

JOSTENT[®] Coronary Stent Graft

Sterile, sterilized with ethylene oxide, for single use only
Do not resterilize

INSTRUCTIONS FOR USE

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Humanitarian Device. Authorized by Federal Law for the 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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These instructions for use are intended for all personnel who handle the JOSTENT® Coronary Stent Graft and should be read and understood before using the product. The clinical techniques and procedures described herein do not represent all medically accepted coronary stent implantation procedures, nor are they intended as a substitute for the physician's experience, but are offered to clinicians as a guide.

1.0 DEVICE DESCRIPTION

The JOSTENT® Coronary Stent Graft System includes:

- Two high-grade surgical steel flexible stents, manufactured from a solid tube using precision laser technology, with an expandable PTFE graft material wrapped between the two stents. The inner diameter of the stent is 1.8 mm, and the outer diameter is 2.4 mm.
- A stent holder used to assist in accurately placing the stent on a marketed high-pressure, non-compliant PTCA Catheter before hand crimping.
- The JOSTENT® Coronary Stent Graft is designed to be physician-mounted on a currently marketed high-pressure, non-compliant PTCA Catheter. The rated burst pressure of the catheter must be at least 14 atm, and the balloon should display less than 10% growth from nominal diameter inflation pressure to rated burst pressure.

The JOSTENT® Coronary Stent Graft has been tested with several non-compliant balloons, including: the Cordis Titan (RBP=16atm), the Scimed NC Ranger (RBP=18atm in a stent), and the Scimed Maxxum (RBP=20atm).

Figure 1 JOSTENT® Coronary Stent Graft

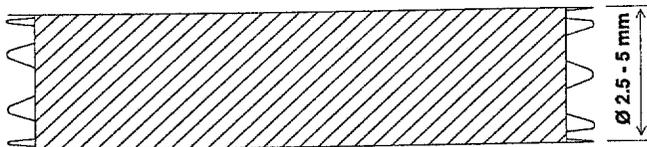


Table 1 Device Specifications

Stent Length	Vessel Diameters	Min. Balloon length	Min. Balloon RBP	Min. Deployment Pressure	Min. Guiding Catheter ID
9 mm	2.75 – 5.0 mm	11 mm	14 atm	14 atm	6 F for stent grafts expanded to ≤3.5 mm
12 mm	2.75 – 5.0 mm	14 mm	14 atm	14 atm	
16 mm	2.75 – 5.0 mm	18 mm	14 atm	14 atm	
19 mm	2.75 – 5.0 mm	21 mm	14 atm	14 atm	7 F for stent grafts expanded to >3.5 mm
26 mm	2.75 – 5.0 mm	28 mm	14 atm	14 atm	

2.0 INDICATIONS

The JOSTENT® Coronary Stent Graft 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.

3.0 CONTRAINDICATIONS

The JOSTENT® Coronary Stent Graft is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.

4.0 WARNING

- Patients allergic to surgical stainless steel or PTFE may suffer an allergic reaction to this implant.

5.0 PRECAUTIONS

(See also Individualization of Treatment)

- Only physicians who have received appropriate angioplasty training should perform implantation of the stent.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass surgery can be readily performed.
- Subsequent restenosis may require re-dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of coronary stents is unknown.
- When multiple stents are required, stent materials should be of similar composition.

5.1 Stent Handling – Precautions

- **For single use only.** Do not resterilize or reuse. Note product “Use Before” date.
- The **JOSTENT®** Coronary Stent Graft is designed to be physician-mounted on a currently marketed high-pressure, non-compliant PTCA Catheter. The rated burst pressure of the catheter must be at least 14 atm, and the balloon should display less than 10% growth from nominal diameter inflation pressure to rated burst pressure.
- Any coating on the delivery PTCA catheter must be removed prior to mounting the stent. The coating on the PTCA catheter is removed by gently wiping the PTCA catheter with a compress soaked in an alcohol solution (e.g 70% Ethanol). Do not manipulate or shorten the stent. Manipulation may cause the stents to separate from the PTFE layer (de-laminate).
- The stent should be placed accurately between the marker bands on the balloon and then hand-crimped into place starting distally and working proximally, rotating the balloon by 90° until the stent is securely fixed. Excessive manipulation may cause dislodgment of the stent from the delivery balloon.
- Special care must be taken not to handle or in any way disrupt the stent position on the delivery device after mounting. This is most important during placement over the guide wire and advancement through the hemostasis valve adaptor and guiding catheter hub.
- Use only appropriate balloon inflation media. Do not use air or any gas medium to inflate the balloon as it may cause uneven expansion and difficulty in deployment of the stent.

5.2 Stent Placement – Precautions

- Prepare and pre-inflate the balloon prior to stent mounting, according to the manufacturer's Instructions for Use. Purge the balloon as directed for mounting of the stent.
- 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 (e.g., CABG, further dilatation, placement of additional stents, or other). Please refer to Table 1 for recommended balloon lengths. The chosen diameter of the balloon should correspond to the vessel diameter (ratio 1:1).
- If more than one stent is required, the distal stent should be placed initially, followed by placement of the proximal stent. Stenting in this order obviates the need to cross the proximal stent when placing the distal stent and reduces the chances for dislodging the proximal stent.

- Do not expand the stent if it is not properly positioned in the vessel (See Stent/System Removal – Precautions)
- Placement of the stent will compromise side branch patency.
- Balloon pressures should be monitored during inflation. **Do not exceed rated burst pressure as indicated on product label.** Use of pressures higher than specified on the product label may possibly result in a ruptured balloon and potential intimal damage and dissection.
- **Do not attempt to pull an unexpanded stent back through the guiding catheter; dislodgment of the stent from the balloon may occur.** (See Stent/System Removal – Precautions)
- Stent retrieval methods (use of additional wires, snares, and/or forceps) may result in additional trauma to the vascular access site. Complications may include bleeding, hematoma, or pseudoaneurysm.

5.3 Stent/System Removal – Precautions

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

When removing the Delivery System as a single unit:

- It's recommended maintaining guidewire placement across the lesion and carefully pulling back the Stent Delivery System until the proximal balloon marker of the Stent Delivery System is aligned with the distal tip of the guiding catheter. **Do not pull the Stent Delivery System into the guiding catheter.**
- The guiding catheter and Stent Delivery system should be carefully removed from the coronary artery as a single unit.
- The system should be pulled back into the descending aorta toward the arterial sheath.
As the distal end of the guiding catheter enters into the arterial sheath, the catheter will straighten allowing safe withdrawal of the Stent Delivery System into the guiding catheter and the subsequent removal of the Stent Delivery System from the arterial sheath.
- Failure to follow these steps and / or applying excessive force to the Stent Delivery System can potentially result in loss or damage to the stent or Stent Delivery System components such as the balloon.

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

5.4 Post-Stent Placement – Precautions

- Care must be exercised when crossing a newly deployed stent with an intravascular ultrasound (IVUS), or a coronary guidewire, or balloon catheter, to avoid disrupting the stent geometry.
- Do not perform Magnetic Resonance Imaging (MRI) scan on patients post-stent implantation until the stent has been completely endothelialized (eight weeks) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

6.0 ADVERSE EVENTS

Data were collected from a total of 41 patients in a multi-center, retrospective analysis of use of the **JOSTENT**[®] Coronary Stent Graft to treat perforations. These patients form the basis of the observed events reported (See Clinical Studies).

6.1 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 implantation.

No patients who received the **JOSTENT**[®] Coronary Stent Graft died, experienced a Q-wave MI, or necessitated emergent CABG during the procedure or in-hospital stay. All stents were successfully delivered.

Table 2 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**[®] implantation, except for a single out of lab effusion that progressed to tamponade and required emergent re-PTCA with placement of a second **JOSTENT**[®], which sealed the perforation.

Table 3 In-hospital Adverse Events

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

Ajluni SC, Glazier S, Blankenship L, O'Neill WW, Safian RD. Perforations after percutaneous coronary interventions: clinical, angiographic, and therapeutic observations. *Cathet Cardiovasc Diagn.* 1994;32:206-12.

6.2 Potential Adverse Events

Adverse events (in alphabetical order) that may be associated with the use of a coronary stent in native coronary arteries may include:

- Acute myocardial infarction
- Arrhythmia's (including VF and VT)
- 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 embolization
- Stent thrombosis/occlusion
- Stroke/Cerebrovascular Accidents
- Total occlusion of coronary artery

7.0 CLINICAL STUDY

7.1 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.

7.2 Design

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

JOMED is aware of a total of 46 perforations treated worldwide with the **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.

7.3 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 (59.0%), previous CABG (27.5%), previous PTCA (30.8%), and CCS 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 4 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 5 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 (75.0%)	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%)	
CCS Class I/II	6 (16.7%)	5
CCS 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 JOMED. No information has been received regarding these cases.

Table 6 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	1
Native vessel	33 (80.5%)
SVG	8 (19.5%)
Average number of stents used	1.3 (range: 1-3)
JOSTENT® deployed successfully	52 (100%)
Perforation closed/vessel sealed	41 (100%)

Table 7 In-Hospital MACE

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

Table 8 Procedural Complications

N=41 subjects	N occurrences
Patients experiencing 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**[®] implantation, except for a single out of lab effusion that progressed to tamponade and required emergent re-PTCA with placement of a second **JOSTENT**[®] that sealed the perforation.

Table 9 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.

7.4 Conclusions

The clinical data from a small retrospective study suggest that the **JOSTENT**[®] Coronary Stent Graft can safely be deployed in coronary arteries to seal free perforations. Use of the **JOSTENT**[®] Coronary Stent Graft is not associated with increased risks compared to conventional treatment of perforations.

8.0 INDIVIDUALIZATION OF TREATMENT

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

8.1 Use in Special populations

The effectiveness of this device for any use has not been demonstrated. The safety of the **JOSTENT**[®] Coronary Stent Graft has not been established for patients with any of the following characteristics:

- Patients with **unresolved vessel thrombus** at the lesion site.
- Patients with coronary artery **reference vessel diameters <2.75 mm**.
- Patients with **lesions located** in the unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation.
- Patients with diffuse disease of **poor outflow distal** to the identified lesions.
- 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 has not been established.

9.0 HOW SUPPLIED

STERILE: This device is sterilized with ethylene oxide. It is intended for single use only. Non-pyrogenic. Do not use if package is opened or damaged.

CONTENTS: One (1) **JOSTENT**[®] Coronary Stent Graft on Stent Holder.
One (1) Instructions for Use Manual.

STORAGE: Store in a cool, dry, dark place.

10.0 OPERATOR'S MANUAL

10.1 Inspection Prior to Use

Carefully inspect the sterile package before opening. It is not recommended that the product be used after the "Use Before Date". If the integrity of the sterile package has been compromised prior to the product "Use Before Date" (e.g., damage of the package), contact your local **JOSTENT**[®] Coronary Stent Graft Representative for return information. Do not use if any defects are noted.

10.2 Materials Required

Quantity	Material
	Appropriate balloon dilatation catheter(s). (High pressure, non-compliant; See Table 1 – Device Specifications)
	Appropriate guiding catheter(s). (See Table 1 – Device Specifications)
1	20 cc syringe
	Heparinized Normal Saline
1	0.014 inch x 300 cm guide wire
1	Rotating hemostatic valve
	Contrast medium diluted 1:1 with Heparinized normal saline
1	Inflation device
1	Torque device
Optional	Three-way stopcock

10.3 Stent Mounting

Step	Action
1	Using aseptic techniques, remove the stent from its sterile package and place it onto the sterile field. Rinse the stent and the stent holder with sterile, heparinized saline.
2	Prepare the delivery balloon catheter system on which the stent will be mounted according to the manufacturer's instructions.
3	Fill a 20 cc syringe with 5 cc of contrast/saline mixture (1:1).
4	Attach to delivery catheter and gently inflate with 2-3 atm while moistening the surface with a saline solution. Note: Any coating on the delivery PTCA catheter must be removed prior to mounting the stent. The coating of the PTCA catheter is removed by wiping with a compress soaked in an alcohol solution.
5	Purge the balloon and apply constant negative pressure to the catheter.
6	Pass the stent holder (on which the stent is mounted) over the balloon, making sure the stent is precisely positioned over the balloon, between the two markers
7	While gently holding the stent, remove the plastic tube, leaving the stent in place. Note: Do not inadvertently remove the stent from its correct position over the balloon.
7a	Insert either the stiffening wire that is provided with the PTCA catheter or a guidewire into the guidewire lumen, before starting to crimp the Stent Graft. This will protect the lumen of the PTCA catheter.
8	Starting distally and working proximal, crimp the stent to the balloon. Turn the balloon by 90° and continue crimping the stent on to the device until it is securely fixed.

8a	To verify adherence, hold the catheter and attempt to dislodge the stent from the balloon using the thumb and index finger.
8b	Visually inspect the stent to ensure that it is centered on the balloon and that the stent struts are not protruding away from the balloon. If there are any protruding struts, re-crimp the stent. If the protruding struts remain or the stent is kinked, DO NOT attempt to use the stent.
9	Release the negative pressure to the balloon.
10	Detach syringe and leave a meniscus of mixture on the hub of the balloon lumen.
11	Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.
12	Attach inflation device to balloon directly insuring no bubbles remain at connection.
13	Leave on ambient pressure (neutral position). Note: Do not pull negative pressure on inflation device after balloon preparation and prior to delivering the stent.
14	Moisten the stent with heparinized saline by submerging the stent into a sterile bowl containing the solution. Note: Do not use gauze sponges to wipe down the stent as fibers may disrupt the stent.
15	Visually inspect the stent to insure the stent is place within the area of the proximal and distal balloon markers.
16	Check the integrity of the stent attachment on the delivery system by gently running the stent segment through the thumb and finger. If not intact, contact your JOSTENT® Coronary Stent Graft Representative and return the unused device to JOMED® .

10.4 Delivery Procedure

Step	Action
1	Prepare vascular access site according to standard PTCA practice.
2	Maintain neutral pressure on inflation device. Open rotating hemostatic valve to allow for easy passage of the stent.
3	Ensure guiding catheter stability before advancing the stent delivery system into the coronary artery.
4	Carefully advance the stent delivery system into the hub of the guiding catheter.
5	Note: If physician encounters resistance to the stent delivery system prior to exiting the guiding catheter, do not force passage. Resistance may indicate a problem and may result in damage to the stent if it is forced. Maintain guidewire placement across the lesion and remove the stent delivery system as a single unit. (See Section 5.3 - Stent/System Removal – Precautions.)
6	Advance delivery system over the guide wire to the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers on the balloon as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed. (See Section 5.3 - Stent/System Removal – Precautions.) Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.
7	Optimal stent placement requires the distal end of the stent to be placed approximately 1 mm beyond the distal end of the lesion.
8	Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed.

10.5 Deployment Procedure

Step	Action
1	Gently deploy the stent by slowly inflating the balloon to a minimum of 14 atm to expand the stent. Note: Refer to balloon catheter labeling and Table 1 for the proper inflation pressure. Do not exceed Rated Burst Pressure or expand stent beyond 5.0 mm.
2	Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3	Note: Under-expansion of the stent may result in stent movement. Care must be taken to properly size the stent to ensure the stent is in full contact with the arterial wall upon deflation of the delivery system balloon.

10.6 Removal Procedure

Step	Action
1	Deflate the balloon by pulling negative pressure on the inflation device. Allow adequate time, at least 15 seconds, for full balloon deflation. Longer balloons may require more time for deflation.
2	Fully open the hemostatic valve.
3	Maintain position of guiding catheter and guidewire to prevent it from being drawn into vessel. Very slowly, withdraw the balloon from the stent maintaining negative suction, allowing movement of the myocardium to gently dislodge the balloon from stent.
4	Tighten the hemostatic valve.
5	Repeat angiography and visually assess the vessel and the stent for proper expansion. Note: The use of IVUS is strongly recommended to ensure complete apposition of the stent graft to the vessel wall.
6	A second balloon inflation may be required to insure optimal stent expansion. In such instances, a non-compliant, high-pressure balloon of adequate size (the same size as the stent delivery system balloon or larger) and length may be used to accomplish this. Note: In smaller or diffusely diseased vessels, the use of high balloon inflation pressures may over-expand the vessel distal to the stent and could result in vessel dissection.
7	The final internal stent diameter should be equal to or slightly larger than the proximal and distal reference vessel diameters.
8	Repeat angiography and, if possible, IVUS, to evaluate and determine procedure status or termination. Note: Should the need arise for placement of a second stent to adequately cover the perforation length, placement of the stent most distal in the artery should be done prior to placement of the proximal stent, if possible.
9	Note: Observation of the patient and angiographic evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement

10.7 *in vitro* Information

Table 10 Expanded Stent Diameter (mm) and Length (mm) Chart

JOSTENT® Coronary Stent Graft 2.75 – 5.0 mm		Expanded	
Wall thickness:	0.30 mm	∅	Length
Profile unexpanded	2.20 mm	(mm)	(mm)
Crimped to a profile:	1.60 mm		
Article number: 010CG09		2.5	8.8
<div style="border: 1px solid black; padding: 5px; width: fit-content;"> Length: 9.0 ∅ 2.75-5.0 mm </div>		3	8.4
		3.5	7.8
		4	7.4
		5	<7.4
Article number: 010CG12		2.5	11.8
<div style="border: 1px solid black; padding: 5px; width: fit-content;"> Length: 12.0 2.75-5.0 mm </div>		3	11.5
		3.5	11.1
		4	9.4
		5	<9.4
Article number: 010CG16		2.5	15.0
<div style="border: 1px solid black; padding: 5px; width: fit-content;"> Length: 16.0 ∅ 2.75-5.0 mm </div>		3	14.7
		3.5	14.4
		4	11.9
		5	<11.9
Article number: 010CG19		2.5	18.2
<div style="border: 1px solid black; padding: 5px; width: fit-content;"> Length: 19.0 ∅ 2.75-5.0 mm </div>		3	18.0
		3.5	17.3
		4	15.9
		5	<15.9
Article number: 010CG26		2.5	24.6
<div style="border: 1px solid black; padding: 5px; width: fit-content;"> Length: 26.0 ∅ 2.75-5.0 mm </div>		3	24.3
		4	22.2
		5	<22.2

Note: Do not exceed rated burst pressure as specified on product label as this may result in a ruptured balloon with possible intimal damage and dissection.

Note: The nominal *in vitro* device specification does not take into account lesion resistance.

Note: The length of the PTFE foil is shorter than the reported stent length. After expansion of the stent, the PTFE foil may be up to 1.6 mm from the each end of the stent graft. The covered length of the stented area may be up to 3.2 mm smaller than the stent length. This information must be considered when choosing an appropriately sized stent graft.

Note: Do not expand the stent beyond 5.0 mm.

Warranty and limitation of liability

JOMED GmbH guarantees that this product has been manufactured, sterilized and packaged in compliance with International Quality Standards for medical devices. Each product is individually tested before it is released for packaging JOMED GmbH will replace any device, which in its opinion was defective at the time of shipment and if defects which were caused during manufacturing or packaging are immediately brought to the attention of JOMED GmbH or its distributors. This warranty is exclusive and in lieu of all other warranties, whether expressed or implied, written or oral, including, but not limited to any implied warranties of merchantability or fitness.

As a result of biological differences in individuals, no product is 100% safe under all circumstances. Due to this fact and since JOMED GmbH has no control over the conditions under which the device is used, the diagnosis of the patient, methods of administration, or its handling after the device has left our possession, JOMED GmbH and its distributors do not guarantee either a good effect or against a poor result following its use. JOMED GmbH and its distributors shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of the device. JOMED GmbH and its distributors shall not be liable for damages arising from reesterilization or reuse of the product.