



Highlights from:

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Site-Specific Transseptal Puncture for Emerging Structural Heart Interventions

INTRODUCTION

- ▶ This article reviews the importance of precision in transseptal puncture to optimize left-sided structural heart procedures such as mitral valve (MV) repair, left atrial appendage (LAA) occlusion, and mitral paravalvular leak closure. In addition, the article discusses the importance of guidance by various views on transesophageal echocardiography (TEE) and intracardiac echocardiography (ICE) and how these imaging modalities help guide site-specific transseptal puncture for structural heart interventions.

METHODS

- ▶ A slightly superior-posterior transseptal puncture (Figure 1) optimizes the MitraClip™ procedure to achieve the adequate 3.5–4 cm height above the MV annulus.
- ▶ A posterior and mid to slightly inferior transseptal puncture (Figure 1) optimizes the LAA procedure to enhance the coaxial sheath orientation towards the LAA.

DISCUSSION AND CONCLUSIONS

- ▶ Repeat transseptal punctures can result in a thick and fibrotic septum, making subsequent transseptal punctures challenging. The **NRG™** Transseptal Needle (Baylis Medical*) provides added value to these cases by providing targeted RF delivery for safe passage into the left atrium without needing the force required with mechanical needles.
- ▶ Precision in transseptal puncture is critical for success in many structural heart procedures.

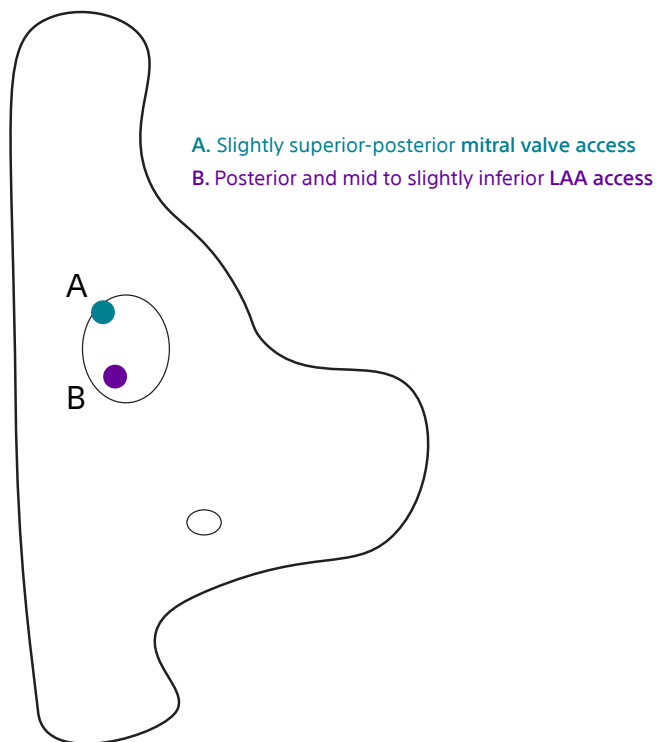


Figure 1. Approximate transseptal puncture locations on the fossa ovalis for structural heart procedures (right anterior oblique view).

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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