ONCOLOGY

Safety Huber needle

qimo**flow** +

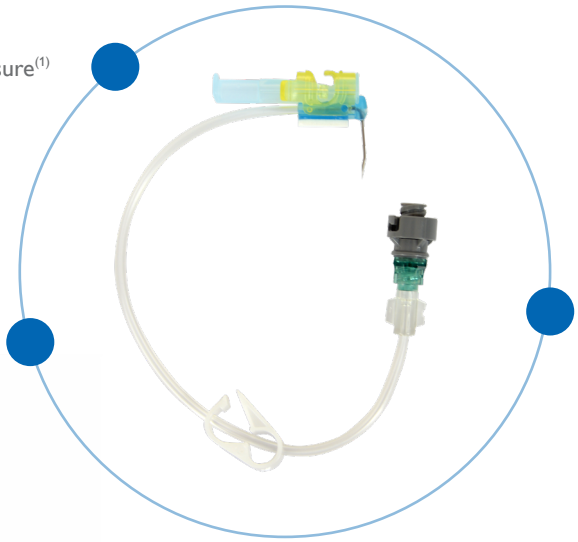
For a safe solution from
"Administration to Withdrawal"

VYGON

Value Life

Safety vs Needle Stick Injury and Catheter Occlusion

Automatic Positive Pressure[1]



A single handed activation needle

Closed system Qimo female

Prevention of needlestick injuries

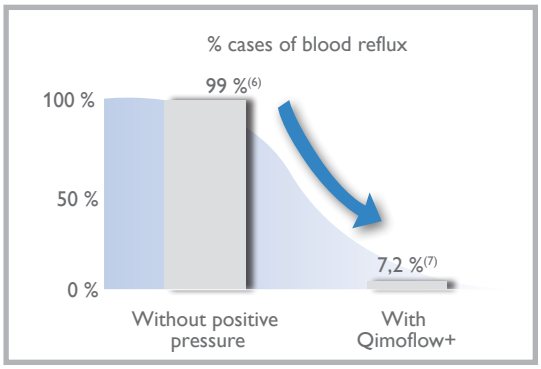
→ Risk reduction from needlestick injury as compared to a two-hands activation system.[2]

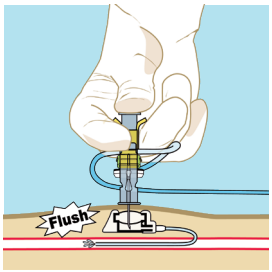
Implantable port	Puncture rate for 10 safety huber needles[7]	95% CI
Two-hands activation	16,13	[6,13 - 26,12]
Single-hand activation	0	-

No contact with the shaft & the tip of the needle

Prevention of catheter occlusion

→ Qimoflow+ significantly reduces catheter occlusion from blood reflux[3][4][5]



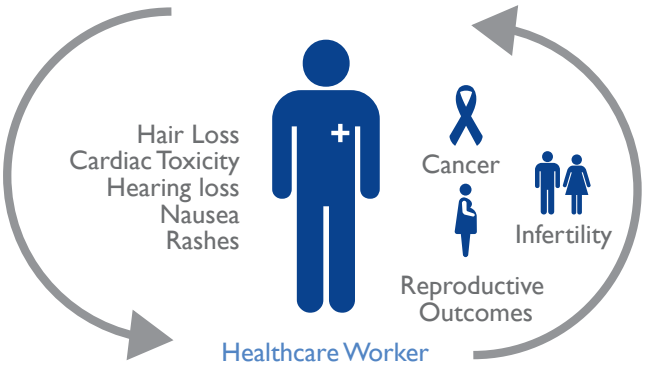


Safety vs Hazardous Drugs

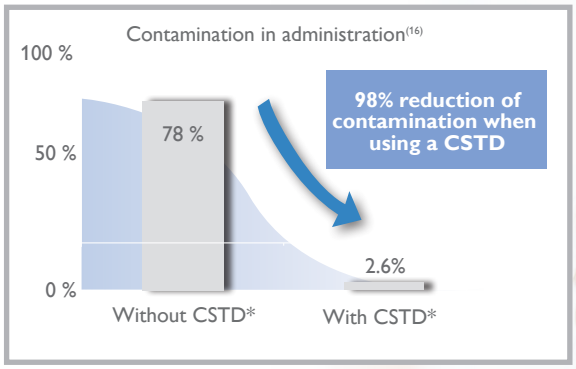
Why using Qimono?

- Tight at disconnection[8] and reduction of contamination risk during administration of Hazardous Drugs[9]
- Prievents Microbial Ingress during 7 days[10]
- Compatible with Hazardous Drugs[11]

Administration of Hazardous Drugs : what are the risks?



Adverse events from occupational exposure to hazardous drugs[12][13][14][15]



Why using a CSTD?*

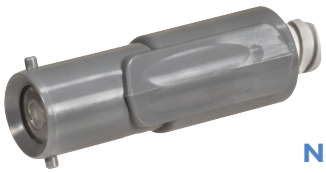
- NIOSH, GERPAC, USP800 and Directive (EU) 2019/130 of the European Parliament and of the Council of January, 16th, 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, recommend the use of Closed System to protect healthcare workers[17][18][19][20]

Qimono Solution

- **Qimo female et Qimo male form a Closed System Transfer Device (CSTD) for the safe admnistration of Hazardous Drugs**

qimo♀

Universal Luer fits with any Male Luer-Lock : syringe, extension tube, or IV infusion line



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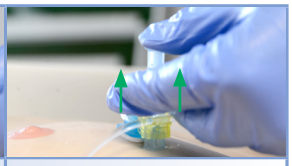
Non-disconnectable Male connector to safely secure IV Line or Syringe

*Closed System Transfer Device

Withdrawal steps

				
Safety disconnection	Normal use position (horizontal piston). Perform a pulsated flush with saline.	Lift the piston from the horizontal position to the vertical position (perpendicular to the patient skin).	Insert the tubing into the notch and pull it downwards.	Place the hand remo-ving the needle on the opposite side of the blue platform. Put your thumb on the pis ton, your forefinger and middle finger under the winglets (on both side of the piston). Pull up the extractor until hearing a « click ».The needle is now with-drawn safely.

Gauge	Ø needle (mm)	Length	Code
22G	0.7	15mm	741507*
		17mm	741707
		20mm	742007
		25mm	742507
		30mm	743007
		35mm	743507
20G	0.9	15mm	741509*
		17mm	741709
		20mm	742009
		25mm	742509
		30mm	743009
		35mm	743509
19G	1.1	15mm	741511*
		17mm	741711
		20mm	742011
		25mm	742511
		30mm	743011
		35mm	743511

Qimoflow+ huber needles are packaged in box of 12 units. Sterilized using ethylene oxide.
*Restricted to paediatric use.

(1) As recommended HAS(Haute Autorité de Santé - France). December 2000.
(2) Survey of the occurrence circumstances of Accidental Blood Exposure due to punctures with safety materials, GERES – AFSSAPS Collaboration, G. Pellissier, 18th Annual GERES conference, 2008.
(3) Prevention of infections associated with venous access implantable ports, SF2H, March 2012.
(4) Carlo JT et al., The American Journal of Surgery 188;722-727, 2004
(5) Milani A. et al. Incidence and Determinants of Port Occlusions in Cancer Outpatients: A Prospective Cohort Study. Cancer Nursing. March 2017
(6) Lapalu J et al., Totaly Implantable Port Management: Impact of positive pressure during needle withdrawal on catheter tip occlusion (An experimental study), The Journal of Vascular Access 2010; 11: 46-51
(7) Levert et al. , A randomized experimental comparison of two safety Huber needles (HN) allowing manual or automatic positive pressure during needle removal: effect on the distal catheter reflux. WoCova congress 2014
(8) Gustave Roussy Institute – Poster Europharmat 2017
(9) Safe disconnection of Elastomeric Pumps. H.Levert et al. Hôpital Saint-Louis. GIFAV January 2019
(10) Microbial Ingress Testing, NAMSA 2018
(11) Graham Sewell : Compatibility of Qimono connectors with cytotoxic drugs 2018
(12)Falck, Lancet 1st evidence of mutagenic activity in nurses administrating chemotherapy. 1979,
(13) Sessink 1999, Drugs Safety Hazardous drugs to Healthcare Workers
(14) Connor et al 2010, JOEM- Evaluation of Antineoplastic Drug exposure of Healthcare workers at 3 University Based US Cancer Centres
(15) Lancharro 2016, Evidence of exposure to cytostatic drugs in healthcare staff: A review of recent literature
(16) Bartel AM J Health-Syst Pharm Vol 75 2018
(17) Professional exposure to Antineoplastic drugs and other dangerous medicines in healthcare centers. September 2004
(18) GERPAC "Preparation & Administration of Hazardous Drugs, at risk for heathcare workers & for the environement", July 2007
(19) USP 800 "Hazardous Drugs handling in healthcare centers", December 2017
(20) Directive (EU) Directive (EU) 2019/130 of the European Parliament and of the Council of January, 16th, 2019

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Qimoflow+ is class IIa medical device, compliant with directive 93/42CEE, and appendix V & VII. Certification established by GMED notified body N°0459. Manufactured by Perouse Medical. Please read carefully Instruction For Use.

INTRAVASCULAR THERAPIES

For further information, please contact: marketingbenelux@vygon.com

The specifications shown in this leaflet are for information only and are not, under any circumstances, of a contractual nature.

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