



ColOff®

Specimen Collection Facilitator Device

What is in this leaflet

1. Product description

The product, a Specimen Collection Facilitator Device, is a plastic sleeve for the toilet seat used for diagnostic tests such as urine and stool tests.

2. What ColOff® is used for

ColOff® is a disposable device that facilitates the stool and urine collection as well as for pregnancy tests in the physiological position (sitting on the toilet seat).

3. ColOff®'s attributes

ColOff® is a hygienic, sterile, disposable, comfortable (used in the physiological position), easy to use and safe device for patients, increasing infection control whilst minimizing specimen contamination.

4. Before using ColOff® for

Stool and urine collection or pregnancy test:

Clean the toilet seat before starting the procedure and/or wear gloves at your convenience. If ColOff® is going to be used for a stool test, ensure that you have urinated and washed your hands before beginning the process.

5. Warning ColOff®

In case of possible danger, problem, or other unpleasant situation, adhere to the following:

- (a) Do not touch the faeces: it may be contaminated.
- (b) To avoid risk of suffocation, keep out of reach of children. Parent supervision is recommended when used by children.
- (c) The collected sample must be sent to the testing laboratory as soon as possible and should be stored at 2°C to 8°C until the sample can be transported.

6. Composition and Information:

Made from Oxo Biodegradable Plastic Film (HDPE - High Density Polyethylene. CAS: 9002-88-4. Inert and Non-toxic. Sterilized using gamma rays, according to AAMI/ISO 11737-2:2009 - Sterilization of medical devices. Sterile unless opened or damaged. Use gloves to preserve sterility. Single use only.

7. Storage Instructions:

Store in a clean, cool, dry place below 30°C. Shelf life: Indefinite.

8. Product TGA registered

IVD Medical Device - AUST R 219634.

9. To find out more about ColOff®

Please read and follow the instruction leaflet carefully before using the product! Consult your doctor for more information.

MAKING THE UNCOMFORTABLE COMFORTABLE



AUSTR R 219634

**Safe
Test**



2014 ColOff.™ Trademark
The sign and logotype are trademarks. All rights reserved
Patent. No. 8,136,175B1



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10. Innovation in healthcare

ColOff® is a new, unique and revolutionary healthcare device. ColOff® improves the process of specimen collection by being handed over along with the plastic container (which means ColOff® is not replacing the container, ColOff® is added to its kit) when patients are requested to undertake a stool / urine test by their GP or specialist.

Therefore ColOff®:

- (a) Allows patients to undertake the test in the physiological position and minimizes the need to cope with any unpleasantness, enhancing patients' dignity and quality of life (ColOff® can also be used in commode chairs).*
- (b) Increases infection control (sterilized via gamma rays)*
- (c) ColOff®'s single use system improves working conditions and staff efficiency, allowing more time to care for other patients (see item 12 for details).*
- (d) ColOff®'s single use system costs significantly less to purchase, operate and maintain than alternative re-usable systems (see item 12 for details).*
- (e) Due to its simplicity, ColOff® increases the number of responses returned to pathology labs for analysis of stool and urine.*

11. Clinical Application

ColOff® facilitates the collection of stool and urine for pathology testing. It aids all patients, especially the elderly and children, who need to undertake stool or urine tests in the physiological position without any stress or improvisation (please follow instructions on this leaflet). It provides a hygienic and comfortable process for the patient and minimizes specimen contamination compared to other procedures such as the sample being extracted from the water inside the toilet (Immunochemical FOBTs' methods). Furthermore, its single use system requires no energy and water compared to re-usable systems (bedpans and urinals). All you need to do is to place ColOff® like a sleeve around the clean toilet seat in the bathroom and it is then ready to use.

12. Benefits and implications

Environmental Benefits:

Lowering environmental impact - ColOff® is disposable and its single use system requires no energy and water compared to re-usable systems (bedpans and urinals) used for specimen collection. Most importantly, it results

in cost savings associated with not using an autoclave - which demands time, electricity and water (autoclave needs to be on for at least 15 - 20 min under high pressure in order to sterilise). Because ColOff® is made from Oxo Biodegradable High Density Polyethylene (HDPE), the degradation process is reduced from hundreds of years to years and/or months. Under appropriate temperatures and humidity conditions.

Nurse Time Benefits:

Increasing productivity and convenience – ColOff®'s single use system helps to improve working conditions and staff efficiency by replacing re-usable systems, allowing more time to care for other patients. ColOff® is convenient because it allows patients to undertake the test in the physiological position, increasing the patient's dignity and minimizing one to cope with unpleasantness.

Diseases Detection Benefits:

Increasing Test responses:

- (a) Due to its simplicity, ColOff® increases the number of responses returned to pathology labs for analysis of stool, urine and FOBT tests and therefore, helps increase the number of bowel cancer cases detected.*
- (b) Based on Australia's Bowel Cancer Screening Program - monitoring report 2012-2013 (relating to those turning 50, 55 or 65), about 33.4% of 963,518 people invited from July 2012 to June 2013 returned a complete bowel cancer screening kit for analysis. The 33.4% participation rate recorded in this report was lower than that reported in the previous monitoring report (35.0%). Reasons for these decreases are not known (Source - Australian Institute of Health and Welfare).*

Infection and Contamination Prevention Benefits:

Raising infection / contamination control standards – ColOff® is sterile and its single use system minimizes concerns of patients and specimen contamination.

Financial Benefits: Reduced running costs – ColOff®'s single use system costs significantly less to purchase, operate and maintain compared to alternative re-usable systems. Further financial benefits are provided through the savings in nursing time and reduction of costly healthcare-associated infections.

PLEASE FOLLOW INSTRUCTIONS ON THIS LEAFLET.

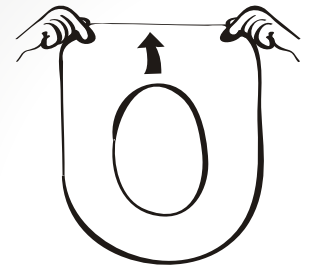
HOW TO USE ColOff®

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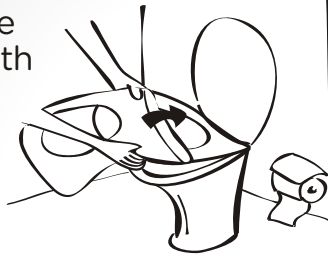
1 Remove **ColOff®** from its packaging, unfold it carefully and check if the product is not damaged.



2 Hold **ColOff®** with the open side upward and face the hole.



3 Place **ColOff®** like a sleeve around the clean toilet seat with the hole facing up and gently push its bottom downwards for adjustment.



4 After your bowel movement, **DO NOT** place any toilet paper inside **ColOff®**. Instead, dispose of the toilet paper in a waste bag.



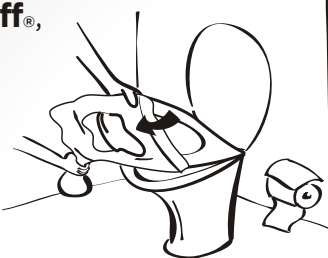
5 Extract a portion of the sample and place it inside the specimen container.



6 Whilst gently lifting the toilet seat, pull **ColOff®** and let the stool and/or urine slide down into the water.



7 To remove **ColOff®**, grasp and hold firmly the centre piece from the bottom and pull it out completely from the toilet seat.



8 Lastly, dispose of **ColOff®** in the waste bag.

IT IS NOT DESIGNED TO BE FLUSHED.

