Medical Safety Information
Pharmaceuticals and Medical Devices Agency
Pmda No.5 June, 2008

Handling of lancing devices for obtaining blood samples

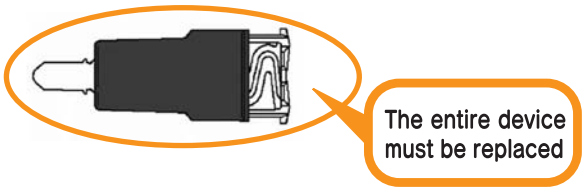
POINT Key points for safe use

1 Types and handling precautions of lancing devices for obtaining blood samples

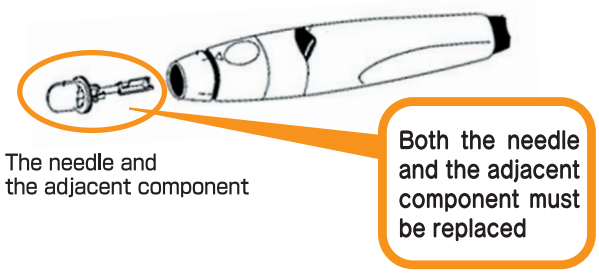
- Lancing devices for obtaining blood samples for glucose monitoring, etc. are classified into the following 3 types depending on their handling differences.

Type	Needle	Adjacent Component	Main Body	Remark
Type 1: An entire device is disposable (note: a disposable single-use lancing device)	Must be replaced			Intended for single use only
Type 2: A component adjacent to a needle is disposable (note: a device wherein a needle and a component adjacent to a needle are connected to each other)	Must be replaced		Not to be replaced	Intended for use on multiple patients
Type 3: A component adjacent to a needle is not disposable (note: a lancing device wherein only a needle is disposable)	Must be replaced	Not to be replaced	Not to be replaced	Not intended for use on multiple patients (for single patient use only)

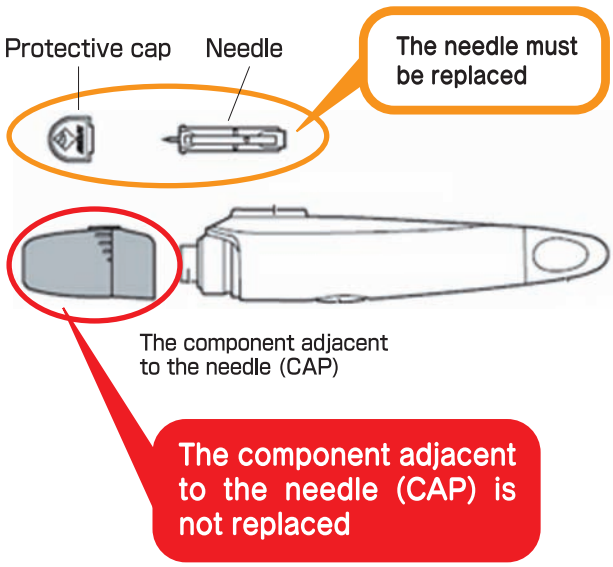
Type 1: An entire device is disposable



Type 2: A component adjacent to a needle is disposable



Type 3: A component adjacent to a needle is not disposable

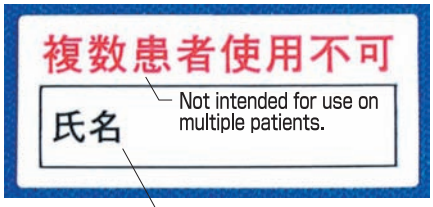


(Case 1) Type 3 lancing device for obtaining blood samples intended for single patient use [wherein a component adjacent to a needle (CAP) is not disposable] was used on multiple patients. An outbreak of infections due to this misuse was suspected.

2 Precautions for Type 3 lancing devices wherein a component adjacent to a needle is not disposable

【Contraindications】
- This device should be used only on a single patient, not on multiple patients. [Use on multiple patients may cause infections from residual blood, etc on the device.]
- This device should not be disassembled, remodeled or used for purposes other than obtaining blood samples.
- A lancet must not be reused and must be replaced with a new one for each use.

Caution such as that shown left is included under the "Contraindications" section of package inserts of these devices. Please be sure to confirm contents of the package insert prior to use.

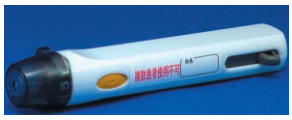


*This part is indicated in Japanese.

Type 3 lancing device with a non-disposable component adjacent to a needle (CAP) has a sticker shown left also on its main body. This device should never be used on multiple patients. This device should be limited to "single patient use".

List of Type 3 lancing devices wherein only a needle is disposable

ARKRAY Factory, Inc.
Multi-Lancet S

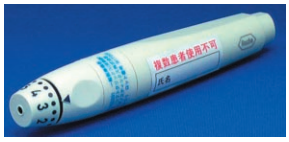


Abbott Japan Co., Ltd.
EasyTouch

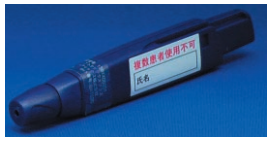
Abbott Japan Co., Ltd.
Lancet Device
(Lancing Device)

Johnson & Johnson K.K.
OneTouch UltraSoft™
(OneTouch® UltraSoft® Adjustable Blood Sampler)

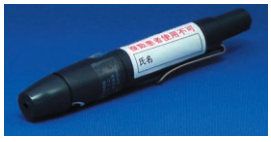
Roche Diagnostics K.K.
Softclix (lancing device)
(Foreign Brand Name: ACCU-CHEK Softclix Classic)



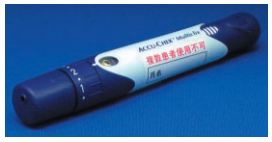
Roche Diagnostics K.K.
Softclix Plus
(Foreign Brand Name: ACCU-CHEK Softclix Plus)



Roche Diagnostics K.K.
Softclix Mini
(Foreign Brand Name: ACCU-CHEK Softclix)

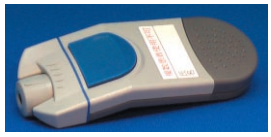


Roche Diagnostics K.K.
Multiclix
(Foreign Brand Name: ACCU-CHEK Multiclix)

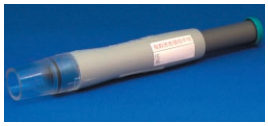


Nippon Becton Dickinson Company, Ltd.
Acelet

Bayer Yakuhin Ltd.
Microlet



Bayer Yakuhin Ltd.
Microlet Choice
Microlet Vaculance



ASAHI POLYSLIDER Inc.
Simple Glucose Monitoring G let

NIPRO CORPORATION
NIPRO FreeStyle Lightshot
FreeStyle Kissei Lancing Device

NIPRO CORPORATION
NIPRO FreeStyle Lightshot FLASH
FreeStyle FLASH Kissei Lancing Device

NIPRO CORPORATION
NIPRO FreeStyle Lightshot FREEDOM
FreeStyle FREEDOM Kissei Lancing Device

NIPRO CORPORATION
Laklet

TERAMECS Co., Ltd.
Auto Lancet Ⅱ

Discontinued in March 2005

Novo Nordisk Pharma Ltd.
Novo Penlet Plus

Discontinued in March 2005

Use of these devices on multiple patients is prohibited because the risk of infection from residual blood on a component adjacent to a needle (CAP) or the inside of the CAP cannot be excluded, even if a needle is replaced!!

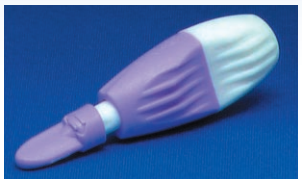
Note) The above are photographs of products currently available to the PMDA through the cooperation of each manufacturer.

3 Other types of lancing devices

Type 1: Entire disposable lancing devices

Roche Diagnostics K.K.
Safe-T-Pro Plus

Nippon Becton Dickinson Company, Ltd.
BD Safety Lancet
(BD Microtainer Contact-Activated Lancet)



Nippon Becton Dickinson Company, Ltd.
BD Genie Lancet

Nippon Becton Dickinson Company, Ltd.
Microtainer Safety Flow Lancet
(BD Microtainer Quikheel Lancet)

- The products shown above prevent reuse of a needle by a mechanism prohibiting the second ejection of the needle.

Type 2: lancing devices wherein a component adjacent to a needle is disposable

Photograph 1

Roche Diagnostics K.K.
Softclix Pro

Terumo Corporation
Medisafe Finetouch Pro

Panasonic Shikoku
Electronics Co., Ltd.
Gentlet

ARKRAY Factory, Inc.
naturalet device

- The above products shown in Photograph 1 prevent reuse of a needle by a mechanism prohibiting the second ejection of the needle.

Photograph 2

Bayer Yakuhin Ltd.
PIN Letter
Glucolet 2

Misawa Medical
Industry Co., Ltd.
Finger-Pit Fingerlet

Terumo Corporation
Medisafe Finetouch

- The above shown in Photograph 2 are the products wherein both a needle and an adjacent component are replaced for each use. However, since these devices allow repeated use of the same needle, please ensure that a needle and an adjacent component are replaced for each use. Please also ensure that they should be immediately removed and disposed after use. These products should never be left unattended with a needle attached thereto.

Caution should be exercised in various situations such as medical institutions, nursing care facilities for the elderly, healthcare service setting including health class. Please make a choice of a device appropriate for each patient!!

(Case 2) A lancing device for obtaining a small amount of blood was inappropriately used on multiple patients because it was mistakenly believed to automatically replace a needle with a new one.

4 Other precautions for directions for use

- Directions for use are different for each type. Please be sure to confirm contents of the package insert and learn how to handle the device properly before use.

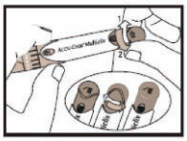
Example of a special lancing device

Roche Diagnostics K.K. Multiclix

One lancet drum contains six lancets.

〈Excerpt from the package insert〉

Direction for use for the second and subsequent lancets



When a subsequent lancet is to be used, rotate the plunger one quarter-turn (90 degrees) in a clockwise direction as far as it will go and a click sound is heard, and back to the original position. This procedure should be performed only once when a new lancet is to be used.

The number of white lines seen in a display portion indicates the number of unused lancets. The number of white lines decreases for each use of a lancet. Disappearance of white lines indicates that all of six lancets contained in the drum have been used up. Please replace it with a new one.

Medical safety managers and safety control managers for medical devices should be encouraged to ensure that information on directions for use and precautions for handling for each device is shared among hospital staff and that staff are educated and trained!!

Ministry of Health, Labour and Welfare (MHLW) has issued a notification related to this Medical Safety Information No. 5:

- "Handling of lancing devices for obtaining blood samples (wherein a component adjacent to a needle is not disposable)" (PFSB/SD Notification No. 0303001 issued by the Safety Division of the Pharmaceutical and Food Safety Bureau of MHLW on March 3, 2006)
- "Handling of lancing devices for obtaining blood samples (wherein a component adjacent to a needle is not disposable) (reminder for healthcare providers)" (Administrative notice issued by MHLW on May 22, 2008)

This notification is posted on the Pharmaceuticals and Medical Devices Information website (http://www.info.pmda.go.jp/mdevices/md2006-0303001.html) (in Japanese).
Pleaserefer to (http://www.info.pmda.go.jp/downfiles/md/whatsnew/companylist/companyframe.html) (in Japanese) for information on the package inserts of lancing devices described in this Medical Safety Information No. 5.

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.

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Contact:
Medical Safety
Information Group
E-mail: safety.info@pmda.go.jp
http://www.info.pmda.go.jp/