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 TAE-CHANG INDUSTRIAL CO.,LTD

# DESIGN DOSSIER FILE

## PRODUCT DESCRIPTION

Approval of the Design dossier file [Product description] is performed in accordance with the responsibility of the following functional area representatives




### Revision history

Rev. No	Rev. Date	Modified contents	Remark
0	November 03, 2009	Firstly prepared	-
1	March 15, 2010	Change to product's intended use	-
2	Nov 16, 2015	Add the range of sizes being offered in the whitare pencil point range And the detailed intended use	-
3	Oct 24, 2017	Add to model name and Hub description description	-
4	Sep 19.2020	Add the change history section. (9.Change History)	


### Attached file information

No	Attached file No.	File name	Location
1	Annex04	Drawings of the product and component	QA team

### Functional area representatives

Division	Department	Name	Date	Signature
Authored by	Quality assurance team	J.H CHA	Sep 19.2020	
Reviewed by	Quality assurance team	H.J KIM	Sep 19.2020	
Approved by	Factory manager	J.H KIM	Sep 19.2020	

Preparation, Review and Approval of the document was performed by the organization that had been approved by our company.

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## 1. PRODUCT NAME AND MODEL CODE

1.1 Product name : STERILE SPINAL NEEDLE

1.2 Model code : ① SP·QB ② SP·PP ③ SP.QB-Small Bore ④ SP.PP-Small Bore

1.3 The meaning of the Model code

- ① SP·QB : Spinal Needle Quincke Bevel
- ② SP·PP : Spinal Needle Whitacre Pencil Point
- ③ SP.QB-Small Bore : Spinal Needle Quincke Bevel Small Bore
- ④ SP.PP-Small Bore : Spinal Needle Whitacre Pencil Point Small Bore

## 2. DESCRIPTION OF THE INTENDED USE

- Intended use of the Spinal Needle Quincke Bevel, Spinal Needle Whitacre Pencil Point
- For use in subarachnoid injection of local anesthetics for spinal anesthesia before surgery, and in lumbar puncture for pain management, and diagnosis on the basis of cerebrospinal fluid.
  - ① The intended patient population : The patient needed anesthesia, diagnosis, treatment or medical administration
  - ② The intended user : This medical device should be used by the qualified doctor.

## 3. CLASSIFICATION APPLIED

3.1 The Spinal Needle Quincke Bevel, Spinal Needle Whitacre Pencil Poin has been classified as **Class III** According to MDD93/42/EEC amended by 07/47/EEC Annex IX, Rule6.

## 4. CHARACTERISTIC


- 4.1 Ethylene oxide gas be sterilized by TAE-CHANG INDUSTRIAL CO.,LTD (Sterilization assurance level[SAL] :  $10^{-6}$ )
- ① Sterilizing agent : 30 : 70(E.O : CO<sub>2</sub>)
  - ② S.A.L. :  $10^{-6}$
- 4.2 This device should be used for Single-use.
- 4.3 Shelf-life : 5years

## 5. USAGE METHOD

- 5.1 Do not use if the packing is damaged or opened.
- 5.2 Removed the protect cap safely when use it.
- 5.3 After use it, waste it recovered protect cap.,

## 6. ATTENTION

- 6.1 Do use the needles by anesthetist only.
- 6.2 Do not resterilize or reuse.
- 6.3 Single use only.
- 6.4 Do not store at extreme temperatures and humidity.

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## 7. PACKAGING METHOD

- 7.1 1<sup>st</sup> packaging : Blister packing by heating (Blister paper + film)
- 7.2 2<sup>nd</sup> packaging : 1<sup>st</sup> packed product is packed in paper box(In-box).
- 7.3 3<sup>rd</sup> packaging : 2<sup>nd</sup> packed product is packed in paper box(Out-box).

## 8. TYPE & CONSTRUCTURE

### 8.1 Marking type



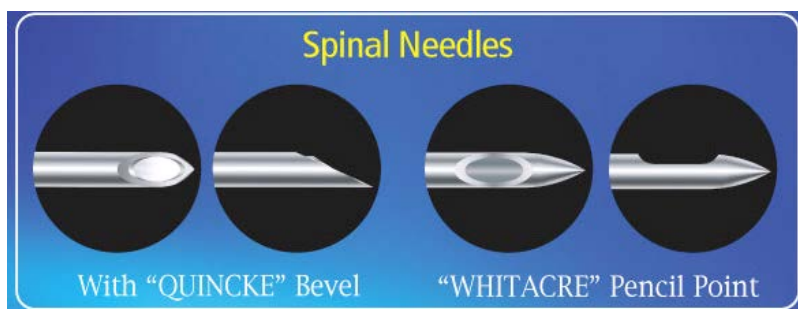
(Marking type)




(Non-marking type)

### 8.2 Needle type

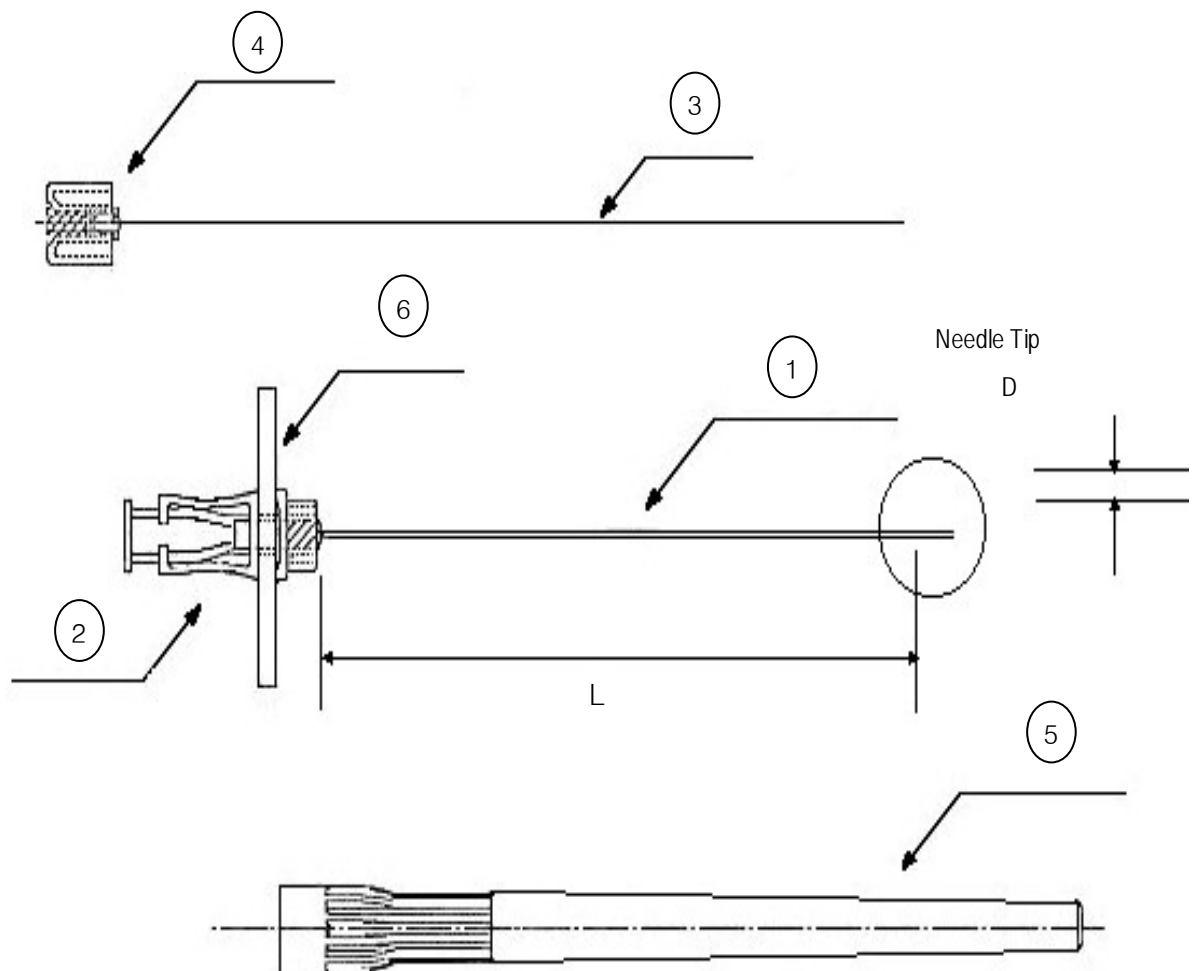
- 1) SP· QB : Spinal Needle Quincke Bevel      SP· PP : Spinal Needle Whitacre Pencil Point



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### 8.3 Constructure

- Tae-chang's sterile spinal needle for single-use is manufactured in accordance with requirements of ISO 7864 and is colored in accordance with the requirements of ISO 6009.




D : Outer diameter of cannula, L : Length of cannula

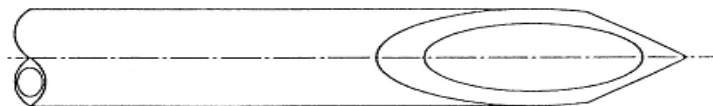
(1) Cannula (2) Hub (for cannula) (3) Stylet (4) Hub (for stylet) (5) Cover (6) Wing

### 8.4 Description of the structure

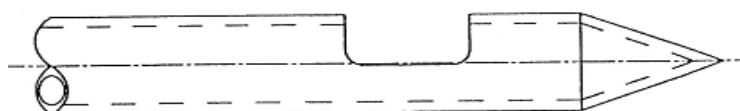
(1) Cannula : This is made of STS 304 specified by KS D 3698 Cold-rolled stainless steel Plates, sheets and strip; the cold-rolled stainless tube is cut and ground according to the specifications to be cleaned. The resultant tube has a sharp blade. Scales may (or may not) be marked every cm to help estimate the depth of puncture needle inserted. There are three shapes of the needle tip, each of which has its own marking as shown in the figure below.

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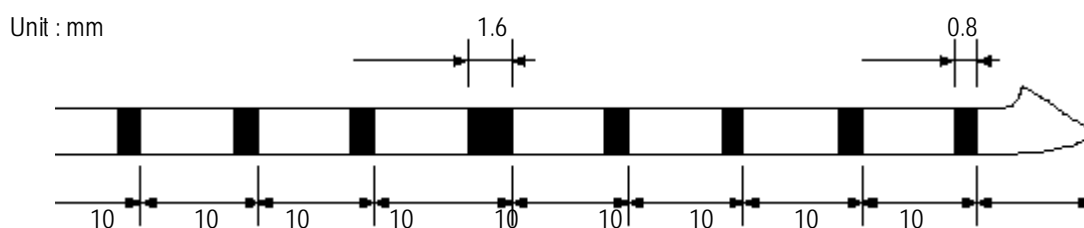
#### I . Quincke Bevel



#### II .Whitacre Pencil Point



\* Marking of the products: 0.8 mm wide lines are marked every cm beginning from the needle point, while a 1.6 mm wide line is marked at the point 5 cm away from the tip.



(2) Hub (for cannula) : This is a transparent rectangle made of ejected synthetic resin which serves to link the injector and ground cannula.

(3) Stylet : This is used to fill the inside of cannula so as not to have the blood leak out of the human tissue when puncture needle is inserted. It is made of STS 304 specified by KS D 3698 Cold-rolled stainless steel Plates, sheets and strip.


(4) Hub (for stylet) : This is made of ejected synthetic resin. It serves to fix stylet to cannula. It has its unique color depending on the sizes of cannula. And Connector has two type.

- ISO80369-7 TYPE : ① SP·QB ② SP·PP

- ISO80369-6 TYPE : ③ SP.QB-Small Bore ④ SP.PP-Small Bore

① SP·QB ② SP·PP	③ SP.QB-Small Bore ④ SP.PP-Small Bore
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## 8. DRAWING LIST

No	Drawing No	Drawing Name	Location
1	PR-1001	CANNULA FOR SP.QB	Q.A TEAM
2	PR-1002	STYLET FOR SP.QB	Q.A TEAM
3	PR-1005	CANNULA FOR SP. PP	Q.A TEAM
4	PR-1006	STYLET FOR SP. PP	Q.A TEAM
5	PR-1008	Cover	Q.A TEAM
6	PR-1019	Needle Hub	Q.A TEAM
7	PR-1020	Cover	Q.A TEAM
8	TC-SNH-16-01	Needle Hub for small bore	Q.A TEAM

## 9. Change History

### History of significant changes of device.

Changes No	Changes. Date	Changes of contents	Remark
1	March 15, 2010	Change to product's intended use	-
2	Nov 16, 2015	Add the range of sizes being offered in the whitare pencil point range And the detailed intended use	-
3	Oct 24, 2017	Add to model name and Hub description description	-

**We verified that there is no significant change to the design, manufacture, materials of construction, packaging, shelf-life, indications/contraindications for use, or warnings have been reported in the submitted information except above changes.**