

4043 Determination of **Bond** Performance for Luer Lock Adaptor Collar of Prefilled Syringes

This method consists of determination for Luer lock adaptor collar torque resistance and determination for pull-off force of Luer lock adaptor collar of prefilled syringes

Method 1: Determination for Luer lock adaptor collar torque resistance

This method is used to determine the torque resistance of Luer lock adaptor collar of prefilled syringes.

Instruments

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

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

Gripper, which is used to grip the Luer lock adaptor collar.

Syringe holder, rotatable, if this alternative is used.

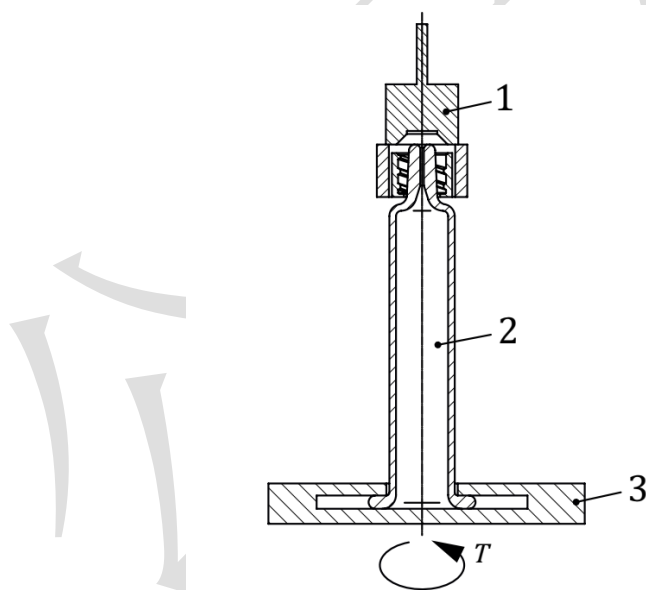


Fig. 1 Example of testing device for the determination of the Luer lock adapter collar torque resistance

1. Luer lock adaptor collar gripper inclusive torque sensor;
2. syringe with Luer lock adaptor;
3. syringe holder/base plate (rotatable)

Determination

Insert the test sample vertically positioned into the syringe holder of the testing device, see Fig. 1. Remove the tip cap. Mount the gripper onto the Luer lock adaptor collar. Set the torque cell

22 to "zero". No significant pre-torque shall be applied. Set the rotation speed at 20r/min or as
23 appropriate. Start the test by rotating the Luer lock adaptor collar by 90° clockwise or counter
24 clockwise (with a rotation angle as appropriate depending on system) . Record the peak of the
25 applied torque.

26 **Result representation**

27 Record the maximum torque peak. This corresponds to the torque where the Luer lock
28 adaptor collar starts to rotate on the syringe.

29 **Method 2: Determination for Luer lock adaptor collar pull-off force**

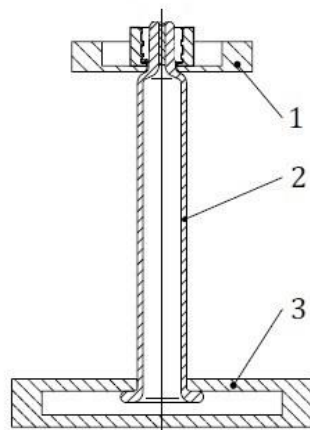
30 This method is used to determine the pull-off force of Luer lock adaptor collar of prefilled
31 syringes.

32 **Instruments**

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

35 Syringe holder/base plate, which is used to fix the flange of the syringe barrel, see Fig. 2.

36 Pulling device, which is used to pull the Luer lock adaptor collar, see Fig. 2.



37

38 Fig. 2 Example of a testing device for the determination of the Luer lock adapter collar pull-off
39 force

40 1. pulling device connected with the tensile testing machine; 2. syringe with Luer lock adapter
41 collar; 3. syringe holder/base plate

42 **Determination**

43 Remove the tip cap. Position the test sample vertically with the Luer lock adapter collar
44 oriented upwards in the pulling device connected with the tensile testing machine . Position the

45 syringe flange into the holder/base plate. The syringe holder/base plate shall avoid applying force
46 to the flange of the barrel such that the syringe will be captured by the holder/base. Set the load
47 cell to “zero”. Set the test rate 20mm/min or as appropriate, start the test. Record the force versus
48 displacement. Stop the test once the Luer lock adaptor collar system is clearly removed from the
49 syringe tip.

50 **Result representation**

51 The test result takes the peak load recorded in the force versus displacement curve as the
52 Luer lock adaptor collar pull-off force.

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