
Guidant MULTI-LINK PIXEL® Coronary Stent Systems
Information for Prescribers



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1.0 DEVICE DESCRIPTION

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

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

Table 1: 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, 13, 18, 23, 28	5F	7	16	81
2.25	8, 13, 18, 23, 28	5F	7	16	83
2.5	8, 13, 18, 23, 28	5F	7	16	84

*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 RX PIXEL Coronary Stent System or Guidant MULTI-LINK OTW PIXEL Coronary Stent System, one (1) protective sheath, and one (1) regrooming sheath, one (1) flushing tool (for Guidant MULTI-LINK RX PIXEL)

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

3.0 INDICATIONS

The Guidant MULTI-LINK PIXEL 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. (See **Individualization of Treatment** [8.1].)

4.0 CONTRAINDICATIONS

The Guidant MULTI-LINK PIXEL Coronary Stent Systems are contraindicated for use in:

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

5.0 WARNINGS AND PRECAUTIONS

(See also **Individualization of Treatment** [8.1].)

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 316L stainless steel (including the major elements iron, chromium, nickel, molybdenum) 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.

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- **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 mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
 - Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

5.2 Stent Placement – Precautions

- **Do not prepare or pre-inflate delivery system prior to stent deployment** other than as directed. Use balloon purging technique described in **Delivery System Preparation** (9.3.2).
- **The labeled stent diameter refers to expanded stent inner diameter. Previous coronary stent systems referred to outside diameter in the expanded state.**
- 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 Rated Burst Pressure 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**.

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- 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 coronary guide wire, balloon or delivery system, exercise care to avoid disrupting the stent geometry.
- The Guidant MULTI-LINK PIXEL Coronary 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

6.1.1 Guidant MULTI-LINK RX PIXEL Coronary Stent System Study (PIXEL Registry)

A total of one hundred and fifty (150) patients were enrolled in a multi-center, consecutive Registry to evaluate the use of the Guidant MULTI-LINK RX PIXEL Coronary Stent System in abrupt or threatened abrupt closure in patients presenting with failed interventional therapy of *de novo* and restenotic native coronary artery lesions (length \leq 25 mm) with reference diameters from 2.0 to 2.5 mm (PIXEL Study). These results were compared to results of the RECREATE Registry (N = 152). In the RECREATE Registry, one hundred and fifty-two (152) patients were enrolled in a non-randomized, multi-center, consecutive registry to evaluate the use of the Guidant MULTI-LINK[®] Stent in patients presenting with abrupt or threatened abrupt closure of native coronary arteries (lesion length \leq 32 mm) with a reference vessel diameter ranging from 2.5 mm to 3.75 mm.

In the PIXEL Study, there were no deaths through the 180-day follow-up. One patient experienced a Q-wave MI while five patients suffered a non-Q-wave MI. Five patients required Target Vessel Revascularization (TVR), which includes the target site, by CABG; fourteen patients required TVR by PTCA through the 180-day follow-up. Two patients received Target Site Revascularization (TSR) by PTCA on two separate occasions. In total, there were twenty-one TVR events. Of the twenty-one TVR events, fifteen were to the target site. One patient experienced a non-hemorrhagic cerebrovascular accident (CVA) at 31 days. One patient experienced a stent thrombosis during the 180-day follow-up period. A total of seven patients suffered bleeding complications through the 180-day follow-up, four of which required transfusions. A total of four vascular complications were noted, one of which was experienced by a patient who also suffered a bleeding complication. Of the four vascular complications, three required transfusions.

Four device failures were experienced in the PIXEL Registry. In two patients the assigned stent was never delivered and in one patient the assigned stent was delivered proximal to the lesion. One patient received the Guidant MULTI-LINK PIXEL stent after pre-dilatation.

Table 2 shows the results of patients receiving the Guidant MULTI-LINK RX PIXEL Stent (PIXEL Study) along with those receiving the Guidant MULTI-LINK Stent (RECREATE Study) through 180-day follow-up. These two studies were non-concurrent and statistical comparison is not appropriate.

Table 2: Principal Adverse Events through 180 Days

	Guidant MULTI-LINK PIXEL (N = 150)	Guidant MULTI-LINK RECREATE (N = 152)
	%, [95% confidence interval], (Number)	
Any Adverse Event	18.7% [12.8%, 25.8%] (28)	19.1% [13.2%, 26.2%] (29)
Early (In-Hospital)	5.3% [2.3%, 10.2%] (8)	5.3% [2.3%, 10.1%] (8)
Out-of-Hospital	15.0% [9.6%, 21.8%] (22)	13.8% [8.8%, 20.3%] (21)
Non-Q-Wave MI Total	3.3% [1.1%, 7.6%] (5)	2.6% [0.7%, 6.6%] (4)
Early (In-Hospital)	0.0% [0.0%, 2.4%] (0)	2.6% [0.7%, 6.6%] (4)
Out-of-Hospital	3.4% [1.1%, 7.8%] (5)	0.0% [0.0%, 2.4%] (0)
Q-Wave MI Total	0.7% [0.0%, 3.7%] (1)	1.3% [0.2%, 4.7%] (2)
Early (In-Hospital)	0.0% [0.0%, 2.4%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.7% [0.0%, 3.7%] (1)	1.3% [0.2%, 4.7%] (2)
PTCA Total	9.3% [5.2%, 15.2%] (14)	5.3% [2.3%, 10.1%] (8)
Early (In-Hospital)	0.0% [0.0%, 2.4%] (0)	0.7% [0.0%, 3.6%] (1)
Out-of-Hospital	9.5% [5.3%, 15.5%] (14)	4.6% [1.9%, 9.3%] (7)
CABG Total	3.3% [1.1%, 7.6%] (5)	7.2% [3.7%, 12.6%] (11)
Early (In-Hospital)	0.0% [0.0%, 2.4%] (0)	1.3% [0.2%, 4.7%] (2)
Out-of-Hospital	3.4% [1.1%, 7.8%] (5)	5.9% [2.7%, 10.9%] (9)
Stent Thrombosis Total	0.7% [0.0%, 3.7%] (1)	0.7% [0.0%, 3.6%] (1)
Early (In-Hospital)	0.0% [0.0%, 2.4%] (0)	0.7% [0.0%, 3.6%] (1)
Out-of-Hospital	0.7% [0.0%, 3.7%] (1)	0.0% [0.0%, 2.4%] (0)
Death Total	0.0% [0.0%, 2.4%] (0)	2.0% [0.4%, 5.7%] (3)
Early (In-Hospital)	0.0% [0.0%, 2.4%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.0% [0.0%, 2.5%] (0)	2.0% [0.4%, 5.7%] (3)
Bleeding Complications	4.7% [1.9%, 9.4%] (7)	2.6% [0.7%, 6.6%] (4)
Early (In-Hospital)	3.3% [1.1%, 7.6%] (5)	2.6% [0.7%, 6.6%] (4)
Out-of-Hospital	1.4% [0.2%, 4.8%] (2)	0.0% [0.0%, 2.4%] (0)
Vascular Complications	2.7% [0.7%, 6.7%] (4)	2.6% [0.7%, 6.6%] (4)
Early (In-Hospital)	2.0% [0.4%, 5.7%] (3)	2.0% [0.4%, 5.7%] (3)
Out-of-Hospital	0.7% [0.0%, 3.7%] (1)	0.7% [0.0%, 3.6%] (1)
Cerebrovascular Accident	0.7% [0.0%, 3.7%] (1)	1.3% [0.2%, 4.7%] (2)
Early (In-Hospital)	0.0% [0.0%, 2.4%] (0)	0.0% [0.0%, 2.4%] (0)
Out-of-Hospital	0.7% [0.0%, 3.7%] (1)	1.3% [0.2%, 4.7%] (2)
Stent Delivery Failure	2.7% [0.7%, 6.7%] (4)	5.3% [2.3%, 10.1%] (8)

- Out-of-hospital calculated based on 147 patients as available for 180-day follow-up.
- [95% Confidence Interval] - calculated using Exact Clopper-Pearson CI.
- Early (in-hospital) refers to events during the hospitalization for stent placement.
- In cases where a patient experienced both an in-hospital and an out-of-hospital event, they are counted once in each group, however, they are counted only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.
- ANY Adverse event includes death, Q-Wave MI, non-Q-Wave MI, emergent CABG, stent thrombosis, bleeding complications, vascular complications, and CVA.

6.2 Potential Adverse Events

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

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

7.0 CLINICAL STUDIES

7.1 Guidant MULTI-LINK RX PIXEL Coronary Stent System Study (PIXEL Registry)

The PIXEL Study was a prospective, non-randomized, consecutive registry conducted in eighteen US centers and two Israeli centers that included 150 patients presenting with abrupt or threatened abrupt closure in *de novo* or restenotic native coronary artery lesions. Both patient cohorts possessed comparable demographics and followed the identical protocol; therefore it was appropriate to combine both the US and Israeli patient populations. The primary endpoint of Target Vessel Failure (TVF) through thirty days was defined as the composite of death, Q-wave MI, non-Q-wave MI and revascularization by CABG or PTCA attributable to the target site or target vessel. An independent Clinical Events Committee adjudicated all primary events.

Of the 150 patients, 68.0% were male and ranged in age from 34 years to 88 years with an average of 62.9 ±12.0 (mean ±SD). Eligible patients presented with angina or a positive functional study, undergoing elective, *de novo* or restenotic lesion treatment in a native coronary artery, and with abrupt or threatened abrupt closure of the vessel of ≥ 2.0 mm and ≤ 2.5 mm in diameter with a visually estimated stenosis of ≥ 50% and < 100% and lesion length ≤ 25 mm.

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

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

Table 3 compares the results of the patients treated in the PIXEL Registry to those treated in the RECREATE Registry through 180 days. These studies were non-concurrent and statistical comparison is not appropriate.

Table 3: Principal Effectiveness and Safety Results through 180 Days

	Guidant MULTI-LINK PIXEL (N = 150)	Guidant MULTI-LINK RECREATE (N = 152)
%, (Number/denominator), [95% confidence interval], or Mean \pm SD {range} (Number)		
Effectiveness Measures		
Device Success by QCA [95% Confidence Interval] ²	97.3% (143/147) [93.2%, 99.3%]	96.7% (145/150) [92.4%, 98.9%]
Clinical Procedure Success by QCA [95% Confidence Interval] ²	100% (147/147) [97.5%, 100%]	95.3% (143/150) [90.6%, 98.1%]
Post-Procedure In-Stent % DS Mean \pm SD ¹ (N) Range (min, max) [95% Confidence Interval] ³	10.3% \pm 11.1% (144) (-24%, 35.8%) [8.5%, 12.1%]	11.2% \pm 11.0% (151) (-28%, 46.8%) [9.5%, 13.0%]
Target Site Revascularization (TSR) [95% Confidence Interval] ²	8.8% (13/147) [4.8%, 14.6%]	12.5% (19/152) [7.7%, 18.8%]
Target Vessel Failure (TVF) [95% Confidence Interval] ²	13.6% (20/147) [8.5%, 20.2%]	17.1% (26/152) [11.5%, 24.0%]
Safety Measures		
In-Hospital Clinical Event Rate (MACE) [95% Confidence Interval] ²	0.0% (0/150) [0.0%, 2.4%]	3.3% (5/152) [1.1%, 7.5%]
Out-of-Hospital Clinical Event Rate (MACE) to 180 Days [95% Confidence Interval] ²	10.2% (15/147) [5.8%, 16.3%]	13.2% (20/152) [8.2%, 19.6%]
Bleeding Complications to 180 Days [95% Confidence Interval] ²	4.8% (7/147) [1.9%, 9.6%]	2.6% (4/152) [0.7%, 6.6%]
Vascular Complications to 180 Days [95% Confidence Interval] ²	2.7% (4/147) [0.7%, 6.8%]	2.6% (4/152) [0.7%, 6.6%]
Stent Thrombosis [95% Confidence Interval] ²	0.7% (1/150) [0.0%, 3.7%]	0.7% (1/152) [0.0%, 3.6%]
Hospitalization Post-Intervention (days) Mean \pm SD ¹ (N) Range (min, max) [95% Confidence Interval] ³	1.5 \pm 2.0 (150) (0, 16) [1.2 , 1.8]	1.9 \pm 2.8 (152) (1, 28) [1.4 , 2.3]

- Device success = Attainment of the final result of < 50% residual stenosis of the target vessel using the assigned treatment device alone (i.e., without the use of other types of stents or new balloon devices).
- Procedure Success = Attainment of the final result of < 50% residual stenosis of the target vessel using the assigned treatment device and freedom from MACE.
- QCA = Quantitative Coronary Angiography.
- % DS = percent diameter stenosis by QCA.
- MACE = Major Adverse Cardiac Event: death, Q-wave MI or non-Q-wave MI, CABG, or PTCA to the treated site.
- TVF = MACE and non-target site, target vessel revascularization.

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- In-Hospital MACE = Any MACE occurring prior to hospital discharge.
 - Out-of-Hospital MACE = Any MACE occurring from hospital discharge through up to 180 days of 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.
 - Subacute Thrombosis = Any cardiac death, subacute closure requiring revascularization of the target site or total closure indicated by QCA within 180 days of the index intervention.

¹ Standard Deviation (SD) calculated assuming a normal distribution.

² Calculated Using Clopper-Pearson Exact Confidence Interval.

³ By normal approximation.

8.0 PATIENT SELECTION AND TREATMENT

8.1 Individualization of Treatment

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

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

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0 mm, intra-procedural thrombus, or poor distal runoff, dissection following stent implantation, and / or cessation of anti-platelet / anti-thrombotic 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 Guidant MULTI-LINK PIXEL 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 a recent **acute myocardial infarction** where there is evidence of thrombus or poor flow.
- 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 RX PIXEL or Guidant MULTI-LINK OTW PIXEL 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 catheters
- 2-3 syringes (10 – 20 cc)
- 1,000 u/500 cc Heparinized Normal Saline (HepNS)
- 0.014 inch 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 protective cover from tip.
2. For use with the Guidant MULTI-LINK RX PIXEL Coronary Stent System, flush guide wire lumen with HepNS until fluid exits **guide wire exit notch**.

For use with the Guidant MULTI-LINK OTW PIXEL Coronary Stent System, flush guide wire lumen with HepNS until fluid exits **the distal tip**.

9.3.2 Delivery System Preparation

1. Prepare inflation device / syringe with diluted contrast medium.
2. Attach inflation device / syringe to stopcock; attach to inflation port.
3. With tip down, orient delivery system vertically.
4. Open stopcock to delivery system; pull negative for 30 seconds; release to neutral for contrast fill.
5. Close stopcock to delivery system; purge inflation device / syringe of all air.
6. Repeat steps 3 through 5 until all air is expelled.

Note: If air is seen in shaft, repeat **Delivery System Preparation** steps 3 through 5 to prevent uneven stent expansion.

7. If a syringe was used, attach a prepared inflation device to stopcock.
8. Open stopcock to delivery system.
9. Leave on neutral.

Note: The labeled stent diameter refers to expanded stent inner diameter. Previous coronary stent systems referred to outside diameter in the expanded state.

9.4 Delivery Procedure

1. Prepare vascular access site according to standard practice.
2. Pre-dilate lesion with 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** for specific delivery system removal instructions.

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

9.5 Deployment Procedure

1. **CAUTION: Refer to product label 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 or expand the stent beyond 3.0 mm.**

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

9.6 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 rotating hemostatic valve.
5. Repeat angiography to assess stented area.
6. If post dilatation is necessary, ensure final stent diameter matches reference vessel diameter. ASSURE STENT IS NOT UNDERDILATED.

10.0 PATIENT INFORMATION

In addition to this Instructions for Use booklet, the Guidant MULTI-LINK PIXEL Coronary Stent Systems are packaged with additional patient specific information that includes:

- A Patient Implant Card that includes both patient and Guidant MULTI-LINK PIXEL Stent specific information. All patients will be expected to keep this card in their possession at all times for procedure / stent identification.
- A Patient Teaching Guide which includes information on Abbott Vascular and the implant procedure.

11.0 PATENTS

This product and / or its use are covered by one or more of the following United States Patents: 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; 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; 6,200,325; 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; 6,312,459; 6,369,355; 6,432,133; 6,485,511; 6,488,694; 6,527,789; 6,561,788; 6,572,813; 6,575,993; 6,620,193; 6,629,991; 6,835,059; 6,908,479; RE 34,564. Other U.S. patents pending. Foreign patents issued and pending.

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CUSTOMER SERVICE











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**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 EO Sterilized Using Ethylene Oxide	STERILE R Sterilized Using Irradiation

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