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(54) FIXTURE DEVICE FOR FOLDING A SEAL MEMBER

BEFESTIGUNGSVORRICHTUNG ZUM FALTEN EINES DICHTUNGSELEMENTS DISPOSITIF DE FIXATION POUR PLIER UN ÉLÉMENT D'ÉTANCHÉITÉ

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Description

FIELD

[0001] The present disclosure relates to a fixture device for folding a seal member for a surgical access device.

BACKGROUND

[0002] In order to facilitate minimally invasive surgery, a working space is created at the desired surgical site. An insufflation fluid, typically CO_2 , is introduced into the abdomen of the patient to create an inflated state called a pneumoperitoneum. Access assemblies are utilized to allow the introduction of surgical instrumentation and endoscopes (or other visualization tools). These access assemblies maintain the pressure for the pneumoperitoneum, as they have one or more seals that adapt to the surgical instrumentation. Typically, a "zero-seal" in the access assembly seals the access assembly in the absence of a surgical instrument in the access assembly, and an instrument seal seals around a surgical instrument that has been inserted through the access assembly.

[0003] The instrument seal includes a seal member that may include a support base and a plurality of stacked petals. The petals may be independently formed and secured to the support base, or the petals may be integrally formed with the support base. The integrally formed seal member is typically formed as a flat sheet with the petals having to be folded relative to the base. To minimize leaking once formed, the petals of the seal member may be interwoven. If the petals are folded without interweaving, the durability of the seal member may be compromised and more likely to leak if torn.

[0004] Folding the petals by hand is a long and tedious process and may result in defective folding. Therefore, it would be beneficial to have a fixation device for assisting in folding the petals of the seal member.PCT application WO 2016/110720 describes a surgical access device comprising a seal assembly and a plurality of sealing member attached to a ring.

SUMMARY

[0005] A fixation device for folding a seal member is provided. The fixation device includes a frame having a horizontal portion and an upright portion, a press assembly secured to the upright portion of the frame, and a nest assembly secured to the horizontal portion of the frame. The press assembly includes a handle assembly and an anvil assembly operably connected to the handle assembly. The nest assembly includes a clamping assembly, a folding assembly supported on the clamping assembly, a support assembly supported on the folding assembly, and a nest member. The support assembly includes a support plate and a seal clamp for securing a seal mem-

ber.

[0006] In some aspects of the disclosure, the seal clamp includes a ring portion and a plurality of arm portions extending radially inward from the ring portion. The nest member may include a hexagonal shape. The nest member may be movable relative to the base between a raised position and a lowered position. A top surface of the nest assembly may define a plurality of openings for receiving retaining pins. The anvil assembly may in-

¹⁰ clude an anvil member configured for selective engagement with the seal member supported on the support assembly.

[0007] In certain aspects, the folding assembly includes an activation ring, a guide member, and a plurality

¹⁵ of arm members supported on the activation ring. The guide member may define a plurality of channels configured to slidably retain the plurality of arm members. First ends of the arm members may be pivotally secured relative to the activation ring. Second ends of the arm mem-

²⁰ bers may be configured to engage flap portions of the seal member. The arm members are movable from a first position to a second position when the activation ring is rotated in a first direction. The plurality of arm members may include six arm members.

²⁵ [0008] A method of folding a seal member using a fixation device is also provided. The method includes loading a seal member on a nest assembly of the fixation device, advancing an anvil member into engagement with a support portion of the seal member to cause folding

 of flap portions of the seal member relative to the support portion of the seal member, retracting the anvil member away from the seal member, activating a folding assembly to continue the folding and interweaving of the flap portions of the seal member, and advancing the anvil
 member into engagement with the flap portions to flatten the flap portions.

[0009] In certain aspects of the disclosure, loading the seal member on the nest assembly includes placing the seal member on a support plate of a support assembly
 and securing a seal clamp to the support plate. Securing the seal clamp to the support plate may include aligning arm portions of the seal clamp with sections of the flap portions of the seal member. The method may further include advancing of the anvil member into engagement

⁴⁵ with the support portion of the seal assembly causing the flap portions of the seal member to interweave. Advancing the anvil member into engagement with the support portion may include lowering a nest member of the nest assembly to a lowered position. The method may further ⁵⁰ include clamping the nest member in the lowered position.

BRIEF DESCRIPTION OF THE DRAWINGS

⁵⁵ [0010] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate aspects of the disclosure and, together with a general description of the disclosure given above, and

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the detailed description of the aspects given below, serve to explain the principles of the disclosure, wherein:

FIG. 1 is a perspective view of a fixture device for folding a seal member according to an aspect of the ⁵ disclosure and a seal member;

FIG. 2 is an enlarged view of the indicated area of detail shown in FIG. 1;

FIG. 3 is an enlarged view of the indicated area of detail shown in FIG. 1;

FIG. 4 is a perspective view of a base, a clamping assembly, and a nest member of a nest assembly of the fixation device shown in FIG. 1;

FIG. 5 is a perspective view of the nest member shown in FIG. 4;

FIG. 6 is a perspective view of the nest assembly shown in FIG. 4, with a seal clamp of a support assembly separated from the support plate, and including the seal member shown in FIG. 3;

FIG. 7 is the perspective view of the nest assembly shown in FIG. 6, with the seal clamp of the support assembly secured to the support plate;

FIG. 8 is a top cross-sectional view of the nest assembly shown in FIG. 7 taken along line 8-8 in FIG. 7, with a clamp member of the clamp assembly in a retracted position;

FIG. 9 is a perspective view of the fixture device shown in FIG. 1, with a press assembly in an activated position;

FIG. 10 is a front cross-sectional view of the nest assembly shown in FIG. 9 taken along section line 10-10 in FIG. 9;

FIG. 11 is a top cross-sectional view of the nest assembly shown in FIG. 10 taken along section line 11-11 in FIG. 10;

FIG. 12 is an enlarged view of the indicated area of detail shown in FIG. 11;

FIG. 13 is a side perspective view of the nest assembly shown in FIGS. 9-11, with the clamp assembly in a locked position and an anvil assembly of the press assembly in retracted position; and

FIG. 14 is the top cross-sectional view shown in FIG. 11, with the clamp assembly in a locked position and an activation ring of a folding assembly in an activated position;

FIG. 15 is the front cross-sectional view shown in FIG. 10, with the seal member in a partially folded condition and the anvil assembly in a partially advanced position;

FIG. 16 is the front cross-sectional view shown in FIG. 10, with the seal member in a folded configuration and the anvil assembly in a fully advanced position;

FIG. 17 is the top cross-sectional view shown in FIG. 11 with the seal member in the folded configuration and the anvil assembly in the fully advanced position; FIG. 18 is the side perspective view shown FIG. 13, with the clamp assembly in an unlocked condition and the anvil assembly in a retracted position; FIG. 19 is a perspective view of the seal member shown in FIG. 3, in a folded configuration;

FIG. 20 is a side perspective view of the fixture device shown in FIG. 7, with an upper retaining member of a retainer assembly and a guard assembly positioned adjacent the folded seal member shown in FIG. 19;

FIG. 21 is the side perspective view shown in FIG.

20, with the anvil assembly engaged with the upper retainer member;

FIG. 22 is a top perspective view of an upper retainer member, a guard assembly, and the seal member shown in FIG. 3; and

FIG. 23 is a bottom perspective view of the upper retainer member, the guard assembly, and the seal member as shown in FIG. 22.

DETAILED DESCRIPTION

[0011] Particular aspects of the disclosure are described hereinbelow with reference to the accompanying drawings; however, it is to be understood that the disclosed devices are merely exemplary of the disclosure and may be embodied in various forms. Well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the disclosure in virtually any appropriately detailed structure. Like reference numerals refer to similar or identical elements throughout the description of the figures.

³⁵ [0012] As used herein, the term "distal" refers to that portion of the instrument, or component thereof which is farther from the user while the term "proximal" refers to that portion of the instrument or component thereof which is closer to the user. As used herein, the term "about" means that the numerical value is approximate and small variations would not significantly affect the practice of the disclosed aspects of the disclosure. Where a numerical limitation is used, unless indicated otherwise by the context, "about" means the numerical value can vary by

⁴⁵ ±10% and remain within the scope of the disclosure.
[0013] FIG. 1 illustrates a device for folding and securing a seal member shown generally as fixation device 100. The fixation device 100 includes a frame 110, a nest assembly 200 operably secured to the frame 110, and a
⁵⁰ press assembly 300 secured to the frame 110.

[0014] The frame 110 includes a base or horizontal portion 112 and a support or upright portion 114. The horizontal portion 112 of the frame 110 supports the nest assembly 200, and the upright portion 114 of the frame 110 supports the press assembly 300. The horizontal portion 112 of the frame 110 is configured to releasably and adjustably receive the nest assembly 200, and the upright portion 114 of the remeting the press of the frame 110 is configured to releasably and adjustably receive the nest assembly 200, and the upright portion 114 of the frame 110 is configured to re-

leasably and adjustably receive the press assembly 300. More particularly, the base portion 112 of the frame 110 defines a channel 113 for receiving the nest assembly 200 and the upright portion 114 of the frame 110 includes a channel 115 for receiving the press assembly 300.

[0015] FIG. 2 illustrates the nest assembly 200 including a base 210, a clamp assembly 220 supported on the base 210, a folding assembly 240 supported on the clamp assembly 220, a support assembly 260 supported on the folding assembly 240, and a nest member 280 operably disposed relative to the base 210, the clamp assembly 220, the folding assembly 240, and the support assembly 260. The clamp assembly 220 is configured to selectively engage the nest member 280 to permit movement of the nest member 280 relative to the base 210, the folding assembly 240 is configured to facilitate folding of the seal member 50 (FIG. 3), the support assembly 260 retains a portion of the seal member 50 during the folding process to facilitate interweaving of flap portions 54a-f of the seal member 50, and the nest member 280 supports the seal member 50 during the folding process.

[0016] FIG. 3 illustrates the seal member 50 configured to be folded and secured to an upper retaining member 70 and a guard assembly 80 using the fixation device 100 (see FIG. 20). The seal member 50 includes a support portion 52 and the first, second, third, fourth, fifth, and sixth flap portions 54a-f integrally formed with the support portion 52. The support portion 52 defines a central opening 51 and a plurality of openings 53 radially spaced about the central opening 51. The flap portions 54 are moveable from a flat configuration (FIG. 3) to a folded configuration (FIG. 19). Each flap portion 54a-f of the plurality of flap portions 54 defines a plurality of openings 55 about a perimeter of each of the flap portions 54a-f. The plurality of openings 55 of the flap portions 54a-f align with the plurality of openings 53 of the support portion 52 when the seal member 50 is in the folded configuration.

[0017] FIG. 4 illustrates the nest assembly 200 with the folding assembly 240 (FIG. 2) and the support assembly 260 removed from the base 210 and the clamp assembly 220 to expose the nest member 280. The clamp assembly 220 is configured to maintain the nest member 280 in either a first or raised position (FIG. 4) or a second or lowered position (FIG. 13).

[0018] FIG. 5 illustrates the nest member 280 including a body 282 having a hexagonal configuration corresponding to the support portion 52 (FIG. 3) of the seal member 50. A top surface 284 of the body 282 of the nest member 280 defines a plurality of openings 283 corresponding to the plurality of openings 53 in the support portion 52 of the seal member 50. The plurality of openings 283 is configured to receive alignment pins 214 (FIG. 6) for maintaining the seal member 50 relative to the nest member 280. The top surface 284 of the body 282 further defines a pair of openings 285 formed along a midline of the nest member 280. The openings 285 receive positioning pins 216 (FIG. 8) for restricting the nest member 280 from lateral movement relative to the base 210 while permitting raising and lowering of the nest member 280 during a folding process.

[0019] The body 282 of the nest member 280 includes 5 six sides 282a-f. Opposed sides 282a, 282d each define a first slot 287 and a second slot 289. The first slots 287 in the body 282 of the nest member 280 are configured to releasably receive legs 224 (FIG. 4) of a clamp member 222 of the clamp assembly 220 to maintain the nest mem-

¹⁰ ber 280 in a first or raised position relative to the base 210, and the second slots 289 in the opposed sides 282a, 282d of the body 282 of the nest member 280 are configured to releasably receive the legs 222 of the clamp member 222 of the clamp assembly 220 to maintain the

¹⁵ nest member 280 in a second or lowered position relative to the base 210.

[0020] FIGS. 6 and 7 illustrate the nest assembly 200 as the seal member 50 is loaded onto the support assembly 260. The support assembly 260 includes a support plate 262 and a seal clamp 270 releasably securable to the support plate 262 to secure the seal member 50 relative to the support plate 262. The support plate 262 defines a central hexagonal opening 261 (FIG. 2) configured to receive the nest member 280 therethrough. A

rim 264 (FIG. 2) extends about an outer surface of the support plate 262. The rim 264 creates a recess 263 (FIG. 3) for accommodating the flap portions 54a-f (FIG. 2) of the seal member 50 when the seal member 50 is loaded on the support plate 262. A plurality of posts 266 extend
from the rim 264 of the support plate 262 and is configured to facilitate attachment of the seal clamp 270 to the support plate 262.

[0021] The seal member 50 is loaded on the support plate 262 when the nest member 280 is supported by the clamp member 222 of the clamp assembly 220 in the raised position. In this manner, the top surface 284 of the nest member 280 is flush with the support plate 262,

thereby facilitating loading of the seal member 50 in its flat configuration on the nest assembly 200. More particularly, the support portion 52 of the seal member 50 is

positioned on the top surface 284 of the nest member 280 and the flap portions 54a-f of the seal member 50 are positioned on the support plate 262 within the recess 263 created by the rim 264. The seal member 50 is

⁴⁵ aligned with the nest member 280 such that the retaining pins 214 received within the plurality of openings 283 in the nest member 280 align with the openings 53 in the seal member 50.

[0022] Once the seal member 50 is loaded on the support plate 262 and the nest member 280, the seal clamp 270 is secured to the support plate 262 to retain the flap portions 54a-f of the seal member 50 relative to the support plate 262. The seal plate 270 includes a ring portion 272 and a plurality of arm portions 274a-f extending radially inward from the ring portion 272. The ring portion 272 of the seal clamp 270 defines a plurality of openings 273 corresponding to the plurality of posts 266 extending from the rim 264 of the support plate 262 for receiving

the plurality of posts 266 and securing the seal clamp 270 relative to the support plate 262. Each arm portion 274a-f of the seal clamp 270 is configured to engage a section of the flap portions 54a-f of the seal member 50 to maintain the flap portions 54a-f relative to the support plate 262 and to facilitate the folding of the flap portions 54a-f relative to the seal member 50. More particularly, the arm portions 274a-f of the seal clamp 270 are configured to interweave the respective flap portions 54a-f of the seal member 54a-f of the seal member 54a-f of the seal member 54a-f of the seal clamp 270 are configured to interweave the respective flap portions 54a-f of the seal member 50 during the folding process.

[0023] FIG. 8 illustrates the nest member 280 being released from the clamp assembly 220. More particularly, the clamp member 222 of the clamp assembly 220 is retracted, as indicated by arrows "A", to disengage legs 224 of the clamp member 222 from the nest member 280, i.e., withdraw the legs 224 from within the first slots 287 in the opposed sides 282a, 282d of the nest member 280. Once the clamp member 222 is disengaged from the nest member 280, the nest member 280 is free to be pressed downwards, against the bias of a spring member 290 (FIG. 10), by the press assembly 300.

[0024] FIG. 9 illustrates activation of the press assembly 300 to engage an anvil assembly 310 of the press assembly 300 with the support member 52 of the seal member 50. More particularly, the press assembly 300 includes the anvil assembly 310 operably secured to a handle assembly 320. Rotational movement of the handle assembly 320, as indicated by arrow "B", causes an anvil member 312 (FIG. 10) of the anvil assembly 310 to advance into engagement with the support portion 52 of the seal member 50, as indicated by arrow "C". Continued advancement of the anvil assembly 310 moves the nest member 280, including the support portion 52 of the seal member 50, relative to the support member 262 of the support assembly 260 against the bias of the spring member 290 (FIG. 10) and through a central passage 241 (FIG. 8) of a guide member 242 (FIG. 11) of the folding assembly 240.

[0025] As the nest member 280 is moved relative to the support assembly 260, the flap portions 54a-f of the seal member 50, of which a section of the flap portions 54a-f are retained in place by arm portions 274a-f of the seal clamp 270 of the support assembly 260, are folded relative to the support portion 52 of the seal member 50. [0026] As the flap portions 54a-f of the seal member 50 are folded relative to the support portion 52 of the seal member 50, the engagement of the sections of the flap portions 54a-f by the respective arm portions 274a-f of the seal clamp 270 cause the flap portions 54a-f to overlap with each other in an alternating or interwoven fashion (see FIG. 12). In this manner, a first section of the first flap portion 54a overlaps a second section of sixth flap portion 54f, a first section of the second flap portion 54b overlaps a second section of the first flap portion 54a, a first section of the third flap portion 54c overlaps a second section of the second flap portion 54b, a first section of the fourth flap portion 54d overlaps a second section of the third flap portion 54c, a first section of the fifth flap

portion 54e overlaps a second section of the fourth flap portion 54d, and a first section of the sixth flap portion 54f overlaps a second section of the fifth flap portion 54e. **[0027]** FIGS. 10-12 illustrate the nest member 280 of

- ⁵ the nest assembly 200 in a fullydepressed position relative to the base 210. In this position, the flap portions 54a-f of the seal member 50 are in a partially folded configuration extending perpendicular to the support portion 52 of the seal member 50 and along the central passage
- 10 241 of the guide member 242 of the folding assembly 240. As noted above, the flap portions 54a-f of the seal member 50 are also disposed in the interwoven fashion (FIG. 12).

[0028] FIG. 11 illustrates the folding assembly 240 including the guide member 242 and an activation ring 244 disposed about and rotatable relative to the guide member 244. The guide member 242 defines first, second, third, fourth, fifth, and sixth channels 243a-f aligned with the respective first, second, third, fourth, fifth, and sixth flap portions 54a-f of the seal member 50. Each of the first, second, third, fourth, fifth and sixth channels 243a-f receives a respective first, second, third, fourth, fifth, and sixth arm member 244a-f. First ends 244a'-f' of the first, second, third, fourth, fifth, and sixth arm member 244a-f.

25 244a-f, respectively, are pivotally secured within respective cam slots 243a-f formed in the activation ring 244. Second ends 244a"-f" of the arm members 244a-f are configured to align with the flap portions 54a-f, respectively, of the seal member 50.

30 [0029] Although the second ends 244a"-f" of the respective arm members 244a-f are aligned with the respective flap portions 54a-f of the seal member 50, the second ends 244a"-f" engage the overlapping section of the adjacent flap portions 54b-a. More particularly, the second end 244a" of the first arm member 244a engages

second end 244a" of the first arm member 244a engages the second flap portion 54b, the second end 244b" of the second arm member 244b engages the third flap portion 54c, the second end 244c" of the third arm member 244c engages the fourth flap portion 54d, the second end

40 244d" of the fourth arm member 244d engages the fifth flap portion 54e, the second end 244e" of the fifth arm member 244e engages the sixth flap portion 54f, and the second end 244f" of the sixth arm member 244f engages the first flap portion 54a.

⁴⁵ [0030] FIG. 13 illustrates the clamp member 222 of the clamp assembly 220 being advanced, as indicated by arrow "D", into engagement with the nest member 280 to lock the nest member 280 relative to the base 210. More particularly, the legs 224 of the clamp member 222
⁵⁰ are received within the second slots 289 (FIG. 5) in the

opposed sides 282a, 282d of the nest member 280 to retain the nest member 280 in the lowered position. Once the nest member 280 is locked in the lowered position, the anvil member 312 is retracted from engagement with
⁵⁵ the support portion 52 of the seal member 50, as indicated by arrow "E" to permit operation of the folding assembly 260.

[0031] FIG. 14 illustrates rotation of the activation ring

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244 in a counterclockwise direction, as indicated by arrows "F". Rotation of the activation ring 244 advances the first, second, third, fourth, fifth, and sixth arm members 244a-f of the folding assembly 240 through the respective first, second, third, fourth, fifth, and sixth channels 243a-f of the guide member 242. As the arm members 244a-f advance through the respective channels 243a-f, the second ends 244a"-f" of the arm members 244a-f move the flap portions 54a-f of the seal member 50 radially inward while maintaining the interwoven configuration of the flap portions 54a-f.

[0032] FIG. 15 illustrates an initial advancement of the anvil member 312 of the anvil assembly 310 of the press assembly 300 into engagement with the partially folded and interwoven flap portions 54a-f of the seal member 50, as indicated by arrow "G".

[0033] FIGS. 16 and 17 illustrate the anvil member 312 of the anvil assembly 310 of the press assembly 300 after being fully advanced relative to the nest member 280.
 When the anvil member 312 of the anvil assembly 310 ²⁰ is in the fully advanced position, the flap portions 54a-f of the seal member 50 are completely interwoven and the seal member 50 is in the folded configuration.

[0034] FIG. 18 illustrates the return of the nest assembly 200 to its initial configuration. More particularly, the anvil member 312 of the anvil assembly 310 of the press assembly 300 is retracted relative to the nest assembly 200, as indicated by arrow "H", and the clamp member 222 of the clamp assembly 220 is withdrawn from engagement with the nest member 280, as indicated by arrow "I". In this manner, the nest member 280, including the seal member 50 in the folded configuration is returned to the raised position through the bias of the spring member 290 (FIG. 16).

[0035] FIG. 19 illustrates the seal member 50 in the ³⁵ folded configuration following the folding procedure with the fixation device 100.

[0036] FIGS. 20 and 21 illustrate an upper retainer member 70 and a guard assembly 80 being secured to the seal member 50. More particularly, the upper retainer member 70 of a retaining assembly and the guard assembly 80 are positioned on the seal member 50 with retaining members 72 of the upper retaining member 70 aligned with the openings 53 in the support portion 52 of the seal member 50 and the corresponding opening 55 of the flap portions 54a-f of the seal member 50. The anvil member 312 of the anvil assembly 310 of the press assembly 300 is then advanced, as indicated by arrow "J", to press fit the upper retaining member 70 and the guard assembly 80 to the seal member 50.

[0037] FIGS. 22 and 23 illustrate the seal member 50, in the folded configuration, secured to the upper retainer member 70 of the retainer assembly (not shown) and the guard assembly 80. For a detailed description of an exemplary retaining assembly and guard assembly, please refer to U.S. Pat. App. Ser. No. 16/774,206, filed January 28, 2020.

[0038] It is envisioned that the folding process de-

scribed above may be modified for use in an automated system. This would enable assembly of seal members at an increased rate.

Claims

a frame (110) including a horizontal portion and an upright portion;

a press assembly (300) secured to the upright portion of the frame, the press assembly including a handle assembly and an anvil assembly (310) operably connected to the handle assembly; and

a nest assembly (200) secured to the horizontal portion of the frame, the nest assembly including a clamping assembly (220), a folding assembly (240) supported on the clamping assembly, a support assembly (260) supported on the folding assembly, and a nest member, wherein the support assembly includes a support plate (262) and a seal clamp (270) for securing a seal member.

- 2. The fixation device of claim 1, wherein the seal clamp (270) includes a ring portion (272) and a plurality of arm portions (274) extending radially inward from the ring portion.
- **3.** The fixation device of claim 1 or claim 2, wherein the nest member has a hexagonal shape.
- **4.** The fixation device of any preceding claim, wherein the nest member is movable relative to a base (210) of the nest assembly between a raised position and a lowered position.
- 5. The fixation device of any preceding claim, wherein a top surface (284) of the nest assembly defines a plurality of openings (283) for receiving retaining pins (214).
- The fixation device of any preceding claim, wherein the anvil assembly (310) includes an anvil member (312) configured for selective engagement with the seal member supported on the support assembly.
- 7. The fixation device of any preceding claim, wherein the folding assembly includes an activation ring (244), a guide member (242), and a plurality of arm members (244) supported on the activation ring; preferably wherein the guide member defines a plurality of channels (243) configured to slidably retain the plurality of arm members.

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^{1.} A fixation device (100) for folding a seal member (50) for a surgical access device, the fixation device comprising:

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- 8. The fixation device of claim 7, wherein first ends of the arm members are pivotally secured relative to the activation ring; preferably wherein second ends of the arm members are configured to engage flap portions of the seal member.
- **9.** The fixation device of claim 8, wherein the arm members are movable from a first position to a second position when the activation ring is rotated in a first direction.
- **10.** The fixation device of any of claims 7 to 9, wherein the plurality of arm members includes six arm members.
- **11.** A method of folding a seal member (50) for a surgical access device using a fixation device (100), the method comprising:

loading a seal member on a nest assembly (200) ²⁰ of the fixation device;

advancing an anvil member (310)into engagement with a support portion of the seal member to cause folding of flap portions (54) of the seal member relative to the support portion of the ²⁵ seal member;

retracting the anvil member away from the seal member;

activating a folding assembly (240) to continue the folding and interweaving of the flap portions of the seal member; and

advancing the anvil member into engagement with the flap portions (54) to flatten the flap portions.

- **12.** The method of claim 11, wherein loading the seal member on the nest assembly includes placing the seal member (50) on a support plate (262) of a support assembly (260) and securing a seal clamp (270) to the support plate.
- **13.** The method of claim 11 or claim 12, wherein securing the seal clamp (270) to the support plate includes aligning arm portions (244) of the seal clamp with sections of the flap portions (54) of the seal member; preferably wherein advancing of the anvil member into engagement with the support portion of the seal assembly causes the flap portions of the seal member to interweave.
- 14. The method of any of claims 11 to 13, wherein advancing the anvil member into engagement with the support portion includes lowering a nest member of the nest assembly to a lowered position.
- **15.** The method of claim 14, further including clamping the nest member in the lowered position.

Patentansprüche

1. Fixiervorrichtung (100) zum Falten eines Dichtungselements (50) für eine chirurgische Zugangsvorrichtung, die Fixierungsvorrichtung umfassend:

> einen Rahmen (110), der einen horizontalen Abschnitt und einen aufrechten Abschnitt einschließt;

eine Pressanordnung (300), die an dem aufrechten Abschnitt des Rahmens befestigt ist, wobei die Pressanordnung eine Griffanordnung und eine Ambossanordnung (310) einschließt, die mit der Griffanordnung wirkverbunden ist; und

eine Nestanordnung (200), die an dem horizontalen Abschnitt des Rahmens befestigt ist, wobei die Nestanordnung eine Klemmanordnung (220), eine Faltanordnung (240), die auf der Klemmanordnung gestützt wird, eine Stützanordnung (260), die auf der Faltanordnung gestützt wird, und ein Nestelement einschließt, wobei die Stützanordnung eine Stützplatte (262) und eine Dichtungsklemme (270) zum Befestigen eines Dichtungselements einschließt.

- 2. Fixiervorrichtung nach Anspruch 1, wobei die Dichtungsklemme (270) einen Ringabschnitt (272) und eine Vielzahl von Armabschnitten (274) einschließt, die sich von dem Ringabschnitt radial nach innen erstreckt.
- **3.** Fixiervorrichtung nach Anspruch 1 oder 2, wobei das Nestelement eine sechseckige Form aufweist.
- Fixiervorrichtung nach einem der vorstehenden Ansprüche, wobei das Nestelement relativ zu einer Basis (210) der Nestanordnung zwischen einer angehobenen Position und einer abgesenkten Position bewegbar ist.
- Fixiervorrichtung nach einem der vorstehenden Ansprüche, wobei eine obere Oberfläche (284) der Nestanordnung eine Vielzahl von Öffnungen (283) zum Aufnehmen von Haltestiften (214) definiert.
- 6. Fixiervorrichtung nach einem der vorstehenden Ansprüche, wobei die Ambossanordnung (310) ein Ambosselement (312) einschließt, das für einen selektiven Eingriff mit dem Dichtungselement konfiguriert ist, das auf der Stützanordnung gestützt wird.
- 7. Fixiervorrichtung nach einem der vorstehenden Ansprüche, wobei die Faltanordnung einen Aktivierungsring (244), ein Führungselement (242) und eine Vielzahl von Armelementen (244) einschließt, die auf dem Aktivierungsring gestützt wird; wobei vorzugsweise das Führungselement eine Vielzahl von

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Kanälen (243) definiert, die konfiguriert sind, um die Vielzahl von Armelementen verschiebbar zu halten.

- 8. Fixiervorrichtung nach Anspruch 7, wobei erste Enden der Armelemente relativ zu dem Aktivierungsring schwenkbar befestigt sind; vorzugsweise wobei zweite Enden der Armelemente konfiguriert sind, um Klappenabschnitte des Dichtungselements in Eingriff zu nehmen.
- **9.** Fixiervorrichtung nach Anspruch 8, wobei die Armelemente von einer ersten Position in eine zweite Position bewegbar sind, wenn der Aktivierungsring in einer ersten Richtung gedreht wird.
- Fixiervorrichtung nach einem der Ansprüche 7 bis 9, wobei die Vielzahl von Armelementen sechs Armelemente einschließt.
- **11.** Verfahren zum Falten eines Dichtungselements (50) ²⁰ für eine chirurgische Zugangsvorrichtung unter Verwendung einer Fixiervorrichtung (100), das Verfahren umfassend:

Laden eines Dichtungselements auf einer ²⁵ Nestanordnung (200) der Fixierungsvorrichtung;

Vorschieben eines Ambosselements (310) in Eingriff mit einem Stützabschnitt des Dichtungselements, um das Falten von Klappenabschnitten (54) des Dichtungselements relativ zu dem Stützabschnitt des Dichtungselements zu veranlassen;

Zurückziehen des Ambosselements weg von dem Dichtungselement;

Aktivieren einer Faltanordnung (240), um das Falten und Verflechten der Klappenabschnitte des Dichtungselements fortzusetzen; und Vorschieben des Ambosselements in Eingriff mit den Klappenabschnitten (54), um die Klappenabschnitte abzuflachen.

- 12. Verfahren nach Anspruch 11, wobei das Laden des Dichtungselements auf der Nestanordnung ein Platzieren des Dichtungselements (50) auf einer Stützplatte (262) einer Stützanordnung (260) und das Befestigen einer Dichtungsklemme (270) an der Stützplatte einschließt.
- 13. Verfahren nach Anspruch 11 oder 12, wobei das Befestigen der Dichtungsklemme (270) an der Stützplatte ein Ausrichten der Armabschnitte (244) der Dichtungsklemme an Bereichen der Klappenabschnitte (54) des Dichtungselements einschließt; vorzugsweise wobei das Vorschieben des Ambosselements in Eingriff mit dem Stützabschnitt der Dichtungsanordnung die Klappenabschnitte des Dichtungselements veranlasst, verflochten zu werden.

- 14. Verfahren nach einem der Ansprüche 11 bis 13, wobei das Vorschieben des Ambosselements in Eingriff mit dem Stützabschnitt ein Absenken eines Nestelements der Nestanordnung in eine abgesenkte Position einschließt.
- **15.** Verfahren nach Anspruch 14, das ferner das Klemmen des Nestelements in der abgesenkten Position einschließt.

Revendications

 Dispositif de fixation (100) pour plier un élément d'étanchéité (50) pour un dispositif d'accès chirurgical, le dispositif de fixation comprenant :

> un cadre (110) comportant une partie horizontale et une partie verticale ;

un ensemble presse (300) fixé à la partie verticale du cadre, l'ensemble presse comportant un ensemble poignée et un ensemble enclume (310) relié de manière fonctionnelle à l'ensemble poignée ; et

un ensemble emboîtement (200) fixé à la partie horizontale du cadre, l'ensemble emboîtement comportant un ensemble serrage (220), un ensemble pliage (240) supporté sur l'ensemble serrage, un ensemble support (260) supporté sur l'ensemble pliage, et un élément d'emboîtement, dans lequel l'ensemble support comporte une plaque de support (262) et une pince d'étanchéité (270) pour fixer un élément d'étanchéité.

- ³⁵ 2. Dispositif de fixation selon la revendication 1, dans lequel la pince d'étanchéité (270) comporte une partie annulaire (272) et une pluralité de parties de bras (274) s'étendant radialement vers l'intérieur depuis la partie annulaire.
 - Dispositif de fixation selon la revendication 1 ou la revendication 2, dans lequel l'élément d'emboîtement a une forme hexagonale.
 - Dispositif de fixation selon l'une quelconque revendication précédente, dans lequel l'élément d'emboîtement est mobile par rapport à une base (210) de l'ensemble emboîtement entre une position relevée et une position abaissée.
 - Dispositif de fixation selon l'une quelconque revendication précédente, dans lequel une surface supérieure (284) de l'ensemble emboîtement définit une pluralité d'ouvertures (283) pour recevoir des broches de retenue (214).
 - 6. Dispositif de fixation selon l'une quelconque revendication précédente, dans lequel l'ensemble enclu-

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me (310) comporte un élément d'enclume (312) conçu pour une mise en prise sélective avec l'élément d'étanchéité supporté sur l'ensemble support.

- 7. Dispositif de fixation selon l'une quelconque revendication précédente, dans lequel l'ensemble pliage comporte un anneau d'activation (244), un élément de guidage (242), et une pluralité d'éléments de bras (244) supportés sur l'anneau d'activation ; de préférence dans lequel l'élément de guidage définit une pluralité de canaux (243) conçus pour retenir de manière coulissante la pluralité d'éléments de bras.
- 8. Dispositif de fixation selon la revendication 7, dans lequel les premières extrémités des éléments de bras sont fixées de manière pivotante par rapport à l'anneau d'activation ; de préférence dans lequel les secondes extrémités des éléments de bras étant conçues pour venir en prise avec des parties de rabat de l'élément d'étanchéité.
- Dispositif de fixation selon la revendication 8, dans lequel les éléments de bras sont mobiles d'une première position à une seconde position lorsque l'anneau d'activation est tourné dans un premier sens.
- Dispositif de fixation selon l'une quelconque des revendications 7 à 9, dans lequel la pluralité d'éléments de bras comporte six éléments de bras.
- Procédé de pliage d'un élément d'étanchéité (50) pour un dispositif d'accès chirurgical à l'aide d'un dispositif de fixation (100), le procédé comprenant :

le chargement d'un élément d'étanchéité sur un ³⁵ ensemble emboîtement (200) du dispositif de fixation ;

l'avancement d'un élément d'enclume (310) en prise avec une partie de support de l'élément d'étanchéité pour provoquer un pliage des parties de rabat (54) de l'élément d'étanchéité par rapport à la partie de support de l'élément d'étanchéité ;

la rétraction de l'élément d'enclume à distance de l'élément d'étanchéité ;

l'activation d'un ensemble pliage (240) pour continuer le pliage et l'entrelacement des parties de rabat de l'élément d'étanchéité ; et l'avancement de l'élément d'enclume en prise

avec les parties de rabat (54) pour aplatir les 50 parties de rabat.

12. Procédé selon la revendication 11, dans lequel le chargement de l'élément d'étanchéité sur l'ensemble emboîtement comporte le placement de l'élément d'étanchéité (50) sur une plaque de support (262) d'un ensemble support (260) et la fixation d'une pince d'étanchéité (270) à la plaque de sup-

port.

- 13. Procédé selon la revendication 11 ou la revendication 12, dans lequel la fixation de la pince d'étanchéité (270) à la plaque de support comporte l'alignement de parties de bras (244) de la pince d'étanchéité avec des sections des parties de rabat (54) de l'élément d'étanchéité ; de préférence dans lequel l'avancement de l'élément d'enclume en prise avec la partie de support de l'ensemble d'étanchéité amène les parties de rabat de l'élément d'étanchéité à s'entrelacer.
- 14. Procédé selon l'une quelconque des revendications 11 à 13, dans lequel l'avancement de l'élément d'enclume en prise avec la partie de support comporte l'abaissement d'un élément d'emboîtement de l'ensemble emboîtement à une position abaissée.
- 20 15. Procédé selon la revendication 14, comportant en outre le serrage de l'élément d'emboîtement dans la position abaissée.
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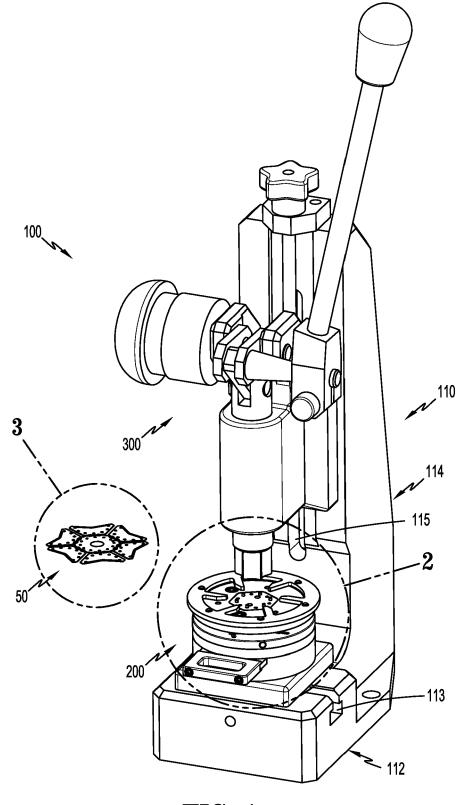
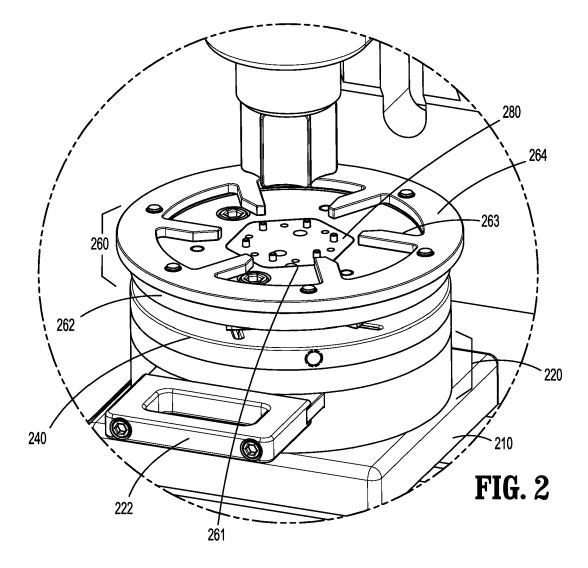
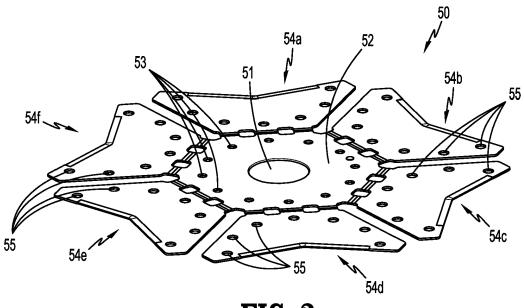
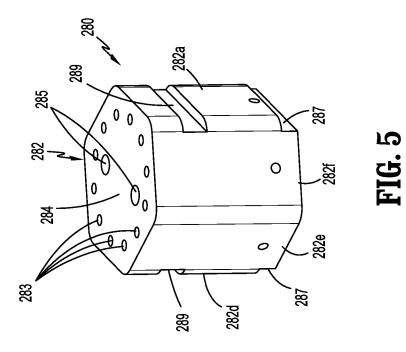


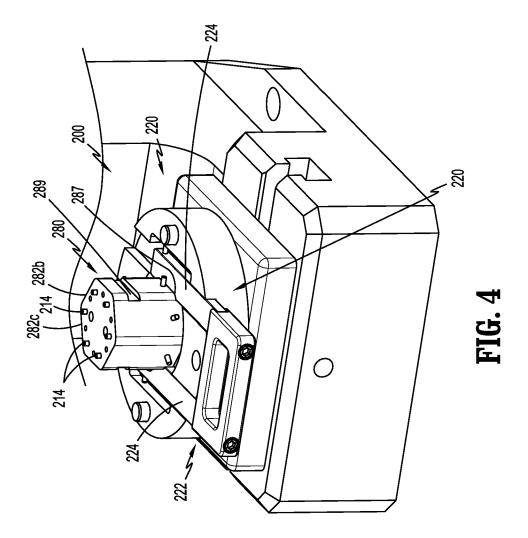
FIG. 1

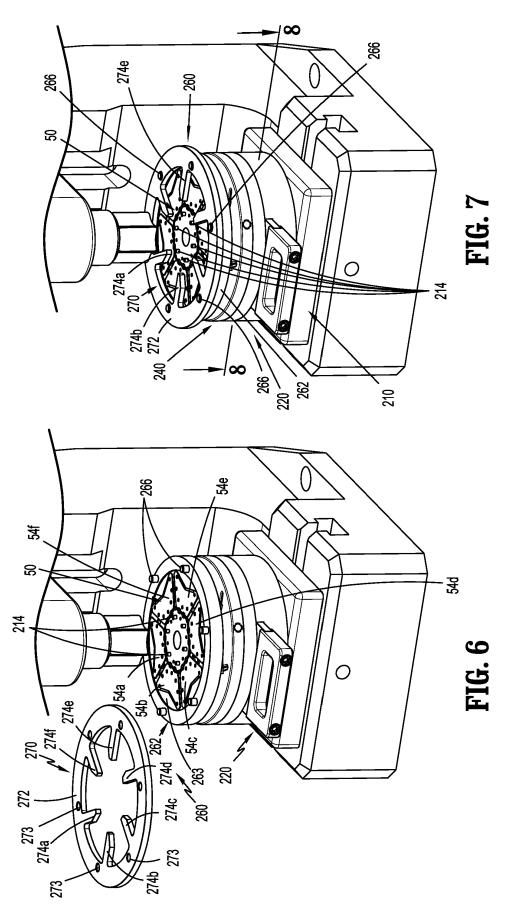


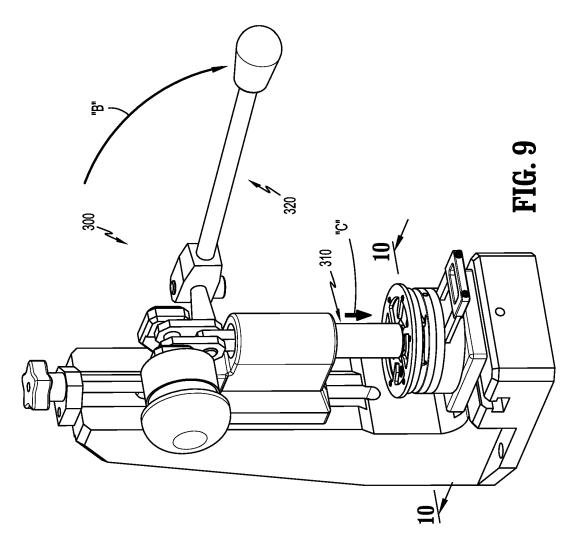


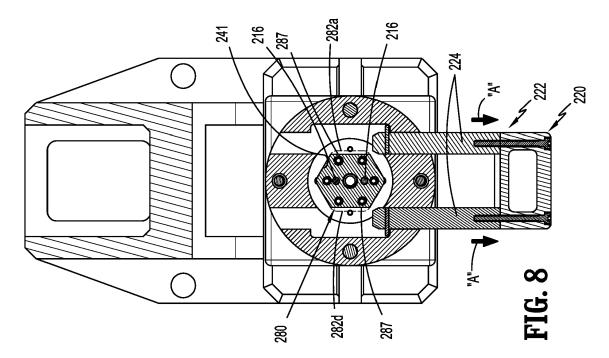


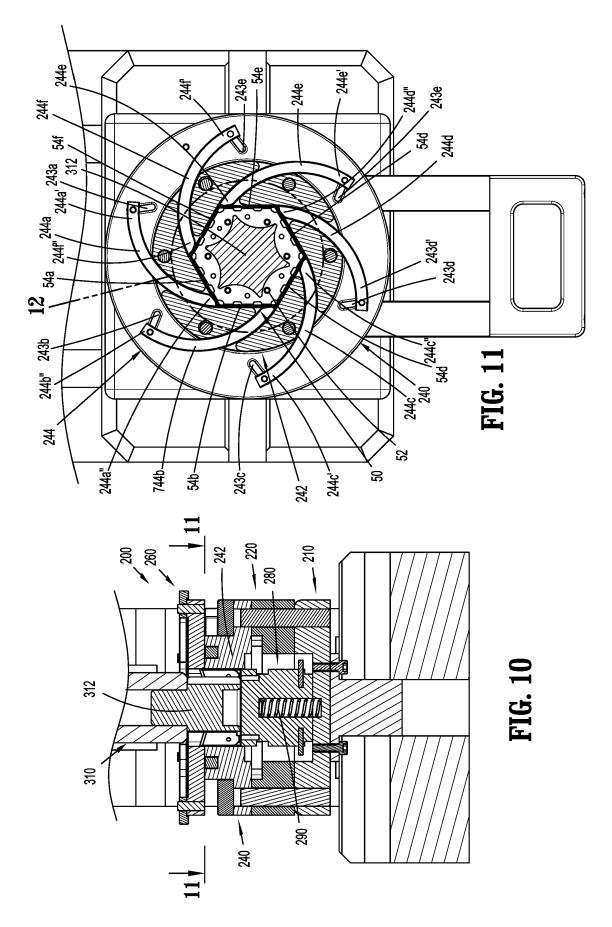


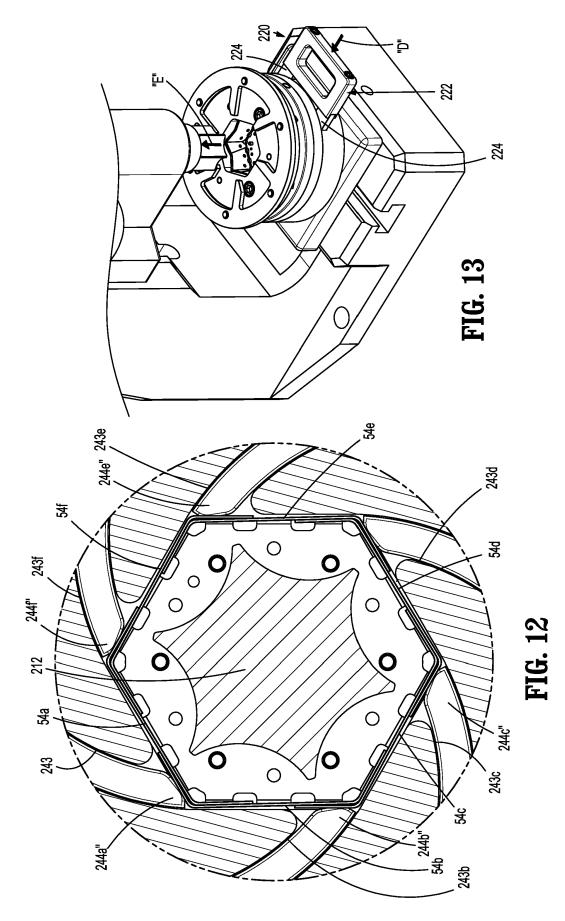


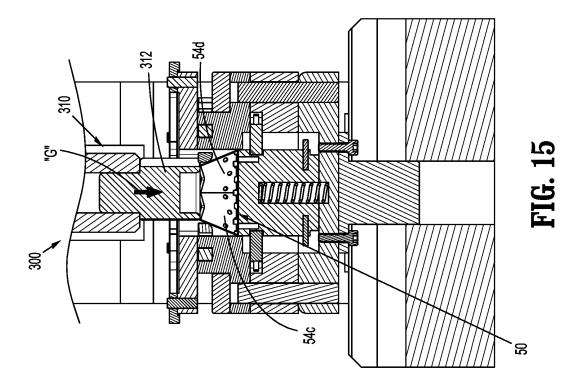


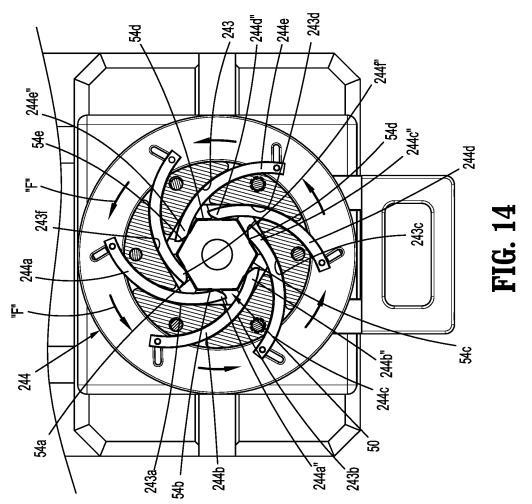


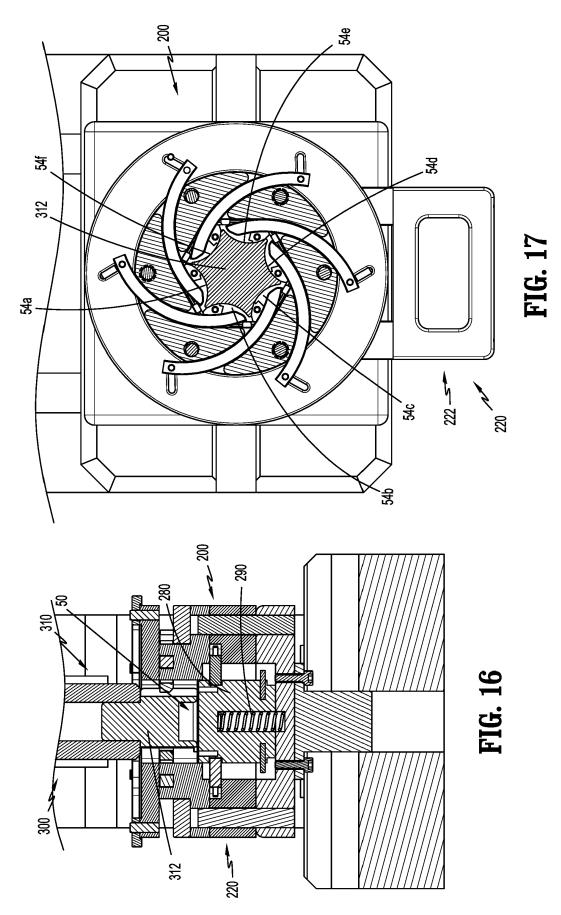












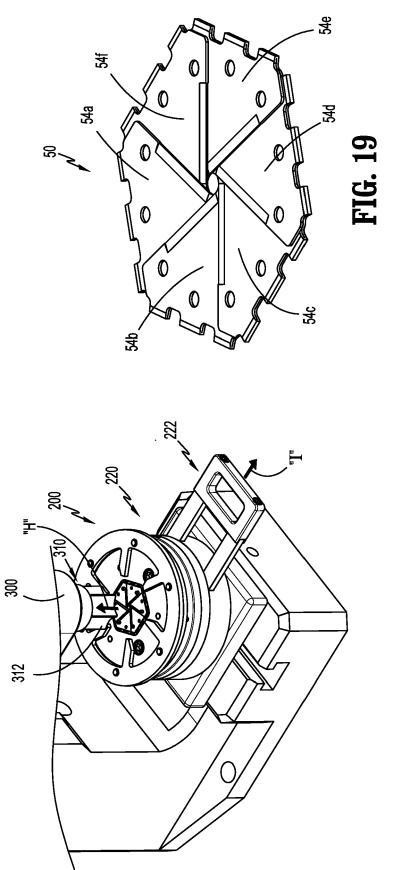
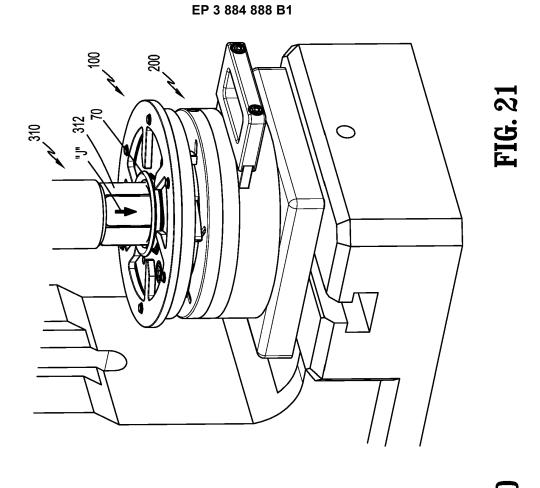
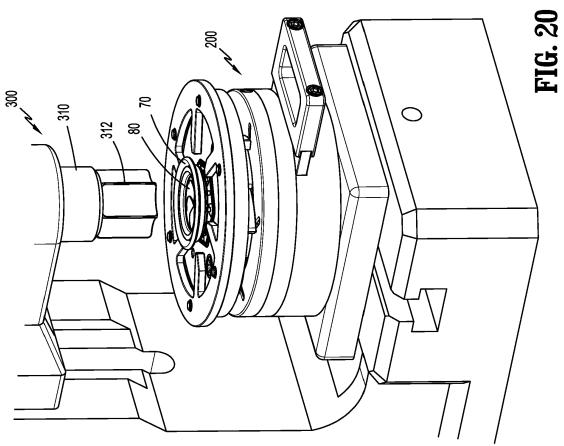
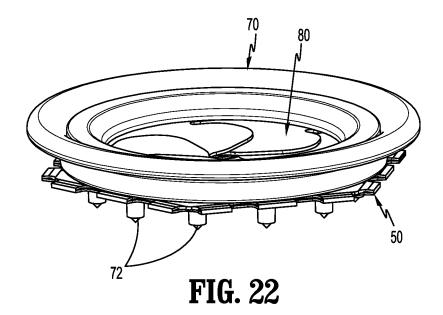


FIG. 18







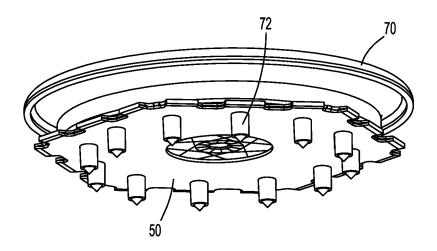


FIG. 23

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

• WO 2016110720 A [0004]

• US 77420620 [0037]