AbsorbaSeal 5.6.7F
Vascular Closure Device

Instructions for Use
AbsorbaSeal 5.6.7F Vascular Closure Device (VCD)

Instructions for Use (IFU)
AbsorbaSeal 5.6.7F Vascular Closure Device

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

DEVICE DESCRIPTION

The AbsorbaSeal 5.6.7F is intended to achieve rapid femoral artery hemostasis by delivering a fully bioabsorbable sealing mechanism to the vessel puncture site. The AbsorbaSeal 5.6.7F consists of the 1) delivery system, 2) seal assembly, which is composed of two bioabsorbable copolymers, and 3) Galt Medical Micro-Access Elite Hemostasis Valve Introducer Set. The delivery system is comprised of an inserter (which houses the seal assembly), a push tube, and a handle with a deployment slide (Figure 1). The seal assembly, delivered through the dedicated and provided Galt Medical Micro 6F Access Sheath, compresses the puncture site between extravascular components – proximal seal and floating foot, and intravascular components – gasket and distal seal, connected via a stem (Figure 2).

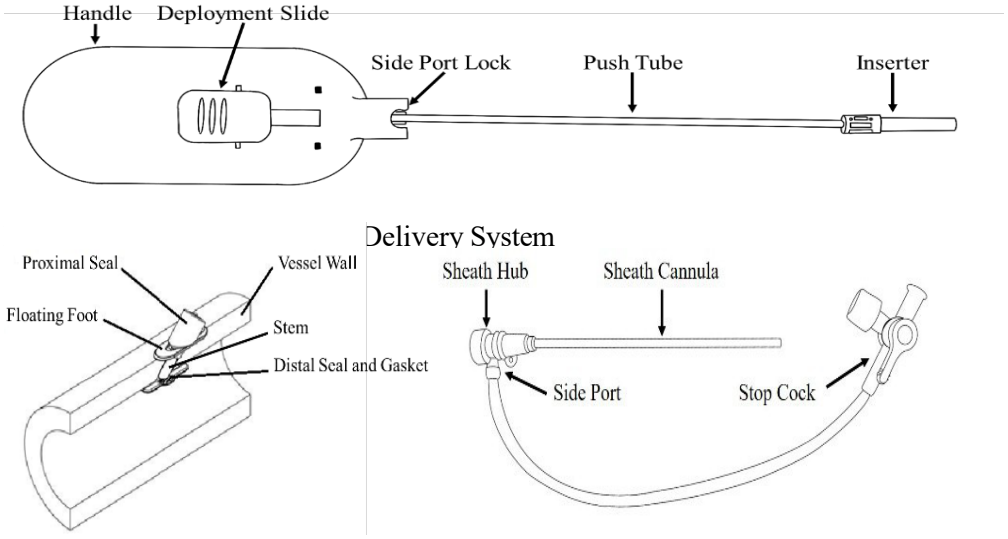


Figure 2: Seal Assembly (left) and Galt Medical Micro 6F Access Sheath (right)

INDICATIONS FOR USE

The AbsorbaSeal 5.6.7F is indicated for percutaneous closure of femoral arterial access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional catheterization procedures utilizing 5, 6, or 7F procedural sheaths.

CONTRAINDICATIONS

There are no known contraindications for the AbsorbaSeal 5.6.7F.

WARNINGS

- The AbsorbaSeal has not been fully evaluated to establish potential for chronic toxicity and carcinogenicity. Prolonged exposure to systemic or carcinogenic toxicants may lead to long-term tissue harm and long- term carcinogenic effects. The risks of these potential harms from the product have not been established clinically specifically. However, the available information from Seal to Heal study and animal study data on the device does not suggest chronic toxicity or carcinogenicity and supports complete device degradation within 1 year.
- Do not use if the temperature indicator dot on package has changed from light gray to dark gray or black.
- Do not use if beyond expiration date on packaging.
- 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 package or the device appear damaged or defective in any way.
- Do not re-sterilize or reuse the AbsorbaSeal 5.6.7F in any manner; it is for SINGLE USE ONLY.
- Do not use if the procedural sheath is < 5F or > 7F.
- Do not use if the patient has a known sensitivity to Poly Lactide-co-Glycolide (PLGA) and/or Poly Lactide-co-ε-Caprolactone (PLCL).
- Do not use if a hematoma or bleeding is present around the procedural sheath.
- Do not use if there is resistance felt or kinking of the sheath during insertion of the dedicated Galt Medical 6F Access Sheath.
- Do not use if there is resistance in advancing the device into the dedicated Galt Medical 6F Access Sheath.
- Do not use if a previous closure device was used in the target common femoral artery ≤ 90 days prior to procedure or if components of a prior VCD are present in the target artery.
- Do not use the AbsorbaSeal 5.6.7F if the sterile field has been broken or where bacterial contamination of the procedural sheath or surrounding tissues may have occurred, as this may result in an infection.
- Do not use the AbsorbaSeal 5.6.7F if the procedural sheath has been placed into the superficial femoral artery or into the profunda femoris artery or placed at or distal to the bifurcation of the superficial femoral artery and the profunda femoris artery.
- Do not use the AbsorbaSeal 5.6.7F if the puncture site is located above the lowest sweep of the inferior epigastric artery (high stick) or in the target vessel side wall (side wall stick).
- Do not use the AbsorbaSeal 5.6.7F if the puncture site is above the inguinal ligament based on bony landmarks, since such a puncture site may result in a retroperitoneal hematoma/bleed. Perform a femoral angiogram to verify the location of the puncture site.
- Do not use the AbsorbaSeal 5.6.7F with any sheath other than the Galt Medical Micro 6F Access Sheath provided.
- Do not use the AbsorbaSeal 5.6.7F if the target artery has a side wall stick.

NOTE: If resistance is encountered or possible kink, confirm proper sheath placement and condition using right or left lateral imaging (>30°).

PRECAUTIONS

- The AbsorbaSeal 5.6.7F is to be used only by a trained licensed physician or other healthcare professional authorized by or under the direction of such physician.
- Use a single-wall puncture technique. Do not puncture the posterior wall of the artery.
- Always observe sterile technique when using the AbsorbaSeal 5.6.7F.
- If femoral access is required within 60 days of femoral artery closure with the AbsorbaSeal 5.6.7F, it should be attempted on the contralateral side. If repuncture of the original access site is required within 60 days of closure of the access site with the AbsorbaSeal 5.6.7F, access the femoral artery at least 1 cm proximal or distal to the original access site.
- Dispose of contaminated device, device components, and packaging materials utilizing standard hospital procedures and universal precautions for bio-hazardous waste.

POTENTIAL ADVERSE EVENTS

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

- Allergic response
- Anemia
- Arterial occlusion
- Arterial thrombus
- Arteriovenous fistula
- Bleeding from the puncture site
- Bruising at the puncture site
- Death
- Device failure/malfunction
- Diminished pulses distal to the closure site
- Edema
- Embolization (thrombus, calcific debris, tissue, device, or air)
- Hematoma
- Infection
- Inflammatory response
- Intimal tear/dissection
- Laceration or perforation of the vessel wall
- Lower extremity ischemia
- Numbness
- Oozing from the puncture site
- Peripheral nerve injury
- Pseudoaneurysm
- Puncture site pain
- Retroperitoneal bleeding
- Vascular injury
- Vasospasm
- Vasovagal response
- Venous thrombus formation
- Wound dehiscence

SPECIAL PATIENT POPULATIONS

The safety and effectiveness of the AbsorbaSeal 5.6.7F has not been evaluated in patients who are/have:

- Pregnant and/or lactating
- Less than 18 years or greater than 80 years of age
- Mean body mass index (BMI) < 20 or > 45 kg/m²
- Common femoral artery lumen < 5 mm in diameter
- Known history of bleeding diathesis, bleeding problems following medical procedures, or coagulopathy, including patients with a known baseline hemoglobin < 10 g/dl, hematocrit < 30%, platelet count < 100,000 cells/mm^3
- Received low molecular weight heparin (LMWH) within 8 hours of the procedure
- ACT > 350 seconds in subjects receiving unfractionated heparin in the absence of a glycoprotein IIb/IIIa inhibitor or > 250 seconds in the presence of a glycoprotein IIb/IIIa inhibitor
- Baseline INR > 1.8 for subjects on warfarin
- Systemic hypertension (systolic BP > 180 mm Hg) or hypotension (systolic BP < 90 mm Hg)
- Vascular grafts at the target access site
- Received vascular surgery or repair near the target access site within 90 days
- Use of an intra-aortic balloon pump in the ipsilateral limb ≤ 90 days prior to the procedure
- Pre-existing vascular stent within 3 cm of the target access site
- Fibrotic or severely calcified vessel within 10 mm of the target access site
- Ipsilateral common femoral artery stenosis > 50%
- Evidence of a pre-existing hematoma, arteriovenous fistula, or pseudoaneurysm at the access site prior to the start of the procedure

The SEAL TO HEAL Study: Study to EvALuate Time TO Hemostasis of AbsorbaSeaL

The SEAL TO HEAL Clinical Study was a multi-center, prospective, non-randomized, single-arm trial designed to evaluate the safety and effectiveness of the study device in sealing percutaneous common femoral artery puncture access sites and providing reduced time to hemostasis (TTH) and time to ambulation (TTA) in subjects undergoing diagnostic and interventional endovascular catheterization procedures performed using 5F, 6F, and 7F introducer sheaths, compared to predetermined TTH and TTA Performance Goals. Performance Goals and Clinical Acceptance Criteria were developed to test the primary and secondary safety endpoints of major and minor access site closure-related complications. A total of 249 subjects were treated with the device at nine clinical sites in the United States. Of these subjects, 220 subjects (102 diagnostic and 118 interventional patients) and 29 roll-in subjects (19 interventional and 10 diagnostic) were treated. An ultrasound sub-study evaluated images of the access site treated with the AbsorbaSeal 5.6.7F, obtained from 53 subjects at 5 sites at the time of the 30-day follow-up

visit. The images from the ultrasound sub-study were uploaded to an independent Ultrasound Core Laboratory for analysis.

To be eligible for enrollment, subjects were required to be between the ages of 18 and 80 years; provide written informed consent; agree to 30 ± 7-day follow-up requirements; be acceptable candidates for an elective, non-emergent diagnostic or interventional vascular catheterization procedure using a 5, 6, or 7F introducer sheath via a femoral arterial approach; and be acceptable candidates for manual compression and/or emergent vascular surgery if necessary. Subjects were excluded from enrollment if they had: prior target artery closure with any vascular closure device ≤ 90 days prior to the procedure, or if components of a prior VCD were present in the target artery; known allergy to Poly lactide-co-glycolide (PLGA) or to contrast medium that could not be adequately pre-medicated; evidence of active systemic infection; known immunodeficiency disorder; known history of bleeding diathesis, bleeding problems following medical procedures, or coagulopathy; known baseline hemoglobin < 10 g/dl, hematocrit < 30%, platelet count < 100,000 cells/mm^3, or baseline INR > 1.8 for subjects on warfarin; known baseline serum creatinine > 2.5 mg/dl; thrombolytic therapy ≤ 24 hours prior to the procedure; administration of low molecular weight heparin (LMWH) within 8 hours of the procedure; inability to ambulate at least 20 feet at baseline; previous target limb amputation below the knee; existing nerve damage in the ipsilateral limb, exclusive of chronic neuropathy that would not confound the ability to detect acute nerve injury in the opinion of the Investigator; life expectancy < 6 months due to severe comorbidities, in the opinion of the Investigator; previous vascular grafts at the target access site; previous vascular surgery or repair in the vicinity of the target access site within the past 90 days; planned endovascular or surgical procedure involving the target access site within the next 60 days; use of an intra-aortic balloon pump in the ipsilateral limb ≤ 90 days prior to the procedure; ineligible for vessel closure in the lab; more than one arterial femoral sheath was required during the procedure; any femoral venous sheath required during the procedure; evidence of a pre-existing hematoma, arteriovenous fistula, or pseudoaneurysm at the access site prior to the start of the procedure; pregnant (known or suspecting) or lactating; or mean body mass index (BMI) < 20 or > 45 kg/m^2.

Subjects were also evaluated intra-operatively for the following exclusion criteria: target vessel has a lumen diameter < 5 mm; pre-existing vascular stent within 3 cm of the target access site; fibrotic or severely calcified vessel within 10 mm of the target access site; target access vessel is highly tortuous or requires a sheath length > 10 cm for the closure procedure; ipsilateral common femoral artery stenosis > 50%; introducer sheath < 5F or > 7F used during the procedure; needle stick problems at the onset of the procedure (multiple stick attempts, back wall stick); difficulty inserting the procedural sheath or evidence of sheath kinking; common femoral artery (CFA) puncture site located above the lowest sweep of the inferior epigastric artery (high stick) or in the target vessel side wall (side wall stick); procedural sheath placement either in the superficial femoral artery or in the profunda femoris artery, or placement at or distal to the bifurcation of the superficial femoral artery and the profunda femoris artery; the puncture site is above the inguinal ligament; forming hematoma or excessive bleeding around the procedural sheath, and/or suspected vascular complications; loss of ipsilateral limb distal pulse during the procedure; ACT > 350 seconds in subjects receiving unfractionated heparin in the absence of a glycoprotein IIb/IIIa inhibitor or > 250 seconds in the presence of a glycoprotein IIb/IIIa inhibitor; systemic hypertension (systolic BP > 180 mm Hg) or hypotension (systolic BP < 90 mm Hg) just prior to access site closure; and procedures that may extend the index hospitalization beyond 12 hours post-procedure (e.g., such as a staged endovascular procedure or a procedure from which a patient is referred directly to CABG surgery).

A total of 220 pivotal subjects, consisting of 102 diagnostic and 118 interventional patients, were enrolled at 8 of the study sites. Among the total subjects, the mean age was 66.3 years, the mean

BMI was 29.9 kg/m^2, 57.7% were male, and 42.3% were female. The study also included 29 roll-in subjects, of whom 10 were diagnostic and 19 were interventional. Among the interventional subjects, 82.2% received unfractionated heparin; 88.1% received at least one oral anticoagulant or antiplatelet agent, and 55.9% received at least 2 of these medications. The mean Activated Clotting Time (ACT) in subjects receiving unfractionated heparin was 237.2 seconds for diagnostic subjects and 253.4 seconds for interventional subjects.

Enrolled subjects were followed for 30 ± 7 days. Of the 220 subjects, 219 (99.5%) subjects completed the 30-day follow-up (shown in **Table 1**). One diagnostic subject was lost to follow-up.

Table 1. Follow-Up Compliance for ITT Pivotal Patients in AbsorbaSeal VCD Clinical Study

	Diagnostic (N = 102)	Interventional (N = 118)	Total (N = 220)
30-Day Visit in Window	95.1% (97/102)	84.7% (100/118)	89.5% (197/220)
30-Day Visit Not in Window	3.9% (4/102)	15.3% (18/118)	10.0% (22/220)
Lost to Follow up [1]	1.0% (1/102)	0% (0/118)	0.5% (1/220)

[1] Diagnostic Patient 05-121 was lost to follow-up prior to the 30-day visit.

SAFETY RESULTS

The primary safety endpoint was the 30 ± 7-day incidence rate of Combined Major Access Site Closure-Related Complications on a per patient basis. The analysis of safety was based on the intent to treat (ITT) cohort of 219 evaluable patients who completed the 30-day follow-up visit. The Performance Goal for the rate of Combined Major Access Site Closure-Related Complications was 6%. There were zero (0) major access site closure-related complications reported in the study, as summarized in **Table 2.** The 1.7% upper bound of the 95% confidence interval for total (diagnostic and interventional) major access site closure-related complications is lower than 6%. Therefore, the performance goal was met ($p<0.0001$).

Table 2. Incidence of Major Complications in ITT Pivotal Patients in AbsorbaSeal VCD Clinical Study[1]

Description of Event	Diagnostic (N = 101 [2])	Interventional (N = 118)	Total (N = 219)
Vascular injury requiring repair (via surgery, ultrasound-guided compression, transcatheter embolization, or stent-graft)	0% (0/101)	0% (0/118)	0% (0/219)
Access site closure-related bleeding requiring transfusion	0% (0/101)	0% (0/118)	0% (0/219)
New ipsilateral lower extremity ischemia causing a threat to the viability of the limb and requiring surgical or endovascular intervention, documented by subject symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram	0% (0/101)	0% (0/118)	0% (0/219)
New onset access site closure-related neuropathy in the ipsilateral lower extremity requiring surgical repair	0% (0/101)	0% (0/118)	0% (0/219)
Permanent access site closure-related nerve injury (> 30 days)	0% (0/101)	0% (0/118)	0% (0/219)
Access site closure-related infection, confirmed by culture and sensitivity, and requiring intravenous antibiotics and/or extended hospitalization	0% (0/101)	0% (0/118)	0% (0/219)
Total Major Access Site Closure-Related Complications	0% (0/101)	0% (0/118)	0% (0/219)
Clinical Acceptance Criteria *for Diagnostic and Interventional Patients* for Total Major Access Site Closure-Related Complications	2.0%	2.0%	
Performance Goal *for All Patients* for Total Major Access Site Closure-Related Complications			6.0%
Wilson Score 95% Confidence Interval	0 – 3.7%	0 – 3.2%	0 – 1.7%

[1] Neither event-based (based on number of events) nor patient-based (based on number of patients with events) was stipulated in the clinical protocol.

[2] Diagnostic Patient 05-121 was lost to follow-up and thus was omitted from the denominator.

The secondary safety endpoint was the 30 ± 7-day incidence rate of Combined Minor Access Site Closure-Related Complications on a per patient basis. The only minor complication was a *New onset of transient access site closure-related neuropathy in the ipsilateral lower extremity that is transient (≥ 24 hours and ≤ 30 days) and does not require surgical repair*, reported to be mild in severity and not clinically significant, in one interventional subject. This event is reported in **Table 3.** The Clinical Acceptance Criteria (CACs) for total minor access site closure-related complications were 5% for diagnostic subjects and 6% for interventional subjects. The 0% rate for combined minor access site closure-related complications for the diagnostic subjects and the 0.8% rate for combined minor access site closure-related complications for the interventional

subjects are numerically less than the CACs of 5% for diagnostic subjects and 6% for interventional subjects.

Table 3. Incidence of Minor Complications in ITT Pivotal Patients in AbsorbaSeal VCD Clinical Study[1]

Description of Event	Diagnostic (N = 101 [2])	Interventional (N = 118)	Total (N = 219)
Pseudoaneurysm not requiring treatment, documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
Pseudoaneurysm requiring thrombin injection or fibrin adhesive injection, documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
Arteriovenous fistula not requiring treatment, documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
Access site closure-related vessel laceration	0% (0/101)	0% (0/118)	0% (0/219)
Access site closure-related hematoma ≥ 6 cm documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
Access site closure-related bleeding requiring > 30 minutes of continual manual compression to achieve initial arterial hemostasis	0% (0/101)	0% (0/118)	0% (0/219)
Late access site closure-related arterial bleeding (following hospital discharge)	0% (0/101)	0% (0/118)	0% (0/219)
Ipsilateral lower extremity arterial emboli	0% (0/101)	0% (0/118)	0% (0/219)
Ipsilateral deep vein thrombosis documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
New onset of transient access site closure-related neuropathy in the ipsilateral lower extremity that is transient (≥ 24 hours and ≤ 30 days) and does not require surgical repair	0% (0/101)	0.8% (1/118)	0.5% (1/219)
Access site wound dehiscence	0% (0/101)	0% (0/118)	0% (0/219)
Localized access site infection, confirmed by culture and sensitivity, and treated with intramuscular or oral antibiotics	0% (0/101)	0% (0/118)	0% (0/219)
Total Minor Access Site Closure-Related Complications	0% (0/101)	0.8% (1/118)	0.5% (1/219)
Clinical Acceptance Criteria *for Diagnostic and Interventional Patients* for Total Minor Access Site Closure-Related Complications	5.0%	6.0%	

[1] Neither event-based (based on number of events) nor patient-based (based on number of patients with events) was stipulated in the clinical protocol.

[2] Diagnostic Patient 05-121 was lost to follow-up and thus was omitted from the denominator.

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Adverse effects that occurred in the PMA clinical study:

A total of 39 Adverse Events, were reported in 28/220 (12.7 %) of the AbsorbaSeal 5.6.7F VCD subjects. Of these 39 Adverse Events, 3 were classified as Serious Adverse Events. . There were no device related Serious Adverse Events nor were there procedure related Serious Adverse Events. Adverse Events with a potential relationship to the device or procedure included, hematomas less than 6 centimeters in diameter (7 events), arterial re-bleeding after initial hemostasis had been confirmed for 5 minutes, prolonged oozing into the tissue tract (4 events), groin pain (1 event), fever (1 event), vasovagal episode (2 events), and *1* New onset of transient access site closure-related neuropathy in the ipsilateral lower extremity that is transient (minor complication see Table 3).

EFFECTIVENESS RESULTS

Tables 3a, 3b, 3c and 3d summarize the primary effectiveness endpoint of Time to Hemostasis (TTH), the key secondary effectiveness endpoint of Time to Ambulation (TTA), and the additional secondary effectiveness endpoints of Time to Discharge Eligibility (TTDE) and Time to Discharge (TTD). The analysis of effectiveness was based on the 220 evaluable ITT subjects at discharge. The Intent-to-Treat (ITT) population, which was defined as all enrolled pivotal subjects, i.e., subjects with the AbsorbaSeal 5.6.7F/ Galt Medical Micro sheath assembly inserted, regardless of successful deployment of the AbsorbaSeal 5.6.7F VCD or not.

The primary effectiveness endpoint was based on TTH (Table 3a) and was stratified by procedure type. TTH for the AbsorbaSeal 5.6.7F was analyzed using a two-sided t-test and Wilcoxon's signed rank test. TTH met the predetermined Performance Goals (PGs) for diagnostic and interventional procedures (diagnostic PG 17 min., and interventional PG 24 min) ($p < 0.0001$). The mean TTH was 1.71 minutes for all subjects, and the median was 0.00 minutes for all subjects.

Table 3a: Primary Effectiveness Endpoint TTH Results

Time to Hemostasis (minutes)[1]	**Diagnostic (n = 102)**	**Interventional (n = 118)**	**Total (n = 220)**
Mean ± Standard Dev (95% C.I.)	0.85 ± 3.14 (0.23, 1.46)	2.46 ± 6.01 (1.37, 3.56)	1.71 ± 4.95 (1.06, 2.37)
Median (95% C.I.)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
Range (Min, Max)	(0.00, 15.93)	(0.00, 23.57)	(0.00, 23.57)
Performance Goal (p-value)	17 min. (<0.0001)	24 min. (<0.0001)	20.8* (<0.0001)

[1] TTH for AbsorbaSeal 567F met the predetermined Performance Goals (PGs) in all three cases (diagnostic PG 17min., interventional PG 24 min., and combined) by both t-test and Wilcoxon's signed rank test ($p<0.0001$).

*Performance goal is calculated based upon the distribution of interventional and diagnostic patient.

TTA for the AbsorbaSeal 5.6.7F was analyzed using a two-sided t-test and Wilcoxon's signed rank test. The mean TTA was 2.54 hours for all subjects, and the median was 2.21 hours for all subjects. The mean TTA was 1.82 hours for diagnostic subjects and 3.15 hours for interventional subjects. TTA met the performance goals for both the diagnostic (PG ≤ 6 hours) and interventional (PG ≤ 11 hours) procedures.

TTH for the AbsorbaSeal 5.6.7Fmet the predetermined Performance Goals (PGs) in all three cases for diagnostic and interventional procedures (diagnostic PG 17min.,17 min.~~,~~ and interventional PG 24 min., and combined) by both two-sided t-test and Wilcoxon's signed rank test ($p <0.0001$).

Table 3b: Secondary Effectiveness Endpoint TTA Results

Time to Ambulation (hours)[1]	**Diagnostic (n = 101) [1]**	**Interventional (n = 118)**	**Total (n = 219)**
Mean ± Standard Dev (95% C.I.)	1.82 ± 0.50 (1.72, 1.92)	3.15 ± 2.41 (2.71, 3.59)	2.54 ± 1.92 (2.28, 2.79)
Median (95% C.I.)	1.76 (1.65, 1.81)	2.55 (2.47, 2.73)	2.21 (2.15, 2.33)
Range (Min, Max)	(1.05, 4.36)	(2.03, 21.13)	(1.05, 21.13)
Performance Goal (p-value) [2]	6 hrs. (<0.0001)	11 hrs. (<0.0001)	9.1*

[1] TTA for AbsorbaSeal 567 F met the predetermined PGs in both cases (diagnostic PG 6 hrs., and interventional PB 11 hrs.) both by t-test and Wilcoxon's signed rank test ($p<0.0001$).
[2] 1 Diagnostic subject could not be evaluated for time to ambulation or time to discharge eligibility.
* Performance goal is calculated based upon the distribution of interventional and diagnostic patients

Table 3c and 3d summarize the additional secondary effectiveness endpoints of Time to Discharge Eligibility (TTDE) and Time to Discharge (TTD).

Table 3c: Secondary Effectiveness Endpoint TTDE Results

Time to Discharge Eligibility (hours)[1]	**Diagnostic (n = 101)**	**Interventional (n = 118)**	**Total (n = 219)**
Mean ± Standard Dev (95% C.I.)	1.91 ± 0.52 (1.80, 2.01)	3.21 ± 2.09 (2.83, 3.59)	2.61 ± 1.70 (2.38, 2.83)
Median (95% C.I.)	1.86 (1.77, 1.94)	2.91 (2.67, 3.05)	2.26 (2.20, 2.38)

Range (Min, Max)	(1.05, 4.39)	(2.06, 22.41)	(1.05, 22.41)

[1] 1 Diagnostic subject could not be evaluated for Time to Ambulation or Discharge Eligibility

Table 3d: Secondary Effectiveness Endpoint TTD Results

Time to Discharge (hours)	**Diagnostic (n = 102)**	**Interventional (n = 118)**	**Total (n = 220)**
Mean ± Standard Dev (95% C.I.)	2.48 ± 0.85 (2.31, 2.64)	5.87 ± 7.51 (4.50, 7.24)	4.30 ± 5.78 (3.53, 5.07)
Median (95% C.I.)	2.13 (2.07, 2.31)	3.18 (2.99, 3.54)	2.83 (2.57, 3.01)
Range (Min, Max)	(1.31, 5.11)	(2.21, 51.83)	(1.30, 51.83)

Table 4 summarizes the secondary effectiveness endpoints of Procedure Success, defined as attainment of final hemostasis using any method and freedom from major access site closure-related complications through 30 days. The Procedure Success Rate was 100%.

Table 4: Secondary Effectiveness Endpoint Procedure Success

	Diagnostic		**Interventional**		**Total**	
Procedure Success						
N	101		118		219	
Success	101	100.0%	118	100.0%	219	100.0%
95% Wilson Score Confidence Interval for Success Rate	96.3%	100.0%	96.8%	100.0%	98.3%	100.0%

*Subject 05-121 was lost to follow-up and omitted from the denominator for Procedure Success tabulation.

Table 5 summarizes the secondary effectiveness endpoint of Device Success, defined as the ability to deploy the delivery system, deliver the implant, and achieve hemostasis with the AbsorbaSeal alone or with adjunctive compression. For the total subjects Device Success was achieved in 93.6% of the cases in which device deployment was attempted.

Table 5: Secondary Effectiveness Endpoint Device Success

	Diagnostic		**Interventional**		**Total**	
Device Success						
N[1]	102		118		220	
Success	98	96.1%	108	91.5%	206	93.6%
95% Wilson Score Confidence Interval for Success Rate	90.3%	98.5%	85.1%	95.3%	89.6%	96.2%

[1] Includes 14 instances of known user error, resulting in incomplete deployment of the device in 4 diagnostic and 10 interventional subjects: excessive force / pull-through = 5; incomplete button advancement = 3; and inadequate sheath hub connection = 6.

Tables 6, 7, 8, and 9 summarize the cumulative data at fixed time points for TTH, TTA, TTDE, and TTD, respectively. Time to hemostasis (TTH) was achieved in 0 seconds in 92.2% of diagnostic and 83.1% of interventional subjects, for a total of 87.3% of all subjects achieving immediate hemostasis. Time to ambulation (TTA) was achieved in ≤ 3 hours by 81.3% of subjects, and in ≤ 4 hours by 94.1% of subjects. Time to Discharge Eligibility (TTDE) was achieved by 93.2% of all subjects in ≤ 4 hours. Time to discharge (TTD) was achieved by 92.3% of all subjects in ≤ 6 hours.

Table 6. Cumulative Time to Hemostasis (TTH) at Fixed Time Points, by Procedure Type

Time Point	Diagnostic		Interventional		Total	
N	102		118		220	
0 seconds	94	92.2%	98	83.1%	192	87.3%
≤ 1 minute	94	92.2%	98	83.1%	192	87.3%
≤ 2 minutes	94	92.2%	98	83.1%	192	87.3%
≤ 3 minutes	95	93.1%	98	83.1%	193	87.7%
≤ 4 minutes	95	93.1%	98	83.1%	193	87.7%
≤ 5 minutes	95	93.1%	98	83.1%	193	87.7%
≤ 10 minutes	97	95.1%	105	89.0%	202	91.8%
≤ 15 minutes	100	98.0%	108	91.5%	208	94.5%
≤ 30 minutes	102	100.0%	118	100.0%	220	100.0%

Table 7. Cumulative Time to Ambulation (TTA) at Fixed Time Points, by Procedure Type

Time Point	Diagnostic		Interventional		Total	
N	101 [1]		118		219	
≤ 1 hour	0	0.0%	0	0.0%	0	0.0%
≤ 2 hours	74	73.3%	0	0.0%	74	33.8%
≤ 3 hours	98	97.0%	80	67.8%	178	81.3%
≤ 4 hours	100	99.0%	106	89.8%	206	94.1%
≤ 5 hours	101	100.0%	111	94.1%	212	96.8%
≤ 7 hours	101	100.0%	115	97.5%	216	98.6%
≤ 9 hours	101	100.0%	115	97.5%	216	98.6%
≤ 10 hours	101	100.0%	116	98.3%	217	99.1%
≤ 15 hours	101	100.0%	116	98.3%	217	99.1%
≤ 20 hours	101	100.0%	117	99.2%	218	99.5%
≤ 30 hours	101	100.0%	118	100.0%	219	100.0%

[1] 1 Diagnostic subject was unable to ambulate due to pain in the feet and also was not assessed for discharge eligibility.

Table 8. Cumulative Time to Discharge Eligibility (TTDE) at Fixed Time Points, by Procedure Type

Time Point	Diagnostic		Interventional		Total	
N	101 *		118		219	
≤ 2 hours	69	68.3%	0	0.0%	69	31.5%
≤ 4 hours	100	99.0%	104	88.1%	204	93.2%
≤ 6 hours	101	100.0%	114	96.6%	215	98.2%
≤ 8 hours	101	100.0%	116	98.3%	217	99.1%
≤ 12 hours	101	100.0%	117	99.2%	218	99.5%
≤ 24 hours	101	100.0%	118	100.0%	219	100.0%

* 1 Diagnostic subject was unable to ambulate due to pain in the feet and also was not assessed for discharge eligibility.

Table 9: Cumulative Time to Discharge (TTD) at Fixed Time Points, by Procedure Type

Timepoint	Diagnostic		Interventional		Total	
N*	102		118		220	
≤ 2 hours	35	34.3%	0	0.0%	35	15.9%
≤ 4 hours	94	92.2%	79	66.9%	173	78.6%
≤ 6 hours	102	100.0%	101	85.6%	203	92.3%
≤ 8 hours	102	100.0%	104	88.1%	206	93.6%
≤ 12 hours	102	100.0%	104	88.1%	206	93.6%
≤ 24 hours	102	100.0%	113	95.8%	215	97.7%
≤ 48 hours	102	100.0%	117	99.2%	219	99.5%
≤ 60 hours	102	100.0%	118	100.0%	220	100.0%

*Includes 2 subjects with I/E deviations for planned stay > 12 hours post-procedure with TTD times of 24.93 hrs. and 51.83 hrs.

Duplex Ultrasound (DUS Sub Study)

A duplex ultrasound subgroup study was prospectively designed to evaluate a minimum of 50 evaluable ultrasounds at up to 5 study sites. The sub-study enrolled a total of 53 patients (21 diagnostic and 32 interventional subjects). Subjects completed the follow-up ultrasound exam at the 30 ± 7 days to assess for access site-related complications. The images were uploaded to an independent Ultrasound Core Laboratory for analysis. Of the 53 subjects enrolled with evaluable ultrasounds, abnormal findings were observed in 2 cases for an event rate of 3.8%. The abnormal findings were one hematoma (sub-clinical) < 6 cm and one arterial thrombus (which the investigator stated was pre-existing). Overall, these results supported the safe use of the AbsorbaSeal VCD. t

Table 15. Abnormal Findings Noted on 30-Day Ultrasound Exams Per Ultrasound Core Lab in Pivotal Patients in AbsorbaSeal VCD Clinical Study[1]

Abnormal Finding	Diagnostic (N = 21)	Interventional (N = 32)	Total (N = 53)

Pseudoaneurysm	0% (0/21)	0% (0/32)	0% (0/53)
Arteriovenous fistula [2]	0% (0/21)	0% (0/29)	0% (0/50)
Dissection	0% (0/21)	0% (0/32)	0% (0/53)
Laceration/Perforation	0% (0/21)	0% (0/32)	0% (0/53)
Hematoma [3]	4.8% (1/21)	0% (0/32)	1.9% (1/53)
Embolism	0% (0/21)	0% (0/32)	0% (0/53)
Arterial thrombus [4]	0% (0/21)	3.1% (1/32)	1.9% (1/53)
Venous thrombus [2]	0% (0/21)	0% (0/29)	0% (0/50)
Total Abnormal Findings	4.8% (1/21)	3.1% (1/32)	3.8% (2/53)

[1] Event-based (based on number of events)

[2] Three (3) interventional patients (Patients 02-104, 02-105, and 02-108) could not be evaluated for arteriovenous fistula or venous thrombus since they had an ultrasound exam without venous images being captured in the exam. Thus, the denominator is smaller.

[3] Sub-clinical hematoma was noted in Diagnostic Patient 05-137 and was 3.95 cm in diameter per the Ultrasound Core Lab.

[4] Arterial thrombus was noted in Interventional Patient 02-114 in the proximal superficial femoral artery. The investigator stated that this thrombus was pre-existing, having been noted on pre-index procedure ultrasound and at the time of access during the index procedure.

CONCLUSIONS

The results from the SEAL TO HEAL clinical study demonstrate that patients who have undergone diagnostic or interventional catheterization procedures utilizing a 5, 6, or 7F procedural sheath and were treated with the AbsorbaSeal 5.6.7F VCD have reduced times to hemostasis and ambulation when compared to predetermined Performance Goals. The study data provide scientifically valid evidence that the device is safe and effective when used in accordance with the device labeling.

HOW SUPPLIED

- AbsorbaSeal 5.6.7F Vascular Closure Device is supplied sterile in a foil and Tyvek pouch. The seal assembly is supplied preloaded into the delivery system.

The standard 6F Galt Medical Micro-Access Elite Hemostasis Valve Introducer Set is packaged and shipped separately in a sterile permeable pouch and includes the following:

- 6F Access Sheath and Vessel Dilator
- Access Needle and 0.035" J-wire (for vessel access and sheath exchange)

ABSORBASEAL 5.6.7F 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 AbsorbaSeal 5.6.7F VCD procedure is composed of three stages:

A. Insert AbsorbaSeal 5.6.7F VCD through Galt Medical Micro 6F Access Sheath
B. Deploy the AbsorbaSeal 5.6.7F VCD Seal Assembly
C. Remove the handle/Galt Medical Micro 6F Access Sheath delivery system.

A. Insert AbsorbaSeal 5.6.7F VCD through Galt Medical Micro 6F Access Sheath

1. Assess the puncture site location and evaluate the common femoral artery characteristics by performing a contrast-enhanced angiogram with A/P and extreme (>30°) right or left lateral positioning through the procedural sheath prior to exchanging the procedural sheath for the Galt Medical Micro 6F Access Sheath.
2. Under strict sterile conditions and sterile protocol, remove the Galt Medical Micro 6F Access Sheath/Dilator from its sterile package.
3. Under strict sterile conditions and sterile protocol, remove the AbsorbaSeal 5.6.7F VCD from its sterile package.
4. Over a 0.035" guidewire, exchange the procedural sheath and insert the Galt Medical Micro 6F vessel dilator and access sheath until the hub of the sheath is at skin level.
5. Remove the Galt Medical Micro 6F vessel dilator and 0.035" guidewire. While removing the Galt Medical 6F vessel dilator and 0.035" guidewire, do not twist or bend the tube below the hub, since this will distort the lumen of the Galt Medical Micro 6F access sheath tube and not allow the seal assembly to pass through.

NOTE: Ensure that the side port hub of the Galt Medical Micro 6F access sheath is straight up at the 12 o'clock position.

6. With the non-dominant hand, secure the hub of the Galt Medical Micro 6F access sheath between the thumb and fingers **(Figure 3)**.
7. With the dominant hand, insert the AbsorbaSeal 5.6.7F inserter into the hub on the Galt Medical Micro 6F access sheath until an audible and tactile click is heard and felt. **(Figure 4)**.



Figure 3

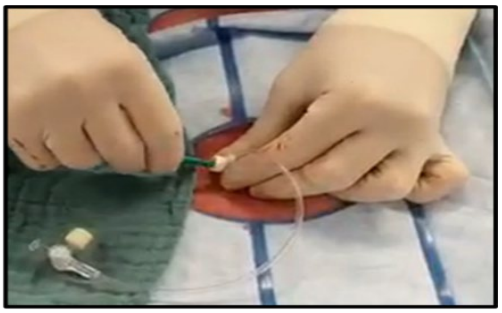


Figure 4

NOTE: The AbsorbaSeal 5.6.7F VCD handle should be flat on the table with the deployment slide on top.

PRECAUTION: Do not overly manipulate, torque, or twist the AbsorbaSeal 5.6.7F inserter or Galt Medical Micro 6F access sheath hub when locking the two components together. Manipulation of the inserter can cause the two halves to separate.

Note: As the inserter penetrates the hemostatic valve of the Galt Medical Micro 6F access sheath hub a pulsatile return of blood will be observed until the seal components are seated into the lumen of the Galt Medical Micro 6F access sheath tube.

8. Using finger and thumb, advance the AbsorbaSeal 5.6.7F push tube 1 to 2 cm into the Galt Medical Micro 6F access sheath **(Figure 5)**.

   PRECAUTION: If resistance is encountered in advancing the push tube, stop and ensure that the inserter is locked into the hub of the Galt Medical Micro 6F access sheath. If the resistance continues, remove the device from the Galt Medical Micro 6F access sheath and recheck the position of the Galt Medical Micro 6F access sheath.

   With the AbsorbaSeal 5.6.7F handle in the dominant hand, advance the handle, and push the tube until the handle locks into the side port lock of the Galt Medical Micro 6F access sheath, creating a single handle/sheath assembly. The distal seal and gasket have now exited the distal tip of the Galt Medical Micro 6F access sheath **(Figure 6)**.

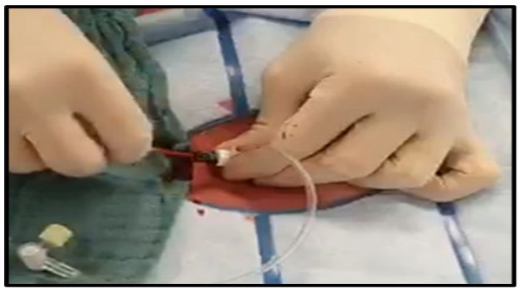


Figure 5



Figure 6

9. While holding the AbsorbaSeal 5.6.7F handle in the dominant hand, stabilize the access vessel by placing the middle and index fingers of the non-dominant hand in front of and behind the Galt Medical Micro 6F access sheath and apply light downward pressure onto the skin **(Figure 7)**.

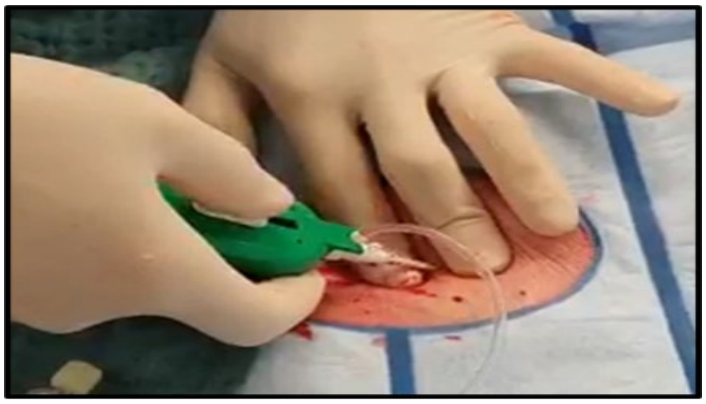


Figure 7

WARNING: Do not push down or advance the deployment slide until ready to deploy the seal assembly.

B. Deploy the AbsorbaSeal 5.6.7F Seal Assembly

11. Slowly and carefully withdraw the handle/Galt Medical Micro 6F sheath assembly along the same angle of puncture tract until resistance of the vessel wall is felt. This resistance signifies that the distal seal and gasket portion of the seal assembly are up against the anterior wall of the vessel. Temporary hemostasis will be achieved **(Figure 8)**.

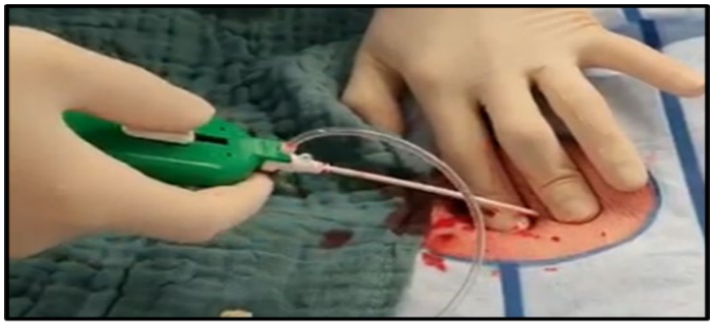


Figure 8

WARNING: Do not withdraw the handle/Galt Medical Micro 6F sheath assembly with excessive force. Excessive pull-back force can lead to the distal seal and gasket portion of the seal assembly being pulled out of the artery.

NOTE: If the distal seal and gasket portion of the seal assembly are inadvertently pulled out of the artery, remove completely the handle/ Galt Medical Micro 6F sheath assembly, and apply manual compression at the puncture site until hemostasis is achieved.

12. Maintaining neutral back pressure on the vessel, depress the deployment slide with the thumb to unlock the sealing mechanism **(Figure 9)** and advance the deployment slide to the furthest proximal position. An audible and tactile click occurs, signaling seal assembly deployment and separation of the seal assembly mechanism from the handle/Galt Medical Micro 6F sheath assembly. **(Figure 10).**

NOTE: Complete deployment occurs only when the deployment slide is advanced to the most proximal position. Incomplete advancement of the deployment slide will result in the seal assembly not separating. Further advancement to the maximum proximal point is needed and should be confirmed with tactile and audible feedback of separation.

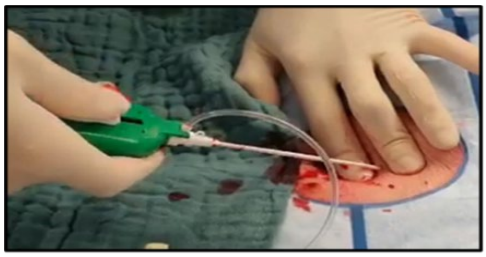


Figure 9

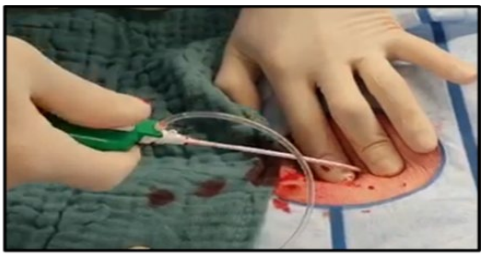


Figure 10

C. Remove handle/Galt Medical Micro 6F Access Sheath delivery system

13. Maintain finger positioning and downward pressure on the skin. Withdraw the AbsorbaSeal 5.6.7F handle/Galt Medical Micro 6F access sheath delivery system by retracting back until the delivery system is removed from the tissue tract and exits the body. Slowly release downward pressure as the fingers lift from the skin and hemostasis is confirmed. **(Figure 11)**.

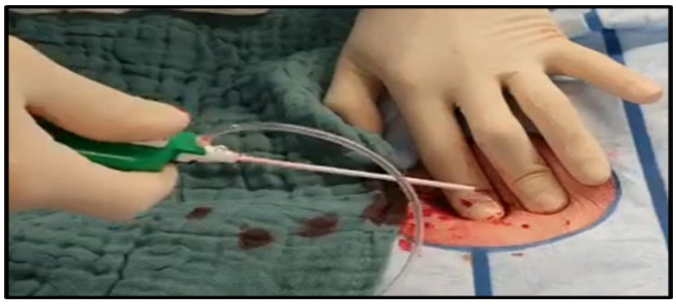


Figure 11

NOTE: Immediately after AbsorbaSeal 5.6.7F delivery system removal, dab the access

site with a sterile 4x4 and assess for signs of arterial bleeding.

PRECAUTION: Applying unnecessary and significant pressure to the puncture site after the device has been deployed may cause disruption of the seal assembly and lead to loss of hemostasis. Never apply direct pressure to the puncture site. Pressure should be held 3-4 cm proximally to the puncture site (3-4 cm distal for antegrade access).

NOTE: If oozing of blood occurs after removing the AbsorbaSeal 5.6.7F handle/sheath assembly, application of light digital pressure (one or two fingers) 3-4 cm proximal to the puncture site (3-4 cm distal for antegrade access) is usually sufficient to produce hemostasis. If manual pressure is necessary, monitor pedal pulses.

PRECAUTION: Mechanical Compression Devices should be considered a last resort in achieving hemostasis. Using Mechanical Compression devices compresses the intravascular sealing components away from the vessel wall and will increase the rate of bleeding.

14. Clean the puncture site with an antiseptic solution/ointment.
15. Apply a sterile dressing to the puncture site so that it can be easily observed during recovery.
16. The AbsorbaSeal 5.6.7F is supplied as a single-use device and should be disposed of per individual institutional protocols.

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 USE.

Caution: See Instructions for Use	
Use Before Date	
Sterilized by ethylene oxide	

For single use only	
Keep dry	
Keep away from sunlight, including UV light	
Store only at temperatures less than 105˚F, 40˚C	40° 
Lot Number	LOT
Model Number ABS5670	REF
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	℞ ONLY
Manufactured for CyndRx, LLC by: CyndRx, LLC 205 Powell Place Suite 124 Brentwood, TN 37027 Phone: (615) 369-0665 Email: info@cyndrx.com	