

Guidance to the required reference connectors and equipment for testing (Luer) small-bore connectors for intravascular or hypodermic applications

ISO 80369-7:2016 Reference Connectors and ISO 80369-20:2015 Test Equipment			
ISO 80369-7:2016 Clause	Required Annex of ISO 80369-20:2015	Enersol equipment required	Required Enersol reference connectors for testing (Luer) intravascular/hypodermic small-bore connectors
Clause 6 - all sub-clauses	Annex B through I requires the assembly of the appropriate reference connector (i.e. from ISO 80369-7 Annex C) with the test sample, using a specified force and torque to assemble them.	S15B - Connector assembly device	Any/all reference connectors
Clause 6.1.1 - Fluid leakage requirement	Evaluate using EITHER leakage by pressure decay, or positive pressure liquid leakage. It is inferred the same method is used after the stress cracking conditioning.		
Clause 6.1.2 - Leakage by pressure decay	Annex B - Leakage by Pressure Decay	S77 or S77B - Automated pressure decay tester	S07 - ISO80369-7 Fig. C.1 - Lock - FC for testing MC S09 - ISO80369-7 Fig. C.4 - Lock - MC for testing FC S11 - ISO80369-7 Fig. C.2 - Slip - MC for testing FC S12 - ISO80369-7 Fig. C.5 - Slip - FC for testing MC
Clause 6.1.3 - Positive pressure liquid leakage	Annex C - Positive Pressure Liquid Leakage	S16B - Positive pressure liquid leakage tester	S07 - ISO80369-7 Fig. C.1 - Lock - FC for testing MC S09 - ISO80369-7 Fig. C.4 - Lock - MC for testing FC S11 - ISO80369-7 Fig. C.2 - Slip - MC for testing FC S12 - ISO80369-7 Fig. C.5 - Slip - FC for testing MC
Clause 6.2 - Subatmospheric pressure air leakage	Annex D - Subatmospheric pressure air leakage	S78 or S78B - Automated subatmospheric pressure air leakage tester	S07 - ISO80369-7 Fig. C.1 - Lock - FC for testing MC S09 - ISO80369-7 Fig. C.4 - Lock - MC for testing FC S11 - ISO80369-7 Fig. C.2 - Slip - MC for testing FC S12 - ISO80369-7 Fig. C.5 - Slip - FC for testing MC
Clause 6.3 - Stress cracking	Annex E - Stress cracking	Use S15B and; S16B for positive pressure liquid leakage or S77/S77B for pressure decay	S07 - ISO80369-7 Fig. C.1 - Lock - FC for testing MC S09 - ISO80369-7 Fig. C.4 - Lock - MC for testing FC S11 - ISO80369-7 Fig. C.2 - Slip - MC for testing FC S12 - ISO80369-7 Fig. C.5 - Slip - FC for testing MC
Clause 6.4 - Resistance to separation from axial load	Annex F - Resistance to separation from axial load	S18B - Separation force device	S08 - ISO80369-7 Fig. C.3 - Lock - FC for testing MC S10 - ISO80369-7 Fig. C.6 - Lock - MC for testing FC S11 - ISO80369-7 Fig. C.2 - Slip - MC for testing FC S12 - ISO80369-7 Fig. C.5 - Slip - FC for testing MC
Clause 6.5 - Resistance to separation from unscrewing	Annex G - Resistance to separation from unscrewing	S19A - Unscrewing torque device	S07 - ISO80369-7 Fig. C.1 - Lock - FC for testing MC S09 - ISO80369-7 Fig. C.4 - Lock - MC for testing FC Test not required for slips
Clause 6.6 - Resistance to overriding	Annex H - Resistance to overriding	Use S15B	S08 - ISO80369-7 Fig. C.3 - Lock - FC for testing MC S10 - ISO80369-7 Fig. C.6 - Lock - MC for testing FC Test not required for slips
KEY: FC = Female Connector MC = Male Connector			