PulseCath iVAC 2L Post-Market Surveillance Form

Operator: _____ Date: _____ Serial n: _____

Hospital: _____ NYHA (Heart failure classification) ☐ I ☐ II ☐ III ☐ IV

Age: _____ Gender: ☐ Male ☐ Female

Weight (Kg): _____ Height (cm): _____

Indication:
☐ ACUTE CORONARY SYNDR. ☐ EMERGENT
☐ STABLE ANGINA ☐ URGENT
☐ OTHER: _____ ☐ ELECTIVE

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

Antecedents – mark if present

☐ 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

	LESION		SEVERITY		
VALVE	REGURG	STENOSIS	MILD	MOD	SEVERE
AORTIC	REGURG	STENOSIS	MILD	MOD	SEVERE
MITRAL	REGURG	STENOSIS	MILD	MOD	SEVERE
TRICUSPID	REGURG	STENOSIS	MILD	MOD	SEVERE
PULMONIC	REGURG	STENOSIS	MILD	MOD	SEVERE

Treatment – indicate lesion severity and mark "STENT" if treated

50% 90% CTO STENT LM (Left Main)	50% 90% CTO STENT LCx (Circumflex)	50% 90% CTO STENT RCA (Right Coronary)
50% 90% CTO STENT LAD (Left Ant. Desc.)	50% 90% CTO STENT 1OM (1st Obtuse Marginal)	50% 90% CTO STENT RPD (Post. Desc.)
50% 90% CTO STENT 1DG (1st Diagonal)	50% 90% CTO STENT 2OM (2st Obtuse Marginal)	50% 90% CTO STENT PL (Posterolateral)
50% 90% CTO STENT 2DG (2st Diagonal)	50% 90% CTO STENT LPD (Left Posterior Desc.)	50% 90% CTO STENT Bypass Graft
50% 90% CTO STENT SB (Septal Branch)	50% 90% CTO STENT RI (Intermediate Branch)	50% 90% CTO STENT Other:

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

☐ UNPROTECTED LEFT MAIN ☐ LAST PATENT VESSEL ☐ IVUS
☐ 3-VESSEL DISEASE ☐ ANTEGR. ART. BYPASS ☐ ROTABLATION

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: __/__/____ ____:____

Intraprocedural Events & Clinical Outcomes – mark if present

☐ Death (intraprocedural)
☐ Hypotension (10 min with MAP < 60)
☐ Shock (30 min with SBP < 90)
☐ Cardiac Massage (CPR)
☐ Defibrillation/cardioversion
☐ Atropine/adrenaline use
☐ Noradrenaline use
☐ Dobutamine use
☐ Intubation (if emergent)
☐ Dislocation of iVAC 2L

☐ Blood transfusion (red cells)
REASON: ☐ BLEEDING / SEVERE ANEMIA ☐ HEMOLYSIS
☐ Hemolysis (clin. Significant)
☐ Failure to implant
☐ Other support used
WHICH: _____
☐ Premature removal of iVAC 2L
☐ Lesion to the aortic valve (TTE)
☐ Angiographic failure
☐ Intrapr. Infusion weaning (dobutamine / noradrenaline / dopamine)

☐ No Major Adverse Events at 30 days

Major Adverse events (mark "x" if occurred)

	PRE DISCHARGE	< 30 DAYS	< 90 DAYS	< 1 YEAR
Cerebrovasc. event				
Acute MI				
Acute Kidney Injury				
Cardiac/vasc. operation				
Major bleeding				
Death				
Emergent Revasc.				

	HEART RATE	BLOOD PRESSURE	PULMONARY PRESSURE	CARDIAC OUTPUT	mPCWP	SpO2 (%)	SpO2 (%) (iVAC2L LEG / CONTRALATERAL LEG)
PRE-SUPPORT							
DURING SUPPORT (min 10 min)							
POST-REMOVAL							

We would greatly appreciate if you could inform PulseCath of any adverse events detected post PCI and post discharge.
Thank you for contributing to our PMS registry! Please send a digitized copy of this form to:
OREN@PULSECATH.COM