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(54) METHOD AND APPARATUS FOR IMPROVED HEMOSTASIS AND DAMAGE CONTROL OPERATIONS

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(52) **U.S. Cl.** **602/48**; 602/57

(57) **ABSTRACT**

Devices and methods are disclosed for achieving hemostasis in traumatized patients. Such haemostatic packing devices and methods are especially useful in the emergency, trauma surgery or military setting. In such cases, the patient may have received trauma to abdominal viscera, the thoracic cavity or the periphery. The devices utilize fluid impermeable outer surfaces and distributed pressure to achieve tamponade and hemostasis, primarily by exertion of pressure. The devices come in a variety of configurations including sheet, rolled sheet, folded sheet and polygonal solids including extruded shapes. The devices are capable of serving as carriers for thrombogenic or antipathogenic agents. The devices are flexible, bendable, and conformable in their wet or dry state so that they exert distributed pressure on the wound. Peripheral haemostatic packing devices include optional adhesive hemostatic barriers to cover the entire wound area over the hemostatic pack. The hemostatic packing devices may be placed and removed by open surgery or laparoscopic access without generating excessive re-bleeding, and may further comprise antimicrobial or thrombogenic regions.

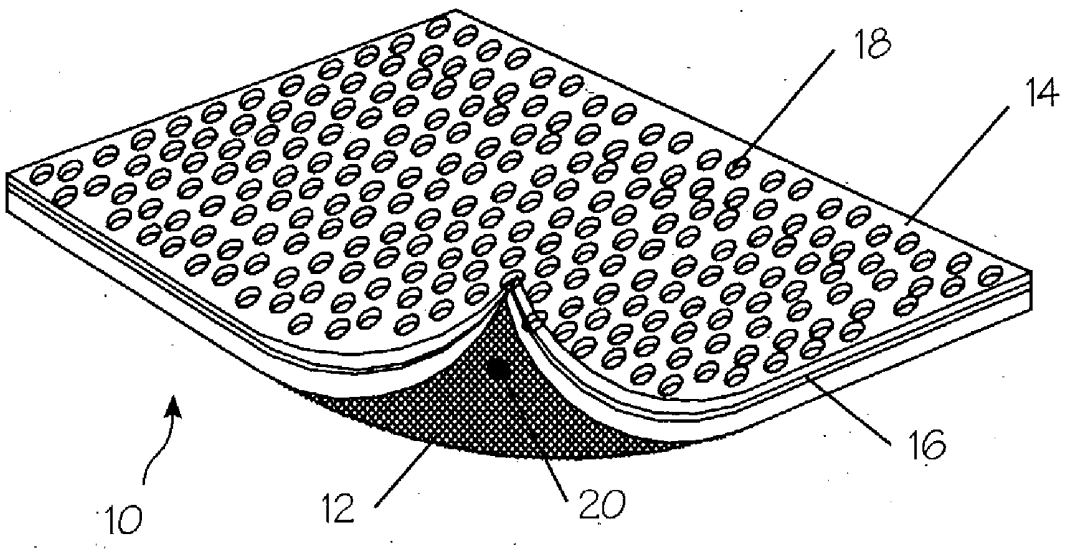


Fig. 1A

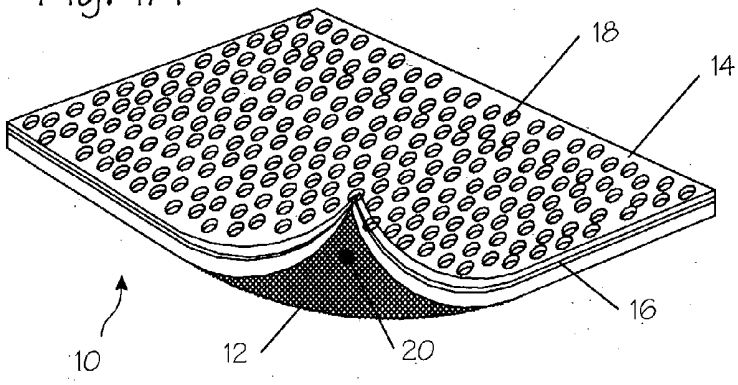


Fig. 1B

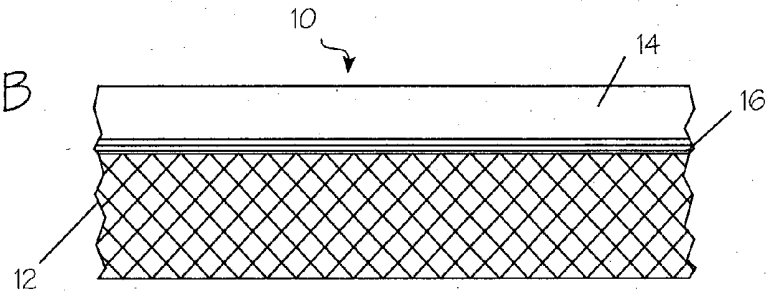


Fig. 1C

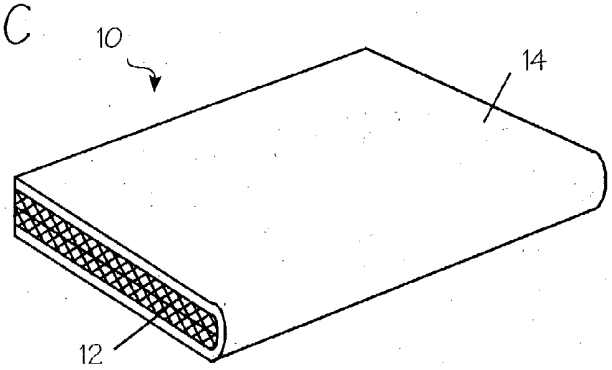


Fig. 1D

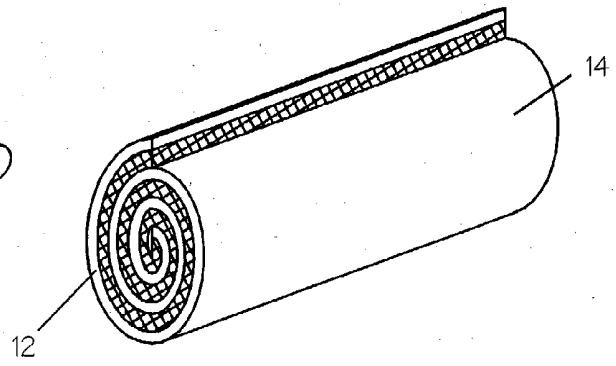


Fig. 2

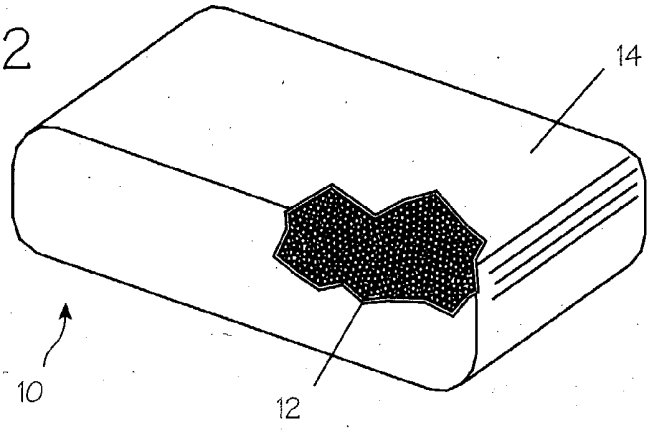


Fig. 3

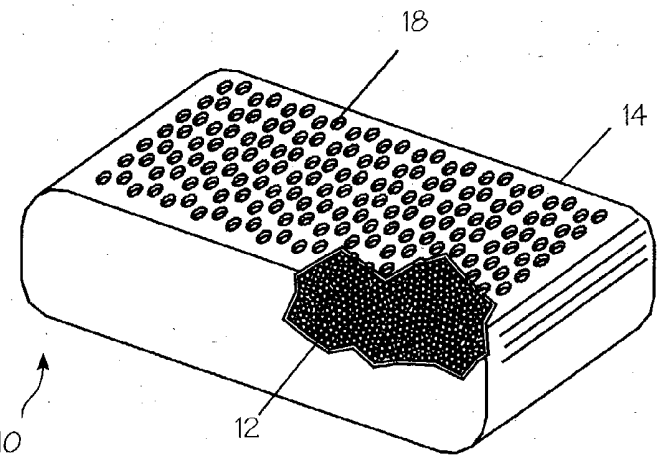


Fig. 4

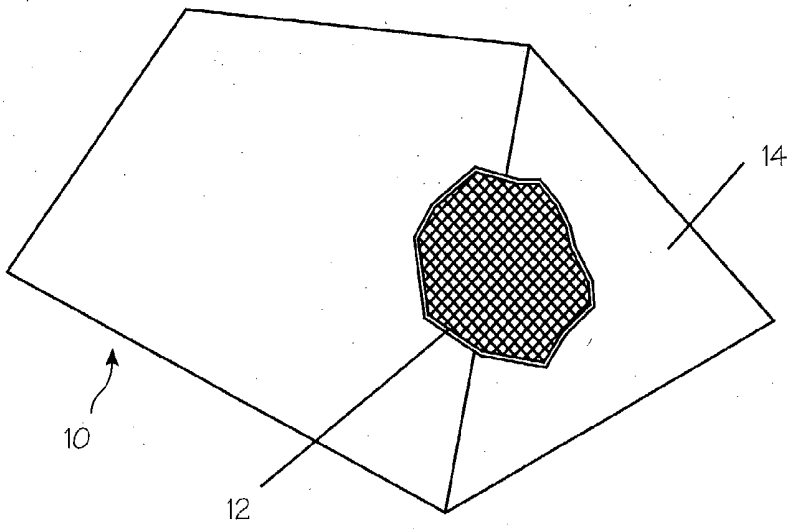


Fig. 5A

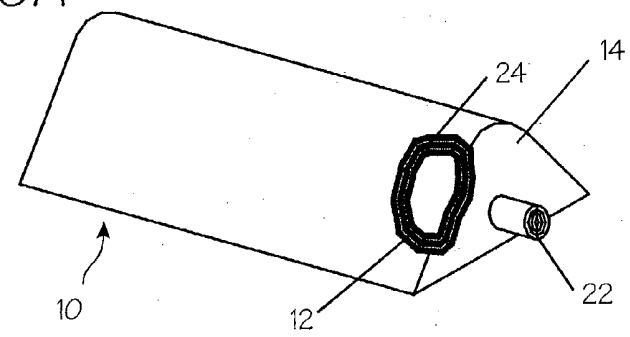
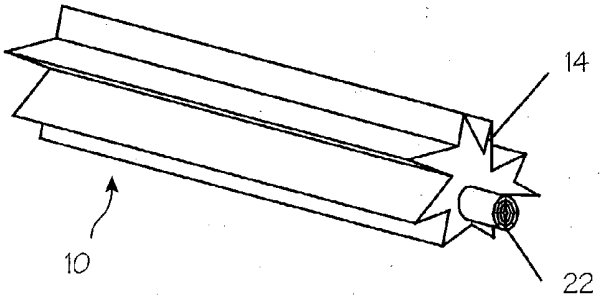


Fig. 5B



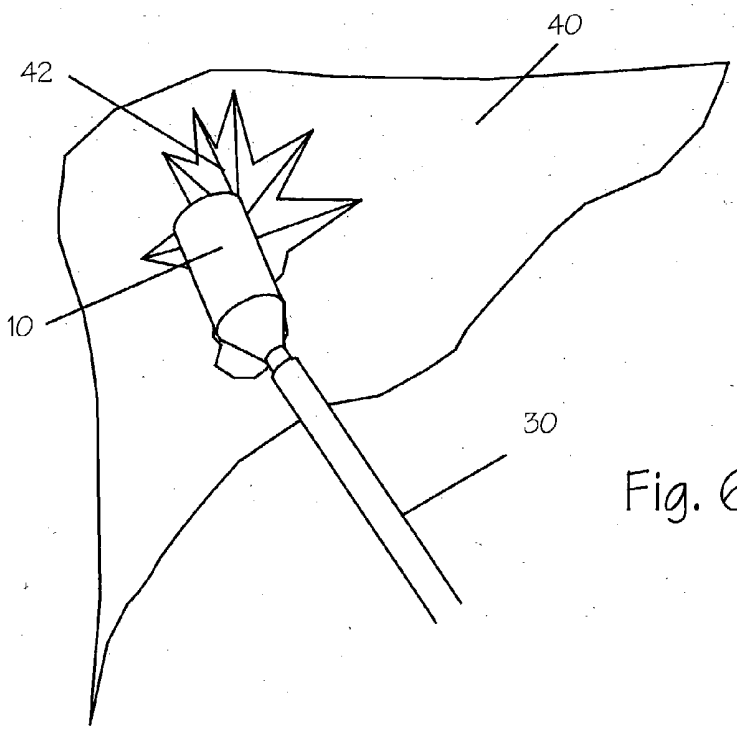


Fig. 6

Fig. 7

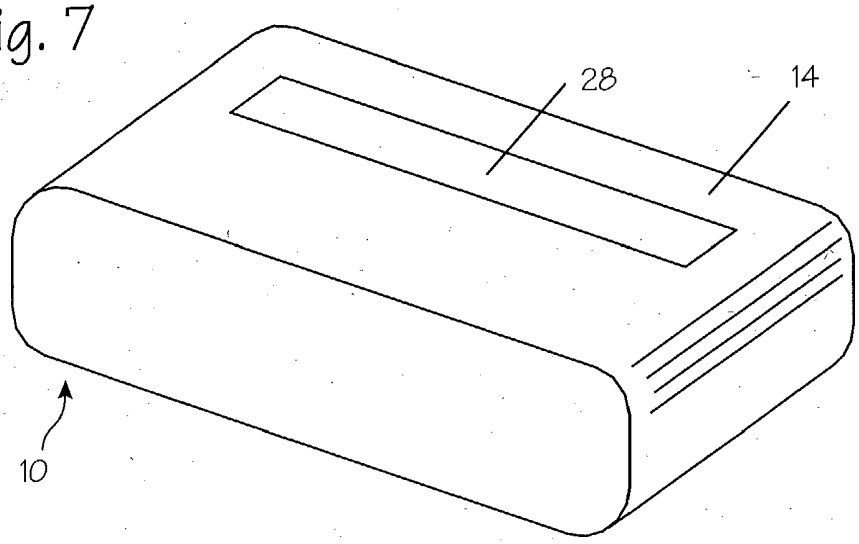


Fig. 8

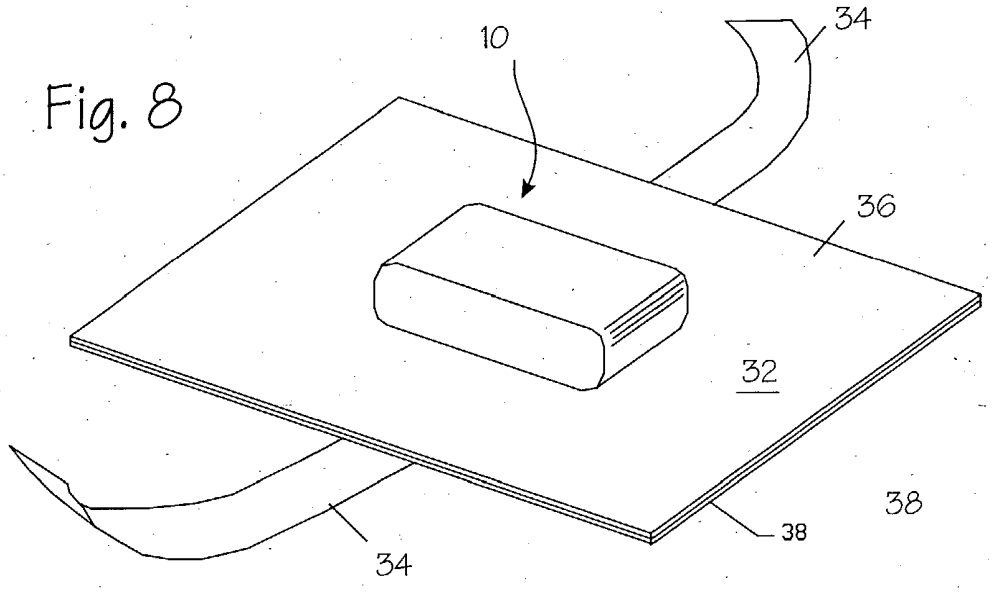


Fig. 9A

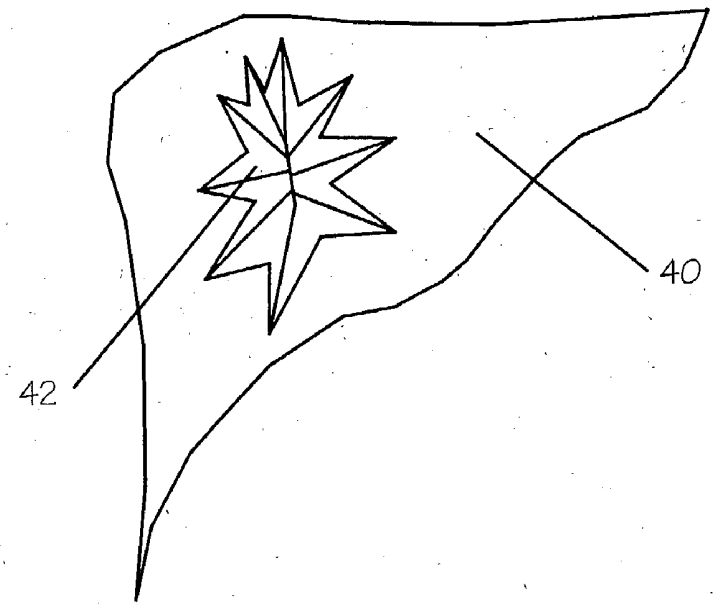
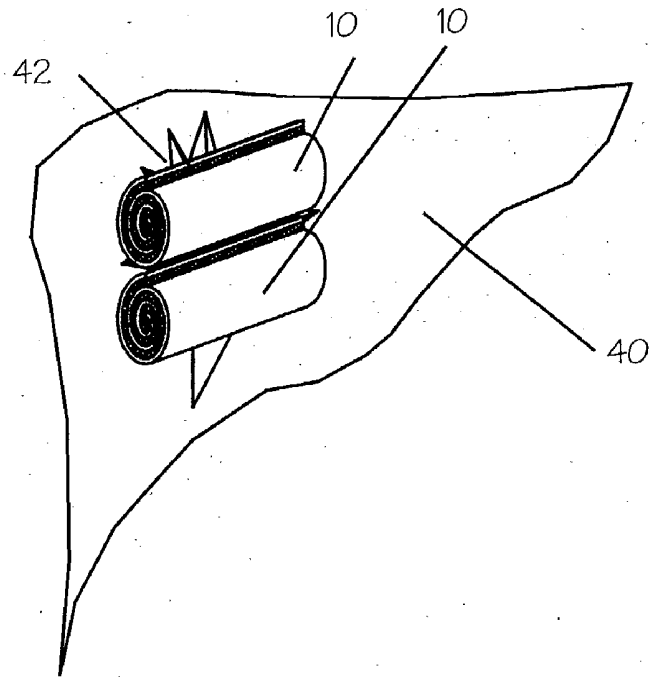


Fig. 9B



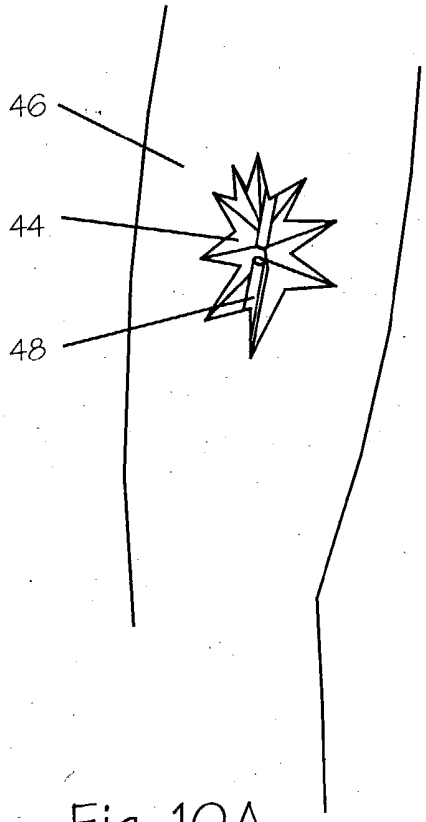


Fig. 10A

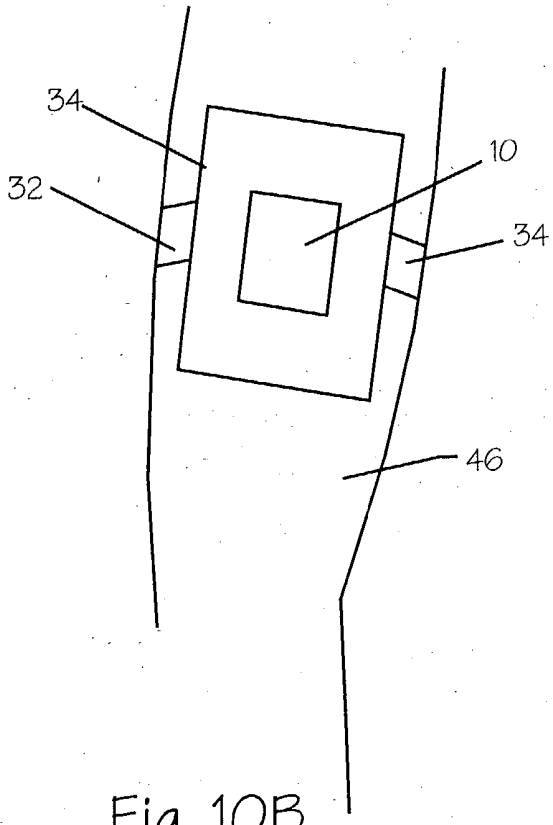


Fig. 10B

Fig. 11

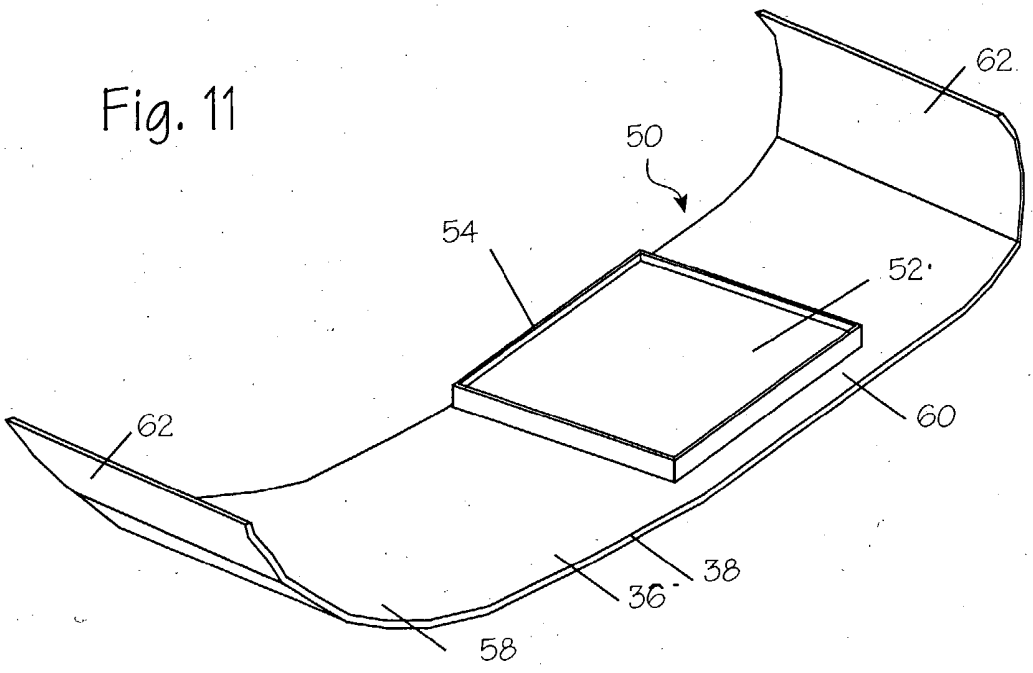


Fig. 12

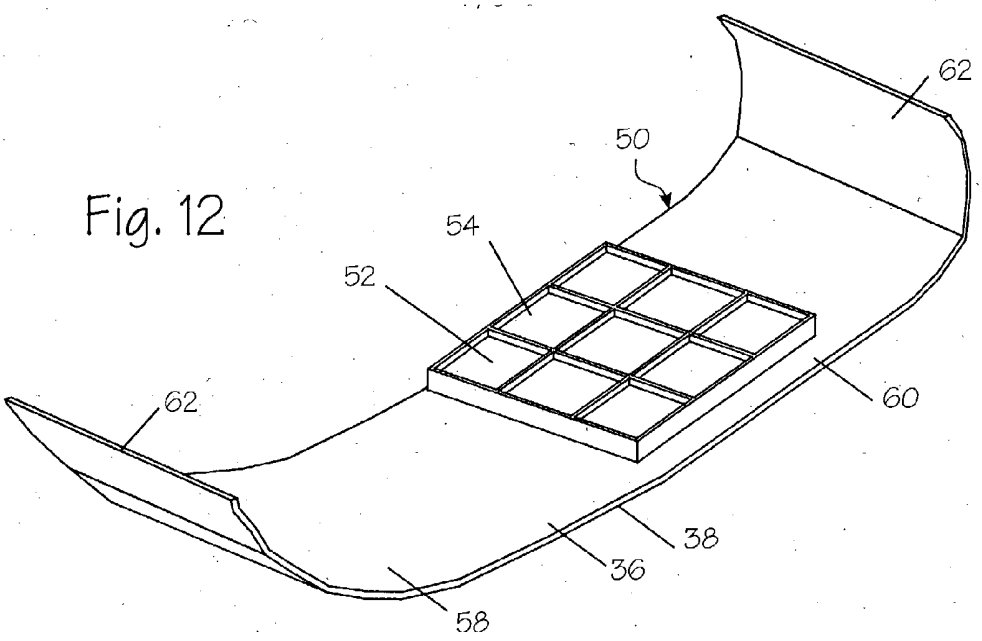


Fig. 13

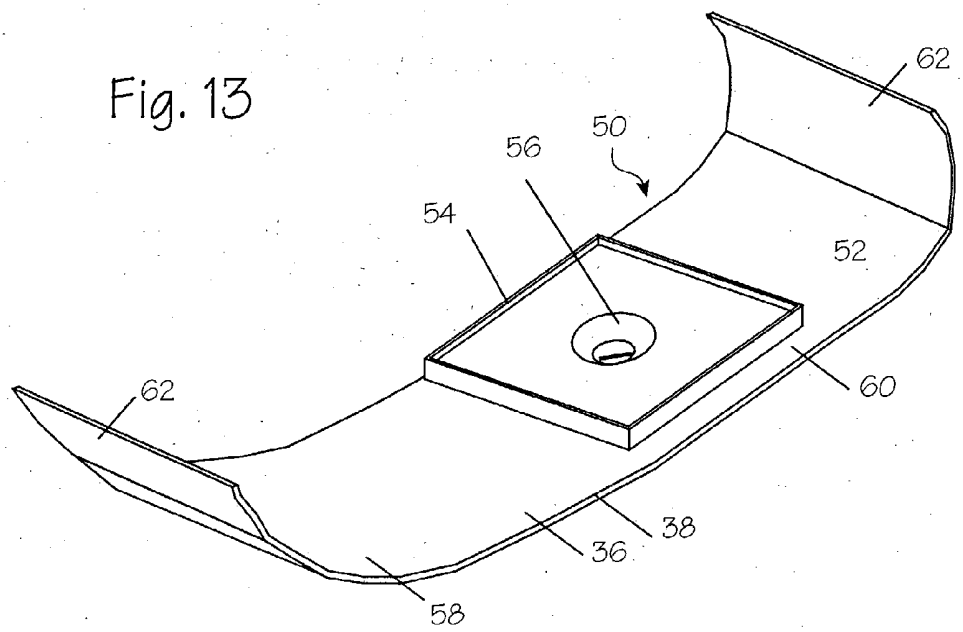


Fig. 14A

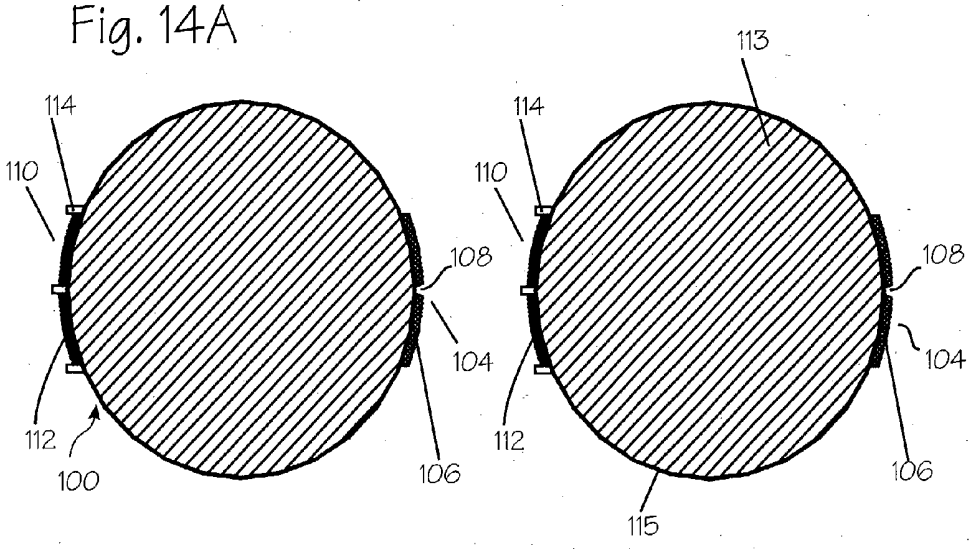


Fig. 14B

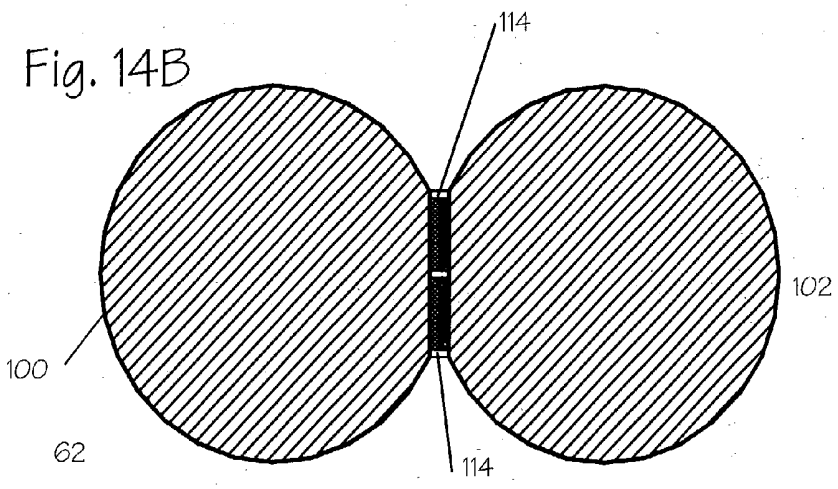
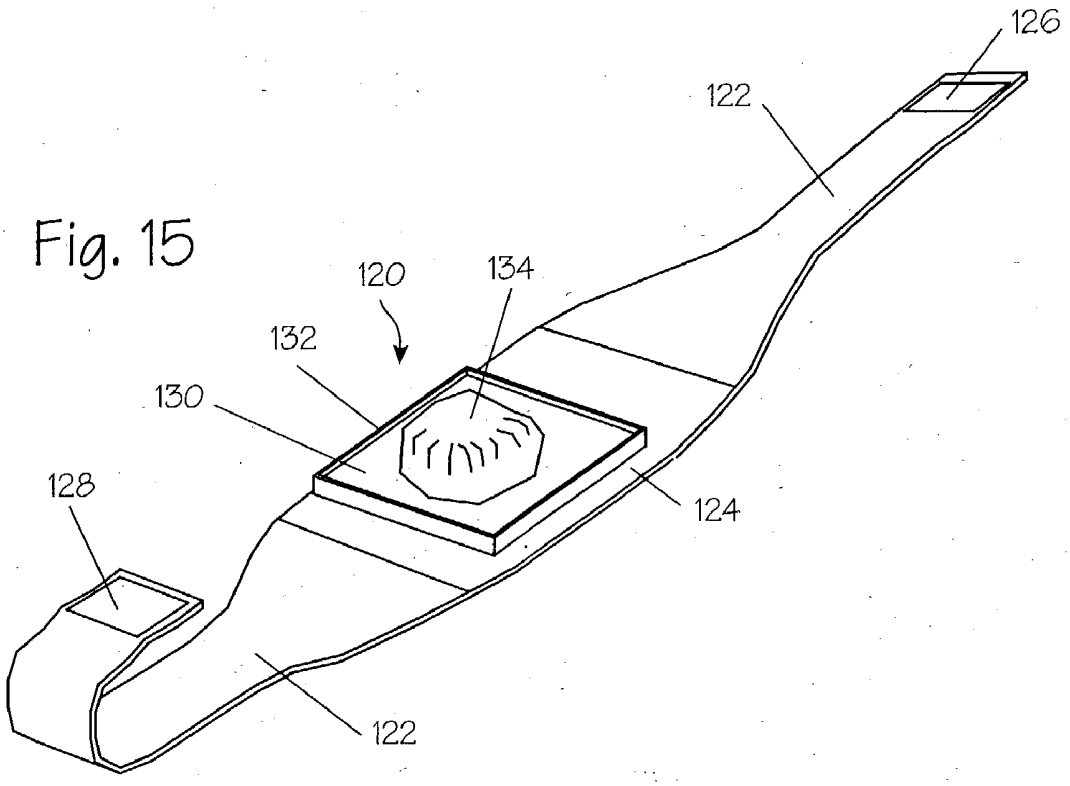


Fig. 15



METHOD AND APPARATUS FOR IMPROVED HEMOSTASIS AND DAMAGE CONTROL OPERATIONS

[0001] The present application claims priority benefit under 35 USC §119(e) from U.S. Provisional Application No. 60/354,429 filed Feb. 4, 2002, entitled "METHOD AND APPARATUS FOR IMPROVED HEMOSTASIS AND DAMAGE CONTROL OPERATIONS" and U.S. Provisional Application No. 60/424,038 filed Nov. 5, 2002, entitled METHOD AND APPARATUS FOR EMERGENCY VESSEL ANASTOMOSES, both of which are herein incorporated by reference.

FIELD OF THE INVENTION

[0002] The field of this invention is wound care during trauma surgery, general surgery, combat medicine, and emergency medical services.

BACKGROUND OF THE INVENTION

[0003] As recently as the early 1990s, surgical operations for trauma were directed at the anatomic repair of all injuries at time of the initial operation. It was observed during these exercises that many patients became hypothermic, acidotic, and coagulopathic. Patients showing these three signs often died. Death often occurred in the operating room due to exsanguinations, or postoperatively, due to the complications of prolonged shock and massive transfusion to replace blood lost as a result of the trauma.

[0004] One of the most notable developments in the recent evolution of surgery has been the introduction of the concept of staged laparotomy to overcome the deficiencies of the repair all-at-once approach. This new strategy of staged laparotomy, employing new tactics that have been termed damage control, is now used in 10% to 20% of all trauma laparotomies.

[0005] Ever since the advent of abdominal surgery, surgeons have relied on the same thinly woven cotton gauze packing pads that are currently in favor. These gauze pads are called laparotomy pads or Mickulitz pads. These pads were designed for use as sponges but not for use as hemostatic tampons. Nonetheless, since World War I, surgeons faced with severe bleeding have relied on packing patients with these sterilizable gauze sponges in an effort to control bleeding. Since World War II, it has been known that abdominal packing using these pads has been associated with abdominal sepsis and re-bleeding after pad removal. Despite these limitations, even today, they are the mainstay of damage control hemostasis.

[0006] The specific issues with the gauze pads are that they are porous and allow the free passage of blood through the mesh. Other unfavorable characteristics include the lack of intrinsic coagulation inducing properties. The pads are easily saturated but these pads do not stick to one another. The pads are capable of promoting infection because they serve as a nidus for bacteria in a contaminated field. They have no intrinsic antiseptic or antimicrobial action. These pads are unsuitable for packing solid viscera because they stick to the visceral wound tissue and cause re-bleeding upon removal. Although generally recognized as sub-optimal, the gauze pads have the advantages of being cheap, familiar and ubiquitous. For these later reasons, they continue to remain the mainstay of damage control hemostasis. Among the opportunities for new technologies and instruments to support the process of damage control, the first requirement is an improvement in the surgical pack.

[0007] Other current pads for hemostasis include gelfoam, Surgicel, and fibrin sponges. These devices are all liquid permeable and require blood coagulation to occur before impermeability and hemostasis are achieved. In addition, the fibrin sponges are very rigid and will not conform to a wound while in the dry state. Typical examples of the prior art in hemostatic packing systems include U.S. Pat. No. 5,643,596 to Pruss et al., U.S. Pat. No. 5,763,411 to Edwardson et al., U.S. Pat. No. 5,800,372 to Bell et al., U.S. Pat. No. 6,054,122 to MacPhee et al., and U.S. Pat. No. 6,056,970 to Greenawalt et al. These patents, all of which are included herein by reference, disclose permeable hemostatic packing and dressings with topical hemostatic coatings. These devices all serve the purpose of stopping bleeding in underlying vessels with an occlusive backing but the backing is still permeable to blood leakage. The lack of impermeability in these prior art patents is not recognized as an issue.

[0008] While hemostatic packing devices are well known in the art, the utility of said packing devices is limited by their propensity to harbor pathogens and their propensity to create re-bleeding by adherence to healing surfaces.

[0009] New devices, procedures and methods are needed to support the strategy of damage control in patients who have experienced massive bodily injury. Such devices and procedures are particularly important in the emergency, military, and trauma care setting. These new devices rely on the principles of impermeability to blood passage, limited nidus formation for bacteria, the ability to carry pro-thrombogenic material, and the lack of intrinsic thrombogenicity except by providing a physical barrier or pressure source.

SUMMARY OF THE INVENTION

[0010] The devices and methods described below provide for improved hemostatic packing in trauma care. The devices comprise impermeable barrier packs with various features provided to improved hemostasis, improved packing and placement of the packs, and easier removal of the pack after hemostasis is achieved. Other features of the pack include foldability and moldability to the anatomical surface. The exterior surface of the pack is not intrinsically thrombogenic but is capable of serving as a carrier for thrombogenic substances. Certain regions of the exterior surface of the pack may optionally comprise thrombogenic properties. The pack may be made with a plurality of surfaces, each with distinct characteristics. An exemplary version of the pack has a thin layer of polyethylene or polypropylene, which is impermeable to liquids, as its entire outer surface. A key advantage of the present invention, in its wet or dry state, is moldability, flexibility and shapability to the anatomical contacting surface, including the ability to pack wounds in solid viscera. The pack is able to distribute pressure within the wound to generate pressure tamponade. The pack is capable of generating pressure tamponade without regions of sharp or high stress such as would be generated by a rigid packing system. This improvement over certain very hard packing devices allows for better fit to the anatomy and the immediate formation of an impermeable barrier without the need to wait for blood coagulation to

occur to form the hemostatic barrier. The hemostatic pack of the present invention is placed via open surgery or through laparoscopic instrumentation. The laparoscopic embodiment includes the capability of reversibly or irreversibly achieving a size and mass change in the device once it is placed within the patient.

[0011] The present invention distinguishes over the cited prior art because it requires no thrombogenic coatings, although it is capable of trapping and carrying such pro-thrombogenic coatings on its surface. The outer surface of the haemostatic packing sponge serves as a carrier by incorporating indents or villi to physically hold the pharmacological, thrombogenic or antibacterial coatings. Since the surface is impermeable to liquids, the arrest of hemorrhage is immediate and does not require thrombosis to occur. When the packing device of the present invention is removed from the patient, re-bleeding does not occur because there is no penetration of the wound tissues or clot into the interstices of the pack. An additional advantage of the impermeable pack is a resistance to bacteria and other pathogenic penetration.

[0012] In another embodiment of the invention, the pack comprises raised ridges or dams on its surface. These ridges or dams are comprised of soft conformable materials that form an edge seal to prevent the escape of blood from a wound. The pack optionally comprises additional regions or borders of enhanced blood clotting or thrombogenesis to assist with the hemostatic properties of the device.

[0013] In yet another embodiment of the present invention, the hemostatic pack comprises adhesives, fasteners, or the like to allow the packs to adhere to each other, thus forming a syncytium, or contiguous barrier comprised of more than one component, to prevent blood from escaping from a wound.

[0014] For purposes of summarizing the invention, certain aspects, advantages and novel features of the invention are described herein. It is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment of the invention. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves one advantage or group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] **FIG. 1A** illustrates a two-sided hemostatic pack comprising a sheet of material that is impermeable to liquid on one side and the other side is a permeable fabric affixed to the impermeable barrier;

[0016] **FIG. 1B** illustrates a cross-sectional view of the two-sided haemostatic pack;

[0017] **FIG. 1C** illustrates the two-sided hemostatic packing device folded with the impermeable surface facing outward toward the wound surface;

[0018] **FIG. 1D** illustrates the two-sided hemostatic pack rolled with the impermeable side out;

[0019] **FIG. 2** illustrates a hemostatic packing device comprising a closed-cell foam that is impermeable on both sides;

[0020] **FIG. 3** illustrates a hemostatic packing device comprising an outer surface that is impermeable on both sides where the upper surface further comprises indentations capable of carrying exogenous thrombogenic substances;

[0021] **FIG. 4** illustrates a hemostatic packing device comprising a polygonal deformable solid with an impermeable outer surface;

[0022] **FIG. 5A** illustrates an inflatable hemostatic packing device;

[0023] **FIG. 5B** illustrates one embodiment of the inflatable hemostatic packing device in its deflated or partially deflated state;

[0024] **FIG. 6** illustrates a hemostatic packing device being introduced into a patient through a laparoscopic instrument;

[0025] **FIG. 7** illustrates a hemostatic packing device comprising an adhesive on at least a portion of the outer impermeable surface of said hemostatic packing device;

[0026] **FIG. 8** illustrates a hemostatic packing device comprising a packing material with an impermeable outer surface affixed to an adhesive impermeable drape;

[0027] **FIG. 9A** illustrates a wound of the liver;

[0028] **FIG. 9B** illustrates the wound of the liver being treated by application of internal tamponade of hemorrhage with the impermeable hemostatic packing device used in a peri-hepatic location;

[0029] **FIG. 10A** illustrates a wound of an exemplary extremity, the thigh, with femoral artery transection;

[0030] **FIG. 10B** illustrates the wound to the thigh being treated by application of an impermeable hemostatic packing device with the adhesive impermeable drape;

[0031] **FIG. 11** illustrates a wound dressing or bandage comprising a blood dam, for treating a wound to the arm or the leg.

[0032] **FIG. 12** illustrates a wound dressing or bandage for treating a wound to the arm or the leg comprising a series of blood dams.

[0033] **FIG. 13** illustrates a wound dressing or bandage for treating a wound to the arm or the leg comprising a blood dam with a communicating valve;

[0034] **FIG. 14A** illustrates a lateral sectional view of two internal hemostatic packs for solid organs, viscera, and the like;

[0035] **FIG. 14B** illustrates a lateral sectional view of two internal hemostatic packs that have been joined together to form a syncytium wherein the barrier regions or dams render the adherent region impermeable to fluids such as blood.

[0036] **FIG. 15** illustrates an oblique view of a preferred wound dressing or bandage for treating a wound to a body part comprising a strap, a blood dam, and a pillow pack.

DETAILED DESCRIPTION OF THE INVENTION

[0037] **FIG. 1A** illustrates a diagram of a two-sided hemostatic packing device **10** of the present invention. The two-sided packing device **10** comprises a blood permeable

layer or substrate **12** and a blood-impermeable sheet **14**. The fluid impermeable sheet **14** further comprises an optional adhesive layer **16**, and a plurality of optional indentations **18** on the exterior surface. The fluid impermeable surface **14** or the substrate **12** may optionally comprise a plurality of radiopaque markers **20**. The hemostatic packing device **10** is a flat sheet that is flexible and deformable. The substrate **12** is a flat sheet configuration and is integral to or affixed to the fluid impermeable sheet **14**. The fluid impermeable surface **14** optionally comprises a plurality of indentations **18**. The radiopaque markers **20** may be wire form, dots or patches of barium-impregnated fabrics.

[**0038**] The substrate **12** is soft in its wet or dry state and may be bent, molded or deformed to maximize surface contact and force distribution on injured tissue. The substrate **12** is fabricated from cotton gauze, open or closed cell foam, sponge, fluids, particulates and the like, or from inflatable or packable masses of particulates. The foam configuration of the substrate **12** may be fabricated from materials such as polypropylene, polyvinyl chloride, polyurethane, polyethylene, silicone rubber, poly methyl methacrylate, polyvinyl alcohol and the like. The particulates of the inflatable embodiment of substrate **12** may be beads of collagen, PTFE, silica and the like. The fluid impermeable sheet **14** is fabricated from materials such as polypropylene, polyvinyl chloride, polyurethane, polyethylene, silicone rubber, poly methyl methacrylate, polyvinyl alcohol, Tyvek® and the like. The fluid impermeable surface **14** may also be fabricated from materials such as paper or cloth that is then coated or sprayed with impermeable materials such as polyethylene, polypropylene and the like. The use of rip-stop fabrics will help prevent tearing of the fluid impermeable surface **14**.

[**0039**] The hemostatic packing device **10** is fabricated in a variety of sizes and thicknesses. The thickness varies from 0.1 mm to 50 mm. The length and width each may vary from 5 mm to 500 mm. The geometry is generally rectangular but may have triangular, circular, or polygonal configurations. The corners may be square or rounded.

[**0040**] The radiopaque markers **20** are fabricated from a group of materials including but not limited to barium impregnated fabrics or polymers, metal wires, and metal solids. Typical metals used for radiopacity include tantalum, platinum, gold, and the like.

[**0041**] The hemostatic packing device **10** is packaged in a sealed, sterile barrier package and is sterilized using standard techniques such as steam, cobalt radiation, ethylene oxide, electron beam and the like.

[**0042**] Referring to **FIG. 1**B, the hemostatic packing device **10** is shown from the side. The substrate **12**, the fluid impermeable surface **14**, and the adhesive layer **16** are clearly visible in this view.

[**0043**] **FIG. 1C** illustrates one embodiment of the hemostatic packing device **10** that is folded with the fluid impermeable surface **14** facing outward in preparation for use.

[**0044**] **FIG. 1D** illustrates another embodiment of the hemostatic packing device **10** that is rolled with the fluid impermeable surface **14** facing outward in preparation for use.

[**0045**] **FIG. 2** illustrates another embodiment of the haemostatic packing device **10** where the substrate **12** and the impermeable outer layer **14** are fabricated from the same material. In this embodiment, the hemostatic packing device **10** is fabricated from closed-cell foam, where the substrate is the foam, and the outer layer is the typically impermeable skin of the foam. The foam material allows for a resilient, deformable substrate while maintaining the outer cover **14** that is impermeable to fluid penetration since it is a closed cell structure.

[**0046**] **FIG. 3** illustrates the hemostatic packing device **10** where the upper side of the fluid impermeable surface **14** comprises indentations **18**, that may be in the form of dimpling or waffling of varying depth that are useful to deliver thrombogenic, pharmaceutical or antibacterial agents. The indentations **18** are formed using molds wherein the outer surface **14** of the closed-cell substrate **12** is formed against the mold. In another embodiment, the indents **18** are formed by impressing the fluid impermeable outer sheet with a mold or other forming device. In yet another embodiment, the outer surface **14** comprises projections, or villi, that serve to trap and carry the pharmaceutical, antibacterial or thrombogenic agents. The projections or indents may be macroscopic or microscopic.

[**0047**] **FIG. 4** illustrates another embodiment of the haemostatic packing device **10** wherein the substrate **12** forms a polygonal solid. The polygonal solids include shapes such as brick or rectangular solid, waffle, pyramid, sheet, and oval. The polygonal solids also include extruded shapes such as cylinders, or extended lengths of cross-sections such as rectangular, oval, circular, trapezoidal, triangular, etc. The lengths of these devices range from 5 mm to 1000 mm. The width dimensions of these devices range from 1 mm to 200 mm. For a typical use, such as v-shaped wounds such as laceration in the leg, the device can be provided in dimensions of about three to four inches long, with triangle side of about 0.5 to 2 inches. At least part of the outer surface **14** of the hemostatic packing device **10** comprises a fluid impermeable barrier. This fluid impermeable barrier **14** may be smooth, indented, or covered by villi, or projections. The substrate **12** is fabricated from materials that allow for deformation in the dry or wet state. These materials include cotton batting, polymeric foams of varying densities, sand, polymer beads, oils including silicone oils, water, and the like.

[**0048**] Referring to **FIGS. 1A, 1B**, 1C, 1D, **2, 3**, and **4**, the hemostatic packing device **10**, in another embodiment, comprises a fluid impermeable layer **14** that is fabricated from resorbable materials. The substrate **12** may be removed and the impermeable layer **14** left behind to complete healing. The resorbable layer **14** is fabricated from resorbable materials such as polyglycolic acid (PGA), polylactic acid (PLA) and the like. The fluid impermeable layer **14** has a complex surface that comprises indentations or villi **18**.

[**0049**] **FIG. 5A** illustrates yet another embodiment of the hemostatic packing device **10** wherein the device may have fluid reversibly or irreversibly introduced to provide for size adjustment. The outer layer **14** is, as in the previous figures, fluid impermeable. It is formed into a closed bladder with a shape adapted to fill typically voids in damaged organs and body parts. An access port **22** provides for fluid communication from the exterior of the packing device to the interior of the device, for introduction of substrate materials or materials to fill the substrate **12** within the outer layer. In this

embodiment, the substrate **12** is bladder formed from a fluid impermeable membrane that is filled with material to achieve the desired volume. The substrate **12** membrane is fabricated either from elastic materials such as silastic or polyurethane, or it is an inelastic bag with folds that allow for size increase. The outer surface of the substrate **12** preferably is not adhered in all places to the outer surface **14** of said device **10** and optionally a lubricating layer **24** is placed between the two structures. The outer layer **14** of said device **10** is fabricated from either elastic materials such as polyurethane or silicone rubber, or it is an inelastic material such as polyethylene terephthalate, polyimide, polypropylene.or polyethylene or a copolymer including one of these materials. The outer layer **14** of the hemostatic packing device **10** may be smooth, indented or include villi. The villi or indents may be macroscopic and have size ranges from 0.1 mm to 10 mm. The villi or indents may also be microscopic and difficult to see with the unaided eye. Such sizes are less than 0.1 mm.

[**0050**] Referring to **FIG. 5A**, the hemostatic packing device **10** comprises a hydrogel material that is placed into a wound and expands upon absorption of fluids from the patient to compress the wound. In this embodiment,. the substrate **12** is fabricated from hydrophilic hydrogels such as those described by Park et al. and are incorporated herein by reference. Hydrogels are made from materials such as, but not limited to, carboxymethyl cellulose, cross-linked sodium starch glycolate, and cross-linked polyvinylpyrrolidone and the like. The substrate **12** can also be fabricated from a water-absorbable sponge that expands once it becomes wet. The water-absorbable sponge may be fabricated from materials such as, but not limited to polyvinyl alcohol, polymethyl cellulose, and the like. In this embodiment, the fluid impermeable outer layer **14** is provided with an opening to allow for fluid penetration into the substrate **12** to allow the expansion to occur. This opening may be the nipple **22** and the fluid to expand the hydrogel or sponge may be injected through the nipple **22**. Alternatively, in the case of the hydrogel, the substrate **12** and the surface **14** may be of the same hydrogel material. Hydrogels generally absorb water but do not adhere to biological surfaces. The hemostatic packing device **10** fabricated from hydrogel would be small enough in its dry state to be introduced through a laparoscopic access port and expand due to water absorption once placed within the body.

[**0051**] The devices of **FIGS. 5A and 5B** may be filled just prior to placement in the patient. The degree to which they are filled may be determined by the doctor or paramedic, depending on nature of the wound, including its size and organ which is wounded. The packs may also be filled or deflated after placement, whether to account for leakage or to adjust the size to account for changes in physiology or to make room for surgical devices. Such intraoperative filling of the bladder may be accomplished in an intraoperative time frame encompassing initial encounter and diagnosis of the patient, field treatment, emergency. treatment and delayed treatment. The devices may also be placed perioperatively for a short period of recovery after surgery performed to repair the trauma.

[**0052**] **FIG. 6** illustrates the hemostatic packing device **10** being introduced into a wound **42** in a liver **40** through a laparoscopic instrument **30**. The laparoscopic instrument **30** is an axially elongate hollow device that provides porthole access to the internal organs of a patient.

[**0053**] **FIG. 7** illustrates the hemostatic packing device **10** comprising an adhesive strip **28** on one side. The adhesive strip **28** is used to permit attachment of the hemostatic packing device **10** to other similar devices so as to create an impermeable syncytium or impermeable contiguous mass. The adhesive strip may also comprise an optional peel away cover that protects the adhesive strip **28** prior to use. The peel away cover is fabricated, preferably, from the same materials use to fabricate the fluid impermeable outer surface **14** of the hemostatic packing device **10**. The adhesive strip is optionally fabricated from materials such as Velcro or even self-adhesive materials such as Coban, marketed by 3M.

[**0054**] **FIG. 8** illustrates another embodiment of the hemostatic packing device **10** further comprising a fluid impermeable drape **32** affixed to the packing device **10**. The fluid impermeable drape **32** is, preferably adhered to the hemostatic packing device **10**. The drape **32** comprises an adhesive layer **36** and a backing layer **38**. The backing **38** is, preferably, fabricated from non-elastomeric materials such as, but not limited to, polyethylene, polypropylene, and the like. It is preferable that the drape **32** does not stretch once applied. The adhesive layer **36** is on the same side of the drape **32** to which the hemostatic packing device **10** is affixed. The hemostatic packing device **10** further optionally comprises a series of straps **34** to assist with fixation of the device to the patient. The straps **34** are fastened with standard buckles, Velcro or the like. This embodiment of the device **10** is useful for treatment of wounds to the periphery and especially those wounds that involve vascular injury. Such periphery includes the thigh, knee, lower leg, arm, shoulder, and forearm.

[**0055**] **FIG. 9A** illustrates the wound **42** to the liver **40**. The liver **40** represents an exemplary case of parenchymal tissue that is friable and becomes severely damaged during an abdominal injury.

[**0056**] **FIG. 9B** illustrates the wound **42** to the liver **40** being treated by application of intra-parenchemal packing using one or more hemostatic packing devices **10**. In this embodiment, two hemostatic packing devices **10** are used to provide hemostasis for the wound **42**. The hemostatic packing devices **10** are applied manually via open surgery or laparoscopically, depending on the nature of the wound and the surgical technique, as determined by the doctor or paramedic placing the packs.

[**0057**] **FIG. 10A** illustrates a wound **44** to the periphery and more specifically, the thigh **46**. The wound **44** has caused femoral artery **48** to become transected.

[**0058**] **FIG. 10B** illustrates the wound **44** to the thigh **46** being treated by application of the impermeable hemostatic packing device **10** with the adhesive impermeable drape **32** and straps **34**.

[**0059**] In yet another embodiment, a wound closure is fabricated from a material that has skin and wound contact surfaces that are impermeable to water, blood and tissue penetration. Preferably, these wound closure devices are fabricated from sheets of materials such as, but not limited to, polyurethane, polypropylene, polyethylene, silicone elastomer, and the like. The skin contact surface is a biocom-

patible adhesive and is further impregnated with anti-microbial agents such as, but not limited to, iodine, betadine and the like. The bandage or wound closure device is large enough to completely surround the wound and seal in the wound so that blood cannot escape. The bandage, optionally, has additional straps that fully surround the body or appendage and seal with Velcro, buckles, clamps or the like. The bandage or wound closure device seals the wound against the full systolic blood pressure and, thus tamponade any bleeding that occurs from damaged vessels other than the one repaired with the shunt **10**. The bandage comprises an adhesive region that sticks to the skin, even if the skin is wet or bloody. The bandage is optionally maintained in place using straps that wrap around the body or appendage and secure the bandage in place with adequate pressure to generate pressure tamponade of the wound.

[**0060**] The preferred wound closure is a large piece of Ioban, a trademark and product of 3M Corporation, the non-adhesive side of which is adhered to a piece of woven gauze or mesh to provide adequate structure to the weak membrane of the Ioban. The Ioban has adhesive and anti-microbial properties preferred for this application. A strap extending from opposing ends of the bandage and terminated with Velcro or 3M Coban, which is self-adherent, assists in maintaining pressure against the wound and proving full tamponade of the hemorrhage. In yet a further embodiment, the central part of the skin contact region comprises a malleable or conformable pad, preferably adhered to the wound closure device, which helps to exert hemostatic force on the wound. The conformable pad evenly distributes the forces throughout the wound so that no areas receive either too high a pressure, or too low a pressure, such as would permit further bleeding. The conformable central pad may be a block of foam covered by the aforementioned impermeable layer, or it may be an impermeable membrane, preferably elastomeric, filled with liquid such as saline or even a particulate material such as, but not limited to, sand, flour, sugar, silicone oil, or the like. In a preferred embodiment, the material used to form the fluid-tight membrane is liquid impermeable but gas permeable. Materials suitable for such permeability requirements include expanded polytetrafluoroethylene (ePTFE) and the like.

[**0061**] **FIG. 11** illustrates a wound dressing or bandage comprising a blood dam, for treating a wound to the arm or the leg. The hemostatic packing device **10** is in the form of a wound dressing or bandage **50**. The wound dressing or bandage **50** further comprises a gauze or absorbent region **52**. The gauze or absorbent region **52** may have material bulked up or rolled up to aid in the application of pressure to cause pressure tamponade of the wound or perforation to the body. The gauze or absorbent region **52** may alternatively be a fluid pouch, which may be inflated or deflated to apply the required pressure tamponade to the wound area. The gauze or absorbent region **52** is further comprised of a peripheral gasket **54** or a plurality of gaskets **54** running in a honeycomb, rectangular or other appropriate pattern throughout and within the gauze or absorbent region **52** of the bandage **50**. The gasket **54** aids in hemodynamic control and is made out of fluid impermeable materials, such as, but not limited to, silicone, C-flex, hydrogels, silicone oil-filled membrane, polyurethane closed-cell foam, and the like. The typical width of the gasket **54** material will be ⅛ to ¼ inch, but the gasket may be made larger for wounds that require greater hemodynamic stabilization which can be achieved by the damming function of a larger gasket. The gasket **54** is wide enough to distribute pressure over the skin area so as not to cause petcheciae, bruising or tissue damage while applying enough pressure to seal against systemic arterial pressure, typically 100 to 300 mm Hg. The dam or gasket **54** generally presses gently into the tissue surrounding the wound to ensure a strong resistance to hemorrhage or leakage of blood beyond the dam. Affixed or integral to the gauze or absorbent region **52** is a plurality of fluid impermeable straps **58** that will wrap around the extremity or wound area. The straps **58** may contain an adhesive layer **36** or may be of material suitable for stretch wrapping. Optionally, the straps **58** may comprise an adhesive layer **36** and a backing layer **38**. The backing **38** is, preferably, fabricated from non-elastomeric materials such as, but not limited to, polyethylene, polypropylene, Tyvek, polytetrafluoroethylene, polyester, and the like. Another option for the straps **58** could be adhesive straps **58** made from materials such as, but not limited to, those manufactured by 3M, Inc., under the trade name of Ioban. This material would be suitable and desirable for use as the straps **58** due to its chemical composition and inherent antiseptic properties. In addition, the wrapping material may also have buckles or Velcro **62** or another means of securing or attaching the bandage in place on the patient. Self-adhesive materials such as, but not limited to, those manufactured by 3M, Inc., under the trade name of Coban are suitable for use as the binding system for the straps **58**. The straps **58** may also be fluid impermeable, so as to aid in the wound containment. The bandage or wound dressing **50** also has a free end or side **60**. Ideally, the wound dressing or bandage **50** would be packaged with a protective, removable layer over the gauze or absorbent region **52** and quite possibly over the entire surface applied to the patient.

[**0062**] **FIG. 12** illustrates another embodiment device illustrated in **FIG. 11**. The hemostatic packing device **10** is in the form of a wound dressing or bandage **50**, as shown in **FIG. 11**. The wound dressing or bandage **50** further comprises a gauze or absorbent region **52**. The gauze or absorbent region **52** is further comprised of a plurality of dams or gaskets **54** running or weaving in a honeycomb, rectangular, diamond, or other appropriate pattern throughout and within the gauze or absorbent region **52** of the bandage **50**. The gasket **54** aids in hemodynamic control and is made out of fluid impermeable materials, such as, but not limited to, silicone, C-flex, hydrogels, silicone oil-filled membrane, polyurethane closed-cell foam, and the like. The typical width of the gasket **54** material will be ⅛ to ¼ inch (again, the gasket may be made larger for wounds that require greater hemodynamic stabilization which can be achieved by the damming function of a larger gasket). The gasket **54** is wide enough to distribute pressure over the skin area so as not to cause petcheciae, bruising or tissue damage but enough pressure to seal against systemic arterial pressure, typically 100 to 300 mm Hg.

[**0063**] **FIG. 13** illustrates a wound dressing with a blood dam as shown in **FIGS. 11 and 12**, modified with the addition of a valve communication from the intended body contacting surface to the intended exterior or superficial side of the wound dressing. The hemostatic packing device **10** is in the form of a wound dressing or bandage **50**, similar to those shown in **FIG. 11** of **12**. The wound dressing or bandage **50** further comprises a gauze or absorbent region **52** and a valve **56**. The valve **56**, which resides within the gasket

54, may be used to remove fluids or add agents to assist in the coagulation or wound containment. The valve **56** may be, but is not limited to, a duck bill type of valve, or the like.

[**0064**] **FIG. 14A** illustrates a system of hemostatic packs which can be releasably attached together just prior to use to form a hemostatic structure as desired by the doctor treating a patient. Hemostatic packs **100** and **102** both comprise solid shapes (such as cylinders, prisms, pyramids, cones, sheres, polyhedrons and extended lengths with other cross-sections such as rectangular, oval, circular, trapezoidal, triangular, etc.), each with an impermeable outer layer **115** and a soft-conformable filler region **113**. The left hand internal pack **100** further comprises a female adhesive region **104** further comprising an adhesive material **106** and a plurality of adhesive material gaps **108**. The right hand internal pack **102** further comprises a male adhesive region **110** further comprising an adhesive material **112** and a plurality of dams **114**. In the preferred embodiment each hemostatic pack has at least one male adhesive region **110** and one female adhesive region **104** so that a plurality of packs can be chained together to form a contiguous blood impermeable barrier. In the preferred embodiment, the adhesive material **106** is the hook style of Velcro® type hook and loop fastener while the adhesive material **112** is the tufted style of Velcro fastener. Thus when the adhesive regions **106** and **112** are brought into contact, they adhere to each other. The adhesive regions **106** and **112** are reversibly adherent to each other and may be separated by manual force, if desired. In another embodiment, the adhesive regions **106** and **112** may be fabricated from materials such as 3M Coban and the like, hydrogel adhesives and the like, and typical adhesives such as are used in medical bandages. Thus, the hemostatic packs are provided with releasable attachment means, and any other suitable releasable attachment means may be use in place of those illustrated. The adhesive material gaps **108**, in the female adhesive region **104** are spaced and designed so that the dams **114** of the male adhesive region impinge on and seal against an impermeable surface of the female adhesive region **104**. The adhesive material gaps **108** and the dams **114** may be configured in a straight line or they may be curved into a wavy pattern to improve the sealing area. Special guide markers either printed on the packs **100** and **102** or fabricated as raised or detented surfaces on the packs **100** and **102** facilitate alignment of the dams **114** and the adhesive material gaps **108**.

[**0065**] **FIG. 14B** illustrates a cross-sectional view of the internal packs **100** and **102** following joining to form a continuous barrier pack. Referring to **FIGS. 14A and 14B**, the dams **114** seal against the impermeable surface **115** through adhesive material gaps **108**. The adhesive regions **106** and **112** are firmly in contact and grip each other to hold the two packs **100** and **102** together without any area of seepage, leakage, or weeping. The dams **114** and the corresponding receiving gaps **108** serve to block any flow of fluid through the hook and loop fastening system (which may initially be somewhat permeable to blood), as well as to provide guides to help doctors assembling a gang of packs assemble them without substantial gaps between adjacent packs. For a typical use, such as internal organ packs (a ruptured liver, for example), the device can be provided in dimensions of about 3 to 4 inches long, about 0.5 to 2 inches in diameter, so that a doctor may assemble several packs into a gang to form a substantial wall to cover a large fracture.

[**0066**] In yet another embodiment of the barrier pack, the mating region between the two packs comprises adhesive regions such as those described for **FIG. 14A**, except that the barrier dams are replaced with fluid impermeable flaps that fold in to cover the adhesive regions following joining. One flap preferably covers each side of the adhesive region. In a preferred embodiment, the flaps cover the adhesive regions until they are needed to join with another barrier pack. At that time, the flap is pulled away, the two packs are joined, and the flap is folded in to cover the adhesive region and form a fluid-tight seal between the two barrier packs.

[**0067**] Referring to **FIG. 1** through **FIG. 14A and 14B**, the hemostatic packing device **10** is used to treat wounds that are typically caused by trauma. In a typical procedure, the surgeon or medic, using aseptic procedure, accesses the wound either by open surgery or laparoscopic surgery. The wound is irrigated and cleaned and excess fluids are removed by suction and blotting with gauze sponges. The surgeon may apply antiseptic agents or thrombogenic agents to the wound. The surgeon places the hemostatic packing device **10** into the wound and the device **10** is secured into place. Using current damage control procedure, it is preferable to stabilize the patient prior to removing the hemostatic packing device **10** and permanently repairing the wound. The hemostatic packing device **10** does not stick or heal into the wound and removal is not traumatic to the patient. The hemostatic packing device **10** is also well suited for a typical "sucking chest wound" because of its inherent impermeable properties. In this use, the one-way valve **56** permits fluid and air to exit the chest cavity but prohibits reflux of air into the chest cavity, a condition which prevents lung function and which is known as pneumothorax.

[**0068**] **FIG. 15** illustrates a preferred embodiment of a wound dressing or bandage **120**. The wound dressing or bandage **120** comprises a backbone **122** with a central region and two ends, a first fastener **126**, a second fastener **128**, a fluid-impermeable barrier **124**, a fluid dam **132**, a pillow pack **134**, and an optional peripheral hemostatic region **130**. The wound dressing or bandage **120** is configured to wrap around a body part, arm, leg, torso, head, etc. and fasten using the first fastener **126** and the second fastener **128**. The fasteners **126** and **128** are of the type including, but not limited to, Velcro, buckles, snaps, jam cleats, buttons, and the like. An optional cinch mechanism to increase mechanical advantage and allow the caregiver to apply the bandage **120** with increased compression may be added to the configuration. The backbone **122** is preferably a woven fabric of material such as, but not limited to cotton, polyester, polypropylene, polyurethane, polyethylene, PTFE, nylon, and the like. The woven backbone is configured to be flexible but have high tensile strength, while porosity is not an important characteristic. The impermeable barrier **124** is preferably applied to the central region of the bandage **120** and is created by a separate polymer layer that is adhered or welded to the backbone **122**. The backbone **122** may also be dipped, sprayed, or coated with materials such as, but not limited to, polyurethane, C-Flex thermoplastic, silicone elastomer, and the like. Since the dressing is intended for short-term application, gas permeability is not considered objectionable but it is desirable. The fluid dam **132** is fabricated from materials including those used to fabricate the fluid impermeable barrier **124**. The fluid dam **132** may also be fabricated from gel-filled membranes, hydrogels, oil-filled membranes, and the like. The membrane of the

fluid dam **132** is preferably, inelastic at the pressures used for filling. The fluid dam **132** is configured to provide a pressure seal against the body and form a complete barrier to prevent blood from escaping the wound. In another embodiment, the fluid dam **132** is inflatable following or before application to the patient through a valve such as a stopcock or standard inflation valve on the exterior surface of the bandage **120**.

[**0069**] Further referring to **FIG. 15**, the pillow pack **134** is adhered to the central region of the bandage **120**, preferably to the fluid impermeable region **124**. The pillow pack **134**, preferably resides within the region described by the fluid dam **132**. The pillow pack **134** outer surface is preferably smooth and resistant to blood adherence but in another embodiment, the pillow pack **134** outer surface may be a fabric mesh or other convoluted surface capable of accelerating thrombosis or of carrying thrombogenic materials or antimicrobial agents. The pillow pack **134** is the primary distributor of force upon the wound to generate pressure tamponade. The pillow pack **134** is capable of extruding into a wound and distributing pressure evenly to generate hemostasis. The pillow pack **134** preferably comprises an elastomeric membrane filled with materials such as, but not limited to, air, water, oil, sand, gel materials, and the like. The pillow pack **134** in the embodiment where gas, air or liquid, is used for inflation, comprises an optional valve such as stopcock on the exterior surface of the bandage **120**. The peripheral hemostasis region **130** preferably resides within the fluid dam **132** and accelerates clotting in the region outside the wound area but within the environs of the bandage **120**. The peripheral hemostasis region **130** is fabricated from materials such as, but not limited to, cotton gauze, polyester knits and the like.

[**0070**] The present invention is suitable for wounds to many parts of the body. The external hemostatic pack works on the arms, the legs, the head, a finger, the torso, etc. The present invention also describes a band-aid type device with the further enhancement that a fluid-tight dam is comprised within the device to prevent blood loss out the side of the band-aid.

[**0071**] The present invention includes apparatus and methods for treating wounds. The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is therefore indicated by the appended claims rather than the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A device adapted for packing a wound and achieving hemostasis comprising:

a three dimensional pack, said pack comprising a soft, pliable substrate at least partially covered with a fluid impermeable covering; and

a releasable attachment means adapted for releasably securing the pack to other packs.

2. The device of claim 1 wherein releasable attachment means comprises an adhesive region on at least a portion of the covering.

3. The device of claim 1 further comprising a plurality of indentations adapted to carry haemostatic agents.

4. The device of claim 1 further comprising anti-pathogenic agents disposed on the covering.

5. The device of claim 1 further comprising haemostatic agents disposed on the covering.

6. The device of claim 1 further comprising a plurality of indentations adapted to carry anti-pathogenic agents.

7. The device of claim 1 further comprising a plurality of indentations filled with haemostatic agents.

8. The device of claim 1 further comprising a plurality of indentations filled with anti-pathogenic agents.

9. The device of claim 1 wherein the device substrate comprises a water swellable hydrogel and a fluid permeable region on at least a portion of said outer surface of said device.

10. The device of claim 1 wherein the substrate comprises cotton gauze.

11. The device of claim 1 wherein said fluid impermeable cover comprises a polymeric membrane.

12. The device of claim 11 wherein said polymeric membrane is comprises polymers chosen from the group of polyurethane, polyester, polyethylene, polypropylene, silic one elastomer, polymethyl methacrylate, polyvinyl chloride or a copolymer including one of these materials.

13. The device of claim 1 wherein said substrate comprises foam.

14. The device of claim 1 wherein said substrate comprises open-cell foam.

15. The device of claim 1 wherein said substrate comprises closed-cell foam.

16. The device of claim 1 wherein said substrate comprises silicone oil.

17. The device of claim 13 wherein said foam comprises polyurethane, polyvinyl chloride, polyethylene, polyvinyl acetate, silicone rubber, polyvinyl chloride, polymethyl methacrylate or a copolymer including one of these materials.

18. A method of achieving wound hemostasis that involves the steps of:

providing a hemostatic packing device, said device comprising a conformable mass with a fluid impermeable cover on at least a part of its exterior surface

packing the wound by placing a hemostatic packing device on the wound; and

removing said device once hemostasis is achieved.

19. The method of claim 18 wherein placement of said hemostatic packing device includes the steps of:

inflating said device with fluids or particulates.

20. The method of claim 18 wherein the placement of said device is accomplished laparoscopically.

21. The method of claim 19 wherein the placement of said device is accomplished laparoscopically.

22. The method of claim 19 wherein deflation of said device is accomplished through an axially elongate hollow introduction device.

23. The method of claim 19 further comprising the steps of removing the packing device laparoscopically.

* * * * *

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摘要(译)

公开了用于在受创伤的患者中实现止血的装置和方法。这种止血包装装置和方法在紧急情况，创伤手术或军事环境中特别有用。在这种情况下，患者可能已经受到腹部内脏，胸腔或周边的创伤。该装置利用流体不可渗透的外表面和分布的压力来主要通过施加压力来实现填塞和止血。这些装置具有各种配置，包括片材，轧制片材，折叠片材和包括挤出形状的多边形固体。该装置能够用作血栓形成剂或抗病原体剂的载体。这些装置在潮湿或干燥状态下是柔性的，可弯曲的和适形的，因此它们在伤口上施加分布的压力。外周止血包装装置包括可选的粘合剂止血屏障，以覆盖止血包装上的整个伤口区域。止血包装装置可以通过开放手术或腹腔镜进入放置和移除，而不会产生过多的再出血，并且可以进一步包括抗微生物或血栓形成区域。