DILATION INTRODUCER FOR ORTHOPEDIC SURGERY

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ABSTRACT
The dilation introducer has a locked assembled configuration for placement of the dilation introducer against a patient's tissue to be treated, and an unlocked, collapsed configuration for dilating the patient's soft tissue down to tissue to be treated. Dilator tubes are successively released and advanced to progressively expand the patient's soft tissue down to the bone tissue to be treated. The dilator tubes and a guide insert may include spikes for engaging bone tissue. The dilation introducer may include a light emitter disposed in a dilator tube. A telescoping expander sleeve is also provided.
DILATION INTRODUCER FOR ORTHOPEDIC SURGERY

CROSS-REFERENCES TO RELATED APPLICATIONS


BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates to bone fixation devices, and more particularly relates to a dilation introducer for introducing a bone fixation device for orthopedic surgery, such as for vertebral fusion.

[0004] 2. General Background and State of the Art

[0005] Fusion of two adjacent vertebrae is a common surgical treatment for back injuries due to damage or defects in a spinal disc between two adjacent vertebrae, such as conditions due to a herniated disc or disc degeneration. The entire disc may be removed by a discectomy procedure, and may be replaced with bone or a bone substitute and/or cage in order to prevent collapse of the disc space between the adjacent vertebrae. Early techniques for stabilizing the adjacent vertebrae included application of a plate or a rod in conjunction with screws across the adjacent vertebrae, after which the adjacent vertebrae would eventually fuse together. However, such techniques commonly required prolonged periods of recovery from the extensive surgery involved, and it would be desirable to provide an improved apparatus and method for providing a minimally invasive procedure that will result in less trauma and improvement in patient recovery.

[0006] Bone fixation devices are known that are useful for connecting two or more bone segments for the healing of broken bones, typically including an elongate pin with a distal anchor and a proximal anchor movable on the pin to accommodate different bone dimensions, and to permit tensioning of the bone segments together. The surgical procedure of attaching two or more parts of a bone with a pin-like device commonly requires an initial incision into the tissue down to the bone, and the drilling of a hole through the bone parts to be joined. Such bone fixation devices can be useful for fusion of vertebrae together, because such a bone fixation device can be used to join adjacent bone segments through a single percutaneous incision or puncture, without the need to expose any other side of the bone segments to be joined. In either type of procedure, there is substantial trauma to the surrounding tissue if a large incision is required. Thus, it would be desirable to provide a minimally invasive dilation introducer to allow the penetration and spreading of soft tissues down to vertebrae to be fused, for use of such a bone fixation device to join adjacent vertebrae, and to allow for more easily performing the delicate maneuvering of drilling adjacent vertebrae and application of one or more bone fixation devices to join the vertebrae to be fused. The present invention satisfies these and other needs.

INVENTION SUMMARY

[0007] Briefly, and in general terms, the invention provides for a telescoping dilation introducer for orthopedic surgery, the dilation introducer having a locked assembled configuration for initial placement of the dilation introducer against a patient's tissue to be treated, and an unlocked, collapsed configuration for dilating the patient's soft surrounding tissue to a desired degree of dilation to permit minimally invasive surgical procedures on the patient's tissue. As the telescoping dilation introducer is inserted, each individual dilator tube is successively released and advanced to progressively expand the patient's soft tissue down to the tissue to be treated. In a particularly useful aspect of the invention, the tissue to be treated is bone tissue which must be prepared prior to attachment of adjacent bone section in a fusion process. While there are many applications of the dilation introducer of the invention, the invention is particularly applicable to fusion of bones in orthopedic surgery using minimally invasive technique, and will be described herein in particular applications of those procedures. The invention also concerns a minimally invasive procedure utilizing the telescoping dilation introducer to insert a bone fixation device into a patient's spine for posterior spine fusion. While posterior spine fusion currently takes up to two hours to complete, and requires a six inch incision, with the apparatus and method of the invention, comparable surgery can be completed in less than thirty minutes, with a dilution port 1.3 mm or less in diameter, thus lowering the chance of damage to the surrounding soft tissue.

[0008] A telescoping dilation introducer is typically operated by pressing the introducer against a relatively hard surface, such as bone tissue being treated. The present invention provides for a guide wire assembly when such a telescoping dilation introducer is to be used in treatment of soft tissue, such as an organ, to provide a surface against which the telescoping dilation introducer can be pushed during operation of the telescoping dilation introducer. In a presently preferred embodiment, a guide wire or K wire assembly is provided for use with a telescoping dilation introducer according to the invention. The guide wire assembly includes an elongated generally cylindrical first section, and an elongated tubular second section that receives the first section. The elongated generally cylindrical first section includes a proximal enlarged head or stop portion, and an elongated body portion with a proximal section and a relatively narrower diameter main section connected to the proximal section, and a pointed distal tip at the distal end of the narrow main section. The second section of the guide wire assembly includes an elongated tubular body with an internal bore adapted to receive the narrow main section, as is illustrated in FIG. 28. The tubular second section advantageously includes a frustoconical distal tip with a narrowed portion at the distal end and an enlarged flat shoulder at the proximal end of the frustoconical distal tip. When the guide wire assembly is assembled, the assembly presents a pointed distal end with a proximal shoulder against which a telescoping dilation introducer can be pushed for operation of the telescoping dilation introducer. The main section thus adds a sharp point to the relatively blunt distal end of the tubular distal section, allowing the guide wire assembly to be inserted through soft tissue for placement in a soft tissue target of interest, such as an organ, and the first section can then be removed to allow a telescoping dilation introducer to be placed over the second section and pressed against the shoulder of the blunt distal end for operation of the telescoping dilation introducer. After the sharp point of the
in the desired location in the soft tissue, the first section can be removed from the second section, leaving the blunt distal end in place at the desired location in the soft tissue, and the telescoping dilation introducer can be placed over the second section and pressed against the shoulder of the blunt distal end for operation of the telescoping dilation introducer.

[0009] In one presently preferred embodiment, the present invention provides for an improvement in a dilation introducer for orthopedic surgery, in which the dilation introducer includes one or more dilator tubes having a distal end and a proximal end, and the distal end of the one or more dilator tubes including a plurality of spikes for engaging bone tissue. In one presently preferred aspect, the spikes may be formed of radiopaque material, for fluoroscopic imaging of the positioning of the one or more dilator tubes, and the spikes may be formed with a rounded shape so as to deflect soft tissue.

[0010] In another presently preferred aspect, the dilation introducer includes a parallel guide insert adapted to be received in the one or more dilator tubes. The parallel guide insert includes a main cylindrical shaft having a proximal end connected to a cylindrical head, and a plurality of longitudinal bores extending the length of the parallel guide insert through the main cylindrical shaft and cylindrical head. The distal tip of the parallel guide insert may be provided with a plurality of spikes for engaging bone tissue. The spikes of the parallel guide insert may be formed of radiopaque material, and may be formed with a rounded shape so as to deflect soft tissue.

[0011] In another presently preferred embodiment, the present invention concerns a dilation introducer for orthopedic surgery having a locked assembled configuration for initial placement of the dilation introducer against a patient’s bone tissue to be treated, and an unlocked, collapsed configuration dilating the patient’s soft tissue down to the bone tissue to be treated to a desired degree of dilation to permit minimally invasive surgical procedures on the patient’s bone tissue to be treated. The dilation introducer includes a first dilator tube having a distal end with a tapered tip and a proximal end with a cylindrical head, and a second dilator tube having a distal end with a tapered tip and a proximal end with a cylindrical head, and an inner lumen with a distal opening and a proximal opening. The first dilator tube is removably received in the second dilator tube for slidable telescoping movement within the second dilator tube. Means are provided for removably connecting the first and second dilator tubes together in a locked configuration. The means for removably connecting the first and second dilator tubes includes a first latching member disposed in the cylindrical head of the first dilator tube. The first latching member has a locking button connected transversely to a shaft with a latching end projecting from the cylindrical head of the first dilator tube toward the distal end of the first dilator tube, with the locking button extending transversely from the shaft through a side aperture in the cylindrical head of the first dilator tube. The locking button is biased outwardly from the cylindrical head, such as by a spring, and the first latching member is received in an upper aperture of the cylindrical head of an adjacent second dilator tube. The upper aperture of the cylindrical head of the second dilator tube includes a latching chamber for retaining the latching end of the latching member when the locking button is biased outwardly, to lock the cylindrical heads of the first and second dilator tubes together. The locking button is moveable inwardly to move the latching member inwardly and to move the latching end of the latching member inwardly out of the latching chamber, to unlock the first and second dilator tubes.

[0012] The dilation introducer may include one or more additional dilator tubes, with the second dilator tube being removably received in the one or more additional dilator tubes for slidable telescoping movement within the one or more additional dilator tubes. The one or more additional dilator tubes likewise have a distal end and a proximal end with a cylindrical head, an inner lumen with a distal opening and a proximal opening, and the distal end having a tapered tip. The second dilator tube and the one or more additional dilator tubes having an unlocked configuration in which the one or more additional dilator tubes may slidably telescope over the second dilator tube to dilate the patient’s soft tissue at the distal end of the dilation introducer. Means are provided for removably connecting the second dilator tube and the one or more additional dilator tubes together in a locked configuration. The means for removably connecting the second dilator tube and the one or more additional dilator tubes include a second latching member disposed in the cylindrical head of the second dilator tube. The second latching member has a locking button connected transversely to a shaft with a latching end projecting from the cylindrical head of the second dilator tube toward the distal end of the second dilator tube, and the locking button extends transversely from the shaft through a side aperture in the cylindrical head of the second dilator tube. The locking button is biased outwardly from the cylindrical head, such as by a spring, and the second latching member is received in an upper aperture of the cylindrical head of the additional dilator tube to be connected. The upper aperture of the cylindrical head of the additional dilator tubes include a latching chamber for retaining the latching end of the second latching member when the locking button is biased outwardly, to lock the cylindrical heads of the second and additional dilator tube together, and the locking button is moveable inwardly to move the second latching member inwardly and the latching end of the second latching member inwardly out of the latching chamber.

[0013] In a presently preferred aspect, the additional dilator tube comprises a handle connected to the proximal end of the additional dilator tube, and the cylindrical head of the additional dilator tube includes a plurality of the upper apertures, each including a latching chamber for receiving the second latching member.

[0014] In another presently preferred embodiment, the present invention provides for an improvement in a dilation introducer for orthopedic surgery, in which the dilation introducer includes a dilator tube having a tubular shaft, a distal end and a proximal end, an inner lumen with a distal opening and a proximal opening, and a light emitter disposed in the dilator tube. In one aspect, the light emitter may include a light emitting diode, and the light emitting diode may be embedded in the tubular shaft of the dilator tube. In another aspect, the light emitter may include a fiber optic, and the fiber optic may be embedded in the tubular shaft of the dilator tube.

[0015] In a presently preferred aspect, the dilator tube includes a handle and a switch for controlling the light
emitter, and at least one battery is disposed in the handle and is connected to the switch to power the light emitter. Where the light emitter includes one or more fiber optics, the light emitter includes a light source providing light conducted to the one or more fiber optics. The light emitter may include one or more elongated energy conducting members disposed on an outer surface of the tubular shaft of the dilator tube, and the one or more elongated energy conducting members may be disposed in a groove on the exterior surface of the tubular shaft. Alternatively, the one or more elongated energy conducting members may be located on the inside of the dilator tube, or may extend through the wall of the dilator tube.

[0016] The present invention also provides for a telescoping expander sleeve adapted to be slidably disposed over a shaft of a dilator tube for dilating a patient's soft tissue down to a bone tissue to be treated to a desired degree of dilation to permit minimally invasive surgical procedures on the patient's bone tissue. The telescoping expander sleeve is moveable between an extended, unexpanded configuration and a collapsed, expanded configuration. The telescoping expander sleeve includes a first generally tubular section having a tubular proximal portion and a distal portion. The tubular proximal portion has an enlarged proximal head, and the distal portion includes two or more active spreader arms each having a proximal end and a distal tip. The tubular proximal portion may optionally be provided with a handle. The two or more active spreader arms are connected at their proximal ends to the tubular proximal portion, and the distal tips of the two or more active spreader arms are moveable radially between an unexpanded configuration and an expanded configuration.

[0017] The telescoping expander sleeve also includes a second generally tubular section slidably disposed over the first generally tubular section. The second generally tubular section includes a tubular proximal portion and a distal portion including two or more passive spreader flaps each having a narrow proximal end and a wide distal tip. The proximal ends of the two or more passive spreader flaps are hingedly connected to the tubular proximal portion, and the distal tips of the two or more passive spreader flaps are moveable radially between an unexpanded configuration and an expanded configuration. The two or more active spreader arms slideably engage the two or more passive spreader flaps, so that as the telescoping expander sleeve telescopes from the extended, unexpanded configuration to the collapsed, expanded configuration, the two or more active spreader arms slide from the narrow proximal ends of the two or more passive spreader flaps to the wider distal ends of the passive spreader flaps to spread the distal ends of the two or more passive spreader flaps apart, and to spread the distal ends of the two or more active spreader arms apart.

[0018] In a presently preferred aspect, the distal tips of the two or more active spreader arms have beveled edges to deflect soft tissue during insertion of the telescoping expander sleeve, and the distal tips of the two or more passive spreader flaps have beveled edges to deflect soft tissue during insertion of the telescoping expander sleeve. The purpose of the active spreader arms and passive spreader flaps is to facilitate the creating of a larger working area adjacent to bone or bone tissues being treated. The spreader arms and flaps may optionally be covered by an expandable material, such as latex, for example, to prevent tissues from being pressed into cavities of the telescoping expander sleeve.

[0019] While the present invention is particularly useful for the purposes of orthopedic surgery, those skilled in the art will recognize that the invention can also be used for the treatment of a variety of internal organs or structures when it is desired to minimize the size of an opening in the patient's soft tissue and the resultant damage and trauma to tissue surrounding the operation site.

[0020] Other features and advantages of the present invention will become more apparent from the following detailed description of the preferred embodiments in conjunction with the accompanying drawings, which illustrate, by way of example, the operation of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. 1 is a plan view of a first embodiment of a dilation introducer in a locked configuration, according to the present invention.

[0022] FIG. 2 is a plan view of the dilation introducer of FIG. 1 shown in an unlocked, collapsed configuration.

[0023] FIG. 3 is a plan view of the first or inner dilator tube of the dilation introducer of FIG. 1.

[0024] FIG. 4 is a plan view of the second or intermediate dilator tube of the dilation introducer of FIG. 1.

[0025] FIG. 5 is a plan view of the third or outer dilator tube of the dilation introducer of FIG. 1.

[0026] FIG. 6A is a top plan view of the first locking clip of the dilation introducer of FIG. 1.

[0027] FIG. 6B is an elevational view of the first locking clip of the dilation introducer of FIG. 1.

[0028] FIG. 6C is a bottom plan view of the first locking clip of the dilation introducer of FIG. 1.

[0029] FIG. 7A is a top plan view of the second locking clip of the dilation introducer of FIG. 1.

[0030] FIG. 7B is an elevational view of the second locking clip of the dilation introducer of FIG. 1.

[0031] FIG. 8 is a perspective view of a second embodiment of a dilation introducer in a locked configuration, according to the present invention.

[0032] FIG. 9 is a perspective view of the dilation introducer of FIG. 8 shown in an unlocked, collapsed configuration.

[0033] FIG. 10 is a perspective view of the first or inner dilator tube of the dilation introducer of FIG. 8.

[0034] FIG. 11 is a perspective view of the second or intermediate dilator tube of the dilation introducer of FIG. 8.

[0035] FIG. 12 is a plan view of the third or outer dilator tube of the dilation introducer of FIG. 8.

[0036] FIG. 13 is a plan view of a third embodiment of a dilation introducer in a locked configuration, according to the present invention.
FIG. 14 is a plan view of the dilation introducer of FIG. 13 shown in an unlocked, collapsed configuration.

FIG. 15 is a plan view of the first or inner dilator tube of the dilation introducer of FIG. 13.

FIG. 16 is a plan view of the second or intermediate dilator tube of the dilation introducer of FIG. 13.

FIG. 17 is a plan view of the third or outer dilator tube of the dilation introducer of FIG. 13.

FIG. 18 is a plan view of the plastic sleeve of the dilation introducer of FIG. 13.

FIG. 19 is a plan view of a fourth embodiment of a dilation introducer in a locked configuration, according to the present invention.

FIG. 20 is a plan view of the dilation introducer of FIG. 19 shown in an unlocked, collapsed configuration.

FIG. 21 is a plan view of the first or inner dilator tube of the dilation introducer of FIG. 19.

FIG. 22 is a plan view of the second or intermediate dilator tube of the dilation introducer of FIG. 19.

FIG. 23 is a plan view of the third or outer dilator tube of the dilation introducer of FIG. 19.

FIG. 24 is a schematic diagram illustrating location of a starting point for insertion of a bone fixation device according to the method of the invention.

FIG. 25 is a schematic diagram of a lateral view illustrating location of a trajectory for insertion of a bone fixation device according to the method of the invention.

FIG. 26 is a schematic diagram of an anterior view illustrating location of a trajectory for insertion of a bone fixation device according to the method of the invention.

FIG. 27 is a plan view of a guide wire assembly for use with the various embodiments of the telescoping dilation introducer of the invention, shown disassembled.

FIG. 28 is a plan view of the guide wire assembly of FIG. 27, shown partially assembled.

FIG. 29 is a plan view of the guide wire assembly of FIG. 27, shown fully assembled.

FIG. 30 is a perspective view of a variation of the outer dilator tube of the embodiment of FIGS. 8-12, with a parallel guide.

FIG. 31 is a perspective view of the parallel guide from FIG. 30.

FIG. 32 is a perspective view of a variation of the outer dilator tube of the embodiment of FIGS. 8-12, with an angled tip and with a parallel guide.

FIG. 33 is a perspective view of the parallel guide with an angled tip from FIG. 32.

FIG. 34 is a perspective of another variation of the outer dilator tube of the embodiment of FIGS. 8-12, with an angled tip and spikes.

FIG. 35 is a perspective view of the outer dilator tube of FIG. 34, with a parallel guide with spikes.

FIG. 36 is a perspective view of a fifth embodiment of a dilation introducer in an unlocked configuration, according to the present invention.

FIG. 37 is a sectional view of a portion of the dilation introducer of FIG. 36.

FIG. 38 is a perspective view of a variation of the dilation introducer of FIG. 36, shown in a locked configuration, according to the present invention.

FIG. 39 is a sectional view of a portion of the dilation introducer of FIG. 36 taken along lines 39-39 of FIG. 38.

FIG. 40 is a top perspective view of the head end of the handle of the dilation introducer of FIG. 36, showing multiple locking locations.

FIG. 41 is a schematic diagram of a variation of the dilation introducer of FIG. 36, with a light emitter and switch for the light emitter.

FIG. 42 is an enlarged view of the tip of the dilation introducer of FIG. 41.

FIG. 43 is a perspective view of another variation of the dilation introducer of FIG. 41, with an exterior groove for one or more elongated energy conducting members.

FIG. 44 is a side elevational view of a telescoping expander sleeve shown in an extended, unexpanded configuration.

FIG. 45 is a side elevational view of the telescoping expander sleeve of FIG. 44 shown in an intermediate partially collapsed, partially expanded configuration.

FIG. 46 is a side elevational view of the telescoping expander sleeve of FIG. 44 shown in a fully collapsed, fully expanded configuration.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, which are provided for purposes of illustration and by way of example, the present invention provides for a telescoping dilation introducer for orthopedic surgery, the dilation introducer having a locked assembled configuration for initial placement of the dilation introducer against a patient’s bone tissue to be treated, and an unlocked, collapsed configuration dilating the patient’s soft tissue down to the bone tissue to be treated to a desired degree of dilation to permit minimally invasive surgical procedures on the patient’s bone tissue to be treated.

While the invention will be described with specificity to a spinal fusion procedure, those skilled in the art will recognize that the apparatus and method of the art will recognize that the apparatus and method of the invention can also be advantageously used for procedures in which the dilation introducer can be brought up against other firm or solid structures in the body or introduced into the body to thereby gain the advantages of the invention for other minimally invasive procedures.

A dilation introducer 30 according to a first preferred embodiment is shown in a locked assembled configuration in FIG. 1, and shown in an unlocked, collapsed configuration in FIG. 2. Referring to FIG. 3, the dilation introducer includes a first or inner dilator tube 32 having a
distal end 34 with a tapered tip 36, and a proximal end 38 with a head 40 including a pair of spaced part rings 42. The first dilator tube has an inner lumen 44 with a distal opening 46 and a proximal opening 48.

[0073] Referring to FIG. 4, the dilatation introducer also includes a shorter second or intermediate dilator tube 52 having a distal end 54 with a tapered tip 56, and a proximal end 58 with a head 60 including a pair of spaced apart rings 62. The second dilator tube has an inner lumen 64 with a distal opening 66 and a proximal opening 68.

[0074] Referring to FIG. 5, in a presently preferred aspect, the dilatation introducer also includes at least one additional dilator tube, such as a second shorter third or outer dilator tube 72 having a distal end 74 with a tapered tip 76, and a proximal end 78 with a handle 80. The third dilator tube has an inner lumen 82 with a distal opening 84 and a proximal opening 86.

[0075] Referring to FIGS. 6A, 6B and 6C, the means for removably connecting the first and second dilator tubes together in a locked configuration includes a first locking clip 88. As is shown in FIGS. 7A and 7B, a means for removably connecting the second and third dilator tubes together in a locked configuration may also be provided, and may include a second locking clip 90. The first locking clip includes a first portion 92 and a second portion 94, and a cross-piece or handle 96 having a first end 98 and a second end 100 connected at right angles between the first and second portions. The first portion includes pair of resilient arms 102 each having a proximal narrow neck portion 104 connected to the cross-piece, and a distal gripping portion 106 extending from the narrow neck portion. The resilient arms have an inner rounded surface 108 adapted to snap over the first dilator tube between the spaced apart rings of the first dilator tube. The second portion currently preferably includes a single arm 112 having a proximal narrow neck portion 114, and a distal gripping portion 116 extending from the narrow neck portion. The gripping portion has an inner rounded surface 118 adapted to fit over the outer surface of the second dilator tube between the spaced apart rings of the second dilator tube, to connect the first and second dilator tubes. Removing the first locking clip allows the second or intermediate dilator tube to slidably telescope over the first inner dilator tube to dilate tissue at the distal end of the dilatation introducer.

[0076] The second locking clip includes a first portion 122 and a second portion 124, and a cross-piece or handle 126 having a first end 128 and a second end 130 connected between the first portion and the second portion at right angles. The first portion includes a pair of resilient arms 132 each having a proximal narrow neck portion 134 connected to the cross-piece, and a distal gripping portion 136 extending from the narrow neck portion. The pair of resilient arms have an inner rounded surface 138 adapted to snap over the outer surface of the second dilator tube between the spaced apart rings of the second dilator tube. The second portion of the second locking clip includes a pair of resilient arms 142 each having a proximal narrow neck portion (not shown) connected to the cross-piece and a distal gripping portion 146 extending from the narrow neck portion, the pair of resilient arms having an inner rounded surface (not shown) adapted to fit over the outer surface of the third dilator tube to connect the second and third dilator tubes. Removing the second locking clip allows the third or outer dilator tube to slidably telescope over the second inner dilator tube to further dilate tissue at the distal end of the dilatation introducer.

[0077] As is shown in FIG. 1, a tubular bone drill or tap 150 can be inserted through an intermediate or outer dilator tube, and the tubular bone drill or tap can be passed or threaded over a guide wire or K wire 151 to contact the surface of the vertebral bone to be treated, as will be further described below. Once the outer dilator tube has been moved to the distal end of the dilatation introducer into position against the vertebra or bone to be treated to fully dilate the soft tissue, the inner dilator tube, the tubular bone drill, and the intermediate dilator tube can be withdrawn and removed to leave the outer dilator tube in place to permit further surgical procedures.

[0078] Referring to FIGS. 8-12, the invention provides for a second presently preferred embodiment of a dilatation introducer 160 shown in a locked assembled configuration in FIG. 8, and shown in an unlocked, collapsed configuration in FIG. 9. Referring to FIG. 10, the dilatation introducer includes a first or inner dilator tube 162 having a distal end 164 with a tapered tip 166, and a proximal end 168 with a cylindrical head 170. The means for removably connecting the first and second dilator tubes together in a locked configuration includes a latching member 172, such as a hook, projecting from the cylindrical head toward the distal end, receiving a locking pin 216, although other latching members, such as a projection with aperture for receiving a locking pin may also be suitable, as will be apparent from the explanation below. The first dilator tube has an inner lumen 174 with a distal opening 176 and a proximal opening 178.

[0079] Referring to FIG. 11, the dilatation introducer includes a shorter second or intermediate dilator tube 182 having a distal end 184 with a tapered tip 186, and a proximal end 188 having a cylindrical head 190. The means for removably connecting the second and third dilator tubes together in a locked configuration includes a latching member 192, such as a hook, projecting from the cylindrical head toward the distal end, receiving a locking pin 218, although other latching members, such as a projection with aperture for receiving a locking pin may also be suitable, as noted above. The second dilator tube has an inner lumen 194 with a distal opening 196, and a proximal opening 198. The cylindrical head includes a first radial aperture 200 for receiving the locking pin 216, and a second longitudinal aperture 201 for receiving the distally projecting latching member of the cylindrical head of the first or inner dilator tube.

[0080] Referring to FIG. 12, in a preferred aspect, the dilatation introducer includes at least one additional dilator tube, such as a still shorter third or outer dilator tube 202 having a distal end 204 with a tapered tip 206, and a proximal end 208 to which a handle 210 is connected at its head end 212. The head end of the handle includes a radial aperture 214 for receiving the locking pin 218, and a longitudinal aperture 215 for receiving the distally projecting latching member of the cylindrical head of the second or intermediate dilator tube. The first locking pin 216 is substantially the same as the second locking pin 218. The third dilator tube has an inner lumen 219 with proximal and distal
openings. A tubular bone drill or tap can be inserted through the first or inner dilator tube, and the tubular bone drill or tap can be threaded over a guide wire or K wire to contact the surface of the vertebra or bone to be treated, as described above.

[0081] With reference to FIGS. 13-18, the invention provides for a third presently preferred embodiment of a dilation introducer 220, shown in a locked assembled configuration in FIG. 13, and shown in an unlocked, collapsed configuration in FIG. 14. As is illustrated in FIG. 15, the dilation introducer includes a first or inner dilator tube 222 having a distal end 224 with a tapered, beveled tip 226, and a proximal end 228 with a cylindrical head 230. The means for removably connecting the first and second dilator tubes together in a locked configuration includes a pair of opposing bayonet pins 232 extending from the proximal end of the first dilator tube. The first dilator tube has an inner lumen 234 with a distal opening 236 and a proximal opening 238.

[0082] As is shown in FIG. 16, the dilation introducer includes a shorter second or intermediate dilator tube 242 having a distal end 244 with a tapered, beveled tip 246, and a proximal end 248 with a cylindrical head 250. In a preferred aspect, the means for removably connecting the second and third dilator tubes together in a locked configuration includes a pair of opposing bayonet pins 252. The second dilator tube has an inner lumen 254 with a distal opening 256 and a proximal opening 258, and as part of the means for removably connecting the second and third dilator tubes together, interior opposing bayonet slots 260 for receiving the pair of opposing bayonet pins of the first or inner dilator tube.

[0083] Referring to FIG. 17, in a preferred aspect, the dilation introducer includes at least one additional dilator tube, such as a still shorter third or outer dilator tube 262 having a distal end 264 with a tapered tip 266, and a proximal end 268 having a pair of opposing handles 270. The third dilator tube has an inner lumen 271, with proximal and distal openings. In another presently preferred aspect, a plastic sleeve 272 is slidably disposed over the shaft of the third or outer dilator tube, and the plastic sleeve preferably has a distal tapered, beveled end 274. A proximal sleeve ring 276 may also be slidably disposed over the shaft of the third or outer dilator tube between the plastic sleeve 272 and the opposing handles.

[0084] As is illustrated in FIGS. 13 and 14, in this embodiment the tapered tips of the dilator tubes and plastic sleeve are beveled or angled at a common angle with respect to the longitudinal axis of the dilation introducer, so that the beveled edges of the tapered tips of the dilator tubes and plastic sleeve can be aligned together generally parallel to the surface of the soft tissue to be dilated, so that the bore and dilation passage of the dilation introducer may be aligned at a predetermined desired angle with respect to the soft tissue to be dilated and the bone tissue to be treated.

[0085] As part of the means for removably connecting the second and third dilator tubes together, the third dilator tube includes interior opposing bayonet slots 278 for receiving the pair of opposing bayonet pins of the second or intermediate dilator tube. A tubular bone drill or tap can be inserted through the first or inner dilator tube, and the tubular bone drill or tap can be threaded over a guide wire or K wire to contact the surface of the vertebra or bone to be treated, as described above.

[0086] With reference to FIGS. 19-23, the invention provides for a fourth embodiment of a dilation introducer 280 shown in a locked assembled configuration in FIG. 19, and shown in an unlocked, collapsed configuration in FIG. 20. Referring to FIG. 21, the dilation introducer includes a first or inner dilator tube 282 having a distal end 284 with a tapered tip 286, and a proximal end 288 having a generally spherical handle or head 290. As part of a means for removably connecting first and second dilator tubes together in a locked configuration, the proximal end of the first dilator tube near the handle includes a bayonet pin 292. The first dilator tube has an inner lumen 294 with a distal opening 296, and a proximal opening 298.

[0087] Referring to FIG. 22, the dilation introducer includes a shorter second or intermediate dilator tube 302 having a distal end 304 with a tapered tip 306, and a proximal end 308 having a generally cylindrical head 310 and a pair of opposing handles 312. The second dilator tube has an inner lumen 314 with a distal opening 316 and a proximal opening 318. As part of the means for removably connecting first and second dilator tubes together in a locked configuration, the proximal end of the second dilator tube includes a bayonet slot 320 formed in the cylindrical head for receiving the bayonet pin of the first or inner dilator tube.

[0088] Referring to FIG. 23, in a preferred aspect, the dilation introducer includes at least one additional dilator tube, such as a still shorter third or outer dilator tube 322, currently preferably formed of plastic, having a distal end 324 with a tapered tip 326, and a proximal end 328 with a generally cylindrical head end or handle 330. The third dilator tube has an inner lumen 332, with proximal and distal openings. A tubular bone drill or tap can be inserted through the first or inner dilator tube, and the tubular bone drill or tap can be threaded over a guide wire or K wire to contact the surface of the vertebra or bone to be treated, as described above.

[0089] Facet Screw Surgical Technique:

[0090] Referring to FIGS. 24-26, a surgical method for spinal fusion utilizing the dilation introducer apparatus and a bone fixation device such as a bone fixation device available under the trade name BONE-LOK from Triage Medical, Inc. of Irvine, Calif., is described. Alternatively, other types of bone screws or fixation devices may also be suitable. The method of the invention involves dilating a patient’s soft tissue down to bone tissue to be treated in orthopedic surgery, and necessarily entails an incision and fluoroscopy to locate an entry point on the bone tissue to be treated.

[0091] An entry point is located on the bone tissue to be treated, and the tip of a guide wire or K-wire 151 is placed at the entry point on the bone tissue to be treated shown in FIG. 25, and driven into the soft tissue of the patient to the target point of the inferior articular facet. A vertical midline incision to a desired depth, such as approximately 17 mm, is made in the skin and fascia of the patient, using the entry point as the middle of the incision. A first dilator tube of the dilation introducer is then passed over the guide wire until the tip of the dilation introducer reaches the target point of the bone. The guide wire is then driven into the facet joint and into the pedicle of the patient, with verification of the trajectory and depth by fluoroscopy. The second dilator tube of the dilation introducer is then released and passed over the
first dilator tube to allow it to progress to the bone, allowing removal of the first dilator tube. This is repeated for the remaining, progressively wider telescoping dilator tubes, to progressively expand the patient’s soft tissue down to the entry point on the bone tissue to be treated, and leaving an outer dilator tube port in place. A depth gauge is then used to verify that the appropriate depth has been reached. A pre-drill is advanced to the desired location, which is then also verified by fluoroscopy. A cortex drill is advanced until its positive stop engages, and the distal tip of a tap is driven into the bone until it reaches the appropriate depth, which is then also verified by fluoroscopy. The drill can be connected through an AO style quick connect, or a Jacobs chuck, as long as they are fully cannulated, to a ratcheting handle which is also preferably cannulated. A bone fixation device is then driven into the bone until it reaches the appropriate depth, which is then also verified by fluoroscopy. The bone fixation device is compressed to achieve appropriate stabilization, which is then also verified by fluoroscopy. Once compression of the bone fixation device has been achieved, the pull pin is removed, the guide wire is removed, and the remaining outer dilator tube port is removed, and the incision can be closed normally.

[0092] Referring to FIGS. 27-29, in one presently preferred embodiment, a guide wire or K wire assembly 340 for use with the telescoping dilation introducer of the invention includes an elongated, generally cylindrical first section 342 and an elongated, tubular second section 344 that is adapted to receive the first section. The first section includes a proximal enlarged head or stop portion 346, and a relatively narrow elongated body portion 348. The elongated body portion is preferably formed with a proximal section 350 having a relatively larger diameter to provide relatively greater strength, rigidity and torqueability for manipulation of the guide wire, and a relatively narrower diameter main section 352 connected to the proximal section, and a pointed distal tip 354 at the distal end 358 of the main section. The elongated tubular second section has a relatively larger diameter than the main section and an internal bore slightly larger in diameter than the main section for receiving the main section, as is illustrated in FIG. 28. The tubular second section advantageously also includes a frustoconical distal tip 362 with a narrowed portion 364 at the distal end 366 of the tubular distal section, and presenting an enlarged flat shoulder 368 at the proximal end of the frustoconical distal tip, so that when the guide wire assembly is assembled as shown in FIG. 29, and the elongated main section is received in the internal bore of the elongated tubular section, and the proximal section of the elongated body portion of the elongated generally cylindrical section is seated against said proximal end of said elongated tubular section, the pointed distal tip extends out of said frustoconical distal tip of said elongated tubular section so that the assembly presents a pointed distal end, with a proximal shoulder against which a telescoping dilation introducer can be pushed for operation of the telescoping dilation introducer. The elongated generally cylindrical first section thus adds a sharp point to the relatively blunt distal end of the elongated tubular second section, allowing the guide wire assembly to be inserted through soft tissue for placement in a soft tissue target of interest, such as an organ. Since the soft tissue present no hard surface against which the telescoping dilation introducer can be pushed, after the sharp point of the guide wire is placed in the desired location in the soft tissue, the first section can be removed from the second section, leaving the blunt distal end in place at the desired location in the soft tissue, and the telescoping dilation introducer can be placed over the second section and pressed against the shoulder of the blunt distal end for operation of the telescoping dilation introducer.

[0093] As is shown in FIG. 30, in one presently preferred variation of the at least one additional or outer dilator tube, such as in the embodiment of FIGS. 8-12 for example, the outer dilator tube 400 includes a parallel guide insert 402, shown in FIG. 31. The outer dilator tube has a distal end 404 with a tapered tip 406, and a proximal portion 408 to which a handle 410 is connected at the extreme proximal or head end 412 of the outer dilator tube. The head end of the outer dilator tube includes a radial aperture 414 for receiving the locking pin 416, and a longitudinal aperture 418 for receiving a distally projecting latching member 420 of the cylindrical head 422 of the parallel guide insert. The outer dilator tube has an inner bore 424 with proximal and distal openings.

[0094] The parallel guide insert includes a main cylindrical shaft 425 connected at a proximal end 426 to the cylindrical head of the parallel guide insert. The parallel guide insert includes a plurality of longitudinal bores 428 extending the length of the parallel guide insert from the distal end 430, with distal openings visible in FIG. 31, to proximal openings (not shown) in the cylindrical head of the parallel guide insert. The insertion of the distally projecting latching member of the cylindrical head of the parallel guide insert in the longitudinal aperture of the head end of the handle of the outer dilator tube insures that the parallel guide insert remains in a fixed position in the outer dilator tube when the parallel guide insert is secured with the locking pin. A single guide wire or K wire or other device may be passed through one or more of the bores of the parallel guide insert, or multiple guide wires or K wires or other devices may be passed through a plurality of the bores simultaneously, as desired. However, the parallel guide insert may be provided without a latching member, in order to allow the parallel guide member to be rotated freely to allow alignment of the desired locations of the guide wires through the holes in the parallel guide insert.

[0095] Referring to FIG. 32, in another presently preferred variation of the at least one additional or outer dilator tube, such as in the embodiment of FIGS. 13-18 for example, the outer dilator tube 440 includes a parallel guide insert 442, shown in FIG. 33. The outer dilator tube has a distal end 444 with an angled tip 446, and a proximal end 448 to which a handle 450 is connected at the extreme proximal or head end 452 of the outer dilator tube. The head end of the outer dilator tube includes a radial aperture 454 for receiving the locking pin 456, and a longitudinal aperture 458 for receiving a distally projecting latching member 460 of the cylindrical head 462 of the parallel guide insert. The outer dilator tube has an inner bore 464 with proximal and distal openings.

[0096] The parallel guide insert includes a main cylindrical shaft 465 connected at a proximal end 466 to the cylindrical head of the parallel guide insert. The parallel guide insert includes a plurality of longitudinal bores 468 extending the length of the parallel guide insert from the angled distal end 470, with distal openings visible in FIG.
33, to proximal openings (not shown) in the cylindrical head of the parallel guide insert. The insertion of the distally projecting latching member of the cylindrical head of the parallel guide insert in the longitudinal aperture of the head end of the handle of the outer dilator tube insures that the parallel guide insert remains in a fixed position in the outer dilator tube when the parallel guide insert is secured with the locking pin. The angled tips of the outer dilator tube and the parallel guide insert are beveled or angled at a common angle with respect to the longitudinal axis of the dilation introducer, so that the angled tips of the outer dilator tube and the parallel guide insert can be aligned together generally parallel to the surface of the soft tissue to be dilated, with the bore and dilation passage of the dilation introducer aligned at a predetermined desired angle with respect to the soft tissue to be dilated and the bone tissue to be treated. A single guide wire or K wire or other device may be passed through one or more of the bores of the parallel guide insert, or multiple guide wires or K wires or other devices may be passed through a plurality of the bores simultaneously, as desired.

[0097] Referring to FIG. 34, in a variation of the outer dilator tube of the embodiment of FIGS. 32-33, the distal tip 480 of an outer dilator tube 482 may be angled or beveled, and may include a plurality of spikes 484 to provide for increased traction of the tip of the outer dilator tube on bone tissue. The spikes may be formed of radiopaque material, such as gold, platinum, tantalum or the like, for use with fluoroscopy. As is illustrated in FIG. 35, a parallel guide 486 disposed in the outer dilator tube has a distal tip 488 that may optionally also be provided with a plurality of embedded spikes 490 for increased traction on bone tissue. The spikes of the outer dilator tube and parallel guide may formed with a rounded shape so as to deflect soft tissue during dilation, and to provide increased traction with bone upon completion of the insertion of the dilator.

[0098] Referring to FIGS. 36-43, the invention provides for a fifth presently preferred embodiment of a dilation introducer 500, which is similar to the embodiment illustrated in FIGS. 8-12, and which is shown in an unlocked configuration in FIG. 36. Referring to FIGS. 36-37, the dilation introducer includes a first or inner dilator tube 502 having distal end (not shown) and a proximal end 504 with a cylindrical head 506. The means for removably connecting the first and second dilator tubes together in a locked configuration includes a first latching member 508, having a shaft 510 and a latching end 512, such as a hook, projecting from the cylindrical head toward the distal end, and connected to a locating button 514, which extends transversely out through a side aperture 516 in the cylindrical head. The locking button includes a shaft 518 and an enlarged head 520 connected to the shaft, and the locking button is biased outwardly from the cylindrical head by a spring 522. The latching member is received in an upper aperture 524 of the adjacent cylindrical head of a second or intermediate dilator tube 526, having a side opening latching chamber 528 for retaining the latching end of the latching member when the locking button is biased outwardly by its spring, to lock the cylindrical heads of the first and second dilator tubes together. The cylindrical heads of the first and second dilator tubes can be unlocked and separated by manually depressing the locking button to move the latching member inwardly and the latching end of the latching member inwardly out of the side opening latching chamber. In all other aspects, the first dilator tube is essentially the same as the first dilator tube of the embodiment of FIGS. 8-12.

[0099] The second or intermediate dilator tube 526 of the dilation introducer has a distal end (not shown) and a proximal end 530 with a cylindrical head 532. The means for removably connecting the second and third dilator tubes together in a locked configuration includes a second latching member 534, having a shaft 536 and a latching end 538, such as a hook, projecting from the cylindrical head toward the distal end, and connected to a second locking button 540, which extends transversely out through a side aperture 542 in the cylindrical head. The locking button includes a shaft 544 and an enlarged head 546 connected to the shaft, and the locking button is biased outwardly from the cylindrical head by a spring 548. The latching member is received in an upper aperture 550 of the adjacent cylindrical head of a third or second intermediate dilator tube 552, having a side opening latching chamber 554 for retaining the latching end of the latching member when the locking button is biased outwardly by its spring, to lock the cylindrical heads of the second and third dilator tubes together. The cylindrical heads of the second and third dilator tubes can be unlocked and separated by manually depressing the second locking button to move the latching member inwardly and the latching end of the latching member inwardly out of the side opening latching chamber. In all other aspects, the second dilator tube is essentially the same as the second dilator tube of the embodiment of FIGS. 8-12.

[0100] The third, or second intermediate, dilator tube 552 of the dilation introducer has a distal end (not shown) and a proximal end 556 with a cylindrical head 558. The means for removably connecting the third dilator tube and the outer dilator tube 560 together in a locked configuration includes a third latching member 562, having a shaft 564 and a latching end 566, such as a hook, projecting from the cylindrical head toward the distal end, and connected to a third locking button 568, which extends transversely out through a side aperture 570 in the cylindrical head. The third locking button includes a shaft 572 and an enlarged head 574 connected to the shaft, and the third locking button is biased outwardly from the cylindrical head by a spring 576. The latching member is received in an upper aperture 578 of the adjacent cylindrical head 580 of the outer dilator tube, having a side opening latching chamber 582 for retaining the latching end of the latching member when the locking button is biased outwardly by its spring, to lock the cylindrical heads of the third and outer dilator tubes together. The cylindrical heads of the third and outer dilator tubes can be unlocked and separated by manually depressing the third locking button to move the latching member inwardly and the latching end of the latching member inwardly out of the side opening latching chamber. In all other aspects, the third dilator tube is essentially the same as the second dilator tube of the embodiment of FIGS. 8-12.

[0101] Referring to FIG. 36, the outer dilator tube includes a distal end (not shown) and a proximal end 584 to which a handle 586 is connected at its cylindrical head end. The head end of the handle preferably includes a plurality of the upper apertures 578 connected to corresponding side opening latching apertures 582 for receiving the latching member of the adjacent dilator tube cylindrical head, as is illustrated in FIG. 40. Although three locking locations 588 of the upper apertures and corresponding side opening...
latching apertures in the cylindrical head of the outer dilator tube are shown, more or fewer locking locations may be provided, and the locking locations may be provided at various positions, to aid in user flexibility as to which hand to use during the dilation procedure, as well as varying the position of the inner dilator tubes and optionally a parallel guide member during use or guide pin placement. In all other aspects, the outer dilator tube is essentially the same as the outer dilator tube of the embodiment of FIGS. 8-12.

[0102] Referring to FIGS. 38 and 39, in a variation of the embodiment shown in FIGS. 36 and 37, the side opening latching chambers of the cylindrical heads of the dilator tubes may be closed so as to form covered latching chambers 590a, b, c for the latching members. In all other aspects, the variation shown in FIGS. 38 and 39 is essentially the same as in FIGS. 36 and 37.

[0103] Referring to FIGS. 41-43, in another variation, an outer dilation tube 600 may be provided with a light emitter 602, such as one or more light emitting diodes (LEDs) or the end of a fiber optic, connected to or embedded in the tubular shaft 604 of the outer dilation tube, and preferably near the distal end 606 of the tubular shaft. As is illustrated in FIGS. 41 and 42, the light emitter may be an LED embedded in the wall 608 of the tubular shaft, with the LED directed to illuminate the interior, exterior, or distal edge of the tubular shaft of the outer dilation tube. As is shown in FIG. 42, one or more elongated energy conducting members 610, such as electrically conductive wires or fiber optics, for example, may be embedded in the tubular shaft, for conducting electricity or light to the light emitter. Referring to FIG. 41, the handle 612 of the outer dilator tube preferably contains one or more batteries 614 connected to a switch 616 which is in turn connected to power the light emitter. The handle may be provided with a battery or batteries, which may be disposable, a switch, resistor and other associated electronics, so that the handle is disposable, or alternatively the handle may be provided with a connector for connection to an external power source. In a presently preferred aspect, the switch is a thumb switch conveniently located on the handle adjacent to the cylindrical head 618 of the outer dilation tube. The handle, cylindrical head, and tubular shaft of the outer dilation tube preferably includes one or more channels 620 for the electrical wires connecting the one or more batteries to the switch and to the light emitter. When the light emitter includes one or more fiber optics, a light source 622 such as one or more LEDs providing light to be conducted through the one or more fiber optics may be placed adjacent to the switch in the handle, with the one or more fiber optics extending through the wall of the tubular shaft of the outer dilator tube.

[0104] Referring to FIG. 43, in another variation of the dilation introducer of FIG. 41, the one or more elongated energy conducting members, such as one or more wires or one or more fiber optics, may be disposed on the outer surface of the tubular shaft of the outer dilation tube. In a presently preferred aspect, the tubular shaft of the outer dilation tube may be formed with a groove 620 running longitudinally on the exterior surface of the tubular shaft, parallel to the longitudinal axis of the outer dilation tube, to accommodate one or more wires or one or more fiber optics. Alternatively, the one or more elongated energy conducting members may be located on the inside of the dilator tube, or may extend through the wall of the dilator tube.

[0105] Referring to FIGS. 44-46, the present invention also provides for a telescoping expander sleeve 630 that is adapted to be slidably disposed over the shaft of an outer dilator tube of any of the foregoing embodiments for expanding the patient’s soft tissue down to the entry point on the bone tissue to be treated, while leaving the outer dilator tube in place, or allowing for replacement of the outer dilator tube with other equipment for treatment of the bone tissue. The tubular proximal portion may optionally be provided with a handle. The expander sleeve may be pre-assembled in combination with one or more of the dilation introducers, adapted to be ready for use. The telescoping expander sleeve has a first or inner generally tubular section 632, having a tubular proximal portion 634 with an enlarged proximal head 636, and a distal portion 638 with at least two substantially identical opposing active spreader arms 640 (one of which is not visible in FIGS. 44-46) connected at one end to the tubular proximal portion and moveable radially at their distal tips 642. The distal tips of the active spreader arms preferably have beveled edges 644 to deflect soft tissue during insertion of the telescoping expander sleeve.

[0106] A second or outer generally tubular section 646 is slidably disposed over the first or inner generally tubular section, and includes a tubular proximal portion 648 and a distal portion 650 with at least two substantial identical opposing passive spreader flaps 652 interposed between the active spreader arms, hingedly connected to the tubular proximal portion at proximal ends 654, and moveable radially at their distal tips 656. The distal tips of the passive spreader flaps preferably also have beveled edges 658 to deflect soft tissue during insertion of the telescoping expander sleeve. The distal tips of the passive spreader flaps when placed together in an unexpanded configuration have a generally circular configuration, so that the distal tips of two passive spreader flaps, for example, have a semi-circular configuration. The passive spreader flaps taper progressively toward their narrowed proximal ends connected to the tubular proximal portion of the outer tubular section. In a presently preferred aspect, the passive spreader flaps are connected to the tubular proximal portion of the outer generally tubular section by rings 656 passing through apertures 658 and 660 in the adjacent ends of the tubular proximal portion and the passive spreader flaps, respectively.

[0107] The active spreader arms are slidably interposed between and engage the passive spreader flaps, so that as the telescoping expander sleeve telescopes from an extended, unexpanded configuration to a collapsed, expanded configuration, as shown in FIG. 44, the active spreader arms slide from the narrow proximal ends of the passive spreader flaps to the wider distal ends of the passive spreader flaps to spread the distal ends of the passive spreader flaps apart, which also forces the distal ends of the active spreader arms apart, as shown in FIG. 46. In a presently preferred aspect, the distal ends of the active spreader arms are slidably connected to slots 662 extending along the inner edges 664 of the passive spreader flaps by loops or rings 666, such as loops of nylon filament or metal rings, for example, which pass through apertures 668 in the distal ends of the active spreader arms. Telescoping of expander sleeve from a collapsed, expanded configuration to an extended, unexpanded configuration thus slides the distal ends of the active spreader arms of the inner tubular section from the wide distal ends of the passive spreader flaps along the inner
edges of the passive spreader flaps to the narrowed proximal ends of the passive spreader flaps, to bring the passive spreader flaps together. The purpose of the active spreader arms and passive spreader flaps is to facilitate the creating of a larger working area adjacent to bone or bone tissues being treated. The spreader arms and flaps may optionally be covered by an expandable material, such as latex, for example, with a central through hole permitting operation of the device, to cover the spreader arms and flaps to prevent tissues from being pressed into cavities of the telescoping expander sleeve.

[0108] In the foregoing embodiments, the components of the dilation introducer may be formed from plastic, stainless steel, or similar materials or combinations thereof, that can be readily sterilized and packaged ready for use, after which the dilation introducer may be disposed of or re-sterilized for subsequent use, as desired. The dilator tubes may be radiopaque, with radiopaque markers located on the tips of one or more of the dilator tubes. The tip of the first dilator may also be scored, grooved, or otherwise be provided with a rough surface, to prevent migration. The dilation introducer may also have curved or otherwise non-linear dilator tubes, and the dilation introducer may also have a non-cylindrical shape, such as an oval shape, for example, to allow the dilation introducer to be inserted around objects or a patient’s organs.

[0109] It should also be appreciated that one or more devices can be inserted through the same dilation introducer, and that the dilation introducer can be repositioned within the same incision for fixation of multiple devices. In addition, fiber optic devices may be inserted through or integrated with the dilation introducer for visual inspection of the target area. While particular locking features have been described for the different embodiments of the dilation introducer, any combination of locking features or alternate locking features may be utilized. The outer dilator tube may not be locked, and a handle on the outer dilator tube may simply be used as a stop. It should also be appreciated that while the invention has been described as being used in the context of orthopedic surgery, and more particularly for implantation of bone fixation devices, the dilation introducer of the invention can also be useful in dilation of soft tissue for percutaneous, minimally invasive surgical procedures such as nephrostomy, neurosurgery, heart valve repair or replacement, gastrointestinal surgery such as for gall bladder or gall stone surgery, hernia removal, transjugular intrahepatic portal-systemic shunt (TIPS) procedures for treatment of the liver, and the like.

[0110] It will be apparent from the foregoing that, while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

1. In a dilation introducer for surgery on an internal body structure, the dilation introducer having a locked assembled configuration for initial placement of the dilation introducer against a patient’s bone tissue to be treated, and an unlocked, collapsed configuration dilating the patient’s soft tissue down to the tissue to be treated to a desired degree of dilation to permit minimally invasive surgical procedures on the patient’s tissue to be treated, the improvement in the dilation introducer comprising:

   at least one dilator tube having a distal end and a proximal end, the distal end of the at least one dilator tube including a plurality of spikes.

2. The dilation introducer of claim 1, wherein said spikes are formed of radiopaque material.

3. The dilation introducer of claim 1, wherein said spikes are formed and are formed with a rounded shape so as to deflect soft tissue.

4. The dilation introducer of claim 1, further comprising a parallel guide insert adapted to be received in said at least one additional dilator tube, said parallel guide insert including a main cylindrical shaft having a proximal end connected to a cylindrical head, and a plurality of longitudinal bores extending the length of the parallel guide insert through the main cylindrical shaft and cylindrical head, and wherein parallel guide insert has a distal tip with a plurality of spikes.

5. The dilation introducer of claim 4, wherein said spikes are formed of radiopaque material.

6. The dilation introducer of claim 4, wherein said spikes are formed and are formed with a rounded shape so as to deflect soft tissue.

7. A dilation introducer for surgery on an internal structure to be treated, the dilation introducer having a locked assembled configuration for initial placement of the dilation introducer against a patient’s tissue to be treated, and an unlocked, collapsed configuration dilating the patient’s soft tissue down to the tissue to be treated to a desired degree of dilation to permit minimally invasive surgical procedures on the patient’s tissue to be treated, comprising:

   a first dilator tube having a distal end with a tapered tip and a proximal end with a cylindrical head;

   a second dilator tube, the first dilator tube being removably received in the second dilator tube for slidable telescoping movement within the second dilator tube, the second dilator tube having a distal end with a tapered tip and a proximal end with a cylindrical head, and an inner lumen with a distal opening and a proximal opening; and

   means for removably connecting the first and second dilator tubes together in a locked configuration including a first latching member disposed in the cylindrical head of the first dilator tube, the first latching member having locking button connected transversely to a shaft with a latching end projecting from the cylindrical head of the first dilator tube toward the distal end of the first dilator tube, the locking button extending transversely from the shaft through a side aperture in the cylindrical head of the first dilator tube, the locking button being biased outwardly from the cylindrical head, the first latching member being received in an upper aperture of the cylindrical head of the second dilator tube, the upper aperture of the cylindrical head of the second dilator tube having a latching chamber for retaining the latching end of the latching member when the locking button is biased outwardly to lock the cylindrical heads of the first and second dilator tubes together, the locking button being moveable inwardly to move the
latching member inwardly and the latching end of the latching member inwardly out of the latching chamber.

8. The dilation introducer of claim 7, further comprising at least one additional dilator tube, the second dilator tube being removably received in the at least one additional dilator tube for said telescoping movement within the at least one additional dilator tube, the at least one additional dilator tube having a distal end and a proximal end with a cylindrical head, an inner lumen with a distal opening and a proximal opening, the distal end having a tapered tip, the second dilator tube and the at least one additional dilator tube having an unlocked configuration in which the at least one additional dilator tube is permitted to slidably telescope over the second dilator tube to dilate the patient's soft tissue at the distal end of the dilation introducer; and

means for removably connecting the second dilator tube and the at least one additional dilator tube together in a locked configuration including a second latching member disposed in the cylindrical head of the second dilator tube, the second latching member having locking button connected transversely to a shaft with a latching end projecting from the cylindrical head of the second dilator tube toward the distal end of the second dilator tube, the locking button extending transversely from the shaft through a side aperture in the cylindrical head of the second dilator tube, the locking button being biased outwardly from the cylindrical head, the second latching member being received in an upper aperture of the cylindrical head of the at least one additional dilator tube, the upper aperture of the cylindrical head of the at least one additional dilator tube having a latching chamber for retaining the latching end of the second latching member when the locking button is biased outwardly, to lock the cylindrical heads of the second and at least one additional dilator tubes together, the locking button being moveable inwardly to move the second latching member inwardly and the latching end of the second latching member inwardly out of the latching chamber.

9. The dilation introducer of claim 8, wherein said at least one additional dilator tube comprises a handle connected to the proximal end of said at least one additional dilator tube, and the cylindrical head of said at least one additional dilator tube including a plurality of said upper apertures each including said latching chamber for receiving the second latching member.

10. In a dilation introducer for orthopedic surgery, the dilation introducer having a locked assembled configuration for initial placement of the dilation introducer against a patient's tissue to be treated, and an unlocked, collapsed configuration dilating the patient's soft tissue down to the tissue to be treated to a desired degree of dilation to permit minimally invasive surgical procedures on the patient's tissue to be treated, the improvement in the dilation introducer comprising:

- at least one dilator tube having a tubular shaft, a distal end and a proximal end, an inner lumen with a distal opening and a proximal opening; and

- a light emitter disposed in said at least one additional dilator tube.

11. The dilation introducer of claim 10, wherein said light emitter comprises a light emitting diode.

12. The dilation introducer of claim 11, wherein said light emitting diode is embedded in said tubular shaft of said at least one dilator tube.

13. The dilation introducer of claim 10, wherein said light emitter comprises a fiber optic.

14. The dilation introducer of claim 13, wherein said fiber optic is embedded in said tubular shaft of said at least one dilator tube.

15. The dilation introducer of claim 10, wherein said at least one dilator tube comprises a handle and a switch for controlling said light emitter, and at least one battery is disposed in said handle, said at least one battery being connected to said switch to power said light emitter.

16. The dilation introducer of claim 13, wherein said light emitter further comprises a light source providing light conducted to said at least one fiber optic.

17. The dilation introducer of claim 10, wherein said light emitter comprises at least one elongated energy conducting member disposed on an outer surface of the tubular shaft of said at least one dilator tube.

18. The dilation introducer of claim 17, wherein said at least one elongated energy conducting member is disposed in a groove on the exterior surface of the tubular shaft.

19. A telescoping expander sleeve adapted to be slidably disposed over a shaft of a dilator tube for dilating a patient's soft tissue down to tissue to be treated to a desired degree of dilation to permit minimally invasive surgical procedures on the patient's tissue to be treated, the telescoping expander sleeve being moveable between an extended, unexpanded configuration and a collapsed, expanded configuration, the telescoping expander sleeve comprising:

- a first generally tubular section having a tubular proximal portion and a distal portion, the tubular proximal portion having an enlarged proximal head, and the distal portion including at least two active spreader arms each having a proximal end and a distal tip, said at least two active spreader arms being connected at the proximal end, respectively, to the tubular proximal portion, said distal tips of said at least two active spreader arms being moveable radially between an unexpanded configuration and an expanded configuration;

- a second generally tubular section slidably disposed over the first generally tubular section, said second generally tubular section including a tubular proximal portion and a distal portion including at least two passive spreader flags each having a narrow proximal end and a wide distal tip, said proximal ends of said at least two passive spreader flags being hingedly connected to said tubular proximal portion, said distal tips of said at least two passive spreader flags being moveable radially between an unexpanded configuration and an expanded configuration, said at least two active spreader arms slidably engaging said at least two passive spreader flags, so that as the telescoping expander sleeve telescopes from the extended, unexpanded configuration to a collapsed, expanded configuration, said at least two active spreader arms slide from the narrow proximal ends of said at least two passive spreader flags to the wider distal ends of the passive spreader flags to spread the distal ends of said at least two passive spreader flags apart and to spread the distal ends of said at least two active spreader arms apart.
20. The telescoping expander sleeve of claim 19, wherein the distal tips of said at least two active spreader arms have beveled edges to deflect soft tissue during insertion of the telescoping expander sleeve.

21. The telescoping expander sleeve of claim 19, wherein the distal tips of said at least two passive spreader flaps have beveled edges to deflect soft tissue during insertion of the telescoping expander sleeve.

22. A guide wire assembly for use with a telescoping dilation introducer in treatment of soft tissue, to provide a surface against which the telescoping dilation introducer can be pushed during operation of the telescoping dilation introducer, comprising:

an elongated tubular section having a proximal end, a distal end, an internal bore, and a frustoconical distal tip with a narrowed portion at the distal end and an enlarged flat shoulder at a proximal portion of the frustoconical distal tip; and

an elongated generally cylindrical section removably received in said internal bore of said elongated tubular section, the elongated generally cylindrical section having a proximal enlarged head and an elongated body portion, said elongated body portion having a proximal end and a distal end, said distal end having a pointed distal tip, such that when said elongated generally cylindrical section is received in said elongated tubular section, said pointed distal tip extends out of the distal end of said frustoconical distal tip to present a sharp point that can be positioned in soft tissue, and such that when said elongated generally cylindrical section is thereafter removed, said enlarged flat shoulder of said frustoconical distal tip provides a surface against which a telescoping dilation introducer can be pushed for operation of the telescoping dilation introducer in treatment of soft tissue.

23. The guide wire assembly of claim 22, wherein said elongated body portion of said elongated generally cylindrical section includes a proximal section adjacent to said proximal enlarged head and an elongated main section connected to the proximal section, said proximal section having a diameter larger than an outer diameter of said elongated tubular section, and said elongated main section having a diameter narrower than the diameter of said internal bore of said elongated tubular section so as to be receivable in said internal bore of said elongated tubular section, such that when said elongated main section is received in said internal bore of said elongated tubular section and said proximal section of the elongated body portion of the elongated generally cylindrical section is seated against said proximal end of said elongated tubular section, said pointed distal tip extends out of said frustoconical distal tip of said elongated tubular section so that said guide wire assembly presents a pointed distal end.

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