BayCuff™: Self-infusion training made simple
Introduction to the program

Welcome to the BayCuff™ self-infusion training program. By now you’ve spoken with your healthcare provider about self-infusion. Learning to self-infuse with factor VIII (FVIII) is a very important step that will help you to become more independent and confident. You’ll learn how to practice self-infusion with BayCuff™ before infusing into your own veins. After you practice with BayCuff™, you’ll be ready to infuse yourself.

Note: Before you use these instructions, you may want to view the video that accompanies this program.

This booklet contains
- An introduction to the program
- Features of BayCuff™
- A guide to self-infusion training with BayCuff™

BayCuff™

BayCuff™ is designed to help you learn how to self-infuse. It can be worn either on the hand or on the arm, and attaches with two Velcro® straps. The cuff has a "window" that represents your skin, with a tube that looks like a vein underneath that you will practice injecting into. This tubing vein is even filled with a red liquid meant to simulate blood. It will enable you to see the effect of a "flash-back"—a flash-back is when you’re successful in accessing a vein. Note that this red liquid is non-toxic and washable; it is for training only and is not to be infused or ingested.

It is natural to feel nervous about learning to self-infuse, but as you practice with BayCuff™ you will gain the skills, knowledge, and confidence that will make self-infusion much less daunting.

A protective plate that comes as part of your BayCuff™ has been designed to help stop you from hurting yourself when you practice. BayCuff™ is designed so you can practice as many times as you need, until you feel confident enough to infuse for real.

Remember what you are trying to achieve as you work through the program—all your hard work will pay off! When you are ready to self-infuse, always follow the reconstitution and administration instructions for your factor.

For additional Important Safety Information, please see page 17.

For important risk and use information, please see full Prescribing Information enclosed.
Features of BayCuff™

BayCuff™ is designed such that it can be placed
■ On the hand, or
■ On the arm (Figure 1)

The features of BayCuff™ that make practicing self-infusion as realistic as possible (Figure 2) include
■ A window that represents your skin
■ A tubing vein that can be felt through the "skin" into which you insert the needle
■ Simulated blood in the tubing vein that mimics the flashback effect you see when you are infusing for real

Figure 1. The two positions of BayCuff™.

Self-infusion training with BayCuff™

I. Set-up and precautions

A. Wash your hands thoroughly.

B. Collect all the items you will need to practice self-infusion with BayCuff™ before you begin.
   The following items are included with your BayCuff™ kit (Figure 3):
   ■ BayCuff™ tote bag
   ■ A tourniquet (a strap that fastens around your arm, to make your veins easier to see)
   ■ BayCuff™ (with protective plate)
   ■ Four prefilled syringes containing water
   ■ Four plunger rods
   ■ Ten tubing veins
   ■ Ten butterfly needles
   ■ Ten alcohol swabs
   ■ Ten dry pads
   ■ Instructional video

Items not included in your kit that you will need are:
■ Surgical tape
■ Sharps container
■ Scissors (to customize your BayCuff™)
■ Trash bin

C. Go to a clean, well-lit area where all of the above items are easily within reach.

D. Do not open the silver bag of tubing veins until you are ready to begin, since the water inside can evaporate with prolonged exposure.

Figure 3. The components of your BayCuff™ kit.
II. Personalizing your BayCuff™

You will only need to complete this section the first time you use your BayCuff™. Your BayCuff™ has been supplied with longer fastening straps than you will need.

A. Put your BayCuff™ on the arm (not the hand position) as shown in Diagram 1.

B. Use the scissors to cut the extra straps, leaving about an inch of overlap as shown in Diagram 2.

III. Preparing your BayCuff™

A. Remove the protective plate from your BayCuff™ (Diagram 3).

B. Open the silver bag and take out a tubing vein. Check the tubing vein for bubbles (Diagram 4). If there are any bubbles, hold the tubing vein with the collection bag up, take the blue clamp off and with your fingers, gently flick the air bubbles up until they are gone. Then, slide the clamp back onto the tube.

C. Holding the plate as shown in Diagram 5, gently squeeze the sides of the plate to open the groove.
D. Place the tubing vein above the open groove and press into place (Diagram 6). The flat end of the tubing vein should be matched with the end of the plate. The clamp should be approximately one inch from the plate edge.

E. Insert the plate with tubing vein back into the cuff. The flat end of the tubing vein should be at the bottom of the cuff (see Diagram 7). Close the Velcro® opening of the pouch.

IV. Self-infusion training: BayCuff™ hand-use method

If you are right-handed, you should put the tourniquet and BayCuff™ on your left hand (and vice versa).

A. Put the tourniquet on loosely, two inches above the wrist, with the strap release on the inside of your arm as shown in Diagram 8.

B. Place BayCuff™ on the back of your hand with the tubing running up your arm. Make sure that you can still see your knuckles (Diagram 9).

C. Attach the straps so that they have a snug but comfortable fit (Diagram 10).

**PLEASE BE AWARE**
The BayCuff™ Self-Infusion Training Program contains actual needles. It is recommended that patients initially use BayCuff™ with the assistance of a parent or healthcare professional. The kit should be kept out of reach of small children unless supervised by a parent or guardian.

There are two locations where you may place BayCuff™: over the back of your hand (hand-use method) and on the inside of the bend in your arm (arm-use method). The following instructions will be for the hand-use method first, and then for the arm-use method. You should practice at both locations as you may need to rotate infusion sites when you begin to inject into your own veins.
Prefering the syringe

D. Remove the tip cap from the syringe (Diagram 11). Attach the plunger rod to the syringe by screwing it in a clockwise direction. Return the prepared syringe to its original packaging.

E. Take the butterfly needle out of the packaging and straighten the tubing by running your fingers down the length of it (Diagram 12). Remove the dry pad from its packaging, and then tear open the alcohol swab so that it is ready to use. Remove the trash from your workspace. Finally, prepare a piece of surgical tape that’s about 1.5–2 inches long. Attach it to the edge of the table.

Inserting the needle

F. Make a fist with your hand (Diagram 13).

G. Palpate (feel) for the tubing vein within the target window (Diagram 14).

H. Swab the target area with the alcohol swab and let it dry (Diagram 15).

I. After removing the protective cap, hold the butterfly needle by the wings, with the textured sides together (Diagram 16).

BayCuff™ has a target window located over the protective plate. The needle should only be inserted into this area.
Self-infusion training with BayCuff™

J. Slowly insert the needle into the target window, and penetrate the tubing vein (Diagram 17).

K. It is important that the angle of insertion is very shallow. The needle should be almost parallel with the window (Diagram 18).

L. Once you have successfully penetrated the tubing vein, you should see the flash-back effect. This is the red dye from the tubing vein entering the butterfly tubing (Diagram 19). It shows that you have successfully accessed the tubing vein. If the insertion is unsuccessful, remove the needle from the window and replace the tubing vein in your BayCuff™. Try again with another insertion. In a real infusion situation, never reuse a needle.

M. Carefully secure the butterfly needle in place with the surgical tape (Diagram 20).

N. Release the blue clamp to open the tubing vein (Diagram 21), and release the tourniquet.

O. Screw the syringe into the butterfly luer lock in a clockwise direction (Diagram 22).
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P. Press the plunger rod down slowly to infuse (Diagram 23). When you have completed the infusion, remove the surgical tape without disturbing the butterfly needle. Follow the same instructions, and pace as if you were actually infusing your prescribed treatment product.

Also, in a real infusion situation, you will attach the syringe to the butterfly set and prime the butterfly tubing with your medication before sticking yourself with the needle.

Q. With the dry pad over the needle, slowly pull the needle out of the tubing vein (Diagram 24). Flip the needle shield into place to cover it. Apply pressure at the puncture site. When you begin self-infusing with actual product, you’ll need to apply pressure for three minutes and then apply an adhesive bandage.

Completing the process

R. Place the butterfly needle and syringe in a sharps bin. Take off your BayCuff™, open the cuff pouch, and remove the protective plate. Grasp the tubing vein (not the collection bag) and in a smooth motion, pull it out of the groove as shown in Diagram 25. Dispose of the used tubing vein in the trash bin.

V. Self-infusion training: BayCuff™ arm-use method

If you are right-handed, you should put the tourniquet and BayCuff™ on your left arm (and vice versa).

A. Apply the tourniquet loosely to the upper arm, above the elbow (Diagram 26).

B. Fasten your BayCuff™ over the inside of the elbow with one strap above the elbow and one below (Diagram 27).

C. Prepare the syringe as previously described (Page 10). Keep your arm straight and relax your shoulder. You can put a rolled-up towel or t-shirt under your elbow for support (Diagram 28).
D. Feel for the tubing vein within the target window. Clean the target area with an alcohol swab and let it dry. Insert the needle as previously discussed into the target window, and penetrate the tubing vein (Diagrams 29 and 30). Follow the steps outlined in the hand-use method from letter L to complete the process. Don’t forget to keep your arm straight during the entire process.

**INDICATIONS**
- Kogenate® FS antihemophilic factor (recombinant) is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A.
- Kogenate FS is used to prevent or control bleeding in adults and children with hemophilia A. Your healthcare provider may give you Kogenate FS when you have surgery. Kogenate FS can reduce the number of bleeding episodes in adults and children when used regularly (prophylaxis). Kogenate FS can reduce the risk of joint damage in children without pre-existing joint damage when used regularly.
- Kogenate FS is not used to treat von Willebrand disease.

**IMPORTANT SAFETY INFORMATION**
- You should not use Kogenate FS if you are allergic to rodents (like mice and hamsters) or are allergic to any ingredients in Kogenate FS.
- Tell your healthcare provider if you have been told you have heart disease or are at risk for heart disease.
- You could have an allergic reaction to Kogenate FS. Call your healthcare provider right away and stop treatment if you get rash or hives, itching, tightness of the chest or throat, difficulty breathing, light-headed, dizziness, nausea or a decrease in blood pressure.
- Your body can make antibodies, called “inhibitors,” against Kogenate FS, which may stop Kogenate FS from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.
- Other common side effects of Kogenate FS are local injection site reactions (pain, swelling, irritation at infusion site) and infections from implanted injection device. Tell your healthcare provider about any side effect that bothers you or does not go away.
- Call your healthcare provider right away if bleeding is not controlled after using Kogenate FS.

You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional important risk and use information, please see full Prescribing Information enclosed.

**Acknowledgment**
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