NEOVASC REDUCER SYSTEM

ERRATA TO THE SPONSOR EXECUTIVE SUMMARY

CIRCULATORY SYSTEM ADVISORY COMMITTEE

MEETING DATE: 27 OCTOBER 2020

Table 13 and Table 19 in the Sponsor's Executive tables had minor typographical errors. Below are the tables with the errors noted in red, followed by the corrected table

Table 13 Error Noted:

Table 1:   REDUCER-I: Baseline Demographics and Medical History

Baseline Characteristics		Arm 1 (Prospective) N-91	Arm 2 (COSIRA Follow-up) N=11	Arm 3 (CE Mark) N=39
Age (years), mean ± SD		68.5 ± 9.6	63.2 ± 9.0	67.9 ± 9.9
Male – n (%)		156 (81.7)	10 (90.9)	27 (69.2)
Previous	Myocardial Infarction	97 (51.3)	6 (54.5)	19 (48.7)
	PCI	135 (71.4)	6 (54.5)	28 (71.8)
	CABG	150 (79.4)	8 (72.7)	31 (79.5)
CCS Class	I	0	0	2 (6.3%)
	II	60 (31.9)	0	6 (18.8)
	III	117 (62.2)	9 (81.8)	20 (62.5)
	IV	11 (5.9)	2 (18.2)	4 (12.5)
Diabetes		83 (43.9)	4 **(35.4)**	20 (51.3)
Current or Previous Smoker		119 (63.0)	7 (63.6)	21 (53.8)
Hypercholesteremia		162 (85.7)	11 (100)	35 (89.7)
Hypertension		154 (81.5)	11 (100)	32 (82.1)

Table 13 Error Corrected:

Table 2:   REDUCER-I: Baseline Demographics and Medical History

Baseline Characteristics		Arm 1 (Prospective) N=191	Arm 2 (COSIRA Follow-up) N=11	Arm 3 (CE Mark) N=39
Age (years), mean ± SD		68.5 ± 9.6	63.2 ± 9.0	67.9 ± 9.9
Male – n (%)		156 (81.7)	10 (90.9)	27 (69.2)
Previous	Myocardial Infarction	97 (51.3)	6 (54.5)	19 (48.7)
	PCI	135 (71.4)	6 (54.5)	28 (71.8)
	CABG	150 (79.4)	8 (72.7)	31 (79.5)
CCS Class	I	0	0	2 (6.3%)
	II	60 (31.9)	0	6 (18.8)
	III	117 (62.2)	9 (81.8)	20 (62.5)
	IV	11 (5.9)	2 (18.2)	4 (12.5)
Diabetes		83 (43.9)	4 **(36.4)**	20 (51.3)
Current or Previous Smoker		119 (63.0)	7 (63.6)	21 (53.8)
Hypercholesteremia		162 (85.7)	11 (100)	35 (89.7)
Hypertension		154 (81.5)	11 (100)	32 (82.1)

Table 19 Error Noted

Table 3: **Supportive Clinical Testing ETT Total Exercise Duration**

Study	Total Exercise Duration at Baseline	Total Exercise Duration at Follow-up (Time Period)
COSIRA Treatment Arm (seconds)	441.29 ± 193.74	**449.81** ± 194.32 (6 months)
Konigstein (2018a) (minutes)	03:43 ± 01:30	04:35 ± 02:18 (6 months)
Giannini (2018a) (seconds)	375 ± 169	388 ± 224 (14 months)

Table 19 Error Corrected:

Table 4: **Supportive Clinical Testing ETT Total Exercise Duration**

Study	Total Exercise Duration at Baseline	Total Exercise Duration at Follow-up (Time Period)
COSIRA Treatment Arm (seconds)	441.29 ± 193.74	499.81 ± 194.32 (6 months)
Konigstein (2018a) (minutes)	03:43 ± 01:30	04:35 ± 02:18 (6 months)
Giannini (2018a) (seconds)	375 ± 169	388 ± 224 (14 months)