

COMPACTA STERILE TEST REPORT

1. **Name of the institution responsible for conducting the research:** Foundation for the Cardiac Surgery Development, Wolnosci 345A, 41-800 Zabrze, Poland.
2. **Name of the institution where the test was carried out:** Experimental Station of the Department of Genetics and Methods of Animal Improvement, Faculty of Animal Breeding and Biology, University of Agriculture in Krakow, Jodłowa Street 12, 30-250 Krakow.
3. **Responsible persons**
 - **Beata Krawczyk:** organization of the experiment, preparation of contracts and necessary documentation
 - **Wilczek Piotr:** supervision and conducting of the experiment
 - **Katarzyna Kasperkiewicz:** supervision and conducting of microbiological tests

The aim of the study:

The aim of the study was to assess the effectiveness of the CompactaSteril ultra clean air system. According to the assumption, the examined device should significantly reduce the risk of contamination of the treatment and operational field. The correctness of this assumption was tested on a small animal's model under simulated conditions in the treatment room

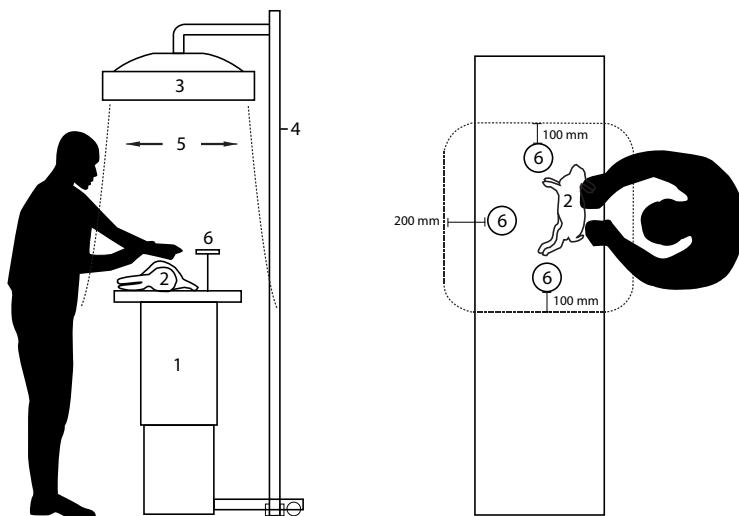
Materials and Methods:

experiment conditions:

For the study the rabbits, New Zealand race was used. The study group was homogeneous in terms of age, weight and sex. Before starting the experiment, the rabbits were properly prepared the hair has been shaved in place of a potential operating field, completely devoid of fur, and then the skin was washed and disinfected. Before the surgery, the animal was covered with sterile undercoats, and a special foil was applied to the skin. The procedure during the treatment was consistent with the one provided by Compacta (figure below)

CompactaSteril

Reducing surgical site infections



1. OP-table, height 700-900 mm enabling sitting or standing work position.
2. Operation object.
3. CompactaSteril unit: 800 mm above object.
4. Unit stand, fixed height 2800 mm.
5. Clean air zone.
6. Agar plates 80-100 mm

Six plates were used for each surgical procedure.

3 plates at time: 0-12 min

3 plates at time: 12-24 min

3 plates at time: 24-36 min

The plates were placed about 2 cm above the animal and close to the simulated "surgical wound". To avoid false negative results (no bacterial growth) the room in which the procedure took place had standard ventilation, the room was not equipped with HEPA filters. The Volume of the operating room was approximately 40 m³. The number of staff was a) two persons during the procedure b) 3-4 persons between each procedure. Staff were wearing sterile surgical clothing during the experiment. During the experiment the door to the treatment room was closed. Frequent opening of the door was also avoided between procedures. The experiment consisted of simulating surgical procedure with minimally invasive access from thoracotomy. During the experiment the animals were not raised or moved, and the personnel do not lean in under the CompactaSteril i.e. putting the head(s) in the clean air zone.

microbiological study:

For the study the sedimentation air sampling method was used. The blood agar plates as growth media was used. The size of the agar plates was 8 cm in diameter. Each plates was exposed 12 min, This was related to previously reported measurements of cfu in operating rooms and calculated/based on an airflow of 0.35 m/s from CompactaSteril on to the 8 cm plates (normally 8 min exposure should have been appropriate but to obtain increased exposure for this test the time was prolonged) Exposure time for plates without CS was determined based on the airflow in the room in combination with the 8 cm plates and set to 60 min Test samples were collected after 12, 24 and 36 min from the start of the procedure. The agar plates were incubated for 48h in 37⁰C. After this period, CFU was counted for each sample. As control groups, rabbits without Compacta Sterile and samples collected in the treatment room were used.

Results

In the case of tests performed using CompactaSterile, the number of CFUs was in the range of 0-3 (Fig. 1-3; Tab. 1). In the case of control animals without CompactaSterile, the amount of CFU was significantly higher (Fig. 4; Tab. 2). A significantly higher amount of CFU was also observed for the samples exposed in the room Fig. 5; Tab 3).

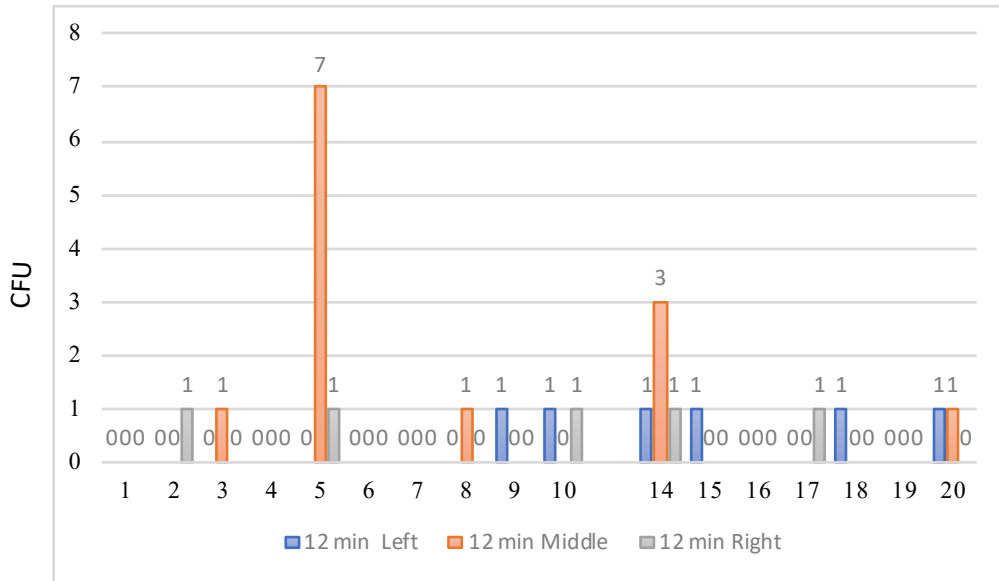


Fig. 1 Amount of CFU in samples tested using CompactaSterile after 12 min exposure

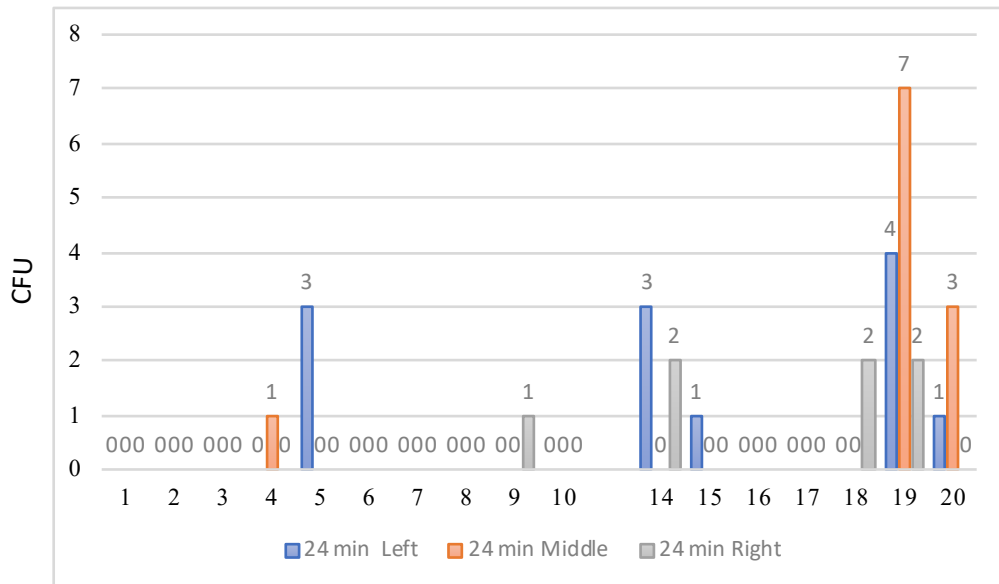


Fig. 2 Amount of CFU in samples tested using CompactaSterile after 24 min exposure

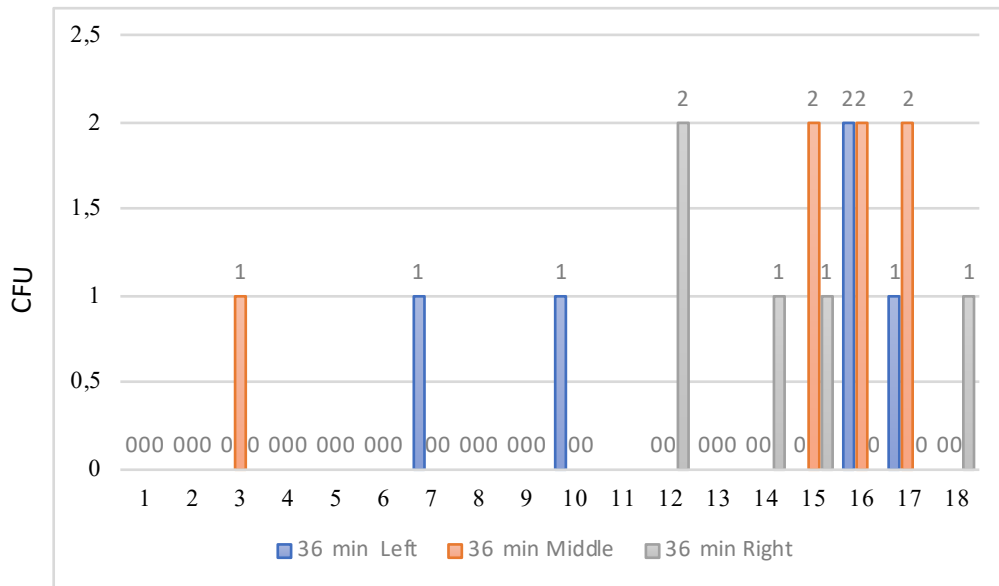


Fig. 3 Amount of CFU in samples tested using CompactaSterile after 36 min exposure

Rabbit no.	Time of exposure								
	12 min Left	12 min Middle	12 min Right	24 min Left	24 min Middle	24 min Right	36 min Left	36 min Middle	36 min Right
1	0	0	0	0	0	0	0	0	0
2	0	0	1	0	0	0	0	0	0
3	0	1	0	0	0	0	0	1	0
4	0	0	0	0	1	0	0	0	0
5	0	7	1	3	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	1	0	0
8	0	1	0	0	0	0	0	0	0
9	1	0	0	0	0	1	0	0	0
10	1	0	1	0	0	0	1	0	0
11	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0
14	1	3	1	3	0	2	0	0	2
15	1	0	0	1	0	0	0	0	0
16	0	0	0	0	0	0	0	0	1
17	0	0	1	0	0	0	0	2	1
18	1	0	0	0	0	2	2	2	0
19	0	0	0	4	7	2	1	2	0
20	1	1	0	1	3	0	0	0	1

Tab. 1 The amount of CFU observed for tests performed using CompactaSterile at individual exposure times for individual animals

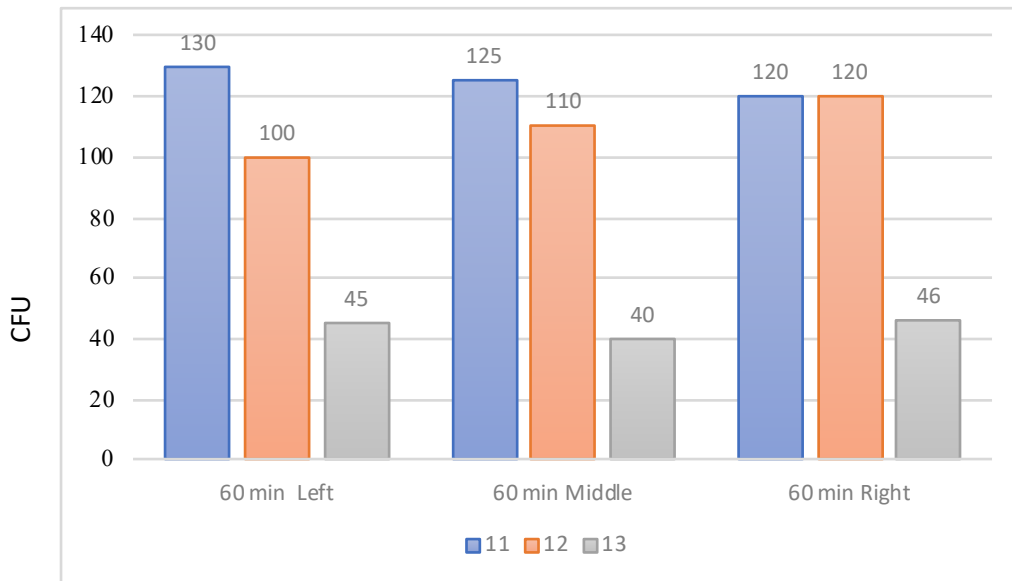


Fig. 4 Amount of CFU in samples tested without the use of CompactaSterile after 60 min exposure

Rabbit no.	60 min Left	60 min Middle	60 min Right
11	130	125	120
12	100	110	120
13	45	40	46

Tab. 2 The amount of CFU observed for tests performed without the use of CompactaSterile at individual exposure times for individual animals

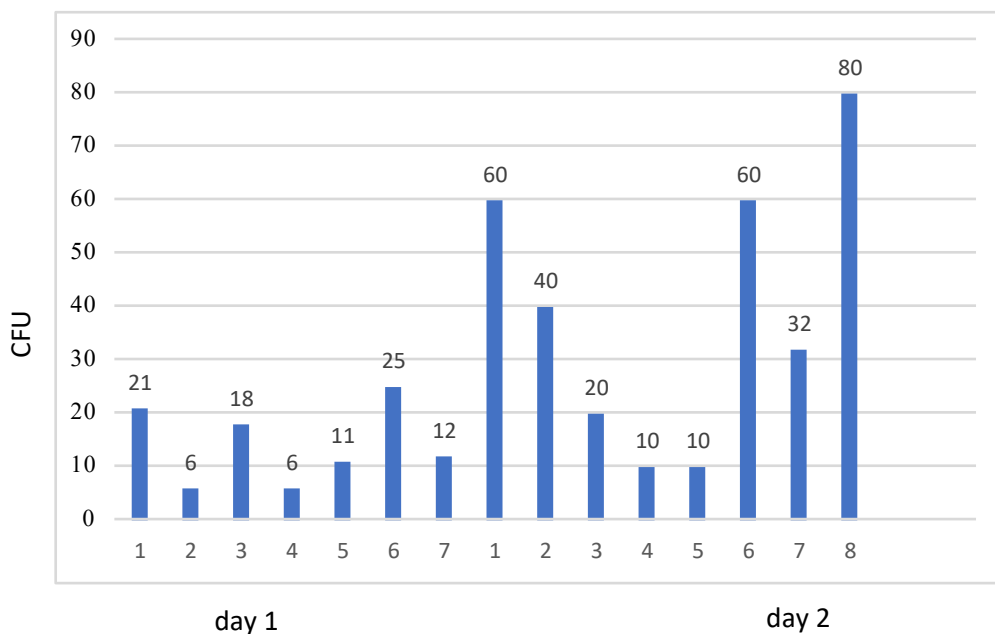


Fig. 5 The amount of CFU observed in the control samples exposed in the room

Sample no.	CFU
1	21
2	6
3	18
4	6
5	11
6	25
7	12

Sample no.	CFU
1	60
2	40
3	20
4	10
5	10
6	60
7	32
8	80

Tab. 3 The amount of CFU observed in the control samples exposed in the room

Rabbit no.	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 1	L 1	0	10:20-10:32
	M 2	0	
	R 3	0	
	L 4	0	10:35 – 10:47
	M 5	0	
	R 6	0	
	L 7	0	10:48- 11:00
	M 8	0	
	R 9	0	
	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 2	L 10	0	11:32 – 11:44
	M 11	0	
	R 12	1	
	L 13	0	11:46 – 11:58
	M 14	0	
	R 15	0	
	L 16	0	12:00 – 12:12
	M 17	0	
	R 18	0	
	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 3	L 19	0	12:15 – 12:27
	M 20	1	
	R 21	0	
	L 22	1	12:30 – 12:42
	M 23	0	
	R 24	0	
	L 25	0	12:43 – 12:55
	M 26	1	
	R 27	0	
	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 4	L 28	0	13:41 – 13:53
	M 29	0	
	R 30	0	
	L 31	0	13:55 – 14:07
	M 32	1	
	R 33	0	
	L 34	0	14:10 – 14:22
	M 35	0	
	R 36	0	

Number of rabbit	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
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	M 74	0	
	R 75	0	
	L 76	0	18:10 – 18:22
	M 77	0	
	R 78	1	
	L 79	0	18:25 – 18:37
	M 80	0	
	R 81	0	
	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 10	L 82	1	18:40 – 18:52
	M 83	0	
	R 84	1	
	L 85	0	18:53 – 19:05
	M 86	0	
	R 87	0	
	L 88	1	19:06 – 19:18
	M 89	0	
	R 90	0	

Room :

Time/exposure time 1 hrs

time	cfu
10:20 – 11:20	21 cfu
12:11 – 13:12	6 cfu
13: 12 – 14:12	18 cfu
14:13 – 15:13	6 cfu
15:33 – 16:33	11 cfu
16:35 -17:35	25 cfu
17:50 – 18:50	12 cfu

Rabbit no.	Plate no Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 1 hrs
Rabbit 11	L1	130	8:40 – 9:40

	M 2	135	
	R 3	120	

Number of rabbit	Plate no Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 1 hrs
Rabbit 12	L 4	100	9:50 – 10:50
	M 5	110	
	R 6	120	
	Plate no Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 1 hrs
Rabbit 13	L7	45	11:00 – 12:00
	M 8	40	
	R 9	46	
	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 14	L 10	1	12:20 – 12:32
	M 11	3	
	R 12	1	
	L 13	3	12:33 - 12:45
	M 14	0	
	R 15	2	
	L 16	0	12:50 - 13:02
	M 17	0	
R 18	2		

Number of rabbit	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 15	L 19	1	13:14 – 13:26

	M 20	0	
	R 21	0	
	L 22	1	13:28 – 13:40
	M 23	0	
	R 24	0	
	L 25	0	13:42 – 13:54
	M 26	0	
	R 27	0	
	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 16	L 28	0	15:05 – 15:17
	M 29	0	
	R 30	0	
	L 31	0	15:19 – 15:31
	M 32	0	
	R 33	0	
	L 34	0	15:33 – 15:45
	M 35	0	
	R 36	1	
	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 17	L 37	0	15:57 – 16:09
	M 38	0	
	R 39	1	
	L 40	0	16:10 – 16:22
	M 41	0	
	R 42	0	
	L 43	0	16:23 – 16:35
	M 44	2	
		R 45	1
	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 18	L 46	1	16:50 – 17:02
	M 47	0	
	R 48	0	
	L 49	0	17:04 – 17:16
	M 50	0	
	R 51	2	
	L 52	2	17:18 – 17:30
	M 53	2	
	R 54	0	

Number of rabbit	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 19	L 55	0	17:45 – 17:57
	M 56	0	

	R 57	0	
	L 58	4	18:00 – 18:12
	M 59	7	
	R 60	2	
	L 61	1	18:15 – 18:27
	M 62	2	
	R 63	0	
	Plate with Compacta	CFU (after 48 hrs of incubation)	Time/exposure time 12 min
Rabbit 20	L 64	1	18:30 – 18:42
	M 65	1	
	R 66	0	
	L 67	1	18:45 – 18:57
	M 68	3	
	R 69	0	
	L 70	0	19:00 – 19:12
	M 71	0	
	R 72	1	

Room:

Time/exposure time 1 hrs

time	cfu
10:00 – 11:00	60 cfu
11:00 – 12:00	40 cfu
12:20-13:20	20 cfu
13:39 – 14:39	10 cfu
15:35 – 16:35	10 cfu
16: 55 – 17:55	60 cfu
18:00 – 19:00	32 cfu
19:05 - 20:05	80 cfu