

Urgent Field Safety Notice

Medical Device Name: GAMMEX® PF
Field Safety Corrective Action Identification Number: FSN01/2015
Type of action: Withdrawal of 8 Specific Lot numbers

Date: xx October 2015

Attention: Vigilance Reporting

Details on affected devices:

Any stock remaining of the following 8 Lot numbers are to be returned to your Distributor:

Lot number	Product name	Product number	Sizes
1411591004	GAMMEX PF	351141	5.5
1411591004	GAMMEX PF	351142	6.0
1411591004	GAMMEX PF	351143	6.5
1411591004	GAMMEX PF	351144	7.0
1411591004	GAMMEX PF	351145	7.5
1411591004	GAMMEX PF	351146	8.0
1411591004	GAMMEX PF	351147	8.5
1411591004	GAMMEX PF	351148	9.0
1411591004	GAMMEX PF	351149	9.5
1411595604	GAMMEX PF	351141	5.5
1411595604	GAMMEX PF	351142	6.0
1411595604	GAMMEX PF	351143	6.5
1411595604	GAMMEX PF	351144	7.0
1411595604	GAMMEX PF	351145	7.5
1411595604	GAMMEX PF	351146	8.0
1411595604	GAMMEX PF	351147	8.5
1411595604	GAMMEX PF	351148	9.0
1411595604	GAMMEX PF	351149	9.5

Lot number	Product name	Product number	Sizes
1412600604	GAMMEX PF	351141	5.5
1412600604	GAMMEX PF	351142	6.0
1412600604	GAMMEX PF	351143	6.5
1412600604	GAMMEX PF	351144	7.0
1412600604	GAMMEX PF	351145	7.5
1412600604	GAMMEX PF	351146	8.0
1412600604	GAMMEX PF	351147	8.5
1412600604	GAMMEX PF	351148	9.0
1412600604	GAMMEX PF	351149	9.5
1412602604	GAMMEX PF	351141	5.5
1412602604	GAMMEX PF	351142	6.0
1412602604	GAMMEX PF	351143	6.5
1412602604	GAMMEX PF	351144	7.0
1412602604	GAMMEX PF	351145	7.5
1412602604	GAMMEX PF	351146	8.0
1412602604	GAMMEX PF	351147	8.5
1412602604	GAMMEX PF	351148	9.0
1412602604	GAMMEX PF	351149	9.5
1412604004	GAMMEX PF	351141	5.5
1412604004	GAMMEX PF	351142	6.0
1412604004	GAMMEX PF	351143	6.5
1412604004	GAMMEX PF	351144	7.0
1412604004	GAMMEX PF	351145	7.5
1412604004	GAMMEX PF	351146	8.0
1412604004	GAMMEX PF	351147	8.5
1412604004	GAMMEX PF	351148	9.0
1412604004	GAMMEX PF	351149	9.5
1412612804	GAMMEX PF	351141	5.5
1412612804	GAMMEX PF	351142	6.0
1412612804	GAMMEX PF	351143	6.5
1412612804	GAMMEX PF	351144	7.0
1412612804	GAMMEX PF	351145	7.5
1412612804	GAMMEX PF	351146	8.0
1412612804	GAMMEX PF	351147	8.5
1412612804	GAMMEX PF	351148	9.0
1412612804	GAMMEX PF	351149	9.5

Lot number	Product name	Product number	Sizes
1501409504	GAMMEX Latex*	330048055	5.5
1501409504	GAMMEX Latex*	330048060	6.0
1501409504	GAMMEX Latex*	330048065	6.5
1501409504	GAMMEX Latex*	330048070	7.0
1501409504	GAMMEX Latex*	330048075	7.5
1501409504	GAMMEX Latex*	330048080	8.0
1501409504	GAMMEX Latex*	330048085	8.5
1501409504	GAMMEX Latex*	330048090	9.0
1501409504	GAMMEX Latex*	330048095	9.5
1503446404	GAMMEX Latex*	330048055	5.5
1503446404	GAMMEX Latex*	330048060	6.0
1503446404	GAMMEX Latex*	330048065	6.5
1503446404	GAMMEX Latex*	330048070	7.0
1503446404	GAMMEX Latex*	330048075	7.5
1503446404	GAMMEX Latex*	330048080	8.0
1503446404	GAMMEX Latex*	330048085	8.5
1503446404	GAMMEX Latex*	330048090	9.0
1503446404	GAMMEX Latex*	330048095	9.5

*GAMMEX PF delivered in new packaging

Please refer to the Attachment for location of Lot numbers on the packaging.

Description of the problem:

Following an investigation due to an adverse trend in complaints relating to holes in GAMMEX PF the manufacturer, Ansell N.P Sdn. Bhd. has decided to withdraw 8 lots as identified above from the market.

While all lots passed the release testing criteria in accordance with EN455-1 a review of production records indicates that these 8 lots may be at a higher risk of defects than is acceptable to Ansell and our customers.

Immediate Action to be taken:

Action 1.

- Investigate lots on hand to identify if any stock of the 8 lots are present. Please see the attached instructions for identification of lot numbers.
- Place the lots in quarantine.
- Contact your distributor to arrange the return of the stock and a Credit Note.
- Please pass this notice on to all those who need to be aware within your organisation or to any organisation where the potentially affected products have been transferred

NAME DISTRIBUTOR

Action 2.

Ansell is requesting the users of our gloves to be extra vigilant around the inspection of gloves prior to use. We also stress the best practice of double donning gloves ie wearing 2 pairs of gloves, whenever possible.

- Prior to and immediately following donning of the gloves, please check for holes in accordance with the instructions provided in the attachment. Holes are most commonly found in the cuff area, on the fingers and between the fingers.
- If holes are found immediately discontinue use. Record the lot number which can be found on the pouch or dispenser as indicated and notify your Distributor immediately.

We sincerely thank you for your collaboration and understanding of our decision. Ansell remains committed to quality in all its products it manufactures and will continue to work closely with all parties in addressing this issues.

Kind regards,



Didier Vincent
VP Sales Medical EMEA



Alison Arnot-Bradshaw
Senior Regulatory Affairs Director EMEA APAC

Ansell Healthcare Europe N.V

Note: All applicable Competent Authorities have been informed of this action.