

Guidance to the required reference connectors and equipment for testing small-bore connectors for Neuraxial applications

ISO 80369-6:2016 Reference Connectors and ISO 80369-20:2015 Test Equipment

ISO 80369-6:2016 Clause	Required Annex of ISO 80369-20:2015	Enersol equipment required	Required Enersol reference connectors for testing Neuraxial small-bore connectors
Clause 6 - all sub-clauses	Annex B through I requires the assembly of the appropriate reference connector (i.e. from ISO 80369-6 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	S67 - ISO80369-6 Fig. C.1 FC for testing MC S69 - ISO80369-6 Fig. C.4 MC for testing FC S71 - ISO80369-6 Fig. C.2 MC for testing FC
Clause 6.1.3 - Positive pressure liquid leakage	Annex C - Positive Pressure Liquid Leakage	S16B - Positive pressure liquid leakage tester	S67 - ISO80369-6 Fig. C.1 FC for testing MC S69 - ISO80369-6 Fig. C.4 MC for testing FC S71 - ISO80369-6 Fig. C.2 MC for testing FC
Clause 6.2 - Subatmospheric pressure air leakage	Annex D - Subatmospheric pressure air leakage	S78 or S78B - Automated subatmospheric pressure air leakage tester	S67 - ISO80369-6 Fig. C.1 FC for testing MC S69 - ISO80369-6 Fig. C.4 MC for testing FC S71 - ISO80369-6 Fig. C.2 MC for testing FC
Clause 6.3 - Stress cracking*	Annex E - Stress cracking	Use S15B and; S16B for positive pressure liquid leakage or S77/S77B for pressure decay	S67 - ISO80369-6 Fig. C.1 FC for testing MC S69 - ISO80369-6 Fig. C.4 MC for testing FC S71 - ISO80369-6 Fig. C.2 MC for testing FC
Clause 6.4 - Resistance to separation from axial load	Annex F - Resistance to separation from axial load	S18A - Separation force device	S68 - ISO80369-6 Fig. C.3 FC for testing MC S70 - ISO80369-6 Fig. C.5 MC for testing FC
Clause 6.5 - Resistance to separation from unscrewing	Annex G - Resistance to separation from unscrewing	S19A - Unscrewing torque device	S67 - ISO80369-6 Fig. C.1 FC for testing MC S69 - ISO80369-6 Fig. C.4 MC for testing FC S71 - ISO80369-6 Fig. C.2 MC for testing FC
Clause 6.6 - Resistance to overriding	Annex H - Resistance to overriding	Use S15B	S68 - ISO80369-6 Fig. C.3 FC for testing MC S70 - ISO80369-6 Fig. C.5 MC for testing FC
			KEY: FC = Female Connector MC = Male Connector

* = There is an error in ISO 80369-6:2016 Clause 6.3. This clause states that the connectors shall meet the requirements of Clause 6.1.2 after stress cracking. This reference to Clause 6.1.2 is a mistake that is intended to be corrected. Clause 6.3 should state Clause 6.1.1 instead of Clause 6.1.2.

Clause 6.1.1 requires that either Clause 6.1.2 (Leakage by pressure decay) or 6.1.3 (Positive pressure liquid leakage) be used. At some stage there will be an update to correct Clause 6.3 to reference Clause 6.1.1.