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(54) ULTRA-LOW WASTE DISPOSABLE SYRINGE WITH SELF-ADJUSTING INTEGRATED SAFETY FEATURES

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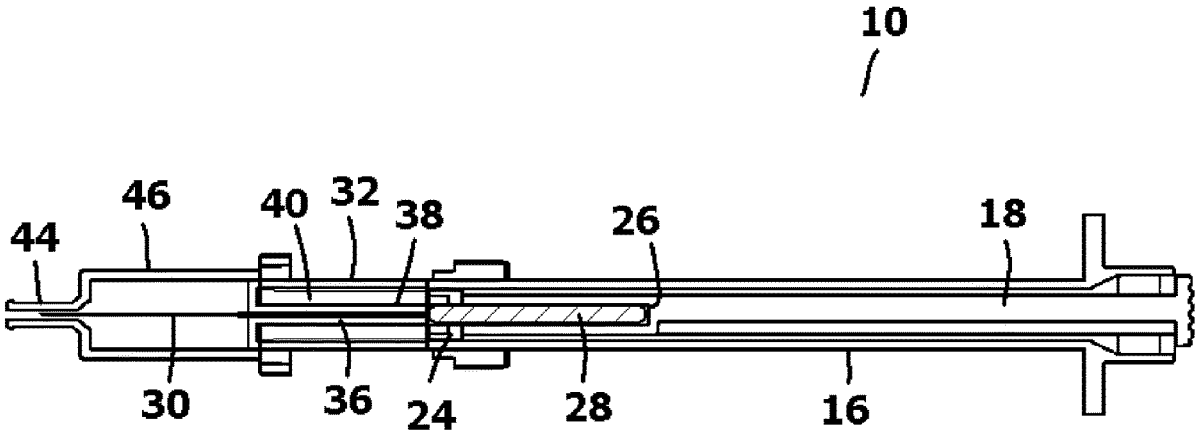
CPC *A61M 5/326* (2013.01); *A61M 5/3129* (2013.01)

(57) **ABSTRACT**

A system with a needle head that attaches to a syringe assembly. The syringe assembly contains a barrel and a plunger. The plunger has a bore opening that is accessible from within the barrel. A tubular spacer is disposed within the barrel. The tubular spacer defines a central opening. The needle head has a needle that extends from a needle base. The needle base extends into the central opening of the tubular spacer. A plug is provided that blocks access to the needle. The plug is displaced out of the central opening of the tubular spacer and into the opening in the plunger as the plunger contacts and displaces the tubular spacer in the barrel. As the plug is displaced from the tubular spacer, the plug transfers into the bore opening within the plunger. This enables the plunger to press flush against the tubular spacer.



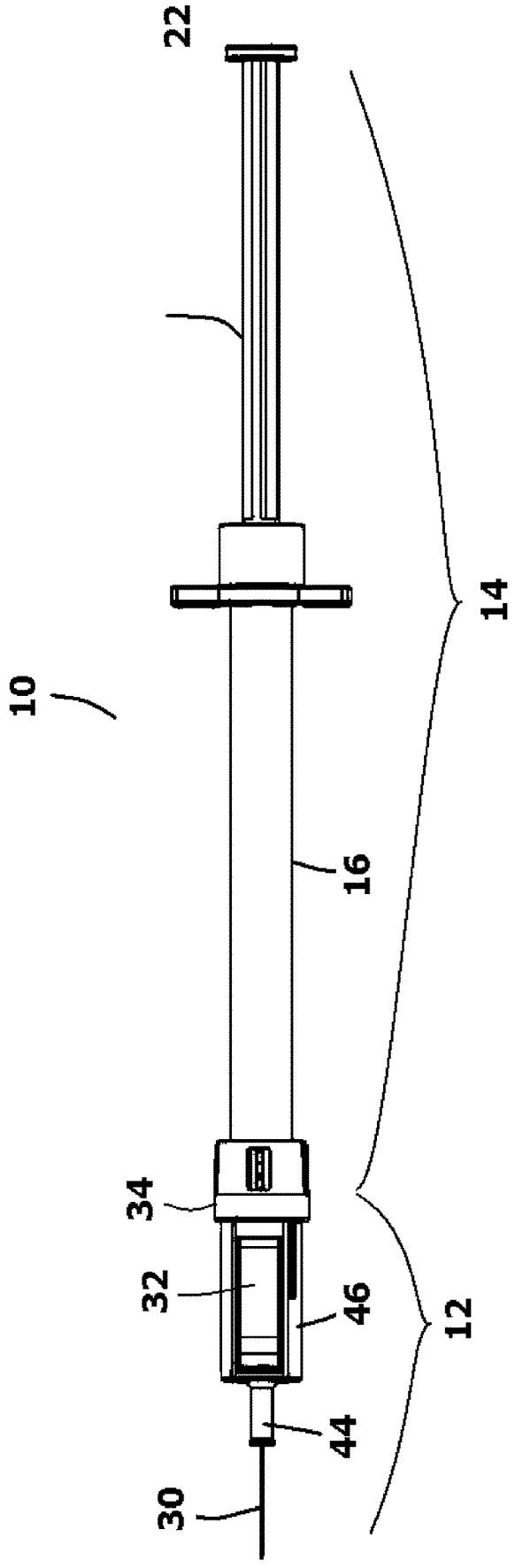


FIG. 1

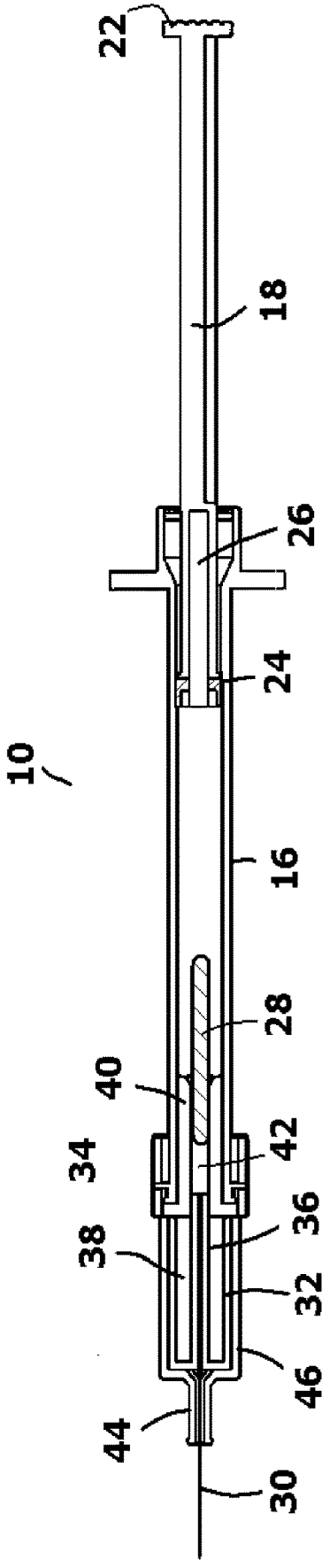


FIG. 2

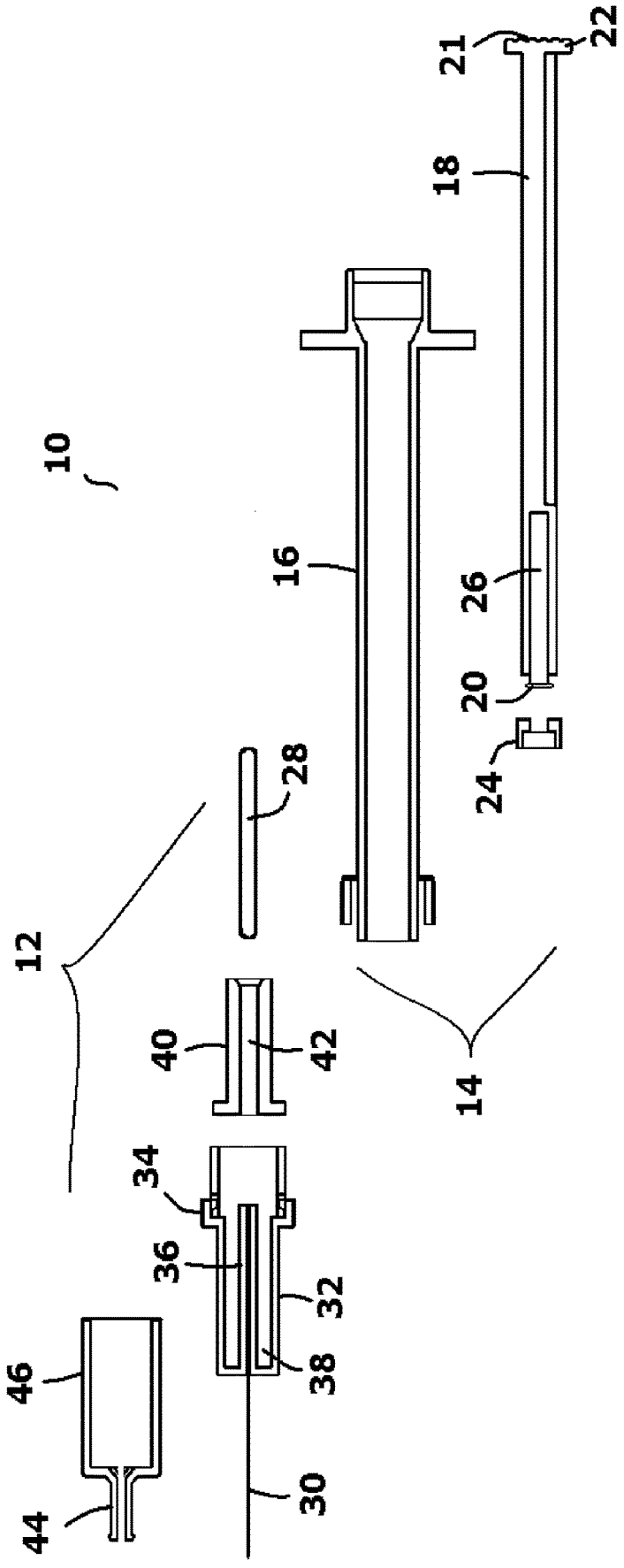


FIG. 3

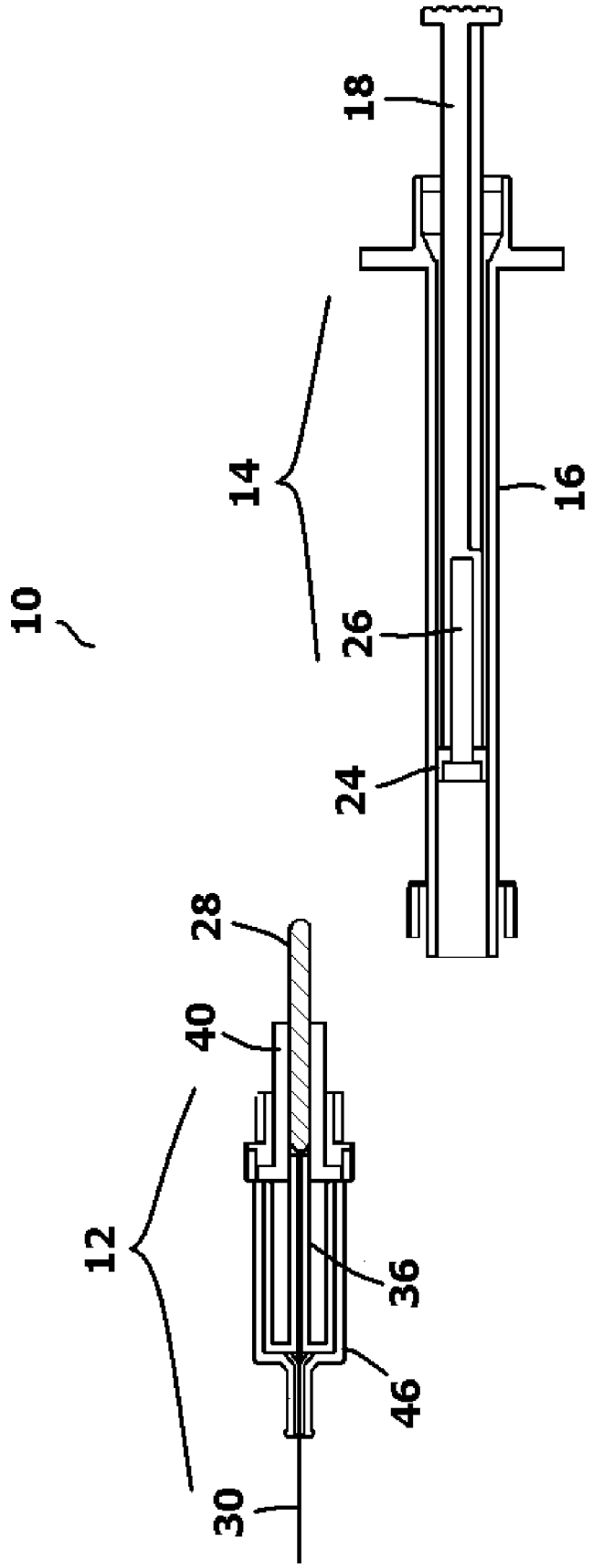


FIG. 4

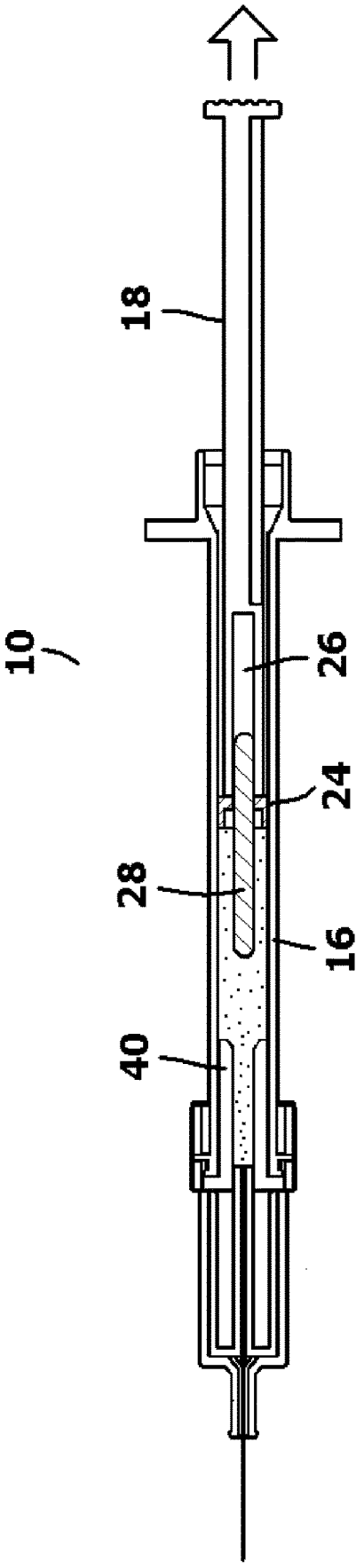


FIG. 5

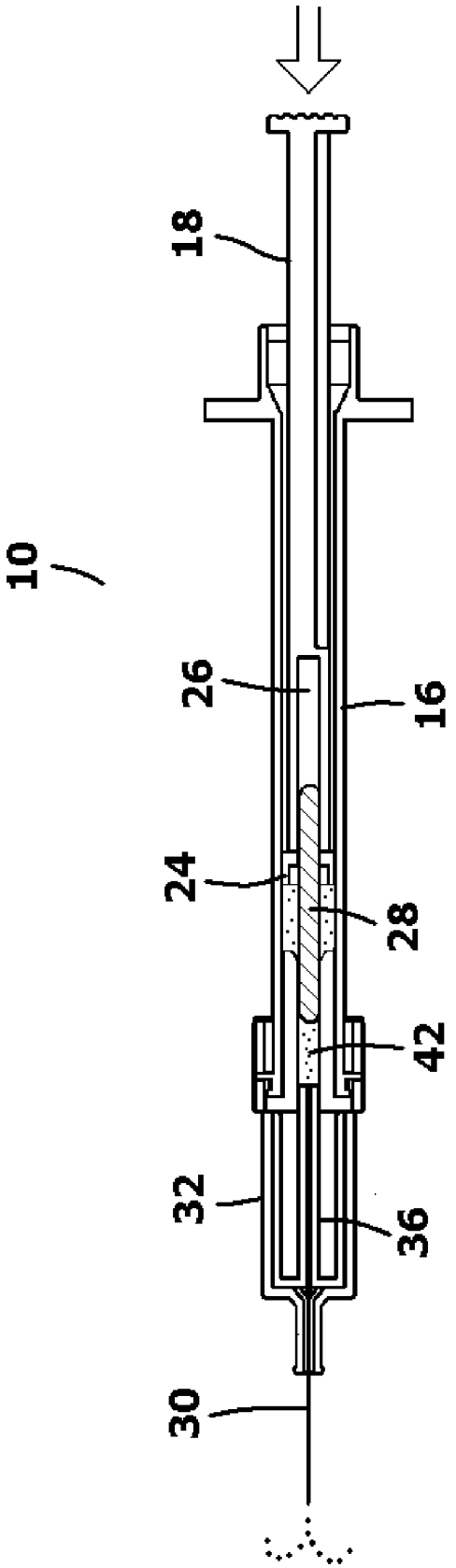


FIG. 6

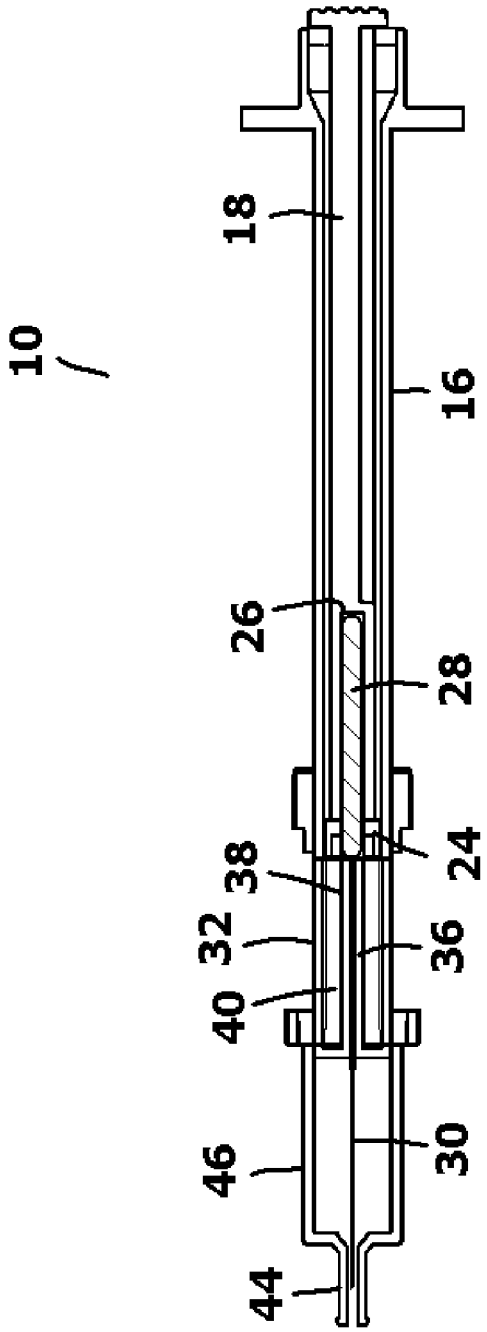


FIG. 7

ULTRA-LOW WASTE DISPOSABLE SYRINGE WITH SELF-ADJUSTING INTEGRATED SAFETY FEATURES

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. provisional patent application No. 62/867,811, filed Jun. 27, 2019.

FIELD OF THE INVENTION

[0002] In general, the present invention relates to syringes that are used to make injections through a needle or cannula. More particularly, the present invention relates to multiple dose syringes that are designed to minimize the amount of injection material retained within the syringe after the syringe is used for the last dose.

PRIOR ART DESCRIPTION

[0003] Millions of injections are performed in the United States of America each year. The injections are typically performed using a hypodermic needle and a syringe. The length of the hypodermic needle and the gauge of the needle depend upon the application and whether the injection is intramuscular, subcutaneous, intravenous, or intradermal. The compounds being injected also vary widely. Some injection materials, such as saline, are very inexpensive. However, many pharmaceutical compounds, such as certain gene therapy compounds, can cost tens of thousands of dollars per injection. As such, a fraction of a milliliter of the pharmaceutical can be worth hundreds of dollars.

[0004] When a traditional hypodermic needle and syringe are used to perform an injection, there is inevitably some volume of injection material that remains within the needle and syringe after the injection is complete. The pharmaceutical material remaining is thrown away with the needle and syringe after the injection. This wasted pharmaceutical material adds up to billions of dollars in wasted pharmaceuticals, when all injections are considered.

[0005] In the prior art, thought is rarely given to the volume of residual material that inherently remains within a hypodermic syringe and needle. Some needle and syringe assemblies have been designed where a syringe plunger and a needle head make flush contact. Such prior art designs are exemplified by U.S. Pat. No. 6,616,636 to Lee and U.S. Pat. No. 5,902,270 to Jentzen. However, in a real healthcare environment, such as a hospital, different syringes are used with many different needle heads, depending upon the specific medical application. Some needle head and syringe combinations are efficient in the discharge of pharmaceutical compounds and some are not.

[0006] The problem becomes more complicated when a needle head and syringe are part of a safety syringe assembly. Safety syringe assemblies are designed to both perform an injection and to provide some mechanism for minimizing the likelihood of a needle stick injury. Needle stick injuries are commonplace among healthcare workers. Needle stick injuries are defined by the United States National Institute of Occupational Safety and Health as injuries caused by needles such as hypodermic needles, blood collection needles, intravenous (IV) stylets, and needles used to connect parts of IV delivery systems. Needle stick injuries can transfer blood-borne pathogens such as Hepatitis B virus, Hepatitis C virus, Human Immunodeficiency Virus (HIV) and Covid-19. For healthcare workers, needle stick injuries are responsible for a significant proportion of these diseases in the healthcare workforce.

[0007] It has been estimated by the Centers for Disease Control, that in the United States of America, more than three million healthcare workers are exposed to blood and bodily fluids via needle mishaps each year. Most healthcare workers are trained in procedures for using and disposing of used needles. For example, needles should not be recapped, in order to prevent the potential for needle stick injuries. However, many studies have revealed that recapping is still prevalent among healthcare workers.

[0008] In an attempt to reduce the number of needle stick injuries, various safety needles have been developed that act to automatically cover a needle the instant the needle is retracted from the skin. This is typically accomplished by advancing a tubular sheath along the shaft of the needle until the sheath covers the tip of the needle. Such prior art is exemplified by U.S. Pat. No. 6,626,863, U.S. Patent Application Publication No. 2007/0016140, U.S. Patent Application Publication No. 2007/0016145, and U.S. Patent Application Publication No. 2008/009808. However, integrating a safety mechanism within a needle head typically takes additional room within the needle head. More room in the needle head means that there is more dead space in the needle head where residual pharmaceutical compounds can collect. As a consequence, there are often opposing concerns that must be balanced in a design. The safety features of a design are balanced with the wasted pharmaceutical retained because of the safety features.

[0009] A need therefore exists for an improved hypodermic needle and syringe assembly where the needle is automatically shielded after an injection and wherein the assembly does not retain any significant volume of the material being injected. This need is met by the present invention as described and claimed below.

SUMMARY OF THE INVENTION

[0010] The present invention is a needle and syringe system, wherein a needle head is attached to a syringe assembly. The syringe assembly contains a barrel and a plunger. The plunger has a bore opening formed in one end that is accessible from within the barrel.

[0011] A tubular spacer is disposed within the barrel. The tubular spacer defines a central opening that extends through the tubular spacer.

[0012] The needle head selectively attaches to the syringe assembly. The needle head has a needle that extends from a needle base. The needle base extends into the central opening of the tubular spacer.

[0013] A plug is provided inside the barrel that blocks access to the needle by blocking the central opening of the tubular spacer. The plug is displaced out of the central opening of the tubular spacer and into the opening in the plunger as the plunger contacts and displaces the tubular spacer in the barrel. As the plug is displaced from the tubular spacer, the plug transfers into the bore opening within the plunger. This enables the plunger to press flush against the tubular spacer.

[0014] As the tubular spacer is displaced by the plunger, the tubular spacer moves a safety sheath that advances and covers the needle, therein rendering the needle safe.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] For a better understanding of the present invention, reference is made to the following description of an exemplary embodiment thereof, considered in conjunction with the accompanying drawings, in which:

[0016] FIG. **1** shows the head of a needle and syringe system in a condition ready for use with its needle exposed;

[0017] FIG. **2** is a cross-sectional view of the exemplary embodiment of FIG. **1**;

[0018] FIG. **3** is an exploded cross-sectional view of the exemplary embodiment of FIG. **1**;

[0019] FIG. **4** is a cross-sectional view of a head subassembly prior to attachment with a syringe subassembly;

[0020] FIG. **5** is a cross-sectional view of the exemplary embodiment of FIG. **1** showing material being drawn into the needle and syringe system;

[0021] FIG. **6** shows a cross-section of the exemplary embodiment of FIG. **1** showing material being displaced from the needle and syringe system; and

[0022] FIG. **7** shows a cross-section of the exemplary embodiment of FIG. **1** showing all material displaced from the needle and syringe system.

DETAILED DESCRIPTION OF THE DRAWINGS

[0023] The present invention needle and syringe system can be configured in many ways and can be adapted for use in many applications. However, only one exemplary embodiment is selected for the purposes of description and illustration. The illustrated embodiment, however, is merely exemplary and should not be considered a limitation when interpreting the scope of the appended claims.

[0024] Referring to FIG. **1**, FIG. **2**, and FIG. **3**, the present invention needle and syringe system **10** is shown. In the shown embodiment, the needle and syringe system **10** includes two primary subassemblies that are selectively joined by a healthcare professional prior to use. The primary subassemblies include a head subassembly **12** and a syringe subassembly **14**. The head subassembly **12** mechanically engages the syringe subassembly **14** with a mechanical connection, as is later explained. Accordingly, different head subassemblies can be selectively attached to different syringe subassemblies according to the needs of the healthcare professional.

[0025] The syringe subassembly **14** includes a syringe barrel **16** and a plunger rod **18** that extends into the syringe barrel **16**. The plunger rod **18** has a first end **20** and an opposite second end **21**. The first end **20** extends into the syringe barrel **16**. The second end **21** terminates with a thumb pad **22** that is used to manually move the plunger rod **18** in the syringe barrel **16** between a fully advanced first position and a fully retracted second position. The first end **20** of the plunger rod **18** is terminated with an elastomeric piston head **24**. The piston head **24** is annular in shape and seals the plunger rod **18** with the interior of the syringe barrel **16**.

[0026] A blind bore **26** is formed in the plunger rod **18**, wherein the bling bore **26** is open at the first end **20** of the plunger rod **18**. The annular shape of the piston head **24** prevents the piston head **24** from blocking access to the blind bore **26** from within the syringe barrel **16**. The blind bore **26** extends for a first length into the plunger rod **18**.

[0027] An elongated plug **28** is provided. The elongated plug **28** has the same length as the bore blind **26** in the plunger rod **18** and is capable of being fully received within the blind bore **26** of the plunger rod **18**. Although the elongated plug **28** moves between the head subassembly **12** and the syringe subassembly **14**, the elongated plug **28** is initially packaged as part of the head subassembly **12**, as will later be explained. The head subassembly **12** holds a needle **30**. The needle **30** extends forward from a plastic needle base **32**. The needle base **32** contains a collar **34** that is sized and shaped to engage the syringe subassembly **14**. The collar **34** engages the syringe barrel **16** with a mechanical connection, such as a threaded connection or a bayonet connection. This enables a healthcare professional to be able to manually connect and disconnect the head subassembly **12** and the syringe subassembly **14**. A central post **36** is concentrically disposed within the collar **34**. A cylindrical cavity **38** separates the collar **34** from the central post **36**. The needle **30** extends into and through the central post **36**. Since the needle **30** is attached to the central post **36**, the central post **36** is attached to the collar **34**, and the collar **34** is attached to the syringe barrel **16**, there is no relative movement between the needle **30** and the syringe barrel **16** during the operation of the needle and syringe system **10**.

[0028] A tubular spacer **40** is provided as part of the head subassembly **12**. The tubular spacer **40** is positioned in the cylindrical cavity **38** between the central post **36** and the collar **34**. The tubular spacer **40** defines a central conduit **42** that receives the central post **36** of the needle base **32**. The length of the cylindrical cavity **38** in the tubular spacer **40** is exactly the same as the length of the central post **36**. The tubular spacer **40** is separate from the needle base **32** and is free to slide along the length of the central post **36**.

[0029] A safety sheath **44** is provided that surrounds part of the needle **30**. The safety sheath **44** is attached to an actuator cap **46**. The actuator cap **46** is sized to extend over the exterior of the needle base **32**. The actuator cap **46** can reciprocally move along the exterior of the needle base **32**. The actuator cap **46** can be selectively locked and unlocked using a mechanical release **48** that is accessible on the exterior of the syringe subassembly **14**. It will therefore be understood that the actuator cap **46** can be selectively released and moved relative to the needle **30** and the needle base **32**.

[0030] Referring to FIG. **4** in conjunction with FIG. **2** and FIG. **3**, it can be seen that prior to use, the elongated plug **28** is part of the head subassembly **12**. The elongated plug **28** is positioned within the central conduit **42** of the tubular spacer **40**. This blocks the needle **30** and isolates the needle **30** within the head subassembly **12** as the head subassembly **12** and the syringe subassembly **14** are interconnected. Once the head subassembly **12** is attached to the syringe barrel **16**, the loading of the needle and syringe system **10** can begin. To load the needle and syringe system **10**, the plunger rod **18** is advanced into the syringe barrel **16**. As the first end **20** of the plunger rod **18** moves toward the head subassembly **12**, the first end **20** contacts the elongated plug **28**. The elongated plug **28** enters the blind bore **26** in the plunger rod **18**. The blind bore **26** receives and retains the elongated plug **28** with an interference fit.

[0031] Referring to FIG. **5** in conjunction with FIG. **4**, it can be seen that after the elongated plug **28** is received into the blind bore **26**, the plunger rod **18** is retracted. The plunger rod **18** retains the elongated plug **28** and pulls the elongated plug **28** out of the tubular spacer **40**. This clears

the needle **30** and enables fluid to be drawn into the syringe barrel **16** through the needle **30**.

[0032] Referring to FIG. **6** and FIG. **7**, it can be seen that after the needle and syringe assembly **10** is filled, the plunger rod **18** is manually advanced into the syringe barrel **16**. The liquid previously drawn into the syringe barrel **16** is displaced through the needle **30**. As the piston head **24** advances toward the head subassembly **12**, the piston head **24** presses the tubular spacer **40** into the cylindrical cavity **38** around the central post **36** of the needle base **32**. Simultaneously, the elongated plug **28** is pressed into the blind bore **26** in the plunger rod **18**. As the piston head **24** contacts the central post **36**, the tubular spacer **40** completely fills the cylindrical cavity **38**. All liquid is displaced from the syringe barrel **16** except for the exceedingly small volume that remains inside the needle **30**.

[0033] As the tubular spacer **40** is pressed forward by the advancing plunger rod **18**, the tubular spacer **40** moves the actuator cap **46** forward relative the needle base **32**. As the actuator cap **46** moves forward, the safety sheath **44** also moves forward, wherein the safety sheath **44** covers the tip of the needle **30**. As a consequence, the needle **30** is shielded and rendered harmless just as the syringe barrel **16** empties.

[0034] It will be understood that the embodiment of the present invention that is illustrated and described is merely exemplary and that a person skilled in the art can make many variations to that embodiment. All such embodiments are intended to be included within the scope of the present invention as defined by the appended claims.

What is claimed is:

1. A needle and syringe system, comprising:

a syringe barrel;

a plunger rod having a first end and an opposite second end, said plunger rod having a bore formed therein that is accessible from said first end, wherein said plunger rod can be reciprocally moved within said syringe barrel between a first position and a second position;

a needle head that attaches to said syringe barrel, wherein said first end of said plunger rod faces said needle head within said syringe barrel; and

a plug disposed within said syringe barrel, wherein said plug transfers from said needle head into said bore on said plunger rod as said plunger rod moves between said first position and said second position.

2. The system according to claim **1**, wherein said bore is sized to receive all of said plug therein.

3. The system according to claim **1**, wherein said plug completely fills said bore when received within said bore.

4. The system according to claim **1**, wherein said needle head includes a tubular spacer that extends into said syringe barrel, wherein said tubular spacer has a central opening that extends through said tubular spacer.

5. The system according to claim **4**, wherein said central opening receives and retains at least part of said plug prior to said plug being transferred to said bore in said plunger rod.

6. The system according to claim **4**, wherein said needle head further includes a collar that selectively connects to said syringe barrel, wherein said collar supports a needle base that extends into said central opening of said tubular spacer.

7. The system according to claim **6**, wherein said needle head further includes a needle that extends from said needle base.

8. The system according to claim **7**, wherein said needle head further includes a safety sheath that surrounds part of said needle, and wherein said safety sheath can move relative said needle to selectively shield said needle.

9. The system according to claim **8**, wherein said plunger rod contacts and advances said spacer as said plunger rod moves from said first position to said second position.

10. The system according to claim **9**, wherein said needle base moves through said central opening in said spacer as said spacer is advanced by said plunger rod.

11. The system according to claim **10**, wherein said needle base displaces said plug out of said needle head as said needle base moves through said central opening in said spacer.

12. A needle and syringe system, comprising:

a syringe assembly that contains a barrel and a plunger, wherein said plunger has an opening formed therein that is accessible from within said barrel;

a tubular spacer disposed in said barrel, said tubular spacer having a central opening extending therethrough;

a needle head that selectively attaches to said syringe assembly, wherein said needle head has a needle that extends from a needle base, wherein said needle base extends into said central opening of said tubular spacer;

a plug that blocks said central opening of said tubular spacer, wherein said plug is displaced out of said central opening of said tubular spacer and into said opening in said plunger as said plunger displaces said tubular spacer in said barrel.

13. The system according to claim **12**, wherein said opening in said plunger is sized to receive all of said plug therein.

14. The system according to claim **12**, wherein said plug completely fills said opening in said plunger when received within said opening.

15. The system according to claim **12**, wherein said needle assembly further includes a safety sheath that surrounds part of said needle, and wherein said safety sheath can move relative said needle between to shield said needle.

16. The system according to claim **12**, wherein said plunger contacts and advances said tubular spacer as said plunger moves toward said needle head within said barrel.

17. The system according to claim **16**, wherein said needle base moves through said central opening in said tubular spacer as said tubular spacer is advanced by said plunger.

18. The system according to claim **17**, wherein said needle base displaces said plug out of said needle head as said needle base moves through said central opening in said spacer.

* * * * *