

## 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

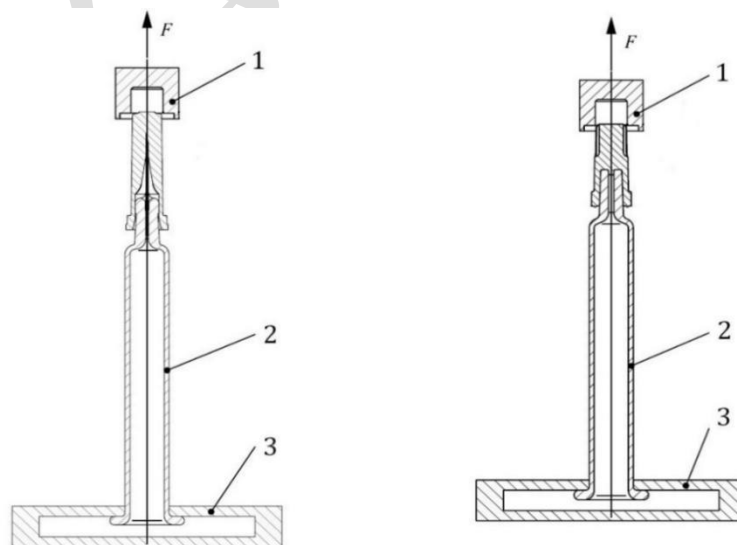
Tensile testing machine or other testing machines that met the requirement of this test. The indicator error of the machine shall be within  $\pm 1\%$  of the actual value.

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

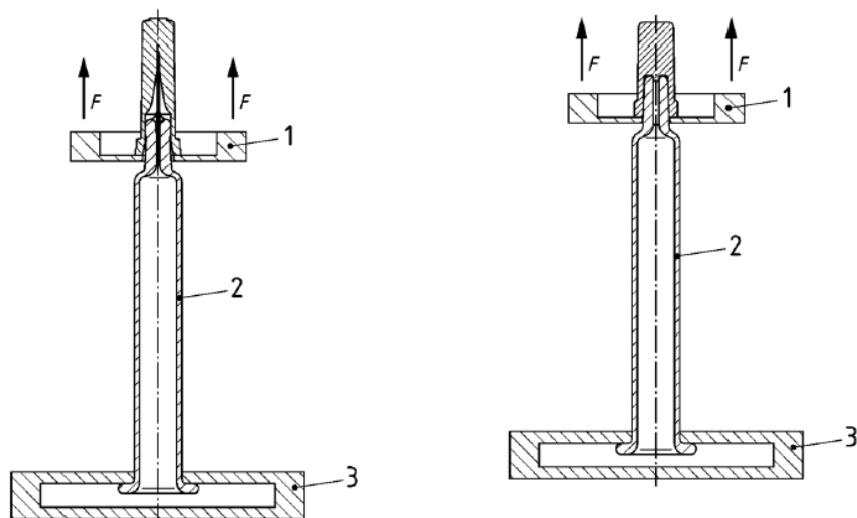
Position the test sample vertically with the tip cap/needle shield oriented upwards in the gripper(see Fig. 1) or pulling device(see Fig. 2) connected with the tensile testing machine. In Fig. 1, apply the grip pressure such that the grip does not slide against or deform the tip cap/needle shield as 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

- 26 Fig. 1 Example 1 of testing devices for the determination of the pull-off force of the tip  
 27 cap/needle shield  
 28 1. gripper connected to the tensile testing machine; 2. syringe with tip cap/needle shield; 3. syringe  
 29 holder/base plate



30

a. Syringe with needle shield

b. Syringe with tip cap

31

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

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

### 36 Result representation

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

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

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

#### 42 Instruments

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

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

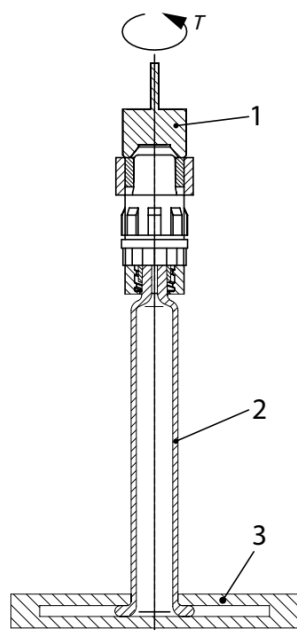
46 Gripper, which is used to grip the tip cap.

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

#### 48 Determination

49 Insert the test sample vertically positioned into the syringe holder of the testing device, see  
 50 Fig. 3. Mount the adapter such to grip the tip cap. Set the torque cell to "zero". No significant  
 51 pre-torque shall be applied. Set the rotation speed at 20r/min or as appropriate. Start the test by  
 52 rotating the tip cap by  $90^\circ$  (or with a rotation angle as appropriate depending on system) in the

53 direction of unscrewing. Record the peak of the applied torque.



54  
55 Fig. 3 Example of testing device for the determination of the Luer lock semi-rigid tip cap  
56 unscrewing torque

57 1. gripper inclusive torque sensor(rotatable); 2. syringe with tip cap; 3. syringe holder/base plate

#### 58 **Result representation**

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

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