

**BIOCOMPATIBILITY TESTING MATRIX**  
 Nelson Laboratories Tests for Consideration  
 [Based on ISO 10993-1:2003(E) and FDA G95-1 Guidelines]

Device Categories		Biological Effect									
		Initial								Other <sup>4</sup>	
Body Contact	Contact Duration	Cytotoxicity	Sensitization	Irritation	Systemic Toxicity	Subacute (Subchronic Toxicity)	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity
	A- Limited [≤ 24 hrs]										
	B- Prolonged [>24 hrs to ≤30 days]										
		C- Permanent [>30 days]									
Surface Devices	Skin	A	■	■	■						
		B	■	■	■						
		C	■	■	■						
	Mucosal Membranes	A	■	■	■						
		B	■	■	■	◇	◇		◇		
		C	■	■	■	◇	■	■	◇		◇
	Breached or Compromised Surfaces	A	■	■	■	◇					
		B	■	■	■	◇	◇		◇		
		C	■	■	■	◇	■	■	◇		◇
External Communicating Devices	Blood Path, Indirect <sup>3</sup>	A	■	■	■	■				■	
		B	■	■	■	■	◇			■	
		C	■	■	◇	■	■	■	◇	■	■
	Tissue <sup>1</sup> /Bone/Dentin Communicating	A	■	■	■	◇					
		B	■	■	■	■	■	■	■		
		C	■	■	■	■	■	■	■		■
	Circulating Blood <sup>3</sup>	A	■	■	■	■		◇ <sup>2</sup>		■	
		B	■	■	■	■	■	■	■	■	
		C	■	■	■	■	■	■	■	■	■
Implant Devices	Tissue/Bone	A	■	■	■	◇					
		B	■	■	■	■	■	■	■		
		C	■	■	■	■	■	■	■		■
	Blood <sup>3</sup>	A	■	■	■	■	■		■	■	
		B	■	■	■	■	■	■	■	■	
		C	■	■	■	■	■	■	■	■	■

<sup>1</sup> "Tissue includes tissue fluids and subcutaneous spaces.

<sup>2</sup> For all devices used in extracorporeal circuits.

<sup>3</sup> Pyrogenicity/Materials Mediated should be considered.

<sup>4</sup> Supplemental tests for consideration

■- ISO Evaluation Tests for Consideration

◇- Additional tests which the FDA considers may be applicable

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