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PERIPHERAL VASCULAR

Percutaneous Plug-Based Arteriotomy Closure Device for Large-Bore Access

A Multicenter Prospective Study

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ABSTRACT

OBJECTIVES The authors sought to study the safety and efficacy of the MANTA Vascular Closure Device (VCD), a novel collagen-based technology dedicated to closure of large-bore arteriotomies.

BACKGROUND Novel transfemoral therapeutic interventions requiring large-bore catheters have become valid minimally invasive options but have inherent access management challenges. To date, no dedicated vascular closure devices exist for large arteriotomies.

METHODS A prospective, single-arm clinical investigation enrolling patients who underwent elective percutaneous interventions with large-bore catheters and planned percutaneous arteriotomy closure in 3 European institutions.

RESULTS A total of 50 patients with a mean age of 79.5 ± 8.3 years underwent high-risk percutaneous coronary intervention, balloon aortic valvuloplasty, or transcatheter aortic valve replacement with large-bore catheters sized 12-F to 19-F. MANTA closure was performed by 9 different operators. The 14-F MANTA VCD was deployed in one-third of the overall cohort (16 of 50, 32%), and the 18-F MANTA VCD in the remainder. The MANTA VCD was deployed successfully in all patients. The mean time to hemostasis was 2 min, 23 s. One patient had a major vascular and major bleeding complication with prolonged femoral bleeding that was successfully treated with a covered stent and eventual surgical repair. There were no other access site-related complications.

CONCLUSIONS This first multicenter experience demonstrates rapid and reliable hemostasis and low complication rates with the use of the plug-based MANTA VCD for large-bore arteriotomy closure. (J Am Coll Cardiol Intv 2017;10:613–9)

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ABBREVIATIONS AND ACRONYMS

CE = Conformité Européenne

CT = computed tomography

OD = outer diameter

RBC = packed red blood cells

TAVR = transcatheter aortic valve replacement

TTH = time to hemostasis

VARC = Valve Academic Research Consortium

VCD = vascular closure device

The advent of endovascular aneurysm repair, transcatheter aortic valve replacement (TAVR), and mechanical circulatory support has offered new, minimally invasive therapeutic options that are rapidly becoming standard of care. These percutaneous transfemoral interventions require large-bore catheters and have created challenges for femoral arterial access management. Current approaches include surgical cut-down with arterial puncture under direct vision, and suture-based "pre-closure." Surgical cut-down is associated with longer procedural time, increased patient discomfort, deeper anesthesia, risk of wound complications including infection, and slower ambulation. The pre-closure technique overcomes many of the disadvantages of surgical cut-down but can be technically demanding, time consuming, and associated with a significant failure rate. Recent randomized TAVR trials have reported major vascular complications in 6% to 8% (1,2). Furthermore, a study on the 2 suture-based closure techniques for management of TAVR access reported a 20% vascular complication rate despite being used by experienced operators (3). Currently, the majority of access site complications result from failed arteriotomy closure (4).

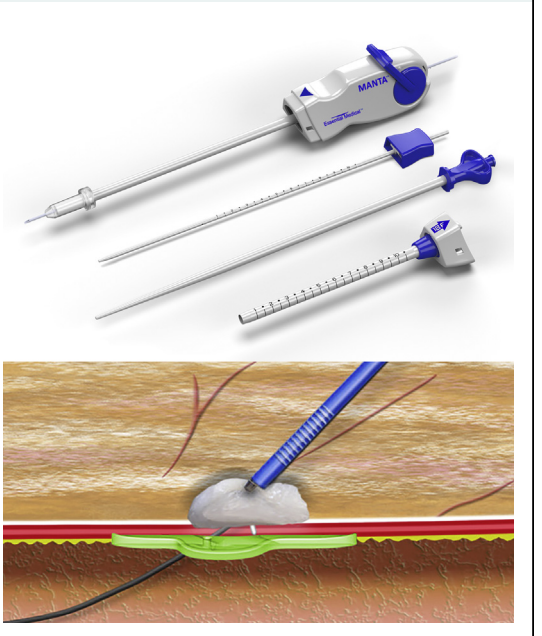
The percutaneous MANTA Vascular Closure Device (VCD) (Essential Medical Inc., Malvern, Pennsylvania) is a novel collagen-based technology dedicated to closure of large-bore arteriotomies (5). The MANTA VCD underwent prospective multicenter evaluation for Conformité Européenne (CE) mark approval in the first detailed report of outcomes achieved with a dedicated large-bore vascular closure device.

METHODS

This prospective, multicenter, nonblinded, single-arm clinical investigation enrolled 50 patients in 3 European institutions. Eligible patients underwent elective percutaneous interventions with large-bore catheters sizes 12-F to 19-F (sheath outer diameter [OD] profile of 16-F to 24.5-F) and planned percutaneous arteriotomy closure. All patients were discussed in a multidisciplinary heart team including interventional cardiologists and cardiac/vascular surgeons. Key exclusion criteria were: 1) arterial puncture outside of the common femoral artery; 2) common femoral artery size inappropriate for the selected sheath size; 3) complicated femoral access, including excessive hematoma surrounding the puncture site, arteriovenous fistula, and posterior wall puncture; 4) renal insufficiency defined by a serum creatinine >2.5 mg/dl; and 5) inability to ambulate at baseline. Patients provided written informed consent before enrollment. Operators were first-time users of the MANTA VCD, and their training included a detailed device description and bench-top training on a dry plastic model. The study design was approved by each institutional review board and was conducted in accordance with the Declaration of Helsinki, Good Clinical Practice principles, and the International Organization for Standardization of medical devices for human subjects (ISO 14155:2011). The study was registered as NCT02521948 (Clinical Study to Evaluate the Safety and Performance of MANTA Vascular Closure Device).

DEVICE DESCRIPTION. A detailed description of the MANTA VCD and its mode of operations has been previously described in detail (5). In brief, the MANTA VCD consists of an implantable closure unit and a delivery system. The delivery system comprises a device handle, a carrier/release tube, a custom introducer and device sheath, and an 8-F puncture location dilator (Figure 1). The location dilator and device sheath have centimeter markers. The closure unit consists of an intra-arterial bioresorbable polymer (poly-lactic-co-glycolic acid) toggle, an

FIGURE 1 MANTA Vascular Closure Device



(Upper panel: from top to bottom) MANTA device with closure unit, 8-F puncture locator, introducer, and sheath. **(Lower panel)** Schematic representation of arteriotomy closure with MANTA toggle and plug.

extra-vascular hemostatic bovine collagen pad, a connecting nonresorbable polyester suture, and a stainless steel suture lock. Hemostasis is achieved primarily by the mechanical means of the toggle-arteriotomy-collagen sandwich, which is supplemented by the coagulation-inducing properties of the collagen. With the exception of the perivascular stainless steel lock (1.6 × 2.9 mm) and the polyester suture that ties the collagen, toggle, and lock together, all MANTA composites are resorbed within 6 months. In the event the patient requires re-access within 6 months from MANTA closure, fluoroscopy should be used to identify the radio-opaque lock, and the common femoral artery should be punctured at least 2.5 cm away from the present MANTA device.

PROCEDURE PLANNING AND EXECUTION. Computed tomography (CT) angiography of the iliofemoral arterial tree was recommended for all patients and was typically available for all TAVR patients. Ultrasound assessment of the common femoral arteries before the procedure, pre-discharge, and at 30 days and 60 days after the procedure, as well as selective angiography following arterial access with a 6-F sheath and after MANTA access closure attempt, were mandatory per protocol. After successful and uncomplicated access confirmation, the initial sheath was exchanged for the MANTA puncture location dilator to measure the distance from the arteriotomy to the skin level. The access was then up-scaled per planned procedural requirements. At the end of the percutaneous intervention, the large-bore access sheath was exchanged for the dedicated MANTA sheath. The MANTA device is inserted into the dedicated sheath and positioned according to puncture distance. Once the toggle is released, the seal is achieved through familiar tamping procedure and confirmed with the included tension gage. Deployment takes 1 to 2 min. The 14-F and 18-F MANTA VCD accommodate 10-F to 14-F (OD profile 14-F to 18-F) and 14-F to 19-F (OD profile 18-F to 24.5-F) access sheath sizes, respectively. All interventions were performed under anticoagulation with heparin, aiming for an activated clotting time between 250 and 300 s. At the time of MANTA VCD deployment, the activated clotting time needed to be below 250 s with a systolic blood pressure <180 mm Hg. Heparin reversal with protamine was at the operator's discretion.

SAFETY AND EFFECTIVENESS. The primary means of evaluating safety was occurrence of any access site-related vascular injury, as well as major and life-threatening/disabling bleeding complications according to the most recent Valve Academic Research Consortium (VARC) definitions (6).

The primary performance endpoint was hemostasis success, defined as hemostasis at the puncture site within 10 min of removing the MANTA sheath without need for manual or mechanical compression and without later re-bleeding. Secondary performance endpoints included time to hemostasis (TTH). TTH was defined as the elapsed time between MANTA deployment (withdrawal of sheath from artery) and the first observed and confirmed arterial hemostasis (no or minimal subcutaneous oozing and the absence of expanding or developing hematoma).

All patients returned for a clinical and ultrasound follow-up including ankle brachial indices and a plain x-ray of the femoral access site.

Demographic, procedural, and endpoint data were entered in electronic case report forms. An independent clinical research organization, Factory-CRO (Bilthoven, the Netherlands), was responsible for study conduction and monitoring, which included on-site monitoring visits. Clinically relevant endpoints, including vascular and bleeding complications, were adjudicated according to the latest VARC definitions (6).

STATISTICAL ANALYSIS. Statistical analysis was conducted using SPSS version 21.0.01 (IBM Corp., Armonk, New York). Continuous variables are presented as mean ± SD or as median (interquartile range), and categorical variables are expressed as percentages. Repeated measurements in individual patients were compared using a paired Student *t* test.

RESULTS

A total of 50 patients were included from 3 European centers between July 2015 and January 2016. Overall, 9 different operators deployed the MANTA VCD. None

TABLE 1 Baseline Patient Characteristics

Age, yrs	79.5 ± 8.3
Female	27 (54)
Weight, kg	75.3 ± 15.6
STS score	5.85 ± 4.31
Prior CABG	1 (2)
Prior PCI	6 (12)
Pacemaker	2 (4)
Atrial fibrillation	1 (2)
Stroke	2 (4)
COPD	2 (4)
Hemodialysis	1 (2)
Creatinine, μmol/l	116 ± 79
Hemoglobin	12.20 ± 1.66

Values are mean ± SD or n (%).

CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; PCI = percutaneous coronary intervention; STS = Society of Thoracic Surgeons.

TABLE 2 MANTA Size Selection per Procedure Type and Sheath Size

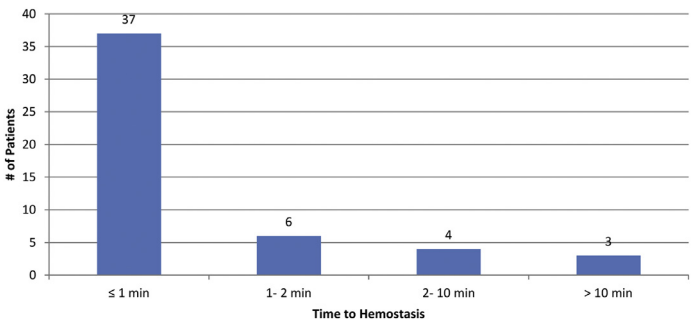
Procedure and Device	Procedure Sheath	Sheath OD Profile (French)	n	MANTA Size
Balloon aortic valvuloplasty	12-F to 14-F Cook*	16–18	2	14-F
Evolut R TAVR†	Sheathless 14-F	18	13	14-F
Continuous flow Circulatory support device‡	14-F	18	1	14-F
Evolut R TAVR†	Sheathless	18	4	18-F
Portico TAVR§	19-F SoloPath‖	23	1	18-F
Direct Flow TAVR¶	18-F Direct Flow¶	22	5	18-F
CoreValve TAVR†	18-F CoreValve†	22	2	18-F
Lotus TAVR (23 mm)#	Small Lotus#	22	5	18-F
Sapien 3 TAVR (23 and 26 mm)**	14-F e-Sheath**	23	9	18-F
Lotus TAVR (25 and 27 mm)#	Large Lotus#	24	3	18-F
Sapien 3 TAVR (29 mm)**	16-F e-Sheath**	24.5	5	18-F

*Cook Medical, Bloomington, Indiana. †Medtronic, Fridley, Minnesota. ‡Thoratec, Pleasanton, California. §St. Jude Medical, Little Canada, Minnesota. ‖Terumo Interventional Systems, Somerset, New Jersey. ¶Direct Flow Medical, Santa Rosa, California. #Boston Scientific, Marlborough, Massachusetts. **Edwards Lifesciences, Irvine, California.

OD = outer diameter; TAVR = transcatheter aortic valve replacement.

of the operators had MANTA experience before entering the study. Baseline demographics are displayed in Table 1. Mean age was 79.5 ± 8.3 years. Women represented 54% of the cohort. The Society of Thoracic Surgeons predicted risk of mortality (STS PROM) was 5.8 ± 4.3. Procedural characteristics are summarized in Table 2. One patient underwent high-risk percutaneous coronary intervention with a 14-F circulatory support system, 2 patients underwent balloon aortic valvuloplasty, and 47 patients TAVR. The large-bore sheath size varied from an internal diameter of 12-F to 19-F, including the use of expandable 14-F and 16-F e-sheaths, with ODs ranging between 14-F and 24.5-F. The 14-F MANTA VCD was applied in one-third of the overall cohort (16 of 50, 32%), including all non-TAVR patients, and the 18-F MANTA VCD in the remainder.

FIGURE 2 Frequency Distribution of Time to Hemostasis



The MANTA VCD was deployed successfully in all patients. Forty-seven of the 50 patients (94%) met the primary performance endpoint of hemostasis success. The mean TTH was 2 min, 23 s. The median TTH was 24 s, with 74% of the patients having hemostasis in <1 min (Figure 2). All-cause mortality at 30 days was 8% (n = 4), none of the deaths were related to the MANTA device or access site. One patient had a minor stroke. Overall, 12 patients required packed red blood cell (RBC) transfusions, but none were for MANTA access site-related issues (Table 3). A total of 6 patients needed 1 unit of packed RBC, 4 patients needed 2 RBC, and 2 patients needed 4 RBC. According to VARC-2 definitions, 1 patient experienced a major vascular and major bleeding complication with prolonged femoral bleeding that was successfully treated with a covered stent and eventual surgical repair because of persistent oozing while needing emergency valve surgery for a misplaced TAVR device. There were no VARC-2 minor vascular complications. One patient needed prolonged balloon inflation to control bleeding (minor bleeding according to VARC-2), and 1 patient needed balloon inflation to treat a pseudoaneurysm. Five patients presented with subcutaneous hematomas without further medical intervention.

Angiography showed widely patent femoral vessels in all subjects (Figure 3). In 3 patients, there was angiographic evidence of extravasation. As described in the preceding text, 2 of these were resolved with femoral balloon inflation, and 1 was repaired surgically as the patient proceeded to emergent surgical valve replacement. Duplex studies immediately post-deployment and at discharge confirmed patency in all vessels. Ultrasound evidence showed stability of the absorbable, intravascular MANTA anchor and extravascular collagen layer up to 60 days. Ankle brachial indices remained stable over the study period: 1.09 ± 0.19 at baseline, 1.01 ± 0.10 at discharge, and 1.02 ± 0.17 at later follow-up (p = 0.111). There were no late vascular complications related to the MANTA device.

DISCUSSION

The prospective multicenter MANTA CE mark study demonstrates rapid and reliable vascular hemostasis after 12-F to 19-F (OD 16-F to 24.5-F) transfemoral arteriotomies with this second-generation, dedicated, large-bore vascular closure device. MANTA VCD was applied in various completely percutaneous interventions including TAVR, balloon aortic valvuloplasty, and mechanical circulatory support.

TABLE 3 MANTA Effectiveness and Safety (N = 50)

Hemostasis success, %	
Overall	94
14-F	100
18-F	91.2
Time to hemostasis, mm:ss	00:24 (00:02-37:10)
Safety*	
All-cause death	4 (8)
Major stroke	0
Minor stroke	1 (2)
VARC bleeding	
Life-threatening/disabling	0
Major	1 (2)
VARC vascular complications	
Major	1 (2)
Minor	0
Hemoglobin	12.20 ± 1.66
Need for any RBC	12 (24)
RBC per patient if RBC required	1.5 (1-4)

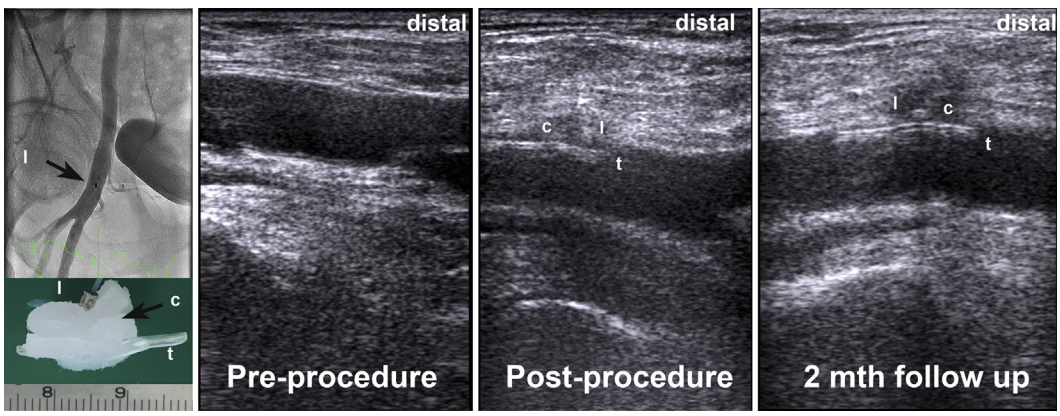
Values are n, median (interquartile range), n (%), or mean ± SD. *Defined according to the Valve Academic Research Consortium (VARC).
mm:ss = min:s; RBC = packed red blood cells.

Vascular and bleeding complications in the MANTA CE mark study were low despite the operators' inexperience with the novel closure device. Overall, vascular complications according to VARC-2 were encountered in 1 patient (2%), including 1 major and 0 minor complications. The CONTROL (Closure Device in Transfemoral Aortic Valve Implantation) multicenter study included 944 patients undergoing TAVR and suture-based arteriotomy closure with either Prostar XL or Perclose Proglide (Abbott Vascular, Redwood City, California) in a propensity matched analysis. VARC major and minor vascular complications were noted in 7.4% and 14.8% with Prostar and 1.9% and 18% with Proglide, respectively (3). Importantly, operators participating in the CONTROL study were experienced with the respective suture-based closure devices, whereas the MANTA study represented the initial learning curve of the participating operators.

A study on 380 consecutive patients undergoing balloon aortic valvuloplasty with a sheath size ranging from 9-F to 13-F reported serious vascular complications, including arterial perforation, pseudoaneurysm formation, arteriovenous fistula, and leg ischemia in 5.5% to 6.7% depending on the closure device used (7). A single-center study including 274 patients undergoing transfemoral TAVR with either surgical cut-down and repair, or suture-based percutaneous closure showed similar acute closure success and access site-related events but more femoral stenosis and dissection with the percutaneous closure (7.1% vs. 0.7%; p = 0.007) and more wound infections and need for surgical debridement with the surgical approach (0.7% vs. 6.7%; p = 0.007) (8). The completely percutaneous approach reduced procedural time and patient morbidity.

Comparison of clinical endpoints like vascular complications across different studies may be difficult

FIGURE 3 MANTA Angiographic and Ultrasound Appearance



(Left upper panel) Angiogram shows the position of the "Manta-plug" in the femoral artery, visible by the metal cm marker appearing as a black spot **(black arrow)**. **(Bottom left panel)** Macro photograph of the plug. The poly-lactate toggle, the collagen, and the nitinol lock are respectively indicated by **t**, **c**, and **l**. Longitudinal ultrasound images of the femoral artery were acquired before the procedure, post-procedure, and at 2 months follow-up. The poly-lactate toggle **(t)** is visible in the lumen against the vessel wall as a long double-layered bright structure. The collagen **(c)** appears as a darker area.

because of nonuniformity in endpoint definitions and reporting bias in the absence of independent clinical event adjudication. The VARC is an initiative by research organizations, academics and regulatory instances to provide consensus definitions on important clinical endpoints (6). These VARC endpoints are currently well adopted and allow more reliable data comparison. In randomized TAVR versus surgical aortic valve replacement trials with controlled and independently adjudicated outcome data, vascular complications were consistently more frequent with TAVR (5.9% vs. 1.7%; $p = 0.003$, in the U.S. CoreValve High-Risk study and 11.3% vs. 3.8%; $p < 0.001$, in the PARTNER [Placement of Aortic Transcatheter Valve] Cohort A), whereas disabling, life-threatening, or major bleedings occurred more often with surgical aortic valve replacement (35% vs. 13.6%; $p < 0.001$, in the U.S. CoreValve High-Risk study, and 26.7% vs. 15.7% in PARTNER Cohort A) (9,10). Over time, the rate of vascular complications has gradually declined due to growing experience, improved access technique with fluoroscopic or ultrasound guidance, and design modifications with smaller profile devices (11,12). Also, additional maneuvers such as the cross-over balloon technique may create a low pressure milieu for optimal closure device functioning at the time of sheath removal and facilitate the percutaneous management of vascular complications (13,14). A relatively small single-center study on 137 patients reported a low rate of major and minor vascular complications of 1% and 8%, respectively (12). However, contemporary rigorous trials with independent clinical event adjudication still report major vascular complications after TAVR in >5% of patients, and two-thirds of these major complications are due to failed arteriotomy closure (1,2,4). Therefore, in the current era, and despite growing operators' experience, vascular complications are still a limitation of TAVR and other large-bore interventions. These vascular complications, bleedings, and the need for transfusions are associated with worse clinical outcomes and thus warrant further improvements in access site management (15).

Plug-based closure is well established for 5-F to 8-F arteriotomies and among the most widely used globally (16). It reduces TTH, promotes early patient ambulation, and improves patient satisfaction compared with manual compression (17,18). So far, no head-to-head comparisons between plug-based and suture-based closure devices exist. One meta-analysis on percutaneous vascular closure devices suggested that only plug-based closure reduced major vascular complications compared with manual compression (odds ratio: 0.51; 95% confidence interval: 0.45 to 0.58), with a neutral effect for suture-based closure (odds ratio: 1.0, 95% confidence interval: 0.13 to 7.48) (19). Clearly, no convincing data have proven the superiority of one closure technique over the other. Of note, for MANTA closure, a prophylactic cross-over balloon technique does not seem beneficial because it is felt that a pressurized vessel is best for spreading the collagen pad over the arteriotomy defect, and collagen in contact with blood and tissue factor is required to develop a stabilizing layer. MANTA closure failure can theoretically occur when the endovascular toggle does not connect with the arteriotomy from the inside (e.g., because it was caught by plaque), the plug does not connect with the vessel wall at the arteriotomy from the outside (e.g., because a growing subcutaneous hematoma has extended the subcutaneous track, and the depth has been underestimated), or too much pulling force has been applied, and the toggle is pulled outside of the vessel. Bail-out strategies in case of MANTA closure failure include prolonged endovascular balloon inflation and manual compression, covered stent placement, or vascular surgery.

STUDY LIMITATIONS. A limitation of the MANTA CE mark study is its relatively small sample size and its nonrandomized nature. Selection bias may have affected the reported clinical results. Yet the involvement of an independent clinical research organization with rigorous data monitoring and the favorable results should spur further research in larger studies, preferably including randomized trials comparing MANTA VCD with current suture-based closure techniques.

CONCLUSIONS

The MANTA VCD is a novel, collagen plug-based, large-bore closure device. It targets large-bore procedures requiring devices up to 19-F (true OD profiles up to 24.5-F). This initial multicenter experience demonstrated rapid and reliable hemostasis and low complication rates. Broader community-based experience and randomized trials comparing the MANTA device to alternative techniques are warranted.

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PERSPECTIVES

WHAT IS KNOWN? No dedicated vascular closure devices exist for large arteriotomies.

WHAT IS NEW? MANTA is a plug-based closure device for large bore arteriotomies with rapid and reliable hemostasis and low complication rates.

WHAT IS NEXT? Randomized trials should compare Manta with suture-based closure for large-bore arteriotomies.

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KEY WORDS closure device, large-bore arteriotomy, MANTA