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

Intersurgical Ltd, Crane House, Molly Millars Lane,
Wokingham, Berkshire, RG41 2RZ, UK
T: +44 (0)118 965 6300 F: +44 (0)118 965 6356
info@intersurgical.com www.intersurgical.com

Urgent Recall Notice

Type of Action: RECALL

Devices: The following Neonatal Resuscitation systems.

REF	DESCRIPTION
6430000	10MM FLEXTUBE NEONATAL RESUSCITATION BREATHING SYSTEM WITH VARIABLE PEEP, DOUBLE SWIVEL ELBOW, 0.8M
6431000	10MM FLEXTUBE NEONATAL RESUS B/S WITH VARIABLE PEEP, DOUBLE SWIVEL ELBOW AND 15F/10F ADAPTORS. ≥ 1.2M
6433000	10MM FLEXTUBE NEONATAL RESUSCITATION BREATHING SYSTEM WITH VARIABLE PEEP, DOUBLE SWIVEL ELBOW, NEOPUFF® AND UNIVERSAL CONNECTORS, 1.2M
6431009	NEONATAL RESUSCITATION SYSTEM, VARIABLE PEEP 2M
6431014	10MM FLEXTUBE RESUSCITATION SYSTEM LOW VOLUME CHAMBER 1.3M

LOT Numbers:

REF	Lot Number
6430000	32054366, 32055044, 32056212, 32013769,
6431000	32009718, 32011698, 32012922, 32013285, 32055153, 32055853, 32056243, 32056356
6433000	32055115, 32056099, 32009831, 32011359, 32012926,
6431009	32055678,
6431014	32056289,

Manufacturer: Intersurgical Ltd

FSCA identifier: 297478 **Date:** 20/01/2021

Attention: Medical Device Safety Officers (MDSO)

Distribution: Neonatal Units and all departments where these products may be used.

Type of action:

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

Description of the problem:
We have received a complaint where the Neonatal Resuscitation systems have been found with incorrect or missing connection interfaces. This may prevent connection of the system to the particular equipment you use.

Action to be taken by the user:
Immediately quarantine all affected product codes and lot numbers listed above and do not use these devices. Please contact Intersurgical using the Response Form below to confirm these have been disposed of locally or arrange collection of the devices and credit. If you have no affected devices in your stock, please confirm this also using the Response Form.

Corrective Action being taken by manufacturer Intersurgical:
We are urgently reviewing our processes to identify a resolution to the problem.
The undersigned confirms this notice has been notified to the appropriate Regulatory Agency.

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.

Ivan Seniut, Group Quality and Regulatory Affairs Director, Intersurgical

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

Urgent Recall Notice Response Form

Devices: The following Neonatal Resuscitation systems.

REF	DESCRIPTION
6430000	10MM FLEXTUBE NEONATAL RESUSCITATION BREATHING SYSTEM WITH VARIABLE PEEP, DOUBLE SWIVEL ELBOW, 0.8M
6431000	10MM FLEXTUBE NEONATAL RESUS B/S WITH VARIABLE PEEP, DOUBLE SWIVEL ELBOW AND 15F/10F ADAPTORS. ≥ 1.2M
6433000	10MM FLEXTUBE NEONATAL RESUSCITATION BREATHING SYSTEM WITH VARIABLE PEEP, DOUBLE SWIVEL ELBOW, NEOPUFF® AND UNIVERSAL CONNECTORS, 1.2M
6431009	NEONATAL RESUSCITATION SYSTEM, VARIABLE PEEP 2M
6431014	10MM FLEXTUBE RESUSCITATION SYSTEM LOW VOLUME CHAMBER 1.3M

LOT Numbers:

REF	Lot Number
6430000	32054366, 32055044, 32056212, 32013769,
6431000	32009718, 32011698, 32012922, 32013285, 32055153, 32055853, 32056243, 32056356
6433000	32055115, 32056099, 32009831, 32011359, 32012926,
6431009	32055678,
6431014	32056289,

Manufacturer: Intersurgical Ltd

FSCA identifier: 297478 **Date:** 20/01/2021

Hospital/Facility Name: _____

Hospital/Facility Address: _____

_____

Please complete the section below, and send it back to …XXXXXXXXXXXXXXX……..

☐ We do not have any remaining stock of the affected products.

☐ We have quarantined our remaining stock of the following affected products and have disposed of these locally or wish to return them. Please arrange credit.

I confirm that I have quarantined the following products and lot numbers.

REF	LOT	Quantity of products per LOT number
[add more rows as required]		

Form Completed and Returned by:

Name: ……

Position: ……

Phone No: ……

E-mail: ……

Date: ……..