

November 15, 2016

To: Surgeons
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Affected Products: Optipac® Bone Cement

| | | | |
|---|---|---|---|
| Optipac Hipset | Optipac 40 Refobacin Bone Cement R | Optipac 60 Refobacin Bone Cement R | Optipac 80 Refobacin Bone Cement R |
| Optipac Softpac Hipset | Optipac-S 40 Refobacin Bone Cement R | Optipac-S 60 Refobacin Bone Cement R | Optipac-S 80 Refobacin Bone Cement R |
| Optipac Knee Refobacin Bone Cement R | Optipac 40 Refobacin Plus Bone Cement | Optipac 60 Refobacin Plus Bone Cement | Optipac 80 Refobacin Plus Bone Cement |
| Optipac-S Knee Refobacin Bone Cement R | Optipac Softpac Refobacin Revision 40 | Optipac-S 60 Refobacin Plus Bone Cement | Optipac-S 80 Refobacin Plus Bone Cement |
| Optipac Knee Refobacin Plus Bone Cement | Optipac Refobacin Revision 40 | | Optipac Refobacin Revision 80 |
| Optipac-S Knee Refobacin Plus Bone Cement | Optipac-S 40 Refobacin Plus Bone Cement | | Optipac-S Refobacin Revision 80 |

Dear Sirs or Madams,

This notice is to inform you that Biomet Orthopaedics Switzerland GmbH is conducting a medical device Field Safety Corrective Action (removal) of Optipac® Bone Cement involving all sizes manufactured since January 2014 (References and affected lots as identified in attachment 2).



Picture 1: Optipac product



During internal investigation, it was identified that Biomet Orthopaedics cannot guarantee that the sterilization process for the Optipac is fully compliant.

The potential risks associated to the issue are the following:

| Risks | | |
|---|--|---|
| Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable | Worst Case |
| | None | None |
| Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable | Worst Case |
| | Inflammation Pain Early Infection Potential Swelling around the joint | Bacteremia (different level of aggressive bacteria/ germs) Infection around the prosthesis, resulting in inflammation around the prosthesis or potential non osseo-integration resulting in both cases in revision surgery (due to infection) Potential undetected long term infection, Sepsis (with potential death depending on the threshold). |

A review of complaints for the Optipac was conducted. The reported rate for the Optipac is 0, 0004 % for infections. It is up to a medical professional to assess whether any patient follow-up for this matter is required, but based on the current results there does not appear to be a need for additional patient follow-up beyond the standard patient follow-up protocol.

Our records indicate you may have received one or more of the affected products.

Surgeon/ Clinic Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected product.
3. Your Zimmer Biomet sales representative will remove the affected product from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
 - a. Return a digital copy to fieldaction.emea@zimmerbiomet.com or to your local Zimmer Biomet contact.
 - b. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your facilities documentation.
5. If after reviewing this notice you have further questions or concerns, please contact your Zimmer Biomet sales representative.

Other Information

This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.



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Specific to Canada only: Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. This action is being taken with the knowledge of Health Canada and is in compliance with regulations set forth by Health Canada. Your urgent cooperation is needed.

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this Field Safety Notice.

Sincerely,

Matthias Bürger

Zimmer Biomet Vice President QARC
For Biomet Orthopaedics Switzerland GmbH



ATTACHMENT 1 Certificate of Acknowledgement

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

Hospital Facility Surgeon (Please check one as applicable)

Printed Name: _____ Signature: _____

Title: _____ Telephone: () _____ - _____ Date: ____/____/____

Facility Name: _____

Facility Address: _____

City: _____ Country: _____ ZIP: _____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: fieldaction.emea@zimmerbiomet.com

or to your local Zimmer Biomet contact:

ATTACHMENT 2

Affected Product List

| Reference | Batch | Product Name |
|--------------|------------|--|
| 4740500394 | 0000864547 | OPTIPAC HIPSET |
| 4710500394 | B336AG2906 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4710500394 | A339AG2906 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4710500394 | A339BG1502 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4710500394 | A339BG2906 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4712500398 | A338BG2906 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4710500394 | A341AI0305 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4711500396 | A330AH1205 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4710500394 | A339BI0306 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4710500394 | A339BI0305 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4712500398 | A341CI0305 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4712500398 | A343AI0305 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4720502083 | A342AI0306 | OPTIPAC 40 REFOBACIN PLUS BONE CEMENT |
| 4730501163 | 211AAI0306 | OPTIPAC REFOBACIN REVISION 40 |
| 4709500392 | A312AF2404 | OPTIPAC KNEE REFOBACIN BONE CEMENT R |
| 4711500396 | A344BI0906 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4710500394 | A341AI0306 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4721502084 | A343BI0906 | OPTIPAC 60G REFOBACIN PLUS BONE CEMENT |
| 4711500396 | B339AI0906 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4711500396 | B339AI0306 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4711500396 | A337BI0906 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4711500396 | B344AI0306 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4722502117 | B343BJ2205 | OPTIPAC 80 REFOBACIN PLUS BONE CEMENT |
| 4711500396 | B344AI0906 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4732501165 | 341CAJ2205 | OPTIPAC REFOBACIN REVISION 80 |
| 4712500398 | A341CI0306 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4712500398 | A343AG1502 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4710500394 | A345BI1803 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4710500394 | A345BG1502 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4709500392 | A344AF2404 | OPTIPAC KNEE REFOBACIN BONE CEMENT R |
| 4720502083 | A345AI0306 | OPTIPAC 40 REFOBACIN PLUS BONE CEMENT |
| 4740500394 | 0000879524 | OPTIPAC HIPSET |
| 4711500396 | B344AJ3103 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4711500396 | B339AJ3103 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 217AA13475 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |



| Reference | Batch | Product Name |
|--------------|------------|---|
| 4710500394 | A346AI0306 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4730501163 | 211AAI1803 | OPTIPAC REFOBACIN REVISION 40 |
| 4720502083 | A345AI1803 | OPTIPAC 40 REFOBACIN PLUS BONE CEMENT |
| 4710500394 | A346AI1803 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4732501165-1 | 235CB13488 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4732501165-1 | 237AA13488 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4722502117-1 | 241AB13488 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4710500394 | A341AI1803 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4712500398 | A343AJ2205 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4721502084-1 | 233DB07545 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4712500398 | B345BI1803 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4711500396 | A344BJ3103 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4711500396 | A348AK1408 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4711500396 | A348AJ3103 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4711500396 | A348AK140A | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4721502084-1 | 233AA07565 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4712500398 | B346AJ2205 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4710500394 | A349BK0503 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4711500396 | B349BK1408 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4721502084 | B336BK1408 | OPTIPAC 60G REFOBACIN PLUS BONE CEMENT |
| 4720502083 | A349AJ2205 | OPTIPAC 40 REFOBACIN PLUS BONE CEMENT |
| 4710500394 | A346AJ2205 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4710500394 | A349BJ2205 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4722502117 | B349AL0301 | OPTIPAC 80 REFOBACIN PLUS BONE CEMENT |
| 4730501163-1 | 235CA07540 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4711500396 | A352AK1408 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4730501163 | 211AAJ2205 | OPTIPAC REFOBACIN REVISION 40 |
| 4710500394-1 | 233BA16970 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4732501165 | 341CAL0301 | OPTIPAC REFOBACIN REVISION 80 |
| 4722502117 | B343BL0301 | OPTIPAC 80 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | 236AA18230 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394 | A404AK0503 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4730501163-1 | 235CA16970 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4719502082-1 | 241AA14273 | OPTIPAC-S KNEE REFOBACIN PLUS BONE CEMENT |
| 4711500396 | 229AAK1408 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | 233BA06400 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394 | A404BK0503 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4712500398 | A401AK1904 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4711500396 | A404CK1408 | OPTIPAC 60 REFOBACIN BONE CEMENT R |



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| Reference | Batch | Product Name |
|--------------|------------|--|
| 4711500396-1 | 217AA15765 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 217BA18235 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 236CA15065 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 217BA15765 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398-1 | 238AA17610 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4722502117 | A329AL0301 | OPTIPAC 80 REFOBACIN PLUS BONE CEMENT |
| 4740500394 | 0000544885 | OPTIPAC HIPSET |
| 4712500398 | A408BA2401 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4711500396 | A352AB1301 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4711500396 | A404CB1301 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4720502083-1 | 233AB14460 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4710500394-1 | 237BA07550 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394 | A404BA2401 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 217BA16975 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4740500394 | 0000910010 | OPTIPAC HIPSET |
| 4710500394 | A351AK0503 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 236CA18235 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4720502083-1 | 233AB06570 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4711500396-1 | 236CA21375 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4740500394-1 | 0000885769 | OPTIPAC SOFTPAC HIPSET |
| 4730501163 | 410AAB1302 | OPTIPAC REFOBACIN REVISION 40 |
| 4711500396-1 | 217AA07545 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398 | A411AB1302 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | 239AA22320 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | 237BA21960 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | 234BA15790 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4721502084-1 | A412C21375 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4711500396-1 | 217BA07555 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4732501165-1 | 237AA14278 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4710500394-1 | 239AA07550 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4730501163 | 410AAK0503 | OPTIPAC REFOBACIN REVISION 40 |
| 4710500394-1 | 243CA14460 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396 | A410BC1301 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | 237BA17620 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 217BA07545 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4722502117-1 | 241BA14188 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4721502084 | B342AB1301 | OPTIPAC 60G REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | 236BA22320 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 234AA07565 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |



| Reference | Batch | Product Name |
|--------------|------------|---|
| 4720502083-1 | 233AB16970 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | 236BA15790 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 217BA13475 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398-1 | 236BA14270 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A217A21960 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4720502083 | A409BK1904 | OPTIPAC 40 REFOBACIN PLUS BONE CEMENT |
| 4710500394 | A407BK1904 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4720502083-1 | 233CA15060 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4710500394-1 | A239A21960 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4712500398-1 | 238BA21370 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4740500394-1 | 0000926853 | OPTIPAC SOFTPAC HIPSET |
| 4732501165-1 | 237AA14188 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4710500394-1 | 244AA21380 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | 244AA21960 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4730501163-1 | 235CA07550 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4710500394-1 | 243CA17620 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | 234BA07550 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 234AA22315 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4709500392-1 | 239AB14273 | OPTIPAC-S KNEE REFOBACIN BONE CEMENT R |
| 4710500394-1 | 239AA17610 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396 | A412BB1301 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4719502082 | A305AJ3103 | OPTIPAC KNEE REFOBACIN PLUS BONE CEMENT |
| 4710500394 | A412AB1302 | OPTIPAC 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | 243BA21805 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4730501163-1 | 235CA03910 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4710500394-1 | A217A04840 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4720502083-1 | 233CA03910 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4711500396 | A412BC1301 | OPTIPAC 60 REFOBACIN BONE CEMENT R |
| 4721502084 | B345AC1301 | OPTIPAC 60G REFOBACIN PLUS BONE CEMENT |
| 4711500396-1 | A421A22325 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398-1 | 236AA04840 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A420A03900 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A421A03715 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4709500392 | A344AJ3103 | OPTIPAC KNEE REFOBACIN BONE CEMENT R |
| 4710500394-1 | A422A04840 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4740500394-1 | 0000943815 | OPTIPAC SOFTPAC HIPSET |
| 4710500394-1 | 243CA03910 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4720502083-1 | 233CA04840 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4710500394-1 | A239A03910 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |



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| Reference | Batch | Product Name |
|--------------|------------|---|
| 4730501163-1 | 237AB05900 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4712500398-1 | 236BA18090 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4722502117-1 | 241BA03728 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4710500394-1 | A420A04830 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A420A18090 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A239A04830 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4720502083-1 | 233DA05900 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4721502084-1 | A412C22325 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4721502084-1 | A429B03715 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4721502084-1 | A429B04835 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4711500396-1 | A433A03915 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A433A17615 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A422A04830 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A433A03905 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A239A05900 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A427A03725 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A420B06370 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A420B04840 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A427A03255 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398 | A419AA2804 | OPTIPAC 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A435B18090 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A435B06370 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4740500394-1 | 0000957203 | OPTIPAC SOFTPAC HIPSET |
| 4710500394-1 | A422A06360 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4712500398-1 | 238BA07520 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A435B08860 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A431A10810 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A431A07520 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4720502083-1 | B429B10810 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4719502082-1 | A445B14463 | OPTIPAC-S KNEE REFOBACIN PLUS BONE CEMENT |
| 4709500392-1 | A444B14463 | OPTIPAC-S KNEE REFOBACIN BONE CEMENT R |
| 4730501163-1 | 245AA04830 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4720502083-1 | B429B11020 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4722502117-1 | B445B05918 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | A441A08850 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A441A08860 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4720502083-1 | C445B04830 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4732501165-1 | A440A18098 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4740500394-1 | 0000968691 | OPTIPAC SOFTPAC HIPSET |



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| Reference | Batch | Product Name |
|--------------|------------|---|
| 4711500396-1 | A448A04835 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A448A03915 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A448A05915 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4720502083-1 | B429B08850 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4740500394-1 | 0000978285 | OPTIPAC SOFTPAC HIPSET |
| 4712500398-1 | A441B08850 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A441B05910 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A448A03715 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4722502117-1 | A415A05918 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | A441B11020 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4730501163-1 | C410A06360 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4730501163-1 | C410A08860 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4712500398-1 | B502A11940 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A412A11940 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A441B11940 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | B444B08850 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4730501163-1 | C410A18230 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4711500396-1 | A448A06365 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4721502084-1 | B415A06365 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | B502A11110 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A504A11110 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4721502084-1 | B345A05915 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4720502083-1 | A409B11940 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4709500392-1 | A444B07513 | OPTIPAC-S KNEE REFOBACIN BONE CEMENT R |
| 4719502082-1 | A445B07513 | OPTIPAC-S KNEE REFOBACIN PLUS BONE CEMENT |
| 4732501165-1 | A440A05918 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4711500396-1 | A502A05915 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A502A05905 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4720502083-1 | C445B11940 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4720502083-1 | C445B17150 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | A504A11940 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4720502083-1 | A409B17150 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | A504A17150 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4720502083-1 | C445B18700 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4722502117-1 | A415A18098 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4720502083-1 | A413A17780 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4730501163-1 | C410A17780 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4730501163-1 | C410A17770 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4720502083-1 | A413A18700 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |



| Reference | Batch | Product Name |
|--------------|------------|--|
| 4719502082-1 | A445B0751A | OPTIPAC-S KNEE REFOBACIN PLUS BONE CEMNT |
| 4711500396-1 | A421A07515 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | B444B18700 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4740500394-1 | 0001027801 | OPTIPAC SOFTPAC HIPSET |
| 4721502084-1 | B413A05905 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4722502117-1 | A415A17148 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4732501165-1 | A440A17148 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4740500394-1 | 0001031845 | OPTIPAC SOFTPAC HIPSET |
| 4711500396-1 | A521A07515 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A502A22325 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4709500392-1 | A444B0751A | OPTIPAC-S KNEE REFOBACIN BONE CEMENT R |
| 4712500398-1 | A522A18700 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | B444B17780 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A521A07525 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4722502117-1 | C521B17148 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4722502117-1 | C521B05918 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4740500394-1 | 0001035362 | OPTIPAC SOFTPAC HIPSET |
| 4720502083-1 | A521B17780 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | A522A17780 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4721502084-1 | B413A11025 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4710500394-1 | A524A17770 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A522A17770 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A526A17770 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A526A02130 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4721502084-1 | B415A07515 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4721502084-1 | C415A07515 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4710500394-1 | A524A18710 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A521A08865 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A524B11115 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4740500394-1 | 0001047530 | OPTIPAC SOFTPAC HIPSET |
| 4732501165-1 | A440A0591A | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4722502117-1 | A415A18718 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4720502083-1 | A521B04770 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4730501163-1 | A523B02130 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4712500398-1 | A526A17150 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A526B03520 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A524A04770 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4732501165-1 | A532B03528 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4719502082-1 | B521B18713 | OPTIPAC-S KNEE REFOBACIN PLUS BONE CEMNT |



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| Reference | Batch | Product Name |
|--------------|------------|---|
| 4712500398-1 | A522A04770 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A526A17780 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A524B11025 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A524B10815 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4722502117-1 | C521B03528 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4709500392-1 | A539A18713 | OPTIPAC-S KNEE REFOBACIN BONE CEMENT R |
| 4720502083-1 | B537B04770 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4720502083-1 | B537B04870 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | A537A05460 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A537A17140 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4720502083-1 | B537B05460 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4721502084-1 | C415A06375 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4722502117-1 | A537C05478 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4711500396-1 | A538B07515 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A526B17770 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A538B07525 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A538B11025 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4732501165-1 | A532B05478 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4711500396-1 | A538B08865 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4730501163-1 | A523B04870 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4710500394-1 | A526B18710 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A538B03715 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | B539A06375 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A537A05470 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A540A04870 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A540B10815 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A541B08070 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4732501165-1 | A532B0547A | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4722502117-1 | A537C10018 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4710500394-1 | A540A05470 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4740500394-1 | 0001059985 | OPTIPAC SOFTPAC HIPSET |
| 4711500396-1 | A540B03255 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4720502083-1 | B537B10010 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4719502082-1 | A537B18713 | OPTIPAC-S KNEE REFOBACIN PLUS BONE CEMENT |
| 4710500394-1 | A541B10010 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A540B17145 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A549B10010 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A549B08700 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A534A04870 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |



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| Reference | Batch | Product Name |
|--------------|------------|--|
| 4710500394-1 | A534A04770 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A534A17770 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A541B29010 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4720502083-1 | A544B05460 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | A549B29010 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4732501165-1 | A547A10018 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4711500396-1 | A548C08705 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A540B08715 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A538B08715 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4720502083-1 | B537B29010 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4720502083-1 | A544B08720 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4730501163-1 | A523B08720 | OPTIPAC SOFTPAC REFOBACIN REVISION 40 |
| 4712500398-1 | A603B09940 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4720502083-1 | B537B08720 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4711500396-1 | A601C09945 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A551B08710 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4709500392-1 | A539A10453 | OPTIPAC-S KNEE REFOBACIN BONE CEMENT R |
| 4711500396-1 | A548C10465 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4722502117-1 | A537C29018 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4740500394-1 | 0000115896 | OPTIPAC SOFTPAC HIPSET |
| 4712500398-1 | A604A11370 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4732501165-1 | A547A29018 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4710500394-1 | A551B10460 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4720502083-1 | A544B10460 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4711500396-1 | A601C11335 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A603B11370 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A601A11330 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4720502083-1 | B602C11330 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | A604A11470 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4732501165-1 | A532B10458 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4732501165-1 | A547A10458 | OPTIPAC SOFTPAC REFOBACIN REVISION 80 |
| 4712500398-1 | A608B11450 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A608B11470 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4711500396-1 | B539A11375 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A548C11375 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4721502084-1 | A602C11455 | OPTIPAC-S 60G REFOBACIN PLUS BONE CEMENT |
| 4710500394-1 | A601A10460 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A548C11455 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A611B11460 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |



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| Reference | Batch | Product Name |
|--------------|------------|---|
| 4709500392-1 | A444B10453 | OPTIPAC-S KNEE REFOBACIN BONE CEMENT R |
| 4722502117-1 | A537C10458 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4720502083-1 | B602C11480 | OPTIPAC-S 40 REFOBACIN PLUS BONE CEMENT |
| 4740500394-1 | 0001110900 | OPTIPAC SOFTPAC HIPSET |
| 4711500396-1 | A548C11465 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A601C11485 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4709500392-1 | A539A1045A | OPTIPAC-S KNEE REFOBACIN BONE CEMENT R |
| 4712500398-1 | A612A00350 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A609B00330 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A610A11465 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A610A11485 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A609B11480 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A612B00335 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A551B11480 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A612B00345 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4710500394-1 | A610B00340 | OPTIPAC-S 40 REFOBACIN BONE CEMENT R |
| 4740500394-1 | 0001116630 | OPTIPAC SOFTPAC HIPSET |
| 4722502117-1 | A537C00328 | OPTIPAC-S 80 REFOBACIN PLUS BONE CEMENT |
| 4712500398-1 | A610C01200 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4712500398-1 | A612C01210 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |
| 4711500396-1 | A613A00325 | OPTIPAC-S 60 REFOBACIN BONE CEMENT R |
| 4740500394-1 | 0001119980 | OPTIPAC SOFTPAC HIPSET |
| 4712500398-1 | A610C01510 | OPTIPAC-S 80 REFOBACIN BONE CEMENT R |