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SEIRIN ACUPUNCTURE NEEDLES



SEIRIN CORPORATION JP-MF-000012274

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Diameter of needle body		Length of needle body (mm)									
(mm)	Gauge size	7	15	30	40	50	60	75	90	120	150
0.10	No. 03	0	0								
0.12	No. 02	0	0	0	0						
0.14	No. 01	0	0	0	0						
0.16	No. 1	0	0	0	0	0					
0.18	No. 2	0	0	0	0	0					
0.20	No. 3	0	0	0	0	0	0				
0.23	No. 4			0	0	0					
0.25	No. 5		0	0	0	0	0	0	0		
0.30	No. 8			0	0	0	0	0	0		
0.35	No. 10					0		0	0		

A circle in the table above indicates that the actual dimensions differ according to the product model. Non-standard products may also be included. Refer to the catalog or other information material.

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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 and/or moxibustion by authorized medical practitioners (specialists) in order to relieve pain and to promote other therapeutic effects.

[Precautions 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 promote bleeding]
- Patients allergic to metals such as nickel, chromium, and other stainless steel components

[Methods 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) Opening/unpacking: Hold the product by the handle when opening or unpacking the package. Do not touch directly with bare fingers.
- 6) Insertion: Depth of insertion should be less than 2/3 of the length of the needle body.
 - When using a Gauge No. 01 (\emptyset 0.14) or thinner with a needle that is 15 mm or longer, the depth of insertion should be less than 1/2 of the length of needle body. Be aware of the depth and angle of insertion to avoid damaging organs and nerves.
 - Always monitor the needles during acupuncture treatment to ensure that there is no change in the state of insertion. Muscle contraction or other movements may draw the needle deeper, leading to organ or nerve damage.
- 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) Intermuscular treatment: In intermuscular treatment, excessive muscle tension may occur, causing the needles to break off. For intermuscular treatment, use needles of Gauge No. 2 (Ø0.18) or a larger diameter. Acupuncture should be performed while helping the patient remain relaxed and paying attention to symptoms such as coughing during treatment. Be aware that the needles may break off if they are twisted or rotated with a force greater than the strength of the metal.
- 9) **Moxibustion:** For moxibustion, use only metal-handle-type needles. During moxibustion, take precautions to prevent local burns, and ensure that the room has proper ventilation. Do not allow the needles or caps to get close to the flame. The needles may distort, and the caps may burn.
- 10) Electroacupuncture: This product is not intended for use in electroacupuncture.
 - In special cases where electroacupuncture is deemed absolutely necessary for treatment, to ensure safety, carefully read the instructions for use of the low-frequency electrical stimulation device with needle electrodes before use.
 - Excessive electrical stimulation ($\geq 100~Hz$ and $\geq 1~mA$ rms, or $\geq 1~C$) could break needles due to needle corrosion or strong muscle contractions.
 - If the needles are used for electroacupuncture in cases where it is deemed absolutely necessary for treatment and the insertion depth is 10 mm or less, severe needle corrosion or biological tissue damage may occur.

[Adverse reactions] The patient may experience pain, itchiness, drowsiness, malaise, feeling of unwellness, or slight bleeding.

[Storage] 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 incidents associated with this device to the manufacturer and health authorities of the member state where the user and/or patient resides.

