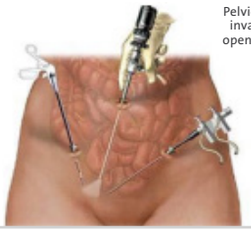
INTERNATIONAL

GYN Primer

WOUNDCLOT®
Advanced Bleeding Control™

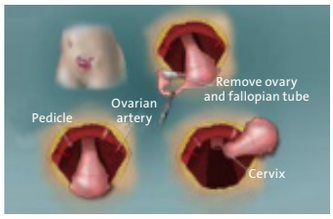
Key Procedures and Potential Bleeding Sites

HYESTERECTOMY Removal of the uterus and cervix and, in many instances, the ovaries and fallopian tubes. The procedure can be performed via open laparotomy, vaginally, laparoscopically/robotically, or a combination procedure labeled laparoscopic assisted vaginal hysterectomy (LAVH).



Pelvic laparoscopy is a less invasive procedure than open surgery and recovery is quicker

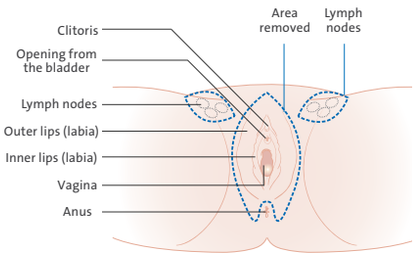
Sites of bleeding



Potential bleeding sites: soft tissue surrounding the pelvic organs, uterine arteries, vaginal cuff, tissue surrounding the bladder

ILLUSTRATION: A.D.A.M.

RADICAL VULVECTOMY AND INGUINAL LYMPHADENECTOMY
Removal of skin surrounding the vagina and deep pelvic and superficial lymph nodes. Performed for cancer of the vagina, vulva, or surrounding skin.

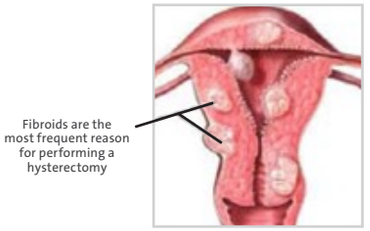


Potential bleeding sites: soft tissue of groin, skin, arterial and venous blood vessels, and base of lymph nodes

ILLUSTRATION: HTTPS://EN.WIKIPEDIA.ORG/WIKI/VULVECTOMY#/MEDIA/FILE:DIAGRAM_OF_A_3_IN_1_INCISION_VULVECTOMY_CRUK_018.SVG

MYOMECTOMY
Removal of benign tumors of the uterus (fibroids) can be done laparoscopically/robotically or via an open laparotomy approach.

Potential bleeding sites: surface and body of the uterus



Fibroids are the most frequent reason for performing a hysterectomy

ILLUSTRATION: A.D.A.M.

ECTOPIC PREGNANCY Pregnancy implantation outside of the uterus (the most common location is in the fallopian tube). Rupture can occur and lead to a surgical emergency. Removal can be performed via laparoscopy/robotically or laparotomy.

Potential bleeding sites: tissue of the fallopian tube, ovary, and surrounding pelvic tissue

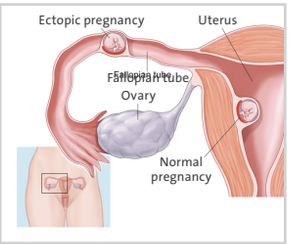


ILLUSTRATION: HTTPS://WWW.BABYCENTER.COM/PREGNANCY/HEALTH-AND-SAFETY/ECTOPIC-PREGNANCY_229

PELVIC ORGAN PROLAPSE (POP) REPAIR FOR URINARY INCONTINENCE
Open and laparoscopic/robotic procedures may be performed to lift the bladder and pelvic organs to treat incontinence. In many cases, a hysterectomy is performed at the same time.

Potential bleeding sites: soft tissue surrounding the bladder, arterial, and venous bleeding, especially from the retropubic space (retzius plexus)

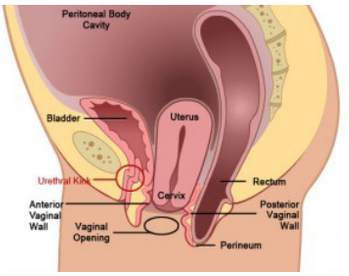
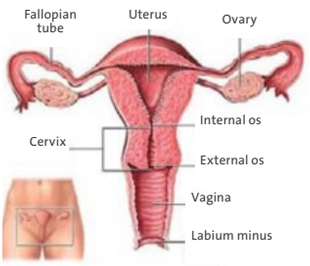


ILLUSTRATION: HTTPS://GYNECOLOGICSURGERY.COM/UTERUS-PROLAPSE-TREATMENT/UTERINE-PROLAPSE-IMAGE-3-300X241/

RADICAL HYSTERECTOMY AND PELVIC LYMPH NODE DISSECTION Removal of pelvic organs, upper portion of vagina, lymph nodes, and pelvic connective tissue. Performed for cancer, eg, uterine cancer and ovarian cancer.

Potential bleeding sites: soft tissue of the pelvis, bleeding tumor vessels, tissue adherent to tumor, soft tissue surrounding bladder, aorta, vena cava, and iliac vessels and vaginal cuff



INDICATIONS FOR USE — CE*

5 cm X 5 cm (2”x2”), 5 cm x 7.5 cm (2”x3”), 10 cm x 10 cm (4”x4”)
CE Class III Surgical Implantable haemostat effective in the management of capillary, venous, and arterial bleeding during surgical procedures.

WoundClot Surgical is indicated for the control of mild, moderate, and severe perioperative and postoperative bleeding for all surgical indications.

*Indication may vary by country outside of Europe.

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CHALLENGES

- Diffuse to aggressive bleeding
- Difficult-to-reach locations
- Damage to sensitive structures such as the bladder, urethra, and ureters
- Bleeding from highly vascular anatomic locations, eg, uterus and vaginal cuff
- Anemia in patients with heavy vaginal bleeding (menorrhagia)

PROBING QUESTIONS FOR HEALTHCARE PROFESSIONALS

- What hemostatic agents do you currently use?
- What are the advantages of these products?
- What are their challenges and/or limitations?
- How do you manage non–technique-related bleeding caused by blood thinning medicines?
- Do you use multiple hemostatic agents? Why?
- Is it sometimes difficult to control bleeding in laparoscopic procedures, such as myomectomy or ectopic pregnancy?
- Are you concerned about damage to sensitive structures like the body of the uterus or fallopian tubes if you need to use cautery to control bleeding?

PROBING QUESTIONS FOR ADMINISTRATORS/SUPPLY CHAIN

- How much time does your staff spend preparing (mixing/thawing) hemostats before a case?
- Are you interested in reducing costs by adopting a product that offers the highest hemostatic efficacy possible at low cost?

SALES SCRIPT

WoundClot is a next generation, ready-to-use bioabsorbable hemostatic gauze indicated for the control of mild, moderate, and severe perioperative and postoperative bleeding. WoundClot is effective in the management of capillary, venous, and arterial bleeding during surgical procedures.

When WoundClot encounters blood, it converts into a thick, tenacious, expanding gel, adhering to wound surfaces. WoundClot does not require the application of manual pressure and will absorb up to 2500% of its weight in fluid. WoundClot offers the highest hemostatic efficacy possible at low cost and is ideal for use in all surgical specialties including: Spine, Neuro, Cardiac, Thoracic, General, GYN, Ortho, Urology.

Would you like to try WoundClot in an upcoming surgical case?

COMMONLY ASKED QUESTIONS

What is WoundClot made from?
WoundClot is made from cellulose, a natural fiber product. WoundClot is the only non-oxidized, non-regenerated cellulose structure (NONRCS) product in the world. Other hemostatics made from cellulose are manufactured utilizing an obsolete method that breaks down cellulose by oxidization, greatly decreasing the product's ability to absorb blood, adhere to wound surfaces, and create an environment that is conducive to achieving hemostasis.

How does WoundClot work?
Unlike any other hemostatic product available today, WoundClot has multiple mechanisms of action. When WoundClot contacts blood, it converts into a thick, tenacious, expanding gel, adhering to wound surfaces. WoundClot does not require the application of manual pressure to be effective. WoundClot is highly absorbent and will absorb up to 2500% of its weight in fluid. It also remains actively absorbent for up to 24 hours in the wound. The product is engineered so it will activate 2 key factors.

Does WoundClot Hemostatic Gauze work on the clotting cascade?
Yes, it is one of the mechanisms of action WoundClot utilizes to achieve rapid hemostasis. WoundClot is engineered to activate Factors XI and XII.

How is WoundClot different from mineral-based hemostatics?
Mineral-based hemostatics are comprised of a nonresorbable, non-woven fiber impregnated with an active ingredient like Kaolin. Kaolin is an inorganic fine, white clay powder, resulting from the natural decomposition of other clays or feldspar. These products utilize a single mechanism of action: activation of Factor XII (Hageman Factor). They require the application of intense manual pressure for at least 3-5 minutes in order to be effective. WoundClot utilizes multiple mechanisms of action: rapid fluid absorption, adherence and expansion in the wound, aggregation of platelets, red blood cells (RBCs), and clotting factors, creation of an environment conducive to clotting, as well activation of Factors XI and XII.

How easily is WoundClot removed from wounds?
WoundClot is easily removed from a wound by simply removing the clot. Rebleeding will not occur and any remaining gel can be easily irrigated out of the wound.