

**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 Clause	ISO 80369-20 Annex	Enersol equipment required	Required Enersol reference connectors for testing Neuraxial small-bore connectors
Clause 6 - all sub-clauses	The test methods require the test sample is assembled with the appropriate reference connector, using a specified force and/or torque to assemble them.	S15B - Connector assembly device	Any/all reference connectors listed below
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 - Fig. C.1 - SC for testing CC S69 - Fig. C.4 - CC for testing SC S71 - Fig. C.2 - CC for testing SC
Clause 6.1.3 - Positive pressure liquid leakage	Annex C - Positive Pressure Liquid Leakage	S16B - Positive pressure liquid leakage tester	S67 - Fig. C.1 - SC for testing CC S69 - Fig. C.4 - CC for testing SC S71 - Fig. C.2 - CC for testing SC
Clause 6.2 - Subatmospheric pressure air leakage***	Annex D - Subatmospheric pressure air leakage***	S78B - Automated subatmospheric pressure air leakage tester*** Or for locations 900m or more above sea level, the S78H is required for this test	S67 - Fig. C.1 - SC for testing CC S69 - Fig. C.4 - CC for testing SC S71 - Fig. C.2 - CC for testing SC
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 - Fig. C.1 - SC for testing CC S69 - Fig. C.4 - CC for testing SC S71 - Fig. C.2 - CC for testing SC
Clause 6.4 - Resistance to separation from axial load	Annex F - Resistance to separation from axial load	S18A - Separation force device	S68 - Fig. C.3 - SC for testing CC S70 - Fig. C.5 - CC for testing SC
Clause 6.5 - Resistance to separation from unscrewing	Annex G - Resistance to separation from unscrewing	S19A - Unscrewing torque device	S67 - Fig. C.1 - SC for testing CC S69 - Fig. C.4 - CC for testing SC S71 - Fig. C.2 - CC for testing SC
Clause 6.6 - Resistance to overriding	Annex H - Resistance to overriding	Use S15B	S68 - Fig. C.3 - SC for testing CC S70 - Fig. C.5 - CC for testing SC
KEY: SC = Socket (Female) Connector    CC = Cone (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.			
*** = NOTE: For laboratories located at 600m-899m or at 900m or more above sea level, please let Enersol know as this affects the S78B units where 80-88kPa subatmospheric pressure is required.			