DRAE hugger vacuum and DRAE hugger corset uterine compression devices

Product Design Specifications

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Function:

Postpartum hemorrhage is an obstetrical emergency that can follow vaginal or cesarean delivery. It is a major source of maternal morbidity and maternal mortality. This uterine compression device would mimic the normal uterine response following delivery by simulating smooth muscle contraction and compressing the uterus in all planes, thus preventing uterine atony and setting placenta accreta. This would prevent the patient from having to undergo a hysterectomy, which would render her infertile. While the DRAE Hugger could be used in both cases of uterine atony and placenta accreta, the DRAE Corset could only be used in emergent cases of uterine atony as its use in placenta accreta is unknown. It would be used in conjunction with a currently used device, the Bakri Balloon. This would provide compression in most planes, providing the desired effect. The DRAE Corset would be a less expensive alternative to the DRAE Hugger, with potential benefits in low income areas both in and out of the United States.

Client Requirements:

- Provide complete compression of the uterus in all directions.
- Ligaments surrounding the uterus should be compressed within the hugger.
- Provide constant suction for at least 24 hours.
- Cellulose mesh that is both durable and absorbable.
- Trocar instrument to remove air from the uterine cavity.
- Device must be easily and quickly inserted into the body cavity.
- Pressures sustained after suction should stay in the physiological range from 70-110 mmHg.

1. Physical and Operational Characteristics

A. Performance Requirements:

The DRAE Hugger must halt postpartum hemorrhaging following conditions of either uterine atony or placenta accreta. The device must mimic normal uterine response by simulating smooth muscle contraction and compressing the uterus in all planes, thus arresting uterine atony and placenta accreta. The device would only be used once, and must be a safe and absorbable material so that device removal would not be necessary. The material, in addition to being absorbable, must be able to provide pressures normally induced by the smooth muscle cells following delivery.

B. Safety

The absorbable material itself must be sterilizable, hemocompatible, and biocompatible. The suction provided by the device should not exceed normal pressures reached by smooth muscle cells (70-110 mmHg).

C. Accuracy and Reliability

The hugger should be within the range of normal physiological pressure and be able to hold that pressure for at least 24 hours. It must also completely halt the progress of postpartum hemorrhage, thus preventing the need of a hysterectomy.

D. Life in Service

The device must maintain constant pressure for at least 24 hours, and be completely degraded by six weeks.

E. Shelf Life

The hugger should be stored in a dry environment to prevent material break-down. The ideal temperature for storage is -20° C in order to preserve the absorbable materials for extended periods of time.

F. Operating Environment

The device will be placed in the body so it must be sterilizable, hemocompatible, and biocompatible. It must also be stored at 20°C when in the operating room and at body temperature (37°C) when in use within the body cavity. The absorbable material must be able to withstand 70-110 mmHg of pressure during vacuum suction.

G. Ergonomics

Materials used in the device must not negatively affect the tissues surrounding the uterus and the device should be positioned around the uterus easily.

H. Size

The device will be 5cm x 8cm x c4m with a volume of 80-200mL. Furthermore, the device must also be portable.

I. Weight

The hugger must be very lightweight as it will be placed within the body.

J. Materials

All components of the materials used must be biocompatible and absorbable.

K. Aesthetics

As the product will be placed within the body, it will not be visible and therefore aesthetics is not the most important component of the design process. However, the device must be easy to use and put in place.

2. Production Characteristics

A. Quantity

Multiple units must be available in each hospital that the product is in use, therefore the quantity of units that must be produced is not yet known. The client would like to end this design process with one “proof of concept” model.

B. Target Product Cost

Current devices range in cost from $1500 to over $3000. The cost of this device will ultimately depend on the materials needed.

3. Miscellaneous

A. Standards and Specifications

All absorbable materials must be biocompatible and FDA approved.

B. Customer

Complete compression of the uterus must be obtained: especially laterally. The device should reach its optimal pressure rapidly. Absorbability within six weeks is optimal.

C. Patient-related concerns

Materials must be easily sterilized and cause minimal discomfort to the patient. The device must quickly and effectively stop postpartum hemorrhaging with little to no side effects.

D. Competition

Some existing methods to prevent postpartum hemorrhage include:

i. Bakri Balloon: Device is inserted into the uterus and filled with sterile fluid to provide compression of the endometrium in the medial/lateral and posterior/anterior directions.
ii. B-Lynch Suture: Insertion of sutures to compress the mid-portion of the uterus.
iii. Hypogastric Artery Ligation: Hypogastric artery is surgically tied up or closed off.
iv. Hysterectomy: Surgical removal of the uterus, renders the woman sterile.