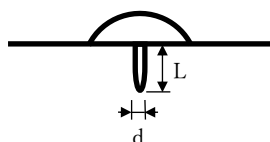


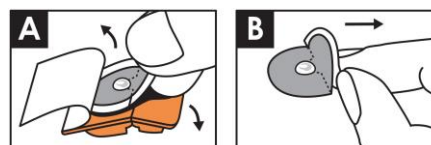
SEIRIN PYONEX NEEDLES



SEIRIN CORPORATION
JP-MF-000012274
147 Ouchi, Shimizu-ku, Shizuoka-shi, Shizuoka, 424-0061, Japan
<https://www.seirin.jp>



L (mm)	0.3	0.6	0.9	1.2	1.5
d (mm)	0.11	0.15	0.17	0.20	0.20



en SEIRIN PYONEX NEEDLE

Current scientific evidence proves that medical devices manufactured from stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

[Intended use, indications]

This product is a device intended to pierce the skin in the practice of acupuncture by authorized medical practitioners (specialists) in order to relieve pain and to promote other therapeutic effects.

[Precaution for use (Must be applied with care to the following patients)]

- Pregnant women (acupuncture may induce labor.)
- Patients with malignant tumors (acupuncture may accelerate the growth or metastasis of malignant tumors.)
- Patients with hemorrhagic disease (acupuncture may lead to bleeding.)
- Patients allergic to metals such as nickel, chromium, and other stainless steel components

[Method of use] • Handle the needles with care to prevent injury because they are sharp.

- 1) **Check:** Check the package for any damage, contamination, or liquid leakage. Do not use the product if the package is damaged, contaminated, or wet.
- 2) **Single use:** Seirin's needles are sterilized, disposable, and single-use only. Reusing them increases the risk of infection.
- 3) **Disinfection:** Use alcohol swabs to clean the areas where needles will be inserted. Allow the skin to dry before inserting needles.
- 4) **Visual inspection:** Inspect needles before use. Do not use needles if they are bent, damaged, or if any other anomaly is detected.
- 5) **Open the package and take out the product** ①: Remove the cover seal from the plastic case and lift up the crescent-shaped tab along with the tape, as shown in the figure. You can easily fold the plastic case back with your fingers.
- 6) **Application** ②: Lift up the crescent-shaped tab along with the tape in order to apply the needle (Pyonex) to the skin without touching the adhesive of the tape and the needle tip. After that, remove the tab and press down the tape.
- 7) **After treatment:** Dispose of the needles in a safe manner, taking precautions to protect against infections. If the needles are not used after the package has been opened, do not use and dispose of them properly.
- 8) The material of the needle cannot tolerate the heat produced by moxibustion. Do not perform moxa heat treatment on the tape.
- 9) This product is not intended for use in electroacupuncture. Do not use it in electroacupuncture.
- 10) Instruct patients to remove the tape on their skin before taking a shower or a bath or swimming because it will come off easily.
- 11) Instruct patients to avoid behavior that puts stress on the site to which the tape is applied.

[Adverse reactions] The patient may experience pain, itchiness, drowsiness, malaise, nausea, redness, swelling and blister. If any abnormal reaction appears in the treatment area, such as redness and itchiness, instruct patients to consult with an authorized medical practitioner in acupuncture after removing the needle.

[Storage method] Store the needles in a safe place protected from water, direct sunlight, high humidity and high temperatures, and chemical contamination. Keep away from children.

[Expiry date] The expiry date (based on self-certification) is indicated on the outer box. Check the expiry date before use. Do not use expired products.

Report all serious events associated with this device to the manufacturer and health authorities of the member state where the user and/or patient resides.