BLEEDING AND HEMOSTASIS
“SURGEON IN THE MIDDLE”
Understanding Hemostatic, Sealant and Adhesive Agents

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Yavapai Regional Medical Center
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DISCLOSURES

• None
LEARNING OBJECTIVES

• Review the surgical challenges and patient factors which impact the risk of bleeding.
• Recognize the elements of a comprehensive Patient Blood Management program as they apply to the surgical patient.
• Explain mechanisms of action, components, and safety considerations for hemostatic, sealant, and adhesive agents, both passive and active.
• Describe those agents acceptable for patients with cultural or religious beliefs.

“SURGEON IN THE MIDDLE”
• Screen for anemia
• Identify underlying disorder(s) causing anemia
• Manage underlying disorder(s)
• Refer for further evaluation if necessary
• Treat iron deficiency, anemia of chronic disease, iron-restricted erythropoiesis
• Note: anemia is a contraindication for elective surgery

• Meticulous hemostasis and surgical techniques
• Blood-sparing surgical techniques
• Anesthetic blood conserving strategies
• Autologous blood options
• Pharmacological/haemostatic agents

• Vigilant monitoring and management of post-operative bleeding
• Avoid secondary hemorrhage
• Rapid warming - maintain normothermia (unless hypothermia specifically indicated)
• Autologous blood salvage
• Minimizing iatrogenic blood loss
• Hemostasis/anticoagulation management
• Prophylaxis of upper GI hemorrhage
• Avoid/treat infections promptly
• Be aware of adverse effects of medications

• Assess/optimize patient’s physiological reserve and risk factors
• Compare estimated blood loss with patient-specific tolerable blood loss
• Formulate patient-specific management plan using appropriate blood conservation modalities to minimize blood loss, optimize red cell mass and manage anemia
• Restrictive, evidence-based transfusion strategies

• Optimize cardiac output
• Optimize ventilation and oxygenation
• Restrictive, evidence-based transfusion strategies

• Optimise tolerance of anaemia
• Treat anaemia
• Maximize oxygen delivery
• Minimize oxygen consumption
• Avoid/treat infections promptly
• Restrictive, evidence-based transfusion strategies

Optimize hemopoiesis
Minimize blood loss & bleeding
Harness & optimize tolerance of anemia
CHALLENGES AND COMPLICATIONS – SURGICAL BLEEDING

BLEEDING CHALLENGES
- Suture line bleeding
- Diffuse soft tissue
- Bone bleeding
- Non-cauterizable sites
- Management of coagulation
- Friable tissue

COMPLICATIONS
- Infection
- Transfusion-related reactions
- Occult bleeding
- Prolonged procedures
- Postoperative coagulopathy

RISK FACTORS FOR PERIOPERATIVE BLEEDING

Patient-related
- Age, nutritional status
- Comorbidities
  - Diabetic, smoker, liver dysfunction, sepsis, acquired or congenital coagulation disorders, multiorgan failure
- Medications
  - Antiplatelet, anticoagulant, thrombolytic, steroids, NSAIDs, antidepressants, OTC supplements, etc.
- Adhesions from prior surgery
- Cultural & religious beliefs
- Allergies

Surgical Considerations
- Surgical approach
- Surgical position
- Surgical procedure
- Type of bleeding
- VIBe Surgical Bleeding Grade expected
- Cell salvage
- Hemostasis plan -
  - Mechanical
  - Thermal
  - Pharmacologic
  - Antifibrinolytic
  - Passive or active hemostatic products
  - Sealants
**Dietary Supplements that Can Increase Bleeding Risk:**

- Arnica
- Chondroitin
- Bilberry
- Capsaicin
- Cat's Claw
- Danshen
- Evening Primrose Oil
- Ginkgo Biloba
- Kava
- Ma-Huang - ephedra
- Omega-3 fatty acids
- St. John's Wort

"Turmeric" - It is an extremely potent antioxidant which intensely reduces levels of fibrinogen in the blood.

- Feverfew
- Bromelain
- Turmeric
- Ginger
- Ginseng
- Cayenne peppers
- Vitamin E
- Garlic
- Cassia Cinnamon
- Grape seed extract
- Green Tea
- Guarana

**How Does Bleeding Stop? Understanding the Coagulation Mechanism of Action**

*Two phases:* Primary and Secondary Hemostasis Pathways

### Primary Hemostasis (Platelets)

- Aggregation & Adhesion
  - Clotting Factor VIII
  - von Willebrand Factor (vWF)
  - The primary hemostasis serves a quick platelet plug against the bleeding, minimizing blood loss.
  - Plugs the hole rather than occlude the vessel lumen.

### Secondary Hemostasis (Clotting Cascade)

- Formation of insoluble, cross-linked fibrin by activated clotting factors specifically Thrombin to form a fibrin clot.
- **Fibrin** stabilizes the primary platelet plug.
- Without the fibrin clot, the platelet plug will not be stable.
## METHODS TO ACHIEVE HEMOSTASIS

<table>
<thead>
<tr>
<th>Mechanical</th>
<th>Thermal</th>
<th>Pharmacologic</th>
<th>Hemostatic Sealants &amp; Adhesive Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digital pressure Packing Clamps Clamps Clips Sutures Bone wax Alkaline oxide copolymer (e.g. Ostene)</td>
<td>Hypothermia Harmonic scalpel Electrocautery Vessel sealants (e.g. Ligasure) Argon beam coagulator Radiofrequency (e.g. Aquamantys Laser)</td>
<td>Hypotensive anesthesia Vasocostrictors Antifibrinolytics (e.g. Aminocaproic acid, TXA) Recombinant Factor VIIa Vitamin K Protamine PCCs Idarucizumab Andexanet alfa</td>
<td>Thrombin – Stand Alone Combination hemostatic agents Fibrin sealants Fibrin patches Synthetic sealants Glues/Adhesives</td>
</tr>
</tbody>
</table>

### MECHANICAL HEMOSTATIC AGENTS
**BONE WAX**

- Introduced to the field of surgery in 1892
- White Bleached Beeswax (cera alba 70%) & Paraffin (petroleum/vasoline based 30%)
- Mechanically stops bleeding on cut surface of cancellous bone through tamponade effect
- Non-absorbable remains at the site indefinitely and does not act biochemically
- Inhibits bone formation and interferes with bone healing
- Can lead to pseudoarthrosis, dehiscence, infection, and sternal erosion
- AATS 2016 - Class III recommendation against use of Bone Wax*

Bone wax is contraindicated where rapid osseous regeneration & fusion is desired


**OSTENE**

- Water-soluble biocompatible polymer wax
  - Resorbable – 48 Hours
  - Alkylene Oxide Copolymer (AOC)
- Mimics hemostatic properties of bone wax
  - Less risk of infection/impaired bone healing
  - Creates physical barrier to bleeding
  - Polymers are eliminated from body through the renal system
PASSIVE HEMOSTATIC AGENTS

Passive products achieve hemostasis by using a patients’ own circulating coagulation factors, therefore, are effective for patients with an intact coagulation system.
PASSIVE ABSORBABLE HEMOSTATIC AGENTS

- No intrinsic hemostatic action
- Requires intact Coagulation Cascade
- Provide mechanical hemostasis
  - Provide a 3D scaffolding
  - Platelet activation – adhere & aggregate
- Can leave in place, but IFUs usually do not recommend
  - If not removed can take weeks to months to be reabsorbed depending on amount used
- Swell factor varies with products 2X - 40X original size

Indicated Bleeding Type:
- Control of capillary, minor venous, or arteriolar bleeding
- Most useful for minor bleeding, general oozing

PASSIVE HEMOSTATIC PRODUCT OPTIONS FOR NON-COAGULOPATHIC PATIENTS

<table>
<thead>
<tr>
<th>Passive Hemostatic Agents</th>
<th>MECHANICAL AGENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gelatin</td>
<td>GELFOAM SPONGE &amp; POWDER</td>
</tr>
<tr>
<td></td>
<td>SURGIFOAM SPONGE &amp; POWDER</td>
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<tr>
<td>Collagen</td>
<td>AVITENE</td>
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<tr>
<td></td>
<td>INSTAT</td>
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<tr>
<td>Oxidized cellulose</td>
<td>SURGICEL ORIGINAL, SURGICEL NU KNIT, SURGICEL FIBRILLAR, SURGICEL POWDER, SURGICEL SNOW</td>
</tr>
<tr>
<td>Polysaccharide spheres</td>
<td>ARISTA</td>
</tr>
</tbody>
</table>
ACTIVE HEMOSTATIC AGENTS

Active agents can achieve hemostasis over a broad range of bleeding grades. An active hemostat is an agent that functions independently of the patient’s ability to generate clotting factors (principally **THROMBIN**) to achieve hemostasis and facilitate tissue healing. The function of the **THROMBIN** component is to be resistant to coagulopathies secondary to clotting factor deficiencies or anticoagulant medications.

Active products cease bleeding regardless of the coagulation status of the patient, and can be used in patients with intact or impaired coagulation.
ACTIVE -THROMBIN-BASED HEMOSTATIC AGENTS

Thrombin

- Bovine (1940's) – JMI Thrombin
- Plasma-derived human (2007) - Evithrom
- Recombinant human (2008) - Recothrom

Biologically active topical hemostatic agent;

Converts fibrinogen → fibrin

- Not affected by antiplatelet or anticoagulant medications
- Not actually indicated for Hemostasis
- May be combined with gelatin or collagen products: Not Surgicel products
- Not for arterial bleeding; Not effective in DIC or Hemophilic patients due to the low fibrinogen levels
- Urine does not inhibit thrombin or thrombin/fibrinogen products
- Speed of clot formation is dependent on thrombin concentration
  - 1,000U/ml – will clot blood in 1 sec

Indicated Bleeding Type:

- aid to hemostasis for low level oozing & minor capillary bleeding

COMBINATION ABSORBABLE ACTIVE HEMOSTATIC AGENTS
COMBINATION ABSORBABLE HEMOSTATIC AGENTS

Mechanism of Action

• Gelatin - Passive
  • Contact activation

• Collagen - Passive
  • Contact activation
  • Platelet aggregation

• Thrombin - Active
  • Converts fibrinogen to fibrin
  • Thrombin amount impacts speed of fibrinogen-fibrin conversion; resulting in a much shorter clotting time

FIBRIN SEALANTS
FIBRIN SEALANTS

Mechanism of Action

• Mimics final stages of the coagulation cascade
• Work independent of the clotting cascade
• High Fibrinogen levels – increased clot strength, adherence & elasticity
• Higher Thrombin levels then blood
• Stronger clots than natural clots
• “Clot in a Box” – Thrombin & Fibrinogen

FIBRIN SEALANTS

Human Thrombin & Fibrinogen

TISSEEL
- Human Fibrinogen 67-106mg/mL
- Human Thrombin 400-625 IU/mL
- Aprotinin (synthetic) - clot stabilizer, stays intact 10-14 days

VISTASEAL
- Human Fibrinogen ~80mg/mL
- Human Thrombin ~500 IU/mL

EVICEL
- Biologic Active Component 2 (BAC2) – w/ 55-85mg/mL human fibrinogen
- Human Thrombin 800-1200 IU/mL
FIBRIN SEALANT PATCHES

Comprised of
• Collagen or cellulose base
• Human thrombin
• Human fibrinogen

Mechanism of Action
• Clot adheres the patch to the wound creating a physical barrier to bleeding
FIBRIN SEALANT PATCHES

**Collagen w/ Human Thrombin & Fibrinogen**

- **TACHOSIL**
  - Equine (HORSE) Collagen
  - Human Thrombin
    - 35.5 mg per square inch
  - Human Fibrinogen
    - 2.9 Units per square inch

**Cellulose w/ Human Thrombin & Fibrinogen**

- **EVARREST**
  - Oxidized regenerated cellulose (SURGICEL)
  - Underlying layer of polyglyactin 910 (VICRYL)
  - Human Thrombin
    - 241.9 Units per square inch
  - Human Fibrinogen
    - 55.5 mg per square inch

ACTIVE HEMOSTATIC PRODUCT OPTIONS FOR COAGULOPATHIC PATIENTS

<table>
<thead>
<tr>
<th>Active Hemostatic Agents</th>
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<tbody>
<tr>
<td><strong>THROMBIN</strong></td>
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<tr>
<td>Bovine</td>
<td>THROMBIN JMI</td>
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<tr>
<td>Human plasma-derived</td>
<td>EVITHROM</td>
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<tr>
<td>Human recombinant</td>
<td>RECO THROM</td>
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<tr>
<td><strong>THROMBIN + MECHANICAL AGENT</strong></td>
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<tr>
<td>Flowable Agents</td>
<td>FLOSEAL</td>
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<td></td>
<td>SURGIFLO</td>
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<td>Slurry of GELFOAM or SURGIFLO powder + thrombin</td>
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<tr>
<td><strong>FIBRIN SEALANT - THROMBIN + FIBRINOGEN “CLOT IN A BOX”</strong></td>
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</tr>
<tr>
<td>Liquid and powder</td>
<td>TISSEEL</td>
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<td></td>
<td>EVICEL</td>
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<tr>
<td></td>
<td>VISTASEAL</td>
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<tr>
<td>Patches</td>
<td>TACHOSIL</td>
</tr>
<tr>
<td></td>
<td>EVARREST</td>
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</table>
SURGICAL SEALANTS & SURGICAL ADHESIVES

Function independently of the coagulation cascade

**Mechanism of Action**

**Synthetic +/- and Human Serum Albumin, Glutaraldehyde/Bovine Serum Albumin**
- Creates a mechanical barrier

**Fibrin Sealant**
- Mimics the final stages of the coagulation cascade
SURGICAL SEALANTS

COSEAL
- 2 synthetic Polyethylene Glycols (PEGs)

PREVELEAK
- Bovine (BEEF) serum albumin (BSA), chitosan (SHELL FISH) chloride, polyaldehyde sodium, sodium hyaluronate, and carboxymethylcellulose

TRIDYNE
- Human Serum Albumin (HSA)
- Polyethylene Glycol (PEG)

PROGEL
- Human Serum Albumin (HSA)
- Polyethylene Glycol (PEG)

DURASEAL
- PEG ester solution
- Trilysine amine solution

BIOGLUE (black box warning)
- 10% Glutaraldehyde
- 45% Bovine (BEEF) Serum Albumin (BSA)

Fig 1. Classification of topical hemostatic agents.

- Thrombin
  - Bovine-derived
  - Human plasma-derived thrombin with porcine gelatin sponge
  - Recombinant thrombin

- Thrombin plus Mechanical Hemostatic Agents (Hemostatic Agents): Gelatin combined with thrombin in a liquid form

- Fibrin Sealants
  - Human plasma-derived
  - Human pooled plasma and porcine collagen

- Synthetic Sealants
  - Bovine serum albumin with glycerol
  - Polyethylene glycol
  - Cyanoacrylate

- Mechanical Hemostatic Agents
  - Collagen
  - Porcine gelatin
  - Oxidized cellulose
  - Polyelectrolyte spheres

Non-active Hemostatic Agents

Shander et al ACS 2014
BE AWARE OF PATIENT ALLERGIES AND PRODUCT COMPONENTS!

<table>
<thead>
<tr>
<th>PORK</th>
<th>BEEF</th>
<th>HORSE</th>
<th>SHELL FISH</th>
<th>HAMSTERS</th>
<th>HUMAN BLOOD PRODUCTS</th>
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<tr>
<td>Gelfoam</td>
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<td>Preveleak</td>
<td>Recothrom</td>
<td>Hemoblast</td>
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<td>Surgifoam</td>
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<td>SurgiFlo</td>
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<td>Hemoblast</td>
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<td>JMI Thrombin</td>
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<td>Evarrest</td>
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<td>Progel</td>
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<td>Vistaseal</td>
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</tbody>
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Siebert T. Avoiding anaphylactic reactions when using absorbable hemostatic agents and surgical sealants to prevent intraoperative bleeding during surgery for improved patient safety; Abstract presented SABM Congress Sept 2019

JEHOVAH’S WITNESS PATIENT

HEMOSTATIC AGENTS CONTAINING BLOOD FRACTIONS ARE GENERALLY ACCEPTABLE. EACH JW PATIENT IS TO MAKE THEIR OWN DECISION TO ALLOW BLOOD FRACTIONS TO BE USED DURING SURGERY.

**Hemostatic & Sealant agents that contain blood fractions:**

- PRP – Plasma & human thrombin & human fibrinogen
- JMI - bovine thrombin
- Evithrom - human thrombin
- Surgiflo Kit with Evithrom - human thrombin
- Floseal with human thrombin
- Hemoblast powder – human thrombin
- Tisseel – human thrombin & human fibrinogen
- Evicel – human thrombin & human fibrinogen
- Evarrest – human thrombin & human fibrinogen
- Vistaseal – human thrombin & human fibrinogen
- Artiss – human thrombin & human fibrinogen
GENERAL CONSIDERATIONS

PLEASE READ PRODUCT INSERTS FOR COMPLETE INDICATIONS, SAFETY DETAILS, WARNINGS, CONTRAINDICATIONS, ETC.

• Know that swell factor varies by product
• Do not inject or place into blood vessels
• What type of bleeding scenario indication
• DO NOT ASPIRATE DIRECTLY INTO CELL SAVER DEVICES
• Passive agents require intact coagulation status
• Active agents can be used with intact and impaired coagulation status

• Thrombin & Fibrinogen Products - DOES NOT NEED TO BE TRACKED AS BLOOD, TISSUE or IMPLANT – per TJC & FDA 21 CFR 821, 1270 & 1271
“Local hemostatic agents are dissimilar products with different indications. A knowledge of the properties of each single agent should be in the armamentarium of surgeons in order to select the appropriate product in different clinical situations.”

A Systemic Review of the Use of Topical Hemostats in Trauma and Emergency Surgery
Chiara et al BMC Surgery (2018) 18:68

DUH...

“Hemostats, irrespective of their nature, are not intended as a substitute for a sound surgical technique and proper application of ligatures or other conventional procedures for hemostasis.”
SABM CLINICAL RESEARCH INITIATIVES

The Use of Topical Hemostatic Agents in Cardiothoracic Surgery

Art Bracey, MD, Aryeh Shander, MD, FCCM, Solomon Aronson, MD, FACC, Bradley A. Boucher, PharmD, FCCM, Domenico Calcaterra, MD, PhD, Michael W. A. Chu, MD, FRCSC, Richard Culbertson, PhD, Karim Jabr, CCP, Henrik Kablet, MD, PhD, Omar Lattouf, MD, S. Chris Malaise, MD, C. David Mazer, MD, Martin M. Oberhoffer, MD, Sherri Ozawa, RN, Theodyn Price, MD, Todd Rosengart, MD, FACS, Bruce D. Spiess, MD, FAHA, and Giuseppe Turchetti, PhD

(Ann Thorac Surg 2017;e[e–e])
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Topical Hemostatic Therapy in Surgery: Bridging the Knowledge and Practice Gap

Aryeh Shander, MD, FCCM, FACC, Lewis J Kaplan, MD, FACS, FCCM, FACP, Michael T Harris, MD, Irwin Gross, MD, Nimesh P Naganeth, MD, Jeffrey Nemeth, BSSH, PharmD, MPA, Sherri Ozawa, RN, Jeffrey B Riley, MHPE, CCP, Maria Ashton, MS, RPh, MBA, Victor A Ferraris, MD, PhD

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FOR MORE INFORMATION, GO TO: SABM.ORG
THANK YOU FOR PARTICIPATING

SUPPLEMENTARY SLIDES
# Passive Absorbable Hemostatic Agents

## Gelatin Based
- **Gelfoam, Surgifoam**
  - Porcine Gelatin (Pork Skin) derived
  - Induce hemostasis through physical properties alone
  - Absorbs up to 40x weight
  - Expands up to 200% of initial size

## Collagen Based
- **Avitene**
  - Bovine collagen (Beef Tendon) derived
  - Flour, sheets, or sponges
  - Significantly reduces the bond strength of methyl methacrylate
  - Use dry, wetting impairs hemostatic efficacy;
  - Absorb 12X weight

## Plant Based
- **Arista**
  - Microporous polysaccharide spheres (Plant-based)
  - Potato starch
  - Dehydrates & Desiccates fluid from blood; gels and concentrates blood proteins & platelets
  - Resorbed in 24-48 hours
  - Use dry
  - Particles swell 500%
  - Do not use for neurologic or ophthalmologic procedures
  - >50Gm elevate Glucose levels

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## Table: Hemostatic Agents

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>HEMOSTATIC AGENTS</th>
<th>SEALANTS</th>
<th>ADHESIVE</th>
</tr>
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<tbody>
<tr>
<td>TYPE</td>
<td>STAND-ALONE</td>
<td>THROMBIN</td>
<td>COMBINATION</td>
</tr>
</tbody>
</table>
| USE      | Capillary | Minor venous Arteriolar | Capillary | Minor venous Arteriolar | Not major arterial or venous | Prevent blood, CSF or air leak | Prevent leakage of local matter | Adhere subcutaneous skin grafts/or surgery
| COMPONENTS | Cellulose | Polysaccharide | Gelatin | Collagen | Bovine Human Recombinant | Gelatin/collagen + thrombin, Recombinant | Collagen or cellulose/ polygalactin 910, + human thrombin/ fibrinogen | PEG +/- HSA Glutaraldehyde + BSA | Fibrinogen + thrombin + fibrinolysis inhibitor |
| MOA | Contact Activation | Platelet Aggregation | Fibrinogen converted to fibrin | Collagen or cellulose/ polygalactin 910, + human thrombin/ fibrinogen | Monics final stages of coag. Cascade Clot in a Box | Clot adheres patch to the wound creating a physical barrier | Create a mechanical barrier | Monics final stages of coag. Cascade Clot in a Box |
| COAG. STATUS | Intact | Intact or Compromised | Intact or Compromised | Independent of coag. cascade | Independent of coag. cascade | Independent of coag. cascade |
| FIELD CONDITION | Wet | Wet | Wet | Dry | Dry | Dry | Dry | Dry |
| ACTIVE/PASSIVE | Passive | Active | Active | Active | Independent | Independent | Independent | Independent | N/A |
| EXAMPLES | SURGICEL FLOSEAL NT ARISTA AH GELFOAM GEL-FLOW NT SURGIFOAM SURGIFLO AVITENE | THROMBIN-JMI EVITHROM RECOITHROM | GELFOAM w/THROMBIN FLOSEAL SURGIFOAM w/THROMBIN HEMOBLAST BELLows | TISSUESE EVICEL VISTASEAL | TACHISEL EVAREST | COSEAL PREVELEAK BROSQUE DURASEAL PROGEL TISSEAL | ARTISS |
WHAT HEMOSTATIC & SEALANT AGENTS CAN BE USED WITHIN THE JW GUIDELINES

- Bonewax
- Ostene
- Hemospray
- Quikclot
- Surgicel products
- Surgicel powder
- NuKnit
- Fibrillar
- Gelfoam Sponge
- Gelfoam Powder
- Surgifoam Sponge
- Surgifoam Powder
- Floseal NT
- Gel-Flow NT

- Recothrom*
- Arista
- Avitene Products
- UltraFoam
- Coseal
- Preveleck
- BioGlue
- Duraseal
- Progel
- Tridyne
- Tranexamic Acid
- Amicar
- Dermabond

*Recothrom is recombinant and considered synthetic

SURGICAL ADHESIVE

ARTISS

- Human Fibrinogen 67-106 mg/mL
- Human Thrombin 5 IU/mL
- Aprotinin (synthetic)

*Only FDA approved/indicated Tissue Adhesive

- NOT a hemostatic product
- Indicated as “tissue glue” - attaching burn skin grafts and adhering face lift (plastic surgery) tissue planes