GUIDANT

Guidant MULTI-LINK RX DUET® and Guidant MULTI-LINK OTW DUET® Coronary Stent Systems

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

Information for Prescribers

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1.0 DEVICE DESCRIPTION

The Guidant MULTI-LINK RX DUET® Coronary Stent System and the Guidant MULTI-LINK OTW DUET® Coronary Stent System (Guidant MULTI-LINK® Coronary Stent and RX and OTW Delivery System) include:

- A pre-mounted 316L stainless steel stent.
- Two radiopaque markers, located underneath the balloon, which fluoroscopically mark the working length of the balloon and between which the stent is placed.
- Two proximal Delivery System shaft markers (95 cm and 105 cm from the distal tip) which indicate the relative position of the Delivery System to the end of a brachial or femoral guide catheter.
- For the Guidant MULTI-LINK RX DUET® Coronary Stent System, a third shaft marker denotes the guide wire exit notch.

Table 1 - *in vitro* Device Specifications

Stent Diameter (mm)	Stent Length (mm)	* Minimum Guide Catheter Compatibility	** *in vitro* Stent Nominal Pressure (atm)	Rated Burst Pressure – RBP (atm)	Stent Free % Area
2.5	8, 13, 18, 23, 28	6 F / 0.064"	9	16	81%
3.0	8, 13, 18, 23, 28, 38	6 F / 0.064"	9	16	84%
3.5	8, 13, 18, 23, 28, 38	6 F / 0.064"	9	16	86%
4.0	8, 13, 18, 23, 28, 38	6 F / 0.064"	9	16	87%

*See Individual manufacturer specifications for (F) equivalent.
**Assure full deployment of the stent (see *Clinician Use Information* Deployment Procedure). Deployment pressures should be based on lesion characteristics.

2.0 HOW SUPPLIED

Sterile. This device is sterilized with electron beam radiation. Non-pyrogenic. Do not use if the package is open or damaged.

Contents. One (1) Guidant MULTI-LINK RX DUET® Coronary Stent System or Guidant MULTI-LINK OTW DUET® Coronary Stent System

Storage. Store in a dry, dark, cool place.

3.0 INDICATIONS

The Guidant MULTI-LINK RX DUET® Coronary Stent System and Guidant MULTI-LINK OTW DUET® Coronary Stent System are indicated for the following uses (see *Individualization of Treatment*):

- Improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete *de novo* or restenotic native coronary artery lesions length ≤ 25 mm with a reference vessel diameter of 3.0 mm to 4.0 mm.
- Improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to lesions in saphenous vein bypass grafts length ≤ 35 mm with a reference vessel diameter of 3.0 mm to 4.0 mm.
- Restoring coronary flow in patients experiencing acute myocardial infarction, as confirmed by ST segment elevation or angiographic findings, who present within 12 hours of symptom onset with native coronary artery lesions of length ≤ 35 mm with a reference vessel diameter of 2.5 mm to 4.0 mm.
- Treatment of abrupt or threatened abrupt closure in patients with failed interventional therapy in lesions length ≤ 35 mm with a reference vessel diameter of 2.5 mm to 4.0 mm.

Long-term outcome (beyond 6 months) for this permanent implant is unknown at present.

4.0 CONTRAINDICATIONS

The Guidant MULTI-LINK RX DUET® and Guidant MULTI-LINK OTW DUET® Coronary Stent Systems are contraindicated for use in:

- Patients in whom anti-platelet and / or anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.

5.0 WARNINGS AND PRECAUTIONS

(see also *Individualization of Treatment*)

WARNINGS

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and / or bleeding events.
- Persons allergic to 316L stainless steel may suffer an allergic reaction to this implant.
- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.

PRECAUTIONS

5.1 Stent Handling - Precautions

- **For single use only.** Do not resterilize or reuse. Note the product "Use By" date.
- **Do not remove stent from its Delivery System** as removal may damage the stent and / or lead to stent embolization. Stent system is intended to perform as a system.
- The Delivery System should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during catheter removal from packaging, placement over guide wire and advancement through the rotating hemostatic valve adapter and guiding catheter hub.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

5.2 Stent Placement - Precautions

- **Do not prepare or pre-inflate Delivery System prior to stent deployment** other than as directed. Use balloon purging technique described in section *9.3.2 Delivery System Preparation.*
- Implanting a stent may lead to dissection of the vessel distal and / or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chance of dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel. (See *Stent / System Removal – Precautions.*)
- Placement of a stent has the potential to compromise side branch patency.
- **Do not exceed Rated Burst Pressure as indicated on product label.** Balloon pressures should be monitored during inflation. Use of pressures higher than specified on the product label may result in a ruptured balloon with possible intimal damage and dissection.
- **Do not attempt to pull an unexpanded stent back through the guiding catheter; dislodgment of the stent from the Delivery System may occur.**
- Stent retrieval methods (use of additional wires, snares and / or forceps) may result in additional trauma to the coronary vasculature and / or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

5.3 Stent / System Removal - Precautions

Should **unusual resistance** be felt at **any time** during either lesion access or removal of the Delivery System post-stent implantation, **remove the entire system as a single unit.**

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the guiding catheter.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating hemostatic valve to secure the Delivery System to the guiding catheter; then remove the guiding catheter and Delivery System as a **single unit.**

Failure to follow these steps and / or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and / or Delivery System components.

If it is necessary to retain guide wire position for subsequent artery / lesion access, leave the guide wire in place and remove all other system components.

5.4 Post Implant - Precautions

- When **crossing a newly deployed stent** with a coronary guide wire, balloon or Delivery System, exercise care to avoid disrupting the stent geometry.

- Do not perform a **magnetic resonance imaging** (MRI) scan on patients post-stent implantation until the stent has completely endothelialized (eight weeks) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

6.0 ADVERSE EVENTS

The following studies were nonconcurrent and statistical comparisons between the studies are not appropriate.

6.1 Observed Adverse Events

DUET Study – *de novo* Lesions
Guidant MULTI-LINK RX DUET® Coronary Stent System

A total of 270 patients were enrolled in a multi-center, consecutive study to evaluate the Guidant MULTI-LINK RX DUET® Coronary Stent System for treatment of symptomatic *de novo* native coronary artery lesions (DUET Study). These results were compared to the results of the *de novo* lesion cohort of 518 patients treated with the Guidant MULTI-LINK® Coronary Stent System in a randomized clinical trial (MULTI-LINK Study).

One patient who received a Guidant MULTI-LINK DUET® Coronary Stent suffered an acute non-cardiac death during the 30-day follow-up period of this study. This death was due to sepsis following amputation of a gangrenous leg. There were no late deaths within the 180-day follow-up period in the Guidant MULTI-LINK DUET® Coronary Stent System treatment group. No deaths occurred in the Guidant MULTI-LINK® Coronary Stent System treatment group during the 30-day follow-up period. Three late deaths occurred, two of which were cardiac related; congestive heart failure (n = 1), and cardiogenic shock (n = 1). One late death was judged not to be cardiac related; ruptured abdominal aortic aneurysm (n = 1).

At 180 days in the DUET Study, the incidence of thrombosis was 1.1% (3/270). Two of these events were related to severe bleeding when discontinuation of anti-platelet therapy and transfusions immediately preceded the thrombotic event. The third event was believed to be related to incomplete Stent expansion. The incidence of vascular complications requiring surgical repair or other vascular complications was 4.8% (13/270). The rate for bleeding requiring transfusion was 2.6% (7/270).

Table 2 shows the results of patients receiving the Guidant MULTI-LINK RX DUET® Coronary Stent System (DUET Study) to those receiving the Guidant MULTI-LINK® Coronary Stent System (MULTI-LINK Study) at 180-day follow-up.

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Table 2 - Principal Adverse Events Through 180 Days – DUET Study
%, [95% Confidence Interval], (Number)

Complication	DUET Study *de novo* (n = 270)	MULTI-LINK Study *de novo* (n = 518)
Any Adverse Event	12.6% [8.9%, 17.1%] (34)	10.4% [7.9%, 13.4%] (54)
Early (In-Hospital)	7.0% [4.3%, 10.8%] (19)	7.9% [5.7%, 10.6%] (41)
Out-of-Hospital 180 days	5.5% [3.1%, 9.0%] (15)	0.8% [1.3%, 4.3%] (13)
Non-Q-Wave Total	1.1% [0.2%, 3.2%] (3)	3.5% [2.1%, 5.4%] (18)
Early (In-Hospital)	0.7% [0.1%, 2.6%] (2)	3.1% [1.8%, 5.0%] (16)
Out-of-Hospital 180 days	0.4% [0.0%, 2.0%] (1)	0.4% [0.0%, 1.4%] (2)
Q-Wave MI	1.1% [0.2%, 3.2%] (3)	0.6% [0.1%, 1.7%] (3)
Early (In-Hospital)	0.7% [0.1%, 2.6%] (2)	0.6% [0.1%, 1.7%] (3)
Out-of-Hospital 180 days	0.4% [0.0%, 2.0%] (1)	0.0% [0.0%, 0.7%] (0)
CABG Total	1.1% [0.2%, 3.2%] (3)	1.4% [0.5%, 2.8%] (7)
Early (In-Hospital)	0.0% [0.0%, 1.4%] (0)	0.6% [0.1%, 1.7%] (3)
Out-of-Hospital 180 days	1.1% [0.2%, 3.2%] (3)	0.8% [0.2%, 2.0%] (4)
Stent Thrombosis Total	1.1% [0.2%, 3.2%] (3)	0.6% [0.1%, 1.7%] (3)
Early (In-Hospital)	0.7% [0.1%, 2.6%] (2)	0.4% [0.0%, 1.4%] (2)
Out-of-Hospital 180 days	0.4% [0.0%, 2.0%] (1)	0.2% [0.0%, 1.1%] (1)
Death Total	0.4% [0.0%, 2.0%] (1)	0.6% [0.1%, 1.7%] (3)
Early (In-Hospital)	0.4% [0.0%, 2.0%] (1)	0.0% [0.0%, 0.7%] (0)
Out-of-Hospital 180 days	0.0% [0.0%, 1.4%] (0)	0.6% [0.1%, 1.7%] (3)
Bleeding Complications	2.6% [1.0%, 5.3%] (7)	1.5% [0.7%, 3.0%] (8)
Vascular Complications	4.8% [2.6%, 8.1%] (13)	1.9% [0.9%, 3.5%] (10)
Cerebrovascular accident	0.4% [0.0%, 2.0%] (1)	0.4% [0.0%, 1.4%] (2)
Stent Delivery Failure	0.0% [0.0%, 1.4%] (0)	1.5% [0.7%, 3.0%] (8)

- *95% confidence interval for one proportion was calculated by Exact Clopper –Pearson C.I.*
- *Early (In-hospital) refers to events during the hospitalization for stent placement.*
- *In cases where a patient experienced both an in-hospital and an out-of-hospital event, they are counted once in each group, however, they are counted only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.*
- *Any Adverse Event includes death, Q-Wave MI, non-Q-Wave MI, emergent CABG, stent thrombosis, bleeding complications, vascular complications, and CVA.*

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REVIVE Study – Saphenous Vein Bypass Graft
Guidant MULTI-LINK RX DUET® Coronary Stent System

The REVIVE Study was a prospective, non-randomized, multi-center, consecutive enrollment registry conducted in 22 US centers that included 160 patients with saphenous vein bypass graft lesions. The primary endpoint of Target Vessel Failure (TVF) at six months post-index procedure was defined as the composite of death, Q-wave MI, non-Q-wave MI and revascularization by CABG or PTCA attributable to the target vessel. An independent Clinical Events Committee adjudicated all MACE.

At 30 days post-procedure, death occurred in three (1.9%) patients, 12 patients suffered non-Q-wave MI (7.5%) and one patient experienced Q-wave MI (0.6%). Two patients (1.3%) underwent CABG for TSR, and one (0.6%) underwent CABG for TVR. No patients experienced subacute (stent) thrombus. Bleeding complications occurred in four (2.5%) patients, four (2.5 %) had vascular complications and two (1.3%) of the patients experienced a CVA.

The 180-day MACE rate of the REVIVE Registry patients was 19.4% (n = 31). Evaluating the combined In- and Out-of-hospital events to 180 days post-procedure, there were five (3.1%) deaths, one (0.6%) Q-wave MI and 17 (10.6%) patients experienced non-Q-wave MI. Five (3.1%) patients required CABG and 12 (7.5%) underwent PTCA (18 total revascularization procedures, 11.3%). No patients experienced stent thrombosis, six (3.8%) had bleeding complications, five (3.1%) had vascular complications and three (1.9%) experienced a CVA.

Table 3 shows the results of patients receiving the GUIDANT MULTI-LINK RX DUET® Coronary Stent System in saphenous vein bypass graft lesions (REVIVE Study) through 180-day follow-up.

Table 3 - Principal Adverse Events Through 180 Days – REVIVE Study
%, [95% Confidence Interval], (Number)

Complication	DUET REVIVE Study SVG (n = 160)	DUET Study *de novo* (n = 270)
Any Adverse Event	26.3% [19.6%, 33.8%] (42)	12.6% [8.9%,17.1%] (34)
Early (In-Hospital)	12.5% [7.8%, 18.6%] (20)	7.0% [4.3%, 10.8%] (19)
Out-of-Hospital 180 days	13.8% [8.8%, 20.1%] (22)	5.5% [3.1%, 9.0%] (15)
Non-Q-Wave MI Total	10.6% [6.3%, 16.5%] (17)	1.1% [0.2%, 3.2%] (3)
Early (In-Hospital)	6.9% [3.5%, 12.0%] (11)	0.7% [0.1%, 2.6%] (2)
Out-of-Hospital 180 days	3.8% [1.4%, 8.0%] (6)	0.4% [0.0%, 2.0%] (1)
Q-Wave MI	0.6% [0.0%, 3.4%] (1)	1.1% [0.2%, 3.2%] (3)
Early (In-Hospital)	0.0% [0.0%, 2.3%] (0)	0.7% [0.1%, 2.6%] (2)
Out-of-Hospital 180 days	0.6% [0.0%, 3.4%] (1)	0.4% [0.0%, 2.0%] (1)
CABG Total	3.1% [1.4%, 8.0%] (5)	1.1% [0.2%, 3.2%] (3)
Early (In-Hospital)	0.6% [0.0%, 3.4%] (1)	0.0% [0.0%, 1.4%] (0)
Out-of-Hospital 180 days	2.5% [0.7%, 6.3%] (4)	1.1% [0.2%, 3.2%] (3)
Stent Thrombosis Total	0.0% [0.0%, 2.3%] (0)	1.1% [0.2%, 3.2%] (3)
Early (In-Hospital)	0.0% [0.0%, 2.3%] (0)	0.7% [0.1%, 2.6%](2)
Out-of-Hospital 180 days	0.0% [0.0%, 2.3%] (0)	0.4% [0.0%, 2.0%] (1)
Death Total	3.1% [1.0%, 7.1%] (5)	0.4% [0.0%, 2.0%] (1)
Early (In-Hospital)	0.6% [0.0%, 3.4%] (1)	0.4% [0.0%, 2.0%] (1)
Out-of-Hospital 180 days	2.5% [0.7%, 6.3%] (4)	0.0% [0.0%, 1.4%] (0)
Bleeding Complications	3.8% [1.4%, 8.0%] (6)	2.6% [1.0%, 5.3%] (7)
Vascular Complications	3.1% [1.0%, 7.1%] (5)	4.8% [2.6%, 8.1%] (13)
Cerebrovascular Accident	1.9% [0.4%, 5.4%] (3)	0.4% [0.0%, 2.0%] (1)
Stent Delivery Failure	2.8% [0.9%, 6.4%] (5)*	0.0% [0.0%, 1.4%] (0)

- *The 95% confidence interval for one proportion was calculated by Exact Clopper-Pearson C.I. method.*
- *Early (In-hospital) refers to events during the hospitalization for the initial stent placement.*
- *In cases where a patient experienced both an in-hospital and an out-of-hospital event, they are counted once in each group, however, they are counted only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.*
- *Any Adverse Event includes death, Q-Wave MI, non-Q-Wave MI, emergent CABG, target lesion revascularization, stent thrombosis, bleeding complications, vascular complications, and CVA*

* *Per protocol, as many as two lesions per target vessel could be treated. Device success by QCA is calculated per lesion (n = 179).*

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RECREATE Registry – Abrupt or Threatened Abrupt Closure
Guidant MULTI-LINK® Coronary Stent System Registry

In this non-randomized, multi-center, consecutive registry, 152 patients were enrolled to evaluate the use of the Guidant MULTI-LINK® Stent in patients presenting with abrupt or threatened abrupt closure of native coronary arteries (lesion length $\leq$ 32 mm) with a reference vessel diameter ranging from 2.5 mm to 3.75 mm.

One patient who received a Guidant MULTI-LINK® Stent died as a result of a ruptured abdominal aortic aneurysm within 30 days of the implantation.

In the RECREATE Registry, the incidence of thrombosis in patients with the Guidant MULTI-LINK® Stent was 0.7% (1/152). The incidence of vascular complication requiring surgical repair after stent placement was 2.6% (4/152), while the rate for bleeding requiring transfusion was 2.6% (4/152).

A total of 10 Guidant MULTI-LINK® Stent failures occurred in the RECREATE Registry. They are comprised of 1 stent misplacement and 9 stent delivery failures. The 9 stent delivery failures are delineated as follows: the operator was unable to deliver the first stent (n = 5), and the assigned Registry stent was never delivered (n = 4). After delivery failure, the stent was deployed outside the lesion site in 2 cases (n = 2), and lost in the peripheral system once (n = 1). Delivery of a second Registry stent was successful in all attempts. A Registry stent was ultimately delivered in all but 2.6% of patients (4/152).

Table 4 shows the results of patients receiving the Guidant MULTI-LINK® Coronary Stent System (RECREATE Registry) to those receiving the Guidant MULTI-LINK® Coronary Stent System (MULTI-LINK Study).

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Table 4 - Principal Adverse Events Through 30 Days – RECREATE Registry
%, [95% Confidence Interval], (Number)

Complication	MULTI-LINK Study *de novo* (n = 518)	RECREATE Registry (n = 152)
Any Adverse Event	8.5% [6.2%, 11.2%] (44)	10.5% [6.1%, 16.5%] (16)
Early (In-Hospital)	7.9% [5.7%, 10.6%] (41)	9.2% [5.1%, 15.0%] (14)
Out-of-Hospital 30 days	0.6% [0.1%, 1.7%] (3)	1.3% [0.2%, 4.7%] (2)
Non-Q-Wave Total	3.1% [1.8%, 5.0%] (16)	2.6% [0.7%, 6.6%] (4)
Early (In-Hospital)	3.1% [1.8%, 5.0%] (16)	2.6% [0.7%, 6.6%] (4)
Out-of-Hospital 30 days	0.0% [0.0%, 0.7%] (0)	0.0% [0.0%, 2.4%] (0)
Q-Wave MI	0.6% [0.1%, 1.7%] (3)	0.0% [0.0%, 2.4%] (0)
Early (In-Hospital)	0.6% [0.1%, 1.7%] (3)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital 30 days	0.0% [0.0%, 0.7%] (0)	0.0% [0.0%, 2.4%] (0)
CABG Total	0.6% [0.1%, 1.7%] (3)	1.3% [0.2%, 4.7%] (2)
Early (In-Hospital)	0.6% [0.1%, 1.7%] (3)	1.3% [0.2%, 4.7%] (2)
Out-of-Hospital 30 days	0.0% [0.0%, 0.7%] (0)	0.0% [0.0%, 2.4%] (0)
Stent Thrombosis Total	0.6% [0.1%, 1.7%] (3)	0.7% [0.0%, 3.6%] (1)
Early (In-Hospital)	0.4% [0.0%, 1.4%] (2)	0.7% [0.0%, 3.6%] (1)
Out-of-Hospital 30 days	0.2% [0.0%, 1.1%] (1)	0.0% [0.0%, 2.4%] (0)
Death Total	0.0% [0.0%, 0.7%] (0)	0.7% [0.0%, 3.6%] (1)
Early (In-Hospital)	0.0% [0.0%, 0.7%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital 30 days	0.0% [0.0%, 0.7%] (0)	0.7% [0.0%, 3.6%] (1)
Bleeding Complications	1.5% [0.7%, 3.0%] (8)	2.6% [0.7%, 6.6%] (4)
Vascular Complications	1.9% [0.9%, 3.5%] (10)	2.6% [0.7%, 6.6%] (4)
Cerebrovascular accident	0.2% [0.0%, 1.1%] (1)	0.0% [0.0%, 2.4%] (0)
Stent Delivery Failure	1.5% [0.7%, 3.0%] (8)	2.6% [0.7%, 6.6%] (4)

- *95% confidence interval for one proportion was calculated by Exact Clopper-Pearson C.I.*
- *Early (In-hospital) refers to events during the hospitalization for stent placement.*
- *In cases where a patient experienced both an in-hospital and an out-of-hospital event, they are counted once in each group, however, they are counted only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.*
- *Any Adverse Event includes death, Q-Wave MI, non-Q-Wave MI, emergent CABG, stent thrombosis, bleeding complications, vascular complications, and CVA*

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CADILLAC Trial - Acute Myocardial Infarction
Guidant MULTI-LINK® and Guidant MULTI-LINK DUET® Coronary Stent System

The CADILLAC Trial was a prospective randomized study to determine the comparative MACE rates defined as the composite of death, disabling stroke, reinfarction and ischemia driven revascularization by CABG or PTCA related to the target vessel, subacute thrombosis (SAT) and bleeding events. The study was conducted at 74 sites including the United States, Europe and South America. After satisfying clinical and angiographic criteria, 2,082 patients were randomized equally to one of four reperfusion strategies, which were PTCA alone, PTCA plus Abciximab, stent alone or stent plus Abciximab.

Patients with clinical symptoms of acute MI (without cardiogenic shock) of at least 30 minutes in duration but no more than 12 hours were screened for eligibility. Angiographic confirmation was required to assure that the lesion was in a native coronary lesion, not previously stented, and visually estimated to be between 2.5 and 4.0 mm in diameter. Lesions had to be covered by no more than two stents, each of which was ≤ 38 mm in length.

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Table 5 - Principal Adverse Events Through 180 days - CADILLAC Trial
Percent, [95% Confidence Interval], (Number)

	PTCA (n = 518)	PTCA plus Abciximab (n = 528)	Stent (n = 512)	Stent plus Abciximab (n = 524)
Any Adverse Event	26.4% [22.7%, 30.5%] (137)	22.3% [18.9%, 26.1%] (118)	18.6% [15.3%, 22.2%] (95)	14.9% [11.9%, 18.2%] (78)
Early (In-Hospital)	10.4% [7.9%, 13.4%] (54)	5.7% [3.9%, 8.0%] (30)	10.2% [7.7%, 13.1%] (52)	5.5% [3.7%, 7.9%] (29)
Out-of-Hospital	16.0% [13.0%, 19.5%] (83)	16.7% [13.6%, 20.1%] (88)	8.4% [6.1%, 11.1%] (43)	9.4% [7.0%, 12.2%] (49)
Any MACE	19.7% [16.4%, 23.4%] (102)	16.3% [13.2%, 19.7%] (86)	11.3% [8.7%, 14.4%] (58)	10.1% [7.7%, 13.0%] (53)
Early (In-Hospital)	6.0% [4.1%, 8.4%] (31)	2.7% [1.5%, 4.4%] (14)	4.9% [3.2%, 7.1%] (25)	2.9% [1.6%, 4.7%] (15)
Out-of-Hospital	13.7% [10.9%, 17.0%] (71)	13.6% [10.8%, 16.9%] (72)	6.4% [4.5%, 8.9%] (33)	7.3% [5.2%, 9.8%] (38)
MI	1.7% [0.8%, 3.3%] (9)	2.7% [1.5%, 4.4%] (14)	1.6% [0.7%, 3.1%] (8)	2.1% [1.1%, 3.7%] (11)
Early (In-Hospital)	0.2% [0.0%, 1.1%] (1)	0.0% [0.0%, 0.7%] (0)	0.8% [0.2%, 2.0%] (4)	0.0% [0.0%, 0.7%] (0)
Out-of-Hospital	1.5% [0.7%, 3.0%] (8)	2.7% [1.5%, 4.4%] (14)	0.8% [0.2%, 2.0%] (4)	2.1% [1.1%, 3.7%] (11)
Ischemic TVR--CABG	3.1% [1.8%, 5.0%] (16)	3.0% [1.7%, 4.9%] (16)	2.7% [1.5%, 4.5%] (14)	1.5% [0.7%, 3.0%] (8)
Early (In-Hospital)	1.5% [0.7%, 3.0%] (8)	0.6% [0.1%, 1.7%] (3)	1.2% [0.4%, 2.5%] (6)	0.6% [0.1%, 1.7%] (3)
Out-of-Hospital	1.5% [0.7%, 3.0%] (8)	2.5% [1.3%, 4.2%] (13)	1.6% [0.7%, 3.1%] (8)	1.0% [0.3%, 2.2%] (5)
Ischemic TVR-PTCA	12.0% [9.3%, 15.1%] (62)	10.6% [8.1%, 13.6%] (56)	5.5% [3.7%, 7.8%] (28)	3.4% [2.0%, 5.4%] (18)
Early (In-Hospital)	2.9% [1.6%, 4.7%] (15)	0.9% [0.3%, 2.2%] (5)	1.8% [0.8%, 3.3%] (9)	0.4% [0.0%, 1.4%] (2)
Out-of-Hospital	9.1% [6.7%, 11.9%] (47)	9.7% [7.3%, 12.5%] (51)	3.7% [2.2%, 5.7%] (19)	3.1% [1.8%, 4.9%] (16)
Subacute Thrombosis*	1.9% [0.9%, 3.5%] (10)	0.8% [0.2%, 1.9%] (4)	1.0% [0.3%, 2.3%] (5)	0.0% [0.0%, 0.7%] (0)
Early (In-Hospital)	1.4% [0.5%, 2.8%] (7)	0.4% [0.0%, 1.4%] (2)	1.0% [0.3%, 2.3%] (5)	0.0% [0.0%, 0.7%] (0)
Out-of-Hospital	0.6% [0.1%, 1.7%] (3)	0.4% [0.0%, 1.4%] (2)	0.0% [0.0%, 0.7%] (0)	0.0% [0.0%, 0.7%] (0)
Death	4.4% [2.8%, 6.6%] (23)	2.5% [1.3%, 4.2%] (13)	2.9% [1.6%, 4.8%] (15)	4.2% [2.6%, 6.3%] (22)
Early (In-Hospital)	1.5% [0.7%, 3.0%] (8)	1.1% [0.4%, 2.5%] (6)	2.0% [0.9%, 3.6%] (10)	1.9% [0.9%, 3.5%] (10)
Out-of-Hospital	2.9% [1.6%, 4.7%] (15)	1.3% [0.5%, 2.7%] (7)	1.0% [0.3%, 2.3%] (5)	2.3% [1.2%, 4.0%] (12)
Bleeding Events *	3.1% [1.8%, 5.0%] (16)	2.7% [1.5%, 4.4%] (14)	4.5% [2.9%, 6.7%] (23)	3.2% [1.9%, 5.1%] (17)
Early (In-Hospital)	2.9% [1.6%, 4.7%] (15)	2.7% [1.5%, 4.4%] (14)	3.3% [1.9%, 5.3%] (17)	2.7% [1.5%, 4.4%] (14)
Out-of-Hospital	0.2% [0.0%, 1.1%] (1)	0.0% [0.0%, 0.7%] (0)	1.2% [0.4%, 2.5%] (6)	0.6% [0.1%, 1.7%] (3)
Disabling Stroke (CVA)	0.2% [0.0%, 1.1%] (1)	0.2% [0.0%, 1.1%] (1)	0.4% [0.0%, 1.4%] (2)	0.4% [0.0%, 1.4%] (2)
Early (In-Hospital)	0.0% [0.0%, 0.7%] (0)	0.0% [0.0%, 0.7%] (0)	0.2% [0.0%, 1.1%] (1)	0.0% [0.0%, 0.7%] (0)
Out-of-Hospital	0.2% [0.0%, 1.1%] (1)	0.2% [0.0%, 1.1%] (1)	0.2% [0.0%, 1.1%] (1)	0.4% [0.0%, 1.4%] (2)

- Displayed are 95% exact Clopper-Pearson confidence intervals for one proportion.
- Any Adverse Event includes MI, ischemic TVR - CABG and PTCA, SAT, death, bleeding complication, and CVA.
- CABG and PTCA are ischemic events at the target vessel, as defined in the study protocol.
- Disabling stroke (CVA) is protocol-defined as an acute, new neurological deficit lasting > 24 hours affecting daily activities, or resulting in death.
- Any Adverse Event counts are straight sums across the individual events. All other counts are patient counts, with patients counted only once at each level of summation.
- Note that only the first occurrence of each event for each patient was recorded in the adjudicated dataset. As a result, only the first of each event is counted for each patient.

** Counts for subacute thrombosis and bleeding complications are through 30 days.*

6.2 Potential Adverse Events

Adverse events may be associated with the use of a coronary stent in native coronary arteries (including those listed in Tables 2-5):

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to anti-platelet agents / contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension / Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis / occlusion
- Stroke / cerebrovascular accident
- Total occlusion of coronary artery

7.0 CLINICAL STUDIES

The following studies were nonconcurrent and statistical comparisons between the studies are not appropriate.

DUET Study – *de novo* Lesions
Guidant MULTI-LINK RX DUET® Coronary Stent System

The DUET Study was a prospective, non-randomized, consecutive enrollment study conducted in 20 US centers that included 295 patients (25 lead-in, 270 study) with *de novo* native coronary artery lesions. The primary endpoint of Major Adverse Cardiac Events (MACE) at 30 days was defined as the composite of death, Q-wave MI, non-Q-wave MI and revascularization by CABG or PTCA attributable to the target site. An independent Clinical Events Committee adjudicated all MACE.

Of the 270 study patients, 64% were male ranging in age from 32 to 88 years with an average of 63 ±11 (mean ±SD). All patients presented with angina or a positive functional study, undergoing elective, single *de novo* lesion treatment in a native coronary artery. Eligible patients had a major coronary artery or major branch with a visually estimated stenosis of ≥ 3.0 mm and ≤ 4.0 mm in diameter and ≤ 25 mm in length.

The Guidant MULTI-LINK RX DUET® Coronary Stent System could be repressurized up to 16 atm to dilate the stent and to assure complete apposition of the stent to the artery wall. Post dilatation with the Delivery System or an alternative balloon could be used to achieve a residual diameter stenosis of 0% to 10%. If needed, further inflations were performed with a non-compliant balloon with a balloon-to-artery ratio of 1.0-1.1:1.0.

All patients were prescribed the following: 325 mg aspirin daily for at least one year post stenting. Ticlopidine, 250 mg twice daily was given the day before the procedure or as a loading dose of 500 mg the day of the procedure, then 250 mg twice daily for 30 days. When an investigator judged an outcome suboptimal, he or she was free to utilize adjunctive anti-coagulant regimens.

Table 6 compares the results of the patients treated in the DUET Study to those treated in the MULTI-LINK Study.

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Table 6 - Principal Effectiveness and Safety Results Through 180 Days – DUET Study
%, [95% Confidence Interval], (Number/Denominator), or Mean ±SD {Range} (Number)
All Patients Treated (n = 788)

Effectiveness Measures	**Guidant MULTI-LINK DUET (n = 270) +**	**Guidant MULTI-LINK (n = 518) ++**
Device Success by QCA	100.0% [98.6%, 100%] (269/269)	97.1% [95.2%, 98.4%] (497/512)
Procedure Success by QCA	98.1% [95.7%, 99.4%] (264/269)	93.9% [91.5%, 95.8%] (481/512)
In-Stent % DS post procedure, mm	9.7% ±9.9% {-31.9%, 34.3%} (269)	7.7% ±10.7% {-39.2%, 42.2%} (506)
In-Stent % DS at 6 month follow up	35.7% ±19.4% {-12.4%, 100%} (228)	32.5% ±18.9% {-16.1%, 100%} (212)
6 Month Follow-up Binary Restenosis Rate	19.7% [14.7%,25.4%] (45/229)	16.0% [11.4%, 21.7%] (34/212)
Safety Measures		
Target Site Revascularization Free (6 month K-M)	89.8%	93.8%
Target Vessel Failure Free (6 month K-M)	87.3%	88.5%
In-Hospital Clinical Event Rate	1.9% [0.6%, 4.3%] (5/270)	4.4% [2.8%, 6.6%] (23/518)
Out-of-Hospital Clinical Event Rate at 6 months	8.5% [5.5%, 12.5%] (23/270)	6.0% [4.1%, 8.4%] (31/518)
Bleeding Complication Rate	2.6% [1.0%, 5.3%] (7/270)	1.5% [0.7%, 3.0%] (8/518)
Vascular Event Rate	4.8% [2.6%, 8.1%] (13/270)	1.9% [0.9%, 3.5%] (10/518)
Subacute Thrombosis Rate	1.1% [0.2%, 3.2%] (3/270)	0.6% [0.1%, 1.7%] (3/518)
Survival at 30 days	99.6% [98.0%, 100%] (269/270)	100.0% [99.4%, 100%] (518/518)
Survival at 180 days	99.6% [98.0%, 100%] (269/270)	99.4% [98.3%, 99.9%] (515/518)
MACE Rate at 6 months	10.4% [7.0%, 14.6%] (28/270)	10.4% [7.9%, 13.4%] (54/518)
Hospitalization Post-Intervention (days)	1.4 ±1.7 {0, 19} (n = 270)	1.6 ±1.6 {1.0, 18.0} (n = 518)

- *Device success – Attainment of the final result of < 50% residual stenosis of the target vessel using the assigned treatment device alone (i.e., without the use of other types of stents or new balloon devices).*
- *Procedure Success = Attainment of the final result of < 50% residual stenosis of the target vessel using the assigned treatment device and freedom from MACE.*
- *QCA – Quantitative Coronary Angiography*
- *% DS – percent diameter stenosis by QCA.*
- *In-Stent Binary Restenosis Rate 6-month follow up ≥ 50% in-stent restenosis per QCA*
- *MACE = Major Adverse Cardiac Event: death, Q-wave MI or non-Q-wave MI, CABG, or PTCA to the treated site.*
- *In-Hospital Clinical Event = Any MACE occurring prior to hospital discharge.*
- *Out-of-Hospital Clinical Event – Any MACE occurring from hospital discharge through up to 180 days of clinical follow-up.*
- *Bleeding Complication = Blood loss necessitating a transfusion.*
- *Vascular Event – Any hematoma > 5 cm, arteriovenous fistula, pseudoaneurysm, retroperitoneal bleed, peripheral nerve disorder or surgical repair.*
- *Subacute Thrombosis = Any cardiac death, subacute closure requiring revascularization of the target site or total closure indicated by QCA within 30 days of the index intervention.*
- *+ Angiographic Core lab data for Guidant MULTI-LINK RX DUET® was calculated with the interpolation method for RVD.*
- *++ Angiographic Core lab data for Guidant MULTI-LINK® was calculated with the user-defined method for RVD.*

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REVIVE Study – Saphenous Vein Bypass Graft
Guidant MULTI-LINK RX DUET® Coronary Stent System

The REVIVE Study was a prospective, non-randomized, multi-center, consecutive enrollment registry conducted in 22 US centers that included 160 patients with saphenous vein bypass graft lesions. The primary endpoint of Target Vessel Failure (TVF) at six months post-index procedure was defined as the composite of death, Q-wave MI, non-Q-wave MI and revascularization by CABG or PTCA attributable to the target vessel. An independent Clinical Events Committee adjudicated all MACE.

Of the 160 study patients, 82.5% were male ranging in age from 41 to 88 years with an average of 67.7 ±9.3 (mean ±SD). All patients presented with angina or a positive functional study and had up to two treatable target lesions in the target graft. The target vessel reference diameter requirement was visual estimation of the vessel to be $\geq$ 3.0 mm and $\leq$ 4.0 mm in diameter and $\leq$ 35 mm in length. Patients were allowed to have an intervention to one of the other two major epicardial vessels with an FDA approved device or another bypass graft.

Pre-dilatation was performed at the discretion of the operator. The Guidant MULTI-LINK RX DUET® Coronary Stent System could be repressurized up to 16 atm to dilate the stent and to assure complete apposition of the stent to the artery wall. Post dilatation with the Delivery System or an alternative balloon could be used to achieve a residual diameter stenosis of 0% to 10%. If needed, further inflations were performed with a non-compliant balloon with a balloon-to-artery ratio of 1.0-1.1:1.0.

All patients received the hospital's standard anti-coagulant and anti-platelet regimen for coronary stent implantation. The activated clotting time (ACT) was monitored and recorded on source documentation during the procedure. The ACT was kept at a therapeutic level for percutaneous coronary interventions per the hospital standard.

The results of the patients treated in the REVIVE Study are shown in Table 7.

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Table 7 - Principal Effectiveness and Safety Results Through 180 Days – REVIVE Study
%, [95% Confidence Interval], (Number/Denominator), or Mean ±SD {Range} (Number)
All Patients Treated (n = 430)

Effectiveness Measures	**Guidant MULTI-LINK DUET® SVG (n = 160)**	**Guidant MULTI-LINK DUET® *de novo* (n = 270)**
Device Success by QCA *	97.2% [93.6%, 99.1%] (174/179)	100% [98.6%, 100%] (269/269)
Clinical Procedure Success by QCA	89.2% [83.3%, 93.6%] (141/158)	98.1% [95.7%, 99.4%] (264/269)
In-Stent % DS post procedure, mm	9.2% ±8.8% {-16%, 41%} (174)	9.7% ±9.9% {-31.9%, 34.3%} (269)
Target Lesion Revascularization (TLR)	10.0% [5.8%, 15.7%] (16/160)	8.1% [5.2%, 12.1%] (22/270)
Target Vessel Failure (TVF)	20.0% [14.1%, 27.0%] (32/160)	9.6% [6.4%, 13.8%] (26/270)
Safety Measures		
In-Hospital Clinical Event Rate (MACE)	8.1% [4.4%, 13.5%] (13/160)	1.9% [0.6%, 4.3%] (5/270)
Out-of-Hospital Clinical Event Rate (MACE)	11.9% [7.3%, 17.9%] (19/160)	8.5% [5.5%, 12.5%] (23/270)
Bleeding Complication Rate	3.8% [1.4%, 8.0%] (6/160)	2.6% [1.0%, 5.3%] (7/270)
Vascular Event Rate	3.1% [1.0%, 7.1%] (5/160)	4.8% [2.6%, 8.1%] (13/270)
Subacute Thrombosis Rate	0.0% [0.0%, 2.3%] (0/160)	1.1% [0.2%, 3.2%] (3/270)
MACE Rate at 180 days	19.4% [13.6%, 26.4%] (31/160)	10.4% [7.0%, 14.6%] (28/270)

- *Device Success = Attainment of final result < 50% (in-lesion) residual stenosis of the target site using GUIDANT MULTI-LINK® Stent System alone (i.e., without the use of other types of stents or non-balloon devices).*
- *Clinical Procedure Success = < 50% diameter stenosis using GUIDANT MULTI-LINK® Stent System and no In-Hospital MACE (death, Q-Wave MI, non-Q-Wave MI, emergent CABG, or repeat target lesion revascularization).*
- *QCA – Quantitative Coronary Angiography.*
- *% DS = Percent diameter stenosis by QCA.*
- *Target Lesion Revascularization (TLR) = Repeat PTCA or CABG to the original site of intervention.*
- *Target Vessel Failure (TVF) = The composite of acute and late-term major events of death, Q-Wave MI or non-Q-Wave MI, CABG, and percutaneous transluminal coronary angioplasty (PTCA) attributable to the target vessel.*
- *MACE – Major Adverse Cardiac Event: death, Q-Wave MI or non-Q-Wave MI, CABG, or PTCA to the treated site.*
- *In-Hospital Clinical Event = Any MACE occurring prior to hospital discharge.*
- *Out-of-Hospital Clinical Event = Any MACE occurring from hospital discharge through 180-day clinical follow-up.*
- *Bleeding Complication – Blood loss necessitating a transfusion.*
- *Vascular Event = Any hematoma > 5 cm, arteriovenous fistula, pseudoaneurysm, retroperitoneal bleed, peripheral nerve disorder or surgical repair.*
- *Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.*

** Per protocol, as many as two lesions per target vessel could be treated. Device Success by QCA is calculated per lesion (n = 179).*

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RECREATE Registry – Abrupt or Threatened Abrupt Closure
Guidant MULTI-LINK® Coronary Stent System Registry

In the non-randomized RECREATE Registry, the Guidant MULTI-LINK® Stent was evaluated in 152 patients at 23 investigational sites in the United States. The protocol specified enrollment of patients presenting with abrupt or threatened abrupt closure of native coronary arteries (lesion length $\leq$ 32 mm) with a reference diameter ranging from 2.5 mm to 3.75 mm. The primary endpoint was defined as Clinical Target Vessel Failure at 30 days, defined as the composite of acute and late term major events of death, myocardial infarction (Q-wave and non-Q-wave), coronary artery bypass surgery (CABG) and percutaneous transluminal coronary angioplasty (PTCA) attributable to the target (treated) vessel. A clinical events committee adjudicated all major endpoints.

The anti-coagulation regimen administered to 96.7% of patients was aspirin 325 mg/day for at least one year and ticlopidine 250 mg BID for at least 30 days. At the discretion of the investigator, alternative therapy was allowed for non-optimal results which were defined as > 2 stents deployed, > 20% residual stenosis, any residual dissection, poor distal runoff or the presence of thrombus.

Follow-up intervals were 2 and 4 weeks, and 6 months. All evaluable patients were included in the efficacy and safety analysis.

Table 8 compares the results of the patients treated in the RECREATE Registry to those treated in the MULTI-LINK Study.

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Table 8 - Principal Effectiveness and Safety Results Through 30 Days - RECREATE Registry
%, [95% Confidence Interval], (Number/Denominator), or Mean ±SD {Range} (Number)
All Patients Treated (n = 670)

Effectiveness Measures	**Guidant MULTI-LINK®** ***de novo*** **(n = 518)**	**Guidant MULTI-LINK RECREATE (n = 152)**
Device Success by QCA	97.1% [95.2%, 98.4%] (497/512)	96.7% [92.4%, 98.9%] (145/150)
Clinical Procedure Success by QCA	93.9% [91.5%, 95.8%] (481/512)	95.3% [90.6%, 98.1%] (143/150)
In-Stent % DS post procedure, mm	7.7% ±10.7% [-39.2%, 42.2%] (506)	11.2% ±11% [-27.9%, 46.8%] (146)
Target Lesion Revascularization (TLR)	1.7% [0.8%, 3.3%] (9/518)	2.0% [0.4%, 5.7%] (3/152)
Target Vessel Failure (TVF)	5.0% [3.3%, 7.3%] (26/518)	4.6% [1.9%, 9.3%] (7/152)
Safety Measures		
In-Hospital Clinical Event Rate (MACE)	4.4% [2.8%, 6.6%] (23/518)	3.3% [1.1%, 7.5%] (5/152)
Out-of-Hospital Clinical Event Rate (MACE)	0.6% [0.1%, 1.7%] (3/518)	0.7% [0.0%, 3.6%] (1/152)
Bleeding Complication Rate	1.5% [0.7%, 3.0%] (8/518)	2.6% [0.7%, 6.6%] (4/152)
Vascular Event Rate	1.9% [0.9%, 3.5%] (10/518)	2.6% [0.7%, 6.6%] (4/152)
Subacute Thrombosis Rate	0.6% [0.1%, 1.7%] (3/518)	0.7% [0.0%, 3.6%] (1/152)
MACE Rate at 30 days	5.0% [3.3%, 7.3%] (26/518)	3.9% [1.5%, 8.4%] (6/152)
Hospitalization Post-Intervention (days)*	1.6 ±1.6 {1.0, 18.0} (518/518)	1.9 ±2.8 {1.0, 28.0} (152/152)

RECREATE Registry Definitions

- *Device Success = Attainment of final result < 50% (in-lesion) residual stenosis of the target site using Guidant MULTI-LINK® Stent System alone (i.e., without the use of other types of stents or non-balloon devices).*
- *Clinical Procedure Success (Procedure Success in ASCENT) = Attainment of a final result of < 50% residual stenosis of the target lesion using Guidant MULTI-LINK® Stent System and any adjunctive device including additional stents without death, emergent bypass surgery, Q-wave and non-Q-wave MI prior to hospital discharge.*
- *QCA = Quantitative Coronary Angiography.*
- *% DS = Percent diameter stenosis by QCA.*
- *Target Lesion Revascularization (TLR) = Repeat PTCA or CABG to the original site of intervention.*
- *Target Vessel Failure (TVF) = The composite of acute and late-term major events of death, CABG, Q-wave MI or non-Q-wave MI, and percutaneous transluminal coronary angioplasty (PTCA) attributable to the target vessel.*
- *MACE = Major Adverse Cardiac Event: death, Q-wave MI or non-Q-wave MI, CABG, or PTCA to the treated site.*
- *In-Hospital Clinical Event = Any MACE occurring prior to hospital discharge.*
- *Out-of-Hospital Clinical Event = Any MACE occurring from hospital discharge through 30-day clinical follow-up.*
- *Bleeding Complication = Blood loss necessitating a transfusion.*
- *Vascular Event = Any hematoma > 5 cm, arteriovenous fistula, pseudoaneurysm, retroperitoneal bleed, peripheral nerve disorder and surgical repair.*
- *Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.*
- ** = Difference is statistically significant, p-value < 0.05 (2-tailed) based on the confidence intervals for the difference in proportions and relative risk ratios.*

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CADILLAC Trial - Acute Myocardial Infarction
Guidant MULTI-LINK® and Guidant MULTI-LINK DUET® Coronary Stent Systems

Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications

Purpose: To compare the composite major adverse cardiac event (MACE) rates between reperfusion strategies as defined by four treatment arms: PTCA alone; PTCA plus Abciximab; stent alone; stent plus Abciximab. Using a primary endpoint of 180 days, the MACE elements included death, disabling stroke, reinfarction, ischemic target vessel revascularization (TVR). Subacute thrombosis (SAT) and bleeding complications were also compared.

Conclusions: In a comparison between PTCA and the Guidant coronary stent in selected patients presenting with acute myocardial infarction (MI), the stent provided similar immediate clinical benefits and resulted in reduced MACE rates at 180 days.

Effectiveness Results: The stent alone as compared to PTCA alone, and as compared to PTCA plus Abciximab, proved to be statistically significant in reducing 180-day MACE rates, (11.3% vs. 19.7%, $p < 0.001$, 11.3% vs. 16.3%, $p < 0.001$). The survival rates between all four reperfusion strategies were statistically similar: stent alone (97.1%), stent plus Abciximab (95.8%), PTCA alone (95.6%) and PTCA plus Abciximab (97.5%) at 180 days.

Safety Results: No unanticipated events that might affect the risk analysis were noted in the CADILLAC trial. Adverse event rates are presented earlier (see Table 5).

Design: A, multi-center, prospective, randomized four-arm trial was conducted at 74 international sites: 61 United States, 7 European, and 6 South America. Patients with clinical symptoms of acute MI (without cardiogenic shock) of at least 30 minutes in duration but no more than 12 hours were screened for eligibility. Diagnosis of acute MI required ST segment elevation or angiographic evidence of high-grade stenosis with wall motion abnormality. Patients who satisfied clinical eligibility criteria were enrolled if the lesion was in a native coronary artery that was not previously stented, and that was visually estimated to be between 2.5 and 4.0 mm in diameter. Lesions had to be covered by no more than two stents, each of which was $\leq$ 38 mm in length.

Demography: The total population consisted of 2,082 patients: 518 PTCA alone; 528 PTCA plus Abciximab; 512 stent alone; 524 stent plus Abciximab. Baseline characteristics were similar across all four treatment arms; factors evaluated included age (median 59.0 years); height (68"); weight (180 lbs); diabetes (17%); pre-existing hypertension (48%); hyperlipidemia (38%); history of smoking (69%), and gender (27% females).

Methods: Using a specific monitoring regimen, data were collected at the index procedure, 2 weeks, 30 days, 6 months, 7 months (with a planned angiographic follow-up for a subset of patients), and 12 months. The data were submitted to a data management group for review and identification of discrepancies. Angiographic outcomes were determined by the angiographic core lab. A clinical events committee performed concurrent reviews and adjudicated all MACE.

Table 9 below summarizes the principal effectiveness and safety results of the CADILLAC Trial at 180 days. Figure 1 provides cumulative MACE rates to 365 days.

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Table 9 - Principal Effectiveness and Safety Results Through 180 Days

Primary Endpoint First Comparison by Evaluating MACE

The first comparison was one of superiority between stent alone and PTCA alone. The stent alone arm of the trial proved to be significantly superior to PTCA alone (11.3% vs. 19.7%, $p < 0.001$).

Primary Endpoint Second Comparison by Evaluating MACE

The second comparison was a test of equivalency between stent alone and PTCA plus Abciximab. The stent alone arm of the trial proved to be not only equivalent, but significantly superior to PTCA plus Abciximab (11.3% vs. 16.3%, $p < 0.001$).

	PTCA (n = 518)	PTCA plus Abciximab (n = 528)	STENT (n = 512)	STENT plus Abciximab (n = 524)
Efficacy Measures				
Lesion Success by QCA	93.1% (461/495)	94.2% (483/513)	94.2% (457/485)	96.8% (491/507)
Clinical Procedure Success by QCA	88.1% (436/495)	92.0% (472/513)	90.7% (440/485)	95.1% (482/507)
Post Procedure MLD (mm), in-lesion / in-stent Mean ±SD (N) Range(min-max)	2.24 ±0.50 (501) (0.40, 3.95)	2.21 ±0.55 (516) (0.00, 4.86)	2.63 ±0.48 (487) (0.00, 4.18)	2.71 ±0.48 (507) (0.00, 4.41)
7-Month Follow-up in-lesion / in-stent % DS Angiographic Subset Patients Mean ±SD (N)	45.10 ±25.15 (144) (-4.70, 100.0)	48.60 ±23.55 (163) (3.30, 100.0)	30.81 ±18.87 (138) (-21.3, 100.0)	32.44 ±19.63 (162) (-28.5, 100.0)
7-Month Follow-up in-lesion / in-stent binary restenosis rate Angiographic Subset Patients	34.7% (50/144)	44.8% (73/163)	13.8% (19/138)	17.9% (29/162)
TVR-free Through 6 months	83.8% (434/518)	85.6% (452/528)	91.4% (468/512)	94.5% (495/524)
TVF-free Through 6 months	79.3% (411/518)	83.0% (438/528)	88.3% (452/512)	89.5% (469/524)
Safety Measures				
In-Hospital MACE Events	6.0% (31/518)	2.7% (14/528)	4.9% (25/512)	2.9% (15/524)
Out-of-Hospital MACE Events Through 180 Days	13.7% (71/518)	13.6% (72/528)	6.4% (33/512)	7.3% (38/524)
Bleeding Events**	3.1% (16/518)	2.7% (14/528)	4.5% (23/512)	3.2% (17/524)
Subacute Thrombosis **	1.9% (10/518)	0.8% (4/528)	1.0% (5/512)	0.0% (0/524)
Survival Through 30 Days	97.5% (505/518)	98.9% (522/528)	97.9% (501/512)	97.3% (510/524)
Survival Through 180 Days	95.6% (495/518)	97.5% (515/528)	97.1% (497/512)	95.8% (502/524)
MACE rate Through 180 Days *	19.7% (102/518)	16.3% (86/528)	11.3% (58/512)	10.1% (53/524)
Length of Hospitalization - US Sites (days) Mean ±SD (N) Range(min - max)	4.26 ±2.78 (418) (1.00, 28.00)	3.74 ±2.43 (424) (1.00, 25.00)	4.33 ±3.58 (409) (0.00, 39.00)	3.80 ±2.51 (423) (1.00, 23.00)
Length of Hospitalization - European Sites (days) Mean ±SD (N) Range(min - max)	8.10 ±4.63 (72) (2.00, 22.00)	8.03 ±5.28 (74) (2.00, 24.00)	8.01 ±4.65 (73) (3.00, 20.00)	8.52 ±6.06 (71) (2.00, 27.00)

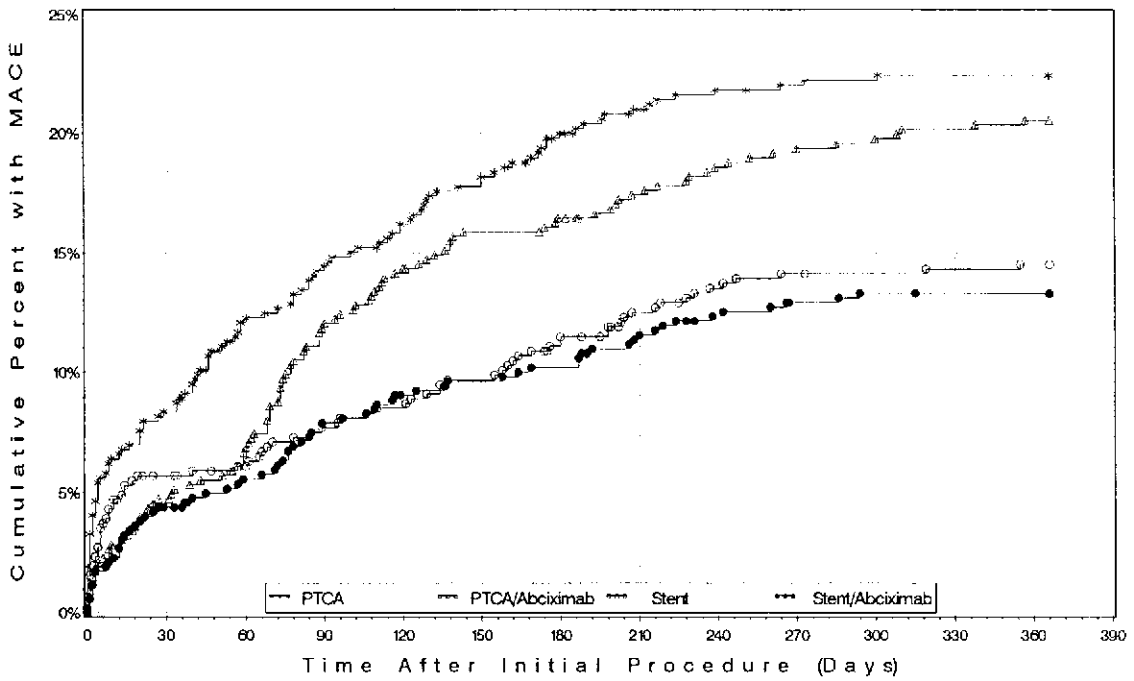
CADILLAC Trial Definitions

- *Lesion success = Attainment of final result, < 50% residual stenosis of the target site with TIMI 3 flow, using Guidant MULTI-LINK System or PTCA and any adjunctive device.*
- *Binary restenosis – ≥ 50% by quantitative coronary analysis*

* *Primary Endpoint*

** *Counts for subacute thrombosis and bleeding complications are through 30 days.*

Figure 1 Kaplan—Meier Curve of Time to MACE (to 365 days)



		Time After Initial Procedure (days)						
Treatment	**Parameter**	**0**	**14**	**30**	**90**	**180**	**270**	**365**
PTCA	# At Risk	518	505.5	478	467	431	398.5	386
	# Events	10	35	43	74	102	112	114
	% with Event	1.93	6.78	8.34	14.43	19.98	21.99	22.4
	% SEM	0.6	1.11	1.22	1.55	1.77	1.84	1.85
PTCA plus Abciximab	# At Risk	528	525	508.5	497	457	431	414
	# Events	2	16	25	63	86	101	107
	% with Event	0.38	3.04	4.75	12.03	16.46	19.37	20.54
	% SEM	0.27	0.75	0.93	1.42	1.62	1.73	1.77
Stent	# At Risk	512	504.5	479	474	461	438	421.5
	# Events	5	27	29	39	58	71	73
	% with Event	0.98	5.29	5.69	7.68	11.48	14.11	14.52
	% SEM	0.43	0.99	1.03	1.18	1.42	1.55	1.57
Stent plus Abciximab	# At Risk	524	523	505.5	496	475.5	461	444.5
	# Events	1	17	23	41	53	67	69
	% with Event	0.19	3.24	4.39	7.86	10.19	12.92	13.31
	% SEM	0.19	0.77	0.9	1.18	1.33	1.47	1.49
Tests Between Groups	Test	Chi-Square	Deg Frdm	P-value				
Stent vs. PTCA	Log-Rank	10.9987	1	0.0009				
Stent vs. PTCA plus Abciximab	Log-Rank	6.0671	1	0.0138				

8.0 PATIENT SELECTION AND TREATMENT

8.1 Individualization of Treatment

The risks and benefits described above should be considered for each patient before use of the Guidant MULTI-LINK RX DUET® Coronary Stent System. Patient selection factors to be assessed should include a judgment regarding risk of anti-platelet therapy. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

In *de novo* lesions in native coronary arteries, premorbid conditions that increase the risk of binary in-stent restenosis (diabetes mellitus and tobacco use) should be reviewed. The relationship of baseline and procedural variables to binary in-stent restenosis was examined. The three statistically significant predictors of binary in-stent restenosis were: post-procedural Minimum Lumen Diameter (MLD), diabetes mellitus, and total stent length. Binary in-stent restenosis was less likely with shorter stent length and larger post-procedure in-stent MLDs.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0 mm, intra-procedural thrombus, or poor distal runoff, dissection following stent implantation, and / or cessation of anti-platelet therapy (ticlopidine / ASA) within 30 days of stent implantation. In patients who have undergone coronary stenting, the persistence of a thrombus or dissection should be considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation.

8.2 Use in Specific Patient Populations

The safety and effectiveness of the Guidant MULTI-LINK DUET® Stent have not been established in:

- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameter < 3.0 mm.
- Patients with lesions located in the left main coronary artery, ostial lesions or lesions located at a bifurcation.
- Patients with diffuse disease or poor outflow distal to the identified lesions.
- Patients with more than two overlapping stents due to risk of thrombosis and / or restenosis.

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters to treat in-stent stenosis have not been established.

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9.0 CLINICIAN USE INFORMATION

9.1 Inspection Prior to Use

Prior to using the Guidant MULTI-LINK RX DUET® or Guidant MULTI-LINK OTW DUET® Coronary Stent System, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent is located between the radiopaque balloon markers. Do not use if any defects are noted.

9.2 Materials Required

Quantity	Material
	Appropriate guiding catheter(s)
2 – 3	10 - 20 cc syringes
1,000 u /500 cc	Heparinized Normal Saline (HepNS)
1	0.014 inch X 175 cm (minimum length) guide wire
1	Rotating hemostatic valve with 0.096 inch minimum inner diameter
	60% contrast diluted 1:1 with normal saline
1	Inflation device
1	Three-way stopcock
1	Torque device
1	Guide wire introducer

9.3 Preparation

9.3.1 Guide Wire Lumen Flush

1	Remove the protective cover from tip.
2	For use with the GUIDANT MULTI-LINK RX DUET® Coronary Stent System, flush the guide wire lumen with HepNS until fluid exits **the guide wire exit notch**. For use with the GUIDANT MULTI-LINK OTW DUET® Coronary Stent System, flush the guide wire lumen with HepNS until fluid exits **the distal tip**.

9.3.2 Delivery System Preparation

1	Prepare inflation device syringe with diluted contrast medium.
2	Attach an inflation device / syringe to stopcock; attach to inflation port.
3	With tip down, orient the Delivery System vertically.
4	Open the stopcock to the Delivery System; pull negative for 30 seconds; release to neutral for contrast fill.
5	Close the stopcock to the Delivery System; purge inflation device / syringe of all air.
6	Repeat steps 3 through 5 until all air is expelled. NOTE: If air is seen in the shaft, repeat Delivery System Preparation steps 3 through 5 to prevent uneven stent expansion.
7	If a syringe was used, attach a prepared inflation device to stopcock.
8	Open the stopcock to the Delivery System.
9	Leave on neutral.

9.4 Delivery Procedure

1	Prepare the vascular access site according to standard practice.
2	Pre-dilate the lesion with PTCA catheter. (In saphenous vein bypass graft lesions, pre-dilatation may be performed at the discretion of the operator.)
3	Maintain neutral pressure on the inflation device. Open the rotating hemostatic valve as widely as possible.
4	Backload the Delivery System onto the proximal portion of the guide wire while maintaining guide wire position across the target lesion.
5	Advance the Delivery System over the guide wire to the target lesion. Utilize radiopaque balloon markers to position the stent across the lesion; perform angiography to confirm stent position. NOTE: Should **unusual resistance** be felt **at any time** during either lesion access or removal of Delivery System post-stent implantation, **remove the entire system as a single unit.** See *Stent / System Removal – Precautions* for specific Delivery System removal instructions.
6	Tighten the rotating hemostatic valve. The stent is now ready to be deployed.

9.5 Deployment Procedure

1	**CAUTION:** Refer to the product label for *in vitro* stent outer diameter and RBP. Deploy the stent slowly by pressurizing the Delivery System in 2 atm increments, every 5 seconds, until the stent is completely expanded. Maintain pressure for 30 seconds. If necessary, the Delivery System can be repressurized or further pressurized to assure complete apposition of the stent to the artery wall. **Do not exceed RBP or expand the stent beyond 4.5 mm.**
2	Deflate the balloon by pulling negative on the inflation device for 30 seconds.

9.6 Removal Procedure

1	Ensure the Delivery System is fully deflated.
2	Fully open the rotating hemostatic valve.
3	While maintaining guide wire position and negative pressure on the inflation device, withdraw the Delivery System. NOTE: Should **unusual resistance** be felt **at any time** during either lesion access or removal of Delivery System post-stent implantation, **remove the entire system as a single unit.** See *Stent / System Removal – Precautions* for specific Delivery System removal instructions.
4	Tighten the rotating hemostatic valve.
5	Repeat angiography to assess the stented area.
6	If post dilatation is necessary, ensure the final stent diameter matches the reference vessel diameter. ASSURE THE STENT IS NOT UNDERDILATED.

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10.0 PATIENT INFORMATION

In addition to this 'Instructions for Use' booklet, the Guidant MULTI-LINK RX DUET® and Guidant MULTI-LINK OTW DUET® Coronary Stent Systems are packaged with additional patient specific information that includes:

- A Patient Implant Card that includes both patient and Guidant MULTI-LINK DUET® Stent specific information. Patients will be expected to keep this card in their possession at all times for procedure / stent identification.

- A Patient Teaching Guide which includes information on Guidant Corporation and the implant procedure.

11.0 PATENTS

This product and its use are protected by one or more of the following patents. United States, 4,411,055; 4,571,240; 4,573,470; 4,581,017; 4,582,181; 4,597,755; 4,616,653; 4,619,263; 4,638,805; 4,641,654; 4,661,094; 4,664,113; 4,692,200; 4,748,982; 4,771,776; 4,771,777; 4,771,778; 4,775,371; 4,782,834; 4,790,315; 4,793,350; 4,821,722; 4,877,031; 4,892,519; 4,938,220; 4,940,062; 4,964,409; 4,976,720; 4,981,478; 4,998,917; 4,998,923; 5,002,532; 5,002,560; 5,003,989; 5,034,001; 5,040,548; 5,042,985; 5,046,503; 5,061,273; 5,090,959; 5,135,535; 5,137,513; 5,154,725; 5,159,937; 5,176,661; 5,180,368; 5,195,971; 5,234,002; 5,242,394; 5,242,396; 5,256,143; 5,263,963; 5,279,562; 5,290,230; 5,300,025; 5,300,085; 5,316,706; 5,318,527; 5,324,259; 5,334,154; 5,342,621; 5,346,505; 5,348,537; 5,350,395; 5,391,172; 5,397,305; 5,409,495; 5,411,476; 5,415,637; 5,421,955 B1; 5,421,955; 5,423,755; 5,423,885; 5,437,083; 5,441,515; 5,443,458; 5,443,500; 5,451,209; 5,451,233; 5,456,667; 5,458,605; 5,458,613; 5,458,615; 5,476,505; 5,480,383; 5,496,275; 5,496,346; 5,498,240; 5,507,301; 5,507,768; 5,507,795; 5,514,154; 5,516,336; 5,525,388; 5,533,968; 5,542,925; 5,546,646; 5,549,551; 5,549,554; 5,554,120; 5,554,121; 5,556,413; 5,558,643; 5,565,523; 5,573,508; 5,573,509; 5,591,197; 5,593,434; 5,603,721; 5,605,696; 5,607,444; 5,618,299; 5,629,077; 5,632,754; 5,632,840; 5,636,641; 5,637,089; 5,637,113; 5,649,977; 5,681,346; 5,693,015; 5,695,506; 5,700,286; 5,707,385; 5,709,658; 5,725,549; 5,728,158; 5,735,893; 5,743,875; 5,747,591; 5,749,888; 5,759,192; 5,769,868; 5,780,807; 5,782,855; 5,807,355; 5,816,923; 5,830,181; 5,849,846; 5,868,706; 5,868,767; 5,891,090; 5,902,290; 5,931,819; 5,989,218; 5,993,460; 6,013,054; 6,013,069; 6,013,728; 6,017,364; 6,019,777; 6,027,475; 6,036,707; 6,036,715; 6,056,776; 6,059,748; 6,059,770; 6,061,588; 6,117,106; 6,126,634; 6,126,635; 6,129,707; 6,131,266; 6,136,011; 6,139,525; 6,156,047; 6,165,152; 6,165,292; 6,179,810; 6,193,686; 6,206,852; 6,217,547; 6,221,425; 6,224,803; 6,238,376; 6,248,092; 6,251,094; 6,273,911; 6,296,655; 6,299,595; RE 33,166; RE 34,564. Other U.S. patents pending. Foreign patents issued and pending.

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Graphical Symbols for Medical Device Labeling