Aspects of the invention are defined in the independent claims. Some optional features of the invention are defined in the dependent claims.

Thus, it may be possible to create an electrode lead and a system for inserting the electrode lead into the tissue, the lead being improved over the aforesaid drawbacks with respect to its anchoring to the tissue.

The implantable extravascular electrode lead comprises an electrode body that has a proximal end and a distal end, wherein the implantable electrode lead is equipped in the region of the proximal end of the electrode lead body with a connecting device by means of which the electrode lead may be connected to an active device. The electrode lead furthermore comprises at least one electrical conductor arranged in the electrode lead body and at least one electrode pole, arranged in the region of the distal end and electrically connected to the at least one electrical conductor, for electrically contacting tissue surrounding the electrode lead when the electrode lead is implanted.

In the distal region of the electrode lead body or at the distal end of the electrode lead body, the electrode lead has a first fixing device by means of which the electrode lead may be fixed to patient body tissue in the extravascular region.

In this patent application, the distal region of the electrode lead body and even the electrode lead is considered that region of the electrode lead body or electrode lead that extends across maximally 30% of the length of the electrode lead body or electrode lead and that includes the distal end of the electrode lead body or electrode lead.

In one exemplary embodiment of the electrode lead, the fixing device extends lateral to the longitudinal axis of the electrode lead.

In one exemplary embodiment, the fixing device is mechanically actuatable. A cable, filament, wire, flexible member, stylet, or catheter may be used as the mechanical actuation means. So that the fixing device may be actuated by mean of the mechanical actuation means, the electrode lead may have a lumen, wherein the lumen extends from the proximal end of the electrode lead body to the distal end of the electrode lead body and runs within the electrode lead body. Depending on the application, the lumen may be open or closed at its distal end.

In another exemplary embodiment, the fixing device is electrically actuatable. For actuating the fixing device, the electrical energy may be transmitted to the fixing device, for example, from outside by means of an electrical lead running along the lead body of the electrode lead. Alternatively, the electrical energy may be transmitted to the fixing device from outside by means of electromagnetic waves.

In another exemplary embodiment, the fixing device is embodied in the shape of a helical element that extends about the electrode lead body. The helical element may have a pointed or sharp end. The helical element may furthermore be attached, with its end opposing the pointed tip, to the lead body. In another exemplary embodiment, the helical element may be attached to the lead body rotatable about the longitudinal axis of the lead body. In this case, the rotational movement required to screw the helical element into the tissue may be transmitted from the proximal end of the electrode lead to the distal end of the electrode lead, and there to the helical element, using a stylet inserted into a lumen of the electrode lead. The helical element in this exemplary embodiment is configured such that it may be screwed into the tissue in the one rotational direction and may be screwed out of the tissue again in the other rotational direction.

In another exemplary embodiment, a system comprising an implantable extravascular electrode lead and a catheter is suggested. In this system, highly elastic lamellae are arranged at the distal end of the electrode lead body of the electrode lead. The lamellae may assume a first loaded state and a second released state. In their loaded state, the tips of the lamellae point in the distal direction with respect to the electrode lead. In their released state, the tips of the lamellae point in the proximal direction with respect to the electrode lead. The lamellae assume their loaded state as long as the electrode lead and the lamellae are inserted completely into the catheter. If the catheter is retracted in the proximal direction with respect to the electrode lead, the lamellae shift to their released state as soon as the distal end of the catheter uncovers the lamellae. Due to their restoring force, which shifts the lamellae to their released state, in their released state the lamellae dig into the tissue, thus fixing the electrode lead to the tissue.

In another exemplary embodiment of the extravascular electrode lead, one or a plurality of elastically deformable fixing elements are used as the fixing device. The fixing elements are free at their first end and with their second end are arranged on the electrode lead body. A fixing device comprises one or a plurality of fixing elements of the type just described. When there

are a plurality of fixing elements, the latter are preferably arranged as a fixing device in a circle about the electrode lead body. A fixing device preferably comprises 2 to 16 fixing elements, more preferably 3 to 12 fixing elements, and more preferably 4 to 8 fixing elements. The fixing elements of the fixing device may be arranged individually on the electrode lead body. Alternatively, a carrier to which the fixing elements of a fixing device are attached and that then itself is arranged on the electrode lead body may be used.

Due to their elastic deformability the fixing elements may assume a first, loaded state and a second, released state. In their first, loaded state, the fixing elements have a largely longitudinally extended shape, while in their second, released state, the fixing elements assume their unrestricted configuration. The unrestricted configuration may preferably be a hook or claw shape. The hook shape is an angled structure, while the claw shape is formed in the shape of an arc or spiral arc. If the second end of the claw runs parallel to the electrode lead body, the arc or spiral segment of a released claw shape covers an angular range of 90° to 360°, preferably 90° to 270°. On the other hand, if the second end of the claw runs perpendicular to the electrode lead body, the arc or spiral segment of a released claw shape covers an angular range of 90° to 270°, preferably 90° to 180°.

An extravascular electrode lead must be fixed at its distal end or near its distal end to tissue so that the distal end of the electrode lead does not migrate over time towards the proximal end of the electrode lead due to body movement. For this it is advantageous when the free ends of the fixing elements of the fixing device arranged at the distal end of the electrode lead, when in their loaded state, point towards the distal end of the electrode lead, and move towards the proximal end when they shift to the released state. Due to their restoring force, which shifts the fixing elements, e.g. in the form of claws, to their released state, the fixing elements dig into or twist themselves into the tissue and, with their curved shape, fix the electrode lead to, e.g., muscle, fat, or fasciae.

In another exemplary embodiment of the extravascular electrode lead, a second fixing device may be arranged on the electrode lead body between the proximal end of the electrode lead body and the fixing device (first fixing device) such that the electrode pole is disposed between the first fixing device and the second fixing device.

For delivering a shock, in their distal region extravascular electrode leads comprise large surface-area electrode poles that may preferably be embodied as helical electrodes, so-called shock coils. In addition to these large surface-area electrode poles, smaller electrode poles for recording cardiac signals may be arranged distal and/or proximal to these large surface-area electrode poles. These recording electrode poles are preferably embodied as annular electrode poles, also called ring electrodes. For reliable operation of an extravascular implantable defibrillator and its extravascular electrode leads, it is furthermore advantageous to secure the electrode leads against unintentional displacement (dislocation) in the region of the electrode poles when they are implanted. Fixing devices provided proximal and distal to the electrode poles are used to this end.

In another exemplary embodiment of the implantable extravascular electrode lead, the second fixing device comprises one or a plurality of fixing elements, wherein the fixing elements of the second fixing device likewise each have a free end, wherein the fixing elements may assume a first, loaded state and a second, released state, wherein in their first, loaded state the free ends of the fixing elements of the first fixing device point in the distal direction of the electrode lead, and in their first, loaded state the free ends of the fixing elements of the second fixing device point in the proximal direction of the electrode lead. In their second, released state, the free ends of the fixing elements of the second fixing device point in the distal direction of the electrode lead. Moreover, these described fixing elements of the second fixing device have the same properties as the previously described fixing elements of the first fixing device described previously.

Due to the mirror symmetrical arrangement of the first fixing device and second fixing device with respect to the longitudinal axis of the electrode lead, the region of the electrode lead arranged between the two fixing devices may be kept twisted and/or secured against unintentional displacements (dislocations) when implanted.

In another exemplary embodiment of the implantable extravascular electrode lead, the second fixing device comprises one or a plurality of fixing elements, wherein the fixing elements of the second fixing device likewise each have a free end, wherein the fixing elements may assume a first, loaded state and a second, released state, wherein, in their first, loaded state, the free ends of the fixing elements of the first fixing device point in the distal direction of the electrode lead, and in their first, released state, as well as in their second, released state, the free ends of

the fixing elements of the second fixing device point in the distal direction of the electrode lead. In this embodiment, the fixing elements of the second fixing device are preferably embodied curved or S-shaped. A curved fixing element in this context shall be construed to be an essentially planar, curved, or spiral-shaped fixing element that covers a circular arc of less than 90°, and wherein the one end of the arc-shaped fixing element is arranged on the electrode lead body and the second end of the arc-shaped fixing element terminates in a free end. An S-shaped fixing element shall be construed to mean that it comprises two arcs connected to one another that are curved in opposition to one another. The two arcs are arranged essentially in a planar manner, wherein the fixing element comprises a first arc that is arranged on the electrode lead body and a second arc that runs out in a free end. The first arc can transition into the second arc or a linear intermediate piece may be arranged between the first arc and the second arc. The first arc and/or the second arc may cover an angle of 30° to 120°, preferably 45° to 110°, and more preferably 60° to 100°.

Due to the arc-shaped or S-shaped configuration of the fixing elements of the second fixing device, due to their restoring force, which shifts the fixing elements to their released state, the fixing elements press into the tissue and, with their arced shape, fix the electrode lead to, e.g., muscle, fat, or fascia to prevent migration of the second fixing device in the distal direction. Since, in their second, released state, the free ends of the fixing elements of the first fixing device point in the proximal direction and, in their second, released state, the free ends of the fixing elements of the second fixing devices point in the distal direction, the region of the electrode lead arranged between the two fixing device may be kept loaded and/or secured against unintentional displacement (dislocation) when implanted.

In another exemplary embodiment, if the second fixing device is formed from S-shaped fixing elements and claw-shaped fixing elements, and if the free ends of the S-shaped fixing elements, when in their released state, point in the distal direction of the electrode lead, and if the free ends of the claw-shaped fixing elements, when in their released state, point in the proximal direction of the electrode lead, then the second fixing device is secured against migration in the distal and proximal directions.

In an electrode lead with a first fixing device at the distal end having claw-shaped fixing elements in which, when the fixing elements are in the released state, the free ends point in the proximal direction of the electrode lead, and with a second fixing device that is arranged

proximal to the first fixing device on the electrode lead body, and in which the second fixing device is equipped with S-shaped fixing elements, the free ends of which, when in the released state, point in the distal direction of the electrode lead, a catheter may be inserted from the proximal end towards the distal end via the electrode lead. If the connecting device of the electrode lead has a larger cross-section than the electrode lead body, during the production process the catheter may first be inserted via the electrode lead and then the plug may be mounted. If the catheter is moved from the proximal to the distal via the electrode lead, the fixing elements of the fixing devices are shifted from their second, released state to their first, loaded state.

In one exemplary embodiment, the second fixing device comprises 2 to 16 fixing elements, more preferably 3 to 12 fixing elements, and more preferably 4 to 8 fixing elements.

In another exemplary embodiment of the extravascular electrode lead, the fixing elements of the first fixing device and/or of the second fixing device are bioresorbable. A bioresorbable fixing element shall be construed to be a fixing element, the components of which may be broken down by the body. The bioresorbability has the effect that the fixing elements dissolve in a certain period of time. Because of this, the electrode lead may be explanted more easily.

In another exemplary embodiment of the extravascular electrode lead, the free ends of the fixing elements of the first fixing device and/or of the second fixing device are embodied as points or cutting edges. The points or cutting edges penetrate slightly into the tissue, thereby strengthening the fixation of the fixing device to the tissue.

In another exemplary embodiment of the extravascular electrode lead, the free ends of the fixing elements of the first fixing device and/or of the second fixing device are embodied as blunt, atraumatic ends. The atraumatic ends lead to less injury to the tissue. They lead the fixing device clawing or digging into the tissues. This leads to the tissue reacting less to the fixing device and therefore leads to less scarring

In another exemplary embodiment, the extravascular electrode lead comprises a lumen into which a stylet may be inserted. In this way the electrode lead may be advanced during the implantation process or, during withdrawal of implantation aids, such as e.g. delivery catheters, the electrode lead may be secured against inadvertent retraction in the proximal direction.

Moreover, a system for inserting an extravascular electrode lead into the tissue is suggested. The system comprises the implantable extravascular electrode lead described in the foregoing and a catheter having a catheter lumen for receiving the electrode lead, the electrode lead being arranged in the lumen of the catheter such that the fixing device is disposed within the lumen of the catheter.

When the electrode lead is inserted into the body, the catheter prevents direct contact between the fixing device and the surrounding tissue. This prevents damage to implantation material and injuries to body tissue caused by the fixing device. The catheter furthermore protects the fixing device from damage during implantation.

In another exemplary embodiment of the system for inserting an extravascular electrode lead, the electrode lead is arranged in the lumen of the catheter such that the fixing elements of the fixing device of the electrode lead assumes its first, loaded state.

In another exemplary embodiment of the system for inserting the electrode lead into the tissue, the electrode lead may be pushed out the catheter in the direction of its distal end such that when they exit from the lumen of the catheter, the fixing elements shift from their first, loaded state to their second, released state.

When the catheter is retracted in the proximal direction with respect to the electrode lead, the fixing elements of the fixing device shift to their second released state as soon as the distal end of the catheter uncovers the fixing elements. In their uncovered state, due to their restoring force, which shifts the fixing elements from their first, loaded state to their second, released state, the fixing elements uncovered by the catheter dig in or twist themselves into the tissue, thus fixing the electrode lead to the tissue.

Now, once the electrode lead has been inserted into an extravascular region of a patient, the fixing device is actively actuatable from outside the body for fixing the electrode lead to body tissue of the patient by means of the catheter.

In another exemplary embodiment, the system for inserting the electrode lead also comprises a stylet inserted into the lumen of the electrode lead. The stylet holds the electrode lead in its

position when the catheter is to be retracted in the proximal direction of the electrode lead, so that, while the catheter is being retracted in the direction of the proximal end of the electrode lead, the electrode lead is not retracted together with the catheter, but instead the distal end of the electrode lead exits from the distal end of the catheter. Alternatively, during implantation the electrode lead with the stylet may be pushed out of the catheter in the distal direction of the electrode lead. This supports the fixing elements penetrating into the tissue and thus attains better fixation of the fixing device to the tissue. Improved fixation because of this has been seen in particular with fixing elements in the shape of claws.

In another exemplary embodiment, the system for inserting the electrode lead additionally comprises a slitter tool for cutting open the catheter while the catheter is being retracted in the proximal direction of the electrode lead. Since the electrode lead is equipped with a connecting device in the region of the proximal end of the electrode lead body, by means of which connecting device the electrode lead may be connected to an active device, a catheter may not be retracted in the proximal direction via the connecting device unless the cross-sectional area of the lumen of the catheter is greater than the cross-sectional area of the connecting device. Since the catheter is positioned close against the electrode lead so that the fixing elements of the fixing device may be held in their first, loaded state, this requires a connecting device that has essentially the cross-sectional area of the electrode lead body. As soon as the connecting device has a larger cross-sectional area than the electrode lead body, the catheter must be widened or opened in order to be able to be retracted over the connecting device. Using a slitting tool, the catheter may be cut open along its length while being retracted so that the electrode lead may be removed from the catheter through the slit thus created.

In another exemplary embodiment, the system for inserting the electrode lead comprises an electrode lead having two fixing devices. In this way the first fixing device and the second fixing device are uncovered one after the other when the catheter is retracted. In this way the region between the two fixing devices is fixed in a tensioned manner.

In another exemplary embodiment of the extravascular electrode lead, two opposing L-shaped hooks are arranged as fixing device at the distal end of the electrode lead body. The hooks have a pointed end. The end of the hook opposing the pointed end points into the lumen of the electrode lead body. In their first state, the hooks are extended out of the lumen of the electrode body, and, in their second state, they are pulled back into the lumen of the electrode lead body.

In their first, extended state the two hooks are in a spread position and open at their pointed ends, and in their second, retracted state the hooks are pressed together and closed at their pointed end. When closed, the pointed ends of the hooks are oriented outward with respect to the longitudinal axis of the electrode lead body. The outwardly oriented pointed ends of the hooks fix the electrode lead in the tissue.

In another exemplary embodiment of the extravascular electrode lead, a helical screw element is arranged as the fixing device in the lumen of the electrode lead body in a rotatable manner and such that it may be screwed out. At its proximal end, the helical screw element has a guide with a slit in which a screw stylet may engage. The helical element may be screwed out of the lumen of the lead body by means of the screw stylet. In one exemplary embodiment of the helical screw element, the radius of the windings when the helical screw element is screwed out of the lumen of the lead body is greater in length than when it is screwed into the lumen, that is, when the helical screw element is retracted into the lumen. When screwed out, the pointed end of the helical screw element catches in the surrounding tissue, thus fixing the electrode lead to the tissue.

In another exemplary embodiment of the extravascular electrode lead, extendable claws are arranged in the lumen of the electrode lead body as the fixing device. At their first end, the claws are provided with a pointed tip and at their second end are attached to a guide device. The guide device may be advanced by means of a stylet inserted into the lumen of the electrode lead body from its first, retracted position in the distal direction of the electrode lead body into a second advanced position. When the guide device is in the retracted position, the claws are arranged within the lumen in their retracted position. The claws are in their loaded state when the claws are in the retracted position. When the claws are in the loaded state, the pointed ends of the claws point in the distal direction with respect to the electrode lead body. When the guide device is in the second, advanced position, the claws are in their extended position. In the extended position, the claws assume their released state. In their extended position, due to their restoring force, which shifts the claws to their released state, the claws dig into the tissue, thus fixing the electrode lead to the tissue.

In another exemplary embodiment of the extravascular electrode lead, the fixing device is realized in the form of self-deploying elements. To this end, the electrode lead body is surrounded by an outer shell that is connected to the lead body at the distal end of the electrode

lead body. The outer shell has at least three parallel longitudinal slits running axially. The longitudinal slits are preferably provided equidistant with respect to the circumferential direction of the outer shell. The elements, each formed by two longitudinal slits in the outer shell, may assume two states. In their first state (starting position) they are straight, and in their second state (fixing position) they are curved. The elements may be shifted from their first, straight state to their second, curved state by moving the outer shell in the distal direction with respect to the electrode lead body. For this, for example the electrode lead body may be fixed to the proximal end and the outer shell may be advanced in the distal direction of the electrode lead. When advanced, the elements shift to their second, curved state. A detent device with which the outer shell may be held in its advanced state is preferably provided at the proximal end of the electrode lead. The detent device is preferably reversible, which means that it may be retracted in the distal direction again, releasable about the outer shell, in order to return the elements from their second curved state to their first straight state. This has the advantage that the electrode lead is moveable again and thus may be repositioned or explanted.

In another exemplary embodiment of the extravascular electrode lead, the fixing device is realized in the form of hooks deploying laterally out of the electrode lead body. The hooks in this case may assume a first side-by-side state and a second spread-apart state. The hooks are moveably connected at their first end to the electrode lead body in order to realize the movability required for the shift from the first state of the hooks to the second state of the hooks. The second, free end of each hook is freely moveable and may be side-by-side against the electrode lead body or spread apart from the electrode lead body. The free end of each hook may be equipped with a pointed tip. For moving the hooks, a lever that extends into the lumen of the electrode lead body may be provided on the side of the deployable hooks facing the lead body. To actuate the levers, a traction element that is connected to the levers runs within the lumen of the lead body. If the traction element is moved from its first, distal position into its second, proximal position, the deployable hooks shift from their first side-by-side state to their second spread-apart state. A tractive force act on the end of the traction element facing the proximal end of the electrode lead in order to shift the traction element from its first position to its second position. The traction element advantageously extends to the proximal end of the electrode lead.

In one preferred exemplary embodiment, the deployable hooks are arranged on the lead body such that the first end of each hook faces the distal end of the lead body and the second end of each hook faces the proximal end of the lead body.

In another exemplary embodiment of the extravascular electrode lead, the fixing device is embodied in the form of an elastic rod that can be bent at three points and that is arranged in the lumen of the electrode lead body. The bendable points of the rod may be called bend points. A bend point may be realized, for example, using a pinching of the rod or using an articulation, etc. Thus the rod comprises 4 segments, of which two segments (end segments) are each adjacent to only one bend point, and the other two segments (center segments) are each adjacent to two bend points. In this case the distal end of the rod facing the distal end of the electrode lead body is connected to the lead body. The proximal end of the rod opposing the distal end of the rod advantageously extends to the proximal end of the electrode lead. Moreover, the electrode lead body is provided with an axially running longitudinal slit at the height of the bend points of the rod.

The segments of the rod in a first state may assume a linear configuration; this means that the segments adjacent to a bend point assume an angle of approx. 180 degree to one another. In a second state, the segments of the rod may assume a V-shaped configuration; this means that the two center segments assume a triangular configuration, while the two end segments continue to follow the course of the electrode lead.

In a first state of the segments of the rod, all of the segments are disposed within the electrode lead body (deactivated fixing device). In the second state of the segments, the two center segments project from the axially running longitudinal slit of the electrode lead body (activated fixing device). The projecting center segments fix the electrode lead in the tissue. The segments may be moved from the first state of the segments to the second state of the segments by pushing the proximal end of the rod in the distal direction with respect to the electrode lead body.

In another exemplary embodiment of the extravascular electrode lead, the fixing device is provided in the form of a spiral band that may be pushed out of the electrode lead by a rotating mechanism arranged within the electrode lead. While it is being pushed out, the band, already pre-shaped in a spiral shape, is disposed in a spiral about the electrode lead body. While it is being screwed out, the tip of the band pushes into the tissue and in this way fixes the electrode

lead to the tissue. The screwing mechanism may be actuated using a screw stylet inserted into the lumen of the electrode lead.

In another exemplary embodiment of the extravascular electrode lead, the fixing device is provided in the form of a balloon arranged at the distal end of the electrode lead body. For filling the balloon, the electrode lead comprises a lumen that runs from the proximal end of the electrode lead into the balloon. The balloon can be filled with a fluid through the lumen. The fluid can be added to the balloon with a syringe detachably arranged at the proximal end of the electrode lead, for example. In another exemplary embodiment, the fluid added to the balloon may cure in the balloon. Moreover, at its proximal end the lumen of the electrode lead may have a closing mechanism. The closing mechanism prevents fluid from exiting the balloon after the balloon has been filled with the fluid.

In another exemplary embodiment of the extravascular electrode lead, the fixing device is provided in the form of a distal region of the electrode lead body provided with apertures. A lumen is arranged within the electrode lead body to transport fluid from the proximal end of the electrode lead to the distal region of the electrode lead body. The apertures in the distal region of the electrode lead body connect the lumen running within the electrode lead body to the outside. The electrode lead can be filled with a fixing fluid at the proximal end. The fixing fluid added may exit from the electrode lead through the apertures in the distal region of the electrode lead body and then, in the implanted state, empties into the tissue. The fixing fluid is preferably a fluid that cures after flowing out of the apertures into the tissue. It is furthermore preferred that the fluid still has a certain flexibility after curing. The electrode lead is attached to the tissue by the fluid.

In another exemplary embodiment of the extravascular electrode lead, bent hooks are provided as the fixing device at the distal end of the electrode lead body and hook into the tissue, and thus fix the electrode lead to the tissue, when the electrode lead body is rotated, like a bayonet closure.

Additional features, advantages, and embodiments of the present invention shall be described, by way of non-limiting example only, in the following, referencing the figures.