BIOCOMPATIBILITY TEST MATRIX

Specific safety evaluation programs follow International Organization for Standardization (ISO) 10993 standards and Food and Drug Administration (FDA) guidance (May 1, 1995). The table is based on ISO 10993-1 Evaluation and testing, 2009 edition. While the table has been developed as a guideline for biocompatibility testing, it is essential that each device be evaluated based on its own unique characteristics.

DEVICE CATEGORIES			BIOLOGICAL EFFECT											
BODY CONTACT		**CONTACT DURATION** **A** = Limited (≤24 Hours) **B** = Prolonged (24 Hours - 30 Days) **C** = Permanent (>30 Days)	Cytotoxicity	Sensitization	Irritation/Intracutaneous	Acute Systemic Toxicity	Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental	Biodegradation
SURFACE DEVICES	Skin	A	x	x	x									
		B	x	x	x									
		C	x	x	x									
	Mucosal Membrane	A	x	x	x									
		B	x	x	x	o	o		o					
		C	x	x	x	o	x	x	o		o			
	Breached or Compromised Surfaces	A	x	x	x	o								
		B	x	x	x	o	o		o					
		C	x	x	x	o	x	x	o		o			
EXTERNALLY COMMUNICATING DEVICES	Blood Path, Indirect	A	x	x	x	x				x				
		B	x	x	x	x	o			x				
		C	x	x	o	x	x	x	o	x	o	o		
	Tissue/Bone/Dentin Communicating[1]	A	x	x	x	o								
		B	x	x	x	x	x	x	x					
		C	x	x	x	x	x	x	x		o	o		
	Circulating Blood	A	x	x	x	x		o[2]		x				
		B	x	x	x	x	x	x	x	x				
		C	x	x	x	x	x	x	x	x	o	o		
IMPLANT DEVICES	Tissue/Bone	A	x	x	x	o								
		B	x	x	x	x	x	x	x					
		C	x	x	x	x	x	x	x		o	o		
	Blood	A	x	x	x	x	x		x	x				
		B	x	x	x	x	x	x	x	x				
		C	x	x	x	x	x	x	x	x	o	o		

X = Tests per ISO 10993-1

O = Additional tests that may be applicable in the U.S.

Note[1] - Tissue includes tissue fluid and subcutaneous spaces

Note[2] - For all devices used in extracorporeal circuits