**Manual vacuum extractor**

Product Description:

Vacuum extractor system to assist vaginal deliveries in a delivery room setting.

Hand-operated suction pump creates required vacuum.

Vacuum range, adjustable: from 0 to -100kPa/-800mmHg.

Gauge dial, minimal graduation: 5kPa/40mmHg.

Accuracy vacuum gauge: ± 2.5kPa.

All parts of the vacuum extractor can be disassembled, relevant parts can be autoclaved at 121 C.

Requires no other than routine maintenance, manageable at the level of the delivery rooms.

System is supplied as a complete set consisting of:

2X Bird type anterior suction/extraction cup (1x 50mm and 1x 60mm diameter) rounded edges.

1X Bird type posterior suction/extraction cup (1x50 mm diameter) rounded edges.

2x Extraction handles for Bird type anterior suction/extraction cup.

Suction/extraction cups and handle: stainless steel, Chrome nickel plated.

2x Soft suction/extraction cup (1x50 and 1x60mm opening diameter).

1x Vacuum/collection bottle, plastic 500ml.

1x Cover plug for vacuum/collection bottle, with 3 holes (2 connector + 1 vacuum gauge).

1x Connector angled, chrome plated.

1x Connector angled with screw valve (vacuum release), chrome plated, with cap and gasket.

1x Vacuum gauge with straight connector, chrome plated.

1x Basket, epoxy coated, supporting vacuum/collection bottle and the suction pump, with large hook allowing to fit it to the delivery table.

2x Tube, silicone, transparent, inner/outer diameter approx. 6/11mm, length 50 and 150cm.

Intended use:

Manual vacuum extractor system to assist vaginal deliveries in a delivery room setting with stainless steel anterior and posterior cups.

Hospital equipment for delivery room.

The vacuum extractor must be cleaned and disinfected after each use.

In view of the fact that the vacuum extractor is used in situations of acute need, it must always be readily available and in good working condition. The vacuum extractor must be operated by adequately trained staff only. It is recommended to follow the manufacturer's instructions at all times.

Supplied with:

1x Spare vacuum/collection bottle, 500ml.

1x Spare tube, silicone, transparent, inner/outer diameter approx. 6/11mm, length 300cm.

1x Spare gasket for the screw valve (vacuum release).

20x Polypropylene bottom plate, for stainless steel suction/extraction cup, 10 for each size, 50 and 60mm.

1x List of accessories and parts, each identified with their product reference.

1x Instructions for use and maintenance, and contact details for repair service, in English, French and Spanish.

Accessories / Spare Parts / Consumables (available but not supplied): Vendor specific.

Packaging and labelling:

Packaging: One (1) manual Bird vacuum system with accessories in protective packaging.

Labels include:

Name and/ or trade name, and address of the manufacturer.

Manufacturer's product code / reference.

Lot number prefixed by the word "LOT" (or equivalent harmonised symbol).

Expiry date: month and year.

CE marking and Notified Body number.

Symbols used according ISO 15223 and EN 980.

Regulation & conformity requirements:

CE mark (conforming to Medical Device Directive MDD 93/42/EEC, MDR 2017/745) or FDA 510k approved or equivalent.

Declaration of Conformity according to ISO 17050.

ISO 13485 certified.

Classification:

Class IIa - Rule 5: Invasive accessory device, short term use (MDD 93/42/EEC, MDR 2017/745)

Safety & product Standards (current version of the following standards):

ISO 14971: Medical Devices- Application of risk management to medical devices.

ISO 10079-2: Medical suction equipment — Part 2: Manually powered suction equipment.

ISO 3529-1: Vacuum technology — Vocabulary — Part 1: General terms.

ISO 3529-2: Vacuum technology — Vocabulary — Part 2: Vacuum pumps and related terms.

ISO 21360-1: Vacuum technology - Standard methods for measuring vacuum-pump performance - Part 1: General description.

ISO 17664: Sterilization devices -- Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

Environmental requirements:

ISO 14001: Environmental management systems.