Biocompatibility Test Matrix

Specific safety evaluation programs follow International Organization for Standardization (ISO) 10993 standards and Food and Drug Administration (FDA) guidance. The matrix is based on ISO 10993-1 Evaluation and Testing within a risk management process 2018 edition, as well as the FDA Guidance released September 2016. While the matrix has been developed as a guideline for biocompatibility evaluation, it is essential that each device be evaluated based on its own unique characteristics.

Medical Device Categorization			Endpoints of Biological Evaluation														
Nature of Body Contact		Contact Duration	Physical and / or Chemical Information	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Material Mediated Pyrogenicity[a]	Acute Systemic Toxicity[b]	Subacute Toxicity[b]	Subchronic Toxicity[b]	Chronic Toxicity[b]	Implantation Effects[b, c]	Hemocompatibility	Genotoxicity[d]	Carcinogenicity[d]	Reproductive / Developmental Toxicity[d, e]	Degradation[f]
Category	**Contact**	A = Limited (≤24 Hours) B = Prolonged (>24 Hours – 30 Days) C = Long Term (>30 Days)															
Surface Medical Device	Intact Skin	A	X[g]	E[h]	E	E											
		B	X	E	E	E											
		C	X	E	E	E											
	Mucosal Membrane	A	X	E	E	E											
		B	X	E	E	E	O	E	E			E					
		C	X	E	E	E	O	E	E	E	E	E		E			
	Breached or Compromised Surfaces	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E	E		
Externally Communicating Medical Device	Blood Path, Indirect	A	X	E	E	E	E	E					E				
		B	X	E	E	E	E	E	E				E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
	Tissue / Bone /Dentin[i]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Circulating Blood	A	X	E	E	E	E	E					E	E[j]			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
Implant Devices	Tissue / Bone[i]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	X	E	E	E	E	E				E	E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

X = Endpoint per ISO 10993-1

O = Endpoint per FDA

E = Endpoint per ISO 10993-1 and FDA

Please see additional Notes on backside.

Note[a] – Refer to ISO 10993-11, Annex F.

Note[b] – Information obtained from comprehensive implantation assessments that include acute systemic toxicity, subacute toxicity, subchronic toxicity and / or chronic toxicity may be appropriate if sufficient specimens and timepoints are included and assessed. It is not always necessary to perform separate studies for acute, subacute, subchronic and chronic toxicity.

Note[c] – Relevant implantation sites should be considered. For instance, medical devices in contact with intact mucosal membranes should ideally be studied / considered in contact with intact mucosal membranes.

Note[d] – If the medical device can contain substances known to be carcinogenic, mutagenic and / or toxic to reproduction, this should be considered in the risk assessment.

Note[e] – Reproductive and developmental toxicity should be addressed for novel materials, materials with a known reproductive or developmental toxicity, medical devices with relevant target populations (e.g. pregnant women) and / or medical devices where there is the potential for local presenceof device materials in the reproductive organs.

Note[f] – Degradation information should be provided for any medical devices, medical device components or materials remaining within the patient that have the potential for degradation.

Note[g] – "X" means prerequisite information for a risk assessment.

Note[h] – "E" means endpoints to be evaluated in the risk assessment (either thrugh the use of existing data, additional endpoint-specific testing or a rationale for why assessment of the endpoint does not require an additional data set). If a medical device is manufactured from novel materials, not previously used in medical device applications and no toxicology data exists in the literature, additional endpoints beyond those marked "E" in this table should be considered. For particular medical devices, there is a possibility that it will be appropriate to include additional or fewer endpoints than indicated.

Note[i] – Tissue includes tissue fluids and subcutaneous spaces. For gas pathway devices or components with only indirect tissue contact, see device specific standards for biocompatibility information relevant to these medical devices.

Note[j] – For all medical devices used in extracorporeal circuits.

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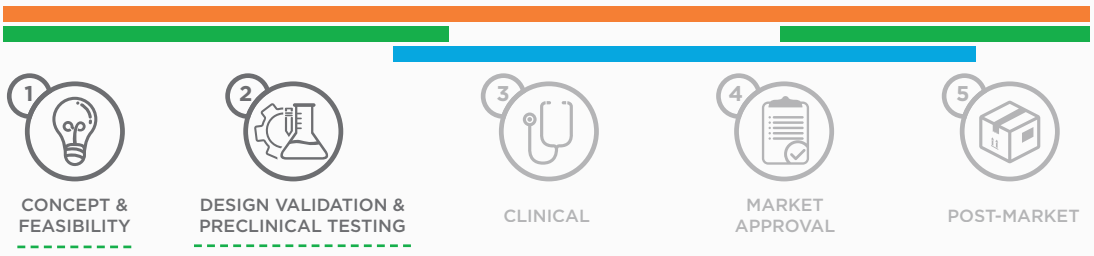

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