AN APPARATUS AND PROCESS FOR MANUFACTURING A MEDICAL SAFETY DEVICE

FIELD OF THE INVENTION

The present invention relates in general to a method of manufacturing medical safety devices. More particularly, the present invention relates to an apparatus and method for manufacturing a retractable needle syringe.

BACKGROUND OF THE INVENTION

The safety of medical personnel have in recent years become an important issue in the delivery of medical services. Developments in medical devices and instruments have also taken this into consideration. One of such concerns is with regard to needle stick injuries from used needles. In the last decade, there have been several developments and inventions of safety syringes that either retract the needle into the syringe barrel or provide sleeves over the needle after use. Regulations in several states of the United States of America have also made the use of such safety syringes mandatory.

However, the concern of cost becomes an issue as some of these safety syringes cost much more than conventional disposable syringes. These safety syringes are also made of substantially more components than conventional syringes. There therefore exists a need for an apparatus for the manufacturing of such multi-component safety syringes at an economical and efficient manner.

An example of such a safety syringe would be a retractable needle syringe. Referring to Fig.1, an example of a prior art retractable needle syringe is made of : a cannula 10, a hub 12, a snap cap 'O'-ring 14, a snap cap 16, a printed syringe barrel 18, a bungee 20, a mandrel 'O'-ring 22, a plunger seal 24, a plunger 26 and a needle cap 28. The bungee 20 is made of a elastomer and provides the elastic force necessary to retract the needle into the syringe barrel 18.

Current methods of assembling conventional syringes lay emphasis on the sheer volume of numbers being assembled. They typically make use of conveyers to hold a plurality of base components while other components are mounted simultaneously onto the base component. Although the throughput of such methods are high, the quality controls are not. The number of samples that have to rejected after each assembly of all the components are very high.

There have also been attempts to fully automate the process of assembling such syringes. However, they have not been successful. Many of the systems in use are semi-automated and require an operator to either load the components manually or even assemble some of the components manually.

OBJECTIVE OF THE PRESENT INVENTION

It is therefore an object of the present invention to provide an effective and economical process for the fully automated assembling of a retractable needle syringe.

It is also an object of the invention to provide an apparatus to carry out the above.

SUMMARY OF THE INVENTION

The present invention provides a novel and efficient fully automated manufacturing system for assembling multi-component devices such as a retractable needle syringe having a cannula, a hub, a snap cap, a snap cap "O"-ring, a printed syringe barrel, a bungee, a mandrel "O"-ring, a plunger and a plunger seal. The manufacturing system comprises a plurality of assembly modules. Each assembly module assembles one sub-assembly and together the assembly modules manufacture the completed article. The assembly modules comprises at least two platforms, one fixed; the second capable of rotation about an axis. A variety of peripheral tools and devices are mounted on the fixed platform. While the second platform is mounted predominantly with jigs for holding the components. The peripheral tools and devices are actuated synchronously by a central gear cam mechanical linkage. While the second platform is rotated by a rotary indexing system, ensuring that the components held in the jigs are always aligned with the peripheral tools and devices of the first platform.

The process for installing and assembling the retractable needle syringe involves the steps of assembling cannula and hub together, mounting snap cap 'O'-ring onto cannula and hub, mounting snap cap onto syringe barrel, mounting mandrel 'O'-ring onto bungee, mounting plunger seal onto plunger, installing bungee into plunger and final assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig.1 shows the components of a retractable needle syringe.

Fig.2 shows a top plan view of the system for assembling a retractable needle syringe.

Fig.3 is a block diagram showing the main steps for the manufacturing of a retractable needle syringe.

Fig.4 is a block diagram showing the detailed steps for the printing of the syringe barrel.

Fig.5 is a block diagram showing the detailed steps for the assembling of a syringe barrel snap cap assembly.

Fig.6 is a block diagram showing the detailed steps for the assembling of a plunger bungee assembly.

Fig.7 is a block diagram showing the detailed steps for the assembling of the final product and its packaging.

Fig.8 is a perspective view showing an example of a peripheral device and jig.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Fig.2, the Retractable Needle Syringe Manufacturing System 190 comprises of the following main modules: the Syringe Barrel Printing Module 30, the Snap cap 'O'-ring/Cannula & Hub Assembly Module 50, the Snap Cap/Cannula & Hub Assembly Module 80, the Syringe Barrel/Snap Cap Assembly Module 100, the Plunger & Bungee Assembly Module 120. The Final Assembly Module 150 and the Packaging Module 180.

The Syringe Barrel printing Module 30 comprises a syringe barrel feeder 32, a orientator/singulation unit 34, a "Corona" treatment system 36, a printing unit 38, an inspection camera 40, a reject tray 42 and a collection hopper 44, for preparing syringe barrels for assembly.

The Snap cap 'O'-ring/Cannula & Hub Assembly Module 50 comprises a hub feeder 52, a hub jig 58, a Snap cap 'O'-ring feeder 54, a Snap cap 'O'-ring assembler 60, a cannula feeder 56, a cannula assembler 62, a sealant dispenser 64, ultra-violet(UV) lamps 66a, 66b, a leakage tester 68, an inspection camera 70, reject tray 72, a snap cap 'O'-ring/cannula & hub assembly feeder 74, and a flipper unit 75.

The Snap Cap/Cannula & Hub Assembly Module 80 comprises a Cannula & Hub assembly jig 82, snap cap assembler 83, a snap cap feeder 84, an inspection camera 85, a snap cap jig 86, a reject tray 90 and a snap cap/cannula & hub Assembly feeder 88.

The Syringe Barrel/Snap Cap Assembly Module 100 comprises a snap cap jig 102, an inspection camera 104, a syringe barrel jig 106, an assembler unit 108 and a syringe barrel assembly loader 110.

The Plunger & Bungee Assembly Module 120 comprises of a bungee feeder 122, a bungee jig 124, a mandrel 'O'-ring feeder 126, a mandrel 'O'-ring assembler 128, a plunger feeder 130, a plunger jig 132, an assembler unit 134, a plunger seal feeder 136, a plunger seal assembler 138, a bungee installation and air leakage tester 140, a reject tray 144 and a plunger and bungee assembly feeder 142.

The Final Assembly Module 150 comprises of a syringe barrel jig 152, a cannula washing unit 154, a blower unit 156, a lubricant dispenser 158, inspection cameras 160, 162, 168 a plunger jig 164, an assembler unit 166, a needle cap feeder 170, a needle cap assembler 172, a reject tray 174 and a Final Product feeder 176.

Referring to Fig.3, the main steps in the manufacturing of a retractable needle syringe comprises of : printing the syringe barrels 220, assembling syringe barrel assembly 230, assembling plunger bungee assembly 240 and the final assembly and packaging 250.

Referring to Fig.2 and Fig.4, the syringe barrel printing module 30 performs the step of printing 220 the graduated scales onto the syringe barrel 18. The unprinted syringe barrels 18 are placed into the syringe barrel feeder 32 and sent for orienting and singulating 310 in the orientator /

singulator unit 34. The syringe barrels then undergo the "Corona" treatment 320 to pre-treat the surface prior to printing. The "Corona" treatment system 36 uses high voltage electricity between 2 electrodes to produce an electrical arc resembling a 'blue mist'. The syringe barrels 18 are exposed to this 'blue mist' during the "Corona" treatment process 315. In the printing unit 38, ink is dispensed onto a template, further transferred onto a silicon pad and a graduated scale is printed 320 onto the syringe barrel 18. Hot air is then blown onto the syringe barrel 18 to cure the ink 325. The newly printed scale on the syringe barrel 18 is then checked 330 by an inspection camera 40. Any smudging or unclear scales would result in the syringe barrel 18 being rejected 332 to the reject tray 42.

Referring to Fig.2, the Snap cap "O"-ring/Cannula & Hub Assembly module 50 , the Snap Cap/Cannula & Hub assembly module 80 and the Syringe Barrel/Snap Cap Assembly Module 100 performs the steps 230 in Fig.5. A hub 12 is sent from the hub feeder 52 to a hub jig 58 where it is held securely. The snap cap "O"-ring 14 is then mounted 410 onto the hub 12 by the snap cap "O"-ring assembler 60. The cannula 10 is then further inserted 415 into the hub 12 by the cannula assembler 62. The sealant dispenser 64 then dispenses sealant 420 onto the cannula 10 and hub 12 interface. Ultra Violet(UV) lamps 66a,66b are used to cure 425 the sealant. The leakage tester 68 tests the cannula and hub assembly for leaks 430 at the cannula 10 and hub 12 interface. The inspection camera 70 then checks 435 the meniscus of the sealant for overflow or underfill. The reject tray 72 collects the rejected 432 samples. At this point, the assembled Snap Cap "O"-ring/Cannula & Hub assembly is oriented with the cannula pointing vertically upwards. A flipper unit 75 flips the assembly over such that the cannula is now oriented pointing vertically downwards. The Snap Cap "O"-ring/Cannula & Hub assembly is then sent to the Snap Cap/Cannula & Hub assembly module 80. The snap cap jig 86 holds the snap cap 16 securely while the snap cap assembler 83 mounts 440 the cannula & hub assembly onto the snap cap 16. The inspection camera 85 checks 445 to ensure presence of a

cannula 10. The reject tray 90 collects the rejected samples. The snap cap/cannula & hub assembly is then sent to the Syringe Barrel/Snap Cap Assembly Module 100. The snap cap assembly is held securely by the snap cap assembly jig 102. The inspection camera 104 checks 445 for the presence of a cannula 10. Printed syringe barrels 18 from the printing module 30 are picked up by the syringe barrel jig 106 and an assembler unit 108 mounts 450 the snap cap assembly onto the syringe barrel 18. The completed syringe barrel assembly is then sent to the Final Assembly module 150.

Referring to Fig.2 and Fig.6, the steps for assembling 240 the plunger and bungee assembly is carried out in the plunger & bungee assembly module 120. The bungee 20 is held securely by the bungee jig 124 and the mandrel "O"-ring assembler 128 mounts 510 the mandrel "O"-ring 22 onto the bungee 20. The bungee jig 124 then arms 515 the bungee by stretching it to a predetermined length. The plunger jig 132 holds the plunger 26 securely while the armed bungee 20 is installed 520 into the plunger 26 by the assembler unit 134. The plunger seal assembler 138 then mounts 525 the plunger seal 24 onto the plunger 26. The bungee installation and air leakage tester 140 then checks 530 the installed bungee 20 to ensure it has been installed properly in the plunger 26. The tip of the bungee 20 protruding from the plunger seal 24 is subjected to a predetermined force not sufficient to activate the bungee. However, if the bungee 20 activates, then the installation has not been done correctly and the part is rejected 532. The plunger and bungee assembly is also further subjected to an air leakage test to ensure that the bungee and plunger seal interface is airtight and not subject to any leakage. Rejected 532 samples are left in the reject tray 144. The completed plunger bungee assembly is then sent to the Final Assembly Module 150.

Referring to Fig.2 and Fig.7, the Final Assembly Module 150 receives the syringe barrel assembly and the plunger bungee assembly. The syringe

barrel jig 152 holds the syringe barrel assembly securely. The cannula washing unit 154 then washes 610 the cannula 10. It then undergoes drying 615 at the blower unit 156. A mist of silicon is sprayed 620 into the syringe barrel assembly by the lubricant dispenser 158. Inspection cameras 160,162 then check the cannula length 625 and the bevel tip 630. The rejected 627 samples are placed in the reject tray 174. The plunger bungee assembly is received and held securely by the plunger jig 164. The assembler unit 166 then inserts 635 the plunger bungee assembly into the syringe barrel assembly. An inspection camera 168 checks 640 the height of the plunger 26 that protrudes out of the syringe barrel 18. A needle cap is then mounted 645 over the cannula 10 and hub 12 by the needle cap assembler 172. At this stage the retractable needle syringe is now completed. The completed syringe is then placed in a Final Product feeder 176 to be sent to the packaging module 180 for packaging 650.

The present manufacturing system according to the invention is made up of the 5 described assembly modules, the printing module and the packaging module. Each assembly module assembles one of the described sub-assemblies and together the assembly modules manufacture the completed article. Each of the assembly modules is controlled by a rotary indexing system with multiple synchronous action through a central gear cam mechanical linkage. The various modules are linked up to each other by a variety of conveying and transporting means. Some examples of these conveying means are : conveyor belts, rollers, rails and movable jigs

Referring to Fig.8, the assembly modules are made up of a variety of peripheral tools and devices mounted on a first circular platform 46. This first circular platform 46 is fixed and immovable. The peripheral devices 49 such as the assembler units and sealant dispensers are actuated by a central gear cam mechanical linkage 45 in tandem with a rotary indexing system. The peripheral devices 49 are designed to have similar interfacing

mechanical linkages. This allows for the configuration of the first circular platform 46 to be easily changed to adapt the assembly module to different products. The peripheral devices 49 are also designed with similar footprints and standard mounting interfaces. This allows for rapid mounting and dismounting of peripheral devices 49 which decreases downtime during maintenance. A faulty peripheral device 49 may be readily dismounted and a serviceable one replaced simply by using simple hand tools.

A second circular platform 47 rotates about an axis and is controlled by the rotary indexing system. Mounted on this second platform 47 are the jigs 48 that are designed to hold the components of the unassembled retractable needle syringe. The second platform 47 rotates and ensures each mounted jig 48 is aligned to a predetermined peripheral device 49 on the first circular platform 46. After the peripheral devices 49 have performed their intended action, the second circular platform 47 then rotates to a next index according to the rotary indexing system. The central gear cam mechanical linkage 45 works together with the rotary indexing system to actuate the peripheral devices 49.

An example of a peripheral devices 49 is the "O"-ring assembler. There are two types of "O"-rings to be assembled in the retractable needle syringe. The snap cap "O"-ring and the mandrel "O"-ring. These "O"-rings are made of soft and flexible materials. The peripheral devices 49 are thus also specially designed to handle such flexible parts and components.

The assembler units as mentioned like the "O"-ring assembler are inherently pick and place units. The pick and place units pick up components and mount them individually onto other components being held by the jigs. This method of assembling such low cost devices does not appear to be cost effective and feasible as compared to conventional manufacturing systems. In the conventional systems, large numbers can be produced in short periods of time, but the quality levels are not high. However, the

present invention advantageously allows for every sub-assembly to be inspected before each sub-assembly proceeds to the next assembly module. If required, each component and uncompleted sub-assembly may be inspected before the next peripheral device is actuated. This provides for an almost 100% good parts output at the packaging module of the entire system.

The peripheral devices 49 further allow for different dimensions of syringes to be manufactured. The jigs 48 and assembler units have extra allowances to handle parts having a predetermined range of dimensions, thus allowing the same equipment to manufacture a variety of size of syringes.

The assembly modules each being driven by a central gear cam mechanical linkage 45 results in a high speed assembling action. The central gear cam linkage 45 actuates the peripheral devices 49 on the first circular platform 46 of each assembly module synchronously. The Rotary Indexing system ensures that each peripheral device 49 carries out its action synchronously. It also ensures that the succeeding peripheral device 49 takes over the action on a component at the next index after rotation. This results in an assembling action that is smooth and rapid.

The use of the circular platform according to the present invention reduces the overall footprint of the assembling modules making them more compact. Such equipment for manufacturing medical devices are inevitably located in a clean room. Such a manufacturing system thus requires a smaller clean room, which ultimately translates into lower costs. A smaller clean room is also easier to manage and it reduces the possibility and avenues for contamination.

As described earlier, all required parameters of the retractable needle syringe undergo automated inspection by inspection cameras and other

tester units. Rejected parts are then placed in open reject trays. This allows for further manual inspection by quality control workers. In the event that the rejected part may be reused or was wrongly rejected, the parts can still be returned into the production system. This is done via the feeders that supply the parts into assembly modules. This further results in increased cost savings as parts are not wasted or inadvertently destroyed. Such a system incorporating multiple automated inspection cameras ensures that the final products being sent to the packaging module 180 are completely free of manufacturing defects. This is possible as the rejected parts have all been dropped of into the many reject trays on each of the assembly modules.

The above description according to one example of the invention does not in any way limit the scope of the invention. It would be apparent to one skilled in the art that the present invention may be modified or used in or with other types of multi-component devices without departing from the scope of the invention.

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CLAIMS

1. An apparatus for assembling an assembly having a plurality of components, said apparatus comprising :
a first platform;
a plurality of peripheral devices mounted on said first platform;
a second platform;
a plurality of jigs mounted on said second platform;
a rotary indexing system for controlling rotation of said second platform,
and a central gear cam mechanical linkage for actuating synchronously said plurality of peripheral devices.

2. An apparatus according to claim 1 wherein said plurality of peripheral devices comprises at least one of the following: said jig for holding one of said plurality of components, an assembler unit for assembling at least two of said plurality of components together, an automated inspection device, a blowers, a dryers, a liquid dispenser and a lamp.

3. An apparatus according to claim 2 wherein said assembler unit comprises of a pick and place arm.

4. An apparatus according to claim 1 wherein said apparatus further comprises a plurality of feeders for feeding components to said plurality of peripheral devices and said plurality of jigs.

5. An apparatus according to claim 2 wherein said automated inspection device further performs inspection of said assembly.

6. A fully automated process for manufacturing a retractable needle syringe having a cannula, a hub, a snap cap, a snap cap "O"-ring, a printed syringe barrel, a bungee, a mandrel "O"-ring, a plunger and a plunger seal, said process comprising the steps :

a. assembling cannula and hub together;
b. mounting snap cap 'O'-ring onto cannula and hub;
c. mounting snap cap onto syringe barrel;
d. mounting mandrel 'O'-ring onto bungee;
e. mounting plunger seal onto plunger;
f. installing bungee into plunger; and
g. final assembly of products from steps d. and g. together.

7. A process according to claim 6 wherein said process further comprises arming of said bungee before step f.

8. A process according to claim 6 wherein said process further comprises printing a graduated scale onto said syringe barrel before step c.

9. A process according to claim 6 wherein said process further comprises conducting quality control checks after each step before proceeding to subsequent steps.

10. A fully automated system for manufacturing a retractable needle syringe, said system comprising:
a first assembly module;
a second assembly module;
a third assembly module;
a fourth assembly module; and
a fifth assembly module;
said first assembly module for assembling a first sub-assembly;
said second assembly module for assembling a second sub-assembly;
said third assembly module for assembling a third sub assembly;
said fourth assembly module for assembling a fourth sub-assembly; and
said fifth assembly module for assembling a final assembly

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11. A fully automated system according to claim 10 wherein said first sub-assembly comprises: a cannula, a hub and a snap cap "O"-ring.

12. A fully automated system according to claim 10 wherein said second sub-assembly comprises: said cannula, said hub, said snap cap "O"-ring and a snap cap.

13. A fully automated system according to claim 10 wherein said third sub-assembly comprises: said cannula, said hub, said snap cap "O"-ring, said snap cap and a syringe barrel.

14. A fully automated system according to claim 10 wherein said fourth sub-assembly comprises: said plunger, said plunger seal and said bungee.

15. A fully automated system according to claim 10 wherein said final assembly comprises: said third sub-assembly and said fourth sub-assembly.

16. A fully automated system according to claim 10 wherein each sub-assembly is subjected to quality control checks before proceeding to next assembly module.

17. A fully automated system according to claim 10 wherein each said assembly module comprises of a plurality of peripheral devices actuated synchronously by a central gear cam mechanical linkage.

18. A fully automated system according to claim 10 wherein said central gear cam mechanical linkage is controlled by a rotary indexing system.