

Comparison of friction force of B.Braun Actreen™ Lite, Hi-Lite and Mini and Coloplast SpeediCath® Compact Female, Compact Eve, Standard, Flex, Navi and Compact Male

Technical Report

Coloplast
July 2022 (Updated March 2023)

Ostomy Care / Continence Care / Wound & Skin Care / Interventional Urology



1. Summary

Coloplast conducts friction tests to objectively measure the smoothness of the surface of intermittent catheters which is important for gentle passage through the urethra. The products are tested at 0 minutes after opening the catheter. Comparing Coloplast's SpeediCath® catheters (SpeediCath® Standard, Flex, Navi, Compact Male, Compact Female and Compact Eve) and B.Braun's Actreen™ Mini, Actreen™ Lite and Actreen™ Hi-Lite, there is a statistically significant difference in the mean friction values between the products at 0 minutes after opening. Based on these results, SpeediCath® products have been found to have a lower surface friction than Actreen™ Mini, Actreen™ Lite and Actreen™ Hi-Lite.

2. Methodology

The products were analysed and compared by an objective catheter friction measurement methodology that Coloplast uses broadly in quality control, manufacturing, research and development and competitor testing. The test method is internally validated, meaning that if you repeat the test, you should get a similar result. The method utilizes precise load cell sensors connected to a computer to accurately measure the friction forces. The tests were performed on minimum two different production lots from each product as there may be variation in friction force from one lot to another. Samples were tested at 0 minutes after opening the catheter. The products described and tested in this report have been evaluated and found suitable for comparison through the test method used.

2.1. Testing process (Harland method):

1. Each sample is prepared individually according to the instructions for use
2. The sample is inserted into the testing equipment
3. The machine automatically conducts the friction testing, the measurement is recorded by a computer
4. The used sample is disposed of, and the equipment is cleaned before another sample is inserted
5. After the predefined number of independent samples is tested, the test is finished, and the data is extracted for the statistical analysis

Table 1. List of performed tests

Test	Test description
Coating friction at 0 minutes	0 minutes means the friction measurement occurred immediately after opening the packaging

3. Statistical analysis

The following is a summary of the statistical analysis. The mean friction values are illustrated in Figure 1 and 2, where the bars indicate the range of the measured frictions. The bars are based on the minimum and maximum friction values. It is evident that SpeediCath® products have the lowest frictions compared to Actreen Mini™, Actreen™ Lite and Actreen™ Hi-Lite at 0 minutes after opening. Immediately after opening, SpeediCath® Compact Female has a mean friction of 10,8 mN, SpeediCath® Compact Eve has a mean friction of 19,0 mN, SpeediCath® Standard has a mean friction of 33,9 mN, SpeediCath® Compact Male has a mean friction of 38,2 mN, SpeediCath® Navi has a mean friction of 55,0 mN, SpeediCath® Flex has a mean friction of 68,5 mN, whereas Actreen Mini™ has a mean friction of 433,3 mN, Actreen™ Lite of 916,2 and Actreen™ Hi-Lite of 493,2 mN.

In addition, SpeediCath® products have a narrower variance of the friction measurements than the tested Actreen™ products. The comparison has been split into two figures, figure 1 (male) and 2 (female) to clarify which catheters are compared.

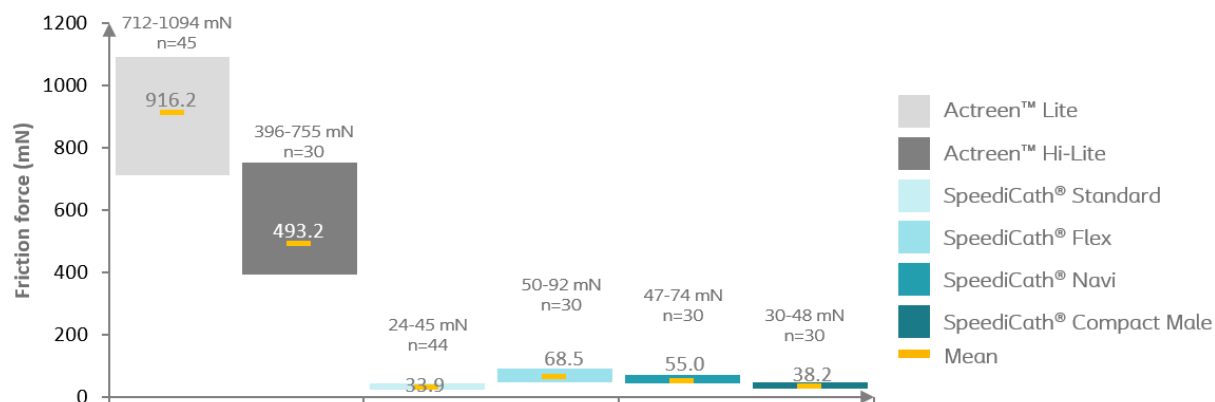


Figure 1. Comparison of the friction force measurements per product at 0 minutes after opening (Male catheters)

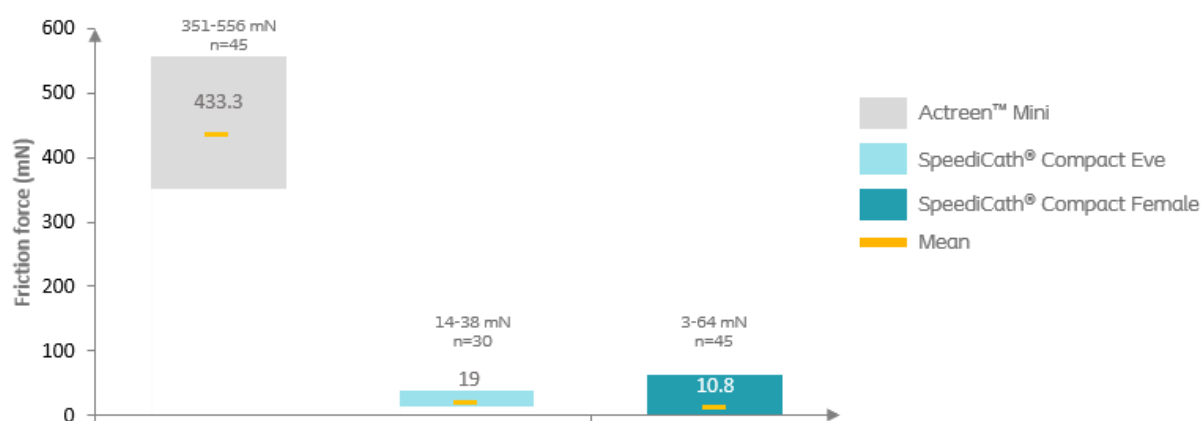


Figure 2. Comparison of the friction force measurements per product at 0 minutes after opening (Female catheters)

Table 2 shows the mean values and standard deviations for these two types. SpeediCath® Compact Female has the lowest mean friction while SpeediCath® Standard has the lowest standard deviation. The lower and upper 95 % values are the upper and lower bound of the confidence interval. This means that if the test was to be repeated, the population parameter will lie between the upper and lower interval in 95% of cases. As documented in the table, the lower bounds of confidence intervals for all the tested Actreen™ products for 0 minutes friction report higher values than the respective upper bounds of SpeediCath® products.

Table 2: Mean friction values, standard deviations and confidence intervals

Surface friction	Product	Sample size	Lots	Mean	Min	Max	Std Dev	Std Err Mean	Lower 95%	Upper 95%
0 min. dry out	Actreen™ Lite	45	20A24E8SNA/20N18E8SNA/21C19E8SNB	916,2	712	1094	95,3	14,2	887,6	944,7
	Actreen™ Hi-Lite	30	20M27E7SWA/21A04E7SWA	493,2	396	755	76,3	13,9	464,7	521,7
	Actreen Mini™	45	21C21E7SWA/21E02E7SWA/2E13E7SWA	433,3	351	556	44,6	6,7	419,9	446,7
	SpeediCath® Compact Female	45	7508746/8037571/8099302	10,8	3	64	11,2	1,7	7,4	14,1
	SpeediCath® Compact Eve	30	8668961/8757365	19,0	14	38	4,9	0,9	17,1	20,8
	SpeediCath® Standard	44	8140954/8159759/8202994	33,9	24	45	4,7	0,7	32,4	35,3
	SpeediCath® Flex	30	8496801/8662554	68,5	50	92	10,4	1,9	64,6	72,3
	SpeediCath® Navi	30	8383446/8383449	55,0	47	74	5,4	1,0	53,0	57,1
	SpeediCath® Compact Male	30	8643216/8683858	38,2	30	48	6,0	1,1	35,9	40,4

It can be concluded that the difference does not appear due to chance, as the p-value of the mean comparison is lower than 0,05 (see Appendix A). Therefore, there is a statistically significant difference between the mean values of the friction of the Actreen™ and SpeediCath® products.

4. Coating and material

The Actreen™ Mini, Hi-Lite and Lite is pre-lubricated with Glycerine. The lubricated material is not chemically bounded to the catheter surface, and it can easily be removed or washed off by water. The surface friction measurement is an indication of surface smoothness, which is shown in figure 1 and 2 (comparison of Speedicath® and Actreen™ catheters). The tube material of Actreen™ Lite contains PVC.

5. Conclusion

The surface friction of SpeediCath® products (SpeediCath® Standard, Flex, Navi, Compact Male, Compact Female and Compact Eve) is lower than the tested Actreen™ catheter types (Lite, Hi-Lite, Mini). There is a significant difference in the mean friction values between Actreen™ (Lite, Hi-Lite, Mini) and SpeediCath® products (SpeediCath® Standard, Flex, Navi, Compact Male, Compact Female and Compact Eve).

The mean surface friction values are significantly lower for SpeediCath® products (SpeediCath® Standard, Flex, Navi, Compact Male, Compact Female and Compact Eve) compared to Actreen™ Lite, Actreen™ Hi-Lite and Actreen™ Mini.

Change Log

Version	Date	Initials	Change description and reason
1.0	July 2022	DKENRA	First version created
2.0	September 2022	DKENRA	- Included Actreen Mini figure 1 to also show the comparison against SC Std. - Merged table 2 and 3 for simplicity to show one overview of the Actreen and SpeediCath products. - Headline changed in section 4 from 'Coating quality' to 'Coating and material' as it also describes catheter material. - Appendix A added, specifying p-values
3.0	March 2023	DKYDON	- Added SC Compact Eve in comparison with Actreen Mini - Added SC Flex, SC Navi and SC Compact Male in comparison with Actreen™ Lite and Hi-Lite - Updated Appendix A to reflect the added SpeediCath catheters in comparison

Appendix A

P-values (Female catheters)

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

Confidence Quantile

q*	Alpha
2,37394	0,05

HSD Threshold Matrix

Abs(Dif)-HSD

	Actreen Mini	SCCE	SCCF
Actreen Mini	-14,18	398,49	408,37
SCCE	398,49	-17,37	-7,65
SCCF	408,37	-7,65	-14,18

Positive values show pairs of means that are significantly different.

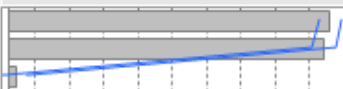
Connecting Letters Report

Level	Mean
Actreen Mini A	433,30489
SCCE B	18,95667
SCCF B	10,75556

Levels not connected by same letter are significantly different.

Ordered Differences Report

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Actreen Mini	SCCF	422,5493	5,973237	408,369	436,7294	<,0001*
Actreen Mini	SCCE	414,3482	6,678283	398,494	430,2021	<,0001*
SCCE	SCCF	8,2011	6,678283	-7,653	24,0549	0,4391



P-values (Male catheters)

Ordered Differences Report

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Actreen Lite	SC standard	882,3671	11,28142	849,909	914,8253	<,0001*
Actreen Lite	SCCM	878,0544	12,54196	841,969	914,1394	<,0001*
Actreen Lite	SC Navi	861,1778	12,54196	825,093	897,2628	<,0001*
Actreen Lite	SC Flex	847,7678	12,54196	811,683	883,8528	<,0001*
Actreen Hi-Lite	SC standard	459,3353	12,59884	423,087	495,5839	<,0001*
Actreen Hi-Lite	SCCM	455,0227	13,73902	415,494	494,5518	<,0001*
Actreen Hi-Lite	SC Navi	438,1460	13,73902	398,617	477,6751	<,0001*
Actreen Hi-Lite	SC Flex	424,7360	13,73902	385,207	464,2651	<,0001*
Actreen Lite	Actreen Hi-Lite	423,0318	12,54196	386,947	459,1168	<,0001*
SC Flex	SC standard	34,5993	12,59884	-1,649	70,8479	0,0708
SC Flex	SCCM	30,2867	13,73902	-9,242	69,8158	0,2403
SC Navi	SC standard	21,1893	12,59884	-15,059	57,4379	0,5454
SC Navi	SCCM	16,8767	13,73902	-22,652	56,4058	0,8225
SC Flex	SC Navi	13,4100	13,73902	-26,119	52,9391	0,9251
SCCM	SC standard	4,3127	12,59884	-31,936	40,5613	0,9994

