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Bohl et al.

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(54) **SYSTEMS AND METHODS FOR A SPINAL SHIELD FOR PROTECTING THE SPINAL CORD AND DURA DURING SURGICAL PROCEDURES**

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(22) Filed: **Feb. 15, 2024**

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A61B 17/02 (2006.01)

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CPC ***A61B 17/025*** (2013.01); *A61B 2017/0262* (2013.01)

(58) **Field of Classification Search**
CPC A61B 2017/0262; A61B 2090/0815; A61B 17/7071; A61B 17/7043
See application file for complete search history.

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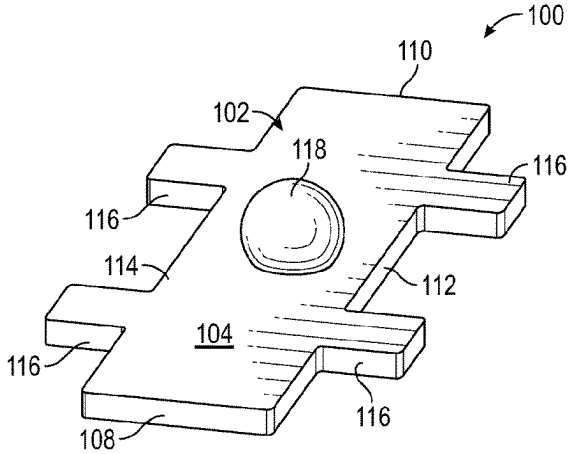
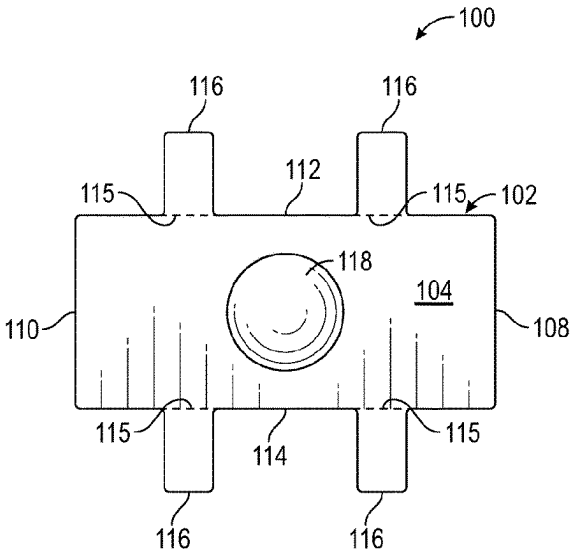
(74) *Attorney, Agent, or Firm* — Polsinelli PC

(57) **ABSTRACT**

Various embodiments of a spinal shield having a shield body including a plurality of lateral extensions configured to be positioned over an exposed spinal canal for establishing a protective barrier around the contents of the exposed spinal canal are disclosed.

3 Claims, 7 Drawing Sheets





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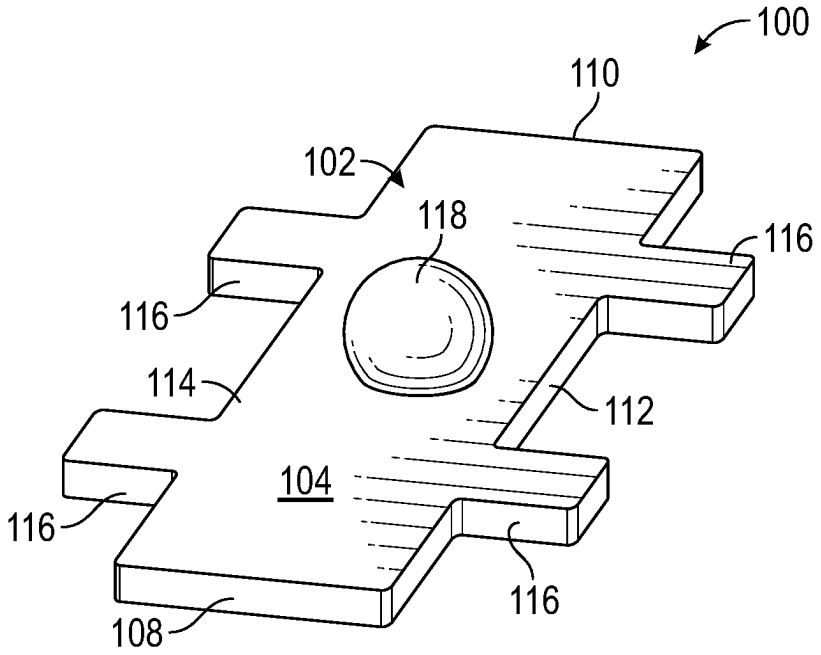
100
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FIG. 1

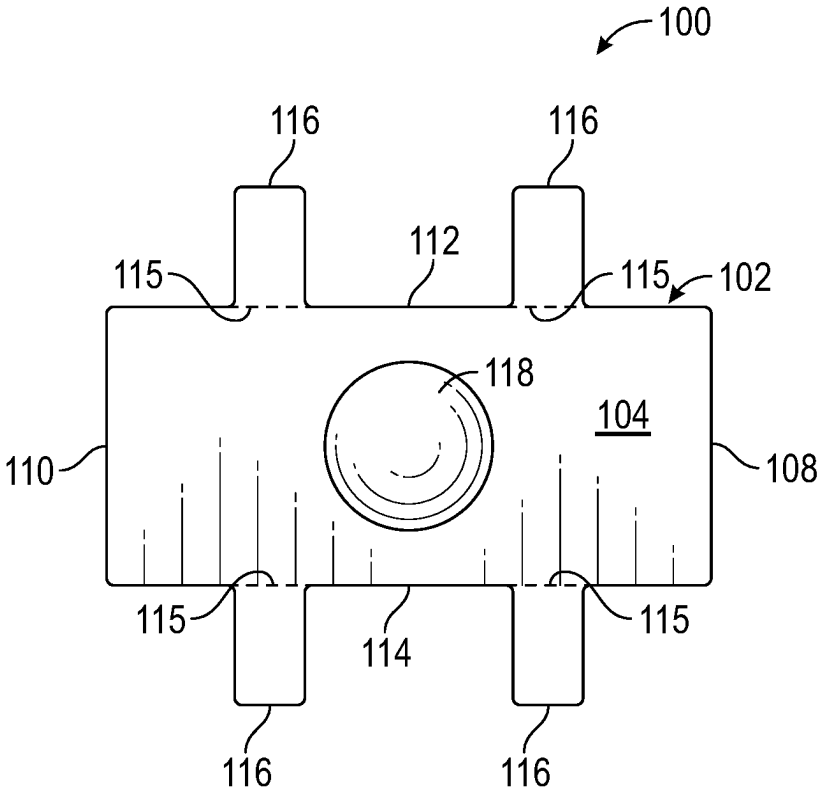
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FIG. 2

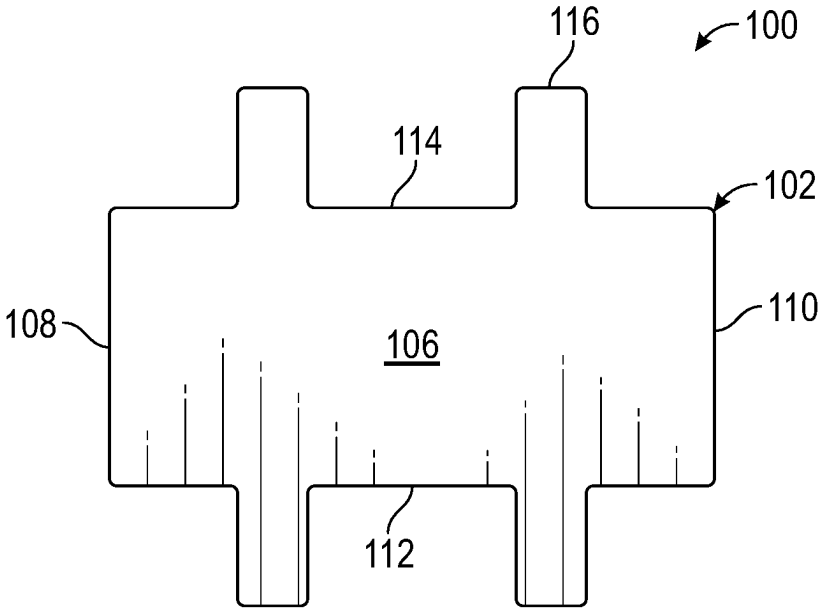


FIG. 3

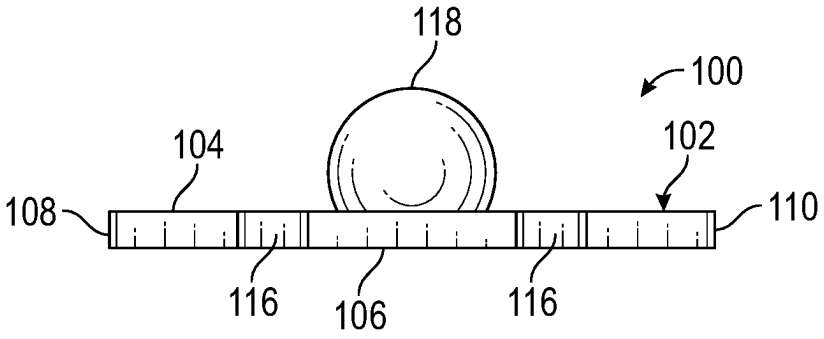


FIG. 4

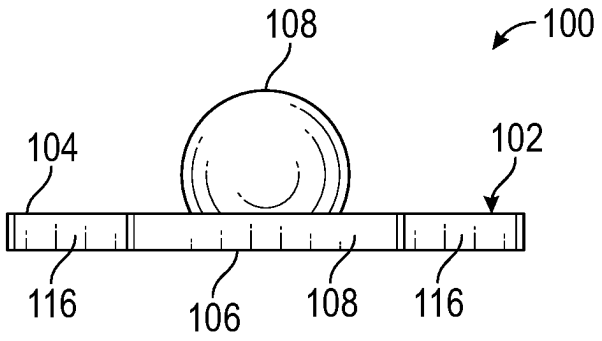


FIG. 5

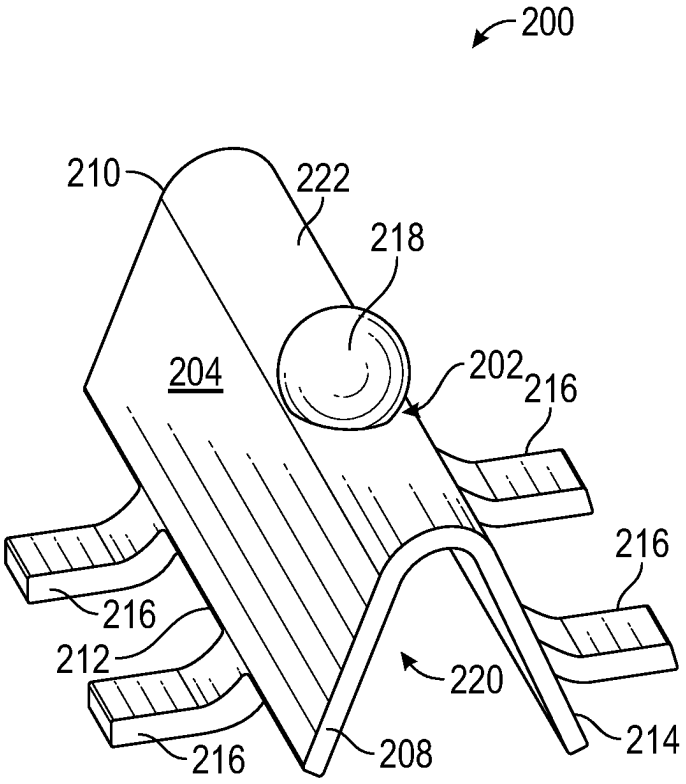
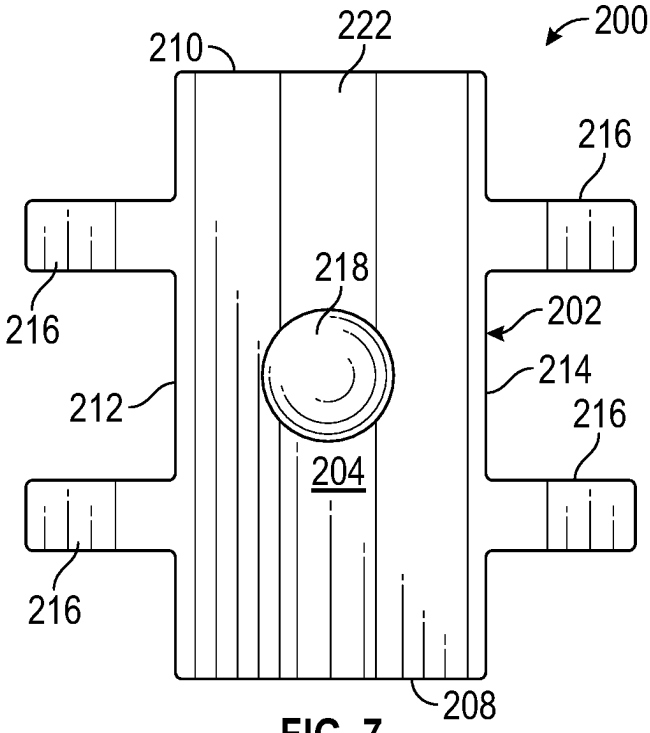


FIG. 6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204
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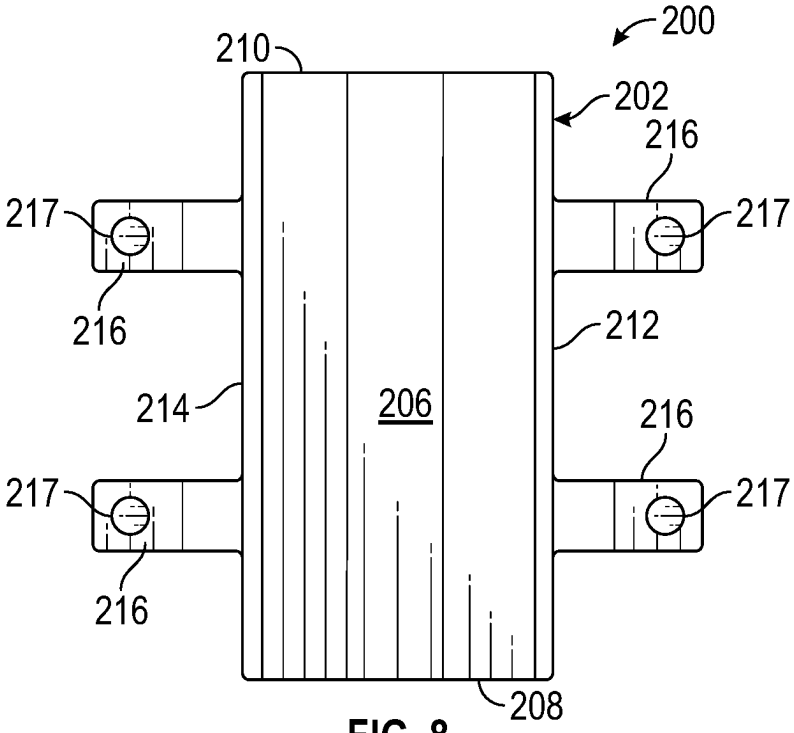
208

FIG. 7


200
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206
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FIG. 8

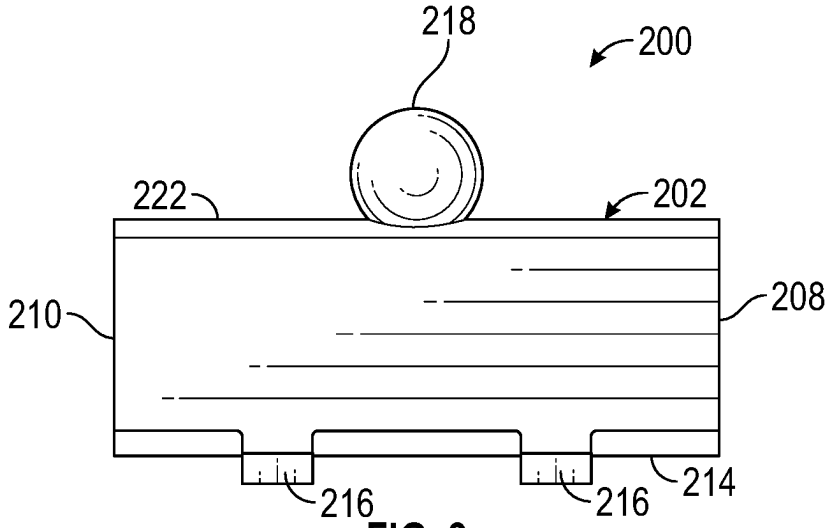
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FIG. 9

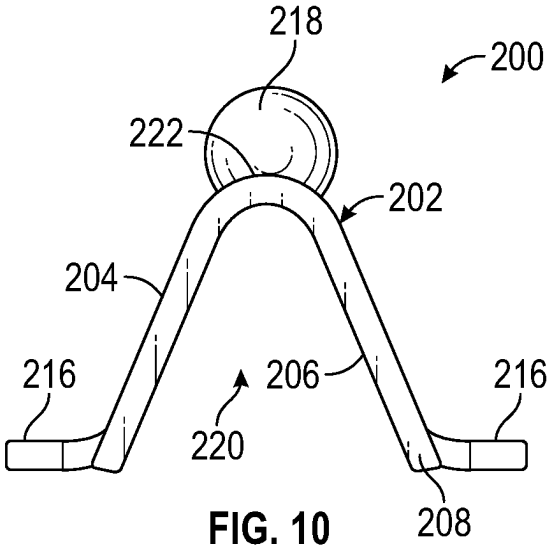
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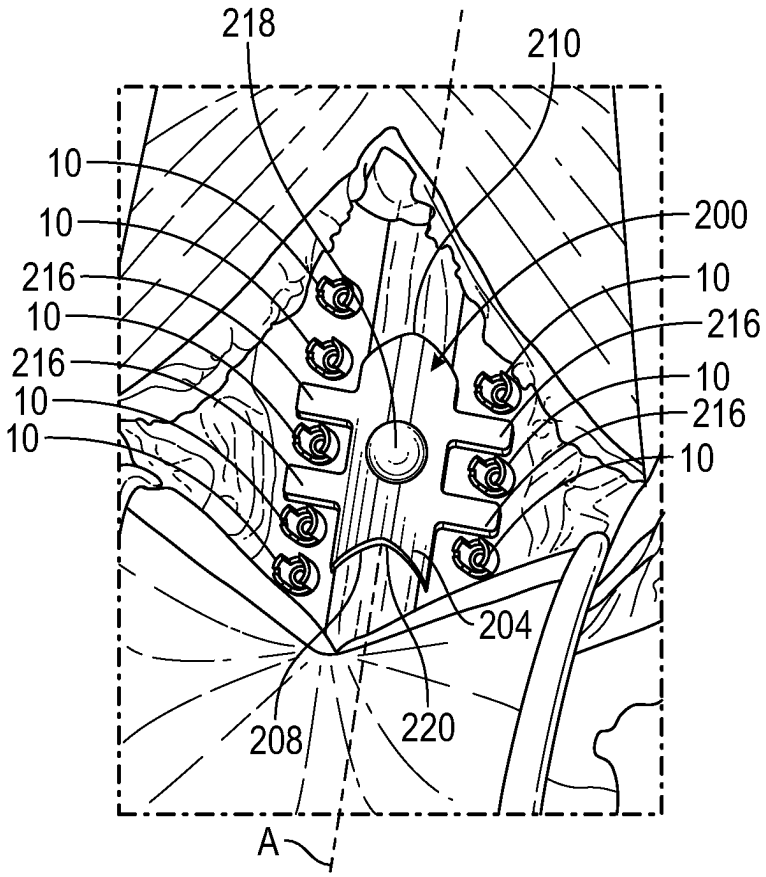
FIG. 10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208
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A

FIG. 11

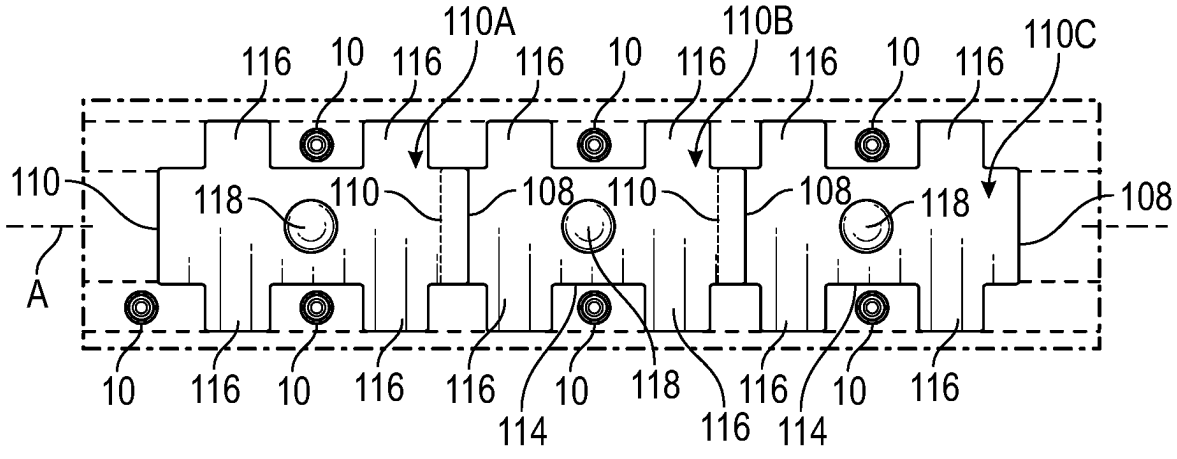
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FIG. 12

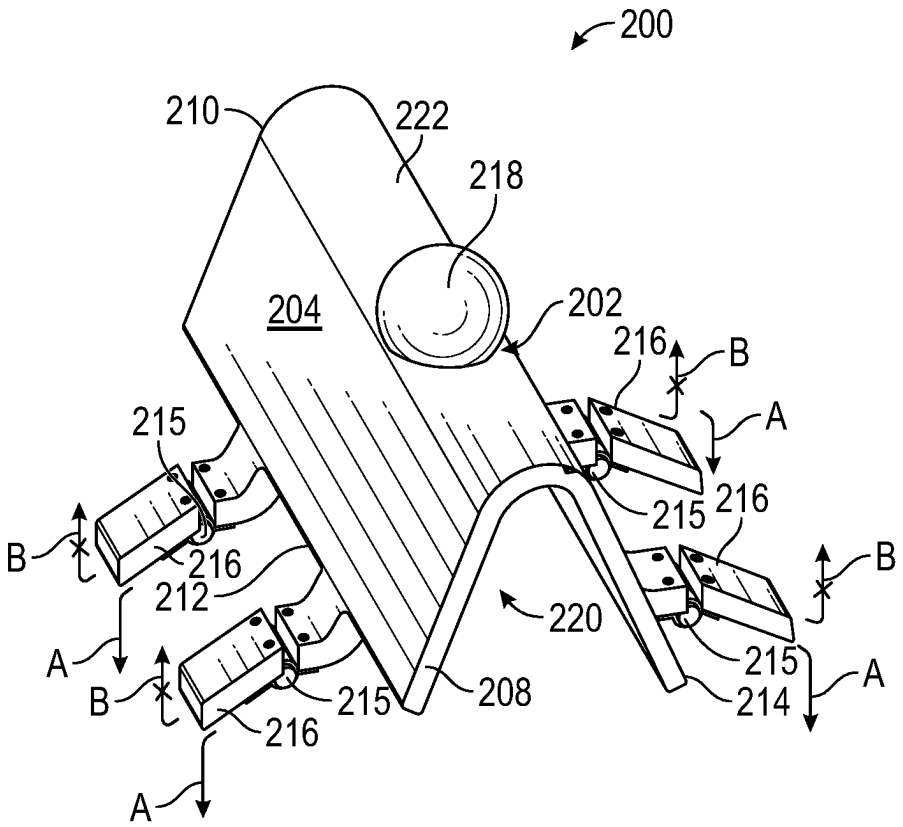
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FIG. 13

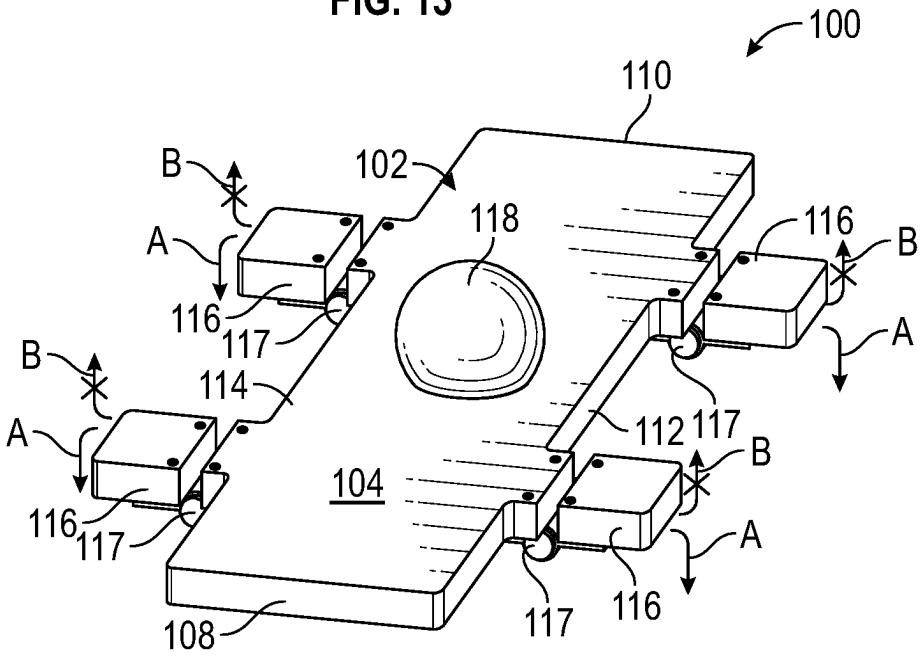
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FIG. 14

SYSTEMS AND METHODS FOR A SPINAL SHIELD FOR PROTECTING THE SPINAL CORD AND DURA DURING SURGICAL PROCEDURES

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 17/693,673 filed on Mar. 14, 2022, which is a divisional of U.S. 371 National application Ser. No. 16/625,195 filed on Dec. 20, 2019, now abandoned, which is a 371 national of PCT International Application No. PCT/US2018/039555 filed on Jun. 26, 2018, which claims the benefit of U.S. Provisional Patent Application Serial Nos. 62/524,653 filed on Jun. 26, 2017; 62/537,068 filed on Jul. 26, 2017; and 62/589,748 filed on Nov. 22, 2017, which all are incorporated by reference in its entirety.

FIELD

The present disclosure generally relates to tools for protecting the spinal canal and its contents during medical procedures that require exposure of the spinal canal, and in particular to systems and methods for a spinal shield that protects the spinal cord and dura during surgical procedures.

BACKGROUND

A laminectomy procedure is employed to treat spine problems, including spinal stenosis, tumors, spinal deformities, and others. This procedure is sometimes referred to as a "spinal decompression surgery". In particular, during a laminectomy, a surgeon may remove the lamina and spinous process to provide access to the spinal canal, which, in turn, can create more space in the spinal canal and relieve pressure on the spinal canal contents.

Surgeons performing a laminectomy typically use rongeurs (bone cutting instrument), osteotomes (a bone chisel), ultra-sonic bone scalpels, and/or high-speed drills to perform laminectomies. After a laminectomy is performed, the contents of the spinal canal (including the dura, spinal cord, nerve roots, and blood vessels) are exposed and at risk to inadvertent injury during the rest of the surgical procedure. Examples of the types of injuries that can occur include dural tear, spinal cord injury, and nerve root injury. These injuries sometimes occur because of inadvertently dropped or mishandled surgical instruments (e.g., over the exposed spinal canal). Results of such mistakes can be mild to severe, and include repairable damage, such as a dural tear and spinal fluid leak, to unrepairable damage, such as spinal cord or nerve root injuries.

The types of surgical procedures that often take place after a laminectomy with the contents of the spinal canal exposed include, but are not limited to, cannulation of vertebral pedicles, placement of spinal fixation hardware (such as pedicle screws, fixating rods, and cap screws), decortication of bone, and placement of surgical drains. Past attempts to reduce the risk of injury to the contents of the spinal canal after a laminectomy have failed to produce a device that is sufficiently effective and easy to use to achieve wide adoption by surgeons.

It is with these observations in mind, among others, that various aspects of the present disclosure were conceived and developed.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a first embodiment of a spinal shield, according to aspects of the present disclosure;

FIG. **2** is a top view of the spinal shield of FIG. **1**, according to aspects of the present disclosure;

FIG. **3** is a bottom view of the spinal shield of FIG. **1**, according to aspects of the present disclosure;

FIG. **4** is a side view of the spinal shield of FIG. **1**, according to aspects of the present disclosure;

FIG. **5** is an end view of the spinal shield of FIG. **1**, according to aspects of the present disclosure;

FIG. **6** is a perspective view of a second embodiment of the spinal shield, according to aspects of the present disclosure;

FIG. **7** is a top view of the spinal shield of FIG. **6**, according to aspects of the present disclosure;

FIG. **8** is a bottom view of the spinal shield of FIG. **6**, according to aspects of the present disclosure;

FIG. **9** is a side view of the spinal shield of FIG. **6**, according to aspects of the present disclosure;

FIG. **10** is an end view of the spinal shield of FIG. **6**, according to aspects of the present disclosure;

FIG. **11** is an illustration showing placement of the spinal shield along the spinal canal, according to aspects of the present disclosure;

FIG. **12** is an illustration showing a plurality of spinal shields arranged in series along the spinal canal during surgery, according to aspects of the present disclosure;

FIG. **13** is a perspective view showing the second embodiment of the spinal shield having hinges that allow the laterally extending legs to only rotate in a downward direction, according to aspects of the present disclosure; and

FIG. **14** is a perspective view showing the first embodiment of the spinal shield having hinges that allow the lateral extensions to only rotate in a downward direction, according to aspects of the present disclosure.

Corresponding reference characters indicate corresponding elements among the view of the drawings. The headings used in the figures do not limit the scope of the claims.

DETAILED DESCRIPTION

As noted above, a laminectomy is a common surgical procedure in which a portion of the posterior spinal column is removed to decompress the spinal cord and nerve roots. This is done to treat numerous spine diseases, including degenerative, infectious, neoplastic, traumatic, and congenital pathologies.

Instruments used after performing a laminectomy, once the contents of the spinal canal are exposed and vulnerable to injury, are highly varied, but typically include, screw drivers, drills, biting rongeurs, mallets, and osteotomes (bone chisels). During surgery, each of these conventional instruments pose a potential threat to the contents of the spinal canal (dura, spinal cord, nerve roots, and blood vessels) if such instruments are inadvertently dropped or mishandled.

Various embodiments of a spinal shield and related methods of use to protect the contents of the exposed spinal canal during a surgical procedure are disclosed herein. In one aspect, embodiments of the spinal shield are used to effectively protect the contents of the spinal canal during a surgical procedure, after a laminectomy has been performed, by establishing a protective structural barrier that surrounds the spinal canal and is configured to accommodate the contents of the spinal canal along various segments of the spinal column. In another aspect, embodiments of the spinal shield are configured to be easily inserted and removed from the surgical site by a surgeon by engaging a handle portion that extends outwardly from the shield body of the spinal

shield. In some embodiments, the shield body defines a plurality of laterally extending legs configured to extend between access points for spinal fixation hardware inserted into the bone tissue after a laminectomy and to allow the shield body to rest above the spinal canal and establish a protective barrier around the spinal cord and dura. In some embodiments, the shield body defines a flat configuration, while in other embodiments of the spinal shield the shield body defines a semi-circular curved configuration. Referring to the drawings, embodiments of a spinal shield are illustrated and generally indicated as **100** and **200** in FIGS. **1-14**.

As shown in FIGS. **1-5**, a first embodiment of a spinal shield, designated **100**, includes a rectangular-shaped shield body **102** having a generally planar configuration and can be generally configured to be placed over the spinal canal and dura of a patient to establish a protective barrier around the exposed spinal canal during a surgical procedure, such as a laminectomy. In some embodiments, the shield body **102** forms a top surface **104** and opposite bottom surface **106** that collectively define a front side **108**, a rear side **110**, a first lateral side **112**, and an opposing second lateral side **114**. As further shown, a plurality of lateral extensions **116** extend outwardly and/or downward from the first and second lateral sides **112**, **114**, respectively. The lateral extensions **116** permit the spinal shield **100** to be placed over the exposed spinal canal such that the lateral extensions **116** extend between the access points **9** to spinal fixation hardware. For example, the lateral extensions **116** may extend between spinal fixation hardware, such as pedicle screws **10** inserted within the access points **9** along both sides of the spinal column in a manner illustrated in FIG. **11**. However, the present disclosure contemplates that other types of spinal fixation hardware may secured within access points **9**.

In some embodiments, referring back to FIGS. **1-5**, a handle portion **118** which acts as a handle may be defined along and extend outwardly from the top surface **104** of the shield body **102** and can be configured to permit a user, such as surgeon, to easily and securely grip the spinal shield **100** and position the shield body **102** over the exposed spinal canal during a surgical procedure as well as grip the shield body **102** again to remove the spinal shield **100** from its position over the spinal canal after surgery has been completed. In some embodiments, the handle portion **118** may have a spherical configuration, although in other embodiments the handle portion **118** may have a square configuration, a rectangular configuration, an asymmetrical configuration, and asymmetrical configuration shaped and sized to permit sure handling of the spinal shield **100** by the surgeon. In some embodiments, the handle portion **118** may be made from a flexible material rather than a rigid material that acts as a flexible tether configured for gripping by the surgeon. In some aspects, the shield body **102** may comprise one or more handle portions **118**.

In some embodiments, the lateral extensions **116** may define a plurality of perforations **115** formed in a line parallel to the shield body **102** that allows each lateral extension **116** to be broken off from the shield body **102** when the spinal shield **100** is removed from the surgical site as shown in FIG. **2**. Alternatively, the lateral extensions **116** do not include any perforations **115**, but may be made of a frangible material that allows for breaking off the lateral extensions **116** using, for example, a bone cutting rongeur or other common surgical instrument, to enable easier removal of the spinal shield **100** from the surgical site after spinal fixation hardware has been placed.

Referring to FIG. **14**, in some embodiments each of the lateral extensions **116** of the shield body **102** may include a hinge **117** that allows each respective lateral extension **116** to bias or rotate in a downward direction A only and is prevented from biasing or rotating in an opposite upward direction B so that the spinal shield **100** can be more easily removed from the surgical site following placement of the spinal fixation hardware.

Referring to FIGS. **6-10**, a second embodiment of the spinal shield, designated **200**, includes a generally arc-shaped/arcuate shield body **202** having a semi-circular configuration and is shaped and sized to be placed over the spinal canal and dura of a patient to establish a protective barrier around the exposed spinal canal during a surgical procedure, such as a laminectomy. In some embodiments, the shield body **202** forms a top surface **204** and an opposite bottom surface **206** that collectively define a front side **208**, a rear side **210**, a first lateral side **212**, and an opposite second lateral side **214**. As shown, the shield body **202** defines an open channel **220** formed between the first lateral side **212** and the opposing second lateral side **214** that provides an open area between the bottom side **206** of the shield body **202** and the exposed spinal canal as illustrated in FIG. **11**. As shown, the top surface **204** forms an apex **222** that extends along the longitudinal axis of the shield body **202**. The configuration of the open channel **220** allows the spinal shield **200** to be positioned above and across the exposed spinal canal such that neither the bottom side **206** nor the first and second lateral sides **212** and **214** of the shield body **202** directly contact the exposed spinal canal and its contents.

As further shown, a plurality of laterally extending legs **216** extend at an angle outwardly and/or downward from the first and second lateral sides **212**, **214**, respectively, of the shield body **202** and are configured to position the spinal shield **200** above and across the exposed spinal canal. In this configuration, the plurality of laterally extending legs **216** will rest on opposing sides of the exposed spinal canal and between each set of access points **9** in which the pedicle screws **10** are secured therein along either side of the exposed spinal canal in a manner illustrated in FIG. **11**.

In some embodiments, the laterally extending legs **216** may have a plurality of perforations formed in a line for that allows each laterally extending leg **216** to be broken off from the shield body **202** when the spinal shield is removed from the surgical site. Alternatively, the lateral extensions **216** do not include a perforated segment but may be made of a material that allows for breaking off the lateral extensions **216** using, for example, a bone cutting rongeur or other common surgical instrument, to enable easier removal of the spinal shield **100** from the surgical site after spinal fixation hardware has been placed.

Referring to FIG. **13**, in some embodiments each of the laterally extending legs **216** of the shield body **202** may include a hinge **215** that allows each respective laterally extending leg **216** to bias or rotate in a downward direction A only and is prevented from biasing or rotating in an opposite upward direction B so that the spinal shield **100** can be more easily removed from the surgical site following placement of the spinal fixation hardware.

In some embodiments, a handle portion **218** may act as a handle defined along and extend outwardly relative to the top surface **204** and is configured to permit a user, such as surgeon, to easily grip the spinal shield **200** and position the shield body **202** over the exposed spinal canal during a surgical procedure as well as easily grip the shield body **202** again to remove the spinal shield **200** from its position over the exposed spinal canal after surgery has been completed. In some embodiments, the handle portion **218** may have a

spherical configuration, although in other embodiments the handle portion **218** may have a square configuration, a rectangular configuration, an asymmetrical configuration, and asymmetrical configuration shaped and sized to permit sure handling of the spinal shield **200** by the surgeon. In some aspects, the shield body **202** may include a plurality of handle portions **218**.

Referring back to FIG. **11**, the spinal shield **200** is shown positioned above and along the longitudinal axis A of the exposed spinal canal such that the laterally extending legs **216** extend laterally on both sides of the exposed spinal canal and rest between each pair of spinal fixation screws **10** secured to either side of the spinal canal. During a surgical procedure, such as a laminectomy, the spinal shield **200** is placed over the exposed spinal canal by the surgeon to establish a protective structural barrier around the exposed spinal canal without contacting the spinal fixation hardware **10**.

Referring to FIG. **12**, a plurality of spinal shields **100** (or spinal shields **200**) may be aligned in series along the longitudinal axis A of the exposed spinal canal such that the entire length of the exposed spinal canal is protected. As shown, each of the spinal shields **100** may overlap one another in series; however, alternatively, the spinal shields **100** (or spinal shields **200**) may directly contact each other end-to-end in series rather than overlap.

In one aspect, spinal shields **100** and **200** may be made from materials that provide substantial structural integrity and rigidity to protect the underlying tissue or muscle from unwanted exposure to physical and chemical elements. For example, in some embodiments spinal shields **100** and **200** may be manufactured or comprised of any number of suitable sterilizable or nonsterilizable materials, such as a metallic material, resin, ceramic, polymer, alloy, biodegradable composite, bioactive material, or any combination thereof. In some embodiments, the surface area of the spinal shields **100** and **200** may be coated with any number of suitable materials to provide, for example, antibacterial properties.

In some embodiments, the spinal shields **100** and **200** may be made of material(s) that make the shield body **102** or **202** substantially flexible to accommodate changes in a patient's physiology. For example, the spinal shields **100** and **200** may be positioned around portions of the patient's body to protected, such as the spine as discussed herein.

In some embodiments, the spinal shields **100** and **200** may have one or more support pads **217** attached to the underside of each lateral extension **116** or laterally extending leg **216**. By way of example as shown in FIG. **8**, a respective support pad **217** may be attached to the underside of each laterally extending leg **216** to reduce or eliminate unwanted movement of the shield body **202** as well as prevent pressing, bumping, or irritation by the spinal shield **200** after placement. In some embodiments, the support pads **217** may have a variety of shapes or configurations, including, but not limited to a square configuration, a rectangular configuration, a circular configuration, an oval configuration or any other shaped suitable for attachment to the underside of either the laterally extending legs **216** or lateral extensions **116**. In some embodiments, the support pads **217** may be coated with an adhesive to assist in fixing the position of the spinal shields **100** and **200** and to further prevent unwanted movement after placement. In some embodiments, the support pads **217** may have a textured surface that allows the spinal shields **100** and **200** to remain in the correct position via the coefficient of friction after placement by the surgeon along the surgical site.

In some embodiments, the entire spinal shields **100** and **200** or portions thereof may define channels, ridges, protrusions, or any combination thereof formed along the shield body **102** or shield body **202** for interacting with the patient's skin and muscle tissue as well as enhancing the gripping capacity of the spinal shields **100** and **200**. In addition, these features may be dispersed across various portions of the shield body **102** or **202** in any known configuration that aligns with the preference of the user. Moreover, these features may be advantageous for interacting or diverting the flow of liquid over the spinal bodies **102** and **202**.

In one method of manufacture, the spinal shields **100** and **200** may be manufactured using 3D printing methods by printing and connecting various discrete components (e.g., shield body, handle portion, etc.) together to assemble the spinal shields **100** and **200**, or alternatively, by unitary construction through injection molding processes. One non-limiting example of a 3D printing method that may be used to manufacture the spinal shields **100** and **200** are disclosed in PCT patent application serial number PCT/US2018/035223 entitled Synthetic Spine, filed on May 30, 2018, and is herein incorporated by reference in its entirety. In some embodiments, the spinal shields **100** and **200** may be manufactured such that any interior portion thereof is hollow (not shown). For example, the lateral extensions **116** or laterally extending legs **216** may have a hollow interior (not shown), while the shield body **102** or **202** may have a substantially solid configuration, or vice versa, or alternatively, both the shield body **102** and **202** and the lateral extensions **116** or laterally extending legs **216** are of a hollow construction.

In some embodiments, the spinal shields **100** and **200** may be made of a substantially transparent material, such as a transparent medical grade polymer in which the user may see through the device and observe the patient's anatomy beneath. Alternatively, the spinal shields **100** and **200** may be made of a substantially translucent material.

In some embodiments, the spinal shields **100** and **200** may be fitted with one or more magnifying devices having a lens arrangement that provides a magnified view of the surgical site.

In some embodiments, a plurality of spinal shields **100** and **200** may be connected together by mechanical components, such as a locking pin, gripping jaws, tethering, texture surfaces, latches, or any combination thereof. In addition, the spinal shields **100** and **200** may be connected to one another using adhesives, fusing, magnets, or any chemical or non-chemical bonding methods. In some embodiments, the spinal shields **100** and **200** may be constructed such that the anterior, posterior, or both ends define a sloped edge configuration (not shown) such that one spinal shield **100** and **200** may slide over the slop edge configuration of another spinal shield **100** and **200**.

In some embodiments, the spinal shields **100** and **200** may include a coupling device or adhesive (not shown) such that the spinal shields **100** and **200** may be temporarily affixed to a patient's anatomy during the duration of a surgery. For example, the spinal shields **100** and **200** may be surgically tethered, fused, fixed, glued, latched, otherwise coupled to or any combination thereof, to the patient's anatomy. In addition, it is contemplated that this fastening method could be used to fasten the spinal shields **100** and **200** to other external components. For example, the spinal shields **100** and **200** may be fastened to a structural rig disposed around a portion of the patient's anatomy.

In some embodiments, the spinal shields **100** and **200** may include lateral extensions **116** of spinal shield **100** or later-

ally extending legs **216** of spinal shield **200** that cannot be broken off as in the embodiment described above. It should be understood from the foregoing that, while particular embodiments have been illustrated and described, various modifications can be made thereto without departing from the spirit and scope of the invention as will be apparent to those skilled in the art. Such changes and modifications are within the scope and teachings of this invention as defined in the claims appended hereto.

What is claimed is:

1. A method of establishing a protective barrier around a surgical site comprising: providing a first spinal shield comprising:

a shield body forming a top side, a bottom side that collectively define a front side, a rear side, a first lateral side, and a second lateral side opposite the first lateral side, wherein the shield body defines a flat configuration;

a plurality of lateral extensions that extend outwardly from the first and second lateral sides, respectively; and

a handle portion that extends outwardly from the shield body in perpendicular relation to the shield body;

grasping the handle portion of the first spinal shield; and

placing the first spinal shield in a position over the exposed surgical site;

wherein each of the plurality of laterally extending legs defines one or more perforations such that each of the plurality of laterally extending legs is broken off along the one or more perforations when removing the spinal shield from the exposed surgical site.

2. The method of claim **1**, further comprising:

placing a second spinal shield in a position adjacent to the first spinal shield.

3. A method of establishing a protective barrier around a surgical site comprising:

providing a first spinal shield comprising:

a shield body forming a top side, a bottom side that collectively define a front side, a rear side, a first lateral side, and a second lateral side opposite the first lateral side, wherein the shield body defines a flat configuration;

a plurality of lateral extensions that extend outwardly from the first and second lateral sides, respectively; and

a handle portion that extends outwardly from the shield body in perpendicular relation to the shield body;

grasping the handle portion of the first spinal shield; and

placing the first spinal shield in a position over the exposed surgical site;

wherein each of the plurality of laterally extending legs is made of a frangible material such that each of the plurality of laterally extending legs is broken off from the shield body when removing the spinal shield from the exposed surgical site.

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