

Helping Patients Gain the Skills to Self-Administer Medication Safely and Confidently

Onboarding Guide

Welcome to VainSim!

This onboarding guide is designed to walk you through the instructions for use document with additional tips and best practices for utilizing VainSim.

What's contained in each kit:

- VainSim sleeve
- Tourniquet
- Two 10mL syringes of simulated blood
- Five 5mL empty syringes
- Five 23-gauge butterfly needles
- One replacement stopcock
- Sharps container
- Gauze
- Instructions for use
- 1-page flyer
- Terms & conditions



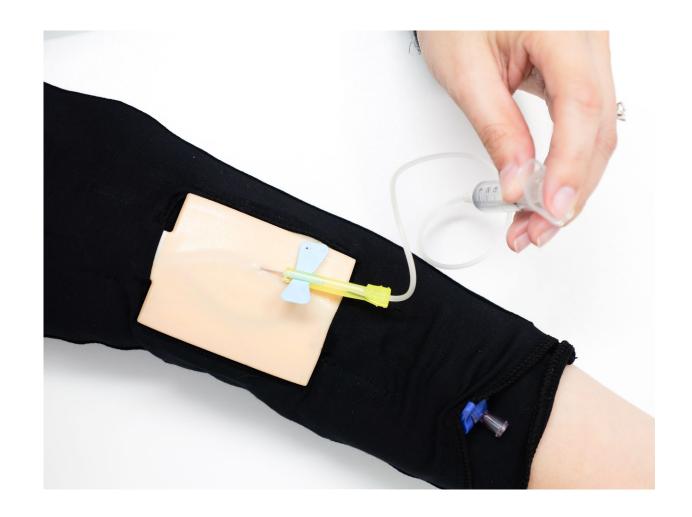




Capabilities

Patients, caregivers, and clinicians can practice and experience:

- Tissue palpation
- Vein location
- Tourniquet application
- Venipuncture (with blood flashback)
- Administration of "medication"
- Pressure releasing





Helpful Information & Links

- To manage or create your account, visit: https://vainsim.com/account
- To watch our instructional video, or download our instructions for use document in pdf format, please visit: https://vainsim.com/pages/faq
- To view our **refund policy**, visit: https://vainsim.com/policies/refund-policy
- To view our terms of service visit: https://vainsim.com/policies/terms-of-service
- If you'd like to **re-purchase materials**, such as extra simulated blood, syringes, stopcocks, tourniquets, or VainSim sleeves, please visit this link: https://vainsim.com/collections/frontpage
- As always, you can contact us with any questions or provide feedback:
 - Email: info@vainsim.com

Please note: Unless an agreement is in place or VainSim has given express notice and approval, you may not re-distribute or re-sell the VainSim devices to third-parties or patients.

With that in mind, let's getting started reviewing the IFU!



Step 1:



- 1. Before using VainSim, make sure to wipe down the surface.
- 2. Unpack the supplies in the kit and lay them out in front of you.

• When learning how to infuse, it is important that the patient wipes down the surface they will be working from with a cleaning wipe (such as Clorox).

**This does not mean clean the device surface.

It is important not to use Clorox or any alcohol products on the device**



Step 2:

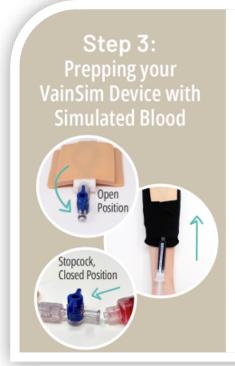


- 1. For the session, fill two separate containers with a quarter (1/4) cup of water each.
- 2. To prepare your practice "medication" for the session, place an empty syringe in one of the containers and pull back the plunger. Fill the syringe with 1 mL of water and set aside.
- In the other container of water, add five drops of synthetic blood and mix until combined. Place another empty syringe in this container and pull back the plunger. Fill the syringe with 5 mL of synthetic blood and set aside.

- If you have a small cup of water near you, you can put 5 or more droplets of fake blood into it. Don't worry, this simulated blood does not stain the skin, surfaces, or if you get it anywhere.
- Once you have the completed putting the droplets in, take your empty syringe, place it inside of the water, and pull back to fill the 5 ml now of simulated blood. Set aside.
- You will have 2 syringes filled after this step one of water (medication) and one of blood.



Step 3:



- Lay the VainSim device on a cleaned surface and locate the stopcock valve with a blue knob on top.
- 2. Open the stopcock by turning the knob 90° to the "open" position (pictured left).
- 3. Take the syringe filled with synthetic blood and twist it onto the opening under the stopcock until it is tight. Do not twist the syringe on too tightly.
- 4. Hold the VainSim device vertically with the end that has the stopcock facing upward.
- Slowly push the plunger on the syringe to fill the VainSim reservoir with the synthetic blood.
- To remove any air, pull back on the syringe slightly until fluid is seen entering the syringe. Gently push the fluid back into the system, avoiding pushing the removed air in.
- 7. Twist the stopcock knob 90° to close the valve. This will seal the device and prevent air from getting inside.
- 8. Unscrew the syringe until it is removed from the stopcock and set it aside.
- First, check to make sure both the stopcock and the reservoir are tightened on the device. If they feel loose, slightly tighten. If you tighten it too hard, the stopcock may break or crack.
- **BEFORE** you start you will want to remove air from the reservoir using an empty syringe. You will do this by opening the stop cock, connecting the syringe, pulling back until no air remains, then turning the stopcock to closed position, and then removing syringe. You can slide the sleeve down to see the reservoir while performing all steps.



Step 4:



- 1. Decide which arm you would like to use to practice with. Slide the sleeve on your arm with the reservoir at the top of the sleeve (pictured left).
- 2. Slide the sleeve up your arm until the skin patch is just under your inner elbow. Ensure the skin patch sits atop your veins to simulate infusion fully.

- If the patient experiences joint issues, such as a bleed, you should carefully slide the device up to the forearm and continue following the provided directions.
- You can sanitize the **inside** of the sleeve in between uses using a standard disinfectant wipe. Do not clean the surface of the VainSim skin.



Step 5:



- 1. Find the quick-release tourniquet in your kit (pictured left). Fasten the end of the tourniquet into the latch to make a loop.
- 2. Slide your arm through the loop and place the tourniquet 2-3 inches above the skin patch. Ensure it sits on top of the VainSim reservoir (pictured left).
- 3. Pull the tourniquet strap to tighten it until it feels like a firm hug or squeeze on your arm. Do NOT pull too tight.
- 4. You can readjust the tourniquet by unbuckling it and releasing it. Repeat these steps until the tourniquet is placed in the correct location and feels comfortable.
- Remember, it is crucial to leave the tourniquet on for a maximum of **3 minutes**. If you are not ready to administer the infusion, wait until the needle is prepared.
- Additionally, when placing the tourniquet on the arm, the reservoir may become stuck inside the connector buckle. If this occurs, you can either adjust or unbuckle the tourniquet to reapply.



Step 6:



1. With the tourniquet in place, press the middle of the skin patch with your finger and locate which vein you want to use. The skin above the vein should be slightly raised, or distended, making the vein easier to locate.

For optimal functionality, it is recommended to infuse in the middle of the device, and at least 1cm away from the top and bottom of the VainSim surface.

2. Dampen a piece of gauze with water and use it to scrub the vein you chose for 15 seconds. Next, allow the area to air dry for 15 seconds. Once you have cleaned the area, do not touch it.

It is essential not to use alcohol on the device to avoid degrading the device surface. When you are learning how to infuse on yourself, you will use alcohol to clean your skin.

• Some patients may mistakenly try to poke the center of the device, thinking it's a vein. However, the middle of the device does not contain a vein and functions the same as the skin outside of the veins.

There are only two veins on the device (right and left).



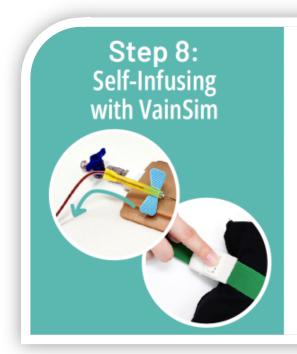
Step 7:



- 1. Locate the syringe you filled with water in Step 2 and a butterfly needle with tubing from your VainSim kit. Carefully open the needle packaging.
- Remove the clear cap at the end of the tubing. Twist the water-filled syringe to the end of the tubing until it is secured tightly.
- 3. To prime the needle, gently press down the syringe plunger so that a small amount of water exits the tip of the needle.
- Remove the safety cap from the end of the needle with care and position the needle so that the bevel, or opening, faces up.
- 5. Grasp the blue "wings" of the butterfly needle with your thumb and index finger on the textured underside and pinch them together until you have a firm grip on the needle.
- Ensure to prime the needle prior to infusion. An unprimed needle can negatively affect the flashback or insert air into the system.
- For optimal functionality, use a new needle for each infusion. Re-using needles can plug the needle with material, potentially causing resistance to infusing.
- Aim for the middle area do not pierce within 0.5 inches of the top or bottom of the skin surface



Step 8:



- 1. Hold the needle at a 30° to 45° angle relative to the location on the skin patch you chose.
- 2. Puncture the skin patch quickly and confidently, reduce the angle of the needle, and advance (or "thread") the needle further into the vein.
- 3. You should see a small amount of synthetic blood in the needle tubing.

 This is called "flashback". If you don't see a flashback, you missed the vein.

 That's okay—try again!
- 4. You may also feel a "pop" when the needle enters the vein. This is due to the pressure change from the needle penetrating the vein. The resistance on the needle decreases once the needle enters the vein.
- 5. Once you have seen flashback in your needle tubing, push the button on top of the tourniquet to release it. Remove the tourniquet from your arm.
- If you push the needle too far past the vein, there will be a tiny bit of flashback, and then you will
 not be able to infuse. If this happens, pull back the needle back a small amount and try again.
 Ensure to insert the needle in line with the vein direction.
- If you infiltrate, liquid will bubble up under the skin. Simply place the needle where the infiltration happened and pull back on the syringe to remove the liquid.
- The reservoir can hold up to 15mL of liquid but should not exceed 10mL for optimal functionality.



Step 9:



- 1. Slowly push down the syringe plunger to simulate infusing your "medication," making sure the syringe plunger is pointing up. Infusing the medication should not feel difficult. If it does, see the troubleshooting section.
- 2. Halfway through the infusion, slowly pull the plunger back and look for synthetic blood to enter the tubing. After checking for this, push down on the plunger again to continue infusing until the syringe is empty.
- 3. Grasp the needle by the "wings" again and slowly pull it away from the skin patch. After the needle exits the device, a small amount of synthetic blood will appear on the surface. Hold a piece of gauze to this area for 10 seconds. VainSim will self-heal and be ready to use again in two minutes.
- 4. Dispose of the needle, tubing, and syringe in the sharps container. Be careful not to touch the tip of the needle.
- To retract the needle, pull back the butterfly wings. The needle will go inside the yellow piece.
- If you want to keep your syringe, now is the time to disconnect the needle. To do so, turn the connector on the luer of the syringe to remove the needle.
- Discard any remaining 'medication'. You can store the syringes for re-use, but do not re-use needles.



Step 10:

Step 10: Practice

- 1. Repeat these steps as often as you would like to continue building your confidence in self-infusion.
- 2. As you continue to practice, ensure the total volume in the system does not exceed 10 mL (or 5 "medication" infusions). You can use an empty syringe to drain fluid from the stopcock when in the open position. Try to rotate poke locations to ensure optimal functionality.
- 3. It is recommended to replace the VainSim device after 30 total infusions or if the device is past its 1 year expiration date on the bottom of the box.
- To remove fluid from the device, once you believe you have reached 10 mL, connect an empty syringe to the stopcock, open the stopcock, and withdraw 5 mL. Ensure no air bubbles are in the reservoir. You can discard this fluid from the syringe after use.
- If you notice functionality issues after 30 infusions with your device, it may be time to replace it. While the devices have been rigorously tested to withstand 50 infusions, some devices may last much longer, depending if infusion locations are rotated properly.



Keep Practicing!



When you are finished practicing, make sure to remove all fluid from the device. To do so, screw an empty syringe onto the stopcock valve until tight. Open the stopcock by turning the knob 90° to the "open" position and pull back on the syringe plunger to remove all synthetic blood from the device. Close the stopcock by turning it 90° and unscrew the syringe from the valve. Store the synthetic blood elsewhere for future use. Now your device is empty and ready to store for use later.

- Practice as much as needed until confidence is established to self-infuse.
- When done practicing, ensure the device is stored with no fluid in the system with the stopcock open to maintain the product. It is recommended to practice every few months to brush up on the skills necessary to self-infuse.



Troubleshooting Guide

TROUBLESHOOTING:

- * If you see any air bubbles in the reservoir, turn the device upside down, reservoir now at the top, and slightly pull back the syringe to remove the bubbles. You will see a slight amount of simulated blood go back into the syringe, that is okay. You will now lock your stopcock, see step below.
- * Before you remove the syringe from the VainSim device, you must lock the stopcock. To lock the stopcock, turn the handle towards the left.
- *If you 'miss' your VainSim vein and inadvertently infuse the VainSim skin elsewhere, the skin patch will bubble up near the syringe insert. This is called 'infiltration'. If this occurs, pull back on the syringe to remove the water.
- *If the needle stops completely, this likely means you have pushed too far, and the needle is hitting the backing behind the device. Do not push any further.
- If there is needle occlusion / no flashback, switch out the needle and flush the system.
- If the stopcock cracks, hold the device with reservoir towards the ground, remove broken stopcock, attach new stopcock by twisting the spinning connector tightly, attach a syringe, and remove any air from the system.
- If the skin is not healing, hold gauze pressure to the location for a minute. Additionally, there may be too much volume in the system, so attempt to remove some fluid and check if the leak persists when pressure is applied by the tourniquet. If the leak persists, the skin surface may be damaged from needle mis-use or over-use. The device may still function in other vein locations.
- If a fluid leak is noticed in the sleeve, check the reservoir or connector attachments to ensure everything is secured tightly. If the leak persists, check the back of the VainSim device for cracks.
- If there is resistance filling the system, ensure the tubing is not kinked and the stopcock is open. Attempt to flush the system by removing fluid and other materials that may impede fluid flow.
- Check if tubing is kinked
- If there are loose strands on your sleeve, use scissors to cut loose ends, and do not pull the strands.



Additional Tips and Safety Information

SAFETY WARNINGS:

SAFETY CAUTION: Do not apply tourniquet for more than 3 minutes. If at any time the tourniquet feels too tight, push the button on the tourniquet to release it.

- * Do not touch the needle, the open end of the butterfly tubing or the tip of the syringe.
- * Dispose your needle into the sharps container that is provided.
- * All equipment should be handled with care.

- * Do not wipe down the VainSim surface with alcohol wipes.
- * Do not put VainSim in the washing machine.
- * Carefully place all used syringes and needles for disposal in the Sharps Container. DO NOT PLACE IN TRASH OR RECYCLE.
- * Contact your healthcare provider with any questions.
- When pulling back for flashback, just re-infuse the flashback to keep volume in the system constant (i.e. do not infuse your 'medication').
- Replace the needle after each pierce. If the needle locks to the syringe, dispose of both the needle and syringe.
- Do not pierce within half an inch of either end of the skin surface.
- Do not bend or twist the skin surface.
- Do not wash or put the device in the washing machine.
- Do not use VainSim on users with open wounds or broken skin.
- Keep kit components out of reach of children without supervision.
- Wash hands before and after use. Do not ingest any fluid.
- Ensure proper sleeve placement on arm to ensure the reservoir is not pinched.





The Impact of Infusion Education





Thank You

If there are any questions, please reach out to info@vainsim.com.