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**Needle Penetration Testing**  
for the  
**Ambu, Inc.**  
**Monopolar Needle**

Report Number: R1801012-01-00  
13 February 2018

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Customer: Ambu, Inc.  
Attn: Brett Alpaugh  
6230 Old Dobbin Lane, Suite 250  
Columbia, MD 21045

Test Performed by:



**Tested and proven.**

*DDL, Inc.*  
10200 Valley View Road, Suite 101  
Eden Prairie, MN 55344  
tel: 952.941.9226 | 800.229.4235  
fax: 952.941.9318

*DDL, West*  
9400 Toledo Way  
Irvine, CA 92618  
tel: 714.979.1712 | 800.229.4235  
fax: 714.979.1721

[www.testedandproven.com](http://www.testedandproven.com)

# TABLE OF CONTENTS

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**Revision Record.....2**

**Introduction .....2**

    Objective ..... 2

    Scope..... 2

**Summary of Tested Samples .....2**

**Product .....3**

**Results Summary.....4**

    Acceptance Criteria ..... 4

    Needle Penetration ..... 4

**Related Documents.....4**

**Logistics .....4**

**Equipment and Materials.....5**

**Test Procedure .....6**

    Needle Penetration ..... 6

**Disclaimer of Warranties .....7**

**Statement of Conformity .....8**

**Appendix A: Needle Penetration.....9**

Report No.	R1801012-01-00	Customer:	Ambu, Inc.	Page 1 of 9
------------	----------------	-----------	------------	-------------

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DDL West ▪ 9400 Toledo Way ▪ Irvine, CA 92618 ▪ Tel: 714-979-1712 ▪ Fax: 714-979-1721

# REVISION RECORD

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Report Revision	Date	Author	Description of Change
R1801012-01-00	13-Feb-18	Andy R. Timm	Initial Release

Table 1: Revision record.

## INTRODUCTION

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### Objective

The objective of this project was to perform needle penetration testing on the Monopolar Needle for Ambu, Inc. as stated in DDL, Inc. quote number Q1801012-00.

### Scope

This report documents needle penetration testing on DDL, Inc. sample numbers 001 – 003. Testing was performed under controlled laboratory conditions with equipment qualified to perform these tests.

## SUMMARY OF TESTED SAMPLES

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DDL Sample Numbers	Manufacturer	Product Name	Ref. Number	Lot Number	Needle Size	Testing Performed
001	Ambu	Neuroline Monopolar	74238-36/40	1000006830	38mm x 28G	Needle Penetration
002	Natus	TECA	902-DMF37-TP	U1709G10	37mm x 28G	
003	Natus	TECA Elite	902-DMF37-S	G1708G08	37mm x 28G	

Table 2: Summary of tested samples.

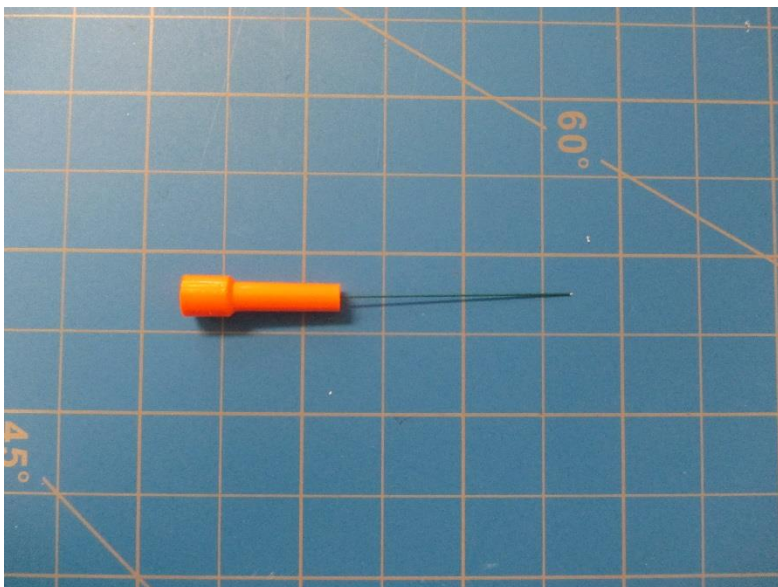
# PRODUCT

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## Monopolar Needle



**Figure 1: Typical Ambu Neuroline Monopolar Needle.**



**Figure 2: Typical Natus TECA and TECA Elite Monopolar Needle.**

Report No.	R1801012-01-00	Customer:	Ambu, Inc.	Page 3 of 9
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## RESULTS SUMMARY

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### Acceptance Criteria

Ambu, Inc. personnel are responsible for determining the acceptance criteria for testing.

### Needle Penetration

Samples were tested guided by DDL, Inc. test method TM9014-03. The table below summarizes the test results.

DDL Sample Number	Number of Sub-Samples Tested	DDL Sub-Sample Numbers	Average Peak Force (N)	Average of Average Drag Force (N)
001	50	1 - 50	0.427	0.091
002	50	1 - 50	1.031	0.413
003	50	1 - 50	0.845	0.194

**Table 3: Needle penetration test results.**

The test data for the needle penetration testing is located in Appendix A of this test report.

## RELATED DOCUMENTS

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References
DDL, Inc. Quote # Q1801012-00
DDL, Inc. Test Method # TM9014-03: <i>Needle Penetration Test</i>

**Table 4: References.**

## LOGISTICS

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Samples 001 – 003 were received on 19 January 2018.

Needle Penetration Testing:

- Started: 31 January 2018
- Completed: 5 February 2018

Samples were retained at DDL, Inc. at the time of this test report.

Report No.	R1801012-01-00	Customer:	Ambu, Inc.	Page 4 of 9
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# EQUIPMENT AND MATERIALS

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The following equipment and materials were used to complete these tests:

<b>Equipment Name (Model)</b>	<b>Asset No.</b>	<b>Calibration Due</b>
Universal Tester (Instron 5967)	004366	11-Jan-19
Load Cell (100N)	005016	11-Jan-19
Hygrometer Probe (Vaisala)	004685	16-Mar-18
<b>Material Name (Manufacturer)</b>	<b>Item Code</b>	<b>Expiration Date</b>
Polyurethane Film (McMaster-Carr)	1446T11	NA

**Table 5: Equipment and materials list.**

# TEST PROCEDURE

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## Needle Penetration

Samples were tested guided by DDL, Inc. test method TM9014-03.

Test sub-samples were mounted vertically in a universal tester. Polyurethane film was stretched over the film holder and clamped in place. A crosshead speed of fifty (50) mm/minute was used to insert the sub-samples through the film to a penetration distance of fifteen (15) mm. The peak force and the average drag force were recorded for each sample.

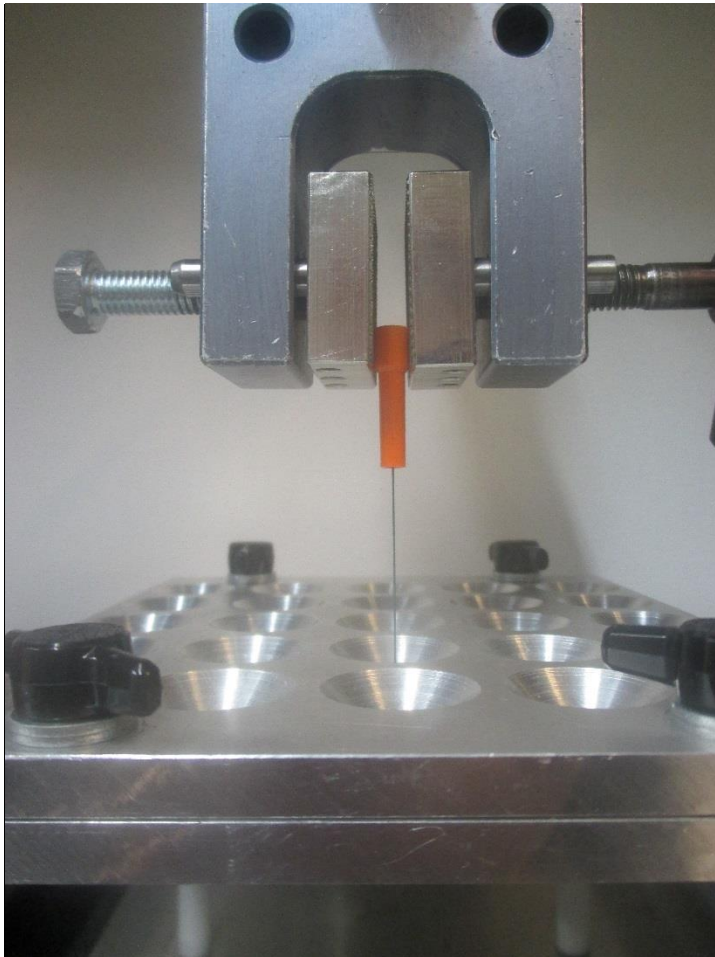


Figure 3: Typical needle penetration test setup.

A summary of the needle penetration testing can be found in the results portion of this test report and the test data is located in Appendix A.

Report No.	R1801012-01-00	Customer:	Ambu, Inc.	Page 6 of 9
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# DISCLAIMER OF WARRANTIES

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ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PRODUCT OR PACKAGING TESTED IS MERCHANTABILITY, FIT FOR A PARTICULAR PURPOSE, OR IN COMPLIANCE WITH ANY FEDERAL, STATE OR LOCAL REGULATIONS, ARE DISCLAIMED. In no event shall DDL, Inc. liability exceed the total amount paid by **Ambu, Inc.** for services rendered.

A Quality Assurance program should be in place to ensure that the manufacturing process produces products/packages of equivalent performance to those tested here. This is solely the responsibility of the manufacturer. DDL, Inc. takes no responsibility for the quality of products/packages produced hereafter, other than to certify the design of those physical test systems actually tested by DDL, Inc. DDL, Inc. takes no responsibility for the use, acceptance or non-acceptance of this data by government regulatory agencies.

In the event of future changes to the referenced test procedure(s), it is the responsibility of **Ambu, Inc.** to determine whether additional testing is necessary to verify that the product and/or packaging certified here remains in compliance with requirements.

This test report shall not be reproduced except in full, without written approval from DDL, Inc.

Report No.	R1801012-01-00	Customer:	Ambu, Inc.	Page 7 of 9
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Form 8278-04



# STATEMENT OF CONFORMITY

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DDL, Inc. has completed the above stated testing services performed in accordance to applicable standard good laboratory practices and/or standards identified within this report. Testing has been completed as described herein.

The following list of exceptions occurred during testing performed at DDL, Inc.:

- *None*

All materials, equipment, methods, and processes used to perform the described testing have been standardized, calibrated, and monitored in accordance with prescribed guidelines, standard operating procedures, and the supervision requirements of DDL, Inc. All raw data obtained from this testing by DDL, Inc. personnel is archived at DDL, Inc.

The signatures below are in compliance with 21 CFR Part 11.

Testing performed by: Dylan D. Peterson & Matt C. Castor

Project Manager: \_\_\_\_\_

Technical Approval: \_\_\_\_\_

Quality Approval: \_\_\_\_\_

Report No.	R1801012-01-00	Customer:	Ambu, Inc.	Page 8 of 9
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Form 8278-04

# APPENDIX A: NEEDLE PENETRATION

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Report No.	R1801012-01-00	Customer:	Ambu, Inc.	Page 9 of 9
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Form 8278-04



Tested and Proven.

Customer: Ambu, Inc.

P.O.: Signed Quote

J/N: 1801012

Product: Monopolar Needles

Test Method: Guided by TM9014-03

Needle Penetration Testing

Compiled By: ART 9-Feb-18  
 Project Manager: ART Date  
 Test Technician: DDP, MCC  
 Test Dates: 31-Jan-18 5-Feb-18  
 Start End

**Machine Parameters:**

Crosshead Speed: 50 mm/min  
 Penetration Distance: 15 mm  
 Rate Verification: DDP

**EQUIPMENT USED**

Universal Tester: Instron 5967 Asset #: 004366 Cal Due: 11-Jan-19 Test Approval:  
 Load Cell: 100N Asset #: 005016 Cal Due: 11-Jan-19 Initials: ART  
 Load Cell Verification: DDP Date: 31-Jan-18  
 Hygrometer Probe: Vaisala Asset #: 004685 Cal Due: 16-Mar-18

**MATERIALS USED**

Polyurethane Film: McMaster-Carr Item Code: 1446T11 Exp. Date NA Photos:  
 Lab Conditions: 23 ± 2°C @ 50 ± 5%RH Setup: X  
 Procedure: —

Ambu/Neuroline Monopolar		Needle Size: 38mm x 28G	
REF #: 74238-36/40		Lot #: 1000006830	
DDL Sample Number	DDL Sub-Sample Number	Peak Force (N)	Average Drag Force (N)
001	1	0.451	0.099
	2	0.399	0.078
	3	0.364	0.086
	4	0.427	0.099
	5	0.517	0.094
	6	0.375	0.082
	7	0.397	0.104
	8	0.431	0.096
	9	0.372	0.101
	10	0.449	0.108
	11	0.380	0.094
	12	0.395	0.120
	13	0.380	0.090
	14	0.577	0.096
	15	0.468	0.088
	16	0.449	0.079



Ambu/Neuroline Monopolar		Needle Size: 38mm x 28G	
REF #: 74238-36/40		Lot #: 1000006830	
DDL Sample Number	DDL Sub-Sample Number	Peak Force (N)	Average Drag Force (N)
001	17	0.394	0.098
	18	0.512	0.087
	19	0.387	0.104
	20	0.441	0.108
	21	0.437	0.090
	22	0.427	0.099
	23	0.352	0.089
	24	0.448	0.098
	25	0.668	0.091
	26	0.421	0.090
	27	0.417	0.082
	28	0.398	0.094
	29	0.438	0.084
	30	0.544	0.076
	31	0.425	0.087
	32	0.382	0.091
	33	0.454	0.090
	34	0.361	0.084
	35	0.409	0.079
	36	0.401	0.098
	37	0.405	0.091
	38	0.400	0.078
	39	0.446	0.085
	40	0.372	0.100
	41	0.389	0.083
	42	0.425	0.083
	43	0.449	0.096
	44	0.377	0.102
	45	0.400	0.085
	46	0.387	0.082
	47	0.383	0.086
	48	0.492	0.087
	49	0.449	0.086
	50	0.523	0.075
	<b>Minimum:</b>	0.352	0.075
	<b>Maximum:</b>	0.668	0.120
	<b>Average:</b>	0.429	0.091
	<b>Std. Dev:</b>	0.060	0.009



Natus / TECA		Needle Size: 37mm x 28G	
REF #: 902-DMF37-TP		Lot #: U1709G10	
DDL Sample Number	DDL Sub-Sample Number	Peak Force (N)	Average Drag Force (N)
002	1	0.827	0.286
	2	1.108	0.296
	3	1.134	0.381
	4	1.008	0.419
	5	1.138	0.434
	6	1.025	0.446
	7	1.020	0.464
	8	0.981	0.398
	9	0.987	0.410
	10	1.091	0.442
	11	1.156	0.368
	12	1.132	0.412
	13	1.207	0.421
	14	0.941	0.398
	15	1.095	0.413
	16	1.150	0.418
	17	1.151	0.386
	18	1.023	0.363
	19	1.016	0.436
	20	0.957	0.393
	21	1.001	0.396
	22	1.052	0.404
	23	0.823	0.304
	24	0.899	0.403
	25	0.960	0.406
	26	1.025	0.420
	27	0.952	0.464
	28	0.895	0.450
	29	1.078	0.412
	30	1.005	0.480
	31	1.050	0.483
	32	1.076	0.360
	33	1.154	0.433
	34	1.050	0.470
	35	1.115	0.417
	36	0.984	0.422
	37	1.065	0.428
	38	1.093	0.407
	39	1.186	0.425
	40	1.125	0.475



Natus / TECA		Needle Size: 37mm x 28G	
REF #: 902-DMF37-TP		Lot #: U1709G10	
DDL Sample Number	DDL Sub-Sample Number	Peak Force (N)	Average Drag Force (N)
002	41	1.177	0.425
	42	1.144	0.425
	43	0.823	0.381
	44	0.977	0.438
	45	0.904	0.431
	46	1.035	0.449
	47	1.027	0.435
	48	0.937	0.428
	49	0.881	0.462
	50	0.915	0.329
	<b>Minimum:</b>	0.823	0.286
	<b>Maximum:</b>	1.207	0.483
	<b>Average:</b>	1.031	0.413
	<b>Std. Dev:</b>	0.099	0.044

Natus / TECA Elite		Needle Size: 37mm x 28G	
REF #: 902-DMF37-S		Lot #: G1708G08	
DDL Sample Number	DDL Sub-Sample Number	Peak Force (N)	Average Drag Force (N)
003	1	0.915	0.196
	2	0.792	0.188
	3	0.890	0.211
	4	0.851	0.188
	5	0.841	0.198
	6	0.815	0.210
	7	0.754	0.192
	8	0.766	0.205
	9	0.756	0.187
	10	0.900	0.186
	11	0.831	0.179
	12	0.822	0.196
	13	0.781	0.208
	14	0.794	0.200
	15	0.810	0.195
	16	0.846	0.193
	17	0.911	0.181
	18	0.879	0.198
	19	0.874	0.201
	20	0.807	0.183



Natus / TECA Elite		Needle Size: 37mm x 28G	
REF #: 902-DMF37-S		Lot #: G1708G08	
DDL Sample Number	DDL Sub-Sample Number	Peak Force (N)	Average Drag Force (N)
003	21	0.837	0.187
	22	0.892	0.185
	23	0.872	0.188
	24	0.837	0.188
	25	0.869	0.202
	26	0.873	0.178
	27	0.811	0.201
	28	0.803	0.190
	29	0.840	0.186
	30	0.881	0.180
	31	1.010	0.201
	32	0.754	0.192
	33	0.771	0.205
	34	0.785	0.206
	35	0.800	0.200
	36	0.769	0.194
	37	0.805	0.198
	38	0.800	0.182
	39	0.861	0.216
	40	0.908	0.191
	41	0.891	0.181
	42	0.850	0.187
	43	0.807	0.201
	44	0.886	0.199
	45	0.950	0.200
	46	0.930	0.189
	47	0.891	0.189
	48	0.968	0.203
	49	0.845	0.206
	50	0.821	0.192
<b>Minimum:</b>		0.754	0.178
<b>Maximum:</b>		1.010	0.216
<b>Average:</b>		0.845	0.194
<b>Std. Dev:</b>		0.058	0.009



Customer	Ambu, Inc.
P.O. #	Signed Quote
Project #	1801012
Test Method	TM9014-03
Product	Monopolar Needle
Manufacturer	Ambu
Product Name	Neuroline Monopolar
Needle Size	38mm X 28G
DDL Sample #	001
Test Frame Asset #	004366
Load Cell Asset #	005016
Crosshead Speed	50 mm/min
Lab Conditions	23±2°C @ 50±5%RH
Technician	DDP

	DDL Sub-Sample #	Peak Force [N]	Average Drag Force [N]
1	1	0.451	0.099
2	2	0.399	0.078
3	3	0.364	0.086
4	4	0.427	0.099
5	5	0.517	0.094
6	6	0.375	0.082
7	7	0.397	0.104
8	8	0.431	0.096
9	9	0.372	0.101
10	10	0.449	0.108
11	11	0.380	0.094
12	12	0.395	0.120
13	13	0.380	0.090
14	14	0.577	0.096
15	15	0.468	0.088
16	16	0.449	0.079
17	17	0.394	0.098
18	18	0.512	0.087
19	19	0.387	0.104
20	20	0.441	0.108
21	21	0.437	0.090
22	22	0.427	0.099
23	23	0.352	0.089
24	24	0.448	0.098
25	25	0.668	0.091
26	26	0.421	0.090
27	27	0.417	0.082
28	28	0.398	0.094
29	29	0.438	0.084
30	30	0.544	0.076
31	31	0.425	0.087
32	32	0.382	0.091
33	33	0.454	0.090
34	34	0.361	0.084
35	35	0.409	0.079
36	36	0.401	0.098
37	37	0.405	0.091

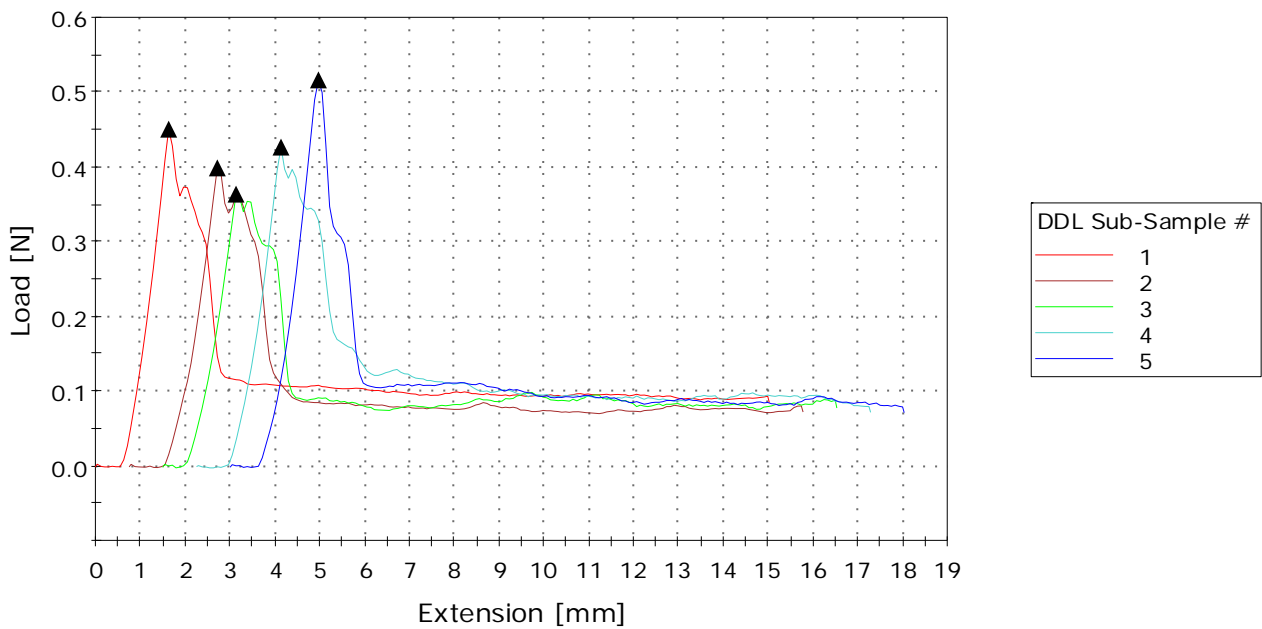




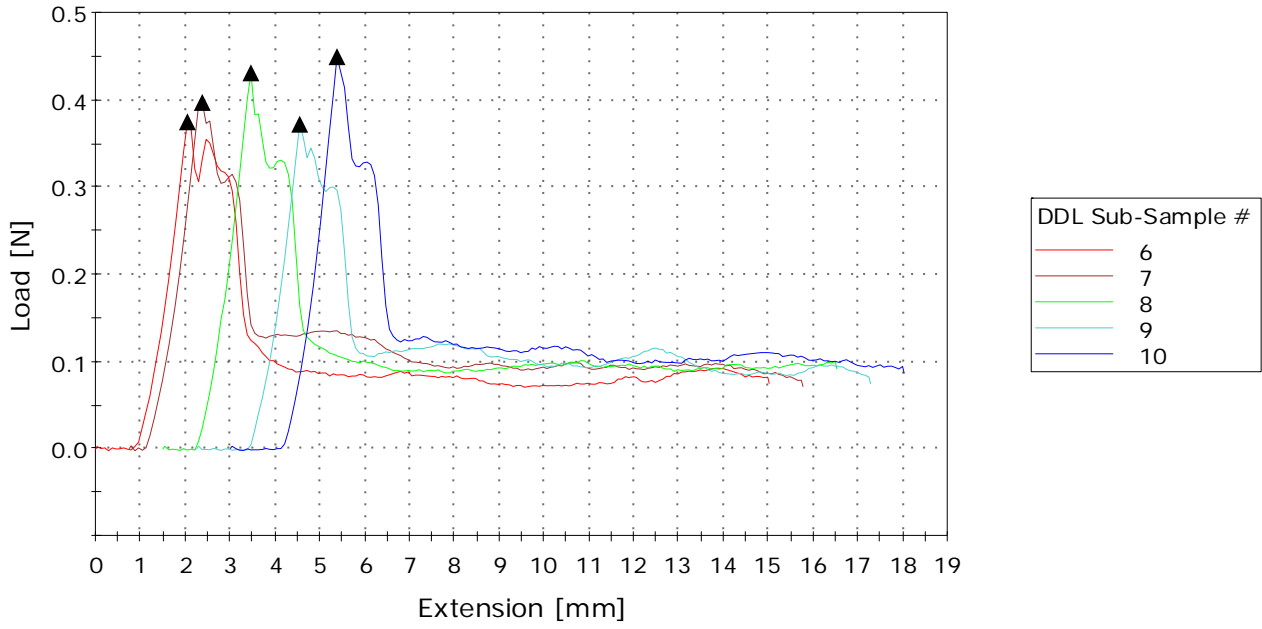
Tested and Proven.

	DDL Sub-Sample #	Peak Force [N]	Average Drag Force [N]
38	38	0.400	0.078
39	39	0.446	0.085
40	40	0.372	0.100
41	41	0.389	0.083
42	42	0.425	0.083
43	43	0.449	0.096
44	44	0.377	0.102
45	45	0.400	0.085
46	46	0.387	0.082
47	47	0.383	0.086
48	48	0.492	0.087
49	49	0.449	0.086
50	50	0.523	0.075
Minimum		0.352	0.075
Maximum		0.668	0.120
Mean		0.429	0.091
Standard deviation		0.060	0.009

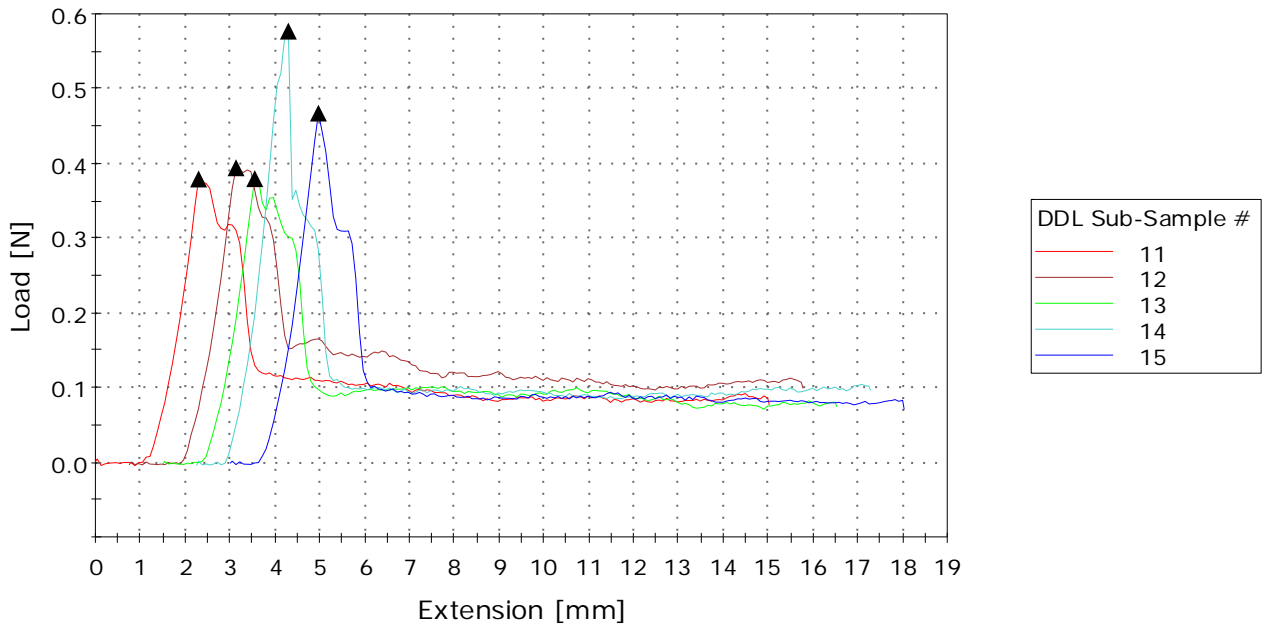
DDL Sample #001



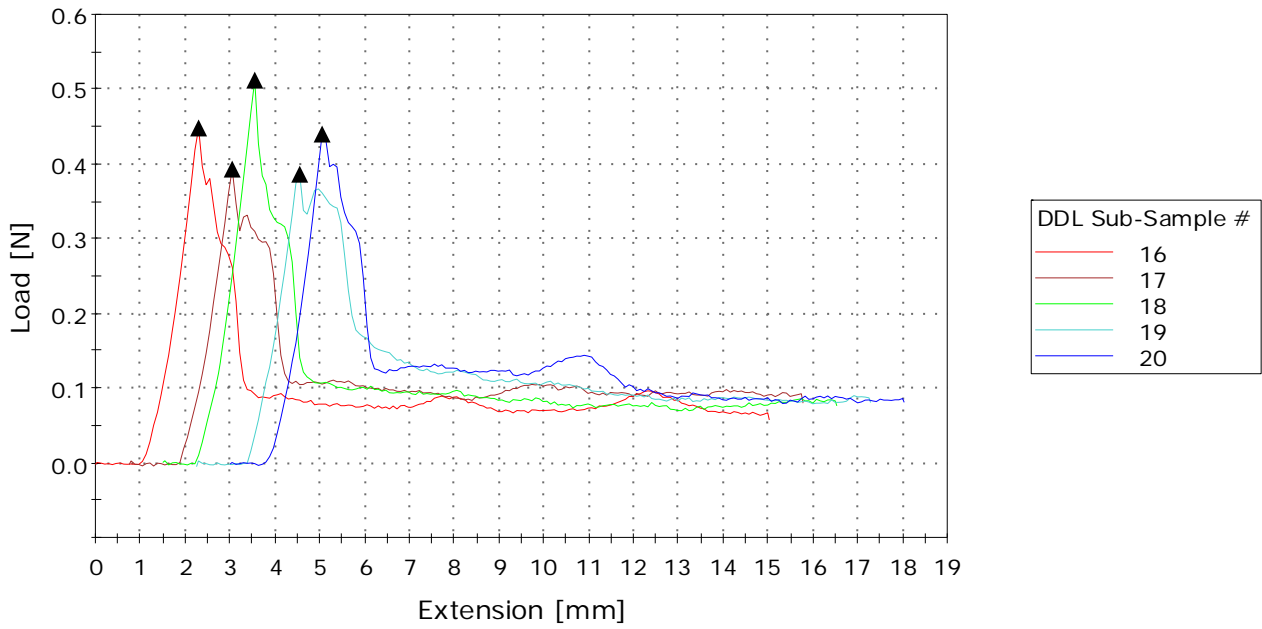
DDL Sample #001



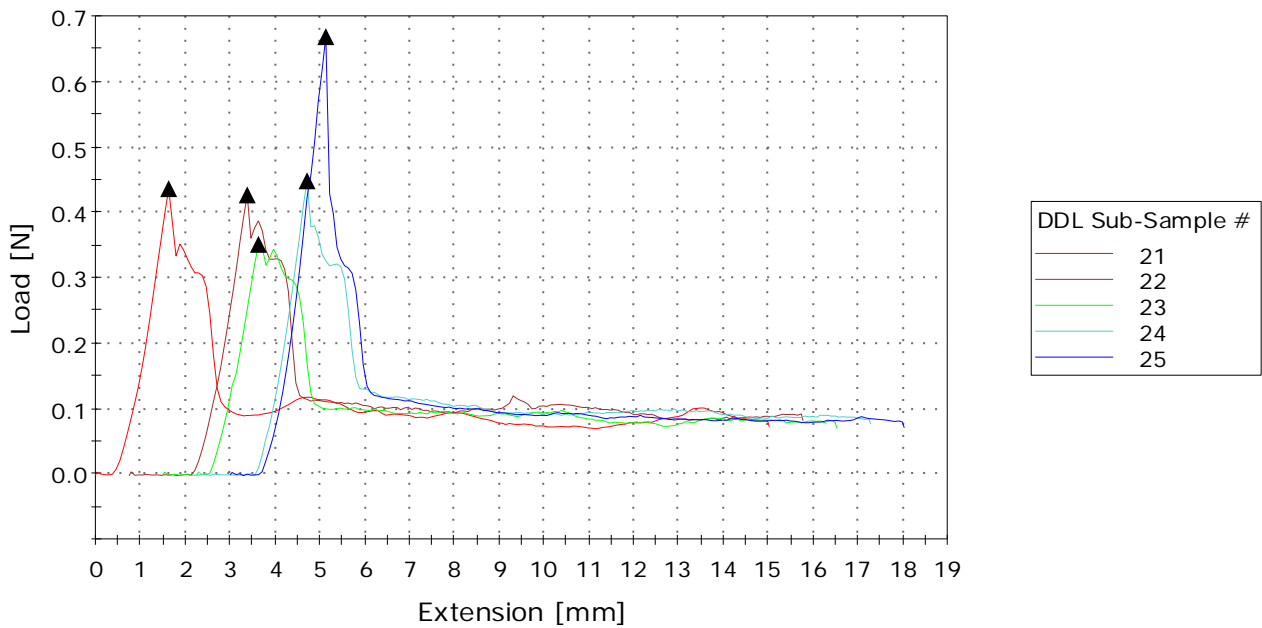
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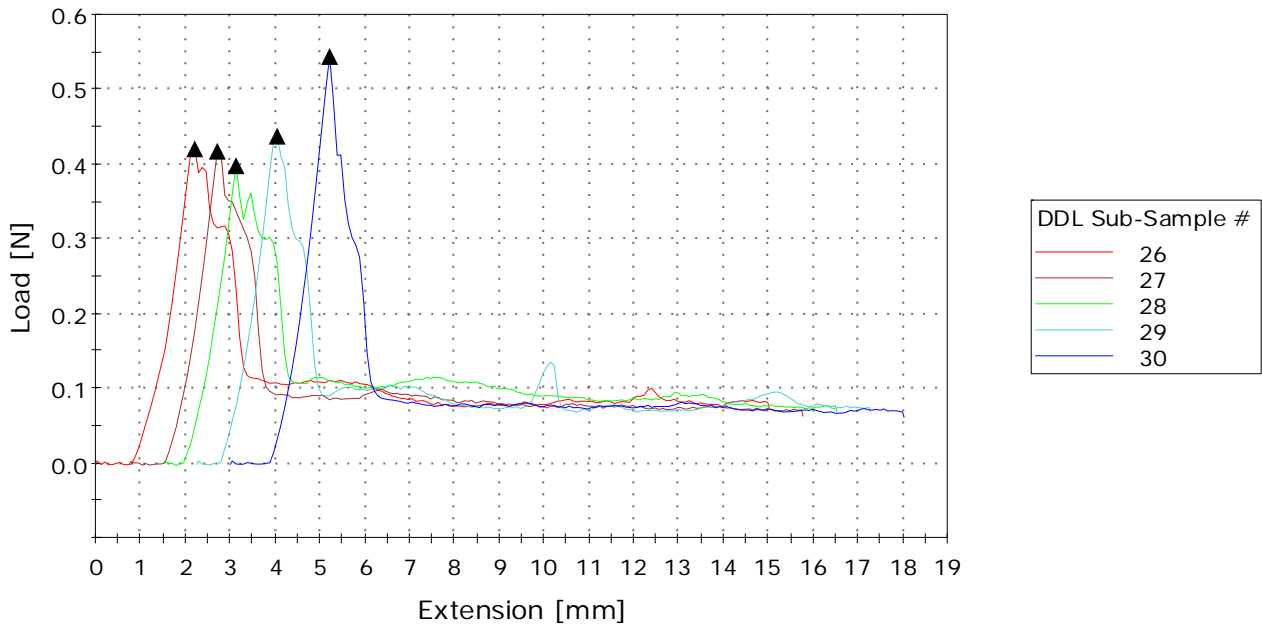
DDL Sample #001



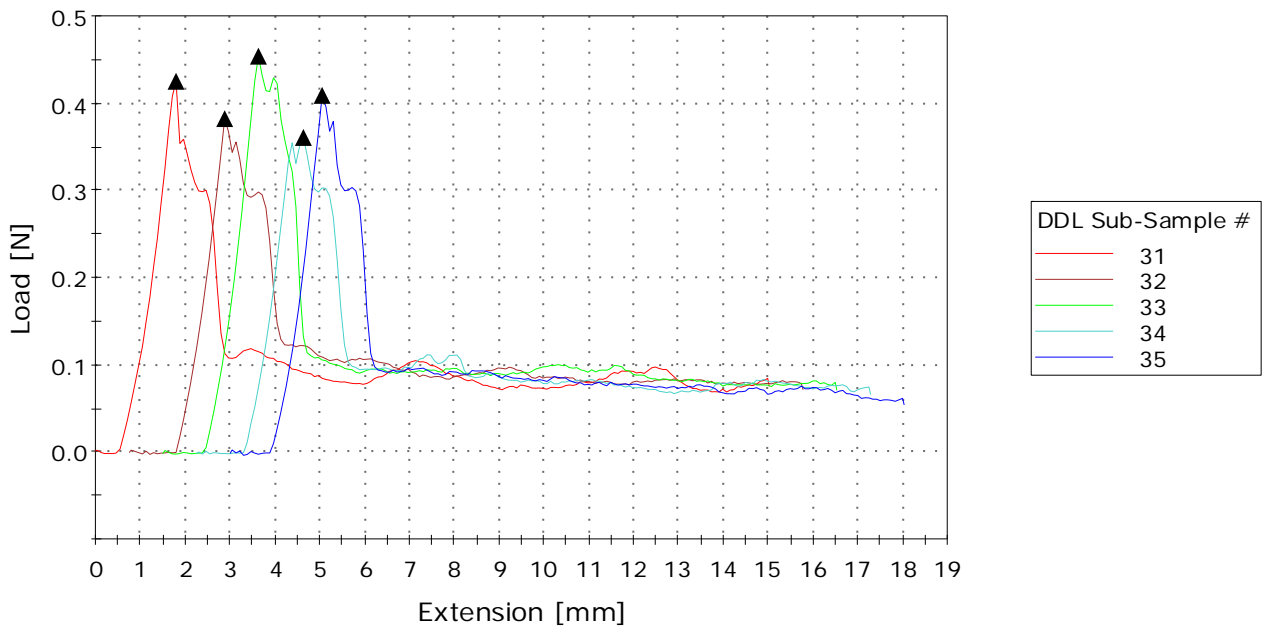
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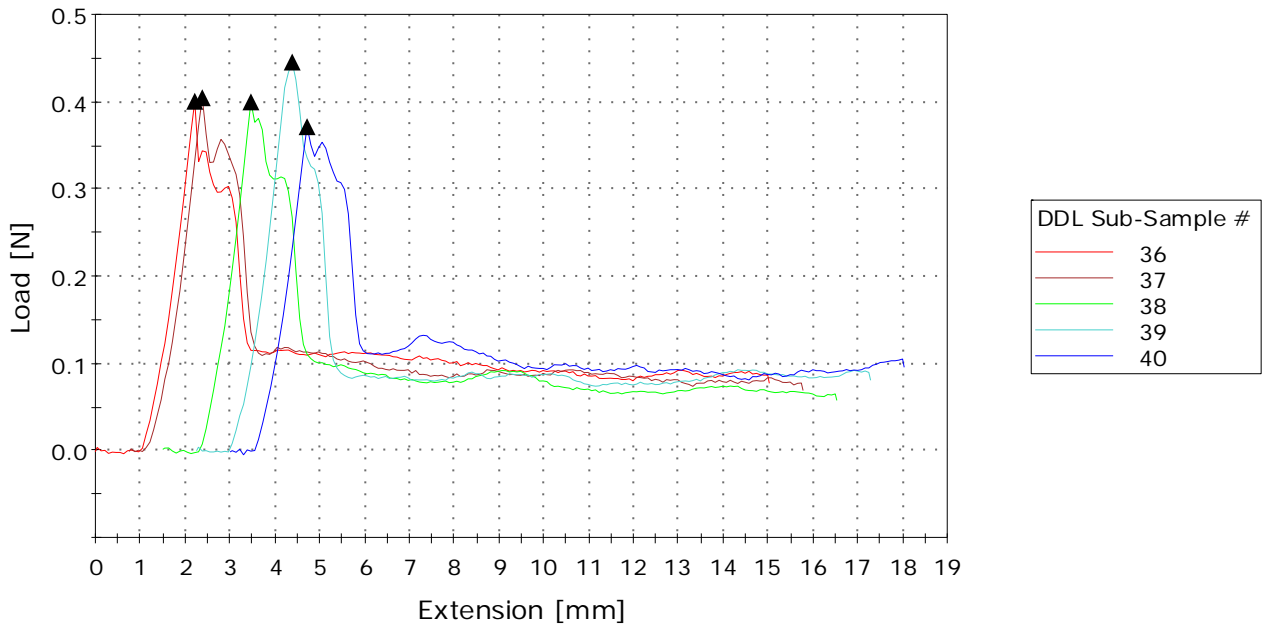
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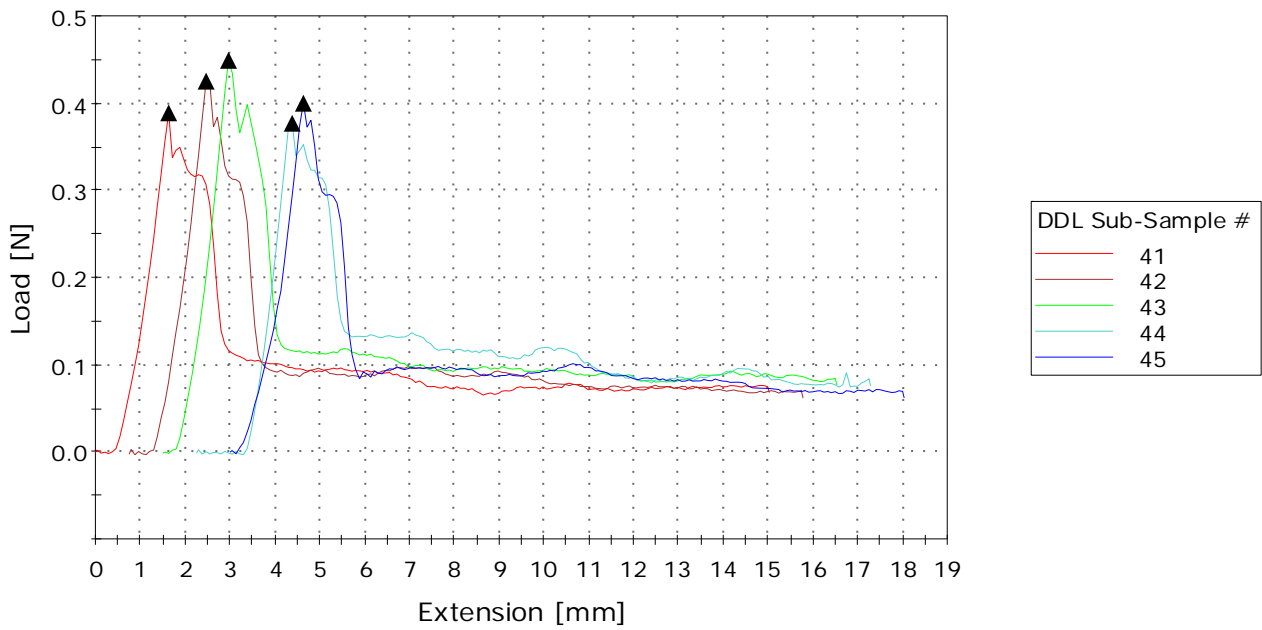
### DDL Sample #001



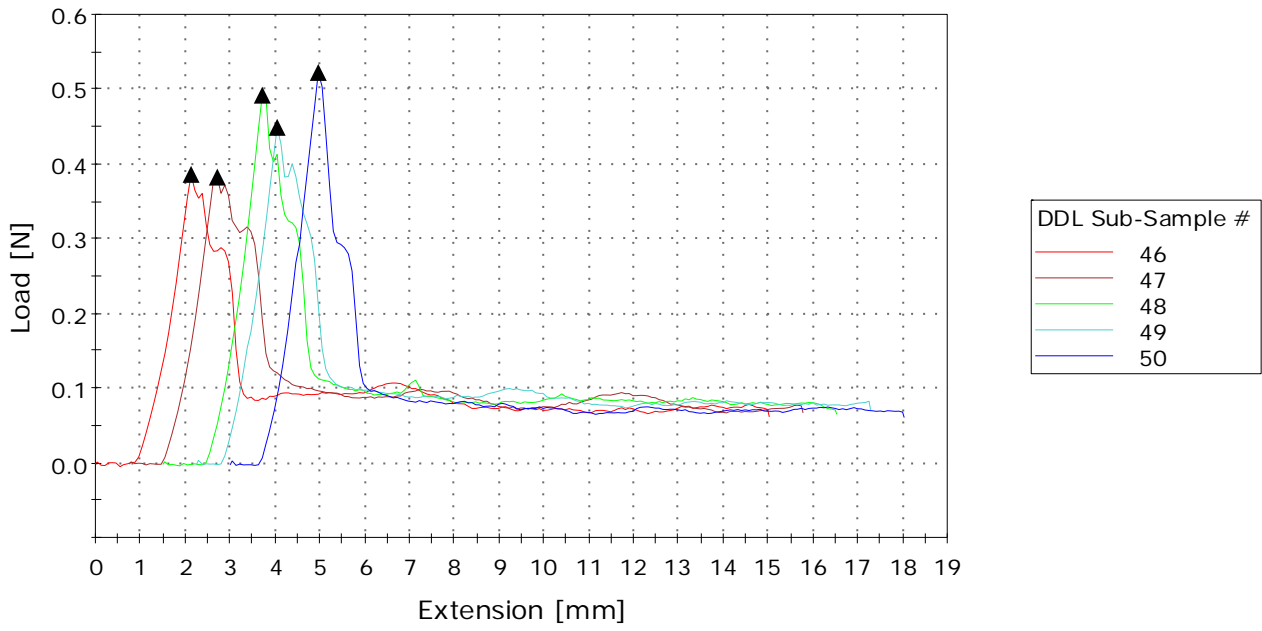
DDL Sample #001



DDL Sample #001



DDL Sample #001





Customer	Ambu, Inc.
P.O. #	Signed Quote
Project #	1801012
Test Method	TM9014-03
Product	Monopolar Needle
Manufacturer	Natus
Product Name	TECA
Needle Size	37mm X 28G
DDL Sample #	002
Test Frame Asset #	004366
Load Cell Asset #	005016
Crosshead Speed	50 mm/min
Lab Conditions	23±2°C @ 50±5%RH
Technician	DDP, MCC

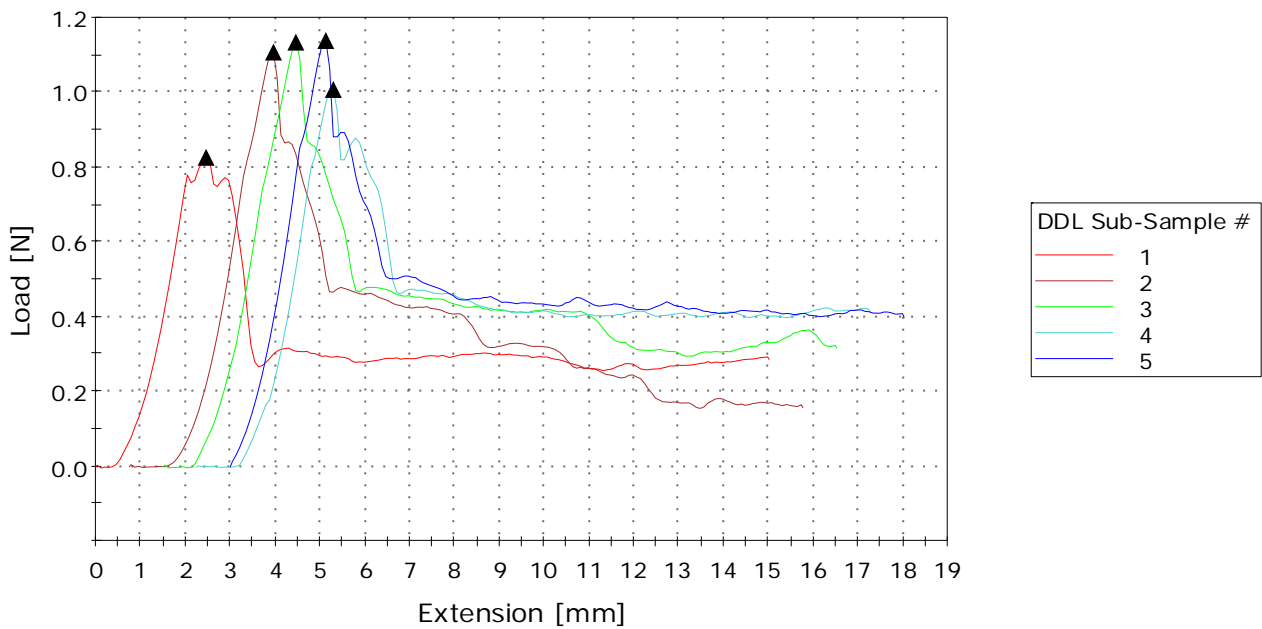
	DDL Sub-Sample #	Peak Force [N]	Average Drag Force [N]
1	1	0.827	0.286
2	2	1.108	0.296
3	3	1.134	0.381
4	4	1.008	0.419
5	5	1.138	0.434
6	6	1.025	0.446
7	7	1.020	0.464
8	8	0.981	0.398
9	9	0.987	0.410
10	10	1.091	0.442
11	11	1.156	0.368
12	12	1.132	0.412
13	13	1.207	0.421
14	14	0.941	0.398
15	15	1.095	0.413
16	16	1.150	0.418
17	17	1.151	0.386
18	18	1.023	0.363
19	19	1.016	0.436
20	20	0.957	0.393
21	21	1.001	0.396
22	22	1.052	0.404
23	23	0.823	0.304
24	24	0.899	0.403
25	25	0.960	0.406
26	26	1.025	0.420
27	27	0.952	0.464
28	28	0.895	0.450
29	29	1.078	0.412
30	30	1.005	0.480
31	31	1.050	0.483
32	32	1.076	0.360
33	33	1.154	0.433
34	34	1.050	0.470
35	35	1.115	0.417
36	36	0.984	0.422
37	37	1.065	0.428



Tested and Proven.

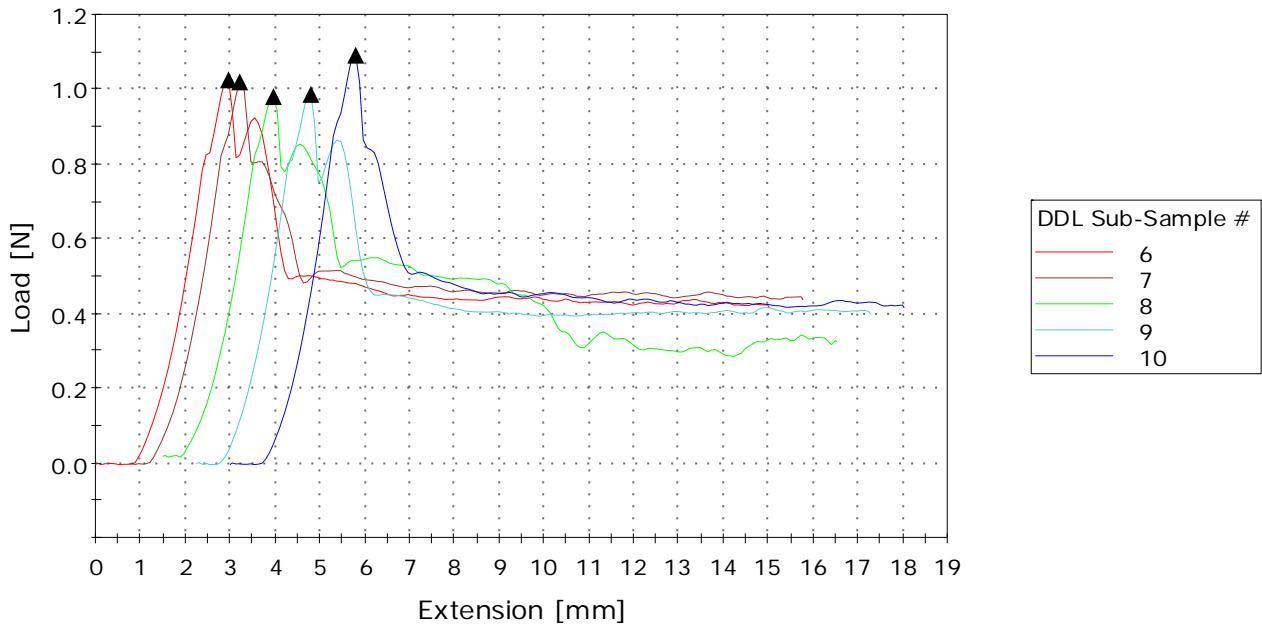
	DDL Sub-Sample #	Peak Force [N]	Average Drag Force [N]
38	38	1.093	0.407
39	39	1.186	0.425
40	40	1.125	0.475
41	41	1.177	0.425
42	42	1.144	0.425
43	43	0.823	0.381
44	44	0.977	0.438
45	45	0.904	0.431
46	46	1.035	0.449
47	47	1.027	0.435
48	48	0.937	0.428
49	49	0.881	0.462
50	50	0.915	0.329
Minimum		0.823	0.286
Maximum		1.207	0.483
Mean		1.031	0.413
Standard deviation		0.099	0.044

DDL Sample #002

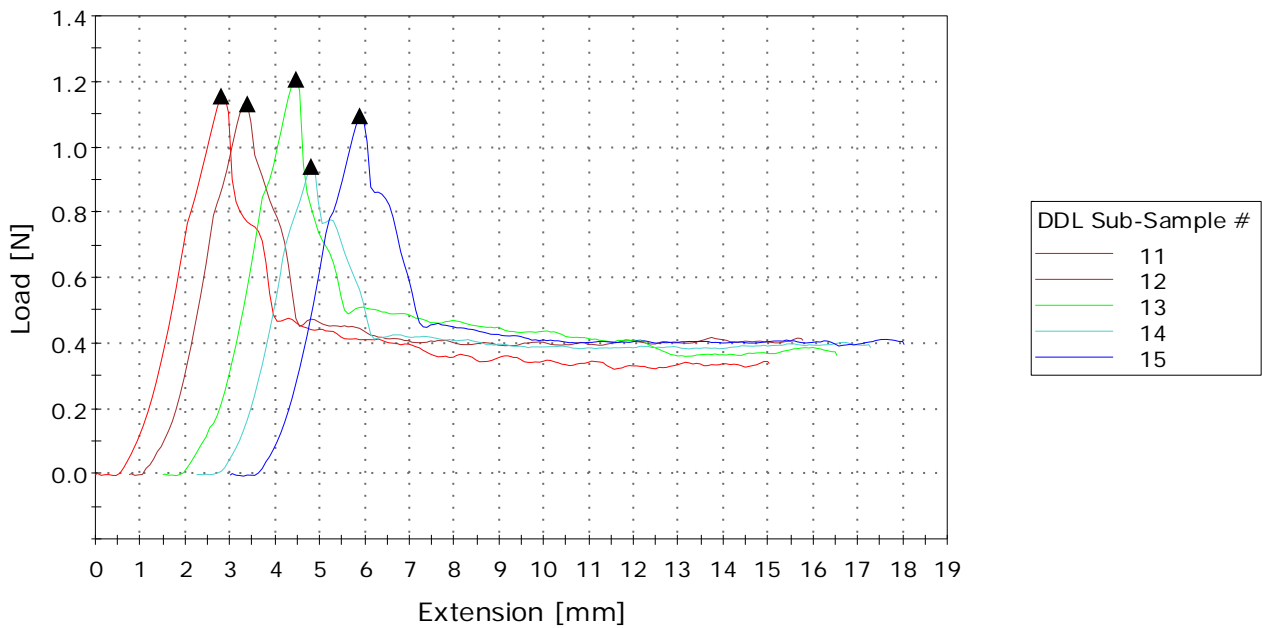




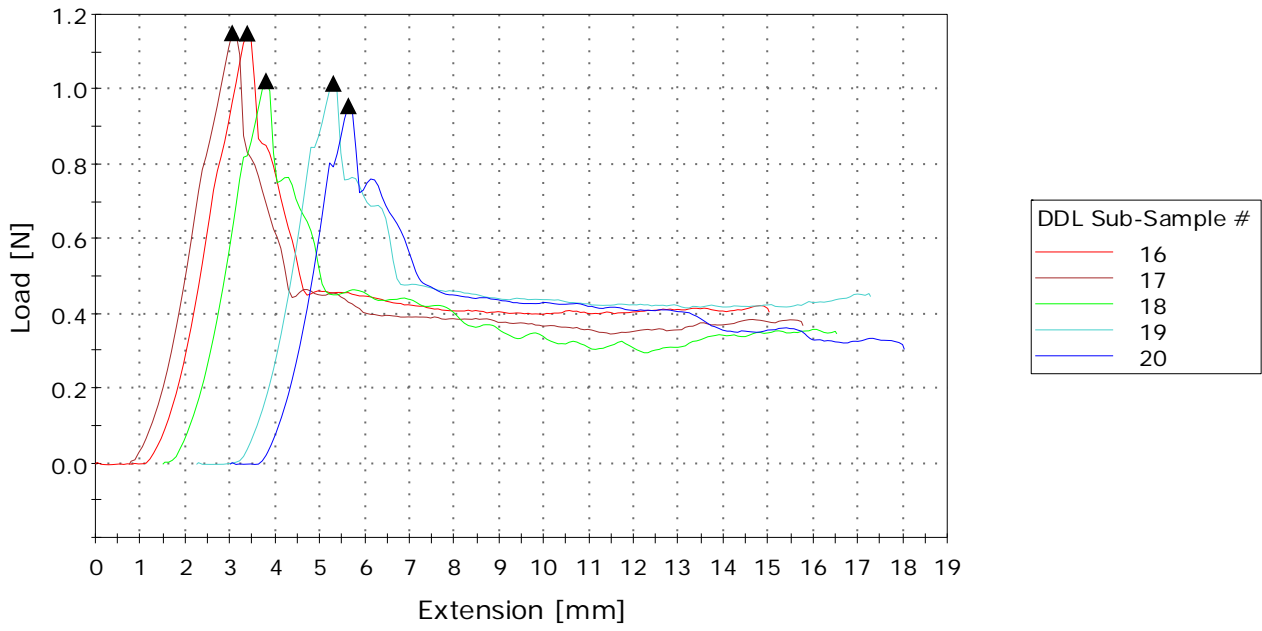
DDL Sample #002



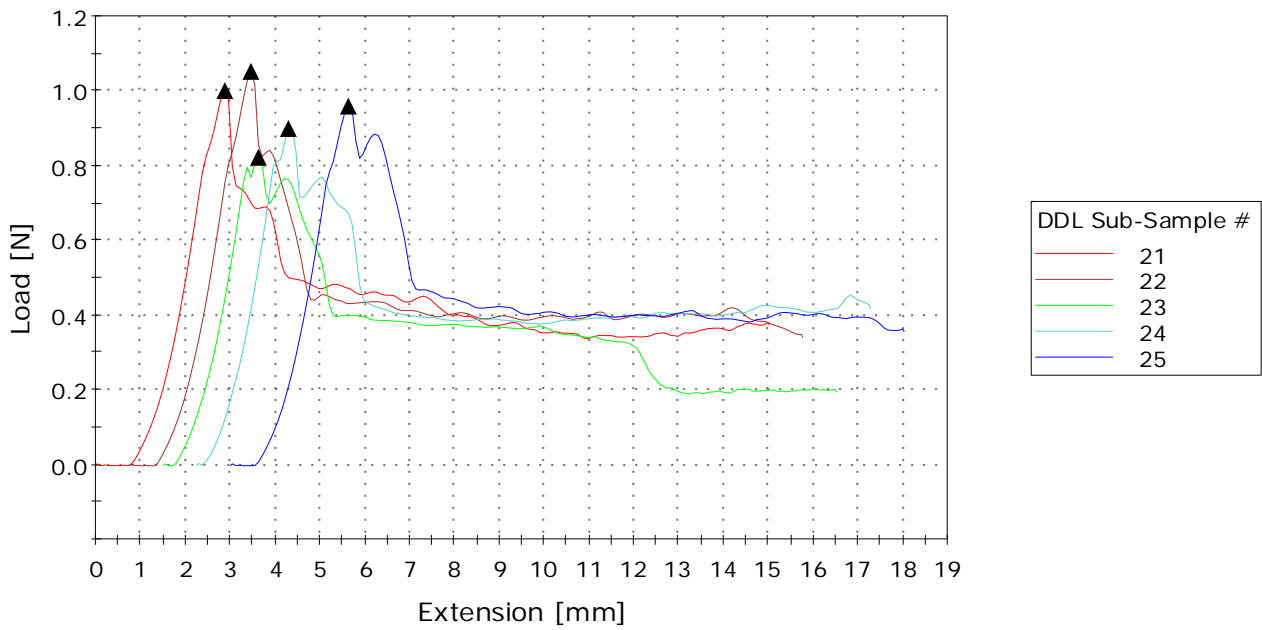
DDL Sample #002



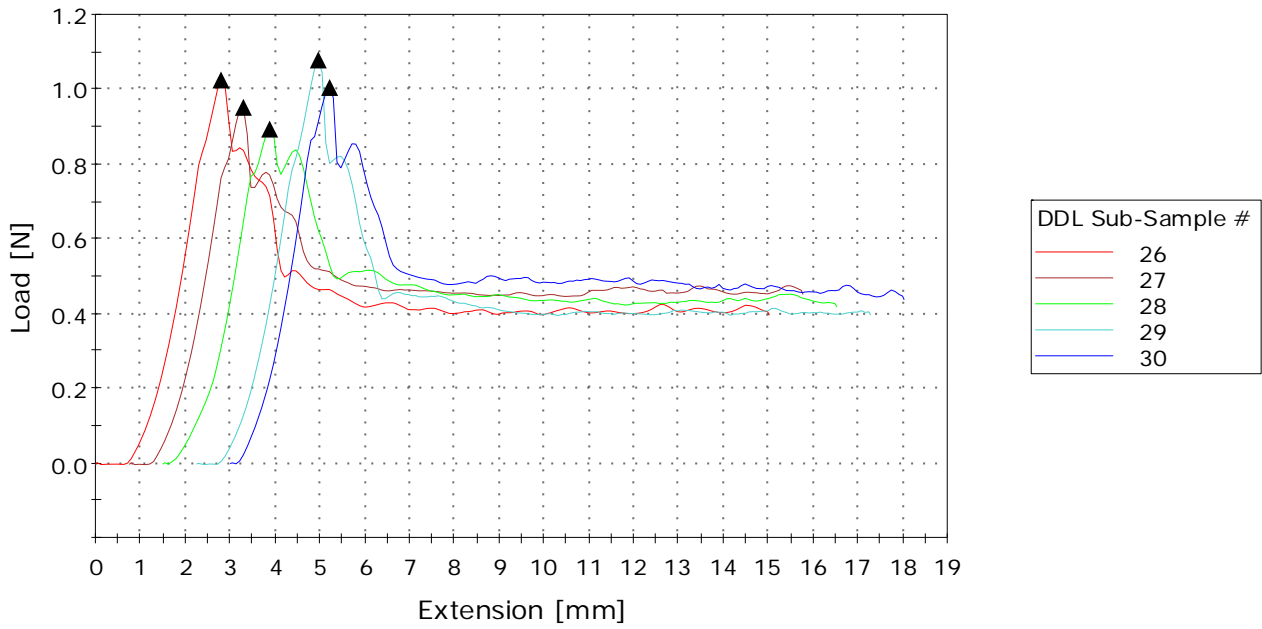
DDL Sample #002



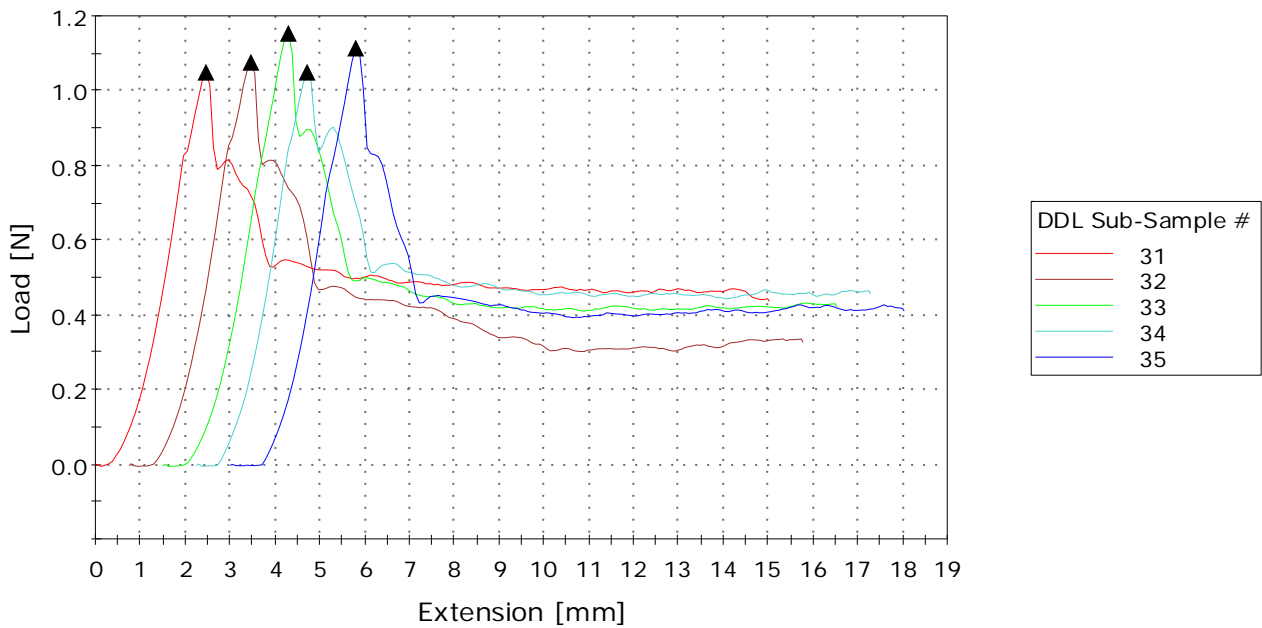
DDL Sample #002



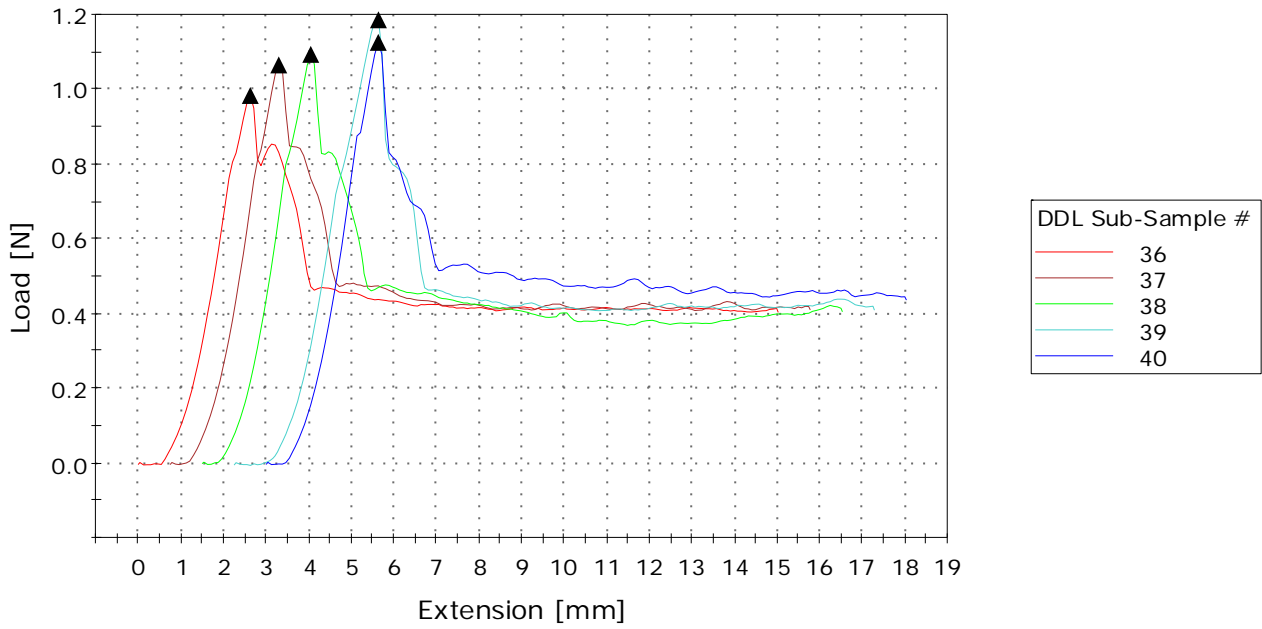
DDL Sample #002



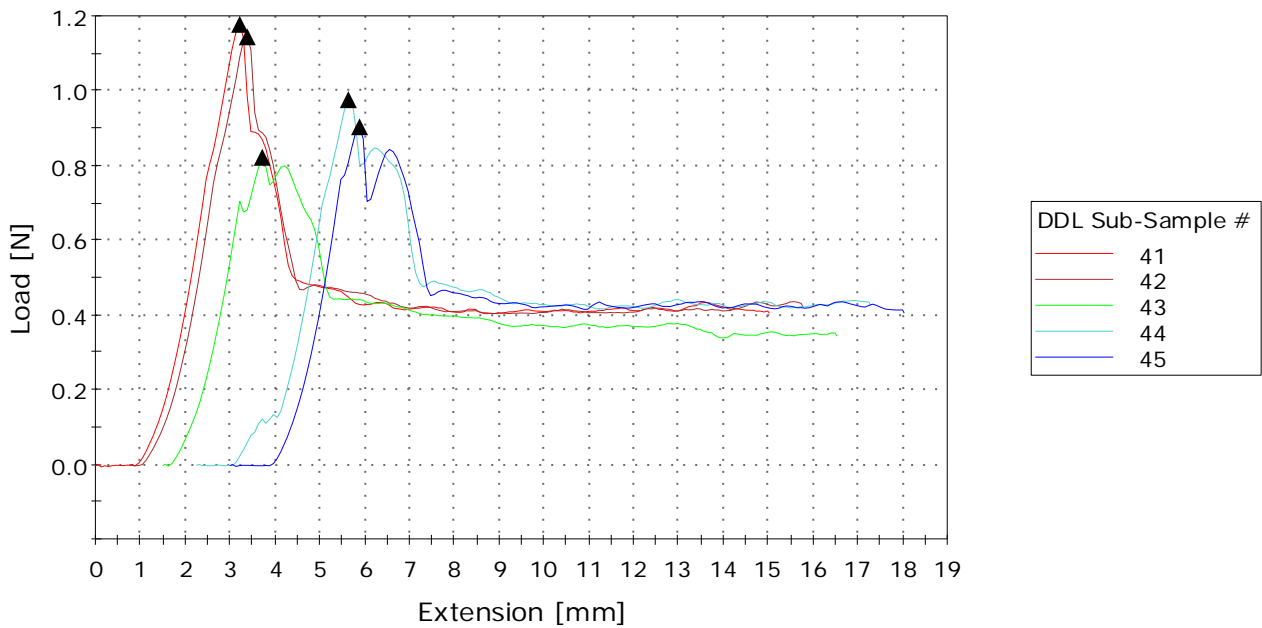
DDL Sample #002



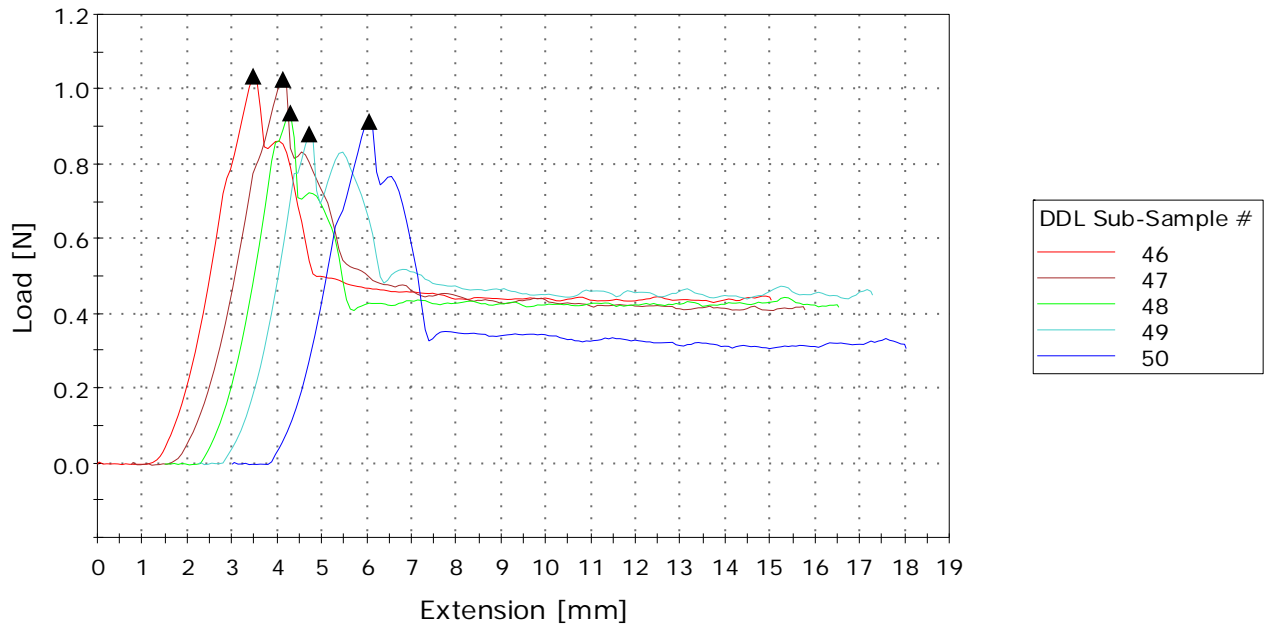
DDL Sample #002



DDL Sample #002



DDL Sample #002





Customer	Ambu, Inc.
P.O. #	Signed Quote
Project #	1801012
Test Method	TM9014-03
Product	Monopolar Needle
Manufacturer	Natus
Product Name	TECA Elite
Needle Size	37mm X 28G
DDL Sample #	003
Test Frame Asset #	004366
Load Cell Asset #	005016
Crosshead Speed	50 mm/min
Lab Conditions	23±2°C @ 50±5%RH
Technician	MCC

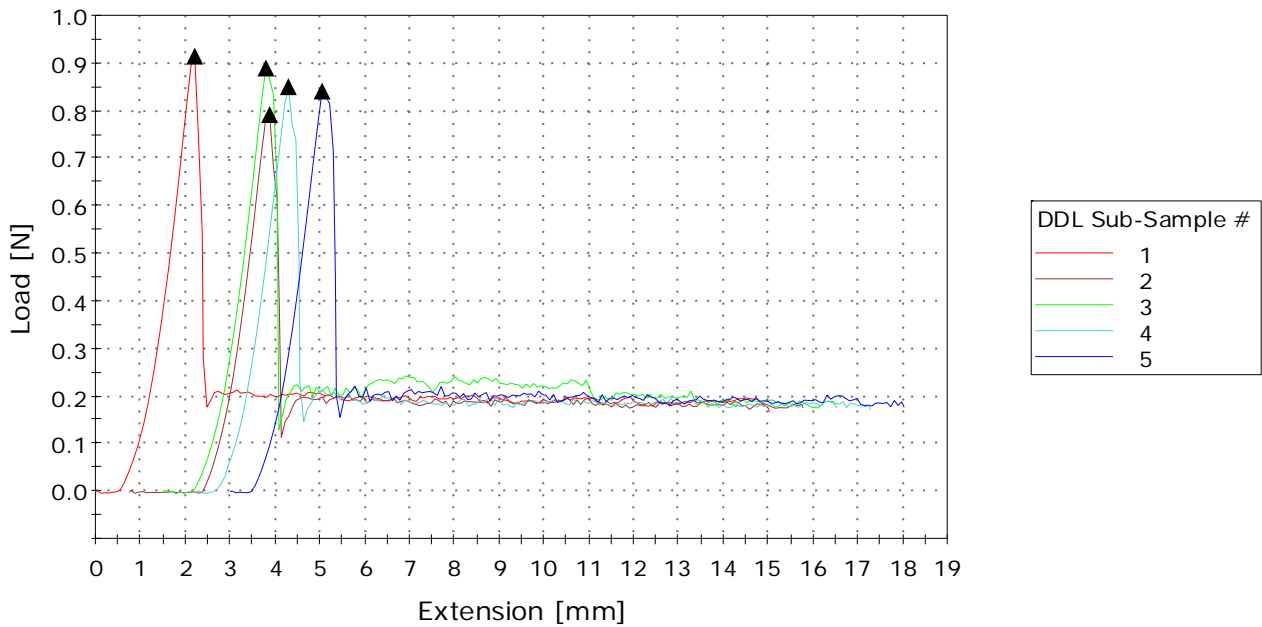
	DDL Sub-Sample #	Peak Force [N]	Average Drag Force [N]
1	1	0.915	0.196
2	2	0.792	0.188
3	3	0.890	0.211
4	4	0.851	0.188
5	5	0.841	0.198
6	6	0.815	0.210
7	7	0.754	0.192
8	8	0.766	0.205
9	9	0.756	0.187
10	10	0.900	0.186
11	11	0.831	0.179
12	12	0.822	0.196
13	13	0.781	0.208
14	14	0.794	0.200
15	15	0.810	0.195
16	16	0.846	0.193
17	17	0.911	0.181
18	18	0.879	0.198
19	19	0.874	0.201
20	20	0.807	0.183
21	21	0.837	0.187
22	22	0.892	0.185
23	23	0.872	0.188
24	24	0.837	0.188
25	25	0.869	0.202
26	26	0.873	0.178
27	27	0.811	0.201
28	28	0.803	0.190
29	29	0.840	0.186
30	30	0.881	0.180
31	31	1.010	0.201
32	32	0.754	0.192
33	33	0.771	0.205
34	34	0.785	0.206
35	35	0.800	0.200
36	36	0.769	0.194
37	37	0.805	0.198



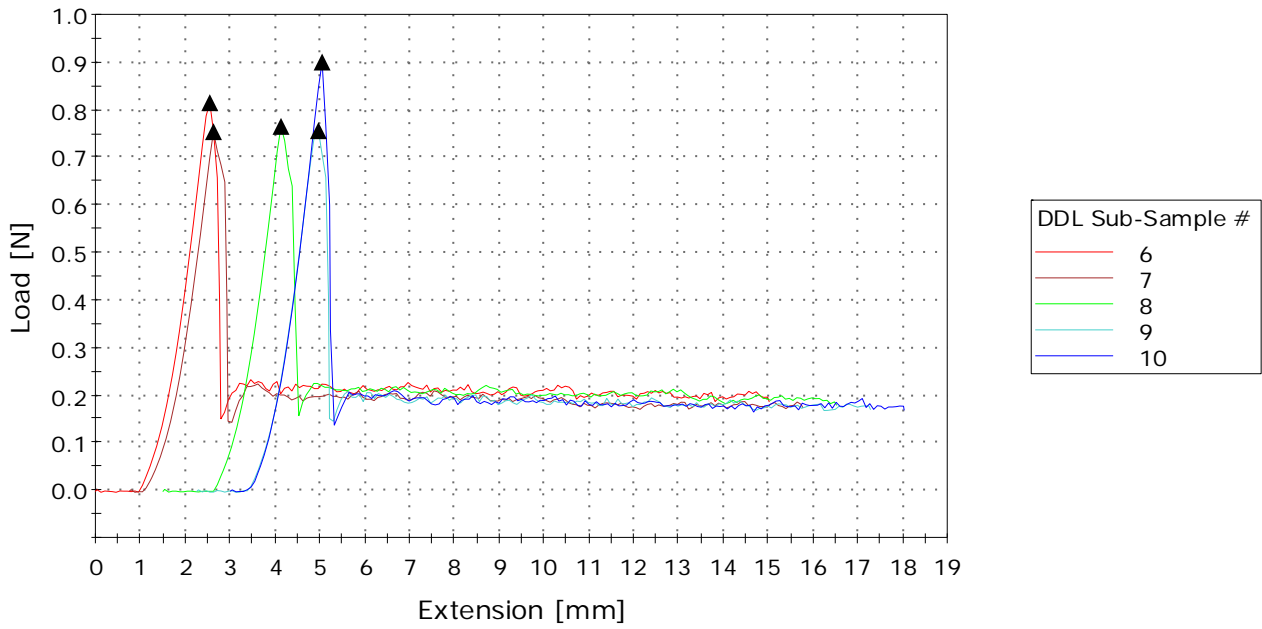
Tested and Proven.

	DDL Sub-Sample #	Peak Force [N]	Average Drag Force [N]
38	38	0.800	0.182
39	39	0.861	0.216
40	40	0.908	0.191
41	41	0.891	0.181
42	42	0.850	0.187
43	43	0.807	0.201
44	44	0.886	0.199
45	45	0.950	0.200
46	46	0.930	0.189
47	47	0.891	0.189
48	48	0.968	0.203
49	49	0.845	0.206
50	50	0.821	0.192
Minimum		0.754	0.178
Maximum		1.010	0.216
Mean		0.845	0.194
Standard deviation		0.058	0.009

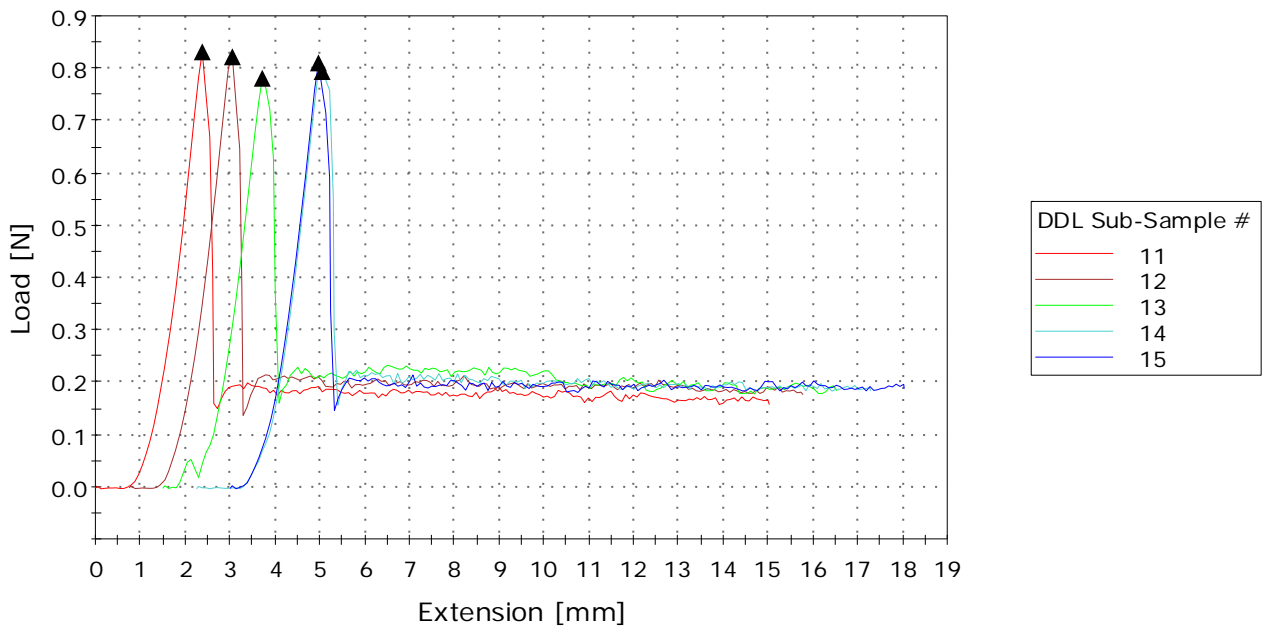
DDL Sample #003



DDL Sample #003

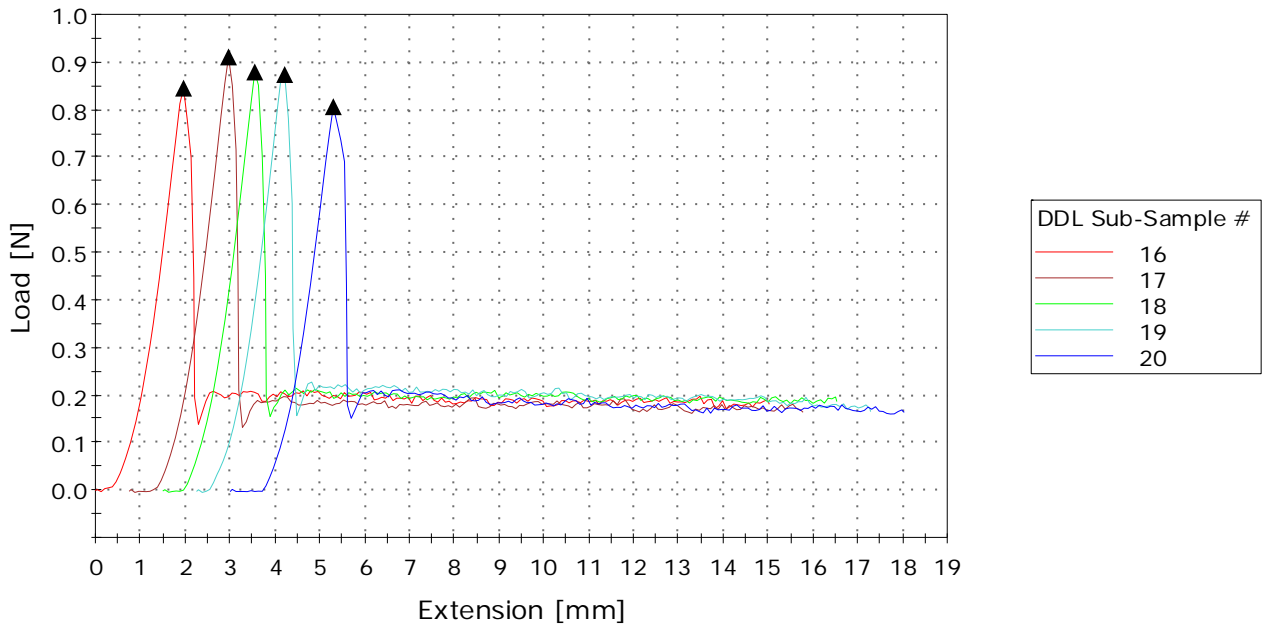


DDL Sample #003

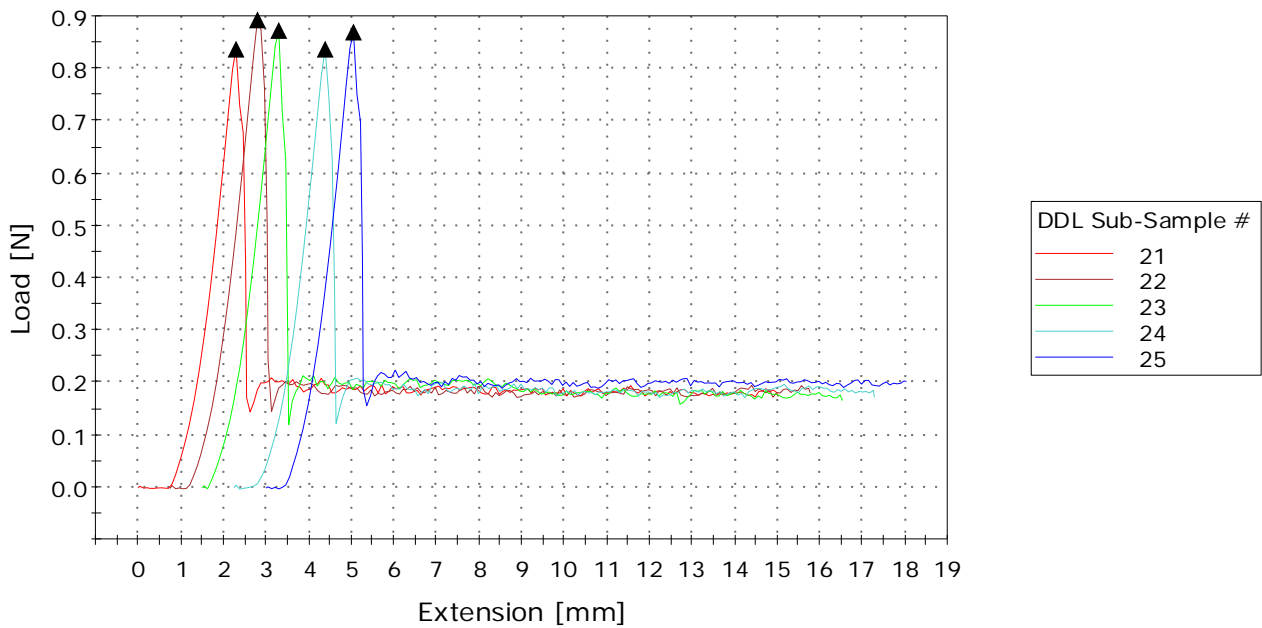




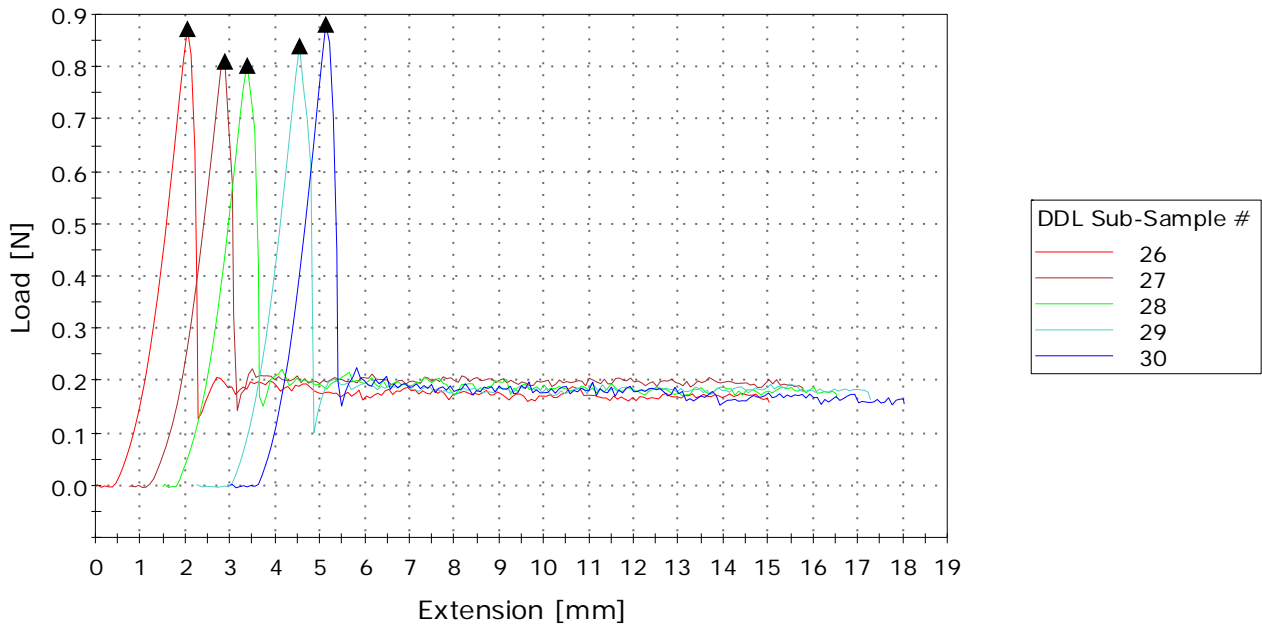
DDL Sample #003



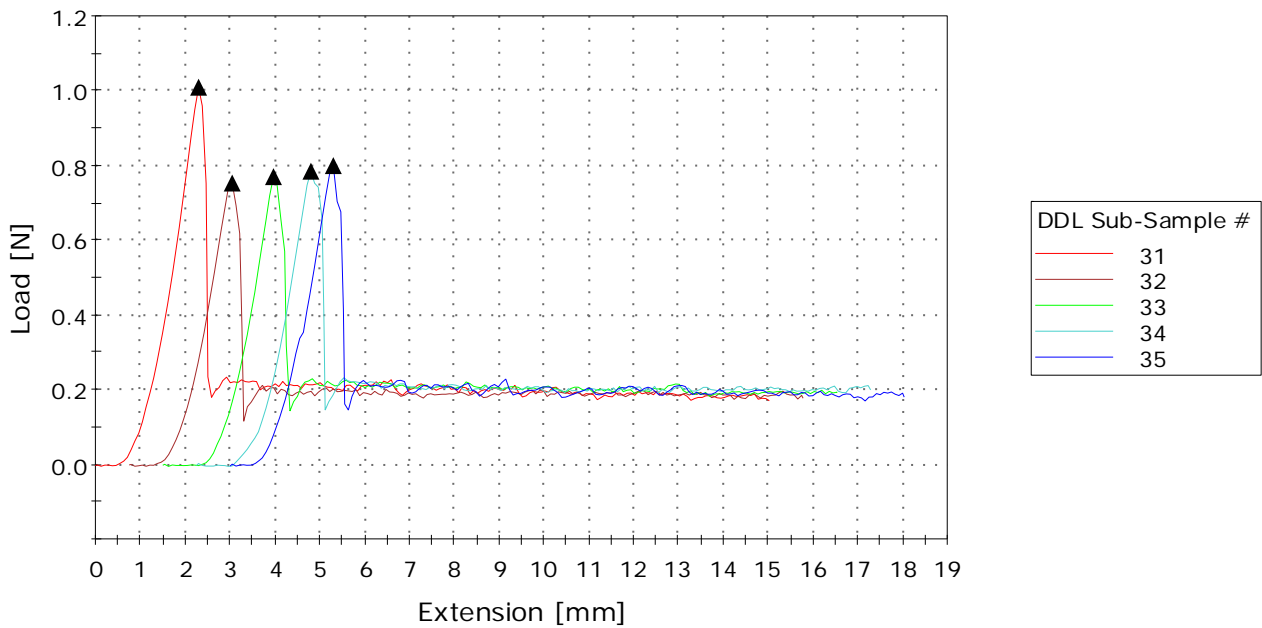
DDL Sample #003



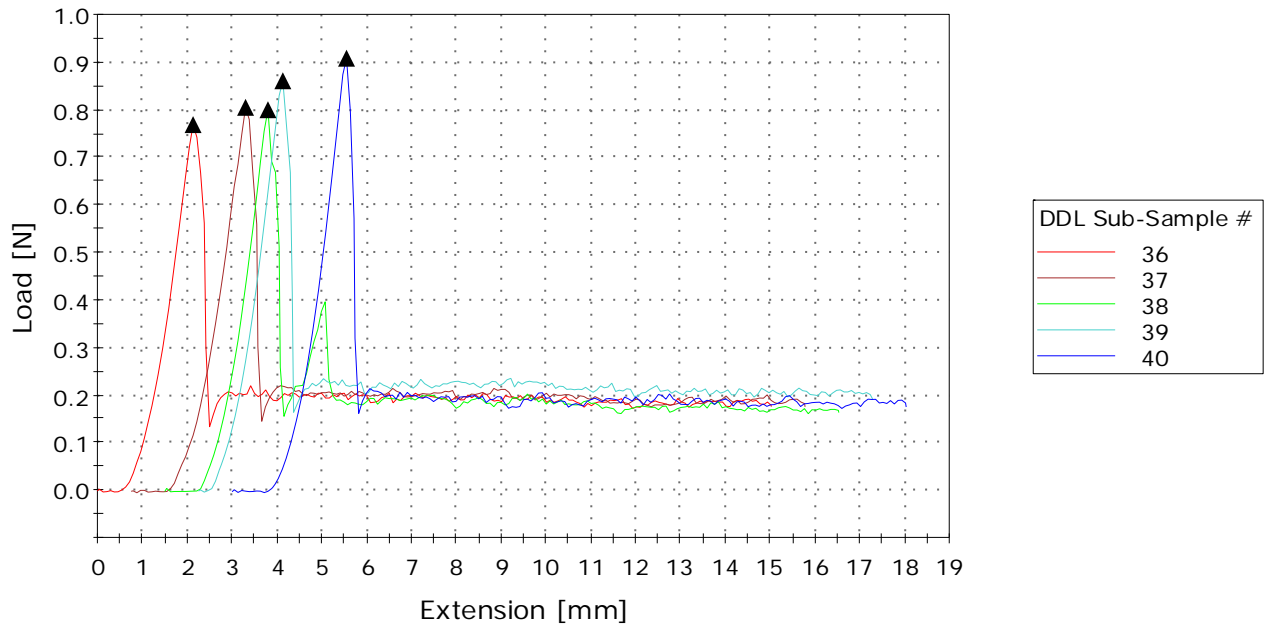
DDL Sample #003



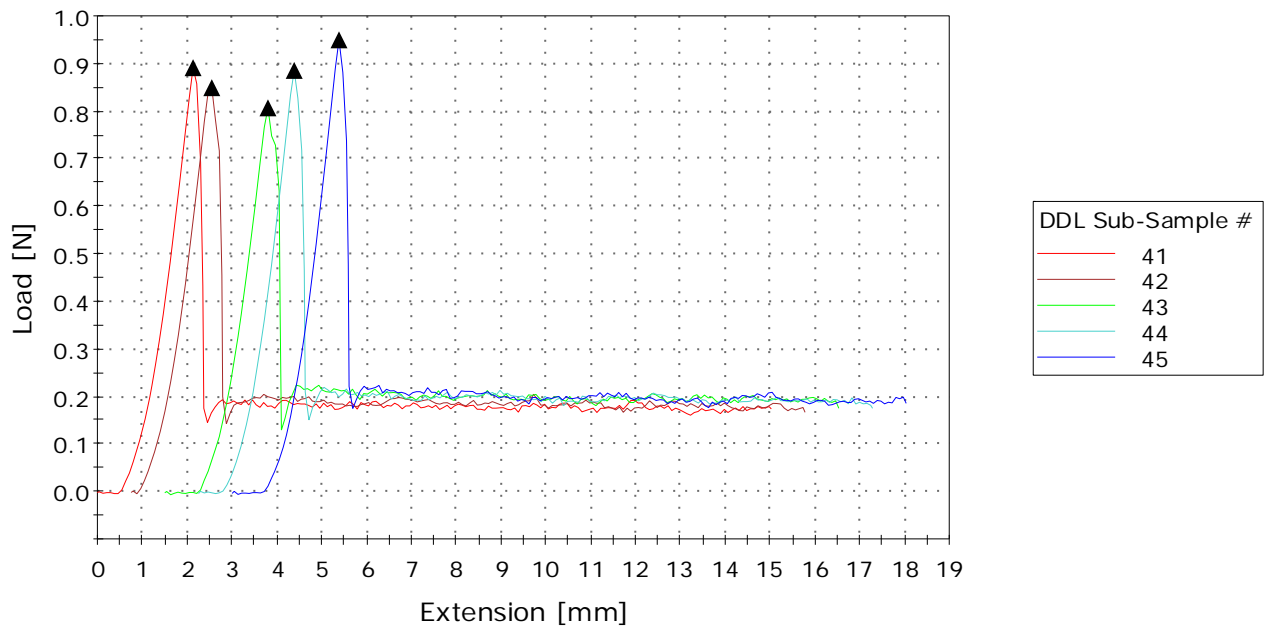
DDL Sample #003



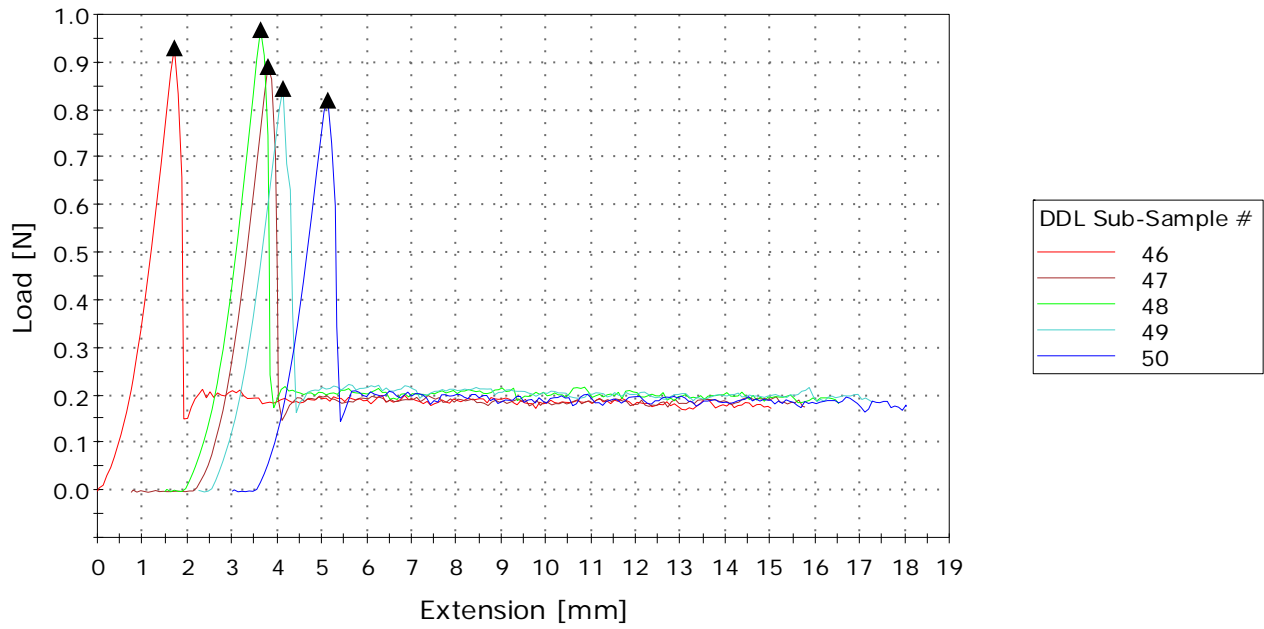
### DDL Sample #003



### DDL Sample #003



### DDL Sample #003





## **Vision Statement**

To be the most customer-oriented, technically competent services provider for the life sciences industry.

## **Mission Statement**

To be a global, independent testing services leader in creating a greater customer experience through exemplary service and quality, a strong organizational culture, technical expertise and by supporting the innovative spirit of our customers.