P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

zimmer

MAR - 2 1998

K973357

Summary of Safety and Effectiveness
Coonrad/Morrey Total Elbow, New Hinge Pin

- **Submitted by:**

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, IN 46581-0708

- **Prepared by:**

  Charlene Brumbaugh
  Specialist
  Global Regulatory Affairs
  Telephone: 219-372-4962
  Telefax: 219-372-4605

- **Date:**

  September 4, 1997

- **Trade Name:**

  Coonrad/Morrey Total Elbow

- **Common Name:**

  Elbow Prosthesis

- **Classification Name:**

  Prosthesis, Elbow, constrained, Cemented

- **Predicate Devices:**

  Coonrad III Total Elbow, marketed by Zimmer

Summary of Safety and Effectiveness
Coonrad/Morrey Total Elbow, New Hinge Pin
(Continued)

- **Device Description**

  The Coonrad/Morrey Total Elbow is closely based on the Coonrad III Total Elbow (K883665) cleared by FDA on February 3, 1989, with several exceptions.

- **Intended Use**

  The Coonrad/Morrey Total Elbow is indicated for:

  - 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
  - Instability or loss of motion when the degree of joint damage precludes less radical procedures

  The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises 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 predominantly 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.

- **Performance Data**

  Performance testing was conducted to determine force required to unlock the hinge pin assembly. Results indicate the product is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Charlene Brumbaugh
Specialist
Global Regulatory Affairs
Zimmer
P.O. Box 708
Warsaw, Indiana 46581-0708

MAR - 2 1998

Re: K973357
Trade Name: Coonrad/Morrey Total Elbow, New Hinge Pin
Regulatory Class: III
Product Code: JDC
Dated: September 4, 1997
Received: September 8, 1997

Dear Ms. Brumbaugh:

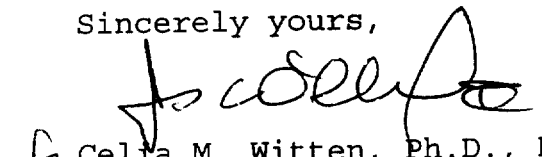
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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

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 "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

510(k) Number (if known): K973357

Device Name: Coonrad/Morrey Total Elbow, New Hinge Pin

Indications For Use:

- 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
- Instability or loss of motion when the degree of joint damage precludes less radical procedures

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises 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 predominantly 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973357

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

RA08702K.510

6JDB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 10-10

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K973357/A2

To: Division Director: OR/DSORD

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

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

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

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

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

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

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

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

_____ No response necessary

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

Reviewed by: Elizabeth Fe ACD 10/22/12

Date: 10/22/12

Frank, Elizabeth L

From: Frank, Elizabeth L
Sent: Monday, October 22, 2012 4:02 PM
To: 'rebecca.dill@zimmer.com'
Subject: Coonrad/Morrey Total Elbow Instrumentation Add-to-Files

Dear Ms. Dill,
We have received your add to files for the Coonrad/Morrey Total Elbow (K973357/A2, K001989/A1, and K053189/A2). It appears these submissions included specific instrumentation listings and you have recently determined these instrumentation listings were not complete. An add-to-file is not the appropriate method to update the device specific instrumentation. If Zimmer believes the Agency's record is not complete and these device specific instruments were not cleared in the original submissions, then a new 510(k) is necessary and it may be possible to bundle these submissions. Please contact us if you would like to discuss bundling of these submissions. However, if you believe these device specific instruments were cleared as part of the submissions, a 510(k) submission is not required. Such a decision should be made by your firm according to "Deciding When to Submit a 510(k) for a Change to an Existing Device" available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf

This email will officially close out the add-to-files for these submissions. Please let me know if you have any additional questions.

Best regards,

Beth

Elizabeth L. Frank, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
Division of Surgical, Orthopedic, and Restorative Devices
Phone: 301-796-6439
Fax: 301-847-8119
elizabeth.frank@fda.hhs.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
10/04/2012		K973357

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☒ Other *(describe submission)*.
☐ Supplement	☐ Supplement			Traditional 510(k) Add-to-File
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Zimmer Inc	1822565		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
N/A	574-372-4964		
Street Address	**FAX Number** *(including area code)*		
P.O. Box 708	574-372-4605		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Warsaw	Indiana	46581-0708	USA
Contact Name			
Carol Vierling			
Contact Title	**Contact E-mail Address**		
Director, Regulatory Affairs	carol.vierling@zimmer.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Zimmer, Inc			
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	(574) 372-4260		
Street Address	**FAX Number** *(including area code)*		
P.O. Box 708	(574) 372-4605		
City	**State / Province**	**ZIP Code**	**Country**
Warsaw	IN	46581-0708	USA
Contact Name			
Rebecca Dill			
Contact Title	**Contact E-mail Address**		
Specialist, Regulatory Affairs	rebecca.dill@zimmer.com		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component or specification
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission.
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*

Zimmer is submitting this add-to-file to ensure that the Agency's record is complete and inclusive of instrumentation required to implant the cleared device

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1 JDC	2	3	4
5	6	7	8

Summary of or statement concerning safety and effectiveness information

☐ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K973357	Coonrad Morrey Total Elbow	Zimmer Inc
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Elbow joint metal polymer constrained cemented prosthesis

	Trade or Proprietary or Model Name for This Device		Model Number
1	Coonrad/Morrey Total Elbow	1	Instruments listed in Exhibit A
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: JDC

C.F.R. Section *(if applicable)*: 21 CFR § 888.3150

Classification Panel: Orthopedics 87

Device Class

☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

see CDRH cover sheet attachment

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 1822565	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Zimmer, Inc		Establishment Registration Number: 1822565
Division Name *(if applicable)*: N/A		Phone Number *(including area code)*: (574) 372-4964
Street Address: P.O. Box 708		FAX Number *(including area code)*: (574) 372-4605
City: Warsaw	State / Province: Indiana	ZIP Code: 46581-0708 — Country: USA
Contact Name: Carol Vierling	Contact Title: Director, Regulatory Affairs	Contact E-mail Address: carol.vierling@zimmer.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code — Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code — Country
Contact Name	Contact Title	Contact E-mail Address

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

In agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number

CDRH Cover Sheet Attachment - Indications for Use

Indications for Use – Coonrad/Morrey Total Elbow

Indications include: 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; revision arthroplasty; and instability or loss of motion when the degree of joint damage precludes less radical procedures.

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises 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.

K973357 1/A2

P.O. Box 708
Warsaw, IN 46581-0708
(574) 267-6131

October 4, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Sir or Madam:

Subject: Add-to-file for Traditional 510(k) K973357: – Coonrad/Morrey Total Elbow

The instruments noted in this submission are used to implant the Coonrad/Morrey Total Elbow, K973357, cleared March 2, 1998. Zimmer believes that the instruments are Class II accessories to an implant cleared under the above 510(k). These instruments were either explicitly described in the submission documentation (i.e., the draft surgical technique), or were implicitly understood by Zimmer and the Agency as being required for the implantation of the subject device. Because these instruments may not have been explicitly listed in the 510(k) submission, Zimmer is submitting this Add-to-File to ensure that the Agency's record is complete.

If you require any additional information or have any questions, please contact me by telephone at (574) 372-4260, by e-mail at rebecca.dill@zimmer.com fax at (574) 372-4605.

Sincerely,

Rebecca Dill

Rebecca Dill
Specialist, Regulatory Affairs

rd/la
Enclosure

Exhibit A –Catalog Numbers

K973357 Class II Accessory Catalog Numbers

Catalog Number	Description
31-8106-040-00	COONRAD/MORREY TOTAL ELBOW PIN REMOVAL TOOL
31-8106-054-00	COONRAD/MORREY TOTAL ELBOW IMPACTION GRAFTING INSTRUMENTATION SLIDE HAMMER ASSEMBLY
31-8106-065-00	COONRAD/MORREY TOTAL ELBOW HUMERAL RASP, REGULAR, 6 IN LENGTH
31-8106-066-00	COONRAD/MORREY TOTAL ELBOW HUMERAL RASP, SMALL, 6 IN LENGTH
31-8106-067-00	COONRAD/MORREY TOTAL ELBOW ULNAR RASP, LEFT STARTER
31-8106-068-00	COONRAD/MORREY TOTAL ELBOW ULNAR RASP, RIGHT STARTER
31-8106-069-00	COONRAD/MORREY TOTAL ELBOW ULNAR RASP PILOT
31-8106-075-00	COONRAD/MORREY TOTAL ELBOW HUMERAL CUTTING GUIDE, REGULAR
31-8106-076-00	COONRAD/MORREY TOTAL ELBOW HUMERAL RASP, SMALL, 4 IN LENGTH
31-8106-077-00	COONRAD/MORREY TOTAL ELBOW HUMERAL RASP, REGULAR, 4 IN LENGTH
31-8106-078-00	COONRAD/MORREY TOTAL ELBOW 6 IN. HUMERAL STARTER RASP
31-8106-080-00	COONRAD/MORREY TOTAL ELBOW T-HANDLE, 3.75 INCHES OVERALL LENGTH
31-8106-081-00	COONRAD/MORREY TOTAL ELBOW HUMERAL ALIGNMENT GUIDE
31-8106-082-00	HUMERAL IMPACTOR FOR USE WITH THE COONRAD/MORREY TOTAL ELBOW
31-8106-084-00	STRAIGHT IMPACTOR FOR USE WITH COONRAD/MORREY TOTAL ELBOW
31-8106-085-00	COONRAD/MORREY TOTAL ELBOW HUMERAL CUTTING GUIDE, SMALL
31-8106-167-00	RUSH AWL REAMER, 2.5 MM DIA, 4.5 IN (114.3 MM) LENGTH
31-8106-168-00	RUSH AWL REAMER, 3 MM DIA, 4.5 IN (114.3 MM) LENGTH
31-8106-169-00	RUSH AWL REAMER, 4.75 MM DIA, 4.5 IN (114.3 MM) LENGTH

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Charlene Brumbaugh
Specialist
Global Regulatory Affairs
Zimmer
P.O. Box 708
Warsaw, Indiana 46581-0708

MAR - 2 1998

Re: K973357
Trade Name: Coonrad/Morrey Total Elbow, New Hinge Pin
Regulatory Class: III
Product Code: JDC
Dated: September 4, 1997
Received: September 8, 1997

Dear Ms. Brumbaugh:

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

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

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 "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for 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

510(k) Number (if known): K973357

Device Name: Coonrad/Morrey Total Elbow, New Hinge Pin

Indications For Use:

- 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
- Instability or loss of motion when the degree of joint damage precludes less radical procedures

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises 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 predominantly 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973357

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

RA08702K.510

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 1997

Ms. Charlene Brumbaugh
Specialist
Global Regulatory Affairs
Zimmer
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K973357
Coonrad/Morrey Total Elbow, New Hinge Pin
Dated: September 4, 1997
Received: September 8, 1997
Class: III

Dear Ms. Brumbaugh:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed the scientific review portion of your premarket notification (510(k)) referenced above. Final clearance of a 510(k) for a class III device requires an FDA inspection that finds the manufacturing facilities, methods and controls in compliance with the applicable device Good Manufacturing Practice (GMP) Regulations (21 CFR Part 820). CDRH will issue a substantially equivalent letter after the inspectional findings have been reviewed and determined to be acceptable. You may not begin commercial distribution of the device manufactured at your facility(ies) until you have received a substantially equivalent letter.

If you have a manufacturing facility which is not prepared for production of the device, amend the 510(k) as soon as possible and notify your District Office to indicate when the facility will be prepared to produce the device so that the FDA inspection can be rescheduled. Where appropriate, amend the 510(k) to include any relevant information regarding the manufacturing facilities, methods or controls not previously submitted. If you have any questions regarding the status of your GMP inspection please contact your District Office or the Office of Compliance, CDRH at (301) 594-4695.

All information regarding this 510(k) should be submitted in duplicate to the address below and reference the above 510(k) number to facilitate processing.

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

If you have any questions concerning this letter, please contact the Premarket Notification 510(k) Section at (301) 594-1190.

Sincerely yours,

Heather S. Rosecrans

Heather S. Rosecrans
Chief, Premarket
Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food And Drug Administration

12/3/97

Memorandum

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

Subject: 510(k) Number K973357

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.)

Class III

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 (does not 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 JDC III	

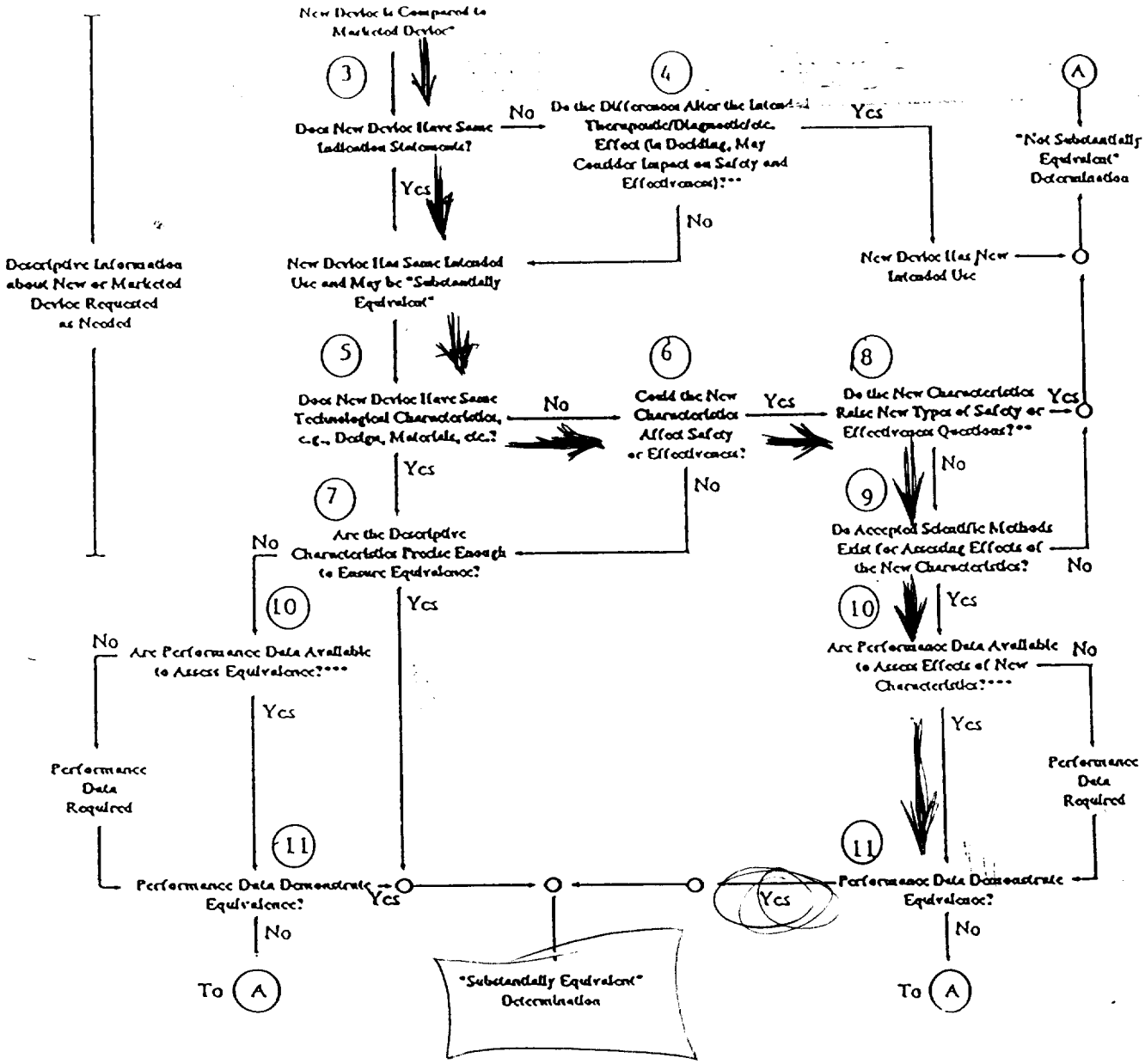
Review: _____ CRDB _____
(Branch Chief) (Branch Code) (Date)

final Review: _____ 12/3/97
(Division Director) (Date)

Revised 11-20-96

6

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.

MEMO RECORD

DATE: December 3, 1997

FROM: Theodore R. Stevens, Biomedical Engineer, HFZ-410
TO: The Record, K973357
SUBJECT: Coonrad/Morrey Total Elbow, New Hinge Pin

Common Name: Total Elbow Prosthesis
Trade Name: Coonrad/Morrey Total Elbow, New Hinge Pin
Classification: 21 CFR 888.3150 Elbow joint metal/polymer constrained cemented prosthesis
Class: III
Product Codes: 87 JDC

☐ 510(k) statement ☒ 510(k) summary
☒ Truth/Accuracy statement
☒ Indications for Use:

- *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*
- *Instability or loss of motion when the degree of joint damage precludes less radical procedures*

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises 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 predominantly 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.

Devices to which compared: K883665 Zimmer Coonrad III Total Elbow

NOTE: Zimmer characterized the predicate device as a "semi-constrained" elbow. However, it has a pivot pin and is therefore linked across the joint, so was cleared as a constrained elbow.

Contact/Telephone number: Charlene Brumbaugh

☎ Contact with sponsor: I telephoned Zimmer on 11/20 and informed Charlene Brumbaugh that, because constrained elbows are Class III pre-Amendments devices, they need to provide a Class III certification and summary. They also need to provide a 510(k) summary of S&E that correctly identifies the device as constrained. Also, a

full characterization of the porous coating, or reference to a previous submission containing that information, is required.

☎ Sponsor response: Zimmer provided a Class III certification and summary by fax, as well as a new cover page identifying the device as constrained, and reference to K953337 for porous coating information. Hard copy was received in ODE Nov. 28, and by reviewer Dec. 2.

Recommendation: Substantially equivalent.

Basis of Recommendation: Minor modification to previously cleared device.

Intended Use: See Indications for use, above. Identical to indication statement in labeling for original Coonrad III elbow.

Device Description: The subject device is a modification of the Coonrad III Total Elbow cleared under K883665, which was itself a modification of the pre-Amendments Coonrad Elbow and Coonrad II. Differences are as follows: The hinge pin has been modified from a solid shaft with C-ring to lock in place, to a 2-piece pin, with the inner pin used as the locking device. The advantage to this design is that instrumentation (a ring spreader) is no longer needed to insert the hinge pin. The change is also intended to address complaints (at least 3 complaints of c-ring loosening). The other difference is the addition of two slightly longer ulnar components: 4.5: small and 4.5" regular.

As with the earlier device, the Coonrad/Morrey Total Elbow consists of humeral and ulnar components, linked by a hinge pin which has UHMWPE bushings. The Coonrad III Elbow has a plasma spray surface, whereas the Coonrad/Morrey has a sintered titanium bead coating on the distal humeral component, identical to the beaded coating on the hip cleard under K953337 (β Hip). Instead of the previous plasma spray coating, the present ulnar component has a PMMA precoat identical to that found on the Moore Hip (K811416).

Articular geometry remains the same, with the design allowing 7° of lateral deviation to either side of center.

Materials:
wrought Tivanium® Ti-6Al-4V alloy per ASTM F136 (humeral and ulnar components, hinge pin)
CP Ti (sintered bead coating on distal humeral stem)
PMMA (pre-coat on proximal ulnar stem)
Zimaloy® CoCrMo alloy per ASTM F799
UHMWPE per ASTM F648 (articulating bushings)

Porous Coating Information: The distal portion of the humeral component has a sintered CP titanium alloy porous coating. The Coonrad III predicate device had a CP Ti plasma spray coating as cleared. This 510(k) erroneously stated the Coonrad III had a sintered coating. A telephone call to Zimmer clarified that the present device does indeed have a sintered bead coating, identical to that on the β Hip cleared under K953337.

Sterility Information: min 25kGy Gamma irradiation, SAL 10^{-6}, Validation per ANSI/AAMI/ISO 11137-1194 "Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization, Method 1." No claims regarding pyrogenicity.

Packaging: thermoformed cavity of polyester, topped with TYVEK® seal.

Labeling: Box labels, package insert and surgical protocol were provided. Labeling contains appropriate indications, contraindications, precautions and warnings, and states that the device is for cemented use only.

Testing: Pull-out testing of the new hinge pin design was performed. Mean pullout load was 343 lb (regular) or 289 lb (small). This exceeds the greatest expected lateral load by at least an order of magnitude.

Answers to YES/NO questions requiring explanation:

5. Same technological characteristics? NO, hinge pin locking mechanism different.
6. Could differences affect S&E? YES, load carrying ability may be different.
8. New type of S&E question? NO, question remains ability to support load.
11. Data demonstrate equivalence? YES, load exceeds greatest expected lateral load.

Recommendation: I recommend the Coonrad/Morrey Total Elbow with modified hinge pin be found substantially equivalent to the predicate Coonrad III constrained elbow.

Theodore R. Stevens

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 973357

Reviewer: Theodore R Stevens

Division/Branch: DGRD/CRDB

Device Name: Conrad/Howmedica Total Elbow, new hinge pin

Product To Which Compared (510(K) Number If Known): K883665

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

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 for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

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 ar 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 SUPPORTINC INFORMATION

K973357/A1

CONFIRMATION OF TELECOPY PREVIOUSLY SENT

ZIMMER, INC.
GLOBAL REGULATORY AFFAIRS
WARSAW, INDIANA
FAX NUMBER 219/372-4605

THIS FACSIMILE MESSAGE IS CONFIDENTIAL AND MAY CONTAIN ATTORNEY PRIVILEGED INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR COMPANY NAMED

If the reader is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please immediately notify us by telephone, so that we may arrange for the return of the original message to us. Thank you.

PLEASE DELIVER THE FOLLOWING FAX MESSAGE

TO: Ted Stephens FAX NUMBER: 301-827-4349

FROM Charlene Brumbaugh

DATE: November 26, 1997

TOTAL NUMBER OF PAGES TRANSMITTED, INCLUDING THIS PAGE: 21

IF TRANSMISSION ERROR, CALL:
Mary Mills at 219/267-6131 ext. 2549

ADDITIONAL INFORMATION:

The original of this fax will be sent to you by UPS.

RECEIVED
Nov 28 2 41 PM '97
FDA/CDRH/OCE/DID

IRAFAX

ZIMMER, INC.
GLOBAL REGULATORY AFFAIRS
WARSAW, INDIANA
FAX NUMBER 219/372-4605

PLEASE DELIVER THE FOLLOWING FAX MESSAGE

TO: Ted Stephens FAX NUMBER: 301-827-4349

FROM Charlene Brumbaugh

DATE: November 26, 1997

TOTAL NUMBER OF PAGES TRANSMITTED, INCLUDING THIS PAGE: 21

IF TRANSMISSION ERROR, CALL:
Mary Mills at 219/267-6131 ext. 2549

ADDITIONAL INFORMATION:

The original of this fax will be sent to you by UPS.

IRAFAX

TRANSMISSION REPORT

THIS DOCUMENT WAS CONFIRMED
(REDUCED SAMPLE ABOVE - SEE DETAILS BELOW)

** COUNT **
TOTAL PAGES SCANNED : 21
TOTAL PAGES CONFIRMED : 21

RESULT OF LAST BATCH SENT
*** SEND ***

No.	REMOTE STATION	START TIME	DURATION	#PAGES	MODE	RESULTS
1	301 827 4349	11-26-97 3:04PM	24'36"	21/ 21	48 EC	COMPLETED 4800
		TOTAL	0:24'36"	21		

NOTE:
No. : OPERATION NUMBER 48 : 4800BPS SELECTED EC : ERROR CORRECT G2 : G2 COMMUNICATION
PD : POLLED BY REMOTE SF : STORE & FORWARD RI : RELAY INITIATE RS : RELAY STATION
MB : SEND TO MAILBOX PG : POLLING A REMOTE MP : MULTI-POLLING RM : RECEIVE TO MEMORY

zimmer

P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

November 25, 1997

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

Attention: Ted Stephens

Subject: 510(K) NUMBER: K973357 COONRAD/MORREY TOTAL ELBOW, NEW HINGE PIN

Dear Mr. Stephens:

The following information is provided in response to the questions which were discussed during our telephone conversation with the FDA on November 21, 1997. You requested:

- Designation of the device as a Class III device, Constrained Cemented Elbow, 888.3150 87JDC
- Identification of another Zimmer device with identical porous bead coating
- Class III Certification
- Class III Summary

The requested information is provided in the enclosed attachments. I trust that this additional information is sufficient to complete your review of the COONRAD/MORREY Total Elbow, New Hinge Pin, K973357. If you require additional information or have further questions, please contact me at 219-372-4962 or (fax) 219-372-4605.

Sincerely,

Charlene Brumbaugh

Charlene Brumbaugh
Specialist
Global Regulatory Affairs

cb/mm
IR11721C.ME
Attachment

15

510(k) Notification

1. Proprietary Name: Coonrad/Morrey Total Elbow

   Common Name: Elbow Prosthesis

   Classification Name and Reference: 21 CFR 888.3150 Prosthesis, Elbow, Constrained. Cemented

   Regulatory Class: Class III

   Device Product Code: 87 JDC, Prosthesis, Elbow, Constrained, Cemented

2. Identification of another Zimmer device with identical porous bead coating:

   Another Zimmer device with porous bead coating is the Beta Hip Prosthesis, K953337, which cleared January 22, 1996.

3. Class III Certification

   I certify, in my capacity as Manager of Regulatory Compliance, of Zimmer, Inc. that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the COONRAD III Total Elbow (the predicate device of the COONRAD/MORREY Total Elbow. I further certify that I am aware of the types of problems to which the COONRAD III Total Elbow is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the COONRAD III is complete and accurate.

Connie Morgan 11/26/97

Connie Morgan
Manager of Regulatory Compliance

4. Class III Summary

Following is a description of adverse events of the predicate device, Coonrad III, K83665, cleared February 3, 1989, as well as a literature search of elbow replacement using the predicate device.

Item Description	Complaint	MDR #	Date Completed
(b) (4)			

,7/1
DIALOG(R)File 154:MEDLINE(R)

09232553 97422314
Semiconstrained total elbow replacement for the treatment of post-traumatic osteoarthrosis.
Schneeberger AG; Adams R; Morrey BF
Mayo Clinic, Rochester, Minnesota 55905, USA.
J Bone Joint Surg Am (UNITED STATES) Aug 1997, 79 (8) p1211-22, ISSN 0021-9355 Journal Code: HJR
Languages: ENGLISH
Document type: JOURNAL ARTICLE
Forty-one consecutive patients were managed for post-traumatic osteoarthrosis or dysfunction of the elbow with use of a non-customized semiconstrained Coonrad-Morrey total elbow prosthesis. The average age at the time of the operation was fifty-seven years (range, thirty-two to eighty-two years). The patients were followed for an average of five years and eight months (range, two to twelve years). Radiographs were made at least two years postoperatively (average, five years and one month; range, two to twelve years) for thirty-nine of the forty-one patients. According to the Mayo elbow performance score, sixteen patients (39 per cent) had an excellent result, eighteen (44 per cent) had a good result, five (12 per cent) had a fair result, and two (5 per cent) had a poor result. Thirty-six (92 per cent) of the thirty-eight patients who had a functioning implant at time of follow-up considered the outcome to be satisfactory. Preoperatively, thirty-seven patients (90 per cent) had moderate or severe pain; postoperatively, thirty (73 per cent) had no or only mild discomfort. Motion improved from an average arc of flexion of 40 to 118 degrees preoperatively to an average arc of flexion of 27 to 131 degrees postoperatively. All thirty-eight functioning implants rendered the elbow stable. Eleven patients (27 per cent) had a major complication. Nine of them (22 per cent of the series) needed an additional operation. There was no aseptic loosening, and most of the complications were primarily due to so-called mechanical failure. The ulnar component fractured in five patients (12 per cent), and the polyethylene bushings wore out in two (5 per cent). These complications were attributed principally to the performance of strenuous physical labor, such as lifting more than ten kilograms on a regular basis, against the advice of the surgeon; excessive preoperative deformity of the joint; or an unstable traumatic injury. Two patients (5 per cent) had an infection. Semiconstrained joint replacement of the elbow can be a reliable form of treatment, and frequently is the only viable option, for the difficult problems encountered with post-traumatic destruction of a joint. Restoration of function, relief of pain, and patient satisfaction can be achieved even when a patient is less than sixty years old if that patient has low demands and a low level of activity. However, the mechanical failures underscore the fact that this procedure is relatively contraindicated in patients who anticipate strenuous physical activity or who are not expected to comply with the postoperative protocol. This observation reflects the tendency for increased and excessive use of a previously functionless joint, after it has been rendered stable and pain-free, to lead to mechanical failure.

6/7/2
LOG(R)File 154:MEDLINE(R)
format only 1997 Knight-Ridder Info. All rts. reserv.

09207051 96115885
Loose-hinge total elbow arthroplasty. An experimental study of the effects of implant alignment on three-dimensional elbow kinematics.
Schuind F; O'Driscoll S; Korinek S; An KN; Morrey BF
Orthopaedic Biomechanics Laboratory, Mayo Clinic/Mayo Foundation, Rochester, Minnesota, USA.
J Arthroplasty (UNITED STATES) Oct 1995, 10 (5) p670-8, ISSN 0883-5403 Journal Code: JAY
Languages: ENGLISH
Document type: JOURNAL ARTICLE
A previous study suggested that the kinematics of a loose-hinge total elbow arthroplasty (TEA) are those of a truly semiconstrained joint. This study addresses the effects of malposition of the implant. The three-dimensional elbow kinematics during simulated active motion were studied in six cadaver specimens using an electromagnetic tracking device. In addition to simulated active elbow flexion, flexion arcs were obtained under an elbow varus or valgus moment, to calculate the structural varus-valgus laxities. The results after four different Coondrad-Morrey TEA positions of implantation were compared with those of the intact elbow. The flexion-extension amplitudes were not significantly decreased after TEA implantation, except with external rotation of the ulnar component, which resulted in a loss of extension. In the intact elbow and after TEA implantation in any position, the mean varus-valgus deviations throughout elbow flexion were in a narrower range than the structural limits imposed by the ligaments (intact elbow) or the TEA hinge design. With internal malrotation of the humeral component over 10 degrees, however, the valgus structural limit was reached and, conversely, the varus limit with external rotation over 10 degrees. The clinical improvement observed with the semiconstrained TEA is derived from the benefits of the less constrained articulation. The proximodistal changes of TEA implantation have no consequence on the kinematic pattern. Rotational malpositioning of either humeral or ulnar component should be avoided, the first because it changes the kinematic pattern toward the structural limits of the implant and, therefore, may lead to excessive stresses at the bone-cement-implant interfaces and to early loosening, and the latter because it causes loss of extension.

6/7/3
DIALOG(R)File 154:MEDLINE(R)
(c) format only 1997 Knight-Ridder Info. All rts. reserv.

09105362 97267296
[Long-term results of therapy of open and closed fractures of the elbow joint]
Langzeitergebnisse der Therapie offener und geschlossene Frakturen des Ellenbogengelenks.
Seekamp A; Regel G; Blauth M; Klages U; Klemme R; Tscherne H
Unfallchirurgische Klinik, Medizinische Hochschule Hannover.
Unfallchirurg (GERMANY) Mar 1997, 100 (3) p205-11, ISSN 0177-5537 Journal Code: UNP
Languages: GERMAN Summary Languages: ENGLISH

Document type: JOURNAL ARTICLE English Abstract

ractures of the elbow joint are quite rare compared with the total ı ɔidence of injuries to the extremities. However, elbow fractures often result in significant disability. Therefore in a retrospective study, we have evaluated criteria that are of prognostic value for late functional outcome. Sixty-four (10.3%) of 622 patients with closed elbow fractures and 107 (89%) of 119 patients with open elbow fractures underwent a physical examination. The mean follow-up time was 8.2 years. The functional outcome was recorded by a modified score (0-max. 15) according to Morrey. Epidemiological data from both groups revealed a greater severity and higher degree of injury in open fractures than in closed fractures. In contrast, both groups presented a comparably good functional result. The most significant factor for poor outcome (score < 5) was identified as nerve lesions. Among all nerve lesions in open fractures, 45% resulted in a functional score of < 5; in 42% of closed fractures combined with a nerve lesion a similarly poor result was also noted. A second major factor appeared to be the method of primary therapy. An external joint transfixation resulted in a score of < 5 in 32% of patients that were treated primarily by transfixation. In cases initially treated with open reduction and internal fixation, only 18.5% of open fractures and 3.1% of closed fractures presented a similar low score. According to our results the late functional outcome of elbow fractures depends less on the type of fracture than on the presence of a nerve lesion and the method of primary treatment, which should facilitate early mobilization.

7/4
LOG(R)File 154:MEDLINE(R)
(c) format only 1997 Knight-Ridder Info. All rts. reserv.

09078667 97238240

Absorbable implants in the treatment of distal humeral fractures in adolescents and adults.

Pelto-Vasenius K; Hirvensalo E; Rokkanen P
Department of Orthopaedics and Traumatology, Helsinki University Central Hospital, Finland.

Acta Orthop Belg (BELGIUM) 1996, 62 Suppl 1 p93-102, ISSN 0001-6462 Journal Code: 1G2
Languages: ENGLISH
Document type: JOURNAL ARTICLE

Between 1986 and 1994, 57 consecutive patients with a distal humeral fracture were treated operatively using absorbable implants, 15 of them were treated by combining absorbable pins or screws with metallic implants. According to the AO/ASIF system, there were 13 Type A, 21 Type B and 10 Type C fractures. Thirteen patients were lost to follow-up. The clinical outcome was reviewed in 44 patients with an average follow-up time of 4.6 years. The functional results by Broberg and Morrey were excellent or good in 36 (81%), fair in three (6,8%) and poor in five (11,2%) patients. Twenty-nine (66%) patients indicated their satisfaction with the outcome of the treatment. The elderly had more severely unstable fractures and more unfavourable results than younger patients. A postoperative redisplacement was seen in 11 (25%) patients and infection in seven (16%) patients. An ɔterial foreign-body reaction occurred in four (9,1%) patients. The ı ɔults were favourable in the noncomminuted epicondylar and condylar fractures of the distal humerus as well as in the humeral capitellum fractures. The results were unsatisfactory in the comminuted intraaticular

distal humeral fractures.

6/7/5
DIALOG(R)File 154:MEDLINE(R)

09078666 97238239
[Retrospective analysis of 78 surgically repaired fractures of the radial head]
Analyse retrospective d'une serie de 78 fractures de la tete radiale operees.
Rochwerger A; Bataille JF; Kelberine F; Curvale G; Groulier P
Service de chirurgie orthopedique et traumatologique, Hopital de la Conception, Mar seille.
Acta Orthop Belg (BELGIUM) 1996, 62 Suppl 1 p87-92, ISSN 0001-6462 Journal Code: 1G2
Languages: FRENCH Summary Languages: ENGLISH
Document type: JOURNAL ARTICLE English Abstract
The authors present a analysis of 78 cases of radial head fracture operated in the same department. 16 cases were added to the first study of 62 cases operated between 1967 and 1988 and published in 1991. According to the Mason classification modified by Morrey, there were 22 type II, 24 type III and 32 type IV. Surgical treatment consisted in an osteosynthesis in 35 cases, a fracture fragment excision in 9 cases, a resection of the head in 24 cases, a silastic prosthesis in 10 cases. The results have been studied c a functional and radiological basis with follow-up from 2 to 23 years an 5 years). The authors noted the good results of the type II fractures which had an osteosynthesis, the satisfactory results in more than 50% of the cases with resection of the radial head. The comparison of both series established the absence of prosthesis in the recent one. The poor results of the comminutive fractures with elbow dislocation lead the authors to consider the prothesis in these fractures, as a possible indication.

6/7/6
DIALOG(R)File 154:MEDLINE(R)

09078142 97265704
[Epicondylopathia humeri. The indication for, technic and clinical results of radiotherapy]
Epicondylopathia humeri. Indikation, Technik, klinische Ergebnisse der Radiotherapie.
Seegenschmiedt MH; Keilholz L; Martus P; Kuhr M; Wichmann G; Sauer R
Strahlentherapeutische Klinik und Poliklinik, Waldkrankenhaus St. Marien, Universitat Erlangen-Nurnberg.
Strahlenther Onkol (GERMANY) Apr 1997, 173 (4) p208-18, ISSN 0179-7158 Journal Code: VCM
Languages: GERMAN Summary Languages: ENGLISH
Document type: JOURNAL ARTICLE English Abstract
BACKGROUND: The efficacy of radiotherapy for degenerative-inflammatory orders is well known, but so far long-term observations and reliable assessment of symptoms according to objective criteria and scores for validation are still missing. PATIENTS AND METHOD: From 1986 to 1991, 104 patients with refractory epicondylopathia humeri were irradiated. 85

 21

patients or 93 elbows (due to double-sided symptoms) were documented in g-term follow-up according to objective criteria. All patients had eived intensive therapy. Pain symptoms were quantified in "categories" and "grades" prior to and 6 weeks after radiotherapy and at last follow-up. In addition, the elbow score of Morrey et al. [36] was used for long-term evaluation. The onset of pain symptoms was acute in 41 and chronic in 52 cases. The mean symptom duration prior to radiotherapy was 16 months. Pain was mostly triggered off during professional (46) or sportive activities (23) or spontaneously (11). Fifty-one patients were severely disabled in professional or sportive activities. The involved elbow(s) received 2 radiotherapy series of 6 x 1 Gy (total 12 Gy) with 3 fractions per week; the second radiotherapy series was started 6 weeks after the first series. Mean follow-up was 4 +/- 2 (1 to 8) years. RESULTS: Forty-three patients (50 elbows) achieved "complete pain relief (CR)" in all pain categories: 59% elbows with pain at strain had "complete pain relief", 79% with pain at night, 84% with permanent pain, 80% with pain at rest and 81% with pain at initiation or morning stiffness. Nineteen elbows gained "major pain relief (PR)", i.e. had minor symptoms (maximum grade 1) in all categories. Thus, a total of 69 (74%) elbows responded to radiotherapy. Seventeen patients (19 elbows) were operated because of persistent symptoms or dissatisfaction in long-term follow-up; 7 of those became completely free of symptoms. The Morrey-Score improved by a mean of 18 points from 78 prior to radiotherapy to 96 points at last follow-up. According to the Morrey-Score only 2 patients became worse in long-term follow-up. Two parameters indicated a negative prognosis in multivariate analysis: long symptom duration prior to radiotherapy and immobilisation with plaster ($p < 0.05$). CONCLUSIONS: R diotherapy for refractory epicondylopathia humeri is highly effective. g symptom duration and long-term immobilisation by plaster are negative prognostic factors for treatment outcome. Due to the low side effects and treatment costs, radiotherapy is a good therapeutic option in comparison to conventional treatment methods and surgery in the chronic stage of epicondylopathia humeri.

6/7/7
DIALOG(R)File 154:MEDLINE(R)

09030692 97223948
Total elbow arthroplasty: revision with use of a non-custom semiconstrained prosthesis.
King GJ; Adams RA; Morrey BF
Mayo Clinic, Rochester, Minnesota 55905, USA.
J Bone Joint Surg Am (UNITED STATES) Mar 1997, 79 (3) p394-400, ISSN 0021-9355 Journal Code: HJR
Languages: ENGLISH
Document type: JOURNAL ARTICLE
The results of revision elbow arthroplasty with use of the semiconstrained Mayo-modified Coonrad implant in forty-one patients were reviewed retrospectively. The average duration of follow-up was six years (range, two to thirteen years). At the time of the latest follow-up evaluation, thirty-eight patients were able to perform activities of daily ing, one had a stiff elbow because of heterotopic ossification, one had w akness secondary to an injury of the radial nerve, and one had an unstable elbow after removal of the prosthesis because of recurrent aseptic loosening. Fourteen patients sustained either a fracture or a perforation

of the cortex at the time of removal of the primary implant. Three of these patients had an injury of the radial nerve; the injury was due to extravasation of the cement from a cortical defect in two of them and was sustained during removal of the cement in one. Eight patients had an intraoperative or postoperative complication that necessitated additional operative intervention. Postoperatively, twenty-two patients had complete relief of pain and sixteen had mild discomfort. Three patients remained disabled: one, because of pain secondary to loosening of the component; one, because of a pre-existing nerve injury; and one, because of the residual effects of an intraoperative injury of the radial nerve. The average Mayo elbow performance score was 87 +/- 16 points at the latest follow-up evaluation, compared with 44 +/- 17 points preoperatively ($p < 0.0001$). Revision elbow arthroplasty restored function to the patients who had had a failed prosthesis without infection.

6/7/8
DIALOG(R)File 154:MEDLINE(R)

09011219 97205038
Osteosynthesis for the treatment of non-union of the lateral humeral condyle in children.
Shimada K; Masada K; Tada K; Yamamoto T
Osaka Koseinenkin Hospital, Japan.
J Bone Joint Surg Am (UNITED STATES) Feb 1997, 79 (2) p234-40, ISSN 0021-9355 Journal Code: HJR
Languages: ENGLISH
Document type: JOURNAL ARTICLE
We reviewed the results of osteosynthesis for the treatment of an established non-union of the lateral humeral condyle in sixteen children whose average age was nine years (range, four to thirteen years) at the time of the operation. The average interval between the injury and the operation was five years (range, five months to ten years). The presenting symptoms were pain in the elbow in seven patients, apprehension in nine, a cubitus valgus deformity in six, limitation of motion in three, and dysfunction of the ulnar nerve in four. The average duration of follow-up was eleven years (range, four to thirty-two years). Osseous union was achieved after the initial operation in thirteen patients. Of the three patients who had a persistent non-union, two had a second operation and the third, who was asymptomatic, refused additional operative intervention. The result was rated excellent in eight patients, good in seven, and poor in one, with use of a modification of the functional rating index of Broberg and Morrey. The patient who had a poor result had evidence of avascular necrosis of the fragment.

6/7/9
DIALOG(R)File 154:MEDLINE(R)

08810606 96315973
prospective controlled trial of the fracture of the humeral medial epicondyle--how to treat?
Partio EK; Hirvensalo E; Bostman O; Rokkanen P
Department Of Orthopaedics and Traumatology, Helsinki University Central

 83

Hospital, Finland.
nn Chir Gynaecol (FINLAND) 1996, 85 (1) p67-71, ISSN 0355-9521
rnal Code: 51N
Languages: ENGLISH
Document type: JOURNAL ARTICLE
Twenty-one patients, 11 male and nine female, with fracture of medial humeral epicondyle were treated. The mean age of the patients was 21 (range 8-52) years. The average initial displacement was 13 (range 3-24) mm, and four out of 21 patients had a dislocation of the elbow joint. Two patients were first treated conservatively, but later on operation for removal of the non-united fragment and reattachment of the ligaments and muscles was necessary. One patient was treated by primary excision of the fragment. Eighteen patients were treated by open reduction and internal fixation using self-reinforced polyglyclycolide (SR-PGA) screws in five patients, poly-l-lactide (SR-PLLA) screw in one, small (SR-PGA) rods in seven and Kirschner-wires in five patients. Solid union took place in 14 out of 18 patients and a good stability of the elbow joint was achieved. Fifteen patients scored an excellent result according to the scale of Broberg and Morrey. Although this series was not randomly allocated in respect of the method of treatment, it shows that medial epicondylar fractures can be fixed with absorbable implants without any need for removal procedure.

6/7/10
DIALOG(R)File 154:MEDLINE(R)

32493 96296780
Arthroscopy for limitation of motion of the elbow.
Kim SJ; Kim HK; Lee JW
Department of Orthopaedic Surgery, Yonsei University College of Medicine, Seodaemoon Seoul, Korea.
Arthroscopy (UNITED STATES) Dec 1995, 11 (6) p680-3, ISSN 0749-8063
Journal Code: ABT
Languages: ENGLISH
Document type: JOURNAL ARTICLE
Twenty-five patients with limitation of motion of the elbow joint caused by the intraarticular pathologies were treated with the following arthroscopic procedures: removal of loose bodies, excision of osteophytes, anterior capsular release, abrasion arthroplasty, and partial excision of the radial head. The extension of the elbow improved by 7 degrees, from a preoperative average of 21 degrees to a postoperative average of 14 degrees. The flexion of the elbow improved by 17 degrees, from a preoperative average of 113 degrees to a postoperative average of 130 degrees. The total range of motion improved by 24 degrees, from a preoperative average of 92 degrees to a postoperative average of 116 degrees. The average score of the Elbow Rating Scale of Morrey improved from a preoperative value of 2.8 to a postoperative value of 4.6. Twenty-three patients (92%) were satisfied with their results. Arthroscopy of the elbow is an effective diagnostic and therapeutic procedure for the limitation of motion caused by the intraarticular problems with minimal morbidity and rapid functional recovery.

6/7/11
DIALOG(R)File 154:MEDLINE(R)

 89

022013 96209458
A floating prosthesis for radial-head fractures.
Judet T; Garreau de Loubresse C; Piriou P; Charnley G
Service d'Orthopedie et Traumatologie, l'Hopital Tenon, Paris, France.
J Bone Joint Surg Br (ENGLAND) Mar 1996, 78 (2) p244-9, ISSN 0301-620X Journal Code: HK7
Languages: ENGLISH
Document type: JOURNAL ARTICLE
We report our experience over seven years with a floating radial-head prosthesis for acute fractures of the radial head and the complications which may result from such injury. The prosthesis has an integrated articulation which allows change of position during movement of the elbow. We present the results in 12 patients with a minimum follow-up of two years. Five prostheses had been implanted shortly after injury with an average follow-up of 49 months and seven for the treatment of sequelae with an average follow-up of 43 months. All prostheses have performed well with an improved functional score (modified from Broberg and Morrey 1986). We have not experienced any of the complications previously reported with silicone radial-head replacement. Our initial results suggest that the prosthesis may be suitable for the early or delayed treatment of Mason type-III fractures and more complex injuries involving the radial head.

6/7/12
[illegible]LOG(R)File 154:MEDLINE(R)

08515206 96144552
Coronal shear fractures of the distal end of the humerus.
McKee MD; Jupiter JB; Bamberger HB
Massachusetts General Hospital, Boston 02114, USA.
J Bone Joint Surg Am (UNITED STATES) Jan 1996, 78 (1) p49-54, ISSN 0021-9355 Journal Code: HJR
Languages: ENGLISH
Document type: JOURNAL ARTICLE
We identified a shear fracture of the distal articular surface of the humerus, with anterior and proximal displacement of the capitellum and a portion of the trochlea, in six patients (five female and one male). The average age of the patients was thirty-eight years (range, ten to sixty-three years). Each fracture was the result of a fall from a standing height. A characteristic radiographic abnormality, which we have termed the double-arc sign, was seen on the lateral radiograph of each patient and represented the subchondral bone of the displaced capitellum and the lateral trochlear ridge. All patients were managed with open reduction, internal fixation, and early motion of the elbow. The average duration of follow-up was twenty-two months (range, eighteen to twenty-six months). The fracture united in all patients at an average of six weeks (range, four to nine weeks), without radiographic evidence of osteonecrosis of the fracture fragment. Flexion of the elbow averaged 141 degrees (range, 130 to 150 degrees), with an average flexion contracture of 15 degrees (range, 0 to 40 degrees). Pronation of the forearm averaged 83 degrees, and supination averaged 84 degrees. All patients had a good or excellent functional result, according to the elbow-rating scale of Broberg and Morrey.

7/13
DIALOG(R)File 154:MEDLINE(R)
(c) format only 1997 Knight-Ridder Info. All rts. reserv.

08447246 96069512
Soft tissue attachments of the ulnar coronoid process. An anatomic study with radiographic correlation.
Cage DJ; Abrams RA; Callahan JJ; Botte MJ
Department of Orthopedics, University of California, San Diego 92103, USA.
Clin Orthop (UNITED STATES) Nov 1995, (320) p154-8, ISSN 0009-921X Journal Code: DFY
Languages: ENGLISH
Document type: JOURNAL ARTICLE
Regan and Morrey proposed a 3-type coronoid fracture classification observing that the incidence of concommitant elbow dislocation was proportional to fragment size. Elbow instability associated with coronoid fractures presumably is related to disrupted bony architecture and ineffective stabilizers attached to the free fragment. Twenty cadaveric elbows were dissected, measuring medial collateral ligament, anterior capsule, and brachialis muscle insertion loci on the coronoid. Radiographs were taken after radiopaque labeling of the stabilizer insertions. The anterior bundle of the medial collateral ligament insertion averaged 18.4 mm dorsal to the coronoid tip. Only in Type III fractures would it be attached to the free fragment. The capsule inserted an average of 6.4 mm distal to the coronoid tip. Rarely should Type I fractures result from a capsular avulsion, because only 3 of 20 specimens had the capsule inserting on the tip. The brachialis had a musculoaponeurotic insertion onto the elbow capsule, coronoid, and proximal ulna. The bony insertion averaged 26.3 mm in length, with its proximal margin averaging 11 mm distal to the coronoid tip. In only Type III fractures is the fragment large enough to include the brachialis bony insertion.

6/7/14
DIALOG(R)File 154:MEDLINE(R)
(c) format only 1997 Knight-Ridder Info. All rts. reserv.

08424336 96053980
Fractures of the radial head treated by internal fixation: late results in 26 cases.
Esser RD; Davis S; Taavao T
Division of Orthopaedic Surgery, Stanford University Medical Center, California 94305, USA.
J Orthop Trauma (UNITED STATES) 1995, 9 (4) p318-23, ISSN 0890-5339 Journal Code: JH4
Languages: ENGLISH
Document type: JOURNAL ARTICLE
Twenty-six patients, ranging in age from 14 to 57 years (average 29 years), were evaluated an average of 7 years and 4 months (range 1-14 years) after open reduction and internal fixation of a displaced radial head fracture. Using Mason's classification, there were 11 type II fractures, 9 type III fractures, and 6 type IV fractures with associated dislocation of the elbow. Seven patients had ipsilateral extremity injuries that included fractures of the coronoid process, capitellum, humerus, and

 24

distal radius. Using the Broberg and Morrey elbow score, good or excellent results were achieved in all Mason type II and type III fractures. Four of the six Mason type IV fractures were rated good or excellent. Fair results were obtained in two patients who had an associated dislocation of the elbow and multiple ipsilateral extremity injuries. In these two patients, secondary excision of the radial head relieved pain and yielded some improvement in flexion and forearm rotation.

6/7/15
DIALOG(R)File 154:MEDLINE(R)

08068382 95049612
[Treatment of displaced and comminuted multifragment fractures of the head of the radius: is resection a therapeutic option?]
Traitement des fractures plurifragmentaires deplacees et comminutives de la tete du radius: la resection est-elle une option therapeutique?
Jung M; Babst R; Rosso R; Renner N; Regazzoni P
Departement de chirurgie de l'Universite, Hopital cantonal, Bale.
Helv Chir Acta (SWITZERLAND) Jul 1994, 60 (5) p681-5, ISSN 0018-0181 Journal Code: G4P
Languages: FRENCH Summary Languages: ENGLISH
Document type: JOURNAL ARTICLE English Abstract
The treatment of displaced comminuted fractures of the radial head type III of the Mason classification is still controversial. The restoration of anatomy including additional lesions with a stable fixation is a requisite of early mobilisation. Removal of the radial head, in case of severe comminution, and complete separation of the fragments from the radial neck remain the exception. Insertion of a prosthesis as a spacer is only recommended if there is a remaining instability of the elbow after resection of the radial head. With this treatment modality we have 22/29 good to very good results evaluated by the Morrey score after a follow-up period of 8 years (4-11 years).

6/7/16
DIALOG(R)File 154:MEDLINE(R)

07984297 94330837
Elbow kinematics during sit-to-stand-to-sit of subjects with rheumatoid arthritis.
Packer TL; Wyss UP; Costigan P
Division of Occupational Therapy, Queen's University, Kingston, Ontario, Canada.
Arch Phys Med Rehabil (UNITED STATES) Aug 1994, 75 (8) p900-7, ISSN 0003-9993 Journal Code: 8BK
Languages: ENGLISH
Document type: JOURNAL ARTICLE
Independence in mobility is dependent on the ability to rise from a chair. Elbow kinematics of subjects with rheumatoid arthritis were compared to those of subjects with no known elbow pathology. Through a case study approach, four subjects with varying elbow pathology and symptoms, were compared with a control group of 10 subjects on four kinematic variables. Results indicated that whereas the overall movement pattern was similar

between the two groups, a trend toward increased deviation occurred with increased elbow involvement (as measured using the Morrey Elbow Evaluation). The total time taken to complete the task increased and the maximum velocity decreased as scores on the Morrey Evaluation decreased. When the minimum flexion angle (maximum extension) used during the activity was compared with the minimum flexion angle available, the angle used was consistently 15 degrees to 20 degrees less than that available. This possible need for a residual range raises questions about the generally accepted belief that activities require between 30 degrees to 130 degrees of flexion and 100 degrees of rotation.

6/7/17
DIALOG(R)File 154:MEDLINE(R)

07960908 94299613
Reconstruction after malunion and nonunion of intra-articular fractures of the distal humerus. Methods and results in 13 adults.
McKee M; Jupiter J; Toh CL; Wilson L; Colton C; Karras KK
St Michael's Hospital, Toronto, Canada.
J Bone Joint Surg Br (ENGLAND) Jul 1994, 76 (4) p614-21, ISSN 0301-620X Journal Code: HK7
Languages: ENGLISH
Document type: JOURNAL ARTICLE
We reviewed the results of 13 adults of secondary reconstruction of malunited and ununited intraarticular distal humeral fractures. Their average age was 39.7 years, and preoperatively all had pain, loss of motion and functional disability; the average arc of motion was only 43 degrees and the average flexion contracture was 45 degrees. Nine patients had ulnar neuropathy. Elbow reconstruction, at an average of 13.4 months after the original injury, included osteotomy for malunion or debridement for nonunion, realignment with stable fixation and autogenous bone grafts, anterior and posterior capsulectomy and ulnar neurolysis. The elbows were mobilised 24 hours postoperatively. There were no early complications and all nonunions and intra-articular osteotomies healed. After a mean follow-up of 25 months, the average arc of motion was 97 degrees with no progressive radiographic degeneration. Ulnar nerve function improved in all cases and clinical assessment using the Morrey score showed two excellent, eight good and three fair results. Reconstruction of intra-articular malunion and nonunion of the distal humerus in young active adults is technically challenging, but can improve function by restoring the intrinsic anatomy of the elbow.

6/7/18
DIALOG(R)File 154:MEDLINE(R)

07571072 93299913
Comminuted fractures of the proximal radius and ulna.
Teasdall R; Savoie FH; Hughes JL
University of Mississippi Medical Center, Jackson.
Clin Orthop (UNITED STATES) Jul 1993, (292) p37-47, ISSN 0009-921X Journal Code: DFY
Languages: ENGLISH

Document type: JOURNAL ARTICLE
Forty-three comminuted fractures of the proximal radius and ulna in 34 patients were treated with operative stabilization using AO/ASIF techniques. The patients were divided into three groups, according to the type of injury: Group I, isolated comminuted fractures of the olecranon (18 patients); Group II, isolated fractures of the radial head (eight patients); Group III, combined olecranon and radial head fractures (eight patients). All fractures were followed until union. The average follow-up period was 18 months (range, 12-48 months). At the time of this review, the average limits of elbow motion were 20 degrees extension, 118 degrees flexion, 65 degrees pronation, and 62 degrees supination. Two patients were unable to return for follow-up examination. Using the functional classification of Broberg and Morrey, results were rated as excellent in nine cases, good in 15, fair in five, and poor in three. The complication rate in this series was 19%: Two patients developed nonunion, and one patient lost reduction during rehabilitation. All of these patients required reoperation, with eventual satisfactory outcome. Three patients developed heterotopic ossification, two of which were minor and one of which produced ankylosis of the elbow joint. Each of these patients had delayed (more than 72 hours postinjury) stabilization. A functional elbow was achieved in 29 of the 32 patients who returned for follow-up examination. Operative stabilization of comminuted fractures of the proximal radius and ulna provides a stable painless joint with a functional, but not full, range of motion.

7/7/19
LOG(R)File 154:MEDLINE(R)
(c) format only 1997 Knight-Ridder Info. All rts. reserv.

07124986 92259492
Semiconstrained arthroplasty for the treatment of rheumatoid arthritis of the elbow.
Morrey BF; Adams RA
Department of Orthopedics, Mayo Clinic, Rochester, Minnesota 55905.
J Bone Joint Surg [Am] (UNITED STATES) Apr 1992, 74 (4) p479-90, ISSN 0021-9355 Journal Code: HJR
Languages: ENGLISH
Document type: JOURNAL ARTICLE
Fifty-four patients in whom a total of fifty-eight semiconstrained modified Coonrad elbow implants had been inserted for rheumatoid arthritis were followed for a mean of 3.8 years (range, two to eight years). At the latest follow-up, there was little or no pain in fifty-three elbows (91 per cent). The arc of motion was from an average point in flexion of 20 degrees to an average point in flexion of 129 degrees, representing an average increase of 12 degrees of extension and 11 degrees of flexion. The average arc of pronation was 78 degrees, an increase of 14 degrees, and the average arc of supination was 77 degrees, an increase of 18 degrees. An additional ten patients who had had insertion of ten modified Coonrad implants during the same period were followed for less than two years but were included in the assessment of complications. Fifteen (22 per cent) of the sixty-eight elbows had a complication: four, infection; eight, acute or delayed [illegible]dylar or ulnar fracture; and one each, ulnar neuritis, avulsion of the [illegible]ceps, and fracture of the implant. Radiographic evaluation was performed for fifty-four of the fifty-eight elbows; the other four were excluded from this evaluation because of infection. A satisfactory radiographic

appearance of the cement--its extent and the absence of skip areas--was ed for all of the ulnar components and for fifty-one (94 per cent) of humeral components. No patient had radiographic evidence of a loose implant. A reoperation was performed in six elbows (10 per cent of the fifty-eight; 9 per cent of the sixty-eight): four were done for infection; one, for insufficiency of the triceps; and one, for a fractured ulnar component. Of the fifty-eight elbows, forty (69 per cent) had an excellent result; thirteen (22 per cent), a good result; four (7 per cent), a fair result; and one, a poor result.

6/7/20
DIALOG(R)File 154:MEDLINE(R)

07088124 92184876
Kinematics of semi-constrained total elbow arthroplasty.
O'Driscoll SW; An KN; Korinek S; Morrey BF
Department of Orthopaedic Surgery, Mayo Clinic, Rochester, Minnesota 55905.
J Bone Joint Surg [Br] (ENGLAND) Mar 1992, 74 (2) p297-9, ISSN 0301-620X Journal Code: HK7
Contract/Grant No.: AR26287, AR, NIAMS
Languages: ENGLISH
Document type: JOURNAL ARTICLE
We used 11 cadaver elbows and a three-dimensional electromagnetic tracking device to record elbow movements before and after implantation of 'loose-hinged' elbow prosthesis (modified Coonrad). During simulated active motion there was a maximum of 2.7 degrees (+/- 1.5 degrees) varus/valgus laxity in the cadaver joints. This increased slightly after total elbow arthroplasty to 3.8 degrees (+/- 1.4 degrees). These values are lower than those recorded for the cadaver joints and for the prostheses at the limits of their varus/valgus displacements, indicating that both behave as 'semi-constrained' joints under physiological conditions. They suggest that the muscles absorb some of the forces and moments that in a constrained prosthesis would be transferred to the prosthesis-bone interface.

6/7/21
DIALOG(R)File 154:MEDLINE(R)

06973284 92100924
[Fractures of the radial head. Analysis of a series of 62 surgically treated cases]
Fractures de la tete radiale. Analyse d'une serie de 62 cas traites chirurgicalement.
Kelberine F; Basseres B; Curvale G; Groulier P
Service de Chirurgie Orthopedique et Traumatologique, Hopital de la Conception, Marseille.
Rev Chir Orthop Reparatrice Appar Mot (FRANCE) 1991, 77 (5) p322-8, N 0035-1040 Journal Code: RMP
Languages: FRENCH Summary Languages: ENGLISH
Document type: JOURNAL ARTICLE English Abstract
The authors present a retrospective analysis of 62 cases of radial head

fracture operated between 1967 and 1989. According to the Mason ssification modified by Morrey, there were 11 Type II fractures, 22 Type fractures and 129 Type IV fractures. Surgical treatment consisted of one of the following: osteosynthesis, fracture fragment excision, or ablation of the head with or without silastic prosthesis. The results have been studied on a functional and radiological basis with follow-up from 2 to 23 years (mean: 5 years). Finally, the authors report the following indications: internal fixation for large two or three-part fractures, resection of the head in cases of comminution, and the lesions they judge to have a poor prognosis (Type IV).

6/7/22
DIALOG(R)File 154:MEDLINE(R)

06901055 92106110
The posterior Monteggia lesion.
Jupiter JB; Leibovic SJ; Ribbans W; Wilk RM
Department of Orthopaedic Surgery, Massachusetts General Hospital, Boston.
J Orthop Trauma (UNITED STATES) 1991, 5 (4) p395-402, ISSN 0890-5339 Journal Code: JH4
Languages: ENGLISH
Document type: JOURNAL ARTICLE
Thirteen posterior Monteggia fracture-dislocations in adults were treated surgically at the Massachusetts General Hospital from 1980 to 1988. A racteristic lesion was observed, consisting of a proximal ulna fracture with a triangular or quandrangular fracture at or near the level of the coronoid, a posterior or posterolateral radiocapitellar dislocation, and, in 10 cases, a radial head fracture. Nine patients were women and four were men, with an average age of 56 years. Following reduction of the radiocapitellar dislocation, the ulnar fractures were treated with plates in each case. Seven fractured radial heads were excised, one replaced with a silicone prosthesis, and three treated by open reduction and internal fixation. The 11 surviving patients were observed using the performance index of Broberg and Morrey at an average follow-up time of 38.4 months. The conditions of three were rated excellent, three good, four fair, and one poor. Incomplete reduction of the ulnar fracture with residual posterior radiocapitellar subluxation was observed in four cases, all leading to loss of forearm supination. We believe this lesion to be more common than previously reported. Recognition of its specific anatomic features is essential to achieve a functional outcome.

6/7/23
DIALOG(R)File 154:MEDLINE(R)

06772818 91302434
Total replacement for post-traumatic arthritis of the elbow.
Morrey BF; Adams RA; Bryan RS
ayo Clinic, Rochester, Minnesota 55905.
Bone Joint Surg [Br] (ENGLAND) Jul 1991, 73 (4) p607-12, ISSN 0301-620X Journal Code: HK7
Languages: ENGLISH

Document type: JOURNAL ARTICLE
ifty-three of 55 consecutive elbow replacements for post-traumatic
hritis were followed for a minimum of two years (mean 6.3, range 2 to 14.4). The patients presented difficult management problems, having undergone an average of two previous operations per joint; 22 joints had suffered prior complications; 18 had less than 50 degrees of flexion and six were flail. One of three versions of the Coonrad prosthesis was employed in all. During the follow-up period, 10 patients underwent 14 revision procedures for aseptic loosening; 38 elbows are currently without progressive radiolucent lines. In two patients an elbow had to be resected, one for deep infection and the other for bone resorption following a foreign-body reaction to titanium. The current design of the Coonrad prosthesis offers a reliable option for the treatment of post-traumatic arthritis but should be used only in carefully selected patients over the age of 60 years.

6/7/24
DIALOG(R)File 154:MEDLINE(R)

05641539 89310562
Stress distribution in the ulna following a hinged elbow arthroplasty. A finite element analysis.
Goel VK; Lee IK; Blair WF
Department of Biomedical Engineering, University of Iowa, Iowa City 52242.
Arthroplasty (UNITED STATES) 1989, 4 (2) p163-71, ISSN 0883-5403
Journal Code: JAY
Languages: ENGLISH
Document type: JOURNAL ARTICLE
The failure rates for total elbow arthroplasty, in comparison to those for hip arthroplasty, are quite high, and a precise understanding of the underlying causes still remains elusive. The presence of abnormal stresses is a known factor that accelerates loosening of hip and knee arthroplasties. Although a large number of biomechanical studies have led to a better understanding of elbow joint kinetics, very little is known about the stress distribution in this joint. The implantation of a Coonrad humeral component increases stresses in the bone and cement adjacent to the stem tip and hinge regions. An analysis of implanted ulnar stresses and a comparison of those stresses to implanted humeral stresses would improve our understanding of hinged elbow arthroplasty. For this reason, the distribution of mechanical stresses in the ulna are investigated in this study. Using a specially developed casting and sectioning technique, three-dimensional finite element meshes were obtained from an intact human cadaver ulna and an ulna fitted with a Coonrad prosthesis. The material properties were derived from values presented in the literature. Stress distributions in response to axial compression, axial torque, and anteroposterior (AP) force were computed. The cancellous bone and cement regions adjacent to the stem tip of the prosthesis exhibited higher stresses than those in the same regions of the intact case. The higher stresses in the ulna with an implanted prosthesis, as compared to the act model, might initiate loosening or failure of the prosthesis. The esses in the cortical bone region adjacent to the prosthesis head were decreased. This is consistent with the clinical observations of bone atrophy following total elbow arthroplasty.(ABSTRACT TRUNCATED AT 250

WORDS)

6/7/25
DIALOG(R)File 154:MEDLINE(R)

05599737 89197986
Total elbow arthroplasty for complete ankylosis of the elbow.
Figgie MP; Inglis AE; Mow CS; Figgie HE 3d
Hospital for Special Surgery, New York City, N.Y. 10021.
J Bone Joint Surg [Am] (UNITED STATES) Apr 1989, 71 (4) p513-20,
ISSN 0021-9355 Journal Code: HJR
Languages: ENGLISH
Document type: JOURNAL ARTICLE

Sixteen patients who received nineteen semiconstrained total elbow replacements for complete ankylosis of the elbow were followed for an average of five and three-quarters years (range, two to twelve years). The average preoperative elbow score was 23 points and the average postoperative score was 84 points. Postoperatively, the average flexion was 115 degrees; extension, 35 degrees; and pronation and supination, 95 degrees. There were fifteen excellent or good results. There was one failure due to a deep infection, but after removal of the prosthesis a satisfactory fascial arthroplasty was achieved in this elbow. Function was improved in all patients, and all patients had relief of the preoperative pain. For the arthroplasty to succeed, the patient must have a good understanding of the procedure and must be willing and able to comply with postoperative rehabilitation program. The use of a semiconstrained, often custom-fit, implant is necessary. The Bryan-Morrey posteromedial approach to the elbow is recommended for the procedure, since this approach allows early institution of range-of-motion exercises.

 33

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

September 08, 1997

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: CHARLENE BRUMBAUGH

510(k) Number: K973357
Received: 08-SEP-97
Product: COONRAD/MORREY TOTAL
ELBOW, NEW HINGE PIN

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

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

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

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

Sincerely yours,

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

 34

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

K 973357 Device Name Coonrad elbow

Division/Branch DGRD/OR

Administrative Reviewer Signature Michael Cantlon Date 9/15/97

Supervisory Signature _____ Date _____

Did the firm request expedited review? _____Yes X 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.

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

_____ Accepted

_____ Refuse To Accept

I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	☐	☐
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	☐	☐
C. Is Device Subject To Review By CDRH?	☐	☐
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision?	☐	☐
(ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	☐	☐
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.)	☐	☐
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?:	☐	☐
1. Device Trade Or Proprietary Name	☐	☐
2. Device Common Or Usual Name Or Classification Name	☐	☐
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	☐	☐
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	☐	☐
5. Classification Panel	☐	☐
6. Action Taken To Comply With Section 514 Of The Act	☐	☐
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	☐	☐

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

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

zimmer

P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

September 4, 1997

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

Dear Sir or Madam:

SUBJECT: 510(k) NOTIFICATION FOR THE COONRAD/MORREY TOTAL ELBOW, NEW HINGE PIN

As required by Section 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of 1976, and in accordance with Title 21 of the Code of Federal Regulations Part 807, Subpart E, the above-noted Premarket Notification is hereby submitted to the Food and Drug Administration. As required by 21 CFR 807.90(e), this document is submitted in duplicate including the original and cover letter.

The Coonrad/Morrey Elbow is based on our previously cleared Coonrad III Total Elbow, K883665, February 3, 1989, with several exceptions. The geometries of the ulnar and humeral components are unchanged, except that two longer ulnar component sizes have been added. This series utilizes an improved design for the hinge pin. The new design improves product safety and ease of assembly during the surgical procedure.

I certify that, in my capacity as Specialist, Global Regulatory Affairs, Zimmer, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted. This premarket notification was assembled using the Draft Guidance Document For The Preparation of Premarket Notification (510[k]) Applications for Orthopedic Devices, dated March 28, 1995. All applicable information specified in that document is addressed within this submission.

OR
II-1

39

I trust that the information submitted is sufficient for your evaluation of this 510(k) notification. If you require any additional information or have any questions regarding this submission, please contact me at 219-372-4962 or (fax) 219-372-4605.

Sincerely,

Charlene Brumbaugh

Charlene Brumbaugh
Specialist
Global Regulatory Affairs

cb/dh
RA08702K.510

COONRAD/MORREY TOTAL ELBOW, NEW HINGE PIN

Table of Contents

September 4, 1997

510(k) Number (if known): _____

Device Name: Coonrad/Morrey Total Elbow, New Hinge Pin

Indications For Use:

- 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
- Instability or loss of motion when the degree of joint damage precludes less radical procedures

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises 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 predominantly 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

RA08702K.510

510(k) Notification

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

1. Device Name

Proprietary Name:	Coonrad/Morrey Total Elbow
Common Name:	Elbow Prosthesis
Classification Name and Reference:	21 CFR 888.3160, Prosthesis, Elbow, Semiconstrained, Cemented
Proposed Regulatory Class:	Class II
Device Product Code:	87 JDB, Prosthesis, Elbow, Semiconstrained, Cemented

2. Manufacturer Identification

Sponsor/Manufacturer:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708 Establishment Registration Number: 1822565
Official Contact Person:	Charlene Brumbaugh Specialist, Global Regulatory Affairs Telephone: 219-372-4962 Telefax: 219-372-4605

3. Section 514 Compliance

Special controls for this Class II device have not been established; therefore, Section 514 of the Act does not apply at this time.

4. Intended Use

The Coonrad/Morrey Total Elbow is indicated for:

- 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
- Instability or loss of motion when the degree of joint damage precludes less radical procedures

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises 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 predominantly 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.

This device has not been previously submitted to the FDA for identical or different intended uses, is not currently being reviewed for different intended uses by the same or different branches within ODE, and has not been previously cleared by the FDA for different intended uses.

5. Device Description

5.1 Materials

The humeral and ulnar components are made from *Tivanium*® Ti-6A1-4V Alloy and meet ASTM F 136, "Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Application." On the distal humeral stem, there is a band of commercially pure titanium sintered beads. The proximal ulnar stem is precoated with polymethyl methacrylate (PMMA). PMMA is manufactured to Zimmer Engineering Specification, 2R-04, (Exhibit E) and according to Quality Control Procedure 161 (Exhibit E). The two coatings are for fixation enhancement.

The hinge pin components are made of *Tivanium* Alloy and *Zimaloy*® Cobalt-Chromium-Molybdenum Alloy, and meet ASTM F 136, "Standard Specification for Wrought Titanium 6AL4V ELI Alloy for Surgical Implant Applications," and ASTM F 799, "Standard Specification for Thermomechanically Processed Cobalt-Chromium-Molybdenum Alloy Surgical Implants," respectively.

The articulating surfaces of the stems are shielded by ultra-high molecular-weight polyethylene (UHMWPE) bushings to prevent metal-to-metal contact. They meet ASTM F 648, "Standard Specification for Ultra-High-Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants."

The pin removal tool is made of wrought 17-4 pH stainless steel and meets ASTM F 899, "Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments."

5.2. Design

The Coonrad/Morrey Total Elbow is based on the Coonrad III Total Elbow, K883665, cleared by the FDA for Zimmer, Inc., on February 3, 1989, with several modifications: the redesigned hinge pin and the addition of two sizes of ulnar components. The hinge pin has been redesigned to allow easier assembly by the surgeon, and the design improves product safety. The prosthesis is a hinge-type with a metallic hinge pin connecting ulnar and humeral components, and utilizes UHMWPE bushings to prevent metal-to-metal contact. The fit between the humeral and ulnar components allows approximately seven degrees of lateral deviation to either side of center.

Another feature of the design is an anterior flange on the lower humeral stem for greater stability. 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.

The distal humeral stem has commercially pure titanium sintered beads for enhanced cement fixation, cleared by the FDA for Zimmer, Inc., in the Coonrad III Total Elbow, K883665, February 3, 1989, and the proximal ulnar stem is precoated with PMMA to provide enhanced cement fixation. An identical PMMA coating was cleared by the FDA for Zimmer, Inc., on August 12, 1981, K811416, on the Moore Hip Prosthesis.

The Coonrad/Morrey Total Elbow is intended to be used with bone cement.

Engineering drawings of the Coonrad/Morrey Total Elbow are included in Exhibit A. Photographs of the elbow components including the hinge pin are included in Exhibit B. In situ illustrations of the hinge pin are also included in Exhibit B. A complete list of catalog numbers is included in Exhibit C. The surgical technique is included in Exhibit D.

6. Performance Testing

Performance testing was performed to determine how much force the pin assembly could withstand before pulling apart. According to the literature references cited by the summary memo to file (Exhibit F), a patient propelling themselves in a wheel chair exerts a medial/lateral force of 65N (14.6 pounds). The weight restriction for a patient with an elbow prosthesis is five pounds.

According to the tests performed (MTN 9703-005/006), the force required to unlock the pin assembly averaged 343 pounds for the regular pin and 289 pounds for the small pin. Assuming a five times safety factor, i.e., 25 pounds weight in hand, the conclusion drawn is that the pull-out strength of the pin assembly is one order of magnitude greater than the performance requirement.

Included in Exhibit F is the article by A. A. Amis that was cited in the Pull-Out Testing Summary.

7. Sterilization

7.1 Sterilization Method

Gamma Irradiation

7.2 Radiation Dose

Minimum 25 kGy

7.3 Sterility Assurance Level (SAL)

10^{-6}

7.4 Sterilization Validation Method

ANSI/AAMI/ISO 11137-1194, "Sterilization of Health Care Products-Requirements for Validation and Routine Control-Radiation Sterilization, Method 1."

7.5 Resterilization

Resterilization is not recommended.

7.6 Pyrogenicity

The Coonrad/Morrey Total Elbow Nail is not labeled as nonpyrogenic. Per USP XXIII(161), orthopedic products are not required to be nonpyrogenic.

7.7 Packaging

A thermoformed cavity of polyester, topped with a TYVEK seal is used for the sterile barrier packaging. Sample labeling with the sterile notation is included in Exhibit G.

8. Labeling

Attached as Exhibit G is the proposed labeling for this device. Included is the package insert for the Coonrad/Morrey Total Elbow and an example of package labeling for the elbow. The labeling contains the "sterile" notation.

9. Statement of Substantial Equivalence

The Coonrad/Morrey Total Elbow is substantially equivalent to the Coonrad III Total Elbow (K883665). See Table 1.

10. Summary of Safety and Effectiveness

A summary of safety and effectiveness is provided in Exhibit H.

11. Confidentiality of Information

Zimmer considers the material in this submission to be confidential and proprietary in nature, and requests notification before the release of any portion of this submission to the public.

RA08702K.510

Table 1

COMPARISON OF COONRAD/MORREY TOTAL ELBOW TO COONRAD III TOTAL ELBOW

Properties/Feature	Coonrad/Morrey Total Elbow	Predicate Device: Coonrad III
Humeral	*Tivanium*® Alloy 4", 6", 8" small 4" ,6" ,8" regular anterior flange	*Tivanium*® Alloy 4" ,6" ,8" small 4", 6", 8" regular anterior flange
Ulnar	*Tivanium*® Alloy 3" small 4.5" small 3.5" regular 4.5" regular Curved to facilitate implantation and to establish correct anatomical carrying angle. Available in right and left.	*Tivanium*® Alloy 3" small 3.5" regular Curved to facilitate implantation and to establish correct anatomical carrying angle. Available in right and left.
Hinge	Anteverted. Approximates center of rotation.	Anteverted. Approximates center of rotation.
Hinge pin	Inner and outer pin. The inner pin is used as the locking device. Assembled without use of instruments.	Solid shaft with a c-ring used to lock the humeral and ulnar components on the shaft. Assembly requires use of locking ring spreader.
Bushings	Ultra-high molecular weight polyethylene	Ultra-high molecular weight polyethylene
Fit between components	Articular design with 7 degree laxity	Articular design with 7 degree laxity

(b) (4) Engineering Drawing

(b) (4) Engineering Drawing

(b) (4) Engineering Drawing

(b) (4) Engineering Drawing

(b) (4) Engineering Drawing

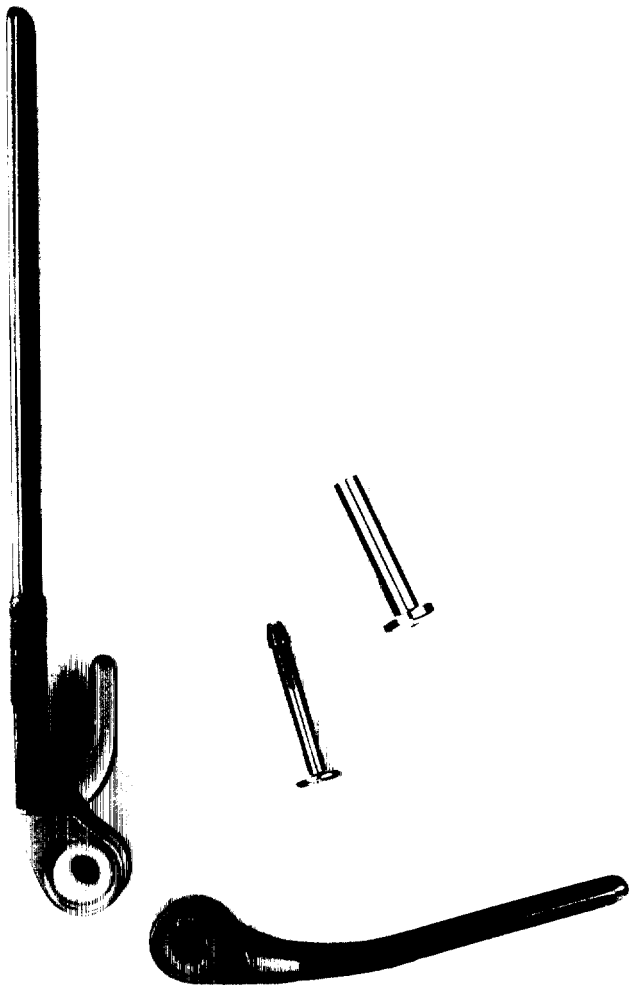
(b) (4) Engineering Drawing

(b) (4) Engineering Drawing

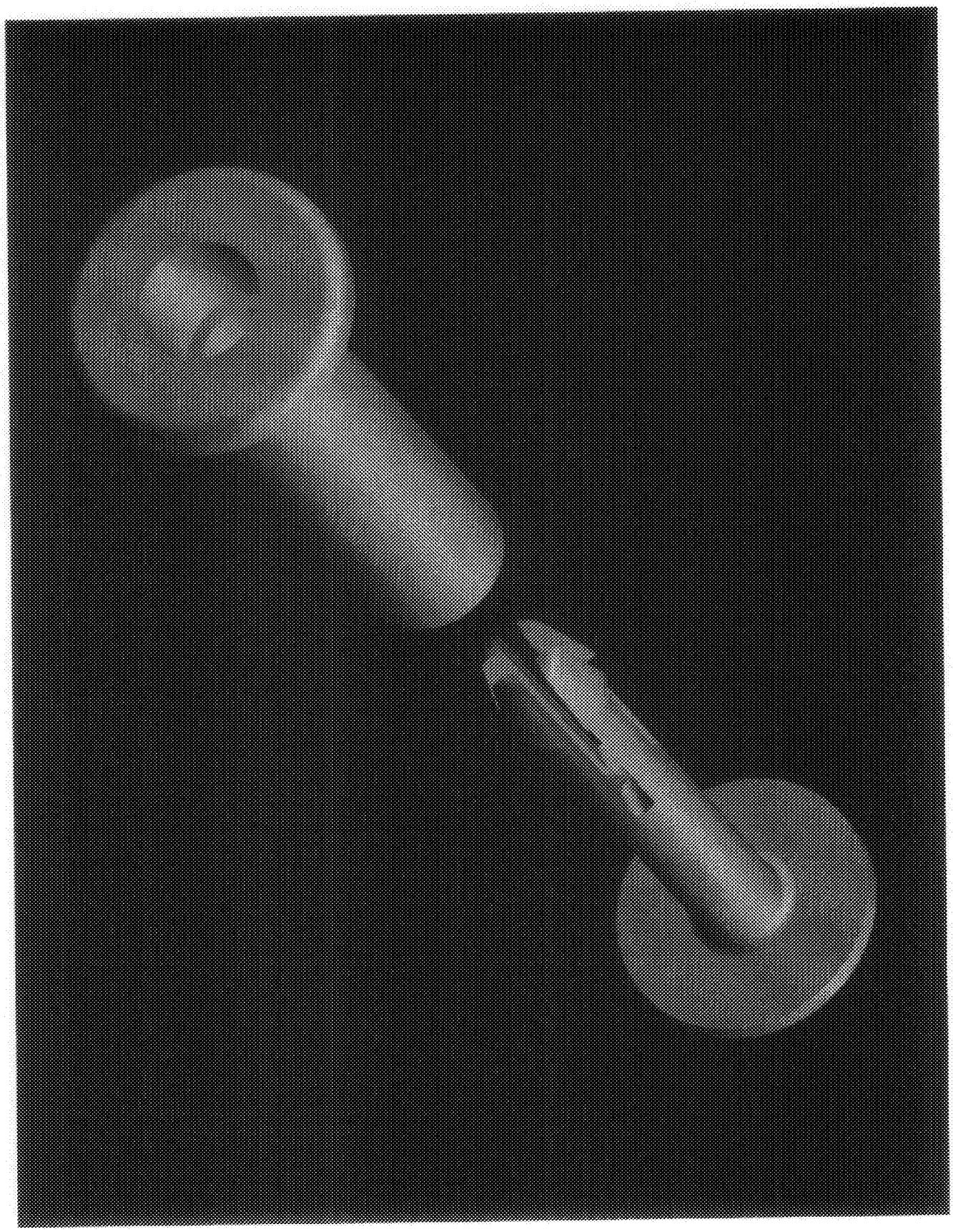
(b) (4) Engineering Drawing

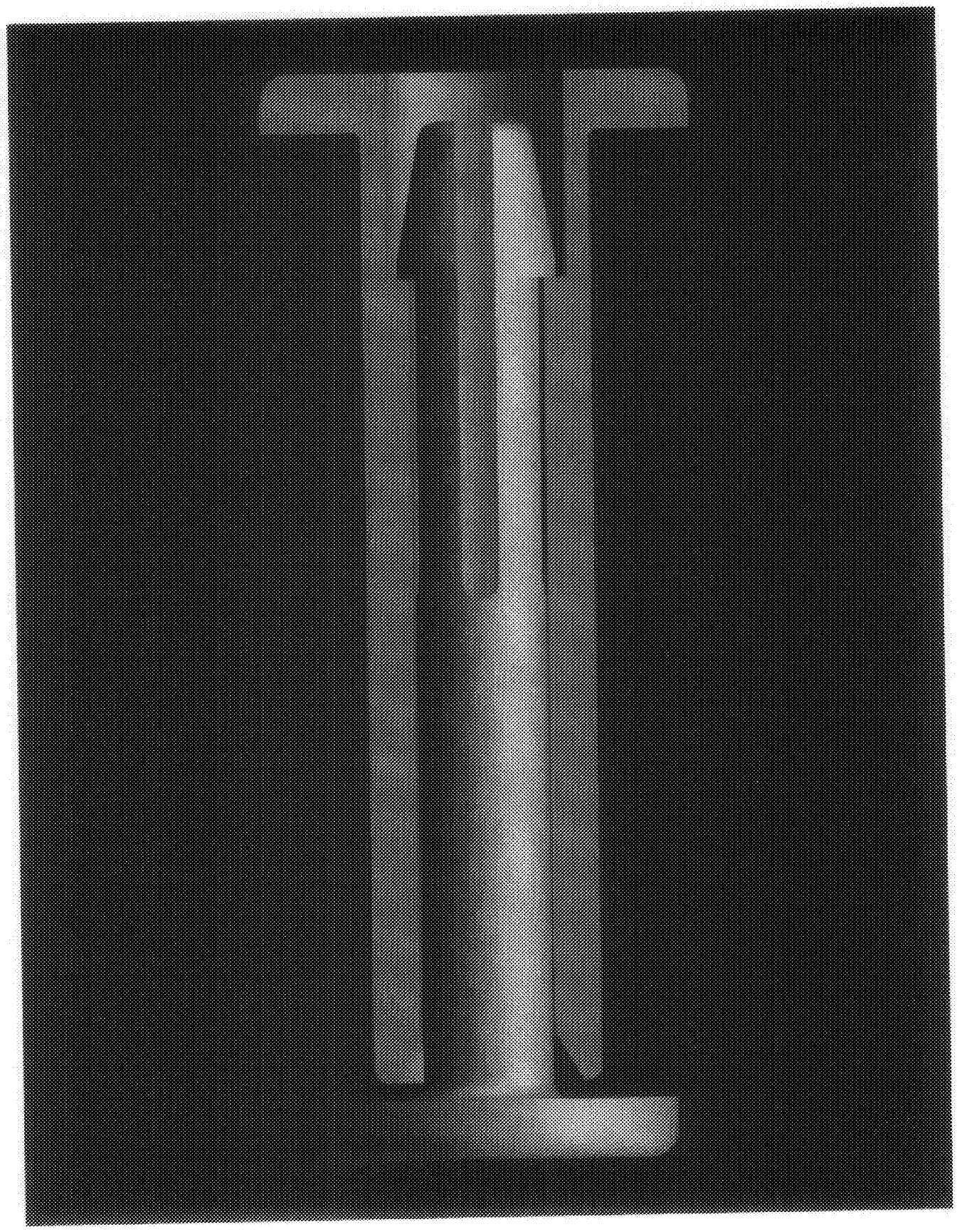
(b) (4) Engineering Drawing

(b) (4) Engineering Drawing



Humeral, Ulnar, and Hinge Pin Components





Coonrad/Morrey Total Elbow

Implants

Description	Catalog Number	Size
Small Series		
Ulnar Assembly With Hinge Pin Assembly	32-8105-051	3 inch left
	32-8105-052	3 inch right
	32-8105-071	4.5 inch left
	32-8105-072	4.5 inch right
Humeral Assembly	32-8105-004	4 inch
	32-8105-006	6 inch
	32-8105-008	8 inch
Pivot Pin Replacement Set	32-8106-000-12	Small
Regular Series		
Ulnar Assembly With Hinge Pin Assembly	32-8105-061	3.5 inch left
	32-8105-062	3.5 inch right
	32-8105-081	4.5 inch left
	32-8105-082	4.5 inch right
Humeral Assembly	32-8105-014	4 inch
	32-8105-016	6 inch
	32-8105-018	8 inch
Pivot Pin Replacement Set	32-8106-000-13	Regular

RA08702K.510

Coonrad/Morrey Total Elbow

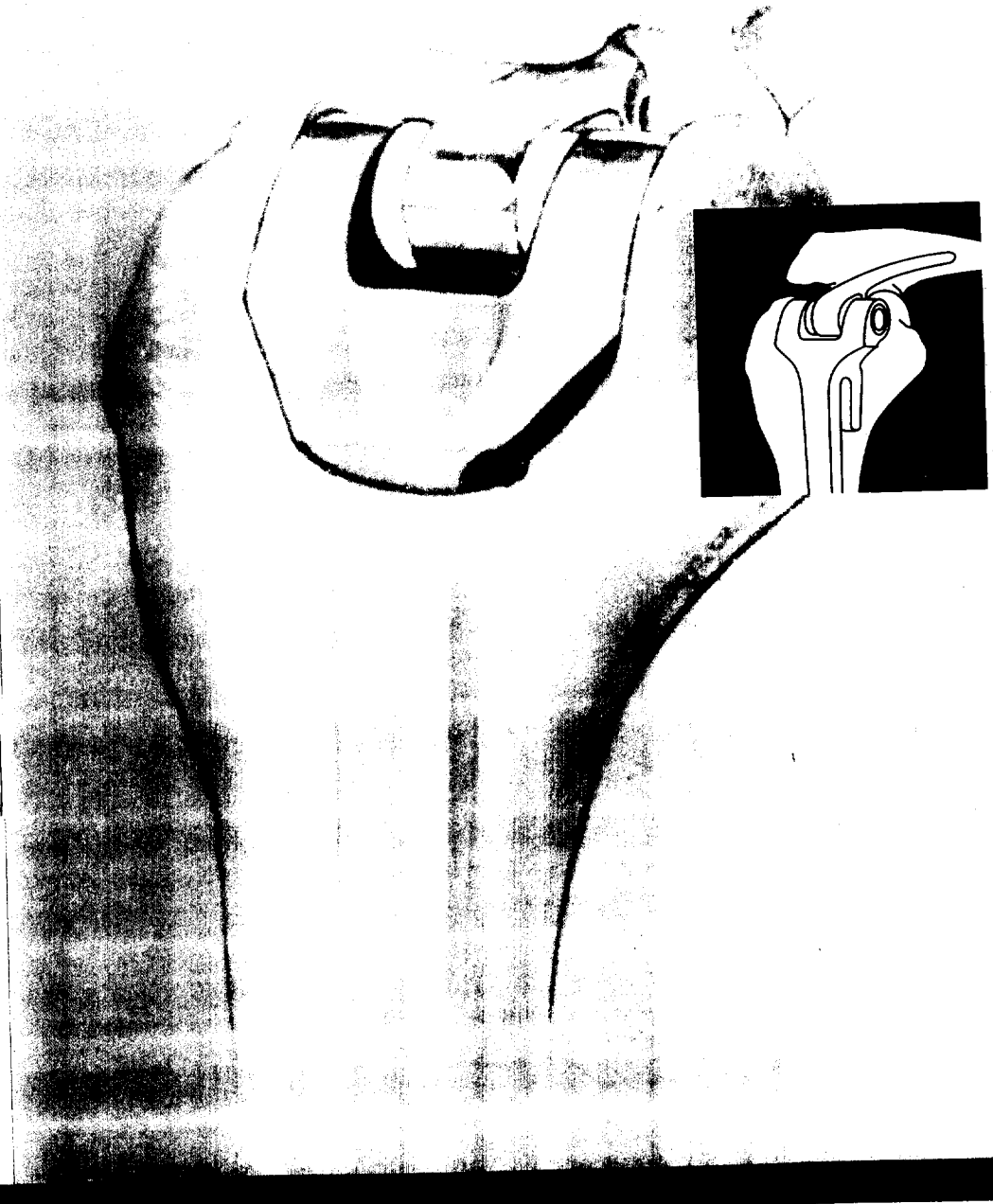
Instruments

Description	Catalog Number Small	Catalog Number Regular
Instrumentation		
Ulnar Rasp, Left	31-8106-63	31-8106-61
Ulnar Rasp, Right	31-8106-64	31-8106-62
Humeral Rasp	31-8106-66	31-8106-65
Humeral Cutting Guide	31-8106-85	31-8106-75
Provisionals		
Ulnar, Left	31-8105-41	31-8105-51
Ulnar, Right	31-8105-42	31-8105-52
Humeral, 4-inch	31-8105-44	31-8105-54
Humeral, 6-inch	31-8105-46	31-8105-56
Humeral, 8-inch	31-8105-48	31-8105-58

Description	Catalog Number
Left Starter Ulnar Rasp	31-8106-067
Right Starter Ulnar Rasp	31-8106-068
Pilot Ulnar Rasp	31-8106-069
Hinge Pin Removal Tool	31-8106-040
T-Handle	31-8106-80
Humeral Alignment Guide	31-8106-81
Humeral Impactor	31-8106-82
Awl Reamer	6601-36
Straight Impactor	31-8106-84
Starter Awl, 2 mm dia.	31-8106-167
Starter Awl, 3 mm dia.	31-8106-168

CONRAD/ MORREY TOTAL ELBOW

Surgical Technique



zimmer

COONRAD/MORREY TOTAL ELBOW SURGICAL TECHNIQUE

by

Ralph W. Coonrad, M.D.

Associate Clinical Professor of Orthopaedics

Duke University Medical Center

Durham, North Carolina

Bernard F. Morrey, M.D.

Chairman, Department of Orthopaedics

Mayo Clinic

Rochester, Minnesota

Illustrations by

Susan M. Balich and John V. Hagen

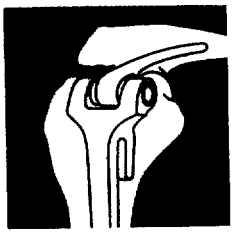
Special acknowledgment and thanks to

Bob Adams, R.P.A., Mayo Clinic,

for his technical assistance.

CONTENTS

[redacted]



PROSTHETIC DESIGN

The Coonrad Total Elbow Prosthesis is a semi-constrained device, initially designed in 1969 and developed in conjunction with the manufacturer in 1970. The 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 removable metallic hinge pin locks in place with a split locking ring.~~ Dislocation, separation, or breakage of the prosthesis has not been reported, once implanted, although the prosthesis is easily disassembled prior to surgery. The prosthesis was released on a restricted prescription basis for clinical trials in mid-1973.

The prosthesis was specifically designed with a right and left contoured quadrangular ulnar stem and a triangular humeral stem of large enough size to minimize intramedullary rotation in both the humerus and ulna. In 1978, the initial design was modified (Coonrad II) to permit 7 degrees of hinge laxity, or toggle, to conform to the average laxity of the normal elbow joint. This change was to diminish the effect of force transmission to the bone cement interface since loosening was the most common complication with a constrained hinge-type prosthesis. An optional eight-inch stem modification was added to take advantage of the normal anatomical anterior bow in the lower humerus and to thereby also mechanically resist torsional forces. This device was designed for use with acrylic cement, and is manufactured in two sizes; a regular, and small, with the largest implantable size being preferable.

The prosthesis was modified by the Mayo Clinic in 1981 (Coonrad/Morrey) with a band of porous coating of the distal humeral and proximal ulnar stems to permit better fixation. In 1992 the porous coating on the proximal ulnar was replaced with Precoat.* This will increase the fatigue strength of the component without sacrificing fixation of PMMA to the implant. The second major modification was the addition of an anterior flange to the lower humeral stem, permitting 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 constrained implants. *This implant is intended to be used with bone cement both for immediate and long-term fixation.* **There are no known indications for implanting this device without cement.**

The humeral stem comes in four-, six-, or eight-inch stem lengths, with the four- or six-inch stems being more commonly utilized. The four-inch stem is used when the shoulder has been or may be replaced with a humeral prosthesis. Loosening, although uncommon now with the semi-constrained hinge type prostheses, is more likely to occur at the cement-bone interface

*U.S. Patents 4,281,420; 4,336,618; 4,491,987

**The removable hinge pin assembly consists of a split inner pin (*Tivanium* Ti-6Al-4V Alloy) which engages and locks into a hollow outer pin (*Zimaloy*® Cobalt-Chromium-Molybdenum Alloy).

when a prosthesis of a small caliber or short stem is used with marginal or inadequate cementing technique.

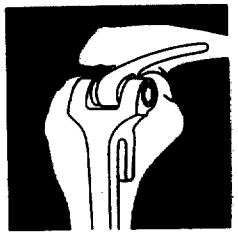
The Coonrad/Morrey Total Elbow Prosthesis is contoured for use with the right or left arm, and is available in a regular and small size with variable humeral and ulnar stem length, provisional (trial) prostheses, and instrumentation for efficient elbow joint replacement.

INDICATIONS AND CONTRAINDICATIONS

The primary indication for joint replacement is pain relief. The Coonrad/Morrey Total Elbow Prosthesis has been satisfactorily used in select cases of elbow joint destruction resulting from arthritis or trauma with associated pain, loss of motion or instability. This device is particularly useful in circumstances of extensive bone loss or gross instability due to trauma, rheumatoid or degenerative arthritis, or for revision surgery.

Specific contraindications include any condition in which the hand is nonfunctional or if motor control of the extremity is severely compromised. Prior joint infection, or osteomyelitis, are contraindications. Excessive scarring of the skin that compromises adequate soft tissue coverage would adversely affect the success of the procedure. Total joint replacement should not be considered in a patient anticipating heavy labor, torsional stress, or competitive sports where non-implant options may be preferable.

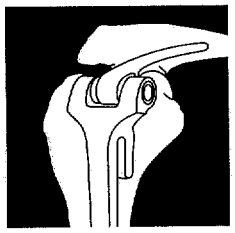
PREOPERATIVE CONSIDERATIONS



For those inexperienced in the technique of elbow arthroplasty, a trial with a fresh amputated, or cadaver specimen, is recommended. The surgeon should be aware of the coupling mechanism and technique of disarticulating the two stems at the hinge joint, the method of spreading to remove or replace the split lock ring. Notice should also be given to the need for bone grafting beneath the anterior flange and if necessary, around the proximal ulnar stem.

In those patients with both shoulder and elbow pathology, the most severely involved joint should be done first. When involvement is comparable, we recommend the shoulder replacement should be performed first. In patients with a pre-existing ipsilateral shoulder replacement, the four-inch implant is to be used. A bone graft plug is inserted in the canal at a distance of approximately 4.5 inches. At least 3cm distance between the cement of the shoulder and elbow components is desirable.

Note: Small and regular humeral and ulnar components are NOT interchangeable.



SURGICAL TECHNIQUE

INCISION

The patient may be positioned according to the preference of the surgeon. The lateral decubitus position is acceptable, but we place the patient supine with a sandbag under the scapula and bring the arm across the chest. A straight incision is made approximately 15 centimeters in length and centered just lateral to the medial epicondyle and just medial to the tip of the olecranon (Figure 1).

The medial aspect of the triceps mechanism is identified and the ulnar nerve is isolated using ocular magnification and a bipolar cautery. The ulnar nerve is very carefully translocated anteriorly into the subcutaneous tissue. It is gently protected throughout the remainder of the procedure (Figure 2).

An incision is made over the medial aspect of the ulna and the ulnar periosteum is elevated along with the forearm fascia (Figure 2). The medial aspect of the triceps is then retracted along with the posterior capsule. The triceps is removed from the proximal ulna by releasing Sharpey's fibers from their insertion. The extensor mechanism is further reflected laterally including the anconeus, allowing complete exposure of the distal humerus, proximal ulna, and the radial head. The entire extensor mechanism is subluxed laterally.

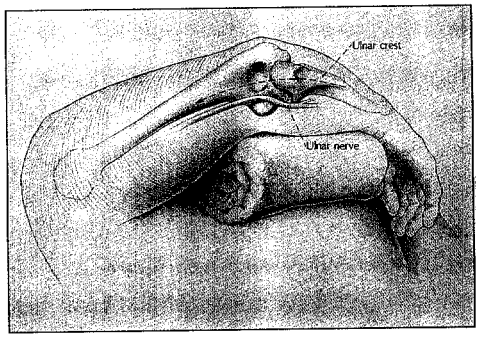


Figure 1

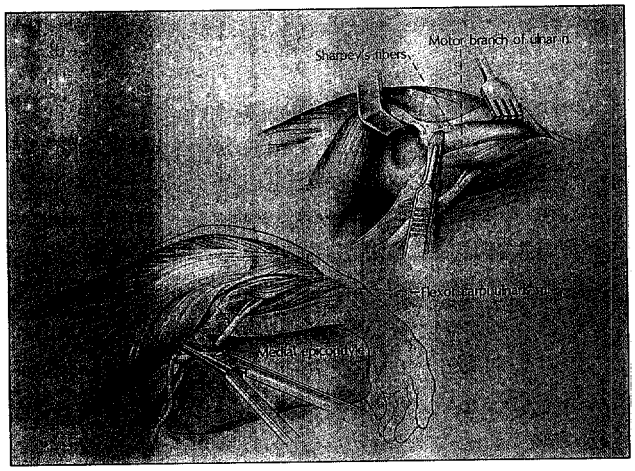


Figure 2

HUMERAL RESECTION

The tip of the olecranon is removed. Depending upon the diagnosis, if additional exposure is required, the medial and lateral collateral ligaments are released from the under side of the epicondyles (Figure 3A) and the distal articulation pivots or rotates about the radial collateral ligament (Figure 3B).

After the ulna and radius have been rotated out of the way, the mid-portion of the trochlea is removed (Figure 3B) to allow the medullary canal of the humerus to be identified by entering it with a burr through the roof of the olecranon fossa (Figure 4). The medullary canal of the humerus is identified with a twist reamer or starter awl (Figure 5). The medial and lateral aspect of the supra-condylar columns should be identified and visualized throughout the preparation of the distal humerus so as to assure proper alignment and orientation.

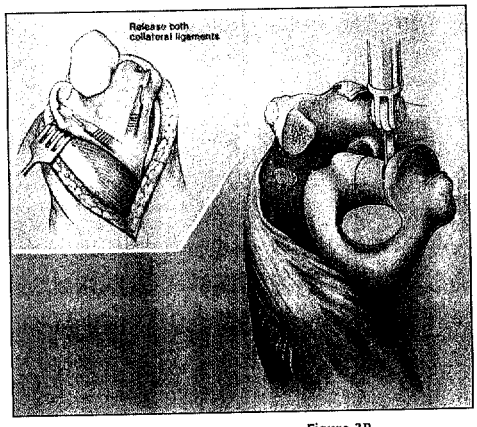


Figure 3A

Figure 3B

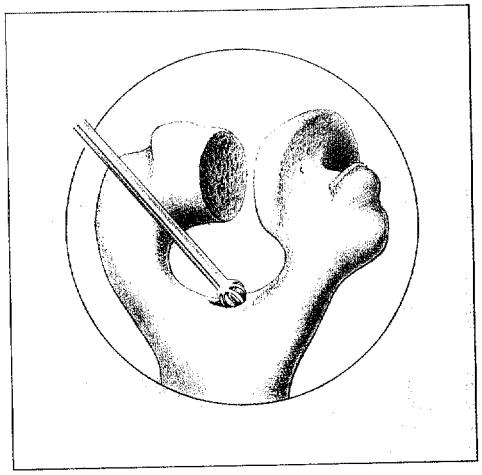


Figure 4

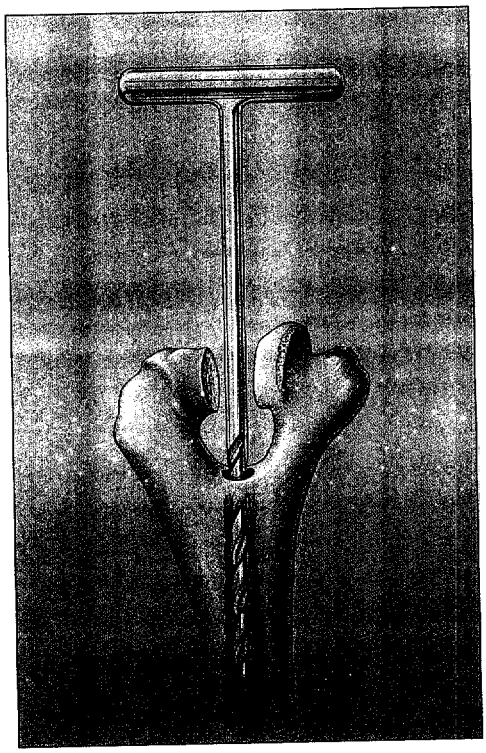
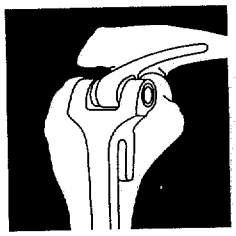
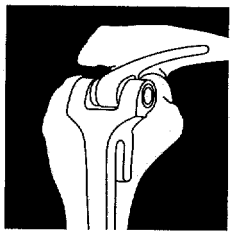


Figure 5





The alignment stem is placed down the canal (Figure 6). The handle is removed and a cutting block attached which allows accurate removal of the articular surface of the distal humerus.

The side arm of the cutting block is attached to the radial side and rests on the capitellum in order to provide the appropriate depth of cut (Figure 7A). With a medial-lateral saw the trochlea is removed according to the reciprocating dimensions of the appropriate cutting block which corresponds to the sizes of the humeral component. Care should be taken to avoid violating either supracondylar bony column since this may cause a stress riser that can result in fracture of this structure (Figure 7B). The proximal cut usually leaves the cortical bone intact on either side of the guide.

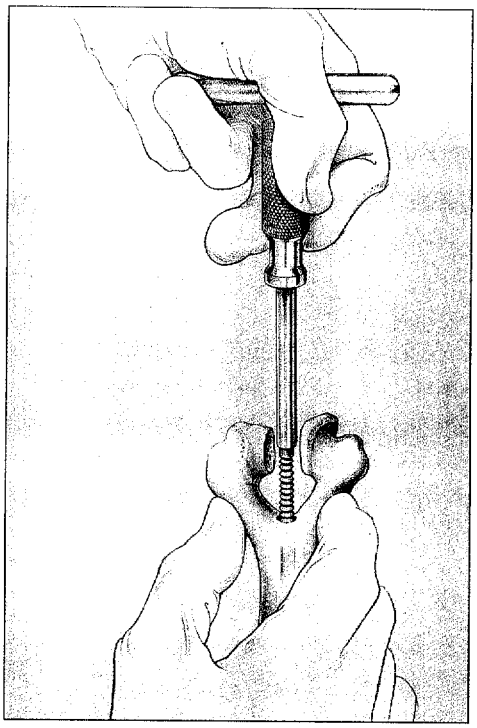


Figure 6

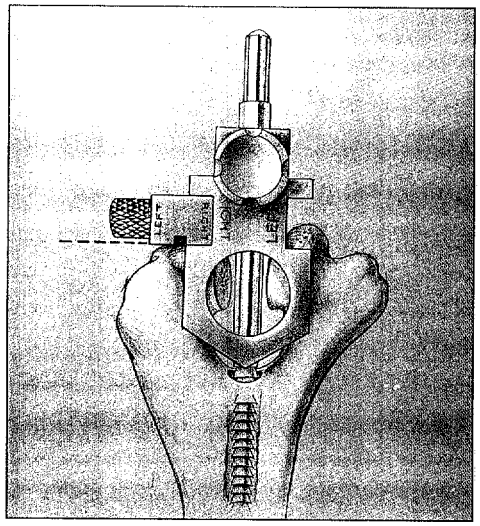


Figure 7A

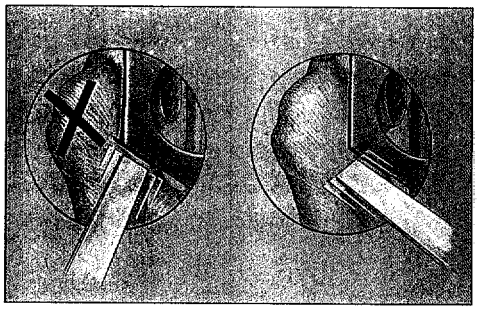


Figure 7B

The humerus is further prepared by serial rasping in such a way as to receive the appropriate size humeral component (Figure 8).

This results in an opening in the roof of the olecranon fossa smaller than that of the diameter of the medullary canal. Thus, effective plugging of the canal requires a special flexible-expansile medullary plug design.

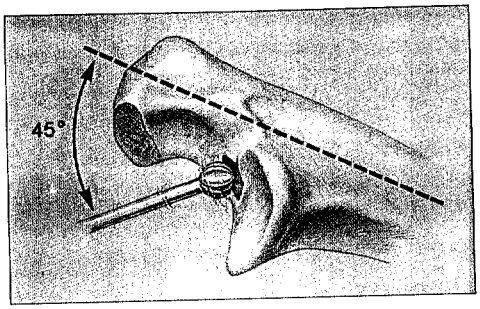
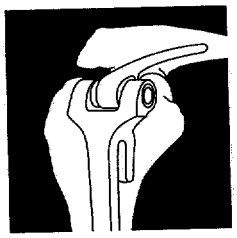


Figure 9A



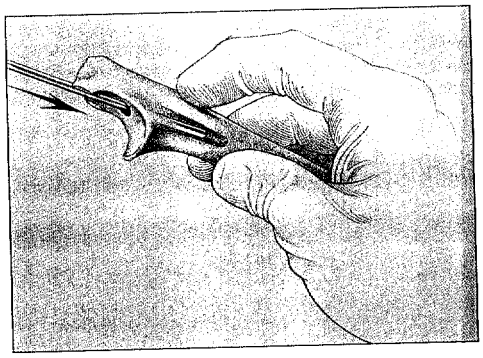


Figure 9B

PREPARATION OF THE ULNA

The medullary canal of the ulna is then identified by using a high-speed burr to remove the subchondral bone (Figure 9A). Placing a finger over the exposed proximal ulna helps prevent violation of the medullary canal. The tip of the olecranon is removed or notched to allow serial reamers to be introduced down the medullary canal (Figure 9B). The appropriate size rasp is

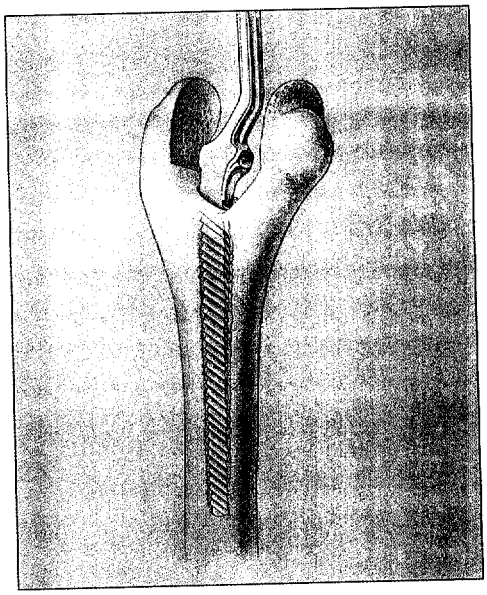
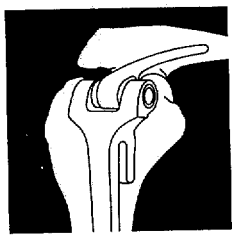


Figure 8



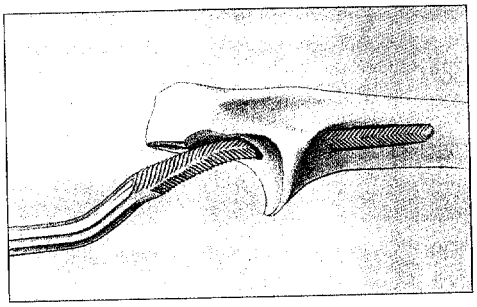


Figure 10

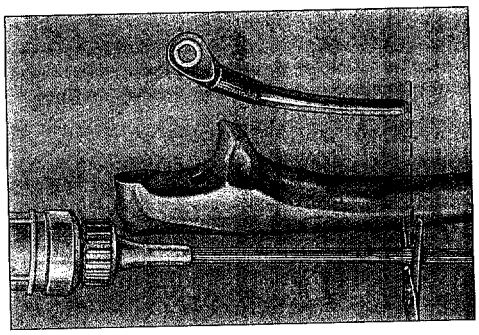


Figure 11

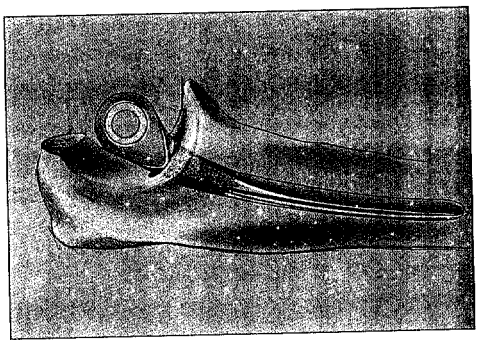


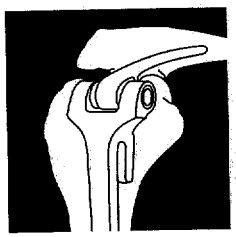
Figure 12

then inserted with a gentle twisting motion (Figure 10). Preparation of the last several millimeters will generally require the use of a mallet to remove the subchondral bone around the coronoid. If the canal is small, flexible reamers are used to prepare the proximal ulna.

CEMENT TECHNIQUE

The medullary cavities of both bones are cleansed with a pulsating lavage irrigation system and dried. Cement is injected down the medullary canal of the ulna or both the ulna and humerus with a special delivery system designed to fit even down the small ulnar canal. The flexible tubing is cut to the appropriate length for either the humeral or ulnar component after it has been inserted through the orifice of the injection cartridge (Figure 11). Because of high resistance the cement should be injected early in the polymerization process. Insertion of the device may be accomplished by cementing the components individually or coupled. It is appropriate to limit the amount of cement. If cemented separately, the ulnar component is inserted first as far distally as the coronoid process. The center of the ulnar component should align with the projected center of the greater sigmoid fossa (Figure12).

Alternatively, two Miller Bone Cement Injector Nozzles (5069-54) are cut to the appropriate length of the humerus and ulna to provide a flexible cement delivery tube.



After the cement has hardened and excess has been removed from around the ulnar component, an identical process is followed for cementing the humeral canal cement (Figure 13). A medullary plug is not routinely used unless revision is being performed. The orifice of the humeral opening is smaller than the medullary canal, making insertion of an intramedullary plug difficult. Pieces of bone graft are used to provide this restraint when indicated. The cement is injected down the medullary canal, again leaving all cement in the canal as back flow provides cement for the yolk.

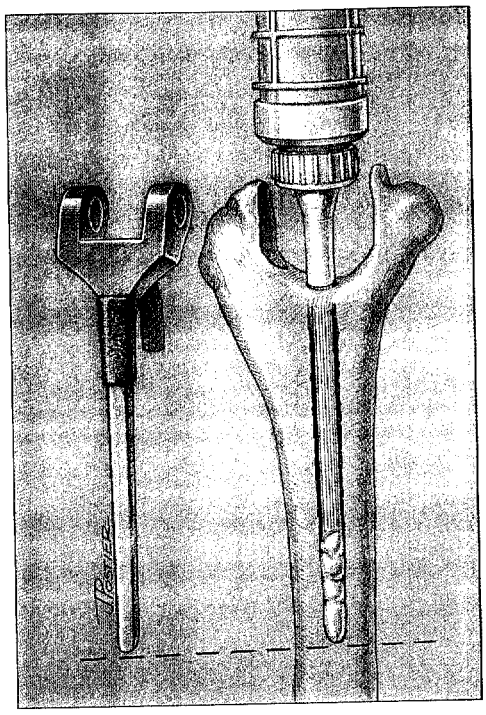


Figure 13

HUMERAL BONE GRAFT

A bone graft has been previously prepared from the excised trochlea or from the iliac crest for revision surgery. The graft should measure about 2 to 3 millimeters in thickness and be about 1.5 centimeters in length and 1 centimeter in width. The bone graft is placed anterior to the anterior cortex of the distal humerus and the humeral component is inserted down the canal to a point that allows both articulation of the device and where the bone graft is partially covered by the flange (Figure 14).

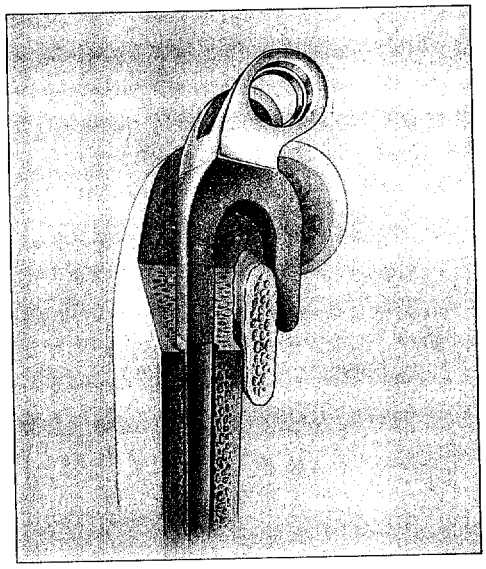
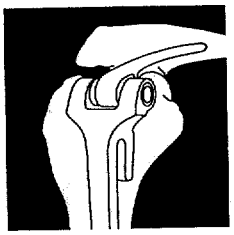


Figure 14



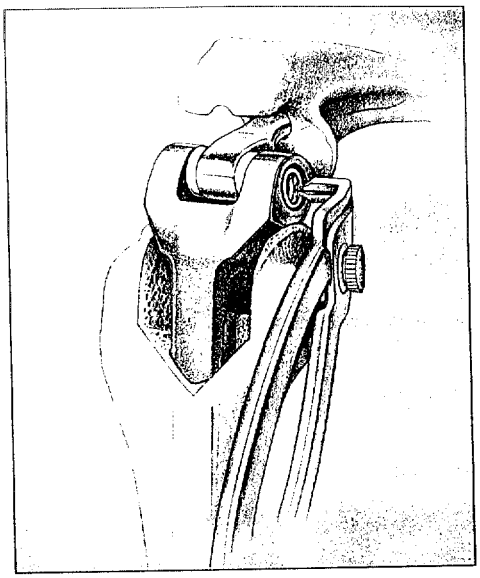


Figure 15

INSERTION, ASSEMBLY, AND IMPACTION

The ulnar component is articulated with the humeral device by placing the* ~~axis through the humerus and ulna and securing it with a split locking ring~~ (Figure 15). After the prosthesis has been coupled, the humeral component is impacted down the medullary canal (Figure 16). In general, the level of insertion is such that the axis of rotation of the prosthesis is at the level of the normal anatomic axis of rotation. This is approximated when the base of the flange is flush to the anterior bone of the olecranon fossa.

Note: Small and regular humeral and ulnar components are NOT interchangeable.

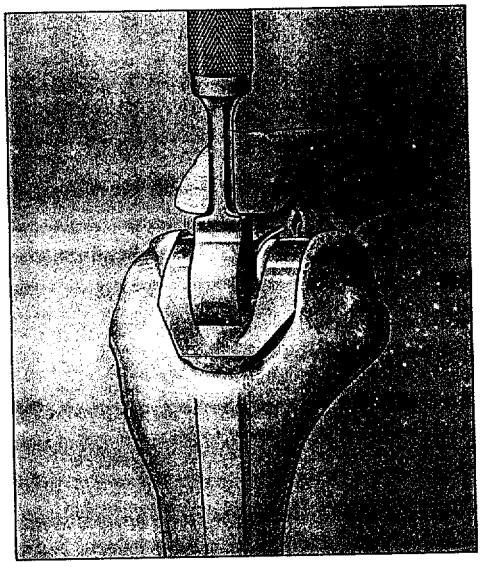
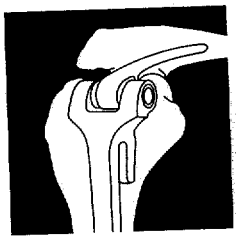


Figure 16

CLOSURE

The tourniquet is deflated and hemostatis is obtained. A single drain is left in the depths and the wound is closed in layers with the triceps mechanism being returned to its anatomic position and secured with sutures placed through cruciate and transverse drill holes in the proximal ulna. A heavy #5 nonabsorbable suture is placed in a criss-cross fashion in the triceps and a second suture placed in a transverse manner.

***hollow outer pin through the humerus and ulna and securing it with the split inner pin.**



These are tied with the elbow flexed at 90 degrees (Figure 17). There is no need to repair the collateral ligaments and the ulnar nerve is protected in a subcutaneous pocket (Figure 18). The remaining portion of the triceps mechanism is repaired with absorbable sutures. The rest of the closure is routine.

A compressive dressing is applied with the elbow in full extension and a ten-ply plaster splint placed anterior to avoid pressure on the incision line. If the elbow is dressed in 90 degrees of flexion, a well padded posterior splint is applied (6-8 layer sheet cotton).

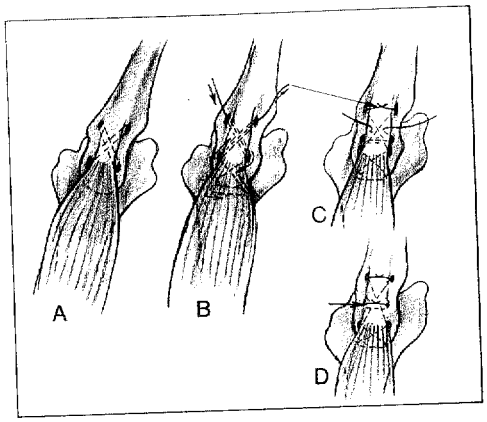


Figure 17

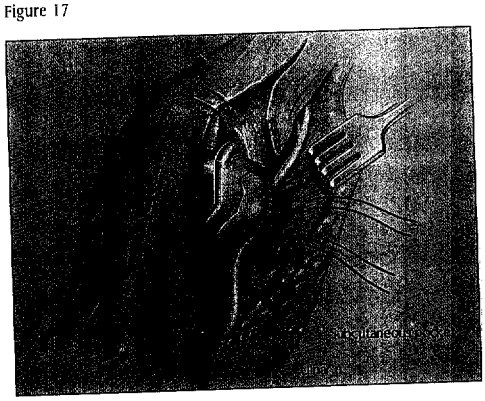


Figure 18

POSTOPERATIVE MANAGEMENT

The arm is elevated postoperatively for four or five days with the elbow above shoulder level. The drains are removed at approximately 24 to 36 hours and the compressive dressing removed on the third to fifth day after surgery. A light dressing is applied and elbow flexion and extension is allowed, as tolerated. A collar and cuff are used and the patient is sent to Occupational Therapy for activities of daily living. No formal physical therapy is generally required or indicated. Strength exercises are avoided. The patient is advised not to lift more than one pound over the next three months, and not more than five pounds with the operated arm.

[redacted]

(b) (4) Zimmer Engineering Specification

(b) (4) Zimmer Engineering Specification

(b) (4) Zimmer Engineering Specification

(b) (4) Zimmer Engineering Specification

(b) (4) Zimmer Engineering Specification

(b) (4) Zimmer Engineering Specification

UNCONTROLLED COPY

This copy will not be updated. Refer to on-line documentation for the most current specification.

QUALITY CONTROL PROCEDURE

PROCEDURE NO.: 161

PROCEDURE TITLE: Q.A. PARAMETERS FOR PMMA COATINGS

REVISION NO.: 15 EFFECTIVE DATE: June 13, 1997

APPROVAL (NAME, TITLE & DATE)		DISTRIBUTION LOCATIONS:
Prepared by:		1
Roger Miller	06-03-97	3
R. Miller, Supervisor, Quality Control	Date	7
		9
		27
Approved by:		35
		47
A. Beckman	06-03-97	52
A. Beckman, Director, Knee Systems Development	Date	
K. Bender	06-03-97	
K. Bender, Director, Quality Assurance	Date	
J. A. Burkart	06-06-97	
J. Burkart, Director, Hip Manufacturing	Date	
R. Lambert	06-04-97	
R. Lambert, Director, Preproduction QA & Engineering	Date	
D. Patmore	06-09-97	
D. Patmore, Director, Knee Manufacturing	Date	

UNCONTROLLED COPY

This copy will not be updated. Refer to on-line documentation for the most current specification.

QUALITY CONTROL PROCEDURE

PROCEDURE NO.: **161**

PROCEDURE TITLE: **Q.A. PARAMETERS FOR PMMA COATINGS**

REVISION NO.: **15** EFFECTIVE DATE: **June 13, 1997**

REVISION SUMMARY SHEET

1. DELETE the following former paragraphs:

   2.5
   2.11
   4.1
   4.2.8.2 through 4.2.8.4
   4.3 (including 4.3.1 through 4.3.4.2)
   4.4 (including 4.4.1 through 4.4.3.1)
   4.5

2. ADD the following paragraphs:

   2.1
   2.4
   2.8
   2.10
   2.13
   2.14
   4 (including 4.1 through 4.3)
   5.1 (including 5.1.1 through 5.1.4)
   5.3 (including 5.3.1 through 5.3.3)

3. CHANGE paragraph 5.2 (formerly 4.2)

   FROM: Visual inspection shall be done by comparing the product to the appropriate visual standards (see Reference Documents/Gage Numbers 25-2000-138/139).

   TO: Visual inspection of the PMMA coated surface shall be done by comparing

UNCONTROLLED COPY

This copy will not be updated. Refer to on-line documentation for the most current specification.

QUALITY CONTROL PROCEDURE

PROCEDURE NO.: **161**

PROCEDURE TITLE: **Q.A. PARAMETERS FOR PMMA COATINGS**

REVISION NO.: **15** EFFECTIVE DATE: **June 13, 1997**

REVISION SUMMARY SHEET

the product to the appropriate visual standards (see Reference Documents/Gage Numbers 25-2000-138/139 and 25-1003-008-00).

4. CHANGE paragraph 5.2.1 (formerly 4.2.1)

   FROM: All visual and dimensional inspection shall be done per sample plan QCP 209-1-2.5.

   TO: All visual and dimensional inspection shall be done per sample plan QCP 209-1-2.5 unless otherwise designated on router.

1. PURPOSE

1.1 To establish a procedure for the visual evaluation of all items that are coated with poly methyl methacrylate powder (PMMA) by electrostatic or wet coat applications.

2. REFERENCED DOCUMENTS/GAGE NUMBERS

2.1 APPENDIX 01 Documentation of Training - PMMA Coating cell Process Inspection

2.2 ASTM 3359 Measuring Adhesion by Tape Test

2.3 ASTM D883-80C Standard Definitions of Terms Relating to Plastics

2.4 Gage No. 25-1003-008-00: Casting Surface Standard Roughness

2.5 Gage No. 25-2000-138-00: PMMA Coating Visual Standards for Precoated *Zimaloy*®

2.6 Gage No. 25-2000-139-00: PMMA Coating Visual Standards for Precoated *Tivanium*®

2.7 OCP 5.920 Material Handling Container Identification for Components and Devices

2.8 OCP 5.925 Recording Data on Process Tickets

2.9 OCP 7.806 Nonconforming Material Report (NCMR)

2.10 QCP 014 Cosmetic Irregularities Definitions for Implant Devices and Instruments

2.11 QCP 143 Qualification and Certification of NDT Personnel

2.12 QCP 209 C = 0 Sampling Methods, Procedures, and Tables for Inspection

2.13 QCP 257 Measuring Thickness of PMMA Coating Using Beta Backscatter Method

2.14 Z-6335 Assembly and Traceability Record

2.15 ZES 4B-33 60 Grit Alumina Dry Blast

2.16 ZES 4T-01 Poly (Methyl Methacrylate) Precoat

2.17 Zimmer Laboratory Notebook

3. DEFINITIONS

3.1 **Chalking** - A powdery residue on the surface of a material often resulting from degradation.

3.2 **Crater** - A small, shallow surface imperfection.

3.3 **Crazing** - Fine cracks which may extend in a network on or under the surface or through a layer of a plastic material.

3.4 **Dark Micro Particle** - Any particle .010 inch in diameter/length or smaller.

3.5 **Dark Minor Particle** - Any particle .011 inch or larger, but less than .026 inch in diameter/length.

3.6 **Dark Major Particle** - Any particle .026 inch or larger in diameter/length.

3.7 **Discoloration** - Any change from the original color, often caused by overheating, light exposure, irradiation, or chemical attack.

3.8 **Flow Marks** - Wavy surface appearance of an object caused by improper flow.

3.9 **Gouge** - An indentation that can be felt as a sharp dent.

3.10 **Haze** - The degree of cloudiness in a plastics material.

3.11 **Orange Peel** - Unintentionally rough surfaces.

3.12 **Overspray** - A light coating of PMMA or stray PMMA particles bonded to any surface not requiring PMMA coating.

3.13 **Pit** - An imperfection, a small crater in the surface of the plastic, with its width of approximately the same order of magnitude as its depth.

3.14 **Pock Marks** - Irregular indentations on the surface.

3.15 **Shark Skin** - A surface irregularity in the form of finely-spaced sharp ridges.

3.16 **Sheeter Lines** - Parallel scratches or projecting ridges distributed over a considerable area of a plastic sheet.

3.17 **Shrink Mark** - An imperfection, a depression in the surface of a material.

3.18 **Sink Mark** - A shallow depression or dimple on the surface.

3.19 **Underspray** - Small areas of missing or very lightly coated PMMA within areas requiring PMMA coating.

4. EMPLOYEE TRAINING REQUIREMENTS

4.1 Employees shall receive documented procedural and inspection technique training prior to performing inspection processes. It is the responsibility of all employees to obtain specific gauging or measurement technique instruction from the appropriate management.

4.1.1 Training documentation sheets (QCP 161 Appendix 01) signed by the employee, the employee's supervisor, and Quality Assurance shall be maintained in the employee's manufacturing and Quality Assurance training files.

4.2 Only employees completing requirements of paragraphs 4.1 and 4.1.1 will be authorized to perform inspections defined in this procedure.

4.3 All training documentation shall be renewed on an annual basis or as needed.

5. PROCEDURE - PRODUCT ACCEPTANCE CRITERIA AND INSPECTION

5.1 Verification

5.1.1 Each operator shall verify that all production lots submitted for inspection contain a router packet and shall verify that each router packet contains a router, drawing, and Process Ticket. The operator shall also assure that:

5.1.1.1 The revision letter of the drawing agrees with that specified on the router.

5.1.1.2 Each order designated as "Lot Controlled" contains a raw material lot number recorded on the Assembly Traceability Record (Z-6335).

5.1.2 Each operator shall verify that all previous operations have been documented. Verification shall be performed by comparing the operations documented on the Process Ticket to those specified on the production router.

5.1.3 The operator shall verify that all material handling containers are properly identified in accordance with OCP 5.920.

5.1.4 Positive product identification using visual or dimensional techniques as required by product identifiers on blueprint.

5.2 Visual inspection of the PMMA coated surface shall be done by comparing the product to the appropriate visual standards (see Reference Documents/Gage Numbers 25-2000-138/139 and 25-1003-008-00.

5.2.1 All visual and dimensional inspection shall be done per sample plan QCP 209-1-2.5 unless otherwise designated on router.

5.2.2 The cured PMMA coating shall have a translucent to transparent colorless surface; therefore, the coating shall:

5.2.2.1 Be free of discoloration and hazing.

5.2.2.2 Be free of stains greater than .010 inch.

5.2.2.3 Be free of foreign materials.

5.2.2.4 Be shiny and smooth.

5.2.2.5 Be free of chalking.

5.2.2.6 Be free of dark particles with the following conditions:

5.2.2.6.1 No dark minor or major particles are permitted.

5.2.2.6.2 Two dark micro particles are permitted per visual PMMA-coated surface provided they are spaced one-fourth inch or more apart.

5.2.3 Articulating or functional surfaces shall be free of PMMA, particles, damage, or acid etching.

5.2.4 Some orange peel and shark skin effects are permitted; however, there shall be no bare spots in the coating. Orange peel and shark skin surface finish to be C-30 or less as measured by comparator 25-1003-008-00.

5.2.5 The coating shall have a uniform appearance.

5.2.6 Small bubbles are acceptable when they occur within .025 inch from a rail and do not make the part cosmetically unattractive.

5.2.7 There shall be no cracks, crazing, pits, pock marks, gouges, sheeter marks, shrink marks, or sink marks greater than .010 inch.

5.2.8 There shall be no overspray on any areas not requiring the coating (see print). For knee products, the following criteria shall be met:

5.2.8.1 There shall be no overspray on articulating surfaces, functional surfaces, or surfaces intended to contact UHMWPE components.

5.2.8.2 For tibial plates, an oversprayed area of .030 inch x .250 inch is acceptable on the side of the rail or multiple smaller areas whose sum equals the same.

5.2.8.3 For all knee product components, underspray is allowed providing the following conditions are met:

5.2.8.3.1 An undersprayed area of .030 inch x .240 inch per visual surface is acceptable on rails, pegs, stems, or posts requiring coating or multiple smaller areas whose sum equals the same.

5.2.8.3.2 Undersprayed areas of .030-inch wide on areas requiring coating are acceptable around the base of all stems, posts, or pegs.

5.2.8.3.3 An undersprayed area of .030 inch x .240 inch per visual surface is acceptable on areas requiring coating along rails and other raised surfaces, or other multiple smaller areas whose sum equals the same.

5.2.8.4 Records of inspection shall be recorded on Internal Process Ticket (per OCP 5.9250).

5.3 Records of inspection shall be recorded on PMMA Internal Process Ticket.

5.3.1 All manufacturing processes performed within the PMMA manufacturing cell that do not meet procedural requirements and require rework within the cell shall be recorded on the PMMA IPT as rework-remove PMMA.

5.3.2 Each workorder processed in the PMMA manufacturing cell shall be included in a monthly report, showing accept or reject status on a first pass basis, for the purpose of process control and trend analysis.

5.3.3 All nonconformances that are found within the PMMA manufacturing cell, but are not a direct result of the application of PMMA within the PMMA manufacturing cell. The certified operator shall inspect the order on a 100% basis for the condition and then place the order on hold for further review and disposition per OCP 7.806.

6. ADHESION AND FLEXIBILITY TESTS

6.1 This test is designed to measure the adhesion of the PMMA coating to the metallic substrate by applying and removing pressure-sensitive tape over cuts made in the coating.

6.2 On a bi-weekly basis, a test specimen will be coated in the same manner as production items with PMMA by electrostatic application.

6.3 The test specimen must be at room temperature before testing begins.

6.4 A crosscut (lattice cutting) tester consisting of a six-blade cutter (1.5 or 2.0 mm spacing) and a 3-inch length of adhesive tape will be needed to proceed further.

6.5 Make two cuts in the coating using the crosscut tester. These cuts are to be at 45- to 90-degree angles to each other.

6.6 Inspect the incisions for reflection of light from the metal substrate. Do not attempt to deepen a previous cut as this may affect adhesion along the incision. Resample if incisions are not adequate.

6.7 Using a length of tape adequate to cover the entire test area, place the center of the tape at the intersection of the cuts. Smooth in place by finger pressure and then rub firmly with the eraser on the end of a pencil.

6.8 Remove the tape by pulling it off rapidly (not jerked).

6.9 Inspect crosscut area for removal of coating. The results must be from classification 3 to 5 (reference Figure 1); i.e., very little or virtually no coating shall be stripped off.

6.10 Log results in the Zimmer Laboratory Notebook.

7. RECORD KEEPING

7.1 Zimmer Laboratory Notebook shall be microfilmed on an annual basis.

DOCUMENTATION OF TRAINING
PMMA COATING CELL PROCESS INSPECTION

YEAR_____

EMPLOYEE_____ EMPLOYEE NO._____ DEPT.NO._____

TRAINING REQUIREMENT	MEETS REQUIREMENT (X)
1. Employee has received documented training for all QCPs and OCPs required of job function. QCPs: -014- 021- 143- 161- 209- 223 -257 OCP: 5.925- 7.806	☐
2. Employee demonstrates required knowledge of the following	
2.1 Use of calipers and ability to read blueprint for purpose of product identifcation	☐
2.2 Measurement of PMMA thickness using Fischerscope MMS as required per QCP 257	☐
2.3 All product cosmetic requirements per QCP-014- 161	☐
2.4 Print locations and specifications for all PMMA coated surfaces	☐
2.5 Ability to perform adhesion and flexabilty test per QCP -161	☐

EMPLOYEE SIGNATURE_____ Date_____

SUPERVISOR SIGNATURE_____ Date_____

QUALITY ASSURANCE SIGNATURE_____ Date_____

TRAINING DOCUMENTATION RENEWAL DUE DATE_____

QCP-161-01

zimmer

Memorandum

To: File

From: Kenneth Shipp

Date: August 22, 1997

SUBJECT: Pull-out Testing of the Coonrad/Morrey Hinge Pin

	INNER PIN	OUTER PIN
Small	00-8106-120-01	00-8106-120-02
Regular	00-8106-121-00	00-8106-121-02

Background

The Coonrad/Morrey Elbow has enjoyed a high success rate since the product was released in 1988. Since that time, the hinge pin assembly has been identified as a component whose performance should be improved. Assembling the old components (00-8106-110-00, 77-6751-066) was difficult. The redesign is significantly easier to assemble. Obviously, the pull-off resistance force of the hinge pin must be higher than the lateral forces the component will experience in vivo. This report compares the results from MTN 9703-005/006 and the lateral force expected in vivo.

Performance Requirement

A literature search was performed to determine lateral joint reaction load on an elbow. Walker and Novick, 1977, reported that the medial-lateral forces at the elbow is "small." The term small is better understood by the joint reaction forces predicted by said authors that are transverse the pin (48 pounds). Emsminger et al., 1995, reported medial-lateral force of 65N (14.6 pounds) for a patient propelling themselves in a wheel chair. Amis et al., 1990, predicated the following:

(b) (4)

[redacted]

Test Results

According to MTN 9308-146, the force required to unlock the pin assembly averaged 343 pounds for the regular pin and 289 pounds for the small.

Conclusion

The pull-out strength of the pin assembly is one order of magnitude greater than the performance requirement. The most strenuous activity of wheelchair propulsion yields a (b) (4) [redacted] Therefore, the conclusion can be drawn that the new pin satisfies the performance requirement for pull-out strength.

KS/jj
TR08711C.ME
cc C. Brumbaugh
E. Cook
R. Larsen

(b) (4) Mechanical Test Request

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

LOT 99999999 CAT. NO. 32-8105-51

COONRAD/MORREY TOTAL ELBOW
ULNAR ASSEMBLY PRECOAT
SMALL LEFT 76.2 MM (3.0 IN.) STEM LENGTH **SPECIMEN**
WITH HINGE PIN ASSEMBLY
TIVANIUM® ALLOY/PMMA/ZIMALOY® ALLOY/UHMWPE
STERILE QTY-1
FOR CEMENT USE ONLY

+99999999999999D

+99999999999T

Zimmer WARSAW INDIANA 46580 0/08 U.S.A.

LOT 99999999 CAT. NO. 32-8105-04

COONRAD/MORREY TOTAL ELBOW
HUMERAL ASSEMBLY BEADED
SMALL 101.6 MM (4.0 IN.) STEM LENGTH
TIVANIUM® ALLOY/UHMWPE STERILE QTY-1
FOR CEMENT USE ONLY

+99999999999999D

SPECIMEN

+99999999999T

zimmer WARSAW, INDIANA 46580 0708 U.S.A.

COONRAD/MORREY TOTAL ELBOW
(For Use With Bone Cement)

DESCRIPTION
The design of this prosthesis is based on the complex kinematics of the elbow joint. This product is a total elbow prosthesis designed for use with acrylic cement, and 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. An articular design with 7° laxity tends to minimize the possibility of prosthetic rotation or loosening in the humerus or ulna. The anterior flange on the humeral stem can accommodate a bone graft to enhance thickening of bone stock at the point where maximum stress on the elbow has been found to occur.

MATERIALS
The ulnar and humeral stems are manufactured from *Tivanium*® Ti-6Al-4V Alloy. The humeral stem has a porous coating of titanium beads. The ulnar stem is precoated with polymethyl methacrylate (PMMA)*. The hinge pin is manufactured from *Tivanium*® Ti-6Al-4V Alloy and *Zimaloy*® Cobalt-Chromium-Molybdenum Alloy. All of these components are shielded in the assembly by ultra-high molecular-weight polyethylene (UHMWPE) bushings to prevent metal-to-metal contact.

INDICATIONS
Indications include: 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; and instability or loss of motion when the degree of joint damage precludes less radical procedures.

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises 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.

IMPORTANT NOTE: This product is marketed for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see **CONTRAINDICATIONS**) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions

contemplating use of this product for other than labeled indications (i.e., off-label use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

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/Morrey Total Elbow should not be considered for patients whose activities would subject the device to significant stress (i.e., heavy labor, torsional stress, or competitive sports).

Additionally, distant foci of infection, such as genitourinary, pulmonary, skin (chronic lesions or ulcerations), 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.

Joints that are neuropathic because of diabetes or other disease involving peripheral neuropathy are relative contraindications to total elbow arthroplasty.

WARNINGS

Loosening between the methacrylate interface and the humerus can occur after implantation of a total elbow hinge prosthesis. A snug mechanical fit within the humerus and ulna will tend to minimize this. Loss or absence of epicondyles or collateral ligaments may increase the risk 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 from the ulna 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 excessive muscular activity, e.g., pounding, carrying loads. 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. Although it may appear undamaged, previous stresses may have created imperfections that would reduce the service life of the implant.

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

Transient bacteremia occurs after dental manipulation, endoscopic examinations, and other minor surgical procedures. To prevent late infection at the implant site, many orthopaedic surgeons advise the use of antibiotic prophylaxis before and after such procedures for their patients with total joint implants. Penicillin V, two grams one hour before the procedure and one gram six hours after the first dose, has been recommended. In patients for whom penicillin is contraindicated, erythromycin, one gram one hour before treatment and 500 mg six hours after the first dose, is recommended.[1]

ADVERSE EFFECTS

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

In addition to the obvious risk that any orthopaedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in the literature that a variety of metals, polymers, chemicals, and other materials utilized with orthopaedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopaedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long-term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissue may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis for soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to these locations during operative and diagnostic procedures such as biopsies and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.[2]

2. Implantation of foreign material in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cement particles) can initiate the process of loosening.[3] While formation of wear debris may be an inevitable consequence of motion at articulating implant

surfaces, optimal technique for cementing or fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or cement/prosthesis interface.

3. Metal sensitivity has been reported following exposure to orthopaedic implants. The most common sensitizers (nickel, cobalt, and chromium) are present in orthopaedic grade stainless steel and cobalt-chrome alloys.[4] Titanium and its alloys (*Tivanium*) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

UTILIZATION AND IMPLANTATION
IMPORTANT NOTE
Do not mix small and regular sizes of the humeral and ulnar components during implantation. Both components must be the same size (small or regular).

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 or cement gun 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: Surgical Technique No. 97-8106-02 is available upon request.

STERILITY
These devices are provided sterile by prior exposure to gamma irradiation. If required, the devices can be resterilized using Association for the Advancement of Medical Instrumentation (AAMI) guidelines and/or Association of Operating Room Nurses (AORN) recommended practices for sterilization. These recommendations do not apply to components which have been implanted or have become contaminated with body fluids or debris. Sterilizer equipment must be in good operating condition and used according to manufacturer's recommendation.

Inspect the package of any sterile product for structural integrity prior to use. If the seal of either the inner or outer thermoformed cavity is broken or if the cavities are otherwise damaged, the product must be assumed to be nonsterile.

The double plastic cavities with TYVEK lids in which sterile implants are supplied should not be reused for resterilization methods in the hospital. Repackaged and resterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

Packaging should be appropriate for the sterilization techniques used. Special precautions must be taken with porous-coated and polymethyl methacrylate (PMMA) precoated implants to prevent surface contamination from lint and debris. Use a lint-free sterilization wrap if resterilization of the component is required.

It is extremely important that any lint or debris be rinsed from the PMMA-precoated component before sterilization using USP purified water and that lint-free wrappers be used. The coating softens slightly during sterilization, therefore, it should not contact the wrapping material or any holding devices in sterilization trays. Slight crazing (very fine lines in the coated area) may develop in the coating, but this will not affect the bonding between the precoat and the polymerizing bone cement. Sterilized precoated components must be allowed to cool naturally. They should not be forcibly cooled by immersion in room-temperature water or saline.

Special precautions should be observed for the heads of femoral hip prostheses. The knitted head covers protecting the articulating surface should only be removed prior to implantation.

Modular femoral heads and stems must be sterilized separately to prevent a potential for bioburden buildup in the dead space. The head and stem may be made from alloys differing in expansion and contraction characteristics which could cause internal stresses during heating and cooling.

Ultra-high molecular-weight polyethylene (UHMWPE) or PMMA components **must not** be exposed to steam sterilization. The temperatures required for these processes may soften, warp or crack the polyethylene or polymethyl methacrylate.

Aluminum oxide or zirconia ceramic femoral heads **must not** be resterilized by any method.

Additional resterilization information is available upon request.

In the USA, call 1-800-348-2759. For calls outside the USA, call the local international access code +1-219-267-6131.

REFERENCES
References to relevant literature (see superscripts) may be obtained by calling the Zimmer Global Regulatory Affairs Department a 1-800-613-6131

CAUTION
This device is intended for cemented use only. THERE ARE NO KNOWN INDICATIONS FOR IMPLANTING THIS DEVICE WITHOUT CEMENT.

*U.S. Patents 4,281,420; 4,336,618; 4,491,987

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Printed in U.S.A.

87-6203-322.FDA

zimmer

P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

Summary of Safety and Effectiveness
Coonrad/Morrey Total Elbow, New Hinge Pin

- **Submitted by:**

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, IN 46581-0708

- **Prepared by:**

  Charlene Brumbaugh
  Specialist
  Global Regulatory Affairs
  Telephone: 219-372-4962
  Telefax: 219-372-4605

- **Date:**

  September 4, 1997

- **Trade Name:**

  Coonrad/Morrey Total Elbow

- **Common Name:**

  Elbow Prosthesis

- **Classification Name:**

  Prosthesis, Elbow, Semiconstrained, Cemented

- **Predicate Devices:**

  Coonrad III Total Elbow, marketed by Zimmer

120

Summary of Safety and Effectiveness
Coonrad/Morrey Total Elbow, New Hinge Pin
(Continued)

- **Device Description**

  The Coonrad/Morrey Total Elbow is closely based on the Coonrad III Total Elbow (K883665) cleared by FDA on February 3, 1989, with several exceptions.

- **Intended Use**

  The Coonrad/Morrey Total Elbow is indicated for:

  - 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
  - Instability or loss of motion when the degree of joint damage precludes less radical procedures

  The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises 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 predominantly 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.

- **Performance Data**

  Performance testing was conducted to determine force required to unlock the hinge pin assembly. Results indicate the product is safe and effective.