REBOA

Todd E. Rasmussen, MD

Development & Implantation of REBOA within the Military Learning Health System

February 8th, 2018

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Associate Dean for Research
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Disclosures

- **Viewpoints are those of the presenter and are not official positions of the DoD or the US Government**

- **Co-inventor of REBOA & vascular shunt technologies, the patents for which are assigned to the US government and the University of Michigan**

- **No consulting, travel, advisory board, or speakers fees, and no stocks or other forms of equity in, or royalties from, any industry entity (past or present)**

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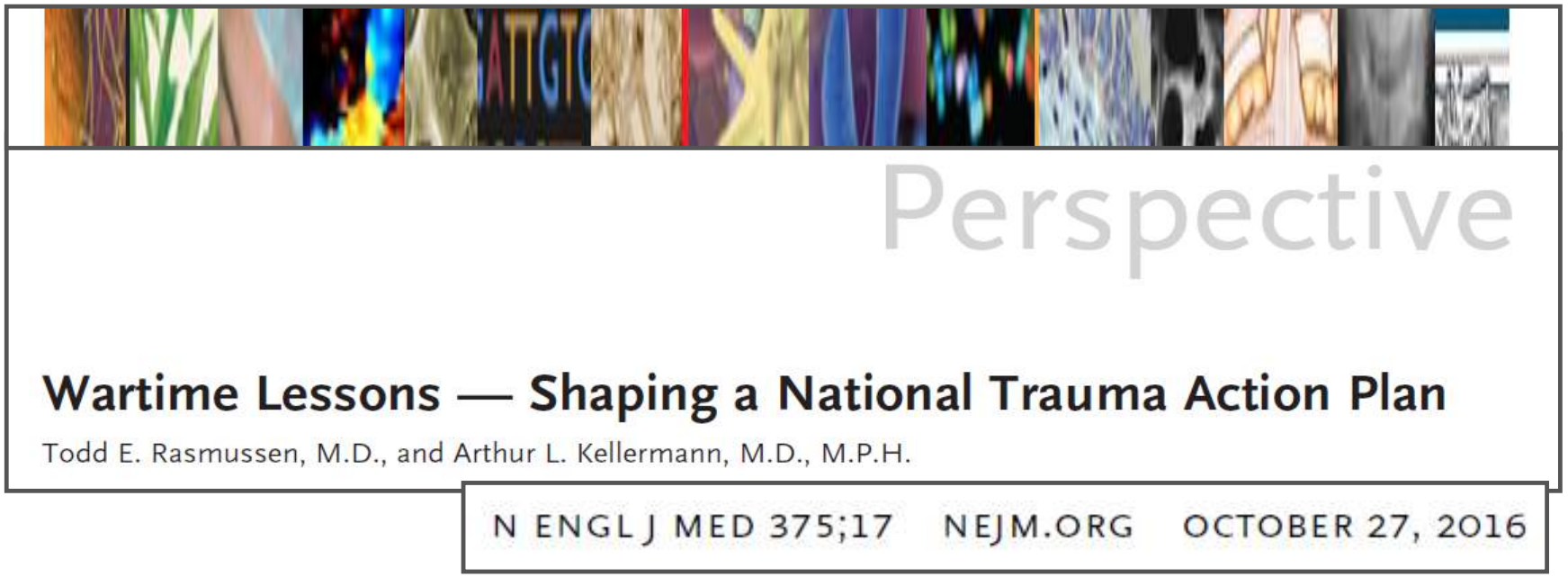
Military-Civilian Partnership to Tackle Challenge



- **In many ways Michigan TQIP and other statewide efforts to have a trauma system (data gathering, guideline-based delivery of care, coordination of care & common training and PI venues) represents a model for the nation as it considers a National Trauma System**

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Reset on REBOA Innovation Effort

CURRENT OPINION

Military-civilian partnership in device innovation: Development, commercialization and application of resuscitative endovascular balloon occlusion of the aorta

Todd E. Rasmussen, MD *and* **Jonathan L. Eliason, MD**, *Bethesda, Maryland*

***J Trauma & Acute Care Surg* 2017;83(4):729-32**

- **Eight factors contributing to origins, development and commercialization of REBOA and ER-REBOA™ catheter (enablers & barriers)**
- **Call for informed and balanced discussion and assessment of device utility (real-world use registries, PI venues, multi-center studies)**

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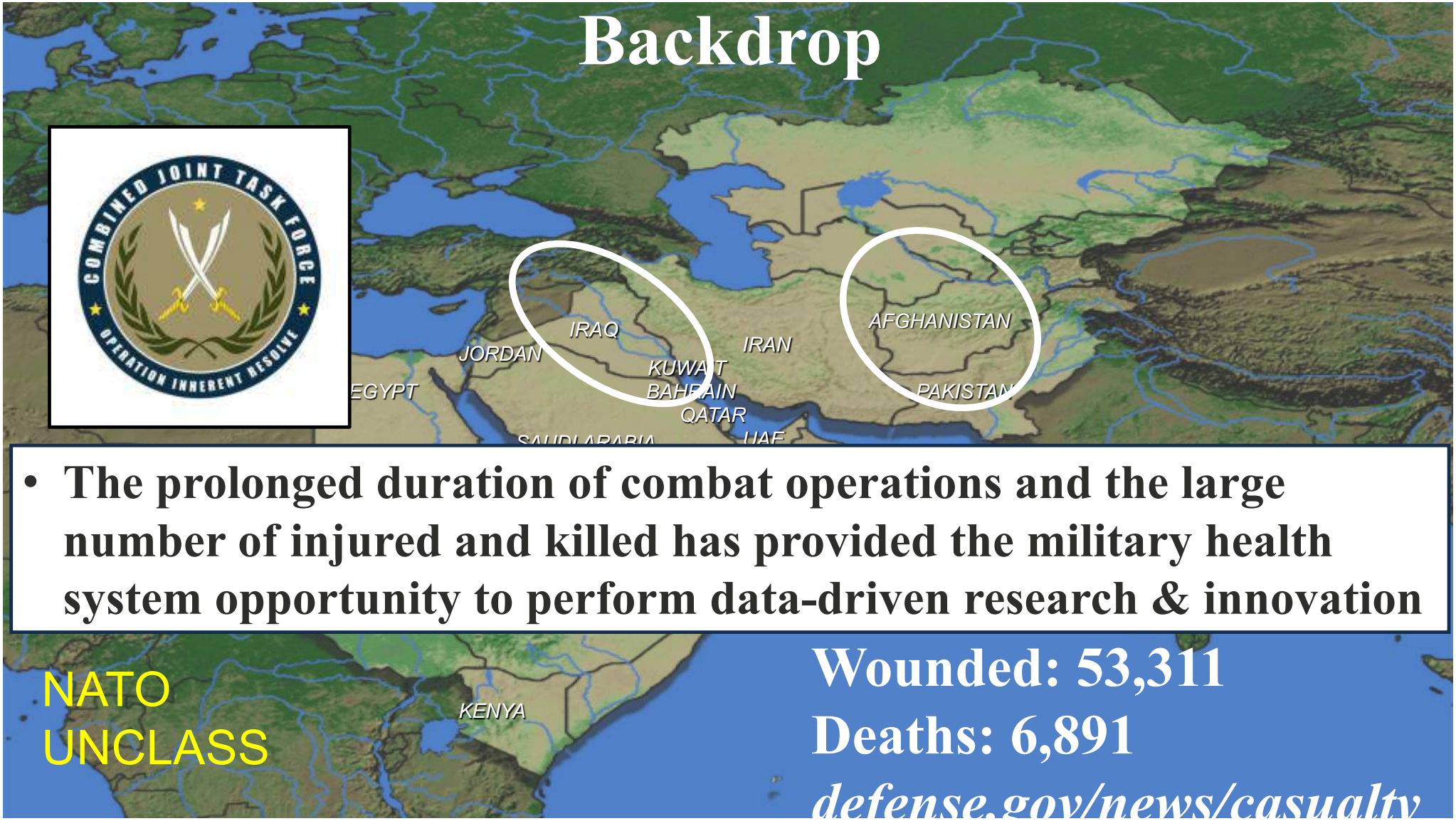
Backdrop



- **The prolonged duration of combat operations and the large number of injured and killed has provided the military health system opportunity to perform data-driven research & innovation**

NATO
UNCLASS

Wounded: 53,311
Deaths: 6,891
defense.gov/news/casualty

Wilford Hall USAF Medical Center

Fall of 2004

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Data Informing Research & Development

Causes of Death in U.S. Special Operations Forces in the Global War on Terrorism

2001–2004

John B. Holcomb, MD, Neil R. McMullin, MD,* Lisa Pearse, MD,† Jim Caruso, MD,†*
Charles E. Wade, PhD, Lynne Oetjen-Gerdes, MA,† Howard R. Champion, FRCS,‡*
Mimi Lawnick, RN, Warner Farr, MD,§ Sam Rodriguez, BS,§ and Frank K. Butler, MD‖*

***Annals of Surgery* 2007;245:986-91**

"…majority of deaths on battlefield are non-survivable. Improved methods of intracavitary, noncompressible hemostasis may increase survival.."

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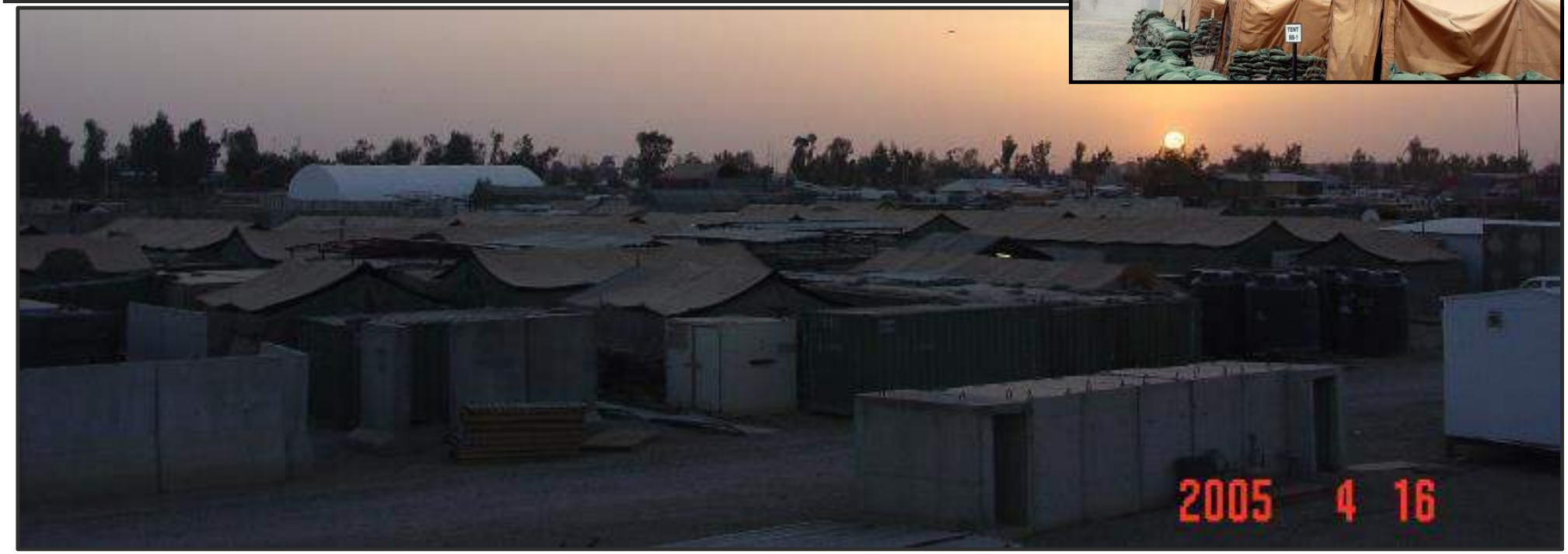
Teams of Military Clinicians & Innovators

Development and Implementation of Endovascular Capabilities in Wartime

Lt. Col. Todd E. Rasmussen, MD, Lt. Col. W. Darrin Clouse, MD, Maj. Michael A. Peck, MD, Lt. Col. Andrew N. Bowser, MD, Maj. Jonathan L. Eliason, MD, Maj. Mitchell W. Cox, MD, Maj. E. Baylor Woodward, MD, Lt. Col. W. Tracey Jones, MD, and Col. Donald H. Jenkins, MD



Development & Implementation of Endovascular

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Data Continued to Inform Research & Innovation

Injury Severity and Causes of Death From Operation Iraqi Freedom and Operation Enduring Freedom: 2003–2004 Versus 2006

Joseph F. Kelly, MD, Amber E. Ritenour, MD, Daniel F. McLaughlin, MD, Karen A. Bagg, MS, Amy N. Apodaca, MS, Craig T. Mallak, MD, Lisa Pearse, MD, Mary M. Lawnick, RN, BSN, Howard R. Champion, MD, Charles E. Wade, PhD, and COL John B. Holcomb, MC

***Journal of Trauma* 2008;64:S21-S27**

Extremity and compressible hemorrhage (axilla, neck, or groin) are two of the three types of hemorrhage evaluated. Controlling these types of hemorrhages is addressed by effective commercial tourniquets and topical hemostatic agents like the widely available hemostatic dressings.[4,24] Continued training and use with these products is warranted. The third type of hemorrhage, and the most challenging type in our study, was noncompressible or torso hemorrhage. There needs to be continued research and clinical practice focusing on intravenous hemostatic adjuncts and damage control resuscitation.[2]

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REBOA is a Data-Driven R&D Effort

ORIGINAL ARTICLE

Death on the battlefield (2001–2011): Implications for the future of combat casualty care

Brian J. Eastridge, MD, Robert L. Mabry, MD, Peter Seguin, MD, Joyce Cantrell, MD, Terrill Tops, MD, Paul Uribe, MD, Olga Mallett, Tamara Zubko, Lynne Oetjen-Gerdes, Todd E. Rasmussen, MD, Frank K. Butler, MD, Russell S. Kotwal, MD, John B. Holcomb, MD, Charles Wade, PhD, Howard Champion, MD, Mimi Lawnick, Leon Moores, MD, *and* Lorne H. Blackbourne, MD

J Trauma Acute Care Surg **2012;73(Suppl1):S431-S437**

- **Of 4,596 wartime casualties, 87% were pre-hospital; of those, 76% non-survivable but 24% (N=976) were potentially survivable - what would you have the military do??**

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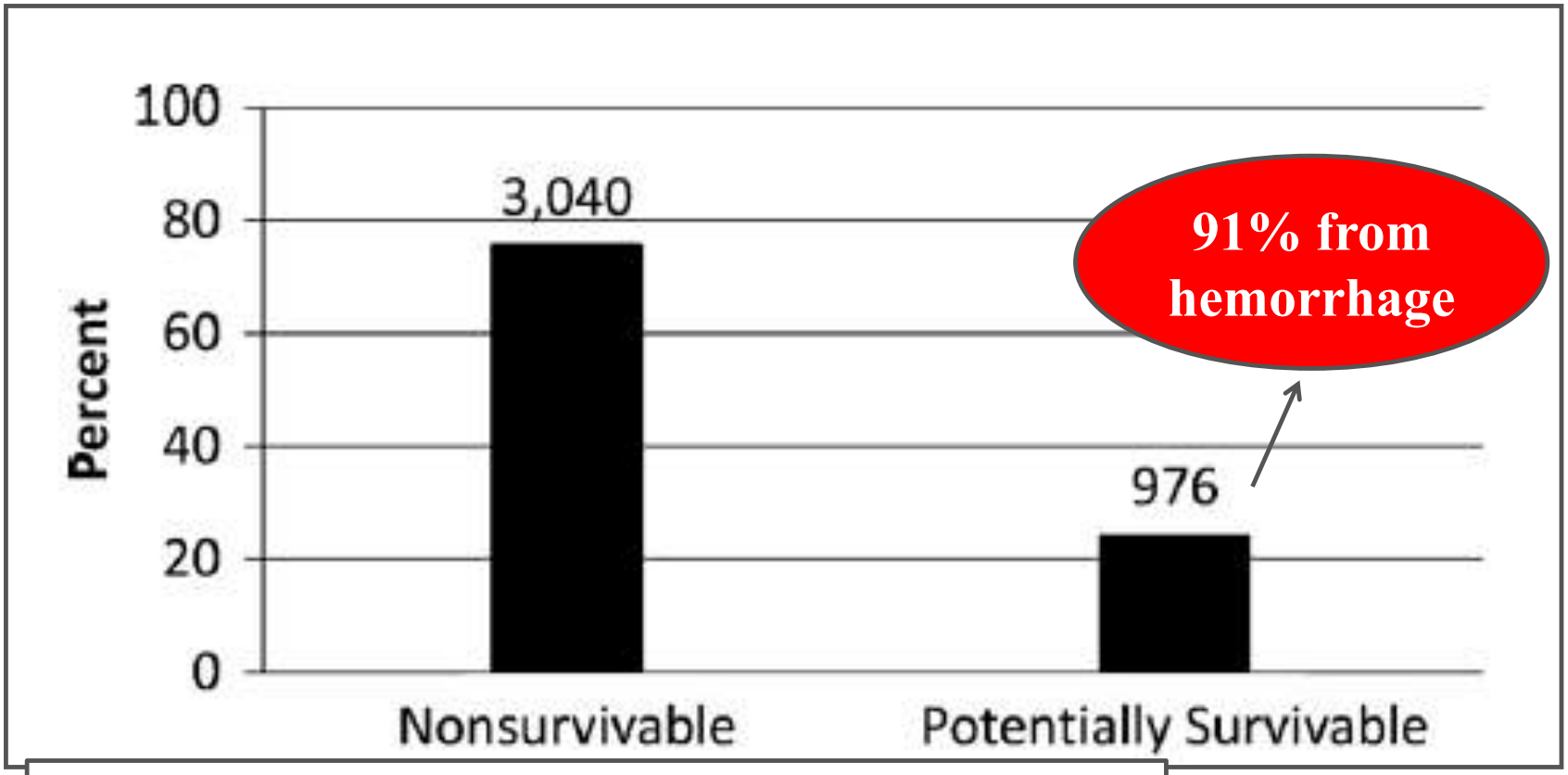
Data Informing Research & Development



J Trauma Acute Care Surg 2012;73(Suppl1):S431-S437

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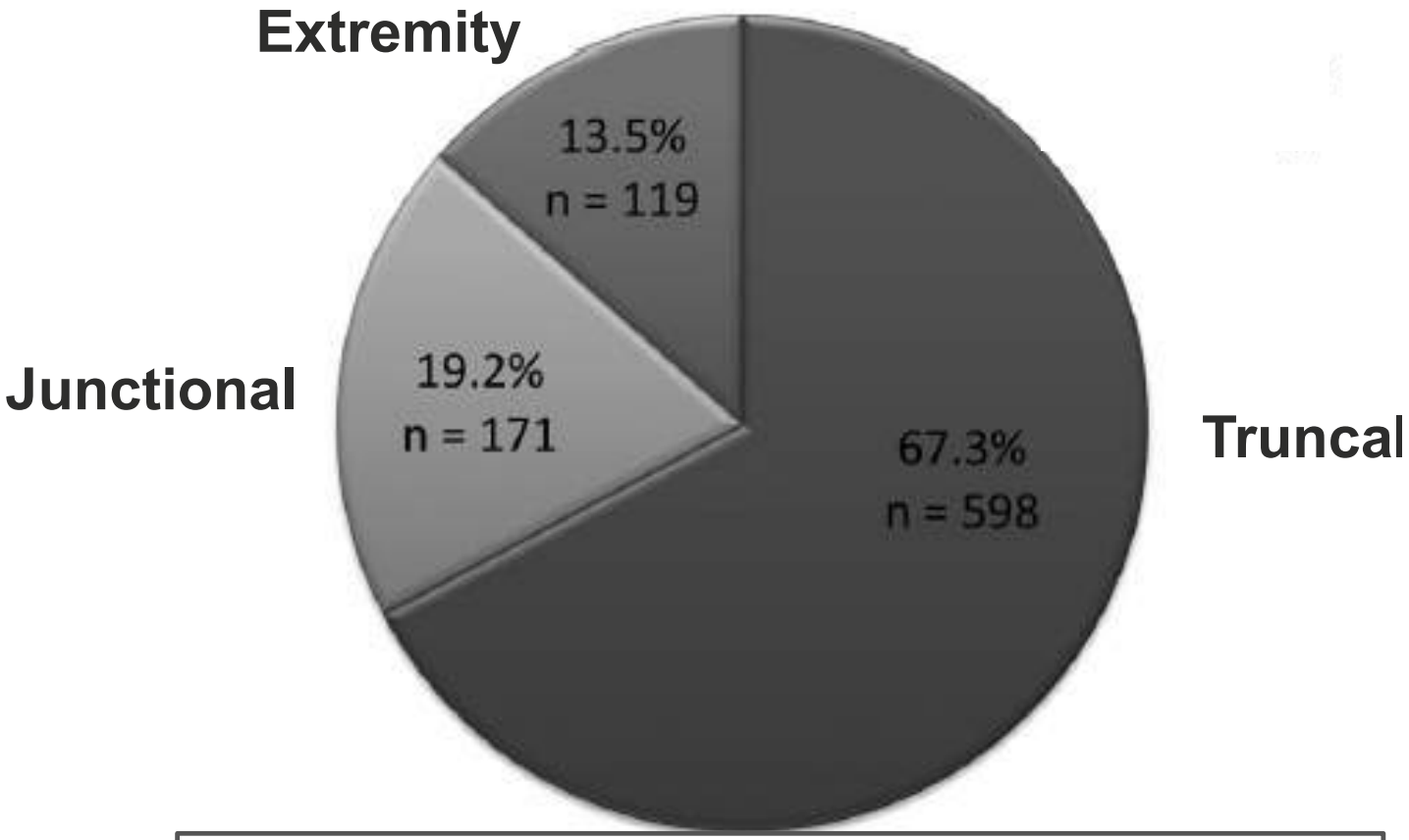
Data Informing Research & Development



J Trauma Acute Care Surg 2012;73(Suppl1):S431-S437

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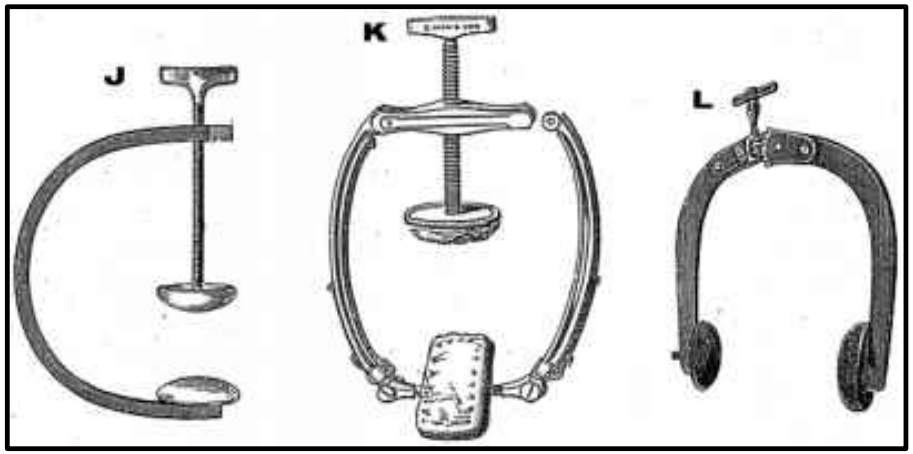
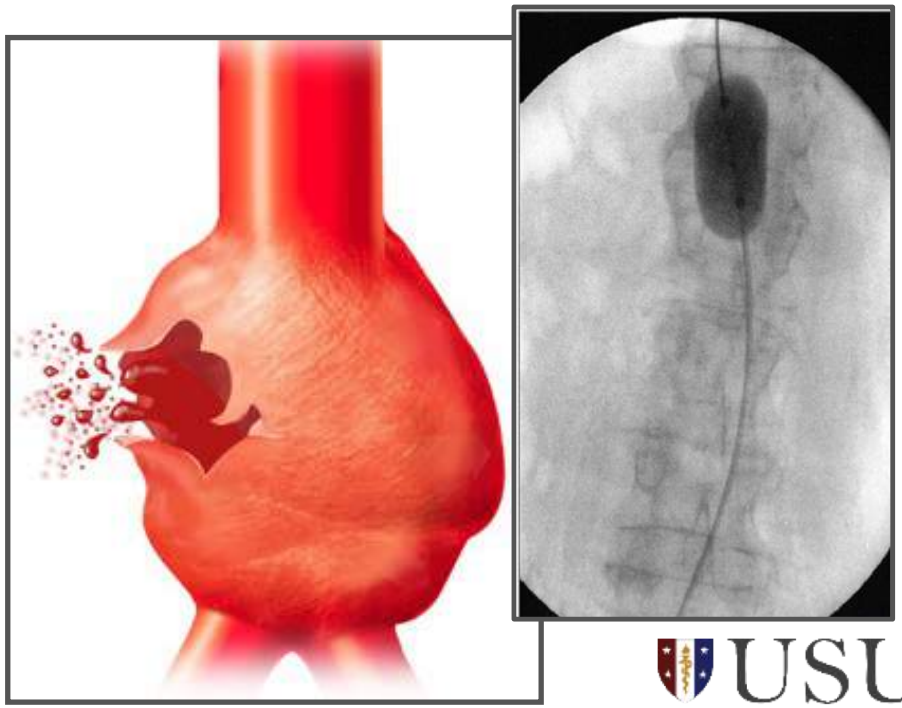
Different Innovation Paths for Bleeding & Shock

- A large portion of traditional surgical & medic communities pursued animal models of hemorrhage, topical hemostatics and variations of the Lister tourniquet



- Others recognized ruptured AAA as a good model & pursued endovascular innovation



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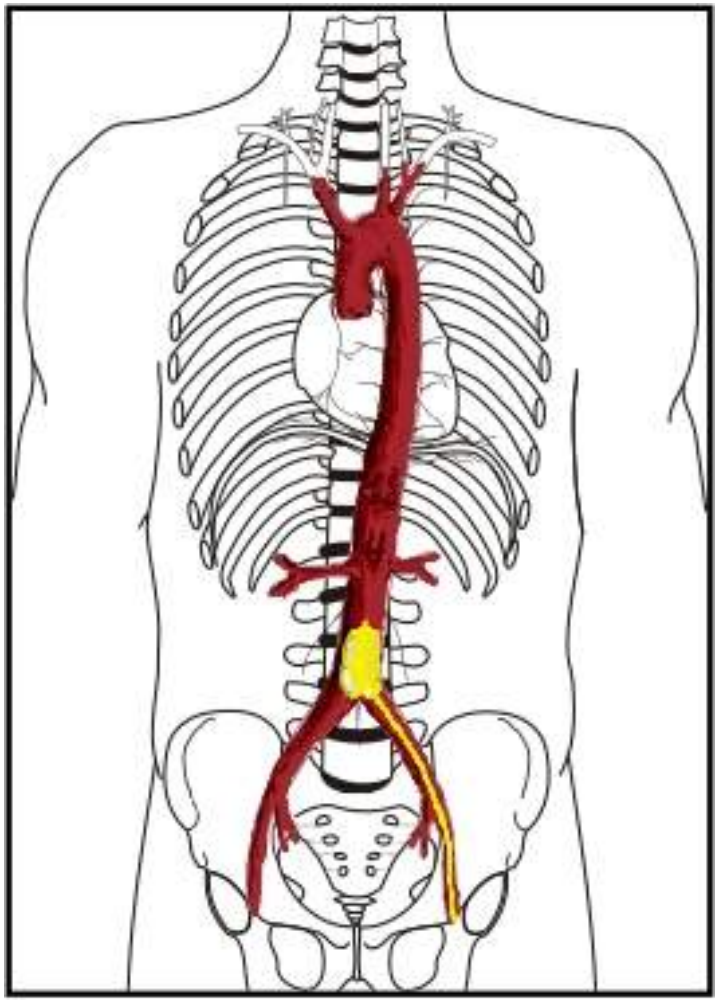
What is REBOA?



- **Resuscitative Endovascular Balloon Occlusion of the Aorta or placement & inflation of a compliant balloon from a remote location into the aorta for the purposes of occlusion**

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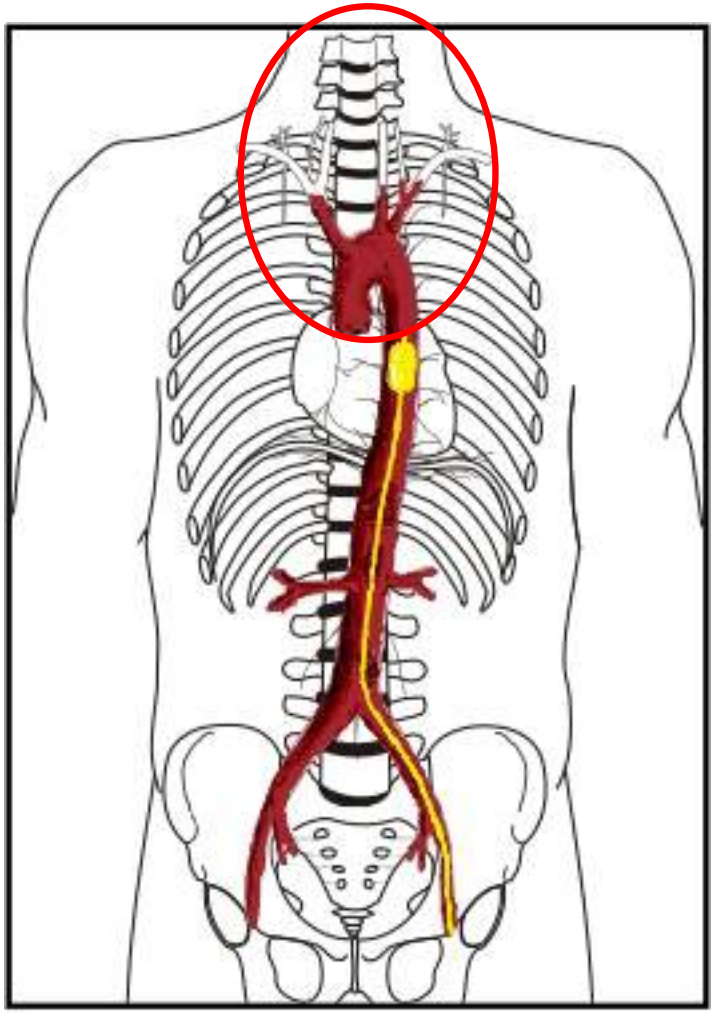
What is REBOA?



- **Performed to provide circulatory support proximal to balloon and inflow (bleeding) control distal or below the balloon**

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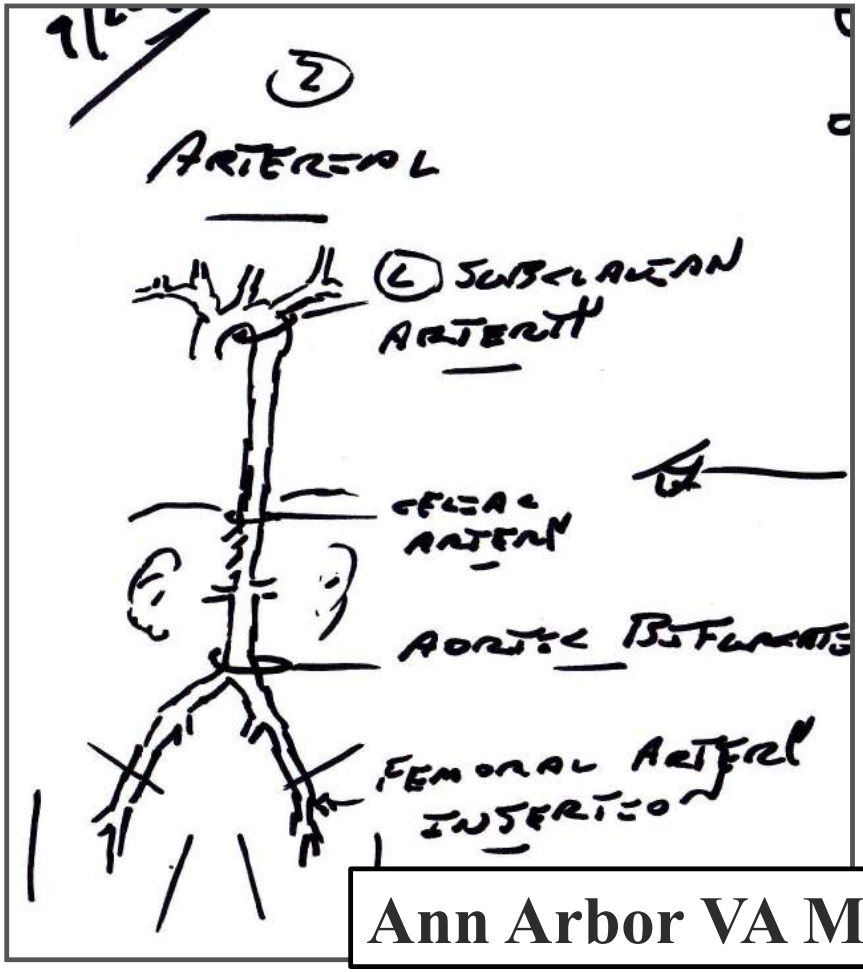
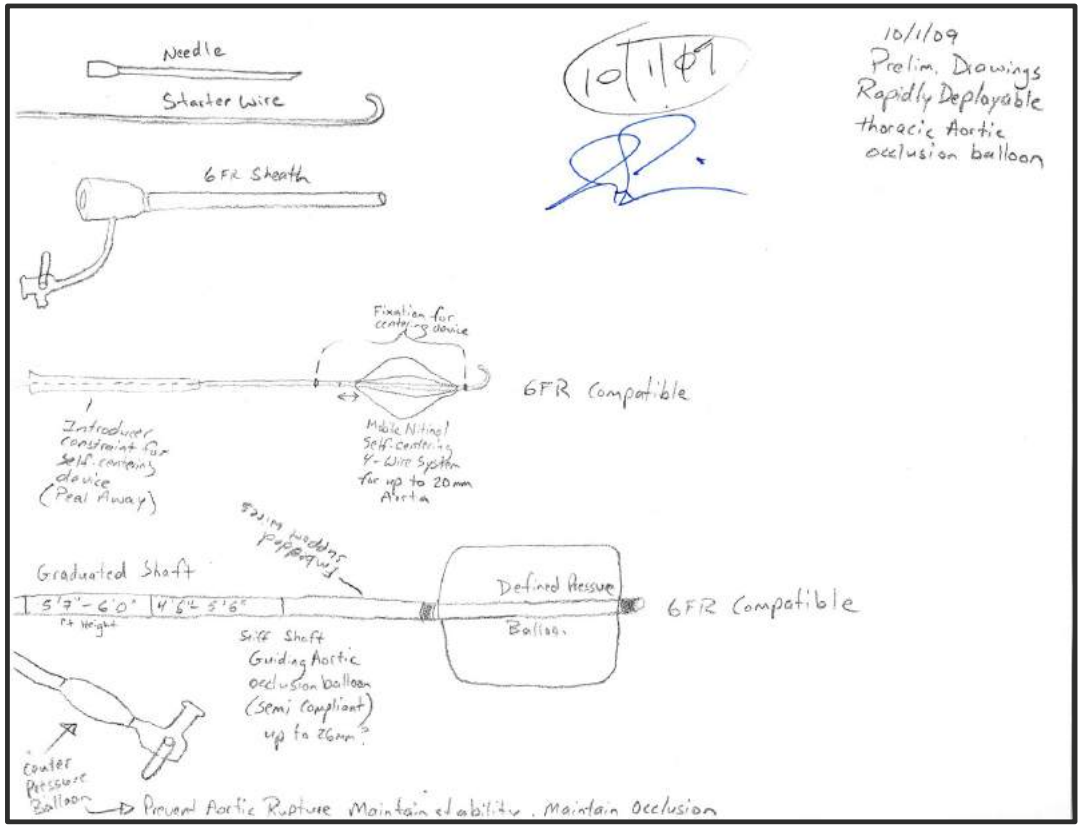
But How to Make Endo- Amenable for Trauma?





Ann Arbor VA Medical Center, October 2009

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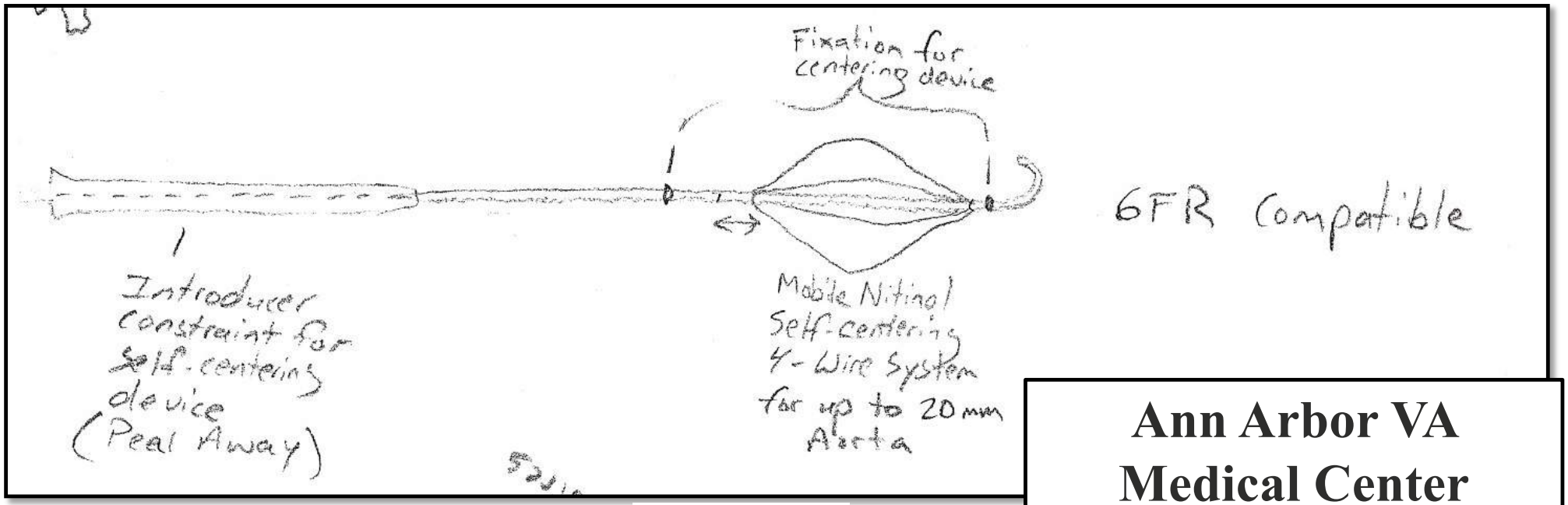
But How to Make Endo- Amenable for Trauma?



Ann Arbor VA Medical Center October 2009

Researcher's six-pack

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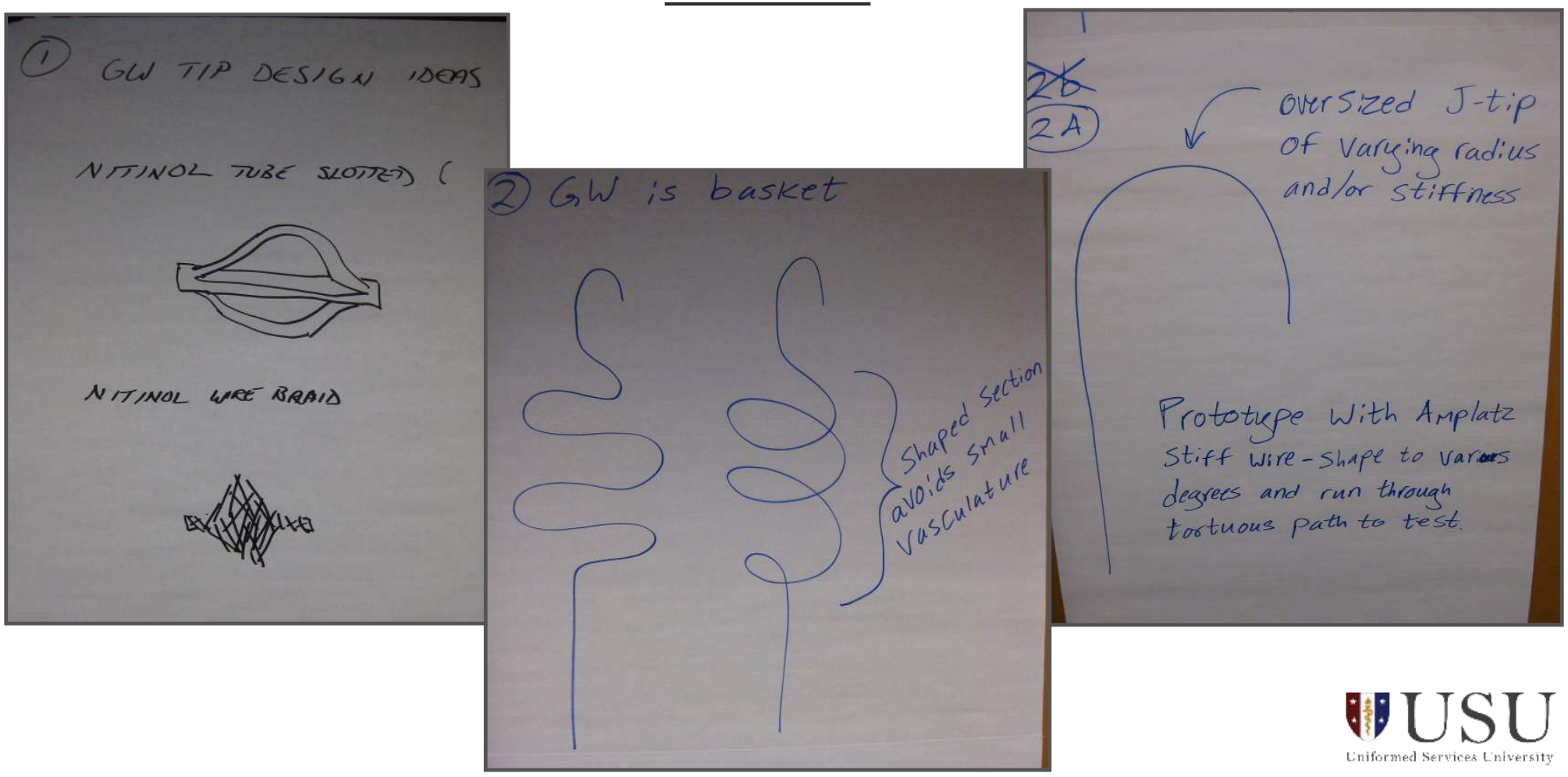
But How to Make Endo- Amenable for Trauma?



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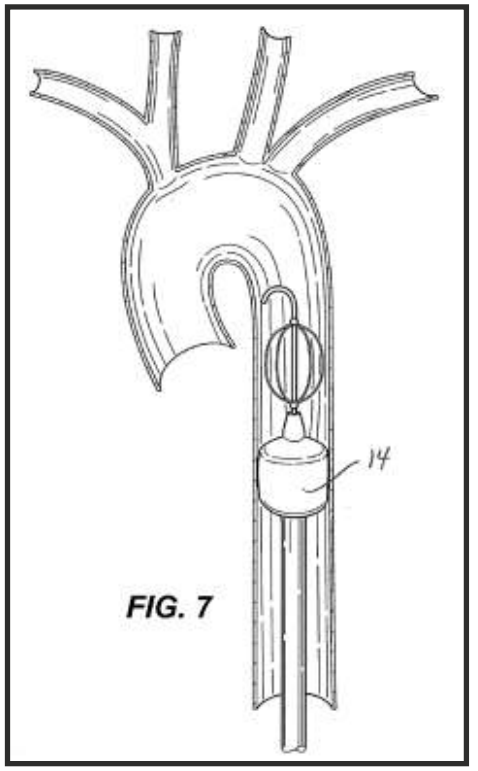
Innovate New Approach for Balloon Occlusion

- **Military-specific IP for new balloon catheter designed to be used in emergency scenarios (public university partnership)**



- **Goals for new balloon catheter technology:**
  - **Reduce the catheter size (7Fr or smaller)**
  - **Obviate need for radiographic imaging**
  - **Obviate need for "over the wire" placement**
  - **Implement arterial monitoring capability**

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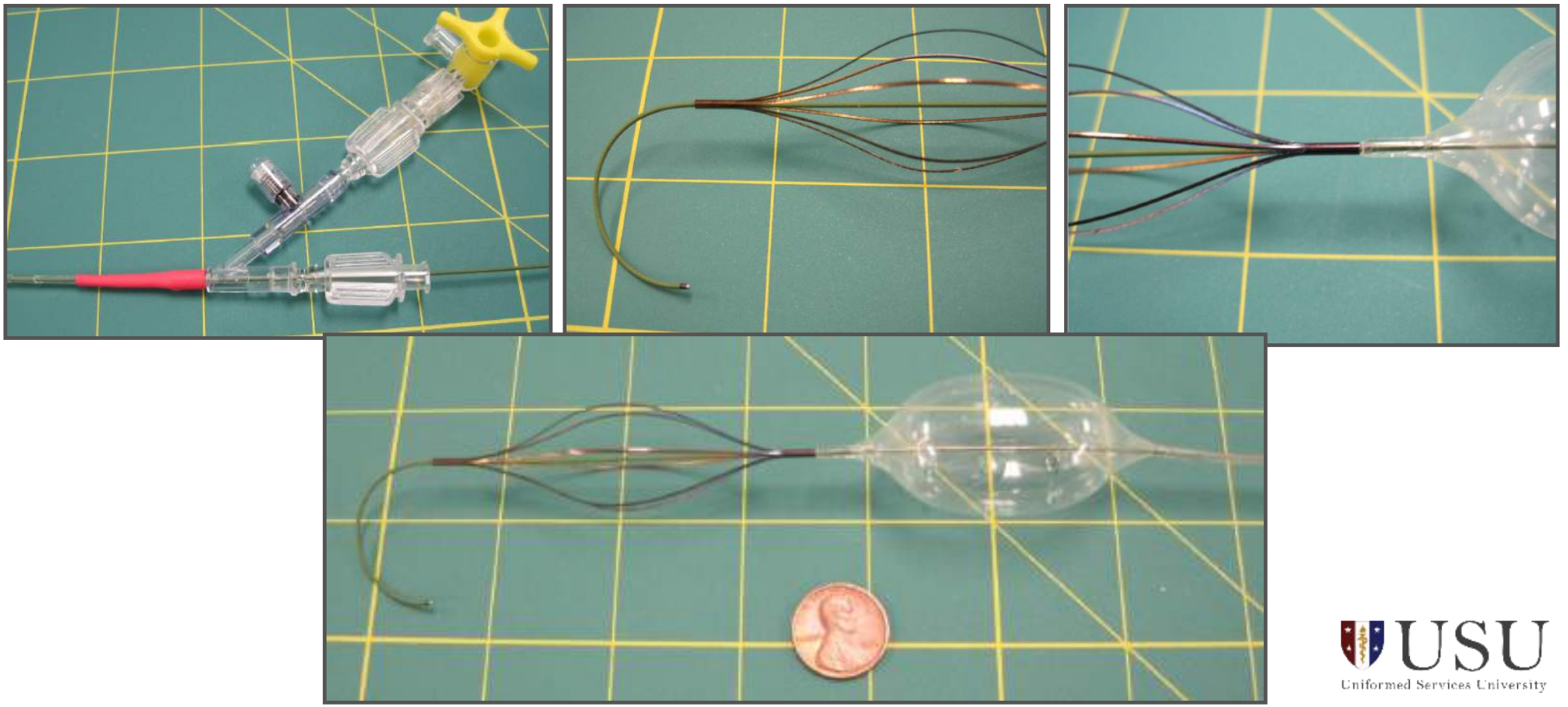
Initial Prototype Funded by University of Michigan and Created by TDC Medical



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Define REBOA for Clinical & Scientific Sectors

PROCEDURES & TECHNIQUES

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an Adjunct for Hemorrhagic Shock

Adam Stannard, MRCS, Jonathan L. Eliason, MD, and Todd E. Rasmussen, MD

Temporary occlusion of the aorta as an operative method to increase proximal or central perfusion to the heart and brain in the setting of shock is not new.[1] Resuscitative aortic occlusion with a balloon was reported as early as the Korean War and has been described in more recent publications.[2–5] Despite potential advantages over thoracotomy with aortic clamping, resuscitative endovascular balloon occlusion of the aorta (REBOA) for trauma has not been widely adopted. Broader application of this procedure may have lagged because of latent technology, a poorly understood skill set, or anticipated ineffectiveness of the technique. However, the recent evolution of endovascular technology and its clear benefit in managing vascular disease such as ruptured abdominal aortic aneurysm suggest that a reappraisal of this technique for trauma is needed. The objective of this report is to provide a technical description of REBOA.

To simplify, this maneuver can be considered in the following five steps each with specific procedural considerations (Table 1):

1. Arterial access
2. Balloon selection and positioning
3. Balloon inflation
4. Balloon deflation
5. Sheath removal

STEP 1: ARTERIAL ACCESS AND POSITIONING OF INITIAL SHEATH

Establishing Arterial Access

At this time, access to the arterial circulation for REBOA for trauma should be obtained through the femoral artery. At the completion of this initial step, a 10- to 15-cm-long sheath will be positioned in the femoral and external iliac artery. Access to the femoral artery can be obtained using one of three techniques: percutaneous, open exposure (i.e., cut down), or exchange over a guidewire from an existing femoral arterial line. Percutaneous access is now commonly accomplished under ultrasound guidance using the same probe applied for the focused abdominal sonography for trauma or focused assessment with sonography for trauma examination. In this scenario, a straight or linear array transducer is superior to a curvilinear transducer. Ultrasound or direct surgical identification of the femoral artery lateral to the vein is especially important in the hypotensive patient without a palpable pulse. Once identified, the artery should be entered at a 45-degree angle with a hollow 18-gauge needle through which a 0.035-inch wire can be passed. After the wire has been passed into the artery, the needle is removed and a small incision made at the interface of the wire and the skin. Next the sheath is placed over the wire into the artery. It is important that any time a sheath is passed over a wire into the arterial system, the sheath's internal dilator is firmly in place to allow a smooth reverse taper from the wire to the diameter of the sheath. Once the dilator and sheath have been advanced over the wire through the skin into the artery, the dilator is removed leaving the sheath as a working port through which other maneuvers can be accomplished. To avoid bleeding from the side port of the sheath after the dilator is removed, it is important that the operator assure that the stopcock is in the "off" position to the patient.

Selection and Positioning of Initial Sheath

Sheaths are measured as French (Fr) (1Fr = 0.333 mm) and are sized based on their internal diameter. Common initial sheaths are 5 Fr to 8 Fr and come in lengths from 8 cm to 15 cm. As long as the operator is confident that the femoral artery has been accessed and the 0.035-inch starter wire passes without resistance, placement of this short sheath can be accomplished without fluoroscopic guidance. As noted, while maintaining arterial access. After a larger opening is created at the wire/skin interface, the short working sheath with its internal dilator in position can be inserted over this wire as previously described.

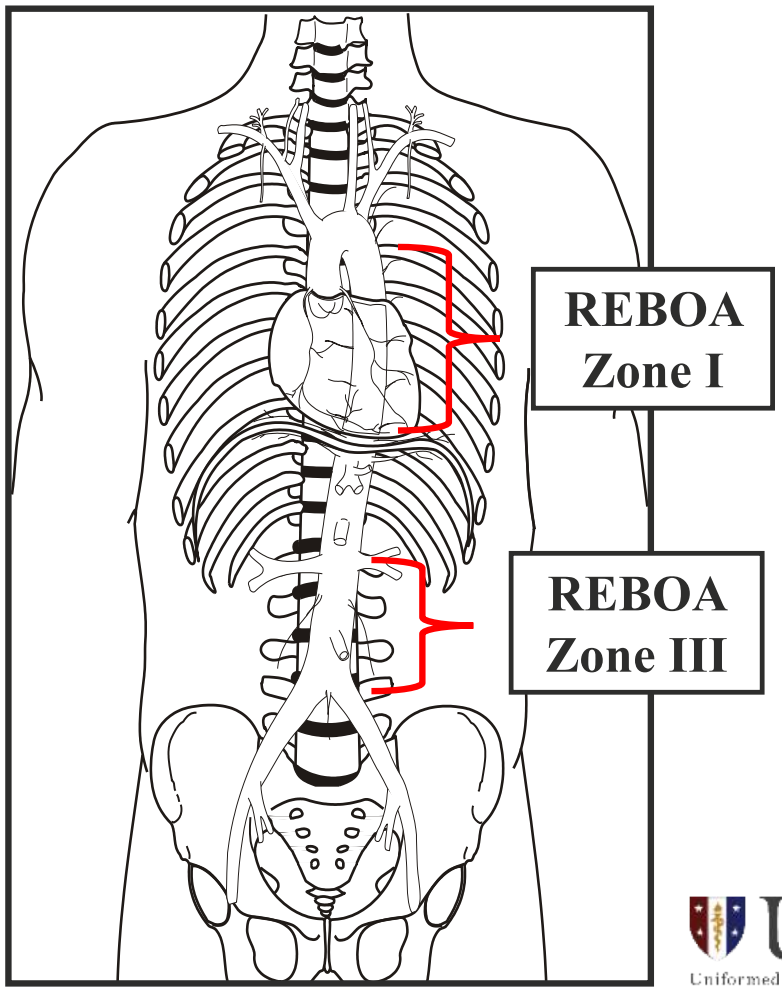
Submitted for publication: October 31, 2011.
Accepted for publication: November 1, 2011.

From the US Army Institute of Surgical Research (A.S., J.L.E., T.E.R.), Fort Sam Houston, San Antonio, Texas; Academic Department of Military Surgery and Trauma

Address for reprints: Todd E. Rasmussen, MD, FACS, US Army Institute of Surgical Research, 3400 Rawley E. Chambers/Suite B, Fort Sam Houston, TX 78234; email: todd.rasmussen@amedd.army.mil.

DOI: 10.1097/TA.0b013e318235fe90c

***J Trauma* 2011;71(6):1869-72**



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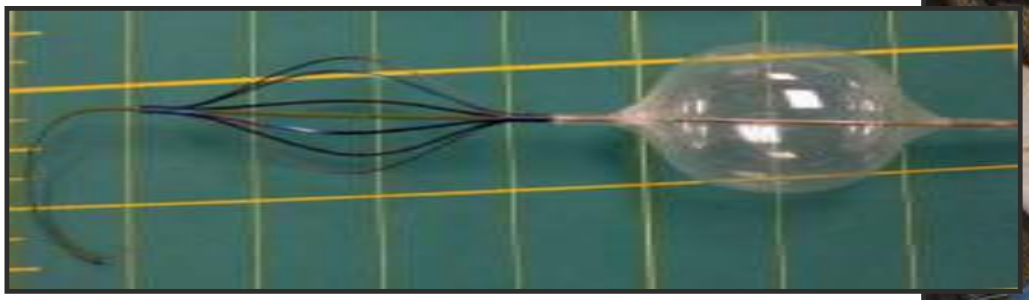
Concept to Prototype Demonstrates Potential

EAST 2013 Poster Paper

A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock

Daniel J. Scott, MD, Jonathan L. Eliason, MD, Carole Villamaria, MD, Jonathan J. Morrison, MRCS, Robert Houston, IV, MD, Jerry R. Spencer, BS, *and* **Todd E. Rasmussen, MD,** *Ann Arbor, Michigan*

***J Trauma Acute Care Surg* 2013;75:122**



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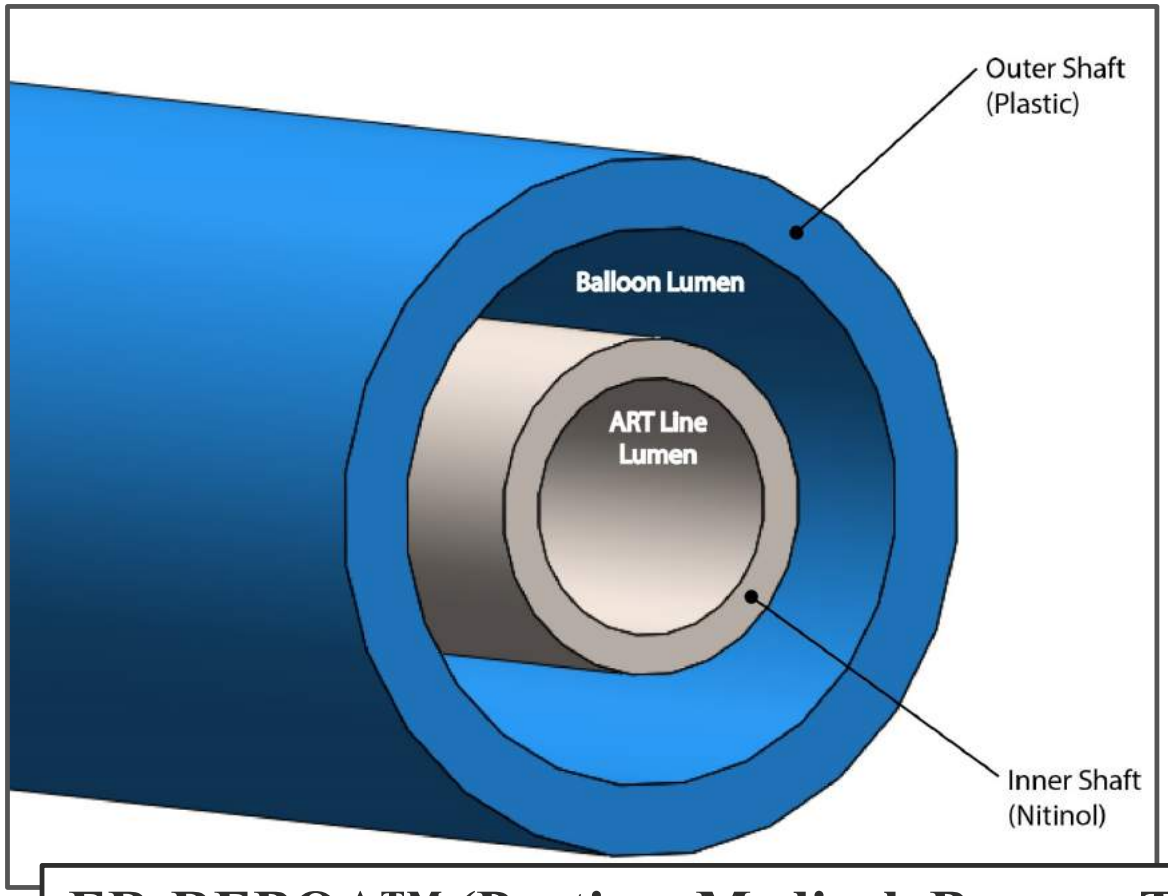
Prototype to Clearance & Commercialization



ER-REBOA™ (Prytime Medical, Boerne, TX)

- **Dual lumen, 6Fr shaft utilizes a "tube in tube" design with an inner, superelastic nitinol tube & a concentric, outer plastic tube**
- **Together, the design & materials create a catheter stiffness obviating the need for traditional "over the wire" insertion**

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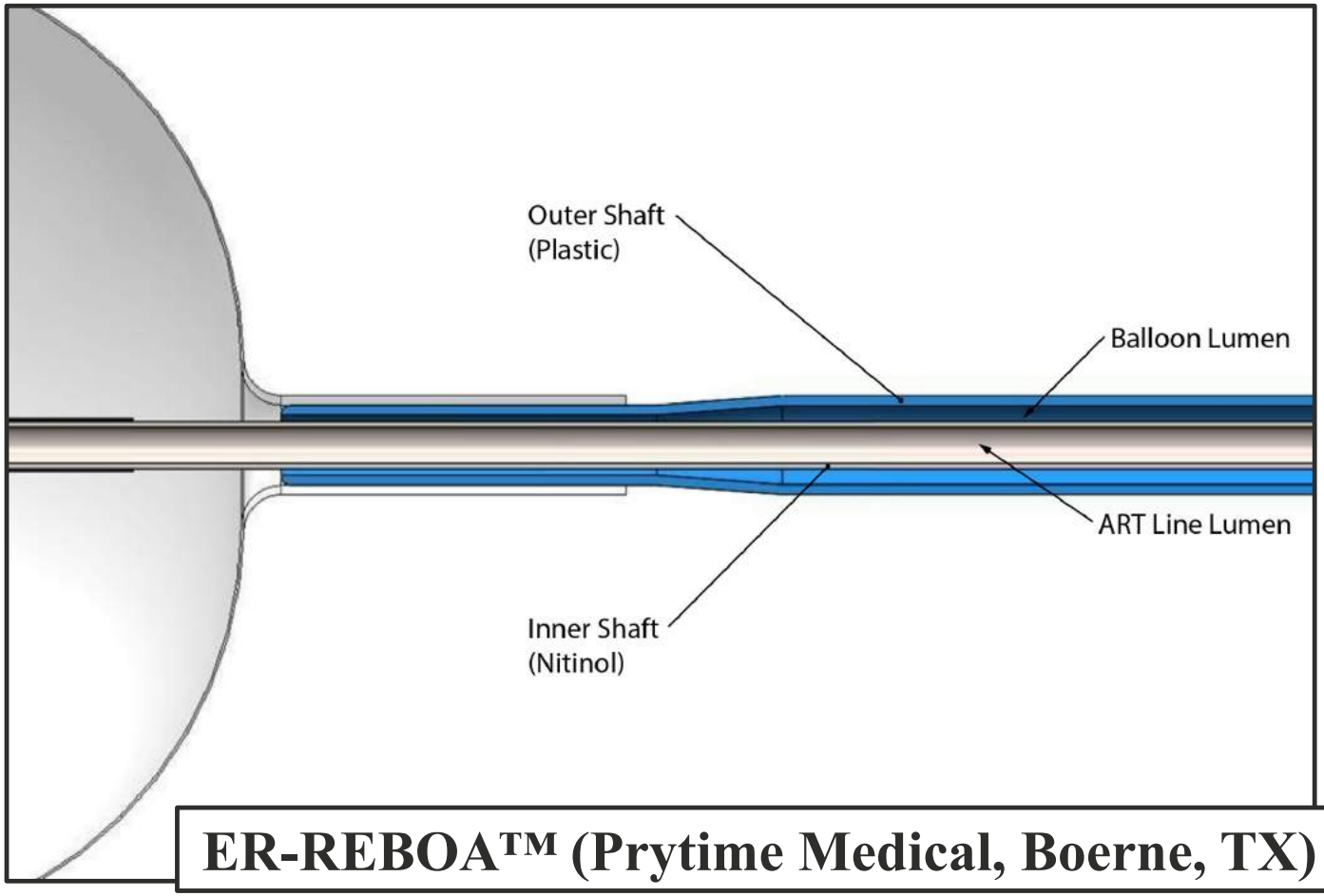
Prototype to Clearance & Commercialization



ER-REBOA™ (Prytime Medical, Boerne, TX)

- **Outer lumen for balloon inflation, inner nitinol lumen for arterial pressure monitor**
- **"P" tip sized to resist side branch entry – catheter shaft has 1cm demarcations**

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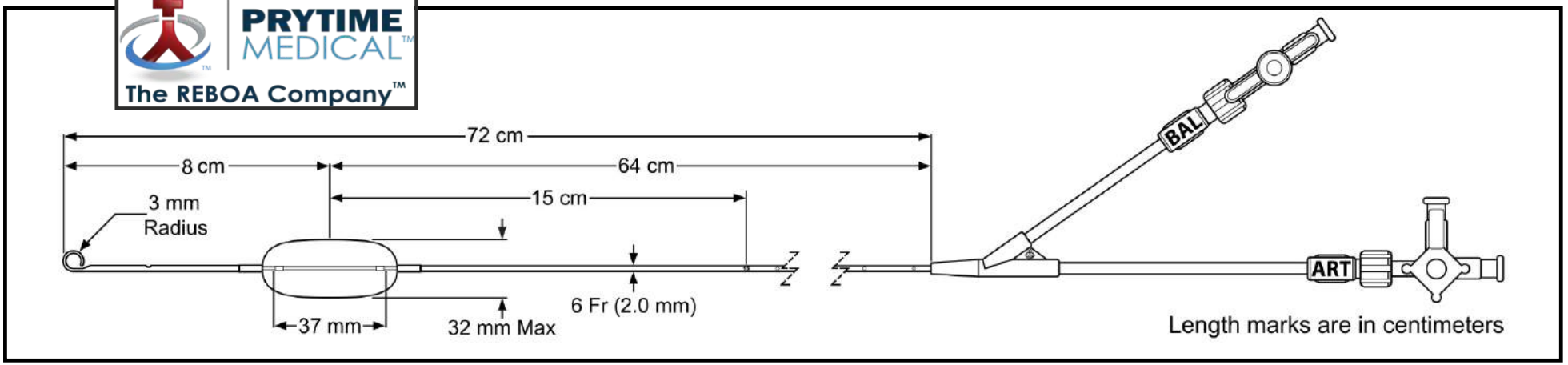
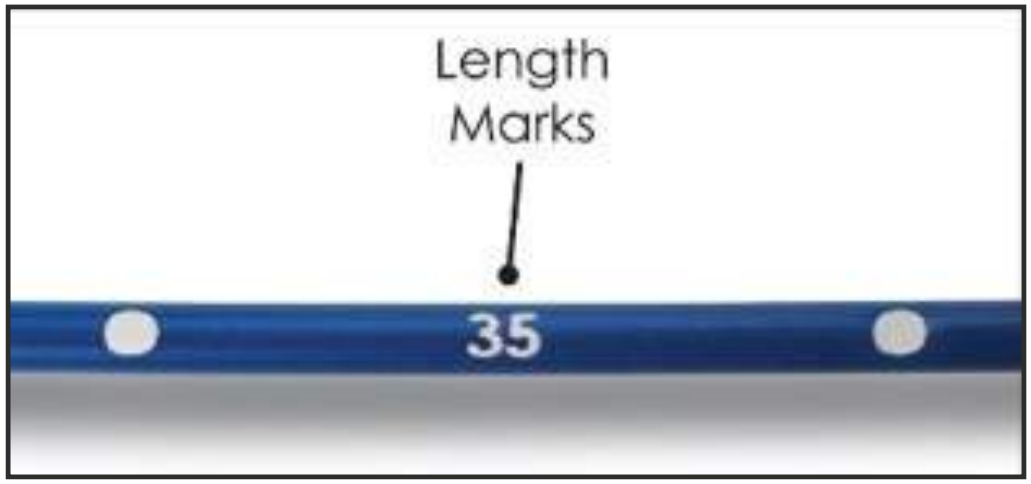
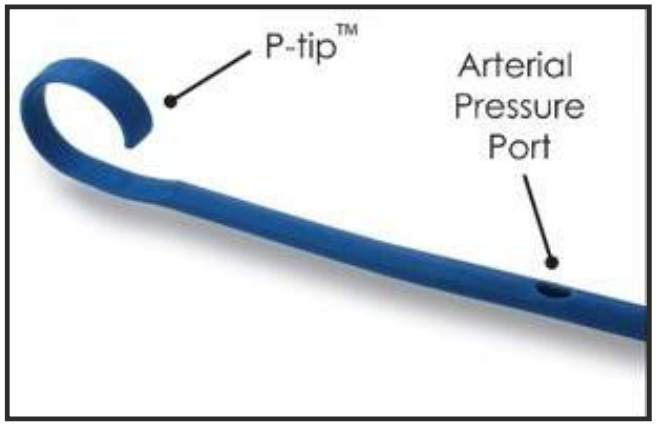
Prototype to Clearance & Commercialization







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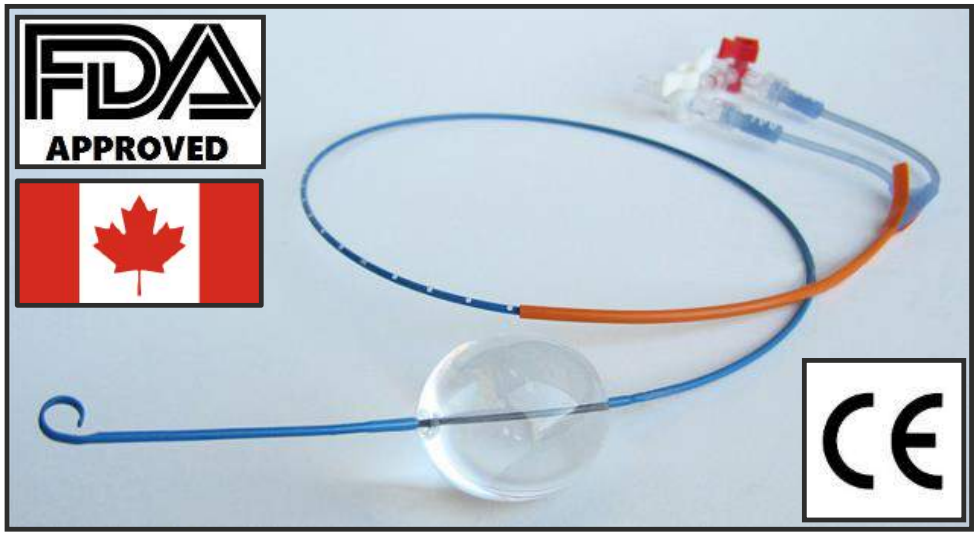
Concept to Prototype to Commercialized Device

Surgical Innovation

Resuscitative Endovascular Balloon Occlusion of the Aorta for Hemorrhagic Shock

JAMA Surg 2017; Published online Sept 20 2017

Todd E. Rasmussen, MD; Curtis J. Franklin, BS; Jonathan L. Eliason, MD



- **Initial experience in medical centers (205 US hospitals & 2000 uses in 24 months since FDA approval)**
- **With increasing familiarity, study & training there is likely to be expanded use, including by non-surgeon & possibly non-physician providers**

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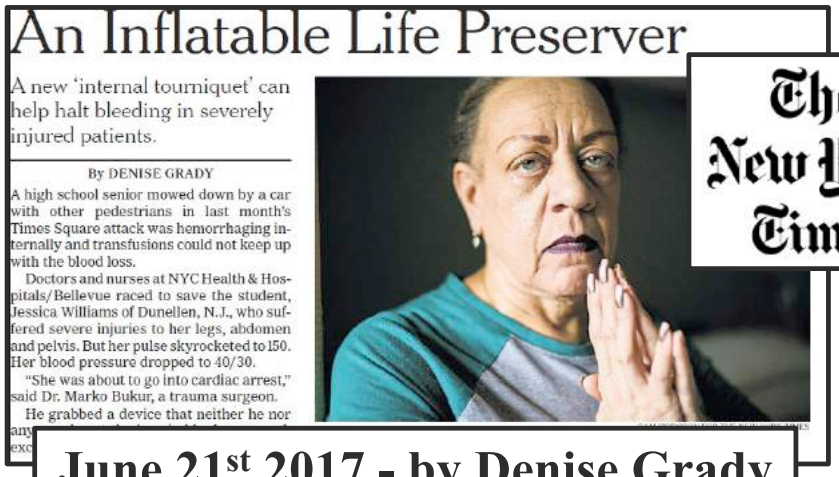
Growing Experience in Civilian Sector

Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage

Laura J. Moore, MD, Megan Brenner, MD, Rosemary A. Kozar, MD, PhD, Jason Pasley, DO, Charles E. Wade, PhD, Mary S. Baraniuk, PhD, Thomas Scalea, MD, *and* John B. Holcomb, MD, *Houston, Texas*

***J Trauma Acute Care Surg* 2015;79(4):524-32**



An Inflatable Life Preserver

A new 'internal tourniquet' can help halt bleeding in severely injured patients.

By DENISE GRADY

A high school senior mowed down by a car with other pedestrians in last month's Times Square attack was hemorrhaging internally and transfusions could not keep up with the blood loss.

Doctors and nurses at NYC Health & Hospitals/Bellevue raced to save the student, Jessica Williams of Dunellen, N.J., who suffered severe injuries to her legs, abdomen and pelvis. But her pulse skyrocketed to 150. Her blood pressure dropped to 40/30.

"She was about to go into cardiac arrest," said Dr. Marko Bukur, a trauma surgeon.

He grabbed a device that neither he nor

The New York Times

June 21st 2017 - by Denise Grady

- **Observational, registry-based studies confirming feasibility & empiric benefit**
- **Reports of "saves" related to use in civilian & military settings**

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Thank you from America's Medical School at the Uniformed Services University

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What's Possible

- **Automated, miniaturized vascular access and acute endovascular mediation of perfusion (i.e. new paradigm of automated hemorrhage mitigation and regional perfusion optimization)**

- **Endovascular manipulation of temperature & delivery of drugs & cell-based therapy to stabilize deranged physiology – bridge to ECLS or definitive hemostasis, resuscitation & reparative surgery**

- **Applications for a range of conditions - including cardiogenic shock (cardiac arrest), post-partum hemorrhage, GI and other forms of bleeding and shock**

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