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T-C TAE-CHANG INDUSTRIAL CO.,LTD

DESIGN DOSSIER FILE

LABEL AND PACKAGING DESIGN

Approval of the Design dossier file [Label and packaging design] 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	May 28, 2010	Add to Instruction for use contents	-
2	Oct. 24, 2017	Add to label design and revised to IFU	-
3	Feb.18.2020	Change Notified body(NB) : CE0120 to CE1639	

Attached file information

No	Attached file No.	File name	Location
1	Annex06	Label design report	QA team
2	Annex07	IFU design report	QA team
3	Annex08	MSDS and Certification of the packaging material	QA team

Functional area representatives

Division	Department	Name	Date	Signature
Authored by	Quality assurance team	J.H CHA	Feb 18.2020	
Reviewed by	Quality assurance team	H.J KIM	Feb 18.2020	
Approved by	Factory manager	J.H KIM	Feb 18.2020	

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

1. LABEL AND PACKAGE OF THE UNIT PACKAGE

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1.1 Label for Unit package

1) SPINAL NEEDLE (Model code:SP.QB)



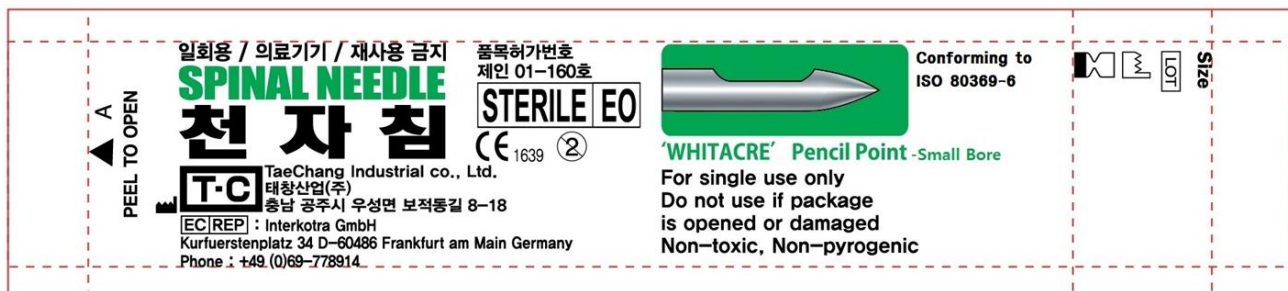
2) SPINAL NEEDLE (Model code: SP.PP)



3) SPINAL NEEDLE (Model code:SP.QB-Small Bore)











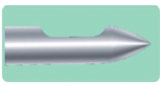



4) SPINAL NEEDLE (Model code: SP.PP-Small Bore)



Description of the symbol on the Label

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No	Used symbol	Description	Used symbol	Description
1		Symbol for 'Manufacturer'	SIZE	Symbol for 'Cannula size'
2		Symbol for 'Authorised Representative in the EC'		Symbol for 'Do not reuse'
3		Symbol for 'Use by'		Symbol for 'Batch code'
4		Symbol for 'Manufacture Date'		Symbol for 'Ethylene oxide gas sterilization'
5		Symbol for 'Caution'		Symbol for 'Peel direction'
6		Symbol for 'Needle type (Quincke bevel)'		Symbol for 'Needle type (WHITACRE Pencil point)'
7		Symbol for 'CE marking approved by SGS'		

1.2 Unit package

1) Unit package size (Wide X High) : 160 X 36mm



2) Material of the unit package

- Paper : ① Product name : Medical grade paper K-CP66
② Chemical name : Virgin papers, Cellulose derirerties, Agheous resin polymer
- Film : ① Product name : Medical grade fiml K-CP120
② Chemical name : LDPE / PP Laminate film

3) Product Quantity packed into the unit package : 1pcs

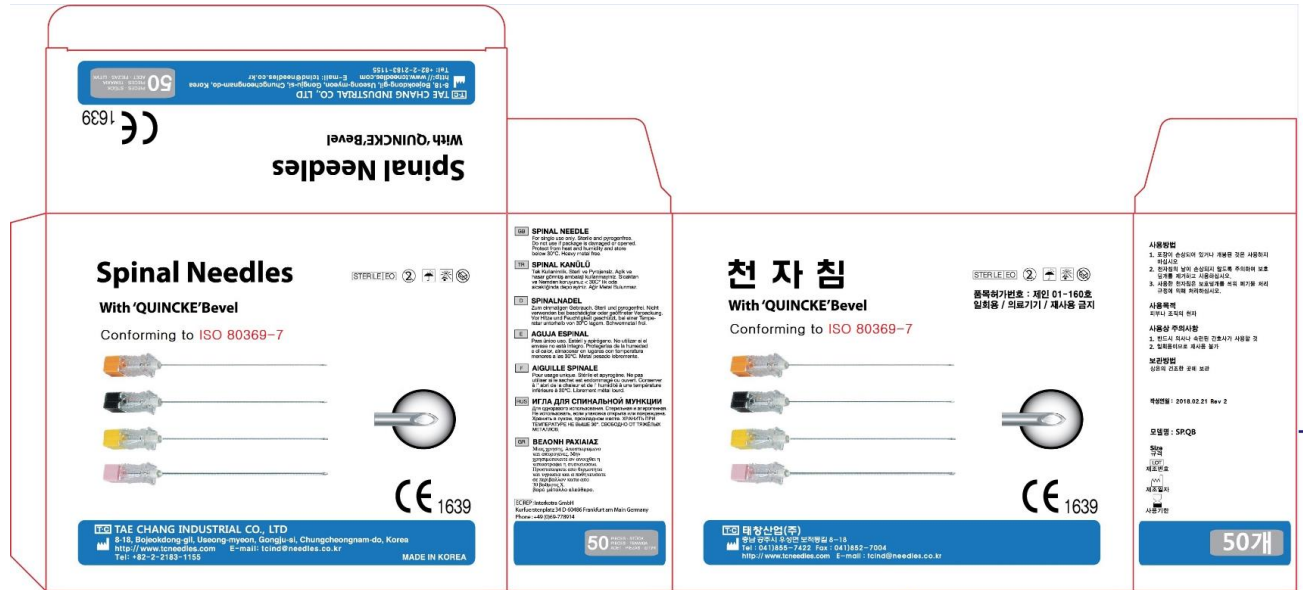
4) How to pack







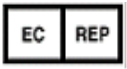


(1) Unit package is to pack 1pcs into one blister pack by blister machine

2. LABEL AND PACKAGE OF THE IN BOX

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2.1 Label for the In-box : The In-box label is printed on the In-Box package.

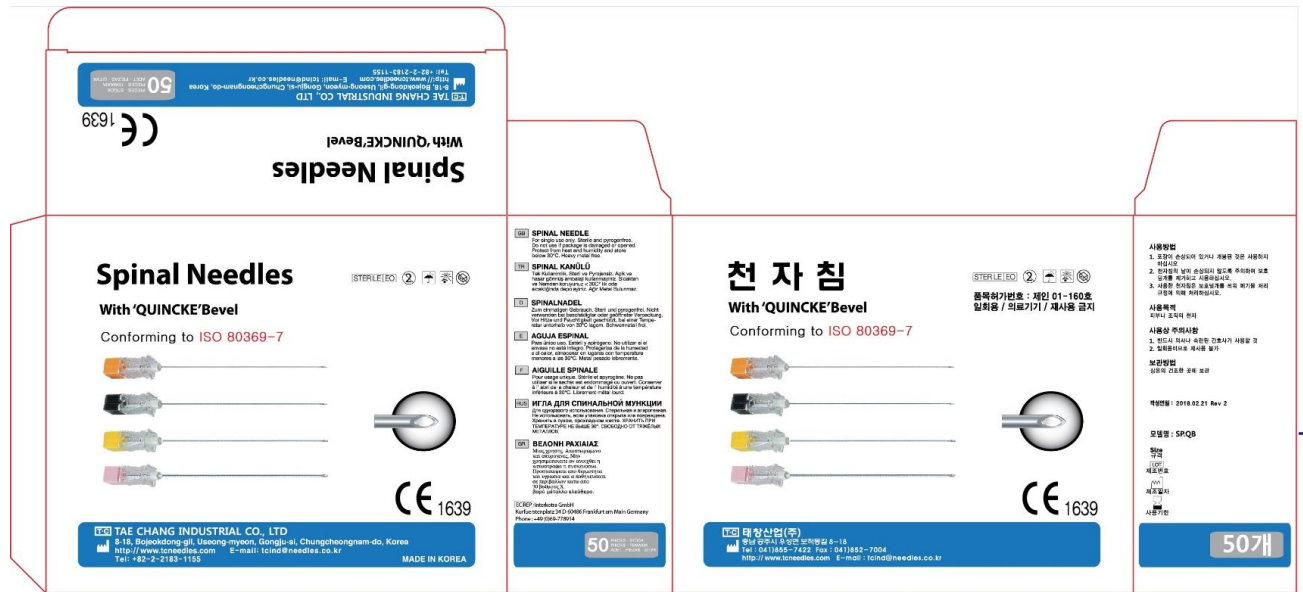


	Symbol for 'Manufacturer'	MODEL	Symbol for 'Product code'
	Symbol for 'CE marking approved by SGS'	SIZE	Symbol for 'Cannula size'
50PCS	Symbol for 'Unit package 50ea is packed into the In-box'	LOT	Symbol for 'Batch code'
	Symbol for 'Needle type Quincke bevel'		Symbol for 'Manufacture Date'
	Symbol for 'Needle type (WHITACRE Pencil point)'		Symbol for 'Use by'
	Symbol for 'Authorized Representative in the EC'		Symbol for 'Do not reuse'
	Symbol for 'Accompanying documents'	STERILEEO	Symbol for 'Ethylene oxide gas sterilization'

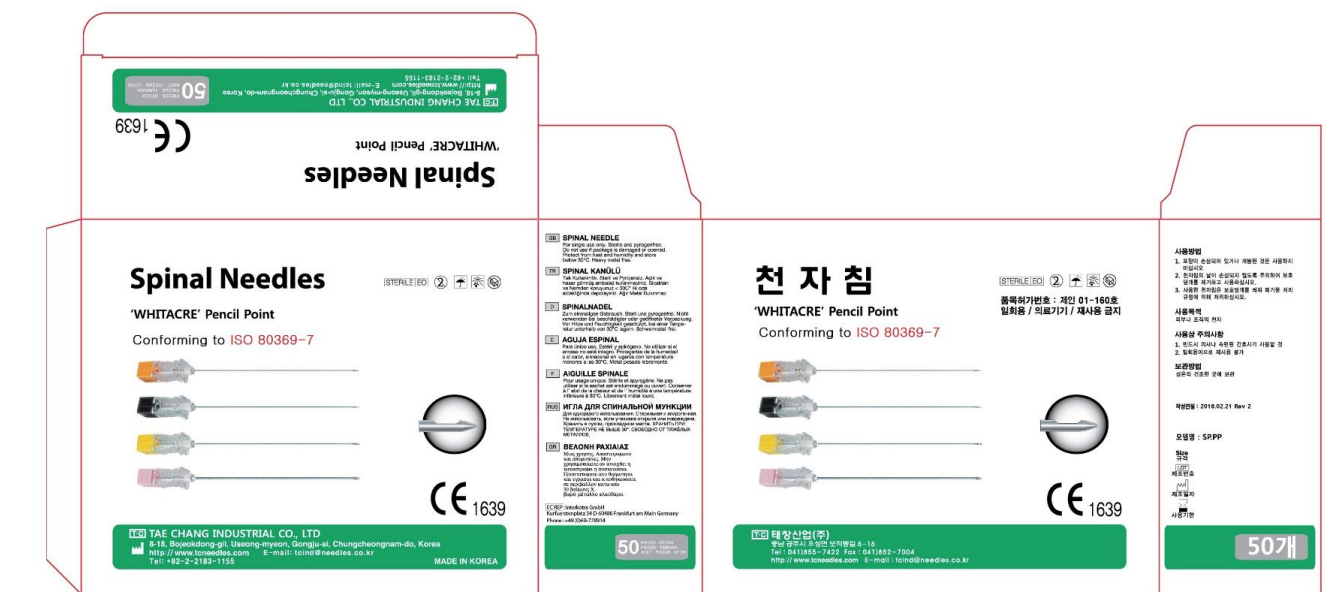
2.2 In-box package

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1) In-box package size for SP.QB (Wide X Length X Height) : 195X70X160 mm



2) In-box package size for SP.PP (Wide X Length X Height) : 195X70X160 mm



3) In-box package size for SP.QB-Small Bore (Wide X Length X Height) : 210X140X100 mm

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4) In-box package size for SP.PP-Small Bore (Wide X Length X Height) : 195X70X160 mm



2) Material of the in-box package

- Paper: Manila paper

3) Product Quantity packed into the In-box package: Unit package 50ea and IFU 1ea

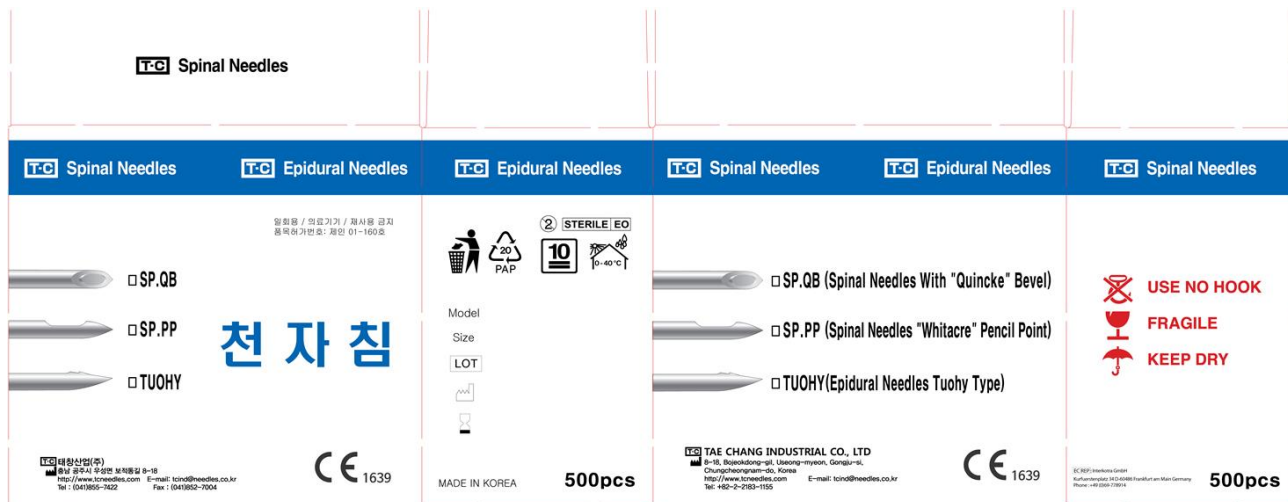
4) How to pack



















(1) Unit package 50ea is to pack into one in-box package.

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3. LABEL AND PACKAGE OF THE OUT- BOX

3.1 Label for the Out-box : The In-box label is printed on the Out-Box package

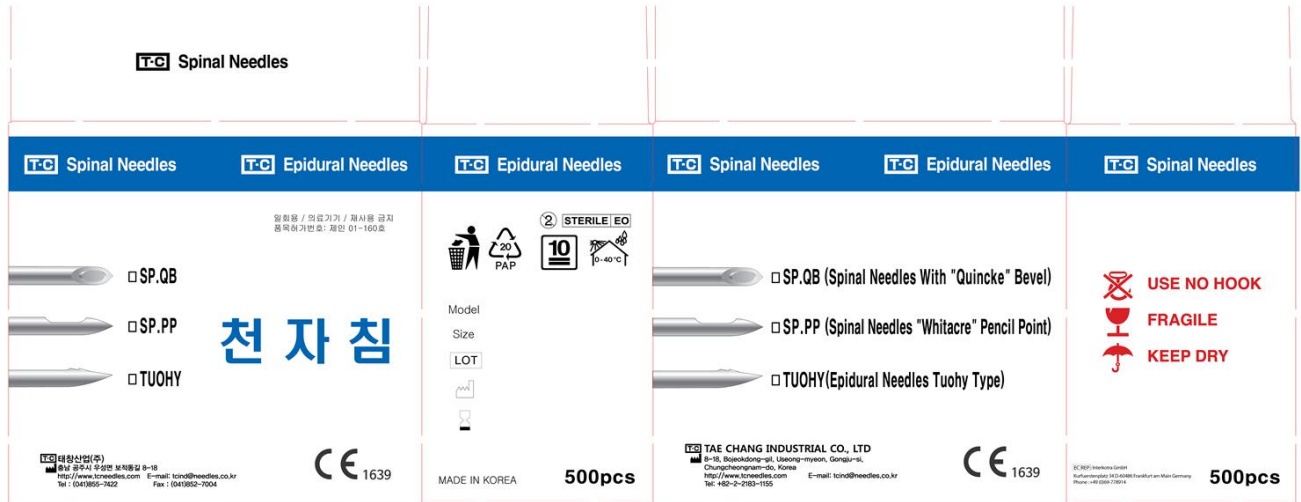


	Symbol for 'Authorised Representative in the EC'		Symbol for 'Needle type (WHITACRE Pencil point)
	Symbol for 'CE marking approved by SGS'		Symbol for 'Needle type Quincke bevel'
MODEL	Symbol for 'Product code'	SIZE	Symbol for 'Cannula size'
	Symbol for 'Batch code'		Symbol for 'Manufacture Date'
	Symbol for 'Use by'	500PCS	Symbol for 'Unit package 500ea is packed into the Out-box'
	environment symbol Exhaust about under dividing		environment symbol Paper Recycle Symbol
	Symbol for 'Manufacturer'		Symbol for 'Do not reuse'
	Symbol for 'Ethylene oxide gas sterilization'		Symbol for 'Accompanying'
	Symbol for 'Do not load the Out-box more than 10box'		Symbol for Custody condition Keep away from sunlight, Dry, limit of Temp
	Symbol for 'Use no hook'		Symbol for 'Fragile'
	Symbol for 'Keep dry'		

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3.2 Out-box package

1) Out-box package size : 363X203X332 mm



2) Material of the in-box package

- Paper : Corrugated cardboard

3) Product Quantity packed into the Out-box package : Unit package 500ea (In-box package 10box)

4) How to pack

(1) In-box package 10box is to pack into one Out-box package.