

# ISO 11040-4 FIXTURES

## Fixtures for Testing Pre-filled Glass Syringes

Pre-filled glass syringes are most commonly tested to ISO 11040-4. As glass syringes are more susceptible to failure than plastic syringes, a wider variety of tests are required to be performed on them. Within ISO 11040-4 there are a total of 10 annexes, each requiring a different mechanical test. All fixtures are compatible with the Torsion Add-On for 5900 systems, as some of the annexes require simple rotation.

Instron® offers modular fixtures to test all 10 annexes in ISO 11040-4, which includes:



Annex C.1 for flange breakage resistance



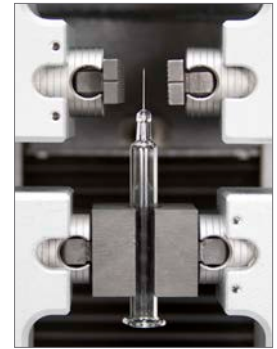
Annex C.2 for Luer cone breakage



Annex E.1 for glide force



Annex F.1 for needle penetration



Annex G.1 for needle pull-out force



Annex G.2 for liquid leakage testing



Annex G.3 for Luer lock collar pull-off



Annex G.4 for Luer lock collar torque



Annex G.5 for Luer tip cap unscrewing torque



Annex G.6 for pull-off force of the needle shield

### The Instron Advantage

- Fixtures are designed to accommodate all syringe sizes per ISO 11040-4
- Fixtures have a modular design to minimize the number of parts needed
- Supported by Instron local service
- Pre-configured test methods are available in the Bluehill® Universal Bio Applications Module
  - Reduced operator training
  - Compatible with the large library of calculations in Bluehill Software
  - IQ/OQ documentation available for both linear and torsion calculations

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