

1 rue de l'Espoir
59260 LEZENNES
France
Tel +33 3 20 67 67 67
Fax + 33 3 20 67 67 68
web vigilance@anios.com

URGENT FIELD SAFETY NOTICE

Date: 09/11/19

Object:

- Batch recall
 Information and/or recommendations

Affected products:

Device Commercial Name	Packaging	Article Code
OPASTER ANIOS	4x5L	2504028C6, 2504028HA, 2504028OB, 2504028E2, 2643028BR, 2504028YS, 2504318UE, 2504028UO, 2504028G4, 2504028Z8, 2504028DL, 2504028JC, 25040282Q

Madam, Sir,

We have identified that you received OPASTER ANIOS as listed in the above table and we have determined that it may contain the gram-negative bacteria *Pseudomonas oryzihabitans* and *Delftia Acidovorans*. We have not received any patient incident report to date about this product but as a precautionary measure, we are recalling all batches (Annex II) as they do not comply with our quality expectations.

Pseudomonas oryzihabitans and *Delftia Acidovorans* are opportunistic environmental bacteria rarely implicated in human infections.

They pose little medical risk to healthy people. However, immunocompromised patients are at higher risk of infection.

Corrective actions to eliminate the contamination source are being implemented and we have introduced additional hygiene security protocols.

For precautionary reasons, we ask that you stop immediately using the recalled products that you may have in stock, as there is a risk they may be contaminated.

We ask you to block and isolate these products. In addition, we need you to inform immediately your end customers and ask them to notify you of the quantities they have in stock. You will be required to collect the completed response form (Annex I) from your customers and share a consolidated form with us of all the products you have recalled to the following e-mail address: Vigilance@anios.com.




Please acknowledge receipt of this communication by returning at your earliest convenience - but no later than 05/12/2019 - the completed and signed reply form.

Your Anios representative will contact you to discuss the return of the recalled product you have in stock. We remain at your entire disposal for any question or assistance that you may need.

The undersigns confirm that this notice has been reported to the appropriate Regulatory Agency.

Please accept our apologies for the inconvenience it may have caused.

Yours faithfully

<p>Isabelle Prévost <i>Quality Manager</i></p>	<p>Dr Monique Manche <i>Materiovigilance Contact Person</i></p>	<p>Thomas Decoster <i>President</i></p>
		

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

This means, if you are a distributor, that this information has to be forwarded to any customers which was delivered with one of the affected batches.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

1 rue de l'Espoir
59260 LEZENNES - France
Tel +33 3 20 67 67 67
Fax + 33 3 20 67 67 68
Email Vigilance@anios.com

ANNEX I CUSTOMER REPLY FORM

1. Field Safety Notice (FSN)

FSN Reference:

FSN_ANIOS_OPASTER_EN_EX EU

Affected products: **Please refer to Annex II**

2. Customer Details

Customer Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	
Print Name*	
Signature*	
Date*	

Mandatory fields are marked with *

3. Customer action undertaken on behalf of Healthcare Organisation

- I confirm receipt of the Field Safety Notice (FSN) and that I read and understood its content.
- I performed all actions requested by the FSN.
- The information and required actions have been brought to the attention of all relevant users and executed, including end customers in case of distribution of those products
- I informed the supplier of the stock I have that is subject of the recall and needs to be returned

PERSON OF CONTACT FOR RETURN OF GOOD: _____

EMAIL OF CONTACT: _____

PHONE NUMBER OF CONTACT: _____

Device Commercial Name	Article Code	Batch N°	Packages Quantity (units)

- No affected devices are available for return
- Other Action (Define):

4. Return acknowledgement to sender

Email	Vigilance@anios.com
Postal Address	Laboratoires ANIOS Service qualité 1, rue de l'Espoir 59260 Lezennes - France
Fax	+33 3 20 67 67 68
Deadline for returning the customer reply form	05/12/2019

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions

**ANNEX II
AFFECTED PRODUCTS BATCHES**

Device commercial name	Packaging	Article code	Batch number
OPASTER'ANIOS	4X5L	250402800	A17117S
			A17819S
			A29105S
			A33405S
			B09205S
			B10707S
			B12012S
			B12705S
			B14507S
			B17003S
			B22506S
			B27801S
			U34216S
			W26313S
		2504028BF	A02612S
			W01915S
			W03912S
			W08116S
			W11018S
			W13912S
			W17208S
			W17711S
			W18406S
			W20511S
			W23316S
			W24909S
			W28407S
			W30006S
		2504028C6	W30712S
			W33114S
			A02612S
			A03908S
			A05713S
			A05913S
			A06711S
			A07410S
			A07906S
			A08211S
			A10112S
			A10909S
			A13813S
			A17117S
			A17313S
			A17711S
			A18416S
			A19412S
			A19907S
A20610S			
A20812S			
A21311S			
A22117S			
A23514S			
A24114S			
A24714S			
A25310S			
A26217S			
A27108S			
A27514S			
A27809S			
A28206S			
A28309S			
A29012S			

OPASTER'ANIOS

4X5L

2504028C6

A29105S
A29204S
A29711S
A29905S
A30415S
A31213S
A31404S
A32003S
A33209S
A34006S
A34104S
A34705S
A35104S
A35312S
A35405S
A35508S
A36106S
B00204S
B00705S
B00806S
B06413S
B06519S
B06722S
B07709S
B09205S
B10707S
B11507S
B12012S
B12705S
B13902S
B14507S
B17003S
B17618S
B22506S
B22523S
B22615S
B22809S
B23109S
B23214S
B23317S
B27801S
B27903S
B28001S
B28011S
B28108S
B28322S
B28414S
U34216S
W01915S
W03912S
W05108S
W07214S
W08116S
W09712S
W11018S
W13912S
W17208S
W17711S
W18406S
W20511S
W23316S
W24909S
W26313S
W28407S
W30006S
W30712S
W33114S

OPASTER'ANIOS

4X5L

2504028C6	W36013S
2504028DL	A05913S
	A10909S
	A17819S
	A17912S
	A19907S
	A21508S
	A22117S
	A23514S
	A26217S
	A27108S
	A28309S
	A32003S
	A33907S
	B23109S
	B23214S
B28001S	
2504028G4	B11507S
	B17003S
	B22809S
2504028HA	A07906S
	A17313S
	A21311S
	A28309S
	A31404S
2504028JC	B13902S
	W36013S
	A19907S
2504028OB	A24714S
	A29905S
	A05913S
	A10112S
	A13813S
	A18011S
	A18416S
	A22117S
	A29905S
	A33907S
	B00204S
	B10707S
	B11507S
	B17618S
	B22809S
	W05108S
	W09712S
	W13912S
	W20511S
	W28407S
W30712S	
W36013S	
2504028YS	A17912S
2504028Z8	A03908S
	A06711S
	A07410S
	A17117S
	A17711S
	A17912S
	A18011S
	A19907S
	A20812S
	A27514S
	A27809S
	A28206S
	A28410S
	A29012S
A29105S	
A29204S	

OPASTER'ANIOS	4X5L	2504028Z8	A29711S
			A30415S
			A32407S
			A32801S
			A33209S
			A33405S
			A33907S
			A34006S
			A34104S
			A34705S
			A35104S
			A35312S
			A35405S
			A35508S
			A36106S
			B10707S
			B12705S
		2504318UE	A34705S
	1X5L	2504922	A05713S
			A10909S
			A35508S
			B09205S
			W13912S
			W17711S
			W36013S