Baxter

Urgent Field Safety Notice

27th January 2015

Replacement of EasySpray Pressure Regulator, Tissomat and DuploSpray MIS Pressure Regulator in the European Union

Product codes: 0600075, 1504275, 0600032, Z9501100999901.

Dear Customer,

As a follow-up to the Referral under Article 31 of Council Directive 2001/83/EC, as amended for Fibrinogen-containing solutions for sealant authorized for administration by spray application (procedure number: EMEA/H/A-31/1337), Baxter would like to inform you that we are undertaking a replacement initiative of concerned pressure regulator devices .

To ensure that the product is used in accordance with the Summary of Product Characteristics (SmPC), the pressure regulator device should deliver a maximum pressure of no more than:

- 2.0 bar (28.5 psi) in open wound surgery and
- 1.5 bar (22 psi) in minimally invasive/laparoscopic procedures.

The previous version of EasySpray can be turned up to 3.0 bar. Since the optimal operating pressure for open surgery ranges from 1.5 – 2.0 bar, the newly developed regulator only allows a maximum pressure of 2.0 bar.

The new DuploSpray is limited to 1.5 bar to comply with the optimal pressure range for laparoscopic procedures which is from 1.2 – 1.5 bar.

Tissomat is no longer sold but installed units are still in use. Tissomat units are being replaced by newly developed EasySpray.

The replacement of existing regulators with the new versions contributes to the safety of the patient by reducing the risk of potential air or gas embolism.

Please note, that all regulators currently in the field function in compliance with CE mark issued by the Notified Body. They do not pose a threat due to any malfunction or defect. All regulators are being replaced with the aim to reduce the risk of using the devices in contradiction to or not in accordance with the operation manual / Instructions for Use (e.g. pressure too high and spraying distance too low).

It should be considered that this replacement initiative and the reduction of the maximum pressure alone may not completely prevent cases of air or gas embolism. As a consequence it is essential to be aware of the correct usage of the spray application system in areas of:

- The type of procedure the devices are used for, the EasySpray is used with medical air for only open procedures and the DuploSpray is used with CO_2 for only laparoscopic/minimal invasive procedures,
- The appropriate pressure ranges for both EasySpray (1.5 – 2.0 bar) and DuploSpray (1.2– 1.5 bar) and
- The optimal spraying distances for both EasySpray (10 – 15cm) and DuploSpray (2 – 5 cm).

These and other details can be found in the respective operation manuals of the regulators and respective instruction for use (IFU) of the Spray Sets and applicators.

As you have been identified as owner of EasySprays (0600075 & 1504275), Tissomats (Z95011*) or DuploSpray Pressure Regulators (0600032) you will be contacted by your Baxter representative to begin the replacement process**.**

Please pass a copy of this letter to all those who need to be aware of this communication within your organisation/ to other organisations/ persons where the devices have been transferred.

In addition, please complete the enclosed customer reply form and return it to Baxter by either fax or scanned email. Returning the customer reply form promptly will prevent you from receiving repeat notifications.

We would like to apologise for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Sincerely,

_____
Ian Gavigan
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Blackrock
Co. Dublin
Ph: 00353 1 206 5500

Baxter

Customer Reply Form

DEVICE EXCHANGE LETTER DATED 27TH JANUARY 2015

EasySpray Pressure Regulator, Tissomat and DuploSpray MIS Pressure Regulator

Product codes: 0600075, 1504275, 0600032, Z9501100999901

Serial numbers*:* All

Please complete and return one copy of this form per facility either by fax (Fax: 01 206 5577) or by e-mail (QA_Dublin@baxter.com) as confirmation that you have received this notification.

A fax cover sheet is not required.

Facility Name and Address:	
Reply Confirmation Completed By: *(Please print name)*	
Title: *(Please print)*	
Email and/or Telephone Number (including Area Code):	

We have received the above-mentioned letter, have disseminated the information / documentation to our staff, other services/facilities and customers, as applicable and the actions outlined in the letter are performed.

Signature/Date: REQUIRED FIELD	_____