Assisted vaginal delivery instrument

Country of origin | Argentina

Health problem addressed
World-wide, 10-20% of deliveries require some form of intervention, frequently a Caesarean section. Instrumental vaginal deliveries (forceps and vacuum extraction) account for 2–23% of deliveries. This profile makes the introduction of a new device which would prioritise maternal and fetal safety, is easy to use, disposable and - particularly relevant - does not require a highly skilled attendant.

Product description
This device has been designed on the basis of a double physical phenomenon consisting of a conveyor belt and an air clamp. It consists of a polyethylene sleeve with a cuff-like fold on the fetal insertion edge, which fits the fetal head diameter. This sleeve is introduced using two flexible plastic spatulas 3-mm thick that allow placing the device in the adequate final position around the foetus’ head.

Product functionality
The atmospheric air entering during the sleeve introduction and application is generally enough to produce the air clamp and fix the sleeve around the fetal’s head. However, this effect may be enhanced by insufflating a small amount of air through an insufflation cannula. This adds to the sliding effect occurring between the inner parts of the fold upon force exertion.

Developer’s claims of product benefits
Medical advantages: The device decreases the risk of fetal-maternal injury, contributes to the physiologic development of the second stage of labour, contributes to contraction forces and maternal pushing efforts, could reduce prolonged second stage, could reduce postpartum hemorrhage (uterine atony) through a reduction in the second stage of labor, could significantly decrease operative delivery, could reduce the incidence of perineal damage, and could decrease perinatal infections acquired through the birth canal.

Technical advantages: The device does not require expertise or individual training, is an easy-to-learn technique as insertion is easy, rapid and smooth, has very low production costs and is disposable.

Operating steps
1. Apply one of the insertion spatulas against the inner cuff on one side of the sleeve. 2. Perform a sliding motion following the fetal cephalic curvature. 3. Repeat steps on opposite side, as well as at positions 12 and 6 o’clock. 4. Withdraw spatulas. Pump air into the air chamber through the insufflation cannula. Use the traction handle to pull until the fetal cephalic pole is extracted. 5. Remove and discard the device.

Development stage
Phase 0 of the research was performed in a childbirth simulator (simulator S 575 – “Noelle”) at the Obstetric Simulation Laboratory in Des Moines University (DMU), WHO collaborating center, Iowa, USA, October 21–23, 2008. Trials were successful. Action physical mechanisms (A- the air clamp and B- conveyor belt) generated upon device placement were objectively proved in the simulator obtaining the expulsion of the cephalic pole.

Future work and challenges
The device is currently undergoing processes for regulatory approval. A phase I study to evaluate feasibility and safety is currently being developed in Buenos Aires, Argentina.

Use and maintenance
User: Nurse, midwife, physician
Training: Pelvic trainer and short length of training.
Maintenance: None

Environment of use
Requirements: None

Product specifications
Dimensions (mm): 385 x 205 x NA
Weight (kg): 0.025
Shelf life: 1 year
Other features: Portable and single-use.

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