

# SECUR BIOP<sup>®</sup>

FORMAL*easy*<sup>®</sup>



In Compliance with European Regulations  
Designed and Made in Italy



## SAFE BIOPSY SPECIMEN CONTAINERS



Innovative & Unique “Closed System Technology”

Secure your health by reducing any exposure to formalin to zero  
Upgrade to the TOP safety standard for your operating room

# RECLASSIFICATION OF FORMALDEHYDE IN THE EU

The Risk Assessment Committee (RAC)<sup>1</sup> decided on 7th December 2012 to classify formaldehyde as CMR<sup>2</sup> carcinogenic category 1B and category 2 mutagenic. Category 1B means that there is sufficient evidence for CMR properties, which could be detected in animals, but human carcinogenic is only suspected. This classification will be implemented in the EU until 1st January 2016 by the amending regulation ((EU( No.2016/491) according to the 6th ATP<sup>3</sup> of CLP<sup>4</sup>-regulation.

In the near future, it can be assumed that other countries/nations will follow and possibly adopt this classification. In particular this assumption considers Canada and the United States, where classification and potential ban of use of formaldehyde releasing substances in metalworking fluids have already been discussed over the last years.



Symbol and Signal word: Danger  
GH508

**1st January 2016**, formaldehyde was reclassified as carcinogenic and mutagenic.

“ With the reclassification of formalin in terms of carcinogenicity, EU intends to ban the use of formalin.... ESP (European Society of Pathology) took seriously into consideration this issue...and have been trying to convince the European Parliament and the Council that they should make an exception so that pathology laboratories may continue to use this indispensable fixative.”

European Society of Pathology,  
Newsletter, winter 2017.

CMR-attribute	Classification of the substance	Classification of the mixture
mutagenity	muta.2; H341	conc. ≥ 1% muta.2; H341*
carcinogenitycarc.	1B; H350	conc. ≥ 0,1% carc. 1B; H350*

\*H341: Can cause genetic defects. \*H350 Can cause cancer

## Problem and Risk

During the biopsy procedure in the operating room, surgeons and nurses are always exposed to a certain level of risk\* when they handle biopsies with the traditional containers.

\*Formalin might accidentally spill on the skin; its vapours might affect the respiratory system & the eyes. Long-term risks.

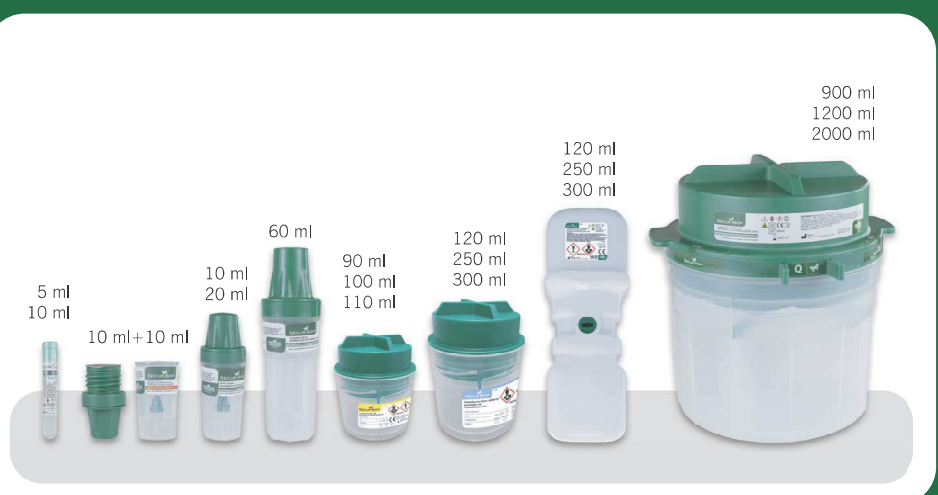
## Our Solution


Unlike any traditional container prefilled with formalin, with SecurBiop® the formalin is sealed in the cap by a membrane. In this way, operators will never get into any direct contact nor inhale any vapours of formalin when they open the container to insert the specimen.

Thanks to our patented\*\* technology and design, SecurBiop® will ONLY release the formalin from its cap into the container once it is completely closed.

\*\*Patents: n°102015000069945 n°T02014A000949 n°102018000005629  
n°W02016/079611A1 n° 1020160000056064 n°102017000001864

- Utmost Professionality
- Highest Level of Safety
- Best Quality
- Easy to Use





# SECUR BIOP<sup>®</sup>

## FORMAL *easy*<sup>®</sup>

When it comes to quality & safety, SecurBiop<sup>®</sup> takes it seriously.

We strive for the most intelligent and comprehensive solutions, in order to deliver the best quality & value to your operating room.

Designed by TRACES and produced by TECH IN GREEN, SecurBiop<sup>®</sup> containers prefilled with formalin, with an advanced «closed system» technology, provide the safest and most professional way to collect, transport and store biopsy specimens.

By prefilling formalin in the cap and sealing it with aluminum membrane, we prevent surgeons and nurses from getting into contact (both direct and indirect) with such carcinogenic chemical.

Insert the specimen into the empty container, then simply close it by screwing the cap. The formalin will automatically flow down from the top.

With 6 exclusive patents of TRACES, SecurBiop<sup>®</sup> and its unique design provide a perfectly hermetic sealing, preventing operators from facing all sorts of risks during biopsy procedures.

When it comes to the concept of formalin-risk-free prefilled container, SecurBiop<sup>®</sup> is the ONLY brand currently on the market providing a complete range of capacities, from 5 ml to 2000 ml...

...and we never stop updating and developing new products and accessories.



cod. **PC900** - Cassette Holder

cod. **S900** - 900 ml  
cod. **S1200** - 1200 ml  
cod. **S2000** - 2000 ml

cod. **S120** - 120 ml  
cod. **S250** - 250 ml  
cod. **S300** - 300 ml

cod. **S60** - 60 ml

cod. **S20** - 20 ml  
cod. **S10** - 10 ml


cod. **S90** - 90 ml  
cod. **S100** - 100 ml  
cod. **S110** - 110 ml

cod. **SMEDI120** - 120 ml  
cod. **SMEDI250** - 250 ml  
cod. **SMEDI300** - 300 ml


cod. **S1010FISIO**  
10 ml+10 ml

cod. **Fe05** - 5 ml  
cod. **Fe05** - 10 ml

Cat No.	Description	Capacity	Packaging
<b>FE05</b>	Prefilled Container, 5ml 10% NBF	5 ml	100 pcs / tray
<b>S20</b>	Prefilled Container, 20ml 10% NBF	20 ml	20 pcs / tray
<b>S1010FISIO</b>	Prefilled Container, 10ml 20% NBF + 10ml NS	20 ml	10 pcs / tray
<b>S60</b>	Prefilled Container, 60ml 10% NBF	60 ml	10 pcs / tray
<b>S120</b>	Prefilled Container, 120ml 10% NBF	120 ml	25 pcs / box
<b>S250</b>	Prefilled Container, 250ml 10% NBF	250 ml	25 pcs / box
<b>S300</b>	Prefilled Container, 300ml 10% NBF	300 ml	25 pcs / box
<b>SMEDI120</b>	Prefilled Container, 120ml 10% NBF	120 ml	20 pcs / box
<b>SMEDI250</b>	Prefilled Container, 250ml 10% NBF	250 ml	20 pcs / box
<b>SMEDI300</b>	Prefilled Container, 300ml 10% NBF	300 ml	20 pcs / box
<b>S90</b>	Prefilled Container, 90ml 10% NBF	90ml	40 pcs / box
<b>S100</b>	Prefilled Container, 100ml 10% NBF	100 ml	40 pcs / box
<b>S110</b>	Prefilled Container, 110ml 10% NBF	110 ml	40 pcs / box
<b>S900</b>	Prefilled Container, 900ml 10% NBF	900 ml	4 pcs / box
<b>S1200</b>	Prefilled Container, 1200ml 10% NBF	1200 ml	4 pcs / box
<b>S2000</b>	Prefilled Container, 2000ml 10% NBF	2000 ml	4 pcs / box
<b>PC900</b>	Hystology Cassette Holder	10 Cassettes	5 pcs + 1 Secure layer / pack



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Enhance staff safety,  
efficiency and  
professionalism  
during the biopsy  
procedures  
with SecurBiop<sup>®</sup>  
Prefilled Biopsy  
Containers.

**SecurBiop<sup>®</sup> upgrades the safety level of the healthcare providers by eliminating any contact with formalin.**

At the same time, we provide comprehensive solutions to equip your operating room and labs with the best products for the collection, transportation and storage of the specimens.

The work in the operating room is so important and delicate that a safe and hazard-free working environment is absolutely essential. This is not only important for our healthcare providers' wellness, but it will also allow them to deliver their best performance to patients as well.



# FLEETWOOD

## HEALTHCARE

EXCELLENCE THROUGH  
INNOVATION

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