

Indication for Use: Control of Difficult Bleeding in the Pelvis, Inguinal Area and Axilla

Bleeding in the pelvis, inguinal and axilla regions constitutes one of the most difficult problems faced in penetrating trauma. Junctional bleeding occurs in areas of the body that are not easily amenable to tourniquet application. They are generally the areas where the torso meets the extremities.

Proximal compression of vessels is still the most effective way of hemorrhage control. The Abdominal Aortic and Junctional Tourniquet (AAJT) accomplishes this by compressing the descending aorta at or near the bifurcation of the aorta, the common femoral artery in the groin or the subclavian artery in the axilla. Human studies show that the device is effective at stopping blood flow at these sites at inflation pressures of 230 mm Hg.

Contraindications for Use in Abdominal Placement

- Known abdominal aortic aneurysm
- Pregnancy

No Contraindications for Inguinal or Axillary Placement

The risks versus benefits of the device should be considered prior to any application. The dangers of junctional bleeding include imminent exsanguination and death. If direct pressure, extremity tourniquet application or hemostatics do not result in cessation of bleeding the Abdominal Aortic & Junctional Tourniquet provides for a direct pressure capability to stop the flow of arterial blood distal to the application site. Inguinal Placement provides for pressure over the hips and pelvis allowing for pelvis stabilization in the event that the pelvis is broken.

Preventive Maintenance Checks and Services (PMCS)

The device is packaged in a ready to use state in vacuum-sealed packaging. If the device remains in the vacuum-sealed packaging no specific PMCS is required. If the packaging appears to be damaged, whether this is signs of environmental stress or physical damage, PMCS should be conducted as followed.

- Remove device from pouch
- Unbuckle and extend belt, inspect for cuts or fraying. Do not use if belt contains a cut extending more than 2 mm.
- Inspect buckles for cracks or breaks.
- Ensure windlass is at its initial state without any twisting.
- Inspect windlass retention hardware for breaks. Do not use if the windlass retention mechanism is broken.
- Inspect tubing for signs of wear and damage, if the tubing appears to be damaged, progress to the next step to ensure there is no air leak in the system.
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Inflate bladder until pressure gauge shows green indicating 250mm Hg pressure. Allow bladder to remain inflated for 5 minutes. If the pressure gauge drops to the point that the green indicator is not visible then do not use device. A pressure leak may be in the system

Instructions for Use

Placement: Indication - bleeding in:	Abdomen Pelvis/ Bilateral Lower Ext	Groin Inguinal area/ Lower Ext	Axilla Axilla/ Upper Ext
1. Buckle device around:	Patient's waist	Hips	Shoulder
2. Position bladder over:	Umbilicus	Effected Groin	Axilla
3. Tighten belt – REMOVE ALL SLACK			
4. Tighten and secure windlass			
5. Inflate bladder until green indicator shows			

THE DEVICE MUST BE VERY TIGHT BEFORE INFLATION

The tighter the belt is prior to inflation (achieved by good firm pulling of strap to take out all slack and tight windlass application), the more stable and effective the device. A tight belt allows arterial compression at lower bladder volumes. Lower bladder volumes result in the device working faster and with less discomfort to the patient.

The inflation system incorporates a bleed-off design to limit pressures under 300 mm Hg. The bench testing on bladder failure show that pressures over 1034 mm Hg can result in RF weld leaking or rupture. Inflation until the pressure indicator reveals a green strip indicates that the pressure in the bladder has reached 250 mm Hg. At 230 mm Hg, 100% of the human subjects had full occlusion of the flow in the femoral arteries

Recommended Application Time for placement: up to 4 hours

DO NOT REMOVE UNTIL DIRECTED TO DO SO BY A PHYSICIAN



For more information contact Compression Works LLC

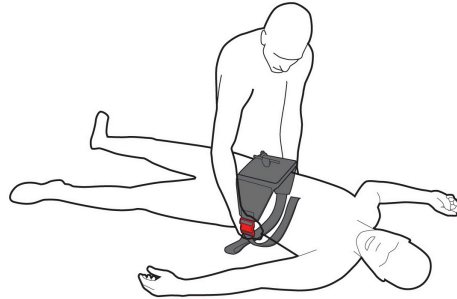
Compression Works LLC
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Hemorrhage Stops Here™

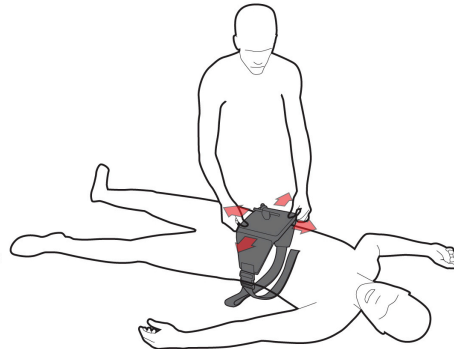
Abdominal Placement

For Pelvic Hemorrhage or Bilateral Groin/Inguinal Hemorrhage

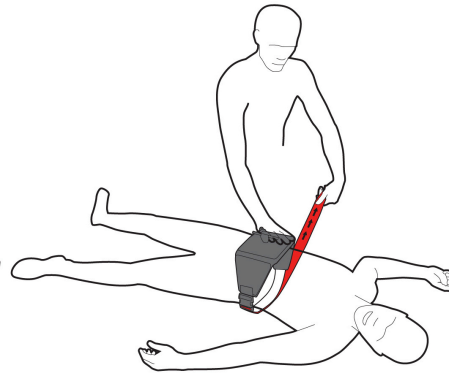
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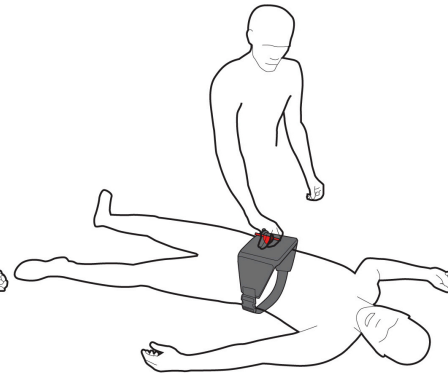
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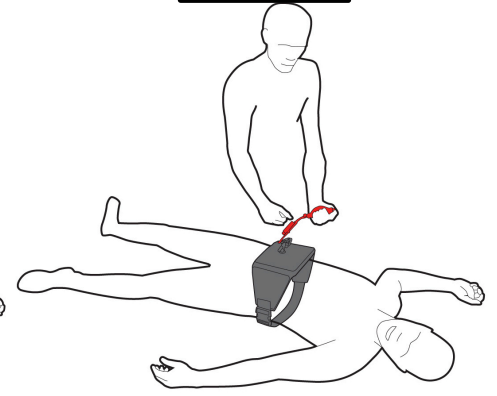
Step 3



Step 4

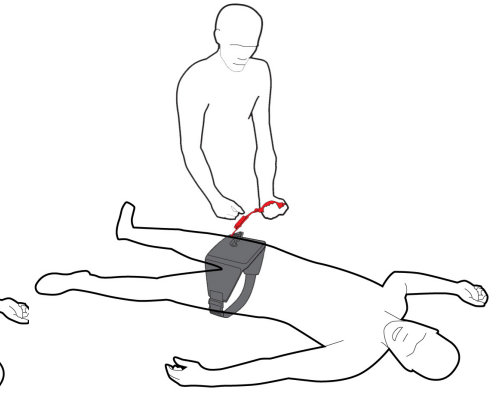
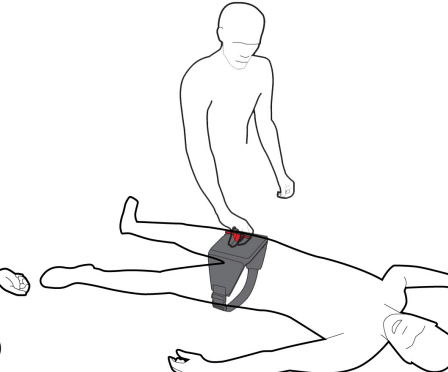
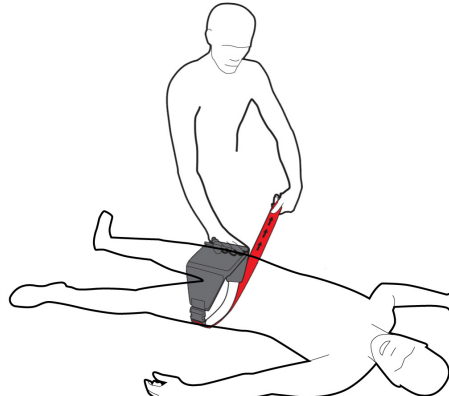
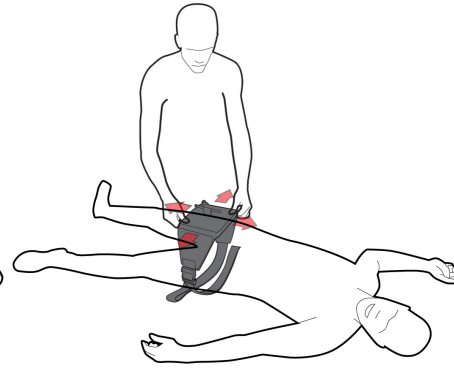
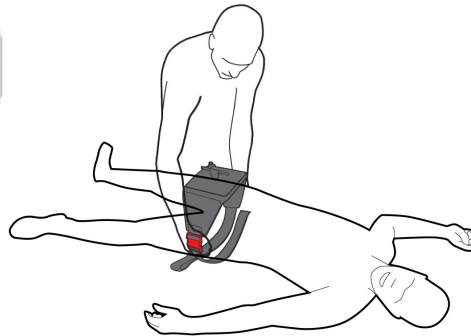
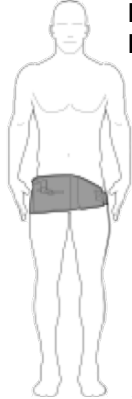


Step 5



Groin Application

For Groin/Inguinal Hemorrhage



Axilla Application

For Axilla Hemorrhage

