Tom Thumb Devices

Benefits of the device against residual risks.

29/09/15

Supporting Documents:
Risk Assessment Document ID#15751 - Carried out by Derek Lamb
Post Market Surveillance Document ID#15747 - Carried out by Derek Lamb
Clinical Evaluation Report -
Document ID# 15731
Document ID# 15732

Further Clinical Evidence / Researched by – Steve Nixon , John Lamb and Derek Lamb
Document ID#15733
Document ID#15734
Document ID#15753
Document ID#15754

In newborns that require positive pressure during resuscitation, the original clinical need for an alternative to self-inflating bags (bag valve mask) is still relevant today. The Tom Thumb T-piece infant resuscitator device provides positive pressure ventilation and facilities target inflation pressures being delivered consistently. In addition we conclude that the residual risk of using the Tom Thumb T-piece infant resuscitator is minimal and outweighed when compared to the benefits.

The above is concluded from our on-going risk assessments and clinical reviews.

From review evidence:

There are no clinical studies in newborns requiring positive pressure during resuscitation to support or refute superiority of the T-piece Resuscitator over bag ventilation in improving outcome.

- In mechanical models, target inflation pressures are delivered more consistently when using T-piece resuscitators than with self-inflating bags. (LOE 5 - Hussey 2004, F490; Oddie 2005, 109; Finer 2001, 299)

- In mechanical models, PEEP is maintained more consistently with T-piece resuscitators compared with self-inflating bags. (LOE 5 – Finer 2001, 299)

- In mechanical models, the ability to deliver a sustained inflation is better with either a T-piece resuscitator or flow-inflating bag compared with a self-inflating bag. (LOE 5 - Bennett 2005, 113)

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POSITION: **Director – Viamed Ltd.**

SIGNED:

DATE: **30th September 2015**