

BIOCOMPATIBILITY TEST MATRIX

Specific safety evaluation programs follow Food and Drug Administration (FDA) guidance (May 1, 1995) and International Organization for Standardization (ISO) 10993 standards. The table is based on ISO 10993-1 Evaluation and testing, 3rd edition 8/01/03.

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	x	x		
	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		x	x		
	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	x	x		
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		x	x		
	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	x	x	x	

X = Tests per ISO 10993-1

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

Note¹ - Tissue includes tissue fluid and subcutaneous spaces

Note² - For all devices used in extracorporeal circuits