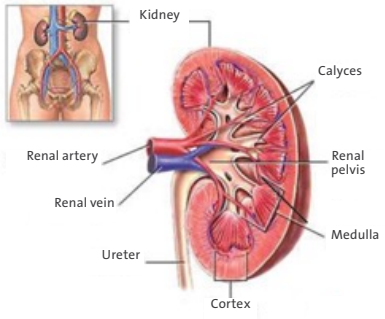
INTERNATIONAL

Urology Primer

WOUNDCLOT®
Advanced Bleeding Control™

Key Procedures and Potential Bleeding Sites

MINI PERCUTANEOUS NEPHROLITHOTOMY
A minimally invasive method of removing kidney stones using a nephroscope and other instruments passed through the skin (percutaneous) into the kidney.



Potential bleeding sites: renal tissue, soft tissue surrounding kidney

ILLUSTRATION: A.D.A.M.

OPEN PARTIAL NEPHRECTOMY
Removal of a portion of the kidney, usually done to remove a tumor, is complicated by renal tissue bleeding.

Potential bleeding sites: renal tissue, soft tissue surrounding kidney, including adhesions

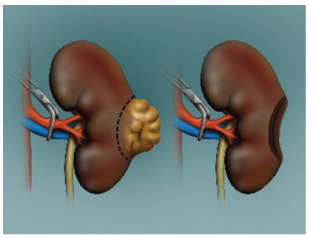


ILLUSTRATION: ©2005 CLEVELAND CLINIC FOUNDATION

PELVIC LYMPH NODE DISSECTION
Removal of lymph nodes in the pelvis and retroperitoneum. Typically done for cancer debulking (partial removal of tumor) or staging.

Potential bleeding sites: soft tissue of the retroperitoneal area and of the pelvis, bleeding tumor vessels, tissue adherent to tumor

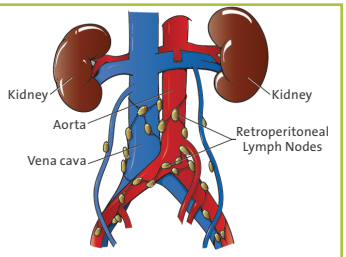
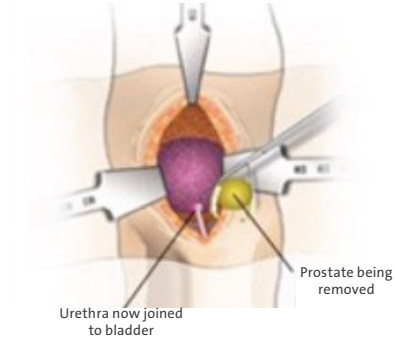


ILLUSTRATION: HTTPS://WWW.MSKCC.ORG/CANCER-CARE/PATIENT-EDUCATION/ABOUT-YOUR-RETROPERITONEAL-LYMPH-NODE-DISSECTION

OPEN PROSTATECTOMY WITH SUPRAPUBIC AND PERINEAL APPROACHES
Prostatectomy is the removal of the prostate gland (as opposed to transurethral resection of the prostate [TURP]). It is usually done open, especially if the gland is markedly enlarged or for advanced cancer, but may also be performed laparoscopically/robotically. Retropubic is the most common approach.



Potential bleeding sites: tissue surrounding prostate (prostatic bed), bleeding tumor vessels, vascular pedicles, tissue adherent to prostate, neurovascular bundle

ILLUSTRATION: ©2008 THE PROSTATE CANCER CENTRE

LAPAROSCOPIC/ROBOTIC PROSTATECTOMY
Removal of the prostate gland using a minimally invasive technique, mainly for cancer limited to the gland. FLOSEAL can reduce the need for cautery and preserve visibility. Reducing the need for cautery can contribute to nerve preservation and increase the likelihood of potency following surgery.

Potential bleeding sites: renal tissue, soft tissue surrounding kidney, including adhesions

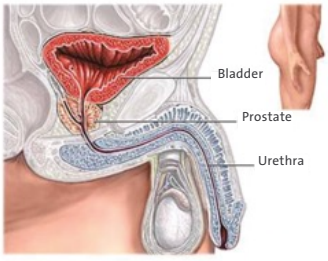


ILLUSTRATION: A.D.A.M.

PELVIC ORGAN PROLAPSE (POP) REPAIR FOR URINARY INCONTINENCE
Open and laparoscopic procedures may be performed to lift the bladder and pelvic organs to treat incontinence.

Potential bleeding sites: soft tissue of the retroperitoneal area and of the pelvis, bleeding tumor vessels, tissue adherent to tumor

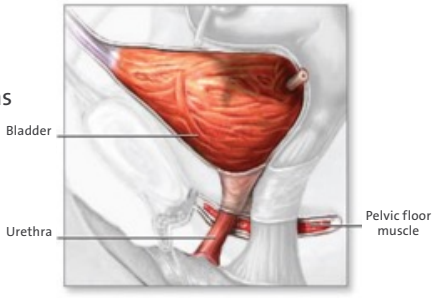


ILLUSTRATION: A.D.A.M.

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 (deep and difficult to diagnose at the beginning)
- Difficult-to-reach locations, such as retropubic space in prostatectomies
- Damage to sensitive structures, such as the bladder, urethra, ureters, and adjacent structures
- Bleeding from highly vascular anatomic locations, eg, renal parenchyma and tumor beds

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?
- Do you perform partial nephrectomies? Open or lap? How long do you typically clamp the renal artery? Would you be interested in reducing the clamp time?
- How do you achieve adequate hemostasis of the renal parenchyma? For open and lap/robotic?
- Do you perform radical prostatectomies? Open or lap/robotic? Are you concerned about nerve damage caused by bipolar cautery? Would you be interested in a product that can maintain visualization throughout the entire procedure and potentially reduce the need for cautery?

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?

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?

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.