Testing of Pre-filled Syringes

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Background/ Experiences:

- Mechanical Engineer / Textile Engineer
- 1997-2003: R&D ITA, RWTH Aachen University (Biomaterials/Implants)
- 2003-2008: R&D Paul Hartmann AG, Heidenheim (Compression/Immobilization products)
- Materials, production, testing, regulatory, launching, patents

Standards for pre-filled syringes

ISO 11040-4: Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled

ISO 80369-7: Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications

ISO 80369-20: Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods

(**ISO 594-2:** Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings)

Pre-filled syringes

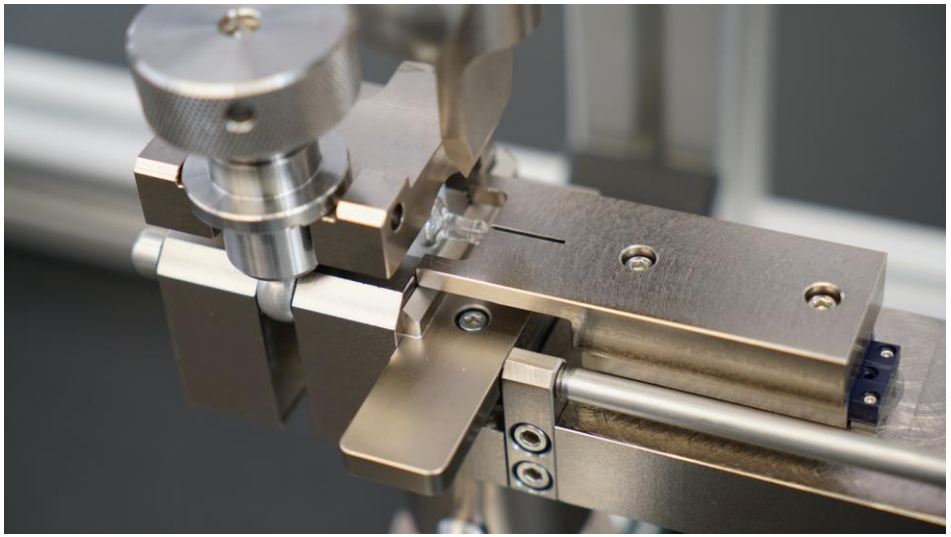
ISO 11040-4: Mechanical characterization

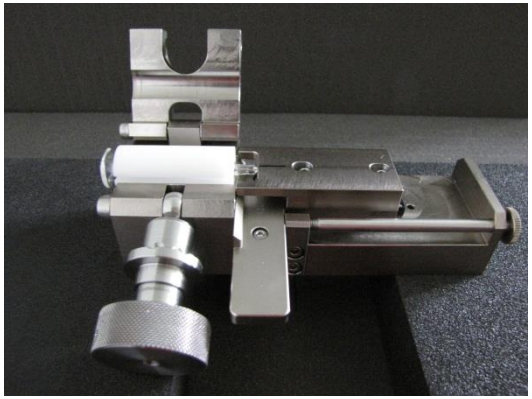
C1 Flange breaking resistance
C2 Luer cone breaking resistance
E Glide force test method to evaluate syringe lubrication
F Needle penetration test
G1 Needle pull-out force
G2 Closure system liquid leakage test
G3 Luer lock adaptor collar pull-off force
G4 Luer lock adaptor collar torque resistance
G5 Luer lock rigid tip cap unscrewing torque
G6 Pull-off force of the tip cap or the needle shield

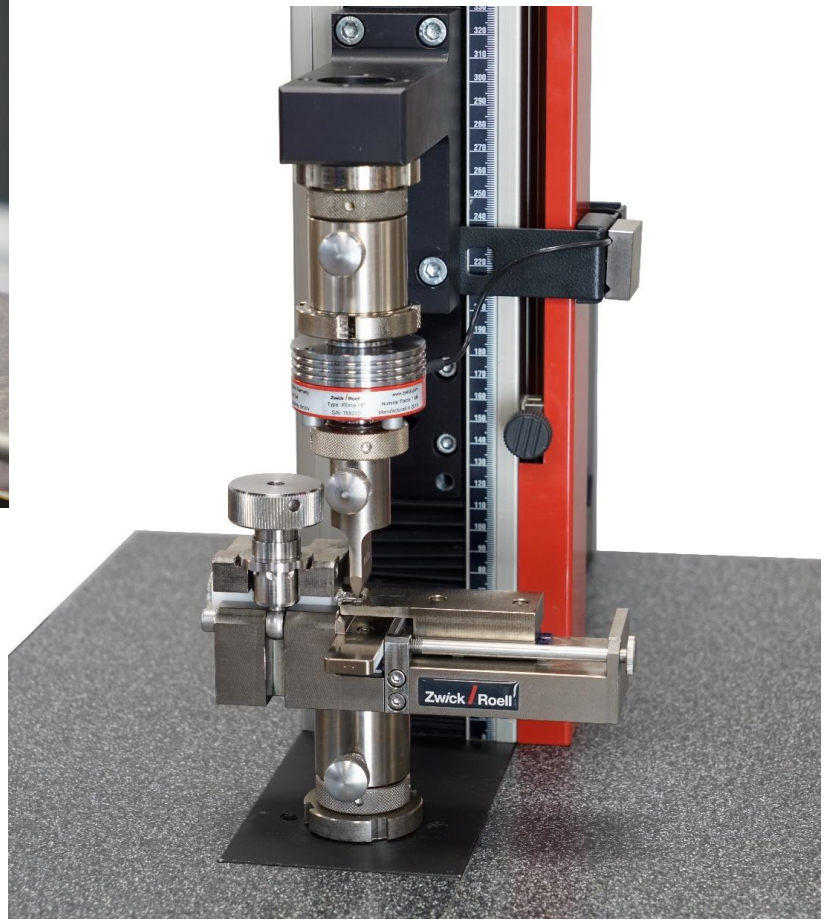
Movie

C1 - Flange breaking resistance

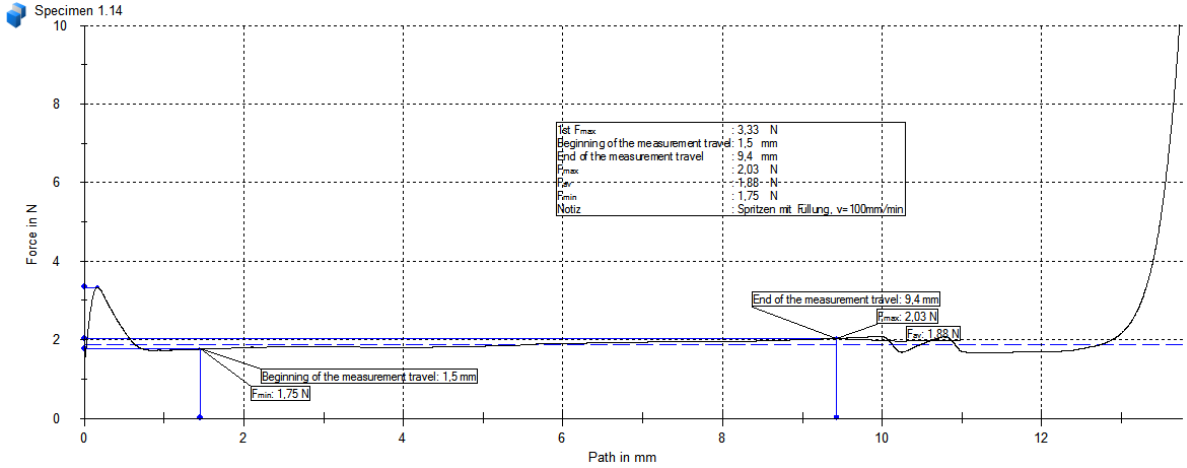
C2 - Luer cone breaking resistance

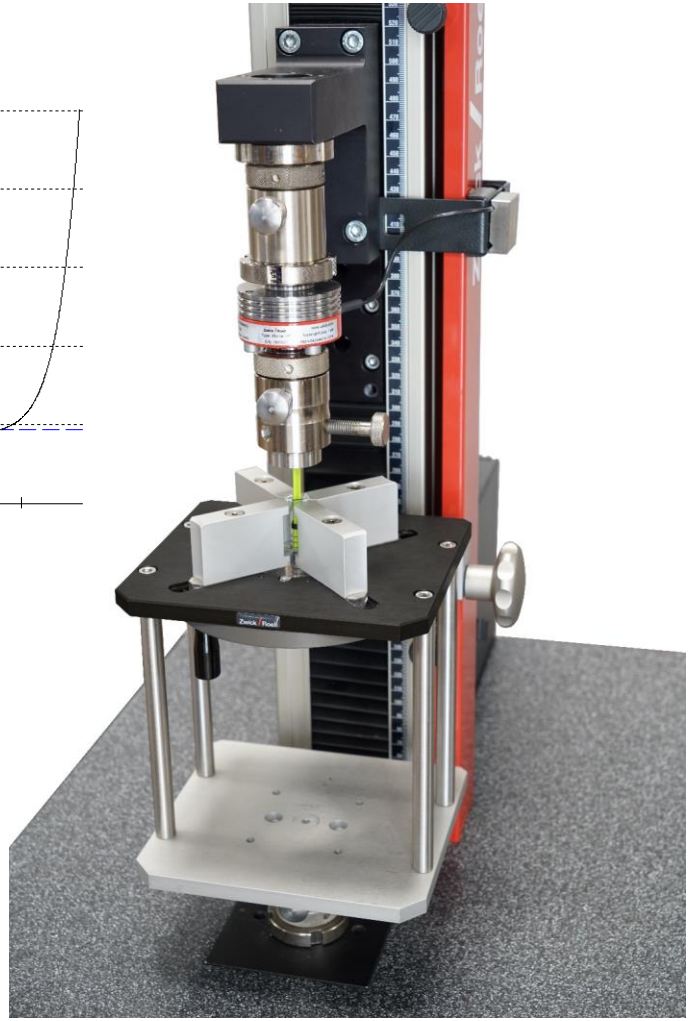




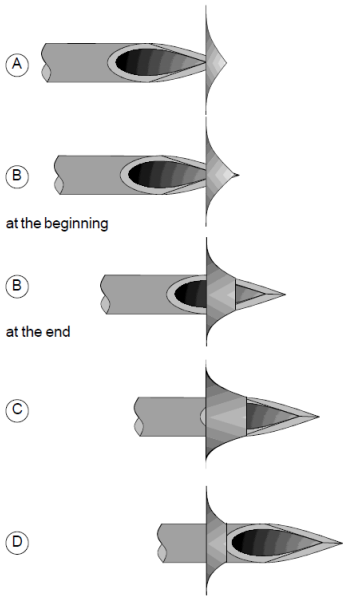


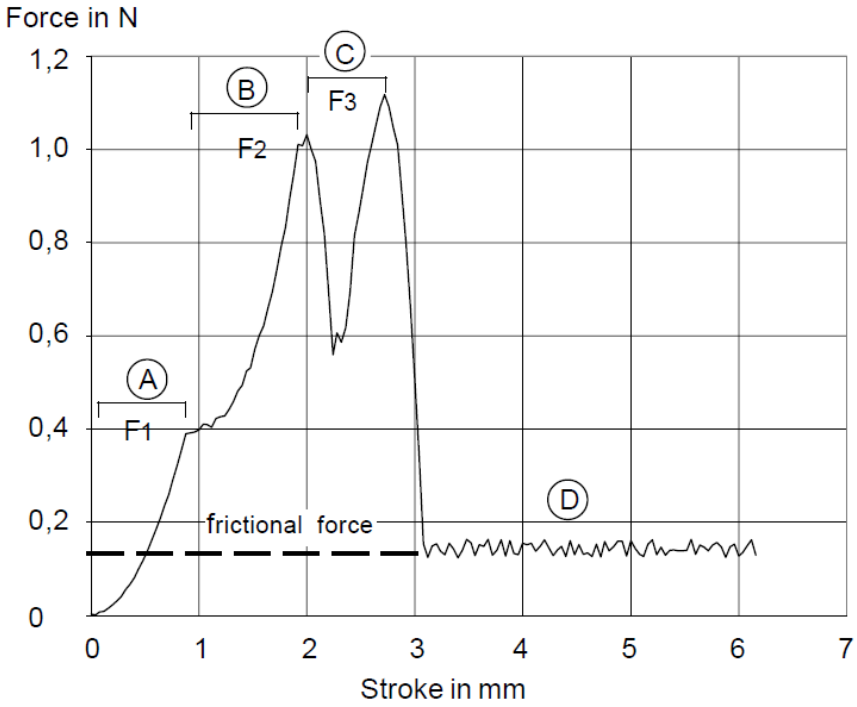
E - Glide force test method to evaluate syringe lubrication



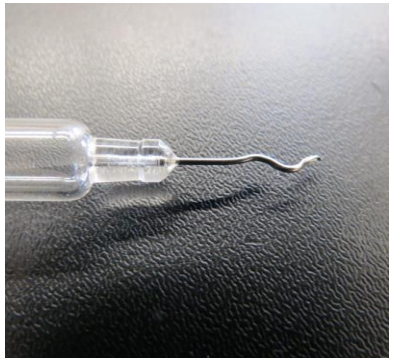


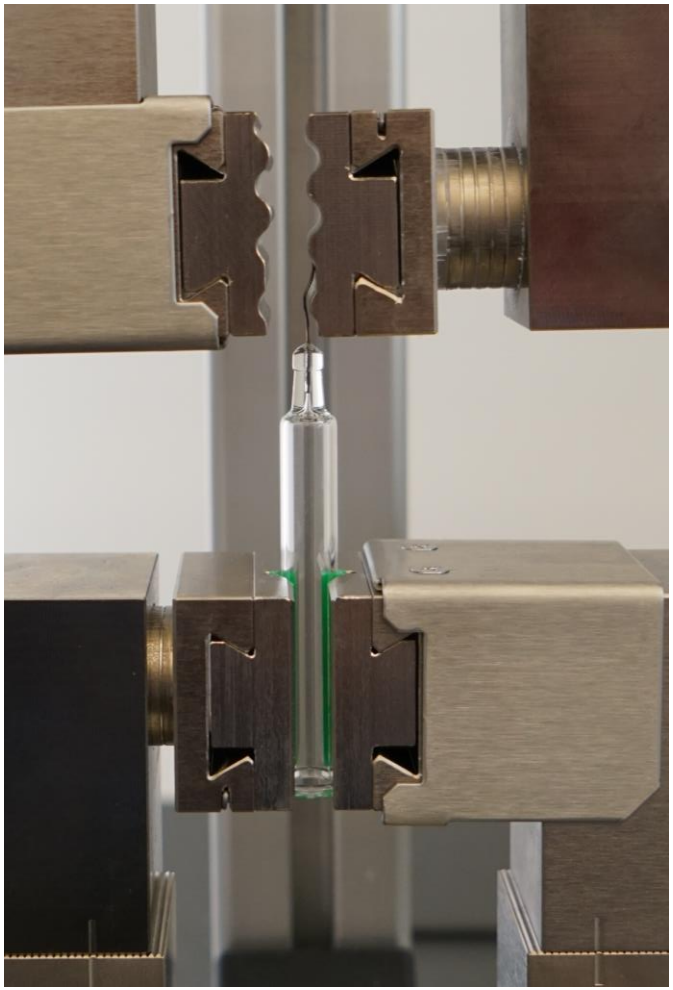
F - Needle penetration test

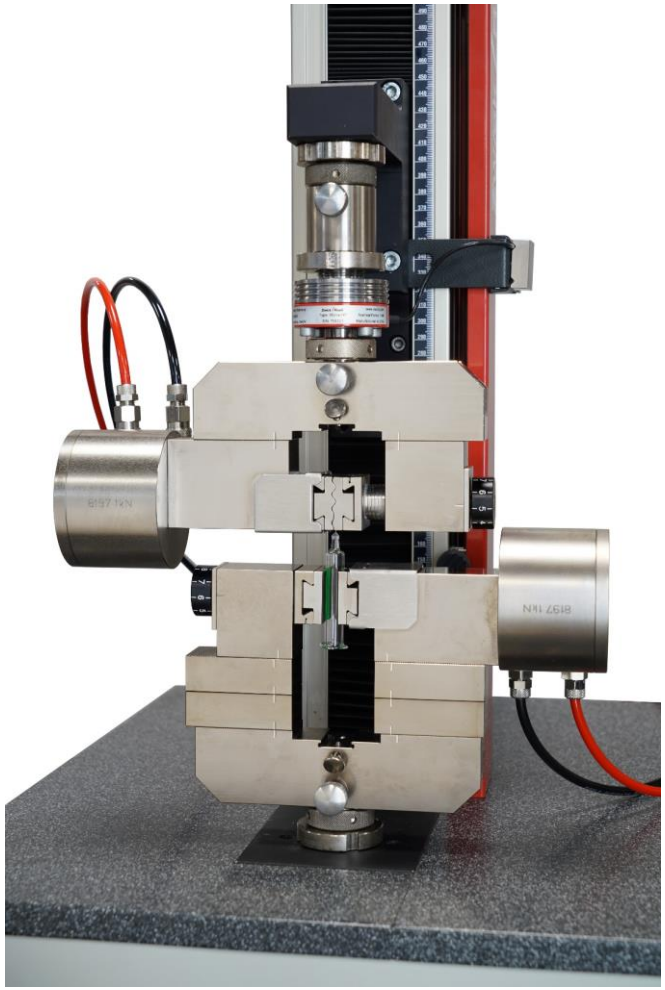




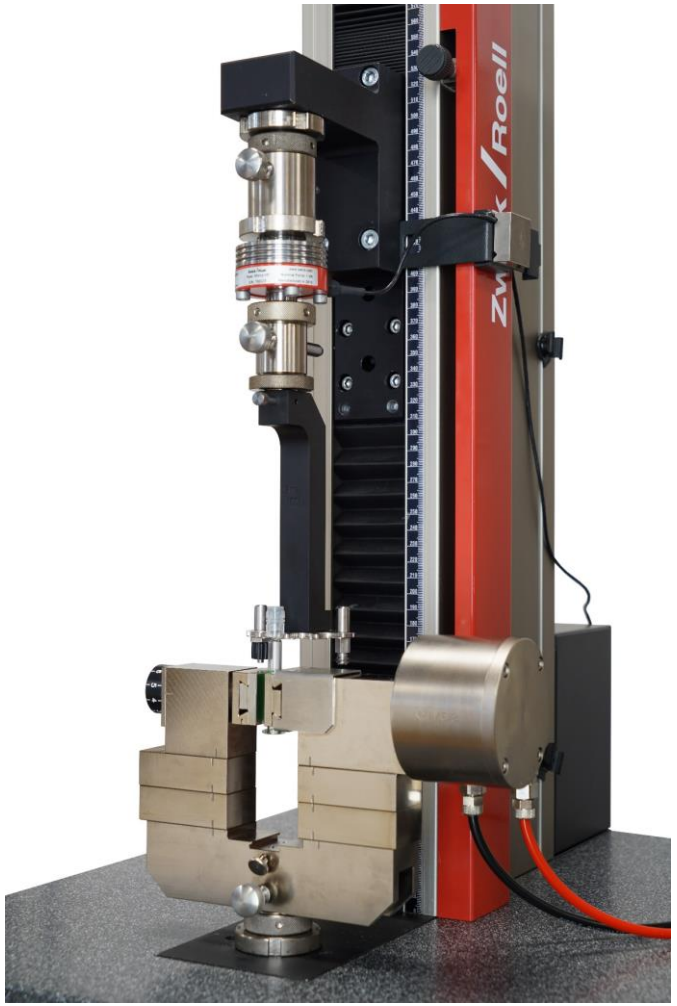
G1 - Needle pull-out force



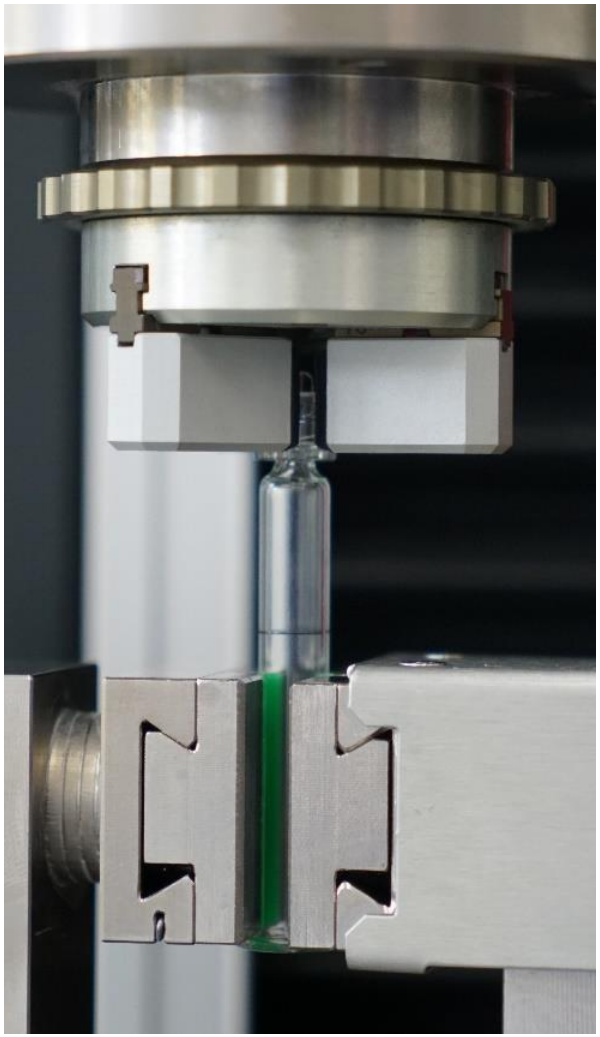




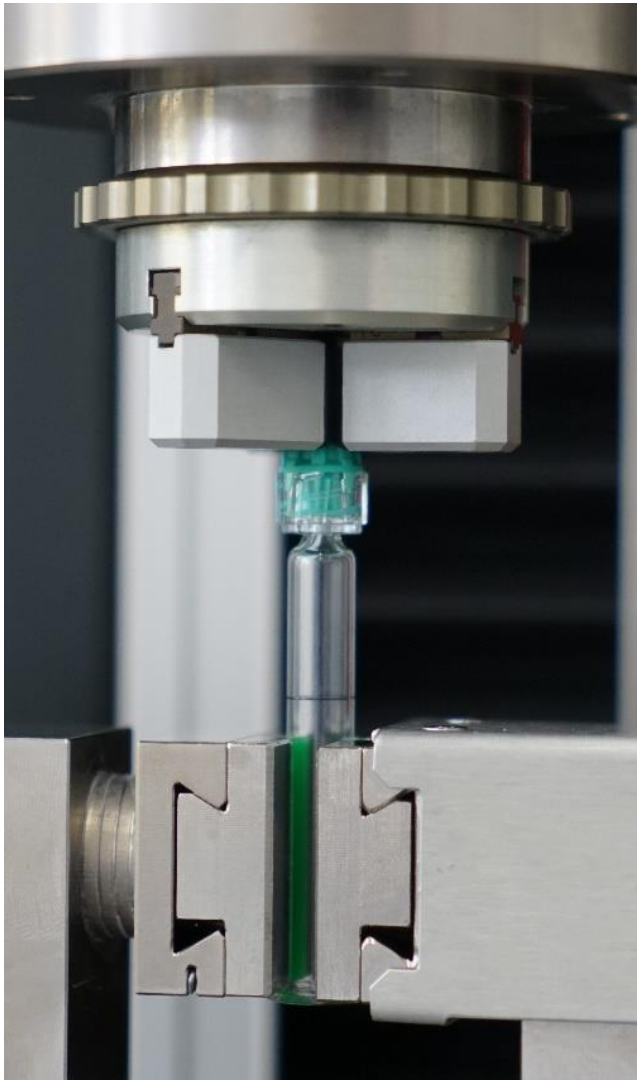
G3 - Luer lock adaptor collar pull-off force



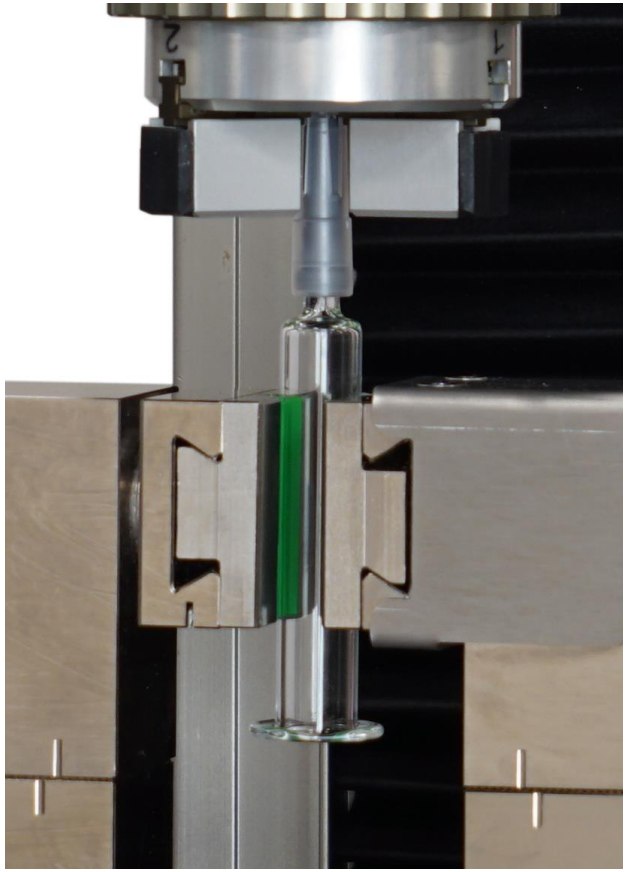
G4 - Luer lock adaptor collar torque resistance

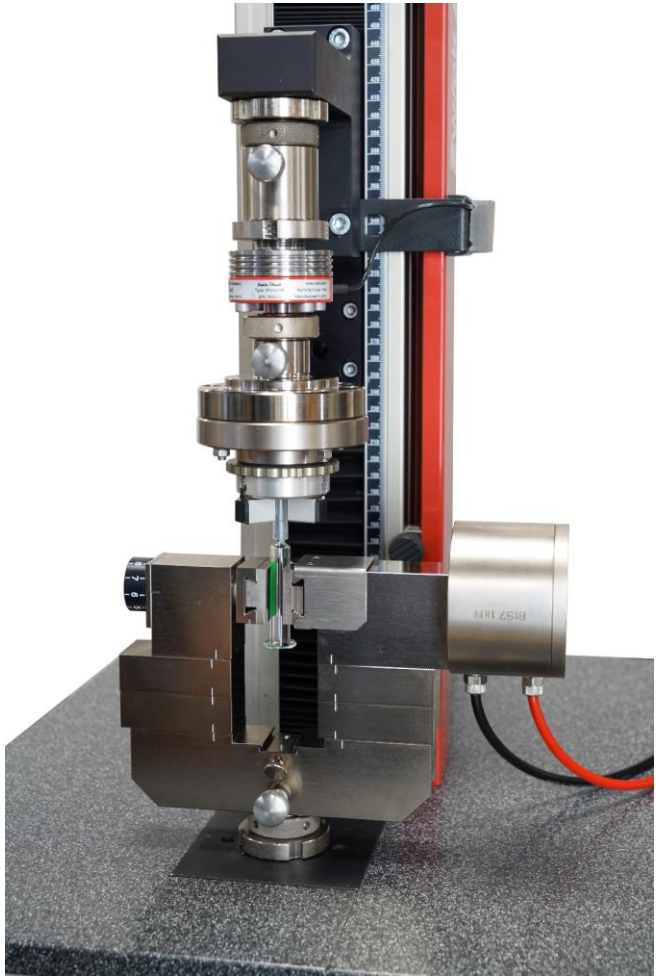


G5 Luer lock rigid tip cap unscrewing torque

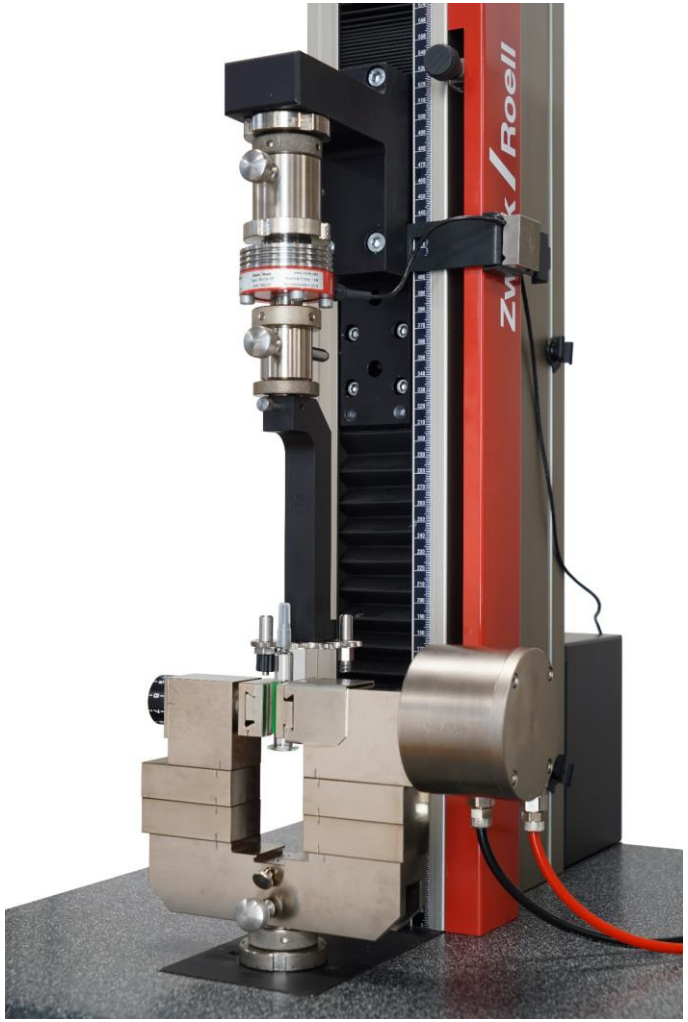


G6 Method 1 Pull-off force of the tip cap or the needle shield

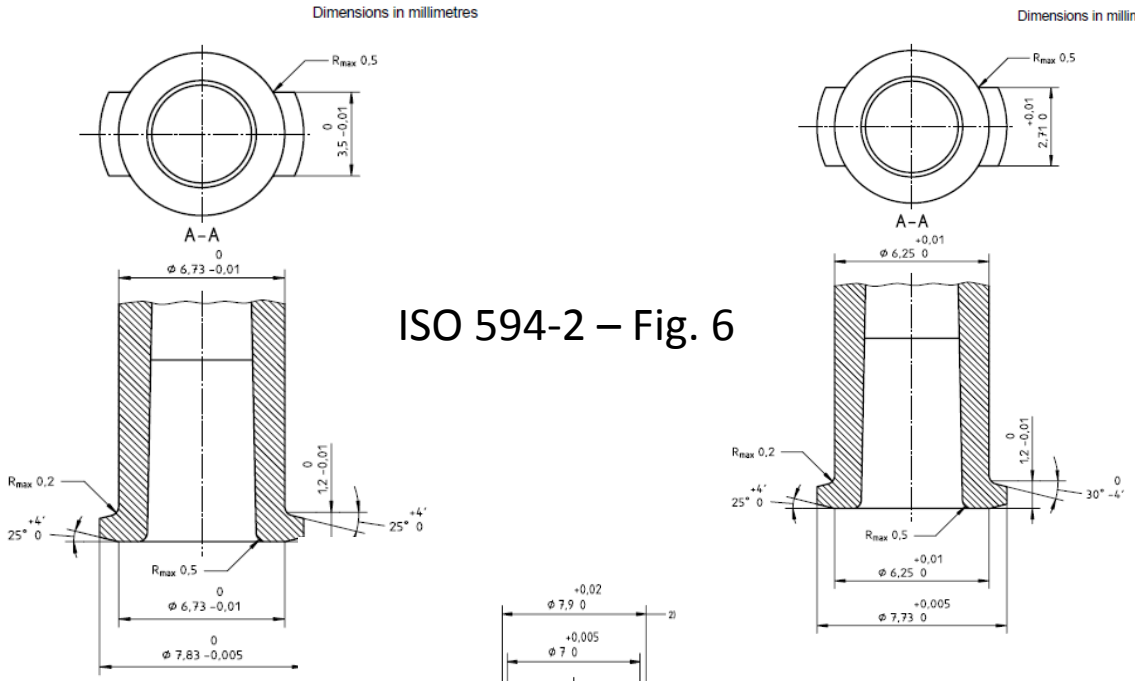




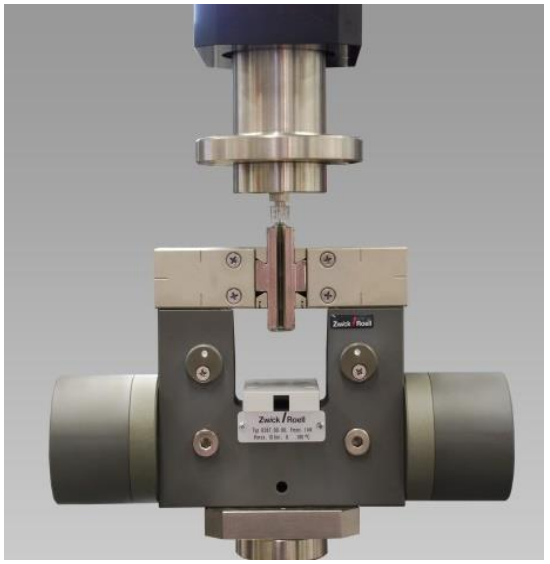
G6 Method 2 Pull-off force of the tip cap or the needle shield

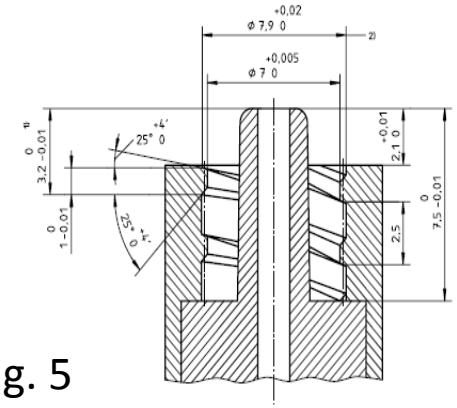


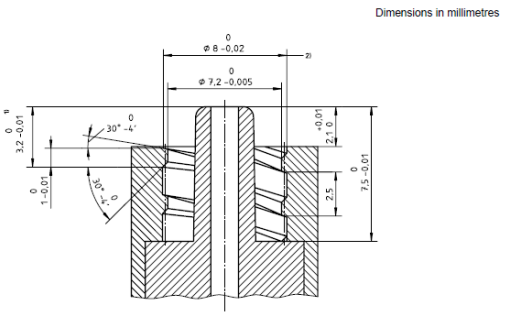
ISO 594-2 (1986)



ISO 594-2 – Fig. 6



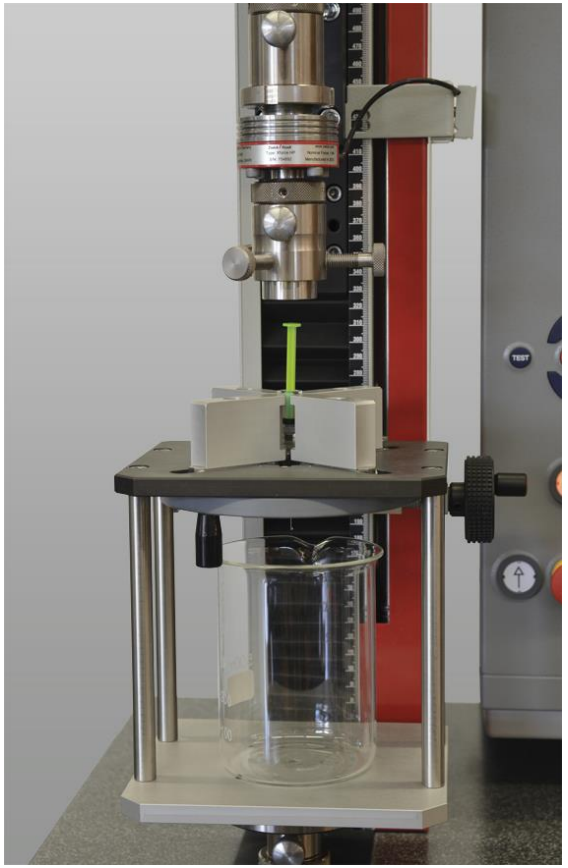




ISO 594-2 – Fig. 5

Zwick accessories for testing break away force and glide force of syringes and cartridges

Testing device following DIN EN ISO 7886-1

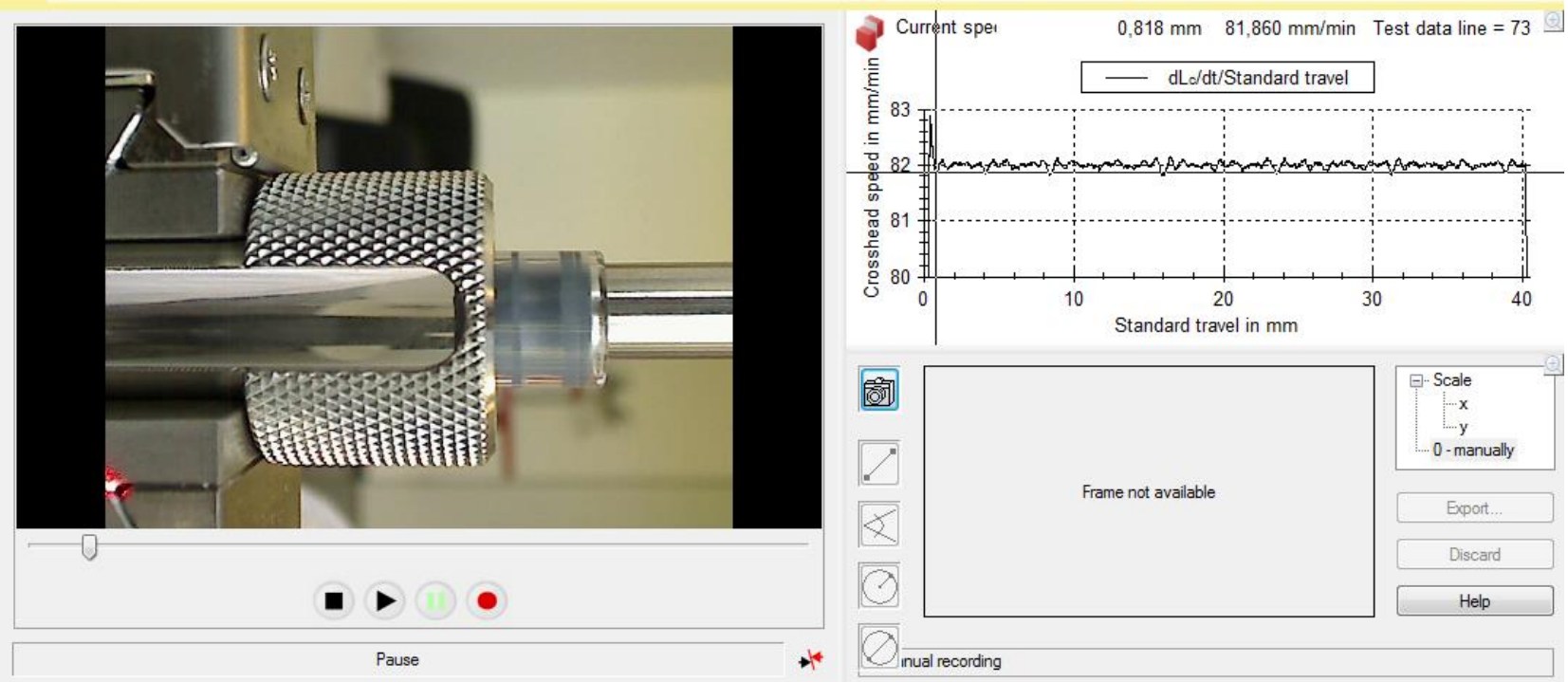


Universal testing rig for syringes and cartridges

Traceability of results and detailed analyzes with recording

- Recording of pictures (setups, samples before/after testing) is integrated in testXpert III.
- Option Videocapture to synchronize testing results with recorded movies of testing sequences (variety of camera systems usable)

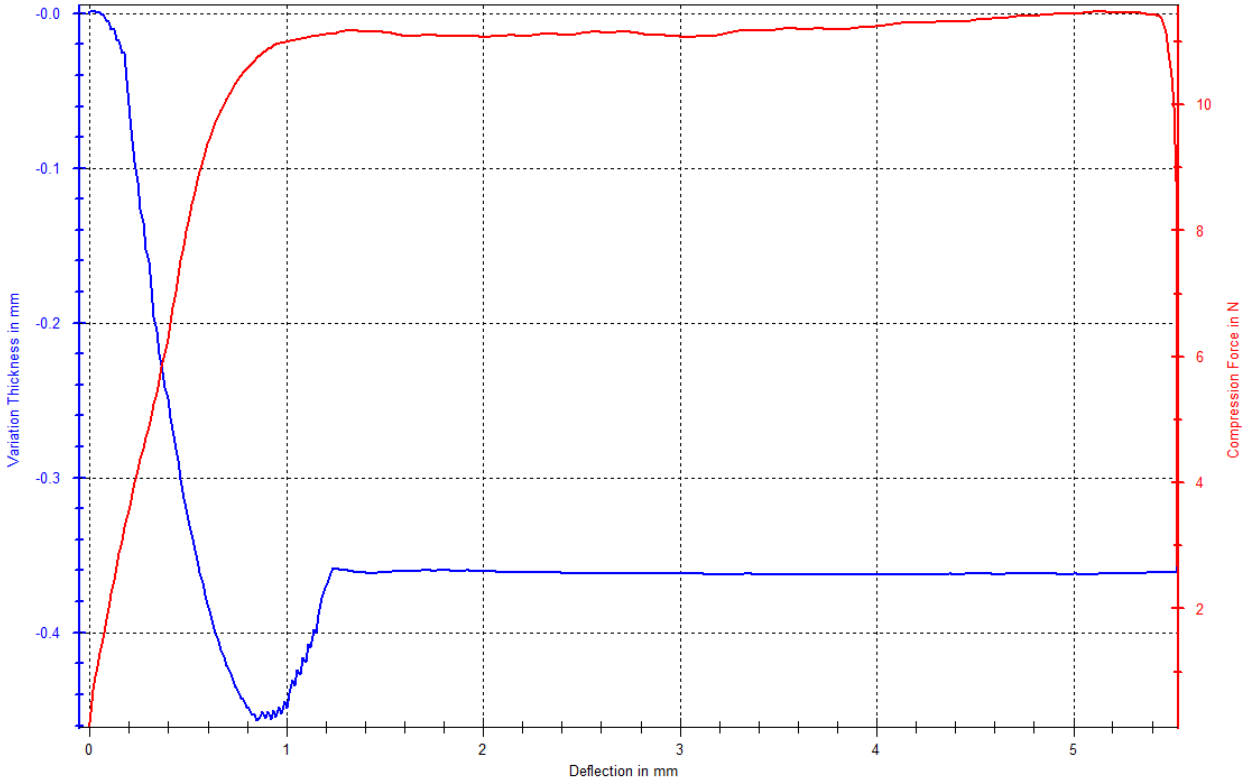
Movie



Use of additional optical extensometer videoXtens for determining the compression of plungers.

Synchronized measuring of the thickness of the plunger while performing a continuous/single ejection test.

Cartridge with plunger



Plunger compression measurement

Biaxial zwicki for superimposed tensile/compression- torsion testing

Advantages

- Compact and robust design, space saving and relatively low-priced
- Single and superimposed tensile/compression/torsion testing, synchronization of both test axes
- Test methods of the two axes can be used in any combination
- High-resolution rotation angle and travel measurement
- Operation with standard PC or laptop (no additional interface card required) and testXpert III testing software
- Optional CE-compliant safety device for use with hazardous specimens and / or higher rotational speeds

Questions?