

PerQseal[®] Elite

INSTRUCTIONS FOR USE

To ensure proper deployment and use of this device and to prevent injury to patients, read all information contained in these instructions

For assistance, contact:
Vivasure Medical customer Service:

Telephone Number (9:00 – 17:00 GMT Mon to Fri)	+353 91 395 440
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Prior to use, the operator must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

Warranty

VIVASURE warrants that this device has been manufactured in a manner consistent with the United States Food and Drug Administration's current Good Manufacturing Practices. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond VIVASURE's control directly affect the device and the results obtained from its use. VIVASURE shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. VIVASURE neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. **VIVASURE assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.**

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Device Description

The PerQseal Elite[®] Vascular Closure Device is a Vascular Closure Device (VCD), designed to percutaneously deliver a bioabsorbable vascular implant (with the presence of an abluminal surface matrix) to seal femoral artery puncture sites following endovascular procedures.

The implant has both intraarterial and extraarterial components. The implant is inserted into the artery through an Introducer-sheath and over a guidewire. The implant is designed to be positioned relative to the arteriotomy and effect a seal.

The PerQseal Elite VCD has a delivery system for the percutaneous delivery of the implant to the arteriotomy. The delivery system has a handle at its proximal end and a flexible shaft, which attaches to the implant at the distal end.

Refer to Figure 1 showing the delivery system and implant, indicating the key features of the PerQseal Elite VCD. The delivery system is designed to ensure single use of the device.

Refer to Figure 2 showing enlarged image of the implant in deployed configuration and identifying each component.

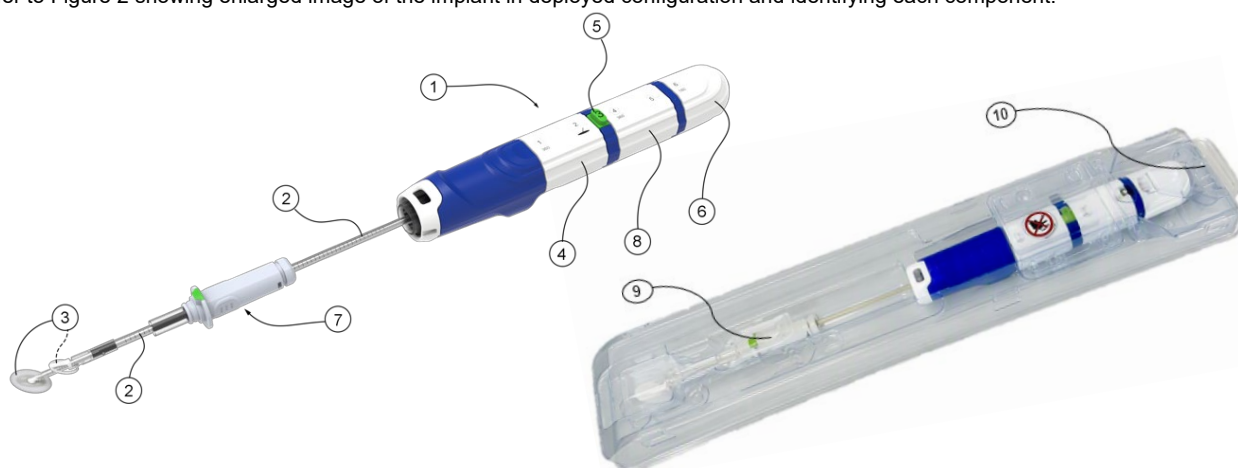


Figure 1. PerQseal[®] Elite VCD

1. Handle	6. Release cam (Back cam)
2. Shaft	7. Loading cannula
3. Implant	8. Fixation cam
4. Sheath cam	9. Funnel lever
5. Cam lock	10. Removable tray lid

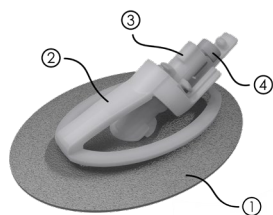


Figure 2. Implant (Deployed configuration)

1. Patch	3. Scaffold
2. External Fixation	4. Guidewire Pin

The *PerQseal Elite* VCD will be used in conjunction with the following:

- PerQseal[®] Elite Introducer (Introducer-sheath and Dilator)
- A 0.035" (0.89 mm) guidewire of minimum length 150 cm – not provided
- 20 ml syringe – not provided

Note: The term 'Device' is defined as the entire VCD system including delivery system, and implant. The term 'Product' is defined as the entire VCD system including delivery system, implant, Instructions for Use (IFU), labelling and packaging.

Implant Composition: < 223 mg Polydioxanone. Polydioxanone is a synthetic, absorbable, low reactivity polymer, degradation of which occurs along the polymer back bone by hydrolysis of the ester bonds. This occurs randomly along the polymer chain cutting the bonds and converting the long polymer chains into (shorter fragments) of natural monomeric acids found in the body. The polymer is thus degraded to non-toxic, low molecular weight residues capable of being eliminated from the body by normal metabolic pathways. The expected lifetime of the implant is ~30 days at which point the intravascular aspect of the implant is expected to be fully encapsulated (no longer in the blood stream) and the implant begins to lose intrinsic mechanical strength and is at the end of its functional life. Total absorption of the implant is expected at 180-days.

This implant has been evaluated and determined to be MR Safe. Patients implanted with this device may safely undergo Magnetic Resonance Imaging (MRI) procedures.

Delivery System Composition: The delivery system materials the patient could be exposed to include stainless steel, nylon, acrylonitrile butadiene styrene (ABS), polyether ether ketone (PEEK).

How Supplied

The packaged device is supplied in the 'PerQseal Elite' procedure pack. Each procedure pack contains the 'PerQseal Elite VCD' in a foil pouch, the 'PerQseal Elite Introducer' in a Tyvek[®] pouch, two separate IFUs for each respective device (PerQseal Elite VCD and PerQseal Elite Introducer) and Quick reference guide. The foil pouch contains a Tyvek pouch which in turn contains the PerQseal Elite VCD, housed in a thermoformed tray. Note the foil pouch is a non-sterile moisture barrier. The PerQseal Elite Introducer pouch contains the Introducer-sheath and Dilator mounted on a support card. **The Tyvek pouches provide the sterile barrier system for their respective contents.** Contents are non-pyrogenic and supplied STERILE. All packaging not contained within the Tyvek pouches is non-sterile. The PerQseal Elite Closure Device is sterilized using an ethylene oxide (EO) process. Please refer to the end of this booklet for graphical symbols for medical device labelling.

Store in a cool, dry, dark place.



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Intended Purpose

The PerQseal Elite Vascular Closure Device is intended for percutaneous common femoral arteriotomy closure following interventional therapeutic endovascular procedures.

Indications for Use

The PerQseal Elite Vascular Closure Device (VCD) is indicated for the percutaneous closure of common femoral arteriotomies in patients following interventional endovascular catheterization procedures utilizing 14 – 22 F sheaths (arteriotomies up to 26 F).

¹ Tyvek[®] is a trademark of DuPont.

Intended Patient Population

Patients who require percutaneous closure of common femoral arteriotomies created with sheath sizes 14 – 22 F (arteriotomies up to 26 F) following interventional endovascular catheterization procedures.

Intended User

The intended users of the PerQseal Elite include, but are not limited to, vascular surgeons, interventional radiologists, interventional cardiologists, cardiothoracic surgeons and angiologists. All users are expected to be medically trained and qualified practitioners who have been trained on the PerQseal Elite device.

Contraindications

There are no contraindications to the use of this device. Attention is drawn to the warnings, precautions, and special patient populations. Furthermore, when used in accordance with these instructions there are no known interactions between the implant material and/or its products of metabolism and other medical devices, medicinal products and/or other substances expected to be used in conjunction with the PerQseal Elite VCD.

Warnings

- Do not use the PerQseal Elite VCD if the patent VCD deployment area of the vessel lumen is less than 7 mm at the narrowest point within the CFA when measured proximal to the proposed access site (in the cephalad direction) to avoid the risk of the implant being trapped within the vessel, intimal dissection, or vessel occlusion, potentially requiring endovascular or surgical intervention. If a stenosis within the CFA reduces the minimum available patent VCD deployment area of the vessel lumen to less than 7 mm diameter, do not use the device.
- Do not use the PerQseal Elite VCD if the puncture site has been made in the profunda femoris artery (PFA), superficial femoral artery (SFA) or located less than 15 mm proximal to the bifurcation of the profunda femoris and superficial femoral artery, since such puncture sites may result in incorrect implant position resulting in a pseudoaneurysm, bleeding, intimal dissection, or vessel occlusion. Perform an oblique femoral angiogram or ultrasound to identify the bifurcation and verify location of the puncture site is within the common femoral artery.
- Do not use the PerQseal Elite closure system if the percutaneous tissue tract is expected to be greater than 8 cm.
- Do not use the PerQseal Elite VCD if the target vessel is very superficial (< 15 mm beneath the skin level).
- Contents supplied STERILE. Do not use if sterile barrier system is damaged.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- Do not use the Product if the packaging has been previously opened or damaged, or if any of the components appear to be damaged or defective. This may result in patient injury, illness or death.
- Discard product if 'Use By date' has passed or 'Use By date' is illegible or labelling is incomplete.
- Do not use the PerQseal Elite VCD if the puncture site has been made proximal to the most inferior border of the inferior epigastric artery (IEA) and/or beneath (sub-inguinal ligament) or cranial to the inguinal ligament based upon bony landmarks, as this may result in retroperitoneal bleeding or hematoma. Perform a femoral angiogram or ultrasound to verify location of the puncture site.

Precautions

- This product is intended for use by physicians experienced in therapeutic endovascular techniques and trained on the use of the device.
- Do not advance, torque or withdraw the PerQseal Elite VCD against excessive resistance. Excessive force used to advance, torque or withdraw the PerQseal Elite VCD should be avoided, as this may lead to significant vessel damage and/or breakage of the device.
- Remove the PerQseal Elite VCD from the patient if it is difficult to reposition to the arteriotomy.
- Remove the PerQseal Elite VCD from the patient if it is difficult to deploy.
- Do not use the PerQseal Elite VCD where bacterial contamination of the procedural sheath or surrounding tissues may have occurred as this may result in an infection.
- Do not use the PerQseal Elite VCD if the puncture is through the posterior wall or if there are multiple punctures, since such punctures may result in retroperitoneal bleeding.
- Do not use the PerQseal Elite VCD if there is a vascular graft or stent within 20 mm of the access site.
- Do not modify the PerQseal Elite VCD.
- As with all percutaneous based procedures, infection is a possibility. Observe sterile techniques at all times when using the PerQseal Elite VCD. Employ appropriate groin management post procedure and post hospital discharge to prevent infection.
- If a patient has had a procedural sheath left in place for longer than 8 hours, consider the use of prophylactic antibiotics before insertion of the PerQseal Elite VCD.
- Do not use the PerQseal Elite VCD subsequent to or in conjunction (in the ipsilateral limb) with any other vascular closure device or techniques, e.g. suturing.
- Do not use the PerQseal Elite VCD in patients who have undergone a percutaneous procedure using a non-absorbable vascular closure device (excluding suture mediated) for hemostasis in the ipsilateral leg.
- Following implantation of the PerQseal Elite VCD, avoid vascular access at the same location within 90 days.
- Consideration should be given to the access site: tortuosity; disease state (including calcification, plaque and thrombus); and arterial diameter relative to the largest sheath size outer-diameter to ensure a successful closure and to minimize vascular complications.

- Excessive extracorporeal compression above the site of implantation may damage the implant and inadvertently cause bleeding.
- Complications associated with use of the PerQseal Elite VCD may require additional intervention, including manual compression, endovascular intervention, surgical repair/surgical closure, and/or transfusion, as clinically indicated. Surgical repair/surgical closure should be considered after less-invasive measures have been deemed insufficient based on the patient's clinical condition and institutional protocol.

Special Patient Populations

The safety of the PerQseal Elite VCD has not been established in the following patient populations:

- Patients with evidence of systemic bacterial or cutaneous infection, including groin infection.
- Patients suffering with known bleeding diathesis, definite or potential coagulopathy, platelet count < 100,000/μL or patients on long term anticoagulants with an INR greater than 2 at time of procedure or known type II heparin-induced thrombocytopenia.
- Patients with evidence of previous groin surgery within the region of the ipsilateral access.
- Patients with severe claudication or peripheral vascular disease (e.g. Rutherford category 3 or greater), documented untreated iliac artery diameter stenosis > 50% or previous bypass surgery/stent placement in the common femoral artery of ipsilateral limb.
- Patients with known allergy to any of the materials used in the PerQseal Elite VCD or PerQseal Introducer.
- Patients who have undergone a percutaneous procedure greater than 8F sheath in the ipsilateral leg, within the previous 90 days.
- Patients who have undergone a percutaneous procedure of 8F sheath or less using a suture mediated closure device or manual/mechanical pressure for hemostasis in the ipsilateral leg, within the previous 30 days.
- Patients who have undergone a percutaneous procedure of 8F sheath or less using an absorbable intravascular closure device for hemostasis, in the ipsilateral leg, within the previous 90 days.
- Patients with evidence of arterial diameter stenosis > 20% or anterior or circumferential calcification within 15 mm proximal or distal to target arteriotomy site.
- Females who were pregnant or lactating or not taking adequate contraceptives.
- Patients with a lower extremity amputation from the ipsilateral or contralateral limb.
- Patients with significant blood loss/transfusion (defined as requiring transfusion of 4 or more units of blood products) during index procedure or within 30 days prior to index procedure.
- Patients with uncontrolled hypertension (systolic blood pressure >180 mmHg or diastolic blood pressure >110 mmHg) at the time of planned vascular closure.
- Patients with systolic blood pressure <90 mmHg at the time of planned vascular closure.
- Patients with an activated clotting time (ACT) > 300 seconds immediately prior to sheath removal or patients where the ACT measurements are expected to be > 300 seconds for more than 24 hours after closure procedure.
- Patients with an acute hematoma >4 cm diameter, arteriovenous fistula, pseudoaneurysm or intraluminal thrombosis at the target access site; or any evidence of arterial laceration or dissection within the external iliac or femoral artery before the use of the PerQseal Elite VCD.
- Patients under the age of 18 years.
- Patients with significant anemia (example: hemoglobin <9 g/dL or hematocrit <27%), within 24 hours prior to procedure.
- Patients with documented left ventricular ejection fraction <20%
- Patients with known existing nerve damage in the target leg
- Patients with renal insufficiency (Glomerular Filtration Rate ≤30 ml/min or baseline serum creatinine >2.5 mg/dl) or on renal replacement therapy
- Patients who are unsuitable for surgical repair of the target leg access site
- Patients with evidence of bleeding around the procedure sheath (VARC type 1/BARC type 2 or higher)
- Patients with difficult dilation during the initial target femoral artery access (e.g., that damages or kinks dilators) while step-dilating up to the large-bore device

Adverse Events & Risks

Complications may occur and may be related to the procedure or the vascular closure. They include, but are not limited to:

- Allergic or foreign body reaction
- Anemia
- Arterial dissection
- Arterial stenosis at the access site
- Arterial thrombus
- Arteriovenous fistula
- Bleeding from the access site
- Bruising at the access site
- Compartment syndrome
- Cutaneous or subcutaneous inflammation at the access site
- Death
- Device malfunction or failure
- Edema related to the access site
- Embolization of the intraarterial implant components
- Embolization of thrombus, calcific debris, tissue, or air
- Hematoma
- Infection
- Inflammatory reaction to the implant material
- Lower extremity ischemia
- Nerve injury
- Numbness related to the access site

- Oozing from the access site
- Pain at the access site
- Partial or complete arterial occlusion
- Pseudoaneurysm
- Pulse deficit(s) at or distal to the access site
- Retroperitoneal bleeding
- Vascular injury, including tear, perforation, or rupture
- Vascular spasm
- Vasovagal response
- Venous thrombus

Serious Incident Reporting

A notice from the user and/or patient that any serious incident has occurred in relation to the device should be reported to the manufacturer and FDA.

PROCEDURE

Exercise care during PerQseal Elite VCD handling to reduce the possibility of accidental device breakage.

Before the primary procedure, utilize pre-procedure CT, angiography, or ultrasound to measure the patent VCD deployment area of the vessel lumen prior to using the PerQseal Elite VCD to ensure the patent VCD deployment area of the vessel lumen is greater than or equal to 7 mm at the narrowest point within the CFA when measured proximal to the proposed access site (in the cephalad direction). If a stenosis within the CFA reduces the minimum available patent VCD deployment area of the vessel lumen to less than 7 mm diameter, do not use the device.

It is recommended to perform angiography in both the Anterior Posterior projection and Oblique projection (Right Anterior Oblique – 30 degrees from the right limb, Left Anterior Oblique – 30 degrees from the left limb) prior to ipsilateral access to identify the bifurcation and ensure that the location of the puncture will be in the common femoral artery at least 15 mm proximal to the femoral bifurcation and at the 12 o'clock position.

Initial access should be performed using either ultrasound or angiographic guided puncture / micropuncture for access via the ipsilateral limb, to ensure a center stick, away from anterior calcification, at least 15 mm proximal to the SFA/PFA bifurcation and access is within the common femoral artery. Doppler ultrasound may be used at the completion of Procedural STEP 2 to ensure implant is correctly positioned juxtaposed to the arteriotomy prior to completing device deployment.

The PerQseal Elite VCD should be used within four hours of opening the foil pouch.

If the PerQseal Elite VCD cannot be positioned juxtaposed to the arteriotomy, due to improper orientation or patient vascular anatomy, or if the proper position of the implant cannot be confirmed, the implant and delivery system should be withdrawn from the patient. Hemostasis can then be achieved by employing good clinical judgement.

Ensure there is no guidewire or sheath/catheter crossing the arteriotomy or within 20 mm distal or proximal to the access site prior to PerQseal Elite use.

Examination of Packaging & Labelling

1. Inspect visually the sterile barrier system (Tyvek Pouch) to ensure there is no damage or breaches of packaging integrity.
2. Check all Labelling to ensure the product is within its use by date.

Opening the packaging

1. Remove the foil pouch from the procedure pack.
2. Inspect the foil pouch to ensure that it has not been breached.
3. Tear open the top of the foil pouch from the side at the notched position.
4. Open the end of the foil pouch and remove the Tyvek pouch.
5. Inspect visually the sterile barrier system (Tyvek Pouch) to ensure no breaches of packaging integrity.
6. While observing aseptic techniques, open the Tyvek pouch by peeling apart the end with the chevron seal (the end with the 'v-shape' seal).
7. The device must be used within 4 hours of opening the foil pouch.
8. Present the exposed tray for aseptic transfer into the sterile field.
9. Have a person in the sterile field remove the tray containing the PerQseal Elite VCD from the Tyvek pouch.

Preparation

1. Insert and position the PerQseal Elite Introducer-sheath over the *in-situ* 0.035" guidewire as per PerQseal Elite Introducer IFU. Ensure at least 50 cm of available guidewire protruding from the Introducer-sheath.
2. Take a note of the number on the graduated scale of the PerQseal Elite Introducer at the skin level (or vessel wall if vessel exposed) when the blood signal first occurs.
3. Ensure that the Introducer-sheath is positioned 4 graduations into the vessel from the blood signal point as per PerQseal Elite Introducer IFU. The Introducer-sheath should be at a low angle, of less than 40° relative to the longitudinal axis of the femoral artery (ideally < 30°).

4. Perform an ACT reading to ensure that ACT is less than 300 seconds.
5. It is recommended to perform an ipsilateral site angiogram to confirm the arteriotomy puncture is within the common femoral artery and to assess presence of:
 - Dissection
 - Stenosis (greater than 20% within 15 mm of the arteriotomy)
 - Perforation other than the access arteriotomy
 - Intraluminal Thrombus

Note: If any of the above is confirmed by the angiogram, do not use the PerQseal Elite VCD.

Tray Loading

- A. With the tray lying flat on the sterile preparation area, fill the recess at the end of the tray (indicated on the tray with “A”) with sterile non-heparinized saline solution (approximately 20 cc) to submerge the implant, Figure 3.

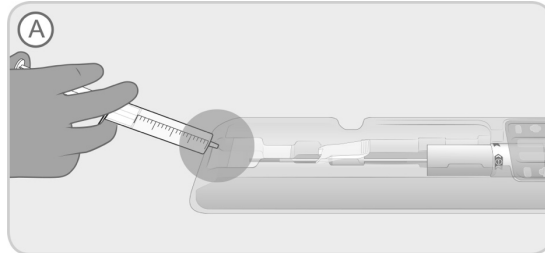


Figure 3.. Fill tray recess with non-heparinized saline.

- B. Pull off the small Removable tray lid, indicated with a “B” on the tray, by lifting the tab as shown in Figure 4 until completely removed.

Note: Do not remove any other lids.



Figure 4. Remove Removable Tray Lid.

- C. Holding the tray steady, grip the rear of the handle (release cam) and pull until a firm stop is reached (indicated on the tray with “C”), Figure 5. The implant is now folded in the loading cannula tube.



Figure 5. Pull device handle back to firm stop.

- D. Flip the funnel lever to a vertical position to release the delivery device from the loading funnel (indicated on the tray with “D” Figure 6.



Figure 6. Flip the funnel lever to release device from tray.

- E. Lifting the Handle End upwards to overcome the stop, continue to pull back and withdraw the PerQseal Elite VCD from the tray.
- F. Visually check the integrity of the implant (within the Loading-cannula); there should be no creases, folds or tears, see Figure 7.



Figure 7. Inspection of Implant (within loading cannula).

- G. The PerQseal Elite VCD is now ready for use.

Note: Use the PerQseal Elite VCD within 30 minutes of completing this step.

Procedural Steps:

Inserting the Device:

- a. Use non-heparinized saline to lubricate the guidewire during insertion. Backload the *in situ* guidewire into the device via the implant within the Loading-cannula, Figure 8, continue to insert the guidewire until it emerges from the rear of the PerQseal Elite VCD handle. Hold the PerQseal Elite Introducer-sheath at a low angle relative to the longitudinal axis of the artery (e.g. 20°) and keep the Introducer-sheath as straight as practical, to avoid kinking.

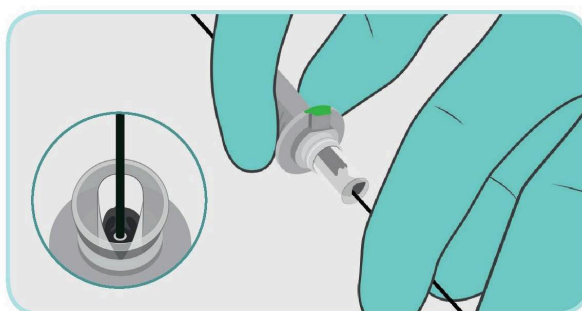


Figure 8. Loading guidewire into device cannula.

First Lock:

- b. Advance the Loading-cannula over the guidewire towards the Introducer-sheath hub. Insert the Loading-cannula into the hub of the Introducer-sheath until fully engaged (using a parallel and concentric orientation). If difficulty is experienced tracking over the guidewire, ensure the guidewire is not kinked and that it is free of coagulated blood and thrombus. The

loading-cannula cap should be fully seated and locked into the Introducer-sheath hub, (with a “click”). The green marking being aligned confirms this step is successfully completed, Figure 8.

Note 1: Hold the guidewire at the rear of the handle during insertion to ensure the device travels over the wire and do not inadvertently insert additional wire into the patient during device insertion/advancement.

Note 2: Only grip the back portion of the Loading cannula during insertion as indicated in Figure 9. Make sure the implant is not protruding from the loading cannula during insertion.

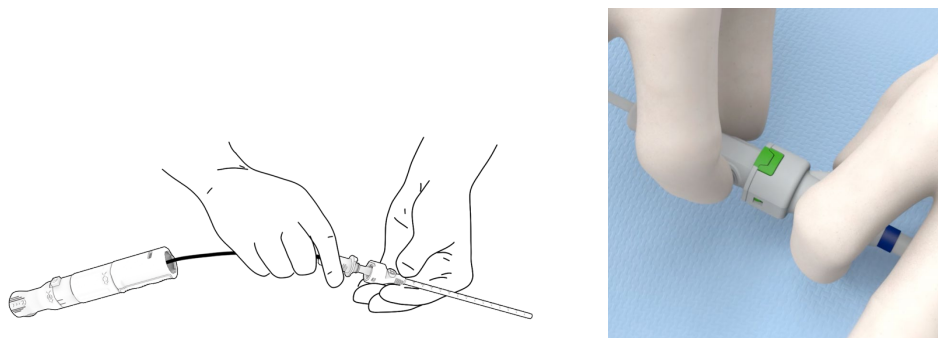


Figure 9. Advance the PerQseal Elite VCD to the Introducer-sheath.

- c. Maintaining the position of the Introducer-sheath and guidewire, advance the device handle to engage with the Loading-cannula cap, this will lock the Loading-cannula cap to the handle (with a “click”), the delivery system and introducer sheath are now one unit, Figure 10. The implant is now positioned within the Introducer-sheath at the tip.

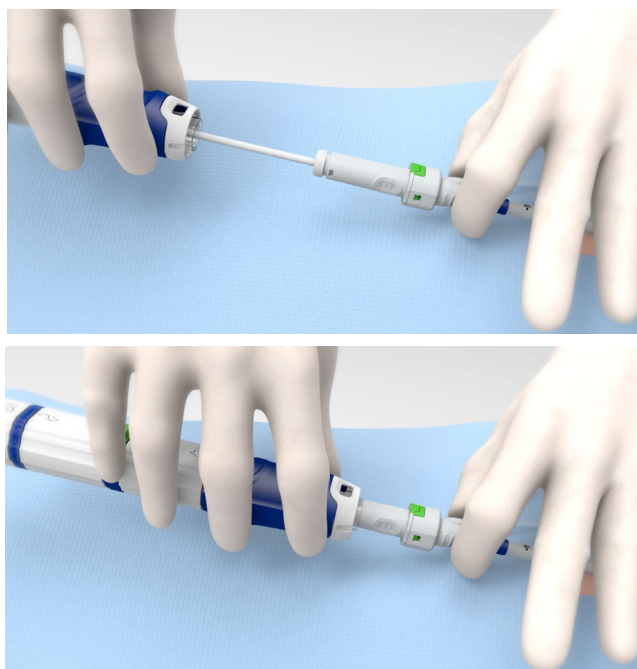


Figure 10. Advance PerQseal Elite VCD handle to engage with Loading-cannula cap.

Device Actuation:

STEP 1 Unsheathing the implant

- a. Rotate the Sheath-cam 360° clockwise (to its non-return stop with a “click”) to withdraw the sheath and expose the implant within the artery, Figure 11.

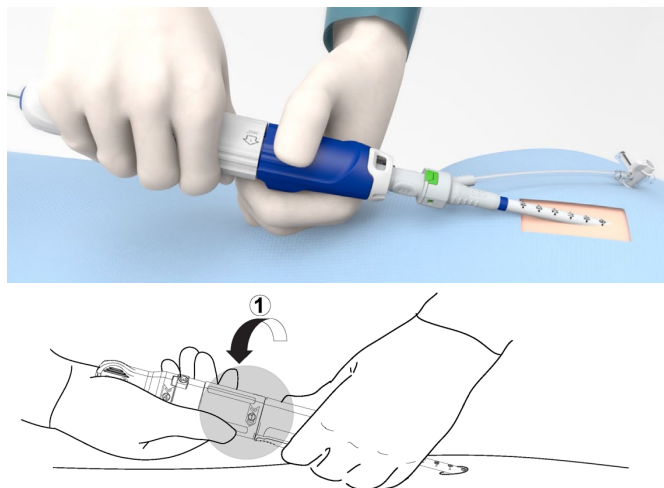


Figure 11. STEP 1 of PerQseal Elite VCD Actuation (*Unsheathing the implant*).

The green mark on the Loading-cannula cap and Introducer-sheath hub will appear in the window on the front of the handle, Figure 12.



Figure 12. Introducer-sheath fully retracted into handle with green marking within handle window.

Note: Ensure the handle does not advance towards the patient during this step and the sheath retracts.

STEP 2 Tamponade

- a. While holding the device handle at its lowest possible angle (≤ 30 degrees), withdraw the delivery system and sheath in a coaxial orientation relative to the vessel (whilst applying light extracorporeal pressure above the access site) until the implant is adjacent to the arteriotomy in the tamponade position. At this point, gentle tactile resistance should be felt as a result of the implant anchoring itself against the inside lumen of the artery wall. This is the tamponade position, and the implant is now controlling the bleeding from the arteriotomy, Figure 13.

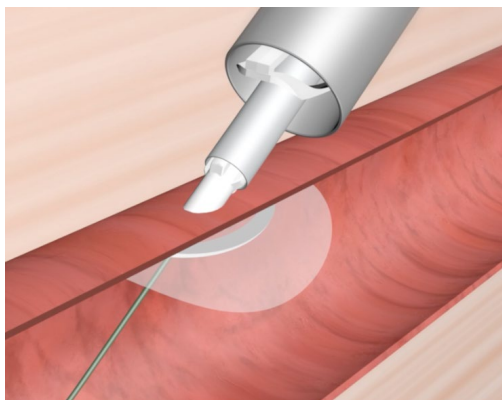


Figure 13. STEP 2 of PerQseal Elite VCD Actuation (*Tamponade*), showing position of implant juxtaposition to the arteriotomy.

Note 1: It is important to confirm the location by gentle resistance of the implant against the arterial wall to avoid the implant being deployed within the tissue tract or fully within the vessel.

Note 2: Avoid excessive tension on the device. Excessive tension on the device will reduce the implant's effectiveness to achieve hemostasis or could result in the implant being pulled out of the arteriotomy.

- b. Slight adjustment of PerQseal Elite VCD position may be necessary to achieve tamponade. Ensure that an acceptable tamponade is achieved before proceeding with deployment.
- c. Open the sidearm three-way tap to confirm tamponade (minimal blood should flow from the sidearm when an acceptable tamponade is achieved).
- d. Use the graduations on the introducer sheath to confirm the position of the implant based on the tissue tract depth. The sheath should be deeper than approximately the depth marker that was used to indicate initial vessel access (when the blood signal first occurred during introducer sheath insertion into the vessel per PerQseal Elite Introducer IFU).
- e. If the position of the implant relative to the vessel wall/arteriotomy cannot be confirmed using steps a-d, use appropriate imaging (i.e. ultrasound or fluoroscopy) techniques to ensure the patch is in tamponade position juxtaposition to the arteriotomy with minimal bleeding from the arteriotomy.

NOTE: If tension is needed to achieve initial tamponade this should be accompanied with counter-tension at the skin level. If the implant is positioned correctly against the lumen, tamponade should be achieved with minimal tension on the device.

STEP 3 Depress Cam-lock

Depress the Cam Lock to release the fixation cam, Figure 14.



Figure 14. Step 3 Depress Cam lock

STEP 4 Fixation

Note: Do not proceed with Fixation step until tamponade position has been confirmed per STEP 2 Tamponade.

- a. Ensure the angle of the device (relative to the parasagittal plane) follows the artery or sheath in its natural lie.
- b. With minimal tension on the device, rotate the Fixation Cam 360° clockwise (to its non-return stop with a “click”) to deploy the External Fixation, Figure 15. Avoid rotation of the handle with the distal grip.

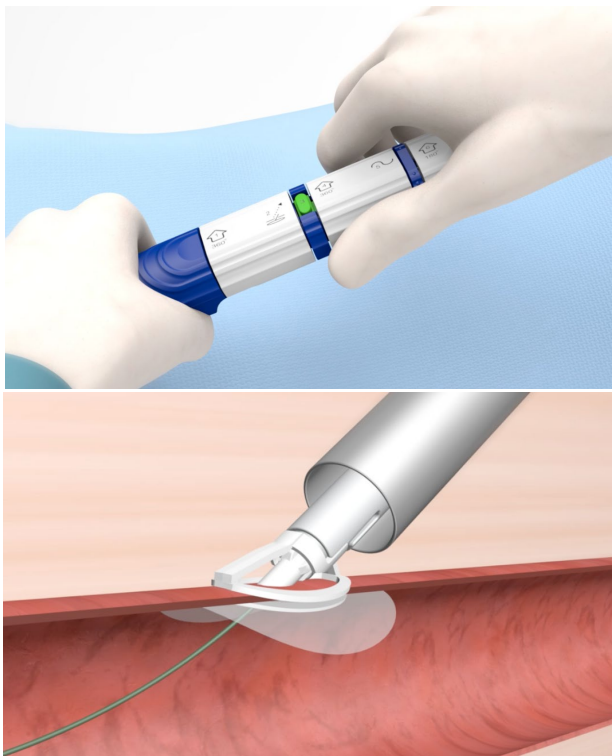


Figure 15. STEP 4 of PerQseal Elite VCD Actuation (Fixation).

STEP 5 Guidewire Removal

Note: Ensure that hemostasis is acceptable before proceeding with guidewire removal.

Remove the guidewire completely from the patient and PerQseal Elite VCD. Guidewire removal may be done by an assistant, Figure 16.

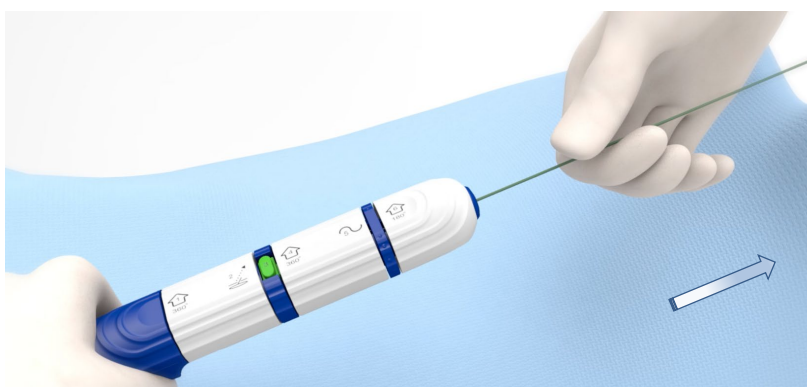


Figure 16. Step 5 Removal of guidewire.

STEP 6 Implant Deployment and Release

- Without delay, once the guidewire is removed, rotate Release Cam 180° clockwise to push home the guidewire pin and release the Implant from the Delivery System, Figure 17. Avoid rotation of the handle with the distal grip.
- Gently withdraw the PerQseal Elite VCD Delivery System & the Introducer-sheath from the tissue tract, Figure 18.

Note: Ensure the hand gripping the distal end of the handle remains fixed and the handle remains stationary without rotation during STEPS 4, 5 & 6.



Figure 17. Step 6 Rotate Release cam.



Figure 18. Removal of deployed device.

- If suitable access is available, an angiogram or color Doppler duplex ultrasound may be performed immediately after PerQseal Elite VCD deployment to confirm arteriotomy hemostasis.

Note: If hemostasis has not occurred, gentle manual compression may be applied proximal to the arteriotomy sufficient to control bleeding. Consult troubleshooting section. It is not recommended to apply manual pressure directly onto the location where implant is situated. Excessive extracorporeal compression directly over the implantation site may damage the implant and adversely cause bleeding.

- Use standard clinical procedures to treat access skin incision.

Post procedural Management

Before considering patient discharge, assess for the following:

- Bleeding from the access site
- Anticoagulation thrombolytic or antiplatelet therapy
- Hematoma at the access site
- Hypotension
- Any condition requiring clinical observation
- Pain, discomfort or transitory local irritation and inflammation at the puncture site
- Local and distal pulse deficits, ischemia.

Trouble Shooting Guide

1. **Cannot insert the loading cannula into the Introducer-sheath hub:**

Ensure that the supplied PerQseal Elite Introducer-sheath is being used and the loading cannula is not damaged. Keep the loading cannula parallel and concentric to the sheath hub during insertion.

2. **Difficult to advance the PerQseal Elite VCD into the Introducer-sheath:**

Ensure that the loading cannula is fully engaged with the Introducer-sheath hub, if not discard the PerQseal Elite VCD and replace with new PerQseal Elite VCD.

3. **PerQseal Elite VCD implant withdrawn from artery during positioning:**

Control bleeding by application of manual compression or inflate an endovascular balloon if *in situ*. Withdraw the PerQseal Elite VCD and Introducer-sheath from the patient, as per Section 1 below (Recommended Recovery Options), ensuring to leave the guidewire *in situ*. Discard the PerQseal Elite VCD and Introducer-sheath and replace with new PerQseal Elite VCD.

4. **Cannot achieve acceptable tamponade during implant positioning prior to deployment:**

- Avoid excessive tension on the PerQseal Elite VCD as excessive tension will reduce the implant's effectiveness to achieve hemostasis and control bleeding.
- Change the angle and/or orientation of the PerQseal Elite VCD (relative to the longitudinal axis of the artery) by using very small adjustments (approximately 5°).
- If acceptable tamponade cannot be achieved do not deploy the PerQseal Elite VCD. Follow the recovery suggestion outlined in Section 1 or 2 below (Recommended Recovery Options).

5. **Difficult to withdraw the guidewire from the PerQseal Elite VCD:**

- Do not force withdrawal of the guidewire.
- Ensure the guidewire is not snagged endovascularly.
- Lower the angle of the PerQseal Elite VCD (relative to the longitudinal axis of the artery).
- If it is not possible to withdraw the guidewire do not deploy the PerQseal Elite VCD and follow the steps outlined in Section 1 or 2 Recommended Recovery Options below.

6. **Hemostasis not achieved post deployment of the PerQseal Elite VCD:**

- Light manual compression may be applied proximal to the implant to control bleeding until hemostasis is achieved.
- Note: It is not recommended to apply manual pressure directly onto the location where implant is situated. Excessive extracorporeal compression directly over the implantation site may damage the implant and adversely cause bleeding.
- Ensure ACT level is below 300 seconds, use clinical judgement and reduce the effects of heparin with agents such as protamine sulphate.
- Coagulating extraarterial agents may be used.
- Temporary use of an endovascular balloon inflated directly beneath the implant may be used (via ipsilateral SFA if other access is not available).
- If bleeding persists or vascular injury is suspected after initial management with manual compression applied proximal to the implant or endovascular balloon angioplasty directly beneath the implant:
 - Evaluate the access site and escalate according to institutional protocol
 - Consider covered stent-graft placement
 - Obtain vascular surgical consultation and surgical repair, if necessary.
- Keep patient under observation until stable.

7. **Difficult to withdraw the delivery device post deployment:**

The device tip may be caught on subcuticular soft tissue. Rotate the device in either direction and try to withdraw.

8. **Guidewire in situ post deployment:**

If the guidewire is still *in situ* post deployment, follow the recovery steps outlined in Section 5 Recommended Recovery Options.

Recommended Recovery Options

1. If it becomes necessary to remove the implant from the artery whilst still attached to the delivery system and prior to the external fixation deployment (Step 4 above) then follow these recommended recovery steps:
 - i) Control bleeding by manual compression or via endovascular balloon inflation proximal to the access site.
 - ii) Ensure Introducer-sheath is withdrawn from the artery (bring device to Step 2 Achieve Tamponade stage).
 - iii) Advance the PerQseal Elite VCD into the artery approximately 10 mm.
 - iv) Rotate the handle 180° **anticlockwise** so that the handle is now facing towards the patient in a downward direction.
 - v) Reduce the device angle to < 20° (or as low as possible) relative to the patient, withdraw the handle to remove the PerQseal Elite VCD and implant from the artery. Ensure the 0.035" guidewire remains *in situ* during withdrawal.
 - vi) Inspect the PerQseal Elite implant to ensure the scaffold and patch have been removed from the patient.
 - vii) Open a new PerQseal Elite VCD procedure pack.
 - viii) Insert a new Introducer-sheath as per PerQseal Elite Introducer IFU.
 - ix) Follow the PerQseal Elite VCD deployment steps outlined above.
2. If it becomes necessary to remove the implant from the artery whilst still attached to the delivery system post the external fixation deployment (Step 4 above) then follow these recommended recovery steps:
 - i. Control bleeding by manual compression or via endovascular balloon inflation proximal to the access site.
 - ii. Ensure Introducer-sheath is withdrawn from the artery (bring device to Step 2 Achieve Tamponade stage).
 - iii. Advance the PerQseal Elite VCD towards the artery and in a cranial direction relative to the arteriotomy as far as possible, approximately 10 – 15 mm.
 - iv. Whilst maintaining pressure on the device in the cranial direction, apply digital pressure proximal to the relative position of the implant to collapse the proximal artery and elevate the device handle and shaft to a vertical position.

- v. Maintain the cranial pressure on the device and reduce the device angle to ~30° relative to the patient, withdraw the handle to remove the PerQseal Elite VCD and implant from the artery. Ensure the 0.035" guidewire remains *in situ* during withdrawal.
 - vi. Inspect the PerQseal Elite implant to ensure the external fixation, scaffold, and patch have been removed from the patient.
 - vii. Open a new PerQseal Elite VCD procedure pack.
 - viii. Insert a new Introducer-sheath as per PerQseal Elite Introducer IFU.
 - ix. Follow the PerQseal Elite VCD deployment steps outlined above.
3. If the implant becomes detached from the delivery system within the artery whilst the Introducer-sheath and guidewire are *in situ* use the following recovery steps to retrieve the implant:
 - i) Withdraw the delivery system and the Introducer-sheath and ensure the guidewire remains *in situ*.
 - ii) Re-cannulate the artery over the 0.035" guidewire
 - iii) Open a new PerQseal Elite VCD Procedure Pack and insert Introducer as per PerQseal Elite Introducer IFU.
 - iv) Remove the dilator.
 - v) Insert an additional 0.035" guidewire to retain access.
 - vi) Snare the original 0.035" guidewire beyond the implant.
 - vii) Withdraw the snare, original 0.035" guidewire and trapped implant into the Introducer-sheath.
 - viii) Ensure the implant is within the Introducer-sheath and remove the snare, original guidewire, trapped implant and Introducer-sheath from the patient, whilst maintaining the position of the second 0.035" guidewire *in situ*.
 - ix) Insert PerQseal Elite Introducer and deploy the new PerQseal Elite VCD as per instructions above.
 4. For recovery of the bioabsorbable implant from within the artery post Introducer-sheath and guidewire removal it is recommended to locate the implant via angiography. Based on the implant's location and the level of perfusion downstream of the implant, use clinical judgement to decide an appropriate strategy for recovery.
 5. If the device has been fully deployed whilst the 0.035" guidewire is still *in situ* use the following recovery steps to retrieve the guidewire.
 - i) Remove the sheath and delivery system from the guidewire.
 - ii) Very slowly increase tension on the guidewire, at the same angle as deployment or approx. 30° to the artery, until movement of the guidewire occurs. Simultaneously apply light extracorporeal pressure slightly distal to the position of the implant.
 - iii) Continue to withdraw the guidewire whilst maintaining light extracorporeal pressure until fully removed.
 - iv) Inspect the guidewire to ensure the entire guidewire has been removed from the patient.
 - v) Expect some bleeding from the guidewire port in the implant. This can be managed by applying sufficient manual compression to control bleeding. Note: excessive extracorporeal compressing directly above the implantation site may damage the implant and adversely cause bleeding.
 - vi) Keep the patient under observation until stable.

Clinical Study – The ELITE Study

Introduction

The safety and effectiveness of the PerQseal Elite VCD was evaluated in the ELITE Study to support the approved indications for use.

Study Design

ELITE was a prospective, multicenter, single-arm study conducted in the EU at 8 clinical centers. The objective of the study was to evaluate the safety and effectiveness of the PerQseal Elite VCD when used to achieve hemostasis of common femoral arteriotomies created by 14 to 22 F sheaths (arteriotomies up to 26 F) in patients undergoing percutaneous catheter-based interventional procedures.

All patients were scheduled for follow-up examinations at 30 minutes, 1 hour, 12-24 hours, 30 days (±7 days), and 180 days (± 30 days) post-PerQseal Elite deployment to monitor the complete bioabsorption of the implant. Follow-up evaluations at scheduled visits included lower extremity pulse assessment, targeted physical exam, ankle brachial index (ABI) of both legs, hemoglobin level, a duplex ultrasound of PerQseal Elite and associated vasculature, and an AE assessment.

Endpoint Definitions

Primary Endpoints

The primary safety endpoint was the rate of major access site complications attributable to the PerQseal Elite device through 30 days, as adjudicated by the Clinical Events Committee (CEC) as study device related.

The primary effectiveness endpoint was the Time to Hemostasis (TTH), defined as the elapsed time in minutes from PerQseal Elite (Introducer-sheath and Delivery Device) removal to first observed cessation of common femoral artery (CFA) bleeding, excluding cutaneous or subcutaneous oozing, and in the absence of a developing hematoma.

Secondary Endpoints

The secondary safety endpoint was the incidence of minor access site complications attributable to the PerQseal Elite device through 30 days, as classified by an independent CEC as study device related.

Five (5) secondary effectiveness endpoints were tested:

- **PerQseal Elite Technical Success Rate:** The number of PerQseal Elite devices that are deployed and achieve hemostasis (i.e., cessation of arterial bleeding excluding cutaneous or subcutaneous oozing) without need for more than 10 minutes of firm, adjunctive manual compression or alternative treatment (other than adjunctive endovascular ballooning) at target access site, divided by the total number of PerQseal devices where deployment was attempted.
- **PerQseal Elite Treatment Success Rate:** The number of subjects who meet PerQseal Elite Technical Success without experiencing a device related Major Access Site Complication (based on CEC adjudication) through 30 days, divided by the total number of subjects where PerQseal Elite device deployment was attempted.
- **Time to Device Deployment (TTDD):** The time from insertion of the PerQseal Elite delivery device into the PerQseal Elite Introducer sheath to complete removal of the PerQseal Elite (Delivery Device and Introducer-sheath) from the subject following PerQseal Elite deployment.
- **Time to Ambulation:** The elapsed time from PerQseal Elite removal until the subject can walk 20 feet/6 meters without arterial re-bleeding at the target access site. This endpoint was evaluated only for subjects who are ambulatory (e.g., not confined to wheelchair or bed) at the time of enrollment.
- **Total Closure Time:** Time to Hemostasis (TTH) plus Time to Device Deployment (TTDD).

Analysis of Primary Endpoints

For both primary endpoints, a null and alternative hypothesis were tested. Both null hypotheses needed to be rejected for the study to be considered successful. The study was a single-arm study, where the primary safety endpoint and primary effectiveness endpoint were compared to respective performance goals. Performance goals were derived from meta-analyses of major vascular complication rates and time to hemostasis for large hole vascular closure devices from relevant contemporary peer-reviewed medical literature.

In addition, the following outcomes were evaluated:

- **Incidence of Major Vascular Access Site Complications per VARC-3¹:** Incidence of major vascular access site complications attributable to the PerQseal Elite device through 30 days, based on CEC adjudication, according to VARC-3 definitions.
- **Incidence of Minor Vascular Access Site Complications per VARC-3:** Incidence of minor vascular access site complications attributable to the PerQseal Elite device through 30-days, based on CEC adjudication.

Analysis Populations

The analysis populations are described below:

Table 1: Analysis Populations

Population	Definition	Number
Modified Intent-to-Treat (mITT)	The subset of the ITT population who underwent attempted access site closure with the PerQseal Elite device, excluding subjects who met procedural exclusion criteria, required an unrelated intervention at the access site compromising the implant, or had the device intentionally removed prior to deployment	121 subjects [^]
Per-Protocol (PP)	mITT subjects with no major protocol deviations who either experienced the primary safety event or completed the 30-day follow-up evaluation	108 subjects
mITT with 30-day follow-up	mITT subjects who completed the 30-day follow-up evaluation	118 subjects
PP with 30-day follow-up	PP subjects with no major protocol deviations who experienced the safety endpoint or completed the 30-day follow-up evaluation	106 subjects
mITT for Primary Effectiveness	mITT subjects for whom Time to Hemostasis (TTH) was measured	113 closures (108 subjects)
PP for Primary Effectiveness	mITT subjects with no major protocol deviations and for whom Time to Hemostasis (TTH) was measured	109 closures (104 subjects)

[^]There were 5 bilateral mITT subjects for a total of 126 closures.

Study Population Baseline Characteristics

The study population in the ELITE study had 121 mITT subjects with an average age of 78.2 ± 7.4 years, with most subjects being male (70.2%) and suffering from prevalent conditions such as hypertension (74.4%), diabetes (24.0%), and antithrombotic medication history (20.7%) (**Table 2** and **Table 3**). No demographic data were required to be collected as part of the ELITE study.

¹ VARC-3 WRITING COMMITTEE; G n reux P, Piazza N, Alu MC, Nazif T, Hahn RT, Pibarot P, Bax JJ, Leipsic JA, Blanke P, Blackstone EH, Finn MT, Kapadia S, Linke A, Mack MJ, Makkar R, Mehran R, Popma JJ, Reardon M, Rodes-Cabau J, Van Mieghem NM, Webb JG, Cohen DJ, Leon MB. Valve Academic Research Consortium 3: Updated Endpoint Definitions for Aortic Valve Clinical Research. J Am Coll Cardiol. 2021 Jun 1;77(21):2717-2746.

Table 2: Baseline Demographics – mITT Subjects

Characteristic	Mean ± SD (N)	% (n/N)
Age (years)	78.2 ± 7.4 (121)	-
Height (cm)	171.7 ± 8.60 (121)	-
Weight (kg)	80.1 ± 13.5 (121)	-
Male	-	70.2% (85/121)
Female	-	29.8% (36/121)

Table 3: Baseline Medical History – mITT Subjects

Condition	% (n/N)
Hypertension	74.4% (90/121)
Diabetes	24.0% (29/121)
Severe acute non-cardiac systemic disease, autoimmune disease or terminal illness	1.7% (2/121)
Clinically significant peripheral vascular disease	0.8% (1/121)
Claudication or rest pain	0.0% (0/121)
Bleeding diatheses	0.0% (0/121)
Previous peripheral vascular surgery involving the aorta or lower extremities	2.5% (3/121)
Previous amputation of either left or right leg	0.0% (0/121)
Previous arterial access performed using the proposed artery	9.9% (12/121)
Antithrombotic medication history	20.7% (25/121)
Pre-existing nerve injury ^a	0.8% (1/121)
Ambulatory	99.2% (120/121)

^a One subject was reported with a neck injury unrelated to the ipsilateral treated leg.

Procedural Data

The majority of procedures (72.7%) utilized the right leg for access, with 4.1% (5/121) of subjects undergoing bilateral access. All subjects received local anesthesia at a minimum, with 8.3% (10/121) receiving general anesthesia, 4.1% (5/121) receiving sedation, and the remainder receiving regional blocks. Intraprocedural anticoagulant or antiplatelet therapy was administered to all subjects (100%). Additional metrics including activated clotting time, estimated blood loss during the primary and index closure procedure, and approximate depth of tissue tract are reported in **Table 4**.

Table 4: Procedural Information – mITT Subjects

Activated Clotting Time (ACT [seconds])	
Mean ± SD (N)	181.8 ± 46.08 (121)
Median (Q1, Q3)	178.0 (147.0, 211.0)
Min, Max	90.0, 300.0
Anticoagulant/antiplatelet therapy given during procedure	100.0% (121/121)
Estimated blood loss during the Primary procedure (cc)	
Mean ± SD (N)	43.5 ± 90.58 (121)
Median (Q1, Q3)	10 (0, 40)
Min, Max	0, 500
Estimated blood loss during the Index closure procedure (cc) [1]	
Mean ± SD (N)	23.5 ± 53.79 (125)
Median (Q1, Q3)	0 (0, 20)
Min, Max	0, 400
Approximate depth of tissue tract (mm) [2]	
Mean ± SD (N)	3.8 ± 1.16 (126)
Median (Q1, Q3)	4.0 (3.0, 4.0)
Min, Max	1.0, 8.0

[1] Refers to blood loss during the index closure procedure.

[2] Subjects may have had procedures in both legs. The N is based on the number of procedures, not the number of subjects.

To accurately reflect the size of the arteriotomy closed by the device, **Table 5** details the outer diameter (OD) of the primary procedure sheaths utilized in the study. The outer diameters ranged from 15 to 26 F, which is the clinically relevant metric for large-bore vascular closure.

Table 5: Largest Primary Procedure Sheath Used – mITT by Procedure

Outer Diameter of Largest Sheath Used (F)*	Endovascular Aneurysm Repair (EVAR)	Transcatheter Aortic Repair (TAVR)	Total
15	1	0	1
16	11	8	19
18	6	28	34
19	5	4	9
20	7	9	16
22	0	25	25
23	1	0	1
24	0	18	18
26	0	3	3
Total	31	95	126

*For procedures that used sheathless devices (11), OD size reported by site was the arteriotomy size. One (1) treatment PCI+PTSMA+BAV was classed as TAVR and one (1) treatment Arteria iliaca communis aneurysm was classed as EVAR.

Safety Results

Primary Safety Endpoint: Rate of Major Access Site Complications Through 30-Days

The primary safety endpoint was the rate of major access site complications attributable to the device through 30 days, as adjudicated by the CEC.

The primary safety endpoint was successfully met across all mITT and PP analysis populations. The upper bound of the one-sided 97.5% confidence interval for major access site complications associated with the device was well below the pre-specified performance goal for safety of 14.05%. Moreover, all related p-values were below the significance threshold of 0.025 (**Table 6**). Major access site complication rates are further stratified by type of complication in **Table 7**.

Table 6: Major Access Site Complication Rates, Confidence Intervals, and p-values Across Four Analysis Populations

Analysis Population	% (n/N) [97.5% CI]	p-value
mITT with 30-day follow-up*	3.4% (4/118) [0.0%, 8.45%]	< 0.001
PP with 30-day follow-up	0.9% (1/106) [0.0%, 5.14%]	< 0.001
All mITT population	3.3% (4/121) [0.0%, 8.25%]	< 0.001
All PP population	0.9% (1/108) [0.0%, 5.05%]	< 0.001

* Primary analysis | CI, Confidence Interval

Table 7: Major Access Site Complication Rate Stratified by Type of Complication in mITT Population with 30-day follow-up

Major Complication Rates by Study Population	% (n/N)
Access site-related bleeding due to a failure of the PerQseal Elite device that requires transfusion of blood product(s)	0.0% (0/118)
Device related vascular injury that requires surgical repair or percutaneous stent-graft placement	3.4% (4/118)
Any new and sustained (> 24 hrs) device-related ipsilateral lower extremity ischemia, documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram, which causes a threat to the viability of the limb, and/or requires surgical repair or additional percutaneous intervention	0.0% (0/118)
Surgery for device-related nerve injury	0.0% (0/118)
Permanent (lasting to 30-days) device-related nerve injury	0.0% (0/118)
Access site infection requiring intravenous antibiotics, drainage and/or extended hospitalization	0.0% (0/118)

Secondary Safety Endpoint: Rate of Minor Access Site Complications Through 30-Days

The secondary safety endpoint was the incidence of minor access site complications attributable to the PerQseal Elite device through 30-days, as classified by the CEC.

Across all analysis populations, the incidence of minor complications remained well below the pre-specified Clinical Acceptance Criterion (CAC) of 20% (**Table 8**). Minor access site complication rates are further stratified by type of complication in **Table 9**.

Table 8: Minor Access Site Complication Rates Across Four Analysis Populations

Analysis Population	Complication Rate [97.5% CI]	p-value
mITT with 30-day follow-up*	0.8% (1/118) [0.0000, 0.0463]	< 0.001
PP with 30-day follow-up	0.9% (1/106) [0.0000, 0.0514]	< 0.001
All mITT population	0.8% (1/121) [0.0000, 0.0452]	< 0.001
All PP population	0.9% (1/108) [0.0000, 0.0505]	< 0.001
*Primary analysis		

Table 9: Minor Access Site Complication Rate Stratified by Type of Complication in mITT Population with 30-day follow-up

Minor Complication Events by Type	% (n/N)
Non-treated pseudoaneurysm documented by ultrasound	0.0% (0/118)
Pseudoaneurysm treated with ultrasound-guided compression, ultrasound-guided thrombin injection, or ultrasound-guided fibrin adhesive injection	0.8% (1/118)
New non-treated or treated arteriovenous (AV) fistula documented by ultrasound	0.0% (0/118)
Access site hematoma greater than or equal to 10 cm, confirmed by ultrasound	0.0% (0/118)
Late (following hospital discharge) access site-related arterial bleeding	0.0% (0/118)
Ipsilateral lower extremity arterial emboli	0.0% (0/118)
Ipsilateral deep vein thrombosis	0.0% (0/118)
Transient access site-related nerve injury	0.0% (0/118)
Access site infection treated with intramuscular or oral antibiotics	0.0% (0/118)

Exploratory Safety Endpoints: Incidence of Major and Minor VARC-3 Defined Complications

Exploratory safety endpoints were the incidence of major and minor VARC-3 defined complications (**Table 10, Table 11**). The upper bound of the one-sided 97.5% confidence interval for major VARC-3 complications was well below the pre-specified performance goal for primary safety of 14.05%. Moreover, all related p-values were below the significance threshold of 0.025. Additionally, minor VARC-3 complications were below the CAC of 20% in all populations.

Table 10: VARC-3 Major Device-Related Vascular Access Site Complication Rates

Analysis Population	% (n/N) [97.5% CI]	p-value
mITT with 30-day follow-up	0.0% (0/118) [0.0%, 3.08%]	< 0.0001
PP with 30-day follow-up	0.0% (0/106) [0.0%, 3.42%]	< 0.0001

Table 11: VARC-3 Minor Device-Related Vascular Access Site Complication Rates

Analysis Population	% (n/N)
mITT with 30-day follow-up	4.2% (5/118)
PP with 30-day follow-up	1.9% (2/106)

Effectiveness Results

Primary Effectiveness Endpoint: TTH

The primary effectiveness endpoint was time to hemostasis (TTH), defined as the elapsed time in minutes from PerQseal Elite (Introducer-sheath and Delivery-Device) removal to first observed cessation of common femoral artery (CFA) bleeding, excluding cutaneous or subcutaneous oozing, and in the absence of a developing hematoma. The analysis of effectiveness in the study was based on mITT subjects who had TTH recorded at the end of the index procedure.

The upper bound of the confidence intervals for mean TTH was well below the pre-specified performance goal of 19.7 minutes. Moreover, all related p-values were below the significance threshold of 0.025 (**Table 12**).

Table 12: Time to Hemostasis – mITT and PP Populations

Analysis Population	Mean in Mins (SD) [Median]	Upper 97.5% CI in Mins	p-value
mITT with TTH* (N = 113)	0.9 (2.33) [0]	1.36	< 0.001
PP with TTH (N = 109)	0.7 (1.77) [0]	1.08	< 0.0001
*Primary analysis			

Secondary Effectiveness Endpoints

The results of the secondary effectiveness endpoints, including technical success rate, treatment success rate, time to device deployment (TTDD), time to ambulation (TTA), and total closure time (TCT) are provided in Table 13.

Table 13: Secondary Effectiveness Endpoints

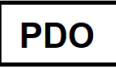
Parameter	Value
Technical Success Rate (% , n/N)	88.9% (112/126)
Treatment Success rate (% , n/N)	89.0% (105/118)
TTDD in min (Mean $\pm$ SD (N))	2.9 $\pm$ 2.83 (113)
Time to Ambulation in hr (Mean $\pm$ SD (N))	15.5 $\pm$ 10.70 (102)
Total Closure Time in min (Mean $\pm$ SD (N))	3.9 $\pm$ 3.88 (113)

Clinical Study Conclusion

The ELITE study evaluated the safety and effectiveness of the PerQseal Elite VCD in patients undergoing percutaneous catheter-based interventional procedures requiring large-bore common femoral arterial access. The endpoints were achieved. In addition, no unanticipated adverse device effects (UADEs) or unanticipated serious adverse device effects (USADEs) were reported during the study, and no device-related deaths were reported. The ELITE study provides direct clinical evidence supporting the safety and effectiveness of the PerQseal Elite VCD.

Overall, the data from the ELITE study establishes that the PerQseal Elite device is safe and effective for its intended use.

Graphical symbols for medical device labelling

 Sterilized using ethylene oxide	 Do not resterilize	 Use-by date
 Batch Code	 Do Not Reuse	 Consult Instruction for Use www.vivasuremedical.com/eifu
 Non-pyrogenic	 Contents of package	 Catalogue Number
 Date of manufacture	 Manufacturer	 Do not use if package is damaged
 Caution: Consult accompanying documents	 Sterile barrier system ('Tyvek® pouch'). Contents are sterile.	 Outer protective packaging layer ('Foil Pouch') with Sterile barrier system ('Tyvek® pouch') inside
 Medical Device	 Implant Composition: Polydioxanone (PDO)	 Caution — Federal law (U.S.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
 Keep Dry	 MR safe (Implant only)	 Not made with (Dry) Natural Rubber Latex

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