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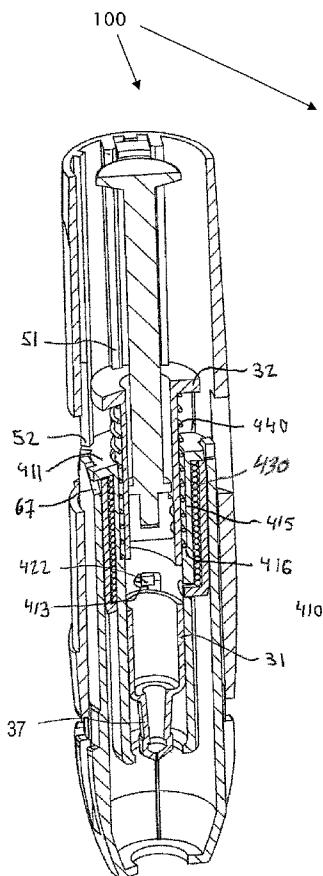
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(54) Title: A DISPOSABLE INJECTING DEVICE WITH AUTO-RETRACTION MECHANISM



(57) Abstract: A disposable auto-injector that facilitate full automation of injection process including auto retraction of the needle into the device at end of delivery without the associated drawbacks that currently exist. The disposable auto-injector comprises a syringe barrel which is opened distally with an outer finger's flange; a needle mounted in the hub of the barrel; a plug slidably located within the barrel; liquid medication delimited inside the barrel between the plug and the needle; and a plunger rod abuts the back of the plug. The injector device utilizes a reservoir containing liquid medication and a needle for delivering the medication that by releasing a safety catch and forcing the device against the injection sight, may automatically manipulate the reservoir and the needle to perform needle penetration into injection sight, drug delivery, and needle retraction at end of delivery.

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AMENDED CLAIMS**received by the International Bureau on 27 February 2008 (27.02.08)**

1. An injecting device for automatically inject a predetermined dose of liquid medication into a tissue at a target injection site, the injection device has a distal end and a proximal end, and houses a medication reservoir having a proximal end and a distal end, wherein the medication reservoir includes: (i) a barrel, wherein said barrel is narrowed and initially closed at the proximal end of said barrel and opened at the distal end of said barrel; (ii) a plug, wherein said plug is slidably disposed inside said barrel; (iii) a plunger rod, wherein the proximal end of said plunger rod extends into the opening at the distal end of said barrel; and (iv) a liquid medication contained in a chamber formed in said barrel between said proximal end of said barrel and said plug, and wherein the injection device further houses a needle, wherein said needle is disposed in front of the proximal narrowed end of said barrel, either affixed to the proximal narrowed end of said barrel or part of a separate needle assembly, arranged to provide a passageway for delivering the medication from said reservoir into the tissue during injection, wherein said medication reservoir is operable to move between a retracted position, wherein said needle is fully secured inside said housing of the device, and a forward position, wherein said needle is partially projected out of an opening at the proximal end of the device, the injection device comprising:

- a) a housing;
- b) an internal assembly comprising: (i) an inner sleeve ending distally with an outer flange and having a bore; (ii) a driving sleeve having a bore, and (iii) a propelling spring, wherein said inner sleeve is slidably disposed with free peripheral space inside said bore of said driving sleeve, wherein said driving sleeve and said inner sleeve are initially interlocked, and wherein said propelling spring is initially restrained in a compressed state inside said free peripheral space; and,
- c) a return spring having a stored potential energy, when said medication reservoir is in said forward position; wherein said energy is significantly smaller with respect to said propelling spring residual energy, at the end of an injection, wherein said return spring is arranged to bias said medication reservoir distally, said return spring is in substantially uncompressed when said medication reservoir is in said retracted position,

whereas said internal assembly is axially disposed inside said housing;

whereas said medication reservoir is slidably mounted inside said bore of said inner sleeve with said needle disposed proximally to said medication reservoir;
whereas said return spring is axially disposed within said internal assembly, acting between said inner sleeve and said medication reservoir; and
whereas said return spring performs automatic retraction of said needle, upon termination of an injection of said medication into said tissue.

2. The device of claim 1, wherein said driving sleeve, upon said unlocking of said initial interlock of said inner sleeve with said driving sleeve, is being driven proximally by said propelling spring, and wherein said inner sleeve is axially situated in a determined location with respect to said housing at least during said injection.
3. The device of claim 2, wherein said driving sleeve further comprising at least one arm extended distally and operatively engaged with said distal end of said plunger rod, wherein when said driving sleeve is driven proximally, said at least one arm is being pulled, thereby pulling said plunger rod proximally to firstly move said medication reservoir from said retracted position to said forward position while compressing said return spring, whereas said medication reservoir is stopped by said inner sleeve, and thereafter, driving proximally said plug along said barrel of said reservoir, thereby expelling said liquid medication through said passageway of said needle.
4. The device of claim 3, wherein said at least one arm extended distally, said outer flange of said inner sleeve contains at least one notch on the circumference of said outer flange, enabling said arms to pass through said outer flange towards said distal ends of said plunger rod.
5. The device of claim 3, wherein said at least one arm is arranged to be disposed outwardly at least during injection.
6. The device of claim 5, wherein said engagement of said distal end of said at least one arm with said distal end of said plunger rod is obtained by providing an inwardly projection (424) at said distal end of said at least one arm, wherein said inwardly projection abuts an outer face of said distal end of said plunger rod by an outwardly inclined face of said projection (424), and wherein said engagement of said projection with said plunger rod being disposed inwardly towards said device central axis respectively to a higher distance from said central axis of a vector of force of said at least one arm being pulled, thereby creating an

outwardly moment on said at least one arm, and thereby causing said outwardly disposition of said arm.

7. The device of claim 3, wherein said medication reservoir is stopped by said inner sleeve when said narrowed proximal end of said barrel of said medication reservoir encounters an inwardly peripheral extension extending from the inner wall of said inner sleeve at said proximal end of said inner sleeve or a few millimeters distally from said proximal end of said inner sleeve.

8. The device of claim 3, wherein said medication reservoir is stopped by said inner sleeve when a finger flange at said distal end of said medication reservoir encounters said distal end of said inner sleeve.

9. The device of claim 5, wherein said housing comprising a gripping barrel, having a proximal opened end and a distal end, and a triggering barrel, having a proximal end and a distal end, wherein said triggering barrel is slidably adopted inside said gripping barrel through said proximal opened end and partially projected from said proximal opened end.

10. The device of claim 9, wherein said triggering barrel is initially in rest position operable to further move a small distance into said gripping barrel to reach a triggering position, wherein an injection is triggered when an external force is applied to operate said movement of said triggering barrel from said initial rest position to said triggering position, thereby causing said internal assembly to unlock said initial interlock of said inner sleeve with said driving sleeve.

11. The device of claim 10, wherein said gripping barrel, having an inner wall, further comprising at least one longitudinal support (53) for supporting said at least one arm of said driving sleeve, thereby holding said outwardly disposition of said at least one arm, thereby preventing said arm from being deformed outwardly and maintaining said engagement of said at least one arm with said plunger rod along said movement of said driving sleeve, wherein said at least one longitudinal support (53) has a proximal end in a location where said at least one longitudinal support stops supporting said at least one arm when substantially all of said medication is delivered, causing said outwardly disposition of said at least one arm to an outwardly deformation of said at least one arm, thereby disengaging from said plunger rod, enabling said compressed return spring to force said medication reservoir back to said retracted position.

12. The device of claims 10, wherein said inner sleeve is axially situated in a determined location with respect to said housing at least during injection by said external force being further applied during injection to bias said triggering barrel distally, thereby said distal end of said triggering barrel forces the proximal side of said outer flange of said inner sleeve against an internal abutment (52) on the inner wall of said gripping barrel, which abuts the distal side of said outer flange of said inner sleeve.

13. The device of claims 1, wherein said unlocking of said initial interlock of said inner sleeve with said driving sleeve is obtain by a limited rotation of said inner sleeve respectively to said driving sleeve, whereas said inner sleeve and said driving sleeve contain locking elements designed to be unlocked by said limited rotation.

14. The device of claims 13, 3 and 10, wherein said triggering barrel is being moved distally into said triggering position, thereby causing said internal assembly to perform said unlocking of said initial interlock of said inner sleeve from said driving sleeve, wherein said distal movement is translated to a limited rotation of said inner sleeve, wherein said driving sleeve is prevented from rotating by said at least one arm of said driving sleeve, guided by limiting ribs (51) on said inner wall of said gripping barrel.

15. The device of claim 14 and 12, wherein said triggering barrel contains at least one inclined side wall at said distal end of said triggering barrel, and wherein said inner sleeve contains at least one notch in said outer flange, and wherein each of said inclined side walls of said triggering barrel biases an adjacent side wall of said notch of said inner sleeve when said triggering barrel is being moved distally into said triggering position to rotate said inner sleeve while said outer flange of said inner sleeve is abutted by said internal abutment (52) on said inner wall of said gripping barrel, thereby preventing distal movement of said inner sleeve.

16. The device of claim 1, wherein said restrained propelling spring is supported at a first end by said outer flange of said inner sleeve and supported at a second end by inwardly peripheral abutment at said proximal end of said driving sleeve.

17. The device of claim 13, wherein said inner sleeve and said driving sleeve contain locking elements designed to be unlocked by said limited rotation wherein said inner sleeve further comprises longitudinal grooves (414) opened proximally and ending distally with notches (413) extending radially from said distal ends.

18. The device of claims 17 and 16, wherein said driving sleeve further comprises dowels (422) extending inwardly from said proximal end, wherein said dowels extend closer to said central axis respectively to said abutment for supporting said propelling spring.

19. The device of claims 18 and 2, wherein said interlock is obtained by said dowels engaged with said notches, and wherein upon said rotating of said inner sleeve with respect to said driving sleeve, said dowels disengage from said notches and engage said longitudinal grooves, thereby enabling said driving sleeve to be driven proximally.

20. The device of claim 1, wherein said medication reservoir is a pre-filled syringe ending proximally with a hub having an orifice, and wherein said needle is initially coupled to said orifice of said hub.

21. The device of claims 20 and 7, wherein said syringe is in said forward position initially closed at the proximal end by a needle shield covering said needle and releasably sealed to said hub, whereas the distal end of said needle shield is abutted by a front face of said inwardly peripheral extension of said inner sleeve.

22. The device of claim 21, wherein said needle shield is encircled by a releaser (90), having a substantially cylindrical body, and wherein said releaser, is arranged to release said sealing coupling of said needle shield and thereafter to remove said needle shield.

23. The device of claim 22, wherein said releaser further comprising a small sectioned arms ended with small inwardly projections arranged to release said sealing coupling, wherein said release is obtained by said releaser being pushed distally, thereby the inwardly projections of said arms push said narrowed end of said syringe and force said syringe distally to said retracted position, while the distal end of said needle shield is being abutted by said inwardly peripheral extensions of said inner sleeve, thereby preventing said needle shield from moving distally, and wherein said removal of said needle shield is obtained by the inner side of said inwardly projections abut the distal end of said needle shield, thereby being removed together with said releaser, when said releaser is removed.

24. The device of claims 1 and 23, wherein said releaser (90) couples said inner sleeve to said triggering barrel, thereby said releaser serves as a safety catch, preventing said inner sleeve from rotating with respect to said triggering barrel, wherein said safety catch is canceled when said releaser (90) is removed.

25. The device of claim 24, wherein said releaser (90) comprises longitudinal ribs, wherein said longitudinal ribs fitly inserted through notches in said opening at said proximal end of said triggering barrel, and through grooves in said inner sleeve.

26. The device of claim 1, wherein said medication reservoir is a cartridge closed proximally with a piercable stopper, and wherein said needle is part of a needle assembly comprising a cannula sharpen at both ends and having a proximal end and a distal end, and a middle wall for initially holding said needle proximally to said cartridge with said distal end of said cannula adjacent to said piercable stopper.

27. The device of claim 1, further comprising a longitudinal window for inspecting said medication barrel, wherein said window comprises respective openings in said gripping barrel, said triggering barrel and said inner sleeve.

28. The device of claim 10, further comprising a safety catch, said safety catch preventing said triggering barrel from moving said small distance into said gripping barrel, thereby preventing activation of an injection.

29. The device of claim 28, wherein said preventing of said triggering barrel from moving said small distance into said gripping barrel is arranged by an "L" shaped groove disposed on the side wall of said gripping barrel; said "L" shaped groove having an axial portion and radial portion, and wherein a dowel extended outwardly from the side wall of said triggering barrel is disposed inside the radial portion of said gripping barrel, thereby preventing said triggering barrel from moving said small distance into said gripping barrel, and wherein said safety catch is released by said limited rotation of said triggering barrel with respect to said gripping barrel, thereby moving said dowel into said axial portion of said "L" shaped groove.

30. The device of claim 28, wherein said safety catch is an annular clip, wherein said annular clip is located between a head portion at a proximal side of said triggering barrel and said proximal end of said gripping barrel, thereby blocking said triggering barrel from moving said small distance into said gripping barrel, and wherein said safety catch is operable to free said blocking by removing of said blocking element.

31. The device of claim 13, further comprising a safety catch, said safety catch preventing said limited rotation of said inner sleeve respectively to said driving sleeve, thereby

preventing said unlocking of said initial interlock of said inner sleeve with said driving sleeve, and thereby preventing activation of an injection.

32. The device of claim 31, wherein said safety catch is a blocking element, wherein said blocking element engaged with said flange of said inner sleeve, thereby preventing said rotation of said inner sleeve with respect to said driving sleeve, and wherein said safety catch is operable to free said blocking by removing of said blocking element.

33. The device of claim 31, wherein said safety catch is a member slidably mounted on a side wall of said gripping barrel, having an internal portion and an external portion, wherein said internal portion is arranged to engage with notches on said outer flange of said inner sleeve, thereby preventing rotation of said inner sleeve with respect to said driving sleeve, and wherein said safety catch is operable to free said blocking by manually pushing said member through the external portion to remove said member out of engagement with said inner sleeve.

34. A method for automatically inject a predetermined dose of medication into a tissue at a target injection site, using an injecting device as in claim 1, the method comprising distally moving said triggering barrel with respect to said gripping barrel, thereby releasing said interlock of said inner sleeve and said driving sleeve.

35. The method of claim 34, further comprising releasing a safety catch prior to said moving of said triggering barrel with respect to said gripping barrel.

36. In a device as in claim 1, a method for removing a needle shield, using a releaser (90), the method comprising the steps of:

- a) forcing said releaser distally towards said device, thereby disengaging said needle shield from said medication reservoir; and
- b) withdrawing said releaser together with said needle shield.

STATEMENT UNDER ARTICLE 19(1)

The amendments made to the claims are mostly for clarification purposes and do not or make just minor changes to the significance of the claims.