COMPACTA STERILE TEST REPORT

1. **Name of the institution responsible for conducting the research**: Fundation 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**

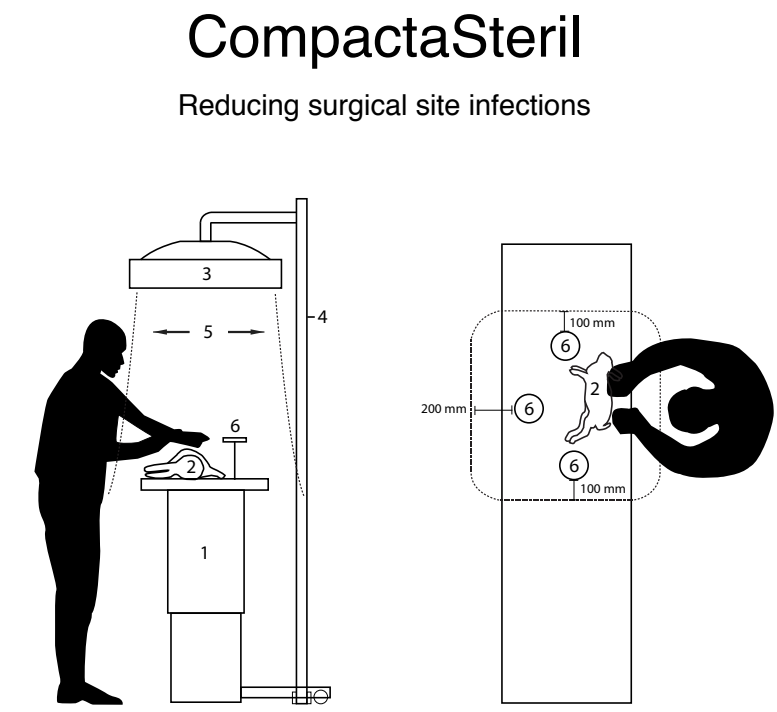
    - **Beata Krawczyk**: organization of the experiment, preparation of contracts and necessary documentation
    - **Wilczek Piotr**: supervision and conducting of the experiment
    - **Katarzyna Kasperkiewicz**: supervision and conducting of microbiological tests

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 Zeeland 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)



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 37^0C. 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).

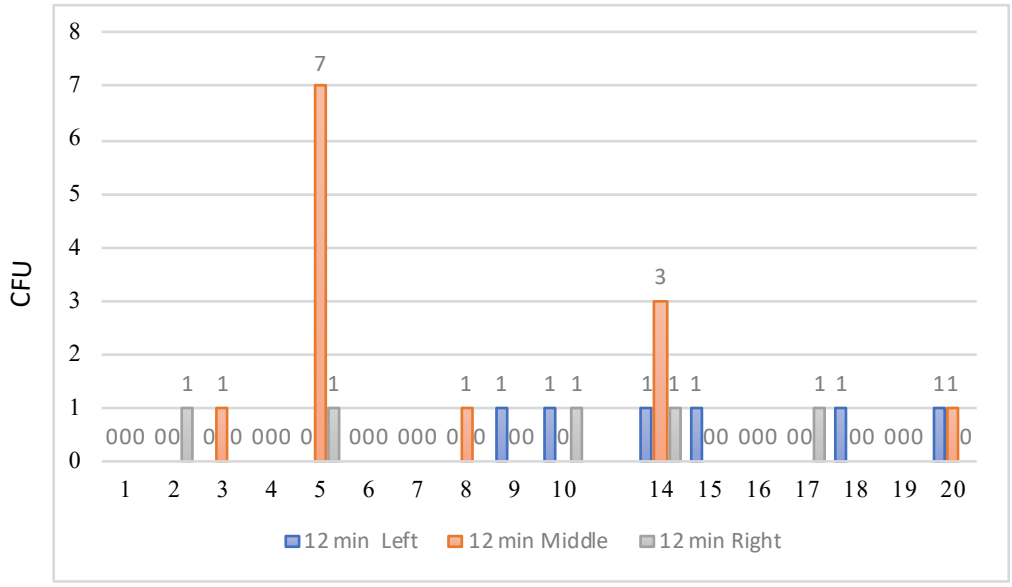


Fig. 1 Amount of CFU in samples tested using CompactaSterile after 12 min exposure

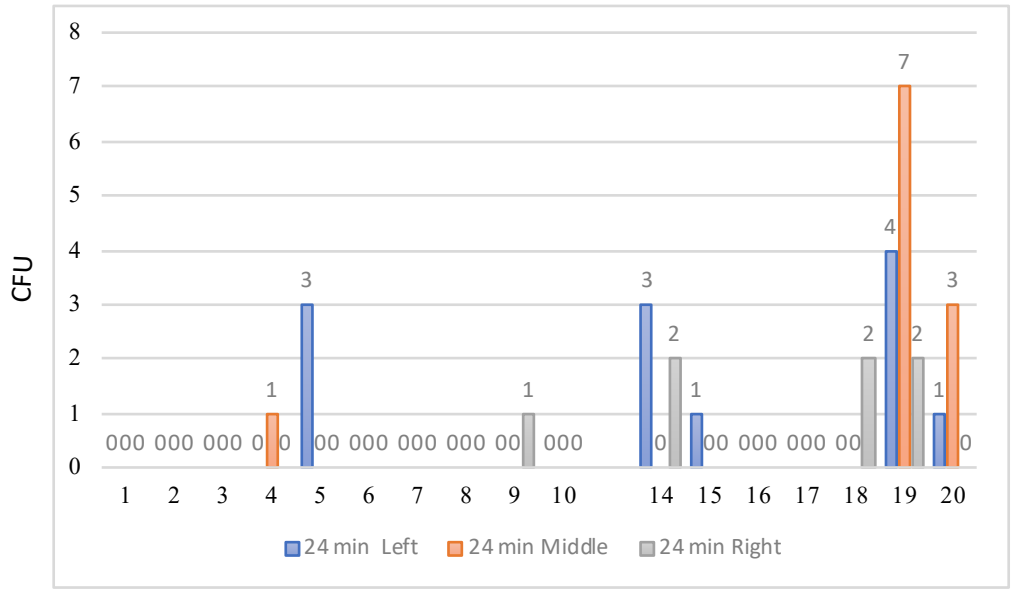


Fig. 2 Amount of CFU in samples tested using CompactaSterile after 24 min exposure

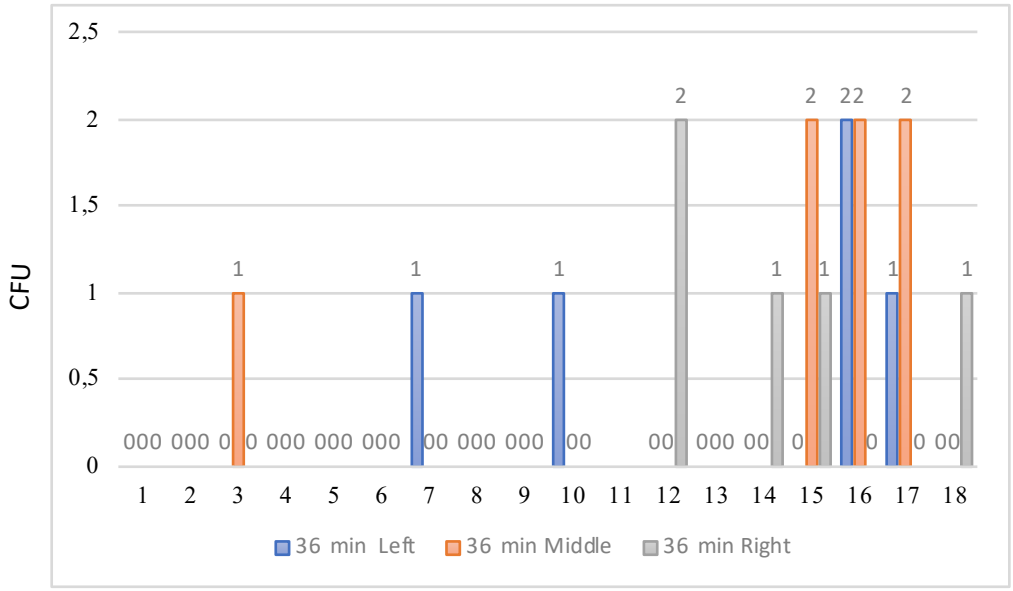


Fig. 3 Amount of CFU in samples tested using CompactaSterile after 36 min exposure

	Time of exposure								
Rabbit no.	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
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

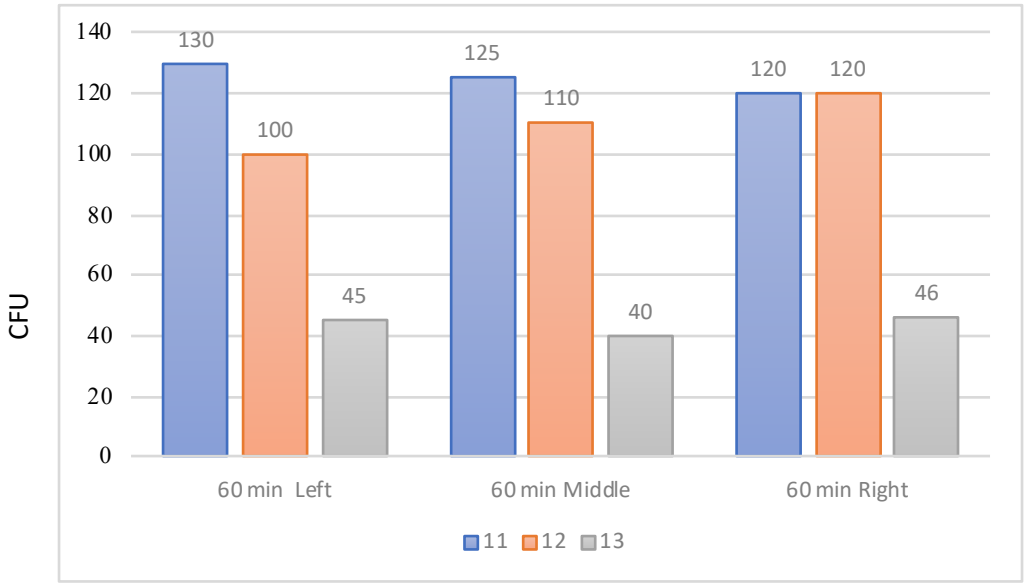


Fig. 4 Amount of CFU in samples tested without the use of CompactaSterile after 60 min exposure

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

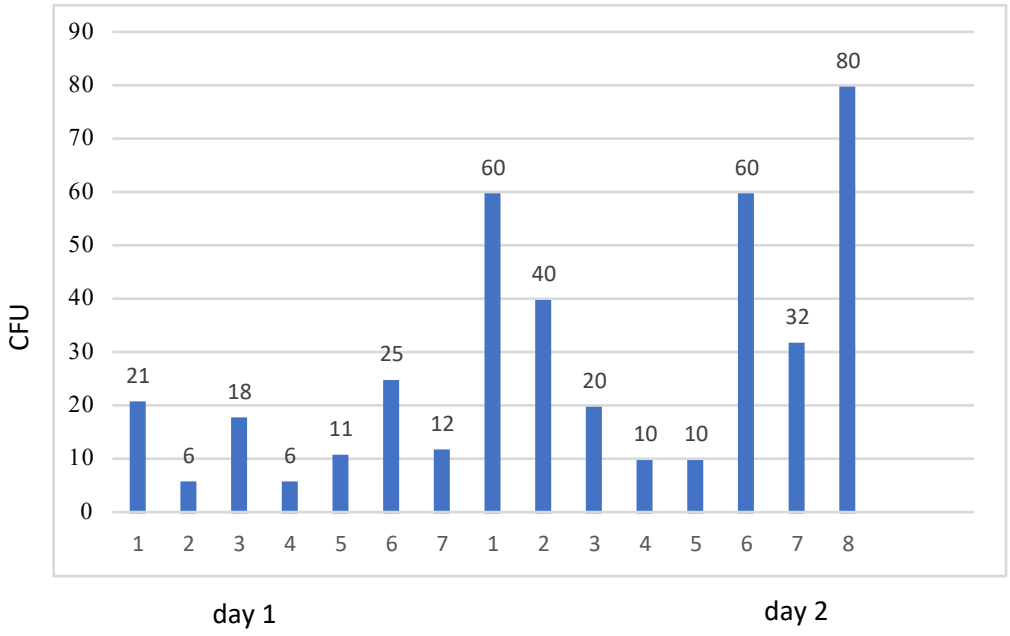


Fig. 5 The amount of CFU observed in the control samples exposed in the room

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**

Rabbit 5	L 37	0	14:32 – 14:44
	M 38	7	
	R 39	1	
	L 40	3	14:56 – 15:08
	M 41	0	
	R 42	0	
	L 43	0	15:10 – 15:22
	M 44	0	
	R 45	0	
	Plate **with Compacta**	**CFU (after 48 hrs of incubation)**	**Time/exposure time 12 min**
Rabbit 6	L 46	0	15:36 – 15:48
	M 47	0	
	R 48	0	
	L 49	0	15:50 – 16:02
	M 50	0	
	R 51	0	
	L 52	0	16:05 – 16:17
	M 53	0	
	R 54	0	
	Plate with Compacta	**CFU (after 48 hrs of incubation)**	**Time/exposure time 12 min**
Rabbit 7	L 55	0	16:20 – 16:32
	M 56	0	
	R 57	0	
	L 58	0	16:34 – 16:46
	M 59	0	
	R 60	0	
	L 61	1	16:48 – 17:00
	M 62	0	
	R 63	0	
	Plate with Compacta	**CFU (after 48 hrs of incubation)**	**Time/exposure time 12 min**
Rabbit 8	L 64	0	17:05 – 17:17
	M 65	1	
	R 66	0	
	L 67	0	17:20 – 17:32
	M 68	0	
	R 69	0	
	L 70	0	17:35 – 17:47
	M 71	0	
	R 72	0	

Number of rabbit	**Plate with Compacta**	**CFU (after 48 hrs of incubation)**	**Time/exposure time 12 min**
Rabbit 9	L 73	1	17: 55 – 18:07

	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

Conclusion

The conducted tests indicate that the use of the CompactaSterile device can significantly reduce the risk of contamination of the treatment area. However, this test should be considered as

preliminary research. It would be worth considering extending the research to assess e.g. potential fungal infections, because such infections can significantly affect the procedure and decide on the risk of early and long term postoperative complications. It also seems that for proper assessment of the CompactaSterile device operation, it is necessary to develop standard procedures and risk assessment.

Usability Questionnaire

1. **What was good about the product?**

   Preliminary tests indicate that the device can reduce the risk of contamination, the device is easy to use

2. **What was bad about the product?**

   Mounting method is inconvenient

3. **What changes would you want to see?**

   Simple e.g. optical methods indicating the correct position of the unit should be used (not manual methods so far).

4. **What would you add (functions, attributes)?**

   It is advisable to add indicators for the correct or emergency operation of the device.

5. **What would you remove?**

   At the moment, after a short time of use, I don't see any elements that should be removed

6. **Is the size of the clean air zone suitable? Too small, too large?**

   The size of the unit seems too small.

7. **In your own words – what would be the optimal ultra clean air zone size and/or setup?**

   Under standard conditions it should allow free operation by medical personnel.

8. **Is the height over the patient suitable? What would be the optimal height variability?**

   The height of the device is suitable

9. **Is there a risk of splatter hitting the product? When/what procedures?**

There seems to be no such risk

10. **What would be the optimum way to clean the product? Using disinfectants? Or removing a single-use protective sheet each time?**

    cleaning should be very simple, e.g. disinfectant, similar to operating lights

11. **Under what circumstances would the product not work as described? When would you not want to use it? Why?**

    It seems that the device will not fulfill its functions during extensive surgical procedures such as cardiac surgery. the requirements for securing the operational field are so great in this case that the use of CompactaSterile may not bring significant benefits

12. **In a final product – how would you like to control the products' height over the patient? Buttons? Manually By hand? By** Remote? Etc?

    Remote control

13. **In a final product – how would you like to control the lighting of the product? Buttons on the product? by Remote? Etc?**

    Remote control

14. **Please describe the optimal control for the full system (related to previous questions)?**

    It seems that the simplest system is the remote control, however, protection should be considered in the form of e.g. a servomechanical system

15. **Is the lighting from the product suitable and enough? Comments?**

    At this stage it is difficult to assess because the device has not been tested in conditions of violation of body coatings, with an blood influx. This can significantly affect lighting conditions

16. **Would it be best to mount this product using mount ceiling arms? Or using a movable stand?**

In my opinion the movable stand is optimal

17. What advantages can you see of using CS in your work?

Reducing the risk of contamination of the treatment area while reducing costs

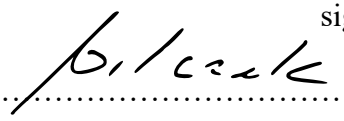
18. Do you or have you used clean air suits during operation? If so - How do you experience the use of such suits? When are clean air suits used? Who are using it? Does the use of clean air suits affect the quality of the surgery or in other ways make the surgery more difficult or cumbersome?

I did not use clean air suits during operation

19. Could the use of CS based on your knowledge decrease the need for clean air suits?

Based on my knowledge the CS could decrease the need for clean air suits?

signature



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(person responsible for preparing the report)