INSTRUCTIONS FOR USE

Angio-Seal™ VIP
Vascular Closure Device

REF

610130, 610131

TERUMO

PM-02943

TO ENSURE PROPER DEPLOYMENT AND USE OF THIS DEVICE AND TO PREVENT INJURY TO PATIENTS, READ ALL INFORMATION CONTAINED IN THESE INSTRUCTIONS FOR USE.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

The instructions for use is recyclable. Dispose of used product and packaging following standard solid biohazard waste procedures.

DEVICE DESCRIPTION

The Angio-Seal™ VIP Vascular Closure Device consists of the Angio-Seal VIP device, an insertion sheath, an arteriotomy locator (modified dilator) and a guidewire. The Angio-Seal VIP device is composed of an absorbable collagen sponge and a specially designed absorbable polymer anchor that are connected by an absorbable self-tightening suture (STS). The device seals and sandwiches the arteriotomy between its two primary members, the anchor and collagen sponge. Hemostasis is achieved primarily by the mechanical means of the anchor-arteriotomy-collagen sandwich, which is supplemented by the coagulation-inducing properties of the collagen. The device is contained in a delivery system that stores and then delivers the absorbable components to the arterial puncture. The delivery system features a Secure Cap that facilitates proper technique for delivery and deployment of the absorbable unit. The implanted components of the device are MRI Safe. The product is not made with natural rubber latex.

INDICATIONS

The Angio-Seal device is indicated for use in closing and reducing time to hemostasis at the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller procedural sheath for the 8F Angio-Seal device and a 6 French or smaller procedural sheath for the 6F Angio-Seal device.

The Angio-Seal device is also indicated for use to allow patients who have undergone diagnostic angiography to ambulate safely as soon as possible after sheath removal and device placement.

The Angio-Seal device is also indicated for use to allow patients who have undergone an interventional procedure to ambulate safely after sheath removal and device placement.

CONTRAINDICATIONS

There are no contraindications to the use of this device. Attention is drawn to the warnings and precautions.

WARNINGS

- Do not use if the temperature indicator dot on package has changed from light gray to dark gray or black.
- Do not use if the package is damaged or any portion of the package has been previously opened.
- Do not use if the items in the kit appear damaged or defective in any way.
- Do not use the Angio-Seal device where bacterial contamination of the procedure sheath or surrounding tissues may have occurred as this may result in an infection.
- Do not use the Angio-Seal device if the procedure sheath has been placed through the superficial femoral artery and into the profunda femoris as this may result in collagen deposition into the superficial femoral artery. This may reduce blood flow through the vessel leading to symptoms of distal arterial insufficiency.
- Do not use the Angio-Seal device if the puncture site is at or distal to the bifurcation of the superficial femoral and profunda femoris artery, as this may result in the 1) anchor catching on the bifurcation or being positioned incorrectly, and/or 2) collagen deposition into the vessel. These events may reduce blood flow through the vessel leading to symptoms of distal arterial insufficiency.
- Do not use the Angio-Seal device if the puncture site is proximal to the inguinal ligament as this may result in a retroperitoneal hematoma.

PRECAUTIONS

Special Patient Populations

The safety and effectiveness of the Angio-Seal device has not been established in the following patient populations:

- Patients undergoing an interventional procedure whom are being treated with warfarin.
- Patients who have known allergies to beef products, collagen and/or collagen products, or polyglycolic or polylactic acid polymers.
- Patients with pre-existing autoimmune disease.
- Patients undergoing therapeutic thrombolysis.
- Patients punctured through a vascular graft.
- Patients with uncontrolled hypertension (>180 mm Hg systolic).
- Patients with a bleeding disorder, including thrombocytopenia (<100,000 platelet count), thrombasthenia, von WilleBrand's disease, or anemia (Hgb<10 mg/dl, Hct<30).
- Pediatric patients or others with small femoral artery size (< 4 mm in diameter). Small femoral artery size may prevent the Angio-Seal™ anchor from deploying properly in these patients.
- Patients who are pregnant or lactating.

Procedure

The Angio-Seal device is to be used only by a licensed physician (or other health care professional authorized by or under the direction of such physician) possessing adequate instruction in the use of the device, e.g., participation in an Angio-Seal physician instruction program or equivalent.

Use a single wall puncture technique. Do not puncture the posterior wall of the artery.

If a patient has had a procedure sheath left in place for longer than 8 hours, consideration should be given to the use of prophylactic antibiotics before insertion of the Angio-Seal device.

The Angio-Seal device should be used within one hour of opening the foil pouch. The biodegradable components will begin to deteriorate upon exposure to ambient conditions.

Observe sterile technique at all times when using the Angio-Seal device.

The Angio-Seal device is for single use only and should not be reused in any manner.

The Angio-Seal device must be inserted through the insertion sheath provided in the kit. Do not substitute any other sheath.

Use only the arteriotomy locator provided in the kit to locate the puncture in the arterial wall.

Follow physician orders regarding patient ambulation and discharge.

If the Angio-Seal device does not anchor in the artery due to improper orientation of the anchor or patient vascular anatomy, the absorbable components and delivery system should be withdrawn from the patient. Hemostasis can then be achieved by applying manual pressure.

If repuncture at the same location of previous Angio-Seal device use is necessary in ≤ 90 days , re-entry 1 cm proximal to the previous access site can be performed safely, based on published medical literature*. Before considering Angio-Seal use, a femoral angiogram of the site is indicated. [*Applegate R; Rankin K; Little W; Kahl F; Kutcher M., **Restick following initial Angioseal use**. *Catheterization and Cardiovascular Interventions - Official Journal of the Society for Cardiac Angiography and Interventions, Feb 2003; 58(2) p181-4].*

"If patients have clinically significant peripheral vascular disease, based on published medical literature, the Angio-Seal device can be deployed safely in patient arteries >5 mm diameter when there is found to be no luminal narrowing of 40% or greater within 5 mm of the puncture site." Abando, A., Hood, D., Weaver, F., Katz, S., **The use of the Angioseal device for femoral artery closure.** *J Vasc Surg 2004;40:287-90.*

Dispose of contaminated device, components, and packaging materials utilizing standard hospital procedures and universal precautions for biohazardous waste.

ADVERSE EVENTS

The Angio-Seal™ device was evaluated in a non-randomized clinical trial involving 306 patients in whom the access sites were closed with the device following diagnostic angiography (n=97) or percutaneous coronary intervention (n=209) procedures. Table 1 reports the adverse events as a percentage of patients who received the Angio-Seal device in the clinical investigation.

Table 1: Percentage of Patients Experiencing Adverse Events

Adverse Event	8F/6F Diagnostic (n=97)	8F Interventional (n=106)	6F Interventional (n=103)
Minor Complication			
Hematoma >6 cm	0%	4 (3.8%)	1 (1.0%)*
Infection w/o hospitalization	0%	0%	0%
False aneurysm w/o intervention	0%	0%	0%
AV Fistula	0%	1 (0.9%)	0%
Deep Vein Thrombosis	0%	0%	0%
Vasovagal Response	0%	1 (0.9%)	0%
Device Non-Deployment	0%	0%	3 (2.9%)
Device Malfunction	0%	0%	0%
Major Complication			
Vascular Repair	0%	0%	1 (1.0%)
Late GI bleeding requiring transfusion	0%	0%	1 (1.0%)** †
Infection w/ hospitalization	0%	0%	0%
False aneurysm requiring intervention	0%	0%	1 (1.0%)**
DVT requiring intervention	0%	0%	0%
AV Fistula requiring intervention	0%	0%	0%
Retroperitoneal bleeding requiring intervention	0%	1 (0.9%)	0%
Any Complication ‡	0%	7 (6.6%)	4 (3.9%) ‡
Major Complication	0%	1 (0.9%)	3 (2.9%)

* One patient had hematoma > 6cm combined with DVT.
** Not device related.
† Patient also experienced a hematoma < 6cm.
‡ Not including device non-deployments.

No deaths occurred during the study.

Based on clinical experience, the following describes possible treatments for risks or situations that are associated with use of the Angio-Seal device or vascular access procedures.

- *Bleeding or hematoma* - Apply light digital or manual pressure to the puncture site. If manual pressure is necessary, monitor pedal pulses.
- *AV fistula or pseudoaneurysm* - If suspected, the condition may be evaluated with duplex ultrasound. When indicated, ultrasound guided compression of a pseudoaneurysm may be used after the Angio-Seal device has been placed.
- *Device non-deployment* - If device pulls out with sheath upon withdrawal, apply manual or mechanical pressure per standard procedure. Examine the device to ensure all absorbable components have been withdrawn.
- *Anchor fracture or embolism* - Examine device to determine if anchor has been withdrawn. If bleeding occurs, apply manual or mechanical pressure to the puncture site per standard procedures. If anchor is not attached to the device, monitor the patient (for at least 24 hours) for signs of vascular occlusion. Clinical experience to date indicates that tissue ischemia from an embolized anchor is unlikely. Should ischemic symptoms appear, treatment options include thrombolysis, percutaneous extraction of the anchor or fragments, or surgical intervention.
- *Infection* - Any sign of infection at the puncture site should be taken seriously and the patient monitored carefully. Surgical removal of the device should be considered whenever an access site infection is suspected.
- *Collagen deposition into the artery or thrombosis at puncture site* - If this condition is suspected, the diagnosis can be confirmed by duplex ultrasound. Treatment of this event may include thrombolysis, percutaneous thrombectomy, or surgical intervention.
- *Very thin patients* - Collagen may protrude from the skin after tamping has been completed. Attempt to push the collagen under the skin using the tamper tube or a sterile hemostat. DO NOT apply vigorous tamping as this may result in anchor fracture. DO NOT cut off the excess collagen, as the suture woven through the collagen may be cut and the integrity of the anchor/collagen sandwich could be compromised.
- *Obese patients* - The tamper tube may not be long enough to be exposed or grasped at the skin. Place fingers on either side of the suture, compress the surrounding tissue, and attempt to expose the tamper tube. If necessary, a sterile hemostat may be used to grasp the tamper tube so the collagen can be tamped adequately.

The following potential adverse reactions or conditions may also be associated with one or more Angio-Seal device components (i.e., collagen, synthetic absorbable suture, and/or synthetic absorbable polymer):

- Allergic reaction
- Foreign body reaction
- Potentiation of infection
- Inflammation
- Edema

CLINICAL TRIALS

Safety and Effectiveness Study

The Angio-Seal Vascular Closure Device with a self-tightening suture was evaluated in a multicenter non-randomized study designed to examine the safety and effectiveness of femoral artery closure using the 8F and 6F Angio-Seal device following arterial cannulation during diagnostic angiography and percutaneous coronary intervention procedures.

The study was conducted in the United States at nine institutions involving 306 patients. Patients eligible for participation included candidates for early ambulation and patients who were clinically indicated for a diagnostic or an interventional cardiac procedure involving access through the femoral artery using an 8F sheath or smaller for the 8F Angio-Seal or a 6F sheath or smaller for the 6F Angio-Seal. Exclusion criteria included patients with known allergies to the materials used in the device, severe acute non-cardiac systemic disease, evidence of systemic infection, coagulopathy, thrombolytic medication use reducing fibrinogen to less than 100 mg/dl, use of intra-aortic balloon pump support (ipsilateral), sheath in place for more than 36 hours, suspected double wall puncture, pre-existing hematoma, pregnancy/lactation, or indication that the puncture had been made in the profunda femoris or at the bifurcation of the common femoral artery.

Patients' ages ranged between 30.3-85.8 (mean 62.7 ± 11.7). Most (71.6%) of the patients were male. The 6F Angio-Seal was used in 85 (88%) diagnostic patients and 103 (49%) interventional patients. A total of 144 (68.9%) interventional patients were being treated with GP IIb/IIIa inhibitors. The mean activated clotting time for interventional patients was 299.6 ± 85.0 seconds.

The effectiveness of the Angio-Seal device was evaluated by times to hemostasis and ambulation. Time to hemostatsis was defined as the elapsed time from device deployment until cessation of bleeding. Time to ambulation was defined as the elapsed time from device deployment to the time the patient walked for five minutes or 100 feet. Major and overall complication rates comprised the safety endpoints. A major complication was defined as surgical vascular repair; bleeding requiring transfusion; infection extending hospitalization; and pseudoaneurysm, AV fistula, deep vein thrombosis, or retroperitoneal bleeding that required treatment by surgical intervention or ultrasound guided compression. Data were analyzed separately in diagnostic, 8F interventional, and 6F interventional arms.

Effectiveness Results

The results of the effectiveness measures are summarized in Tables 2 and 3.

Table 2: Time to Hemostasis

Time to Hemostasis (minutes)	Diagnostic Patients (n = 97)	8F Interventional Patients (n = 105)*	6F Interventional Patients (n = 103)
Mean ± SD Range	0.3 ± 1.3 0-10	7.2 ± 35.5 0-240	18.7 ± 70.3 0-520
Distribution t = 0 t ≤ 1 t ≤ 2 t ≤ 5 t ≤ 10 t > 10	Cumulative N (%) 89 (92%) 91 (94%) 92 (95%) 96 (99%) 97 (100%) 97 (100%)	Cumulative N (%) 84 (80%) 92 (88%) 94 (90%) 95 (90%) 99 (94%) 105 (100%)	Cumulative N (%) 70 (68%) 73 (71%) 77 (75%) 85 (82%) 90 (87%) 103 (100%)

* In one patient, the physician lost access. No time to hemostasis was recorded.

Table 3: Time to Ambulation

Time to Ambulation (hours)	Diagnostic (n = 92)	8F Interventional (n = 98)	6F Interventional (n = 99)
Mean ± SD Range	1.1 ± 0.9 0-4.4	6.2 ± 7.3 0.2-48.0	6.1 ± 6.6 1.9-43.0
Distribution* t ≤ 0.25 t ≤ 0.5 t ≤ 1 t ≤ 2 t ≤ 3 t ≤ 4 t ≤ 5 t > 5	Cumulative N (%) 14 (15%) 28 (30%) 51 (55%) 77 (84%) 88 (96%) 91 (99%) 92 (100%) 92 (100%)	Cumulative N (%) 1 (1%) 1 (1%) 3 (3%) 10 (10%) 36 (37%) 53 (54%) 73 (74%) 98 (100%)	Cumulative N (%) 0 (0%) 0 (0%) 0 (0%) 10 (10%) 35 (35%) 57 (58%) 68 (69%) 99 (100%)

*Time to ambulation varied across investigational centers and may have been a result of variable clinical approaches taken by physicians when ambulating patients.

Early Ambulation and Discharge Study in 6F Diagnostic Patients

In a clinical study to evaluate safety and efficacy of early ambulation and discharge, the Angio-Seal STS device was clinically evaluated in patients who had undergone diagnostic angiography procedures using a 6 French or smaller procedural sheath. The Angio-Seal STS was evaluated for safety and efficacy when ambulating patients as soon as possible following device deployment and discharging patients as early as 30 minutes following ambulation.

Methods:

Patients who met all inclusion and no exclusion criteria were enrolled during a pre-procedure screening evaluation. Four U.S. investigational centers participated in the study. The primary endpoints studied were 1) rate of major complications, 2) time to ambulation and 3) time to discharge.

Results:

A total of 132 patients (75% male; mean age 61.89 years) received the 6F Angio-Seal STS device from March 14, 2002 through September 6, 2002 after diagnostic angiography and were included in analyses of study endpoints. The evaluation of time to ambulation and time to discharge were relative to the time of deployment being defined as time “zero”. The median time to ambulation from device deployment was 9.00 minutes (mean 18.95 ± 30.7 minutes) and the median time to discharge from deployment was 70.00 minutes (mean 78.65 ± 32.54). Hypothesis testing on the median yielded a p-value of <0.001 for time to ambulation and <0.001 for time to discharge, supporting the study hypothesis that the median time to ambulation is less than one hour and the median time to discharge is less than three hours. If the time of discharge is evaluated relative to the time of ambulation, with the time of ambulation defined as time “zero”, the median time to discharge is 60 minutes (mean 59.91 ± 15.87 minutes).

No “Major” complications were reported for the study patients, with only one “Minor” complication noted. Hypothesis testing yielded a p-value of 0.005, supporting the conclusion that the major complication rate is less than 5%.

Table 4: Results of Early Ambulation and Discharge Study

Endpoint	Study Patients
Time to ambulation (minutes post deployment) Mean ± Std. Dev. (95% C.I.) Median (95% C.I.) Range (N)	 18.95 ± 30.71 (13.64, 24.26) 9.00 (7, 15) 1 to 323 (131)
Time to discharge (minutes post deployment) Mean ± Std. Dev. (95% C.I.) Median (95% C.I.) Range (N)	 78.65 ± 32.54 (73.01, 84.30) 70.00 (67, 75) 38 to 368 (130)
Time to discharge (minutes post ambulation) Mean ± Std. Dev. (95% C.I.) Median (95% C.I.) Range (N)	 59.91 ± 15.87 (57.15, 62.66) 60.00 20 to 120 (130)
Endpoint	**Study Patients**
Major complications (N)	0 (n=125)
z-statistic; p-value	-2.56; 0.005
Minor complications	1

Conclusions:

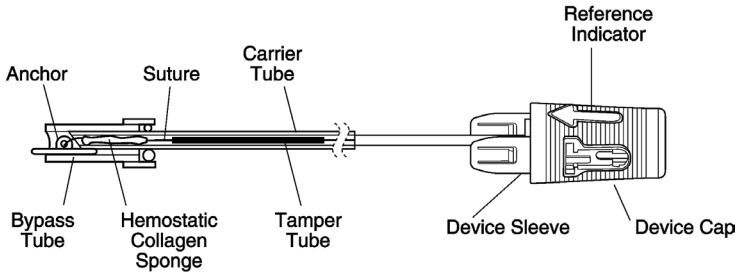
Results of the clinical study demonstrate that patients that have undergone diagnostic angiography and have received a 6F Angio-Seal device can safely and effectively ambulate in less than 20 minutes and be discharged one hour post ambulation.

HOW SUPPLIED

The Angio-Seal™ device kit is supplied sterile in a poly bag. The bag includes a sealed tray containing the following supplies:

- 1 each Insertion Sheath
- 1 each Arteriotomy Locator
- 1 each 6F - 70 cm, 0.035 in./0.89 mm Guidewire with J–Straightener
  8F - 70 cm, 0.038 in./0.96 mm Guidewire with J-Straightener
- 1 each Angio-Seal Device (refer to device component figure)

Device Components



ANGIO-SEAL™ DEVICE INSERTION PROCEDURE

The medical techniques and procedures described in these Instructions for Use do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the clinician’s experience and judgment in treating any specific patient.

The Angio-Seal procedure is composed of three stages:

A. Locate the Artery

B. Set the Anchor

C. Seal the Puncture

A. Locate the Artery

1. Assess the puncture site location and evaluate the femoral artery characteristics prior to placing the Angio-Seal device by injecting contrast medium through the procedure sheath followed by an angiogram.
2. Under strict sterile conditions and using a sterile field, remove the Angio-Seal device contents from the foil package, taking care to pull foil apart completely before removing the Angio-Seal device.

   NOTE: The Angio-Seal device must be used within one hour after opening the foil pouch due to the moisture-sensitive nature of the product.

3. Insert the arteriotomy locator into the Angio-Seal™ insertion sheath (Figure 1), making sure the two pieces snap together securely. To ensure proper orientation of the arteriotomy locator with the sheath, the hub of the locator and the sheath cap fit together only in the correct position. The reference indicator on the locator hub must align with the reference indicator on the sheath cap.

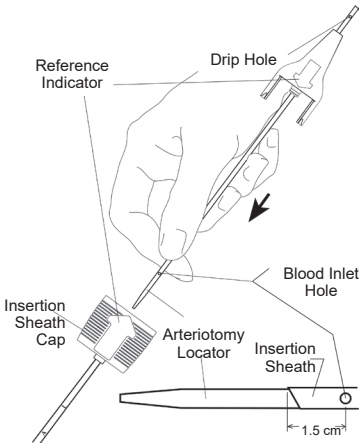


Fig. 1

4. Insert the Angio-Seal™ guidewire into the procedure sheath that is currently in the patient. If the procedure sheath is smaller than the Angio-Seal sheath, it is advisable to ensure that the skin incision is of sufficient size to accommodate the Angio-Seal insertion sheath.
5. Remove the procedure sheath, leaving the guidewire in place to maintain vascular access.
6. Thread the Angio-Seal arteriotomy locator/insertion sheath assembly over the guidewire; the drip hole (located above the arteriotomy locator hub) will be oriented down and away so the flow of blood can be observed. Make sure the reference indicator on the insertion sheath is facing up, insert the assembly into the puncture tract. When the tip of the insertion sheath is about 1.5 cm into the artery blood will begin to flow from the drip hole in the locator (Figure 2).

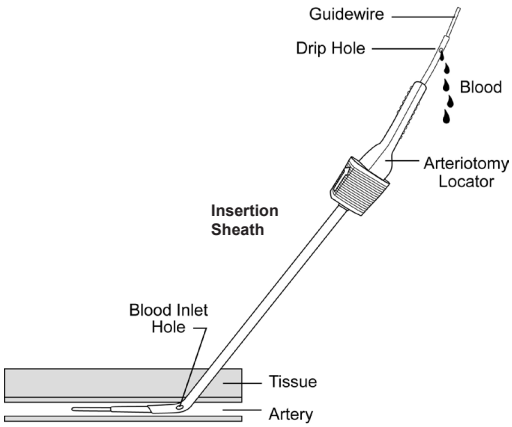


Fig. 2

NOTE: When resistance is encountered at the anterior vessel wall during over-the-guidewire advancement of the Angio-Seal locator/insertion sheath assembly, rotate the assembly 90 degrees so the reference indicator is facing away from the user. This places the beveled tip of the insertion sheath perpendicular to the anterior vessel wall.

7. Slowly withdraw the arteriotomy locator/insertion sheath assembly until blood slows or stops flowing from the drip hole. This indicates that the distal locator holes of the Angio-Seal insertion sheath have just exited the artery (Figure 3).

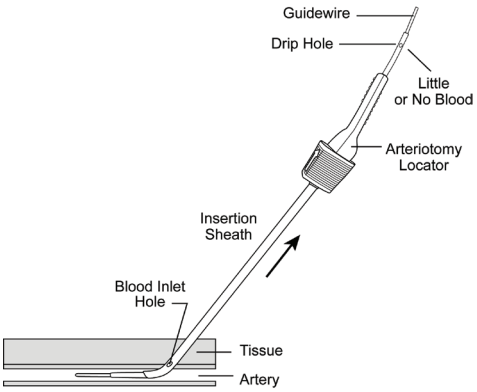


Fig. 3

8. From this point, advance the arteriotomy locator/insertion sheath assembly until blood begins to flow from the drip hole on the locator.

   NOTE: Overinsertion of the arteriotomy locator/insertion sheath assembly into the artery, beyond 2 cm, may increase the chance of premature anchor hook up or interfere with the anchor's performance to achieve hemostasis.

   If blood flow does not resume, repeat Steps A-7 and A-8 until blood flows from the drip hole again upon advancement of the assembly into the artery.

9. Holding the insertion sheath steady, without moving it into or out of the artery,
   a) remove the arteriotomy locator and guidewire from the insertion sheath by flexing the arteriotomy locator upward at the sheath hub (Figure 4).

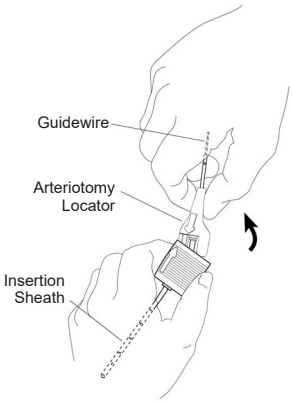


Fig. 4

   b) if necessary, rotate the insertion sheath so that the reference indicator on the insertion sheath cap is facing up (Figure 5).

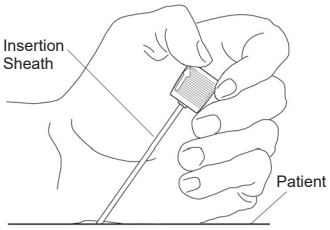


Fig. 5

WARNING: Under normal conditions, the Angio-Seal™ insertion sheath should not move into or out of the artery for the remainder of the Angio-Seal™ device deployment procedure. Using the sheath markings as a guide, ensure that the sheath position has not changed. If re-advancement is necessary, the guidewire and puncture locator must be inserted prior to advancing the Angio-Seal insertion sheath.

B. Set the Anchor

1. Confirm that the device sleeve has remained in the rear holding position, (Figure 6). Carefully grasp the Angio-Seal™ device at the bypass tube. Cradle the Angio-Seal™ carrier tube in the palm of the hand and, with the reference indicator facing up, slowly insert the bypass tube and carrier tube into the insertion sheath hemostatic valve (Figure 7).

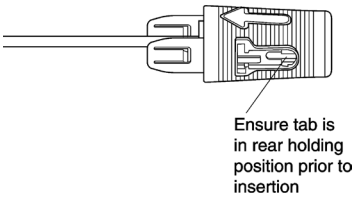


Fig. 6

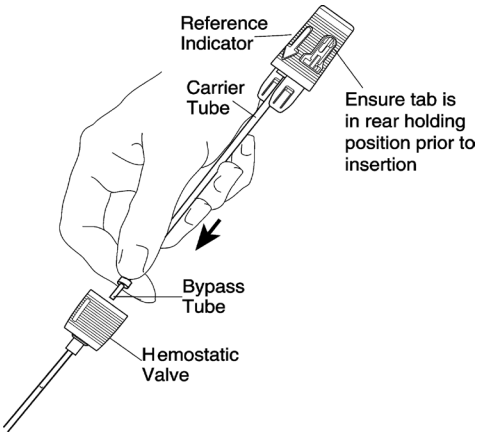


Fig. 7

2. Confirm that the reference indicator on the insertion sheath is facing up. To ensure proper orientation of the Angio-Seal device with the sheath, the sheath cap and the device sleeve only fit together in the correct position. The reference indicator on the device cap should align with the reference indicator on the insertion sheath cap (Figure 8). Keeping the insertion sheath in place, carefully advance the Angio-Seal device in small increments until completely inserted into the insertion sheath. The sheath cap and the device sleeve will snap together when properly fitted.

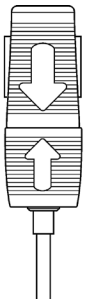


Fig. 8

NOTE: If significant resistance to carrier tube advancement is encountered when insertion is almost complete, the anchor may be impinging on the posterior wall of the artery. DO NOT CONTINUE TO ATTEMPT TO ADVANCE. In this case, slight repositioning of the sheath, either by reducing the angle of the sheath with respect to the skin surface or by pulling the sheath back by 1-2 mm, may permit normal deployment.

3. With one hand continue to hold the insertion sheath cap steady to prevent movement of the sheath into or out of the artery. With the other hand, grasp the device cap and slowly and carefully pull back. Slight resistance will be felt when the device cap is pulled out from rear holding position. Continue pulling on the device cap until resistance from the anchor catching on the distal tip of the insertion sheath is felt.
4. To ensure the correct anchor position, confirm that the edge of the device cap falls within the colored bands on the device sleeve.

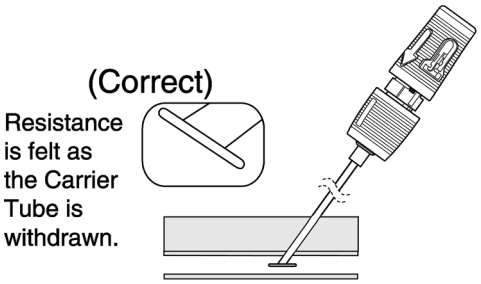


Fig. 9 (Correct)

5. Maintain grip on the insertion sheath and pull the device handle straight back into the full rear locked position (Figure 10). Resistance will be felt as the device handle and sleeve snap lock. The device sleeve colored bands should now be completely visible.

   NOTE: If the device sleeve separates from the sheath while attempting full rear lock positioning, do not push the Angio-Seal™ device forward to reattach the sheath cap. Complete sealing of the puncture following instructions in C-1.

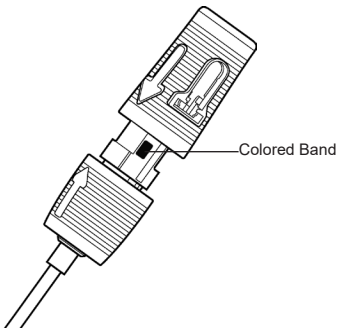


Fig. 10

6. Incorrect Indicator Alignment

   The Distal end of device cap completely covers the colored indicator band on the device sleeve (Figure 11). If the anchor catches prematurely as in Figure 11, advance the device into the insertion sheath again. It may be necessary to push the device cap back into the rear holding position in order to get full extension of the anchor from the sheath. Then withdraw the device until the anchor catches correctly.

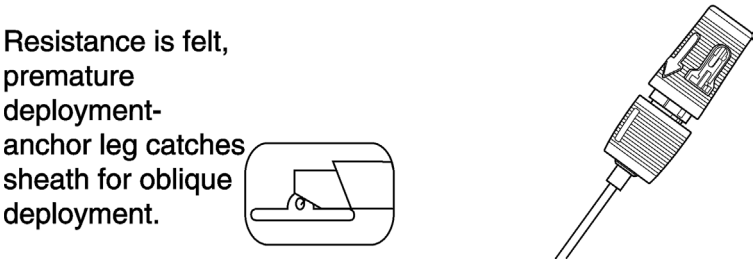


Fig. 11 (Incorrect)

NOTE: Do not proceed until you are certain that the anchor has been properly deployed (Figure 9). If the anchor is improperly deployed, the Angio-Seal device will not function.

C. Seal the Puncture

1. Once the anchor has been deployed correctly (Figure 9), and the device cap has been locked into the rear position (Figure 10), slowly and carefully withdraw the device/sheath assembly along the angle of the puncture tract to position the anchor against the vessel wall (Figure 12).

   NOTE: Do not re-insert the device. Re-insertion of the device after partial deployment could cause collagen to be deposited in the artery.

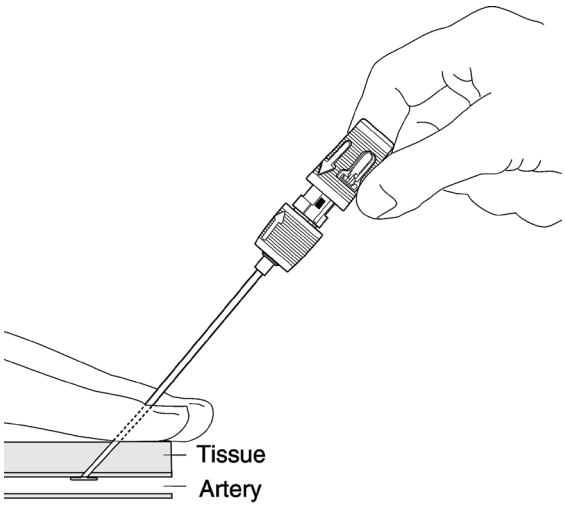


Fig. 12

2. When the insertion sheath clears the skin, a tamper tube will appear (Figure 13). At this stage, grip the tamper tube and gently advance the knot and collagen while maintaining tension on the suture.

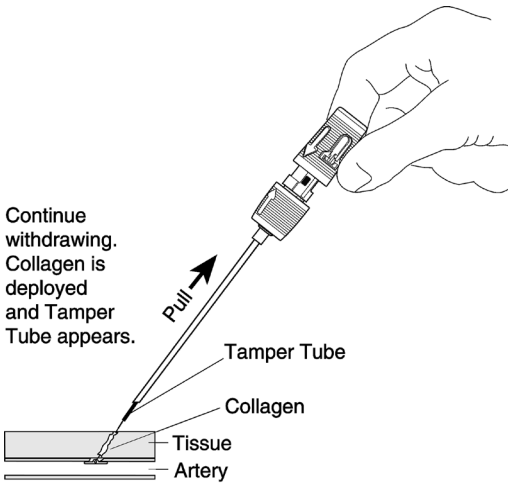


Fig. 13

WARNING: Failure to maintain tension on the suture while advancing the collagen could cause the collagen to enter the artery.

3. Continue to withdraw the insertion sheath and device until the clear stop on the suture appears (Figure 14). Continue to pull until all of the suture has been deployed. The suture will then lock within the device cap where it is attached. Maintain tension on the suture.

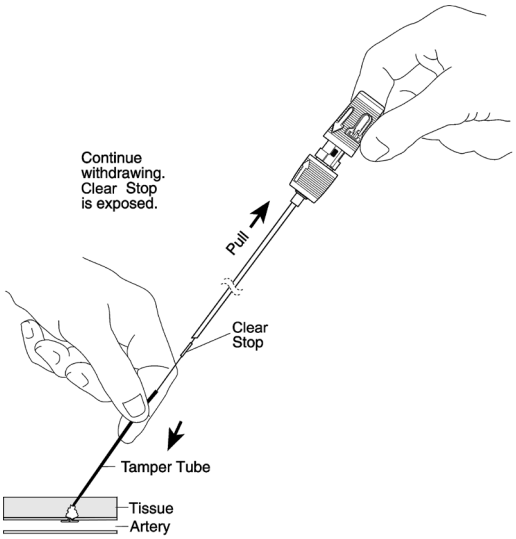


Fig. 14

4. Continue to maintain tension on the suture while continuing to advance the knot and collagen with the tamper tube, following the puncture tract angle (Figure 15). A complete seal is indicated when resistance is felt and hemostasis is achieved. As a guide, in most cases a black compaction marker will be revealed. The essential indicators for a seal are resistance, hemostasis, and in most cases a black compaction marker is revealed.

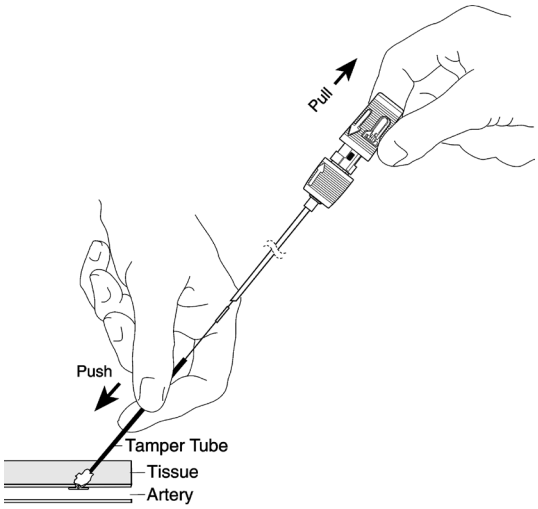


Fig. 15

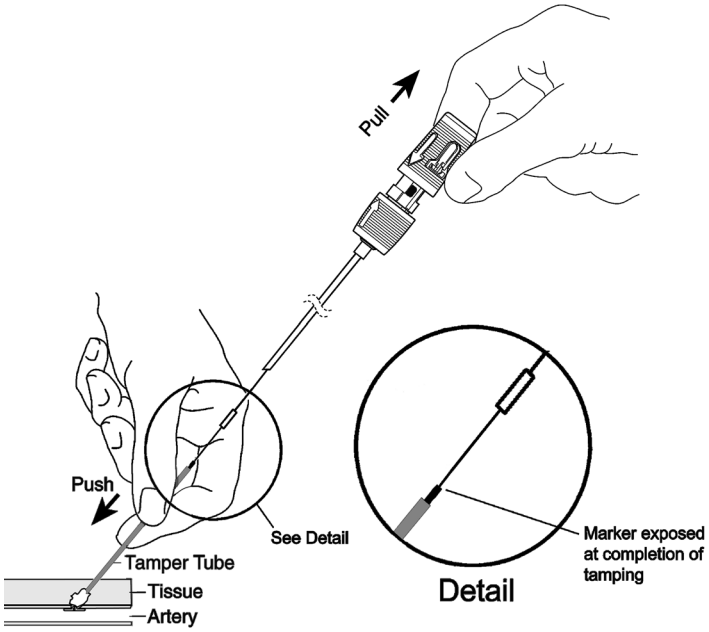


Fig. 16

NOTE: The black compaction marker is usually exposed. If not, repeat step C-4. Sufficient resistance will indicate completion of sealing and the black compaction marker will usually be exposed (Figure 16).

NOTE: In some cases the compaction marker will be fully exposed when resistance is felt. In such a case the clinician should check for hemostasis before completing the procedure.

NOTE: Once hemostasis is achieved, do not tamp to intentionally go beyond the distal end of the black compaction marker (as shown in Figure 17) in order to prevent anchor deformation and/or collagen tearing.

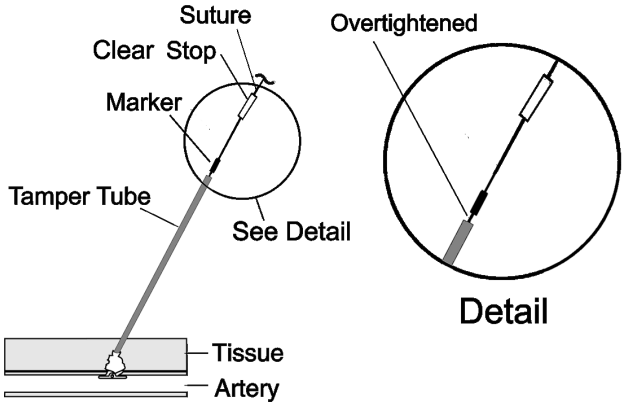


Fig. 17

5. Cut the suture below the clear stop (Figure 18). Remove the tamper tube using a slight twirling upward motion.

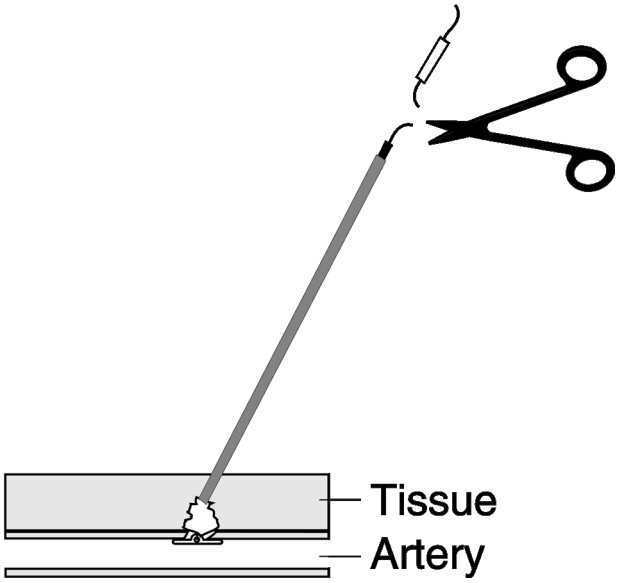


Fig. 18

6. Gently pull up on the suture. Push down on the skin using a sterile instrument. Cut the suture below the skin level, making sure to cut below the black compaction marker (Figure 19).

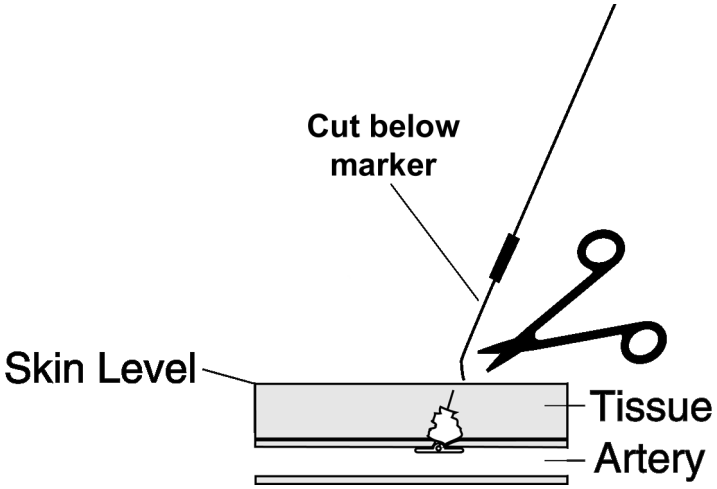


Fig. 19

<u>The black compaction marker is non-absorbable – it must be removed.</u>

NOTE: Make sure the suture retracts below skin level to avoid infection.

NOTE: If seeping of blood occurs after placing the Angio-Seal™ Device, or after removing the tamper tube, application of gentle digital pressure (one or two fingers) at the puncture site is usually sufficient to produce hemostasis. If manual pressure is necessary, monitor pedal pulses.

7. Clean the puncture site with an antiseptic solution/ointment.
8. Apply a sterile dressing to the puncture site so that it can be easily observed during recovery.

SYMBOLS

	Consult instructions for use
	Quantity
	Use By
	Date of Manufacture
STERILE R	Sterilized by gamma radiation
	For single use only
Rx ONLY	CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a physician.
	Keep dry
	Keep away from sunlight, including UV light
25° C / 15° C	Store only at temperatures between 15°C and 25°C
REF	Reorder Number or Catalog Number
LOT	Lot Number
	Do not use if temperature indicator dot on package has changed from light gray to dark gray or black
	Manufacturer
VASCULAR CLOSURE DEVICE	Vascular Closure Device
	Caution: See Instructions for Use
CONTENTS	Contents of the package
MR	Implanted components are MRI SAFE
	Do not use if packaging is damaged
STERILIZE	Do not resterilize

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