

Comparison of friction force of Convatec GentleCath™ Glide, GentleCath Air™ Male and Female and Coloplast SpeediCath® Compact Female, Compact Eve, Standard, Compact Male, Flex, Navi and Soft Technical Report

Coloplast

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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® Compact Female, Compact Eve, Compact Male, Standard, Soft, Navi, Flex) and Convatec's GentleCath™ Glide, GentleCath Air™ Male and Female, there is a statistically significant difference in the mean friction values between the products at 0 minutes after opening. Based on these results, SpeediCath® catheters (SpeediCath® Compact Female, Compact Eve, Compact Male, Standard, Soft, Navi, Flex) have been found to have a lower surface friction than GentleCath™ Glide, GentleCath Air™ Male and Female.

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 30-45 samples of each product from minimum two different production lots 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 that they are 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 error bars indicate the range of the measured frictions. The bars are based on the minimum and maximum friction values. It is evident that SpeediCath® catheters (SpeediCath® Compact Female, Compact Eve, Compact Male, Standard, Soft, Navi, Flex) have the lowest frictions compared to GentleCath™ Glide™, GentleCath™ Air Male and Female 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® Flex has a mean friction of 68,5 mN, SpeediCath® Soft has a mean friction of 51,4 mN, SpeediCath® Navi has a mean friction of 55,0 mN whereas GentleCath™ Glide has a mean friction of 360,4 mN, GentleCath™ Air Female of 160,1 and GentleCath™ Air Male of 197,1 mN. In addition, SpeediCath® catheters (SpeediCath® Compact Female, Compact Eve, Compact Male, Standard, Soft, Navi, Flex) have a narrower variance of the friction measurements than the tested GentleCath™ products.

The comparison has been split into two figures, figure 1 and 2 to clarify which catheters can be compared. That is to say that the male catheters should be compared to one another, and female catheters should be compared. GentleCath™ Glide is available for both male and female and can therefore be used for comparison in both scenarios. It should be noted that the large standard deviation of the GentleCath catheters can be explained as a result of poor adhesion and low thickness of unevenly lubricated tube.

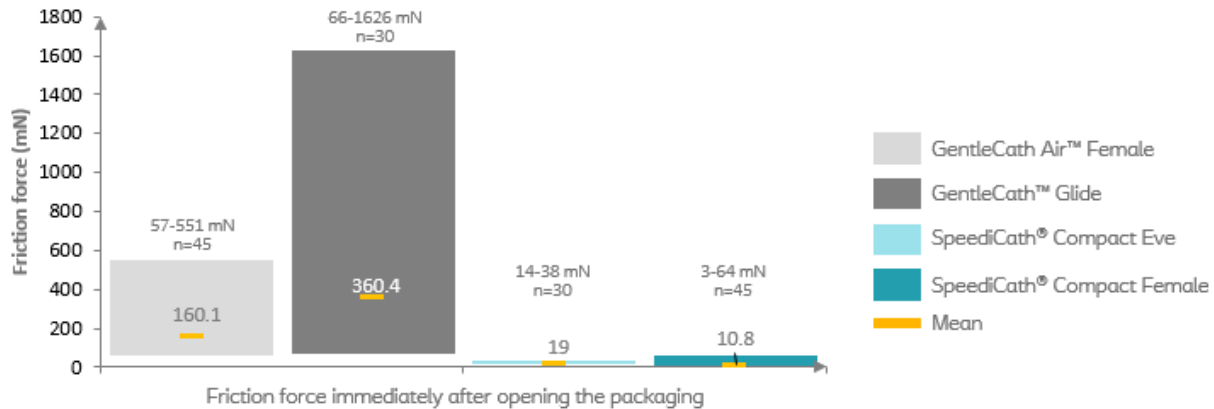


Figure 1. Comparison of the friction force measurements per product at 0 minutes after opening (Female catheters)

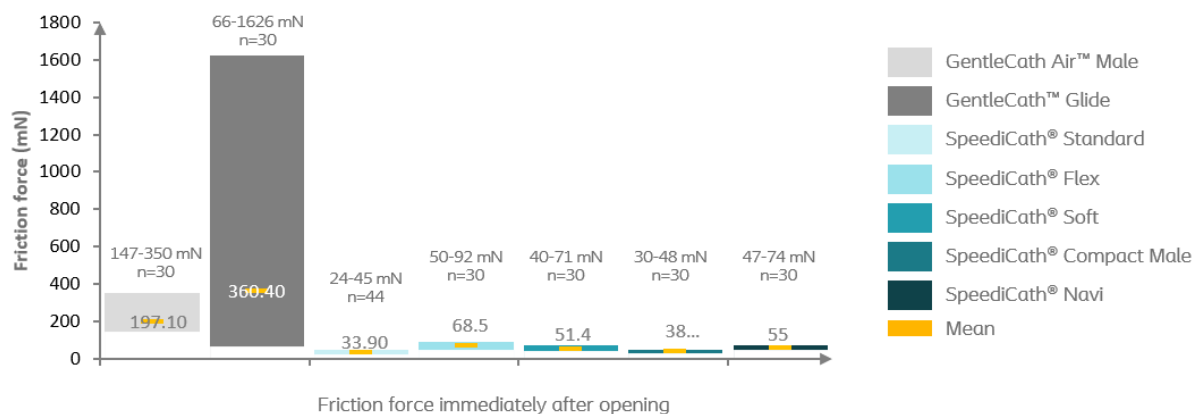


Figure 2. Comparison of the friction force measurements per product at 0 minutes after opening (Male catheters)

Table 2 and 3 show the mean values and standard deviations for the female and male catheters separately. SpeediCath® catheters have the lowest mean friction and standard deviation compared to the tested GentleCath types. 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 GentleCath™ products for 0 minutes friction report higher values than the respective upper bounds of SpeediCath® catheters.

Table 2: Mean friction values, standard deviations and confidence intervals (Female catheters)

Surface friction	Product	Sample size	Lots	Mean	Min	Max	Std Dev	Std Err Mean	Lower 95%	Upper 95%
0 min. dry out	GentleCath™ Air Female	45	0J01908/1L00298	160,1	57	551	121,1	18,1	123,7	196,5
	GentleCath™ Glide	30	1B00293/1C01210	360,4	66	1626	383,1	70,0	217,4	503,5
	SpeediCath® Compact Female	45	7508746/8037574/8099302	10,8	3	64	11,2	1,7	7,4	14,1

	SpeediCath® Compact Eve	30	8668961/8757365	19,0	14	38	4,93	0,90	17,1	20,8
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Table 3: Mean friction values, standard deviations and confidence intervals (Male catheters)

Surface friction	Product	Sample size	Lots	Mean	Min	Max	Std Dev	Std Err Mean	Lower 95%	Upper 95%
0 min. dry out	GentleCath™ Air Male	30	1L03143/1L03315	197,1	147	350	39,8	7,3	182,3	212,0
	GentleCath™ Glide	30	1B00293/1C01210	360,4	66	1626	383,1	70,0	217,4	503,5
	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	10,37	1,89	64,6	72,3
	SpeediCath® Soft	30	7808724/8038808	51,4	40	71	7,02	1,28	48,8	54,0
	SpeediCath® Compact Male	30	8643216/8683858	38,2	30	48	5,98	1,09	35,9	40,4
	SpeediCath® Navi	30	8383446/8383449	55,0	47	74	5,44	0,99	53,0	57,1

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 GentleCath™ products and those of SpeediCath® products.

4. Coating quality

The surface of the GentleCath™ catheters is lubricated. The material is not chemically bound to the surface and can be easily rubbed off, which can be one of the reasons for surface high friction variation in between samples. The thickness of the lubricated materials of the GentleCath™ catheters compared to SpeediCath coating is very low, which results in lower water swelling and faster drying of surface (VV-0375774).

5. Conclusion

The surface friction of SpeediCath® catheters (SpeediCath® Compact Female, Compact Eve, Compact Male, Standard, Soft, Navi, Flex) is lower than the tested GentleCath™ catheter (GentleCath Glide™, GentleCath™ Air Male and Female). There is a significant difference in the mean friction values between SpeediCath® catheters and the tested GentleCath™ catheter types.

The mean surface friction values are significantly lower for SpeediCath® catheters (SpeediCath® Compact Female, Compact Eve, Compact Male, Standard, Soft, Navi, Flex) compared to GentleCath™ Air Male and Female and GentleCath™ Glide. In terms of female catheters, SpeediCath® Compact Female and Compact Eve have a lower surface friction than GentleCath Glide™ and GentleCath™ Air Female. In terms of male catheters, SpeediCath® Compact Male, Standard, Soft, Navi and Flex have a lower surface friction than GentleCath Glide™ and GentleCath™ Air Male.

Change Log

Version	Date	Initials	Change description and reason
1.0	May 2022	DKENRA	First version created
2.0	March 2023	DKYDON	Added SCCE, SCCM, SC Navi, SC Flex and SC Soft in the comparison of surface friction Added Appendix A, the p-values of compared products

Appendix A

P-values (Female catheters)

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

Confidence Quantile

q*	Alpha
2,59888	0,05

HSD Threshold Matrix

Abs(Dif)-HSD

	GentleCath Glide	GentleCath Air-Female	SCCE	SCCF
GentleCath Glide	-123,04	88,02	218,43	237,35
GentleCath Air-Female	88,02	-100,46	28,81	48,87
SCCE	218,43	28,81	-123,04	-104,12
SCCF	237,35	48,87	-104,12	-100,46

Positive values show pairs of means that are significantly different.

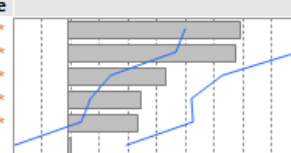
Connecting Letters Report

Level		Mean
GentleCath Glide	A	360,42400
GentleCath Air-Female	B	160,08667
SCCE	C	18,95667
SCCF	C	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
GentleCath Glide	SCCF	349,6684	43,21737	237,352	461,9850	<,0001*
GentleCath Glide	SCCE	341,4673	47,34225	218,431	464,5040	<,0001*
GentleCath Glide	GentleCath Air-Female	200,3373	43,21737	88,021	312,6539	<,0001*
GentleCath Air-Female	SCCF	149,3311	38,65479	48,872	249,7901	0,0010*
GentleCath Air-Female	SCCE	141,1300	43,21737	28,813	253,4466	0,0074*
SCCE	SCCF	8,2011	43,21737	-104,115	120,5177	0,9976



P-values (Male catheters)

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

Confidence Quantile

q*	Alpha
2,97626	0,05

HSD Threshold Matrix

Abs(Dif)-HSD

	GentleCath Glide	GentleCath Air Male	SC Flex	SC Navi	SC Soft	SCCM	SC standard
GentleCath Glide	-108,31	54,99	183,67	197,08	200,75	213,95	227,25
GentleCath Air Male	54,99	-108,31	20,37	33,78	37,45	50,65	63,95
SC Flex	183,67	20,37	-108,31	-94,90	-91,23	-78,02	-64,72
SC Navi	197,08	33,78	-94,90	-108,31	-104,64	-91,43	-78,13
SC Soft	200,75	37,45	-91,23	-104,64	-108,31	-95,10	-81,80
SCCM	213,95	50,65	-78,02	-91,43	-95,10	-108,31	-95,01
SC standard	227,25	63,95	-64,72	-78,13	-81,80	-95,01	-89,43

Positive values show pairs of means that are significantly different.

Connecting Letters Report

Level		Mean
GentleCath Glide	A	360,42400
GentleCath Air Male	B	197,12300
SC Flex	C	68,45000
SC Navi	C	55,04000
SC Soft	C	51,37000
SCCM	C	38,16333
SC standard	C	33,85068

Levels not connected by same letter are significantly different.

Ordered Differences Report

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value	
GentleCath Glide	SC standard	326,5733	33,37045	227,254	425,8923	<,0001*	
GentleCath Glide	SCCM	322,2607	36,39046	213,953	430,5680	<,0001*	
GentleCath Glide	SC Soft	309,0540	36,39046	200,747	417,3614	<,0001*	
GentleCath Glide	SC Navi	305,3840	36,39046	197,077	413,6914	<,0001*	
GentleCath Glide	SC Flex	291,9740	36,39046	183,667	400,2814	<,0001*	
GentleCath Glide	GentleCath Air Male	163,3010	36,39046	54,994	271,6084	0,0002*	
GentleCath Air Male	SC standard	163,2723	33,37045	63,953	262,5913	<,0001*	
GentleCath Air Male	SCCM	158,9597	36,39046	50,652	267,2670	0,0004*	
GentleCath Air Male	SC Soft	145,7530	36,39046	37,446	254,0604	0,0016*	
GentleCath Air Male	SC Navi	142,0830	36,39046	33,776	250,3904	0,0024*	
GentleCath Air Male	SC Flex	128,6730	36,39046	20,366	236,9804	0,0089*	
SC Flex	SC standard	34,5993	33,37045	-64,720	133,9183	0,9449	
SC Flex	SCCM	30,2867	36,39046	-78,021	138,5940	0,9813	
SC Navi	SC standard	21,1893	33,37045	-78,130	120,5083	0,9956	
SC Soft	SC standard	17,5193	33,37045	-81,800	116,8383	0,9985	
SC Flex	SC Soft	17,0800	36,39046	-91,227	125,3874	0,9992	
SC Navi	SCCM	16,8767	36,39046	-91,431	125,1840	0,9992	
SC Flex	SC Navi	13,4100	36,39046	-94,897	121,7174	0,9998	
SC Soft	SCCM	13,2067	36,39046	-95,101	121,5140	0,9998	
SCCM	SC standard	4,3127	33,37045	-95,006	103,6317	1,0000	
SC Navi	SC Soft	3,6700	36,39046	-104,637	111,9774	1,0000	