
MULTI-LINK MINI VISION® Coronary Stent Systems
Information for Prescribers

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1.0 DEVICE DESCRIPTION

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

- A pre-mounted L-605 cobalt chromium alloy (CoCr) (major elements include cobalt, chromium, tungsten, nickel) 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 guide catheter. Working catheter length is 143 cm.
- For the MULTI-LINK MINI VISION RX Coronary Stent System only, a shaft color change denotes the guide wire exit notch.

Table 1. *in vitro* Device Specifications

Stent Diameter (mm)	Stent Length (mm)	*Minimum Guiding Catheter Compatibility ID 5F (0.056" / 1.42 mm)	** <i>in vitro</i> Stent Nominal Pressure (atm)	Rated Burst Pressure – RBP (atm)	Stent Free % Area
2.0	8, 12, 15, 18, 23, 28	5F	8	16	81
2.25	8, 12, 15, 18, 23, 28	5F	9	16	83
2.5	8, 12, 15, 18, 23, 28	5F	9	16	85

*See individual manufacturer specifications for (F) equivalent.

Assure full deployment of the stent (See **Clinician Use Information – Deployment Procedure [9.0]). 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) MULTI-LINK MINI VISION Coronary Stent System, One (1) Protective sheath, One (1) Flushing Tool (for the MULTI-LINK MINI VISION RX System)

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

3.0 INDICATIONS

The MULTI-LINK MINI VISION RX and MULTI-LINK MINI VISION OTW Coronary Stent Systems are indicated for improving coronary luminal diameter in patients with abrupt or threatened abrupt closure with failed interventional therapy of *de novo* and restenotic native coronary artery lesions (length \leq 25 mm) with reference vessel diameters from 2.0 mm to 2.5 mm.

4.0 CONTRAINDICATIONS

The MULTI-LINK MINI VISION Coronary Stent Systems are contraindicated for use in:

- Patients in whom antiplatelet and / or anticoagulant 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** [8.1].)

WARNINGS

Long term outcome for this permanent implant is unknown at present.

- 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 CoCr alloy (including the major elements cobalt, chromium, tungsten, nickel) 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 (MULTI-LINK VISION® Coronary Stent) in combination with a 316L stainless steel alloy stent (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 the stent from its delivery system** as removal may damage the stent and / or lead to stent embolization. Stent system is intended to perform together 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 recommended balloon inflation medium. Never 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**.
- 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, stent the distal lesion prior to stenting 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** [5.3].)
- Placement of a stent has the potential to compromise side branch patency.
- **Do not exceed the Rated Burst Pressure as indicated on the product label.** Monitor balloon pressures 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

When **crossing a newly deployed stent** with a guide wire, balloon or delivery system, exercise care to avoid disrupting the stent geometry.

5.4.1 MRI (Magnetic Resonance Imaging) Statement

The MULTI-LINK MINI VISION stent has been shown in non-clinical testing to be MRI safe immediately following implantation. **MRI test conditions used to evaluate this stent were: for magnetic field interactions, a static magnetic field strength of 3 tesla with a maximum spatial gradient magnetic field of 3.3 tesla/meter; for MRI-related heating, a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging.** While a single stent produced a temperature rise of less than 0.6°C and should not migrate under these conditions, the response of overlapping stents or stents with fractured struts is unknown. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3 tesla. MR image 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 MINI VISION Coronary Stent was obtained in the VISION SVS Registry. See **CLINICAL STUDIES** (7.0) for more complete descriptions of the study design and results.

6.1.1 *VISION SVS (Small Vessel Stent) Registry – Abrupt or Threatened Abrupt Closure*

The VISION SVS Registry was a prospective, non-randomized, multi-center, consecutive enrollment registry for the evaluation of the Guidant MULTI-LINK MINI VISION RX Coronary Stent System (CSS) in the treatment of patients with abrupt or threatened abrupt closure (ATC) of *de novo* or restenotic lesions in native coronary arteries or arterial bypass graft conduits.

The primary endpoint was the measure of Target Vessel Failure (TVF) at 14 days (defined as the composite of death, myocardial infarction (MI), revascularization to the target site or target vessel).

The secondary endpoints included acute success (device success and procedural success); ischemic, hemorrhagic and vascular complications; Major Adverse Cardiac Event (MACE) rate defined as the composite of death, MI and target site revascularization (TSR) by coronary artery bypass surgery (CABG) or percutaneous coronary intervention (PCI) in-hospital and at 14 days, 30 days, 180 days, 270 days and 365 days; and, TVF rate in-hospital and at 30 days, 180 days, 270 days and 365 days.

A total of 77 Guidant MULTI-LINK MINI VISION Coronary Stents were implanted in 75 patients.

Table 2 summarizes the Principal Adverse Events Through 14 Days and Table 3 summarizes the Principal Adverse Events Through 180 Days.

Results of the VISION SVS Registry were compared descriptively to the results of the PIXEL Registry. The VISION SVS Registry was not powered to detect differences between the study endpoints. No statistical inferential tests were applied to the comparisons. The sample size of 75 patients was not based on statistical hypothesis testing. The primary and secondary endpoints were analyzed on an intent-to-treat basis at 14-day follow-up.

VISION SVS Registry
Table 2. Principal Adverse Events through 14 Days
Comparison of MULTI-LINK MINI VISION vs. MULTI-LINK PIXEL® CSS

Complication	MULTI-LINK MINI VISION (N=75)	MULTI-LINK PIXEL (N=150)
Any Adverse Event	4.0% [0.8%, 11.2%] (3)	6.7% [3.2%, 11.9%] (10)
Early (In-Hospital)	2.7% [0.3%, 9.3%] (2)	6.0% [2.8%, 11.1%] (9)
Out-of-Hospital	1.3% [0.0%, 7.2%] (1)	1.3% [0.2%, 4.7%] (2)
Non-Q-Wave MI Total	0.0% [0.0%, 4.8%] (0)	0.7% [0.0%, 3.7%] (1)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	0.7% [0.0%, 3.7%] (1)
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Q-Wave MI Total	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
TSR CABG Total	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
TSR PCI Total	0.0% [0.0%, 4.8%] (0)	*
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	*
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	*
Subacute Thrombosis Total	0.0% [0.0%, 4.8%] (0)	0.7% [0.0%, 3.7%] (1)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	0.7% [0.0%, 3.7%] (1)
Death Total	1.3% [0.0%, 7.2%] (1)	0.0% [0.0%, 2.4%] (0)
Early (In-Hospital)	1.3% [0.0%, 7.2%] (1)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Bleeding Complications Total	2.7% [0.3%, 9.3%] (2)	3.3% [1.1%, 7.6%] (5)
Early (In-Hospital)	2.7% [0.3%, 9.3%] (2)	*
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	*
Vascular Complications Total	1.3% [0.0%, 7.2%] (1)	2.7% [0.7%, 6.7%] (4)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	*
Out-of-Hospital	1.3% [0.0%, 7.2%] (1)	*
Cerebrovascular Accident Total	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	*
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	*
Stent Delivery Failure	2.7% [0.3%, 9.3%] (2)	2.7% [0.7%, 6.7%] (4)

* Data was not analyzed at this time point in the PIXEL Registry Clinical report.

- Early (In-Hospital) was considered to be less than or equal to 7 days if the patient had a prolonged hospitalization.
- 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.
- Any adverse event includes death, Q-Wave MI, non-Q-Wave MI, TSR PCI, TSR CABG, subacute thrombosis, bleeding complications, vascular complications, and CVA.

VISION SVS Registry
Table 3. Principal Adverse Events through 180 Days
Comparison of MULTI-LINK MINI VISION vs. MULTI-LINK PIXEL CSS

Complication	MULTI-LINK MINI VISION (N=75)	MULTI-LINK PIXEL (N=150)
Any Adverse Event	17.3% [9.6%, 27.8%] (13)	16.3% [10.7%, 23.3%] (24)
Early (In-Hospital)	2.7% [0.3%, 9.3%] (2)	5.3% [2.3%, 10.2%] (8)
Out-of-Hospital	14.7% [7.6%, 24.7%] (11)	10.9% [6.4%, 17.1%] (16)
Q-Wave MI Total	0.0% [0.0%, 4.8%] (0)	0.7% [0.0%, 3.7%] (1)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	0.7% [0.0%, 3.7%] (1)
Non-Q-Wave MI Total	1.3% [0.0%, 7.2%] (1)	3.4% [1.1%, 7.8%] (5)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	1.3% [0.0%, 7.2%] (1)	3.4% [1.1%, 7.8%] (5)
TSR CABG Total	1.3% [0.0%, 7.2%] (1)	3.4% [1.1%, 7.8%] (5)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	1.3% [0.0%, 7.2%] (1)	3.4% [1.1%, 7.8%] (5)
TSR PCI Total	8.0% [3.0%, 16.6%] (6)	*
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	*
Out-of-Hospital	8.0% [3.0%, 16.6%] (6)	*
Subacute Thrombosis Total	0.0% [0.0%, 4.8%] (0)	0.7% [0.0%, 3.7%] (1)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	0.7% [0.0%, 3.7%] (1)
Death Total	1.3% [0.0%, 7.2%] (1)	0.0% [0.0%, 2.4%] (0)
Early (In-Hospital)	1.3% [0.0%, 7.2%] (1)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	0.0% [0.0%, 2.4%] (0)
Bleeding Complications Total	4.0% [0.8%, 11.2%] (3)	4.8% [1.9%, 9.6%] (7)
Early (In-Hospital)	2.7% [0.3%, 9.3%] (2)	*
Out-of-Hospital	1.3% [0.0%, 7.2%] (1)	*
Vascular Complications Total	2.7% [0.3%, 9.3%] (2)	2.7% [0.7%, 6.8%] (4)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	*
Out-of-Hospital	2.7% [0.3%, 9.3%] (2)	*
Cerebrovascular Accident Total	0.0% [0.0%, 4.8%] (0)	0.7% [0.0%, 3.7%] (1)
Early (In-Hospital)	0.0% [0.0%, 4.8%] (0)	*
Out-of-Hospital	0.0% [0.0%, 4.8%] (0)	*
Stent Delivery Failure	2.7% [0.3%, 9.3%] (2)	3.3% [1.1%, 7.6%] (5)

* Data was not analyzed at this time point in the PIXEL Registry Clinical report.

- Early (In-Hospital) was considered to be less than or equal to 7 days if the patient had a prolonged hospitalization.
- 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.
- Any adverse event includes death, Q-Wave MI, non-Q-Wave MI, TSR CABG, TSR PCI, subacute thrombosis, bleeding complications, vascular complications, and CVA.

6.2 Potential Adverse Events

Adverse events may be associated with the use of a coronary stent in native coronary arteries:

- Acute myocardial infarction
- Allergic reaction to contrast
- Arterial perforation
- Arterial rupture
- Arteriovenous fistula
- Cardiac arrhythmias
- Bleeding complications (including transfusions)
- Coronary spasm
- Death
- Dissection of the coronary artery
- Drug reaction to antiplatelet agent
- Emergency or non-emergent coronary artery bypass graft surgery
- Entry site complications
- Hypotension / hypertension
- Infection
- Injury to the coronary artery
- Ischemia
- Pseudoaneurysm
- Restenosis of the stented segment
- Stent embolization
- Stent thrombosis / emboli
- Stroke / cerebrovascular accident
- Total occlusion of the coronary artery
- Unstable angina pectoris
- Vascular complications

7.0 CLINICAL STUDIES

7.1 VISION SVS (Small Vessel Stent) Registry – Abrupt or Threatened Abrupt Closure

Purpose: To demonstrate clinical safety and efficacy of the Guidant MULTI-LINK MINI VISION RX Coronary Stent System (CSS) when used to treat patients with abrupt or threatened abrupt closure (ATC) of *de novo* or restenotic lesions in native coronary arteries or arterial bypass graft conduits.

Conclusions: The Guidant MULTI-LINK MINI VISION Coronary Stent System represents the first cobalt chromium stent fabricated by Guidant for small vessels (2.0 mm – 2.5 mm) and this study represented the first human use of these stent sizes. The descriptive comparison of results through 180-day follow-up between the VISION SVS Registry and the PIXEL Registry supported the long-term safety and efficacy of the Guidant MULTI-LINK MINI VISION CSS for the treatment of patients with ATC of *de novo* or restenotic lesions in native coronary arteries or arterial bypass graft conduits.

Design: A prospective, non-randomized, multi-center, consecutive enrollment registry at 11 United States sites where a total of 75 patients were enrolled presenting with abrupt or threatened abrupt closure in a *de novo* or restenotic lesion in a native coronary artery or arterial bypass graft conduit 2.0 mm to 2.5 mm in diameter and \leq 25 mm in length.

Demography: The study population consisted of male and female patients, at least 18 years of age, who satisfied the clinical and angiographic criteria and developed ATC of a *de novo* or restenotic lesion. Restenotic lesions had to be the result of prior balloon angioplasty, not prior stenting. To meet the ATC criteria at time of enrollment, the patient must have had two or more of the following: angina or anginal equivalent symptoms; ischemic electrocardiographic changes; diameter stenosis \geq 50%; NHLBI Type B or C dissection with dissection length $>$ 5 mm and \leq 25 mm; NHLBI Type D, E, or F dissection length \leq 25 mm or TIMI 0-2 flow due primarily to mechanical obstruction of the treated site.

Methods: Clinical or telephone follow-up was collected In-Hospital and at 14, 30, 180, 270 and 365 days. Clinical follow-up occurred at 180 days \pm 14 days and there were no patients lost to follow-up at the 180-day time point. The Clinical Events Committee (CEC) adjudicated primary endpoint events except target site revascularization (TSR) by PCI and target vessel revascularization (TVR) by PCI. These events were adjudicated by the angiographic core lab. Participating investigators were not included in the CEC.

Results: In the VISION SVS Registry, the 14-day target vessel failure (TVF) rate (primary endpoint) was 2.7% (2/75) as shown in Table 4. At 180 days, the observed results of the VISION SVS Registry compared favorably to the results of the PIXEL Registry. The TVF rates in the VISION SVS and PIXEL Registries were 14.7% and 13.6%, respectively, as shown in Table 5. While the study was not powered to detect statistical significance, the observed 180-day safety and efficacy data appear to be similar between the two registries.

VISION SVS Registry

Table 4. Principal Effectiveness and Safety Results through 14 Days

Effectiveness Measures	MULTI-LINK MINI VISION (N=75)
Device Success by QCA [95% Confidence Interval]	98.7% (74 / 75) [92.8, 100]
Procedure Success by QCA [95% Confidence Interval]	97.3% (73 / 75) [90.7, 99.7]
In-Hospital MACE Rate [95% Confidence Interval]	1.3% (1 / 75) [0.0, 7.2]
Out-of-Hospital MACE Rate [95% Confidence Interval]	0.0% (0 / 75) [0.0, 4.8]
Bleeding Complications [95% Confidence Interval]	2.7% (2 / 75) [0.3, 9.3]
Vascular Complications [95% Confidence Interval]	1.3% (1 / 75) [0.0, 7.2]
Subacute Thrombosis [95% Confidence Interval]	0.0% (0 / 75) [0.0, 4.8]
Survival Rate [95% Confidence Interval]	98.7% (74 / 75) [92.8, 100]
MACE Rate [95% Confidence Interval]	1.3% (1 / 75) [0.0, 7.2]
TVF Rate [95% Confidence Interval]	2.7% (2 / 75) [0.3, 9.3]
TSR Rate [95% Confidence Interval]	0.0% (0 / 75) [0.0, 4.8]
Length of Hospitalization Post-Intervention (days)	
Mean \pm SD(N)	1.2 \pm 0.7 (75)
Range (min, max)	(0, 5)
[95% Confidence Interval]	[1.0, 1.3]

Data was not analyzed at this time point in the PIXEL Registry Clinical report.

VISION SVS Registry

**Table 5. Principal Effectiveness and Safety Results through 180 Days
Comparison of MULTI-LINK MINI VISION vs. MULTI-LINK PIXEL CSS**

Effectiveness Measures	MULTI-LINK MINI VISION (N=75)	MULTI-LINK PIXEL (N=150)
Device Success by QCA [95% Confidence Interval]	98.7% (74 / 75) [92.8, 100]	97.3% (143 / 147) [93.2, 99.3]
Procedure Success by QCA [95% Confidence Interval]	97.3% (73 / 75) [90.7, 99.7]	100% (147 / 147) [97.5, 100.0]
In-Hospital MACE Rate [95% Confidence Interval]	1.3% (1 / 75) [0.0, 7.2]	0.0% (0 / 150) [0.0, 3.3]
Out-of-Hospital MACE Rate [95% Confidence Interval]	10.7% (8 / 75) [4.7, 19.9]	10.2% (15 / 147) [5.8, 16.4]
Bleeding Complications [95% Confidence Interval]	4.0% (3 / 75) [0.8, 11.2]	4.8% (7 / 147) [1.9, 9.7]
Vascular Complications [95% Confidence Interval]	2.7% (2 / 75) [0.3, 9.3]	2.7% (4 / 147) [0.7, 7.0]
Subacute Thrombosis [95% Confidence Interval]	0.0% (0 / 75) [0.0, 4.8]	0.7% (1 / 150) [0.0, 4.1]
Survival Rate [95% Confidence Interval]	98.7% (74 / 75) [92.8, 100]	*
TVF Rate [95% Confidence Interval]	14.7% (11 / 75) [7.6, 24.7]	13.6% (20 / 147) [8.5, 20.3]
TSR Rate [95% Confidence Interval]	9.3% (7 / 75) [3.8, 18.3]	8.8% (13 / 147) [4.8, 14.8]
Length of Hospitalization Post-Intervention (days)		
Mean ±SD (N)	1.2 ±0.7 (75)	1.5 ±2.0 (150)
Range (min, max)	(0, 5)	(0, 16)
[95% Confidence Interval]	[1.0, 1.3]	[1.2, 1.8]

* Data was not analyzed at this time point in the PIXEL Registry Clinical report.

VISION SVS Registry Definitions:

Acute Myocardial Infarction

A positive diagnosis of myocardial infarction was made when one of the following criteria was met:

- Q-wave MI – the development of new abnormal Q-waves not present on the patient's baseline ECG in association with CK enzyme elevation of three times upper normal limit and presence of CK-MB.
- Non-Q-wave MI – CK enzyme elevations by more than three times the upper limit of normal and presence of CK-MB.

Abrupt or Threatened Abrupt Closure (ATC)

Failure of an interventional procedure resulting in an occlusive dissection, that if left untreated may result in an acute myocardial infarction or the need for coronary artery bypass surgery of the treated vessel.

Acute Success

Acute Success is measured by assessing the rates of Device Success and Procedural Success:

- 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.

Cerebrovascular Accident (CVA)

Acute, new neurologic deficit lasting > 24 hours affecting daily activities, or resulting in death, classified by a physician as a stroke.

Hemorrhagic (Bleeding) Complications

These may include hematoma requiring treatment (surgical repair, transfusion), any bleed requiring transfusion or surgical repair, retroperitoneal bleed, GI bleed. The occurrence of any peri or post-procedural hemorrhagic event will be carefully documented and recorded on the Adverse Event Case Report Form.

In-Hospital

Seven days post index procedure for patients not yet discharged.

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).

QCA – Quantitative Coronary Angiography

Subacute Thrombosis (SAT)

Any cardiac death < 30 days. Any subacute (outside of cath lab) closure requiring revascularization of the target site < 30 days, any total closure indicated by Quantitative Coronary Angiography (QCA) < 30 days, with the presence of thrombus at the target site.

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 surgery (CABG) or percutaneous coronary intervention (PCI).

Target Site Revascularization (TSR)

Repeat PCI or CABG to the target site.

Target Vessel Revascularization (TVR)

Repeat PCI or CABG to the target vessel.

Vascular Complications

These may include arteriovenous fistula, pseudoaneurysm, peripheral nerve disorder, peripheral ischemia, thromboemboli, air emboli, pulmonary emboli, any vascular event requiring transfusion or surgical repair. The occurrence of any peri or post-procedural vascular event will be carefully documented and recorded on the Adverse Event Case Report Form.

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 MULTI-LINK MINI VISION CSS. Patient selection factors to be assessed should include a judgment regarding risk of antiplatelet therapy. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

Premorbid conditions that increase the risk of binary in-stent restenosis (diabetes mellitus and tobacco use) should be reviewed.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 2.0 mm, intra-procedural thrombus, or poor distal runoff, dissection following stent implantation, and / or cessation of antiplatelet / antithrombotic therapy 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 MULTI-LINK MINI VISION Coronary Stent have not been established in:

- Patients with **unresolved vessel thrombus** at the lesion site.
- Patients with coronary artery **reference vessel diameter < 2.0 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 MULTI-LINK MINI VISION CSS, 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 OD) 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

- | |
|---|
| <ol style="list-style-type: none">1. Remove protective cover from tip.2. <ul style="list-style-type: none">• For use with the MULTI-LINK MINI VISION RX Coronary Stent System, flush guide wire lumen with HepNS until fluid exits the guide wire exit notch.• For use with the MULTI-LINK MINI VISION OTW Coronary Stent System, flush 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.
3. Maintain neutral pressure on inflation device. Open rotating hemostatic valve as widely as possible.
4. Back load 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** (5.3) for specific delivery system removal instructions.

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

9.5 Deployment Procedure

CAUTION: Refer to the product label for *in vitro* stent inner diameter, nominal pressure and RBP.

1. 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.

<u>Nominal Stent Diameter</u>	<u>Dilatation Limit</u>
2.0 mm to 2.5 mm	3.25 mm

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

9.6 Stent Removal Procedure

1. Ensure 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 **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 (5.3)** for specific delivery system removal instructions.

4. Tighten the rotating hemostatic valve.
5. Repeat angiography to assess the stented area.

If post dilatation is necessary, ensure final stent diameter matches reference vessel diameter. Assure that the stent is not under-dilated.

10.0 PATIENT INFORMATION

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

- A Patient Implant Card that includes both patient and MULTI-LINK MINI 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 Abbott Vascular, the implant procedure, and the MULTI-LINK MINI VISION Coronary Stent System.

11.0 PATENTS

This product and / or its use are covered by one or more of the following United States Patents: 5,040,548; 5,061,273; 5,154,725; 5,234,002; 5,242,396; 5,350,395; 5,451,233; 5,496,346; 5,514,154; 5,569,295; 5,603,721; 5,636,641; 5,649,952; 5,728,158; 5,735,893; 5,759,192; 5,780,807; 5,868,706; 6,056,776; 6,131,266; 6,179,810; 6,273,911; 6,309,412; 6,312,459; 6,369,355; 6,419,693; 6,432,133; 6,482,166; 6,485,511; 6,629,991; 6,629,994; 6,651,478; 6,656,220; 6,746,423; 6,827,734; 6,887,219; 6,890,318; 6,908,479; 6,921,411; 6,929,657; 6,939,373. Additional patents pending.

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Abbott Vascular

Santa Clara, CA 95054-2807 USA

CUSTOMER SERVICE











TEL: (800) 227-9902

FAX: (800) 601-8874

Outside USA TEL: (951) 914-4669

Outside USA FAX: (951) 914-2531

Graphical Symbols for Medical Device Labeling

 Manufacturer	 Inner Diameter
REF Catalogue Number	 Outer Diameter
F French Size	 Stent Length
 Guiding Catheter	 Date of Manufacture
 Consult instructions for use	 Use By
 Contents (Numeral represents quantity of units inside.)	LOT Batch Code
 Do Not Reuse	STERILE R Sterilized Using Irradiation
STERILE EO Sterilized Using Ethylene Oxide	

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