



FINAL DRAFT International Standard

ISO/FDIS 6559

Traditional Chinese medicine — Sterile three-edge needle for single use

*Médecine traditionnelle chinoise — Aiguille stérile à trois bords à
usage unique*

ISO/TC 249

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Introduction

Originating in ancient China, the three-edge needle is one of major types of acupuncture needles. The three-edge needle was originally called "Feng Zhen", which literally means "sharp-edge needle". Its clinical application for the specific indications was earliest recorded in *Huangdi's Canon of Medicine*, which is the earliest writing about traditional Chinese medicine. The therapy which applies the three-edge needle is called three-edge needle therapy.

The three-edge needle has a special needle body structure like an arrow head with three sharp edges. This structure was designed in order to meet specific clinical requirements, such as bloodletting and draining abscesses mainly by the manipulation methods including shallow pricking, deep pricking, multi-point shallow pricking, pricking in and edge cutting out, and needle scratching. Of the manipulation methods, pricking in and edge cutting out (mainly for breaking the fibrous tissue) and needle scratching (leaving marks on skin) can only be practiced by the three-edge needle, which cannot be replaced by other bloodletting medical instruments such as the blood point lancet and the syringe.

It is due to the special structure of the three-edge needle that the practitioner can bleed the clinically required blood amount by controlling the depth instead of repeated pricking which induces pain in patients. This structural advantage of the three-edge needle outweighs the blood point lancet and the syringe both in clinical function, such as draining an abscess, and in obtaining a clinically required amount of blood.

Since the three-edge needle is an invasive medical instrument, it is important to use the sterile needle only once. The quality of the three-edge needle has a direct impact on the safety of patients and the quality of the therapy. Therefore, this document specifies the technical parameters of the sterile three-edge needle for single use to ensure its quality and safety.

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