

# 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

- |  |   |  |  |
|--|---|--|--|
| <input type="checkbox"/> Diabetes II       | <input type="checkbox"/> Periph. Artery Disease | <input type="checkbox"/> Limb ischemia     | <input type="checkbox"/> Frailty         |
| <input type="checkbox"/> Hypertension      | <input type="checkbox"/> Ischemic Stroke        | <input type="checkbox"/> Venous thrombosis | <input type="checkbox"/> Hemodialysis    |
| <input type="checkbox"/> Kidney Failure    | <input type="checkbox"/> Hemorrhagic Stroke     | <input type="checkbox"/> Myoc. Infarction  | <input type="checkbox"/> Surgery Refusal |
| <input type="checkbox"/> Smoking           | <input type="checkbox"/> Atrial Fibrillation    | <input type="checkbox"/> Previous PCI      | <input type="checkbox"/> COPD            |
| <input type="checkbox"/> Dyslipidemia      | <input type="checkbox"/> Ventr. Tachyc. / fibr  | <input type="checkbox"/> Previous CABG     | <input type="checkbox"/> Cancer          |
| <input type="checkbox"/> Chronic Anticoag. | <input type="checkbox"/> Thrombophilia          | <input type="checkbox"/> Prosthetic valve  |  |

	LESION		SEVERITY		
	REG	STN	MILD	MOD	SEV
AORTIC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MITRAL	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TRIC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PULM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Echocardiographic parameters

	EDV	ESV	IVStd	PWtd	LVOT	AV peak velocity	VTILVOT	VTIAV	e/e'	AR grade	Isovolum. Contr. Time	Ejection Time
PRE-iVAC 2L												
POST-iVAC 2L												

## Treatment – indicate lesion severity and mark “STENT” if treated stented

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 (1 <sup>st</sup> Obtuse Marginal)	50% 90% CTO STENT	RPD (Post. Desc.)
50% 90% CTO STENT	1DG (1 <sup>st</sup> Diagonal)	50% 90% CTO STENT	2OM (2 <sup>nd</sup> Obtuse Marginal)	50% 90% CTO STENT	PL (Posterolateral)
50% 90% CTO STENT	2DG (2 <sup>nd</sup> 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:

Number of lesions treated:  Number of stents deployed:  Highest observed ACT:

ULM  3-VESSEL DIS.  LAST PATENT VESSEL  
 IVUS  ROTABLATION  ANTEGR. ART.

iVAC start:  (DD/MM/YYYY)  :  :

iVAC end:  (DD/MM/YYYY)  :  :

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:  (DD/MM/YYYY)  (HH:MM)

Hospital Discharge:  (DD/MM/YYYY)  (HH:MM)

## Intraprocedural Events & Clinical Outcomes – mark if present

<input type="checkbox"/> Death (intraprocedural)	<input type="checkbox"/> Blood transfusion (red cells)	<input type="checkbox"/> No Major Adverse Events at 30 days
<input type="checkbox"/> Hypotension (10 min with MAP < 60)	<input type="checkbox"/> REASON: <input type="text"/> BLEEDING / SEVERE ANEMIA HEMOLYSIS <input type="checkbox"/>	<b>Major Adverse events (mark “x” if occurred)</b>
<input type="checkbox"/> Shock (30 min with SBP < 90)	<input type="checkbox"/> Hemolysis (clin. Significant)	PRE DISCHARGE   < 30 DAYS   < 90 DAYS   < 1 YEAR   Cerebrovasc. event
<input type="checkbox"/> Cardiac Massage (CPR)	<input type="checkbox"/> Failure to implant	PRE DISCHARGE   < 30 DAYS   < 90 DAYS   < 1 YEAR   Acute MI
<input type="checkbox"/> Defibrillation/cardioversion	<input type="checkbox"/> Other support used	PRE DISCHARGE   < 30 DAYS   < 90 DAYS   < 1 YEAR   Acute Kidney Injury
<input type="checkbox"/> Atropine/adrenaline use	<input type="checkbox"/> WHICH: <input type="text"/>	PRE DISCHARGE   < 30 DAYS   < 90 DAYS   < 1 YEAR   Cardiac/vasc. operation
<input type="checkbox"/> Noradrenaline use	<input type="checkbox"/> Premature removal of iVAC 2L	PRE DISCHARGE   < 30 DAYS   < 90 DAYS   < 1 YEAR   Major bleeding
<input type="checkbox"/> Dobutamine use	<input type="checkbox"/> Lesion to the aortic valve (TTE)	PRE DISCHARGE   < 30 DAYS   < 90 DAYS   < 1 YEAR   Death
<input type="checkbox"/> Intubation (if emergent)	<input type="checkbox"/> Angiographic failure	PRE DISCHARGE   < 30 DAYS   < 90 DAYS   < 1 YEAR   Emergent Revasc.
<input type="checkbox"/> Dislocation of iVAC 2L		

