

SINGLE ATTACHMENT PART DRUG DELIVERY DEVICE

The present disclosure relates to a drug delivery device and in particular to a drug delivery device for oral administration. The drug delivery device is advantageously configured for
5 delivery of an active drug substance in the gastrointestinal tract including the stomach and/or intestines, such as the small intestines and/or the large intestines (colon).

BACKGROUND

A number of for example low permeable and/or low water soluble active drug substances are currently delivered by i.e. subcutaneous, intradermal, intramuscular, rectal, vaginal or
10 intravenous route. Oral administration has the potential for the widest patient acceptance and thus attempts to deliver low permeable and/or low water soluble active drug substances through the preferred oral route of administration has been tried but with limited success in particular due to lack of stability and limited absorption from the gastrointestinal tract.

15 Stability both relates to the stability of the active drug substance during manufacturing and storage of the delivery device, and to the stability of the active drug substance during the passage in the gastrointestinal tract before it become available for absorption.

Limited gastrointestinal absorption is due to the gastrointestinal wall barrier preventing active drug substance from being absorbed after oral dosing because of the low
20 permeability of the active drug substance, which is for example due to pre-systemic metabolism, size and/or the charges and/or because of the water solubility of the active drug substance.

Multiple approaches to solve these stability and absorption challenges have been suggested, but an effective solution to the challenges remain unresolved.

25 SUMMARY

Thus, there is an unmet need to provide a drug delivery device, which is capable of delivering drug substances for absorption in the gastrointestinal tissue. More generally, there remains a need for drug products and methods that enable enhanced drug delivery, when drug products are administered orally to patients.

A drug delivery device is disclosed. The drug delivery device has a central axis. The drug delivery device comprises a first body part. The drug delivery device comprises a second body part. The drug delivery device comprises an attachment part. The attachment part can be attached to the first body part. The attachment part can have a distal end. The
5 drug delivery device comprises an actuator mechanism. The actuator mechanism can be configured to rotate the first body part in relation to the second body part about a primary axis of the drug delivery device. The drug delivery device comprises only a single attachment part.

It is an advantage of the present disclosure that the drug delivery device secures stability
10 of the active drug substance during passage in the gastrointestinal tract and facilitates effective absorption of the active drug substance from the gastrointestinal tract after oral administration.

Further, it is advantage of the present disclosure that the drug delivery device provides an active attachment of the drug delivery device to the gastro-internal wall, such as the
15 stomach wall and/or intestine wall.

Further, the present disclosure advantageously provides oral delivery of low permeable active drug substances in or at the gastro-internal tissue.

Further, the present disclosure advantageously reduces complexity of the drug delivery device while maintaining effective usage, such as for the delivery of an active drug
20 substance.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other features and advantages of the present invention will become readily apparent to those skilled in the art by the following detailed description of exemplary embodiments thereof with reference to the attached drawings, in which:

25 Fig. 1 shows an exploded view of an exemplary drug delivery device,

Figs. 2A-2B show perspective views of an exemplary drug delivery device,

Fig. 3 shows an encapsulated drug delivery device,

Fig. 4 shows an exploded view of an exemplary drug delivery device having a rotatable attachment part,

Fig. 5A shows a drug delivery device,

Fig. 5B shows the drug delivery device of Fig. 5A in an exploded view, and

Figs. 6A-6C show differing views of an exemplary drug delivery device.

DETAILED DESCRIPTION

- 5 Various exemplary embodiments and details are described hereinafter, with reference to the figures when relevant. It should be noted that the figures may or may not be drawn to scale and that elements of similar structures or functions are represented by like reference numerals throughout the figures. It should also be noted that the figures are only intended to facilitate the description of the embodiments and the functionalities
- 10 associated therewith. They are not intended as an exhaustive description of the invention or as a limitation on the scope of the invention or the physical appearance of the invention. In addition, an illustrated embodiment needs not have all the aspects or advantages shown. An aspect or an advantage described in conjunction with a particular embodiment is not necessarily limited to that embodiment and can be practiced in any
- 15 other embodiments even if not so illustrated, or if not so explicitly described.

A drug delivery device having a central is disclosed. The drug delivery device comprises a first body part. The drug delivery device comprising a second body part. The drug delivery device comprises an attachment part. The attachment part can be attached to the first body part. The attachment part has a distal end. The drug delivery device comprises an

20 actuator mechanism. The actuator mechanism can be configured to rotate the first body part in relation to the second body part about a primary axis of the drug delivery device. The drug delivery device comprises only a single attachment part.

The drug delivery device may have a size and geometry designed to fit into a pharmaceutical composition for oral administration.

- 25 The drug delivery device/pharmaceutical composition may be configured to be taken into the body via the oral orifice. Thus, the outer dimensions of the drug delivery device/pharmaceutical composition may be small enough for a user to swallow. The drug delivery device may be adapted to carry a drug substance into the body of the user, via the digestive system, so that the drug delivery device may e.g. travel from the mouth of
- 30 the user into the stomach, via the oesophagus. The drug delivery device may further

travel into the intestines from the stomach, and may optionally travel into the bowels and out through the rectum.

The drug delivery device may be configured to deliver the drug in any part of the digestive system of the user, where in one example it may be configured to deliver a drug

- 5 substance into the stomach of the user. In another example, the drug delivery device may be adapted to initiate the drug delivery when the device has passed the stomach and has entered the intestine of the user. In other words, the drug delivery device may be configured to attach to a wall of the stomach or a wall of the intestines, e.g. depending on the desired release position of the active drug substance.

- 10 The attachment part (e.g., single attachment part, only attachment part) of the drug delivery device may be configured to interact with the inner surface linings of the gastrointestinal tract, so that the drug delivery device may e.g. be attached to the inner surface (mucous membrane) of the stomach, or alternatively to the mucous membrane of the intestines. The attachment part may be configured to interact with the mucous
- 15 membranes, e.g. in order to fix or attach the drug delivery device, e.g. for a period of time, inside the body of the user. By attaching the drug delivery device, it will allow a drug substance to be delivered into a part of the digestive system, in order to provide a drug substance to the body of the user. The attachment part may be configured to interact with the mucous membranes, e.g. in order to inject drug substance into the gastrointestinal
- 20 tract wall.

- As discussed herein, the attachment part is considered the only attachment part on the drug delivery device. Therefore, the attachment part is the only attachment part on the drug delivery device. The attachment part is a single attachment part. The drug delivery device can include the attachment part and no other attachment parts. The drug delivery
- 25 device can include only one attachment part. The drug delivery device may include other features, but only a single attachment part configured to interact with tissue. Attachment part and single attachment part may be used interchangeably.

- There are difficulties in using a single attachment part drug delivery device that have been overcome by the disclosure. As a non-limiting example, the drug delivery device may
- 30 have modified inertia, such as due to weight, increased friction elements, outdents, and/or other features, between portions of the drug delivery device. Further, the attachment part may have proper force to penetrate tissue with only a single attachment part. Moreover, over-rotating may be limited or reduced in the drug delivery device.

The drug delivery device has a central axis optionally extending from a first end to a second end of the drug delivery device. The drug delivery device may have a length (e.g. largest extension from first end to second end along central axis), in the range from 3 mm to 35 mm, such as in the range from 5 mm to 26 mm. The drug delivery device may be
5 elongated.

The drug delivery device may have a width and/or height (e.g. largest extensions along width axis and height axis, respectively) in the range from 1 mm to 20 mm. Height and width are the largest extensions of the drug delivery device perpendicular to the central axis.

- 10 In one or more exemplary drug delivery devices, the dimensions of the drug delivery device, at least in an initial state or first state prior to actuation of the attachment part, may be represented by a length (largest extension along central axis), a width (largest extension along width axis perpendicular to the central axis) and a height (largest extension along height axis perpendicular to the central axis and the width axis). The
15 height of the drug delivery device may be in the range from 1 mm to 15 mm. The width of the drug delivery device may be in the range from 1 mm to 15 mm.

- In one or more exemplary drug delivery devices, the drug delivery device may be constructed in a way that secures the drug delivery part to deliver a payload or active drug substance into the internal tissue or internal surface for distribution of the active drug
20 substance in the subject through the blood vessels.

- Advantageously, the drug delivery device may be attached, and may deliver the active drug substance, to a particular location in a patient's intestinal wall. Of course, the delivery device may be attached, and may deliver the active drug substance, to other places as well. In one or more exemplary drug delivery devices, the drug delivery device, such as
25 the spike, may penetrate the muscularis mucosa. In one or more exemplary drug delivery devices, the drug delivery device, such as the spike, may not penetrate the muscularis externa. In one or more exemplary drug delivery devices, the spike may be positioned in the submucosa. In one or more exemplary drug delivery devices, the spike may be positioned in the submucosa parallel to the gut wall.

- 30 The drug delivery device comprises a first body part. The first body part may be a two-part body part, i.e. the first body part may comprise a first primary body part and a first

secondary body part. The first body part has an outer surface. A first primary recess and/or a first secondary recess may be formed in the outer surface of the first body part.

The drug delivery device optionally comprises a shell having a first shell part. An outer surface of the first body part may constitute at least a part of the first shell part.

- 5 The drug delivery device comprises an attachment part. The attachment part may comprise a base part and/or a needle, e.g. a spike. The attachment part has a proximal end and a distal end. Accordingly, the drug delivery device may have only one, or a single, base part and needle (e.g. spike).

The attachment part, such as the needle or spike, optionally has or extends along an
10 attachment axis. A tip of the needle forms the distal end. In other words, the distal end is a tip of the needle. The base may be arranged at or constitute the proximal end of the attachment part. The needle may have a length in the range from 1 mm to 15 mm such, as in the range from 3 mm to 10 mm. Thereby sufficient penetration into the internal tissue may be provided for while at the same time reducing the risk of damaging the internal
15 tissue. The distal end of the attachment part may be provided with a tip configured to penetrate a biological tissue. The distal end of the attachment part may be provided with a gripping part configured to grip a biological tissue.

The needle may have a cross-sectional diameter in the range from 0.1mm to 5mm, such as in the range from 0.5mm to 2.0mm.

- 20 The needle may be straight and/or curved. The needle may comprise a primary section that is straight. The needle may comprise a secondary section, e.g. between the primary section and the distal end or between the base and the primary section. The secondary section may be curved.

The needle may include two or more straight portions formed at an angle. For example,
25 the needle may have a proximal portion that extends at a first angle from a connection point to the drug delivery device and a distal portion that extends at a second angle from a connection point to the drug delivery device. The first angle and the second angle may be different. The proximal portion may connect to the distal portion at a joint (e.g., bend, connection, angle) and have a joint angle between the proximal portion and the distal
30 portion. The joint angle may be an acute angle, an obtuse angle, or a right angle. The angle may be, for example, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 130 140, 150,

160, or 170 degrees. This can advantageously allow for different angles of attach when the needle interacts with inner surface linings. This may allow for improved attachment of the drug delivery device, while helping to reduce or avoid tissue damage. Further, the joint may be flexible. Alternatively, the joint may not be flexible.

- 5 The joint may be located at a center, or generally at a center, of a length of the needle. Alternatively, the joint may be located 40, 45, 55, 60, or 65% up a length of the needle from the proximal end.

In one or more exemplary attachment part, the needle may have three, four, or five different portions at different angles, each connected by a joint. In some iterations, any or
10 all of the different portions may be straight or curved. Each joint may be flexible or not flexible.

The attachment part of the drug delivery device may be seen as any kind of attachment part that may be capable of attaching the drug delivery device to a biological tissue, such as a stomach wall, a wall of the bowels and/or intestines of a human or animal body. The
15 attachment part may be adapted to extend in a direction away from the central axis of the drug delivery device, and/or a central axis of the attachment part. This may mean that the attachment part, e.g. at least in an activated state or second state of the drug delivery device, may extend in a direction away from a peripheral surface (in radial direction) of the first body part and/or the second body part, so that the attachment part extends farther in
20 a radial direction than the peripheral or outer surface of the body part.

The attachment part may be fixed or rotationally attached to the first body part.

In one or more exemplary drug delivery devices, the drug delivery device comprises a second body part. The second body part may be a two-part body part, i.e. the second body part may comprise a second primary body part and a second secondary body part.
25 The attachment part may be fixed or rotationally attached to the second body part instead of the first body part. A second primary recess and/or a second secondary recess may be formed in the outer surface of the second body part.

Accordingly, the attachment part may be fixed or rotationally attached to either the first body part or the second body part. The attachment part may be fixed or rotationally
30 attached to only one of the first body part or the second body part. As mentioned above, the drug delivery device has only a single attachment part, attached to one of the first

body part or the second body part. If the attachment part is attached to the first body part, the second body part will not have an attachment part attached. If the attachment part is attached to the second body part, the first body part will not have an attachment part attached.

- 5 In one or more exemplary drug delivery devices, the actuator mechanism is configured to rotate the first body part in relation to the second body part about a primary axis of the drug delivery device. The primary axis may be parallel to and/or coinciding with the central axis.

- In one or more exemplary drug delivery devices, the first body part is configured to rotate
10 in a first direction and/or the second body part is configured to rotate in a second direction opposite to the first direction.

- The drug delivery device may comprise a frame part, where different parts, such as the first body part and/or the second body part are attached, e.g. fixed or rotatably attached to the frame part. In one or more exemplary drug delivery devices, the actuator mechanism,
15 or parts thereof, may be attached to the frame part. Thereby, separate rotation of the first body part and the second body part in relation to the frame part may be provided for

- The rotational connection between the first body part and the second body part allows the first body part to rotate relative to the second body part, without the two parts separating from each other before the attachment part interacts with the internal tissue, such as
20 mucous membranes. Such a connection may be obtained in a plurality of ways, where in one example the first body part has a plug connection and the second body part has a socket connection, where this plug and socket configuration allows the first body part to rotate relative to the second body part. A second example could be to provide an axle that may be coaxial with the central axis and/or the primary axis, where the first body part and
25 the second body part are configured to receive the axle, and a stopping device is arranged at first and second ends of the axle, on each side of the combined first and second body part, preventing the first body part and the second body part to slide in a longitudinal direction along the axle. The axle may be integrated in the first body part or in the second body part.

- 30 If an axle were used, the axle can be made of any number of different materials. For example, the axle can be made of metals and/or alloys and/or polymers and/or composites and/or composites and/or combinations thereof.

The first and/or the second body part may be arranged to rotate freely relative to each other, e.g. at least in the second state, and thereby allowing the attachment part to rotate. For example, if the attachment part is on the first body part, it can rotate relative to the second body part. Alternatively, if the attachment part is on the second body part, it can
5 rotate relative to the first body part.

Thus, the attachment part may be adapted to come into contact and/or penetrate tissue of the gastrointestinal tract. The rotation of the body parts relative to each other using a resilient force may move the attachment part in such a way that it is capable of penetrating the mucous membrane in order to fix the drug delivery device at a location in
10 the gastrointestinal tract, such as the stomach or intestines. The penetrating force may come from the actuator mechanism/resilient part, where the resilient part may be adapted to store a resilient force that is capable of forcing the attachment part towards tissue when the resilient force of the resilient part has been at least partly unleashed. The resilient part may e.g. be in the form of a spring or spring element, for example a torsional spring or a
15 power spring, where the spring may be wound up to store mechanical energy, where the mechanical energy may be transmitted to the first and/or the second body part. When the mechanical energy is released, the first body part may rotate relative to the second body part, and where the mechanical energy may be transferred into the attachment part via the body parts. The actuator mechanism can comprise a resilient part configured to apply
20 force to the first body part and/or the second body part.

Within the context of the present description the term "rotational force" may be seen as Torque, moment, moment of force, rotational force or "turning effect". Another definition of the term "rotational force" may be the product of the magnitude of the force and the perpendicular distance of the line of action of force from the axis of rotation. The rotational
25 force may be seen as the force which is transferred from the resilient part to the attachment part of the drug delivery device via the body parts.

The rotational force may be defined as being large enough to penetrate into the gastrointestinal tissue. When the rotational force is applied to both the first and the second body part, the attachment part may come into contact with the surface to be attached to.
30 In one or more exemplary drug delivery devices, the drug delivery device may include one or more resistive features. The one or more resistive features can be configured to change the resistance to motion of at least a portion of the drug delivery device. The one or more resistive features may be located on the first body part. The one or more resistive

features may be located on the second body part. The one or more resistive features may be located on the first body part and the second body part. In one or more exemplary drug delivery devices, the drug delivery device may not include any resistive features. In one or more example drug delivery devices, the first body part and/or the second body part can
5 include a resistive feature.

In one or more example drug delivery devices, the resistive feature can be selected from one or more of: a high friction surface, a feature configured to change inertia, and a feature configured to create turbulent flow. The resistive feature can include micro and/or micro spikes. The resistive feature can include flexible mine-tubes. The resistive feature
10 can include a bio adhesive feature. The resistive feature can be a retentive element or a retentive feature.

For example, the drug delivery device may include a high friction surface. This surface may have higher friction than any other surface of the drug delivery device. For example, the high friction surface may include one or more of: bumps, corrugations, protrusions,
15 films, paddles, fins, and bulges.

In one or more example drug delivery devices, the resistive feature can be one or more barbs (or spikes). The one or more barbs can be positioned in an opposite direction relative to the attachment part to resist movement upon completion of rotation of the first body part or second body part when counter rotation occurs.

20 In one or more example drug delivery devices, the resistive feature can include weight displacement of the drug delivery device.

In one or more example drug delivery devices, the attachment part can include a feature configured to lower resistance of the attachment part. For example, the attachment part can be a small gauge. Further, the attachment part may include a piercing and/or a cutting
25 feature. This can be used in conjunction with the resistive feature, or alternative to the resistive feature.

In one or more example drug delivery devices, the second body part can have a higher inertia than the first body part. In one or more example drug delivery devices, the first body part can have a lower inertia than the second body part.

30 For example, the first body part and/or the second body part may include an outdent. The outdent can be configured to push the attachment part toward

For example, the first body part may have a lower weight than the second body part. The drug delivery device may have an off-centered weight balance. The first body part and the second body part may have different surface ratios. The first body part may have a pin connection to the second body part. The drug delivery device may be shaped and/or
5 configured to generate turbulent movement. For example, the drug delivery device may be egg shaped. The drug delivery device may be shaped like a spinning top.

In one or more example drug delivery devices, the second body part can have a higher weight than the first body part. In one or more example drug delivery devices, the second body part can have a lower weight than the first body part. In one or more example drug
10 delivery devices, the second body part can have a higher or lower weight than the first body part.

In one or more example drug delivery devices, the second body part can have a higher density than the first body part. In one or more example drug delivery devices, the second body part can have a lower density than the first body part.

15 In one or more example drug delivery devices, the drug delivery device may have a density greater than body tissue. For example, the drug delivery device can have a density greater than stomach tissue. The drug delivery device can have a density greater than intestinal tissue, such as one or more of the small intestine and large intestine.

The drug delivery device can have a density greater than liquid held within the
20 gastrointestinal system. This may advantageously allow for the drug delivery device to reside at the bottom of a given organ, such as adjacent to tissue.

For example, the drug delivery device may have a density greater than gastric acid, such as stomach acid, in the stomach. The drug delivery device may have a density greater than fluids and/or liquids held, such as retained, within the stomach. The drug delivery
25 device may have a density that allows the drug delivery device to reside at a bottom of the stomach.

For example, the drug delivery device may have a density greater than fluids and/or liquids held, such as retained, within the intestine, such as one or more of the small intestine and the large intestine. The drug delivery device may have a density that allows
30 the drug delivery device to reside at a bottom of the intestine, such as one or more of the small intestine and the large intestine.

In one or more exemplary drug delivery devices, a distance between the attachment axis of the attachment part and the primary axis, e.g. at least in an activated state or second state of the drug delivery device and optionally in an initial state of the drug delivery device, is larger than 0.5 mm.

In one or more exemplary drug delivery devices, the attachment part is rotationally attached to the first body part, e.g. via a first joint connection having a first rotation axis. In one or more exemplary drug delivery devices, the attachment part is rotationally attached to the first body part via a hinge and configured to rotate about a first rotation axis perpendicular or parallel to the primary axis. In other words, the attachment part is optionally configured to rotate about a first rotation axis, e.g. in relation to the first body part. The first rotation axis may be parallel to the central axis and/or the primary axis. The first rotation axis may form a first angle with the central axis and/or the primary axis. The first angle may be less than 15°. The first angle may be in the range from 75° to 105°, such as 90°±5° or 90°.

In one or more exemplary drug delivery devices, the first body part may define a first body recess (e.g., cavity, slot, hole) extending to an outer surface of the first body part. The first body recess may be formed by solid walls on all sides except an outermost surface which is open. The attachment part may be rotationally connected within the first body recess along a first attachment part axis. The first attachment part axis may be, for example, a pin (e.g., arm, support). The first attachment part axis may be parallel to the central axis and/or the primary axis. The first attachment part axis may be angled with respect to the central axis and/or the primary axis. Accordingly, the attachment part may be configured to rotate within the recess along the first attachment part axis. Further, rotation of the attachment part may be stopped at end surfaces of the recess.

The first body recess may extend along a portion of the outer surface of the first body. The first body recess may extend fully along an outer circumference of the first body. The first body recess may extend around 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100% of an outer circumference of the first body. The first body recess may extend around greater than 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, or 95% of an outer circumference of the first body. The first body recess may extend around less than 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100% of an outer circumference of the first body.

The first body recess may extend from an outer surface toward the central axis through 5, 10, 15, 20, 25, 30, 35, or 40% of the drug delivery device. The first body recess may extend from an outer surface toward the central axis through greater than 5, 10, 15, 20, 25, 30, 35, or 40% of the drug delivery device. The first body recess may extend from an
5 outer surface toward the central axis through less than 5, 10, 15, 20, 25, 30, 35, or 40% of the drug delivery device.

In one or more exemplary drug delivery devices, the first body recess may extend circumferentially, or partially circumferentially around the first body with the central axis being the longitudinal direction. The first body recess may extend perpendicularly with
10 respect to the central axis and/or the primary access (e.g., may extend along a cross section of the drug delivery device perpendicular to the central axis and/or the primary access). The first body recess may have any number of shapes. For example, the first body recess can be a portion of a circle, such as a half circle. The first body recess can be a triangle. The first body recess can be a sector of a circle. The first body recess can be a
15 curved edge connected by two straight edge. The first body recess can be two curved edges connected to each other by two straight edges.

Thus, the attachment part may rotate on the first attachment part axis in order to move perpendicular to the central axis and/or the primary axis. In certain embodiments, the attachment part may rotate at an angle between perpendicular and parallel with respect to
20 the central axis and/or the primary axis.

In one or more exemplary drug delivery devices, when the first body part and/or the second body part rotate with respect to one another, the attachment part can rotate out of its recess (e.g., first body recess or second body recess) due to the rotation of the first body part and/or the second body part. The continued rotation of the first body part and/or
25 the second body part then causes the attachment part to pierce tissue to hold the drug delivery device in place.

In one or more exemplary drug delivery devices, the attachment part extends, e.g. at least in an activated state of the drug delivery device and optionally in an initial state of the drug delivery device, in a direction away from the first body part. In other words, the needle
30 may extend, e.g. at least in an activated state of the drug delivery device and optionally in an initial state, from an outer surface of the first body part. Formulated differently, the first attachment part axis may, e.g. at least in an activated state of the drug delivery device and optionally in an initial state of the drug delivery device form an angle of at least 45°

with the central axis and/or the primary axis. An attachment part extending in a direction is to be understood as the direction from proximal end of attachment part/needle part to distal end of attachment part along the attachment axis of the attachment part.

The attachment part may in a first state of the drug delivery device extend in a first
5 primary direction and in a second state of the drug delivery device extend in a first secondary direction. The first primary direction and the first secondary direction may form an angle of at least 30° . The first primary direction may be parallel or substantially parallel to the central axis. The first primary direction may form an angle less than 60° with the central axis. The first secondary direction may form an angle of at least 60° such as about
10 90° with the central axis. The first secondary direction may be perpendicular to the central axis.

The distal end of the attachment part may be configured to move or be moved from a first primary position in a first state of the drug delivery device to a first secondary position in the second state.

15 In one or more exemplary drug delivery devices, the attachment part is rotationally attached to the second body part instead of the first body part, e.g. via a joint connection, such as a hinge, having a rotation axis. In other words, the attachment part is optionally configured to rotate about a second rotation axis, e.g. in relation to the second body part. The second rotation axis may be parallel to the central axis and/or the primary axis. The
20 second rotation axis may form a second angle with the central axis and/or the primary axis. The second angle may be less than 15° . The second angle may be in the range from 75° to 105° , such as $90^\circ \pm 5^\circ$ or 90° .

In one or more exemplary drug delivery devices, the second body part may define a second body recess (e.g., cavity, slot, hole) extending to an outer surface of the second
25 body part. The second body recess may be formed by solid walls on all sides except an outermost surface which is open. The attachment part may be rotationally connected within the second body recess along a second attachment part axis. The second attachment part axis may be, for example, a pin (e.g., arm, support). The second attachment part axis may be parallel to the central axis and/or the primary axis. The
30 second attachment part axis may be angled with respect to the central axis and/or the primary axis. Accordingly, the attachment part can be configured to rotate within the

recess along the second attachment part axis. Further, rotation of the attachment part may be stopped at end surfaces of the second body recess.

The second body recess may extend along a portion of the outer surface of the second body. The second body recess may extend fully along an outer circumference of the
5 second body. The second body recess may extend around 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100% of an outer circumference of the second body. The second body recess may extend around greater than 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, or 95% of an outer circumference of the second
10 body. The second body recess may extend around less than 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100% of an outer circumference of the second body.

The second body recess may extend from an outer surface toward the central axis through 5, 10, 15, 20, 25, 30, 35, or 40% of the drug delivery device. The second body
15 recess may extend from an outer surface toward the central axis through greater than 5, 10, 15, 20, 25, 30, 35, or 40% of the drug delivery device. The second body recess may extend from an outer surface toward the central axis through less than 5, 10, 15, 20, 25, 30, 35, or 40% of the drug delivery device.

In one or more exemplary drug delivery devices, the second body recess may extend circumferentially, or partially circumferentially around the second body with the central
20 axis being the longitudinal direction. The second body recess may extend perpendicularly with respect to the central axis and/or the primary access (e.g., may extend along a cross section of the drug delivery device perpendicular to the central axis and/or the primary access). The second body recess may have any number of shapes. For example, the second body recess can be a portion of a circle, such as a half circle. The second body
25 recess can be a triangle. The second body recess can be a sector of a circle. The second body recess can be a curved edge connected by two straight edge. The second body recess can be two curved edges connected to each other by two straight edges.

Thus, the attachment part may rotate on the second attachment part axis in order to move perpendicular to the central axis and/or the primary axis. In certain embodiments, the
30 attachment part may rotate at an angle between perpendicular and parallel with respect to the central axis and/or the primary axis.

- In one or more example drug delivery systems, the first body part may have a first body recess while the second body part does not have a second body recess. In one or more example drug delivery systems, the second body part may have a second body recess while the first body part does not have a first body recess. The body part with the
- 5 particular recess can be dependent on which body part includes the attachment part. For example, if the attachment part is on the first body part, the first body part may have the first body recess while the second body part does not have the second body recess. Alternatively, if the attachment part is on the second body part, the second body part may have the second body recess while the first body part does not have the first body recess.
- 10 In one or more exemplary drug delivery devices, when the first body part and/or the second body part rotate with respect to one another, the attachment part can rotate out of its respective recesses (e.g., first body recess and second body recess) due to the rotation of the first body part and/or the second body part. The continued rotation of the first body part and/or the second body part then causes the attachment part to pierce
- 15 tissue to hold the drug delivery device in place.

- In one or more exemplary drug delivery devices, the attachment part extends, e.g. at least in an activated state of the drug delivery device and optionally in an initial state of the drug delivery device, in a direction optionally away from the second body part. In other words, the needle may extend, e.g. at least in an activated state of the drug delivery device and
- 20 optionally in an initial state, from an outer surface of the second body part. Formulated differently, the second attachment axis may, e.g. at least in an activated state of the drug delivery device and optionally in an initial state of the drug delivery device form an angle of at least 45° with the central axis and/or the primary axis.

- The attachment part may in a first state of the drug delivery device extend in a second
- 25 primary direction and in a second state of the drug delivery device extend in a second secondary direction. The second primary direction and the second secondary direction may form an angle of at least 30°. The second primary direction may be parallel or substantially parallel to the central axis. The second primary direction may form an angle less than 60° with the central axis. The second secondary direction may form an angle of
- 30 at least 60°, such as about 90° with the central axis. The second secondary direction may be perpendicular to the central axis.

The distal end of the attachment part may be configured to move or be moved from a second primary position in a first state of the drug delivery device to a second secondary position in the second state.

The drug delivery device comprises an actuator mechanism. The actuator mechanism is
5 configured to move the attachment part in relation to the second body part or the first body part, e.g. at least during a part of a rotation, such as in a first rotation and optionally in a second rotation. In one or more exemplary drug delivery devices, the actuator mechanism is configured to move the distal end by rotating, e.g. in a second state of the drug delivery device, the first body part in relation to the second body part and/or vice
10 versa. The actuator mechanism may be configured to rotate the first body part at least 90°, such as at least 450°, at least 810°, at least 1170°, at least 1530°, or even at least 1890° in relation to the second body part about the primary axis. The actuator mechanism may be configured to rotate the first body part in relation to the second body part about the primary axis in a stepwise manner. In other words, to rotate the first body part in
15 relation to the second body part about the primary axis may comprise a plurality of rotations including a first rotation and a second rotation, e.g. a first rotation followed by a first time period with reduced or no rotation followed by a second rotation. A first rotation followed by a second rotation after a first time period may increase the possibility of the drug delivery device attaching to the biological tissue. The first time period or in general
20 time periods between rotations allows the drug delivery to move to other positions in the gastrointestinal tract. In other words, if the drug delivery does not attach to the biological tissue during a first rotation, further rotations increase the chance of attachment to the internal tissue. The first rotation may be at least 90°, and the second rotation may be at least 180°. The plurality of rotations may comprise a third rotation. The third rotation may
25 be at least 180°.

The actuator mechanism optionally comprises a resilient part such as a spring element configured to apply force to the first body part and/or the second body part. The resilient part may comprise a first part, such as a first end, connected to the first body part. The resilient part may comprise a second part, such as a second end, connected to the
30 second body part.

In one or more exemplary drug delivery devices, the actuator mechanism optionally comprises a swelling media, i.e. a media increasing its volume, e.g. upon contact with a fluid, e.g. in order to provide rotation of parts in relation to each other. In one or more

exemplary drug delivery devices, a swelling medial provides rotation of the attachment part in relation to the first body part or provides rotation of the attachment part in relation to the second body part. In one or more exemplary drug delivery devices, a swelling medial provides rotation of the first body part in relation to the second body part.

- 5 The actuator mechanism, such as the resilient part, may be configured to rotate the attachment part about the first rotation axis in relation to the first body part.

The actuator mechanism, such as the resilient part, may be configured to rotate the attachment part about the second rotation axis in relation to the second body part.

- In one or more exemplary drug delivery devices, the drug delivery device comprises a first
10 compartment, the drug delivery device being configured to deliver an active drug substance from the first compartment to the surroundings of the drug delivery device. The first compartment may be arranged in the attachment part, such as in the first needle, e.g. within a distance of 8 mm, such as within 5 mm, from the first distal end. The attachment part, such as the first needle may have one or more openings providing access to the first
15 compartment. In one or more exemplary drug delivery devices, the first compartment is formed as a through-going bore in the first needle.

- The first compartment may be arranged in any part of the drug delivery device, such as in the form of a cavity inside a volume of the first body part, the second body part or both of the first body part and the second body part. Additionally, or alternatively, the first
20 compartment may be a compartment which is inside the attachment part, where the penetration of the attachment part into a biological tissue may release a drug substance in the first compartment into the biological tissue. Additionally or alternatively, the first compartment may be compartment that is in the form of a depression or opening or spike or hollow spike on the outer surface of the first and/or the second body part, where the
25 drug delivery device may be adapted to release the drug substance inside the organ of the body which the drug delivery device is adapted to pass through.

- In one or more exemplary drug delivery devices, the first compartment may be open from an inner volume of the drug delivery device and towards an outer part of the drug delivery device. In one or more examples, the first compartment may be inside the first body part,
30 and where the first compartment is in fluid connection with the attachment part, so that when the distal end of the attachment part has penetrated the biological tissue, the drug substance may be released from the first compartment and into the biological tissue via

the attachment part. This may e.g. be where the attachment part is a tubular part, which has a distal end in fluid communication with the first compartment of the drug delivery device.

In one or more exemplary drug delivery devices, the drug delivery device comprises a second compartment, the drug delivery device being configured to deliver an active drug substance from the second compartment to the surroundings of the drug delivery device. The second compartment may be arranged in the attachment part, such as in the needle, e.g. within a distance of 8 mm, such as within 5 mm, from the distal end. The attachment part, such as the needle may have one or more openings providing access to the second compartment. In one or more exemplary drug delivery devices, the second compartment is formed as a through-going bore in the needle.

In one or more exemplary drug delivery devices, the rotational force of the first body part and the second body part may force the active drug substance out of the drug delivery device, such as out of the first compartment or the second compartment. For example, kinetic force of the rotation can eject (e.g., expel, release, force out) the active drug substance from the drug delivery device, such as out of the first compartment or the second compartment. The kinetic force may come from a force independent of the rotation.

The drug delivery device may have a first compartment or a second compartment. For example, if the attachment part is attached to the first body part, the drug delivery device may have a first compartment but not a second compartment. For example, if the attachment part is attached to the second body part, the drug delivery device may have a second compartment but not a first compartment.

In one or more exemplary drug delivery devices, the drug delivery device has a first state, also denoted initial state, where the first body part and the second body part are rotationally stationary relative to each other and a second state, also denoted activated state, where the first body part and the second body part are rotationally mobile relative to each other, e.g. can rotate about the primary axis of the drug delivery device. In other words, the first body part may be locked, e.g. prevented from rotating, in relation to the second body part. The first state may e.g. be an initial state or introduction state, where the drug delivery device is adapted to be introduced into the body, and where the first body part and the second body part are stationary relative to each other. In the first state

the resilient part may have a predefined amount of stored energy, where the energy level is stationary in the resilient part while the body parts are stationary.

In one or more example drug delivery devices, the drug delivery device can have a first state where the first body part and the second body part are rotationally stationary relative to each other and a second state where the first body part and the second body part are rotationally mobile relative to each other.

In one or more exemplary drug delivery devices, the drug delivery device has a first state where the resilient part has a constant resilient force load and a second state where the resilient part at least partly releases the resilient force load. In other words, the resilient part may be biased or preloaded in the first state of the drug delivery and upon release, e.g. by release of a locking mechanism, (i.e. the drug delivery device being in the second state) the force from the resilient part may affect a rotation of the first body part in relation to the second body part, i.e. including a movement of the first distal end towards the second distal.

In one or more exemplary drug delivery devices, the actuator mechanism is configured to move the distal end from a primary position, e.g. in first state of the drug delivery device, with a primary radial distance from a central axis of the delivery device to a secondary position, e.g. in second state of the drug delivery device, with a secondary radial distance from the central axis and/or primary axis, wherein the secondary radial distance is larger than the primary radial distance. Thus, the distal end of the attachment may be in a primary position when the drug delivery device is in the first state and/or the distal end of the attachment part may be in a secondary position when the drug delivery device is in the second state.

The primary radial distance may be less than 10 mm, such as less than 8 mm or even less than 5 mm. The secondary radial distance may be larger than the primary radial distance. The secondary radial distance may be larger than 5 mm, such as larger than 6 mm, or larger than 8 mm. In one or more exemplary drug delivery devices, the secondary radial distance is in the range from 6 mm to 15 mm.

In one or more exemplary drug delivery devices, the attachment part, such as a part of the needle and/or the distal end, may, in the first state be arranged or at least partly arranged within a first body recess of the first body part. In the first state, the distal end may be arranged inside the first body part.

In one or more exemplary drug delivery devices, the attachment part, such as a part of the needle and/or the distal end, may, in the second state be arranged or at least partly arranged outside the first body recess of the first body part.

In one or more exemplary drug delivery devices, the attachment part, such as a part of the
5 needle and/or the distal end, may, in the first state be arranged within a second body recess of the second body part. Thereby, the attachment part may be configured to lock the first body part in relation to the second body part in the first state of the drug delivery device.

In one or more exemplary drug delivery devices, the attachment part, such as a part of the
10 needle and/or the distal end, may, in the second state be arranged outside the second body part and/or at least outside the second body recess of the second body part.

In one or more exemplary drug delivery devices, the actuator mechanism is configured to move, e.g. by rotation about a first rotation axis of the attachment part (base part), the distal end from a primary angular position of primary position to a secondary angular
15 position of secondary position in relation to a proximal end of the attachment part. An angle between the primary angular position and the secondary angular position may be larger than 10°, such as larger than 45° or larger than 60°.

In one or more exemplary drug delivery devices, the drug delivery device comprises a locking mechanism. The locking mechanism may be configured to lock, e.g. prevent
20 rotation of, the first body part in relation to the second body part in a first state of the drug delivery device. The locking mechanism may be configured to lock the attachment part in a primary position, e.g. in relation to the first body part, when the drug delivery device is in the first state. Upon release of the locking mechanism, the attachment part may be allowed to move from a primary position to a secondary position. The locking mechanism
25 may upon release be configured to allow rotation of the first body part in relation to the second body part, e.g. in a second state of the drug delivery device.

The locking mechanism may comprise a first locking element optionally configured to lock and/or unlock (release) the first body part in relation to the second body part. The first locking element may be configured to lock and/or unlock (release) the attachment part in
30 relation to the first body part or the second body part. The first locking element may be arranged in a first primary recess of the first body part and/or in a second primary recess of the second body part. The first locking element may be configured to dissolve when the

drug delivery device enters the gastrointestinal tract or at a desired location in the gastrointestinal tract, thereby releasing the first body part in relation to the second body part and allowing the actuator mechanism to rotate the first body part in relation to the second body part and thereby moving the distal end resulting in attachment of the drug
5 delivery device to the internal tissue.

The first locking element may be a first locking band (e.g., ring, loop, partial ring, partial loop). The first locking band may have a circumferential length greater than a longitudinal width. For example, the circumferential length may be 2x, 3x, 4x, 5x, 6x, 7x, 8x, 9x, or 10x the longitudinal width.

- 10 The first locking band may fit on an outer surface of the drug delivery device. For example, the first locking band may be located on an outer surface of the first body part or the second body part. The first locking band may be mechanically fit onto the drug delivery device. For example, the first locking band may be snap fit onto the drug delivery device. The first locking band may be chemically attached onto the drug delivery device.
- 15 In one or more exemplary drug delivery devices, the first locking band could be in the shape of a capsule part. For example, the first locking band could form a first half of a capsule. The first locking band could form a first half of a capsule and a second locking band could form a second half of the capsule. When fitted together, the first locking band and the second locking band could form a full capsule.
- 20 The first locking band may partially or fully cover the first body recess if located on the first body. Thus, the first locking band may prevent motion of the attachment part if in the first body part. The first locking band may partially or fully cover the second body recess if located on the second body. Thus, the first locking band may prevent motion of the attachment part if in the second body part.
- 25 The first locking band may extend fully along an outer circumference of the drug delivery device. The first locking band may extend around 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100% of an outer circumference of the drug delivery device. The first locking band may extend around greater than 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, or 95% of an outer circumference of the drug
30 delivery device. The first locking band may extend around less than 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100% of an outer circumference of the drug delivery device.

In one or more exemplary drug delivery devices, the first locking band may include one or more locking protrusions (e.g., extensions, tabs, fingers, projections, teeth). For example, the first locking band may include 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 locking protrusions. The locking protrusions may only extend longitudinally from one side of the first locking band.

- 5 The locking protrusions may extend longitudinally from both sides of the first locking band. The locking protrusions may be equally spaced along the first locking band. The locking protrusions may be unequally spaced along the first locking band.

- The one or more locking protrusions may extend towards a longitudinal center of the drug delivery device (e.g., along an outer surface of the body towards the second body part if
10 the first locking band is located on the first body part, or along an outer surface of the body towards the first body part if the first locking band is located on the second body part).

- The one or more locking protrusions may be triangular, square, rectangular, rounded, or other polygonal shapes. The one or more locking protrusions may vary in shape along the
15 first locking band.

- In one or more exemplary drug delivery devices, the drug delivery device may include mating features. The mating features can be configured to mate with the one or more protrusions of the first locking band. The mating features can include one or more mating protrusions (e.g., extensions, tabs, fingers, projections, teeth) extending radially outward
20 from an outer surface of the drug delivery device. The mating features can extend from the first body part, the second body part, or both. The mating features can be formed in one or more circumferential rows. For example, there can be one circumferential row of mating features or two circumferential rows of mating features. Both circumferential rows can be on the same body part (e.g., the first body part or the second body part). In
25 alternative implementations, one circumferential row of mating features can be on the first body part and a second circumferential row of mating features can be on the second body part.

- The one or more mating protrusions may be triangular, square, rectangular, rounded, or other polygonal shapes. The one or more mating protrusions may vary in shape along the
30 first locking band. The one or more mating protrusions may be angled in a circumferential direction to form a mating recess (e.g., curve, cavity, space, gap). This mating recess can help lock the one or more mating protrusions to the one or more protrusions of the first locking band. Further, the mating recess can prevent unwanted release of the first locking

band. Accordingly, when the first locking band is attached to the drug delivery device, the one or more locking protrusions can fit between the one or more mating protrusions. The one or more locking protrusions can fit within adjacent mating protrusions. This can prevent rotation of the first body with respect to the second body. For example, the first
5 body will be impeded in rotating by the first locking band. In some embodiments, the locking protrusion can be located between two mating protrusions, each of the mating protrusions angled in opposite directions to hold the locking protrusion in place.

In some implementations the mating features may be recesses extending internally into the drug delivery device. The locking protrusions can then extend radially inward instead
10 of longitudinally to mate with the mating features.

As discussed above, when the first locking band is attached and the one or more protrusions mate with the mating features, the first body part is locked in place with relation to the second body part. The first body part and the second body part may be released from the first locking band when the first locking band dissolves as discussed
15 herein.

Further, the dissolving of the first locking band can allow the attachment part to further rotate out of one of the first body recess or second body recess. Thus, when the first body and the second body rotate with respect to one another, the attachment part can rotate for inserting into tissue.

20 In one or more exemplary drug delivery devices, the first locking band can include a plurality of square-shaped locking protrusions and a plurality of triangle-shaped locking protrusions. The square-shaped locking protrusions may be used to keep the cover in place under the force of the mating protrusions. The triangle-shaped locking protrusions may be used to properly locate the first locking band.

25 In one or more exemplary drug delivery systems, the whole of the first locking band can be dissolvable. In one or more exemplary drug delivery systems, only the square-shaped locking protrusions may be formed from a dissolvable material. Once the square-shaped locking protrusions dissolve, the first body part and the second body part may be allowed to rotate. Rotation of the first body part with respect to the second body part can cause
30 the first locking band to translate, e.g. move, change position, relocate. This can occur as the mating protrusions can squeeze the triangle-shaped locking protrusions, pushing them

longitudinally away. For example, rotation can cause the first locking band to translate along the central axis.

This translation can expose the attachment part. The translation can fully translate the first locking band off of the drug delivery device. The translation can partially translate the first locking band to expose the attachment part with the first locking band remaining
5 associated with, e.g. attached to, the drug delivery device.

The locking mechanism may comprise a second locking element optionally configured to lock and/or unlock (release) the first body part in relation to the second body part. The second locking element may be arranged in a first secondary recess of the first body part
10 and/or in a second secondary recess of the second body part. The second locking element may be configured to dissolve when the drug delivery device enters the gastrointestinal tract, thereby unlocking or releasing the first body part in relation to the second body part and allowing the actuator mechanism to rotate the first body part in relation to the second body part and thereby moving the first distal end towards the
15 second distal end in turn resulting in attachment of the drug delivery device to the internal tissue.

One or more exemplary drug delivery devices may include a first cover band (e.g., ring, loop, partial ring, partial loop). The first cover band can be used in conjunction with the first locking element, e.g. locking element, locking mechanism. In one or more exemplary
20 drug delivery devices, the first cover band can be the first locking band. In one or more exemplary drug delivery devices, the first cover band can include any or all features discussed above with respect to the first locking band. The first cover band may have a circumferential length greater than a longitudinal width. For example, the circumferential length may be 2x, 3x, 4x, 5x, 6x, 7x, 8x, 9x, or 10x the longitudinal width.

25 The first cover band may fit on an outer surface of the drug delivery device. For example, the first cover band may be located on an outer surface of the first body part or the second body part.

In one or more exemplary drug delivery devices, the first cover band could be in the shape of a capsule part. For example, the first cover band could form a first half of a
30 capsule. The first cover band could form a first half of a capsule and a second cover band could form a second half of the capsule. When fitted together, the first cover band and the second cover band could form a full capsule.

The first cover band may be mechanically fit onto the drug delivery device. For example, the first cover band may be snap fit onto the drug delivery device. The first cover band may be chemically attached onto the drug delivery device.

5 The first cover band may partially or fully cover the first body recess if located on the first body part. Thus, the first cover band may prevent motion of the attachment part if located on the first body part. The first cover band may partially or fully cover the second body recess if located on the second body. Thus, the first cover band may prevent motion of the attachment part if located on the second body part.

10 The first cover band may extend fully along an outer circumference of the drug delivery device. The first cover band may extend around 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100% of an outer circumference of the drug delivery device. The first cover band may extend around greater than 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, or 95% of an outer circumference of the drug delivery device. The first cover band may extend around less than 10, 15, 20, 25, 30, 35, 40, 45,
15 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100% of an outer circumference of the drug delivery device.

In one or more exemplary drug delivery devices, the first cover band may include one or more mating protrusions (e.g., extensions, tabs, fingers, projections, teeth). For example, the first cover band may include 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 mating protrusions. The
20 mating protrusions may only extend longitudinally from one side of the first cover band. The mating protrusions may extend longitudinally from both sides of the first cover band. The mating protrusions may be equally spaced along the first cover band. The mating protrusions may be unequally spaced along the first cover band.

The one or more mating protrusions may extend towards a longitudinal center of the drug
25 delivery device (e.g., along an outer surface of the body towards the second body part if the first cover band is located on the first body part, or along an outer surface of the body towards the first body part if the first cover band is located on the second body part).

In one or more exemplary drug delivery devices, the drug delivery device may include mating features. The mating features can be configured to mate, e.g. receive, hold,
30 contact, with the one or more mating protrusions of the first cover band. The mating features can include one or more body mating protrusions (e.g., extensions, tabs, fingers, projections, teeth) extending radially outward from an outer surface of the drug delivery

device. The mating features can extend from the first body part, the second body part, or both. The mating features can be formed in one or more circumferential rows. For example, there can be one circumferential row of mating features or two circumferential rows of mating features. Both circumferential rows can be on the same body part (e.g.,
5 the first body part or the second body part). In alternative implementations, one circumferential row of mating features can be on the first body part and a second circumferential row of mating features can be on the second body part.

The one or more mating protrusions may be triangular, square, rectangular, rounded, or other polygonal shapes. The one or more mating protrusions may vary in shape along the
10 first cover band. The one or more mating protrusions may be angled in a circumferential direction to form a mating recess (e.g., curve, cavity, space, gap). This mating recess can help fit the one or more body mating protrusions to the one or more protrusions of the first cover band. Further, the mating recess can prevent unwanted release of the first cover band.

15 Accordingly, when the first cover band is attached to the drug delivery device, the one or more mating protrusions can fit between the one or more mating features. The one or more mating protrusions can fit within adjacent mating features. This can help properly align the first cover band.

In some implementations the mating features may be recesses extending internally into
20 the drug delivery device. The mating protrusions can then extend radially inward instead of longitudinally to mate with the mating features. In one or more exemplary drug delivery devices, rotation of the first body part with respect to the second body part can cause the cover band to translate, e.g. move, change position, relocate. For example, rotation can cause the cover band to translate along the central axis. This translation can expose the
25 attachment part. This can occur, for example, as the mating protrusions can squeeze triangle-shaped mating protrusions, or other shaped mating protrusions, pushing them longitudinally away. The translation can fully translate the cover band off of the drug delivery device. The translation can partially translate the cover band to expose the attachment part with the cover band associated with, e.g. attached to, the drug delivery
30 device.

In one or more exemplary drug delivery devices, the first cover band may be dissolvable. The dissolving of the first cover band can allow the attachment part to further rotate out of one of the first body recess or second body recess. Thus, when the first body and the

- second body rotate with respect to one another, the attachment part can rotate for inserting into tissue. The material and/or properties of the first locking element and/or the second locking element may be selected such that the release of the body parts and/or activation of the drug delivery is controlled to take place at a desired location in the
- 5 gastrointestinal tract, such as in the stomach or in the intestines. The material of the first locking element and/or the second locking element may comprise one or more of sugars, sugar derivatives, hydrophilic polymers, pH dependent polymers, and pharmaceutically acceptable excipients that disperses, dissolves, swells, and/or gels upon contact with water/fluid.
- 10 In one or more exemplary drug delivery devices, at least part of the attachment part may be made of a biodegradable material, absorbable material, or similar material which allows the material of the attachment part to be broken down, degraded and/or dissolved by processes that are present in the body, such as corrosion, degradation, hydrolysis and/or proteolytic enzymatic degradation. Thus, when the attachment part has been
- 15 inside the human body for a period of time, the attachment part may dissolve, decompose or degrade to such a degree that the attachment part may lose its structural stability, which may in turn release the drug delivery device from the surface it has attached itself to. Thus, after a period, e.g. when the drug substance has been released from the attachment part, the attachment part may deteriorate to such a degree that the drug
- 20 delivery device may be released and may continue its journey through the gastrointestinal tract to be released through natural intestinal and/or bowel movements of the user or patient.

- In one or more example drug delivery devices, the drug delivery device can be partially biodegradable. In one or more example drug delivery devices, the drug delivery device
- 25 can be fully biodegradable. For example, every component of the drug delivery device can be biodegradable. Accordingly, nothing needs to be excreted from a patient after swallowing the drug delivery device. In one or more example drug delivery devices, the drug delivery device is biodegradable. In one or more example drug delivery devices, the drug delivery device can be biocompostable.
- 30 For example, the first body part, the second body part, the attachment part, and the actuator mechanism may all be biodegradable. Further, any connecting components between may also be biodegradable.

In one or more exemplary drug delivery devices, the rotational axis of the first body part and/or the second body part (primary axis) may be the central axis of the drug delivery device, e.g. the primary axis of the first body part may be coaxial to the central axis. Thus, the central axis intersects both the first body part and the second body part, and may
5 define the primary axis.

In one or more exemplary drug delivery devices, the first body part and the second body part may be substantially symmetrical in a radial direction perpendicular to the central axis. This may mean that the first body part and/or the second body part may have a circular periphery, where the periphery may extend in a radial direction away from and
10 perpendicular to the central axis.

The first attachment axis may be seen as an axis that is coaxial with the length of the attachment part. The second attachment axis may be seen as an axis that is coaxial with the length of the attachment part. In case the attachment part has a shape that is not straight, the first attachment axis may be defined as an axis that intersects the distal end
15 and the proximal end of the attachment part. Further, the second attachment axis may be defined as an axis that intersects the distal end and the proximal end of the attachment part.

In one or more exemplary drug delivery devices, the first attachment axis may be positioned at a first distance from the central axis, while the second attachment axis may
20 be positioned at a second distance from the central axis and/or primary axis.

For example, the first attachment axis may be positioned at a first primary distance from the central axis in the first state of the drug delivery device. The first primary distance may be larger than 0.5 mm, such as in the range from 1 mm to 15 mm or larger than 1 mm, e.g. 2 mm, 3 mm, 4 mm, 5 mm, 6mm, 7 mm, 8mm, 9mm, 10mm, 11mm, 12mm, 13 mm,
25 or 14 mm.

The first attachment axis may cross or be close to (distance less than 0.5 mm) the central axis in the first state of the drug delivery device.

The first attachment axis may be positioned at a first secondary distance from the central axis in the second state of the drug delivery device. The first secondary distance may be
30 larger than 0.5 mm, such as in the range from 1 mm to 15 mm or larger than 1 mm, e.g. 2

mm, 3 mm, 4 mm, 5 mm, 6mm, 7 mm, 8mm, 9mm, 10mm, 11mm, 12mm, 13 mm, or 14 mm.

The first attachment axis may cross or be close to (distance less than 0.5 mm) the central axis in the second state of the drug delivery device.

- 5 For example, the second attachment axis may be positioned at a second primary distance from the central axis in the first state of the drug delivery device. The second primary distance may be larger than 0.5 mm, such as in the range from 1 mm to 15 mm or larger than 1 mm, e.g. 2 mm, 3 mm, 4 mm, 5 mm, 6mm, 7 mm, 8mm, 9mm, 10mm, 11mm, 12mm, 13 mm, or 14 mm.
- 10 The second attachment axis may cross or be close to (distance less than 0.5 mm) the central axis in the first state of the drug delivery device.

The second attachment axis may be positioned at a second secondary distance from the central axis in the second state of the drug delivery device. The second secondary distance may be larger than 0.5 mm, such as in the range from 1 mm to 15 mm or larger

- 15 than 1 mm, e.g. 2 mm, 3 mm, 4 mm, 5 mm, 6mm, 7 mm, 8mm, 9mm, 10mm, 11mm, 12mm, 13 mm, or 14 mm.

The second attachment axis may cross or be close to (distance less than 0.5 mm) the central axis in the second state of the drug delivery device.

- In one or more exemplary drug delivery devices, the first body part may be configured to
- 20 rotate in a first direction and the second body part may be configured rotate in a second direction, where the first direction is opposite to the second direction. Thus, as an example, the first body part may rotate in a clockwise direction, while the second body part may rotate in an opposed anti clockwise direction. In one or more examples where the drug delivery device comprises three or more body parts, abutting or neighbouring
- 25 body parts may rotate in opposite directions. This may also mean that every second body part may rotate in the same direction. For example, where a first body part and a third body part rotate in the same first direction, then a second body part and/or a fourth body part may rotate in a second direction opposite the first direction.

- In one or more exemplary drug delivery devices, the actuator mechanism may comprise
- 30 one or more resilient parts, such as a plurality of resilient parts.

In one or more exemplary drug delivery devices, the distal end of the attachment part may be provided with a tip configured to penetrate a biological tissue. In one or more exemplary drug delivery devices, the distal end of the attachment part may be provided with a sharp tip configured to penetrate a biological tissue. The sharp tip may be
5 positioned in the vicinity of the distal end of the attachment part, where the sharp tip may be configured to have a diameter at the distal end which is smaller than a diameter of the attachment part at a distance from the distal end. The sharp tip may be configured in such a manner that when a rotational force is applied to the attachment part the attachment part may cause the sharp tip to penetrate the biological tissue due to the force applied by
10 the actuator mechanism.

When the attachment part penetrates the biological tissue due to the rotation between the first body part and the second body part (the distal end moving), the penetration point in the biological tissue may be utilized to deliver a drug substance from the drug delivery device into the biological tissue, and where the drug substance may be introduced into the
15 biological tissue that is beyond the mucous membrane. Thereby, the drug substance may enter the bloodstream more easily than if the drug substance is released in the stomach or intestinal lumen, and the drug delivery may be more effective. An example of this is when the drug substance is insulin, where insulin may degrade inside the gastrointestinal tract and is not capable of being absorbed from the gastrointestinal tract, but where a
20 mucous membrane has been penetrated, and the insulin released through the penetrated gastrointestinal wall, the insulin will remain intact and reach the bloodstream of the user via the blood vessels in the intestinal layer beyond the mucous membrane (surface).

In one or more exemplary drug delivery devices, the attachment part may be provided with a gripping part configured to grip a biological tissue. The gripping part may be utilized
25 to improve traction between the attachment part and a mucous membrane, allowing the attachment part to anchor the drug delivery device inside the body of the user. The gripping part may be a part that increases a mechanical friction between the attachment part and the surface to be attached to, where the gripping part may e.g. have a hook shape, so that the biological tissue which is positioned near the attachment part is gripped
30 by the part.

In one or more exemplary drug delivery devices, a part of the resilient part may be connected to the first body part and a second part of the resilient part may be connected to the second body part. This means that the resilient part may be utilized to store energy,

such as rotational energy or rotational force which is applied to the first body part and the second body part, where the energy is stored in the resilient part. Furthermore, when the energy is released, e.g. when a locking element is dissolved or degraded, the force may be released to both the first body part and the second body part, which in turn transfers
5 the force to the attachment part. The resilient part may e.g. be in the form of a helical spiral spring (mainspring) and/or a spiral torsion spring, where the first body part may be wound relative to the second body part by rotating the first body part relative to the second body part. This stores energy in the mainspring by twisting the spiral tighter. The stored force of the mainspring may then rotate the first body part in the opposing direction
10 as the mainspring unwinds. Thus, the force of the mainspring may cause the attachment part to travel, and where the attachment part may penetrate the tissue in order to attach the drug delivery device to the biological tissue.

When the drug delivery device has entered the body, and has e.g. entered the desired part in the gastrointestinal tract, the drug delivery device may be configured to transform
15 from the first state to the second state. The transformation may be initiated by different means, where e.g. the first and the second body parts may be held in the first state using a locking mechanism e.g. comprising one or more locking elements made of a dissolvable, expandable or degradable material, where the material reacts with the surroundings, such as fluids, inside the desired body part, thereby unlocking or releasing
20 the locking mechanism. The material of the locking elements may be a material that loses its structural force when in contact with the surroundings inside the desired body part. An example may be where locking element(s) is made of a polymeric material or a sugary substance which may dissolve, expand or degrade when it comes into contact with a certain kind of fluid which may include an enzyme or a certain kind of acid inside the
25 digestive system. When the locking element comes into contact with the reagent, the material may dissolve, expand or degrade over time, and when the rotational force of the drug delivery device exceeds the static force of the locking element, the rotational force may be released via a rotation of the first body part relative to the second body part, or vice versa.

30 In one or more exemplary drug delivery devices, a locking element may fix an attachment part in a position where the attachment element locks the first body part in relation to the second part, i.e. prevents the first body part from rotating in relation to the second body part. When the locking element dissolves or degrades, the attachment part can move to a secondary position where the attachment part does not lock the first body part in relation

to the second part, e.g. by the actuator mechanism causing a rotation of the attachment part about a rotation axis in relation to the body part to which the attachment part is rotationally attached.

The second state of the drug delivery device may be seen as the state which is initiated
5 by the release of energy stored in the actuator mechanism, e.g. resilient part(s) of the actuator mechanism into a rotational force of the first and/or the second body part and/or a rotational force of the attachment part in relation to the first body part or the second body part. A termination of the second state may be seen as a point in time where the energy stored in the resilient part becomes stationary again, i.e. when the attachment part
10 has gripped or penetrated biological tissue and/or the rotational movement between the first body part and the second body part is stopped.

In one or more exemplary drug delivery devices, the drug delivery device may have a first state where the actuator mechanism has a constant resilient force load and a second state where the actuator mechanism releases the resilient force load. In the first state, the
15 constant resilient force load may be seen as the energy stored in the actuator mechanism, and where the resilient force load is larger than zero. The second state may be seen as a state where the actuator mechanism releases its resilient force load, where the resilient force load is reduced, e.g. approaches zero, e.g. by rotating the first body part in relation to the second body part. The second state may be terminated when the attachment part
20 comes into contact with or penetrates a biological tissue and the resilient force load does not change, even though it has not reached zero. Thus, a third state may follow the second state, when the drug delivery device has been attached to a wall of biological material, and the resilient force load is stationary after a resilient force release.

The attachment part may have an unfolding function, where during the first state of the
25 drug delivery device, i.e. the initial state of the drug delivery device, the attachment part is positioned or arranged inside the first or the second body part, or alternatively where the attachment part may be folded along the side of the body parts. Other ways of obtaining the same may be envisioned. The folded state (first state) may e.g. be maintained using a releasable locking mechanism in the form of an encapsulation similar to a drug substance
30 capsule, a band or plug, e.g. made of gelatine, sugars or other dissolvable materials or materials that lose their structural force. Thus, the attachment part may be held in place until the drug delivery device has entered the gastrointestinal tract, e.g. the stomach, so that the attachment part does not interfere or damage the lining of the mouth and/or the

oesophagus. Prior to or during the transition to the second state the attachment part may extend from the body parts and outwards, making the attachment part ready to interact with a lining of the digestive system. When the attachment part is in a folded or collapsed position, the distance from the central axis to the distal end of the attachment part being
5 longer in the second state than in a first state. Thus, the diameter of the drug delivery device in the first state will be less in than the diameter of the drug delivery device in the second state.

In one or more exemplary drug delivery devices, at least part of the attachment part, such as the needle may be made of material comprising one or more of magnesium, titanium,
10 iron and zinc which allows for accurate and precise control of the size and/or shape/geometry of the attachment part in turn allowing for a delivery device with desired attachment capabilities and/or small production variances which is in particular important in the pharmaceutical industry.

The attachment part, such as the needle, may be made of material comprising one or
15 more of magnesium, titanium, iron and zinc. The material of the attachment part/ needle may be biocompatible and/or biodegradable such as a biocompatible material and/or a biodegradable material. The material of the attachment part/ needle may comprise one or more biodegradable polymers such as PLA and/or POLGA. Some of, part of, most of, substantially all, or all of the material of the attachment part/ needle may be biocompatible
20 and/or biodegradable. The material of the attachment part, such as the needle, may comprise, consist of, or essentially consist of, biocompatible and/or biodegradable material such as biocompatible and/or biodegradable metals. The material of the attachment part, such as the needle, may comprise a biodegradable or bioresorbable metal or metal alloy, such as magnesium, zinc, and/or iron or an alloy comprising one or
25 more of magnesium, zinc and iron. A biodegradable or bioresorbable metal or metal alloy may be understood as a metal or metal alloy that degrades safely within e.g. a human body in a practical amount of time, for example related to their application. The material of the attachment part, such as the needle, may comprise one or more metals such as a combination of one or more metals e.g. as a metal alloy.

30 An advantage of having a biodegradable material used in the attachment part may be that the delivery device is able to deliver an active drug substance or payload arranged in the attachment part and/or body parts of the delivery device at a specific part of the body of the subject, e.g. such as the stomach or intestines after the delivery device has attached

to the internal surface, e.g. the intestinal wall, thanks to the sharp properties of the material of the attachment part, and for an extended period of time, since the biodegradable material will degrade gradually in time. Further, when the material of the attachment part is biodegradable, the attachment part will degrade in the human body and
5 disappear after having delivered the payload/active drug substance comprised in the drug delivery device, thereby avoiding harming the human subject over time. The attachment part may be configured to degrade in a period of time of hours, e.g. 2 hours, 5 hours, 10 hours, 20 hours, or 24 hours, days, e.g. 1 day, 2 days, 5 days, or weeks, e.g. 1 week, 2 weeks, 3 weeks, or 5 weeks.

- 10 The material of the attachment part, such as the needle, may comprise one or more or a combination of magnesium (Mg), zinc (Zn), and/or iron (Fe). An advantage of having the attachment part of a material comprising Mg, Zn, and/or Fe may be that the shape and size of the attachment part can be precisely controlled thereby providing improved attachment to the internal surface, for example to an internal wall of the intestines of the
15 human subject.

For example, the material of the attachment part, such as the needle, may comprise 0,001 wt% to 100wt% of biodegradable metal such as 0,001wt% to 100wt% of magnesium, 0,001wt% to 100wt% of zinc, 0,001wt% to 100wt% of iron.

- The material of the attachment part, such as the needle, may for example comprise 0,001
20 wt% of Mg, 0,005 wt% of Mg, 0,01 wt% of Mg, 0,05 wt% of Mg, 0,1 wt% of Mg, 0,5 wt% of Mg, 1 wt% of Mg, 5 wt% of Mg, 10 wt% of Mg, 20 wt% of Mg, 30 wt% of Mg, 40 wt% of Mg, 50 wt% of Mg, 60 wt% of Mg, 70 wt% of Mg, 80 wt% of Mg, 90 wt% of Mg, or 100 wt% of Mg.

- The material of the attachment part, such as the needle, may for example comprise 0,001
25 wt% of Zn, 0,005 wt% of Zn, 0,01 wt% of Zn, 0,05 wt% of Zn, 0,1 wt% of Zn, 0,5 wt% of Zn, 1 wt% of Zn, 5 wt% of Zn, 10 wt% of Zn, 20 wt% of Zn, 30 wt% of Zn, 40 wt% of Zn, 50 wt% of Zn, 60 wt% of Zn, 70 wt% of Zn, 80 wt% of Zn, 90 wt% of Zn, or 100 wt% of Zn.

- The material of the attachment part, such as the needle, may for example comprise 0,001
wt% of Fe, 0,005 wt% of Fe, 0,01 wt% of Fe, 0,05 wt% of Fe, 0,1 wt% of Fe, 0,5 wt% of
30 Fe, 1 wt% of Fe, 5 wt% of Fe, 10 wt% of Fe, 20 wt% of Fe, 30 wt% of Fe, 40 wt% of Fe, 50 wt% of Fe, 60 wt% of Fe, 70 wt% of Fe, 80 wt% of Fe, 90 wt% of Fe, or 100 wt% of Fe.

The material of the attachment part, such as the needle, may comprise a metal alloy such as Zn-Mg, Zn-Fe, Mg-Fe, or Zn-Mg-Fe. The material of the attachment part, such as the needle, may for example comprise an alloy of Zn-Mg with 0,001 wt% of Mg, 0,005 wt% of Mg, 0,01 wt% of Mg, 0,05 wt% of Mg, 0,1 wt% of Mg, 0,5 wt% of Mg, 1 wt% of Mg, 5 wt% of Mg, 10 wt% of Mg, 20 wt% of Mg, 30 wt% of Mg, 40 wt% of Mg, 50 wt% of Mg, 60 wt% of Mg, 70 wt% of Mg, 80 wt% of Mg, or 90 wt% of Mg.

The material of the attachment part, such as the needle, may for example comprise an alloy of Zn-Fe with 0,001 wt% of Fe, 0,005 wt% of Fe, 0,01 wt% of Fe, 0,05 wt% of Fe, 0,1 wt% of Fe, 0,5 wt% of Fe, 1 wt% of Fe, 5 wt% of Fe, 10 wt% of Fe, 20 wt% of Fe, 30 wt% of Fe, 40 wt% of Fe, 50 wt% of Fe, 60 wt% of Fe, 70 wt% of Fe, 80 wt% of Fe, or 90 wt% of Fe.

The material of the attachment part, such as the needle, may for example comprise an alloy of Mg-Fe with 0,001 wt% of Fe, 0,005 wt% of Fe, 0,01 wt% of Fe, 0,05 wt% of Fe, 0,1 wt% of Fe, 0,5 wt% of Fe, 1 wt% of Fe, 5 wt% of Fe, 10 wt% of Fe, 20 wt% of Fe, 30 wt% of Fe, 40 wt% of Fe, 50 wt% of Fe, 60 wt% of Fe, 70 wt% of Fe, 80 wt% of Fe, or 90 wt% of Fe.

The material of the attachment part, such as the needle, may for example comprise an alloy of Zn-Mg-Fe with 0,001 wt% of Fe, 0,005 wt% of Fe, 0,01 wt% of Fe, 0,05 wt% of Fe, 0,1 wt% of Fe, 0,5 wt% of Fe, 1 wt% of Fe, 5 wt% of Fe, 10 wt% of Fe, 20 wt% of Fe, 30 wt% of Fe, 40 wt% of Fe, 50 wt% of Fe, 60 wt% of Fe, 70 wt% of Fe, 80 wt% of Fe, 90 wt% of Fe, 0,001 wt% of Mg, 0,005 wt% of Mg, 0,01 wt% of Mg, 0,05 wt% of Mg, 0,1 wt% of Mg, 0,5 wt% of Mg, 1 wt% of Mg, 5 wt% of Mg, 10 wt% of Mg, 20 wt% of Mg, 30 wt% of Mg, 40 wt% of Mg, 50 wt% of Mg, 60 wt% of Mg, 70 wt% of Mg, 80 wt% of Mg, 90 wt% of Mg, 0,001 wt% of Zn, 0,005 wt% of Zn, 0,01 wt% of Zn, 0,05 wt% of Zn, 0,1 wt% of Zn, 0,5 wt% of Zn, 1 wt% of Zn, 5 wt% of Zn, 10 wt% of Zn, 20 wt% of Zn, 30 wt% of Zn, 40 wt% of Zn, 50 wt% of Zn, 60 wt% of Zn, 70 wt% of Zn, 80 wt% of Zn, or 90 wt% of Zn.

The attachment part, such as the needle, may be made of a material comprising one or more thermoplastic or thermoset polymers. The material of the attachment part, such as the needle, may comprise one or more active drug substances. Thus, an active drug substance may be embedded in the material of the attachment part, such as the needle, to form a pharmaceutical composition.

In some embodiments, the attachment part, such as the needle, may comprise for example water soluble, water insoluble, biodegradable, non-biodegradable and/or pH dependent soluble materials. In some embodiments, the attachment part, such as the needle, may comprise a water soluble, biodegradable and/or pH-dependent material that
5 may dissolve and/or degrade so that the attachment part, such as the needle, lodged in the intestinal tissue may gradually degrade and/or dissolve. In some embodiments, the attachment part, such as the needle, may comprise a water-soluble material to allow immediate release or modified release of the active drug substance depending of the material selected. In some embodiments, a water insoluble or biodegradable material may
10 allow depot of the active drug substance in the attachment part, such as the needle, for longer release duration (for example days, weeks or months). In some embodiments, a pH dependent soluble material may allow the attachment part, such as the needle, to stay intact at pH conditions below the physiologic for example a pH of approximately 7.4 to remain intact in the gastrointestinal lumen, but then may dissolve once inside the
15 gastrointestinal wall. In some embodiments, one or more water soluble, water insoluble, biodegradable and/or pH dependent materials may optionally be combined to control release of the active drug substance for example by diffusion or erosion of the attachment part, such as the needle, for controlled release duration (for example minutes, hours, days, weeks, or months).

20 In some embodiments, the attachment part, such as the needle, may be made from different compositions. For example, an outer part of the attachment part, such as the needle, may be made of one composition and an inner core of the attachment part, such as the needle, may be made from another composition. In some embodiments, the outer part and the inner core of the attachment part, such as the needle, may be composed of
25 for example a water soluble, a water insoluble, a biodegradable, and/or a pH dependent material. In some embodiments, one or more water soluble, water insoluble, biodegradable and/or pH dependent materials may be combined to control the release of the active drug substance once the attachment part, such as the needle, may move its position from the lumen to the internal tissue for example the gastrointestinal lumen to the
30 gastrointestinal tissue.

In some embodiments, the attachment part, such as the needle, may be tubular and may include a tubular body and the tubular body may comprise an active drug substance for example a liquid payload comprising the active drug substance, optionally connected to a tubular attachment part so the payload with the active drug substance may flow though

the attachment part, such as the needle, into the internal tissue for example the intestinal tissue. In some embodiments, the tubular body may contain expandable such as swelling excipients that may expand by a chemical reaction for example when mixed expand in volume and/or produce a gas to advance the delivery of the payload. In some
5 embodiments, the expansion is by osmosis.

In some embodiments, the first compartment (compartment to hold active drug substance) may comprise a closure part for closing the first compartment. The closure part may contribute to improved control of release of the active drug substance. In some
10 embodiments, the closure part may be composed of for example a water soluble, a water insoluble, a biodegradable, and/or a pH dependent material. In some embodiments, one or more water soluble, water insoluble, biodegradable and/or pH dependent materials may be combined to control the release of the active drug substance from the first compartment once the attachment part, such as the needle, moves its position from the lumen to the internal tissue for example from the gastrointestinal lumen to the
15 gastrointestinal tissue.

Fig. 1 shows an exploded view of a drug delivery device 2 in accordance with the disclosure, where the drug delivery device comprises a first body part 4, having a first end 6 and a second end 8, a second body part 10 having a first end 12 and a second end 14. When assembled, the first body part 4 is rotatably connected to the second body part 10,
20 where the first end 6 of the first body part abuts the first end 12 of the second body part when connected.

The drug delivery device 2 further comprises an actuator mechanism 16 comprising a resilient part 16A, in this example in the form of a spiral torsion spring. A first part 18 of the resilient part 16A (first end of spiral torsion spring) is positioned on an outer periphery
25 22 of the spiral torsion spring, and a second part 20 of the resilient part 16A (second end of spiral torsion spring) is in a center part 24 of the spiral torsion spring.

The first body part 4 comprises an inner volume 26, where the inner volume is adapted to receive the resilient part 16A, and where an inner surface 28 of the inner volume 26 comprises one or more first engagement parts 30 which are configured to engage with the
30 first part 18 of the resilient part 16A, and where the first engagement parts can maintain the position of the first part during rotational movement of the first body part 4 and the second body part 10 relative to each other. The second part 20 of the resilient part 16A is configured to engage with a second engagement part which is positioned centrally inside

the second body part 10. The second engagement part is configured to extend into the central part 24 of the spring, when the spring is positioned inside the inner volume 26 of the first body part 4. The second engagement part comprises a slit or a groove which is adapted to engage with the second part 20 of the resilient part 16A, so that a rotational
5 movement of the first 4 and/or the second body part 10 can wind up the resilient part 16A, when the first part 18 is in engagement with the first engagement part 30.

The drug delivery device 2 has a central axis A, which extends in a direction from the second end 8 of the first body part 4 (first end of drug delivery device) towards the second end 14 of the second body part (second end of drug delivery device). The central axis A
10 may be seen as defining the primary axis about which the first body part 4 and the second body part 10 rotates.

The first engagement part 30 and the first part 18 of the resilient part 16A may have an engagement which means that when the load in the spring exceeds a predefined level, the first end releases the first engagement part 30, and jumps into engagement with the
15 next engagement part 30'. This means that the drug delivery device may have a torque limiter, where the torque limiter ensures that the stored energy inside the resilient member 16 cannot exceed a predefined limit.

The drug delivery device 2 comprises an attachment part 36 having a proximal end 38 and a distal end 40. The attachment part 36 comprises a straight needle 37 (or spike) and
20 is fixedly attached to the first body part 4. The attachment part 36 extends along a first attachment axis, from an outer surface 42 of the first body part 4 in a direction away from the outer surface 42. The distal end 40 of the attachment part 36 may be a sharp tip in order to allow penetration of biological tissue, where the rotational force provided by the resilient member 16A may be used to penetrate a bodily tissue.

25 The distal end 40 attachment part 36 may be a sharp tip, where the sharp tip may be similar to a sharp tip of a hypodermic needle, where the sharp tip is capable of penetrating bodily tissue, such as a mucous membrane of the intestine, stomach, bowels, or other parts of the digestive system and/or the gastrointestinal system. The needle 37 may be hollow with an opening at the distal end 40, so that an active drug substance may be
30 introduced via the opening into a bodily tissue after the attachment part 36 have penetrated the biological tissue.

The resilient force of the resilient part 16A is used to rotate the first body part in a first direction B and the second body part in a second direction C about the central axis A being the primary axis. In other words, the actuator mechanism 16 (resilient part 16A) is configured to move the first distal end 40 towards the second distal end 48.

- 5 The first body part 4 has a first primary recess 64 in the outer surface 42 and the second body part 10 has a second primary recess 66 in the outer surface 50. The first primary recess 64 and the second primary recess 66 are part of a locking mechanism for locking, e.g. preventing rotation of the first body part 4 in relation to the second body part 10 when the drug delivery device 2 is in the first state by arranging a first locking element in the first
10 primary recess 64 and the second primary recess 66.

Fig. 2A shows drug delivery device 2 in a first state. The drug delivery device comprises a locking mechanism indicated with dotted oval 70 comprising first primary recess 64, second primary recess 66 and a first locking element 72 arranged in the first primary recess 64 and the second primary recess 66. The first locking element 72 is capable of
15 preventing rotational movement of the first body part 4 and the second body part 10 relative to each other, to maintain a static relationship between the body parts 4, 10. The first locking element 72 may be in the form of a degradable material, such as a sugary substance, where a contact with the fluids of the gastrointestinal tract leads to the degradation of the first locking element 72 material. When the rotational force applied to
20 the body parts 4, 10 via the resilient member 16A exceeds the static force of the (degraded) first locking element 72, the first locking element 72 will release the body parts 4, 10, and allow the resilient member 16A to discharge of its stored energy, causing the rotation of the first body part 4 relative to the second body part 10 in a second state of the drug delivery device.

- 25 Fig. 2B shows the drug delivery device 2, where the first locking element 72 has been degraded or dissolved, and the first body part 4 and second body part 10 have rotated in the directions B and C (respectively) relative to each other. Thus, the attachment member 36 has rotated, via the rotational force (torque) applied to the body parts 4, in order to pierce tissue, such as via needle 37.

- 30 Fig. 3 shows an exemplary pharmaceutical composition 100 comprising drug delivery device 2 where the drug delivery device 2 is encapsulated in a housing 76 optionally made of dissolvable material. The pharmaceutical composition 100 comprises active drug substance arranged in a first compartment and/or a second compartment. The housing 76

may enclose the drug delivery device 2 to make it easier to swallow. The dissolvable housing 76 may dissolve inside the gastrointestinal tract, and where the drug delivery device 2 cannot engage or attach before the housing 76 is dissolved. These kinds of housings are known in the art, in the form of a drug capsule, where the material of drug capsule may e.g. be a gelatin, similar to hard drug capsule shells known in the art. In one or more exemplary pharmaceutical compositions, the drug delivery device may be coated with a coating.

Fig. 4 shows an exploded view of an exemplary drug delivery device according to the present disclosure. The drug delivery device 2A has a central axis A and comprises a two-part first body part 4 comprising first primary body part 4A and first secondary body part 4B. The first body part 4 can include a cylindrical first base 39.

The drug delivery device 2A comprises a two-part second body part 10 comprising second primary body part 10A and second secondary body part 10B. The drug delivery device 2A comprises an attachment part 36 comprising a base 36A and needle 37 attached to the base 36A. The attachment part 36 has a distal end 40 and is optionally rotationally attached to the second body part 10 via a second joint connection formed by cylindrical second base 41 and corresponding cylindrical cavity in the second body part 10, the second joint having a second rotation axis X_R_2. Thus, the attachment part 36 is configured to rotate about first rotation axis in relation to the second body part 4. The second rotation axis X_R_2 is parallel to the central axis A.

The drug delivery device 2A comprises a frame part 78 formed as an axle member or rod, where different parts, such as the first body part 4 and/or the second body part 10 are attached, e.g. fixed or rotatably attached to the frame part 78.

The drug delivery device 2A comprises actuator mechanism 16 comprising resilient part 16A configured to move the attachment part 36, specifically the distal end of the attachment part 40 by rotating the first body part 4 in relation to the second body part 10.

Fig. 5A shows an exemplary drug delivery device 2B, with Fig. 5B showing an exploded version of the exemplary drug delivery device 2B. The drug delivery device 2B may include any and/or all of the features discussed above with respect to Figs. 1-4 unless otherwise noted.

As shown, the drug delivery device 2B can include a first body recess 108 configured to allow rotation of the attachment part 104. The attachment part 104 can include a joint 116, thereby forming a bent needle or spike. This can allow for easier penetration of tissue.

Additionally, as shown the drug delivery system 2B can include a first locking band 102.

- 5 The first locking band 102 can prevent rotation of the first body part 4 with respect to the second body part 10. First locking band 102 can be used instead of a locking element 72. Alternatively, the first locking band 102 can act as a first cover band 103 and be used in conjunction with a locking element 72. Specifically, the first locking band 102 can include a plurality of locking protrusions 112. The locking protrusions 112 can fit within the mating
10 features 114 of the drug delivery system 2B. Once mated, the locking protrusions 112 prevent rotation of the first body part 4 and the second body part 10. The first locking band 112 can then dissolve to allow rotation.

- Figs. 6A-6C illustrate views of a drug delivery device 2C. The drug delivery device 2C can include any and/or all of the features discussed above with respect to Figs. 1-5B unless
15 otherwise noted.

- As shown, the drug delivery device 2C can include a central axis A, a first body part 4 and a second body part 10. The drug delivery device 2C can further include an attachment part 36 attached to the first body part 4 and having a distal end 40. The attachment part 36 can include a base 36A and a needle (or spike) 37. The attachment part 36 can be
20 rotatably within the first body recess 108. The distal end 40 of the attachment part 36, such as needle 37) is provided with a tip configured to penetrate a biological tissue.

- The drug delivery device 2C can include a first compartment, the drug delivery device 2C being configured to deliver an active drug substance from the first compartment to the surroundings of the drug delivery device 2C. For example, once the attachment part 36
25 penetrates tissue, the drug delivery device 2C can release an active drug substance into the tissue.

- The drug delivery device 2C can also include an actuator mechanism (not shown, but may include resilient part 16A discussed above) configured to rotate the first body part 4 in relation to the second body part 10 about a primary axis (such as, but not limited to,
30 central axis A) of the drug delivery device 2C. As shown, the drug delivery device 2C only contains a single attachment part 36. The actuator mechanism can include a resilient part configured to apply force to the first body part 4 and/or the second body part 10. The first

body part 4 is configured to rotate in a first direction and the second body part 10 is configured to rotate in a second direction opposite to the first direction.

The drug delivery device 2C can have a first state where the first body part 4 and the second body part 10 are rotationally stationary relative to each other and a second state
5 where the first body part 4 and the second body part 10 are rotationally mobile relative to each other. Thus, the actuator mechanism can be configured to move the distal end 40 from a primary position with a primary radial distance from the central axis A of the delivery device 2C to a secondary position with a secondary radial distance from the central axis A, wherein the secondary radial distance is larger than the primary radial
10 distance.

Accordingly, upon rotation of the first body part 4 in relation to the second body part 10, the attachment part 36 can rotate out of the first body recess 108 for penetration of tissue. The attachment part 36 can be rotationally attached to the first body part 4 via a hinge, such as on base 36A, and be configured to rotate about a first rotation axis perpendicular
15 or parallel to the primary axis A.

Further, as shown the drug delivery device 2C can include a locking mechanism 70 including a first locking element 72 held to prevent rotation of the first body part 4 in relation to the second body part 10. The locking mechanism 70 can be configured to lock the first body part 4 in relation to the second body part 10 in a first state of the drug
20 delivery device 2C.

Optionally, the first body part 4 and/or the second body part 10 may include a resistive feature 118. As shown, the resistive feature 118 is located on the second body part 10. The resistive feature 118 can be selected from one or more of: a high friction surface, a feature configured to change inertia, and a feature configured to create turbulent flow.

25 The second body part 10 may have a higher inertia than the first body part 4. The second body part 10 may have a higher or lower weight than the first body part 4. This can, for example, improve the penetration of the attachment part 36 into tissue.

The drug delivery devices 2, 2A, 2B, 2C can be biodegradable, such as fully biodegradable.

30 Also disclosed are delivery devices, methods, and compositions according to any of the following items.

- Item 1. A drug delivery device having a central axis, the drug delivery device comprising:
a first body part;
a second body part;
5 an attachment part attached to the first body part and having a distal end; and
an actuator mechanism configured to rotate the first body part in relation to the
second body part about a primary axis of the drug delivery device;
wherein the drug delivery device comprises only a single attachment part.
- 10 Item 2. Drug delivery device according to Item 1, wherein the first body part and/or the
second body part includes a resistive feature.
- Item 3. Drug delivery device according to Item 2, wherein the resistive feature is selected
from one or more of: a high friction surface, a feature configured to change inertia, and a
15 feature configured to create turbulent flow.
- Item 4. Drug delivery device according to any of the preceding Items, wherein the second
body part has a higher inertia than the first body part.
- 20 Item 5. Drug delivery device according to any of the preceding Items, wherein the second
body part has a higher or lower weight than the first body part.
- Item 6. Drug delivery device according to any of the preceding Items, wherein the actuator
mechanism comprises a resilient part configured to apply force to the first body part
25 and/or the second body part.
- Item 7. Drug delivery according to any of the preceding Items, wherein the first body part
is configured to rotate in a first direction and the second body part is configured to rotate
in a second direction opposite to the first direction.
- 30 Item 8. Drug delivery device according to any of the preceding Items, wherein the distal
end of the attachment part is provided with a tip configured to penetrate a biological
tissue.

Item 9. Drug delivery device according to any of the preceding Items, wherein the drug delivery device comprises a first compartment, the drug delivery device being configured to deliver an active drug substance from the first compartment to the surroundings of the drug delivery device.

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Item 10. Drug delivery device according to any of the preceding Items, wherein the drug delivery device has a first state where the first body part and the second body part are rotationally stationary relative to each other and a second state where the first body part and the second body part are rotationally mobile relative to each other.

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Item 11. Drug delivery device according to any of the preceding Items, wherein the actuator mechanism is configured to move the distal end from a primary position with a primary radial distance from the central axis of the delivery device to a secondary position with a secondary radial distance from the central axis, wherein the secondary radial

15 distance is larger than the primary radial distance.

Item 12. Drug delivery device according to any of the preceding Items, wherein the drug delivery device comprises a locking mechanism configured to lock the first body part in relation to the second body part in a first state of the drug delivery device.

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Item 13. Drug delivery device according to any of the preceding Items, wherein the attachment part is rotationally attached to the first body part via a hinge and configured to rotate about a first rotation axis perpendicular or parallel to the primary axis.

25 Item 14. Drug delivery device according to any of the preceding Items, wherein the drug delivery device is biodegradable.

The use of the terms "first", "second", "third" and "fourth", "primary", "secondary", "tertiary" etc. does not imply any particular order, but are included to identify individual elements.

Moreover, the use of the terms "first", "second", "third" and "fourth", "primary",

30 "secondary", "tertiary" etc. does not denote any order or importance, but rather the terms "first", "second", "third" and "fourth", "primary", "secondary", "tertiary" etc. are used to distinguish one element from another. Note that the words "first", "second", "third" and "fourth", "primary", "secondary", "tertiary" etc. are used here and elsewhere for labelling purposes only and are not intended to denote any specific spatial or temporal ordering.

Furthermore, the labelling of a first element does not imply the presence of a second element and vice versa.

It is to be noted that the word "comprising" does not necessarily exclude the presence of other elements or steps than those listed.

- 5 It is to be noted that the words "a" or "an" preceding an element do not exclude the presence of a plurality of such elements.

It should further be noted that any reference signs do not limit the scope of the claims, that the exemplary embodiments may be implemented at least in part by means of both hardware and software, and that several "means", "units" or "devices" may be
10 represented by the same item of hardware.

Although features have been shown and described, it will be understood that they are not intended to limit the claimed invention, and it will be made obvious to those skilled in the art that various changes and modifications may be made without departing from the spirit and scope of the claimed invention. The specification and drawings are, accordingly to be
15 regarded in an illustrative rather than restrictive sense. The claimed invention is intended to cover all alternatives, modifications, and equivalents.

LIST OF REFERENCES

- 2, 2A, 2B, 2C drug delivery device
- 4 first body part
- 4A first primary body part
- 5 4B first secondary body part
- 6 first end of first body part
- 8 second end of first body part
- 10 second body part
- 10A second primary body part
- 10 10B second secondary body part
- 12 first end of second body part
- 14 second end of second body part
- 16 actuator mechanism
- 16A resilient part
- 15 18 first part of resilient part
- 20 second part of resilient part
- 22 outer periphery of spiral torsion spring
- 24 center part of spiral torsion spring
- 26 inner volume
- 20 28 inner surface
- 30 first engagement part
- 30' first engagement part
- 36 attachment part
- 36A base
- 25 37 needle
- 38 proximal end of attachment part
- 40 distal end of attachment part
- 42 outer surface of first body part
- 50 outer surface of second body part
- 30 64 first primary recess in first body part
- 66 second primary recess in second body part
- 70 locking mechanism
- 72 first locking element
- 76 housing
- 35 100 pharmaceutical composition

- 102 first locking band
- 103 first cover band
- 104 attachment part
- 108 first body recess
- 5 112 locking protrusion
- 114 mating feature
- 116 joint
- 118 resistive feature
- A central axis/primary axis
- 10 B rotational direction
- C rotational direction

CLAIMS

1. A drug delivery device having a central axis, the drug delivery device comprising:
a first body part;
5 a second body part;
an attachment part attached to the first body part and having a distal end; and
an actuator mechanism configured to rotate the first body part in relation to the
second body part about a primary axis of the drug delivery device;
wherein the drug delivery device comprises only a single attachment part.
10
2. Drug delivery device according to claim 1, wherein the first body part and/or the second
body part includes a resistive feature.
3. Drug delivery device according to claim 2, wherein the resistive feature is selected from
15 one or more of: a high friction surface, a feature configured to change inertia, and a
feature configured to create turbulent flow.
4. Drug delivery device according to any of the preceding claims, wherein the second
body part has a higher inertia than the first body part.
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5. Drug delivery device according to any of the preceding claims, wherein the second
body part has a higher or lower weight than the first body part.
6. Drug delivery device according to any of the preceding claims, wherein the actuator
25 mechanism comprises a resilient part configured to apply force to the first body part
and/or the second body part.
7. Drug delivery according to any of the preceding claims, wherein the first body part is
configured to rotate in a first direction and the second body part is configured to rotate in a
30 second direction opposite to the first direction.
8. Drug delivery device according to any of the preceding claims, wherein the distal end of
the attachment part is provided with a tip configured to penetrate a biological tissue.

9. Drug delivery device according to any of the preceding claims, wherein the drug delivery device comprises a first compartment, the drug delivery device being configured to deliver an active drug substance from the first compartment to the surroundings of the drug delivery device.

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10. Drug delivery device according to any of the preceding claims, wherein the drug delivery device has a first state where the first body part and the second body part are rotationally stationary relative to each other and a second state where the first body part and the second body part are rotationally mobile relative to each other.

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11. Drug delivery device according to any of the preceding claims, wherein the actuator mechanism is configured to move the distal end from a primary position with a primary radial distance from the central axis of the delivery device to a secondary position with a secondary radial distance from the central axis, wherein the secondary radial distance is
15 larger than the primary radial distance.

12. Drug delivery device according to any of the preceding claims, wherein the drug delivery device comprises a locking mechanism configured to lock the first body part in relation to the second body part in a first state of the drug delivery device.

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13. Drug delivery device according to any of the preceding claims, wherein the attachment part is rotationally attached to the first body part via a hinge and configured to rotate about a first rotation axis perpendicular or parallel to the primary axis.

25 14. Drug delivery device according to any of the preceding claims, wherein the drug delivery device is biodegradable.

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