DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB - 3 1989

Mr. Henry A. Quello
Regulatory Affairs
Zimmer
P.O. Box 708
Warsaw, Indiana 46580-0708

Re: K883665
Coonrad III Total Elbow
Regulatory Class: III
Dated: December 6, 1988
Received: December 14, 1988

Dear Mr. Quello:

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 to devices marketed in interstate commerce prior to May 28, 1976. This decision is based on porous-coated devices being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.

2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) 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. 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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan for CAL

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

FEB - 3 198

Mr. Henry A. Quello
Regulatory Affairs
Zimmer
P.O. Box 708
Warsaw, Indiana 46580-0708

Re: K883665
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Regulatory Class: III
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Sincerely yours,

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

cc:
HFZ-401 DMC
HFZ-410 DSRD
f/t:HFZ-410/BHastings/mb/1/31/89

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
410	Walker	2/1/89	410	Callahan	2/2/89			
410	McGuigan	2/2/89						

4

*U.S. GPO: 1988-210-708

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Baz Hastings

Subject 510(k) NOTIFICATION K883665/A

To THE RECORD

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

✓ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

_____ (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments: SE for cemented use only! 7° retroversion. CP titanium plasma spray coating. See attached memo for more information

BH 1/27/89

The submitter requests:

[redacted] No Confidentiality

✓ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

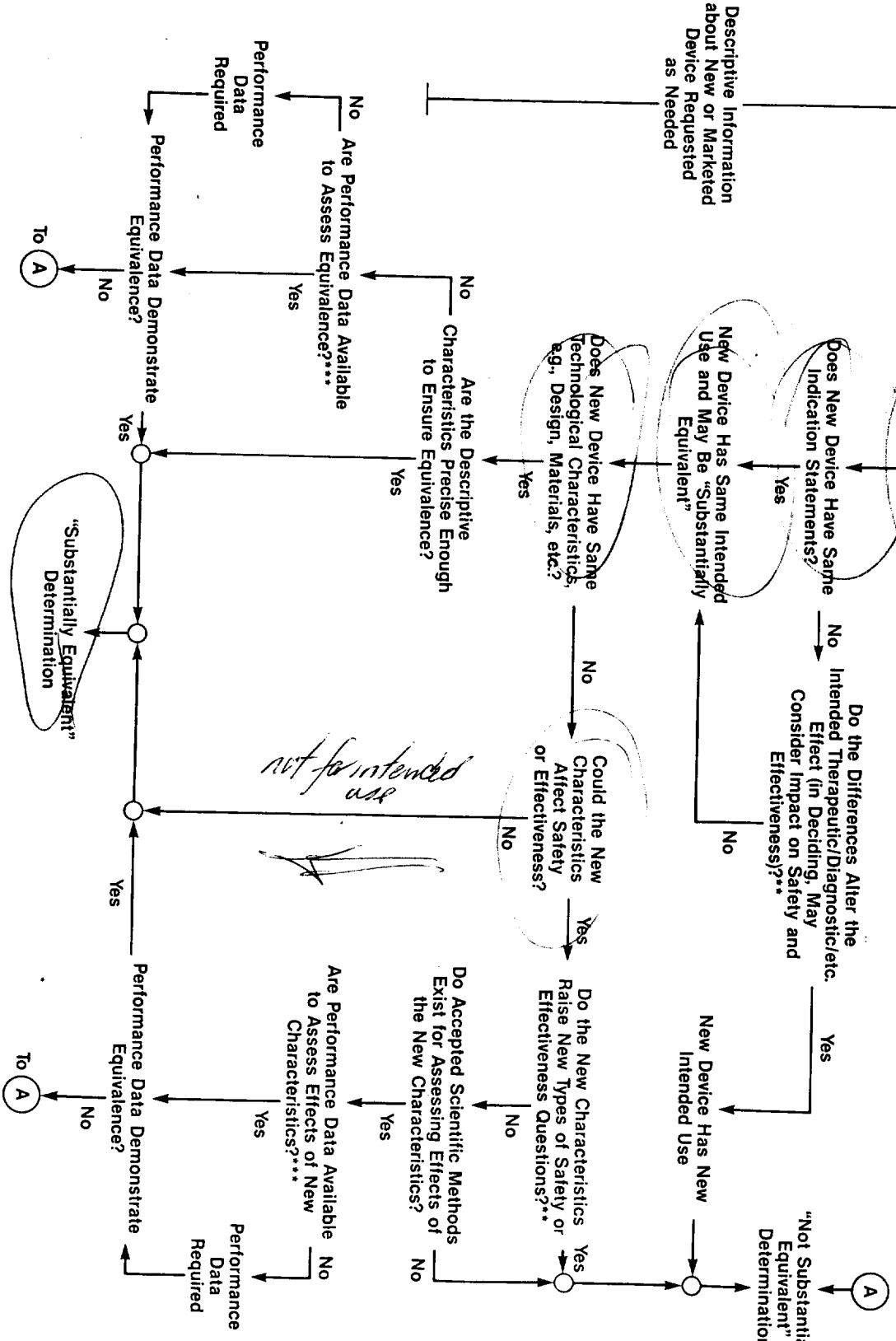
Class Code w/Panel: JDC/87 class III constrained cemented elbow prosthesis 888.3150

REVIEW: Daniel S. McGeough 2/2/89
(BRANCH CHIEF) (DATE)

FINAL REVIEW: T. J. Callahan for CDRL 2/2/89
(DIVISION DIRECTOR) (DATE)

5/

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.

M-E-M-O-R-A-N-D-U-M

TO: FILE
DATE: 01/26/89
FROM: BOB HASTINGS/BIOMED. ENGR.
DSRD, ORTHOPAEDICS

SUBJECT: COONRAD III TOTAL ELBOW
ZIMMER, MAX SHERMAN (219) 267-6131

D.C.#: K883665

RECOMMENDATION

This device should be determined substantially equivalent to the original Coonrad device which is a preamendment device. Some modifications were made to the original device and marketed as the Coonrad II device. There has never been a premarket notification submitted for the Coonrad II device. The Coonrad III device is classified as class III with three letter code JDC this can be tied back to the regulations 888.3150.

REVIEW

Description of device:

There are six components to this device. The humeral and ulnar components, one hinge pin, two UHMWPE bushings which have flanges, one UHMWPE cylindrical bushing and a lock ring.

There have been a few modifications since the introduction of the Coonrad II device (the Coonrad II device was introduced in 1978-1979 with no premarket notification). These include the addition of the anterior flange to the humeral component and addition of plasma spray surface to the distal humeral component and the proximal ulnar component.

The humeral and ulnar components are mfg from forged TIVANIUM and the plasma spray is commercially pure titanium. The pin and locking ring are mfg from TIVANIUM.

From references:

Typical indications for elbow arthroplasty include:
Rheumatoid arthritis, degenerative arthrosis, traumatic arthrosis, bone stock loss, and failed arthroplasty.

Typical contraindications include:
Infection,other than sedentary life, ankylosis of the shoulder, and neurotrophic joints.

Complications may include:
Triceps rupture, attenuation, or deficiency from scarring is

probably more common than reported. Thin tissue over the posterior elbow makes subsequent reinforcement by tendon transfers difficult and facia lata grafting has not been routinely successful. Where the humeral epicondyles are absent, long-term results with many prostheses have not been as reliable.

Asher (1973) found that there could be a load of approximately 2.6xBW transmitted across the elbow during lifting. Hui found that forces are greater in extension than flexion and that large shearing and torsional moments occur. The greatest force component at the distal humerus is in the posterior direction. This tends to cause an anterior tilt of the proximal stem of the humeral component with possible bony resorption of the anterior humeral cortex.

The locus of the instant center of rotation of the elbow is located in the center of the Trochlear, in line with the anterior cortex of the humerus but is constantly changing with rotation of the long axis of the ulna during passive motion.

60% of the transmitted force across the elbow joint from the hand passes across the capitellar-radial portion of the joint.
In the early 1970's there was a 25% loosening rate for elbow arthroplasty.

A few preamendment devices are reviewed here:

The Mayo Clinic Design (Howmedica, 1972)

This design consisted of a loose snap fitting hinged ulnohumeral component and a varying sized radial head component. The two stems of the ulnohumeral component were metallic and the radial component was solid UHMWPE. The bushing in the snap fitting hinge of the ulnohumeral component was UHMWPE. The ulnohumeral component was implanted with bone cement and the radial component may have been implanted with or without cement (it is not clear if the radial component was implanted with cement). Briefly, in a five year follow-up of 53 patients there was a 12% loosening rate.

The Pritchard-Walker design (DePuy, 1974)

This design consisted of a hinged metal to UHMWPE joint. The looseness in the hinge allowed 5-7 degrees of mediolateral and rotary laxity. The original design had a solid UHMWPE humeral stem. Due to reports of breakage of 2 stems the design was changed to a metal stem with a UHMWPE bearing.

The Coonrad design (Zimmer, 1973)

This design consisted of a metal to UHMWPE hinge. The joint laxity side-to-side and rotary direction was increased from 2-3 degrees to approximately 7 degrees in 1978-1979 (this was the Coonrad II design). This device had large titanium metal stems and was implanted with bone cement. A long stem was added in 1977. 84-95% satisfactory results.
B.F. Morrey (1987) stated that in 1981, the Coonrad II device was modified

by adding a flange on the anterior aspect of the distal part of the humeral component, together with a plasma spray that provided the potential for biological fixation.

The Volz design (Zimmer, 1975)

This design consisted of a metal to UHMWPE hinge allowing 15 degrees of laxity and included a radial component (three components altogether). This device was first implanted in 1980.

The Triaxial HSS design (Codman, 1974)

This was a hinged design, metal polymer with a loose fit. Originally , this design consisted of a UHMWPE humeral stem which was later replaced with metal. 70-95% satisfactory results.

The Schlein design (Howmedica, 1974)

This design consisted of a small loose fitting hinge. Components were metal with a UHMWPE bushing. No good follow-up of clinical experience.

Ewald Design (Codman, 1974)

This design was nonconstrained consisting of a stemmed metal humeral component articulating with a UHMWPE ulnar shoe. Both components were implanted with bone cement. 87% satisfactory results reported although there is a potential for dislocation.

London design (Wright Dow Corning, 1976)

This design was nonconstrained resurfacing with a metal humeral component and a UHMWPE ulnar component.

Steven Street design (Zimmer, 1974)

This design was nonconstrained resurfacing. It was essentially a metal resurfacing device for the distal humerus. It had capitellar and trochlear contours.

1/25/89 Telecon with Dr. B.F. Morrey

Dr. B.F. Morrey has reported 6 cases of black synovitis for the Coonrad III device. He ~~believes~~ believes it is a result of the plasma spray coating. He made the suggestion to Zimmer to change this coating to Ti titanium beads. However, I would not expect black synovitis to occur in these patients with the cobalt implants with bone cement!

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

DECEMBER 14, 1988

ZIMMER
ATTN: HENRY A. QUELLO
P.O. BOX 708
WARSAW, IN 46580

D.C. Number : K883665
Received : 12-14-88
Product : COONRAD III TOTAL ELBOW

The additional information you have submitted has been received.

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

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

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

Sincerely yours,

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

K883665

December 6, 1988

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

Gentlemen:

SUBJECT: K883665, COONRAD III TOTAL ELBOW

This amendment is in response to Mr. Robert Hastings' telecon of November 22, regarding additional information.

a) Porous coating characterization:

(b) (4)

[redacted]

zimmer • P.O. Box 708 • Warsaw, IN 46580-0708 • 219-267-6131

(b) (4)

We consider the above information to be confidential and exempt from public disclosure.

b) Engineering drawing for one size prosthesis:

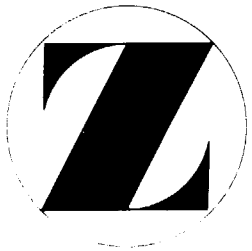
(b) (4)

c) Sizes available are:

Small left, humeral lengths 4", 6", 8"; ulnar length 3"
Small right, humeral lengths 4", 6", 8"; ulnar length 3"
Regular left, humeral lengths 4", 6", 8"; ulnar length 3.5"
Regular right, humeral lengths 4", 6", 8"; ulnar length 3.5"

d) Range of motion:

(b) (4)



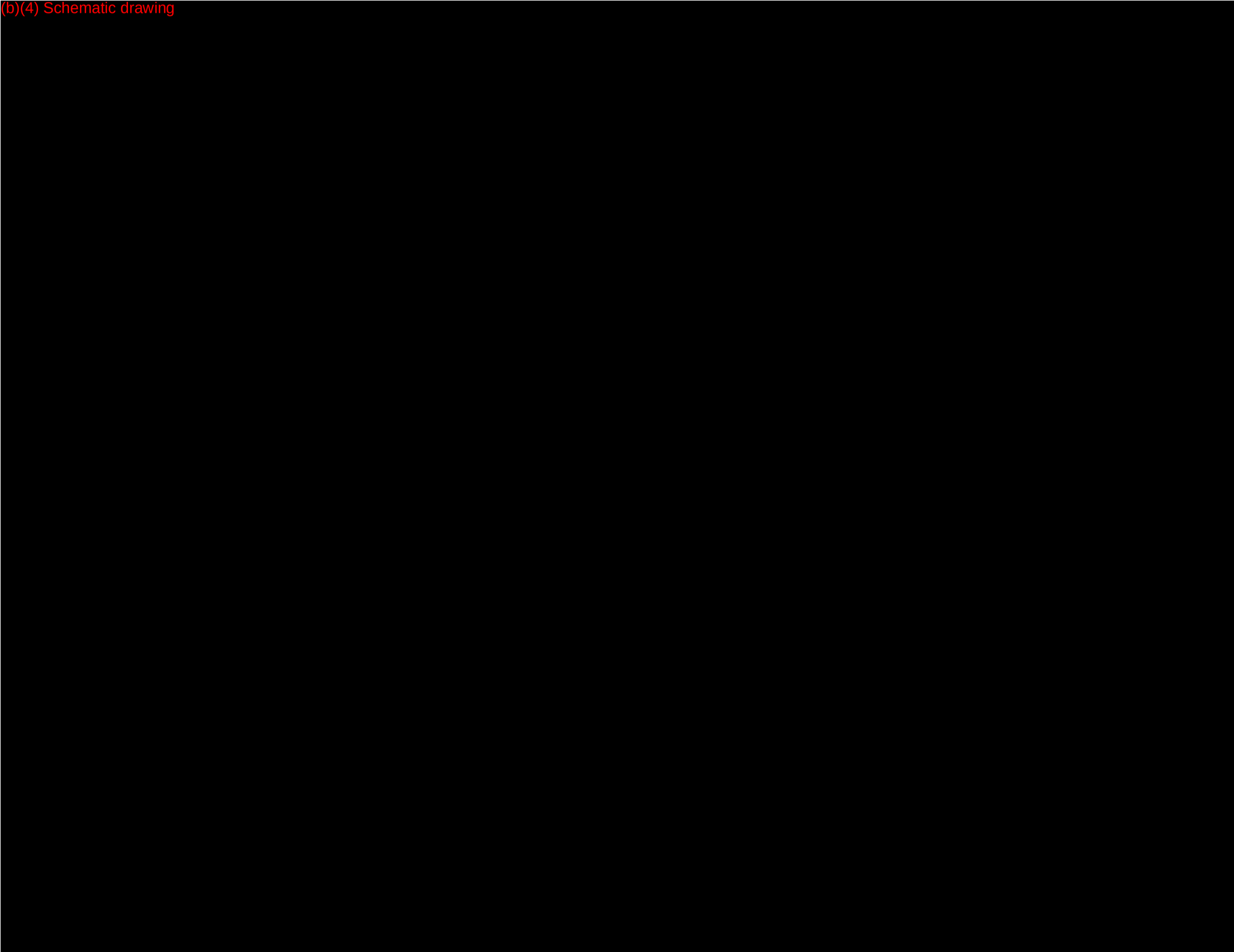
Hopefully, these data are sufficient for an approval of our premarket notification submission. Call me if you have additional questions.

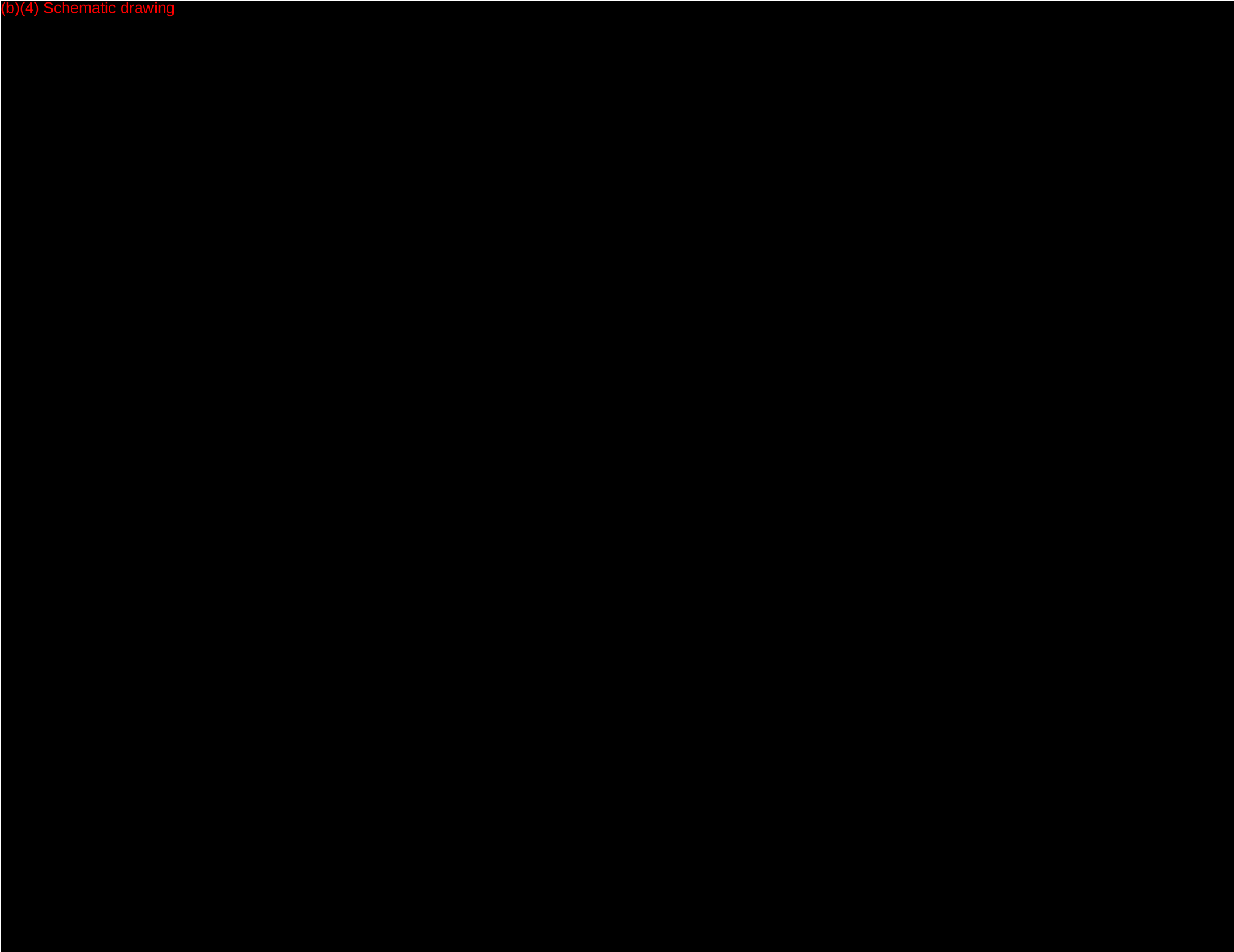
Sincerely,

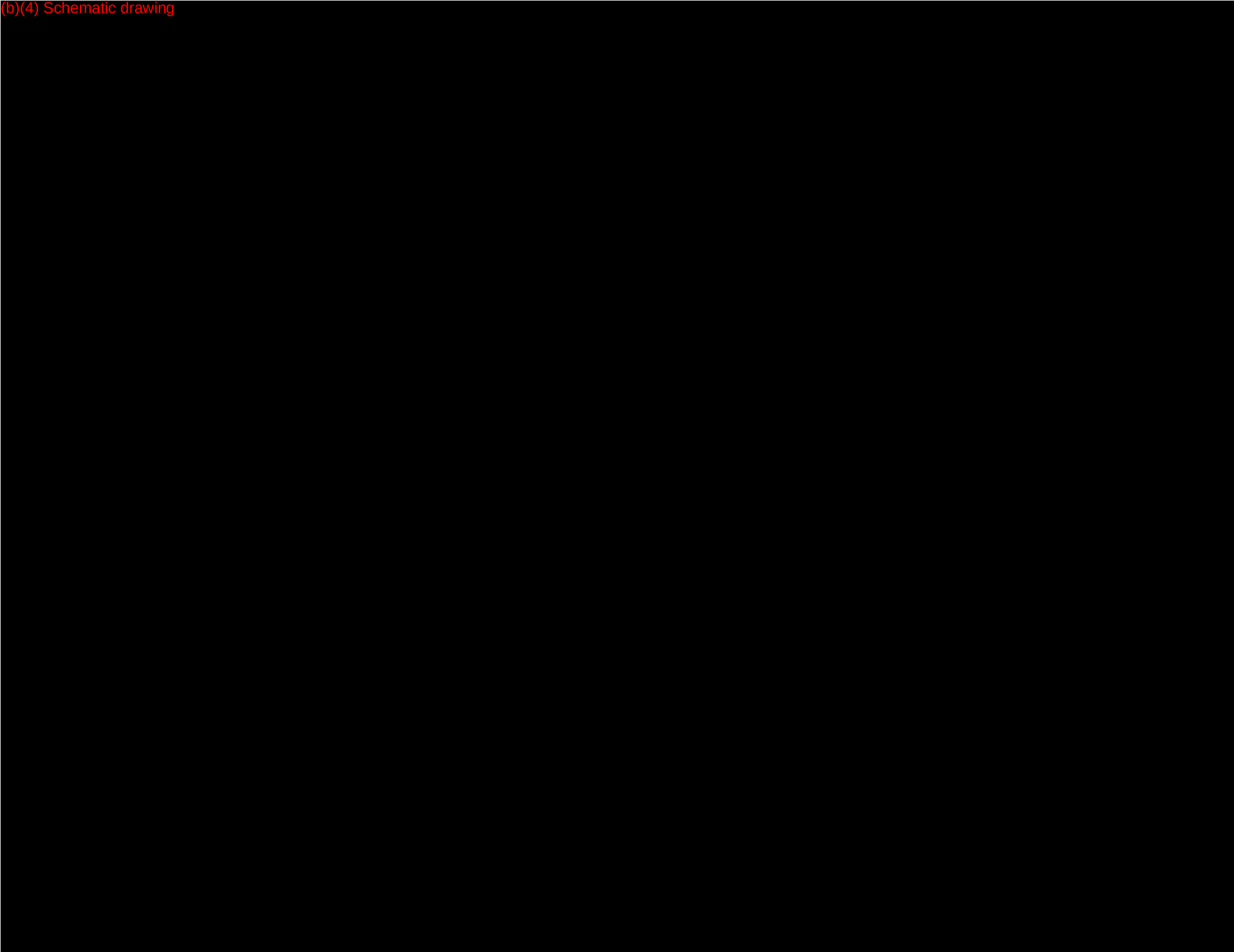
Henry A. Quello

Henry A. Quello
Regulatory Affairs

HQ/ss
RG/LT12010C
Enclosures
cc C. Larson, Ph.D.


(b)(4) Schematic drawing


(b)(4) Schematic drawing


(b)(4) Schematic drawing

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

NOVEMBER 22, 1988

ZIMMER
ATTN: HENRY A. QUELLO
P.O. BOX 708
WARSAW, IN 46580

Ref : K883665
Product : COONRAD III TOTAL ELBOW

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

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

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

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

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

Sincerely yours,

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

DO NOT REMOVE THIS ROUTE SLIP!!!!

11/22/88

K-88-3665

FROM: ZIMMER ATTN: HENRY A. QUELLO P.O. BOX 708 WARSAW, IN 46580 SHORT NAME: ZIMMER	LETTER DATE: 08/18/88 LOGIN DATE: 08/26/88 TYPE OF DOCUMENT: 510 (k) ESTABLISHMENT NO: 1822565	DUE DATE: 11/24/88 CONTROL #: K883665
TO: ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : OR PAN/PROD CODE(S): OR/ / /	

SUBJECT:
COONRAD III TOTAL ELBOW

DECISION: DECISION DATE: / /	RQST INFO DATE: 11/22/88 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: 12/22/88 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

.e

From — REVIEWER(S) - NAME(S) BOB HASTINGS

Subject — 510(k) NOTIFICATION K883665

To — THE RECORD

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

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

__X__ (C) Requires more data.

_____ (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

Asked for more information re:
1.) Characterization of the plasma spray surface
2.) Engineering drawings of each component
3.) List of sizes available
4.) ROM

RSH

The submitter requests:

_____ No Confidentiality

__X__ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Class Code w/Panel:

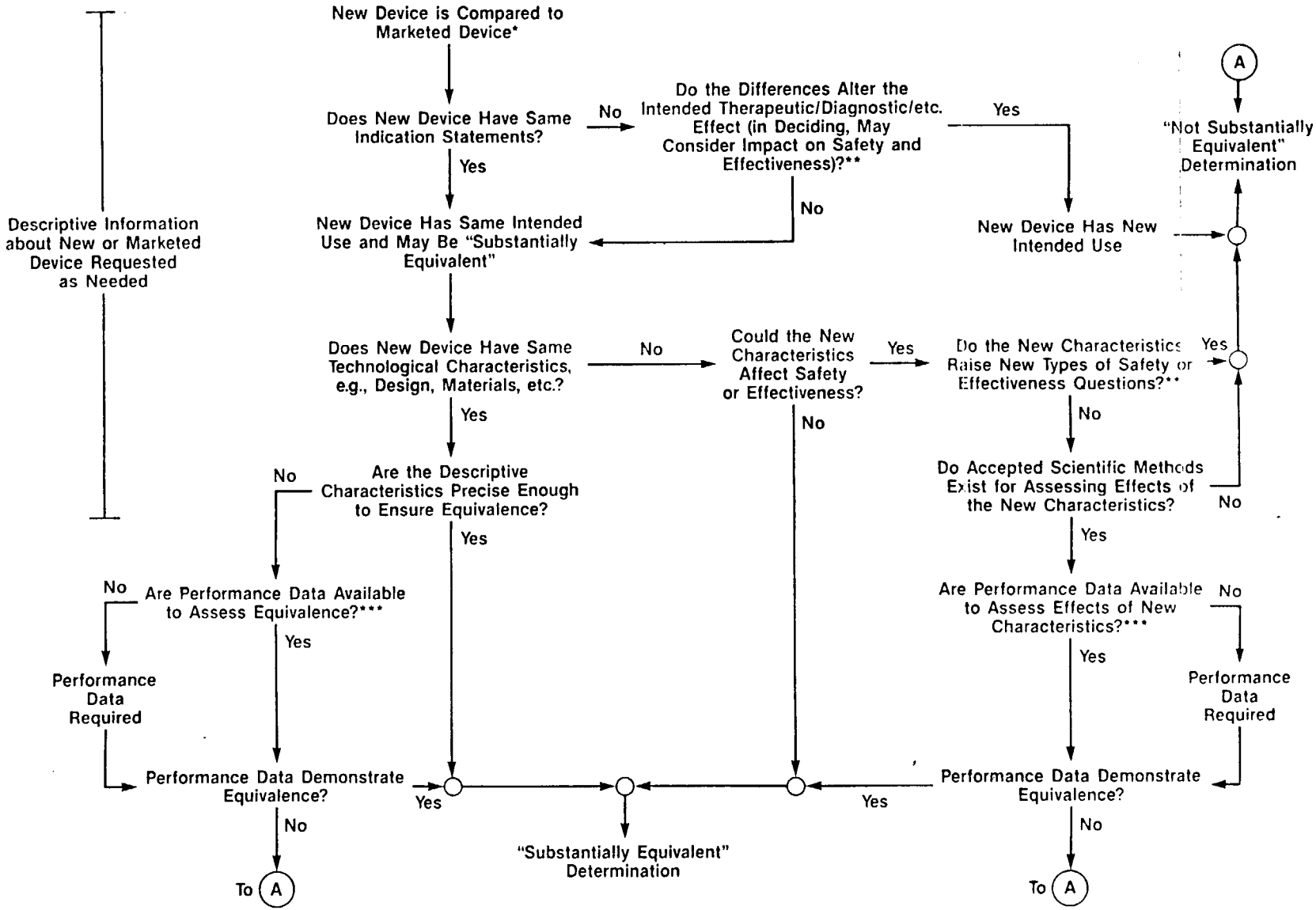
JDC/87 CLASS III
CONSTRAINED CEMENTED ELBOW PROSTHESIS

REVIEW: _____
(BRANCH CHIEF) (DATE)

FINAL REVIEW: _____
(DIVISION DIRECTOR) (DATE)

19 X

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



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DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

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

AUGUST 31, 1988

ZIMMER
ATTN: HENRY A. QUELLO
P.O. BOX 708
WARSAW, IN 46580

D.C. Number : K883665
Received : 08-26-88
Product : COONRAD III TOTAL ELBOW

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

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

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Office of Device Evaluation
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8757 Georgia Avenue
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Sincerely yours,

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

K883665

August 18, 1988

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Sir:

Subject: 510(k) Notification - Coonrad III Total Elbow

Enclosed is the Zimmer Premarket Notification for the marketing of the Coonrad III Total Elbow. This is in accordance with 21 CFR 807.87.

Sincerely,

Henry A. Quello

Henry A. Quello
Regulatory Affairs

Enclosures

cc C. Larson, Ph.D.

RG/LT08014C

FDA-CDRH-ODE
AUG 2 6 1988
DOCUMENT MAIL CENTER

zimmer • P.O. Box 708 • Warsaw, IN 46580-0708 • 219-267-6131

510(k) Notification

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("Act") and in accordance with Subpart E of Part 807 of Title 21 of the Code of Federal Regulations, Zimmer, Inc., a Delaware Corporation, hereby submits the following information as premarket notification for the following product:

A. Device Name

Trade Name: Coonrad III Total Elbow

Classification Name: Prosthesis, Elbow, Semiconstrained

B. Establishment Registration Number of Zimmer, Inc.:

18-22565

C. Classification of Device:

The Orthopaedic Panel has classified this type of device into Class II. (See 21 CFR 888.3160, 52 FR, September 4, 1987.)

D. Section 514 Compliance:

Section 514 of the Act does not apply to this type of device at this time.

E. Labeling and Advertising:

Attached as Exhibit A is proposed labeling for this device and as Exhibit B, photographs of the device.

F. Statement as to Substantial Equivalency:

Attached as Exhibit C are catalog pages regarding Coonrad and Coonrad II Total Elbow prostheses and a brochure for the Coonrad Total Elbow. The Coonrad III Total Elbow is substantially equivalent to these devices.

The surgical procedures for implantation, indications, and contraindications for use and required bone resection for these devices are essentially the same. The intramedullary stems of the components of these devices have triangular or rectangular cross-sections to resist rotation within the cement mantle.

Fixation is achieved for these devices by using acrylic bone cement, and basic instrumentation includes respective rasps. The devices provide a metal-to-plastic articular or bearing surface and are available for right or left elbows. The basic motion of these devices is a hinge action and the

humeral component anteverts the hinge axis to approximate the anatomical hinge location, minimizing reorientation of muscle forces.

G. Materials:

(b) (4)

H. Design:

The present design of the Coonrad III Total Elbow evolved from experiences with the Coonrad Total Elbow and later Coonrad II Total Elbow. The original Coonrad design was considered a semiconstrained prosthesis in contrast to the totally constrained metal-to-metal hinge types of Dee, McKee. The Coonrad metal-to-polyethylene hinged prosthesis had a laxity in the joint in side-to-side and rotary direction improvement in the Coonrad II model. In order to reduce the stress at the stem/bone interface, a less constrained joint evolved which allows greater lateral movement.

This prosthesis is manufactured from TIVANIUM Ti-6Al-4V alloy, is of hinge-type, with a metallic hinge pin connecting ulnar and humeral components, and utilizes ultra-high molecular-weight polyethylene bushings to prevent metal-to-metal contact. The fit between the humeral and ulnar components allows approximately 7° of lateral deviation to either side of center.

Other features of the evolutionary design are the addition of an anterior flange to the lower humeral stem for greater stability and plasma sprayed/sintered coating on fixation surfaces to enhance cement fixation. The flange permits the insertion of a bone graft anteriorly to enhance thickening of bone stock at the point where maximum stress has been found to occur. The flange and bone graft are designed to resist torsional and posteriorly directed forces associated with loosening of the implant. (Dr. B. F. Morrey reports on using the flanged design in the last article in Exhibit D, titled "Elbow Reconstructive Surgery," pp. 791, 798, 799, 800, 803.)This device is intended to be used with bone cement both for immediate and long-term fixation.

To further the comments regarding substantial equivalency, attached as Exhibit D are articles reporting on the Coonrad designs and equivalent devices. [Goldberg, V. M., et al., (1988), Current concepts review total elbow arthroplasty, pp. 779, 780, 781, JBJS 70-A (5):778-783. Morrey, B. F., et al., (1987), Revision total elbow arthroplasty, pp. 523,524, 529, 530, 531, JBJS 69-A (4):523-532. London, J. (1985) Custom arthroplasty and hemiarthroplasty of the elbow, p. 544, The elbow and its disorders, Morrey, B. F., chapter 33:540-545, W. B. Saunders Co. Morrey, B. F., et al., (1985) Total joint replacement, pp. 551, 552, 558, 559, 560, The elbow and its disorders, Morrey, B. F., chapter 34:546-569, W. B. Saunders Co. Morrey, B. F. (1985) Revision joint replacement, pp. 576, 578, 580, 581, The elbow and its disorders, Morrey, B. F., chapter 35:570-581, W. B. Saunders Co. Morrey, B. F., (1988) Elbow reconstructive surgery, pp. 791, 798, 799, 800, 803, Operative Orthopaedics, Vol. 1, chapter 62:789-805, J. B. Lippincott Co.]

I. Confidentiality of Information:

We consider our intent to market this device to be confidential commercial information.

We believe this product is substantially equivalent to those on the market prior to May 28, 1976, and, hence, is not automatically classified in Class III by Section 513(f) of the Act.

If you desire any further information or have any questions relating to this submission, please contact me at 219/372-4346.

Sincerely,

Henry A. Quello

Henry A. Quello
Regulatory Affairs

RG/PT08001K

EXHIBIT A

LOT NO. SAMPLE

CAT. NO. SAMPLE

COONRAD III TOTAL ELBOW
REGULAR RIGHT
6 IN.
QTY-1

STERILE

zimmer
WARSAW, INDIANA 46580, U.S.A.

LOT NO. SAMPLE

CAT. NO. SAMPLE

COONRAD III TOTAL ELBOW
REGULAR LEFT
8 IN.
QTY-1

STERILE

zimmer
WARSAW, INDIANA 46580, U.S.A.

Issued August 1988

COONRAD III TOTAL ELBOW

DESCRIPTION

The design of this prosthesis is based on the complex kinematics of the elbow joint. This product is a total elbow prosthesis available in regular and small sizes, in both left and right configurations. The ulnar component is curved to facilitate implantation and to establish the correct anatomical carrying angle. The anteverted hinge approximates the anatomical center of rotation and location to minimize the reorientation of muscle forces and skin trauma. Stem design with 7° laxity tends to minimize the possibility of prosthetic rotation or loosening in the humerus or ulna.

MATERIALS

(b) (4)

INDICATIONS AND USAGE

Post-traumatic lesions or bone loss contributing to elbow instability. Ankylosed joints, especially in cases of bilateral

ankylosis from causes other than sepsis. Advanced rheumatoid or degenerative arthritis with incapacitating pain or loss or motion when the degree of joint damage precludes less radical procedures.

The candidate for total elbow arthroplasty should exhibit significant joint destruction significantly compromising the activities of daily living. Patients with single joint involvement (generally those with traumatic or degenerative arthritis) or significant lower extremity disability which require walking aids are less amenable to treatment than patients with advanced and predominately upper extremity involvement. If possible, elbow replacement should be done after hip or knee surgery to avoid excessive stress to the prosthesis required by crutch walking during total hip or knee rehabilitation.

CONTRAINDICATIONS

Prior infection, paralysis, joint neuropathy, significant hand dysfunction, or excessive scarring of the skin which could prevent adequate soft tissue coverage are distinct contraindications.

Use of the Coonrad III Total Elbow should not be considered for patients whose activities would subject the device to significant stress.

Additionally, distant foci of infection, such as genitourinary, pulmonary, skin, or other sites, are relative contraindications because hematogenous dissemination to the implant site may occur. The foci of infection should be treated prior to, during, and after implantation.

WARNINGS

For safe and effective use of this implant, the implantation procedure for the device should be consulted and carefully followed (see Utilization and Implantation).

In every case, accepted surgical practices should be followed meticulously in postoperative care. The patient must be impressed with the dangers of weight bearing or other excessive muscular activity. The patient must be made to realize the limitations of the prosthesis and should be instructed to govern activities accordingly.

PRECAUTIONS

An implant should never be reused. Even though the implant may appear undamaged, it will be fatigued from previous stresses or may have developed imperfections which may lead to failure.

Proper handling of this implant is important. Contouring (bending) of the humeral or ulnar stems of the Coonrad III Total Elbow should be avoided. An alteration of this type may produce defects and stresses which could become the focal point for implant failure.

ADVERSE EFFECTS

Loosening, late infection, nerve injury, and triceps rupture or insufficiency have been reported in the literature for hinge-type elbow prostheses.

Implantation of foreign material in tissues results in histological reactions involving various sizes of macrophages and fibroblasts. The actual clinical significance of this effect is uncertain, as similar changes may occur as a precursor to, or during the normal wound healing process.

Metal sensitivity in patients following joint replacement have been rarely reported.

UTILIZATION AND IMPLANTATION

The cementing technique is extremely important. The medullary canal should be copiously irrigated to remove blood, fat, and bone debris, and then thoroughly dried. Syringe use, as recommended for inserting the femoral component of a total hip prosthesis, is equally applicable for fixation of both the humeral and ulnar components.

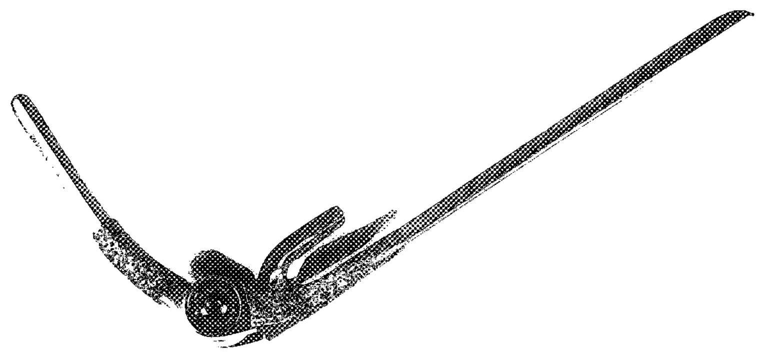
NOTE: Consult product brochure for surgical procedure.

STERILITY

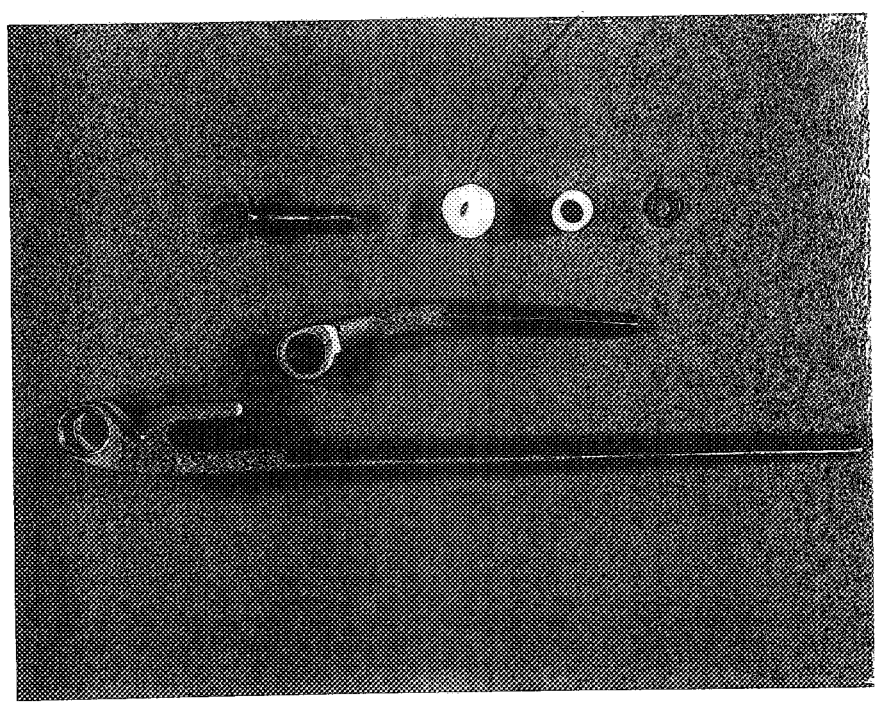
(b) (4)

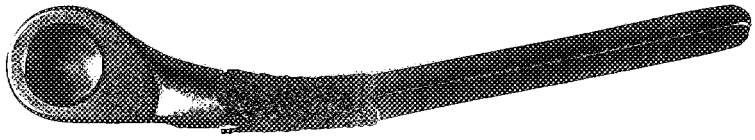
RG/PT08002K/ss

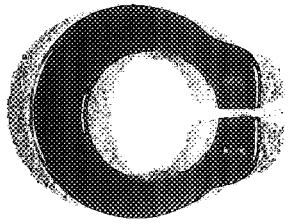
EXHIBIT B

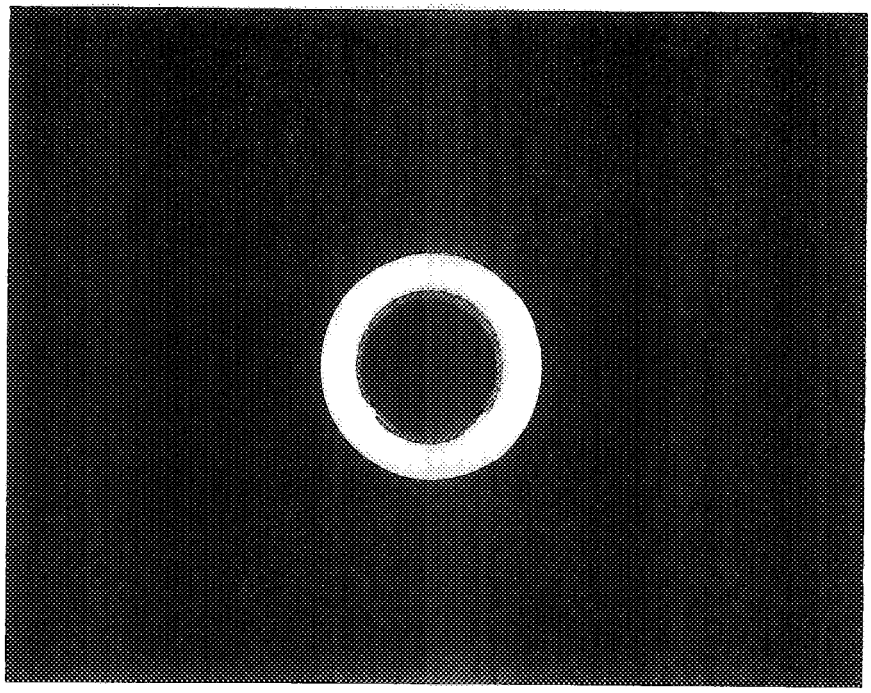


two of these are required for full assembly RSF, per telecon w/ Phil Shannon 1/27/89









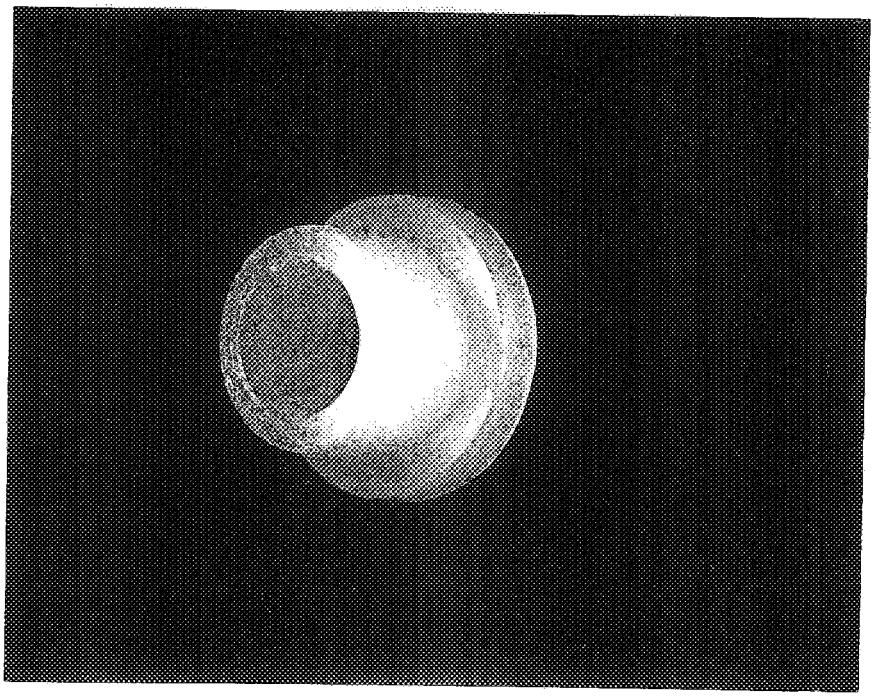


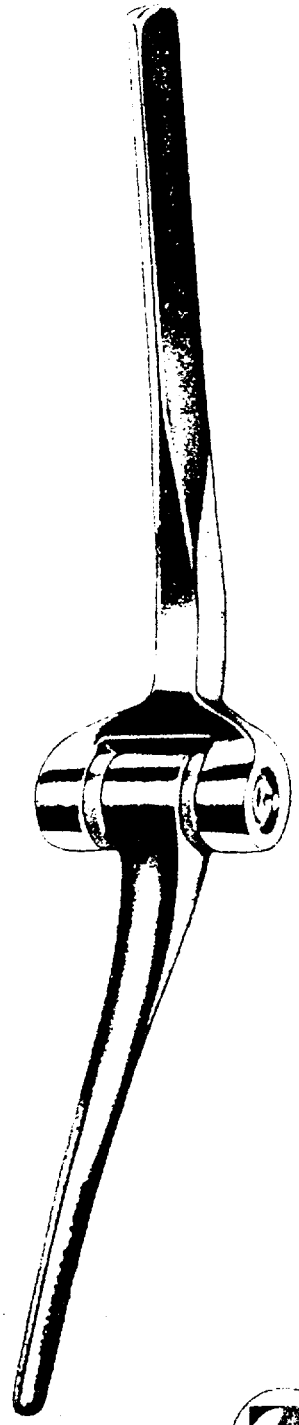
EXHIBIT C

COONRAD TOTAL ELBOW

A versatile total elbow prosthesis allowing selective preservation of epicondyles and the olecranon that is generally indicated for use with traumatic loss of elbow stability or bone substance, advanced rheumatoid or degenerative arthritis with incapacitating pain or loss of motion where the degree of joint damage precludes lesser procedures, and bilateral elbow ankylosis from many causes other than sepsis.

Specific contraindications include any condition in which the function of the hand is poor and neurovascular damage is severe enough to make any improvement unlikely. Prior joint infection or osteomyelitis are contraindications and excessive scarring of the skin making adequate soft tissue coverage impossible would also adversely affect the success of the procedure. This type of prosthesis should not be considered in any patient involved in heavy labor, torsional stress or competitive sports where fusion would likely be preferable.

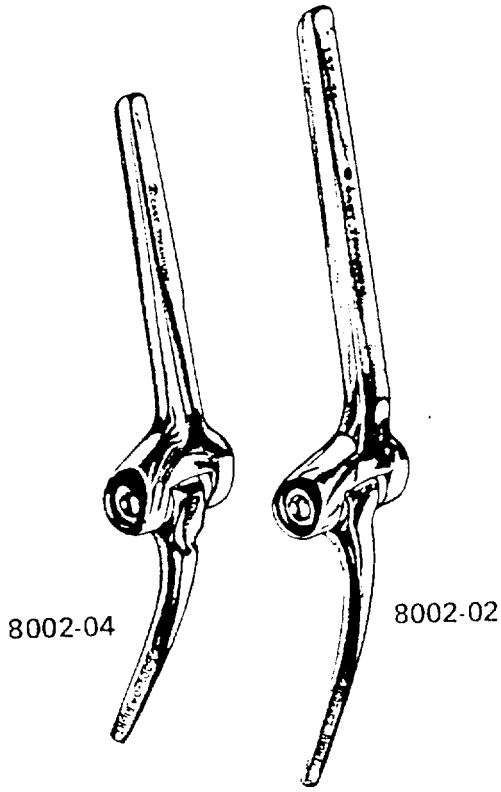
Available in both standard and small sizes with complete instrumentation. Right and left ulnar components curve to facilitate implantation and establish correct anatomical carrying angle. Anteverted hinge approximates anatomical hinge location, minimizing reorientation of muscle forces and skin slough complication. Stem design minimizes possibility of prosthetic rotation in the humerus or ulna. The ulnar and humeral stems and hinge pin are manufactured of TIVANIUM® (a Ti-6AL-4V alloy of titanium) shielded by ultra-high molecular weight polyethylene bushings to prevent metal-to-metal contact.



Suggested References:

1. Coonrad RW: Coonrad total elbow surgical protocol. *ZIMMER · USA*, November 1975.
2. Goodfellow JW and Bullough PC: The pattern of ageing of the anticular cartilage of the elbow joint. *JBJS*, 49B:1, February, 1967, 175-181.
3. Souter WA: Arthroplasty of the elbow, with particular reference to metallic hinge arthroplasty in rheumatoid patients. *Orthop Clinc North Am*, 4:2, April 1973, 395-413.
4. Dee R: Total replacement of the elbow joint. *Orthop Clinc North Am*, 4:2, April 1973, 415-433.

Coonrad total elbow



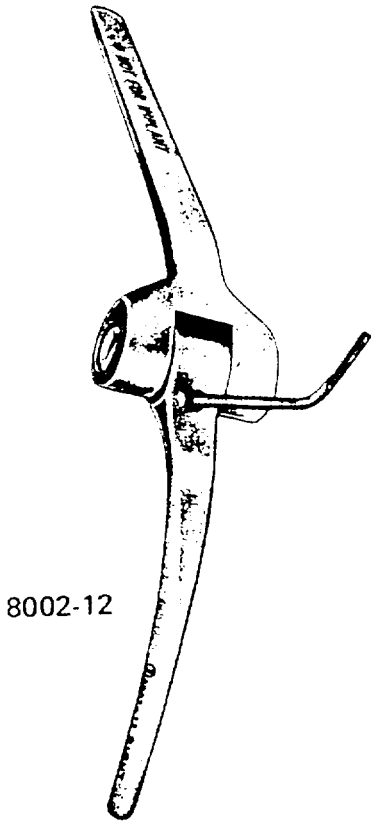
8002-01,02 COONRAD TOTAL ELBOW, REGULAR

8002-03,04 COONRAD TOTAL ELBOW, SMALL

Application: Total elbow joint replacement prosthesis permitting a full range of motion. Utilizes a hinge design with a metallic hinge pin connecting the ulnar and humeral stems with metal-to-metal contact prevented by ultra-high molecular weight polyethylene (UHMWPE) bushings. Available as left and right elbow implants in two sizes – regular and small.

Spec.: Material: TIVANIUM®

Size	Prosthetic Size		
	Left Elbow	Right Elbow	Overall Length
Regular	8002-01	8002-02	9.5 in. (24.1cm)
Small	8002-03	8002-04	8.5 in. (21.5cm)



8002-11, 12 COONRAD PROVISIONAL (TRIAL) PROSTHESES, REGULAR

8002-13, 14 COONRAD PROVISIONAL (TRIAL) PROSTHESES, SMALL

Application: To verify full elbow motion and adequate contouring of the humeral and ulnar intramedullary canals. Use of a provisional (trial) prosthesis protects the actual implant from surface damage prior to actual implantation.

Spec.: Material: TIVANIUM®

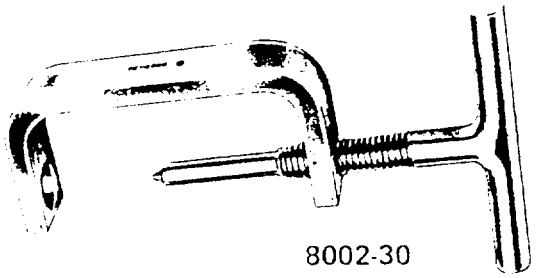
Size	Provisional Prostheses		
	Left Elbow	Right Elbow	Overall Length
Regular	8002-11	8002-12	9.5 in. (24.1cm)
Small	8002-13	8002-14	8.5 in. (21.5cm)

Coonrad total elbow

8002-30 C-CLAMP

Application: Removal and reinsertion of prosthetic hinge as required.

Spec.: Material: Stainless steel



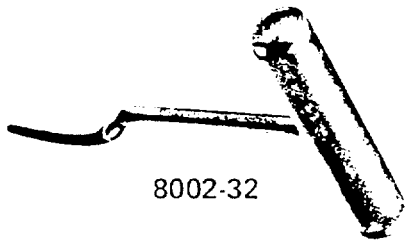
8002-30

8002-31, 32 COONRAD ULNAR RASP, REGULAR

8002-34, 35 COONRAD ULNAR RASP, SMALL

Application: Right and left ulnar rasps in both regular and small sizes provide for contouring of the intramedullary canal in a manner corresponding to the ulnar stem configuration of the matching left or right prosthesis.

Spec.: Material: Stainless steel



8002-32

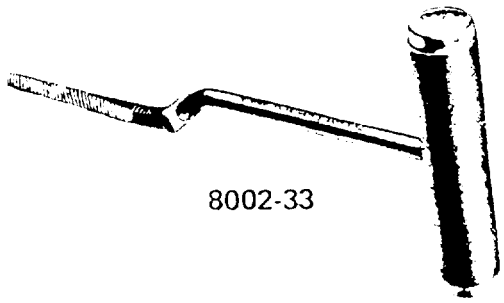
Size	Ulnar Rasp		
	Left	Right	Overall Length
Regular	8002-31	8002-32	9.12 in. (23.1cm)
Small	8002-34	8002-35	8.5 in. (21.5cm)

8002-33 HUMERAL RASP, REGULAR

8002-36 HUMERAL RASP, SMALL

Application: The regular and small humeral rasps are used for preparation of both the right or left intramedullary canal prior to test insertion of the appropriate corresponding regular or small size provisional prosthesis.

Spec.: Material: Stainless steel



8002-33

Size	Humeral Rasp	Overall Length
Regular	8002-33	10.1 in. (25.6cm)
Small	8002-36	9.5 in. (24.1cm)

8002-84 COONRAD STERILIZING CASE

Application: Lightweight DACRON® case to provide a safe protective cover for Coonrad instruments and implants. Cases roll up easily and dry quickly after autoclave.

Spec.: Material: DACRON

Coonrad total elbow

RECOMMENDED ADDITIONAL STANDARD INSTRUMENTS

Cat. No.	Description	Page Ref.
155-02	Mallet	D31
2887-00-02, 04, 06	Smith Peterson Osteotomes, Straight	D24
2888-00-02, 04, 06	Smith Peterson Osteotomes, Curved	D24
2910	Key Periosteal Elevator	D17
2977-02	Chandler Elevator	D17
3005	Senn Retractor	D13
3008	Mayo-Collins Retractor	D1
3010-04	Volkman Rake Retractor (Four-Prong)	D7
3019	Gelpi Retractor	D9
3122	Kern Bone Holding Forceps	D46
3180	Needle Nose Pliers – Cutters	D67
3323-02	Ruskin Bone Rongeur	D39
3410	Stille-Liston Bone Cutting Forceps	D36
3680-00-02, 03, 05	Brun bone curette	D34

Roentgenogram Templates available through ZIMMER representative.

COONRAD TOTAL ELBOW

BRIEF SUMMARY OF PACKAGE INSERT

Issued: March 1976

INDICATIONS

Post-traumatic lesions or bone loss contributing to elbow instability. Ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis. Advanced rheumatoid or degenerative arthritis with incapacitating pain or loss of motion when the degree of joint damage precludes less radical procedures.

CONTRAINDICATIONS

Use of this prosthesis is contraindicated in: 1) Any condition in which there is poor function of the hand and neurovascular damage is severe enough to preclude improvement. 2) Osteomyelitis, overt or prior joint infection. 3) Excessive scarring of the skin which could prevent adequate soft tissue coverage and adversely affect the success of the procedure.

Use of the Coonrad Total Elbow should not be considered for patients whose activities would subject the device to significant stress.

WARNINGS AND PRECAUTIONS

LOOSENING BETWEEN THE METHACRYLATE INTERFACE AND THE HUMERUS CAN OCCUR AFTER IMPLANTATION OF A TOTAL ELBOW HINGE PROSTHESIS IF A SNUG MECHANICAL FIT WITHIN THE HUMERUS IS NOT ACHIEVED. IF POSSIBLE, THE INNER CORTEX OF THE HUMERUS SHOULD BE NOTCHED TO FIT THE STEM CONTOUR WHILE REAMING TO FURTHER PREVENT LOOSENING. IF POSSIBLE, THE EPICONDYLES SHOULD BE PRESERVED TO REDUCE THE POSSIBILITY OF LOOSENING.

For safe and effective use of this implant, the implantation procedure for the device should be consulted and carefully followed (See Utilization and Implantation).

The amount of bone removed should be sufficient to permit full elbow motion on the operating table when the appropriate provisional prosthesis is fully inserted. The surgeon is further cautioned to check for full range of elbow motion at appropriate times during the surgery.

In every case, accepted surgical practices should be followed meticulously in postoperative care. The patient must be impressed with the dangers of weight bearing or other excessive muscular activity. The patient must be made to realize the limitations of the prosthesis and should be instructed to govern activities accordingly.

An implant should never be reused. Even though the implant may appear undamaged, it will be fatigued from previous stresses or may have developed imperfections which may lead to failure.

Proper handling of this implant is important. Contouring (bending) of the humeral or ulnar stems of the Coonrad Total Elbow should be avoided. An alteration of this type may produce defects and stresses which could become the focal point for implant fracture.

ADVERSE EFFECTS

Loosening of a prosthesis due to metal sensitivity has been rarely reported. Patch testing may be advisable prior to implantation whenever metal sensitivity is suspected. The true significance, however, of metal sensitivity and its effects await further clinical evidence and evaluation.

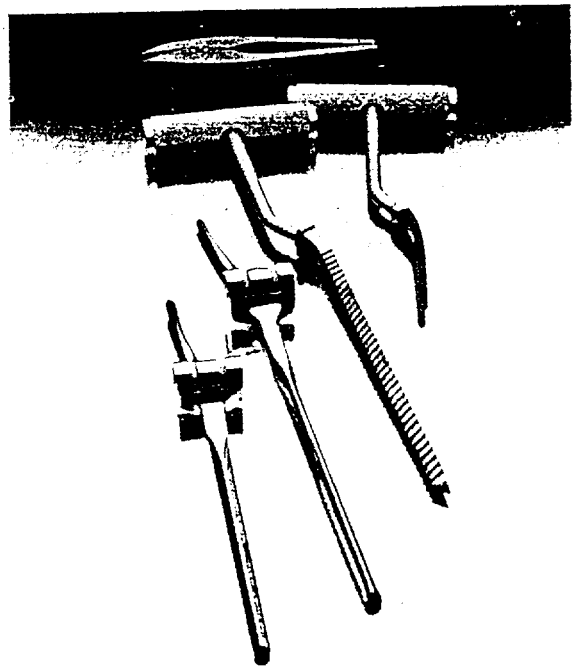
Macrophage and foreign body reaction resulting from foreign material in tissues adjacent to implants has been reported.

Temporary ulnar nerve paresthesias may occur.

COONRAD II TOTAL ELBOW

The Coonrad II Total Elbow was designed to conform to the average laxity in the normal elbow joint. The prosthesis incorporates quadrangular ulnar and triangular humeral contoured stems to minimize intramedullary rotation.

The Coonrad II prosthesis is supplied in right and left arm models, both in regular and small sizes. The regular size prosthesis is available with an 8-inch humeral stem and the small model is available with a 6-inch humeral stem. The two primary components, humeral and ulnar, rarely require disarticulation at the time of surgery. A full range of elbow joint motion is permitted with the prosthesis.



8006-01/04 COONRAD II TOTAL ELBOW PROSTHESIS

Application: Total elbow joint replacement prosthesis permitting a full range of motion. Utilizes a hinge design with a metallic hinge pin connecting the ulnar and humeral stems with metal-to-metal contact prevented by ultra-high molecular-weight polyethylene (UHMWPE) bushings. Available as left and right elbow implants in two sizes—regular and small.

Spec.: Materials:

Prosthesis: TIVANIUM* Ti-6Al-4V Alloy

Bushings: UHMWPE Ultra-High Molecular-Weight Polyethylene

Packaging: Individually packaged assembled and sterile

8006-01/04

8006-11/14 COONRAD II PROVISIONAL PROSTHESIS

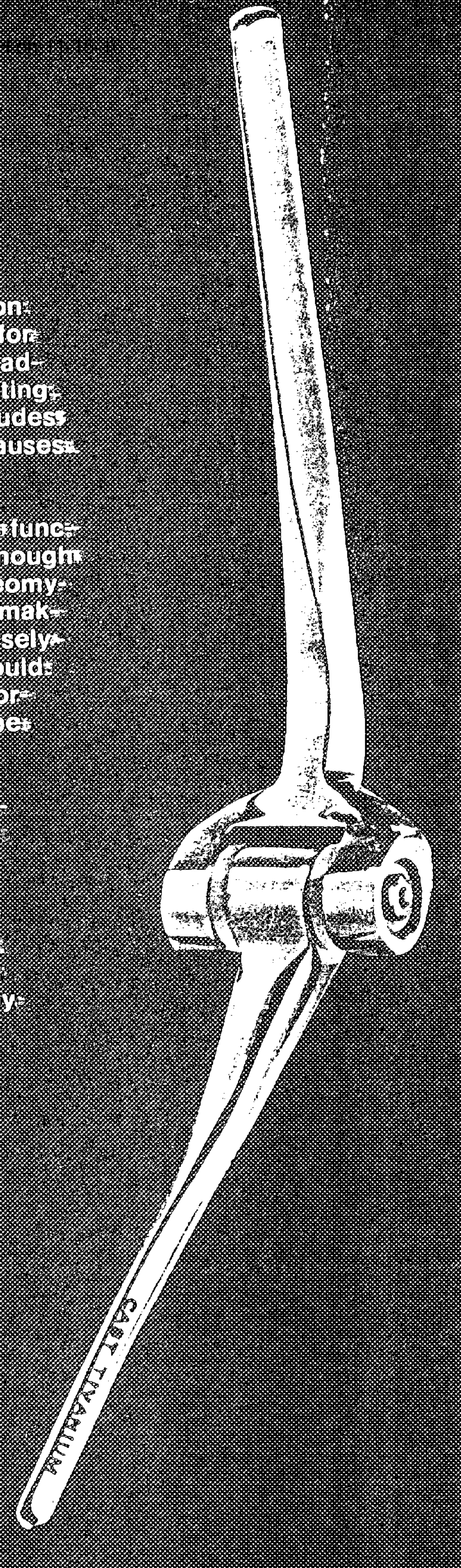
Application: To verify full elbow motion and adequate contouring of the humeral and ulnar intramedullary canals. Use of a provisional (trial) prosthesis protects the actual implant from surface damage prior to implantation.

Spec.: Material: TIVANIUM Ti-6Al-4V Alloy and Stainless steel

Prosthesis Cat. No.	Desc.	Humeral Length	Ulnar Length	Provisional Cat. No.	Humeral Rasp	Ulnar Rasp
8006-01	Left Reg.	8 in.	3.5 in.	8006-11	8006-31	8002-31
8006-03	Left Small	6 in.	3.0 in.	8006-13	8006-32	8002-34
8006-02	Right Reg.	8 in.	3.5 in.	8006-12	8006-31	8002-32
8006-04	Right Small	6 in.	3.0 in.	8006-14	8006-32	8002-35

Coonrad Total Elbow

Coonrad Total Elbow



A versatile total elbow prosthesis allowing selective preservation of epicondyles and the olecranon that is generally indicated for use with traumatic loss of elbow stability or bone substance, advanced rheumatoid or degenerative arthritis with incapacitating pain or loss of motion where the degree of joint damage precludes lesser procedures, and bilateral elbow ankylosis from many causes other than sepsis.

Specific contraindications include any condition in which the function of the hand is poor and neurovascular damage is severe enough to make any improvement unlikely. Prior joint infection or osteomyelitis are contraindications and excessive scarring of the skin making adequate soft tissue coverage impossible would also adversely affect the success of the procedure. This type of prosthesis should not be considered in any patient involved in heavy labor, torsional stress or competitive sports where fusion would likely be preferable.

Available in both standard and small sizes with complete instrumentation. Right and left ulnar components curve to facilitate implantation and establish correct anatomical carrying angle. Anteverted hinge approximates anatomical hinge location, minimizing reorientation of muscle forces and skin slough complication. Stem design minimizes possibility of prosthetic rotation in the humerus or ulna. The ulnar and humeral stems and hinge pin are manufactured of Tivanium® (a Ti-6Al-4V alloy of titanium) shielded by ultra-high molecular weight polyethylene bushings to prevent metal-to-metal contact.

Suggested References:

- Ralph W. Coonrad, *Coonrad Total Elbow Surgical Protocol*, Zimmer•USA, November, 1975.
- John W. Goodfellow and Peter C. Bullough, *The Pattern of Ageing of the Articular Cartilage of the Elbow Joint*, *JBJS*, vol. 49B, no. 1, February 1967, pp. 175-181.
- William A. Souter, *Arthroplasty of the Elbow, with Particular Reference to Metallic Hinge Arthroplasty in Rheumatoid Patients*, *Orthopedic Clinics of North America*, vol. 4, no. 2, April, 1973, pp. 395-413.
- Roger Dee, *Total Replacement of the Elbow Joint*, *Orthopedic Clinics of North America*, vol. 4, no. 2, April, 1973, pp. 415-433.

Surgical protocol.

The Coonrad Total Elbow procedure is most frequently carried out with the patient supine and the arm positioned across the chest. Alternately, the patient may be positioned prone with the elbow flexed over a small table. A topical antibiotic (generally either a Neomycin or Bacitracin solution) is used with irrigation intermittently during surgery, with the patient prepped with Betadine and appropriately draped. Tourniquet hemostasis is carried out with approximately 300 mm of mercury for a period not to exceed two hours. Pressure is checked before, during, and after the procedure. A straight posterior, postero-lateral or postero-medial incision is made (Fig. 1) and the ulnar nerve identified and protected, or mobilized and transplanted away from the major operative site. Hemostasis should be controlled with electrocautery.

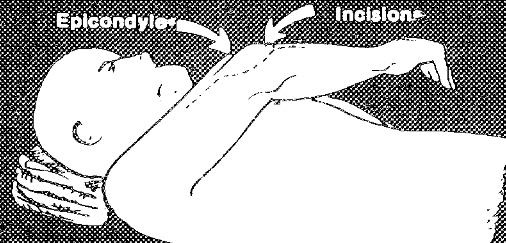


Fig. 1

The triceps tendon is preferably split over the olecranon and retracted half medially and half laterally, or detached intact from the olecranon, making sure to preserve all soft tissue and periosteum for later anatomical reattachment. Alternately, the triceps tendon may be left intact and bluntly or sharply dissected in continuity with the periosteum away from the olecranon, and later replaced. (See Fig. 2)

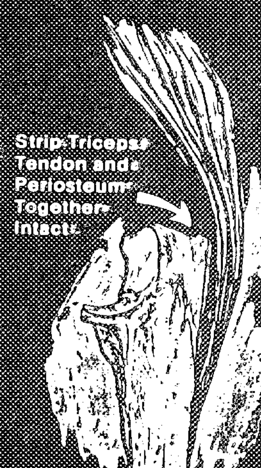


Fig. 2

The distal humerus and proximal ulna are totally stripped of soft tissue subperiosteally. Joint cultures are taken immediately after opening the joint capsule. Bone removal from the proximal ulna gives excellent exposure and can include almost the entire olecranon and notch, using either a small osteotome or a Hall® Air Driver/Osteotomy attachment with appropriate Osteotomy saw blade (See Fig. 3a). An alternative resection removes the articular surfaces while preserving the major portion of the olecranon. (Fig. 3b)

Fig. 3a.

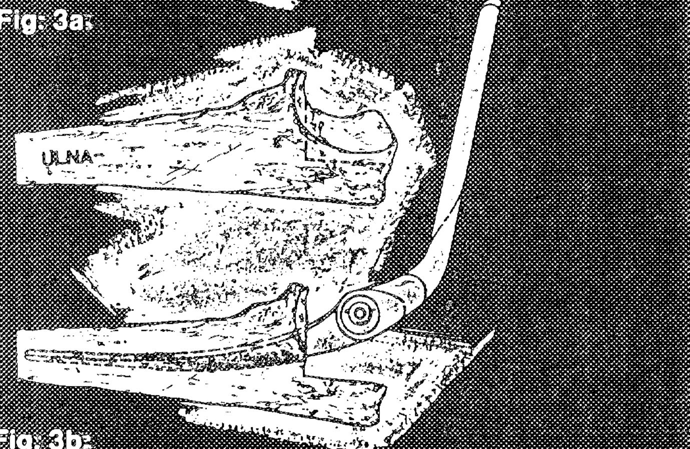


Fig. 3b.

Bone removal from the distal humerus can include both epicondyles to a level just proximal to the flaring so as to correctly seat the humeral stem (Fig. 4 & 4a). Or, preferably, the central notch may be removed from the inter-epicondylar region to "tailor" the bone contours to fit the shoulder portion of the prosthesis stem (Fig. 5 and 5a). This second alternative affords less chance of humeral loosening of the prosthesis and creates more bony covering of the prosthetic hinge mechanism.

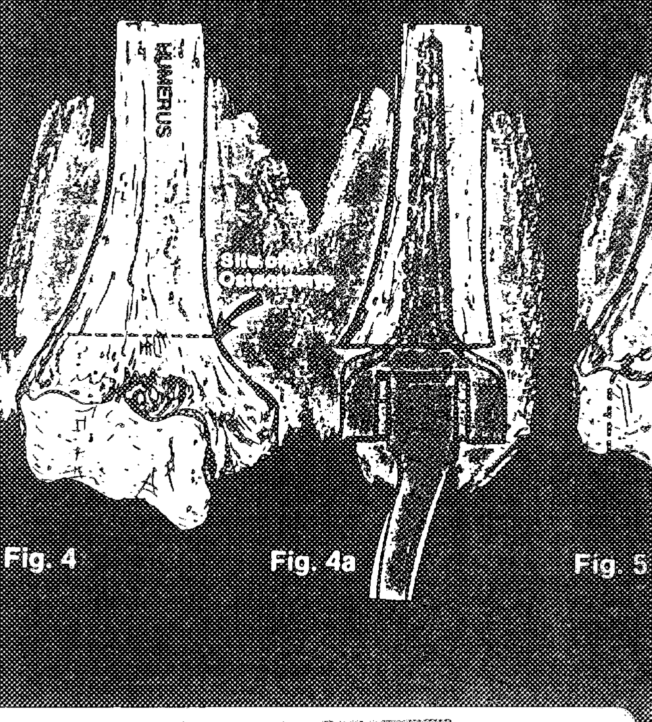


Fig. 4 Fig. 4a Fig. 5

The amount of bone removed should be sufficient to permit full elbow motion on the operating table when the appropriate provisional prosthesis is fully inserted and the surgeon is further cautioned to check for full range of elbow motion at appropriate times during the surgery. Special rasps are provided in both regular and small sizes for contouring the humeral and ulnar intramedullary canals prior to test insertion of the appropriate corresponding regular or small size provisional prosthesis. Right and left ulnar rasps (Fig. 6) correspond to the ulnar configuration of the matching right or left prosthesis. The regular and small humeral rasps are used for preparation of either the right or left humeral intramedullary canal (Fig. 7).

The implantable prosthesis (8002-01, Left-Regular; 8002-02, Right-Regular; 8002-03, Left-Small; 8002-04, Right-Small) *should not be disassembled* ordinarily during the procedure and is inserted intact into the prepared medullary cavities of the humerus and ulna at the same time with the elbow acutely flexed (Fig. 8).

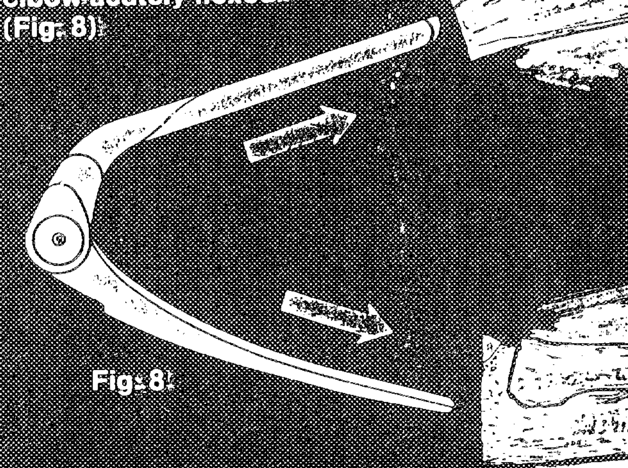


Fig. 8

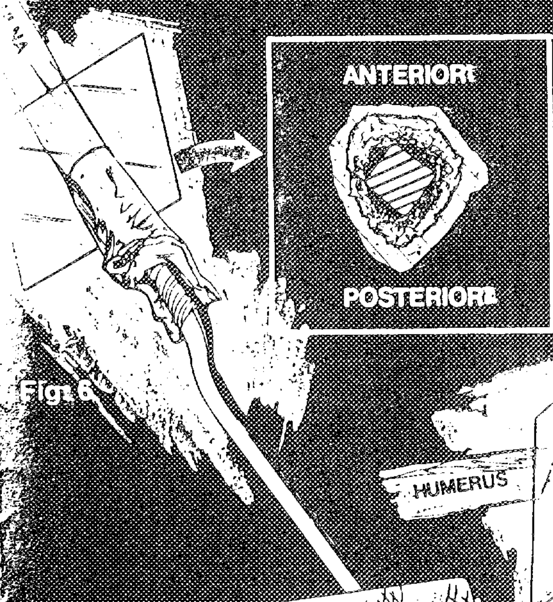


Fig. 6

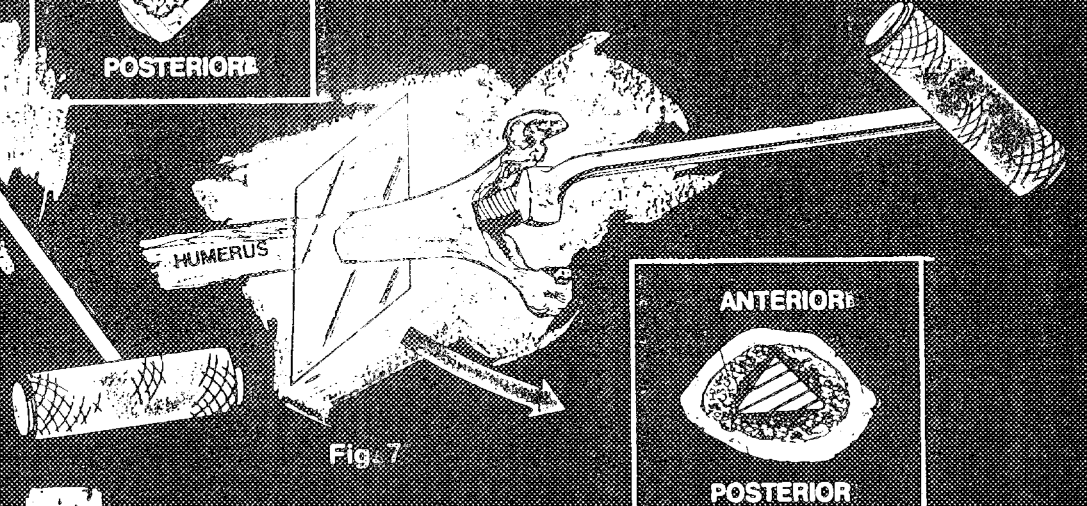


Fig. 7

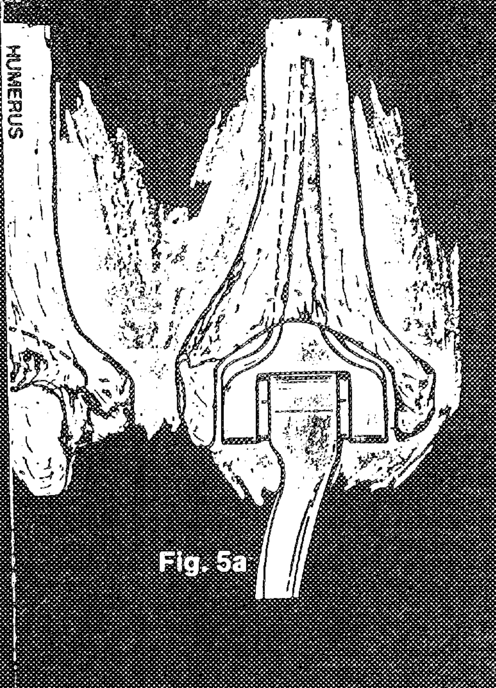
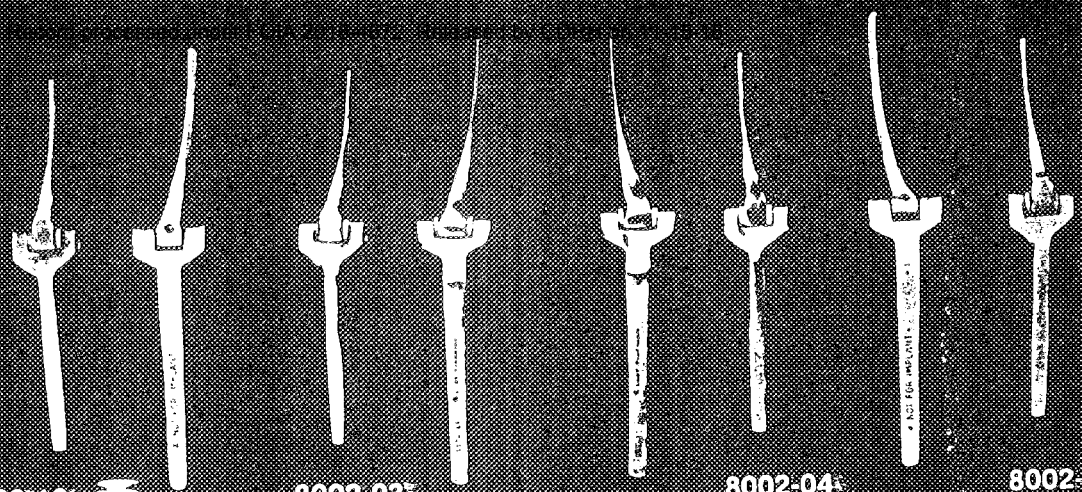
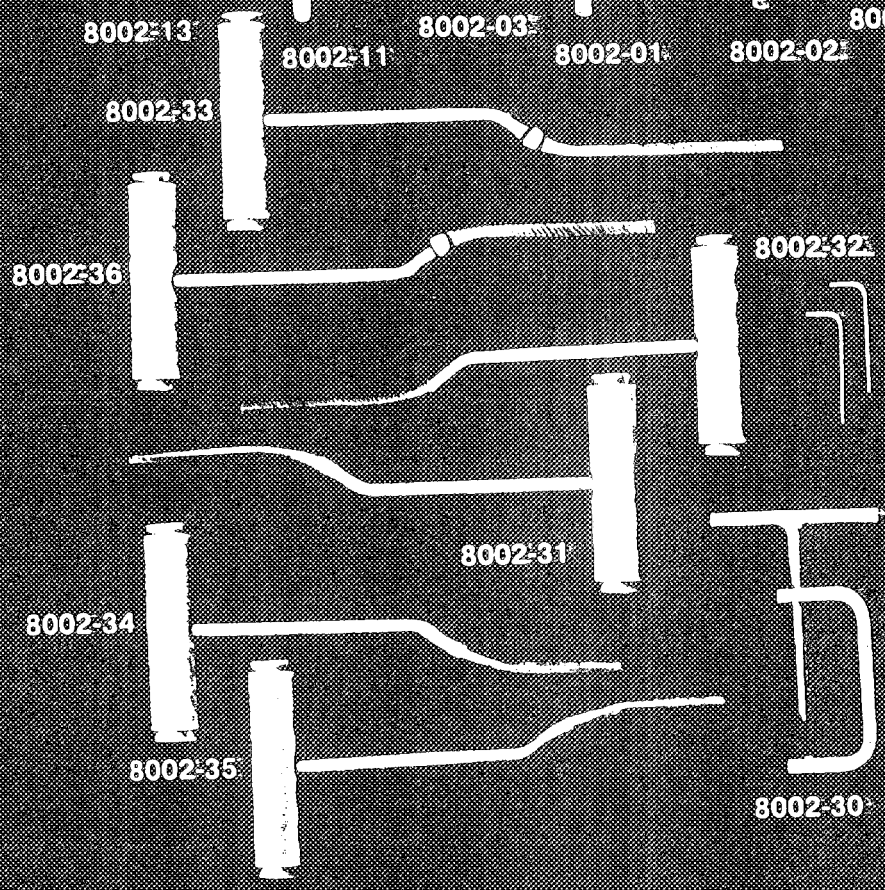


Fig. 5a

the Coonrad Instrumentation





8002-01 Coonrad Total Elbow, Left, Regular.

8002-02 Coonrad Total Elbow, Right, Regular.

8002-03 Coonrad Total Elbow, Left, Small.

8002-04 Coonrad Total Elbow, Right, Small.

8002-11 Coonrad Total Elbow, Provisional Left, Regular.

8002-12 Coonrad Total Elbow, Provisional Right, Regular.

8002-13 Coonrad Total Elbow, Provisional Left, Small.

8002-14 Coonrad Total Elbow, Provisional Right, Small.

8002-30 Coonrad Total Elbow C-Clamp.

8002-31 Coonrad Total Elbow Left Ulnar Rasp, Regular.

8002-32 Coonrad Total Elbow Right Ulnar Rasp, Regular.

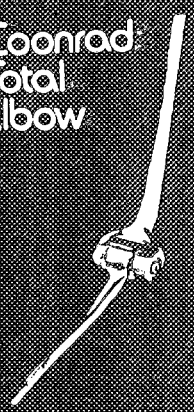
8002-33 Coonrad Total Elbow Humeral Rasp, Regular.

8002-34 Coonrad Total Elbow Left Ulnar Rasp, Small.

8002-35 Coonrad Total Elbow Right Ulnar Rasp, Small.

8002-36 Coonrad Total Elbow Humeral Rasp, Small.

Coonrad Total Elbow



- ☐ Please send me a complete Surgical Protocol for the Coonrad Total Elbow.
- ☐ Please have my Zimmer representative arrange to show me the Coonrad Total Elbow Surgical Protocol Audiovisual Program.

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In rare instances, it may be necessary to disassemble the prosthesis. A C-clamp (8002-30) is provided to force the hinge pin out of the bushings for disassembly and to reinsert the pin after the stem components are placed *in situ.* (Fig. 9) The hinge pin is removed from lateral to medial on the left prostheses (8002-01, -03) and from medial to lateral on the right prostheses (8002-02, -04). On insertion, a distinct snap is heard when the hinge pin seats itself in the ultra-high molecular weight polyethylene (UHMWPE) bushings. Repeated assembly and disassembly of the implant is not recommended as the retention power of the bushings may become compromised. Use of a provisional prosthesis will indicate whether or not the implantable prosthesis must be disassembled for separate insertion to the humerus and ulna.

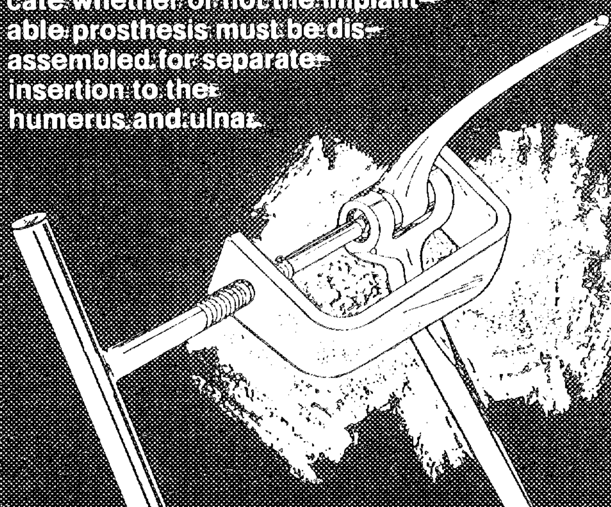
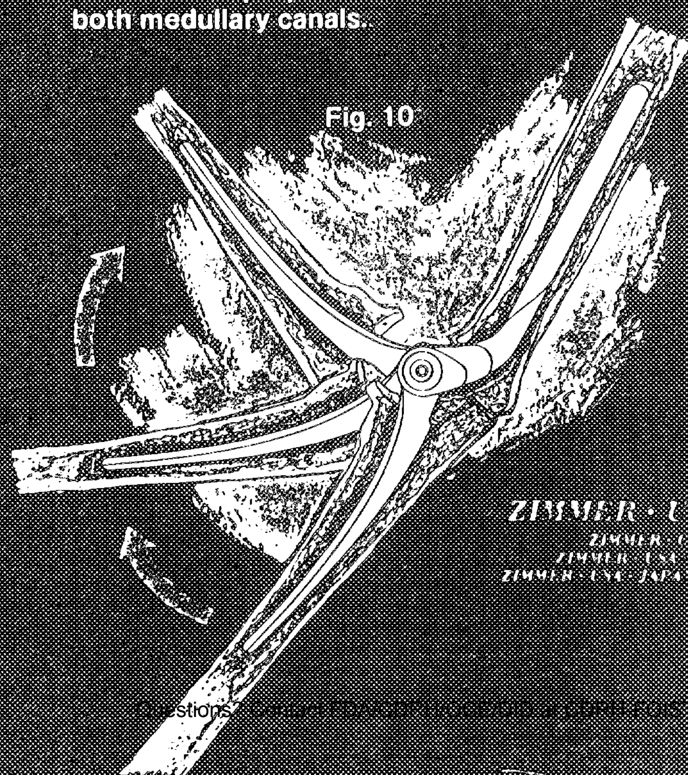


Fig. 9

The provisional prosthesis can be used to test the range of motion and the carrying angle. (See Fig. 10) *(A full range of motion must be achieved at this time.)* If motion is limited, added bone removal from the ulna, humerus or both may be indicated. Bone cement is then prepared and inserted into both medullary canals.

Fig. 10



The appropriate *implantable* prosthesis is then simultaneously inserted into both the humeral and ulnar medullary canals. (See Fig. 11) and the joint extended while the bone cement hardens, thus seating the stems of the prosthesis. Excess bone cement is then cleaned away with an osteotome from the bone margins.

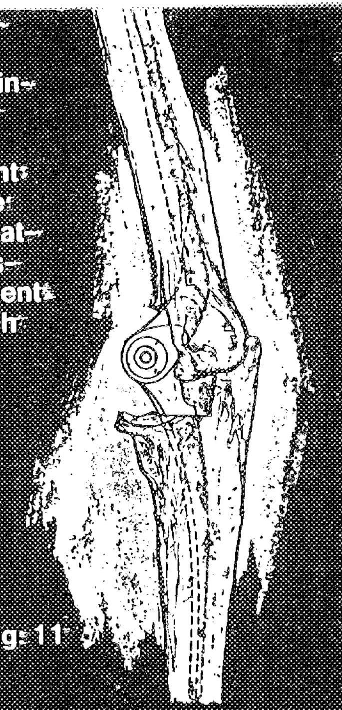


Fig. 11

If the radial head limits rotation or impinges on the prosthesis, it should be excised. Otherwise, it is left undisturbed.

At this point, it is appropriate to stress several important implantation steps: First, the *amount of bone removed from the humerus and ulna must permit full elbow motion with the prosthesis inserted.* Second, the prosthesis will be inserted with the elbow acutely flexed and the prosthesis *preferably* fully assembled. Next, the ulnar and humeral stems should be viewed to ensure that the prosthesis is *fully* seated in each medullary canal. Finally, polymerization of the bone cement should occur with the elbow fully extended.

The joint capsule is closed with the triceps snugly sutured with nonabsorbable suture material and the ulnar nerve transferred subcutaneously if it appears that there is danger of interference between the ulnar nerve and the prosthesis. The remainder of the wound is then closed in anatomical layers with Snyder Hemovac closed system drainage inserted through the skin flap paralleling the incision. The wound margins are again prepped with Betadine and a dry dressing applied.

A bulky compression dressing using 5-6 layers of sheet cotton is applied with the elbow in 90° flexion and a posterior shell plaster cast added.

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EXHIBIT D

Current Concepts Review

Total Elbow Arthroplasty

BY VICTOR M. GOLDBERG, M.D.*, HARRY E. FIGGIE III, M.D.*, CLEVELAND, OHIO, ALLAN E. INGLIS, M.D.†,
AND MARK P. FIGGIE, M.D.†, NEW YORK, N.Y.

Revision Total Elbow Arthroplasty*

BY BERNARD F. MORREY, M.D.†, AND RICHARD S. BRYAN, M.D.†, ROCHESTER, MINNESOTA

CHAPTER 33

Custom Arthroplasty and Hemiarthroplasty of the Elbow

JAMES LONDON

THE ELBOW AND ITS DISORDERS

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CHAPTER 34

Total Joint Replacement

B. F. MORREY and R. S. BRYAN

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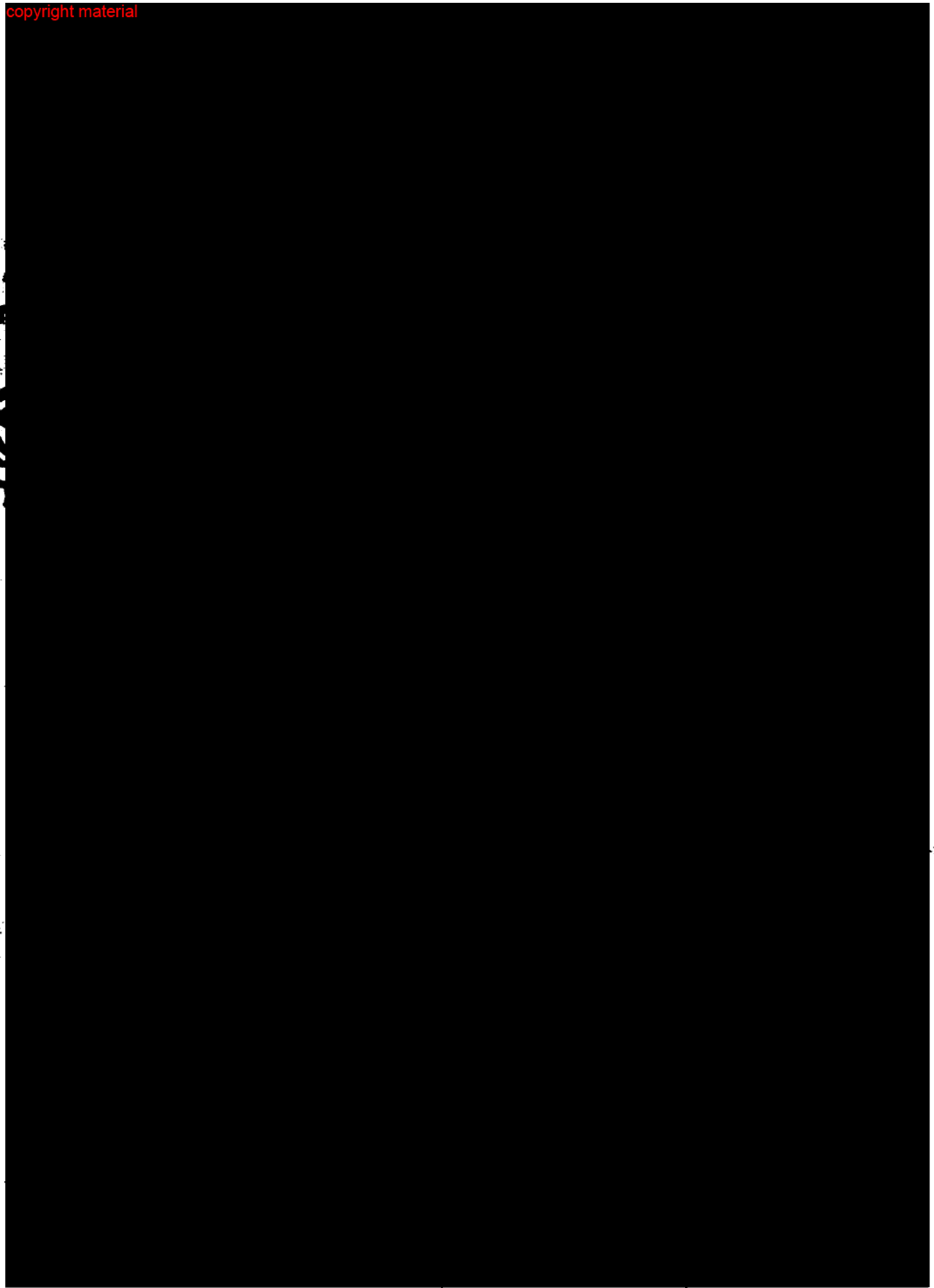

CHAPTER 35

Revision Joint Replacement

B. F. MORREY

CHAPTER 62

Elbow Reconstructive Surgery

BERNARD F. MORREY

Operative Orthopaedics

Volume 1

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