



Instructions for Use
for
SafeBreak[®] Vascular

PRODUCT DESCRIPTION:

SafeBreak® Vascular is installed in-line with the infusion set to stop fluid flow when excessive tension comes across the intravenous (IV) and intraosseous (IO) administration line (“administration line”). No matter the access device type, SafeBreak® connects with one standard male and one standard female luer between the administration tubing and the patient’s access device. When excessive force is applied to the administration line, SafeBreak® Vascular separates at a force lower than the force required to dislodge a catheter or disrupt a securement dressing (1-5 lbf). When SafeBreak® Vascular separates, fluid flow is stopped from the infusion pump and blood flow is stopped from the patient’s catheter. SafeBreak® Vascular may be used for a maximum of seven days.

INDICATIONS FOR USE / INTENDED USE:

SafeBreak® Vascular is intended to separate when excessive tension is exerted across intravenous (IV) and intraosseous (IO) administration sets. When SafeBreak® Vascular separates, fluid flow is stopped from the infusion pump and blood flow is stopped from the patient’s IV or IO catheter.

SafeBreak® Vascular is intended to aid in reduction of IV and IO mechanical complications requiring IV and IO replacement.

SafeBreak® Vascular is intended to be used on peripheral IV catheters, midlines, peripherally inserted central catheter (PICCs), central venous catheters (CVCs), IV ports and port needles, and IOs in adults and pediatric populations two (2) weeks of age and older receiving intermittent or continuous infusions with an electronic pump.

PEDIATRIC CONSIDERATIONS:

- Choking hazard – discard small parts such as end caps and check area for potential hazards.
- Be aware of the potential risk of strangulation with the associated IV or IO tubing and, as much as possible, take appropriate measures to keep the tubing away from pediatric patients, especially the head and neck.
- Not for use with umbilical vessel catheters.
- Skin integrity is important. Exercise caution when applying or removing securements, given the fragility of the skin, particularly in neonates and infants.
- Ensure proper securements appropriate for pediatric use and for each anatomical site and route of administration.
- Assess luer connections prior to use and after disconnections and separations to ensure integrity is maintained.
- Ensure all packaging and unused contents are properly discarded.
- Make sure no needles, instruments, etc. are left in the vicinity of the child.
- Discourage tugging, pulling, or tampering with the device. Educate children and adolescents who are able to understand consequences.
- Follow precautions for prevention of air emboli. Risk increases with multiple lumens.

CONTRAINDICATIONS:

- Not for use in patients less than two (2) weeks of age.
- Not for intra-arterial use.
- Not for use in-line during the transfusion of blood, blood products or biologics.
- Not for use with power injection systems or high-pressure infusion systems.
- Not for use with feeding systems (e.g., nasogastric and gastrostomy tubes, etc.).
- Not for use with contrast media.

WARNINGS:

- **Any delays in therapy due to SafeBreak® Vascular separation, including SafeBreak® Vascular exchanges, during infusions of medications with short half-lives, may impact patient safety.**
- **In case of medical emergency (e.g., in critically ill patients, code blue), consider the risks of unidentified separations.**
- Do not attempt to reconnect a separated SafeBreak® Vascular back together.
- Do not use SafeBreak® Vascular during infusions higher than 999 mL/hour or lower than 1 mL/hour.
- Failure to properly prime SafeBreak® Vascular can result in air embolism which can lead to death. Do not leave any air in the IV or IO tubing or SafeBreak® Vascular.
- SafeBreak® Vascular may not separate if the securement dressing is not correctly placed or if it is not adhering to the patient skin adequately (e.g., diaphoretic skin, inadequate adhesive, etc.).
- Use aseptic techniques whenever installing or removing SafeBreak® Vascular.
- Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. Do not use if original packaging for SafeBreak® Vascular is compromised, torn or damaged or the expiration date has passed.
- Sterilized by ethylene oxide. Do not reuse, reprocess, or re-sterilize SafeBreak® Vascular.
- Once SafeBreak® Vascular device has separated, the separated components should be removed immediately. If the separated components have been on the IV or IO administration tubing and/or needleless connector for longer than two (2) hours, replace the entire infusion set (e.g., IV or IO catheter, extension tubing, needleless connector, and IV or IO administration tubing.).
- Not for use with needles (except indicated port needles), blunt cannula systems, luer connections with visible defects or non-ISO 80369-7 luer connections.
- SafeBreak® Vascular should not be used for any type of fluid administration other than intravenous or intraosseous (e.g., not for use with feeding tubes, drains, etc.).
- Not for use with umbilical vessel catheters.
- Not for use with gravity IV infusions.
- Do not use SafeBreak® Vascular as an end cap. When infusions are temporarily stopped, SafeBreak® Vascular may be left attached to the administration set and must be protected with an endcap per hospital protocol. Alternatively, SafeBreak® Vascular may be completely removed and discarded as described in the “Removal of an intact SafeBreak® Vascular section.” Do not leave an intact SafeBreak® Vascular attached to a patient’s IV or IO access (e.g., needleless connector).
- Do not attempt to withdraw blood or fluids through the device. SafeBreak® Vascular contains a one-way valve.
- If the IV or IO administration line or access device luer is intentionally disconnected from SafeBreak® Vascular for any reason, ensure that SafeBreak® Vascular’s luer connections are scrubbed for 15 seconds and the device is fully primed before reconnecting the administration line to SafeBreak® Vascular and infusing fluids again.
- It is important to monitor and inspect the IV or IO administration line per each institution’s normal IV or IO inspection/rounding requirements. Replace SafeBreak® Vascular according to the facility’s administration tubing change protocol, or at least every 7 days.
- Do not attempt to connect either end of a separated SafeBreak® Vascular to a luer connection.
- If an IV or IO catheter dislodges and SafeBreak® Vascular did not separate, discard the SafeBreak® Vascular device and replace the entire infusion set (IV or IO access device and IV or IO administration line) per hospital policy.

PRECAUTIONS:

- Carefully read and follow all instructions prior to use.
- Do not connect SafeBreak® Vascular to another SafeBreak® Vascular. SafeBreak® Vascular is not designed to have multiple SafeBreak® Vascular devices attached to one another.
- If tape is placed across SafeBreak® Vascular or the device is tampered with, the device's ability to separate may be impeded and dislodgement of the IV or IO catheter may occur.
- Exercise care with securements and consider adverse effects on the skin- assess skin integrity before installation and during removal, particularly in children and patients with fragile skin.
- SafeBreak® Vascular is not a needleless connector.
- SafeBreak® Vascular may not separate appropriately if adhesive is placed across or on the device, a patient lies on SafeBreak® Vascular or other objects are resting on SafeBreak® Vascular.
- Leaving an excessive amount of IV or IO administration line between the adhesive or securement device on the patient and SafeBreak® Vascular could cause the IV or IO administration line to recoil upon separation, potentially causing injury.
- SafeBreak® Vascular may not separate if any knots are in the IV or IO administration line. Do not tie any knots in the IV or IO administration line.
- If any leakage of fluid is experienced from or around the connections to SafeBreak® Vascular, stop the infusion, discard the existing SafeBreak® Vascular and install a new SafeBreak® Vascular following the normal installation procedures.
- If SafeBreak® Vascular becomes unintentionally disconnected at either of the luer connections but it has not separated into two pieces, stop the infusion and discard SafeBreak® Vascular. Install a new SafeBreak® Vascular according to the installation instructions. Assess whether or not the IV or IO tubing or IV or IO access device should be replaced.
- If SafeBreak® Vascular separates and the infusion needs to be urgently restarted before a replacement SafeBreak® Vascular is available, remove the separated SafeBreak® Vascular components from the IV or IO administration set and patient IV or IO access sides and connect the IV or IO administration set directly to the patient's IV or IO access, as per hospital policy and procedures.
- Do not attempt to rejoin separated or partially separated SafeBreak pieces with any adhesive tapes or other entity.
- Avoid use with rapid infusers, or power injectors that have not been studied with this device.
- The device has not been evaluated with total parenteral nutrition applications.
- Avoid erroneous connection to other devices with tubes.
- Assess luer connection integrity prior to use.
- Improper placement of SafeBreak® Vascular between the catheter and a needleless connector could alter the displacement characteristics of the needleless connector (e.g., positive or negative displacement). If using a needleless connector, SafeBreak® Vascular should be installed in-line between the needleless connector and the IV or IO administration tubing (see **Figure 6** and **Figure 7**).
- When SafeBreak® Vascular separates and an IV pump is in use, it will cause an occlusion and the pump alarm will sound. There may be a slight delay in the time it takes for the occlusion alarm to sound when SafeBreak® Vascular is installed on the IV or IO administration line.
- If more than five (5) separation events occur within 24 hours, consider discontinuing use of SafeBreak® Vascular and utilizing alternative IV or IO administration line protection measures.
- Federal (USA) law restricts SafeBreak® Vascular to sale by or on the order of a physician.
- For use by licensed healthcare personnel or certified IV or IO infusion personnel.

INSTALLATION STEPS:

Infusion Access Device Preparation

1. Perform proper hand hygiene before each procedure.
2. No matter the infusion device (e.g., PIV, midline, PICC, CVC, IV port or IO), SafeBreak® Vascular connects with one standard male and one standard female luer between the IV or IO administration tubing (“administration line”) and the patient’s access device.
3. Trace administration lines before connection. Verify the administration line being connected to SafeBreak® Vascular is an appropriate infusion therapy line.
4. Don gloves. At the junction of the needleless connector/vascular access device and the IV tubing, aseptically disconnect the tubing and aseptically place the IV tubing end to the side to ensure the male luer connection is not contaminated.
5. Grasp the female luer connection of the patient’s access device and scrub the hub of the luer connection for 15 seconds (**Figure 1**). Aseptically place the access device to the side to ensure the female luer connection is not contaminated. Discard the alcohol pad.



Figure 1.
Scrub the Hub

Connect SafeBreak® Vascular and Prime

6. Open SafeBreak® Vascular by peeling off the lid from any of the corners, as shown in **Figure 2**, and aseptically remove SafeBreak® Vascular from the package.
7. Grasp the luer connection of the administration line. Engage and tighten the threads of the administration line’s male luer connection with the exposed female luer connection of SafeBreak® Vascular until it no longer turns as shown in **Figure 3**. Ensure that the male luer of SafeBreak® Vascular does not become contaminated.
8. Prime SafeBreak® Vascular with infusion fluid until a drop of fluid is visible exiting the male luer connection of SafeBreak® Vascular as shown in **Figure 4**. Ensure infusion is paused or stopped before moving on to the next step.
WARNING: Do not leave any air in the IV or IO tubing or SafeBreak® Vascular.
9. Grasp the previously cleaned female luer connection, as shown in **Figure 1**, of the patient’s access device. Engage and tighten the female luer threads of the access device with the SafeBreak® Vascular male luer connection until it no longer turns as shown in **Figure 5**.



Figure 2.
Open Package



Figure 3.
Connect to pump side tubing



Figure 4.
Prime the Device



Figure 5.
Connect to Patient-Side Tubing

Assess Securement and Administration Line

10. Release all of the clamps in the administration line, if necessary, and re-start the infusion. Check the entire assembly to ensure that the infusion is adequately administering the fluid(s) and that no occlusions or leaks are detected in the administration line.
11. Reinforce the access device with tape, dressing or another securement method per institution's standard practice. Especially for pediatric patients, minimize the amount of tubing that the patient can grab between the secured access device and SafeBreak® Vascular, but still allow adequate flexibility for medical staff to access the luer connection for flushing and direct infusions. Reducing the length of excess extension tubing between the secured access device and SafeBreak® Vascular can be done by either forming a J-loop (typical for PIVs, see **Figure 6**), or circling (i.e., looping the extension tube as shown in Figure 7) excess extension tubing and securing it under the securement adhesive (typical for CVCs and ports).



Figure 6. Example of J-Loop



Figure 7. Example of Circling Tubing

WARNING: Leaving an excessive amount of IV or IO administration line between the adhesive or securement device on the patient and SafeBreak® Vascular could cause the IV or IO administration line to recoil upon separation, potentially causing injury.

REMOVAL of a Separated SafeBreak® Vascular:

Locate Separated Components and Remove

1. Don gloves. Ensure that all of the administration lines are clamped as necessary and the infusion is stopped before proceeding.
2. Locate the separated SafeBreak® Vascular components. Grasp and disconnect the separated component extending from the administration line. Discard the separated piece of SafeBreak® Vascular according to hospital policy. The separated components are shown in **Figure 8**.



Figure 8.
Locate Separated Components

WARNING: Do not attempt to reconnect the separated components, (**Figure 9**).

3. Inspect the luer connection for damage and ensure the administration line luer connection is free of debris. If the luer connection is damaged or visibly soiled, replace the administration line.
4. Aseptically place the IV tubing end to the side to ensure the male luer connection is not contaminated.
5. Grasp and disconnect the other separated SafeBreak® Vascular component from the patient's access device, shown in **Figure 10**. Discard the separated piece of SafeBreak® Vascular according to hospital policy.



DO NOT RECONNECT!
Figure 9.
Do NOT Attempt to Reconnect



Figure 10.
Remove Separated Components
and Dispose

Assess Access Site

6. Inspect the luer connection for damage and ensure the connection is free of debris. If the luer connection is damaged or soiled, replace the patient's access device or needleless connector.
7. Follow standard practice techniques to verify that the patient's access is in place and functional. If needed, replace the patient's access per the institution's protocol. If the access is functional, grasp the female luer connection of the patient's access device and place to the side in an aseptic manner to prevent contamination.
8. Follow the INSTALLATION directions (Shown in **Figures 1-7**) to install a new SafeBreak® Vascular.
CAUTION: If SafeBreak® Vascular separates and the infusion needs to be urgently restarted before a replacement SafeBreak® Vascular is available, remove the separated SafeBreak® Vascular components from the administration set and patient access sides and connect the administration set directly to the patient's access, as per hospital policy and procedures.
9. If a separated SafeBreak® Vascular component will not unthread from the luer connection of the administration line or patient access device, ensure that no adhesives or tape are across the luer connection. Make sure that the separated SafeBreak® Vascular component is clean of all liquids and lubricants and that gloves are clean and dry. Attempt to unthread the SafeBreak® Vascular component again. If SafeBreak® Vascular will still not unthread, it is recommended that the connected portion of the administration line (e.g., catheter, extension tubing, needleless connector, and/or administration tubing) be replaced.

REMOVAL of an intact SafeBreak® Vascular:

Locate SafeBreak® Vascular device in the administration line

1. Don gloves. Ensure that all of the administration lines are clamped as necessary and the infusion is stopped before proceeding.
2. Trace the administration line and find the SafeBreak® Vascular device.
3. Unthread the SafeBreak® Vascular device from the female luer connection of the needleless connector/vascular access device.
4. Unthread the SafeBreak® Vascular device from the male luer of the administration line. Place the male luer connection aside in an aseptic manner to prevent contamination of the administration line.
5. Dispose of the SafeBreak® Vascular device according to your facility's policy.
6. Reassess securements to make sure they are still robust.

SYMBOLS:



Does not contain DEHP
di-(2-ethylhexyl) phthalate



Not made with natural rubber
latex



Do not resterilize; single use
only.



Do not use if packaging is
damaged.



Non-pyrogenic



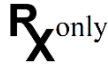
Ethylene Oxide
Sterilized



Expires by



Manufacturer



For prescription
use only



MR Safe



See instructions for use



Reference Number



Lot Number



Caution



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