



Highlights from:

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Left atrial appendage occlusion using a Watchman device in a transplanted heart with biatrial anastomosis

INTRODUCTION

- ▶ Biatrial anastomosis orthotopic heart transplant (OHT) results in enlarged atria, scarred and thickened interatrial septum, and leftward rotation of the heart, thereby complicating left atrial appendage (LAA) closure.
- ▶ This report describes successful LAA occlusion in a patient with previous biatrial anastomosis OHT using the WATCHMAN™ Device and the radiofrequency (RF) NRG™ Transseptal Needle (Baylis Medical*) for controlled crossing of the septum.

METHODS AND RESULTS

Transseptal puncture

- ▶ Transesophageal echocardiography (TEE) indicated a thickened interatrial septum from the prior biatrial anastomosis and scar tissue.
- ▶ Site-specific transseptal puncture in the inferio-posterior location of the fossa ovalis was achieved using the NRG™ Needle with minimal additional force.

LAA occlusion

- ▶ Standard TEE views (0°, 45°, 90°, and 135°) were adjusted by 10–20° to account for the effects of biatrial anastomosis and replicate the desired LAA ostial views for appropriate device sizing.
- ▶ Successful deployment of a 21 mm WATCHMAN™ Device into the LAA was achieved with no complications.
- ▶ 45 days post-operative TEE indicated no thrombus formation or residual flow in the LAA.
- ▶ Anticoagulation was administered for 45 days, while antiplatelet therapy was continued for six months post-procedure, respectively.

DISCUSSION AND CONCLUSIONS

- ▶ Changes in atrial morphology and leftward rotation of the heart, such as those seen in this patient with biatrial anastomosis OHT, can make standard WATCHMAN™ implantation difficult.
- ▶ Site-specific transseptal puncture and firm engagement of the interatrial septum can be complicated by scarring and thickening of the septum, and may result in accidental puncture and perforation.
- ▶ Additional balloon dilation of the septum may be required to advance the large LAA occluder sheath into the left atrium.
- ▶ The NRG™ Transseptal Needle was used to provide controlled site-specific crossing of the interatrial septum without complications.
- ▶ Using a radiofrequency needle can enable simpler and safer access to the left atrium, without requiring extra force application.
- ▶ LAA occlusion using the WATCHMAN™ Device in a patient with prior biatrial anastomosis OHT can be safely and successfully performed using the described procedural modifications.

Brief Summary | NRG™ Transseptal Needle

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS: The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The NRG™ Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG™ Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.

PRECAUTIONS: • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

ADVERSE EVENTS: Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

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Brief Summary | WATCHMAN FLX™ Device

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The WATCHMAN FLX Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who: Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASC scores and are recommended for anticoagulation therapy. • Are deemed by their physicians to be suitable for anticoagulation therapy. • and Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

CONTRAINDICATIONS: Do not use the WATCHMAN FLX Device if: Intracardiac thrombus is present • An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present. • The LAA anatomy will not accommodate a Closure Device (see Table 45 of the eIFU). • The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section of the eIFU) such that the use of the WATCHMAN FLX Device is contraindicated. • Any of the customary contraindications for other percutaneous catheterization procedure (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present. • There are contraindications to the use of anticoagulation therapy, aspirin, or P2Y12 inhibitor.

WARNINGS: Implantation of the WATCHMAN FLX Device should only be performed by interventional cardiologists and/ or electrophysiologists who are trained in percutaneous and transseptal procedures and who have completed the WATCHMAN FLX Physician Training program. • This device has not been studied in pregnant or breastfeeding women. Careful consideration should be given to use of the Closure Device in pregnant and/ or breastfeeding women due to the risk of significant exposure to x-rays and the use of anticoagulation medication. • Device selection should be based on accurate LAA measurements obtained using echocardiographic imaging guidance in multiple views (TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]) to avoid improper Closure Device sizing. • Do not release (i.e., unscrew) the WATCHMAN FLX Device from the core wire unless all release criteria are satisfied to avoid suboptimal results. • Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period. • Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section (of the eIFU) for further detail.

PRECAUTIONS: The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated. • The LAA is a thin-walled structure. Use caution when accessing the LAA, and deploying, recapturing, and repositioning the Closure Device. • Use caution when introducing a WATCHMAN Access System to prevent damage to cardiac structures. • Use caution when introducing the Delivery System to prevent damage to cardiac structures. • To prevent damage to the Delivery Catheter or Closure Device, do not allow the WATCHMAN FLX Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath. • If using a power injector, the maximum pressure should not exceed 100 psi.

PATIENT SELECTION FOR TREATMENT: In considering the use of the WATCHMAN FLX Device, the rationale for seeking an alternative to long-term anticoagulation therapy and the safety and effectiveness of the device compared to anticoagulation should be taken into account. • The presence of indication(s) for long-term anticoagulation therapy, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, hypercoagulable states, recurrent deep venous thrombosis). • Details regarding the indications, contraindications, warnings, and precautions for oral anticoagulants approved for patients with non-valvular atrial fibrillation are provided in their respective Instructions for Use. Of note: • The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated. • Factors that need to be considered for the WATCHMAN FLX Device and implantation procedure include the following: • Overall medical status, including conditions which might preclude the safety of a percutaneous, transcatheter procedure. • Suitability for percutaneous, transseptal procedures, including considerations of: ◦ Cardiac anatomy relating to the LAA size and shape. ◦ Vascular access anatomy (e.g., femoral vein size, thrombus, or tortuosity). ◦ Ability of the patient to tolerate general or local anesthesia. ◦ Ability of the patient to undergo required imaging. ◦ Ability to comply with the recommended post-WATCHMAN FLX Device implant pharmacologic regimen (see Post-Procedure Information section) especially for patients at high risk for bleeding.

ADVERSE EVENTS: Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to: Air embolism • Airway trauma • Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medications • Altered mental status • Anemia requiring transfusion • Anesthesia risks • Angina • Anoxic encephalopathy • Arrhythmias • Atrial septal defect • Bruising, hematoma, or seroma near the catheter insertion site • Cardiac perforation • Chest pain discomfort • Confusion post procedure • Congestive heart failure • Contrast related nephropathy • Cranial bleed • Death • Decreased hemoglobin • Deep vein thrombosis • Device embolism • Device fracture • Device thrombosis • Edema • Embolism • Excessive bleeding • Fever • Fistula • Groin pain • Groin puncture bleed • Hematuria puncture • Hemoptysis • Hypotension • Hypoxia • Improper wound healing • Inability to reposition, recapture, or retrieve the device • Infection/pneumonia • Interatrial septum thrombus • Intratracheal bleeding • Major bleeding requiring transfusion • Misplacement of the device/improper seal of the appendage/movement of device from appendage wall • Myocardial erosion • Nausea • Oral bleeding • Pericardial effusion/tamponade • Pleural effusion • Prolonged bleeding from a laceration • Pseudoaneurysm • Pulmonary edema • Renal failure • Respiratory insufficiency/failure • Stroke - Hemorrhagic • Stroke - Ischemic • Surgical removal of the device • TEE complications (e.g., throat pain, bleeding, esophageal trauma) • Thrombocytopenia • Thrombosis • Transient ischemic attack (TIA) • Valvular or vascular damage • Vasovagal reactions • There may be other potential adverse events that are unforeseen at this time.

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