COMPARISON OF COMPLICATIONS WITH PREDICATES

Complications and Potential Risks	Collagen Scaffold (ReGen)	Restore (DePuy)	Fistula Plug (Cook Biotech)	Surgisis /Stratasis (Cook Biotech)	CuffPatch (Organo-genesis)	TissueMend (TEI)	ZCR Patch, Enduragen, Permacol, Pelvicol (TSL)	Peri-Guard (Synovis)
Infection		X*†	X*	X†			X†	
Abscess		X†	X*	X†			X†	
Wound drainage / incisional dehiscence/ Op site blister		X†			X†	X†	X†	X†
Inflammation / Swelling / Redness / Pain / Fever / Granuloma tissue/ Cyst/ Synovitis		X*†	X*	X†	X†	X†	X†	
Sterile Effusion		X*†			X†			
Seroma/Hematoma Formation			X*				X†	
Induration			X*				X†	
Allergic reaction		X*	X*					
Immunologic reaction		X*†						
Adhesion / Agglutination		X*					X†	
Fistula Formation			X*	X†			X†	
Device Stretch / Fracture / Tear/ Instability		X*					X†	X†
Device Migration / Extrusion			X*		X†		X†	X†
Delayed or failed incorporation / inadequate healing / Recurrence of Defect		X*†	X*	X†	X†	X†	X†	X†
Tissue necrosis							X†	
Restricted Freedom of Movement / Stiffness		X*†						
Prolonged Post-op Rehab		X*						
Patient non-compliance with rehab		X*						

General surgical risks such as neurological, cardiac or respiratory deficit		X*						
Death		X†						

*From Product Labeling
†From MAUDE Database