INSTRUCTIONS FOR USE

Manual Vacuum Aspiration (MVA Kit)

***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

SMDPL/IFU/MVA/01. Rev. No.:00, Dt. 12.08.2023

PRODUCT DESCRIPTION:

Manual vacuum aspiration (MVA) is a "safe and effective method of abortion that involves evacuation of the uterine contents by the use of a hand-held plastic aspirator", which is "associated with less blood loss, shorter hospital stays and a reduced need for anesthetic drugs".

Manual vacuum aspiration involves the use of a self-contained vacuum syringe that can be used in place of electric vacuum aspiration for suction curettage in the first trimester.

Manufactured from polypropylene polymer. Specially designed Syringe to apply suction during surgical abortion procedure. Available in Single Valve and Double Valve Syringe.

Syringe (Single) with Acc. Karman Cannula (PP/LDPE) (SMD 805 SP & SMD 805 SL):

MVA Kit consists of PP/LDPE Karman Cannula, Single Pinch valve PP Syringe and Silicon used for suction during surgical abortion procedure.

Syringe (Double Valve) with Acc. Karman Cannula (PP/LDPE) (SMD 805 DP & SMD 805 DL):

MVA Kit consists of PP/LDPE Karman Cannula, Double Pinch valve PP Syringe and Silicon used for suction during surgical abortion procedure.

Acc. Karman Cannula (PP/LDPE) (SMD 800 P & SMD 800 L):

A semi-rigid or rigid plastic PP/LDPE tube shaped surgical instrument that is inserted through the cervix into the uterus and used for suction during surgical abortion procedure.

INTENDED PURPOSE:

Used for manual termination of pregnancy (surgical abortion procedure) for transit use.

INDICATIONS:

- Retained placenta after vaginal delivery (postpartum)
- Retained products of conception after missed, incomplete, or inevitable abortion/miscarriage (see the image below) Ultrasound of a missed miscarriage.
- Elective first-trimester abortion.
- Molar pregnancy.
- Evaluation of abnormal uterine bleeding.

CONTRAINDICATIONS:

- Gestation Exceeding 12+0 weeks
- Allergy to local anesthetic drugs (unless client declines use of local anesthesia)
- Acute cervicitis or pelvic infection

INTENDED USER

Doctors or trained healthcare professionals.

INTENDED PATIENT POPULATION

Adults (Female)

DIRECTIONS FOR USE:

- Read the Instructions Carefully
- Place the patient in a dorsolithotomy position
- Make a manual examination of the vagina
- Expose and clean upper vagina and uterus with an antiseptic solution
- Insert a Vaginal speculum & fix the uterus in relation to the cannula.
- Ascertain the size and depth of the uterus in relation to the cannula.
- Now administer local anesthesia to render uterus numb
- Insert the size pre-sterilized and disposable cannula into the uterus.
- Connect it to the aspirator either using a pre fixed adopter or fix an adopter to the distal and of cannula.
- Make sure that the adopter and the aspirator are fixed properly and make a leakproof union.
- Release the rear ends of pinch valve buttons to start evacuation.
- Hold the aspirator by holding valve body& evacuate by rotating it clockwise & anti clockwise as also moving it to & for unit flow stops or the uterus is completely emptied.

WARNING:

The use of this product is restricted to a qualified Doctor or Healthcare professional only.

PRECAUTIONS AND CAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury.
- ***STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE.***
- For single Patient use only.
- Discard after Single use.
- The product should be used immediately after opening the packing.
- Do not use the device after expiry Date mentioned on the Label.
- If the patient is sensitive or allergic to PVC, do not use the device.

ADVERSE EFFECTS:

- Uterine cramping
- Bleeding
- Infection

CLINICAL BENEFITS:

- Reduce bleeding
- Reduce pain and cramps
- High patient satisfaction
- Well tolerated by patients
- Reduce Pelvic inflammatory disease
- No uterine perforation
- No adverse events
- Improved post-abortion care

RESIDUAL RISKS:

- Uterine perforation
- Bleeding, Infection

SUPPLY:

Syringe (Single Valve) with Acc. Karman Cannula (LDPE) - SMD 805 SL

Syringe (Single Valve) with Acc. Karman Cannula (PP) - SMD 805 SP

Syringe (Double Valve) with Acc. Karman Cannula (LDPE) - SMD 805 DL

INSTRUCTIONS FOR USE

Manual Vacuum Aspiration (MVA Kit)

***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

SMDPL/IFU/MVA/01. Rev. No.:00, Dt. 12.08.2023

Syringe (Double Valve) with Acc. Karman Cannula (PP) - SMD 805 DP

Acc. Karman Cannula (LDPE) - SMD 800 L

Acc. Karman Cannula (PP) - SMD 800 P

SYMBOLS:

REF	**Catalogue No.**		**See instructions for Use**
	Cautions		**Keep Dry**
	Do not use it if the packaging is damaged.		**Sterile Barrier System**
	Single-Use		**Do not Re-sterilize**
LOT	**Batch / Lot No.**	STERILE EO	**Ethylene Oxide Sterilized**
	Date of Mfg.	LATEX	**Latex Free**
	Date of Exp.	MD	**Medical Device**
	Avoid Direct Sunlight	45°C 5°C	**Keep in a dry place between 5°C to 45°C**
PHT DEHP	**Phthalate Free**		**Pyrogen Free**
UDI	**Unique Device Identifier**		

MATERIALS USED:

Component	Material	Specification/Grade
Syringe	PP (Poly Propylene)	Medical Grade
Karman Cannula	LDPE (Low Density Poly Ethylene) & PP (Poly Propylene)	Medical Grade

STERILITY`:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused devices.

STORAGE:

The Device should be stored in their original box in a cool and dry place between 5 to 45° C, preferably away from direct and indirect sources of light and heat. Do not use after expiry.

DEVICE DISPOSAL:

Used Devices may be contaminated with infectious and/or other hazardous materials. Discard used tubes in the container meant for infectious waste. Unused expired products should be disposed of as per local regulations.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

EC REP

CE 0123

OBELIS S.A. Bd, General Wahis, 53,
1030, Brussels, Belgium
Email:mail@obelis.net

Sterimed Group, 501 Ring Road Mall,
21, Manglam Place, Rohini Sec-3 Delhi-85
Manufactured by:

Sterimed Medical Devices Pvt. Ltd.

Plot No. 211A, Sector-16, HSIIDC, Bahadurgarh,
Jhajjar, Haryana - 124507 (INDIA)
Customer Care No.: +91-11-42466196/396
Email : info@sterimedgroup.com
Website : www.sterimedgroup.com
EN ISO 13485:2016 Certified Company
Mfg. Lic. No.: MFG/MD/2018/000086