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SURGICAL SCREW CADDY

Abstract

A screw caddy device has material and structure to stabilize surgical screws for transport and engagement with a patient. The device includes non-rigid elastomeric material. The non-rigid elastomeric material is formed with openings to receive the screws for transport and to stabilize the screws while being extended into the patient. Lower exterior surfaces of the non-rigid elastomeric material may even be configured to engage holes in a surgical plate to assist with extending the screws into the plate and patient. Also disclosed are methods for manufacturing, providing, and using screw caddy device(s) consistent with present principles.

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Background/Summary

FIELD

[0001] The disclosure below relates generally to surgical screw caddies for use in craniomaxillofacial (CMF) fracture reductions and other surgical procedures.

BACKGROUND

[0002] Miniature surgical screws are often difficult to package, handle, deliver, and trace. Current surgical room techniques involve loading the screw onto a screwdriver tip (or blade tip) at a back table and then moving the screw and screwdriver together to the patient. The surgeon then attempts to insert the screw into a surgical plate hole using the screwdriver, which requires precision or else the screw can become dislodged from the driver and dropped. Even if aligned correctly with the plate hole, it is often difficult to then stably drive the screw through the plate hole and into the bone of the patient, creating more opportunity for dislodgement of the screw as well as less than optimal screw positioning within the patient themselves.

SUMMARY

[0003] Accordingly, the disclosure below relates to surgical screw caddies/loaders that can be used in sterile surgical environments. Each caddy may use material and structure to stabilize the screws while being transported from a surgical back table to the patient themselves, and to stabilize the screws while being driven through the caddy and into the patient.

[0004] Accordingly, in one aspect a medical device includes a cartridge. The cartridge includes a first opening configured to receive a screw. The first opening is formed at least in part by a non-rigid elastomeric material. The non-rigid elastomeric material is configured on the cartridge to stabilize the screw within the cartridge. The medical device also includes a rigid member engaged with an upper surface of the cartridge. The rigid member includes a second opening that aligns with the first opening for the screw to pass through the second opening and into the first opening for engagement with the non-rigid elastomeric material.

[0005] In various examples, the non-rigid elastomeric material itself may include silicone, thermoplastic elastomer, and/or other elastomer(s).

[0006] In some implementations, the cartridge and rigid member may establish at least part of a head that is engageable with a handle, and the medical device may even include the handle itself. The handle may be integral with at least a portion of the head, or may be detachable from the head. If detachable from the head, in specific examples the handle and head may be engageable with each other via a ball and socket assembly. Additionally, if desired the medical device may include the ball and socket assembly itself, with the ball of the ball and socket assembly being disposed on the head and with the socket of the ball and socket assembly being disposed on the handle. The medical device may even include a locking mechanism to lock the ball into the socket to secure the head on the handle while still allowing articulation of the head with respect to the handle.

[0007] If desired, the medical device may include and/or be vended with the screw(s) themselves.

[0008] Also in various example embodiments, an exterior surface of the non-rigid elastomeric material may taper distally at a distal end portion to receive a hole of a surgical plate. Also, a bottom portion of the cartridge may be configured to removably engage with the surgical plate. Additionally or alternatively, the medical device may include an engagement mechanism extending downward from the rigid member to removably engage the cartridge with the surgical plate. If desired, the medical device may include the surgical plate itself, with the plate being a plate through which the screw is extendable.

[0009] In another aspect, a method includes extending a screw into a first opening in a cartridge. The first opening is formed at least in part by a non-rigid material, with the non-rigid material configured on the cartridge to stabilize the screw within the cartridge. The method also includes

extending the screw through the first opening and into a surgical plate on a patient.
[0010] In some examples, the non-rigid material may include silicone and/or thermoplastic elastomer.
[0011] In still another aspect, a device includes a cartridge. The cartridge includes a first opening configured to receive a surgical fastener. The first opening is formed at least in part by a non-rigid material configured on the cartridge to stabilize the surgical fastener within the cartridge. The non-rigid material may include silicone and/or thermoplastic elastomer in various examples.
[0012] If desired, the device may also include a rigid member engageable with an upper surface of the cartridge. The rigid member may include a second opening that aligns with the first opening for the surgical fastener to pass through the second opening and into the first opening for engagement with the non-rigid material.
[0013] Also if desired, the device may include a surgical plate and mechanism for engaging the surgical plate with the cartridge.
[0014] The details of the present application, both as to its structure and operation, can best be understood in reference to the accompanying drawings, in which like reference numerals refer to like parts, and in which:

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0015] FIG. **1** illustrates a first example embodiment of a medical device in front isometric view consistent with present principles;
[0016] FIG. **2** illustrates the first example embodiment in rear isometric view consistent with present principles;
[0017] FIGS. **3** and **6** illustrate the first example embodiment in left side elevational views according to unlocked and locked configurations consistent with present principles;
[0018] FIGS. **4** and **7** illustrate the first example embodiment in bottom plan views according to unlocked and locked configurations consistent with present principles;
[0019] FIGS. **5** and **8** illustrate the first example embodiment in right side elevational views according to unlocked and locked configurations consistent with present principles;
[0020] FIG. **9** shows an example non-rigid cartridge and example rigid member in exploded isometric view consistent with present principles;
[0021] FIG. **10** shows the cartridge assembly in upper isometric view consistent with present principles;
[0022] FIG. **11** shows the cartridge assembly in lower isometric view consistent with present principles;
[0023] FIG. **12** shows the cartridge assembly in front cross-section view consistent with present principles;
[0024] FIG. **13** shows a close-up cross-section view of part of the cartridge assembly as also shown in FIG. **12**;
[0025] FIG. **14** shows a close-up cross-section view of the cartridge assembly with a screw inserted into the cartridge consistent with present principles;
[0026] FIG. **15** shows an upper isometric view of the cartridge assembly with screws loaded consistent with present principles;
[0027] FIGS. **16-19** graphically illustrate different steps that may be taken to assemble the first example embodiment consistent with present principles;
[0028] FIGS. **20** and **21** graphically illustrate articulation of the device's head with respect to the device's handle consistent with present principles;
[0029] FIG. **22** shows a second example embodiment of a medical device in upper isometric view

consistent with present principles;
[0030] FIG. **23** shows the second example embodiment in front cutaway cross-section view consistent with present principles;
[0031] FIG. **24** shows the second example embodiment in side cutaway cross-section isometric view consistent with present principles;
[0032] FIGS. **25-27** show upper isometric views of a third example embodiment of a medical device in upper isometric view in various stages of assembly consistent with present principles;
[0033] FIG. **28** shows a bottom isometric view of the third example embodiment as assembled together with a surgical plate consistent with present principles;
[0034] FIG. **29** shows a bottom isometric partial view of the third example embodiment as engaged with a handle of the device consistent with present principles;
[0035] FIG. **30** shows an upper isometric view of the third example embodiment as engaged with a handle of the device consistent with present principles;
[0036] FIGS. **31** and **32** show isometric views of the third example embodiment in polyaxial articulation consistent with present principles;
[0037] FIG. **33** shows an isometric view of a cartridge assembly and handle according to a fourth example embodiment of a medical device consistent with present principles;
[0038] FIG. **34** shows an example method in flow chart format for surgically using a medical device consistent with present principles;
[0039] FIG. **35** shows an example method in flow chart format for manufacturing a medical device consistent with present principles;
[0040] FIG. **36** shows an example method in flow chart for providing a medical device consistent with present principles;
[0041] FIGS. **37**A-**37**E show respective front, top, right side, cross section right, and isometric views of an example burr-shape embodiment consistent with present principles;
[0042] FIGS. **38**A, **38**B, and **38**C show respective exploded isometric, exploded side, and exploded isometric views of the same setup as FIGS. **37**A-**37**E;
[0043] FIGS. **39**A-**37**E show respective front, top, right side, cross section right, and isometric views of an example H-shape embodiment consistent with present principles;
[0044] FIGS. **40**A, **40**B, **40**C, and **40**D show respective exploded isometric, exploded side, exploded isometric, and exploded cross-sectional views of the same setup as FIGS. **39**A-**39**E;
[0045] FIGS. **41**A-**41**E show respective front, top, right side, cross section right, and isometric views of an example dog-bone shape embodiment consistent with present principles;
[0046] FIGS. **42**A, **42**B, and **42**C show respective exploded isometric, exploded side, and exploded isometric views of the same setup as FIGS. **41**A-**41**E;
[0047] FIGS. **43**A-**43**E show respective front, top, right side, cross section right, and isometric views of an example square-shape embodiment consistent with present principles; and
[0048] FIGS. **44**A, **44**B, and **44**C show respective exploded isometric, exploded side, and exploded isometric views of the same setup as FIGS. **43**A-**43**E.

DETAILED DESCRIPTION

[0049] Present principles recognize that craniomaxillofacial (CMF) fracture reduction screw handling and driving can be technically improved. However, present principles are not limited to CMF fracture reduction devices and techniques and may also be used in other types of surgical procedures, including other types of open reduction, internal fixation fracture reductions and cranial trauma procedures, cranial reconstruction procedures, and craniotomy procedures. Present principles may also be used in orthopedic procedures not involving the head, including femur fracture reduction, ulna or radius fracture reduction, and others. Present principles may even be used for fastener handling, delivery, and installation in non-medical contexts, including delivering and installing fasteners in carpentry, automotive, mechanical, and assembly/manufacturing contexts.

[0050] Accordingly, various example caddies are discussed below. Each caddy can accept and retain CMF and/or neuro screws or other types of fasteners. In some instances, each caddy can even accept and retain a CMF plate, neuro plate, or other type of internal bone fixation plate. Each caddy may be delivered sterile with the plate itself attached to the instrument, whether the plate is a burr hole plate, straight plate, etc. The caddy might even be pre-loaded with 1.5×5 mm screws and/or screws of other sizes. The caddy may allow delivery of the screws into the bone via a driver/blade (e.g., cruciform head screwdriver) while retaining the screws and even the plate itself when accidentally dropped or otherwise jostled.

[0051] The caddies may be configured in various shapes to match corresponding plate shapes, with the screw-to-screw distance and arrangement of the screw openings in each caddy being equal to the screw-to-screw distance and arrangement of the screw holes on the respective plate itself. Example shapes include generally rectangular/straight-line hole shapes, rounded burr hole cover shapes, double-Y or dog bone shapes, single-Y shapes, U-shapes, and X-shapes. These caddies may be included as different modular heads that each have a rigid backing/member and non-rigid elastomer material, and the heads can be swapped in and out on a given handle while in the operating room. In some cases, an articulating caddy head may be used so that the head articulates with respect to the handle. Caddies may be configured to accept any desired plate and/or screw for a given procedure.

[0052] Additionally, the number of fastener openings that might be included on a given caddy can vary, depending on desired implementation. The fasteners themselves might be self-drilling screws, self-tapping screws, and/or bone screws. The screws may be manual screws or power-driven screws. However, the openings in the caddies may be used for other types of fasteners as well, such as surgical tacks or nails.

[0053] The various caddies disclosed herein may also allow adequate visibility to the wound surface, screws, and/or surgical plates. Additionally, the various components of the example devices disclosed below may be manufactured with non-reflective surface finishes (e.g., matte finishes) to reduce glare into the eyes of the surgeon that might otherwise occur due to light reflections from headlamps or other light sources and that could obstruct vision to the surgical site.

[0054] In terms of caddy handles, each handle may be assembled with a respective caddy at manufacture or in an operating room. Either way, the handle may be included in a single-use peel packaging that also encloses the caddy, screws, and surgical plate for direct-to-patient delivery.

[0055] Caddies consistent with present principles may thus improve the reliability and ease of screw delivery. Caddies consistent with present principles may also improve surgical workflow, allowing for secure multi-screw loading at the back surgical table in situ.

[0056] Now in cross-reference to the front and rear isometric views of FIGS. **1** and **2**, an example medical device **100** consistent with present principles is shown. As shown, the device **100** may include a head **110** and elongated, rigid handle **120**. The head **110** and handle **120** may be made integral with each other in certain examples, while in other examples the head **110** and handle **120** may be detachable and engageable with each other via a ball and socket joint/assembly **130** (or other mechanism). Either way, the head **110** may attach to the handle **120** with an approximately central axis that extends at an angle between 0 and 90 degrees relative to the long axis of the bone screw(s). The head **110** may be generally rectangular-shaped in the non-limiting example shown. The head **110** may have solid components described in more detail below, along with hollow openings for receiving fasteners such as screws. The cross-sectional shape of the handle **120** may be generally rectangular.

[0057] If a ball and socket assembly **130** is to be used, the ball **140** of the ball and socket assembly **130** may be disposed on the head **110** (e.g., made integrally with other portions of the head **110**), while the socket **150** of the ball and socket assembly **130** may be disposed on the handle **120**, or vice versa. The socket **150** may be established by a spherical opening of a larger diameter than the ball **140**.

[0058] Additionally, the device **100** may include a locking mechanism **160** to lock the ball **140** into the socket **150** to secure the head **110** on the handle **120** while still allowing articulation of the head **110** with respect to the handle **120**. The locking mechanism **160** may be established by a collet **170** and inner teeth/lock ring **180**. The teeth **180** may extend longitudinally under the collet **170** according to a longitudinal axis of the handle **120**. As shown, the teeth **180** may have protrusions at distal ends nearest the head **110**. The protrusions may extend generally inward toward a transverse center of the socket **150** to lock the ball **140** into the socket **150** when the collet **170** is screwed at least partially over top of the teeth **180**, while still permitting the ball **140** to rotate within the socket **150** in this locked configuration. The teeth **180** may also be configured to move back and forth toward and away from the transverse center of the socket **150** when the collet **170** is not in the locked position, allowing the ball **140** to pass in and out of the socket **150** to engage or disengage the ball **140** from the socket **150**. The teeth **180** may then be locked into place by screwing the collet **170** over the teeth **180**, with the protrusions on the teeth **180** creating interference between the ball **140** and teeth **180** that locks the ball **140** within the socket **150**, disallowing the ball **140** from passing out of the socket **150** but still permitting articulation of the head **110** with respect to the handle **120**.

[0059] Thus, note that in some examples outer sidewalls of the teeth **180** may be threaded with female threads to engage male threads on the inside of the collet **170** as the collet **170** is screwed onto the teeth **180**, moving the collet **170** distally in the process. Additionally or alternatively, the collet **170** may engage female threads on another portion of the handle to screw the collet **170** onto the teeth **180**. Either way, also note for completeness that the teeth **180** may be configured to abut each other in close interference fit in the locked configuration in some examples, while in other examples adjacent teeth **180** may still be radially spaced apart from each other as shown in FIG. **1**.

[0060] FIGS. **3-5** show the mechanism **160** in unlocked configuration respectively in left side elevational, bottom plan, and right side elevational views. FIGS. **6-8** then show the mechanism **160** in locked configuration respectively in left side elevational, bottom plan, and right side elevational views. Note per FIGS. **3-5** that the collet **170** is located more proximal to the body of the handle **120** while the mechanism **160** is unlocked, and more distally away from the body of the handle **120** while the mechanism **170** is locked per FIGS. **6-8** (after being rotationally screwed down onto and over top of the teeth **180**).

[0061] Now referring back to FIGS. **1** and **2** and describing the handle **120** in more detail, it may be arced or bowed in the transverse dimension as shown, with an apex of the arc or bow being located at a midway point of the handle **120** according to the longitudinal dimension. Therefore, as shown in these figures, the arc or bow may extend transversely upward relative to a top surface of the handle **120**. The handle **120** may also have one or more grooves **190** for ergonomic hand gripping by a surgeon. Also note that a distal portion of the handle **120** establishes a collar **200** that slopes inward distally until it engages proximal inner surfaces of the collet **170** to couple the collet **170** to the rest of the handle **120**.

[0062] Now describing the head **110** in more detail, note that an arm **210** on the head **110** may be integral with the ball **140** and extend distally away from the ball **140**. An opposing, distal end of the arm **210** may engage a clamp or holder **220** on the head **110**. The holder **220** may have a distal opening as shown to receive a cartridge assembly/caddy **230** consistent with present principles.

[0063] Now in reference to FIG. **9**, the cartridge assembly/caddy **230** is shown in greater detail in exploded upper isometric view. As shown, the assembly/caddy **230** may include a cartridge **300**. The cartridge **300** may be radiolucent for the surgeon to visualize screw trajectory. The cartridge **300** may be smooth on the outside. The cartridge **300** may also be soft and pliable/flexible yet resilient due to the non-rigid elastomer with which it is constructed, able to deform when a screw passes through but still able to resume a preconfigured size and shape after the screw passes through.

[0064] The cartridge **300** may be solid but include one or more first openings **310** that are each

configured to receive a respective screw or other fastener. The first openings **310**, and indeed some or all of the cartridge **300** itself, may be formed using the non-rigid material. The non-rigid material may be an elastomer such as silicone alone, rubber alone, thermoplastic elastomer (TPE) alone, a combination of silicone and/or rubber and/or thermoplastic elastomer, or a combination of silicone/rubber/thermoplastic elastomer and other material. In one specific non-limiting example, thermoplastic polyurethane (TPU) may be used, while in another non-limiting example elastic medical-grade liquid silicone rubber (LSR) may be used.

[0065] The composition of the non-rigid elastomeric material, along with its arranged structure on the cartridge **300** as described in greater detail below, help to stabilize the screws (or other fasteners) within the first openings **310** of the cartridge **300**, also allowing the screws to still be moved independently of each other while each screw is still in a respective opening **310**. One screw at a time may then be aligned with a hole in a surgical plate for the screw to then be screwed through the respective opening **310** and into the surgical plate (and hence patient), or multiple screws may be concurrently aligned with holes on the plate to then keep the cartridge **300** immobile with respect to the plate as different screws are progressively screwed in via the openings **310**.

[0066] As also shown in FIG. **9**, the openings **310** in this example may form a single row, with the openings **310** being linearly aligned with each other and spaced apart from each other in a transverse dimension (labeled **320** in FIG. **9**) to establish a linear opening configuration. In other examples, multiple rows of openings **310** may be included on the cartridge **300** to establish a rectangular hole configuration. Other hole configurations are also encompassed by present principles, including a circular/burr hole configuration, a double-Y or dog bone configuration, a single-Y configuration, etc.

[0067] FIG. **9** also shows that the assembly/caddy **230** may include a rigid member **350**. In the example shown in FIG. **9**, a distal portion of the rigid member **350** may be transversely elongated left to right. The member **350** may be engaged/engageable with one or more upper surfaces of the cartridge **300**. The upper surfaces of the cartridge **300** may include outer sidewalls and/or inner sidewalls **315** of the cartridge **300** that extend up from a top face **410** of the cartridge, and/or the top face **410** itself, for example. The rigid member **350** may include edges **355** tapering outward and downward to sidewalls **357**. In one specific instance, the lower portions of the rigid member **350**, including the sidewalls **357**, may be reciprocal with and seated within the open-top bay created by the upper sidewalls **315** and top face **410** of the cartridge **300** (the bay best shown in FIG. **9**) to engage the cartridge **300** with the member **350**. The edges **355** and sidewalls **357** may be bulbous in the proximal-distal plane, undulating between bulbed portions that surround each respective second opening **360** as located on the member **350** and described in more detail later.

[0068] FIG. **10** therefore shows the cartridge **300** and rigid member **350** coupled to each other via snap fit or interference fit of the member **350** within the cartridge's bay. Note that in the example shown, the rigid member **350** covers most if not all of the top face **410** of the cartridge **300**.

[0069] In addition to or in lieu of snap or interference fit, the cartridge **300** and member **350** may be inseparably bonded together using an adhesive/glue at manufacture (inseparably bonded save for the combined assembly itself being broken/deconstructed). As another example, the non-rigid elastomeric material (e.g., TPE, silicone and/or other elastomer) of the cartridge **300** may be over-molded onto the member **350** at manufacture so that the two components are inseparably bonded (again save for the combined assembly itself being broken/deconstructed).

[0070] The member **350** may be established by a rigid metal such as medical-grade steel or aluminum, for example. Additionally or alternatively, the member **350** may be established by a hard plastic and/or other hardened polymer. As referenced above, the member **350** may also have a matte finish or other non-reflective finish to minimize any glare off the member **350** in a surgical environment.

[0071] Still in reference to FIGS. **9** and **10**, as mentioned above the distal portion of the rigid member **350** may include one or more second openings/counterbores **360**. The openings **360** may

vertically align with respective first openings **310** on the cartridge **300** for a respective screw to pass vertically through a respective second opening **360** and into an aligned first opening **310** for engagement of the screw with the non-rigid material of the cartridge **300**.
[0072] As also shown in FIGS. **9** and **10**, the rigid member **350** may be made integral with or otherwise coupled to a rigid male dovetailed element **370** extending proximally away from the cartridge **300** to meet the holder **220**. The element **370** may be made of the same rigid metal or other material as the rest of the member **350**. In the particular example shown, the element **370** may transversely slide into a reciprocal distal opening on the holder **220** from either side, mating the cartridge **300** and member **350** with other portions of the head **110** and/or handle **120**. Thus, as also shown in these figures, the element **370** may include protrusions extending upward and downward, even sloping proximally upward and downward from a main body portion of the element **370**, to mate with the reciprocal distal opening on the holder **220**. The element **370** may thus closely engage the holder **220** in interference and/or friction fit, providing added stability and immobility of the element **370** and member **350** with respect to the holder **220**.
[0073] Turning to FIG. **11**, this figure shows a bottom isometric view of the assembly **230** as it might have been sterilely assembled at a factory or other facility prior to being provided to healthcare professionals. As shown, the non-rigid cartridge **300** may include non-rigid connectors/ribs **380** that are formed integrally with and located between the generally cylindrical portions **400** of the cartridge **300** that themselves establish the openings **310** (e.g., as formed through injection molding, 3D printing, etc.). The connectors **380** may be parallelepiped in shape, such as rectangular box-shaped. The connectors **380** may be included to add stability and structural integrity to the cartridge **300**, providing some rigidity upon screw insertion into the openings **310**.
[0074] Further note that side arms **390** may also be formed integrally with the outer-most cylindrical portions **400** on each side of the cartridge **300** as shown, also for stability and structural integrity. In some examples, the side arms **390** may be rounded or taper inward at the lower ends as shown. Note that lower surfaces **395** of the upper sidewalls **315** may taper down to a flat horizontal surface **397**. Additionally, tapering walls **399** may extend proximally downward from the surface **397** to meet both vertical sidewalls of the cylindrical portions **400** and the sidewalls of the connectors **380**.
[0075] As for the generally cylindrical portions **400** of the cartridge **300** that establish the openings **310**, they may include a respective cylindrical upper chamber **420** that is proximal to the rigid member **350** and integral with the horizontal structure of the cartridge **300** forming the top face **410**. Thus, the top face **410** may be perpendicular to the longitudinal axes of the cylindrical upper chambers **420**.
[0076] Distal to the cylindrical upper chambers **420**, the exterior surface of each respective portion **400** may taper distally inward at a respective distal end portion **430** to receive a respective hole of a surgical plate. In some specific implementations, each end portion **430** may also include a raised rib **435** midway down the portion **430**, with the rib **435** circumscribing the end portion **430** perpendicularly to the longitudinal/vertical axis of the respective chamber **420**. The rib **435** may be included to add further stability and structural integrity to each opening **310** and providing added rigidity during screw insertion.
[0077] To reiterate, the connectors **380** and portions **400** may be made of LSR, TPE, and/or other non-rigid elastomeric material as set forth above. The tapering distal end portions **430** may therefore be gently positioned to extend at least partially into aligned holes on the surgical plate itself without undue jostling or force that might translate to the patient. The non-rigid, pliable (yet resilient) characteristics of the non-rigid material also advantageously allow a screw with a slightly larger screw shaft diameter (larger than the diameter of the respective opening **310**) and larger-diameter screw head to still be driven through the portion **400** and into the hole in the surgical plate in a stable, controlled manner during fracture reduction.
[0078] The rigid nature of the rigid member **350** also lends its own advantages, since control of it

via the handle **120** allows the screws to be driven through the openings **310** in the cartridge **300** under adequate hand control without undue action in the non-rigid material. The rigidness of the rigid member **350** also allows the screwdriver or driving blade to be removed from the assembly **230** without adhering to the non-rigid material or screw itself, reducing the chance of undue and unintended force being translated to the patient at or near the fracture site. Thus, in one specific example, the screwdriver may be separated from the screw by toggling the driver bit at an acute angle and lifting the driver away from the screw head once disengaged.

[0079] What's more, in some examples the tapering distal end portions **430** of the cartridge **300** may be configured to removably engage the surgical plate using a plate engagement mechanism, coupling the surgical plate to the cartridge **300** and indeed the device **100** itself so that the entire assembly can be transported from a back surgical table to the patient as a single unit (with screws already loaded into the openings **310**). The assembly including bottom surgical plate may then be aligned with a fracture site of the patient as desired. This allows the cartridge assembly **230** to remain locked and immobile with respect to the plate so that the plate may be placed on the patient where desired and then the screws may be screwed into the plate/patient through the assembly **230** one at a time without the assembly **230** or screws needing to be realigned each time the surgeon moves from one screw to another on the assembly **230**.

[0080] Now in refence to FIG. **12**, a front elevational view of the cartridge assembly **230** is shown. Note that certain outer front surfaces of the cartridge **300** are shown transparently for illustration to demonstrate the inner structure of the first openings **310** on the cartridge **300** and aligned second openings **360** on the rigid member **350**. As may be appreciated from FIG. **12**, the openings **310** may establish inner open chambers to closely receive surgical screws.

[0081] The structure of the openings **310** and **360** may be further appreciated from FIG. **13**, which shows a close-up front view of the left-most openings **310**/**360** shown in FIG. **12**. As shown in FIG. **13**, the opening **360** may include a cylindrical/disc-shaped open area **1300** in which the head of the screw may sit (e.g., flush or sub-flush to the top surface of the rigid member **350**) when the screw is disposed within the cartridge **300**. Beneath the area **1300**, the opening **310** may connect and taper inward into a cylindrical retention neck/bottleneck **1310** to retain the screw, with the bottleneck **1310** having a lesser diameter than the disc-shaped area **1300**. Recognizing that in certain non-limiting examples an average CMF surgical screw shaft width might be between 1.0 mm and 1.6 mm, the diameter of the bottleneck **1310** may be 0.8 mm to 1.0 mm. The non-rigid material at the bottleneck **1310** is therefore able to expand to receive the screw shaft, stabilizing the screw in the process owing to the interference fit.

[0082] FIG. **13** also shows that the bottleneck **1310** may then taper outward at a lower/distal end toward a cylindrical chamber **1320** of the opening **310**. The chamber **1320** may have a wider diameter than the bottleneck **1310**, and in some examples the diameter of the chamber **1320** may be wider than the outer limit of average-diameter CMF surgical screw shafts. As such, the diameter of the chamber **1320** may be 1.7 mm to 2.0 mm in non-limiting examples. Note further that the diameter of the chamber **1320** may still be less than the diameter of the area **1300** and head of the surgical screw itself so add further stability as the screw head passes through the chamber **1320** and into the plate/patient.

[0083] Accordingly, as the screw is driven into the patient, the screw shaft will be initially stabilized in the bottleneck **1310** while threading into the patient begins (before additional support is provided via the bone structure itself). As driving continues, the bottleneck **1310** may expand even further to allow the screw head to pass therethrough, stabilizing the screw head in the process. Then as the patient's bone structure/screw interface begins providing additional screw stabilization during driving, the head of the screw may pass into and through the chamber **1320** where, owing to less interference/lateral force existing between the screw head and chamber **1320** compared to the force exerted by the bottleneck **1310**, the screw may be more easily driven into the patient. Thereafter, the screw head may pass through a tapering funnel **1330** of the opening **310**, with the

funnel **1330** formed inside the distal end portion **430**.
[0084] It may thus be appreciated that the structure of the opening **310** is optimized for both stabilization early in screw driving and ease of driving later in screw driving (of the same screw). The funnel **1330** may then provide greater interference/pressure on the screw head at the end of driving, allowing the cartridge **300** to stay in position without becoming dislodged from the plate so that the surgeon can then drive another pre-loaded screw through another opening **310** as might already be aligned with another hole on the same surgical plate.
[0085] FIG. **14** therefore shows an example where a surgical screw **1400** (with head **1410** and shaft **1420**) has been pre-loaded into a respective opening **310** of the cartridge **300** for subsequent driving into a patient per the above. The position of the screw **1400** within the openings **310**/**360** as shown in this figure may establish the positioning of the screw **1400** as pre-loaded at manufacture and/or at a back surgical table of an operating room before transport to the fracture site of the patient.
[0086] FIG. **15** shows an upper isometric view of the cartridge assembly **230** with the cartridge **300** and rigid member **350** coupled to each other and with screws **1400** pre-loaded into the openings **310**. It may be appreciated from FIG. **15** that the geometry of the assembly **230** allows adequate surgeon visibility to the wound surface (e.g., through the scalloped indents in the sidewalls **315**).
[0087] FIGS. **16-19** show example steps for assembling the device **100** at a back surgical table of an operating room during a CMF fracture reduction procedure. As shown in FIG. **16**, the rigid member **350** may be engaged with the cartridge **300** if not already, with it being further recognized that in non-limiting examples the rigid member **350** and cartridge **300** may already be inseparably bonded together at manufacture. FIG. **17** then shows that after engagement, the screws **1400** may be loaded into the openings **310**. FIG. **18** then demonstrates that the cartridge assembly **230** may be slidably engaged with the holder **220** as described above.
[0088] Note here that while these three steps might be performed by medical professionals in an operating room, in other instances one or more of these steps may be performed in a sterile manufacturing facility during manufacture of the device **100**. For example, the assembled cartridge assembly **230** and pre-loaded screws **1400**, possibly as themselves loaded onto the rest of the device **100**, may be sterilely packaged together at manufacture and then sold (or otherwise provided) to the medical professionals in advance of a CMF fracture reduction procedure or other type of procedure for which the device **100** is to be used.
[0089] FIG. **19** therefore shows the assembled device **100** with screws pre-loaded. The upper isometric view of FIG. **20** and side elevational view of FIG. **21** then show that, owing to the ball and socket assembly **130** (in its locked position) allowing the assembly **230** to articulate radially about a longitudinal axis of the socket **150** and/or handle **120**, the assembly **230** may be rotated to the left and right as shown.
[0090] FIG. **22** shows an isometric view of an example where a device **1000** consistent with present principles is loaded with screws **1400**. A straight-hole H-plate **2200** is also shown as being located nearby. The front cutaway view of FIG. **23** then shows that certain openings **310** in the cartridge **300** may be aligned with respective holes **2210** in the plate **2200**. The tapered distal end portions **430** of the cartridge **300** may thus nest into the counterbores on the bone plate **2200** to help locate and extend each screw **1400** into the desired plate hole. Each tapered distal end portion **430** may thus be progressively aligned into a respective plate hole one screw at a time, or multiple distal end portions **430** may be simultaneously aligned with different holes in the plate **2200**.
[0091] The side cutaway isometric view of FIG. **24** then demonstrates that a fork, vice, clip, tangs, cam levers/cantilever arms, or other plate engagement mechanism **2400** may extend downward from the middle of the rigid member **350** to engage a neck of the plate **2200** between the holes **2210**, removably engaging the plate **2200** with lower distal end portions of the cartridge **300** and indeed device **1000** itself for the device **1000** with plate **2200** to be subsequently aligned with the fracture site of a patient as a single unit. The mechanism **2400** may be integral with the member

350 if desired and made of the same material (e.g., aluminum).
[0092] Also note here that according to this example, the arm **210** itself has been formed integral with the rigid member **350** as a unitary element (e.g., using aluminum or another rigid material mentioned above for the element **350**). This example embodiment may therefore omit the element **370** and holder **220**. FIG. **24** also shows that the distal ends of the fork or vice **2400** may include a step inward on inner surfaces as shown to closely receive the neck of the plate **2200**. If desired, a rachet or other clamping mechanism located elsewhere on the device **1000** may then be used to clamp the plate **2200** within the fork or vice **2400**, exerting lateral force on the plate **2200** to hold the plate **2200** in place.
[0093] FIGS. **25** and **26** show another example embodiment consistent with present principles. Here, a cartridge **2500** (e.g., silicone/TPE) and rigid member **2510** (rigid metal backing) are shown together as a caddy. Save being generally circular/cylindrical as shown, the cartridge **2500** may be similar in function and configuration to the cartridge **300** and the rigid member **2510** may be similar in function and configuration to the rigid member **250**. As such, the cartridge **2500** may include first openings **2520** similar to the first openings **310** discussed above, while the rigid member **2510** may include second openings **2530** similar to the second openings **360** discussed above.
[0094] FIGS. **25** and **26** also show that the rigid member **2510** may be made integral with an arm **2540** extending back to a ball **2550**. FIG. **26** shows that the ball **2550** may be received into the socket **150** on the handle **120** for locking therein via the collet **170**. Note that the arm **2540** may be formed with the member **2510** as a unitary element, and as such the arm **2540** may be made of aluminum, steel, and/or another rigid material.
[0095] FIG. **26** also shows that screws **2600** may be inserted through respective vertically aligned openings **2520**/**2530** and into a surgical burr hole plate **2650** that has reciprocal holes through which the screws **2600** may be threaded to thereby couple the plate **2650** to the assembly **2500**/**2510**.
[0096] Additionally or alternatively, the plate **2650** may be coupled to the assembly **2500**/**2510** through a boot or bay on a bottom portion of the cartridge **2500**, establishing another type of plate engagement mechanism but established by the non-rigid elastomer of the cartridge **2500** itself. The boot or bay may therefore be integral with other portions of the cartridge **2500**, formed by downward cartridge sidewalls and a flat, horizontal, downward-facing surface on the bottom of the cartridge **2500**. This boot in the bottom of the cartridge **2500** (e.g., full-perimeter boot that captures the outer perimeter of the plate **2650**) may receive the upper face and inset sidewalls (shown in FIG. **26**) on the top portion of the plate **2650** in interference fit to removably engage the cartridge **2500** with the plate **2650**.
[0097] FIGS. **27** and **28** then show the combined plate/caddy assembly coupled together as a device head to then use with a device handle for fracture reduction. FIG. **27** shows the combined assembly in top isometric view, while FIG. **28** shows the combined assembly in bottom isometric view.
[0098] FIGS. **29** and **30** show the combined plate/caddy assembly of FIGS. **27** and **28** as engaged with a handle **120** via socket **150** that is locked into locked configuration via the collet **170** as described above. FIG. **29** is a bottom isometric partial view, while FIG. **29** is an isometric view. It may be appreciated from these figures that an all-in-one plate and screw delivery device is provisioned. It may also be appreciated that the geometry of the assembly **2500**/**2510** allows adequate surgeon visibility to the plate and wound surface and plate **2650**.
[0099] FIGS. **31** and **32** then show the same assembled medical device in polyaxial articulation via isometric views.
[0100] Now in reference to FIG. **33**, another example embodiment is shown. Here, the assembly **230** described above has been manufactured together and loaded with a screw **3300**. The assembly **230** may then be transversely slid onto either holder **3310**, **3320** at opposing ends of an hourglass-

shaped handle **3300**. The holders **3310**, **3320** may be shaped to closely receive the contours of the rigid dovetailed male element **370** in friction fit similar to other embodiments described above. Also note that the holders **3310**, **3320** may be inverted **180** degrees relative to each other about a longitudinal axis **3340** defined by the handle **3330**, but with both holders **3310**, **3320** still having openings facing outward.

[0101] Continuing the detailed description in reference to FIG. **34**, an example method/process flow for surgically using a medical device consistent with present principles is shown in flow chart format. Beginning at block **3400**, the surgical process may begin with a medical professional receiving a non-rigid cartridge (e.g., the cartridge **300**) already coupled to a rigid member (e.g., the member **350**) from manufacture. The process may then proceed to block **3410** where the medical professional may load or otherwise extend surgical screws of a desired size into the cartridge (e.g., using a screwdriver) and then engage the cartridge assembly with a device handle at block **3420**. The process may then flow to block **3430** where the medical professional may couple a surgical plate that will be used for fracture reduction to the rest of the device (e.g., using a clamp or vice as described above)

[0102] Thereafter, the logic may proceed to block **3440** where the medical professional may align device holes and aligned plate holes over a fracture site as desired for fracture reduction. Then at block **3450** the medical professional may drive or otherwise extend the screws through the cartridge and into the patient, securing the plate to the patient for fracture reduction in the process. Thereafter, the process may move to step **3460** where the medical professional may slowly move the medical device away from the patient to disengage the screw heads from the tapering funnels at the lower ends of the cartridge openings.

[0103] Note that while some steps above have been described as being performed by a medical professional, in other instances certain steps may be performed by a manufacturer or other third party, such as a manufacturer that might pre-assemble the medical device **100** and pre-load it with screws or other fasteners. Also note that some of the steps of FIG. **34** may be performed in a different order than that described above (e.g., steps **3400**-**3430**), and that certain steps may not be performed at all. For example, a medical device consistent with present principles may be loaded with screws and then the device may be used to engage the screws with a surgical plate for facture reduction without the surgical plate ever being removably engaged to the medical device itself.

[0104] Now in reference to FIG. **35**, an example method/process flow for manufacturing a medical device consistent with present principles is shown in flow chart format. Beginning at block **3500**, the manufacturing process may begin with a manufacturer manufacturing a rigid member consistent with present principles (e.g., a member **350**), such as through injection molding, three-dimensional (3D) printing, computer numerical control (CNC) manufacturing, or other methods. Also at block **3500**, the manufactured rigid member may be sterilized.

[0105] The process may then flow to block **3510** where the manufacturer may manufacture a non-rigid cartridge consistent with present principles (e.g., a cartridge **300**). This might be done through injection molding, three-dimensional (3D) printing, or other methods. Also at block **3510**, the manufactured cartridge may be sterilized. Sterilization of the cartridge (and other components) may involve use of ethylene oxide, gamma radiation, e-beam radiation, chlorine dioxide, etc., for example.

[0106] From block **3510** the process may then proceed to block **3520**. At block **3520** and while still in a sterile environment, the manufacturer may couple the sterilized cartridge to the sterilized rigid member as a permanent assembly (e.g., if not done already via over-molding of the cartridge onto the rigid member during manufacture of the cartridge itself). For example, at block **3520** an adhesive may be used to couple the two components together. Then at block **3530** while still in the sterile environment, the manufacturer may insert sterilized screws into the cartridge (e.g., using a screwdriver) and then, at block **3540**, attach the cartridge assembly (with screws) to a handle like the handle **120** in a manner as described above. The process may then flow to block **3550** where,

still in the sterile environment, the manufacturer may attach a surgical plate to the cartridge assembly and then, at block **3560**, package the entire assembly together in sterile packaging for shipment.

[0107] Note that while some steps above have been described as being performed by a manufacturer, in other instances certain steps may be performed by a medical professional or other third party, such as a medical professional loading the cartridge with screws or loading the cartridge assembly onto the handle. Also note that the steps of FIG. **35** may be performed in a different order than that described above, and that certain steps may not be performed at all.

[0108] Turning now to FIG. **36**, yet another example process flow is shown. The process flow of FIG. **36** may be used for vending or otherwise providing a medical device consistent with present principles through the channels of commerce to a medical professional.

[0109] FIG. **36** is also shown in flow chart format and, beginning at block **3600**, the process may start with the provider providing a cartridge like the cartridge **300** consistent with present principles. Then at step **3610** the provider may provide a rigid member like the member **350** consistent with present principles, again noting that in certain examples the cartridge and rigid member may be coupled/bonded together at manufacture prior to being provided. Thereafter, at step **3620** the provider may provide a handle like the handle **120** consistent with present principles. Then at step **3630** the provider may provide screws and, at step **3640**, a surgical plate.

[0110] Note that while some steps above have been described as being performed by a provider, in other instances certain steps may be performed by a manufacturer or other third party. Also note that the steps of FIG. **36** may be performed in a different order than that described above, and that certain steps may not be performed at all.

[0111] Now in reference to FIGS. **37**A-**37**E, these figures show respective front, top, right side, cross section right, and isometric views of an example device consistent with present principles. The device may include the handle **120** as well as a CMF burr hole cartridge assembly **2500**/**2510**. Among other things, these figures demonstrate that the collar **200** on the handle **120** may include markings **3750** indicating a first direction in which the collet **170** may be twisted to lock the ball **2550** within the socket (the direction of the locked graphical lock shown) and indicating an opposite direction in which the collet **170** may be twisted to unlock the ball **2550** from the socket (the direction of the unlocked graphical lock shown). Note that female threads **3710** onto which the male threads inside the collet **170** may screw are also shown.

[0112] FIG. **38**A then shows an exploded isometric view of screws **3800** prior to being inserted into the assembly **2500**/**2510** and showing a boot-style plate holder similar to as described above in reference to FIG. **26**. FIG. **38**B shows an exploded side view, and **38**C another exploded isometric view, of the same setup.

[0113] FIGS. **39**A-**39**E show respective front, top, right side, cross section right, and isometric views of the example device **100** according to the first example embodiment above consistent with present principles. As such, the assembly **230** is coupled to the handle **120**, and the markings **3750** are also included here. As shown in FIGS. **39**B and **39**E in particular, a measurement or marking **3900** may be included in the middle of the rigid member **350** to help the surgeon align the assembly **230** and H-plate **2200** as desired over a fracture site (e.g., bone plate alignment across fracture line). Other measurements and markings may also be included on other portions of the cartridge and rigid member, if desired. In certain specific examples, each measurement or marking may be established by laser-marking.

[0114] FIG. **40**A then shows an exploded isometric view of the device **100** with screws **4000** prior to being inserted into the assembly **230**, and shows the element(s) **2400** as described above to attach the plate **2200** to the cartridge **300** as also described above. FIG. **40**B shows an exploded side view, and **40**C another exploded isometric view, of the same setup. FIG. **40**D shows an exploded cross-sectional view of the same setup.

[0115] FIGS. **41**A-**41**E show respective front, top, right side, cross section right, and isometric

views of another embodiment consistent with present principles. It may be appreciated that many of the elements of this embodiment are the same as others described above (e.g., the handle **120**), with the difference here being that a caddy/cartridge assembly **4100** and plate **4110** are configured in a dog bone shape as shown. FIG. **42**A then shows an exploded isometric view of screws **4200** prior to being inserted into the assembly **4100**. FIG. **42**B shows an exploded side view, and **42**C another exploded isometric view, of the same setup.

[0116] FIGS. **43**A-**43**E show respective front, top, right side, cross section right, and isometric views of another embodiment consistent with present principles. It may be appreciated that many of the elements of this embodiment are the same as others described above (e.g., the handle **120**), with the difference here being that a caddy/cartridge assembly **4300** and plate **4310** are configured in a square shape as shown. FIG. **44**A then shows an exploded isometric view of screws **4400** prior to being inserted into the assembly **4300**. FIG. **44**B shows an exploded side view, and **44**C another exploded isometric view, of the same setup. Note that per this setup, the bottom of the assembly **4300** may establish a boot-style plate holder similar to as described above in reference to FIG. **26**, but in square shape.

[0117] It may now be appreciated that devices and methods have been disclosed related to surgical screw caddies/cartridge assemblies, where each opening/screw holder of the caddy may be reuseable multiple times during a given surgery (e.g., multiple screws extended through the same opening on the caddy). The caddies may be sterile and relatively low-cost, including being sterilely packed for distribution.

[0118] In some specific examples, a kit may be manufactured, vended/provided, and/or used during a fracture reduction procedure consistent with present principles. The kit may include three or four (or even more) different cartridge assemblies/heads that can lock into an articulating handle. Screws and surgical plates to use with the rest of the kit may also be included in the kit. The surgeon may thus decide on the fly which plate/caddy combination to use depending on whatever circumstances the surgeon might encounter during the surgery.

[0119] Components included in one embodiment can be used in other embodiments in any appropriate combination. For example, any of the various components described herein and/or depicted in the Figures may be combined, interchanged, or excluded from other embodiments.

[0120] The term “a” or “an” in reference to an entity refers to one or more of that entity. As such, the terms “a” or “an”, “one or more”, and “at least one” can be used interchangeably herein.

[0121] “A system having at least one of A, B, and C” (likewise “a system having at least one of A, B, or C” and “a system having at least one of A, B, C”) includes systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.

[0122] It is to be understood that whilst present principals have been described with reference to some example embodiments, these are not intended to be limiting, and that various alternative arrangements may be used to implement the subject matter claimed herein. Accordingly, while particular techniques and devices are herein shown and described in detail, it is to be understood that the subject matter which is encompassed by the present application is limited only by the claims.

Claims

1. A medical device, comprising: a cartridge comprising a first opening, the first opening configured to receive a screw, the first opening formed at least in part by a non-rigid elastomeric material, the non-rigid elastomeric material configured on the cartridge to stabilize the screw within the cartridge; and a rigid member engaged with an upper surface of the cartridge, the rigid member comprising a second opening that aligns with the first opening for the screw to pass through the second opening and into the first opening for engagement with the non-rigid elastomeric material;

wherein the cartridge and rigid member have respective structure for one or more of: snap-fit engagement of the cartridge with the rigid member, interference fit engagement of the cartridge with the rigid member.

2. The medical device of claim 1, wherein the cartridge and rigid member have respective structure for snap-fit engagement of the cartridge with the rigid member.

3. The medical device of claim 1, wherein the cartridge and rigid member have respective structure for interference fit engagement of the cartridge with the rigid member

4. The medical device of claim 1, wherein the cartridge and rigid member establish at least part of a head that is engageable with a handle.

5. The medical device of claim 4, comprising the handle.

6. The medical device of claim 5, wherein the handle is detachable from the head.

7. The medical device of claim 6, comprising a ball and socket assembly, wherein the handle and head are engageable with each other via the ball and socket assembly, and wherein the medical device comprises a locking structure to lock the ball into the socket to secure the head on the handle while still allowing articulation of the head with respect to the handle.

8. The medical device of claim 7, wherein the ball of the ball and socket assembly is disposed on the head, and wherein the socket of the ball and socket assembly is disposed on the handle.

9. The medical device of claim 1, wherein the non-rigid elastomeric material comprises silicone.

10. The medical device of claim 1, wherein the non-rigid elastomeric material comprises thermoplastic elastomer.

11. The medical device of claim 1, comprising the screw.

12. The medical device of claim 1, wherein an exterior surface of the non-rigid elastomeric material tapers distally at a lower distal end portion to extend at least partially into a hole that aligns with the first and second openings, the hole being located in a surgical plate.

13. The medical device of claim 12, comprising the surgical plate.

14. The medical device of claim 12, comprising an engagement structure extending downward from the rigid member to removably engage the cartridge with the surgical plate.

15. The medical device of claim 1, wherein the first and second openings are circular-bounded openings.

16. The medical device of claim 1, wherein the first and second openings are formed by the non-rigid elastomeric material of the cartridge.

17. A method, comprising: providing a cartridge comprising a first opening, the first opening configured to receive a screw, the first opening formed at least in part by a non-rigid elastomeric material, the non-rigid elastomeric material configured on the cartridge to stabilize the screw within the cartridge; and providing a rigid member engaged with an upper surface of the cartridge, the rigid member comprising a second opening that aligns with the first opening for the screw to pass through the second opening and into the first opening for engagement with the non-rigid elastomeric material; wherein the cartridge and rigid member have respective structure for one or more of: snap-fit engagement of the cartridge with the rigid member, interference fit engagement of the cartridge with the rigid member

18. A device, comprising: a cartridge comprising a first opening, the first opening configured to receive a screw, the first opening formed at least in part by a non-rigid elastomeric material, the non-rigid elastomeric material configured on the cartridge to stabilize the screw within the cartridge; and a rigid member engaged with an upper surface of the cartridge, the rigid member comprising a second opening that aligns with the first opening for the screw to pass through the second opening and into the first opening for engagement with the non-rigid elastomeric material; wherein the non-rigid elastomeric material is over-molded onto the rigid member.

19. The device of claim 18, comprising a handle, wherein the cartridge and rigid member establish at least part of a head that is engageable with the handle.

20. The device of claim 18, comprising a ball and socket assembly, wherein the handle and head

are engageable with each other via the ball and socket assembly, wherein the ball of the ball and socket assembly is disposed on the head, wherein the socket of the ball and socket assembly is disposed on the handle, and wherein the medical device comprises a locking structure to lock the ball into the socket to secure the head on the handle while still allowing articulation of the head with respect to the handle.