Title: IFU, Guidant MULTI-LINK VISION™ Coronary Stent Systems, RX & OTW, US

IFU Type	Domestic
Languages	English

NOTE: English text in this document is for content reference only and should not be used for artwork placement verification

Generic Specification	PK2011944 for requirements not listed
Receiving Inspection Requirements	Refer to PK2011944
Material Requirements	40lb. Opaque offset, white
Ink Color	PMS Cool Gray 11 U
Dimensional Requirements	15" W x 21" L
Fold Configurations	Map Final Fold – 5" W x 7" L (± 1/4" tolerance)
Artwork Date	5/9/03
Label Control Level	A
Package Requirements	Double bagged or shrink wrapped Bag parts in box to prevent contamination
Barcode Reads (When Scanned)	DI2040375

Guidant MULTI-LINK VISION™ Coronary Stent Systems
Information for Prescribers

Table of Contents

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

1.0 DEVICE DESCRIPTION

The Guidant MULTI-LINK VISION™ RX Coronary Stent System and the Guidant MULTI-LINK VISION™ OTW Coronary Stent System (Guidant MULTI-LINK VISION™ Coronary Stent and RX or OTW Delivery System) include:

- A pre-mounted L-605 cobalt chromium alloy (CoCr) stent.
- Two radiopaque markers, located underneath the balloon, which fluoroscopically mark the working length of the balloon and the expanded stent length.
- Two proximal Delivery System shaft markers (95 cm and 105 cm from the distal tip) that indicate the relative position of the Delivery System to the end of a brachial or femoral guiding catheter. Working catheter length is 143 cm.
- For the Guidant MULTI-LINK VISION™ RX Coronary Stent System only, a shaft color change denotes the guide wire exit notch.

Table 1: Device Specifications

Stent Inner Diameter (mm)	Stent Length (mm)	*Minimum Guiding Catheter Compatibility (ID) 5F (0.056" / 1.42 mm)	**_in vitro_ Stent Nominal Pressure (atm)	Rated Burst Pressure – RBP (atm)	Stent Free % Area
3.0	8, 12, 15, 18, 23, 28	5F	9	16	87
3.5	8, 12, 15, 18, 23, 28	5F	9	16	85
4.0	8, 12, 15, 18, 23, 28	5F	9	16	87

*See Individual manufacturer specifications for (F) equivalent.
Assure full deployment of the stent (see **Clinician Use Information Deployment Procedure (9.5)). Deployment pressures should be based on lesion characteristics.

2.0 HOW SUPPLIED

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

Contents. One (1) Guidant MULTI-LINK VISION™ RX Coronary Stent System or Guidant MULTI-LINK VISION™ OTW Coronary Stent System, One (1) protective / regrooming sheath, One (1) flushing tool (for Guidant MULTI-LINK VISION™ RX Coronary Stent System)

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

3.0 INDICATIONS

The Guidant MULTI-LINK VISION™ RX and Guidant MULTI-LINK VISION™ OTW Coronary Stent Systems are indicated for improving coronary luminal diameter in the following (see **Individualization of Treatment** (8.1)):

- Patients with symptomatic ischemic heart disease due to discrete *de novo* or restenotic native coronary artery lesions (length $\leq$ 25 mm) with reference vessel diameters ranging from 3.0 mm to 4.0 mm.

- Patients with symptomatic ischemic heart disease due to lesions in saphenous vein bypass grafts (length $\leq$ 25 mm) with reference vessel diameters ranging from 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 $\leq$ 25 mm with a reference vessel diameter of 3.0 mm to 4.0 mm.

Outcome (beyond 9 months) for this permanent implant is unknown at present.

4.0 CONTRAINDICATIONS

The Guidant MULTI-LINK VISION™ RX and Guidant MULTI-LINK VISION™ OTW 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 **Individualization of Treatment** (9.1))

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 L-605 cobalt chromium alloy 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. Placing multiple stents of different metals in contact with each other may increase the potential for corrosion. The risk of *in vivo* corrosion does not appear to increase based on *in vitro* corrosion tests using an L-605 CoCr alloy stent (Guidant MULTI-LINK VISION™ Coronary Stent) in combination with a 316L stainless steel alloy stent (Guidant MULTI-LINK TETRA™ Coronary Stent).

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.

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 rotating hemostatic valve adapter and guiding catheter hub.

Do not manipulate (e.g.,"roll") the 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 **Delivery System Preparation** (9.3.2).

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 chances for dislodging the proximal stent.

Do not expand the stent if it is not properly positioned in the vessel. (See **Stent / System Removal - Precautions** (5.3)

Placement of a stent has the potential to compromise side branch patency.

Do not exceed Rated Burst Pressure (RBP) as indicated on product label. Balloon pressures should be monitored during inflation. Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.

An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. Should **any resistance** be felt **at any time** during withdrawal of the Coronary Stent System, the entire system should be **removed as a single unit**.

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 **any resistance** be felt **at any time** during either lesion access or removal of the Delivery System post-stent implantation, the entire system should be **removed 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

Care must be exercised when **crossing a newly deployed stent** with a coronary guide wire, balloon or Delivery System to avoid disrupting the stent geometry.

5.4.1 MRI Statement

The Guidant MULTI-LINK VISION™ Coronary Stent has been shown to be MRI safe immediately following implantation at field strengths of 1.5 tesla or less, a maximum spatial gradient of 450 gauss/cm, gradient magnetic fields of 6.3 mT/m or less and a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 15 minutes of MR imaging. MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

6.0 ADVERSE EVENTS

6.1 Observed Adverse Events

Observed adverse event experience for the Guidant MULTI-LINK VISION™ Coronary Stent was obtained in the VISION Registry. See Section 7 - **CLINICAL STUDIES** for more complete descriptions of the study design and results.

6.1.1 VISION Registry - *de novo* Lesions

The VISION Registry was a multi-center, non-randomized, prospective study conducted to assess the safety and efficacy of the Guidant MULTI-LINK VISION™ RX Coronary Stent System in native *de novo* coronary artery lesions in 267 patients. The primary endpoint was target vessel failure (TVF) at 180 days defined as a composite of death, Q-Wave Myocardial Infarction (QMI), Non-Q-Wave Myocardial Infarction (Non-QMI), Target Site Revascularization (TSR) or Target Vessel Revascularization (TVR) by Coronary Artery Bypass Graft (CABG) or Percutaneous Coronary Intervention (PCI). Secondary endpoints of MACE and in-hospital TVF at 270 days were also evaluated. These results were compared to results of the 202 *de novo* lesion patients treated with the Guidant MULTI-LINK RX TETRA™ Coronary Stent System in the TETRA Registry.

A total of 297 Guidant MULTI-LINK VISION™ Coronary Stents were implanted in 267 patients. For the 180-day time point, there were three (1.2%) deaths, two (0.8%) Q-Wave MIs, two (0.8%) Non Q-Wave MIs, 13 (5.0%) TSR by PCI, 0 (0.0%) TSR by CABG, one (0.4%) Subacute Thrombosis, three (1.2%) Cerebrovascular Accidents, six (2.3%) Serious Bleeding Events, and four (1.6%) Serious Vascular Events.

There were two (0.8%) device malfunctions reported in the VISION Registry: inability to cross the lesion on the first attempt and inaccurate stent placement. These two device malfunctions did not result in adverse events. There was one stent delivery failure that resulted in the stent being lost in the peripheral system. The patient suffered no adverse events and a subsequent Guidant MULTI-LINK VISION™ Coronary Stent was successfully deployed.

Table 2 summarizes the Principal Adverse Events of patients receiving the Guidant MULTI-LINK VISION™ RX Coronary Stent System at 180 and 270 days, along with those receiving the Guidant MULTI-LINK TETRA™ Coronary Stent System at 180 days.

Table 2: VISION Registry - Principal Adverse Events Through 180 & 270 Days
percent [95% confidence interval] (number)

	180-Day Comparison - *de novo* Registries		270-Day Data
Complication	MULTI-LINK VISION (N = 267)[1]	MULTI-LINK TETRA (N = 202)	MULTI-LINK VISION (N = 267)[1]
Any Adverse Event	**13.2%** [9.3%, 17.9%] (34)	**20.9%** [15.4%, 27.3%] (41)	**20.5%** [15.7%, 25.9%] (53)
Early (In-Hospital)	**5.0%** [2.7%, 8.5%] (13)	**7.9%** [4.6%, 12.5%] (16)	**5.0%** [2.7%, 8.4%] (13)
Out-of-Hospital	**8.5%** [5.4%, 12.6%] (22)	**12.8%** [8.4%, 18.3%] (25)	**15.8%** [11.6%, 20.9%] (41)
Death Total	**1.2%** [0.2%, 3.4%] (3)	**0.5%** [0.0%, 2.8%] (1)	**1.2%** [0.2%, 3.3%] (3)
Early (In-Hospital)	**0.4%** [0.0%, 2.1%] (1)	**0%** [0.0%, 1.8%] (0)	**0.4%** [0.0%, 2.1%] (1)
Out-of-Hospital	**0.8%** [0.1%, 2.8%] (2)	**0.5%** [0.0%, 2.8%] (1)	**0.8%** [0.1%, 2.8%] (2)
QMI Total	**0.8%** [0.1%, 2.8%] (2)	**0%** [0.0%, 1.9%] (0)	**0.8%** [0.1%, 2.8%] (2)
Early (In-Hospital)	**0.4%** [0.0%, 2.1%] (1)	**0%** [0.0%, 1.8%] (0)	**0.4%** [0.0%, 2.1%] (1)
Out-of-Hospital	**0.4%** [0.0%, 2.1%] (1)	**0%** [0.0%, 1.9%] (0)	**0.4%** [0.0%, 2.1%] (1)
Non-Q MI Total	**0.8%** [0.1%, 2.8%] (2)	**2.6%** [0.8%, 5.9%] (5)	**0.8%** [0.1%, 2.8%] (2)
Early (In-Hospital)	**0.8%** [0.1%, 2.8%] (2)	**2.0%** [0.5%, 5.0%] (4)	**0.8%** [0.1%, 2.8%] (2)
Out-of-Hospital	**0%** [0.0%, 1.4%] (0)	**0.5%** [0.0%, 2.8%] (1)	**0%** [0.0%, 1.4%] (0)
TSR CABG Total	**0%** [0.0%, 1.4%] (0)	**1.0%** [0.1%, 3.6%] (2)	**0.4%** [0.0%, 2.1%] (1)
Early (In-Hospital)	**0%** [0.0%, 1.4%] (0)	**0%** [0.0%, 1.8%] (0)	**0%** [0.0%, 1.4%] (0)
Out-of-Hospital	**0%** [0.0%, 1.4%] (0)	**1.0%** [0.1%, 3.6%] (2)	**0.4%** [0.0%, 2.1%] (1)
TSR PCI Total	**5.0%** [2.7%, 8.5%] (13)	**8.7%** [5.1%, 13.5%] (17)	**11.2%** [7.6%, 15.7%] (29)
Early (In-Hospital)	**0.8%** [0.1%, 2.8%] (2)	**0%** [0.0%, 1.8%] (0)	**0.8%** [0.1%, 2.8%] (2)
Out-of-Hospital	**4.7%** [2.4%, 8.0%] (12)	**8.7%** [5.1%, 13.5%] (17)	**10.8%** [7.3%, 15.2%] (28)
*SAT Total	**0.4%** [0.0%, 2.1%] (1)	**0%** [0.0%, 1.9%] (0)	**0.4%** [0.0%, 2.1%] (1)
Early (In-Hospital)	**0.4%** [0.0%, 2.1%] (1)	**0%** [0.0%, 1.8%] (0)	**0.4%** [0.0%, 2.1%] (1)
Out-of-Hospital	**0%** [0.0%, 1.4%] (0)	**0%** [0.0%, 1.9%] (0)	**0%** [0.0%, 1.4%] (0)
*Cerebrovascular Accident Total	**1.2%** [0.2%, 3.4%] (3)	**0.5%** [0.0%, 2.8%] (1)	**1.2%** [0.2%, 3.3%] (3)
Early (In-Hospital)	**0.4%** [0.0%, 2.1%] (1)	**0%** [0.0%, 1.8%] (0)	**0.4%** [0.0%, 2.1%] (1)
Out-of-Hospital	**0.8%** [0.1%, 2.8%] (2)	**0.5%** [0.0%, 2.8%] (1)	**0.8%** [0.1%, 2.8%] (2)
*Bleeding Complications Total	**2.3%** [0.9%, 5.0%] (6)	**3.1%** [1.1%, 6.5%] (6)	**2.7%** [1.1%, 5.5%] (7)
Early (In-Hospital)	**0.8%** [0.1%, 2.8%] (2)	**3.0%** [1.1%, 6.4%] (6)	**0.8%** [0.1%, 2.8%] (2)
Out-of-Hospital	**1.6%** [0.4%, 3.9%] (4)	**0%** [0.0%, 1.9%] (0)	**1.9%** [0.6%, 4.4%] (5)
*Vascular Complications Total	**1.6%** [0.4%, 3.9%] (4)	**4.6%** [2.1%, 8.5%] (9)	**1.9%** [0.6%, 4.4%] (5)
Early (In-Hospital)	**1.2%** [0.2%, 3.4%] (3)	**3.0%** [1.1%, 6.4%] (6)	**1.2%** [0.2%, 3.3%] (3)
Out-of-Hospital	**0.4%** [0.0%, 2.1%] (1)	**1.5%** [0.3%, 4.4%] (3)	**0.8%** [0.1%, 2.8%] (2)
Stent Delivery Failure	**0.4%** [0.0%, 2.1%] (1)	**0.5%** [0.0%, 2.7%] (1)	**0.4%** [0.0%, 2.1%] (1)

[1]268 patients enrolled but patient 306-4002 is excluded due to VISION stent being implanted in SVG, so n = 267.

- *Secondary endpoints were analyzed on per protocol evaluable patients. There were n = 258 patients available at the 180 day f/u time point and there were n = 259 patients available at the 270 day f/u time point.
- ANY Adverse event includes death, Q-Wave MI, Non-Q-Wave MI, TSR CABG, TSR PCI, SAT, cerebrovascular accident, serious bleeding event, and serious vascular event.
- Early (In-Hospital) refers to events during the hospitalization for stent placement. If the patient had a prolonged hospitalization, in-hospitalization was considered to be less than or equal to 7 days post-procedure.
- 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 total patients for that category. Hence, the sum of the in-hospital and out-of hospital rate may not equal the total rate.
- See Table 5 Footnotes for additional VISION Registry definitions.

6.1.2 REVIVE Study - Saphenous Vein Bypass Grafts

Guidant MULTI-LINK DUET™ RX Coronary Stent System
Based on equivalency in *de novo* lesions and the similarities in design and manufacture of the Guidant MULTI-LINK DUET™ Coronary Stent Systems, the following study data demonstrates suitability of the Guidant MULTI-LINK VISION™ Coronary Stent System for use in saphenous vein bypass grafts.

The REVIVE Study was a multi-center, non-randomized, prospective, consecutive enrollment study 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 Study 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. Six (3.8%) 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 summarizes the Principal Adverse Events of patients receiving the Guidant MULTI-LINK DUET™ RX Coronary Stent System in saphenous vein bypass graft lesions (REVIVE Study) through 180-day follow-up.

Table 3: REVIVE Study - Principal Adverse Events Through 180 Days
percent [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	**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	**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	**0.6%** [0.0%, 3.4%] (1)	**0.4%** [0.0%, 2.0%] (1)
CABG Total	**3.8%** [1.4%, 8.0%] (6)	**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	**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	**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	**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 using Exact Clopper-Pearson C.I.
- 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.
- 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.
- See Table 6 Footnotes for additional REVIVE Study definitions.

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

6.1.3 CADILLAC Trial - Acute Myocardial Infarction
Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications

Guidant MULTI-LINK® and Guidant MULTI-LINK DUET™ Coronary Stent System
Based on equivalency in *de novo* lesions and the similarities in design and manufacture of the Guidant MULTI-LINK DUET™ Coronary Stent Systems, the following study data demonstrates suitability of the Guidant MULTI-LINK VISION™ Coronary Stent System for use in acute myocardial infarctions as defined below.

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 $\leq$ 38 mm in length.

Table 4 summarizes the Principal Adverse Events of the CADILLAC Trial at 180 days.

Table 4: CADILLAC Trial - Principal Adverse Events Through 180 days

percent [95% confidence interval] (number/denominator)

	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 Complications *	**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 counts are straight sums across the individual events. All other counts are patient counts, with patients counted only once at each level of summation.
- ANY Adverse Event includes MI (Myocardial Infarction), ischemic TVR(Target Vessel Revascularization) - CABG (Coronary Artery Bypass Graph surgery) and PTCA (Percutaneous Transluminal Coronary Angioplasty), subacute thrombosis, death, bleeding complication, and CVA (Cerebrovascular Accident / Disabling stroke).
- 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.
- 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.
- See Table 7 Footnotes for additional CADILLAC Trial definitions.

* 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:

- 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 / or 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

7.1 VISION Registry - *de novo* Lesions

Purpose: To assess the safety and efficacy of the Guidant MULTI-LINK VISION™ RX Coronary Stent System in reducing target vessel failure in *de novo* native coronary artery lesions.

Conclusions: In selected patients, the VISION Registry demonstrated the 180-day and 270-day safety and efficacy of this stent for the treatment of patients with *de novo* lesions in native coronary arteries.

Design: A prospective, non-randomized, multi-center, global (18 North American, 1 European and 3 Asia-Pacific sites), consecutive enrollment study. Patients were at least 18 years of age, with angina or a positive functional study, undergoing elective, single *de novo* lesion treatment in a native coronary artery. Patients were required to have a target vessel with the following coronary angiographic features: major coronary artery or major branch with a visually estimated stenosis of $\geq$ 50% and $<$ 100%, a reference diameter visually estimated to be $\geq$ 3.0 mm and $\leq$ 4.0 mm, and a lesion length visually estimated to be $\leq$ 25 mm.

The primary endpoint for the VISION Registry was target vessel failure (TVF) at 180 days, defined as a composite of death, Q-Wave MI, Non-Q-Wave MI, TSR, or TVR by CABG or PCI. The primary endpoint was analyzed on an intent-to-treat basis defined as patients who had the investigational device introduced into the body (stent system advanced through distal end of the guiding catheter). Secondary endpoints, including but not limited to angiographic in-stent binary restenosis, TVF and MACE at 270 days, were analyzed on a per-protocol evaluable basis defined as patients who had successful procedures and were available for follow-up.

All patients received the hospital's standard anti-coagulant and anti-platelet regimen for coronary stent implantation. The 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.

Demography: The total population consisted of 268 patients, but analysis was performed on 267 patients because one patient had the Guidant MULTI-LINK VISION™ Coronary Stent implanted in an SVG. Baseline characteristics for the VISION Registry indicated 68.2% were male and ranged in age from 37 to 91 years with an average age of 63.6 ± 10.7 (mean ± SD), 23.2% had diabetes requiring medication, 61.4% had hypertension requiring medication, 23.6% were current smokers, and 63.7% had hyperlipidemia requiring medication. From a clinical perspective, the patient demographics were similar between the VISION and TETRA Registries.

Methods: Clinical or telephone follow-up was collected in-hospital and at 14, 30, 180, 270 and 365 days. 80.9% (216/267) of VISION Registry patients underwent angiographic follow-up at the 180-day clinical visit. Guidant personnel performed data monitoring. The angiographic core lab adjudicated revascularizations by PCI. An independent Clinical Events Committee adjudicated all other primary endpoints.

Results: In the VISION Registry, the 180-day and 270-day TVF rates were 6.7% and 14.7% (respectively); in the TETRA Registry, the 180-day TVF rate was 12.8%. The representative sample of patients from the VISION Registry followed clinically for up to 9 months (270 days) demonstrates that the clinical outcomes achieved with the MULTI-LINK VISION™ CSS are similar to those observed at 180 days in the TETRA Registry. No unanticipated events that might affect the risk analysis were noted in the VISION Registry. Adverse event rates are presented in Table 2.

Table 5 compares the principal effectiveness and safety results of patients treated in the VISION Registry at 180 and 270 days to those treated in the TETRA Registry at 180 days.

Table 5: VISION Registry - Principal Effectiveness and Safety Results Through 180 and 270 Days
percent [95% confidence interval] (number/denominator), or mean ± SD {range} (number)

	VISION Stent – 180 Days (n = 267) [1]	TETRA Stent – 180 Days (n = 202)	VISION Stent – 270 Days (n = 267) [1]
Effectiveness Measures			
Device Success by QCA	100% [98.6%, 100.0%] (267/267)	99.5% [97.3%, 100.0%] (201/202)	100% [98.6%,100.0%] (267/267)
Procedure Success by QCA	98.9% [96.8%, 99.8%] (264/267)	97.5% [94.3%, 99.2%] (197/202)	98.9% [96.8%, 99.8%] (264/267)
Binary Restenosis Rate	15.7% [11.2%, 21.3%] (34/216)	23.6% [17.5%, 30.6%] (41/174)	N/A
Post-Procedure In-Stent %DS	4.9% ± 9.2% (266) {-20.1%, 31.9%} [3.8%, 6.0%]	5.7% ± 8.4% (201) {-43.1%, 28.9%} [4.6%, 6.9%]	N/A
Follow-up In-Stent %DS	29.2% ± 19.2% (216) {-7.4%, 100%} [26.6%, 31.8%]	34.6% ± 22.7% (173) {-9.2%, 98.0%} [31.2%, 38.0%]	N/A
Safety Measures			
In-Hospital MACE Rate	1.5% [0.4%, 3.8%] (4/267)	2.0% [0.5%, 5.0%] (4/202)	1.5% [0.4%, 3.8%] (4/267)
Out-of-hospital MACE Rate	5.0% [2.7%, 8.5%] (13/258)	10.2% [6.3%, 15.3%] (20/196)	11.6% [8.0%, 16.1%] (30/259)
MACE Rate	6.2% [3.6%, 9.9%] (16/258)	12.2% [8.0%, 17.7%] (24/196)	12.7% [8.9%, 17.4%] (33/259)
TVF Rate	6.7% [4.0%, 10.4%] (18/267)	12.8% [8.4%, 18.3%] (25/196)	14.7% [10.6%, 19.6%] (38/259)
Survival	98.8% [96.6%, 99.8%] (255/258)	99.5% [97.2%, 100.0%] (195/196)	98.8% [96.7%, 99.8%] (256/259)
TVF Free (KM)	92.9%	86.4%	85.5%
Target Site Revascularization Free (KM)	94.8%	88.5%	88.4%
Target Vessel Revascularization (not at Target Site) Free (KM)	98.4%	N/A	97.3%
Subacute Thrombosis *	0.4% [0.0%, 2.1%] (1/258)	0% [0.0%, 1.9%] (0/196)	0.4% [0.0%, 2.1%] (1/259)
Bleeding Complications	2.3% [0.9%, 5.0%] (6/258)	3.1% [1.1%, 6.5%] (6/196)	2.7% [1.1%, 5.5%] (7/259)
Vascular Complications	1.6% [0.4%, 3.9%] (4/258)	4.6% [2.1%, 8.5%] (9/196)	1.9% [0.6%, 4.4%] (5/259)
Hospitalization Post-Intervention (days)	1.3 ● 1.0 {0, 10} [1.2, 1.4] (267)	1.3 ± 0.8 {0, 6} [1.2, 1.4] (201)	1.3 ± 1.0 {0, 10} [1.2, 1.4] (267)

- [1] 268 patients enrolled but one patient is excluded because the VISION stent was implanted in an SVG, so n = 267.
- Primary endpoint (180-day TVF) was analyzed on an intent-to-treat basis, n = 267.
- 180-day clinical data was available on 258 patients for the VISION Registry and 196 patients for the TETRA Registry.
- 180-day angiographic data was available on 216 patients for the VISION Registry and 174 patients for the TETRA Registry.
- Secondary endpoints were analyzed on per protocol evaluable patients. There were n = 258 patients available at the 180 day f/u time point and there were n = 259 patients available at the 270 day f/u time point.
- KM = Kaplan-Meier.

* Subacute Thrombosis is based on 30 days.

VISION Registry Definitions

- **QCA** - Quantitative Coronary Angiography.
- **Device Success** - Attainment of final result of < 50% residual stenosis of the target site using the designated treatment device.
- **Procedure Success** - Attainment of final result of < 50% residual stenosis of the target site using the designated treatment device and any other adjunctive device, including additional stents, without death, emergent bypass surgery, or Q-Wave or Non-Q-Wave MI post procedure prior to hospital discharge.
- **Binary restenosis** - ≥ 50% by QCA.
- **% DS** - Percent diameter stenosis by QCA.
- **In-Hospital MACE** - Any MACE occurring prior to hospital discharge.

- **Out-of-Hospital MACE** - Any MACE occurring from hospital discharge through 180-day clinical follow-up.
- **Major Adverse Cardiac Event (MACE)** – The composite of death, Q-Wave MI, Non-Q-Wave MI and Target Site Revascularization (TSR) by Coronary Artery Bypass Surgery (CABG) or Percutaneous Coronary Intervention (PCI).
- **Target Vessel Failure (TVF)** – The composite of death, Q-Wave MI, Non-Q-Wave MI, Target Site Revascularization (TSR) or Target Vessel Revascularization (TVR) by Coronary Artery Bypass Graft Surgery (CABG) or Percutaneous Coronary Intervention (PCI).
- **Target Site Revascularization (TSR)** – Repeat Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Graft (CABG) surgery.
- **Subacute Thrombosis (SAT)** - Any cardiac death < 30 days. Any subacute (outside of cath lab) closure requiring revascularization of the target site < 30 days with presence of thrombus at the target site, any total closure indicated by Quantitative Coronary Angiography (QCA) < 30 days.
- **Bleeding Complication** – Blood loss necessitating a transfusion.
- **Vascular Complication** – Any hematoma > 5 cm, arteriovenous fistula, pseudoaneurysm, retroperitoneal bleed, peripheral nerve disorder or surgical repair.
- **Q-Wave Myocardial Infarction (QMI)** – The development of new abnormal Q-Waves not present on the patient's baseline ECG – through blinded evaluation by the ECG Core Laboratory – in association with CK enzyme elevation of three times upper normal limit and presence of CK-MB.
- **Non Q-Wave Myocardial Infraction (Non QMI)** – CK enzyme elevations by more than three time the upper limit of normal and presence of CK-MB.
- **CABG** – Coronary Artery Bypass Graft surgery.
- **PCI** – Percutaneous Coronary Intervention.
- **Cerebrovascular Accident (CVA)** – Acute, new neurologic deficit lasting > 24 hours affecting daily activities, or resulting in death, classified by a physician as a stroke.
- **Stent Delivery Failure** – Inability to deliver the stent to the intended target lesion.

7.2 REVIVE Study – Saphenous Vein Bypass Grafts
Guidant MULTI-LINK DUET™ RX Coronary Stent System

Based on equivalency in *de novo* lesions and the similarities in design and manufacture of the Guidant MULTI-LINK DUET™ Coronary Stent Systems, the following study data demonstrates suitability of the Guidant MULTI-LINK VISION™ Coronary Stent System for use in saphenous vein bypass grafts.

Purpose: To establish the safety and efficacy of stenting in saphenous vein bypass grafts (SVG).

Conclusions: The primary endpoint of Target Vessel Failure (TVF) rate at six months post-procedure for the 162 intent-to-treat patients was 19.8%, which is similar to the TVF rate of 20.0% for the 160 evaluable patients only. The upper CL of the TVF rate (25.6%) is less than 33%, therefore the alternative hypothesis would be accepted based on intent-to-treat patients.

Design: A prospective, non-randomized, multi-center, consecutive enrollment registry conducted in 22 US centers. The primary endpoint of 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.

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.

All patients received the hospital's standard anti-coagulant and anti-platelet regimen for coronary stent implantation. The 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.

Demography: The total population consisted of 162 patients, 160 of whom were evaluable; 82.5% were male ranging in age from 41 to 88 years with an average of 67.7 ± 9.3 (mean ± SD). Current cigarette use, diabetes, hypertension and hyperlipidemia requiring medication were 11.9%, 25.6%, 58.8% and 67.5% respectively.

Methods: Using a specific monitoring regimen, data were collected at the index procedure, 2 weeks, 1 month and 6 months post-index procedure. A Clinical Events Committee (CEC) adjudicated all TVF and major adverse cardiac event (MACE) endpoints.

Results: The device success and procedure success rates for the Guidant MULTI-LINK DUET™ RX Coronary Stent System were 97.2% and 89.2%, respectively. No unanticipated events that might affect the risk analysis were noted in the REVIVE Study. Adverse event rates are presented in Table 3.

Table 6 summarizes the principal effectiveness and safety results of patients treated in the REVIVE Study.

Table 6: REVIVE Study - Principal Effectiveness and Safety Results Through 180 Days
percent [95% confidence interval] (number/denominator), or mean ± SD {range} (number)

	Guidant MULTI-LINK DUET™ SVG (n = 160)	Guidant MULTI-LINK DUET™ *de novo* (n = 270)
Effectiveness Measures		
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 (MACE)	**8.1%** [4.4%, 13.5%] (13/160)	**1.9%** [0.6%, 4.3%] (5/270)
Out-of Hospital Clinical Event (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	**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)

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

REVIVE Study 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** – < 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 Complication** – Any hematoma > 5 cm, arteriovenous fistula, pseudoaneurysm, retroperitoneal bleed, peripheral nerve disorder or surgical repair.
- **Non-Q-Wave MI** – Non Q-Wave Myocardial Infarction, CK enzyme elevations by more than three time the upper limit of normal and presence of CK-MB.
- **Q-Wave MI** – Q-Wave Myocardial Infarction (The development of new abnormal Q-Waves not present on the patient's baseline ECG – through blinded evaluation by the ECG Core Laboratory – in association with CK enzyme elevation of three times upper normal limit and presence of CK-MB.)
- **CABG** – Coronary Artery Bypass Graph surgery.
- **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.
- **Cerebrovascular Accident / CVA** – Acute, new neurologic deficit lasting > 24 hours affecting daily activities, or resulting in death, classified by a physician as a stoke.
- **Stent Delivery Failure** – Inability to deliver the stent to the intended target lesion.

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

Based on equivalency in *de novo* lesions and the similarities in design and manufacture of the Guidant MULTI-LINK DUET™ Coronary Stent Systems, the following study data demonstrates suitability of the Guidant MULTI-LINK VISION™ Coronary Stent System for use in acute myocardial infarctions as defined below.

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.

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.

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.

Using a primary endpoint of 180 days, the MACE elements included death, disabling stroke, reinfarction, and ischemic Target Vessel Revascularization (TVR). Subacute Thrombosis (SAT) and bleeding complications were also compared.

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. The angiographic core lab determined angiographic outcomes. A clinical events committee performed concurrent reviews and adjudicated all MACE.

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. No unanticipated events that might affect the risk analysis were noted in the CADILLAC Trial. Adverse event rates are presented in Table 4.

Table 7 summarizes the principal effectiveness and safety results of patients treated in the CADILLAC Trial at 180 days. Figure 1 provides the cumulative MACE rates to 365 days.

Table 7: CADILLAC Trial - 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 Alone (n = 518)	PTCA plus Abciximab (n = 528)	Stent Alone (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 Complications **	**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)

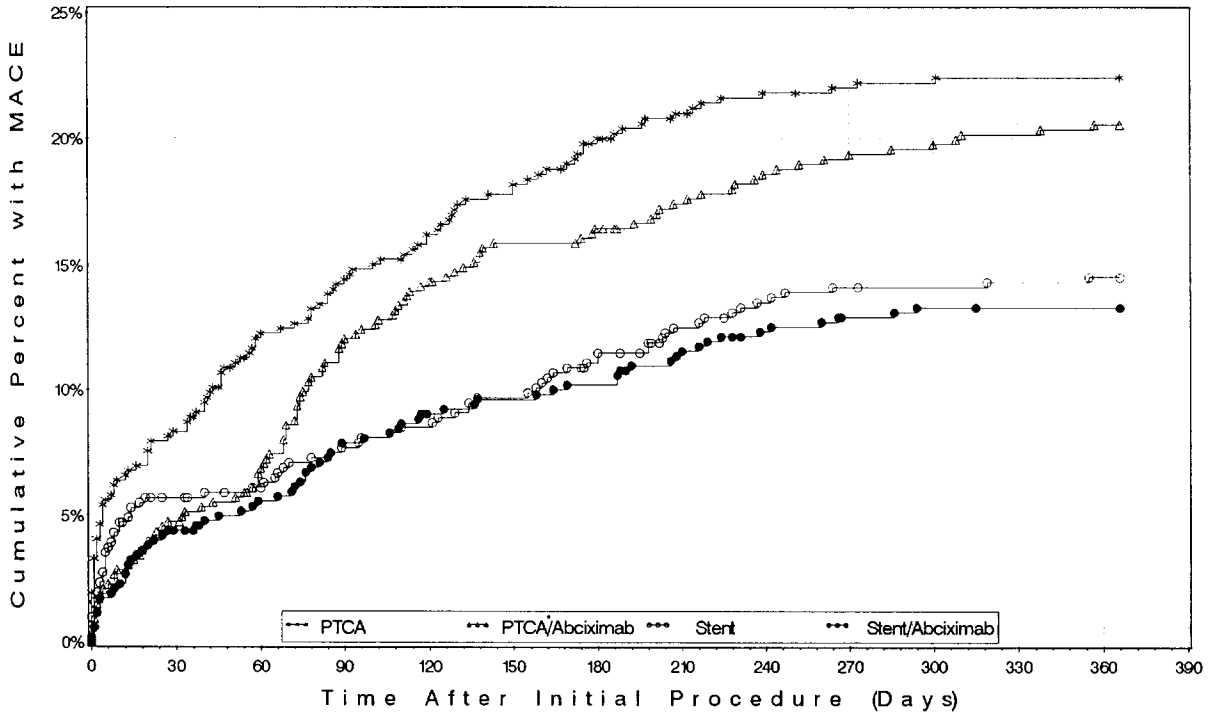
CADILLAC Trial Definitions

- **QCA** – Quantitative Coronary Angiography.
- **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.
- **Clinical Procedure success** – Lesion Success without death; emergency bypass surgery, repeat PTCA of the target vessel or re-infarction (QMI or non-QMI) within seven days of the procedure.
- **MLD** – Minimal Lumen Diameter.
- **% DS** – Percent diameter stenosis by QCA.
- **Binary restenosis** – ≥ 50% by quantitative coronary analysis.

- **Target Vessel Revascularization (TVR)** – Bypass surgery or repeat angioplasty precipitated by an ischemic event (angina or a positive exercise test) (each event will be adjudicated by the CEAC).
- **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.
- **In-Hospital MACE** – Any MACE occurring prior to hospital discharge.
- **Out-of-Hospital MACE** – Any MACE occurring from hospital discharge through 180-day clinical follow-up.
- **MACE** - death, repeat Myocardial Infarction (Q-Wave or Non-Q-Wave MI), ischemia-driven TVR including Coronary Artery Bypass surgery (CABG), Percutaneous Intervention (PTCA with or without stent) and non-fatal disabling stroke.
- **Bleeding Complications** – Blood loss necessitating a transfusion, may include a gastrointestinal (GI) bleed, and hemoglobin drop of > 5 g/dl) documented on the Hemorrhagic Event CRF.
- **Subacute Thrombosis (SAT)** – Any cardiac death < 30 days. Any subacute (outside of cath lab) closure requiring revascularization of the target site < 30 days with presence of thrombus at the target site, any total closure indicated by Quantitative Coronary Angiography (QCA) < 30 days.
- **Disabling Stroke / CVA** – Acute, new neurologic deficit lasting > 24 hours affecting daily activities, or resulting in death, classified by a physician as a stroke.

* 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 VISION™ RX or Guidant MULTI-LINK VISION™ OTW Coronary Stent Systems. Patient selection factors to be assessed should include a judgment regarding risk of anti-platelet therapy.

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 univariate predictors of angiographic in-stent binary restenosis with $p < 0.05$ included post procedure in-stent Minimal Lumen Diameter (MLD), post procedure Reference Vessel Diameter (RVD) and pre-procedure RVD. Lesion length was close with a p value of 0.0954. The multivariate predictors of angiographic in-stent binary restenosis with $p < 0.05$ included post-procedure in-stent MLD.

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 VISION™ Coronary 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 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.

9.0 CLINICIAN USE INFORMATION

9.1 Inspection Prior to Use

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

9.2 Materials Required

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

9.3 Preparation

9.3.1 Guide Wire Lumen Flush

1. Remove the protective cover from the tip.
2. For use with the Guidant MULTI-LINK VISION™ RX 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 VISION™ OTW Coronary Stent System, flush the guide wire lumen with HepNS until fluid exits **the distal tip**.

9.3.2 Delivery System Preparation

1. Prepare an inflation device / syringe with diluted contrast medium.
2. Attach an inflation device / syringe to stopcock; attach it to the inflation port.
3. With the 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 the 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 the stopcock.
8. Open the stopcock to the Delivery System.
9. Leave on neutral.

9.4 Delivery Procedure

1. Prepare vascular access site according to standard practice.
2. Pre-dilate the lesion with a PTCA catheter. (In saphenous vein bypass graft lesions, pre-dilatation may be performed at the discretion of the operator.)
3. Maintain neutral pressure on inflation device. Open rotating hemostatic valve as widely as possible.
4. Backload Delivery System onto proximal portion of guide wire while maintaining guide wire position across target lesion.
5. Advance Delivery System over guide wire to target lesion. Utilize radiopaque balloon markers to position stent across lesion; perform angiography to confirm stent position.

   Note: Should **any resistance** be felt **at any time** during either lesion access or removal of Delivery System post-stent implantation, the entire system should be **removed as a single unit**. See *Stent / System Removal - Precautions* for specific Delivery System removal instructions.

6. Tighten the rotating hemostatic valve. Stent is now ready to be deployed.

9.5 Deployment Procedure

1. **Caution:** Refer to the product label and the compliance chart in 9.6 below for *in vitro* stent inner diameter, nominal pressure and RBP. Deploy stent slowly by pressurizing Delivery System in 2 atm increments, every 5 seconds, until 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.**

   FURTHER EXPANSION OF THE DEPLOYED STENT:

   If the deployed stent size is still inadequate with respect to reference vessel diameter, a larger balloon may be used to further expand the stent. If the initial angiographic appearance is sub-optimal, the stent may be further expanded using a low profile, high pressure, non-compliant balloon dilatation catheter. If this is required, the stented segment should be carefully recrossed with a prolapsed guide wire to avoid disrupting the stent geometry. Deployed stents should not be left under-dilated.

   Caution: Do not dilate the stent beyond the following limits.

Nominal Stent Diameter	**Dilatation Limit**
3.0 mm	**3.75 mm**
3.5 to 4.0 mm	**4.5 mm**

2. Deflate balloon by pulling negative on inflation device for 30 seconds.

9.6 *In Vitro* Information

Table 8 Typical MULTI-LINK VISION™ Stent & Balloon Compliance

Stent Diameter (mm)	Inflation Pressure (atm)									
	9	10	11	12	13	14	15	16	17	18
3.00	3.00	3.05	3.11	3.17	3.21	3.25	3.29	3.33	3.37	3.41
3.50	3.50	3.58	3.65	3.71	3.76	3.81	3.86	3.90	3.94	3.99
4.00	4.00	4.06	4.13	4.19	4.24	4.30	4.35	4.40	4.43	4.48
	Nominal							RBP*		

***DO NOT EXCEED RBP.** The Compliance Data are based on *in vitro* bench testing at 37°C.

9.7 Removal Procedure

1. Ensure Delivery System is fully deflated.
2. Fully open rotating hemostatic valve.
3. While maintaining guide wire position and negative pressure on inflation device, withdraw Delivery System.

   Note: Should **any resistance** be felt **at any time** during either lesion access or removal of Delivery System post-stent implantation, the entire system should be **removed 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 stented area.

   If post dilatation is necessary, ensure final stent diameter matches reference vessel diameter. ASSURE THAT THE STENT IS NOT UNDERDILATED.

10.0 PATIENT INFORMATION

In addition to this Instructions for Use booklet, the Guidant MULTI-LINK VISION™ RX and Guidant MULTI-LINK VISION™ OTW Coronary Stent System are packaged with additional patient specific information, which includes:

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

- A Patient's Guide to Stent Implantation, which includes information on Guidant Corporation, the implant procedure, and the MULTI-LINK VISION™ Coronary Stent System.

11.0 PATENTS

This product and its use are protected by one or more of the following patents. United States, 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; 6,309,412; 6,369,355; 6,419,693; 6,432,133; 6,482,166; 6,485,511; 6,488,655; 6,488,694; RE 33,166; RE 34,564. Other U.S. patents pending. Foreign patents issued and pending.

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