Extracorporeal Life Support Organization (ELSO)

ELSO Cardiac Addenda
4/15/2024

For all comments, questions and concerns please email
registrysupport@elso.org

ELSO Registry Cardiac Addendum Data Definitions

The CARDIAC ADDENDUM is being updated and expanded with the intention of more accurately reflecting the cardiac physiology and anatomy of patients who are supported with ECMO in order to:

1. Collect data which reflects the complexity of underlying cardiac diagnoses, using the lowest number of data points made up of standardized objective and meaningful data, in order to:
2. Collate clinically meaningful data to help inform medical team decisions based on outcomes of patients with equivalent physiology and anatomy; and
3. Facilitate more accurate anatomical and physiological diagnoses for comparative and outcome studies

Entire Cardiac Addendum is NON-Mandatory, but if centers chose to submit data elements of the Cardiac Addendum, there is a CORE DATASET which is maintained by many of the Cardiac Addendum elements being MANDATORY fields

Mandatory Fields and Major Complications

We indicate mandatory fields in two ways. First, the box for the **Field Name** has a red background (see below). Second, the **Definition/ Explanation/ Example** includes the sentence "**This is a required field.**" See example below:

Mandatory Data Field

Changes for this rollout

We indicate items that have been added or changed usingn this green highlighted box throughout this document to bring your attention to what is new and changed in this version. See example below:

Changes Highlighted

ELSO Cardiac Addenda

Selecting Cardiac as the indication for ECMO on the Main Registry Form will automatically brings this addendum up, but the Cardiac Addenda (Congenital or Adult) are not mandatrory data elements.

Pre ECLS Assessment

Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
NYHA (>18yrs) or Ross (<18yrs) Category:	Measured at time of admission to the hospital. This field collects the NYHA or Ross category. The **New York Heart Association (NYHA)** Classification provides a simple way of classifying the extent of heart failure by placing patients in one of four categories based on their limitations during physical activity. **Class I** - No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc. **Class II** - Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity. **Class III** - Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20—100 m).Comfortable only at rest. **Class IV** - Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients. *https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure*	Must select one classification based on age of patient. If >/= 18yoa then NYHA; If<18yoa then Ross		Cardiac.Cardiac2022Addendum	NYHACategory RossCategory

	The **Ross Heart Failure Classification** was developed to provide a global assessment of heart failure severity in infants, and has subsequently been modified to apply to all pediatric ages. The modified Ross Classification incorporates feeding difficulties, growth problems, and symptoms of exercise intolerance into a numeric score comparable with the NYHA classification for adults. The modified Ross heart failure classification for children is widely cited and is as follows: **Class I**: Asymptomatic **Class II**: Mild tachypnea or diaphoresis with feeding in infants; Dyspnea on exertion in older children **Class III**: Marked tachypnea or diaphoresis with feeding in infants and prolonged feeding times with growth failure; marked dyspnea on exertion in older children **Class IV**: Tachypnea, retractions, grunting or diaphoresis at rest. *Ross RD. The Ross classification for heart failure in children after 25 years: a review and an age-stratified revision. Pediatr Cardiol. 2012 Dec;33(8):1295-300.*				
SCAI Category (Admission)	This field collects the Pre-ECLS SCAI Category: Society for Cardiovascular Angiography and Interventions (SCAI) shock stage classification. Measured at 24h prior to ECLS cannulation. If cannulation is <24 hours of admission, then will be stage at admission. **Select One:**	Must select one stage. Must be after admission, at 24h prior to cannulation, unless date and time of admission is	04/15/2024 Unknown option added	Cardiac.Cardiac2022Addendum	SCAIcAdmission Stage A=1 Stage B=2 Stage C=3 Stage D=4 Stage E=5 Unknown=6

	Stage A: "at risk" for cardiogenic shock, **Stage B:** "beginning" shock **Stage C**: "classic" cardiogenic shock **Stage D**: "deteriorating" **Stage E:** "extremis" **Definitions**: The difference between Stages B and C is the presence of hypoperfusion which is present in Stages C and higher. Stage D implies that the initial set of interventions chosen have not restored stability and adequate perfusion despite at least 30 minutes of observation and Stage E is the patient in extremis, highly unstable, often with cardiovascular collapse. *Baran et al 2019, SCAI clinical expert consensus statement on the classification of cardiogenic shock endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), the Society of Critical Care Medicine (SCCM), and the Society of Thoracic Surgeons (STS) in April 2019, Catheterization and Cardiovascular Interventions, 94:29-37.*	within 24h of cannulation. A=1 B=2 C=3 D=4 E=5			
SCAI Category Immediately Pre-ECMO	This field collects the SCAI category assessed immediately pre-ECMO initiation. **Select One:** **Stage A:** "at risk" for cardiogenic shock, **Stage B:** "beginning" shock **Stage C**: "classic" cardiogenic shock **Stage D**: "deteriorating" **Stage E:** "extremis"	Must select one stage. Must be before and closest to ECLS start time. A=1 B=2 C=3 D=4 E=5	04/15/2024 Unknown option added	Cardiac.Cardiac2022Addendum	SCAIcPreECMO Stage A=1 Stage B=2 Stage C=3 Stage D=4 Stage E=5 Unknown=6
Vasoactive Intotrope Score	This field collects the vasoactive score for the patient 4 hours prior to ECMO Initiation. Exclude patients who transition from Cardiopulmonary bypass to ECMO.	Soft Minimum score = 1, softmaximum score = 100	04/15/2024 min/max values updated	Cardiac.Cardiac2022Addendum	VasoactiveIntScore

	Calculate score as: VIS = dopamine dose (µg/kg/min) + dobutamine dose (µg/kg/min) + 100 x epinephrine dose (µg/kg/min) + 10 x milrinone dose(µg/kg/min) + 10,000 x vasopressin dose (U/kg/min) + 100 x norepinephrine dose (µg/kg/min)	Hard minimum score = 1, hard maximum score = 200 Closest to ECLS start time but within 4h			
Pre-ECLS Cardiac Catheterization	This field collects if a patient had a cardiac catheterization during the ECMO hospitalization but prior to ECLS Support. Select **yes** or **no** or unknown **Yes** will prompt the entry of the **date and time**, and selection of Diagnostic Only, Interventional Only or Diagnostic and Interventional. Further details will be selected. **Diagnostic only:** then select the purpose as **Left Heart Cath**, **Right Heart Cath**, or **Coronary Arteries Dilation or Stent.** Selecting **Coronary Arteries, then select all that apply:** **LMCA:** Left main coronary artery **LAD:** Left anterior descending **RCA:** Right coronary artery **Circumflex Artery** **Diagonal Arteries** **PDA:** Posterior Descending Artery **Interventional only:** then select all of the interventions performed for each catheterization. Aortic arch balloon Aortic arch stent Aortic valvuloplasty ASD device closure Atrial septostomy/septoplasty/stent	Mandatory to select whether a cardiac cath was performed. Must certify whether was during the current ECMO hospitalization. Must be prior to ECLS support. Details regarding date and time as well as type of procedure not mandatory. May select multiple indications. Other allows open free text field.	04/15/2024	Cardiac.Cardiac2022Addendum Cardiac.Cardiac2022Diagnostics Cardiac.Cardiac2022Interventions cardiac.Cardiac2022CathSets	PreCathYesNo PreCathOption CodeId cardiac.Cardiac2022CathSets SetType = 1 (pre) SetType = 2 (during) PreCathDateTime Lookup tables: Cardiac.Cardiac2022InterventionalCodes Cardiac.Cardiac2022DiagnosticCodes CodeId

	Creation of Potts shunt Creation of Fontan Fenestration Endomyocardial biopsy EP arrhythmia ablation Mitral Clip Occlusion of aortopulmonary collateral Occlusion of venous collateral Other PDA device closure Percutaneous aortic valve (TAVI) Percutaneous Mitral Valve Clip Percutaneous Mitral Valve Implantation Percutaneous pulmonary valve Placement for a right sided Impella device Placement for a transaortic Impella device Placement of a Tandem Heart Placement of EKOS catheter or other direct thrombolytic catheters for Thrombus in Pulmonary Artery Placement of IVC or SVC stent Placement of LA cannula Placement of MBTS stent Placement of PDA stent Placement of RV-PA stent (incl Sano) Placement of venous stent (vertical vein, azygous, hemi-azygous) Pulmonary artery balloon Pulmonary artery stent Pulmonary valvuloplasty Removal/aspiration of Thrombus in Pulmonary Artery Removal/aspiration of thrombus in systemic vein (including Glenn and Fontan) SVC balloon dilation Trans Myocardial Revascularization Transcatheter Mitral Valve Implantation Transcatheter Pulmonic Valve Implantation Transcatheter Tricuspid Valve Implantation				

	Transmyocardial Revascularization (TMR) VSD device closure				

Cardiac ECLS Indications					
Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
ECLS Cannulation	This field collects the circumstances of cannulation to ECLS. **Planned Cannulation:** Refers to cannulation in the setting of progression of patient symptoms of cardiac failure despite escalating therapy, and prior to any progression to cardiopulmonary arrest. **Failure to wean from Cardiopulmonary Bypass:** Patient is cannulated in the OR and transitioned from CPB. **Emergent or ECPR:** Rapid deployment VA ECMO to provide circulatory support in patients whom CPR is unsuccessful in achieving ROSC. Please refer to the ECPR addendum for more details and complete the ECPR addendum. **Progression of critical illness despite VAD/temporary support:** Cardiac failure despite pre-existing ventricular assist device. **please select the type of temporary or durable device** and enter **date of implantation or estimated or unknown.** If selected: Type of temporary or durable device Date of implantation prior to ECMO	May only select one. Type of assist device to be write in. Date: __/__/__ Estimated Unknown		Cardiac.Cardiac2022Addendum	ECLSCannulation VADTempSupp VADDateImplementation VADEstimatedUnknown
Precipitating Event	This field collects the predominant indication for ECLS. Identify the cardiac failure resulting in ECMO support. This would be supported by ICD-10 diagnostic codes. **Low Cardiac Output - left ventricular failure:** Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels or patient with declining LV function despite	May only select one. If ECPR is selected, prompt box should come up to suggest completing		Cardiac.Cardiac2022Addendum	PrecipitatingEvent

	intravenous inotropic support (INTERMACS profiles 1 and 2) **Low Cardiac Output - right or biventricular failure:** Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels or patient with declining biventricular function despite intravenous inotropic support (INTERMACS profiles 1 and 2). NOTE: This would include those patients with ventricular failure secondary to arrhythmia **Low Cardiac Output – Not specified:** Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels with unknown echocardiographic status (INTERMACS profiles 1 and 2). **Combined cardiac and respiratory failure:** Patients with neither purely ventricular failure or respiratory failure **Cardiac Arrest ECPR:** ECPR is the application of rapid-deployment venoarterial extracorporeal membrane oxygenation to provide circulatory support in patients in whom conventional cardiopulmonary resuscitation (CPR) is unsuccessful in achieving sustained return of spontaneous circulation (ROSC). Sustained ROSC is deemed to have occurred when chest compressions are not required for 20 consecutive minutes and signs of circulation persist. **Unknown** *Jacobs et al, Cardiac arrest and CPR outcome reports: Utstein templates from ILCOR Circulation.2004; 110 (21):3385-97; and Conrad et al, The Extracorporeal Life Support Organization Maastricht Treaty for Nomenclature in Extracorporeal Life Support. A Position Paper of the Extracorporeal Life*	the ECPR addenda			

	Support Organization. Am J Respir Crit Care Med. 2018; 198(4):447-451.				
Contributing Diagnoses	This field collects the diagnoses contributing to the precipitating event. Occurs within 4 hours of precipitating event. Can include acute exacerbations of chronic condition. Select at least one. **Select all that apply.** **Acute pulmonary edema:** Radiographic evidence of pulmonary edema and/or clinical signs of respiratory distress in the setting of LV failure **Pulmonary hypertension:** Mean PA pressure >20mmHg in the setting of normal Left Atrial Pressure **Pumonary embolism:** Confirmed by imaging CT/MRI/Angiogram) **Tamponade:** Low cardiac output secondary to constrictive physiology (may be fluid/blood/clot collection, pericardial disease, chest wall disease) **Acute myocardial infarction (or acute coronary syndrome):** Elevated cardiac biomarkers with at least one value above the 99th percentile of upper reference limit together with evidence of myocardial ischemia with at least one of the codes listed. **If selected:** enter Time of onset of chest pain or select unknown. Then, **select** at least one symptom: **Symptoms of ischemia** **ECG changes** indicative of new ischemia (new ST-T wave changes or new LBBB) **Development of pathological Q waves** in ECG **Imaging evidence of new loss of viable myocardium** or new regional wall motion abnormality *(Thygesen et al. Circ 2007;116:2634-2653)*	Select at least one. **If AMI selected:** either enter Time of onset of chest pain or unknown		Cardiac.Cardiac2022ContributingDiagnoses Cardiac.Cardiac2022Addendum	AcuteCSDateTime AcuteCSUnknown GraftFailure GraftTransplantDate GraftTransplantDateUnknown Lookup table: Cardiac2022ContributingDCodes CodeId

	Low Cardiac Output (Left, Right or Biventricular): Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels or patient with declining cardiac function despite intravenous inotropic support **Arrhythmias:** Telemetry proven arrhythmia with loss of cardiac output leading to cannulation **Hypoxemia:** Persistent SpO2 <60% leading to cannulation **Post heart transplant graft failure:** Cardiac failure post orthotopic heart transplantation. If selected then choose: **Early Graft Failure:** < 24 hours prior to ECMO cannulation **Late Graft Failure:** >24 hours prior to ECLS cannulation but typically less than 48h. May be years later. Transplant Date: _____. Unknown? Total ischemic time of graft in hours. Unknown? **Ischemic cardiomyopathy:** heart disease characterized by a decreased ability to pump blood resulting in an enlarged, dilated and weak myocardium due to ischemia. This is typically caused by coronary artery disease (may be congenital). **Non-ischemic or Chronic Cardiomyopathy:** Heart disease characterized by a decreased ability to pump blood resulting in dilated or thickened and weak myocardium. without evidence of ischemia and not caused by coronary artery disease. If selected then choose best type: **Dilated cardiomyopathy:** heart disease characterized by a decreased ability to pump				

	blood resulting in an enlarged, dilated and weak myocardium unrelated to ischemia. Typically caused by either genetic, auto-immune, or metabolic derangements. **Hypertrophic cardiomyopathy:** heart disease thickened (hypertrophied) heart muscle resulting in pump failure. This can be from a variety of causes, (e.g., genetic, endocrinologic, metabolic, etc.) **Restrictive cardiomyopathy:** heart disease characterized by progressive lack of relaxation in ventricular myocardium preventing appropriate filling. This can be Idiopathic or Infiltrative. Example includes Sarcoidosis. **Stress induced cardiomyopathy (Takotsubo):** heart disease characterized by transient dysfunction and ballooning of the left ventricle of the heart. It mostly affects elderly women and is often triggered by severe physical or emotional stress. **Post-Partum cardiomyopathy:** idiopathic cardiomyopathy that presents with heart failure secondary to left ventricular (LV) systolic dysfunction toward the end of pregnancy or in the months after delivery, in the absence of any other cause of heart failure. **Other:** non ischemic chronic heart failure not listed here **Endocarditis:** Cardiac failure secondary to infective endocarditis confirmed by modified Duke criteria **Myocarditis:** Cardiac failure secondary to myocardial infection and inflammation proven by biopsy or MRI, or suspected **Unknown:** None identified				

Cardiac Cannuation Details					
Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
Cannulation Location	This field collects the location of cannulation to ECLS. Please select one of the following: **Ambulatory/Outpatient:** Non-inpatient facility within a healthcare setting or hospital which also manages inpatient care **ED:** Established unit resourced to provide acute assessment and management to ill and injured patients **Inpatient Ward:** According to the local ELSO center, a healthcare facility for assessment and management of illness and/or injury **HDU:** According to the local ELSO center, a healthcare facility resourced to provide more acute care than general hospital admission **ICU (specify):** According to the local ELSO center, a healthcare facility resourced to provide intensive care. Drop down list to select specific ICU: Adult Medicine ICU, Adult Surgical ICU, Mixed ICU, Adult Cardiac or Cardiovascular ICU, Adult Coronary Care Unit, Pediatric Intensive Care Unit, Pediatric Cardiac Intensive Care Unit, Neonatal Intensive Care Unit) **Cardiac Cath Lab**: According to the local ELSO center, a specialized operating room or suite equipped with fluoroscopy for cardiac catheterization. **Diagnostic or Intervention Suite (other than Cardiac Cath lab)**: According to the local ELSO center, a specialized operating room or suite equipped for diagnostic and interventional procedures. **OR:** According to the local ELSO center, a specialized operating room for procedures.	To be populated from ECPR addenda and vice versa if already completed		Cardiac.Cardiac2022Addendum	CannulationLocation Lookup table: `Cardiac2022CannulationLCodes` CodeId

	PACU: According to the local ELSO center, a specialized room or suite for post anesthesia recovery after surgical procedures. **Delivery Room:** According to the local ELSO center, a healthcare environment specialized for the care of gravid women and newborn infants. **Other Inpatient:** Location not listed above				
LV Decompression Procedures	This field collects any procedure undertaken to decompress the Left Ventricle once on ECLS. Select all that apply. For **For each procedure enter date and time** or **unknown** **Atrial septostomy:** creation of atrial communication for the purpose of decompressing L side **LA vent:** Drainage cannula in Left Atrium **LV vent:** Drainage cannula in Left Ventricle **PA vent:** Drainage cannula in Pulmonary Artery **Intra-aortic balloon pump:** In situ during ECMO **Impella --> Trans aortic Valve impella:** LV-Ao device **Tandem Heart:** **L-VAD:** Systemic ventricle support **R-VAD:** Sub-pulmonary ventricle support **Other:** Specify in free text field	May select multiple. Enter date and time for each, or unknown		Cardiac.Cardiac2022LVDecompression	Lookup table: Cardiac2022LVDecompressionCodes CodeId
Reason for LV Decompression	This field collects the rationale for the LV decompression procedure. Select all that apply. **Institutional Routine** **Progressive pulmonary Edema on CXR** **Left Atrial Hypertension** **Lack of native ejection** **Aortic Valve Regurgitation** **Decreased pulse pressure on arterial waveform** **Evidence of ischemia** **Other**	May select multiple.		Cardiac.Cardiac2022Addendum Cardiac.Cardiac2022LVReasons	LVDecOther Lookup table: Cardiac.Cardiac2022LVReasonCodes CodeId

Cardiac Surgical Procedures					
Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
Cardiac Procedure Location	This field collects whether a cardiac procedure was performed during the hospital admission. **Yes** or **No** If **Yes then select:** **Surgical procedure at bedside** **Surgical procedure in OR** **Cardiac catheter procedure** **Other – Specify in the free text field**	Surgical procedure at bedside =1 Surgical procedure in OR =2 Cardiac catheter procedure = 3 Other =4		Cardiac.Cardiac2022Addendum	CardiacProcedure SurgProcBedside SurgProcOR OtherProcDesc
Cardiac Procedure	Select 'Add new procedure' for each procedure performed. Enter all that apply during the ECLS hospitalization including procedures performed pre, during and post ECLS. Each separate procedure should have a date/time entered. See ELSO cardiac procedure list in supporting documents. These can be found on the ELSO website at: https://www.elso.org/Registry/SupportDocuments/ ELSOCardiacProcedureCodes.aspx Enter procedure code then select **Date and Time** **Estimated** **Unknown** For each procedure enter: **Was the Cardiac surgery on CPB?** Select whether the procedure(s) were completed on cardiopulmonary bypass **Yes** or **No. If Yes, then complete:**	If 1 or 2 to above question then must answer May enter multiple procedures with date/time/ estimated/ unknown Must be within current hospital admission. Hard error: duplicate procedure codes with	04/15/2024	Cardiac.Cardiac2022Procedures	CodeId ProcDateTime EstimatedUnknown SurgeryCPB CPBRunsTotal CCTime CPBTime ICUOpen Lookup table: Cardiac.ProcedureCodes CodeId

	CPB runs total: Enter total number of runs of Cardiopulmonary bypass during a single OR trip/procedure **Cross clamp time (mins) –** Enter total minutes for cross clamping during a single OR trip/procedure **CPB time (mins):** Enter the total minutes for cardiopulmonary bypass during a single OR trip/procedure **Returned to ICU with open sternum: Yes** or **No**	same time cant exist Hard error: Cardiac procedure date must be after ECLS admission date Hard error: Cardiac procedure date cannot be after than the date of death Hard error: Cardiac procedure date must be before discharge date. If yes selected for cardiac surgery on CPB, then CPB runs total and Returned to ICU with open sternum must be entered.			
Cardiac Catheterization	This field collects if a patient had a cardiac catheterization procedure during or after ECLS Support but during the hospitalization.	Mandatory to select whether a		Cardiac.Cardiac2022Addendum Cardiac.Cardiac2022Diagnostics	DuringCathYesNo DuringCathOption

	Select **yes** or **no** **Yes** will prompt the entry of the **date and time**, and selection of Diagnostic Only, Interventional Only or Diagnostic and Interventional. Further details will be selected. **Diagnostic only:** then select the purpose as **Left Heart Cath**, **Right Heart Cath**, or **Coronary Arteries Dilation or Stent**. Selecting **Coronary Arteries, then select all that apply:** **LMCA:** Left main coronary artery **LAD:** Left anterior descending **RCA:** Right coronary artery **Circumflex Artery** **Diagonal Arteries** **Posterior Descending Artery** **Interventional only:** then select all of the interventions performed for each catheterization. Aortic arch balloon Aortic arch stent Aortic valvuloplasty ASD device closure Atrial septostomy/septoplasty/stent Creation of Potts shunt Creation of Fontan Fenestration Endomyocardial biopsy EP arrhythmia ablation Mitral Clip Occlusion of aortopulmonary collateral Occlusion of venous collateral Other PDA device closure Percutaneous aortic valve (TAVI) Percutaneous Mitral Valve Clip Percutaneous Mitral Valve Implantation Percutaneous pulmonary valve Placement for a right sided Impella device Placement for a transaortic Impella device	cardiac cath was performed. Details regarding date and time as well as type of procedure not mandatory. Yes - Date must be after ECMO cannulation date/time and before hospital discharge or death. May select multiple indications. Other allows open free text field.		Cardiac.Cardiac2022Interventions	DuringCathDateTime AfterCathYesNo AfterCathOption AfterCathDateTime Lookup tables: Cardiac.Cardiac2022DiagnosticCodes Cardiac.Cardiac2022InterventionalCodes CodeId

	Placement of a Tandem Heart Placement of EKOS catheter or other direct thrombolytic catheters for Thrombus in Pulmonary Artery Placement of IVC or SVC stent Placement of LA cannula Placement of MBTS stent Placement of PDA stent Placement of RV-PA stent (incl Sano) Placement of venous stent (vertical vein, azygous, hemi-azygous) Pulmonary artery balloon Pulmonary artery stent Pulmonary valvuloplasty Removal/aspiration of Thrombus in Pulmonary Artery Removal/aspiration of thrombus in systemic vein (including Glenn and Fontan) SVC balloon dilation Trans Myocardial Revascularization Transcatheter Mitral Valve Implantation Transcatheter Pulmonic Valve Implantation Transcatheter Tricuspid Valve Implantation Transmyocardial Revascularization (TMR) VSD device closure				