TAE-CHANG

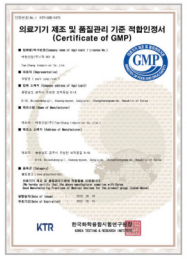
Quality Oriented Manufacturer of
Medical Needle Products

INTRODUCTION

"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 is 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	2009	Obtained approval of manufacturing veterinary pharmaceutical products by Animal and Plant Quarantine Agency
July	2010	Obtained certification of CE class III 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-DEHP blood bag (Gumi plant)
December	2017	Obtained certification of excellent small and medium enterprises by Gongju-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 neuraxial 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 8-18, 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

SINCE 1991

INSULIN PEN NEEDLE

INSULIN PEN NEEDLE

I Tae-Chang insulin pen needle comply with ISO11608 standard

I Produced using SUS 304 stainless steel tube

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

I Various needle designs including evolutionary and multi bevel are available

1) With electro-polished and improved needle point together with high grade siliconized surface, Tae-Chang triple bevel needle is one of the most comfortable needles of choice with lowest penetration and gliding force

2) Tae-Chang multi bevel needle tip further reduces penetration force compared to the traditional triple bevel needle

3) Tae-Chang evolutionary bevel needle is designed to cut skin cleaner with less bending during the injection to minimize tissue damage

INSUFINE

I Features that make Tae-Chang 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 Tae-Chang pen needles for maximum flow rate. Reduced injection time provides virtually pain free experience

4) Tae-Chang pen needles are anti-coring with no fragmentation

Compatible with Differing Brands of Insulin Pen Models

BYETTA® Pen, Omnican®Pen 31, Omnican®Pen 32, BerliPen®301, BerliPen®302, BerliPen®aero, BerliPen®aero2, BerliPen®JUNIOR, BerliPen®PRECISION, HumaPen®MEMOIR, HumaPen®L U X U R A, HumaPen®L U X U R A HD, HumaPen®E r g o, HumaPen®E r g o II, Humalog KwikPen™, Humulin®N Pen, HumaPen®savvio, i-Pen®, NovoPen®3, NovoPen®4, NovoPen®Junior, NovoPen Echo®, FlexPen®, FlexTouch®, Victoza®pre-filled pen, NovoLet®, OptiPen®Pro1, OptiPen®Pro2, TactiPen®, ClikSTAR®, SoloSTAR®, i-pen, Autopen®Classic, Autopen®24, ypsopen®

Length	Use
4mm (+/-1.25mm)	· Shortest Tae-Chang pen needle for patients without pinch-up, children, adolescents or very thin patient · Reduces needle fear · Ideal for children
5mm (+/-1.25mm)	· For patients without pinch-up, children adolescents or very thin patient · Reduces needle fear · Recommended for patients to reduce intramuscular injections
6mm (+/-1.25mm)	· For normal weight adults without pinch-up · For new patients for injection on therapy · Patients with needle anxiety and without pinch-up
8mm (+/-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	Cannula Outer Diameter
29G	0.324mm-0.351mm
30G	0.298mm-0.320mm
31G	0.254mm-0.267mm
32G	0.229mm-0.241mm

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 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

- 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	3.36	26

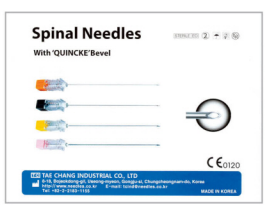
Needle Specification

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	0.324-0.351	0.133	

ANESTHESIA NEEDLE

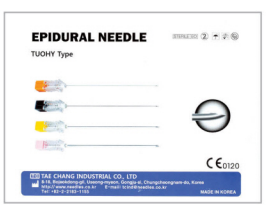
- Comply with ISO 80369-6 standard
- Tae-Chang puncture / spinal needle is designed to prevent needle rotation and tissue coring with very tactile feeling
- Transparent hub ensures user has view of drug injection process
- Color coded stylet hub
- Detachable wing for greater control
- Depth mark is available
- 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

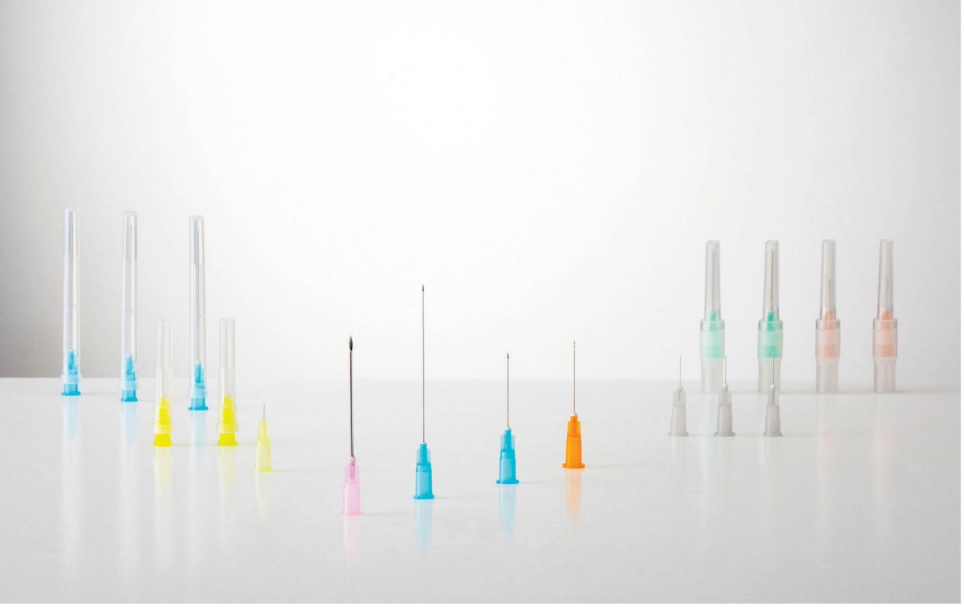


Spinal Needle – Whitacre Pencil Point

Epidural Needle – Tuohy



Gauge [ODmm]	Stylet Color Code	Spinal Needle			Epidural Needle	Length
		Quincke Bevel	Whitacre Pencil Point	Seldinger	Tuohy	
14G[2.10]	White	√	√	-	√	
16G[1.60]	White	√	-	-	√	1 1/2"[38mm]
17G[1.40]	Red Violet	√	-	-	√	2.0"[50mm]
18G[1.20]	Pink	√	√	√	√	2 3/4"[70mm]
19G[1.10]	Cream	√	√	√	√	3.0"[75mm]
20G[0.90]	Yellow	√	√	√	√	3 1/4"[80mm]
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[0.55]	Medium Purple	√	√	√	√	4 3/4"[120mm]
25G[0.50]	Orange	√	√	√	√	5 1/4"[132mm]
26G[0.45]	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 6009 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

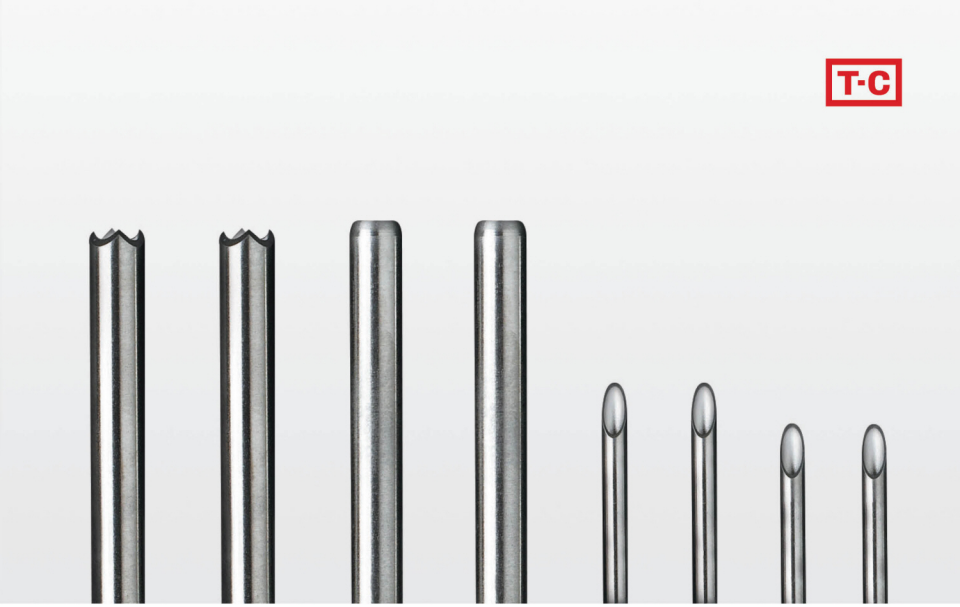
- Produced using SUS 304 stainless steel tube
- Various sizes of soft needle and hypodermic needle used for aesthetic purposes depending on customer need are available
- Extra thin wall technology is used for maximum flow rate. The technology allows Tae-Chang aesthetic needles compatible with high concentration solutions used for filler and botulinum toxin therapy
- For user convenience, hubs are marked with 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 purposed 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	OD [mm]	Hub Color	Length												
			-	-	-	-	3/8"	1/2"	5/8"	3/4"	4/5"	1.0"	1-1/4"	1-1/2"	2"	2-1/2"
			2mm	4mm	5mm	6mm	10mm	13mm	16mm	19mm	20mm	25mm	30mm	40mm	50mm	60mm
15G	1.750 - 1.900	Blue Grey								•		•	•	•	•	•
16G	1.600 - 1.690	White								•		•	•	•	•	•
17G	1.400 - 1.510	Red Violet								•		•	•	•	•	•
18G	1.200 - 1.300	Pink								•		•	•	•	•	•
19G	1.030 - 1.100	Cream								•		•	•	•	•	•
20G	0.860 - 0.920	Yellow								•		•	•	•	•	•
21G	0.800 - 0.830	Deep Green							•	•		•	•	•		•
22G	0.698 - 0.730	Black							•	•		•	•	•		•
23G	0.600 - 0.673	Deep Blue							•	•		•	•	•		•
24G	0.550 - 0.580	Medium Purple				•	•	•	•	•	•	•	•	•	•	•
25G	0.500 - 0.530	Orange				•	•	•	•	•	•	•	•	•	•	•
26G	0.440 - 0.470	Brown				•	•	•	•	•	•	•	•	•	•	•
27G	0.400 - 0.420	Medium Grey	•	•	•	•	•	•	•	•		•	•	•		
28G	0.349 - 0.370	Blue Green	•	•	•	•	•	•	•	•		•	•	•		
29G	0.324 - 0.351	Red	•	•	•	•	•	•	•	•		•	•	•		
30G	0.298 - 0.320	Yellow	•	•	•	•	•	•	•	•		•	•	•		
31G	0.254 - 0.267	White	•	•	•	•	•	•	•	•		•	•	•		



STAINLESS STEEL TUBE

| Tae-Chang stainless steel tube complies with ISO 15510 and ISO 9626 standards

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

Size		Outer Diameter [mm]		Inner Diameter [mm]		
Gauge	Nominal [mm]	Min	Max	ISO NW	ISO TW	ISO ETW
				Min	Min	Min
32G	0.230	0.229	0.241	0.089	0.105	
31G	0.250	0.254	0.267	0.114	0.125	
30G	0.300	0.298	0.320	0.113	0.165	
29G	0.330	0.324	0.351	0.133	0.190	
28G	0.360	0.349	0.370	0.133	0.190	
27G	0.400	0.400	0.420	0.184	0.241	
26G	0.450	0.440	0.470	0.232	0.292	
25G	0.500	0.500	0.530	0.232	0.292	
24G	0.550	0.550	0.580	0.280	0.343	
23G	0.600	0.600	0.650	0.317	0.370	0.460
22G	0.700	0.698	0.730	0.390	0.440	0.522
21G	0.800	0.800	0.830	0.490	0.547	0.610
20G	0.900	0.860	0.920	0.560	0.635	0.687
19G	1.100	1.030	1.100	0.648	0.750	0.850
18G	1.200	1.200	1.300	0.790	0.910	1.041
17G	1.400	1.400	1.510	0.950	1.156	1.244
16G	1.600	1.600	1.690	1.100	1.283	1.390
15G	1.800	1.750	1.900	1.300	1.460	1.560
14G	2.100	1.950	2.150	1.500	1.600	1.727
13G	2.400	2.300	2.500	1.700	1.956	
12G	2.700	2.650	2.850	1.950	2.235	
11G	3.000	2.950	3.150	2.200	2.464	
10G	3.400	3.300	3.500	2.500	2.819	

CANNULA

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

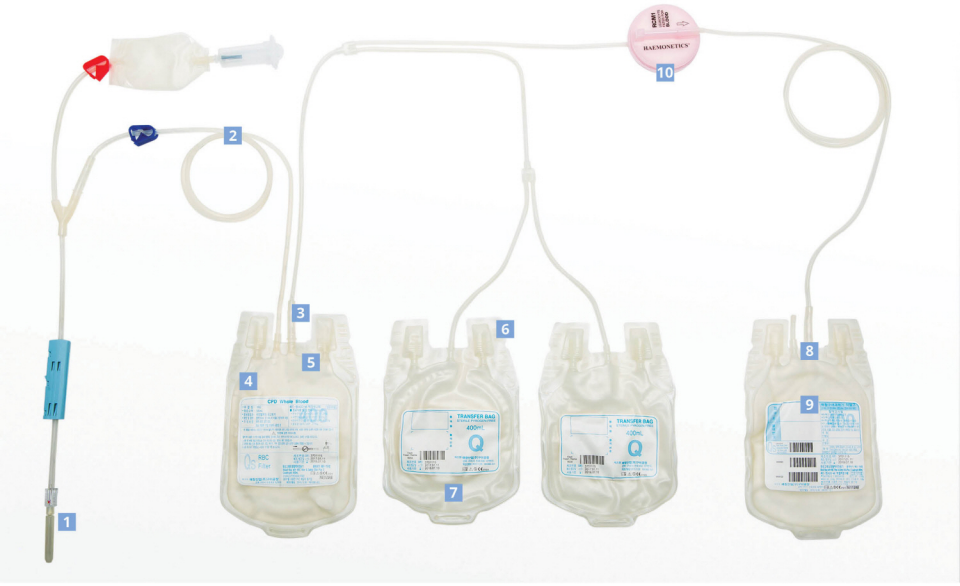
| Produced using SUS 304 stainless steel tube

| 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 thorough inner and outer cleansing of cannula

| 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 ETW
33G	0.2	0.203 - 0.216	0.089 - 0.104	0.105-	-
32G	0.23	0.229 - 0.241	0.089 - 0.104	0.105-	-
31G	0.25	0.254 - 0.267	0.114 - 0.124	0.125-	-
30G	0.30	0.298 - 0.320	0.133 - 0.164	0.165-	-
29G	0.33	0.324 - 0.351	0.133 - 0.189	0.190-	-
28G	0.36	0.349 - 0.370	0.133 - 0.189	0.190-	-
27G	0.40	0.400 - 0.420	0.184 - 0.240	0.241-	-
26G	0.45	0.440 - 0.470	0.232 - 0.291	0.292-	-
25G	0.50	0.500 - 0.530	0.232 - 0.291	0.292-	-
24G	0.55	0.550 - 0.580	0.280 - 0.342	0.343-	-
23G	0.60	0.600 - 0.673	0.317 - 0.369	0.370 - 0.459	0.460
22G	0.70	0.698 - 0.730	0.390 - 0.439	0.440 - 0.21	0.522
21G	0.80	0.800 - 0.830	0.490 - 0.546	0.547 - 0.609	0.610
20G	0.90	0.860 - 0.920	0.560 - 0.634	0.635 - 0.686	0.687-
19G	1.10	1.030 - 1.100	0.648 - 0.749	0.750 - 0.849	0.850-
18G	1.20	1.200 - 1.300	0.790 - 0.909	0.910 - 1.040	1.041-
17G	1.40	1.400 - 1.510	0.950 - 1.155	1.156 - 1.243	1.244-
16G	1.60	1.600 - 1.690	1.100 - 1.282	1.283 - 1.389	1.390-
15G	1.80	1.750 - 1.900	1.300 - 1.459	1.460 - 1.559	1.560-
14G	2.10	1.950 - 2.150	1.500 - 1.599	1.600-	-
13G	2.40	2.300 - 2.500	1.700 - 1.955	1.956-	-
12G	2.70	2.650 - 2.850	1.950 - 2.234	2.235-	-
11G	3.00	2.950 - 3.150	2.200 - 2.436	2.464-	-
10G	3.40	3.300 - 3.500	2.500 - 2.818	2.819-	-



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
- Kink resistant
- Serial numbering for identification
- Hermetically sealed

3) BAV (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

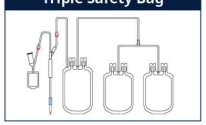
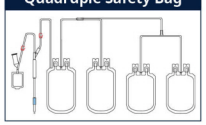
6) Outlet Port
- Tear-off type protector [Tamper-evident]
- Minimize contamination
- Easy to pierce

7) Satellite Bag
- Platelet concentrates 5 day storage
- Superior gas [O2, CO2] permeability
- High survival rate of components

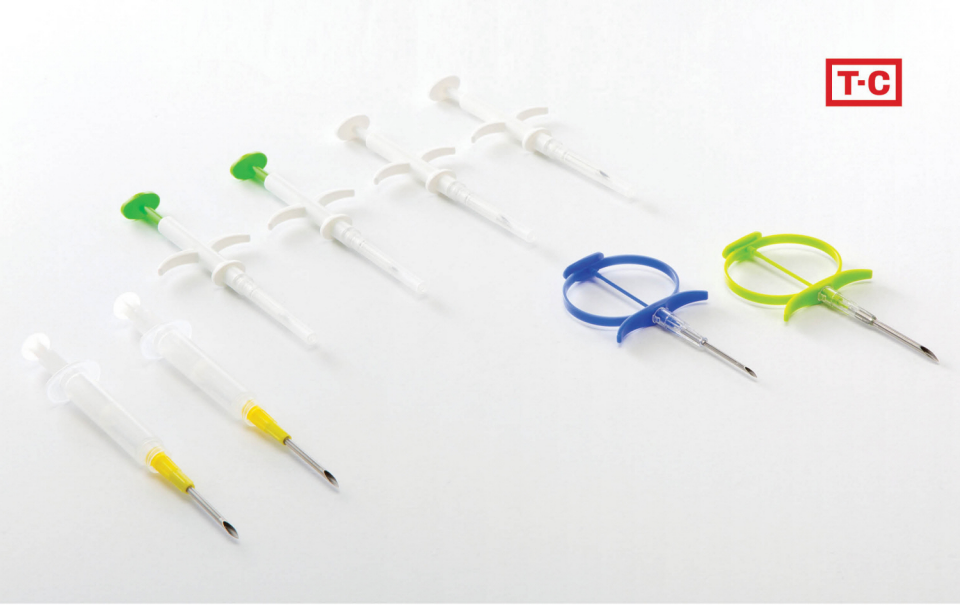
8) SAGM Blood Additive
- GMP
- USP Specification

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

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

I 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 1.956	28, 32
14G	1.950 - 2.150	Min 1.600	28, 32
15G	1.750 - 1.900	Min 1.460	28, 32

UMBILICAL CORD CLAMP [UCC]

I Tae-Chang 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