INSTRUCTIONS FOR USE

VASCULAR SOLUTIONS DUETT™ SEALING DEVICE

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEVICE DESCRIPTION

Each Vascular Solutions Duett™ sealing device (DUETT) includes the following components:

- Single-use, disposable catheter
- Foil pouch containing 10ml collagen syringe (250mg collagen) with attached mixing luer
- Vial of thrombin (10,000 units)
- Vial of diluent (5 ml)
- Procoagulant mixing accessories (syringe (10ml) and 20 gauge needle)

The catheter is a sterile, sub-4F balloon catheter which is deployed through the existing introducer sheath to create a temporary seal of the arteriotomy. The procoagulant, a suspension of thrombin, collagen, and diluent, is mixed utilizing two syringes connected by a mixing luer. The procoagulant formulation is 2000 units/ml thrombin and 50 mg/ml collagen in approximately 5 ml of diluent.

The thrombin is a protein substance produced through a conversion reaction in which prothrombin of bovine origin is activated by tissue thromboplastin of bovine-origin in the presence of calcium chloride. It is supplied as a sterile powder that has been freeze-dried in the final container. Also contained in the thrombin vial are mannitol and sodium chloride. Mannitol is included to make the dried product friable and more readily soluble. The material contains no preservative and has been chromatographically purified. Thrombin requires no intermediate physiological agent for its reaction. It converts fibrinogen directly to fibrin.

The collagen is an absorbable hemostatic agent prepared as a dry, sterile, fibrous, partial hydrochloric acid salt of purified bovine corium collagen. It is prepared in a loose fibrous form. In its manufacture, swelling of the native collagen fibrils is controlled by ethyl alcohol to permit non-covalent attachment of hydrochloric acid to amine groups on the collagen molecule and preservation of the essential morphology of native collagen molecules. Dry heat and sterilization causes some cross-linking which is evidenced by reduction of hydrating properties, and a decrease of molecular weight which implies some degradation of collagen molecules. However, the characteristics of collagen which are essential to its effect on the blood coagulation mechanisms are preserved. Collagen attracts platelets that adhere to the fibrils and undergo the release phenomenon to trigger aggregation of platelets into thrombi in the interstices of the fibrous mass. The effect on platelet adhesion and aggregation is not inhibited by heparin in vitro.

The diluent is a sterile buffered solution of sodium phosphate and water. Both the thrombin and collagen are reconstituted with the diluent prior to use. The procoagulant is delivered to the exterior surface of the artery through the sidearm of the introducer sheath. Hemostasis is achieved by the physiological coagulation-inducing properties of the procoagulant. After procoagulant delivery, the deflated balloon is elongated through use of the catheter's integrated moveable core wire. A non-adherent, thermoplastic sleeve covers the deflated balloon to minimize its profile during both insertion and removal.

Revision/ print date: June 16, 2000

INDICATIONS

The DUETT is indicated forsealing femoral arterial puncture sites and reducing time to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures using a 5F - 9F introducer sheath with an overall length not exceeding 15.2 cm.

CONTRAINDICATIONS

The DUETT is contraindicated inpatients with known sensitivity to bovine-derived materials.

WARNINGS

Thrombin must not be injected. The thrombin is for use only with the DUETT.

The use of topical bovine thrombin preparations has occasionally been associated with abnormalities in hemostasis ranging from asymptomatic alterations in laboratory determinations, such as prothrombin time (PT) and partial thromboplastin time (PTT), to severe bleeding or thrombosis which rarely have been fatal. These hemostatic effects appear to be related to the formation of antibodies against bovine thrombin and/or factor V which in some cases may cross react with human factor V, potentially resulting in factor V deficiency. Repeated clinical applications of topical bovine thrombin increase the likelihood that antibodies against thrombin and/or factor V may be formed. Consultation with an expert in coagulation disorders is recommended if a patient exhibits abnormal coagulation laboratory values, abnormal bleeding, or abnormal thrombosis following the use of topical thrombin. Any interventions should consider the immunologic basis of this condition. Patients with antibodies to bovine thrombin preparations should not be re-exposed to these products.

The DUETT should not be used in patients withsuspected arterial puncture distal to the common femoral artery bifurcation, clinically severe peripheral vascular disease (refer to Individualization of Treatment section), or a common femoral artery estimated to be less than 6 mm in diameter. Use of the DUETT in these situations may lead to inadvertent intravascular delivery of the procoagulant. The acute onset of severely diminished or absent peripheral pulses in the limb treated with the DUETT may indicate that inadvertent intravascular delivery of the procoagulant has occurred. If this is suspected, immediately perform appropriate diagnostic and therapeutic procedures for thrombus dissolution/removal.

The DUETT should not be used if posterior arterial wall puncture is suspected, as this may lead to incomplete sealing and bleeding complications.

PRECAUTIONS

The DUETT deployment procedure should be performed by physicians or physician-directed allied health care professionals with adequate training in the use of the device.

To minimize the risk of puncture site infections:

- observe sterile technique at all times when using the DUETT
- do not use the DUETT if the sterile packages (barrier bag and collagen foil pouch) have been damaged or opened
- do not proceed with DUETT deployment in potentially contaminated puncture sites

The DUETT should be kept dry; it contains materials that are degraded by heat and moisture.

The DUETT is for single use only. Do not resterilize.

A limited femoral angiogram should be performed prior to DUETT deployment to confirm that:

- the arteriotomy is above the common femoral artery bifurcation
- the femoral artery is ≥ 6mm in diameter
- no significant plaque is present in the vicinity of the arterial sheath.

In the event that proper positioning of the DUETT balloon prior to procoagulant delivery cannot be achieved, remove the device and proceed with an alternate method of puncture site closure.

In the event that hemostasis is not achieved with the DUETT, apply manual or mechanical compression until bleeding is controlled.

ADVERSE EVENTS

The DUETT was evaluated in a randomized, controlled clinical investigation involving 695 patients and in a non-randomized, multi-center Continued Access Registry (CAR) involving 236 patients.

Randomized Multi-center Investigation

The randomized investigation compared the performance of the DUETT to that of Standard Compression (e.g manual or mechanical methods). Sixty-five (65) of the patients enrolled in this investigation were non-randomized DUETT run-in patients. Of the 630 randomized patients, 392 (62%) were randomized to DUETT and 238 (38%) were randomized to Standard Compression. Of the patients randomized to DUETT, 266 (68%) were post-intervention and 126 (32%) were post-diagnostic angiography. Of the patients randomized to Standard Compression, 155 (65%) were post-intervention and 83 (35%) were post-diagnostic angiography.

A total of 5 deaths (4 DUETT, 1 Standard Compression) were reported during the randomized investigation. None of these deaths were determined to be device-related.

Table 1 summarizes the adverse events reported within the randomized investigation's 30-day follow-up period. Events are summarized by percentage of randomized patients experiencing the event during the clinical investigation.

Table 1: Incidence of All Complications:
Percentage/Number of Patients With An Event (N= 630)

Description of Event	Duett N = 392	Standard Compression N = 238†	Difference [95% C.I.] (a)
Major Complications			
Vascular Repair			
Surgery for Vascular Complication	2.0% (8/392)	0.8% (2/237)	
Ultrasound Guided Compression	1.5% (6/392)	0.4% (1/237)	
PTA or Other Percutaneous Procedure	0.5% (2/392)	0.0% (0/237)	
Subtotal: Any Vascular Repair	3.1% (12/392)	0.8% (2/237)	
Bleeding Requiring Transfusion	1.5% (6/392)	1.3% (3/237)	
Infection Requiring Extended Hospitalization (with antibiotics)	0.5% (2/392)	0.0% (0/237)	
*Total: Any Major Complication	3.6% (14/392)	1.7% (4/237)	1.9% [4.97%] (c)
Vascular Complications			
Hematoma ≥ 6 cm	5.9% (23/392)	3.0% (7/237)	
Pseudoaneurysm	2.3% (9/392)	0.8% (2/237)	
AV Fistula	0.3% (1/392)	0.0% (0/237)	
Retroperitoneal Bleed	0.3% (1/392)	0.0% (0/237)	
Peripheral Arterial Occlusion or Peripheral Nerve Injury	0.8% (3/392)	0.4% (1/237)	
Total: Any Vascular Complication	7.1% (28/392)	3.8% (9/237)	3.3% [-1.3%, 7.8%] (b)
Device Malfunctions	5.4% (21/392)	NA	NA
Failure to Deploy	2.3% (9/392)	NA	NA

(a) C.I.: Confidence Interval for Difference in rates
(b) two-sided 95% confidence interval
(c) one-sided 95% upper confidence limit
Difference = Duett – Standard Compression
*Primary endpoint for the trial was constructed using a 1-sided hypothesis (Blackwelder)
†The number of patients reported below is less than the total patients studied due to missing data for some patients.

Continued Access Registry

In the Registry, patients received the DUETT sealing device following diagnostic and interventional endovascular procedures and were monitored up to hospital discharge for device-related complications. Of the initial 236 patients, 69 (29%) were post-intervention and 167 (71%) were post-diagnostic angiography.

One death was reported during the Registry, which was determined not to be device-related.

Table 2 summarizes the adverse events reported during the Continued Access Registry.

Table 2: Principal Safety Results: Percentage/Number of Patients With An Event (N=236)

Safety Measures	All patients
Vascular Repair	0.8% (2/236)
Transfusion	0.4% (1/236)
Infection	0.0% (0/236)
Hematoma ≥ 6 cm	1.7% (4/236)
Pseudoaneurysm	0.8% (2/236)
Periph. Arterial Occlusion Or Periph. Nerve Injury	0.4% (1/236)
Any Complication	2.5% (6/236)
No Major Complication	98.7% (233/236)
Device Malfunctions	6.8% (16/236)
Failure to Deploy	5.5% (13/236)

The following adverse events were NOT observed during the clinical investigation, but are recognized as potential complications associated with balloon catheter, thrombin, or collagen usage. Events are listed in alphabetical order:

- adhesion formation
- allergic reaction
- abscess formation
- foreign body reaction
- wound dehiscence.

A recognized rare potential reaction associated with the use of bovine derived thrombin is the development of inhibitory antibodies which interferes with hemostasis.

Although clinical reports of DUETT-related femoral artery access site infections were very few, tissue necrosis was noted with intra-muscular implantation of the mixed procoagulant in a rabbit model.

CLINICAL INVESTIGATIONS

The DUETT was evaluated in a multicenter, randomized (5:DUETT: 3 Control) clinical investigation involving 630 patients (at fourteen U.S sites and one European site) and in a non-randomized continued access registry involving 236 patients to-date (at 5 U.S. sites).

Randomized Multi-center Investigation

The study compared the performance of the DUETT (N=392) with that of Standard Compression (N=238) in sealing a femoral arterial puncture site following a diagnostic or interventional endovascular procedure. Standard Compression was defined as arterial puncture site closure using either manual pressure or a mechanical clamp. The study was designed as an equivalency trial for the 30 day primary combined safety endpoint of freedom from major complications, and as a superiority trial for the primary effectiveness endpoints of time to hemostasis (time from the end of the antecedent procedure to the time that hemostasis is first observed) and ambulation (time from the end of the antecedent to when the patient stands at the bedside and walks 110 feet without re-bleeding). Major complications included: need for vascular repair (vascular surgery, ultrasound-guided compression, PTA or other percutaneous

intervention), bleeding requiring transfusion, and infection requiring extended hospitalization and antibiotic administration. Secondary endpoints were procedure success rate and device success rate.

Patients undergoing an endovascular procedure (33.2% diagnostic, 66.8% interventional) performed via a 5F - 9F short length introducer sheath in the common femoral artery were eligible. A total of 24% of the patients studied received GPIIb/IIIa receptor blockers. Exclusion criteria included patients who had significant peripheral vascular disease, bleeding disorders, hypertension (>180/110) refractory to medical therapy, or known allergies to bovine-derived products. Patients who were pregnant, experienced a hematoma ≥ 6 cm prior to sheath removal, or had an ACT >400 seconds at the conclusion of the endovascular procedure were also excluded.

There were no significant differences between the two randomized groups with respect to gender, age, risk factors, peri-procedural medications, body size, or blood pressure. However, activated clotting times (ACT) at the time of sheath removal were higher in the DUETT treatment arm [220.0 ± 74.4 seconds (DUETT) versus 147.6 ± 41.6 seconds (Standard Compression); $p < 0.001$].

Thirty-day clinical follow-up was performed in 94.8% of patients in accordance with the protocol. In a sub-group of 193 patients, a duplex ultrasound of the femoral artery was performed to rule out pseudoaneurysm and other abnormalities.

In both the diagnostic and interventional groups, use of the DUETT resulted in statistically significant decreases in time to hemostasis and time to ambulation as compared to Standard Compression. (Table 3). There was no significant difference in the major complication rate overall between the DUETT group as compared to the Standard Compression group (3.6% vs. 1.7%, p=0.220).

Table 3: Effectiveness Endpoints for all patients (N = 630)

	Duett N = 392 †	Standard Compression N = 238 †	Difference [95% C.I.]
Time to Hemostasis (min) Median (Interquartile) Mean (std. dev.) N	14.0 (10, 17) 20.4 (41.6) 388	195.0 (46, 351) 228.4 (206.9) 225	-208.0 [-235.5, -180.5]
Time to Ambulation (min) Median (Interquartile) Mean (std. dev.) N	337.5 (223, 526) 535.4 (711.2) 366	705.0 (400, 1120) 834.2 (622.6) 217	-298.8 [-413.2, -184.4]
Device Success (a)	93.1% (365/392)	NA	NA
Procedure Success (b)	96.4% (378/392)	98.3% (233/237)	-1.9% [-5.5%, 1.8%]

(a) Device Success = number of patients in whom hemostasis was achieved using the Duett sealing device alone with freedom from major complications vs. the number attempted.
(b) Procedure Success = number of patients in whom hemostasis was achieved with freedom from major complications vs. the number attempted.
† The number of patients reported below is less than the total patients studied due to missing data for some patients.

Table 4: Endpoint Outcomes for Patient Subgroups (N = 630)

	Diagnostic		Intervention	
	Duett N = 126†	Standard Compression N = 83†	Duett N = 266†	Standard Compression N = 155†
Time to Hemostasis (min) Median (Interquartile) Mean (std. dev.) N	12.0 (9, 16) 12.8 (5.3)) 125	38.0 (29, 52) 67.1 (171.6) 77	14.0 (11, 19) 24.0 (50.0) 263	296.5 (195, 384) 312.3 (171.2) 148
Time to Ambulation (min) Median (Interquartile) Mean (std. dev.) N	155.0 (121, 262) 349.1 (752.7) 120	359.0 (285.5, 421.5) 485.3 (646.3) 72	385.0 (325, 732) 626.2 (673.1) 246	960.0 (692, 1204) 1007.4 (533.2) 145

† The number of patients reported below is less than the total patients studied due to missing data for some patients.

Continued Access Registry

The performance of the DUETT (N=236) in sealing a femoral arterial puncture site following a diagnostic or interventional endovascular procedure was further evaluated in a Continued Access Registry. Primary endpoint data collected included time to hemostasis, time to ambulation, and the composite endpoint of major complications. The treatment protocol for the registry was nearly identical to that used during the randomized investigation. Follow-up until discharge was performed in all 236 patients in accordance with the protocol.

Patients enrolled in the Registry displayed a 1.3% rate of major complications at the time of hospital discharge. The effectiveness endpoint results were as follows:

Table 5: Endpoint Outcomes (N = 236)

	All Duett patients N= 236†	Diagnostic patients N = 167†	Interventional patients N = 69†
Time to Hemostasis (min) Median (Interquartile) Mean (std. dev.) N	11.0 (9, 17) 20.0 (51.1) 227	11.0 (8, 16) 14.2 (10.2) 164	12.0 (10, 17) 35.2 (94.4) 63
Time to Ambulation (min) Median (Interquartile) Mean (std. dev.) N	199.0 (140, 390) 445.9 (782.9) 224	163.0 (133, 245) 312.9 (774.4) 163	681.0 (289, 1219) 801.0 (694.6) 61
Device Success (a)	89.0% (210/236)	92.2% (154/167)	81.2 % (56/69)
Procedure Success (b)	98.7 % (233/236)	99.4% (166/167)	97.1% (67/69)

(a) Device Success = number of patients in whom hemostasis was achieved using the Duett sealing device alone with freedom from major complications vs. the number attempted.

(b) Procedure Success = number of patients in whom hemostasis was achieved with freedom from major complications vs. the number attempted.

† The number of patients reported below is less than the total patients studied due to missing data for some patients.

INDIVIDUALIZATION OF TREATMENT

As noted in the warning section, the DUETT should not be used in patients with severe peripheral vascular disease. Severe peripheral vascular disease is defined as:

- severe claudication when ambulating < 100 feet
- weak or absent pulses in the affected limb
- ABI < 0.5 at rest
- known stenosis ≥ 50% in the iliac or femoral artery on the affected side
- prior vascular bypass surgery involving the affected femoral artery
- prior stent placement in the vicinity of the arterial puncture site

Note that the safety and effectiveness of the DUETT have not been established in the following patient populations:

- patients younger than 18 years of age
- women who are pregnant or lactating
- patients with a suspected posterior femoral artery puncture
- patients with an antegrade femoral artery puncture
- patients with a hematoma ≥ 6 cm prior to sheath removal
- patients with a known bleeding disorder, including thrombocytopenia (platelet count <100,000), thrombasthenia, hemophilia, or von Willebrand's disease
- patients with significant anemia (Hgb < 10 g/dL, Hct < 30)
- patients with a baseline INR > 1.5 (e.g. coumadin therapy)
- patients who received thrombolytic therapy (streptokinase, urokinase, t-PA) in the preceding 24 hours
- patients with an ACT > 400 seconds at the conclusion of the endovascular procedure

- patients with an elevated blood pressure (SBP >180 or DBP >110 mm Hg) despite medical therapy
- patients in whom continued heparin or other anticoagulant therapy (with the exception of Glycoprotein IIb/IIIa receptor blockers) is planned following completion of the endovascular procedure

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the DUETT. The techniques and procedures described do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient.

Supplies

The DUETT package contains the following:

- (1) DUETT catheter
- (1) thrombin vial U.S.P. (10,000 units)
- (1) diluent vial, 5 ml
- (1) 10 ml mixing syringe with attached 20-gauge needle
- (1) foil pouch containing:
  collagen, 250 mg, in 10cc syringe
  attached mixing luer

Other materials required but not provided are:

- (1) 5F - 9F introducer sheath with an overall length not exceeding 15.2 cm
- (1) 10 ml syringe (for catheter preparation and balloon inflation)
- sterile normal saline (for sheath sidearm flush and DUETT balloon inflation)

Procedure

Carefully inspect the DUETT packaging (barrier bag and foil pouch) and components for damage prior to use. Using sterile technique, transfer the components into the sterile field.

NOTE: Before transferring components into the sterile field, remove the foil pouch from the front pocket of the barrier bag. The outside of the foil pouch is NOT sterile and needs to be opened separately.

Confirm that the existing introducer sheath is 5F - 9F with an overall length not exceeding 15.2 cm.

The DUETT deployment procedure consists of 3 main parts:
1) mixing the procoagulant
2) deploying the DUETT catheter
3) delivering the procoagulant and removing the DUETT catheter

Mixing the Procoagulant

NOTE: The procoagulant can be prepared up to one hour prior to deployment.

1. Remove the caps from the thrombin and diluent vials to expose the rubber stoppers.

2. Using the 10 ml mixing syringe and attached 20-gauge needle, withdraw all diluent from the diluent vial and transfer it into the thrombin vial.

3. Withdraw the mixing syringe and attached 20-gauge needle from the thrombin vial. Gently agitate the vial to reconstitute the thrombin. DO NOT SHAKE.

4. When the thrombin is completely dissolved, withdraw all reconstituted thrombin (approximately 5 ml) from the thrombin vial again using the mixing syringe. Remove and discard the needle from the mixing syringe.

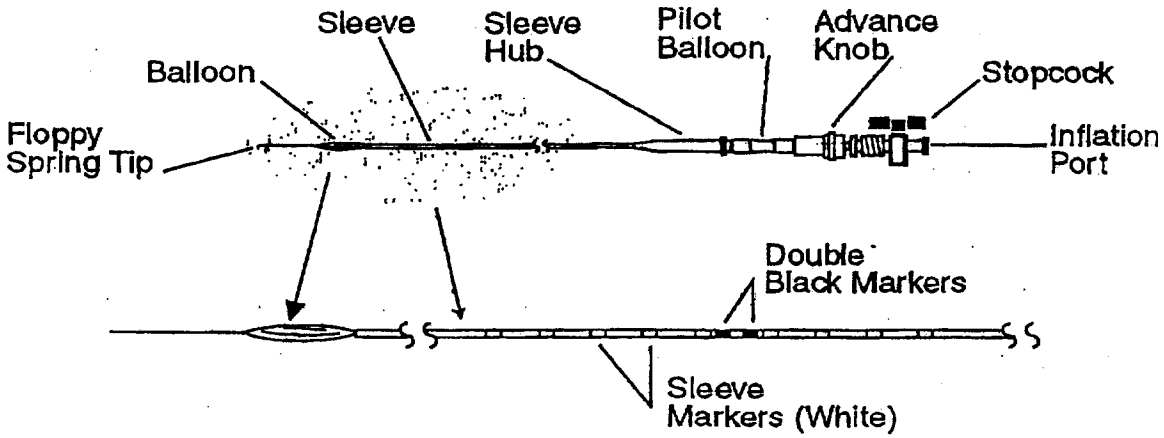
5. Attach the collagen syringe with attached mixing luer to the 10 ml mixing syringe.

6. Push the reconstituted thrombin into the collagen syringe. Next, push the entire thrombin/collagen mixture back into the mixing syringe. Continue exchanging the procoagulant until all components are thoroughly mixed (approximately 10 exchanges).

7. Leaving the syringes connected, set the procoagulant aside until needed.

Deploying the DUETT catheter

Review the schematic drawing of the DUETT catheter below for terminology used in the following deployment procedure.



The DUETT catheter is deployed through the introducer sheath (5F - 9F, short length) used for the antecedent endovascular procedure. Prior to deploying the DUETT catheter, ensure that the sheath is positioned in the femoral artery and is free of all devices. Remove any sutures maintaining the introducer sheath at the skin surface.

Deploy the DUETT catheter according to the following steps:

1. Perform a limited femoral angiogram via the sidearm of the introducer sheath to confirm that:

   - the arteriotomy is above the common femoral artery bifurcation
   - the femoral artery is ≥6 mm in diameter
   - no significant plaque (e.g. stenosis ≥ 50%) is present in the vicinity of the arterial sheath.

   *NOTE: If any of the above conditions are not met, do NOT deploy the DUETT catheter. Use an alternate method of puncture site closure.

2. Using a 10 ml syringe (not supplied) filled with sterile normal saline, thoroughly flush the sidearm of the introducer sheath.

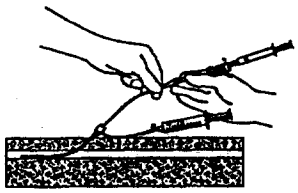
3. To prepare the catheter, draw 2-3 ml sterile normal saline into the same 10 ml syringe. Attach the syringe to the **stopcock** on **Inflation port** of the DUETT balloon catheter. Open

the **stopcock**, aspirate with the syringe, and hold for 10 seconds to create a vacuum. Turn the **stopcock** off, disconnect the syringe, remove all air from the syringe, create a miniscus, and reconnect the syringe to the **stopcock**.

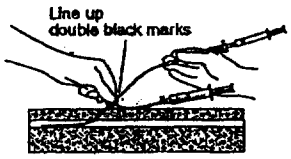
*NOTE: If a continuous stream of air bubbles is noted in the saline-filled syringe during aspiration, a leak may be present in the system. Tighten the syringe-stopcock connection and aspirate again. If air bubbles are still present, DO NOT use this DUETT catheter. Obtain a new DUETT catheter and continue with the procedure.

4. Ensure that the **sleeve** is completely covering the **floppy spring tip**. Insert the DUETT catheter through the hemostasis valve and advance it 3-5 cm into the introducer sheath.

5. With one hand holding the **sleeve hub** stationary, use the other hand to advance the shaft of the DUETT catheter until the **proximal assembly** meets the **sleeve hub**. The **distal balloon** and **floppy spring tip** are now exposed for atraumatic entry into the femoral artery.



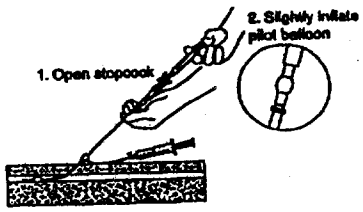
6. Continue advancing the entire DUETT catheter into the introducer sheath until the **double black markers** on the **sleeve** line up with the hub of the introducer sheath. The **distal balloon** is now positioned outside of the sheath and inside the femoral artery.



7. Obtain the previously prepared procoagulant and perform two final exchanges. With all of the procoagulant in the mixing syringe, disconnect the empty collagen syringe and mixing luer and discard. Attach the procoagulant syringe to the stopcock connected to the sidearm of the sheath.

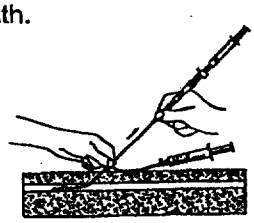
*NOTE: Once the procoagulant syringe has been attached to the sheath sidearm, DO NOT open the sheath sidearm stopcock until you are ready to deliver the procoagulant. Since the introducer sheath is positioned in the artery at this point, opening the stopcock will allow a free flow of blood into the procoagulant. Coagulation will then occur inside the syringe.

8. Inflate the **distal balloon** by opening the **stopcock** on the DUETT catheter **inflation port** and pushing the syringe plunger until the **pilot balloon** shows a definite bulge. This confirms that the **distal balloon** has reached an adequate diameter. Close the **stopcock** on the **inflation port**. Observe pilot balloon throughout the procedure to ensure continued system inflation.

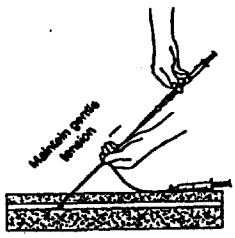


*NOTE: Approximately 0.75 - 1 ml of saline will be required to adequately fill both the distal and pilot balloons.

9. Holding the introducer sheath stationary with one hand, grip the **sleeve** with the other hand. Gently withdraw the DUETT catheter until resistance is felt. The **distal balloon** is now abutting the introducer sheath.



10. Continue withdrawing the introducer sheath and DUETT catheter together as a unit until resistance is again felt. The **distal balloon** is now abutting and temporarily sealing the puncture site.

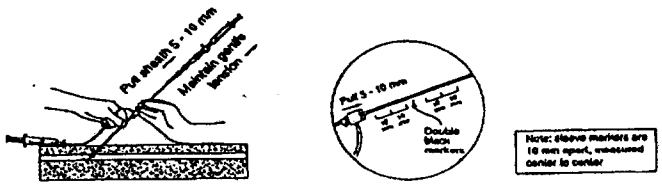


*NOTE: Observe the sleeve markers to ensure that the introducer sheath and DUETT catheter are withdrawn as a unit. The position of the introducer sheath's head relative to the DUETT catheter sleeve should not change during sheath and DUETT withdrawal.

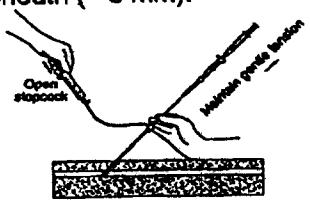
Delivering the Procoagulant and Removing the DUETT catheter

NOTE: Gentle constant tension **must** be maintained on the DUETT catheter at all times during procoagulant delivery (Steps 1-3).

1. With the **distal balloon** abutting the puncture site, maintain constant gentle tension on the DUETT catheter parallel to the tissue tract. Using the **white sleeve markers** for guidance, withdraw the introducer sheath slightly (~ 5 mm). The white sleeve markers are positioned 10 mm apart center to center.

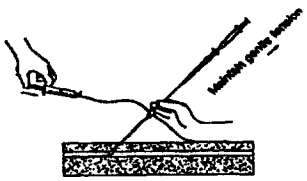


2. Confirm proper position and inflation of the balloon by opening the stopcock on the sidearm of the introducer sheath and aspirating with the procoagulant syringe. If blood is observed in the sidearm of the introducer sheath, gently increase tension on the DUETT catheter and again slightly withdraw the sheath (~ 5 mm).



WARNING: If blood flow into the sidearm of the introducer sheath continues or resistance is met during procoagulant delivery, do not proceed with deployment. Intravascular delivery of the procoagulant may occur, leading to serious injury. Deflate the distal/pilot balloons and remove the DUETT catheter from the artery. Following removal of the DUETT catheter and introducer sheath, use an alternate method of puncture site closure.

3. While maintaining constant gentle tension on the DUETT catheter, slowly (~1 ml/second) deliver 3 ml of procoagulant. Continue to deliver the remaining procoagulant while slowing withdrawing the introducer sheath through the tissue tract. Stop delivering procoagulant when the introducer sheath exits the skin surface or when procoagulant begins exiting the tissue tract.

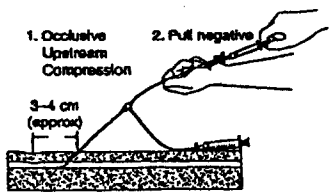


*NOTE: Once the introducer sheath exits the skin surface, it should NOT be reintroduced into the patient.

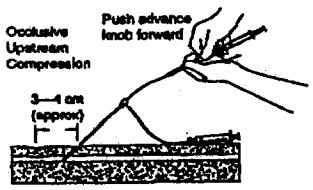
*NOTE: Deliver a minimum of 3 ml of procoagulant (post-diagnostic procedures) or 5 ml (post-interventional procedures). If the minimum quantity of procoagulant for the type of procedure is not administered, sealing may not occur. Standard mechanical compression should be applied.

Steps 4-7 may be performed with the assistance of a second person.

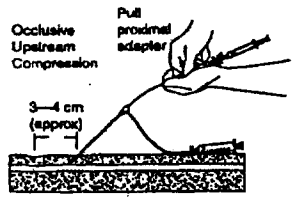
4. Apply occlusive pressure 3-4 cm proximal to the arterial puncture site. Release tension on the DUETT catheter. Open the **stopcock on the inflation port** and aspirate to deflate the distal/pilot balloons. Close the **stopcock** on the **inflation port.**



5. Push the **advance knob** on the **proximal assembly**. The deflated **distal balloon** is now elongated for recapture.



6. With one hand holding the **sleeve hub** stationary, grip the **proximal assembly** with the other hand and withdraw the **distal balloon** into the **sleeve** until reaching a positive stop. The **distal balloon** and **floppy spring tip** are now covered by the sleeve.



7. Completely remove the DUETT catheter and introducer sheath from the patient.

8. Apply direct, non-occlusive manual pressure to the puncture site and release proximal occlusive pressure. Continue applying pressure until hemostasis is achieved (typically 2-5 minutes).

9. Upon completion of DUETT use, dispose of the device in accordance with generally accepted biohazard disposal practice.

Post-Procedure Patient Management

1. Confirm that the puncture site remains dry and no hematoma forms once direct, non-occlusive manual pressure is released.

2. Apply a pressure dressing securely to the puncture site for one hour (recommended).

3. Assess the puncture site per institutional protocol.

4. Ambulate the patient per physician discretion or institutional sealing device protocol.

5. If re-access of the puncture site is necessary, follow the same institutional practice guidelines used for re-access following standard compression.

PACKAGE LABEL REFERENCES

The DUETT is for single use only. 

The DUETT should be kept dry. 

The DUETT should be stored at temperatures between 2° C and 25° C. 

The DUETT components have been sterilized in the following manner:

Component	Sterilization Method
Catheter	STERILE EO Ethylene oxide
Foil pouch containing 250 mg microfibrillar collagen in 10 ml Syringe; attached mixing luer	STERILE High temperature
Vial of thrombin, U.S.P. (10,000 units)	STERILE A Aseptic filtration
Vial of diluent, 5 ml	STERILE High temperature
10 ml mixing syringe with 20 gauge needle	STERILE EO Ethylene oxide

DUETT expiration date  YYYY-MM

Warning: "Attention, consult Instructions for Use (IFU)" 

DUETT lot number MXXXXXX

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the Vascular Solutions Duett sealing device is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Vascular Solutions, Inc. shall not be liable for any incidental, special, or consequential damages arising from the use of the Vascular Solutions Duett sealing device. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

No employee, agent, or distributor of Vascular Solutions, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Vascular Solutions, Inc.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF VASCULAR SOLUTIONS, INC.

Vascular Solutions, Inc.
2495 Xenium Lane North
Minneapolis, Minnesota 55441 USA
Tel: 763-656-4300
Fax: 763-656-4250
Website: www.vascularsolutions.com

PN 0181 Rev A 06/00

Vascular Solutions, Inc.
PMA Amendment: Vascular Solutions Duett™ sealing device
PMA Number: P990037
Final Duett Package Labels

Pouch (Barrier Bag) Label

DUETT

Sealing Device

Fits all 5F-9F introducer sheaths
(overall length ≤ 15.2cm)

Contents

1 Catheter	STERILE EO
1 Collagen Syringe	STERILE
1 Thrombin U.S.P.	STERILE A
1 Mixing Syringe	STERILE EO
1 Diluent, 5ml	STERILE

CAUTION
Federal (USA) law restricts this device to sale or on the order of a physician.

Model 1000

LOT MXXXXXX

YYYY-MM

Sterile unless package damaged or opened; do not resterilize.

Vascular Solutions
2495 Xenium Lane North
Minneapolis, MN 55441 USA
Office: (763) 656-4300
FAX: (763) 656-4250
Customer Service: (888)-240-6001

Vascular Solutions, Inc.
PMA Amendment: Vascular Solutions Duett™ sealing device
PMA Number: P990037
Final Duett Package Labels

10-pack Box Label

DUETT

Sealing Device

Fits all 5F-9F introducer sheaths
(overall length ≤ 15.2cm)

Model 1000

Contents:
10 Duett Sealing Devices
Instructions For Use

CAUTION - Federal (USA) law restricts this device to sale by or on the order of a physician.

LOT
FXXXXXX

YYYY-MM

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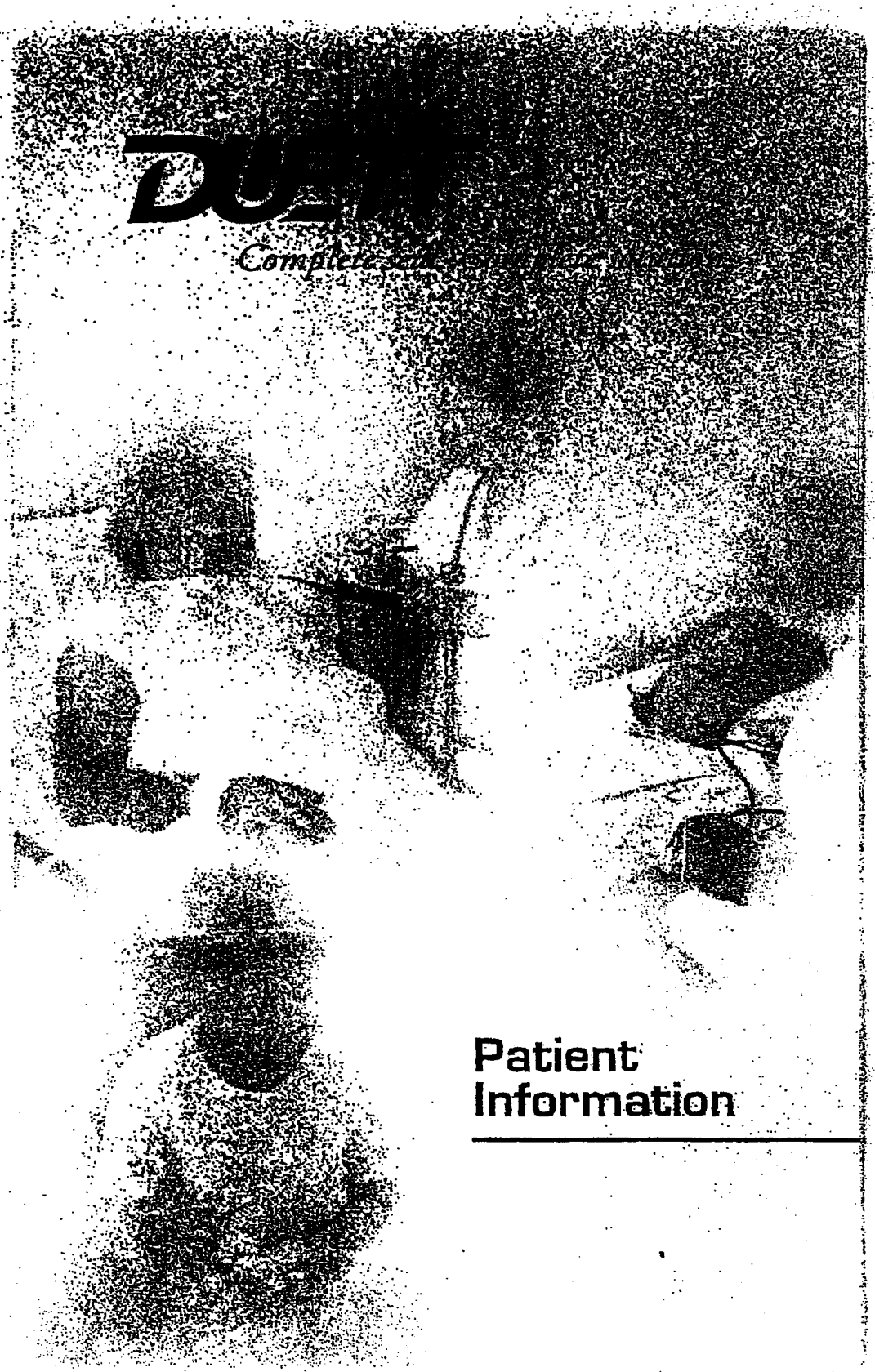

Patient
Information

Your doctor offers puncture the Vascular Solutions Duett

Who can receive the Duett sealing device?

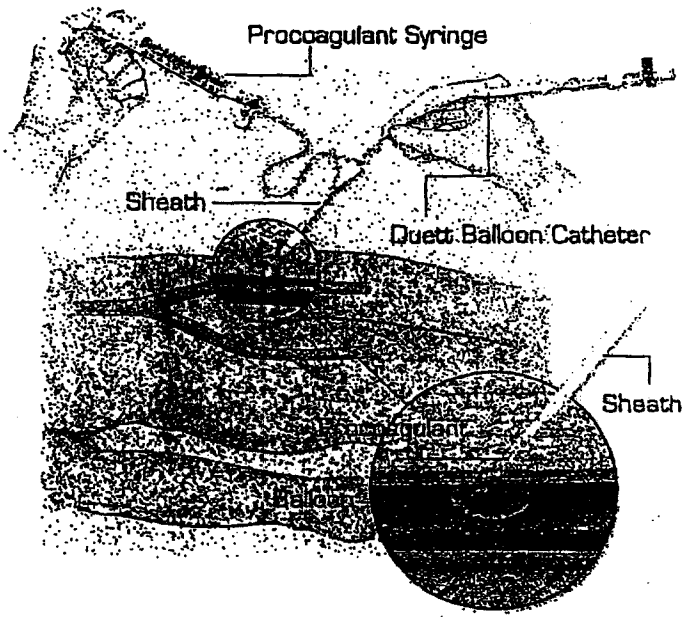
The Duett sealing device can be placed in adults who have had a catheterization procedure through a sheath in the femoral artery. You may not receive the Duett if you are allergic to cattle products, have a blood clotting disorder, or your blood pressure is too high (>180/110) at the end of your catheterization procedure. You also may not receive the Duett if you have severe blockages or bypass grafts in your leg arteries on the side where the sheath is placed. Be sure to notify your doctor if you are pregnant, have been taking Coumadin® (Warfarin) or frequently have pain in your legs when you walk.

What is the Duett sealing device?

The Duett sealing device consists of 2 parts:

a balloon catheter and

a procoagulant mixture.



site sealing
sealing device

The **balloon catheter** is a short plastic tube with a small balloon attached to the end. The balloon catheter will be inserted through the sheath in your leg. The balloon will then be inflated inside your femoral artery and pulled back against your artery's inside wall to temporarily prevent bleeding from the puncture site.

The **procoagulant** mixture is a liquid "glue-like" substance. The procoagulant mixture will be attached to the sheath and delivered to the puncture site to permanently seal it. The balloon is then deflated, and the sheath and Duett balloon catheter are removed. After 2-5 minutes of light pressure to the puncture site, the puncture site is sealed.

How does the Procoagulant Form the Seal?

The procoagulant is a mixture of 2 substances naturally found in the human body: **collagen** and **thrombin**. When a blood vessel is injured, the collagen contained within a blood vessel wall is exposed. **Collagen** starts the natural healing process by bringing about blood clotting. Collagen attracts platelets found in the blood and activates them. Platelets then stick together and form a "platelet plug" at the injured site.

The "platelet plug", however, is not strong enough to prevent blood loss from an artery. **Thrombin**, a protein found in the blood, then rapidly converts an inactive substance in the blood (fibrinogen) to its active form (fibrin). Fibrin forms strands that make up the meshwork of a blood clot and give it strength to prevent bleeding even when pressure is exerted on the injured site.

This natural sealing process in an artery usually takes 2-12 hours – sometimes longer if clot-preventing medications are present in the bloodstream. The Duett procoagulant (collagen and thrombin) is delivered directly to your puncture site in quantities that will cause rapid sealing. The seal will form in 2-5 minutes, and it will be strong enough for you to get up and walk within 1-6 hours. **The Duett procoagulant causes natural sealing to occur; it just occurs faster.**

What will you feel?

While the Duett is being used, you may feel some pressure at the puncture site. This is because the introducer sheath is holding tissues surrounding the puncture site during procoagulant delivery. You will also feel a medical professional holding some light pressure over the site for 2-5 minutes after the procoagulant is in place.

Afterwards, you may experience some mild discomfort at the puncture site related to the catheterization procedure itself. Visual evidence of the procoagulant at the puncture site should disappear very quickly, and you may have difficulty even finding the puncture site in a few days.

What should I do after the Duett is used?

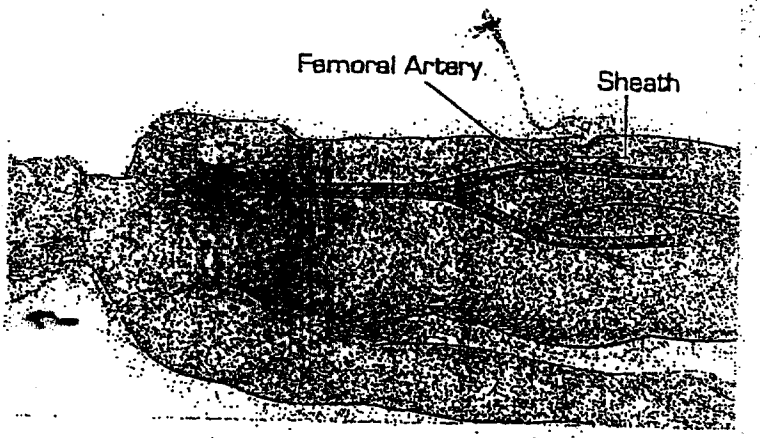
After Duett use, you will be required to lie still in bed without moving your leg for 1 hour. You may have the head of your bed raised up slightly. You also may have a tight dressing in place over your puncture site during that hour. After the first hour, your nurse may elevate the head of your bed to a "sitting" position, and you may gently move your leg while in bed. Depending on the type of procedure you had and the amount of clot-preventing medications you received, you may get up and walk within 1-6 hours.

When you go home, you should keep your puncture site clean, and you may shower normally. Avoid lifting heavy objects (over 25 lbs.) or straining for several days. It is normal to see evidence of the body's natural reaction to your catheterization procedure – such as mild bruising or swelling at the site. If you notice slight bleeding from your puncture site, apply pressure to the site until the bleeding stops. If the bleeding is heavier or you notice increased swelling or discomfort at the puncture site, apply pressure and contact your doctor immediately. Also, if you notice any signs of infection such as redness or discharge from your puncture site, contact your doctor immediately.

Always follow your doctor's instructions. If your doctor has given you instructions different from those in this pamphlet, be sure that you follow his/ her instructions instead.

What is "vascular sealing"?

Your doctor has recommended that you undergo a **catheterization** procedure to either diagnose or treat a medical condition you may have. During your catheterization, your doctor will use your femoral artery to gain access to your body's blood vessel network. Your **femoral artery** is located on the top of your leg near your groin area. Using a needle, your doctor will make a small hole in your femoral artery (the "**puncture site**") and place a tube through the hole and into the artery. The tube, or "**sheath**", stays in place during the entire catheterization procedure. The sheath allows the doctor to work within your body's blood vessel network while preventing bleeding from the puncture site.



After your catheterization procedure is finished, the sheath will be removed. In order to prevent blood loss from the hole created by the sheath, your doctor or another medical professional must **seal** the puncture site. A common technique for sealing the puncture site is the use of **compression**. With this technique, a medical professional will exert hand pressure or place a mechanical clamp over the puncture site for 15-30 minutes. Afterwards, a sandbag or pressure dressing may be placed over the site, and you will be required to lie still in bed for 4-12 hours. If you received a significant amount of clot-preventing medication during the catheterization procedure, there may be a 3-12 hour delay before your sheath can be removed. While the sheath is in place in your femoral artery, you will also be required to lie still in bed.

The puncture site can also be sealed through the use of **puncture sealing devices**. These devices allow the sheath to be removed immediately after the catheterization – even if you have received clot-preventing medication. These devices typically stop bleeding from the puncture site within 2-5 minutes and may allow you to get up and walk around 1-6 hours after the procedure.

General Information

Your doctor used the Duett on (date):_____

He/She used it in the (circle one): left / right groin

Doctor's Instructions_____

_____

_____

Always follow your doctor's instructions after the procedure . .

. . .and always call your doctor if you have ANY questions about any symptoms you notice at your puncture site.

Doctor's name:_____

Doctor's phone number:_____

Attach to patient's chart

DUETT Ambulation time:

____/____ @ ___:____ am/pm

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Website www.vascularsolutions.com

Vascular SOLUTIONS

~~SAMPLE~~ ML1042 Rev. 02