

Evaluation of the tightness of a Closed System Needleless Connector - QIMONO® (Vygon)

Marie-Laure VIGNES, Hervé REMY, Amélie GAUDIN,
Gustave Roussy, Département de Pharmacie Clinique, 114, rue Édouard Vaillant - 94805 Villejuif Cedex - France

Preparation



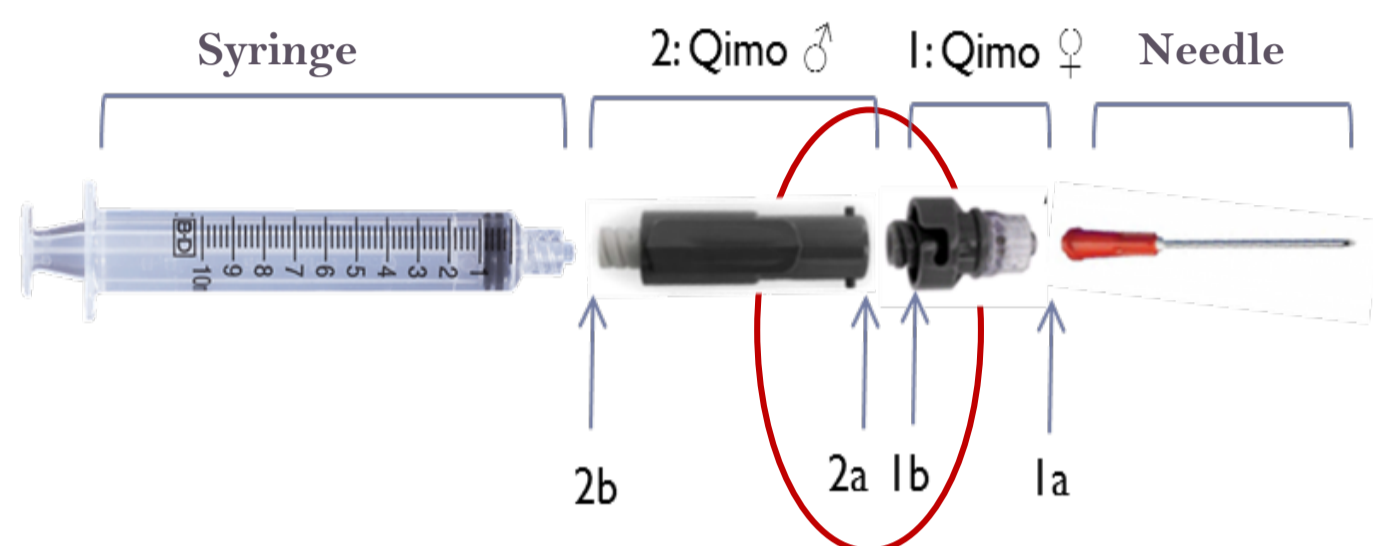
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INTRODUCTION

QIMONO® system (Vygon) is a Medical Device (MD) offering a safe connection featuring a closed system for preparation and administration of hazardous drugs through syringes. In the perspective of using this MD in our Hematology Dept, we decided to evaluate its tightness properties.

MATERIAL AND METHODS



Empty syringe + Qimo ♀
+ Qimo ♂ + needle



Remove needle

- Needle alone
- Empty syringe + Qimo ♀ + Qimo ♂



Part 1:
Qimo ♀

- Sampling → 1a & 1b
- Qimo ♀
- Empty syringe + Qimo ♂



Part 2:
Qimo ♂

- Sampling → 2a & 2b
- Qimo ♂
- Empty syringe

QIMONO® is made of 2 components:

- Qimo Male ♂, safety connector directly attached to the chemotherapy syringe
- Qimo Female ♀, multipurpose connector, attached to the perfusion line of the electric syringe pump

Tightness indicators :

- Radioactivity; quantitative technique, with ^{99m}Tc (E= 140KeV, T_{1/2} = 6h) ; Activity= 200 MBq, V = 5mL ; considered as 100%.
- Azorubicine, qualitative technique, as coloured visual indicator.

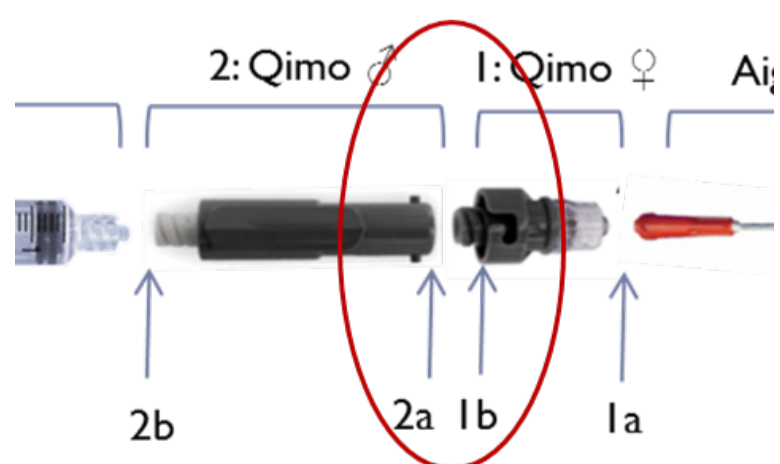
The Tightness test has been performed from a standardized preparation: a 5mL syringe with 200MBq of ^{99m}Tc with a final volume of 5mL azorubicine. QIMONO® (♂ and ♀) has been connected to the syringe then the solution has been injected in an empty vial.

The tightness properties of the connection has been tested by swabbing the external membranes of both Qimo ♂ and Qimo ♀. The activity for each phase of this preparation has also been measured.

The measurement of the activity must be 2 times higher than the one of the background noise to prove the presence of radioactivity.

RESULTS

34 QIMONO systems have been tested. We report the main measurements in group 2a and 1b in the table below :



| | 2a | 1b |
|-----------------------------|------------------------|-------|
| Measured Activity (MBq) | 0,066 | 0,085 |
| Activity (%) | 0,021 | 0,026 |
| Azorubicine identified | NO | NO |
| Background noise (MBq)/ (%) | 0,101 MBq i.e. 0,035 % | |

CONCLUSION

QIMONO® membranes seem tight since absolute activity values are not superior to two times those of the background noise : Qimo ♂:0,066<0,101MBq, Qimo ♀:0,085<0,101 MBq and activity percentages are low, respectively 0.021% et 0.026%, vs used initial activity 200Mbq (100%).

This simple, fast and reproducible method gave us the opportunity to evaluate the tightness properties of this MD.