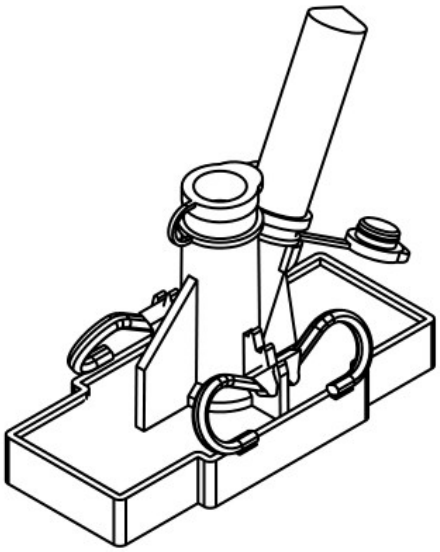
20610.EN rev.1

MPW MED. INSTRUMENTS

USER MANUAL



CYTO INSERT

(CYTO insert cytology rotor, type 610)

Read before use!

CE IVD

This manual was prepared with special care. MPW MED. INSTRUMENTS may change the manual at any time and without notice because of improvements, typographical errors or improvements to facilities

You can find the current version of the user manual on our website under:
www.mpw.pl DOWNLOAD section (one should choose demanded language version of website).

Contents

1. Safety

Before starting work, familiarize yourself with this manual. Do not proceed to work before carefully reading all procedures described in this document and always follow the recommendations and markings contained in it. In case of doubt, please contact the manufacturer.

The product is intended for single use.

The shelf life of the insert is 24 months from the date of purchase.

2. Technical specification

manufacturer	"MPW MED. INSTRUMENTS" SPÓŁDZIELNIA PRACY, Boremlowska 46 Street, 04-347 Warsaw
product name	CYTO INSERT type 610 for cytological rotor
cat. no (REF)	16610
capacity	4x2ml
max. speed (RPM)	2500
g-force (RCF)	769 x g
compatible rotor	12452C (centrifuges MPW M-DIAGNOSTIC, MPW-352, MPW-352R, MPW-352RH)

3. Purpose and principle of operation

Cytological insert CYTO is designed to make a uniform cell preparation. In addition, it allows to obtain a supernatant that can be used in further diagnostic procedures.

Under the influence of centrifugal force, morphotic elements (cell pellet) separate from the suspension and settle on a microscope slide. If the method is chosen without obtaining supernatant, the cell-free supernatant is absorbed by the filter paper, and in the case of the supernatant method, the supernatant is discharged into the sink tube.

This solution is used in medicine and veterinary medicine, as well as in biology, biochemistry, cytology and histopathology. During one centrifugation cycle it is possible to obtain 4 preparations.

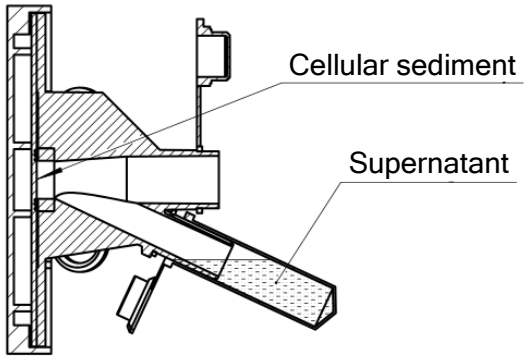


Figure 1. Cross-section of the insert in the method with obtaining the supernatant.

4. Components

Cat. no (REF)	No	Component name	pieces
16611	1	Support	100
	2	Overlay	100
	2a	Central plug	100
	2b	Side plug	100
16614	3	Microscope slide	100
16116	4	Filter paper with Ø9,5mm hole	100
16617	5	Filter paper with Ø12,5mm hole	100
15123	6	Tube 2,2ml with cup (PP)	100

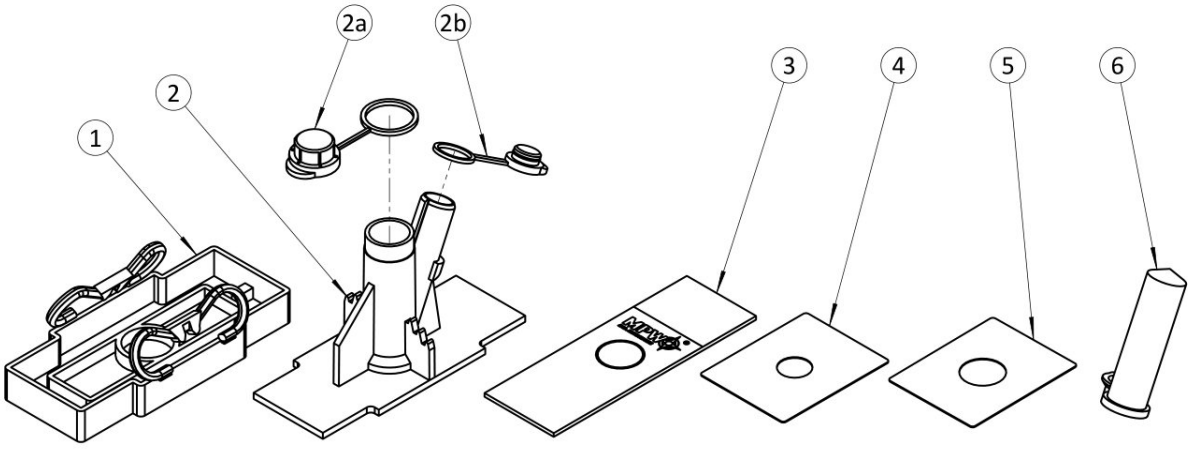


Figure 2. CYTO components (contents of the package)

5. Preparation of the rotor

All four rotor hangers should be placed in the rotor as shown in the figure below, such that the suspension locking element (element A) is located on those sides of the rotor arms that have a sliding locking element (element B).

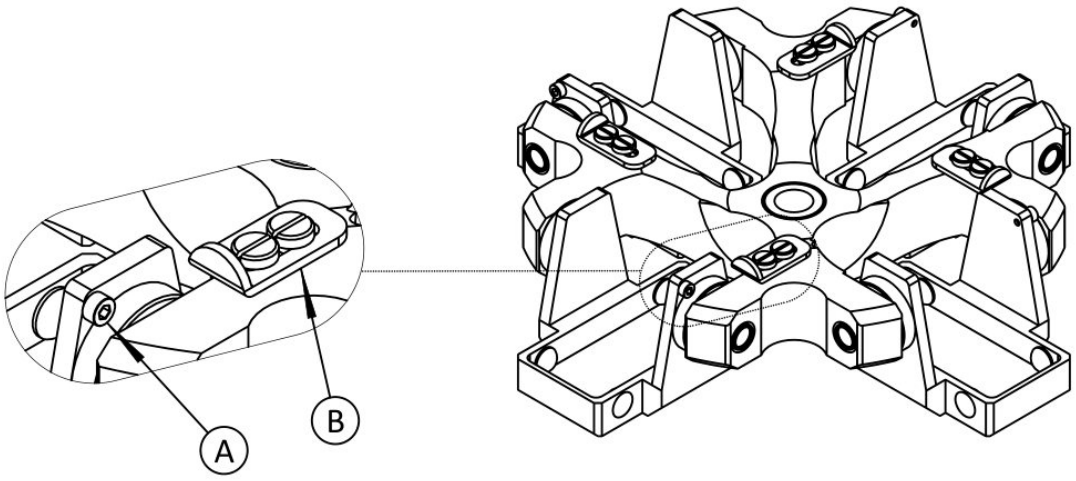


Figure 3. The way of placing the hangers in the rotor.

6. Preparation of the insert

6.1. With obtaining the supernatant

1) In order to improve the adhesion of cells to the microscope slide, it is recommended to lay them with phytolysin. The prepared and described microscope slide should be placed in the support (manufacturer's mark pointing upwards).
2) Place a filter paper with a Ø12,5mm hole on the slide.
3) Place the cover in the stand and fasten the buckles evenly.
4) Pour the prepared liquid sample (max. 2 ml) into the central cylindrical hole of the insert (marked with a dash) and then plug the hole with the cup.
5) Place the collecting tube on the second cylindrical hole of the insert.

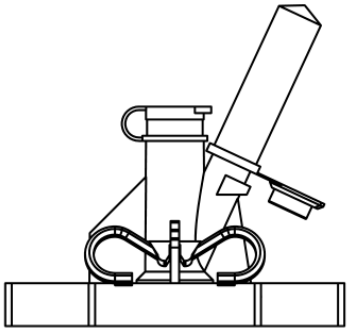


Figure 4. The insert is prepared for centrifugation to obtain supernatant.

6.2. Without obtaining the supernatant

1) In order to improve the adhesion of cells to the microscope slide, it is recommended to lay them with phytolysin. The prepared and described microscope slide should be placed in the support (manufacturer's mark pointing upwards).
2) Place a filter paper with a Ø 9.5mm hole on the slide.
3) Place the cover in the stand and fasten the buckles evenly.
4) Pour the prepared liquid sample (max. 2 ml) into the central cylindrical hole of the insert (marked with a dash) and then plug the hole with the cup.
5) Plug the second cylindrical opening of the insert with a cup.

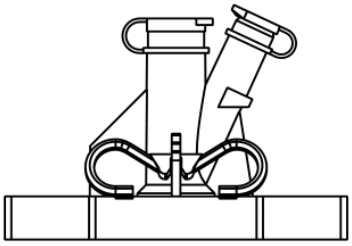


Figure 5. The insert is prepared for centrifugation without obtaining supernatant.

7. First spin

The selection of the centrifugation parameters (time and speed of centrifugation) depends on the type of the sample being tested, the cell strength on the centrifugal force.

1) Prepare the centrifuge and rotor for operation in accordance with the instructions in the centrifuge operating manual.
2) Place the hangers in the rotor in accordance with the instructions described in the previous chapter.
3) Fill the inserts with the sample liquid immediately before centrifuging (fill the inserts outside the centrifuge).
4) Insert the inserts directed with the sink cylinder into the rotor axis (4 pieces or 2 in opposite seats) for the hangers.

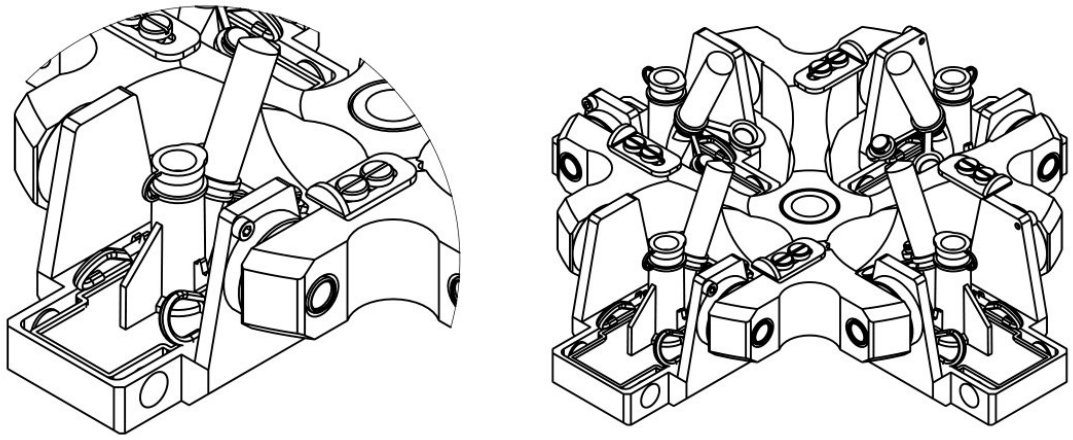


Figure 6. The way of placing the inserts in the rotor in the variant with obtaining the supernatant.

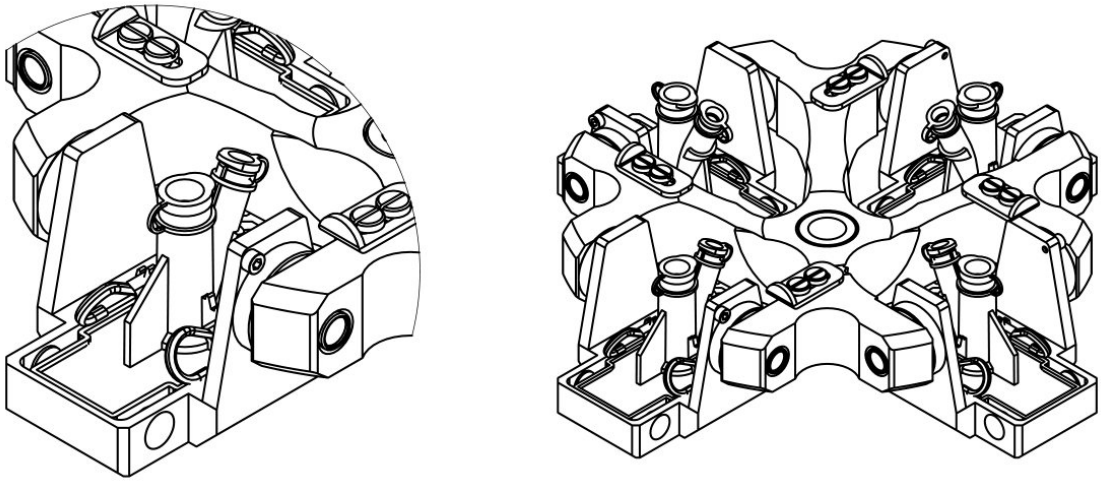


Figure 7. The way of placing the inserts in the rotor in the variant without obtaining the supernatant.

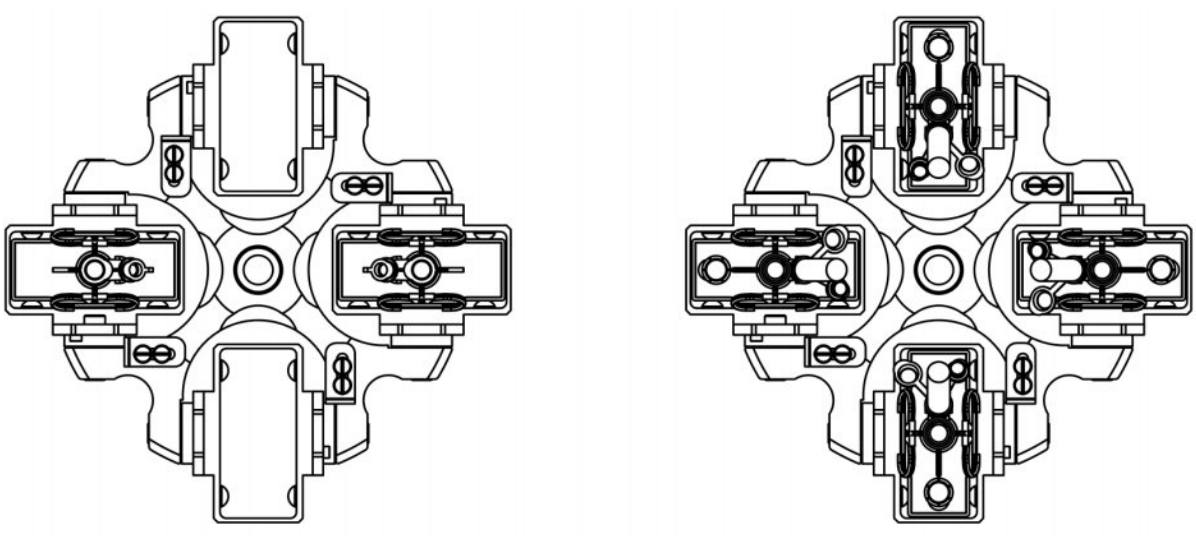


Figure 8. Placement of inserts in the rotor in case of 2 or 4 pieces spinning.

5) Close the centrifuge lid.
6) Set the spin parameters (time, speed), and then start the spin.
7) At the end of the spin, the lid will open automatically or it should be opened with the COVER button (depending on the centrifuge settings).

8. Second spin (drying of samples)

8.1. With obtaining the supernatant

Remove the insert from the hanger keeping its vertical position in which it will be after the centrifugation (the sinking tube will be pointing downwards).

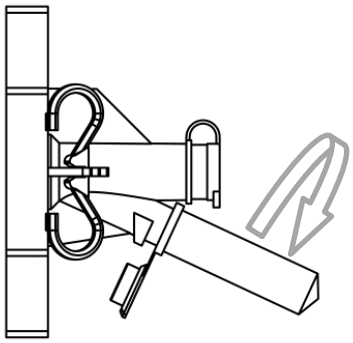


Figure 9. The insert after centrifugation in the variant with obtaining the supernatant.

With gentle torsional movement remove the sink tube (containing the supernatant) and plug cup.

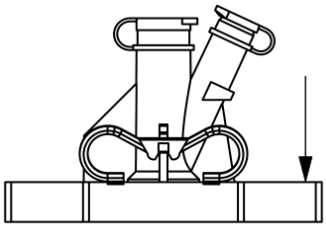


Figure 10. The insert after centrifugation in the variant with obtaining the supernatant.

Place the insert on one-side foil paper and remove the clips from the hooks. Then, in the area indicated by the arrow, gently press to raise the cover at an angle of 45 ° (around the shorter side) and release the microscope slide.

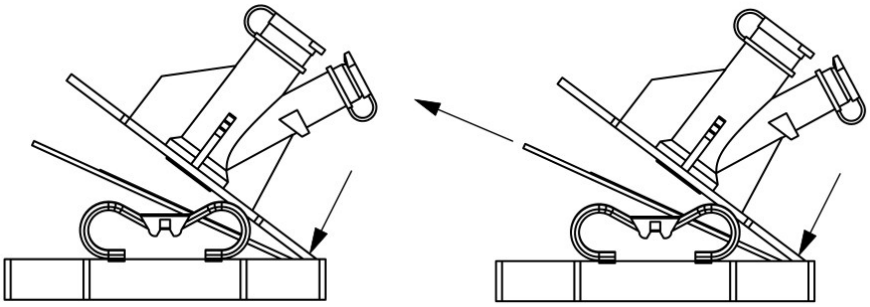


Figure 11. The way of removing the microscope slide

Carefully remove the slide, then remove the filter paper with pliers or tweezers and then put the paper filter with Ø9,5mm hole in the same place, trying not to move the remaining drop of the preparation.

Put the overlay on the support with the slide, and then fasten the clips evenly. Perform a second spin at the same speed as in the previous process. The preparation will be partially dried.

After the centrifugation, remove the microscope slide and remove the filter paper using tweezers or tweezers. The preparation is fixed and stained with selected techniques.

8.2. Without obtaining the supernatant

Remove the insert from hanger keeping its vertical position, in which it will be after the centrifugation. Due to the possibility of pouring out excess liquid (supernatant), which has not been absorbed by the filter paper, the inserts should not be tilted.

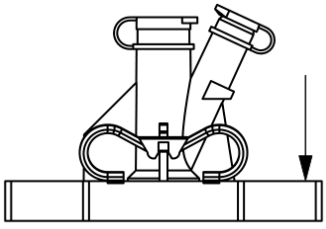


Figure 12. The insert after centrifugation in the variant without obtaining the supernatant.

Place the insert on one-side foil paper and remove the clips from the hooks. Then, in the area indicated by the arrow, gently press to raise the cover at an angle of 45 ° (around the shorter side) and release the microscope slide.

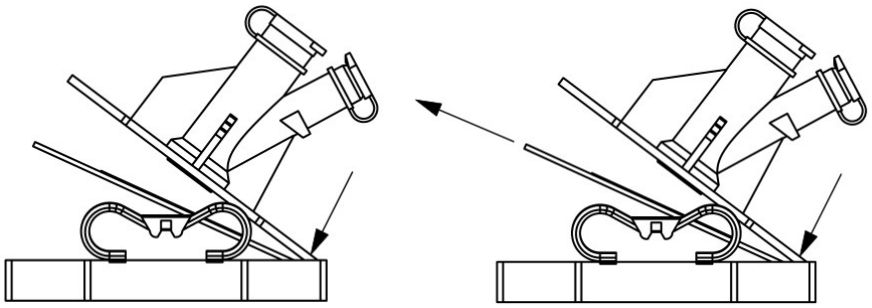


Figure 13. The way of removing the microscope slide.

After the centrifugation, remove the microscope slide carefully and remove the filter paper using tweezers or tweezers. The preparation is fixed and stained with selected techniques.

9. Disposal

The 16610 insert is a disposable product. After use, the insert should be disposed of in accordance with the procedures in force in the laboratory.

10. Manufacturer

"MPW MED. INSTRUMENTS" SPÓŁDZIELNIA PRACY
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E0008530W - registration number given by Chief Inspectorate Of Environmental Protection

PL/CA01-01782 - identification number given by Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

11. Distributor's info

DISTRIBUTOR:

12. Declaration of conformity

MPW MED. INSTRUMENTS

DECLARATION OF CONFORMITY

Product	**CYTO insert cytology rotor, type 610**
Type	**Type 610**
Catalogue number	**16610**

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product classification on the basis of the Directive 98/79/EC	Non classified to list A or B and not for self-testing

Product complies with the requirements:

· Directive 98/79/EC (IVD), including the requirements of harmonised standards:

EN 15223-1:2016	EN ISO 14971:2012
EN 13612:2002	EN ISO 18113-1:2011
EN 13612:2002/AC:2002	EN ISO 18113-3:2011
EN 13975:2003	EN 62366:2008

„MPW MED. INSTRUMENTS"
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w Warszawie

Członek Zarządu
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"MPW MED. INSTRUMENTS"
SPÓŁDZIELNIA PRACY
Warsaw, 46 Boremlowska Street
applies Quality Management System in line with PN-EN ISO 9001:2015, PN-EN ISO 13485:2016
Certifying authority:

TÜV NORD PN-EN ISO 9001
TÜV NORD PN-EN ISO 13485

Warsaw, 2018.09.15

no. 10.610.04.en

Suggestions regarding this manual should be directed to
www.mpw.pl/contact

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