

1 Medical Line Tension Mitigation Securement Device

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4 CROSS REFERENCE TO RELATED APPLICATIONS

5 U.S. Provisional application No. 63/325,671, filed on March 31, 2022

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7 BACKGROUND OF THE INVENTION

8 1. Field of the Invention

9 Embodiments of the present disclosure relate generally to medical line tension mitigation
10 and securement devices.

11

12 2. Background

13 Clinicians and patients currently have no tools or products that can prevent line pulls
14 (including IV tubing, cables, cords and the like) or dislodgement from patient insertion sites
15 when patients need to be mobilized. Currently in the USA, 19 million lines pull out annually, and
16 this issue is underreported. Mobilization includes transporting or moving patients; bed transfers;
17 including clinicians moving around the patient or bed; patient tasks such as sitting up, standing,
18 moving to a chair, walking to the bathroom; or performing rehabilitative therapy. Currently 64%
19 of early mobility therapy in Intensive Care Unit (ICU) settings is spent detangling and securing
20 lines.

21 Following invasive procedures or injury, early mobility therapy is one of the best ways of
22 increasing the rate of healing. However, most patients with serious hospitalizations have multiple
23 lines and cords and are connected to life saving medical equipment. During early mobility

1 therapy, these connections pose real issues and barriers as patients experience discomfort, pain,
2 and fear of significant injury. Once discomfort is felt, it is human nature to not repeat that same
3 activity. So, if discomfort is felt from a line pulling on a line insertion site during therapy, the
4 patient will not want to perform that therapy again which may hinder the patient's ability to heal.
5 Or worse, lines are accidentally pulled out of a patient insertion site which may contain life
6 support lines or diagnostic monitoring equipment required for life support. If a life support line is
7 pulled out of an insertion site, patient death can occur unless emergency interventions are
8 quickly and accurately performed. Several types of trauma, from mental fear, to physical pain, to
9 the risk of death prevent the desire to perform the needed therapy that promotes healing.

10 Tapes or adhesives and sutured-in lines are the commonly used methods to secure lines at
11 patient insertion sites onto patient skin. This has many drawbacks such as, nagging discomfort,
12 skin tears, skin irritation, blemishes and skin infections. Adhesives provide only a minimal
13 amount of strength to grip lines, between 4-9 lbs. (1.8 – 4.1 kg) of pull force can pull off typical
14 adhesives. Clinicians have also used tape and medicine cups or tongue depressors to group IV
15 lines and cords to bedrails or have used rolled up incontinence pads and taped IV lines to the
16 pads and then pinned them to patient gowns for an attempt at minimal securement with limited
17 success. Line pulls and pullouts are a known problem, and the mentioned solutions are the best
18 that resourceful clinicians have come up with to attempt a means of controlling and providing
19 some sort of safety to their patients. There is currently nothing available that is reliable, reusable,
20 and will secure multiple IV lines, tubes and cords in a in single location while also providing
21 tension mitigation of a pull force up to and over at least 9 lbs. (4.1 kg) of pull force applied to
22 said line, tube, or cord.

23

1 SUMMARY OF THE INVENTION

2 It is the object of the invention to provide a device inserted between the attachment site of
3 lines, tubes, or cords on a patient's body and the source of a pull force (such as by a tug or yank)
4 on the lines, tubes, or cords, the device preventing displacement of each line, tube or cord at the
5 patient attachment or insertion site, as can routinely occur during patient movement, treatment,
6 or therapy in a hospital or medical environment.

7 Another object of the invention is to provide an apparatus that is comprised of a minimal
8 quantity of parts which are easy to manufacture.

9 In accordance with a first embodiment, the invention relates to an apparatus which
10 comprises an armband, a securement body attached to the armband, a securement strap
11 configured to cause the securement body to displace, and a strap attached to the armband utilized
12 to secure the armband to a secure structure, such as a patient, a bed, an IV pole, a crutch, etc. The
13 securement body is configured to securely hold at least one line, tube, or cord and the strap may
14 additionally secure at least one transducer or another device to the armband. Further, the
15 armband is biocompatible with human skin and able to be worn by a patient for at least a day, but
16 preferably up to or exceeding 30 days.

17 In accordance with a second embodiment, the securement body may secure a single line
18 or multiple lines within a single securement body, further the the securement strap and
19 securement body may be formed integral to each other.

20 In accordance with a third embodiment, the securement body may be a shape and
21 material composition designed to provide mitigation of a specific amount of pull force, such as 9
22 lbs. (4.1 kg) or 20 lbs. (9.1 kg) or even 70 lbs. (31.8 kg) or more.

1 The invention also relates to a method for mitigating the undesired removal of lines,
2 tubes, and cords attached to a patient beginning with securing the securement device with a
3 securement strap, at least one grip channel, and at least one a flange, wherein the flange is
4 extending toward the top of the securement body, around a secure structure, such as a patient's
5 arm, in an orientation so the flanges and slots of the securement device are facing upward. Next,
6 the patient attached lines, tubes, and cords at patient insertion sites are each attached to the
7 securement device. Last, the securement body is put under compression causing each flange to
8 touch the neighboring flange and each slot width to reduce, thereby securing the securement
9 device to each line, tube and cord so if any of the secured lines, tubes, or cords are yanked or
10 pulled, each line, tube, and cord inserted into the patient will remain in place at their insertion
11 sites, unaffected, as the pull force from the yank or pull is mitigated by the device.

12

13 BRIEF DESCRIPTION OF THE DRAWINGS

14 FIG 1. is an enlarged rear perspective view of an embodiment of the present invention;

15 FIG 2. is a front exploded view of an embodiment of the present invention;

16 FIG 3. is a perspective view of a fully assembled embodiment of the present invention;

17 FIG 4. is a front perspective view of an embodiment present invention;

18 FIG 5. is a perspective view of an embodiment of securement body 102;

19 FIG 6. is a top view of an embodiment of securement body 102;

20 FIG 7A. is a left side view of an embodiment of securement body 102 without first
21 portion 130 and second portion 132 not shown before compression from securement strap 106;22 FIG 7B. is a left side view of an embodiment of securement body 102 without first
23 portion 130 and second portion 132 not shown after compression from securement strap 106;

1 FIG 8. is a front perspective view of an alternative embodiment of the present invention
2 with a transducer 158 attached;

3 FIG 9. is perspective view of the alternative embodiment of the present invention
4 connected to a patient;

5 FIG 10. a perspective view of the alternative embodiment of the present invention
6 connected to a patient;

7 FIG 11. is a perspective view of the alternative embodiment of the present invention
8 secured to a stationary object;

9 FIG 12A. is a perspective view of another alternative embodiment of the present
10 invention in an open position;

11 FIG 13B. is a perspective view of another alternative embodiment of the present
12 invention in a closed position;

13 FIG 13. is a left side view of an alternative embodiment of body 102.
14

15 DETAILED DESCRIPTION OF THE INVENTION

16 For the following defined terms, these definitions shall be applied, unless a different
17 definition is given in the claims or elsewhere in this specification. All numeric values are herein
18 assumed to be modified by the term “about,” whether or not explicitly indicated. The term “about,”
19 in the context of numeric values, generally refers to a range of numbers that one of skill in the art
20 would consider equivalent to the recited value (e.g., having the same function or result). In many
21 instances, the term “about” may include numbers that are rounded to the nearest significant figure.
22 Other uses of the term “about” (e.g., in a context other than numeric values) may be assumed to

1 have their ordinary and customary definition(s), as understood from and consistent with the context
2 of the specification, unless otherwise specified.

3 For the following defined terms, these definitions shall be applied, unless a different
4 definition is given in the claims or elsewhere in this specification. Although some suitable
5 dimensions, ranges, and/or values pertaining to various components, features and/or specifications
6 are disclosed, one of skill in the art, incited by the present disclosure, would understand desired
7 dimensions, ranges, and/or values may deviate from those expressly disclosed.

8 As used in this specification and the appended claims, the singular forms “a”, “an”, and
9 “the” include plural referents unless the content clearly dictates otherwise. As used in this
10 specification and the appended claims, the terms “and” and “or” are generally employed in its
11 sense including “and/or” unless the content clearly dictates otherwise. It is to be noted that in order
12 to facilitate understanding, certain features of the disclosure may be described in the singular, even
13 though those features may be plural or recurring within the disclosed embodiment(s). Each
14 instance of the features may include and/or be encompassed by the singular disclosure(s), unless
15 expressly stated to the contrary.

16 As used herein, the terms “lines,” “tubing,” “IV,” and “cords” are intended to be
17 interchangeable and mean any flexible medical grade material used to carry fluid, gas, information,
18 or electricity.

19 A medical line tension mitigation securement device, system, and method will now be
20 described with references in FIGS. 1-13. Turning to the drawings, where the reference characters
21 indicate corresponding elements throughout the several figures, attention is first directed to FIG.
22 1 where an enlarged rear perspective view of an embodiment of the present invention is shown,

1 illustrating its composition, the apparatus is generally indicated by reference character 100.
2 Medical line tension mitigation securement device 100 is designed to eliminate hazardous pulling
3 and line or cord dislodgement from a patient during therapy, transport, and patient movement.
4 Securement device 100 may be single use or reusable with the current embodiment being tested to
5 operate effectively for up 30 days. Securement device 100 is configured to secure and organize
6 one or more various sized and type of medical tubes, lines, and cords along a X, Y, and Z axis
7 against pull forces along the X, Y, and Z axis. Securement device 100 is also designed to include
8 a minimal set of components that are easily manufacturable and provide a much-needed solution
9 to a recognized clinical problem, undesired tube or cord removal from patient insertion sites,
10 potentially causing tube or cord attached equipment malfunction, patient pain and in some cases,
11 death. The simplicity and optimization of securement device 100 is the outcome of 30+ iterations
12 of design and thousands of hours of effort. Securement device 100 comprises a line securement
13 body 102 comprised of a tacky elastomer material that is affixed to a flexible securement band
14 104, such as an armband (which will be used to refer to element 104, however it should be noted
15 armband 104 is not limited to securement around a patient's arm). In the preferred embodiment
16 line securement body 102 is permanently attached to armband 104 (such as by molding, adhesive,
17 Velcro®, sewing, ultrasonic welding, or other methods), although it may be removable or adhered
18 together using known methods to fix two or more dissimilar materials together. Securement device
19 100 further comprises a securement strap 106 wrapped around securement body 102, wherein
20 securement strap 106 is configured to provide a variable amount of tension to securement body
21 102 while also preventing cords or lines held by securement body 102 from moving or being pulled
22 out of the securement body (see FIG. 10). Additionally, securement device 100 further comprises
23 a strap 118 which extends through securement body 102 and comprises a first end 108 configured

1 to removably connect to armband 104 to tighten and secure armband 104 around a user's arm, or
2 other secure structure, while strap 118 also comprises a second end 110 configured to secure to
3 armband 104. Second end 110 may also be configured to secure at least one transducer (see FIG.
4 8 and FIG. 9), and preferably 3, to armband 104.

5 Armband 104 comfortably wraps around a secure structure, such as a patient's appendage,
6 such as an arm or leg, much like a blood pressure cuff, and without adhesives. It should be noted
7 that securement device 100, via armband 104, may be configured by subtle shape modifications to
8 securement body 102, to mount to a patient other than by an arm or leg, such as the case with
9 ECMO tubing, femoral catheters, Swan Ganz, oncology, labor and delivery, breathing tubing,
10 Flight for Life, neo-natal ICU (NICU), military or other desired situations for line tension
11 mitigation. Armband 104 can also be mounted to almost any rigid body, such as, but not limited
12 to, an IV pole or bedrail and is intended to travel with the patient. Strap 118 is used to tightened
13 and secure armband 104 around the arm, or other securement structure. Strap 118 must be properly
14 secured with the appropriate tension to armband 104 in order to keep armband 104 from moving
15 along the securement structure, such as a patient's arm, which may also require a different tension
16 for each patient. It is contemplated the length and width of armband 104 may be varied to
17 accommodate a specific patient characteristic, such as for bariatric, pediatric, or neonatal patients.

18 Turning to FIG. 2 and FIG. 3, a front exploded view of an embodiment of the present
19 invention and a perspective view of a fully assembled embodiment of the present invention is
20 shown. Armband 104 is further comprised of at least an upper layer 120 with a body aperture 124
21 formed therethrough and configured to allow a portion of securement body 102 to extend through
22 it wherein a portion of body 102 (base 112, first portion 130, and second portion 132 described
23 below) remain below upper layer 120, and a lower layer 122 located below upper layer 120 and

1 securement body 102, and an adhesive located between upper layer 120 and lower layer 122 (and
2 the portion of securement body 102 between upper layer 120 and lower layer 122) to adhere the
3 layers together (preferably permanently) with body 102, thereby securely sandwiching securement
4 body 102 (via first portion 130 and second portion 132 described below) to armband 104. Body
5 aperture 124 is the shape of the perimeter of securement body 102 without first protrusion 130 or
6 second protrusion 132 (described below) of base 112 along the X and Y axis (in the XY-plane)
7 (the perimeter of flanges 150, first termination end 114, and second termination end 116 described
8 below), which is rectangular with rounded corners with the longest sides being curvilinear. Body
9 aperture 124 is oriented to have its longest side extend across the width (X-axis) of armband 104,
10 although aperture 124 may be located in an alternative location and position on armband 104 if
11 desired to operate with securement body 102. Upper layer 120 is comprised of foam (or other
12 flexible material such as fabric, plastic, etc.) with a top surface 134, wherein top surface 134 is
13 covered with a loop fastener (not shown), such as Velcro®. Top surface 134 further comprises
14 artwork 140 printed on, embossed with, or otherwise made viewable on top surface 134 of upper
15 layer 120 to indicate the appropriate orientation of device 100 when securing to a patient. The
16 orientation of securement body 102 is important for optimizing tube or cord securement during
17 tugging as the orientation of securement body 102 attributes to the ability of securement device
18 100 to prevent cord or cable pullout from tugging from various directions (described more below).
19 In the current embodiment, the artwork 140 includes the text “UP” with an arrow graphic is located
20 near one edge of the top surface of upper layer 120 to indicate device 100 should be oriented so
21 the artwork 140 is located closest to, and aiming towards the direction of a patient’s head, or the
22 top of the securement body. The direction coincides with the direction of securement body flanges
23 150 and corresponding slots 144 (discussed below). Armband 104 further comprises at least one

1 score mark 164, but preferably a plurality, located across the width and in various locations along
2 the length of upper layer 120 and lower layer 122 and configured to allow armband 104 to be
3 flexible to easily wrap and secure around a secure structure.

4 Lower layer 122 is preferably comprised of a USP Class VI medical grade and skin
5 biocompatible material configured to reduce or eliminate pressure sores which may develop on a
6 patient from extended wearing of device 100, as well as provide a non-absorbent barrier against
7 sweat and moisture. To apply armband 104 to a patient, armband 104 is applied around a patient's
8 arm with direct skin contact, not over clothing. Lower layer 122 may also be comprised of foam
9 (or other comfortable flexible material) and is configured to provide a useful amount of friction as
10 to not slide freely along the surface of the skin (similar to the tension provided by flexible neoprene
11 knee brace to remain in position) and does not require excessive tightening or retightening to stay
12 in place. Armband 104 (via upper layer 120 and lower layer 122) in the current embodiment is
13 about 17.75 in. (450.85 mm) long along the Y-axis and 4 in. (101.6 mm) wide along the X-axis
14 with a score mark 164 located about every 1 inch (25.4 mm) along the length of armband 104 with
15 the center of body aperture 124 located about 2 in. (50.8 mm) from one lengthwise end of armband
16 104.

17 Strap 118 is preferably comprised of Velcro® hook fastener material on at least one side
18 with first end 108 being wider (about 1.88 in. (47.75 mm)) along the X-axis and longer (about 3
19 in. (76.2 mm)) along the Y-axis than second end 110 (about 0.75 in. (19.1 mm) wide along the X-
20 axis by 2.75 in. (69.9 mm) long along the Y-axis in order to provide more surface area to adhere
21 the hook fastener material of strap 118 to top surface 134 of upper layer 120, although the
22 dimensions of first end 108 and second end 110 may be altered if desired. The hook fastener
23 material of strap 118 faces toward top surface 134 of armband 104 to ensure removable adherence

1 of strap 118 to armband 104. Strap 118 further comprises a middle portion 152 located in between
2 first end 108 and second end 110 and has a length (along the X-axis) and width (along the Y-axis)
3 less than the length and width of strap aperture 148 of securement body 102 (described below),
4 however other dimensions as desired may be used. In the preferred embodiment middle portion
5 152 is wider than first end 108, but can be the same width as first end 108 if preferred.

6 Turning to FIG. 4, a front view of an embodiment of the present invention is shown. Line
7 securement body 102 comprises a base 112 with a first termination end 114 connected on one side
8 of base 112 and a second termination end 116 connected on the other side of base 112, and at least
9 one securement flange 150, with seven shown in the present embodiment, located in-between (or
10 sandwiched between) first termination end 114 and second termination end 116 and formed
11 integral with and extending away from base 112, wherein each flange 150 is located in-line with
12 one another and first termination end 114 and second termination end 116. Securement body 102
13 further comprises at least one grip channel 142 formed therethrough base 112 along the Y-axis and
14 primarily circular or cylindrical in shape and configured to hold at least a portion of a tube, line,
15 or cord. Other lines and cords besides IV lines may be inserted into similarly sized grip channels
16 142 such as oxygen tubes or electrical cables like pulse-oximetry lines, which are flexible but rigid
17 radially and cannot be crushed like hollow fluid lines. These other lines or cords may be different
18 sizes depending on the application as previously mentioned. Grip channel 142 is located between
19 first termination end 114 and the at least one flange 150, between the at least one flange 150 and
20 another flange 150, and between a flange 150 and the second termination end 116. Each grip
21 channel 142 is further connected to a slot 144 which extends away from the grip channel 142,
22 wherein slot 144 is configured to allow a tube, line, or cord to slide through said slot into the
23 corresponding connected grip channel 142. Each slot 144 is defined by a flange 150 and another

1 flange 150, a flange 150 and a first termination end 114, or a flange 150 and a second termination
2 end 116. The overall shape of first line securement body 102 is purposefully curvilinear, in the
3 XZ-plane, along the tops of first termination end 114, each flange 150, and second termination end
4 116 in order to utilize the concept of hoop stress (described below) to ensure securement body 102
5 adequately secures tubing within grip channels 142 by applying force to a held line or tube around
6 the circumference of the held line or tube. Securement body 102 is also curvilinear shaped in the
7 XY-plane (see FIG. 6) with the flange 150 located at the center point of body 102 the longest
8 (along the Y-axis) with each subsequent flange 150 toward first termination end 114 and second
9 termination end 116 reducing in length (along the Y-axis) to create a tapering effect (in part for at
10 least ornamental design reasons) (see FIG. 6). Securement body 102 is symmetrically shaped along
11 the XZ and XY-plane in the current embodiment. In addition, if there is more than one flange 150
12 attached to base 112, all of the flanges 150 may be varied lengths, preferably symmetrical along
13 the X-axis about a central flange 150 that centrally located on securement body 102 and is the
14 tallest as compared to the other flanges 150. In the current embodiment base 112 is about 3.13 in.
15 (79.4 mm) in length (along the X-axis), and a width varying from about 1.5 in. (38.1 mm) at the
16 center of base 112 length tapering to 1.25 in. (31.8 mm) wide at first termination end 114 and
17 second termination end 116 (flanges 150 follow this width range as well with a thickness ranging
18 from 0.125 in. (3.18 mm) to about 0.25 in. (6.35 mm) and slot 144 length varying between about
19 0.125 in. (3.18 mm) and 0.75 in. (19.05 mm)) however these dimensions may be altered if desired
20 for such reasons as including, but not limited to: varying line quantity secured by securement body
21 102 (by changing grip channel 142 quantity), variation in force applied to secured lines, and
22 variation in secured line diameter. Each slot 144 is preferably straight (as defined by two
23 securement flanges 150 next to each other, a segment flange 150 and first termination end 114, or

1 a flange 150 and second termination end 116) but can be curvilinear or varied in shape if desired
2 (see FIG. 13). It is important to note that while grip channel 150 is preferably circular or cylindrical
3 (to accommodate at least a portion of circular or cylindrical tubing) but could be other shapes to
4 accommodate other shaped flexible tubing. The diameter of a grip channel 150 is specific for a
5 specific range of IV-line, tubing, or cord diameters to ensure proper and optimal securement. While
6 medical tube lines and cords do not follow standard size guidelines, there are similarities between
7 manufacturers that are in a tight enough size range that an average nominal line size could be
8 determined as common for significant enough sized tubes, lines, and cords to warrant a value to
9 be used in creating a common grip channel 142 size to house each range of tubes, lines, and cords.
10 There are an infinite range of lines, tubes, and cords as well, but the nominal grouping chose in
11 the current embodiment is about 1/8" (or close to 3 mm) and about 1/4" (or close to 6 mm). Each
12 grip channel 142 in securement body 102 accommodates the width of slot 144 needed for
13 manufacturability of securement body 102 (preferably via injection molding or other molding
14 process) and to allow insertion of tubes matched to a particular grip channel 150 diameter so that
15 the grip channel 150 size, when securement body 102 is in its constraining state, via tightening of
16 securement strap 106, each slot 144 is closed or minimized by each flange 150, flange 150 and
17 termination end 114 or 116 touching, so grip channel 142 matches this nominal 1/8" and 1/4"
18 diameter size so grip channel 142 touches the outer surface of the held tubing around its
19 circumference. A secure fit of tubing to grip channel 142 is critical as the grip channel 142 size
20 that most closely matches the tube, line, or cord will yield the greatest effect on restraining line
21 tension (and preventing pullout of the tube in patient insertion sites). It is contemplated a grip
22 channel 142 may comprise other nominal diameter sizes and line securement body 102 may contain
23 any desired number of securement flanges 150 and thus grip channels 142 and slots 144 as desired

1 for a specific application. Similarly, grip channel 142 should be as close to a circle in shape as
2 possible to provide a uniform load around the held tubing to exhibit a strong grip all around the
3 secured tubing and to prevent fluid restriction within the tubing. In the event that grip channel 142
4 is an oval, square, triangle, or anything besides a circle (assuming a circular tube is being held by
5 grip channel 142), the gripping force exerted on tubing held within grip channel 150 will not be
6 consistent around the circumference of the tubing and will thus be weaker than compared to a
7 circle. First termination end 114 located on one end of secure body 102 (along the X-axis) and is
8 generally curved or partially tear drop shaped on one side and may also comprise a flange 150,
9 while second termination end 116 is located on the opposing end of secure body 102 (also along
10 the X-axis) and is generally curved in the opposite direction as first termination end 114 and may
11 include an extension 168 protruding in the opposing direction as flanges 150, wherein extension
12 168 helps to form a grip channel 150 and slot 144 between termination end 116 and neighboring
13 flange 150.

14 If a pull force occurs (IV, line, tubing, or cord becomes tugged or yanked) on a line which
15 has been secured to a grip channel 142 via compression of body 102 by securement strap 106, the
16 pull force is mitigated at the device 100 by channeling the pull force from device 100 to the
17 securement structure (patient's arm for example), leaving the patient's insertion site unaffected.
18 Securement device 100 easily mitigates 20+ lbs. (9.1 kg) of pull force (see below for further
19 description), and preferably up to 80+ lbs. of pull force. To give some context regarding the
20 importance of mitigating at least 20+ lbs. (9.1 kg) of pull force, central venous catheters can pull
21 out with between just 4-9 lbs. (1.8 – 4.1 kg) of pull force. Further, due to the design of device 100,
22 it does not crush or crimp lines, allowing for safe fluid flow even under significant gripping
23 conditions.

1 Base 112 of securement body 102 further comprises a strap aperture 148 formed
2 therethrough and configured to allow strap 118 to extend through strap aperture 148. Strap aperture
3 148 is positioned above upper layer 120 of armband 104 to allow movement of strap 118 through
4 strap aperture 148 for various needs of a user (such as installing one or more transducers on first
5 end of strap 118 or to provide additional length to armband 104 for a securement purpose. In the
6 current embodiment strap aperture 148 is about 1 inch (25.4 mm) along the X-axis and about 1.5
7 in. (38.1 mm) along the Y-axis, however strap aperture 148 may be changed in size and
8 configuration if desired. Strap aperture 148 is rectangular with rounded corners and about 0.0625
9 in. (1.59 mm) tall along the Z-axis, about 1 in. (25.4 mm) along the X-axis, and 1.56 in. (39.6 mm)
10 along the Y-axis, but can be configured into a different shape and dimensions as desired.

11 Turning to FIG. 5 and FIG. 6, a perspective view and a top view of an embodiment of
12 securement body 102 is shown. Securement body 102 further comprises a first protrusion 130
13 connected to base 112 and extending away from base 112 (along the Y-axis), perpendicular to each
14 flange 150 and parallel to each grip channel 142, and a second protrusion 132 connected to base
15 112 and extending away from base 112 (along the Y-axis), perpendicular to each flange 150 and
16 parallel to each grip channel 142, wherein the second protrusion 132 is a mirror image of the first
17 protrusion 130 and located on the opposite wall of first protrusion 130. Both first protrusion 130
18 and second protrusion 132 are generally rectangular with rounded corners but could be configured
19 into a different shape and configuration as desired per other potential methods for optimal bonding
20 to armband 104. First protrusion 130 and second protrusion 132 are configured to be sandwiched
21 between upper layer 120 and lower layer 122 and secure securement body 102 to armband 104,
22 preferably permanently. The securement of body 102 to armband 104 is important and significant
23 to ensure device 100 can withstand the 20+ lbs. (9.1 kg) of pull force on secured tubing, lines, or

1 cables within grip channels 142 and transfer the pull force to the securement body 102 the device
2 100 is attached to. Turning to FIG. 6, as mentioned above, the widths of flanges 150, first
3 termination end 114, and second termination end 150 can vary, in the current embodiment they
4 form a generally curvilinear shape. The bottom of base 112 is flat (although due to the material
5 securement body 102 is produced from base 112 is flexible) in order to allow easy part measuring
6 for improved quality assurance practices during molding / manufacturing and also to allow easy
7 tooling to assemble and bond to upper layer 120 and lower layer 122 but is flexible enough to
8 allow securement body 102 to deform when put under tension by securement strap 106, allowing
9 flanges 150 overlap each other (and / or first termination end 114 and second termination end 116),
10 slots 144 reduce in size, and grip channels 142 pressing against the portions of secured tubes
11 secured within grip channels 142, causing securement body 102 becomes symmetrical or nearly
12 symmetrical in shape along the XZ-plane, thus providing more uniform hoop stress (uniform
13 compression forces / load applied around the circumference of the tubing portion held within
14 securement body 102 which provides optimal tension mitigation by device 100 from tubing pull
15 forces) on secured tubing within grip channels 142 (see. FIG 7B).

16 Turning back to FIG. 2 and FIG. 4, securement strap 106 is comprised of a flexible material
17 with a top surface 154, a bottom surface 156, and a buckle 138 fixed to one end. Securement strap
18 106 further comprises a hook fastener portion 128 located on bottom surface 156 located near the
19 end of strap 106 opposite of buckle 138 and extending toward buckle 138, about 2.5 in. (25.4 mm)
20 in the current embodiment (however other sizes may be used), and a loop fastener portion 146 also
21 on the bottom surface 156 extending from buckle 138 to loop fastener portion 146, about 6.5 in.
22 (165.1 mm), but can be other shapes as desired. It should be noted the width of securement strap
23 106 is important as the width of the current embodiment is about 1 inch (25.4 mm) and it has been

1 found with the current size characteristics of securement body 102, a width of securement strap
2 106 less than 1 inch (25.4 mm) increases the pressure placed on secured lines in each grip channel
3 142 as compared to a securement strap 106 width of 1 inch (25.4 mm) with the same tension force
4 (about 10 lbs. (4.5 kg) in the current embodiment), which can be useful in some embodiments. In
5 use, securement strap 106 surrounds and tightens itself against securement body 102 in the XZ-
6 plane, thereby causing flanges 150 to touch or overlap and securement body 102 to compress
7 around tubing contained within each grip channel 142, thereby securing the tubing from moving
8 within securement body 102 due to a yank or tug. Top surface 154 of securement strap 106 comes
9 into slidable contact with the securement body 102 along the XZ-plane, and securement strap 106
10 threads through buckle 138 so that loop fastener portion 146 is in contact with hook fastener
11 portion 128 at the desired tension, however it is contemplated at least a portion of securement strap
12 106 may be fixed to securement body 102 or armband 104. The tension securement strap 106
13 applies to securement body 102 is variable and dependent on the length of securement strap 106
14 threaded through buckle 138. While other types and brands of material may be used for loop
15 fastener portion 146 and hook fastener portion 128, Velcro® brand is preferred. Further,
16 securement strap 106 remains slidable between the bottom of base 112 and lower layer 122 of
17 armband 104 to allow the variable tension to be applied to body 102. Securement strap 106 is
18 ideally comprised of Velcro® but other securement strap methodologies known in the art may be
19 employed, such as zip ties, a string, a clamp, a clasp, or an elastomer closure strap.

20 It was found during pull force testing of lines, tubes, and cords secured within securement
21 device 100 that the direction of each slot 144 (and thus each flange 150), which allows insertion
22 or removal of each line, poses a slight weakness in securement body 102 when a pull force is
23 applied in the same direction and alignment as slot 144, even when securement body 102 is under

1 compression by securement strap 106. So, as patients and their arms are statistically upright during
2 sitting, standing, and therapy, each slot 144 and securement flange 150, when device 100 is secured
3 to a patient, is configured to face upward, toward the top of the arm (or a person's head) in order
4 to reduce the likelihood of a pull force on a line secured in device 100 along the direction of a slot
5 144 since most line pulls are downward due to gravity (toward the floor). As such, each slot 144
6 are oriented in the least likely direction for a line pull to occur where maximum line securement
7 retention exists. Additionally, the angle of the each securement flange 150 (and thus each slot 144)
8 allows for each securement flange 150 to overlap the neighboring securement flange 150 or second
9 termination end 116 (and to allow first termination end 114 to overlap neighboring flange 150)
10 and provide a compressive load on any IV lines, tubes, or cords within each grip channel 142 when
11 the securement strap 106 is tightened down (for example 10 lbs. (4.5 kg) of strap force may be
12 adequate to provide at least 20 lbs. (9.1 kg) of pull force mitigation on a line or tube secured within
13 a grip channel 142), rather than potential buckling of the line, tube, or cord if the each securement
14 flange 150 (and thus each slot 144) were purely vertically (or perpendicular to base 112) oriented.

15 Turning to FIG. 7A and 7B, a left side view of an embodiment of securement body 102
16 without first portion 130 and second portion 132 before compression from securement strap 106
17 and after compression by securement strap 106 (not shown) is shown. After numerous tests, the
18 preferred angle of securement flange 150 to allow ease of cord insertion, cord removal, and
19 maximum cord securement due to the uniform overlapping nature of flanges 150 over each other
20 to secure lines within each grip channel 142 to transmit the compressive loads through the body
21 when under load is between 20 and 50 degrees (in relation to base 112) without securement strap
22 106 tightened, and about 35 degrees (in relation to base 112) when the securement strap 106 is
23 tightened, and compressive load is applied to any IV lines, tubes, or cords within each grip channel

1 150. It is contemplated the angle of each securement flange 150 may vary depending on what is
2 desired to be secured, the common direction of pull forces to occur, the material of line securement
3 body, and the diameter size of the grip channels.

4 Securement device 100 is an elastomeric system that uses a tension setting by way of
5 securement strap 106 around securement body 102 that distorts the securement body 102 to then
6 apply a compressive load generated by securement strap 106 to IV lines within the grip channels
7 150 in an analog, or infinitely adjustable, tension level between an open state and a closed state
8 by holding the IV lines with a high degree of force without compressing them by way of a pinch
9 or in a manner to disrupt fluid flow within the flexible line. Further, as mentioned above, first
10 termination end 114 and second termination end 116 sandwich the securement flanges 150
11 wherein first termination end 114, second termination end 116 and flanges 150 are all located in-
12 line with one another and configured in a curvilinear shape. This type of shape, while having
13 ornamental and aesthetically pleasing characteristics, also allows securement body 102 to grip
14 onto IV lines, tubes, and cords securely. This type of shape acts to carry and transmit loads (pulls
15 or yanks on the IV lines, tubes, and cables) held in each grip channel 142 in a more uniform
16 manner by gripping more surface area of held lines, tubes, and cables. When securement strap
17 106 is tightened to cause compression of the securement body 102 to surround and grip the IV
18 lines, tubes, or cables (in grip channel 150), securement body 102 displaces significantly to a
19 balanced shape, providing equal force applied to each line secured in each grip channel 150
20 around each grip channel. Securement strap 106 closes each slot 144 between each flange 150,
21 first termination end 114, and second termination end 116, which were used to install the lines
22 into grip channels 142 initially, causing line securement body 102 to become a more uniform
23 oval shape (see FIG. 7B). This oval shape then transmits the securement strap 106 force to the IV

1 lines, tubes, or cables through a physics phenomenon known as hoop stress. A cylindrical, or
2 circular shape of body 102 would be a theoretically ideally balanced and provide the highest
3 amount of strength on all lines in such an embodiment (depending on the width of slots 144
4 allowing the lines to be inserted), but is likely not comfortable on a patient, and would make for
5 a large and awkward device to be attached based on its size or height from armband 104. In the
6 event that a maximum amount of securement is desired, and device 100 wouldn't necessarily be
7 flush against a patient's arm, a circular shape of securement body 102 may be desirable for the
8 greatest ability to resist pull forces. So, a curvilinear or modified-semi-circle shape of
9 securement body 102 combined with the armband 104 provides the best balance of
10 manufacturability, weight, size, performance, and patient comfort for securement of lines,
11 tubing, and cords. Alternatively, it is contemplated the curvilinear curvature in at least the XZ-
12 plane mentioned above may be altered as desired. The greater the amount of curvature of flanges
13 150, first termination end 114, and second termination end 116 of securement body 102, when in
14 its secure and compression state (securement strap 106 is tightened and securement flanges 150
15 overlap each other), the greater the amount of resistance can be translated onto secured IV lines
16 with grip channels 150, tubing, or cords in the event of a line pull.

17 While securement body 102 is a tacky elastomer material, the key is the balance between
18 the ease of tube insertion, safety, and comfort to the patient and the strength of device 100 to
19 hold compression on the inserted tubes to prevent movement of the inserted tubes in securement
20 body 102 by up to at least 9 lbs. (4.1 kg) of pull force, but preferable 20 lbs. (9.1 kg). The
21 material properties of securement body 102 may be altered if desired for different situations. For
22 example, in the event of a flight-for-life or military application and extra securement is desired,
23 the shape could be changed for greater overall grip on inserted tubing, or the hardness of the

1 material of securement body 102 could be changed to increase the strength of the grip around
2 held lines at the expense of installation ease. In the preferred embodiment, the device 100 can
3 withstand at least 20 lbs. (9.1 kg) of pull force in any direction (along the X, Y, or Z axis) but
4 preferably up to 80 lbs. (36.3 kg) or more between all of the lines held by the device (assuming a
5 force of about 10 lbs. (4.5 kg) is used to secure securement strap 106 around body 102). That is,
6 the device would mitigate 20 lbs. (9.1 kg) of force applied to one line secured in a grip channel
7 142, or 5 lbs. (2.3 kg) of force applied to each of 4 lines secured in four grip channels 142. The
8 ability of the device to withstand a pull force of 20 lbs. (9.1 kg) or more is a substantial
9 improvement over any current solutions and has been a long-standing problem to be solved.
10 However, it is important to note that the amount of pull force device 100 can mitigate depends on
11 a number of factors, including, but not limited to, the securement strap 106 tension applied to
12 securement body 102, the diameter of the cords, lines, and tubes being secured within grip
13 channels 142, and whether the lines, tubes, and cords are rigid/stiff or flexible/pliable. In
14 addition, the directional vector of the pull force applied to the lines, tubes, and cords and the rate
15 of speed at which the pull force is applied can be a factor.

16 Turning to FIG. 8 and FIG. 9, a front perspective view of an alternative embodiment of
17 the present invention with a transducer 158 attached to upper layer 120 of armband 104 via first
18 end 108 of strap 118, and a perspective view of the alternative embodiment of the present
19 invention attached to a patient is shown. Transducer 158 further comprises a base 160 with at
20 least one transducer aperture 162 located on at least one side of transducer base 160 configured
21 to allow first end 108 of strap 118 to thread through at least one transducer aperture 162, thereby
22 securing transducer 158 to upper layer 120 via hook fastener of first end 108 affixing to loop
23 fastener on top surface 134 of upper layer 120 of armband 104. First end 108 of strap 118 is

1 presently configured to secure up to 3 transducers 158 in-line with one another to armband 104,
2 however first end 108 may be made longer or shorter to accommodate a different quantity of
3 transducers 158 or other desirable devices to be secured to securement device 100. Turning to
4 FIG. 11, the location and position of first end 108 of strap 118 is important for transducer use as
5 each transducer 158, via armband 104 placement on a patient, device 100 allows correct
6 positioning of transducer 158 to be in-line or level with the right atrium of a patient's heart 230
7 (see dotted line), which is critical for correct monitoring of life support medications via
8 transducer 158 based on real-time blood pressure readings. Transducers were designed to be
9 placed on IV poles but are more commonly attached to patient gowns with a clothespin, or taped
10 to their arm, or through using a product that was intended to hold catheters in place on a patient's
11 legs, which unfortunately falls down the patient's arm regularly, causing unnecessary potentially
12 life-threatening disruptions. None of these methods can appropriately secure the transducer in the
13 correct position as mentioned above by device 100, which is crucial for proper hemodynamic
14 monitoring after operations such as open-heart surgery or transplants.

15 Turning to FIG. 10 and FIG. 11, a perspective view of the alternative embodiment of the
16 present invention connected to a patient and secured to a stationary object is shown. Ultimately,
17 medical line tension mitigation securement device 100 is a tension mitigation, or strain relief,
18 device and system, where the device translates tension in the IV lines from a force vector, such
19 as a yank or tug, to device 100 on the patients arm and not to the IV-line insertion site into the
20 patient, providing a unique ability to prevent painful line pulling and dangerous dislodgement at
21 patient insertion site(s). An example of this is illustrated in FIG. 10 where device 100 separates
22 at least one line 222 (four lines in the current embodiment) attached to a patient into a load side
23 224 and a secure side 226. When the lines on load side 224 of device 100 experience a force

1 vector, such as a tug, device 100 absorbs and translates the force vector to the patient's arm
2 instead of transferring to the secure side 226 of the lines, which are connected to patient insertion
3 sites (locations where a line is attached to or extends into a patient's skin or body), thereby
4 potential preventing pain and injury to the patient from the force vector. When secured lines 222
5 are not under load, securement device 100 is still constantly applying a compressive grip force to
6 lines 222 that the patient does not feel. That is, a compression load, via securement strap 106, is
7 constantly being applied to hold the IV lines 222 in place by securement body 102, and that
8 compression load is independent of armband 104 surrounding the patient's arm, ensuring device
9 100 is always ready to protect against a tug or yank. That is, the compression load on body 102 is
10 independent (and can be adjusted independently) of the force used to tighten armband 104
11 around the patient's arm. The compression load on securement body 102 from securement strap
12 106 forces securement body 102 into an oval shape which promotes even distribution of
13 compression load on any secured lines 222 around the circumference of each line 222, ensuring a
14 strong grip on each line 222. However, when an external tension or pull force is applied to lines
15 222 secured within body 102, that load is translated to the securement body 102 performing the
16 compression load onto the lines, which is translated onto armband 104, which is then transferred
17 to the patient arm (or other secure structure). Turning to FIG. 11, device 100 is secured around a
18 pole, such as an IV pole, via armband 104.

19 Turning to FIG. 12A and FIG. 12B, a perspective view of another alternative
20 embodiment of the present invention in an open and a closed (or compression) position is shown.
21 In this alternative embodiment, armband 104 may comprise one or more individual securement
22 bodies 200, secured to armband 104 in the same manner as securement body 102 (via
23 sandwiching a first and second protrusion (not shown) located on the base 212 of body 200

1 between upper layer 120 and lower layer 122 of armband 104). Securement body 200 comprises
2 a base 212 with a securement strap 202 formed integral to securement body 200 (replacing
3 securement strap 106 on the previous embodiment), a single securement flange 204 and a single
4 termination end 206 forming a grip channel 214 and a slot 216, wherein securement strap 202,
5 securement flange 204, and termination end 206 are all connected to base 212. Termination end
6 206 further comprises a protrusion 208 extending away from securement flange 204. Securement
7 strap 202 further comprises at least one opening 210 formed therethrough and configured to
8 secure over protrusion 208, which is essentially a hook feature to hold onto opening 210. Varied
9 tension may be applied to securement body 200 by securing different openings 210, where an
10 opening 210 formed closer to where securement strap 202 is connected to base 212 would yield
11 greater tension on securement body 200 and an opening 210 formed in securement strap 202
12 formed further away from base 212 would yield reduced tension on securement body 202. Such
13 an embodiment allows for a single line to be removed or adjusted in a particular securement
14 body 200 without affecting the tension of any adjacent securement bodies 200, or the lines they
15 secure, should multiple securement bodies 200 be located on a single armband 104. In the open
16 position, a line may be placed into grip channel 214 via slot 216. In the closed position, line is
17 secured in grip channel 214 when securement strap 202 overlaps securement flange and
18 termination end 206, thereby positioning opening 210 of strap 202 over protrusion 208 of
19 termination end 206, thereby providing tension on securement body 200 and any held line in grip
20 channel 214. In addition, in any embodiment, it is contemplated the width of each slot 216 of
21 securement body 202 could be increased or modified in conjunction with modification to the
22 shape or material choices of body 202 to allow easier insertion of IV lines, tubing, or cords to be
23 placed in a grip channel 214.

1 Turning to FIG. 13 a left side view of alternative embodiment of body 102 (without first
2 first protrusion 130 or second protrusion 132 shown and after securement strap 106 is under
3 tension) is shown. In this embodiment securement flanges 150 and slots 144 could be configured
4 to be curved, in a “torturous path” type of slot. Such a configuration could prevent line 222 held
5 in grip channel 142 from being pulled in a straight direction out of grip channel 142 and slot 144,
6 which is the path of least resistance in the event of a force vector 218 or 220 in that direction.
7 Knowing force vectors are typically linear and are being pulled from a constant location and
8 position, a curved flange 150 and slot 144 configuration would significantly decrease the
9 likelihood of a line pulling straight through a straight (whether vertical or angled slot). A curved
10 or zig-zag shape of slot 144 would be a secondary defense against the pulling of line 222 straight
11 up and out of body 102 with the “pinching” affect and friction being applied to the line to keep it
12 in place while the line is under tension. If a line pulls through slot 144 and is under load against
13 securement strap 106, it will otherwise have an insignificant load reduction capacity during a
14 significant line pull force. After such line pull incidents, the armband shall be inspected to ensure
15 the lines are back in their proper grip channels.

16 A method to use securement device 100 begins first with configuring device 100 with at
17 least one slot 144, at least one flange 150, a first termination end 114, a second termination end
18 116, and a securement strap 106 around a securement body with each slot 144 on securement
19 body 102 facing up or toward the sky. Next, medical tubes, IV lines, and/ cords are inserted into
20 the grip channel 142 of securement body 102 that most closely resemble the size of the line
21 diameter (device 100 is in an open state). Next, securement strap 106 is fastened and tightened,
22 causing each flange 150 to touch the neighboring flange 150 or second termination end 116
23 (device 100 is in a closed position). Also, in the event of a catastrophic or adverse load applied to

1 device 100, if and when a line is in this position shown by line 222 or in any of the embodiments
2 mentioned, fluid flow and drug delivery to the patient via the line will not be altered or
3 compromised as the line is not pinched fully based on the design, shape, size, and materials of
4 device 100 as described in this application.

5 While the present invention has been described above in terms of specific embodiments,
6 it is to be understood that the invention is not limited to these disclosed embodiments. Many
7 modifications and other embodiments of the invention will come to mind of those skilled in the
8 art to which this invention pertain, and which are intended to be and are covered by both this
9 disclosure and the appended claims. It is indeed intended that the scope of the invention should
10 be determined by proper interpretation and construction of the appended claims and their legal
11 equivalents, as understood by those of skill in the art relying upon the disclosure in this
12 specification and the attached drawings. Likewise, where this document refers to technologies
13 that would be apparent or known to one of ordinary skill in the art, such technologies encompass
14 those apparent or known to the skilled artisan now or at any time in the future.

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CLAIMS

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2 1. A securement device comprising:
3 a securement band;
4 a securement body attached to the securement band and configured to secure at
5 least a portion of at least one tube, line, or cord;
6 a securement strap configured to apply variable tension to the securement body;
7 and
8 a strap attached to the securement band and configured to secure the securement
9 band around a secure structure,
10 wherein the securement body is configured, when under tension, to provide a
11 compressive load to the portion of the at least one line, tube, or cord to secure the portion
12 of the at least one line, tube, or cord from movement.
13 2. The device of claim 1 wherein the securement body is configured, when under tension, to
14 provide an uniform compressive load around the circumference of the secured portion of
15 the at least one line, tube, or cord.
16 3. The device of claim 1 wherein the securement body, when under tension, is configured to
17 absorb and transmit a force applied to the secured line, tube, or cord to the securement
18 band.
19 4. The device of claim 2 wherein the securement body is configured to prevent the secured
20 portion of the at least one line, tube, or cord from movement due to a pull force applied
21 to the at least one line, tube or cord of at least 9 lbs. (4.1 kg).
22 5. The device of claim 1 wherein the strap is configured to extend through the securement
23 body.

- 1 6. The device of claim 1 wherein the armband is further comprised of an upper layer with an
2 aperture formed therethrough and a lower layer, wherein a portion of the securement
3 body is secured between the upper layer and lower layer.
- 4 7. The device of claim 6 wherein the securement body extends partially through the aperture
5 in the upper layer.
- 6 8. The device of claim 6 wherein the lower layer is comprised of a USP Class VI medical
7 grade material.
- 8 9. The device of claim 1 wherein the securement strap is configured to surround the
9 securement body along a plane.
- 10 10. A securement device comprising:
11 a securement band;
12 a securement body attached to the securement band, the securement body
13 comprising an aperture formed therethrough and configured to hold at least one
14 tube, line or cord;
15 a securement strap configured to apply tension to the securement body; and
16 a strap attached to the securement band and configured to secure the securement
17 band around a secure structure,
18 wherein the securement body is configured, when under tension, to prevent at
19 least a portion of the line held by securement body from movement within the securement
20 body due to a pull force.
- 21 11. The device of claim 10 wherein the securement body comprises:
22 a base;
23 a strap aperture formed in the base and configured to operate with the strap;

- 1 at least one grip channel configured to hold a line and formed within the base;
2 at least one flange connected to the base and at least one grip channel; and
3 at least one termination end,
4 wherein the at least one flange and a second flange or at least one termination end define
5 a slot connected to the grip channel.
- 6 12. The device of claim 10 wherein the at least one flange is at an angle between 20 and 50
7 degrees in relation to the base.
- 8 13. The device of claim 10 wherein the securement body further comprises:
9 a first protrusion extending from the base; and
10 a second protrusion extending from the base,
11 wherein the first protrusion and second protrusion are configured to attach the securement
12 body to the securement band.
- 13 14. The device of claim 10 wherein one end of the strap is configured to secure at least one
14 transducer to the securement band and to extend through the aperture in the base.
- 15 15. The device of claim 14 wherein the strap is further configured to maintain the at least one
16 transducer in-line with the heart of a patient when the securement band is secured to the
17 patient's arm.
- 18 16. The device of claim 10 wherein the securement body is comprised of a tacky elastomer.
- 19 17. A method for securing a line to a securement device comprising:
20 Securing a securement band comprising a securement body with a securement
21 strap, at least one grip channel, and at least one a flange to a secure structure, wherein
22 the at least one flange extends upward;
23 inserting a tube, line, or cord into the at least one grip channel; and

- 1 tightening the securement strap around the securement body, causing the
2 securement body to compress against at least a portion of the tube, line, or cord and
3 preventing at least the portion of the tube, line, or cord from movement.
- 4 18. The method of claim 17 wherein the diameter of the grip channel closely matches the
5 outer diameter of the tube, line, or cord.
- 6 19. The method of claim 17 wherein the securement body portion forming the at least one
7 grip channel compresses around the circumference of the tube, line, or cord.
- 8 20. The method of claim 17 wherein the securement device further comprises a strap.
- 9 21. The method of claim 17 wherein the securement device prevents the portion of tube, line,
10 or cord inside the securement device from a pull force of at least 9 lbs. (4.08 kg).
- 11 22. A securement device comprising:
12 a securement band configured to removably attach to a secure structure by
13 tension;
14 a securement body configured to secure at least one line, the securement body
15 attached to the securement band; and
16 a securement strap configured to apply tension to the securement body,
17 wherein the securement body is configured, when under tension by the
18 securement strap, to separate the at least one line secured by the securement body into a
19 load side and a secure side, the securement body is configured to transfer a load applied
20 to the load side of the at least one line to the securement body and then to secure
21 structure instead of to the secure side of the line.

1 23. The securement device of claim 22, wherein the securement band tension can be different
2 from and adjusted independently from the securement strap tension on the securement
3 body.

4 24. The securement device of claim 22 wherein the securement strap is made integral with
5 the securement body.

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