









WX BYYYY-MM-DD (1)



## Caution!

The user should read and understand the User Manual completely and if necessary be trained to correctly install the filter before using.

# Attention!

- Check the expiration date on the label.
- Recommended storage condition is 5°C 35°C, however storage temperature should never exceed 50°C or be less than -5°C as this might result in irreparable damage.
- Relative humidity during storage should be between RH 30% and 70%, an ambient humidity between RH 40% and 60% is recommended.
- Avoid direct sunlight and protect from rain, snow or any other forms of moisture.
- Do not use filter if it appears damaged or if the primary packaging is not sealed upon receiving the product.
- Filter should not be removed from their individual packaging until it is required to be installed.
- Recommended pressure is 1.5 bar and must not exceed 2 bars.
- Increase and decrease pressure slowly.
- Use original attachments supplied by the manufacturer for the 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;
- Oosafe® Filters are made of polystyrene (PS) and are recyclable. Please dispose filters according to local regulations.
- Ensure that the gas supply to Filters is SWITCHED OFF, when the incubator with Oosafe inline filter installed, is turned off. If the gas supply remains on when the incubator is off, there will be a pressure built up inside the filter which might lead to explosion of the filter.



Please carefully read this instruction manual before using the product.



# **Table of contents**

L. Oosafe® Filter 4 summary	4
2. Oosafe® Filter 6 summary	5
3. Accessories to be used with Oosafe® Filters	6
1. Initial Installation with Soft and Hard Tubing	7
5. Filter Replacement Instruction	.10
5. Symbols Explanation	12



#### 1. OOSAFE® FILTER 4

- Oosafe® Filter 4 is produced in a class 7 cleanroom.
- Oosafe® Filter 4 is specially designed to reduce contaminants such as Volatile Organic Compounds (VOCs), Chemical Active Contaminants (CACs), bacteria, dust and particles which could affect oocytes, embryos, sperm and other cells and tissues cultured in the gas supplied incubator.
- Oosafe® Filter 4 is composed of high quality HEPA (High Efficiency Particulate Air) filter, granular activated carbon and double pre-filter.
- Greater amount of carbon ensures higher adsorption of contaminants and reduces risk of contamination.
- Oosafe® Filter 4 is recommended to be changed every 4 months after first use of the product.
- Oosafe® Filter 4 is CE marked and manufactured in an EN ISO 13485:2016 certified facility.



4





Oosafe® Filter 4 is individually packed and shipped as four pieces in a cardboard box, including a Certificate of Conformity.



#### 2. OOSAFE® FILTER 6

- Oosafe<sup>®</sup> Filter 6 is produced in a class 7 cleanroom.
- Oosafe® Filter is specially designed to reduce contaminants such as Volatile Organic Compounds (VOCs), Chemical Active Contaminants (CACs), bacteria, dust and particles, which could affect oocytes, embryos, sperm and other cells and tissues cultured in the gas supplied incubator.
- Oosafe<sup>®</sup> Filter 6 is composed of high quality HEPA (High Efficiency Particulate Air) filter, granular activated carbon and three pre-filters.
- Greater amount of carbon ensures higher adsorption of contaminants and reduces risk of contamination.
- Oosafe<sup>®</sup> Filter 6 is recommended to be changed every 6 months after first use of the product.
- Oosafe® Filter 6 is CE marked and manufactured in an EN ISO 13485:2016 certified facility.



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Oosafe<sup>®</sup> Filter 6 is individually packed and shipped as four pieces in a cardboard box, including a Certificate of Conformity.



#### 3. ACCESSORY TO BE USED WITH OOSAFE® FILTERS

# OOSAFE® FILTER CONNECTION SET FOR BENCHTOP INCUBATORS

Leak-free connection set for installation of Oosafe® Filter 4 and Oosafe® Filter 6 to the benchtop incubators using metal gas pipes.





- Easy to Install: Connection set is easily connectable to the filter, incubator and gas source.
- Ready to Use: Connection set contains all necessary connectors and tubing needed to install the filter.
- Original Connectors: Supplied with the same type of connectors as metal gas pipe manufacturer to ensure no gas leak or connection problems.
- Connection Set includes: 2 x Polyethylene 6 mm hard tubing (50 cm long each), 2 x 6 mm connectors, 2 x Swagelok metal connectors (same as metal pipe manufacturer).

#### **ACCESSORIES TO BE USED WITH OOSAFE® FILTERS**



Magnet Holder for Oosafe® Filters





Connector for Oosafe® Filters 6 mm diameter hard tubing



**REF** AS-852086



Connector for Oosafe® Filters 8 mm diameter soft tubing



**REF** AS-852085



Oosafe® Filters

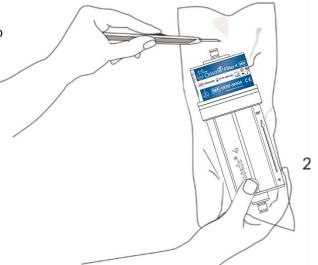
Doc. No.: OOIF - 16 Issue No. 06, Issue Date 13.02.2023

# 4. INITIAL INSTALLATION WITH OOSAFE® FILTERS, 6 MM DIAMETER HARD TUBING / 8 MM DIAMETER SOFT TUBING

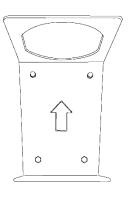
**1.** Make sure that the Oosafe® Filter pack is completely sealed and the Filter is not damaged.



**2.** Open the sealed plastic pack in a clean environment to use the Oosafe® Filter. Preferably in the laboratory.



**3.** Place the magnet holder on the incubator or any metallic surface. The arrow sign on the magnet holder must be pointing upwards.

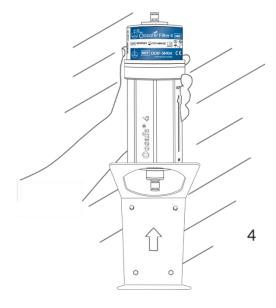


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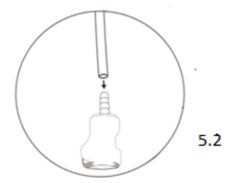
**4.** Take the Filter and place it in the magnet holder. Follow "Inlet for gas" and "Outlet for gas" symbols on the label of the Oosafe® Filter to install the filter in the right direction.



- **5.** Make sure to connect 6 mm diameter hard or 8 mm diameter soft tubing connectors to the tubes first, before affixing them to the filter. Connect the tubes to these connectors as described below:
- **5.1.** For **6** mm hard tubing connection, 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.



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

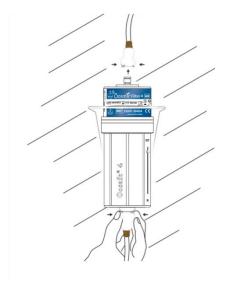




Oosafe® Filters

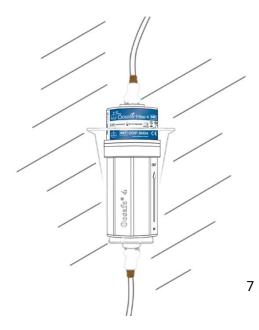
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**6.** After connecting tubes to the connector, press the metal part on the side of the connectors to affix it to the filter's inlet and outlet. Make sure you press tightly until you hear the click sound. Ensure connectors are not loose.



6

7. Release the gas and increase the pressure slowly (Recommended pressure - 1.5 bar, pressure limit max 2 bar).

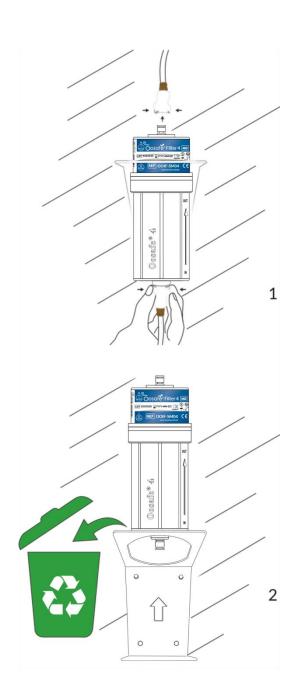


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#### 5. FILTER REPLACEMENT INSTRUCTION

1. Press the spring clip on the attachment to easily separate the filter from the gas pipe.

2. Take out the old filter from the original holder. Please dispose of the old filter immediately according to local regulations.



3. Go back to page 6 and follow the steps 1-6 for initial installation with 6 mm and 8 mm tubing.

## 6. SYMBOLS EXPLANATION

Explanation of the symbols used on the labels according to the standard ISO 15223-1:2021

Symb	ool	Description of the symbol	ISO 15223-1 reference number
1.		Manufacturer	5.1.1
2.	$\subseteq$	Use-by date	5.1.4
3.	LOT	Batch code	5.1.5
4.	REF	Catalogue number (Product reference)	5.1.6
5.		Do not use if package is damaged	5.2.8
6.	Ţ	Fragile, handle with care	5.3.1
7.	<del>*</del>	Keep dry	5.3.4
8.	5°C -35°C	Temperature limit	5.3.7
9.	2	Do not re-use	5.4.2
10.	www.sparmed.dk	Consult electronic instructions for use	5.4.3
11.	MD	Medical device	5.7.7
12.	UDI	Unique device identifier	5.7.10
13.	C€	Conformity Mark	



#### Explanation of the symbols used on equipment

Symbol	Description of the symbol	Standard/Symbol Number
	Outlet for gas; output for gas	IEC 60417 /6027
	Inlet for gas; input for gas	IEC 60417 /6026
∑ I≤2 bar	Pressure guage indication ≤2 bar	ISO 1219

#### Explanation of the symbols introduced by the manufacturer used on the labels

Symbol	Description of the symbol	
	Product drawing, in combination with multiplication symbol indicates number of product pieces inside the packaging.	

#### Explanation of the internationally recognized symbols used on the labels

Symbol	Description of the symbol	
×	Multiplication sign	



For additional information and translations please contact the manufacturer and local distributor



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