• Peter Rhee MD, MPH
my opinion...
Not a New Problem

Roller Bandage From the Trojan War
#1 Cause of Preventable Death After Injury
Coagulopathy
Acidosis
Hypothermia
DR. RHEE'S
TRAUMA SUPPLIES

FOR ANY ATV
CRASHES
Please Faxes/Calls:
Dr. Terence O'Keefe - 9364
Cell (520) 275 - 8464
or
Sue Hammash - (928) 481 - 1397
During the hours of 6am to 10pm
Active Hemostatics

- ACS+
- InstaClot
- Woundstat
- CELOX
- X-Sponge
- BloodSTOP
- Alpha Bandage
- HemCon
- Chitoflex
- FP-21
types

- Dressings
- Glues
- Flowables
- Powders
- Granules
- Active
- Passive
AccessClosure, Inc.; Alltracel; Pharmaceuticals plc;
Angiotech; Baxter International;
Biomet; C.R. Bard, Inc.; Covidien; Cryolife, Inc.
CSL Ltd./CSL; Behring; Gelita AG; Genzyme;
Haemacure Corporation; HyperBranch Medical Technology;
Johnson & Johnson/Ethicon;
King Pharmaceuticals; Neomed, Inc.; Nycomed
International Mgmt GmbH; Ormrix Biopharmaceuticals Inc.; Orthovita; Pfizer; Pharming Group N.V.; St. Jude Medical;
Synovis Life Technologies, Inc.;
ThermoGenesis Corporation; Tissuemed Ltd.; Vascular Solutions Inc.; Vivostat A/S; Z-Medica Corporation; Zymogenetics, Inc.
Categories

Dressing
- Passive
- Active

Granular
- Active

Flowable (active)
- Liquid
- Powder

Polysaccharide spheres

Arista™ (Medafor)
gelatin / cellulose / collagen

- **Gelfoam (Surgifoam)**
  - Purified pork skin gelatin
  - Jello®

- **Surgicel (Oxycel)**
  - Oxidized cellulose

- **Avitene**
  - Collagen from bovine skin
Passive Dressings

Porcine gelatin
- Gelfoam® (Pfizer, Pharmacia)
- Surgifoam® (Ethicon, J&J)

Cellulose
- Avitene Sheets® (non-woven web) (Davol)
- Ultrafoam™ Collagen Sponge (Davol)
- Surgicel® (J&J)
- Surgicel Nu-Knit™ (J&J)

Bovine collagen
- Surgicel® (J&J)
• Spongostan powder
• Surgicel
• Nu-knit
• Surgifoam
Active Dressings
• Gelfoam Plus
  – Human thrombin
• Tachosil
  – Equine
  – Collagen sponge
  – Human fibrinogen
  – Human thrombin
• Aorta
• Spleen
• Liver
Treatment of a Large Corneal Perforation With a Multilayer of Amniotic Membrane and TachoSil.

TachoSil surgical patch versus conventional haemostatic fleece material for control of bleeding in cardiovascular surgery: a randomised controlled trial.

TachoSil, n=59; standard treatment, n=60
• aorta (56%), right ventricle (16%) or right atrium (13%), more often from a vessel (68%) than tissue (32%), and was assessed to be arterial in 74% of cases. TachoSil was significantly superior to standard haemostatic fleece in controlling bleeding after insufficient primary haemostasis
• Throacic
• Suture
• dura
Hydrogel

- Ophthalmic – OcuSeal™
- Dural - Adherus ™
- Hernia - Adherus ™
- Spinal
- Cardiovascular
Flowables (active)

liquids

Powder

Polysaccharide spheres

Arista™
(Medafor)
Flowable sealants

- Synthetic agents (Cyanoacrylates)
- Collagen-Based
- Fibrin sealants
• BioGlue
  – 20 – 30 seconds
  – 2,5,10 cc
  – Bovine serum albumin
  – Glutaraldehyde
  – CE Mark Approval
    • Cardiac
    • Vascular
    • Pulmonary
    • Genitourinary
    • Dural
    • Gut
    • Pancrease
    • Spleen
    • Liver
    • biliary
BioFoam

- Mechanical Barrier
• BioGlue
• CryoLife-O’Brien
• Stentless Porcine Aortic Bioprosthesis
• ProPatch Soft Tissue Repair Matrix
• Hemostase MPH
• CardioWrap
Collagen-based

- FocalSeal-L (Genzyme Biosurgery)
- CoSeal (Cohesion Technologies)
- FloSeal
- Prodeed
- Costasis
• Adept
• Tisseel
  – Fibrin sealant
  – Cardiovascular
  – Spleen
• Coseal
  – Vascular
  – No refrig
  – Sells up to 4 times
  – Bovine + glutaldehyde
• Floseal
  – Bovine gelatin granules coated in
  – human derived thrombin
• Artiss
  – human Fibrin sealant
## Our prices

<table>
<thead>
<tr>
<th>Product</th>
<th>Volume</th>
<th>Price</th>
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<tbody>
<tr>
<td>TISSEEL</td>
<td>4 ml</td>
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<tr>
<td>TISSEEL</td>
<td>8 ml</td>
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</tr>
<tr>
<td>FLOSEAL</td>
<td>5 ml</td>
<td>$150.00</td>
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<tr>
<td>FLOSEAL</td>
<td>10ml</td>
<td>$275.00</td>
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<tr>
<td>COSEAL</td>
<td>2 ml</td>
<td>$316.00</td>
</tr>
<tr>
<td>COSEAL</td>
<td>4 ml</td>
<td>$509.00</td>
</tr>
<tr>
<td>COSEAL</td>
<td>8 ml</td>
<td>$788.00</td>
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</table>
Baxter BioSurgery Portfolio

Active Agents (Thrombin)

Synthetic Sealant

For Topical Use Only

- Evicel
  - Fibrin sealant
  - Frozen liquid
  - One minute prep time

- Evithrom Thrombin Topical (Human)
### COMPARISON OF TIME TO HEMOSTASIS - FIRST TREATED LESION

<table>
<thead>
<tr>
<th></th>
<th>HemoStase MPH</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (n) (min, max)</td>
<td>Median (n) (min, max)</td>
</tr>
<tr>
<td><strong>Median Time to Hemostasis (minutes)</strong></td>
<td>1.0 (144) (1.0, 56.8)</td>
<td>2.0 (143) (1.0, 19.2)</td>
</tr>
<tr>
<td><strong>General</strong></td>
<td>2.0 (72) (1.0, 19.5)</td>
<td>2.0 (72) (1.0, 15.0)</td>
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<tr>
<td><strong>Cardiac</strong></td>
<td>2.0 (38) (1.0, 56.8)</td>
<td>3.5 (34) (1.0, 19.2)</td>
</tr>
<tr>
<td><strong>Orthopedic</strong></td>
<td>1.0 (34) (1.0, 6.2)</td>
<td>2.0 (37) (1.0, 7.0)</td>
</tr>
</tbody>
</table>

BioGlue® Surgical Adhesive
• Freeze dried PEG
QuikClot Use in Trauma for Hemorrhage Control: Case Series of 103 Documented Uses

Peter Rhee, MD, MPH, Carlos Brown, MD, Matthew Martin, MD, Ali Salim, MD, Dave Plurad, MD, Donald Green, MD, Lowell Chambers, MD, Demetrios Demetriades, MD, PhD, George Velmahos, MD, and Hassan Alam, MD
- Bagged
- Cold formulation
What is Chitosan?
Neomend

- Hydrogel
- Human serum Albumin
- Plus PEG
Cochrane

- 16 randomized controlled trails
- 1,642 patients
- 6 trails – significant reduction in air leaks
- 3 trails – significant reduction in chest tube days.
- 3 trails – significant reduction in LOS
- Cannot recommend sealants as it did not reduce LOS
Prospective, randomized, controlled clinical trial of a novel matrix hemostatic sealant in children undergoing adenoidectomy.


Fibrin sealant reduces the duration and amount of fluid drainage after axillary dissection: a randomized prospective clinical trial.

Fibrin sealants

• Laparoscopic hernia repair
• Sealant vs tacs
• Less pain
• More seroma


TCCC

• Tactical Combat Casualty Care
  – Care under fire
  – Tactical Care
  – Care while evacuation
CO  TCCC

• Care under fire
  – tourniquet
• Tactical field care
  – Pressure dressing
  – Combat Gauze
  – Celox Dressing
Care Under Fire

6) Stop *life threatening* external hemorrhage:
   - Self aid if able
   - Tourniquet
U.S. Army
One-Handed
Tourniquet
Example of a Wound That DOES NOT Need a Tourniquet
The Hartford Consensus III: Implementation of Bleeding Control

If you SEE something

DO something

by Lenworth M. Jacobs, Jr., MD, MPH, FACS,

and the Joint Committee to Create a National Policy to Enhance Survivability from Intentional Mass-Casualty and Active Shooter Events
Hartford Consensus III participants. Seated, left to right: Drs. McSwain, Warshaw, Jacobs, Woodson, Brinsfield, and Levy; and Mr. Elliott. Standing left to right: Dr. Rhee, Mr. Mitchell, Drs. Eastman, Conn, O’Connor, Stewart, Butler, Burns, Weireter, Hunt, Holcomb, and Fabbri; and Commander Anderson.
One-handed tourniquet application
HARTFORD CONSENSUS III

Immediate responder hemorrhage control
THREAT

- Treat suppression
- Hemorrhage Control
- Rapid Extrication to safety
- Assessment by medical providers
- Transport to definitive care
Kit

- Gloves
- Guaze
- Hemostatic agents
- Torniquet
Let's try something new!
Randomized clinical trial of fibrin sealant versus titanium tacks for mesh fixation in laparoscopic umbilical hernia repair.


- 38 patients in Denmark
- FS for mesh caused less pain
- No recurrences in one month – yea


- No difference between sealant and control
- 104 patients


- 760 patients
- Less leak

- 14 patients and 24 control
- Saves time


- Anesthesia mixed with sealant
- 60 patients (20 in three groups)
- Less pain

- 115 patients (58 control, 57 collagen sponge)
- Less drain output
- Less transfusions
- Less complications
- Shorter hospital LOS

- 23 patients vs 47 in control group
- Shorter fistula time

Risk factors for postoperative pancreatic fistula in distal pancreatectomy.


• The use of polyethylene glycolic acid felt (PGA) with fibrin sealant and blood loss during operation were the significant factors for severe POPF
Polyethylene Glycol Hydrogel Spinal Sealant (DuraSeal Spinal Sealant) as an Adjunct to Sutured Dural Repair in the Spine: Results of a Prospective, Multicenter, Randomized Controlled Study.

• Data does not support the use of sealant in breast surgery


• Reduced drain output
**CELX™**
Controls life-threatening bleeding fast.

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**Features & Benefits**

**Effective**
- Saves lives by stopping bleeding within minutes.
- Works in hypothermic conditions.
- Works on heparinized blood.

**Safe**
- No heat – No burning.
- Sterile, waterproof packaging.
- No special storage requirements.

**Easy to Use**
- Single-dose and easy-open packaging.
- Easily self-administered.
- Easy to remove from wound.

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FDA Approved
Celox Granules

- Chitosan formulation
- Chemical/mechanical linkage of RBCs
- Independent of clotting factors
- Easy storage/transport
Fibrin sealant (evicel® [quixil®/crosseal™]): a review of its use as supportive treatment for haemostasis in surgery.

Dhillon S.

Two pivotal, randomized studies showed that Evicel® was significantly more effective than manual compression in patients undergoing vascular surgery, and significantly more effective than Surgicel® in patients undergoing retroperitoneal or intra-abdominal surgery, as assessed by the proportion of patients achieving haemostasis. In another similarly designed pivotal study in patients undergoing liver resection, Crosseal™ was significantly more effective than standard haemostatic agents (e.g. Surgicel®), as assessed by the mean time to haemostasis. The incidences of treatment-emergent adverse events in these studies were generally similar between the Evicel® or Crosseal™ groups and the comparator groups. Quixil® was also generally well tolerated and an effective haemostatic agent in endonasal surgeries, and tonsillectomies and/or adenoidectomies, with some benefit of treatment with Evicel® or Quixil® also observed in orthopaedic surgeries.
Topical thrombins vary in the ways in which they are manufactured and their safety profiles, storage requirements, and costs. Human recombinant thrombin and human plasma-derived thrombin have each been shown to have hemostatic efficacy comparable to that of bovine thrombin. Bovine thrombin carries the risk of formation of cross-reactive antibodies to bovine thrombin, factor V, and other impurities that may be present in these formulations. Immunogenicity data for the currently marketed, highly purified bovine thrombin relative to older formulations of bovine thrombin could not be found. Whether the potential safety advantage justifies the added cost of the human products remains to be established.
Tissue Adhesive Glues

- Biogluce
- Focal Seal-L
- CoSeal
### Packing Agents and Absorbents

<table>
<thead>
<tr>
<th>Product</th>
<th>Made from</th>
</tr>
</thead>
<tbody>
<tr>
<td>• QuikClot</td>
<td>• Gauze</td>
</tr>
<tr>
<td>• HemCon</td>
<td>• Bovine collagen and cellulose</td>
</tr>
<tr>
<td>• Rapid Deployment Hemostatic Bandage</td>
<td>• Bone wax</td>
</tr>
<tr>
<td>• American Red Cross Hemostatic Bandage</td>
<td>• Gelatin</td>
</tr>
<tr>
<td></td>
<td>• Microfibrillar collagen</td>
</tr>
<tr>
<td></td>
<td>• Oxidized cellulose</td>
</tr>
</tbody>
</table>
Rapid Deployment Hemostat Bandage (Navy)

- Fermented algae product
- Polysaccharide
- Activated gel not dependent on coagulation system
- Gauze backing