Intersurgical Ltd, Crane House, Molly Millars Lane,
Wokingham, Berkshire, RG41 2RZ, UK
T: +44 (0)118 9656 300 F: +44 (0)118 9656 356
info@intersurgical.com www.intersurgical.com

Relevant Country Contact Name
Tel.: Relevant country telephone
Fax: Relevant country fax
Email: Relevant country email

Field Safety Notice

Type of Action: AWARENESS

Devices: The following devices that include an Economy Anaesthetic Face Mask, 22F

REF:	DESCRIPTION
1514000	Economy, Anaesthetic Face Mask, Size 3, Small Adult, 22F
1515000	Economy, Anaesthetic Face Mask, Size 4, Medium Adult, 22F
1516000	Economy, Anaesthetic Face Mask, Size 5, Large Adult, 22F
1517000	Economy, Anaesthetic Face Mask, Size 6, Extra Large Adult, 22F

LOT Numbers:

REF:	DESCRIPTION
1514000	381968, 381979, 382683, 383078, 383689, 390392
1515000	381956, 381969, 381980, 382687, 382690, 385070, 386256, 386267, 386280, 390393, 390398
1516000	382686, 382688, 383074, 383075, 383076, 383077, 390394
1517000	381957, 382684, 385036, 385056, 385071

Manufacturer: Intersurgical Ltd

FSCA-identifier: 238507 **Date:** XX/08/2019

Attention: Medical Device Safety Officers (MDSO)

Distribution: All Theatre, Resuscitation & Anaesthetic department clinical staff, all Ambulance Managers and users of the above products

Type of action: All users of the products and lot numbers listed above must follow the instructions described in the Actions section below before use.

Intersurgical Limited Registered in England No. 1488409
Directors S. K. Williams • H. Bellm • K. Jacob • D. Williams • M. Hinton

Intersurgical Ltd is certified to ISO 14001, ISO 9001 and ISO 13485

Description of the problem: As a result of reports from the market we have identified a possible variation in the size of the 22F mask taper connection where some masks may be larger than standard limits. This may create a loose or insecure connection with the mating device, and in some circumstances this could result in possible disconnection from the mask taper. We would expect the problem to be identified during set up for use and to date there have been no reports of patient harm.

Action to be taken by the user:

Although the reported risk of possible loose connection is low, this notice is intended to inform users of the potential problem and provide details to help prevent problems occurring during use.

Before use, check the connection between the 22F Mask taper and mating device is secure using a push and twist action.

If any problems are identified with any of these masks please inform us to arrange the return and replacement of the affected masks. Please note this is not a recall of the listed products.

NB. If you are a Distributor please ensure this FSN is distributed to all of your customers that have been supplied with the potentially affected products listed above.

Corrective Action being taken by manufacturer Intersurgical:

We are currently assessing our stocks as well as the manufacturing process to eliminate this problem.

Transmission of this Field Safety Notice:

This notice should be transmitted to all those who need to be aware within your organisation, or to any organisation where these potentially affected devices have been transferred.

Intersurgical apologises for any inconvenience this may cause. If you have any questions, please contact your distributor or local Intersurgical representative.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Please maintain awareness of this Field Safety Notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

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INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

Relevant Country Contact Name
Tel.: Relevant country telephone
Fax: Relevant country fax
Email: Relevant country email

Field Safety Notice Response Form

Devices: The following devices that include an Economy Anaesthetic Face Mask, 22F

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1516000	382686, 382688, 383074, 383075, 383076, 383077, 386268, 386281, 390394
1517000	381957, 382684, 385036, 385056

Manufacturer: Intersurgical Ltd

FSCA-identifier: 238507 **Date:** XX/08/2019

Hospital/Facility Name: _____

Hospital/Facility Address: _____

Please complete the section below, and send it back to the e-mail address above.

☐ We confirm we have received this FSN and have distributed it within our facility as necessary.

☐ **Distributors Only:** We confirm we have received this FSN and have distributed it to our customers that have been supplied with the potentially affected products listed above.

Form Completed and Returned by:

Name: …….. **Phone No: ……..**

Position: …….. **E-mail: ……**

Date: ……