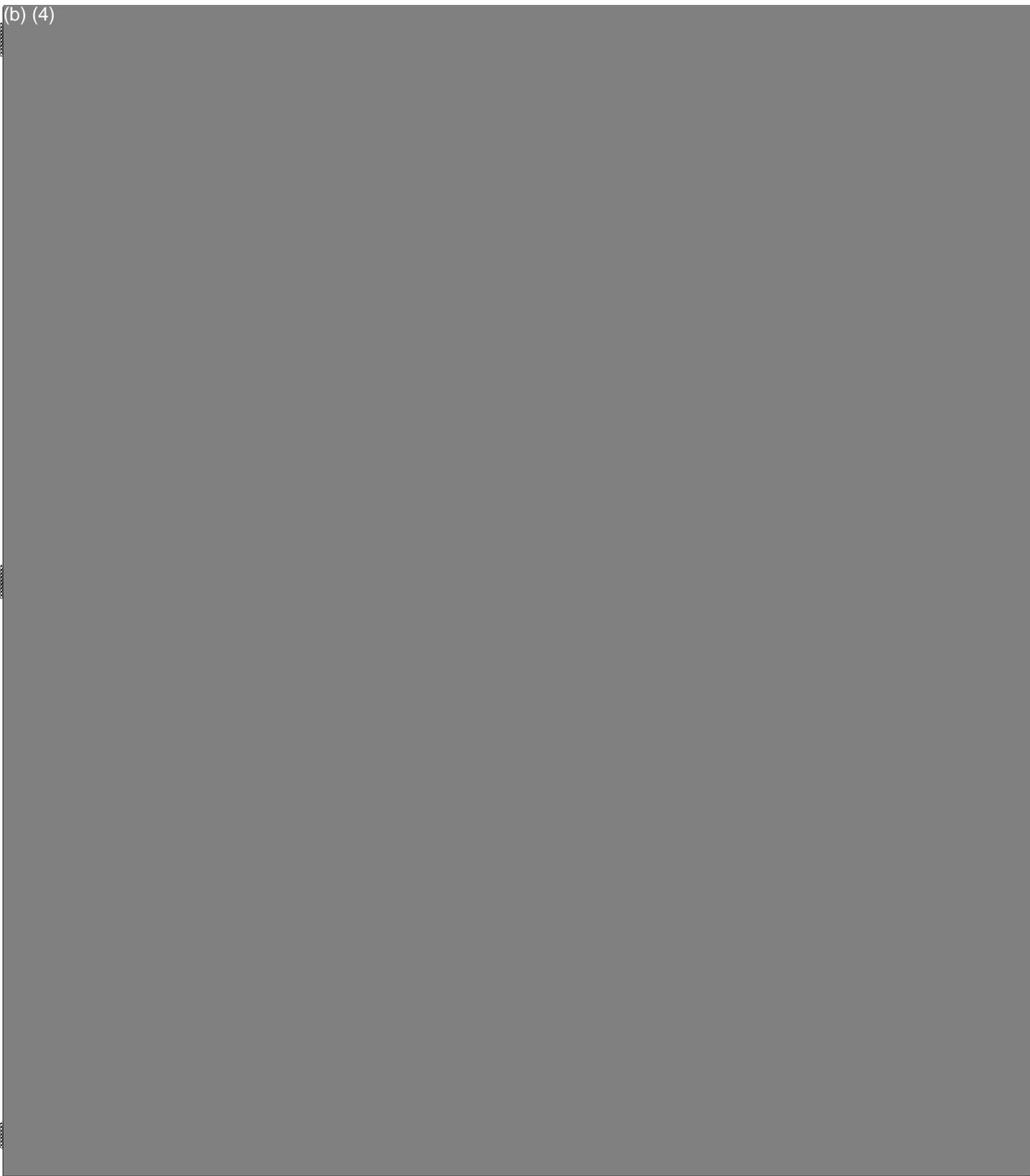


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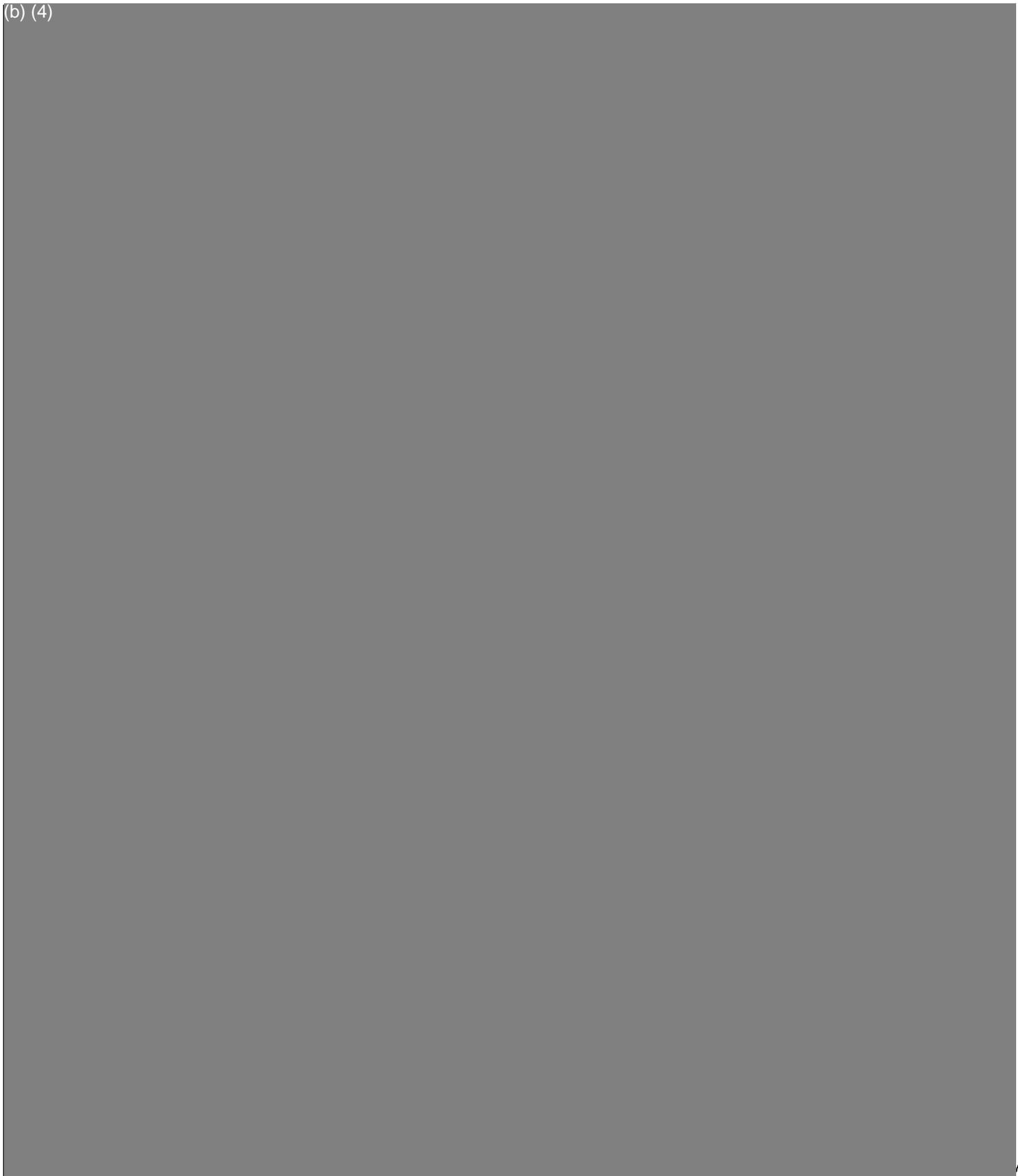
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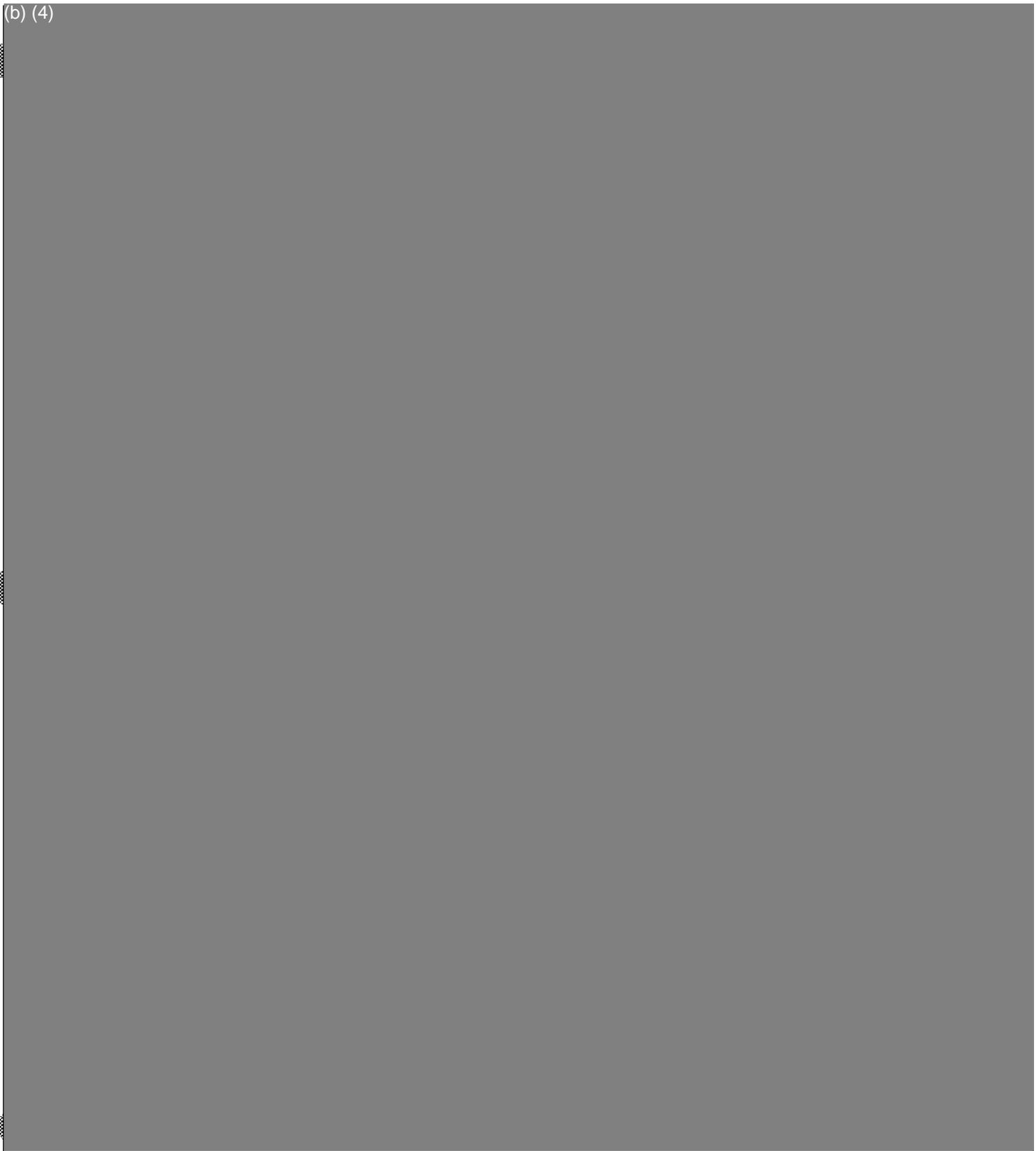
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EXHIBIT V

Predicate Device Information

Howmedica Untrax Unipolar System

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Howmedica

UNIPOLAR HEAD COMPONENT
AVAILABLE IN 20 SIZES,
38mm-62mm

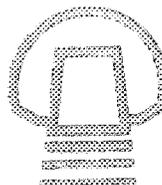
4 SLEEVE SIZES (-4mm, Std., +8mm, +10mm)
ALLOW NECK LENGTH ADJUSTMENTS
WITH INDEPENDENT SIZING
OF ACETABULUM AND FEMUR

COMPATIBLE WITH
ALL HOWMEDICA®
TRIMMER NECK
FEMORAL STEM
COMPONENTS

TAPER LOCKING
PROVIDES BASE OF ASSEMBLY
W/ METAL-TO-METAL
COLD-WELD SECURITY

Organized
Options

UNITRAX
UNIPOLAR SYSTEM



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UNITRAX

UNIPOLAR SYSTEM



Organized Options

The Howmedica® Unifrax System provides an organized package of the options expected by surgeons in the 1990's for modern endoprosthesis surgery.

Through the use of Modular Neck Adjustment Sleeves that interface between the Unifrax heads and any Howmedica® triunion-neck femoral stem components, the Unifrax Unipolar System offers the surgeon options that were once available only in total hip systems:

- Independent sizing of the acetabulum and the femur
- Re-establishment of proper joint biomechanics
- Revision without stem removal

Four Neck Adjustment Sleeves/ Twenty Modular Heads

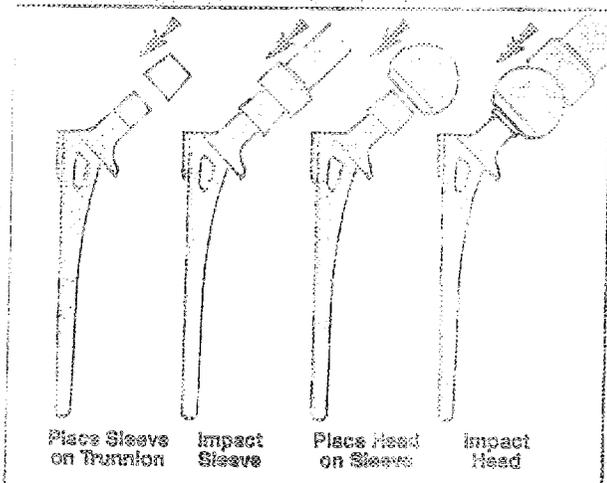
NO other modular endoprosthesis system has such a comprehensive range of neck-length and head-size options.

— 4mm Neck Adjustment Sleeve

Quite commonly, the endoprosthesis patient is an elderly, osteoporotic one with smaller anatomic features. This Howmedica® Unifrax System—unlike any other modular endo system—provides the surgeon with a 4mm Neck Adjustment Sleeve. This option allows the surgeon to re-establish the anatomy of the smaller endoprosthesis patient.

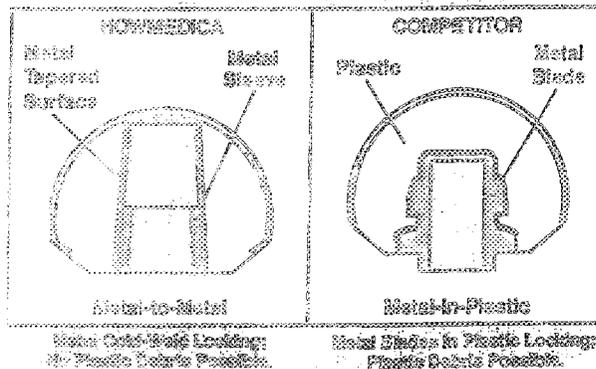
Quick, Secure, Proven Component Locking

Through the use of locking tapers, metal blows instantly cold weld the metal surfaces of the neck, sleeve, and head. This mechanism is designed to assure the surgeon of a lock which is able to resist the significant rotational forces of the hip.



Metal blows instantly cold weld the metal surfaces of the neck, sleeve, and head.

Howmedica's metal-to-metal locking mechanism cannot produce plastic debris. This is distinctly different from the competitive design that is assembled by forcing a locking sleeve with metal blades into the plastic core of the eric head. Metal blades in plastic could produce plastic debris. Howmedica's all-metal taper lock holds no such unfortunate possibility.

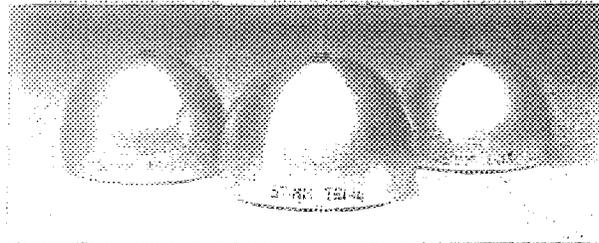


Organized, Modular System Reduces Hospital Storage Space Requirements

While providing an extensive number of implant size options, the Unifrax System significantly decreases the storage space required with traditional fixed-head endo systems. More shelf organization and less inventory space are immediate benefits for the Unifrax hospital.

Modern, Easily Read Trial System

The Unifrax System employs its own neck sleeve trials and the clearly marked, metal Centrax Bipolar System® trials. The Centrax trials allow the surgeon to do a full trial reduction in both bipolar and unipolar procedures. The Unifrax System provides the surgeon with the trial components that maximize the ease, organization, and effectiveness of modern endoprosthesis surgery.



Centrax Bipolar System Metal Trials

Howmedica

Your orthopedic resource

359 Vearens Boulevard
Rutherford, New Jersey 07070-2564
In Canada: Pfizer Hospital Products Ltd.

Division of Pfizer Hospital Products Group, Inc.

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Howmedica is a Registered Trademark of Pfizer Hospital Products Group, Inc.
U.S. Patent Nos. 4,782,881 and 4,784,882.

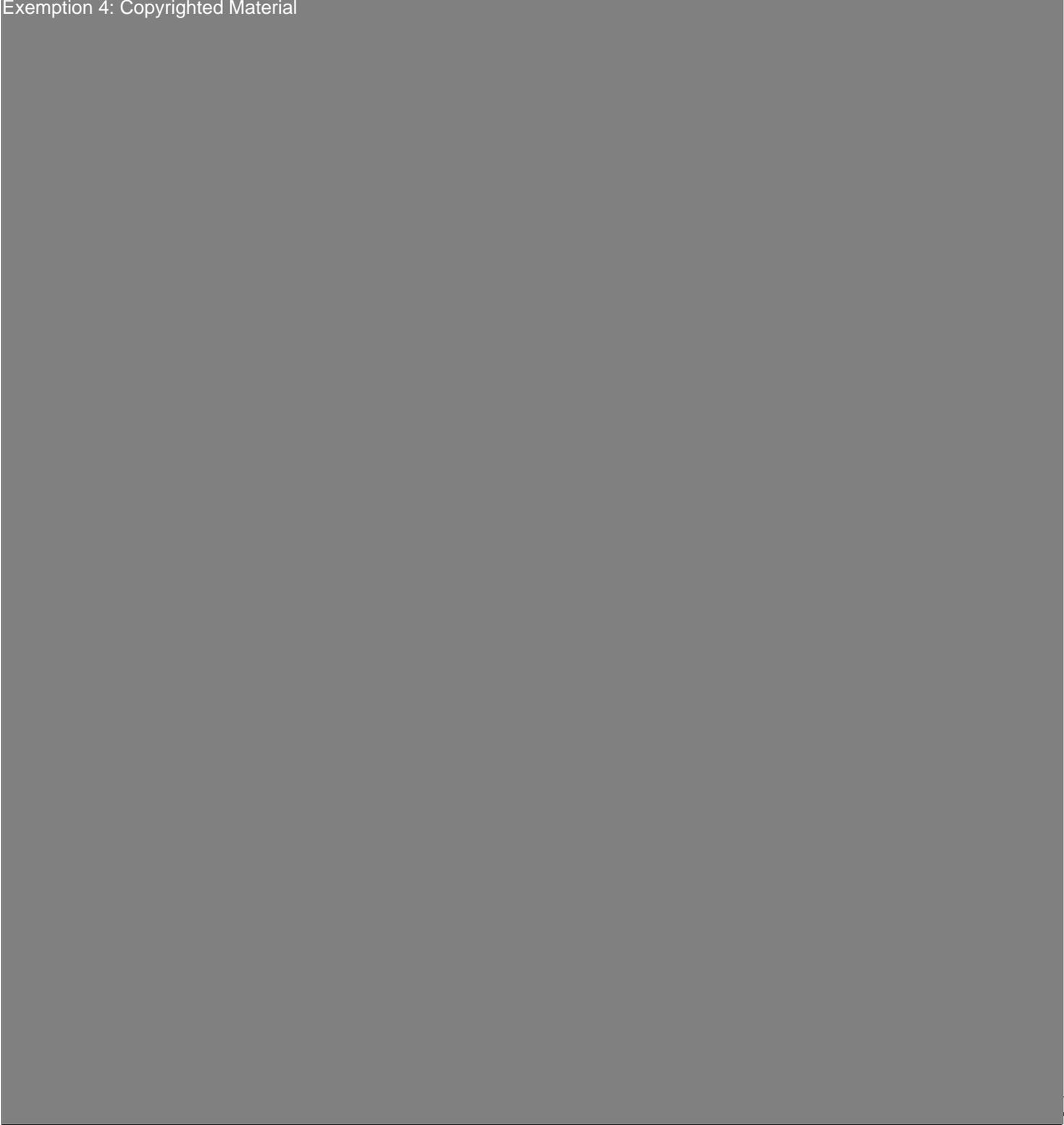
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EXHIBIT VI
Scientific Articles

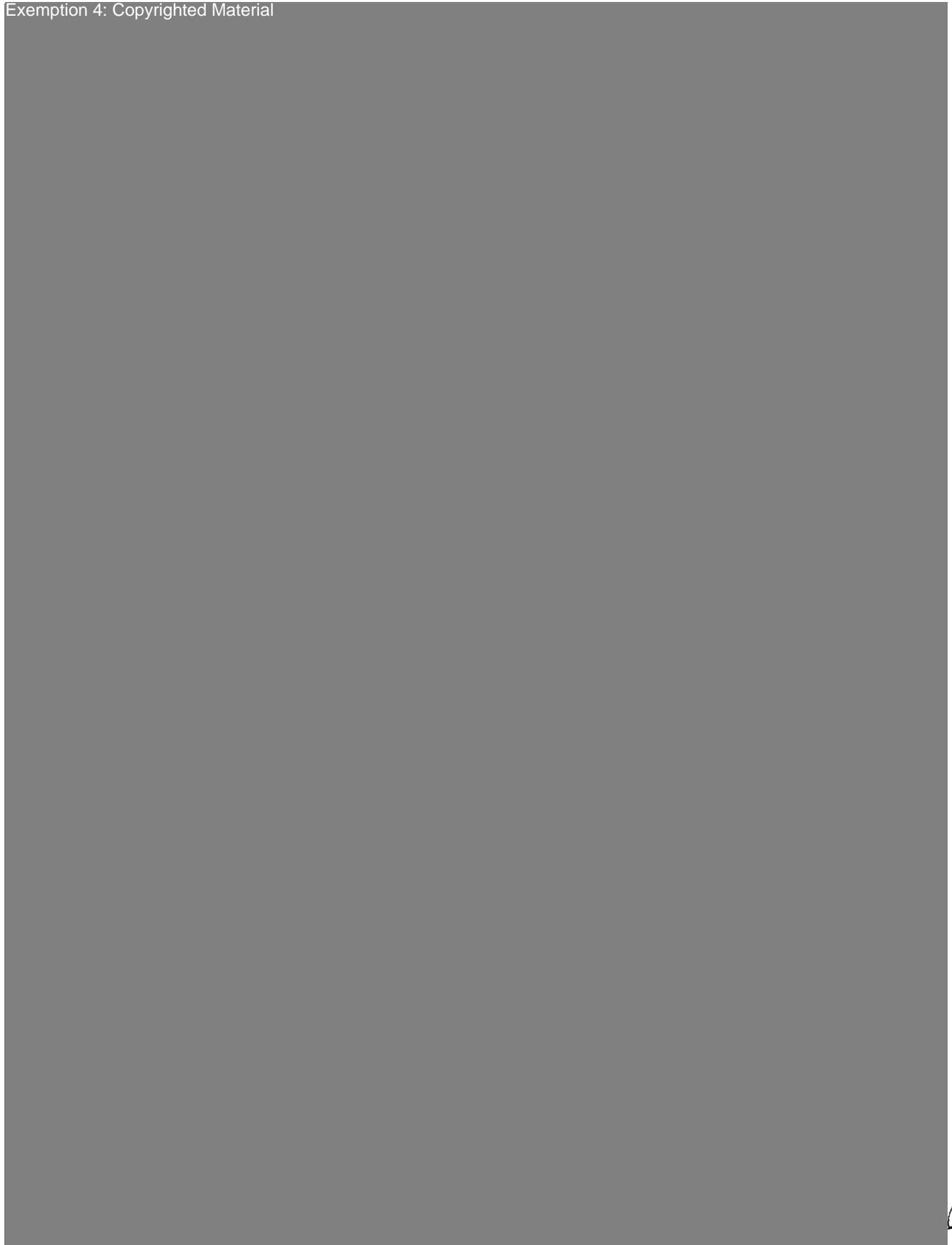


Mixed-metal fretting corrosion of Ti6Al4V and wrought cobalt alloy

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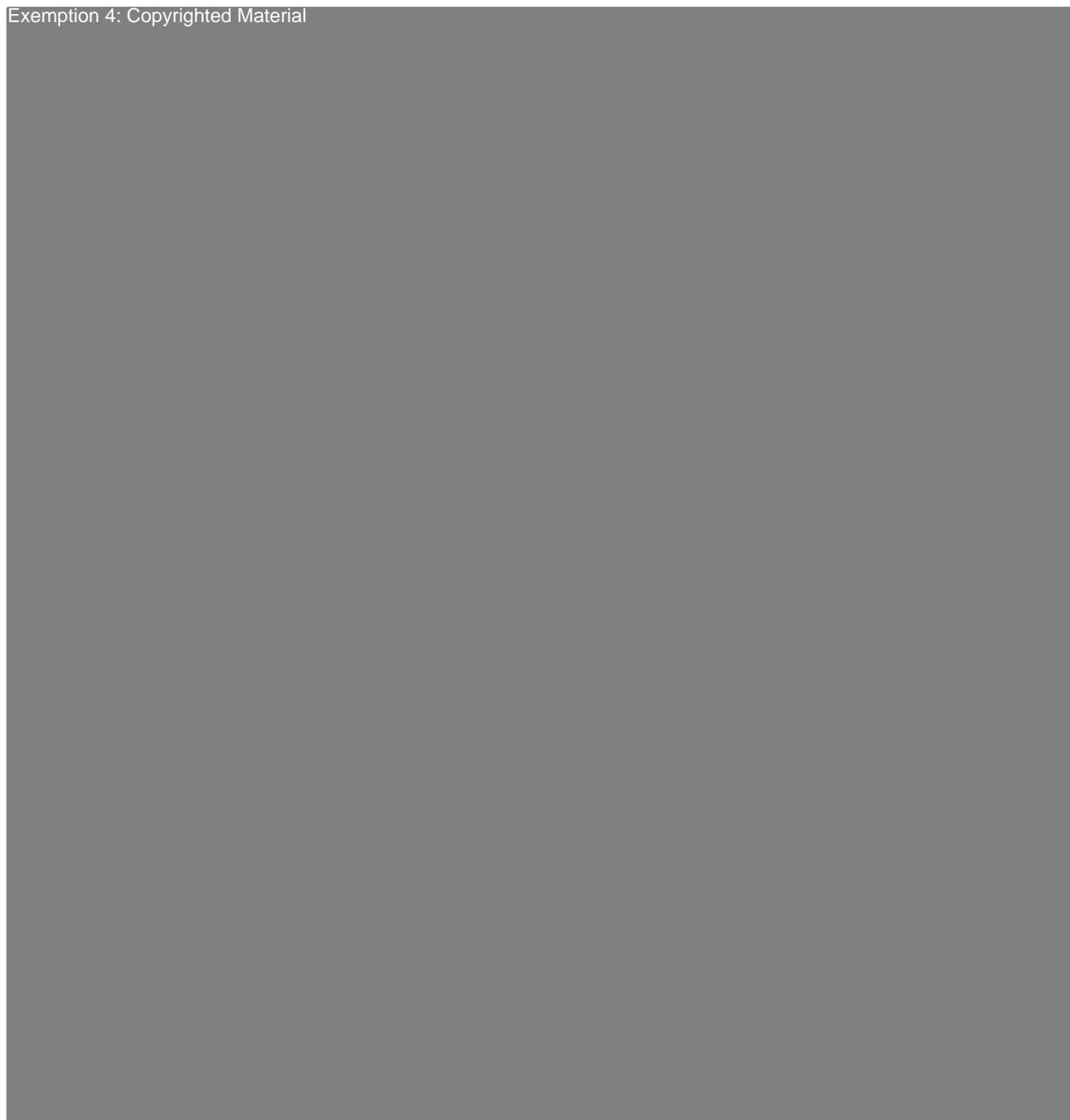
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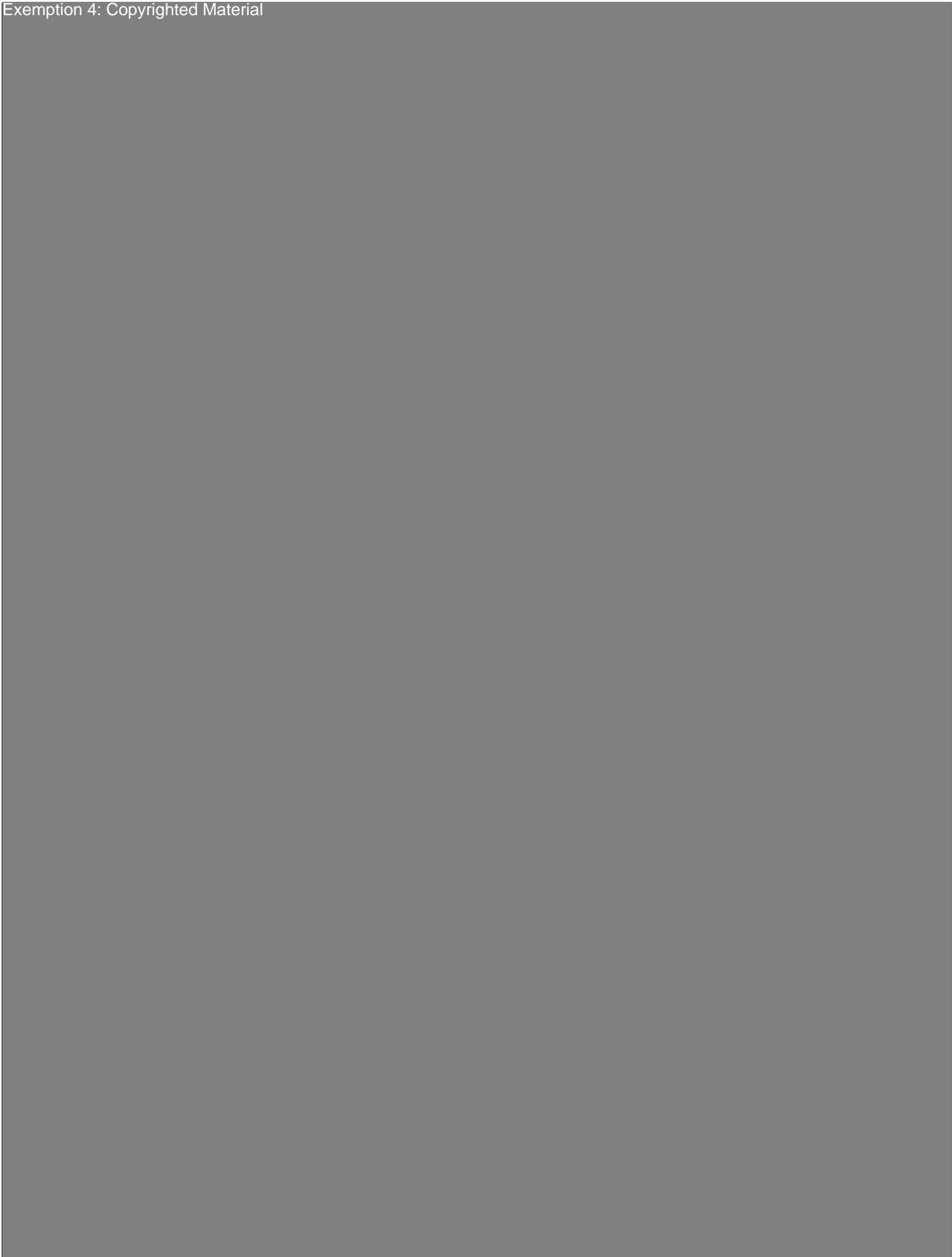
Fretting Corrosion Accelerates Crevice Corrosion of Modular Hip Tapers

S. A. Brown,* C. A. C. Flemming,* J. S. Kawalec,* H. E. Placko,* C. Vassaux,* K. Merritt,* J. H. Payer,[†]
and M. J. Kraay[‡]

Departments of *Biomedical Engineering, †Materials Science and Engineering, and ‡Orthopaedics, Case Western Reserve University, Cleveland, Ohio

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The Tradeoffs Associated With Modular Hip Prostheses

John P. Collier, DE; Michael B. Mayor, MD**;
Ian R. Williams, BA*; Victor A. Surprenant, BA*;
Helene P. Surprenant*; and Barbara H. Currier**

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