This procedure is performed on patients who meet the determined patient selection criteria attached and agree to sign the detailed informed consent and financial liability statement if not covered by their insurance provider.

**POLICY:**

1. **Education:** M.D. or D.O.
2. **Training:**
   - A. Interventional Cardiologist or
   - B. Cardiovascular Surgeon with Endovascular Training

AND

- C. Fellowship must include training in PFO closure with a competency letter from the program director, or
- D. Successful completion of PFO training course

3. **Proctoring:**
   - A. 5 cases proctored by a currently credentialed SJRMC physician, or
   - B. 2 cases proctored by a currently credentialed SJRMC physician if the physician has documentation of 5 cases performed at an outside facility

4. **Current Competence:**
   - A. 2 ASD/PFO cases required at reappointment

**References/Standards:**
- Policy Origin Date: May 2007
- Review Date: December 2009, December 2012, December 2015
- Revised Date: December 2009, September 2010, September 2015
- Effective Date: June 2007
- Reviewed/Recommended By: Medical Executive Committee
- Policy 171
PFO Patient Selection Criteria

Category 1 PFO Closure of symptomatic Patients without a cryptogenic stroke.
   a. Significant right to left shunt in the setting of an RV infarct or dysfunction resulting in symptomatic hypoxemia
   b. Significant right to left shunt in the setting of massive pulmonary embolus resulting in hypoxemia which is nonresponsive to oxygen therapy
   c. Orthodeoxia
   d. Air embolism in scuba divers
   e. Other events resulting in right to left shunting with significant hypoxemia refractory to oxygen therapy

Category 2 PFO Closure in the setting of embolic events
   a. Atrial septal aneurysm in patients who are not a candidate for antiplatelet or anticoagulation therapy,
   b. Atrial septal aneurysm in patients who refuse medical therapy
   c. Embolic events in patients with deep venous thrombosis and are at high risk for recurrent deep venous thrombosis
   d. Atrial septal aneurysm in patients with significant bidirectional shunt may be reviewed by Department Chair or Medical Director of Echo Lab who will amend the report to state that the PFO is truly an acquired ASD by definition (PFO can only have right to left shunting)
   e. Any other reason with consensus agreement from the cardiovascular peer review committee
   f. Patients with a PFO who have recurrent embolic events on antiplatelet or anticoagulation therapy when no other cause of embolic event can be found

Patients must agree to sign the detailed informed consent stating that this is either a Class II or III indication for closure of PFO to reduce the risk of paradoxical embolus.

Patients must also agree to a financial liability statement if not covered by their insurance provider.

PFO procedures will be tracked and trended. If the volume of PFOs exceeds expectations, case reviews may be performed by CMO or designee to assure procedures follow above criteria, have appropriate informed consent and reimbursement.
RELEASE OF LEGAL LIABILITY AND CONSENT TO PFO CLOSURE
Saint Joseph Regional Medical Center

I, __________________________________________, hereby voluntarily authorize Saint Joseph Regional Medical Center, Inc., an Indiana nonprofit corporation, and its employees, agents, and contractors, including, without limitations, ________________________, M.D. and ________________________, M.D. and their respective colleagues and assistants (collectively, "SJRMCRMC"), to perform upon me a procedure to close the Patent Foramen Ovale ("PFO"), an opening in my heart (the "Procedure").

I understand that one or both of the doctors named above have determined that my PFO opening is the likely cause of my symptoms of heart attack, stroke or Transient Ischemic Attack (TIA) or other illness considered to be a blood clot injury to another organ in my body (the "Symptoms"). I understand that the Procedure is done by inserting two tubes (or catheters) through the skin in my groin into a vein. One tube will contain an ultrasound probe (an intra-cardiac echocardiography probe) that the doctor will use to view my heart and place the patch in the opening in the upper chamber of my heart. The other tube will contain the patch used to close the PFO.

One or both of the doctors named above has also informed me that in some cases, cardiologist will assist by inserting a different type of echocardiographic probe into my mouth and throat to help direct the patch into the small opening in my heart. I understand that I will receive sedation medication and be monitored during the entire Procedure. An anesthesiologist may help during the Procedure if needed. I consent, therefore, to anesthesia care.

I will be monitored after this Procedure until the next day or longer if needed to insure my safety.

I have been given an opportunity to ask questions about the Procedure, and all of my questions have been answered fully and satisfactorily. I acknowledge that no guarantees or assurances have been made to me concerning the results intended from the Procedure.

Possible Risks or Discomforts that I may have
The Procedure involves the insertion of tubes into the veins in my leg. I could have bleeding when these tubes are removed or while the tubes are present in my vein. This could cause swelling and discomfort in my groin area. Because I will receive anticoagulation medications, I might bleed from another distant organ and blood transfusion may be needed. Possible complications will include changes in my heart rhythm that could require treatment including possible electrical cardioversion. A perforation could occur in my heart or large vessel that may require further procedures or surgery. A stroke, heart attack, or other complication from movement of the patch may require that it be snared or possibly removed surgically. Other possible complications could include death, and other unforeseen complications.

Alternate Treatments and Effectiveness of Procedure
The alternate treatment for this opening in my heart is to take anticoagulation medication on an indefinite basis to prevent a blood clot from forming and causing more damage or symptoms.

SJRMCRMC has information me that as of the date hereof, no clinical studies have concluded that the Procedure is a more effective method of managing or alleviating the Symptoms than the alternative treatment of consistent and indefinite use of anticoagulation medication. I understand and acknowledge that the Procedure is not more effective at managing or alleviating the Symptoms than consistent and indefinite use of anticoagulation medication.
Further Care for Complications of Treatment
My physician performing the Procedure will provide further care and monitoring of any complication that occurs because of this Procedure.

Financial Responsibility
SJRMC has informed me, and I understand, that the Procedure and any follow up care required to address complications related to the Procedure may not be covered by insurance carriers or government health care programs such as Medicare, Medicaid and Tricare. Further, SJRMC has informed me, and I agree, that SJRMC will attempt to bill my health plan for the Procedure and all follow up care related to the Procedure provided by SJRMC, but if my health plan refuses to pay for any such services, I am responsible for the FULL AMOUNT of all SJRMC's charges for the services my health plan refuses to cover. SJRMC has explained the potential amount of my financial liability in the event my health plan does not cover the Procedure and any related follow up care I may require.

Use of an FDA Approved Device for a Non-FDA Approved Indication
My physician has informed me that he/she will use a medical closure device that is approved by the United States Food and Drug Administration ("FDA") for closure of a different type of opening in the heart. The FDA has approved these devices for use in people who have an atrial septal defect or a ventricular septal defect (a hole in the wall in the upper or lower chamber of the heart). I have been informed that other cardiologists and heart specialists in the U.S. and other countries use these devices routinely for people with a PFO.

RELEASE OF ALL LEGAL LIABILITY. I HEREBY RELEASE AND FOREVER DISCHARGE SJRMC, AND ALL OF ITS DIRECTORS, OFFICERS, TRUSTEES, INSURERS AND ATTORNEYS, PAST, PRESENT, AND FUTURE, AND ALL PREDECESSORS, HEIRS, SUCCESSORS, AND ASSIGNS THEREOF OF AND FROM ANY AND ALL LEGAL LIABILITY, CLAIMS, DEMANDS, DAMAGES, EXPENSES, OBLIGATIONS, AND LIABILITIES OF ANY NATURE OR KIND WHATSOEVER BASED ON ANY ACT OR OMISSION IN CONNECTION WITH OR IN ANY WAY RELATED TO OR ARISING OUT OF THE PROCEDURE, INCLUDING, BUT WITHOUT LIMITATION, LIABILITY AND CLAIMS FOR NEGLIGENCE OR OTHER UNREASONABLE ACTS OR OMISSIONS.

Other
I understand that I also will be asked to sign a general consent for cardiac catheterization that will be part of this procedure to place this patch. I have read this consent, I understand the procedure and risks involved and all of my questions have been answered to my satisfaction.

I confirm that I have read and fully understand the above, and I have read and fully understand this Release of Legal Liability and Consent to PFO Closure. A copy of this Release of Legal Liability and Consent to PFO Closure will be as valid as the original.

Date and Time: _____________________
Signature: __________________________________________

Signature of Relative, Guardian, or Authorized Person if Patient is a Minor, Mentally Incompetent, or Physically Unable to Sign this Form: __________________________________________

Witness Signature: __________________________________________

Print Name: __________________________________________
Title: PATENT FORAMEN OVALE (PFO) IN ADULTS

Physician Certification

I have explained the nature, purpose, benefits, risks, and alternatives to the Procedure (including no treatment and attendant risks) to the patient or patient representative who has signed this Release of Legal Liability and Consent to PFO Closure. I have solicited and fully answered all questions about the Procedure posed by such individual. I believe that the consenting individual understands what I have explained.

Signature: ________________________________________________________

Date: ____________________________
Title: PATENT FORAMEN OVALE (PFO) IN ADULTS

A. Notifier: Saint Joseph Regional Medical Center, 5215 Holy Cross Pkwy, Mishawaka, IN 46545
(574) 335-5000

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn’t pay for D. the items/services described below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the D. items/services described below.

<table>
<thead>
<tr>
<th>D. Items/Services</th>
<th>E. Reason Medicare May Not Pay:</th>
<th>F. Estimated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent Foramen Ovale (PFO) closure and related items and services.</td>
<td>No clinical studies have concluded that PFO closure is more effective than medical management. PFO closure is therefore typically not covered by Medicare.</td>
<td>[Estimate must fall within 25% of actual costs]</td>
</tr>
</tbody>
</table>

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the D. items/services listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

- OPTION 1. I want the D. items/services listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn’t pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

- OPTION 2. I want the D. items/services listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.

- OPTION 3. I don’t want the D. items/services listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:  

J. Date:  

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.