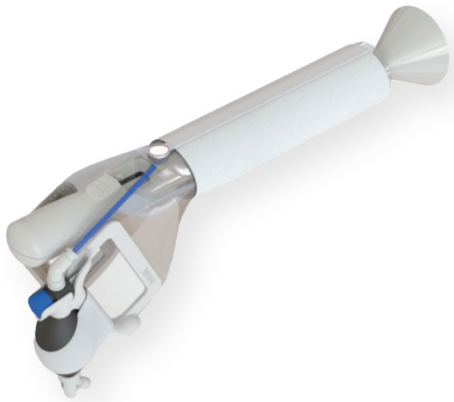
Technical Specifications
OdonAssist™



Device Information

Product Name: OdonAssist™

Reference Number: CAT-126

Legal Manufacturer: Maternal Newborn Health Innovations Singapore Pte. Ltd., 298 Tiong Bahru Road, #05-01, Central Plaza, Singapore 168730

Distributor: Maternal Newborn Health Innovations Europe S.A.S. 26 avenue Jean Kuntzmann, 38330 Monbonnot-Saint-Martin, France

Intended Use: OdonAssist is used to perform assisted vaginal birth in women with term pregnancies and cephalic vertex presentation (occiput anterior, occiput posterior and occiput transverse fetal head positions) with fetal stations at 1 cm or below ischial spines.

Medical Device Classification: (EU MDR 2017/745): [Class I, Sterile]

EMDN Code: U1004

RDM Number: 2813739

Technical & Design Specifications

Biocompatibility: OdonAssist has been evaluated according to EN ISO 10993-1 and demonstrated to be safe for clinical application.

Dimensions: Case carton (10 devices, Unit of Sale) is 400 mm (L) × 330 mm (W) × 500 mm (H)

Device Weight: < 600 grams

Packaging: The unit of purchase is a case carton consisting of 10 OdonAssist devices individually packaged.

Storage, Handling and Transportation: Product does not have special handling requirements. Product storage temperature shall be at room temperature. Transit temperature should not be lower than -29°C and not higher than 50°C.

Maintenance: Device is for single use and therefore does not need preventive and regular maintenance, or preparatory cleaning / disinfection.

Sterility: OdonAssist is a single use product. It is terminally sterilized using gamma radiation.

Shelf Life: 12 months from the date of manufacture.

Disposal: Discard after one procedure. Disposal should be done according to local appropriate procedures.

Performance & Safety Data

Clinical Performance: Two clinical studies have been conducted to evaluate the safety and performance of OdonAssist. Detailed findings are available in the following peer-reviewed publications:

1. ASSIST II Study
2. ASSIST BESANCON Study

Contraindications: The use of OdonAssist is contraindicated in the following conditions: cervix is not fully dilated; any clinical sign of cephalopelvic disproportion; fetal head not fully engaged; undefined presentation; any non-vertex presentation; membranes are not ruptured; umbilical cord prolapse; contraindications for vaginal births according to national or local guidelines.

General Precautions: As with other devices for assisted vaginal birth, the following precautions should be taken before applying OdonAssist to ensure that conditions for safe application of the device are met: confirm full dilation of cervix, fetal head station at 1cm or below the ischial spines; confirm cephalic vertex presentation (occiput anterior, occiput posterior, occiput transverse positions); confirm rupture of membranes; provide adequate analgesia according to facility procedures; position woman lying flat in lithotomy position; empty bladder (deflate balloon if in-dwelling catheter); re-confirm fetal position.

Compatibility & Accessories

Compatible Equipment: Not applicable.

Accessories & Consumables: Not applicable.

Latex: The bulb pump which is used to inflate the air chamber contains natural rubber latex.

Labeling & Regulatory Markings

CE Marking & Notified Body Number: OdonAssist is CE Marked (CE Cert #MDR 790861) by BSI (Notified Body Number: 2797)

Basic UDI-DI (Unique Device Identifier): 8881300626ODONASSISTU2

Declaration of conformity available upon request.

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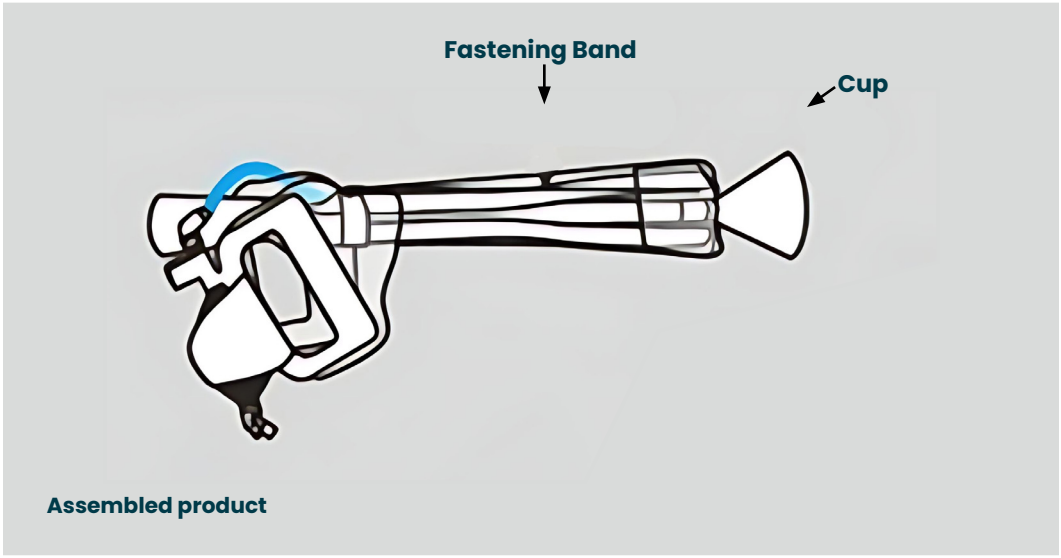
Fig. 1 Schematic drawing of OdonAssist



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