

May-17

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

ISO80369-6:2016	Required Annex of ISO 80369-20:2015	Enersol equipment required	Required Enersol reference connectors for Neuraxial connectors
Clause 6 - all sub-clauses	Assemble the reference connector from ISO80369-6 Annex C with the test sample	S15A - Connector assembly device	All
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	ISO80369-20 Annex B - Leakage by Pressure Decay	S77 - Automated pressure decay tester	S67 - ISO80369-6 Fig. C.1 S69 - ISO80369-6 Fig. C.4 S71 - ISO80369-6 Fig. C.2
Clause 6.1.3 - Positive pressure liquid leakage	ISO80369-20 Annex C - Positive Pressure Liquid Leakage	S16A - Positive pressure liquid leakage tester	S67 - ISO80369-6 Fig. C.1 S69 - ISO80369-6 Fig. C.4 S71 - ISO80369-6 Fig. C.2
Clause 6.2 - Sub-atmospheric pressure air leakage	ISO80369-20 Annex D - Sub-atmospheric pressure air leakage	S78 - Automated sub-atmospheric pressure air leakage tester	S67 - ISO80369-6 Fig. C.1 S69 - ISO80369-6 Fig. C.4 S71 - ISO80369-6 Fig. C.2
Clause 6.3 - Stress cracking*	ISO80369-20 Annex E - Stress cracking	Use S15A	S67 - ISO80369-6 Fig. C.1 S69 - ISO80369-6 Fig. C.4 S71 - ISO80369-6 Fig. C.2
Clause 6.4 - Resistance to separation from axial load	ISO80369-20 Annex F - Resistance to separation from axial load	S18A - Separation force device	S68 - ISO80369-6 Fig. C.3 S70 - ISO80369-6 Fig. C.5
Clause 6.5 - Resistance to separation from unscrewing	ISO80369-20 Annex G - Resistance to separation from unscrewing	S19A - Unscrewing torque device	S67 - ISO80369-6 Fig. C.1 S69 - ISO80369-6 Fig. C.4 S71 - ISO80369-6 Fig. C.2
Clause 6.6 - Resistance to overriding	ISO80369-20 Annex H - Resistance to overriding	Use S15A	S68 - ISO80369-6 Fig. C.3 S70 - ISO80369-6 Fig. C.5

* = There is an error in clause 6.3. The standard states 6.1.2 be performed after stress cracking. It was a mistake that is intended to be corrected. Clause 6.3 SHOULD require 6.1.1 which then allows for either 6.1.2 or 6.2.3 to be used. There will be an update to the standard in due course.