

Setting a new standard for neonatal resuscitation and ventilation

Market need and potential

Prematurity is a predictor of death and respiratory disease for infants. In EU about 300 000 infants needs respiratory support at birth and of those 40 000 are pre-term where ventilation is standard of care for both resuscitation and stabilization. In US numbers are higher with 380 000 infants born preterm. The use of continuous positive airway pressure (CPAP) is one of the key recommended interventions to reduce morbidity and mortality in preterm infants. Avoiding intubation is an important key performance indicator in neonatal care.

Background

Neores is closely linked to an academic research group at the Karolinska Institute in Stockholm, Sweden, consisting of clinically active MDs with specialization in neonatology, anesthesiology and intensive care. The aim of the group is to improve neonatal ventilation. The work within academia led to the development of a new resuscitation system – rPAP. To commercialize the innovation a company, Neores, was founded by one member of the research group, Thomas Drevhammar, together with a colleague who have taken innovations in neonatal care to market before, Kjell Nilsson.

Approach

rPAP is a patented system composed of a unique valve with nasal prongs and hoses. rPAP is a single use product and can be connected to all major ventilators used in neonatal care in hospitals. It is the first new resuscitation system in 30 years to reach the market. rPAP has in a large clinical trial showed significant improvement in terms of less death and less intubation in comparison to the standard of care.

Business Idea

Neores owns all IP and clinical results around rPAP. Neores will focus their efforts around R&D and clinical development and licence their products to partners for production and sales. Today Neores have made a licence agreement with Inspiration Healthcare Group in UK for production, regulatory approval and sales of rPAP.

Competition

Standard of care today is the T-piece. Resuscitation of infants using T-piece resuscitators (TPR) allow positive pressure ventilation with positive end expiratory pressure (PEEP). This system has some limitations and can only be used with a face mask and has a very high resistance to breathing. These two features are considered negative and leaves room for improvement. Neores have addressed these in a new resuscitation system marketed as rPAP.

Advantages

rPAP has proven to give a significant better outcome in terms of death and intubation compared to the standard of care in the CORSAD trial. It has therefore been lifted in European Guidelines.

The key features are:

- Low resistance for breathing
- Ventilation through nose
- Stable placement
- Suitable for mother-child/skin-to-skin
- Flexible and portable
- For resuscitation and post-ventilation

Current Status

- rPAP is CE marked under MDD
- rPAP is manufactured and sold by Inspiration Healthcare (UK) under a licence agreement.
- rPAP is in clinical use in Sweden and UK.
- Entering the US market is priority to improve clinical impact.
- Preparations to certify under MDR and FDA has started
- rPAP will be updated before new registrations.
- Neores as a company is transitioning from an academic spin-off to a professional company taking more control of the commercialization process
- Neores is collecting competences and knowledge to decide on futures strategy which also will impact capital need.
- Open to partnerships with industry partners as well as investors to get the greatest clinical impact with rPAP

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IPR

Patent granted

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