

UNLOADING-DYNAMIC INTERVERTEBRAL DEVICE

The scope of the invention is an unloading-dynamic intervertebral device, used in spinal surgery. The device is used for an even, steady and adjustable decompression of the intervertebral interspinous space and for maintaining the distance between at least two vertebrae, and also for the treatment of pathologic lateral deformations of the spine by supporting the device on bony elements of the posterior spinal column, especially on spinous processes and neural arches. Stabilizers used for interspinous spinal stabilization using a surgical posterior approach are usually known in the form of one or several cooperating carrying elements situated in the interspinous space, ended with profiled sockets for spinous processes. Such stabilizers situated in the axis of the spine serve mainly for one-level stabilization of the adjoining vertebrae.

Solutions are also known in the form of lamellar or rod bearing elements with an adjustable length, installed in the interspinous space and comprising hook elements resting against on spinous processes. Such stabilizers can be used for supporting the spine on one and several levels.

The solutions described above are additionally provided with elements attached to the bone using screws, pins, other mechanical latches or flexible ligaments. In most of such solutions, elements are supported on spinous processes and this requires using a bilateral surgical approach.

An interspinous implant situated non-axially in relation to the spine is known from the patent application W02007/127550, comprising superior and inferior bearing elements cooperating in a sliding way along the axis corresponding to the axis of the spine. Laterally separated bearing elements are ended with brackets for fastening onto superior and inferior spinal interspinous processes, respectively. In a folded position, the device is of the height allowing its installation between spinal processes and the interspinous space is increased by distraction of both elements.

An axial interspinous implant in the form of a frame embracing exteriorly vertebral processes is disclosed in the patent application WO 2007/127694. The frame is in the form of a ring or its parts provided with holes situated on both sides of the axis, through which elastic bands are drawn out. The bands constitute bearing elements pulling off

superior and inferior processes respectively to the superior and inferior part of the frame. The place of connection of the implant with the bone can be secured by sharp projections constituting an integral part of internal surfaces of the frame.

From the patent application US 2006/0241614 an interspinous implant is known which contains a bearing supporting part with profiled sockets located axially between adjoining spinous processes and two hook elements connected by an elastic band which passes through the support. The hooks fasten the processes from the superior side preventing excessive flexion of the spinal motion segment. The patent application WO 01/91658 discloses a device and the method of its application for distraction of adjacent spinous processes. The device has got a bracket with a guide fastened by a connector to a laterally separated rod element ended with hooks, which embrace spinous processes. The construction of the device allows rotational movement between the bracket and the hook.

A multi-segment stabilizer for controlling the intervertebral space is known from the patent application US 4611582 . It comprises a longitudinal, laterally separated bearing body and two laminar clamps. The clamps are in the form of two alternating hooks, both of them are adapted for a rigid, bilateral embrace of a part of one vertebra. The body is dual, it consists of movable cooperating parts connected with each other by threaded elements fastening and adjusting body's length.

The patent application US 5439463 refers to a spinal device which consists of two clamp elements ended with hook parts: a fixed one with a rod setting the distance, and an adjustable one. The surface of the rod and the corresponding surface of the adjustable clamp cooperate in a sliding way through toothed surfaces and their cooperation is secured by a distance fastening element provided with a clamping ring and threaded screw.

A device for implantation and distraction of spinal spinous processes is known from the patent application WO 2008/085445. It consists of a longitudinal body and two sliding elements. Each of them is composed of the main part cooperating with the body and hook arms for support on the bone. In an embodiment of the device, the arms are provided with a rough surface increasing friction in the area of contact of the implant and a spinous process.

All the solutions described above do not secure steady, even and controlled intraoperative distraction which is the essential purpose of the treatment of spinal dysfunctions.

Corrective actions are performed after previously locating the implant in the interspinous space, thus necessitating acquisition of a dimensional series of types of implants and precise selection of implant's dimension for the interspinous space. Most of the solutions are intended for being fastened to biomechanically weak interspinous processes and they are designed only for such a fastening. The use of such solutions is also limited to only one segment of the spine, especially in the lumbar segment or on the lumbosacral border. Constructions used in the above described solutions are frequently complicated and made up of many elements. Thus a surgeon is forced to use a wide surgical approach and to adjust surgically the spinous processes to the bearing surface of the implant. Yet another inconvenience of the solutions referred to above is their great surgical invasiveness resulting from the necessity of dissection of soft tissues from both sides of the spine and also from the necessity of disrupting the supraspinous ligament or its separation from processes and withdrawing during installation of the implant.

The unloading-dynamic intervertebral device is free of the above drawbacks. It consists of two bars cooperating with each other, where each of them is ended from one side with a shaped bearing for bony elements of the spine. According to the invention, one of the bars is provided with a guideline, whereas the other with a guide. Moreover, the first bar is provided with at least one tang, situated in the corresponding shaped gap of the other bar, assuring rotatable and rotatable-sliding cooperation of the bars crossing in the open position of the device. The device is equipped with a mechanism blocking rotational movement of the bars in the closed position.

Depending on the construction of the device, there is at least one shaped gap in the guide, and the guideline is provided with at least one tang situated in the guide's gap or at least one shaped gap made in the guideline cooperates with the ends of the tang fixed in the guide. In one embodiment of the device provided with one-arm guideline, in the through hole of the guide there is a tang fixed in the guideline or conversely, the tang connected with the guide is situated in the guideline.

A notch located in the end of the guide and a projection made in the guideline which cooperates with the guide constitute the mechanism blocking rotational movement of the bars and their mutual location in the closed position of the device. In another embodiment, the mechanism blocking rotational movement of the bars in the closed position of the device is formed by a projection made in the end of the guide cooperating with the notch

made in the guideline. Depending on the construction of the device the guide or the guideline are provided with at least one shaped gap ended with a socket. The tang constituting an element of the mechanism blocking rotational movement of the bars in the closed position of the device is situated in the socket.

Preferably, shaped gaps in the guideline or the guide of the device are through. It is also preferable to connect the shaped gap with the input canal, thus enabling introduction of the tang.

In one embodiment of the device, wherein shaped gaps are made in the guideline, the mechanism blocking rotational movement of the bars in the closed position of the device preferably comprises a plate situated in the shaped gaps of the two-arm guideline. In the embodiment, a pin setting the mutual position of the guide and the guideline constitute the mechanism blocking movement of the bars in the closed position.

Preferably, at least one shaped bearing constitutes a separate element moveably connected to the corresponding bar.

For a better adjustment of the device to the construction of bone elements of the patient's spine, at least one bearing is provided with at least one incision, thus imparting resilience to the construction.

Preferably, the device is provided with a scale showing the value of distraction, which will be obtained in the closed position of the device.

For securing the position of the device in the patient's body, the bars of the device are provided with at least one means for guiding the band.

The unloading-dynamic intervertebral device according to the invention is used to support dysfunctions of any spinal segment, including also deformities. The device can be used at one or many levels with unilateral or bilateral support on spinous processes and/or simultaneously on bony elements adjoining the spinous processes, such as neural arches. The device according to the invention offers the possibility of steady and even intervertebral distraction already during the process of installation between bony elements, which is not possible in other solutions, it decreases the risk of an incorrect selection of implant's dimensions, excludes the use of additional surgical instruments, such as distracters, and decreases the load on tissues included in stabilization. Owing to mutual mobility of interconnected arms, possibilities of their angular alignment and thanks

to an adjustable point of rotation, the device assures an adjustable range of distraction with the use of only one device, without the necessity of having the full dimensional series. Application of multilevel stabilization allows distribution of loads on a greater surface and a longer spinal segment, and it also improves spinal biomechanics. Stabilization of many spinal levels affects unloading dysfunctional vertebrae, which can be additionally supported by employing other ways of stabilization. The device and the method of its implantation are characterized by small invasiveness, unilateral surgical approach, which allows for retainment of the supraspinous ligament, which is of importance in stabilizing the posterior spinal column. In some cases, justified by the clinical condition, the device can also be used bilaterally. Implantation of the device is easy and quick, thus affecting the duration of surgery and can be realized in variants, depending on restrictions of the operating field following from the level and anatomy of the osteoarticular system being stabilized.

Depending on the manner of cooperation with the bone or type of bone on which the implant is resting, the plane of closing the device by rotational and rotational-sliding movement can be approximate to the sagittal plane of the spine or can be inclined to it at an angle of 90° , which gives an operating surgeon greater possibilities of installation. The construction and dimensions of the device offer possibilities of treating patients from various age groups.

The device is presented in examples of several embodiments in the accompanying figures wherein, where fig. 1 illustrates one embodiment of the device depicting elements of the blocking mechanism; fig. 2 shows in the section a fragment of the movable connection of the bars; fig. 3 illustrates one embodiment of the device in axonometric projection in an open position with perpendicular orientation of bearings and a part section depicting the blocking mechanism; fig. 4 illustrates in axonometric projection one embodiment of the device with shaped gaps provided with sockets and the movable bearing and plate of the blocking mechanism; fig. 5 illustrates in axonometric projection one embodiment of the device with the one-arm guideline, blocking mechanism in the form of a pin and clamping band, whereas fig. 6 presents in axonometric projection an embodiment of the device equipped with a scale and incisions in the bearing.

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The unloading-dynamic intervertebral device is composed of two movable cooperating bars 1,2, whose implantation in the area of spinal dysfunction consists in passing from the open position to closed position making use of the simultaneous displacement of bony elements during distraction. Each bar 1, 2 is ended from one side with a shaped bearing 3, 4 for vertebral bony elements, such as: the spinous process or the neural arch. From the other end, one of the bars - bar 1 is ended with a two-arm guideline 5, whereas the other bar - bar 2 with a guide 6. Sliding-rotational and rotational cooperation of bars 1, 2 crossing in an open position is realized by: tangs 7 situated on internal surfaces of guideline 5 and blind shaped gaps 8 in guide 6, as shown in fig. 2.

In a closed position of the device, the reverse movement of bars 1, 2 is blocked by a blocking mechanism. This mechanism consists of notch 9 situated on the end of guide 6 and projection 10 made in the guideline 3 cooperating with it. In one embodiment of the invention shown in fig. 3, notch 9 is made in guideline 3, whereas projection 10 constitutes a constructional fragment of the end of guide 6. Sliding-rotational and rotational cooperation of bars 1, 2 which cross with each other in the open position is realized by the ends of tang 7 fastened in guide 6 which cooperate with two through shaped gaps 8 made in the guideline 5. Moreover, variously oriented bearings 3, 4 allow the device to rest at the same time on the spinous process of one vertebra and the neural arch of the other vertebra. In one embodiment of the invention illustrated in fig. 4, shaped gaps 8 in the guideline 5 are provided with sockets 11 situated in pairs and cooperating with two tangs 7 situated in the guide 6. Such a configuration constitutes the mechanism blocking the sliding-rotational movement of bars 1, 2 and assures an adjustable range of distraction with the use of only one device, without the necessity of having a full series of dimensions. To facilitate the introduction of the tang 7, shaped gaps 8 are provided with an input canal 12.

Preferably, the device is provided with an additional mechanism blocking the rotational movement of bars 1, 2 in the closed position in the form of a plate 13 located in gaps 8 of the two-arm guideline 5 and rested on the guide, as shown in fig. 4. For a better adjustment to bony elements in various parts of vertebrae, it is preferable to apply the movable connection of at least one bar 1 with the bearing 3. Elements of the connection may constitute a three-dimensional joint, as in fig. 4 or a flat one, as shown in fig. 5.

In one embodiment of the device according to the invention illustrated in fig. 5, a threaded pin 14 passing through the one-arm guideline 5 and guide 6 constitutes the blocking mechanism. Preferably, the device is provided with means 15 which guides band 16, which secures the device, thanks to its fixation to bony elements, against shifting in the patient's body.

In one embodiment of the device illustrated in fig. 6, the bearing 4 is provided with two incisions 17 increasing its resilience and giving the device dynamic features.

The device is equipped with scale 18 of angular arrangement of bars 1, 2 in an open position, which provides information about the range of distraction in the closed position of the device.

Claims

1. The unloading dynamic intervertebral device consisting of two bars cooperating with each other, where each of them is ended on one side with a shaped bearing for bony elements of the spine, is characterized in that one of the bars (1,2) is provided with a guideline (5) and the other in a guide (6). Moreover, one of the bars (1,2) is provided with at least one tang (7), situated in the corresponding shaped gap (8) of the other bar (2,1), which secures rotational and rotational-sliding cooperation of bars (1,2) which cross with each other in the device's open position, and the device is provided with a mechanism blocking rotational movement of bars (1,2) in the closed position.
2. The device according to claim 1 is characterized in that at least one shaped gap (8) is made in the guide (6), whereas the guideline (5) is provided with at least one tang (7) situated in a gap (8) of the guide (6).
3. The device according to claim 1 is characterized in that at least one shaped gap (8) is made in the guideline (5), and ends of tang (7) fixed in the guide (6) cooperate with the gap.
4. The device according to claim 1 is characterized in that the mechanism blocking rotational movement of bars (1,2) in the closed position is constituted by: a notch (9) situated on the end of the guide (6) and a projection (10) made in the guideline (5) cooperating with it.
5. The device according to claim 1 is characterized in that the mechanism blocking rotational movement of bars (1,2) in the closed position of the device comprises: projection (10) situated on the end of the guide (6) which cooperates with the notch (9) made in the guideline (5).
6. The device according to claim 2 or 3 is characterized in that the shaped gap (8) is provided with at least one socket (11) constituting elements of the mechanism blocking rotational movement of bars (1,2) in the closed position of the device; the tang (7) is situated in a socket (11).
7. The device according to claim 1 is characterized in that the shaped gap (8) is through.

8. The device according to claim 1 is characterized in that the shaped gap (8) is connected with the input canal (12) for introducing the tang (7).
9. The device according to claim 4 is characterized in that the mechanism blocking rotational movement of bars (1,2) in the closed position of the device consists of a plate (13) situated in shaped gaps (8) of the two-arm guideline (5).
10. The device according to claim 1 is characterized in that the mechanism blocking movement of bars (1,2) in the closed position of the device is provided by a pin (14).
11. The device according to claim 1 is characterized in that at least one shaped bearing (3,4) constitutes a separate element connected movably to the corresponding bar (1,2).
12. The device according to claim 1 is characterized in that at least one bearing (3,4) is provided with at least one incision (17).
13. The device according to claim 1 is characterized in that it is provided with a scale (18) indicating the range of distraction, which will be gained in the closed position of the device.
14. The device according to claim 1 is characterized in that bars (1,2) are provided with at least one means (15) which guides the band (16).