

TAE-CHANG

Quality Oriented Manufacturer of
Medical Needle Products

INTRODUCTION



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 KFDA
September	2008	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 syringe, 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-DHP Mood Ring (Gumi plant)
December	2017	Obtained certification of excellent small and medium enterprises by Gyeonggi-do
December	2017	Being awarded 10 Million Dollar Export Tower by Ministry of Trade, Industry and Energy
June	2018	Obtained certification of ISO 80369-8 (small-bore variants with female neurosurgical 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.

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SINCE 1991



INSULIN PEN NEEDLE

INSULIN PEN NEEDLE

- | Tae-Chang insulin pen needle comply with ISO11608 standard
 - | Produced using SUS 304 stainless steel tube
 - | Use of optimized automatic grinding machine as well as medical grade lubricant that minimizes penetration resistance
 - | Various needle designs including evolutionary and multi bevel are available
 - | With electro-polished and improved needle slot together with high grade siliconized surface, Tae-Chang triple bevel needle is one of the most comfortable needles of choice with lowest penetration and gingival tissue
 - | Tae-Chang multi bevel needle further reduces penetration force compared to the traditional triple bevel needle.
 - | Tae-Chang evolutionary bevel needle is designed to cut skin easier with less bending during the injection to minimize tissue damage

INSUFINE

- Features that make Tae-Chung pen needle virtually pain free

- 1) All needles are electro-polished to eliminate any imperfection on the needle to provide smoother and more comfortable injection.
 - 2) Highest possible medical grade silicon treatment on the needle surface for maximum comfort for patients.
 - 3) Extra thin wall technology is used in all Tai-Chung pen needles for maximum flow rate. Reduced injection time provides virtually pain-free experience.
 - 4) Tai-Chung pen needles are anti-clogging with no fragmentation.

Compatible with Differing Brands of Insulin Pen Models

Length	0.16
 4 mm (+/- 1.25mm)	Shortest Tae-Chang pen needle for patients without pinch-up, children, adolescents or very thin patient. Reduces needle fear Ideal for children
 5 mm (+/- 1.25mm)	For patients without pinch-up, children, adolescents or very thin patient Reduces needle fear Recommended for patients to reduce intramuscular injections
 6 mm (+/- 1.25mm)	For normal weight adults without pinch-up For new patients for injection or therapy Patients with needle anxiety and without pinch-up
 8 mm (+/- 1.25mm)	For patients who use a lifted skin-fold technique or those who prefer a longer needle Suitable for most adults

* Other sizes are available depending on the customer need.

Gauge	Camlock Outer Diameter
28G	1.038mm-1.051mm
30G	1.296mm-1.329mm
31G	1.354mm-1.377mm
32G	1.229mm-1.241mm

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 airtight. 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

| Tae-Chang insulin syringe comply with ISO8537 standard

| Produced using SUS 304 stainless steel tube

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

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

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

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

| Available finished product

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

| 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")
30G	0.298-0.320	0.133	12mm (1/2")
29G	0.324-0.351	0.153	



ANESTHESIA NEEDLE

- Comply with ISO 80399-4 standard
- Tae-Chang puncture / spinal needle is designed to prevent needle rotation and tissue tearing 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

Spinal Needles
With standard hubSpinal Needles
Without hub/capEPIDURAL NEEDLE
Tuohy type

Gauge (ID/mm)	Stylet Color Code	Spinal Needle			Epidural Needle	Length
		Quincke Bevel	Whitacre Pencil Point	Wing		
24G(0.10)	White	✓	✓	-	✓	1 1/2"(38mm)
18G(1.60)	White	✓	-	-	✓	1 1/2"(38mm)
17G(1.40)	Red/Violet	✓	-	-	✓	2.0"(56mm)
19G(1.20)	Pink	✓	✓	✓	✓	2.3/4"(70mm)
18G(1.10)	Cream	✓	✓	✓	✓	3.0"(75mm)
20G(0.90)	Yellow	✓	✓	✓	✓	3 1/4"(80mm)
21G(0.80)	Deep Green	✓	✓	✓	✓	3 1/2"(89mm)
22G(0.70)	Black	✓	✓	✓	✓	4.0"(100mm)
23G(0.60)	Deep Blue	✓	✓	✓	✓	4 1/8"(103mm)
26G(0.55)	Medium Purple	✓	✓	✓	✓	4 3/4"(120mm)
26G(0.50)	Orange	✓	✓	✓	✓	5 1/4"(132mm)
26G(0.48)	Brown	✓	✓	✓	-	6.0"(150mm)
27G(0.40)	Medium Grey	✓	✓	✓	-	-

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 bevel 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



HYPODERMIC NEEDLE

|Tae-Chang hypodermic needles comply with ISO 7854 sterile hypodermic needles for single use standard as well as ISO 6069 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



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	DG (mm)	Hub Color	Length											
			100	120	140	160	180	200	220	240	260	280	300	320
160	1,750 - 1,900	Blue/Grey												
160	1,600 - 1,690	White												
170	1,400 - 1,510	Red/Violet												
180	1,200 - 1,300	Pink												
190	1,000 - 1,100	Green												
200	8,600 - 8,900	Yellow												
210	8,000 - 8,300	Deep Green												
200	8,600 - 8,730	Black												
200	8,600 - 8,675	Deep Blue												
240	8,000 - 8,500	Medium Purple												
250	8,000 - 8,500	Cobalt												
260	8,400 - 8,475	Brown												
270	8,400 - 8,425	Medium Grey	*	*	*	*	*	*	*	*	*	*	*	*
280	8,300 - 8,325	Blue/Green	*	*	*	*	*	*	*	*	*	*	*	*
290	8,324 - 8,351	Red	*	*	*	*	*	*	*	*	*	*	*	*
300	8,254 - 8,280	Yellow	*	*	*	*	*	*	*	*	*	*	*	*
310	8,254 - 8,280	White	*	*	*	*	*	*	*	*	*	*	*	*



STAINLESS STEEL TUBE

I Tae-Chang stainless steel tube complies with ISO 15519 and ISO 9628 standards

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

Gauge	Nominal [mm]	Outer Diameter [mm]		Inner Diameter [mm]		
		Min	Max	ISO NW	ISO TW	ISO ETW
206	9.296	9.129	9.466	9.089	9.105	
208	9.288	9.226	9.327	9.114	9.125	
210	9.289	9.226	9.328	9.112	9.125	
212	9.290	9.228	9.329	9.113	9.125	
214	9.291	9.229	9.330	9.114	9.125	
216	9.292	9.230	9.331	9.115	9.125	
218	9.293	9.231	9.332	9.116	9.125	
220	9.294	9.232	9.333	9.117	9.125	
222	9.295	9.233	9.334	9.118	9.125	
224	9.296	9.234	9.335	9.119	9.125	
226	9.297	9.235	9.336	9.120	9.125	
228	9.298	9.236	9.337	9.121	9.125	
230	9.299	9.237	9.338	9.122	9.125	
232	9.300	9.238	9.339	9.123	9.125	
234	9.301	9.239	9.340	9.124	9.125	
236	9.302	9.240	9.341	9.125	9.125	
238	9.303	9.241	9.342	9.126	9.125	
240	9.304	9.242	9.343	9.127	9.125	
242	9.305	9.243	9.344	9.128	9.125	
244	9.306	9.244	9.345	9.129	9.125	
246	9.307	9.245	9.346	9.130	9.125	
248	9.308	9.246	9.347	9.131	9.125	
250	9.309	9.247	9.348	9.132	9.125	
252	9.310	9.248	9.349	9.133	9.125	
254	9.311	9.249	9.350	9.134	9.125	
256	9.312	9.250	9.351	9.135	9.125	
258	9.313	9.251	9.352	9.136	9.125	
260	9.314	9.252	9.353	9.137	9.125	
262	9.315	9.253	9.354	9.138	9.125	
264	9.316	9.254	9.355	9.139	9.125	
266	9.317	9.255	9.356	9.140	9.125	
268	9.318	9.256	9.357	9.141	9.125	
270	9.319	9.257	9.358	9.142	9.125	
272	9.320	9.258	9.359	9.143	9.125	
274	9.321	9.259	9.360	9.144	9.125	
276	9.322	9.260	9.361	9.145	9.125	
278	9.323	9.261	9.362	9.146	9.125	
280	9.324	9.262	9.363	9.147	9.125	
282	9.325	9.263	9.364	9.148	9.125	
284	9.326	9.264	9.365	9.149	9.125	
286	9.327	9.265	9.366	9.150	9.125	
288	9.328	9.266	9.367	9.151	9.125	
290	9.329	9.267	9.368	9.152	9.125	
292	9.330	9.268	9.369	9.153	9.125	
294	9.331	9.269	9.370	9.154	9.125	
296	9.332	9.270	9.371	9.155	9.125	
298	9.333	9.271	9.372	9.156	9.125	
300	9.334	9.272	9.373	9.157	9.125	
302	9.335	9.273	9.374	9.158	9.125	
304	9.336	9.274	9.375	9.159	9.125	
306	9.337	9.275	9.376	9.160	9.125	
308	9.338	9.276	9.377	9.161	9.125	
310	9.339	9.277	9.378	9.162	9.125	
312	9.340	9.278	9.379	9.163	9.125	
314	9.341	9.279	9.380	9.164	9.125	
316	9.342	9.280	9.381	9.165	9.125	
318	9.343	9.281	9.382	9.166	9.125	
320	9.344	9.282	9.383	9.167	9.125	
322	9.345	9.283	9.384	9.168	9.125	
324	9.346	9.284	9.385	9.169	9.125	
326	9.347	9.285	9.386	9.170	9.125	
328	9.348	9.286	9.387	9.171	9.125	
330	9.349	9.287	9.388	9.172	9.125	
332	9.350	9.288	9.389	9.173	9.125	
334	9.351	9.289	9.390	9.174	9.125	
336	9.352	9.290	9.391	9.175	9.125	
338	9.353	9.291	9.392	9.176	9.125	
340	9.354	9.292	9.393	9.177	9.125	
342	9.355	9.293	9.394	9.178	9.125	
344	9.356	9.294	9.395	9.179	9.125	
346	9.357	9.295	9.396	9.180	9.125	
348	9.358	9.296	9.397	9.181	9.125	
350	9.359	9.297	9.398	9.182	9.125	
352	9.360	9.298	9.399	9.183	9.125	
354	9.361	9.299	9.400	9.184	9.125	
356	9.362	9.300	9.401	9.185	9.125	
358	9.363	9.301	9.402	9.186	9.125	
360	9.364	9.302	9.403	9.187	9.125	



CANNULA

I Tae-Chang cannula complies with ISO 9626 stainless steel needle tubing for manufacture of medical devices

- 1) Produced using SUS 304 stainless steel tube
- 2) Using state of art automatic grinding technology, Tae-Chang manufactures various types of cannula in distinguished bevel, angle and length specifications
- 3) Fully automatic cannula cleaning system enables thorough inner and outer cleansing of cannula
- 4) R&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 NW	ISO TW	ISO ETW
216	0.4	0.335-0.345	0.305-0.315	0.295	0.295	0.295
218	0.5	0.350-0.360	0.320-0.330	0.310	0.310	0.310
220	0.6	0.364-0.374	0.334-0.344	0.324	0.324	0.324
222	0.7	0.378-0.388	0.348-0.358	0.338	0.338	0.338
224	0.8	0.392-0.402	0.362-0.372	0.352	0.352	0.352
226	0.9	0.406-0.416	0.376-0.386	0.366	0.366	0.366
228	1.0	0.420-0.430	0.390-0.400	0.380	0.380	0.380
230	1.1	0.434-0.444	0.404-0.414	0.394	0.394	0.394
232	1.2	0.448-0.458	0.418-0.428	0.408	0.408	0.408
234	1.3	0.462-0.472	0.432-0.442	0.422	0.422	0.422
236	1.4	0.476-0.486	0.446-0.456	0.436	0.436	0.436
238	1.5	0.490-0.500	0.460-0.470	0.450	0.450	0.450
240	1.6	0.504-0.514	0.474-0.484	0.464	0.464	0.464
242	1.7	0.518-0.528	0.488-0.498	0.478	0.478	0.478
244	1.8	0.532-0.542	0.502-0.512	0.482	0.482	0.482
246	1.9	0.546-0.556	0.516-0.526	0.496	0.496	0.496
248	2.0	0.560-0.570	0.530-0.540	0.500	0.500	0.500
250	2.1	0.574-0.584	0.544-0.554	0.514	0.514	0.514
252	2.2	0.588-0.598	0.558-0.568	0.528	0.528	0.528
254	2.3	0.602-0.612	0.572-0.582	0.542	0.542	0.542
256	2.4	0.616-0.626	0.586-0.596	0.556	0.556	0.556
258	2.5	0.630-0.640	0.600-0.610	0.570	0.570	0.570
260	2.6	0.644-0.654	0.614-0.624	0.584	0.584	0.584
262	2.7	0.658-0.668	0.628-0.638	0.608	0.608	0.608
264	2.8	0.672-0.682	0.642-0.652	0.622	0.622	0.622
266	2.9	0.686-0.696	0.656-0.666	0.636	0.636	0.636
268	3.0	0.700-0.710	0.670-0.680	0.650	0.650	0.650
270	3.1	0.714-0.724	0.684-0.694	0.664	0.664	0.664
272	3.2	0.728-0.738	0.708-0.718	0.678	0.678	0.678
274	3.3	0.742-0.752	0.722-0.732	0.692	0.692	0.692
276	3.4	0.756-0.766	0.736-0.746	0.706	0.706	0.706
278	3.5	0.770-0.780	0.750-0.760	0.720	0.720	0.720
280	3.6	0.784-0.794	0.764-0.774	0.734	0.734	0.734
282	3.7	0.798-0.808	0.778-0.788	0.748	0.748	0.748
284	3.8	0.812-0.822	0.792-0.802	0.762	0.762	0.762
286	3.9	0.826-0.836	0.806-0.816	0.776	0.776	0.776
288	4.0	0.840-0.850	0.820-0.830	0.790	0.790	0.790
290	4.1	0.854-0.864	0.834-0.844	0.804	0.804	0.804
292	4.2	0.868-0.878	0.848-0.858	0.818	0.818	0.818
294	4.3	0.882-0.892	0.862-0.872	0.832	0.832	0.832
296	4.4	0.896-0.906	0.876-0.886	0.846	0.846	0.846
298	4.5	0.910-0.920	0.890-0.900	0.860	0.860	0.860
300	4.6	0.924-0.934	0.904-0.914	0.874	0.874	0.874
302	4.7	0.938-0.948	0.918-0.928	0.888	0.888	0.888
304	4.8	0.952-0.962	0.932-0.942	0.902	0.902	0.902
306	4.9	0.966-0.976	0.946-0.956	0.916	0.916	0.916
308	5.0	0.980-0.990	0.960-0.970	0.930	0.930	0.930
310	5.1	0.994-0.100	0.974-0.984	0.944	0.944	0.944
312	5.2	1.008-1.018	0.988-0.998	0.958	0.958	0.958
314	5.3	1.022-1.032	1.002-1.012	0.972	0.972	0.972
316	5.4	1.036-1.046	1.016-1.026	0.986	0.986	0.986
318	5.5	1.050-1.060	1.030-1.040	1.000	1.000	1.000
320	5.6	1.064-1.074	1.044-1.054	1.014	1.014	1.014
322	5.7	1.078-1.088	1.058-1.068	1.028	1.028	1.028
324	5.8	1.092-1.102	1.072-1.082	1.042	1.042	1.042
326	5.9	1.106-1.116	1.086-1.096	1.056	1.056	1.056
328	6.0	1.120-1.130	1.100-1.110	1.070	1.070	1.070



BLOOD BAGS

1) Donor Needle

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

2) Tubing

- Highly Flexible & Soft
- Kink resistant
- Serial numbering for identification
- Hemostatic tested

3) BAV (Break-Away-Value)

- Easy to break off
- Free flow in both directions
- Harness, Round-corner design
- Minimize loss of blood
- Highly yield of blood components

4) Primary Bag

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

5) CPD Anticoagulant

- GMP
- USP Specification

6) Ductlet Port

- Tear-off type processor
- Tamper-evident
- Minimal contamination
- Easy to pierce

7) Satellite Bag

- Rosterizes concentrates safely 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

- Leukocyte 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

I Tae-Chang 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	2.300 - 2.500	Min 1.950	28, 32
14G	1.950 - 2.150	Min 1.600	28, 32
15G	1.750 - 1.900	Min 1.400	28, 32

UMBILICAL CORD CLAMP [UCC]

I Tae-Chang Umbilical Cord Clamp is available sterilized



T-C

www.needles.co.kr

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