

SELF-CONTROLLABLE LOAD SPRING WASHER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Patent Application No. 62/872,017, filed July 9, 2019, and U.S. Utility Patent Application No. 16/922,137 filed July 7, 2020 the contents of which are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present disclosure relates generally to spring washers useful as replacements for helical coil springs for medical devices, and, in particular embodiments or aspects, to injection devices including spring washers, including elastomeric spring washers.

Description of Related Art

[0003] Medical injection devices often utilize resilient members, such as springs, placed between various components, to bias the components in order to ensure more accurate drug delivery. However, there are shortcomings to the use of current resilient members used in medical injection devices, such as a lack of control and load recovery. Accordingly, there is a need in the art for a more robust component to allow for greater load recovery.

SUMMARY OF THE INVENTION

[0004] Provided herein is a load spring washer configured for use with a medical injection device, having a main body having a proximal surface and a distal surface; and one or more protrusions extending proximally away from the proximal surface of the main body.

[0005] Also provided herein is a load spring washer configured for use with a medical injection device, having a circular main body having a proximal surface and a distal surface, wherein a cross-sectional profile of the main body taken along a plane extending between the proximal surface and the distal surface has a sinusoidal shape.

[0006] Also provided herein is a load spring washer configured for use with a medical injection device, having a circular main body having a frustoconical shape.

[0007] Also provided herein is a load spring washer configured for use with a medical injection device, having a main body comprising a ring having a proximal surface and a distal surface, the load spring washer comprising at least one arm and/or one flange projecting parallel to a longitudinal axis defined by the proximal surface and distal surface of the main body.

[0008] Also provided herein is a medical injection device having a housing; a brake member received within the housing; a cartridge received within the housing and holding a composition therein; a load spring washer as described herein, received within the housing and positioned between the brake member and the housing; an injection needle in fluid communication with the cartridge; and an actuation member at a proximal end of the housing, the actuation member configured to actuate the medical injection device to deliver the composition through the injection needle.

[0009] Further embodiments or aspects are set forth in the following numbered clauses:

[0010] 1. A load spring washer configured for use with a medical injection device, comprising: a main body having a proximal surface and a distal surface; and one or more protrusions extending proximally away from the proximal surface of the main body.

[0011] 2. The load spring washer of clause 1, wherein the main body is substantially circular.

[0012] 3. The load spring washer of clause 1 or clause 2, wherein the main body defines an aperture, such that the main body is ring shaped.

[0013] 4. The load spring washer of any of clauses 1-3, wherein a cross-sectional profile of the one or more protrusions taken along a plane extending between the proximal surface and the distal surface comprises a parallelogram.

[0014] 5. The load spring washer of any of clauses 1-3, wherein the one or more protrusions have a cylindrical shape.

[0015] 6. The load spring washer of clause 5, wherein a cross-sectional profile of the one or more protrusions taken along a plane extending between the proximal surface and the distal surface comprises a cylindrical shape.

[0016] 7. The load spring washer of clause 5 or clause 6, wherein the cylindrical shape defines a hollow interior.

[0017] 8. The load spring washer of clause 7, wherein the hollow interior is filled with a gas.

[0018] 9. The load spring washer of clause 7, wherein the hollow interior comprises a vacuum.

[0019] 10. The load spring washer of any of clauses 1-3, wherein a cross-sectional profile of the one or more protrusions taken along a plane extending between the proximal surface and the distal surface comprises a rhomboid.

[0020] 11. The load spring washer of any of clauses 1-3, wherein a cross-sectional profile of the one or more protrusions taken along a plane extending between the proximal surface and

the distal surface comprises an s-shape.

[0021] 12. The load spring washer of any of clauses 1-3, wherein a cross-sectional profile of the one or more protrusions taken along a plane extending between the proximal surface and the distal surface comprises an l-shape.

[0022] 13. The load spring washer of any of clauses 1-3, wherein the main body comprises a plurality of rings.

[0023] 14. The load spring washer of clause 13, wherein the plurality of rings comprise concentric circles, with a gap between each of the concentric circles.

[0024] 15. The load spring washer of clause 14, wherein at least one of the concentric circles has a width that is greater than a width of another of the concentric circles.

[0025] 16. The load spring washer of any of clauses 13-15, wherein a cross-sectional profile of the one or more protrusions taken along a plane extending between the proximal surface and the distal surface comprises a u-shape, wherein the u-shape comprises: a first arm connected to a first of the plurality of rings of the main body and a second arm connected to a second of the plurality of rings of the main body, both the first arm and the second arm extending parallel to a longitudinal axis defined by the proximal surface and the distal surface of the main body; and a cross-member connected to the first arm and the second arm and extending perpendicular to the longitudinal axis defined by the proximal surface and the distal surface of the main body.

[0026] 17. The load spring washer of any of clauses 13-15, wherein the one or more protrusions comprise an arch comprising: a first arm connected to a first of the plurality of rings of the main body and a second arm connected to a second of the plurality of rings of the main body, both the first arm and the second arm extending parallel to a longitudinal axis defined by the proximal surface and the distal surface of the main body; and a curved portion connected to the first arm and the second arm.

[0027] 18. The load spring washer of any of clauses 1-3, wherein the protrusion comprises a frustoconical portion.

[0028] 19. The load spring washer of any of clauses 1-18, wherein the load spring washer comprises an elastomeric material.

[0029] 20. The load spring washer of any of clauses 1-19, wherein the load spring washer comprises a rubber.

[0030] 21. The load spring washer of any of clauses 1-20, wherein the load spring washer is formed of an ethylene propylene diene monomer rubber.

[0031] 22. The load spring washer of any of clauses 1-21, wherein a Shore A hardness of

the load spring washer is 20-40, preferably 30-40.

[0032] 23. A load spring washer comprising a circular main body having a proximal surface and a distal surface, wherein a cross-sectional profile of the main body taken along a plane extending between the proximal surface and the distal surface comprises a sinusoidal shape.

[0033] 24. A load spring washer comprising a circular main body having a frustoconical shape.

[0034] 25. A load spring washer comprising a main body comprising a ring having a proximal surface and a distal surface, the load spring washer comprising at least one arm and/or one flange projecting parallel to a longitudinal axis defined by the proximal surface and distal surface of the main body.

[0035] 26. The load spring washer of any of clauses 23-25, wherein the load spring washer comprises an elastomeric material.

[0036] 27. The load spring washer of any of clauses 23-26, wherein the load spring washer comprises a rubber.

[0037] 28. The load spring washer of any of clauses 23-27, wherein the load spring washer is formed of an ethylene propylene diene monomer rubber.

[0038] 29. The load spring washer of any of clauses 23-28, wherein a Shore A hardness of the load spring washer is 20-40, preferably 30-40.

[0039] 30. A medical injection device comprising a housing; a brake member received within the housing; a cartridge received within the housing and holding a composition therein; a load spring washer according to any of clauses 1-29, received within the housing and positioned between the brake member and the housing; an injection needle in fluid communication with the cartridge; and an actuation member at a proximal end of the housing, the actuation member configured to actuate the medical injection device to deliver the composition through the injection needle.

BRIEF DESCRIPTION OF THE DRAWINGS

[0040] **FIGS. 1A-1C** show various embodiments or aspects of a load spring washer as described herein;

[0041] **FIG. 2** shows a schematic image of a load spring washer according to one non-limiting embodiment or aspect;

[0042] **FIGS. 3A-3B** show a schematic image of a load spring washer according to one non-limiting embodiment or aspect and a force diagram showing flexing of the pillars of the load

spring washer;

[0043] **FIGS. 4A-4B** show schematic images of a load spring washer according to non-limiting embodiments or aspects;

[0044] **FIG. 5** shows a schematic image of a load spring washer according to one non-limiting embodiment or aspect;

[0045] **FIGS. 6A-6D** show schematic images of a load spring washer according to non-limiting embodiments or aspects;

[0046] **FIGS. 7A-7C** show schematic images of a load spring washer according to non-limiting embodiments or aspects;

[0047] **FIGS. 8A-8D** show schematic images of a load spring washer according to non-limiting embodiments or aspects;

[0048] **FIGS. 9A-9B** show schematic images of a load spring washer according to non-limiting embodiments or aspects;

[0049] **FIGS. 10A-10B** show schematic images of a load spring washer according to non-limiting embodiments or aspects;

[0050] **FIGS. 11A-11E** show various embodiments or aspects of a load spring washer as described herein;

[0051] **FIGS. 12A-12B** show a load spring washer and placement of the same within the housing of a drug delivery device according to a non-limiting embodiment or aspect;

[0052] **FIGS. 13A-13B** show a load spring washer and placement of the same within the housing of a drug delivery device according to a non-limiting embodiment or aspect;

[0053] **FIGS. 14A-14B** show a load spring washer and placement of the same within the housing of a drug delivery device according to a non-limiting embodiment or aspect;

[0054] **FIGS. 15A-15B** show a load spring washer and placement of the same within the housing of a drug delivery device according to a non-limiting embodiment or aspect; and

[0055] **FIG. 16** is an exploded view of a medical injection device including a load spring washer as described herein;

[0056] **FIG. 17** is a graph showing load against extension for one non-limiting embodiment or aspect of a load spring washer described herein;

[0057] **FIGS. 18A-18B** are schematic images of a load spring washer according to non-limiting embodiments or aspects; and

[0058] **FIGS. 19A-19B** are schematic images of a load spring washer according to non-limiting embodiments or aspects.

DESCRIPTION OF THE INVENTION

[0059] The use of numerical values in the various ranges specified in this application, unless expressly indicated otherwise, are stated as approximations as though the minimum and maximum values within the stated ranges are both preceded by the word “about”. As used herein, the term “about” means the stated value $\pm 10\%$. In this manner, slight variations above and below the stated ranges can be used to achieve substantially the same results as values within the ranges. Also, unless indicated otherwise, the disclosure of these ranges is intended as a continuous range including every value between the minimum and maximum values. For definitions provided herein, those definitions refer to word forms, cognates and grammatical variants of those words or phrases.

[0060] The figures accompanying this application are representative in nature, and should not be construed as implying any particular scale or directionality, unless otherwise indicated. For purposes of the description hereinafter, the terms “upper”, “lower”, “right”, “left”, “vertical”, “horizontal”, “top”, “bottom”, “lateral”, “longitudinal” and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations and step sequences, except where expressly specified to the contrary. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0061] Provided herein is a load spring washer for use as a replacement for a spring in a medical device. A spring washer, as is known to those of skill in the art, is a washer having axial flexibility. As used herein, the “spring” aspect of a spring washer for use in a medical device is a washer that has axial flexibility by virtue of the material from which the washer is formed (e.g., compressibility/expandability derived from the elastomeric nature of materials), by virtue of a shape or form of the washer, and combinations thereof. In non-limiting embodiments or aspects, the load spring washer is formed of an elastomeric material. In non-limiting embodiments or aspects, the elastomeric material is a highly resilient elastomeric material. In non-limiting embodiments or aspects, the load spring washer is formed of a rubber. In non-limiting embodiments or aspects, the rubber is polyisoprene rubber, silicone rubber, and/or butyl rubber. In non-limiting embodiments or aspects, the rubber is butyl rubber (IIR), isoprene rubber (IR), butadiene rubber (BR), styrene-butadiene rubber (SBR), ethylene-propylene rubber (EPM), ethylene-propylene-diene rubber (EPDM), chlorosulphonated polyethylene (CSM), ethylene-vinyl acetate copolymer (EVA), styrene-isoprene rubber (SIR), thermoplastic elastomers, and/or natural rubbers.

[0062] In non-limiting embodiments or aspects, the load spring washer is formed of a

elastomeric copolymer, including, without limitation, thermoplastic elastomers, thermoplastic vulcanizates, styrene copolymers such as styrene-butadiene (SBR or SBS) copolymers, styrene-isoprene (SIS) block polymers or styrene-isoprene/butadiene (SIBS), in which the content of styrene in the styrene block copolymer ranges from about 10% to about 70%, and preferably from about 20% to about 50%. The elastomer composition can include, without limitation, antioxidants and/or inorganic reinforcing agents to preserve the stability of the elastomer composition, a vulcanizing agent, a vulcanizing accelerator, a vulcanizing activator, a processing aid, a filler, etc. to maintain and improve the physical properties and heat resistance of the rubber material.

[0063] In non-limiting embodiments or aspects, the load spring washer is formed of a material having a Shore A value of 20-40 optionally 30-40, all values and subranges therebetween inclusive. In non-limiting embodiments or aspects, the load spring washer is formed of a material comprising an ethylene propylene diene monomer (EPDM) rubber. In non-limiting embodiments or aspects, the load spring washer is formed of a material comprising an EPDM rubber, and various fillers/additives. In non-limiting embodiments or aspects, the load spring washer is formed of an ultra-high molecular weight EPDM rubber (e.g., KELTAN 9565Q), various fillers (e.g., MISTRON Vapor), mineral oil, zinc oxide, stearic acid, antioxidant(s) (e.g., SONGNOX 1076), curing accelerator(s) (e.g., TBzTD), vulcanizing agent(s) (e.g., VULTAC 710), and sulfur (such as a wettable sulfur).

[0064] In non-limiting embodiments or aspects, the load spring washer is formed of a foam. In non-limiting embodiments or aspects, the load spring washer is formed of a mixture of materials, for example, and without limitation, a metal and/or polymer, together with a rubber and/or foam. For example, and without limitation, a load spring washer as described below can include a main body that is a metal, a polymer, or a mix, together with a protrusion that is formed of an elastomeric material, such as a rubber, foam, or elastomeric polymer.

[0065] Turning to **FIGS. 1A-1C**, shown are various load spring washers **100** as described herein. The load spring washers shown in **FIGS. 1A-1C** are substantially circular; however, those of ordinary skill in the art will appreciate that any suitable shape can be used, depending on the intended use/application. **FIGS. 11A-11E** show various non-limiting embodiments or aspects of shapes that can be utilized for load spring washers **100** as described herein, including a circular, ring shape, a star shape, and an h-shape. It is to be understood that the illustrated shapes are merely exemplary, and that the present disclosure is not so limited.

[0066] Turning to **FIG. 2**, shown is a schematic view of a load spring washer **100** according to a non-limiting embodiment or aspect. In non-limiting embodiments or aspects, load spring

washer **100** can include a main body **105** and one or more protrusions **110**, such as pillars, extending from the main body **105**. Main body includes proximal surface **101** and distal surface **102**, defining a longitudinal axis therebetween. Without wishing to be bound by the theory, it is believed that pillars **110** allow for modification of the compressive force of the load spring washer by providing resistance to compression. While **FIG. 2** (and other figures) show specific numbers of protrusions, such as pillars, it is to be understood that the number of protrusions, such as pillars **110**, can be modified to provide appropriate modification of compressive forces for intended applications. Protrusions **110** may assume any useful shape and orientation on the load spring washer main body **105**. Those of skill in the art will appreciate that the thickness (depth) and circumferential size (width) of the main body **105** can be adjusted, so long as the load spring washer exhibits the characteristics described herein in terms of flex, or buckling when force or pressure is applied parallel to the longitudinal axis defined by the proximal surface **101** and distal surface **102** of the main body **105**.

[0067] Turning to **FIG. 3A**, shown is a schematic view of a load spring washer **100** according to a non-limiting embodiment or aspect. Load spring washer **100** includes main body **105** and one or more s-shaped protrusions **110**, with a gap **120** between the proximal (uppermost) portion of the s-shaped protrusion and the main body **105** having a predetermined height. The design of protrusions **110** in **FIG. 3** allows for the protrusions to, when force is applied in a direction perpendicular to the main body **105**, flex or buckle to a flat orientation, as shown in **FIG. 3B**, such that the height of gap **120** is smaller than when no force is applied to the load spring washer **100**. As noted above, protrusions, here s-shaped protrusions, including individual portions thereof, can be of any suitable size, and gap **120** may similarly be of any suitable size.

[0068] Turning to **FIGS. 4A-4B**, shown is a schematic view of a load spring washer **100** according to a non-limiting embodiment or aspect. Load spring washer **100** includes main body **105** and one or more l-shaped protrusions **110**, with a gap **120** between the proximal (uppermost) portion of the l-shaped protrusion **110** and the main body **105**. As noted above, protrusions, here l-shaped protrusions, including individual portions thereof, can be of any suitable size, and gap **120** may similarly be of any suitable size.

[0069] Turning to **FIG. 5**, shown is a schematic view of a load spring washer **100** according to a non-limiting embodiment or aspect. Load spring washer **100** includes a multi-piece main body, including an inner portion **107** and an outer portion **109**. In non-limiting embodiments or aspects, inner portion **107** and outer portion **109** are at least two concentric circles. In non-limiting embodiments or aspects, at least one of the concentric circles has a width that is greater

than a width of another of the concentric circles. Lock spring washer **100** further includes one or more protrusions **110**. In the illustrated embodiment or aspect, protrusion includes a proximal (uppermost) end and a distal (bottommost) end, and the protrusion **110** bridges the inner **107** and outer **109** portions of the main body, with a gap **120** between the proximal end of the protrusion **110** and the inner **107** and outer **109** portions of the main body. Protrusions **110** have a rectangular shape in **FIG. 5**; however, the present disclosure is not so limited, and the protrusions **100** may assume any useful shape or orientation, such as, for example and without limitation an arc or arch shape.

[0070] Turning to **FIGS. 6A-6D**, shown are schematic top (**FIG. 6A**), side (**FIG. 6B**), cross-sectional (**FIG. 6C**), and perspective views (**FIG. 6D**) of a load spring washer **100** according to a non-limiting embodiment or aspect. Load spring washer **100** includes a main body **105** and protrusion **110**. In the illustrated non-limiting embodiment or aspect, protrusion has a cylindrical shape, optionally with a dome **125** at a proximal (uppermost) end. In non-limiting embodiments or aspects, interior of cylinder may be hollow, defining a chamber **130**. The presence of chamber **130**, which may be subject to vacuum during manufacture such that no air is present therein, allows for the dome (**120**) and/or the walls of protrusion **110** to collapse, or buckle, inward towards the distal (bottommost) end of the load spring washer **100** when force is applied to the load spring washer **110** in a direction parallel to the longitudinal axis defined by proximal surface **101** and distal surface **102** of main body **105**. In non-limiting embodiments or aspects, outermost circumference of main body **105** can include one or more protrusions to provide greater frictional engagement between the outer diameter of main body **105** and the inner diameter of a medical device housing into which the load spring washer **100** may be introduced.

[0071] Turning to **FIGS. 7A-7C**, shown are schematic top (**FIG. 7A**) and side (**FIGS. 7B-7C**) views of a load spring washer **100** according to a non-limiting embodiment or aspect. In the illustrated non-limiting embodiment or aspect, load spring washer **100** has a wave shape. While **FIGS. 7B-7C** show a sine wave, including peaks **150** and troughs **140**, it is to be understood that the present disclosure is not so limited, and various wave shapes, for example and without limitation square waves, sawtooth waves, and triangle waves, may be used, so long as the wave shape provides the desired buckling characteristics described herein. In addition, while not illustrated in **FIGS. 7A-7C**, in non-limiting embodiments or aspects the wave shape load spring washer **100** further includes one or more protrusions **110** as described herein.

[0072] Turning to **FIGS. 8A-8D**, shown are top (**FIG. 8A**), side (**FIG. 8B**), cross-sectional

(**FIG. 8C**), and perspective (**FIG. 8D**) views of a load spring washer **100** according to a non-limiting embodiment or aspect. In the illustrated non-limiting embodiment or aspect, load spring washer **100** includes main body **105** and a frustoconical portion **170** at a proximal (uppermost) end of the main body **105**. Frustoconical portion **170** may assume the orientation illustrated in **FIGS. 8B-8C** (larger circumference at the proximal end thereof) or an inverted orientation (larger circumference at the distal (bottommost) end thereof, not shown). In the illustrated non-limiting embodiment or aspect, where the portion of the frustoconical portion **170** having the larger circumference is arranged at the proximal (uppermost) end, gap **180** having a height is defined between proximal (uppermost) end of frustoconical portion **170** and proximal surface **101** of main body **105**. In the illustrated non-limiting embodiment or aspect, proximal-most end of frustoconical portion **170** buckles towards the distal (bottommost) end of the load spring washer **100** when force is applied to the load spring washer **110** in a direction parallel to the longitudinal axis defined by proximal surface **101** and distal surface **102** of main body **105**, such that the height of gap **180** is smaller than when no force is applied to the load spring washer **100**.

[0073] Turning to **FIGS. 9A-9B**, shown are perspective (**FIG. 9A**) and cross-sectional (**FIG. 9B**) views of a load spring washer **100** according to a non-limiting embodiment or aspect. In the illustrated non-limiting embodiment or aspect, load spring washer **100** has a frustoconical shape, with proximal surface **101** being narrower (smaller circumference) than distal surface **102**, though the opposite orientation may be employed. In the illustrated non-limiting embodiment or aspect, proximal surface **101** buckles towards the distal surface **102** of the load spring washer **100** when force is applied to the load spring washer **110** in a direction parallel to the longitudinal axis defined by proximal surface **101** and distal surface **102**.

[0074] Turning to **FIGS. 10A-10B**, shown are perspective (**FIG. 10A**) and cross-sectional (**FIG. 10B**) views of a load spring washer **100** according to a non-limiting embodiment or aspect. Load spring washer **100** illustrated in **FIGS. 10A-10B** includes protrusions **110**. Protrusions **110** are oriented in such a manner that, as best illustrated in cross-sectional view in **FIG. 10B**, the protrusions, when considered with main body **105**, provide a frustoconical shape to load spring washer **100**. In the illustrated non-limiting embodiment or aspect, protrusions **110** buckle towards the distal surface **102** of the load spring washer **100** when force is applied to the load spring washer **110** in a direction parallel to the longitudinal axis defined by proximal surface **101** and distal surface **102** of main body **105**.

[0075] Turning to **FIGS. 12A-12B**, shown is a non-limiting embodiment or aspect of a load spring washer **200** including main body **205** and at least one flange **210** and/or at least one arm **225**. **FIG. 12B** shows load spring washer **200** in a medical injection device housing **250**. Flange **210** can be defined by a portion **215** extending outward from an outer diameter of main body **205**, and a portion **220** extending substantially perpendicular to portion **215**. The lengths of portions **215** and **220** can be adjusted based on the medical device into which the load spring washer **200** is introduced.

[0076] Arm **225** can include portion **215** extending outward from an outer diameter of main body **205**, and a portion **220** extending substantially perpendicular to portion **215**. Arm **225** further includes portion **230** extending substantially perpendicular to portion **220**. In non-limiting embodiments or aspects, portion **230** is substantially parallel to portion **215**.

[0077] Turning to **FIGS. 13A-13B**, shown is a non-limiting embodiment or aspect of a load spring washer **300**. **FIG. 13B** shows load spring washer **300** in a medical injection device housing **350**. In the illustrated non-limiting embodiment or aspect, load spring washer **300** is a ring-shaped foam member.

[0078] Turning to **FIGS. 14A-14B**, shown is a non-limiting embodiment or aspect of a load spring washer **400**. **FIG. 14B** shows load spring washer **400** in a medical injection device housing **450**. In the illustrated non-limiting embodiment or aspect, load spring washer **400** includes one or more protrusions **410** and/or patterns cut into proximal surface **401**. In the illustrated non-limiting embodiment or aspect, load spring washer **400** is a ring-shaped rubber-based member. Without wishing to be bound by the theory, it is believed that the pattern allows for buckling of various portions of the load spring washer **400** as described herein.

[0079] Turning to **FIGS. 15A-15B**, shown is a non-limiting embodiment where a load spring washer is not employed. Rather, the brake tower **500** of a medical injection device (described in greater detail below) includes one or more elastomeric protrusions **510** on a proximal surface thereof. Without wishing to be bound by the theory, it is believed that the elastomeric protrusions **510** allow for buckling as described herein. **FIG. 15B** shows brake tower **500** in a medical injection device housing **550**.

[0080] Also provided herein is a medical injection device including a load spring washer as described above. Such devices, such as injection pens, are described in, for example and without limitation, U.S. Patent No. 9,421,334, which is incorporated herein by reference in its entirety. With reference to **FIG. 16**, shown is an exploded view of an injection pen **51** for delivery of a composition to a user. As shown, the injection pen **51** includes a pen upper body or housing **1**, which houses a plurality of dose setting and injection components. The pen upper

body **1** is connected to a cartridge holder **14**, which houses a medication cartridge **15**. The injection pen **51** may also include a lower pen cap **12** to cover the cartridge **15** and cartridge holder **14** when the injection pen is not in use. As shown, the injection pen **51** can include a dose set knob **2** that includes a knob-like portion that is rotated by a user to set a desired dose. The dose set knob **2** can also include a plurality of numerals, corresponding to a number of dosage units that is visible through a window **13** provided on the pen upper body **1**. A user rotates the dose set knob **2** until the desired dose is visible in the window **13**. The pen upper body **1** can include an arrow or other indicator **53** to precisely indicate the set dose. Once the desired dose is set, a user presses the button **3** until the set dosage amount is completely injected. An outer shield **69** can cover a needle **56** to prevent accidental needle sticks upon removal of the lower pen cap **12**.

[0081] Injection pen **51** includes a push button **3**, provided at a proximal end, closest to a user and farthest from a needle **56**, of the pen upper body **1**. The push button **3** can include an annular bead or rim **57** that engages with a corresponding annular groove (not shown) provided on the internal surface of the dose set knob **2**. The annular rim and groove connection can be a friction fit that maintains the push button **3** in a biased position on the dose set knob **2** under the force of a button spring **10**, but allows the push button **3** to be pushed into the dose set knob **2** for injecting a set dose. The interior of the push button **3** can accommodate a setback bearing insert **8** that rests on an internal surface at a proximal end of a setback member or driver **9**. The push button **3** can be designed to rotate freely on the setback bearing insert **8**.

[0082] The setback member or driver **9** can be a cylindrical member, coaxial with and surrounded by the dose set knob **2**. The setback member **9** can be provided co-axially around a brake tower **5** that is axially and rotatably fixed to the pen upper body **1**. The brake tower **5** co-axially surrounds a piston rod **6**. The piston rod **6** includes a set of keys **62** that engage a slot (not shown) internal to the brake tower **5** to rotatably lock the piston rod **6** to the brake tower **5**. The piston rod **6** can include a plurality of threads (not shown) provided on the interior surface thereof. The piston rod **6** can co-axially surround a lead screw **4** that includes a series of threads **42** at least at its distal end. The lead screw threads **42** can be configured to be in threaded engagement with the internal threads (not shown) provided on the interior of piston rod **6**. Due to its threaded engagement with the lead screw **4**, the piston rod **6** can be moved into the cartridge **15** during injection to press on a stopper **16** provided inside the cartridge **15** to expel a dose of medication.

[0083] With reference to the present disclosure, injection pen **51** includes load spring washer **11**, provided between a distal end of the brake tower **5** and the cartridge **15** and/or

cartridge holder **14**, to bias the cartridge **15** in a distal direction, thereby reducing/preventing movement of the cartridge **15**. Reducing and/or preventing movement of the cartridge **15** can reduce rattling and improve needle **56** penetration into the cartridge **15** before priming.

Example

[0084] Load spring washers were formed out of a highly resilient elastomeric material including the following ingredients:

Table 1

Ingredient	PHR	Density (g/ml)	Formulation Volume (ml)	Batch Weight (g)	Batch Weight (lbs)
KELTAN 9565Q	150 (equivalent to 100 PHR of the polymer)	0.87	172.4	1719	3.8
MINSTRON Vapor	37	2.80	13.2	424	0.9
Mineral Oil	10	0.87	11.5	115	0.3
Zinc Oxide	5	5.61	0.9	57	0.1
Stearic Acid	1	0.94	1.1	11	0.0
SONGNOX 1076	2	0.90	2.2	23	0.1
TBzTD	2.5	1.40	1.8	29	0.1
VULTAC 710	6.5	0.80	8.1	75	0.2
Sulfur/80	1	2.07	0.5	11	0.0

[0085] The above material was utilized to manufacture load spring washers of various orientations/shapes, as shown in **FIG. 11**. Data is shown presented in the tables below.

Table 2

Sample	Compressive Load at Max Load (N)	Area Loading (mJ)	Area Unloading (mJ)
Ring (Cycle 1)	21.070760	12.11671	
Ring (Cycle 2)	27.06701	16.34493	
Ring (Cycle 3)	28.86325	18.21729	
Ring (Cycle 4)	28.57111	18.33210	
H-Shape (Cycle 1)	39.58269	22.04388	-19.03213
H-Shape (Cycle 2)	54.70945	34.01410	
H-Shape (Cycle 3)	55.12173	33.77259	
Star-Shape 7 (Cycle 1)	34.50593	18.54269	

Star-Shape 7 (Cycle 2)	36.79152	19.66360	
Star-Shape 6 (Cycle 1)	23.41913	10.59406	-9.08724
Star-Shape 6 (Cycle 2)	37.52744	19.25595	
Star Shape 5 (Cycle 1)	20.81262	8.90632	
Star Shape 5 (Cycle 2)	35.15383	16.75382	
Star-Shape 8 (Cycle 1)	24.83673	10.29839	
Star-Shape 8 (Cycle 2)	46.02887	23.23951	
Mean	34.31326	18.80640	-14.05969
Standard Deviation	11.00674	7.46342	7.03210

Table 3

Sample	Compressive Load at 0.06 mm (N)	Compressive Load at 0.1 mm (N)	Area Loading- Unloading
Ring (Cycle 1)	0.11229	0.12129	
Ring (Cycle 2)	0.12245	0.14109	
Ring (Cycle 3)	0.14285	0.18381	
Ring (Cycle 4)	0.14561	0.20023	
H-Shape (Cycle 1)	0.14093	0.16526	22.02485
H-Shape (Cycle 2)	0.37301	0.69075	
H-Shape (Cycle 3)	0.38491	0.72202	
Star-Shape 7 (Cycle 1)	0.21051	0.33861	
Star-Shape 7 (Cycle 2)	0.26773	0.38741	
Star-Shape 6 (Cycle 1)	0.12589	0.14490	10.58497
Star-Shape 6 (Cycle 2)	0.18198	0.27805	
Star Shape 5 (Cycle 1)	0.12710	0.16690	
Star Shape 5 (Cycle 2)	0.14909	0.18438	
Star-Shape 8 (Cycle 1)	0.13538	0.15526	
Star-Shape 8 (Cycle 2)	0.16724	0.22068	
Mean	0.18580	0.27358	16.30491
Standard Deviation	0.08791	0.19092	8.08921

[0086] In addition, data (compressive load vs. compressive extension) from the above samples is presented in **FIG. 17**.

[0087] In addition, 19 more samples were produced from a silicone-based rubber material durometer Shore A 35 where the silicone rubber rings were cut using a 14 mm outer diameter cutting die and the internal diameter was subsequently punched with a 10 mm (samples 5, 6, and 7 on Tables 4 and 5) or 12 mm (otherwise) cutting dies. The rings were cut from ASTM rubber plates 6.5" L x 6.5" W and 1.8-2.0 mm thick. All samples in Tables 4 and 5 are the same test but with the forces specified at different compression distance. The maximum compression extension was 1.5 mm

[0088] Tables 6 and 7 are the same test but with the forces specified at different compression distance. The maximum compression extension was 1.5 mm.

[0089] All samples for Tables 4 and 5, 6 and 7 were made in the same way, by punching rings from a rubber slab, with dimensions as provided in **FIGS. 18A-18B** (**FIG. 18A** is a top view, **FIG. 18B** is a cross-sectional view), with data presented below:

Table 4

Sample	Compressive Load at Max Load (N)	Area Loading (mJ)
1	93.88897	0.18077
2	10.45748	0.03745
3	16.52684	0.04315
4	10.11987	0.03775
5	95.78949	0.12344
6	83.01142	0.06146
7	84.12963	0.06087
8	47.08079	0.04381
9	60.84618	0.05374
10	51.33612	0.04990
11	34.94950	0.04530
12	34.81499	0.03465
13	56.72254	0.03722
14	62.92496	0.03778
15	50.73323	0.06551
16	46.06429	0.07922
17	34.00679	0.08139
18	27.50728	0.05415
19	24.93059	0.03774

Mean	48.72847	0.06133
Standard Deviation	26.58819	0.03616

Table 5

Sample	Compressive Load at 0.06 mm (N)	Compressive Load at 0.1 mm (N)
1	2.05477	4.63418
2	0.46023	0.70048
3	0.507741	0.75857
4	0.44663	0.69240
5	1.43243	3.13971
6	0.72140	1.35426
7	0.72024	1.31258
8	0.50808	0.95933
9	0.61815	1.16032
10	0.58744	1.06286
11	0.53254	0.92751
12	0.41074	0.63211
13	0.43921	0.68218
14	0.44336	0.71033
15	0.71995	1.71387
16	0.91263	1.96137
17	0.95401	1.95577
18	0.61690	1.30184
19	0.41083	0.88197
Mean	0.71038	1.39693
Standard Deviation	0.41041	1.00186

[0090] Lastly, 14 additional samples were produced with dimensions as provided in **FIGS. 19A-19B** (**FIG. 19A** is a top view, **FIG. 19B** is a cross-sectional view), with data presented below:

Table 6

Sample	Compressive Load at Max Load (N)	Area Loading (mJ)
1	24.69491	0.04113
2	37.05007	0.04490
3	33.01292	0.05191
4	37.35841	0.02748
5	34.43204	0.02544
6	47.63247	0.04586
7	41.19097	0.01437
8	41.629663	0.08237
9	21.41265	0.10109
10	17.45964	0.04048
11	43.15011	0.05729
12	38.22097	0.06700
13	30.09437	0.07706
14	26.62738	0.05819
Mean	33.85475	0.05247
Standard Deviation	8.80111	0.02371

Table 7

Sample	Compressive Load at 0.06 mm (N)	Compressive Load at 0.1 mm (N)
1	0.45692	1.02958
2	0.48036	1.30489
3	0.56545	1.37173
4	0.30807	0.57717
5	0.28093	0.54226
6	0.50611	1.24077
7	0.14521	0.31382
8	0.96456	2.14320
9	1.18252	2.40098
10	0.43440	1.05093
11	0.65224	1.42832
12	0.76420	1.74184
13	0.85138	2.07813
14	0.66296	1.38261
Mean	0.58966	1.32902
Standard Deviation	0.28198	0.61696

[0091] The rings tested in Table 4 and 5 and 6 and 8 performed as expected showing different orders of buckling and limiting the developed forces for compression extension up to 1.5 mm below. The variations on the max compressions forces is due to either the width of the ring 1.5 mm on samples 5, 6, and 7 on Tables 4 and 5 or the variation on the punching and centering of the dies during the ring manufacturing. In fact, the variability of the process created asymmetric cross sections of the rings which facilitate the buckling concept approach.

[0092] Although the devices have been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the systems and methods are not limited to the disclosed embodiments, but on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present systems and methods contemplate that, to the extent possible, one or more features of any embodiment can be combined with one

or more features of any other embodiment.

THE INVENTION CLAIMED IS

1. A medical injection device comprising:
 - a housing having a proximal end, a distal end, and sidewall therebetween defining an interior;
 - a brake member received within the interior of the housing;
 - a cartridge holder received within the interior of the housing, distal of the brake member;
 - a cartridge received within the cartridge holder and holding a composition therein;
 - a load spring washer comprising:
 - a main body having a proximal surface and a distal surface; and
 - one or more protrusions extending proximally away from the proximal surface of the main body, the load spring washer received within the interior of the housing and positioned between the brake member and the cartridge holder such that, when the medical injection device is assembled, the one or more protrusions abuts the brake member and the distal surface abuts the cartridge and/or the cartridge holder;
 - an injection needle in fluid communication with the cartridge and arranged at a distal end of the housing; and
 - an actuation member arranged at the proximal end of the housing, the actuation member configured to actuate the medical injection device to deliver the composition through the injection needle.
2. The medical injection device of claim 1, wherein a cross-sectional profile of the one or more protrusions of the load spring washer, taken along a plane extending between the proximal surface and the distal surface, comprises a parallelogram.
3. The medical injection device of claim 1, wherein a cross-sectional profile of the one or more protrusions of the load spring washer, taken along a plane extending between the proximal surface and the distal surface, comprises a cylindrical shape.
4. The medical injection device of claim 3, wherein the cylindrical shape defines a hollow interior.

5. The medical injection device of claim 4, wherein the hollow interior is filled with a gas.
6. The medical injection device of claim 4, wherein the hollow interior comprises a vacuum.
7. The medical injection device of claim 1, wherein a cross-sectional profile of the one or more protrusions of the load spring washer, taken along a plane extending between the proximal surface and the distal surface, comprises a rhomboid.
8. The medical injection device of claim 1, wherein a cross-sectional profile of the one or more protrusions of the load spring washer, taken along a plane extending between the proximal surface and the distal surface, comprises an s-shape.
9. The medical injection device of claim 1, wherein a cross-sectional profile of the one or more protrusions of the load spring washer, taken along a plane extending between the proximal surface and the distal surface, comprises an l-shape.
10. The medical injection device of claim 1, wherein the main body of the load spring washer comprises a plurality of rings.
11. The medical injection device of claim 10, wherein the plurality of rings comprise concentric circles, with a gap between each of the concentric circles.
12. The medical injection device of claim 11, wherein at least one of the concentric circles has a width that is greater than a width of another of the concentric circles.

13. The medical injection device of claim 10, wherein a cross-sectional profile of the one or more protrusions of the load spring washer, taken along a plane extending between the proximal surface and the distal surface, comprises a u-shape, wherein the u-shape comprises:

a first arm connected to a first of the plurality of rings of the main body and a second arm connected to a second of the plurality of rings of the main body, both the first arm and the second arm extending parallel to a longitudinal axis defined by the proximal surface and the distal surface of the main body; and

a cross-member connected to the first arm and the second arm and extending perpendicular to the longitudinal axis defined by the proximal surface and the distal surface of the main body.

14. The medical injection device of claim 10, wherein the one or more protrusions of the load spring washer comprise an arch comprising:

a first arm connected to a first of the plurality of rings of the main body and a second arm connected to a second of the plurality of rings of the main body, both the first arm and the second arm extending parallel to a longitudinal axis defined by the proximal surface and the distal surface of the main body; and

a curved portion connected to the first arm and the second arm.

15. The medical injection device of claim 1, wherein the one or more protrusions of the load spring washer comprise a frustoconical portion.

16. The medical injection device of claim 1, wherein the load spring washer comprises an elastomeric material.

17. The medical injection device of claim 16, wherein the load spring washer comprises an ethylene propylene diene monomer rubber.

18. The medical injection device of claim 16, wherein the load spring washer has a Shore A hardness of 20-40.

19. A load spring washer configured for biasing an injection sub-assembly of a medical injection device, comprising:

a circular main body having a proximal surface and a distal surface, the distal surface configured to abut a cartridge holder and/or cartridge of a medical injection device; and
one or more protrusions extending proximally away from the proximal surface of the main body, wherein the one or more protrusions are configured to abut a brake member of a medical injection device.

20. The load spring washer of claim 19, wherein the load spring washer comprises an elastomeric material having a Shore A hardness of 20-40.