Manufacturing Process and Characteristics of Modern Acupuncture Needles

1. History of disposable acupuncture needles (Single use acupuncture needle)

Disposable acupuncture needles (hereafter referred to as "single use acupuncture needles") were first mass-produced and introduced to the market by Seirin Corporation in 1978. Subsequently, China money and the funds of Chinese companies were invested for the manufacture in about 1995 and the sales started on a full scale around 1997. These needles are packaged in blister packs. About ten brands are now sold on the world markets. This has accelerated the use of single use acupuncture needles.

Importance of single use acupuncture needles is adequate sterilization being ensured and needle points uniformly shaped. This makes the techniques of acupuncturists to be transmitted as they are, resulting in therapy efficacy. Since the single use acupuncture needle is a medical tool, it is required to satisfy international legal requirements. Adequate sterilization is an important issue and counts of living microbes including bacteria, attached to the product, that are likely to propagate need to be reduced to the least possible. Thus, the manufacture has to be carried out under a specifically clean environment. Following is the manufacturing process of single use acupuncture needles.

2. Manufacturing process of disposable acupuncture needles

(1) incoming inspection

All Seirin needles are manufactured from high quality raw materials made to specifications established by adding our company's original requirements to the specifications of stainless steel wires prescribed by JIS standards applicable to wires made in Japan. No effort is spared to perform the trace control of stainless wires that were used.

(2) process of setting straight

By having established inimitable straightening technologies, we perform straight line processing without damaging surfaces and carry out wire materials processing, which forms the basis of needles with high roundness.

(3) process flow inspection

Measurements are made of the true wire diameters, cut dimensions, etc. of cut parts on which straight line processing was performed and standard size cutting operation was completed, thereby controlling conditions where uniform needlepoint processing can be carried out in subsequent processes.

(4) grinding process

Seirin's original needlepoint technology is utilized to finish products into uniform, rounded, and smooth forms that serve to minimize pains.

(5) process flow inspection

After completion of needlepoint operation, in-process inspections are performed, with each production lot as a unit, thus severely checking needle lengths in terms of accuracy requirements. Then needles flow to the cleaning process, which is the next one.

(6) washing process

Cleaning work is performed in a number of stages to prevent oil, foreign objects, etc. from adhering to needles. Distilled water cleaning is carried out in a clean booth for which strict environmental control is conducted, and final cleaning is performed by a dust-free dryer. In this work setup, no human hand comes into contact with needles.

(7) process flow inspection

A magnifying microscope is used to carefully check the needlepoint condition, with each production lot as a unit.

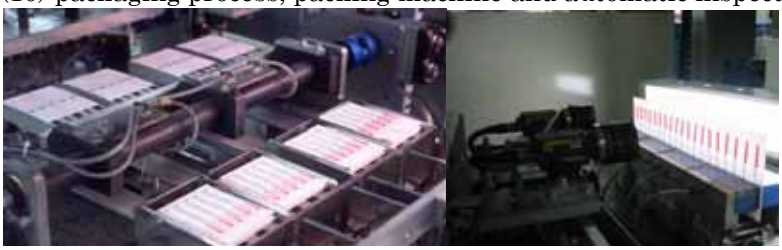
(8) assemnly process and inspection of auto-assembly machine

Inspection devices are installed in all automatic assembly line sections where no human hand comes into contact with needles. Thus uniform disposable acupuncture needles are assembled.

(9) process flow inspection

Items such as the needlepoint condition, the adhesion strength of joints between needle shafts and needle tubes, and the drawing tension between needle shafts and needle bodies are subjected to in-process inspections, with each production lot as a unit, thereby achieving the quality suitable for the next process.

(10) packaging process, packing machine and automatic inspection



An automatic packaging machine for packing individual needles is used to strictly control the sealing condition capable of steadfastly maintaining sterility. Inspection devices including an image processing apparatus are used to make sure that no defects are overlooked.

(11) process flow inspection

In-process inspections are performed, with each production lot as a unit, to check the indication condition, the sealing condition, etc., thereby providing products with air-tightness capable of steadfastly maintaining product sterility suitable for the sterilization process, which is the next one.

(12) process of diminishing germs

The environment in the production processes are controlled on a thoroughgoing basis, and sterilization validation is performed, thereby reliably ensuring sterility.

(13) product warehouse

Products are managed in a room subjected to controlled air conditioning.

(14) shipping inspection

Final functional inspections are performed including the confirmation of the in-process inspections conducted in all production processes. Also, culture examinations for biological indicators are conducted.

(15) numbered lot

(16) shipping

The production lot number and the expiration date are printed on the back of each blister package formed in the packaging process. By searching for production lot numbers, it is possible to clarify data ranging from shipment inspection histories to sterilization histories and to stainless wire purchase histories. Any product for which such production lot trace is unclear is not allowed to be distributed even if it has passed shipment inspection.

(Materials provided by SEIRIN CORPORATION)