

Product Information

Fixture for Testing of Medical Small-Bore-Connectors for Liquids and Gases to ISO 80369

CTA: 235886 235887



Applications

ISO 80369 describes a test method for small-bore connectors for liquids and gases in healthcare applications. These can be used with cannulas, syringes, catheters and infusion tubes.

The connectors must be tested for the following stresses:

- Leakage by pressure decay
- Falling drop positive-pressure liquid leakage
- Subatmospheric-pressure air leakage
- Stress cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding
- Disconnection by unscrewing = I

Advantages and features

- Compliance with the contents of standards
ISO 80369 - 1
ISO 80369 - 7
ISO 80369 - 6
ISO 80369 - 20
- Fully integrated test sequence via a semi-automated assembly process with subsequent test sequence. This minimizes error influences and saves on both time and costs.
- Calibrated pressure and vacuum device for leakage testing of gases and liquids.
- Standard-compliant reference gauges for mechanical and physical testing of the medium.
- The variable gripping system allows for testing of various specimen geometries.
- testXpert III integrated test program to ISO 80369 with all benefits including, for example expanded traceability to 21 CFR Part 11 and EU GMP Annex 11.

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The following machine configuration is the basic recommendation for testing Luer lock connections:

Description	ArticleNumber
zwickiLine Z2.5 TN+	1039527
Enlarged base for zwickiLine with torsion drive	1041715
Emergency stop link (2x)	1023870
Ethernet switch for 10/100/1000 MBit	1026425
I/O module for analog and digital signal processing	029448
Torsion drive, 2 Nm or higher	1020233
Alignment fixture for axial offset and angle correction	3006208
Adjustment rod for alignment fixture	3006211
Xforce HP 500 N load cell	069529
Torque transducer, 2 Nm	069536
testXpert III basic program	1035154
testXpert III advanced control mode	1035959
testXpert III test program correction curve/calibration, torsion	1042159
Personal computer	1076395
TFT monitor	028997
Documentation, English	347188
Spare parts lists, English	354856

Optional:

Description	ArticleNumber
Safety device	059078
Increase rotation speed	063785
Safety door link tCII (2x)	1041273
testXpert III expanded traceability to 21 CFR Part 11 and EU GMP Annex 11	1035624

Test fixture components

Software

Description	ArticleNumber
testXpert III test sequence to ISO 80369	3008477

Test device, upper

Description	ArticleNumber
Compensation device for specimens with threaded closure	1082919

Test device, lower

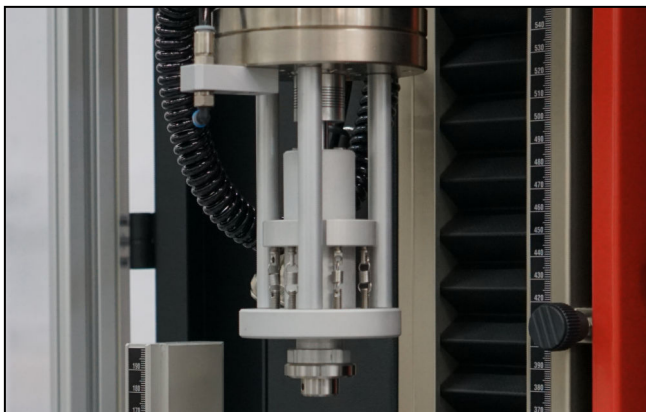
Description	ArticleNumber
Universal holder for Luer lock connectors	3008461
Specimen jaws with non-slip surface for specimen with \varnothing 5-12 mm	1088183

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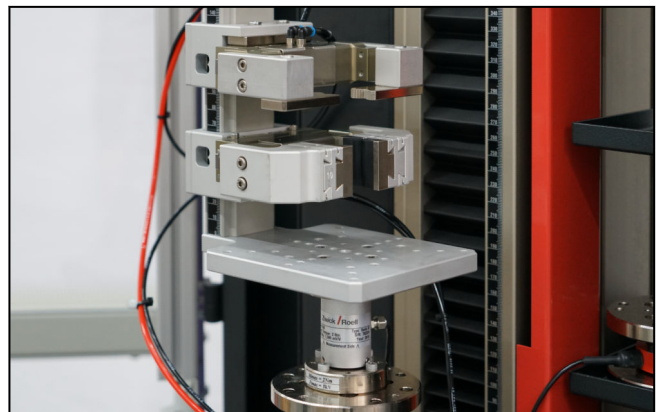
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Description	ArticleNumber
Specimen jaws with non-slip surface for specimen with \varnothing 12-35 mm	1088184
Pneumatic control unit with inching mode	057427

CTA: 235888,235889



Compensation device for 8 mm locking pin



Universal holder for Luer lock connectors including specimen jaws with non-slip surface

Pressure / vacuum control unit

Description	ArticleNumber
Control unit for pressure and vacuum test Pressure range: -0.8 to 5 bar	3008469
Pressure sensor with sensor plug Measurement range: -0.8 to 5 bar Accuracy: 0.05 % of the end value	3008467

CTA: 235890



Vacuum / pressure control unit including sensor

All data at ambient temperature.

Subject to change in the course of further development.

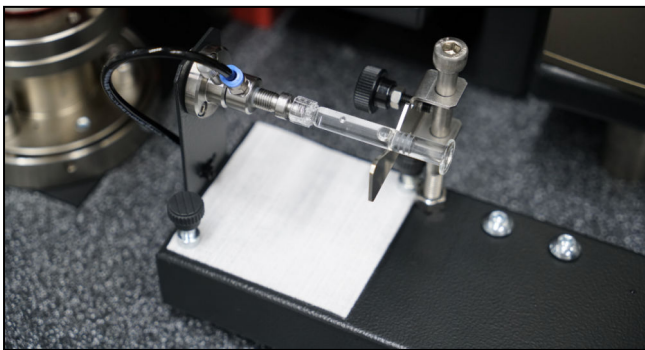
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Testing device for falling drop positive-pressure liquid leakage test

Description	ArticleNumber
Testing device for falling drop positive-pressure liquid leakage test Specimen adaptation via 8 mm locking pins. Including magnets to hold blotting paper.	3008463

CTA: 235891



Various metal luer connectors Fig. C1 - C6 are available for the respective sample geometry. If the sample material to be tested made of glass, the plastic luer connector is required for the leakage test.

ISO 80369	Specimen material plastics						Specimen material glass							
	Mechanical Test			Leakage Test			Mechanical Test			Leakage Test				
	F	G	H	B	C	D	E	F	G	H	B	C	D	E
-20 Annex														
Fig. C1		-6 -7		-6 -7	-6 -7	-6 -7	-6 -7		-6 -7					
Fig. C2	-7			-6 -7	-6 -7	-6 -7	-6 -7	-7						
Fig. C3	-6 -7		-6 -7					-6 -7		-6 -7				
Fig. C4		-6 -7		-6 -7	-6 -7	-6 -7	-6 -7		-6 -7					
Fig. C5	-6 -7		-6	-6 -7	-6 -7	-6 -7	-6 -7	-6 -7		-6				
Fig. C6	-7		-7					-7		-7				
Luer plastics											-6 -7	-6 -7	-6 -7	-6 -7

	Description	80369-20	80369-6	80369-7
Leakage Test	Leakage by pressure decay	B	6.1.2	6.1.2
	Falling Drop fluid leakage	C	6.1.3	6.1.3
	Subatmospheric-pressure air leakage	D	6.2	6.2
Mechanical Test	Stress cracking	E	6.3	6.3
	Resistance to separation from axial load	F	6.4	6.4
	Resistance to separation from unscrewing	G	6.5	6.5
	Resistance to overriding	H	6.6	6.6

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Luer connectors¹⁾ to ISO 80369-6

Description	ArticleNumber
Luer connector to ISO 80369-6 Fig. C1	3014264
Luer connector to ISO 80369-6 Fig. C2	3014265
Luer connector to ISO 80369-6 Fig. C3	3014266
Luer connector to ISO 80369-6 Fig. C4	3014267
Luer connector to ISO 80369-6 Fig. C5	3014268

Luer connectors¹⁾ to ISO 80369-7

Description	ArticleNumber
Luer connector to ISO 80369-7 Fig. C1	3008475
Luer connector to ISO 80369-7 Fig. C2	3008474
Luer connector to ISO 80369-7 Fig. C3	3008473
Luer connector to ISO 80369-7 Fig. C4	3008472
Luer connector to ISO 80369-7 Fig. C5	3008471
Luer connector to ISO 80369-7 Fig. C6	3008470
Luer plastic connector for performance of pressure and vacuum tests on glass syringes	1087884

Adapter for Luer connectors²⁾

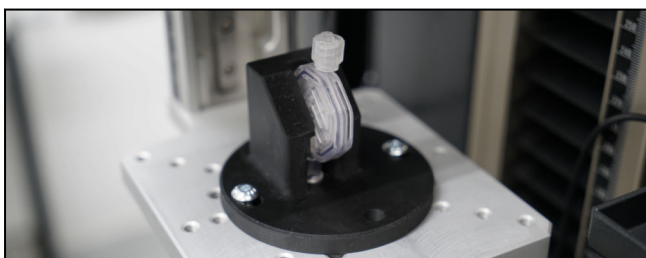
Required to mechanically connect the Luer connectors to the upper test device. With the pressure and control unit, internal pressure can be applied to the connecting elements via an integrated air channel.

Description	ArticleNumber
Adapter (8 mm locking pin) for ZwickRoell Luer connectors	1084432
Adapter (8 mm locking pin) for Enersol Luer connectors	1084433

Customized mounting for complex / asymmetrical specimen geometries

For asymmetrical specimen geometries the connectors can be centrally aligned by using special specimen grips and specimen grip inserts. For this, the specimen data (STEP files) of the outer contour are required. Production is carried out via additive manufacturing processes. Using the standardized drill pattern on the universal holder, the specimen is positioned in the axis and secured.

Description	ArticleNumber
Mounting for complex Luer lock geometries.	3008462



CTA: 235692

¹⁾ One adapter (Item No. 1084432) required per Luer connector

²⁾ One adapter is required per connector.

All data at ambient temperature.

Subject to change in the course of further development.