

4042 Determination of Opening Performance for Tip Cap/Needle Shield of Prefilled Syringes

This method consists of determination for pull-off force of the tip cap/needle shield and determination for Luer lock semi-rigid tip cap unscrewing torque of prefilled syringes

Method 1: Determination for pull-off force of the tip cap/needle shield

This method is used to determine the pull-off force of the unlocked tip cap/needle shield of a prefilled syringe.

Instruments

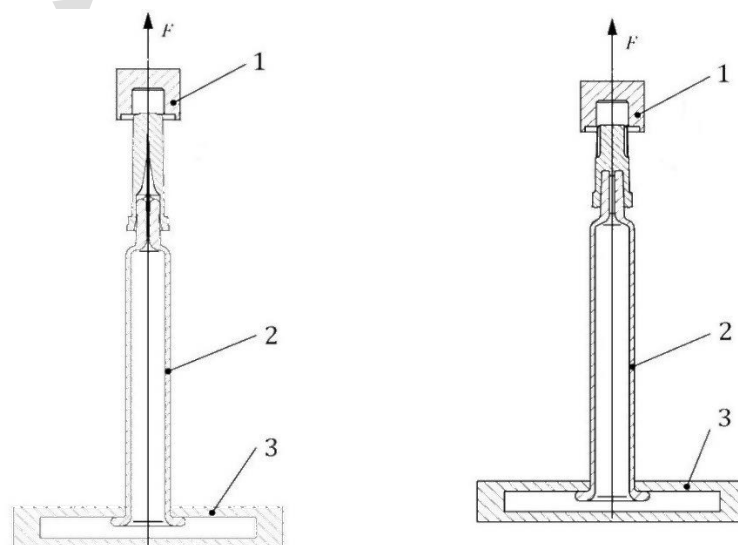
Tensile testing machine. The indicator error of the machine shall be within $\pm 1\%$ of the actual value.

Syringe holder/base plate. It is used to fix the flange of the syringe barrel, see Fig.1 and Fig.2.

Tip cap/needle shield gripper/pulling device. It is used to grip/pull the tip cap/needle shield, see Fig.1/Fig.2.

Determination

Position the test sample vertically with the tip cap/needle shield oriented upwards in the gripper (see Fig.1) or pulling device (see Fig.2) connected with the tensile testing machine. In Fig.1, apply the grip pressure such that the grip does not slide against or deform the tip cap/needle shield as far as possible. In Fig.2, the pulling device shall avoid applying force to the tip of the barrel. With the syringe unconstrained, set the load cell to "zero". Position the syringe holder/base plate such that the syringe will be captured by the holder/base plate when an axial tension force is applied. Set the test rate 100mm/min or as appropriate, record the force versus displacement. Stop the test once the tip cap/needle shield is completely removed from the syringe tip.

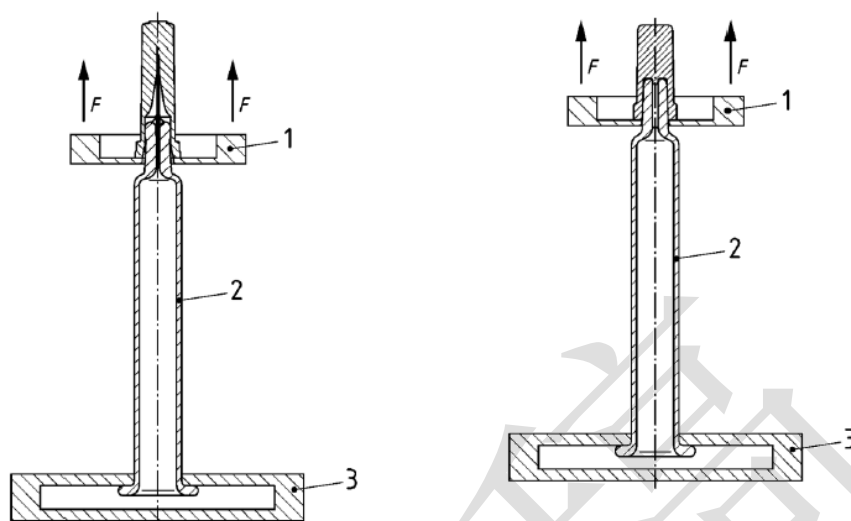


a. Syringe with needle shield

b. Syringe with tip cap

Fig.1 Example 1 of testing devices for the determination of the pull-off force of the tip

- 30 cap/needle shield
 31 1. gripper connected to the tensile testing machine; 2. syringe with tip cap/needle
 32 shield; 3. syringe holder/base plate



33
 34 a. Syringe with needle shield

b. Syringe with tip cap

35 Fig.2 Example 2 of testing devices for the determination of the pull-off force of the tip
 36 cap/needle shield

- 37 1. Pulling device connected to the tensile testing machine; 2. Syringe with tip
 38 cap/needle shield; 3. Syringe holder/base plate

39 Result representation

40 The test result takes the maximum load recorded in the force versus displacement
 41 curve as the tip cap/needle shield pull-off force.

42 Method 2: Determination of Luer lock semi-rigid tip cap unscrewing torque

43 This method is used to determine the Luer lock semi-rigid tip cap unscrewing
 44 torque of a prefilled syringe.

45 Instruments

46 Torque tester combined with a rotation device; the indicator error of the machine
 47 shall be within $\pm 5\%$ of the actual value; rotation speed is 20r/min or as appropriate.

48 Note: For this test, either the syringe barrel or the closure can be rotated.

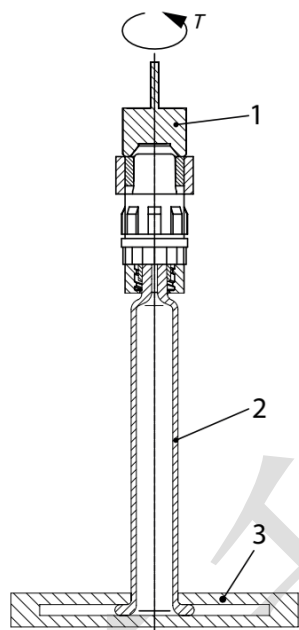
49 Gripper, which is used to grip the tip cap.

50 Syringe holder, rotatable, if this alternative is used.

51 Determination

52 Insert the test sample vertically positioned into the syringe holder of the testing
 53 device, see Fig.1. Mount the adapter such to grip the tip cap. Set the torque cell to
 54 "zero". No significant pre-torque shall be applied. Set the rotation speed at 20r/min or

55 as appropriate. Start the test by rotating the tip cap by 90° (or with a rotation angle as
56 appropriate depending on system) in the direction of unscrewing. Record the peak of
57 the applied torque.



58
59 Fig.1 Example of testing device for the determination of the Luer lock semi-rigid tip
60 cap unscrewing torque
61 1. gripper inclusive torque sensor(rotatable); 2. syringe with tip cap; 3. syringe
62 holder/base plate

63 **Result representation**

64 Record the maximum torque peak. This corresponds to the torque where the tip
65 cap starts to rotate on the syringe.

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