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Revolution in Hypodermic Injection, Parenteral Drugs and the Cost of Injection

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Abstract: How can we advance the hypodermic syringe solving or at least dramatically improving its inherited problems without affecting the main purpose of the device – injecting and extracting liquid and gas substances to and from places difficult to reach? The answer is quite simple – it has to be a syringe that has no plunger and, therefore, no opening in the barrel for the plunger to operate. That would construct an enclosed and completely sealed system capable of preserving sterility, vacuum or any original conditions, working in both directions (injection and extraction), providing for the shelf-life of the chemical inside to match its molecular stability, and simplifying shipping, storage, logistics and packaging, reducing, at the same time, the human error. No more short-shelf-life chemicals, squeezing out air, and the poisonous vapors in the environment. That's a tall order is not it. That would open doors for unlimited new opportunities in medical research and development while the other industries would start knocking on our doors. The level of healthcare would improve greatly and rapidly while the cost of it would go down due to this revolution in hypodermic injection.Now, it looks as the answer was found by Mr. Boris Zubry (New Wave Medical, L.L.C.) in his US Patent # 7,255,684 (Magnetic Plungerless Injection System). This patent covers proprietary single-dosage cartridges and a magnetic actuator. The principal benefits of this system are: 1) lower cost for manufacturers, providers and end-users, 2) improved packaging, storage, shipping and logistics, 3) extended shelf life of pharmaceutical products and 4) enhanced safety and regulatory compliance. All this combined answers many, if not all, questions raised above.
Keywords: Pre-filled syringe; medication; injection; plungerless; shelf life; expiration date; hypodermic; vacuum; patent; invention; New Wave Medical; Boris Zubry; Parenteral drugs; extraction; packaging; healthcare; magnetic field.

Parenteral Medication is a well known method, other than that of ingestion, for drug delivery and is being quite widely used since thousands of year ago. This could be employed as, IV, IM, Sub-Q, or mucosal and it holds a permanent position among healing techniques. There are three major advantages of injection:

Rapid drug delivery;
It produces direct results;
Drugs are absorbed directly into the bloodstream.

Injections are mostly used:

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When patient is in the state that makes any other drug deliveries difficult;
To avoid and, therefore, not irritate the digestive system of the patient;
To deliver a precise dosage of medication to a targeted area.

Parenteral drugs are currently filled into multi-dosage vials and single-dosage glass ampoules for use with regular syringes, a cartridge for a reusable syringe, and/or a pre-filled syringe system.

The hypodermic **s**yringe is a medical instrument used for injecting Parenteral Medication into either muscles or bloodstream (medical application) and is one of the oldest known medical devices. It was described by ancient Greeks and Romans more then two thousand years ago. The hypodermic **s**yringe consists of a small graduated tube (barrel) with a close-fitting piston (plunger assembly) and a nozzle onto which a hollow needle can be fitted. The barrel has an opening on one end for the plunger to move freely in and out and on the other end for the fluid to pass into the needle. Needle connects syringe barrel and the recipient body.

Hypodermic syringes are actually pumps commonly employed to transfer some relatively small amounts of liquids to or from otherwise inaccessible (internal organs of the living organism or aggressive environments, for example) areas. This instrument could be made out of wood, paper, and glass, plastic, metal or any other materials strong enough to hold fluids for a short period of time. It operates on the principle of suction by filling the barrel with the fluid material at the opening when the plunger is drawn out, and pressure by expelling the fluid material when the plunger is depressed. The process of administering a substance with a syringe that has a needle attached is called an injection. Regular syringes could be used for extraction and injection. The word syringe comes from the Greek ***"syrinx"***, which means ***"tube".***

NEEDLE SYRINGES AND PARENTERAL DRUGS.

Syringes are commonly applied in medicine in conjunction with hypodermic needles for injections of liquids into body tissues, or for their removal from the body. They may also be used as parts of medical and scientific devices, containers, or scientific apparatus such as in certain types of chromatography. Syringes may also be incorporated when cooking meat to enhance flavor and texture by injecting juices inside the meat, and in baking to inject filling inside a pastry. Syringes have also been used for refilling ink cartridges with ink and for injecting glue and special fillings into cracks and openings during construction and restoration processes. The injection of gas into a blood vessel is extremely undesirable, as it may cause a gas embolism leading often to the fatal results. Prevention of embolisms by removing air from the syringe is the source of the familiar image of holding a syringe upside down, tapping it, and expelling a small

amount of liquid before an injection into the bloodstream. That operation guarantees no air or any other gas in the barrel and in the needle of the syringe.

Over the years, hypodermic syringes have transformed from the barrel made out of a hardened piece of bamboo with a hollow fishbone attached to it all the way to a very sophisticated single use safety syringe with a retractable needle and the precise measurement for the injected material. The present syringes are made out of class, metals and plastics and designed mainly for single use. The most common trend today is a variation on a single use pre-filled syringe with a safety needle. Yes, we can see the tremendous change in appearance, quality of manufacturing, safety and the simplicity of use of the syringe. More and more medication can be administered at the home setting by the end-user without participation of the medical professional. Multiple use, single use, safety, cartridge, pen, multi-chamber and variations of all above syringes are available today on the syringe market. Industry is still pushing it toward the easy solution that would incorporate simple design; user friendly application; home injections; low cost of drug, syringe and shipping, and the better safety, compliance and the waste management.

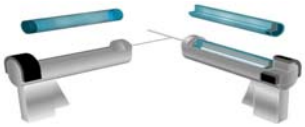
But how much did syringe really change over the years? As we know, drug longevity mostly depends on three factors: light, temperature and air. The issue of light is solved by additives and colored materials used for packaging (vials, ampoules and syringes). Temperature is controlled through cold storage and air is removed by vacuum or displaced by purging Nitrogen. For thousands of years this device is still operated through drawing and depressing a plunger and, therefore, the opening in the barrel is a must. No matter what materials are used and how well it all done, the opening is there. This opening is an attractive invitation for air, impurities, germs and the bacteria to squeeze in and attack the drug inside affecting its potency and often results of its administration. Given a little time, the substance inside the syringe would spoil before its stability runs out if it was stored properly. Even the best made pre-filled syringes are not desirable for the long storage of medication due to shelf-life limitations stated above. Therefore, a dosage, which may come in an ampoule and a vial (the decades of drug shelf-live are limited only by the drug stability and/or by opening of the storage vessel and introducing air and other impurities) and in a pre-filled and/or cartridge syringe (the drug shelf-life, usually less then a year, is limited by the quality of the fill and the seal between the piston and the wall of the syringe in the opening left for the plunger to operate). In short, in order to administer the drug, we need a syringe and a dosage in a vial or an ampoule (long shelf-life) or a variation of the pre-filled syringe (short shelf-life). Sounds expensive, complicated and much is left open for the human error. And, what do we do with an expired medication? There is a whole industry built just around that issue. The less shelf-life of the drug the more has to be disposed of and destroyed. How much does it add to the cost of the healthcare? How much of so needed funds we have to spend there instead of putting it into research and new developments? How many sicknesses and the lost productivity of the healthcare professionals can be attributed to breathing in medication while squeezing the air out the syringe before injection? Not even EPA can tell us that? We can create the most sophisticated safety needles and protect people from sticking but how can we protect the environment from the used syringes leaking the leftover medication from the opening at the end for the plunger to operate? The syringe disposal containers mostly protect from sharp objects inside and not the poisonous vapors of the remains of medication. These vapors mix inside the containers building concoctions we cannot even predict, and that leaks from millions of such containers into environment. And, the present syringes cannot really handle gasses and what if we need that? Ordering syringes, vials and ampoules, logistics, shipping and storage of all components adds another pretty penny to the cost of healthcare and who pays for it but us, the end-users.

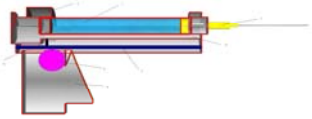
So, the question remains the same: how can we advance the hypodermic syringe solving or at least dramatically improving problems stated above without affecting the main purpose of the device – injecting

and extracting liquid and gas substances to and from places difficult to reach? The answer is quite simple – it has to be a syringe that has no plunger and, therefore, no opening in the barrel for the plunger to operate. That would construct an enclosed and completely sealed system capable of preserving sterility, vacuum or any original conditions, working in both directions (injection and extraction), providing for the shelf-life of the chemical inside to match its molecular stability, and simplifying shipping, storage, logistics and packaging, reducing, at the same time, the human error. No more short-shelf-life chemicals, squeezing out air, and the poisonous vapors in the environment. That's a tall order is not it. That would open doors for unlimited new opportunities in medical research and development while the other industries would start knocking on our doors. The level of healthcare would improve greatly and rapidly while the cost of it would go down due to this revolution in hypodermic injection.

Now, It looks as the answer was found by Mr. Boris Zubry (New Wave Medical, L.L.C.) in his US Patent # 7,255,684 (Magnetic Plungerless Injection System). This patent covers proprietary single-dosage cartridges and a magnetic actuator. The principal benefits of this system are: 1) lower cost for manufacturers, providers and end-users, 2) improved packaging, storage, shipping and logistics, 3) extended shelf life of pharmaceutical products and 4) enhanced safety and regulatory compliance. All this combined answers many, if not all, questions raised above.

The Magnetic Plungerless Injection System is a hand-held apparatus with a magnetically driven piston capable of displacing, moving and transferring liquid or gas through a cartridge chamber and into a sterile needle for injections. The device can also be applied to extract liquid or gas substances. This apparatus works on the principle that a magnetic field penetrates glass and plastic walls of the cartridge. A magnet located on the outside of the cartridge wall and a ferrous piston positioned inside of the cartridge create strong coupling with the ferrous piston repeating the movements of the magnet. Movement of the piston in one direction generates insertion of liquid and/or gas substances and movement in the other direction produces extraction. This device incorporates storage for solid, gas and liquid substances and an injection system for gasses and liquids at the same time.





HOW DOES THE DEVICE SOLVE THOSE PROBLEMS?

A trigger mechanism, designed to use magnetic energy, moves a piston inside the fully sealed cartridge to inject and/or withdraw, eliminating plunger assembly and creating a fully preserved system with a solid back wall. Dosages come in a completely sealed cartridge (solid back wall) that is placed into a trigger mechanism (injector). Dosages now have an increased shelf life limited only by the stability of the drug that could be estimated (in the ideal conditions) in years, if not decades. This is achieved though introduction of vacuum and/or Nitrogen during the filling process. This device is a combination of the syringe and a storage vessel at the same time. Reduced cost and storage space; simplified shipping and logistics achieved through eliminating of vials and ampoules and modification of the syringe filling and assembly process. Also larger batches of medication could be produced. The syringe features combine: pre-filled syringes, usage of empty and filled cartridges due to the piston movement in both direction; long drug shelf life cartridges, simplification of the drug manufacturing process, less packaging, shipping, handling, storage and logistics. Also it could be used for liquid, powder and gas chemicals. This syringe would increase safety and decrease medical waste dramatically moving injection closer to the green approach.

VERSATILITY

Small, compact, **inexpensive** and easy to store and use design and construction. The trigger mechanism (injector) and the cartridge are light weight and can be used for liquid, gas and powder drugs and chemicals;

Works in both directions and, therefore, capable of injection and extraction of drugs, chemicals, body fluids and samples of air, gases, chemicals and the bacteriological substances;

This syringe will standardize industry even more reducing the unnecessary varieties of syringes and cutting the cost of injection even further. It will reduce waste due to elimination of the plunger that is accountable for a half of the waste of the disposable syringe. Increased safety due to reduction in possible human errors in dosages. Also due to usage vacuum and Nitrogen there would be no air bubble.

Ways it will benefit the healthcare industry:

Magnetic syringe saves money due to the less expensive manufacturing of the drug and the cartridge, usage, cost of logistics, storage, disposal and transportation;

Syringes will be pre-filled which would save critical time, assures accuracy and total compliance of medication (decreases human error and protects environment);

Magnetic syringe's weight and size would contribute dramatically to the life-saving medical service. It decreases medical waste because it has no plunger and uses less packaging. Dual function of the completely sealed cartridges is that they can be used for collection of samples in cases of chemical and biological incidents

Now, lets discuss a few issues in greater details

1) Lows cost for manufacturers, providers and the end-users:

Manufacturing of Parenteral Drugs presently is done in batches. Batch size is determent through the amount of sales; shelf life, expiration date of medication and equipment capability. You run a batch and then you have to clean the equipment, do the batch paperwork, inspections and preparation for the next batch. It could be another batch of the same medication. Considering that modern equipment is quite high speed downtime could be greater than manufacturing time. You may run your machinery for 4 hours to produce the whole month worth of a specific drug and than clean it and do the paperwork for the whole shift. If, for example, you could group up 12 batches (1 year of sales) and run the machines for the whole week and than do the cleaning for a shift, your productivity would increase dramatically and manufacturing cost go down. But pharmaceutical companies don't do that now because they don't want to store drug that may go out of date. Shelf life is too short.

Now, if we could increase shelf life that we would not care about storage for a year or so, we could solve that problem and low our manufacturing cost dramatically increasing batches. The answer is in that vacuum. The vacuum technique is well known and well used only: you can't apply vacuum to an ampoule due to the heat seal at the end of the process and when you apply vacuum to a multi-dose vial you lose it with the first injection. In the case of the pre-filled syringe (cartridge) vacuum may suck the plunger in breaking the seal in the opening at the end for plunger to operate. The plungerless syringe solves that problem allowing for vacuum and, therefore, extended shelf life and expiration dates of medication.

Providers would benefit even more than in one area. Manufacturers would shift some of their savings to the providers making it less expensive. Drugs would be pre-filled and with a long expiration date and could be purchased in larger numbers and stored. Purchasing in larger numbers would decrease cost even more. There would be no need for additional syringes. Disposal would become less expensive because instead of disposal of a vial and a syringe one would dispose only the cartridge. Cartridge is about a half weight of the syringe. The future disposal cost would be about a half of the present disposal cost. There would be no danger of contamination of drugs used and the environment due to the sealed system. Less waste would enter environment protecting it from the contaminants. And, much more.

End-users would be able to employ more self injections at home without going to the medical professionals. Sealed cartridges could be easily shipped by mail and injected in accordance with instructions.

2) Improves storage, shipping and logistics:

Storage of just cartridges becomes very easy. You store only cartridges and no syringes or vials and ampoules. Shipping of pre-filled syringes is done presently in specially designed containers. Leakage and contamination is high. Losses are high. Vibration may damage the seal at the plunger opening of the

syringe. Many companies have to manufacture or fill drug locally in order to avoid the shipping issues and that means low runs and the high cost. Logistics are affected because you don't order syringes anymore.

3) Extended shelf life of pharmaceutical products:

Extended shelf life leads to larger batches and, therefore, low manufacturing cost; longer storage and less complicated shipping; sales in larger quantities; drug availability in remote areas; less waste and better environment; better safety and compliance and unlimited possibilities for new research. In short, we would have a much less expensive solution for Parenteral Drugs and injections and with much better quality.

Some would say: "Well, where is this wonderful syringe? It sounds great. I want to use it." And the answer is: the Plungerless Magnetic Injection System is still in development due to financial issues. If you have any ideas, any good idea would be considered. New Wave Medical L.L.C.: 721-329-0189.

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