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# MEDEXEL

**INSULIN PEN NEEDLES**  
**INSULIN SAFETY PEN NEEDLES**



**MedExel**

# MEDEXEL



## HELLO. WE ARE MEDEXEL.

Started on July 1, 2000 and started to produce related products such as insulin syringes, fennel, and a set of fluids for insulin injection. Built with automated facilities to design and manufacture to meet customer needs, successful global experience and excellence.

We are a medical device manufacturer that continuously grows with technology and performs corporate ethics and social responsibility.

MedExel is a medical device manufacturing company which has manufactured insulin pen needles since 1, July 2000. MedExel designs the product for customers' needs and always cares for the social responsibility based on the global experience and technology of the automatic system.

Founded in 2000 as a joint venture among German, US and Korean companies, MedExel has been innovated to meet customers' needs, which are more comfortable and less painful devices for hypodermic injection of insulin for Diabetic cares. Accumulated experience in developing various kinds of diabetic items for hypodermic injection has lead us to develop high-quality pen needles, which are compatible with most of the existing insulin pens. We have been able to successfully supply high quality and less painful pen needles, approved by CE, FDA 510K, NMPA and world wide customers.

MedExel is studying to develop more useful, safe product and trying to control quality for the customer's satisfaction. The ultimate objective of MedExel is growing as a global leader by contributing to health of worldwide humanity. Creativity and innovation is our future by accepting change with mind of challenge and enthusiasm. We would like to provide sincere service to our customers and do our best to continue developing more comfortable and less painful pen needles by keeping our ears open to customers' opinions.

**Thank you.**

We always think of the following three things as very important

honesty  
with no concession

practice  
for performance

desire  
for change

## GLOBAL BUSINESS

MedExel is a global company that exports to more than 20 countries. Starting with winning the prize of \$5 million in 2015, the company has been selected as one of the 300 most promising export companies in Gyeonggi Province.





# CERTIFICATE

## Patents



Safety protection system for pen needles



Pen-Type syringe cover



One touch for pen-type syringe and pen cover cap



Cap of needle length adjustment

## Certificates



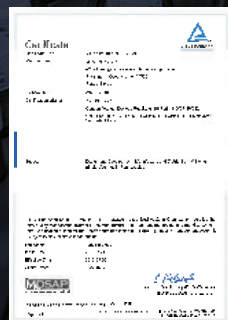
KGMP (REPUBLIC OF KOREA)



ISO 13485



CEMD (EUROPE)



MDSAP (USA, CANADA)



ANVISA (BRAZIL)



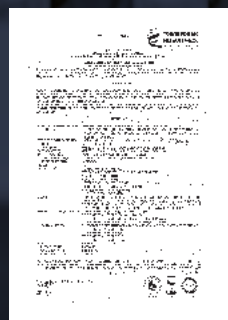
NMPA (CHINA)



FDA 510K (USA)



TGA (AUSTRALIA)



INVIMA (COLOMBIA)



HEALTH CANADA (CANADA)

# Needle Specification

## MEDEXEL Needle Specification

### Relevant standards

ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices  
–Requirements and test methods

According to the classification in ISO 9626 paragraph 5.6. Dimensions, the Wall specification of MedExel needle is TW (Thin Wall)

### Dimensions of tubing

Designated metric size (mm)	Gauge	ODMIN (mm)	ODMAX (mm)	Wall	IDMIN (mm)
0.18	34	0.178	0.191	RW	0.064
				TW	0.091
				ETW	0.105
0.20	33	0.203	0.216	RW	0.089
				TW	0.105
				ETW	0.125
0.23	32	0.229	0.241	RW	0.089
				TW	0.105
				ETW	0.125
				UTW	0.146
0.25	31	0.254	0.267	RW	0.114
				TW	0.125
				ETW	0.146
				UTW	0.176
0.30	30	0.298	0.320	RW	0.133
				TW	0.165
				ETW	0.190
				UTW	0.240
0.33	29	0.324	0.351	RW	0.133
				TW	0.190
				ETW	0.240
0.36	28	0.349	0.370	UTW	0.265
				RW	0.133
				TW	0.190
0.40	27	0.400	0.420	RW	0.184
				TW	0.241
0.45	26	0.440	0.470	RW	0.232
				TW	0.292
0.50	25	0.500	0.530	RW	0.232
				TW	0.292
0.55	24	0.550	0.580	RW	0.280
				TW	0.343
0.60	23	0.600	0.673	RW	0.317
				TW	0.370
				ETW	0.460

**NOTE1:** RW=Regular wall, TW=Thin Wall, ETW=Extra Thin Wall, UTW=Ultra Thin wall

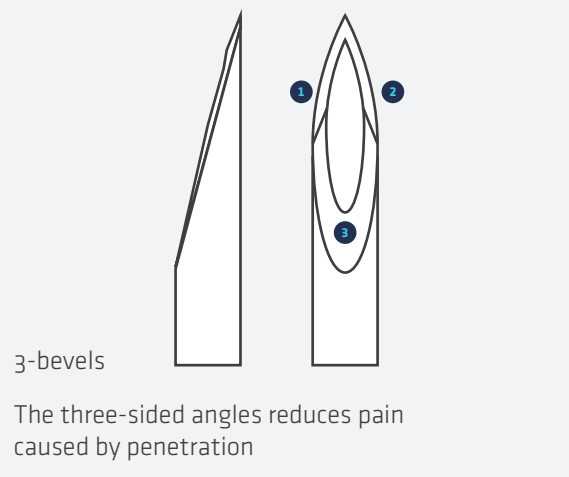
**NOTE2:** Needle sizes below 0.25mm, consideration can be made to the measurement uncertainty of existing measurement equipment.

**NOTE3:** This International Standard does not specify maximum inner diameter.

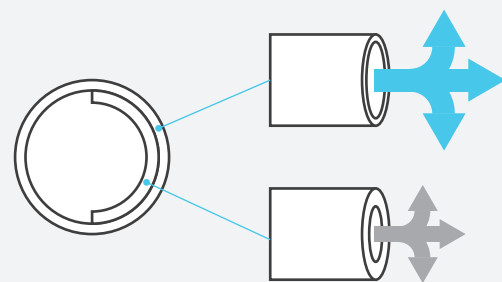
**NOTE4:** OD=outer diameter, ID=inner diameter

### Features of Needle

#### Needle design

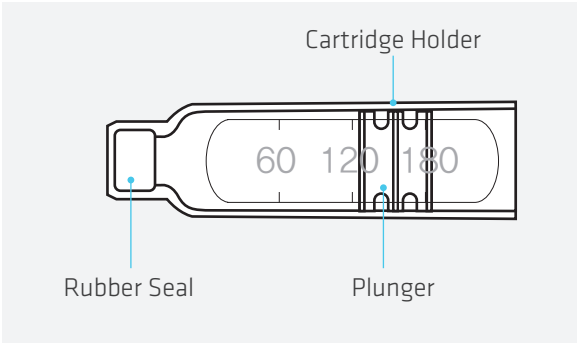
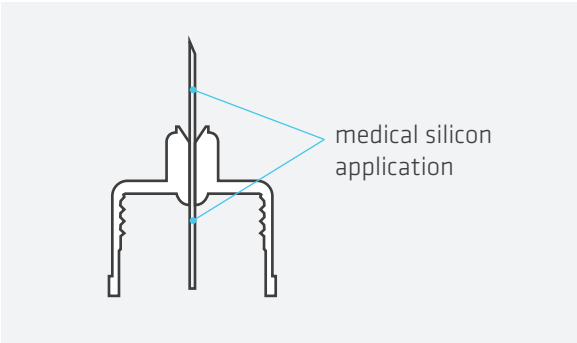


#### Different from Rear wall to Thin wall

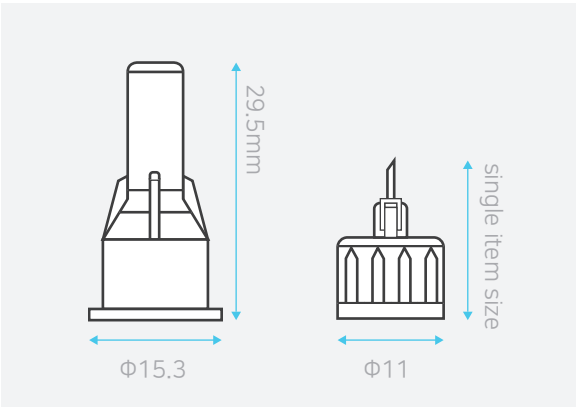


### Strong point of MedExel Pen Needle

- MedExel needle has smoother drug input amount and flow than general regular wall.
- Due to silicon coated needle surface, pain of patient gets a lot lower since it decreases friction with the skin when the injection is made.
- MedExel has silicon coatings for both front and back side of the needle.
- Purpose of coating for front side needle: It minimizes the friction with the skin and decreases pain of patient when the injection is made.
- Purpose of coating for back side needle: It prevents possible damage of rubber seal when assemble with pen type syringe.



### Product Size



### MedExel Needle Specifications

Gauge	External Diameter (mm)	Internal Diameter (mm)
29G	0.324 ~ 0.351	0.133 ~ 0.189
30G	0.298 ~ 0.320	0.133 ~ 0.164
31G	0.254 ~ 0.267	0.114 ~ 0.124
32G	0.229 ~ 0.241	0.089 ~ 0.104
33G	0.203 ~ 0.216	0.089 ~ 0.115
34G	0.181 ~ 0.201	0.090 ~ 0.115

### Needle length

4mm	5mm	6mm	8mm	10mm	12mm	12.7mm
item size (mm)						
14.78~15.78	15.78~16.78	16.78~17.78	18.78~19.78	20.78~21.78	22.78~23.78	23.48~24.48

# Kinking Test

## Test method

The kinking test indicates the bearable kinking load (axial load) of the needle. Within the test the needle tip runs against a non pierceable material and starts bending and sub-sequentially kinks with further forwarding. This test is performed following the Euler Kinking Cases 1 resp. 2. The recorded characteristics indicate the elastical area and plastical area of the kinking.

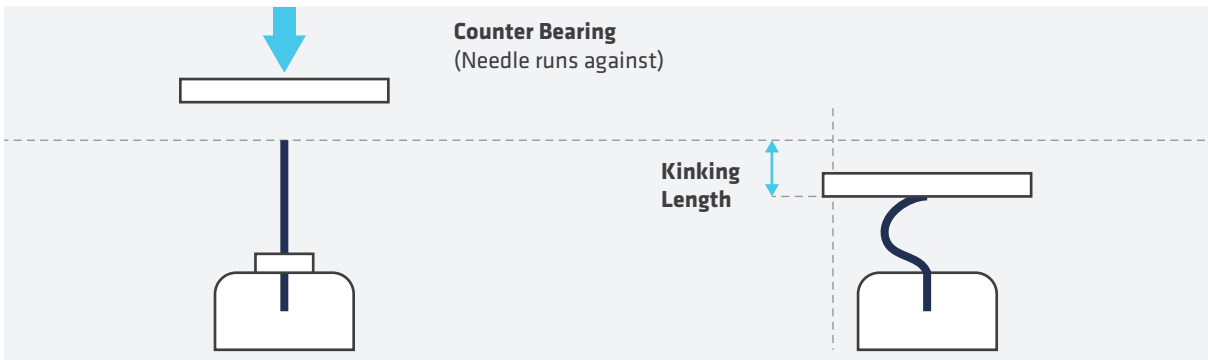
## Measuring equipment

Penetrometer DEKA 9

Stereo Microscope SZH

## Parameter

Testing speed	20mm / min
Testing length	2mm
Testing direction	axial



# Pulling Test

## Measuring equipment

AIKOH 1310 N/SL (Loadmeter)

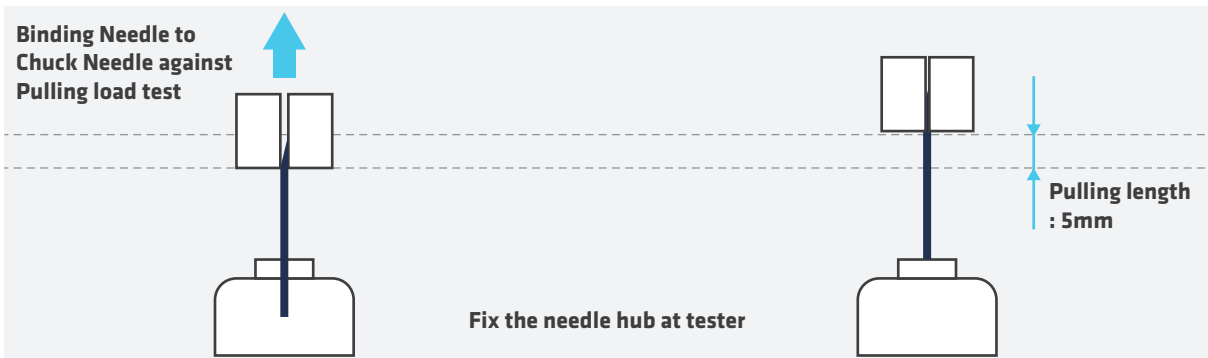
AIKOH FA1015A (Force analyzer)

## Parameter

Testing speed	80mm / min
Testing length	5mm
Testing direction	axial

Acceptance criteria of pulling against force with 31G is at least 22N according to ISO11608-2 clause 4.9

Figure 1 : Arrangement of the Pulling Test



**Result of Pulling Test**    MIN : 26.3(N)    MAX : 44.8(N)    AVE : 35.4(N)





# PRECAUTIONS

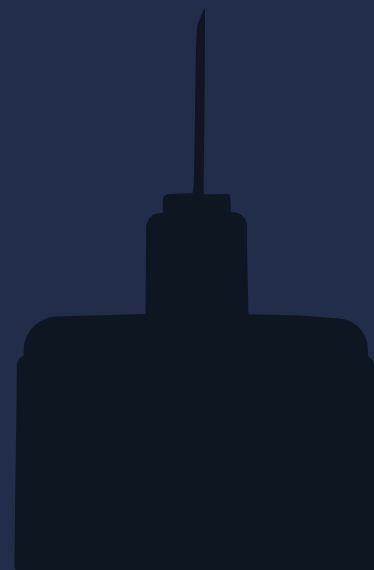
## Precautions when using

1. It must necessarily be checked that the needle is blockage free before you inject insulin.
2. Do not inject on your upper arm. It is uncomfortable to make an injection and may be necessary to bring other persons help to remove it.
3. Do not make any intramuscular injections. Insulin will be absorbed arrhythmically and pain will also become together.
4. Since the sterilization has already gone, do not use a needle more than once. The needle tip gets already damaged. Extra injection of the same needle hurts more and may cause lipos. The needle may be blocked due to residues.
5. Since the muscle will be pinched up together, do not squeeze too strong. You will meet a risk of intramuscular injection, if you do so.
6. Always role up your sleeves and inject directly on your skin. Otherwise, the needle will be blocked by fabric stuff and it may also be entered into your skin. In addition, it will be removed the silicone of the needle and weaken tip gets bent.
7. Do not close the cap to reuse it. Protection is now unavailable and the sterilization has already gone as well. Due to the small cap, you might hurt yourself also.
8. Do not make any collections of the needles in cans or bottles for disposal. Such storages may be broken or punctured. Everyone can face risks by those unclosed needles.
9. Do not inject near your belly button. Always keep in mind that the injection must be avoided for moles, lipos, blemished skin or cracked blood vessels.
10. You must make FULL insertion of the needle into the skin. The needle should NOT be inserted PARTLY in order to reach the fatty tissue. Visible of the needle is not correct.

# 01

PRODUCT OF MEDEXEL

# INSULIN PEN NEEDLE



# MEDEXEL

# INSULIN PEN NEEDLES



## Product Features

### Anti Coring

Needle body and tip are electro polished to remove small blemishes and rough spots for a smooth penetration.

### Silicone

Silicone lubricant for smooth gliding and less friction.

### Thin Wall Technology

Allows effortless flow of medication to be delivered easily and more freely for the same diameter needle.

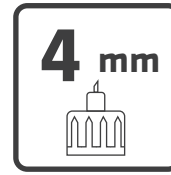
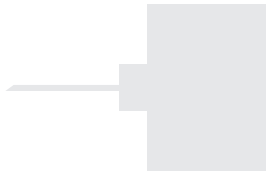
### Multi Bevel Needle

Triple Sharpened bevelled edged needle tip for clean and precise skin penetration.

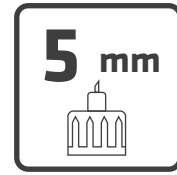
## Product Lineup

### 34 GAUGE

0.18mm



34G (0.18mm)  
x 4 mm

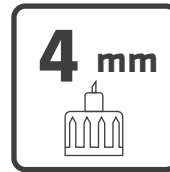


34G (0.18mm)  
x 5 mm

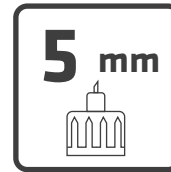
Recommend for people who are sensitive, and have fear of injection. The thinner needle will minimize the pain you feel everyday.

### 32 GAUGE

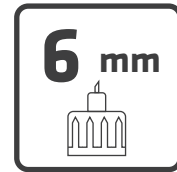
0.23mm



32G (0.23mm)  
x 4 mm



32G (0.23mm)  
x 5 mm

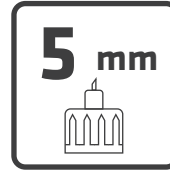


32G (0.23mm)  
x 6 mm

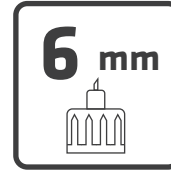
Recommend for most people

### 31 GAUGE

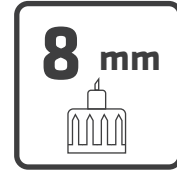
0.25mm



31G (0.25mm)  
x 5 mm



31G (0.25mm)  
x 6 mm



31G (0.25mm)  
x 8 mm

## Stable Quality Product

- Auto-Manufacturing Line
- Own Sterilizer : SAL 10<sup>6</sup> , EO Gas, BI Test, CI Test, Sterility Test, ISO11135

## Environmental Control (ISO13485:2016 , CE 0197, 21CFR 820, MDSAP)

- Clean Room : Particle Control, Federal Standard 209E, ISO 14644
- Clean Room (Class 100,000) by the installation with HEPA Filter in the last stage of process
- Air Control : Bioburden Test, ISO 11737-1

## Compatible Pen List

- |                      |                      |                  |
|----------------------|----------------------|------------------|
| - HumaPen Savvio     | - HumaPen Luxura     | - Humalog Mix25  |
| - Humulin Pen        | - NovoPen 3          | - NovoPen 4      |
| - NovoPen 5          | - Novo Echo          | - NovoPen Junior |
| - Novo Let N         | - NovoMix 30 FlexPen | - Induo          |
| - Lantus Solosta Pen | - Allstar Pro        | - JuniorStar     |
| - Sanofi Optiset     | - Core Tropin        | - Wangbang       |
| - Owen Autopen       | - BD Pen             | - Delfu          |
| - Humatropen         |                      |                  |



**MedExel**  
**Always**  
**with you**



# 02

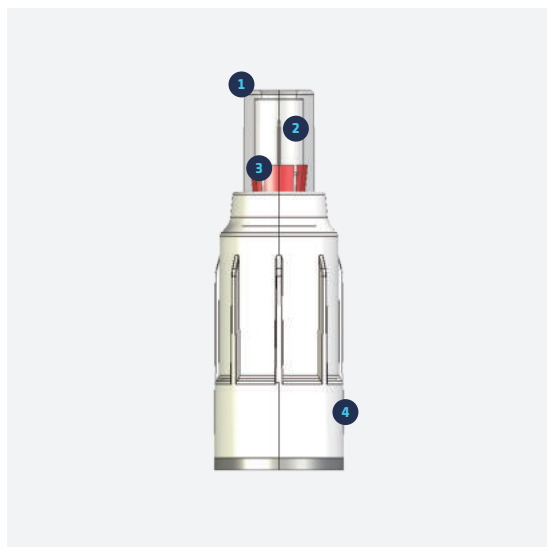
PRODUCT OF MEDEXEL

## INSULIN SAFETY PEN NEEDLE



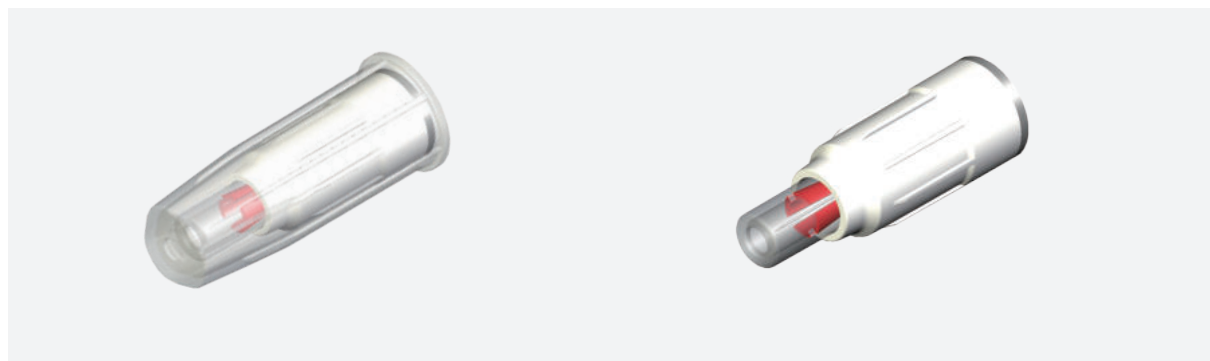
# INSULIN SAFETY PEN NEEDLE

MedExel insulin safety pen needle is designed to automatically locked itself after use.  
The purpose of this product is to prevent re-use and secondary infection.  
As it is globally recommended to use recently, it proves Medexel's technology and quality.

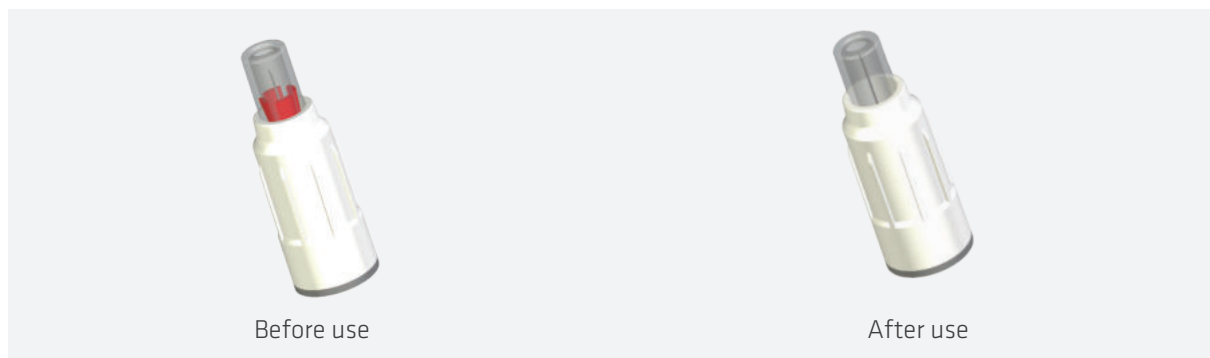


- 1. needle cap
- 2. needle
- 3. safety shield
- 4. middle cap

## Product Appearance



## Safety Shield Function



## Product size



## Supporting power of Safety shield (In-house standard)

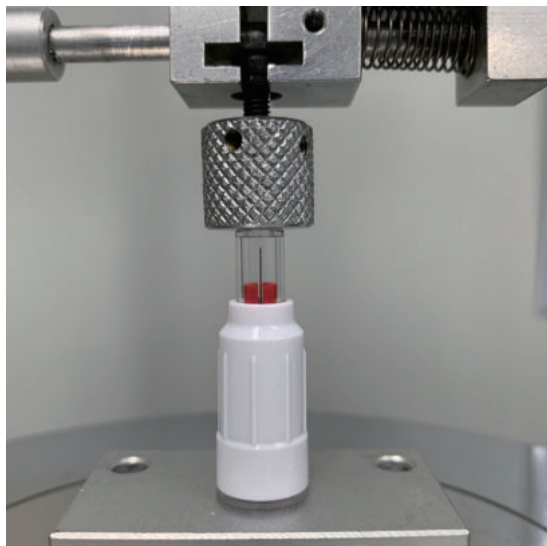
### Test method

In-house standard.

### Test standard

- Activate the SPN's Safety Shield function.
- Place the SPN on the JIG.
- Using the 500N load cell, press the SPN at 20mm/min. Stop the press when SPN's supporter is broken.

### Test equipment



### Result

Test sample quantity: 25EA

Category	Data (N)
MIN	126.0
MAX	165.0
AVR	143.3
STD	12.03

# ISO 23908 Sharps Injury Protection Test

## Test method

ISO23908 Annex B

### Test Description for sharps injury protection required by ISO 23908 (Annex B)

A sphere having a radius of 6 mm (simulating a finger tip) shall not contact the extremity of the needle point or sharps when positioned against the safety feature of the device. For needle-based devices with through-the-lumen blunting safety features, the sphere shall not contact the needle tip when the sphere is positioned in-line and in front of the extended blunting feature.

## Test method



Carrying out a test using 6mm radius steel ball.



Placing a steel ball on the SPN and checking if the needle tip touches the surface of the steel ball.

### Test result (Test standard is the gap between design specifications and actual needle length)

Model	Test standard	Test result
32Gx4mm	5.5mm	5.46mm
32Gx5mm	4.5mm	4.48mm
32Gx6mm	3.5mm	3.42mm
32Gx8mm	1.5mm	1.49mm

# Compatibility between the SPN and prefilled insulin pen (based on ISO 11608-2,clause11)

## Test method

- a. ISO 11608-2 clause11.4.1
- b. Limits of assembly torque:  $0.060\text{Nm} \leq x \leq 0.080\text{Nm}$   
(All the data should be in the limits after 120 times of the test)
- c. Limits of the removal torque:  $\leq 0.100\text{Nm}$   
(If over 3 of data deviate from the limits after 120 times of the test, this test is disqualified.)

## Test description

- a. Prepare 120EA of 32Gx5mm SPN
- b. Prepare the spinning torque tester  
(Set the type of measuring unit to “Nm”)
- c. Fix the SPN to the torque tester as the picture below.
- d. Screw the SPN onto the insulin pen until it is no longer rotated. After waiting 10 seconds, record the maximum value of the torque.
- e. Set the measure value to zero.
- f. Remove the insulin pen from the SPN and record the maximum value of the spinning torque.
- g. After one test, replace the SPN with the new SPN.  
Conduct the test 120times in the same way.



## Test result

Category	Assembly torque	Removal torque
MIN	0.060	0.021
MAX	0.074	0.067
AVR	0.066	0.045
STD	0.004	0.013



# MEDEXEL

# INSULIN SAFETY PEN NEEDLES



## Product Features

### 6 side ribs for anti-slip (Large Cap)

Special design to avoid slip during disassembling the primary container and screwing onto the insulin pen

### Triangle shaped design (Large Cap)

Unique design distinguished from other brand safety pen needle.

### Solid structure (Large Cap)

Solid structure prevents inner pen needle damage from external impact.

### Streamlined design (Needle Cap)

Streamlined design maximizes the contact area between the needle cap and skin. Our design prevents the pain from injection and improves the emotional quality.

### 8 side ribs for anti-slip (Middle Cap)

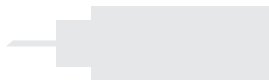
Special design to avoid slip during disassembling the primary container and screwing onto the insulin pen.

### Wide range of color and solid structure

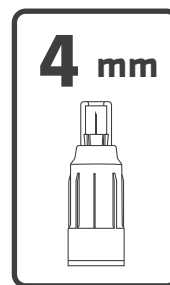
Medexel's Safety Pen Needle is made of ABS which improves solidity and implementing a wide range of color. Needle Cap (Transparent or Tinted) / Middle Cap (White or Gray) / Safety Shield (Red or Green)

## 32 GAUGE

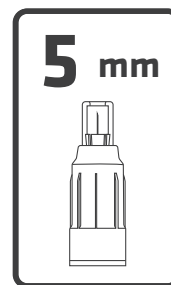
0.23mm



Recommend for people who are sensitive, and have fear of injection. The thinner needle will minimize the pain you feel everyday.



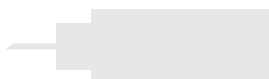
32G (0.23mm)  
x 4 mm



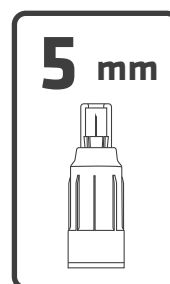
32G (0.23mm)  
x 5 mm

## 31 GAUGE

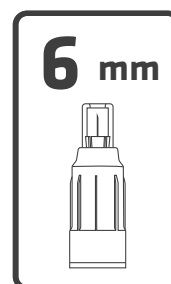
0.25mm



Recommend for most people



31G (0.25mm)  
x 5 mm



31G (0.25mm)  
x 6 mm

### Stable Quality Product

- Auto-Manufacturing Line
- Own Sterilizer : SAL 10<sup>-6</sup> , EO Gas, BI Test, CI Test, Sterility Test, ISO11135

### Environmental Control (ISO13485:2016 , CE 0197, 21CFR 820, MDSAP)

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| - Humulin Pen        | - NovoPen 3          | - NovoPen 4      |
| - NovoPen 5          | - Novo Echo          | - NovoPen Junior |
| - Novo Let N         | - NovoMix 30 FlexPen | - Induo          |
| - Lantus Solosta Pen | - Allstar Pro        | - Sanofi Optiset |
| - BD Pen             | - Owen Autopen       | - JuniorStar     |
| - Core Tropin        | - Delfu              | - Wangbang       |
| - Humatropen         |                      |                  |