

## Patient Safety Notice

### Varilite Cushion Valve Seating Integrity

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**Issue Date:**

19<sup>th</sup> August 2016

**Notice:**

Cascade Designs Inc. have identified that their Varilite production department's subcontractor had changed the material used to create the "vent tube" part of the valves used on their pressure care cushions which has meant that there is the possibility that a number of valves are not seated tightly within the cushion, and may be at risk of coming loose.

Due to the possibility of the valve coming loose, there is a low level risk that the air-tight seal of the cushion could be compromised. As the construction of the Varilite cushion makes use of the benefits of an air/foam mix, the cushion will "fail-safe" if air leaks out, since the client will then be sitting on foam alone. However, the full benefit of the air component will not be experienced, and the effective life of the cushion could be shortened, if more air is released than intended when the valve is working effectively.

**Batch range where valve may be affected:**

2010291 to 2087910

The batch number is printed on the internal cushion and also on the BES delivery note and invoice.

**Actions to be taken:**

A manual test should be carried out on a cushion from within the batch number range stipulated, by pulling out the valve to see if the valve will come loose from its fitting. As standard, it should not be possible to remove a Varilite cushion valve without utilising tools.

If the valve does come loose it will need to be set in position using adhesive. This action will rectify the issue.

BES will provide valve replacement kits, free of charge, to all affected customers. If required, BES will also secure the valves in place for the customer if this is preferred.

Cascade Designs Inc. have confirmed that they have reverted to the old manufacturing materials for the valve vent tubes and have checked all remaining stocks held of the possibly affected batches, to ensure that future customer purchases are not affected.

BES has conducted a thorough check of its stock to ensure that no further at-risk cushions are sent out.

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