

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

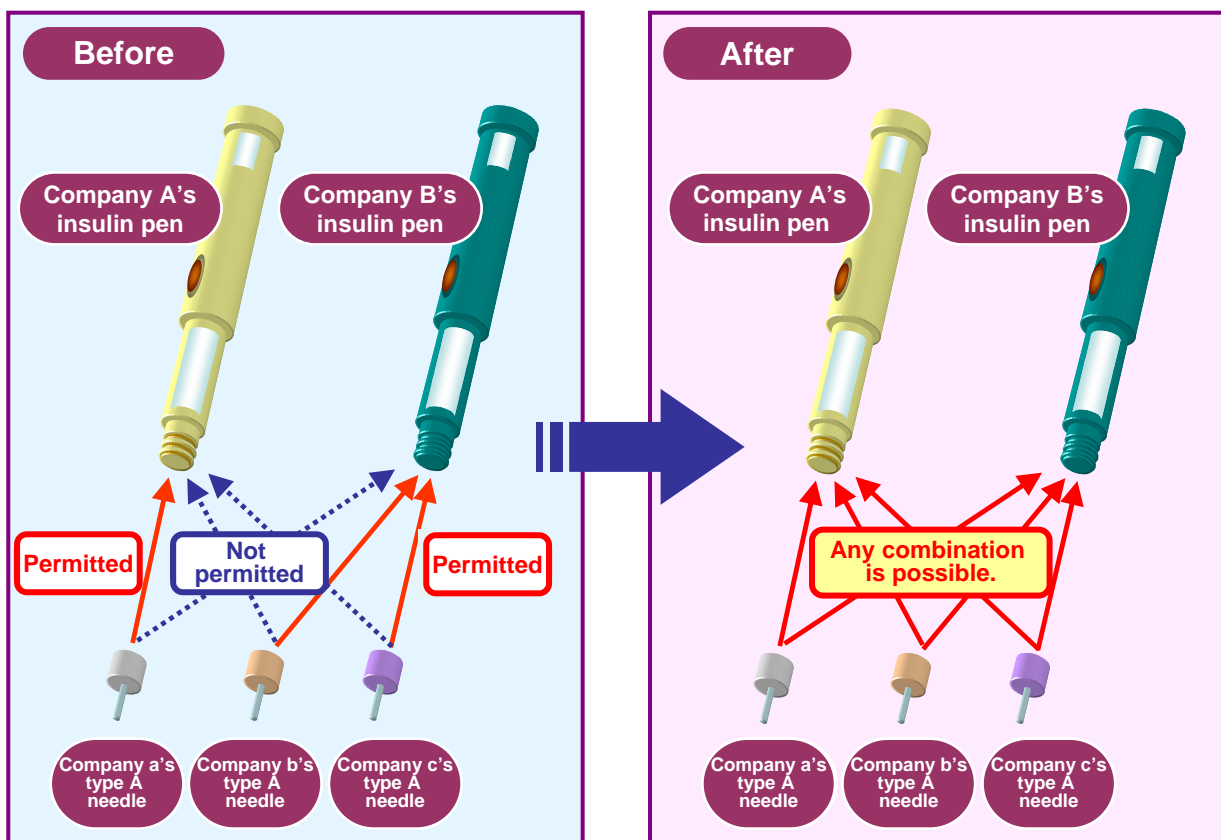
pmda No. 8 February, 2009

Compatibility between a “Type A” Needle (JIS T 3226-2) and a Insulin Pen (JIS T 3226-1)

POINT Key points for safe use

1 Compatibility between a “Type A” needle and a Insulin pen

- Every insulin pen had some specific “Type A” needles to use with (cartridge type, kit type). Supported combinations were shown in the respective package inserts and instruction manuals.
- As the result of the verification tests conducted by the manufacturers of insulin pens, it has been found that **any combinations of the currently marketed insulin pens and type A needles are acceptable, and no problem has been reported from these tests.** The related package inserts and instruction manuals have been revised accordingly.



Insulin pens to which any of "Type A" needles can be used

Novo Nordisk Pharma Ltd. products



**NovoRapid
(30 Mix, for injection)*FlexPen**



Levemir FlexPen



**Novolin
(R, N, 30R, 40R, 50R)*
FlexPen**



**InnoLet
(R, N, 30R, 40R, 50R)***



NovoPen 300



NovoPen 300 Demi

* One of the names in () is included in a brand name.

Contact for product inquiries : 0120-180363, Novo Care Support Line, Novo Nordisk Pharma Ltd.

Eli Lilly Japan K.K. insulin pens



**Humalog
(Mix 25, Mix 50, N, for injection)*
MirioPen**



**Humulin
(R, 3/7, N)* Kit**



**Humalog
(Mix 25, Mix 50, N, for injection)*
Kit**



HumaPen LUXURA

* One of the names in () is included in a brand name.

Contact for product inquiries : 0120-360-605, Lilly Answers, Eli Lilly Japan K.K.

sanofi-aventis K.K insulin pens



OptiClik

Need your caution in selecting a pen needle to use with OptiClik (refer to page 4)



Lantus Inj. SoloStar



iTango

Contact for product inquiries : 0120-49-7010, Opti Call 24, sanofi-aventis K.K.

People who are under insulin self-injection therapy and healthcare professionals who assist the insulin self-injection training for patients in medical institutions should also **carefully read package inserts and instruction manuals to understand their usage properly.**



Type A needles with which insulin pens can be used

Nippon Becton Dickinson Company, Ltd. products

Outer package



Inner bag



Needle



BD Micro-Fine +
31G Thin Wall 5 mm

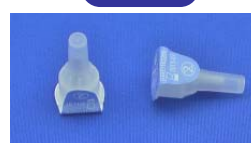
Outer package



Inner bag



Needle



BD Micro-Fine +
31G Thin Wall 8 mm

Terumo Corporation products

Outer package



Inner bag



Needle



Nanopass Needle

NIPRO Corporation products

Outer package



OptiClik requires special cautions in using with a pen needle. (refer to page 4)

Outer package



Inner bag



Needles



Pen needle 30G 8 mm

Inner bag



Needles



Pen needle 32G Taper

2 Precautions for the combination of OptiClick and a pen needle

- OptiClick can be used with some pen needles if the names of “JIS T 3226-2 Type A” on both front and back of the inner bag or “NIPRO” on the protective sticker of needle case are found.
- Pen needles without “JIS T 3226-2 Type A” nor “NIPRO” cannot be used with OptiClick.

Pen needle 30G 8 mm		Pen Needle 32G Taper	
Not applicable with OptiClick	Applicable with OptiClick	Not applicable with OptiClick	Applicable with OptiClick
Front of inner bag	Front of inner bag	Front of inner bag	Front of inner bag
Back of inner bag	Back of inner bag	Back of inner bag	Back of inner bag
Protective seal	Protective seal	Protective seal	Protective seal



See and read the indication of the package and the protective seal of “Type A” needles.

Ministry of Health, Labour and Welfare (MHLW) issued notifications related to PMDA Medical Safety Information No. 8:

- “Revisions etc. of PRECAUTIONS for combination use of an insulin pen and a pen needle” (PFSB/ELD Notification No. 1117005 issued by Evaluation and Licensing Division, MHLW and PFSB/SD Notification No. 1117003 issued by Safety Division, MHLW on November 17, 2008)

Information on this notification is available

at the Pharmaceuticals and Medical Devices Information website (in Japanese)
<http://www.info.pmda.go.jp/mdevices/file/md2008-1117005.pdf>

About this information

- * PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Pharmaceutical Affairs Law.
- * We have endeavored to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy into the future.
- * This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.