PPL2082232 (2/1/13)

# GRAFTMASTER® RX

## Coronary Stent Graft System

Abbott

## Graphical Symbols for Medical Device Labeling

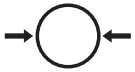
Manufacturer


Sterilized using ethylene oxide


Catalogue number


Batch code


French size



Outer diameter

Do not reuse

Inner diameter

Consult instructions for use

Guiding catheter

Date of manufacture


Contents (numeral represents quantity of units inside)

Use by


MR Conditional

Do not resterilize

**Humanitarian Device**

***Instructions for Use***

℞ ONLY

**Humanitarian Device. Authorized by Federal law for use in the treatment of free perforations, defined as free contrast extravasation into the pericardium, in native coronary vessels or saphenous vein bypass grafts ≥ 2.75 mm in diameter. The effectiveness of this device for this use has not been demonstrated.**

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## 1.0 DEVICE DESCRIPTION

The GRAFTMASTER RX Coronary Stent Graft is constructed using a sandwich technique, whereby an ultra-thin layer of expandable polytetrafluoroethylene (PTFE) is placed between two GRAFTMASTER stents, which are then pre-mounted on a balloon catheter delivery system. The stents are fabricated from medical-grade 316L stainless steel.

The GRAFTMASTER RX delivery system is a rapid exchange co-axial design with the balloon and stent graft at the distal end of the catheter. The proximal lumen provides for inflation of the balloon with contrast medium. The central distal lumen permits a guide wire to be inserted through the lumen. The annular space between the distal outer member and the central distal lumen provides a fluid passage path from the proximal lumen to the balloon. The shaft of the catheter, the tip, and the tapers of the balloon are coated with HYDROCOAT® hydrophilic coating.

Two radiopaque markers located on the distal end of the inner member are positioned to mark the working length of the balloon. The radiopaque markers fluoroscopically aid in positioning the stent graft pre-deployment and the delivery system for post-deployment dilatation. The balloon is designed to deliver an expandable stent graft of known diameter and length at specified pressures. Markers located on the proximal outer shaft help the physician gauge the delivery catheter position relative to the guiding catheter tip.

An adaption arm on the proximal end of the catheter provides access to the inflation lumen. It is designed with a luer-lock fitting to facilitate connection to an inflation device.

**Note:** During stent graft deployment with the stent graft delivery system from crimped state to 4.8 mm, the stent graft may shorten up to 20%. Maximum post dilatation that can be achieved with a noncompliant post dilatation balloon is a maximum of 5.5 mm. With expansion to this diameter, the system may shorten up to 25%. When choosing a GRAFTMASTER RX system for expansion in larger vessels, a longer stent graft length is recommended to ensure the treatment area is covered by the stent graft.

## 2.0 HOW SUPPLIED

**Sterile** – This device is sterilized with ethylene oxide gas. Non-pyrogenic. It is intended for **single use only. Do not resterilize**. Do not use if package is opened or damaged.

**Contents** – One (1) GRAFTMASTER RX Coronary Stent Graft System; one (1) protective sheath; one (1) Flexi-Clip; one (1) flushing tool.

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

## 3.0 INDICATIONS

The GRAFTMASTER RX is indicated for use in the treatment of free perforations, defined as free contrast extravasation into the pericardium, in native coronary vessels or saphenous vein bypass grafts ≥ 2.75 mm in diameter. The effectiveness of this device for this use has not been demonstrated. Long-term outcome for this permanent implant is unknown at present.

## 4.0 CONTRAINDICATIONS

The GRAFTMASTER RX is contraindicated for use in:

- Patients in whom antiplatelet and / or anticoagulation therapy is contraindicated
- Patients who are judged to have a treatment area that prevents complete inflation of an angioplasty balloon or proper placement of the stent graft

## 5.0 WARNINGS

Ensure that the sterile barrier has not been opened or damaged prior to use.

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) or PTFE may suffer an allergic reaction to this implant.

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).

## 6.0 PRECAUTIONS

### 6.1 General Precautions

Implantation of the stent graft should be performed only by physicians who have received appropriate training.

Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent graft. The long-term outcome following repeat dilatation of endothelialized stent grafts is unknown at present.

Care should be taken to control the guiding catheter tip during stent graft delivery, deployment, and balloon withdrawal. Before withdrawing the stent graft delivery system, visually confirm complete balloon deflation by fluoroscopy to avoid guiding catheter movement into the vessel and subsequent arterial damage.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

Note the product “Use by” date specified on the package.

### 6.2 Stent Graft Handling – Precautions

This device is intended for single-use only; do not reuse. Do not resterilize, as this can compromise the device performance and increase the risk of cross contamination due to inappropriate reprocessing.

**Do not remove the stent graft from its delivery system.** Removing the stent graft from the delivery system may damage the stent graft and / or lead to stent graft embolization.

The delivery system should not be used in conjunction with other stents.

Special care must be taken not to handle or in any way disrupt the stent graft position on the delivery system. This is most important during placement over the guide wire and the advancement through the hemostasis valve adaptor and guiding catheter hub.

Excessive manipulation (e.g., rolling the mounted stent graft) may cause dislodgement of the stent graft from the delivery balloon.

**Do not manipulate, touch, or handle the stent graft** with your fingers, as this may cause contamination or dislodgement of the stent graft from the delivery balloon.

Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon, as it may cause uneven expansion and difficulty in deployment of the stent graft.

### 6.3 Stent Graft Placement – Precautions

#### *6.3.1 Stent Graft Preparation – Precautions*

Do not prepare or pre-inflate balloon prior to stent graft deployment other than as directed. Use the balloon purging technique described in Section 10.2.3 *Delivery System Preparation.*

While introducing the delivery system into the vessel, do not induce negative pressure on the delivery system. This may cause dislodgement of the stent graft from the balloon.

Use guiding catheters which have lumen sizes that are suitable to accommodate the stent graft delivery system (See Section 10.1 *Materials Required* or product label).

#### *6.3.2 Stent Graft Implantation – Precautions*

Pre-dilatations of the vessel must take into account proximal atherosclerotic plaque beyond the treatment area, which may prevent advancement of the device to the treatment area. Failure to do so may increase the difficulty of stent graft placement and cause procedural complications.

Implanting a stent graft may lead to dissection of the vessel distal and / or proximal to the stent graft, and may cause closure of the vessel, requiring additional intervention (e.g., coronary artery bypass surgery, further dilatation, placement of additional stents, etc.).

If more than one stent graft is required, the distal stent graft should be placed initially, followed by placement of the proximal stent graft. Stent graft placement in this order obviates the need to cross the proximal stent graft when placing the distal stent graft, and reduces the chances for dislodging the proximal stent graft.

Do not expand the stent graft if it is not properly positioned in the vessel. (See Section 6.4 *Stent Graft / System Removal – Precautions*.)

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

**Do not exceed the rated burst pressure (RBP) as indicated on the product label.** Monitor balloon pressures during inflation. Use of pressures higher than specified on the product label may result in a ruptured balloon with possible intimal damage and dissection.

An unexpanded stent graft may be retracted into the guiding catheter one time only. An unexpanded stent graft should not be reintroduced into the artery once it has been pulled back into the guiding catheter. Subsequent movement in and out through the distal end of the guiding

catheter should not be performed, as the stent graft may be damaged when retracting the undeployed stent graft back into the guiding catheter.

Stent graft retrieval methods (use of additional wires, snares, and / or forceps) may result in additional trauma to the vasculature and / or the vascular access site. Complications may include bleeding, hematoma, or pseudoaneurysm.

### 6.4 Stent Graft / System Removal – Precautions

#### *6.4.1 Removal of the Delivery System Prior to Stent Graft Deployment*

If removal of the stent graft system is required prior to deployment, ensure that the guiding catheter is coaxially positioned relative to the stent graft delivery system, and cautiously withdraw the stent graft delivery system into the guiding catheter.

Should unusual resistance be felt at any time, either during access of the treatment area or during removal of the delivery system post-stent graft implantation, the delivery system and guiding catheter **should be removed as a single unit.** This must be done under direct visualization and fluoroscopy.

#### *6.4.2 Withdrawal of the Stent Graft Delivery System from the Deployed Stent Graft*

1. Deflate the balloon by pulling negative on the inflation device. Confirm balloon deflation under fluoroscopy and wait 10 – 15 seconds longer.
2. Position the inflation device to “negative” or “neutral” pressure.
3. Stabilize guide catheter position just outside coronary ostium and anchor in place. Maintain guide wire placement across the stent graft segment.
4. Gently remove the stent graft delivery system with slow and steady pressure.
5. Tighten the rotating hemostatic valve.

**Note: If, during withdrawal of the catheter, resistance is encountered, use the following steps to improve balloon rewrap:**

- Re-inflate the balloon up to nominal pressure.
- Repeat steps 1 through 5 above.

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

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

Retrieval methods (i.e., additional wires, snares, and / or forceps) may result in additional trauma to the coronary vasculature and / or the vascular access site. Complications may include, but are not limited to, bleeding, hematoma, or pseudoaneurysm.

### 6.5 Post-Stent Graft Placement – Precautions

Care must be exercised when crossing a newly deployed stent graft with an intravascular ultrasound (IVUS) catheter, a coronary guide wire, a balloon catheter, or delivery system to avoid disrupting the stent graft geometry, apposition, and / or geometry.

Antiplatelet therapy should be administered post-procedure (See Section 9.0 *Individualization of Treatment*). Patients who require early discontinuation of antiplatelet therapy (e.g., secondary to active bleeding) should be monitored carefully for cardiac events. At the discretion of the patient’s treating physician, the antiplatelet therapy should be restarted as soon as possible.

If the patient requires imaging, see Section 6.6 *MRI Statement.*

### 6.6 MRI Statement

Nonclinical testing has demonstrated that the GRAFTMASTER RX Coronary Stent Graft, in single and in overlapped configurations up to 44 mm in length, is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla
- Spatial gradient field of 2500 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) for up to 15 minutes of scanning for each duration of a sequence

The GRAFTMASTER stent graft should not migrate in this MRI environment. Nonclinical testing at field strengths greater than 3 Tesla has not been performed to evaluate stent graft migration or heating. MRI at 1.5 or 3 Tesla may be performed immediately following the implantation of the GRAFTMASTER stent graft.

Stent graft heating was derived by using the measured nonclinical, *in vitro* temperature rises in a GE Excite 3 Tesla scanner and in a GE 1.5 Tesla coil in combination with the local specific absorption rates (SARs) in a digitized human

heart model. The maximum whole-body-averaged SAR was determined by validated calculation. At overlapped lengths of up to 44 mm, the GRAFTMASTER stent graft produced a nonclinical maximum local temperature rise of 1.8˚C at a maximum whole-body-averaged SAR of 2.0 W/kg (normal operating mode) for 15 minutes. These calculations do not take into consideration the cooling effects of blood flow.

The effects of MRI on overlapped stent grafts greater than 44 mm in length or stent grafts with fractured struts are unknown.

As demonstrated in nonclinical testing, the image artifact extends approximately 15 mm from the device, both inside and outside the device lumen, when scanned using the sequence: gradient echo in a 3T GE Sigma HDxt software release 15.0_M4_0910.z MR system with a Body Transmit coil. Therefore, it may be necessary to optimize the MR imaging parameters for the presence of the GRAFTMASTER stent graft.

It is suggested that patients register the conditions under which the implant can be safely scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

## 7.0 ADVERSE EVENTS

Data were collected from a total of 41 patients in a multicenter, retrospective analysis of use of the physician-mounted JOSTENT® Coronary Stent Graft to treat perforations. These patients form the basis of the observed adverse events reported. (See Section 8.0 *Clinical Study*.)

### 7.1 Observed Adverse Events

A total of 14 of 41 patients (34.1%) receiving the JOSTENT Coronary Stent Graft experienced one or more adverse events during the procedure. Only one patient (1/41, 2.4%) experienced events post-JOSTENT implantation, due to an incompletely sealed perforation. All other adverse events can be attributed to the perforation since they occurred prior to stent graft implantation.

No patients who received the JOSTENT Coronary Stent Graft died, experienced a Q-wave myocardial infarction (MI), or necessitated emergent CABG during the procedure or in-hospital stay. All stent grafts were successfully delivered.

**Table 1: Procedural Adverse Events**

| | N occurrences |
|---|---|
| Any Adverse Event | 14 (35.0%) |
| Procedural Complications[1] | |
| Pericardial effusion | 9 (22.5%) |
| Tamponade | 5 (12.5%) |
| Pericardiocentesis | 6 (15.0%) |
| Cardiac arrest | 1 (2.5%) |
| Hypotension | 5 (12.5%) |
| Cardiogenic shock | 4 (10.0%) |
| Bradycardia | 4 (10.0%) |

[1] All complications occurred in the cardiac catheterization laboratory prior to JOSTENT Stent Graft implantation, except for a single out-of-lab effusion that progressed to tamponade and required emergent re-PTCA (percutaneous transluminal coronary angioplasty) with placement of a second JOSTENT Stent Graft, which sealed the perforation.

**Table 2: In-hospital Adverse Events**

| | N occurrences | Historical Data[1] | |
|---|---|---|---|
| In-hospital MACE | | Free Perforations | All Perforations |
| Death | 0 | 20% | 9% |
| Emergent CABG | 0 | 60% | 37% |
| Q-wave MI | 0 | 10% | 6% |

[1] Ajluin SC, Glazier S, Blankenship L, O'Neill WW, Safian RD. Perforations after percutaneous coronary interventions: clinical, angiographic, and therapeutic observations. *Catheterization and Cardiovascular Diagnosis*. 1994;32:206-12.

### 7.2 Potential Adverse Events

Adverse events (in alphabetical order) that may be associated with the use of the GRAFTMASTER RX Coronary Stent Graft in native coronary arteries may include:

- Acute myocardial infarction
- Arrhythmias (including ventricular fibrillation and ventricular tachycardia)
- Coronary artery bypass surgery
- Death
- Dissection
- Drug reactions to antiplatelet 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 graft embolization
- Stent graft thrombosis / occlusion
- Stroke / cerebrovascular accidents
- Total occlusion of coronary artery

## 8.0 CLINICAL STUDY

### 8.1 Objective

The objective of this study was to evaluate the technical success and safety of the JOSTENT Coronary Stent Graft as a life-saving treatment in cases of coronary artery perforation.

### 8.2 Design

This study was multicenter, retrospective, and nonrandomized. Demographic, clinical, and angiographic data were collected on the target population, including in-hospital and limited follow-up data.

Abbott Vascular Devices is aware of a total of 46 perforations treated worldwide with the physician-mounted JOSTENT Coronary Stent Graft. Full procedural case report forms have been received for 41 of the 46 subjects. Follow-up forms were received for 27 of the 41 evaluable subjects. The follow-up time ranged from one week to one year. All subjects were enrolled after undergoing urgent or emergent use of the JOSTENT Coronary Stent Graft to treat a native coronary artery or saphenous vein graft perforation.

### 8.3 Results

Demographics were collected for the 41 subjects. Sixty-five percent of the subjects were male. The subjects had a high incidence of previous MI (59%), previous CABG (27.5%), previous PTCA (30.8%), and Canadian Cardiovascular Society Class III / IV angina (83.3%). For this population, the in-hospital major adverse cardiac event (MACE) rate was 0%. There were no in-hospital incidents of death, Q-wave MI, or emergent CABG. In all cases, the JOSTENT Coronary Stent Graft was deployed successfully. No device malfunctions were noted. In all cases, the perforation was sealed.

**Table 3: Summary Table**

| | N occurrences |
|---|---|
| JOSTENT deployed successfully | 52/52 (100%) |
| Perforation closed / vessel sealed | 41/41 (100%) |
| In-hospital MACE | |
| Death | 0 |
| Emergent CABG | 0 |
| Q-wave MI | 0 |

**Table 4: Patient Demographics**

| N = 41 subjects[1] | Occurrences (%) | Not reported |
|---|---|---|
| Average age, years | 65.2 | 1 |
| Male | 26 (65.0%) | 1 |
| Hx of MI | 23 (59.0%) | 2 |
| Hx of CAD | 30 (75%) | 1 |
| Hx of CABG | 11 (27.5%) | 1 |
| Hx of PTCA | 12 (30.8%) | 2 |
| Hx of CHF | 2 (6.4%) | 10 |
| Hx of HTN | 11 (36.7%) | 11 |
| Angina | 41 (100%) | – |
| Class I / II | 6 (16.7%) | 5 |
| Class III / IV | 30 (83.3%) | 5 |
| Diabetes | 6 (23.1%) | 15 |

[1] Procedural forms were never received for 5 of the total 46 cases reported to Abbott Vascular Devices. No information has been received regarding these cases.

**Table 5: Procedural Information**

| N = 41 subjects | | N occurrences |
|---|---|---|
| Index procedure elective | | 38/40 (95.0%) |
| Index procedure emergent | | 2/40 (5.0%) |
| JOSTENT indication | | |
| Perforation | | 37 (90.2%) |
| Others: | Aneurysm | 1 |
| | Fistula | 2 |
| | Rescue after embolized stent graft | 1 |
| Native vessel | | 33 (80.5%) |
| SVG | | 8 (19.5%) |
| Average number of stent grafts used | | 1.3 (range: 1 – 3) |
| JOSTENT Stent Graft deployed successfully | | 52 (100%) |
| Perforation closed / vessel sealed | | 41 (100%) |

**Table 6: In-hospital MACE**

| N = 41 subjects | N occurrences |
|---|---|
| Death | 0 |
| Emergent CABG | 0 |
| Q-wave MI | 0 |

**Table 7: Procedural Complications**

| N = 41 subjects | N occurrences |
|---|---|
| Patients experience any complication | 14 (34.1%) |
| Procedural Complications[1] | |
| Pericardial effusion | 9 (22.0%) |
| Tamponade | 5 (12.2%) |
| Pericardiocentesis | 6 (14.6%) |
| Cardiac arrest | 1 (2.4%) |
| Hypotension | 5 (12.2%) |
| Cardiogenic shock | 4 (9.8%) |
| Bradycardia | 4 (9.8%) |

[1] All complications occurred in the cardiac catheterization laboratory prior to JOSTENT Stent Graft implantation, except for a single out-of-lab effusion that progressed to tamponade and required emergent re-PTCA with placement of a second JOSTENT Stent Graft that sealed the perforation.

**Table 8: Complications at Follow-up**

| Complication | N occurrences |
|---|---|
| Target vessel / lesion revascularization (TVR / TLR) | 4 |
| TVR only | 1 |
| Myocardial Infarction (MI) | 3 |
| Non-Q-wave MI | 2 |
| Occlusion of the target lesion[1] | 2 |
| Revascularization[1] | 1 |

[1] No further information was provided.

### 8.4 Conclusions

The clinical data from a small, retrospective study suggest that the physician-mounted JOSTENT Coronary Stent Graft can be deployed in coronary arteries to seal free perforations. These data also suggest that the use of the JOSTENT Coronary Stent Graft is not associated with increased risks compared to conventional treatment of perforations.

## 9.0 INDIVIDUALIZATION OF TREATMENT

The risks and benefits described above should be carefully considered for each patient before use of the GRAFTMASTER RX Coronary Stent Graft System. Patient selection factors to be assessed should include a judgment regarding risk of prolonged anticoagulation. Stent graft placement is generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease).

### 9.1 Use in Special Populations

**The effectiveness of this device for any use has not been demonstrated.** The safety of the GRAFTMASTER RX Coronary Stent Graft System has not been established for patients with any of the following characteristics:

- Patients with unresolved vessel thrombus at the treatment area
- Patients with coronary artery reference vessel diameters < 2.75 mm
- Patients with treatment areas located in the unprotected left main coronary artery, ostial treatment areas, or treatment areas located at a bifurcation
- Patients with diffuse disease or poor outflow distal to the identified treatment areas
- Patients with recent acute myocardial infarction, where there is evidence of thrombus or poor flow
- Patients with more than two overlapping stents due to risk of thrombus or poor flow

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.

## 10.0 OPERATOR'S MANUAL

### 10.1 Materials Required

- Appropriate guiding catheter(s) – 7F / 0.074" ID for 4.50 – 4.80 mm diameter GRAFTMASTER RX, or 6F / 0.068" ID for 2.80 mm – 4.00 mm diameter GRAFTMASTER RX
- 2 – 3 syringes (10 – 20 cc)
- 1,000 u/500 cc heparinized normal saline (HepNS)
- 0.014 inch (0.36 mm) x 175 cm (minimum length) guide wire
- Rotating hemostatic valve with 0.096 inch (2.44 mm) minimum inner diameter
- Contrast material diluted 1:1 with normal saline
- Inflation device
- Three-way stopcock
- Torque device
- Guide wire introducer
- Appropriate arterial sheath
- Appropriate anticoagulation and antiplatelet drugs

### 10.2 System Preparation

**Note: During stent graft deployment with the stent delivery system from crimped state to 4.8 mm, the graft may shorten up to 20%.**

#### *10.2.1 Packaging Removal*

Carefully remove the delivery system from its protective tubing for preparation of the delivery system. Do not bend or kink the hypotube during removal.

Remove the product mandrel and protective stent graft sheath by grasping the catheter just proximal to the stent graft (at the proximal balloon bond site), and with the other hand, grasp the stent graft protector and gently remove distally. If unusual resistance is felt during product mandrel and stent graft sheath removal, do not use this product and replace with another. Follow product returns procedure for the unused device.

Visually inspect the stent graft for uniformity, protruding coils, and centering on the balloon and verify that the stent graft does not extend beyond the radiopaque balloon markers.

#### *10.2.2 Guide Wire Lumen Flush*

Flush the guide wire lumen with HepNS using the flushing tool supplied with the product. Insert the flushing tool into the tip of the catheter and flush until fluid exits the guide wire exit notch.

**Note:** Avoid manipulation of the stent graft while flushing the guide wire lumen, as this may disrupt the placement of the stent graft on the balloon.

#### *10.2.3 Delivery System Preparation*

1. Prepare an inflation device / syringe with diluted contrast medium.
2. Attach an inflation device / syringe to the stopcock and attach it to the inflation port of the product. Do not bend the product hypotube when connecting to the inflation device / syringe.
3. With the tip down, orient the delivery system vertically.
4. Open the stopcock to the delivery system, pull negative for 30 seconds, and release to neutral for contrast fill.
5. Close the stopcock to the delivery system and purge the inflation device / syringe of all air.
6. Repeat steps 3 through 5 until all air is expelled. If bubbles persist, do not use the product.
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.
10. Moisten the stent graft with heparinized saline by submerging the stent graft into a sterile bowl containing the solution. **Note:** Do not use gauze sponges to wipe down the stent graft as fibers may disrupt the stent graft.

**Note:** While introducing the delivery system into the vessel, do not induce negative pressure on the delivery system. This may cause dislodgement of the stent graft from the balloon.

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

### 10.3 Delivery Procedure

1. Prepare the vascular access site according to standard practice.
2. Pre-dilatations of the vessel must take into account proximal atherosclerotic plaque beyond the treatment area, which may prevent advancement of the device to the treatment area. Failure to do so may increase the difficulty of the stent graft placement and cause procedural complications.
3. Maintain neutral pressure on the inflation device attached to the delivery system. Open the rotating hemostatic valve as widely as possible.
4. Backload the delivery system onto the proximal portion of the guide wire while maintaining guide wire position across the treatment area.
5. Carefully advance the delivery system into the guiding catheter and over the guide wire to the treatment area. Be sure to keep the hypotube straight. Ensure guiding catheter stability before advancing the stent graft system into the coronary artery.
6. Advance the delivery system over the guide wire to the treatment area under direct fluoroscopic visualization. Utilize the radiopaque balloon markers to position the stent graft across the treatment area. Perform angiography to confirm stent graft position. If the position of the stent graft is not optimal, it should be carefully repositioned or removed. Expansion of the stent graft should not be undertaken if the stent graft is not properly positioned in the treatment area.

**CAUTION: If resistance is encountered, do not force passage. Resistance may indicate damage to the device or movement of the stent graft on the balloon.**

**Note:** If removal of a stent graft system is required prior to deployment, ensure that the guiding catheter is coaxially positioned relative to the stent graft delivery system, and cautiously withdraw the stent graft delivery system into the guiding catheter. The stent graft delivery system and the guiding catheter should be removed as a single unit. This should be done under direct visualization with fluoroscopy.

7. Tighten the rotating hemostatic valve. The stent graft is now ready to be deployed.

**CAUTION: Avoid over-tightening the Tuohy-Borst valve, as this may restrict the flow of contrast medium in and out of the balloon, thereby slowing inflation / deflation.**

### 10.4 Deployment Procedure

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

1. Prior to deployment, reconfirm the correct position of the stent graft relative to the treatment area using the radiopaque balloon markers.
2. Deploy the stent graft slowly by pressurizing the delivery system in 2-atm increments, every 5 seconds, until the stent graft is completely expanded. Fully expand the stent graft by inflating to nominal pressure at a minimum. Accepted practice generally targets an initial deployment pressure that would achieve a stent graft

inner diameter ratio of about 1.1 times the reference vessel diameter (refer to product label for *in vitro* stent graft inner diameter, nominal pressure, and RBP).

3. Maintain pressure for 30 seconds. If necessary, the delivery system can be repressurized or further pressurized to ensure complete apposition of the stent graft to the artery wall. Maintain pressure for 30 seconds for full expansion of the stent graft. Fluoroscopic visualization during stent graft expansion should be used in order to properly judge the optimum stent graft diameter as compared to the proximal and distal native coronary artery diameters (reference vessel diameters). Optimal stent graft expansion and proper apposition require that the stent graft be in full contact with the arterial wall.

**Note:** See Section 10.5 *Removal Procedure* for instruction on withdrawal of stent graft delivery system.

4. If necessary, the delivery system can be repressurized or further pressurized to ensure complete apposition of the stent graft to the artery wall.

**CAUTION: Do not exceed the labeled RBP of 16 atm (1621 kPa).**

5. Deflate the balloon by pulling negative on the inflation device for 30 seconds. Confirm complete balloon deflation before attempting to move the delivery system. If unusual resistance is felt during stent graft delivery system withdrawal, pay particular attention to guiding catheter position.
6. Confirm stent graft position and deployment using standard angiographic techniques. Fluoroscopic visualization during stent graft expansion should be used in order to properly judge the optimum expanded stent graft diameter as compared to the proximal and distal coronary artery diameter(s). Optimal expansion requires that the stent graft be in full contact with the artery wall. Stent graft wall contact should be verified through routine angiography.
7. If the deployed stent graft size is still inadequate with respect to reference vessel diameter, a larger balloon may be used to further expand the stent graft. If the initial angiographic appearance is suboptimal, the stent graft may be further expanded using a low profile, high pressure, noncompliant balloon dilation catheter. If this is required, the stented segment should be carefully recrossed with a prolapsed guide wire to avoid disrupting the stent graft geometry. Deployed stent graft should not be left underdilated.

**Note: Maximum post dilatation that can be achieved with a noncompliant post dilatation balloon is a maximum of 5.5 mm. With expansion to this diameter the system may shorten up to 25%. When choosing a GRAFTMASTER RX system for expansion in larger vessels, a longer stent graft length is recommended to ensure the treatment area is covered by the stent graft.**

**CAUTION: Do not dilate the stent graft beyond 5.5 mm.**

### 10.5 Removal Procedure

**Withdrawal of the Stent Graft Delivery System from the Deployed Stent Graft:**

1. Deflate the balloon by pulling negative on the inflation device. Confirm balloon deflation under fluoroscopy and wait 10 – 15 seconds longer.
2. Position the inflation device to “negative” or “neutral” pressure.
3. Stabilize guide catheter position just outside coronary ostium and anchor in place. Maintain guide wire placement across the stent graft segment.
4. Gently remove the stent graft delivery system with slow and steady pressure.
5. Tighten the rotating hemostatic valve.

**Note: If, during withdrawal of the catheter, resistance is encountered, use the following steps to improve balloon rewrap:**

- Re-inflate the balloon up to nominal pressure.
- Repeat steps 1 through 5 above.

## 11.0 *IN VITRO* INFORMATION

**Table 9: GRAFTMASTER RX Compliance Chart – Stent Graft Inner Diameter vs. Pressure**

| Pressure | | Stent ID (mm) by System Diameter | | | | |
|---|---|---|---|---|---|---|
| **atm** | **kPa** | **2.80** | **3.50** | **4.00** | **4.50** | **4.80** |
| 11 | 1115 | 1.37 | 1.83 | 2.30 | 2.86 | 2.98 |
| 12 | 1216 | 1.67 | 2.34 | 2.74 | 3.20 | 3.57 |
| 13 | 1317 | 1.91 | 2.47 | 2.90 | 3.30 | 3.89 |
| 14 | 1419 | 2.08 | 2.63 | 3.08 | 3.52 | 3.98 |
| **15 (nominal)** | **1520** | **2.18** | **2.81** | **3.31** | **3.79** | **4.16** |
| **16 (RBP)*** | **1621** | **2.32** | **3.01** | **3.54** | **3.98** | **4.34** |
| 17 | 1723 | 2.47 | 3.19 | 3.72 | 4.15 | 4.52 |
| 18 | 1824 | 2.62 | 3.32 | 3.86 | 4.31 | 4.64 |
| 19 | 1925 | 2.73 | 3.43 | 3.96 | 4.42 | 4.77 |

**Table 10: GRAFTMASTER RX Compliance Chart – Stent Graft Outer Diameter vs. Pressure**

| Pressure | | Stent OD (mm) by System Diameter | | | | |
|---|---|---|---|---|---|---|
| **atm** | **kPa** | **2.80** | **3.50** | **4.00** | **4.50** | **4.80** |
| 11 | 1115 | 1.89 | 2.35 | 2.82 | 3.38 | 3.50 |
| 12 | 1216 | 2.19 | 2.86 | 3.26 | 3.72 | 4.09 |
| 13 | 1317 | 2.43 | 2.99 | 3.42 | 3.82 | 4.41 |
| 14 | 1419 | 2.60 | 3.15 | 3.60 | 4.04 | 4.50 |
| **15 (nominal)** | **1520** | **2.70** | **3.33** | **3.83** | **4.31** | **4.68** |
| **16 (RBP)*** | **1621** | **2.84** | **3.53** | **4.06** | **4.50** | **4.86** |
| 17 | 1723 | 2.99 | 3.71 | 4.24 | 4.67 | 5.04 |
| 18 | 1824 | 3.14 | 3.84 | 4.38 | 4.83 | 5.16 |
| 19 | 1925 | 3.25 | 3.95 | 4.48 | 4.94 | 5.29 |

**Note:** These nominal data are based on *in vitro* testing at 37°C and do not take into account treatment area resistance.
Ensure full deployment of the stent graft (See Section 10.4 *Deployment Procedure*) and confirm the stent graft sizing angiographically.
*Do not exceed the RBP.

## 12.0 TRADEMARKS

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