INTERNATIONAL

Spine Primer

WOUNDCLOT®
Advanced Bleeding Control™

Key Procedures and Potential Bleeding Sites

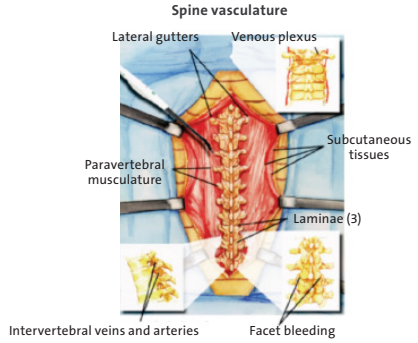
POSTERIOR LUMBAR INTERBODY FUSION (PLIF) Removal of intervertebral disk (1) and fusion of the anterior vertebral bodies. Requires removal of posterior sections of vertebrae (lamina) (3) and manipulation of spinal nerves. A bone graft is placed in the disk space and sides of spine. A longitudinal incision is made in the midline of the low back over the spinal levels to be fused.

ANTERIOR CERVICAL DISCECTOMY FUSION (ACDF) Removal of intervertebral disk (1) and fusion of the anterior vertebral bodies in the cervical region. Surgery is performed through a transverse incision in the front of the neck, just off of the midline.

TRANSFORAMINAL INTERBODY FUSION (TLIF) Removal of intervertebral disk (1) and fusion of the anterior vertebral bodies. Approach is posterior (as in PLIF), but retraction of spinal nerves is not necessary. A longitudinal incision is made in the midline of the low back over the spinal levels to be fused.

ANTERIOR LUMBAR INTERBODY FUSION (ALIF) Removal of intervertebral disk (1) and fusion of the anterior vertebral bodies. Surgery is done through the abdomen (anterior) rather than the back (posterior).

NEUROTRAUMA Fusion of the transverse processes (2) and the lateral aspect of the facet joint. Bone graft is placed in the back and lateral areas of the spine. A longitudinal incision is made in the midline of the low back over the spinal levels to be fused.



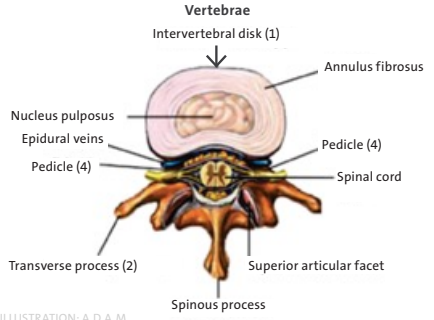


ILLUSTRATION: A.D.A.M.

BRAIN/SPINAL CORD TUMOR REMOVAL SURGERY

Removal of part of the skull (craniotomy) or spinal column (laminectomy) to gain access to the brain or spine. After opening the dura mater, the surgeon removes the tumor (most cases using a microsurgery technique). After tumor removal, meticulous hemostasis is required. Once hemostasis has been achieved, the bone is put back in place and is frequently held in place with a metal plate. However, method of fixation is surgeon-dependent and varies from sutures and small plates with screw fixation to larger plates (in the case of trauma) and bone replacement material.

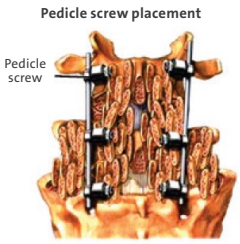
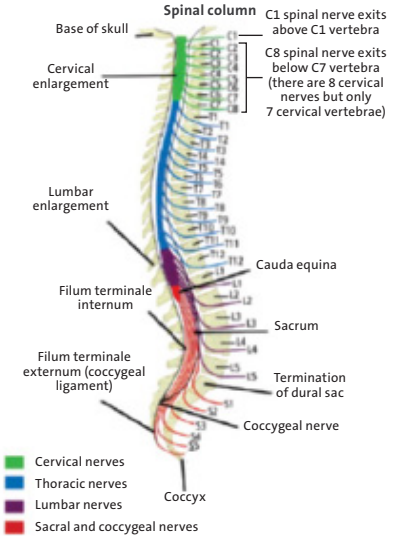


ILLUSTRATION: A.D.A.M.

DISK SURGERY

Degeneration of the bones of the spine or the intervertebral disks can cause compression of the spinal nerves. Surgery typically involves removal of portions of bones of the spine and the disks and fusion of vertebrae.



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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.

Potential bleeding sites:

- Epidural and venous plexus oozing
- Cut bone surface bleeding
- Paravertebral musculature
- Intervertebral and facet-decorticated surfaces
- Autograft donor sites
- Hardware replacement sites

*Indication may vary by country outside of Europe.

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CHALLENGES

- Wet, pooling bleeding
- Blood loss from anticoagulated patients and patients with acquired postoperative coagulopathies
- Patients with osteoporosis
- Cauterization around nerves

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.