U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K150850 - 559 pages
COMPANY:	BIOMET, INC. (BIOMET)
PRODUCT:	BONE CEMENT, ANTIBIOTIC (MBB)
SUMMARY:	Product: REFOBACIN BONE CEMENT R
DATE REQUESTED:	Apr 27, 2016
DATE PRINTED:	Apr 27, 2016
Note:	Printed

K150860

BIOMET

FDA CDRH DMC
MAR 31 2015
Received

March 25, 2015

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

Dear Sir or Madam:

SUBJECT: Traditional 510(k) – Refobacin® Bone Cement R

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and relevant amendments thereto, Biomet Orthopedics is submitting the attached premarket notification for **Refobacin® Bone Cement R**. This notification is submitted in duplicate: please find enclosed one paper copy and one electronic copy (e-copy). The e-copy is an exact duplicate of the paper submission. There have been no prior submissions for the subject device.

Refobacin® Bone Cement R is a bone cement containing gentamicin, for use in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. Additionally an alternative packaging configuration; the **Optipac®**, a mixing and application system pre-packed with **Refobacin® Bone Cement R**, is included in this submission.

The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued August 12, 2005.

Basis for Submission: New Bone Cement and alternative packaging configuration

Per the provisions of 21 CFR §807.95(b), we request the FDA hold as confidential the existence and information provided within this submission. We consider the intent to market the subject device as confidential information and have taken precautions to protect the confidentiality of such intent. Further, this notification contains information that is trade secret or confidential commercial information under 21 CFR§20.61 and therefore, exempt from disclosure under the Freedom of Information Act (FOIA). Biomet requests that FDA consult with the Company as provided in 21 CFR §20.47 prior to public disclosure of information contained herein.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)[A]?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart		X

C)?[A]		
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?	X	
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	
Is the subject device an in-vitro diagnostic device (IVD)?		X

[A] A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

I trust that the enclosed information is adequate to facilitate your review. Please contact me by phone (574-371-3024), fax (574-372-1683) or email (carmen.albany@biomet.com) should you require additional information or, as an alternate contact, Axel Steiof, Director Global Regulatory Affairs: Bone Cements, Antibiotics, Pharma, by (+49 (0) 30 84581 217), fax (+49 (0)30 8458114217) or email (axel.steiof@biomet.com).

Sincerely,

Carmen Albany

Carmen Albany, DVM
Sr. Regulatory Affairs Specialist, US

1 Medical Device User Fee Coversheet (Form FDA-3601)

Form Approved OMB No 0910-0511 Expiration Date April 30, 2016 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)[redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

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

BIOMET INC
P O BOX 587 56 EAST BELL DRIVE
WARSAW
IN 46580
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****(b)(4)[redacted]

2. CONTACT NAME
Carmen Albany

2.1 E-MAIL ADDRESS
carmen.albany@biomet.com

2.2 TELEPHONE NUMBER (include Area code)
574-371-3024

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
574-371-1683

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 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. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. 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
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics 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

7. 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

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)[redacted]
19-Jan-2015

Form FDA 3601 (05/13)

2 Table of Contents

Table of Contents

3 CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
03/25/2015	(b)(4)	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Addi ional Informa ion	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Addi ional Informa ion	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Ins itu ion Name: Biomet Inc	Establishment Registration Number *(if known)*: 1825034		
Division Name *(if applicable)*: Biomet Manufacturing Corp	Phone Number *(including area code)*: 574-371-3024		
Street Address: 56 East Bell Drive	FAX Number *(including area code)*: 574-371-1683		
City: Warsaw	State / Province: IN	ZIP/Postal Code: 46581	Country: USA
Contact Name: Carmen Albany, DVM			
Contact Title: Sr Regulatory Affairs Specialist	Contact E-mail Address: carmen albany@biomet com		

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

Company / Ins itu ion Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

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

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

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

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

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

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ O her *(specify below)*

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

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

- ☐ Response to FDA correspondence:

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substan ial equivalence is claimed

1	LOD	2	MBB	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K031673	1	Palacos G	1	Heraeus Kulzer GmbH & Co KG
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Bone Cement

	Trade or Proprietary or Model Name for This Device		Model Number
1	Refobacin Bone Cement R	1	5003920002, 5003940001, 5003940002, 5003960001
2	Optipac-Refobacin Bone Cement R	2	5709500392, 5710500394, 5711500396, 5712500398,
3	Optipac - Refoabcin Bone Cement R - continued	3	5740500394
4		4	
5		5	

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

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

Data Included in Submission

☒ Laboratory Tes ing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Sec ion *(if applicable)*	Device Class
MBB, LOD	888 3027	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Orthopedic		

Indications *(from labeling)*

Refobacin Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registra ion.	FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Ins itu ion Name Biomet France SARL		Establishment Registration Number 3006946279		
Division Name *(if applicable)*		Phone Number *(including area code)* +33 (0) 475759100		
Street Address Plateau de Lautagne		FAX Number *(including area code)*		
City		State / Province Valence	ZIP Code 26000	Country France
Contact Name Christophe Mironneau	Contact Ti le Director Quality, Regulatory Compliance		Contact E-mail Address christophe mironneau@biomet com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Ins itu ion Name (b)(4)		Establishment Registration Number (b)(4)		
Division Name *(if applicable)*		Phone Number *(including area code)* (b)(4)		
Street Address (b)(4)		FAX Number *(including area code)* (b)(4)		
City (b)(4)		State / Province	ZIP Code (b)(4)	Country (b)(4)
Contact Name (b)(4)	Contact Ti le (b)(4)		Contact E-mail Address (b)(4)	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Ins itu ion Name (b)(4)		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* (b)(4)		
Street Address (b)(4)		FAX Number *(including area code)* (b)(4)		
City (b) r		State / Province	ZIP Code (b)(4)	Country (b)(4)
Contact Name (b)(4)	Contact Ti le		Contact E-mail Address (b)(4)	

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	D732	ASTM	Standard Test Method for Shear Strength of Plastics by Punch Tool	2010	04/01/2010
2	5833	ISO	Implant for Surgery-Acrylic Resin Cements Second Edition	2002	05/01/2002
3	F451	ASTM	Standard Specification for Acrylic Bone Cement	2008	08/01/2008
4	F2118	ASTM	Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	2010	12/01/2010
5	F1980	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2007	04/01/2007
6	11135-1	ISO	Sterilization of health care products-Ethylene oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2007	05/01/2007
7	13408-1	ISO	Aseptic Processing of Health Care Products-Part 1: General requirements-Second Edition	2008	06/15/2008

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

4 Cover Letter

BIOMET

March 25, 2015

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

Dear Sir or Madam:

SUBJECT: Traditional 510(k) – Refobacin® Bone Cement R

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Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)[A]?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart		X

C)?[A]		
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?	X	
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	
Is the subject device an in-vitro diagnostic device (IVD)?		X

[A] A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

I trust that the enclosed information is adequate to facilitate your review. Please contact me by phone (574-371-3024), fax (574-372-1683) or email (carmen.albany@biomet.com) should you require additional information or, as an alternate contact, Axel Steiof, Director Global Regulatory Affairs: Bone Cements, Antibiotics, Pharma, by (+49 (0) 30 84581 217), fax (+49 (0)30 8458114217) or email (axel.steiof@biomet.com).

Sincerely,

Carmen Albany

Carmen Albany, DVM
Sr. Regulatory Affairs Specialist, US

5 Acceptance Checklist for Traditional 510(k)s

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K Date Received by DCC:

Lead Reviewer:

Branch: Division: Center/Office:

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments? Subject device is combination product per 21 CFR 3.2 (e)		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments? CDRH		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments? Not Applicable. A request for Designation has not been submitted for the subject device		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments? A 510(k) is appropriate as the device is a Class II device per 21 CFR §888.3027		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		×
Comments? No there is not PMA pending for the same device with the same indications for use.		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		×
Comments? No clinical data submitted as part of this submission.		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation.*		
	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments? Type of 510(k) is identified as a Traditional 510(k) in the Cover Letter in Section 4		

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			X
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
Comments? See CDRH cover sheet Section F and Section G				
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			X
Comments? See Section 6, Indications for Use Statement				
4) Submission contains 510(k) Summary or 510(k) Statement	X			X
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
Comments? See Section 7, 510(k) Summary				
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			X
Comments? See Section 8, Truthful and Accuracy Statement				
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	X
Comments? Not applicable, submission is not a Class III 510(k)				
7) Submission contains clinical data			X	X
Comments? Not applicable, submission does not contain clinical data				
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			X
Comments? See Section 12 for SF 3654 Forms				
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			X

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
Comments? There have been no prior submission for the subject device (also stated in cover letter-Section 4) and CDRH cover sheet (Section 3).				
B. Device Description				
10)				X
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
Comments? Guidance documents are referenced in Device Description (section 14). There are no other known device-specific guidance documents referenced in this submission other than the special controls guidance document referenced in Section 14.				
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments? Above information is included in the Device Description (Section 14).				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			X
Comments? Engineering drawings are provided in Section 14.				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				X
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.			X	

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
Comments? Information regarding accessories is contained within Section 14 Device Description. Accessories identified in the submission are distributed as part of a convenience kit. A Kit Certification is provided. Accessories included in the kit are classified as Class I Exempt and thus no 510(k) clearance is required.				
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			X
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
Comments? Above information is included in the Substantial Equivalence Section (Section 15).				
15) Submission includes a comparison of the following for the predicate(s) and subject device				X
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
Comments? Above information is included in the Substantial Equivalence Section (Section 15).				
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			X
Comments? Above information is included in the Substantial Equivalence Section (Section 15).				
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
Comments? See section 16, Proposed Labeling. Layperson exemption statement included in Section 16.				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			X
Comments? Prescription use statement included in IFUs and "Rx only" symbol on labels included in Section 16.				
19) General labeling provisions				X
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
Comments? See Section 16 for Proposed Labeling.				
20)				X
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
Comments? Guidance documents are referenced in Section 14, Device Description. Labeling (section 16) contains required information. There are no other known device-specific guidance documents referenced in this submission other than the special controls guidance document referenced in Section 14.				
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				X
Submission states that the device and/or accessories are: (one of the below must be checked)				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? Above information included in Section 17 (Sterilization and Shelf Life).				
22) Assessment of the need for sterilization information				X
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
Comments? Above information included in Section 17 (Sterilization and Shelf Life).				
23) If the device, and/or accessory, and/or a component is provided sterile:				X
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
Comments? Above information included in Section 17 (Sterilization and Shelf Life).				
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	X
Comments? Not Applicable. Subject Device is provided sterile.				
25)				X
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.	X			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
Comments? Guidance documents are referenced in Section 14 (Device Description). Sterilization and Shelf Life section (section 17) contains required information. There are no other known device-specific guidance documents referenced in this submission other than the special controls guidance document referenced in Section 14.				
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			X
Comments? Above information included in Section 17 (Sterilization and Shelf Life).				
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			X
Comments? Above information included in Section 17 (Sterilization and Shelf Life).				
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			X
Comments? Above information included in Section 17 (Sterilization and Shelf Life).				
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				X
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? Above information included in Section 18 (Biocompatibility).				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			X

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Comments? Above information included in Section 18 (Biocompatibility).				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			X
Comments? Above information included in Section 18 (Biocompatibility).				
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			X
Comments? Above information included in Section 18 (Biocompatibility).				
H. Software				X
Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
X does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? Statement that submission does not include Software (Section 19).				
I. EMC and Electrical Safety				X
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
X does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? Not Applicable to subject device. See statement in Cover Letter and Section 20.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			X

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
Comments? Above information is included in Section 21				
37)				X
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
Comments? Guidance documents are referenced in Section 14, Device Description. Performance Testing Section (Section 21) contains required information. There are no other known device-specific guidance documents referenced in this submission other than the special controls guidance document referenced in Section 14.				
38) If literature is referenced in the submission, submission includes:				X
a) Legible reprints or a summary of each article.	X			
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	X			
Comments? Supporting references provided following test reports in Section 21.				
39) For each completed nonclinical (i.e., animal) study conducted			X	X
Comments? Not applicable, animal testing not required to demonstrate substantial equivalence.				
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				X
Submission states that the device: (one of the below must be checked)				
is an in vitro diagnostic device.				
X is not an in vitro diagnostic device.				
Comments? Subject Device is not an IVD. See statement in Cover Letter (Section 4).				

Decision: ◯ Accept ◯ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

6 Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Refobacin Bone Cement R

Indications for Use *(Describe)*
Refobacin Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

7 510(k) Summary

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Refobacin® Bone Cement R 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact: Carmen Albany, DVM
Sr. Regulatory Affairs Specialist, US
Phone: 574-371-3024
Fax: 574-372-1683

Date: March 25, 2015

Subject Device: **Trade Name:** Refobacin® Bone Cement R

Classification Name:

- MBB, LOD– Refobacin® Bone Cement R (21 CFR 888.3027)

Alternative Packaging Configuration Classification Name:

- MBB, LOD–Optipac®- Refobacin® Bone Cement R (21 CFR 888.3027)
- JDZ– Optipac®- Refobacin® Bone Cement R (21 CFR 888.4210)
- KIH– Optipac®- Refobacin® Bone Cement R (21 CFR 888.4200)

Legally marketed devices to which substantial equivalence is claimed:

- PALACOS®G Bone Cement (K031673)*
  *The product obtained for testing and labeling comparison is labeled as Palacos® R+G

Reference Device

- PALACOS®R + G pro (K142157)

Device Description

Refobacin® Bone Cement R is a fast setting polymer containing gentamicin, for use in bone surgery. Mixing of the two component system, consisting of a powder and a liquid, produces a paste, which is used to anchor the prosthesis to the bone. The hardened bone cement allows stable fixation of the prosthesis and transfers all stresses produced in a movement to the bone via the large interface. Insoluble zirconium dioxide is included in the cement powder as an X ray contrast medium. The chlorophyll additive in the liquid component serves as optical marking of the bone cement at the site of the operation.

Indications for Use

Refobacin® Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

Summary of Technological Characteristics

The intended use, indications for use, materials, sterilization methods, cement design, and principle of operation of the subject device are the same as the predicate device. Differences in size offerings, packaging configurations, and shelf life do not introduce any new risks of safety and efficacy. Refobacin® Bone Cement R is substantially equivalent to Palacos® G for the primary intended use of fixation of prosthetic components as described in the device labeling.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
  - Comparative in-vitro testing was performed and the results for Refobacin® Bone Cement R and Optipac® Refobacin® Bone Cement R were compared to that of the predicate, Palacos® G. The results showed that Refobacin® Bone Cement R and Refobacin® Bone Cement R as packaged in the Optipac® possess mechanical, chemical, physical and handling characteristics necessary to fulfill their intended use. Refobacin® Bone Cement R and Optipac® Refobacin® Bone Cement R are substantially equivalent to Palacos® G for their primary intended use of fixation of prosthetic components as described in the device labeling.
- Clinical Tests
  - Clinical data was not required to establish substantial equivalence between the subject Biomet Refobacin® Bone Cement R and the predicate device.

Substantial Equivalence Conclusion

Based on the similarities in design, function, indications for use and fundamental scientific technology, the devices that are the subject of this submission are similar to the predicate devices and do not introduce any new risks of safety or efficacy. Therefore, Biomet concludes that the subject device is substantially equivalent to the predicate device.

8 Truthful and Accuracy Statement

Premarket Notification Truthful and Accurate Statement
[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Research Engineer of Biomet Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Kyle Jones, Ph.D.

23 Mar 2015

Date

9 Class III Summary and Certification

9.1 Class III Summary and Certification

21 CFR § 807.94 is not applicable to this submission.

10 Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Biomet, Inc

2. Date of the Application/Submission Which This Certification Accompanies
03/25/2015

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
56 East Bell Drive

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City: Warsaw
State/Province/Region: Indiana
Country: United States
ZIP or Postal Code: 46581-0587

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*
(Tel): 574-371-3024
(Fax): 574-371-1683

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

MBB, LOD, JDZ, KIH (21 CFR §888.3027, 21 CFR §888.4210, CFR §888.4200)
Trade Name: Refobacin Bone Cement R, Optipac Refobacin Bone Cement R
Common Name: Bone Cement

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Carmen Albany, DVM	Senior Regulatory Affairs Specialist

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	56 East Bell Drive
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	Warsaw
State/Province/Region	Indiana
Country	USA
ZIP or Postal Code	46581

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 574-371-3024

(Fax): 574-371-1683

14. Date of Certification

3/23/2015

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

Carmen Albany

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

11 Financial Certification or Disclosure Statement

11.1 Financial Certification or Disclosure Statement

No covered clinical studies (or specific clinical studies) are submitted in support of this premarket notification [510(k)] submission; therefore, no certification or disclosure is made.

12 Standards Data Report Forms

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM D732-10 Standard Test Method for Shear Strength of Plastics by Punch Tool

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegula ionandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and he name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes he standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM D732-10 Standard Test Method for Shear Strength of Plastics by Punch Tool

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.1	Pre-Test Conditioning	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Not pre-conditioned according to Procedure A of ASTM D618

D
(b)(4) [redacted]

JUSTIFICATION
Pre-conditioning in water at normal body temperature more accurately depicts in vivo conditions

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 5833 Implant for surgery-Acrylic Resin Cements

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegula ionandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 5833 Implant for surgery-Acrylic Resin Cements

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
No Deviations

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F451-08 Standard Specification for Acrylic Bone Cement

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-185	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegula ionandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F451-08 Standard Specification for Acrylic Bone Cement

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
No Deviations

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2118-10 Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-204	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegula ionandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2118-10 Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2.1	Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Option: testing at three different stress levels

D
(b)(4) [redacted]

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.2.1.2	Direct Molding	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Molds were not held in (b)(4) [redacted] during curing

DESCRIPTION
Specimens were cured in (b)(4) [redacted] prior to de-molding, samples were held in (b)(4) [redacted] prior to testing and during all testing.

JUSTIFICATION
(b)(4) [redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1980-07: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-229	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegula ionandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1980-07: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Med Dev.	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Adoption of standard for acrylic bone cement convenience kit items comprised of polymeric materials

DESCRIPTION
Standard was applied to acrylic bone cement convenience kit items comprised of polymeric materials

JUSTIFICATION
Items tested are comprised of polymeric materials and standard includes accelerated aging discussion for polymers (same class of materials as the convenience kit items)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Med Dev.	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Adoption of standard for acrylic bone cement packaging system (Optipac) comprised of polymeric materials

DESCRIPTION
Application of accelerated aging equation to acrylic bone cement packaging system (Optipac)

JUSTIFICATION
Optipac is comprised of polymeric materials

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 13408-1: Aseptic Processing of Health Care Products-Part 1: General requirements-Second Edition

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-427	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 13408-1: Aseptic Processing of Health Care Products-Part 1: General requirements-Second Edition

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Aseptic Processing of Health Care Products	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
NA

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

11135-1 Sterilization of Health Care Products-Ethylene Oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices-2007

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
11135-1 Sterilization of Health Care Products-Ethylene Oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices-2007

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Appendix B	Conservative determination of lethal rate of sterilization process-overkill	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Half-cycle method

DESCRIPTION
Half-cycle method is used to verify the full cycle minimum parameters

JUSTIFICATION
Conservative method for demonstrating sterility assurance

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under “justification.” Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under “type of deviation or option selected,” “description” and “justification” on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

13 Executive Summary

13.1 Executive Summary

13.1.1 Device Description

Refobacin® Bone Cement R is a fast setting polymer containing gentamicin, for use in bone surgery. Mixing of the two component system, consisting of a powder and liquid, produces a paste, which is used to anchor the prosthesis to the bone. The hardened bone cement allows stable fixation of the prosthesis and transfers all stresses produced in a movement to the bone via the large interface. Insoluble zirconium dioxide is included in the cement powder as an X-ray contrast medium. The chlorophyll additive in the liquid component serves as optical marking of the bone cement at the site of the operation.

This submission includes a new bone cement product, Refobacin® Bone Cement R. Refobacin® Bone Cement R is available via two packaging configurations in multiple sizes of each type of packaging.

13.1.2 Predicate Device

- K031673 Palacos® G*
  *The product obtained for testing and labeling comparison is labeled as Palacos® R+G

13.1.3 Indications for Use

Refobacin® Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

13.1.4 Technological Characteristics

The subject device has similar technological characteristics when compared to the predicate device. The intended use, indications for use, materials, sterilization methods, cement design and principle of operation of Refobacin® Bone Cement R are the same as the predicate device, Palacos® G (K031673).

Details of substantial equivalence for the subject device are provided in Section 15 of this submission.

13.1.5 Substantial Equivalence Discussion

Refobacin® Bone Cement R, the subject device has similar technological characteristics as the predicate device, Palacos® G. Details of substantial equivalence for the subject device are provided in Section 15 of this submission.

13.1.6 Summary of Performance Testing – Bench, Animal, and Clinical

The summary tables presented in Section 21 show that the subject device (including the subject device packaged in Optipac®) meets all the consensus standards for bone cement, as well as being substantially equivalent to the predicate device. However, as is to be expected when performing such a large number and diversity of tests, the summary also shows that there were several differences between the subject device and the predicate device. Some of these differences were statistically significant. In some cases, the predicate device outperformed the subject device, while in other cases the subject device outperformed the predicate device. In nearly all of the cases, the differences, even if statistically significant, were of small magnitude(b)(4) [redacted]. This variation is in line with past cement testing experiences, thus the test results demonstrate that the device is substantially equivalent.

13.2 Conclusions

The proposed device has the same intended use as the predicate(s). The proposed device has similar technological characteristics to the predicate(s), and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate device(s).

14 Device Description

The following information is based on the FDA Guidance Document: '*Format for Traditional and Abbreviated 510(k) s'*, issued August 12, 2005 and in consideration of the applicable sections of the *Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA issued July 17, 2002*.

14.1 Device Description

Refobacin® Bone Cement R is a fast setting polymer containing gentamicin, for use in bone surgery. Mixing of the two component system, consisting of a powder and a liquid, produces a paste, which is used to anchor the prosthesis to the bone. The hardened bone cement allows stable fixation of the prosthesis and transfers all stresses produced in a movement to the bone via the large interface. Insoluble zirconium dioxide is included in the cement powder as an X ray contrast medium. The chlorophyll additive in the liquid component serves as optical marking of the bone cement at the site of the operation.

When the powder (copolymer) and the liquid (monomer) are mixed, the dimethyl-p-toluidine in the liquid activates the benzoyl peroxide catalyst in the powder. This initiates the polymerization of the monomer, which then binds together granules of polymer. As polymerization proceeds, a sticky dough-like mass is formed, which, after about 30 seconds, can be manipulated for about 5 minutes. Polymerization is an exothermic reaction and although the spontaneous generation of heat accelerates the reaction, the polymerization of this self-curing resin occurs even if the temperature is reduced by irrigation with a cool physiologic saline solution.

Refobacin® Bone Cement R can be mixed in an open bowl or a vacuum mixing system, and is applied to the operative site either manually or with a bone cement gun. Refobacin® Bone Cement R is available in two packaging configurations, each of which are available in multiple sizes. Refobacin® Bone Cement R is available as an individual bone cement product i.e., packaging containing only the monomer (liquid) and powder (copolymer) components (sizes and package details are provided in Tables 14.3 and 14.4). In the second configuration, Refobacin® Bone Cement R is available via a pre-packed, closed mixing and application system, the Optipac® (sizes and package details are provided in Tables 14.5 and 14.6). This closed system minimizes the amount of free monomer in the operating room and the application method reduces direct contact with the bone cement.

(b)(4) [redacted]

Figure 1: Cured disk of Refobacin® Bone Cement R

14.1.1 Performance Specifications

Test reports are provided in support of the subject device and the subject device as packaged in the alternative packaging configuration, including:

Refobacin® Bone Cement R Testing:

Fatigue	Porosity (non-vacuum)
Bending	Free Monomer
Compression	Release of monomer
Tensile	Residual monomer
Fracture Toughness	Mean particle size
Creep	Powder moisture
Shear	Cytotoxicity
Handling Properties	Trace Elements
BPO	Monomer stability
Molecular Weight	Powder morphology
Radiopacifier content	Volumetric shrinkage
Radiopacity	Gentamicin Elution
Zone of Inhibition	

Optipac®-Refobacin® Bone Cement R Testing:**
Monomer Stability
Max Temp
Setting Time
Intrusion
Compressive Strength
Bending Modulus
Bending Strength
Cytotoxicity

**Testing plan modeled after those evaluations listed in the 510(k) summary for K142157 PALACOS® R+G pro, see Section 24 for device 510k Summary.

A summary of the testing for the subject device is provided below in **Table 14.1**. A summary of the testing for the subject device in alternative packaging is provided in

Table 14.2. A detailed testing summary and supporting test reports are included in **Section 21**.

Table 14.1: Performance Testing Summary- **Refobacin® Bone Cement R** (as compared to Palacos® G*)

Property	Test Method	Result
(b)(4) [redacted]		

Property	Test Method	Result
(b)(4) [redacted]		

Property	Test Method	Result
(b)(4) [redacted]		

*The product obtained for testing and labeling comparison is labeled as Palacos® R+G

**A copy of the reference is located in Section 21 with Tension testing documents

Table 14.2: Performance Testing Summary **Optipac®-Refobacin® Bone Cement R** (as compared to Palacos® G*)

Property	Test Method	Result
(b)(4) [redacted]		

Property	Test Method	Result
(b)(4) [redacted]		

Please refer to Sections 18-20 for a comprehensive review of the performance evaluation of the subject device and subject device as packaged in the alternative packaging configuration.

14.1.2 Principle of Operation

Refobacin® Bone Cement R provides two separate, pre-measured sterilized components which when mixed in an open bowl or a vacuum mixer, form a radiopaque, rapidly setting bone cement containing Gentamicin. Green pigment (Chlorophyll VIII) is added to the monomer (liquid) to produce a greenish tint in the final cement. This renders it possible to distinguish between bone and cement within the surgical field.

When the powder (copolymer) and the monomer (liquid) are mixed, the dimethyl-p-toluidine in the liquid activates the benzoyl peroxide catalyst in the powder. This initiates the polymerization of the monomer, which then binds together granules of polymer. As polymerization proceeds, a sticky dough-like mass is formed, which, after about 30 seconds can be manipulated for about 5 minutes. The bone cement can be applied to the operative site either manually or with a bone cement dispenser/gun and completes curing after implantation. See curves and tables for temperature variations in the package inserts found in Section 16.1.1. Polymerization is an exothermic reaction and although the spontaneous generation of heat accelerates the reaction, the polymerization of this self-curing resin occurs

even if the temperature is reduced by irrigation with a cool physiologic saline solution.

Optipac®-Refobacin® Bone Cement R
The Optipac® provides two separate, pre-measured sterilized components which when mixed form radiopaque rapidly setting bone cement. To combine the components and begin the chemical process detailed above, the mixing rod is screwed onto the cylinder after the transport lid is removed. The safety spacer is removed from the blue monomer holders. The blue monomer holders are pushed towards the middle of the cylinder. This push causes a sharp cannula to puncture the monomer pouches and initiates the flow of monomer through the cannula(s) into the mixing cylinder. When the two components are mixed using the mixing rod, the chemical reaction detailed above is initiated. The cement is applied after the cylinder is prepared for application which includes: discontinuing and disconnecting the vacuum, removing the mixing rod and bottom part of the cylinder, unscrewing the blue plug and attaching a nozzle, and placing the cylinder with nozzle attached in a cement gun. Detailed, step-by-step instructions (including illustrations) are provided in the Optipac®-Refobacin® Bone Cement R IFU in Section 16.

14.1.3 Intended Use and Indications for Use

This device is intended for use in arthroplasty procedures for the hip, knee and other joints.

Please see **Section 6** for the Indications for Use verbiage.

14.1.4 Device Components

Refobacin® Bone Cement R provides two separate, pre-measured sterilized components which when mixed form radiopaque rapidly setting bone cement and is available in two types of packaging. Each type of packaging is available in multiple sizes and pack configurations. A detailed description of the powder (copolymer) and liquid (monomer) components are provided for each size of Refobacin® Bone Cement R in Table 14.3. See Table 14.4 for a list of the contents of the Refobacin® Bone Cement R configurations by part number. Tables 14.5 and 14.6 list the components and contents of Optipac®- Refobacin® Bone Cement R. Engineering Drawings are included in Section 14.1.8.

Table 14.3: Component Composition of **Refobacin® Bone Cement R**

Size	Powder Composition	Monomer Composition
Refobacin® Bone Cement R 20	1 pouch of 20.4 g powder contains: 0.4 g gentamicin sulphate (corresponding to 0.3 g gentamicin) 16.7 g poly (methyl acrylate, methyl methacrylate) 3.1 g zirconium dioxide	1 ampoule (10 ml liquid) contains: 9.2 g methyl methacrylate 0.2 g N, N-dimethyl-p-toluidine Other constituents: Chlorophyll VIII

	0.2 g benzoyl peroxide	Hydroquinone
Refobacin® Bone Cement R 40	1 pouch of 40.8 g powder contains: 0.8 g gentamicin sulphate (corresponding to 0.5 g gentamicin) 33.6 g poly (methyl acrylate, methyl methacrylate) 6.1 g zirconium dioxide 0.3 g benzoyl peroxide	1 ampoule (20 ml liquid) contains: 18.4 g methyl methacrylate 0.4 g N, N-dimethyl-p-toluidine Other constituents: Chlorophyll VIII Hydroquinone
Refobacin® Bone Cement R 60	1 pouch of 61.3 g powder contains: 1.3 g gentamicin sulphate (corresponding to 0.8 g gentamicin) 50.3 g poly (methyl acrylate, methyl methacrylate) 9.2 g zirconium dioxide 0.5 g benzoyl peroxide	1 ampoule (30 ml liquid) contains: 27.6 g methyl methacrylate 0.6 g N, N-dimethyl-p-toluidine Other constituents: Chlorophyll VIII Hydroquinone

Table 14.4: Proposed **Refobacin® Bone Cement R** Pack Sizes

Item Number	Description	Pack Contents	Sterility
5003920002	REFOBACIN BONE CEMENT R 2X20 US	Pack consists of: 2 pouches* of 20.4 g powder each 2 ampoules* of 10 ml liquid each	Powder component: sterilized with ethylene oxide gas. Liquid component: sterilized by sterile filtration and aseptically filled. The exterior of the glass ampoule containing the liquid component is sterilized by ethylene oxide.
5003940001	REFOBACIN BONE CEMENT R 1X40	Pack consists of: 1 pouch* of 40.8 g powder 1 ampoule* of 20 ml liquid	
5003940002	REFOBACIN BONE CEMENT R 2X40	Pack consists of: 2 pouches* of 40.8 g powder each 2 ampoules* of 20 ml liquid each	
5003960001	REFOBACIN BONE CEMENT R 1X60 US	Pack consists of: 1 pouch* of 61.3 g powder 1 ampoule* of 30 ml liquid	

*See Table 14.3 for materials contained within pouches and ampoules

Table 14.5: Component Composition of **Optipac® Refobacin® Bone Cement R**

Size	Powder Composition	Monomer Composition
Optipac® Knee Refobacin® Bone Cement R	1 Mixing Cartridge of 25.2g powder contains: 0.5g gentamicin sulphate (corresponding to 0.3g gentamicin) 20.7g poly (methyl acrylate, methyl methacrylate)	1 softpac of 12.4 ml Liquid contains: 11.4g methyl methacrylate 0.2gN, N-dimethyl-p-toluidine Other constituents:

	3.8g zirconium dioxide 0.2g benzoyl peroxide	Chlorophyll VIII Hydroquinone
Optipac® Refobacin® Bone Cement R 40	1 mixing cartridge of 40.8 g powder contains: 0.8 g gentamicin sulphate (corresponding to 0.5 g gentamicin) 33.6 g poly (methyl acrylate, methyl methacrylate) 6.1 g zirconium dioxide 0.3 g benzoyl peroxide	1 softpac of 20.0 ml Liquid contains: 18.4 g methyl methacrylate 0.4 g N, N-dimethyl-p-toluidine Other constituents: Chlorophyll VIII Hydroquinone
Optipac® Refobacin® Bone Cement R 60	1 mixing cartridge of 61.3 g powder contains: 1.3 g gentamicin sulphate (corresponding to 0.8 g gentamicin) 50.3 g poly (methyl acrylate, methyl methacrylate) 9.2 g zirconium dioxide 0.5 g benzoyl peroxide	2 softpacs of 15.0 ml (30ml total) Liquid contains: 27.6 g methyl methacrylate 0.6 g N, N-dimethyl-p-toluidine Other constituents: Chlorophyll VIII Hydroquinone
Optipac® Refobacin® Bone Cement R 80	1 mixing cartridge of 81.6 g powder contains: 1.6 g gentamicin sulphate (corresponding to 1.0 g gentamicin) 67.2 g poly (methyl acrylate, methyl methacrylate) 12.2 g zirconium dioxide 0.6 g benzoyl peroxide	2 softpacs of 20.0 ml (40ml total) Liquid contains: 36.8 g methyl methacrylate 0.8 g N, N-dimethyl-p-toluidine Other constituents: Chlorophyll VIII Hydroquinone
Optipac® Hip Set RBCR	1 mixing cartridge of 81.6 g powder contains: 1.6 g gentamicin sulphate (corresponding to 1.0 g gentamicin) 67.2 g poly (methyl acrylate, methyl methacrylate) 12.2 g zirconium dioxide 0.6 g benzoyl peroxide 1 mixing cartridge of 40.8 g powder contains: 0.8 g gentamicin sulphate (corresponding to 0.5 g gentamicin) 33.6 g poly (methyl acrylate, methyl methacrylate) 6.1 g zirconium dioxide 0.3 g benzoyl peroxide	2 softpacs of 20.0 ml (40ml total) Liquid contains: 36.8 g methyl methacrylate 0.8 g N, N-dimethyl-p-toluidine 1 softpac of 20.0 ml Liquid contains: 18.4 g methyl methacrylate 0.4 g N, N-dimethyl-p-toluidine Other constituents: Chlorophyll VIII Hydroquinone

Table 14.6: Proposed **Optipac®-Refobacin® Bone Cement R** Pack Sizes

Item Number	Description	Pack Contents	Sterility
5709500392	OPTIPAC KNEE REFOBACIN BONE CEMENT R	• 1 mixing system pre-packed with polymer powder and monomer liquid* • 1 mixing rod • 1 knee nozzle (breakable) • 1 vacuum line with sterile	Powder component and convenience kit items: sterilized with ethylene oxide gas. Liquid component: sterilized by sterile

		filter	filtration and aseptically filled. Exterior of Softpac sterilized with ethylene oxide gas as part of Optipac® system.
5710500394	OPTIPAC 40 REFOBACIN BONE CEMENT R	• 1 mixing system pre-packed with polymer powder and monomer liquid* • 1 mixing rod • 1 breakaway cement nozzle • 1 knee nozzle (breakable) • 1 vacuum line with sterile filter	
5711500396	OPTIPAC 60 REFOBACIN BONE CEMENT R	• 1 mixing system pre-packed with polymer powder and monomer liquid* • 1 mixing rod • 1 breakaway cement nozzle • 1 vacuum line with sterile filter • 1 femoral pressurizer	
5712500398	OPTIPAC 80 REFOBACIN BONE CEMENT R	• 1 mixing system pre-packed with polymer powder and monomer liquid • 1 mixing rod • 1 breakaway cement nozzle • 1 vacuum line with sterile filter • 1 femoral pressurizer	
5740500394	OPTIPAC HIP SET RBCR	Optipac 80: • 1 mixing system pre-packed with polymer powder and monomer liquid • 1 mixing rod • 1 breakaway cement nozzle • 1 vacuum line with sterile filter 1 femoral pressurizer And Optipac 40: • 1 mixing system pre-packed with polymer powder and monomer liquid* • 1 mixing rod • 1 breakaway cement	

		nozzle • 1 knee nozzle (breakable) • 1 vacuum line with sterile filter	

*See Table 14.5 for materials contained within mixing system and Softpacs.

Figure 2: Assembled Optipac®- Refobacin® Bone Cement R with one or two Softpac pouches

14.1.4.1 Compatible Device Components – Implants

As is standard with cleared bone cements the subject device is compatible with joint arthroplasty implants indicated for cemented use. The specific implant IFU should be referenced to confirm use with bone cement.

14.1.4.2 Convenience Kit

The subject device, when packaged in the Optipac®, is distributed as part of a convenience kit. The sterile, single use items included in the kit are used in the application of bone cement to the surgical site. Section 14.5 provides kit certification information for the items included in the kit.

14.2 Manufacturing Information

(b)(4)

[redacted]

(b)(4)

[redacted]

[redacted].

14.3 Minor Modifications to the Device, and Implant-Specific Accessories Since the Last Clearance

Refobacin® Bone Cement R is not currently cleared for use in the US, thus there are no modifications since last clearance to list.

14.4 Engineering Drawings – Implants

BIOMET

Specification
PMMA Cement

Specification of Refobacin Bone Cement R 20 Ref. 300392

	#	Parameter	Specification	Unit	Responsibilities
Powder					
	1)	Appearance	(b)(4)	-- / --	(b)(4)
	2)	Fill weight (sachet)	(b)(4)	g	(b)(4)
	2a)	Mean weight of sachet	(b)	g	(b)(4)
	3)	Content MMA / MA copolymer	(b)(4)	%	(b)(4)
	4)	Total Content Dibenzoyl peroxide	(b)(4) (b)(4)	% (g)	(b)(4)
	5)	Content Zirconium dioxide	(b)(4) (b)(4)	% (g)	(b)(4)
	6)	Content Gentamicin as active base	(b)(4)	mg / sachet	(b)(4)
optional	6a)	Release 1. day Release 3. day Release 5. day	(b)(4) (b) (b)	µg / specimen[1] µg / specimen µg / specimen	(b)(4) (b)(4)
	7)	Sterility	(b)	-- / --	(b)(4)
	8)	Content Ethylene oxide	(b)	ppm	(b)(4)
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 5833)	[redacted]	MPa	(b)(4) (b)(4)
	10)	Bending Strength (ISO 5833)	(b)	MPa	(b)(4) (b)(4)
	11)	Bending Modulus (ISO 5833)	(b)	MPa	(b) (b)(4)
	12)	Setting Time (ISO 5833)	(b)(4)	min:sec	(b)(4)

(b)(4)

(b)(4)

Schilke	Date 14.06.2012	Signature:	(b)(4)
Gharzouli	Date 14 juin 2012	Signature:	

BIOMET

Specification of Refobacin Bone Cement R 40 Ref. 300394

	#	Parameter	Specification	Unit	Responsibilities
Powder			(b)(4) [redacted]		(b)(4) [redacted]
	1)	Appearance		-- / --	
	2)	Fill weight (sachet)		g	
	2a)	Mean weight of sachet		g	
	3)	Content MMA / MA copolymer		%	
	4)	Total Content Dibenzoyl peroxide		% (g)	
	5)	Content Zirconium dioxide		% (g)	
	6)	Content Gentamicin as active base		mg / sachet	
optional	6a)	Release 1. day Release 3. day Release 5. day		µg / specimen[1] µg / specimen µg / specimen	
	7)	Sterility		-- / --	
	8)	Content Ethylene oxide		ppm	
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 5833)		MPa	
	10)	Bending Strength (ISO 5833)		MPa	
	11)	Bending Modulus (ISO 5833)		MPa	
	12)	Setting Time (ISO 5833)		min:sec	

1 (b)(4) [redacted]

(b)(4) [redacted]	Date 12.04.2012	Signature:	(b)(4) [redacted]
	Date 24/04/12	Signature:	

BIOMET

Specification of Refobacin Bone Cement R 60 Ref. 300396

	#	Parameter	Specification	Unit	Responsibilities
Powder			(b)(4) [redacted]		(b)(4) [redacted]
	1)	Appearance		-- / --	
	2)	Fill weight (sachet)		g	
	2a)	Mean weight of sachet		g	
	3)	Content MMA / MA copolymer		%	
	4)	Total Content Dibenzoyl peroxide		% (g)	
	5)	Content Zirconium dioxide		% (g)	
	6)	Content Gentamicin as active base		mg / sachet	
optional	6a)	Release 1. day Release 3. day Release 5. day		µg / specimen[1] µg / specimen µg / specimen	
	7)	Sterility		-- / --	
	8)	Content Ethylene oxide		ppm	
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 5833)		MPa	
	10)	Bending Strength (ISO 5833)		MPa	
	11)	Bending Modulus (ISO 5833)		MPa	
	12)	Setting Time (ISO 5833)		min:sec	

(b)(4) [redacted]

(b)(4) [redacted]

Date	12.04.2012	Signature:	(b)(4) [redacted]
Date	24/04/12	Signature:	

BIOMET

Formblatt
Specification
PMMA Cement

Specification of Refobacin Bone Cement R 20

	#	Parameter	Specification	Unit	Respon-sibilities
Powder			(b)(4) [redacted]		(b)(4) [redacted]
	1)	Appearance		-- / --	
	2)	Fill weight (sachet)		g	
	2a)	Mean weight of sachet		g	
	3)	Content MMA / MA copolymer		%	
	4)	Total Content Dibenzoyl peroxide		% (g)	
	5)	Content Zirconium dioxide		% (g)	
	6)	Content Gentamicin as active bas		mg / sachet	
optional	6a)	Release 1. day Release 3. day Release 5. day		µg / specimen[1] µg / specimen µg / specimen	
	7)	Sterility		-- / --	
	8)	Content Ethylene oxide		ppm	
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 5833)		MPa	
	10)	Bending Strength (ISO 5833)		MPa	
	11)	Bending Modulus (ISO 5833)		MPa	
	12)	Setting Time (ISO 5833)		min:sec	

[1] (b)(4) [redacted]

(b)(4) [redacted]	Datum 29.01.2009	Unterschrift:	(b)(4) [redacted]
	Datum 24.02.2009	Unterschrift:	

Specification of Refobacin Bone Cement R 40

	#	Parameter	Specification	Unit	Respon-sibilities
Powder					
	1)	Appearance	(b)(4) [redacted]	-- / --	(b)(4) [redacted]
	2)	Fill weight (sachet)	[redacted]	g	[redacted]
	2a)	Mean weight of sachet	[redacted]	g	[redacted]
	3)	Content MMA / MA copolymer	[redacted]	%	[redacted]
	4)	Total Content Dibenzoyl peroxide	[redacted]	% (g)	[redacted]
	5)	Content Zirconium dioxide	[redacted]	% (g)	[redacted]
	6)	Content Gentamicin as active base	[redacted]	mg / sachet	[redacted]
optional	6a)	Release 1. day Release 3. day Release 5. day	[redacted]	µg / specimen[1] µg / specimen µg / specimen	[redacted]
	7)	Sterility	[redacted]	-- / --	[redacted]
	8)	Content Ethylene oxide	[redacted]	ppm	[redacted]
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 5833)	[redacted]	MPa	[redacted]
	10)	Bending Strength (ISO 5833)	[redacted]	MPa	[redacted]
	11)	Bending Modulus (ISO 5833)	[redacted]	MPa	[redacted]
	12)	Setting Time (ISO 5833)	[redacted]	min:sec	[redacted]

(b)(4) [redacted]

(b)(4) [redacted]	Datum	29.01.2009	Unterschrift:	(b)(4) [redacted]
	Datum	24.02.2009	Unterschrift:	

BIOMET

Formblatt
Specification
PMMA Cement

Specification of Refobacin Bone Cement R 60

	#	Parameter	Specification	Unit	Respon-sibilities
Powder			(b)(4) [redacted]		(b)(4) [redacted]
	1)	Appearance		– / –	
	2)	Fill weight (sachet)		g	
	2a)	Mean weight of sachet		g	
	3)	Content MMA / MA copolymer		%	
	4)	Total Content Dibenzoyl peroxide		% (g)	
	5)	Content Zirconium dioxide		% (g)	
	6)	Content Gentamicin as active base		mg / sachet	
optional	6a)	Release 1. day Release 3. day Release 5. day		µg / specimen[1] µg / specimen µg / specimen	
	7)	Sterility		– / –	
	8)	Content Ethylene oxide		ppm	
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 5833)		MPa	
	10)	Bending Strength (ISO 5833)		MPa	
	11)	Bending Modulus (ISO 5833)		MPa	
	12)	Setting Time (ISO 5833)		min:sec	

(b)(4) [redacted]

(b)(4) [redacted]

Datum	29.01.2009	Unterschrift:	(b)(4) [redacted]
Datum	24.02.2008	Unterschrift:	

BIOMET

Specification
Monomer Ampoule

REF 3000197001

Specification of 10 ml Monomer Liquid for Biomet Bone Cement

#	Parameter	Specification	Unit	Responsibilities
1)	Appearance	(b)(4) [redacted]	-- / --	(b)(4) [redacted]
2)	Fill weight (ampoule)	[redacted]	g	[redacted]
2a)*	Mean fill weight (ampoule)	[redacted]	g	[redacted]
3)	Identification Chlorophyll (E645 nm)	[redacted]	-- / --	[redacted]
4)	Identification Hydroquinone	[redacted]	-- / --	[redacted]
5)	Content Methylmethacrylate	[redacted]	%	[redacted]
6)	Content N,N-Dimethyl-p-toluidin	[redacted]	%	[redacted]
7)	Refractive Index	[redacted]	-- / --	[redacted]
8)	Stability (ISO 5833)	[redacted]	-- / --	[redacted]
9)	Sterility Liquid	[redacted]	-- / --	[redacted]
10)	Sterility Blister	[redacted]	-- / --	[redacted]
11)*	Content Hydroquinone	[redacted]	ppm	[redacted]

*) For information only. No specification.

(b)(4) [redacted]

Date: 13.04.2011 Signature: (b)(4) [redacted]

Date: 26-4-2011 Signature:

BIOMET

Specification
Monomer Ampoule

REF 3005927001

Specification of 20 ml Monomer Liquid for Biomet Bone Cement

#	Parameter	Specification	Unit	Responsibilities
		(b)(4) [redacted]		(b)(4) [redacted]
1)	Appearance		-- / --	
2)	Fill weight (ampoule)		g	
2a)*	Mean fill weight (ampoule)		g	
3)	Identification Chlorophyll (E645 nm		-- / --	
4)	Identification Hydroquinone		-- / --	
5)	Content Methylmethacrylate		%	
6)	Content N,N-Dimethyl-p-toluidin		%	
7)	Refractive Index		-- / --	
8)	Stability (ISO 5833)		-- / --	
9)	Sterility Liquid		-- / --	
10)	Sterility Blister		-- / --	
11)*	Content Hydroquinone		ppm	

*) For information only. No specification.

(b)(4) [redacted]

Date: 13.04.2011 Signature (b)(4) [redacted]

Date: 26-4-2011 Signature

BIOMET

Specification
Monomer Ampoule

REF 3005227001

Specification of 30 ml Monomer Liquid for Biomet Bone Cement

#	Parameter	Specification	Unit	Responsibilities
		(b)(4) [redacted]		(b)(4) [redacted]
1)	Appearance		-- / --	
2)	Fill weight (ampoule)		g	
2a)*	Mean fill weight (ampoule)		g	
3)	Identification Chlorophyll (E645		-- / --	
4)	Identification Hydroquinone		-- / --	
5)	Content Methylmethacrylate		%	
6)	Content N,N-Dimethyl-p-toluidir		%	
7)	Refractive Index		-- / --	
8)	Stability (ISO 5833)		-- / --	
9)	Sterility Liquid		-- / --	
10)	Sterility Blister		-- / --	
11)*	Content Hydroquinone		ppm	

*) For information only. No specification.

(b)(4) [redacted]

Date:	13.04.2011	Signature:	(b)(4) [redacted]
Date:	26-4-2011	Signature:	

BIOMET

Specification of Optipac Knee Refobacin Bone Cement Ref. 500392

	#	Parameter	Specification	Unit	Responsibilities
Powder					
	1)	Appearance	(b)(4) [redacted]	-- / --	(b)(4) [redacted]
	2)	Fill weight (cylinder)	[redacted]	g	[redacted]
	2a)	Mean fill weight of cylinder	[redacted]	g	[redacted]
	3)	Content MMA / MA copolymer	[redacted]	%	[redacted]
	4)	Total Content Dibenzoyl peroxide	[redacted]	% (g)	[redacted]
	5)	Content Zirconium dioxide	[redacted]	% (g)	[redacted]
	6)	Content Gentamicin as active ba	[redacted]	mg / cylinder	[redacted]
optional	6a)	Release 1. day Release 3. day Release 5. day	[redacted]	µg / specimen[1] µg / specimen µg / specimen	[redacted]
	7)	Sterility	[redacted]	-- / --	[redacted]
	8)	Content Ethylene oxide	[redacted]	ppm	[redacted]
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 583	[redacted]	MPa	[redacted]
	10)	Bending Strength (ISO 5833)	[redacted]	MPa	[redacted]
	11)	Bending Modulus (ISO 5833)	[redacted]	MPa	[redacted]
	12)	Setting Time (ISO 5833)	[redacted]	min:sec	[redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Date: 12.04.2012 Signature: (b)(4) [redacted]

Date: 19/04/12 Signature: [redacted]

BIOMET

Specification of Optipac 40 Refobacin Bone Cement Ref. 500394

	#	Parameter	Specification	Unit	Responsibilities
Powder					
	1)	Appearance	(b)(4) [redacted]	-- / --	(b)(4) [redacted]
	2)	Fill weight (cylinder)	[redacted]	g	[redacted]
	2a)	Mean fill weight of cylinder	[redacted]	g	[redacted]
	3)	Content MMA / MA copolymer	[redacted]	%	[redacted]
	4)	Total Content Dibenzoyl peroxide	[redacted]	% (g)	[redacted]
	5)	Content Zirconium dioxide	[redacted]	% (g)	[redacted]
	6)	Content Gentamicin as active base	[redacted]	mg / cylinder	[redacted]
optional	6a)	Release 1. day Release 3. day Release 5. day	[redacted]	µg / specimen[1] µg / specimen µg / specimen	[redacted]
	7)	Sterility	[redacted]	-- / --	[redacted]
	8)	Content Ethylene oxide	[redacted]	ppm	[redacted]
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 5833)	[redacted]	MPa	[redacted]
	10)	Bending Strength (ISO 5833)	[redacted]	MPa	[redacted]
	11)	Bending Modulus (ISO 5833)	[redacted]	MPa	[redacted]
	12)	Setting Time (ISO 5833)	[redacted]	min:sec	[redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Date 12.04.2012 Signature: (b)(4) [redacted]

Date 19.04.2012 Signature: [redacted]

BIOMET

Specification of Optipac 60 Refobacin Bone Cement Ref. 500396

	#	Parameter	Specification	Unit	Responsibilities
Powder					
	1)	Appearance	(b)(4) [redacted]	-- / --	(b)(4) [redacted]
	2)	Fill weight (cylinder)		g	
	2a)	Mean fill weight of cylinder		g	
	3)	Content MMA / MA copolymer		%	
	4)	Total Content Dibenzoyl peroxide		% (g)	
	5)	Content Zirconium dioxide		% (g)	
	6)	Content Gentamicin as active base		mg / cylinder	
optional	6a)	Release 1. day Release 3. day Release 5. day		µg / specimen[1] µg / specimen µg / specimen	
	7)	Sterility		-- / --	
	8)	Content Ethylene oxide		ppm	
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 5833)		MPa	
	10)	Bending Strength (ISO 5833)		MPa	
	11)	Bending Modulus (ISO 5833)		MPa	
	12)	Setting Time (ISO 5833)		min:sec	

(b)(4) [redacted]

(b)(4) [redacted]	Date 12.04.2012	Signature:	(b)(4) [redacted]
	Date 19/04/12	Signature:	

BIOMET

Specification of Optipac 80 Refobacin Bone Cement Ref. 500398

	#	Parameter	Specification	Unit	Responsibilities
Powder					
	1)	Appearance	(b)(4) [redacted]	-- / --	(b)(4) [redacted]
	2)	Fill weight (cylinder)	[redacted]	g	[redacted]
	2a)	Mean fill weight of cylinder	[redacted]	g	[redacted]
	3)	Content MMA / MA copolymer	[redacted]	%	[redacted]
	4)	Total Content Dibenzoyl peroxide	[redacted]	% (g)	[redacted]
	5)	Content Zirconium dioxide	[redacted]	% (g)	[redacted]
	6)	Content Gentamicin as active bas	[redacted]	mg / cylinder	[redacted]
optional	6a)	Release 1. day Release 3. day Release 5. day	[redacted]	µg / specimen µg / specimen µg / specimen	[redacted]
	7)	Sterility	[redacted]	-- / --	[redacted]
	8)	Content Ethylene oxide	[redacted]	ppm	[redacted]
Powder / Monomer Combination					
	9)	Compressive Strength (ISO 5833	[redacted]	MPa	[redacted]
	10)	Bending Strength (ISO 5833)	[redacted]	MPa	[redacted]
	11)	Bending Modulus (ISO 5833)	[redacted]	MPa	[redacted]
	12)	Setting Time (ISO 5833)	[redacted]	min:sec	[redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Date	12.04.2012	Signature:	(b)(4) [redacted]
Date	19/04/12	Signature:	[redacted]

BIOMET

Specification
Monomer Optipac

REF 402713

Specification of Monomer Liquid in Soft Pouch for

Optipac Knee Refobacin Bone Cement (1 Pouch)

Optipac Knee Refobacin Plus Bone Cement (1 Pouch)

#	Parameter	Specification	Unit	Responsibilities
1)	Appearance	(b)(4) [redacted]	-- / --	(b)(4) [redacted]
2)	Fill weight (pouch)		g	
2a)*	Mean fill weight (pouch)		g	
3)	Identification Chlorophyll (E645 nm)		-- / --	
4)	Identification Hydroquinone		-- / --	
5)	Content Methylmethacrylate		%	
6)	Content N,N-Dimethyl-p-toluidin		%	
7)	Refractive Index		-- / --	
8)	Sterility Liquid		-- / --	
9)	Content Hydroquinone		ppm	
10)	Content Chlorophyll		ppm	

*) For information only. No specification.

(b)(4) [redacted]	Date: 08/05/2012	Signature:	(b)(4) [redacted]
	Date: 12/06/2012	Signature:	

BIOMET

Specification
Monomer Optipac

REF 402720

Specification of 20 ml Monomer Liquid for Optipac in Soft Pouch for

Optipac 40 Refobacin Bone Cement R (1 Pouch)

Optipac 80 Refobacin Bone Cement R (2 Pouches)

Optipac 40 Refobacin Plus Bone Cement (1 Pouch)

Optipac 40 Refobacin Revision (1 Pouch)

#	Parameter	Specification	Unit	Responsibilities
1)	Appearance	(b)(4) [redacted]	-- / --	(b)(4) [redacted]
2)	Fill weight (pouch)	[redacted]	g	[redacted]
2a)*	Mean fill weight (pouch)	[redacted]	g	[redacted]
3)	Identification Chlorophyll (E645 nm	[redacted]	-- / --	[redacted]
4)	Identification Hydroquinone	[redacted]	-- / --	[redacted]
5)	Content Methylmethacrylate	[redacted]	%	[redacted]
6)	Content N,N-Dimethyl-p-toluidin	[redacted]	%	[redacted]
7)	Refractive Index	[redacted]	-- / --	[redacted]
8)	Sterility Liquid	[redacted]	-- / --	[redacted]
9)	Content Hydroquinone	[redacted]	ppm	[redacted]
10)	Content Chlorophyll	[redacted]	ppm	[redacted]

*) For information only. No specification.

(b)(4) [redacted]

Date: 08/05/2012 Signature: (b)(4) [redacted]

Date: 12/06/2012 Signature: [redacted]

BIOMET

Specification
Monomer Optipac

REF 402715

Specification of 15 ml Monomer Liquid for Optipac in Soft Pouch for

Optipac 60 Refobacin Bone Cement R (2 Pouches)

Optipac 60 Refobacin Plus Bone Cement (2 Pouches)

#	Parameter	Specification	Unit	Responsibilities
1)	Appearance	(b)(4) [redacted]	-- / --	(b)(4) [redacted]
2)	Fill weight (pouch)		g	
2a)*	Mean fill weight (pouch)		g	
3)	Identification Chlorophyll (E645 nm)		-- / --	
4)	Identification Hydroquinone		-- / --	
5)	Content Methylmethacrylate		%	
6)	Content N,N-Dimethyl-p-toluidin		%	
7)	Refractive Index		-- / --	
8)	Sterility Liquid		-- / --	
9)	Content Hydroquinone		ppm	
10)	Content Chlorophyll		ppm	

*) For information only. No specification

(b)(4) [redacted]

Date: 08/05/2012 Signature: (b)(4) [redacted]

Date: 12/06/2012 Signature:

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

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14.5 Kit Certification Information

(b)(4)Certification

15 Substantial Equivalence Discussion

15.1 Substantial Equivalence Discussion

15.1.1 Predicate Devices

The predicate devices for **Refobacin® Bone Cement R** are listed in Table 15.1

Table 15.1: Predicate Devices

Device	Manufacturer	510(k) Number
Palacos® G*	Heraeus Kulzer GmbH & Co.KG	K031673

*The product obtained for testing and labeling comparison is labeled as Palacos® R+G

The 510(k) Summary and IFU for the predicate device can be found at the end of this section (Attachment 1 and 2 respectively).

15.1.2 Intended Use and Indications for Use

The subject device has the same indications for use as the predicate device.

15.1.3 Technological Characteristics

The subject device has similar technological characteristics as the predicate. Both the predicate and subject devices are fast setting polymer systems containing gentamicin for use in bone surgery. Both devices provide two separate, pre-measured sterilized components which when mixed form a radiopaque rapidly setting bone cement. (b)(4) [redacted] Refobacin® Bone Cement R powder does not contain Chlorophyll VIII; however it is present in the monomer. The lack of Chlorophyll VIII in the subject device powder does not raise issues of safety/effectiveness as it is present in the monomer and serves the optical marking of the bone cement at the site of the operation.

The shelf life of the subject device, Refobacin® Bone Cement R, is less than that of the predicate device, Palacos® G. Shelf life of Class II medical devices is established by testing performed by the manufacturer and is considered as part of a 510(k) submission. However, extensions to the cleared shelf life of a Class II medical device may be completed by the manufacturer as long as certain conditions are met and internal documentation is compiled and kept on file by the manufacturer. The difference in shelf life between the subject and predicate device does not raise issues of safety/effectiveness as the initial cleared shelf life may be extended at the discretion of the individual manufacturers over the lifetime of the medical devices.

The subject device is available in multiple sizes and different packaging configurations as compared to the predicate device. The subject device is available in two packaging configurations, while the predicate device is available in one. The

first packaging configuration (powder pouches, amber glass ampoule) for the subject device is identical to the predicate and does not raise new issues of safety/effectiveness. The other (Optipac®) is a mixing and application system pre-packed with the subject device. The biocompatibility testing indicates that the subject device packaged with the Optipac® does not raise issues of safety with regards to cytotoxic potential.

The predicate device is available in one size and the subject device is available in multiple sizes (see Section 14 for additional details). (b)(4) [redacted] The sterilization methods for the powder and monomer for the different sizes and packaging configurations of the subject device are the same as the predicate device. The amounts of the materials used in the subject device vary depending on the cement unit size; however, (b)(4) [redacted] same sterilization for the powder and monomer, (b)(4) [redacted] and thus the differences described above do not raise new issues of safety/effectiveness.

15.1.4 Performance -- Test Results

The test results (Section 21) show that the subject device (including the subject device packaged in Optipac®) meets all the consensus standards for bone cement, as well as being substantially equivalent to the predicate device. However, as is to be expected when performing such a large number and diversity of tests, the summary also shows that there were several differences between the subject device and the predicate device. Some of these differences were statistically significant. In some cases, the predicate device outperformed the subject device, while in other cases the subject device outperformed the predicate device. In nearly all of the cases, the differences, even if statistically significant, were of small magnitude (b)(4) [redacted] This variation is in line with past cement testing experiences, thus the test results demonstrate that the subject device is substantially equivalent.

15.1.5 Manufacturing

(b)(4) [redacted]

(b)(4)

[redacted]

15.1.6 Substantial Equivalence Comparison Table

Please see the Substantial Equivalence Comparison Table (Section 15.2).

15.1.7 Conclusion

The proposed Refobacin® Bone Cement R has the same intended use and indications for use as the predicate device. The proposed device has similar technological characteristics to the predicate, and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate device.

15.2 Substantial Equivalence Comparison Table

Device Comparison	Subject Device	Predicate Device (K031673)
Name	Refobacin® Bone Cement R	Palacos® G
Manufacturer	Biomet France SARL	Heraeus Kulzer GmbH & Co. KG
Product Code	MBB, LOD	MBB, LOD
Intended Use	The primary use for bone cement is in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone with reconstruction is necessary.	The primary use for bone cement is in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone with reconstruction is necessary.
Indications for Use	Refobacin® Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.	Palacos® R+G** is indicated for use as bone cement in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.
Cement Design	Refobacin® Bone Cement R and Optipac® Refobacin® Bone Cement R provide two separate, pre-measured sterilized components which when mixed form a radiopaque rapidly setting bone cement.	Palacos® R+G provides two separate, pre-measured sterilized components which when mixed form a radiopaque rapidly setting bone cement.
Principle of Operation	When the powder (copolymer) and the liquid (monomer) are mixed, the dimethyl-p-toluidine in the liquid activates the benzoyl peroxide catalyst in the powder. This initiates the polymerization of the monomer,	When the powder (copolymer) and the liquid (monomer) are mixed, the dimethyl-p-toluidine in the liquid activates the benzoyl peroxide catalyst in the powder. This initiates the polymerization of the monomer,

Device Comparison	Subject Device	Predicate Device (K031673)
	which then binds together granules of polymer. As polymerization proceeds, a sticky dough-like mass is formed, which, after about 30 seconds, can be manipulated for about 5 minutes. Polymerization is an exothermic reaction and although the spontaneous generation of heat accelerates the reaction, the polymerization of this self-curing resin occurs even if the temperature is reduced by irrigation with a cool physiologic saline solution.	which then binds together granules of polymer. As polymerization proceeds, a sticky dough-like mass is formed, which, after about 30 seconds, can be manipulated for about 5 minutes. Polymerization is an exothermic reaction and although the spontaneous generation of heat accelerates the reaction, the polymerization of this self-curing resin occurs even if the temperature is reduced by irrigation with a cool physiologic saline solution.
Powder Constituents (Materials)	Poly (methyl acrylate, methyl methacrylate) Zirconium dioxide (X-ray contrast medium) Hydrous benzoyl peroxide Gentamicin sulphate	Poly (methyl acrylate, methyl methacrylate) Zirconium dioxide (X-ray contrast medium) Hydrous benzoyl peroxide Gentamicin sulphate Chlorophyll VIII
Monomer Constituents (Materials)	Methyl methacrylate N, N-dimethyl-p-toluidine Hydroquinone Chlorophyll VIII	Methyl methacrylate N, N-dimethyl-p-toluidine Hydroquinone Chlorophyll VIII

Device Comparison	Subject Device	Predicate Device (K031673)
Sterilization Methods: powder and monomer	**Powder Component** Ethylene Oxide (EO) **Liquid Monomer Component** Sterile Filtered	**Powder Component** Ethylene Oxide (EO) **Liquid Monomer Component** Sterile Filtered
Packaging Configurations	(b)(4) [redacted]	1 Configuration: **Powder Component** Double packaged in gas permeable sterile packets, enclosed in a non-sterile paper-foil protective pouch. **Liquid Monomer Component** Glass Ampoule packaged in a protective Tyvek blister pack.
Sizes	**Refobacin Bone Cement R** REFOBACIN® BONE CEMENT R 2X20 REFOBACIN® BONE CEMENT R 1X40 REFOBACIN® BONE CEMENT R 2X40 REFOBACIN®BONE CEMENT R 1X60 **Optipac- Refobacin Bone Cement R** OPTIPAC® KNEE OPTIPAC® 40 OPTIPAC® 60	Palacos® R+G 1x40

Device Comparison	Subject Device	Predicate Device (K031673)
	OPTIPAC® 80 OPTIPAC® HIP SET RBCR	
Shelf Life	**Refobacin® Bone Cement R** 3 years **Optipac® Refobacin® Bone Cement R** 18 months	4 years
Chemical **Handling** **Physical** **Mechanical**	See Section 21	See Section 21

**K031673 Palacos® G was identified as the predicate in the FDA Pre-Market (510k) database. However, the actual, commercialized product located for testing and labeling comparison is labeled as Palacos® R+G.

K031673 page 1 of 1

Heraeus

MAY 2 5 2004

510(k) Summary

Applicant's name and address	Heraeus Kulzer GmbH & Co. KG Grüner Weg 11 D-63450 Hanau
Contact persons	Dr. K.-D. Kühn phone: +49 6081 959-264 fax: +49 6081 959-288 klaus-dieter.kuehn@heraeus.com Dr. C. Tuchscherer phone: +49 6081 959-278 fax: +49 6081 959-288 christian.tuchscherer@heraeus.com
Date of actualized summary	May 11th, 2004
Device trade name	PALACOS® G
Classification name	Bone Cement
Identification of the marketed device to which equivalence is claimed	PALACOS® R BONE CEMENT PMA Number: P810020
Description of the device	Palacos® G is an acrylic bone cement for use in orthopedic surgery. It is formed from powder and liquid by exothermic polymerization. It secures the fixation of the grafted artificial joint improving the transfer of forces at the interface implant - bone.
Intended use	The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.
Comparison of technological characteristics	This is the well known Refobacin®-Palacos® R being marketed for many years in Europe. It performs most similar to Palacos R.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2004

Dr. Klaus-Dieter Kühn
Heraeus Kulzer GmbH & Co. KG
Grüner Weg 11
D-63450 Hanau
Germany

Re: K031673
Trade/Device Name: Palacos G
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD and MBB
Dated: February 24, 2004
Received: February 27, 2004

Dear Dr. Kühn:

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.

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) 594-4639. 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 may be obtained 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,

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

Indications for Use

510(k) Number (if known): K031673

Device Name: PALACOS G

Indications For Use:

PALACOS G is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

Prescription Use yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use no (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K031673

Page 1 of _____

Symbols

Manufacturer	Do not store above 25° (77°F)
STERILE EO Sterilized using ethylene oxide	STERILE A Sterilized using aseptic processing techniques
Consult instructions for use	Do not re-use
Flammable liquid – Flashpoint 10 °C	Use by date
LOT Batch code	Keep away from sunlight

Cat. No.: 00-1113-140-01

PALACOS® R+G

Radiopaque bone cement containing gentamicin

Instructions for use

zimmer

Distributed by:
Zimmer Surgical, Inc.
200 West Ohio Avenue
Dover, Ohio 44622 U.S.A.

Heraeus

Manufacturer:
Heraeus Medical GmbH
Philipp-Reis-Strasse 8/13
61273 Wehrheim, Germany

66020500/04289
01/12

PALACOS® R+G

Uses and properties
PALACOS® R+G is a fast setting polymer containing gentamicin, for use in bone surgery. Mixing of the two component system, consisting of a powder and a liquid, initially produces a liquid and then a paste, which is used to anchor the prosthesis to the bone. The hardened bone cement allows stable fixation of the prosthesis and transfers all stresses produced in a movement to the bone via the large interface. Insoluble zirconium dioxide is included in the cement powder as an X ray contrast medium. The chlorophyll additive serves as optical marking of the bone cement at the site of the operation.

Indications
PALACOS® R+G is indicated for use as bone cement in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

Contraindications
PALACOS® R+G must not be used during pregnancy or the nursing period.
PALACOS® R+G must not be used in patients with infectious arthritis.
PALACOS® R+G must not be used in active infection of the joint or joints to be replaced.
PALACOS® R+G must not be used in cases of known hypersensitivity to gentamicin or to other constituents of the bone cement. A history of hypersensitivity or serious toxic reactions to other aminoglycosides may contraindicate use of gentamicin because of known cross-sensitivity of patients to drugs in this class.
Relative contraindications include:
(1) uncooperative patient or patient with neurologic disorder who is incapable of following directions
(2) metabolic disorders which may impair bone formation
(3) osteomalacia
(4) distant foci of infections which may spread to the implant site
(5) rapid joint destruction, marked bone loss or bone resorption, vascular insufficiency, muscular atrophy, or neuromuscular disease
(6) hypotension
(7) congestive heart failure
(8) renal impairment

Adverse effects
Neurotoxicity
(1) manifested as both auditory and vestibular ototoxicity, including irreversible hearing loss;
(2) numbness;
(3) skin tingling;
(4) muscle twitching; and
(5) convulsions.
Nephrotoxicity
(1) usually in patients with pre-existing renal damage; and
(2) also in patients with normal renal function to whom aminoglycosides are administered for longer periods or in higher doses than recommended, the symptoms of which may manifest after cessation of therapy.

Composition	PALACOS® R+G
	1 pouch of 40.8 g powder contains:
poly(methyl acrylate, methyl methacrylate)	33.6 g
zirconium dioxide	6.1 g
hydrous benzoyl peroxide	0.3 g
gentamicin base (as sulphate)	0.50 g
	1 ampoule of 20 ml liquid contains:
methyl methacrylate	18.4 g
N,N-dimethyl-p-toluidine	0.4 g
Other constituents:	In the powder: chlorophyll VIII In the liquid: chlorophyll VIII in an oily solution, hydroquinone

Disclaimer
It has not been clinically proven that the antibiotic effect of the drug gentamicin holds for the gentamicin-loaded bone cement.

Side effects
After preparation of the prosthesis bed or directly after the implantation of the cement and prosthesis, pressure rise in the medullary canal may cause a temporary fall in blood pressure. In addition to hypotension, pulmonary embolism and cardiac arrest with their potentially fatal consequences have been encountered in rare cases. These cardiovascular and respiratory side effects known as the implantation syndrome are caused by infiltration of bone marrow constituents into the venous vascular system.
The site of the prosthesis should therefore be rinsed thoroughly with an isotonic solution (e.g. physiological saline) before implantation. To minimize the large pressure increase in the medullary canal during the prosthesis implantation, suction drainage is recommended. In the presence of pulmocardiovascular disturbances, the liquid volume must be monitored as appropriate and anaesthesiological measures may be required e.g. in the event of acute respiratory failure. The gentamicin content of **PALACOS® R+G** may cause hypersensitivity reactions in isolated cases.
Application of gentamicin may, in principle, trigger the typical adverse reactions of this antibiotic, which are in particular, damage to hearing and to the kidneys. However, these adverse reactions are very unlikely to occur as the serum levels required to cause damage are not reached.

Precautions
Monitoring:
(1) patients receiving gentamicin should be periodically monitored with peak and trough levels of the antibiotic, serum electrolytes, serum renal function, urinalysis, and audiograms (in the elderly and/or dehydrated patient in whom there is a higher risk of adverse events associated with gentamicin use).
(2) Use of gentamicin should be avoided in the following situations:
(a) concurrent/sequential use of other neurotoxic/nephrotoxic antibiotics;
(b) Other aminoglycosides:
(c) Cephaloridine;
(d) Viomycin;
(e) Polymixin B;
(I) Colistin;
(g) Cisplatin; and
(h) Vancomycin.

Pediatric use
A pediatric use of **PALACOS® R+G** should be thought over well by the surgeon. The cement should be used only if the risk/benefit analysis gives a clear indication.

Warnings
PALACOS® R+G is considered most unlikely to cause gentamicin overdosage, since only low (< 1 µg/ml) and shortlived serum concentrations are obtained during the first few postoperative hours from the high local gentamicin concentrations (Wahlig
et al.: Pharmacokinetic study of Gentamicin-loaded cement in total hip replacements. Comparative effects of varying dosage. J. Bone Joint Surg. 66-B: 175–179).
*Since the concentration of gentamicin may reach the nerve and the kidney, ototoxic and nephrotoxic reactions may happen following the use of **PALACOS® R+G** bone cement.* Monitor patients carefully for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements. Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. Patients should be monitored carefully for any change in blood pressure during and immediately following the application of bone cement.
Using **PALACOS® R+G** under conditions other than the indicated use is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. Follow the handling, mixing and canal preparation instructions carefully.

- Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated monomer vapors, which may produce irritation of the respiratory tract, eyes, and possibly the liver. Personnel wearing contact lenses should not be near or involved in mixing this bone cement.
- Polymerization of the bone cement is an exothermic reaction, which occurs while the cement is hardening in situ. The released heat may damage bone or other tissues surrounding the implant.
- Inadequate fixation or unanticipated postoperative events may affect the cement-bone interface and lead to micro motion of cement against bone surface. A fibrous tissue layer may develop between the cement and the bone, and loosening of the prosthesis may occur leading to implant failure. Long-term followup is advised for all patients on a regularly scheduled basis.
- When working with the monomer or the cement, gloves must be worn to ensure adequate protection against the penetration of the monomer (methyl methacrylate) into the skin. PVP (three-layer polyethylene, ethylene-vinyl alcohol-copolymer, polyethylene) and Viton/Butyl gloves have proved to provide good protection over an extended period. Putting on two pairs of gloves – one pair of polyethylene surgical gloves over a pair of standard latex surgical gloves has also proved to offer adequate protection.

The use of latex or polystyrene-butadiene gloves, however, must be avoided. Please request the confirmation of your glove supplier whether the respective gloves are suitable for the use of this cement.
Avoid over-pressurization of the bone cement because this may lead to extrusion of the bone cement beyond the site of its intended application and damage to the surrounding tissues.

Interactions
Concurrent administration of muscle relaxants and ether may potentize the neuromuscular blocking properties of gentamicin. However, due to the low serum concentrations this is unlikely to happen.

Incompatibilities
Aqueous (e.g. antibiotic-containing) solutions must not be mixed with the bone cement, as this reduces the strength considerably.

Dosage
The amount of bone cement required depends on the patient's anatomy and on the implant used. One or more complete units (the contents of one pouch and one ampule) must always be mixed together. In practice, more than four dose units per implantation are only rarely used. Even with this dose only low serum levels were determined in clinical studies.

Notes on use
Before using **PALACOS® R+G** the surgeon must be thoroughly familiar with its properties, handling and use, and must have read the relevant literature. Because the handling and curing characteristics of this bone cement vary with temperature, humidity and mixing technique, they are best determined by the surgeon's actual experience. For special mixing and application techniques (e.g. vacuum mixing, vacuum application, use of a femoral cement restrictor), the relevant instructions of these mixing and application system must be consulted. Before using **PALACOS® R+G** for the first time, a test mixing should be carried out to become familiar with the characteristics of **PALACOS® R+G.** The protective aluminum packaging and outer non sterile polyethylene pouch ("peel off" package) and the ampule packaging should be opened, maintaining sterility, by the circulating nurse. The ampule and powder pouch are then taken out under sterile conditions and placed on a sterile working surface. The ampule is opened by breaking the neck and the inner pouch is cut open with sterile scissors.

Mixing
PALACOS® R+G can be mixed by two different methods:
- Mixing without vacuum
- Mixing under vacuum after pre-chilling of the components at 4–7 °C (39–45 °F)

Mixing without vacuum
Pour the liquid into a sterile mixing bowl and add all the powder. Stir carefully with a sterile stirring rod until a homogeneous mass is obtained. The mixture should not be stirred longer than 30-sec, irrespective of the room temperature. The temperature/time diagrams must be consulted.

Vacuum mixing
To obtain a bone cement with lower porosity the components must be mixed under vacuum after pre-chilling (at least 24 h at 4–7 °C [39–45 °F]). This method requires an airtight closed system and rapid generation of sufficient vacuum (approx. 200 mbar [150 mmHg] absolute pressure) in the mixing bowl. The stirring time for vacuum mixing is the same as for mixing without vacuum (30 sec) – working time and setting time are prolonged by pre-chilling. Method of mixing is given in the instructions for the system used and must be consulted.

Use in joint surgery
An appropriate up to date cementing technique must be used with **PALACOS® R+G** to limit side effects and to achieve a stable and long lasting anchorage of the prosthesis. A prerequisite for this is careful preparation of the prosthesis site by thorough rinsing (e.g. with physiological saline) before application of the cement. Suction drainage is recommended to avoid any pressure build up in the medullary canal during implantation. Further prerequisites for better prosthesis anchoring include filling of the entire medullary canal with cement (using a femoral cement restrictor), the production of a cement mantle completely surrounding the implant (ideal thickness 3 5 mm), and biomechanically optimal siting of the implant in bone.

Working procedure
After careful preparation of the medullary canal, **PALACOS® R+G** can be applied manually or using a cement syringe or some alternative application system. Method of application is given in the instructions for the system used and must be consulted. The working time and the rate of polymerization are strongly dependent on ambient temperature and on temperature of the components. The hardening time is shorter at high temperatures and longer at low temperatures. Viscosity increases as polymerization progresses, i.e. as the cement hardens.

Manual application
The working phase starts when the paste no longer adheres to the instruments or surgical gloves and ends when the paste becomes rubbery/elastic with visible separation lines while kneading. The cement and the prosthesis must be applied within the working phase. Applying the cement after the end of the working phase may cause an uneven and inadequate filling of the medullary canal, thereby resulting in possible early loosening of the implant (see graphs).
The cement and the prosthesis must be applied within the working phase. After positioning of the implant any movement must be avoided, to ensure the anchoring of the prosthesis.

Application with a cement syringe
After mixing, the cement is poured directly into a cement syringe. The working time depends on the ambient temperature and the temperature of the components (see graphs). The times may vary depending on the syringe system used.

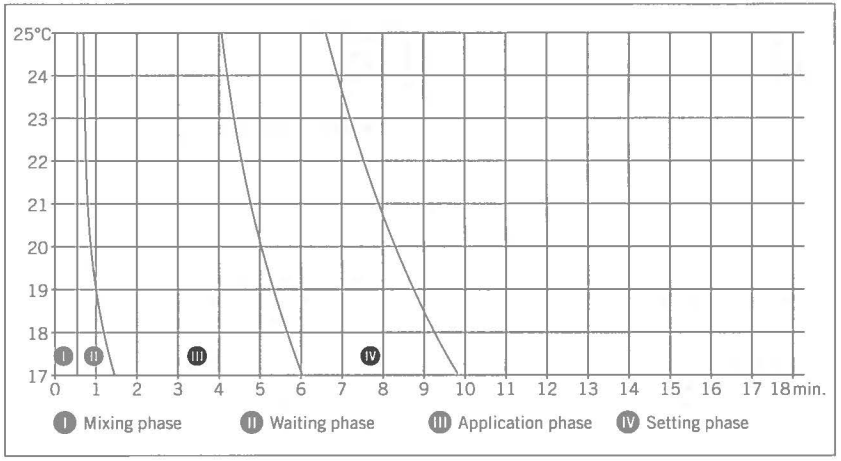
Application of vacuum-mixed cement
Pre-chilled vacuum-mixed cement is usually applied with a syringe. Consider the graphs. The instructions of the Mixing system used must be consulted.

Storage
Do not store above 25 °C (77° F).

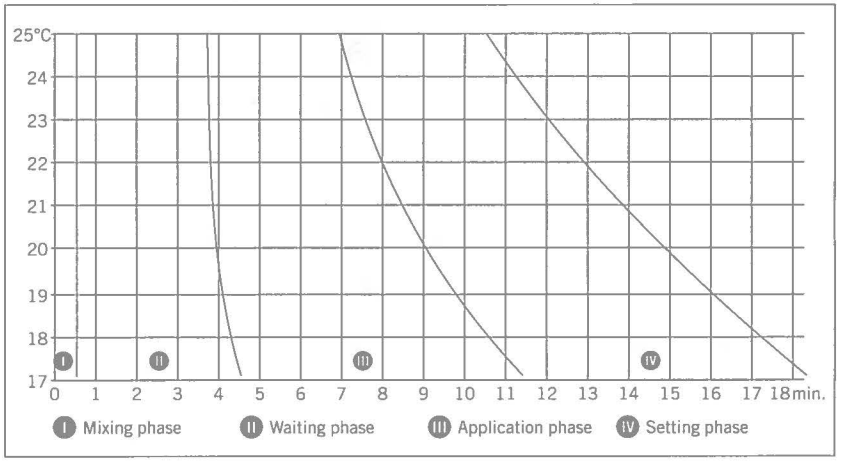
Shelf life/sterility
The expiration date is printed on the outer carton, the protective aluminum packaging and the inner pouch.
PALACOS® R+G must not be used after the expiration date.
The contents of unused but opened or damaged packs must not be resterilized and are therefore to be discarded.
PALACOS® R+G is sterilized with ethylene oxide gas and must not be resterilized.
If the polymer powder shows a yellow discoloration, it must not be used.

Information status 08/2011

Manual processing



Processing with the vacuum mixing system



Heraeus

Manufacturer:
Heraeus Medical GmbH
Philipp-Reis-Strasse 8/13
61273 Wehrheim, Germany

Under license from Heraeus Kulzer GmbH, Hanau, Germany.

CE 0123

zimmer

Distributed by:
Zimmer Surgical, Inc.
200 West Ohio Avenue
Dover, Ohio 44622 U.S.A.

16 Proposed Labeling

16.1 Proposed Labeling

Draft labeling is included as follows:

- Section 16.1.1 – Proposed Instructions for Use (IFU)
- Section 16.1.2 – Proposed/Sample Labeling

(b)(4)

[redacted]

The subject device Refobacin® Bone Cement R is intended for professional use only and, as such, the devices are exempt (per 21 CFR 801 Subpart D) from providing directions for laypersons (per 21 CFR 801.5). The draft IFUs state "Caution: Federal law (USA) restricts this device to sale by or on the order of a physician."

16.1.1 Proposed Instructions for Use (IFU)

Biomet France SARL
Plateau de Lautagne
26000 Valence France

Distributed By:
Biomet Orthopedics
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581 USA

01-50-1268
Revision A
Date: 2015-03

Refobacin Bone Cement R
ATTENTION OPERATING SURGEON

DESCRIPTION
Refobacin Bone Cement R is a fast setting polymer containing gentamicin, for use in bone surgery. Mixing of the two component system, consisting of a powder and a liquid, produces a paste, which is used to anchor the prosthesis to the bone. The hardened bone cement allows stable fixation of the prosthesis and transfers all stresses produced in a movement to the bone via the large interface. Insoluble zirconium dioxide is included in the cement powder as an X ray contrast medium. The chlorophyll additive in the liquid component serves as optical marking of the bone cement at the site of the operation.

Presentation and pack sizes

Refobacin Bone Cement R 2x20
Original pack consists of:
2 pouches of 20.4 g powder each
2 ampoules of 10 ml liquid each

Refobacin Bone Cement R 40
Original pack consists of:
1 pouch of 40.8 g powder
1 ampoule of 20 ml liquid

Refobacin Bone Cement R 2x40
Original pack consists of:
2 pouches of 40.8 g powder each
2 ampoules of 20 ml liquid each

Refobacin Bone Cement R 60
Original pack consists of:
1 pouch of 61.3 g powder
1 ampoule of 30 ml liquid

Materials
Refobacin Bone Cement R 20
1 pouch of 20.4 g powder contains:
0.4 g gentamicin sulphate (corresponding to 0 3 g gentamicin)
16.7 g poly (methyl acrylate, methyl methacrylate)
3.1 g zirconium dioxide
0.2 g benzoyl peroxide

1 ampoule (10 ml liquid) contains:
9.2 g methyl methacrylate
0.2 g N, N-dimethyl-p-toluidine

Other constituents:
In the liquid: chlorophyll VIII, hydroquinone

Refobacin Bone Cement R 40
1 pouch of 40.8 g powder contains:
0.8 g gentamicin sulphate (corresponding to 0 5 g gentamicin)
33.6 g poly (methyl acrylate, methyl methacrylate)
6.1 g zirconium dioxide
0.3 g benzoyl peroxide

1 ampoule (20 ml liquid) contains:
18.4 g methyl methacrylate
0.4 g N, N-dimethyl-p-toluidine

Other constituents:
In the liquid: chlorophyll VIII, hydroquinone

Refobacin Bone Cement R 60
1 pouch of 61.3 g powder contains:
1.3 g gentamicin sulphate (corresponding to 0.8 g gentamicin)
50.3 g poly (methyl acrylate, methyl methacrylate)
9.2 g zirconium dioxide
0.5 g benzoyl peroxide

1 ampoule (30 ml liquid) contains:
27.6 g methyl methacrylate
0.6 g N, N-dimethyl-p-toluidine

Other constituents:
In the liquid: chlorophyll VIII, hydroquinone

INDICATIONS
Refobacin Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

CONTRAINDICATIONS
Refobacin Bone Cement R must not be used in the presence of active or incompletely treated infection of the joint or joints to be replaced.
Refobacin Bone Cement R must not be used during pregnancy or the nursing period. The safety of the bone cement in pregnant women or in children has not been established. Bone cement may adversely affect bone growth and fetal health.
Refobacin Bone Cement R must not be used in cases of known hypersensitivity to gentamicin or other constituents of bone cement. A history of hypersensitivity of serious toxic reactions to other aminoglycosides may contraindicate the use of gentamicin because of known cross-sensitivity of patients to drugs in this class.
Relative contraindications include:
(1) an uncooperative patient or a patient with neurologic disorders who is incapable of following directions,
(2) metabolic disorders which may impair bone formation,
(3) osteomalacia,
(4) distant foci of infections which may spread to the implant site,
(5) rapid joint destruction, marked bone loss or bone resorption, vascular insufficiency, muscular atrophy, neuromuscular disease
(6) hypotension
(7) congestive heart failure
(8) renal impairment.

WARNINGS
Adulteration of this bone cement may negatively affect performance characteristics.
Refobacin Bone Cement R is considered most unlikely to cause gentamicin overdosage, since only low (< 1 µg/ml) and short-lived serum concentrations are obtained during the first few postoperative hours from the high local gentamicin concentrations. (Wahlig et al.: Pharmacokinetic study of Gentamicin-loaded cement in total hip replacements. Comparative effects of varying dosage. J. Bone Joint Surg. 66-B: 175-179).
Since the concentration of gentamicin may reach the nerve and the kidney, ototoxic and nephrotoxic reaction may happen following the use of ***Refobacin Bone Cement R.***
Monitor patients carefully for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements. Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 second to 5 or more minutes. Some have progressed to cardiac arrest. Patients should be monitored carefully for any change in blood pressure during and immediately following the application of bone cement.

Cardiovascular and respiratory side effects (e.g. hypotension, pulmonary embolism, and cardiac arrest) known as bone cement implantation syndrome (BCIS) are mainly caused by infiltration of bone marrow constituents into the venous vascular system. The site of the prosthesis should therefore be meticulously irrigated and dried. In the presence of pulmocardio-vascular disturbances, the patient should be monitored closely and anaesthesiological measures may be required, e.g. in the event of acute respiratory failure. In high-risk patients, for example those sustaining hip fractures, care should be taken not to over-pressurize the cement and to insert the prosthesis slowly.

Using **Refobacin Bone Cement R** under conditions other than the indicated use is unlikely to provide benefit to the patient and increases the risk of development of drug-resistant bacteria.

Follow the handling and mixing instructions carefully.

- Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated monomer vapors, which may produce irritation of the respiratory tract, eyes, general feeling of ill health such as nausea and headache and possibly irritation of the liver. Such symptoms can be minimized through adequate ventilation or by using a closed mixing system. Personnel wearing contact lenses should not be near or involved in mixing this bone cement.
- Polymerization of the bone cement is an exothermic reaction, which occurs while the cement is hardening in situ. The released heat may damage bone or other tissues surrounding the implant.
- Inadequate fixation or unanticipated postoperative event may affect the cement-bone interface and lead to micro motion of cement against the bone surface. A fibrous tissue layer may develop between the cement and the bone, and loosening of the prosthesis may occur leading to implant failure. Long-term follow-up is advised for all patients on a regularly scheduled basis.

Do not allow the liquid component to contact rubber or latex gloves. The liquid component is a powerful lipid solvent. Should contact occur, the gloves may dissolve and tissue damage may occur. Wearing a second pair of gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The mixed bone cement should not make contact with the gloved hand until the cement has acquired the consistency of dough. This usually occurs between one and two minutes after the liquid and powder components are mixed.

Avoid over-pressurization of the bone cement because this may lead to extrusion of the bone cement beyond the site of its intended application and damage the surrounding tissues. In addition, over-pressurization of the bone cement should be avoided during the insertion of the bone cement and implant in order to minimize the occurrence of pulmonary embolism and BCIS.

PRECAUTIONS

Do not use this product after the expiration date printed on the package. This device may not be safe or effective beyond its expiration date.
Follow the handling and mixing instructions to avoid contact dermatitis. Strict adherence to the instructions for mixing the powder and liquid components may reduce the incidence of this complication.
Adequately ventilate the operating room to eliminate as much monomer vapor as possible. The liquid monomer is highly volatile and flammable. Ignition of monomer fumes caused by use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported. It has been recommended by manufacturers of soft contact lenses that such lenses should be removed “in the presence of noxious and irritating vapors”. Since soft contact lenses are quite permeable, they should not be worn in an operating room where methyl methacrylate is being mixed.
Dispose of the polymer component in an authorized waste facility. The liquid component should be evaporated under a well-ventilated hood or absorbed by an inert material and transferred in a suitable container for disposal.

Monitoring:
(1) patients receiving gentamicin should be periodically monitored with peak and trough levels of the antibiotic, serum electrolytes, serum renal function, urinalysis, and audiograms (in the elderly and/or dehydrated patient in whom there is a higher risk of adverse events associated with gentamicin use).
(2) Use of gentamicin should be avoided in the following situations:
(a) concurrent/sequential use of other neurotoxic/nephrotoxic antibiotics;
(b) other aminoglycosides:
(c) cephaloridine;
(d) viomycin;
(e) polymixin B;
(f) colistin;
(g) displatin; and
(h) vancomycin.

Interactions

Concurrent administration of muscle relaxants and ether may potentiate the neuromuscular blocking properties of gentamicin. However, due to the low serum concentrations this is unlikely to happen.

Incompatibilities

Aqueous (e.g. antibiotic containing) solutions must not be mixed with the bone cement, as this reduces the strength.

POSSIBLE ADVERSE EFFECTS

The constituents of bone cement in **Refobacin Bone Cement R** may lead to local irritations or hypersensitivity reactions in isolated cases.
Application of gentamicin may, in principle, trigger the typical adverse reactions of this antibiotic:
Neurotoxicity
(1) manifested as both auditory and vestibular ototoxicity, including irreversible hearing loss;
(2) numbness;
(3) skin tingling;
(4) muscle twitching; and
(5) convulsions.
Nephrotoxicity
(1) usually in patients with pre-existing renal damage; and
(2) also in patients with normal renal function to whom aminoglycosides are administered for longer periods or in higher doses than recommended, the symptoms of which may manifest after cessation of therapy.

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements include myocardial infarction, cardiac arrest, cerebrovascular accident, and pulmonary embolism. The most frequent adverse reactions reported with acrylic bone cements are a transitory fall in blood pressure, thrombophlebitis, hemorrhage and hematoma, loosening or displacement of the prosthesis, superficial or deep wound infection, trochanteric bursitis, and short-term cardiac conduction irregularities. Other reported adverse reactions include heterotopic new bone formation and trochanteric separation.
Other reported adverse events for acrylic bone cements include pyrexia due to an allergy to the bone cement, hematuria, dysuria, bladder fistula, delayed sciatic nerve entrapment due to extrusion of the bone cement beyond the region of its intended application, and adhesion and stricture of the ileum due to the heat released during polymerization.

DISCLAIMER

It has not been clinically proven that the antibiotic effect of the drug gentamicin holds for the gentamicin-loaded bone cement.

Dosage

The amount of bone cement required depends on the patient’s anatomy and on the implant used. One or more complete units (the contents of one pouch and one ampoule) must always be mixed together. In practice, more than four dose units per implantation are only rarely used. Even with this dose only low serum levels were determined in clinical studies.

Notes on use

Before using **Refobacin Bone Cement R** the surgeon should, by specific training and experience, be thoroughly familiar with the properties, handling characteristics, and application of bone cements. Because the handling and curing characteristics of this bone cement vary with temperature, humidity, and mixing technique, they are best determined by the surgeon's actual experience. Before using **Refobacin Bone Cement R** for the first time, a test-mixing should be carried out to become familiar with the characteristics of **Refobacin Bone Cement R**.

For special mixing and application techniques (e.g. vacuum mixing, vacuum application, use of a femoral cement restrictor), the relevant instructions of these mixing and application systems must be consulted.

The protective aluminum packaging and outer non-sterile polyethylene pouch (“peel-off” package) and the ampoule packaging should be opened, maintaining sterility, by the circulating nurse. The ampoule and powder pouch

are then taken out under sterile conditions and placed on a sterile working surface. The ampoule is opened by breaking the neck and the inner pouch is cut open with sterile scissors.

Mixing
Refobacin Bone Cement R can be mixed by three different methods:

- Mixing without vacuum
- Mixing under vacuum
- Mixing under vacuum after pre-chilling of the components at 4 C (39 F)

Mixing without vacuum
Pour the liquid into a sterile mixing bowl and add all the powder. Stir carefully with a sterile stirring rod until a homogeneous mass is obtained. The mixture should not be stirred longer than 30 sec, irrespective of the room temperature. The temperature/time diagrams must be consulted (Figs 1 and 4).

Vacuum mixing
To obtain bone cement with lower porosity the use of a vacuum mixing system is recommended. This method requires an airtight closed system and rapid generation of sufficient vacuum (approx. 200 mbar [150 mmHg] absolute pressure) in the mixing bowl. The stirring time for vacuum mixing is the same as for mixing without vacuum (30 sec) (Figs 2 and 5). Method of mixing is given in the instructions for the system used and must be consulted.

Vacuum mixing after pre-chilling
Pre-chilling of the cement components leads to reduction of viscosity thus making mixing more convenient. To obtain optimal results concerning porosity pre-chilling of the cement components at 4 C [39 F]) for at least 24 hours is recommended. Mixing time is the same as for non-pre-chilled cement, however working time and setting time are prolonged

Working procedure
After careful preparation of the surgical site, **Refobacin Bone Cement R** can be applied manually or using a cement syringe or some alternative application system. Method of application is given in the instructions for the system used and must be consulted. The working time and the rate of polymerization are strongly dependent on ambient temperature and on temperature of the components. The hardening time is shorter at high temperatures and longer at low temperatures. Viscosity increases as polymerization progresses, i.e. as the cement hardens.

Manual Application
The working phase starts when the paste no longer adheres to the instruments or surgical gloves and ends when the paste becomes rubbery/elastic with visible separation lines while kneading. The cement and the prosthesis must be applied within the working phase.

Applying the cement after the end of the working phase may cause uneven and/or inadequate cement-bone bonding, thereby resulting in possible early loosening of the implant (see graphs). Depending on the ambient temperature and the temperature of the components, the following schedule applies (Fig. 1). Fig. 4 shows the processing times as a function of temperature. After positioning of the implant any movement must be avoided, to ensure the anchoring of the prosthesis.

Application with a cement syringe
After mixing, the cement is poured directly into a cement syringe. The working time depends on the ambient temperature and the temperature of the components (see graphs). The times may vary depending on the syringe system used.

Application of vacuum-mixed cement
Vacuum-mixed cement is usually applied with a syringe. Depending on the ambient temperature, and whether the cement has been pre-chilled or not, the following schedules apply: Fig 2 & 5, 3 & 6 respectively. The instructions of the mixing system used must be consulted.

Storage
Do not store above 25 C (77 F).

SHELF LIFE/STERILITY
The expiration date is printed on the outer carton, on the protective aluminum packaging and on the inner pouch. **Refobacin Bone Cement R** must not be used after the expiration date. The contents of unused but opened or damaged packs must not be resterilized and are therefore to be discarded.

This product is for single use only and has not been designed or tested for re-use. Do not attempt to clean or re-sterilize the product due to the risk of cross infection and/or possible alterations in the product performance.

The powder component of **Refobacin Bone Cement R** is sterilized with ethylene oxide gas. If the polymer powder shows a yellow discoloration, it must not be used. The liquid component of **Refobacin Bone Cement R** is sterilized by sterile filtration and aseptically filled. The exterior of the glass ampoule containing the liquid component is sterilized by ethylene oxide.

MR

REFOBACIN BONE CEMENT R IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT
None of the components of **Refobacin Bone Cement R** include conductive, metallic, or magnetic materials. Therefore, in accordance with the definition stated in ASTM-F2503, *Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment,* **Refobacin Bone Cement R** is classified as "MR Safe"- an item that poses no known hazards in any MR Environment.

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

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

Fig. 1

Ambient and component temperature	66°F (19°C)	70°F (21°C)	73°F (23°C)
Mixing at ambient temperature	0'30"	0'30"	0'30"
Start of application phase	1'50"	1'30"	1'15"
End of application phase	5'30"	5'00"	4'30"
Hardening	11'30"	10'15"	9'00"

Fig. 2

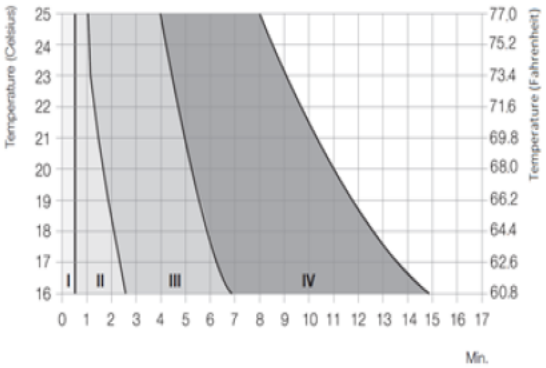
Ambient and component temperature	66°F (19°C)	70°F (21°C)	73°F (23°C)
Mixing under vacuum at ambient temperature	0'30"	0'30"	0'30"
Start of application phase	1'50"	1'30"	1'15"
End of application phase	4'50"	4'15"	3'50"
Hardening	11'00"	9'30"	8'20"

Fig. 3

Ambient and component temperature	66°F (19°C)	70°F (21°C)	73°F (23°C)
Mixing under vacuum after pre-chilling at 4 C (39 F)	0'30"	0'30"	0'30"
Start of application phase	4'15"	4'00"	3'45"
End of application phase	9'40"	8'20"	7'20"
Hardening	16'00"	13'45"	12'00"

Fig. 4

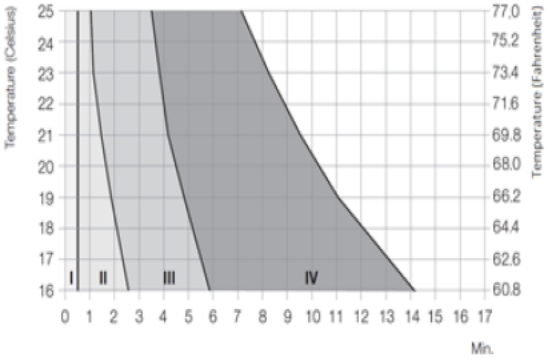
Manual application of **REFOBACIN BONE CEMENT R**



I: mixing
II: waiting phase
III: application phase
IV: final hardening phase

Fig. 5

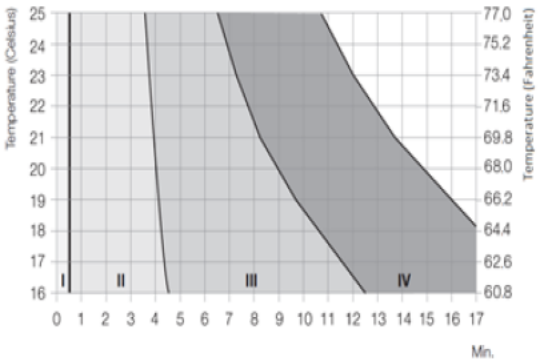
Application of non-prechilled **REFOBACIN BONE CEMENT R** mixed under vacuum



I: mixing
II: waiting phase
III: application phase
IV: final hardening phase

Fig. 6

(4°C) **REFOBACIN BONE CEMENT R** mixed under vacuum



I: mixing
II: waiting phase
III: application phase
IV: final hardening phase

Symbol Legend

Manufacturer

Date of Manufacture

Do Not Reuse

Do not resterilize

Caution, see instructions for use

STERILE EO — Sterilized using Ethylene Oxide

STERILE R — Sterilized using Irradiation

STERILE — Sterile

STERILE A — Sterilized using Aseptic Processing Techniques

STERILE — Sterilized using Steam or Dry Heat

Rx Only — Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Do not use if package damaged

MR — MR Safe

Use By

WEEE Device

REF — Catalogue Number

LOT — Batch Code

FLAMMABLE — Flammable

EC REP — Authorized Representative in the European Community

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OPTIPAC Refobacin Bone Cement R
ATTENTION OPERATING SURGEON

DESCRIPTION
Optipac is a mixing and application system pre-packed with **Refobacin Bone Cement R. Refobacin Bone Cement R** is a fast setting polymer containing gentamicin, for use in bone surgery. Mixing of the two component system, consisting of a powder and a liquid, produces a paste, which is used to anchor the prosthesis to the bone. The hardened bone cement allows stable fixation of the prosthesis and transfers all stresses produced in a movement to the bone via the large interface. Insoluble zirconium dioxide is included in the cement powder as an X ray contrast medium. The chlorophyll additive in the liquid component serves as optical marking of the bone cement at the site of the operation. The closed system minimizes the amount of free monomer in the operating room. The application method reduces direct contact with the bone cement. The components are packed in an inner blister pack, with the bottom of the tray serving as the working area. The blister pack is packed in a polyethylene-Tyvek pouch.

Composition of the system:
The Optipac System comes pre-packed with rapid curing and radiopaque bone cement. It is available in different sizes: 40, 60 and 80, Hip Set (40 & 80) and Optipac Knee Refobacin Bone Cement R.

Optipac Contains:
1 sterile blister pack containing the following:
- 1 mixing system pre-packed with polymer powder and monomer liquid
- 1 mixing rod
- 1 breakaway cement nozzle (not included in the Knee version)
- 1 knee nozzle breakable (only included in the knee and 40 versions)
- 1 vacuum line with sterile filter
- 1 femoral pressurizer (only included in the 60 and 80 versions)

Composition:
Optipac Knee Refobacin Bone Cement R
Powder 25.2g
0.5g gentamicin sulphate (corresponding to 0.3g gentamicin)
20.7g poly (methyl acrylate, methyl methacrylate)
3.8g zirconium dioxide
0.2g benzoyl peroxide

Liquid 12.4 ml
11.4g methyl methacrylate
0.2g N, N-dimethyl-p-toluidine
Other constituents:
Chlorophyll VIII, hydroquinone

Optipac Refobacin Bone Cement R 40
Powder 40.8 g
0.8 g gentamicin sulphate (corresponding to 0.5 g gentamicin)
33.6 g poly (methyl acrylate, methyl methacrylate)
6.1 g zirconium dioxide
0.3 g benzoyl peroxide

Liquid 20ml
18.4 g methyl methacrylate
0.4 g N, N-dimethyl-p-toluidine
Other constituents:
Chlorophyll VIII, hydroquinone

Optipac Refobacin Bone Cement R 60
Powder 61.3 g
1.3 g gentamicin sulphate (corresponding to 0.8 g gentamicin)
50.3 g poly (methyl acrylate, methyl methacrylate)
9.2 g zirconium dioxide
0.5 g benzoyl peroxide

Liquid 30 ml (2x15 ml)
27.6 g methyl methacrylate
0.6 g N, N-dimethyl-p-toluidine
Other constituents:
Chlorophyll VIII, hydroquinone

Optipac Refobacin Bone Cement R 80
Powder 81.6 g
1.6 g gentamicin sulphate (corresponding to 1.0 g gentamicin)
67.2 g poly (methyl acrylate, methyl methacrylate)
12.2 g zirconium dioxide
0.6 g benzoyl peroxide

Liquid 40ml (2x20 ml)
36.8 g methyl methacrylate
0.8 g N, N-dimethyl-p-toluidine
Other constituents:
Chlorophyll VIII, hydroquinone

In addition needed:
- Optigun Cement Gun or Optigun Cement Gun-Ratchet
- Vacuum Pump

INDICATIONS
Refobacin Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

CONTRAINDICATIONS
Refobacin Bone Cement R must not be used in the presence of active or incompletely treated infection of the joint or joints to be replaced.
Refobacin Bone Cement R must not be used during pregnancy or the nursing period. The safety of the bone cement in pregnant women or in children has not been established. Bone cement may adversely affect bone growth and fetal health.
Refobacin Bone Cement R must not be used in cases of known hypersensitivity to gentamicin or other constituents of bone cement. A history of hypersensitivity of serious toxic reactions to other aminoglycosides may contraindicate the use of gentamicin because of known cross-sensitivity of patients to drugs in this class.
Relative contraindications include:
(1) an uncooperative patient or a patient with neurologic disorders who is incapable of following directions,
(2) metabolic disorders which may impair bone formation,
(3) osteomalacia,
(4) distant foci of infections which may spread to the implant site,
(5) rapid joint destruction, marked bone loss or bone resorption, vascular insufficiency, muscular atrophy, neuromuscular disease
(6) hypotension
(7) congestive heart failure
(8) renal impairment.

WARNINGS
Refobacin Bone Cement R is considered most unlikely to cause gentamicin overdosage, since only low (< 1 µg/ml) and short-lived serum concentrations are obtained during the first few postoperative hours from the high local gentamicin concentrations. (Wahlig et al.: Pharmacokinetic study of Gentamicin-loaded cement in total hip replacements. Comparative effects of varying dosage. J. Bone Joint Surg. 66-B: 175-179).

Please note: the system has to be discarded if one of the pouches is not penetrated. Optipac components should be disposed after use and never reused. Never attempt to re-sterilize used components.
Since the concentration of gentamicin may reach the nerve and the kidney, ototoxic and nephrotoxic reaction may happen following the use of ***Refobacin Bone Cement R.***

Monitor patients carefully for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements. Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 second to 5 or more minutes. Some have progressed to cardiac arrest. Patients should be monitored carefully for any change in blood pressure during and immediately following the application of bone cement.

Cardiovascular and respiratory side effects (e.g. hypotension, pulmonary embolism, and cardiac arrest) known as bone cement implantation syndrome (BCIS) are mainly caused by infiltration of bone marrow constituents into the venous vascular system. The site of the prosthesis should therefore be meticulously irrigated and dried. In the presence of pulmocardio-vascular disturbances, the patient should be monitored closely and anaesthesiological measures may be required, e.g. in the event of acute respiratory failure. In high-risk patients, for example those sustaining hip fractures, care should be taken not to over-pressurize the cement and to insert the prosthesis slowly.

Using **Refobacin Bone Cement R** under conditions other than the indicated use is unlikely to provide benefit to the patient and increases the risk of development of drug-resistant bacteria. Follow the handling, mixing instructions carefully.

- Methyl Methacrylate is a volatile flammable liquid. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated monomer vapors, which may produce irritation of the respiratory tract, eyes, general feeling of ill health such as nausea and headache and possibly irritation of the liver. Such symptoms can be minimized through adequate ventilation or by using a closed mixing system. Personnel wearing contact lenses should not be near or involved in mixing this bone cement.
- Polymerization of the bone cement is an exothermic reaction, which occurs while the cement is hardening in situ. The released heat may damage bone or other tissues surrounding the implant.
- Inadequate fixation or unanticipated postoperative event may affect the cement-bone interface and lead to micro motion of cement against the bone surface. A fibrous tissue layer may develop between the cement and the bone, and loosening of the prosthesis may occur leading to implant failure. Long-term follow-up is advised for all patients on a regularly scheduled basis.

Do not allow the liquid component to contact rubber or latex gloves. The liquid component is a powerful lipid solvent. Should contact occur, the gloves may dissolve and tissue damage may occur. Wearing a second pair of gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The mixed bone cement should not make contact with the gloved hand until the cement has acquired the consistency of dough. This usually occurs between one and two minutes after the liquid and powder components are mixed.

Avoid over-pressurization of the bone cement because this may lead to extrusion of the bone cement beyond the site of its intended application and damage the surrounding tissues. . In addition, over-pressurization of the bone cement should be avoided during the insertion of the bone cement and implant in order to minimize the occurrence of pulmonary embolism and BCIS.

PRECAUTIONS
Do not use this product after the expiration date printed on the package. This device may not be safe or effective beyond its expiration date.
Follow the handling and mixing instructions to avoid contact dermatitis. Strict adherence to the instructions for mixing the powder and liquid components may reduce the incidence of this complication.
Adequately ventilate the operating room to eliminate as much monomer vapor as possible. The liquid monomer is highly volatile and flammable. Ignition of monomer fumes caused by use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported. It has been recommended by manufacturers of soft contact lenses that such lenses should be removed “in the presence of noxious and irritating vapors”. Since soft contact lenses are quite permeable, they should not be worn in an operating room where methyl methacrylate is being mixed.
Dispose of the polymer component in an authorized waste facility. The liquid component should be evaporated under a well-ventilated hood or absorbed by an inert material and transferred in a suitable container for disposal.

Monitoring:
(1) patients receiving gentamicin should be periodically monitored with peak and trough levels of the antibiotic, serum electrolytes, serum renal function, urinalysis, and audiograms (in the elderly and/or dehydrated patient in whom there is a higher risk of adverse events associated with gentamicin use).
(2) Use of gentamicin should be avoided in the following situations:
(a) concurrent/sequential use of other neurotoxic/nephrotoxic antibiotics;
(b) other aminoglycosides:
(c) cephaloridine;
(d) viomycin;
(e) polymixin B;
(f) colistin;
(g) displatin; and
(h) vancomycin.

Interactions
Concurrent administration of muscle relaxants and ether may potentiate the neuromuscular blocking properties of gentamicin. However, due to the low serum concentrations this is unlikely to happen.

Incompatibilities
Aqueous (e.g. antibiotic containing) solutions must not be mixed with the bone cement, as this reduces the strength.

POSSIBLE ADVERSE EFFECTS
The constituents of bone cement in **Refobacin Bone Cement R** may lead to local irritations or hypersensitivity reactions in isolated cases.
Application of gentamicin may, in principle, trigger the typical adverse reactions of this antibiotic:
Neurotoxicity
(1) manifested as both auditory and vestibular ototoxicity, including irreversible hearing loss;
(2) numbness;
(3) skin tingling;
(4) muscle twitching; and
(5) convulsions.
Nephrotoxicity
(1) usually in patients with pre-existing renal damage; and
(2) also in patients with normal renal function to whom aminoglycosides are administered for longer periods or in higher doses than recommended, the symptoms of which may manifest after cessation of therapy.

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements include myocardial infarction, cardiac arrest, cerebrovascular accident, and pulmonary embolism. The most frequent adverse reactions reported with acrylic bone cements are a transitory fall in blood pressure, thrombophlebitis, hemorrhage and hematoma, loosening or displacement of the prosthesis, superficial or deep wound infection, trochanteric bursitis, and short-term cardiac conduction irregularities. Other reported adverse reactions include heterotopic new bone formation and trochanteric separation.
Other reported adverse events for acrylic bone cements include pyrexia due to an allergy to the bone cement, hematuria, dysuria, bladder fistula, delayed sciatic nerve entrapment due to extrusion of the bone cement beyond the region of its intended application, and adhesion and stricture of the ileum due to the heat released during polymerization.

DISCLAIMER
It has not been clinically proven that the antibiotic effect of the drug gentamicin holds for the gentamicin-loaded bone cement.

Dosage
The amount of bone cement required depends on the patient’s anatomy and on the implant used. The Optipac system is available with 25.2g, 40.8g, 61.3g, and 81.6g cement powder.

Notes on use
Before using the **Optipac System with Refobacin Bone Cement R** the surgeon should, by specific training and experience, be thoroughly familiar with the properties, handling characteristics, and application of bone cements. Because the handling and curing characteristics of this bone cement vary with temperature, humidity, and mixing technique, they are best determined by the surgeon's actual experience. Before using the **Optipac System** for the first time, a test-mixing should be carried out to become familiar with the characteristics of the system. It is recommended to use the **Optipac System** without pre-chilling the system (see Fig. 1). If a longer handling and setting time is desired, the **Optipac** system can be pre-chilled (see Fig.2)

Mixing Options
- After storage of components at ambient tem (see Fig. 1)
- After storage of components at 4 C (39 F)

Mixing
See operating instructions on page 4.

Note: Maintain sterility at all times.
Do not squeeze the monomer pouches

Circulating Nurse:
1. Open the outer carton.
2. Open the non-sterile breather bag.

Operating nurse:
3. Take out the sterile blister pack with the products and place it on the sterile bench top.
4. Remove the Tyvek lid.
5. Place the products on the sterile bench top.
6. Remove the blue transport lid from the cylinder.
7. Screw on the mixing rod and tighten firmly.
8. Have the circulating nurse attach the end of the vacuum line with the sterile filter to the vacuum pump. Attach the other end of the vacuum line to the vacuum connection on the top of the cylinder. Fasten the line to the table with adhesive tape (optional).
9. The pump should be attached to an air or nitrogen source with pressure between 5 and 9 bar (70-130 psi).
10. Start the vacuum pump by using the foot switch and evacuate for a minimum of 15 seconds.
11. Dry mix the bone cement by moving the mixing rod all the way up and down in the cylinder two times, rotating the mixing rod at the same time.
12. Remove the safety spacer from the blue monomer holders.
13. Push the blue monomer holders towards the middle of the cylinder with a two hand grip. Start the clock.
14. Mix for 30 seconds. Mix by moving the mixing rod all the way up and down; rotating at the same time. Fully extract the mixing rod when mixing is completed.
15. Finish by twisting the mixing rod in the fully extracted position.
16. Place the cylinder on the releasing knobs in the tray. Twist the cylinder a quarter turn clockwise. The plunger will move up, collecting the cement under vacuum to the top of the cylinder.
17. Stop the vacuum pump. Unscrew and discard the empty bottom cylinder.
    NOTE: Make sure that the plunger has moved all the way up and has passed the bottom cylinder before unscrewing the bottom cylinder.
18. Snap off the mixing rod with a firm, quick movement by holding the thumb on the cylinder top (see operating instructions for correct hand grip). Save the mixing rod for later use (optional).
19. Remove the vacuum line.
20. Unscrew the blue plug.
21. Attach the nozzle. Please note that it is a breakaway cement nozzle. If a short nozzle is needed, break it off at the circular mark.
22. Position the cylinder in the cement gun with the cement nozzle positioned at 12 o'clock. Release the cement gun plunger and push it forward. Start cement delivery once the cement reaches the desired viscosity (see Figs 1& 3, for prechilled cement see Figs 2 & 4).
23. If additional cement is needed, use the mixing rod to extract the remaining cement from the nozzle.

Working procedure
After careful preparation of the surgical site, apply **Refobacin Bone Cement R** with the Optipac system. The working time and the rate of polymerization are strongly dependent on ambient temperature and on temperature of the components. The hardening time is shorter at high temperatures and longer at low temperatures. Viscosity increases as polymerization progresses, i.e. as the cement hardens.

Application Options
- **a)** After storage of components at ambient temperature (see Figs.1 and 3)
- **b)** After storage of components at 4°C (39°F) (See Figs. 2 and 4)

Application
The cement and the prosthesis must be applied during the working phase. Applying the cement after the end of the working phase may cause uneven and/or inadequate cement-bone bonding, thereby resulting in possible early loosening of the implant. Depending on ambient temperature and temperature of the components, the following schedule applies: fig. 3 & 4 shows the processing times as a function of temperature. After positioning the implant, avoid movement to ensure anchoring of the prosthesis.

Storage
Do not store above 25 C (77 F).

SHELF LIFE/STERILITY
The expiration date is printed on labels placed on the outer carton and on the Tyvek-pouch. Optipac System must not be used after the expiration date. Once removed from the Tyvek-pouch, the system cannot be re-sterilized and must be discarded.

Reuse is unsafe because of:
- Cross-infection
- Inability to clean and decontaminate
- Material alteration
- Mechanical failure

The Optipac System is sterilized with ethylene oxide gas and must not be resterilized. The monomer is filled into the pouches by sterile filtration. If the polymer powder shows a yellow discoloration, it must not be used.

MR

REFOBACIN BONE CEMENT R IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT
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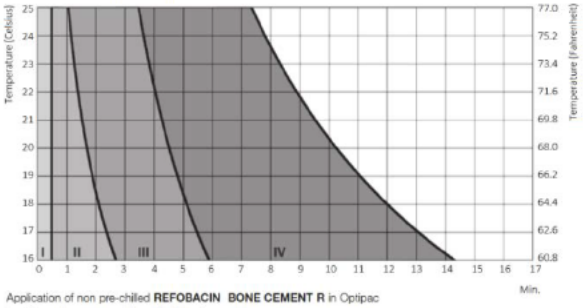
End of application phase	4'45"	4'15"	3'45"
Hardening	11'00"	9'30"	8'15"

Fig. 2

Ambient and component temperature	66°F (19°C)	70°F (21°C)	73°F (23°C)
Mixing under vacuum after pre-chilling at 4°C (39°F)	0'30"	0'30"	0'30"
Start of application phase	4'15"	4'00"	3'45"
End of application phase	9'45"	8'30"	7'30"
Hardening	17'00"	15'00"	13'15"

Fig. 3

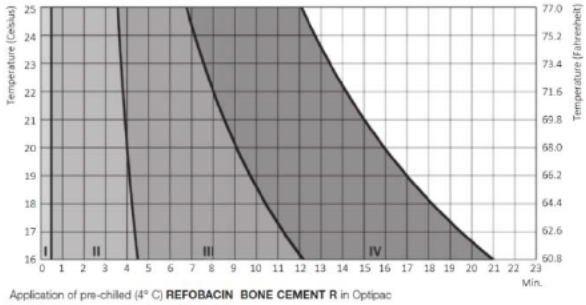
Our recommendation is to use Optipac without pre-chilling the system.



Application of non pre-chilled **REFOBACIN BONE CEMENT R** in Optipac
I: mixing phase III: application phase
II: waiting phase IV: final hardening phase

Fig. 4

If you want to achieve a longer handling- and setting time, the Optipac system can be pre-chilled.



Application of pre-chilled (4° C) **REFOBACIN BONE CEMENT R** in Optipac
I: mixing phase III: application phase
II: waiting phase IV: final hardening phase

Symbol Legend

Manufacturer

Date of Manufacture

Do Not Reuse

Do not resterilize

Caution, see instructions for use

STERILE EO — Sterilized using Ethylene Oxide

STERILE R — Sterilized using Irradiation

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Use By

WEEE Device

REF — Catalogue Number

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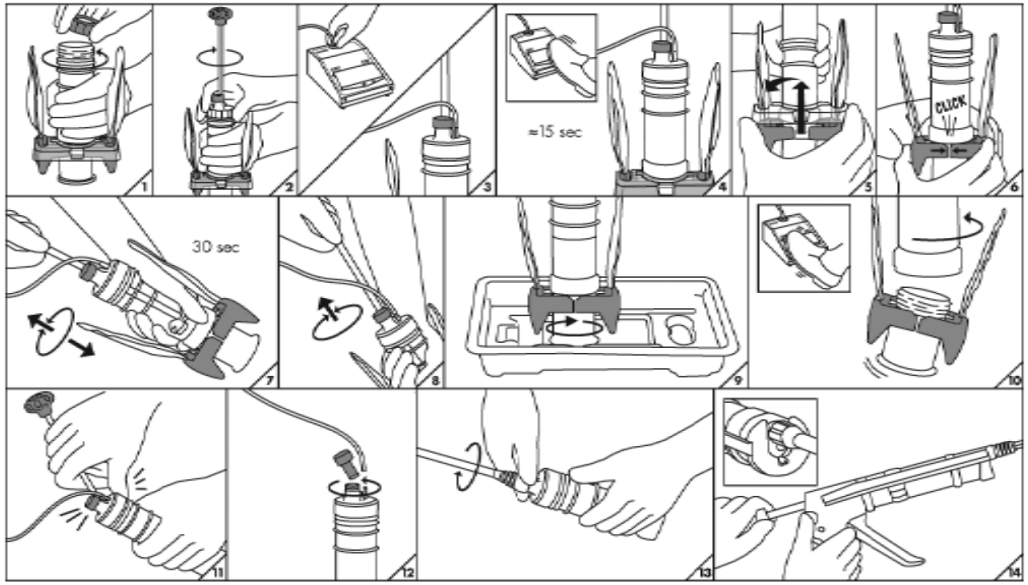
FLAMMABLE — Flammable

EC REP — Authorized Representative in the European Community

Optipac®

BIOMET®



16.1.2 Proposed/Sample Labeling

Patient Label

Attach to patient's record

REF **5003920002** **Refobacin Bone Cement R 20x2 US**

LOT **123123**

(01) 0 7350023 77411 6

(17) 200210 (10) 123123

Manufactured by:
BIOMET France
Plateau de Lautagne
26000 Valence
FRANCE

Distributed By:
BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA

2018-07

2020-02

Outer label

REF **5003920002**

Refobacin Bone Cement R 20x2 US

LOT **123123**

2020-02

CONSULT IFU

(01) 0 7350023 77411 6

(17) 200210 (10) 123123

REF : 500392002

US Additional label

REF **5003920002**

LOT **123123**

Use By: YYYY-MM-DD
2020-12-31

Rx Only

DO NOT REUSE

CONSULT IFU

CONSULT IFU

STERILE A
Sterilized Using Aseptic Process

STERILE EO
Sterilized Using Ethylene Oxide Gas

Flammable

Do Not Resterilize

DO NOT USE IF PACK DAMAGED

Mfg'r

Manufactured by:
BIOMET France
Plateau de Lautagne
26000 Valence
FRANCE

Distributed by:
BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA

Patien Label

Attach to patient's record

REF 5710500394 OPTIPAC 40 REFOBACIN

LOT T123456789 BONE CEMENT R

(01) 0 3599870 11226 7

(17) 160731 (10) T123456789

Manufactured by:
BIOMET France
Plateau de Lautagne
26000 Valence
FRANCE

Distributed By:
BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA

2018-07

2020-02

Outer label

REF 5710500394

Optipac 40 Refobacin
Bone Cement R

LOT T123456789

2016-07

CONSULT IFU

(01) 0 3599870 11226 7

(17) 160731 (10) T123456789

REF : 5710500394

US Additional label

REF 5710500394

LOT T123456789

Use By: YYYY-MM-DD
2020-12-31

Rx Only

DO NOT REUSE

CONSULT IFU

CONSULT IFU

STERILE A
Sterilized Using Aseptic Process

STERILE EO
Sterilized Using Ethylene Oxide Gas

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Manufactured by:
BIOMET France
Plateau de Lautagne
26000 Valence
FRANCE

Distributed by:
BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA

Refobacin® Bone Cement R

Rapid curing synthetic resin for bone surgery containing gentamicin - Radiopaque

2 x 20

DE

Refobacin® Bone Cement R 2 x 20
Schnellhärtender Kunststoff für die Knochenchirurgie – Röntgenpositiv
Inhalt:
2 Beutel zu je 20,4 g Pulver
2 Ampullen zu je 10 ml Flüssigkeit
Zusammensetzung
Pulver:
0,4 g Gentamicinsulfat (entspricht 0,3 g Gentamicin)
16,7 g Poly(methylacrylat, methylmethacrylat)
3,1 g Zirkoniumdioxid
0,2 g Benzoylperoxid
Flüssigkeit:
9,2 g Methylmethacrylat
0,2 g N,N-Dimethyl-p-toluidin, Chlorophyll VIII

Nicht nachsterilisieren!
Nicht über 25° C lagern

IT

Refobacin® Bone Cement R 2 x 20
Materia plastica a presa rapida per chirurgia ossea – Radio-opaca
Contiene:
2 bustine da 20,4 g di polvere ciascuna
2 ampolle da 10 ml di liquido ciascuna
Composizione
Polvere:
0,4 g gentamicina solfato (corrispondenti a 0,3 g di gentamicina)
16,7 g poli(metilacrilato, metilmetacrilato)
3,1 g diossido zirconio
0,2 g benzoil perossido
Liquido:
9,2 g metilmetacrilato
0,2 g N,N-dimetil-p-toluidina, clorofilla VIII

Non resterilizzare!
Conservare a temperature non superiori a 25° C

FR

Refobacin® Bone Cement R 2 x 20
Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – Radio-opaque
Contenu:
2 sachets de poudre de 20,4 g chacun
2 ampoules de liquide de 10 ml chacune
Formule unitaire
Poudre:
0,4 g Sulfate de gentamicine (soit 0,3 g de gentamicine)
16,7 g Polyl(acrylate de méthyle, méthacrylate de méthyle)
3,1 g Dioxyde de zirconium
0,2 g Peroxyde de benzoyle
Liquide:
9,2 g Méthacrylate de méthyle
0,2 g N,N-diméthyl-p-toluidine, Chlorophylle VIII

Ne pas restériliser!
Température maximale de stockage 25° C

SE

Refobacin® Bone Cement R 2 x 20
Snabbhärdande syntetiskt benocement för ortopedisk kirurgi – röntgentätt
Innehåller:
2 påsar innehållande 20,4 g pulver vardera
2 ampuller innehållande 10 ml vätska vardera
Sammansättning
Pulver:
0,4 g gentamicinsulfat (motsvarande 0,3 g gentamicin)
16,7 g poly(metylakrylat, metylmetakrylat)
3,1 g zirkoniumdioxid
0,2 g benzoylperoxid
Vätska:
9,2 g metylmetakrylat
0,2 g N,N-dimetyl-p-toluidin, klorofyll VIII

Får ej omsteriliseras!
Förvaras ej över 25° C

ES

Refobacin® Bone Cement R 2 x 20
Cemento quirúrgico de endurecimiento rápido – Radiopaco
Contiene:
2 sobres con 20,4 g de polvo cada uno
2 ampollas con 10 ml de líquido cada una
Composición
Polvo:
0,4 g sulfato de gentamicina (correspondiente a 0,3 g de gentamicina)
16,7 g poli(metilacrilato, metilmetacrilato)
3,1 g dióxido de circonio
0,2 g peróxido de benzoilo
Líquido:
9,2 g metilmetacrilato
0,2 g N,N-dimetil-p-toluidina, clorofila VIII

¡No resterilizar!
No almacenar a temperaturas superiores a 25° C

NL

Refobacin® Bone Cement R 2 x 20
Snelhardend synthetisch botcement voor orthopedische chirurgie – röntgenpositief
Inhoud:
2 zakjes met elk 20,4 g poeder
2 ampullen met elk 10 ml vloeistof
Samenstelling
Poeder:
0,4 g gentamicinesulfaat (overeenstemmend met 0,3 g gentamicine)
16,7 g poly(methylacrylaat, methylmethacrylaat)
3,1 g zirconiumdioxide
0,2 g benzoylperoxide
Vloeistof:
9,2 g methylmethacrylaat
0,2 g N,N-dimethyl-p-toluidine, chlorofyl VIII

Niet hersteriliseren!
Niet boven 25° C bewaren

Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH 8953 Dietikon, Switzerland
www.biomet.com

Refobacin® Bone Cement R
2 x 20

BIOMET

Refobacin® Bone Cement R

2 x 20

Rapid curing synthetic resin for bone surgery containing gentamicin - Radiopaque
Schnellhärtender Kunststoff für die Knochenchirurgie mit Gentamicin - Röntgenpositiv

GENTAMICIN

STERILE EO STERILE A

BIOMET

Refobacin® Bone Cement R
2 x 20

Contents:
2 sachets containing 20.4 g powder each
2 ampoules containing 10 ml liquid each
Composition:
Powder:
1 sachet contains:

0.4 g	gentamicin sulphate (corresponding to 0.3 g gentamicin)
16.7 g	poly(methyl acrylate, methyl methacrylate)
3.1 g	zirconium dioxide
0.2 g	benzoyl peroxide

Liquid:

9.2 g	methyl methacrylate
0.2 g	N,N-dimethyl-p-toluidine chlorophyll VIII

Do not re-sterilise!
Maximum storage temperature 25°C

CE 0123

Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH- 8953 Dietikon, Switzerland
www.biomet.com

7Y

REF7803003922

®

Refobacin Bone Cement R 1x20 g

Gentamicin 0.3 g

BIOMET®

Rapid curing synthetic resin for bone surgery – radiopaque.

Non-sterile protective sachet containing:
20.4 g radiopaque polymer powder.

Components:

Gentamicin sulphate 0.4 g (corresponding to 0.3 g gentamicin), Poly(methyl acrylate, methyl methacrylate) 16.7 g, Zirconium dioxide 3.1 g, Benzoyl peroxide 0.2 g. Maximum storage temperature 25°C!

Schnellhärtender Kunststoff für die Knochenchirurgie – röntgenpositiv.

Diese unsterile Schutzverpackung enthält:
20,4 g röntgenpositives Polymerpulver.

Zusammensetzung:

Gentamicinsulfat 0,4 g (entspricht 0,3 g Gentamicin), Poly(methylacrylat, methylmethacrylat) 16,7 g, Zirkoniumdioxid 3,1 g, Benzoylperoxid 0,2 g. Nicht über 25°C lagern!

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – radio-opaque.

Sachet de protection non stérile contenant:
20,4 g de poudre polymère radio-opaque.

Composition:

Sulfate de gentamicine 0,4 g (soit 0,3 g de gentamicine), Poly(acrylate de méthyle, méthacrylate de méthyle) 16,7 g, Dioxyde de zirconium 3,1 g, Peroxyde de benzoyle 0,2 g. Ne pas stocker à une température supérieure à 25°C!

Cemento quirúrgico de endurecimiento rápido – radiopaco.

Sobre protector no estéril contiene:
20,4 g de polvo polimero radiopaco.

Composicion:

Sulfato de gentamicina 0,4 g (correspondiente a 0,3 g de gentamicina base), Poli(metilacrilato, metilmetacrilato) 16,7 g, Dioxido de circonio 3,1 g, Peróxido de benzoilo 0,2 g. ¡No almacenar a temperaturas superiores a 25°C!

Materia plastica a presa rapida per chirurgia ossea – radio-opaca.

Bustina protettiva non sterile contiene:
20,4 g di polvere polimerica radio-opaca.

Composizione:

Solfato di gentamicina 0,4 g (corrispondente a 0,3 g di gentamicina, Poli(metilacrilato, metilmetacrilato) 16,7 g, Diossido di zirconio 3,1 g, Perossido di benzoile 0,2 g. Conservare a temperature non superiori a 25°C!

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi – röntgentätt.

Icke-steril skyddspåse innehållande:
20,4 g röntgentätt polymerpulver.

Innehåll:

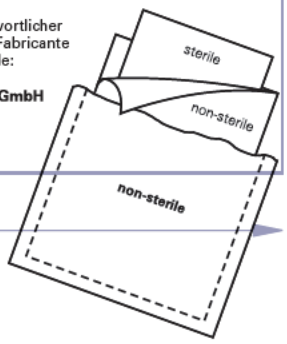
Gentamicinsulfat 0,4 g (motsvarar 0,3 g gentamicin), Poly(metylakrylat, metylmetakrylat) 16,7 g, Zirkoniumdioxid 3,1 g, Benzoylperoxid 0,2 g. Förvaras ej över 25°C!

STERILE | EO

CE 0123

File: 7577300392- 2

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable: Fabricante responsable: Produttore responsable: Ansvarig tillverkare:
Biomet Orthopaedics Switzerland GmbH
CH-8953 Dietikon, Switzerland



209

156.6

Co m 20205 27/9/10 01

SteriPack Medical Limited

Operator: Date: SteriPack 27/9/10
Biomet 7577300392 02
Order No.: Reprographics Revision.: SteriPack Approval:
Reprographic Ref.: Colours: SteriPack QA Approval:
Customer Part Number: SteriPack Artwork Rev. #:

REPROGRAPHIC SYSTEMS ARTWORK FOR APPROVAL - PLEASE CHECK CAREFULLY. SIGN IN SPACE PROVIDED IF THIS ARTWORK MEETS YOUR SPECIFIC REQUIREMENTS.

102

139.7

Refobacin® Bone Cement R 1x20 g

Gentamicin 0.3 g

Rapid curing synthetic resin for bone surgery – radiopaque.

20.4 g radiopaque polymer powder.

Components:
Gentamicin sulphate 0.4 g (corresponding to 0.3 g gentamicin), Poly(methyl acrylate, methyl methacrylate) 16.7 g, Zirconium dioxide 3.1 g, Benzoyl peroxide 0.2 g. To be mixed with 10 ml of liquid, i.e. contents of one ampoule. Maximum storage temperature 25°C!

Schnellhärtender Kunststoff für die Knochenchirurgie – röntgenpositiv.

20,4 g röntgenpositives Polymerpulver.

Zusammensetzung:
Gentamicinsulfat 0,4 g (entspricht 0,3 g Gentamicin), Poly(methylacrylat, methylmethacrylat) 16,7 g, Zirkoniumdioxid 3,1 g, Benzoylperoxid 0,2 g. Pulver in 10 ml Flüssigkeit (Inhalt einer Ampulle) auf einmal einrühren. Nicht über 25°C lagern!

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – radio-opaque.

20,4 g de poudre polymère radio-opaque.

Composition:
Sulfate de gentamicine 0,4 g (soit 0,3 g de gentamicine), Poly(acrylate de méthyle, méthacrylate de méthyle) 16,7 g, Dioxyde de zirconium 3,1 g, Peroxyde de benzoyle 0,2 g. A mélanger avec 10 ml de liquide, soit le contenu d'une ampoule. Ne pas stocker à une température supérieure à 25°C!

Cemento quirúrgico de endurecimiento rápido – radiopaco.

20,4 g de polvo polimero radiopaco.

Composicion:
Sulfato de gentamicina 0,4 g (correspondiente a 0,3 g de gentamicina base), Poli(metilacrilato, metilmetacrilato) 16,7 g, Dioxido de circonio 3,1 g, Peróxido de benzoilo 0,2 g. Mezclar todo el contenido del sobre con 10 ml de liquido (contenido de una ampolla). ¡No almacenar a temperaturas superiores a 25°C!

Materia plastica a presa rapida per chirurgia ossea – radio-opaca.

20,4 g di polvere polimerica radio-opaca.

Composizione:
Solfato di gentamicina 0,4 g (corrispondente a 0,3 g di gentamicina, Poli(metilacrilato, metilmetacrilato) 16,7 g, Diossido di zirconio 3,1 g, Perossido di benzoile 0,2 g. Mescolare una bustina di polvere in 10 ml di liqiudo (contenuto di un'ampolla). Conservare a temperature non superiori a 25°C!

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi – röntgentätt.

20,4 g röntgentätt polymerpulver.

Innehåll:
Gentamicinsulfat 0,4 g (motsvarar 0,3 g gentamicin), Poly(metylakrylat, metylmetakrylat) 16,7 g, Zirkoniumdioxid 3,1 g, Benzoylperoxid 0,2 g. Blandas med 10 ml vätska, dvs innehållet i en ampull. Förvaras ej över 25°C!

STERILE EO

CE 0123

File: 7576300392-02
Ident. 20203
CO 8-0824

Responsible manufacturer: Verantwortlicher Hersteller:
Fabricant responsable: Fabricante responsable:
Produttore responsible: Ansvarig tillverkare:
Biomet Orthopaedics Switzerland GmbH
CH-8953 Dietikon, Switzerland

1

SteriPack Medical Limited		
Operator: Rachel	Date: 30.09.10	SteriPack Customer:
Order No.: 20203	Reprographics Revision.: 02	SteriPack Approval:
Reprographic Ref.: 91431	Colours: 1	SteriPack QA Approval:
SteriPack Customer Part Number: Biomet 7576300392		SteriPack Artwork Rev. #: 01

REPROGRAPHIC SYSTEMS ARTWORK FOR APPROVAL - PLEASE CHECK CAREFULLY. SIGN IN SPACE PROVIDED IF THIS ARTWORK MEETS YOUR SPECIFIC REQUIREMENTS.

Refobacin® Bone Cement R

Rapid curing synthetic resin for bone surgery containing gentamicin - Radiopaque

1 x 40

DE

Refobacin® Bone Cement R 1 x 40
Schnellhärtender Kunststoff für die Knochenchirurgie – Röntgenpositiv
Inhalt:
1 Beutel zu 40,8 g Pulver
1 Ampulle zu 20 ml Flüssigkeit
Zusammensetzung
Pulver:
0,8 g Gentamicinsulfat (entspricht 0,5 g Gentamicin)
33,6 g Poly(methylacrylat, methylmethacrylat)
6,1 g Zirkoniumdioxid
0,3 g Benzoylperoxid
Flüssigkeit:
18,4 g Methylmethacrylat
0,4 g N,N-Dimethyl-p-toluidin, Chlorophyll VIII

Nicht nachsterilisieren!
Nicht über 25° C lagern

IT

Refobacin® Bone Cement R 1 x 40
Materia plastica a presa rapida per chirurgia ossea – Radio-opaca
Contiene:
1 bustina da 40,8 g di polvere
1 ampolla da 20 ml di liquido
Composizione
Polvere:
0,8 g gentamicina solfato (corrispondenti a 0,5 g di gentamicina)
33,6 g poli(metilacrilato, metilmetacrilato)
6,1 g diossido zirconio
0,3 g benzoil perossido
Liquido:
18,4 g metilmetacrilato
0,4 g N,N-dimetil-p-toluidina, clorofilla VIII

Non resterilizzare!
Conservare a temperature non superiori a 25° C

FR

Refobacin® Bone Cement R 1 x 40
Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – Radio-opaque
Contenu:
1 sachet de poudre de 40,8 g
1 ampoule de liquide de 20 ml
Formule unitaire
Poudre:
0,8 g Sulfate de gentamicine (soit 0,5 g de gentamicine)
33,6 g Poly(acrylate de méthyle, méthacrylate de méthyle)
6,1 g Dioxyde de zirconium
0,3 g Peroxyde de benzoyle
Liquide:
18,4 g Méthacrylate de méthyle
0,4 g N,N-diméthyl-p-toluidine, Chlorophylle VIII

Ne pas restériliser!
Température maximale de stockage 25° C

SE

Refobacin® Bone Cement R 1 x 40
Snabbhärdande syntetiskt benocement för ortopediskt kirurgi – röntgentätt
Innehåller:
1 påse innehållande 40,8 g pulver
1 ampull innehållande 20 ml vätska
Sammansättning
Pulver:
0,8 g gentamicinsulfat (motsvarande 0,5 g gentamicin)
33,6 g poly(metylakrylat, metylmetakrylat)
6,1 g zirkoniumdioxid
0,3 g benzoylperoxid
Vätska:
18,4 g metylmetakrylat
0,4 g N,N-dimetyl-p-toluidin, klorofyll VIII

Får ej omsteriliseras!
Förvaras ej över 25° C

ES

Refobacin® Bone Cement R 1 x 40
Cemento quirúrgico de endurecimiento rápido – Radiopaco
Contiene:
1 sobre con 40,8 g de polvo
1 ampolla con 20 ml de líquido
Composición
Polvo:
0,8 g sulfato de gentamicina (correspondiente a 0,5 g de gentamicina)
33,6 g poli(metilacrilato, metilmetacrilato)
6,1 g dióxido de circonio
0,3 g peróxido de benzoilo
Líquido:
18,4 g metilmetacrilato
0,4 g N,N-dimetil-p-toluidina, clorofila VIII

¡No reesterilizar!
No almacenar a temperaturas superiores a 25° C

NL

Refobacin® Bone Cement R 1 x 40
Snelhardend synthetisch botcement voor orthopedische chirurgie – röntgenpositief
Inhoud:
1 zakje met 40,8 g poeder
1 ampul met 20 ml vloeistof
Samenstelling
Poeder:
0,8 g gentamicinesulfaat (overeenstemmend met 0,5 g gentamicine)
33,6 g poly(methylacrylaat, methylmethacrylaat)
6,1 g zirconiumdioxide
0,3 g benzoylperoxide
Vloeistof:
18,4 g methylmethacrylaat
0,4 g N,N-dimethyl-p-toluidine, chlorofyl VIII

Niet hersteriliseren!
Niet boven 25° C bewaren

Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH 8953 Dietikon, Switzerland
www.biomet.com

BIOMET

Refobacin® Bone Cement R

1 x 40

GENTAMICIN

BIOMET

Refobacin® Bone Cement R

1 x 40

Rapid curing synthetic resin for bone surgery containing gentamicin - Radiopaque
Schnellhärtender Kunststoff für die Knochenchirurgie mit Gentamicin - Röntgenpositiv

STERILE EO | STERILE A

BIOMET

Refobacin® Bone Cement R

1 x 40

Contents:
1 sachet containing 40.8 g powder
1 ampoule containing 20 ml liquid
Composition:
Powder:
1 sachet contains:

0.8 g	gentamicin sulphate (corresponding to 0.5 g gentamicin)
33.6 g	poly(methyl acrylate, methyl methacrylate)
6.1 g	zirconium dioxide
0.3 g	benzoyl peroxide

Liquid:

18.4 g	methyl methacrylate
0.4 g	N,N-dimethyl-p-toluidine chlorophyll VIII

Do not re-sterilise!
Maximum storage temperature 25°C

CE 0123

Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH- 8953 Dietikon, Switzerland
www.biomet.com

7Y

7803003941

Refobacin® Bone Cement R 2 x 40
Schnellhärtender Kunststoff für die Knochenchirurgie – Röntgenpositiv
Inhalt:
2 Beutel zu je 40,8 g Pulver
2 Ampullen zu je 20 ml Flüssigkeit
Zusammensetzung
Pulver:
0,8 g Gentamicinsulfat (entspricht 0,5 g Gentamicin)
33,6 g Poly(methylacrylat, methylmethacrylat)
6,1 g Zirkoniumdioxid
0,3 g Benzoylperoxid
Flüssigkeit:
18,4 g Methylmethacrylat
0,4 g N,N-Dimethyl-p-toluidin, Chlorophyll VIII

Nicht nachsterilisieren!
Nicht über 25° C lagern

DE

Refobacin® Bone Cement R 2 x 40
Materia plastica a presa rapida per chirurgia ossea – Radio-opaca
Contiene:
2 bustine da 40,8 g di polvere ciascuna
2 ampolle da 20 ml di liquido ciascuna
Composizione
Polvere:
0,8 g gentamicina solfato (corrispondenti a 0,5 g di gentamicina)
33,6 g poli(metilacrilato, metilmetacrilato)
6,1 g diossido zirconio
0,3 g benzoil perossido
Liquido:
18,4 g metilmetacrilato
0,4 g N,N-dimetil-p-toluidina, clorofilla VIII

Non resterilizzare!
Conservare a temperature non superiori a 25° C

IT

Refobacin® Bone Cement R 2 x 40
Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – Radio-opaque
Contenu:
2 sachets de poudre de 40,8 g chacun
2 ampoules de liquide de 20 ml chacune
Formule unitaire
Poudre:
0,8 g Sulfate de gentamicine (soit 0,5 g de gentamicine)
33,6 g Poly(acrylate de méthyle, méthacrylate de méthyle)
6,1 g Dioxyde de zirconium
0,3 g Peroxyde de benzoyle
Liquide:
18,4 g Méthacrylate de méthyle
0,4 g N,N-diméthyl-p-toluidine, Chlorophylle VIII

Ne pas restériliser!
Température maximale de stockage 25° C

FR

Refobacin® Bone Cement R 2 x 40
Snabbhärdande syntetiskt benocement för ortopediskt kirurgi – röntgentätt
Innehåller:
2 påsar innehållande 40,8 g pulver vardera
2 ampuller innehållande 20 ml vätska vardera
Sammansättning
Pulver:
0,8 g gentamicinsulfat (motsvarande 0,5 g gentamicin)
33,6 g poly(metylakrylat, metylmetakrylat)
6,1 g zirkoniumdioxid
0,3 g benzoylperoxid
Vätska:
18,4 g metylmetakrylat
0,4 g N,N-dimetyl-p-toluidin, klorofyll VIII

Får ej omsteriliseras!
Förvaras ej över 25° C

SE

Refobacin® Bone Cement R 2 x 40
Cemento quirúrgico de endurecimiento rápido – Radiopaco
Contiene:
2 sobres con 40,8 g de polvo cada uno
2 ampollas con 20 ml de líquido cada una
Composición
Polvo:
0,8 g sulfato de gentamicina (correspondiente a 0,5 g de gentamicina)
33,6 g poli(metilacrilato, metilmetacrilato)
6,1 g dióxido de circonio
0,3 g peróxido de benzoilo
Líquido:
18,4 g metilmetacrilato
0,4 g N,N-dimetil-p-toluidina, clorofila VIII

¡No reesterilizar!
No almacenar a temperaturas superiores a 25° C

ES

Refobacin® Bone Cement R 2 x 40
Snelhardend synthetisch botcement voor orthopedische chirurgie – röntgenpositief
Inhoud:
2 zakjes met elk 40,8 g poeder
2 ampullen met elk 20 ml vloeistof
Samenstelling
Poeder:
0,8 g gentamicinesulfaat (overeenstemmend met 0,5 g gentamicine)
33,6 g poly(methylacrylaat, methylmethacrylaat)
6,1 g zirconiumdioxide
0,3 g benzoylperoxide
Vloeistof:
18,4 g methylmethacrylaat
0,4 g N,N-dimethyl-p-toluidine, chlorofyl VIII

Niet hersteriliseren!
Niet boven 25° C bewaren

NL

Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH 8953 Dietikon, Switzerland
www.biomet.com

Refobacin® Bone Cement R
Rapid curing synthetic resin for bone surgery containing gentamicin - Radiopaque
2 x 40

BIOMET

Refobacin® Bone Cement R
2 x 40

Refobacin® Bone Cement R
2 x 40
Rapid curing synthetic resin for bone surgery containing gentamicin - Radiopaque
Schnellhärtender Kunststoff für die Knochenchirurgie mit Gentamicin - Röntgenpositiv

BIOMET

GENTAMICIN

STERILE EO STERILE A

7Y

REF 7803003942

BIOMET

Refobacin® Bone Cement R
2 x 40

Contents:
2 sachets containing 40.8 g powder each
2 ampoules containing 20 ml liquid each
Composition:
Powder:
1 sachet contains:

0.8 g	gentamicin sulphate (corresponding to 0.5 g gentamicin)
33.6 g	poly(methyl acrylate, methyl methacrylate)
6.1 g	zirconium dioxide
0.3 g	benzoyl peroxide

Liquid:

18.4 g	methyl methacrylate
0.4 g	N,N-dimethyl-p-toluidine chlorophyll VIII

Do not re-sterilise!
Maximum storage temperature 25°C

CE 0123

Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH-8953 Dietikon, Switzerland
www.biomet.com

156.6

Refobacin Bone Cement R 1x40 g

Gentamicin 0.5 g

BIOMET®

0 3 g Conservare a temperature non superiori a 25°C!

Rapid curing synthetic resin for bone surgery – radiopaque.

Non-sterile protective sachet containing:
40.8 g radiopaque polymer powder.

Components:
Gentamicin sulphate 0.8 g (corresponding to 0.5 g gentamicin), Poly(methyl acrylate, methyl methacrylate) 33.6 g, Zirconium dioxide 6.1 g, Benzoyl peroxide 0.3 g.
Maximum storage temperature 25ºC!

Schnellhärtender Kunststoff für die Knochenchirurgie – röntgenpositiv.

Diese unsterile Schutzverpackung enthält:
40,8 g röntgenpositives Polymerpulver.

Zusammensetzung:
Gentamicinsulfat 0,8 g (entspricht 0,5 g Gentamicin), Poly(methylacrylat, methylmethacrylat) 33,6 g, Zirkoniumdioxid 6,1 g, Benzoylperoxid 0,3 g.
Nicht über 25ºC lagern!

CO 8 0824

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – radio-opaque.

Sachet de protection non stérile contenant:
40,8 g de poudre polymère radio-opaque.

Composition:
Sulfate de gentamicine 0,8 g (soit 0,5 g de gentamicine), Poly(acrylate de méthyle, méthacrylate de méthyle) 33,6 g, Dioxyde de zirconium 6,1 g, Peroxyde de benzoyle 0,3 g. Ne pas stocker à une température supérieure à 25ºC!

Cemento quirúrgico de endurecimiento rápido – radiopaco.

Sobre protector no estéril contiene:
40,8 g de polvo polímero radiopaco.

Composición:
Sulfato de gentamicina 0,8 g (correspondiente a 0,5 g de gentamicina base), Poli(metilacrilato, metilmetacrilato) 33,6 g, Dioxido de circonio 6,1 g, Peróxido de benzoilo 0,3 g.¡No almacenar a temperaturas superiores a 25ºC!

Materia plastica a presa rapida per chirurgia ossea – radio-opaca.

Bustina protettiva non sterile contiene:
40,8 g di polvere polimerica radio-opaca.

Composizione:
Solfato di gentamicina 0,8 g (corrispondente a 0,5 g di gentamicina), Poli(metilacrilato, metilmetacrilato) 33,6 g, Diossido di zirconio 6,1 g, Perossido di benzoile

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi – röntgentätt.

Icke-steril skyddspåse innehållande:
40,8 g röntgentätt polymerpulver.

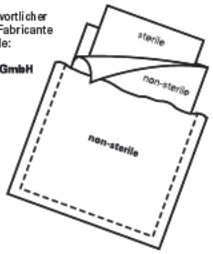
Innehåll:
Gentamicinsulfat 0,8 g (motsvarar 0,5 g gentamicin), Poly(metylakrylat, metylmetakrylat) 33,6 g, Zirkoniumdioxid 6,1 g, Benzoylperoxid 0,3 g.
Förvaras ej över 25ºC!

STERILE EO

CE 0123

File: 7577300394-

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable: Fabricante responsable: Produttore responsible: Ansvarig tillverkare:
Biomet Orthopaedics Switzerland GmbH
CH-8953 Dietikon, Switzerland



Refobacin Bone Cement R 1x40 g

Gentamicin 0.5 g

BIOMET®

0 3 g Conservare a temperature non superiori a 25°C!

Rapid curing synthetic resin for bone surgery – radiopaco.

Non-sterile protector no estéril contiene:
40.8 g de polvo polímero radiopaco.

Componentes:
Sulfato de gentamicina 0.8 g (correspondiente a 0.5 g de gentamicina), Poli(metil acrylate, metil methacrylate) 33.6 g, Dioxido de circonio 6.1 g, Peróxido de benzoilo 0.3 g.¡No almacenar a temperaturas superiores a 25ºC!

Schnellhärtender Kunststoff für die Knochenchirurgie – röntgenpositiv.

Diese unsterile Schutzverpackung enthält:
40,8 g röntgenpositives Polymerpulver.

Zusammensetzung:
Gentamicinsulfat 0,8 g (entspricht 0,5 g Gentamicin), Poly(methylacrylat, methylmethacrylat) 33,6 g, Zirkoniumdioxid 6,1 g, Benzoylperoxid 0,3 g.
Nicht über 25ºC lagern!

CO 8 0824

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – radio-opaque.

Sachet de protection non stérile contenant:
40,8 g de poudre polymère radio-opaque.

Composition:
Sulfate de gentamicine 0,8 g (soit 0,5 g de gentamicine), Poly(acrylate de méthyle, méthacrylate de méthyle) 33,6 g, Dioxyde de zirconium 6,1 g, Peroxyde de benzoyle 0,3 g. Ne pas stocker à une température supérieure à 25ºC!

Cemento quirúrgico de endurecimiento rápido – radiopaco.

Sobre protector no estéril contiene:
40,8 g de polvo polímero radiopaco.

Composición:
Sulfato de gentamicina 0,8 g (correspondiente a 0,5 g de gentamicina base), Poli(metilacrilato, metilmetacrilato) 33,6 g, Dioxido de circonio 6,1 g, Peróxido de benzoilo 0,3 g.¡No almacenar a temperaturas superiores a 25ºC!

Materia plastica a presa rapida per chirurgia ossea – radio-opaca.

Bustina protettiva non sterile contiene:
40,8 g di polvere polimerica radio-opaca.

Composizione:
Solfato di gentamicina 0,8 g (corrispondente a 0,5 g di gentamicina), Poli(metilacrilato, metilmetacrilato) 33,6 g, Diossido di zirconio 6,1 g, Perossido di benzoile

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi – röntgentätt.

Icke-steril skyddspåse innehållande:
40,8 g röntgentätt polymerpulver.

Innehåll:
Gentamicinsulfat 0,8 g (motsvarar 0,5 g gentamicin), Poly(metylakrylat, metylmetakrylat) 33,6 g, Zirkoniumdioxid 6,1 g, Benzoylperoxid 0,3 g.
Förvaras ej över 25ºC!

STERILE EO

CE 0123

File: 7577300394-

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable: Fabricante responsable: Produttore responsible: Ansvarig tillverkare:
Biomet Orthopaedics Switzerland GmbH
CH-8953 Dietikon, Switzerland

SteriPack Medical Limited

Operator:
Order No.:
Reprographic Ref.:
Customer Part Number:
Date:
Reprographics Revision.:
Colours:
SteriPack Customer:
SteriPack Approval:
SteriPack QA Approval:
SteriPack Artwork Rev. #:

102

139.7

Refobacin® Bone Cement R

Gentamicin 0.5 g

Rapid curing synthetic resin for bone surgery – radiopaque.

40.8 g radiopaque polymer powder.

Components:
Gentamicin sulphate 0.8 g (corresponding to 0.5 g gentamicin), Poly(methyl acrylate, methyl methacrylate) 33.6 g, Zirconium dioxide 6.1 g, Benzoyl peroxide 0.3 g. To be mixed with 20 ml of liquid, i.e. contents of one ampoule. Maximum storage temperature 25°C!

Schnellhärtender Kunststoff für die Knochenchirurgie – röntgenpositiv.

40,8 g röntgenpositives Polymerpulver.

Zusammensetzung:
Gentamicinsulfat 0,8 g (entspricht 0,5 g Gentamicin), Poly(methylacrylat, methylmethacrylat) 33,6 g, Zirkoniumdioxid 6,1 g, Benzoylperoxid 0,3 g.
Pulver in 20 ml Flüssigkeit (Inhalt einer Ampulle) auf einmal einrühren. Nicht über 25°C lagern!

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – radio-opaque.

40,8 g de poudre polymère radio-opaque.

Composition:
Sulfate de gentamicine 0,8 g (soit 0,5 g de gentamicine), Poly(acrylate de méthyle, méthacrylate de méthyle) 33,6 g, Dioxyde de zirconium 6,1 g, Peroxyde de benzoyle 0,3 g. A mélanger avec 20 ml de liquide, soit le contenu d'une ampoule. Ne pas stocker à une température supérieure à 25°C!

1x40 g

Cemento quirúrgico de endurecimiento rápido – radiopaco.

40,8 g de polvo polimero radiopaco.

Composicion:
Sulfato de gentamicina 0,8 g (correspondiente a 0,5 g de gentamicina base), Poli(metilacrilato, metilmetacrilato) 33,6 g, Dioxido de circonio 6,1 g, Peróxido de benzoilo 0,3 g. Mezclar todo el contenido del sobre con 20 ml de liquido (contenido de una ampolla). ¡No almacenar a temperaturas superiores a 25°C!

Materia plastica a presa rapida per chirurgia ossea – radio-opaca.

40,8 g di polvere polimerica radio-opaca.

Composizione:
Solfato di gentamicina 0,8 g (corrispondente a 0,5 g di gentamicina), Poli(metilacrilato, metilmetacrilato) 33,6 g, Diossido di zirconio 6,1 g, Perossido di benzoile 0,3 g. Mescolare una bustina di polvere in 20 ml di liqiudo (contenuto di un'ampolla). Conservare a temperature non superiori a 25°C!

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi – röntgentätt.

40,8 g röntgentätt polymerpulver.

Innehåll:
Gentamicinsulfat 0,8 g (motsvarar 0,5 g gentamicin), Poly(metylakrylat, metylmetakrylat) 33,6 g, Zirkoniumdioxid 6,1 g, Benzoylperoxid 0,3 g.
Blandas med 20 ml vätska, dvs innehållet i en ampull.
Förvaras ej över 25°C!

STERILE EO

CE 0123

File: 7576300394-02
Ident. 20206
CO 8-0824

Responsible manufacturer: Verantwortlicher Hersteller:
Fabricant responsable: Fabricante responsable:
Produttore responsible: Ansvarig tillverkare:
Biomet Orthopaedics Switzerland GmbH
CH-8953 Dietikon, Switzerland

1

SteriPack Medical Limited		
Operator: Rachel	Date: 30.09.10	SteriPack Customer:
Order No.: 20206	Reprographics Revision.: 02	SteriPack Approval:
Reprographic Ref.: 91427	Colours: 1	SteriPack QA Approval:
SteriPack Customer Part Number: Biomet 7576300394		SteriPack Artwork Rev. #: 01

REPROGRAPHIC SYSTEMS ARTWORK FOR APPROVAL - PLEASE CHECK CAREFULLY. SIGN IN SPACE PROVIDED IF THIS ARTWORK MEETS YOUR SPECIFIC REQUIREMENTS.

Refobacin® Bone Cement R

Rapid curing synthetic resin for bone surgery containing gentamicin - Radiopaque

1 x 60

Refobacin® Bone Cement R 1 x 60 — DE

Schnellhärtender Kunststoff für die Knochenchirurgie Röntgenpositiv

Inhalt:
1 Beutel zu 61,3 g Pulver
1 Ampulle zu 30 ml Flüssigkeit

Zusammensetzung
Pulver:
1,3 g Gentamicinsulfat (entspricht 0,8 g Gentamicin)
50,3 g Poly(methylacrylat, methylmethacrylat)
9,2 g Zirkoniumdioxid
0,5 g Benzoylperoxid
Flüssigkeit:
27,6 g Methylmethacrylat
0,6 g N,N Dimethyl p toluidin, Chlorophyll VIII

Nicht nachsterilisieren!
Nicht über 25° C lagern

Refobacin® Bone Cement R 1 x 60 — IT

Materia plastica a presa rapida per la chirurgia ossea Radio opaca

Contiene:
1 bustina da 61,3 g di polvere
1 ampolla da 30 ml di liquido

Composizione
Polvere:
1,3 g gentamicina solfato (corrispondenti a 0,8 g di gentamicina)
50,3 g poli (metilacrilato, metilmetacrilato)
9,2 g diossido zirconio
0,5 g benzoil perossido
Liquido
27,6 g metilmetacrilato
0,6 g N,N dimetil p toluidina, clorofilla VIII

Non restar lizzare!
Conservare a temperature non superiori a 25° C

Refobacin® Bone Cement R 1 x 60 — FR

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse Radio opaque

Contenu:
1 sachet de poudre de 61,3 g
1 ampoule de liquide de 30 ml

Formule unitaire
Poudre:
1,3 g Sulfate de gentamicine (soit 0,8 g de gentamicine)
50,3 g Poly(acrylate de méthyle, méthacrylate de méthyle)
9,2 g Dioxyde de zirconium
0,5 g Peroxyde de benzoyle
Liquide:
27,6 g Méthacrylate de méthyle
0,6 g N,N diméthyl p toluidine, Chlorophylle VIII

Ne pas restériliser!
Température maximale de stockage 25° C

Refobacin® Bone Cement R 1 x 60 — SE

Snabbhärdande syntetiskt benecement för ortopedisk kirurgi röntgentätt

Innehåller:
1 påse innehållande 61,3 g pulver
1 ampull innehållande 30 ml vätska

Sammansättning
Pulver:
1,3 g gentamicinsulfat (motsvarande 0,8 g gentamicin)
50,3 g poly(metylakrylat, metylmetakrylat)
9,2 g zirkoniumdioxid
0,5 g benzoylperoxid
Vätska:
27,6 g metylmetakrylat
0,6 g N,N dimetyl p toluidin, klorofyll VIII

Får ej omsteriliseras!
Förvaras ej över 25° C

Refobacin® Bone Cement R 1 x 60 — ES

Cemento quirúrgico de endurecimiento rápido Radiopaco

Contiene:
1 sobre con 61,3 g de polvo
1 ampolla con 30 ml de líquido

Composición
Polvo:
1,3 g sulfato de gentamicina (correspondiente a 0,8 g de gentamicina)
50,3 g poli(metilacrilato, metilmetacrilato)
9,2 g dióxido de circonio,
0,5 g peróxido de benzoilo
Líquido:
27,6 g metilmetacrilato
0,6 g N,N dimetil p toluidina, clorofila VIII

¡No esterilizar!
No almacenar a temperaturas superiores a 25° C

Refobacin® Bone Cement R 1 x 60 — NL

Snelhardend synthetisch botcement voor orthopedische chirurgie röntgenpositief

Inhoud:
1 zakje met 61,3 g poeder
1 ampul met 30 ml vloeistof

Samenstelling
Poeder:
1,3 g gentamicinesulfaat (overeenstemmend met 0,8 g gentamicine)
50,3 g poly(methylacrylaat, methylmethacrylaat)
9,2 g zirconiumdioxide
0,5 g benzylperoxide
Vloeistof:
27,6 g methylmethacrylaat
0,6 g N,N dimethyl p toluidine, chlorofyl VIII

Niet herster lisseren!
Niet boven 25° C bewaren

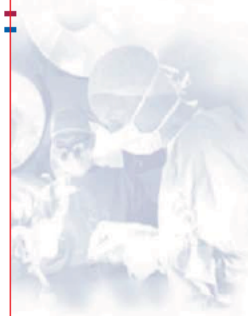
Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH 8953 Dietikon, Switzerland
www.biomet.com

BIOMET

Refobacin® Bone Cement R

1 x 60

GENTAMICIN



BIOMET

Refobacin® Bone Cement R

1 x 60 Rapid curing synthetic resin for bone surgery containing gentamicin - Radiopaque
Schnellhärtender Kunststoff für die Knochenchirurgie mit Gentamicin - Röntgenpositiv

GENTAMICIN

STERILE EO | STERILE A

BIOMET

Refobacin® Bone Cement R

1 x 60

Contents:
1 sachet containing 61.3 g powder
1 ampoule containing 30 ml liquid

Composition:
Powder:
1 sachet contains:
1.3 g gentamicin sulphate (corresponding to 0.8 g gentamicin)
50.3 g poly(methyl acrylate, methyl methacrylate)
9.2 g zirconium dioxide
0.5 g benzoyl peroxide
Liquid:
27.6 g methyl methacrylate
0.6 g N,N-dimethyl-p-toluidine chlorophyll VIII

Do not re-sterilise!
Maximum storage temperature 25°C

CE 0123

Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH 8953 Dietikon, Switzerland
www.biomet.com

25mm

250

Refobacin® Bone Cement R 1x60 g

Gentamicin 0.8 g

BIOMET®

Rapid curing synthetic resin for bone surgery – radiopaque.

Non-sterile protective sachet containing: 61.3 g radiopaque polymer powder.

Components:

Gentamicin sulphate 1.3 g (corresponding to 0.8 g gentamicin), Poly(methyl acrylate, methyl methacrylate) 50.3 g, Zirconium dioxide 9.2 g, Benzoyl peroxide 0.5 g. Maximum storage temperature 25°C!

Schnellhärtender Kunststoff für die Knochenchirurgie – röntgenpositiv.

Diese unsterile Schutzverpackung enthält: 61,3 g röntgenpositives Polymerpulver.

Zusammensetzung:

Gentamicinsulfat 1,3 g (entspricht 0,8 g Gentamicin), Poly(methylacrylat, methylmethacrylat) 50,3 g, Zirkoniumdioxid 9,2 g, Benzoylperoxide 0,5 g.

Nicht über 25°C lagern!

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – radio-opaque.

Sachet de protection non stérile contenant: 61,3 g de poudre polymère radio-opaque.

Composition:

Sulfate de gentamicine 1,3 g (soit 0,8 g de gentamicine), Poly(acrylate de méthyle, méthacrylate de méthyle) 50,3 g, Dioxyde de zirconium 9,2 g, Peroxyde de benzoyle 0,5 g. Température maximale de stockage 25°C!

Cemento quirúrgico de endurecimiento rápido – radiopaco.

Sobre protector no estéril contiene: 61,3 g de polvo polimero radiopaco.

Composicion:

Sulfato de gentamicina 1,3 g (correspondiente a 0,8 g de gentamicina base), Poli(metilacrilato, metilmetacrilato) 50,3 g, Dióxido de circonio 9,2 g, Peróxido de benzoilo 0,5 g. ¡No almacenar a temperaturas superiores a 25°C!

Materia plastica a presa rapida per chirurgia ossea – radio-opaca.

Bustina protettiva non sterile contiene: 61,3 g di polvere polimerica radio-opaca.

Composizione:

Solfato di gentamicina 1,3 g (corrispondente a 0,8 g di gentamicina), Poli(metilacrilato, metilmetacrilato) 50,3 g, Diossido di zirconio 9,2 g, Perossi do di benzoile 0,5 g. Conservare a temperature non superiori a 25°C!

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi – röntgentätt.

Icke-steril skyddspåse innehållande: 61,3 g röntgentätt polymerpulver.

Innehåll:

Gentamicinsulfat 1,3 g (motsvarar 0,8 g gentamicin), Poly(metylakrylat, metylmetakrylat) 50,3 g, Zirkoniumdioxid 9,2 g, Benzoylperoxid 0,5 g.

Förvaras ej över 25°C!

0

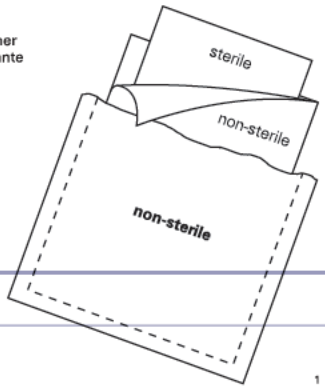
STERILE EO

File: 7577300396- 2
Ident. 20210

CE 0123

CO 8 - 0824

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable: Fabricante responsable: Produttore responsible: Ansvarig tillverkare:
Biomet Orthopaedics Switzerland GmbH
CH-8953 Dietikon, Switzerland



1

174.6

Co m 27 09 10

SteriPack Medical Limited

Operator:	Date: 91415	SteriPack Customer:	
Order No.:	Reprographics Revision.: 01	SteriPack Approval:	02
Reprographic Ref.:	Colours: 1	SteriPack QA Approval:	
SteriPack Customer Part Number: Biomet 7577300396		SteriPack Artwork Rev. #:	

REPROGRAPHIC SYSTEMS ARTWORK FOR APPROVAL - PLEASE CHECK CAREFULLY. SIGN IN SPACE PROVIDED IF THIS ARTWORK MEETS YOUR SPECIFIC REQUIREMENTS.

120

169.16

Refobacin® Bone Cement R

Gentamicin 0.8 g

1x60 g

Rapid curing synthetic resin for bone surgery – radiopaque.

61.3 g radiopaque polymer powder.

Components:
Gentamicin sulphate 1.3 g (corresponding to 0.8 g gentamicin), Poly(methyl acrylate, methyl methacrylate) 50.3 g, Zirconium dioxide 9.2 g, Benzoyl peroxide 0.5 g. To be mixed with 30 ml of liquid, i.e. contents of one ampoule. Maximum storage temperature 25°C!

Schnellhärtender Kunststoff für die Knochenchirurgie – röntgenpositiv.

61,3 g röntgenpositives Polymerpulver.

Zusammensetzung:
Gentamicinsulfat 1,3 g (entspricht 0,8 g Gentamicin), Poly(methylacrylate, methylmethacrylate) 50,3 g, Zirkoniumdioxid 9,2 g, Benzoylperoxid 0,5 g. Pulver in 30 ml Flüssigkeit (Inhalt einer Ampulle) auf einmal einrühren. Nicht über 25°C lagern!

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse – radio-opaque.

61,3 g de poudre polymère radio-opaque.

Composition:
Sulfate de gentamicine 1,3 g (soit 0,8 g de gentamicine), Poly(acrylate de méthyle, méthacrylate de méthyle) 50,3 g, Dioxyde de zirconium 9,2 g, Peroxyde de benzoyle 0,5 g. A mélanger avec 30 ml de liquide, soit le contenu d´une ampoule. Température maximale de stockage 25°C!

Cemento quirúrgico de endurecimiento rápido – radiopaco.

61,3 g de polvo polimero radiopaco.

Composicion:
Sulfato de gentamicina 1,3 g (correspondiente a 0,8 g de gentamicina base), Poli(metilacrilato, metilmetacrilato) 50,3 g, Dióxido de circonio 9,2 g, Peróxido de benzoilo 0,5 g. Mezclar todo el contenido del sobre con 30 ml de liquido (contenido de una ampolla). ¡No almacenar a temperaturas superiores a 25°C!

Materia plastica a presa rapida per chirurgia ossea – radio-opaca.

61,3 g di polvere polimerica radio-opaca.

Composizione:
Solfato di gentamicina 1,3 g (corrispondente a 0,8 g di gentamicina), Poli(metilacrilato, metilmetacrilato) 50,3 g, Diossido di zirconio 9,2 g, Perossido di benzoile 0,5 g. Mescolare una bustina di polvere in 30 ml di liqiudo (contenuto di un´ampolla). Conservare a temperature non superiori a 25°C!

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi – röntgentätt.

61,3 g röntgentätt polymerpulver.

Innehåll:
Gentamicinsulfat 1,3 g (motsvarar 0,8 g gentamicin), Poly(metylakrylat, metylmetakrylat) 50,3 g, Zirkoniumdioxid 9,2 g, Benzoylperoxid 0,5 g. Blandas med 30 ml vätska, dvs innehållet i en ampull. Förvaras ej över 25°C!

STERILE EO

CE 0123

File: 7576300396-02
CO 8-0824

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable: Fabricante responsable: Produttore responsible: Ansvarig tillverkare:
Biomet Orthopaedics Switzerland GmbH
CH-8953 Dietkon, Switzerland

1

100mm

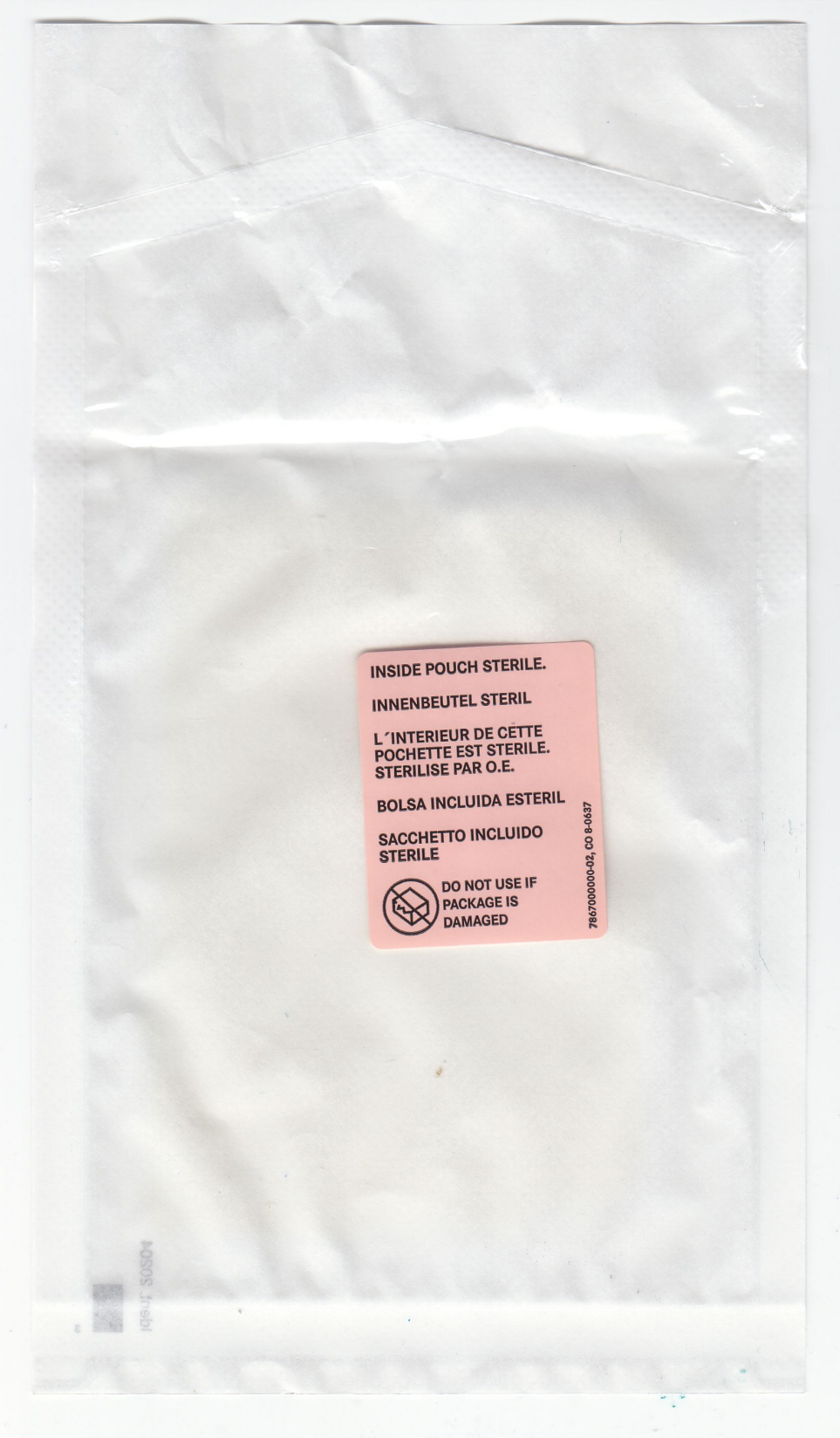
LINE SHOULD BE 100mm LONG WHEN ARTWORK 100% SIZE

SteriPack Medical Limited		
Operator: Lynne	Date: 01/12/2010	SteriPack Customer:
Order No.: 20208	Reprographics Revision: 01	SteriPack Approval:
Reprographic Ref.: 93154	Colours: 1	SteriPack QA Approval:
SteriPack Customer Part Number: AAP 19-7576300396		SteriPack Artwork Rev. #: 01

25mm

REPROGRAPHIC SYSTEMS ARTWORK FOR APPROVAL - PLEASE CHECK CAREFULLY. SIGN IN SPACE PROVIDED IF THIS ARTWORK MEETS YOUR SPECIFIC REQUIREMENTS.

In the case of queries, please contact artwork@steripackgroup.com


INSIDE POUCH STERILE.
INNENBEUTEL STERIL
L´INTERIEUR DE CETTE POCHETTE EST STERILE. STERILISE PAR O.E.
BOLSA INCLUIDA ESTERIL
SACCHETTO INCLUIDO STERILE
DO NOT USE IF PACKAGE IS DAMAGED
7867000000-02, CO 8-0637

INSIDE POUCH STERILE.

INNENBEUTEL STERIL

L´INTERIEUR DE CETTE POCHETTE EST STERILE. STERILISE PAR O.E.

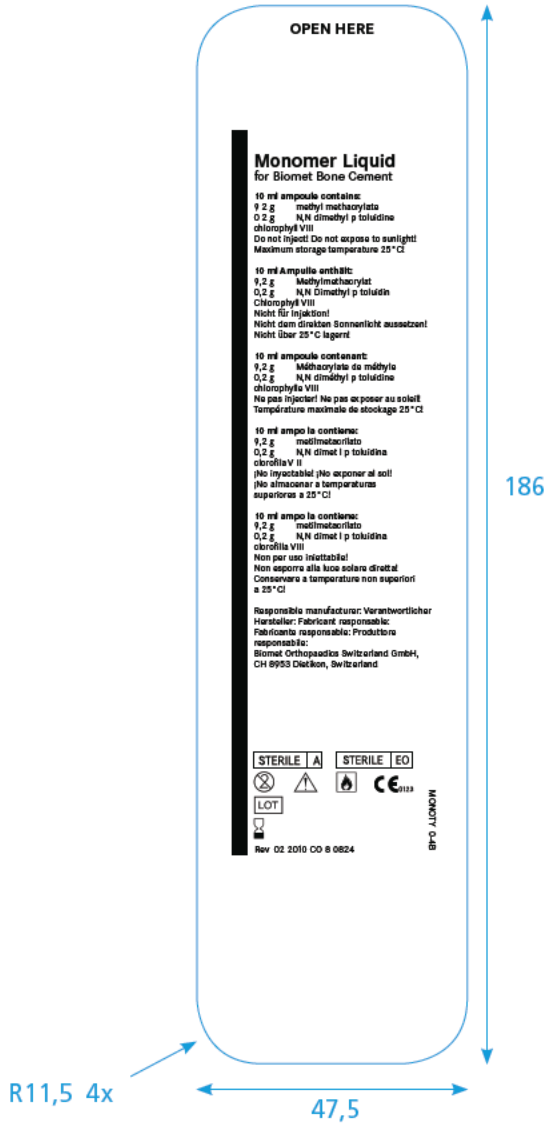
BOLSA INCLUIDA ESTERIL

SACCHETTO INCLUIDO STERILE

DO NOT USE IF PACKAGE IS DAMAGED

7867000000-02, CO 8-0637

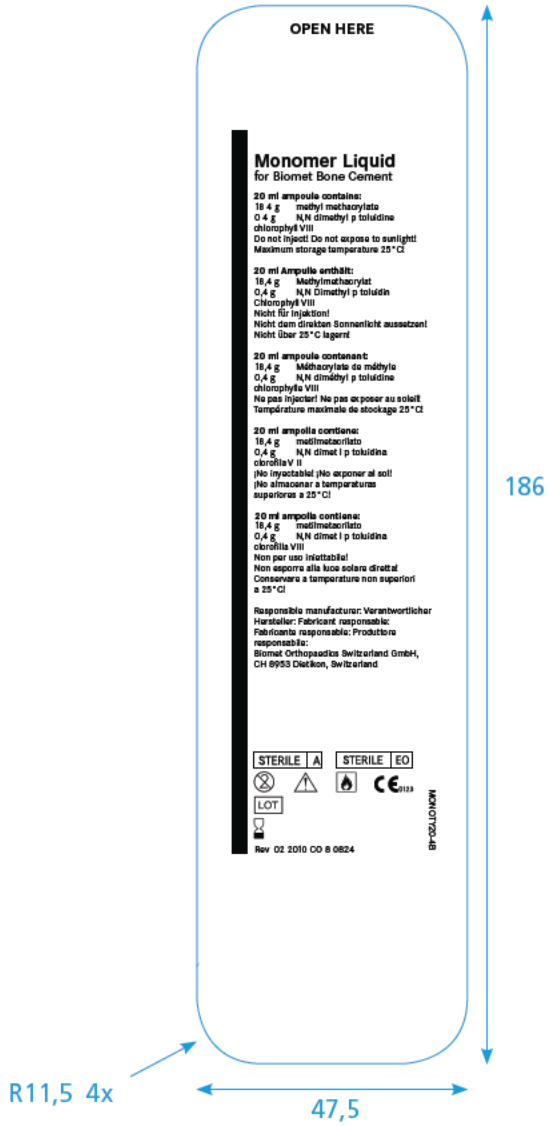
OLIVER-TOLAS HEALTHCARE PACKAGING



Lidding material uncoated side

End Customer P/N	:				
Customer P/N	: (b)(4) [redacted]				
OMP P/N	(b) [redacted]	Platenr	: 536318	Colour	: black
Material	(b)(4) [redacted]	Platenr	:	Colour	:
Proof type	: PDF	Platenr	:	Colour	:
Revisionnr	: new	Platenr	:	Colour	:
Date	(b)(4) [redacted]	Platenr	:	Colour	:
Resp.	(b)(4) [redacted]	Platenr	:	Colour	:
Approved by	:	Platenr	:	Colour	:
Company	:	Dienr	: 533923		
Date	:			All sizes are in mm	
Signature	:	Signature artwork	(b)(4) [redacted] (b)(4) [redacted]	Signature artwork check	(b)(4) [redacted] (b)(4) [redacted]

OLIVER-TOLAS HEALTHCARE PACKAGING



Lidding material uncoated side

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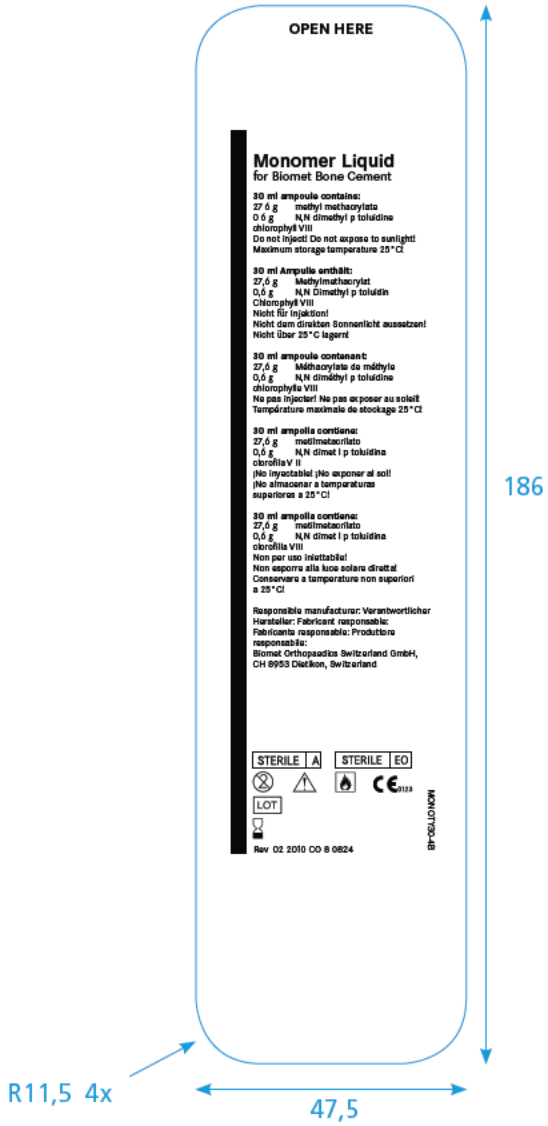
Proof type	: PDF	Platenr	:	Colour	:
Revisionnr	: new	Platenr	:	Colour	:
Date	: (b)(4) [redacted]	Platenr	:	Colour	:
Resp.	(b)(4) [redacted]	Platenr	:	Colour	:
Approved by	:	Platenr	:	Colour	:
Company	:	Dienr	: 533923		
Date	:			All sizes are in mm	
Signature	:	Signature artwork	(b)(4) [redacted] (b)(4) [redacted]	Signature artwork check	(b)(4) [redacted] (b)(4) [redacted]

OLIVER-TOLAS HEALTHCARE PACKAGING



Lidding material uncoated side

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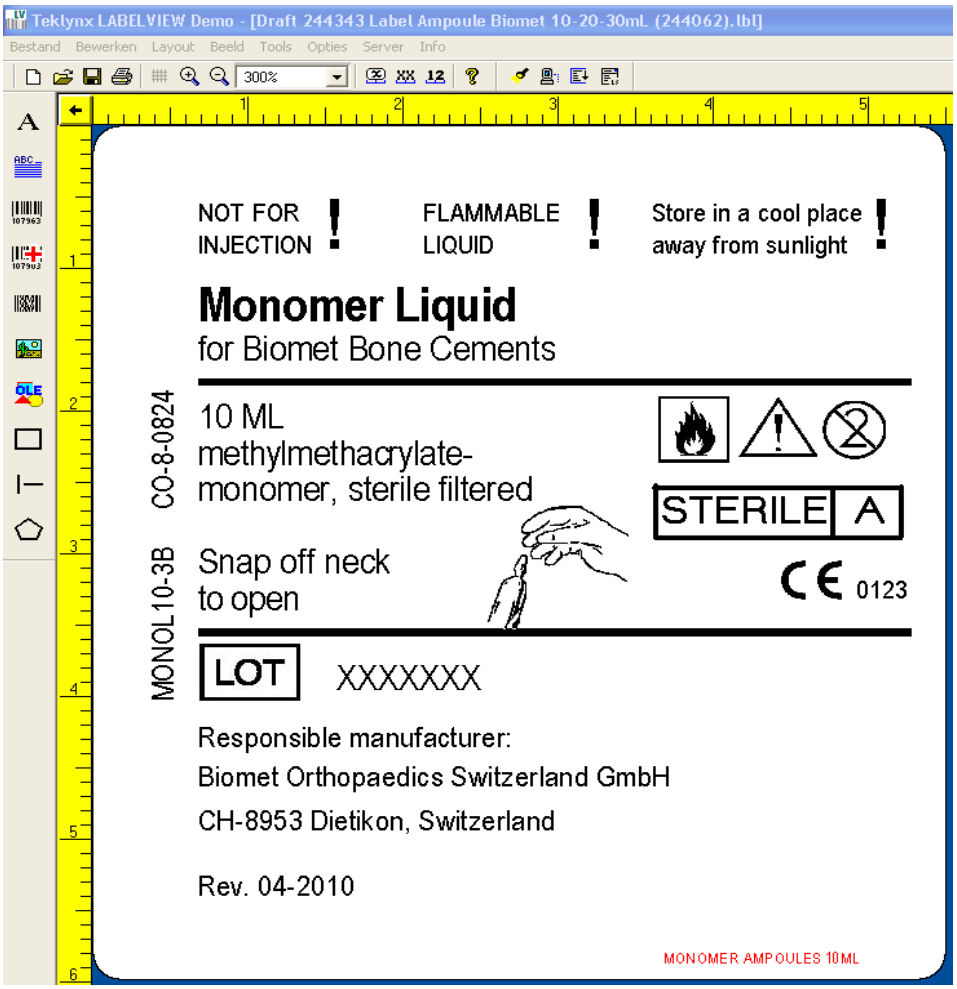
OMP P/N	(b)(4) [redacted]	Platenr	: 536321	Colour	: black
Material	(b)(4) [redacted]	Platenr	:	Colour	:
Proof type	: PDF	Platenr	:	Colour	:
Revisionnr	: new	Platenr	:	Colour	:
Date	(b)(4) [redacted]	Platenr	:	Colour	:
Resp.	(b)(4) [redacted]	Platenr	:	Colour	:
Approved by	:	Platenr	:	Colour	:
Company	:	Dienr	: 533923		
Date	:			All sizes are in mm	
Signature	:	Signature artwork	(b)(4) [redacted] (b)(4) [redacted]	Signature artwork check	(b)(4) [redacted] (b)(4) [redacted]

Article: 244343 Date: 11 October 2010

Name: Label Ampoule Biomet 10-20-30mL

Print colour: White



Text in red will not be printed on the label on label

(b)(4) [redacted] Date: Signature:

(b)(4) [redacted] / (b)(4) [redacted]

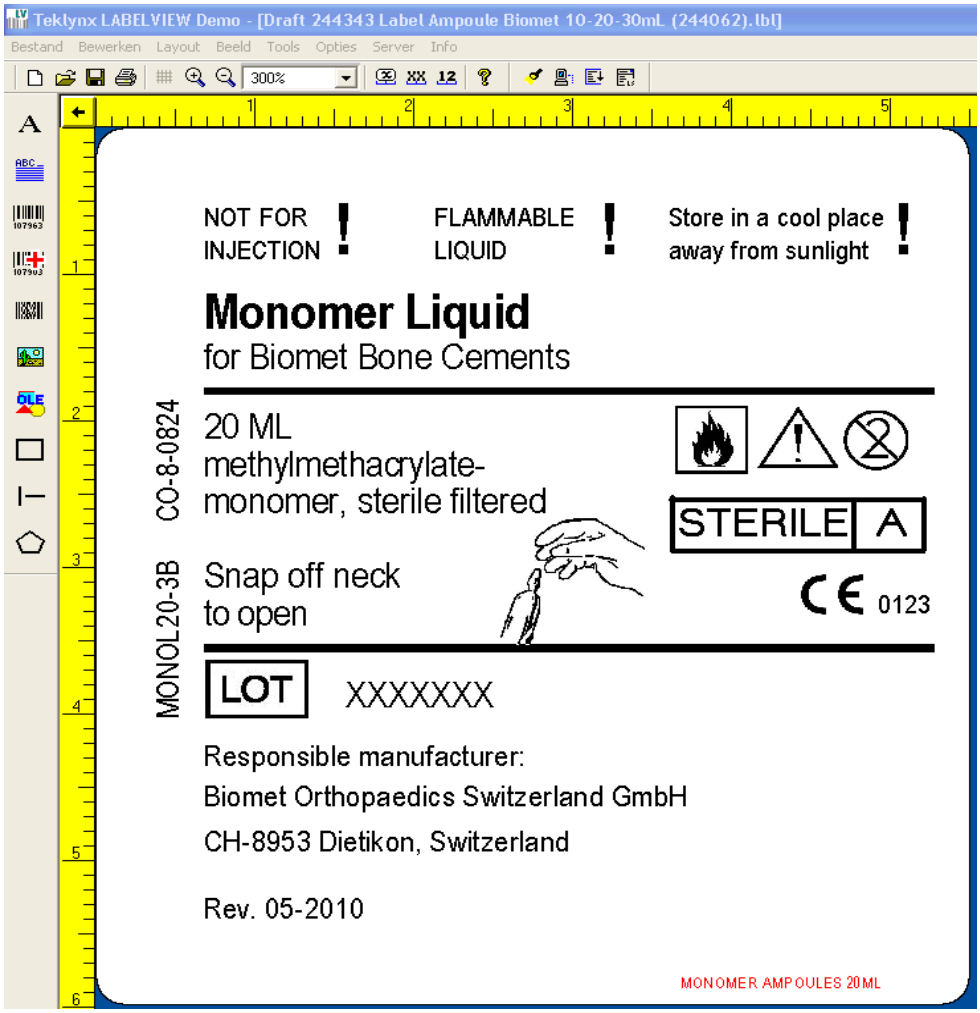
Approved by (Biomet) Date:

/

Article: 244343 Date: 11 October 2010

Name: Label Ampoule Biomet 10-20-30mL

Print colour: White



Text in red will not be printed on the label on label

(b)(4) [redacted] Date: Signature:

(b)(4) [redacted] / (b)(4) [redacted] _____

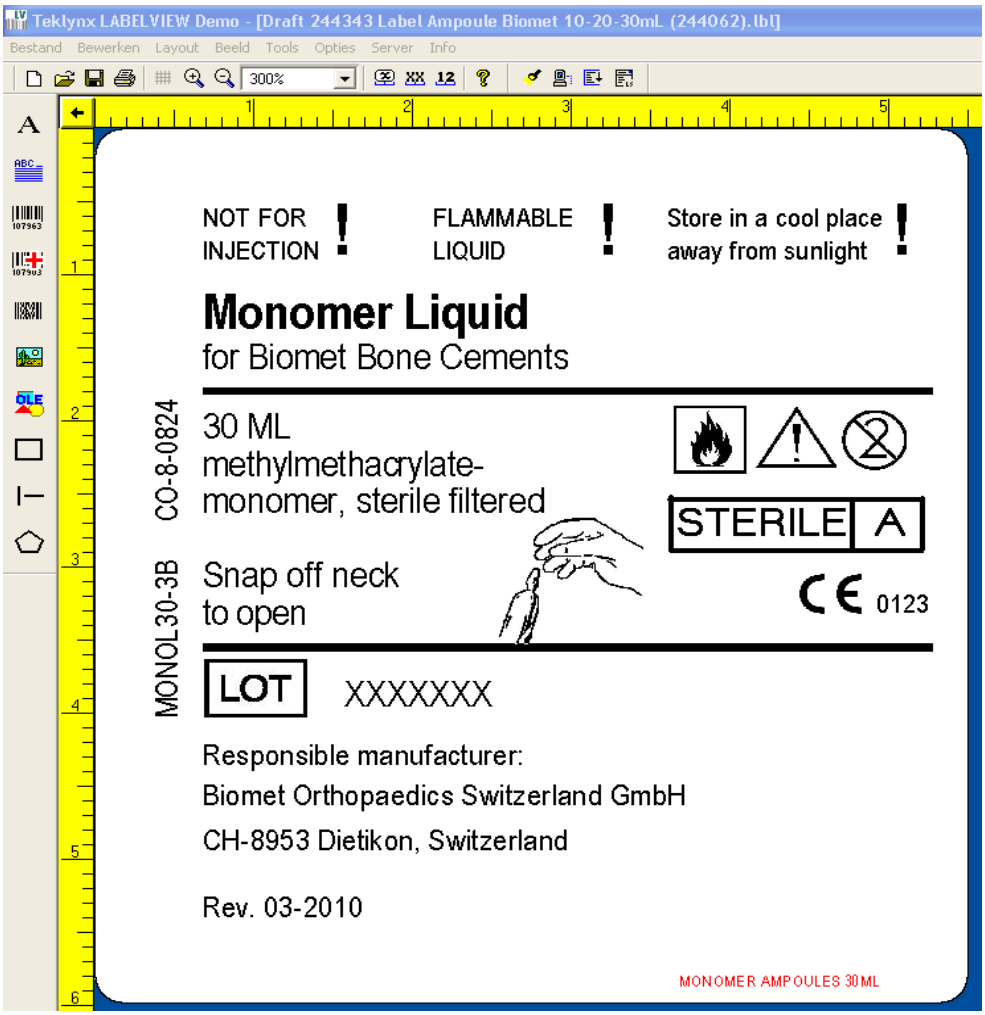
Approved by (Biomet) Date:

_____ / _____ _____

Article: 244343 Date: 11 October 2010

Name: Label Ampoule Biomet 10-20-30mL

Print colour: White



Text in red will not be printed on the label on label

(b)(4) [redacted] Date: Signature:

(b)(4) [redacted] / (b)(4) [redacted]

Approved by (Biomet) Date:

/

7800500392SP

Optipac® Knee
Refobacin® Bone Cement R

BIOMET

Optipac® Knee – Refobacin® Bone Cement R

Optipac® Knee
Refobacin® Bone Cement R E

Gentamicin 0.3 g

Rapid curing synthetic resin for bone surgery pre-packed in a vacuum mixing system – radiopaque

1 blister tray with a pre-packed mixing system containing 25.2 g polymer powder and 12.4 ml monomer liquid, accessories

Composition:

Powder: gentamicin sulphate 0.5 g (corresponding to 0.3 g gentamicin), poly(methyl acrylate, methyl methacrylate) 20.7 g, zirconium dioxide 3.8 g, benzoyl peroxide 0.2 g

Liquid: methyl methacrylate 11.4 g, N,N-dimethyl-p-toluidine 0.2 g, chlorophyll VIII

Do not re-sterilise!
Maximum storage temperature 25° C!

Optipac® Knee
Refobacin® Bone Cement R ES

Gentamicina 0.3 g

Cemento quirúrgico de endurecimiento rápido, preenvasado en un sistema de mezclado al vacío – radiopaco

1 bandeja blíster con un sistema de mezclado preenvasado que contiene 25.2 g de polímero en polvo y 12.4 ml de monómero líquido, accesorios

Composición:

Polvo: sulfato de gentamicina 0.5 g (correspondiente a 0.3 g de gentamicina), poli(metilacrilato, metilmetacrilato) 20.7 g, dióxido de circonio 3.8 g, peróxido de benzoilo 0.2 g

Líquido: metilmetacrilato 11.4 g, N,N-dimetil-p-toluidina 0.2 g, clorofila VIII

¡No reesterilizar!
¡No almacenar a temperaturas superiores a 25° C!

Optipac® Knee
Refobacin® Bone Cement R D

Gentamicin 0.3 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in einem Vakuumanmischsystem – röntgenpositiv

1 Blisterschale mit vorgefülltem Anmischsystem, enthält 25.2 g Polymerpulver und 12.4 ml Monomerflüssigkeit, Zubehör

Zusammensetzung:

Pulver: 0.5 g Gentamicinsulfat (entspricht 0.3 g Gentamicin), 20.7 g Poly(methylacrylat, methylmethacrylat), 3.8 g Zirkoniumdioxid, 0.2 g Benzoylperoxid

Flüssigkeit: 11.4 g Methylmethacrylat, 0.2 g N,N-Dimethyl-p-toluidin, Chlorophyll VIII

Nicht nachsterilisieren!
Nicht über 25° C lagern!

Optipac® Knee
Refobacin® Bone Cement R S

Gentamicin 0.3 g

Snabbhärdande syntetisk bencement för ortopedisk kirurgi, paketerat i ett vakuumblandningssystem – röntgentätt

1 blisterförpackning med ett förpaketerat blandningssystem innehållande 25.2 g polymerpulver och 12.4 ml monomervätska, tillbehör

Sammansättning:

Pulver: 0.5 g gentamicinsulfat (motsvarar 0.3 g gentamicin), 20.7 g poly(metylakrylat, metylmetakrylat), 3.8 g zirkoniumdioxid, 0.2 g benzoylperoxid

Vätska: 11.4 g metylmetakrylat, 0.2 g N,N-dimetyl-p-toluidin, klorofyll VIII

Får ej omsterliliseras!
Förvaras ej över 25° C!

Optipac® Knee
Refobacin® Bone Cement R F

Gentamicine 0.3 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse, pré-conditionné en système de mélange sous vide – radio-opaque

1 plateau sous blister avec un système de mélange contenant 25.2 g de polymère en poudre et 12.4 ml de monomère liquide, accessoires

Composition :

Poudre : 0.5 g de sulfate de gentamicine (correspondant à 0.3 g de gentamicine), 20.7 g de poly(acrylate de méthyle, méthacrylate de méthyle), 3.8 g de dioxyde de zirconium, 0.2 g de peroxyde de benzoyle

Liquide : 11.4 g de méthacrylate de méthyle, 0.2 g de N,N-diméthyle-p-toluidine, chlorophylle VIII

Ne pas restériliser !
Température maximale de stockage 25° C !

Optipac® Knee
Refobacin® Bone Cement R I

Gentamicina 0.3 g

Materia plastica a presa rapida per chirurgia ossea, preconfezionata in un sistema di miscelazione sotto vuoto – radio-opaco

1 vassoio blister preconfezionato con un sistema di miscelazione contenente 25.2 g di polvere polimerica e 12.4 ml di monomero liquido, accessori

Composizione:

Polvere: solfato di gentamicina 0.5 g (equivalente a 0.3 g di gentamicina), poli(metilacrilato, metilmetacrilato) 20.7 g, diossido di zirconio 3.8 g, perossido di benzoile 0.2 g

Liquido: metilmetacrilato 11.4 g, N,N-dimetil-p-toluidina 0.2 g, clorofilla VIII

Non risterilizzare!
Conservare a temperature non superiori a 25° C!

Biomet Orthopaedics Switzerland GmbH
Riedmuos 6
CH-4913 Diessbach, Switzerland
www.biomet.com

CE 0123

BIOMET

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Optipac® Knee
Refobacin® Bone Cement R

59914/S019/A

BIOMET

Optipac® Knee
Refobacin® Bone Cement R

GENTAMICIN

STERILE EO STERILE A

Order : O/66469	Klant : Biomet-Merck	Aantal Kleuren: 4
Smurfit Kappa	Doosnr.: 59914	FOR APPROVAL
	Bedr nr.: 59914-B-019-A	Name :
	Cadnr.: TP59914B	Signature:
14/05/2012 11:03	Omschrijving : Folding box optipac knee R	
Opmaak : BVB	Code kL: 7800500392SP	Date:

ONLY FOR TEXT AND POSITION NOT FOR COLOR

Cyan	Magenta	reeflijn
100% 80% 60% 20% 5%	100% 80% 60% 20% 5%	
Yellow	Black	
100% 80% 60% 20% 5%	100% 80% 60% 20% 5%	

7800500394SP

Optipac® 40
Refobacin® Bone Cement R

Optipac® 40
Refobacin® Bone Cement R EN

Gentamicin 0.5 g

Rapid curing synthetic resin for bone surgery pre-packed in a vacuum mixing system – radiopaque

1 blister tray with a pre-packed mixing system containing 40.8 g polymer powder and 20 ml monomer liquid, accessories

Composition:

Powder: gentamicin sulphate 0.8 g (corresponding to 0.5 g gentamicin), poly(methyl acrylate, methyl methacrylate) 33.6 g, zirconium dioxide 6.1 g, benzoyl peroxide 0.3 g

Liquid: methyl methacrylate 18.4 g, N,N-dimethyl-p-toluidine 0.4 g, chlorophyll VIII

Do not re-sterilise!
Maximum storage temperature 25° C!

Optipac® 40
Refobacin® Bone Cement R ES

Gentamicina 0.5 g

Cemento quirúrgico de endurecimiento rápido, preenvasado en un sistema de mezclado al vacío – radiopaco

1 bandeja blíster con un sistema de mezclado preenvasado que contiene 40.8 g de polímero en polvo y 20 ml de monómero líquido, accesorios

Composición:

Polvo: sulfato de gentamicina 0.8 g (correspondiente a 0.5 g de gentamicina), poli(metilacrilato, metilmetacrilato) 33.6 g, dióxido de circonio 6.1 g, peróxido de benzoilo 0.3 g

Líquido: metilmetacrilato 18.4 g, N,N-dimetil-p-toluidina 0.4 g, clorofila VIII

¡No reesterilizar!
¡No almacenar a temperaturas superiores a 25° C!

Optipac® 40
Refobacin® Bone Cement R DE

Gentamicin 0.5 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in einem Vakuummischsystem – röntgenpositiv

1 Blisterschale mit vorgefülltem Anmischsystem, enthält 40.8 g Polymerpulver und 20 ml Monomerflüssigkeit, Zubehör

Zusammensetzung:

Pulver: 0.8 g Gentamicinsulfat (entspricht 0.5 g Gentamicin), 33.6 g Poly(methylacrylat, methylmethacrylat), 6.1 g Zirkoniumdioxid, 0.3 g Benzoylperoxid

Flüssigkeit: 18.4 g Methylmethacrylat, 0.4 g N,N-Dimethyl-p-toluidin, Chlorophyll VIII

Nicht nachsterilisieren!
Nicht über 25° C lagern!

Optipac® 40
Refobacin® Bone Cement R SE

Gentamicin 0.5 g

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi, pakterat i ett vakuumblandningssystem – röntgentätt

1 blisterförpackning med ett förpakterat blandningssystem innehållande 40.8 g polymerpulver och 20 ml monomervätska, tillbehör

Sammansättning:

Pulver: 0.8 g gentamicinsulfat (motsvarar 0.5 g gentamicin), 33.6 g poly(metylakrylat, metylmetakrylat), 6.1 g zirkoniumdioxid, 0.3 g benzoylperoxid

Vätska: 18.4 g metylmetakrylat, 0.4 g N,N-dimetyl-p-toluidin, klorofyll VIII

Får ej omsterilliseras!
Förvaras ej över 25° C!

Optipac® 40
Refobacin® Bone Cement R FR

Gentamicine 0.5 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse, pré-conditionné en système de mélange sous vide – radio-opaque

1 plateau sous blister avec un système de mélange contenant 40.8 g de polymère en poudre et 20 ml de monomère liquide, accessoires

Composition :

Poudre : 0.8 g de sulfate de gentamicine (correspondant à 0.5 g de gentamicine), 33.6 g de poly(acrylate de méthyle, méthacrylate de méthyle), 6.1 g de dioxyde de zirconium, 0.3 g de peroxyde de benzoyle

Liquide : 18.4 g de méthacrylate de méthyle, 0.4 g de N,N-diméthyl-p-toluidine, chlorophylle VIII

Ne pas restériliser !
Température maximale de stockage 25° C !

Optipac® 40
Refobacin® Bone Cement R IT

Gentamicina 0.5 g

Materia plastica a presa rapida per chirurgia ossea, preconfezionata in un sistema di miscelazione sotto vuoto – radio-opaca

1 vassoio blister preconfezionato con un sistema di miscelazione contenente 40.8 g di polvere polimerica e 20 ml di monomero liquido, accessori

Composizione:

Polvere: solfato di gentamicina 0.8 g (equivalente a 0.5 g di gentamicina), poli(metilacrilato, metilmetacrilato) 33.6 g, diossido di zirconio 6.1 g, perossido di benzoile 0.3 g

Liquido: metilmetacrilato 18.4 g, N,N-dimetil-p-toluidina 0.4 g, clorofilla VIII

Non risterilizzare!
Conservare a temperature non superiori a 25° C!

Biomet Orthopaedics Switzerland GmbH
Bösch 69
CH-6331 Hünenberg, Switzerland
www.biomet.com

CE 0123

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Optipac® 40 – Refobacin® Bone Cement R

BIOMET

Optipac® 40
Refobacin® Bone Cement R

GENTAMICIN

Optipac® 40
Refobacin® Bone Cement R

J

59914B/020A

Order : O/66469	Klant : Biomet-Merck	Aantal Kleuren: 4
Smurfit Kappa	Docnm.: 59914	FOR APPROVAL
	Bedr nr.: 59914-B-020-A	Name :
	Cadnr.: TP59914B	Signature:
5/06/2012 14:13	Omschrijving : FOLDING BOX OPTIPAC 40	
Opmaak : BVB	Code KL: 7800500394SP	Date:

ONLY FOR TEXT AND POSITION NOT FOR COLOR

Cyan	Magenta	merlin
100% 80% 60% 20% 5%	100% 80% 60% 20% 5%	
Yellow	Black	
100% 80% 60% 20% 5%	100% 80% 60% 20% 5%	

7800500396SP

Optipac® 60
Refobacin® Bone Cement R

BIOMET

Optipac® 60 – Refobacin® Bone Cement R

Optipac® 60
Refobacin® Bone Cement R EN

Gentamicin 0.8 g

Rapid curing synthetic resin for bone surgery pre-packed in a vacuum mixing system – radiopaque

1 blister tray with a pre-packed mixing system containing 61.3 g polymer powder and 30 ml monomer liquid (2x15 ml), accessories

Composition:

Powder: gentamicin sulphate 1.3 g (corresponding to 0.8 g gentamicin), poly(methyl acrylate, methyl methacrylate) 50.3 g, zirconium dioxide 9.2 g, benzoyl peroxide 0.5 g

Liquid: methyl methacrylate 27.6 g, N,N-dimethyl-p-toluidine 0.6 g, chlorophyll VIII

Do not re-sterilize!
Maximum storage temperature 25° C!

Optipac® 60
Refobacin® Bone Cement R ES

Gentamicina 0.8 g

Cemento quirúrgico de endurecimiento rápido, preenvasado en un sistema de mezclado al vacío – radiopaco

1 bandeja blíster con un sistema de mezclado preenvasado que contiene 61.3 g de polímero en polvo y 30 ml de monómero líquido (2x15 ml), accesorios

Composición:

Polvo: sulfato de gentamicina 1.3 g (correspodiente a 0.8 g de gentamicina), poli(metilacrilato, metilmetacrilato) 50.3 g, dióxido de circonio 9.2 g, peróxido de benzoilo 0.5 g

Líquido: metilmetacrilato 27.6 g, N,N-dimetil-p-toluidina 0.6 g, clorofila VIII

¡No reesterilizar!
¡No almacenar a temperaturas superiores a 25° C!

Optipac® 60
Refobacin® Bone Cement R DE

Gentamicin 0.8 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in einem Vakuummischsystem – röntgenpositiv

1 Blisterschale mit vorgefülltem Anmischsystem, enthält 61.3 g Polymerpulver und 30 ml Monomerflüssigkeit (2x15 ml), Zubehör

Zusammensetzung:

Pulver: 1.3 g Gentamicinsulfat (entspricht 0.8 g Gentamicin), 50.3 g Poly(methylacrylat, methylmethacrylat), 9.2 g Zirkoniumdioxid, 0.5 g Benzoylperoxid

Flüssigkeit: 27.6 g Methylmethacrylat, 0.6 g N,N-Dimethyl-p-toluidin, Chlorophyll VIII

Nicht nachsterilisieren!
Nicht über 25° C lagern!

Optipac® 60
Refobacin® Bone Cement R SE

Gentamicin 0.8 g

Snabbhärdande syntetisk bencement för ortopedisk kirurgi, paketerat i ett vakuumblandningssystem – röntgentätt

1 blisterförpackning med ett förpaketerat blandningssystem innehållande 61.3 g polymerpulver och 30 ml monomervätska (2x15 ml), tillbehör

Sammansättning:

Pulver: 1.3 g gentamicinsulfat (motsvarar 0.8 g gentamicin), 50.3 g poly(metylakrylat, metylmetakrylat), 9.2 g zirkoniumdioxid, 0.5 g benzoylperoxid

Vätska: 27.6 g metylmetakrylat, 0.6 g N,N-dimetyl-p-toluidin, klorofyll VIII

För ej omsterilisera!
Förvaras ej över 25° C!

Optipac® 60
Refobacin® Bone Cement R FR

Gentamicine 0.8 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse, pré-conditionné en système de mélange sous vide – radio-opaque

1 plateau sous blister avec un système de mélange contenant 61.3 g de polymère en poudre et 30 ml de monomère liquide (2x15 ml), accessoires

Composition :

Poudre : 1.3 g de sulfate de gentamicine (correspondant à 0.8 g de gentamicine), 50.3 g de poly(acrylate de méthyle, méthacrylate de méthyle), 9.2 g de dioxyde de zirconium, 0.5 g de peroxyde de benzoyle

Liquide : 27.6 g de méthacrylate de méthyle, 0.6 g de N,N-diméthyle-p-toluidine, chlorophylle VIII

Ne pas restériliser !
Température maximale de stockage 25° C !

Optipac® 60
Refobacin® Bone Cement R IT

Gentamicina 0.8 g

Materia plastica a presa rapida per chirurgia ossea, preconfezionata in un sistema di miscelazione sotto vuoto – radio-opaca

1 vassoio blister preconfezionato con un sistema di miscelazione contenente 61.3 g di polvere polimerica e 30 ml di monomero liquido (2x15 ml), accessori

Composizione:

Polvere: solfato di gentamicina 1.3 g (equivalente a 0.8 g di gentamicina), poli(metilacrilato, metilmetacrilato) 50.3 g, diossido di zirconio 9.2 g, perossido di benzoile 0.5 g

Liquido: metilmetacrilato 27.6 g, N,N-dimetil-p-toluidina 0.6 g, clorofilla VIII

Non risterilizzare!
Conservare a temperature non superiori a 25° C!

Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH-8953 Dietikon, Switzerland
www.biomet.com

CE 0123

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Optipac® 60
Refobacin® Bone Cement R

S9914B/0210/A

BIOMET

Optipac® 60
Refobacin® Bone Cement R

GENTAMICIN

STERILE EO STERILE A

Order : O/66469	Klant : Biomet-Merck	Aantal Kleuren: 4
Smurfit Kappa	Doosnr.: S9914	FOR APPROVAL Name : Signature:
	Bedr nr.: S9914-B-021-A	
	Cadnr.: TP6991B	
14/05/2012 11:02	Omschrijving : Folding box optipac 60	
Opmaak : BVB	Code Id.: 7800500396SP	Date:
ONLY FOR TEXT AND POSITION NOT FOR COLOR		

Cyan 100% 80% 60% 20% 5%
Magenta 100% 80% 60% 20% 5%
matlijn
Yellow 100% 80% 60% 20% 5%
Black 100% 80% 60% 20% 5%

Order : O/66469	Klant : BIOMET-MERCK	Aantal Kleuren: 4
Smurfit Kappa	Doeno.: 69914	FOR APPROVAL
	Bedr nr.: 69914-B-022-A	Name :
	Cadnr.: TP59914B	Signature:
14/05/2012 11:01	Omschrijving : Folding Box Optipac 80	
Opmaak : TLA	Code kL: 78005003985P	Date:

ONLY FOR TEXT AND POSITION NOT FOR COLOR

Cyan	Magenta	Medium
100% 80% 50% 20% 5%	100% 80% 50% 20% 5%	100% 80% 50% 20% 5%
Yellow	Black	
100% 80% 50% 20% 5%	100% 80% 50% 20% 5%	

78005003985P

Optipac® 80
Refobacin® Bone Cement R

Optipac® 80
Refobacin® Bone Cement R EN

Gentamicin 1.0 g

Rapid curing synthetic resin for bone surgery pre-packed in a vacuum mixing system – radiopaque

1 blister tray with a pre-packed mixing system containing 81.6 g polymer powder and 40 ml monomer liquid (2x20 ml), accessories

Composition:

Powder: gentamicin sulphate 1.6 g (corresponding to 1.0 g gentamicin), poly(methyl acrylate, methyl methacrylate) 67.2 g, zirconium dioxide 12.2 g, benzoyl peroxide 0.6 g

Liquid: methyl methacrylate 36.8 g, N,N-dimethyl-p-toluidine 0.8 g, chlorophyll VIII

Do not resterilise!
Maximum storage temperature 25° C!

Optipac® 80
Refobacin® Bone Cement R ES

Gentamicina 1.0 g

Cemento quirúrgico de endurecimiento rápido, preenvasado en un sistema de mezclado al vacío – radiopaco

1 bandeja blíster con un sistema de mezclado preenvasado que contiene 81.6 g de polímero en polvo y 40 ml de monómero líquido (2x20 ml), accesorios

Composición:

Polvo: sulfato de gentamicina 1.6 g (correspondiente a 1.0 g de gentamicina), poli(metilacrilato, metilmetacrilato) 67.2 g, dióxido de circonio 12.2 g, peróxido de benzoilo 0.6 g

Líquido: metilmetacrilato 36.8 g, N,N-dimetil-p-toluidina 0.8 g, clorofila VIII

¡No reesterilizar!
¡No almacenar a temperaturas superiores a 25° C!

Optipac® 80
Refobacin® Bone Cement R DE

Gentamicin 1.0 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in einem Vakuummischsystem – röntgenpositiv

1 Blisterschale mit vorgefülltem Anmischsystem, enthält 81.6 g Polymerpulver und 40 ml Monomerflüssigkeit (2x20 ml), Zubehör

Zusammensetzung:

Pulver: 1.6 g Gentamicinsulfat (entspricht 1.0 g Gentamicin), 67.2 g Poly(methylacrylat, methylmethacrylat), 12.2 g Zirkoniumdioxid, 0.6 g Benzoylperoxid

Flüssigkeit: 36.8 g Methylmethacrylat, 0.8 g N,N-Dimethyl-p-toluidin, Chlorophyll VIII

Nicht nachsterilisieren!
Nicht über 25° C lagern!

Optipac® 80
Refobacin® Bone Cement R SE

Gentamicin 1.0 g

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi, paketerat i ett vakuumblandningssystem – röntgentätt

1 blisterförpackning med ett förpaketerat blandningssystem innehållande 81.6 g polymerpulver och 40 ml monomervätska (2x20 ml), tillbehör

Sammansättning:

Pulver: 1.6 g gentamicinsulfat (motsvarar 1.0 g gentamicin), 67.2 g poly(metylakrylat, metylmetakrylat), 12.2 g zirkoniumdioxid, 0.6 g benzoylperoxid

Vätska: 36.8 g metylmetakrylat, 0.8 g N,N-dimetyl-p-toluidin, klorofyll VIII

Får ej omsterilisieras!
Förvaras ej över 25° C!

Optipac® 80
Refobacin® Bone Cement R FR

Gentamicine 1.0 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse, pré-conditionné en système de mélange sous vide – radio-opaque

1 plateau sous blister avec un système de mélange contenant 81.6 g de polymère en poudre et 40 ml de monomère liquide (2x20 ml), accessoires

Composition :

Poudre : 1.6 g de sulfate de gentamicine (correspondant à 1.0 g de gentamicine), 67.2 g de poly(acrylate de méthyle, méthacrylate de méthyle), 12.2 g de dioxyde de zirconium, 0.6 g de peroxyde de benzoyle

Liquide : 36.8 g de méthacrylate de méthyle, 0.8 g de N,N-diméthyle-p-toluidine, chlorophylle VIII

Ne pas restériliser !
Température maximale de stockage 25° C !

Optipac® 80
Refobacin® Bone Cement R IT

Gentamicina 1.0

Materia plastica a presa rapida per chirurgia ossea, preconfezionata in un sistema di miscelazione sotto vuoto – radio-opaco

1 vassoio blister preconfezionato con un sistema di miscelazione contenente 81.6 g di polvere polimerica e 40 ml di monomero liquido (2x20 ml), accessori

Composizione:

Polvere: solfato di gentamicina 1.6 g (equivalente a 1.0 g di gentamicina), poli(metilacrilato, metilmetacrilato) 67.2 g, diossido di zirconio 12.2 g, perossido di benzoile 0.6 g

Liquido: metilmetacrilato 36.8 g, N,N-dimetil-p-toluidina 0.8 g, clorofilla VIII

Non risterilizzare!
Conservare a temperature non superiori a 25° C!

Biomet Orthopaedics Switzerland GmbH
Riedstrasse 6
CH-8953 Dietikon, Switzerland
www.biomet.com

CE 0123

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Optipac® 80 – Refobacin® Bone Cement R

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Optipac® 80
Refobacin® Bone Cement R

GENTAMICIN

Optipac® 80
Refobacin® Bone Cement R

G

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Optipac® Hip Set (40 & 80)

Refobacin® Bone Cement R

Optipac® Hip Set (40 & 80)
Refobacin® Bone Cement R

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Optipac® Hip Set (40 & 80)
Refobacin® Bone Cement R

BIOMET

GENTAMICIN

STERILE EO STERILE A

Optipac® Hip Set (40 & 80)
Refobacin® Bone Cement R

EN

Optipac® Hip Set (40 & 80)
Refobacin® Bone Cement R

Optipac® 40
Gentamicin 0.5 g
Rapid curing synthetic resin for bone surgery prepacked in a vacuum mixing system
- radiopaque

1 blister tray with a prepacked mixing system containing 40.8 g polymer powder and 20 ml monomer liquid, accessories

Composition:
Powder: gentamicin sulphate 0.8 g (corresponding to 0.5 g gentamicin), polymethyl acrylate, methyl methacrylate 33.4 g, zirconium dioxide 4.1 g, benzoyl peroxide 0.6 g
Liquid: methylmethacrylate 19.4 g, N,N-dimethyl-p-toluidine 0.6 g, chlorophyll

Optipac® 80
Gentamicin 1.0 g
Rapid curing synthetic resin for bone surgery prepacked in a vacuum mixing system
- radiopaque

1 blister tray with a prepacked mixing system containing 81.6 g polymer powder and 40 ml monomer liquid (2 x 20 ml), accessories

Composition:
Powder: gentamicin sulphate 1.6 g (corresponding to 1.0 g gentamicin), polymethyl acrylate, methyl methacrylate 67.2 g, zirconium dioxide 12.2 g, benzoyl peroxide 0.6 g
Liquid: methylmethacrylate 38.8 g, N,N-dimethyl-p-toluidine 0.8 g, chlorophyll

Do not re-sterilise!
Maximum storage temperature 25° C!

ES

Optipac® Hip Set (40 & 80)
Refobacin® Bone Cement R

Optipac® 40
Gentamicina 0.5 g
Cemento quirúrgico de endurecimiento rápido, preparado en un sistema de mezcla al vacío
- radiopaco

1 bandeja blíster con un sistema de mezclado preenvasado que contiene 40.8 g de polímero en polvo y 20 ml de monómero líquido, accesorios

Composición:
Polvo: sulfato de gentamicina 0.8 g (correspondiente a 0.5 g de gentamicina), polimetilacrilato, metilmetacrilato 33.4 g, dióxido de circonio 4.1 g, peróxido de benzoilo 0.6 g
Líquido: metilmetacrilato 19.4 g, N,N-dimetil-p-toluidina 0.6 g, clorofila

Optipac® 80
Gentamicina 1.0 g
Cemento quirúrgico de endurecimiento rápido, preparado en un sistema de mezcla al vacío
- radiopaco

1 bandeja blíster con un sistema de mezclado preenvasado que contiene 81.6 g de polímero en polvo y 40 ml de monómero líquido (2 x 20 ml), accesorios

Composición:
Polvo: sulfato de gentamicina 1.6 g (correspondiente a 1.0 g de gentamicina), polimetilacrilato, metilmetacrilato 67.2 g, dióxido de circonio 12.2 g, peróxido de benzoilo 0.6 g
Líquido: metilmetacrilato 38.8 g, N,N-dimetil-p-toluidina 0.8 g, clorofila

No esterilizar!
No almacenar a temperaturas superiores a 25° C!

DE

Optipac® Hip Set (40 & 80)
Refobacin® Bone Cement R

Optipac® 40
Gentamicin 0.5 g
Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in einem Vakuummischsystem
- röntgendicht

1 Blisterschale mit vorgefülltem Anmischsystem, enthält 40.8 g Polymerpulver und 20 ml Monomerflüssigkeit, Zubehör

Zusammensetzung:
Pulver: 0.8 g Gentamicinsulfat (entspricht 0.5 g Gentamicin), 33.4 g Polymethylacrylat, methylmethacrylat, 4.1 g Zirkoniumoxid, 0.6 g Benzoylperoxid
Flüssigkeit: 19.4 g Methylmethacrylat, 0.6 g N,N-Dimethyl-p-toluidin, Chlorophyll

Optipac® 80
Gentamicin 1.0 g
Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in einem Vakuummischsystem
- röntgendicht

1 Blisterschale mit vorgefülltem Anmischsystem, enthält 81.6 g Polymerpulver und 40 ml Monomer-Flüssigkeit (2 x 20 ml), Zubehör

Zusammensetzung:
Pulver: 1.6 g Gentamicinsulfat (entspricht 1.0 g Gentamicin), 67.2 g Polymethylacrylat, methylmethacrylat, 12.2 g Zirkoniumoxid, 0.6 g Benzoylperoxid
Flüssigkeit: 38.8 g Methylmethacrylat, 0.8 g N,N-Dimethyl-p-toluidin, Chlorophyll

Nicht nachsterilisierbar!
Nicht über 25° C lagern!

SE

Optipac® Hip Set (40 & 80)
Refobacin® Bone Cement R

Optipac® 40
Gentamicin 0.5 g
Snabbhärdande syntetisk bencement för ortopedisk kirurgi, paketerat i ett vakuumblandningssystem
- röntgentätt

1 blisterförpackning med ett förpackstort blandningssystem innehållande 40.8 g polymerpulver och 20 ml monomervätska, tillbehör

Sammansättning:
Pulver: 0.8 g gentamicinsulfat (motsvarar 0.5 g gentamicin), 33.4 g polymetylakrylat, metylmetakrylat, 4.1 g zirkoniumoxid, 0.6 g bensoylperoxid
Vätska: 19.4 g metylmetakrylat, 0.6 g N,N-dimetyl-p-toluidin, klorofyll

Optipac® 80
Gentamicin 1.0 g
Snabbhärdande syntetisk bencement för ortopedisk kirurgi, paketerat i ett vakuumblandningssystem
- röntgentätt

1 blisterförpackning med ett förpackstort blandningssystem innehållande 81.6 g polymerpulver och 40 ml monomervätska (2 x 20 ml), tillbehör

Sammansättning:
Pulver: 1.6 g gentamicinsulfat (motsvarar 1.0 g gentamicin), 67.2 g polymetylakrylat, metylmetakrylat, 12.2 g zirkoniumoxid, 0.6 g bensoylperoxid
Vätska: 38.8 g metylmetakrylat, 0.8 g N,N-dimetyl-p-toluidin, klorofyll

Icke resterilisera!
Förvaras ej över 25° C!

FR

Optipac® Hip Set (40 & 80)
Refobacin® Bone Cement R

Optipac® 40
Gentamicine 0.5 g
Ciment chirurgical durcissement rapide pour la chirurgie osseuse, préconditionné en système de mélange sous vide
- radio-opaque

1 plateau sous blister avec un système de mélange contenant 40.8 g de polymère en poudre et 20 ml de monomère liquide, accessoires

Composition :
Poudre : 0.8 g de sulfate de gentamicine (correspondant à 0.5 g de gentamicine), 33.4 g de polymethacrylate de méthyle, méthacrylate de méthyle, 4.1 g de dioxyde de zirconium, 0.6 g de peroxyde de benzoyle
Liquide : 19.4 g de méthacrylate de méthyle, 0.6 g de N,N-dimethyle-p-toluidine, chlorophyle

Optipac® 80
Gentamicine 1.0 g
Ciment chirurgical durcissement rapide pour la chirurgie osseuse, préconditionné en système de mélange sous vide
- radio-opaque

1 plateau sous blister avec un système de mélange contenant 81.6 g de polymère en poudre et 40 ml de monomère liquide (2 x 20 ml), accessoires

Composition :
Poudre : 1.6 g de sulfate de gentamicine (correspondant à 1.0 g de gentamicine), 67.2 g de polymethacrylate de méthyle, méthacrylate de méthyle, 12.2 g de dioxyde de zirconium, 0.6 g de peroxyde de benzoyle
Liquide : 38.8 g de méthacrylate de méthyle, 0.8 g de N,N-dimethyle-p-toluidine, chlorophyle

Ne pas restériliser!
Température maximale de stockage 25° C !

IT

Optipac® Hip Set (40 & 80)
Refobacin® Bone Cement R

Optipac® 40
Gentamicina 0.5 g
Materia plastica a presa rapida per chirurgia ossea, preconfezionata in un sistema di miscelazione sotto vuoto - radio-opaca

1 vassoio blister preconfezionato con un sistema di miscelazione contenente 40.8 g di polvere polimerica e 20 ml di monomero liquido, accessori

Composizione:
Polvere: solfato di gentamicina 0.8 g (equivalente a 0.5 g di gentamicina), polimetilacrilato, metilmetacrilato 33.4 g, dioxido di zirconio 4.1 g, perossido di benzoile 0.6 g
Liquido: metilmetacrilato 19.4 g, N,N-dimetil-p-toluidina 0.6 g, clorofilla

Optipac® 80
Gentamicina 1.0 g
Materia plastica a presa rapida per chirurgia ossea, preconfezionata in un sistema di miscelazione sotto vuoto - radio-opaca

1 vassoio blister preconfezionato con un sistema di miscelazione contenente 81.6 g di polvere polimerica e 40 ml di monomero liquido (2 x 20 ml), accessori

Composizione:
Polvere: solfato di gentamicina 1.6 g (equivalente a 1.0 g di gentamicina), polimetilacrilato, metilmetacrilato 67.2 g, dioxido di zirconio 12.2 g, perossido di benzoile 0.6 g
Liquido: metilmetacrilato 38.8 g, N,N-dimetil-p-toluidina 0.8 g, clorofilla

Non risterilizzare!
Conservare a temperature non superiori a 25° C!

Biomet Orthopaedics Switzerland GmbH
Bösch 69
CH-6331 Hünenberg, Switzerland
www.biomet.com
CE 0123

BIOMET

Order : P/28762	Klant : BIOMET	Aantal Kleuren: 4
Smurfit Kappa	Doorn.: 59915	FOR APPROVAL
	Bestr nr.: 59915-A-000-A	Name :
	Cadv.: TP59915A	Signature:
6/06/2012 12:38	Omschrijving : Folding box optipac hipset	
Opmaak : IVR	Code 128: 7800500399	Date:

ONLY FOR TEXT AND POSITION NOT FOR COLOR

Cyan 100% 80% 60% 40% 0%
Magenta 100% 80% 60% 40% 0%
Yellow 100% 80% 60% 40% 0%
Black 100% 80% 60% 40% 0%

Inside sterile when indicator is green

Optipac® Knee
Refobacin® Bone Cement R

Optipac® Knee
Refobacin® Bone Cement R

EN

Gentamicin 0.3 g

Rapid curing synthetic resin for bone surgery
pre-packed in a vacuum mixing system – radiopaque.
1 blister tray with a pre-packed mixing system containing 25.2 g
polymer powder and 12.4 ml monomer liquid, accessories.
Maximum storage temperature 25° C!
Inside sterile when indicator is green.

Optipac® Knee
Refobacin® Bone Cement R

DE

Gentamicin 0,3 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in
einem Vakuumanmischsystem – röntgenpositiv.
1 Blisterschale mit vorgefülltem Anmischsystem, enthält 25,2 g
Polymerpulver und 12,4 ml Monomerflüssigkeit, Zubehör.
Nicht über 25° C lagern!
Inhalt steril, wenn Indikator grün.

Optipac® Knee
Refobacin® Bone Cement R

FR

Gentamicine 0,3 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse,
pré-conditionné en système de mélange sous vide – radio-opaque.
1 plateau sous blister avec un système de mélange contenant 25,2 g de
polymère en poudre et 12,4 ml de monomère liquide, accessoires.
Température maximale de stockage 25° C !
Intérieur stérile si l'indicateur est de couleur verte.

Optipac® Knee
Refobacin® Bone Cement R

ES

Gentamicina 0,3 g

Cemento quirúrgico de endurecimiento rápido, preenvasado
en un sistema de mezclado al vacío – radiopaco.
1 bandeja blíster con un sistema de mezclado preenvasado que contiene
25,2 g de polímero en polvo y 12,4 ml de monómero líquido, accesorios.
¡No almacenar a temperaturas superiores a 25° C!
Interior estéril si el indicador es de color verde.

Optipac® Knee
Refobacin® Bone Cement R

SE

Gentamicin 0,3 g

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi,
paketerat i ett vakuumblandningssystem – röntgentätt.
1 blisterförpackning med ett förpaketerat blandningssystem innehållande
25,2 g polymerpulver och 12,4 ml monomervätska, tillbehör.
Förvaras ej över 25° C!
Sterilt inuti när indikatorn är grön.

Optipac® Knee
Refobacin® Bone Cement R

IT

Gentamicina 0,3 g

Materia plastica a presa rapida per chirurgia ossea, preconfezionata
in un sistema di miscelazione sotto vuoto – radio-opaca.
1 vassoio blister preconfezionato con un sistema di miscelazione contenente
25,2 g di polvere polimerica e 12,4 ml di monomero liquido, accessori.
Conservare a temperature non superiori a 25° C!
Interiore sterile se l'indicatore è di colore verde.

STERILE EO STERILE A CE 0123

Not made with natural rubber latex

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable
Fabricante responsable: Ansvarig tillverkare: Produttore responsabile:
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574735-03

Inside sterile when indicator is green

Optipac® 40
Refobacin® Bone Cement R

Optipac® 40
Refobacin® Bone Cement R

EN

Gentamicin 0.5 g

Rapid curing synthetic resin for bone surgery
pre-packed in a vacuum mixing system – radiopaque.
1 blister tray with a pre-packed mixing system containing 40.8 g
polymer powder and 20 ml monomer liquid, accessories.
Maximum storage temperature 25° C!
Inside sterile when indicator is green.

Optipac® 40
Refobacin® Bone Cement R

DE

Gentamicin 0,5 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in
einem Vakuumanmischsystem – röntgenpositiv.
1 Blisterschale mit vorgefülltem Anmischsystem, enthält 40,8 g
Polymerpulver und 20 ml Monomerflüssigkeit, Zubehör.
Nicht über 25° C lagern!
Inhalt steril, wenn Indikator grün.

Optipac® 40
Refobacin® Bone Cement R

FR

Gentamicine 0,5 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse,
pré-conditionné en système de mélange sous vide – radio-opaque.
1 plateau sous blister avec un système de mélange contenant 40,8 g de
polymère en poudre et 20 ml de monomère liquide, accessoires.
Température maximale de stockage 25° C !
Intérieur stérile si l'indicateur est de couleur verte.

Optipac® 40
Refobacin® Bone Cement R

ES

Gentamicina 0,5 g

Cemento quirúrgico de endurecimiento rápido, preenvasado
en un sistema de mezclado al vacío – radiopaco.
1 bandeja blíster con un sistema de mezclado preenvasado que contiene
40,8 g de polímero en polvo y 20 ml de monómero líquido, accesorios.
¡No almacenar a temperaturas superiores a 25° C!
Interior estéril si el indicador es de color verde.

Optipac® 40
Refobacin® Bone Cement R

SE

Gentamicin 0,5 g

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi,
paketerat i ett vakuumblandningssystem – röntgentätt.
1 blisterförpackning med ett förpaketerat blandningssystem innehållande
40,8 g polymerpulver och 20 ml monomervätska, tillbehör.
Förvaras ej över 25° C!
Sterilt inuti när indikatorn är grön.

Optipac® 40
Refobacin® Bone Cement R

IT

Gentamicina 0,5 g

Materia plastica a presa rapida per chirurgia ossea, preconfezionata
in un sistema di miscelazione sotto vuoto – radio-opaca.
1 vassoio blister preconfezionato con un sistema di miscelazione contenente
40,8 g di polvere polimerica e 20 ml di monomero liquido, accessori.
Conservare a temperature non superiori a 25° C!
Interiore sterile se l'indicatore è di colore verde.

STERILE EO STERILE A CE 0123

Not made with natural rubber latex

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable
Fabricante responsable: Ansvarig tillverkare: Produttore responsabile:
Biomet Orthopaedics Switzerland GmbH, Riedstrasse 6, CH-8953 Dietikon, Switzerland
www.biomet.com

574710-05

Inside sterile when indicator is green

Optipac® 60
Refobacin® Bone Cement R

Optipac® 60
Refobacin® Bone Cement R

EN

Gentamicin 0.8 g

Rapid curing synthetic resin for bone surgery
pre-packed in a vacuum mixing system – radiopaque.
1 blister tray with a pre-packed mixing system containing 61,3 g polymer powder and 30 ml monomer liquid (2 x 15 ml), accessories.
Maximum storage temperature 25° C!
Inside sterile when indicator is green.

Optipac® 60
Refobacin® Bone Cement R

DE

Gentamicin 0,8 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in einem Vakuumanmischsystem – röntgenpositiv.
1 Blisterschale mit vorgefülltem Anmischsystem, enthält 61,3 g Polymerpulver und 30 ml Monomerflüssigkeit (2 x 15 ml), Zubehör.
Nicht über 25° C lagern!
Inhalt steril, wenn Indikator grün.

Optipac® 60
Refobacin® Bone Cement R

FR

Gentamicine 0,8 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse, pré-conditionné en système de mélange sous vide – radio-opaque.
1 plateau sous blister avec un système de mélange contenant 61,3 g de polymère en poudre et 30 ml de monomère liquide (2 x 15 ml), accessoires.
Température maximale de stockage 25° C !
Intérieur stérile si l'indicateur est de couleur verte.

Optipac® 60
Refobacin® Bone Cement R

ES

Gentamicina 0,8 g

Cemento quirúrgico de endurecimiento rápido, preenvasado en un sistema de mezclado al vacío – radiopaco.
1 bandeja blíster con un sistema de mezclado preenvasado que contiene 61,3 g de polímero en polvo y 30 ml de monómero líquido (2 x 15 ml), accesorios.
¡No almacenar a temperaturas superiores a 25° C!
Interior estéril si el indicador es de color verde.

Optipac® 60
Refobacin® Bone Cement R

SE

Gentamicin 0,8 g

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi, paketerat i ett vakuumblandningssystem – röntgentätt.
1 blisterförpackning med ett förpaketerat blandningssystem innehållande 61,3 g polymerpulver och 30 ml monomervätska (2 x 15 ml), tillbehör.
Förvaras ej över 25° C!
Sterilt inuti när indikatorn är grön.

Optipac® 60
Refobacin® Bone Cement R

IT

Gentamicina 0,8 g

Materia plastica a presa rapida per chirurgia ossea, preconfezionata in un sistema di miscelazione sotto vuoto – radio-opaca.
1 vassoio blister preconfezionato con un sistema di miscelazione contenente 61,3 g di polvere polimerica e 30 ml di monomero liquido (2 x 15 ml), accessori.
Conservare a temperature non superiori a 25° C!
Interiore sterile se l'indicatore è di colore verde.

STERILE EO STERILE A CE 0123

Not made with natural rubber latex

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable
Fabricante responsable: Ansvarig tillverkare: Produttore responsabile:
Biomet Orthopaedics Switzerland GmbH, Riedstrasse 6, CH-8953 Dietikon, Switzerland
www.biomet.com

574711-04

Inside sterile when indicator is green

Optipac® 80
Refobacin® Bone Cement R

Optipac® 80
Refobacin® Bone Cement R

EN

Gentamicin 1.0 g

Rapid curing synthetic resin for bone surgery
pre-packed in a vacuum mixing system – radiopaque.
1 blister tray with a pre-packed mixing system containing 81.6 g
polymer powder and 40 ml monomer liquid (2 x 20 ml), accessories.
Maximum storage temperature 25° C!
Inside sterile when indicator is green.

Optipac® 80
Refobacin® Bone Cement R

DE

Gentamicin 1,0 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in
einem Vakuumanmischsystem – röntgenpositiv.
1 Blisterschale mit vorgefülltem Anmischsystem, enthält 81,6 g
Polymerpulver und 40 ml Monomerflüssigkeit (2 x 20 ml), Zubehör.
Nicht über 25° C lagern!
Inhalt steril, wenn Indikator grün.

Optipac® 80
Refobacin® Bone Cement R

FR

Gentamicine 1,0 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse,
pré-conditionné en système de mélange sous vide – radio-opaque.
1 plateau sous blister avec un système de mélange contenant 81,6 g de
polymère en poudre et 40 ml de monomère liquide (2 x 20 ml), accessoires.
Température maximale de stockage 25° C !
Intérieur stérile si l'indicateur est de couleur verte.

Optipac® 80
Refobacin® Bone Cement R

ES

Gentamicina1,0 g

Cemento quirúrgico de endurecimiento rápido, preenvasado
en un sistema de mezclado al vacío – radiopaco.
1 bandeja blíster con un sistema de mezclado preenvasado que contiene 81,6 g
de polímero en polvo y 40 ml de monómero líquido (2 x 20 ml), accesorios.
¡No almacenar a temperaturas superiores a 25° C!
Interior estéril si el indicador es de color verde.

Optipac® 80
Refobacin® Bone Cement R

SE

Gentamicin 1,0 g

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi,
paketerat i ett vakuumblandningssystem – röntgentätt.
1 blisterförpackning med ett förpaketerat blandningssystem innehållande 81,6 g
polymerpulver och 40 ml monomervätska (2 x 20 ml), tillbehör.
Förvaras ej över 25° C!
Sterilt inuti när indikatorn är grön.

Optipac® 80
Refobacin® Bone Cement R

IT

Gentamicina 1,0 g

Materia plastica a presa rapida per chirurgia ossea, preconfezionata
in un sistema di miscelazione sotto vuoto – radio-opaca.
1 vassoio blister preconfezionato con un sistema di miscelazione contenente
81,6 g di polvere polimerica e 40 ml di monomero liquido (2 x 20 ml), accessori.
Conservare a temperature non superiori a 25° C!
Interiore sterile se l'indicatore è di colore verde.

STERILE EO STERILE A CE 0123

Not made with natural rubber latex

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable
Fabricante responsable: Ansvarig tillverkare: Produttore responsabile:
Biomet Orthopaedics Switzerland GmbH, Riedstrasse 6, CH-8953 Dietikon, Switzerland
www.biomet.com

574712-05

Inside sterile when indicator is green

Optipac® Hip Set – Refobacin® Bone Cement R

EN

Optipac® 40
Gentamicin 0.5 g

Rapid curing synthetic resin for bone surgery pre-packed in a vacuum mixing system – radiopaque.
1 blister tray with a pre-packed mixing system containing 40.8 g polymer powder and 20 ml monomer liquid, accessories.

Optipac® 80
Gentamicin 1.0 g

Rapid curing synthetic resin for bone surgery pre-packed in a vacuum mixing system – radiopaque.
1 blister tray with a pre-packed mixing system containing 81.6 g polymer powder and 40 ml monomer liquid (2 x 20 ml), accessories.

Maximum storage temperature 25° C! Do not re-sterilise!
Inside sterile when indicator is green.

DE

Optipac® 40
Gentamicin 0,5 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in einem Vakuumanmischsystem – röntgenpositiv.
1 Blisterschale mit vorgefülltem Anmischsystem, enthält 40,8 g Polymerpulver und 20 ml Monomerflüssigkeit, Zubehör.

Optipac® 80
Gentamicin 1,0 g

Schnellhärtender Kunststoff für die Knochenchirurgie, vorgefüllt in einem Vakuumanmischsystem – röntgenpositiv.
1 Blisterschale mit vorgefülltem Anmischsystem, enthält 81,6 g Polymerpulver und 40 ml Monomerflüssigkeit (2 x 20 ml), Zubehör.

Nicht über 25° C lagern! Nicht nachsterilisieren!
Inhalt steril, wenn Indikator grün.

FR

Optipac® 40
Gentamicine 0,5 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse, pré-conditionné en système de mélange sous vide – radio-opaque.
1 plateau sous blister avec un système de mélange contenant 40,8 g de polymère en poudre et 20 ml de monomère liquide, accessoires.

Optipac® 80
Gentamicine 1,0 g

Ciment chirurgical à durcissement rapide pour la chirurgie osseuse, pré-conditionné en système de mélange sous vide – radio-opaque.
1 plateau sous blister avec un système de mélange contenant 81,6 g de polymère en poudre et 40 ml de monomère liquide (2 x 20 mm), accessoires.

Température maximale de stockage 25° C ! Ne pas restéreliser !
Intérieur stérile si l'indicateur est de couleur verte.

ES

Optipac® 40
Gentamicina 0,5 g

Cemento quirúrgico de endurecimiento rápido, preenvasado en un sistema de mezclado al vacío – radiopaco.
1 bandeja blíster con un sistema de mezclado preenvasado que contiene 40,8 g de polímero en polvo y 20 ml de monómero líquido, accesorios.

Optipac® 80
Gentamicina 1,0 g

Cemento quirúrgico de endurecimiento rápido, preenvasado en un sistema de mezclado al vacío – radiopaco.
1 bandeja blíster con un sistema de mezclado preenvasado que contiene 81,6 g de polímero en polvo y 40 ml de monómero líquido (2 x 20 ml), accesorios.

¡No almacenar a temperaturas superiores a 25° C! ¡No reesterilisar!
Interior estéril si el indicador es de color verde.

SE

Optipac® 40
Gentamicin 0,5 g

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi, paketerat i ett vakuumblandningssystem – röntgentätt.
1 blisterförpackning med ett förpaketerat blandningssystem innehållande 40,8 g polymerpulver och 20 ml monomervätska, tillbehör.

Optipac® 80
Gentamicin 1,0 g

Snabbhärdande syntetiskt bencement för ortopedisk kirurgi, paketerat i ett vakuumblandningssystem – röntgentätt.
1 blisterförpackning med ett förpaketerat blandningssystem innehållande 81,6 g polymerpulver och 40 ml monomervätska (2 x 20 ml), tillbehör.

Förvaras ej över 25° C! Får ej omsteriliseras!
Sterilt inuti när indikatorn är grön.

IT

Optipac® 40
Gentamicina 0,5 g

Materia plastica a presa rapida per chirurgia ossea, preconfezionata in un sistema di miscelazione sotto vuoto – radio-opaca.
1 vassoio blister preconfezionato con un sistema di miscelazione contenente 40,8 g di polvere polimerica e 20 ml di monomero liquido, accessori.

Optipac® 80
Gentamicina 1,0 g

Materia plastica a presa rapida per chirurgia ossea, preconfezionata in un sistema di miscelazione sotto vuoto – radio-opaca.
1 vassoio blister preconfezionato con un sistema di miscelazione contenente 81,6 g di polvere polimerica e 40 ml di monomero liquido (2 x 20 ml), accessori.

Conservare a temperature non superiori a 25° C!
Interiore sterile se l'indicatore è di colore verde.

STERILE EO STERILE A CE 0123

Not made with natural rubber latex

Responsible manufacturer: Verantwortlicher Hersteller: Fabricant responsable
Fabricante responsable: Ansvarig tillverkare: Produttore responsabile:
Biomet Orthopaedics Switzerland GmbH, Riedstrasse 6, CH-8953 Dietikon, Switzerland
www.biomet.com

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Design Ref:	P1 Biomet 14411310_40559
Job ID Number:	51pw0u
Number of Colours Printing in Job:	2
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Customer:	P1
Design Reference:	EI14411310 40559v1
Customer contact:	
Date:	13/04/11

P286 K

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174.00 mm

Optipac

BIOMET

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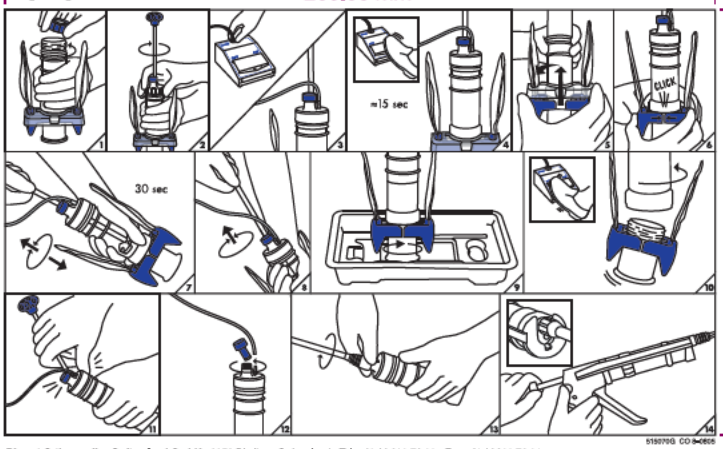
120.00 mm



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The colours on the artwork are for illustration purposes only. As PC screens and inkjet printers are generally not colour calibrated, the colours may not match the finished label. For spot colours, where possible please refer to a recent Pantone reference chart. For process images the only true representation will be the finished label.

We take every precaution to avoid mistakes in preparing artwork, but we CANNOT accept responsibility for errors once the artwork has been approved. Alterations which are departures from the original copy may be charged for and requested proofs will be invoiced if the order is not placed.

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17 Sterilization and Shelf Life

17.1 Subject Device: Sterilization

The subject device, Refobacin® Bone Cement R, is sterilized by a combination of methods including ethylene oxide gas and sterile filtration. The powder is packed into the primary (b)(4) [redacted] pouch and secondary (b)(4) [redacted] pouch and is sterilized by ethylene oxide gas by (b)(4) [redacted]

After blending, the components of the monomer (liquid) are sterilized via sterile filtration and aseptically filled into the sterile ampoules by (b)(4) [redacted] The sterile ampoules are filled (b)(4) [redacted], and sealed-off again immediately. The ampoules are packed in (b)(4) [redacted] and sealed at (b)(4) [redacted]. The sterilization methods used for the powder (EO) and monomer (sterile filtration) components of Refobacin® Bone Cement R are the same as for the powder (EO) and monomer (sterile filtration) components of Palacos® G Bone Cement (K031673), thus they are substantially equivalent.

Sterilization validations are complete for all Refobacin® Bone Cement R components.

17.1.1 Sterile Devices: Refobacin Bone Cement R

The subject device is provided sterile by exposure to ETO gas and sterile filtration as follows:

Table 17.1: Monomer Sterile Filtration Information

Filter Size	(b)(4) [redacted]
Sterility Validation Method	
Sterilization Site	
Labeling	Packaging will display a statement that the device has been sterilized using aseptic processing techniques.

Table 17.2: Powder and Powder Pouch ETO Sterilization Information

Sterility Assurance Level (SAL)	10^{-6}
Sterility Validation Method	(b)(4) [redacted]

	(b)(4) [redacted]
Pyrogenicity	No pyrogen-free claims are made.
Sterilization Site	(b)(4) [redacted]
Labeling	All packages will display a statement that the device has been sterilized by ETO.

Steriliant residuals for EO sterilized powder components of Refobacin® Bone Cement R is (b)(4) [redacted]. EO residuals measured during the sterilization validation of Refobacin® Bone Cement R are in conformance with the limits identified in ISO 10993-7.

17.1.2 Optipac® Refobacin® Bone Cement R - Alternative Packaging Configuration

Optipac®, the alternative packaging configuration, comes pre-filled with the components of Refobacin® Bone Cement R (powder and liquid). As noted in Section 14, Optipac®-Refobacin® Bone Cement R is distributed as part of a convenience kit. The pre-packaged powder (contained in mixing cylinder), the liquid monomer (loaded into Softpac pouches via sterile filtration), and other convenience kit sterile, single use-items are sterilized by ethylene oxide gas (EO) by (b)(4) [redacted] The sterilization methods used for the filling of the monomer liquid into the sterilized softpac pouches (sterile filtration) and for the final packaged Optipac® System (EO), are the same as those used for Palacos® G Bone Cement (K031673), thus they are substantially equivalent.

Sterilization validations are complete for all Optipac®-Refobacin® Bone Cement R components. (b)(4) [redacted]

(b)(4) [redacted]

Steriliant residuals for EO sterilized powder components of the Optipac® are (b)(4) [redacted] EO residuals of Optipac®-Refobacin® Bone Cement R are in conformance with the limits identified in ISO 10993-7.

Table 17.3: Optipac® EO Sterilization Information

Sterility Assurance Level (SAL)	10^{-6}
Sterility Validation Method	(b)(4) [redacted]
Pyrogenicity	No pyrogen-free claims are made.
Sterilization Site	(b)(4) [redacted]
Labeling	All packages will display a statement that the product has been sterilized by EO.

17.2 Packaging

17.2.1 Sterile Implants/Accessories

The packaging configurations for the subject device are summarized below.

Refobacin® Bone Cement R

The powder is packaged in a sealed inner pouch (b)(4) [redacted] that is placed in a sealed secondary pouch (b)(4) [redacted] Both pouches are then packaged in a sealed aluminum/paper pouch. Labeling information is provided on the inner pouch and aluminum/paper pouch. The secondary pouch has a small orange label that notifies user to not use if the package is damaged and that the contents are sterile. The monomer is packaged in amber-glass ampoules. The ampoules are placed in an individual blister tray and a (b)(4) [redacted] lid heat-sealed to the trays. Labeling information is provided on the ampoules and (b)(4) [redacted] lid. The sealed trays are placed in a cardboard insert for stability and placed in the carton with the powder pouches, patient labels and IFU. Upon visual comparison, this packaging configuration for the subject device is identical to the packaging configuration for the predicate device.

Optipac®-Refobacin® Bone Cement R

The powder component is packaged in the mixing cylinder and secured via a threaded sealing lid with gas permeable filter. A separate sealing lid and mixing rod are included in the blister tray for mixing purposes. The monomer liquid is packaged in Softpac pouches which are secured to the mixing cylinder via the blue bag holders on the distal end of the mixing cylinder. As specified in Section 14, different sizes of the Optipac®-Refobacin® Bone Cement contain the following in addition to the powder cylinder, monomer pouches, and mixing rod as part of the convenience kits:

- 1 breakaway cement nozzle (not included in the Knee version)
- 1 knee nozzle breakable (only included in the knee and 40 versions)
- 1 vacuum line with sterile filter
- 1 femoral pressurizer (only included in the 60 and 80 versions)

The sterile single use items-including the powder cylinder, monomer pouches, and mixing rod are placed in a blister tray and a (b)(4) [redacted] lid heat sealed to the tray. The sealed tray is then placed in a polyethylene (b)(4) [redacted] breather bag and placed in cardboard boxes. Labeling information is provided on the breather bag and (b)(4) [redacted] lid.

17.3 Shelf Life

Refobacin® Bone Cement R

The shelf life of Refobacin® Bone Cement R was validated using a combination of real-time and accelerated aging testing. The cement performance after aging was validated using real time testing of Refobacin® Bone Cement R 40 components. Samples were maintained in storage conditions as specified in the Instructions for Use for 36 months (max. 25°C). (b)(4) [redacted] The samples met the specifications for the powder, monomer, and final cement as provided in Section 14 for Refobacin® Bone Cement R 40 and the 20mL monomer liquid specification.

Packaging shelf life of the powder pouches was validated using samples accelerated aged to the equivalent of 5 years. (b)(4) [redacted] met established acceptance criteria. Shelf life testing for blister trays with ampoules was performed on EO sterilized samples that had been stored for 36 months real time. The packaging validation demonstrated that the blister tray configuration maintains its integrity over the proposed 36-month shelf life. Ampoules were visually inspected after testing and no changes to the ampoules were noted. Based on the combined shelf life validations of the subject device and packaging, a 36-month shelf life is appropriate.

The product is only intended for single use and the expiry date is clearly displayed in the package label.

Optipac®- Refobacin® Bone Cement R

The shelf life of Optipac®-Refobacin® Bone Cement R was validated using a combination of real-time and accelerated aging testing of the cement and its packaging components.

Cement:

The cement performance after aging was validated using real time testing of Optipac®-Refobacin® Bone Cement R 80 components. Samples were maintained in storage conditions as specified in the Instructions for Use for 18 months (max. 25°C). (b)(4) [redacted] were examined. The samples met the specifications for the powder, monomer, and final cement as provided in Section 14 for Optipac®-Refobacin® Bone Cement R 80 and the 20mL Optipac®-Refobacin® Bone Cement R monomer liquid specification.

Packaging:
Packaging shelf life testing was conducted with products, manufactured and sterilized per standard procedures, maintained in storage conditions as specified in the Instructions for Use for 18-months real time (max. 25°C). The breather bag, (b)(4) blister tray, and outer carton were evaluated as part of a shelf life assessment. The packaging components were visually inspected for defects and in the case of the blister tray and breather bag if defects (e.g. scratches, bended plastic) were noted, dye penetration tests were performed to assess the viability of the seal. The breather bag, (b)(4) blister tray, and outer carton met the established acceptance criteria of the shelf life testing for an 18-month shelf life.

(b)(4)

Additional functional testing was completed on Optipac® mixing cartridges that were both real time and accelerated aged. The oldest existing products (including EO sterilization) were (b)(4) old. In order to bridge the final (b)(4) gap additional samples approximately twice the current shelf life were used in the attached test report (b)(4). Functional characteristics of the Optipac® and its interactions with the other items

in the convenience kit were evaluated and found to meet the established acceptance criteria.

Multiple components and their shelf lives have to be considered in determining the shelf life of Optipac®-Refobacin® Bone Cement R. The cement and its components meet the required specifications after 18 months of real time aging providing evidence that the subject device performance is not adversely affected by aging. The packaging (outer carton, breather bag, (b)(4) [redacted] blister tray) met established acceptance criteria using 18-month real time samples that it maintains its integrity for the duration of the 18-month shelf life. Changes to the monomer packaging do not affect the 18-month shelf life as the stability for the packaging materials has been demonstrated for 7+ year real time aged samples for the colored monomer. Functionality of the plastic components of the Optipac® were evaluated utilizing a combination of real time and accelerated aged samples and met established acceptance criteria. Based on the combined shelf life validations of the subject device and packaging, an 18-month shelf life is appropriate.

17.4 Test Reports

(b)(4) [redacted]

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

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[redacted]

(b)(4)Testing

[redacted]

(b)(4)Testing

[redacted]

(b)(4)Testing

[redacted]

(b)(4)Testing

[redacted]

18 Biocompatibility & Color Additives

18.1 Biocompatibility

This submission includes devices which have direct patient contact. Refobacin® Bone Cement R is intended for permanent implantation into the human body. The intended body contact, including duration, of Refobacin® Bone Cement R is identical to the intended contact of the predicate device Palacos® G (K031673).

(b) (4) [redacted] A comparison of the subject device and predicate device IFUs reveals the only difference in material composition between the two devices is Refobacin® Bone Cement R powder does not contain a colorant; only the monomer. Chlorophyll VIII is used as the colorant in Refobacin® Bone Cement R which is the same as in the predicate device Palacos® G. Additionally, the powder and monomer components of Refobacin® Bone Cement R and Palacos® G are sterilized via the same methods (i.e., powder-EO, monomer-sterile filtration) regardless of packaging configurations (i.e. Optipac®). EO residuals measured during the sterilization validation of Refobacin® Bone Cement R and Optipac®-Refobacin® Bone Cement R are in conformance with the limits identified in ISO 10993-7. As the subject and predicate device materials and sterilization methods are the same and the subject device performance testing results to the predicate results are equivalent, a full biocompatibility characterization of the subject device is not required. Cytotoxicity testing was performed on the subject device as packaged in both packaging configurations and the reports are included in Section 18.2.

Table 18.1: Palacos® G and Refobacin® Bone Cement R Powder and Monomer Material Comparison

Palacos® G Powder Component	Refobacin® Bone Cement R Powder Component	Material Standard
Poly(methyl acrylate, methyl methacrylate)	Poly(methyl acrylate, methyl methacrylate)	NA
Zirconium Dioxide	Zirconium Dioxide	NA
Hydrous benzoyl peroxide	Hydrous benzoyl peroxide	NA
Gentamicin (as sulphate)	Gentamicin (as sulphate)	NA
Chlorophyll VIII	No color additive	NA
Monomer Component	**Monomer Component**	
Methyl methacrylate	Methyl methacrylate	NA
N, N-dimethyl-p-toluidine	N, N-dimethyl-p-toluidine	NA
Chlorophyll VIII in an oily	Chlorophyll VIII* in an oily	NA

solution, hydroquinone	solution, hydroquinone	

*See Section 18.2 for a copy of the Certificate of Analysis (COA)

As described above, Refobacin® Bone Cement R, as packaged with or without Optipac®, is comprised of the same materials, has the same intended body contact, and uses the same sterilization methods as Palacos® G and its materials which have a long history of clinical use in orthopedic implants. Additionally results of cytotoxicity testing indicate that Refobacin® Bone Cement R, packaged with or without the Optipac®, does not possess cytotoxic potential. Therefore, Refobacin® Bone Cement R meets the ISO 10993-1 standard requirements for biocompatibility and no further characterization testing is required.

18.2 Test Reports/Certificate of Analysis

(b)(4)Testing

[redacted]

(b)(4)Testing

b)(4) Testing

b)(4) Testing

b)(4) Testing

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(b)(4) resting

19 Software

19.1 Software

This device does not contain software; this section is not applicable to this premarket notification [510(k)] submission.

20 Electromagnetic Compatibility and Electrical Safety

20.1 Electromagnetic Compatibility and Electrical Safety

This section is not applicable to this premarket notification [510(k)] submission. The subject device does not require EMC and Electrical Safety evaluation.

21 Performance Testing – Bench

21.1 Performance Testing – Bench

Performance testing was conducted with Refobacin® Bone Cement R in support of substantial equivalence. The following reports detail: 1) the methodology used to demonstrate the device is substantially equivalent; 2) the results from the performance tests and 3) the interpretation of this data from which these claims were objectively established. Collectively, these reports demonstrate the Refobacin® Bone Cement R will perform as intended and is substantially equivalent to the predicate device referenced in the submission.

Table 21.1 and 21.2 summarizes the results of the required testing outlined in ASTM F451 & ISO 5833; copies of the reports are located in Section 21.2. Testing was conducted on product exposed to ETO/sterile filtration and representative of the final manufacturing process.

The summary tables below show that the subject device (including the subject device packaged in Optipac®) meets all the consensus standards for bone cement, as well as being substantially equivalent to the predicate device. However, as is to be expected when performing such a large number and diversity of tests, the summary also shows that there were several differences between the subject device and the predicate device. Some of these differences were statistically significant. In some cases, the predicate device outperformed the subject device, while in other cases the subject device outperformed the predicate device. In nearly all of the cases, the differences, even if statistically significant, were of small magnitude ((b) (4) [redacted] This variation is in line with past cement testing experiences, thus the test results demonstrate that the device is substantially equivalent.

Table 21.1: **Refobacin® Bone Cement R vs. Palacos® G*: Summary of Chemical, Physical, Handling & Mechanical Testing**

(b) (4)

[redacted]

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

21.2 Test Reports

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

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22 Performance Testing – Animal

22.1 Performance Testing - Animal

No animal testing was performed in support of this premarket notification; therefore, this section is not applicable.

23 Performance Testing – Clinical

23.1 Performance Testing - Clinical

No clinical testing was performed in support of this premarket notification. This section is not applicable to this submission.

24 Other Information

Heraeus
Heraeus Medical GmbH

61273 Wehrheim, Germany

PALACOS® R+G pro

Radiopaque bone cement with gentamicin

Special 510(k) **510(k) Summary**

Date of summary	July 25th, 2014
Applicant's name and address	Heraeus Medical GmbH Philipp-Reis-Straße 8/13 61273 Wehrheim Germany
Device trade name	PALACOS® R+G pro
Common name	PMMA Bone Cement
Classification	PMMA Bone Cement : Class II special control per 21 CFR 888.3027 Cement Mixer for Clinical Use: Class I Exempt per 21 CFR 888.4210 Cement Dispenser: Class I Exempt per 21 CFR 888.4200
Classification name	Polymethylmethacrylate (PMMA) bone cement
Device code	LOD, MBB, KIH, JDZ
Identification of the marketed device to which equivalence is claimed	PALACOS® R+G, K031673
Reference device	SmartMix Cemvac Pre-filled with SmartSet GHV Gentamicin bone cement, K053445
Description of the device	PALACOS® R+G pro is an acrylic bone cement for use in orthopedic surgery. It is formed from powder and liquid by exothermic polymerization. It secures the fixation of the grafted artificial joint improving the transfer of forces at the interface implant - bone. The bone cement powder and liquid of PALACOS® R+G pro are pre-packed in a vacuum mixing and application system. This reduces the user steps and processing time during mixing of the bone cement. It also decreases the exposure to monomer fumes. PALACOS® R+G pro is available in one size: 75 g and is

61273 Wehrheim, Germany

PALACOS® R+G pro

Radiopaque bone cement with gentamicin

Special 510(k) **510(k) Summary**

	for single use. The PALACOS® R+G pro device includes: • The mixing and application device pre-packed with the bone cement powder • One ampoule of monomer liquid pre-packed in a monomer cartridge • Accessories: a nozzle, a femur pressurizer, a vacuum sealed vacuum tube and in a separate box, an adaptor ring for the use with bone cement gun
Indications for use	PALACOS® R+G pro is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.
Comparison of technological characteristics	Bone cement is derived by mixing a powder component and a monomer liquid. The only difference between the subject and predicate device exists in a change to the primary packaging into a pre-packed application device to simplify the user handling of the components.
Discussion of nonclinical tests	The stability of liquid component, maximum temperature, setting time, intrusion, compressive strength, bending modulus and bending strength of PALACOS® R+G pro was characterized per ISO 5833. In addition, impact and bending strength were measured according to Dynstat test method. EtO sterilization was validated per ISO 11135. Biocompatibility testing, including cytotoxicity, irritation, sensitization, acute systemic toxicity, implantation, genotoxicity and chemical characterization was performed per ISO 10993.
Clinical performance data	No clinical data was provided.

Heraeus

Heraeus Medical GmbH

61273 Wehrheim, Germany

PALACOS® R+G pro

Radiopaque bone cement with gentamicin

Special 510(k) **510(k) Summary**

Conclusions from nonclinical and clinical data	PALACOS® R+G pro is substantial equivalent to PALACOS® R+G.
Submitted by	Dr. Astrid Marx Phone: + 49 (0) 6181.35-2963 Fax: + 49 (0) 6181.35-2910 astrid.marx@heraeus.com
US contact information	Aptiv Solutions, 62 Forest Street, Suite 300, Marlborough, MA 01752, Tina Wu (Phone: +1 443.352.3909, tina.wu@aptivsolutions.com)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 5, 2014

Heraeus Medical GmbH
Dr. Astrid Marx
Junior Regulatory Affairs Manager
Philipp-Reis-Straße 8/13
61273 Wehrheim
Germany

Re: K142157
Trade/Device Name: PALACOS® R+G pro
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD, MBB, KIH, JDZ
Dated: July 25, 2014
Received: August 6, 2014

Dear Dr. Marx

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142157

Device Name
PALACOS® R+G pro

Indications for Use *(Describe)*

PALACOS® R+G pro is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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FDA CDRH DMC

JUN 22 2015

Received

K150850/S1

BIOMET

June 19, 2015

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

SUBJECT: Traditional 510(k) – K150850: Refobacin® Bone Cement R- Request to remove AINN hold

Dear Ms. Sloan:

This letter is being sent as a follow up to the telephone conversation and email correspondence that occurred between June 1, 2015 and June 5, 2015 regarding an AINN hold for K150850. Due to the Biomet-Zimmer merger, divestments of certain product lines were required. Biomet had requested an AINN hold for K150850 until a full understanding of the divestment agreements and their impact on the products presented in this submission could be reached. Once a business strategy was identified Biomet was to respond to the Agency clarifying which, if any, of the products would be withdrawn or if the submission as a whole would be withdrawn.

Biomet would like to confirm at this time that it is requesting removal of the AINN hold and that the Agency resume its review of all products currently included in the submission.

As per our telephone conversation on June 17, 2015 Biomet has included the response to the most recent interactive request for additional information received via email on May 29, 2015. The enclosed information is submitted in duplicate. An electronic copy is being provided with this submission as one of the required copies; it is an exact duplicate of the paper submission. If you require any additional information please contact me by phone (574-371-3024), fax (574-372-1683) or email (carmen.albany@biomet.com) or, as an alternate contact Lynnette Jackson, Vice President, Global Regulatory Affairs by phone (574) 372-3982 or email (lynnette.jackson@biomet.com).

50

Sincerely,

Carmen Albany, DVM
Sr. Regulatory Affairs Specialist, US

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/19/2015	NA	NA

SECTION A — TYPE OF SUBMISSION

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

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Biomet Inc.	Establishment Registration Number *(if known)*: 1825034		
Division Name *(if applicable)*: Biomet Manufacturing Corp.	Phone Number *(including area code)*: 574-371-3024		
Street Address: 56 East Bell Drive	FAX Number *(including area code)*: 574-371-1683		
City: Warsaw	State / Province: IN	ZIP/Postal Code: 46581	Country: USA
Contact Name: Carmen Albany, DVM			
Contact Title: Sr. Regulatory Affairs Specialist	Contact E-mail Address: carmen.albany@biomet com		

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

Company / Institution Name: Same as above			
Division Name *(if applicable)*:	Phone Number *(including area code)*:		
Street Address:	FAX Number *(including area code)*:		
City:	State / Province:	ZIP Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

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

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

- ☐ Other Reason *(specify):*

SECTION D2 — REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify):*

SECTION D3 — REASON FOR SUBMISSION - 510(k)

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

- ☒ Other Reason *(specify):*

Request for additional information

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LOD	2	MBB	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K031673	1	Palacos G	1	Heraeus Kulzer GmbH & Co.KG
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Bone Cement

	Trade or Proprietary or Model Name for This Device		Model Number
1	Refobacin Bone Cement R	1	5003920002, 5003940001, 5003940002, 5003960001
2	Optipac-Refobacin Bone Cement R	2	5709500392, 5710500394, 5711500396, 5712500398,
3	Optipac-Refobacin Bone Cement R-continued	3	5740500394
4		4	
5		5	

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

1 none	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Tes ing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
MBB, LOD	888.3027	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Orthopedic

Indica ions *(from labeling)*

Refobacin Bone Cement R is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Biomet France SARL		Establishment Registration Number: 3006946279	
Division Name *(if applicable)*		Phone Number *(including area code)*: +33 (0) 475759100	
Street Address: Plateau de Lautagne		FAX Number *(including area code)*	
City		State / Province: Valence	ZIP Code: 26000 / Country: France
Contact Name: Christophe Mironneau	Contact Title: Director Quality, Regulatory Compliance	Contact E-mail Address: christophe.mironneau@biomet.com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: EMCM B.V.		Establishment Registration Number: 9614559	
Division Name *(if applicable)*		Phone Number *(including area code)*: +31 24 371 52 52	
Street Address: Middenkampweg 17		FAX Number *(including area code)*: +31 24 371 52 53	
City: Nijmegen		State / Province	ZIP Code: 6545 CH / Country: The Netherlands
Contact Name: Patrick Guelen	Contact Title: Customer Service Officer	Contact E-mail Address: customerservice@emcm.com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Rose GmbH Medizin und Sterilisiertechnik		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: (0651) 82714-33	
Street Address: Gottbillstraße 25-30		FAX Number *(including area code)*: (0651) 82714-44	
City: Trier		State / Province	ZIP Code: D-54294 / Country: Germany
Contact Name: Weber Jurgen	Contact Title	Contact E-mail Address: juergen.weber.rose@datevnet.de	

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	D732	ASTM	Standard Test Method for Shear Strength of Plastics by Punch Tool	2010	04/01/2010
2	5833	ISO	Implant for Surgery-Acrylic Resin Cements Second Edition	2002	05/01/2002
3	F451	ASTM	Standard Specification for Acrylic Bone Cement	2008	08/01/2008
4	F2118	ASTM	Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	2010	12/01/2010
5	F1980	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2007	04/01/2007
6	11135-1	ISO	Sterilization of health care products-Ethylene oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2007	05-01-2007
7	13408-1	ISO	Aseptic Processing of Health Care Products-Part 1: General requirements-Second Edition	2008	06/15/2008

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Table of Contents

June 19, 2015

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

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Sincerely,

Carmen Albany, DVM
Sr. Regulatory Affairs Specialist, US

	FDA QUESTION	BIOMET RESPONSE
Q1	Please provide a comparison of the Refobacin® Bone Cement R 20 gentamicin content as compared to the 40g Palacos® R+G predicate.	The calculation used to determine the gentamicin content of all sizes of Refobacin® Bone Cement R and Optipac® Refobacin® Bone Cement R is based on the amount of active gentamicin. For each size of Refobacin® Bone Cement R and Optipac® Refobacin® Bone Cement R in production, 1.25% of the base cement powder weight* is the amount of active gentamicin added to the other cement powder components. 1.25% is the same percentage of active gentamicin added to the base cement powder weight for the 40g Palacos® R+G. This means that the percentage of active gentamicin vs. base cement powder weight is kept constant regardless of product size and patient exposure to active gentamicin in the smaller subject device size is the same as that in the predicate device. (b) (4) [redacted] *Base cement powder weight means the combined weight of all other components of the cement powder without the gentamicin component.