Hysterectomy and GPS®III Kit/
Plasmax® PLUS Concentration Kit
**Key Terms**

**Uterus**: A hollow, pear-shaped organ located in the lower abdomen between the bladder and rectum. Also called the womb, this is where a fetus develops.

**Endometrium**: The mucous membrane that lines the uterus. It thickens throughout the menstruation cycle, and if pregnancy does not occur, it is shed at the end of the cycle.

**Ovaries**: Part of the female reproductive system located on each side of the uterus in the lower abdomen. The ovaries contain eggs that develop and are released into the fallopian tubes for fertilization.

**Fallopian Tube**: A tube that connects the uterus to the ovaries. When an ovary releases an egg, it travels down the fallopian tube and into the uterus.

**Cervix**: The lower part of the uterus, which opens into the vagina.

**Abbreviations**

- AH: Abdominal Hysterectomy
- VH: Vaginal Hysterectomy
- LAVH: Laparoscopically-assisted Vaginal Hysterectomy
- TLH: Total Laparoscopic Hysterectomy
- LSH: Laparoscopic Supracervical Hysterectomy
- MRSA: Methicillin-resistant Staphylococcus Aureus
- MSSA: Methicillin-sensitive Staphylococcus Aureus
- ESBL: Extended Spectrum Beta Lactamase (a strain of E. coli)
Introduction

Hysterectomy is the surgical removal of a woman’s uterus. Approximately 1.8 million procedures are performed worldwide each year. The most common causes include:

1. Uterine fibroids, also called leiomyoma3–5
2. Endometriosis: growth of endometrium outside of the uterus3–5
3. Chronic vaginal bleeding3–5
4. Cancers of the cervix, ovaries, endometrium or uterus3–5
5. Uterine prolapse: descent of the uterus into the vagina due to weakening of its supporting ligaments3–5
6. Pelvic inflammatory disease: infection of the lining of the uterus, the fallopian tubes or the ovaries3–5
7. Endometrial hyperplasia: pre-cancerous growth of the endometrium3–5
8. Childbirth complications such as hemorrhage3–5

Types of Hysterectomy3,7

1. Subtotal Hysterectomy. Also called Partial or Supra-cervical Hysterectomy:
   • Removal of the uterus but not the cervix
   • Usually performed for uterine fibroids, abnormal bleeding or to relieve pelvic pain

2. Total Hysterectomy:
   • Removal of the entire uterus and cervix
   • Usually performed for uterine and cervical cancer
   • Most common form of hysterectomy

3. Total Hysterectomy with Bilateral Salpingo-oophorectomy:
   • Removal of the uterus, cervix, ovaries and fallopian tubes

4. Radical Hysterectomy:
   • Removal of the uterus, cervix, upper part of the vagina, fallopian tubes, ovaries and associated lymph nodes and channels
   • Usually performed for cervical cancer
   • Requires the longest hospital stay and the longest recovery period3
Surgical Approaches

1. Abdominal Hysterectomy:
   - A 4-6 inch incision is made in the lower abdomen
   - The blood vessels, fallopian tubes and ligaments are cut away from the uterus
   - The uterus is lifted out
   - Between 60% and 70% of hysterectomies are performed in this manner

2. Vaginal Hysterectomy:
   - An incision is made near the top of the vagina
   - The ligaments, blood vessels and fallopian tubes are cut and tied off
   - The uterus is removed through the vagina
   - Between 20% and 30% of hysterectomies are performed in this manner

3. Laparoscopically-Assisted Vaginal Hysterectomy:
   - Laparoscopic techniques are used to assist in cutting and tying off blood vessels, ligaments and fallopian tubes
   - The uterus and sometimes the fallopian tubes and ovaries are removed through the vaginal route
   - This technique is used with less frequency than abdominal and vaginal hysterectomy but is quickly gaining popularity due to shorter postoperative recovery (see table below)

4. Total Laparoscopic Hysterectomy:
   - The entire hysterectomy is performed via a laparoscope

For all procedures, the average time to normal sexual activity is 6-8 weeks.

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Surgical Procedure Information: Hysterectomy

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Technique

Plasmax® Plasma Concentrate is sprayed inside the abdominal cavity (peritoneum). Possible areas to be sprayed include but are not limited to:

- Uterine/Ovarian pedicles: the connective tissue and blood vessels that connect the uterus and ovaries to each other and to the abdominal wall. These blood vessels and ligaments are clamped, cut or sutured

- Vaginal cuff: the portion of the vaginal tissues cut from the cervix and sutured together to form a blind pouch

- Any other cut, abraded, ligated or sutured surface

Platelet-rich plasma (PRP) is sprayed outside the abdominal cavity. Possible areas to spray include but are not limited to:

- For vaginal hysterectomy, the area between the peritoneum and the closed vaginal cuff

- On incision in open procedures

- In ports in laparoscopic procedures

Plasmax® Plasma Concentrate is sprayed on sutured vaginal cuff and on any cut or abraded surfaces inside peritoneum.

PRP is sprayed on muscle and fascia layers upon closure. This includes the ports used during laparoscopic procedures.
Surgical concerns addressed by PRP and Plasmax® Plasma Concentrate

The reported overall complication rate for hysterectomies is 3.6-4.0%.

The following complications and rates are the most common:

1. Hemorrhage occurs in 1.8-3.4% of cases. Fibrin sealants and PRP have been used to reduce postoperative bleeding and prevent hemorrhage in many different types of surgery, including cardiac, orthopaedic, ear, nose, and throat and obstetric.

2. Postoperative fever or infection occur in 0.8-4.0% of cases. The use of PRP has been shown to inhibit the growth of MRSA, MSSA, ESBL and E. coli, which are responsible for many postoperative infections.

3. Adhesions occur in 60-90% of all patients undergoing gynaecological surgery. They cause intestinal obstruction in 2-3% of all hysterectomy cases and as many as 5% of cases when radical hysterectomy was performed. Fibrin sealants have been shown to help prevent adhesion formation when sprayed onto surgical sites after gynaecological procedures.
ATTENTION OPERATING SURGEON

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable kit after one use, using acceptable disposal method for potentially contaminated blood products.

DESCRIPTION
Plasmax™ Plus Plasma Concentrator
Plasmax™ Plus Plasma Concentrator aids in the concentration of the patient’s own plasma proteins by centrifugation, utilizing a Biomet Biologics centrifuge. Excess water is removed from the platelet-poor-plasma (PPP) when mixed with desalting beads.

GPS® III Platelet Concentrate Separation Kit with ACD-A
The GPS® III Platelet Concentrate Separation Kit with ACD-A aids separation of the patient’s own blood components by density using a Biomet Biologics centrifuge.

MATERIALS
The Plasmax™ Plus Plasma Concentrator consists of medical-grade polymers suitable for use in medical devices, and contains porous polyacrylamide desalting beads.

GPS® III Platelet Concentrate Separation Kit with ACD-A includes syringes, needles, tubing, connectors, and platelet separators which also consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices. Blood-draw kit components in this kit are packaged, labeled and sterilized as indicated by the manufacturer’s labeling. All components in this kit are latex free.

ACD-A is an anticoagulant supplied by Citra Anticoagulants, Inc., Braintree, MA, and manufactured by Cytosol Laboratories, Inc., Braintree, MA. For further information regarding ACD-A, please contact the supplier at 1-800-299-3411.

NOTE: Use standard aseptic technique throughout the following procedures.

INSTRUCTIONS FOR USE

PROCEDURE ONE: Use the GPS® III Platelet Concentrate Separation Kit with ACD-A to prepare PPP and platelet-rich-plasma (PRP).

1. DRAW: Draw 6ml of anticoagulant into 60ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 54ml of patient’s own blood into the 60ml syringe primed with ACD-A. Gently, but thoroughly mix the whole blood and ACD-A upon collection to prevent coagulation.

2. LOAD: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED PER SPIN, and that the platelet separator remains upright. Unscrew clear cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 60ml syringe (6ml of ACD-A mixed with 54ml of patient’s whole blood) into center blood port #1. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap back onto port #1. Place platelet separator filled with anticoagulated blood into a Biomet Biologics centrifuge.

3. BALANCE: Fill blue GPS® counterbalance tube (800-0508) with 60ml of sterile saline/water (equal to amount of whole blood plus ACD-A dispensed in the platelet separator). Place filled counterbalance directly opposite from the platelet separator in the centrifuge.

4. SPIN: Close centrifuge lid. Set RPM to 2.0 (x 1,000) and the time to 2 minutes. Press the start button. Once spin is complete, open centrifuge.

5. EXTRACT PPP: Unscrew yellow cap on port #2 and save yellow cap. Connect 30ml syringe to port #2, invert platelet separator, and extract exactly 25ml of PPP. Remove 30ml syringe from port #2, cap with a sterile syringe cap, and set aside. Replace yellow cap on port #2.

6. If (PRP) is desired, follow steps 7 – 8.

7. SUSPEND PRP: Holding platelet separator in the upright position, unscrew red cap on port #3. Attach sterile 10ml syringe to port #3. Extract 2ml of PRP into the 10ml syringe. Leave the syringe attached. Shake platelet separator gently for 30 seconds.

8. EXTRACT PRP: Immediately after suspending the platelets, extract remaining PRP into the attached 10ml syringe. Remove 10ml syringe from port #3, and cap with a sterile syringe cap.

PROCEDURE TWO: Use the Plasmax™ Plus Plasma Concentrator to prepare platelet-poor-plasma concentrate (PPC).

1. LOAD: Unscrew cap on port #1. Slowly load the 25ml PPP collected in 30ml syringe into port #1. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1.

2. MIX: Twist and piston the mixing paddle for 30 seconds. Be sure to push and twist the paddle to the floor of the Plasmax™ Plus Plasma Concentrator’s upper chamber to saturate the beads. There should be no white beads visible. Place into centrifuge.

3. BALANCE: Place the green Plasmax™ Plus counterbalance tube (800-0512) directly opposite from the Plasmax™ Plus Plasma Concentrator in the centrifuge.

4. SPIN: Close centrifuge lid and set RPM to 2.0 (x 1,000) and the time to 2 minutes. Press the start button. Once spin is complete, open centrifuge.

5. EXTRACT PPC: Unscrew red cap on port #2 and extract PPC using a sterile 10ml syringe. Remove 10ml syringe from port #2, and cap with a sterile syringe cap.

Comments regarding this device can be directed to Attn: Regulatory Dept, Biomet. P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-1683.

These devices are only approved for distribution outside the United States.

GPS is a registered trademark in the United States.

Authorized Representative: Biomet U.K., Ltd. Waterton Industrial Estates Bridgend, South Wales CF31 3XA, U.K.

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References:


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