**Title:** FIXATION ELEMENT INSERTION DEVICE

**Abstract:** The invention relates to a device for attaching elements to bone, having a longitudinal member with a channel extending therein adapted for receiving at least one fixation element. A shaft extends within the channel and is positioned coaxially within at least a portion of the longitudinal member and at least a portion of the shaft is retained within the longitudinal member and a distal end of the shaft is configured and adapted to contact at least a portion of the fixation element received within the longitudinal member. The shaft is moveable with respect to the longitudinal member to drive the fixation element into bone.
FIXATION ELEMENT INSERTION DEVICE

Field of the Invention

The present invention relates to a device for the storage and dispensing of osteosynthetic fixation elements, and in particular to a device for attaching fixation elements to bone.

Background of Invention

In the surgical treatment of fractures in the maxillofacial area, as well as fractures of the foot and hand, a trend toward preferring ever-smaller implants can clearly be noted. The reason for this is the generally increased understanding of the biomechanical bases of osteosynthesis. In the field of treating maxillofacial fractures, more attention can be paid to the cosmetic results of osteosynthesis, thanks to the miniaturization of implants. In the field of hand surgery, restrictions on movement in the area of the fingers can be avoided. In this regard, smaller osteosynthetic implants in the fingers can be placed under the tendons. In the case of an implant with a large cross-section, the tendons need no longer be extended to their full length.

The dimensions of some smaller implants (screws, plates and tacks) are in the range of about 0.8 mm to about 2.0 mm. Problems in the area of packaging, storage and manipulation during surgery arise due to this miniaturization. Handling in the operating room, particularly in the maxillofacial area, has proved difficult. Depending on the degree of severity of the fracture or correction, up to 40 bone fixation elements, such as tacks or screws, may be required. These screws must be taken individually by the operating room nurse from a so-called screw rack, checked for length, placed on a screwdriver and given to the surgeon. The surgeon must, in turn, insert them through the osteosynthesis plate into pre-drilled screw holes. During the transfer of the screw and the attempted insertion of the screw, it often falls off the screwdriver, into the wound or onto the operating room floor. The attempt to find a lost screw is often excessively time-consuming, given their dimensions and extends the time spent in surgery. The frequent loss of screws in the operating room, and during packing and sterilization, causes unnecessary costs for the hospital.

An additional problem in dealing with mini-screws arises during their implantation. After the surgeon has selected the osteosynthesis plate proper for the fracture in question, a plate is positioned over the fracture. A hole is then drilled for the screw (0.5-1.5 mm diameter) through one of the plate holes. After drilling, the screw is received
from an operating room nurse and screwed into the bone through the plate. Commonly problems arise in finding the core drill hole in the bone, since the bone surface is covered with blood or soft tissue and the plate can slip on the smooth bone surface.

In addition, problems arise in controlling the amount of force applied during the insertion of the screw and or tack. For example, if a surgeon is required to insert a screw or tack with manual force, the manula force could be transmitted to the surrounding bone, which could bend thin and/or flexible bone in young patients.

Also, problems such as surgical gloves tearing or hand pinching can arise if the insertion device has parts that move externally during the firing of the device.

Thus, a need exists for an insertion device that minimizes the manual force exertion required and to minimize the gross forces applied to the surrounding bone during insertion.

Summary of Invention

The present invention relates to a device for attaching fixation elements to bone, including a longitudinal member extending along a longitudinal axis from a proximal end to a distal end and having a channel extending therein adapted for receiving at least one fixation element. A shaft extends within the channel and is positioned coaxially within at least a portion of the longitudinal member and at least a portion of the shaft is retained within the longitudinal member and a distal end configured and adapted to contact at least a portion of the fixation element received within the longitudinal member. The longitudinal member is moveable with respect to the shaft to drive the fixation element into bone.

In one embodiment, the longitudinal member can include a first member for receiving at least one fixation element at the distal end and a second member attached coaxially to the first member, and the first member is movable with respect to the second member. A spring can be housed within the channel to engage the first member for resiliently biasing the first member in the axial direction. In one preferred embodiment, the first and second members are substantially cylindrical and the first member is movable telescopingly within the second member. The first and second members can be interlocked in the axial direction. The shaft is substantially cylindrical and can have at least two portions with different diameters. The distal end of the longitudinal member includes a pronged tip for resiliently holding a fixation element therein.

Another device for attaching fixation elements to bone according to the present invention comprises a longitudinal member having a channel extending therein and a plurality of spacers positionable within the channel. Each spacer has a tip portion at a distal end configured and dimensioned for holding a fixation element. In one embodiment,
the spacer has a cavity at a proximal end configured and dimensioned for receiving a tip portion of an adjacent spacer. The spacer can have a frustoconical portion. The fixation element is held to the tip portion by a friction fit and the spacer has a shoulder at a base of the tip portion configured for contacting a proximal end of an adjacent spacer when such spacers are in abutting relationship. In one preferred embodiment, the spacers are stackable such that a plurality of spacers are positionable in abutting relationship and the spacers can be axially alignable within the channel.

In another embodiment, the device includes a shaft located centrally with respect to the channel for moving the spacers axially with respect to the shaft. The shaft can include a frustoconical tip at a distal end and the tip can be received in the proximal end of the spacer. In one embodiment, a tab extends radially outward from the shaft and is configured to be movable by a human finger to move the shaft with respect to the longitudinal member. A spring engages a slot in the longitudinal member for locating the shaft at a plurality of preselected locations with respect to the longitudinal member.

In one embodiment, the channel has a front opening at the distal end of the longitudinal member and the spacers can travel through the opening. The channel can also include a back opening at the proximal end of the longitudinal member and the spacer can travel through the back opening. A handle is connected to the proximal end of the longitudinal member.

The present invention is also directed to a device for holding a fixation element, including a holding portion configured to hold the fixation element, and a receiving portion connected to the holding portion and configured to receive an adjacent fixation element holder and fixation element. The holding portion is configured to releasably hold the fixation element and the receiving portion can include a body having a cavity therein. The holding portion has an exterior contour and the interior cavity has an internal contour, and the interior contour is configured and dimensioned to conform to the exterior contour.

**Brief Description of the Drawings**

Fig. 1 is a perspective view of one embodiment of an insertion device according to the present invention;

Fig. 2 is a perspective view of a fixation element for use with the insertion device of Fig. 1;

Figs. 3-4 illustrate the placement of a fixation element within a pre-drilled hole in bone;
Fig. 5 is a cross-sectional view of another embodiment of an insertion device;

Fig. 6 is a partial cross-sectional view of a portion of the device of Fig. 5;

Fig. 7 is a perspective view of another embodiment of an insertion device;

Fig. 8 is a cross-sectional view of the embodiment of Fig. 7;

Fig. 9 is a side view of a fixation element spacer for use with the insertion device of Fig. 7;

Fig. 10 is a perspective view of another embodiment of an insertion device;

Fig. 11 is a cross-sectional view of the embodiment of Fig. 10;

Fig. 12 is a partially transparent elevated view of one embodiment of an insertion device according to the present invention;

Figs. 13-14 illustrate the placement of a fixation element within a pre-drilled hole in bone;

Fig. 15 is a partially transparent elevated view of another embodiment of an insertion device;

Fig. 16 a partial elevated view of the device of Fig. 15;

Fig. 17 is a partially transparent elevated view of another embodiment of an insertion device;

Fig. 18 is a cross-sectional view of the embodiment of Fig. 17;

Fig. 19 is a partial cross-sectional view of a portion A of the device of Fig. 18;

Fig. 20 is an elevated view of another embodiment of an insertion device;

and

Fig. 21 is an elevated view of a cam member of the device of Fig. 20.

**Detailed Description of the Preferred Embodiments**

Referring to Fig. 1, a preferred fixation element insertion device 10 according to the present invention generally includes a longitudinal member extending along a longitudinal axis 12 from a proximal end 14 to a distal end 16 and having a channel 18 extending therein. The insertion device is preferably used to drive an osteosynthetic fixation element, such as a resorbable tack, into bone tissue. Channel 18 is configured and dimensioned to receive at least one fixation element for storage, transport, dispensing, and or insertion into bone.

Referring to Fig. 2, one preferred fixation element compatible with insertion device 10 comprises a tack 20 having a shaft 22 integral with a head 24 at a proximal end
thereof. The distal end of shaft 22 has a conical nose 26 to facilitate the insertion of tack 20 into bone tissue. A plurality of circular ribs 28 extend radially from the exterior of shaft 22 to prevent the removal of the tack from the bone tissue after it has been inserted. Head 24 has an outer diameter greater than the diameter of shaft 22 and contacts or rests against the bone or bone plate when the tack is inserted into bone tissue. In the preferred embodiment, the tack is made from a resorbable material so that it remains in the bone tissue temporarily and is absorbed by the body. In alternate embodiments, tack 20 can have numerous different configurations and dimensions. Also, different types of fixation elements altogether can be used with insertion device 10. For example, biocompatible screws, nails, anchors, rivets, or other similar implants can also be inserted using insertion device 10.

Referring again to Fig. 1, insertion device 10 has a handle 30 at the proximal end that is configured to conform to the shape of a person's hand or palm for easily gripping and applying force with the device. Channel 18 generally comprises a socket defined at the distal end 16 and an elongate applicator extension 32 extends between distal end 16 and handle 30. Socket or channel 18 fits about the proximal end of fixation element 20 to hold element 20 in insertion device 10 by an interference or friction fit. In the embodiment of Fig. 1, an individual tack 20 can be held at distal end 16 and head 24 of tack 20 is preferably held within the socket or channel 18 while the shaft 22 of tack 20 projects outside thereof, as shown in Fig. 3.

Referring to Figs. 3-4, the insertion device can be used to fasten a plate 40 or other device to a bone 41. In operation, a hole 42 is pre-drilled in the bone tissue at the desired insertion location and the insertion device 10 is placed adjacent the insertion location and the conical nose 26 of tack 20 is inserted into hole 42 and then shaft 22 of tack 20 is driven into the bone tissue by applying force in the axial direction to the handle, such as by a person's hand. As shown in Fig. 4, once tack 20 is inserted into bone, insertion device 10 is withdrawn from the insertion location and tack 20 is separated from channel 18. When the insertion device 10 is withdrawn, the forces holding shaft 22 of tack 20 to bone 41 are greater than the forces of the interference fit between head 24 and channel 18 so that head 24 of tack 20 is separated from distal end 16, leaving tack 20 secured to the bone.

In a preferred embodiment, insertion device 10 is a reusable device and is autoclavable between uses.

Referring to Figs. 5-6, an alternate embodiment of an insertion device 50 includes a handle 52 at a proximal end and a spring loaded elongate applicator extension 54 extending between distal end 56 and handle 52. Extension 54 comprises a spring cover 58 attached to handle 52 for housing spring 60 and a holding sleeve 62 coaxially attached to
the distal end of spring cover 58 in a telescoping fashion for receiving a fixation element. Sleeve 62 has slightly smaller external dimensions than the internal dimensions of cover 58 so that the proximal end of sleeve 62 can be inserted into the distal end of cover 58 and sleeve 62 can move in the axial direction with respect to cover 58. Sleeve 62 includes prongs 64 that interlock with ridges 66 on the interior of cover 58 so that when sleeve 62 is inserted into cover 58, sleeve 62 is not inadvertently removed from cover 58 in the distal direction. In a preferred embodiment, sleeve 62 has prongs 64 that are flexible and are collapsible or bendable into the interior of sleeve 62 so that sleeve 62 can be removed from cover 58 for cleaning, disassembly, or replacement. Prongs 64 are biased radially outwardly so that sleeve 62 can be easily reattached by simply pushing the sleeve into the cover in the proximal direction. At the distal end of sleeve 62 is a pronged tip for retaining a fixation element. Pronged tip 68 is generally flexible and when the distal end of sleeve 62 is pressed, the prongs of sleeve 62 flex around the head of a fixation element to pick up and retain the element. In this way, it is possible to pick up a relatively small fixation element in a simple, single action.

A central channel 70 extends within handle 52 and through extension 54. A shaft member 72 is housed within central channel 70 and extends generally the entire length of channel 70 within extension 54 and is preferablyfixedly attached to handle 52. Shaft 72 is generally cylindrical and includes a base portion 74 that engages the interior of channel 70 within handle 52 preferably by press fit, a mid-section 76 having a smaller diameter than base portion 74, and a tip portion 78 having a smaller diameter than mid-section 76. A first shoulder 80 is positioned at the transition of base portion 74 and mid-section 76. Spring 60 is housed within spring cover 58 and extends around mid-section 76 and is compressible between first shoulder 80 and the proximal end of sleeve 62, biasing sleeve 62 axially in the distal direction.

The method of operation or use of device 50 is similar to the method described above with respect to device 10. The insertion device 50 is placed adjacent an insertion location with a pre-drilled hole in bone and the fixation element or tack is driven into the bone tissue by applying axial force in the distal direction to handle 52, moving sleeve 62 in the proximal direction. When sleeve 62 is moved in the proximal direction, spring 60 biases sleeve 62 in the distal direction and shaft 72 is moved in the distal direction due to the force applied on the handle. Thus, when sleeve 62 is moved further in the proximal direction, such as by applying axial force in the distal direction during fixation element insertion, sleeve 62 is retracted within cover 58 and shaft 72 is forced in the distal direction through the distal end of sleeve 62. Tip portion 78 of shaft 72 engages the
proximal end of a fixation element and separates the fixation element from pronged tip 68 and drives the fixation element into bone. In this way, the fixation element is automatically disengaged from distal end 56 of device 50 and there is no need to manually slide holding sleeve 58 or rock the insertion device to disengage the fixation element. After the fixation element has been inserted completely, insertion device 50 can be removed from the insertion location and sleeve 62 will spring back to its original starting position, shown in Fig. 5. In an alternate embodiment, shaft 72 is moveable in the axial direction with respect to handle 52.

Referring to Figs. 7-8, an alternate embodiment of an insertion device 90 includes a central channel 92 that extends through device 90 for receiving fixation elements or tacks 94. Channel 92 can store a plurality of tacks 94 and when insertion device 90 is used, a sufficient supply of tacks are available for quick and easy insertion into bone. A handle 96 is at a proximal end of device 90 and an elongate applicator extension 98 extends between a distal end 100 and handle 96. Once a tack 94 is inserted into bone, another tack is advanced toward distal end 100 and into position to be inserted. In this way, a surgeon or nurse does not need to repeatedly attach or load fixation elements into an insertion device and there is a ready supply of fixation elements housed within the device. Thus, the device only needs to be loaded once, thereby reducing operating time.

In the preferred embodiment, the tacks are attached to carriers or spacers 102 and are aligned coaxially within the central channel 92 of device 90. In a preferred embodiment, spacer 102 is hollow and has an exterior contour and an interior contour, and the interior contour is generally configured and dimensioned to conform to the exterior contour so that a plurality of spacers are easily stacked. As best seen in Fig. 9, each spacer 102 has a circular cross section which tapers from a hollow proximal end 104 to a distal end 106 having a socket 108 for receiving a tack 94. Like the embodiment of Fig. 1, tack 94 is held in socket 108 by an interference or friction fit. Each spacer can accommodate at least one fixation element at the distal end, and a plurality of spacers can be inserted into central channel 92 of insertion device 90, each with a tack attached to the distal end. The spacers are aligned coaxially within central channel 92 such that each spacer 102 proximal end 104 is aligned to receive a distal end 106 of an adjacent spacer so that the spacers can be axially stacked in abutting relation within channel 92, as shown in Fig. 8. Each spacer 102 comprises a cylindrical nose or tip portion 110 toward distal end 106 and has a diameter d. Tip portion 110 extends an axial distance l from an angled mid-section portion 112. A shoulder 114 is formed at the intersection of tip portion 110 and mid-section portion 112. Back portion 116 extends from mid-section portion 112 and includes a slot 118 extending
around the outer periphery. Back portion 116 is preferably substantially cylindrical having a diameter D and mid-section portion 112 is preferably substantially frusto-conical. Back portion 116 diameter D is larger than tip portion 110 diameter d so that tip portion 110 of a spacer 102 can be accommodated within the interior of back portion 116. In a preferred embodiment, shoulder 114 extends radially beyond the perimeter of tip portion 110 and is configured and dimensioned to rest against or abut the proximal end 104 of back portion 116. Mid-section portion 112 and back portion 116 extend an axial distance L from shoulder 114 to proximal end 104, and distance L is preferably greater than distance l. In this way, when a fixation element or tack 94 is attached to a tip portion of a first spacer and then inserted into the interior of a proximal end of a second spacer, there is sufficient space within the interior of the second spacer to accommodate the tip portion of the first spacer and a fixation element attached thereto.

The spacers 102 are individually moveable within channel 92. For example, spacers 102 are advanced in the distal direction when an additional spacer is introduced into the proximal end of channel 92. When a spacer is inserted into the proximal end of channel 92, shoulder 114 of the spacer being inserted contacts the proximal end 104 of the most proximal spacer in channel 92 and pushes or forces all of the spacers in the channel in the axial direction toward distal end 100 of device 90. The most distal spacer extends from distal end 100 of driver 90 and the shaft of tack 94 extends beyond socket 108 of spacer 102 in a position ready to be inserted into bone. In the preferred embodiment, an elastic ring 120 is positioned on the interior of channel 92 adjacent the proximal end for engaging slot 118 to prevent movement of the spacers in the proximal direction. Ring 120 extends radially inward into channel 92 and engages slot 118 of the most proximal spacer, and when channel 92 is full of spacers, the spacers do not move in the proximal direction.

In operation of insertion device 90, a tack is inserted in the bone tissue by means of an axial force exerted on the proximal end of the device, much the same as for device 10 of Fig. 1. After the tack is inserted in the bone, the device is removed from the insertion location thus separating the element from the distal most spacer at the distal end of the device, and leaving the tack in the bone. In a preferred embodiment, the now empty distal most spacer is then removed from the distal end of channel 92 and reinserted into the proximal end thereof, advancing the remaining spacers distally in the channel and moving the distal most spacer and tack to the distal end 100 of the device and ready to insert the tack. This method can be repeated as desired for the particular application. In a preferred embodiment, channel 92 is configured to accommodate about ten spacers, however the invention is also applicable to different size insertion devices with various channel lengths.
to accommodate more or less spacers or fixation elements as desired. Similarly, differing spacer dimensions or fixation element dimensions can also influence the fixation element holding capacity of the insertion device. Also, it is not required that empty spacers be introduced into the proximal end of channel 92, and spacers having tacks attached thereto can also be introduced, thereby providing a continuous supply of fixation elements.

Referring to Figs. 10-11, an alternate embodiment of an insertion device 130 includes a handle 132 at the proximal end 134 and an elongate applicator extension 136 extends from handle 132 in the distal direction. Applicator extension 136 has a central channel 138 for receiving a plurality of fixation elements or tacks 140 and a piston 142 is axially aligned with channel 138 and movable therein to advance the tacks in the distal direction. Piston 142 is positioned at the proximal end of channel 138 and a tab 144 extends laterally from one side of piston 142 and through a longitudinal slot 146 in extension 136. Tab 144 includes a knurled or textured portion 148 for engaging a person’s finger to allow for manual advancement of piston 142 within channel 138. In a preferred embodiment, slot 146 includes angled portions 150 and a spring (not shown) is attached to tab 144 to engage angled portions 150 of slot 146 and prevent piston 142 from moving in a proximal direction. Channel 138 forms a fixation element supply chamber, and like the insertion device of Figs. 7-8, the fixation elements are attached to spacers 152 and are aligned coaxially within channel 138 to be inserted into bone tissue one at a time as described above. The configuration and design of the spacers 152 used with device 130 are the same as spacer 102 shown in Fig. 9. Also, the fixation elements are held at the distal end of each spacer by the same interference or friction fit used in the device of Figs. 7-8. In a preferred embodiment, channel 138 is configured to accommodate about four spacers, however the invention is also applicable to different size insertion devices with various channel lengths to accommodate more or less spacers or fixation elements as desired.

In operation of insertion device 130, the distal end of piston 142 interfaces engages the proximal end of the last or proximal most spacer aligned within channel 138 to force the spacer in the distal direction and advance all of the aligned spacers in the channel. In a preferred embodiment, piston 142 exterior substantially corresponds to the interior of the mid-section and back portion of spacer 152. For example, piston 142 is preferably generally cylindrical with a tapered portion 154 at the distal end and tapered portion 154 is angled to generally correspond to the interior of mid-section portion of spacer 152.

Referring to Fig. 12, an alternate fixation element insertion device 210 generally includes a longitudinal member extending along a longitudinal axis 212 from a proximal end 214 to a distal end 216 and having a channel 218 extending therein. Channel
218 is configured and dimensioned to receive at least one fixation element for storage, transport, dispensing, and or insertion into bone.

Insertion device 210 has a handle 230 at the proximal end that is configured to conform to the shape of a person's hand or palm for easily gripping the device and an applicator extension 232 for holding and dispensing the fixation element. A central channel 270 extends within handle 230 and through extension 232 and is in communication with channel 218 at distal end 216. Channel 218 generally comprises a socket defined at the distal end 216 and an elongate applicator extension 232 extends between distal end 216 and handle 230. Extension 232 can be a unitary extension or can include multiple parts. Socket or channel 218 fits about the proximal end of fixation element 20 to hold element 20 in insertion device 210 by an interference or friction fit. In the embodiment of Fig. 12, an individual tack 20 can be held at distal end 216 and head 24 of tack 20 is preferably held within the socket or channel 218 while the shaft 22 of tack 20 projects outside thereof, as shown in Fig. 14. At the distal end of extension 232 is a pronged tip 234 for retaining a fixation element. Pronged tip 234 is generally flexible and when the distal end of extension 232 is pressed, the prongs 234 of sleeve 232 flex around the head of a fixation element to pick up and retain the element. In this way, it is possible to pick up a relatively small fixation element in a simple, single action.

A shaft member 236 and a firing spring 238 are housed within central channel 240. Shaft member 236 extends longitudinally within handle 230 and extension 232 and is preferably moveable along axis 212 with respect to handle 230 and extension 232. Firing spring 238 is positioned at the proximal end of handle 230 and is compressible between a force adjustment dial 239 at proximal end 214 and a proximal end of shaft member 236, biasing shaft member 236 in the distal direction. Shaft 236 is generally cylindrical and includes a base portion 242 that slidingly engages the interior of channel 240 within handle 230, a mid-section 244 having a smaller diameter than base portion 242, and a tip portion 246 having a smaller diameter than mid-section 244. A first shoulder 243 is positioned at the transition of base portion 242 and mid-section 244 and a second shoulder 245 is positioned at the transition of mid-section 244 and tip portion 246.

Shaft 236 is moveable from a loaded position (shown in Fig. 12) to an unloaded position for inserting a fixation element into bone. An activation button 248 extends within channel 240 for activating the movement of shaft 236 from a loaded position to an unloaded position. Button 248 is positioned along a portion of handle 230 and partially extends within channel 240 for engaging shaft 236. Referring to Fig. 12, when shaft 236 is in the loaded position ledge 249 at the proximal end of button 248 engages
second shoulder 245 preventing shaft 236 from moving in the distal direction or to the unloaded position. When button 248 is depressed by an operator, ledge 249 is moved out of engagement with shoulder 245, thereby permitting shaft 236 to move in the distal direction under the force exerted by firing spring 238 on shaft 236. As a result, tip portion 246 of shaft 236 is advanced in the distal direction to force fixation element out of extension 232 and shaft 236 is moved to an unloaded position.

In a preferred embodiment, button 248 is pivotably positioned about a pin 247 and the distal portion of button 248 is biased radially outward by a spring 250 so that ledge 249 at the proximal portion of button 248 is biased inward toward engagement with shoulder 282. In this regard, a collar 251 is preferably positioned within handle 230 for engaging spring 250 in the radial direction and permitting mid-section 244 of shaft 236 to slide therethrough without engaging spring 251. When button 248 is depressed, ledge 249 is pivoted radially outward and out of engagement with shoulder. In alternate embodiments, different button assemblies or triggering mechanisms can be used.

In a preferred embodiment, a thumb slide 252 is positioned along a portion of handle 230 opposite activation button 248 and is moveable in the longitudinal direction for moving shaft 236 from an unloaded to a loaded position. Thumb slide 252 partially extends within channel 240 for engaging shaft 236 and moving shaft 236 in the longitudinal direction. In an unloaded position, shoulder 245 engages an inner ledge 253 of thumb slide 252 and when thumb slide 252 is moved in the proximal direction by an operator, shaft 236 is also retracted. To move shaft 236 to the loaded position, thumb slide 252 is moved in the proximal direction until shoulder 245 slides beyond ledge 249 of button 248 and ledge 249 engages shoulder 245, thereby locking shaft 236 in the loaded position. This shaft retraction will also compress firing spring 238. In a preferred embodiment, a spring 254 is housed within handle 230 and biases thumb slide 252 in the distal direction and once shaft 236 is in the loaded position, the thumb slide is released and returns to its resting position. Once shaft 236 is again in the loaded position, another tack can be inserted into the extension 232.

Referring to Figs. 13-14, once the insertion device is loaded, the insertion device can be used to fasten a plate 256 or other device to a bone 257. In operation, a hole 258 is pre-drilled in the bone tissue at the desired insertion location and the insertion device 210 is placed adjacent the insertion location and the tack is aligned with hole 242. The activation button 248 is depressed to release shaft 236, and shaft 236 is driven in the distal direction by the force of firing spring 238 thereby driving tack 20 into the bone tissue. As shown in Fig. 14, once tack 20 is inserted into bone, insertion device 210 is withdrawn from
the insertion location and tack 20 is separated from channel 218. When the insertion device 210 is withdrawn, the forces holding shaft 22 of tack 20 to bone 257 are greater than the forces of the interference fit between head 24 and channel 218 so that head 24 of tack 20 is separated from distal end 216, leaving tack 20 secured to the bone. The device 210 can then be reloaded by moving the thumb slide in the proximal direction as explained above and inserting another tack into extension 232. The steps are then repeated for each tack until the plate 256 is adequately secured. Advantageously, the thumb slide and activation button configuration of device 210, permits a surgeon to cock and fire, or load and unload the device using only one hand. It also noteworthy that no external parts of device 210 move during the firing or unloading movement of the device which desirably minimizes the chances that a surgeon’s hand is pinched or a glove is torn. Also, in a preferred embodiment, insertion device 210 is constructed from stainless steel and anodized aluminum and as a result is a reusable device and autoclavable between uses.

Referring again to Fig. 12, extension applicator 232, preferably comprises a stem 260 with a holding sleeve 262 removably attached thereto by a coupling member 264. Holding sleeve 262 can be removed and replaced with various sized holding sleeves to accommodate tacks of differing shapes and sizes. In a preferred embodiment, holding sleeve 262 can be easily removed without the need for tools or hardware.

Referring again to Fig. 12, preferably a force adjustment dial 239 is positioned at proximal end 214 of the device 210 and threadably engages handle 230. Dial 239 can be rotated and moved in the proximal and distal direction with respect to handle 230 for varying the amount of compression of firing spring 238 and thereby adjusting the amount of force exerted upon shaft 236 and overall force of insertion of tack 20. Also in another embodiment shown in Fig. 16, a force adjustment gauge 266 can be inserted in handle 230 for delineating the amount of force applied. For example, a line on a force adjustment gauge can show the relative position between minimum and maximum force settings and be visible through a cutaway in the handle. This feature desirably allows a surgeon to gauge the level of insertion force and adjust according to bone quality and surgeon preference.

Referring to Fig. 15, in an alternate embodiment, a pair of activation buttons 248 can be used instead of a single button. In this embodiment, both buttons must be depressed in order to release shaft 236, thereby providing a safety feature so that a tack is not accidentally fired. As seen in Fig. 15, activation buttons 248 are positioned on opposite sides of handle 230 and are offset 90° with respect to thumb slide 252. Of course, other safety features can also be incorporated into device 210 to prevent accidental firing.
Referring to Figs. 17-19, an alternate embodiment of an insertion device 270 is shown that has an alternative loading mechanism. Insertion device 270 includes a handle 272 at a proximal end and a spring loaded elongate applicator extension 274 extending between distal end 276 and handle 272. Extension 274 comprises a spring cover 278 attached to handle 272 for housing spring 280 and a holding sleeve 282 coaxially attached to the distal end of spring cover 278 in a telescoping fashion for receiving a fixation element. Sleeve 282 has slightly smaller external dimensions than the internal dimensions of cover 278 so that the proximal end of sleeve 282 can be inserted into the distal end of cover 278 and sleeve 282 can move in the axial direction with respect to cover 278. As best seen in Fig. 19, sleeve 282 can include prongs that interlock with ridges on the interior of cover 278 so that when sleeve 282 is inserted into cover 278, sleeve 282 is not inadvertently removed from cover 278 in the distal direction. In a preferred embodiment, sleeve 282 has prongs 284 that are flexible and are collapsible or bendable into the interior of sleeve 282 so that sleeve 282 can be removed from cover 278 for cleaning, disassembly, or replacement. Prongs 284 are biased radially outwardly so that sleeve 282 can be easily reattached by simply pushing the sleeve into the cover in the proximal direction. The distal end of sleeve 282 preferably has a pronged tip similar to that described previously for retaining a fixation element.

A central channel 290 extends within handle 272 and through extension 274 and houses a firing spring 291 and a shaft member 292 similar to the embodiment of Fig. 12. Firing spring 291 is biased between force adjustment dial 293 and the proximal end of shaft 292. Adjustment dial 293 includes a knob 300 with internal threading that engages an externally threaded adjustment slider 302 that is slidably housed within channel 290. When knob 300 is rotated, adjustment slider 302 slidably moves within channel 290 and compresses or decompresses spring 291 for adjusting the amount of force that is exerted on shaft 292 and consequently the tack during insertion. A pair of knob retaining screws 304 extend radially inward from the exterior of handle 272 and engage a circular groove in knob 300 for retaining knob 300 in the proximal end of handle 272. A guide screw 306 extends inward from handle 272 and engage a longitudinal groove in adjustment slider 302 to prevent the slider from rotating.

Shaft 292 extends longitudinally within handle 272 and is generally identical to shaft 236 described above, moving between a loaded and an unloaded position. Shaft 292 includes a base portion 294, a mid-section 296 having a smaller diameter than base portion 294, and a tip portion 298 having a smaller diameter than mid-section 296. A first shoulder 295 is positioned at the transition of base portion 295 and mid-section 296 and a
second shoulder 297 is positioned at the transition of mid-section 296 and tip portion 298. Device 270 includes an activation button 308 similar to button 248 described above for facilitating movement of shaft 292 from the loaded to the unloaded position in the same fashion as described with respect to the embodiment of Fig. 12. To move shaft 292 from the unloaded to the loaded position, holding sleeve 282 and tip portion 298 of shaft 292 is retracted in the proximal direction until shoulder 297 of shaft 292 slides beyond button 308 and the button engages shoulder 297, thereby locking shaft 292 in the loaded position in a similar fashion to button 248 described above. Also, insertion device 270 preferably has a spring 280 housed within spring cover 278 that biases holding sleeve 282 in the distal direction and once shaft 292 is in the loaded position, the holding sleeve is released and returns to its resting position. In this way, shaft 292 can be easily moved from the unloaded to the loaded position, by depressing device 270 in the distal direction against a solid object, such as a table or a surgeon's hand. In all other respects, the method of operation or use of device 270 is similar to the method described above with respect to device 210.

Referring to Figs. 20-21, another embodiment of an insertion device 310 is shown that has yet another alternative loading mechanism. In all other respects, device 310 is similar to device 270 described previously. Insertion device 310 has a cam 312 for moving shaft 292 from the unloaded to the loaded position. In this embodiment, shaft 292 has pins 314 extending outwardly therefrom that engage an internal ramp 316 within cam 312 and when cam 312 is rotated pins 314 slide along ramp 316 in the proximal direction and thereby move shaft 292 in the proximal direction and shaft 292 is retracted until shoulder 297 of shaft 292 slides beyond button 308 and the button engages shoulder 297, thereby locking shaft 292 in the loaded position in a similar fashion to button 248 described above. After shaft 292 is locked into the loaded position, cam 312 is rotated to provide clearance for pins 314 to move in the distal direction during the unloading or firing movement of shaft 292.

While it is apparent that the illustrative embodiments of the invention herein disclosed fulfill the objectives stated above, it will be appreciated that numerous modifications and other embodiments may be devised by those skilled in the art. Therefore, it will be understood that the appended claims are intended to cover all such modifications and embodiments which come within the spirit and scope of the present invention.
THE CLAIMS

What is claimed is:

1. A device for attaching a fixation element to bone, comprising:
   a longitudinal member extending along a longitudinal axis from a proximal end to a
distal end and having a channel extending therein adapted for receiving at least a portion of
one fixation element; and
   a shaft positioned coaxially within and extending along at least a portion of the
longitudinal member, at least a portion of the shaft retained within the channel of the
longitudinal member and having a distal end configured and adapted to contact at least a
portion of the fixation element,
   wherein the shaft is moveable with respect to the longitudinal member to drive the
fixation element into bone.

2. The device of claim 1, wherein the longitudinal member includes a first
   member for receiving at least one fixation element at the distal end and a second member
attached coaxially to the first member, and the first member is movable with respect to the
second member.

3. The device of claim 2, further comprising a spring housed within the channel
   and engaging the first member for resiliently biasing the first member in the axial direction.

4. The device of claim 2, wherein the first and second members are
   substantially cylindrical and the first member is movable telescopingly within the second
member.

5. The device of claim 2, wherein the first and second members are interlocked
   in the axial direction.

6. The device of claim 1, wherein the shaft is substantially cylindrical and has
   at least two portions with different diameters.

7. The device of claim 1, wherein the distal end of the longitudinal member
   includes a pronged tip for resiliently holding a fixation element therein.
8. A device for attaching a fixation element to bone, comprising:
a handle member adapted for being held by a user and having a recess extending
therein;
a longitudinal member extending along a longitudinal axis from a proximal end to a
distal end and having a channel extending therein adapted for receiving at least a portion of
one fixation element, the proximal end of the channel communicating with the recess in the
handle member; and
a shaft positioned coaxially and extending within at least a portion the channel of the
longitudinal member, the shaft coupled to the handle at a proximal end, and having a distal
end adapted to contact at least a portion of the fixation when the fixation element is driven
into the bone,
wherein the longitudinal member is moveable with respect to the shaft to drive the
fixation element into bone.

9. A device for attaching a bone tack having a head portion and an insertion end
to bone, comprising:
a handle adapted for receiving a force from a user, the handle having a recess
extending therein;
an elongated sleeve having a longitudinal axis, a proximal end, a distal end, and a
hollow portion extending along the longitudinal axis between the proximal end and the
distal end, the hollow portion of the sleeve communicating with the recess in the handle to
form a channel, the sleeve telescopically moveable with respect to the handle, the sleeve
adapted to hold the head portion of the tack;
a shaft at least a portion of which extends within the channel, the shaft having a
proximal end fixedly attached to the handle and a distal end adapted to contact the head of
the tack when it is driven into the bone, the shaft also having an enlarged head portion; and
a spring housed within the channel and coaxial with the shaft, the spring engaging
the head portion of the shaft and at least one of the sleeve and handle,
wherein when a force is applied to the handle, the channel shortens in length and the
distal end of the shaft contacts the head of the bone tack and drives the bone tack into bone.

10. A device for attaching fixation elements to bone, comprising:
a longitudinal member extending along a longitudinal axis extending from a
proximal end to a distal end and having a channel extending therein; and
a plurality of carrier members positionable within the channel, wherein each carrier member comprises a body extending from a distal body end to a proximal body end and the distal body end is adapted to receive at least a portion of a fixation element.

11. The device of claim 10, wherein the carrier member has a cavity at the proximal body end configured and dimensioned for receiving a distal body end of an adjacent carrier member.

12. The device of claim 10, wherein the carrier member has a frustoconical portion.

13. The device of claim 10, wherein the fixation element is held to the distal body end by a friction fit.

14. The device of claim 10, wherein the carrier member includes a conical tip portion adjacent the distal body end and a shoulder is positioned adjacent the tip portion and extends radially outward therefrom for contacting the proximal body end of an adjacent carrier member when such carrier members are in abutting relationship.

15. The device of claim 10, wherein the carrier members are stackable such that a plurality of carrier members are positionable in abutting relationship.

16. The device of claim 10, wherein the carrier members are axially alignable within the channel.

17. The device of claim 10, further comprising a shaft located centrally with respect to the channel for moving the carrier members axially with respect to the shaft.

18. The device of claim 17, wherein the shaft includes a frustoconical tip at a distal end and the tip is configured and dimensioned to be received in the proximal body end of the carrier member.

19. The device of claim 18, further including a tab extending radially outward from the shaft, the tab configured to be movable by a human finger such that the shaft may be moved with respect to the longitudinal member.
20. The device of claim 19, further comprising a spring which engages a slot in the longitudinal member for locating the shaft at a plurality of preselected locations with respect to the longitudinal member.

21. The device of claim 10, wherein the channel has a front opening at the distal end of the longitudinal member such that the carrier members can travel through the opening.

22. The device of claim 21, wherein the channel further includes a back opening at the proximal end of the longitudinal member and the carrier member can travel through the back opening.

23. The device of claim 10, wherein a handle is connected to the proximal end of the longitudinal member, the handle configured and dimensioned to receive the hand of a user.

24. A device for holding a fixation element, comprising:
   a carrier body extending from a distal body end to a proximal body end, said body comprising,
   a holding portion positioned at the distal body end adapted to releasably hold the fixation element, and
   a receiving portion integral to the holding portion positioned at the proximal body end and defining an interior cavity adapted to receive the distal body end of an adjacent carrier body, and said adjacent carrier bodies are stackable

25. The device of claim 24, wherein the holding portion has an exterior contour and the interior cavity has an internal contour, and the interior contour is configured and dimensioned to conform to the exterior contour.

26. A device for attaching a fixation element to bone, comprising:
   a longitudinal member extending along a longitudinal axis from a proximal end to a distal end and having a channel extending therein adapted for receiving at least a portion of one fixation element; and
   a shaft positioned coaxially within and extending along at least a portion of the longitudinal member, at least a portion of the shaft retained within the channel of the
longitudinal member and having a distal end configured and adapted to contact at least a portion of the fixation element,

a spring positioned adjacent the shaft for resiliently biasing the shaft in an axial direction,

wherein the shaft is moveable with respect to the longitudinal member to drive the fixation element into bone.

27. The device of claim 26, further comprising an adjustment gauge for adjusting the bias of the spring.

28. The device of claim 26, wherein the shaft is moveable from a loaded position to an unloaded position.

29. The device of claim 28, further comprising a locking mechanism for engaging the shaft, wherein the locking mechanism is moveable from a first position to a second position, and when the locking mechanism is in the first position the shaft is locked in the loaded position and when the shaft is in the second position the shaft is moveable to the second unloaded position.

30. The device of claim 29, wherein the locking mechanism is pivotally mounted to the longitudinal member and is resiliently biased into the locking position.

31. The device of claim 28, further comprising a loading mechanism for engaging the shaft and moving the shaft from the unloaded to the loaded position.

32. The device of claim 31, wherein the loading mechanism comprises a slide member moveably mounted to the longitudinal member that is operable by a user to manually move the shaft in an axial direction.

33. The device of claim 32, wherein the slide member is resiliently biased out of engagement with the shaft.

34. The device of claim 28, wherein the shaft is moveable to the loaded position by applying force on the distal end of the device.
35. The device of claim 31, further comprising at least one pin member rigidly mounted to the shaft and extending radially therefrom, and wherein the loading mechanism comprises a cam mechanism that has an internal ramp for engaging the pin and moving the shaft in the axial direction.
Fig. 9
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B 17/88 A61B 17/068

According to International Patent Classification (IPC) or to both national classification and IPC.

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbol)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched.

Electronic database consults during the international search (name of data base and, where practicable, search terms used).

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 5 893 856 A (JACOB) 13 April 1999 (1999-04-13) figures 2-4</td>
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<td>EP 0 834 281 A (USSC) 8 April 1998 (1998-04-08) figure 11</td>
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<td>EP 1 090 591 A (ETHICON) 11 April 2001 (2001-04-11) figures 1-6</td>
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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents:
  - "A" document defining the general state of the art which is not considered to be of particular relevance.
  - "E" earlier document but published on or after the international filing date.
  - "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another document or other special reason (as specified).
  - "O" document referring to an oral disclosure, use, exhibition or other means.
  - "P" document published prior to the international filing date but later than the priority date claimed.

**letters**
- "I" later document published after the international filing date or priority date and not in conflict with the invention, cited to understand the principle or theory underlying the invention.
- "X" document of particular relevance; the claimed invention cannot be considered novel, or cannot be considered to involve an inventive step when the document is taken alone.
- "Y" document of particular relevance; the claimed invention cannot be considered novel, or cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "S" document member of the same patent family.

Date of the actual completion of the international search: 2 September 2002

Date of mailing of the international search report: 14, 10, 02

Name and mailing address of the ISA:

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 346-2040, Tx 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer:

BARTON, S
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INTERNATIONAL SEARCH REPORT

**Box I** Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. □ Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. □ Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. □ Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II** Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. □ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. □ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. □ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

   1-5, 8, 9

**Remark on Protest**

□ The additional search fees were accompanied by the applicant's protest.

□ No protest accompanied the payment of additional search fees.
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-5,8,9
   Bone fixing applier with telescopic outer tubular member.

2. Claims: 1,6
   Bone fixing applier with shaft with stepped diameter.

3. Claims: 1,7
   Bone fixing applier with pronged tip.

4. Claims: 10-23
   Multiple bone fixing applier.

5. Claims: 24,25
   Fixing holder

6. Claims: 26,27
   Bone fixing applier with adjustable spring bias.
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