

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

TSCL/AE/MD:

1. PATIENT DETAILS											
Patient's Initials:	Gender:		☐ Male	☐ Female Age:		Age:					
2. SUSPECTED EVENT(s)											
Adverse Event(s)	Start date	Stop d	ate /ongoing	Intensity			*Outcome				
				□Mild	□Moderate	Severe	□1	□ 2	□3	□4	□ 5
				□Mild	□Moderate	Severe	□ 1	□ 2	□3	□4	□5
				□Mild	□Moderate	Severe	□1	2	□3	□4	□5
				□Mild	□Moderate	Severe	□1	□2	□3	□4	□5
*Keys: 1= Recovered 2= Recovering 3= Not re	ecovered 4= l	Jnknown 5=	= Serious (SAE)	, if SAE, ref	er below to de	fine the type					
If you consider the reaction(s) as SAE, please tick all that apply of the following:											
☐ Death ☐ Life threatening ☐ Hospitalization or prolonged hospitalization ☐ Persistent or significant disability/incapacity ☐											
Congenital anomaly/Birth defect											
Event Details:				tests/Laboratory data with dates/ any treatment received:							
Other Concomitant drug(s):											
3. SUSPECTED MEDICAL DEVICE											
Therapeutic □ Diagnostic □ Both □ Preventive □ others □ Specify											
Device (Brand Name)	Indica	ation for U	se	Route of	Administration	n Dat	te of	D	ate of	E	Batch
						Usa	age	re	emova	1	
4. REPORTER DETAILS											
Type of Reporter (a) Manufacture □ (b) Importer □ (c) Distributor □ (d) HCP □											
(a) Deticate C (6) others C associte											
(e) Patient □ (f) others □ specify											
Name:Signature:					Source: ☐ HCP ☐ Study ☐ other						
							_		_		
Date:Address (Professional):						Type □ Initial □ Follow up					

Please send the completed form by e-mail to The Searle Company Ltd Pakistan. E-mail: pv@searlecompany.com, You may send the completed form to: PV Department, The Searle Company Ltd Pakistan, 2nd Floor, One IBL Centre, Plot# 1, Block 7 & 8, DMCS, Tipu Sultan Road, Off. Shahrah-e-Faisal, Karachi, Pakistan. Phone: +92 21 3567-4321 or Fax: +92 21 3568-7693