

TAE-CHANG

Quality Oriented Manufacturer of
Medical Needle Products

INTRODUCTION

T-C

“ **Quality Oriented Manufacturer
of Medical Needle Products** ”



Tae-Chang Industrial Co., Ltd. is a customer and quality-oriented manufacturer of various medical needle products.

Since its establishment, it has exported its products to more than 50 countries and built its reputation as a reliable supplier of high-quality products. With years of accumulated knowledge in quality management system and production technology, all products manufactured by Tae-Chang as well as its facilities are GMP, ISO & CE quality certified.



COMPANY HISTORY

June	1991	Established Tae-Chang Industrial
January	1997	Obtained approval of manufacturing of medical device by Ministry of Health and Welfare
January	2003	Being selected as promising export firm
January	2004	Obtained certification of ISO 9001, ISO 13485, CE Mark by SGS
April	2007	Obtained approval of GMP by MFDA
September	2009	Obtained approval of manufacturing veterinary pharmaceutical products by Animal and Plant Quarantine Agency
July	2010	Obtained certification of CE class II for spinal needle by SGS
October	2011	Established Gumi Plant
November	2011	Obtained approval of manufacturing medical device by Ministry of Health and Welfare (Gumi plant)
January	2012	Obtained approval of manufacturing insulin syringes, pen needle and dental needle by Ministry of Health and Welfare (Gumi plant)
January	2012	Obtained approval of GMP by KFDA (Gumi plant)
January	2012	Obtained certification of ISO 9001, ISO 13485, CE Mark by SGS (Gumi plant)
January	2014	Obtained approval of FDA 510k (Needle, Hypodermic, Single Lumen) (Gumi plant)
December	2014	Started injection molding of pen needle parts (Gumi plant)
December	2014	Being awarded Self-Audit of veterinary medical device by Animal and Plant Quarantine Agency
October	2016	Completed FDA onsite audit (Spinal needle)
November	2017	Obtained approval of manufacturing Non-OEMF blood bag (Gumi plant)
December	2017	Obtained certification of excellent small and medium enterprises by Gyeongju-city
December	2017	Being awarded 10 Million Dollar Export Tower by Ministry of Trade, Industry and Energy
June	2018	Obtained certification of ISO 80369-6 (Small bore variants with female hexaxial lock connectors) by SGS
July	2018	Obtained certification of GMP by UL (Pen needle) (Gumi plant)
March	2019	Completed FDA onsite audit (Pen needle) (Gumi plant)

PLANT FACILITIES

With years of accumulated knowledge in quality management system and production technology, Tae-Chang develops and maintains its facilities to manufacture products that meet the level of customer satisfaction.

Seoul Office Room 1014, East Building, Teheran-ro 322, Gangnam-gu, Seoul, Korea
TEL +82-2-2183-1155 FAX +82-2-2183-1154

Gongju Plant 8-1B, Bojeokdong-gil, Useong-myeon, Gongju-si, Chungcheongnam-do, Korea
TEL +82-41-854-7422 FAX +82-41-852-7004

Gumi Plant 127, Sariho-daero, Gumi-si, Gyeongsangbuk-do, Korea
TEL +82-54-465-0062 FAX +82-54-461-5594

INSULIN PEN NEEDLE TIPS

Q: / I wonder why I feel pain during injection sometimes.

A: Pen needle might be used multiple times. Use pen needle only once (Single use only).

Q: / What can I do when insulin back flows from the injection channel?

A: We can guess that the pen needle was removed before completing insulin delivery or insulin was not distributed as injection is too fast. In this case, inject insulin slowly and remove the pen needle slowly (Count to 10).

Q: / I can see lack or over-pronounced efficacy of insulin occasionally.

A: Injection site could be unsuitable (Ex. Scar tissue, Hardening of skin). Find suitable injection sites.

A: We can guess that the pen needle was removed before completing insulin delivery or insulin was not distributed as injection is too fast. In this case, inject insulin slowly and remove the pen needle slowly (Count to 10).

A: We also can guess that insulin in the cartridge has not been mixed well. You can roll the pen 10 times before each injection, following the instructions of your healthcare professional and the instructions of the insulin manufacturer in this case.

A: If the pen needle is clogged, use a new pen needle.

Q: / The dosage button of the insulin pen is not pressed. What should I do?

A: Rubber seal of the cartridge might not be pierced. Use a new pen needle and keep in mind that pen needle must be changed after each injection.

A: If the pen needle is too loose, ensure that the pen needle is securely fixed.



INSULIN SYRINGE

I Tae-Chang insulin syringe comply with ISO8537 standard

I Produced using SUS 304 stainless steel tube

I U-100 insulin syringes in 1ml(100unit) and 1/2ml(50unit) are available

I Use of optimized automatic grinding machine as well as medical grade lubricant minimized penetration resistance

I Smooth movement of plunger and minimized dead space alleviates patient discomfort

I Semi-transparent material and clear prints on the syringe allows users to inject exact amount of insulin needed

I Available finished product.

I Multi-bevel needle design, which reduces the penetration force, is also available

I Extra thin wall technology is used for maximum flow rate. reduced injection time provides virtually pain free experience

Syringe Specification

Syringe Type	Barrel Length (mm)	Outer Diameter (mm)	Inner Diameter (mm)	Cap Length (mm)
1.0mL	81.4	6.73	4.50	26
0.5mL	75.1	5.50	3.30	26

Needle Specification

Gauge	Outer Diameter (mm)	Inner Diameter (mm)	Length
31G	0.254-0.267	0.114	8mm (5/16") 12mm (1/2")
30G	0.298-0.320	0.133	
29G	0.326-0.351	0.133	



ANESTHESIA NEEDLE

- Comply with ISO 80369-4 standard
- Tae-Chang puncture / spinal needle is designed to prevent needle rotation and tissue coring with very tactile feeling
- Transparent hub ensures user has view of drug injection process
- Color coded stylet hub
- Detachable wing for greater control
- Depth mark is available
- Produced using SUS 304 stainless steel tube
- Other kinds of spinal needles are available depending on customer need
- Bevel orientation allows convenience on the user

Spinal Needle - Quincke Bevel



Spinal Needle - Whitacre Pencil Point



Epidural Needle - Tuohy



Gauge (ID/mm)	Stylet Color Code	Spinal Needle			Epidural Needle	Length
		Quincke Bevel	Whitacre Pencil Point	Side Wing	Tuohy	
14G(2.10)	White	✓	✓	-	✓	
16G(1.60)	White	✓	-	-	✓	1 1/2"(38mm)
17G(1.40)	Red Violet	✓	-	-	✓	2.0"(51mm)
18G(1.20)	Pink	✓	✓	✓	✓	2 3/4"(70mm)
19G(1.10)	Cream	✓	✓	✓	✓	3.0"(75mm)
20G(0.90)	Yellow	✓	✓	✓	✓	3 1/4"(86mm)
21G(0.80)	Deep Green	✓	✓	✓	✓	3 1/2"(90mm)
22G(0.70)	Black	✓	✓	✓	✓	4.0"(100mm)
23G(0.60)	Deep Blue	✓	✓	✓	✓	4 1/8"(103mm)
24G(0.50)	Medium Purple	✓	✓	✓	✓	4 3/4"(120mm)
25G(0.45)	Orange	✓	✓	✓	✓	5 1/4"(132mm)
26G(0.40)	Brown	✓	✓	✓	-	6.0"(150mm)
27G(0.40)	Medium Grey	✓	✓	✓	-	



HYPODERMIC NEEDLE

Tae-Chang hypodermic needles comply with ISO 7864 sterile hypodermic needles for single use standard as well as ISO 6809 needle hub color coding

Produced using SUS 304 stainless steel tube

Produced in automatic assembly line located inside clean room

Medical grade lubricant was used to minimize penetration resistance

Both sterile and non-sterile products are available

Bulk, blister and hard pack type packaging available



AESTHETICS NEEDLE



Produced using SUS 304 stainless steel tube

Various sizes of soft needle and hypodermic needle used for aesthetic purposes depending on customer need are available

Extra thin wall technology is used for maximum flow rate. The technology allows Tae-Chang aesthetic needles compatible with high concentration solutions used for filler and botulinum toxin therapy

For user convenience, hubs are marked with level mark and color coded

Soft blister pack is available for both soft needle and hypodermic needle. Added feature of hard pack is available for hypodermic needle that are frequently used for aesthetic purposes such as mesotherapy

IRRIGATION NEEDLE

Tae-Chang endo irrigation needles are designed for dental application

Produced using SUS 304 stainless steel tube

Various needle sizes are available depending on the area of the application

Hubs are color coded

* Model: Straight type, Bending type, Single side vent type, Double side vent type

Gauge	CG (mm)	Hub Color	Length																	
			25mm	30mm	35mm	40mm	45mm	50mm	55mm	60mm	65mm	70mm	75mm	80mm	85mm	90mm				
150	1,720 - 1,900	Blue Grey																		
16G	1,600 - 1,690	White																		
17G	1,490 - 1,570	Pink/Violet																		
18G	1,390 - 1,390	Pink																		
19G	1,280 - 1,330	Green																		
20G	960 - 950	Yellow																		
21G	880 - 830	Deep Green																		
22G	670 - 670	Black																		
23G	600 - 600	Deep Blue																		
24G	530 - 530	Medium Purple																		
25G	460 - 450	Orange																		
26G	410 - 410	Brown																		
27G	400 - 420	Medium Grey																		
28G	330 - 330	Blue Green																		
29G	320 - 330	Red																		
30G	270 - 320	Yellow																		
31G	250 - 250	White																		



STAINLESS STEEL TUBE

Tae-Chang stainless steel tube complies with ISO 15510 and ISO 9628 standards

- 1) Produced using SUS 304 stainless steel tube
- 2) Using laser laser welding technology, Tae-Chang produces highest quality stainless steel tube
- 3) Customized tubing available based on customer requirement

Gauge	Size		Outer Diameter [mm]		Inner Diameter [mm]		
	Nominal [mm]		Min	Max	ISO NW	ISO TW	ISO ETW
500	5.20		5.19	5.21	5.00	5.16	
500	5.20		5.20	5.20	5.14	5.18	
380	3.80		3.79	3.81	3.72	3.78	
380	3.80		3.80	3.80	3.73	3.79	
280	2.80		2.79	2.81	2.72	2.78	
280	2.80		2.80	2.80	2.73	2.79	
270	2.80		2.80	2.80	2.74	2.78	
260	2.60		2.60	2.60	2.52	2.58	
250	2.50		2.50	2.50	2.43	2.52	
240	2.40		2.40	2.40	2.30	2.42	
230	2.30		2.30	2.30	2.17	2.29	0.46
220	2.20		2.20	2.20	2.09	2.23	0.52
210	2.10		2.10	2.10	2.02	2.15	0.57
200	2.00		2.00	2.00	1.94	2.07	0.62
190	1.90		1.90	1.90	1.86	1.98	0.67
180	1.80		1.80	1.80	1.78	1.90	0.72
170	1.70		1.70	1.70	1.70	1.82	0.77
160	1.60		1.60	1.60	1.62	1.74	0.82
150	1.50		1.50	1.50	1.54	1.66	0.87
140	1.40		1.40	1.40	1.46	1.58	0.92
130	1.30		1.30	1.30	1.38	1.50	0.97
120	1.20		1.20	1.20	1.40	1.52	1.02
110	1.10		1.10	1.10	1.42	1.54	1.07
100	1.00		1.00	1.00	1.44	1.56	1.12



CANNULA

Tae-Chang cannula complies with ISO 9628 stainless steel needle tubing for manufacture of medical devices

Produced using SUS 304 stainless steel tube

Using state of art automatic grinding technology, Tae-Chang manufactures various types of cannula in distinguished bevel, angle and length specifications

Fully automatic cannula cleaning system enables through inner and outer deansing of cannula

IR&D department strives to design cannula shapes that alleviates penetration resistance

Gauge	Nominal [mm]	Outer Diameter [mm]	Inner Diameter [mm]		
			ISO NW	ISO TW	ISO ETW
350	3.5	3.50-3.51	3.49	3.54	3.55
330	3.3	3.30-3.31	3.49	3.54	3.55
310	3.1	3.10-3.11	3.14	3.19	3.20
290	2.9	2.90-2.91	2.93	2.94	2.95
270	2.7	2.70-2.71	2.73	2.74	2.75
250	2.5	2.50-2.51	2.53	2.54	2.55
230	2.3	2.30-2.31	2.32	2.33	2.34
210	2.1	2.10-2.11	2.12	2.13	2.14
190	1.9	1.90-1.91	1.92	1.93	1.94
170	1.7	1.70-1.71	1.72	1.73	1.74
150	1.5	1.50-1.51	1.52	1.53	1.54
130	1.3	1.30-1.31	1.32	1.33	1.34
110	1.1	1.10-1.11	1.12	1.13	1.14
90	0.9	0.90-0.91	0.92	0.93	0.94
70	0.7	0.70-0.71	0.72	0.73	0.74
50	0.5	0.50-0.51	0.52	0.53	0.54
30	0.3	0.30-0.31	0.32	0.33	0.34
15	0.15	0.150-0.151	0.152	0.153	0.154
10	0.1	0.100-0.101	0.102	0.103	0.104
5	0.05	0.050-0.051	0.052	0.053	0.054



BLOOD BAGS

1) Donor Needle

- Tamper-evident
- Easy & Safe to remove needle cover
- Sharp & Smooth (Ultra thin wall)
- Collection needle

2) Tubing

- Highly flexible & Soft
- HNK resistant
- Serial numbering for identification
- Hermetically sealed

3) BWV (Break-Away-Valve)

- Easy to break off
- Free flow in both directions

4) Primary Bag

- Narrower, Round-corner design
- Minimize loss of blood
- Highly yield of blood components

5) CPD Anticoagulant

- GMP
- USP Specification

6) Outlet Port

- Tear-off type protector (tamper-evident)
- Minimize contamination
- Easy to pierce

7) Satellite Bag

- Potent concentrates & long storage
- Superior gas (O₂, CO₂) permeability
- High survival rate of components

8) SAGM Blood Additive

- GMP
- USP Specification

9) Label

- Peel resistant
- Tamper-evident
- Easy to write on

10) RBC FILTER

- Leucocyte reduction filter
- High efficiency of leukocyte removal

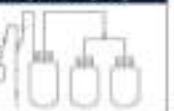
Single Safety Bag



Double Safety Bag



Triple Safety Bag



Quadruple Safety Bag



Capacity

120ml, 200ml, 250ml, 300ml, 320ml, 350ml, 400ml, 450ml, 500ml

Solution

CPDA-1 and CPD/SAGM

ANIMAL IDENTIFICATION

The-Cheng animal identification system is a safe RFID Microchip insertion system for animals that has minimized penetration resistance and does not require second shot

Available in both sterilized and bulk

Gauge	Outer Diameter [mm]	Inner Diameter [mm]	Needle Length [mm]
12G	2.650 - 2.850	Min 2.235	28, 32
13G	2.380 - 2.500	Min 1.950	28, 32
14G	1.950 - 2.150	Min 1.600	28, 32
15G	1.750 - 1.900	Min 1.480	28, 32

UMBILICAL CORD CLAMP [UCC]

The-Cheng Umbilical Cord Clamp is available sterilized





www.needles.co.kr

Seoul Office

Room 1014, East Building, Teheran-ro 322, Gangnam-gu, Seoul, Korea

TEL +82-2-2183-1155 **FAX** +82-2-2183-1154

Gongju Plant

8-18, Bojeokdong-gil, Useong-myeon, Gongju-si, Chungcheongnam-do, Korea

TEL +82-41-854-7422 **FAX** +82-41-852-7004

Gumi Plant

127, Sanho-daero, Gumi-si, Gyeongsangbuk-do, Korea

TEL +82-54-465-0062 **FAX** +82-54-461-5594