TECHNICAL DESCRIPTION

Revolutionary Syringe/Extended Stability - Storage Device

This patented invention comprises a method and apparatus for storing and transferring medical and non-medical material. It includes a cartridge with a rodless piston magnetically coupled to an actuator positioned along the cartridge. This is the handheld magnetically actuated apparatus (syringe/injector) with the rodless piston device (cartridge) for fluid, semi-fluid, and gas storage, displacement, movement, and transfer, and to be used for storage (extended and improved), extraction, and insertion of liquid, semi-liquid and gaseous substances. This is the only device of this type capable of handling viscous and gaseous materials.

This apparatus works on magnetic principles: squeezing the trigger activates the magnet's movement, which affects the piston's movement in the cartridge. The magnetic field created between the magnet and the rodless Ferrous piston inside the cartridge chamber will move the piston in the direction of the magnet movement. Movement of the piston in one direction will create the insertion of liquid and gaseous substances and movement in another direction will provide extraction of the same. Change in the direction of the magnet movement will be accomplished by a simple mechanism located in the handle/trigger area. Cartridges could be made of plastic, ceramic, non-magnetic metals, and/or glass. They would be used empty for extraction purposes or prefilled with gas/liquid and powder substances for insertion, with glass being the preferred material. Tools, like needles, nipples, tubes, and others, can be attached to the adjustable guards and through the rubber stopper to connect the cartridge chamber and the subject of extraction or insertion of the gas or liquid. The usage range is extensive, and not all potential applications are known.

To use this syringe, one has to take a cartridge (full or empty, depending on the intended use) and place it within the actuator. Attach the needle. The needle would consist of two parts: the short end goes into the rubber stopper, penetrating it and into the cartridge, and the longer end is the one that goes into the body of the subject (or used to draw something in). This needle will have the self-threading flange that goes over the tip on the body of the actuator (hub), creating a reliable connection. Squeezing the trigger will start the movement of the magnet. The magnetic field would begin pulling the magnet when the magnet comes over the Ferrous disk (piston) inside the cartridge. The disk would push the fluid in the cartridge, displacing it out through the needle (or, if moved in reverse, displacing it into the cartridge). Remove the cartridge after it is finished. Disposal of the used cartridge or the following use of the just-filled cartridge will depend on the usage and the regulations. Typically, it is not different from the present conditions. One can use containers for sharps and medical material disposal procedures.

Avicenna's Plungerless Prefilled Syringe is a storage cartridge device with extended drug stability and guaranteed sterility and product integrity that could be converted into an injection device with an attachment of a needle and placing it within the injector suitable for the application. The design of the injector is relatively not crucial as long as it has a magnetic drive (pen syringe, regular syringe, pistol, or anything else desired by the customer). Other

instruments, besides the needle, could be used with the storage part (cartridge) to meet the desired requirement (nozzles, forming tools, brushes, packing tools, sprayer, and as such). In those cases, the injector would become an applicator. The best way to describe Avicenna's Plungerless Prefilled Syringe is as a "storage/injection device**.**"

1. The syringe/storage container is filled with vacuum/inert gas. It can hold it indefinitely due to a completely sealed system design. A completely sealed syringe/storage container is filled with the chemical/biological substance and vacuum or inert gas. Among the other benefits, it prevents heat transfer, improving the shelf life of the substance inside. It could be used by any industry for any suitable products, providing that design modifications were incorporated.
2. When the syringe/cartridge container is placed within the injector/applicator, and a needle or any other tool is attached to connect the cartridge/container with the recipient body, the mechanism would apply pressure (through the magnetic field) on the ferrous piston and execute injection or an application.
3. The presence of a vacuum or inert gas would modify the atmosphere in the syringe/cartridge container, making it ambient and allowing for extended stability and guaranteed sterility. Depending on the vacuum/inert gas pressure level, the extended stability is limited only by the product composition and its natural shelf-life:
    a. The vacuum would reduce the moisture and the Oxygen content and pull the molecules further apart. That would slow or even stop all chemical/physical/biological reactions in Avicenna's device's chemical/biological composition, increasing stability. It will also prevent heat transfer.
    b. Guaranteed sterility comes with a completely sealed system that remains sealed until punctured by the injection/application tool, regardless of any conditions outside the cartridge/cartridge container.
    c. Inert gas would displace the moisture and Oxygen and push molecules closer (increased pressure), changing the atomic dynamics and slowing all chemical/physical/biological reactions in the chemical/biological composition in the syringe/container of Avicenna TT Storage/Injection device, significantly increasing stability.
4. Usage of this packaging approach for injectable drugs allows removing vials, ampoules, and syringes from employment, streamlining the entire injection process. Only that will reduce the cost of injection and overall healthcare dramatically. It also reduces the cost of injection while maintaining the same level of compliance and safety. The storage container (cartridge) becomes the syringe. That syringe becomes the prefilled syringe that can be delivered anywhere and used for any chemical/biological substance, including liquids, semi-liquids, and gasses, and by anyone.
5. This storage/injection device is virtually unbreakable and would not leak in any situation.
6. The cartridge has low, if at all, dead space, thus saving the cost.
7. This storage/injection device has no moving parts in contact with the chemical/biological composition inside the vacuum-sealed syringe/cartridge container. Thus, no Silicon Oil is required to reduce friction, and no leachable/extractable impurities exist. This is a massive development in product integrity.
8. There is no air bubble (bubble-free technology) in the container. Thus, overfill, as it is now, is not needed.
9. All components are disposable and mostly recyclable.
10. All components are compact, lightweight, easy to manufacture, and low-cost.

11. The extended stability and guaranteed sterility allow new markets and new R&D. It also allows new drugs to become injectable and in the prefilled form.
12. Many materials suggest that some drugs in this syringe/cartridge container may not require cold storage due to improved stability and an ambient atmosphere in the cartridge.
13. Many materials suggest that some drugs in this syringe/cartridge container may not require lyophilizing due to improved stability.
14. This is truly green technology.
15. Yet, the lion's share of the added value for this type of device comes from the changes in the dynamics of the drug manufacturing process. Presently, all drugs are manufactured in batches. The size of the batch is determined by the sales volumes and manufacturing considerations. No one wants to work for the warehouse because of the limitations imposed by the drug stability and, therefore, shelf-life. This type of waste is costly. Thus, manufacturers produce what they have orders for and can sell fast. Yet, occasionally, they come short and have to catch up at the higher cost (overtime, cost of raw materials air shipped, etc.). The recent flu vaccine shortage is a good example. After every batch is produced (could be just hours), the whole manufacturing line (that includes cleaning the facility) has to be broken down, cleaned, inspected, and documented (could be a shift). Then, the new batch starts, and the cycle continues. In some cases, downtime is greater than the production time, keeping the plant utilization low and contributing to the overall cost of products. If batches are made larger, machines could run for days with much fewer interruptions and cleanups, increasing plant utilization and lowering the overall cost of manufacturing.

    a. The most advanced pharmaceutical companies display plant utilization of 55 - 65%, a significant number due to the volumes of the mass-produced products. Pharmaceutical companies must employ tens of thousands of very qualified people, massive facilities, and dozens, if not hundreds, of production lines with hundreds, if not thousands, of machines that cost billions just to meet the demand, considering the necessary downtime. The cost of manufacturing is enormous, which translates into healthcare costs. An increase in the size of manufacturing batches based on the extended stability of the drug in Avicenna's vacuum-sealed syringe/cartridge container would lead to an increase in plant utilization. If batches are larger, the plant utilization could be pushed to 75 – 85%, which was proven. The larger the batches are (some manufacturing limitations would still apply), the higher the plant utilization is, thus, the profits. If the utilization is high enough, fewer employees are needed to produce the same product, smaller facilities are required, and less machinery is employed. All that translates into energy consumption, utilities, land, S&H, etc. Ultimately, the cost of the drugs would go down exponentially, and so would the cost of healthcare. The product availability and variety would increase, and the profit percentage would remain the same. Also, let's not forget that the increase in the batch size would allow for purchasing larger quantities of raw materials, leading to the low cost of materials. Avicenna's vacuum-sealed syringe is a low-cost alternative to the vial/ampoule/syringe system. It is the future of healthcare.
    b. Biotech manufacturing would present a different challenge. While the changes in manufacturing dynamics would not affect Biotech as much despite the plant utilization in the 20 – 30% range, the other added benefits would play their role in full. Everything

stated above would be in effect. Biotech manufacturing is boutique manufacturing compared to pharmaceuticals. Due to somewhat low volumes and higher cost of products, Biotech is not as susceptible to plant utilization as big pharma. If you increase the batch size and reduce downtime, you will have nothing else to produce. Each Biotech company has a limited number of products and volumes. Shifting products from one facility to another or even from one line to another may present cross-contamination problems, cleaning, living organisms, etc. The Biological market is vast, but not due to the volumes - the price of the drug. Batch size and improving the logistics approach is not a real ADDED VALUE there. Yet, by increasing batches due to better stability and improved logistics, they can advance the plant utilization ratio. The more critical issue for Biotech is that Avicenna's vacuum-sealed syringe could prevent some products from being lyophilized, and some would not have to be refrigerated. All that would improve the product availability, the variety of products, the product state (liquids/semi-liquids/gasses), shipping and handling, manufacturing logistics, ordering and storage, R&D, prefilled syringe approach, compliance, self-administration, and home use.

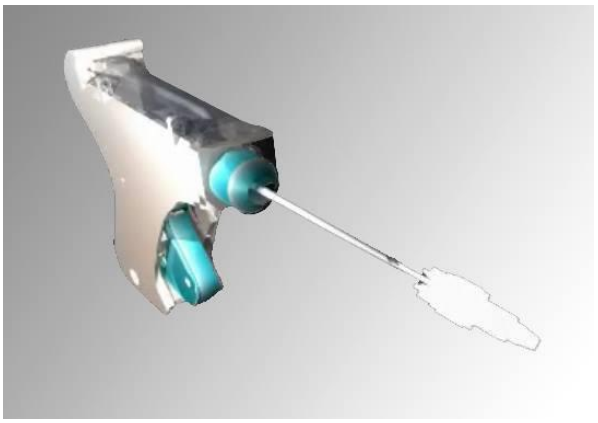
Employing vacuum-sealed single-use cartridges is one of the leading innovative features of the MIST™ system. While the cartridge's small size will help to reduce conventional packaging, storage, handling, and shipping costs, it will also reduce cold chain supply management costs associated with parenteral drugs offered in prefilled syringe formats. For example, the MIST™ small cartridge size can dramatically increase cold chain storage capacity and markedly reduce expenses related to shipping and stockpiling of drugs that require refrigeration, i.e., a greater number of MIST™ cartridges can be stored or shipped in refrigerated containers initially designed for larger and bulkier prefilled syringe-barrel formats. Also, vacuum-sealed cartridges (after filling) ensure greater drug sterility over the product's lifetime. It reduces contamination risks commonly associated with the filling and packaging prefilled syringes.

In some cases, the cold supply line may not be required. Vacuum-sealed cartridges offer greater tamper-proof evidence than that associated with current commercially available prefilled syringe designs. Avicenna-tt syringe is not only better but completely different from anything we have today, and it offers to break the mold and move forward in healthcare and many other industries.

Besides, improvements to patient ease-of-use experience offered by the MIST™ will enhance drug regimen compliance rates and offer patients, healthcare professionals, and caregivers a competitive, facile solution to many existing prefilled syringe designs. From a patient perspective, the Avicenna magnetic plungerless system is a single-dose, easy-to-use prefilled syringe option. Its cartridge-based delivery mechanism provides patients with new storage and shipping options previously unavailable with existing prefilled syringe formats. Because of low manufacturing costs and likely reductions in per-patient healthcare expenditures, the Avicenna magnetic plungerless system represents a new prefilled syringe option that is likely to be embraced by patients and healthcare professionals alike. From a drug manufacturing and filling perspective, the Avicenna system offers drug makers more flexibility with manufacturing lot sizes. This could result in tremendous cost savings by lowering machinery downtime and improving drug manufacturing efficiencies.

Finally, both the Avicenna injector and cartridges are inexpensive to manufacture. Also, with few moving parts, the injector can be readily cleaned, autoclaved, or sterilized (when necessary) and repeatedly used by patients and healthcare professionals. Likewise, Avicenna's vacuum-sealed cartridges are simple in design, disposable, and compatible with the current syringe and cartridge filling paradigms. Therefore, the cost of converting conventional prefilled syringes to Avicenna cartridges should be nominal.

MAGNETIC SYRINGE.mp4 – (video)



Another video

NEW SYRINGE 2.mp4