

Medical Device Operation Manual

Product name: Ultra Fine Dry Needles

Sterilization method: Co-60 irradiation sterilization

Specification: Needle body Diameter× Needle body Length

Needle body Diameter:Φ0.14mm-Φ0.80mm

Needle body Length:7mm-100mm

Product performance and structure:

Ultra Fine Dry Needles consists of a stainless steel wire(ASTM 304) as the needle body, with a stainless steel wire handle, a copper wire handle or polystyrol handle. The handles make the needles easier to manipulate and place.

The Ultra Fine Dry Needles are sterilized and disposable

Intended use: Ultra Fine Dry Needles are intended to pierce the skin in the practice of acupuncture therapy by qualified practitioners or acupuncture doctors as determined by the states.

Product operation instruction:

1. Read operation manual before use.
2. Disinfect acupoints in the affected part with alcohol cotton. Keep skin dry and clean.
3. Tear open Permeable paper on needle handle. Hold it with finger. Take out Ultra Fine Dry Needle from blister.
4. Hold needle handle with finger, with needle tip pointing towards acupoint. Insert tip to the skin with acupuncture area. (If the acupuncture needles are with plastic pipe, professional acupuncturists can decide whether to use it for needle positioning or not. If using the plastic pipe, hold it with one hand and hold the needle handle with the fingers of the other hand, insert the needle into the skin, then remove the plastic pipe.)
5. Keep pressing needle handle with finger until the tip goes to a proper depth.

Precautions and Warnings:

1. As a medical device, it must be used by qualified physician.
2. Do not use when the package is damaged.
3. Do not reuse because it is single-use.
4. Use it within the validity time.
5. Those who are allergic to the material of the needle body should use with caution or follow the instruction of an acupuncture physician
6. Please throw used acupuncture needles into designated dustbin.
7. After the sterile barrier system is opened, the Ultra Fine Dry Needles should be used up at one time, the unused Ultra Fine Dry Needles cannot be used for other operations or patients, and should be discarded into designated trash bins.
8. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Potential side-effects or complications:

Possible side-effects include minimal bruising, bleeding or pain at needle site, and tiredness. Potential complications include infection and pneumothorax.




















Contraindication:

1. Pregnant women should use with caution;
2. Acupuncture should not be used for habitual abortion;

3. Acupuncture needles should not be used on skin ulcers, scars or tumors;

4. Patients with spontaneous bleeding or hemophilia should not use acupuncture needles.

Symbol interpretation:

	Sterilized using irradiation		Date of manufacture		Use-by date		Keep dry
	Sterile		Manufacturer		Caution		This way up
	Single-use product		Batch code		Do not use if package is damaged		Fragile, handle with care
	Medical device		Consult instructions for use or consult electronic instructions for use		Unique device identifier		Stacking limit by number
Rx ONLY	Federal law restricts this device to sale by or on the order of a physician.		Catalogue number		Do not re sterilize		Single sterile barrier system

Validity for Ultra Fine Dry Needles: within 3 years from sterilization date

Transport conditions: Ultra Fine Dry Needles should be protected from heavy pressure, direct sunlight and rain and snow when transported.

Storage conditions: Packaged Ultra Fine Dry Needles should be stored indoors with non-corrosive substance and good ventilation, and with relative humidity below 80%.

Manufacture date/ expiry date: as shown on the packing box.

Distributed by:

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