

INSTRUCTIONS FOR USE
Quick-Close® Vascular Suturing System

REF IT-077001

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

CAUTION: Federal (U.S.A.) Law limits this device to sale by, or on the order of, a physician.

DEVICE DESCRIPTION

Following an interventional or diagnostic procedure involving intravascular access through the femoral artery, the Quick-Close® Vascular Suturing System (Quick-Close® System) is used for the closure of a femoral artery wound. The Quick-Close® Suture Applier places a single stitch of size 3-0, non-absorbable, monofilament suture and secures the suture in the closed, hemostatic position by means of a stainless steel cinch.

The Quick-Close® System consists of two separate devices that are supplied together in a single blister pack:

- Suture delivery mechanism (Quick-Close® Suture Applier)
- Suture closure (cinching) apparatus (Quick-Ti™ Cinch Applier).

Quick-Close® Suture Applier: The Quick-Close® Suture Applier has a pistol-grip configuration and shaft for gaining access to the femoral artery wound site. The applier houses a single strand of polybutester (Novafil™) suture fitted with stainless steel needles at either end. Using manual control, and relying on tactile feedback, the device is used to place one end of the suture through one edge of the arterial wound where the needle is captured by a stainless steel ferrule. The applier is then re-positioned and the other end of the suture is placed through the opposite edge of the wound site in a similar fashion. As the applier is withdrawn from the wound site, the 24" length of suture is deployed out of its housing within the applier.

Quick-Ti™ Cinch Applier: The Quick-Ti™ Cinch Applier has a syringe-type configuration with an extended shaft. The device is used to gather the two ends of the suture so as to allow for tissue approximation. The applier places a stainless steel cinch that acts in place of a knot to secure the suture in a closed, hemostatic position.

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The Quick-Close® Vascular Suturing System is indicated to close femoral artery access sites and to reduce time-to-hemostasis and time-to-ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5, 6, 7, or 8 French procedural sheath. Additionally, the Quick-Close® Vascular Suturing System is indicated to reduce time-to-hemostasis in patients who have undergone interventional endovascular procedures, utilizing a 5, 6, 7, or 8 French procedural sheath, who have received intraprocedural glycoprotein IIb/IIIa inhibitor therapy.

CONTRAINDICATIONS

There are no known contraindications to the use of the device. Attention is drawn to the Warnings, Precautions, and Special Patient Populations.

WARNINGS

- This product is provided sterile for SINGLE PATIENT USE ONLY. DO NOT RESTERILIZE.
- Do not use if components or packaging appear to be damaged or defective or if any portion of the packaging has previously been opened.

PRECAUTIONS

- The Quick-Close® System should only be used by a trained licensed physician or healthcare professional.
- Before using product, read all information thoroughly.
- If suture breakage occurs at any point during the procedure, remove the suture (by pulling) from the body and apply conventional compression methods.
- Use conventional compression methods in the event bleeding from the femoral artery access site persists after the use of the Quick-Close® System.

SPECIAL PATIENT POPULATIONS

The safety and effectiveness of Quick-Close® System has not been established in the following patient populations:

- a) Patients ineligible for in-catheterization lab arterial sheath removal

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- b) Patients with pre-existing hematoma (visual and/or palpable), arterio-venous fistula, or pseudoaneurysm; or bleeding during the procedure
- c) Patients who have had treatment with another suture or collagen vascular hemostasis device at the access site within the previous 3 months
- d) Patients with a Dacron graft or patch at the access site
- e) Patients who have had more than one arterial puncture site during the intervention necessitating closure
- f) Patients who have puncture sites in the profunda femoris or superficial femoral artery or at the bifurcation of the arteries
- g) Patients with fluoroscopically visible calcium at the femoral artery puncture site
- h) Patients where the diameter of the target femoral artery is < 4 mm
- i) Patients where the posterior wall of the intended artery was thought to have been punctured during the interventional procedure
- j) Patients who have a history of bleeding diathesis, coagulopathy, or a blood dyscrasia
- k) Patients who are morbidly obese [defined as abdominal panniculus hangs below the level of the groin or obesity precludes the use of a standard introducer needle (i.e., Seldinger Needle)]
- l) Patients where the introducer sheath insertion prior to the interventional procedure was difficult due to scarring of the vessel wall
- m) Patients who have a venous sheath
- n) Patients who have a hemoglobin level ≤ 10.5 g/dl
- o) Patients with angiographic evidence of common femoral artery stenosis > 50% at the access site
- p) Patients with no distal pulses in the access site leg
- q) Patients who have received thrombolytic therapy within 48 hours prior to procedure; unless patient has an Activated Clotting Time (ACT) within the reasonable and usual practice standard for ACT levels that are applied to vascular hemostasis devices at the institution
- r) Patients whose ACT levels do not meet the reasonable and usual practice standard for ACT levels that are applied to vascular hemostasis devices at the institution
- s) Patients who have had the same artery punctured in the previous 14 days
- t) Patients with a known allergy to PEEK (polyetherether ketone), HDPE (high density polyethylene) nylon, or polybutester
- u) Patients known to be pregnant or lactating

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- v) Patients with a severe noncardiac systemic disease or illness with a life expectancy of less than one year
- w) Patients with evidence of systemic or cutaneous infection
- x) Patients where there has been use of an intra-aortic balloon pump through the arterial puncture site

ADVERSE EVENTS

The Quick-Close® System was evaluated in a prospective, multi-center, randomized clinical study that enrolled 367 patients undergoing diagnostic or interventional cardiac catheterization procedures. Patients were randomized in a 2:1 randomization (test:control) scheme. Patients randomized to the test group received treatment with the Quick-Close® Vascular Suturing System while patients randomized to control received manual compression. The major and minor complications for this study, as adjudicated by the Clinical Events Committee (CEC), are listed in Tables 1-4.

Table 1. Summary of CEC Reported Major Complications by Combined Procedure Group – Event Level (Intent-to-Treat Patients)

Complication	Manual Compress (N=124)	Quick-Close (N=243)	p-value*
Total complications	3 (2.4%)	5 (2.1%)	1.0000
Death	0 (0.0%)	0 (0.0%)	NA
Myocardial infarction**	0 (0.0%)	1 (0.4%)	1.0000
Groin related transfusion	0 (0.0%)	2 (0.8%)	0.5526
Device failure with adverse consequences to the patient	0 (0.0%)	1 (0.4%)	1.0000
Hematoma requiring extended hospitalization	0 (0.0%)	1 (0.4%)	1.0000
Retroperitoneal hemorrhage	1 (0.8%)	0 (0.0%)	0.3379
Vascular repair or the need for vascular repair	1 (0.8%)	0 (0.0%)	0.3379
Groin related infection requiring IV antibiotics and/or extended hospitalization	0 (0.0%)	0 (0.0%)	NA
Permanent groin related nerve injury or surgery for groin related nerve injury	0 (0.0%)	0 (0.0%)	NA
Any new ipsilateral lower extremity ischemia defined by a 1 class change in Rutherford score	0 (0.0%)	0 (0.0%)	NA
> 20% drop in hemoglobin requiring transfusion**	1 (0.8%)	0 (0.0%)	0.3379

Intent-to-Treat patients are defined as those patients who are randomized in the study.

* Test for equality of complication rates (exact test for comparing two Poisson rates, using StatXact – 8).

**Myocardial infarction and >20% drop in hemoglobin are not defined as major complications in the protocol but were adjudicated as major complications by the Clinical Events Committee (CEC).

'NA' indicates that there is insufficient data in either or both treatment arms to conduct the test.

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Table 2. Summary of CEC Reported Minor Complications by Combined Procedure Group – Event Level (Intent-to-Treat Patients)

Complication	Manual Compress (N=124)	Quick-Close (N=243)	p-value*
Total complications	14 (11.3%)	15 (6.2%)	0.1161
Groin-related bleeding > 30 min to achieve hemostasis	11 (8.9%)	11 (4.5%)	0.1177
Hematoma > 6cm	2 (1.6%)	3 (1.2%)	1.0000
Late groin-related bleeding	0 (0.0%)	1 (0.4%)	1.0000
Localized groin-related infection treated w/intramuscular or oral antibiotics	0 (0.0%)	0 (0.0%)	NA
Other Serious	0 (0.0%)	0 (0.0%)	NA
Pseudoaneurysm documented by ultrasound	1 (0.8%)	0 (0.0%)	0.3379
AV fistula documented by ultrasound	0 (0.0%)	0 (0.0%)	NA
Ipsilateral lower extremity arterial emboli	0 (0.0%)	0 (0.0%)	NA
Ipsilateral deep vein thrombosis	0 (0.0%)	0 (0.0%)	NA
Groin related vessel laceration	0 (0.0%)	0 (0.0%)	NA
Groin wound dehiscence	0 (0.0%)	0 (0.0%)	NA
Transient loss of ipsilateral lower extremity pulse	0 (0.0%)	0 (0.0%)	NA
Transient groin related nerve injury	0 (0.0%)	0 (0.0%)	NA

Intent-to-Treat patients are defined as those patients who are randomized in the study.

* Test for equality of complication rates (exact test for comparing two Poisson rates, using StatXact – 8).

'NA' indicates that there is insufficient data in either or both treatment arms to conduct the test.

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Table 3. Summary of CEC Reported Major Complications by Procedure Group – Event Level (Intent-to-Treat Patients)

Complication	Diagnostic			Interventional		
	Manual Compress (N=70)	Quick-Close (N=136)	p-value*	Manual Compress (N=54)	Quick-Close (N=107)	p-value*
Total complications	0 (0.0%)	2 (1.5%)	0.5513	3 (5.6%)	3 (2.8%)	0.6708
Death	0 (0.0%)	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	NA
Myocardial infarction**	0 (0.0%)	0 (0.0%)	NA	0 (0.0%)	1 (0.9%)	1.0000
Groin related transfusion	0 (0.0%)	0 (0.0%)	NA	0 (0.0%)	2 (1.9%)	0.5542
Device failure with adverse consequences to the patient	0 (0.0%)	1 (0.7%)	1.0000	0 (0.0%)	0 (0.0%)	NA
Hematoma requiring extended hospitalization	0 (0.0%)	1 (0.7%)	1.0000	0 (0.0%)	0 (0.0%)	NA
Retropertitoneal hemorrhage	0 (0.0%)	0 (0.0%)	NA	1 (1.9%)	0 (0.0%)	0.3354
Vascular repair or the need for vascular repair	0 (0.0%)	0 (0.0%)	NA	1 (1.9%)	0 (0.0%)	0.3354
Groin related infection requiring IV antibiotics and/or extended hospitalization	0 (0.0%)	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	NA
Permanent groin related nerve injury or surgery for groin related nerve injury	0 (0.0%)	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	NA
Any new ipsilateral lower extremity ischemia defined by a 1 class change in Rutherford score	0 (0.0%)	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	NA
> 20% drop in hemoglobin requiring transfusion**	0 (0.0%)	0 (0.0%)	NA	1 (1.9%)	0 (0.0%)	0.3354

Intent-to-Treat patients are defined as those patients who are randomized in the study.

*Test for equality of complication rates (exact test for comparing two Poisson rates, using StatXact – 8).

NA indicates that there is insufficient data in either or both treatment arms to conduct the test.

**Myocardial infarction and >20% drop in hemoglobin are not defined as major complications in the protocol but were adjudicated as major complications by the Clinical Events Committee (CEC).

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Table 4. Summary of CEC Reported Minor Complications by Procedure Group - Event Level (Intent-to-Treat Patients)

Complication	Diagnostic		Interventional		p-value*	p-value*
	Manual Compress (N=70)	Quick-Close (N=136)	Manual Compress (N=54)	Quick-Close (N=107)		
Total complications	3 (4.3%)	2 (1.5%)	11 (20.4%)	13 (12.1%)	0.3450	0.2787
Groin-related bleeding > 30 min to achieve hemostasis	2 (2.9%)	1 (0.7%)	9 (16.7%)	10 (9.3%)	0.5557	0.2267
Hematoma > 6cm	1 (1.4%)	0 (0.0%)	1 (1.9%)	3 (2.8%)	0.3398	1.0000
Late groin-related bleeding	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	1.0000	NA
Localized groin-related infection treated w/intramuscular or oral antibiotics	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
Other Serious	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
Pseudoaneurysm documented by ultrasound	0 (0.0%)	0 (0.0%)	1 (1.9%)	0 (0.0%)	NA	0.3354
AV fistula documented by ultrasound	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
Ipsilateral lower extremity arterial emboli	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
Ipsilateral deep vein thrombosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
Groin related vessel laceration	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
Groin wound dehiscence	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
Transient loss of ipsilateral lower extremity pulse	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
Transient groin related nerve injury	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA

Intent-to-Treat patients are defined as those patients who are randomized in the study.

*Test for equality of complication rates (exact test for comparing two Poisson rates, using StatXact - 8).

NA indicates that there is insufficient data in either or both treatment arms to conduct the test.

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A subset of 3 patients in the Diagnostic group and a subset of 48 patients in the Interventional group received glycoprotein (GP) IIb/IIIa inhibitor therapy during their procedures. The CEC adjudicated major and minor complications for the Interventional patients receiving GP IIb/IIIa inhibitor therapy are listed in Tables 5 and 6.

Table 5. Summary of CEC Reported Major Complications for Interventional Group – Event Level with GP IIb/IIIa Inhibitor (Intent-to-Treat Patients)

Complication	Interventional		p-value*
	Manual Compress (N=17)	Quick-Close (N=31)	
Total complications	1 (5.9%)	3 (9.7%)	1.0000
Death	0 (0.0%)	0 (0.0%)	NA
Myocardial infarction**	0 (0.0%)	1 (3.2%)	1.0000
Groin related transfusion	0 (0.0%)	2 (6.5%)	0.5425
Device failure with adverse consequences to the patient	0 (0.0%)	0 (0.0%)	NA
Hematoma requiring extended hospitalization	0 (0.0%)	0 (0.0%)	NA
Retroperitoneal hemorrhage	0 (0.0%)	0 (0.0%)	NA
Vascular repair or the need for vascular repair	0 (0.0%)	0 (0.0%)	NA
Groin related infection requiring IV antibiotics and/or extended hospitalization	0 (0.0%)	0 (0.0%)	NA
Permanent groin related nerve injury or surgery for groin related nerve injury	0 (0.0%)	0 (0.0%)	NA
Any new ipsilateral lower extremity ischemia defined by a 1 class change in Rutherford score	0 (0.0%)	0 (0.0%)	NA
> 20% drop in hemoglobin requiring transfusion**	1 (5.9%)	0 (0.0%)	0.3542

Intent-to-Treat patients are defined as those patients who are randomized in the study.

*Test for equality of complication rates for device (exact test for comparing two Poisson rates, using StatXact – 8).

**Myocardial infarction and >20% drop in hemoglobin are not defined as major complications in the protocol but were adjudicated as major complications by the Clinical Events Committee (CEC).

NA indicates that there is insufficient data in either or both treatment arms to conduct the test.

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Table 6. Summary of CEC Reported Minor Complications for Interventional Group – Event Level with GP IIb/IIIa Inhibitor (Intent-to-Treat Patients)

Complication	Interventional		p-value*
	Manual Compress (N=17)	Quick-Close (N=31)	
Total complications	5 (29.4%)	5 (16.1%)	0.5104
Groin-related bleeding > 30 min to achieve hemostasis	4 (23.5%)	2 (6.5%)	0.1946
Hematoma > 6cm	1 (5.9%)	3 (9.7%)	1.0000
Late groin-related bleeding	0 (0.0%)	0 (0.0%)	NA
Localized groin-related infection treated w/intramuscular or oral antibiotics	0 (0.0%)	0 (0.0%)	NA
Other Serious	0 (0.0%)	0 (0.0%)	NA
Pseudoaneurysm documented by ultrasound	0 (0.0%)	0 (0.0%)	NA
AV fistula documented by ultrasound	0 (0.0%)	0 (0.0%)	NA
Ipsilateral lower extremity arterial emboli	0 (0.0%)	0 (0.0%)	NA
Ipsilateral deep vein thrombosis	0 (0.0%)	0 (0.0%)	NA
Groin related vessel laceration	0 (0.0%)	0 (0.0%)	NA
Groin wound dehiscence	0 (0.0%)	0 (0.0%)	NA
Transient loss of ipsilateral lower extremity pulse	0 (0.0%)	0 (0.0%)	NA
Transient groin related nerve injury	0 (0.0%)	0 (0.0%)	NA

Intent-to-Treat patients are defined as those patients who are randomized in the study.

*Test for equality of complication rates for device (exact test for comparing two Poisson rates, using StatXact – 8).

'NA' indicates that there is insufficient data in either or both treatment arms to conduct the test.

METHOD OF USE

The Quick-Close® System is designed for use following a 5 to 8 French femoral artery access procedure.

CLINICAL STUDY OVERVIEW

The pivotal phase study for the Quick-Close® System was a prospective, randomized, multi-center study conducted at 8 medical centers in the United States. For this study the test group was treated with the Quick-Close® System and the control group with manual compression.

The study included patients having undergone a 5 to 8 French diagnostic or interventional cardiac catheterization procedure performed percutaneously via the femoral artery. Once the interventional or diagnostic procedure was completed, the patient was enrolled in the study if all inclusion and exclusion criteria were met.

Diagnostic and Interventional patients were randomized separately in a 2:1 (test:control) allocation. For patients randomized to the Quick-Close® System arm, Quick-Close® treatment was completed while the patient remained in the cardiac catheterization lab following his/her

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percutaneous procedure. For patients randomized to Manual Compression, manual compression was initiated in the cardiac catheterization lab following removal of the introducer sheath or on the floor depending on the patient's ACT. Manual compression was applied until hemostasis was achieved.

Among a total of 367 randomized patients in the study, 243 patients were treated with the Quick-Close® System and 124 patients were treated with manual compression. The patients were 67.9% male and 32.1% female in the Quick-Close® System treatment group, and 61.3% male and 38.7% female in the Manual Compression group. The patients ranged in age from 38 – 89 years.

Patient characteristics that were evaluated included age; gender; race; height; weight; diastolic blood pressure; systolic blood pressure; history of smoking; peripheral vascular disease; diabetes mellitus; and bleeding diathesis; coagulopathy, or blood dyscrasia.

There were no statistically significant differences in patient characteristics between patients in the Manual Compression and Quick-Close® System arms in the Interventional group.

In the Diagnostic group, there were differences in weight between the Quick-Close® System and Manual Compression arms. Mean weight was 189.4 pounds in the Quick-Close® arm compared to 177.9 pounds in the Manual Compression arm with a p-value of 0.0398 using the ANOVA model. Additionally, diabetes mellitus was more common in those Quick-Close® System patients compared to those patients treated using manual compression. There were 30/136 (22.1%) patients with diabetes mellitus in the Quick-Close® System arm compared to 7/70 (10.0%) patients in the manual compression arm with a p-value of 0.0357 using the ANOVA model. These differences were not considered to be clinically significant given the nature of the study.

A subset of 3 patients in the Diagnostic group and a subset of 48 patients in the Interventional group received glycoprotein (GP) IIb/IIIa inhibitor therapy during their procedures.

The primary objective of the study was to demonstrate the safety and efficacy of the Quick-Close® System for the percutaneous delivery of sutures to close the femoral artery access site. The study included the following effectiveness and safety endpoints:

Primary Effectiveness Endpoints:

- *Time to Hemostasis*
- *Time to Ambulation*

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Secondary Effectiveness Endpoints:

- *Time to Dischargability*
- *Procedure Success*
- *Device Success*

Primary Safety Endpoint:

- *Combined Rate of Major Complications*

Secondary Safety Endpoint:

- *Combined Rate of Minor Complications*

EFFECTIVENESS RESULTS

Table 7 summarizes the time to hemostasis achieved for patients randomized to treatment with the Quick-Close® Vascular Suturing System compared to Manual Compression for the Diagnostic and Interventional Groups combined. The mean time to hemostasis for patients randomized to Quick-Close® was 10.4 minutes with a median time of 1.0 minutes (SD = 38.5, min = 0, max = 386). The mean time to hemostasis for patients randomized to Manual Compression was 23.4 minutes with a median time of 20.0 minutes (SD = 29.6, min = 5, max = 310).

Further analysis of the time to hemostasis data showed 52.7% of the patients randomized to treatment with the Quick-Close® Vascular Suturing System achieved hemostasis in ≤ 1 minute and 77.4% in ≤ 5 minutes. None of the patients randomized to Manual Compression achieved hemostasis in ≤ 1 minute and only 3.2% achieved hemostasis in ≤ 5 minutes.

The results for the Combined Procedure Groups demonstrate improvement in the time to hemostasis in the Quick-Close® arm compared to the Manual Compression arm ($p < 0.0001$, log-rank test).

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**Table 7. Summary of Time to Hemostasis by Combined Procedure Groups
(Intent-to-Treat Patients)**

Parameter	Randomized			p-value*
	Manual Compress (N=124)	Quick-Close (N=243)	Total (N=367)	
Overall Time to Hemostasis (minutes)				<0.0001
No. of Patients	124	243	367	
Mean (SD)	23.4 (29.56)	10.4 (38.50)	14.8 (36.22)	
Median	20.0	1.0	5.0	
(Minimum, Maximum)	(5.0,310.0)	(0.0,386.0)	(0.0,386.0)	

Intent-to-Treat patients are defined as those patients who are randomized in the study.
* p-values are obtained from log-rank test for the survivor analysis.

Tables 8 and 9 summarize the time to hemostasis achieved for patients randomized to treatment with the Quick-Close® device compared to Manual Compression for the separate Diagnostic and Interventional Groups.

**Table 8. Summary of Time to Hemostasis (Minutes) by Procedure Group
(Intent-to-Treat Patients)**

Parameter	Diagnostic		p-value*	Interventional		p-value*
	Manual Compress (N=70)	Quick-Close (N=136)		Manual Compress (N=54)	Quick-Close (N=107)	
Time to Hemostasis (minutes)			<0.0001			<0.0001
No. of Patients	70	136		54	107	
Mean (SD)	16.6 (11.97)	3.5 (6.52)		32.3 (41.22)	19.1 (56.51)	
Median	15.0	1.0		26.5	2.0	
(Minimum, Maximum)	(5.0,100.0)	(0.0, 44.0)		(5.0,310.0)	(0.0,386.0)	

Intent-to-Treat patients are defined as those patients who are randomized in the study.
*p-values are obtained by using log-rank test for survival analysis.

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Table 9. Summary of Time to Hemostasis (Minutes) by Procedure Group (Intent-to-Treat Patients)

Parameter	Diagnostic		Interventional	
	Manual Compress (N=70)	Quick-Close (N=136)	Manual Compress (N=54)	Quick-Close (N=107)
Time to Hemostasis (minutes) [n %]				
<= 1	0 (0.0%)	79 (58.1%)	0 (0.0%)	49 (45.8%)
<= 5	2 (2.9%)	114 (83.8%)	2 (3.7%)	74 (69.2%)
<= 10	20 (28.6%)	122 (89.7%)	6 (11.1%)	83 (77.6%)
<= 15	40 (57.1%)	128 (94.1%)	12 (22.2%)	91 (85.0%)
<= 20	57 (81.4%)	131 (96.3%)	22 (40.7%)	92 (86.0%)
<= 30	68 (97.1%)	135 (99.3%)	45 (83.3%)	96 (89.7%)
<= 60	69 (98.6%)	136 (100.0%)	51 (94.4%)	100 (93.5%)
<= 120	70 (100.0%)	136 (100.0%)	53 (98.1%)	101 (94.4%)
> 120	0 (0.0%)	0 (0.0%)	1 (1.9%)	6 (5.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Intent-to-Treat patients are defined as those patients who are randomized in the study.

Table 10 summarizes the time to ambulation achieved for patients randomized to treatment with the Quick-Close® device compared to Manual Compression for the Diagnostic and Interventional Groups combined. The mean time to ambulation for patients randomized to Quick-Close® was 4.4 hours with a median time of 3.3 hours (SD = 3.7, min = 1, max = 22). The mean time to ambulation for patients randomized to Manual Compression was 6.9 hours with a median time of 5.0 hours (SD = 5.5, min = 2, max = 47).

The results for the Combined Procedure Group demonstrate improvement in the time to ambulation in the Quick-Close® arm compared to the Manual Compression arm (p < 0.0001, log-rank test).

Table 10. Summary of Time to Ambulation (Hours) by Combined Procedure Group (Intent-to-Treat Patients)

Parameter	Randomized			p-value*
	Manual Compress (N=124)	Quick-Close (N=243)	Total (N=367)	
Time to Ambulation (hours)				<0.0001
No. of Patients	122	242	364	
Mean (SD)	6.9 (5.45)	4.4 (3.73)	5.2 (4.53)	
Median	5.0	3.3	4.1	
(Minimum, Maximum)	(1.7, 46.5)	(1.0, 22.1)	(1.0, 46.5)	

Intent-to-Treat patients are defined as those patients who are randomized in the study.

* p-values are obtained from log-rank test for the survival analysis.

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Tables 11 and 12 summarize the time to ambulation achieved for patients randomized to treatment with the Quick-Close® device compared to Manual Compression for the separate Diagnostic and Interventional Groups.

Table 11. Summary of Time to Ambulation (Hours) by Procedure Group (Intent-to-Treat Patients)

Parameter	Diagnostic		p-value*	Interventional		p-value*
	Manual Compress (N=70)	Quick-Close (N=136)		Manual Compress (N=54)	Quick-Close (N=107)	
Time to Ambulation (hours)			<0.0001			0.0010
No. of Patients	68	135		54	107	
Mean (SD)	4.8 (5.59)	2.8 (1.96)		9.5 (4.01)	6.3 (4.46)	
Median	4.1	2.2		8.7	5.0	
(Minimum, Maximum)	(1.7, 46.5)	(1.0, 15.5)		(2.3, 18.7)	(1.2, 22.1)	

Intent-to-Treat patients are defined as those patients who are randomized in the study.

* p-values are obtained from log-rank test for the survival analysis.

Table 12. Summary of Time to Ambulation (Hours) by Procedure Group (Intent-to-Treat Patients)

Parameter	Diagnostic		Interventional	
	Manual Compress (N=70)	Quick-Close (N=136)	Manual Compress (N=54)	Quick-Close (N=107)
Time to Ambulation (hours) [n %]				
≤ 1	0 (0.0%)	2 (1.5%)	0 (0.0%)	0 (0.0%)
≤ 2	5 (7.1%)	59 (43.4%)	0 (0.0%)	9 (8.4%)
≤ 3	19 (27.1%)	93 (68.4%)	2 (3.7%)	20 (18.7%)
≤ 4	29 (41.4%)	110 (80.9%)	3 (5.6%)	34 (31.8%)
≤ 5	53 (75.7%)	121 (89.0%)	8 (14.8%)	53 (49.5%)
≤ 6	63 (90.0%)	127 (93.4%)	10 (18.5%)	67 (62.6%)
≤ 12	65 (92.9%)	134 (98.5%)	39 (72.2%)	96 (89.7%)
≤ 18	67 (95.7%)	135 (99.3%)	53 (98.1%)	103 (96.3%)
≤ 24	67 (95.7%)	135 (99.3%)	54 (100.0%)	107 (100.0%)
> 24	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	2 (2.9%)	1 (0.7%)	0 (0.0%)	0 (0.0%)

Intent-to-Treat patients are defined as those patients who are randomized in the study.

Table 13 summarizes the time to dischargability achieved for patients randomized to treatment with the Quick-Close® device compared to Manual Compression for the Diagnostic and Interventional Groups combined. The mean time to dischargability for patients randomized to Quick-Close® was 11.7 hours with a median time of 5.7 hours (SD = 11.9, min = 1, max = 80). The mean time to dischargability for patients randomized to Manual Compression was 11.9 hours with a median time of 6.1 hours (SD = 11.9, min = 2, max = 75).

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The results for the Combined Procedure Group demonstrate no improvement in the time to dischargability in the Quick-Close® arm compared to the Manual Compression arm ($p = 0.8999$, log-rank test). In both the Quick-Close® and Manual-Compression groups, patients undergoing diagnostic procedures showed significantly shorter average times to dischargability compared to interventional patients (Quick Close®: 5.4 hrs. vs. 19.6 hrs.; manual closure: 6.7 hrs. vs. 18.9 hrs.)

**Table 13. Summary of Time to Dischargability (Hours)
By Combined Procedure Group (Intent-to-Treat Patients)**

Parameter	Randomized			p-value*
	Manual Compress (N=124)	Quick- Close (N=243)	Total (N=367)	
Time to Dischargability (hours)				0.8999
No. of Patients	122	242	364	
Mean (SD)	11.9 (11.87)	11.7 (11.85)	11.8 (11.84)	
Median	6.1	5.7	5.9	
(Minimum, Maximum)	(2.0, 74.5)	(1.1, 79.8)	(1.1, 79.8)	

Intent-to-Treat patients are defined as those patients who are randomized in the study.

*p-values are obtained from log-rank test for the survival analysis.

Tables 14 and 15 summarize the time to dischargability achieved for patients randomized to treatment with the Quick-Close® device compared to Manual Compression for the separate Diagnostic and Interventional Groups.

**Table 14. Summary of Time to Dischargability (Hours)
By Procedure Group (Intent-to-Treat Patients)**

Parameter	Diagnostic		p-value*	Interventional		p-value*
	Manual Compress (N=70)	Quick- Close (N=136)		Manual Compress (N=54)	Quick- Close (N=107)	
Time to Dischargability (hours)			0.0062			0.0822
No. of Patients	70	135		52	107	
Mean (SD)	6.7 (9.97)	5.4 (8.65)		18.9 (10.60)	19.6 (10.53)	
Median	4.7	2.7		16.9	19.4	
(Minimum, Maximum)	(2.0, 74.5)	(1.1, 79.8)		(5.0, 64.0)	(1.6, 67.7)	

Intent-to-Treat patients are defined as those patients who are randomized in the study.

*p-values are obtained from log-rank test for the survival analysis.

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**Table 15. Summary of Time to Dischargability (Hours)
 By Procedure Group (Intent-to-Treat Patients)**

Parameter	Diagnostic		Interventional	
	Manual Compress (N=70)	Quick-Close (N=136)	Manual Compress (N=54)	Quick-Close (N=107)
Time to Dischargability (hours) [n %]				
<= 1	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
<= 2	1 (1.4%)	33 (24.3%)	0 (0.0%)	1 (0.9%)
<= 3	14 (20.0%)	74 (54.4%)	0 (0.0%)	2 (1.9%)
<= 4	20 (28.6%)	92 (67.6%)	0 (0.0%)	5 (4.7%)
<= 5	41 (58.6%)	104 (76.5%)	1 (1.9%)	8 (7.5%)
<= 6	59 (84.3%)	113 (83.1%)	1 (1.9%)	10 (9.3%)
<= 7	63 (90.0%)	117 (86.0%)	1 (1.9%)	12 (11.2%)
<= 8	64 (91.4%)	121 (89.0%)	2 (3.7%)	16 (15.0%)
<= 9	64 (91.4%)	121 (89.0%)	2 (3.7%)	17 (15.9%)
<= 10	64 (91.4%)	121 (89.0%)	3 (5.6%)	17 (15.9%)
<= 11	65 (92.9%)	121 (89.0%)	6 (11.1%)	18 (16.8%)
<= 12	65 (92.9%)	121 (89.0%)	6 (11.1%)	19 (17.8%)
<= 24	67 (95.7%)	129 (94.9%)	47 (87.0%)	87 (81.3%)
<= 36	68 (97.1%)	134 (98.5%)	48 (88.9%)	99 (92.5%)
<= 48	69 (98.6%)	134 (98.5%)	50 (92.6%)	105 (98.1%)
> 48	1 (1.4%)	1 (0.7%)	2 (3.7%)	2 (1.9%)
Missing	0 (0.0%)	1 (0.7%)	2 (3.7%)	0 (0.0%)

Intent-to-Treat patients are defined as those patients who are randomized in the study.

The time to hemostasis and time to ambulation data for the Interventional patients receiving GP IIb/IIIa inhibitor therapy are provided in Tables 16-19.

**Table 16. Summary of Time to Hemostasis (Minutes) for Interventional Group
 with GP IIb/IIIa Inhibitor (Intent-to-Treat Patients)**

Parameter	Interventional		p-value*
	Manual Compress (N=17)	Quick-Close (N=31)	
Time to Hemostasis (minutes)			0.0015
No. of Patients	17	31	
Mean (SD)	43.6 (70.38)	13.1 (35.85)	
Median	20.0	1.0	
(Minimum, Maximum)	(10.0, 310.0)	(0.0, 193.0)	

Intent-to-Treat patients are defined as those patients who are randomized in the study.

*p-values are obtained from log-rank test for the survival analysis.

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Table 17. Summary of Time to Hemostasis (Minutes) for Interventional Group with GP IIb/IIIa Inhibitor (Intent-to-Treat Patients)

Parameter	Interventional	
	Manual Compress (N=17)	Quick-Close (N=31)
Time to Hemostasis (minutes) [n %]		
<= 1	0 (0.0%)	16 (51.6%)
<= 5	0 (0.0%)	21 (67.7%)
<= 10	1 (5.9%)	24 (77.4%)
<= 15	3 (17.6%)	26 (83.9%)
<= 20	9 (52.9%)	26 (83.9%)
<= 30	13 (76.5%)	28 (90.3%)
<= 60	15 (88.2%)	30 (96.8%)
<= 120	16 (94.1%)	30 (96.8%)
> 120	1 (5.9%)	1 (3.2%)
Missing	0 (0.0%)	0 (0.0%)

Intent-to-Treat patients are defined as those patients who are randomized in the study.

Table 18. Summary of Time to Ambulation (Hours) for Interventional Group with GP IIb/IIIa Inhibitor (Intent-to-Treat Patients)

Parameter	Interventional		p-value*
	Manual Compress (N=17)	Quick-Close (N=31)	
Time to Ambulation (hours)			0.9053
No. of Patients	17	31	
Mean (SD)	8.0 (4.14)	8.0 (6.09)	
Median	7.0	5.5	
(Minimum, Maximum)	(2.3, 18.7)	(1.6, 22.1)	

Intent-to-Treat patients are defined as those patients who are randomized in the study.

*p-values are obtained from log-rank test for the survival analysis.

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Table 19. Summary of Time to Ambulation (Hours) for Interventional Group with GP IIb/IIIa Inhibitor (Intent-to-Treat Patients)

Parameter	Interventional	
	Manual Compress (N=17)	Quick-Close (N=31)
Time to Ambulation (hours) [n %]		
≤ 1	0 (0.0%)	0 (0.0%)
≤ 2	0 (0.0%)	1 (3.2%)
≤ 3	1 (5.9%)	5 (16.1%)
≤ 4	2 (11.8%)	8 (25.8%)
≤ 5	4 (23.5%)	14 (45.2%)
≤ 6	6 (35.3%)	18 (58.1%)
≤ 12	14 (82.4%)	25 (80.6%)
≤ 18	16 (94.1%)	27 (87.1%)
≤ 24	17 (100.0%)	31 (100.0%)
> 24	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)

Intent-to-Treat patients are defined as those patients who are randomized in the study.

The procedure success and device success data for the Combined Procedure Group and for the separate Diagnostic and Interventional Groups are provided in Tables 20 and 21.

Table 20. Summary of Quick Close Procedure and Device Success By Combined Procedure Group (Intent-to-Treat Patients)

Parameter	Manual Compress (N=124)	Quick-Close (N=243)	Total (N=367)	p-value*
Procedure Success				1.0000
Failure	3 (2.4%)	5 (2.1%)	8 (2.2%)	
Success	121 (97.6%)	238 (97.9%)	359 (97.8%)	
Device Success				
Failure	N/A	5 (2.1%)	N/A	
Success	N/A	238 (97.9%)	N/A	

Intent-to-Treat patients are defined as those patients who are randomized in the study.

Procedure success is defined as attainment of hemostasis using any method with no major complication. Table includes CEC adjudicated major complications.

Protocol defines Device Success as successful deployment of the Quick-Close®; for the purpose of this table, any subject with a reported Device Failure was considered "Failure" for Device Success.

*p-values are obtained using two-sided Fisher exact test.

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Table 21. Summary of Quick Close Procedure and Device Success By Procedure Group (Intent-to-Treat Patients)

Parameter	Diagnostic		p-value*	Interventional		p-value*
	Manual Compress (N=70)	Quick-Close (N=136)		Manual Compress (N=54)	Quick-Close (N=107)	
Procedure Success			0.5491			0.4038
Failure	0 (0.0%)	2 (1.5%)		3 (5.6%)	3 (2.8%)	
Success	70 (100.0%)	134 (98.5%)		51 (94.4%)	104 (97.2%)	
Device Success						
Failure	N/A	3 (2.2%)		N/A	2 (1.9%)	
Success	N/A	133 (97.8%)		N/A	105 (98.1%)	

Intent-to-Treat patients are defined as those patients who are randomized in the study.

Procedure success is defined as attainment of hemostasis using any method with no major complication. Table includes CEC adjudicated major complications.

Protocol defines Device Success as successful deployment of the Quick-Close®; for the purpose of this table, any subject with a reported Device Failure was considered "Failure" for Device Success.

*p-values are obtained using two-sided Fisher exact test.

The time to hemostasis, time to ambulation, and time to dischargability results by post-procedure time interval for the Combined Procedure Group are provided in Tables 22-24.

Table 22. Summary of Time to Hemostasis (Minutes) by Combined Procedure Group (Intent-to-Treat Patients)

Parameter	Manual Compress (N=124)	Quick-Close (N=243)	Total (N=367)
Time to Hemostasis (minutes) [n %]			
<= 1	0 (0.0%)	128 (52.7%)	128 (34.9%)
<= 5	4 (3.2%)	188 (77.4%)	192 (52.3%)
<= 10	26 (21.0%)	205 (84.4%)	231 (62.9%)
<= 15	52 (41.9%)	219 (90.1%)	271 (73.8%)
<= 20	79 (63.7%)	223 (91.8%)	302 (82.3%)
<= 30	113 (91.1%)	231 (95.1%)	344 (93.7%)
<= 60	120 (96.8%)	236 (97.1%)	356 (97.0%)
<= 120	123 (99.2%)	237 (97.5%)	360 (98.1%)
> 120	1 (0.8%)	6 (2.5%)	7 (1.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)

Intent-to-Treat patients are defined as those patients who are randomized in the study.

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Table 23. Summary of Time to Ambulation (Hours) by Combined Procedure Group (Intent-to-Treat Patients)

Parameter	Manual Compress (N=124)	Quick-Close (N=243)	Total (N=367)
Time to Ambulation (hours) [n %]			
<= 1	0 (0.0%)	2 (0.8%)	2 (0.5%)
<= 2	5 (4.0%)	68 (28.0%)	73 (19.9%)
<= 3	21 (16.9%)	113 (46.5%)	134 (36.5%)
<= 4	32 (25.8%)	144 (59.3%)	176 (48.0%)
<= 5	61 (49.2%)	174 (71.6%)	235 (64.0%)
<= 6	73 (58.9%)	194 (79.8%)	267 (72.8%)
<= 12	104 (83.9%)	230 (94.7%)	334 (91.0%)
<= 18	120 (96.8%)	238 (97.9%)	358 (97.5%)
<= 24	121 (97.6%)	242 (99.6%)	363 (98.9%)
> 24	1 (0.8%)	0 (0.0%)	1 (0.3%)
Missing	2 (1.6%)	1 (0.4%)	3 (0.8%)

Intent-to-Treat patients are defined as those patients who are randomized in the study.

Table 24. Summary of Time to Dischargability (Hours) by Combined Procedure Group (Intent to Treat Patients)

Parameter	Manual Compress (N=124)	Quick-Close (N=243)	Total (N=367)
Time to Dischargability (hours) [n %]			
<= 1	0 (0.0%)	0 (0.0%)	0 (0.0%)
<= 2	1 (0.8%)	34 (14.0%)	35 (9.5%)
<= 3	14 (11.3%)	76 (31.3%)	90 (24.5%)
<= 4	20 (16.1%)	97 (39.9%)	117 (31.9%)
<= 5	42 (33.9%)	112 (46.1%)	154 (42.0%)
<= 6	60 (48.4%)	123 (50.6%)	183 (49.9%)
<= 7	64 (51.6%)	129 (53.1%)	193 (52.6%)
<= 8	66 (53.2%)	137 (56.4%)	203 (55.3%)
<= 9	66 (53.2%)	138 (56.8%)	204 (55.6%)
<= 10	67 (54.0%)	138 (56.8%)	205 (55.9%)
<= 11	71 (57.3%)	139 (57.2%)	210 (57.2%)
<= 12	71 (57.3%)	140 (57.6%)	211 (57.5%)
<= 24	114 (91.9%)	216 (88.9%)	330 (89.9%)
<= 36	116 (93.5%)	233 (95.9%)	349 (95.1%)
<= 48	119 (96.0%)	239 (98.4%)	358 (97.5%)
> 48	3 (2.4%)	3 (1.2%)	6 (1.6%)
Missing	2 (1.6%)	1 (0.4%)	3 (0.8%)

Intent-to-Treat patients are defined as those patients who are randomized in the study.

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CONCLUSIONS

The safety and effectiveness of the Quick-Close® System was evaluated in a randomized, multi-center clinical trial comparing it to manual compression. The primary effectiveness endpoints were time to hemostasis and time to ambulation. Both of these endpoints were significantly shorter in the Quick-Close® arm.

This trial included patients undergoing diagnostic and interventional procedures. Each of these subgroups receiving the Quick-Close® device had a significantly shorter time to hemostasis and ambulation as compared to the Manual Compression control group. The main purpose of PAC (percutaneous arterial closure) devices, such as the Quick-Close®, is to decrease these times so *that the patient is able to ambulate earlier.*

The secondary effectiveness endpoints in this study were time to dischargability, procedure success, and device success. There were no differences in the time to dischargability and procedure success endpoints between the Quick-Close® arm and the Manual Compression arm. The procedure success with Quick-Close® was 97.9% for the Combined Procedure Group.

The primary safety endpoint in this study was the combined rate of major complications in the Quick-Close® arm compared to that in the Manual Compression arm. There were no statistically significant differences in major complications between the Quick-Close® arm and the Manual Compression arm in the Combined Procedure, Diagnostic, and Interventional Groups. The overall complication rates were low in both the Quick-Close® and Manual Compression arms in the Combined Procedure and Diagnostic Groups. For the Combined Procedure Group, the rate was 2.1% in the Quick-Close® arm and 2.4% in the Manual Compression arm.

The secondary safety endpoint in the study was the combined rate of minor complications in the Quick-Close® arm compared to that in the Manual Compression arm. There were no statistically significant differences in minor complications between the Quick-Close® arm and the Manual Compression arm in the Combined Procedure, Diagnostic, and Interventional Groups. For the Combined Procedure Group, the rate was 6.2% in the Quick-Close® arm and 11.3% in the Manual Compression arm.

In the study discussed above, the Quick-Close® device met all established performance and safety criteria. The data demonstrate that the Quick-Close® is safe and effective for its intended use.

HOW SUPPLIED

One Quick-Close® Vascular Suturing System includes:

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One Quick-Close® Suture Applier
One Quick-Ti™ Cinch Applier

The Quick-Close® Suture Applier places a single stitch of size 3-0, non-absorbable, monofilament suture. The Quick-Close® is inserted into the vessel over a .035" or .038" guidewire (not supplied with the device). The suture is secured by means of a stainless steel cinch placed external to the vessel using the Quick-Ti™ Cinch Applier. Following placement of the cinch, the extraneous suture material is clipped immediately distal to (above) the cinch and removed.

The suture, along with its stainless steel cinch, will remain in place throughout the healing period. Post-procedural removal of the cinch is not required. The intra-vascular segment of the suture is minimal in length (approximately 1 mm or less) and held snug to the vessel wall to preclude a nidus for thrombus formation. To minimize the potential for infection, no externally-communicating materials are left in place. Likewise, no materials other than the non-absorbable suture and stainless steel cinch are left in place. The device relies solely on suture mediation to create and maintain vessel wound closure.

PROCEDURAL STEPS

The techniques and procedures provided below for the use of the Quick-Close® Vascular Suturing System are not intended to substitute for the physician's experience and judgment in treating a specific patient.

Step 1 Bloodport

When the interventional or diagnostic procedure is complete, the guidewire is reinserted and the standard introducer sheath is removed. The physician introduces the Quick-Close® Suture Applier by inserting the monorail of the device over the wire and into the vessel (see Figure 1). After the applier is inserted into the vessel (as illustrated), the guidewire is removed. Bleed-back in the shaft and blood exiting near the rear of the instrument (bloodport) indicate that the "jaws" of the device are properly placed in the vessel.

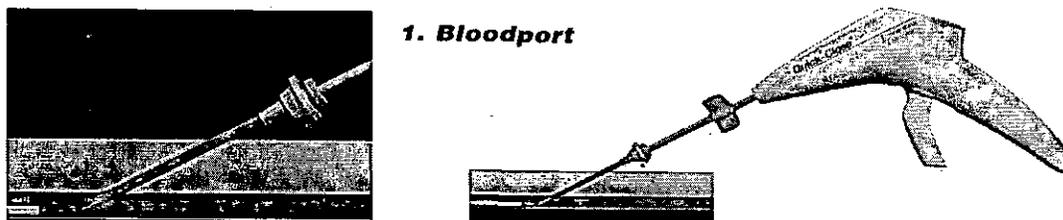


Figure 1. Insertion of the Quick-Close® Suture Applier into the Vessel