INSTRUCTIONS FOR USE FOR:

GORE TIGRIS®

VASCULAR STENT

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English

INSTRUCTIONS FOR USE FOR

GORE® TIGRIS® Vascular Stent

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

DESCRIPTION

The GORE® TIGRIS® Vascular Stent is a flexible, self-expanding endoluminal stent consisting of a nitinol (NiTi = Nickel:Titanium) stent and an external fluoropolymer lattice extending along its entire length (Figure 1). The CBAS® Heparin Surface on the GORE® TIGRIS® Vascular Stent consists of stable, covalent, end-point attached heparin of porcine origin. The stent is compressed and attached to a tri-axial delivery catheter (Figure 2). The central catheter lumen is used for flushing and guidewire introduction. The delivery catheter handle assembly has one port for flushing and guidewire insertion. To facilitate accurate stent placement, two radiopaque metallic bands are attached to the catheter shaft, marking the ends of the compressed stent. The GORE® TIGRIS® Vascular Stent is supplied STERILE. The GORE® TIGRIS® Vascular Stent should not be resterilized.

FIGURE 1: *GORE® TIGRIS®* VASCULAR STENT

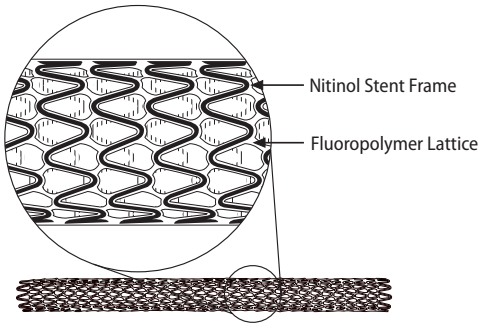
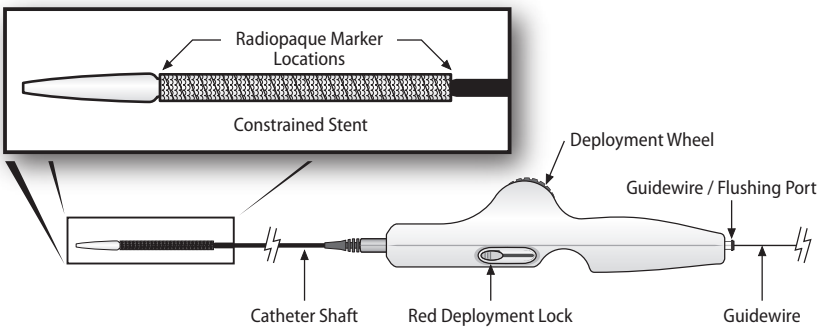


FIGURE 2: *GORE® TIGRIS®* VASCULAR STENT DELIVERY SYSTEM



INTENDED USE / INDICATIONS

The GORE® TIGRIS® Vascular Stent is intended to improve luminal diameter in patients with symptomatic de-novo or restenotic lesions or occlusions in the native superficial femoral artery (SFA) and proximal popliteal artery (PPA) with reference vessel diameters ranging from 4.0 - 6.5 mm and lesion lengths up to 240 mm.

CONTRAINDICATIONS

The GORE® TIGRIS® Vascular Stent is contraindicated for non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. The GORE® TIGRIS® Vascular Stent is contraindicated in patients with contraindication to antiplatelet and/or anticoagulation therapy. DO NOT use the GORE® TIGRIS® Vascular Stent in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II.

TABLE 1: SIZING TABLE

Device Sizing		Introducer Sheath Size (Fr)	Guidewire Diameter	Recommended Balloon Diameter for Device Touch-up (mm)
Labeled Device Diameter (mm)	Recommended Vessel Diameter[1] (mm)			
5	4.0 – 4.7	6	0.035" (0.889 mm)	5.0
6	4.8 – 5.5	6	0.035" (0.889 mm)	6.0
7	5.6 – 6.5	6	0.035" (0.889 mm)	7.0

[1] Recommended stent compression within the vessel is approximately 5 – 20%.

PACKAGE HANDLING

Store in a cool dry place. This product has an expiration date and should be used before the labeled "use by" (expiration) date marked on the box. The foil pouch for the GORE® TIGRIS® Vascular Stent is both a moisture barrier and a sterile barrier. DO NOT use or store the device if the foil pouch has been compromised.

METHOD

- Preparation of patients receiving the GORE® TIGRIS® Vascular Stent should include initiation of an appropriate dosage of oral antiplatelet medication prior to and following the procedure. Effective anticoagulation therapy should be maintained throughout the procedure and continued into the postoperative period, as deemed appropriate by the treating physician.
- **Prior to implantation of the GORE® TIGRIS® Vascular Stent, the physician should refer to the Sizing Table (Table 1) and read the Directions for Use.**
- Proper placement of the stent should be monitored and confirmed using fluoroscopy.
- Sterile precautions should be the same as for any device implant procedure.
- Post-deployment stent dilation with an appropriately sized balloon is recommended to ensure complete stent-to-vessel apposition. If performed, select an appropriately sized balloon (**Table 1**) that matches the size of the reference vessel but one that is not larger than the labeled stent diameter.

WARNINGS

- Do not use the GORE® TIGRIS® Vascular Stent for the treatment of ostial lesions or lesions involving a major side branch that may be crossed by the stent.
- Do not use in patients with a history of intolerance or adverse reaction to antiplatelet and / or anticoagulation therapies, bleeding diathesis, severe hypertension or renal failure.
- With any vascular procedure, the possibility of HIT may exist. The incidence of HIT type II is extremely low in vascular patients receiving heparin over a period of several days. If HIT type II is diagnosed, established procedures for the treatment of this condition, including immediate cessation of systemic heparin administration, should be followed.[1,2] If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures, including ligation or removal of the device, may be considered at the discretion of the attending physician.
- Do not use a kinked introducer sheath. A kinked introducer sheath may increase the force necessary to deploy the stent and may cause a deployment failure or catheter breakage on removal.
- Should it become necessary to remove the GORE® TIGRIS® Vascular Stent from the vessel after unlocking the device, DO NOT reuse the GORE® TIGRIS® Vascular Stent. This can result in premature deployment.
- Inadvertent, partial, or failed deployment or migration of the stent may require surgical intervention.

PRECAUTIONS

- The GORE® TIGRIS® Vascular Stent is designed for single use only.
- Do not use the GORE® TIGRIS® Vascular Stent if the sterile package is compromised or the GORE® TIGRIS® Vascular Stent is damaged.
- Do not use the GORE® TIGRIS® Vascular Stent after the labeled "use by" (expiration) date.
- Do not resterilize the GORE® TIGRIS® Vascular Stent.
- The GORE® TIGRIS® Vascular Stent should only be used by physicians trained in endovascular techniques.
- Follow the *Directions for Use* supplied with all accessories used in conjunction with the GORE® TIGRIS® Vascular Stent.
- The stent is not designed for repositioning once deployment is started.
- Do not dilate the stent with a balloon longer than the labeled stent length. Refer to Sizing Table (**Table 1**) for selection of appropriate balloon diameter.
- Do not attempt to withdraw or reposition a balloon catheter within the lumen of the deployed stent unless the balloon is completely deflated.
- Antiplatelet medication should be initiated prior to placement of the GORE® TIGRIS® Vascular Stent. Effective anticoagulation therapy should be maintained at a dosage deemed appropriate by the physician. The presence of heparin on the GORE® TIGRIS® Vascular Stent is not intended to serve as an alternative to the physician's chosen intraoperative or postoperative anticoagulation regimens.

MRI SAFETY INFORMATION MR CONDITIONAL

Non-clinical testing has demonstrated that the GORE® TIGRIS® Vascular Stent is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla
- Maximum spatial gradient magnetic field of 4000-Gauss/cm (extrapolated)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode) for 15 minutes of scanning.

Under the scan conditions defined above, the GORE® TIGRIS® Vascular Stent is expected to produce a maximum temperature rise of less than 4.7ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the GORE® TIGRIS® Vascular Stent when imaged with a spin echo or gradient echo pulse sequence and a 3T MRI system. The lumen could be visualized using spin echo and gradient echo pulse sequences.

HAZARDS AND ADVERSE EVENTS

Procedure Related: As with all procedures that utilize techniques for introducing a catheter into a vessel, complications may be expected. These complications include, but are not limited to: access site infection; entry site bleeding and / or hematoma; hemorrhage; nausea or vomiting; vasospasm; vessel thrombosis, occlusion, pseudoaneurysm, aneurysm, and trauma to the vessel wall (including rupture or dissection); distal embolization; the need for urgent intervention or surgery; arteriovenous fistula formation; drug reactions; hypotension/hypertension; transient or permanent contrast induced renal failure; renal toxicity; sepsis; shock; radiation injury; fever; pain; arrhythmia; bradycardia; angina; myocardial infarction; stroke; leg pain or claudication; extremity ischemia or amputation; tissue ischemia or necrosis; cerebral vascular accident; malposition; malapposition; inflammation; and / or death.

Device Related: Complications and adverse events can occur when using any endovascular device. These complications include, but are not limited to: allergic reaction; hematoma; stenosis, restenosis; thrombosis or occlusion; distal embolism; vessel wall injury including perforation, trauma, dissection, and rupture; false aneurysm; infection; inflammation; fever and / or pain in the absence of infection; deployment failure; migration; stent fracture; target lesion revascularization; and device failure. A possible complication which may occur in conjunction with the use of any heparin-containing product: HIT type II.

SUMMARY OF CLINICAL INFORMATION

IDE Study

The primary objective of this randomized study was to evaluate the safety and effectiveness of the GORE® TIGRIS® Vascular Stent in the treatment of de novo and restenotic atherosclerotic lesions ≤ 24 cm in length in the superficial femoral artery (SFA) and proximal popliteal artery (PPA) of patients with symptomatic PAD. This study was conducted at 33 investigational sites throughout the US and at three sites in the EU (36 total sites). As a condition of US FDA pre-market approval for the GORE® TIGRIS® Vascular Stent, a Post-Approval Study was performed to demonstrate the long term safety and efficacy of the GORE® TIGRIS® Vascular Stent. This study consisted of continued follow up to 3 years for subjects of the IDE study.

The IDE study utilized an unblinded, prospective, multi-center, randomized control design. Outcomes of study subjects randomly assigned to therapy with the GORE® TIGRIS® Vascular Stent were compared to those of subjects randomly assigned to therapy with the BARD® LifeStent® Vascular Stent (Control). A total of 274 subjects were randomized using a 3:1 ratio, (GORE® TIGRIS® Vascular Stent:Control device). Cases of eligibility violations were reviewed and adjudicated by the Data Safety Monitoring Board (DSMB). Subjects who were deemed by the DSMB to have had protocol deviations that could affect the evaluation of primary endpoints were excluded from the per-protocol (PP) population. All endpoint data reported is based on the PP population, unless otherwise specified. Data analyses for other important patient cohorts (Intent-to-Treat and As-Treated) demonstrated similar results.

Baseline subject demographics and medical history are summarized in **Table 2**. Procedural characteristics are summarized in **Table 3**.

TABLE 2: BASELINE DEMOGRAPHICS AND MEDICAL HISTORY

Variable	GORE® TIGRIS® Vascular Stent	Control Device	P-value*
Number of Subjects (unless otherwise specified)	**N=197**	**N=70**	
Location of Site			
US	142 (72.1%)	54 (77.1%)	
Outside US	55 (27.9%)	16 (22.9%)	
Gender - Male	141 (71.6%)	49 (70.0%)	0.878
Total Occlusions	83 (42.1%)	26 (37.1%)	0.483
Smoking History	180 (91.4%)	60 (85.7%)	0.460
Body Mass Index (BMI) Mean (Std Dev)	28.0 (5.0)	28.4 (6.0)	0.626**
Diabetes Mellitus	79 (40.1%)	30 (42.9%)	0.777
Hypertension	171 (86.8%)	55 (78.6%)	0.122
Hyperlipidemia	137 (69.5%)	48 (68.6%)	0.881
Hypercholesterolemia	107 (54.3%)	40 (57.1%)	0.780
Coronary Artery Disease (CAD)	98 (49.7%)	32 (45.7%)	0.580
Myocardial Infarction (MI)	36 (18.3%)	10 (14.3%)	0.581
Baseline Rutherford Category			0.772
Category 2 - Moderate Claudication	62 (31.5%)	22 (31.4%)	
Category 3 - Severe Claudication	125 (63.5%)	43 (61.4%)	
Category 4 - Ischemic Rest Pain	10 (5.1%)	5 (7.1%)	
Age at Procedure (yrs)	**N=195**	**N=70**	0.385**
Mean (Std Dev)	66.8 (9.30)	67.9 (8.87)	
Baseline ABI	**N=193**	**N=70**	0.545**
Mean (Std Dev)	0.66 (0.164)	0.65 (0.157)	
Calcification	**N=189**	**N=66**	0.442
None or mild	99 (52.4%)	28 (42.4%)	
Moderate or severe	90 (47.6%)	38 (57.6%)	
Tibial Runoff Vessels	**N=187**	**N=69**	0.156
1	21 (11.2%)	11 (15.9%)	
2	106 (56.7%)	30 (43.5%)	
3	60 (32.1%)	28 (40.6%)	

* P-value obtained with the Fisher's Exact Test unless otherwise noted.

** P-value obtained with the t-test.

TABLE 3: PROCEDURAL CHARACTERISTICS

Variable	GORE® TIGRIS® Vascular Stent	Control Device	P-value*
Number of Subjects (unless otherwise specified)	**N=197**	**N=70**	
Total Implanted Length (mm) Mean (Std Dev)	129.0 (73.3)	148.7 (75.4)	0.057**
Min - Max	0 - 340	20 - 300	
Ongoing Spasm Post-procedure	0 (0.0%)	0 (0.0%)	1.000
Implants(s) Successfully Deployed	196 (99.5%)	70 (100%)	1.000
Significant Distal Embolization That Was Not Successfully Treated	0 (0.0%)	0 (0.0%)	1.000
Maximum Residual Stenosis < 30%	**N=196**	**N=70**	0.263
Yes	196 (100%)	69 (98.6%)	
Number of Implants	**N=196**	**N=70**	0.033
1	101 (51.5%)	44 (62.9%)	
2	55 (28.1%)	22 (31.4%)	
3	36 (18.4%)	4 (5.7%)	
4	4 (2.0%)	0 (0.0%)	
Implant(s) Fully Apposed Post-dilation Balloon	**N=196**	**N=69**	1.000
Yes	196 (100.0%)	69 (100.0%)	

* P-value obtained with the Fisher's Exact Test unless otherwise noted.

** P-value obtained with the t-test.

Primary Safety Endpoint

The primary safety endpoint in this study was freedom from major adverse events (MAE) observed within 30 days of implantation, with MAE defined as death, target vessel revascularization (TVR), and amputation above the metatarsals in the treated leg (index limb amputation). The safety of the GORE® TIGRIS® Vascular Stent was found to be statistically non-inferior to that of the Control device measured 30 days after implant ($p<0.001$* using a one-sided z-test with a pooled variance estimate and a 12% margin). In the GORE® TIGRIS® Vascular Stent group, 99.5% (187/188) of subjects were free from MAEs at 30 days, as compared to 100.0% (69/69) of subjects in the Control device group. By demonstrating non-inferiority to the Control device, the GORE® TIGRIS® Vascular Stent met the primary safety endpoint of the study. Primary safety endpoint data is summarized in **Table 4**.

TABLE 4: PRIMARY SAFETY ENDPOINT - 30 DAY FREEDOM FROM MAE

Variable	GORE® TIGRIS® Vascular Stent	Control Device	P-value*
Freedom from MAE	**N=188**	**N=69**	
Yes	187 (99.5%)	69 (100.0%)	<0.001
95% Confidence Interval**	[97.1%, 100.0%]	[94.8%, 100.0%]	

* The non-inferiority test with a 12% margin was performed using a one-sided z-test with a pooled variance estimate.

** Confidence interval calculated using binomial exact test.

The one GORE® TIGRIS® Vascular Stent MAE within 30 days consisted of a TVR performed on the day of the procedure to treat a procedural complication. After deployment of the GORE® TIGRIS® Vascular Stent, occlusion of the popliteal artery was noted above the knee, but distal to the margins (outside) of the deployed GORE® TIGRIS® Vascular Stent. A guidewire was passed through the occlusion to restore flow, and a prophylactic balloon angioplasty was performed in the peroneal and distal popliteal arteries.

Primary Effectiveness Endpoint

The primary effectiveness endpoint in this study is primary patency at 12 months (365 ± 45 days) after implantation, with primary patency defined as uninterrupted patency without target lesion revascularization (TLR), including the proximal and distal margins, and no restenosis as documented by a PSVR ≤ 2.5 by Color Doppler Ultrasound (CDUS). The effectiveness of the GORE® TIGRIS® Vascular Stent was statistically non-inferior to that of the Control device measured 12 months after implant ($p=0.002$ using a one-sided z-test with a pooled variance estimate and a 19% margin). By demonstrating non-inferiority to the Control device, the GORE® TIGRIS® Vascular Stent met the primary efficacy endpoint of the study. In the GORE® TIGRIS® Vascular Stent group, 57.1% (97/170) of subjects maintained primary patency at 12 months (365 ± 45 days), whereas 54.7% (35/64) of subjects in the Control device group maintained primary patency at this time point. Primary effectiveness endpoint data is summarized in **Table 5**.

TABLE 5: PRIMARY EFFECTIVENESS ENDPOINT – 12 MONTH (365 ± 45 DAYS) PRIMARY PATENCY

	GORE® TIGRIS® Vascular Stent	Control Device	P-value*
Patent at 12 Months	**N=170**	**N=64**	
Yes	97 (57.1%)	35 (54.7%)	0.002
95% Confidence Interval**	[49.3%, 64.6%]	[41.8%, 67.2%]	

* The non-inferiority test with a 19% margin was performed using a one-sided z-test with a pooled variance estimate.

** Confidence interval calculated using binomial exact test.

Post-Approval Study Primary Endpoint

The primary endpoint is primary patency at 36 months and was estimated using Kaplan-Meier time-to-event analysis. Primary patency is defined as uninterrupted patency without TLR, including the proximal and distal margins, and no restenosis as documented by a PSVR ≤2.5 by CDUS. The GORE® TIGRIS® Vascular Stent met the primary endpoint of the Post-Approval Study. The primary endpoint of primary patency at 36 months are similar for the GORE®TIGRIS® device (53.5%) in comparison to the Control device (46.0%) through end of study at 36 months. The primary endpoint data is summarized in **Table 6**.

TABLE 6: PRIMARY PATENCY - 36 MONTH (1095 DAYS)

	GORE® TIGRIS® Vascular Stent	Control Device
Patent at 36 Months	**N=197**	**N=70**
Yes	53.5%	46.0%
95% Confidence Interval	[45.6%, 60.9%]	[33.0%, 58.0%]

Percentages and confidence intervals estimated using Kaplan-Meier time-to-event analysis.

Secondary Endpoints

Secondary safety and effectiveness endpoint data is summarized in **Table 7**.

TABLE 7: SECONDARY ANALYSES – 12 MONTH (365 ± 45 DAYS) UNLESS OTHERWISE NOTED

Variable	GORE® TIGRIS® Vascular Stent	Control Device
Number of Subjects (unless otherwise specified)	**N=197**	**N=70**
Procedural Success[1]	196 (99.5%)	68 (97.1%)
Device Success [2]	196 (99.5%)	70 (100.0%)
Freedom from TVR [3]	74.1%	81.9%
Freedom from TLR [3]	76.3%	81.9%
Freedom from MAE [3]	72.3%	80.1%
Assisted primary patency [3]	93.3%	93.4%
Secondary patency [3]	98.9%	98.3%
Rutherford Improvement [4]	**N=165**	**N=58**
Yes	145 (87.9%)	52 (89.7%)
Ankle-Brachial Index (ABI) improvement	**N=160**	**N=57**
Mean (Std Dev): baseline minus 12 month	0.249 (0.2269)	0.314 (0.2107)
Stent frame fracture [5]	**N=270**	**N=70**
Total	0 (0.0%)	19 (27.1%)
Grade 1	0 (0.0%)	1 (1.4%)
Grade 2	0 (0.0%)	1 (1.4%)
Grade 3	0 (0.0%)	7 (10.0%)
Grade 4	0 (0.0%)	5 (7.1%)
Grade 5	0 (0.0%)	5 (7.1%)

[1] Defined as successful device implantation with a residual stenosis < 30% without acute (within 48 hours) serious adverse events (AEs) defined as: death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the treated leg, or thrombosis of the target vessel occurring after or not successfully treated during the implant procedure.

[2] Defined as successful delivery of implant to the intended site and successful implant deployment.

[3] Day 365 Kaplan-Meier Point estimate.

[4] Defined as improvement in Rutherford Classification by 1 class versus baseline.

[5] "N" shown represents number of implanted devices in patients with available data at 12 month (365±45 days). Fracture grade defined by Jaff, M. et al. Standardized Evaluation and Reporting of Stent Fractures in Clinical Trials of Noncoronary Devices, Catheterization and Cardiovascular Interventions 70:460–462 (2007).

Secondary safety and effectiveness endpoint data from the Post-Approval Study is summarized in **Table 8**.

TABLE 8: SECONDARY ANALYSES - 36 MONTH (1095 ± 45 DAYS) UNLESS OTHERWISE NOTED

Variable	GORE® TIGRIS® Vascular Stent	Control Device
Number of Subjects (unless otherwise specified)	**N = 197**	**N = 70**
Freedom from TVR[1]	63.5%	64.1%
Freedom from TLR[1]	65.7%	63.8%
Freedom from MAE[1]	56.3%	59.7%
Assisted primary patency[1]	89.9%	83.3%
Secondary primary patency[1]	96.9%	96.7%
Rutherford Improvement[2]	**N = 128**	**N = 44**
Yes	90.6%	90.9%
Ankle-Brachial Index (ABI) improvement	**N = 121**	**N = 40**
Mean (Std Dev): baseline minus 36 month	0.259 (0.2293)	0.249 (0.2472)
Stent frame fracture[3]	**N = 183**	**N = 53**
Total	0 (0.0%)	21 (39.6%)
Grade 1	0 (0.0%)	1 (1.9%)
Grade 2	0 (0.0%)	1 (1.9%)
Grade 3	0 (0.0%)	4 (7.5%)
Grade 4	0 (0.0%)	8 (15.1%)
Grade 5	0 (0.0%)	7 (13.2%)

[1] Day 1095 Kaplan-Meier point estimate.

[2] Defined as improvement in Rutherford Classification by 1 class versus baseline.

[3] "N" shown represents number of implanted devices in patients with available data at 12 month (1095±45 days). Fracture grade defined by Jaff, M. et al. Standardized Evaluation and Reporting of Stent Fractures in Clinical Trials of Noncoronary Devices, Catheterization and Cardiovascular Interventions 70:460–462 (2007).

Efficacy Analyses by Lesion Length and Gender

Additional efficacy analyses are summarized in the tables below. All analyses by lesion length are Kaplan-Meier time-to-event analyses using site-reported lesion lengths, and include day 1080 performance estimates. Subjects are considered to have known status if they either lost patency prior to day 1081, or had a follow-up visit with the required testing performed at or after day 1080.

TABLE 9: PRIMARY PATENCY BY LESION LENGTH

Time Points	Day 360			Day 720			Day 1080		
Lesion Lengths	**0-16 cm**	**17-24 cm**	**All**	**0-16 cm**	**17-24 cm**	**All**	**0-16 cm**	**17-24 cm**	**All**
GORE® TIGRIS® Vascular Stent	68.4%	43.6%	63.1%	62.0%	39.7%	57.3%	57.3%	39.7%	53.5%
Control Device	72.9%	52.4%	66.4%	59.1%	31.7%	50.6%	52.8%	31.7%	46.0%

TABLE 10: FREEDOM FROM TLR BY LESION LENGTH

Time Points	Day 360			Day 720			Day 1080		
Lesion Lengths	**0-16 cm**	**17-24 cm**	**All**	**0-16 cm**	**17-24 cm**	**All**	**0-16 cm**	**17-24 cm**	**All**
GORE® TIGRIS® Vascular Stent	82.4%	57.9%	77.2%	74.6%	52.4%	69.9%	69.3%	52.4%	65.7%
Control Device	80.2%	81.8%	80.7%	70.9%	59.7%	67.6%	70.9%	46.4%	63.8%

TABLE 11: SECONDARY PATENCY BY LESION LENGTH

Time Points	Day 360			Day 720			Day 1080		
Lesion Lengths	**0-16 cm**	**17-24 cm**	**All**	**0-16 cm**	**17-24 cm**	**All**	**0-16 cm**	**17-24 cm**	**All**
GORE® TIGRIS® Vascular Stent	99.3%	97.4%	98.9%	99.3%	94.5%	98.3%	98.4%	91.6%	96.9%
Control Device	97.7%	100%	98.4%	97.7%	93.8%	96.7%	97.7%	93.8%	96.7%

TABLE 12: PRIMARY PATENCY AT 12 MONTHS (365±45 DAYS) BY GENDER

Variable	GORE® TIGRIS® Vascular Stent	Control Device
Females	**N=47**	**N=19**
Patent at 12 Months	25 (53.2%)	9 (47.4%)
95% Confidence Interval*	[38.1%, 67.9%]	[24.5%, 71.1%]
Males	**N=123**	**N=45**
Patent at 12 Months	72 (58.5%)	26 (57.8%)
95% Confidence Interval*	[49.3%, 67.4%]	[42.2%, 72.3%]

* Confidence interval calculated using binomial exact test.

IDE STUDY STRENGTHS AND WEAKNESSES

A major strength of the study was the prospective, multicenter, randomized-control design that directly compared two treatment modalities for de novo and restenotic atherosclerotic lesions in the SFA and PPA of patients with symptomatic PAD. Additionally, the 36 month follow-up Post-Approval Study allowed for long-term evaluation of safety and effectiveness. A potential limitation of the study was that the 3:1 randomization scheme provided relatively smaller numbers of patients in the control group, limiting subsequent subgroup analysis. A second potential limitation of the study was the availability of longer lengths of the Control device (up to 170 mm length devices) while the GORE® TIGRIS® Vascular Stent was available only up to 100 mm. This may have compounded the effects of longer lesion length and overlapped devices when treating longer lesions.

IDE STUDY RESULTS SUMMARY AND CONCLUSIONS

The safety of the GORE® TIGRIS® Vascular Stent was found to be statistically non-inferior to that of the Control device measured 30 days after implant ($p<0.001$). Furthermore, the frequency and types of reported adverse events (AEs) were comparable between the two treatment groups, and no unanticipated device- or procedure-related events were reported.

The effectiveness of the GORE® TIGRIS® Vascular Stent was found to be statistically non-inferior to that of the Control device measured 12 months after implant ($p=0.002$).

Data presented demonstrate that the GORE® TIGRIS® Vascular Stent is safe and effective in improving blood flow in patients with symptomatic peripheral artery disease in superficial femoral and proximal popliteal artery lesions.

MATERIALS REQUIRED FOR IMPLANTATION

- GORE® TIGRIS® Vascular Stent
- Marker guidewire or catheter (for calibrated measurement reference)
- Syringe filled with heparinized saline
- Introducer sheath of appropriate size (**Table 1**)
- Appropriate guidewire [a 0.035" (0.889 mm) diameter guidewire is recommended]
- A guidewire with a length at least twice the length of the GORE® TIGRIS® Vascular Stent delivery catheter
- Appropriate angioplasty balloon catheters and accessories (**Table 1**)
- Appropriate diagnostic catheters and accessories

DIRECTIONS FOR USE

Treatment of Vessel Obstruction

A. Access

1. Using standard techniques, gain access to the vessel and insert the vascular introducer sheath.

B. Imaging and Measurement

1. To determine the appropriate device size, measure the vessel diameter and lesion length using standard imaging techniques.

C. Percutaneous Transluminal Angioplasty (PTA) (if required at the discretion of the attending physician)

1. Refer to manufacturer's *Directions for Use*.
2. Inflate the angioplasty balloon to its nominal pressure according to manufacturer's *Directions for Use*. Ensure full expansion of the balloon within the lesion.
   Note: Carefully mark the margins of the angioplasty treatment segment in order to ensure complete coverage with the stent.
3. Following deflation of the angioplasty balloon, evaluate the results angiographically.

D. Sizing and Selection of the GORE® TIGRIS® Vascular Stent

1. Prior to opening the Sterile Package, check that the diameter and length of the stent as well as the delivery catheter length are correct.
   a. In selecting the appropriate size stent, a careful assessment of the vessel is necessary. In general, to assure adequate anchoring, the diameter of the stent should be approximately 5 – 20% larger than the healthy vessel diameter immediately proximal and distal to the lesion (**Table 1**).

b. Where possible it is recommended to extend the stent into healthy vessel at least 1 cm beyond the proximal and distal margins of the lesion.
c. Verify that there is sufficient catheter length to access the treatment site.

2. When overlapping (telescoping) multiple devices, the following are suggested:
   - Balloon touch-up (post-dilation) should be performed on the first device prior to placing the second device.
   - To ensure proper seating, at least 1 cm of overlap between devices is suggested.
   - Overlapping devices should not differ by more than 1 mm in diameter.
   - If unequal device diameters are used, the smaller device should be placed first and then the larger device should be placed inside of the smaller device.

E. Preparation of the GORE® TIGRIS® Vascular Stent

1. Open the sterile package. Carefully inspect the packaging for damage to the sterile barrier. Do not use the GORE® TIGRIS® Vascular Stent after the "use by" (expiration) date. Peel back the outer pouch and remove the sterile inner pouch, coil and backer card containing the GORE® TIGRIS® Vascular Stent. Beginning at one corner, peel back the edge of the inner pouch and gently remove the GORE® TIGRIS® Vascular Stent.
2. Inspection Prior to Use.
   - Prior to using the GORE® TIGRIS® Vascular Stent, all materials and equipment to be used for the procedure should be carefully examined for bends, kinks, or other damage. **Do not manipulate the constrained stent.**
   - Do not use any defective equipment.
   - Do not use the GORE® TIGRIS® Vascular Stent if the sterile package is compromised or the GORE® TIGRIS® Vascular Stent is damaged.
3. Preparation of the GORE® TIGRIS® Vascular Stent delivery catheter.
   a. Flush the delivery catheter by attaching a syringe of heparinized saline to the flushing port on the handle (Figure 2). Continue flushing until a steady stream of fluid exits the tip of the catheter.
   b. After flushing the catheter, remove the syringe.
4. Do not let the surface of the GORE® TIGRIS® Vascular Stent dry once it has been wetted.

F. Introduction and Positioning of the GORE® TIGRIS® Vascular Stent

1. Select the compatible introducer sheath size from **Table 1**.
2. Ensure the guidewire is 0.035" (0.889 mm). The guidewire must have a length at least twice that of the delivery catheter.
3. Be sure to remove the balloon catheter while maintaining the position of the guidewire beyond the target lesion.
4. **Do not manipulate the constrained stent.**
5. With the delivery catheter as straight as possible, insert the guidewire into the tip of the delivery catheter while supporting the delivery catheter and the compressed stent. Carefully advance the device in small increments (approximately 0.5 cm) over the guidewire, through the hemostasis valve and introducer sheath, and into the access vessel. **Note:** If excessive resistance is felt as the GORE® TIGRIS® Vascular Stent is introduced through the hemostasis valve, remove and inspect the delivery system for damage. Do not reuse the GORE® TIGRIS® Vascular Stent if damaged. Ensure a compatible introducer sheath size (**Table 1**), and that the introducer sheath is free of kinks. To decrease introduction force, consider GENTLY moistening constrained stent using standard techniques. **DO NOT TWIST THE DEVICE WHILE INSERTING IT THROUGH THE INTRODUCER SHEATH.**
6. Using fluoroscopic guidance, advance the delivery catheter over the guidewire via the sheath. Advance cautiously, especially if resistance is felt. If excessive resistance is felt, remove the delivery catheter.
7. Position the GORE® TIGRIS® Vascular Stent across the target lesion using the radiopaque markers on the catheter. These markers identify the proximal and distal ends of the stent, respectively. **Note:** If PTA is performed, the stent length should cover the entire vessel segment treated with balloon angioplasty. For treatment of stenotic or occlusive lesions, the stent should extend at least 1 cm proximal and distal to the margins of the lesion.

G. Final Positioning and Deployment of the GORE® TIGRIS® Vascular Stent

1. While keeping the extracorporeal segment of the catheter as straight as possible (Figure 3A), unlock the device by pushing the deployment lock on the handle inward and simultaneously sliding toward the rear of the handle until it reaches its full extent of travel (Figure 3B). Note that the nose of the handle will retract during the unlocking operation.
   Note: If resistance is encountered during the unlock procedure, gently push the nose of the handle toward the handle and continue to deploy.
2. After the unlock procedure is completed, finalize the position of the stent across the target lesion and verify fluoroscopically.
3. Stabilize the handle against the table and the delivery catheter at the hemostasis valve of the introducer sheath. It is also important to stabilize the delivery catheter and introducer sheath relative to the patient. This will minimize catheter movement during deployment and ensure accurate stent positioning.
4. Rotate the deployment wheel as shown (Figure 3C) to deploy the stent.
   Note: Deployment of the stent will occur from the tip of the delivery catheter toward the hub.

Note: Once deployment has started, repositioning of the stent or advancing the delivery system should not be attempted.
Note: Should it become necessary to remove the GORE® TIGRIS® Vascular Stent from the vessel after unlocking the device, DO NOT reuse the GORE® TIGRIS® Vascular Stent. This can result in premature deployment.

FIGURE 3A:

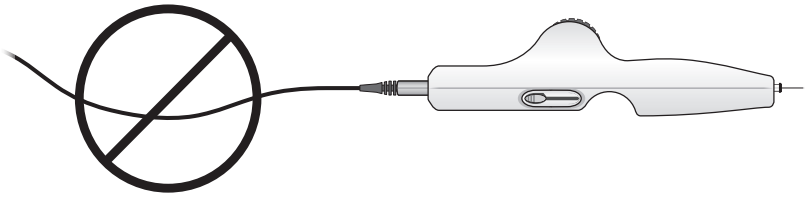


FIGURE 3B:

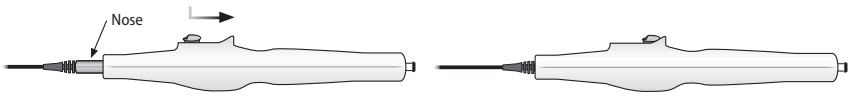
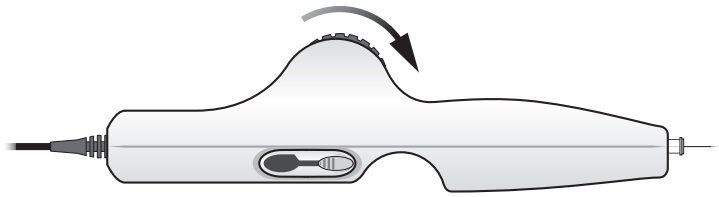


FIGURE 3C:



5. While maintaining the position of the guidewire across the treated lesion, carefully withdraw the delivery catheter through the lumen of the stent and remove it via the introducer sheath. Moderate resistance may be felt when the distal tip is withdrawn through the introducer sheath. Excessive or abrupt force during catheter removal may damage the stent, delivery catheter, or introducer sheath.
6. After deployment, it is recommended to inflate an angioplasty balloon within the stent to ensure complete apposition to the vessel wall. Balloon diameter should be selected according to **Table 1** and should be inflated to the desired diameter along the entire length of the stent. If the stent length exceeds that of the balloon, multiple inflations may be needed. After the balloon is inflated throughout the stent, attention is required to ensure complete deflation of the balloon prior to cautious removal of the balloon catheter to prevent stent displacement. **Do not extend balloon dilation beyond the ends of the device and into healthy vessel as this may induce restenosis.**
7. Using contrast angiography, evaluate the treated segment prior to completing the procedure. A final angiographic run to evaluate vessel patency is recommended.
8. When clinically appropriate, remove the introducer sheath and achieve hemostasis of the puncture site.

REFERENCES

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2. Warkentin TE. Heparin-coated intravascular devices and heparin-induced thrombocytopenia. In: Warkentin TE, Greinacher A, eds. *Heparin-Induced Thrombocytopenia*. 5th ed. New York, NY: Informa Healthcare USA; 2012;(20):573-590.

DEFINITIONS

EC REP Authorised Representative in the European Community

LOT Batch Code

REF Catalogue Number

Caution

℞ Only CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

Consult Instructions for Use

Date of Manufacture

Do Not Resterilize

Do Not Reuse

Do Not Use if Package is Damaged

Keep Dry

Manufacturer

MR Conditional

SN Serial Number

STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

Store in a Cool Place

Use By

Catheter Working Length

Delivery Profile

Diameter

Guidewire Compatibility

Vessel Diameter

20053240

Manufacturer

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