Uterine compression device: a treatment for postpartum hemorrhage

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. The uterine compression device would mimic normal uterine response by simulating smooth muscle contraction by compressing the uterus in all planes, thus preventing uterine atony. The device could also be used in the setting of placenta accreta, allowing for manual removal of the placenta followed by compression using the device. The device would have to compress the uterus in all planes and suppress hemorrhaging for over twenty-four hours. This could be used in conjunction with a currently used device such as the Bakri Balloon. All aspects of the uterine compression device that are inserted into the patient should be absorbed within six months.

Client Requirements:

- Provide complete compression of the uterus in all direction.
- Ligaments surrounding uterus should be compressed within the hugger.
- Provide constant compression for at least 24 hours.
- Bioabsorbable material that is both durable and absorbable
- Trocar instrument to remove air from uterine cavity.
- Device must be easily and quickly interested into the abdominal cavity.
- Pressures sustained after suction should stay in physiological range: minimum of 100mmHg.

1. Physical and Operational Characteristics

A. Performance Requirements:

The DRAE Hugger must stop excess Post-Partum Hemorrhaging bleeding when caused by either uterine atony or placenta accreta. The device must mimic normal uterine response post-partum by simulating smooth muscle contraction and compressing the uterus in all planes, thus halting uterine atony. The device must also stop bleeding post removal of the placenta in cases of placenta accreta. The device would only be used once, and must be a safe absorbable material so that device removal would not be necessary. The material, in addition to being absorbable, must be able to withstand pressures normally caused by the smooth muscle cells after birth.

B. Safety:

The absorbable material itself must be sterilizable, hemocompatible, and biocompatible. The suction provided by the vacuum device should be at least 100mmHg. There is no maximum pressure due to the excellent blood supply to the uterus.

C. Accuracy and Reliability:

The hugger should be within the range of physiological pressure: a minimum of 100mmHg for at least 24 hours. It must also completely half 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 within six months.

E. Shelf Life:

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

F. Operating Environment:

The device will be placed in the body, so must be sterilizable, hemocompatible, and biocompatible. It must also be stored at a range of 20 degrees Celsius when in the operating room, and at body temperature (37 degrees Celsius) when in use within the abdominal cavity. The absorbable material must be able to withstand a minimum of 100mmHg of pressure during vacuum suction.

G. Ergonomics:

Materials used in the device must not negatively affect the tissue 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 be portable.

I. Weight

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

J. Materials

All components of 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 uses the product, 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. Although there is no set budget for this device, we have set the budget around $1000.

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 optimal pressure rapidly. Absorbability in six months 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 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 midportion of the uterus.

iii. Hypogastric Artery Ligation: Hypogastric artery is surgically tied up or closed off.

iv. Hysterectomy: Surgical removal of the uterus.