

Customer

Director Quality Management
and Regulatory Affairs

Tel.: 0241 / 91 30 0
Fax.: 0241 / 91 30 106

Aachen, 20.12.2019

Urgent Recall on bipacingball, Code 1144.05, Batches 051119GD, 141119GD and 221119GD

Dear Madam, dear Sir,

We supply a double sterile packaged product. We have identified a non systematic manufacturing problem, which might lead to potential unsterility at the product's outer pouch. As the inner blister packaging is undamaged, sterility of the product itself is not in danger.

The following products are involved in this recall:

Product Description	Code No.	Batch No.
bipacingball	1144.05	051119GD 141119GD 221119GD

We therefore ask you to immediately withdraw these batches from services and to return them according to our instructions below.

Please acknowledge receipt of this letter and complete and return the attached form by indicating the quantities withdrawn from your institution.

The Federal Institute for Drugs and Medical Devices (BfArM) has been informed about this Field Safety Notice, FSN.

If you should you require further information, please contact your Vygon sales contact, or sales administration via telephone number detailed below :

We apologize for any inconvenience this Recall may cause.

Yours sincerely,

Director of Quality Management and Regulatory Affairs

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ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM page 1/3

Please complete and return this form:
by fax: xxxxxxxxxxxx or e-mail to : xxxxxxxxxxxx

Name and address of the institution :	
Full name of the person to contact:	
Function :	
☎ Phone Number:	
✉ Email:	

We acknowledge receipt of the above FSN and that the information contained in this field safety notice has been shared with all recipients/ end users of above products within our organization.

Please tick the appropriate box:

We have the following products available on stock :

Code 1144.05, Batch 051119GD Yes NO If you have units, number of units removed: _____

Code 1144.05, Batch 141119GD Yes NO If you have units, number of units removed: _____

Code 1144.05, Batch 221119GD Yes NO If you have units, number of units removed: _____

Signature and Date : _____