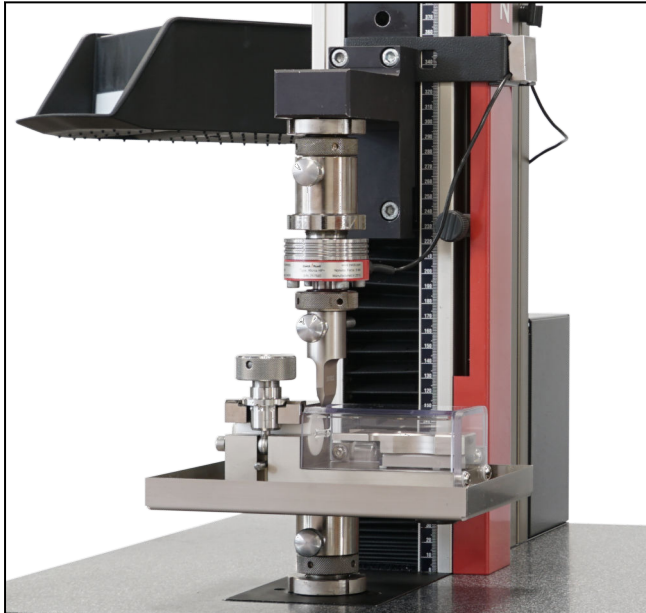


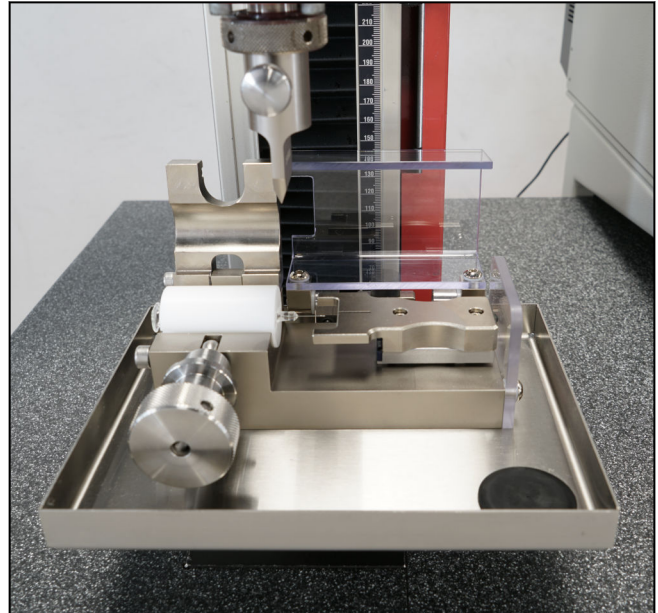
Product Information

ISO 11040-4/-6 Annex C2 - Luer cone breakage resistance

CTA.: 262657 262658



Test arrangement with compression die, syringe holder and hinged shatter protection



Detail view with syringe holder, distance setting and shatter protection

Applications

Testing is performed on glass or plastic syringe barrels for injectables and sterilized subassembled syringes ready for filling.

In Annex C2 of the standard, the breakage resistance of the Luer cone is tested.

To perform the test, the syringe is inserted into the mounting with the corresponding holder diameter. Correct positioning of the syringe is set with the integrated limit stop adjustment slide.

A compression die is used to apply force to the Luer cone until it breaks. The test speed is 25 mm/min.

The expected force range is 350 N.

The test results contain the following information:

- Sampling rate
- Test speed
- Distance from tip to loading point
- Force at break
- Number of syringes tested
- Deviations

Advantages and features

- All syringe sizes listed in the standard can be tested with this device.
- Mountings for syringes with diameters 6.8 / 8.2 / 10.9 / 14.5 / 17.1 / 22.1 mm
- Adjustable syringe mounting for different syringe diameters and lengths
- Quick-lock system for secure holding
- Reproducible distance adjustment of the syringe
- Prevention of glass splinters due to shatter protection
- high stiffness and precise crosshead guidance with zwickiLine
- maximum safety for user, test results, specimen material and testing system.
- online correction of machine compliance guarantees very high travel-measurement and positioning accuracy
- traceable, reliable test results in accordance with FDA 21 CFR Part 11, guaranteeing complete, tamper-proof documentation of all actions and changes performed in the testXpert III testing software

Product Information

ISO 11040-4/-6 Annex C2 - Luer cone breakage resistance

Technical data

Type Item No.	Test fixture for breakage tests on syringe barrels 1100129		
Test load F_{max}	1		kN
Syringe mountings			
0.5 ml	Ø 6.9		mm
1 ml, long	Ø 8.2		mm
2.25 ml	Ø 10.9		mm
Ambient temperature	+10 ... +35		°C
Connection, upper	Studs Ø 20 or 8 (via connector included)		mm
Connection, lower	Stud Ø 20		mm

Optional accessories

Syringe mountings

Description	ArticleNumber
Mounting with Ø 10.9 mm; for syringe with 1 ml volume (short)	1101973
Mounting with Ø 10.9 mm; for syringe with 2 ml volume	1101972
Mounting with Ø 14.5 mm; for syringe with 5 ml volume	1101971
Mounting with Ø 17.1 mm; for syringe with 10 ml volume	1101970
Mounting with Ø 22.1 mm; for syringe with 20 ml volume	1101969