

Insulin Pens and Their Mechanisms

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ABSTRACT AND INTRODUCTION

Several types of insulin intended for injection by the diabetes patient are available in a convenient disposable administration device called an *insulin pen*. In two popular types, the Novo Nordisk *FlexPen* and the Eli Lilly *KwikPen*, the device is dispensed pre-filled with 3 ml of insulin solution, corresponding to 300 international units (IU), which may be used for numerous "shots". For each shot, the user attaches a disposable needle and sets the desired dose with a knob, operating in 1 IU steps up to 60 IU. Then, after insertion of the needle at the injection site, the user presses an operating plunger, accurately delivering the preset dose. This article describes these two popular types of insulin pen and discusses in detail, with illustrations, the operation of their ingenious mechanisms.

THE INSULIN PENS

General

The two insulin pens described by this article are:

- FlexPen, a product of Novo Nordisk, headquartered in Denmark (in particular, the one loaded with Levemir, a long-acting insulin)
- KwikPen, a product of Eli Lilly and Company, headquartered in Indianapolis, Indiana, USA (in particular, the one loaded with Humalog, a quick-acting insulin)

Both pen types are available with several types of insulin, and similar designs are used for other injectable medication as well.

Both pens are used with replaceable needles having a common ISO standard screw thread attachment. Needles are available in several gauges and penetration lengths. It is recommended that a needle be used only for one "shot".

Both pens are typically dispensed prefilled with 3 ml of deliverable insulin solution, corresponding to 300 international units (IU). (There is a little additional solution that cannot be delivered.) After the entire deliverable contents has been delivered, the pen is discarded. It cannot be refilled in the field.

Essentially, the pens consist of a fairly-conventional hypodermic syringe arrangement with a “rubber” piston, integrated with an ingenious precision controllable-dose syringe operating mechanism. Although the overall appearance and mode of user operation of the two pens are almost identical, their mechanisms are dramatically different in principle.

Figure 1 shows a Novo Nordisk Levemir-filled FlexPen, with the pen cap removed and a needle in place. The outer and inner needle sheaths (on the needle as it is supplied) are also shown. (There is also a foil seal tab, not shown, closing the open end of the outer sheath.)



Figure 1. Novo Nordisk Levemir FlexPen

Figure 2 shows an Eli Lilly Humalog-filled KwikPen, with the pen cap removed and a needle in place.



Figure 2. Eli Lilly Humalog KwikPen

Mode of operation

To take a “shot”, the user first removes the cap from the pen. A new fully-sheathed needle is screwed on, using the outer sheath as a “thimble”. The “back end” of the needle passes through a resilient “rubber” diaphragm on the tip of the syringe section, entering the chamber holding the insulin solution. The outer needle sheath is then removed, followed by the inner sheath (the latter being discarded).

The user then “arms” the pen for the desired dose by turning the setting knob clockwise. This turns the operating plunger, which is supported in the pen housing by a helical thread of substantial pitch. Thus, as the plunger turns, it advances longitudinally, “screwing itself out of the housing”.

On the operating plunger there is a set of index marks, deployed along a helical path on the plunger. As the cylinder moves helically, these pass successively under the window in the housing. There is a fiducial mark on the edge of the window against which the marks are read. The marks correspond to setting increments of one international unit (IU) of the insulin solution. The even numbered marks (and the mark for "1") are labeled.

The maximum rotation of the plunger is three turns, which corresponds to 60 units. Thus when it reaches the end of its travel, the mark "60" will be in the window, aligned with the fiducial. At this point, the plunger has emerged approximately 1.2" from the housing compared to its "closed" position (the exact stroke varies between the two units).

In figure 3, we see the FlexPen armed to a dose of 20 IU.



Figure 3. FlexPen armed to a dose of 20 IU

The user then inserts the needle at the injection site. Holding the pen body with the fingers of one hand, the thumb of that hand is used to press on the setting knob itself (KwikPen) or an inset button on the setting knob (FlexPen) in order to drive the operating plunger back into the pen body.

The initial pressure on the knob or button shifts the mechanism from the "arming" mode to the "delivery" mode. As the operating plunger spirals back into the pen housing, the mechanism moves the syringe piston (by a much shorter, accurately scaled distance). This delivers the dose through the needle.

When the operating plunger returns to its home position (showing "0" on the scale), the dose delivery is complete. The user withdraws the needle from the injection site, replaces the outer sheath on the needle, and using it as a "thimble", unscrews the needle from the pen and discards it.

The cap is replaced on the pen.

The syringe piston is visible through the transparent syringe barrel, which is provided with a scale showing approximately the amount of insulin solution still available for delivery.

The mechanism keeps track of the amount of insulin solution remaining available for delivery, and does not allow the user to set a dose greater than that. If there is no insulin solution available for delivery, the setting knob cannot be turned at all.

THE MECHANISMS IN DETAIL

Introduction

Although the two types of insulin pens described here have similar appearance and almost identical operation from the standpoint of the user, they use quite different mechanisms. In this section we will describe the operation of these mechanisms in considerable detail with the use of detailed illustrations.

The illustrations are generally to scale, and the components are shown so as to give a useful impression of their actual configuration and juxtaposition. Many liberties have been taken with their details in the interest of clarifying the presentation and minimizing the illustration labor. Special "schematic" notation is used for functional features such as clutches, detents, and ratchets.

When two parts can move with respect to each other, an exaggerated clearance gap is shown between them. Where no clearance is shown, either the two parts are fastened together, there is no prospect of movement between them, or (in the particular figure) one has been pressed against the other preparatory to pushing it longitudinally.

When two parts are "keyed" so that they must rotate together although moving longitudinally with respect to one another (such as in the case of a *telescoping joint*), dashed lines on either side of the clearance gap indicate this.

Where one part engages another with a helical thread, a coarse crosshatch pattern across the clearance indicates this. In the case of the threaded rod (jackscrew) that appears in both mechanisms, the familiar overall crosshatch is used to show the thread; in the "nut plate" through which it is threaded, a crosshatch pattern near the edge indicates the threads. In either case, crosshatch lines going up to the right indicate a left-hand thread, just as we would see the actual threads on the near side of the male part.

The Novo Nordisk FlexPen

The Novo Nordisk FlexPen uses a straightforward mechanism, nicely executed, with a number of very clever details.

Figure 4 is a schematic diagram of this mechanism. Note the special schematic symbols used to call attention to the way certain parts interact.

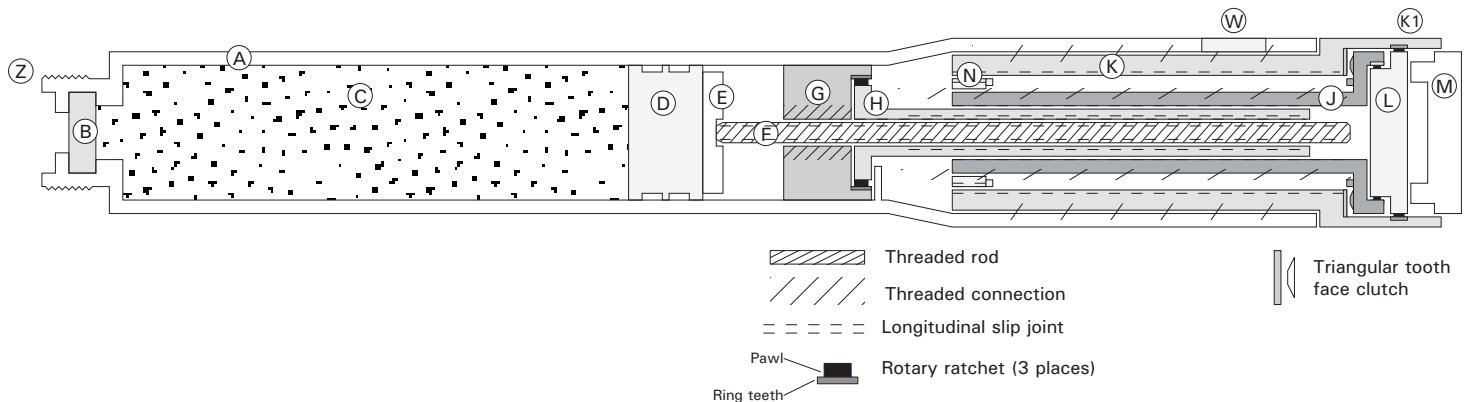


Figure 4. Novo Nordisk FlexPen mechanism (schematic)

The components illustrated are:

- Z Threaded nipple onto which the needle attaches.
- A Body of the pen
- B Rubber diaphragm pierced by the “back end” of the needle.
- C Insulin solution
- D Rubber syringe piston
- E Piston push plate
- F Threaded jackscrew
- G Jackscrew nut plate
- H Jackscrew driving spindle
- J Intermediate cylinder
- K Operating plunger
- K1 Setting knob (part of K)
- L Ratchet rotor
- M Button
- N Content monitor traveler
- W Setting window

Further details of these components will be covered as we learn of their roles in the overall operation.

Arming phase

In order to “arm” the pen for a certain dose, the user turns the setting knob K1 clockwise. The operating plunger K, of which the knob is an integral part, is supported in the pen housing A by a helical thread of substantial pitch. Thus, as the plunger turns, it advances longitudinally (to the right in the figure), “screwing itself out of the housing”.

On the operating plunger there is a set of index marks, deployed along a helical path on the plunger. As the plunger moves helically, these pass successively by the window, W, in the housing. There is a fiducial mark on the edge of the window against which the marks are read. The marks correspond to setting increments of one international unit (IU) of the insulin solution. The even numbered marks (and the mark for “1”) are labeled.

The maximum rotation of the plunger is three turns, which corresponds to 60 units. Thus when the plunger reaches the end of its travel, the mark “60” will be in the window, aligned with the fiducial. At this point, the plunger has emerged approximately 1.31” from the housing compared to its “closed” position.

The intermediate cylinder J follows the operating plunger longitudinally, but does not rotate. It is in fact prevented from rotating by a pawl on its left end operating on a ring ratchet on the fixed nut plate G, which would only allow J to rotate counter-clockwise.

There is a ratchet mechanism between the setting cylinder and ratchet wheel L. Its actual purpose is as a “one way detent”, assuring that K comes to rest at an integral setting position. It clicks for each unit of advance of the knob. L cannot turn to avoid that action, because of a second ratchet mechanism between it and J, which cannot rotate clockwise since it is connected through a sliding coupling to H, and the ratchet between H and fixed nut plate G prevents H from rotating clockwise.

Should the user overshoot the intended setting, and turn the setting knob K1 and operating plunger K counterclockwise to reduce the setting value, ratchet wheel L is forced to rotate as well, since this is not the permissive direction for the K/L ratchet. However, L is able to turn because this is the permissive direction of motion of a second ratchet between L and J. Thus this second ratchet now serves as the “one-way detent”, assuring that now the plunger will again stop at an integral setting position.

There is some drag as this second ratchet (L/J) slips, which will attempt to turn J, which will in turn attempt to turn H (they are connected by a telescoping slip joint), and in this operation this is in

the direction that is permissible for the ratchet between H and the fixed nut plate G, However, the minimum torque required to move the H/G ratchet is greater than the torque for the L/J ratchet, and thus there is not enough torque on J so that it and H will turn.

In figure 5, we see the pen after rotation of the setting cylinder to its maximum dose setting (60 IU).

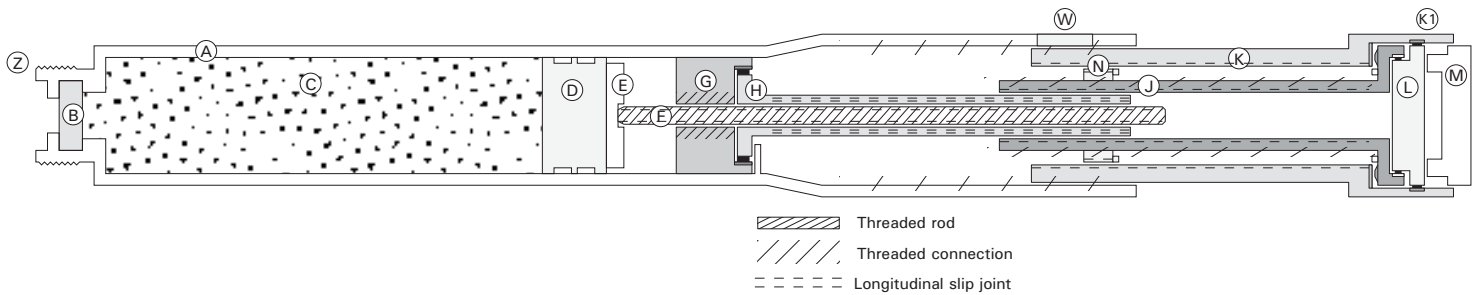


Figure 5. Armed to the maximum settable dose

Delivery phase

Now the user, having inserted the needle into the injection site, presses on button M to drive the operating plunger back into the pen. The first result of this is shown on figure 6.

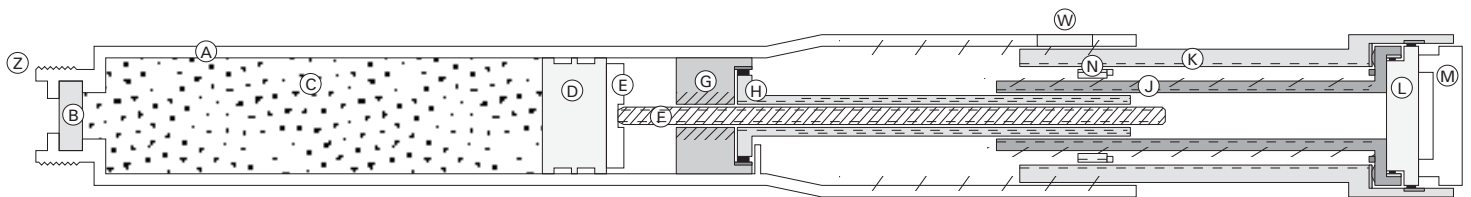


Figure 6. Button depressed at start of delivery stroke

The button M moves against ratchet wheel L, which moves against the face of auxiliary cylinder J, which is pressed slightly to the left, until the left side of its flange presses against the step in cylinder K. The step in K has a saw-toothed face pattern, and several teeth on J press into that. Thus J becomes locked to K.

Further pressure on the button M thus causes J and K together to spiral back into the pen (because of the helical thread on which K is supported).

The rotation of J causes a corresponding rotation of H (they are coupled by a telescoping slip joint). The ratchet between H and G allows this, which is in the permissible direction (now there is substantial torque).

H then turns jackscrew F (they are coupled by a telescoping slip joint). F screws through nut plate G, advancing to the left and, pressing on plate E, moves syringe piston D, delivering the insulin solution through the needle.

When the cylinder returns to its "home" position (beyond which it will not move further into the housing), the correct value of insulin solution will have been delivered.

Figure 7 shows the pen at the completion of this phase of operation.

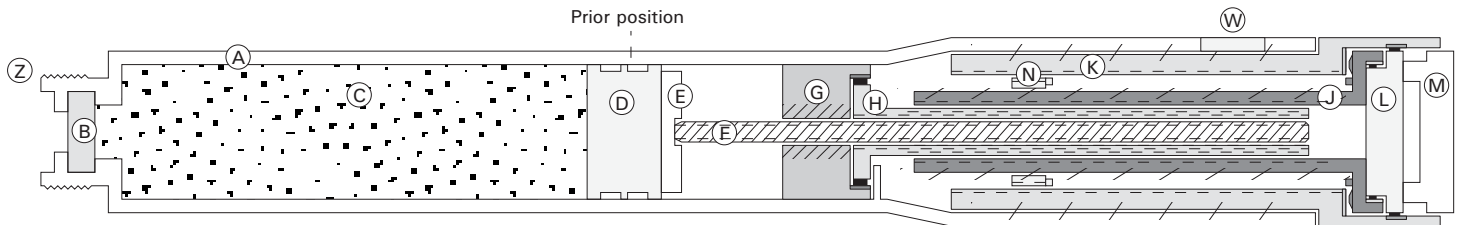


Figure 7. Delivery completed

The dotted line above syringe piston D shows its initial position before this cycle. Thus we can see the amount that it has moved.

The delivery phase is accompanied by the sound of the ratchet between H and G.

Aborting the "shot"

Suppose that for some reason, the user does not discharge the full dose (perhaps the needle is clogged), and decides to abandon the "shot" for the time being.

The user can just turn the operating plunger counterclockwise, with knob K1, until it reaches the home position. Since there is now no pressure on button M, the face clutch between K and J is not engaged, and so this rotation of K does not turn J. Thus there is no further motion of H and F, and no solution is expelled. The pen is now ready for a new attempt "from scratch".

Monitoring of remaining usable content

To simplify the discussion, we have so far ignored the function of component N, the content monitor traveler.

Its purpose is to prevent the user from arming the system for a dose greater than the useable content remaining in the syringe.

Essentially, the position of N along J corresponds to the amount of insulin solution so far discharged by the earlier cycles of the pen plus any amount “committed” by a current setting¹.

How does this happen? The traveler is like a nut, with coarse internal threads, which ride on external threads on the outside of J. It also has a slot on its exterior that rides on a “rib” on the inside of K, thus keying N in rotation to K.

When the user turns the setting knob, K is rotated, and the keying rib on K rotates N, which screws itself along the thread on J (which does not rotate during arming) by an amount corresponding to the setting amount. We in fact see this after the first arming cycle in figure 5.

During discharge, both K and J rotate, and thus there is no movement of N along J. Accordingly, the net advance of N along J during this cycle remains proportional to the setting, and thus to the amount of insulin solution discharged as the cycle is completed. This movement of N along J accumulates in this way for each cycle.

We see this after completion of the discharge for the first cycle in figure 7.

Suppose that the usable remaining content (a small amount will by intent remain unused) corresponds to 25 IU. Then N will be very near the right-hand end of its travel along J. We see this with the operating plunger “at home” in figure 8.

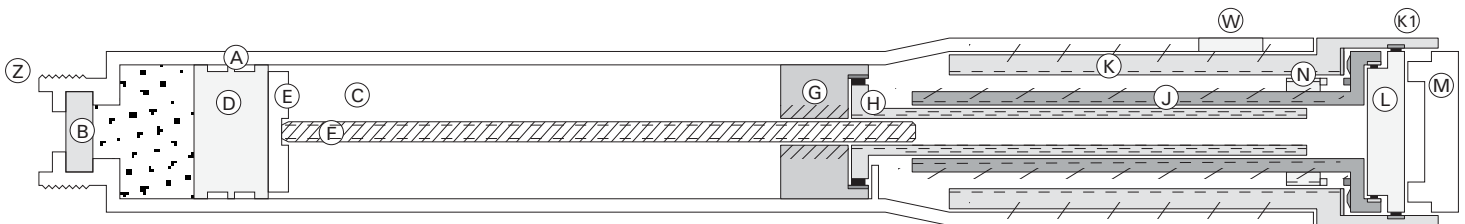


Figure 8. Small usable content remaining

Suppose the user would like to arm the pen for a dose of 35 IU. As discussed above, as K is rotated, the rib on K rotates N, which as before screws itself along the thread on J (which does not rotate during arming). When the setting cylinder reaches 25, N has come to the end of its travel along J. A pair of lugs on the right face of N then comes up against a pair of lugs on the left face of the flange of J, preventing any more relative rotation between N and J. N is keyed to K. Thus, K, J, and N are locked together.

¹ This is like accrual accounting.

Figure 9 shows this situation. The small circle calls attention to the lower lug on N interacting with a lug on J.

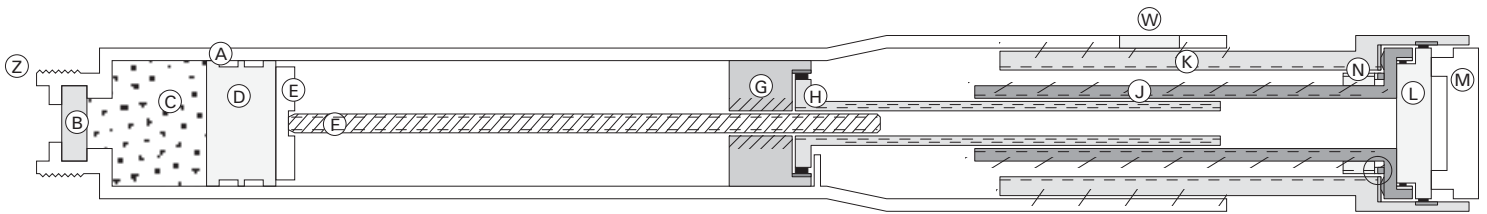


Figure 9. Armed for maximum available dose

Thus K can turn no more unless J turns too, but J is linked to H, and H is prevented from turning clockwise by the ratchet between it and fixed part G. Thus further motion of K is arrested—with it reading exactly “25”. Thus, the user realizes that there is only 25 IU of insulin left.

Noting that, he may decide shoot that 25 IU dose, move the needle to a new pen, and shoot 10 IU from it. Alternatively, he may decide he will only take 25 IU right now, discard the exhausted pen, and go on about his business. Or he may take the needle off the pen, discard the pen (wasting 20 IU of insulin solution), put the needle on a new pen, and shoot the full 35 IU dose from it.

If the user aborts the discharge before completion, and returns the setting cylinder to “home” by turning the knob, the relative rotation between K and J (which does not move during this maneuver) partially resets N, thus crediting the discharge reckoning with part of the amount already “charged” during arming but not actually discharged.

Figure 10 shows the situation after discharge of all available content.

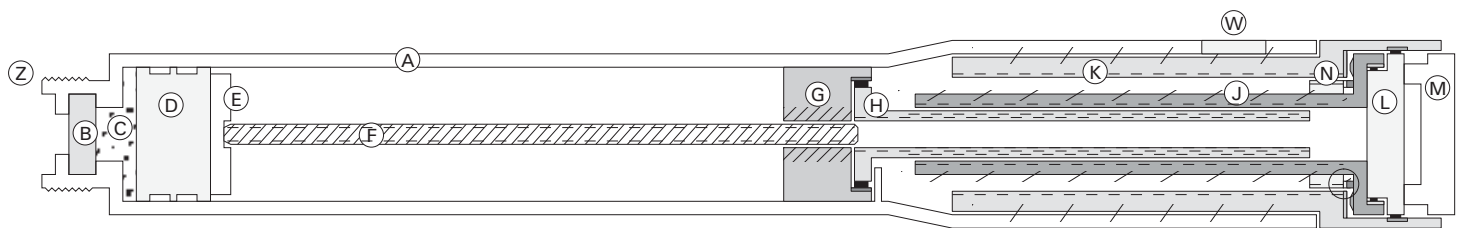


Figure 10. After discharge of all available content

We note that, with the pen in its “home” position, N is already at the far right of its travel along J, and we see (in the circle) its lug already engaging the lug on the left face of the flange of J. Now, K cannot be turned at all to attempt to arm the pen for a new cycle.

A peek at the real parts

Now that we understand what the parts of the FlexPen do, let's look at how some of the more interesting ones are actually made.

In figure 11, we see the operating plunger k, with its knob K1 at the right.

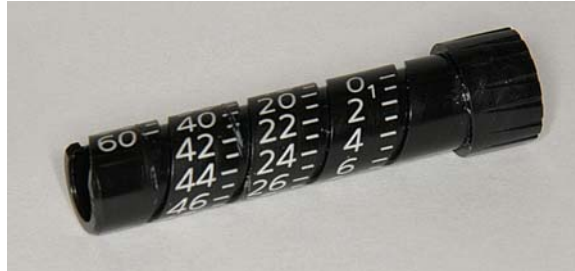


Figure 11. FlexPen operating plunger (K)

Figure 12 shows some of the other parts.

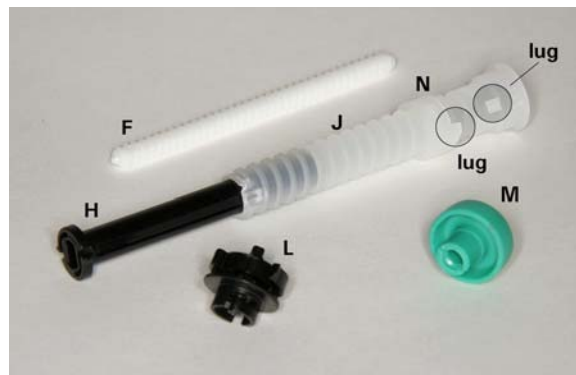


Figure 12. FlexPen parts

We see the jackscrew F; the jackscrew driving spindle K emerging from the intermediate cylinder J; on J, the content monitor traveler N, riding on the external threads on J; the ratchet rotor L; and the button M.

Jackscrew F has flats, and it passes into a flat-sided bore on K, making a telescoping rotary drive joint.

On L, the pawl fingers nearest us engage J; those on the far side engage K (actually at the interior of knob K1).

We see the lug on N and the lug on J it engages when all content is delivered or committed (contrast emphasized in the circles).

The Eli Lilly KwikPen

Although the overall appearance and functionality of the Eli Lilly KwikPen is almost indistinguishable from that of the FlexPen, the mechanisms are entirely different. The KwikPen uses a convoluted scheme of movements of three screw mechanisms, with differing rates and algebraic signs. During arming, all three are summed, but their total cancels out, so the syringe piston is not moved. During discharge, one of those movements is disabled, and the algebraic sum of the remaining two moves the piston at the proper ratio.

Figure 13 shows the arrangement of the mechanism. Note the special schematic symbols used to call attention to the way certain parts interact.

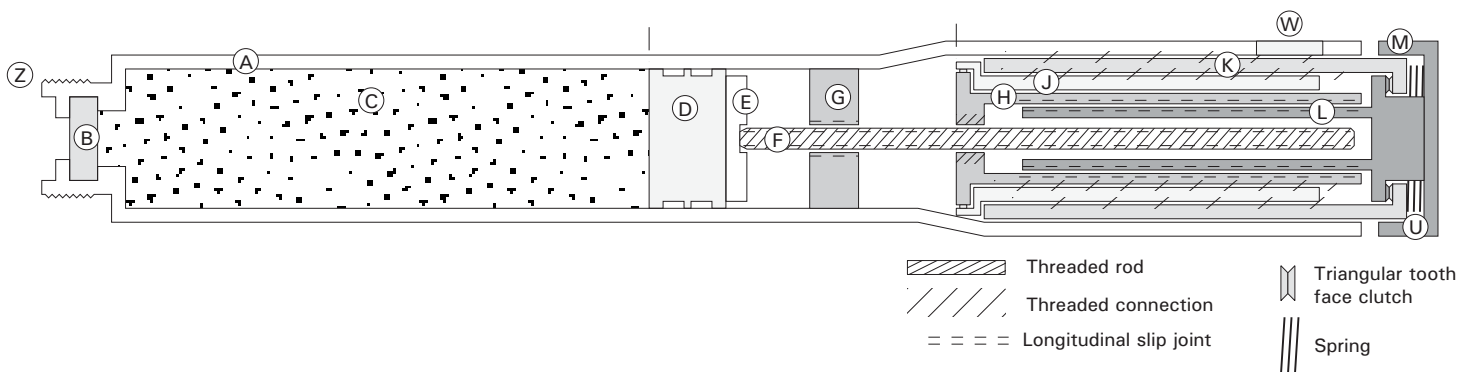


Figure 13. Eli Lilly KwikPen mechanism (schematic)

The components illustrated are:

- Z Threaded nipple onto which the needle attaches.
- A Body of the pen
- B Rubber diaphragm pierced by the “back end” of the needle.
- C Insulin solution
- D Rubber syringe piston
- E Piston push plate
- F Threaded jackscrew
- G Jackscrew guide plate (prevents rotation of jackscrew)
- H Jackscrew driving cylinder²
- K Operating plunger
- J Control cylinder

² In reality, H and L are not concentric cylinders, as suggested by the drawing, but partial cylinders of the same diameter. Each has a pair of “prongs” that nestle into the spaces between the prongs of the other one. This is difficult to illustrate on the schematic drawing, so I took the liberty seen.

- L Clutch cylinder
- M Knob
- W Setting window
- U Clutch engaging spring

Further details of these components will be covered as we learn of their roles in the overall operation.

Arming phase

In order to “arm” the pen for a certain dose, the user turns knob M clockwise. It is rigidly attached to the clutch cylinder L. Spring U holds L against the left edge of the flange on the operating plunger K. There is a sawtooth clutch at that point, which is held engaged by the spring force. Thus L and K are (for now) coupled together for rotation.

Turning the knob turns L and K. The operating plunger K is supported in the pen housing A by a helical thread of substantial pitch. Thus, as the cylinder turns, it advances longitudinally, “screwing itself out of the housing”.

On the operating plunger there is a set of index marks, deployed along a helical path on the plunger. As the plunger moves helically, these pass successively by the window, W, in the housing. There is a fiducial mark on the edge of the window against which the marks are read. The marks correspond to setting increments of one international unit (IU) of the insulin solution. The even numbered marks (and the mark for “1”) are labeled.

The maximum rotation of the operating plunger is three turns, which corresponds to 60 units. Thus when it reaches the end of its travel, the mark “60” will be in the window, aligned with the fiducial. At this point, the plunger has emerged approximately 1.125” from the housing compared to its “closed” position.

Control cylinder J is suspended inside setting cylinder K on a set of helical threads with pitch slightly less than the pitch of the threads by which K is supported in the housing. Fins in the housing A engage slots on the left end of J (not seen in the drawing) to prevent J from turning.

Thus, as the operating plunger K “screws itself” out of the housing to the right, it expels control cylinder J out its tail to the left. But this motion is not at the same rate as the longitudinal advance of K (since the pitch of the threads by which J is suspended in K is less than the pitch of the threads by which K is suspended in the housing A). Thus J has a net movement to the right, just slower than the motion of K.

Cylinders H and L are connected by a telescoping finger joint. Thus during the arming process, H rotates as well. A detent between H and J (J is not rotating) assures that when the user lets go of the knob, the rotating members (H and K) are at an integral dose setting.

As H moves slowly to the right, we would think it would pull jackscrew F along. But the jackscrew is connected to H by being screwed into a threaded hole in the left wall of H. The direction of the thread on F is such that the rotation of H expels F from the tail of H as H moves to the right. The pitch of the thread on F is such that there is no net movement of F during this process. (See "The algebra of the movement", below.)

In figure 14, we see the system after the completion of an arming operation for nearly the maximum settable dose.

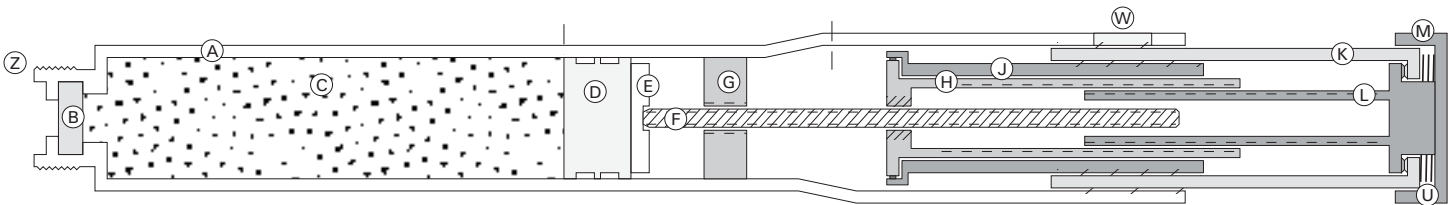


Figure 14. Armed for near maximum dose

The dotted lines show the initial positions of syringe piston D and the left end of cylinder h. We can see that cylinder H has moved to the right, but not as far as operating plunger K. And we see that syringe piston D hasn't moved at all.

Delivery phase

Now the user inserts the needle into the injection site, grasps the pen with his fingers, and presses on the knob M with his thumb. The initial effect is seen on figure 15.

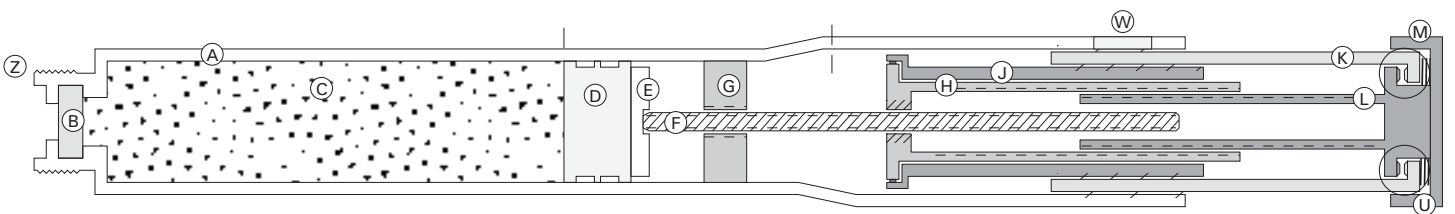


Figure 15. Knob depressed at start of delivery stroke

The pressure on knob M moves the knob and inner cylinder L to the left. This disengages the sawtooth face clutch between L and K (see in the circles).

Further movement of M pushes L and (once spring U fully compresses) K to the left. K will “screw itself back into the housing”. But the rotation of K does not force L to rotate, since the clutch has been disengaged.

The differential thread arrangement from the housing through K to J, which we saw at work during the arming phase, now works the other way, with J moving to the left (but more slowly than the leftward movement of K). J then pushes H (slowly) to the left.

We heard earlier that there is no torque to turn L, so there is no torque from L to turn H. And in fact the detent between H and J (J cannot rotate, being keyed to the housing) keeps H from turning from miscellaneous torque. (See “Disadvantages”, below.)

With H not turning, it will not “suck” jackscrew F back into its tail. Thus the leftward movement of H will move F the same amount. This in turn pushes syringe piston D (via plate E), discharging insulin solution through the needle.

Figure 16 shows the situation after completion of the delivery stroke.

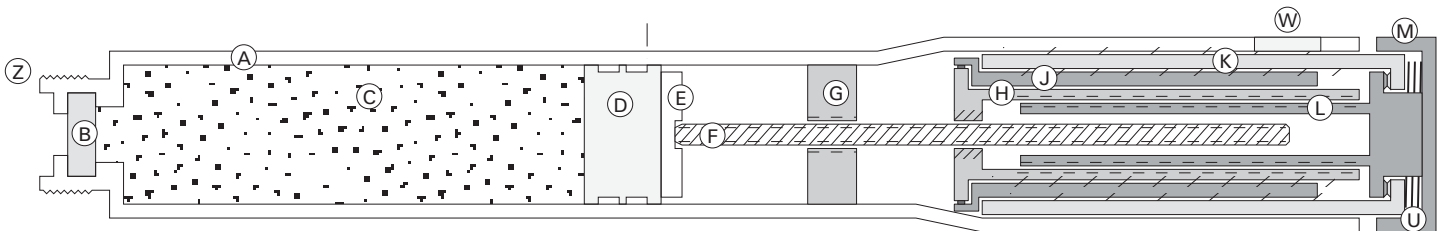


Figure 16. Delivery stroke completed

Again, the dotted line shows us the previous position of the syringe piston D.

The delivery operation is ordinarily silent, no ratchets or detents being exercised during the process (but see later under “Disadvantages”).

Aborting the “shot”

Suppose that for some reason, the user does not discharge the full dose (perhaps the needle is clogged), and decides to abandon the “shot” for the time being.

The user can just turn the setting cylinder counterclockwise, with knob M, until it reaches the home position (“0”). Since there is now no longitudinal pressure on knob M, pressure on the button, the face clutch between K and L is engaged. Thus K, L, and H rotate together,

just as during the arming operation, but in the opposite direction. The interaction of the three screw motions means that there is no motion of jackscrew F (just as during arming). After the operating plunger has returned to its home position, the pen is ready for a new attempt “from scratch”.

Monitoring of remaining usable content

We also have here a way of preventing attempts to arm the system to deliver a dose greater than the available content left in the syringe. It is very simple (about time). We can follow its operation on figure 17.

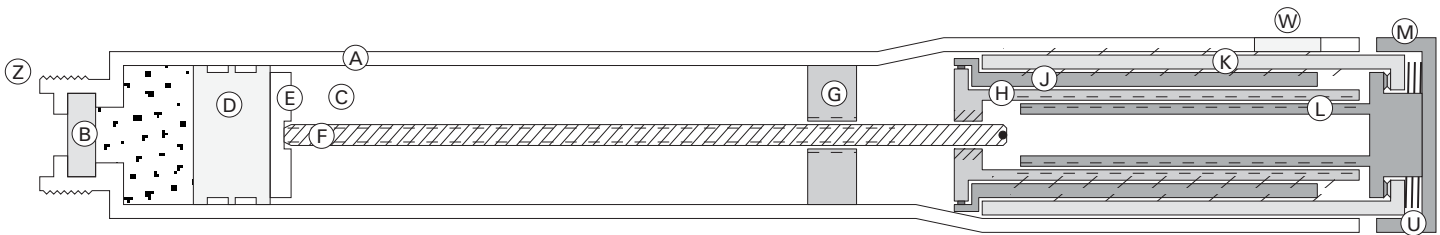


Figure 17. Only small usable content remaining

Here, previous cycles have almost delivered the entire usable content. Note that the right end of jackscrew F is almost up to the threaded plate on the left of H.

The thread grooves on F have a “closed end” (F is a “two-lead” thread, with two distinct land/groove pairs). If the end attempts to actually enter the thread plate, the end of each “land” in the threaded hole will contact the closed end of the corresponding groove on F, and prevent any further rotation between F and H. (The black dot reminds us of the closed-end thread.)

In the situation shown, when the user next attempts to arm the pen, as H moves to the right, rotating, it will “unscrew itself” along F, preventing F from moving (as is normal during arming). But shortly, H will come to the end of the thread on F. Thus no further rotation of H, L and K can occur and arming motion must halt. The pen will be armed to only deliver the available insulin solution, and the scale will indicate that dose.

A peek at the real parts

Now that we understand what the parts of the KwikPen do, let’s look at how two of the more interesting ones are actually made.

In figure 18, we see control cylinder J and jackscrew driving cylinder H.



Figure 18. KwikPen control cylinder J and jackscrew driving cylinder H

On J we see the threads by which it is supported inside operating plunger K.

In figure 19, we see these two parts mated as they are in the completed pen.



Figure 19. Jackscrew driving cylinder H in control cylinder J

Prongs on the fingers near the left end of J act on sets of teeth just right of the flange at the left end of H to provide the H/J detent.

The algebra of the movement

It is interesting to examine the curious operation of the setting and delivery mechanism operations algebraically. I will use the following notation:

- P_{ka} The pitch of the thread by which operating plunger K is suspended in housing A.
- P_{jk} The pitch of the thread by which cylinder J is suspended in operating plunger K.
- P_{fh} The pitch of the thread on jackscrew F (operating into H).
- A_k The angular movement (in turns) of operating plunger K.

- x_k The longitudinal movement of K with respect to the entire pen (positive to the right)
- x_{jk} The longitudinal movement of J with respect to K (positive to the right)
- x_{fh} The longitudinal movement of F with respect to H (positive to the right)
- x_f The longitudinal movement of F with respect to the entire pen (positive to the right)
- S The amount of the setting (in turns of the operating plunger, K), positive clockwise

Now, in the setting phase, as we turn operating plunger K through an angle $A_k = S$:

$$x_k = SP_k \quad (1)$$

$$x_{jk} = -SP_{jk} \quad (2)$$

$$x_{fb} = -SP_{fb} \quad (3)$$

the minus signs in the last two being the result of the “hand” of the respective threads and which member rotates with respect to what.

These three motions are summed to give the absolute motion of F as follows:

$$x_f = SP_k - SP_{jl} - SP_{fb} \quad (4)$$

or

$$x_f = S(P_k - P_{jl} - P_{fb}) \quad (5)$$

Now, the design of the system is evidently such that:

$$P_{fb} = P_k - P_{jl} \quad (6)$$

which we can restate as:

$$P_k - P_{jl} - P_{fb} = 0 \quad (7)$$

Thus, substituting equation 7 into equation 5, we get:

$$x_f = 0 \quad (8)$$

showing that there is no motion of jackscrew F during setting.

Now, during the delivery phase, H does not rotate, and there is thus no relative motion between F and H (i.e., $x_{fh}=0$). Note that here the change in angle of K is $-S$ (since we are returning K to its home position, with counter-clockwise rotation).

Now, the absolute motion of F is given by:

$$x_f = -S(P_k - P_{jl}) \quad (9)$$

The design is such that $P_k > P_{jl}$. Thus the term in parentheses is positive, and x_f will be negative—motion of F to the left, moving syringe piston D in the direction to deliver insulin solution.

Numerical example

In the specimen unit, the approximate pitches are (I have forced them to add up as required by the design concept):

P_{ka} 0.375"

P_{jk} 0.260"

P_{fh} 0.115"

Assume that the user arms the unit to deliver 20 IU, with one turn of the operating plunger K. For that one turn (clockwise) of K, it moves to the right by 0.375". Jackscrew driving cylinder H moves to the left **with respect to K** by 0.260", and thus the net movement of H is to the right by 0.115". But H, which is rotating, unscrews itself along jackscrew F, also by 0.115", so F does not move at all.

During delivery, for the full stroke, the operating plunger K makes one turn counterclockwise. It moves to the left by 0.375". Jackscrew driving cylinder H moves to the right with respect to K by 0.260", and thus the net movement of H is to the left by 0.115" (K and H now being back to their normal home positions).

But since H does not turn during the delivery phase, it does not "screw itself to the left along F", but rather just pushes F to the left by 0.115", delivering 0.2 ml (20 IU) of insulin.

Why all this?

Especially having seen the direct approach of the FlexPen to operation in the setting mode, it is hard to imagine where the roundabout scheme of the KwikPen came from. The most likely notion is that it was contrived to avoid patents (such as those covering the FlexPen design).

Disadvantages

The author notes two potential disadvantages of the KwikPen mechanism design.

1. During the delivery phase, pressure on the operating plunger knob M disengages the sawtooth face clutch between L and K. This allows L and K to move longitudinally, without rotation, as K spirals back into the housing. The lack of rotation of H is a predicate for the proper motion of the jackscrew F (see equation 9).

But if K overly-enthusiastically starts its spiral movement back into the housing (propelled, in a sense, by the spring, U), the gap in the clutch may close, and K as it rotates will attempt to turn L. The detent between H and J resists the turning of L (which is keyed to H). As the user's thumb pressure on M continues, M and L move more to the left, disengaging the clutch. Then perhaps K will again jump ahead in its spiral movement, again reengaging the clutch, and so on.

The result of this repeated partial engagement and then disengagement of the clutch is an unexpected buzzing sound (the delivery operation is normally silent). This can be very disconcerting to the user.³

It seems that ordinarily the friction attending the movement of K means that K will not "jump ahead" under the influence of spring U (waiting instead until spring U is fully compressed, and then moving longitudinally in pace with M and L), and this phenomenon will not usually occur.

2. [For completeness, I will repeat the first passage from the case above, which is also applicable to this issue.] During the delivery phase, pressure on the operating plunger knob M disengages the sawtooth face clutch between L and K. This allows L and K to move longitudinally, without rotation, as K spirals back into the housing. The lack of rotation of H is a predicate for the proper motion of the jackscrew F (see equation 9).

Although there is no torque from the rotation of K onto H (the clutch being disengaged), what would prevent H from rotating under the influence of some hypothetical "extraneous" torque? Only the resistance of the detent between H and J (J never rotates, as it is keyed to the housing).

³ It was in fact my encountering of this phenomenon in a KwikPen newly put into service that prompted this entire investigation of the pen mechanisms.

Where could such an extraneous torque come from? Note that knob M is rigidly attached to L. Suppose the user, instead of pressing on M with his thumb, grasped M with the other hand to push it in. If the user inadvertently placed any torque on M while doing this, that torque would go directly to L and through the sliding joint to H. It could easily overcome the resistance of the H/J detent. The result might be some unwanted rotation of H, causing the advance of F to not be as desired, delivering an improper dose.

The same could occur with thumb actuation if there was significant friction between the thumb and knob M, especially if the thumb motion has a rotary aspect (perhaps the thumb of the opposite hand is used).

In any case, as we see from equation 9, the rotation of H would add an unwanted component to the intended motion of jackscrew F, resulting in an inaccurate delivery of the insulin dose.

The likelihood of such misbehavior is of course slight. Still, it is disappointing that the design admits it.

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