

4043 Determination of 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.

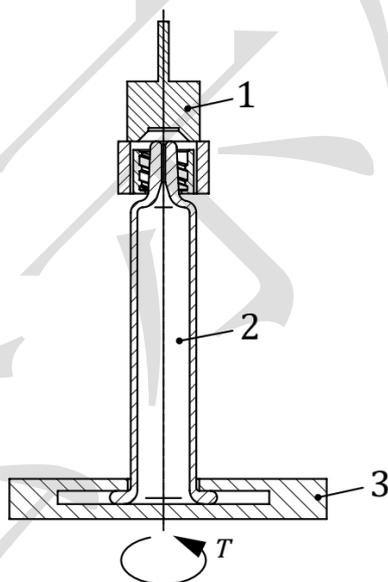


Fig.1 Example of testing device for the determination of the Luer lock adapter collar torque resistance

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 to “zero”. No significant pre-torque shall be applied. Set the rotation speed at 20r/min or as appropriate. Start the test by rotating the Luer lock adaptor collar by 90° clockwise or counter clockwise (with a rotation angle as

26 appropriate depending on system). Record the peak of the applied torque.

27 **Result representation**

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

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

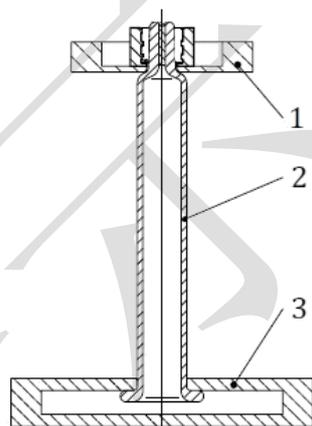
31 This method is used to determine the pull-off force of Luer lock adaptor collar of
32 prefilled syringes.

33 **Instruments**

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

36 Syringe holder/base plate, which is used to fix the flange of the syringe barrel,
37 see Fig.1.

38 Pulling device, which is used to pull the Luer lock adaptor collar, see Fig.1.



39

40 Fig.1 Example of a testing device for the determination of the Luer lock adapter collar
41 pull-off force

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

44 **Determination**

45 Remove the tip cap. Position the test sample vertically with the Luer lock adapter
46 collar oriented upwards in the pulling device connected with the tensile testing
47 machine. Position the syringe flange into the holder/base plate. The syringe
48 holder/base plate shall avoid applying force to the flange of the barrel such that the
49 syringe will be captured by the holder/base. Set the load cell to “zero”. Set the test
50 rate 20mm/min or as appropriate, start the test. Record the force versus displacement.
51 Stop the test once the Luer lock adapter collar system is clearly removed from the
52 syringe tip.

53 **Result representation**

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

起草单位：山东省医疗器械和药品包装检验研究院

联系电话：0531-82682915

参与单位：江苏省医疗器械检验所、山东威高普瑞医药包装有限公司、山东省药用玻璃有限公司、宁波正力药品包装有限公司、山东永聚医药科技有限公司、肖特玻璃科技（苏州）有限公司、碧迪医疗器械（上海）有限公司

威高集团