

URGENT FIELD SAFETY NOTICE

Rocket[®] Uterine Sounds

Dear Customer,

This notice is precautionary and does not constitute a recall. Please distribute this notice to any and all users at your organisation who may be affected by its contents.

This advisory Safety Notice refers to: **Rocket[®] Uterine Sounds produced in 2008:**

- **R57420 LOT: 416163**
- **R60547 LOTS: 416367, 416818**

Rocket Medical Reference INC617

Rocket Medical plc are advising customers that 4 examples of incorrectly moulded Uterine Sounds have been returned to the company.

The moulded stem of the uterine sounds have been incorrectly filled, producing a sound which is approximately 1.5cm shorter than normal.

In the clinical environment this 'short moulding' could give rise to concerns that the end of the device has fractured; leaving the tip in the uterus.

As a result, there is the increased risk that a patient may be subjected to additional and unnecessary procedures searching for a 'lost' tip which in fact was not actually present prior to insertion into the uterus.

Although the total defect rate represents only 0.008% of production, Rocket Medical plc have voluntarily taken the precautionary measure of advising users who may have residual stock produced in 2008 from one or more of the implicated batches.

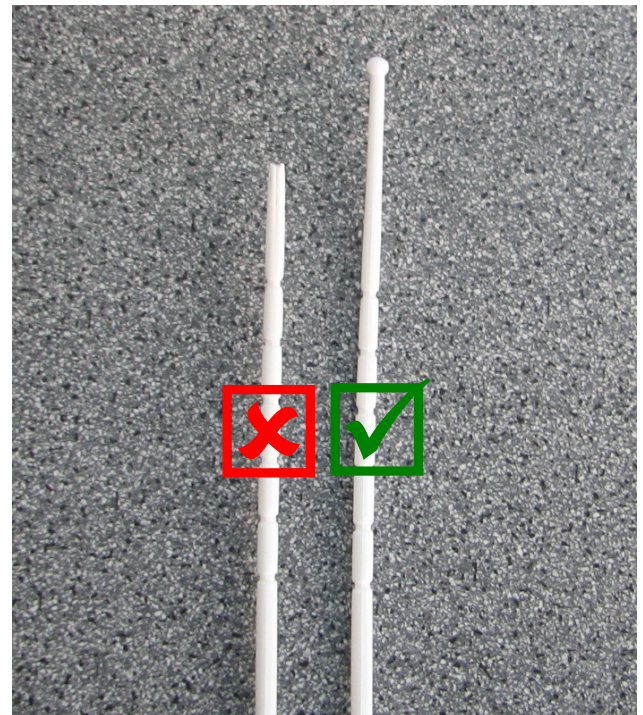
Corrective action to resolve the manufacturing fault was implemented in 2008 and no subsequent reports of defects from future batches have been received. The MHRA have been notified of this corrective action.

If you have product from any of these 3 batches, please check that the moulding is complete before continuing with the procedure. Or if preferred, contact our Customer Service Team to arrange immediate replacement.

For further technical information contact:

Ms. Jackie B. Irwin
Quality Assurance Manager
jackie@rocketmedical.com

Tel 0191 419 4488



Customer Information Bulletins for our products can be found on our web site at: www.rocketmedical.com

