SAFETY Blood Collection/Infusion Set Instructions for Use for non-DEHP sets

Intended Use

The SAFETY Blood Collection/Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a luer connector. The SAFETY Blood Collection/Infusion Set is used for blood collection and/or the short-term infusion of intravenous fluids. The tubing is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

Product Description

The SAFETY Blood Collection/Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a luer connector. It is available in various combinations. The SAFETY Blood Collection/Infusion Set is individually wrapped, sterile and can be used with a luer system (e.g. HOLDEX®). The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.

Safety Blood Collection/Infusion Set Individually wrapped and sterile allowing set to be used with a luer system.

SAFETY Blood Collection Set with Luer Adapter (for use with e.g. Standard Tube Holder).

SAFETY Blood Collection Set with Luer Adapter + Holder Individually wrapped and sterile ready to be used with blood collection set.

The SAFETY Blood Collection/Infusion Set does not contain any components made of dry natural rubber and is non-DEHP®. Acrylates containing latex will be marked as such on the packaging.

Procedure

1. Remove SAFETY Blood Collection/Infusion Set from packaging.
2. Check to make sure the hub is securely locked in place. NOTE: If individual packaging has been opened or tempered with, please choose another needle.
3. Select site for venipuncture. Apply tourniquet and prepare site with antiseptic wipes. DO NOT PUNCTURE site after cleansing.

For Blood Collection

1. Select appropriate tube(s) and SAFETY Blood Collection/Infusion Set and, if necessary, connect it to the desired collection system.
2. Carefully remove needle cap from safety-winged needle.
3. Perform venipuncture with patient’s arm in downward position. Flashback will confirm successful venipuncture.
4. Imbibe the winged needle with tape when necessary.
5. Hold the hub with one hand to release flashback. Pull the hub backwards.
6. After complete puncture place gauge over collection site without applying pressure.
7. With one hand, activate the safety mechanism by pressing in both sides of the hub to the end of the month indicated.
8. Pull the safety mechanism backward until an audible click is heard. The click is a sign that the safety mechanism has been correctly activated.
9. Apply gentle pressure to the puncture site using the gauze pad according to facility protocol.
10. Promptly dispose of SAFETY Blood Collection/Infusion Set in an approved disposal container in accordance with the procedure of your facility.

For short-term IV Infusion

1. For infusion purposes, remove any male device (HOLDEX®). Luer Adapter or Luer Adapter + Holder from the set prior to connection to the female luer port.
2. Carefully remove needle protective cap from safety-winged needle and prime set in accordance with recommended procedure.

Label Information

- Maximum Priming Volume

<table>
<thead>
<tr>
<th>Tubing</th>
<th>21G</th>
<th>25G</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 cm</td>
<td>0.27</td>
<td>0.27</td>
</tr>
<tr>
<td>15 cm</td>
<td>0.43</td>
<td>0.41</td>
</tr>
<tr>
<td>30 cm</td>
<td>0.56</td>
<td>0.56</td>
</tr>
</tbody>
</table>

- Maximum Flow Rate

<table>
<thead>
<tr>
<th>Tubing</th>
<th>21G</th>
<th>25G</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 cm</td>
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<td>9.5</td>
</tr>
<tr>
<td>15 cm</td>
<td>22.8</td>
<td>9.6</td>
</tr>
<tr>
<td>30 cm</td>
<td>20.8</td>
<td>9.0</td>
</tr>
</tbody>
</table>

Precautions/Cautions

- The device will perform as intended when the instructions are followed accordingly.
- A re-infusion of completely releasing the lock, or forcibly releasing the lock may damage the integrity of the device.
- Examine individual package for integrity prior to use. If packaging has been damaged, do not use.
- Any used needle is considered contaminated. Discard all sets used together with the holder in biohazard containers approved for their disposal.
- Do not forcefully release or re-activate the safety mechanism after it has been activated.
- Keep hands behind needle at all times during use and disposal.
- Do not bend the needle.
- Do not use for indiscriminate infusion or injection.
- Handle all biological samples and blood collection “sharps” (lances, needles, Luer adapters, and blood collection sets) according to the policies and procedures of your facility.
- Obtain appropriate medical attention in the case of any exposure to biological samples (for example, through a puncture injury), since they may transmit HIV (AIDS), viral hepatitis, or other infectious disease.
- Avoid blood leakage and any air in the tubing during infusion procedure.
- A reuse of the product may cause harmful infections, injury or death.
- Transcribe every patient’s blood type and Rh factor. Special care has to be taken when used on pregnant or nursing women or children.
- Caution must be taken when collecting blood samples from immobile, hemaphilic or epileptic patients, for example. 
- Every used needle and tubing should be placed in a biohazard container the moment removed.
- Never cover the safety mechanism with adhesive tape.
- Make sure air is removed by priming prior to use as short-term IV infusion device.
- Please use each device for either blood collection or infusion but not for both.

Storage of SAFETY Blood Collection Sets before use

Store the SAFETY Blood Collection Sets at 4°C–30°C (40-98°F). Keep from direct or indirect light. Exceeding the maximum recommended storage temperature may lead to impairment of the SAFETY Blood Collection/Infusion Set quality.

Label Information

- Date Format: Product can be used until the end of the month indicated.

Example 1

- An audible click is heard when the safety mechanism has been correctly activated. The needle will be completely retracted into the body of the device. Verify that the safety mechanism is securely locked.

Example 2

- The device will perform as intended when the instructions are followed accordingly. 
- When the blood collection/infusion has been completed, it is recommended to activate the safety mechanism while the SAFETY Blood Collection/Infusion Set is still in the patient’s vein.
- Apply gentle pressure to the puncture site using the gauze pad according to facility protocol.
- After completion place gauze over collection site without applying pressure.
- Use the device for either blood collection or infusion but not for both.

Example 3

- Do not forcefully release or re-activate the safety mechanism after it has been activated.
- Keep hands behind needle at all times during use and disposal.
- Do not bend the needle.
- Do not use for indiscriminate infusion or injection.
- Handle all biological samples and blood collection “sharps” (lances, needles, Luer adapters, and blood collection sets) according to the policies and procedures of your facility.