Handling of lancing devices for obtaining blood samples

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.

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

Type 1: An entire device is disposable

- The entire device must be replaced

Type 2: A component adjacent to a needle is disposable

- The needle and the adjacent component must be replaced

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

- The needle must be replaced
- The component adjacent to the needle (CAP) is not replaced
(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

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.

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 Secten Dickinson Company, Ltd.
Acellet

Bayer Yakuhin Ltd.
Microlet

Bayer Yakuhin Ltd.
Microlet Choice
Microlet Vaculance

ASAHI POLYSLIDER Inc.
Simple Glucose Monitoring System

NIPRO CORPORATION
NIPRO FreeStyle Lightshet
FreeStyle Kissei Lancing Device

NIPRO CORPORATION
NIPRO FreeStyle Lightshet FLASH
FreeStyle FLASH Kissei Lancing Device

NIPRO CORPORATION
NIPRO FreeStyle Lightshet FREEDOM
FreeStyle FREEDOM Kissei Lancing Device

NIPRO CORPORATION
Laklet

TERAMECS Co., Ltd.
Auto Lancet II

Novo Nordisk Pharma Ltd.
Novo Penet Plus

Discontinued in March 2005

Discontinued in March 2005

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

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!!
3 Other types of lancing devices

Type 1: Entire disposable lancing devices

- 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

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

- 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. Multilix

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)


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.