VYGON
Value Life

OBJECT : COMMUNICATION LETTER ABOUT MULTICATH HIGH PRESSURE TESTING

Dear Customers,

We are pleased to share the results of recent dynamic and static pressure testing carried out on some of our Multicath (please find the references at the end of this communication), central venous catheters (CVCs) in collaboration with St George's University Hospitals NHS Foundation Trust. These tests were conducted to ensure that the distal lumen of theses references are fully compatible with the high-pressure power injection procedures required for modern radiology practice, including CT angiography and multiphase imaging.

Testing Methodology and Clinical Relevance

- Dynamic Testing: Conducted at a flow rate of 6 ml/sec (via the distal lumen) using the CT motion power injector system employed across St George's radiology departments.
- Static Testing ISO 10555-1: Pressure hold tests of the distal lumen with no flow, designed to identify the maximum pressure tolerance before catheter failure.
- Contrast Media: Both Omnipaque 350 (20.3 cP viscosity) and Omnipaque 300 (10.3 cP viscosity) were used at a room temperature of 24 °C, reflecting the typical clinical environment. Warming of contrast media, standard practice in many radiology departments, further reduces viscosity, ensuring safer injection profiles.
- Oversight: All tests were performed sequentially with direct support from the Neuroradiology team and oversight by the Trust's Medical Device Safety Officer. This ensures rigorous governance and alignment with NHS clinical standards.

Key Findings

- Dynamic Testing: No rupture, distortion, or bloating of the catheters was observed, even under high flow rates and typical clinical contrast viscosity. Maximum dynamic pressures reached up to 253.8 psi.
- Static Testing: All tested catheters withstood pressures greater than 300 psi.
- Compatibility Confirmation: These results confirm the Multicath CVC tested are suitable for high-pressure power injection, consistent with or exceeding the performance of other CVC manufacturers.

RECEPTION
Tel: 01.39.92.63.63
Fax: 01.39.92.64.44
questions@vygon.com

CUSTOMER SERVICE FRANCE
Tel: 01.39.92.63.81
Fax: 01.39.90.29.37
E-mail: commandes@vygon.com

CUSTOMER SERVICE EXPORT
Tel: 01.39.92.64.17
Fax: 01.34.29.19.34
E-mail: export@vygon.com

ACCOUNTING DEPARTMENT
Customers: Tel: 01.39.92.63.36
Suppliers: Tel: 01.39.92.65.20
Fax: 01.39.92.64.44
E-mail: comptaclients@vygon.com
comptafournisseur@vygon.com

POSTAL ADDRESS
8 rue de Paris 95440 Ecouen - France

HEADQUARTER
5 rue Adeline 95440 Ecouen - France

Société par Actions Simplifiée au capital de 19 463 088 €
RCS PONTOISE 325 241 750

www.vygon.com

Additional Points of Assurance

- The testing was designed to reflect real-world clinical scenarios and standard NHS practice, using the same equipment and processes employed for patient care.
- The absence of any observed rupture or mechanical deformation during dynamic testing, even in repeated testing cycles, strongly confirms the mechanical integrity of the Multicath tested under high-pressure injection scenarios via the distal lumen.
- The collaboration with the Neuroradiology team and the Trust's Medical Device Safety Officer ensures confidence in both technical and governance aspects of this validation.
- Warning: Any in situ catheter should be thoroughly checked for patency by adequate blood return and flush of the distal lumen used for injection. Never proceed to the injection via a partially or completely obstructed lumen.

Conclusion

Based on the comprehensive testing completed in collaboration with St George's University Hospitals NHS Foundation Trust, we are confident that the Multicath Expert and Multicath HF tested meet the highest standards for safety and reliability in power injection procedures. The results provide assurance that these lines are suitable for clinical use in radiology settings requiring high-pressure contrast administration.

Should you require further data, detailed test logs, or direct technical discussion, please do not hesitate to contact us.

Kind regards,

Aurélie Martino-Gauchi
International Marketing Director
Hemodynamic Management

MULTICATH REFERENCES TESTED :

Code	Description	Batch
8158.052	4 lumens 12.5 cm	150724GN
8158.152	4 lumens 16 cm	040225GN
8158.252	4 lumens 20 cm	191224GN
159.912	5 lumens 12.5 cm HF	270125GG
159.916	5 lumens 16 cm HF	070225GH
159.920	5 lumens 20 cm HF	051124GG