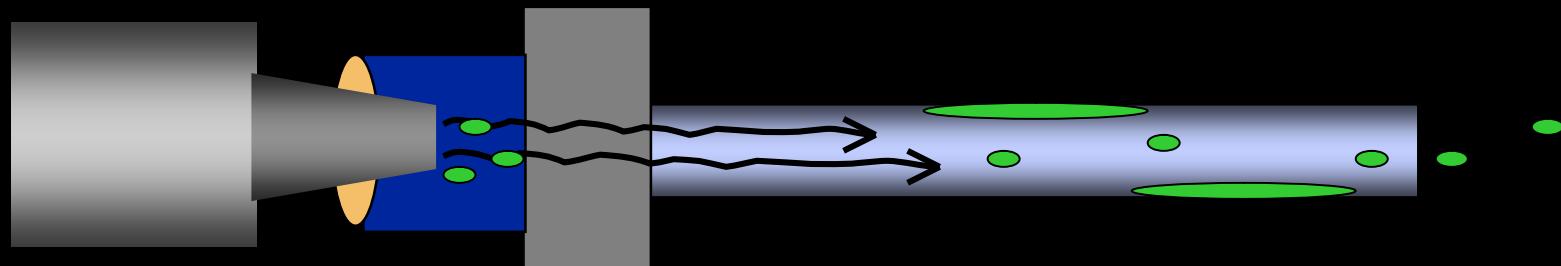


# NEEDLELESS DEVICES

---

....how device design effects  
the development of biofilm

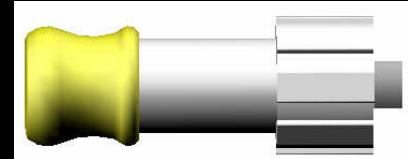
Marcia Ryder PhD MS RN



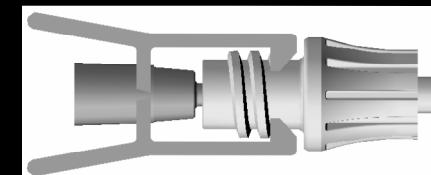
Sponsored by: ICU Medical Inc.

# NEEDLELESS CONNECTORS: EVOLUTION OF DESIGN ENGINEERING

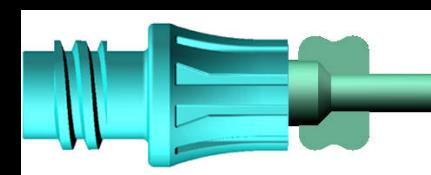
LATEX INJECTION PORTS  
NEEDLES



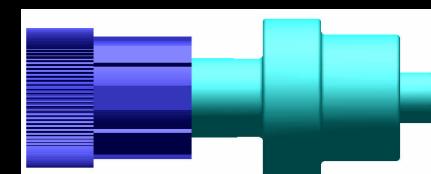
SHIELDED NEEDLE  
ADAPTERS



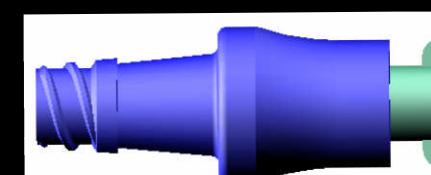
SPLIT SEPTUM  
BLUNT CANNULA



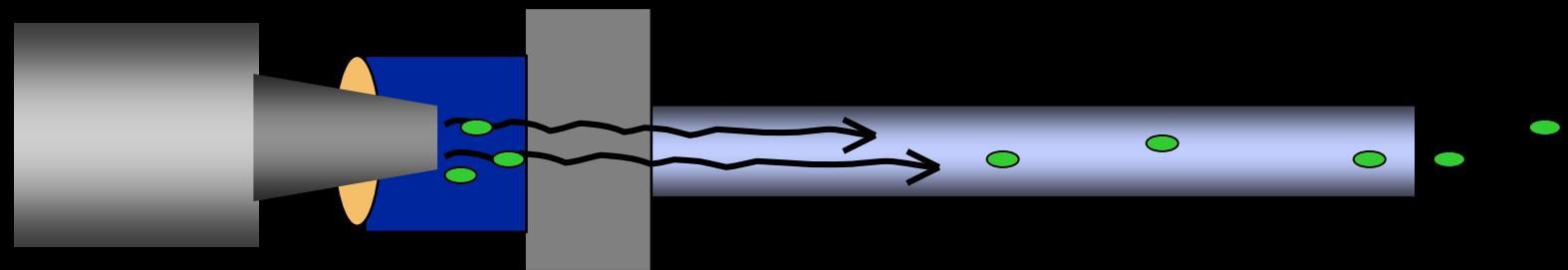
CAPPED LUER-ACTIVATED  
DEVICES



SWABBABLE LUER-  
ACTIVATED DEVICES



*....do needleless devices increase  
the risk of bloodstream infection?*



# PATHOGENESIS

PRESENCE OF BACTERIA  
AT PORTAL OF ENTRY



MICROBIAL ENTRY



MICROBIAL ATTACHMENT

*BIOFILM  
FORMATION*



COLONIZATION

*BIOFILM  
GROWTH  
AND MATURITY*

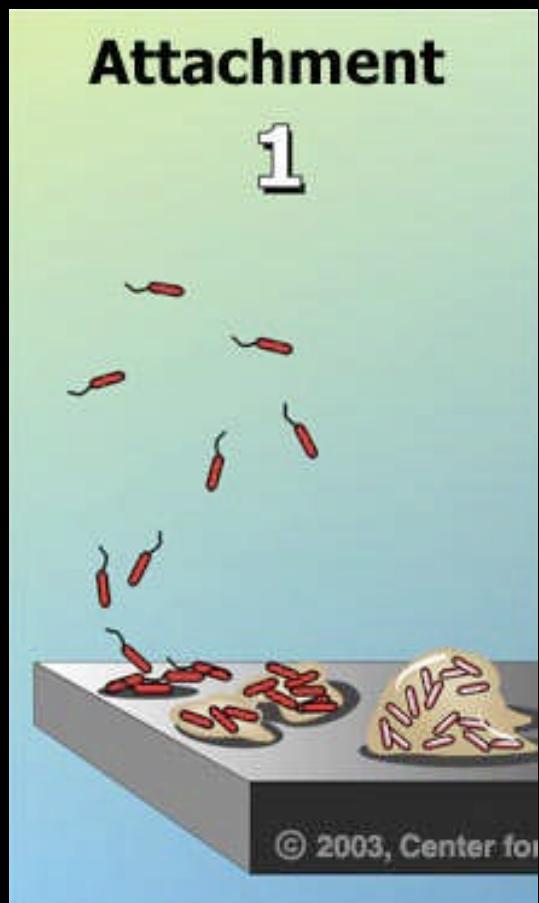


BLOODSTREAM INFECTION

*BIOFILM  
DISPERSAL*

# BIOFILM LIFE CYCLE

---

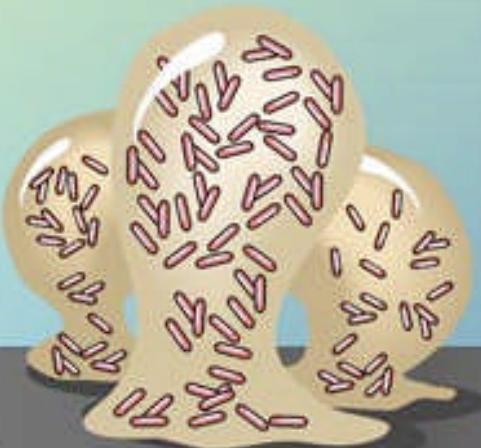


# BIOFILM LIFE CYCLE

---

Growth

2



Biofilm Engineering at MSU-Bozen

# BIOFILM LIFE CYCLE

## Detachment

days to months to years



# INFUSION/ASPIRATION

---

Fluid/Drug Infusion



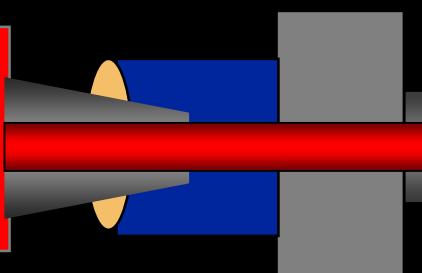
Parenteral nutrition

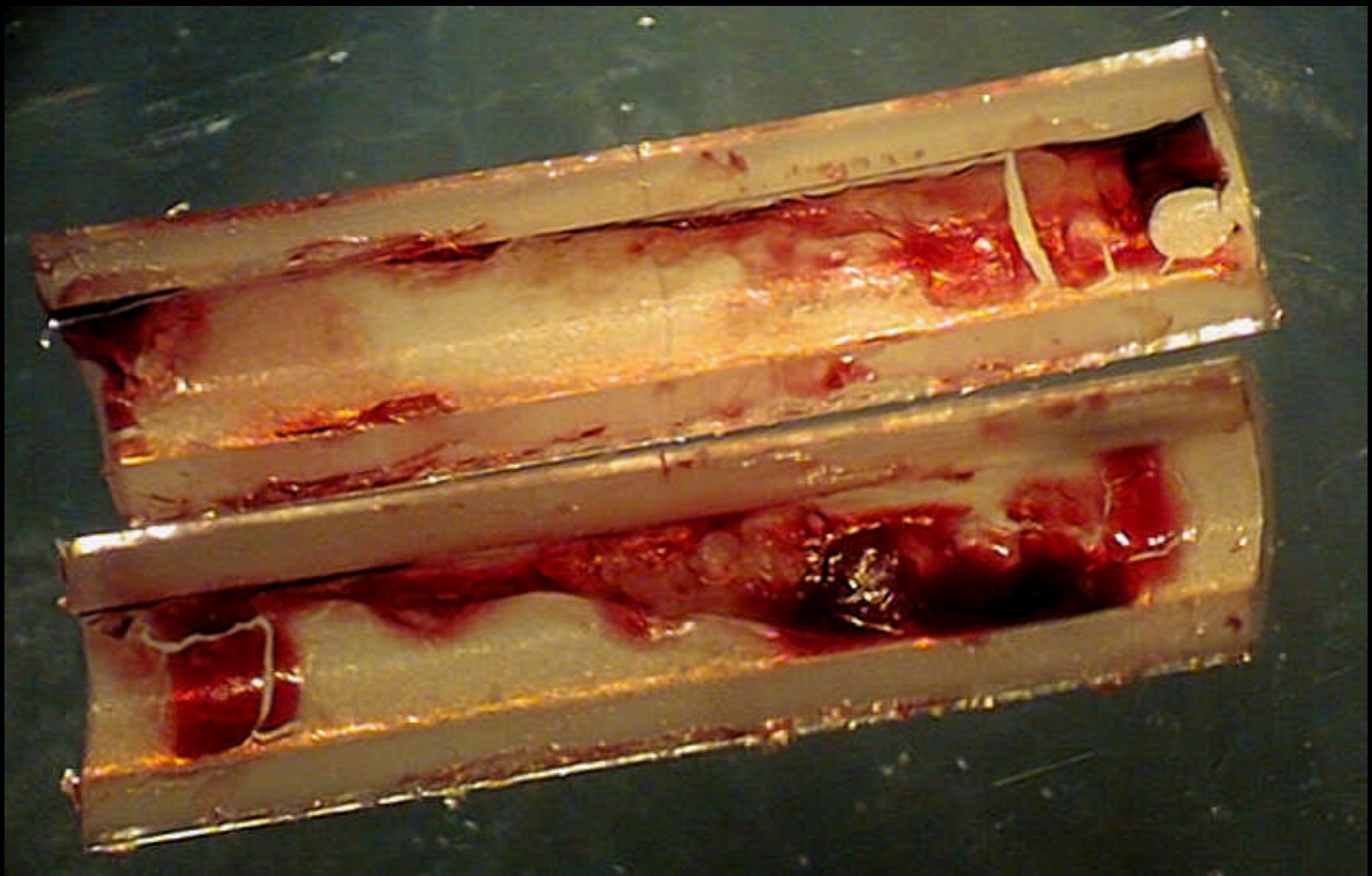


Blood / blood products

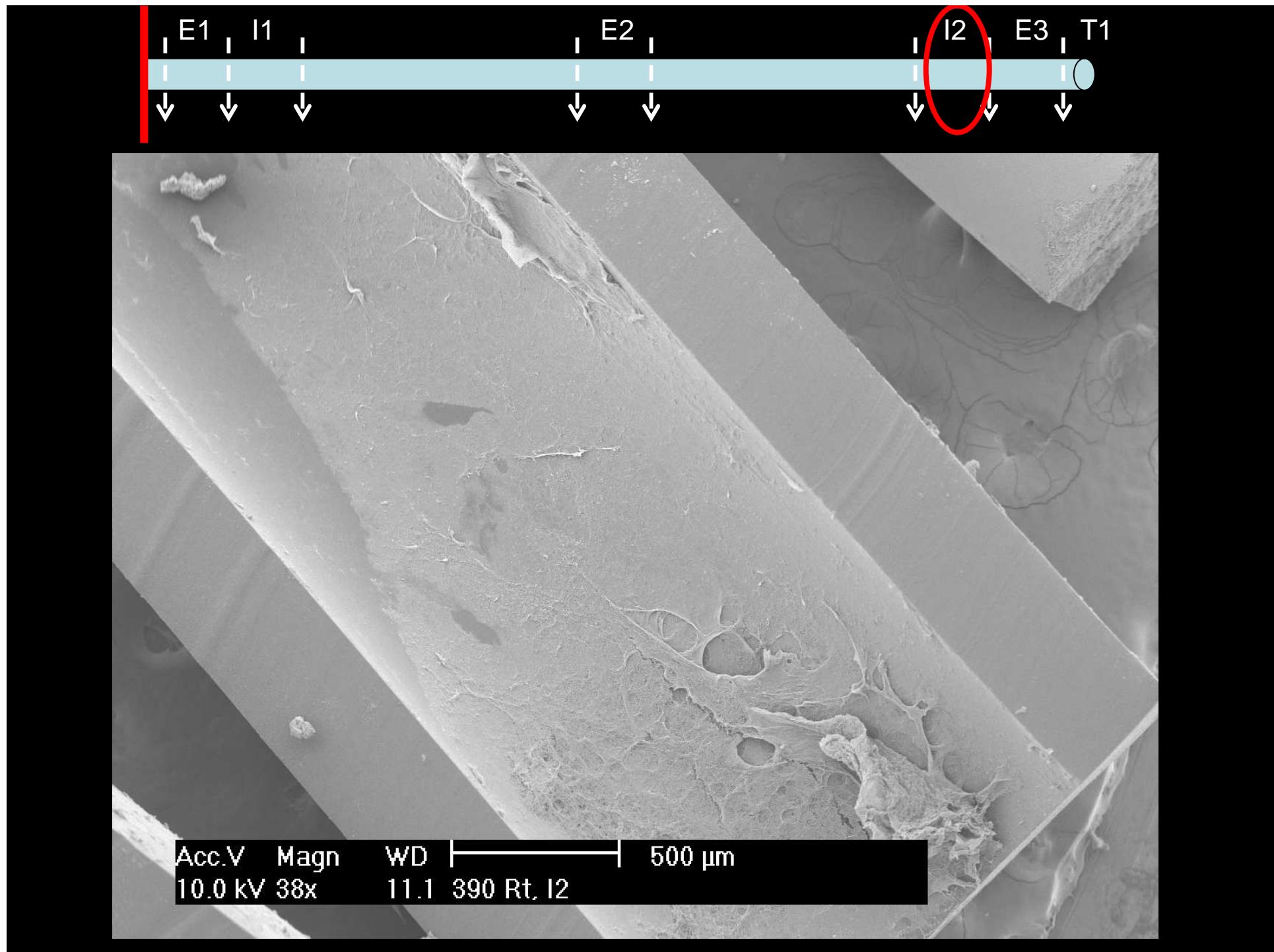


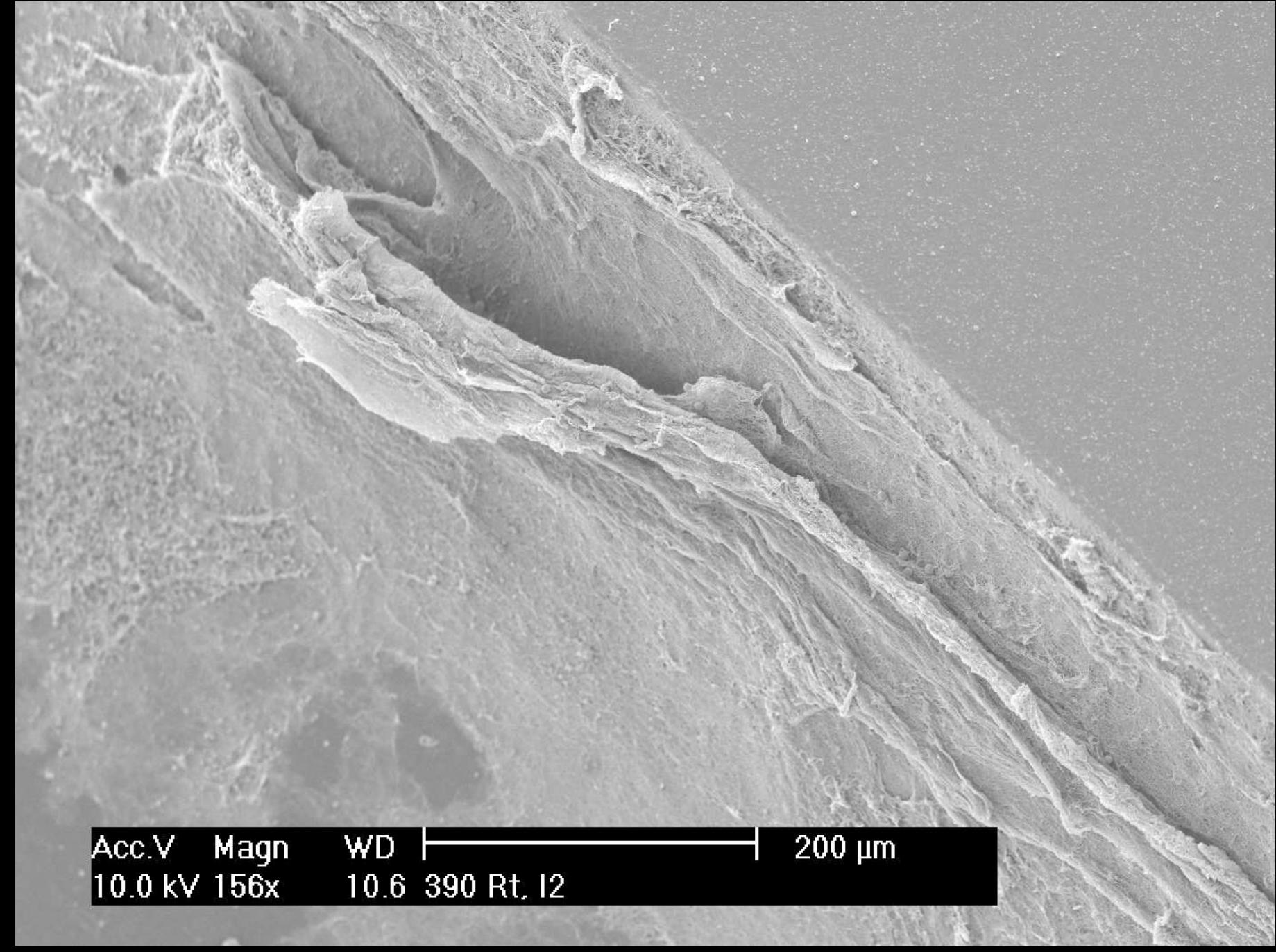
Blood draws



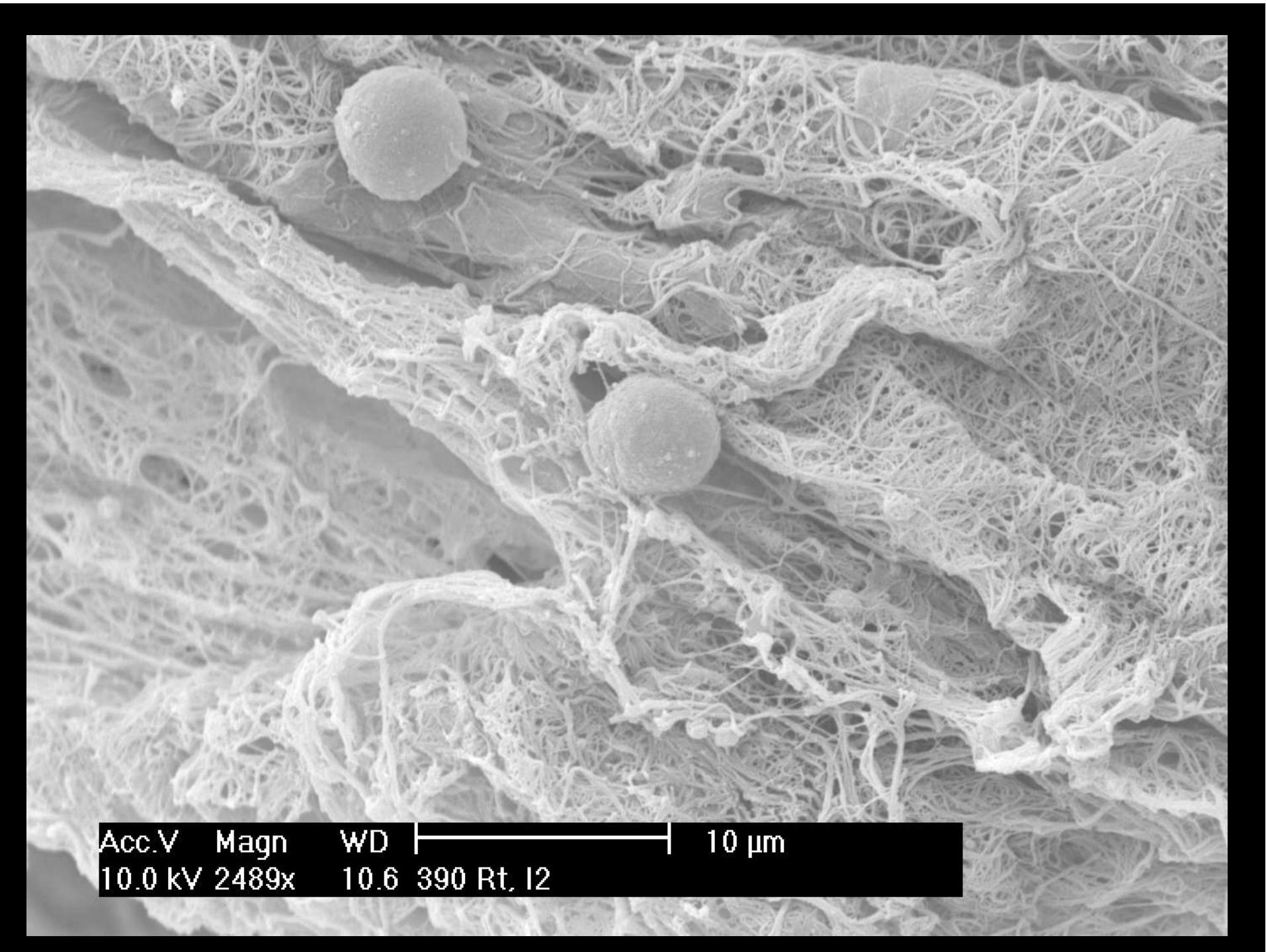


Courtesy of ICU Medical, Inc.

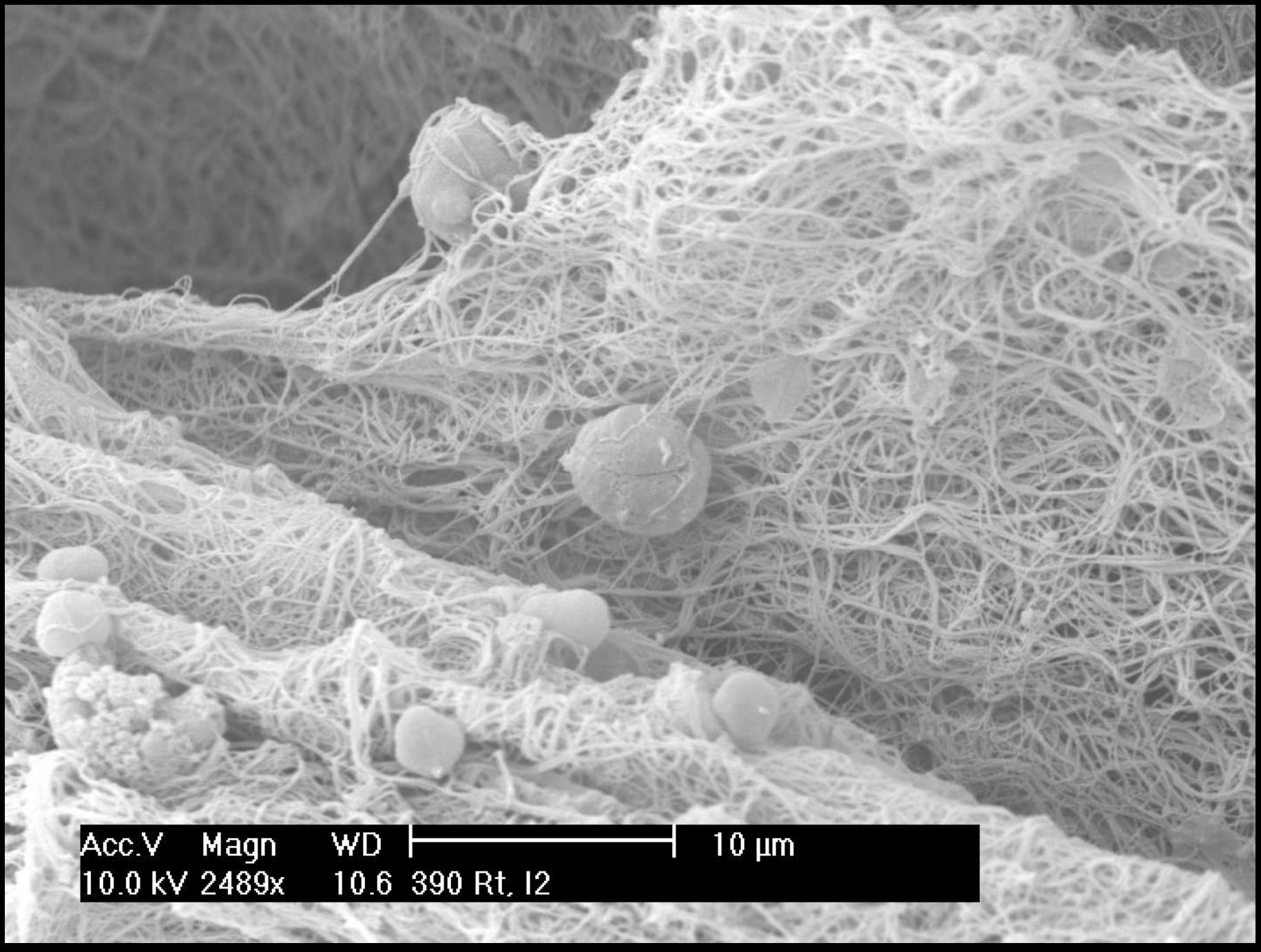




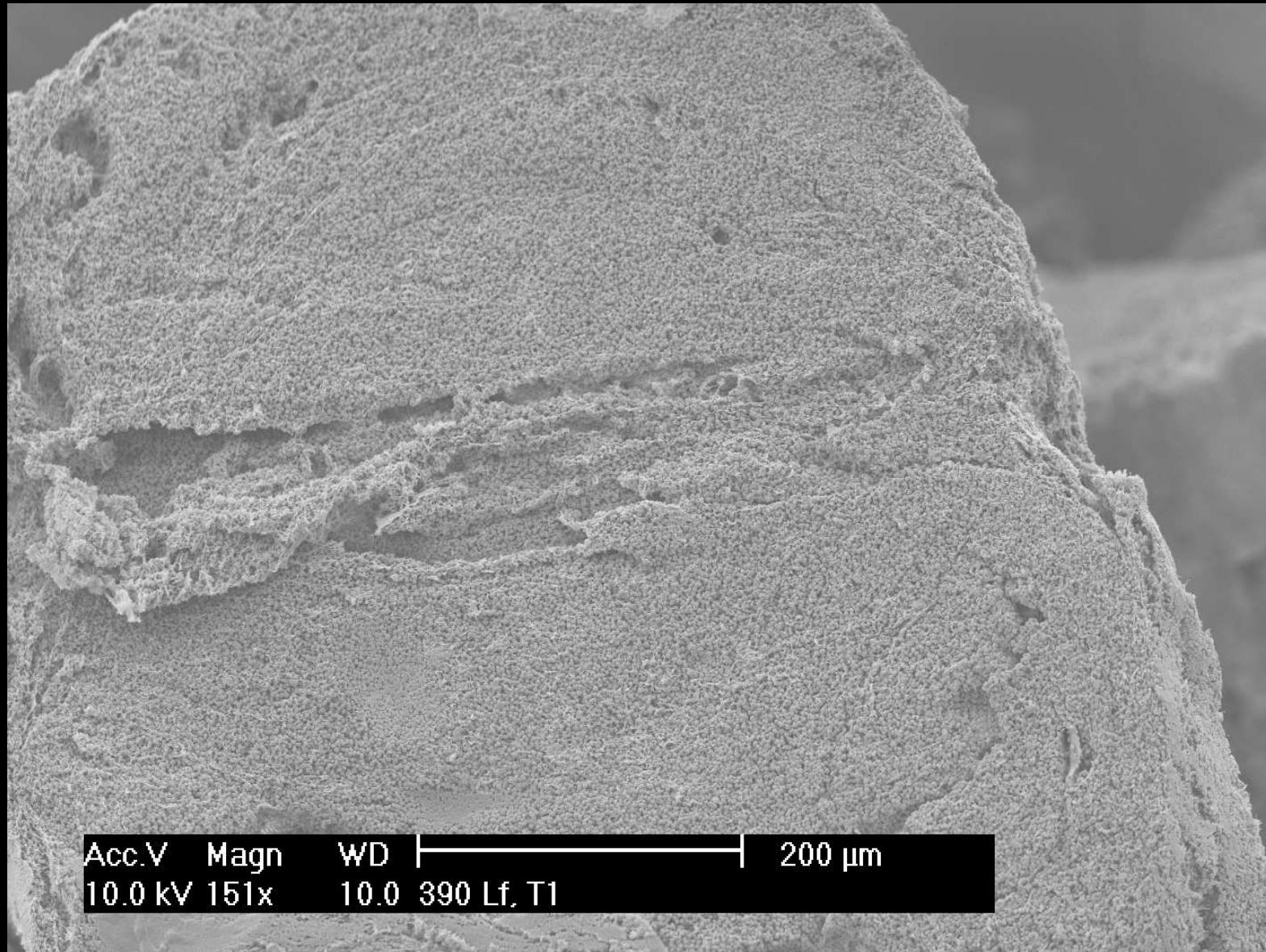
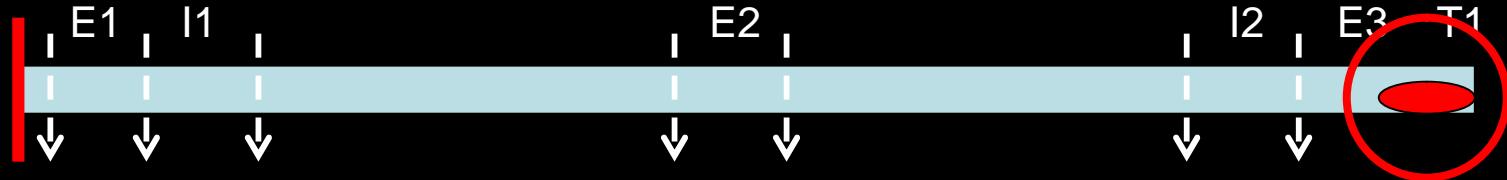
Acc.V Magn WD 200 µm  
10.0 kV 156x 10.6 390 Rt. I2



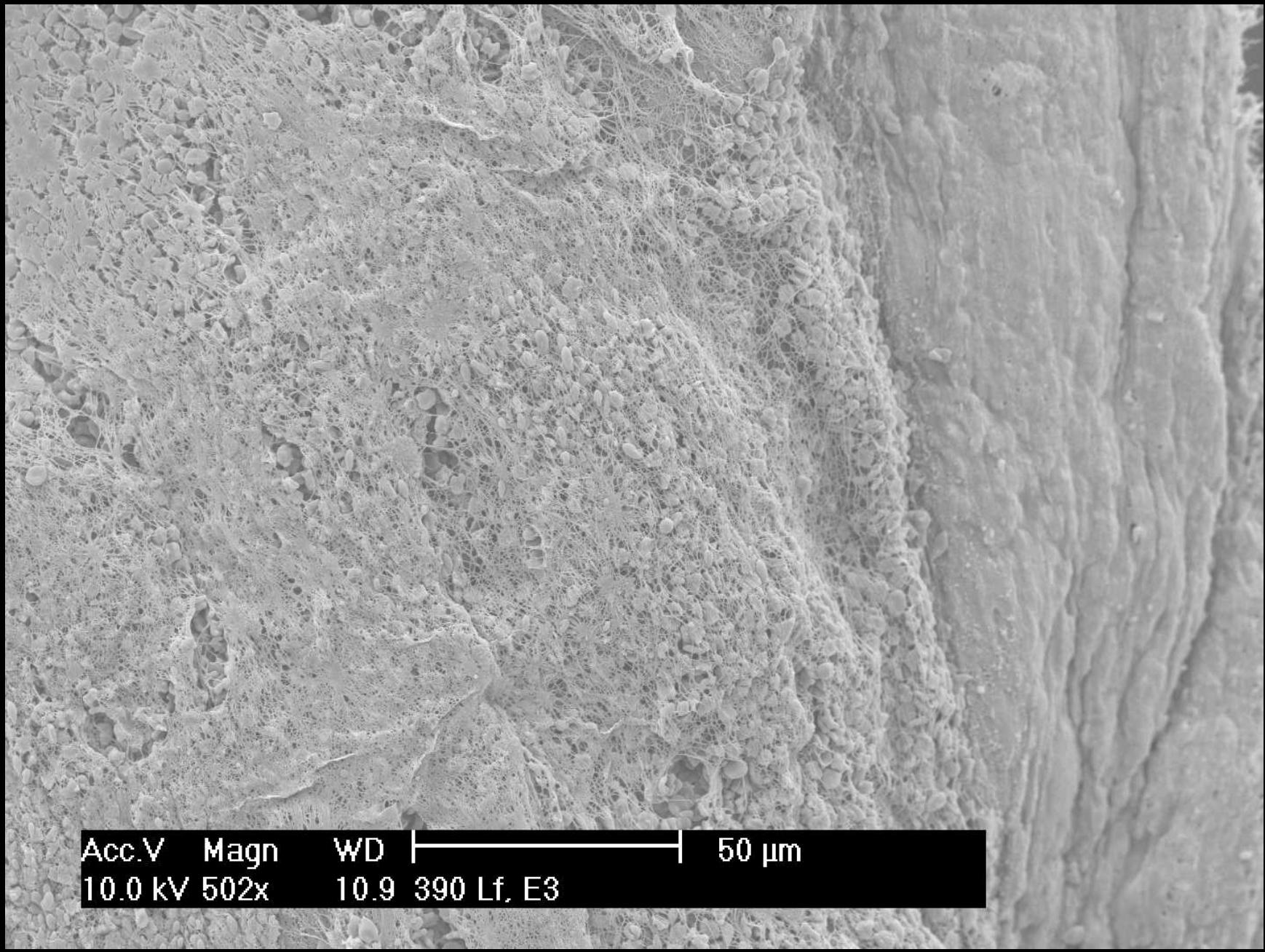
Acc.V Magn WD | 10 μm  
10.0 kV 2489x 10.6 390 Rt. I2



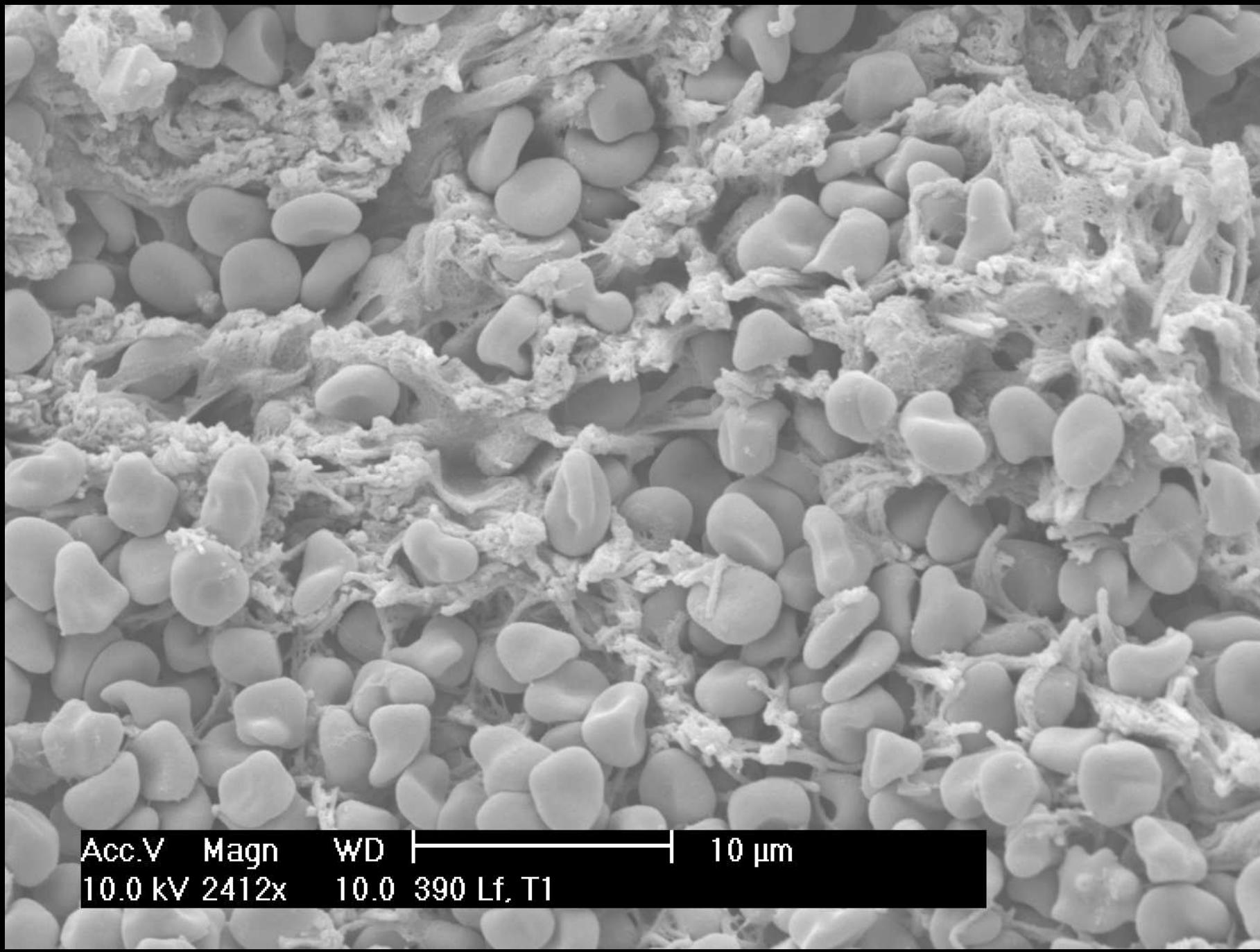
Acc.V    Magn    WD    10 μm  
10.0 kV 2489x    10.6 390 Rt. I2



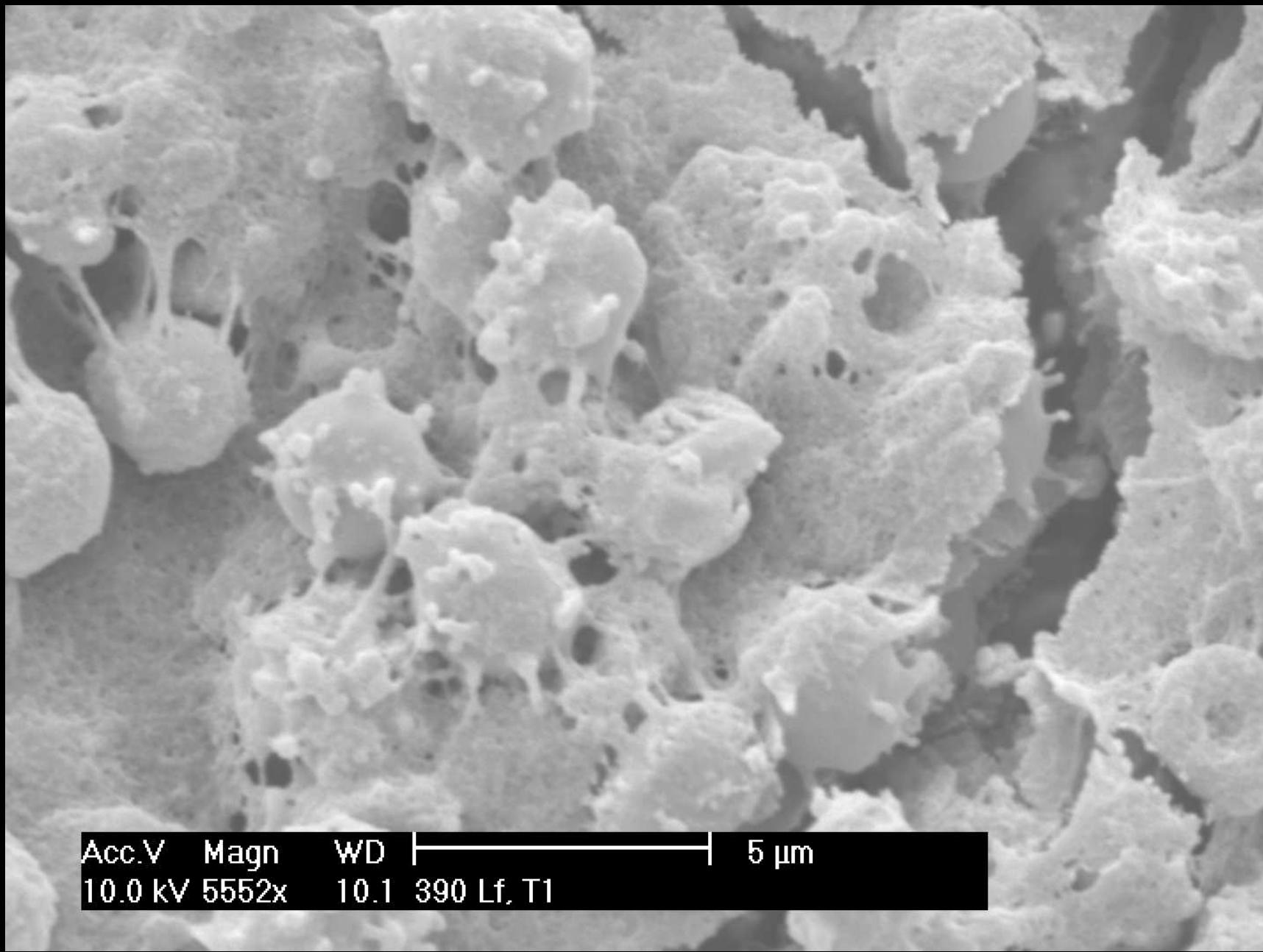
Acc.V Magn WD 200 µm  
10.0 kV 151x 10.0 390 Lf, T1



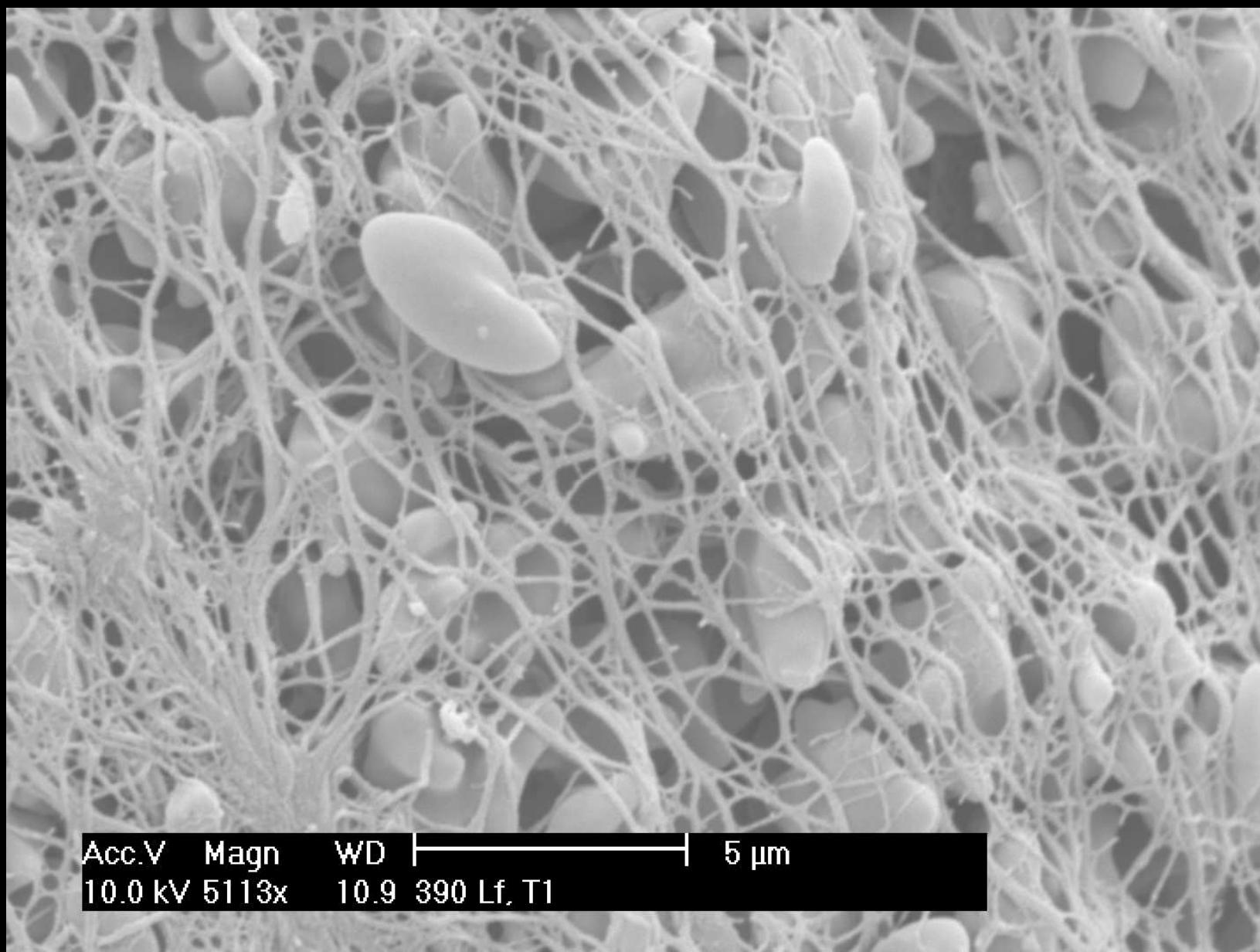
Acc.V    Magn    WD    50 µm  
10.0 kV 502x    10.9 390 Lf, E3



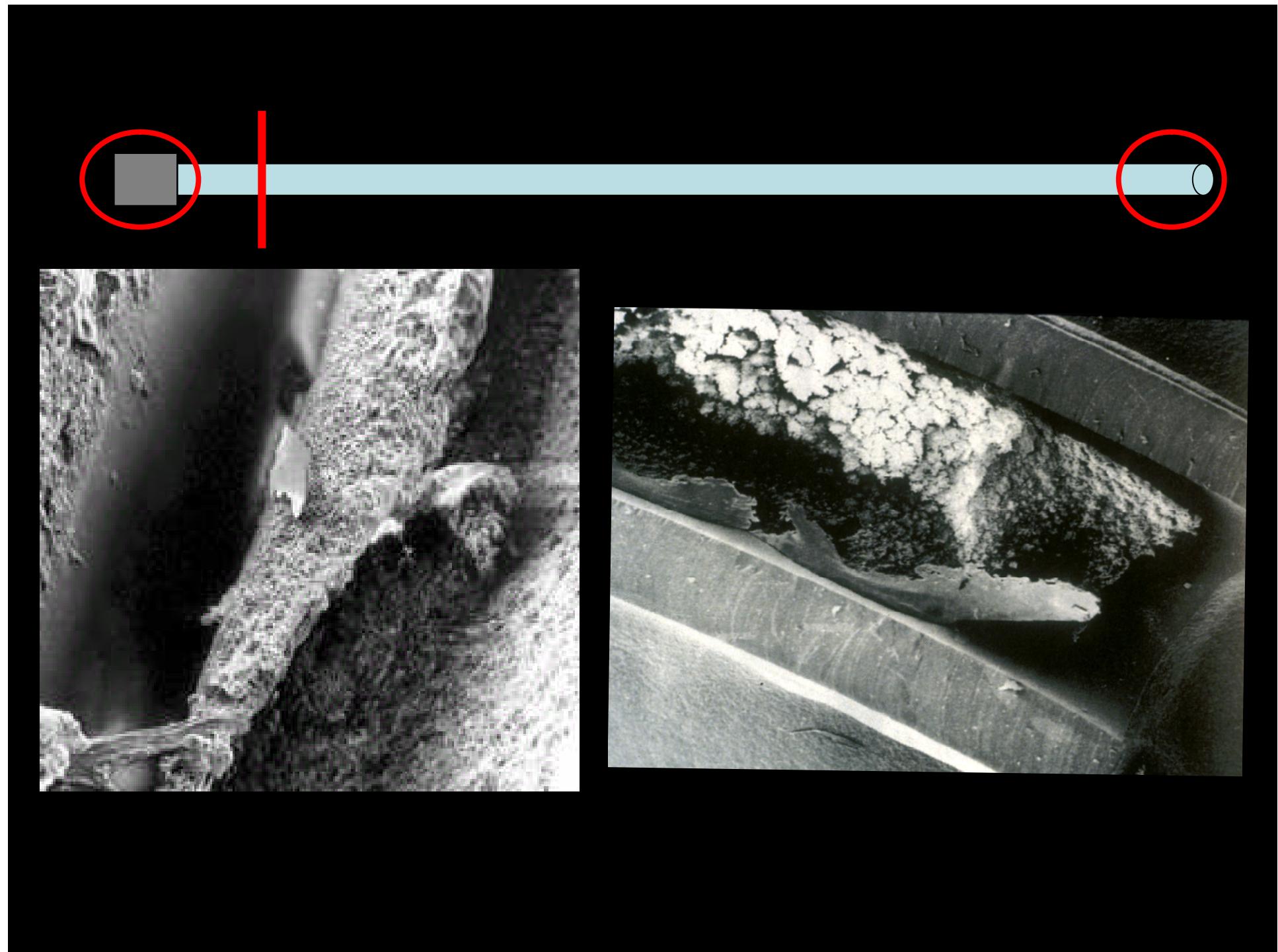
Acc.V    Magn    WD    10 μm  
10.0 kV 2412x    10.0 390 Lf, T1



Acc.V    Magn    WD | 5 μm  
10.0 kV 5552x    10.1 390 Lf, T1

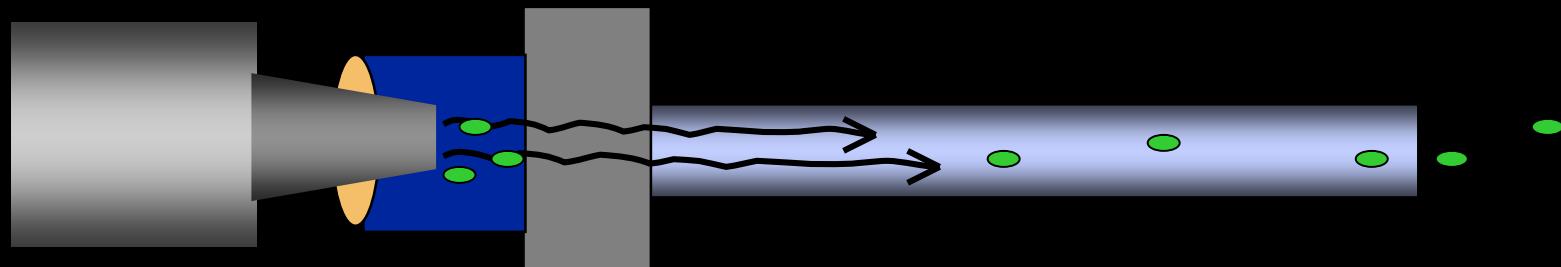


Acc.V    Magn    WD    5  $\mu$ m  
10.0 kV 5113x    10.9 390 Lf, T1



*....do needleless devices increase  
the risk of bloodstream infection?*

*....does device design effect  
the development of biofilm?*



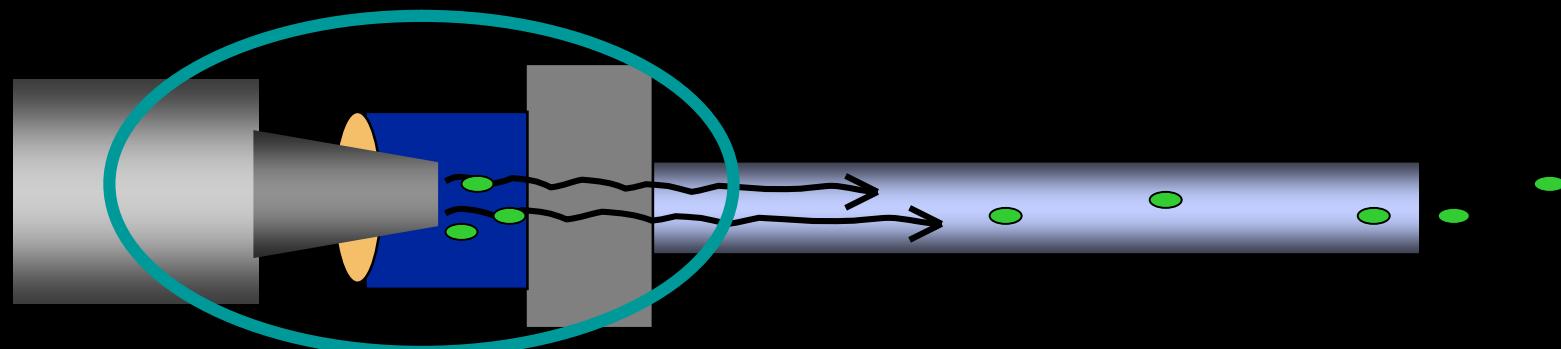
# PATHOGENESIS

**PRESENCE OF BACTERIA  
AT PORTAL OF ENTRY**

**MICROBIAL ENTRY**

**MICROBIAL ATTACHMENT**

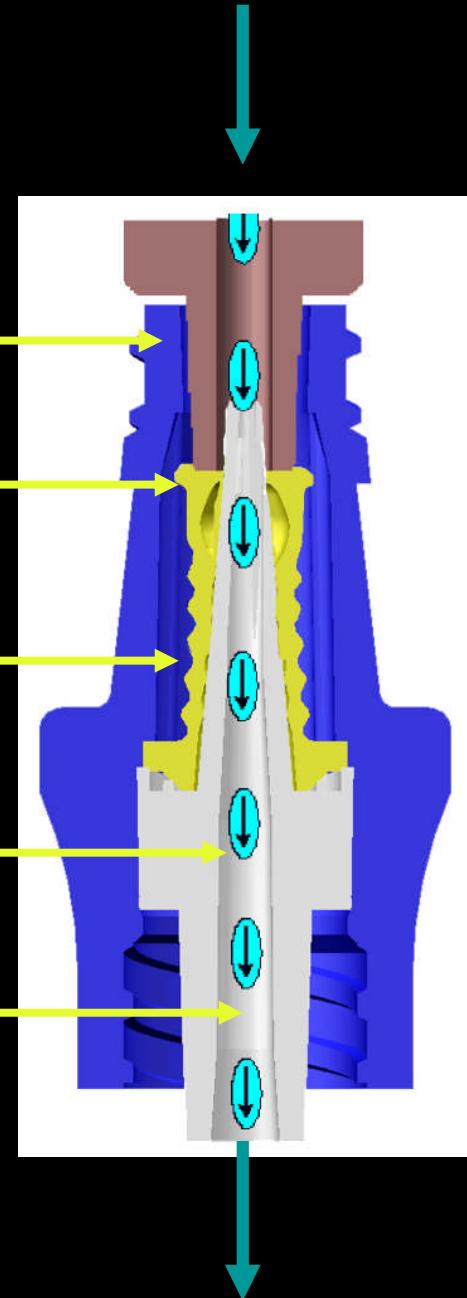
**BIOFILM  
FORMATION**



# DEVICE DESIGN

---

- EXTERNAL HOUSING
- ACCESS SEAL
- INTERNAL COMPONENTS
- FLUID PATH
- LUER LOCK



# FLOW PATH

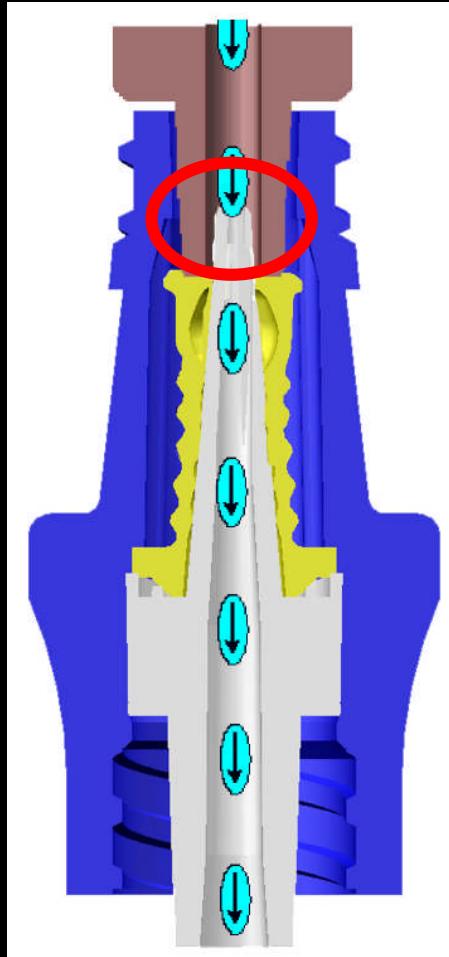
SIMPLE vs COMPLEX

SURFACE AREA

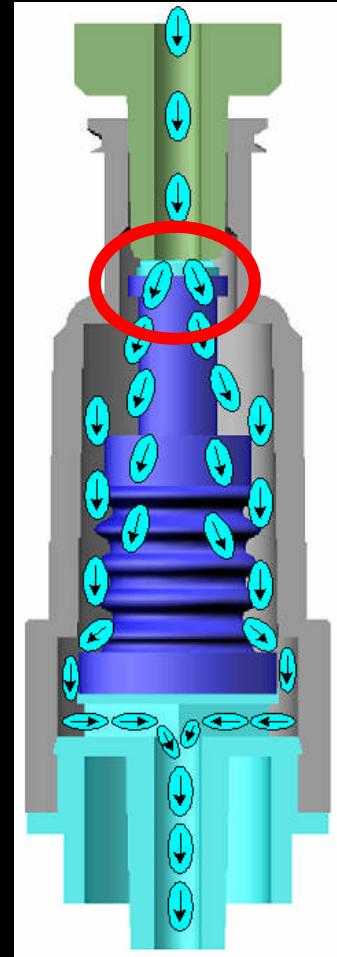
Access surface  
Flow path

RESIDUAL VOLUME

- Blood clearance
- Biofilm formation
- Drug retention

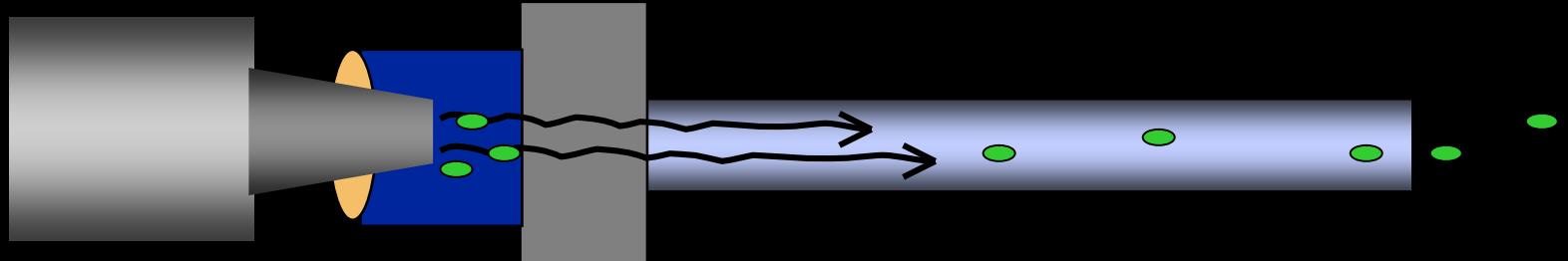


0.06cc



0.35cc

....does device design effect  
the development of biofilm  
and bloodstream infection?



# CENTER FOR BIOFILM ENGINEERING MONTANA STATE UNIVERSITY





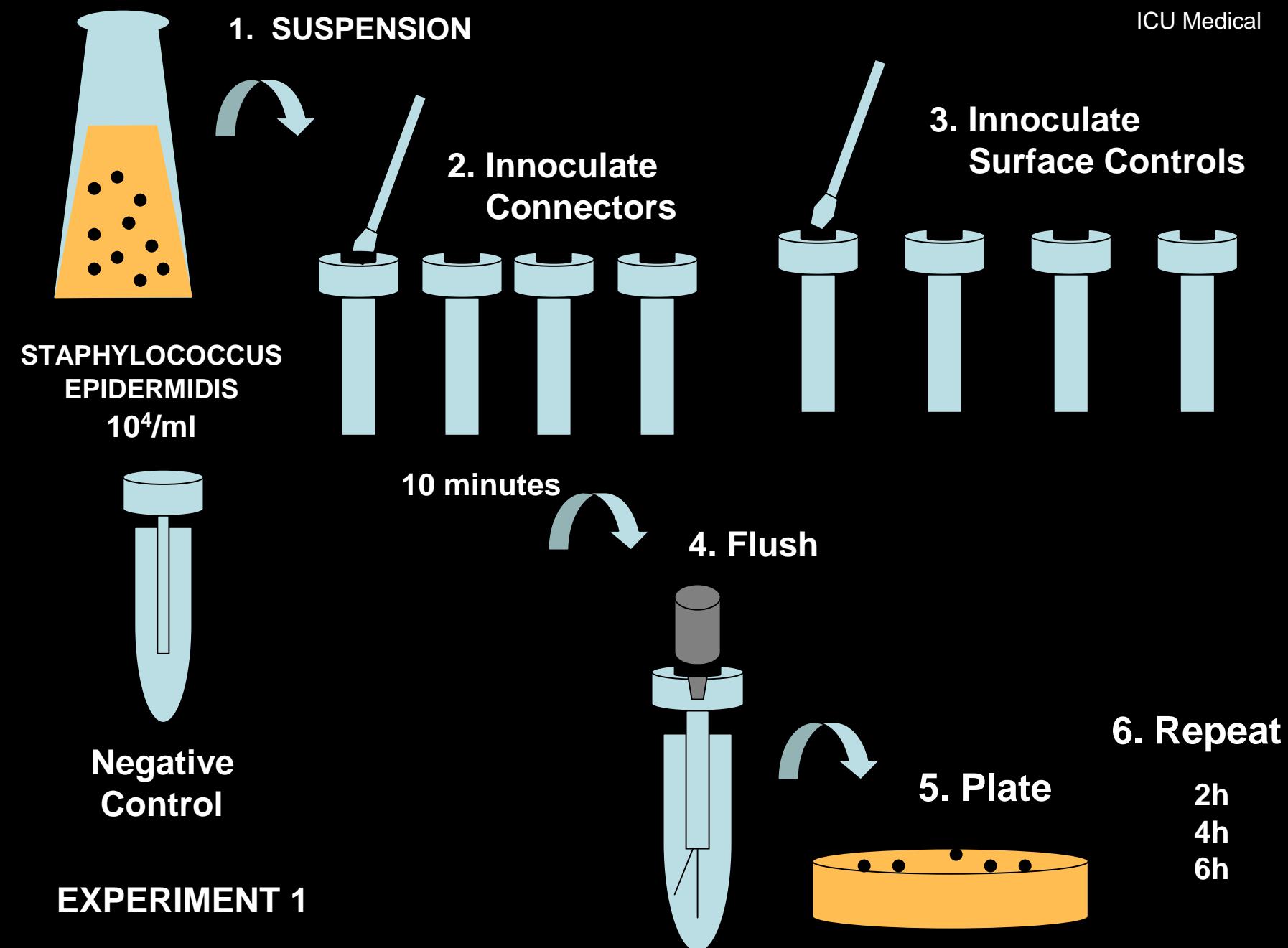
**Dr. Garth James**

**Steve Fisher**

**Dr. Elinor Pulchini**

# **STUDY AIMS**

1. To quantify the number of bacteria transferred through each connector
2. To quantify the number of bacteria transferred through the connectors after swabbing
3. To observe the potential for biofilm formation within the flow path over 96 hours



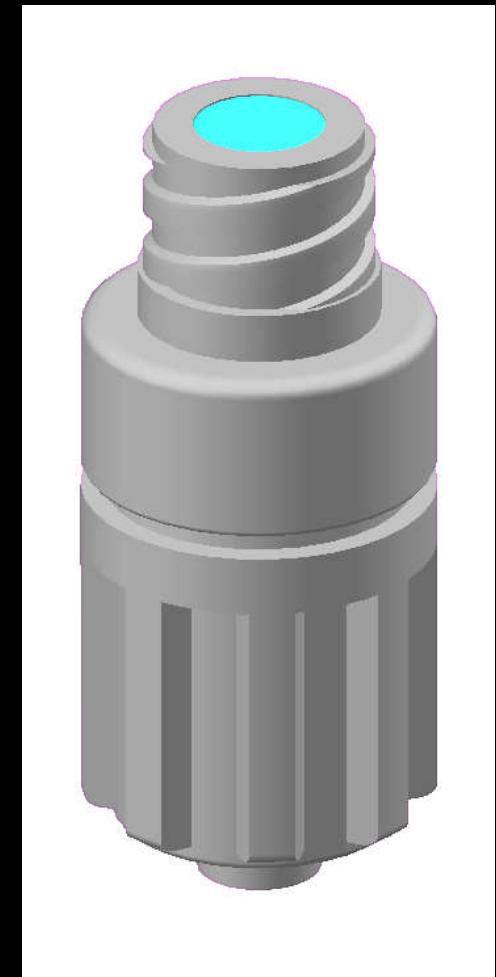
## EXPERIMENT 1



CLAVE



SMART SITE

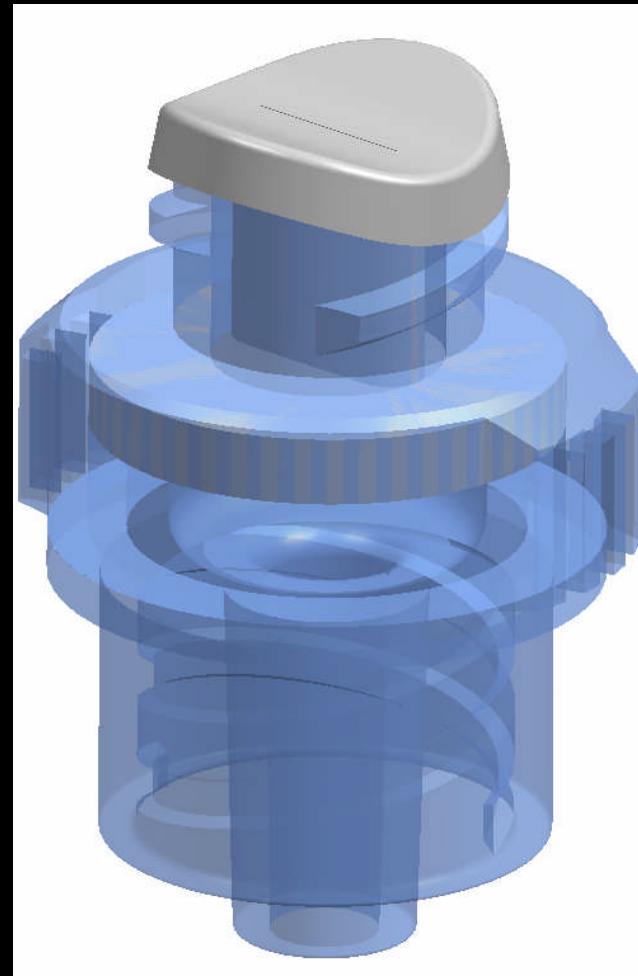


CLEAR LINK

## EXPERIMENT 2



CLAVE



Q SYTE



MAX PLUS

## RESULTS: Surface Counts

	Time				
	0	2	4	6	mean
	(Log density)				

CLAVE	4.1	4.4	4.4	4.5	4.3
-------	-----	-----	-----	-----	-----

SMART SITE	4.3	4.4	4.4	4.3	4.4
------------	-----	-----	-----	-----	-----

Q-SYTE	4.6	4.4	4.9	4.6	4.5
--------	-----	-----	-----	-----	-----

CLAVE	4.0	4.4	4.5	4.4	4.3
-------	-----	-----	-----	-----	-----

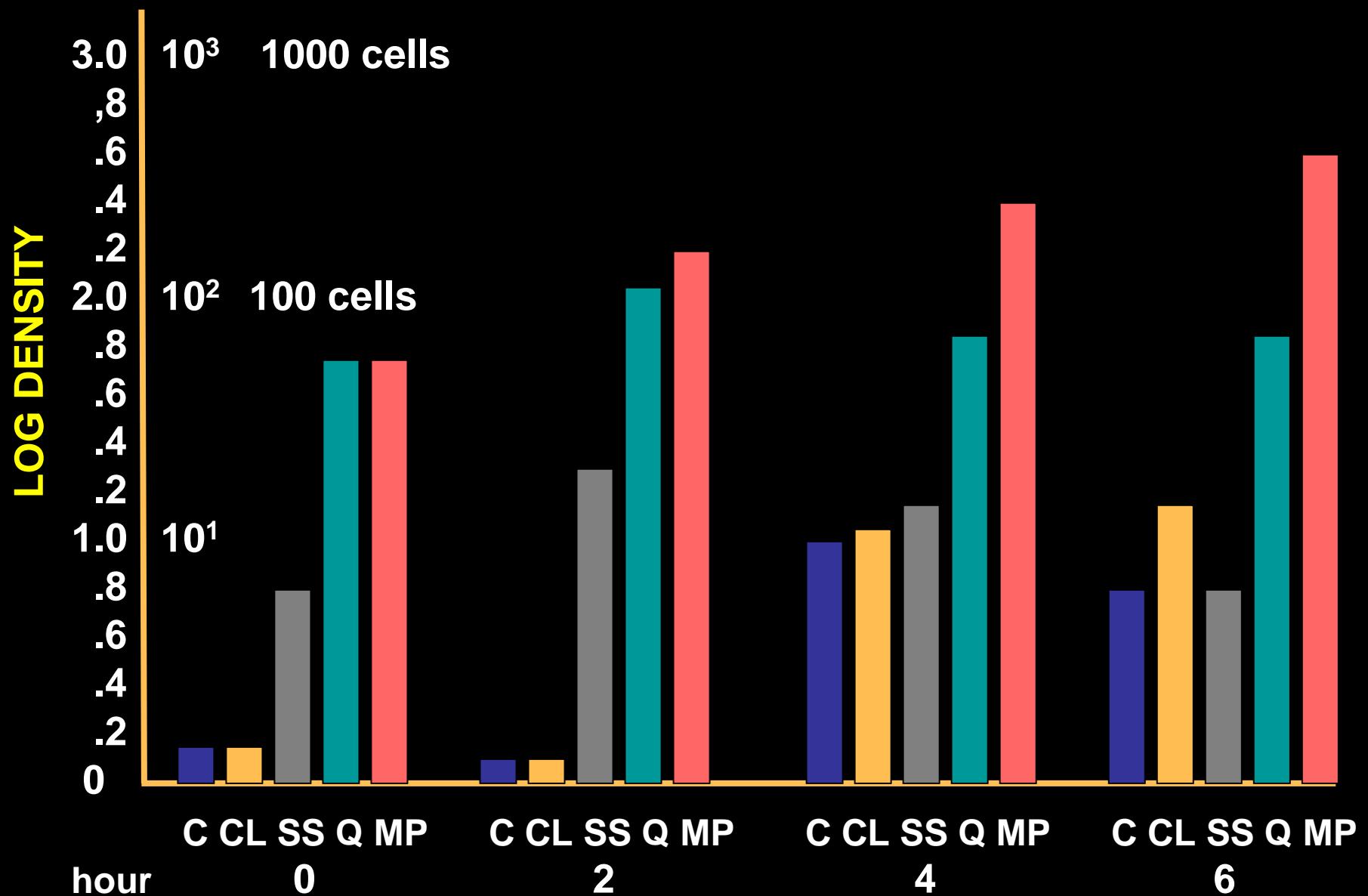
CLEARLINK	4.3	3.9	4.3	4.3	4.2
-----------	-----	-----	-----	-----	-----

MAX PLUS	4.2	4.2	4.4	4.2	4.3
----------	-----	-----	-----	-----	-----

## RESULTS: Flush Counts

	Time			
	0	2	4	6
	(Log Density)			
CLAVE	0.2	0.9	1.0	0.8
SMART SITE	0.8	1.3	1.1	0.8
CLEARLINK	0.2	0.9	1.1	1.2
Q-SYTE	1.7	2.2	1.9	1.9
MAX PLUS	1.7	2.3	2.4	2.5

# RESULTS: Flush Counts



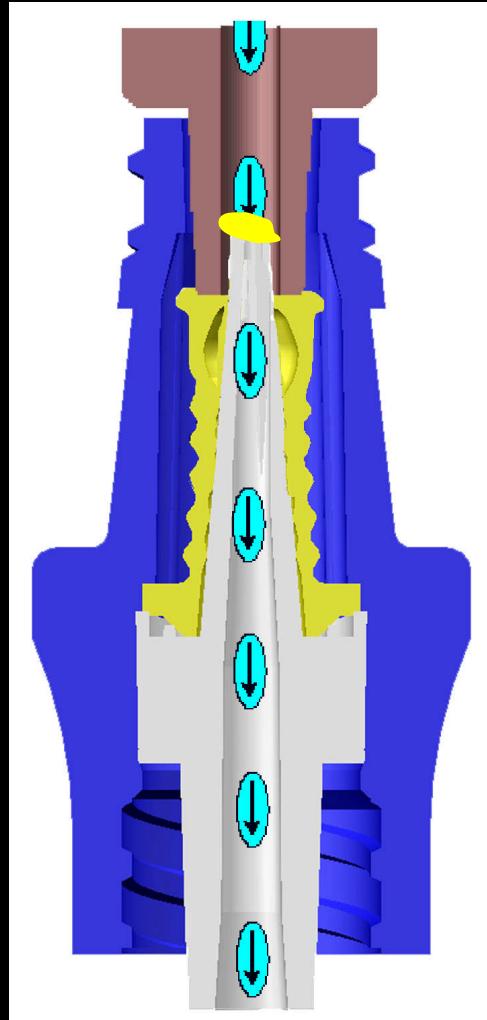
## RESULTS:

### Flush Counts

Cells  
0    2    4    6    24    96

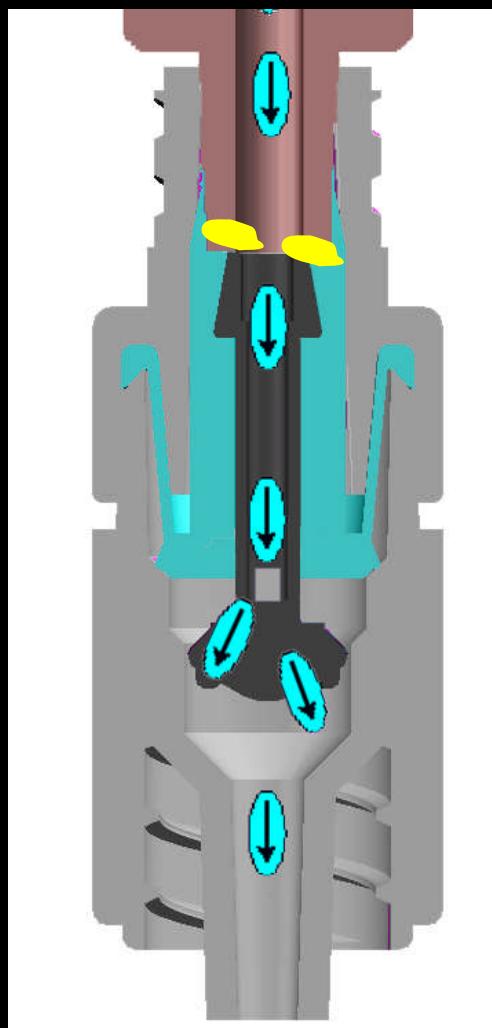
	(CFU/ml)					
CLAVE	2	9	10	8	29	120
10 <sup>2</sup>						
CLEARLINK	2	9	11	12	34	136
SMART SITE	8	30	20	8	66	264
Q-SYTE	65	220	190	190	465	1860
10 <sup>3</sup>						
MAX PLUS	70	230	240	250	790	3160

I



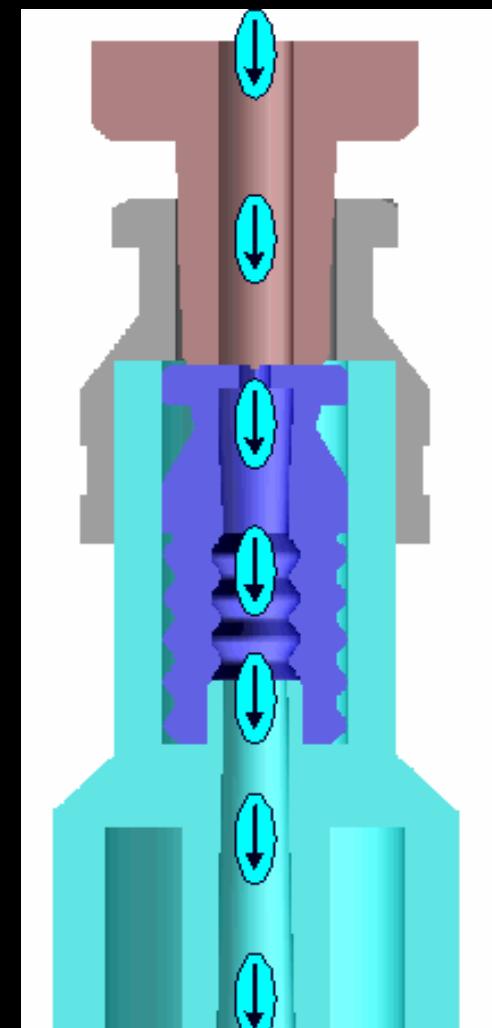
**0.06 cc**

I

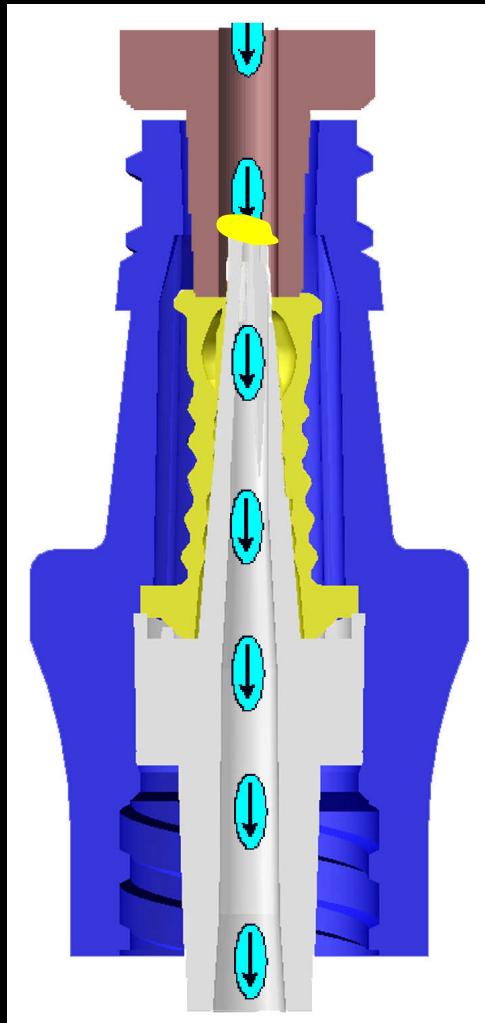
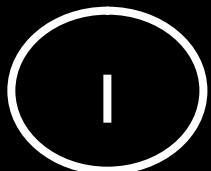


**0.13 cc**

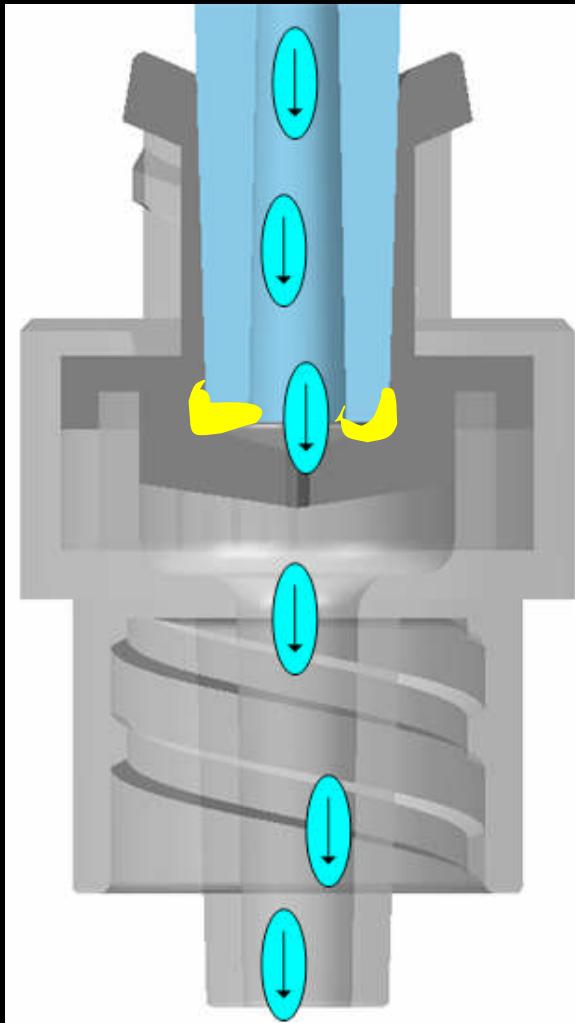
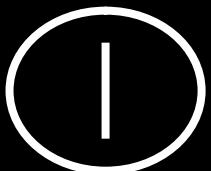
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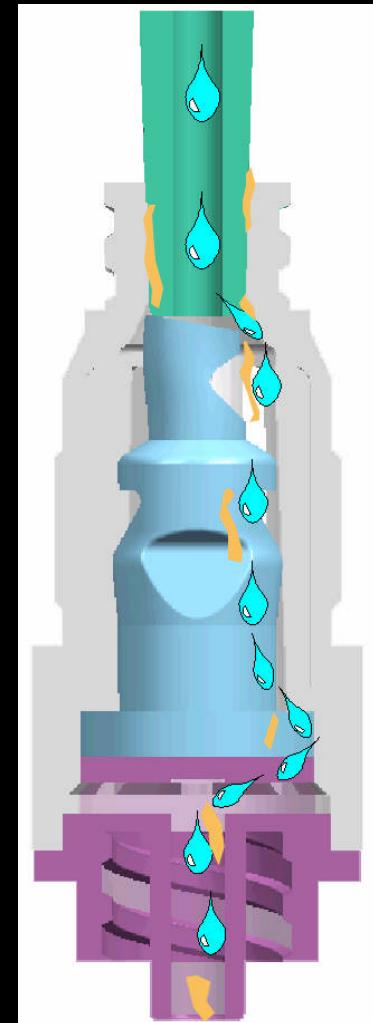
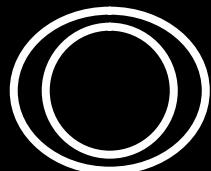
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**0.06 cc**

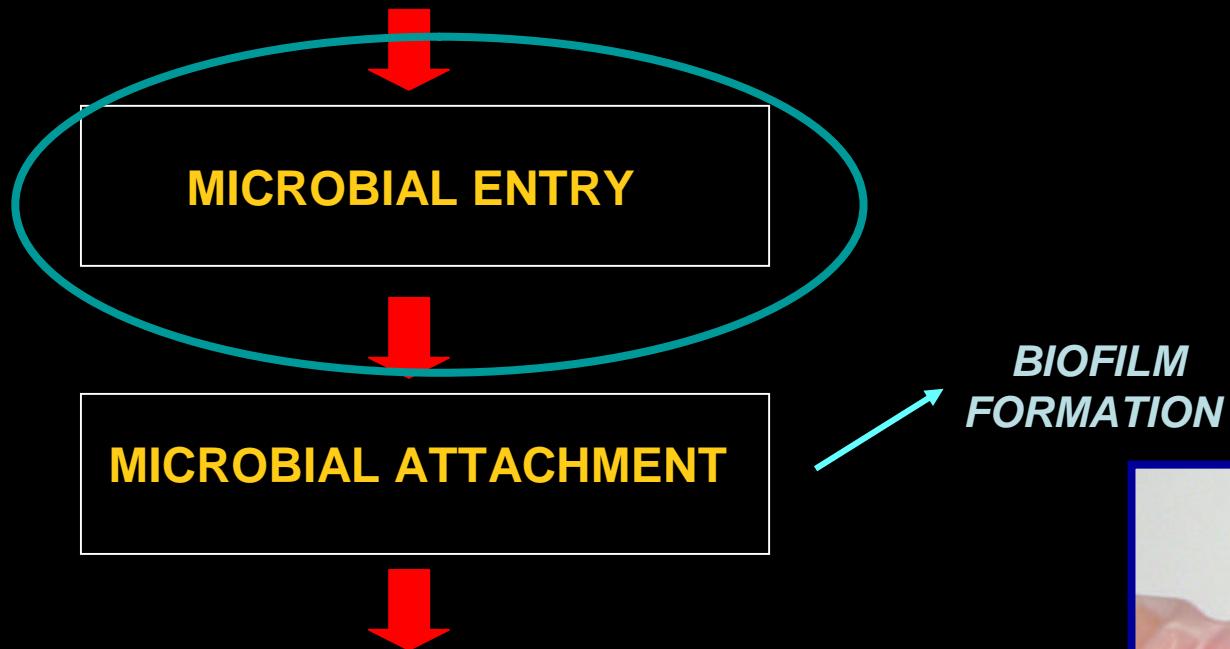


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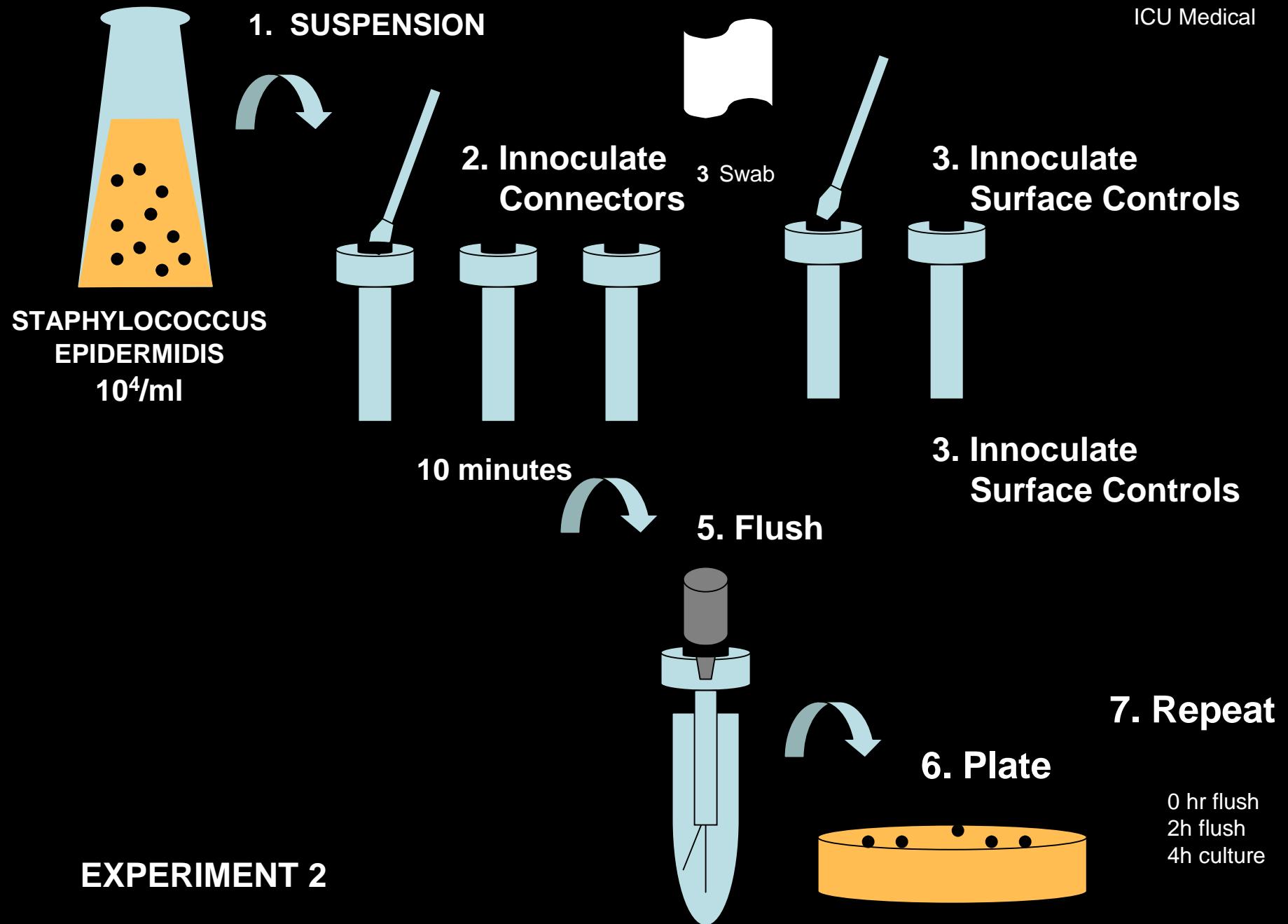
**0.32**

**PRESENCE OF BACTERIA  
AT PORTAL OF ENTRY**



# **STUDY AIMS**

1. To quantify the number of bacteria transferred through each connector
2. To quantify the number of bacteria transferred through the connectors after swabbing
3. To observe the potential for biofilm formation within the flow path over 96 hours



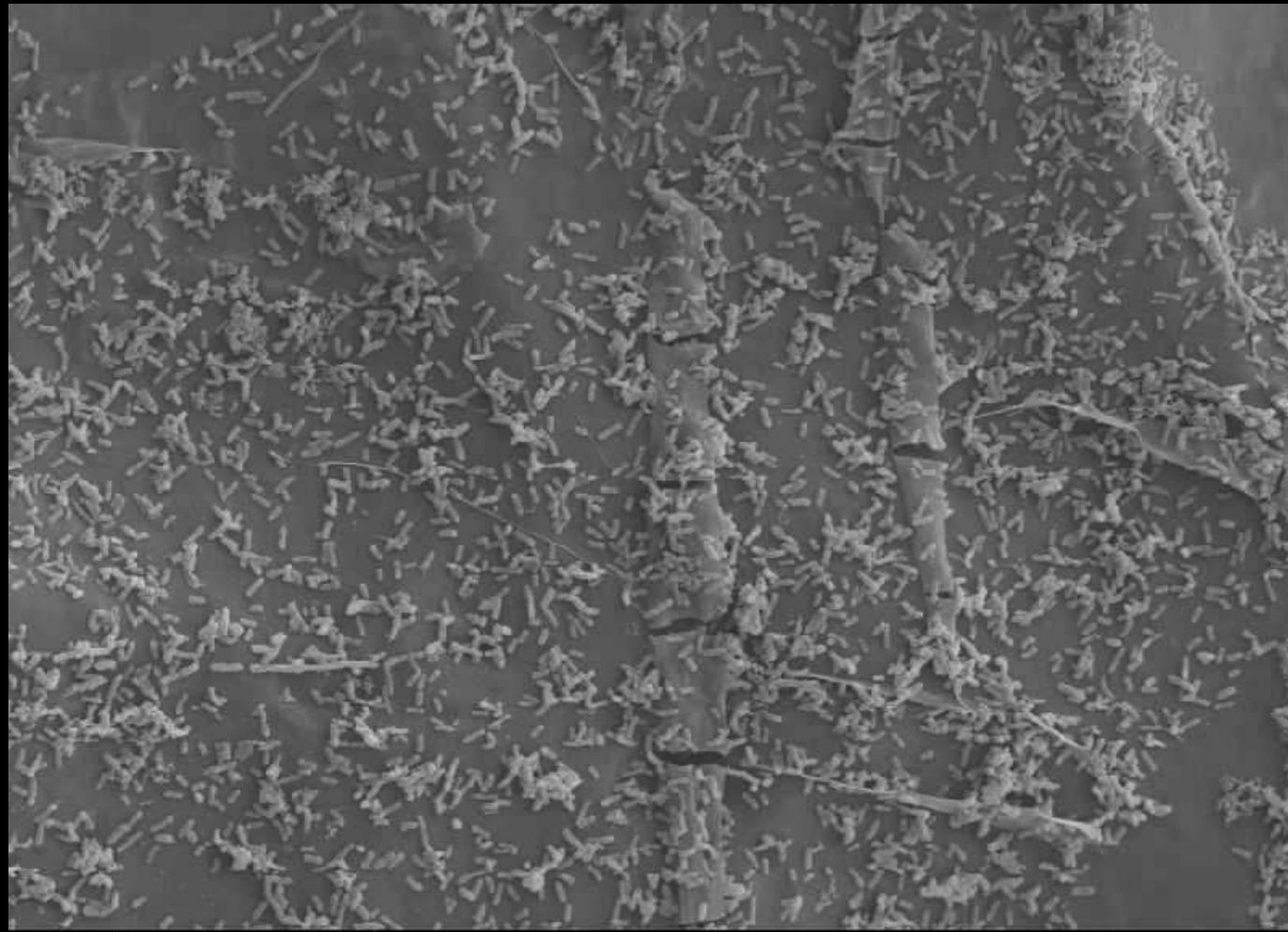
## RESULTS: Flush Counts

CLAVE	time	mean	mean
		Surface Count	Flush Count
	0	0.0	0.0
	2	0.0	0.0
	4	0.0	0.0
	6	0.0	0.0
	0	0.7	0.0
	2	1.0	0.0
	4	1.6	0.0
	6	0.0	0.0

# **STUDY AIMS**

1. To quantify the number of bacteria transferred through each connector
2. To quantify the number of bacteria transferred through the connectors after swabbing
3. To observe the potential for biofilm formation within the flow path over 96 hours

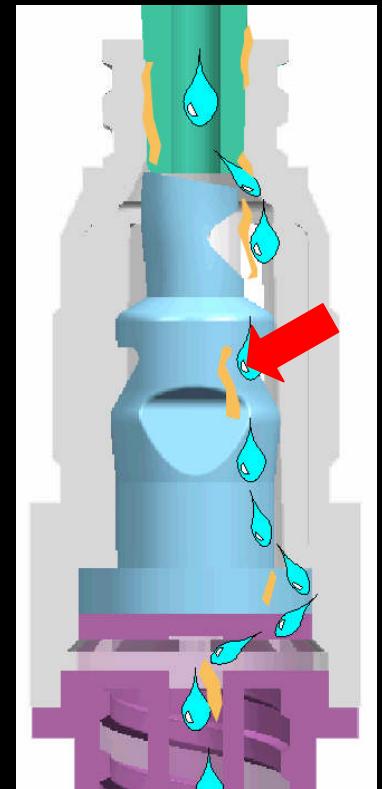
**96 hours**



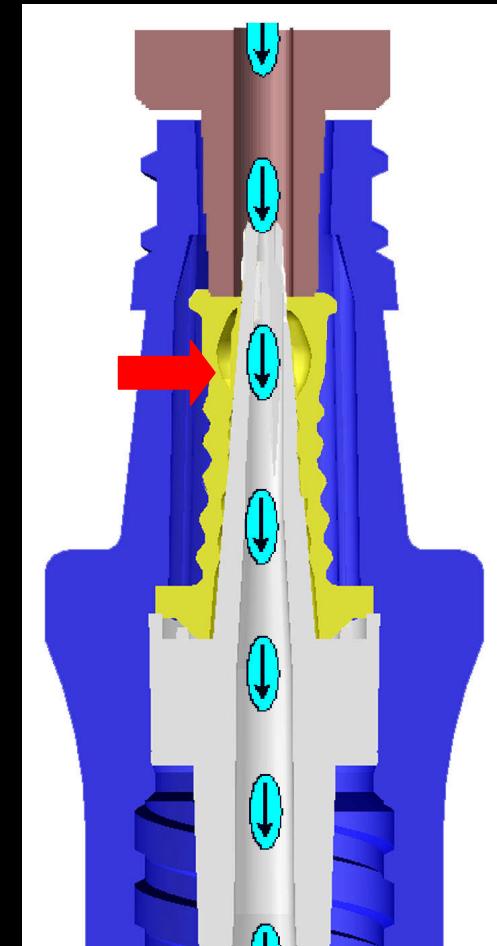
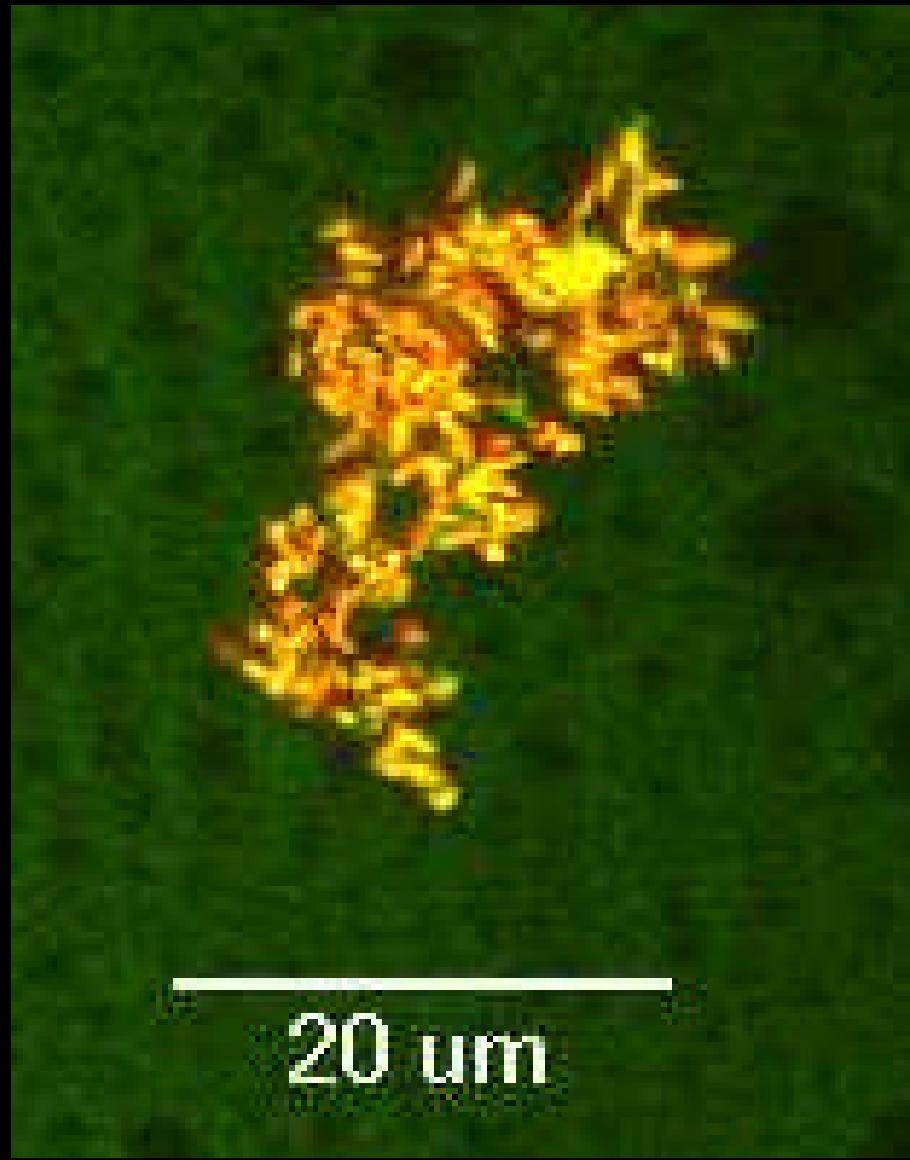
6/8/06 x1400 WD14 10kV

Max-H+1%

20  $\mu$ m

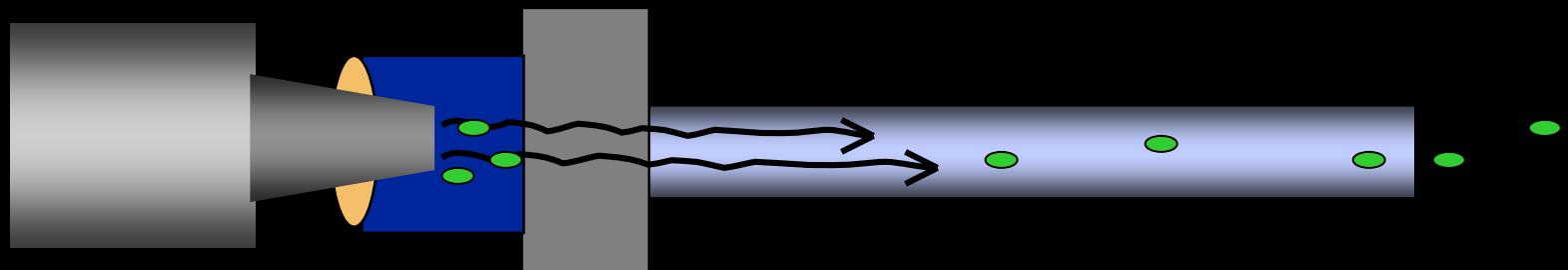


**96 hours**



*....do needleless devices increase  
the risk of bloodstream infection?*

*questions?*

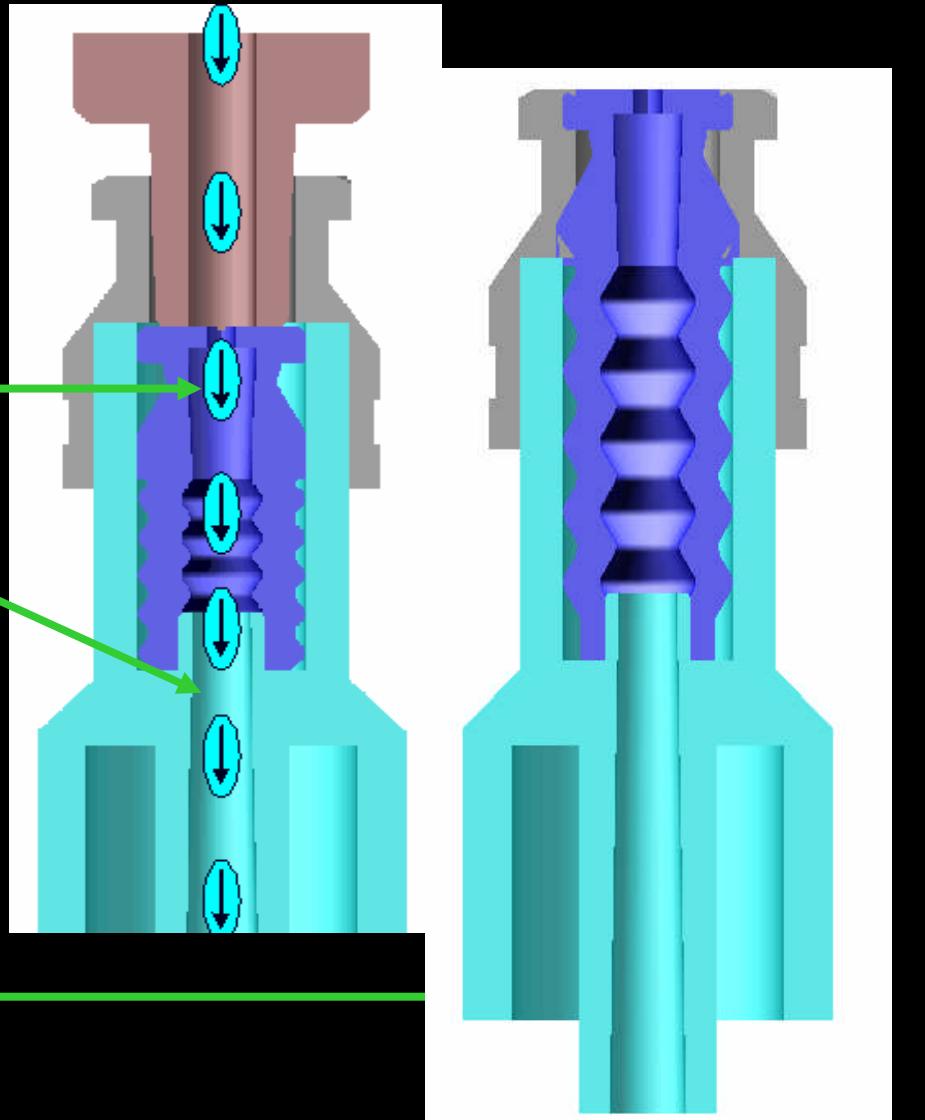


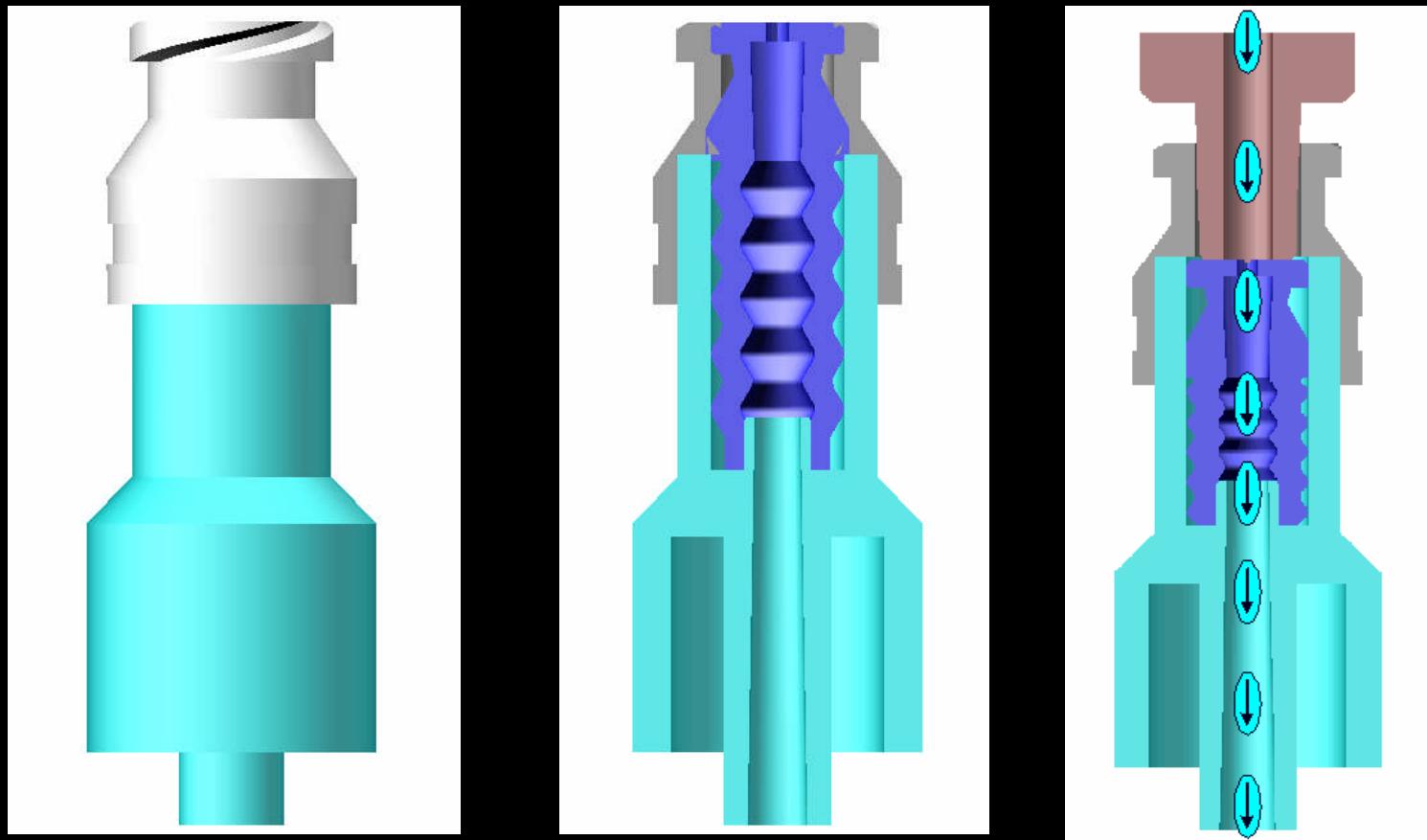
# PRODUCT MATERIALS

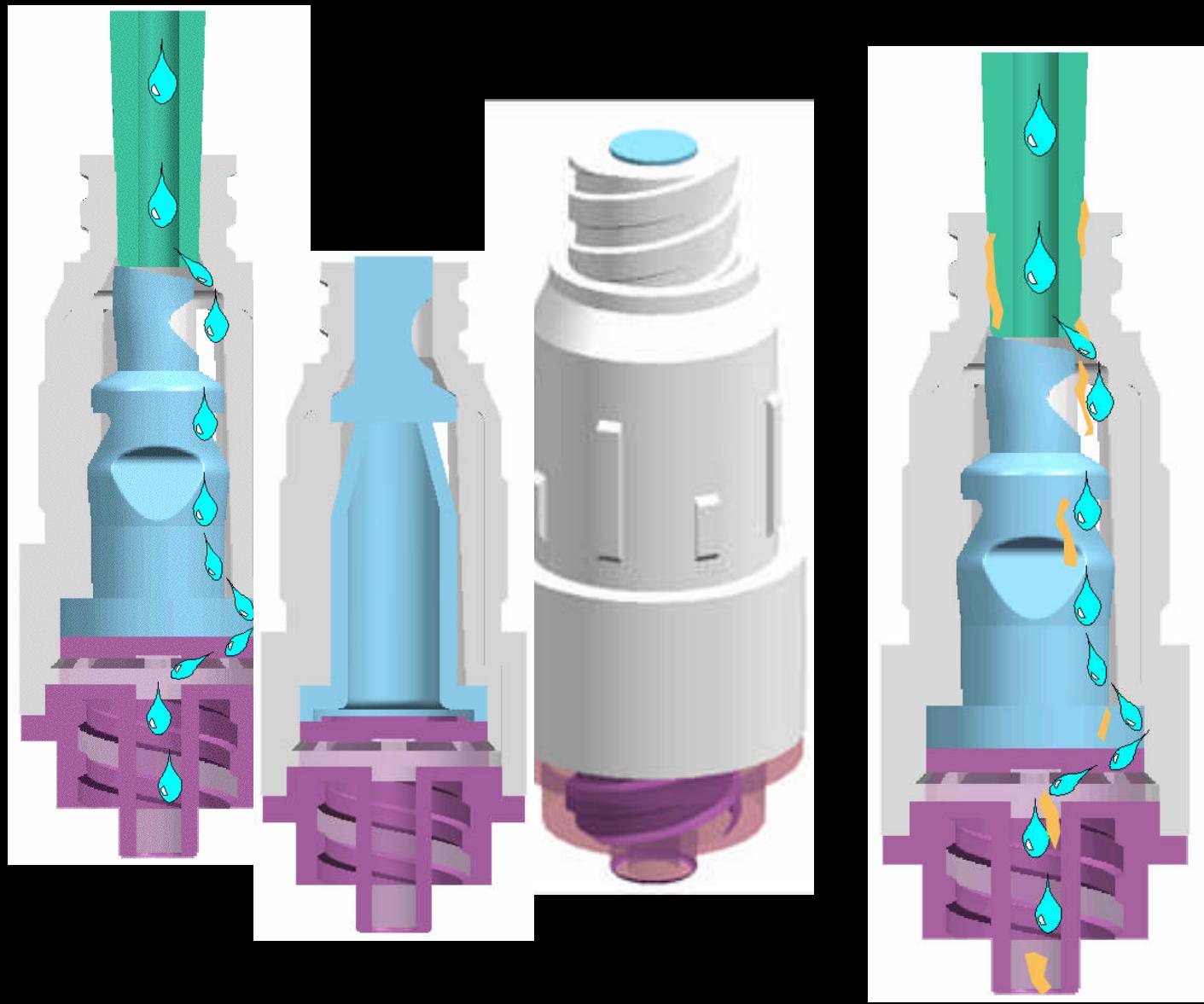
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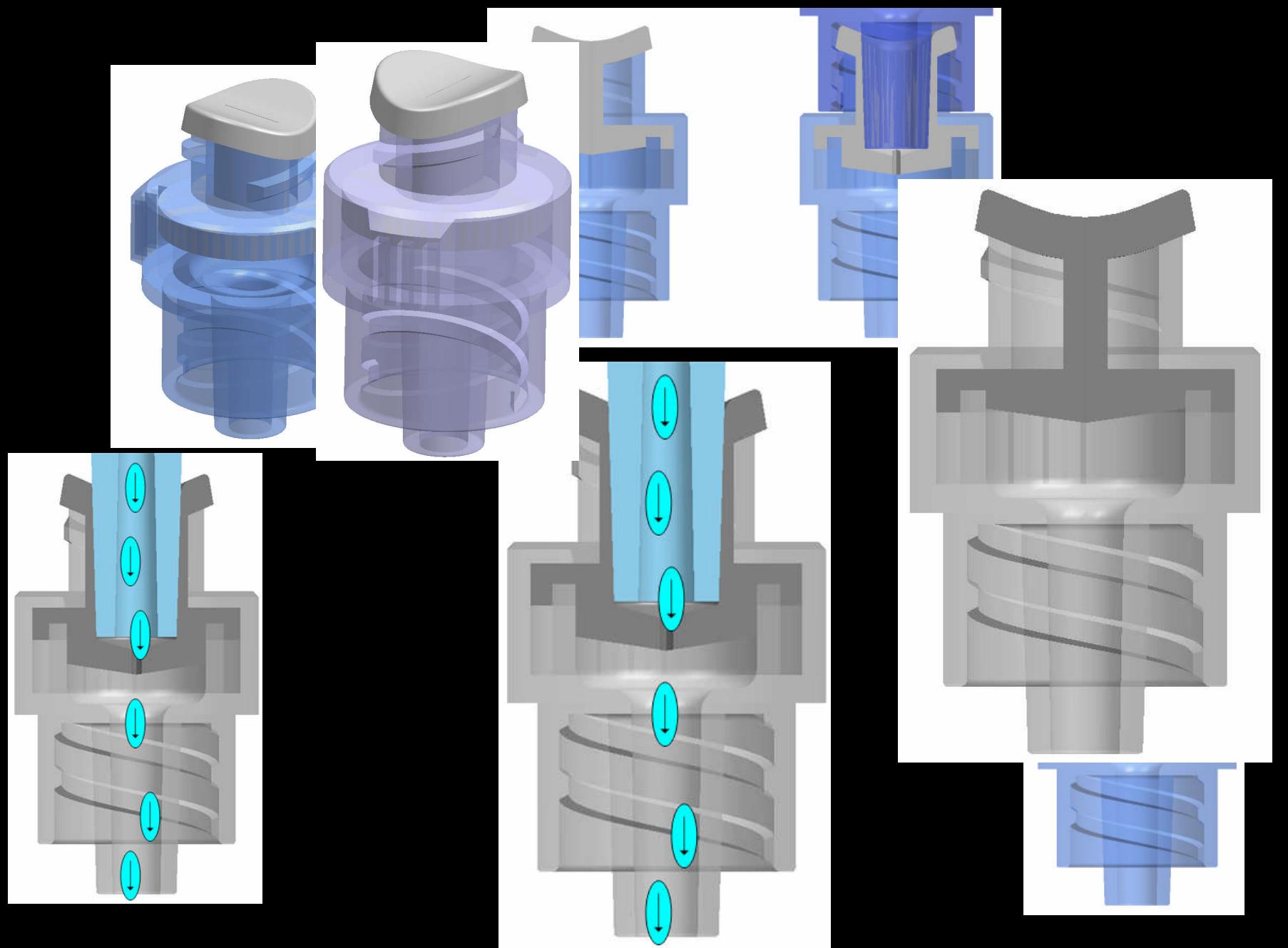
## FLOW PATH

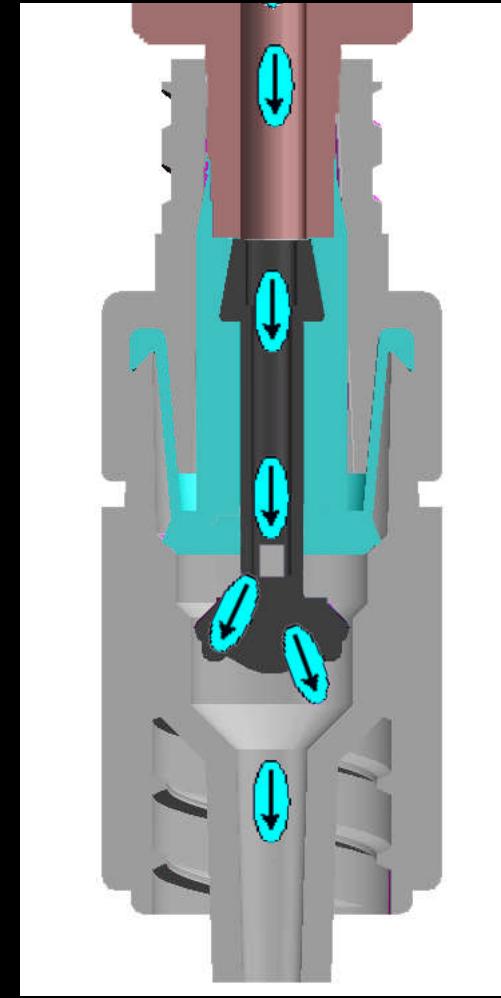
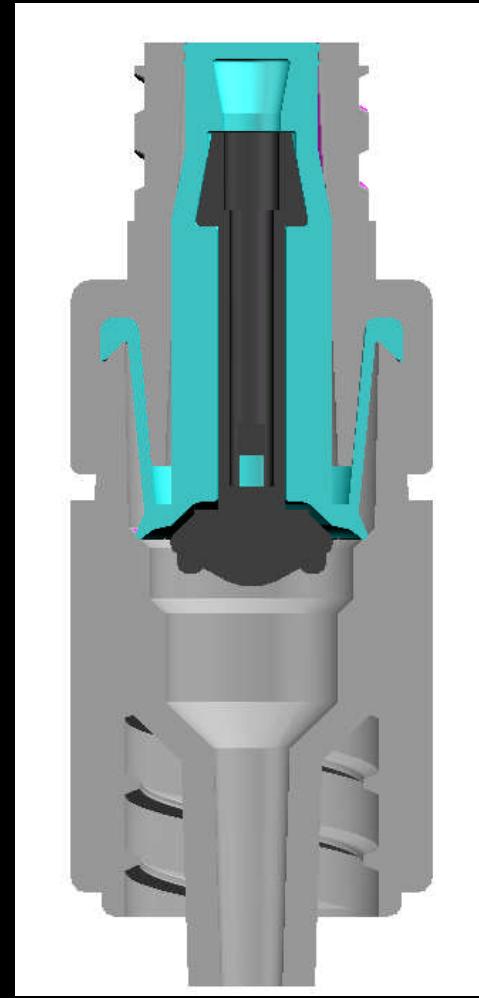
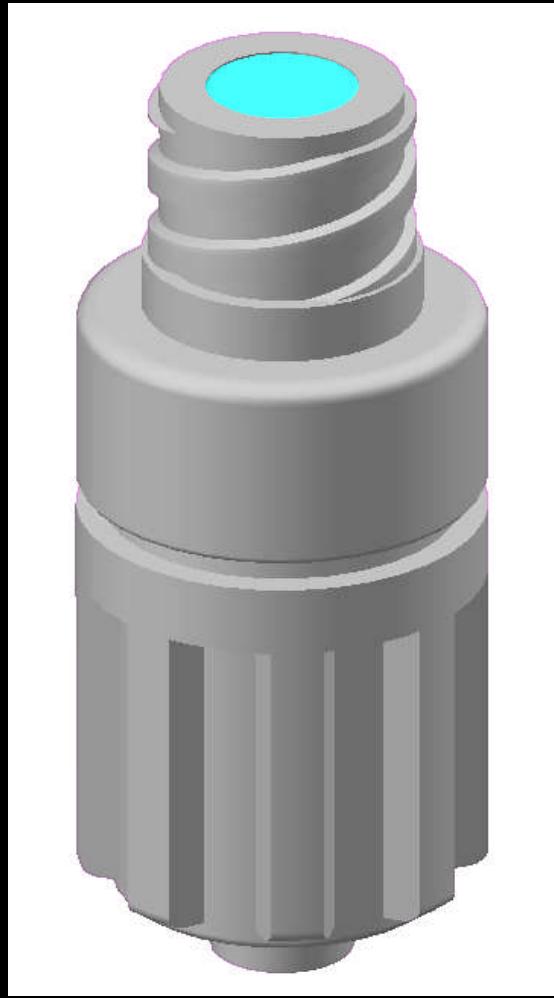
- SILICONE
- POLYCARBONATE
- POLYETHYLENE
- SILICONE
- STAINLESS STEEL











# LIFESTYLE #1: FLOW

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## INFUSION/ASPIRATION

**Fluid/Drug Infusion**



**Parenteral nutrition**



**Blood / blood products**



**Blood draws**

