Static Human Blood Clot Tests

(Midline Catheters)

Comparing the Hydromer 2018-20M and Hydromer EF50L coatings to an uncoated Midline catheter.

Presented by Martin von Dyck

(Executive VP-Hydromer)

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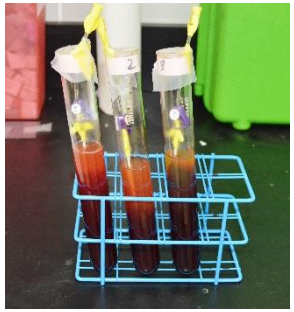


"STATIC HUMAN BLOOD CLOT TEST"

- **OBJECTIVE**: The objective of this test is to compare the gross thrombo-resistivity of a Midline (made using using 95A Tecothane®) catheters when soaking in re-calcified citrated human blood.
- After 5 hours soaking in the blood at 37°C the catheters will be gently rinsed in PBS and photographed.
- This test will provide a gross indication of how the respective catheters and coatings should perform in the more detailed testing to follow.

"STATIC HUMAN BLOOD CLOT TEST" Protocol

- Midline catheters were coated with Hydromer 2018-20M and Hydromer EF50L as per Hydromer's coating procedures.

- A Crystal Violet stain test will confirmed the presence and uniformity of the Hydromer coatings.

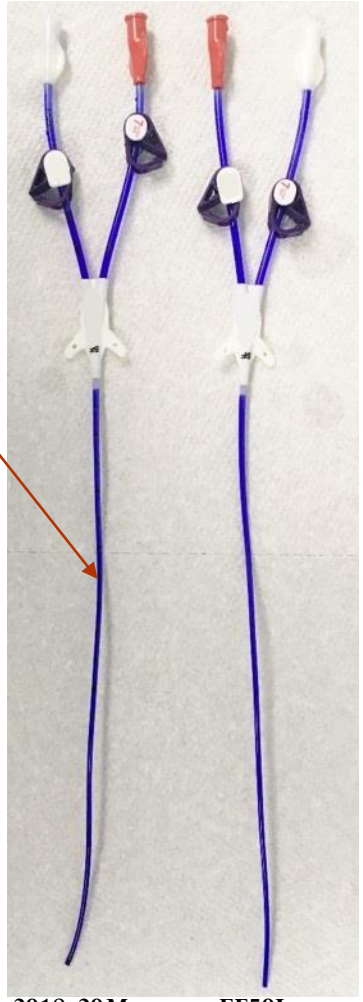
- *All* catheter samples (uncoated or coated) will be incubated in re-calcified citrated human whole blood for 5 hours @ 37^0C and then gently rinsed with PBS and photographed.

- *Blood Source*: Human Unspun Whole Blood with Sodium Citrate was drawn from a male on July 31, 2017. (4 days prior to testing.)

- *Blood Prep.:* Blood recalcification was performed by Hydromer R&D using 200ml Citrated Whole Human Blood and adding 0.92ml of $CaCl_2$ resulting in a 4 milliMolar final concentration. Complete clot formation was verified at 45min.

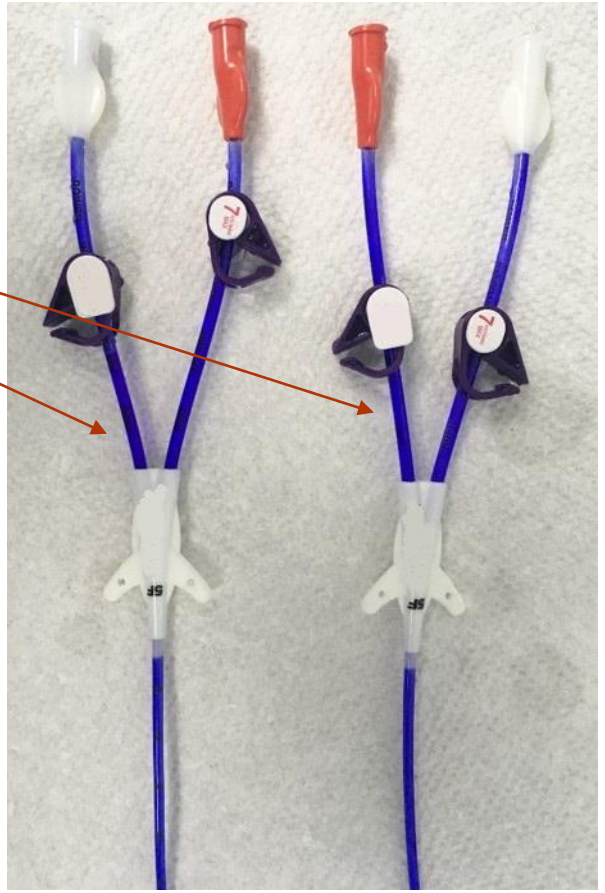
Hydromer coating “Crystal Violet stain test” to confirm coating uniformity.

Crystal Violet stain confirmed the presence of the coating distal from the suture junction.



2018-20M EF50L

Crystal Violet stain confirmed the presence of the coating in the lumens.



2018-20M EF50L

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Static Blood Clot Test set-up

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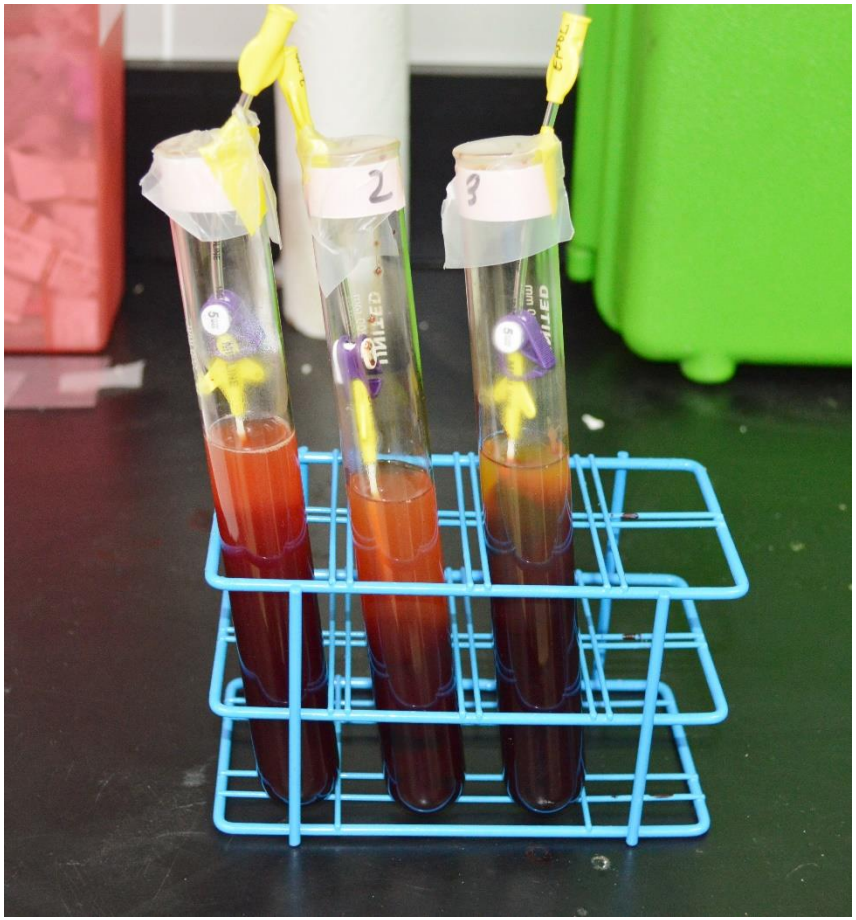
Sample tested
#1 Uncoated Control
#2 Hydromer 2018-20M
#3 Hydromer EF50L



Static Blood Clot Test set-up

Positive control verifying that the blood clotted before the 5 hour test limit. Actual clotting occurred at 45 minutes.

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Static Blood Clot Test
Uncoated Midline catheter

Catheters incubated in re-calcified citrated human whole blood.

(For 5 hours at 37^{0}C)

Uncoated Catheter was completely covered by clotted blood. Distal end of blood clot contracted during removal from glass test tube exposing the distal end of the Uncoated catheter.

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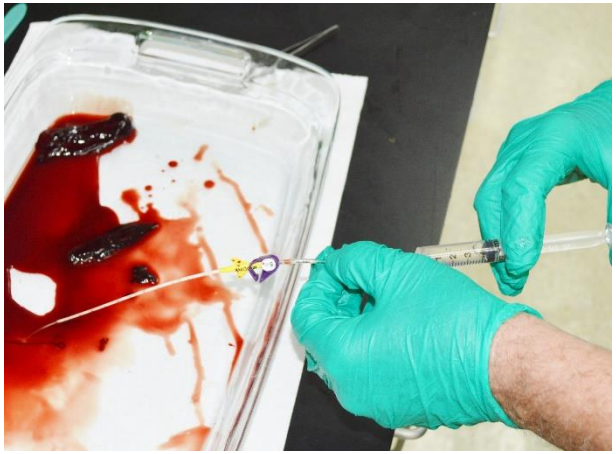
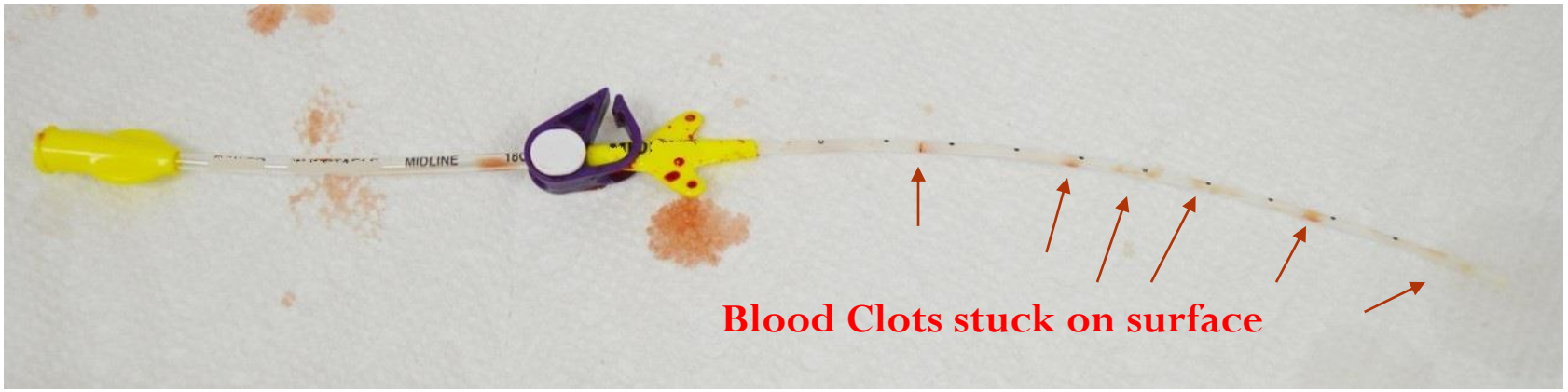
Static Blood Clot Test
Uncoated Midline catheter

Catheters incubated in re-calcified citrated human whole blood.
(For 5 hours at 37^{0}C)



Clot Sheath was physically removed from Uncoated Midline and flushed.



Static Blood Clot Test
Hydromer 2018-20M coated Midline catheter

Catheters incubated in re-calcified citrated human whole blood.
(For 5 hours at 37^{0}C)

The blood clot slipped off of the Hydromer coated catheter showing no residual clot bonds on the catheter.

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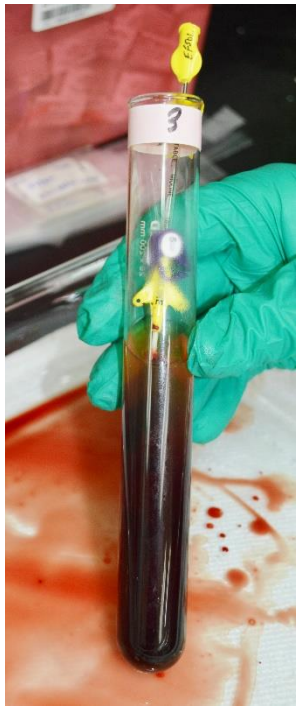
Lumens are clear!
Exterior is clear!

Static Blood Clot Test
Hydromer EF50L coated Midline catheter

Catheters incubated in re-calcified citrated human whole blood.
(For 5 hours at 37^{0}C)



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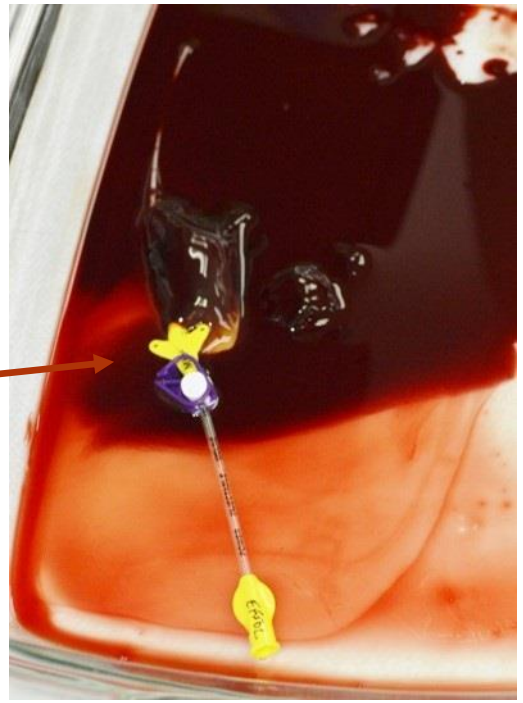
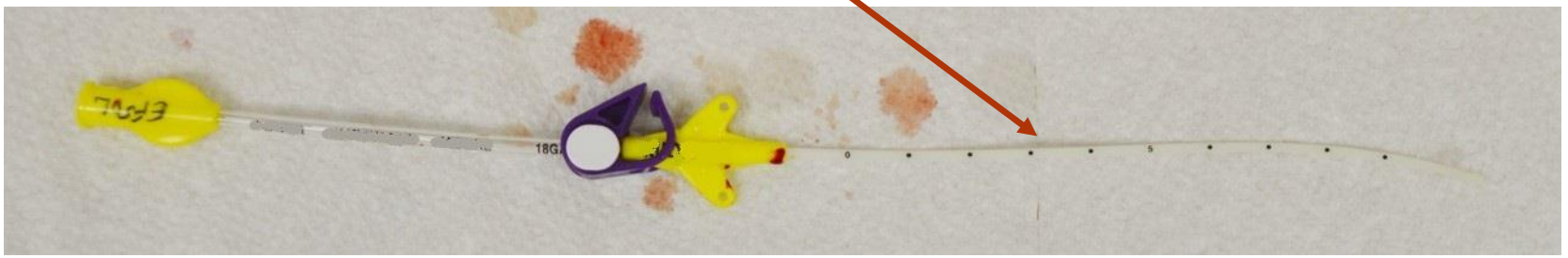
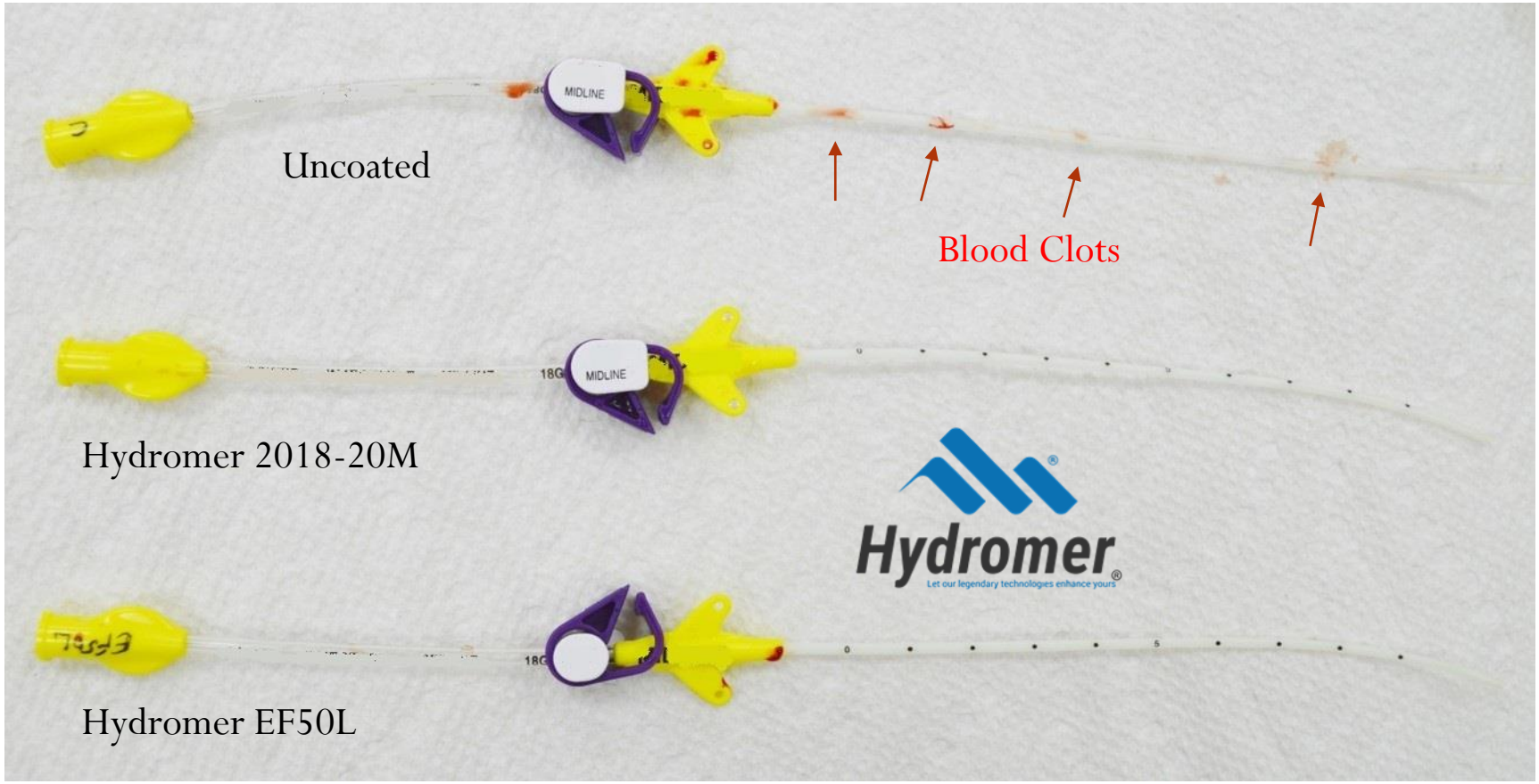




Catheters incubated in re-calcified citrated human whole blood.
(For 5 hours at 37^{0}C)



Conclusion

Based on this in-vitro laboratory Static Blood Clot Test, both of the Hydromer coating candidates, EF50L and 2018-20M, resisted blood clot adhesion on polyurethane Midline catheteres.