

PulseCath iVAC 2L Post-Market Surveillance Form

NAME EMPLOYEE: _____ COMPANY: _____ SERIAL NUM.: _____ CONTACT EMAIL: _____

OPERATOR: _____ CENTER: _____ DATE AND SIGNATURE: _____

Age: _____ Gender: Male Female
 Weight (Kg): _____ Height (cm): _____

Patient status pre-implantation

AT ADMISSION: STABLE UNSTABLE HYPOTENSIVE SHOCKED
 AT PROCEDURE START: STABLE UNSTABLE HYPOTENSIVE SHOCKED

Indication

ACUTE COR. SYNDR. STABLE ANGINA EMERGENT
 STEMI NSTEMI/UNST. ANGINA URGENT
 CARDIOG. SHOCK HEART FAILURE ELECTIVE
 ABLATION TEER (MITRACLIP®) PROPHYLACTIC
 V. SEPTAL DEFECT OTHER: _____ BAIL-OUT

SYNTAX I: _____
 STS mort.: _____
 EF (%): _____

Antecedents/ background

Diabetes II Periph. Artery Disease Venous thrombosis
 Hypertension Ischemic Stroke Myoc. Infarction
 Kidney Failure Hemorrhagic Stroke Previous PCI
 Smoking /COPD Atrial Fibrillation Previous CABG
 Dyslipidemia Ventricular Arrhythmias Surgery Refusal
 Chronic Anticoag. Hemodialysis Cancer

VALVE _____
 AORTIC _____
 MITRAL _____
 TRICUSPID _____
 PULMONIC _____

LESION		SEVERITY		
REGURG	STENOSIS	MILD	MOD	SEVERE
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

NYHA CLASS: I II III IV

Report all existing lesions if > 50% and mark "STENT" when treated

PROX	50%	90%	CTO	STENT	Lesion	PROX	50%	90%	CTO	STENT	Lesion
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LM (Left Main)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RCA (Right Coronary)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LAD (Left Ant. Desc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RPD (Post. Desc.)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1DG (1 st Diagonal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PL (Posterolateral)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2DG (2 nd Diagonal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bypass Graft
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SB (Septal Branch)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other: _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LCx (Circumflex)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1OM (1 st Obtuse Marginal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2OM (2 nd Obtuse Marginal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LPD (Left Posterior Desc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RI (Intermediate Branch)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

N. of lesions treated: _____ N. of stents deployed: _____ Highest ACT: _____

UNPROTECTED LEFT MAIN LAST PATENT VESSEL LM EQUIVALENT IVUS
 3-VESSEL DISEASE ANTEGR. ART. BYPASS ROTABLATION SHOCKWAVE

iVAC start: ____/____/____ : ____:____
 iVAC end: ____/____/____ : ____:____
 Max. iVAC2L flow (L/min): _____ Access Site: _____ Sheath (name/size/serial n): _____

Assist Mode: 1:1 synch 1:3 synch Internal
 Vasc. Closure: MANTA PROGLIDE SURGICAL
 Total IV fluids (mL): _____ Total contrast (mL): _____
 Hospital Admission: ____/____/____ : ____:____
 Hospital Discharge: ____/____/____ : ____:____

Follow up performed at discharge? YES NO Date: ____/____/____
 Follow up performed at 30 days? YES NO Date: ____/____/____
 Follow up performed at 90 days? YES NO Date: ____/____/____
 Follow up performed at 1 year? YES NO Date: ____/____/____
 Complete Revascularization? YES NO

Intraprocedural Events and Clinical Outcomes – mark if occurred after insertion of iVAC2L

Death (while iVAC2L is on) Blood transfusion (red cells)
 Hypotension (10 min with MAP < 60) REASON: _____
 Shock (30 min with SBP < 90) Hemolysis (clin. Significant)
 Cardiac Massage (CPR) Failure to implant
 Defibrillation/cardioversion Other support used
 Atropine/adrenaline use WHICH: _____
 Noradrenaline use Premature removal of iVAC 2L
 Started: Before During After iVAC2L
 Dobutamine use Lesion to the aortic valve (TTE)
 Started: Before During After iVAC2L
 Intubation (if emergent) Angiographic failure
 Performed: Before During After iVAC2L
Angiographic failure: Post-procedural TIMI flow ≤ 1 on any treated lesion located in the three main coronary arteries.
 Dislocation of iVAC 2L Intraprocedural weaning of Noradrenaline and/or Dobutamine
 Thromboembolic event (any) iVAC 2L stopped for prolonged period
 Thrombosis of the iVAC 2L (clots in the lumen / membrane pump)

NO Major Adverse Events at 90 days

Major Adverse events (mark "x" if occurred)

	IN THE CATHLAB	BEFORE DISCHARGE	< 30 DAYS	< 90 DAYS	< 1 YEAR
DEATH (ALL CAUSES)	_____	_____	_____	_____	_____
ACUTE MI	_____	_____	_____	_____	_____
STROKE OR TIA	_____	_____	_____	_____	_____
MAJOR BLEEDING	_____	PRE DISCHARGE	< 30 DAYS	< 90 DAYS	< 1 YEAR
MAJOR VASCULAR COMPLICATIONS	_____	PRE DISCHARGE	< 30 DAYS	< 90 DAYS	< 1 YEAR
NEED FOR CARDIAC OR VASCULAR SURGERY	_____	PRE DISCHARGE	< 30 DAYS	< 90 DAYS	< 1 YEAR
REPEAT REVASCULARIZATION	_____	PRE DISCHARGE	< 30 DAYS	< 90 DAYS	< 1 YEAR
ACUTE KIDNEY INJURY	_____	PRE DISCHARGE	< 30 DAYS	< 90 DAYS	< 1 YEAR

	HEART RATE	BLOOD PRESSURE	PULMONARY PRESSURE	CARDIAC OUTPUT	mPCWP	SpO2 (%)
PRE-SUPPORT	_____	_____	_____	_____	_____	_____
DURING SUPPORT (min 10 min)	_____	_____	_____	_____	_____	_____
POST-REMOVAL	_____	_____	_____	_____	_____	_____