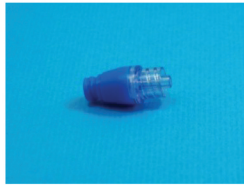




Yiken Needlefree Series

Yiken Corporation Ltd.



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Company Profile

YI KEN incorporates the values of sincerity, responsibility, and professionalism into the development of our products as well as the interactions with our customers in order to sustain our long term viability and success.

WE offer OEM/ODM manufacturing services for medical disposables at the finished assembly, sub-assembly and components level. By standardizing the production process control, we have made the development of precise and high-level medical consumptives. We perform under directives of specialized technology, ensuring product control, devotion to our service, and sincerely being the best disposable medical product provider company for all businesses.



Our facilities have obtained ISO 9001/13485, GMP certification and the majority of our products have received CE certification and/or UL approval. As an international service provider, YI KEN also follows US FDA QSR820 and Europe Directive 93/42/EEC requirements for medical device product design and manufacturing control.



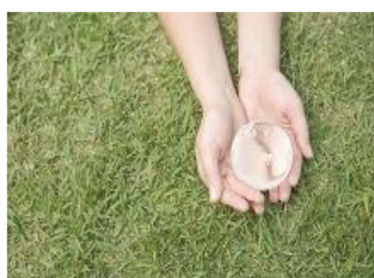
Name	Yiken Corporation Ltd.
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Mission Statement



1. Business with Honesty and Integrity
2. Providing best quality medical disposable products
3. We are confident to give our customers the fullest satisfaction!

Concept of operations



- Made the development of precise and high-level medical disposables products
- OEM/ODM manufacturing services
- Provide you with personalized service, high quality, and long term success at all levels of supply chain

Product and Services

YI KEN specialize in the disposable medical supplies, such as needle free series, fluid delivery set products, etc. We also offer a full OEM/ODM service, with a manufacturing focus on medical disposables at the finished assembly, sub-assembly and components level. By standardizing the production process control, we have made the development of precise and high-level medical disposables.



OEM & ODM



ODM stands for original Design Manufacturing, and OEM refers to Original Equipment Manufacturing. An OEM company is responsible for designing and building a product according to their own specifications, and then selling the product to another company or firm, which is responsible for its distribution. An ODM company or firm is responsible for designing and building a product as per another company's specifications.

OEM Benefit

An OEM project in medical disposables is the development of a new product under your own brand name using hardware modules or completed devices by third-party manufacturers. Such a business model considerably reduces the time to market.

ODM Benefit

This model is especially used in Taiwan and China, where a local ODM is used to produce goods for a foreign company which sees some advantage in the transaction, such as low labor inputs, transport links or proximity to markets. Innovative and/or patented technologies developed/owned by the ODM are another cause for this product distribution model.

OEM/ODM Service

YI KEN can supply you with OEM or ODM products. We shape our products according to your needs. From the very first concept and design of a product, to research and development, to the final stage of manufacturing, YI KEN provides its customers with a total support package, and uses its know-how in their OEM/ODM orders also. Our facilities have obtained ISO 9001/13485, GMP certification and the majority of our products have received CE certification and/or UL approval. As an international service provider, YI KEN also follows US FDA QSR820 and Europe Directive 93/42/EEC requirements for medical device product design and manufacturing control.

What YKN OEM / ODM Offer

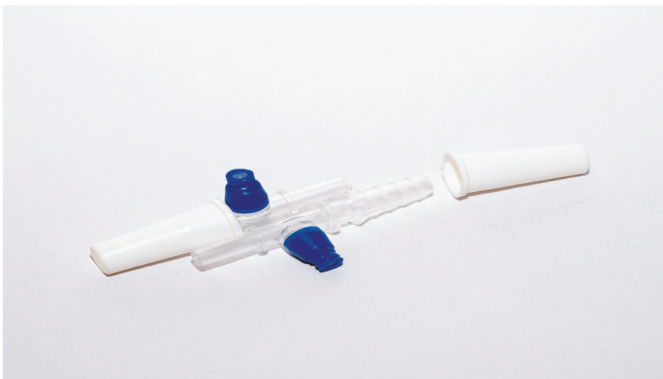
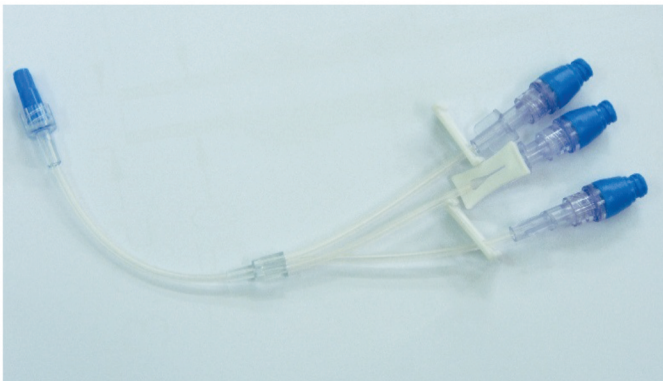
- ◆ *Different Types of Goods*
- ◆ *Reduced Cost*
- ◆ *Customization*
- ◆ *Product design and improvement*
- ◆ *High-Quality Products*



All kinds of Needlefree Connectors Products

YI KEN specialize in the disposable Needle Free devices, such as needle free connectors, needle free injections device, needle free extension tube, needle free connector for chemo drug preparation system etc. We also offer a full OEM/ODM service, with a manufacturing focus on Needle Free Connectors at the finished assembly, sub-assembly, etc.

We make strict testing for every samples to bring perfect production for our customers. These extension sets are widely used in Anesthesia, ICU, related bloodstream and the other way.



Product Overview

- **Compatible with all ISO standard female and male luer connectors.**
- **Connection set 1-way, 2-way with or without filter**
- **Yiken extension sets Needle-Free are available in various size, length and dimensions to accommodate various applications.**
- **Designed to prevent dislodgment of IV catheter and offers ease of use during connection**



Why Do We Need to Worry about Needles sticks?

Needle stick injuries usually happen to healthcare workers in hospitals, clinics, and labs. A dirty needle may contain blood that carries germs which may cause disease or infection. These diseases may be spread to anyone who gets pricked by the dirty needle.

- ✓ Health caregivers who use needles most of the time while working
- healthcare workers are exposed to blood-borne viruses risk through unsafe needle
- Exposure to potentially dangerous drug
- ✓ Patient Protection

How to Deal With a Needle Stick Injury at Work?

- ◆ The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) estimates 62 to 88 percent of "sharps" injuries can potentially be prevented by use of safer medical devices.
- ◆ The Needlestick Safety and Prevention Act took effect on April 18, 2001. The Act mandated additional requirement for employers to identify, evaluate, and implement safer medical devices.

The Act directed OSHA to revise its Bloodborne Pathogens Standard. The revision defines Engineering Controls as "controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.



YKN Needlefree connector to help
you meet your clinical needs.

YKN Needlefree Series

YKN-1 Negative pressure type



- ◆ **Only three components for assemble**
- ◆ **MRI compatibility**
- ◆ **Blood compatibility**
- ◆ **Lipid and alcohol resistance**
- ◆ **Components are sonic welded together for high reliability and safety**
- ◆ **Luer fittings are compatible with American National Standard for luer and taper fittings under ISO 594.**
- ◆ **Functional activation : 200**
- ◆ **Smooth and tight seal, easy to disinfect**
- ◆ **Easy observe and determine whether flushing was complete**
- ◆ **Cost Effective**
- ◆ **Fast Flow Rate : 150ml/minute**

Material

Makrolon RX-1805

Odour: odourless

Softening point: > 130 - 160 °C

Decomposition temperature: ≥ 380 °C

Density: ca. 1.2 - 1.4 g/cm³

Bulk density: 600 - 700 kg/m³

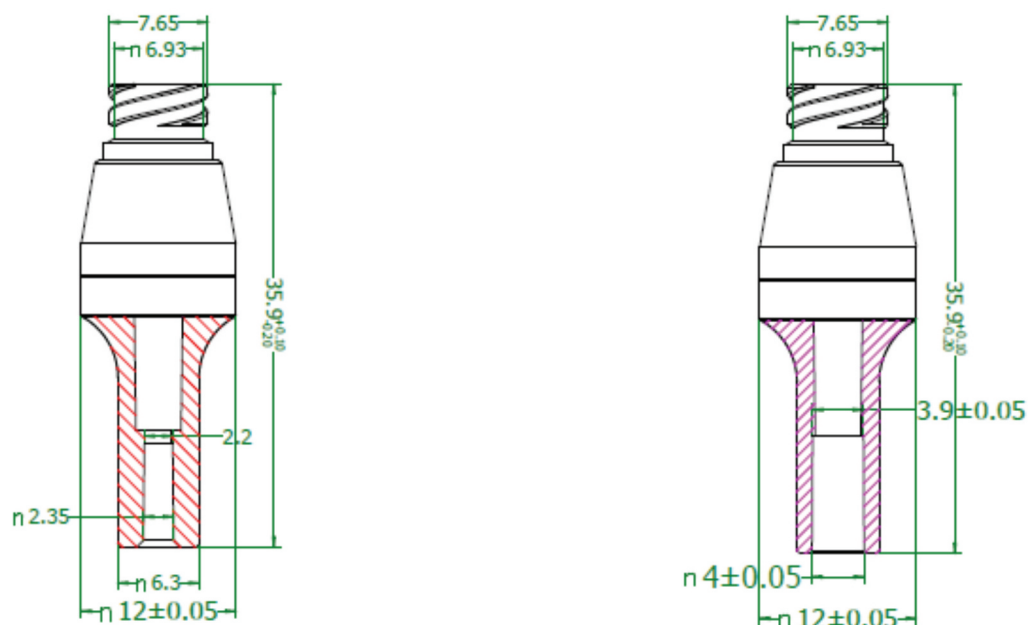
Vapour pressure: not applicable

Viscosity, dynamic: not applicable **Water solubility:** practically insoluble **pH:** not applicable

Ignition temperature: > 450 °C

Autoignition temperature: not applicable

Explosion Limits : not applicable



YKN Needlefree Series

YKN-2 Neutral Type / Slow flow rate



- ◆ **MRI compatibility**
- ◆ **Blood compatibility**
- ◆ **Lipid and alcohol resistance**
- ◆ **Components are sonic welded together for high reliability and safety**
- ◆ **Luer fittings are compatible with American National Standard for luer and taper fittings under ISO 594.**
- ◆ **Functional activation : 200**
- ◆ **Smooth and tight seal, easy to disinfect thoroughly**
- ◆ **Easy observe and determine whether flushing was complete**
- ◆ **Cost Effective**
- ◆ **Neutral Type**
- ◆ **Slow flow Rate**
- ◆ **Smaller Size than Competitor**
- ◆ **Extremely little liquid to wash**
- ◆ **No reflux**

Material

Makrolon RX-1805

Odour: odourless

Softening point: > 130 - 160 °C

Decomposition temperature: ≥ 380 °C

Density: ca. 1.2 - 1.4 g/cm³

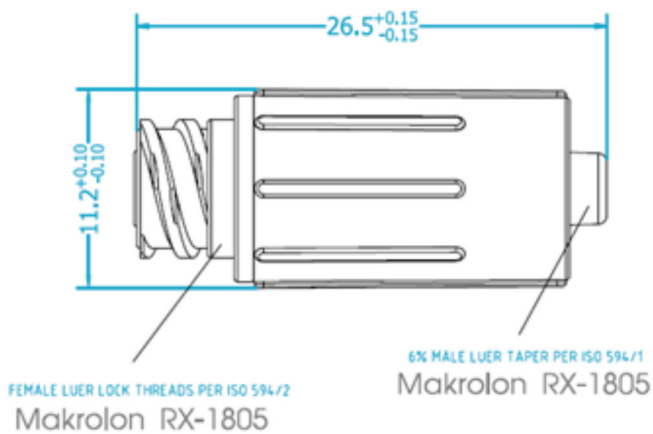
Bulk density: 600 - 700 kg/m³

Vapour pressure: not applicable

Viscosity, dynamic: not applicable **Water solubility:** practically insoluble **pH:** not applicable **Ignition temperature:** > 450 °C

Autoignition temperature: not applicable

Explosion limits: not applicable



Inside

TERLUX 2812TR

N-70U

XE20-523-4U

Features of YKN Needlefree Series

	Feature	YKN-1 Negative pressure type	YKN-2 Neutral type	Comment
1	Reflux Volume	0.3ml	-0.03ml	Volume Expelled upon disconnect
2	Priming Volume	0.3ml	0.03ml	Volume required to prime cap
3	Flush Volume	ok	ok	Use 1.5ml salt water rinse internal pharmaceutical residues can completely cleansed
4	Flow Rate	150ml/minute	130ml/minute	36 inch head height
5	Alcohol/Lipid Resistant	ok	ok	Cap maintains integrity 96 hr. use life
6	Pressure Leakage	7kg/cm	4kg	30 seconds
7	Assembly parts	3 parts	5 parts	
8	MRI Compatible	No metal	No metal	Acceptable in Radiology
9	Fittings	ok	ok	Male and Female leurs ISO compliant
10	Pediatric and Blood Collection	with 594-1 design objective	with 594-1 design objective	compatible compliant
11	Low Disconnect Force	<1kg	<1.5kg	Disconnect without use of instruments (e.g. forceps)
12	Multiple leur insertions	Repeated insertion for over 200times	Repeated insertion for over 200times	Maintain swabbability



Q&A



Pic.1/original design

Pic.2 final design

Carefusion Smartsite

Q : Why needle free connector surface is not smooth?

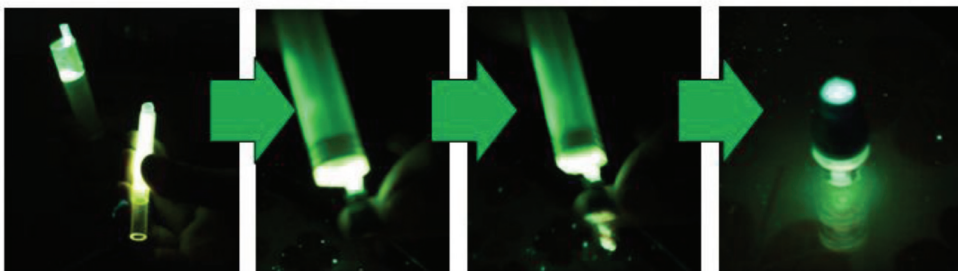
A : Regarding this issue, our original design (Pic1) is just like Carefusion Smartsite (Pic3). However, our clinical consultants had different view, emphasized that surface design should take the finger tip shape into consideration. That is the reason why YIKEN needle-free connector final design (Pic2) has a little curve on the surface.

Q : About the disinfect issue mention

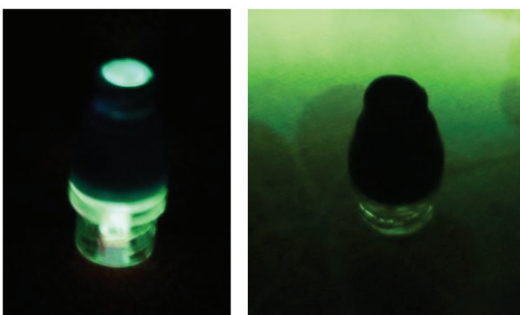
A : We have done the in house disinfect test, using fluorescent.

The result came out that needle free connector can be thoroughly disinfect by the alcohol pad. Please refer to following test report.

Fluorescent test procedure:



Fluorescent test procedure:



Before disinfect **After disinfect: No bacteria in surface**

Toothpaste Test

ICU / MicroClave



Before



Application of Toothpaste



After 3 second swab and access with male lue

HR



Before



Application of Toothpaste



After 3 second swab and access with male lue

YKN Needlefree Connector



Before



Application of Toothpaste



After 3 second swab and access with male lue

→use the least liquid to wash the inner space, provide adapter that has superior hermetic characteristics to prevent back flow of liquid medicine and injection of air.

YKN Needlefree Connector

- ✓ Smooth and tight seal, easy to disinfect thoroughly
- ✓ Luer fittings are compatible with American National Standard for luer
- ✓ Reduce the cost
- ✓ reduce patient discomfort
- ✓ Only three components for assemble, components are sonic welded together for high reliability and safety
- ✓ Minimal residual liquid in the world
- ✓ Latex Free

STUDY REPORT

Infusion giving set accessories-needle free valves

In Vitro Cytotoxicity Test

Testing Institution: SGS Taiwan Ltd. 2013 Jun

The scores of the cytotoxicity test, including morphological evaluation, observation of monolayer confluency, and relative inhibition of cell viability. Based on the average score, we concluded that the Infusion giving set accessories-needlefree valves extract induced non-cytotoxicity to L929 cells according to ISO.

Cell Morphology

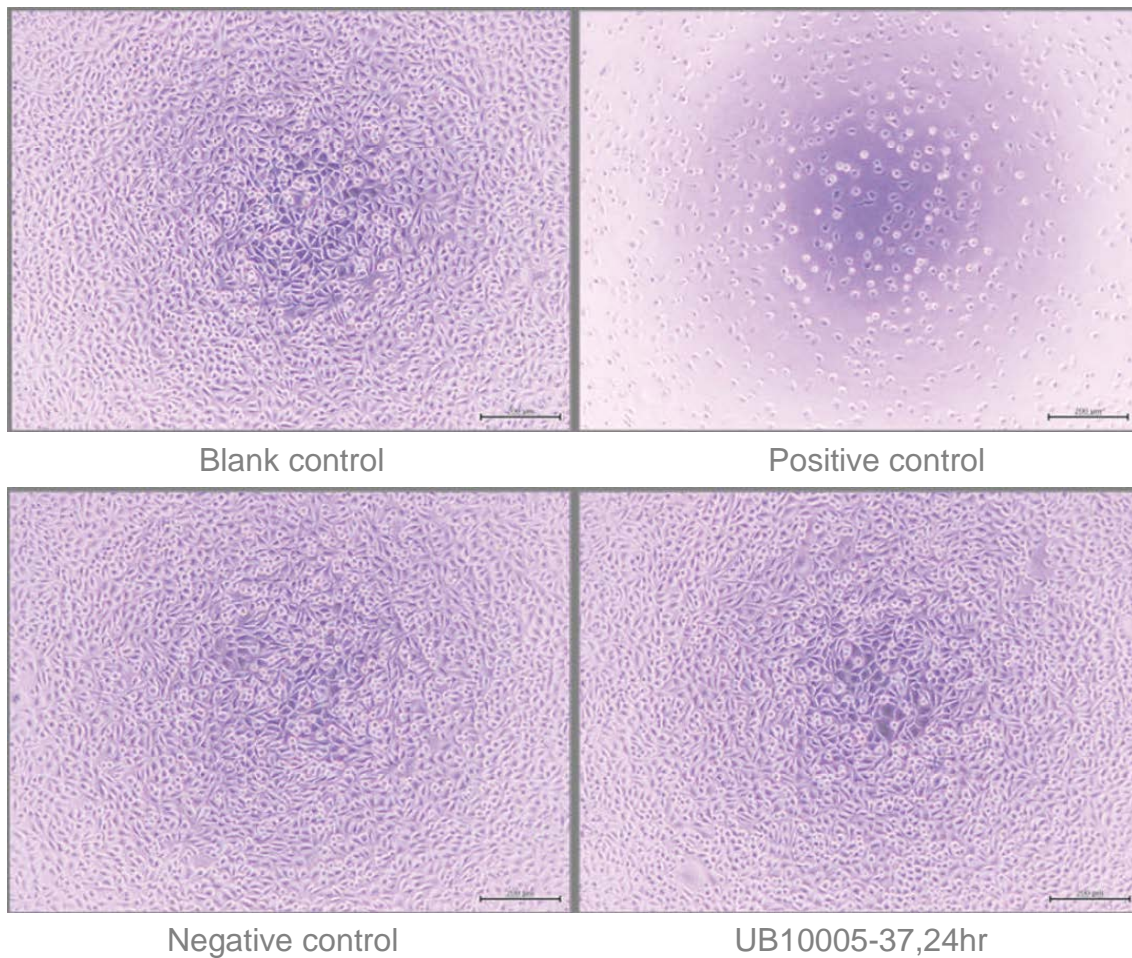


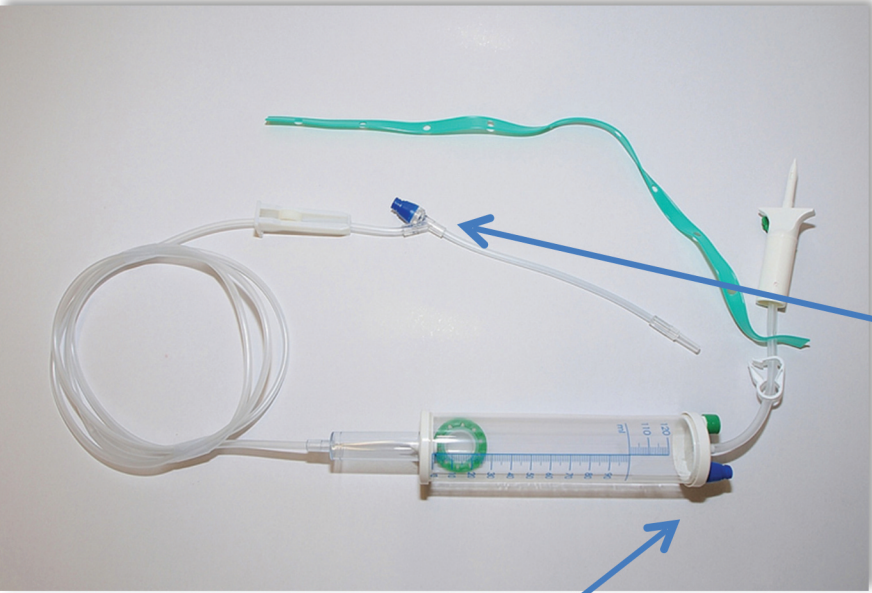
Figure : Morphology and confluency of L929 cells after being exposed to sample or control extracts for 24 hours

How to use Needlefree Connector?

Needlefree System IV Administration Sets



Needlefree
Y-connector



Needlefree
Y-connector

Needlefree
Assembled burette
upper lid

YKN Needlefree series



B11004
4mm
silicone,ABS,PC



B11003
connector Y,4mm
silicone,ABS,PC



B11006
injection pin
silicone,ABS,PC



B11002
male luer
injection cap
silicone,ABS,PC

B11012
2mm
silicone,ABS,PC

B11013
connector Y,3mm
silicone,ABS,PC



B11014
connector Y,4mm
silicone,ABS,PC



B11016
4mm
silicone,ABS,PC



B11018
male luer injection cap
silicone,ABS,PC



B11022
male luer
injection cap
silicone,ABS,PC



B11023
4mm
Neutral Pressure
silicone,ABS,PC

B11015
connector Y,3mm
silicone,ABS,PC

B11017
2mm
silicone,ABS,PC

B11024
2mm
Neutral Pressure
silicone,ABS,PC



B11007
burette lid
silicone,ABS,PC





億肯企業有限公司

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