MANTA™ Vascular Closure Device

INSTRUCTIONS FOR USE

To ensure proper deployment and use of this device and to prevent injury to patients, read all information contained in these instructions for use.

14F **18F**

Essential Medical, Inc.
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CAUTION

Federal law restricts this device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in interventional catheterization procedures and who has been trained in MANTA device use by an authorized representative of Essential Medical.

INDICATIONS FOR USE

The MANTA Vascular Closure Device is indicated for closure of femoral arterial access sites while reducing time to hemostasis following the use of 10-20F devices or sheaths (12-25F OD) in endovascular catheterization procedures.

DEVICE DESCRIPTION

The MANTA™ Vascular Closure Device consists of the MANTA Closure, an Insertion Sheath with Introducer, and a Depth Locator. The MANTA Closure is composed of a delivery handle containing an absorbable collagen pad, a stainless-steel locking component, and an absorbable polymer anchor that are connected by a non-absorbable suture. Hemostasis is achieved primarily by the mechanical means of the anchor-arteriotomy-collagen sandwich, which is supplemented by the coagulation-inducing properties of the collagen. The extra-vascular radiopaque lock secures and marks the location of the absorbable unit. The MANTA Vascular Closure Device components are not made from latex rubber.

The 14F MANTA™ Vascular Closure Device is indicated for closure of femoral arterial access sites while reducing time to hemostasis following the use of 10-14F devices or sheaths (maximum OD/profile of 18F) in endovascular catheterization procedures, and the 18F MANTA™ Vascular Closure Device is indicated for closure of femoral arterial access sites while reducing time to hemostasis following the use of 15-20F devices or sheaths (maximum OD/profile of 25F) in endovascular catheterization procedures.

CONTRAINDICATIONS

There are no known contraindications to the use of this device.

WARNINGS

- Do not use if the puncture site is proximal to the inguinal ligament or above the most inferior border of the epigastric artery (IEA), as this may result in retroperitoneal bleeding.
- Do not use in patients with severe calcification of the access vessel and/or common femoral artery stenosis resulting in a vessel <5mm in diameter for the 14F MANTA or <6mm in diameter for the 18F MANTA, or >50% diameter femoral or iliac artery stenosis.
- Do not use in patients with severe peripheral vascular disease, as evidenced by severe claudication when ambulating <100 feet, weak or absent pulses in the affected limb, or ABI <0.5 at rest.
- Do not use if the temperature indicator dot on package has changed from light gray to dark gray or black.
- Do not use if the package is damaged or any portion of the package has been previously opened.
- Do not use if the items in the package appear damaged or defective in any way.
- Do not REUSE or RESTERILIZE. The MANTA Device is single use only. The MANTA Device contains bioresorbable materials that cannot be reused or re-sterilized. Reuse or re-sterilization may cause degradation to the integrity of the device, leading to device failure which may result in patient injury, illness, or death.
- Do not use the MANTA Device where bacterial contamination of the procedure sheath or surrounding tissues may have occurred, as this may result in infection.
- Do not use if the MANTA delivery system becomes kinked.
- Do not inflate a contralateral balloon in the femoral or iliac artery during MANTA Sheath exchange or the MANTA Closure procedure.

- Do not use MANTA if there has been a femoral artery puncture in same vessel within the prior 30 days, recent femoral artery puncture in same groin that has not healed appropriately, and/or recent (<30 days) vascular closure device placement in same femoral artery.
- Do not use if the puncture site is at or distal to the bifurcation of the superficial femoral and profunda femoris artery, as this may result in the 1) anchor catching on the bifurcation or being positioned incorrectly, and/or 2) collagen deposition into the vessel.
- Do not use if there is difficult dilation from initial femoral artery access (e.g., damaging or kinking dilators) while step dilating up to the large-bore device. Difficult dilation of the puncture tract due to scar tissue may lead to swelling of surrounding tissue, thus compromising the accuracy of the puncture depth determined during the puncture location procedure.
- Do not use if sheath insertion is in a vessel other than the femoral artery.
- Do not use if there is marked tortuosity of the femoral or iliac artery.
- Do not use if the patient has marked obesity or cachexia (BMI >40 kg/m^2 or <20 kg/m^2).
- Do not use if the patient has post-procedure blood pressure >180 mmHg that cannot be lowered prior to access site closure.
- Do not use in patients who cannot be adequately anticoagulated for the procedure.
- Do not use the MANTA Device in patients with known allergies to bovine products, collagen and/or collagen products, polyglycolic or polylactic acid polymers, stainless steel or nickel.

PRECAUTIONS

- The MANTA Device should only be used by a licensed physician or healthcare provider trained in the use of this device.
- This device contains a small radiopaque stainless-steel lock that is implanted in the puncture tract. See MRI information in these instructions for use and patient implant card.
- In the event that bleeding from the femoral access site persists after the use of the MANTA Device, the physician should assess the situation. Based on the physician assessment of the amount of bleeding, use manual or mechanical compression, application of balloon pressure from a secondary access site, placement of a covered stent, and/or surgical repair to obtain hemostasis.

SPECIAL PATIENT POPULATIONS

The safety and effectiveness of the MANTA Device has not been established in the following patient populations:

- Patients who are immunocompromised or have a pre-existing autoimmune disease.
- Patients with systemic infection or a local infection at or near the access site or possible contamination of the procedure sheath or surrounding tissues.
- Patients undergoing therapeutic thrombolysis.
- Patients with a bleeding disorder, including thrombocytopenia (<100,000 cells/UL platelet count), thrombasthenia, hemophilia, von Willebrand disease, or anemia (Hgb<10g/dl, Hct<30%).
- Pediatric patients or others with small femoral artery size <5mm (for 14F MANTA) or <6mm (for 18F MANTA) in diameter.
- Patients who are pregnant or lactating.
- Patients with unilateral or bilateral lower extremity amputation.

- Patients on continuous oral anticoagulants or patients with INR >1.8 at the time of the procedure.
- Patients who had previous iliofemoral intervention in region of access site, including but not limited to prior atherectomy, stenting, surgical or grafting procedures in the access area.
- Patients who have undergone use of an intra-aortic balloon pump through the arterial access site within the previous 30 days.
- Patients with ipsilateral femoral venous sheath.
- Patients who are suspected of having more than one femoral arterial puncture in the same vessel during initial access for the interventional procedure.
- Patients with an antegrade puncture during the index procedure.
- Patients who are suspected of having intra-procedural complications at the femoral access site pre-sheath removal including: bleeding or swelling around the large bore sheath that may indicate hematoma formation and/or pseudoaneurysm formation, and/or peri-procedural angiographic evidence of thrombus formation or significant injury in the aorta or iliac vessels associated with procedural large bore sheath placement and/or sub-optimal anticoagulation.

ADVERSE EVENTS

The following potential adverse events related to the deployment of Vascular Closure Devices have been identified:

- Ischemia of the leg or stenosis of the femoral artery.
- Local trauma to the femoral or iliac artery wall, such as dissection.
- Retroperitoneal bleeding as a result of access above the inguinal ligament or the most inferior border of the epigastric artery (IEA).
- Perforation of iliofemoral arteries, causing bleeding/hemorrhage.
- Thrombosis formation or embolism.
- Nerve damage or neuropathy.
- Other access site complications leading to bleeding, hematoma, pseudoaneurysm, or arterio-venous fistula, possibly requiring blood transfusion, surgical repair, and/or endovascular intervention.

Potential Adverse Events associated with any large bore intervention, including the use of the MANTA Vascular Closure Device, include but are not limited to:

- Arterial damage
- Arterio-venous fistula
- Bradycardia
- Compartment syndrome
- Death related to the procedure
- Deep vein thrombosis
- Ecchymosis
- Edema
- Infection at the puncture site which may require antibiotics or extended hospitalization
- Inflammatory response
- Late arterial bleeding
- Oozing from the puncture site
- Pressure in groin/access site region
- Vessel laceration or trauma
- Wound dehiscence

The MANTA device was evaluated in a multicenter, prospective, single-arm clinical investigation, the MANTA U.S. pivotal study (PSD-109), in subjects undergoing percutaneous transcatheter interventional procedures (TAVI or EVAR) using a large-bore procedure sheath. The study was conducted at 20 medical

centers, of which 19 were in the United States and one was in Canada. Following a large-bore interventional procedure, subjects were treated with either the MANTA 14F or 18F Vascular Closure Device to achieve post-procedure hemostasis at the femoral access site and were followed for 60 days. The study evaluated times to hemostasis and ambulation, technical success, ambulation success, treatment success, procedure time, and the rate of major and minor access-site-related complications. The major complications primary safety endpoint was compared to a Performance Goal (PG) derived from published literature and the clinical judgment of expert advisors. The time to hemostasis primary effectiveness endpoint was compared to a PG derived from published literature. The minor complications secondary safety endpoint was compared to a clinical acceptance criterion derived from the clinical judgment of expert advisors.

Table 1, Table 2, Table 3 and **Table 4** summarize the reported major and minor complications per protocol, and VARC-2 major vascular complications. Note: If an event qualified by multiple definition elements, all are included. A subject is counted only once per element regardless of the number of contributing events, and the overall analysis of each endpoint is also a per-subject analysis.

The primary safety hypothesis was that the exact one-sided 97.5% upper confidence bound of the Major Complication rate (proportion of subjects with one or more Major Complications) would be less than the Performance Goal (PG) of 19.9%. The overall Major Complication rate within 30 days in the Safety Evaluation Set (SES) population, which was the same as the Primary Analysis Cohort (PAC), was 5.3%. The exact one-sided 97.5% upper confidence bound was 8.8%, which compares favorably to the performance goal of 19.9%. A Kaplan-Meier analysis of Major Complications was also performed. The results of the Kaplan-Meier analysis were identical to the simple proportion (5.3% Major Complications with a 97.5% upper confidence bound of 8.8%). In addition, the p-value for the comparison of the Major complication rate to the PG was <0.0001. Therefore, the null hypothesis was rejected, and the study met the primary safety endpoint.

Table 1: Major Complications Compared to PG

Cohort	Observed Major Complication Rate	97.5% Upper Confidence Bound[1]	P-value (2-sided)
Overall SES Population	5.3% (14/263)	8.8%	<.0001
TAVI Subjects	6.2% (13/210)	10.4%	<.0001
EVAR Subjects	1.9% (1/53)	10.1%	0.0010

[1] Performance goal (PG) for rate of Major Complications = 19.9%

Table 2: Details of Major Complications

Major Complication Type	N=263	
Subjects with Any Major Complications within 30 days of procedure	**14** [1]	**5.3%**
Access site-related bleeding that is attributable to failure of or sub-optimal performance of the MANTA device and that results in transfusion	5	1.9%
Access site-related infection requiring intravenous antibiotics and/or extended hospitalization	0	0%
Access site-related nerve injury attributable to the MANTA device that is permanent (lasting >30 days) or requires surgical repair	0	0%
New onset ipsilateral lower extremity ischemia that originates with the common femoral artery, is attributable to the MANTA device, causes a threat to the viability of the limb, and requires surgical repair or additional percutaneous intervention	9	3.4%
Vascular injury attributable to the MANTA device requiring surgical repair or stent-graft	1	0.4%

[1] The 14 patients had 15 major complication events.

The overall Minor Complication rate within 30 days was 2.7% (7/263) in the SES (PAC) population. Per the study protocol, the Minor Complication rate was qualitatively compared to the Clinical Acceptance Criterion (CAC) established for this endpoint, which was 20%. The Minor Complication rate of 2.7% was well below the 20% CAC for Minor Complications; thus, the study met this secondary safety endpoint.

Table 3: Details of Minor Complications

Minor Complication Type	N=263	
Subjects with Any Minor Complications within 30 days of procedure	**7** [1]	**2.7%**
Access site hematoma that is attributable to failure of or sub-optimal performance of the MANTA device, is ≥10 cm and is confirmed by ultrasound	0	0%
Access site wound dehiscence	0	0%
Ipsilateral lower extremity arterial emboli attributable to the MANTA device	0	0%
Ipsilateral vein thrombosis attributable to the MANTA device	0	0%
Late (following hospital discharge) access site-related bleeding	0	0%
Localized access site infection treated with intramuscular or oral antibiotics	0	0%
Non-treated or treated arteriovenous (AV) fistula attributable to the MANTA device and documented by ultrasound	0	0%
Non-treated pseudoaneurysm attributable to the MANTA device and documented by ultrasound;	3	1.1%
Pseudoaneurysm treated with ultrasound-guided compression, ultrasound-guided thrombin injection or ultrasound-guided fibrin adhesive injection.	3	1.1%
Transient access site-related nerve injury	1	0.4%

[1] The 7 patients had 8 minor complication events.

The overall VARC-2 Major Vascular Complication rate within 30 days in the SES population was 4.2%. Note that the VARC-2 Major Vascular Complications definition significantly overlaps the definition for Major Complications; the two definitions and events are not mutually exclusive. Therefore, all the events that were classified as a VARC-2 Major Vascular Complication are also classified as a Major Complication. Three subjects had events that were adjudicated as a Major Complication but that did

not count as a VARC-2 Major Vascular Complication; these were access site related major bleeding events which did not meet the VARC-2 complication definition.

Table 4: Details of VARC-2 Major Vascular Complications

VARC-2 Major Vascular Complication Type	N=263	
Subjects with Any VARC-2 Major Vascular Complications within 30 days of procedure	**11**	**4.2%**
Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) leading to death, life threatening or major bleeding,* visceral ischemia, or neurological impairment	10	3.8%
Any new ipsilateral lower extremity ischemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram	7	2.7%
Distal embolization (noncerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage	0	0%
Permanent access site-related nerve injury	0	0%
Surgery for access site-related nerve injury	0	0%
The use of unplanned endovascular or surgical intervention associated with death, major bleeding, visceral ischemia or neurological impairment	10	3.8%

MANTA VCD Clinical Trial

Patients were eligible for the MANTA U.S. pivotal study if they were undergoing elective TAVR, EVAR, or Impella VAD use with a minimum common femoral artery diameter on screening computed tomography angiography (CTA) of 5mm for the 14F MANTA and 6mm for the 18F MANTA. No Impella subjects were enrolled. Key baseline exclusion criteria included: 1) significant anemia (hemoglobin < 10 g/dL, hematocrit < 30%); 2) morbid obesity or cachexia (BMI > 40 kg/m2 or < 20 kg/m2); 3) known bleeding disorder or coagulopathy including thrombocytopenia (platelet count < 100,000 cells/UL); 4) common femoral artery with extensive calcium, as determined by baseline CTA, precluding safe percutaneous access in the opinion of the investigator; and 5) severe peripheral vascular disease as evidenced by severe claudication, weak or absent pulses in the affected limb, or an ankle-brachial index (ABI) of < 0.5 at rest. Key intra procedural exclusion criteria included: 1) puncture site in the profunda femoris artery, superficial femoral artery, or at the bifurcation of these arteries; 2) marked tortuosity of the femoral or iliac artery precluding safe percutaneous closure in the opinion of the investigator; and 3) intra-procedural complication(s) at the femoral access site pre-sheath removal including bleeding or swelling around the large bore sheath that may indicate hematoma formation and/or pseudoaneurysm formation and angiographic evidence of thrombus formation or significant injury in the aorta or iliac vessels prior to large bore sheath removal.

Baseline evaluation included CTA, medication review, physical exam, ankle-brachial index (ABI), medical history and laboratory tests. Following the large-bore intervention, ACT was measured, and then the MANTA device was deployed, and time to hemostasis was recorded. Duplex ultrasound was performed prior to hospital discharge. Follow-up visits took place at 30- and 60-days post procedure, with repeat duplex ultrasound at 30 days (ultrasound was also performed at 60-days if abnormalities were found at 30-days). Adverse events were recorded throughout, and an independent Clinical Events Committee adjudicated potential endpoint events (major complications, minor complications, and VARC-2 major vascular complications).

The trial involved a total of 341 patients, 263 in the primary analysis cohort (PAC) and 78 in the roll-in cohort. Up to 2 roll-in patients per operator were allowed to give investigators an opportunity to learn how to use the MANTA device. The roll-in patients were analyzed separately from the primary analysis cohort. Results for the PAC population are reported here.

The mean age was 79.4 ± 8.4 (range 42 - 95 years) and 65% were male. The mean BMI was 28.6 ± 4.4 and pre-procedure hemoglobin 8.1 ± 0.9 mmol/L. The index procedure was TAVI in 210 (79.8%) subjects and EVAR in 53 (20.2%) subjects. Sixteen percent (16%) of the PAC population had some level of peripheral arterial disease (PAD), based on baseline ankle-brachial index (ABI) of ABI ≥ 0.5 and < 0.9; patients with ABI < 0.5 were excluded. The mean artery diameter was 7.9 ± 1.4 mm (range 5 to 16 mm). The 14F MANTA device was used in 42 cases (16.0%) and the 18F in 221 (84.0%). The mean effective sheath OD (puncture size) in the study was 22.1F (range 17 to 24.5F), and mean sheath to femoral artery ratio was 1.0 ± 0.2 (range 0.5 to 1.6). All subjects received unfractionated intravenous heparin during the large-bore procedure. Mean ACT was 176.9 ± 41 seconds prior to MANTA deployment.

Of the 263 PAC patients, 228 patients (86.7%) completed both the 30-day and 60-day follow-up visits, 244 total patients (92.8%) completed the 30-day visit, and 236 total patients (89.7%) completed the 60-day visit.

EFFECTIVENESS RESULTS

Table 5, Table 6 and **Graph 1** summarize the primary effectiveness endpoint, Time to Hemostasis (TTH) in the PAC population. Time to Hemostasis (TTH) was defined as the elapsed time between MANTA deployment (withdrawal of sheath from artery) and first observed and confirmed arterial hemostasis (no or minimal subcutaneous oozing and the absence of expanding or developing hematoma). Mean TTH was 1.09 ± 2.63 minutes, with a range of 0.07–17.92 minutes. The one-sided upper 97.5% confidence bound was 1.41 minutes, which compares favorably to the performance goal (PG) of 10 minutes. In addition, the p-value for the comparison of TTH to the PG was < 0.0001. The null hypothesis was thus rejected, and the study met its primary effectiveness endpoint. The vast majority of PAC subjects experienced a TTH of < 1 minute, and only a small number of subjects had a TTH > 5 minutes (N=15).

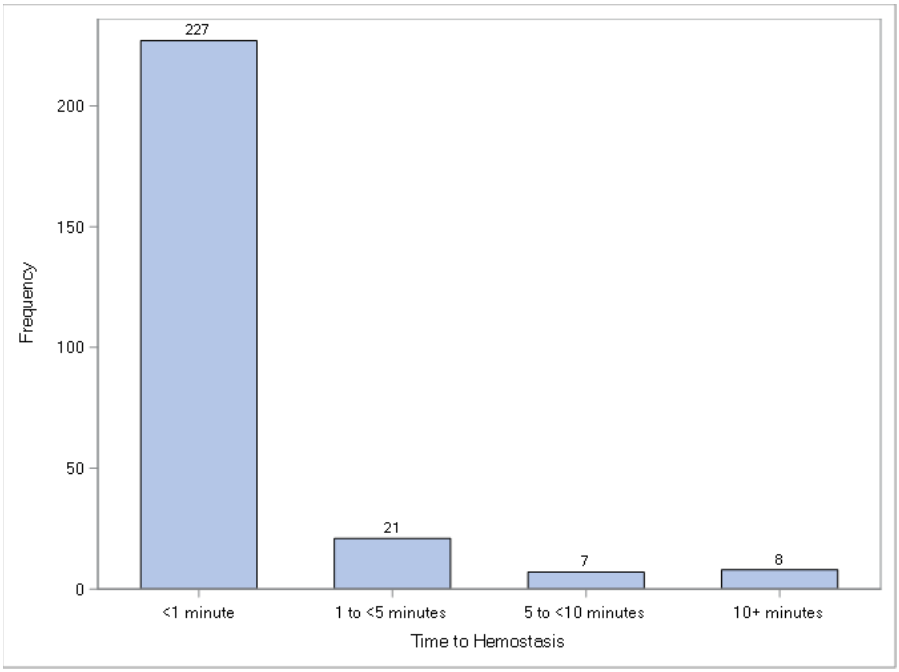
Table 5: Time to Hemostasis Compared to PG

Cohort	Observed Hemostasis Time (Minutes, mean)	97.5% Upper Confidence Bound[1]	P-value (2-sided)
Overall PAC Population	1.09 ± 2.63	1.41	<.0001
TAVI Subjects (N=210)	1.22 ± 2.83	1.60	<.0001
EVAR Subjects (N=53)	0.58 ± 1.52	1.00	<.0001

[1] Performance goal (PG) for Time to Hemostasis = <10 minutes

Table 6: Time to Hemostasis (PAC)

Endpoint	Statistic	All Subjects	One-Sided Upper 97.5% Confidence Bound
Time to Hemostasis (minutes)	N	263	
	Mean (SD)	1.09 (2.63)	1.41
	Median	0.4	
	Minimum, Maximum	0.07, 17.92	



Analysis Dataset	PAC	
Time to Hemostasis	**Frequency (N=263)**	**Percent**
<1 minute	227	86.3%
1 to <5 minutes	21	8.0%
5 to <10 minutes	7	2.7%
10+ minutes	8	3.0%

Graph 1: Frequency of TTH for N=263 PAC Subjects (with Data Table)

Table 7 summarizes the secondary effectiveness endpoints Mean Time to Ambulation and Mean Procedure Time, which were analyzed for informational purposes only. Time to Ambulation is defined as the elapsed time between MANTA deployment (withdrawal of sheath from artery) and when ambulation is achieved (subject standing and walking at least 20 feet/6 meters without re-bleeding).

Procedure Time is defined as elapsed time from initial skin break (first needle insertion) to time when the post-deployment angiogram is completed.

Table 7: Time to Ambulation (Mean/Median and by Time-Point) and Procedure Time (Mean/Median) (PAC)

Endpoint	Statistic	N=263
Time to Ambulation (hours)		
	Mean (SD)	22.02 (25.63)
	Median	16.87
	Minimum, Maximum	4.13, 236.05
Procedure Time (minutes)		
	Mean (SD)	79.91 (39.23)
	Median	74.72
	Minimum, Maximum	28, 309.78

Analysis Dataset	PAC	
Time to Ambulation	**Frequency (N=263)**	**Percent**
<6 hours	25	9.5%
6 to <12 hours	68	25.9%
12 to <24 hours	103	39.2%
1 to <2 days	48	18.3%
2 to <4 days	14	5.3%
4+ days	5	1.9%

Table 8 summarizes additional secondary effectiveness endpoints, percentage of subjects with Technical Success, with Ambulation Success, and with Treatment Success.

Table 8: Secondary Success Endpoints

Endpoint	N=263	
Ambulation Success Able to ambulate for at least 20 feet/6 meters without re-bleeding	255	97%
Technical Success Percutaneous vascular closure is obtained with the MANTA device without the use of unplanned endovascular or surgical intervention	257	97.7%
Treatment Success Time to Hemostasis <= 10 minutes and has no Major Complications	246	93.5%

SAFETY RESULTS

Refer to section titled ADVERSE EVENTS above.

Except in two cases, the observations that were noted during the follow-up ultrasound examinations of the study patients were minor adverse findings that are expected with large-bore interventional procedures like TAVI and EVAR which the study patients underwent. Two subjects had peri-procedural stenosis due to partial or complete intra-arterial device deployment, were adjudicated as having a major complication and had residual stenosis diagnosed on ultrasound, which was not a new finding. Other than these two major complications, the other ultrasound findings did not meet the criteria for the minor complications constituting the secondary safety endpoint, were asymptomatic, and/or were not noted by the study investigators.

CONCLUSION

In conclusion, the U.S. pivotal study of the MANTA Vascular Closure Device met the primary effectiveness endpoint, Time to Hemostasis, compared to a PG. The study also met its primary and secondary safety endpoints, Major Complications and Minor Complications, respectively. The study therefore establishes that the MANTA device is safe and effective for its intended use.

PROCEDURE REQUIREMENTS

The MANTA Device is to be used only by a licensed physician (or other health care professional authorized by or under the direction of such physician) possessing adequate instruction in the use of the device.

Pre-procedure CTA is recommended to assess femoral artery anatomy.

Arterial access should be gained using micro-puncture technique using ultrasound guidance to puncture the midline of the femoral artery. Do not puncture the posterior wall of the artery.

Anticoagulation should be administered at procedure initiation per the hospital's standard of care.

Activated clotting time (ACT) should be below 250 seconds prior to closure.

Puncture location using the supplied Depth Locator must occur prior to step dilation of the vessel and before the large-bore procedure is performed.

If a patient has had a procedure sheath left in place for longer than 6 hours, consideration should be given to the use of prophylactic antibiotics before insertion of the MANTA Device.

Observe sterile technique at all times when using the MANTA Device. Repeat application of an appropriate skin preparation solution to existing sheath and surrounding area. Refresh drapes and operator gloves as appropriate.

The MANTA Device is for single use only and should not be reused in any manner.

MANTA Sheath placement must be performed utilizing the MANTA Introducer provided in the system.

The MANTA Closure must be deployed using the MANTA Sheath provided in the MANTA package. Do not substitute any other sheath.

If the MANTA Closure does not deploy properly in the artery and hemostasis is not achieved, the closure and all absorbable components may be removed from the patient if medically necessary.

Dispose of contaminated device, components, and packaging materials utilizing standard hospital procedures and universal precautions for biohazardous waste.

The collagen utilized in the MANTA vascular closure device is a non-viable, highly-purified derivative from bovine hide and undergoes substantial chemical processing to purify while ensuring physical integrity. With the exception of those patients with allergies to beef or collagen products, the collagen found in the MANTA device will not elicit a reaction to surrounding body tissue or standard materials used during the endovascular procedure. The physician should inform the patient of the aforementioned information that the collagen plug will be resorbed in several months.

HOW SUPPLIED / DEVICE COMPONENTS

The MANTA Device system is supplied sterilized and sealed with a poly-foil pouch in a tray containing the following supplies:

1 each 14F or 18F MANTA Sheath
1 each 14F or 18F MANTA Closure
1 each 14F or 18F MANTA Introducer
1 each Depth Locator

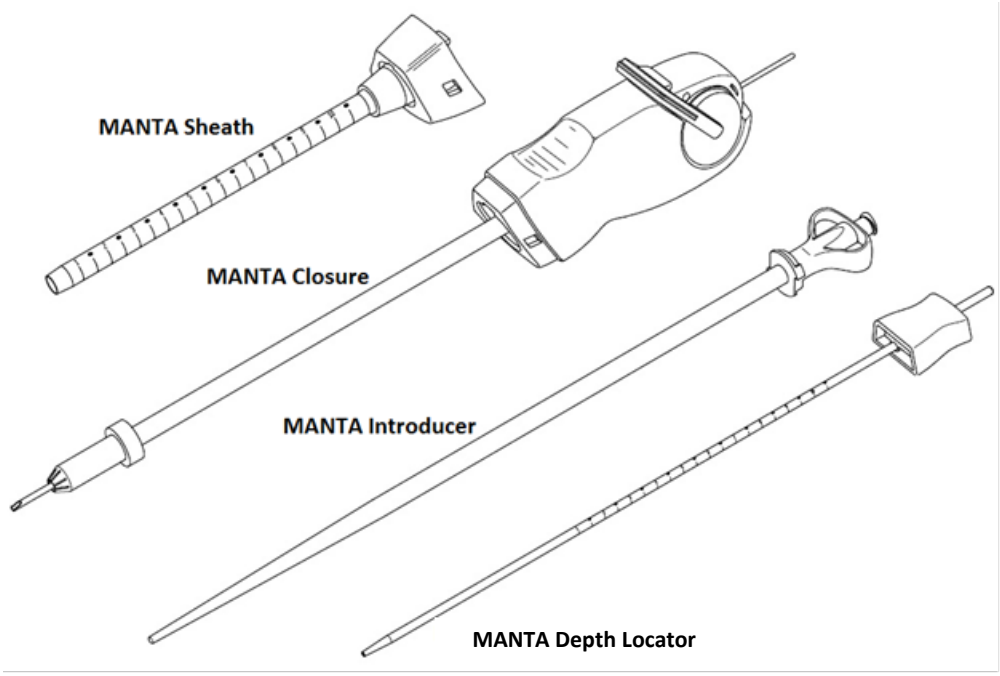


Figure 1 – MANTA Device Components

PROCEDURE PREPARATION

Confirm via femoral arteriogram:

- Single wall puncture in the common femoral artery.
- Vessel size ≥6mm for 18F and ≥5mm for 14F and evidence of adequate blood flow.
- No evidence of significant peripheral vascular disease or calcification in the region of the arteriotomy.

DEVICE USE STEPS

BEFORE step dilation and large-bore procedure

Step 1: Arteriotomy Location Procedure

Prior to step-dilating the artery, the Depth Locator must be used to locate the vessel wall.

- Flush Depth Locator with sterile heparinized saline to ensure good puncture locating blood flow.
- Insert the Depth Locator over a 0.035" guidewire.
- Advance the Depth Locator over the guidewire and fully into the vessel. A steady flow of blood will be visible jetting perpendicular to the Dilator at the proximal end.
- Using your left hand to keep the skin at a neutral position, slowly withdraw the Depth Locator from the vessel until blood flow ceases. Note the first visible marking near the skin puncture (Figure 2). The mark will be either a whole number or a dot. A dot signifies the half centimeter mark between whole numbers. Add one (1) cm to this number/marker to arrive at the proper deployment depth for the MANTA Closure and Sheath.
    - NOTE: If blood flow ceases deeper than 9.5cm, the vessel is too deep to use MANTA. DO NOT use the MANTA device.
- Advance the Depth Locator fully into the vessel once again. Keeping the skin at a neutral position, withdraw the dilator slowly. Confirm steady blood flow at the deployment depth (measured depth plus one (1) cm). Continue to withdraw the dilator until blood flow ceases. Confirm to previous measurement.
- If blood flow ceases at a different depth, repeat the full insertion and withdraw step (blood flow ceases) and one (1) cm advancement (blood flow is visible) of the Depth Locator to confirm puncture location.

MANTA Deployment Depth = flow stop measurement at skin + one (1) cm

NOTE: The deployment depth will correspond to a MANTA Sheath marking when positioning the MANTA closure device for anchor release in Step 4.

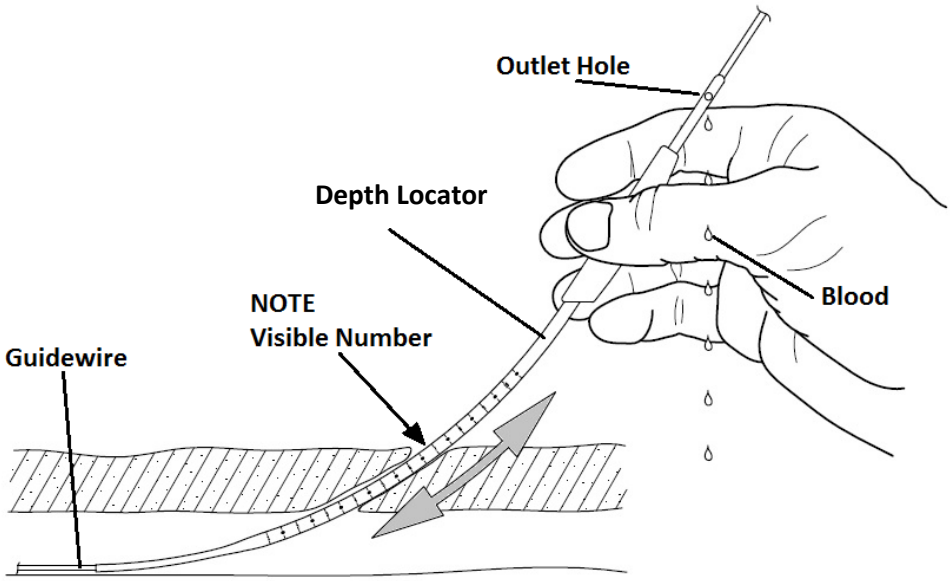


Figure 2 – Using the Depth Locator to determine puncture depth prior to large-bore procedure

AFTER large-bore procedure

Step 2: Exchange and Position Sheath

Prior to using the MANTA Closure, the procedure sheath must be exchanged for the MANTA Sheath:

- Flush the Introducer with heparinized saline. Insert the MANTA Introducer into the MANTA Sheath until the hub of the Introducer aligns with the Sheath hub. Turn the Introducer hub clockwise ¼ turn to lock into the Sheath (Figures 3 and 4).

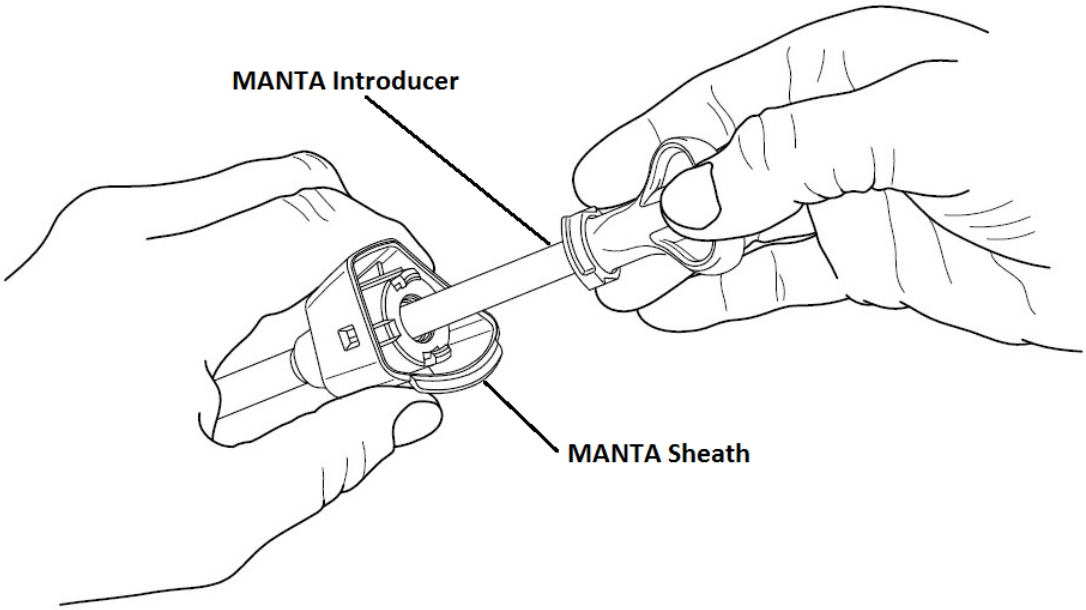


Figure 3 – Inserting the MANTA Introducer into the MANTA Sheath

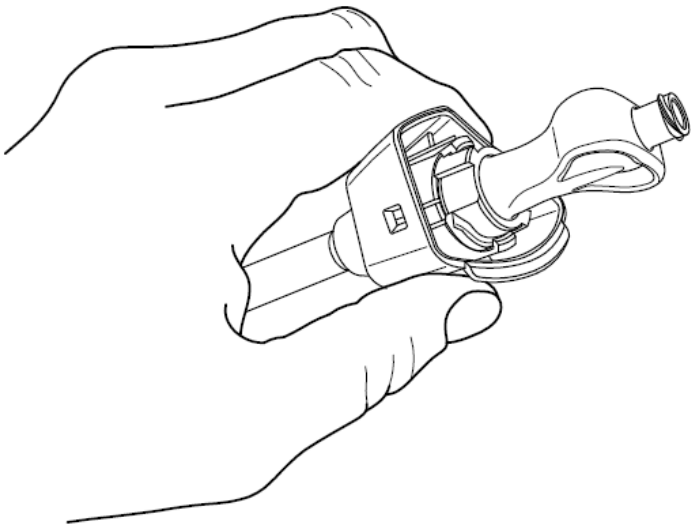


Figure 4 – The Assembled MANTA Introducer and Sheath

- Remove the large-bore procedure sheath while maintaining vessel access with the guidewire. Utilize digital pressure as needed during this step.
- Advance the assembled MANTA Sheath and MANTA Introducer over the guidewire as far as the patient anatomy will permit.

  NOTE: If significant resistance is felt advancing the MANTA Sheath and Introducer into the vessel, this may be indicative of swelling, scar tissue, calcification, or tortuosity. DO NOT proceed with MANTA Closure as the device may become damaged.

- Remove the MANTA Introducer from the MANTA Sheath, leaving the guidewire and MANTA Sheath in position. The MANTA Introducer hub must be rotated ¼ turn counter-clockwise to unlock and remove from the Sheath. The MANTA Sheath is now in position to receive the MANTA Closure (Figure 5).

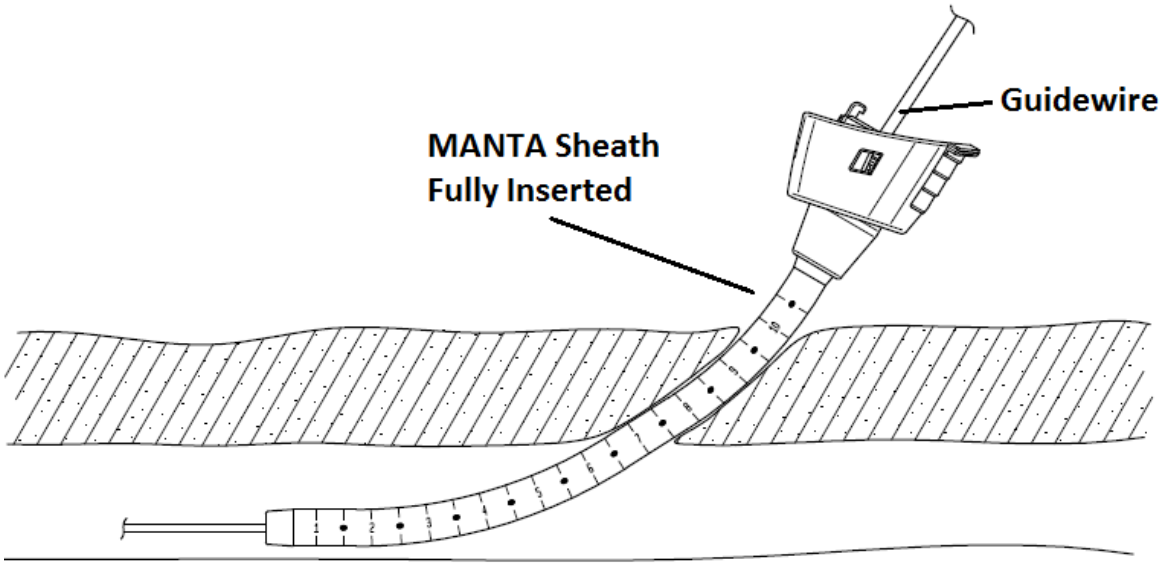


Figure 5 – Fully Inserted MANTA Sheath Positioning

Step 3: Insert Device

With the MANTA Sheath in place, the MANTA Closure may now be inserted and deployed:

- Insert the guidewire into the distal guidewire lumen on the MANTA Closure (Figure 6).

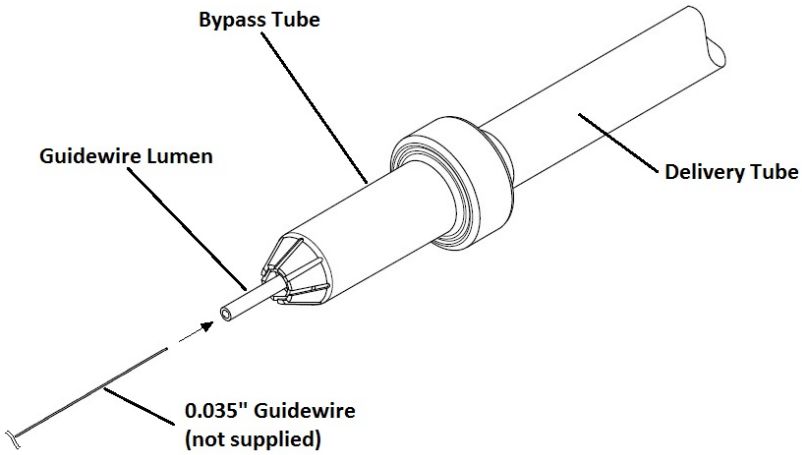


Figure 6 – Insertion of Guidewire into MANTA Closure

- As the guidewire emerges from the back of the MANTA handle and pushes the lumen out of the handle, grasp the lumen and remove from device and guidewire. Discard the lumen. Continue inserting guidewire through MANTA device.
- Ensure the bypass tube is fully covering and protecting the anchor.

- Holding the bypass tube between thumb and forefinger (Figure 7), while grasping the MANTA Closure by the delivery tube AND bypass tube, insert the bypass tube gradually into the hemostasis valve and into the MANTA Sheath hub.

  NOTE: If significant resistance is felt inserting the bypass tube into the MANTA Sheath, remove the entire system and open a new device.

- Push the bypass tube into the Sheath hub and observe that the bypass tube is completely inserted. Note that the device must be upright with orientation markers visible and facing upward.

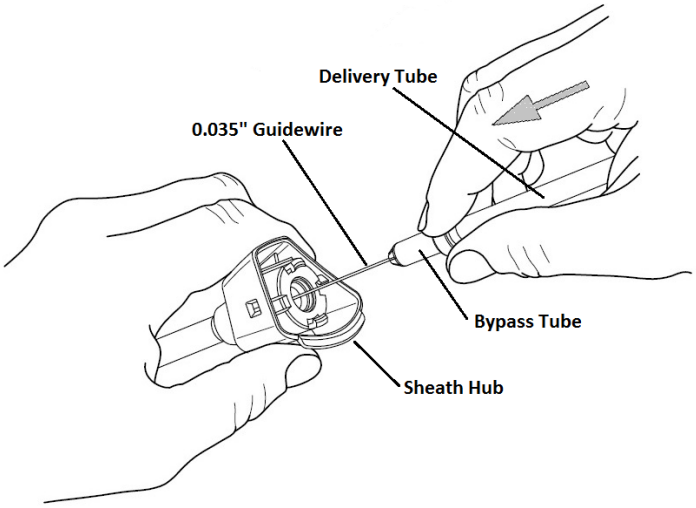


Figure 7 – Insertion of MANTA Closure - Holding the Bypass Tube

- Advance the delivery tube of the MANTA Closure THROUGH the bypass tube and down the MANTA Sheath until the MANTA delivery handle approaches the Sheath hub. Make small advancements to avoid kinking the delivery tube of the MANTA Closure (Figure 8).

  NOTE: If the MANTA delivery system becomes kinked during insertion into the Sheath, remove the entire system and open a new device.

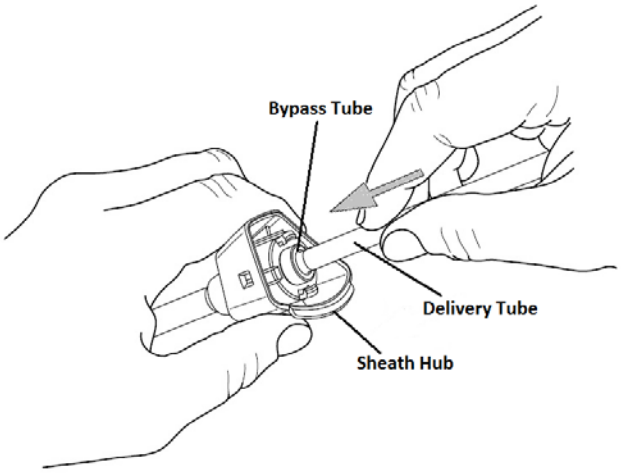


Figure 8 – Advance Delivery Tube and MANTA Closure into MANTA Sheath

- Align the MANTA delivery handle to the Sheath hub (Figure 9) and carefully advance the MANTA Closure until the delivery handle snaps to the Sheath hub where an audible click will be heard. The MANTA Closure is now fully inserted into the MANTA Sheath (Figure 10).

  NOTE: DO NOT advance MANTA Closure fully into Sheath if significant resistance is felt, indicating that the anchor is meeting resistance in entering the vessel. Reposition the Sheath by slightly retracting the Sheath if necessary.

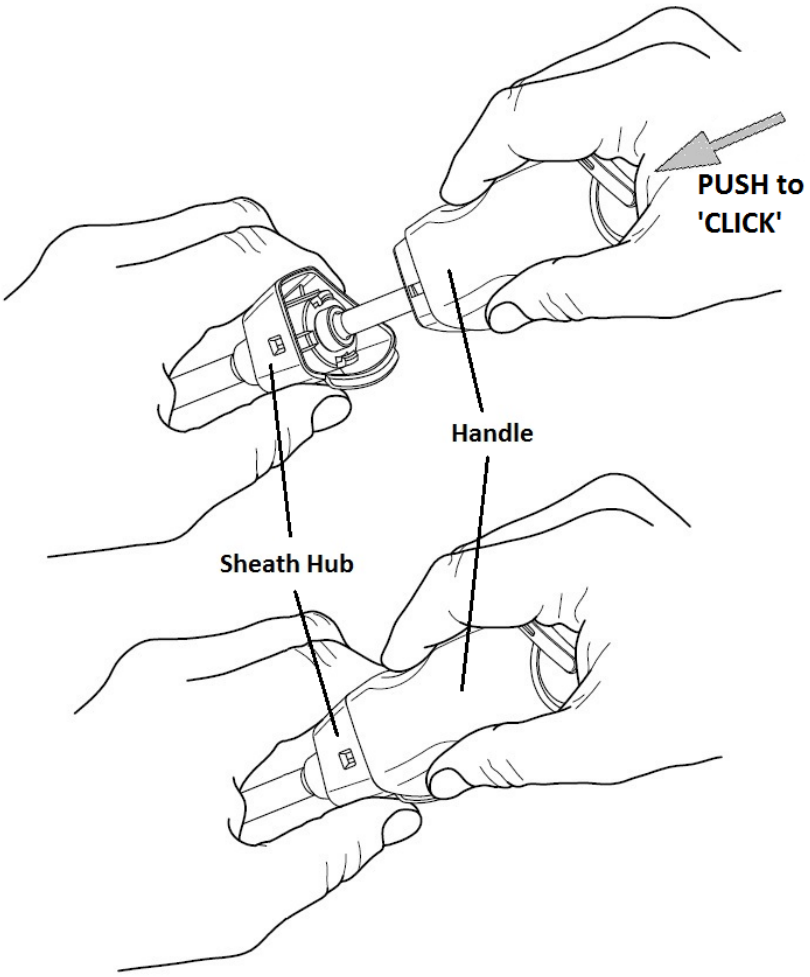


Figure 9 – MANTA Closure Insertion into MANTA Sheath

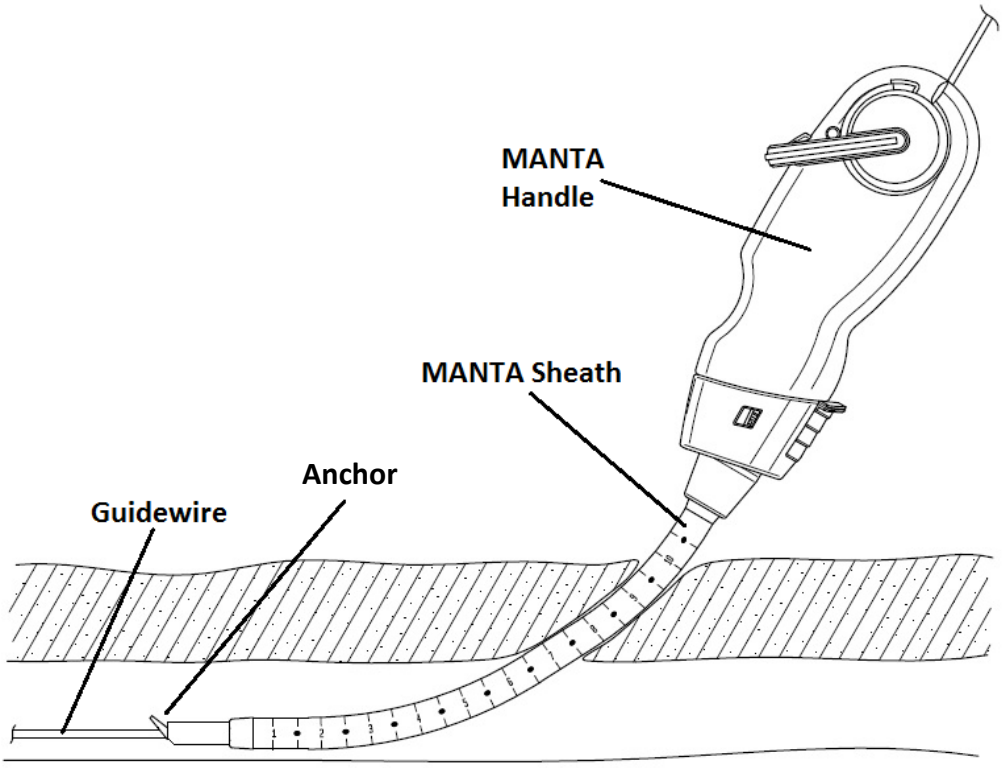


Figure 10 – MANTA Closure Device fully inserted into vessel

Step 4: Position Device

Before Deploying the device and releasing the anchor, position the MANTA Closure and Sheath according to the deployment depth noted in 'Step 1: Arteriotomy Locating Procedure.'

- Grasp the MANTA Delivery handle and slowly withdraw the MANTA Closure and Sheath until the depth marking appears that corresponds to the deployment depth noted during Step 1. The MANTA Closure is now in deployment position (Figure 11) and ready for anchor release.

  NOTE: DO NOT re-advance the MANTA Closure and Sheath deeper into the vessel if they are withdrawn past the deployment depth. If this occurs prior to rotating the lever, remove the entire system and open a new device.

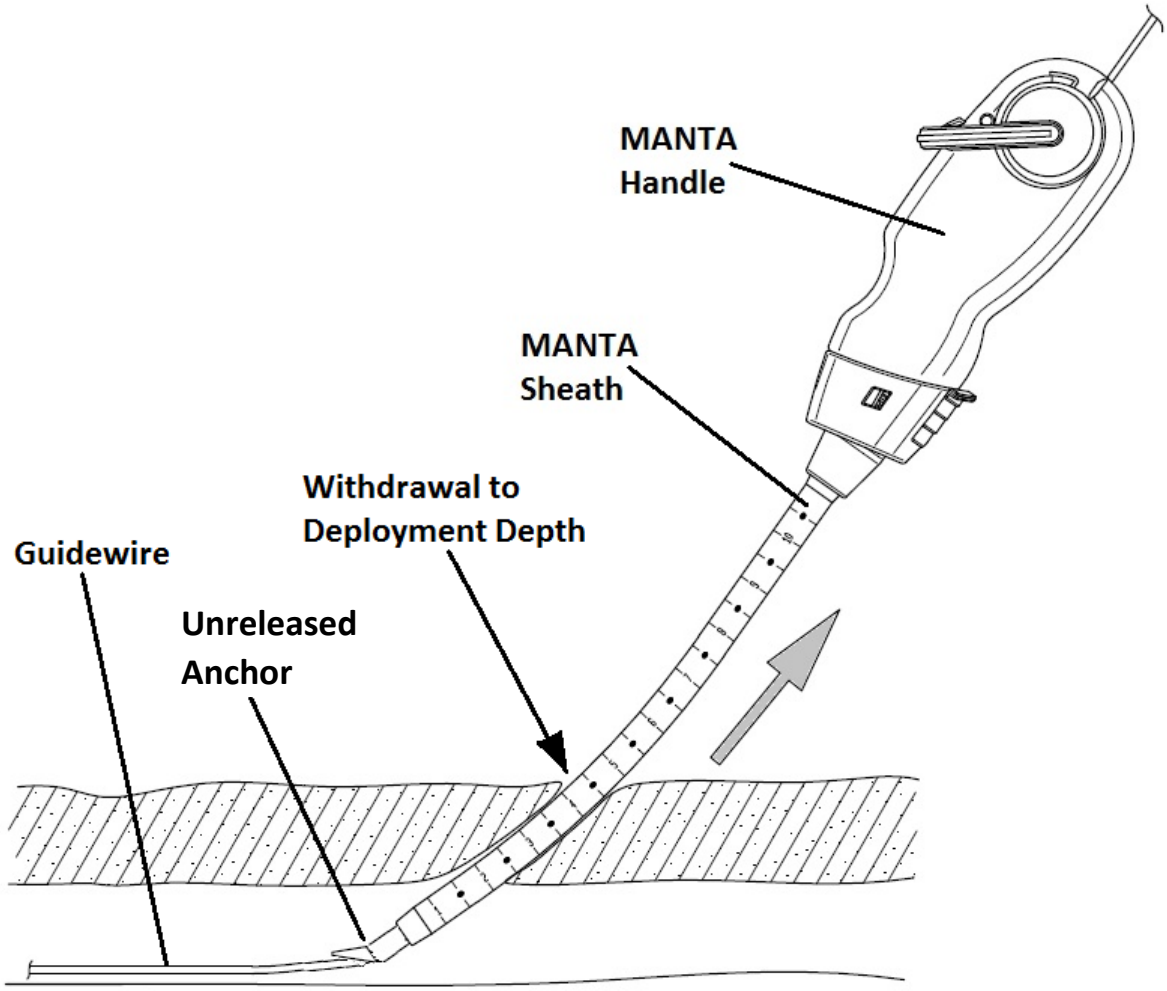


Figure 11 – Positioning the MANTA Closure and Sheath

Step 5: Deploy Device and Seal Puncture

- Hold the MANTA Handle in the right hand at a 45 degree angle to the leg. While grasping the proximal handle end of the MANTA Closure with the right hand, completely actuate the lever arm in the clockwise/ proximal direction. This deploys and releases the anchor within the vessel (Figure 12).

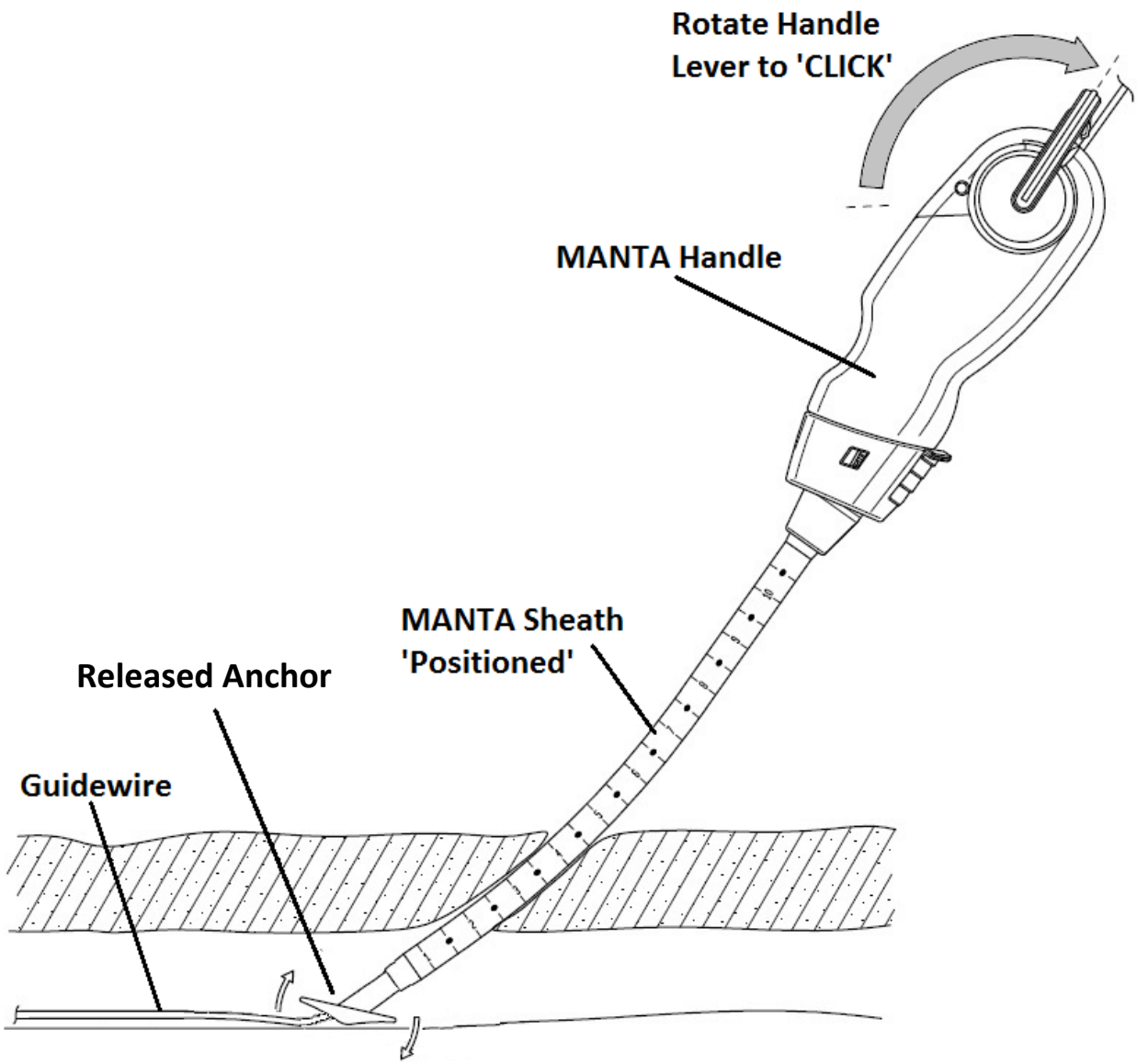


Figure 12 – Actuating the Handle Lever and Releasing the Anchor

- While maintaining neutral digital pressure at the puncture with the fingers of the left hand, withdraw the MANTA slowly and carefully from the patient along the angle of puncture, approximately 45 degrees (Figure 13).

  NOTE: DO NOT apply compressive or occlusive manual/digital pressure to the vessel while rotating lever, releasing the anchor, or withdrawing the MANTA device. Only support the skin enough to prevent distension of the vessel.

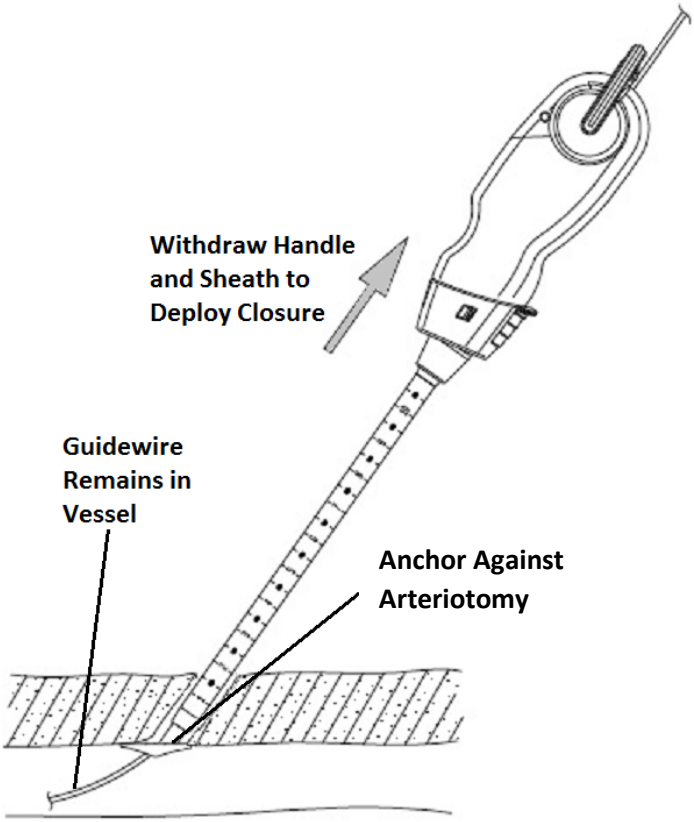


Figure 13 – Deploy Along Angle of Tract

- Continue to withdraw the MANTA Closure until the tension gauge begins to show YELLOW/GREEN in the tension window (Figure 14). The BLUE lock advancement tube will emerge (Figure 15).

  NOTE: DO NOT pull past GREEN. Excessive force may cause vessel damage. Only light tension (YELLOW/GREEN) is required.

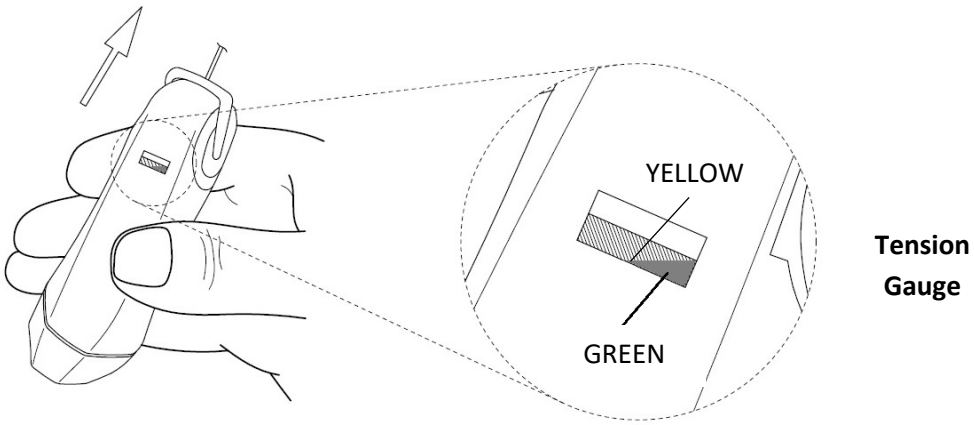


Figure 14 – Tension Gauge Visual

The collagen plug has now been deployed, and the radiopaque lock must be advanced to fully seal:

- MAINTAIN constant YELLOW/GREEN tension while the BLUE lock advancement tube emerges from the MANTA Closure (Figure 15). Note that the tension gauge indicator will show a RED zone when excessive force is applied.
- While maintaining light tension as indicated by the YELLOW/GREEN to full GREEN indicator, grasp the BLUE lock advancement tube.

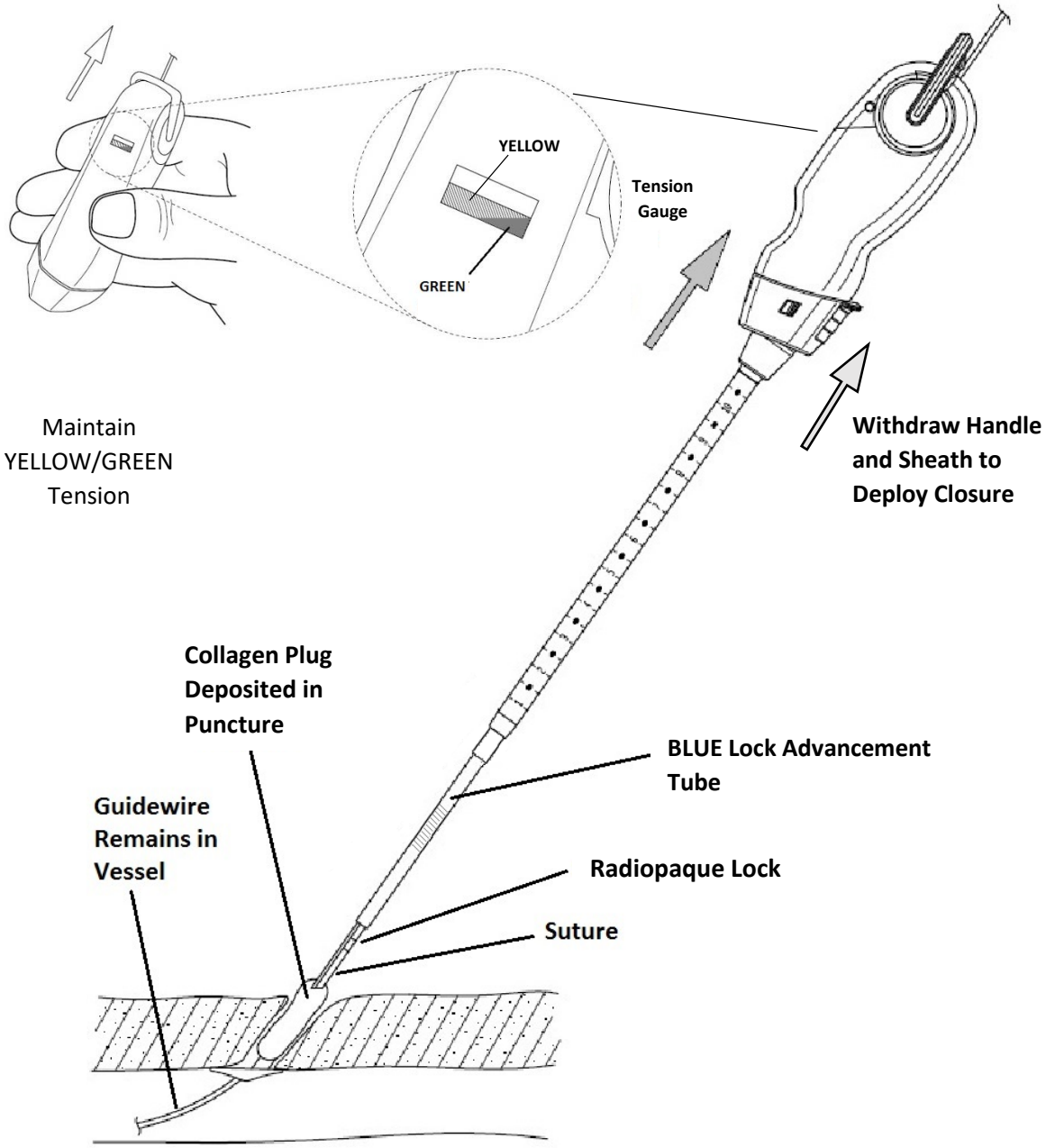


Figure 15 – Collagen Deployment Prior to Advancing Radiopaque Lock

- Lightly slide the BLUE lock advancement tube down the suture and advance the radiopaque lock distally to secure the implant (Figure 16), maintaining constant tension (indicator showing GREEN) on the MANTA Closure handle with the right hand.
- While maintaining the position of the BLUE lock advancement tube, increase tension on the MANTA Closure handle slightly, until an audible click is heard.

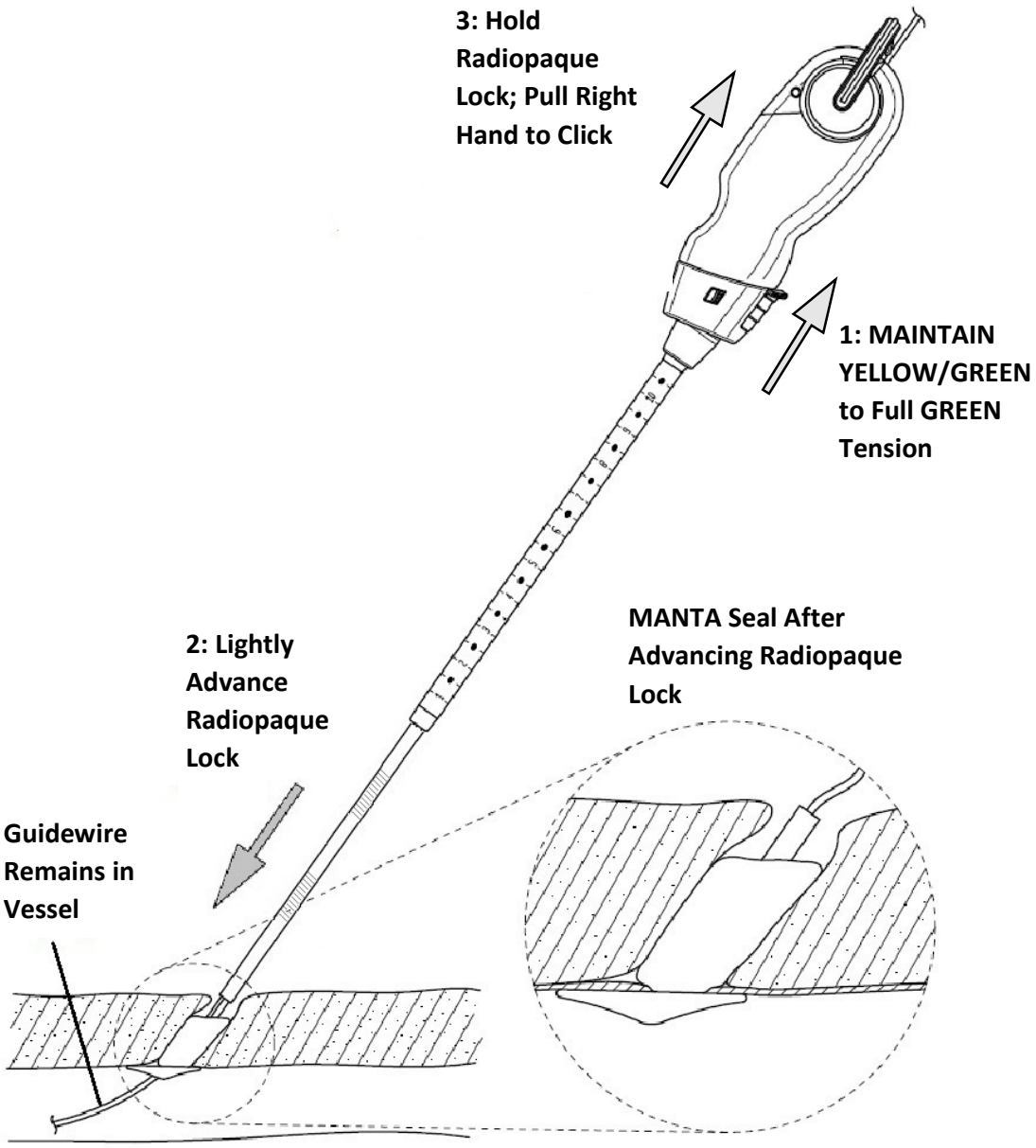


Figure 16 – Pull to Tension Indicator and Advance Radiopaque Lock

- Relax upward tension on the MANTA Closure handle. Slide the BLUE lock advancement tube up the suture and out of the puncture tract. Observe the puncture site and confirm hemostasis.

- If pulsatile arterial bleeding (greater than subcutaneous oozing) persists, advance the BLUE lock advancement tube a second time after achieving GREEN/YELLOW tension on the MANTA handle. If bleeding is non-pulsatile, DO NOT perform a second lock advancement. Apply manual pressure to facilitate hemostasis.

  NOTE: With tension removed, a visible GRAY indicator band at the proximal tip of the delivery tube will confirm the radiopaque lock is fully advanced and collagen is compacted (Figure 17).

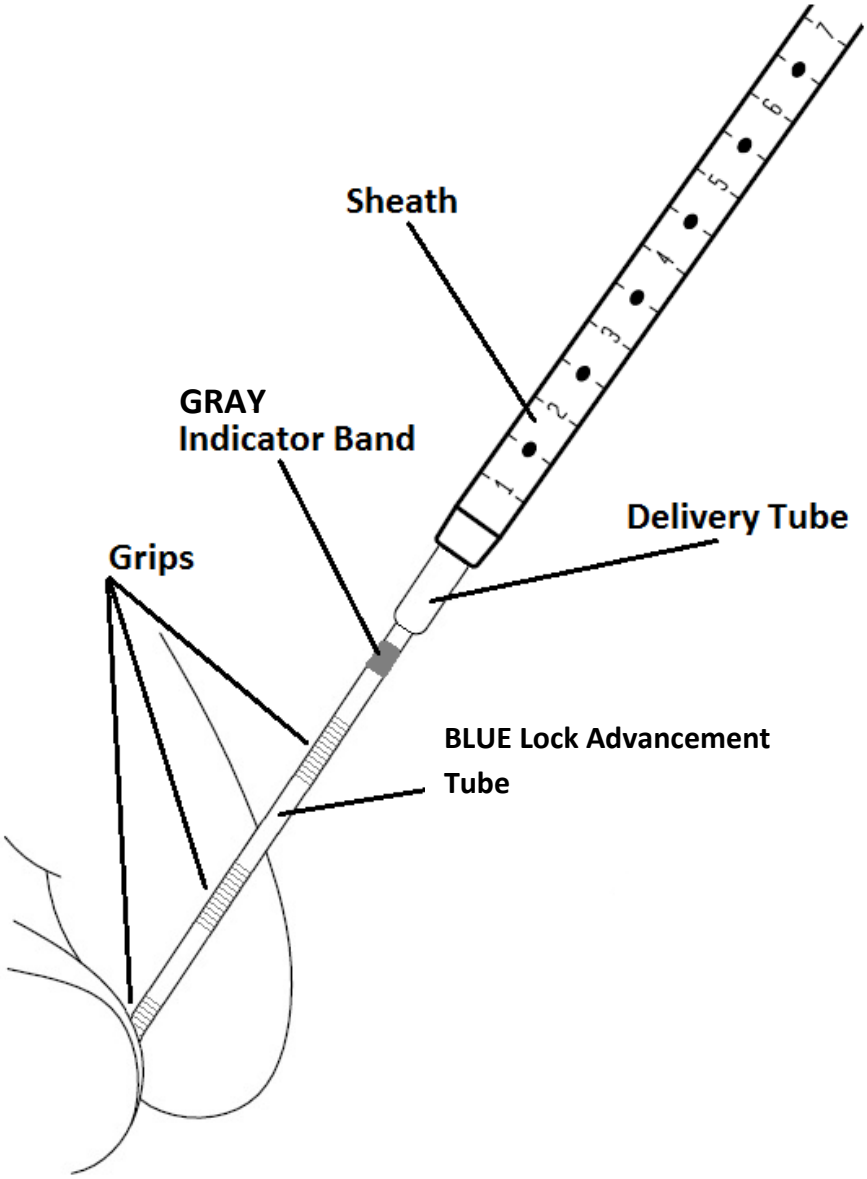


Figure 17 – Note GRAY Indicator Band, Indicates Full Collagen Compaction

- If hemostasis has still not been achieved, additional light, non-occlusive manual pressure should facilitate hemostasis.

  NOTE: A femoral angiogram may be performed to confirm patency and lack of extravasation.

- Once arterial hemostasis has been achieved, remove the guidewire.
- Press down on the skin at the puncture tract and cut the suture below the level of the skin (Figure 18).

  NOTE: Visible suture at skin level may lead to infection.

- A small sterile dressing or pressure bandage may be applied to the access site as needed.

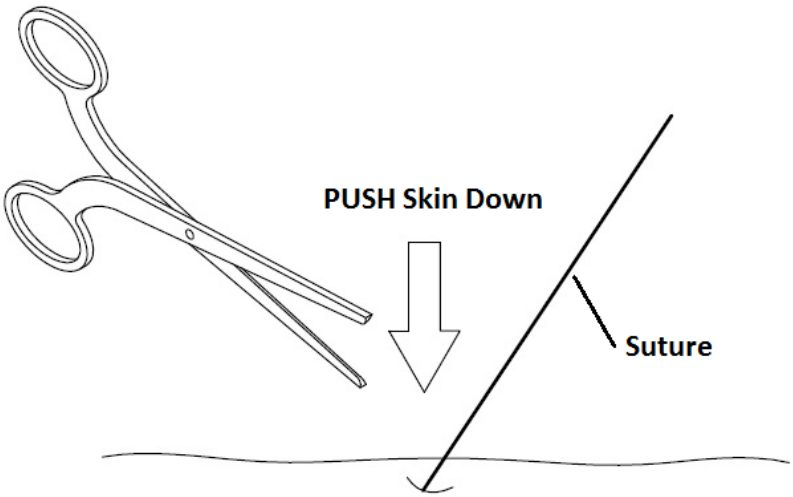


Figure 18 – Cut Suture below Skin

Recatheterization/Reintervention

In the event that a patient requires reintervention after a MANTA Closure has been placed:

- Using X-ray, locate the existing MANTA Closure Device(s), visible by the small radiopaque marker.
- Select a puncture site on the common femoral artery at least 2.5 cm above or below the existing MANTA Closure Device(s) to avoid interference from scar tissue or unresorbed MANTA components.
  NOTE: When selecting puncture site, take care to observe "Warnings" section above.
- Proceed with device deployment per "Device Use Steps" above.

PRODUCT INFORMATION DISCLOSURE

Essential Medical, Inc. has taken reasonable care in the manufacture of MANTA and excludes all warranties, expressed or implied, by operation of law or otherwise, including but not limited to any implied warranties of merchantability or fitness, since handling or storage of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Essential Medical, Inc.'s control directly affect the MANTA and the result obtained from its use. Essential Medical, Inc. shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of MANTA. Essential Medical, Inc. neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with MANTA.

MRI Safety Information:

MR CONDITIONAL

Non-clinical testing demonstrated that the MANTA is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic fields of 1.5-Tesla and 3-Tesla
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode

Under the scan conditions defined for, the MANTA is expected to produce a maximum temperature rise of 2°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the MANTA extends approximately 10-mm from the MANTA when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Safety Information:

	Do Not Reuse – Single Use Only		Use By Date
	Do Not Resterilize – Single Use Only	STERILE R	Sterilized Using Irradiation
	Read Instructions For Use		Manufacturer
	Keep Dry – Protect From Moisture	15°C 49°C	Temperature Limitation – 15-49C
	Do Not Use if Package is Open or Damaged	REF	Catalog Number
	Keep Away From Sunlight	LOT	Lot Number
Rx	Prescription Use Only		

Revision History

Revision	Date	Description	ECN
A	23May2016	Original Issue	N/A
B	20July2016	Added exclusion criteria for patients unable to receive anti-coagulation therapy. Included anti-coagulation as a procedural requirement.	N/A
C	27 Jul 2016	Changed Tamper design that affected Figures 15 -18 and associated text.	N/A
D	23 Aug 2016	-Removed Procedure Requirement: “If a patient has had a procedure sheath left in place for longer than 8 hours, consideration should be given to the use of prophylactic antibiotics before insertion of the MANTA Device.” Patients with interventional sheaths or devices left in place for longer than 6 hours will be excluded from the study per PSD-109. -Clarified vessel sizes in the Procedure Preparation section to align with PSD-109.	N/A
E	15 Dec 2016	-Changed “index” procedure to “large-bore” procedure throughout document for clarity. -Added enhanced banners of BEFORE and AFTER large-bore procedure for clarity.	N/A
F	21 Aug 2017	- Device Deployment will occur at Blood Flow Stop +1 cm instead of +2cm - Blue Tamper Tube Renamed to Blue Lock Advancement Tube - No occlusive/compressive pressure should be exerted on the vessel during device deployment - During puncture location, specific attention should be paid to maintaining a neutral skin position - Added bypass tube inspection step.	N/A
G		-Updated Essential Medical Address, logos, revised “Caution” note on first page -Added “BLUE” before “lock advancement tube” references, capitalized DO NOT and colors throughout -Contraindications – added to match PSD-016 -Warnings – Added 6th, 7th, and 8th bullets, clarified wording in 10th and 11th bullets, removed “Do not use if the procedure sheath has been placed through the superficial femoral artery and into the profunda femoris artery, as this may result in collagen deposition into the superficial femoral artery.” -Precautions – Clarified wording in 2nd and 3rd bullets -Special Patient Populations – added to match PSD-016-Adverse Events – Added 4th, 6th, and 7th bullets, clarified wording in 1st, 2nd, 3rd, 5th, and 8th bullets, removed “damage to the superficial femoral artery” Adverse Events – Added in potential adverse events associated with any large bore intervention from PSD-109 that were not included above. Added study description, Tables 1,2, and 3 and discussions.- Manta Clinical Trial - Added MANTA Clinical Trial section - Effectiveness Results – Added section along with Table 4, 5, and 6 and Figure 1 - Safety Results – Added section - Conclusion – Added section -Procedure Requirements - Added 1st, 2nd, 5th, 7th, and 14th requirements, clarified wording in 12th requirement -Step 1 – Changed 9 ½ to 9.5 cm. Clarified wording in 6th bullet -Step 2 – Added Note -Step 3 – Added 1st and 2nd Notes, clarified wording on 4th bullet and separated into another bullet (5th) -Step 4 – Added Note -Step 5 – Clarified wording in 1st, 6th, 7th, 8th, 9th, 10th, and 13th bullets, Figures 12 and 16, and Note 1 for clarity. Rearranged bullets for clarity, added 3rd, 4th, and 5th notes -Safety Information - updated upper limit of temperature limitation to 49 C, removed EC representative block, added Rx block and symbol	464
H		To be completed	