Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

K032163

Summary of Safety and Effectiveness

Contact Person:

Denise Duchene
Sr. Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17 South
Allendale, NJ 07401
(201) 831-5612 (Phone)
(201) 831-6038 (FAX)

Date: June 24, 2003

Device: Duracon® Total Knee System

Classification: Knee Joint; Patellofemorotibial; Metal/polymer; Porous-coated; Uncemented prosthesis - Class II - 21 CFR 888.3565

Predicate Devices: Duracon® Total Knee System

Indications for Use: The Duracon® Total Knee System components are for use in total knee arthroplasty to relieve pain and restore knee function for indications such as: noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and, irreparable fracture of the knee.

These products are intended to achieve fixation with and without the use of bone cement

Proposed Modification: Additional indication for use of product without bone cement.

Device Description: The device includes femoral, tibial and patellar components of a total knee system. These components are used for the replacement of the bearing and/or articulating surfaces of the distal femur, proximal tibia to relieve pain, instability and the restriction of motion due to degenerative bone disease, including osteoarthritis, rheumatoid arthritis, failure of other devices or trauma.

page 1 of 2

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

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Summary of Data: A risk analysis and research and development testing have been performed to demonstrate equivalence of the proposed products to the predicate devices. The testing includes porous coating characterization, baseplate fatigue testing, contact area / stress analyses; range of motion range of constraint testing; locking mechanism testing; UHMWPe material properties in accordance with the Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA," dated January 16, 2003. The results demonstrate that the Duracon Total Knee System meets the requirements of this document.

page 2 of 2

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2003

Ms. Denise Duchene
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401

Re: K032163
Trade/Device Name: Duraco® Total Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Product Code: MBH
Dated: July 11, 2003
Received: July 21, 2003

Dear Ms. Duchene:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

510(k) Number (if known): K032163

Device Name: Duracon® Total Knee System

Indications for Use:

The Duracon® Total Knee System components included in this submission are intended for use in total knee arthroplasty to relieve pain and restore knee functions for indications such as:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;
- Post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee.

These products are intended to achieve fixation with and without the use of bone cement.

(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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032163

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

K032163/A1

stryker®
Howmedica
OSTEONICS

59 Route 17 South
Allendale, NJ 07401

August 22, 2003

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

Via Federal Express

FDA/CDRH/ODE/PMO
2003 AUG 25 A 9:58

Re: 510(k) Notification Amendment – Duracon® Total Knee System K032163

Document Mail Staff:

Howmedica Osteonics Corp. would like to correct information contained in the submission identified above. In the pending 510(k) Submission it was stated that only the Condylar and AP Lipped Tibial Inserts could be used in conjunction with the Cruciform Tibial Baseplate. However, this is incorrect the CS Lipped Inserts are also compatible with the Cruciform Baseplates.

The Cruciform Baseplates are not compatible with the Posterior Stabilized and Total Stabilized Tibial Inserts. These inserts are not the subject of this submission. The reason the Cruciform Baseplates are not compatible with these components because of the "locking mechanism' for these inserts.

The Condylar, AP Lipped and CS Lipped Tibial Inserts all have the same locking mechanism and therefore, are compatible with the Cruciform Baseplates.

Please refer any questions regarding this submission to Denise Duchene at (201) 831-5612.

Sincerely,
HOWMEDICA OSTEONICS CORP.

Denise Duchene

Denise Duchene
Sr. Regulatory Affairs Specialist

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

5167

13

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2003

Ms. Denise Duchene
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401

Re: K032163
Trade/Device Name: Duraco® Total Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Product Code: MBH
Dated: July 11, 2003
Received: July 21, 2003

Dear Ms. Duchene:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). 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.

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

510(k) Number (if known): K032163

Device Name: Duracon® Total Knee System

Indications for Use:

The Duracon® Total Knee System components included in this submission are intended for use in total knee arthroplasty to relieve pain and restore knee functions for indications such as:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;
- Post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee.

These products are intended to achieve fixation with and without the use of bone cement.

(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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032163

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

July 22, 2003

HOWMEDICA OSTEONICS CORP.
59 ROUTE 17 SOUTH
ALLENDALE, NJ 07401
ATTN: DENISE DUCHENE

510(k) Number: K032163
Received: 21-JUL-2003
Product: DURACON TOTAL KNEE SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA 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
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

July 15, 2003

HOWMEDICA OSTEONICS CORP.
59 ROUTE 17 SOUTH
ALLENDALE, NJ 07401
ATTN: DENISE DUCHENE

510(k) Number: K032163
Received: 15-JUL-2003
Product: DURACON TOTAL KNEE
User Fee ID Number: 8684

The Food and Drug Administration (FDA) Center for Devices and Radiological Heath (CDRH), 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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. The payment information we need in order to begin the review of your 510(k) includes, the user fees cover sheet with the payment ID faxed to the Office of Financial Management at (301) 827-9213 and a check mailed to:

By Regular Mail	By Private Courier (e.g., Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should also be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at http://www.fda.gov/oc/mdufma.

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/cdrh/dsmamain.html, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016 K032183

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: B(4) Product Specifications

Write the Payment Identification Number on your check.

See Instructions Before Completing This Cover Sheet

A completed cover sheet must accompany each original premarket application or supplement listed in Box 3 of this cover sheet. Other premarket application types do not require the use of this cover sheet; see list in the instructions. Payment instructions and fee rates can be found at the following website: http://www.fda.gov/oc/mdufma. The following three actions *must be taken to properly submit your premarket* application and fee payment:

1. FAX a copy of this completed cover sheet to the Food and Drug Administration at (301) 827-9213 before payment is sent.
2. *Include a copy* of this completed cover sheet with the check made payable to the Food and Drug Administration and mail them to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. *(Note: In no case should payment be submitted with the premarket application.)* Also remember that the Payment Identification Number must be written on the check. If you prefer to send a check *by a courier, the courier may deliver* the check and cover sheet to: US Bank, 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4831 if you have any questions concerning courier delivery.)
3. Include a copy of this completed cover sheet in volume one of the *premarket application when submitting* to the Food and Drug Administration at either the CBER or CDRH Document Mail Center.

FDA/CDRH/ODE/PMO RECEIVED 2003 JUL 15 A 10: 26

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

HOWMEDICA OSTEONICS CORP
59 ROUTE 17 SOUTH
ALLENDALE, NJ 07401
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
222183590

2. CONTACT NAME
DENISE DUCHENE

2.1 E-MAIL ADDRESS
dduchene@howost.com

2.2 TELEPHONE NUMBER (Include area code)
201-831-5612

2.3 FACSIMILE (FAX) NUMBER (Include area code)
201-831-6038

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma)

Select an application type:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologic License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

☐ YES, *I meet the small business criteria* and have submitted the required qualifying documents to FDA

☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- ☐ This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- ☐ This biologic application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ *The sole purpose of the application is to support* conditions of use for a pediatric population
- ☐ *The application is submitted* by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

☐ YES ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

B(4)

5K20

OR

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

stryker®
Howmedica
OSTEONICS

59 Route 17 South
Allendale, NJ 07401

July 11, 2003

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

Via Federal Express

Re: 510(k) Notification – Duracon® Total Knee System

Document Mail Staff:

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, notification is made of the intention of Howmedica Osteonics Corp. to introduce into interstate commerce a modified total knee system. The FDA Orthopedic panel considers these devices as Class II, knee joint, patellofemorotibial metal/polymer porous-coated uncemented prostheses.

It is the understanding of Howmedica Osteonics that prior to the promulgation of regulations or the issuance of specific FDA direction, post market surveillance requirements are not operative for Class I and II devices.

The information contained in this submission is considered confidential within the meaning of 21 CFR Part 20.

Your early attention to this submission is appreciated. Please refer any questions regarding this submission to Denise Duchene at (201) 831-5612.

Sincerely,
HOWMEDICA OSTEONICS CORP.

Debra L. Bing
Manager, Regulatory Affairs

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: B(4) Product Specifications

Write the Payment Identification Number on your check.

See Instructions Before Completing This Cover Sheet

A completed cover sheet must accompany each original premarket application or supplement listed in Box 3 of this cover sheet. Other premarket application types do not require the use of this cover sheet; see list in the instructions. Payment instructions and fee rates can be found at the following website: http://www.fda.gov/oc/mdufma.The following three actions must be taken to properly submit your premarket application and fee payment:

1. FAX a copy of this completed cover sheet to the Food and Drug Administration at (301) 827-9213 before payment is sent.
2. Include a copy of this completed cover sheet with the check made payable to the Food and Drug Administration and mail them to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. *(Note: In no case should payment be submitted with the premarket application.)* Also remember that the Payment Identification Number must be written on the check.
   If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to: US Bank, 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
3. Include a copy of this completed cover sheet in volume one of the premarket application when submitting to the Food and Drug Administration at either the CBER or CDRH Document Mail Center.

FDA/CDRH/OCE/PMO
2003 JUL 15 A 10:26
RECEIVED

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

HOWMEDICA OSTEONICS CORP
59 ROUTE 17 SOUTH
ALLENDALE, NJ 07401
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
222183590

2. CONTACT NAME
DENISE DUCHENE

2.1 E-MAIL ADDRESS
dduchene@howost.com

2.2 TELEPHONE NUMBER (Include area code)
201-831-5612

2.3 FACSIMILE (FAX) NUMBER (Include area code)
201-831-6038

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma)

Select an application type:

- [x] Premarket notification (510(k)); except for third party reviews
- [ ] Biologic License Application (BLA)
- [ ] Premarket Approval Application (PMA)
- [ ] Modular PMA
- [ ] Product Development Protocol (PDP)
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3.1 Select one of the types below:

- [x] Original Application

Supplement Types:

- [ ] Efficacy (BLA)
- [ ] Panel Track (PMA, PMR, PDP)
- [ ] Real-Time (PMA, PMR, PDP)
- [ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- [ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- [x] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- [ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- [ ] The sole purpose of the application is to support conditions of use for a pediatric population
- [ ] This biologic application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- [ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

- [ ] YES
- [x] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

B(4)

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stryker®
Howmedica
OSTEONICS

59 Route 17 South
Allendale, NJ 07401

July 11, 2003

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

Via Federal Express

FDA/CDRH/ODE/PMO
2003 JUL 15 A 10: 26
RECEIVED

Re: 510(k) Notification – Duracon® Total Knee System

Document Mail Staff:

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, notification is made of the intention of Howmedica Osteonics Corp. to introduce into interstate commerce a modified total knee system. The FDA Orthopedic panel considers these devices as Class II, knee joint, patellofemorotibial metal/polymer porous-coated uncemented prostheses.

It is the understanding of Howmedica Osteonics that prior to the promulgation of regulations or the issuance of specific FDA direction, post market surveillance requirements are not operative for Class I and II devices.

The information contained in this submission is considered confidential within the meaning of 21 CFR Part 20.

Your early attention to this submission is appreciated. Please refer any questions regarding this submission to Denise Duchene at (201) 831-5612.

Sincerely,
HOWMEDICA OSTEONICS CORP.

Debra L. Bing
Manager, Regulatory Affairs

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

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510(k) Number (if known): K032163

Device Name: Duracon® Total Knee System

Indications for Use:

The Duracon® Total Knee System components included in this submission are intended for use in total knee arthroplasty to relieve pain and restore knee functions for indications such as:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;
- Post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee.

These products are intended to achieve fixation with and without the use of bone cement.

(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)

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

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Premarket Notification
Truthful and Accurate Statement
[as required by 21 CFR 807.87(k)]

I certify that, in my capacity as Manger, Regulatory Affairs for Howmedica Osteonics Corp., I believe to the best of my knowledge that all information and data submitted in this premarket notification [510(k)] are truthful and that no material facts have been willfully omitted.

Debra L. Bing
Manger, Regulatory Affairs

7 / 11 / 03
Date

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

TRADITIONAL 510(k) PREMARKET NOTIFICATION

DURACON® TOTAL KNEE SYSTEM
JULY 11, 2003

stryker
Howmedica
OSTEONICS
59 ROUTE 17 SOUTH
ALLENDALE, NJ 07401

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

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

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

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K032163

Summary of Safety and Effectiveness

Contact Person:

Denise Duchene
Sr. Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17 South
Allendale, NJ 07401
(201) 831-5612 (Phone)
(201) 831-6038 (FAX)

Date: June 24, 2003

Device: Duracon® Total Knee System

Classification: Knee Joint; Patellofemorotibial; Metal/polymer; Porous-coated; Uncemented prosthesis - Class II - 21 CFR 888.3565

Predicate Devices: Duracon® Total Knee System

Indications for Use: The Duracon® Total Knee System components are for use in total knee arthroplasty to relieve pain and restore knee function for indications such as: noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and, irreparable fracture of the knee.

These products are intended to achieve fixation with and without the use of bone cement

Proposed Modification: Additional indication for use of product without bone cement.

Device Description: The device includes femoral, tibial and patellar components of a total knee system. These components are used for the replacement of the bearing and/or articulating surfaces of the distal femur, proximal tibia to relieve pain, instability and the restriction of motion due to degenerative bone disease, including osteoarthritis, rheumatoid arthritis, failure of other devices or trauma.

page 1 of 2

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

33

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Summary of Data: A risk analysis and research and development testing have been performed to demonstrate equivalence of the proposed products to the predicate devices. The testing includes porous coating characterization, baseplate fatigue testing, contact area / stress analyses; range of motion range of constraint testing; locking mechanism testing; UHMWPe material properties in accordance with the Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA," dated January 16, 2003. The results demonstrate that the Duracon Total Knee System meets the requirements of this document.

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

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SECTION I

ADMINISTRATIVE INFORMATION

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

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A. Name and Address of Sponsor:

Howmedica Osteonics Corp.
59 Route 17 South
Allendale, NJ 07401
Registration Number: 2243265

B. Name and Address of Manufacturers:

B(4) Manufacturing Information

[redacted]

C. Name and Address of Distributor:

Howmedica Osteonics Corp.
300 Commerce Ave
Mahwah, NJ 07430
Registration Number: 2249697

D. 510(k) Contact Person

Denise Duchene
Sr. Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17 South
Allendale, NJ 07401
(201) 831-5612 (Phone)
(201) 831-6038 (FAX)
dduchene@howost.com (e-mail)

E. Device Name

Duracon® Total Knee System

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

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F. Device 21 CFR Designation

888.3565 – Knee joint, patellofemorotibial, metal/polymer, porous-coated, uncemented prosthesis

G. Device Class

Class II

H. Device Panel / Product Code

87 MBH

I. Compliance with Section 514 of the FD&C Act

No performance standards for the Duracon® Total Knee system components have been promulgated under Section 514 of the Federal Food, Drug and Cosmetic Act. However, the components of the Duracon Total Knee system comply with "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous Coated Uncemented Prostheses; Guidance for Industry and FDA," dated January 16, 2003.

J. Purpose for 510(k) Submission

This 510(k) submission is being supplied to the U.S. FDA to provide authorization to market Duracon® Total Knee system for use with and without bone cement.

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

K. Premarket Notification [510(k)] Checklist

K_____ Device Name: Duracon® Total Knee System_____

Division / Branch: Division of General and Restorative & Neurological Devices_____

Administrative Reviewer Signature _____ Date _____

Supervisory Signature _____ Date_____

Did the firm request expedited review? ☐ Yes ☒ No

Did we grant expedited review? ☐ Yes ☒ No

Truthful and Accurate statement enclosed? ☒ Yes ☐ No

	Yes Present Omission Justified	No Inadequate Omitted
I. Critical Elements:		
A. Is the product a device?	☒	☐
B. Is the device exempt from 510(k) by regulation or policy?	☐	☒
C. Is the 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)?	N/A	☐
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.)	N/A	☐
F. Does the submission contain the information required under Section 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	☒	☐

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

	Yes Present Omission Justified	No Inadequate Omitted
2. Device common or usual name or classification name?	☒	☐
3. Establishment registration number (only applies if the establishment is registered)	☒	☐
4. Class into which the device is classified (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 and a Class III Summary.	N/A	☐
10. Photographs of the device.	N/A	☐
11. Engineering drawings for the device.	☒	☐
12. The marketed device to which equivalence is claimed including labeling and description of the device.	☒	☐
13. The statement of similarities and differences with marketed devices.	☒	☐
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	N/A	☐
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	☒	☐

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

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	Yes Present Omission Justified	No Inadequate Omitted
C. Performance Data	☒	☐
Marketed Device:		
Bench Testing	☒	☐
Animal Testing	N/A	☐
Clinical Testing	N/A	☐
New Device:		
Bench Testing	☒	☐
Animal Testing	N/A	☐
Clinical Testing	N/A	☐
D. Sterilization Information	☒	☐
E. Software Information	N/A	☐
F. Hardware Information	N/A	☐
G. If this 510(k) is for a kit, has the kit certification statement been provided?	N/A	☐
H. Is this device subject to issues that have been addressed in specific guidance document(s)?	☒	☐
If yes, continue with review with checklist from any appropriate guidance documents.	N/A	☐
If no, is 510(k) sufficiently complete to allow substantive review?	☒	☐
I. Other (specify)	N/A	☐

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

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SECTION II

DEVICE INFORMATION

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

A. Introduction

This 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the Duracon® Total Knee system components for use with and without bone cement. Copies of test reports have been provided in Appendix C of this submission. These reports had been previously submitted to FDA in prior 510(k) Submissions and are being provided to ease referencing.

B. Intended Use

The Howmedica Osteonics **Duracon® Total Knee System Components** are intended for the replacement of the bearing and/or articulating surfaces of the distal femur and proximal tibia to relieve pain, and the restriction of motion.

These components are designed for single use only and are intended for cemented or uncemented fixation in patients indicated for total knee arthroplasty. The components may be used for primary and/or revision applications.

C. Device Description

The Duracon® Total Knee System is a series of femoral components, tibial components and patellar components designed to be used in total knee arthroplasty with and without bone cement for implant fixation. The femoral, tibial baseplate and patellar components contain a porous coating, which provides for bone ingrowth so the components may be used without bone cement for fixation. This porous coating is made up of cobalt chromium alloy sintered beads, and a detailed description of the coating is included on page 13 of this submission.

(b)(4)

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

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(b)(4)

[redacted]

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

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(b)(4)

component dimensions.

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

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(b)(4)

[redacted]

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

(b)(4)

[redacted]

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

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D. Device Materials

(b)(4)

Components and Materials

Proposed Component	Material	Function

(b)(4)

E. Summary of Data

(b)(4)

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

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(b)(4)

F. Sterilization Information

B(4) Product Specifications

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

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G. Packaging

The Duracon® Knee System femoral and tibial baseplate components are packaged as a single unit in a double blister. The packaged unit is protected by a rigid outer carton and shrink-wrapped per written procedures. Polyethylene components (tibial inserts, metal backed patellae, and conversion patella inserts) are subject to an additional heat treatment stabilizing processing step. These polyethylene components are referred to as Duration stabilized components. This process for packaging was cleared under K936292. Duracon® CS Lipped polyethylene components are also available in N_2Vac style – these polyethylene components are packaged in the basic double blister, but to create an inert environment the component packages are flushed with nitrogen and then sealed per written procedures. This process for packaging the CS Lipped Tibial inserts was cleared under K021451. All packaging is suitable for gamma radiation sterilization and for maintaining sterility.

H. Labeling

Refer to Appendix B, page 100 for proposed product labeling and instructions for use. Current product labeling and instructions for use are included in Appendix D, page 537.

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

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SECTION III

SUBSTANTIAL EQUIVALENCE

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

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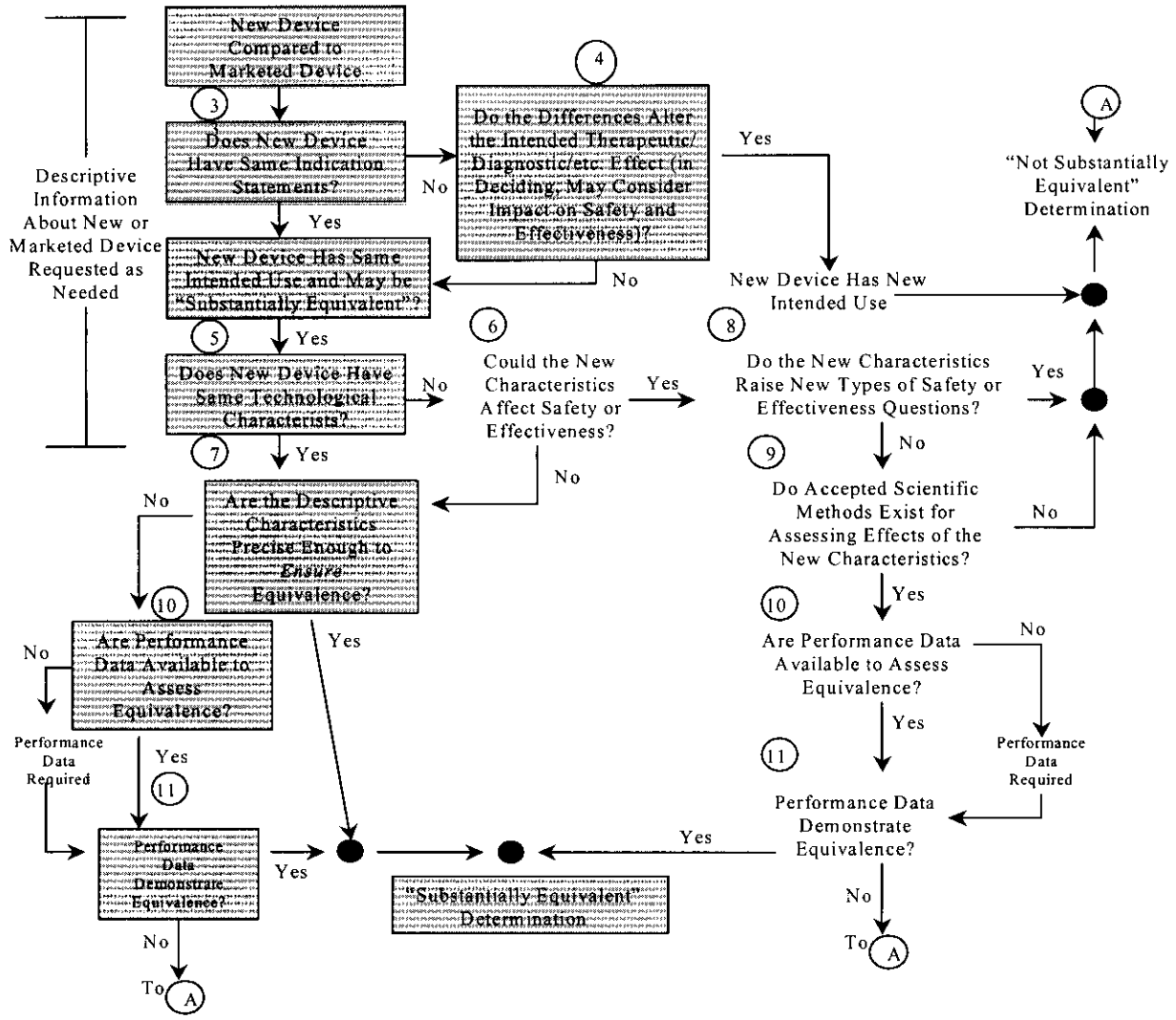
A. Substantial Equivalence Decision Tree

The numbers on the decision tree are used as reference points in the substantial equivalence decision table that follows. The numbers are used to cross reference the information in the 510(k) submission to the decision point within the substantial equivalence decision tree. The decision path is highlighted.



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

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B. Substantial Equivalence Decision Table

Tree Question	Summary Response	510(k) Reference
3. Does new device have the same indication statements?	**NO:** The Duracon® Total Knee System has the same indications for use. However, the current product is intended for cemented use only; whereas the proposed product will be intended for both cemented and uncemented fixation.	Section II; pg. 9 Section III; pg. 18 Appendix B; pg 100 Appendix D; pg 537
4. Do the differences alter the intended therapeutic / diagnostic / etc. effect?	**NO:** The Duracon Total Knee System has the same basic intended use / therapeutic effect to relieve pain and restriction of motion in total knee arthroplasty.	Section II; pg 9 Section III; pg 18 Appendix B; pg 100 Appendix D; pg 537
5. Does new device have the same technological characteristics, e.g., design materials, etc…	**YES:** The proposed product has the same basic design; follows the same operational principles and is manufactured from the same materials as the predicate devices. There are no differences between the proposed product and the predicate devices.	Section II; pg. 9 Section III; pg 18 Appendix A; pg 100 Appendix D; pg 537
7. Are descriptive characteristics precise enough to ensure equivalence?	**NO:** Due to the changes in the intended use, Howmedica Osteonics is providing test data in accordance with Special Controls guidance document for uncemented knee prostheses, dated January 16, 2003. This data was supplied in earlier 510(k) submissions and is being provided to ease referencing.	Section II; pg 9 Appendix C; pg 120
10. Are performance data available to assess equivalence?	**YES:** Testing and a risk analysis as required by the guidance document for uncemented knee prostheses, dated January 16, 2003 was performed to ensure the product design does not have a an effect on the new intended use proposed for these devices.	Section II; Page 9 Appendix C; pg 120
11. Performance data demonstrate equivalence?	**YES:** Test data and the risk analysis performed demonstrate that the Duracon Total Knee System can be used without bone cement in total knee arthroplasty.	Section II; page 9 Appendix C; pg 120

C. Substantial Equivalence Discussion

The components of the Duracon Total Knee System for use with and without bone cement are equivalent to the components of the Duracon Total Knee System for cemented use only determined substantially equivalent under the following 510(k) Submissions: K910235, K915512, K920034, K926228, K936292, K972752, K021451, K023724. Both the proposed product and the predicate devices have the exact same design and manufacturing processing and are used in total knee arthroplasty. However, the proposed product is intended for use with and without bone cement whereas the predicate devices are for cemented use only. The Duracon Total Knee System for use

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

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with and without cement complies with the "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA," dated January 16, 2003. The company has performed a risk analysis in accordance with the requirements of the guidance document. The risk analysis meets the requirements of the Failure Mode Effects Analysis Method of performing risk analyses. Also included in this section is a table of the similarities and differences between the predicate device and the proposed products.

D. Comparison Table of Products

Product Features – Intended/Indications for Use		
	Proposed Product	**Duracon Total Knee System**
Product Type	Femoral, tibial and patellar components for total knee arthroplasty	Femoral, tibial and patellar components for total knee arthroplasty
Intended Use	B(4) Product Specifications [redacted]	The Duracon® Total Knee System components are for use in total knee arthroplasty to relieve pain and restore knee function for indications such as: noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; post traumatic lost of join anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and, irreparable fracture of the knee. For cemented use only.
Length of Use	[redacted]	B(4) Product Specifications [redacted]
Anatomical Placement	[redacted]	[redacted]
Mean Porous Coating Thickness	[redacted]	[redacted]
Mean Pore Volume	[redacted]	[redacted]
Sizes – Femoral Components	[redacted]	[redacted]
Sizes – Tibial Baseplate Components	[redacted]	[redacted]
Sizes – Tibial Insert Components	[redacted]	[redacted]
Thickness (mm) – Tibial Insert Components	[redacted]	[redacted]
Compatible Tibial Inserts	[redacted]	[redacted]
Compatible Femoral Components	[redacted]	[redacted]
Compatible Tibial Trays	[redacted]	[redacted]

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

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Product Features – Intended/Indications for Use		
	Proposed Product	**Duracon Total Knee System**
Product Type	B(4) Product Specifications [redacted]	
Compatible Patella components		
Femoral Component Material		
Tibial Insert Component Material		
Method of insert attachment to tibial tray		
Cruciate Retaining Components Available		
Sterilization Method		
Packaging		

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

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APPENDIX A

CATALOG NUMBERS AND ENGINEERING DRAWINGS

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

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Catalog Numbers

CATALOG NUMBER	DESCRIPTION	SIZE	MATERIAL	CEMENTED USE ONLY 510(K) #
6630-0-010	Beaded Standard Femoral Component – Left	X-X Small	B(4) Product Specifications [redacted]	K910235
6630-0-020	Beaded Standard Femoral Component – Right	X-X Small		K910235
6630-0-110	Beaded Standard Femoral Component – Left	X-Small		K910235
6630-0-120	Beaded Standard Femoral Component – Right	X-Small		K910235
6630-0-210	Beaded Standard Femoral Component – Left	Small		K910235
6630-0-220	Beaded Standard Femoral Component – Right	Small		K910235
6630-0-310	Beaded Standard Femoral Component – Left	Medium		K910235
6630-0-320	Beaded Standard Femoral Component – Right	Medium		K910235
6630-0-410	Beaded Standard Femoral Component – Left	Medium/ Large		K910235
6630-0-420	Beaded Standard Femoral Component – Right	Medium/ Large		K910235
6630-0-510	Beaded Standard Femoral Component – Left	Large		K910235
6630-0-520	Beaded Standard Femoral Component – Right	Large		K910235
6630-0-610	Beaded Standard Femoral Component – Left	X-Large		K910235
6630-0-620	Beaded Standard Femoral Component – Right	X-Large		K910235
6630-0-710	Beaded Standard Femoral Component – Left	X-X Large		K910235
6630-0-720	Beaded Standard Femoral Component – Right	X-X Large		K910235
6632-0-210	Beaded Modular Femoral Component – Left	Small		K920034
6632-0-220	Beaded Modular Femoral Component – Right	Small		K920034
6632-0-310	Beaded Modular Femoral Component – Left	Medium		K920034
6632-0-320	Beaded Modular Femoral Component – Right	Medium		K920034
6632-0-410	Beaded Modular Femoral Component – Left	Medium/ Large		K920034
6632-0-420	Beaded Modular Femoral Component – Right	Medium/ Large		K920034
6632-0-510	Beaded Modular Femoral Component – Left	Large		K920034
6632-0-520	Beaded Modular Femoral Component – Right	Large		K920034
6632-0-610	Beaded Modular Femoral Component – Left	X-Large		K920034

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

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CATALOG NUMBER	DESCRIPTION	SIZE	MATERIAL	CEMENTED USE ONLY 510(K) #
6632-0-620	Beaded Modular Femoral Component – Right	X-Large	B(4) Product Specifications [redacted]	K920034
6632-0-710	Beaded Modular Femoral Component – Left	X-X Large		K920034
6632-0-720	Beaded Modular Femoral Component – Right	X-X Large		K920034
6632-3-301	Beaded Cruciform Tibial Baseplate – 62mm x 37mm	X-Small 1		K926228
6632-3-303	Beaded Cruciform Tibial Baseplate – 64mm x 39mm	X-Small 2		K926228
6632-3-305	Beaded Cruciform Tibial Baseplate – 67mm x 42mm	Small 1		K926228
6632-3-310	Beaded Cruciform Tibial Baseplate – 69mm x 45mm	Small 2		K926228
6632-3-315	Beaded Cruciform Tibial Baseplate – 72mm x 48mm	Medium 1		K926228
6632-3-320	Beaded Cruciform Tibial Baseplate – 74mm x 50mm	Medium 1		K926228
6632-3-325	Beaded Cruciform Tibial Baseplate – 77mm x 53mm	Large 1		K926228
6632-3-330	Beaded Cruciform Tibial Baseplate – 79mm x 55mm	Large 2		K926228
6632-3-335	Beaded Cruciform Tibial Baseplate – 82mm x 58mm	X-Large 1		K926228
6632-3-340	Beaded Cruciform Tibial Baseplate – 85mm x 60mm	X-Large 2		K926228
6632-3-701	Beaded Universal Tibial Baseplate – 62mm x 37mm	X-Small 1		K915512
6632-3-703	Beaded Universal Tibial Baseplate – 64mm x 39mm	X-Small 2		K915512
6632-3-705	Beaded Universal Tibial Baseplate – 67mm x 42mm	Small 1		K915512
6632-3-710	Beaded Universal Tibial Baseplate – 69mm x 45mm	Small 2		K915512
6632-3-715	Beaded Universal Tibial Baseplate – 72mm x 48mm	Medium 1		K915512
6632-3-720	Beaded Universal Tibial Baseplate – 74mm x 50mm	Medium 1		K915512
6632-3-725	Beaded Universal Tibial Baseplate – 77mm x 53mm	Large 1		K915512
6632-3-730	Beaded Universal Tibial Baseplate – 79mm x 55mm	Large 2		K915512
6632-3-735	Beaded Universal Tibial Baseplate – 82mm x 58mm	X-Large 1		K915512
6632-3-740	Beaded Universal Tibial Baseplate – 85mm x 60mm	X-Large 2		K915512
6642-1-009	Condylar Tibial Insert – 9mm	X-Small		K915512 K936292 (Duration Pkg.)
6642-1-011	Condylar Tibial Insert – 11mm	X-Small		K915512 K936292 (Duration Pkg.)
6642-1-013	Condylar Tibial Insert – 13mm	X-Small		K915512 K936292 (Duration Pkg.)

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

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CATALOG NUMBER	DESCRIPTION	SIZE	MATERIAL	CEMENTED USE ONLY 510(K) #
6642-1-016	Condylar Tibial Insert – 16mm	X-Small	B(4) Product Specifications [redacted]	K915512 K936292 (Duration Pkg.)
6642-1-109	Condylar Tibial Insert – 9mm	Small	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-111	Condylar Tibial Insert – 11mm	Small	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-113	Condylar Tibial Insert – 13mm	Small	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-116	Condylar Tibial Insert – 16mm	Small	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-119	Condylar Tibial Insert – 19mm	Small	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-209	Condylar Tibial Insert – 9mm	Medium	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-211	Condylar Tibial Insert – 11mm	Medium	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-213	Condylar Tibial Insert – 13mm	Medium	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-216	Condylar Tibial Insert – 16mm	Medium	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-219	Condylar Tibial Insert – 19mm	Medium	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-309	Condylar Tibial Insert – 9mm	Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-311	Condylar Tibial Insert – 11mm	Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-313	Condylar Tibial Insert – 13mm	Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-316	Condylar Tibial Insert – 16mm	Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-319	Condylar Tibial Insert – 19mm	Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-409	Condylar Tibial Insert – 9mm	X-Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-411	Condylar Tibial Insert – 11mm	X-Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-413	Condylar Tibial Insert – 13mm	X-Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-416	Condylar Tibial Insert – 16mm	X-Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-419	Condylar Tibial Insert – 19mm	X-Large	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-509	A/P Lipped Tibial Insert, 9mm	X-Small	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-511	A/P Lipped Tibial Insert, 11mm	X-Small	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-513	A/P Lipped Tibial Insert, 13mm	X-Small	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-516	A/P Lipped Tibial Insert, 16mm	X-Small	[redacted]	K915512 K936292 (Duration Pkg.)
6642-1-609	A/P Lipped Tibial Insert, 9mm	Small	[redacted]	K915512 K936292 (Duration Pkg.)

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Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

CATALOG NUMBER	DESCRIPTION	SIZE	MATERIAL	CEMENTED USE ONLY 510(K) #
6642-1-611	A/P Lipped Tibial Insert, 11mm	Small	B(4) Product Specifications [redacted]	K915512 K936292 (Duration Pkg.)
6642-1-613	A/P Lipped Tibial Insert, 13mm	Small		K915512 K936292 (Duration Pkg.)
6642-1-616	A/P Lipped Tibial Insert, 16mm	Small		K915512 K936292 (Duration Pkg.)
6642-1-619	A/P Lipped Tibial Insert, 19mm	Small		K915512 K936292 (Duration Pkg.)
6642-1-622	A/P Lipped Tibial Insert, 22mm	Small		K915512 K936292 (Duration Pkg.)
6642-1-625	A/P Lipped Tibial Insert, 25mm	Small		K915512 K936292 (Duration Pkg.)
6642-1-709	A/P Lipped Tibial Insert, 9mm	Medium		K915512 K936292 (Duration Pkg.)
6642-1-711	A/P Lipped Tibial Insert, 11mm	Medium		K915512 K936292 (Duration Pkg.)
6642-1-713	A/P Lipped Tibial Insert, 13mm	Medium		K915512 K936292 (Duration Pkg.)
6642-1-716	A/P Lipped Tibial Insert, 16mm	Medium		K915512 K936292 (Duration Pkg.)
6642-1-719	A/P Lipped Tibial Insert, 19mm	Medium		K915512 K936292 (Duration Pkg.)
6642-1-722	A/P Lipped Tibial Insert, 22mm	Medium		K915512 K936292 (Duration Pkg.)
6642-1-725	A/P Lipped Tibial Insert, 25mm	Medium		K915512 K936292 (Duration Pkg.)
6642-1-809	A/P Lipped Tibial Insert, 9mm	Large		K915512 K936292 (Duration Pkg.)
6642-1-811	A/P Lipped Tibial Insert, 11mm	Large		K915512 K936292 (Duration Pkg.)
6642-1-813	A/P Lipped Tibial Insert, 13mm	Large		K915512 K936292 (Duration Pkg.)
6642-1-816	A/P Lipped Tibial Insert, 16mm	Large		K915512 K936292 (Duration Pkg.)
6642-1-819	A/P Lipped Tibial Insert, 19mm	Large		K915512 K936292 (Duration Pkg.)
6642-1-822	A/P Lipped Tibial Insert, 22mm	Large		K915512 K936292 (Duration Pkg.)
6642-1-825	A/P Lipped Tibial Insert, 25mm	Large		K915512 K936292 (Duration Pkg.)
6642-1-909	A/P Lipped Tibial Insert, 9mm	X-Large		K915512 K936292 (Duration Pkg.)
6642-1-911	A/P Lipped Tibial Insert, 11mm	X-Large		K915512 K936292 (Duration Pkg.)
6642-1-913	A/P Lipped Tibial Insert, 13mm	X-Large		K915512 K936292 (Duration Pkg.)
6642-1-916	A/P Lipped Tibial Insert, 16mm	X-Large		K915512 K936292 (Duration Pkg.)
6642-1-919	A/P Lipped Tibial Insert, 19mm	X-Large		K915512 K936292 (Duration Pkg.)
6642-1-922	A/P Lipped Tibial Insert, 22mm	X-Large		K915512 K936292 (Duration Pkg.)

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

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CATALOG NUMBER	DESCRIPTION	SIZE	MATERIAL	CEMENTED USE ONLY 510(K) #
6642-1-925	A/P Lipped Tibial Insert, 25mm	X-Large	B(4) Product Specifications	K915512 K936292 (Duration Pkg.)
6642-2-140	Metal Backed Symmetric Patella – 33mm x 9mm	X-Small		K000091
6642-2-300	Metal Backed Asymmetric Patella – 36 M/L x 11mm	Small		K923573 K936292 (Duration Pkg.)
6642-2-350	Metal Backed Asymmetric Patella – 39 M/L x 11mm	Medium		K923573 K936292 (Duration Pkg.)
6642-2-400	Metal Backed Asymmetric Patella – 42 M/L x 11mm	Large		K923573 K936292 (Duration Pkg.)
6642-2-450	Metal Backed Asymmetric Patella – 44 M/L x 11mm	X-Large		K923573 K936292 (Duration Pkg.)
6642-2-700	Metal-Backed Conversion Patella	Small		K972752
6642-2-705	Metal-Backed Conversion Patella	Medium		K972752
6642-2-710	Metal-Backed Conversion Patella	Large		K972752
6642-2-715	Metal-Backed Conversion Patella	X-Large		K972752
6642-2-720	Metal-Backed Conversion Patella Insert	Small		K972752
6642-2-725	Metal-Backed Conversion Patella Insert	Medium		K972752
6642-2-730	Metal-Backed Conversion Patella Insert	Large		K972752
6642-2-735	Metal-Backed Conversion Patella Insert	X-Large		K972752
6742-4-009	CS Lipped Tibial Insert – 9mm	X-Small		K023724
6742-4-011	CS Lipped Tibial insert – 11mm	X-Small		K023724
6742-4-013	CS Lipped Tibial Insert – 13mm	X-Small		K023724
6742-4-016	CS Lipped Tibial Insert – 16mm	X-Small		K023724
6742-4-109	CS Lipped Tibial Insert – 9mm	Small		K021451
6742-4-111	CS Lipped Tibial Insert – 11mm	Small		K021451
6742-4-113	CS Lipped Tibial Insert –13mm	Small		K021451
6742-4-116	CS Lipped Tibial Insert – 16mm	Small		K021451
6742-4-119	CS Lipped Tibial Insert –19mm	Small		K021451
6742-4-122	CS Lipped Tibial Insert – 22mm	Small		K021451
6742-4-125	CS Lipped Tibial Insert – 25mm	Small		K021451
6742-4-209	CS Lipped Tibial Insert – 9mm	Medium		K021451
6742-4-211	CS Lipped Tibial Insert – 11mm	Medium		K021451
6742-4-213	CS Lipped Tibial Insert –13mm	Medium		K021451
6742-4-216	CS Lipped Tibial Insert – 16mm	Medium		K021451
6742-4-219	CS Lipped Tibial Insert –19mm	Medium		K021451
6742-4-222	CS Lipped Tibial Insert – 22mm	Medium		K021451
6742-4-225	CS Lipped Tibial Insert – 25mm	Medium		K021451
6742-4-309	CS Lipped Tibial Insert – 9mm	Large		K021451
6742-4-311	CS Lipped Tibial Insert – 11mm	Large		K021451
6742-4-313	CS Lipped Tibial Insert –13mm	Large		K021451
6742-4-316	CS Lipped Tibial Insert – 16mm	Large		K021451
6742-4-319	CS Lipped Tibial Insert –19mm	Large		K021451
6742-4-322	CS Lipped Tibial Insert – 22mm	Large		K021451

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CATALOG NUMBER	DESCRIPTION	SIZE	MATERIAL	CEMENTED USE ONLY 510(K) #
6742-4-325	CS Lipped Tibial Insert – 25mm	Large	B(4) Product Specifications [redacted]	K021451
6742-4-409	CS Lipped Tibial Insert – 9mm	X-Large		K021451
6742-4-411	CS Lipped Tibial Insert – 9mm	X-Large		K021451
6742-4-413	CS Lipped Tibial Insert – 13mm	X-Large		K021451
6742-4-416	CS Lipped Tibial Insert – 16mm	X-Large		K021451
6742-4-419	CS Lipped Tibial Insert – 19mm	X-Large		K021451
6742-4-422	CS Lipped Tibial Insert – 22mm	X-Large		K021451
6742-4-425	CS Lipped Tibial Insert – 25mm	X-Large		K021451

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

B(4) Product Drawing Design

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APPENDIX B

DRAFT LABELING AND DRAFT PACKAGE INSERT

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

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Howmedica OSTEONICS

CE 0473

Howmedica Osteonics Corp
300 Commerce Court
Mahwah, NJ 07430 USA
A Subsidiary of Stryker Corp.

Authorised Representative in Europe
RA/QA Manager, STRYKER® France
BP 50040 – 95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

REF 6630 – 0 – 010 STERILE R Cast Vitallium® Alloy LOT **C1212 SAMPLE**

DURACON® Totale knæ PERLEKÆDEAGTIGT fem. kompon. XX-SMALL VENSTRE	DURACON® totale knie femurdeel MET RAND EXTRA EXTRA KLEIN, LINKS
Compon. femoral SINTERIZADO p/Joelho Total DURACON® XX-PEQUENO ESQUERDO	
DURACON® Totaalipolvi UURRETTU Reisiluuosa XX-PIENI VASEN	

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002 – 01 Made in Ireland **2** **2007 – 01** U.S. Pat. 4,550,448; 4,834,756, 5,192,324&5,441,537

+E025663000101-

+$C1212SAMPLE-$

REF 6630 – 0 – 010

DURACON® TOTAL KNEE
BEADED Femoral Component
XX-SMALL LEFT

Système total du genou DURACON®
Composant fémoral microbille
XX-petit, gauche

DURACON® Totalkniesystem
Femurkomponente mit Kugel-
beschichtung, XX-klein, Links

LOT **C1212 SAMPLE** **2007 – 01**

REF 6630 – 0 – 010

LOT **C1212 SAMPLE**

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Howmedica OSTEONICS

CE 0473

Howmedica Osteonics Corp
300 Commerce Court
Mahwah, NJ 07430 USA
A Subsidiary of Stryker Corp.

Authorised Representative in Europe
RA/QA Manager, STRYKER® France
BP 50040 – 95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

REF 6632 – 0 – 210 STERILE R Vitallium® Alloy LOT **D6212 SAMPLE**

DURACON® Totale knæ Modulær fem. kompon. PORØST VENSTRE SMALL	DURACON® totale knie modulair femurdeel POREUS LINKS, KLEIN
Comp. Fem. Modular POROSO p/Joelho Total DURACON ESQUERDO PEQUENO	
DURACON® Totaalipolvi Modul. reisiluucsa HUOKOINEN VASEN PIENI	

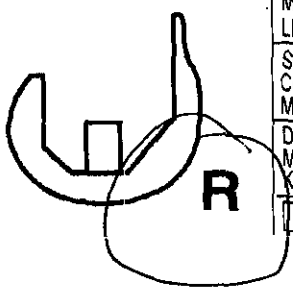
Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2003 – 06 Made in Ireland 2 2008 – 06 U.S. Pat. 4,550,448; 4,834,756&5,192,324

+E025663202101/

+$D6212SAMPLE/6

REF 6632 – 0 – 210



DURACON® TOTAL KNEE
MODULAR Fem. Compon. POROUS
LEFT SMALL

Système de genou DURACON®
Composant fémoral modulaire
Microbillé, gauche, petit

DURACON® Totalkniesystem
Modular Femur-Komp., zementfrei
Klein, Links

LOT **D6212 SAMPLE** 2008 – 06

REF 6632 – 0 – 210

LOT **D6212 SAMPLE**

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

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Catalog No. **6642-1-009**

DURACON® TOTAL KNEE

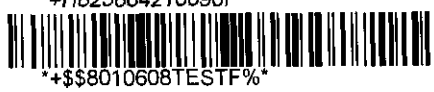
A

Condylar Tibial Insert

- DURATION®
- X-Small
- 9mm Thick

HOWMEDICA OSTEONICS CORP.
Stryker Ireland
Carrigtwohill Industrial Estate,
Carrigtwohill,
Co. Cork,
Ireland

+H825664210090F



+$$8010608TESTF%

Authorized representative in Europe
RA/QA Manager
STRYKER France
BP 50040-95946 Roissy CDG Cedex
FRANCE
Tel.(33) 1.48.17.50.00

2008-06

UHMWPE

STERILE R ⚠ CE0473 ⊗

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

RECORD / REORDER

HOW / OST # **6642-1-009**
DURACON® *Total Knee Condylar*
Tibial Insert 9mm A

CASE CODE: TEST

ID#:

SAMPLE

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

Catalog No. **6642-1-509**

DURACON® TOTAL KNEE

A-P Lipped Tibial Insert

A

- DURATION®
- X-Small
- 9mm Thick

HOWMEDICA OSTEONICS CORP.
Stryker Ireland
Carrigtwohill Industrial Estate,
Carrigtwohill,
Co. Cork,
Ireland

+H825664215090K

+$$8010608TESTK4

Authorized representative in Europe
RA/QA Manager
STRYKER France
BP 50040-95946 Roissy CDG Cedex
FRANCE
Tel.(33) 1.48.17.50.00

2008-06

UHMWPE

STERILE R ⚠ CE0473 ⊗

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

RECORD / REORDER

HOW / OST # **6642-1-509**
DURACON® Total Knee A-P
Lipped Tibial Insert 9mm A

CASE CODE: TEST

ID#: SAMPLE

104

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

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Howmedica Osteonics Corp
300 Commerce Court
Mahwah, NJ 07430 USA
A Subsidiary of Stryker Corp.

Authorised Representative in Europe
RA/QA Manager, STRYKER® France
BP 50040 – 95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

REF 6742 – 4 – 009 STERILE R | Duration® Stabilized UHMWPE | LOT D6212 SAMPLE

DURACON® Totale knæ CS Tibialt indlæg m. udbuet kant Extra Small 9mm	DURACON® Total Knie CS Gelipt Tibia-inzetstuk Extraklein 9mm
DURACON® CS p/Joelho Total Insert Tibial c/Rebordo Extra-pequeno, 9 mm	
DURACON® Totaali polvi CS Reunallinen sääriluun sisäke Erittäin pieni 9mm	

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

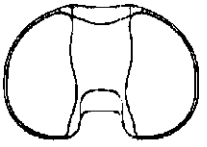
2003 – 06 | 2 | 2008 – 06 | U.S. Pat. 6,372,814 6,174,934; 5,728,748 & 5,543,471

Made in Ireland

+E0256742400919

+$D6212SAMPLE9I

REF 6742 – 4 – 009



DURACON® Total Knee
CS Lipped Tibial Insert
Extra Small 9mm

P.lot.gen.DURACON®
Insert tibial CS contraint
Extra petit 9mm

DURACON® Totalknie
CS Tibia-Einsatz mit Lippe
Extraklein, 9 mm

LOT D6212 SAMPLE | 2008 – 06

REF 6742 – 4 – 009

LOT D6212 SAMPLE

105

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

Howmedica OSTEONICS

CE 0473

Howmedica Osteonics Corp
300 Commerce Court
Mahwah, NJ 07430 USA
A Subsidiary of Stryker Corp.

Authorised Representative in Europe
RA/QA Manager, STRYKER® France
BP 50040 – 95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

REF 6632 – 3 – 301 STERILE R | Cast Vitallium® Alloy | LOT **D6212 SAMPLE**

XS-1 DURACON® Totale knæ Korsdannet tibial bundplade SINTRET	XS-1 DURACON® totale knie kruisvormige tibiabasisplaat MET RAND
Placa de base tibial cruciforme P/JOELHO TOTAL DURACON® XP-1, SINTERIZADA	
XS-1 DURACON® Tot. polvi Sääriluun ristikkoalusievy UURRETTU	

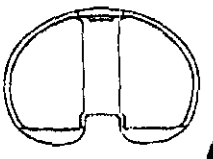
Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2003 – 06 Made in Ireland | 2 | 2008 – 06 | U.S. PAT. 4,550,448; 4,834,756; 5,192,324 & 5,441,537

+E0256632330111

+$D6212SAMPLE1A

REF 6632 – 3 – 301



A

XS-1 DURACON® TOTAL KNEE
Cruciform Tibial Baseplate
BEADED

Système total du genou DURACON®
Embase tibiale cruciforme
X-petit-1, microbillé

DURACON® Totalkniesystem
Kreuzschaft Tibiabasisplatte
kugelbeschichtet, XS1,

LOT **D6212 SAMPLE** | 2008 – 06

REF 6632 – 3 – 301

LOT **D6212 SAMPLE**

This Tibial Baseplate is NOT compatible with 6630 – Series Tibial Inserts.

Cette embase tibiale n'est PAS compatible avec les inserts tibiaux de série 6630.

Diese Tibiabasisplatte ist NICHT mit den Tibiaeinsätzen des Katalognummernkreises 6630 kompatibel.

Estaplaca base tibial NO es compatible con los insertos tibiales de la serie 6630.

La presente base tibiale NON é compatibile con gli inserti tibiali di serie 6630.

Denna tibiala basplatta kan EJ användas tillsammans med tibiala insatser ur 6630 – serie

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

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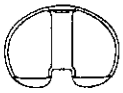
Howmedica

REF 6632-3-715



G

HOWMEDICA® UNIVERSAL™
TIBIAL BASEPLATE BEADED
MEDIUM-1 72mm M/L 48mm A/P

HOWMEDICA® UNIVERSAL™
Embase tibiale microbillée
Moyen-1 72mm M/L 48mm A/P

HOWMEDICA® UNIVERSAL™
Tibiabasisplatte, zementfrei
M1, 72mm M/L 48mm A/P

LOT SAMPLE
SAMPLE

2008-05

Howmedica Osteonics Corp.
300 Commerce Court Mahwah, New Jersey 07430
A Subsidiary of Stryker Corp.

CE 0473

Authorized Representative in Europe:
RA/QA Manager Stryker France
BP 50040-95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

LOT SAMPLE
SAMPLE

REF 6632-3-715 STERILE R Cast Vitallium® Alloy

HOWMEDICA® UNIVERSAL™ TIBIAL BASEPLATE BEADED MEDIUM-1 72mm M/L 48mm A/P	HOWMEDICA® UNIVERSAL™ BASE TIBIALE MADREPORICA MEDIO-1 72mm M/L 48mm A/P
HOWMEDICA® UNIVERSAL™ Embase tibiale microbillée Moyen-1 72mm M/L 48mm A/P	HOWMEDICA® UNIVERSAL™ Base Tibial Porosa A/P Med.1 72mm M/L 48mm
HOWMEDICA® UNIVERSAL™ Tibiabasisplatte, zementfrei M1, 72mm M/L 48mm A/P	Howmedica® Universal™ Tibiabasplatta porösbelagd Medel-1 72mm m/l 48mm A/P

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

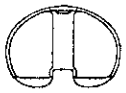
2003-05 2008-05 U.S. Pat. 4,550,448; 5,192,324 & 4,834,756
Made in: USA

+H825663237151L

+$D5DE SAMPLE L-

Howmedica

REF 6632-3-715



G

HOWMEDICA® UNIVERSAL™
BASE TIBIALE MADREPORICA
MEDIO-1 72mm M/L 48mm A/P

HOWMEDICA® UNIVERSAL™
Base Tibial Porosa A/P
Med.1 72mm M/L 48mm

Howmedica® Universal™
Tibiabasplatta porösbelagd
Medel-1 72mm m/l 48mm A/P

LOT SAMPLE
SAMPLE

2008-05

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CE 0473

Authorized Representative in Europe:
RA/QA Manager Stryker France
BP 50040-95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

LOT SAMPLE
SAMPLE

REF 6632-3-715 STERILE R Cast Vitallium® Alloy

HOWMEDICA® UNIVERSAL™ TIBIAL BASEPLATE BEADED MEDIUM-1 72mm M/L 48mm A/P	HOWMEDICA® UNIVERSAL™ BASE TIBIALE MADREPORICA MEDIO-1 72mm M/L 48mm A/P
HOWMEDICA® UNIVERSAL™ Embase tibiale microbillée Moyen-1 72mm M/L 48mm A/P	HOWMEDICA® UNIVERSAL™ Base Tibial Porosa A/P Med.1 72mm M/L 48mm
HOWMEDICA® UNIVERSAL™ Tibiabasisplatte, zementfrei M1, 72mm M/L 48mm A/P	Howmedica® Universal™ Tibiabasplatta porösbelagd Medel-1 72mm m/l 48mm A/P

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital

2003-05 2008-05 U.S. Pat. 4,550,448; 5,192,324 & 4,834,756
Made in: USA

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

107
139

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Howmedica

REF 6642-2-705

S

DURACON® TOTAL KNEE SYSTEM
CONVERSION PATELLA MEDIUM
DURATION® METALBACKED

Système total genou Duracon®
Conversion rotule, moyenne
Plaquette dos métal Duration®

Duracon® Kompl. Kniesystem
Übergangspatella, mittelgroß
Duration® m/Metallrücks

LOT SAMPLE SAMPLE

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300 Commerce Court Mahwah, New Jersey 07430
A Subsidiary of Stryker Corp.

CE 0473

Authorized Representative in Europe:
RA/QA Manager Stryker France
BP 50040-95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

LOT SAMPLE SAMPLE

REF 6642-2-705 STERILE R Vitallium® Alloy and Dur. Stabil. UHMWPE

DURACON® TOTAL KNEE SYSTEM CONVERSION PATELLA MEDIUM DURATION® METALBACKED	Sistema total ginocchio Duracon® Conversione patella media Lastra rinforz metallo Duration®
Système total genou Duracon® Conversion rotule, moyenne Plaquette dos métal Duration®	Sist total de rodilla Duracon® Conversión rótula mediana c/ref. met. Duration®
Duracon® Kompl. Kniesystem Übergangspatella, mittelgroß Duration® m/Metallrücks	Duracon® Total Knee-system Omvandlingspatella medel Duration® metallbaksida

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2003-05 2008-05 U.S. Pat.
Made in USA

+H825664227051K

+$D5DE SAMPLE KZ

Howmedica

REF 6642-2-705

S

Sistema total ginocchio Duracon®
Conversione patella media
Lastra rinforz metallo Duration®

Sist total de rodilla Duracon®
Conversión rótula mediana
c/ref. met. Duration®

Duracon® Total Knee-system
Omvandlingspatella medel
Duration® metallbaksida

LOT SAMPLE SAMPLE

2008-05

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300 Commerce Court Mahwah, New Jersey 07430
A Subsidiary of Stryker Corp.

CE 0473

Authorized Representative in Europe:
RA/QA Manager Stryker France
BP 50040-95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

LOT SAMPLE SAMPLE

REF 6642-2-705 STERILE R Vitallium® Alloy and Dur. Stabil. UHMWPE

DURACON® TOTAL KNEE SYSTEM CONVERSION PATELLA MEDIUM DURATION® METALBACKED	Sistema total ginocchio Duracon® Conversione patella media Lastra rinforz metallo Duration®
Système total genou Duracon® Conversion rotule, moyenne Plaquette dos métal Duration®	Sist total de rodilla Duracon® Conversión rótula mediana c/ref. met. Duration®
Duracon® Kompl. Kniesystem Übergangspatella, mittelgroß Duration® m/Metallrücks	Duracon® Total Knee-system Omvandlingspatella medel Duration® metallbaksida

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital

2003-05 2008-05 U.S. Pat.
Made in USA

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Label 1 of 1 REF 6642-2-705 LOT SAMPLE SAMPLE

108
140

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stryker
Howmedica
OSTEONICS

Total Knee Joint Replacement Prostheses ~~For Cement Applications~~

Howmedica Osteonics Corp.
359 Veterans Boulevard
Rutherford, NJ USA 07070
A Subsidiary of Stryker Corp.

Howmedica Osteonics Corp.
300 Commerce Court
Mahwah, NJ 07430
A Subsidiary of Stryker Corp.

Howmedica Osteonics Corp.
Stryker Ireland
Carrigtwohill Industrial Estate
County Cork
Ireland

Authorized Representative in Europe:
RA/QA Manager Stryker France
BP 50040-95946 Roissy CDG Cedex
FRANCE Tel (33) 1.48.17.50.00

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0095-3-201J

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TOTAL KNEE JOINT REPLACEMENT
PROSTHESES ~~FOR CEMENT APPLICATIONS~~

PROTHESES A CIMENTER POUR
ARTHROPLASTIES TOTALES DU GENOU

KNIEGELENKTOTALENDOPROTHESEN
FÜR ZEMENTIERTE ANWENDUNGEN

PROTESI TOTALI RICOSTRUTTIVE DI
GINOCCHIO CON USO DI CEMENTO

SUSTITUCIÓN TOTAL DE LA ARTICULACIÓN DE LA RODILLA
PRÓTESIS PARA APLICACIONES CEMENTADAS

SUBSTITUIÇÃO TOTAL DE ARTICULAÇÃO DO JOELHO
PRÓTESE PARA APLICAÇÕES CIMENTADAS

TOTAL KNÄLEDSPLASTIK
PROTES FÖR CEMENTERAD APPLIKATION

KOKOPOLVINIVELPROTEESI
SEMENTILLISIÄ SOVELLUKSIA VARTEN

FULDSTÆNDIG KNÆLEDS SUBSTITUTIONS
PROTESE TIL CEMENT APPLIKATIONER

VOLLEDIGE KNIEGEWRICHTVERVANGINGI
PROTHESE VOOR CEMENTTOEPASSINGEN

ΟΛΙΚΗ ΑΝΤΙΚΑΤΑΣΤΑΣΗ ΓΟΝΑΤΟΥ
ΠΡΟΘΕΣΕΙΣ ΓΙΑ ΕΦΑΡΜΟΓΕΣ ΜΕ ΤΣΙΜΕΝΤΟ

人工膝関節全置換術
セメント使用人工関節

English
PACKAGE INSERT
ATTENTION OPERATING SURGEON

The advancement of total knee replacement has provided the surgeon with a means of restoring mobility, correcting deformity, and reducing pain with the use of implanted prosthetic devices. These devices, while proven successful, are manufactured from metal and plastic materials. No prosthetic device can therefore be expected to withstand activity levels and loads in the same way as would a normal healthy joint. The prosthetic system, therefore, will not be as strong, reliable, or durable as a natural human knee joint.

In using total knee joint implants, the surgeon should be aware of the following:

A. **The correct selection and positioning of the implant is extremely important.** Success in total joint replacement requires the selection of the proper size, shape, and designed implants. Total joint prostheses require careful seating, rigid fixation and adequate bone support.

B. **In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:**

1) **The patient's weight.** An overweight or obese patient can produce higher loads on the prosthesis which can lead to failure of the device. The effect of these loads will be accentuated when a small sized prosthesis must be used because of bone size in such patients.

2) **The patient's occupation or activity.** If the patient is involved in an occupation or activity which includes significant impact loads (walking, running, lifting or twisting), the resultant forces can cause failure of the fixation, the device, or both. High levels of physical activities over the course of years can also accentuate the normal wear that occurs with prosthetic joints. The prosthesis will not restore function to the level expected with a normal healthy joint, and the patient should not have, and should be disabused of, unrealistic functional expectations. (See **PRECAUTIONS** section for more information.)

3) **A condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

4) **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

5) **Orthopaedic history.** The prognosis for success of the procedure is dependent upon the patient's orthopaedic history. Patients who have had multiple previous procedures and/or implants should be carefully counseled regarding the anticipated outcome of the procedure.

6) **Quality of bone.** Survivorship of the total knee replacement may be affected by weakened bone stock, which may be the result of certain systemic or metabolic diseases such as those treated with steroids, immunosuppressants or chemotherapeutics.

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DESCRIPTION

Howmedica manufactures a wide variety of tricompartment reconstructive knee systems in various sizes and styles to accommodate various patient and surgeon requirements for primary and revision ~~cemented~~ applications. The selection of the prosthesis system is dependent upon the type of surgery required. Femoral, tibial and patellar components
are available for knee reconstruction. The metallic components (the femoral component, tibial and patellar baseplates, sintered beads, wedges and spacers) are manufactured from cast cobalt-chromium-molybdenum alloy (Vitallium® Alloy) conforming to ASTM standard F75. The screws and stem extenders are manufactured from wrought cobalt-chromium-molybdenum alloy (Vitallium® Alloy) conforming to ASTM standard F1537.
The polyethylene components are manufactured from ultra-high-molecular-weight polyethylene (UHMWPE) conforming to ASTM standard F648.

Femoral Components

Femoral components (except superstabilizer) are available with porous and non-porous coated options, condylar, stabilizer and superstabilizer configurations. Certain femoral components can be converted from one configuration to another, e.g., condylar to stabilizer, by the addition of a modular stabilizer box.

Tibial Components

The tibial components are available in a wide range of sizes and thicknesses. Tibial components include one piece all-polyethylene and modular styles consisting of a polyethylene insert and metallic baseplate. The baseplates are available with porous and non-porous coating options and adjunct fixation options. The inserts are available with varying degrees of constraint in the condylar styles, stabilizer and superstabilizer configurations.

Patellar Components

The patellar components are available in all-polyethylene or metal-backed with porous coating.

Accessories

Stem extenders are designed to attach to the stem of the femoral or tibial component to provide additional stability. Wedges are designed for cemented applications to provide additional spacing where there are tibial bone defects. Spacers are designed to provide additional spacing where there are femoral bone defects and may be mechanically secured to the femoral component or cemented in place. Screws are available for adjunct assembly of tibial inserts to baseplates or tibial baseplate to tibial bone.

Product label

The product label provides information regarding the specific material(s) from which the device is manufactured.

INDICATIONS

Indications for use of total knee replacement prostheses include:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
2) rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed;
5) post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
6) irreparable fracture of the knee.

CONTRAINDICATIONS

Absolute contraindications include:

1) overt infection;
2) distant foci of infections (which may cause hematogenous spread to the implant site);
3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4) skeletally immature patients;
5) cases where there is poor bone stock which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

1) uncooperative patient or patient with neurological disorders who is incapable of following instructions;
2) osteoporosis;
3) metabolic disorders which may impair bone formation;
4) osteomalacia; and,
5) previous arthrodesis.

A higher incidence of implant failure has also occurred in paraplegics, cerebral palsy and patients with Parkinson's disease.

WARNINGS

Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions and reduced service life of the prosthetic implant. The surgeon should be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

Cemented application. Care should be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Complete cleaning (complete removal of bone chips,

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bone cement fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surfaces of the implant.

Prosthetic components. Femoral, tibial and patellar components of different prosthetic systems, or from different manufacturers, should not be mixed, since tolerances or materials may be incompatible. Modular components must be assembled securely to prevent disassociation. Repeated assembly and disassembly of the modular components could compromise the critical locking action of the components and should be avoided. Surgical debris must be cleaned from components before assembly. Debris may interfere with the locking mechanism of modular components, which in turn may lead to early failure of the procedure.

Patella Component. Because the patella component has the smallest bearing and fixation surfaces, the patella or patella component is more vulnerable to subluxation and loosening/dislocation. Particular attention, during surgery, to patella tracking is necessary for success of the procedure.

Fixation screws. Fixation screws, when used, should be fully seated to maximize stable fixation, and to avoid interference with the proper seating of components. Use only screws recommended for the specific prosthesis to avoid improper fit, and to avoid improper mixing of metals. These bone screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Metal components. Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such a phenomenon, in spite of the millions of implants in use. (See reference 1.)

Alignment of components. Care should be taken to restore the proper joint alignment and to balance ligamentous tension. Misalignment of the limb or joint can cause excessive wear, loosening of the prosthesis and pain leading to earlier-than-desired revision of one or more of the prosthetic components.

Polyethylene wear. As would be expected, wear of the polyethylene surfaces of tibial and patella components has been reported following total knee replacement. Higher rates of wear may be initiated by particles of cement, metal or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear likely will shorten the useful life of the prosthesis, and lead to an earlier-than-desired revision to replace the worn prosthetic components.

PRECAUTIONS

Information for patients. The patient should be advised of the short and long term limitations of the procedure and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

The patient should be cautioned to limit activities, protect the replaced joint from unreasonable stresses and follow the instructions of the physician with respect to follow-up care and treatment.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device cannot and does not replicate a normal healthy joint, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device has a finite expected service life and may need to be replaced at some time in the future.

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have also been associated with transient bacteremia. To prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Instruments. Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components.

While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage, prior to surgery.

Re-use. An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.

Handling. Handling of implants is important, particularly porous coated implants. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials. All implants where the coating has been damaged or contaminated should be discarded. The highly polished portion of the implant should not come in contact with hard surfaces.

ADVERSE EFFECTS

1) With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around or remote from the prosthetic components as a consequence of foreign body reaction to particulate matter. Particulate matter is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondarily, particulate matter can also be generated by third-body wear. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. (See **IMPORTANT PHYSICIAN INFORMATION** section for more information.)
2) Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in cellular reactions that may include lymphocytes, macrophages and fibroblasts.
3) Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may be a result of surgical trauma.
4) Dislocation and subluxation of implant components can result from improper

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positioning and/or migration of the components. Soft tissue laxity including muscle, fibrous tissue and ligaments can also contribute to these conditions.

5) Implants can loosen or migrate due to trauma or loss of fixation.
6) Infection can lead to failure of the joint replacement.
7) While rare, fatigue fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment or extreme duration of service.
8) Soft tissue (ligamentous) imbalance can cause excessive wear and/or failure of the implant.
9) Intraoperative fracture of the femur, tibia or patella can occur while preparing the bone sites and/or seating of the implants.
10) Allergic reactions to the materials utilized in the implant, although uncommon, can occur.

Intraoperative and early postoperative complications can include, but are not limited to:

1) deep venous thrombosis;
2) damage to blood vessels;
3) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
4) a sudden drop in intraoperate blood pressure associated with the use of bone cement;
5) varus-valgus deformity with resultant limb/prosthesis malalignment;
6) cardiovascular disorders including, pulmonary embolism or myocardial infarction;
7) hematoma;
8) delayed wound healing;
9) deep wound infection (early or late), a potentially serious complication of all joint replacement which may necessitate removal of the prosthesis and subsequent arthrodesis. Appropriate antibiotic prophylaxis and strict adherence to aseptic procedures is mandatory; and,
10) femoral, tibial or patella bone or component fracture.

Late postoperative complications can include, but are not limited to:

1) late (or early) loosening, change in position of the components, wear, and bending or cracking of one or more prosthetic components. (Clinical experience suggests that particular attention to the items contained in the Warnings and Precautions sections of this package insert may help minimize the risk of their occurring.);
2) patellar fracture as a result of excess tension, or inadvertent intraoperative weakenin
3) aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy;
4) late ligamentous instability;
5) periarticular calcification or ossification, with or without impediment to joint mobility;
6) inadequate range of motion due to improper selection or positioning of components, impingement or periarticular calcification and dystrophy; and,
7) bone fractures, dislocation, subluxation, flexion contracture, decreased range of motion, or lengthening or shortening of the leg, all of which have been reported in association with total knee replacement.

IMPORTANT PHYSICIAN INFORMATION

A. **Bone Resorption and Osteolysis.** Bone resorption can occur as a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Localized progressive bone resorption due to reasons other than stress shielding or infection may occur around the prosthetic components as well as between the components and bone, and this has been termed osteolysis. It is generally agreed that osteolysis is a result of localized foreign-body reaction to particulate debris (e.g., cement, metal, UHMWPE, and ceramics), generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Regarding the etiology, it has been hypothesized that particulate debris generated by articulation of the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris as well as the rate of debris generation. The phagocytic action has been demonstrated in vitro to induce release of cytokines and cellular mediators (IL-1, IL-2, IL-6, PGE2, TNF3). These mediators have been shown to modulate osteoclastic bone resorption. Clinical and basic research is continuing in order to better understand the scientific basis for the causes of this phenomenon and explore potential ways to reduce its occurrence.

   Since osteolysis is frequently asymptomatic, routine periodic radiographic examination is vital to help detect and minimize any serious future complication. However, radiographs may not completely define the extent of osteolysis. Presence of focal lesions which are progressive may necessitate replacement of the prosthetic component(s).

B. **Polyethylene Thickness.** Theoretical analyses have indicated that contact stresses in the tibial component vary with the thickness of the polyethylene component. In general, thicker inserts are thought to have lower contact stresses than thinner ones. These stresses may affect the wear of the implant components; however, the clinical implications of the theoretical stress differences have not been conclusively established. The physician should consider the trade-off between additional tibial bone resection and the use of a thicker insert. Patient related factors, such as weight, age and activity level should be part of the decision.

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

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C. **Component Matching.** There are corresponding tibial widths designed to articulate and conform with the appropriately-sized femoral components. Failure to correctly match components could result in premature failure of the tibial component and contribute to joint laxity.

D. **Product Label.** See product label for information regarding the specific product referenced in this package insert.

HOW SUPPLIED

These products are delivered sterile in containers which have been exposed to a minimum of 25 kGy of gamma radiation from a cobalt 60 source. The package of all sterile products should be examined prior to use for possible breaks in the sterile barrier.

RESTERILIZATION

Devices containing POLYETHYLENE, POROUS COATING, PLASMA SPRAY, HYDROXYAPATITE, CERAMICS or METHYLMETHACRYLATE CANNOT BE AUTOCLAVED OR RESTERILIZED BY THE USER.

Components that have **not** been contaminated with fluids, in particular body fluids, can be resterilized using the following parameters in a gravity displacement steam autoclave:

	250° F (121° C) 20 PSI (1.4 Bars)	270° F (132° C) 30 PSI (2 Bars)
Wrapped individual Component (single or multi component) or Sterilization Case	40 minutes	20 minutes

The double wrapping method used is the AAMI CSR technique. These cycles were developed with only this item in the chamber and using the middle shelf. Any cycle should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

CAUTION

Federal Law in the USA restricts this device to sale by or on the order of a physician.

REFERENCES

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study In Sweden," Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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

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stryker
Howmedica
OSTEONICS

CE 0473

Duracon® CS Lipped Tibial Insert

Howmedica Osteonics Corp.
300 Commerce Court
Mahwah, New Jersey
A Subsidiary of Stryker Corporation

Authorized Representative in Europe:
RA/QA Manager STRYKER France
BP 50040-95946 Roissy CDG Cedex
France Tel. (33) 1.48.17.50.00

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Duracon® CS Lipped Tibial Insert

The Duracon® CS (Condylar Stabilizing) Lipped Tibial Inserts are intended to be used with Duracon® Universal and Cruciform tibial baseplates, Duracon® Cruciate Retaining femoral components and Duracon® patellar components as part of a total knee system in primary cemented total knee arthroplasty. These inserts are intended to be used in cases where there is destruction of the joint surfaces with or without bone deformity, where the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The collateral ligaments should be intact if this insert is utilized. This tibial insert may also be used in situations where the posterior cruciate ligament is present - its geometry will accommodate that ligament.

Materials

ASTM F-648 ultra-high molecular weight polyethylene (UHMWPE)	Tibial insert

Indications

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee

Contraindications

Absolute contraindications include:

- Overt infection,
- Distant foci of infections (which may cause hematogenous spread to the implant site),

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- Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram,
- Skeletally immature patients
- Cases where there is poor bone stock which would make the procedure unjustifiable,

Conditions presenting an increased risk of failure include:

- Uncooperative patient or patient with neurological disorders who is incapable of following instructions,
- Osteoporosis,
- Metabolic disorders which may impair bone formation,
- Osteomalacia, and
- Previous arthrodesis

Sterilization

- This total knee component has been sterilized by gamma radiation.
- If the package is opened, but the product is not used, the component **must not be resterilized** and must be discarded or returned to the supplier.

CAUTION: This device is intended for single use only. The sale or use of this device is restricted to a licensed physician.

~~This product is marketed in the United States for use with bone cement.~~

Please refer to Total Knee Package Insert for general warnings and precautions.

Insert tibial contraint à stabilisation condylienne Duracon®

Les inserts tibiaux contraints Duracon® CS (à stabilisation condylienne) doivent être utilisés avec les embases tibiales cruciformes et Universal Duracon®, avec les composants fémoraux Duracon® conservant le ligament croisé et avec les composants rotuliens Duracon® en tant que partie intégrante d'une prothèse totale du genou lors d'une arthroplastie totale du genou primaire par prothèse cimentée. Ces inserts doivent être utilisés en cas de destruction des surfaces articulaires avec ou sans déformation osseuse, lorsque les ligaments croisés sont déficients, absents ou ne peuvent être conservés pendant l'intervention chirurgicale, en particulier lorsque la stabilité antéro-postérieure est affectée en raison d'une rotule absente. Cet insert exige que les ligaments latéraux soient intacts. Il peut également être utilisé lorsque le ligament croisé postérieur est présent car sa géométrie est adaptée à ce ligament.

Matériaux	Insert tibial
Polyéthylène de masse moléculaire très élevée ASTM F-648 (UHMWPE)	

Indications

- Arthrose non-inflammatoire y compris la gonarthrose, l'arthrite due à un traumatisme ou la nécrose avasculaire,
- Polyarthrite rhumatoïde,
- Correction de la déformation fonctionnelle,
- Perte de l'anatomie articulaire à la suite d'un traumatisme, en particulier lors d'une érosion fémoro-rotulienne, un dysfonctionnement ou une patellectomie préalable,
- Fracture irréparable du genou

Contre-indications

Parmi les contre-indications absolues, on note :

- Une infection manifeste,
- Des foyers distants d'infections (qui peuvent causer une propagation hématogène au site de l'implant),

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IMPORTANT INFORMATION FOR THE OR STAFF
READ BEFORE OPENING STERILE PACKAGE

INFORMATIONS IMPORTANTES POUR LE PERSONNEL DE SALLE D'OPÉRATION
LIRE AVANT D'OUVRIR LE CONDITIONNEMENT STÉRILE

WICHTIGE INFORMATION FÜR DAS OP PERSONAL
VOR DEM ÖFFNEN DER STERILEN PACKUNG LESEN

INFORMAZIONE IMPORTANTE PER IL PERSONALE DI SALA OPERATORIA
LEGGERE PRIMA DI APRIRE LA CONFEZIONE STERILE

INFORMACION IMPORTANTE PARA EL PERSONAL DEL QUIROFANO
LEER ANTES DE ABRIR EL ENVASE ESTERIL

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Howmedica International S. de R.L.
Raheen Business Park
Limerick, Ireland.

Distributed in the United States by

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Revised November, 1999

0090-6-207

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IMPORTANT INFORMATION FOR THE OR STAFF

READ BEFORE OPENING STERILE PACKAGE

The process employed to create Duration™ Stabilized UHMWPE requires the use of ***very high strength seals on the inner package. As a result, the blister packages, particularly the inner package, will require significantly greater force to peel open*** than you may be accustomed to.

Please follow these instructions to facilitate opening of Duration™ Stabilized UHMWPE sterile packages.

To open the OUTER BLISTER

With **dry** hands/gloves:

1. Grip the bottom of the blister very firmly.
2. Grip the lid's thumb tab securely.
3. Exerting firm and steady force, slowly pull back the tab to remove the lid.

To open the INNER BLISTER

With **dry** gloves:

4. Grip the protruding corner of the blister flange firmly with one hand. (Figure 1)
5. Peel the lid's thumb tab with the other hand (as if opening a peel pouch). (Figure 2)

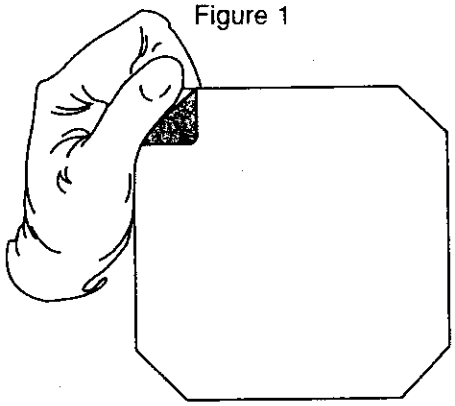
Figure 1

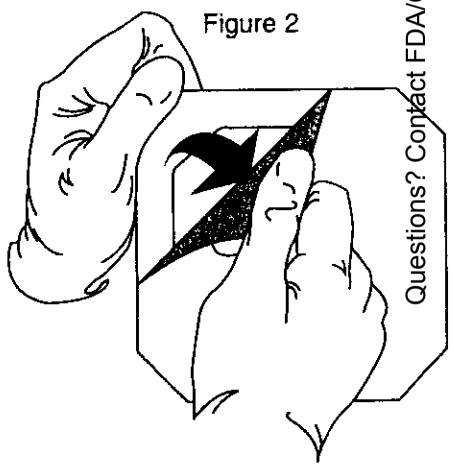
Figure 2

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APPENDIX C

TECHNICAL REPORTS

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(b)(4)

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(b)(4)

TEST DATA

(b)(4)

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APPENDIX I
METALLURGICAL ANALYSIS OF THE PCA® COATING AND THE SUBSTRATE MATERIALS [redacted])

B(4)
Test

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Designation: F 799 – 87

Standard Specification for Thermomechanically Processed Cobalt-Chromium-Molybdenum Alloy for Surgical Implants[1]

This standard is issued under the fixed designation F 799; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the material requirements of high-strength, thermomechanically processed, cobalt-chromium-molybdenum alloys used for surgical implants. Material conforming to this specification has been evaluated for biocompatibility and corrosion resistance[2] and has been found to be comparable to material conforming to Specification F 75. The properties specified in this document specifically apply to finished or semifinished parts that receive no subsequent metallurgical processing.

1.2 The values stated in inch-pound units are to be regarded as the standard. The metric equivalents of the inch-pound units may be approximate.

2. Referenced Documents

ASTM Standards:

, Methods of Tension Testing of Metallic Materials[3]

" 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[3]

E 112 Test Methods for Determining the Average Grain Size[3]

E 354 Methods for Chemical Analysis of High Temperature, Electrical, Magnetic and Other Similar Iron, Nickel and Cobalt Alloys[4]

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[5]

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[5]

2.2 *Aerospace Material Specifications:*[6]

AMS 2269C Chemical Check Analysis Limits, Wrought Nickel Alloy and Cobalt Alloys

AMS 2248B Chemical Check Analysis Limits, Wrought Heat, and Corrosion-Resistant Steels and Alloys

2.3 *American Society for Quality Control Standard:*[7]

ASQC C1-1968 Specification of General Requirements for a Quality Program

3. Significance and Use

3.1 The purpose of this specification is to characterize the material properties of currently available cobalt-chromium-molybdenum implant parts manufactured by processes other than conventional casting techniques.

4. Ordering Information

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

4.1.1 Quantity,
4.1.2 ASTM designation and date of issue,
4.1.3 Mechanical properties,
4.1.4 Form (semifinished parts, part No.),
4.1.5 Applicable dimensions or print number,
4.1.6 Condition (as hipped, forged, heat treated, annealed),
4.1.7 Special tests, and
4.1.8 Other requirements.

5. Condition

5.1 Finished or semifinished parts conforming to this specification may be prepared by a variety of methods including powder consolidation and forging; and may be in a heat-treated, hot-worked or annealed condition.

6. Chemical Requirements

6.1 The cobalt-chromium-molybdenum alloy supplied to the manufacturer for the production of surgical implants shall conform to the chemical composition limits specified in Table 1. The product analysis tolerances shall conform to the requirements in Table 2.

TABLE 1 Chemical Requirements

	Composition, %	
	min	max
Chromium	26.0	30.0
Molybdenum	5	7
Nickel	—	1.0
Iron	—	0.75
Carbon	—	0.35
Silicon	—	1.0
Manganese	—	1.0
Nitrogen	—	0.25[A]
Cobalt[B]	balance	

[A] If N < 0.10, content does not have to be reported.

[B] Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage of cobalt by difference is not required to be reported.

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved Sept. 25, 1987. Published November 1987. Originally published as F 799 – 82. Last previous edition F 799 – 82.

[2] Supporting data are available on loan from ASTM Headquarters, 1916 Race St., Philadelphia, PA 19103. Request Research Report RR: F04 - 0000.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] *Annual Book of ASTM Standards*, Vol 03.05.

[5] *Annual Book of ASTM Standards*, Vol 13.01.

[6] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

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

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

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TABLE 2 Product Analysis Tolerances[A]

Element	Permissible Variation Under the Minimum Limit or Over the Maximum Limit, %[B]
Chromium	0.30
Molybdenum	0.15
Nickel	0.05
Iron	0.03
Carbon	0.02
Silicon	0.05
Manganese	0.03
Nitrogen[C]	0.02

[A] Refer to AMS Standard 2269C for Chemical Check Analysis Limits (except nitrogen).

[B] For elements where only a maximum percentage is indicated, the "under minimum limit" is not applicable.

[C] Refer to AMS 2248B.

TABLE 3 Mechanical Requirements

Ultimate Tensile Strength, min, psi, (MPa)	Yield Strength (0.2 % offset), min, psi (MPa)	Elongation,[A] min, %	Reduction in Area, min, %	Hardness, R_c, min
170 000 (1172)	120 000 (827)	12	12	35

[A] Gage length = 4 × diameter.

7. Mechanical Requirements

7.1 *Tensile Properties:*

7.1.1 Tensile properties shall be determined in accordance with Methods E 8.

7.1.2 The mechanical properties of test specimens prepared from finished or semifinished parts shall conform to the requirements in Table 3.

7.1.3 Tension specimens shall be produced from finished or semifinished parts or from material having the same process history as that which exists in the final su implant device. Tension specimens may have a ground fi on the reduced section and may be taken in a direc parallel to the long axis of the finished or semifinished p

7.1.4 A minimum of two test specimens shall be teste one specimen falls below the specified tensile requirem or breaks outside the gage limits, two additional specim shall be tested and both must pass.

7.2 *Hardness*—Finished or semifinished parts conform to this specification shall have a minimum Rockwell C ha ness of 35 HRC. The hardness determination shall be formed in accordance with Methods E 18.

8. Special Tests

8.1 Finished or semifinished parts conforming to specification shall have a homogeneous microstructure a grain size of ASTM No. 5 or finer when measured accordance with Test Methods E 112.

9. Certification

9.1 A certification shall be provided by the alloy produ that the material meets the requirements in Table 1.

10. Quality Program Requirements

10.1 The alloy producer and any processors shall ma tain a quality program such as, for example, is defined ASQC C1-1968.

10.2 The manufacturer of surgical implants or medic devices shall be assured of the producer's quality program conformance to the intent of ASQC C1-1968 or oth recognized programs.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose for this standard is to characterize composition and properties to assure consistency in thermomechanically processed cobalt-chromium-molybdenum finished or semifinished parts used in the manufacturing of medical devices that receive no subsequent metallurgical processing.

X1.2 Material conforming to this specification has been evaluated for biocompatibility and corrosion resistance and has been found to be identical to material conforming to Specification F 75. Materials conforming to Specification F 75 have been used as a control in Practice F 981.

X1.3 Published data[8,9] indicate that material with fine-grained homogeneous metallurgical structure resultin from thermomechanical processing will be superior wit respect to tensile strength and fatigue resistance compared t material conforming to Specification F 75. Based upon thi requirements include fine-grained microstructure and hig tensile strength.

X1.4 The maximum iron content has been lowered t coincide with compositions that are commercially availabl

[8] Bardos, D. I., "High Strength Co-Cr-Mo Alloy for Prostheses," *Curr Concepts of Internal Fixation of Fractures*, edited by H. Uhthoff, Springer Ver New York, NY, 1980, p 111.

[9] Weisman, S., "Vitallium FHS Forged High-Strength Alloy," *Current Conc of Internal Fixation of Fractures*, p 118.

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

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

Designation: F 75 – 87

Standard Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[1]

This standard is issued under the fixed designation F 75; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the requirements for cast cobalt-chromium-molybdenum alloy, shot, bar, or ingot for surgical implant applications.

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

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Test Methods of Tension Testing of Metallic Materials[2]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[2]

E 354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[3]

F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[4]

2.2 *Aerospace Material Specification:*

AMS 2269C Chemical Check Analysis Limits, Wrought Nickel Alloy and Cobalt Alloys[5]

2.3 *American Society for Quality Control Standard:*

ASQC Cl-1968 General Requirements for a Quality Program[6]

3. Ordering Information

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

3.1.1 Quantity (weight),

3.1.2 ASTM designation,

3.1.3 Mechanical properties (if applicable),

3.1.4 Form (shot, bar, ingot),

3.1.5 Applicable dimensions or print number,

3.1.6 Condition,

3.1.7 Special tests, and

3.1.8 Other requirements.

4. Chemical Requirements

4.1 The heat analysis shall conform to the requirements as to chemical composition prescribed in Table 1. The product analysis tolerances shall conform to the requirements prescribed in Table 2.

4.2 For referee purposes, Test Methods E 354 shall be used.

5. Mechanical Requirements

5.1 *Tensile Properties:*

5.1.1 Tensile properties shall be determined in accordance with Test Methods E 8.

5.1.2 Tension specimens shall be melted and cast from the metal under test by the same general procedure used in casting surgical implants and shall be in accordance with the ¼-in. (6.35-mm) diameter specimen in Fig. 8 of Methods E 8 which

TABLE 1 Chemical Requirements

Element	Composition, %	
	min	max
Chromium	27.0	30.00
Molybdenum	5.0	7.00
Nickel	...	1.00
Iron	...	0.75
Carbon	...	0.35
Silicon	...	1.00
Manganese	...	1.00
Cobalt	balance	balance

TABLE 2 Product Analysis Tolerances[A]

Element	Tolerance Under the Minimum Limit or Over the Maximum Limit[B]
Chromium	0.30
Molybdenum	0.15
Nickel	0.05
Iron	0.03
Carbon	0.02
Silicon	0.05
Manganese	0.03

[A] Refer to AMS Standard 2269C for Chemical Check Analysis Limits.

[B] For elements where only a maximum percentage is indicated, the "under minimum limit" is not applicable.

TABLE 3 As-Cast Mechanical Property Requirements

Property	
Tensile strength, min, psi (MPa)	95 000 (655)
Yield strength (0.2 % offset), min, psi (MPa)	65 000 (450)
Elongation, min, %	8
Reduction of area, min, %	8

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[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices, and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved Sept. 25, 1987. Published November 1987. Originally published as F 75 – 67. Last previous edition F 75 – 82.

[2] *Annual Book of ASTM Standards*, Vol 03.01.

[3] *Annual Book of ASTM Standards*, Vol 03.05.

[4] *Annual Book of ASTM Standards*, Vol 13.01.

[5] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

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

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ay have a ground finish on the reduced section.

5.1.3 A minimum of two test specimens shall be tested. If one specimen falls below the specified tensile requirements or breaks outside the gage limits, two additional specimens shall be tested and both must pass.

5.1.4 The material shall conform to the requirements as to mechanical property prescribed in Table 3.

5.2 *Hardness:*

5.2.1 Material conforming to this specification typically will have Rockwell C-Scale hardness of 25 to 35 HRC as in the as-cast condition. The hardness determination shall be performed in accordance with Methods E 18.

5.2.2 Hardness values are for guidelines only, and shall not be used as a criteria for rejection.

6. Certification

6.1 A certification shall be provided by the manufacturer of the material that the material was manufactured and tested in accordance with this specification. A report of the test results shall be furnished at the time of shipment.

7. Quality Program Requirements

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

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

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this standard is to characterize composition and properties to assure consistency in the starting material used in the manufacturing of orthopedic implants.

X1.2 The material has been shown to produce a well characterized level of local biological response following long term clinical use and has been used as controlled material in Recommended Practice F 361.

X1.3 Upper composition limits for nickel have been decreased to realistic limits practiced by industry.

X1.4 The upper limit for the hardness has been increased to realistic limits for the material having chemical composition on the upper side of the limit.

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

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

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APPENDIX II
COATING THICKNESS

CONFIDENTIAL

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Appendix A
ASTM STANDARD F1160

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

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Standard Test Method for Constant Stress Amplitude Fatigue Testing of Porous Metal-Coated Metallic Materials[1]

This standard is issued under the fixed designation F 1160; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers the procedure for the performance of constant amplitude axial and bending fatigue tests to obtain the high cycle fatigue strength of porous-coated metallic materials. This includes testing uncoated substrate materials to act as a reference from which the effect of the porous coating may be compared. This test method is limited to the fatigue testing of axial, bending, and rotating beam specimens in air at room temperature. This test method is not intended for application in fatigue tests of components or parts; however, the method which most closely replicates the actual loading configuration is preferred.

1.2 The values stated in SI units are to be regarded as the standard.

1.3 *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

E 206 Definitions of Terms Relating to Fatigue Testing and the Statistical Analysis of Fatigue Data[2]

E 466 Practice for Constant Amplitude Axial Fatigue Tests of Metallic Materials[2]

E 467 Practice for Verification of Constant Amplitude Dynamic Loads in an Axial Load Fatigue Testing Machine[2]

E 468 Practice for the Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials[2]

3. Definitions

3.1 The terms used in this test method shall be as defined in Definitions E 206.

4. Significance and Use

4.1 The axial load, rotating beam, and other bending fatigue tests are used to determine the effect of variations in material, geometry, surface condition, stress, microstructure, grain size, etc., on the fatigue resistance of porous-coated metallic materials subjected to direct stress for a relatively large number of cycles. The test may be used as a relative guide to the selection of porous-coated metallic materials for service under conditions of repeated direct stress.

4.2 In order that such basic fatigue data be comparable, reproducible, and can be correlated among laboratories, it is essential that uniform fatigue practices be established.

4.3 The results of the fatigue test may be used for basic material property design. Actual components should not be tested using this test method.

5. Specimen Design

5.1 The type of specimen used will depend on the objective of the test program, the type of equipment, the equipment capacity, and the form in which the material is available. However, the design must meet certain general criteria as follows:

5.1.1 The design of the specimen should be such that failure occurs in the test section (reduced area as shown in Figs. 1 through 5). In the case of porous-coated samples, failure should be in or adjacent to the porous coating.

5.1.2 For the purpose of calculating the applied loads on the test specimen for determining the applied stresses, measure the dimensions from which the substrate area is calculated to the nearest 0.03 mm (0.001 in.) for dimensions equal to or greater than 5.08 mm (0.200 in.) and to the nearest 0.013 mm (0.0005 in.) for dimensions less than 5.08 mm (0.200 in.). Surfaces intended to be parallel and straight should be so in a manner consistent with 8.1.

5.1.3 Take all measurements on the substrate material prior to application of a porous coating. Base the applied load on substrate dimensions. Perform measurements of the coating thickness. Since the presence of the porous coating may have an effect on the specimen modulus (and therefore the actual stress) some estimate of the stresses in the porous layer should be made.

5.1.4 The number of specimens required for testing, as well as the methods in which fatigue data can be interpreted, can vary. Several test methods are referenced in this test method (see Refs **(1)** and **(2)**).[3]

5.2 *Specimen Substrate Dimensions:*

5.2.1 Dimensional characteristics of the specimen substrate shall be in accordance with Practice E 466, section 5.2.

5.2.2 Specimens employing a flat tapered beam configuration may be used. The taper should be calculated such that a constant surface stress exists in the test section when the

[1] This test method is under the jurisdiction of ASTM Committee Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

[2] Current edition approved Oct. 3, 1991. Published August 1991.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[3] The boldface numbers in parentheses refer to the list of references at the end of this test method.

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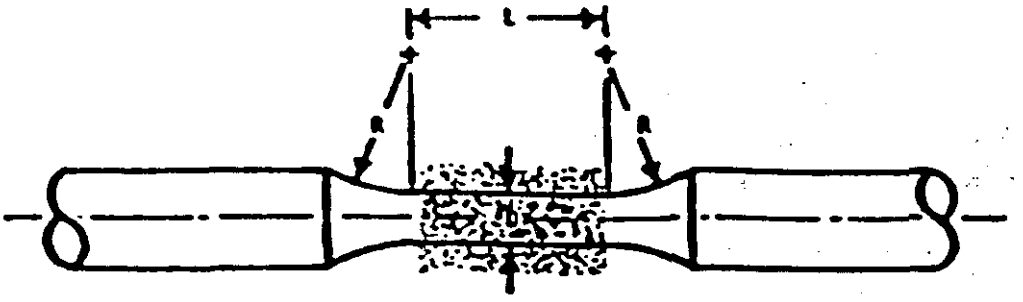

FIG. 1 Specimens with Tangentially Blending Fillets Between the Test Section and the Ends for Rotating Beam or Axial Loading

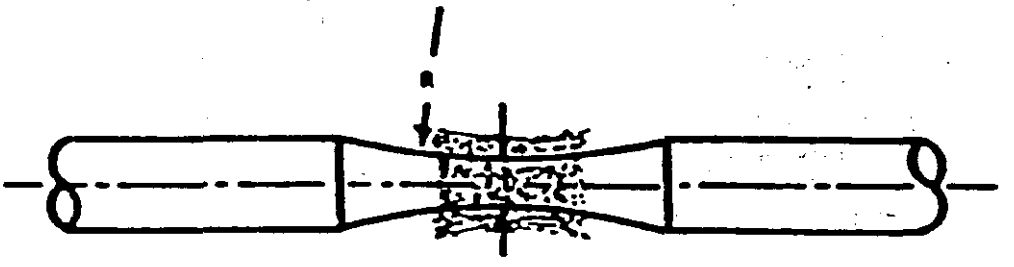

FIG. 2 Specimens with a Continuous Radius Between Ends for Rotating Beam or Axial Loading

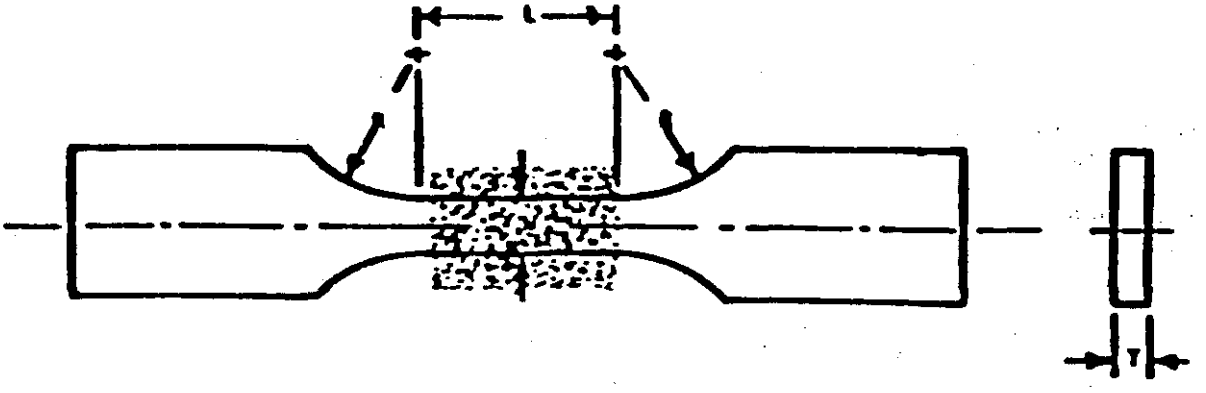

FIG. 3 Specimens with Tangentially Blending Fillets Between the Uniform Test Section and the Ends for Axial Loading

specimen is constrained at one end and point loaded perpendicularly to the beam axis at the other end (that is, cantilever bending).

5.2.3 Rotating beam specimens may have unique dimensions depending upon the type of machine. Appropriate manufacturers specifications for these specimens should be followed.

6. Specimen Preparation

6.1 *Specimen Coating Preparation:*

6.1.1 Porous metal coatings may be applied by any one of a number of techniques. The coating should be applied in the same manner as to the actual device. These coatings should be applied such that they are an integral part of the test specimen. The coating should not easily be removed from the substrate upon normal handling.

6.1.2 All thermal treatments normally performed on the finished porous coated products should be performed on the test specimen.

6.1.3 The coating morphology should be characterized on an actual test specimen. Data such as pore size, percent porosity, and an indication of degree of bonding (necking) should be characterized and be comparable to the actual device.

6.1.4 If employed, passivation and sterilization techniques should be consistent with that used for actual implants. These treatments should not affect the coating/coating and coating/substrate bond.

6.1.5 Porous-coated material should be applied to the region in which the test specimen is expected to fail. Coatings outside this region shall be regarded as acceptable if they do not interfere with gripping the specimen in the test fixture or do not significantly alter the stress in the test region.

6.1.6 *Inspection*—Visual inspections should be performed

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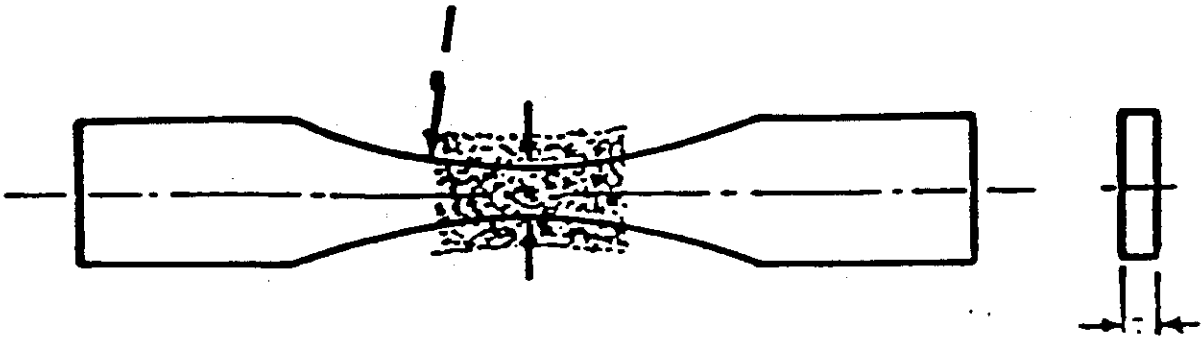

FIG. 4 Specimens with Continuous Radius Between Ends for Axial Loading

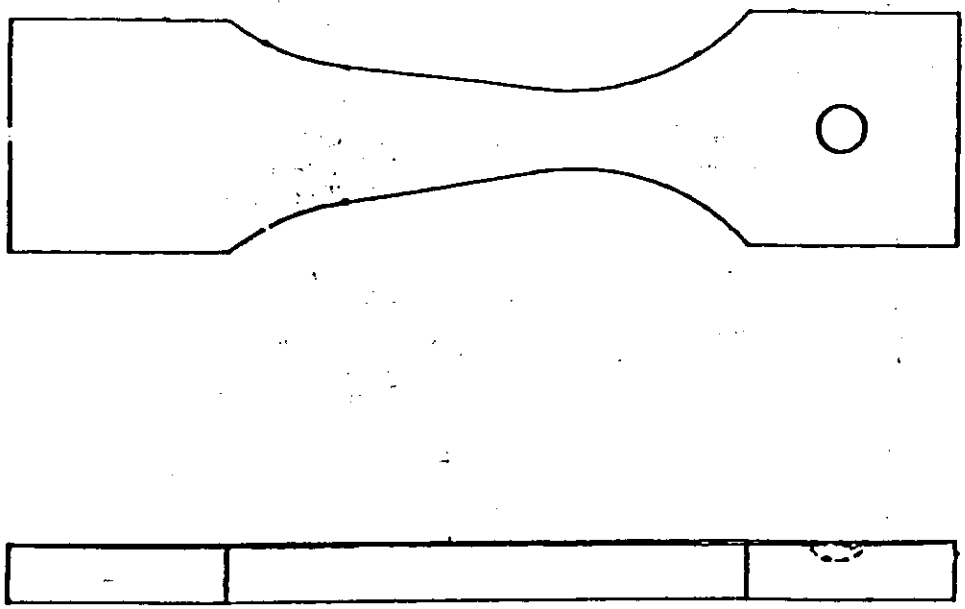

FIG. 5 An Example of a Specimen with a Tapered Beam Configuration for Bend Testing

on 100 % of the test specimens. Lack of coating in highly stressed regions, as well as non-uniform coating density, shall be cause for specimen rejection. Areas appearing to be non-porous should also cause specimen rejection, unless a portion of the coating is intentionally manufactured in this manner.

6.1.6.1 Since the possibility of specimen warpage due to thermal cycling exists, some acceptance/rejection criterion should be established. Specimen warpage may be corrected by minor machining of uncoated regions subsequent to thermal cycling. It is imperative that subsequent machining operations do not detract from the proper functionality of the test specimen. Specimen warpage should not be corrected by mechanical straightening techniques.

6.2 *Specimen Substrate Surface Preparation:*

6.2.1 The surface of the test specimen should be prepared in a manner consistent with that of an actual implant.

6.2.2 Some method of characterizing surface finish may be performed. This may include surface condition both before and after thermal processing (in uncoated regions).

6.2.3 If post-thermal processing of the surface is performed, it should be reported.

7. Equipment Characteristics

7.1 Equipment characteristics shall be in accordance with Practice E 466, Section 7.

8. Procedure for Testing

8.1 Axial testing procedures shall be in accordance with Practice E 466, Section 8.

8.2 *Rotating Beam Testing:*

8.2.1 *Mounting the Specimen*—Alignment of the specimen is crucial. Factors such as poorly machined specimens and misalignment of machine parts might result in excessive vibration. Verify alignment using appropriate measuring instruments, and confirm visually with the specimen running at full speed.

8.2.2 When mounting the specimen, do not apply the load until the machine is operating at the frequency desired for testing.

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8.3 *Bend Testing*—Bending fatigue testing may be performed in order to evaluate the bending characteristics. Recommended specimens include three and four point bending, as well as cantilever bending (for example, the flat tapered beam configuration shown in Fig. 5).

9. Substrate Fatigue Testing

9.1 Appropriate testing of the substrate material, upon which the coating will be applied, should be performed. This should include specimens tested both before and after thermal treatment. These tests shall serve as a baseline from which the effects of the porous coating may be evaluated.

10. Test Termination

10.1 Continue the tests until the specimen fails or until a predetermined number of cycles has been applied to the specimen. Failure should be defined as: (*1*) complete separation, (*2*) as a visible crack at a specified magnification, (*3*) as a crack of certain dimensions, (*4*) as a spalling off of the coating, or (*5*) by some other criterion. In reporting the results, state the criterion selected for defining failure.

11. Report

11.1 The report shall include the following:

11.1.1 Report the fatigue test specimens, procedures, and results in accordance with Practice E 468. The report shall also address possible effects of the porous coating on the specimen section modulus. Ignoring the specimen sectional modulus contribution of the coating may lead to erroneous results.

11.1.2 The use of this test method is limited to metallic specimens tested in a suitable environment, generally atmospheric air at room temperature. However, because the environment can influence the test results, periodically monitor and record environmental conditions such as temperature and relative humidity during the test and report.

11.1.3 Generally, the fatigue tests may be carried out using a periodic forcing function, usually sinusoidal. However, regardless of the nature of the forcing function, it should be reported (sine, ramp, saw tooth, etc.).

11.1.4 When noticeable yielding is evident in the fatigue test specimens after testing the data point shall be declared invalid.

11.1.5 Substrate dimensions, as well as the final coating thickness.

11.1.6 All necessary information required to provide traceability regarding heat-treatments applied to test specimens.

11.1.7 All appropriate test results acquired as a result of coating characterization.

11.1.8 Stress and corresponding cycles to failure (or runout number of cycles), as well as the failure mode.

11.1.9 Surface finish both before thermal processing, as well as after any post-thermal surface modifications in uncoated regions.

11.1.10 *R* ratio (minimum stress/maximum stress) used.

11.1.11 Test frequency employed; shall not exceed 170 Hz[3].

12. Precision and Bias

12.1 *Precision*—The precision of this test method is being established. Test results that might allow statistical evaluation for this statement are herewith solicited.

12.2 *Bias*—The bias of these methods includes quantitative estimates of the uncertainties of the dimensional measuring devices, the calibrations of test equipment, and the skill of the operators. At this time, statements on bias should be limited to the documented performance of particular laboratories.

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APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 This standard is needed to assure a high quality material for use in load-bearing orthopaedic prostheses. A review of the literature indicates that the fatigue behavior of porous-coated implants is too complex to be treated by Practice E 466 (Refs (4) through (6)). The influence of porous coatings on fatigue behavior must be viewed as the combined influence of the heat-treatment required to apply the coating, as well as the influence that the coating has on the device. It is the purpose of this test method to judge the relative influence of different porous coating techniques on the resultant fatigue behavior of the material. Round robin testing of this standard is not available at this time.

REFERENCES

(1) Collins, J. A., *Failure of Materials in Mechanical Design*, John Wiley & Sons, New York, 1981.
(2) *Handbook of Fatigue Testing, ASTM STP 566*, ASTM, 1974.
(3) Frost, N. C., Marsh, K. J., and Pook, C. P., *Metal Fatigue*, Oxford University Press, London, 1974.
(4) Cook, S. D., et al., "Fatigue Properties of Carbon and Porous-Coated Ti-6Al-4V," *Journal of Biomedical Materials Research*, Vol 18, 1984, pp. 497–512.
(5) Georgette, F. S., et al., "The Effect of HIP'ing on the Fatigue and Tensile Strength of a Cast, Porous-Coated Co-Cr-Mo Alloy," *Journal of Biomedical Materials Research*, Vol 20, 1986, pp. 1229–1248.
(6) Yue, S., Pilliar, R. M., and Weatherly, G. C., "The Fatigue Strength of Porous-Coated Ti-6%al-4%V Implant Alloy," *Journal of Biomedical Materials Research*, Vol 18, 1984, pp. 1043–1058.

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

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Appendix B

(b)(4) [redacted] Testing

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Designation: E 8 – 89

American Association State
Highway and Transportation Officials Standard
AASHTO No.: T 68

Standard Test Methods of Tension Testing of Metallic Materials[1]

This standard is issued under the fixed designation E 8; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This standard has been approved for use by agencies of the Department of Defense to replace method 211.1 of Federal Test Method Standard No. 151b. Consult the DoD Index of Specifications and Standards for the specific year of issue which has been adopted by the Department of Defense.

1. Scope

1.1 These test methods cover the tension testing of metallic materials in any form at room temperature, specifically, the methods of determination of yield strength, yield point, tensile strength, elongation, and reduction of area.

NOTE 1—A complete metric companion to Test Methods E 8 has been developed—E 8M; therefore, no metric equivalents are shown in these test methods.

NOTE 2—Gage lengths in these test methods are required to be 4D for most round specimens.

NOTE 3—Exceptions to the provisions of these methods may need to be made in individual specifications or test methods for a particular material. For examples, see Test Methods and Definitions A 370 and Methods B 557.

NOTE 4—Room temperature shall be considered to be 50 to 100°F unless otherwise specified.

1.2 *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

A 356/A 356M Specification for Heavy-Walled, Carbon, Low Alloy, and Stainless Steel Castings for Steam Turbines[2]

A 370 Test Methods and Definitions for Mechanical Testing of Steel Products[3]

B 557 Methods of Tension Testing Wrought and Cast Aluminum- and Magnesium-Alloy Products[4]

E 4 Practices for Load Verification of Testing Machines[5]

E 6 Terminology Relating to Methods of Mechanical Testing[5]

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications[6]

E 83 Practice for Verification and Classification of Extensometers[5]

E 345 Test Methods of Tension Testing of Metallic Foil[5]

3. Terminology

3.1 *Definitions*—The definitions of terms relating to tension testing appearing in Terminology E 6 shall be considered as applying to the terms used in these methods of tension testing.

4. Significance and Use

4.1 Tension tests provide information on the strength and ductility of materials under uniaxial tensile stresses. This information may be useful in comparisons of materials, alloy development, quality control, and design under certain circumstances.

4.2 The results of tension tests of specimens machined to standardized dimensions from selected portions of a part or material may not totally represent the strength and ductility properties of the entire end product or its in-service behavior in different environments.

4.3 These methods are considered satisfactory for acceptance testing of commercial shipments. The methods have been used extensively in the trade for this purpose.

5. Apparatus

5.1 *Testing Machines*—Machines used for tension testing shall conform to the requirements of Practices E 4. The loads used in determining tensile strength and yield strength or yield point shall be within the verified loading range of the testing machine as defined in Practices E 4.

5.2 *Gripping Devices:*

5.2.1 *General*—Various types of gripping devices may be used to transmit the measured load applied by the testing machine to the test specimens. To ensure axial tensile stress within the gage length, the axis of the test specimen should coincide with the center line of the heads of the testing machine. Any departure from this requirement may introduce bending stresses that are not included in the usual stress computation (load divided by cross-sectional area).

NOTE 5—The effect of this eccentric loading may be illustrated by calculating the bending moment and stress thus added. For a standard ½-in. diameter specimen, the stress increase is 1.5 percentage points for each 0.001 in. of eccentricity. This error increases to 2.24 percentage points/0.001 in. for a 0.350-in. diameter specimen and to 3.17 percentage points/0.001 in. for a 0.250-in. diameter specimen.

5.2.2 *Wedge Grips*—Testing machines usually are equipped with wedge grips. These wedge grips generally

[1] These test methods are under the jurisdiction of ASTM Committee E-28 on Mechanical Testing and are the direct responsibility of Subcommittee E28.04 on Tensile Testing.

Current edition approved May 15, 1989. Published July 1989. Originally publ. as E 8 – 24 T. Last previous edition E 8 – 88.

[2] *Annual Book of ASTM Standards*, Vol 01.02.

[3] *Annual Book of ASTM Standards*, Vols 01.01–01.05 and 03.01.

[4] *Annual Book of ASTM Standards*, Vols 02.02 and 03.01.

[5] *Annual Book of ASTM Standards*, Vol 03.01.

[6] *Annual Book of ASTM Standards*, Vols 02.03, 03.01, and 14.02.

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furnish a satisfactory means of gripping long specimens of ductile metal and flat plate test specimens such as those shown in Fig. 1. If, however, for any reason, one grip of a pair advances farther than the other as the grips tighten, an undesirable bending stress may be introduced. When liners are used behind the wedges, they must be of the same thickness and their faces must be flat and parallel. For best results, the wedges should be supported over their entire lengths by the heads of the testing machine. This requires that liners of several thicknesses be available to cover the range of specimen thickness. For proper gripping, it is desirable that the entire length of the serrated face of each wedge be in contact with the specimen. Proper alignment of wedge grips and liners is illustrated in Fig. 2. For short specimens and for specimens of many materials it is generally necessary to use machined test specimens and to use a special means of gripping to ensure that the specimens, when under load, shall be as nearly as possible in uniformly distributed pure axial tension (see 5.2.3, 5.2.4, and 5.2.5).

5.2.3 *Grips for Threaded and Shouldered Specimens and Brittle Materials*—A schematic diagram of a gripping device for threaded-end specimens is shown in Fig. 3, while Fig. 4 shows a device for gripping specimens with shouldered ends. Both of these gripping devices should be attached to the heads of the testing machine through properly lubricated spherical-seated bearings. The distance between spherical bearings should be as great as feasible.

5.2.4 *Grips for Sheet Materials*—The self-adjusting grips shown in Fig. 5 have proven satisfactory for testing sheet materials that cannot be tested satisfactorily in the usual type of wedge grips.

5.2.5 *Grips for Wire*—Grips of either the wedge or snubbing types as shown in Figs. 5 and 6 or flat wedge grips may be used.

5.3 *Dimension-Measuring Devices*—Micrometers and other devices used for measuring linear dimensions shall be accurate and precise to at least one half the smallest unit to which the individual dimension is required to be measured.

6. Test Specimens

6.1 *General:*

6.1.1 Test specimens shall be either substantially full size or machined, as prescribed in the product specifications for the material being tested.

6.1.2 Improperly prepared test specimens often are the reason for unsatisfactory and incorrect test results. It is important, therefore, that care be exercised in the preparation of specimens, particularly in the machining, to assure the desired precision and bias in test results.

6.1.3 It is desirable to have the cross-sectional area of the specimen smallest at the center of the reduced section to ensure fracture within the gage length. For this reason, a small taper is permitted in the reduced section of each of the specimens described in the following sections.

6.1.4 For brittle materials it is desirable to have fillets of large radius at the ends of the gage length.

6.2 *Plate-Type Specimens*—The standard plate-type test specimen is shown in Fig. 1. This specimen is used for testing metallic materials in the form of plate, shapes, and flat material having a nominal thickness of 3/16 in. or over. When product specifications so permit, other types of specimens may be used, as provided in 6.3, 6.4, and 6.5.

6.3 *Sheet-Type Specimens:*

6.3.1 The standard sheet-type test specimen is shown Fig. 1. This specimen is used for testing metallic materials the form of sheet, plate, flat wire, strip, band, hoc rectangles, and shapes ranging in nominal thickness frc 0.005 to 5/8 in. When product specifications so permit, oth types of specimens may be used, as provided in 6.2, 6.4, a 6.5.

NOTE 6—Test Methods E 345 may be used for tension testing materials in thicknesses up to 0.0059 in.

6.3.2 Pin ends as shown in Fig. 7 may be used. In order avoid buckling in tests of thin and high-strength materials, may be neccessary to use stiffening plates at the grip ends.

6.4 *Round Specimens:*

6.4.1 The standard 0.500-in. diameter round test spe imen shown in Fig. 8 is used quite generally for testi metallic materials, both cast and wrought.

6.4.2 Figure 8 also shows small-size specimens propc tional to the standard specimen. These may be used when is necessary to test material from which the standa specimen or specimens shown in Fig. 1 cannot be prepare Other sizes of small round specimens may be used. In a such small-size specimen it is important that the gage leng for measurement of elongation be four times the diameter the specimen.

6.4.3 The shape of the ends of the specimen outside of t gage length shall be suitable to the material and of a shape fit the holders or grips of the testing machine so that t loads may be applied axially. Figure 9 shows specimens wi various types of ends that have given satisfactory results.

6.5 *Specimens for Sheet, Strip, Flat Wire, and Plate*—I testing sheet, plate, flat wire, and strip one of the followir types of specimens shall be used:

6.5.1 For material ranging in nominal thickness fro 0.005 to 5/8 in., the sheet-type specimen described in 6.3.

NOTE 7—Attention is called to the fact that either of the fl specimens described in 6.2 and 6.3 may be used for material from 3/16 5/8 in. in thickness, and one of the round specimens described in 6.4 m also be used for material 1/2 in. or more in thickness.

6.5.2 For material having a nominal thickness of 3/16 in. c over (Note 7), use the plate-type specimen described in 6.2

6.5.3 For material having a nominal thickness of 1/2 in. c over (Note 7), use the largest practical size of specime described in 6.4.

6.6 *Specimens for Wire, Rod, and Bar:*

6.6.1 For round wire and rod, test specimens having th full cross-sectional area of the wire or rod shall be use wherever practicable. The gage length for the measuremen of elongation of wire less than 1/8 in. in diameter shall be a prescribed in product specifications. In testing wire of 1/8-in or larger diameter, unless otherwise specified, a gage lengt equal to four times the diameter shall be used. The tota length of the specimens shall be at least equal to the gag length plus the length of wire required for the full use of th grips employed.

6.6.2 For wire of octagonal, hexagonal, or square cros section, for rod or bar of round cross section where th specimen required in 6.6.1 is not practicable, and for rod o bar of octagonal, hexagonal, or square cross section, one o

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the following types of specimens shall be used:

6.2.1 *Full Cross Section* (Note 8)—It is permissible to e the test section slightly with abrasive cloth or paper, machine it sufficiently to ensure fracture within the gage ks. For material not exceeding 0.188 in. in diameter or distance between flats, the cross-sectional area may be reduced to not less than 90 % of the original area without changing the shape of the cross section. For material over 0.188 in. in diameter or distance between flats, the diameter or distance between flats may be reduced by not more than 0.010 in. without changing the shape of the cross section. Square, hexagonal, or octagonal wire or rod not exceeding 0.188 in. between flats may be turned to a round having a cross-sectional area not smaller than 90 % of the area of the maximum inscribed circle. Fillets, preferably with a radius of ⅜ in., but not less than ⅛ in., shall be used at the ends of the reduced sections. Square, hexagonal, or octagonal rod over 0.188 in. between flats may be turned to a round having a diameter no smaller than 0.010 in. less than the original distance between flats.

NOTE 8—The ends of copper or copper alloy specimens may be flattened 10 to 50 % from the original dimension in a jig similar to that shown in Fig. 10, to facilitate fracture within the gage marks. In flattening the opposite ends of the test specimen, care shall be taken to ensure that the four flattened surfaces are parallel and that the two parallel surfaces on the same side of the axis of the test specimen lie in the same plane.

6.6.2.2 For rod and bar, the largest practical size of round specimen as described in 6.4 may be used in place of a test ı ıen of full cross section. Unless otherwise specified in the product specification, specimens shall be parallel to the (ion of rolling or extrusion.

6.7 *Specimens for Rectangular Bar*—In testing rectangular bar one of the following types of specimens shall be used:

6.7.1 *Full Cross Section*—It is permissible to reduce the width of the specimen throughout the test section with abrasive cloth or paper, or by machining sufficiently to facilitate fracture within the gage marks, but in no case shall the reduced width be less than 90 % of the original. The edges of the midlength of the reduced section not less than ¾ in. in length shall be parallel to each other and to the longitudinal axis of the specimen within 0.002 in. Fillets, preferably with a radius of ⅜ in. but not less than ⅛ in. shall be used at the ends of the reduced sections.

6.7.2 Rectangular bar of thickness small enough to fit the grips of the testing machine but of too great width may be reduced in width by cutting to fit the grips, after which the cut surfaces shall be machined or cut and smoothed to ensure failure within the desired section. The reduced width shall be not less than the original bar thickness. Also, one of the types of specimens described in 6.2, 6.3, and 6.4 may be used.

6.8 *Shapes, Structural and Other*—In testing shapes other than those covered by the preceding sections, one of the types of specimens described in 6.2, 6.3, and 6.4 shall be us

Specimens for Pipe and Tube (Note 9):

6.9.1 For all small tube (Note 9), particularly sizes 1 in. a. nder in nominal outside diameter, and frequently for larger sizes, except as limited by the testing equipment, it is standard practice to use tension test specimens of full-size tubular sections. Snug-fitting metal plugs shall be inserted far enough into the ends of such tubular specimens to permit the testing machine jaws to grip the specimens properly. The plugs shall not extend into that part of the specimen on which the elongation is measured. Figure 11 shows a suitable form of plug, the location of the plugs in the specimen, and the location of the specimen in the grips of the testing machine.

NOTE 9—The term "tube" is used to indicate tubular products in general, and includes pipe, tube, and tubing.

6.9.2 For large-diameter tube that cannot be tested in full section, longitudinal tension test specimens shall be cut as indicated in Fig. 12. Specimens from welded tube shall be located approximately 90° from the weld. If the tube-wall thickness is under ¾ in., either a specimen of the form and dimensions shown in Fig. 13 or one of the small-size specimens proportional to the standard ½-in. specimen, as mentioned in 6.4.2 and shown in Fig. 8, shall be used. Specimens of the type shown in Fig. 13 may be tested with grips having a surface contour corresponding to the curvature of the tube. When grips with curved faces are not available, the ends of the specimens may be flattened without heating. If the tube-wall thickness is ¾ in. or over, the standard specimen shown in Fig. 8 shall be used.

6.9.3 Transverse tension test specimens for tube may be taken from rings cut from the ends of the tube as shown in Fig. 14. Flattening of the specimen may be either after separating as in *A*, or before separating as in *B*. Transverse tension test specimens for large tube under ¾ in. in wall thickness shall be either of the small-size specimens shown in Fig. 8 or of the form and dimensions shown for Specimen 2 in Fig. 13. When using the latter specimen, either or both surfaces of the specimen may be machined to secure a uniform thickness, provided not more than 15 % of the normal wall thickness is removed from each surface. For large tube ¾ in. and over in wall thickness, the standard specimen shown in Fig. 8 shall be used for transverse tension tests. Specimens for transverse tension tests on large welded tube to determine the strength of welds shall be located perpendicular to the welded seams, with the welds at about the middle of their lengths.

6.10 *Specimens for Forgings*—For testing forgings, the largest round specimen described in 6.4 shall be used. If round specimens are not feasible, then the largest specimen described in 6.5 shall be used.

6.11 *Specimens for Castings*—In testing castings either the standard specimen shown in Fig. 8 or the specimen shown in Fig. 15 shall be used unless otherwise provided in the product specifications.

6.11.1 Test coupons for castings shall be made as shown in Fig. 16 and Table 1.

6.12 *Specimen for Malleable Iron*—For testing malleable iron the test specimen shown in Fig. 17 shall be used, unless otherwise provided in the product specifications.

6.13 *Specimen for Die Castings*—For testing die castings the test specimen shown in Fig. 18 shall be used unless otherwise provided in the product specifications.

6.14 *Specimens for Powdered Metals*—For testing powdered metals the test specimens shown in Figs. 19 and 20

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TABLE 1 Details of Test Coupon Design for Castings (See Fig. 16)

NOTE 1—*Test Coupons for Large and Heavy Steel Castings:* The test coupons in Fig. 16 are to be used for large and heavy steel castings. However, at the option of the foundry the cross-sectional area and length of the standard coupon may be increased as desired. This provision does not apply to Specification A 356/A 356M.

NOTE 2—*Bend Bar:* If a bend bar is required, an alternate design (as shown by dotted lines in Fig. 16) is indicated.

Log Design (5 in.)		Riser Design	
1. *L* (length)	A 5-in. minimum length will be used. This length may be increased at the option of the foundry to accommodate additional test bars (see Note 1).	1. *L* (length)	The length of the riser at the base will be the same as the top length of the leg. The length of the riser at the top therefore depends on the amount of taper added to the riser.
2. End taper	Use of and size of end taper is at the option of the foundry.	2. Width	The width of the riser at the base of a multiple-leg coupon shall be *n* (2¼ in.) − ⅝ in. where *n* equals the number of legs attached to the coupon. The width of the riser at the top is therefore dependent on the amount of taper added to the riser.
3. Height	1¼ in.		
4. Width (at top)	1¼ in. (see Note 1)		
5. Radius (at bottom)	½ in. max		
6. Spacing between legs	A ½-in. radius will be used between the legs.		
7. Location of test bars	The tensile, bend, and impact bars will be taken from the lower portion of the leg (see Note 2)		
8. Number of legs	The number of legs attached to the coupon is at the option of the foundry providing they are equispaced according to Item 6.	3. *T* (riser taper)	Use of and size is at the option of the foundry.
		Height	The minimum height of the riser shall be 2 in. The maximum height is at the option of the foundry for the following reasons: (*a*) many risers are cast open, (*b*) different compositions may require variation in risering for soundness, or (*c*) different pouring temperatures may require variation in risering for soundness.
9. R_s	Radius from 0 to approximately 1/16 in.		

shall be used, unless otherwise provided in the product specifications.

6.15 *Gage Length of Test Specimens:*

6.15.1 The gage length for the determination of elongation shall be in accordance with the product specifications for the material being tested. Gage marks shall be stamped lightly with a punch, scribed lightly with dividers or drawn with ink as preferred. For material that is sensitive to the effect of slight notches and for small specimens, the use of layout ink will aid in locating the original gage marks after fracture.

6.15.2 Extensometers with gage lengths equal to or shorter than the nominal gage length (dimension shown as "*G*-Gage Length" in the accompanying figures) of the specimen may be used to determine the yield phenomenon.

6.16 *Location of Test Specimens:*

6.16.1 Unless otherwise specified, the axis of the test specimen shall be located as follows:

6.16.1.1 At the center for products 1½ in. or less in thickness, diameter, or distance between flats.

6.16.1.2 Midway from the center to the surface for products over 1½ in. in thickness, diameter, or distance between flats.

6.16.2 For forgings, specimens shall be taken as provided in the applicable product specifications, either from the predominant or thickest part of the forging from which a coupon can be obtained, or from a prolongation of the forging, or from separately forged coupons representative of the forging. When not otherwise specified, the axis of the specimen shall be parallel to the direction of grain flow.

6.17 *Surface Finish of Specimens*—When materials are tested with surface conditions other than as manufactured, the surface finish of the test specimens shall be as provided in the applicable product specifications.

NOTE 10—Particular attention should be given to the uniformity and quality of surface finishes of specimens for high strength and very low ductility materials since this has been shown to be a factor in the variability of test results.

7. Procedures

7.1 *Measurement of Dimensions of Test Specimens:*

7.1.1 To determine the cross-sectional area of a test specimen, measure the dimensions of the cross section at the center of the reduced section. For referee testing of specimens under 3/16 in. in their least dimension, measure the dimensions where the least cross-sectional area is found. Measure and record the cross-sectional dimensions of tension test specimens 0.200 in. and over to the nearest 0.001 in.; the cross-sectional dimensions from 0.100 in. but less than 0.200 in., to the nearest 0.0005 in.; the cross-sectional dimensions from 0.020 in. but less than 0.100 in., to the nearest 0.0001 in.; and when practical, the cross-sectional dimensions less than 0.020 in., to at least the nearest 1 % but in all cases to at least the nearest 0.0001 in.

NOTE 11—Rough surfaces due to the manufacturing process such as hot rolling, metallic coating, etc., may lead to inaccuracy of the computed areas greater than the measured dimensions would indicate. Therefore, cross-sectional dimensions of test specimens with rough surfaces due to processing may be measured and recorded to the nearest 0.001 in.

7.1.2 Determine cross-sectional areas of full-size test specimens of nonsymmetrical cross sections by weighing a length not less than 20 times the largest cross-sectional dimension and using the value of density of the material. Determine the weight to the nearest 0.5 % or less.

7.1.3 When using specimens of the type shown in Fig. 13 taken from tubes, the cross-sectional area shall be determined as follows:

If D/W ≤6:

$$A = [(W/4) \times (D^2 - W^2)^{1/2}] + [(D^2/4) \times \arcsin(W/D)] - [(W/4) \times ((D - 2T)^2 - W^2)^{1/2}] - [((D - 2T)/2)^2 \times \arcsin(W/(D - 2T))]$$

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where:

= exact cross-sectional area, in.^{2},
= width of the specimen in the reduced section, in.,
= measured outside diameter of the tube, in., and
T = measured wall thickness of the specimen, in.

arcsin values to be in radians

If D/W > 6, the exact equation or the following equation may be used:

$$A = W \times T$$

where:

A = approximate cross-sectional area, in.^{2},
W = width of the specimen in the reduced section, in., and
T = measured wall thickness of the specimen, in.

7.2 *Speed of Testing:*

7.2.1 Speed of testing may be defined (*a*) in terms of free-running crosshead speed (rate of movement of the crosshead of the testing machine when not under load), (*b*) in terms of rate of separation of the two heads of the testing machine during a test, (*c*) in terms of the elapsed time for completing part or all of the test (*d*) in terms of rate of stressing the specimen, or (*e*) in terms of rate of straining the specimen.

NOTE 12—For some materials, the free-running crosshead speed, which is the least accurate, may be adequate, while for other materials one of the remaining methods, listed in decreasing order of precision, may be necessary in order to obtain test values within acceptable limits.

7.2.1.1 Specifying suitable numerical limits for speed and selection of the method are the responsibilities of the product committees. Suitable limits for speed of testing should be specified for materials for which the differences resulting from the use of different speeds are of such magnitude that the test results are unsatisfactory for determining the acceptability of the material. In such instances, depending upon the material and the use for which the test results are intended, one or more of the methods described in the following paragraphs is recommended for specifying speed of testing.

NOTE 13—Speed of testing can affect test values because of the rate sensitivity of materials and the temperature-time effects.

7.2.2 *Rate of Straining*—The allowable limits for rate of straining shall be specified in inches per inch per minute. Some testing machines are equipped with pacing or indicating devices for the measurement and control of rate of straining, but in the absence of such a device the average rate of straining can be determined with a timing device by observing the time required to effect a known increment of strain.

7.2.3 *Rate of Stressing*—The allowable limits for rate of stressing shall be specified in pounds per square inch per minute. Many testing machines are equipped with pacing or indicating devices for the measurement and control of the rate of stressing, but in the absence of such a device the average rate of stressing can be determined with a timing device by observing the time required to apply a known increment of stress.

7.2.4 *Elapsed Time*—The allowable limits for the elapsed time from the beginning of loading (or from some specified stress) to the instant of fracture, to the maximum load, or to the other stated stress, shall be specified in minutes or seconds. The elapsed time can be determined with a timing device.

7.2.5 *Free-Running Crosshead Speed*—The allowable limits for the rate of movement of the crosshead of the testing machine, when not under load, shall be specified in inches per inch of length of reduced section (or distance between grips for specimens not having reduced sections) per minute. The limits for the crosshead speed may be further qualified by specifying different limits for various types and sizes of specimens. The average crosshead speed can be experimentally determined by using suitable length measuring and timing devices.

7.2.6 *Rate of Separation of Heads During Tests*—The allowable limits for rate of separation of the heads of the testing machine during a test shall be specified in inches per inch of length of reduced section (or distance between grips for specimens not having reduced sections) per minute. The limits for the rate of separation may be further qualified by specifying different limits for various types and sizes of specimens. Many testing machines are equipped with pacing or indicating devices for the measurement and control of the rate of separation of the heads of the machine during a test, but in the absence of such a device the average rate of separation of the heads can be experimentally determined by using suitable length-measuring and timing devices.

7.2.7 Unless otherwise specified, any convenient speed of testing may be used up to one half the specified yield strength or yield point, or up to one quarter the specified tensile strength, whichever is smaller. The speed above this point shall be within the limits specified. If different speed limitations are required for use in determining yield strength, yield point, tensile strength, elongation, and reduction of area, they should be stated in the product specifications. In the absence of any specified limitations on speed of testing the following general rules shall apply:

7.2.7.1 The speed of testing shall be such that the loads and strains used in obtaining the test results are accurately indicated.

7.2.7.2 During the conduct of the test to determine yield strength or yield point the rate of stress application shall not exceed 100 000 psi/min.

7.2.7.3 After the yield strength or yield point has been determined, the speed may be increased to correspond to a maximum strain rate of 0.5 in./in/min. The extensometer and strain rate indicator may be used to set the strain rate prior to its removal. If the extensometer and strain rate indicator are not used to set this strain rate, the speed should be set not to exceed 0.5 in./in. of the length of the reduced section (or distance between the grips for specimens not having reduced sections) per minute.

7.3 *Determination of Yield Strength*—Determine yield strength by either of the methods described in 7.3.1 or 7.3.2.

7.3.1 *Offset Method*—To determine the yield strength by the "offset method," it is necessary to secure data (autographic or numerical) from which a stress-strain diagram may be drawn. Then on the stress-strain diagram (Fig. 21) lay off *Om* equal to the specified value of the "offset," draw *mn* parallel to *OA*, and thus locate *r*, the intersection of *mn* with the stress-strain diagram (Note 14). In reporting values of yield strength obtained by this method, the specified value of offset used should be stated in parentheses after the term yield strength. Thus:

Yield strength (offset = 0.2 %) = 52 000 psi

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In using this method a Class B2 extensometer (see Practice E 83) would be sufficiently sensitive for most materials.

7.3.2 *Extension-Under-Load Method*—To determine the yield strength by the extension-under-load (EUL) method, it is necessary to secure data as follows: (*1*) by autographic or numerical devices so that a stress-strain (or load elongation) diagram may be drawn from which the value of the stress occurring at the specified value of extension may be ascertained; or (*2*) by a device attached to or part of an extensometer that indicates when the specified extension occurs so that the stress then occurring may be ascertained; either or both the devices attached to the extensometer or the load-indicating device may be automatic. This method is illustrated in Fig. 22. The extension can be satisfactorily determined by the use of a Class B2 extensometer (see Practice E 83). The stress that occurs at the specified extension shall be reported thus:

Yield strength (EUL = *XX*) = *YY* psi

where *XX* is the specified value of extension.

NOTE 14—If the load drops before the specified offset or extension-under-load is reached, technically the material does not have a yield strength (for that offset or extension-under-load), but the stress at the maximum load attained before the specified offset or extension-under-load is reached may be reported instead of the yield strength.

NOTE 15—When there is disagreement over the results of this test, the offset method for determining yield strength is recommended as the referee method.

7.4 *Determination of Yield Point:*

7.4.1 For materials that exhibit discontinuous yielding, determine the yield point by either of the methods described in 7.4.1.1 or 7.4.1.2.

7.4.1.1 *Halt-of-the-Load Method*—Apply an increasing load to the specimen at a uniform deformation rate. When the yield point of the material is reached, the increase of the load stops. At that time, there is a halt or hesitation of the load-indicating mechanism. When the increase in load stops or hesitates, record the corresponding stress as the yield point.

NOTE 16—This method was formerly known as the halt-of-the-pointer method and also as the drop-of-the-beam method.

7.4.1.2 *Autographic Diagram Method*—Obtain a stress-strain (or load-elongation) diagram by an autographic device. Record the stress (or load) corresponding to the maximum point at the onset of discontinuous yielding, as the yield point. This method is illustrated in Fig. 23.

7.4.2 When test specimens do not exhibit a well-defined disproportionate deformation that characterizes a yield point as measured by the drop-of-the-beam, halt-of-the-pointer, or autographic diagram methods described above, a value equivalent to the yield point in its practical significance may be determined by the following methods and may be substituted for the yield point:

7.4.2.1 *Strain Rate Method*—Attach a Class B2 extensometer to the specimen at the gage marks. When the specimen is in place and the extensometer attached, increase the load at a reasonably uniform rate. Watch the elongation of the specimen as shown by the extensometer and note for this determination the load at which the rate of elongation shows a sudden increase.

7.4.2.2 *Extension-Under-Load Method*—Attach a Class C extensometer to the specimen. When the load producing a specified extension is reached, record the stress corresponding to this load as the yield point, and remove the extensometer. This same value may be obtained from an autographic stress-strain diagram (Fig. 22).

NOTE 17—The appropriate value of the total extension should be specified. For steel with yield point specified not over 80 000 psi, an appropriate value is 0.005 in./in. of gage length. For higher strength steels, yield strength should be specified in preference to yield point.

NOTE 18—A suitable device that automatically determines the load at the specified extension without plotting a stress-strain curve may be used if its accuracy has been demonstrated to be satisfactory.

NOTE 19—When no other means of measuring elongation are available, a pair of dividers or similar device can be used to determine a point of detectable elongation between two gage marks on the specimen. The gage length shall be 2 in. The stress corresponding to the load at the instant of detectable elongation can be recorded as "approximate" yield point.

7.5 *Tensile Strength*—Calculate the tensile strength by dividing the maximum load carried by the specimen during a tension test by the original cross-sectional area of the specimen.

7.6 *Elongation:*

7.6.1 In reporting values of elongation, give both the original gage length and the percentage increase.

Example: elongation = 30 % increase (2-in. gage length)

7.6.2 When the specified elongation is greater than 3 %, fit ends of the fractured specimen together carefully and measure the distance between the gage marks to the nearest 0.01 in. for gage lengths of 2 in. and under, and to at least the nearest 0.5 % of the gage length for gage lengths over 2 in. A percentage scale reading to 0.5 % of the gage length may be used.

7.6.3 When the *specified* elongation is 3 % or less, determine the elongation of standard round specimens (see Fig. 8) using the following procedure, except that the procedure given in 7.6.2 may be used instead when the *measured* elongation is greater than 3 %.

7.6.3.1 Measure the original gage length of the specimen to the nearest 0.002 in.

7.6.3.2 Remove partly torn fragments that will interfere with fitting together the ends of the fractured specimen or with making the final measurement.

7.6.3.3 Fit the fractured ends together with matched surfaces and apply an end load along the axis of the specimen sufficient to close the fractured ends together. If desired, this load may then be removed carefully, provided the specimen remains intact.

NOTE 20—The use of an end load of approximately 2000 psi has been found to give satisfactory results on test specimens of aluminum alloy.

7.6.3.4 Measure the final gage length to the nearest 0.002 in. and report the elongation to the nearest 0.2 %.

7.6.4 Specimens other than the standard specimen described in Fig. 8 are exempt from the requirement of 7.6.3 except as required by the applicable product specification.

7.6.5 If any part of the fracture takes place outside of the middle half of the gage length or in a punched or scribed mark within the reduced section, the elongation value obtained may not be representative of the material. In acceptance testing, if the elongation so measured meets the

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minimum requirements specified, no further testing is required. But if the elongation is less than the minimum requirements, discard the test and retest.

7.6.6 In determining extension at fracture (elastic plus plastic extension), autographic or automated methods using extensometers may be employed.

7.6.6.1 In determining percent elongation from extension at fracture data, only the plastic extension shall be used. The elastic portion can be estimated graphically or by calculation and then subtracted from the total extension at fracture.

7.7 *Reduction of Area:*

7.7.1 *Specimens with Originally Circular Cross Sections*—Fit the ends of the fractured specimen together and measure the reduced diameter to the same accuracy as the original measurement.

NOTE 21—Because of anisotropy, circular cross sections often do not remain circular during straining in tension. The shape is usually elliptical, thus, the area may be calculated by $\pi \cdot d_1 \cdot d_2/4$, where d_1 and d_2 are the major and minor diameters, respectively.

7.7.2 *Specimens with Original Rectangular Cross Sections*—Fit the ends of the fractured specimen together and measure the thickness and width at the minimum cross section to the same accuracy as the original measurements.

NOTE 22—Because of the constraint to deformation that occurs at the corners of rectangular specimens, the dimensions at the center of the original flat surfaces are less than those at the corners. The shape of these surfaces are often assumed to be parabolic. When this assumption is made, effective thickness, t_e, may be calculated as follows: $(t_1 + 4t_2 + t_3)/6$, where t_1 and t_3 are the thicknesses at the corners, and t_2 is the thickness at mid-width. An effective width may be similarly calculated.

7.7.3 Calculate the reduced area based upon the dimensions determined in 7.7.1 or 7.7.2. The difference between the area thus found and the area of the original cross section expressed as a percentage of the original area, is the reduction of area.

7.7.4 If any part of the fracture takes place outside the middle half of the reduced section or in a punched or scribed gage mark within the reduced section, the reduction of area value obtained may not be representative of the material. In acceptance testing, if the reduction of area so calculated meets the minimum requirements specified, no further testing is required, but if the reduction of area is less than the minimum requirements, discard the test results and retest.

7.7.5 Results of measurements of reduction of area shall be rounded using the procedures of Recommended Practice E 29 and any specific procedures in the product specifications. In the absence of a specified procedure, it is recommended that reduction of area test values in the range from 0 to 10 % be rounded to the nearest 0.5 % and test values of 10 % and greater to the nearest 1 %.

7.8 *Rounding Reported Tests Data for Yield Strength, Yield Point, and Tensile Strength*—Test data should be rounded using the procedures of Practice E 29 and the specific procedures in the product specifications. In the absence of a specified procedure for rounding the test data, one of the procedures described in the following paragraphs is recommended.

7.8.1 For test values up to 50 000 psi, round to the nearest 100 psi; for test values of 50 000 psi and up to 100 000 psi, round to the nearest 500 psi; for test values of 100 000 psi and greater, round to the nearest 1000 psi.

NOTE 23—For steel products, see Test Methods and Definitions A 370.

7.8.2 For all test values, round to the nearest 100 psi.

NOTE 24—For aluminum- and magnesium-alloy products, see Methods B 557.

7.8.3 For all test values, round to the nearest 500 psi.

7.9 *Replacement of Specimens*—A test specimen may be discarded and a replacement specimen selected from the same lot of material in the following cases:

7.9.1 The original specimen had a poorly machined surface,

7.9.2 The original specimen had the wrong dimensions,

7.9.3 The specimen's properties were changed because of poor machining practice,

7.9.4 The test procedure was incorrect,

7.9.5 The fracture was outside the gage length,

7.9.6 For elongation determinations, the fracture was outside the middle half of the gage length, or

7.9.7 There was a malfunction of the testing equipment.

NOTE 25—The tension specimen is inappropriate for assessing some types of imperfections in a material. Other methods and specimens employing ultrasonics, dye penetrants, radiography, etc., may be considered when flaws such as cracks, flakes, porosity, etc., are revealed during a test and soundness is a condition of acceptance.

8. Report

8.1 Test information on materials not covered by a product specification should be reported in accordance with 8.2 or both 8.2 and 8.3.

8.2 Test information to be reported shall include the following when applicable:

8.2.1 Material and specimen identification.

8.2.2 Yield strength and the method used to determine yield strength (see 7.3).

8.2.3 Yield point and the method used to determine yield point (see 7.4).

8.2.4 Tensile strength (see 7.5).

8.2.5 Elongation (report both the original gage length and the percentage increase) (see 7.6.)

8.2.6 Reduction of area (see 7.7).

8.3 Test information to be available on request shall include:

8.3.1 Specimen type (Section 6).

8.3.2 Specimen test section dimension(s).

8.3.3 Equation used to calculate cross-sectional area of rectangular specimens taken from large-diameter tubular products.

8.3.4 Speed and method used to determine speed of testing (see 7.2).

8.3.5 Method used for rounding of test results (see 7.8).

8.3.6 Reasons for replacement specimens (see 7.9).

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9. Precision and Bias

9.1 *Precision*—An interlaboratory test program[7] gave the following values for coefficients of variation for the most commonly measured tensile properties:

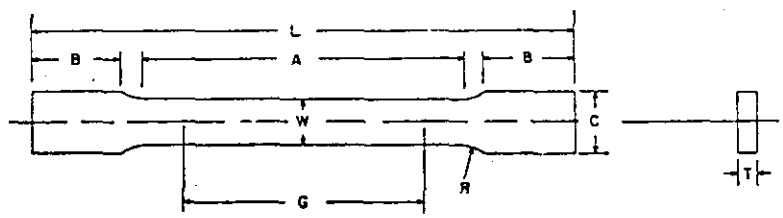
Coefficients of Variation, %

	Tensile Strength	Yield Strength (offset= 0.02 %)	Yield Strength (offset= 0.2 %)	Elongation (gage length= 4 diameter)	Reduction of Area
Within Laboratories	0.9	2.7	1.4	2.8	2.8
Between Laboratories	0.7	3.5	1.6	4.5	3.5

[7] Supporting data are available from ASTM Headquarters. Request RR: E28-1004.

9.1.1 The values shown are the averages from tests on six frequently tested metals, selected to include most of the normal range for each property listed above. When these materials are compared, a large difference in coefficient of variation is found. Therefore, the values above should not be used to judge whether the difference between duplicate tests of a specific material is larger than expected. The values are provided to allow potential users of this test method to assess, in general terms, its usefulness for a proposed application.

9.2 *Bias*—The procedures in Test Methods E 8 for measuring tensile properties have no bias because these properties can be defined only in terms of a test method.



Dimensions

	Standard Specimens		Subsize Specimen
	Plate-Type, 1½-in. Wide	Sheet-Type, ½-in. Wide	¼-in. Wide
	in.	in.	in.
G—Gage length (Notes 1 and 2)	8.00 ± 0.01	2.000 ± 0.005	1.000 ± 0.003
W—Width (Notes 3 and 4)	1½ + ⅛, −¼	0.500 ± 0.010	0.250 ± 0.005
T—Thickness (Note 5)		thickness of material	
R—Radius of fillet, min (Note 6)	1	½	¼
L—Over-all length, min (Notes 2 and 7)	18	8	4
A—Length of reduced section, min	9	2¼	1¼
B—Length of grip section, min (Note 8)	3	2	1¼
C—Width of grip section, approximate (Notes 4 and 9)	2	¾	⅜

NOTE 1—For the 1½-in. wide specimen, punch marks for measuring elongation after fracture shall be made on the flat or on the edge of the specimen and within the reduced section. Either a set of nine or more punch marks 1 in. apart, or one or more pairs of punch marks 8 in. apart may be used.

NOTE 2—When elongation measurements of 1½-in. wide specimens are not required, a minimum length of reduced section (*A*) of 2¼ in. may be used with all other dimensions similar to those of the plate-type specimen.

NOTE 3—For the three sizes of specimens, the ends of the reduced section shall not differ in width by more than 0.004, 0.002 or 0.001 in., respectively. Also, there may be a gradual decrease in width from the ends to the center, but the width at each end shall not be more than 0.015, 0.005, or 0.003 in., respectively, larger than the width at the center.

NOTE 4—For each of the three sizes of specimens, narrower widths (*W* and *C*) may be used when necessary. In such cases the width of the reduced section should be as large as the width of the material being tested permits; however, unless stated specifically, the requirements for elongation in a product specification shall not apply when these narrower specimens are used.

NOTE 5—The dimension *T* is the thickness of the test specimen as provided for in the applicable material specifications. Minimum thickness of 1½-in. wide specimens shall be 3/16 in. Maximum thickness of ½-in. and ¼-in. wide specimens shall be ⅝ in. and ¼ in., respectively.

NOTE 6—For the 1½-in. wide specimen, a ½-in. minimum radius at the ends of the reduced section is permitted for steel specimens under 100 000 psi in tensile strength when a profile cutter is used to machine the reduced section.

NOTE 7—To aid in obtaining axial loading during testing of ¼-in. wide specimens, the over-all length should be as large as the material will permit, up to 8.00 in.

NOTE 8—It is desirable, if possible, to make the length of the grip section large enough to allow the specimen to extend into the grips a distance equal to two thirds or more of the length of the grips. If the thickness of ½-in. wide specimens is over ⅜ in., longer grips and correspondingly longer grip sections of the specimen may be necessary to prevent failure in the grip section.

NOTE 9—For the three sizes of specimens, the ends of the specimen shall be symmetrical in width with the center line of the reduced section within 0.10, 0.05 and 0.005 in., respectively. However, for referee testing and when required by product specifications, the ends of the ½-in. wide specimen shall be symmetrical within 0.01 in.

NOTE 10—Specimens with sides parallel throughout their length are permitted, except for referee testing, provided: (*a*) the above tolerances are used; (*b*) an adequate number of marks are provided for determination of elongation; and (*c*) when yield strength is determined, a suitable extensometer is used. If the fracture occurs at a distance of less than 2*W* from the edge of the gripping device, the tensile properties determined may not be representative of the material. In acceptance testing, if the properties meet the minimum requirements specified, no further testing is required, but if they are less than the minimum requirements, discard the test and retest.

FIG. 1 Rectangular Tension Test Specimens

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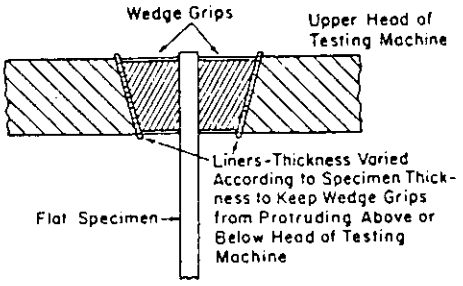

FIG. 2 Wedge Grips with Liners for Flat Specimens

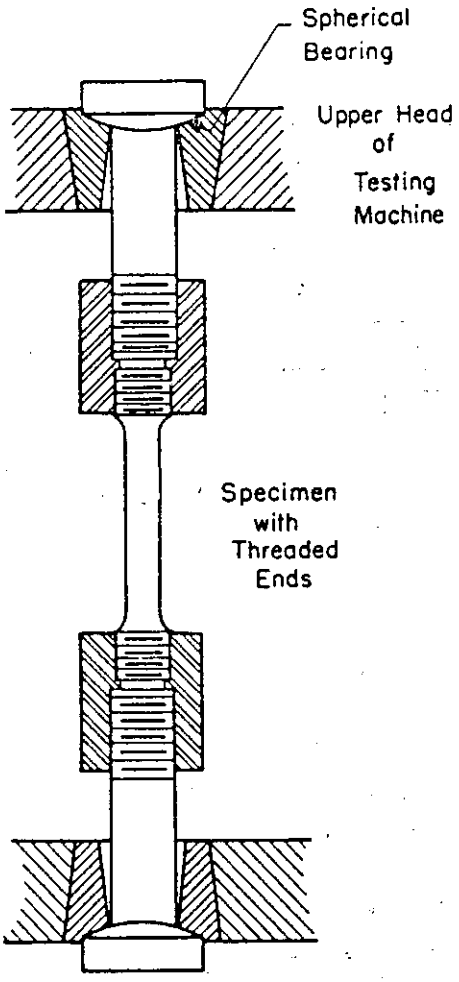

FIG. 3 Gripping Device for Threaded-End Specimens

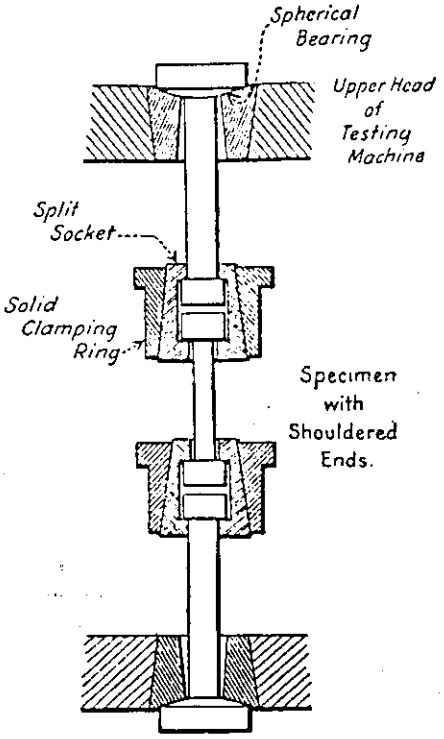

FIG. 4 Gripping Device for Shouldered-End Specimens

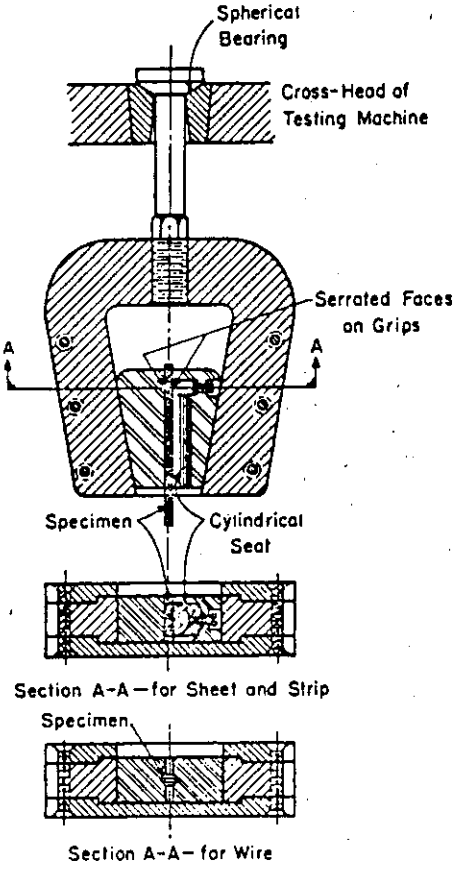

FIG. 5 Gripping Devices for Sheet and Wire Specimens

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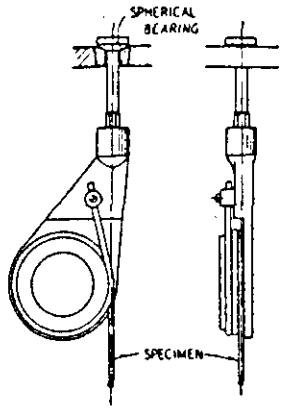
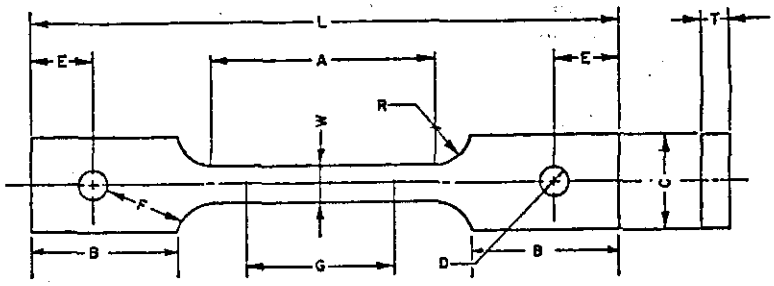


FIG. 6 Snubbing Device for Testing Wire



Dimensions

	in.
G—Gage length	2.000 ± 0.005
W—Width (Note 1)	0.500 ± 0.010
T—Thickness, max (Note 2)	⅝
R—Radius of fillet, min (Note 3)	½
L—Over-all length, min	8
A—Length of reduced section, min	2¼
B—Length of grip section, min	2
C—Width of grip section, approximate	2
D—Diameter of hole for pin, min (Note 4)	½
E—Edge distance from pin, approximate	1½
F—Distance from hole to fillet, min	½

NOTE 1—The ends of the reduced section shall differ in width by not more than 0.002 in. There may be a gradual taper in width from the ends to the center, but the width at each end shall be not more than 0.005 in. greater than the width at the center.

NOTE 2—The dimension *T* is the thickness of the test specimen as stated in the applicable product specifications.

NOTE 3—For some materials, a fillet radius *R* larger than ½ in. may be needed.

NOTE 4—Holes must be on center line of reduced section, within ±0.002 in.

NOTE 5—Variations of dimensions *C, D, E, F,* and *L* may be used that will permit failure within the gage length.

FIG. 7 Pin-Loaded Tension Test Specimen with 2-in. Gage Length

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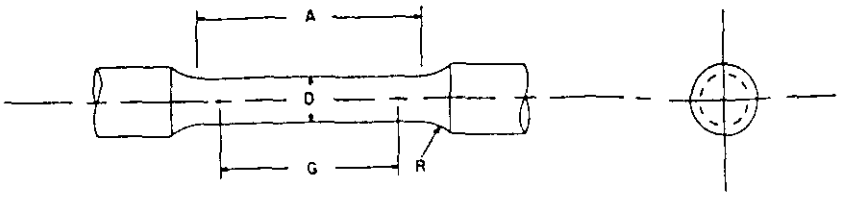


Dimensions

	Standard Specimen	Small-Size Specimens Proportional to Standard			
	in.	in.	in.	in.	in.
Nominal Diameter	0.500	0.350	0.250	0.160	0.113
G—Gage length	2.000 ± 0.005	1.400 ± 0.005	1.000 ± 0.005	0.640 ± 0.005	0.450 ± 0.005
D—Diameter (Note 1)	0.500 ± 0.010	0.350 ± 0.007	0.250 ± 0.005	0.160 ± 0.003	0.113 ± 0.002
R—Radius of fillet, min	3/8	1/4	3/16	5/32	3/32
A—Length of reduced section, min (Note 2)	2 1/4	1 3/4	1 1/4	3/4	5/8

NOTE 1—The reduced section may have a gradual taper from the ends toward the center, with the ends not more than 1 % larger in diameter than the center (controlling dimension).

NOTE 2—If desired, the length of the reduced section may be increased to accommodate an extensometer of any convenient gage length. Reference marks for the measurement of elongation should, nevertheless, be spaced at the indicated gage length.

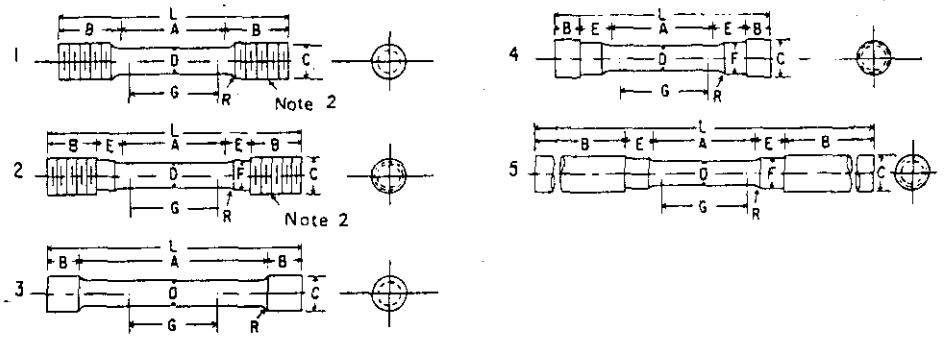
NOTE 3—The gage length and fillets may be as shown, but the ends may be of any form to fit the holders of the testing machine in such a way that the load shall be axial (see Fig. 9). If the ends are to be held in wedge grips it is desirable, if possible, to make the length of the grip section great enough to allow the specimen to extend into the grips a distance equal to two thirds or more of the length of the grips.

NOTE 4—On the round specimens in Figs. 8 and 9, the gage lengths are equal to four times the nominal diameter. In some product specifications other specimens may be provided for, but unless the 4-to-1 ratio is maintained within dimensional tolerances, the elongation values may not be comparable with those obtained from the standard test specimen.

NOTE 5—The use of specimens smaller than 0.250-in. diameter shall be restricted to cases when the material to be tested is of insufficient size to obtain larger specimens or when all parties agree to their use for acceptance testing. Similar specimens require suitable equipment and greater skill in both machining and testing.

NOTE 6—Five sizes of specimens often used have diameters of approximately 0.505, 0.357, 0.252, 0.160, and 0.113 in., the reason being to permit easy calculations of stress from loads, since the corresponding cross-sectional areas are equal or close to 0.200, 0.100, 0.0500, 0.0200, and 0.0100 in.^{2}, respectively. Thus, when the actual diameters agree with these values, the stresses (or strengths) may be computed using the simple multiplying factors 5, 10, 20, 50, and 100, respectively. (The metric equivalents of these five diameters do not result in correspondingly convenient cross-sectional areas and multiplying factors.)

FIG. 8 Standard 0.500-in. Round Tension Test Specimen with 2-in. Gage Length and Examples of Small-Size Specimens Proportional to the Standard Specimen



Dimensions

	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
	in.	in.	in.	in.	in.
G—Gage length	2.000 ± 0.005	2.000 ± 0.005	2.000 ± 0.005	2.000 ± 0.005	2.000 ± 0.005
D—Diameter (Note 1)	0.500 ± 0.010	0.500 ± 0.010	0.500 ± 0.010	0.500 ± 0.010	0.500 ± 0.010
R—Radius of fillet, min	3/8	3/8	1/16	3/8	3/8
A—Length of reduced section	2 1/4, min	2 1/4, min	4, approximately	2 1/4, min	2 1/4, min
L—Over-all length, approximate	5	5 1/2	5 1/2	4 3/4	9 1/2
B—Length of end section (Note 3)	1 3/8, approximately	1, approximately	3/4, approximately	1/2, approximately	3, min
C—Diameter of end section	3/4	3/4	23/32	7/8	3/4
E—Length of shoulder and fillet section, approximate	. . .	5/8	. . .	3/4	5/8
F—Diameter of shoulder	. . .	5/8	. . .	5/8	19/32

NOTE 1—The reduced section may have a gradual taper from the ends toward the center with the ends not more than 0.005 in. larger in diameter than the center.

NOTE 2—On Specimens 1 and 2, any standard thread is permissible that provides for proper alignment and aids in assuring that the specimen will break within the reduced section.

NOTE 3—On Specimen 5 it is desirable, if possible, to make the length of the grip section great enough to allow the specimen to extend into the grips a distance equal to two thirds or more of the length of the grips.

FIG. 9 Various Types of Ends for Standard Round Tension Test Specimens

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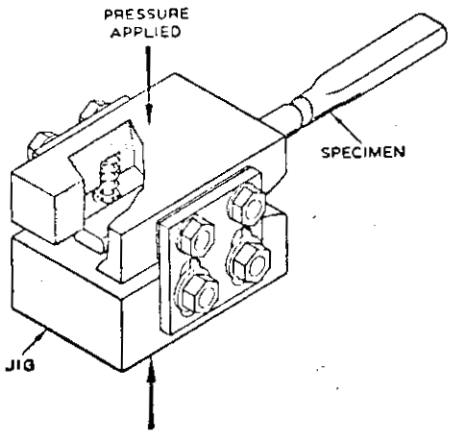
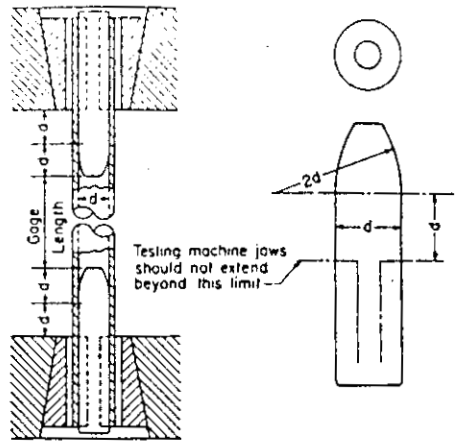
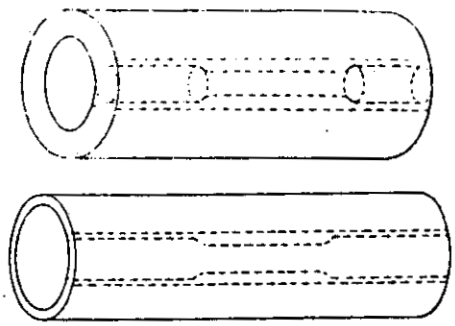


FIG. 10 Squeezing Jig for Flattening Ends of Full-Size Tension Test Specimens



NOTE—The diameter of the plug shall have a slight taper from the line limiting the test machine jaws to the curved section.

FIG. 11 Metal Plugs for Testing Tubular Specimens, Proper Location of Plugs in Specimen and of Specimen in Heads of Testing Machine



NOTE—The edges of the blank for the specimen shall be cut parallel to each other.

FIG. 12 Location from Which Longitudinal Tension Test Specimens Are to be Cut from Large-Diameter Tube

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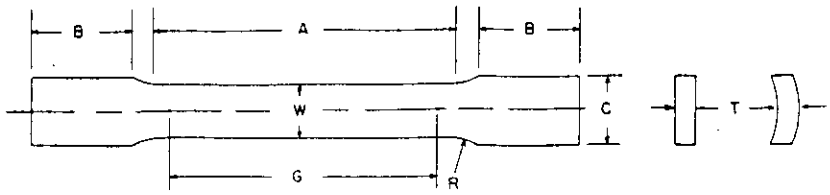


Dimensions

	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	Specimen 6	Specimen 7
	in.	in.	in.	in.	in.	in.	in.
G—Gage length	2.000 ± 0.005	2.000 ± 0.005	8.00 ± 0.01	2.000 ± 0.005	4.000 ± 0.005	2.000 ± 0.005	4.000 ± 0.005
W—Width (Note 1)	0.500 ± 0.010	1½ + ⅛, −¼	1½ + ⅛, −¼	0.750 ± 0.031	0.750 ± 0.031	1.000 ± 0.062	1.000 ± 0.062
T—Thickness	measured thickness of specimen						
R—Radius of fillet, min	½	1	1	1	1	1	1
A—Length of reduced section, min	2¼	2¼	9	2¼	4½	2¼	4½
B—Length of grip section, min (Note 2)	3	3	3	3	3	3	3
C—Width of grip section, approximate (Note 3)	1 1/16	2	2	1	1	1½	1½

NOTE 1—The ends of the reduced section shall differ in width by not more than 0.002 in. for specimen 1, and 4, and not more than 0.005 in. for specimens 2, 3, 5, 6, and 7. There may be a gradual taper in width from the ends to the center, but the width at each end shall be not more than 0.005 in. greater than the width at the center for 2-in. gage length specimens, not more than 0.008 in. greater than the width at the center for 4-in. gage length specimens, and not more than 0.015 in. greater than the width at the center for 8-in. gage length specimens.

NOTE 2—It is desirable, if possible, to make the length of the grip section great enough to allow the specimen to extend into the grips a distance equal to two thirds or more of the length of the grips.

NOTE 3—The ends of the specimen shall be symmetrical with the center line of the reduced section within 0.05 in. for specimens 1, 4, and 5, and 0.10 in. for specimens 2, 3, and 7.

NOTE 4—For circular segments, the cross-sectional area may be calculated by multiplying *W* and *T*. If the ratio of the dimension *W* to the diameter of the tubular section is larger than about ¼, the error using this method to calculate the cross-sectional area may be appreciable and it may be desirable to use a more exact method (see 7.1.3) for determining the area.

NOTE 5—Specimens with *G*/*W* less than 4 should not be used for determination of elongation.

NOTE 6—Specimens with sides parallel throughout their length are permitted, except for referee testing, provided: (*a*) the above tolerances are used; (*b*) an adequate number of marks are provided for determination of elongation; and (*c*) when yield strength is determined, a suitable extensometer is used. If the fracture occurs at a distance of less than 2*W* from the edge of the gripping device, the tensile properties determined may not be representative of the material. If the properties meet the minimum requirements specified, no further testing is required, but if they are less than the minimum requirements, discard the test and retest.

FIG. 13 Tension Test Specimens for Large-Diameter Tubular Products

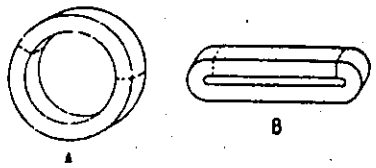
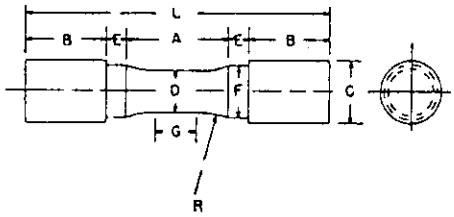


FIG. 14 Location of Transverse Tension Test Specimen in Ring Cut from Tubular Products



Dimensions

	Specimen 1	Specimen 2	Specimen 3
	in.	in.	in.
G—Length of parallel section	Shall be equal to or greater than diameter *D*		
D—Diameter	0.500 ± 0.010	0.750 ± 0.015	1.25 ± 0.02
R—Radius of fillet, min	1	1	2
A—Length of reduced section, min	1¼	1½	2¼
L—Over-all length, min	3¾	4	6⅜
B—Length of end section, approximate	1	1	1¾
C—Diameter of end section, approximate	¾	1⅛	1⅞
E—Length of shoulder, min	¼	¼	5/16
F—Diameter of shoulder	⅝ ± 1/64	15/16 ± 1/64	1 7/16 ± 1/64

NOTE—The reduced section and shoulders (dimensions *A*, *D*, *E*, *F*, *G*, and *R*) shall be as shown, but the ends may be of any form of fit the holders of the testing machine in such a way that the load can be axial. Commonly the ends are threaded and have the dimensions *B* and *C* given above.

FIG. 15 Standard Tension Test Specimen for Cast Iron

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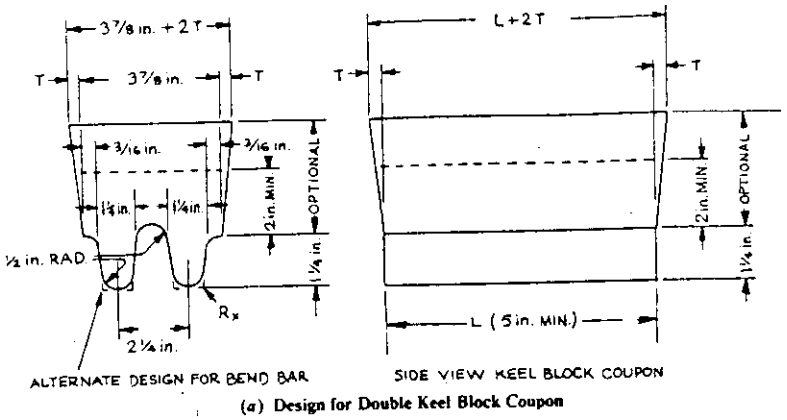
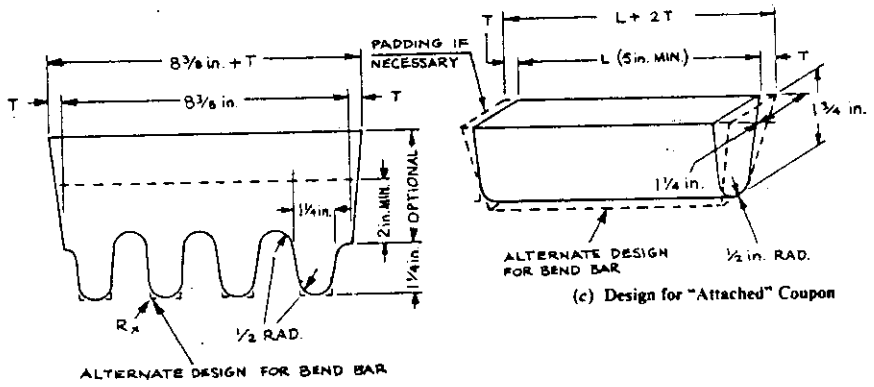


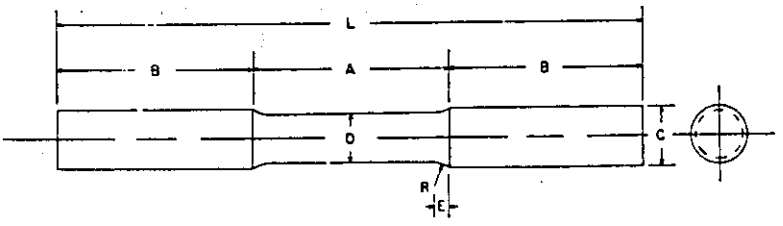
(*a*) Design for Double Keel Block Coupon



(*b*) Design for Multiple Keel Block Coupon (4 Legs)

(*c*) Design for "Attached" Coupon

FIG. 16 Test Coupons for Castings (see Table 1 for Details of Design)



Dimensions

	in.
D—Diameter	⅝
R—Radius of fillet	5/16
A—Length of reduced section	2½
L—Over-all length	7½
B—Length of end section	2½
C—Diameter of end section	¾
E—Length of fillet	3/16

FIG. 17 Standard Tension Test Specimen for Malleable Iron

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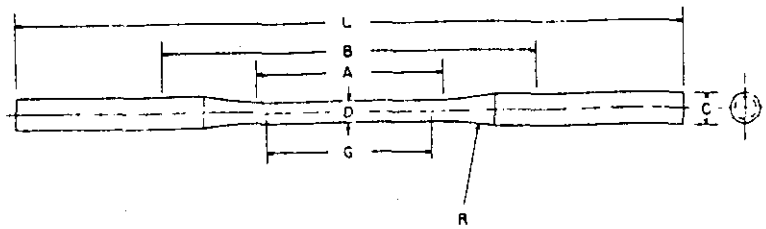
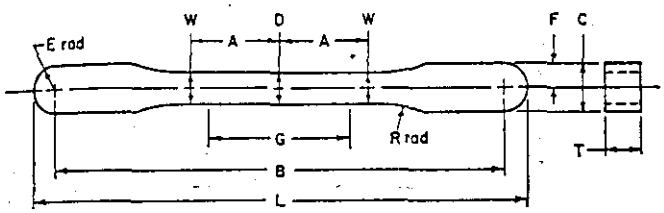


Dimensions

	in.
G—Gage length	2.000 ± 0.005
D—Diameter (see Note)	0.250 ± 0.005
R—Radius of fillet, min	3
A—Length of reduced section, min	2¼
L—Over-all length, min	9
B—Distance between grips, min	4½
C—Diameter of end section, approximate	⅜

NOTE—The reduced section may have a gradual taper from the ends toward the center, with the ends not more than 0.005 in. larger in diameter than the center.

FIG. 18 Standard Tension Test Specimens for Die Castings

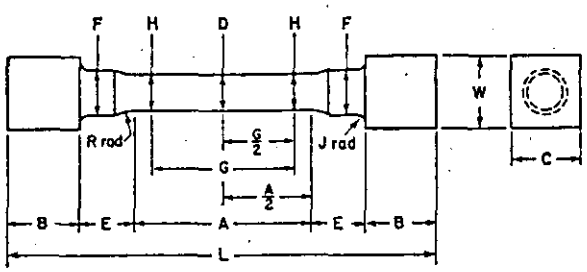


Pressing Area = 1.00 in.²
Dimensions Specified, are Those of the Die

Dimensions

	in.
G—Gage length	1
D—Width at center	0.225 ± 0.001
W—Width at end of reduced section	0.235 ± 0.001
T—Compact to this thickness	0.200 to 0.250
R—Radius of fillet	1
A—Half-length of reduced section	⅝
B—Grip length	3.187 ± 0.001
L—Over-all length	3.529 ± 0.001
C—Width of grip section	0.343 ± 0.001
F—Half width of grip section	0.1715 ± 0.0010
E—End radius	0.171 ± 0.001

FIG. 19 Standard Flat Unmachined Tension Test Specimens for Powdered Metal Products



Pressing Area of Unmachined Compact = 1.5 in.²
Machining Recommendations

1. Rough Machine to 5/16 in. dia
2. Finish Turn 0.250 in. dia with Radii and Taper
3. Polish with 00 Emery Cloth
4. Lap with Crocus Cloth

Dimensions

	in.
G—Gage length	1
D—Diameter at center of reduced section	0.250 ± 0.001
H—Diameter at ends of gage length	0.250 + (0.001/0.002)
R—Radius of fillet	¼
A—Length of reduced section	1¼
L—Over-all length (die cavity length)	3
B—Length of end section	½
C—Compact to this end thickness	0.500 ± 0.050
W—Die cavity width	½
E—Length of shoulder and fillet	⅜
F—Diameter of shoulder	5/16
J—End fillet radius, max	1/16

NOTE—The gage length and fillets of the specimen shall be as shown. The ends as shown are designed to provide a total pressing area of 1.00 in.² Other end designs are acceptable, and in some cases are required for high-strength sintered materials. Some suggested alternative end designs include:

1. *Longer ends, of the same general shape and configuration as the standard,* provide more surface area for gripping.
2. Shallow transverse grooves, or ridges, may be pressed in the ends to be gripped by jaws machined to fit the contour of the specimen.

FIG. 20 Standard Round Machined Tension Test Specimen for Powdered Metal Products

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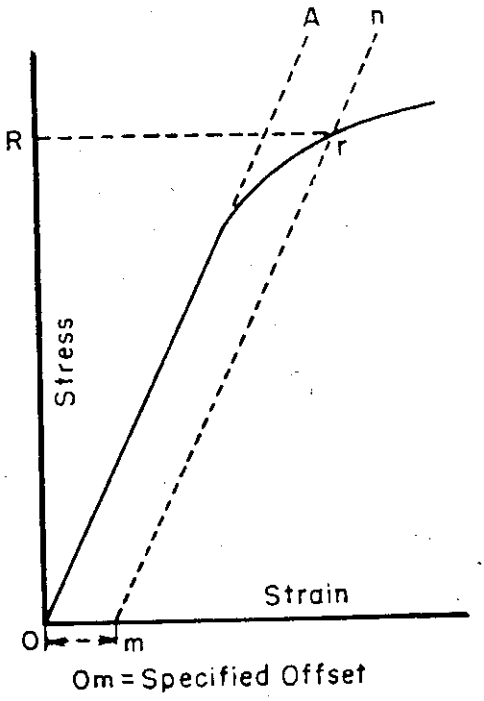

FIG. 21 Stress-Strain Diagram for Determination of Yield Strength by the Offset Method

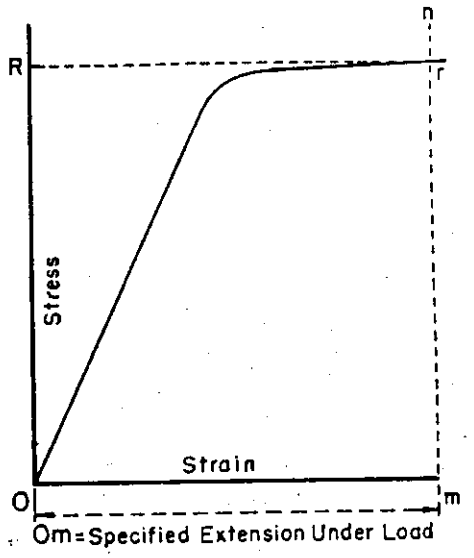

FIG. 22 Stress-Strain Diagram for Determination of Yield Strength or Yield Point by the Extension-Under-Load Method

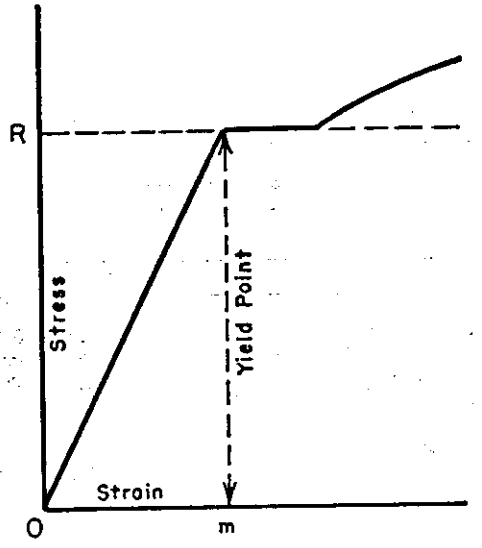

FIG. 23 Stress-Strain Diagram Showing Yield Point Corresponding with Top of Knee

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

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MECHANICAL TEST REPORT

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(b)(4) [redacted] TESTING

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Technical Report

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CONTACT AREA / STRESS ANALYSES
CONDYLAR AND AP LIPPED TIBIAL INSERTS
CS LIPPED TIBIAL INSERT
AND
PATELLA

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

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RANGE OF MOTION / RANGE OF CONSTRAINT TESTING
CONDYLAR AND AP LIPPED TIBIAL INSERTS
CS LIPPED TIBIAL INSERTS

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

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APPENDIX D

PREDICATE DEVICE LABELING

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CE 0473

Howmedica Osteonics Corp
300 Commerce Court
Mahwah, NJ 07430 USA
A Subsidiary of Stryker Corp.

Authorised Representative in Europe
RA/CA Manager, STRYKER® France
BP 50040 – 95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

REF 6630 – 0 – 010 STERILE R | Cast Vitallium® Alloy | LOT **C1212 SAMPLE**

DURACON® Totale knæ PERLEKÆDEAGTIGT fem. kompon XX-SMALL VENSTRE	DURACON® totale knie femurdeel MET RAND EXTRA EXTRA KLEIN, LINKS
Compon. femoral SINTERIZADO p/Joelho Total DURACON® XX-PEQUENO ESQUERDO	
DURACON® Totaalipolvi UURRETTU Reisiluuosa XX-PIENI VASEN	

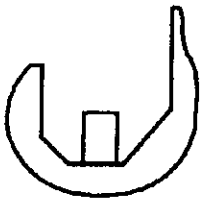
Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002 – 01 Made in Ireland | 2 | 2007 – 01 | U.S. Pat. 4,550,448; 4,834,756, 5,192,324&5,441,537

+E025663000101-

+$C1212SAMPLE-$

REF 6630 – 0 – 010



DURACON® TOTAL KNEE
BEADED Femoral Component
XX-SMALL LEFT

Système total du genou DURACON®
Composant fémoral microbillé
XX-petit, gauche

DURACON® Totalkniesystem
Femurkomponente mit Kugel-
beschichtung, XX-klein, Links

LOT **C1212 SAMPLE** | 2007 – 01

REF 6630 – 0 – 010

LOT **C1212 SAMPLE**

DEVICE IS INTENDED FOR CEMENT USE ONLY IN THE U.S.A.

6XX | 0095-0-270

538

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

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BP 50040 – 95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

REF 6632 – 0 – 210 STERILE R Vitallium® Alloy LOT D6212 SAMPLE

DURACON® Totale knæ Modulær fem. kompon. PORØST VENSTRE SMALL	DURACON® totale knie modulair femurdeel POREUS LINKS, KLEIN
Comp. Fem. Modular POROSO p/Joelho Total DURACON ESQUERDO PEQUENO	
DURACON® Totaalipolvi Modul. reisiluuosa HUOKOINEN VASEN PIENI	

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2003 – 06 Made in Ireland 2 2008 – 06 U.S. Pat. 4,550,448; 4,834,756&5,192,324

+E025663202101/

+$D6212SAMPLE/6

REF 6632 – 0 – 210

R

DURACON® TOTAL KNEE
MODULAR Fem. Compon. POROUS
LEFT SMALL

Système de genou DURACON®
Composant fémoral modulaire
Microbillé, gauche, petit

DURACON® Totalkniesystem
Modular Femur-Komp., zementfrei
Klein, Links

LOT D6212 SAMPLE 2008 – 06

REF 6632 – 0 – 210

LOT D6212 SAMPLE

DEVICE IS INTENDED FOR CEMENT USE ONLY IN THE U.S.A.

KX9 0095-0-270

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

Catalog No. **6642-1-009**

DURACON® TOTAL KNEE

Condylar Tibial Insert

A

- DURATION®
- X-Small
- 9mm Thick

HOWMEDICA OSTEONICS CORP.
Stryker Ireland
Carrigtwohill Industrial Estate,
Carrigtwohill,
Co. Cork,
Ireland

+H825664210090F

+$$8010608TESTF%

Authorized representative in Europe
RA/QA Manager
STRYKER France
BP 50040-95946 Roissy CDG Cedex
FRANCE
Tel.(33) 1.48.17.50.00

2008-06

UHMWPE

STERILE R

CE0473

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

RECORD / REORDER

HOW / OST # **6642-1-009**
DURACON® Total Knee Condylar
Tibial Insert 9mm A

CASE CODE: TEST

ID#:

SAMPLE

I.D.
SN

SAMPLE

WARNING-This Device is Intended for Cemented Use Only in the U.S.A.

572

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Catalog No. **6642-1-509**

DURACON® TOTAL KNEE

A-P Lipped Tibial Insert

A

- DURATION®
- X-Small
- 9mm Thick

HOWMEDICA OSTEONICS CORP.
Stryker Ireland
Carrigtwohill Industrial Estate,
Carrigtwohill,
Co. Cork,
Ireland

+H825664215090K

+$$8010608TESTK4

Authorized representative in Europe
RA/QA Manager
STRYKER France
BP 50040-95946 Roissy CDG Cedex
FRANCE
Tel.(33) 1.48.17.50.00

2008-06

UHMWPE

STERILE R ⚠ CE0473 ⊗

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

RECORD / REORDER

HOW / OST # **6642-1-509**
DURACON® Total Knee A-P
Lipped Tibial Insert 9mm A

CASE CODE: TEST

ID#:

SAMPLE

I.D.
SN

SAMPLE

WARNING-This Device is Intended for Cemented Use Only in the U.S.A.

541

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RA/QA Manager, STRYKER® France
BP 50040 – 95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

REF 6742 – 4 – 009 STERILE R | Duration® Stabilized UHMWPE | LOT D6212 SAMPLE

DURACON® Totale knæ CS Tibialt indlæg m. udbuet kant Extra Small 9mm	DURACON® Total Knie CS Gelipt Tibia-inzetstuk Extraklein 9mm
DURACON® CS p/Joelho Total Insert Tibial c/Rebordo Extra-pequeno, 9 mm	.
DURACON® Totaali polvi CS Reunallinen säänluun sisäke Erittäin pieni 9mm	.

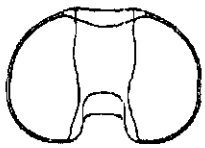
Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2003 – 06 Made in Ireland | 2 | 2008 – 06 | U.S. Pat. 6,372,814 6,174,934; 5,728,748 & 5,543,471

+E0256742400919

+$D6212SAMPLE9I

REF 6742 – 4 – 009



DURACON® Total Knee CS Lipped Tibial Insert Extra Small 9mm
P.tot.gen.DURACON® Insert tibial CS contraint Extra petit 9mm
DURACON® Totalknie CS Tibia-Einsatz mit Lippe Extraklein, 9 mm

LOT D6212 SAMPLE | 2008 – 06

REF 6742 – 4 – 009

LOT D6212 SAMPLE

DEVICE IS INTENDED FOR CEMENT USE ONLY IN THE U.S.A.

6XX

0095-0-270

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

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Howmedica OSTEONICS

CE 0473

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300 Commerce Court
Mahwah, NJ 07430 USA
A Subsidiary of Stryker Corp.

Authorised Representative in Europe
RA/QA Manager, STRYKER® France
BP 50040 – 95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

REF 6632 – 3 – 301 STERILE R | Cast Vitallium® Alloy | LOT **D6212 SAMPLE**

XS-1 DURACON® Totale knæ Korsdannet tibial bundplade SINTRET	XS-1 DURACON® totale knie *kruisvormige* tibiabasisplaat MET RAND
Placa de base tibial cruciforme P/JOELHO TOTAL DURACON® XP-1, SINTERIZADA	
XS-1 DURACON® Tot. polvi Sääriluun ristikkoalusievy UURRETTU	

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2003 – 06 | 2 | 2008 – 06 | U.S. PAT. 4,550,448; 4,834,756; 5,192,324 & 5,441,537

Made in Ireland

+E0256632330111

+$D6212SAMPLE1A

REF 6632 – 3 – 301

XS-1 DURACON® TOTAL KNEE
Cruciform Tibial Baseplate
BEADED

Système total du genou DURACON®
Embase tibiale cruciforme
X-petil-1, microbillé

DURACON® Totalkniesystem
Kreuzschaft Tibiabasisplatte
kugelbeschichtet, XS1,

LOT **D6212 SAMPLE** | 2008 – 06

A

REF 6632 – 3 – 301

LOT **D6212 SAMPLE**

This Tibial Baseplate is NOT compatible with 6630 – Series Tibial Inserts.

Cette embase tibiale n'est PAS compatible avec les inserts tibiaux de série 6630.

Diese Tibiabasisplatte ist NICHT mit den Tibiaeinsätzen des Katalognummernkreises 6630 kompatibel.

Esta placa base tibial NO es compatible con los insertos tibiales de la serie 6630.

La presente base tibiale NON è compatibile con gli inserti tibiali di serie 6630.

Denna tibiala basplatta kan EJ användas tillsammans med tibiala insatser ur 6630 – serie

DEVICE IS INTENDED FOR CEMENT USE ONLY IN THE U.S.A.

6XX 0095-0-270

543
575

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

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Howmedica

REF 6642-2-705

S

DURACON® TOTAL KNEE SYSTEM
CONVERSION PATELLA MEDIUM
DURATION® METALBACKED

Système total genou Duracon®
Conversion rotule, moyenne
Plaquette dos métal Duration®

Duracon® Kompl. Kniesystem
Übergangspatella, mittelgroß
Duration® m/Metallrücks

LOT SAMPLE
SAMPLE

2008-05

Howmedica Osteonics Corp.
300 Commerce Court Mahwah, New Jersey 07430
A Subsidiary of Stryker Corp.

CE 0473

Authorized Representative in Europe:
RA/QA Manager Stryker France
BP 50040-95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

LOT SAMPLE
SAMPLE

REF 6642-2-705 STERILE R Vitallium® Alloy and Dur. Stabil. UHMWPE

DURACON® TOTAL KNEE SYSTEM CONVERSION PATELLA MEDIUM DURATION® METALBACKED	Sistema total ginocchio Duracon® Conversione patella media Lastra rinforz metallo Duration®
Système total genou Duracon® Conversion rotule, moyenne Plaquette dos métal Duration®	Sist total de rodilla Duracon® Conversión rótula mediana c/ref. met. Duration®
Duracon® Kompl. Kniesystem Übergangspatella, mittelgroß Duration® m/Metallrücks	Duracon® Total Knee-system Omvandlingspatella medel Duration® metallbaksida

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2003-05 2008-05 U.S. Pat.
Made in USA

+H825664227051K

+$D5DE SAMPLE KZ

DEVICE IS INTENDED FOR CEMENT USE ONLY IN THE U.S.A.

0095-0-270

KX9

Howmedica

REF 6642-2-705

S

Sistema total ginocchio Duracon®
Conversione patella media
Lastra rinforz metallo Duration®

Sist total de rodilla Duracon®
Conversión rótula mediana
c/ref. met. Duration®

Duracon® Total Knee-system
Omvandlingspatella medel
Duration® metallbaksida

LOT SAMPLE
SAMPLE

2008-05

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CE 0473

Authorized Representative in Europe:
RA/QA Manager Stryker France
BP 50040-95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

LOT SAMPLE
SAMPLE

REF 6642-2-705 STERILE R Vitallium® Alloy and Dur. Stabil. UHMWPE

DURACON® TOTAL KNEE SYSTEM CONVERSION PATELLA MEDIUM DURATION® METALBACKED	Sistema total ginocchio Duracon® Conversione patella media Lastra rinforz metallo Duration®
Système total genou Duracon® Conversion rotule, moyenne Plaquette dos métal Duration®	Sist total de rodilla Duracon® Conversión rótula mediana c/ref. met. Duration®
Duracon® Kompl. Kniesystem Übergangspatella, mittelgroß Duration® m/Metallrücks	Duracon® Total Knee-system Omvandlingspatella medel Duration® metallbaksida

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2003-05 2008-05 U.S. Pat.
Made in USA

544
576

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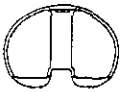
Howmedica

REF 6632-3-715



G

HOWMEDICA® UNIVERSAL™
TIBIAL BASEPLATE BEADED
MEDIUM-1 72mm M/L 48mm A/P

HOWMEDICA® UNIVERSAL™
Embase tibiale microbillée
Moyen-1 72mm M/L 48mm A/P

HOWMEDICA® UNIVERSAL™
Tibiabasisplatte, zementfrei
M1, 72mm M/L 48mm A/P

LOT SAMPLE SAMPLE

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BP 50040-95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

LOT SAMPLE SAMPLE

REF 6632-3-715 STERILE R *Cast Vitallium®* Alloy

HOWMEDICA® UNIVERSAL™ TIBIAL BASEPLATE BEADED MEDIUM-1 72mm M/L 48mm A/P	HOWMEDICA® UNIVERSAL™ BASE TIBIALE MADREPORICA MEDIO-1 72mm M/L 48mm A/P
HOWMEDICA® UNIVERSAL™ Embase tibiale microbillée Moyen-1 72mm M/L 48mm A/P	HOWMEDICA® UNIVERSAL™ Base Tibial Porosa A/P Med.1 72mm M/L 48mm
HOWMEDICA® UNIVERSAL™ Tibiabasisplatte, zementfrei M1, 72mm M/L 48mm A/P	Howmedica® Universal™ Tibiabasplatta porösbelagd Medel-1 72mm m/l 48mm A/P

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2003-05 Made in: USA 2008-05 U.S. Pat. 4,550,448; 5,192,324 & 4,834,756

+H82566323715 1L

+$D5DE SAMPLE L-

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0095-0-270

KX9

Howmedica

REF 6632-3-715

G

HOWMEDICA® UNIVERSAL™
BASE TIBIALE MADREPORICA
MEDIO-1 72mm M/L 48mm A/P

HOWMEDICA® UNIVERSAL™
Base Tibial Porosa A/P
Med.1 72mm M/L 48mm

Howmedica® Universal™
Tibiabasplatta porösbelagd
Medel-1 72mm m/l 48mm A/P

LOT SAMPLE SAMPLE

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RA/QA Manager Stryker France
BP 50040-95946 Roissy CDG Cedex
FRANCE Tel. (33) 1.48.17.50.00

LOT SAMPLE SAMPLE

REF 6632-3-715 STERILE R Cast Vitallium® Alloy

HOWMEDICA® UNIVERSAL™ TIBIAL BASEPLATE BEADED MEDIUM-1 72mm M/L 48mm A/P	HOWMEDICA® UNIVERSAL™ BASE TIBIALE MADREPORICA MEDIO-1 72mm M/L 48mm A/P
HOWMEDICA® UNIVERSAL™ Embase tibiale microbillée Moyen-1 72mm M/L 48mm A/P	HOWMEDICA® UNIVERSAL™ Base Tibial Porosa A/P Med.1 72mm M/L 48mm
HOWMEDICA® UNIVERSAL™ Tibiabasisplatte, zementfrei M1, 72mm M/L 48mm A/P	Howmedica® Universal™ Tibiabasplatta porösbelagd Medel-1 72mm m/l 48mm A/P

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2003-05 Made in: USA 2008-05 U.S. Pat. 4,550,448; 5,192,324 & 4,834,756

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54-577

Label 1 of 1 REF

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stryker
Howmedica
OSTEONICS

Total Knee Joint Replacement Prostheses For Cement Applications

Howmedica Osteonics Corp.
359 Veterans Boulevard
Rutherford, NJ USA 07070
A Subsidiary of Stryker Corp.

Howmedica Osteonics Corp.
300 Commerce Court
Mahwah, NJ 07430
A Subsidiary of Stryker Corp.

Howmedica Osteonics Corp.
Stryker Ireland
Carrigtwohill Industrial Estate
County Cork
Ireland

Authorized Representative in Europe:
RA/QA Manager Stryker France
BP 50040-95946 Roissy CDG Cedex
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TOTAL KNEE JOINT REPLACEMENT
PROSTHESES FOR CEMENT APPLICATIONS

PROTHESES A CIMENTER POUR
ARTHROPLASTIES TOTALES DU GENOU

KNIEGELENKTOTALENDOPROTHESEN
FÜR ZEMENTIERTE ANWENDUNGEN

PROTESI TOTALI RICOSTRUTTIVE DI
GINOCCHIO CON USO DI CEMENTO

SUSTITUCIÓN TOTAL DE LA ARTICULACIÓN DE LA RODILLA
PRÓTESIS PARA APLICACIONES CEMENTADAS

SUBSTITUIÇÃO TOTAL DE ARTICULAÇÃO DO JOELHO
PRÓTESE PARA APLICAÇÕES CIMENTADAS

TOTAL KNÄLEDSPLASTIK
PROTES FÖR CEMENTERAD APPLIKATION

KOKOPOLVINIVELPROTEESI
SEMENTILLISIÄ SOVELLUKSIA VARTEN

FULDSTÆNDIG KNÆLEDS SUBSTITUTIONS
PROTESE TIL CEMENT APPLIKATIONER

VOLLEDIGE KNIEGEWRICHTVERVANGINGI
PROTHESE VOOR CEMENTTOEPASSINGEN

ΟΛΙΚΗ ΑΝΤΙΚΑΤΑΣΤΑΣΗ ΓΟΝΑΤΟΥ
ΠΡΟΘΕΣΕΙΣ ΓΙΑ ΕΦΑΡΜΟΓΕΣ ΜΕ ΤΣΙΜΕΝΤΟ

人工膝関節全置換術
セメント使用人工関節

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English

PACKAGE INSERT

ATTENTION OPERATING SURGEON

The advancement of total knee replacement has provided the surgeon with a means of restoring mobility, correcting deformity, and reducing pain with the use of implanted prosthetic devices. These devices, while proven successful, are manufactured from metal and plastic materials. No prosthetic device can therefore be expected to withstand activity levels and loads in the same way as would a normal healthy joint. The prosthetic system, therefore, will not be as strong, reliable, or durable as a natural human knee joint.

In using total knee joint implants, the surgeon should be aware of the following:

A. **The correct selection and positioning of the implant is extremely important.** Success in total joint replacement requires the selection of the proper size, shape, and designed implants. Total joint prostheses require careful seating, rigid fixation and adequate bone support.

B. **In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:**

1) **The patient's weight.** An overweight or obese patient can produce higher loads on the prosthesis which can lead to failure of the device. The effect of these loads will be accentuated when a small sized prosthesis must be used because of bone size in such patients.

2) **The patient's occupation or activity.** If the patient is involved in an occupation or activity which includes significant impact loads (walking, running, lifting or twisting), the resultant forces can cause failure of the fixation, the device, or both. High levels of physical activities over the course of years can also accentuate the normal wear that occurs with prosthetic joints. The prosthesis will not restore function to the level expected with a normal healthy joint, and the patient should not have, and should be disabused of, unrealistic functional expectations. (See **PRECAUTIONS** section for more information.)

3) **A condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

4) **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

5) **Orthopaedic history.** The prognosis for success of the procedure is dependent upon the patient's orthopaedic history. Patients who have had multiple previous procedures and/or implants should be carefully counseled regarding the anticipated outcome of the procedure.

6) **Quality of bone.** Survivorship of the total knee replacement may be affected by weakened bone stock, which may be the result of certain systemic or metabolic diseases such as those treated with steroids, immunosuppressants or chemotherapeutics.

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DESCRIPTION

Howmedica manufactures a wide variety of tricompartment reconstructive knee systems in various sizes and styles to accommodate various patient and surgeon requirements for primary and revision cemented applications. The selection of the prosthesis system is dependent upon the type of surgery required. Femoral, tibial and patellar components
are available for knee reconstruction. The metallic components (the femoral component, tibial and patellar baseplates, sintered beads, wedges and spacers) are manufactured from cast cobalt-chromium-molybdenum alloy (Vitallium® Alloy) conforming to ASTM standard F75. The screws and stem extenders are manufactured from wrought cobalt-chromium-molybdenum alloy (Vitallium® Alloy) conforming to ASTM standard F1537.

The polyethylene components are manufactured from ultra-high-molecular-weight polyethylene (UHMWPE) conforming to ASTM standard F648.

Femoral Components

Femoral components (except superstabilizer) are available with porous and non-porous coated options, condylar, stabilizer and superstabilizer configurations. Certain femoral components can be converted from one configuration to another, e.g., condylar to stabilizer, by the addition of a modular stabilizer box.

Tibial Components

The tibial components are available in a wide range of sizes and thicknesses. Tibial components include one piece all-polyethylene and modular styles consisting of a polyethylene insert and metallic baseplate. The baseplates are available with porous and non-porous coating options and adjunct fixation options. The inserts are available with varying degrees of constraint in the condylar styles, stabilizer and superstabilizer configurations.

Patellar Components

The patellar components are available in all-polyethylene or metal-backed with porous coating.

Accessories

Stem extenders are designed to attach to the stem of the femoral or tibial component to provide additional stability. Wedges are designed for cemented applications to provide additional spacing where there are tibial bone defects. Spacers are designed to provide additional spacing where there are femoral bone defects and may be mechanically secured to the femoral component or cemented in place. Screws are available for adjunct assembly of tibial inserts to baseplates or tibial baseplate to tibial bone.

Product label

The product label provides information regarding the specific material(s) from which the device is manufactured.

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INDICATIONS

Indications for use of total knee replacement prostheses include:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
2) rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed;
5) post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
6) irreparable fracture of the knee.

CONTRAINDICATIONS

Absolute contraindications include:

1) overt infection;
2) distant foci of infections (which may cause hematogenous spread to the implant site);
3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4) skeletally immature patients;
5) cases where there is poor bone stock which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

1) uncooperative patient or patient with neurological disorders who is incapable of following instructions;
2) osteoporosis;
3) metabolic disorders which may impair bone formation;
4) osteomalacia; and,
5) previous arthrodesis.

A higher incidence of implant failure has also occurred in paraplegics, cerebral palsy and patients with Parkinson's disease.

WARNINGS

Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions and reduced service life of the prosthetic implant. The surgeon should be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

Cemented application. Care should be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Complete cleaning (complete removal of bone chips,

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bone cement fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articulating surfaces of the implant.

Prosthetic components. Femoral, tibial and patellar components of different prosthetic systems, or from different manufacturers, should not be mixed, since tolerances or materials may be incompatible. Modular components must be assembled securely to prevent disassociation. Repeated assembly and disassembly of the modular components could compromise the critical locking action of the components and should be avoided. Surgical debris must be cleaned from components before assembly. Debris may interfere with the locking mechanism of modular components, which in turn may lead to early failure of the procedure.

Patella Component. Because the patella component has the smallest bearing and fixation surfaces, the patella or patella component is more vulnerable to subluxation and loosening/dislocation. Particular attention, during surgery, to patella tracking is necessary for success of the procedure.

Fixation screws. Fixation screws, when used, should be fully seated to maximize stable fixation. and to avoid interference with the proper seating of components. Use only screws recommended for the specific prosthesis to avoid improper fit, and to avoid improper mixing of metals. These bone screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Metal components. Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such a phenomenon, in spite of the millions of implants in use. (See reference 1.)

Alignment of components. Care should be taken to restore the proper joint alignment and to balance ligamentous tension. Misalignment of the limb or joint can cause excessive wear, loosening of the prosthesis and pain leading to earlier-than-desired revision of one or more of the prosthetic components.

Polyethylene wear. As would be expected, wear of the polyethylene surfaces of tibial and patella components has been reported following total knee replacement. Higher rates of wear may be initiated by particles of cement, metal or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear likely will shorten the useful life of the prosthesis, and lead to an earlier-than-desired revision to replace the worn prosthetic components.

PRECAUTIONS

Information for patients. The patient should be advised of the short and long term limitations of the procedure and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

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The patient should be cautioned to limit activities, protect the replaced joint from unreasonable stresses and follow the instructions of the physician with respect to post-op care and treatment.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device cannot and does not replicate a normal healthy joint, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device has a finite expected service life and may need to be replaced at some time in the future.

Transient bacteremia *can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have also been associated with transient bacteremia. To prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.*

Instruments. Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components.

While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage, prior to surgery.

Re-use. An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.

Handling. Handling of implants is important, particularly porous coated implants. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials. All implants where the coating has been damaged or contaminated should be discarded. The highly polished portion of the implant should not come in contact with hard surfaces.

ADVERSE EFFECTS

1) With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around or remote from the prosthetic components as a consequence of foreign body reaction to particulate matter. Particulate matter is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondarily, particulate matter can also be generated by third-body wear. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. (See **IMPORTANT PHYSICIAN INFORMATION** section for more information.)
2) Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in cellular reactions that may include lymphocytes, macrophages and fibroblasts.
3) Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may be a result of surgical trauma.
4) *Dislocation and subluxation of implant components can result from improper*

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pectoralis major and/or muscle, joint capsule and/or soft tissue including muscle, fibrous tissue and ligaments can also contribute to these conditions.

5) Implants can loosen or migrate due to trauma or loss of fixation.
6) Infection can lead to failure of the joint replacement.
7) *While rare, fatigue fracture of the implant can occur as a result of trauma,* strenuous activity, improper alignment or extreme duration of service.
8) Soft tissue (ligamentous) imbalance can cause excessive wear and/or failure of the implant.
9) Intraoperative fracture of the femur, tibia or patella can occur while preparing the bone sites and/or seating of the implants.
10) Allergic reactions to the materials utilized in the implant, although uncommon, can occur.

Intraoperative and early postoperative complications can include, but are not limited to:

1) deep venous thrombosis;
2) damage to blood vessels;
3) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
4) a sudden drop in intraoperate blood pressure associated with the use of bone cement;
5) varus-valgus deformity with resultant limb/prosthesis malalignment;
6) *cardiovascular disorders including, pulmonary embolism or myocardial* infarction;
7) hematoma;
8) delayed wound healing;
9) *deep wound infection (early or late), a potentially serious complication of all* joint replacement which may necessitate removal of the prosthesis and subsequent arthrodesis. Appropriate antibiotic prophylaxis and strict adherence to aseptic procedures is mandatory; and,
10) femoral, tibial or patella bone or component fracture.

Late postoperative complications can include, but are not limited to:

1) late (or early) loosening, change in position of the components, wear, and bending or cracking of one or more prosthetic components. (Clinical experience suggests that particular attention to the items contained in the Warnings *and Precautions* sections of this package insert may help minimize the risk of their occurring.).
2) patellar fracture as a result of excess tension, or inadvertent intraoperative weakenin
3) aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy;
4) late ligamentous instability;

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5) periarticular calcification or ossification, with or without impediment to joint motion;
6) inadequate range of motion due to improper selection or positioning of components, impingement or periarticular calcification and dystrophy; and,
7) bone fractures, dislocation, subluxation, flexion contracture, decreased range of motion, or lengthening or shortening of the leg, all of which have been reported in association with total knee replacement.

IMPORTANT PHYSICIAN INFORMATION

A. **Bone Resorption and Osteolysis.** Bone resorption can occur as a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Localized progressive bone resorption due to reasons other than stress shielding or infection may occur around the prosthetic components as well as between the components and bone, and this has been termed osteolysis. It is generally agreed that osteolysis is a result of localized foreign-body reaction to particulate debris (e.g., cement, metal, UHMWPE, and ceramics), generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Regarding the etiology, it has been hypothesized that particulate debris generated by articulation of the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris as well as the rate of debris generation. The phagocytic action has been demonstrated in vitro to induce release of cytokines and cellular mediators (IL-1, IL-2, IL-6, PGE2, TNF3). These mediators have been shown to modulate osteoclastic bone resorption. Clinical and basic research is continuing in order to better understand the scientific basis for the causes of this phenomenon and explore potential ways to reduce its occurrence.

   Since osteolysis is frequently asymptomatic, routine periodic radiographic examination is vital to help detect and minimize any serious future complication. However, radiographs may not completely define the extent of osteolysis. Presence of focal lesions which are progressive may necessitate replacement of the prosthetic component(s).

B. **Polyethylene Thickness.** Theoretical analyses have indicated that contact stresses in the tibial component vary with the thickness of the polyethylene component. In general, thicker inserts are thought to have lower contact stresses than thinner ones. These stresses may affect the wear of the implant components; however, the clinical implications of the theoretical stress differences have not been conclusively established. The physician should consider the trade-off between additional tibial bone resection and the use of a thicker insert. Patient related factors, such as weight, age and activity level should be part of the decision.

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C. **Component Matching.** There are corresponding tibial widths designed to articulate and conform with the appropriately-sized femoral components. Failure to correctly match components may result in improper fit of the tibial component and contribute to joint laxity.

D. **Product Label.** See product label for information regarding the specific product referenced in this package insert.

HOW SUPPLIED

These products are delivered sterile in containers which have been exposed to a minimum of 25 kGy of gamma radiation from a cobalt 60 source. The package of all sterile products should be examined prior to use for possible breaks in the sterile barrier.

RESTERILIZATION

Devices containing POLYETHYLENE, POROUS COATING, PLASMA SPRAY, HYDROXYAPATITE, CERAMICS or METHYLMETHACRYLATE CANNOT BE AUTOCLAVED OR RESTERILIZED BY THE USER.

Components that have **not** been contaminated with fluids, in particular body fluids, can be resterilized using the following parameters in a gravity displacement steam autoclave:

	250° F (121° C) 20 PSI (1.4 Bars)	270° F (132° C) 30 PSI (2 Bars)
Wrapped individual Component (single or multi component) or Sterilization Case	40 minutes	20 minutes

The double wrapping method used is the AAMI CSR technique. These cycles were developed with only this item in the chamber and using the middle shelf. Any cycle should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

CAUTION

Federal Law in the USA restricts this device to sale by or on the order of a physician.

REFERENCES

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study In Sweden," Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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INFORMATION DESTINÉE AU CHIRURGIEN

Grâce aux progrès réalisés dans le domaine des arthroplasties totales du genou, le chirurgien peut maintenant rétablir la mobilité, corriger les déformations et réduire la douleur en ayant recours à des implants prothétiques. Le succès incontesté de ces implants ne doit pas faire oublier qu'ils sont fabriqués à partir de matériaux métalliques ou plastiques. On ne peut donc pas demander à un implant prothétique de supporter des niveaux d'activités et de charges équivalents à une articulation saine. Une prothèse ne saurait être aussi résistante, fiable ou durable que l'articulation anatomique humaine du genou.

Le chirurgien qui envisage d'implanter une prothèse totale du genou ne doit pas ignorer les éléments suivants :

A. **Il est très important de bien choisir et de bien positionner l'implant.** Le succès d'une arthroplastie passe par la sélection d'un implant adapté de par sa taille, sa forme et sa géométrie. Une prothèse articulaire totale requiert un positionnement précis, une fixation rigide, et un support osseux adéquat.

B. **Pour poser une indication d'arthroplastie totale, il importe de prendre en compte plusieurs facteurs dont dépend largement l'éventuel succès de l'intervention :**

1) **Poids du patient.** Si le patient est en surcharge pondérale ou obèse, des charges trop importantes peuvent solliciter l'implant qui risque alors de se rompre. L'effet de ces charges se verra amplifié si l'on est contraint d'utiliser une prothèse de petite taille adaptée à l'ossature de ces patients.

2) **Travail ou activité du patient.** Si le travail ou l'activité du patient l'obligent à fournir des efforts significatifs (tels que marcher, courir, soulever des charges ou subir des torsions), les forces résultantes peuvent provoquer la rupture de la fixation, du dispositif ou des deux à la fois. Une activité physique intense et soutenue pendant plusieurs années peut également accentuer l'usure normale des prothèses articulaires. Une prothèse ne permet pas de rétablir la fonction d'un os sain et le patient devra en être informé afin que ses attentes de récupération fonctionnelle ne dépassent pas la réalité. (Pour plus d'informations, se reporter au paragraphe **PRECAUTIONS**).

3) **Sénilité, maladie mentale ou alcoolisme.** Ces états peuvent, parmi d'autres, faire que le patient ne respecte pas certaines précautions ou limites imposées par l'utilisation de l'implant, avec pour conséquence sa rupture ou d'autres complications.

4) **Réaction à corps étrangers.** Lorsque l'on soupçonne des allergies, il faut procéder à des tests avant de choisir le matériau ou de procéder à l'implantation.

5) **Antécédents orthopédiques.** Les chances de succès d'une arthroplastie totale dépendent des antécédents orthopédiques du patient. Dans le cas

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cas d'un patient qui aurait déjà subi plusieurs interventions et plusieurs poses d'implants, une préparation psychologique sérieuse quant aux chances de succès d'une réintervention est indispensable.

6) **Qualité de l'os.** La durabilité d'une arthroplastie totale du genou peut se voir réduite par un stock osseux de mauvaise qualité, imputable à certaines maladies systémiques ou métaboliques comme celles que l'on traite par des stéroïdes, des immunosuppresseurs ou des chimiothérapies.

DESCRIPTION

Howmedica fabrique une large gamme de prothèses tricompartimentales de reconstruction du genou, dans des tailles et des modèles variés, de manière à répondre aux différents besoins des patients et des chirurgiens pour les cas d'implantations cimentées de première intention ou de reprise. Le choix de la prothèse dépend du type d'intervention requis. On dispose, pour la reconstruction du genou, de pièces fémorales, tibiales et rotuliennes. Les pièces en métal (composant fémoral, embases tibiales ou rotuliennes, billes frittées, cales ou butées d'espacement) sont fabriquées à partir d'un alliage coulé de chrome-cobalt-molybdène (alliage Vitallium®) conforme à la norme ASTM F75. Les vis et les tiges allonges sont fabriquées à partir d'un alliage forgé de chrome-cobalt-molybdène (alliage Vitallium®) conforme à la norme ASTM F1537. Les composants en polyéthylène sont fabriqués à partir de polyéthylène à très haute masse moléculaire (UHMWPE) conforme à la norme ASTM F648.

Composants fémoraux

Les composants fémoraux sont disponibles en différents modèles : Condylien, Stabilisé ou Superstabilisé ; et en revêtement poreux ou non poreux (à l'exception du Superstabilisé). Certains composants fémoraux sont modulables : il suffit par exemple de leur ajouter un boîtier de stabilisation modulaire pour les transformer de Condyliens en Stabilisés.

Composants tibiaux

Ces composants existent dans une vaste gamme de tailles et d'épaisseurs. Il s'agit soit d'une pièce unique tout en polyéthylène, soit d'un composant modulaire qui comprend un insert en polyéthylène et une embase métallique. Les embases sont disponibles en revêtement poreux et revêtement non poreux, et en différentes *options de fixation complémentaire*. Les inserts peuvent être plus ou moins contraints, suivant le modèle choisi: Condylien, Stabilisé, ou Superstabilisé.

Composants rotuliens

Les composants rotuliens existent en deux versions : soit entièrement polyéthylène, soit metal-back avec revêtement poreux.

Accessoires

Les tiges allonges sont destinées à être fixées à l'extrémité de la pièce fémorale ou de la pièce tibiale pour accroître leur stabilité. Les cales sont destinées aux applications cimentées, et permettent d'obtenir un espacement supplémentaire dans les cas de pertes osseuses tibiales. Les butées permettent d'obtenir un espacement supplémentaire dans les cas de pertes osseuses fémorales ; on peut les fixer à la pièce fémorale

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par des moyens mécaniques ou les cimenter en position. Il existe des vis permettant de fixer les insertes aux composantes tibiales [illegible]

Étiquette du produit

L'étiquette de ce produit contient les informations nécessaires concernant les matériaux de fabrication spécifiques de ce dispositif.

INDICATIONS

Les indications d'emploi des prothèses totales de genou sont les suivantes :

1) les arthropathies dégénératives non inflammatoires, notamment la gonarthrose, l'arthrose post- traumatique ou la nécrose avasculaire ;
2) l'arthrose rhumatoïde ;
3) la correction d'une difformité fonctionnelle ;
4) les interventions de reprise lorsque le traitement ou l'implant antérieurs ont échoué ;
5) les lésions anatomiques de l'articulation suite à un traumatisme, surtout dans les cas d'érosion fémoro-patellaire, de dysfonctionnement ou de patellectomie antérieure; et
6) la fracture irréparable du genou.

CONTRE-INDICATIONS

Les cas suivants constituent des contre-indications absolues :

1) une infection patente ;
2) des foyers infectieux distants (qui peuvent causer une propagation hématogène au niveau du site d'implantation) ;
3) une évolution rapide de la maladie qui se manifeste par la destruction de l'articulation ou une résorption osseuse apparente sur les clichés radiologiques ;
4) les patients dont le squelette est immature ;
5) lorsque le capital osseux est de mauvaise qualité, ce qui rendrait la procédure injustifiable.

Parmi les cas présentant un risque d'échec accru, on citera :

1) les patients difficiles, ou les patients souffrant de troubles neurologiques, incapables de respecter les instructions ;
2) l'ostéoporose;
3) les troubles du métabolisme qui risqueraient de compromettre la repousse osseuse ;
4) l'ostéomalacie; et
5) une arthrodèse antérieure.

On a constaté une plus grande incidence d'échecs d'implants chez les paraplégiques, les patients atteints d'infirmité motrice cérébrale, et les patients atteints de la maladie de Parkinson.

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MISES EN GARDE

Une erreur de sélection, de pose, de positionnement ou de fixation des composants prothétiques risque de créer des contraintes inhabituelles et de diminuer la longévité de l'implant. Il importe que le chirurgien se familiarise avec la technique opératoire, l'ancillaire et les caractéristiques de l'implant choisi avant de réaliser l'intervention. Il est recommandé d'assurer un suivi périodique et à long terme du patient, de manière à surveiller le positionnement et l'état de la prothèse ainsi que l'état de l'os environnant.

Prothèse cimentée. On veillera à ce que les différentes parties de la prothèse qui sont scellées dans le ciment osseux soient complètement soutenues, de manière à éviter des concentrations de contraintes qui pourraient faire échouer l'intervention. Il est indispensable de nettoyer entièrement le site d'implantation (en enlevant tous les copeaux d'os, les fragments de ciment chirurgical et les débris métalliques) afin d'éviter une usure précoce des surfaces articulaires de l'implant.

Pièces prothétiques. On veillera à ne pas mélanger les composants fémoraux, tibiaux et rotuliens appartenant à des systèmes prothétiques différents, ou provenant de fabricants différents, pour ne pas risquer des incompatibilités de matériaux ou des intolérances. On prendra soin également d'assembler solidement les composants modulaires pour éviter leur dissociation. On évitera de monter et de démonter à plusieurs reprises les composants modulaires afin de ne pas endommager leur mécanisme de verrouillage. Des débris pourraient entraver ce mécanisme et cela pourrait entraîner l'échec précoce de l'intervention.

Composant rotulien. Ses surfaces d'appui et de fixation étant les plus petites, le composant ou médaillon rotulien est le plus susceptible de subluxation et de descellement/luxation. On accordera donc un soin tout particulier au mouvement de la rotule dans le rail trochléen pendant l'intervention, afin d'assurer son succès.

Vis de fixation. Les vis de fixation, si utilisées, doivent être entièrement installées afin d'assurer une fixation stable et d'éviter une interférence avec la propre disposition des composants. Ces vis ne doivent pas être utilisées pour la fixation à des éléments postérieurs (pédicules) de la colonne cervicale, dorsale ou lombaire.

Composants en métal. Certains des alliages utilisés dans la fabrication des implants orthopédiques contiennent des éléments métalliques pouvant être carcinogènes sur des cultures tissulaires ou des organismes intacts, dans des situations bien particulières. La littérature scientifique s'est interrogée sur l'éventuelle carcinogénicité de ces alliages pour les receveurs d'implant. Les études conduites sur le sujet n'ont pas permis d'apporter des preuves convaincantes d'un tel phénomène, malgré les millions de dispositifs déjà implantés. (cf. Bibliographie 1).

Alignement des composants. On veillera à rétablir l'alignement de l'articulation et à équilibrer la tension des ligaments. Un mauvais alignement du membre ou de l'articulation peut entraîner une usure excessive, un descellement de la prothèse et des douleurs qui obligeront à procéder à la révision précoce de l'un ou de plusieurs composants prothétiques.

Usure du polyéthylène. On ne s'étonnera pas d'observer un certain phénomène d'usure des surfaces en polyéthylène des pièces tibiales et rotuliennes dans les arthro-

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plasties totales du genou. Des taux d'usure plus élevés peuvent être dus à des particules de ciment, de métal ou d'autres débris nuisibles. Des taux de lésions tissulaires et d'usure plus élevés risquent de réduire la longévité de la prothèse et de conduire à une révision précoce afin de remplacer les composants prothétiques usés.

PRECAUTIONS

Information au patient. Il convient d'expliquer au patient les limites à court et à long terme de l'intervention et la nécessité d'attendre qu'une fixation et une cicatrisation correctes soient intervenues pour soumettre l'implant à une mise en charge complète. Une activité excessive ou un traumatisme de l'articulation prothésée peuvent entraîner l'échec de la reconstruction articulaire par descellement, fracture ou /et usure des implants prothétiques. Le descellement des pièces prothétiques peut entraîner une production accrue de particules d'usure, et endommager l'os, ce qui rendrait une éventuelle reprise plus difficile.

On conseillera au patient de réduire ses activités, de ne pas soumettre la prothèse à des sollicitations excessives, et de respecter les instructions de son médecin quant aux soins et traitements postopératoires.

On avertira le patient des risques chirurgicaux et on l'informera quant aux effets indésirables possibles. On lui expliquera qu'une prothèse ne saurait être l'égale d'une articulation saine, qu'un implant peut se fracturer ou être endommagé par des activités trop intenses ou par un traumatisme, et enfin qu'une prothèse a une durée de vie limitée et qu'il pourra s'avérer nécessaire de la remplacer un jour ou l'autre.

Des bactériémies passagères peuvent survenir dans la vie quotidienne. Elles peuvent notamment être liées à des soins dentaires, des examens endoscopiques et autres interventions chirurgicales mineures. Pour prévenir une infection sur le site d'implantation on pourra envisager une prophylaxie antibiotique avant et après de telles interventions.

Instrumentation. Il existe une instrumentation spécifique et elle doit être utilisée afin de garantir la précision de l'implantation des pièces prothétiques.

Même s'il s'agit d'un incident rare, il peut arriver que l'on brise ou casse les instruments en per-opératoire. Un ancillaire qui a beaucoup servi ou qui a été soumis à des forces excessives peut se rompre. On vérifiera les instruments au niveau résistance ou dommage avant l'intervention.

Réutilisation. Il ne faut jamais réutiliser un implant. Même s'il semble intact, un implant déjà utilisé peut présenter des défauts ou une atteinte latente de son intégrité qui pourraient réduire sa durée de vie.

Manipulation. La manipulation des implants est importante, surtout celle des implants à revêtement poreux. Veillez à ne pas mettre les surfaces poreuses en contact avec des étoffes ou des matériaux qui perdent leurs fibres. Rejetez tout implant dont le revêtement est endommagé ou contaminé. La partie hautement polie de l'implant ne doit pas être mise en contact avec des surfaces dures.

EFFETS INDESIRABLES

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1) Dans toutes les arthroplasties, il peut se produire une résorption osseuse (ostéolyse) asymptomatique, localisée et progressive, à la périphérie ou à

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distance des implants prothétiques, suite à une réaction à corps étrangers déclenchée par des débris [illegible] sont le résultat du frottement des pièces prothétiques entre elles et sur l'os, et sont produits surtout par un mécanisme d'usure par adhésion, abrasion, et fatigue. Dans une moindre proportion, ces débris peuvent également être dus à un phénomène d'usure par un troisième corps. L'ostéolyse peut être la cause de complications ultérieures qui demanderont l'explantation et le remplacement des composants prothétiques. (Se référer à la section intitulée **"INFORMATION MEDICALE IMPORTANTE"** pour plus de détails.

2) Bien qu'étant rares, des cas d'allergie au métal ont été observés après une arthroplastie. L'implantation de matériaux étrangers dans les tissus peut déclencher des réactions cellulaires telles que la formation de lymphocytes, de macrophages et de fibroblastes.
3) On a observé des cas de neuropathies périphériques suite à des arthroplasties totales. Des cas de lésions nerveuses subcliniques sont parfois constatés, imputables peut-être au traumatisme chirurgical.
4) La luxation et la subluxation des pièces prothétiques peuvent être dues à leur mauvais positionnement et/ou à leur migration. L'hyperlaxité des muscles, du tissu fibreux et des ligaments peut également être un facteur contribuant.
5) Les implants peuvent se descceller ou migrer sous l'effet d'un traumatisme ou d'une perte de la fixation.
6) Une infection peut entraîner l'échec de l'arthroplastie.
7) Bien qu'étant rare, la fracture en fatigue de l'implant peut survenir sous l'effet d'un traumatisme, d'une activité trop intense, d'un mauvais alignement ou d'une durée de service extrême.
8) Un déséquilibre (ligamentaire) dans les parties molles peut entraîner une usure excessive de l'implant, voire même sa rupture.
9) La fracture, en per-opératoire, du fémur, du tibia ou de la rotule peut survenir lors de la phase de préparation des sites osseux et/ou lors de l'implantation.
10) Bien qu'étant rares, des réactions allergiques aux matériaux de l'implant peuvent se produire.

Parmi les risques de complications per-opératoires et postopératoires précoces on citera notamment :

1) une thrombose veineuse profonde ;
2) une lésion au niveau des vaisseaux sanguins ;
3) des lésions nerveuses temporaires ou permanentes qui entraînent des douleurs ou un engourdissement du membre affecté ;
4) une chute soudaine, en per-opératoire, de la pression sanguine, liée à l'emploi de ciment chirurgical ;
5) une déformation en varus-valgus qui entraîne un mauvais alignement membre/prothèse;

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6) des troubles cardio-vasculaires, notamment embolie pulmonaire ou infarctus du myocarde ;
7) un hématome ;
8) un retard de cicatrisation ;
9) une infection profonde de la plaie (précoce ou tardive) est un risque de complication grave pour toute arthroplastie et pouvant nécessiter l'ablation de la prothèse suivie d'une arthrodèse. Une prophylaxie antibiotique adaptée s'impose ainsi qu'un respect scrupuleux des règles d'asepsie. Enfin,
10) la fracture du fémur, du tibia ou de la rotule, ou la rupture des pièces prothétiques.

Parmi les complications postopératoires tardives, on citera notamment :

1) le descellement tardif ou précoce, la migration des composants prothétiques, l'usure, et le cintrage ou fissurage d'un ou plusieurs de ces éléments. (L'expérience clinique semble indiquer que l'on peut réduire ces risques en veillant à respecter tous les points énumérés dans les sections "Mises en garde" et "Précautions" de cette notice) ;
2) La fracture de la rotule imputable à une tension excessive, ou à un affaiblissement per-opératoire imprévu ;
3) l'aggravation des problèmes éprouvés au niveau du membre affecté ou au niveau de l'extrémité controlatérale du fait d'une inégalité de longueur de jambe ;
4) une instabilité ligamentaire tardive ;
5) une calcification ou ossification péri-articulaire, qui peut s'accompagner d'une limitation du jeu articulaire ;
6) une mobilité articulaire insuffisante imputable à un choix inadéquat ou à un mauvais positionnement des composants prothétiques, à un conflit ou à une calcification péri-articulaire accompagnée de dystrophie ; enfin,
7) des fractures osseuses, luxations, subluxations, flessum, restriction du jeu articulaire, allongement ou raccourcissement de la jambe, sont des complications qui ont été observées dans des cas d'arthroplastie totale du genou.

INFORMATIONS IMPORTANTES A L'ATTENTION DU CHIRURGIEN

A. **Résorption osseuse et ostéolyse.** La résorption osseuse peut survenir comme conséquence naturelle de l'implantation du dispositif, due à des remaniements osseux. Les changements distribution des forces causés par l'implantation agissent sur le remodelage osseux. Une résorption extensive autour du dispositif conduit à une laxité de l'implant et à sa rupture. La résorption osseuse progressive localisée due à des raisons autres que la force de cisaillement ou l'infection, peut survenir autour des composants et l'os et ceci a été appelé l'ostéolyse. Il est généralement admis que l'ostéolyse est le résultat d'une réaction localisée d'un corps étranger aux débris de particules, (c'est à dire ciment, métal, polyéthylène à très haute masse moléculaire (UHMWPE). et céramiques), générée par interaction entre les composants

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ainsi qu'entre les composants et l'os, au travers de mécanisme de résistance [illegible] Au regard de l'étiologie, il a été mis en hypothèse que les débris de particules générés par l'articulation des composants d'un dispositif migrent dans la cavité synoviale et l'interface os/implant où ils recrutent des macrophages et stimulent l'action phagocytaire. Le degré de recrutement est déterminé par la taille, la distribution et la quantité de débris particulaires ainsi que le taux de génération de débris. Il a été démontré que l'action phagocytaire in vitro induit la libération de cytokines et de médiateurs cellulaires (IL-1, IL-2, IL-6, PGE2, TNF3). Il a été mis en évidence que ces médiateurs modulaient la résorption osseuse par les ostéoclastes. La recherche clinique et fondamentale se poursuit de façon à comprendre les fondements scientifiques pour les causes de ce phénomène et explore les manières potentielles de réduire son occurrence.

L'ostéolyse étant fréquemment asymptomatique, des examens radiographiques périodiques de suivi sont indispensables pour aider à sa détection et minimiser toute complication future sérieuse. Cependant, ces radiographies ne donnent pas une image complète de l'étendue de l'ostéolyse. La présence de lésions locales progressives peut nécessiter le remplacement du ou des éléments prothétiques.

B. **Epaisseur du polyéthylène.** Des analyses théoriques ont montré que les contraintes de contact dans le composant tibial varient suivant l'épaisseur du composant en polyéthylène. D'une manière générale, il semble que les contraintes d'usure soient plus faibles avec les inserts épais qu'avec les inserts plus minces. Il est possible que ces contraintes aient une incidence sur l'usure de l'implant; toutefois, on n'a pas établi de manière concluante les implications cliniques des différences de contraintes théoriques. Le chirurgien devra donc faire un compromis entre une résection plus large du tibia et l'emploi d'un insert plus épais. Il tiendra compte de certains facteurs propres au patient, comme son âge, son poids, son niveau d'activité.

C. **Assemblage des composants.** Les pièces tibiales existent en plusieurs largeurs conçues pour s'articuler sur les pièces fémorales correspondantes. Si on ne prend pas soin d'assembler correctement les composants, on court le risque d'un échec prématuré de l'élément tibial et d'accroître la laxité articulaire.

D. **Etiquette du produit.** Consulter l'étiquette du produit pour des renseignements supplémentaires se rapportant au produit mentionné dans cette notice de conditionnement.

CONDITIONNEMENT

Ces produits sont livrés sous emballage stérile après avoir été exposés à un rayonnement gamma d'au moins 25kGy émis à partir d'une source de cobalt 60. Avant l'utilisation d'un produit stérile, il est nécessaire de s'assurer que l'emballage interne ou externe n'a subi aucun dommage.

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der Tibia- oder der Femurkomponente angebracht werden können. Um für die zementierte Anwendung zusätzlichen Raum zu schaffen, werden bei Vorliegen tibialer Knochendefekte keile eingesetzt, bei Femurknochendefekten Distanzstücke, die mechanisch an der Femurkomponente befestigt oder auch einzementiert werden. Mit Schrauben können Tibiaeinsätze auf Basisplatten montiert oder letztere auf die Tibia geschraubt werden.

Produktetikett

Informationen über die zur Herstellung des in dieser Packungsbeilage beschriebenen Produkts verwendeten Materialien finden Sie auf dem Produktetikett.

INDIKATIONEN

Die Indikationen für eine Kniegelenktotalendoprothese umfassen:

1) nichtentzündliche degenerative Gelenkerkrankungen einschließlich Osteoarthritis, traumatischer Arthritis und ischämischer Nekrose;
2) rheumatoide Arthritis;
3) Korrektur funktionaler Deformitäten;
4) Revisionsoperationen nach Versagen anderer Behandlungen oder Prothesen;
5) posttraumatischer Verlust von Teilen des Gelenks, insbesondere bei patellofemoraler Erosion; Funktionsstörung oder vorheriger Patellektomie;
6) irreparable Fraktur des Knies.

KONTRAINDIKATIONEN

Absolute Kontraindikationen umfassen:

1) offene Infektion;
2) entfernte Infektionsherde (welche die hämatogene Ausbreitung zur Implantationsstelle verursachen können);
3) rasche Krankheitsprogredienz in Form radiologisch nachweisbarer Gelenkdestruktion oder Knochenresorption;
4) Patienten mit unausgewachsenem Skelett;
5) Fälle, bei denen geringe Knochensubstanz den Eingriff nicht zulassen würde.

Bedingungen, die mit einem erhöhten Versagensrisiko einhergehen, umfassen:

1) unkooperativer Patient oder Patient, der durch neurologische Störungen unfähig ist, Anweisungen zu befolgen;
2) Osteoporose;
3) Stoffwechselstörungen, die die Knochenbildung beeinträchtigen oder den Verlust an Knochensubstanz verursachen können;
4) Osteomalazie;
5) vorherige Arthrodese.

Implantatversagen ist häufiger auch bei Querschnittsgelähmten sowie bei Patienten mit Zerebralparese oder Parkinson-Krankheit aufgetreten.

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WARNHINWEISE

[illegible] Implantatkomponenten kann zu ungewöhnlichen Belastungen und somit zu einer verkürzten Lebensdauer des prothetischen Implantats führen. Der Operateur sollte sich mit dem chirurgischen Eingriff, den Instrumenten und den Implantateigenschaften vor der Operation gründlich vertraut machen. Regelmäßige Langzeitnachsorge zur Kontrolle von Position und Zustand der Prothese sowie zur Überwachung des angrenzenden Knochens ist zu empfehlen.

Zementierte Anwendung

Es ist sorgfältig darauf zu achten, daß alle in den Knochen einzementierten Implantatteile gut vom Zement umschlossen sind, um Belastungszonen zu vermeiden, die zum Mißerfolg des Eingriffs führen können. Vor dem Wundverschluß ist eine vollständige Reinigung (komplette Entfernung aller Knochensplitter, Knochenzementfragmente und Metallreste) der Implantationsstelle unerläßlich, um eine frühzeitige Abnutzung der artikularen Implantatflächen zu verhindern.

Prothesenkomponenten

Femur-, Tibia- und Patellakomponenten von verschiedenen Prothesensystemen oder von verschiedenen Herstellern dürfen nicht miteinander kombiniert werden, da die Parameter bzw. die Materialien nicht kompatibel sein könnten. Modulare Komponenten müssen sorfältig montiert werden, so daß sich die Verbindung nicht wieder lösen kann. Wiederholtes Zusammenbauen und Auseinandernehmen der modularen Komponenten könnte den wichtigen Verriegelungsmechanismus zwischen den Komponenten schädigen und ist daher zu vermeiden. Chirurgischer Detritus muß vor der Montage von den modularen Komponenten entfernt werden, da er deren Verriegelungsmechanimus behindern kann, was wiederum zum Mißerfolg des Eingriffs führen kann.

Patellakomponente

Da die Patellakomponente die kleinsten Gelenk- und Fixationsflächen hat, ist sie anfälliger für Subluxation und Lockerung/Dislokation. Daher ist es für den Operationserfolg entscheidend, während des Eingriffs besondere Aufmerksamkeit auf die Patellaführung zu richten.

Fixationsschrauben

Wenn Fixationsschrauben verwendet werden, sollten diese fest eingeschraubt werden, um die Stabilität der Fixation zu maximieren und den ordnungsgemäßen Sitz der Komponenten zu gewährleisten. Dabei dürfen nur die für die jeweilige Prothese vorgeschriebenen Schrauben verwendet werden, um einen inkorrekten Sitz und unzulässige Metallkombinationen zu vermeiden. Diese Knochenschrauben sind nicht zur Befestigung oder Fixation an den posterioren Elementen (Pedikeln) der Hals-, Brust- oder Lendenwirbelsäule vorgesehen.

Metallkomponenten

Einige für die Herstellung von orthopädischen Implantaten verwendete Legierungen enthalten Metalle, die in Gewebekulturen oder intakten Organismen unter bestimmten Bedingungen karzinogen sein können. In der wissenschaftlichen Literatur wurden Fragen aufgeworfen, ob bei Implantatempfängern die Legierungen selbst karzinogen wirken

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können. Studien über dieses Thema konnten trotz Millionen implantierter Prothesen keinen [illegible] Zusammenhang feststellen. Siehe Literaturnachweis 1.)

Ausrichtung der Komponenten

Die korrekte Gelenkausrichtung und ausgeglichene Bänderspannung sind sorgsam wiederherzustellen. Fehlstellung der Extremität oder des Gelenks kann übermäßigen Verschleiß, Luxation der Prothese und Schmerzen verursachen, wodurch eine vorzeitige Revision einer oder mehrerer Prothesenkomponenten erforderlich werden kann.

Verschleiß des Polyethylens

Erwartungsgemäß wurden nach Einsetzen von Knietotalendoprothesen Verschleißerscheinungen bei den aus Polyethylen bestehenden Gleitflächen der Tibia- und Patellakomponenten beobachtet. Erhöhter Verschleiß, der unter Umständen auf Gleitflächenabrieb durch Zement-, Metall- und andere Partikel zurückzuführen ist, kann die Lebensdauer der Prothese verkürzen und eine verfrühte Revision zum Ersatz der abgenutzten Prothesenkomponenten erforderlich machen.

VORSICHTSMASSNAHMEN

Aufklärung des Patienten. Der Patient muß von den kurz- und langfristigen Einschränkungen durch die Rekonstruktion sowie der Notwendigkeit, das Implantat bis zur ausreichenden Fixation und Bruchheilung vor voller Belastung zu schützen, unterrichtet werden. Übermäßige Aktivitäten und Trauma mit Auswirkung auf die Befestigung bzw. Fixation wurden für das Versagen der Rekonstruktion durch Lockerung, Bruch oder Abnutzung des Implantats verantwortlich gemacht. Eine Lockerung der Komponenten kann zu vermehrter Produktion von Abriebpartikeln sowie zur Schädigung des Knochens führen, wodurch eine erfolgreiche Revision erschwert würde.

Der Patient sollte angewiesen werden, seine Aktivitäten zu beschränken, den Gelenkersatz vor unangemessenen Belastungen zu schützen und die Anweisungen des Arztes in bezug auf Nachsorge und Nachbehandlung zu befolgen.

Der Patient muß über Operationsrisiken und mögliche unerwünschte Wirkungen aufgeklärt werden. Es muß ihm verdeutlicht werden, daß die Prothese die Leistungen eines gesunden Gelenks nicht erbringen kann und wird, daß das Implantat durch anstrengende Aktivitäten oder durch Trauma brechen oder beschädigt werden kann und daß es eine begrenzte Lebensdauer hat und gegebenenfalls nach einer gewissen Zeit ersetzt werden muß.

Im täglichen Leben kann jederzeit eine vorübergehende Bakteriämie auftreten. Auch Zahnbehandlungen, endoskopische Untersuchungen und andere kleinere chirurgische Eingriffe wurden mit vorübergehender Bakteriämie in Zusammenhang gebracht. Daher mag es ratsam sein, vor und nach solchen Eingriffen prophylaktisch Antibiotika zu verabreichen, um eine Infektion an der Implantationsstelle zu vermeiden.

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Instrumentarium. Es stehen spezielle Instrumente zur Verfügung, die zur Gewährleistung einer präzisen Implantation der Prothesenkomponenten verwendet werden müssen.

In seltenen Fällen kann es intraoperativ zu Frakturen oder zum Bruch von Instrumenten kommen. Bei Instrumenten, die übermäßig lange benutzt worden sind oder extremen

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Kräften ausgesetzt waren, besteht erhöhte Bruchgefahr. Alle Instrumente müssen vor dem Eingriff auf Abnutzungserscheinungen und Funktionsfähigkeit geprüft werden.

Wiederverwendung. Ein Implantat darf niemals wiederverwendet werden. Auch wenn keine Beschädigungen erkennbar sind, kann ein gebrauchtes Implantat kleine Fehler oder nicht sichtbare Beschädigungen aufweisen, die seine Lebensdauer reduzieren würden.

Handhabung. Die sachgemäße Handhabung von Implantaten, insbesondere solcher mit poröser Beschichtung, ist äußerst wichtig. Die Oberflächen mit poröser Beschichtung dürfen nicht mit Stoff oder anderen fusselnden Materialien in Kontakt kommen. Alle Implantate mit beschädigter oder verunreinigter Beschichtung müssen entsorgt werden. Der hochpolierte Teil des Implantats darf nicht mit harten Gegenständen in Berührung kommen.

UNERWÜNSCHTE WIRKUNGEN

1) Bei jeglichem Gelenkersatz kann im unmittelbaren oder entfernteren Bereich der prothetischen Komponenten infolge einer Fremdkörperreaktion auf Materialpartikel eine asymptomatische lokalisierte, progrediente Knochenresorption (Osteolyse) auftreten. Die Partikel entstehen durch die Interaktion der Komponenten miteinander sowie der Komponenten mit dem Knochen, und zwar vorrangig durch Abnutzungsmechanismen wie Adhäsion, Abrieb und Materialermüdung. Ferner können Materialpartikel auch durch anderweitige Abnutzungsmechanismen freigesetzt werden. Osteolyse kann zu weiteren Komplikationen führen, welche die Entfernung und den Ersatz der prothetischen Komponenten erforderlich machen. (Weitergehende Informationen sind dem Abschnitt **„WICHTIGE INFORMATIONEN FÜR DEN ARZT"** zu entnehmen.)
2) In seltenen Fällen wurden bei Patienten nach einem Gelenkersatz Überempfindlichkeitsreaktionen auf die verwendeten Metalle beobachtet. Die Implantation körperfremden Materials in das Gewebe kann Zellreaktionen mit Lymphozyten, Makrophagen und Fibroblasten hervorrufen.
3) Nach totalem Gelenkersatz wurden periphere Neuropathien beobachtet, ferner subklinische Nervenschädigungen, die als Folge des chirurgischen Traumas auftreten können.
4) Nach unsachgemäßer Positionierung und/oder Migration der Komponenten kann es zur Dislokation und Subluxation von Implantatkomponenten kommen. Bänderschlaffheit sowie schlaffes Muskel- und Bindegewebe können zu diesem Umstand beitragen.
5) Durch Trauma oder Fixationsverlust kann es zur Lockerung bzw. Migration von Implantaten kommen.
6) Infektionen können zum Versagen des Gelenkersatzes führen.
7) In seltenen Fällen können Ermüdungsfrakturen des Implantats durch Trauma, belastende Aktivitäten, unsachgemäße Ausrichtung oder extrem lange Einsatzdauer auftreten.

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8) Ungleiche Belastung der Weichteile (Ligamente) kann übermäßigen Verschleiß und/oder Versagen des Implantats verursachen.
9) Beim Vorbereiten des Operationsfeldes und/oder beim Einsetzen der Implantate kann es zur intraoperativen Fraktur des Femurs, der Tibia oder Patella kommen.
10) In seltenen Fällen kann es zu allergischen Reaktionen auf die im Implantat verwendeten Materialien kommen.

Intraoperative und frühe postoperative Komplikationen umfassen u. a.:

1) tiefe Venenthrombose;
2) Verletzung von Blutgefäßen;
3) Schmerz oder Taubheitsgefühl in der betroffenen Extremität infolge vorübergehender oder bleibender Nervenschädigung;
4) plötzliches Absinken des Blutdrucks während der Operation im Zusammenhang mit der Verwendung von Knochenzement;
5) Varus-Valgus-Deformität mit Fehlstellung der Extremität/Prothese;
6) kardiovaskuläre Erkrankungen einschließlich Venenthrombose, Lungenembolie oder Myokardinfarkt;
7) Hämatom;
8) verzögerte Wundheilung ;
9) tiefe Wundinfektion (früh oder spät), die eine potentiell ernsthafte Komplikation eines jeden Gelenkersatzes darstellt, welche die Entfernung der Prothese mit nachfolgender Arthrodese erfordern kann und daher eine angemessene antibiotische Prophylaxe und strikte Einhaltung aseptischer Bedingungenunerläßlich macht;
10) Fraktur des Femurs, der Tibia, Patella oder einer Prothesenkomponente.

Späte postoperative Komplikationen umfassen u. a.:

1) späte (oder frühe) Lockerung, Positionsveränderung, Verschleiß und Verbiegung oder Rißbildung an einer oder mehreren Prothesenkomponenten (Klinische Erfahrung hat gezeigt, daß das Komplikationsrisiko minimiert wird, wenn der Information in den Abschnitten „Warnhinweise" und „Vorsichtsmaßnahmen" besondere Aufmerksamkeit geschenkt wird.);
2) Patellafraktur infolge übermäßiger Spannung oder ungewollter intraoperativer Schwächung;
3) ernste Probleme mit der betroffenen oder kontralateralen Extremität durch unterschiedliche Beinlänge;
4) späte Bandinstabilität;
5) periartikuläre Kalzifikation oder Ossifikation mit oder ohne Beeinträchtigung der Gelenkmobilität;
6) unzureichender Bewegungsspielraum durch unsachgemäße Auswahl bzw. Positionierung oder durch Eindringen der Komponenten sowie durch periartikuläre Kalzifikation und Dystrophie;

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7) Knochenfraktur, Dislokation, Subluxation, Flexionskontraktur, eingeschränkter Bewegungsspielraum oder Verlängerung bzw. Verkürzung der Extremität: über all diese Faktoren wurde in zu Hachinohe, [illegible] mit totalem Kniegelenkersatz berichtet.

WICHTIGE INFORMATIONEN FÜR DEN ARZT

A. **Knochenresorption und Osteolyse.** Die Knochenresorption kann als natürliche Folge einer totalen Gelenkarthroplastik aufgrund von Veränderungen im Knochenumbau auftreten. Der Knochenumbau wird durch Veränderungen der Belastungsverteilung als Folge der Implantation verursacht. Eine weitreichende Knochenresorption in der Umgebung der Prothese führt zur Lockerung und zur Schädigung des Implantates. Umschriebene progressive Knochenresorption infolge anderer Ursachen als Belastungsschutz oder Infektion kann um die prothetischen Komponenten herum und zwischen den Komponenten und dem Knochen auftreten; dieser Vorgang wird als Osteolyse bezeichnet. Es wird allgemein angenommen, daß die Osteolyse die Folge einer lokalisierten Fremdkörperreaktion auf vorhandene Partikel (z.B. Zement, Metall, ultrahochmolekulares Polyethylen [UHMWPE] und Keramik) ist, welche durch Wechselwirkung zwischen einzelnen Komponenten oder zwischen den Komponenten und dem Knochen erzeugt werden. vorwiegend bedingt durch Verschleißmechanismen wie Adhäsion, Abrasion und Materialermüdung. Im Hinblick auf die Ätiologie geht man davon aus, daß Fremdpartikel, die durch Artikulation der Prothesenkomponenten entstehen, in die Synovialhöhle und die Kontaktfläche zwischen Knochen und Implantat wandern, wo sie Makrophagen rekrutieren und die Phagozytenaktivität stimulieren. Das Ausmaß der Rekrutierung wird durch Größe, Verteilung und Menge der Trümmerpartikel sowie die Geschwindigkeit der Partikelbildung bestimmt. In vitro konnte nachgewiesen werden, daß die Phagozytenaktivität die Freisetzung von Zytokinen und Zellmediatoren (IL-1, IL-2, IL-6, PGE2 und TNF3) induziert. Diese Mediatoren modulieren nachweislich den osteoklastenvermittelten Abbau von Knochensubstanz. Weitere klinische Studien und Grundlagenforschung werden durchgeführt, um zu einem besseren Verständnis der wissenschaftlichen Grundlagen für die Ursachen dieser Erscheinung zu gelangen und um mögliche Wege zu erforschen, das Auftreten der Osteolyse zu reduzieren.

Da die Osteolyse häufig asymptomatisch auftritt, sind regelmäßige röntgendiagnostische Untersuchungen äußerst wichtig, um eventuell später auftretende schwere Komplikationen zu erkennen und möglichst gering zu halten. Dennoch läßt sich das volle Ausmaß der Osteolyse radiologisch nicht vollständig darstellen. Fokale, progressive Läsionen können einen Ersatz der prothetischen Komponente(n) erforderlich machen.

B. **Stärke des Polyethylens.** Theoretische Analysen haben gezeigt, daß die Kontaktbelastungen an der Tibiakomponente je nach Stärke der Polyethylenkomponente variieren. Im allgemeinen wird davon ausgegangen, daß dickere Einsätze geringeren Kontaktbelastungen ausgesetzt sind als dünnere. Diese Belastungen mögen einen Einfluß auf den Verschleiß der Implantatkom-

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ponenten haben; allerdings sind die klinischen Implikationen der theoretischen Belastungsunterschiede noch nicht endgültig festgestellt worden. Der Operateur sollte die Vor- und Nachteile einer zusätzlichen Tibiaresektion gegenüber einem dickeren Einsatz abwägen. Patientenspezifische Faktoren wie Körpergewicht, Alter und Aktivitätsniveau sollten in die Entscheidungsfindung mit einfließen.

C. **Abstimmung der Komponenten.** Passend zu den anforderungsgemäß gewählten Größen der Femurkomponenten gibt es jeweils entsprechende und artikulierende Tibiabreiten. Wenn die Komponenten nicht genau aufeinander abgestimmt werden, kann dies zu verfrühtem Versagen der Tibiakomponente und zu Gelenkschlaffheit führen.

D. **Produktetikett.** Spezifische Informationen über das in dieser Packungsbeilage beschriebene Produkt finden Sie auf dem Produktetikett.

PRODUKTZUSTAND BEI LIEFERUNG

Die Produkte werden steril in Behältern geliefert, die einer Gammastrahlung von mindestens 25 kGy aus einer Kobalt-60-Quelle, ausgesetzt worden sind. Die Verpackung aller sterilen Produkte sollte vor deren Verwendung auf mögliche Beschädigungen des Sterilsiegels hin überprüft werden.

RESTERILISATION

Prothesen, die POLYETHYLEN, PORÖSE BESCHICHTUNGEN, SPRÜHPLASMA, HYDROXYLAPATIT, KERAMIK oder METHYLMETHACRYLAT enthalten, DÜRFEN DURCH DEN ANWENDER WEDER AUTOKLAVIERT NOCH RESTERILISIERT WERDEN

Komponenten, die **nicht** mit Flüssigkeiten, insbesondere mit Körperflüssigkeiten kontaminiert sind, können in einem Autoklaven im Gravitationsverfahren mit folgenden Parametern resterilisiert werden:

	121 °C (250 °F) 1.4 Bar (20 PSI)	132 °C (270 °F)s 2 Bar (30 PSI)
Individuell verpackte Komponente (Einzel- oder Multikomponente) oder Sterilisationsbehälter	40 Minuten	20 Minuten

Die angewandte Doppelverpackungsmethode ist die sogenannte AAMI CSR-Technik. Bei der Entwicklung dieser Zyklen befand sich nur dieser Gegenstand auf dem mittleren Regal in der Kammer. Jeder Zyklus sollte für die verschiedenen Sterilisationskammern, Verpackungsmethoden und/oder verschiedenen Beschickungskonfigurationen validiert werden.

VORSICHT

Nach US-amerikanischem Recht darf dieses Produkt nur an einen Arzt bzw. auf Anordnung eines Arztes verkauft werden.

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LITERATURNACHWEISE

1. Olof Hyren, Joseph R. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study in Sweden". Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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Italiano

AVVERTENZE E PRECAUZIONI PER IL CHIRURGO OPERANTE

I progressi realizzati nelle protesi totali di ginocchio danno al chirurgo la posssibilità di ripristinare la mobilità, correggere le deformità ed attenuare il dolore grazie all'uso di impianti protesici sempre più perfezionati. È opportuno tener presente che tali protesi, di provato successo, sono pur sempre corpi estranei di metallo e di materiale plastico. Non si può pretendere che una protesi possa sostenere lo stesso livello di attività e di carico di una articolazione umana sana e normale. Il sistema protesico, necessariamente, non sarà altrettanto forte, sicuro e durevole quanto un'articolazione di ginocchio naturale.

Il chirurgo, nell'usare protesi totali di ginocchio, dovrebbe tener presente quanto segue:

A. **Di primaria importanza sono la scelta giusta dell'impianto e il suo corretto posizionamento.** Il successo del sistema ricostruttivo totale di ginocchio impone la scelta delle protesi più adatte in quanto a design, dimensioni e forma. Le protesi totali di ginocchio richiedono posizionamento corretto, fissaggio solido e supporto osseo adeguato.

B. **Al momento della scelta dei pazienti da operare per la protesizzazione totale di ginocchio, i fattori seguenti possono essere di estrema importanza per il successo dell'intervento:**

1) **Peso del paziente.** Un paziente in sovrappeso od obeso esercita un carico maggiore sulla protesi, carico che può provocare il fallimento dell'impianto. L'effetto di questo carico sarà accentuato qualora si debbano usare protesi piccole per via delle particolari dimensioni delle ossa in tali soggetti.

2) **Occupazione o attività del paziente.** Se l'occupazione o attività del paziente comporta un carico d'urtosignificativo (marcia, corsa, sollevamento o movimento di torsione), le forze derivanti possono provocareil fallimento del fissaggio, della protesi o di entrambi. Inoltre, un alto grado di attività fisica può accentuare, col passare degli anni, l'usura che subiscono normalmente le articolazioni protesiche. Laprotesi non recupererà la funzionalità al livello che presumibilmente raggiungerebbe un'articolazione normale e sana, quindi, se il paziente dovesse nutrire speranze irrealistiche circa la funzionalità dell'impianto protesico, sarebbe bene disilluderlo. (Vedi **PRECAUZIONI** per ulteriori informazioni).

3) **Senilità, malattia mentale o alcoolismo.** Queste condizioni possono, tra l'altro, indurre il paziente a trascurare quelle limitazioni o precauzioni che occorre seguire quando si è protesizzati, pena il fallimento dell'impianto o l'insorgere di altre complicanze.

4) **Sensibilità ai corpi estranei.** Laddove si sospetti sensibilità al materiale, prima di scegliere il materialestesso o di collocare la protesi, occorrerebbe svolgere prove appropriate.

5) **Profilo ortopedico.** La prognosi quanto al successo dell'intervento dipende dal profilo ortopedico del paziente. Quei pazienti che hanno già

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avuto interventi e/o impianti molteplici dovrebbero venire informaticirca
[illegible]

6) **Qualità dell'osso.** La durata della protesi totale di ginocchio può essere compromessa dall'osso fragilizzato quale conseguenza di certe malattie sistemiche o metaboliche come quelle curate con steroidi, immunosoppressori o sostanze chemioterapiche.

DESCRIZIONE

La Howmedica fabbrica un'ampia gamma di sistemi ricostruttivi di ginocchio tricompartimentali in varie misure e stili al fine di venire incontro alle esigenze diverse di pazienti e chirurghi in occasione di interventi sia primari, sia di revisione.La scelta del sistema protesico dipende dal tipo d'intervento chirurgico necessario. Per la chirurgia ricostruttiva di ginocchio sono disponibili componenti femorali, tibiali e rotulee. Le componenti metalliche (componente femorale, basi tibiali e rotulee, palline sinterizzate, spessori e distanziatori) sono fabbricate a partire da una lega fusa di cobalto-cromo-molibdeno (lega Vitalium®) conforme alla norma ASTM F75. Viti e fittoni sono in lega lavorata cobalto-cromo-molibdeno (lega Vitalium®) conforme alla norma F1537 ASTW. Le componenti polietileniche sono costituite di polietilene ad altissimo peso molecolare (UHMWPE) conforme alla norma F648 ASTM.

Componenti femorali

Le componenti femorali (eccetto la componente superstabilizzata) sono disponibili nelle opzioni con rivestimento poroso e non poroso, in versione condiloidea, stabilizzata e superstabilizzata. Certe componenti femorali possono trasformarsi da una configurazione a un'altra, per esempio da condiloidea a stabilizzata grazie all'aggiunta di una parte modulare atta a stabilizzare il pezzo.

Componenti tibiali

Le componenti tibiali sono disponibili in un'ampia gamma di taglie e spessori. Le componenti tibiali possono essere sotto forma di un singolo pezzo tutto di polietilene o di parti modulari con inserto di polietilene e base metallica. Le basi tibiali sono disponibili tanto in versione porosa, quanto non porosa e possono presentare possibilità di fissaggio supplementari. Gli inserti sono offerti con gradi diversi di contenimento, in versione condiloidea, stabilizzata e superstabilizzata.

Componenti rotulee

Le componenti rotulee sono disponibili sia tutte in polietilene, sia su supporto metallico con rivestimento poroso.

Accessori

I fittoni sono concepiti per ancorarsi allo stelo delle componenti femorali e tibiali così da dare una maggiore stabilità. Gli spessori sono da usarsi con il cemento al fine di fornire uno spessore ulteriore laddove vi siano difetti nell'osso tibiale. I distanziatori servono a dare maggiore spazio in caso di difetti nell'osso femorale, e possono essere fissati alla componente femorale o meccanicamente o cementandoli in loco. Le viti fornite costituiscono un'ulteriore possibilità di fissaggio degli inserti tibiali con le basi tibiali o delle basi tibiali con l'osso tibiale

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Etichetta del prodotto

L'etichetta apposta sul prodotto fornisce informazioni sui materiali specifici di cui è composto il dispositivo.

INDICAZIONI

Indicazioni per l'impiego di protesi totali ricostruttive di ginocchio:

1) malattie degenerative e non infiammatorie delle articolazioni, come artrite traumatica o necrosi avascolare;
2) artrite reumatoide;
3) correzione di una deformità funzionale;
4) procedure di revisione, qualora non abbiano avuto successo altri trattamenti o impianti;
5) perdita dell'anatomia dell'articolazione in seguito a trauma, particolarmente in presenza di erosione patello-femorale, di disfunzione o di patellectomia pregressa;
6) frattura irreparabile del ginocchio.

CONTROINDICAZIONI

Controindicazioni assolute includono:

1) infezione manifesta;
2) focolai lontani d'infezione (possono provocare la diffusione ematogena dell'infezione fino a raggiungere il sito della protesi);
3) rapida progressione della malattia con distruzione dell'articolazione o riassorbimento dell'osso, come evidenziato dalle radiografie;
4) pazienti dallo scheletro immaturo;
5) casi in cui la massa ossea è così scadente da non giustificare l'intervento.

Condizioni che comportano un maggior rischio di fallimento:

1) paziente poco disposto a collaborare o paziente affetto da disturbi neurologici, incapace di seguire le istruzioni;
2) osteoporosi;
3) disturbi metabolici che possono compromettere la formazione dell'osso o provocarne la perdita;
4) osteomalacia;
5) artrodesi pregressa.

Un'incidenza più elevata di insuccesso delle protesizzazione si è riscontrata in soggetti paraplegici e in pazienti affetti da paralisi cerebrale o da morbo di Parkinson.

AVVERTENZE

Qualora le componenti protesiche vengano selezionate, collocate, posizionate o fissate incorrettamente, c'è il rischio che si creino sollecitazioni indebite atte a ridurre la durata utile dell'impianto protesico. Prima di eseguire l'intervento, il chirurgo dovrebbe già

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conoscere perfettamente la procedura chirurgica, lo strumentario e le caratteristiche dell'impianto. Si raccomanda un controllo periodico da effettuarsi su un lungo arco di tempo allo scopo di seguire la posizione e l'evoluzione in atto dei componenti protesici, nel delle condizioni dell'osso adiacente.

Applicazioni con cemento. Bisognerebbe fare attenzione a dare un supporto completo a tutte le parti del pezzo rivestite di cemento, al fine di impedire una concentrazione di sollecitazioni tale da far fallire l'intervento. Per evitare un'usura accelerata delle superfici articolari dell'impianto, è d'importanza critica la pulizia accurata del sito dell'impianto (con rimozione completa dei frammenti d'osso, di cemento osseo e di detriti metallici).

Componenti protesiche. Non si dovrebbero mescolare componenti femorali, tibiali e rotulee appartenenti a sistemi protesici diversi o provenienti da fabbricanti diversi, in quanto le tolleranze o i materiali possono essere incompatibili. Le componenti modulari devono essere assemblate solidamente affinché non si distacchino. Da evitarsi assemblaggio e smontaggio ripetuto delle componenti modulari-operazioni atte a compromettere la funzione critica di bloccaggio delle componenti. Prima dell'assemblaggio è necessario rimuovere tutti i residui provocati dall'intervento chirurgico. Infatti, i residui possono fare inceppare il meccanismo di bloccaggio delle componenti modulari, il che, a sua volta, può comportare il fallimento precoce dell'intervento.

Componenti rotulee. Visto che la componente rotulea è quella avente le superfici di carico e di fissaggio più piccole, la rotula, o componente rotulea, è decisamente più vulnerabile di altre componenti alla sublussazione, alla lussazione e all'allentamento. Perché abbia buon esito l'intervento, è essenziale, nel corso dell'intervento stesso, prestare particolare attenzione all'orientamento della rotula.

Viti di fissaggio. In caso di impiego di viti di fissaggio, sarebbe bene avvitarle fino in fondo al fine di ottenere un ancoraggio particolarmente stabile, evitando così interferenze con il posizionamento corretto delle componenti. Sono da utilizzarsi soltanto le viti raccomandate per una determinata protesi onde evitare fenomeni di instabilità e associazioni di metalli inadatti tra di loro. Tali viti ossee non sono da impiegarsi a scopo di collegamento o fissaggio con gli elementi posteriori (peduncoli) della spina cervicale, toracica o lambare.

Componenti metalliche. Ci sono leghe utilizzate per le protesi ortopediche-contenenti elementi metallici-che possono rivelarsi cancerogene in colture di tessuto o in organismi intatti, in circostanze particolari. Nella letteratura scientifica ci si è chiesti se tali leghe possano, di per sè, diventare cancerogene nei soggetti protesizzati. Tuttavia, gli studi svolti per valutare tale possibilità non si sono rivelati probanti, e ciò nonostante siano in uso milioni di protesi. (Vedi Bibliografia 1.)

Allineamento delle componenti. È opportuno fare attenzione a ripristinare l'allineamento corretto dell'articolazione e ad equilibrare la tensione ligamentosa. L'allineamento incorretto dell'arto o dell'articolazione può provocare usura eccessiva, allentamento della protesi e dolori, fattori che comportano la revisione di una o più componenti protesiche prima del previsto.

Usura del polietilene. Come prevedibile, in seguito alla protesizzazione totale di ginocchio si è rilevata l'usura delle superfici in polietilene delle componenti tibiali e

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rotulee. D'altra parte, l'abrasione delle superfici articolari provocata da particelle di cemento, metallo o altri detriti, darà inoltre un processo [illegible] prima del voluto, un intervento di revisione per sostituire le componenti protesiche usurate.

PRECAUZIONI

Informazioni ai pazienti. Si dovrebbe informare il paziente circa le limitazioni, a breve e a lungo termine, dell'intervento e circa la necessità di mettere l'impianto sotto pieno carico soltanto quando si sarà consolidato il fissaggio, e a cicatrizzazione avvenuta. Si è dimostrato che attività eccessive e movimenti traumatici esercitano un effetto, nei confronti del sistema ricostruttivo dell'articolazione, che provoca il fallimento della protesi, tramite allentamento, frattura e/o usura della stessa. La mobilizzazione delle componenti può dare origine ad una maggiore quantità di particelle d'usura che, oltre a danneggiare l'osso, rendono più difficile il successo dell'intervento di revisione.

Si dovrebbe consigliare al paziente di limitare le attività, di proteggere l'articolazione protesica da sollecitazioni indebite e di seguire le istruzioni del medico in fatto di terapia e di cure successive.

Sarebbe bene, inoltre, mettere in guardia il paziente dai rischi chirurgici e sensibilizzarlo alla possibilità di effetti negativi. Bisognerebbe avvisare il paziente che la protesi non è, né sarà mai, identica ad una articolazione sana e normale, e che l'impianto può rompersi o danneggiarsi quale conseguenza di attività o traumi eccessivi, e che, avendo la protesi una durata prevista limitata, ad un certo punto in futuro si rivelerà probabilmente necessario effettuare un altro intervento per sostituire il pezzo.

Nella vita di ogni giorno può succedere che vi sia una batteremia passeggera. Interventi dentali, esami endoscopici e altri piccoli interventi chirurgici apparentemente sono connessi all'insorgenza di batteremia transitoria. Al fine di impedire infezioni laddove si mette la protesi, può essere consigliabile una profilassi antibiotica prima e dopo tali interventi.

Strumentario. È disponibile uno strumentario speciale il cui impiego si impone per garantire un'accurata collocazione delle componenti protesiche.

Seppur raramente, può succedere che lo strumentario si rompa nel corso dell'intervento. Strumenti troppo usati o sottoposti a sollecitazioni eccessive sono soggetti a rompersi più facilmente. Prima dell'operazione, è buona regola esaminare attentamente lo strumentario per vedere se vi sia usura o danno.

Reimpiego. Le protesi non dovrebbero mai venire riutilizzate. Anche se possono sembrare perfette, le protesi usate possono aver acquisito difetti o fratture latenti atti a comprometterne l'integrità, fenomeno che ridurrebbe la loro durata utile.

Manipolazione. È importante il modo in cui vengono maneggiati gli impianti protesici, particolarmente quelli con rivestimento poroso. Non è consentito mettere in contatto superfici porose con tessuti o altri materiali che possono perdere fibre. Sono da escludersi tutti gli impianti il cui rivestimento sia stato danneggiato o contaminato. La parte levigata della protesi non dovrebbe mai entrare in contatto con superfici dure.

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EFFETTI NEGATIVI

1) Con qualsiasi protesi può insorgere un fenomeno del riassorbimento osseo (osteolisi) progressivo, localizzato e asintomatico, vicino o lontano dalla protesi. Questo fenomeno deriva dalla reazione deicorpi estranei alle particelle di materia che vengono generate dall'interazione tra componenti e osso, inprimo luogo attraverso i meccanismi di usura quali adesione, abrasione e fatica e, secondariamente, tramite usura di corpi estranei. Col passare del tempo, l'osteolisi può provocare complicanze che imporranno la rimozione o sostituzione delle componenti protesiche. (Per ulteriori dettagli vedi sezione sulle **INFORMAZIONI IMPORTANTI PER IL MEDICO)**
2) Si sono registrati casi sporadici di reazioni di sensibilità ai metalli in pazienti sottoposti a protesizzazionedell'articolazione. Infatti, l'introduzione di corpi estranei nei tessuti può causare reazioni cellulari che coinvolgono macrofagi, linfociti e fibriblasti.
3) Si sono verificati casi di neuropatie periferiche in seguito alla protesizzazione totale dell'articolazione. Effettivamente, si sono registrati episodi di lesione subclinica al nervo, probabilmente quale conseguenzadi trauma chirurgico.
4) Le lussazione o sublussazioni delle componenti protesiche possono essere il risultato di un posizionamento incorretto e/ di migrazione delle componenti. La lassità dei tessuti molli, compresi muscoli, tessutofibroso e legamenti, può contribuire altresl a questi fenomeni.
5) Gli impianti possono allentarsi o migrare quale conseguenza di trauma o di ancoraggio poco solido.
6) Le infezioni possono essere causa d'insuccesso degli interventi di protesizzazione.
7) Per quanto raramente, può succedere che si creino fratture da fatica negli impianti protesici, in seguito atrauma, attività eccessiva, allineamento incorretto o durata utile spinta ai limiti estremi.
8) Lo squilibrio dei tessuti molli (ligamentosi) può essere causa di usura eccessiva e/o di fallimento dell'impianto.
9) In corso di preparazione della sede ossea e/o dell'alloggiamento dell'impianto, possono fratturarsi, intraoperatoriamente, femore, tibia o rotula.
10) Seppur raramente, possono registrarsi casi di reazione allergica ai materiali utilizzati nella protesi.

Complicanze intraoperatorie e postoperatorie precoci possono riguardare, tra l'altro, i seguenti casi:1) perforazioni femorali o acetabolari, o fratture;

1) trombosi venosa profonda;
2) lesione ai vasi sanguigni;
3) lesione ai nervi permanente o temporanea provocante dolore o insensibilità all'arto colpito;
4) calo improvviso, intraoperatoriamente, della pressione sanguigna connesso all'uso del cemento osseo;

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RESTERILISATION

Les implants contenant du POLYETHYLENE, du [illegible], du POLYMAT, de L'HYDROXYAPATITE, de la CERAMIQUE, du POLYMETHACRYLATE DE METHYLE NE DOIVENT PAS ETRE AUTOCLAVES OU RESTERILISES PAR L'UTILISATEUR.

Les composants qui **n'ont pas** été contaminés par des liquides, en particulier les liquides organiques, peuvent être restérilisés en utilisant les paramètres suivants à l'autoclave :

	121° C (250° F) 1.4 bars (20 psi)	132° C (270° F) 2 bars (30 psi)
Application individuelle sous emballage (composants simples ou multiples)	40 minutes	20 minutes

La méthode de conditionnement sous double poche utilisée est la technique AAMI CSR. Ces cycles ont été développés avec seulement cet élément présent dans la chambre et en utilisant le plateau médian. Tout cycle doit être validé pour différentes chambres de stérilisation, méthodes d'emballage et configurations de charge.

ATTENTION

La loi fédérale des Etats-Unis d'Amérique restreint la vente de ce dispositif par ou sur prescription d'un Médecin.

BIBLIOGRAPHIE

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risks After Hip Replacement With Metal Implants; A Population Based Cohort Study In Sweden", Journal Of The National Cancer Institute, Volume 87, Number 1, January 4. 1995.

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DEM OPERATEUR ZUR KENNTNIS

Die Fortschritte auf dem Gebiet des totalen Kniegelenkersatzes ermöglichen dem Chirurgen die Wiederherstellung der Mobilität des Patienten, die Korrektur von Deformitäten und die Schmerzlinderung mittels implantierter Prothesen. Obgleich diese Ziele im großen und ganzen mit diesen Implantaten erreicht werden, ist zu bedenken, daß sie aus Metall und Kunststoffmaterialien bestehen. Daher kann nicht erwartet werden, daß eine Prothese denselben Aktivitäten und Belastungen standhalten kann wie ein normales, gesundes Gelenk, da das System in bezug auf seine Stabilität, Zuverlässigkeit oder Haltbarkeit mit dem natürlichen menschlichen Kniegelenk nicht zu vergleichen ist.

Bei der Verwendung von totalen Kniegelenkimplantaten sollte der Operateur folgendes berücksichtigen:

A. **Die korrekte Auswahl und Positionierung des Implantats ist äußerst wichtig.** Der Erfolg eines totalen Gelenkersatzes hängt von der Wahl der richtigen Größe und Form sowie des Implantatdesigns ab. Diese Prothesen erfordern eine sorgfältige Anpassung, feste Fixation und ausreichende Unterstützung durch den vorhandenen Knochen.

B. **Die Erwägung folgender Patientenmerkmale kann für den erfolgreichen Ausgang des Eingriffs von entscheidender Bedeutung sein:**

1) **Gewicht des Patienten.** Ein übergewichtiger oder adipöser Patient kann Belastungen auf die Prothese ausüben, die zum Versagen des Implantats führen können. Die Auswirkungen dieser Belastung sind von besonderer Bedeutung, wenn aufgrund der Knochenmaße des Patienten eine Prothese von kleiner Größe verwendet werden muß.

2) **Beruf oder Tätigkeit des Patienten.** Wenn der Patient einen Beruf oder eine Tätigkeit ausübt, die mit erheblichen Stoßbelastungen (wie Gehen, Laufen, Heben oder Drehen) verbunden ist, können die hierbei entstehenden Kräfte zum Versagen der Fixation und/oder der Prothese führen. Intensive physische Aktivitäten über Jahre hinaus können ebenso den normalen Abnutzungsprozeß von Gelenkprothesen verstärken. Die Prothese kann die volle Funktion eines normalen, gesunden Gelenks nicht wiederherstellen; daher muß der Patient vor unrealistischen Erwartungen in bezug auf die Funktion gewarnt werden. (Weitere Informationen finden Sie im Abschnitt **„VORSICHTSMASSNAHMEN"**.)

3) **Senilität, Geisteskrankheit und Alkoholismus.** Durch diese und andere Zustände könnte der Patient dazu neigen, gewisse notwendige Beschränkungen und Vorsichtsmaßnahmen im Zusammenhang mit dem Implantat zu ignorieren, was zu Versagen der Prothese oder anderen Komplikationen führen kann.

4) **Fremdkörperüberempfindlichkeit.** Bei Verdacht auf eine Materialüberempfindlichkeit sind vor der Auswahl des Materials bzw. der Implantation entsprechende Tests durchzuführen.

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5) **Orthopädische Vorgeschichte.** Die Erfolgsaussichten des Verfahrens sind von der orthopädischen Anamnese des Patienten abhängig. Patienten, bei denen bereits mehrfach Eingriffe vorgenommen oder Prothesen implantiert wurden, sollten in bezug auf das zu erwartende Ergebnis des Verfahrens gewissenhaft beraten werden.

6) **Knochenqualität.** Die anhaltende Lebensdauer des totalen Kniegelenkersatzes hängt von der Qualität der Knochensubstanz ab. Unzureichende Knochenqualität kann eine Folge von bestimmten System- oder Stoffwechselerkrankungen sein, die mit Steroiden, immundepressiva oder Chemotherapeutika behandelt werden.

BESCHREIBUNG

Howmedica stellt eine breite Palette trikompartimentärer, rekonstruktiver Kniesysteme in unterschiedlichen Größen und Ausführungen her, die sowohl den Anforderungen des Chirurgen als auch den Bedürfnissen des Patienten bei zementierten Anwendungen in Primär- und Revisionseingriffen gerecht werden. Je nach der Art des erforderlichen Eingriffs ist das entsprechende Prothesensystem zu wählen. Für die Rekonstruktion des Knies stehen Femur-, Tibia- und Patellakomponenten zur Verfügung. Die Metallkomponenten (die Femurkomponente, die Tibia- und die Patella-Basisplatte, die aufgesinterten Kügelchen, die Knochenkeile und die Distanzstücke) sind aus einer Kobalt-Chrom-Molybdän-Gußlegierung (Vitallium®-Legierung) nach ASTM-Norm F75 hergestellt. Die Schrauben und Schaftverlängerungen bestehen aus einer Kobalt-Chrom-Molybdän-Knetlegierung (Vitallium®-Legierung) nach ASTM-Norm F1537. Die Polyethylen-Komponenten sind aus ultrahochmolekularem Polyethylen (UHMWPE) gemäß ASTM-Norm F648 hergestellt.

Femurkomponenten

Die Femurkomponenten sind als kondyläre Ausführung, als Stabilizer- und Superstabilizer-Konfiguration erhältlich, und zwar (mit Ausnahme des Superstabilizers) mit poröser oder unporöser Beschichtung. Die Konfiguration bestimmter Femurkomponenten ist konvertierbar: z. B. kann durch Hinzufügen einer modularen Stabilizer-Box die kondyläre zur Stabilizer-Ausführung modifiziert werden.

Tibiakomponenten

Tibiakomponenten werden in einer Vielzahl von Größen und Stärken angeboten, darunter einteilige, vollständig aus Polyethylen gefertigte Komponenten und modulare Modelle, die aus einem Polyethyleneinsatz und einer Metallbasisplatte bestehen. Die Basisplatten sind wahlweise mit poröser oder unporöser Beschichtung sowie mit zusätzlichen Fixationsoptionen erhältlich. Polyethyleneinsätze stehen in verschiedenen Versionen zur Verfügung: von kondylären Einsätzen, wahlweise mit geringerer oder stärkerer Konformität, über Stabilizer- bis hin zu Superstabilizereinsätzen.

Patellakomponenten

Die Patellakomponenten sind entweder ganz aus Polyethylen oder metallverstärkt mit poröser Beschichtung erhältlich.

Zubehör

Schaftverlängerungen sind so konstruiert, daß sie für zusätzliche Stabilität am Schaft

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cemento, metallo, polietilene UHMWPE, dal peso molecolare ultra elevato, e ceramica). Questa reazione ha conseguenze che vanno dalla che tra componenti e osso, essenzialmente attraverso i meccanismi d'usura dell'adesione, abrasione e della fatica. Quanto all'eziologia, si è ipotizzato che le particelle dei detriti generati dal movimento delle componenti protesiche dell'articolazione migrino nella cavità sinoviale e nell'interfaccia osso-impianto dove, attirando i macrofagi, stimolano la fagocitosi. Il grado di attrazione è determinato dalle dimensioni, dalla distribuzione e quantità di particelle di detriti, oltre che dalla rapidità di formazione dei detriti stessi. Si è dimostrato, in vitro, che l'azione fagocitica contribuisce alla liberazione di citochine e di mediatori cellulari (IL-1,IL2, IL-6,PGE 2, TNF3). È provato che tali mediatori modulano il riassorbimento osseo osteoclastico. Continuano le ricerche sia cliniche, sia di base per capire la causa scientificache scatena il fenomeno e per ridurne l'insorgenza.

Visto che l'osteolisi è spesso asintomatica, esami radiografici periodici, regolari sono essenziali per individuare e minimizzare complicanze gravi che si possano verificare in futuro. Tuttavia è possibile che le radiografie non rilevinocompletamente l'estensione dell'osteolisi. La presenza di lesioni focali progressive può imporre la sostituzione delle componenti protesiche.

B. **Spessore del polietilene.** Analisi teoriche indicano che le sollecitazioni da contatto nella componente tibiale variano con lo spessore della componente polietilenica. Si ritiene che, in genere, gli inserti più grossi subiscano sollecitazioni da contatto più deboli di quanto avviene nel caso di inserti più sottili. Tali sollecitazioni possono incidere sull'usura delle componenti protesiche, anche se non si è ancora giunti a una conclusione definitiva circa le conseguenzecliniche derivanti dalle differenze teoriche di sollecitazione. Il medico dovrebbe giudicare sulla soluzione-migliore: se una resezione in più dell'osso tibiale, o un inserto più grosso. Fattori connessi al paziente, quali peso, età e grado di attività dovrebbero tutti essere presi in considerazione al momento di decidere.

C. **Componenti congruenti.** La larghezza delle parti tibiali è concepita in modo da adattarsi ad una determinata dimensione delle componentifemorali, rendendo così possibile l'articolazione dei pezzi tra di loro. Se le componenti non si incastrano bene, ilrisultato può essere il fallimento precoce della componente tibiale, con lassità dell'articolazione stessa.

D. **Etichetta del prodotto.** Vedere l'etichetta del prodotto per informazioni riguardo al prodotto specifico indicato in questo inserto della confezione.

FORNITURA

I prodotti sono forniti in condizioni sterili, in contenitori esposti ad un minimo di 25 kGy di radiazioni gamma provenienti da una fonte di cobalto 60. Prima dell'uso, le confezioni di prodotti sterili dovrebbero essere esaminate per controllare un'eventuale rottura della barriera sterile.

RISTERILIZZAZIONE

Le componenti contenenti POLIETILENE, SUPERFICI POROSE, PLASMA SPRAY,

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5) deformità in varo-valgo con conseguente allineamento incorretto arto/protesi;
6) lesioni cardiovascolari, ischemia, trombosi, embolia polmonare o infarto miocardico;
7) ematoma;
8) cicatrizzazione lenta della ferita;
9) infezione profonda della ferita (precoce o tardiva), complicanza potenzialmente grave in tutti i casi di protesizzazione dell'articolazione, tanto da necessitare la rimozione della protesi, e successivamente un'artrodesi. Si impone assolutamente una profilassi antibiotica appropriata, con osservanza rigorosa diuna procedura asettica;
10) frattura della componente femorale, tibiale o rotulea.

Complicanze post-operatorie tardive possono comprendere, tra l'altro, i casi seguenti:

1) allentamento tardivo (o precoce), cambiamento di posizione delle componenti, usura e piegamento o criccaturadi una o più componenti protesiche. (L'esperienza clinica insegna che un'attenzione particolare a quanto indicatonelle sezioni Avvertenze e Precauzioni di questo package può contribuire a minimizzare il rischio che si verifichino i fenomeni di cui sopra);
2) frattura della rotula quale conseguenza di tensione eccessiva o di indebolimento inavvertito nel corso dell'operazione;
3) problemi maggiori dell'arto colpito o dell'estremità controlaterale provocati dalla dismetria dell'arto;
4) instabilità tardiva dei legamenti;
5) calcificazione o ossificazione periarticolare, con o senza ostacolo alla mobilità dell'articolazione;
6) arco di movimento insufficiente, a causa di scelta o posizionamento incorretti delle componenti, con infrazioneo calcificazione e distrofia periarticolare;
7) fratture ossee, lussazione, sublussazione, flessione contratta, arco di movimento più limitato, allungamento oaccorciamento della gamba, tutti fenomeni chiamati in causa nella protesizzazione totale di ginocchio.

INFORMAZIONI IMPORTANTI PER IL MEDICO

A. **Riassorbimento osseo e osteolisi.** Un fenomeno che può intervenire, quale conseguenza naturale dell'artroplasticatotale dell'articolazione, è il riassorbimento osseo - fenomeno provocato dai cambiamenti che interessano gli schemi di rimodellamento dell'osso. Infatti, collocando la protesi, cambia la distribuzione delle sollecitazioni, distribuzione che, mutando, provocail rimodellamento osseo. Un riassorbimento osseo periprotesico esteso comporta l'allentamento e, quindi, il fallimento dell'impianto. Oltre allo stress-shielding (deformazione elastica) e all'infezione, possono intervenire altri fenomeniatti a provocare riassorbimento osseo progressivo e localizzatochiamato osteolisi-non soltanto intorno alle componenti protesiche, ma anche tra osso e componenti. È generalmente risaputo che l'osteolisi deriva dalla reazione localizzata dei corpi esstranei alle particelle di detriti (per esempio

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IDROSSIAPATITE, CERAMICHE O METILMETACRILATO NON POSSONO ESSERE STERILIZZATI A VAPORE A SPOSTAMENTO DI GRAVITÀ.

I componenti che **non** sono stati contaminati con liquidi, ed in particolare con quelli corporei, possono essere risterilizzati in autoclave a vapore a spostamento per gravità, utilizzando i parametri seguenti:

	121° C (250° F) 1.4 bar (20 PSI)	132° C (270° F) 2 bar (30 PSI)
Componenti individuali imballati (componente singolo o multiplo) o cassa di sterilizzazione	40 minuti	20 minuti

Il metodo a doppio imballo viene utilizzato nelle tecniche CSR AAMI. Questi cicli sono stati sviluppati solamente con questo articolo nella camera ed utilizzando lo scaffale medio. Tutti i cicli devono essere validati per differenti camere di sterilizzazione, metodi di imballaggio e/o varie configurazioni di carico.

ATTENZIONE

La legge federale statunitense limita la vendita di questo dispositivo dietro prescrizione medica.

BIBLIOGRAFIA

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk after Hip Replacement with Metal Implants: A Population Based Cohort Study in Sweden", Journal of the National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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Los avances logrados en la sustitución total de la rodilla permiten que el cirujano disponga de los medios necesarios para restituir la movilidad, corregir la deformidad y reducir el dolor utilizando dispositivos protésicos implantados. Aunque el éxito de estos dispositivos está comprobado, los mismos se fabrican de metal y materiales plásticos, por lo tanto no se puede esperar que un dispositivo protésico resista grados de actividad y de carga como lo haría una articulación normal y sana. Por lo tanto el sistema protésico no tendrá la misma resistencia, fiabilidad o durabilidad que la articulación natural de la rodilla humana.

Al utilizar artroplastias totales de la rodilla, el cirujano tendrá que tener en mente lo siguiente:

A. **La selección y el posicionamiento correctos del implante son extremadamente importantes.** Para lograr una sustitución total de la articulación exitosa, es necesario seleccionar la talla y la configuración apropiadas e implantes diseñados. Las artroplastias totales requieren una colocación meticulosa, una fijación rígida y un apoyo óseo adecuado.

B. **Al seleccionar a los pacientes para la artroplastia sustitutiva total, los siguientes factores pueden ser determinantes para el éxito subsiguiente del procedimiento:**

1) ***El peso del paciente.*** Un paciente con exceso de peso u obeso puede producir solicitationes mayores en la prótesis, que pueden llevar al fallo del dispositivo. Si se coloca una prótesis de talla pequeña, debido al tamaño del hueso en tales pacientes, se incrementará el efecto de dichas cargas.

2) **La ocupación o actividad del paciente.** Si el paciente tiene una ocupación o se dedica a actividades que implican solicitudes de impacto importantes (como caminar, correr, levantar objetos pesados o contorcerse), las fuerzas resultantes pueden ocasionar el fracaso de la fijación, del dispositivo o de ambos. Una actividad física excesiva en el curso de los años también puede acentuar el desgaste normal que ocurre en las articulaciones protésicas. La prótesis no restituirá la función al nivel esperado de una articulación normal y sana, y el paciente no debería tener, o tendría que ser disuadido de, expectativas funcionales poco realistas. (Para más información, consulte la sección **PRECAUCIONES**).

3) **Afecciones como la senectud, enfermedades mentales o alcoholismo.** El paciente que padece de estos morbos, entre otros, podría ignorar algunas limitaciones y precauciones necesarias en caso de implante, ocasionando su fallo u otras complicaciones.

4) **Sensibilidad a cuerpos extraños.** Cuando se sospeche sensibilidad a materiales determinados, se tendrán que llevar a cabo las pruebas apropiadas antes de elegir el material o llevar a cabo la implantación.

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5) **Historial ortopédico.** El buen pronóstico del procedimiento depende del (los) ortopédico del paciente. Los pacientes sometidos a múltiples intervenciones previas e/o implantes, tendrán que ser asesorados cuidadosamente sobre el resultado esperado de la intervención.

6) **Calidad del hueso.** La supervivencia de la artroplastia total de rodilla podrá verse afectada por un sustrato óseo debilitado, lo cual puede ser consecuencia de ciertas enfermedades sistémicas o metabólicas, tales como aquellas tratadas con esteroides, inmunosupresores o quimioterápicos.

DESCRIPCIÓN

Howmedica produce una gran variedad de sistemas reconstructivos tricompartimentales de rodilla en varias tallas y configuraciones, para responder a los diferentes requisitos de pacientes y cirujanos en casos de aplicaciones primarias y de revisión cementadas. La selección del sistema protésico dependerá del tipo de cirugía requerido. Existen componentes femorales, tibiales y rotulianos para la reconstrucción de la rodilla. Los componentes metálicos (el componente femoral y las bases tibiales y rotulianas, bolitas sinterizadas, cuñas y espaciadores) son fabricados de aleación moldeada de cromo-cobalto-molibdeno (Aleación Vitallium®) de conformidad con la norma F75 de la ASTM. Los tornillos y los extensores de vástago son fabricados de aleación forjada de cromo-cobalto-molibdeno (Aleación Vitallium®) de conformidad con la norma F1537 de la ASTM. Los componentes de polietileno son fabricados de polietileno de peso molecular ultra alto (UHMWPE) de conformidad con la norma F648 de la ASTM.

Componentes Femorales

Los componentes femorales (con la excepción del super-estabilizador) existen en versiones con revestimiento poroso o no-poroso y configuraciones condilar, estabilizador y super-estabilizador. Algunos componentes femorales pueden ser convertidos de una configuración a otra, por ej., condilar a estabilizador, agregando una caja estabilizadora modular.

Componentes Tibiales

Los componentes tibiales existen en una gran variedad de tallas y grosores. Los componentes tibiales incluyen piezas fabricadas totalmente de polietileno y las versiones modulares que consisten en el espesor de polietileno y la base metálica. Las bases existen en opciones con revestimiento poroso o no-poroso y opciones de fijación adjunta. En las configuraciones condilar, estabilizador y super-estabilizador las piezas de inserción existen con varios grados de constreñimiento.

Componentes Patelares

Los componentes patelares pueden ser solo de polietileno o pueden tener dorso metálico con revestimiento poroso.

Accesorios

Los extensores de vástago están diseñados para ser fijados al vástago del componente femoral o tibial con el fin de ofrecer una estabilidad adicional. Las cuñas están

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diseñadas y destinadas a aplicaciones cementadas para ofrecer espaciamiento adicional en casos de defectos óseos tibiales. Los emaciadores están diseñados para ofrecer espaciamiento adicional en casos de defectos óseos femorales y podrán ser fijados mecánicamente al componente femoral o podrán ser cementados. Los tornillos pueden ser utilizados para ensamblar el espesor tibial con la base o la base tibial con el hueso tibial.

Etiqueta del producto

La etiqueta del producto proporciona información referente al material o materiales específicos de los que está manufacturado el dispositivo.

INDICACIONES

Las indicaciones para la artroplastia total de la rodilla incluyen:

1) enfermedad articular degenerativa no-inflamatoria, incluso artrosis, artrosis traumática o necrosis avascular;
2) artritis reumatoidea;
3) corrección de una deformidad funcional;
4) procedimientos de revisión en los casos en que otro tratamiento u otros dispositivos hayan fallado;
5) pérdida post-traumática de la anatomía articular, particularmente cuando existe erosión patelo-femoral, disfunción o patelectomía previa; y
6) fractura irreparable de la rodilla.

CONTRAINDICACIONES

Entre las contraindicaciones absolutas cabe citar:

1) infección manifiesta;
2) focos distantes de infección (que podrían ocasionar infección por vía hematógena en el lugar del implante);
3) progresión rápida de la enfermedad, como la manifiesta por destrucción articular o resorción ósea en estudios radiográficos;
4) pacientes con esqueleto inmaduro;
5) casos en los cuales el sustrato óseo es deficiente, lo cual no justificaría la intervención.

Entre las condiciones que representan mayor riesgo de fracaso se incluyen:

1) pacientes que no cooperan o pacientes con trastornos neurológicos, incapaces de seguir las instrucciones;
2) osteoporosis;
3) trastomos metabólicos que inciden en la formación ósea o causan pérdida ósea;
4) osteomalacia; y
5) artrodesis previa.

También ha ocurrido una mayor incidencia de fallos del implante en casos de paraplegia, parálisis cerebral y enfermedad de Parkinson.

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ADVERTENCIAS

La selección, colocación, posicionamiento y fijación inadecuados de los componentes del implante pueden resultar en condiciones de solicitaciones inusuales y una vida útil reducida del implante protésico. El cirujano tendrá que conocer a fondo el procedimiento quirúrgico, el instrumental y las características del implante antes de realizar la intervención. Se recomienda un seguimiento regular a largo plazo para controlar la posición y el estado de los componentes protésicos, al igual que las condiciones del hueso adyacente.

Aplicación cementada. Es necesario cerciorarse del apoyo completo de todas las partes del dispositivo empotrado en el cemento óseo para evitar concentraciones de solicitaciones que podrían tener como consecuencia el fallo del procedimiento. La limpieza minuciosa del lecho del implante (extracción completa de astillas óseas, fragmentos de cemento óseo y partículas metálicas) es de importancia crucial para evitar la usura acelerada de las superficies articulares del implante.

Componentes protésicos. No se han de combinar componentes femorales, tibiales y patelares de diferentes sistemas protésicos o de diferentes fabricantes, pues puede haber incompatibilidad en la tolerancia o en los materiales. Se han de ensamblar bien los componentes modulares a fin de evitar una posible disociación. Se han de evitar el montaje y el desmontaje repetido de componentes modulares, pues esto podría afectar su efecto de encerrojado, de importancia decisiva. Antes de proceder al montaje, se tendrán que limpiar los componentes de todo detritus quirúrgico, de lo contrario los residuos podrán interferir en el mecanismo de encerrojado de los componentes modulares, lo cual a su vez podría ocasionar un fallo precoz del procedimiento.

Componente patelar. Debido a que el componente patelar tiene las superficies de carga y fijación más pequeñas, la patela o el componente patelar es más vulnerable a la subluxación y al aflojamiento/dislocación. Para lograr el éxito del procedimiento, es necesario prestar especial atención a la traslación patelar durante la intervención.

Tornillos de fijación. Si se utilizan tornillos de fijación, estos tendrán que estar bien atornillados para permitir una fijación estable óptima y para evitar posibles interferencias con el anclaje adecuado de los componentes. Utilize únicamente los tornillos recomendados para una prótesis específica, para evitar así un desajuste y una combinación inapropiada de metales. Estos tornillos óseos no han sido concebidos para ser atornillados o fijados a los elementos posteriores (pediculos)de las vértebras cervicales, torácicas o lumbares.

Componentes metálicos. Algunas de las aleaciones utilizadas en la producción de implantes ortopédicos contienen elementos metálicos que, bajo circunstancias extraordinarias, podrían ser carcinógenos en cultivos de tejido o en organismos intactos. En la bibliografía científica se ha considerado si estas aleaciones de por sí podrían ser carcinogénicas en el huésped que recibe el implante. Los estudios llevados a cabo a este fin, no han dado evidencia convincente sobre un tal fenómeno, a pesar de los millones de implantes que se han realizado (Véase referencia 1).

Alineación de los componentes. Se han de tomar las precauciones necesarias para restituir el alineamiento adecuado de la articulación y para equilibrar la tensión ligamentosa. Una malalineación del miembro o de la articulación puede causar un desgaste excesivo, aflojamiento de la prótesis y dolor, lo cual podría conducir a una revisión indeseable y antes de tiempo de uno o más componentes protésicos.

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Desgaste de polietileno. Como era de esperar, han habido informes sobre la cerna de polietileno en pacientes de componentes tibiales o cabezas de las artroplastias totales de rodilla. Las partículas de cemento, metal u otros detritus podrían provocar tasas mayores de usura, que podrían causar abrasión de las superficies articulares. Es probable que una tasa más altas de usura acorte la vida útil de la prótesis y ocasione una revisión indeseable y antes de tiempo, para sustituir los componentes protésicos desgastados.

PRECAUCIONES

Información para los pacientes. El paciente tendrá que ser informado sobre las limitaciones del procedimiento a corto y largo plazo y sobre la necesidad de proteger el implante de la carga total, hasta que la fijación y la curación sean adecuadas. Se ha señalado que las actividades excesivas y los traumatismos que afecten la artroplastia provocan el fallo de la reconstrucción, por causar aflojamiento y/o usura del implante protésico. El aflojamiento de los componentes puede resultar en una mayor producción de partículas de usura, también puede lesionar el hueso, dificultando la cirugía de revisión exitosa.

Se deberá avisar al paciente que limite sus actividades, que proteja la artroplastia de solicitaciones poco razonables y que siga las instrucciones del facultativo con respecto al seguimiento y al tratamiento.

Se deberá advertir al paciente sobre riesgos quirúrgicos y se le ha de informar sobre posibles efectos adversos. También se le prevendrá que el dispositivo no es y no puede ser una réplica de una articulación normal sana, que el implante puede fracturarse o deteriorarse como resultado de actividades vigorosas o traumatismos, que el dispositivo tiene una vida útil finita y que quizás se tenga que reemplazar en el futuro.

En la vida cotidiana puede ocurrir una **bacteremia transitoria**. Los procedimientos odontológicos, los exámenes endoscópicos y otros procedimientos quirúrgicos de menor importancia también han sido asociados a una bacteremia pasajera. Para prevenir una infección en el lugar del implante, puede ser recomendable una antibioprofilaxis antes y después de tales procedimientos.

Instrumentos. Existe un instrumental especializado que ha de ser utilizado para asegurar la implantación correcta de los componentes protésicos.

Aunque sucede rara vez, puede ocurrir una fractura o rotura de instrumentos en el peroperatorio. Aquellos instrumentos expuestos a uso extenso o a fuerza excesiva pueden fracturarse. Antes de la intervención, el instrumental tendrá que ser examinado para constatar un posible desgaste o deterioro.

Reutilización. Nunca se ha de volver a utilizar un implante. Aunque parezca estar intacto, un implante usado puede presentar imperfecciones o defectos latentes que reducirían su vida útil.

Manejo. El manejo de los implantes es importante, sobretodo el de los implantes con revestimiento poroso. No permita que las superficies porosas entren en contacto con tejidos u otros materiales que suelten fibras. Se tendrán que desechar todos los implantes que tengan un revestimiento dañado o contaminado. La parte muy pulida del implante no ha de entrar en contacto con superficies duras.

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EFECTOS ADVERSOS

1) En todas las sustituciones articulares puede ocurrir una reacción celular asintomática, localizada y progresiva (osteólisis) alrededor de los componentes protésicos o a distancia de los mismos, como consecuencia de una reacción de cuerpo extraño a una sustancia particulada. Las sustancias particuladas se generan por una interacción entre los componentes y también entre los componentes y el hueso, en primer lugar a través de mecanismos de usura que consisten en adhesión, abrasión y fatiga. En segundo lugar, las sustancias particuladas también pueden ser generadas por usura de un tercer cuerpo. La osteólisis puede causar complicaciones futuras que requerirán la extracción y la sustitución de los componentes protésicos. (Para más información, consulte la sección **INFORMACIÓN IMPORTANTE PARA EL FACULTATIVO**).
2) Aunque ocurren rara vez, se han reportado reacciones de sensibilidad a metales en pacientes sometidos a una sustitución articular. La implantación de un material extraño en los tejidos puede resultar en reacciones celulares, estas pueden presentar linfocitos, macrófagos y fibroblastos.
3) Se han reportado neuropatías periféricas después de cirugía articular total. También se han reportado lesiones nerviosas sub-clínicas, que pueden ser el resultado de un traumatismo quirúrgico.
4) La dislocación o subluxación de los componentes del implante puede ser el resultado de una colocación inadecuada y/o migración de los componentes. También pueden contribuir a estas patologías la laxitud de los tejidos blandos, incluso los músculos, el tejido fibroso y los ligamentos.
5) Los implantes se podrán aflojar o podrán migrar debido a un traumatismo o a una pérdida de la fijación.
6) Una infección puede causar el fallo de la sustitución articular.
7) Aunque sucede rara vez, la fractura del implante por fatiga puede ocurrir como resultado de traumatismo, actividad vigorosa, alineación defectuosa o cuando se trata de un implante de muy larga data.
8) Un desequilibrio de los tejidos blandos (ligamentos) puede causar usura excesiva y/o fallo del implante.
9) La fractura del fémur, de la tibia o de la rótula pueden ocurrir en el peroperatorio al preparar el lecho óseo y/o el lugar de colocación de los implantes.
10) Aunque son poco comunes, pueden ocurrir reacciones alérgicas a los materiales utilizados en el implante.

Entre las complicaciones que pueden ocurrir en el peroperatorio y en el postoperatorio inmediato cabe mencionar (aunque no necesariamente se limiten a estas):

1) trombosis venosa profunda;
2) lesión de vasos sanguíneos;
3) lesión pasajera o permanente de un nervio que resulta en dolor o parestesia en el miembro afectado;

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4) [illegible] apropiada de la tensión arterial en el peroperatorio, asociada a la utilización de cemento óseo;

5) deformidad en varo/valgo con la malalineación resultante del miembro/prótsis;

6) trastornos cardiovasculares, incluso embolismo pulmonar o infarto de miocardio;

7) hematoma;

8) curación retardada de la herida;

9) infección profunda de la herida (inmediata o tardía), se trata de una complicación potencialmente grave en todas las artroplastias que podrá requerir explante de la prótesis y artrodesis subsiguiente. Se impone una profilaxis con antibióticos apropiada y el cumplimiento estricto de los procedimientos asépticos; y

10) fractura del hueso o el componente femoral, tibial o patelar.

Entre las complicaciones tardías del postoperatorio cabe citar (aunque no necesariamente se limiten a estas):

1) aflojamiento tardío (o precoz), cambio en la posición de los componentes, desgaste y doblamiento o fisura de uno o más componentes protésicos. (La experiencia clínica sugiere que se puede reducir el riesgo de la ocurrencia de estos fenómenos, si se sigue con atención lo estipulado en la sección Advertencias y Precauciones de este impreso);

2) fractura patelar, como resultado de una tensión excesiva o un debilitamiento accidental ocurrido en el peroperatorio;

3) problemas agravados en el miembro afectado o en la extremidad contralateral, causados por dismetría;

4) inestabilidad ligamentosa tardía;

5) calcificación u osificación periarticular, con o sin interferencia sobre la movilidad articular;

6) arco de movimiento inadecuado, debido a una selección o una colocación inapropiada de los componentes, atrapamiento o calcificaciones periarticulares y distrofia; y

7) fracturas óseas, dislocación, subluxación, contractura de flexión, arco de movimiento disminuido, alargamiento o acortamiento de la pierna, todas estas patologías han sido reportadas en relación con sustituciones totales de rodilla.

INFORMACION IMPORTANTE PARA EL FACULTATIVO

A. **Reabsorción ósea y osteólisis.** La resorción ósea puede ocurrir como consecuencia natural de la artroplastia total, debido a los cambios que se producen en los patrones de remodelación ósea. La remodelación ósea se facilita por los cambios en la distribución de solicitaciones, causados por la implantación. Una resorción extensa alrededor de la prótesis provoca el aflo-

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jamiento del implante y su fallo. Puede ocurrir una resorción ósea localizada progresiva al alejarse los componentes protésicos, tanto también entre los componentes y el hueso, por razones distintas a la protección de la carga (stress shielding) o la infección. Esto se ha designado con el término osteólisis. Existe un acuerdo general que indica que la osteólisis es el resultado de una reacción localizada de cuerpo extraño a residuos particulados (por ej. cemento, metal, UHMWPE y cerámicas), producido por la interacción entre los componentes, como también entre los componentes y el hueso, sobretodo por mecanismos de desgaste, a saber, adhesión, abrasión y fatiga. En lo que se refiere a la etiología, se ha emitido la hipótesis que los residuos particulados, generados por la articulación de los componentes de la prótesis, migran a la cavidad sinovial y a la interfaz entre hueso e implante, en donde recrutan macrófagos y estimulan la fagocitosis. El grado de reacción celular está determinado por el tamaño, la distribución y la cantidad de residuos particulados, al igual que por la tasa de producción de detritus. Se ha demostrado in vitro, que la acción fagocitósica induce liberación de citocinas y mediadores celulares (IL-1, IL-2, IL-6, PGE2, TNF3). También se ha señalado que estos mediadores modulan la resorción osteoclástica del hueso. La investigación clínica y básica continúa, con el fin de lograr una mejor comprensión de la base científica que explique las causas de este fenómeno y para explorar las posibles alternativas que reduzcan la frecuencia de su ocurrencia.

Debido a que la osteólisis con frecuencia es asintomática, se imponen los exámenes radiográficos regulares de rutina, para poder detectar y reducir al mínimo cualquier complicación futura grave. Sin embargo es posible que las radiografías no definan con exactitud la extensión de la osteólisis. La presencia de lesiones focales que sean progresivas, podrá requerir el reemplazo del componente o de los componentes protésicos.

B. **El grosor de polietileno.** Los análisis teóricos han indicado que las solicitaciones de contacto en el componente tibial varían con el grosor del componente de polietileno. En términos generales, se considera que las piezas de inserción más gruesas tienen solicitaciones de contacto menores que las más delgadas. Estas solicitaciones podrán afectar el desgaste de los componentes del implante; sin embargo, las implicaciones clínicas de las diferencias teóricas de las solicitaciones todavía no son conclusivas. El cirujano ha de sopesar las ventajas de una resección ósea tibial más profunda con la utilización de una pieza de inserción más gruesa. Los factores relacionados con el paciente, tales como peso, edad y grado de actividad, también han de formar parte de la decisión.

C. **Congruencia de los Componentes.** Existen piezas tibiales correspondientes, diseñadas para articular y concordar con los componentes femorales de talla apropiada. La falta de congruencia entre componentes podría resultar en un fallo prematuro del componente tibial y podría contribuir a la laxitud articular.

D. **Etiqueta del producto.** Véase la etiqueta del producto para la información referente al producto específico al que se hace referencia en este folleto.

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SUMINISTRO

Estos productos son suministrados en condiciones estériles dentro de los contenedores que han sido expuestos a un mínimo de 25kGy de radiación gamma, proveniente de una fuente de cobalto 60. Antes de su utilización, el embalaje de todo producto estéril tendrá que ser examinado para detectar una posible interrupción de la barrera estéril.

REESTERILIZACION

Los dispositivos con POLIETILENO, SUPERFICIE POROSA, PULVERIZADORES DE PLASMA, HIDROXIAPATITA, CERÁMICAS o METILMETACRILATO NO PUEDEN REESTERILIZARSE POR AUTOCLAVE NI SER REESTERILIZADOS POR PARTE DEL CLIENTE.

Los componentes que no hayan sido contaminados por líquidos, en particular líquidos corporales, pueden volverse a esterilizar en un autoclave de vapor con desplazamiento por la gravedad, usando los siguientes parámetros:

	121° C (250° F) 1.4 baras (20 PSI)	132° C (270° F) 2 baras (30 PSI)
Componente individual envuelto (componente sencillo o múltiple) o caja de esterilización	40 minutos	20 minutos

El método de doble envoltorio se denomina técnica AAMI CSR. Los ciclos indicados se formularon teniendo solamente este elemento en la cámara y usando el anaquel del centro. Todo ciclo se debe validar para diferentes cámaras de esterilización, métodos de envoltura y/o varias configuraciones de carga.

PRECAUCIÓN

La Legislación Federal de E.E.U.U. solo permite la venta de este dispositivo por un médico o por orden de un facultativo.

BIBLIOGRAFIA

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk after Hip Replacement with Metal Implants: A Population Based Cohort Study in Sweden", Journal of the National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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ATENÇÃO CIRURGIÃO OPERADOR

O sucesso na substituição parcial e total do joelho forneceu ao cirurgião meios para restaurar a mobilidade, corrigir deformidades e reduzir a dor com o uso de aparelhos protéticos implantados. Embora se tenha comprovado que esses aparelhos foram amplamente bem-sucedidos em alcançar esses objectivos, eles são fabricados com material plástico ou metal. Portanto, não se pode prever que nenhum aparelho protético possa suportar os níveis de actividades e cargas de uma articulação sadia normal. Consequentemente, o sistema protético não será tão forte, digno de confiança ou duradouro como a articulação do joelho humano natural..

Ao usar implantes de articulação totais, o cirurgião deverá estar ciente do seguinte:

A. **A selecção e o posicionamento correctos do implante são extremamente importantes.** O sucesso na substituição da articulação total requer a selecção do tamanho, forma e desenho adequados do implante. As próteses de articulação totais requerem um assentamento cuidadoso e um suporte ósseo adequado.

B. **Ao seleccionar os pacientes para substituições de articulação totais, os seguintes factores poderão ser de extrema importância para o êxito final do procedimento:**

1) **Peso do paciente.** Um paciente obeso ou com excesso de peso pode produzir cargas mais elevadas sobre a prótese, podendo levar à falha do aparelho. O efeito dessas cargas será acentuado quando uma prótese de tamanho pequeno precisar de ser usada, devido ao tamanho do osso nesses pacientes.

2) **A ocupação ou actividade do paciente.** Se o paciente estiver envolvido numa ocupação ou actividade que inclua cargas de impacto significativas (caminhar, correr, levantar peso, ou torcer-se), as forças resultantes poderão causar falha da fixação, do aparelho, ou de ambas as coisas. Altos níveis de actividade física, com o decorrer dos anos, também poderão acentuar o processo de desgaste normal que ocorre com as articulações protéticas. A prótese não restaurará a função do nível esperado com o osso sadio normal e o paciente não deverá ter – e disso deverá ser dissuadido - expectativas funcionais irrealistas. (Veja a secção de **PRECAUÇÕES** para mais informações.)

3) **Uma condição de senilidade, doença mental ou alcoolismo.** Essas condições, entre outras, poderão fazer com que o paciente ignore certas limitações e precauções necessárias no uso do implante, levando à falha ou a outras complicações.

4) **Sensibilidade a corpos estranhos.** Quando a sensibilidade do material for suspeita, deverão fazer-se os testes apropriados antes da selecção do material ou da implantação.

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5) **Histórico Ortopédico.** O prognóstico para o sucesso do procedimento depende do histórico ortopédico do paciente. Pacientes que tenham tido fraturas, necrose ou problemas articulares devem ser cuidadosamente aconselhados com relação ao resultado previsto do procedimento.

6) **Qualidade do osso.** A sobrevivência da substituição total do joelho pode ser afectada por osso enfraquecido, que pode resultar de certas doenças sistémicas ou metabólicas, como as tratadas com esteróides, imunossupressores ou quimioterapêutica.

DESCRIÇÃO

A Howmedica fabrica uma ampla variedade de sistemas de reconstrução total do joelho de três compartimentos em vários tamanhos e estilos para satisfazer os diversos requisitos de pacientes e cirurgiões para aplicações cimentadas primárias e de revisão. A selecção do sistema protético depende do tipo de cirurgia requerido. Componentes femorais, tibiais e patelares estão disponíveis para a reconstrução do joelho. Os componentes metálicos (o componente femoral, as placas básicas tibial e patelar, pérolas sinterizadas, cunhas e espaçadores) são fabricados com liga fundida de cobalto-cromo-molibdênio (Liga Vitallium®) em conformidade com a norma F75 da ASTM. Os parafusos e extensores de haste são fabricados com liga forjada de cobalto-cromo-molibdênio (Liga Vitallium®) em conformidade com a norma F1537 da ASTM.

Os componentes de polietileno são fabricados com polietileno de peso molecular ultra-alto (UHMWPE) em conformidade com a norma F648 da ASTM.

Componentes femorais

Os componentes femorais (excepto o superestabilizador) são oferecidos com opções de revestimento poroso e não poroso, nas configurações condilar, estabilizadora e superestabilizadora. Alguns componentes femorais podem ser convertidos de uma configuração para outra, por ex., condilar para estabilizadora, pelo acréscimo de uma caixa estabilizadora modular.

Componentes tibiais

Os componentes tibiais são oferecidos em uma vasta gama de tamanhos e espessuras. Eles incluem os estilos modular e inteiriço totalmente em polietileno, consistindo em uma inserção de polietileno e uma placa básica metálica. As placas básicas são oferecidas com opções de revestimento poroso e não poroso e opções de fixação adjunta. As inserções são oferecidas em vários graus de restrição, nos estilos condilar e nas configurações estabilizadora e superestabilizadora.

Componentes patelares

Os componentes patelares são oferecidos totalmente em polietileno ou com reforço de metal com revestimento poroso.

Acessórios

Os extensores de haste são projectados para serem instalados na haste do componente femoral ou tibial a fim de proporcionar estabilidade adicional. As cunhas são projectadas para aplicações de cimentação a fim de proporcionar espaçamento

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adicional onde houver defeitos no osso tibial. Os espaçadores são projectados para proporcionar espaçamento adicional onde houver defeitos no osso femoral e podem ser individualmente fixados ao componente femoral ou cimentados no lugar. Há parafusos para a montagem adjunta de inserções tibiais nas placas básicas ou da placa básica tibial no osso tibial.

Rótulo do produto

O rótulo do produto fornece informações relativas ao(s) material(is) específico(s) com o(s) qual(is) o dispositivo é fabricado.

INDICAÇÕES

As indicações para uso das próteses de substituição total do joelho incluem:

1) doença de articulação degenerativa não inflamatória do joelho, incluindo osteoartrite, artrite traumática e necrose avascular;
2) artrite reumática;
3) correcção de deformidade funcional;
4) processos de revisão em que tenham falhado outros tratamentos ou outros aparelhos;
5) 5) perda pós-traumática da anatomia da articulação, particularmente quando houver erosão patelo-femoral, disfunção ou patelectomia anterior; e
6) 6) fractura irreparável do joelho.

CONTRA-INDICAÇÕES

As contra-indicações absolutas incluem:

1) a superinfecção;
2) focos distantes de infecções (que podem causar infiltração hematógena no local do implante);
3) progressão rápida da doença, manifestada por meio da destruição da articulação ou da absorção óssea aparente no roentgenograma
4) pacientes esqueleticamente imaturos; e,
5) casos em que haja estoque ósseo pobre, que tornaria este procedimento injustificável.

As condições que apresentam maior risco de falha incluem:

1) paciente não cooperativo ou paciente com desordens neurológicas, incapaz de seguir instruções;
2) osteoporose
3) distúrbios metabólicos que possam prejudicar a formação óssea;
4) osteomalacia; e
5) artrodese anterior

Há também registro de maior incidência de falha de implantes em paraplégicos, pacientes com paralisia cerebral e com doença de Parkinson.

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ADVERTÊNCIAS

A selecção inapropriada, posicionamento e fixação dos componentes de implante podem resultar em condições de estresse fora do comum com relação à subsequente na duração do implante protético. O cirurgião deverá familiarizar-se totalmente com o procedimento cirúrgico, instrumentos e características do implante, antes de realizar a cirurgia. Recomenda-se o acompanhamento periódico a longo prazo para monitorizar a posição e condição dos componentes protéticos, assim como a condição do osso adjacente.

Aplicação cimentada. Deve-se ter cuidado garantir o suporte completo de todas as partes do aparelho, embebidas em cimento ósseo para evitar concentrações de estresse que possam levar à falha do procedimento. A limpeza completa (remoção total de fragmentos de osso, fragmentos de cimento de osso e detritos metálicos) do local do implante é fundamental para impedir o desgaste acelerado das superfícies articulares do implante.

Componentes protéticos. Os componentes femorais, tibiais e patelares de diferentes sistemas protéticos ou de diferentes fabricantes não devem ser misturados, uma vez que as tolerâncias ou os materiais podem ser incompatíveis. Os componentes modulares devem ser montados firmemente para evitar dissociação. A montagem e desmontagem repetida dos componentes modulares pode comprometer a acção de bloqueamento fundamental dos componentes e deve ser evitada. Devem-se limpar os detritos cirúrgicos dos componentes antes da montagem. Os detritos podem interferir com o mecanismo de bloqueamento dos componentes modulares, que por sua vez pode causar a falha prematura do procedimento.

Componente patelar. Uma vez que o componente patelar tem as menores superfícies de apoio e fixação, a patela ou componente patelar é mais vulnerável à subluxação e ao afrouxamento/deslocamento. Deve-ser prestar atenção particular à patela para o sucesso do procedimento.

Parafusos de fixação. Quando usados, os parafusos de fixação devem ser totalmente assentados para maximizar a estabilidade da fixação e para evitar interferência com o assentamento correcto dos componentes. Use somente os parafusos recomendados para a prótese específica, a fim de evitar encaixe inadequado e a mistura incorrecta de metais. Estes parafusos de osso não se destinam à fixação a elementos posteriores (pediculos) da espinha cervical, torácica ou lombar.

Componentes de metal. Algumas das ligas utilizadas para produzir implantes ortopédicos contêm alguns componentes metálicos que podem ser carcinogénicos mas em culturas de tecido ou organismos intactos em circunstâncias únicas. Levantaram-se questões na literatura científica quanto ao facto de essas próprias ligas poderem ser ou não carcinogénicas em recipientes de implantes. Estudos realizados para avaliar este assunto não identificaram evidência convincente de tal fenómeno, apesar de milhões de implantes em uso. (Veja a referência 1.)

Alinhamentos dos componentes. Deve-se ter cautela para restaurar o alinhamento correcto da articulação e equilibrar a tensão dos ligamentos. O mau alinhamento de um membro ou articulação pode causar desgaste excessivo, afrouxamento da prótese

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e dor, levando a uma revisão antes do esperado do(s) componente(s) tibiais e/ou mais dos componentes protéticos.

Desgaste de polietileno. Como era de se esperar, o desgaste das superfícies articuladas de polietileno de componentes tibiais e patelares tem sido verificado após a substituição de joelho total. Índices mais elevados de desgastes poderão ser originados por partículas de cimento, metal, ou outros resíduos que podem causar erosão das superfícies articuladas. Índices mais elevados de desgaste poderão reduzir a vida útil das próteses e levar à revisão cirúrgica mais cedo que o desejado para substituir os componentes protéticos desgastados.

PRECAUÇÕES

Informações para pacientes. Deverá aconselhar-se o paciente quanto às limitações de curto e longo prazo do procedimento e à necessidade de protecção do implante contra o suporte de peso total até que a fixação adequada e a cicatrização tenham ocorrido. A actividade excessiva e o trauma que afectam a substituição da articulação têm contribuído para a falha da reconstrução, através do afrouxamento, fractura e/ou desgaste dos implantes protéticos. O afrouxamento dos componentes podem resultar numa produção mais elevada de partículas de desgaste, assim como em danos ao osso, tornando mais difícil o êxito de uma revisão cirúrgica.

O paciente deve ser alertado para a necessidade de limitar as actividades e proteger a articulação substituída contra o estresse irrazoável, e seguir as instruções do médico com respeito ao cuidado e tratamento de acompanhamento.

O paciente deve ser alertado contra o risco cirúrgico e estar ciente dos efeitos adversos possíveis. O paciente deve ser alertado quanto ao facto de o aparelho não permitir uma sã articulação normal, de o seu implante poder quebrar-se ou danificar-se como resultado de uma actividade estrênua ou traumática, e de o seu aparelho ter uma duração limitada de vida e de ter de ser substituído no futuro.

Poderá ocorrer uma **bacteremia transitória** no dia a dia do paciente. Tratamento de dentes, exame endoscópico e outras intervenções cirúrgicas menores também têm sido associados com uma bacteremia transitória. Para evitar a infecção no local do implante, pode ser aconselhável o uso de profilaxia antibiótica antes e depois de tais intervenções.

Instrumentos. Existem instrumentos especializados no mercado, os quais deverão ser utilizados para assegurar a implantação exacta dos componentes protéticos.

Embora rara, poderá ocorrer a fractura intraoperatória ou a quebra de instrumentos. Os instrumentos que hajam tido uso excessivo ou que tenham estado sujeitos a força excessiva têm mais tendência a quebrar-se. Os instrumentos devem ser examinados quanto ao desgaste, ou dano, antes da cirurgia.

Reutilização. Um implante nunca deve ser reutilizado. Embora possa aparentar não estar danificado, o implante usado pode ter sofrido arranhões ou outros danos que possam ter contribuído para a redução da sua duração de vida.

Manuseio. O manuseio dos implantes é importante, particularmente o de implantes com revestimento poroso. Não permita que superfícies porosas entrem em contacto

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com outros materiais que liberam fibras ou partículas. Os implantes que não tenham sido pré-polimerizados devem ser descartados. A parte altamente polida do implante não deve entrar em contacto com superfícies duras.

EFEITOS ADVERSOS

1) Com todas as substituições de articulações, a reabsorção óssea progressiva, localizada e assintomática (osteólise), pode ocorrer em torno dos componentes protéticos ou longe deles como consequência da reacção de um corpo estranho à matéria particulada. A matéria particulada é gerada pela interacção entre os componentes, assim como entre os componentes e o osso, principalmente através de mecanismos de desgaste de adesão, abrasão e fatiga. A osteólise pode levar a complicações futuras, tornando necessária a remoção e substituição de componentes protéticos. (Veja a secção de **INFORMAÇÕES IMPORTANTES PARA O MÉDICO** para mais informações.)
2) Embora raras, as reacções de sensibilidade têm ocorrido em pacientes, após a substituição de articulação. A implantação de um material estranho em tecidos pode resultar em reacções celulares que podem incluir linfócitos, macrófagos e fibroblastos.
3) Têm-se verificado neuropatias periféricas, após cirurgias de articulação total. Tem-se verificado também danificação de nervos sub-clínicos, podendo ocorrer como resultado de trauma cirúrgico.
4) Deslocamento e subluxação de componentes de implantes podem resultar do posicionamento inadequado e/ou migração dos componentes. A lassidão de tecidos moles e fibrosos e de ligamentos pode também contribuir para essas condições.
5) Os implantes podem afrouxar ou migrar, devido a trauma, ou perder a fixação.
6) A infecção pode levar à falha de substituição da articulação.
7) Embora rara, a fractura devido à fadiga do implante pode ocorrer como resultado de trauma, da actividade estrénua, de alinhamento inadequado, ou da duração extrema de serviço.
8) O desequilíbrio do tecido mole (ligamentoso) pode causar desgaste excessivo e/ou falha do implante.
9) Poderá ocorrer fractura intra-operatória do fémur, da tíbia ou patela enquanto se preparam os locais de osso e/ou o assentamento do implante.
10) Embora raramente, poderão ocorrer reacções alérgicas aos materiais utilizados no implante.

As complicações pós-operatórias precoces e intra-operatórias podem incluir, entre outras:

1) Trombose venosa profunda;
2) Danos nos vasos sanguíneos;
3) Danos permanentes ou temporários no nervo, resultando em dor ou dormência do membro afectado;

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4) Queda repentina da pressão sanguínea intra-operatória associada com o uso de cimento ósseo;
5) Deformidade varo-valgo com resultante desalinhamento do membro/prótese;
6) Distúrbios cardiovasculares, incluindo embolia pulmonar e infarto do miocárdio;
7) hematoma;
8) Cicatrização retardada da ferida; e,
9) Infecção profunda da ferida (precoce ou tardia), uma séria complicação potencial da substituição da articulação que pode requerer a remoção da prótese e subsequente artrodese. Profilaxia apropriada com antibióticos e aderência rígida a procedimentos assépticos são obrigatórias; e,
10) Fractura do osso femoral, tibial ou patelar ou do componente

As complicações pós-operatórias tardias podem incluir, entre outras:

1) Afrouxamento tardio (ou precoce), mudança da posição dos componentes, desgaste e dobramento ou rachadura de um ou mais dos componentes protéticos. (Experiências clínicas sugerem que atenção particular aos itens contidos nas secções de Advertências e Precauções deste prospecto de embalagem pode ajudar a minimizar o risco de sua ocorrência);
2) Fractura patelar como resultado de tensão excessiva, ou enfraquecimento intra-operatório inadvertido;
3) Problemas do membro afectado ou extremidade contralateral causada por discrepância do comprimento da perna,
4) Instabilidade ligamentosa tardia;
5) Calcificação periarticular ou ossificação, com ou sem impedimento da mobilidade da articulação;
6) Faixa inadequada de movimento devido à selecção ou posicionamento inadequado dos componentes, colisão e/ou calcificação periarticular e distrofia; e,
7) Fracturas ósseas, deslocamento, subluxação, contratura flexional, redução da faixa de movimento ou alongamento ou encurtamento da perna, todos tendo sido relatados em associação à substituição total do joelho.

INFORMAÇÕES IMPORTANTES PARA O MÉDICO

A. **A reabsorção óssea e a osteólise.** A reabsorção óssea pode ocorrer como consequência natural da artroplastia da articulação total, devido à mudança em padrões de remodelação óssea. A remodelação óssea é mediada pela mudança na distribuição de estresse causado pela implantação. A reabsorção extensiva em torno da prótese leva ao afrouxamento e à falha do implante. A reabsorção óssea progressiva localizada, devido a outras causas que não sejam o estresse ou a infecção, poderá ocorrer em torno de componentes protéticos, assim como entre os componentes e o osso, e a isto chama-se osteólise. Em geral, crê-se que a osteólise é o resultado da reacção de um

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corpo estranho localizado nos resíduos particulados (exemplo, cimento ósseo, UHMWPE, e cerâmica), gerados pelo próprio processo de substituição articular. Os componentes e o osso, principalmente através de mecanismos de desgaste de adesão, abrasão e fatiga. Com relação à etiologia, tem-se levantado a hipótese de que os resíduos de particulados gerados pela articulação dos componentes de uma prótese migram para o interior da cavidade sinovial e a interface de implante ósseo, onde recrutam macrófagos e estimulam a acção fagocítica. O nível de recrutamento é determinado pelo tamanho, distribuição e quantidade de resíduos de particulados, assim como pelo índice de geração de resíduos. Tem-se demonstrado que a acção fagocítica, in vitro, reduz a libertação de citocinese e mediadores celulares (IL-1, IL-2, IL-6, PGE2, TNF3). Tem-se demonstrado que esses mediadores modulam a reabsorção osteoclástica. A pesquisa clínica e básica está prosseguindo, a fim de compreender melhor a base científica para a causa desse fenómeno e explorar formas potenciais para a redução da sua ocorrência.

Como a osteólise é frequentemente assintomática, o exame radiográfico periódico de rotina é vital para ajudar a detectar e a minimizar qualquer complicação futura grave. Contudo, as radiografias podem não definir completamente a magnitude da osteólise. A presença de lesões focais, progressivas, pode necessitar da substituição de componente(s) protético(s).

B. **Espessura do polietileno.** Análises teóricas têm indicado que tensões de contacto no componente tibial variam de acordo com a espessura do componente de polietileno. Em geral, considera-se que inserções mais espessas têm menos tensão de contacto que as mais finas. Estas tensões podem afectar o desgaste dos componentes do implante. Entretanto, as implicações clínicas das diferenças teóricas de tensão não foram estabelecidas conclusivamente. O médico deve considerar as vantagens e desvantagens da ressecção do osso tibial e o uso de uma inserção mais espessa. Factores relacionados com o paciente, como peso, idade e nível de actividade devem fazer parte da decisão.

C. **Correspondência de componentes.** Há larguras tibiais correspondentes projectadas para articular e conformar-se a componentes femorais de tamanho apropriado. Se a correspondência dos componentes não for feita correctamente, poderá ocorrer falha prematura do componente tibial, contribuindo para a lassidão da articulação.

D. **Rótulo do produto.** Veja o rótulo do produto quanto a informações relativas ao produto específico mencionado no prospecto da embalagem.

FORMA DE APRESENTAÇÃO

Esses produtos são entregues estéreis em recipientes que têm sido expostos a um mínimo de 25 kGy de radiação gama de uma fonte de cobalto 60. O pacote de todos os produtos estéreis devemos ser examinados antes do uso quanto a rupturas possíveis na barreira estéri.

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REESTERILIZAÇÃO

Aparelhos que contem POLIETILENO, REVESTIMENTO POROSO, PULVERIZAÇÃO DE PLASMA, HIDROXIAPATITA, CERMICA ou METILMETACRILATO NÃO PODEM SER AUTOCLAVADOS OU REESTERILIZADOS PELO USUÁRIO.

Os componentes que **não** tenham sido contaminados com fluidos, em fluidos corporais específicos, podem ser reesterilizados usando os seguintes parâmetros em uma autoclave a vapor de deslocamento de gravidade:

	250° F (121° C) 1.4 Bars (20 PSI)	270° F (132° C) 2 Bars (30 PSI)
Componente individual involucrado (componentes variados ou únicos) ou Steriliseringsfodral	40 minutos	20 minutos

O método de invólucro duplo usado é a técnica AAMI CSR. Esses ciclos foram desenvolvidos com apenas este item na câmara e usando a prateleira do meio. Qualquer ciclo deverá ser validado para diferentes câmaras de esterilização, métodos de involucramento e/ou várias configurações de carga.

CUIDADO

A Lei Federal nos EUA restringe este dispositivo à venda por um médico ou com a sua autorização.

REFERÊNCIAS

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study in Sweden," Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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Svenska

TILL KIRURGEN

Tack vare framstegen inom total knäledsplastik har kirurgen fått möjligheter att återställa mobilitet, korrigera missbildningar och reducera smärta med hjälp av användning av implanterade proteser. Dessa produkter har visserligen visat sig vara huvudsakligen framgångsrika när det gäller att uppnå dessa målsättningar, men de är dock tillverkade av metall- eller plastmaterial, eller båda delar. Därför kan man inte förvänta sig att en protes skall kunna klara samma aktivitets- eller belastningsnivåer som en normal, frisk led. Protessystemet kommer därför inte att bli lika starkt, pålitligt eller hållbart som en naturlig mänskig knäled.

Vid användning av totala knäledsimplantat, skall kirurgen beakta det följande:

A. **Det är ytterst viktigt att man väljer korrekt implantat och att det placeras korrekt.** För att total knäledsplastik skall vara framgångsrik måste man välja korrekt storlek, form och design på implantatet. Totala ledproteser kräver noggrann placering, rigid fixering och adekvat benmassa till stöd.

B. **Då patienter övervägs som möjliga kandidater för total ledplastik, kan följande faktorer vara av yttersta vikt för ett framgångsrikt ingrepp:**

1) **Patientens vikt.** En överviktig patient eller en patient som lider av fetma kan belasta protesen på sådant sätt att produkthaveri uppstår. Effekten av sådana belastningar förstärks om en liten protes måste användas till följd av patientens skelettstorlek.

2) **Patientens yrke eller aktiviteter.** Om patienten ägnar sig åt ett yrke eller åt aktiviteter som innebär betydande belastningar (promenerande, springande, lyft eller vridningar), kan de åtföljande påfrestningarna medföra misslyckad fixering, produkthaveri eller båda delar. Höga nivåer av fysisk aktivitet över åren kan också förstärka den normala nedslitningsprocess som alltid sker med ledproteser. Protesen kommer inte att kunna återställa funktionen till samma nivå som i ett fall med ett normalt friskt skelett och patienten skall inte hysa några orealistiska förväntningar rörande funktionen. (Se avsnittet med **FÖRSIKTIGHETSÅTGÄRDER** för ytterligare information.)

3) **Senilitet, mentalsjukdom, kemiskt beroende eller alkoholism.** Dessa är några av de omständigheter som kan göra att patienten struntar i vissa nödvändiga begränsningar och försiktighetsåtgärder vid användning av implantatet, vilket kan medföra produkthaveri eller andra komplikationer.

4) **Överkänslighet för främmande kropp.** I de fall då man misstänker överkänslighet mot vissa material, skall lämpliga tester genomföras innan man väljer material eller implanterar produkten.

5) **Ortopedisk historia.** Prognosen för framgång med ingreppet beror på patientens ortopediska historia. Patienter som har erfarenhet från flera tidigare ingrepp och/eller implantat skall noga informeras angående ingreppets förväntade utkomst.

6) **Skelettkvalitet.** Framgången med total knäledsplastik kan påverkas av försvagad benmassa, vilket kan uppstå till följd av vissa systemiska eller

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metabolska sjukdomar, t.ex. vid behandling med steroider, immunosup-
pressionsmedel eller hormonersättningsterapi.

BESKRIVNING

Howmedica tillverkar ett brett sortiment av rekonstruktiva knäsystem med tre kammare, i olika storlekar och former, för att tillmötesgå olika behov från patienter och kirurger för cementerade primära applikationer samt för revisionskirurgi. Valet av protessystem beror helt på den typ av operation som skall genomföras. Femorala, tibiala och patellara komponenter finns att tillgå för knäledsplastik. Metallkomponenterna (den femorala komponenten, tibiala och patellara basplattor, sintrade pärlor, kilar och brickor) tillverkas av gjuten koboltkrom-molybdenlegering (Vitallium®-legering), vilken uppfyller kraven i ASTM-standarden F75. Skruvar och stamförlängningar tillverkas av smidd koboltkrom-molybdenlegering (Vitallium®-legering), vilken uppfyller kraven i ASTM-standarden F1537. Polyetylenkomponenterna tillverkas av polyetylen av ultrahög molekylvikt (UHMWPE) som uppfyller kraven i ASTM-standarden F648.

Femorala komponenter

Femorala komponenter (utom superstabiliserare) finns att tillgå med antingen porös eller icke-porös beläggning, samt i kondylisk, stabiliserande och superstabiliserande konfiguration. Vissa femorala komponenter kan omvandlas från en konfiguration till en annan, exv. kondylisk till stabiliserande, genom att lägga till den modulära stabiliseringslådan.

Tibiala komponenter

De tibiala komponenterna finns att tillgå i ett brett sortiment av storlekar och tjocklekar. Bland tibiala komponenter finns de som är tillverkade helt av polyetylen i ett stycke, och modulära komponenter med en polyetyleninsats och en basplatta av metall. Basplattorna finns med porös eller icke-porös beläggning och tillhörande fixeringsalternativ. Insatserna finns med olika grader av restriktion i de kondyliska modellerna, och i de stabiliserande och superstabiliserande konfigurationerna.

Patellara komponenter

De patellara komponenterna finns att tillgå, antingen tillverkade helt av polyetylen eller med bakstycke av metall med porös beläggning.

Tillbehör

Stamförlängningar är avsedda att fästas vid stammen på den femorala eller tibiala komponenten för att skapa ytterligare stabilitet. Kilar har utformats för cementerad applikation för att skapa ytterligare mellanrum där det finns tibiala skelettdefekter. Brickor har utformats för att skapa ytterligare mellanrum där det finns femorala skelettdefekter och de kan fästas mekaniskt vid den femorala komponenten eller cementeras på plats. Skruvar finns att tillgå för intilliggande montering av tibiala insatser vid basplattor eller tibiala basplattor vid tibia.

Produktetikett

Produktetiketten ger information angående särskilda material av vilka produkten är tillverkad.

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INDIKATIONER

Bland indikationerna för användning av totala knäledsprotser återfinns:

1) icke-inflammatorisk degenerativ ledsjukdom, bl.a. osteoartrit och avaskulär nekros;
2) reumatoid artrit;
3) korrigering av funktionell deformitet;
4) revision då andra behandlingar eller produkter inte har varit framgångsrika;
5) post-traumatisk förlust av ledanatomi, i synnerhet vid förekomst av patella-femoral erosion, dysfunktion eller föregående patellektomi; samt
6) irreparabel fraktur av knät.

KONTRAINDIKATIONER

Bland absoluta kontraindikationer återfinns:

1) tydlig infektion;
2) infektionshärdar på andra ställen (vilka kan medföra hematogen spridning till implantationsstället);
3) snabbt sjukdomsförlopp som visas av ledförstöring eller benabsorption som visas på röntgenbilder;
4) skelettomogenhet hos patienten; samt
5) patienter med dålig benmassa vilket skulle göra ingreppet oförsvarbart.

Bland sådana omständigheter som medför ökad risk för produkthaveri återfinns:

1) omedgörlig patient eller patient med neurologisk sjukdom, oförmåga att följa instruktioner;
2) osteoporos;
3) metaboliska sjukdomar vilka kan hindra benbildningen;
4) osteomalaki; samt
5) tidigare artrodes.

En högre frekvens av implantatshaveri har också förekommit hos paraplegiker och patienter med cerebral pares och Parkinsons sjukdom.

VARNINGAR

Felaktigt val, placering, position och fixering av implantatets komponenter kan medföra ovanliga påfrestningar och efterföljande reduktion av den implanterade protesens livslängd. Kirurgen måste vara väl förtrogen med det kirurgiska ingreppet, instrumenten och implantatets egenskaper innan operationen genomförs. Regelbunden, långsiktig uppföljning rekommenderas för att övervaka proteskomponenternas placering och skick, samt för att kontrollera tillståndet på omgivande skelett.

Cementerad applikation. Var noga med att tillförsäkra att det finns tillräckligt stöd för alla delar av produkten som är inbäddade i bencement, för att på så vis förhindra belastningskoncentrationer vilka kan leda till att ingreppet misslyckas. Det är nödvändigt att full-

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ständigt rengöra (helt avlägsna benflisor, bencementsfragment och metallskräp) implantatet för att förebygga accelererad nedslitning av implantatets artikulerande ytor.

Protesens komponenter. Femorala, tibiala och patellara komponenter från olika protessystem eller från olika tillverkare skall inte blandas, eftersom de olika materialens toleransnivåer kan vara inkompatibla. Modulära komponenter måste monteras stadigt för att förebygga lossning. Upprepad montering och demontering av de modulära komponenterna kan komprometera den avgörande låsningen av komponenterna, och skall därför undvikas. Komponenterna måste rengöras från kirurgiskt avfall före monteringen. Avfall kommer att hindra låsmekanismen i de modulära komponenterna, vilket i sin tur kan medföra ett tidigt haveri av produkten.

Patellakomponent. Eftersom patellakomponenten har de minsta lager- och fixeringsytorna, är patellan eller patellakomponenten mera utsatt för subluxation och lossning/dislokation. Det är nödvändigt för ett framgångsrikt ingrepp att man är extra noga med att kontrollera patellans placering under operationen.

Fixeringsskruvar. Vid användning av fixeringsskruvar skall dessa föras in helt och hållet – så att det åstadkommes en så stabil fixering som möjligt och för att de inte skall utgöra hinder vid korrekt placering av komponenterna. Använd endast skruvar som rekommenderas för protesen i fråga, för att tillförsäkra korrekt passform och för att undvika olämplig blandning av metaller. Dessa benskruvar är inte avsedda för fastskruvning eller fixering vid de bakre elementen (pedikklarna) av halskotor, bröstkotor eller ländryggraden.

Metallkomponenter. En del av de legeringar som används för att tillverka ortopediska implantat, innehåller en del metallkomponenter som kan vara cancerframkallande vid vävnadsodlingar eller intakta organismer under unika omständigheter. I den vetenskapliga litteraturen har man ifrågasatt om inte dessa legeringar i sig själva kan vara karcinogena hos implantatpatienter. De undersökningar som har gjorts för att utvärdera denna fråga har inte kunnat påvisa övertygande bevis för detta, trots att det finns miljontals implantat som är i bruk. (Se litteraturhänvisning 1.)

Inriktning av komponenter. Var noga med att återställa korrekt ledinriktning och att utjämna ligamentspänningen. Felinriktning av benet eller leden kan medföra för stor nedslitning, proteslossning och smärta, vilket i sin tur kan nödvändiggöra alltför tidig revision av en eller flera av protesens komponenter.

Polyetylennedslitning. Som man kan förvänta sig har nedslitning av ledytorna av polyetylen rapporterats efter total höftledsplastik. Högre nedslitningshastighet kan orsakas av cement- eller metallpartiklar eller annat skräp som kan orsaka abrasion på ledytorna. En högre nedslitningshastighet kan medföra nedkortad livslängd för protesen, och medföra behov av förhållandevis tidig revision för att byta ut de nedslitna proteskomponenterna.

FÖRSIKTIGHETSÅTGÄRDER

Patientinformation. Patienten måste informeras om såväl protesens begränsningar som om behovet av att skydda implantatet från fullständig belastning innan adekvat fixering och läkning har skett. För mycket aktiviteter eller trauma som påverkar ledplastiken har utpekats som orsak till protesens haveri, till följd av lossning, fraktur och/eller nedslitning av protesimplantaten. Om komponenterna lossnar kan följden bli ökad pro-

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duktion av nedslitningspartiklar, samt skada på skelettet, varvid en framgångsrik revision blir svårare att genomföra.

Patienten skall förmanas att begränsa sin aktivitetsnivå och att skydda den nya leden från onödiga påfrestningar, samt att iaktta uppföljande värd- och behandlingsföreskrifter.

Patienten skall varnas för operationsriskerna, och skall göras medveten om möjliga biverkningar. Patienten bör varnas för att produkten inte är likvärdig med en normal, frisk led, att implantatet kan gå sönder eller skadas till följd av påfrestande aktivitet eller trauma samt att implantatet kan behöva bytas ut i framtiden

Övergående bakteriemi kan uppstå i det dagliga livet. Tandvård, endoskopiska undersökningar och andra mindre kirurgiska ingrepp har också förknippats med övergående bakteriemi. För att förebygga infektion vid implantationsstället, kan profylaktisk användning av antibiotika före och efter ingreppet vara att rekommendera.

Instrument. Särskilda instrument finns att tillgå och måste användas för att tillförsäkra exakt implantation av proteskomponenterna.

I sällsynta fall kan intraoperativ fraktur eller brott på instrumenten uppstå. Det är större risk att instrument som har använts mycket eller utsatts för stora påfrestningar går sönder. Undersök instrumenten för tecken på nedslitning eller skada före operationen.

Återanvändning. Ett implantat får aldrig återanvändas. Det kan visserligen förefalla oskadat, men ett använt implantat kan ha erhållit skador eller latent kompromettering av dess integritet, vilket reducerar dess funktionella livslängd.

Hantering. Det är viktigt hur implantaten hanteras, i synnerhet implantat med porösa beläggningar. Ytor med porös beläggning får inte komma i kontakt med tyg eller andra fiberavgivande material. Alla implantat vars beläggning har skadats eller kontaminerats bör kastas. Implantatets högpolerade yta får inte komma i kontakt med hårda ytor.

BIVERKNINGAR

1) I likhet med all ledplastik kan asymptomatisk, lokaliserad progressiv benresorption (osteolys) uppstå runt de prostetiska komponenterna som en följd av en reaktion mot främmande kropp. Partiklar uppstår genom interaktion mellan komponenter inbördes såväl som mellan komponenter och ben, huvudsakligen genom materialnedbrytning vid adhesion, slipverkan och materialtrötthet. Osteolys kan förorsaka framtida komplikationer, vilka kan medföra att proteskomponenterna måste avlägsnas och bytas ut. (Se **VIKTIG INFORMATION TILL LÄKAREN** för ytterligare upplysningar.)
2) I sällsynta fall har överkänslighet mot metall uppstått hos patienter efter ledplastik. Implantation av främmande material i vävnader kan medföra cellulära reaktioner, vilka bland annat kan vara lymfocyter, makrofager och fibroblaster.
3) Periferiska neuropatier har rapporterats efter total höftledsplastik. Subkliniska nervskador har rapporterats, vilket kan uppstå till följd av operationstrauma.
4) Dislokation och subluxation av implantatets komponenter kan uppstå till följd av felaktig placering och/eller förflyttning av komponenterna. Slapphet i mjuka

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vävnader; bland annat muskler, ligamenter och senor kan orsaka medverka till dessa tillstånd.

5) Implantat kan lossna eller förflyttas till följd av trauma eller förlorad fixering.
6) Infektion kan leda till att ledprotesen fallerar.
7) I sällsynta fall kan fraktur på implantatet till följd av materialtrötthet orsakas av trauma, ansträngande aktiviteter, felaktig inriktning, och/eller implantatets höga ålder.
8) Obalans i mjuka vävnader (ligamentös obalans) kan medföra för stor nedslitning och/eller implantatshaveri.
9) Intraoperativ fraktur av lårben, tibia eller patella kan uppstå medan förberedelse sker av benställena och/eller införing av implantaten.
10) Allergiska reaktioner mot de material som används i implantatet kan i sällsynta fall uppstå.

Bland intraoperativa och tidiga postoperativa komplikationer återfinns:

1) djup ventrombos;
2) skada på blodkärl;
3) tillfällig eller permanent nervskada med åtföljande smärta eller avdomning av benet i fråga;
4) ett plötsligt fall i intraoperativt blodtryck, vilket kan förknippas med användning av bencement;
5) varus-valgus deformitet med åtföljande felinriktning av ben/protes;
6) kardiovaskulära rubbningar, bland annat lungemboli eller myokardinfarkt;
7) hematom;
8) fördröjd sårläkning;
9) djup sårinfektion (tidig eller sen) - detta är en potentiellt allvarlig komplikation vid all ledplastik, som kan nödvändiggöra avlägsnande av protesen och efterföljande artrodes (steloperation). Lämplig profylaktisk behandling med antibiotika och strikt iakttagande av aseptisk teknik är obligatoriskt; samt
10) fraktur på lårben, tibia eller patella eller fraktur på komponenterna.

Till sena postoperativa komplikationer hör bland andra följande:

1) sent (eller tidigt) lossnande, förändring av komponenternas placering, nedslitning och sprickor i en eller flera proteskomponenter. (Kliniska erfarenheter visar att det kan bidra till ett förebyggande av att något av detta sker, om särskild uppmärksamhet ägnas åt avsnitten *"Varningar" och "Försiktighetsåtgärder"* i denna förpackningsbilaga.);
2) patellar fraktur till följd av för stor anspänning eller oavsiktlig intraoperativ försvagning;
3) förvärrade besvär i det påverkade benet eller i den kontralaterala extremiteten till följd av avvikande benlängd;

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4) sen ligamentös instabilitet;
5) periartikulär kalcifikation (förkalkning eller ossifikation (förbening), med eller utan minskad rörlighet leden;
6) otillräcklig rörelsefrihet på grund av felaktigt val eller placering av komponenter, störning eller periartikulär kalcifikation och dystrofi; samt
7) benfrakturer, dislokation, subluxation, flexionskontraktur, minskad rörelseräckvidd eller förlängning eller förkortning av benet. Alla dessa komplikationer har rapporterats i samband med total knäledsplastik.

VIKTIG INFORMATION TILL LÄKAREN

A. **Benresorption och osteolys.** Benresorption kan uppstå som en naturlig följd av total ledplastik, på grund av förändringar i skelettets remodelleringsmönster. Skelettets remodellering åstadkommes av de förändringar som implantationen orsakar. Överdriven resorption runt protesen leder till implantatlossning och haveri. Lokaliserad progressiv benresorption av andra skäl än belastningsavskärmning eller infektion kan uppstå runt proteskomponenterna samt mellan komponenterna och skelettet. Detta har kallats osteolys. Det är allmänt accepterat att osteolys är en följd av en lokaliserad reaktion mot främmande kropp, närmare bestämt partikelutfällningar (exv. cement, metall, UHMWPE och keramik), vilka uppstår genom interaktion mellan komponenterna och mellan komponenterna och skelettet, huvudsakligen genom nedslitningsmekanismerna adhesion, abrasion och materialtrötthet. Beträffande etiologin har man spekulerat i att partiklar som uppstår till följd av artikulering av komponenterna förflyttas till den synoviala håligheten och gränssnittet mellan ben och implantat, där de hämtar upp makrofager och stimulerar fagocytär verksamhet. Upphämtningens omfattning beror på storleken, spridningen och mängden partikelavfall samt på den hastighet med vilken partiklarna bildas. Den fagocytära verksamheten har in vitro visats orsaka frigöring av cytokiner och cellmediatorer (IL-1, IL-2, IL-6, PGE2, TNF3). Dessa mediatorer har visats modulera osteoklastisk benresorption. Klinisk och grundläggande forskning fortsätter i syfte att erhålla bättre förståelse av den vetenskapliga grunden för orsakerna till detta fenomen och för att utforska eventuella möjligheter till att minska uppträdandet därav.

   Eftersom osteolys ofta är asymptomatiskt, är rutinmässig regelbunden röntgen-undersökning avgörande för att upptäcka och minimera eventuella framtida komplikationer. Det kan dock hända att röntgenbilder inte helt kan definiera osteolysens omfattning. Förekomst av koncentrerade lesioner, som är progressiva, kan medföra att utbyte av proteskomponenterna blir nödvändigt.

B. **Polyetylentjocklek.** Teoretisk analys har indikerat att kontaktbelastningen i den tibiala komponenten varierar med tjockleken på polyetylenkomponenten. I allmänhet gäller att tjockare insatser anses har lägre kontaktbelastning än tunnare insatser. Dessa belastningar kan ha nedslitande effekt på implantatets komponenter. De kliniska implikationerna av de teoretiska

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belastningsskillnaderna har emellertid inte fastställts säkert. Läkaren bör vara uppmärksam på beroende av en ökad användningen av ej cementerade insats. Patientrelaterade faktorer, t.ex. vikt, ålder och aktivitetsnivå, skall också övervägas innan beslut fattas.

C. **Komponentanpassning.** Det finns tibiala bredder som är utformade för att artikulera och passa till femorala komponenter av lämplig storlek. Underlåtelse att passa ihop komponenterna på ett korrekt sätt kan leda till för tidigt haveri av den tibiala komponenten och medverka till ledslapphet.

D. **Produktetikett.** Läs på produktens etikett för information angående den specifika produkt som anges i denna förpackningsbilaga.

LEVERANS

Dessa produkter som levereras sterila i behållare som har utsatts för minst 25 kGy gammastrålning från en kobolt 60-källa. Förpackningen till alla sterila produkter skall undersökas innan produkten används, för eventuella brott i den sterila barriären.

OMSTERILISERING

Produkter som innehåller POLYETYLEN, PORÖS BELÄGGNING, PLASMASPRAY, HYDROXIAPATIT, KERAMIK eller METYLMETAKRYLAT KAN INTE AUTOKLAVERAS ELLER OMSTERILISERAS AV ANVÄNDAREN.

Komponenter som <u>inte</u> har kontaminerats med vätskor, i synnerhet kroppsvätskor, kan omsteriliseras med hjälp av följande parametrar i en ångautoklav med gravitationsförskjutning:

	250° F (121° C) 20 PSI (1.4 Bar)	270° F (132° C) 30 PSI (2 Bar)
Inslagen enskild komponent (enkel eller multikomponent) eller Steriliseringsfodral	40 minuter	20 minuter

Dubbel inslagning används i AAMI CSR-tekniken. Dessa cykler utvecklades då endast ett föremål fanns i kammaren och med användning av mitthyllan. Alla cykler skall kontrolleras för olika steriliseringskammare, inslagningsmetoder och/eller varierande belastnings-konfigurationer.

VAR FÖRSIKTIG

Enligt federal lagstiftning (USA) får denna produkt endast säljas av läkare eller på läkares ordination

LITTERATUR

1. Olof Hyren, Joseph K. McLaughlin et al.,"Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study In Sweden," (Cancerrisk efter höftledsplastik med metallimplantat) Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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Polvilonkkaproteesien edistyksellisyys antaa kirurgeille mahdollisuuden palauttaa liikkuvuuden, poistaa epämuodostumia ja vähentää kipuja siirrännäisiä proteesilaitteita käyttämällä. Vaikkakin nämä laitteet ovat onnistuneet näiden tavoitteiden saavuttamisessa, on muistettava, että ne valmistetaan metalli-tai muovimateriaalista. Mikään proteesi ei kestä normaalin terveen luun kaltaista aktiviteettitasoa ja kuormitusta. Järjestelmä ei siten ole yhtä vahva, luotettava tai kestävä kuin ihmisen luonnollinen polvinivel.

Kirurgin tulisi huomioida seuraava kokopolvinivelimplantteja käytettäessä:

A. **Asianmukaisen implantin valinta on erittäin tärkeää.** Jotta toimenpide onnistuisi, kokonivelimplantin tulee olla oikean kokoinen, muotoinen ja oikein suunniteltu. Kokonivelproteesit vaativat huolellista istutusta, tiukkaa fiksaatiota ja tarpeeksi hyvää luutukea.

B. **Seuraavat tekijät voivat olla erittäin tärkeitä toimenpiteen onnistumiselle valittaessa potilaita kokonivelproteeseja varten:**

1) **Potilaan paino.** Ylipainoisen tai lihavan potilaan tapauksessa proteesin kuormitus on kovempi, mikä voi johtaa laitteen toimintahäiriöön. Tämän kuormituksen merkitys lisääntyy silloin, kun joudutaan käyttämään pienikokoista proteesia kyseessäolevien potilaiden luiden koon vuoksi.

2) **Potilaan ammatti tai aktiviteetit.** Jos potilas on ammatissa tai osallistuu aktiviteetteihin, joissa on huomattavaa iskukuormitusta (kävely, juoksu, nosto tai kierto), niiden voimakkuus voi aiheuttaa fiksaation, laitteen tai molempien toimintahäiriön. Jos potilas harrastaa paljon fyysisiä aktiviteetteja vuosien mittaan, se voi nopeuttaa proteesinivelissä tapahtuvaa normaalia kulumista. Proteesi ei palauta toimintatasoa normaalin terveen luun toiminnan tasolle, ja potilaalla ei tulisi olla, ja häntä tulisi auttaa vähentämään, epärealistisia odotuksia toiminnallisuuden suhteen. (Katso **VAROTOIMENPITEITÄ** –osaa lisätietoja saadaksesi.)

3) **Seniilisy, mielisairaus, kemiallinen riippuvuus tai alkoholismi.** Nämä tilat, muiden muassa, voivat johtaa siihen, että potilas ei ota huomioon tiettyjä tarpeellisia rajoituksia ja varotoimenpiteitä implantin käytössä, mikä johtaa toimintahäiriöön tai muihin komplikaatioihin.

4) **Herkkyys vierasesineille.** Asianmukaiset testit tulisi suorittaa ennen valintaa ja implantointia silloin, kun epäillään materiaaliherkkyyttä.

5) **Ortopedinen tausta.** Toimenpiteen onnistumisprognoosi riippuu potilaan ortopedisestä taustasta. Sellaisille potilaille, joille on tehty useita aikaisempia toimenpiteitä ja/tai implantteja, tulisi kertoa seikkaperäisesti toimenpiteen odotetusta tuloksesta.

6) **Luun laatu.** Kokopolvinivelproteesin kestoon voi vaikuttaa heikentynyt luusto, jonka syynä saattavat olla sellaiset tietyt systeemiset ja metaboliset sairaudet, joita on hoidettu steroidien, immunosuppressorien tai kemoterapian avulla.

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KUVAUS

Howmedica valmistaa laajan valikoiman erikokoisia ja -tyyppisiä kolmiosastoisia [tricompartmental] polven rekunstruktiojärjestelmiä, jotka vastaavat erilaisten potilaiden ja kirurgien vaatimuksia ensi- ja uusintaleikkauksissa käytettävien sovelluksien suhteen. Proteesijärjestelmän valinta riippuu vaadittavasta leikkaustyypistä. Polven rekonstruktiota varten on olemassa reisiluu-, sääriluu- ja polvilumpiokomponentteja. Metalliset komponentit (reisiluukomponentin, sääriluun ja polvilumpion pohjalevy, sintratut helmet, kiilat ja keskittäjät) valmistetaan valetusta koboltti-kromi-molybdeenimetalliseoksesta (Vitallium® -metalliseos), joka on ASTM-standardin F75 mukaista. Ruuvit ja varren ojentaja valmistetaan taotusta koboltti-kromi-molybdeenimetalliseoksesta (Vitallium® -metalliseos), joka on ASTM-standardin F1537 mukaista. Polyeteenikomponentit valmistetaan korkean molekyylipainon polyeteenistä (UHMWPE), joka on ASTM-standardin F648 mukaista.

Reisiluukomponentit

Reisiluukomponentteja (supervakauttajaa [superstabilizer] lukuunottamatta) on saatavina huokoisina ja ei-huokoisina päällystettyinä malleina, kondylaarisina, vakauttaja- ja supervakauttajakokoonpanoina. Jotkut reisiluukomponentit voidaan muuntaa yhdestä kokoonpanosta toiseen, ts. kondylaarisesta vakauttajaan, lisäämällä modulaarinen vakauttajaosa.

Sääriluukomponentit

Sääriluukomponentteja on saatavina laaja valikoima eri kokoja ja paksuuksia. Sääriluukomponentteihin kuuluu yksiosainen kokonaan polyeteenistä tehty komponentti ja modulaarisia malleja, jotka on tehty polyeteenisestä sisäosasta ja metallisesta pohjalevystä. Pohjalevyjä on saatavina sekä huokoisella että ei-huokoisella päällysteellä ja liitosfiksaatiovaihtoehtoina. Sisäosia on saatavina eritasoisilla pidikkeillä kondylaarisissa, vakauttaja- ja supervakauttajakokoonpanoissa.

Polvilumpiokomponentit

Polvilumpiokomponentteja on saatavina kokonaan polyeteenistä tehtyinä tai metalliselkäisinä, huokoisella päällysteellä päällystettyinä.

Lisälaitteet

Varren ojentajat on suunniteltu kiinnittymään reisiluu-tai sääriluukomponenttiin stabiliteetin lisäämiseksi. Kiilat on suunniteltu sementillisiä sovelluksia varten ja ne antavat lisätilaa sääriluun epämuodostumien ollessa kyseessä. Keskittäjät on suunniteltu antamaan lisätilaa reisiluun epämuodostumien ollessa kyseessä, ja ne voidaan kiinnittää mekaanisesti reisiluukomponenttiin tai sementoida paikalleen. Ruuveja on olemassa sääriluun sisäosien lisäkiinnittämiseen pohjalevyihin tai sääriluun pohjalevyn kiinnittämiseen sääriluuhun.

Tuotteen nimilappu

Tuotteen nimilapussa on tietoja siitä erityisestä materiaalista (niistä erityisistä materiaaleista), joita laitteen valmistuksessa on käytetty

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INDIKAATIOT

Kokopolvinivelproteesin käyttöindikaatioihin kuuluvat:

1) tulehdukseton nivelrappeutumistauti mukaan lukien osteoartriitti, traumaattinen artriitti tai avaskulaarinen nekroosi;
2) nivelreuma;
3) toiminnallisen epämuodostuman korjaus;
4) uusintatoimenpiteet silloin, kun muut hoidot tai laitteet eivät toimineet;
5) post-traumaattinen nivelen anatomian menetys, erityisesti polvilumpion ja reisiluun eroosion, dysfunktion tai alemman patellektomian ollessa kyseessä; ja,
6) polven murtuma, jota ei voi korjata.

KONTRAINDIKAATIOT

Absoluutteihin kontraindikaatioihin kuuluvat:

1) avoin infektio;
2) kaukaiset infektiopesäkkeet (jotka saattavat levitä veren kautta siirrännäisen paikkaan);
3) taudin nopea eteneminen, jota osoittaa niveltuho tai röntgenogrammissa näkyvä luun absorptio;
4) potilaat, joilla on immatuuri luuranko; ja,
5) tapaukset, joissa luusto on niin huonolaatuista, että toimenpiteen suorittaminen ei olisi perusteltua.

Tiloihin, joissa epäonnistumisen riski lisääntyy kuuluvat mm.:

1) yhteistyöhaluton potilas tai potilas jolla on neurologisia sairauksia, ja joka ei pysty seuraamaan ohjeita;
2) osteoporoosi;
3) metaboliset sairaudet, jotka voivat heikentää luuston muodostumista;
4) osteomalasia; ja,
5) aiempi artodeesi.

Implanttien epäonnistumisaste on myös ollut korkeampi halvaantuneilla potilailla, aivohalvauspotilailla ja Parkinsonin tautia sairastavilla potilailla.

VAROITUKSIA

Implanttikomponenttien virheellinen valinta, asetus, asemointi ja fiksaatio voi johtaa epätavallisiin rasitustiloihin ja niitä seuraavaan prosteettisen implantin käyttöiän lyhenemiseen. Kirurgin tulisi tuntea kirurginen toimenpide, instrumentit ja implantin ominaisuudet täydellisesti ennen leikkauksen suorittamista. Ajoittainen pitkäaikainen seuranta on suositeltavaa, jotta voidaan seurata proteesikomponenttien paikkaa ja tilaa, kuten myös siihen liittyvän luun tilaa.

Sementoitu sovellus. Tarkista, että luusementtiin upotetun laitteen kaikkia osia tuetaan, jotta vältytään rasituskeskityksiltä, jotka saattavat johtaa toimenpiteen epäonnistumiseen. Implantin alueen täydellinen puhdistaminen (luusirujen, luusementtipalojen ja metallijät-

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tuen [illegible] kulumisen nopeutuminen.

Proteesin komponentit. Eri proteesijärjestelmien, tai eri valmistajien järjestelmien, reisiluu-, sääriluu- ja polvilumpiokomponentteja ei tulisi koskaan sekoittaa keskenään, koska toleranssit tai materiaalit eivät saata sopia yhteen. Modulaariset komponentit on pantava kokoon lujasti, jotta vältytään dissosiaatiolta. Modulaaristen komponenttien kokoaminen ja purkaminen useaan kertaan saattaa vaarantaa komponenttien kriittisen lukkiutumistoiminnan ja sitä tulisi välttää. Kirurginen jäte on puhdistettava komponenteista ennen niiden kokoonpanoa. Jäte voi häiritä modulaaristen komponenttien lukkiutumismekanismia, mikä puolestaan voi johtaa toimenpiteen aikaiseen epäonnistumiseen.

Polvilumpiokomponentti. Koska polvilumpiokomponentissa on pienikokoisimmat tuki- ja fiksaatiopinnat, polvilumpion tai polvilumpiokomponentin kohdalla on subluksaation ja irtoamisen/siljoiltaanmenon mahdollisuus suurempi. Polvilumpion tilaa on seurattava erityisen huolellisesti leikkauksen aikana, jotta toimenpide onnistuisi.

Kiinnitysruuvit. Kiinnitysruuvit, silloin kun niitä käytetään, tulisi istuttaa täydellisesti fiksaation stabiliuden maksimoimiseksi, ja jotta ne eivät olisi komponenttien oikean istutuksen esteenä. Käytä ainoastaan tietylle proteesille suositeltuja ruuveja, jotta varmistetaan niiden sopivuus, ja jotta vältytään metallien väärältä sekoittamiselta. Näitä luuruuveja ei ole tarkoitettu kiinnitettäviksi servikaalisen, rinta- tai lumbaalisen selkärangan posteriorisiin elementteihin (varret).

Metallikomponentit. Jotkut ortopedisten implanttien valmistamisessa käytetyt metalliseokset sisältävät joitakin metallisia komponentteja, jotka voivat tietyissä olosuhteissa olla karsinogeenisia kudosviljelyissä tai hyväkuntoisissa organismeissa. Tieteellisessä kirjallisuudessa on esitetty kysymyksiä siitä, voivatko nämä metalliseokset itsessään olla karsinogeenisiä implantin saajissa. Tämän asian tiimoilta tehdyissä tutkimuksissa ei ole löydetty vakuuttavia todisteita tuollaisesta ilmiöstä huolimatta siitä, että käytössä on miljoonia implantteja (Katso Viite 1.)

Komponenttien asettaminen oikeaan asentoon. Nivelten palauttaminen oikeaan asentoon ja ligamenttien jännitteen tasaaminen on tehtävä huolella. Jos raaja tai nivel on väärässä asennossa, se saattaa johtaa liialliseen kulumiseen, proteesin irtoamiseen ja kipuun, mikä voi johtaa yhden tai useamman proteesin komponentin haluttua aiempaan uusimiseen.

Polyeteenin kuluminen. Kokopolvinivelproteesileikkausta seuraavaa sääriluun ja polvilumpion komponenttien polyeteenipintojen kulumista on odotetusti raportoitu. Korkeampi kulumisaste saattaa johtua sementtimetallihiukkasista tai muusta jätteestä, jotka voivat aiheuttaa nivelpintojen hankautumista. Korkeammat kulumisasteet lyhentävät proteesin käyttöikää ja johtavat haluttua aiempaan uusintaleikkaukseen, jossa korvataan kuluneet proteesikomponentit.

VAROTOIMENPITEITÄ

Potilaalle annettavat tiedot. Potilasta täytyy neuvoa toimenpiteen lyhyt- ja pitkäaikaisista rajoituksista ja tarpeesta olla asettamatta koko painoa implantin päälle kunnes tarvittava fiksaatio ja parantuminen on tapahtunut. Liiallinen aktiviteetti ja nivelproteesiin

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kohdistuva trauma ovat johtaneet rekonstruktion epäonnistumiseen siten, että proteesi-implantit ovat joutuneet murtumaan. Jos implantti murtuu, komponentteja voi olla kulumishiukkasten lisääntyneeseen tuotantoon sekä luuvaurioon, mikä tekee onnistuneen uusintaleikkauksen yhä vaikeammaksi.

Potilasta tulisi neuvoa rajoittamaan aktiviteetteja ja suojelemaan nivelproteesia kohtuuttomalta rasitukselta, ja seuraamaan lääkärin antamia seurantahoitoon liittyviä ohjeita.

Potilasta tulisi varoittaa leikkausriskeistä, ja hänelle tulisi antaa tietoja mahdollisista haittavaikutuksista. Potilasta tulisi varoittaa siitä, että laite ei voi korvata eikä korvaa normaalia tervettä niveltä, että implantti voi rikkoutua tai vahingoittua rasittavan aktiviteetin tai trauman johdosta, ja että laitteella on rajattu käyttöikä ja se voidaan joutua vaihtamaan tulevaisuudessa.

Ohimenevä bakteremia on mahdollista jokapäiväisessä elämässä. Hammaslääketieteelliset toimenpiteet, endoskooppitutkimus tai muut pienet leikkaustoimenpiteet on myös yhdistetty ohimenevään bakteremiaan. Tulehduksen välttämiseksi implantin alueella voi olla suositeltavaa käyttää antibioottiprofylaksia tuollaisia toimenpiteitä ennen ja niiden jälkeen.

Instrumentit. Erityisinstrumenttejä on saatavana ja niitä täytyy käyttää, jotta varmistetaan proteesikomponenttien oikea implantointi.

Vaikkakin se on harvinaista, leikkauksen aikana tapahtuva instrumenttien murtuminen tai rikkoutuminen on mahdollista. Instrumentit, joita on käytetty paljon tai voimallisesti murtuvat helpommin. Instrumentit tulisi tarkastaa kulumisen ja vahingoittumisen suhteen ennen leikkausta.

Uudelleenkäyttö. Implanttia ei saa koskaan käyttää uudelleen. Vaikka se näyttäisi vahingoittumattomalta, käytetyssä implantissa saattaa olla vikoja tai piilevä integriteettivaara, mikä vähentäisi sen käyttöikää.

Käsittely. Implanttien oikea käsittely on tärkeää etenkin huokoisten päällystettyjen implanttien tapauksessa. Huokoisten päällystettyjen pintojen ei saa antaa joutua kosketuksiin kankaan tai muiden kuitujä irtipäästävien materiaalien kanssa. Implantit, joiden päällyste on vahingoittunut tai kontaminoitunut, tulisi poistaa käytöstä. Implantin kiillotettu osa ei saa joutua kosketuksiin kovien pintojen kanssa.

HAITTAVAIKUTUKSET

1) Kuten kaikkien nivelproteesien tapauksessa, oireetonta paikallista luuresorptiota (osteolyysi) saattaa esiintyä proteesin komponenttien ympärillä vierasesine-hiukkasmateriaalireaktion johdosta. Hiukkasmateriaalia syntyy komponenttien vuorovaikutuksen johdosta, samoin kuin komponenttien ja luun välillä pääasiassa kiinnittymisen, hankauksen ja väsymisen kulumismekanismien johdosta. Myös kolmannen osan aiheuttama kuluminen voi toissijaisesti tuottaa hiukkasmateriaalia. Osteolyysi voi johtaa tulevaisuudessa komplikaatioihin, joiden takia voi olla tarpeellista poistaa proteesikomponentit ja vaihtaa ne uusiin. (Katso **Katso LÄÄKÄRILLE TARKOITETTUJA TÄRKEITÄ TIETOJA** ¬osaa lisätietoja saadaksesi.)

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2) Vaikkakin ne ovat harvinaisia, metallijn liittyviä herkkyysreaktioita on havaittu [illegible] kudokseen voi johtaa sellulaarisiin reaktioihin kuten lymfosyytteihin, makrofageihin ja fibroplasteihin.
3) Perifeerisiä neuropatioita on raportoitu kokonivelleikkauksen jälkeen. Subkliinisiä hermovaurioita on raportoitu, ja niitä saattaa esiintyä leikkaustrauman johdosta.
4) Implantin komponenttien sijoiltaanmeno ja subluksaatio voi johtua komponettien väärästä asemoinnista/ja tai liikkumisesta. Pehmytkudoksen, kuten lihas- ja sidekudoksen ja ligamenttien laksiteetti voi myös osaltaan vaikuttaa näiden tilojen muodostumiseen.
5) Implantit voivat irrota ja liikkua trauman tai fiksaation katoamisen johdosta.
6) Infektio voi johtaa nivelproteesileikkauksen epäonnistumiseen.
7) Vaikkakin se harvinaista, implantin rasitusmurtuma voi tapahtua trauman, rasittavan aktiviteetin, vääran kohdistamisen ja/tai ylipitkän käyttöiän johdosta.
8) *(Ligamenttien) pehmytkudoksen epätasapaino* voi johtaa liialliseen kulumiseen ja/tai implantin toimintahäiriöön.
9) Leikkauksen aikana tapahtuva reisiluun, sääriluun tai polvilumpion murtuminen on mahdollista siiloin kun luualueita valmistellaan ja/tai implanttia istutetaan.
10) Implantissa käytettyihin materiaaleihin liittyvät allergiset reaktiot ovat mahdollisia, joskin harvinaisia.

Leikkauksen aikaisiin ja heti leikkauksen jälkeisiin komplikaatioihin voivat kuulua, mutta niihin eivät rajoitu, seuraavat:

1) syvälaskimotromboosi;
2) *verisuonivauriot;*
3) väliaikainen tai pysyvä hermovaurio, joka johtaa kyseessäolevan raajan kipuihin tai puutumiseen;
4) äkillinen leikkauksen aikainen verenpaineen laskeminen. joka liittyy luusementin käyttöön;
5) varus-valgus epämuodostuma, joka aiheuttaa raajan/proteesin vinoutumisen;
6) kardiovaskulaariset sairaudet mukaan lukien keuhkoembolia ja sydäninfarkti;
7) hematooma;
8) haavan viivästynyt parantuminen
9) *syvähaavainfektio (aikainen tai myöhäinen)*, potentiaalisesti vakava nivelproteesileikkausten komplikaatio, joka voi johtaa proteesin poistamiseen ja sen jälkeiseen artrodeesiin. Asianmukainen antibioottiprofylaksi ja aseptisten toimenpiteiden kirjallinen seuraaminen on pakollista; ja,
10) reisiluun, sääriluun tai polvilumpion komponentin murtuma.

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Myöhempiin leikkauksen jälkeisiin komplikaatioihin voivat kuulua, mutta niihin [illegible]

1) myöhäinen (tai aikainen) irtoaminen, komponenttien paikan muutos, kuluminen ja yhden tai useamman proteesin komponentin taipuminen tai rakoilu. (Kliinisen kokemus osoittaa, että tämän pakkausselosteen Varoituksia ja Varotoimenpiteitä-osien tietojen tarkka lukeminen voi auttaa niiden riskin minimoinnissa.);
2) liiallisesta jännitteestä johtuva polvilumpion murtuma, tai tahaton leikkauksen aikainen heikentyminen;
3) kyseessä olevan raajan tai kontralateraalin raajan pahentuneet ongelmat, jotka johtuvat jalan pituuksien erilaisuudesta;
4) myöhäinen ligamenttien instabiliteetti;
5) perinivelen kalsifikaatio tai luutuminen, joka joko estää tai ei estä nivelen liikkumista;
6) komponenttien väärästä valinnasta tai asemoinnista johtuva huono liikkumisväli, iskut [impingement] tai perinivelkalsifikaatio ja dystrofia; ja,
7) luunmurtumat, sijoiltaanmeno, subluksaatio, fleksion kontraktuuri, liikkumisvälin vaheneminen, tai jalan piteneminen tai lyheneminen; näitä on raportoitu kokopolvinivelproteesileikkausten yhteydessä.

LÄÄKÄRILLE TARKOITETTUJA TÄRKEITÄ TIETOJA

A. **Luuresorptio ja osteolyysi.** Luuresorptio voi tapahtua kokonivelartroplastian luonnollisena seurauksena, ja se johtuu muutoksista luiden uudelleenmuovautumismalleissa. Luun uudelleenmuovautumiseen vaikuttavat välillisesti implantin aiheuttamat rasituksen jakautumisen muutokset. Proteesin ympärillä tapahtuva ekstensiivinen resorptio johtaa implantin irtoamiseen ja epäonnistumiseen. Paikallista progressiivista luuresorptiota, joka johtuu muista syistä kuin rasitussuojauksesta tai infektiosta, voi tapahtua proteesin komponenttien ympärillä samoin kuin komponenttien ja luun välissä, ja tätä kutsutaan osteolyysiksi. Yleisesti ottaen ollaan sitä mieltä, että osteolyysi johtuu paikallisesta vierasesineen reaktiosta hiukkasjätteeseen (esim. sementti, metalli, UHMWPE ja keraamiset aineet), ja sen tuottaa komponenttien välinen sekä komponenttien ja luun välinen vuorovaikutus, mikä tapahtuu lähinnä kulumismekanismien kuten kiinnittymisen, hankautumisen ja väsymisen kautta. Etiologisesti on oletettu, että proteesin komponenttien niveltämisen tuottama hiukkasjäte kulkeutuu nivelonteloon ja luuimplantin liitäntäalueelle, missä se tuottaa makrofageja ja stimuloi fagosyyttien toimintaa. Tuottamisaste määräytyy hiukkasjätteen koon, jakelualueen ja määrän mukaan, kuten myös jätteen tuottamisvauhdin mukaan. Fagosyyttien toimintaa on esitelty in vitro-kokeissa, joissa indusoidaan sytokiini-ja sellulaarisia mediaattoreita (IL-1, IL-2, IL-6, PGE2, TNF3). Testit osoittavat näiden mediaattorien moduloivan osteoklastista luuresorptiota. Kliiniset ja perustutkimukset jatkuvat edelleen, jotta voitaisiin paremmin ymmärtää tämän ilmiön tieteellisiä syitä ja tutkia mahdollisia keinoja sen tapahtumatiheyden vähentämiseksi.

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Koska osteolyysi on usein oireeton, rutiininomaisesti suoritettu radiografinen tutkimus on [illegible] ja minimoimiseksi. Radiografia ei kuitenkaan saata täysin selvittää osteolyysin määrää. Progressiivisten fokaalisten vaurioiden läsnäolo saattaa tehdä proteesin komponentin/komponenttien vaihtamisen uuteen tarpeelliseksi.

B. **Polyeteenin paksuus.** Teoreettinen analyysi osoittaa, että sääriluun kontaktirasitustaso vaihtelee polyeteenikomponentin paksuuden mukaan. Yleensä ottaen paksummilla sisäosilla oletetaan olevan alempi kontaktirasitustaso kuin ohuemmilla. Rasitus saattaa vaikuttaa implantin komponenttien kulumiseen; teoreettisten rasituserojen kliinistä merkitystä ei kuitenkaan ole konklusiivisesti todistettu. Lääkärin tulisi pohtia sääriluun lisäresektion ja paksumman sisäosan käyttämisen vaihtoehtoisuutta. Sellaiset potilaaseen liittyvät tekijät kuten paino, ikä ja aktiviteettitaso tulisi ottaa huomioon päätöstä tehtäessä.

C. **Komponenttien yhteensovittaminen.** On olemassa vastaavia sääriluuleveyksiä, jotka on suunniteltu niveltymään ja mukautumaan oikeankokoisiin reisiluukomponentteihin. Komponenttien väärä yhteensovittaminen saattaa johtaa sääriluukomponentin ennenaikaiseen epäonnistumiseen ja saattaa lisätä nivelen laksiteettia.

D. **Tuotteen nimilappu.** Katso tuotteen nimilappua saadaksesi lisätietoja siitä tuotteesta, johon tässä pakkausselosteessa viitataan.

MITEN TUOTTEET TOIMITETAAN

Nämä tuotteet toimitetaan steriileinä pakkauksissa, jotka on altistettu vähintään 25 kGy:n gammasäteilylle koboltti 60 -lähteestä. Kaikkien steriilien tuotteiden pakkaus tulisi tarkistaa ennen käyttöä mahdollisten aukkojen löytämiseksi steriilissä suojassa.

UUDELLEENSTERILOINTI

Laitteita, jotka sisältävät POLYETEENIÄ, HUOKOISTA PÄÄLLYSTETTÄ, PLASMARUISKUA, HYDROKSIAPATIITTIA, KERAAMISIA AINEITA tai METYYLIMETAKRYLAATTIA EI VOI AUTOKLAAVATA TAI STERILOIDA UUDELLEEN KÄYTTÄJÄN TOIMESTA.

Komponentit, jotka **eivät** ole nestemäisten aineiden, etenkin kehon nesteiden, kontaminoimia, voidaan steriloida uudelleen painovoimasiirtolsessa höyryautokiaavissa seuraavia parametrejä käyttäen:

	250° F (121° C) 20 PSI (1.4 bars)	270° F (132° C) 30 PSI (2 bars)
Kääritty yksittäinen komponentti (yksi tai useampi komponentti) tai sterilointilaatikko	40 minuuttia	20 minuuttia

Kaksoiskäärinnässä käytetään AAMI CSR-menetelmää. Nämä ohjelmat kehitettiin vain tälle kammiossa olevalle esineelle ja niissä käytetään keskihyllyä. Mikä tahansa ohjelma tulisi validoida erilaisia sterilointikammioita, käärintämenetelmiä ja/tai eri kuormakokoonpanoja varten.

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VAROITUS

Yhdysvaltain liittovaltioiden laki rajoittaa tämän laitteen myymisen lääkärin toimesta tai määräyksestä tapahtuvaksi.

VIITTAUKSET

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study In Sweden," Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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Fremgang inden for fuldstændig knæ substitution har givet kirurgen et middel i hænde til at gengive bevægelighed, rette deformiteter, og reducere smerte ved hjælp af en implanteret protetisk anordning. Disse anordninger, der har vist sig at være succesfulde, er fremstillet af metal og plastik. Ingen protetisk anordning kan derfor forventes at modstå aktiviteter og vægt som et normalt sundt led. Det protetiske system vil derfor ikke være lige så stærkt, pålideligt, eller varigt som et naturligt menneskeligt knæled.

Ved anvendelsen af fuldstændig knæleds implantater bør kirurgen være opmærksom på følgende:

A. **Korrekt udvælgelse og placering af implantatet er yderst vigtig.** For at opnå succes ved fuldstændig led substitution er det nødvendigt at udvælge implantater af den rette størrelse, facon og form. Fuldstændige led proteser kræver omhyggelig indsætning, rigid fastgørelse og tilstrækkelig knogle støtte.

B. **I udvælgelsen af patienter til fuldstændig led substitution, kan følgende faktorer være af stor betydning for procedurens eventuelle succes:**

1) **Patientens vægt.** En overvægtig eller en patient der lider af obesitet kan lægge højere vægt på protesen, hvilket eventuelt kan føre til anordningens svigt. Virkningen af den højere vægt vil blive yderligere accentueret når en lille størrelse protese skal bruges på grund af knogle størrelse i sådanne patienter.

2) **Patientens beskæftigelse eller aktiviteter.** Hvis patienten er involveret i en beskæftigelse eller aktivitet der er karakteriseret ved signifikant slagvægt på knoglerne (hurtig gang, løbning, løftning, eller kropsdrejninger) kan de resulterende effekter forårsage svigt af indsættelsen, anordningen, eller begge dele. En høj grad af fysisk aktivitet over årene kan også accentuere den normale slid proces, der forekommer med protese led. Protesen vil ikke gengive bevægelighed og funktion på samme niveau som normalt sunde knogler medfører, og patienten bør bringes ud af urealistiske forventninger vedrørende funktion og bevægelighed. (Der henvises til sektionen om **FORHOLDSREGLER** for yderligere oplysninger).

3) **En tilstand af senilitet, mental sygdom, eller alkoholisme.** Disse tilstande (blandt andre), kan forårsage, at patienten ignorerer visse nødvendige begrænsninger og forholdsregler i brugen af implantatet, hvilket kan føre til svigt eller andre komplikationer.

4) **Følsomhed overfor fremmed legemer.** Hvor man har mistanke om følsomhed overfor visse materialer, bør man foretage passende prøver før materiale valg eller implantat påbegyndelse.

5) **Ortopædisk historie.** Prognosen for procedurens succes afhænger af patientens ortopædiske historie. Patienter som har haft mange tidligere

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procedurer og/eller implantater bør rådgives med omhu med hensyn til det forventede resultat af proceduren.

6) **Knogle kvalitet.** Levetid af en fuldstændig knæ substitution kan være påvirket af svækket knogle kvalitet, som kan være forårsaget af visse systemiske eller af stofskifte sygdomme, således som dem, der bliver behandlet med steroider, immun dæmpere eller kemiske stoffer.

BESKRIVELSE

Howmedica fremstiller et bredt udvalg af tre-delte rekonstruktive knæsystemer i forskellige størrelser og arter for at tilgodese forskellige krav fra patienter og kirurger til primære og revisions cementerede applikationer. Valget af det protetiske system afhænger af den type kirurgi der skal udføres. Lår, skinnebens, og knæskals komponenter kan fås til knæ rekonstruktioner. Metal komponenterne (lår komponenterne, skinnebens og knæskals basis plader, sintrerede kanter (beads), kiler og afstandsskiver) er fremstillet af en støbt kobolt-krom-molybden legering (Vitallium ® legering), der er i overensstemmelse med ASTM standard F75. Skruerne og stamme (stem) forlængerne er fremstillet af en forarbejdet kobalt-krom-molybden legering (Vitallium ® legering) der er i overensstemmelse med ASTM standard F1537.

Polyethylen komponenterne er fremstillet af ultra-høj-molekulær-vægt polyethylen (UJHMWPE), der er i overensstemmelse med F648.

Lår komponenter

Lår komponenter (undtagen super stabilisatorer) fås med porøse og ikke-porøse belægninger, i konfigurationer med kondylarer, stabilisatorer og super stabilisatorer. Visse lår komponenter kan omdannes fra en konfiguration til en anden, f.eks. kondylar til stabilisator, ved tilføjelse af en modul stabilisator boks.

Skinnebens komponenter

Skinnebens komponenter fås i et stort udvalg af størrelser og tykkelser. Skinnebens komponenter omfatter et-stykket hel-polyethylen samt modul udformninger bestående af et polyethylen indsæg og en metal basisplade. Basis pladen kan fås med porøs og ikke-porøs belægning og supplerende fastsættelses valg. Indlæggene fås med forskellige grader af konstriktion i kondylar udformningerne, og i stabilisator og super stabilisator konfigurationerne.

Knæskal komponenter

Knæskal komponenterne fås i hel-polyethylen eller metal forstærket med porøs belægning.

Udstyr

Stamme (stem) forlængere er fremstillet til at fastsættes til stammen på lår- eller skinnebens komponenten for at give yderligere stabilitet. Kiler er fremstillet til cementerede applikationer for at give yderligere mellemrum i tilfælde hvor der er skinnebens defekter. Afstandsskiver er fremstillet til at give ekstra afstand i tilfælde hvor der er lårknogle defekter og de kan enten blive mekanisk sikrede til lår komponenten eller cementeret på plads. Skruer fås til supplerende samling af skinnebens indlæg eller til samling af skinnebens basispladen til skinnebenet.

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Produkt mærkat
Produkt mærkaten giver oplysninger vedrørende det, særligt dokumentation(er) hvorfor anordningen er fremstillet.

INDIKATIONER

Absolutte kontraindikationer omfatter:

1) ikke-betændt degenerativ ledsygdom, inklusive slidgigt, traumatisk gigt, eller ikke-vaskuløs vævshenfald;
2) reumatisk gigt;
3) rettelse af funktions deformitet;
4) revisions procedurer hvor andre behandlinger eller anordninger har svigtet;
5) post-traumatisk tab af led anatomi, særligt hvor der er knæskals-lårknogle-erosion, dysfunktion eller tidligere knæskals kirurgi; og
6) uoprettelig brud på knæet.

KONTRAINDIKATIONER

Absolutte kontraindikationer omfatter:

1) åbenbar infektion;
2) fjernt liggende infektioner (som kan spredes via blodbaner til implantatstedet)
3) hurtig sygdoms fremgang som manifesteret ved led ødelæggelse eller knogle absorption vist ved røntgenbilleder;
4) umoden skelet opbygning; og
5) tilfælde hvor der er ringe knogle kvalitet, hvilket ville gøre proceduren uberettiget.

Tilstande der giver forøget svigt risiko omfatte:

1) ikke-samarbejdsvillige patienter eller patienter med neurologiske uregelmæssigheder, som gør dem ude af stand til at følge instruktioner;
2) osteoporose;
3) stofskifte problemer som kan svække knogle formation;
4) osteomalaki; og,
5) tidligere artrodesi.

En større forekomst af implantat svigt er også forekommet i paraplegiske patienter, spastisk lammede, og patienter med Parkinson's sygdom.

ADVARSLER

Forkert udvælgelse, placering, positionering, og fastgørelse af implantats komponenterne kan resultere i usædvanlig belastning der kan medføre en reduktion i den implanterede proteses levetid. Kirurgen bør være vel kendt med den kirurgiske procedure, instrumenterne, og implantats teknikker før operationen påbegyndes. Opfølgning med mellemrum anbefales for at overvåge positionen og tilstanden af de protetiske komponenter, såvel som tilstanden af den omkring-liggende knoglebygning.

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Cementerede applikationer. Man bør være omhyggelig med at sikre fuldstændig støtte af alle anordningens dele der er udsat. Knogle cement er et kræftfremkaldende koncentrationer, som kan føre til svigt af proceduren. Fuldstændig renselse (fuldstændig fjernelse af knoglesplinter, knogle cement splinter, og metal affaldsstoffer) af implantat stedet er kritisk for at forebygge fremskyndet slitage af de artikulerede overflader på implantatet.

Protetiske komponenter. Lår-, skinnebens-, og knæskals komponenter fra forskellige protetiske systemer, eller fra forskellige fabrikanter, bør ikke blandes, da tolerance og materialer kan være inkompatible. Modul komponenter bør samles forsvarligt for at forhindre disassociation. Gentagen samling og udtagning af modul komponenterne kan kompromittere komponenternes kritiske låse aktion og bør undgås. Kirurgiske affaldsstoffer skal fjernes fra komponenterne før samling. Affaldsstoffer kan forstyrre låse mekanismen på modul komponenterne, hvilket igen kan føre til tidlig svigt af proceduren.

Knæskals komponenter. Fordi knæskals komponenten har de mindste bære- og fastsættelses overflader, er knæskallen og knæskals komponenten mere sårbar overfor subluksation og løsning/løsrivelse. Særlig opmærksomhed må gives til knæskals sporing under kirurgi for en succesfuld procedure.

Fastsættelses skruer. Fastsættelses skruer, skal, når de bruges, sættes helt ind for at maksimere stabil fastsættelse, og for at undgå forstyrrelse med de korrekte indsætning af komponenter. Brug kun de anbefalede skruer til den specifikke protese for at undgå forkert tilpasning, og for at undgå ukorrekt blanding af metaller. Disse ben skruer er ikke beregnede til skrue sammensætning eller fastgørelse til de bagerste elementer (pedikler) på den cervikale, thorakiske eller lumbale rygrad.

Metal komponenter. Nogle af de legeringer der er anvendt til at producere ortopædiske implantater indeholder metal komponenter, der kan være kræftfremkaldende i vævskulturer eller intakte organismer under unikke omstændigheder. Spørgsmål har været rejst i den videnskabelige litteratur om selve disse legeringer kan være kræftfremkaldende i modtagere af implantater. Studier udført for at besvare disse spørgsmål har ikke identificeret overbevisende bevis for et sådant fænomen, på trods af de millioner af implantater der er i brug. (Se ref. 1.)

Ligestilling af komponenter. Man må være omhyggelig med at genskabe den korrekte led ligestilling og at balancere tension mellem ligamenter. Uligestilling af lemmet eller leddet kan forårsage stærkt slid, løsgørelse af protesen og smerte der vil føre til tidligere end ønsket revision af en eller flere af de protetiske komponenter.

Polyethylen slid. Som det kunne forventes, er slid af polyethylen overfladerne på skinnebens og knæskals komponenterne blevet rapporteret efterfølgende fuldstændig knæ substitution. Højere slitage hastigheder kan initieres af cement og metal partikler, eller andre affaldspartikler, som kan forårsage afskrabninger på de artikulerede overflader. Større hastigheder af slitage vil sandsynligvis afkorte protesen brugbare levetid, og vil føre til tidligere end ønsket revision for at udskifte de nedslidte komponenter.

FORHOLDSREGLER

Oplysninger til patienten. Patienten bør adviseres om procedurens kortids- og langtids begrænsninger og nødvendigheden af at beskytte implantatet fra fuld vægt-

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bæring indtil tilstrækkelig fastsættelse og heling har taget plads. Overdreven aktivitet og trauma kan påvirke led substitution og har ofte implantat-relaterede komplikationer som udsigelse, brække og/eller slide protesens implantater. Løsgøring af komponenterne kan resultere i forøget produktion af slitage partikler, og dette kan videre skade knogler og gøre revisions kirurgi mere besværligt.

Patienter bør begrænse deres aktiviteter og beskytte det substituerede led mod urimelig belastning ligesom de bør følge lægens instruktioner vedrørende efterbehandling og kontrol.

Patienten bør advares om kirurgiske risici, og gøres opmærksom på mulige bivirkninger. Patienten bør oplyses om, at anordningen ikke kan erstatte et normalt sundt led, at implantatet kan brække, eller blive beskadiget efter anstrengende aktivitet eller trauma, og at anordningen har en begrænset levetid således at det kan blive nødvendigt at udskifte den på et senere tidspunkt.

Kortvarig bacteriæmi kan forekomme. Tandlæge besøg, endoskopiske undersøgelser og andre mindre kirurgiske procedurer er blevet forbundet med kortvarig bacteriæmi. For at forebygge betændelse på implantatstedet, kan det være fornødent at anvende antibiotika før og efter sådanne procedurer.

Instrumenter. Særlige instrumenter forefindes og skal bruges for at sikre nøjagtig implantat af protesens komponenter.

Skønt sjældent, kan intra-operative brud eller beskadigelse af instrumenter forekomme. Det er mere sandsynligt, at instrumenter der har været meget brugte eller som har været udsat for stærkt pres, vil fremvise brækage. Instrumenter bør undersøges for slid, eller beskadigelse før kirurgi påbegyndes.

Genbrug. Et implantat bør aldrig genbruges. Skønt det kan have et ubeskadiget udseende, kan et brugt implantat have været udsat for skader eller dets fuldstændighed (integritet) kan være latent kompromitteret, hvilket vil reducere dets levetid.

Håndtering. Håndtering af implantater er vigtigt, særligt porøst belagte implantater. Porøse overflader må ikke komme i kontakt med tekstiler eller andre fiber frigørende materialer. Alle implantater hvoraf belægningen er blevet beskadiget eller kontamineret bør kasseres. Den højt polerede del af implantatet bør ikke komme i kontakt med hårde overflader.

BIVIRKNINGER

1) I forbindelse med alle led substitutioner kan asymptomatisk, lokaliseret, progressiv knogle absorption (osteolyse) forekomme omkring eller fjernt fra de protetiske komponenter som et resultat af fremmed legeme reaktion til særskilte (particulate) partikler. Særskilte (particulate) materiale dannes ved indvirkninger mellem komponenter, såvel som mellem komponenterne og knoglen, primært ved slitage mekanismer som klæbning, afskrabning og træthed. Særskilt (particulate) materiale kan også sekundært dannes ved slitage af tredie legeme (third-body). Osteolyse kan føre til fremtidige komplikationer der kan nødvendiggøre fjernelse og remplacering af protetiske komponenter. (Se afsnittet **VIGTIGE OPLYSNINGER TIL LÆGEN** for yderligere information).

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2) Skønt sjældent forekommende, har med [illegible] implantater i patienter, efterfølgende led remplacering været rapporteret. Implantatets [illegible] materiale i væv kan resultere i cellulære reaktioner, der kan omfatte lymfocyter, makrofager og fibersprængninger (fibroblasts).
3) Periferisk neuropati er blevet rapporteret efterfølgende fuldstændig led substitution, og kan forekomme som et resultat af kirurgisk trauma.
4) Forskydning og subluksation af implantat komponenter kan være et resultat af forkert positionering og/eller vandring af komponenterne. Blødt vævs slaphed, der omfatter muskler, fibervæv og ligamenter kan også kontribuere til disse tilstande.
5) Implantater kan løsne sig eller vandre på grund af trauma eller tab af fastgørelse.
6) Infektion kan føre til svigt af led substitutten.
7) Skønt sjælden, kan træthæds brud af implantatet forekomme som et resultat af traume, anstrengende aktivitet , forkert stilling eller langtids brug af implantatet.
8) Blødt vævs (med ligamenter) ubalance kan forårsage forstærket slitage og/eller implantats svigt.
9) Intra-operativt brud på femuren, skinnebenet, eller knæskallen kan forekomme medens knogle stederne forberedes og/eller under indsætning af implantaterne.
10) Allergiske reaktioner til de anvendte materialer af implantatet, skønt sjældne, kan forekomme.

Intra-operative og tidligere post-operative komplikationer kan omfatte, men er ikke begrænsede til:

1) dyb vene trombose;
2) Skade til blodvæv;
3) Kortvarig eller permanent nerveskade der afstedkommer smerte eller følelseshed i det pågældende lem.
4) et pludseligt fald i intra-operativt blodtryk associeret med brugen af knogle cement.
5) varus-valgus deformitet med resulterende lem/protese ulighed;
6) kardiovaskulære forstyrrelser inklusive lunge emboli eller hjerte infarkt;
7) hæmatom;
8) forsinket sår heling;
9) dyb sår infektion (tidlig eller sen), en potentiel alvorlig komplikation af hele led remplaceringen, hvilket kan nødvendiggøre fjernelse af protesen og efterfølgende artrodese. Passende antibiotisk forebyggelse og nøje observation af aseptiske procedurer er obligatorisk; og,
10) brud på lår, skinnebens, eller knæskal, eller komponent brud.

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Βίδες Καθήλωσης. Οι βίδες καθήλωσης, όταν χρησιμοποιούνται, πρέπει να τοποθετούνται πλήρως για να μειώσουν τον κίνδυνο [illegible] μόνο τις βίδες που συστήνονται για τη συγκεκριμένη πρόθεση για να αποφευχθεί η ακατάλληλη προσαρμογή, και η ακατάλληλη ανάμιξη μετάλλων. Αυτές οι οστικές βίδες δεν προορίζονται για την προσάρτηση βιδών ή την καθήλωση στα οπίσθια στοιχεία (αυχένας τόξου σπονδύλων) της τραχηλικής, θωρακικής ή οσφυϊκής σπονδυλικής στήλης.

Μεταλλικά Εξαρτήματα. Μερικά από τα κράματα που χρησιμοποιούνται για να παράγουν ορθοπεδικά εμφυτεύματα περιέχουν ορισμένα μεταλλικά εξαρτήματα που μπορεί να είναι καρκινογόνα σε καλλιέργειες ιστού ή σε άθικτους οργανισμούς υπό ορισμένες συνθήκες. Έχουν δημιουργηθεί ερωτήματα σε επιστημονικές εκδόσεις για το εάν ή όχι αυτά τα ίδια τα κράματα είναι καρκινογόνα στα άτομα που γίνονται εμφυτεύσεις. Οι μελέτες που έγιναν για να αξιολογήσουν αυτό το θέμα δεν έχουν προσδιορίσει αποδεικτή ένδειξη τέτοιου φαινόμενου, παρά το γεγονός ότι έχουν γίνει εκατομμύρια εμφυτεύσεις. (Δείτε την παραπομπή 1).

Ευθυγράμμιση των εξαρτημάτων. Θα πρέπει να δοθεί προσοχή για να αποκατασταθεί η σωστή ευθυγράμμιση της άρθρωσης και να ισορροπηθεί η συνδεσμική τάση. Η ακατάλληλη ευθυγράμμιση του άκρου ή της άρθρωσης μπορεί να προκαλέσει υπερβολική φθορά, χαλάρωση της πρόθεσης και πόνο που οδηγούν σε γρηγορότερη από ότι επιθυμείται επανόρθωση ενός ή περισσότερων προσθετικών εξαρτημάτων.

Φθορά πολυαιθυλένιου. Όπως αναμένεται, έχουν αναφερθεί φθορές στις επιφάνειες πολυαιθυλένιου των κνημιαίων και επιγονατιδικών εξαρτημάτων μετά από ολική αντικατάσταση γονάτου. Μπορεί να δημιουργηθούν υψηλότερα επίπεδα φθοράς από μόρια τσιμέντου, μετάλλου ή άλλων υπολειμμάτων που μπορεί να προκαλέσουν εκδορά των αρθρωτών επιφανειών. Οι υψηλότεροι ρυθμοί φθοράς είναι πιθανόν να μειώσουν τη χρήσιμη διάρκεια της πρόθεσης, και να οδηγήσουν σε γρηγορότερη από ότι επιθυμείται επανόρθωση για την αντικατάσταση του φθαρμένου προσθετικού εξαρτήματος.

ΠΡΟΦΥΛΑΞΕΙΣ

Πληροφορίες για τον ασθενή. Θα πρέπει να δοθούν συμβουλές στον ασθενή σχετικά με τα βραχυπρόθεσμα και μακροχρόνια όρια της επέμβασης καθώς και για την ανάγκη προστασίας του εμφυτεύματος από πλήρες φορτίο μέχρις ότου έχει επιτευχθεί πλήρης καθήλωση και επούλωση. Η υπερβολική δραστηριότητα και το τραύμα που επιδρούν στην αντικατάσταση άρθρωσης έχουν διακινδυνεύσει την αποκατάσταση χαλαρώνοντας, προκαλώντας θλάση και/ή φθορά στις εμφυτευόμενες προθέσεις. Η χαλάρωση των εξαρτημάτων μπορεί να οδηγήσει σε αυξανόμενη παραγωγή μορίων φθοράς, καθώς επίσης και στη βλάβη του οστού, καθιστώντας την επιτυχία της επανορθωτικής εγχείρησης ακόμη δυσκολότερη.

Θα πρέπει να δοθούν συμβουλές στον ασθενή να περιορίσει τις δραστηριότητες και να προστατεύσει την αντικατάσταση άρθρωσης από αδικαιολόγητη πίεση και να τηρήσει τις οδηγίες του γιατρού σε σχέση με την παρακολούθηση και τη θεραπεία.

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Θα πρέπει να προειδοποιηθεί ο ασθενής σχετικά με τους κινδύνους της εγχείρησης, [illegible] Θα πρέπει να [illegible] ασθενής ότι η συσκευή δεν είναι παρόμοια με φυσική ανθρώπινη άρθρωση, ότι τα εξαρτήματα μπορούν [illegible] σπάσει ή να χαλάσει ως αποτέλεσμα υπερβολικής δραστηριότητας ή τραύματος, και ότι η συσκευή έχει ορισμένη διάρκεια ζωής και μπορεί να χρειαστεί να αντικατασταθεί στο μέλλον.

Μπορεί να **παρουσιαστεί παροδική βακτηριαιμία** στην καθημερινή ζωή. Οι οδοντιατρικές εργασίες, η ενδοσκοπική εξέταση και άλλες μικρές χειρουργικές επεμβάσεις σχετίζονται επίσης με παροδική βακτηριαιμία. Για να αποφευχθεί η μόλυνση στην περιοχή εμφυτεύματος, μπορεί να χρειαστεί να χρησιμοποιηθεί αντιβιοτική προφύλαξη πριν και μετά από κάθε τέτοια επέμβαση.

Όργανα. Διαθέτονται και πρέπει να χρησιμοποιηθούν τα αποστειρωμένα όργανα για να εξασφαλιστεί η σωστή εμφύτευση των προσθετικών εξαρτημάτων.

Αν και είναι σπάνιο, μπορεί εν τούτοις να παρουσιαστεί ενδοεγχειρητική θλάση ή σπάσιμο των οργάνων. Τα όργανα που έχουν χρησιμοποιηθεί πολλές φορές ή με υπερβολική δύναμη είναι πιο ευαίσθητα και μπορεί να σπάσουν. Τα όργανα θα πρέπει να επιθεωρηθούν για φθορά, ή βλάβη, πριν από την εγχείρηση.

Επαναχρησιμοποίηση. Ενα εμφύτευμα δεν πρέπει ποτέ να επαναχρησιμοποιηθεί. Ακόμη και αν δεν παρουσιάζει βλάβη, ένα χρησιμοποιημένο εμφύτευμα μπορεί να έχει ελαττώματα ή να βρίσκεται σε λανθάνουσα κατάσταση πράγμα το οποίο θα ελάττωνε τη διάρκεια ζωής του.

Χειρισμός. Ο χειρισμός των εμφυτευμάτων είναι σημαντικός, ειδικά σε εμφυτεύματα με πορώδη επικάλυψη. Μην αφήνετε τις επιφάνειες με πορώδη επικάλυψη να έρθουν σε επαφή με πανί ή άλλα υλικά που αφήνουν ίνες. Θα πρέπει να απορριφτούν όλα τα εμφυτεύματα των οποίων η επικάλυψη έχει καταστραφεί ή έχει μολυνθεί. Το υψηλά γυαλισμένο τμήμα του εμφυτεύματος δεν πρέπει να έρθει σε επαφή με σκληρές επιφάνειες.

ΔΥΣΜΕΝΕΙΣ ΕΠΙΔΡΑΣΕΙΣ

1) Όπως συμβαίνει με όλες τις αντικαστάσεις αρθρώσεων, μπορεί να συμβεί ασυμπτωματική, τοπική εξελισσόμενη επιαναρρόφηση οστού (οστεόλυση) γύρω από τα εξαρτήματα της πρόθεσης ως επακόλουθο αντίδρασης ξένου σώματος σε μοριακό υλικό. Το μοριακό υλικό δημιουργείται από την αλληλεπίδραση μεταξύ των εξαρτημάτων, καθώς επίσης και μεταξύ των εξαρτημάτων και του οστού, αρχικά διαμέσου μηχανισμών φθοράς επικάλλησης, εκδορας και κόπωσης. Επίσης, το μοριακό υλικό μπορεί να δημιουργηθεί από φθορά τρίτου σώματος. Η οστεόλυση μπορεί να οδηγήσει σε μελλοντικές επιπλοκές που καθιστούν αναγκαία την αφαίρεση και αντικατάσταση των εξαρτημάτων της πρόθεσης. (Δείτε το τμήμα **ΑΛΛΕΣ ΣΗΜΑΝΤΙΚΕΣ ΠΛΗΡΟΦΟΡΙΕΣ** για περισσότερες πληροφορίες).

2) Αν και είναι σπάνιο, έχει εμφανιστεί αντίδραση ευαισθησίας στο μέταλλο σε ασθενείς μετά από αντικατάσταση της άρθρωσης. Η εμφύτευση ξένων υλικών σε ιστό μπορεί να έχει ως αποτέλεσμα κυτταρικές αντιδράσεις που μπορεί να περιλαμβάνουν τα λεμφοκύτταρα, τα μακροφάγα και τους ινοβλάστες.

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3) Έχει αναφερθεί περιφερική νευροπάθεια κατά μήκος της γραμμής άρθρωσης. Έχει αναφερθεί υποκλινική βλάβη νεύρου, και μπορεί να συμβεί ως αποτέλεσμα του χειρουργικού τραύματος
4) Η εξάρθρωση και το υποεξάρθρημα των εμφυτευόμενων εξαρτημάτων μπορεί να είναι το αποτέλεσμα ακατάλληλης τοποθέτησης και/ή εκτόπισης των εξαρτημάτων. Η χαλάρωση μαλακού ιστού περιλαμβανομένων και των μυών, ινώδους ιστού και συνδέσμων μπορεί επίσης να συνεισφέρει σ' αυτές τις συνθήκες.
5) Τα εμφυτεύματα μπορεί να χαλαρώσουν ή να μετατοπιστούν λόγω τραύματος ή απώλειας της καθήλωσης.
6) Η μόλυνση μπορεί να οδηγήσει σε αποτυχία της αντικατάστασης άρθρωσης.
7) Αν και είναι σπάνιο, μπορεί να συμβεί θλάση κόπωσης του εμφυτεύματος ως αποτέλεσμα τραύματος, ενεργητικής δραστηριότητας, ακατάλληλης ευθυγράμμισης ή υπερβολικής διάρκειας ζωής της συσκευής.
8) Η ανισορροπία του μαλακού ιστού (συνδεσμικού) μπορεί να προκαλέσει υπερβολική φθορά και/ή αποτυχία του εμφυτεύματος.
9) Μπορεί να συμβεί ενδοεγχειρητική θλάση του μηρού, της κνήμης ή της επιγονατίδας όταν προετοιμάζονται οι περιοχές οστού και/ή τοποθετούνται τα εμφυτεύματα.
10) Μπορεί να συμβούν αλλεργικές αντιδράσεις στα υλικά που χρησιμοποιούνται στο εμφύτευμα, αν και είναι σπάνιο.

Οι ενδοεγχειρητικές και πρόωρα μετεγχειρητικές επιπλοκές μπορεί να περιλαμβάνουν:

1) βαθιά φλεβική θρόμβωση,
2) βλάβη στα αιμοφόρα αγγεία,
3) προσωρινή ή μόνιμη βλάβη στα νεύρα με αποτέλεσμα το άλγος ή το μούδιασμα του προσβεβλημένου άκρου,
4) η απότομη πτώση στην ενδοεγχειρητική πίεση αίματος σχετίζεται με τη χρήση οστικού τσιμέντου,
5) παραμόρφωση ραιβού-βλαισού με αποτέλεσμα την ακατάλληλη ευθυγράμμιση άκρου/πρόθεσης,
6) καρδιαγγειακές ασθένειες συμπεριλαμβανομένων και του πνευμονικού εμβολισμού, ή του εμφράγματος του μυοκαρδίου,
7) αιμάτωμα,
8) κοθυστερημένη επούλωση του τραύματος,
9) λοίμωξη εν τω βάθει (πρόωρα ή μεταγενέστερα), μία πιθανώς σοβαρή επιπλοκή όλων των αντικαταστάσεων αρθρώσεων που μπορεί να καταστήσει απαραίτητη την αφαίρεση της πρόθεσης και την επακόλουθη αρθρόδεση. Πρέπει οπωσδήποτε να δοθεί αντιβιοτική προφύλαξη και να τηρηθούν αυστηρά οι ασηπτικές επεμβάσεις, και

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10) [illegible] ή εξαρτήματος.

Οι όψιμες μετεγχειρητικές επιπλοκές μπορεί να περιλάμβάνουν:

1) όψιμη (ή πρόωρη) χαλάρωση, αλλαγή στη θέση των εξαρτημάτων, φθορά, και λύγισμα ή σπάσιμο ενός ή περισσοτέρων προσθετικών εξαρτημάτων. (Η κλινική εμπειρία συνιστά την ιδιαίτερη προσοχή σε όσα περιέχονται στο τμήμα Προειδοποιήσεις και Προφυλάξεις αυτής της συσκευασίας για να ελαχιστοποιηθεί ο κίνδυνος εμφάνισης αυτών των παρενεργειών),
2) επιγονατιδική θλάση ως αποτέλεσμα υπερβολικής τάσης, ή ακούσιας ενδοεγχειρητικής εξασθένησης,
3) επιδεινόμενα προβλήματα στο προσβεβλημένο άκρο ή στο αντίπλευρο άκρο που προκαλούνται από αντιφατική επιμήκυνση του ποδιού,
4) όψιμη οστάθεια συνδέσμου,
5) περιαρθρωτική αποτιτάνωση ή οστεοποίηση, με ή χωρίς προσβολή στην κινητικότητα της άρθρωσης,
6) ανεπαρκές εύρος κίνησης λόγω ακατάλληλης επιλογής ή τοποθέτησης των εξαρτημάτων, πρόσκρουση ή περιαρθρωτική αποτιτάνωση και δυστροφία, και,
7) θλάσεις οστού, εξάρθρωση, υποεξάρθρωση, συστολή κάμψης, μειωμένο εύρος κίνησης, ή επιμήκυνση ή βράχυνση του ποδιού, τα οποία έχουν αναφερθεί στο σύνολό τους σχετικά με την ολική αντικατάσταση γονάτου.

ΣΗΜΑΝΤΙΚΕΣ ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΤΟ ΓΙΑΤΡΟ

A. **Επαναρρόφηση οστού και οστεόλυση**. Μπορεί να συμβεί επαναρρόφηση οστού ως φυσικό επακόλουθο σε ολική αρθροπλαστική άρθρωσης λόγω αλλαγών στα σχέδια επαναδημιουργίας του οστού. Η επαναδημιουργία του οστού γίνεται από αλλαγές στη διανομή πίεσης που προκαλείται από την εμφύτευση. Η υπερβολική επαναρρόφηση γύρω από την πρόθεση οδηγεί στη χαλάρωση του εμφυτεύματος και στην αποτυχία. Η τοπική εξελισσόμενη επαναρρόφηση οστού λόγω αιτιών διαφορετικών από την προστασία πίεσης ή τη μόλυνση μπορεί να συμβεί επίσης και γύρω από τα προσθετικά εξαρτήματα καθώς επίσης και μεταξύ των εξαρτημάτων και του οστού, και αυτό ορίζεται ως οστεόλυση. Συμφωνείται γενικά ότι η οστεόλυση είναι το αποτέλεσμα τοπικής αντίδρασης ξένου σώματος σε υπολείμματα μορίων (π.χ. τσιμέντο, μέταλλο, UHMWPE, και κεραμικά), που δημιουργείται από αλληλεπίδραση μεταξύ των εξαρτημάτων, καθώς επίσης και μεταξύ των εξαρτημάτων και του οστού, κυρίως διαμέσου μηχανισμών φθοράς αποκόλλησης, εκδοράς και κόπωσης. Σχετικά με την αιτιολογία, υποθέτεται ότι τα υπολείμματα μορίων που δημιουργούνται από άρθρωση αυτών των εξαρτημάτων της πρόθεσης μετακινούνται στην αρθρική κοιλότητα και στη διασύνδεση του εμφυτευόμενου οστού, όπου παίρνουν μακροφάγα και προσομειώνουν τη φαγοκυτταρική δράση. Ο βαθμός απόκτησης καθορίζεται από το μέγεθος, τη διανομή και το ποσοστό των μοριακών υπολειμμάτων καθώς επίσης και το ρυθμό δημιουργίας των υπολειμμάτων. Η φαγοκυτταρική

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Η εξέλιξη της ολικής αντικατάστασης γονάτου παρέχει στο χειρουργό τα μέσα για αποκατάσταση κινητικότητας, τη διόρθωση παραμόρφωσης και τη μείωση του άλγους με τη χρήση εμφυτευόμενων συσκευών πρόθεσης. Ενώ αυτές οι συσκευές έχουν αποδειχτεί επιτυχείς, κατασκευάζονται από μεταλλικά ή πλαστικά υλικά. Για αυτό το λόγο, καμία συσκευή πρόθεσης δεν μπορεί να αναμμένεται να αντέξει τα επίπεδα δραστηριότητας και τα φορτία ενός φυσιολογικού υγιούς οστού. Γι' αυτό το λόγο, το προσθετικό σύστημα δε θα είναι τόσο δυνατό, αξιόπιστο ή ανθεκτικό όσο το φυσιολογικό ανθρώπινο γόνατο.

Κατά τη χρήση εμφυτευμάτων ολικού γονάτου, ο χειρουργός πρέπει να λάβει υπόψη τα παρακάτω:

A. **Είναι εξαιρετικά σημαντική η σωστή επιλογή και τοποθέτηση του εμφυτεύματος.** Η πιθανότητα επιτυχίας σε ολική αντικατάσταση άρθρωσης απαιτεί την επιλογή του σωστού μεγέθους, σχήματος και σχεδίου του εμφυτεύματος. Οι προθέσεις ολικής άρθρωσης απαιτούν προσεκτική τοποθέτηση, ακριβή καθήλωση και επαρκή υποστήριξη οστού.

B. **Κατά την επιλογή ασθενών για ολικές αντικαστάσεις άρθρωσης, οι ακόλουθοι παράγοντες μπορεί να είναι εξαιρετικά σημαντικοί για την τελική επιτυχία της επέμβασης:**

1) **Το βάρος του ασθενή.** Ενας παχυσαρκής ασθενής μπορεί να προσθέσει υψηλότερα φορτία στην πρόθεση πράγμα το οποίο μπορεί να οδηγήσει στη δυσλειτουργία της συσκευής. Το αποτέλεσμα αυτών των φορτίων θα μεγεθυνθεί όταν πρέπει να χρησιμοποιηθεί μια πρόθεση μικρότερου μεγέθους λόγω του μεγέθους οστού σε τέτοιους τύπους ασθενών.

2) **Το επάγγελμα ή οι δραστηριότητες του ασθενή.** Εάν ο ασθενής έχει επάγγελμα ή δραστηριότητες που περιλαμβάνουν σημαντικά φορτία (βάδισμα, τρέξιμο, άρση φορτίων ή περιστροφή), οι προκύπτουσες δυνάμεις μπορεί να προκαλέσουν αποτυχία της καθήλωσης, της συσκευής ή και των δύο. Τα υψηλά επίπεδα φυσικής δραστηριότητας με το πέρασμα του χρόνου μπορεί επίσης να μεγεθύνουν τη φυσιολογική διαδικασία φθοράς που συμβαίνει με αρθρώσεις προθέσεων. Η πρόθεση δεν θα αποκαταστήσει τη λειτουργία στο επίπεδο που αναμμένεται με ένα φυσιολογικό, υγιές οστό, και ο ασθενής δεν πρέπει να πιστεύει, και πρέπει να συμβουλευτεί, για να μην προσδοκεί φανταστικές προσδοκίες λειτουργικότητας. (Δείτε το τμήμα **ΠΡΟΦΥΛΑΞΕΙΣ** για περισσότερες λεπτομέρειες).

3) **Συνθήκες γηραμάτων, διανοητικής ασθένειας, ή αλκοολισμού.** Αυτές οι συνθήκες, μεταξύ άλλων, μπορεί να προκαλέσουν στον ασθενή να αγνοήσει ορισμένα απαραίτητα όρια και προφυλάξεις στη χρήση αυτού του εμφυτεύματος, που μπορεί να οδηγήσουν σε δυσλειτουργία ή άλλες επιπλοκές.

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4) **Ευαισθησία σε βοηθητικά στοιχεία.** Οποιοδήποτε ιστορικό αλλεργικής ευαισθησίας σε υλικό, θα πρέπει να γίνουν τα καταλληλα τεστ πριν από την επιλογή του υλικού ή την εμφύτευση.

5) **Ορθοπεδικό ιστορικό.** Η πρόγνωση για την επιτυχία της επέμβασης εξαρτάται από το ορθοπεδικό ιστορικό του ασθενή. Θα πρέπει να δοθούν αυστηρές οδηγίες στους ασθενείς που υποβλήθηκαν σε πολλαπλές προηγούμενες επεμβάσεις καυή εμφυτεύματα, σχετικά με το αναμένο αποτέλεσμα της επέμβασης.

6) **Ποιότητα οστού.** Η επιβίωση της ολικής αντικατάστασης γονάτου μπορεί να επηρεαστεί από εξασθενισμένη οστική μάζα, πρόγμα το οποιο μπορεί να είναι το αποτέλεσμα ορισμένων συστημικών ή μεταβολικών ασθενειών όπως αυτές που θεραπεύονται με στεροειδή, ανοσοκατασταλτικά ή χημειοθεραπευτικά.

ΠΕΡΙΓΡΑΦΗ

Η Howmedica κατασκευάζει ποικιλία τριδιαμερισματικών ανακατασκευαστικών συστημάτων γονάτου σε διάφορα μεγέθη και τύπους για να ανταποκρίνεται στους διάφορους ασθενείς και στις χειρουργικές ανάγκες για πρωταρχικές και επανορθωτικές εφαρμογές με τσιμέντο. Η επιλογή του προσθετικού συστήματος εξαρτάται από τον τύπο εγχείρησης που απαιτείται. Διαθέτονται μηριαία, κνημιαία και επιγονατιδικά εξαρτήματα για επανόρθωση του γονάτου. Τα μεταλλικά εξαρτήματα (το μηριαίο εξάρτημα, οι κνημιαίες και επιγονατιδικές πλάτες βάσης, οι πυριτικές χάντρες, οι σφήνες και οι διαχωριστές) κατασκευάζονται από κράμα κοβαλτίου-χρωμιου-μολύβδου (Κράμα Vitallium®) που συμβιβάζεται με το πρότυπο ASTM (Αμερικανικός Σύλλογος Δοκιμών και Υλικών) F75. Οι βίδες και οι επεκτάσεις στελεχών κατασκευάζονται από κατεργασμένο κράμα κοβαλτίου-χρωμίου-μολύβδου (Κράμα Vitallium®) που συμβιβάζεται με το πρότυπο ASTM F1537.

Τα εξαρτήματα από πολυαιθυλένιο κατασκευάζονται από πολυαιθυλένιο υπερυψηλού μοριακού βάρους (UHMWPE) που συμβιβάζεται με το πρότυπο ASTM F648.

Μηριαία Εξαρτήματα

Τα μηριαία εξαρτήματα (εκτός από τον υπερσταθεροποιητή) διαθέτονται σε επιλογές πορώδων και μη πορώδων επικαλύψεων, κονδυλικές, σταθεροποιητικές και υπερσταθεροποιητικές διαμορφώσεις. Ορισμένα μηριαία εξαρτήματα μπορουν να αλλαχτούν από μία διαμόρφωση σε άλλη, π.χ. από κονδυλική σε σταθεροποιητική, προσθέτοντας ένα τμηματικό κουτί σταθεροποιητή.

Κνημιαία Εξαρτήματα

Τα κνημιαία εξαρτήματα διαθέτονται σε μεγάλη ποικιλία μεγεθών και πάχους. Τα κνημιαία εξαρτήματα περιλαμβάνουν ένα τεμάχιο εξ ολοκλήρου από πολυαιθυλένιο και τμηματικούς τύπους που αποτελούνται από πολυαιθυλένιες προσφύσεις και μεταλλική πλάκα βάσης. Οι πλάκες βάσεις διαθέτονται σε επιλογές με πορώδεις ή μη πορώδεις επικαλύψεις και επιλογές βοηθητικής καθήλωσης. Οι προσφύσεις διαθέτονται σε διάφορους βαθμούς περιορισμού στους κονδυλικούς τυπους και στις διαμορφώσεις σταθεροποιητή και υπερσταθεροποιητή.

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Επιγονατιδικό Εξαρτήματα

Τα επιγονατιδικά εξαρτήματα διαθέτονται είτε εξ ολόκληρου από πολυαιθυλένιο είτε με μεταλλική επένδυση με πορώδη επικάλυψη.

Αξεσουάρ

Μερικές προεκτάσεις έχουν σχεδιαστεί έτσι ώστε να προσαρμόζονται στο στέλεχος του μηριαίου ή κνημιαίου εξαρτήματος για να παρέχουν συμπληρωματική σταθεροποίηση. Οι σφήνες έχουν σχεδιαστεί για εφαρμογές με τσιμέντο για να παρέχουν συμπληρωματικό χώρισμα όπου υπάρχουν ελατώμματα του κνημιαίου οστού. Οι διαχωριστές έχουν σχεδιαστεί για να παρέχουν συμπληρωματικό χώρισμα όπου υπάρχουν ελατώμματα του μηριαίου οστού και μπορούν να ασφαλιστούν μηχανικά στο μηριαίο εξάρτημα ή να τσιμεντοποιηθούν στη θέση τους. Διαθέτονται βίδες για βοηθητική συναρμολόγηση των κνημιαίων προσφύσεων στις πλάκες βάσης ή των κνημιαίων πλακών βάσης στο κνημιαίο οστό.

Ετικέτα προϊόντος

Η ετικέτα του προϊόντος παρέχει πληροφορίες σχετικά με τα ειδικά υλικά από τα οποία κατασκευάζεται η συσκευή.

ΕΝΔΕΙΞΕΙΣ

Οι ενδείξεις για χρήση προθέσεων σε ολική αντικατάσταση γονάτου περιλαμβάνουν:

1) μη φλεγμονώδη εκφυλιστική ασθένεια αρθρώσεων περιλαμβανομένης της οστεοαρθρίτιδας, τραυματικής αρθρίτιδας και ανάγγειας νέκρωσης,
2) ρευματοειδή αρθρίτιδα,
3) διόρθωση λειτουργικής παραμόρφωσης,
4) επανορθωτικές επεμβάσεις όπου άλλες θεραπειες ή συσκευές έχουν αποτύχει,
5) μετατραυματική απώλεια ανατομίας της άρθρωσης, ειδικά όπου υπάρχει επιγονατιδική-μηριαία διάβρωση, δυσλειτουργία προηγούμενης επιγονατιδικής τομής, και,
6) *ανεπανόρθωτη θλάση του γονάτου.*

ΑΝΤΕΝΔΕΙΞΕΙΣ

Οι απόλυτες αντενδείξεις περιλαμβάνουν:

1) έκδηλη μόλυνση,
2) απόμακρη εστία μολύνσεων (που μπορεί να προκαλέσει αιματογενή επέκταση στην περιοχή εμφύτευσης),
3) ταχείο εξέλιξη ασθένειας όπως εκδηλώνεται από καταστροφή της άρθρωσης ή απορρόφηση οστού όπως εμφανίζεται σε ακτινογράφημα,
4) σκελετικά ανώριμοι ασθενείς,
5) περιπτώσεις όπου υπάρχει εξασθενισμένη οστική μάζα που μπορεί να *καταστίσει την επέμβαση αδικαιολόγητη.*

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Οι συνθήκες που ενέχουν αυξημένο κίνδυνο αποτυχίας περιλαμβάνουν:

1) ασθενή που δεν συμμορφώνεται με τις οδηγίες ή ασθενή με ψυχολογικές διαταραχές, ο οποίος είναι ανίκανος να τηρήσει τις οδηγίες,
2) οστεοπόρωση,
3) διαταραχές μεταβολισμού που μπορεί να διακινδυνεύσουν τη δημιουργία οστού,
4) οστεομαλακία, και,
5) προηγούμενη αρθρόδεση.

Εχει επίσης συμβεί μεγαλύτερο ποσοστό δυσλειτουργίας των εμφυτευμάτων σε παράπληκτους, ασθενείς με εγκεφαλική παράλυση και ασθενείς που πάσχουν από την ασθένεια του Parkinson.

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ

Η ακατάλληλη επιλογή, τοποθέτηση, θέση και καθήλωση των εξαρτημάτων του εμφυτεύματος μπορεί να έχουν ως αποτέλεσμα συνθήκες υπερβολικής πίεσης και επακόλουθη μείωση της διάρκειας ζωής του προσθετικού εμφυτεύματος. Ο χειρουργός πρέπει να είναι πλήρως εξοικειωμένος με τη χειρουργική διαδικασία, τα όργανα, και τα χαρακτηριστικά του εμφυτεύματος πριν από την εγχείρηση. Ανά περιόδους, συνιστάται η μακροχρόνια παρακολούθηση για να παρακολουθείται η θέση και η κατάσταση των προσθετικών εξαρτημάτων, καθώς και η κατάσταση των γειτονικών οστών.

Εφαρμογή με Τσιμέντο. Θα πρέπει να δοθεί προσοχή για να εξασφαλιστεί πλήρη υποστήριξη όλων των εξαρτημάτων της συσκευής που έχουν εισαχθεί σε οστικό τσιμέντο για να αποφευχθούν οι συγκεντρώσεις πίεσης που μπορεί να οδηγήσουν σε αποτυχία της διαδικασίας. Είναι κρίσιμο το πλήρες καθάρισμα (πλήρης αφαίρεση των κομματιών οστού, κομματιών οστικού τσιμέντου, και μεταλλικών υπολειμμάτων) στην περιοχή εμφύτευσης για να αποφευχθεί η επιταχυνόμενη φθορά των αρθρωτών επιφανειών του εμφυτεύματος.

Προσθετικά εξαρτήματα. Δεν πρέπει να αναμιχτούν μηριαία, κνημιαία και επιγονατιδικά εξαρτήματα διαφορετικών προσθετικών συστημάτων, ή διαφορετικών κατασκευαστών, διότι η ανοχή αυτών των υλικών μπορεί να μην είναι συμβατή. Τα τμηματικά εξαρτήματα πρέπει να συναρμολογούνται σταθερά για να αποφευχθεί η αποκόλληση. Η επαναλαμβανόμενη συναρμολόγηση και αποσυναρμολόγηση των τμηματικών εξαρτημάτων μπορεί να διακινδυνεύσει την κρίσιμη δράση ασφάλισης των εξαρτημάτων και πρέπει να αποφευχθεί. Πρέπει να καθαριστούν τα εγχειρητικά υπολείμματα από τα εξαρτήματα πριν από τη συναρμολόγηση. Τα υπολείμματα μπορεί να παρεμποδίσουν το μηχανισμό ασφάλισης των τμηματικών εξαρτημάτων, πράγμα το οποίο μπορεί να οδηγήσει σε πρόωρη αποτυχία της επέμβασης.

Επιγονατιδικό Εξάρτημα. Επειδή το επιγονατιδικό εξάρτημα έχει τις μικρότερες επιφάνειες στήριξης και καθήλωσης, η επιγονατίδα ή το επιγονατιδικό εξάρτημα είναι πιο ευαίσθητο στην υποεξάρθρωση και χαλάρωση. Είναι απαραίτητο να δοθεί ιδιαίτερη προσοχή, κατά την εγχείρηση, στην τοποθέτηση της επιγονατίδας για να επιτύχει η επέμβαση.

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Senkomst postoperative komplikationer kan omfatte, men er ikke begrænsede til:

1) sen (eller tidlig) løsgøring, forandring i komponenternes stilling, slid, og bøjning eller revne dannelse på en eller flere af de protetiske komponenter (Kliniske erfaringer påpeger, at særlig opmærksomhed til punkterne omtalt i sektionen omhandlende advarsler og forholdsregler i dette pakke indlæg kan hjælpe med at formindske risikoen for disse hændelser);
2) knæskals brud som et resultat af for stor tension, eller uagtsom intra-operativ svækkelse;
3) skærpede problemer i det påvirkede lem eller i det andet forårsaget af ulighed mellem benlængde;
4) sen ligament stabilitet;
5) peri-artikulær forkalkning eller forbening, med eller uden hindringer for led bevægelighed;
6) utilstrækkelig bevægelsesfrihed på grund af forkert valg eller placering af komponenter, kollision eller peri-artikulær forkalkning og dystrofi; og
7) knoglebrud, forvridning, subluksation, fleksions sammentrækning, formindsket bevægelighed, forlængelse eller forkortelse af benet (alle disse forhold har været rapporteret i forbindelse med fuldstændig knæ substitution).

VIGTIGE OPLYSNINGER TIL LÆGEN

A. **Knogle absorption og osteolyse.** Knogle absorption kan forekomme som en naturlig følge af fuldstændig led artroplastik på grund af forandringer i knogle re-modellerings mønstre. Knogle re-modellering er formidlet af forandringerne i belastnings distribution, forårsaget af implantatet. Omfattende re-absorption omkring protesen fører til implantatets løsgørelse og svigt. Lokaliseret progressiv knogle re-absorption forårsaget af andre grunde end belastnings undgåelse eller infektion kan forekomme omkring protese komponenterne, lige såvel som mellem komponenterne og knoglerne, og disse forhold går under navnet osteolyse. Der er generel enighed om at osteolyse er et resultat af lokaliseret reaktion mod fremmed legemer (som for eksempel cement, metal, UHMWPE, og keramiske affaldspartikler), der er dannet ved aktiviteter mellem komponenter, så vel som mellem komponenter og knogler, primært ved slitage mekanismer som klæbning, afskrabning, og træthed. Med hensyn til ætiologien, er der fremsat hypoteser om at affaldspartikler dannet ved artikulation af protese komponenter vandrer ind i berøringsfladen mellem den synoviale hulning og knogle implantatet, hvor de rekrutterer makrofager og stimulerer fagocytik aktion. Størrelsen af denne rekruttering afhænger af størrelsen, distributionen og mængden af affaldspartikler så vel som af hastigheden af affaldsdannelsen. Den fagocytiske aktion er blevet demonstreret in vitro til at foranledige frigørelse af cytokiner og cellulære mellemled (IL-1, IL-2, IL-6, PGE2, TNF3). Det er påvist, at disse mellemled (mediators) modulerer osteoklastisk knogle re-absorption. Klinisk og anden grund forskning fortsætter for at opnå en bedre forståelse for årsagerne til dette fænomen og udforske potentielle måder til at reducere dets forekomst.

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Da osteolysis ofte er uden symptomer, det vitalt med mellemrum at foretage rutinemæssige røntgenundersøgelser for at opdage og minimisere alvorlige fremtidige komplikationer. Imidlertid kan røntgen ikke altid definere omfanget af osteolyse. Tilstedeværelsen af fokalt progressive læsioner kan nødvendiggøre gen-placering af de(n) prostetiske komponenter.

B. **Polyethylen tykkelse.** Teoretiske analyser har indiceret at kontakt belastninger i skinnebens komponenten varierer med tykkelsen af polyethylen komponenten. Generelt kan det siges, at tykkere indlæg synes at have lavere kontakt belastning end tyndere. Disse belastninger kan påvirke slitage på implantatets komponenter; men de kliniske implikationer af disse teoretiske belastnings forskelle er dog endnu ikke etablerede. Lægen bør overveje forskelle mellem yderligere skinnebens tilbageskæring og brugen af et tykkere indlæg. Patient forbundne faktorer, såsom vægt, alder og aktivitets niveau bør medtages i denne beslutning.

C. **Komponent tilpasning.** Der findes modsvarende skinnebens vidder, fremstillet til at artikulere og give konformitet med størrelses tilpassede lår komponenter. Undladelse af korrekt at tilpasse komponenter kan resultere i tidlig svigt af skinnebens komponenten og kontribuere til led svaghed.

D. **Produkt mærkat.** Se produkt mærkaten for oplysning vedrørende det særlige produkt der er omhandlet i dette pakke indlæg.

LEVERINGSMÅDE

Disse produkter leveres sterile i beholdere som er blevet udsat for et minimum af 25 kGy gamma bestråling fra en 60 kobolt kilde. Pakken med alle de sterile produkter skal undersøges før brug for mulige brud på den sterile barriere.

RE-STERILISATION

Anordninger der indeholder POLYETHYLEN, PORØS BELÆGNING, SPRØJTET PLASMA, HYDROXYAPATIT, KERAMIK ELLER METHYMETHACRYLAT KAN IKKE AUTOKLAVERES ELLER RE-STERILISERES AF BRUGEREN.

Komponenter der ikke er blevet kontamineret med væsker, i særdeleshed krops væsker, kan re-steriliseres ved at anvende de følgende parametre i en tyngde forskydnings damp autoklav:

	250 graders F (121 graders C) 20 PSI (1.4 Bars)	270 graders F (132 graders C) 30 PSI (2 Bars)
Pakket individuel komponent (en eller flere komponenter) eller sterilisations etui	40 minutter	20 minutter

Den anvendte dobbelt indpaknings metode følger AAMI CSR teknikken. Disse cyklus blev udviklet kun med denne ene del i kammeret og ved at bruge den midterste hylde. Enhver cyklus skal godtgøres for forskellige sterilisations kamre, indpaknings metoder og/eller forskellige ladnings konfigurationer.

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BEMÆRK

USA's lovgivning forbeholder salget af denne anordning til eller efter anfordring af en *læge*.

REFERENCER

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study In Sweden," Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995

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OPGELET OPERERENDE CHIRURG

De vooruitgang in volledige knievervanging heeft de chirurg voorzien van een middel om mobiliteit terug te brengen en pijn te verminderen met het gebruik van geïmplanteerde prothetische apparaten. Alhoewel deze apparaten hebben bewezen in grote mate succesvol te zijn, zij zijn gefabriceerd uit metaal of plastic. Er kan daarom niet van een prothese apparaat worden verwacht om de activiteitniveaus en belastingen te weerstaan van een normaal gezond gewricht. Het prothesesysteem is daarom niet zo sterk, zo betrouwbaar of zo duurzaam als een natuurlijk menselijk kniegewricht.

Bij het gebruik van volledige kniegewrichtimplantaties, dient de chirurg zich van het volgende bewust te zijn:

A. **De juiste selectie en plaatsing van het implantaat is buitengewoon belangrijk.** De mogelijkheid op succes bij volledige gewrichtvervanging vereist de selectie van de juiste maat, vorm en ontwerp van het implantaat. Volledige gewrichtprotheses vereisen zorgvuldige plaatsing, stijve bevestiging en voldoende botondersteuning.

B. **Bij het selecteren van patiënten voor volledige gewrichtvervangingen kunnen de volgende factoren van buitengewoon belang zijn voor het uiteindelijke succes van de procedure:**

1) **Het gewicht van de patiënt.** Een te zware of zwaarlijvige patiënt kan zwaardere belastingen op de prothese veroorzaken wat tot het falen van het apparaat kan leiden. Het effect van deze belastingen wordt benadrukt wanneer een kleine maat prothese moet worden gebruikt vanwege de botgrootte in dergelijke patiënten.

2) **Het werk of de activiteit van de patiënt.** Indien de patiënt is betrokken bij werk of activiteiten waarbij aanzienlijke schokbelastingen (lopen, hardlopen, optillen, of draaien) worden veroorzaakt, kunnen de resulterende krachten het falen van de bevestiging, het apparaat of beide veroorzaken. Hoge fysieke activiteitniveaus voor vele jaren kunnen eveneens het normale slijtproces accentueren dat zich voordoet bij prothesegewrichten. De prothese brengt de functie niet terug naar het niveau van normaal gezond bot, en de patiënt dient zich te ontdoen van onrealistische functionele verwachtingen. (Zie het hoofdstuk **VOORZORGSMAATREGELEN** voor meer informatie.)

3) **Een conditie van seniliteit, mentale ziekte of alcoholisme.** Deze condities, met andere, kunnen ertoe leiden dat de patiënt bepaalde nodige beperkingen en voorzorgsmaatregelen negeert bij het gebruik van het implantaat, dat tot mislukking of andere complicaties leidt.

4) **Gevoeligheid voor vreemde voorwerpen.** De juiste testen dienen te worden uitgevoerd wanneer gevoeligheid voor vreemde voorwerpen wordt vermoed, vóór materiaalselectie of implantatie.

5) **Orthopedische geschiedenis.** De prognose voor het succes van de procedure is afhankelijk van de orthopedische geschiedenis van de patiënt.

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Patiënten die verkwetsuur vorende procedures hebben ondergaan en/of implantaten dienen goed van advies te worden voorzien over de verwachte uitslag van de procedure.

6) **Botkwaliteit.** Overleving van de volledige knievervanging kan worden beïnvloed door verzwakt bot, dat het gevolg kan zijn van bepaalde systemische of metabolische aandoeningen, zoals die welke zijn behandeld met steroïden immunosuppressieven of chemotherapieën.

BESCHRIJVING

Howmedica fabriceert een breed assortiment uit drie compartimenten bestaande kniesystemen in verschillende maten en modellen, om bij verschillende patiënten te passen en te voldoen aan de vereisten van de chirurg, voor primaire en herziende gecementeerde toepassingen. De selectie van het prothesesysteem hangt af van het soort benodigde operatie. Componenten voor het femur, de tibia en basisplaten voor de patella zijn verkrijgbaar voor kniereconstructie. De metalen componenten (componenten voor het femur, tibia en basisplaten voor de patella, gesinterde kralen, wiggen en afstandstukken) worden gefabriceerd uit een gegoten kobalt-chroom-molybdeen legering (Vitallium® legering) in overeenstemming met de ASTM-norm F75. De schroef- en stiftverlengers zijn gefabriceerd uit een gesmede kobalt-chroom-molybdeen legering (Vitallium® legering) in overeenstemming met de ASTM-norm F1537.

De polyethyleen componenten zijn gefabriceerd uit ultra-hoog-moleculair-gewicht polyethyleen (UHMWPE) in overeenstemming met de ASTM-norm F648.

Femurcomponenten

Femurcomponenten (behalve superstabilisator) zijn naar keuze verkrijgbaar met poreuze en niet-poreuze bedekkingen (coatings), condyl, stabilisator en superstabilisator configuraties. Bepaalde femurcomponenten kunnen worden omgezet van één configuratie naar een andere, bijv. condyl naar stabilisator, door de toevoeging van een modulaire stabilisatordoos.

Componenten van de tibia

De componenten van de tibia zijn verkrijgbaar in een brede sortering maten en dikten. Componenten van de tibia bevatten uit één stuk bestaande volledige polyethyleen en modulaire modellen bestaande uit polyethyleen inlegstukken en een metalen basisplaat. De basisplaten zijn verkrijgbaar, naar keuze, met poreuze en niet-poreuze bedekkingen en bijkomende bevestigingskeuzen. De inlegstukken zijn verkrijgbaar met verschillende beperkinggraden in de condylmodellen-, stabilisator- en superstabilisator configuraties.

Componenten van de patella

De componenten van de patella zijn verkrijgbaar in volledige polyethyleen of door metaal gesteund met poreuze bedekking.

Toebehoren

Stiftverlengers zijn ontworpen om te worden bevestigd aan de stift van de component van het femur of de tibia, om in aanvullende stabiliteit te voorzien. Wiggen zijn ontworpen voor gecementeerde toepassingen om in aanvullende afstand te voorzien als er

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aan het bot van de tibia defecten zijn. Afstandstukken zijn ontworpen om in aanvul-
lende mate te voorzien als er aanzienlijk bot verlies aan de defecten zijn en kunnen
mechanisch worden vastgezet aan het femurcomponent of op de plaats worden
gecementeerd. Er zijn schroeven verkrijgbaar voor adjunct assemblage van tibia
inlegstukken naar basisplaten of tibia basisplaat naar het bot van de tibia.

Productetiket

Het productetiket voorziet in informatie over specifiek materiaal(en) waaruit het apparaat is gefabriceerd.

INDICATIES

Indicaties voor gebruik van volledige knievervangingprothese zijn:

1) niet-ontstekende degeneratieve gewrichtaandoening met inbegrip van osteoartritis, traumatische artritis en avasculaire necrose;
2) reumatoïde artritis;
3) correctie van functionele deformiteit
4) herzieningprocedures waar andere behandelingen of apparaten zijn mislukt;
5) post traumatisch verlies van de gewrichtanatomie, in het bijzonder wanneer er erosie van de patella en het femur aanwezig is, gestoorde functie of voorgaande patellectomie; en,
6) onherstelbare fractuur van de knie.

CONTRAINDICATIES

Absolute contra-indicaties zijn:

1) open infectie;
2) afgelegen focus van infecties (die hematologische verspreiding naar de implantatie site kan veroorzaken);
3) snelle ontwikkeling van de aandoening zoals dit wordt gemanifesteerd door gewrichtafbraak of botabsorptie duidelijk weergegeven op het röntgengram;
4) wat het skelet betreft onvolwassen patiënten;
5) gevallen waarbij er slecht bot is waardoor de procedure niet te verantwoorden is.

Condities die een verhoogd risico of mislukking met zich meebrengen zijn:

1) niet meewerkende patiënt, of een patiënt met neurologische aandoeningen, die niet in staat is om instructies op te volgen;
2) osteoporose;
3) metabolische aandoeningen die het vormen van bot vermindert;
4) osteomalacie; en,
5) voorgaand operatief vastmaken of bevestigen van een gewricht ("arthrodesis").

Vaker mislukken van een implantaat heeft zich eveneens voorgedaan in paraplegie, spastische verlamming en patiënten met de ziekte van Parkison.

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WAARSCHUWINGEN

Een juiste selectie, plaatsing, positie en bevestiging van de componenten van het implantaat kan ongewone stress tot gevolg hebben en/of een vermindering van de levensduur van de service van het prothetische implantaat. De chirurg moet grondig bekend zijn met de chirurgische procedure, instrumenten en eigenschappen van het implantaat, alvorens de operatie uit te voeren. Periodieke follow-up over een lange termijn wordt aanbevolen om de positie en de conditie van de prothetische componenten te controleren, en de conditie van het aangrenzende bot.

Gecementeerde toepassing. Zorg dient te worden besteed om volledige ondersteuning te verzekeren van alle onderdelen van het apparaat dat is vastgezet in botcement om spanningconcentraties te voorkomen die tot mislukking van de procedure kunnen leiden. Volledige reiniging (volledige verwijdering van botsplinters, fragmenten van botcement en metaalachtig débris) van de plaats van het implantaat is kritiek om versnelde slijtage van de gewrichtsoppervlakken van het implantaat te voorkomen.

Prothetische componenten. De componenten van het femur, tibia en de patella van verschillende prothetische systemen, of van verschillende fabrikanten, dienen niet te worden gemengd, daar toleranties of materialen niet verenigbaar kunnen zijn. Modulaire componenten moeten goed worden geassembleerd om ontbinding te voorkomen. Herhaalde assemblage en disassemblage van de modulaire componenten kan de kritieke vergrendelingactie van de componenten in gevaar brengen en dient te worden vermeden. Operatief débris moet vóór assemblage van de componenten worden verwijderd en vervolgens worden gereinigd. Débris kan het vergrendelmechanisme of modulaire componenten hinderen, wat op zijn beurt tot het vroege falen van de procedure kan leiden.

Componenten van de patella. Omdat de componenten van de patella het kleinste draag- en bevestigingsoppervlak hebben, is de patella of zijn de patellacomponenten kwetsbaarder voor subluxatie en losraken/dislocatie. Tijdens de operatie dient bijzondere aandacht te worden geschonken aan het sporen van de patella voor het succes van de procedure.

Bevestigingsschroeven. Bevestigingsschroeven, indien gebruikt, dienen volledig ingeschroefd te zijn om stabiele bevestiging te verzekeren en om hindering met de juiste plaatsing van de componenten te vermijden. Gebruik alleen de aanbevolen schroeven voor de specifieke prothese, om het onjuiste passen en het onjuiste mengen van metalen te vermijden. Deze botschroeven zijn niet bedoeld voor schroefbevestiging of het vastmaken aan de elementen (steeltjes) aan de rugzijde van de cervicale, thoracale of lumbale ruggengraat.

Metalen componenten. Sommige legeringen die worden gebruikt om orthopedische implantaten te produceren bevatten sommige metaalachtige componenten die carcinogeen in weefselculturen kunnen zijn, of intacte organismes onder unieke omstandigheden. In de wetenschappelijke literatuur zijn vragen opgeworpen of deze legeringen zelf carcinogeen kunnen zijn bij hen die implantaten ontvangen. Onderzoekingen die zijn uitgevoerd om deze kwestie te bepalen hebben geen overtuigend bewijs van een dergelijk fenomeen aangetoond, ondanks de miljoenen implantaten die in gebruik zijn. (Zie verwijzing 1)

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Uitlijning van componenten. Er dient zorg te worden besteed om de juiste gewrichtuitlijning en ligamentaire spanning in balans te brengen. Uitlijnverkeerd uitlijnen van de prothese en pijn, wat leidt tot vroeger dan gewenste herziening van één of meer prothetische componenten.

Polyethyleenslijtage. Zoals verwacht, er is na een volledige knievervanging slijtage gerapporteerd van de polyethyleenoppervlakken van de componenten van de tibia en patella. Grotere slijtages kunnen worden veroorzaakt door cementdeeltjes, metaal of ander débris dat schuring van de gelede oppervlakken kan veroorzaken. Grotere slijtage verkort zeer waarschijnlijk de nuttige levensduur van de prothese en leidt tot een vroeger dan gewenste herziening om de versleten prothetische componenten te vervangen.

VOORZORGSMAATREGELEN

Informatie voor de patiënt. De patiënt dient te worden geïnformeerd over de beperkingen van de procedure op korte en lange termijn, en de behoefte voor bescherming van het implantaat tegen volle gewichtbelasting, totdat adequate bevestiging en genezing heeft plaatsgevonden. Buitensporige activiteit en trauma die invloed uitoefenen op de gewrichtvervanging zijn geïmpliceerd in de mislukking van de reconstructie door het loskomen van, of de fractuur en/of de slijtage van de prothetische implantaten. Het loskomen van componenten kan leiden tot verhoogde productie van slijtagedeeltjes en schade aan het bot, waardoor het uitvoeren van succesvolle herzieningsoperaties moeilijker wordt

De patiënt dient tot voorzichtigheid te worden gemaand om activiteiten te beperken en het vervangen gewricht te beschermen tegen onredelijke spanningen, en om de instructies van de arts op te volgen over follow-up zorg en behandeling.

De patiënt dient te worden gewaarschuwd voor operatieve risico's en mogelijke nadelige gevolgen. De patiënt dient te worden gewaarschuwd dat het apparaat een normaal gezond gewricht niet kan en niet zal kopiëren. Dat het implantaat kan breken of kan worden beschadigd door veeleisende activiteit of trauma, dat het apparaat een beperkte verwachte servicelevensduur heeft en dat het nodig kan zijn om het in de toekomst te vervangen.

Transiënte bacteriemie kan zich in het dagelijkse leven voordoen. Tandheelkundige handelingen, endoscopische onderzoekingen en andere kleinere chirurgische procedures zijn eveneens in verband gebracht met transiënte bacteriemie. Het kan aanbevelenswaardig zijn om antibiotische profylaxis te gebruiken vóór en na een dergelijke procedure om infectie op de site van het implantaat te voorkomen.

Instrumenten. Gespecialiseerde instrumenten zijn verkrijgbaar en moeten worden gebruikt om de nauwkeurige implantatie te verzekeren van prothetische componenten.

Alhoewel dit zelden voorkomt, intra operatieve fracturen of het breken van instrumenten kan voorkomen. Instrumenten die heel veel zijn gebruikt of onder grote kracht hebben gestaan zijn eerder geneigd te breken. Instrumenten dienen vóór de operatie te worden onderzocht op slijtage of schade.

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Hergebruik. Een implantaat mag nooit opnieuw worden gebruikt. Alhoewel het er [illegible] van uit dat een hergebruikt implantaat dezelfde volledige mogelijkheden hebben opgelopen of latente gevaren van integriteit hebben die de mogelijke levensduur beyorke.

Hantering. Het hanteren van implantaten is belangrijk, speciaal bij poreus bedekte implantaten. Laat poreus bedekte oppervlakken niet in aanraking komen met stof of ander materiaal dat vezels afgeeft. Alle implantaten waarvan de bedekking is beschadigd of besmet, dienen te worden weggeworpen. Het hoog gepolijste deel van het implantaat dient niet in aanraking te komen met harde oppervlakken.

NADELIGE GEVOLGEN

1) Met alle gewrichtvervangingen kan zich niet symptomatische, gelokaliseerde, progressieve botresorptie (osteolysis) voordoen rond, of op afstand, van de prothetische componenten als een gevolg van een reactie op vreemde voorwerpen van stofdeeltjes. Stofdeeltjes worden opgewekt door interactie tussen componenten, en tussen de componenten en bot, primair door slijtagemechanismen van adhesie, schuren en vermoeidheid. Secundair, kunnen stofdeeltjes eveneens worden opgewekt door "third-body wear" (derde lichaamslijtage). Osteolysis kan leiden tot toekomstige complicaties die de verwijdering en vervanging van prothetische componenten nodig maken. (Zie hoofdstuk **BELANGRIJKE ARTSENINFORMATIE**voor meer informatie.)
2) Alhoewel dit zelden gebeurt, gevoeligheidreacties tegen metaal na gewrichtvervanging zijn gerapporteerd. Implantatie van vreemd materiaal in weefsels kan cellulaire reacties teweegbrengen met mogelijk inbegrip van lymfocyten, macrofagen en fibroblasten.
3) Perifere neuropathie is gerapporteerd na volledige gewrichtoperatie. Sub klinische zenuwschade is gerapporteerd en kan zich voordoen als gevolg van operatief trauma.
4) Dislocatie en gedeeltelijke of onvolledige dislocatie van implantaatcomponenten kan het gevolg zijn van het onjuist plaatsen en/of het migreren van de componenten. Laxitas van zacht weefsel met inbegrip van spieren, vezelachtig weefsel en ligamenten kunnen eveneens bijdragen tot deze condities.
5) Implantaten kunnen loskomen en migreren vanwege trauma of het verlies van bevestiging.
6) Infectie kan leiden tot mislukking van de gewrichtvervanging.
7) Alhoewel zeldzaam, een vermoeidheidfractuur van het implantaat kan zich voordoen als gevolg van trauma, veeleisende activiteit, onjuiste uitlijning of extreem lange duur van de service.
8) Het uit balans zijn van het zachte weefsel (ligamentair) kan overdadige slijtage veroorzaken en/of mislukking van het implantaat.
9) Een intra operatieve fractuur van het femur, tibia of de patella kan zich voordoen bij het voorbereiden van de plaats van het bot en/of het plaatsen van de implantaten.
10) Allergische reacties tegen de gebruikte materialen in het implantaat, alhoewel ongewoon, het kan zich voordoen.

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Intra operatieve en vroege postoperatieve complicaties kunnen zijn:

1) diepe aderlijke trombose;
2) schade aan bloedkanalen;
3) tijdelijke of permanente zenuwschade dat pijn of een gevoel van verdoving van het betreffende lichaamsdeel tot gevolg heeft;
4) een plotselinge val in intra operatieve bloeddruk, verbonden aan het gebruik van botcement;
5) varus-valgus (horrelvoet – vulgusstand) deformiteit met resulterende verkeerde uitlijning van het lichaamsdeel/de prothese
6) cardiovasculaire aandoening met inbegrip van longembolie of myocardische infarct;
7) hematoom;
8) vertraagde wondgenezing;
9) diepe wondinfectie (vroeg of laat), een mogelijk serieuze complicatie van alle gewrichtvervangingen die de verwijdering van de prothese nodig kan maken en het daarop volgend voorgaand operatief vastmaken of bevestigen van een gewricht ("arthrodesis"). De juiste antibiotica profylaxe en strikte navolging van aseptische procedures is vereist; en,
10) fractuur van het bot of de component van het femur, tibia of patella.

Late postoperatieve complicaties kunnen zijn:

1) laat (of vroeg) losraken, verandering in de positie van de componenten, slijtage, en buiging of barsten van één of meer prothetische componenten. (Klinische ervaring suggereert dat het schenken van bijzondere aandacht aan de vermelde items in de hoofdstukken Waarschuwingen en voorzorgsmaatregelen van deze bijsluiter, kan helpen om het risico van het voordoen ervan te minimaliseren.);
2) fractuur van de patella als gevolg van buitensporige spanning, of onopzettelijk intra operatief zwak worden;
3) verergerde problemen van het betrokken lichaamsdeel of contra laterale lichaamsdeel, veroorzaakt door een afwijking van de beenlengte;
4) late ligamentaire instabiliteit;
5) verkalking rond een gewricht of ossificatie, met of zonder beletsel voor de mobiliteit van het gewricht;
6) ontoereikend bewegingsbereik als gevolg van onjuiste selectie of plaatsing van componenten, botsing van het femur en of verkalking rond een gewricht en dystrofie; en,
7) botfracturen, dislocatie, subluxatie, buigingcontractuur, verminderd bewegingsbereik, of het verlengen of verkorten van het been, al deze complicaties zijn gerapporteerd in verband met volledige knievervanging.

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A. **Botresorptie en osteolysis.** Botresorptie kan zich voordoen als een natuurlijke uitwerking van volledige gewricht arthroplastiek vanwege veranderingen in de distributie van spanning veroorzaakt door implantatie. Uitgebreide resorptie rond de prothese leidt tot het losraken van het implantaat en, mislukking. Locale progressieve botresorptie anders dan door stresbescherming of infectie veroorzaakt, kan zich voordoen rond de prothetische componenten en tussen de componenten en het bot, en dit wordt osteolysis genoemd. Men is het over het algemeen over eens dat osteolysis het gevolg is van locale reactie op vreemde voorwerpen tegen deeltjesdébris (bijv. cement, metaal, UHMWPE en keramiek), die is ontstaan door interactie tussen componenten, en tussen componenten en bot, voornamelijk door slijtagemechanismen van adhesie, schuring en vermoeidheid. Men heeft ten aanzien van de etiologie verondersteld dat deeltjesdébris veroorzaakt door aaneenkoppeling van componenten van een prothese naar de synoviale holte van de interface van het botimplantaat migreren, waar deze macrofagen opnemen en fagocytaire actie stimuleren. De mate van opname wordt bepaald door de grootte, distributie en de hoeveelheid deeltjesdébris en de mate van het opwekken van débris. De fagocytaire actie is aangetoond in vitro om het vrijlaten van cytokinen en celachtige mediatoren teweeg te brengen. (IL-1, IL-2, IL-6, PGE2, TNF3).

   Deze mediatoren hebbeen aangetoond om osteoclastische botresorptie te moduleren. Klinische en fundamentele research wordt voortgezet om de wetenschappelijke basis beter te begrijpen van de oorzaken van dit fenomeen en mogelijke wegen te onderzoeken om het voorkomen ervan te verminderen.

B. **Dikte van polyethyleen.** Theoretische analyses hebben aangetoond dat contactspanningen in de component van de tibia variëren met de dikte van de polyethyleen component. Het wordt over het algemeen aangenomen dat dikkere inlegstukken minder contactspanningen hebben dan dunnere. Deze spanningen kunnen invloed uitoefenen op de slijtage van de implantaatcomponenten, echter de klinische implicaties van de theoretische spanningsverschillen zijn niet afdoende bewezen. De chirurg dient de inruil in overweging te nemen tussen extra botresectie van de tibia en het gebruik van een dikker inzetstuk. Aan de patiënt verwante factoren, zoals gewicht, leeftijd en activiteitsniveau dienen deel van de beslissing te zijn.

C. **Componenten bij elkaar passen.** Er zijn overeenkomstige breedtes van de tibia die zijn ontworpen om te articuleren in overeenstemming met de juiste maat femurcomponenten. Nalaten om de componenten juist bij elkaar te passen zou vroegtijdige mislukking van de component van de tibia tot gevolg kunnen hebben en bijdragen tot laxitas van het gewricht.

D. **Productetiket.** Zie het productetiket voor informatie over het specifieke product waaraan in deze bijsluiter wordt verwezen.

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HOE GELEVERD

Deze producten worden steriel geleverd in containers die zijn blootgesteld aari minimaal 25 kGy gammastraling van een kobalt 60 bron. De verpakking van alle steriele producten dienen vóór gebruik te worden onderzocht op mogelijke breuken in de steriele barrière.

HERSTERILISATIE

Apparaten die POLYETHELEEN, POREUZE BEDEKKINGEN, PLASMABESPUITING, "HYDROXYAPATITE", KERAMIEKEN of METHYLMETACRYLAAT bevatten KUNNEN NIET IN EEN AUTOCLAAF WORDEN BEHANDELD OF DOOR DE GEBRUIKER OPNIEUW WORDEN GESTERILISEERD.

Componenten die **niet** zijn besmet met vloeistoffen, speciaal lichaamsvloeistoffen, kunnen opnieuw worden gesteriliseerd met de volgende parameters in een zwaartekracht verdringende stoomautoclaaf:

	250° F (121° C) 20 PSI (1,4 Bars)	270° F (132° C) 30 PSI (2 Bars)
Verpakte individuele componenten (enkele of veelvoudige componenten) of sterilisatiedoos	40 minuten	20 minuten

De gebruikte dubbele verpakkingsmethode is de AAMI CSR-techniek. Deze cycli werden ontwikkeld met alleen dit item in de kamer en met gebruik van de middenplank. Elke cyclus dient te worden gevalideerd voor verschillende sterilisatiekamers, verpakkingsmethoden en/of verschillende belastingconfiguraties.

VOORZICHTIG

De federale wetgeving in de VS beperkt de verkoop van dit apparaat door of per order van een arts.

VERWIJZINGEN

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study In Sweden," Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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δράση έχει αποδειχθεί ερχαστηριακά για την παραγωγή άφεσης κυττάρων [illegible] έχουν αποδείξει ότι ρυθμίζουν την οστεοκλαστική επαναρρόφηση οστού. Η κλινική και βασική έρευνα συνεχίζεται για να κατανοήσουμε καλύτερα την επιστημονική βάση για τις αιτίες αυτού του φαινομένου και να βρούμε πιθανούς τρόπους για τη μείωση εμφάνισής του.

Λόγω του ότι η οστεόλυση είναι συνήθως ασυμπτωματική, είναι κρίσιμη ή τακτική ακτινογραφική εξέταση για να βοηθηθείτε στην ανίχνευση και στη μείωση σοβαρών μελλοντικών επιπλοκών. Ωστόσο, οι ακτινογραφίες μπορεί να μην ορίσουν πλήρως την επέκταση της οστεόλυσης. Η παρουσία εστιακών βλαβών που εξελίσσονται μπορεί να καταστήσει απαραίτητη την αντικατάσταση των εξαρτημάτων της πρόθεσης.

Β. Πάχος Πολυαιθυλένιου. Η θεωρητική ανάλυση υποδεικνύει ότι οι τάσεις επαφής στο κνημιαίο εξάρτημα διαφέρει ανάλογα με το πάχος του εξαρτήματος από πολυαιθυλένιο. Γενικά, οι προσφύσεις μεγαλύτερου πάχους έχουν μικρότερη τάση επαφής από ότι οι προσφύσεις μικρότερου πάχους. Αυτές οι τάσεις μπορεί να επηρρεάσουν τη φθορά των εξαρτημάτων του εμφυτεύματος. Ωστόσο, οι κλινικές επιπλοκές των θεωρητικών διαφορών τάσης δεν έχουν καθιερωθεί οριστικά. Ο γιατρός πρέπει να λάβει υπόψη τα υπέρ και τα κατά μεταξύ της συμπληρωματικής εκτομής του κνημιαίου οστού και της χρήσης παχύτερης πρόσφυσης. Οι παράγοντες που σχετίζονται με τον ασθενή, όπως το βάρος, η ηλικία και το επίπεδο δραστηριότητας πρέπει να αποτελούν μέρος αυτής της απόφασης.

Γ. Ταίριασμα των Εξαρτημάτων. Υπάρχουν αντίστοιχα πλάτη κνήμης που έχουν σχεδιαστεί για να αρθρώνονται και να ταιριάζουν με τα μηριαία εξαρτήματα κατάλληλου μεγέθους. Εάν δεν ταιριαστούν σωστά τα εξαρτήματα μπορεί το αποτέλεσμα να είναι η πρόωρη αποτυχία του κνημιαίου οστού και η συμβολή στη χαλάρωση της άρθρωσης.

Δ. Ετικέτα προϊόντος. Δείτε την ετικέτα του προϊόντος σχετικά με το συγκεκριμένο προϊόν που αναφέρεται στο ένθετο αυτής της συσκευασίας.

ΤΡΟΠΟΣ ΔΙΑΘΕΣΗΣ

Τα προϊόντα αυτά παρέχονται αποστειρωμένα σε δοχεία που έχουν εκτεθεί σε ακτινοβολία γάμμα τουλάχιστον 25 kGy από πηγή κοβαλτίου 60. Η συσκευασία όλων των αποστειρωμένων προϊόντων πρέπει να επιθεωρείται πριν από τη χρήση για τυχόν σπάσιμο της αποστειρωμένης σφραγίδας.

ΕΠΑΝΑΠΟΣΤΕΙΡΩΣΗ

Οι συσκευές που περιέχουν ΠΟΛΥΑΙΘΥΛΕΝΙΟ, ΠΟΡΩΔΗ ΕΠΙΚΑΛΥΨΗ, ΣΠΡΕΥ ΠΛΑΣΜΑΤΟΣ, ΥΔΡΟΞΥΑΠΑΤΙΤΗ, ΚΕΡΑΜΙΚΑ ή ΜΕΘΑΚΡΥΛΙΚΟ ΑΛΑΣ ΔΕΝ ΠΡΕΠΕΙ ΝΑ ΕΙΣΑΓΟΝΤΑΙ ΣΕ ΑΥΤΟΚΑΥΣΤΟ ΟΥΤΕ ΝΑ ΕΠΑΝΑΠΟΣΤΕΙΡΩΝΟΝΤΑΙ ΑΠΟ ΤΟ ΧΡΗΣΤΗ.

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Τα εξαρτήματα που δεν έχουν μολυνθεί από υγρά, και ειδικά υγρά του σώματος, [illegible] αυτόκαυστο με εκτάπιση βάρους:

	250Γ F (121Γ C) 20 PSI (1.4 Bars)	270Γ F (132Γ C) 30 PSI (2 Bars)
Τυλιγμένο Ατομικό Εξάρτημα (ατομικό ή πολλαπλό εξάρτημα) ή Θήκη Αποστείρωσης	40 λεπτά	20 λεπτά

Η μέθοδος διπλού τυλίγματος που χρησιμοποιείται είναι η τεχνική **AAMI CSR.** Οι κύκλοι ανεπτύχθηκαν μόνο με αυτό το αντικείμενο στο θάλαμο χρησιμοποιώντας το μεσαίο ράφι. Θα πρέπει ο κάθε κύκλος να επικυρωθεί για διαφορετικούς θαλάμους αποστείρωσης, μεθόδους τυλίγματος και/ή διαφορετικές διαμορφώσεις φορτίων.

ΠΡΟΣΟΧΗ

Το Ομοσπονδιακό Δίκαιο των ΗΠΑ περιορίζει την πώληση αυτής της συσκευής μόνο από γιατρούς ή με συνταγή γιατρού.

ΒΙΒΛΙΟΓΡΑΦΙΑ

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study In Sweden." Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995

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人工膝関節全置換術の進歩のおかげで、移植人工関節装置を使用して、可動性の回復、変形の矯正、および痛みの緩和方法を手術医に提供してきました。これらの装置は、こういった目的に対する成功例では実績があります。しかし、金属やプラスチックといった材質で製造されているため、いかなる人工関節装置においても、健常関節と同様な活動レベルや荷重には耐えられるとは期待されていません。そのため、人工関節システムは、ヒトの自然の膝関節と、強度、信頼性や耐久性といった点では同じではあり得ません。

全人工膝関節インプラントを使用する場合は、手術医は、次のことに注意を払う必要があります。

A. **インプラントを適切に選び、適切に位置決めするのは、極めて重要です。**全関節置換術で成功を収めるには、適切なサイズ、形、目的にかなったインプラントを選ぶことが必要となります。人工膝関節全置換術には、念入りなはめ込みや強固な固定、さらには適切な骨のサポートが要求されます。

B. **人工膝関節全置換術を行う患者を選ぶ際には、処置を最終的に成功させるために次の要因が極めて重要だと思われます。**

1) **患者の体重。**体重オーバーおよび肥満の患者では人工関節へより大きな負荷がかかり、装置の損傷につながる可能性があります。これらの荷重の影響は患者の骨のサイズに比べ人工関節が小さい場合に特に大きくなります。

2) **患者の職業と活動。**患者がかなりの衝撃荷重（歩行、走る、持ち上げる、ひねる）を、仕事あるいはその他の活動で負う場合、その時の力が固定部および装置そのもの、あるいは両方を損傷する原因となります。長年にわたり高いレベルの運動をすると、人工関節で起きる通常の磨耗過程をさらに強めることにもなります。人工関節は健常骨レベルの機能までは回復できません。そこで、非現実的な期待を持たずにその迷いを覚ます必要があります。（「注意」の項目を参照ください）

3) **老化、精神病やアルコール中毒症の状態が存在する場合。**特にこれらの状態が存在する場合は、患者がインプラント使用の際に必要な制限事項や注意事項を無視する原因となる場合があり、その結果、インプラントの破損やその他の合併症を併発する恐れがあります。

4) **異物過敏性。**材質にたいし感受性があると疑われた場合は、材質の選択あるいは移植に先立って適切な試験を行う必要があります。

5) **整形外科での既往症。**処置が成功するかどうかの予後状態は、患者の整形外科の既往症歴に左右されます。以前に複数回にわたり処置および/ないしはインプラントを受けたことのある患者には、処置に関して予想される予後を慎重に話し合う必要があります。

6) **骨質。**全膝関節置換術の予後は、台骨が脆弱になっているかどうかでも影響される場合があります。この状態は、ステロイド、免疫抑制薬や化学療

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説明

ハウメディカ社では、3 つのコンパートメントから構成された幅広い膝再建システムを多種多様のサイズと形態で製造しており、初回手術または修正再手術で行うセメント使用に対しての外科医と患者の様々な要求に合わせるようにしています。必要とされる手術のタイプにより、人工関節の選択が決定されます。大腿や脛骨、および膝蓋骨のコンポーネントも膝再建術用に用意しています。金属製コンポーネント（大腿骨コンポーネント、脛骨や膝蓋骨用のベースプレート、燒結ビード、ウェッジ、スペーサー）は、ASTM（米国材料試験協会）の規格 F 75 に準拠した鋳造コバルトクロムモリブデン合金（Vitallium® 合金）から製造されています。ネジやステム エクステンダーは、ASTM 規格 F 1537 に準拠した精錬コバルトクロムモリブデン合金（Vitallium® 合金）から製造されています。

ポリエチレン製のコンポーネントは、ASTM 規格 F 648 に準拠した超高分子量ポリエチレン（UHMWPE）から製造されています。

大腿骨コンポーネント

大腿骨コンポーネント（スーパースタビライザーを除く）は、コーティングに多孔質か非多孔質かのオプションがあり、形は楕円形、スタビライザー、スーパースタビライザーの中から選べます。大腿骨コンポーネントによっては、任意の形態から別の形態へと変更することも可能です。つまり、モジュールのスタビライザー ボックスを追加することで、楕円形からスタビライザーへと変換できます。

脛骨コンポーネント

脛骨コンポーネントは、サイズや太さで幅広く取り揃えています。脛骨コンポーネントには、全ポリエチレン製一体型ならびにポリエチレン製インサートと金属製ベースプレートからできたモジュール式があります。ベースプレートは、コーティングには多孔質か非多孔質かのオプションがあり、補助の固定オプションもあります。インサートは、多岐にわたる拘束の度合いが用意されており、さらに、楕円形、スタビライザー、スーパースタビライザーの中から選べます。

膝蓋骨コンポーネント

膝蓋骨コンポーネントは、全ポリエチレン製、または多孔質で裏が金属製になっているものから選べます。

付属品

ステム エクステンダーは、大腿骨コンポーネントあるいは脛骨コンポーネントのステムへと結合させて安定性を強化するように設計されています。ウェッジは、脛骨の欠損が存在する場所にセメント使用が余分のスペースを与えるように設計されています。スペーサーは、脛骨の欠損が存在し、大腿骨コンポーネントに機械的に安定させてから所定の位置にセメント固定する場所に余分のスペースを与えるように設計されています。ネジは、補助として脛骨用のインサートをベースプレートに組み立てるか、脛骨用のベースプレートに脛骨を組み立てる場合に使います。

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製品ラベル

製品ラベルには、該当の装置の製造材料となる特定の素材についての情報が記載されています。

適応症

全膝関節置換術での人工関節の使用に対する適応症には、次の症状が含まれます。

1) 変形性関節炎、外傷性関節炎、または無血管性壊死を含めた非炎症性変形性関節疾患
2) 慢性関節炎リウマチ
3) 機能的変形の矯正
4) 他の治療や装具ではうまく行かなかった場合の修正処置
5) 外傷後の関節構造の欠損、特に膝蓋大腿関節の侵食や機能不全が存在したり、過去に膝蓋骨切除術を行った場合
6) 非回復性の膝骨折

禁忌事項

絶対的禁忌事項は、次の通りです。

1) 類性感染症
2) 感染による遠位病巣（インプラント部位に血行性転移をもたらす）
3) X線写真に表れた関節破壊あるいは骨吸収により悪化する急性疾患の進行
4) 骨が未熟な患者
5) 処置の実行がうまくいきそうにないほど、台骨の量、質とも不十分である症例

置換を不成功にするリスクを増大する状態：

1) 自分勝手で非協力的な患者、指示に従えない神経障害のある患者
2) 骨粗しょう症
3) 骨形成に障害をきたすような代謝異常
4) 骨軟化症
5) 関節固定術歴を持つ場合

これまでに、対麻痺、脳性麻痺やパーキンソン病歴のある患者では、インプラントの不成功は、高い確率で発生してきました。

警告

インプラントコンポーネントを不適切に選択、設置、配置、ならびに固定すると、異常なストレスが溜まり、人工関節インプラントの寿命がかなり減少されます。手術医は、手術の前に、手術方法、用具、およびインプラントの特性を熟知しておく必要があります。長期間にわたる定期的な追跡調査を行い、隣接骨の状態とともに人工関節の位置や状態をモニターすることをお勧めします。

骨セメントの使用。骨セメント内に埋められたデバイスの全部品が完全にサポートされていることを確認し、インプラント部位を完全に清浄すること（骨細片、骨セメントの

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に大切です。

人工関節コンポーネント。異なる人工関節システムや異なるメーカー製の大腿骨、脛骨、膝蓋骨のコンポーネントは、絶対に混合しないでください。それは、耐性または材質が適合しない場合があるからです。モジュラー式コンポーネントは、解体しないように固定して組み立てる必要があります。モジュラー式コンポーネントの組み立てと解体を繰り返して行うと、コンポーネントにとって重要な固定作用を損なう恐れがあり、絶対に繰り返して行わないでください。手術による破片は、組み立てを行う前にコンポーネントからきれいにしておく必要があります。破片があると、モジュラー式コンポーネントの固定機能を妨げる可能性があり、その結果として、処置後早期にすでに不成功につながる原因ともなります。

膝蓋骨コンポーネント。膝蓋骨コンポーネントでは支え面と固定面が最小であるので、膝蓋骨または膝蓋骨コンポーネントは亜脱臼とゆるみや脱臼の症状をさらに受けやすくなります。処置の成功を収めるためには、手術中に膝蓋骨トラッキングに特に注意を払うことが必要です。

固定ネジ。 固定ネジを使用する場合には十分にはめこんで安定のある固定を最大限にし、またコンポーネントの適切なはめ込みとの邪魔にならないようにする必要があります。ある種の人工関節に対して不適切な適合や不適切な金属の混合を避けるためには、推奨されたネジに限ってお使いください。これらの骨用ネジは、頚椎、胸椎または腰椎の後方（椎弓根部）にネジを結合ないしは固定させるのには設計されておりません。

金属コンポーネント。 整形外科用インプラント製造に使用される合金の種類によっては、特定な環境条件下で組織培養物あるいは正常臓器に発ガン性を示す金属化合物を含んでいます。これらの合金自身がインプラント移植者に発ガン性を与えるかどうかについては、科学文献においていまだ疑問視されています。この問題を評価するために行われた研究でも、数百万のインプラントに対して調査しましたが、この現象についての証拠は挙がっていません。（参考文献の 1 を参照してください。）

コンポーネントの位置決め。適切な関節を回復させたり、靭帯張力のバランスを取るように注意する必要があります。肢や関節の位置決めを不良に行うと過度の摩耗、人工関節のゆるみや痛み、さらには 1 つ以上の人工関節コンポーネントに対して通常予期されている時期よりも早い修正手術の原因となる場合があります。

ポリエチレンの摩耗。予想されているように、脛骨コンポーネントと膝蓋骨コンポーネントのポリエチレン面の摩耗は、人工膝関節全置換術の後で報告されています。摩耗が高い率で発生するのは、セメント、金属やその他の破片の微粒子によって最初起こり、さらには、関節面の剥離を起こす原因となる場合があるからです。摩耗が高い率で発生すると、人工関節の有効寿命を縮めやすく、摩耗した人工関節コンポーネントの推定置換時期よりも早い修正手術が必要となります。

使用上の注意

患者への情報。患者へは、処置の短期と長期にわたる処置の制限事項ならびに適切な固定と治癒が完了するまで全身の体重負荷からインプラントを保護する必要性について必ず指示する必要があります。関節置換に影響を与えるような過度な活動や外傷は、結果として人工関節インプラントのゆるみ、骨折、および/あるいは摩耗により再建術を不成功に終わらせてきました。コンポーネントのゆるみは、骨への損傷と同様に、再置換を困難にさせる磨耗粒子の生成を増加させる可能性があります。

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患者には、活動の制限（不用意な荷重の負荷、過度の関節運動、保護装置の使用、体重の制限）に関する医師の指示に従うように注意を与えなければなりません。

患者には手術リスクについて必ず警告をし、起こりうる副作用についても知らせておく必要があります。一方患者は、該当の装置により通常の健常関節が複製されることも、されず得ることもないこと、また激しい活動度や外傷によってインプラントが破損したり損傷したりすること、さらに装置には限定された推定寿命があり後日再置換する必要があることなどが起こり得ることを知っておく必要があります。

菌血症は日常生活で起こり得ることです。歯の処置、内視鏡試験また他の鏡類を使用した手術処置もまた菌血症に関連してきました。移植部位での感染を避けるために、これらの処置の前後に抗生物質による予防を行うことを勧めます。

用具。特殊な用具が搬っており、人工関節コンポーネントの正確な移植を確実にするためにそれらを使用してください。

まれですが、術中骨折や用具の破損が起こることもあります。長年にわたり過度な力をかけて使用した用具は、より骨折に導く可能性があります。用具は手術前に、磨耗あるいは損傷試験を行う必要があります。

再使用。インプラントは絶対に再使用しないでください。見かけ上損傷がないように見えても使用済みのインプラントには、寿命を短縮させるような傷があったり、その信頼性を追求できない何かがすでに起きているかもしれません。

取り扱い注意事項。インプラントの取り扱いは重要で、特に多孔質コーティングのインプラントの場合にはそうです。多孔質面と材質を放出している布やその他の繊維と接触させないようにしてください。コーティングが損傷したり汚染されたコンポーネントのインプラントはすべて廃棄する必要があります。精密研磨加工済みのインプラントコンポーネントには、硬い面と接触させないようにする必要があります。

副作用

1) 関節置換のすべてにおいて、無症状性で局所進行性の骨吸収（骨溶解）が、粒子状物質に対する異物反応の結果として人工関節コンポーネントの周囲またはコンポーネントから離れた部位で発生する可能性があります。粒子状物質は、コンポーネント同士の相互作用、またはコンポーネントと骨の間の相互作用により生成し、主に癒着、剥離や疲労から発生する摩耗機能が原因で起こります。第二の原因として、粒子状物質は、骨コンポーネント以外の他の部分の磨耗が原因でも発生する場合があります。骨溶解は、後日に合併症発生につながる場合があり、こういった合併症は人工関節コンポーネントの切除術ならびに置換術を余儀なく必要とします。（詳しくは、**「担当医への重要情報」**セクションを参照してください。）

2) まれですが、患者の中には、関節置換術の後に金属過敏反応が報告されています。組織に異物を移植することで、リンパ球、拒食細胞や線維芽細胞などを含めた細胞性反応を引き起こす場合があります。

3) 末梢神経症は関節全置換術の後に報告されています。無症状な神経損傷が報告されており、手術の外傷の結果起きるもとの思われます。

4) インプラント コンポーネントの脱臼と亜脱臼は、コンポーネントの不適切な配置および/またはコンポーネントの移動が原因で起こる場合があります。筋肉、線維組織や靭帯を含めた軟組織の弛緩症がこれらの状態の一因となります。

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5) インプラントは外傷あるいは固定が失われると、ゆるむが移動する可能性があります。(外傷による関節
ります。
6) 感染症は関節置換を不成功に終わらせる可能性があります。
疾患)。
7) まれですが、インプラントの疲労骨折が、外傷、激しい活動、不適切な位置決
めや極度な耐用期間の結果として発生する場合があります。
8) 軟組織(靭帯)の平衡異常があると、インプラントの過度な摩耗および/または
破損の原因となる場合があります。
9) 骨の部位および/またはインプラントのはめ込みを準備中に、大腿骨、脛骨や
膝蓋骨の術時における骨折が起こる場合があります。
10) インプラントの材質とのアレルギー反応は、たまに起こることがあります。

術中および術後早期に起こりうる合併症には、次の症状を含みますが、これらに限定されるわけではありません。

1) 深部静脈血栓症
2) 血管の損傷
3) 一時的あるいは永久的神経損傷により影響を受けた四肢の痛みあるいはしびれ
4) 骨セメントに関連して起こる手術時における急激な血圧低下
5) 足関節内反もしくは外反の変形ならびにその結果として生じる四肢と人工関節
のアラインメントの不具合
6) 肺塞栓症や心筋梗塞症を含めた循環器疾患
7) 血腫
8) 創傷治癒の遅れ
9) 関節置換のすべてにおいて潜在的に重度の合併症となり得る、深創傷の感染症
(早期または晩期)。これにより、人工関節の切除術とこれに伴う関節固定術が
必要となる場合があります。適切な抗生物質を使って予防することおよび無菌
処置を徹底して守ることは、必須です。
10) 大腿骨、脛骨、膝蓋骨やコンポーネントの骨折

術後晩期に起こりうる合併症には、次の症状を含みますが、これらに限定されるわけではありません。

1) 晩期(または早期)に起こるゆるみ、コンポーネントの位置の変化、摩耗なら
びに1つ以上の人工関節コンポーネントの曲がりやひび割れ。(臨床体験によ
ると、この添付文書にある「Warnings」と「使用上の注意」のセクションに記
載されている事項に特に注意を払うことで、これらの状況が発生する危険性を
最小限に抑えるのに役立つ場合があります。)
2) 過度な引張力や偶発的に術中に発生する脆弱性による膝蓋骨の骨折
3) 脚の長さが違うことが原因となって、該当する下肢や反対側の下肢においての
問題の悪化
4) 晩期における靭帯の不安定性

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5) 関節の可動性にとって妨げとなるかならないかに関係なく起こる、関節周囲における石灰化または骨化
6) インプラントの不適切な選択ないしは位置決め、衝撃、または関節周囲における石灰化およびジストロフィーが原因で起こる不適当な可動域
7) 骨折、脱臼、亜脱臼、屈曲拘縮、可動域制限、または下肢の延長ないしは短縮。

これらの症状すべては、人工膝関節全置換術と関連して報告されています。

担当医への重要情報

A. **骨吸収および骨溶解。** 骨吸収は骨の再形成パターンの変化による全関節形成の自然な結果として起こり得ます。骨の再形成は移植によるストレス分布の変化により媒介されます。人工関節周囲での過度な骨吸収は、インプラントの緩みや不成功につながります。ストレルスシールドや感染以外の理由で起こる局所進行性骨吸収は、骨とコンポーネント間だけでなく人工関節コンポーネントの周囲でも起こり、これは骨溶解と呼ばれています。骨溶解は局在化した微粒子破片（セメント、金属、UHMWPE、セラミックなどの）と異物反応の結果です。微粒子はコンポーネントと骨の間およびコンポーネント間の相互作用の結果で、おもに摩耗、剥離、疲労などの摩耗メカニズムにより生じます。病因学による仮説では、人工関節をコンポーネントに繋ぐことにより生じた微粒子破片は、滑液穴や骨インプラント対面内に移動し、そこで破片は巨食細胞を新たに取り入れ食細胞の作用を刺激するといわれています。その取り入れる割合は、微粒子生成速度を始め、サイズ、分布、および量によって決まります。食細胞の作用はin vitro でサイトカインおよび細胞メディエーター（IL-1、IL-2、IL-6、PGE2、TNF3）の放出を誘発するときに明らかにされてきました。これらのメディエーターは破骨細胞による骨吸収を調整することが示されてきました。この現象の理由に対する科学的根拠を理解し、その発生を現象させる可能な方法を探すために、臨床および基礎研究が続けられています。

骨溶解がよく無症状であるので、定期的なX線写真をとることが、将来起こり得る重篤な合併症を発見し、最小に留めるために必ず役立ちます。しかし、X線写真は骨溶解の範囲を完全には示さないでしょう。進行性の病変中心部が存在する場合は人工関節コンポーネントに置換する必要があります。

B. **ポリエチレンの厚さ。** 理論的な分析によると、脛骨コンポーネントにおける接触ストレスは、ポリエチレンコンポーネントの厚さによって変化することを示しています。一般的に、厚みのあるインサートは、厚みの少ないインサートに比べて接触ストレスが少ないと考えられています。これらのストレスは、インプラントコンポーネントの摩耗に影響を与える場合があります。ただし、こういった理論上でのストレスの差異についての臨床における意味は、最終的には確立されていません。担当医には、脛骨の骨切除術をさらに行うことと厚みのあるインサートを使うことのどちらを取るかの兼ね合いを検討することが必要です。体重、年齢、活動レベルなどの患者に関連した要因は、意思決定の一環として必要です。

C. **コンポーネントの整合。** 適切なサイズの大腿骨コンポーネントを関節でつなぎ、適合するように対応する脛骨の幅がとってあります。コンポーネントを正確に整合させないと、脛骨コンポーネントが寿命よりも早期に障害が出るという結果になる可能性があり、 関節の弛緩の一因となります。

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D. 製品ラベル：この添付文書に記載されている特定の製品に関する情報について
は、製品ラベルを参照してください。

販売時の状態

これらの製品はコバルト60を放射源とし、25kGyの最小のγ線に暴露させた滅菌状態で、容器に入って配送されます。すべての滅菌製品の包装は使用する前に、滅菌防壁が破れていないかを試験してください。

再滅菌

ポリエチレン、多孔質コーティング、プラズマ噴霧器、ハイドロキシアパタイト、セラミック、あるいはメタアクリル酸メチルを含む装置を、ユーザーがオートクレーブ処理あるいは再滅菌することは出来ません。

液体特に体液に触れていないコンポーネントは、次の条件で重力置換蒸気オートクレーブで再滅菌可能です。

	121℃ 4 バール	132℃ 2 バール
ラップされた個々のコンポーネント (単、複数のコンポーネント あるいは滅菌ケース	40 分	20 分)

AAMI CSR法により 2 重にラップされます。該当滅菌物のみをチャンバー内にいれ、真中の棚を使用してこれらのサイクルを行います。いづれのサイクルも異なる滅菌チャンバー、ラップ方法、および/または様々な作業構成に対しても、有効でなくてはなりません。

注意

米国連邦法により、本装置の販売注文は医師のみに限られています。

参考文献

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study In Sweden," Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

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Howmedica
OSTEONICS

Duracon® CS Lipped Tibial Insert

Howmedica Osteonics Corp.
300 Commerce Court
Mahwah, New Jersey
A Subsidiary of Stryker Corporation

Authorized Representative in Europe:
RA/QA Manager STRYKER France
BP 50040-95946 Roissy CDG Cedex
France Tel. (33) 1.48.17.50.00

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Duracon' CS Lipped Tibial Insert

The Duracon' CS (Condylar Stabilizing) Lipped Tibial Inserts are intended to be used with Duracon' Universal and Cruciform tibial baseplates, Duracon' Cruciate Retaining femoral components and Duracon' patellar components as part of a total knee system in primary cemented total knee arthroplasty. These inserts are intended to be used in cases where there is destruction of the joint surfaces with or without bone deformity, where the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The collateral ligaments should be intact if this insert is utilized. This tibial insert may also be used in situations where the posterior cruciate ligament is present - its geometry will accommodate that ligament.

Materials

ASTM F-648 ultra-high molecular weight polyethylene (UHMWPE)	Tibial insert

Indications

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee

Contraindications

Absolute contraindications include:

- Overt infection,
- Distant foci of infections (which may cause hematogenous spread to the implant site), 688

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- Rapid disease progression as manifested by joint destruction or bone absorption apparent on radiographs.

- Skeletally immature patients

- Cases where there is poor bone stock which would make the procedure unjustifiable.

Conditions presenting an increased risk of failure include:

- Uncooperative patient or patient with neurological disorders who is incapable of following instructions,

- Osteoporosis,

- Metabolic disorders which may impair bone formation,

- Osteomalacia, and

- Previous arthrodesis

Sterilization

- This total knee component has been sterilized by gamma radiation.

- If the package is opened, but the product is not used, the component **must not be resterilized** and must be discarded or returned to the supplier.

CAUTION: This device is intended for single use only. The sale or use of this device is restricted to a licensed physician.

This product is marketed in the United States for use with bone cement.

Please refer to Total Knee Package Insert for general warnings and precautions.

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Les inserts tibiaux contraints Duracon® CS (à stabilisation condylienne) doivent être utilisés avec les embases tibiales cruciformes et Universal Duracon® , avec les composants fémoraux Duracon® conservant le ligament croisé et avec les composants rotuliens Duracon® en tant que partie intégrante d'une prothèse totale du genou lors d'une arthroplastie totale du genou primaire par prothèse cimentée. Ces inserts doivent être utilisés en cas de destruction des surfaces articulaires avec ou sans déformation osseuse, lorsque les ligaments croisés sont déficients, absents ou ne peuvent être conservés pendant l'intervention chirurgicale, en particulier lorsque la stabilité antéro-postérieure est affectée en raison d'une rotule absente. Cet insert exige que les ligaments latéraux soient intacts. Il peut également être utilisé lorsque le ligament croisé postérieur est présent car sa géométrie est adaptée à ce ligament.

Matériaux

Polyéthylène de masse moléculaire très élevée ASTM F-648 (UHMWPE)	Insert tibial

Indications

- Arthrose non-inflammatoire y compris la gonarthrose, l'arthrite due à un traumatisme ou la nécrose avasculaire.
- Polyarthrite rhumatoïde,
- Correction de la déformation fonctionnelle,
- Perte de l'anatomie articulaire à la suite d'un traumatisme, en particulier lors d'une érosion fémoro-rotulienne, un dysfonctionnement ou une patellectomie préalable,
- Fracture irréparable du genou

Contre-indications

Parmi les contre-indications absolues, on note :

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- Une infection manifeste,
- Des foyers distants d'infections (qui peuvent causer une propagation hématogène au site de l'implant),

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- Maladie rapidement évolutive se manifestant par la destruction de l'articulation ou la résorption osseuse visibles sur la radiographie.

- Patients atteints d'une immaturité du squelette

- Cas où le capital osseux est médiocre et qui ne justifierait pas la procédure,

Les conditions augmentant le risque d'échec sont les suivantes :

- Patient peu coopérant ou présentant des troubles neurologiques ou qui n'est pas en mesure de suivre les instructions,

- Ostéoporose,

- Troubles du métabolisme qui peuvent entraver l'ostéogenèse,

- Ostéomalacie et

- Arthrodèse précédente

Stérilisation

- Ce composant de la prothèse totale du genou a été stérilisé au rayonnement gamma.

- Si le conditionnement est ouvert mais le produit n'est pas utilisé, le composant **ne doit pas être restérilisé** et doit être éliminé ou rendu au fournisseur.

MISE EN GARDE : ce dispositif est à usage unique. Seul un médecin habilité a le droit de le vendre ou de l'utiliser.

Ce produit est commercialisé aux Etats-Unis pour être utilisé avec du ciment osseux.

Veuillez vous référer à la notice contenue à l'intérieur du conditionnement de la prothèse totale du genou pour les mises en garde générales et les précautions à suivre.

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Die Duracon® CS (Kondylärstabilisierende) Tibia-Einsätze mit Lippe sind gedacht zur Verwendung mit Duracon® universalen und kruziformen Tibiagrundplatten, Duracon® kreuzbandhaltenden Femurkomponenten und Duracon® Patellarkomponenten als Teil einen totalen Kniesystems in primär zementierten Knieartroplastiken. Diese Einsätze werden verwendet bei: Zerstörung von Gelenksoberflächen, mit und ohne Knochendeformation, bei ungenügenden Kreuzbändern, die entweder ganz fehlen oder bei der Operation nicht erhalten werden können, besonders wenn die anteriore-posterieore Stabilität durch das Fehlen der Patella beeinträchtigt ist. Die Außenbänder sollten bei der Verwendung dieses Einsatzes intakt sein. Dieser Tibia-Einsatz kann auch verwendet werden, wenn das posteriore Kreuzband vorhanden ist- seine Geometrie bietet Raum für das Band.

Materialien

ASTM F-648 mit ultrahohem Molekulargewicht Polyethylen (UHMWPE) — Tibia-Einsatz

Indikationen

- Nichtentzündliche degenerative Gelenkerkrankung einschließlich Osteoarthritis, traumatischer Arthritis oder avaskulärer Nekrose,
- rheumatoide Arthritis,
- Korrektur funktioneller Missbildungen,
- posttraumatischer Gelenkverlust, besonders bei Patello-femoraler Erosion, Dysfunktion oder vorheriger Patellektomie.
- Nicht reparabler Bruch des Knies

Kontraindikationen

Zu den absoluten Kontraindikationen gehören:

- Offene Infektion.
- Entfernt liegende Infektionsherde (die sich eventuell hämatogen zur Implantationsstelle ausbreiten können).

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- Rasanter Krankheitsverlauf, der sich im Röntgenbild als Gelenkszerstörung oder Knochenzerstörung [illegible]
- Patienten mit unreifem Skelett
- Fälle, in denen schlechte Knochenmasse einen solchen Eingriff nicht gerechtfertigt erscheinen lassen.

Zu den Umständen, die das Risiko eines Fehlschlags erhöhen, gehören:

- Ein unkooperativer Patient oder ein Patient mit neurologischen Erkrankungen, der unfähig ist, Anweisungen zu befolgen.
- Osteoporose.
- Stoffwechselstörungen, die eventuell die Knochenbildung beeinträchtigen können.
- Osteomalazie und
- Vorherigen Arthrodese

Sterilisierung

- Diese Totalknieko[illegible]nente wird mit Gammastrahlung sterilisiert.
- Falls die Verpackung offen, aber das Implantat nicht verwendet wurde, darf das Implantat **nicht wieder sterilisiert werden**, sondern es muss entweder entsorgt oder an den Lieferanten zurückgesandt werden

VORSICHT: Dieses Implantat ist nur für den einmaligen Gebrauch bestimmt. Dieses Produkt darf nur von einem Arzt oder unter rechtlich gültiger Anweisung eines Arztes verkauft oder verwendet werden.

In den USA wird das Produkt zur Verwendung mit Knochenzement vermarktet.

Allgemeine Warnhinweise und Vorsichtsmaßnahmen finden Sie in der Packungsbeilage des Totalknies.

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Los Insertos Tibiales Labiados Duracon® CS (Condylar Stabilizing, estabilización condilar) han sido diseñados para ser utilizados con bandejas tibiales Duracon® Universal y Cruciform, componentes femorales Duracon® Cruciate Retaining y componentes patelares Duracon® como parte de un sistema total de rodilla para artroplastia primaria cementada de rodilla completa. Estos insertos están pensados para casos en los que hay destrucción de las superficies de la articulación, con o sin deformidad ósea, donde los ligamentos cruzados son inadecuados, no existen, o no pueden ser conservados durante la intervención quirúrgica, especialmente cuando la estabilidad antero-posterior está dañada a causa de la ausencia de patela. Cuando se utilice este inserto, los ligamentos colaterales deben estar intactos. Este inserto tibial puede también utilizarse en situaciones en las que existe el ligamento cruzado posterior -su geometría acomoda ese ligamento.

Materiales

ASTM F-648 polietileno de peso molecular ultra alto (UHMWPE) Inserto tibial

Indicaciones

- Enfermedad degenerativa no inflamatoria de la articulación, incluyendo osteoartritis, artritis traumática o necrosis avascular,
- Artritis reumatoide,
- Corrección de deformidad funcional,
- Pérdida postraumática de la anatomía de la articulación, especialmente cuando existe erosión patelo-femoral, disfunción o patelectomía anterior; y
- Fractura irreparable de la rodilla

Contraindicaciones

Las contraindicaciones absolutas incluyen:

- Infección clara,
- Focos distantes de infección (la sangre puede transportar los microorganismos patógenos hasta el lugar del implante),

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- Rápida progresión de la enfermedad, manifestada a través de la apreciación de destrucción de la [illegible]

- Pacientes con esqueletos inmaduros.

- Casos en los que queda poca cantidad de hueso, que hace que la intervención no esté justificada.

Estados que incrementan el riesgo de falla:

- Pacientes no cooperativos, o pacientes con desórdenes neurológicos que los incapacitan para seguir instrucciones,

- Osteoporosis.

- Desórdenes metabólicos que pueden impedir la formación de hueso.

- Osteomalacia, y

- Artrodesis previa

Esterilización

- Este componente de rodilla completa ha sido esterilizado por radiaciones gamma.

- Si se abre el envase pero no se utiliza el producto, el componente **no debe reesterilizarse**, y debe desecharse o devolverse al proveedor.

ATENCIÓN: Producto para un solo uso. La venta o utilización de este producto está limitada exclusivamente a un médico.

Comercializado en los EE.UU. para su uso con cemento óseo.

Consulte las advertencias generales y las precauciones en las instrucciones de empleo del embalaje de Rodilla Completa.

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Inserto tibiale con bordi in Duracon® CS

Gli inserti tibiali con bordi in Duracon® CS (Duracon Stabilizing = stabilizzazione condiloidea) sono concepiti per l'impiego con piastre di base tibiali universali e cruciformi in Duracon®, con componenti femorali Cruciate Retaining in Duracon® e con componenti rotulei in Duracon®, in quanto parti di un sistema completo per ginocchio (Total Knee) in artroplastica primaria per protesi totale del ginocchio con cemento. Gli inserti sono concepiti per l'impiego nei casi in cui si è verificata una distruzione delle superfici articolari con o senza deformità ossea, nei casi in cui i legamenti crociati sono insufficienti, assenti o non possono essere conservati durante la procedura operatoria, specialmente quando la stabilità antero-posteriore è compromessa a causa dell'assenza della rotula. I legamenti collaterali devono essere intatti, se si utilizza questo inserto. Questo inserto tibiale può essere usato anche in situazioni in cui è presente il legamento crociato posteriore - la sua geometria si adeguerà a tale legamento.

Materiali:

ASTM F-648 polietilene a peso molecolare ultra alto (UHMWPE) — inserto tibiale

Indicazioni

- Artropatia degenerativa non infiammatoria, inclusa osteoartrite, artrite traumatica o necrosi avascolare,
- artrite reumatoide,
- correzione della deformità funzionale,
- perdita post-traumatica dell'anatomia articolare, in particolare in presenza di un'erosione patello-femorale, disfunzione o patellectomia antecedente e
- frattura irreparabile del ginocchio

Controindicazioni

Le controindicazioni assolute includono:

- infezione in atto,
- focolai di infezione distanti (che possono causare diffusione ematogena al sito d'impianto),

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- rapida progressione della patologia come manifestato dalla distrazione articolare o dal riassorbimento osseo visibile dai raggi X;

- pazienti con struttura scheletrica non completamente sviluppata casi di scarso bone stock, che non giustificherebbe l'intervento,

Le condizioni che presentano un maggior rischio di insuccesso includono:

- paziente non cooperativo o paziente con disturbi neurologici, pertanto incapace di attenersi alle indicazioni,

- osteoporosi,

- disturbi del metabolismo che possono danneggiare l'osteogenesi,

- osteomalacia e

- artrodesi antecedente

Sterilizzazione

- Questo componente Total Knee è stato sterilizzato a raggi gamma.

- In caso di confezione aperta, ma con prodotto non utilizzato, il componente **non deve essere risterilizzato** e deve essere scartato o restituito al fornitore.

ATTENZIONE: questo dispositivo è monouso. La vendita o l'impiego di questo dispositivo sono limitati ad un medico autorizzato.

Questo prodotto è commercializzato negli Stati Uniti per l'impiego con cemento osseo.

Per le avvertenze e le precauzioni generali, fare riferimento al foglietto illustrativo della confezione Total Knee.

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Insert Tibial com Rebordo Duracon® CS

O Insert Tibial com Rebordo Duracon® CS (Estabilização condilíana) destina-se a ser utilizado com as placas de base Universal e Cruciforme Duracon®, com os componentes femorais de Retenção Cruzada Duracon® e com os componentes rotulianos Duracon® como parte de uma prótese total do joelho na artroplastia total cimentada do joelho primária. Estes inserts estão indicados para serem utilizados em casos nos quais existe destruição das superfícies ósseas com ou sem deformidade óssea ou em casos nos quais os ligamentos cruzados são inadequados, estão ausentes ou não podem ser preservados durante o procedimento operatório, especialmente nos casos em que a estabilidade antero-posterior é deficiente devido à ausência da rótula. Os ligamentos laterais têm de estar intactos se este insert for utilizado. Este insert tibial também pode ser utilizado em situações nas quais o ligamento cruzado posterior está presente – a sua geometria adapta-se a este ligamento.

Materiais

Polietileno de peso molecular ultra-elevado (UHMWPE) ASTM F-648 — Insert tibial

Indicações

- Doença articular degenerativa não inflamatória incluindo osteoartrite, artrite traumática ou necrose avascular,
- Artrite reumatóide,
- Correcção de uma deformidade funcional,
- Perda pós-traumática da anatomia da articulação, especialmente nos casos em que existe erosão femoro-rotuliana, disfunção ou patelectomia prévia e
- Fractura irreparável do joelho

Contra-indicações

As contra-indicações absolutas incluem:

- Infecção manifesta.
- Focos distantes de infecções (que podem causar a disseminação hematogénica para o local de implante).

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- Progressão rápida da doença manifestada por destruição articular ou absorção óssea, evidente nos exames radiográficos
- Doentes com imaturidade esquelética
- Casos em que existe uma massa óssea deficiente quer torna o procedimento injustificável.

Condições que acarretam um risco acrescido de insucesso incluem:

- Doente não cooperante ou doente com patologias neurológicas e incapaz de seguir as instruções.
- Osteoporose,
- Doenças metabólicas que podem alterar a formação óssea,
- Osteomalácia e
- Artrodese prévia

Esterilização

- Este componente da prótese total do joelho foi esterilizado por radiação gama.
- Se a embalagem estiver aberta e o produto não tiver sido utilizado, o componente **não deve ser reesterilizado** e deve ser eliminado ou devolvido ao fornecedor.

CUIDADO: Este dispositivo destina-se apenas a utilização única. A venda ou utilização deste dispositivo está limitada a um médico qualificado.

Este produto está comercializado nos Estados Unidos *para uso com cimento* ósseo.

Consulte o Folheto Informativo da *Prótese Total do Joelho no* que respeita às advertências e precauções gerais.

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Duracons' tibialinlägg med CS-läpp (kondylär stabilisering) är avsedda för användning med Duracons' tibialbottenplattor Universal och Cruciform, Duracons' fasthållande femoralkomponenter Cruciate och Duracons' patellärkomponenter, som en del av ett helknäsystem, för användning vid primär cementerad helknäartroplastik. Inläggen är avsedda för användning i fall då det föreligger destruktion av ledytorna, med eller utan bendeformitet, och då korsbanden är otillräckliga, saknas eller inte kan bevaras vid det operativa förfarandet, och särskilt då stabiliteten anterior/posterior är nedsatt till följ av avsaknad av knäskålen. Kollateraligamenten ska vara intakta när detta inlägg används. Detta tibialinlägg kan även användas i situationer där det bakre korsbandet är på plats – dess geometri ger plats för detta ligament.

Material

ASTM F-648 med ultrahög molekylvikt polyetylen (UHMWPE)	Tibialinlägg

Indikationer

- Icke-inflammatorisk, degenerativ ledåkomma inklusive artros, traumatisk artrit och avaskulär nekros,
- reumatoid artrit,
- korrigering av funktionell deformitet,
- posttraumatisk förlust av ledanatomi, i synnerhet då patellofemoral erosion föreligger, dysfunktion eller tidigare patellektomy samt
- irreparabel knäfraktur.

Kontraindikationer

Detta är några absoluta kontraindikationer:

- Uppenbar infektion,
- avlägsen infektionsfokus (som kan ge upphov till hematogen spridning till implantatplatsen),

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- snabb sjukdomsutveckling *som kommer* till uttryck i form av leddestruktion eller benabsorption i röntgenbilder,

- skelettmässigt omogna patienter samt

- fall med dåligt bennaterial, som gör förfarandet olösvarligt.

Detta är några förhållanden som medför en ökad feltisk:

- Samarbetsovillig patient, eller patient *med neurologiska* rubbningar, som är oförmögen att följa *instruktioner*,

- osteoporos,

- metaboliska rubbningar som kan sätta ner benbildningen,

- *osteomalaci* och

- idigare steloperation

Sterilisering

- Denna helknäkomponent har steriliserats med gammastrålning.

- Om paketet öppnas, men produkten inte öppnas **får komponenten inte steriliseras om**, utan den måste då kasseras och återsändas till leverantören.

FÖRSIKTIGHET: Anordningen är endast avsedd för engångsbruk. Den får endast säljas *till* och användas av behörig läkare.

Produkten marknadsförs i USA för användning med bencement.

Se förpackningsbilagan *för helk*näkomponenten för allmänna varningar och försiktighetsanvisnin gar.

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Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 3

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Duracon® CS (condylar stabilizing) -reunalliset sääriluun sisäkkeet on tarkoitettu käytettäviksi osana totaalia polvijärjestelmää, primaarissa sementtilisessä polven artroplastiassa, seuraavien komponenttien kanssa: Duracon® -universaalit sääriluun aluslevyt ja ristikkoaluslevyt, Duracon®-ristikkositeen säästävät reisiluukomponentit sekä Duracon®-polvilumpiokomponentit. Sisäkkeitä käytetään, jos nivelpinta on tuhoutunut, myös jos luu on epämuodostunutta. Sisäkkeitä käytetään myös, jos ristisiteiden toiminta on puutteellinen, niitä ei ole tai niitä ei voida säästää leikkauksen aikana ja varsinkin jos antero-posteriorinen stabiilius on heikentynyt puuttuvan polvilumpion johdosta. Tätä sisäkettä käytettäessä on sivusiteiden oltava vahingoittumattomia. Sisäkettä voidaan käyttää myös, jos takaristiside on paikoillaan – sisäkkeen geometria ottaa takaristisiteen huomioon.

Materiaalit

ASTM F-648 ultrasuurimolekyylinen polyeteeni (UHMWPE)	Sääriluun sisäke

Käyttöaiheet

- Ei-tulehduksellinen degeneratiivinen luusairaus, esim. nivelrikko, traumaattinen niveltulehdus tai avaskulaarinen nekroosi,
- Nivelreuma,
- Toiminnallisen deformaation korjaus,
- Trauman aiheuttama nivelosan menetys, varsinkin jos kyseessä on polvilumpion ja reisiluun eroosio, toiminnallinen häiriö tai polvilumpion poistoleikkauksen jälkitila; sekä
- Polvimurtuma, jota ei voida korjata

Vasta-aiheet

Ehdottomia vasta-aiheita ovat mm:

- Ilmeinen infektio,
- Etäinen infektiopesäke (joka saattaa levitä veriteitse implantin asetuskohtaan),

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- Nopea sairauden eteneminen, joka on havaittavissa niveltuhona tai luun absorptiona
- [illegible]
- Potilaat, joiden luusto on kasvuvaiheessa.
- Huono luuaines, jonka perusteella kirurgia ei olisi perusteltua.

Seuraaviin tiloihin liittyy suurentunut epäonnistumisen riski:

- Yhteistyöhaluton potilas tai neurologisista häiriöistä kärsivä yhteistyökyvytön potilas,
- Osteoporoosi,
- Luun muodostusta häiritsevä aineenvaihdunnallinen häiriö,
- Osteomalasia ja
- Aikaisemmin suoritettu artrodeesi

Sterilointi

- Tämä totaalin polven komponentti on steriloitu gammasäteilyllä.
- Jos pakkaus on avattu, mutta tuotetta ei ole käytetty, komponenttia **ei saa steriloida uudelleen**, vaan se on joko hävitettävä tai palautettava myyjälle.

HUOMIO: Tämä laite on tarkoitettu vain kertakäyttöä varten. Vain laillisteiot lääkärit saavat ostaa tai käyttää tätä laitetta.

Yhdysvalloissa tuotetta markkinoidaan luusementin kanssa käytettäväksi.

Totaalin polvijärjestelmän pakkaustiedotteesta saat lisätietoja yleisistä varoituksista ja varotoimista.

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Duracon® CS (kondyl stabiliserende) tibiale indlæg med udbuet kant er beregnet til brug sammen med Duracon® universelle og korsdannede tibiale bundplader. Duracon korsdannede femorale låsekomponenter og Duracon® knæskalskomponenter som del af et totalt knæsystem i primært cementeret totalt knæartroplastik. Disse indlæg er beregnet til brug i tilfælde, hvor ledoverfladerne er ødelagte med eller uden knogledefornitet, hvor korsbåndene er utilstrækkelige, ikke forefindes eller ikke kan bevares under operationsproceduren, især når for- og bagstabiliteten er svag på grund af den manglende knæskal. De kollaterale bånd skal være intakte, hvis dette tibiale indlæg anvendes. Dette tibiale indlæg kan også anvendes i situationer, hvor det bageste korsbånd forefindes – dets geometri vil give plads for korsbåndet.

Materialer

ASTM F-648 ultrahøj molekulær vægt polyetylen (UHMWPE)	Tibialt indlæg

Indikationer

- Ikke betændt, degenerativ ledsygdom herunder slidgigt, traumatisk ledbetændelse eller karfri nekrose;
- Rheumatoid arthritis;
- Korrektion af funktionel derformitet;
- Posttraumatisk tab af ledanatomi, især når der foreligger knæskals-/femoral erosion, funktionsfejl eller tidligere patellektomi; og
- Irreparabelt knæbrud

Kontraindikationer

Absolutte kontraindikationer inkluderer:

- Åbenlys infektion;
- Fjerne infektionssteder (som kan forårsage hæmatogen spredning til implantatstedet);

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- Hurtig sygdomsudvikling, der manifesteres ved ledødelæggelse eller knogleabsorbtion, som er [illegible]
- Skeletmæssigt umodne *patienter*
- Tilfælde med dårlig knoglestamme, *hvor proceduren* derved ikke kan rettærdiggøres.

Tilstande, der udgør en øget risiko for svigt, *inkluderer:*

- Uvillig patient eller patient med *neurologiske sygdomme*, der er ude af stand til at følge instruktioner.
- Osteoporose,
- Stofskiftesygdomme, der kan svække knogledannelse,
- Knogleblødhed og
- Tidligere arthrodese

Sterilisering

- Denne totale knækomponent er blevet steriliseret ved gammastråling.
- Hvis pakken er åbnet, men produktet ikke har været brugt, **må** komponenten **ikke gensteriliseres** og skal kasseres eller returneres til leverandøren.

ADVARSEL: Komponenten er kun til engangsbrug. Denne komponent må kun sælges eller anvendes af en læge.

Dette produkt markedsføres i De forenede Stater til brug sammen med knoglecement.

Der henvises til brugsanvisningen i det totale knæs pakning angående generelle advarsler og forholdsregler.

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De Duracon® CS (contoïns stabilisatie) gelipte tibia-inzetstukken zijn bestemd voor gebruik met Duracon® universele en kruisvormige tibia-basisplaten, Duracon® cruciate retentie femur-componenten en Duracon® patella-componenten, als onderdeel van een totaalsysteem voor de primaire gecementeerde totale knie-artroplastiek. Deze inzetstukken dienen te worden gebruikt in geval van beschadiging van de gewrichtsoppervlakken met of zonder buigdeformiteiten, waarbij de kruisbanden inadequaat zijn, ontbreken of niet kunnen worden gevrijwaard tijdens de operatieve ingreep. Ze zijn vooral aangewezen wanneer de anterior-posteriore stabiliteit in het gedrang komt door het ontbreken van de patella. De collaterale ligamenten moeten intact zijn voor het gebruik van deze inzetstukken. Dit tibiale inzetstuk kan ook worden gebruikt in situaties waarin de achterste kruisband aanwezig is - zijn geometrie laat ruimte voor dit ligament.

Materialen

ASTM F-648 polyethyleen met een ultrahoog moleculair gewicht (UHMWPE) — Tibia-inzetstuk

Indicaties

- Niet-inflammatoire degeneratieve gewrichtsaandoeningen, onder meer osteoartritis, traumatische artritis of avasculaire necrose,
- Reumatoïde artritis,
- Correctie van functionele deformiteit,
- Posttraumatisch verlies van gewrichtsanatomie, in het bijzonder in geval van patello-femorale erosie, distinctie of eerdere patellectomie en
- Onherstelbare kniefractuur

Contra-indicaties

Tot de onvoorwaardelijke contra-indicaties behoren:

- Duidelijke infectie,
- Infectiehaarden op een afgelegen plaats (die zich via de bloedbaan kunnen verspreiden naar de implantatieplaats),

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- Snelle progressie van de aandoening, te merken aan gewrichtsafbraak of botabsorptie, die te zien [illegible]
- Patiënten met een onvolgroeid beendergestel.
- Patiënten met onvoldoende botmateriaal, bij wie de *ingreep niet* verantwoord zou zijn.

De volgende omstandigheden houden een verhoogd risico op mislukking in:

- Patiënt die *niet goed meewerkt* of patiënt met een neurologische aandoening, die *niet in staat is* om *instructies* op te volgen,
- Osteoporose,
- Metabole aandoeningen die *de botvorming* bemoeilijken.
- Osteomalacie en
- Eerdere artrodese

Sterilisatie

- Deze totale knie-component werd gesteriliseerd met gamma*stralen*.
- Een niet gebruikt product uit een reeds *geopende verpakking* **mag niet opnieuw worden gesteriliseerd**, maar moet *worden* weggeworpen of teruggestuurd naar de fabrikant.

LET OP: *Dit product* is uitsluitend bestemd voor eenmalig gebruik. *Dit product mag uitsluitend* worden verkocht aan en gebruikt door een gekwalificeerd *arts*.

Dit product wordt in de Verenigde Staten *verkocht voor* toepassing met botcement.

Lees de algemene waarschuwingen en voorzorgsmaatregelen in de bijsluiter van het Totale Knie-pakket.

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Κνημιαίο ένθετο Duracon® CS με χείλος

Τα κνημιαία ένθετα Duracon® CS (σταθεροποίησης κονδύλου) με χείλος προορίζονται για χρήση σε συνδυασμό με κνημιαίες βασικές πλάκες Duracon®, σταυροειδείς και γενικής χρήσης, με μηριαία εξαρτήματα συγκράτησης χιαστού Duracon® και με εξαρτήματα επιγονατίδας Duracon® ως τμήματα ενός ολικού συστήματος γονάτου σε επεμβάσεις πρωτογενούς ολικής αρθροπλαστικής γονάτου με τσιμέντο. Τα ένθετα αυτά προορίζονται για χρήση σε περιπτώσεις όπου υπάρχει καταστροφή των αρθρικών επιφανειών με ή χωρίς οστική δυσμορφία και όπου οι χιαστοί σύνδεσμοι είναι ανεπαρκείς, είναι απόντες ή δεν μπορούν να διατηρηθούν κατά τη διάρκεια της χειρουργικής επέμβασης, ιδιαίτερα όταν η προσθιοπίσθια σταθερότητα είναι μειωμένη λόγω απουσίας της επιγονατίδας. Για τη χρήση του ενθέτου αυτού, οι πλάγιοι σύνδεσμοι θα πρέπει να είναι ακέραιοι. Αυτό το κνημιαίο ένθετο μπορεί επίσης να χρησιμοποιηθεί σε καταστάσεις όπου ο οπίσθιος χιαστός σύνδεσμος είναι παρών – η γεωμετρία του ενθέτου παρέχει χώρο για αυτόν τον σύνδεσμο.

Υλικά

Πολυαιθυλένιο υπερυψηλού μοριακού βάρους (UHMWPE) ASTM F-648	Κνημιαίο ένθετο

Ενδείξεις

- Μη φλεγμονώδης εκφυλιστική αρθροπάθεια, συμπεριλαμβανομένης της οστεοαρθρίτιδας, της τραυματικής αρθριτίδας και της ανάγκης νέκρωσης,
- Ρευματοειδής αρθρίτιδα,
- Αποκατάσταση λειτουργικής παραμόρφωσης,
- Μετατραυματική απώλεια της διαμόρφωσης της άρθρωσης, ιδιαίτερα όταν υπάρχει επιγονατιδοσηριαία διάβρωση, δυσλειτουργία ή προηγούμενη επιγονατιδεκτομή και
- Μη επανορθώσιμο κάταγμα γονάτου.

Αντενδείξεις

<u>Στις απόλυτες αντενδείξεις συγκαταλέγονται:</u>

- Εμφανής λοίμωξη,
- Απομακρυσμένες οστίτες λοιμώξης, οι οποίες ενδέχεται να εξαπλωθούν αιματογενώς στο σημείο εμφύτευσης,

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- Τραύματα εξάλλου καταλήξεων οστών σε βλάβη ή καταστροφή της άρθρωσης ή από πλήρωσή οστού ή φύση ή ακτινογραφίες.

- Ασθενείς με σκελετική ανωριμότητα.

- Περιπτώσεις στις οποίες υπάρχει ανεπαρκές οστικό απόθεμα, με αποτέλεσμα να μην δικαιολογείται η επέμβαση.

Στις καταστάσεις που εμφανίζουν αυξημένο κίνδυνο αποτυχίας, συγκαταλέγονται:

- Μη συνεργάσιμοι ασθενείς ή ασθενείς με νευρολογικές διαταραχές οι οποίοι δεν είναι ικανοί να ακολουθήσουν τις παρακάτω οδηγίες.

- Οστεοπόρωση.

- Μεταβολικές διαταραχές, οι οποίες ενδέχεται να εμποδίζουν το σχηματισμό οστού,

- Οστεομαλακία και

- Προηγούμενη αρθρόδεση.

Αποστείρωση

- Αυτό το ολικό εξάρτημα γονάτου έχει αποστειρωθεί με ακτινοβολία γάμμα.

- Εάν ανοιχθεί η συσκευασία χωρίς να χρησιμοποιηθεί το προϊόν, το εξάρτημα **δεν πρέπει να επαναποστειρωθεί** αλλά θα πρέπει να απορριφθεί ή να επιστραφεί στον προμηθευτή.

ΠΡΟΣΟΧΗ: Η συσκευή αυτή προορίζεται για μία μόνον χρήση. Η πώληση ή η χρήση αυτής της συσκευής επιτρέπεται μόνον σε ιατρούς.

Το προϊόν αυτό διατίθεται προς πώληση στις Ηνωμένες Πολιτείες για χρήση με οστικό τσιμέντο.

Για τις γενικές προειδοποιήσεις και προφυλάξεις, ανατρέξτε στο ένθετο της συσκευασίας ολικού γονάτου.

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デュラコン®CS（粗状、スタビライジング）リップド脛骨インサートは、一次性セメントトータル膝関節形成術のトータル膝関節システムとしてデュラコン®ユニバーサル十字形脛骨ベースプレート、デュラコン®十字形リテイニング大腿骨コンポーネントおよびデュラコン®膝蓋骨コンポーネントと共に使用するよう意図されています。これらのインサートは、骨変形を伴う、または伴わない関節表面が破壊された場合、十字形靭帯が不適切、存在しない、または術中保持できない場合、特に膝蓋骨欠損のため前方－後方の安定性が保たれない場合に使用します。このインサートを使用する場合は、側副靭帯を損失しないよう注意してください。この脛骨インサートはまた、後方十字形靭帯がある場所に使うこともできます。このジオメトリは靭帯に適応します。

材質

ASTM F-648 超高分子量 ポリエチレン (UHMWPE)	脛骨インサート

適応

- 変形性関節症、外傷性関節炎、虚血壊死を含む非炎症性変形性関節症
- リウマチ様関節炎、
- 機能性変形の矯正、
- 外傷後の関節解剖学的構造の欠損、特に不斉菌状縁のある膝蓋骨－大腿骨、機能不全または過去に膝蓋骨切除している；および、
- 回復不能な膝骨折

禁忌

<u>絶対的な禁忌には：</u>

- 明白な感染
- 感染の遠隔病巣（血液源を移植部位に広げる原因となる）、

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- X線像で明らかな関節破壊または骨吸収によって現れる急速な進行性疾患、
- 骨格が未熟な患者
- 骨株が乏しいと手技が適切に行えない原因となります。

失敗に終わる危険性を高める条件には：

- 協力的でない患者または、神経障害があり、指示に従うことのできない患者、
- 骨粗しょう症、
- 骨形成に悪影響を及ぼす可能性のある代謝障害、
- 骨軟化症、および
- 過去の関節固定術

滅菌

- 本トータル膝関節コンポーネントは、γ線滅菌済です。
- パッケージを開封したにもかかわらず、使用しない場合でも、絶対に再滅菌しないでください。必ず廃棄するか、または供給業者に返却してください。

注意：本品は単回使用です。本品の販売および使用は、医師のみに義務付けられています。

本品は、米国において骨セメントと共に使用するように販売されています。

一般的な警告および注意事項に関しては、トータル膝関節の使用説明書を参照してください。

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Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 3

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

IMPORTANT INFORMATION FOR THE OR STAFF
READ BEFORE OPENING STERILE PACKAGE

INFORMATIONS IMPORTANTES POUR LE PERSONNEL DE SALLE D'OPÉRATION
LIRE AVANT D'OUVRIR LE CONDITIONNEMENT STÉRILE

WICHTIGE INFORMATION FÜR DAS OP PERSONAL
VOR DEM ÖFFNEN DER STERILEN PACKUNG LESEN

INFORMAZIONE IMPORTANTE PER IL PERSONALE DI SALA OPERATORIA
LEGGERE PRIMA DI APRIRE LA CONFEZIONE STERILE

INFORMACION IMPORTANTE PARA EL PERSONAL DEL QUIROFANO
LEER ANTES DE ABRIR EL ENVASE ESTERIL

stryker Howmedica OSTEONICS

Howmedica International S. de R.L.
Raheen Business Park
Limerick, Ireland.

Distributed in the United States by
stryker Howmedica OSTEONICS Rutherford, N.J. 07070

Revised November, 1999

0090-6-207

IMPORTANT INFORMATION FOR THE OR STAFF

READ BEFORE OPENING STERILE PACKAGE

The process employed to create Duration™ Stabilized UHMWPE requires the use of ***very high strength seals on the inner package. As a result, the blister packages, particularly the inner package, will require significantly greater force to peel open*** than you may be accustomed to.

Please follow these instructions to facilitate opening of Duration™ Stabilized UHMWPE sterile packages.

To open the OUTER BLISTER

With **dry** hands/gloves:

1. Grip the bottom of the blister very firmly.
2. Grip the lid's thumb tab securely.
3. Exerting firm and steady force, slowly pull back the tab to remove the lid.

To open the INNER BLISTER

With **dry** gloves:

4. Grip the protruding corner of the blister flange firmly with one hand. (Figure 1)
5. Peel the lid's thumb tab with the other hand (as if opening a peel pouch). (Figure 2)

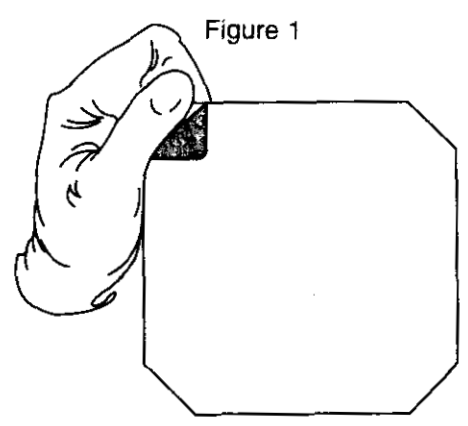
Figure 1

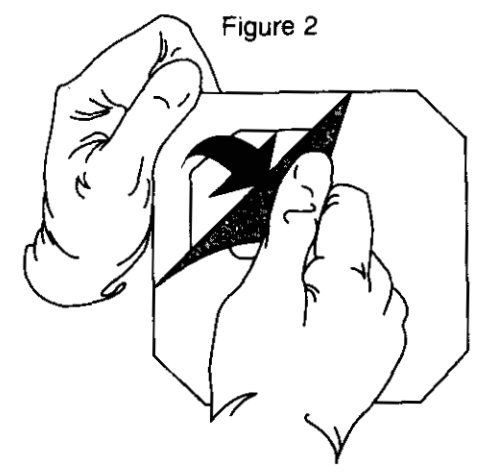
Figure 2

INFORMATIONS IMPORTANTES POUR LE PERSONNEL DE SALLE D'OPÉRATION

LIRE AVANT D'OUVRIR LE CONDITIONNEMENT STÉRILE

Le procédé DURATION™ de stabilisation du polyéthylène à très haute masse moléculaire nécessite l'utilisation d'un ***conditionnement interne avec joints à forte adhérence. Cela signifie que pour enlever les opercules de blisters en particulier celui du blister intérieur, on doit exercer une force plus grande*** que de coutume.

Respecter les instructions suivantes afin de faciliter l'ouverture des conditionnements stériles Duration™.

Pour ouvrir le BLISTER EXTERNE

Avec les mains **sèches** ou des gants secs:

1. Tenir fermement le fond du blister.
2. Agripper la languette de l'opercule.
3. Pour enlever l'opercule, tirer lentement la languette vers l'arrière en exerçant une force continue.

Pour ouvrir le BLISTER INTERNE

Avec des gants **secs**:

4. D'une main, agripper le coin en saille du rebord du blister (voir Figure 1).
5. De l'autre main, tirer sur la languette de l'opercule, comme pour l'ouverture d'une pochette à fermeture pelable (voir Figure 2).

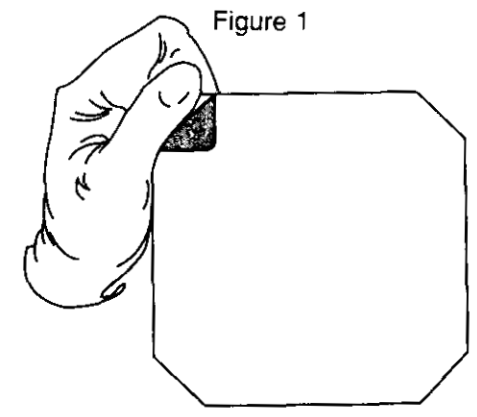
Figure 1

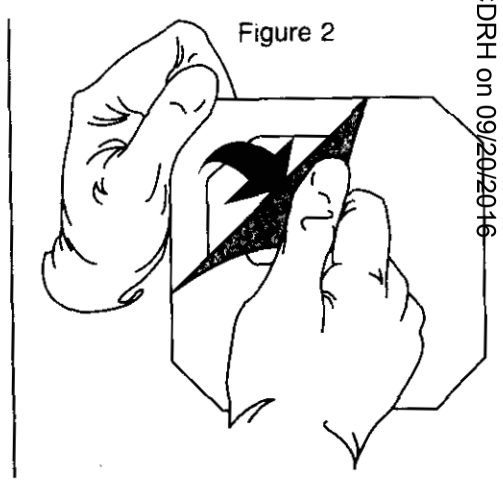
Figure 2

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

WICHTIGE INFORMATION FÜR DAS OP PERSONAL

VOR DEM ÖFFNEN DER STERILEN PACKUNG LESEN

Das Herstellungsverfahren für Duration™ Stabilized UHMWPE erfordert die Verwendung ***von hochverstärkten Verschlüssen für die innere Verpackung. Dadurch muss für das Öffnen der Blisterpackungen, insbesondere der inneren Verpackung, weitaus mehr Kraft angewendet werden***, als Sie es vielleicht von herkömmlichen Verschlüssen gewohnt sind.

Folgen Sie bitte diesen Anweisungen, um das Öffnen der sterilen Verpackungen von Duration™ Stabilized UHMWPE zu erleichtern.

Öffnen der
ÄUSSEREN BLISTERPACKUNG

Mit **trockenen** Händen/Handschuhen:

1. Halten Sie den unteren Teil der Blisterpackung fest in der Hand.
2. Halten Sie die Lasche des Deckels sicher fest.
3. Ziehen Sie die Lasche fest und mit gleichbleibender Kraft zurück, um den Deckel abzunehmen.

Öffnen der
INNEREN BLISTERPACKUNG

Mit **trockenen** Handschuhen:

4. Halten Sie mit einer Hand die vorstehende Ecke des Verpackungsflansches sicher fest. (Abbildung 1)
5. Ziehen Sie die Lasche des Deckels mit Hilfe der anderen Hand ab. (Abbildung 2)

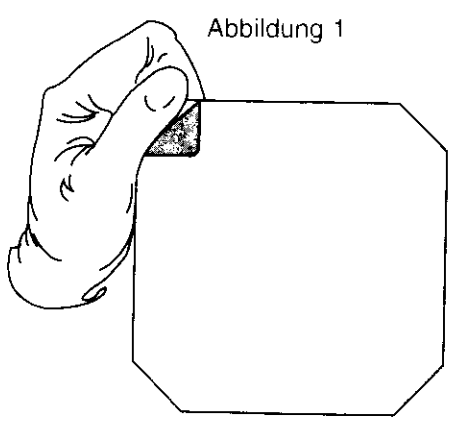
Abbildung 1

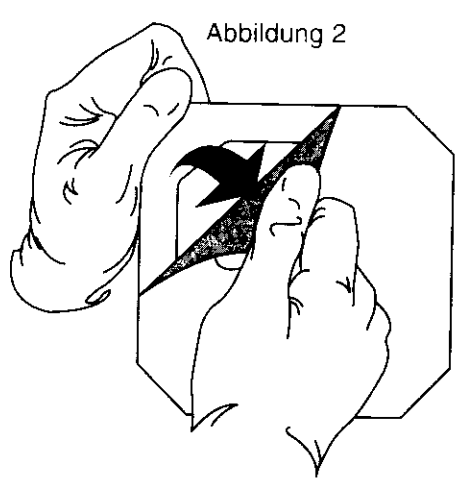
Abbildung 2

INFORMAZIONE IMPORTANTE PER IL PERSONALE DI SALA OPERATORIA

LEGGERE PRIMA DI APRIRE LA CONFEZIONE STERILE

Il procedimento impiegato per realizzare il polietilene stabilizzato Duration™ richiede l'uso di ***chiusure a tenuta molto elevata nell'imballaggio interno. Come conseguenza, i blister di imballaggio, in particolare quello interno, richiederanno una forza di apertura notevolmente maggiore*** di quanto Voi siate in genere abituati.

Si prega pertanto di seguire queste istruzioni per agevolare l'apertura delle confezioni sterili dei componenti contenenti polietilene stabilizzato Duration™.

Per aprire il
BLISTER ESTERNO

Con mani/guanti **asciutti**:

1. Afferrare saldamente il fondo del blister.
2. Afferrare con decisione l'estremità della linguetta della pellicola sigillante.
3 Esercitare forza con decisione e costanza, tirando lentamente indietro la linguetta per rimuovere la pellicola.

Per aprire il
BLISTER INTERNO

Con guanti **asciutti**:

4. Afferrare con decisione l'angolo sporgente del bordo del blister con una mano. (Figura 1)
5. Tirare l'estremità della linguetta del coperchio con l'altra mano (come se si aprisse un sacchetto termosigillato). (Figura 2)

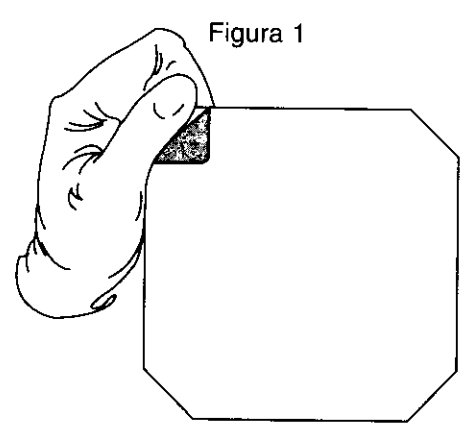
Figura 1

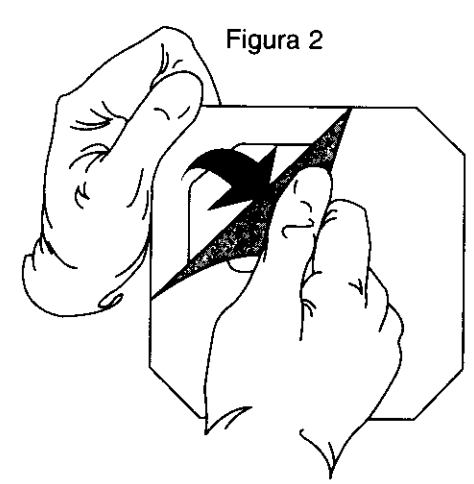
Figura 2

INFORMACION IMPORTANTE PARA EL PERSONAL DEL QUIROFANO

LEER ANTES DE ABRIR EL ENVASE ESTERIL

El proceso empleado para el Duration™ Stabilized UHMWPE requiere emplear ***superficies de cierre de gran resistencia en el envase interior. Como resultado, los envases de ampolla (blister), particularmente el envase interior, exigen aplicar considerablemente mas fuerza para despegarlos*** que la acostumbrada.

Sirvase seguir estas instrucciones para facilitar la maniobra de abrir los envases estériles Duration™ Stabilized UHMWPE.

Para abrir el
BLISTER EXTERIOR

Con manos o guantes **secos**:

1. Sujete la base del blister con fuerza.
2. Tome la lengüeta con firmeza.
3. Aplicando una fuerza firme y constante, tire hacia atras de la lengüeta hasta quitar la tapa.

Para abrir el
BLISTER INTERIOR

Con guantes **secos**:

4. Tome la esquina saliente de la pestaña del blister firmemente con una mano. (Figura 1)
5. Con la otra mano despegue la lengüeta de la tapa (como si estuviese abriendo un sobre autoadhesivo). (Figura 2)

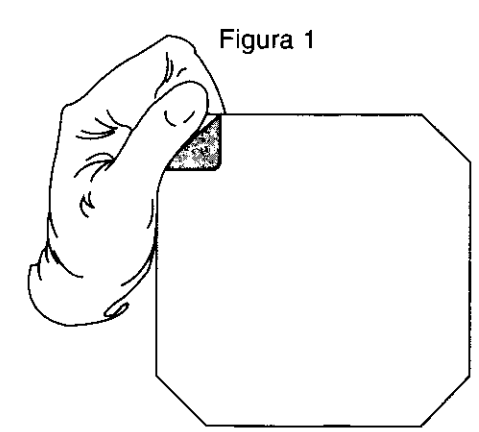
Figura 1

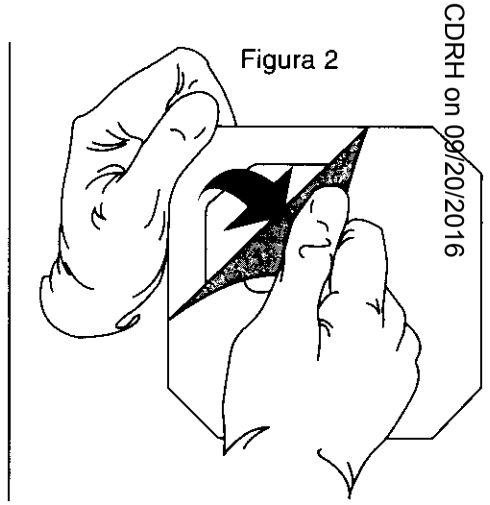
Figura 2

717

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Jonathan Peck

Subject: 510(k) Number K032163

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

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

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) No

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 87 MBH Class II

Additional Product Code(s) with panel (optional): 888.3565

Review: [signature] (Branch Chief) CRDB (Branch Code) 9/11/03 (Date)

Final Review: Miriam C. Provost (Division Director) 9/12/03 (Date)

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

Records Processed under FOIA request 2016-4640; Released by CDRH on 09/20/2016

510(k) MEMORANDUM

To:	K032163
From:	Jonathan H. Peck, Biomedical Engineer ODE/DGRND/Orthopedic Devices Branch
Date:	August 12, 2003
Subj:	Duracon Total Knee System (for uncemented use) Product Code: 87 MBH; 21 CFR 888.3565 – Knee joint patellofemorotibial, metal/polymer, porous-coated, uncemented prosthesis
Firm:	**Howmedica Osteonics Corp.** 59 Route 17 South Allendale, NJ 07401
Contact:	Denise Duchene Phone: (201) 831-5612 Fax: (201) 831-6038 Email: dduchene@howost.com
Decision:	**SE**

Recommendation:
The only change being made to the predicate device is the addition of uncemented use to the indications statement. The characteristics of the porous coating meet the requirements within "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA." Therefore, I recommend the subject device be found substantially equivalent (SE) to other legally marketed predicate devices.

Administrative Requirements:
The sponsor has included a Truthful and Accuracy Statement, a 510(k) Summary, and an Indications for Use page.

Explanations for "yes" responses to questions 4, 6, 8, and 11, and every "no" response in the Substantial Equivalence (SE) Decision Making Checklist:

3. Does new device have the same indication statements?

No. The Duracon Total Knee System has the same indications for use. However, the current product is intended for cemented use only; whereas the proposed product will be intended for both cemented and uncemented fixation.

7. Are descriptive characteristics precise enough to ensure equivalence?

No. Due to changes in the intended use, Howmedica Osteonics is providing test data in accordance with Special Controls guidance document for uncemented knee prostheses, dated January 16, 2003.

11. Performance data demonstrate equivalence?

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

Yes. The characteristics of the porous coating meet the requirements within "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA."

Device Description:
All components of the Duracon Total Knee System have been previously cleared for cemented use. Under the Substantial Equivalence Section of the submission, the sponsor states "There are no differences between the proposed product and the predicate devices" and "The components of the Duracon Total Knee System for use with and without bone cement are equivalent to the components of the Duracon Total Knee System for cemented use only under the following 510(k) Submissions: K910235, K915512, K920034, K926228, K936292, K972752, K021451, K023724." **The only change for the subject devices will be the addition of uncemented use to the indications statement**.

The previously cleared components are summarized in the table below:

Cemented Use Only 510(k) #	Description	Sizes	Material	Other
K910235	Beaded Standard Femoral Componenet (Left and Right)	X-X Small, X Small, Small, Medium, Medium/Large, Large, X-Large, X-X Large	B(4) Product Specification	B(4) Product Specifications
K920034	Beaded Modular Femoral Component (Left and Right)	Small, Medium, Medium/Large, Large, X-Large, X-X Large		
K926228	Beaded Cruciform Tibial Baseplate	X-Small 1, X-Small 2, Small 1, Small 2, Medium 1, Medium 2, Large 1, Large 2, X-Large 1, X-Large 2		
K915512	Beaded Univeral Tibial Baseplate	X-Small 1, X-Small 2, Small 1, Small 2, Medium 1, Medium 2, Large 1, Large 2, X-Large 1, X-Large 2		
K915512	Condylar Tibial Insert	X-Small, Small, Medium, Large, X-Large		
K915512	A/P Lipped Tibial Insert	X-Small, Small, Medium, Large, X-Large		
K936292	Condylar Tibial Insert A/P Lipped Tibial Insert Metal Backed	Same as above		

	Asymmetric Patella (Duration Pkg.)			
K000091	Metal Backed Symmetric Patella – 33mm x 11mm	X-Small	B(4) Product Specifications [redacted]	
K923573	Metal Backed Asymmetric Patella	Small, Medium, Large, X-Large		
K972752	Metal Backed Conversion Patella Metal Backed Conversion Patella Insert	Small, Medium, Large, X-Large		
K023724	CS Lipped Tibial Insert	X-Small		
K021451	CS Lipped Tibial Insert	Small, Medium, Large, X-Large		

Femoral Components:

B(4) Product Specifications [redacted]

Tibial Inserts:

B(4) Product Specifications [redacted]

B(4) Product Specifications [redacted]

Tibial Baseplates:
B(4) Product Specifications [redacted]

Patella Components:
B(4) Product Specifications [redacted]

Materials:
Component materials and standards to which they conform are summarized in the table below:

Proposed Component	Material	Function
B(4) Product Specifications [redacted]		

Porous Coating:

B(4) Product Specifications

[redacted]

Physical characteristics of the coating are summarized in the table below:

Measurement	Plant	Min.	Max.	Mean	S.D.

B(4) Product Specifications

[redacted]

B(4) Product Specifications

[redacted]

Mechanical properties of the porous coating are summarized below:

Measurement	Plant	Min	Mean	S.D.

B(4) Product Specifications

[redacted]

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B(4) Product Specifications [redacted]

Intended Use:
The Duracon Total Knee System components are for use in total knee arthroplasty to relieve pain and restore knee function for indications such as: noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and, irreparable fracture of the knee.

These products are intended to achieve fixation with and without the use of bone cement.

Sterilization:
Method: Gamma Irradiation – Cobalt 60 Isotope, Dose 25kGy
Validation: ANSI/AAMI/ISO 11137
Sterility Assurance Level (SAL): 10^{-6}

Packaging:
The Duracon Knee System femoral and tibial baseplate components are packaged as a single unit in a double blister. The packaged unit is protected by a rigid outer carton and shrink-wrapped per written procedures. Polyethylene components (tibial inserts, metal backed patellae, and conversion patella inserts) are subject to an additional heat treatment stabilizing processing step. These polyethylene components are referred to as Duration stabilized components. This process for packaging was cleared under K936292. Duracon CS Lipped polyethylene components are also available in N2Vac style – these polyethylene components are packaged in the basic double blister, but to create an inert environment the component packages are flushed with nitrogen and then sealed per written procedures. This process for packaging the CS Lipped Tibial inserts was cleared under K021451. All packaging is suitable for gamma radiation sterilization and for maintaining sterility.

Pyrogenicity:
Howmedica Osteonics does not make any pyrogenicity claims for these products. They have not been tested for pyrogenicity. This is adequate.

Labeling:
Draft package labels are adequate.
The draft package insert is adequate.

Testing:
All components in this submission have been cleared, as they are, in previous 510(k) submissions for use with cement. The subject device is to be used without bone cement. Therefore, the only additional information needed is a characterization of the porous coating to bone ingrowth standards. This was done above. No additional testing is necessary.

Sponsor's information in support of SE:
The sponsor has claimed SE to the legally marketed devices in the "previously cleared components" table above.

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

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The sponsor states that the Duracon Total Knee System has not changed. The only change in the subject devices will be the intended use. The subject devices are meant to be used with or without bone cement.

Correspondence:
On the morning of August 26th, I noticed the following inconsistency. In this submission the sponsor stated, "The Cruciform Baseplate is only designed for use with the Condylar and A/P Lipped tibial inserts." In K032418 (Duracon Total Knee System with Peri-Apatite) the sponsor states, "The Cruciform Baseplate is designed for use with the Condylar, A/P Lipped and CS Lipped tibial inserts."

I received a 510(k) Notification Amendment from Diane Duchene on the afternoon of August 26th stating that a mistake had been made in this submission (K032163) and that the Cruciform Baseplate was in fact compatible with all three tibial inserts in this submission. The Notification Amendment is attached.

Summary:
The only change being made to the predicate device is the addition of uncemented use to the indications statement. The characteristics of the porous coating meet the requirements within "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA." The devices that are part of the Duracon Total Knee System will remain unchanged. Therefore, I recommend the device be found SE.

Concur
MP 9/12/03

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

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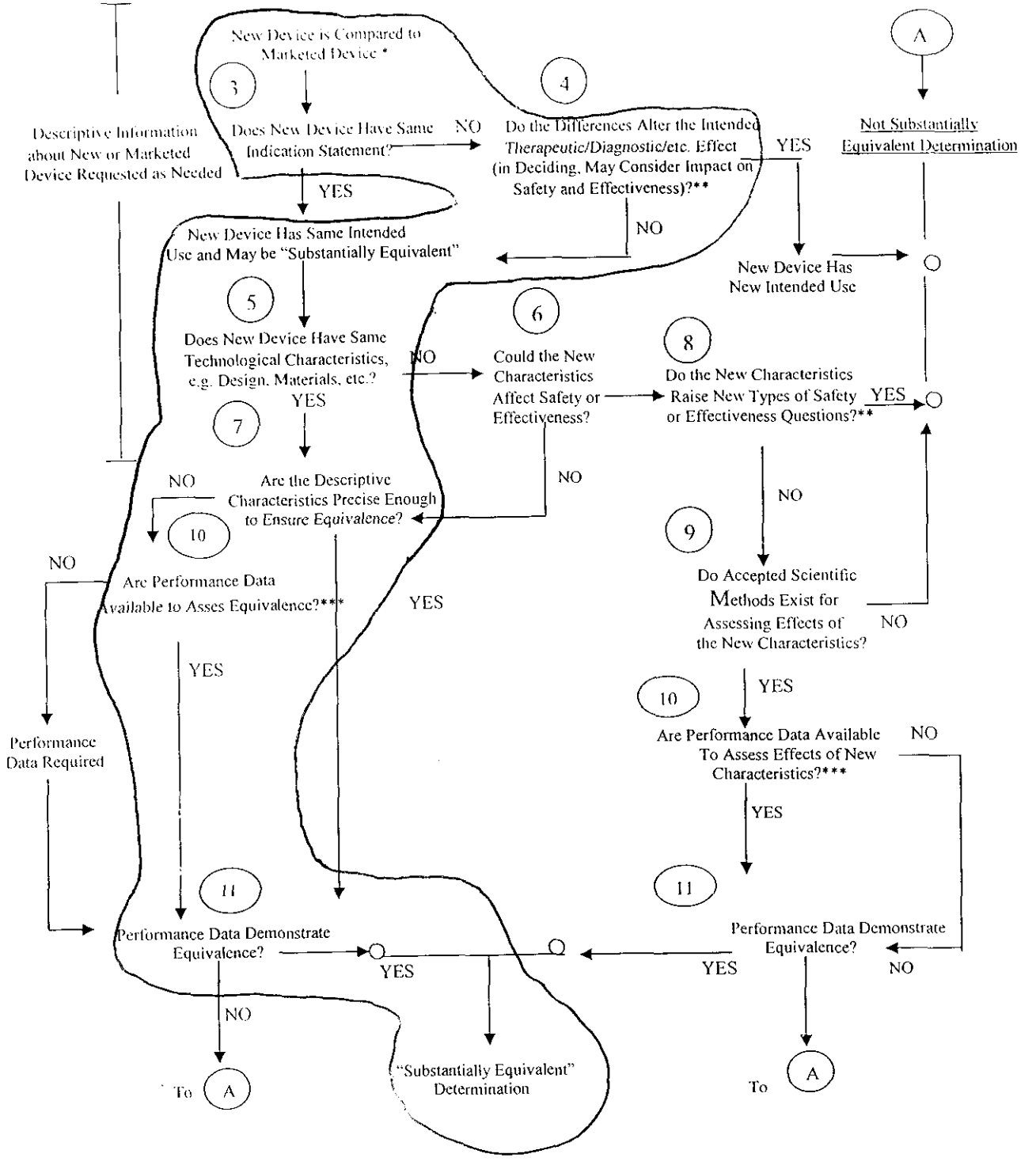
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 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 maybe in the 510(k), other 510(k)s, *the Center's classification files, or the literature.*

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

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K032163

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☑ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which		

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is posted with the 510(k) boilers on the H drive.] For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No
Reviewer: Jonathan Peck
Concurrence by Review Branch: ____

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

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Date:

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

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

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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 032163

Reviewer: Jonathan Peck

Division/Branch: OGRND/ORDB

Device Name: Duracon Total Knee System

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

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?		X	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If YES = Stop NE
5. Same Technological Characteristics?	X		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		X	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?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

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.

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

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See Memo

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 over-the-counter 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 are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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Internal Administrative Form

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