Doc. No. QC_4.14.9 Rev. No. 04 Date 01-06-2021

GOosafe in IVF Laboratories
SparMED ApS
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Oosafe® Filter 6

Installation Instructions:

1. Ensure that the plastic packaging of the Oosafe® Filter is completely sealed. Do not use any filter if it is not packed properly or if the primary packaging is punctured.
2. Open the sealed plastic packaging in a clean environment and carefully take out the Oosafe® Filter.
3. To remove the previously installed filter, press the spring clip on the side of the attachments to separate the Oosafe® Filter from the gas pipes.
4. Take out the old Oosafe® Filter from the original holder and change it with the new one. Please dispose the old filter immediately according to local regulations.
5. While placing the magnet holder on the incubator or any metallic surface, ensure that the arrow sign on the magnet holder is pointing upwards.
6. Take the Filter and place it in the magnet holder. Follow 'Toward Gas Source – Inlet' and 'Toward Incubator – Outlet' signs on the label of the Filter to install it in the right direction.
7. Connect the 6 mm diameter hard or 8 mm diameter soft tubing connectors to the tubes first, before affixing them to the filter as described below:

For **6 mm hard tubing**, unscrew the nut from the connector and slide it onto gas tube. Push tube firmly onto connector nipple. Bring the nut back down from the tube to the connector and screw tightly to ensure it is properly sealed (Figure 1).

For **8 mm soft tubing** connection, attach the tube to connector nipple, ensuring tube is fitted as close to connector as possible (Figure 2).

Figure 1

Figure 2

8. After connecting tubes to the connector, press the metal part on the side of the connectors to affix it to the filter's inlet and outlet. Make sure you press tightly until you hear the click sound. Ensure that the connectors are not loose (Figure 3).

Oosafe® Filter 6 is recommended to be changed every 6 months after first use of the product!

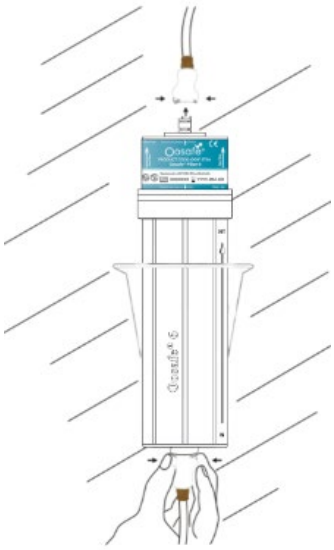

Figure 3

Precautions:

- Use original attachments for best performance. Original attachments will block gas flow while changing the filter. You can easily change the filter while the incubator and the gas flow are on.
- Use the original holder to keep the Oosafe® Filter in upright position. It prevents the gas pipe from being bent which may result in an undesired gas flow blockage. The holder is magnetic and can be placed on the side of the incubator or any metallic surface.
- Recommended pressure is 1.5 bar and for safety reasons do not exceed 2 bars.
- Recommended storage condition is room temperature.

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Symbol explanation

Symbol	Description of the symbol
1. 	Indication of 4 pieces of filter in a box
2. 	Consult instructions for use or consult electronic instructions for use
3. 	Manufacturer
4. 	Use by date
5. 	Temperature limit
6. 	Batch code
7. 	Fragile, handle with care
8. 	Do not use if package is damaged
9. 	Do not re-use
10. 	Conformity Mark
11. 	Inlet for gas; input for gas
12. 	Outlet for gas; output for gas
13. 	Pressure limit ≤2 bar
14. 	Installation date
15. 	Replace 6 month after the installation date
16. 	Catalogue number (Product reference)
17. 	Medical device
18. 	Keep dry

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Certificate of Conformity

Manufacturer	**SparMED ApS**
Brand name	**Oosafe® Filter 6**
Product Code	**OOIF-ST06**
Description	**Carbon-HEPA**
Quantity of Activated Carbon	**135 g ± 5 %**
Lot no.	**S210901**
Expiry date	**2026-09-01**

SparMED is the manufacturer of Oosafe® Filters and is an EN ISO 13485:2016 and ISO 9001:2015 certified company. SparMED declares that the above-mentioned product LOT of Oosafe® Filter 6 has been inspected in accordance with the Quality Management Systems and applicable standards.

Oosafe® Filter 6 is CE marked as Medical Device Class I and manufactured in a cleanroom.

It contains activated carbon granules, HEPA filter and pre-filters which ensures high VOC removal capacity and traps microorganisms and particles (H14 efficiency ≥ 99.995%). The filter is safe for use in IVF labs.

Esraa Baker
Quality Assurance Engineer
SparMED ApS
Date: 19 10 2021
SIGN and STAMP

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