

PMW RAYON SWAB

Device Name

Product Name: PMW Spun Swab
Model Name: PMW RAYON SWAB

General Description

PMW RAYON SWAB is comprised of blister pack containing a RAYON SWAB applicator for collecting clinical specimens. The PMW RAYON SWAB features RAYON fiber swabs that optimize specimen collection.

Intended Purpose

Rayon swab is intended for use in the collection and transport of clinical specimens from the nasal or throat secretions from the nose and throat. The sample is then analyzed for the presence of organisms or other clinical markers for disease.

Performance Characteristics

PMW RAYON SWAB is a specimen collection swab that has rayon fiber. The rayon specimen collection swabs have a solid plastic shaft of body.

To collect the sample, the swab is inserted in the nasal and oral cavity. The swab is then rotated for a specified period time to collect secretions, then the swab is removed.

PMW RAYON SWAB is a method for collecting a clinical test sample of nasal or oral secretions. The sample is then analyzed for the presence of organisms or other markers for disease.

Indications

The swab is suitable for short contact with nasopharyngeal and oropharyngeal of the human body.

Contra-indications

There are no known specified contraindications.

Patient Target Group

| | | | | | |
|--------|--------------|--------|--------------|---------------|--------------|
| Age | Not relevant | Weight | Not relevant | Nationality | Not relevant |
| Gender | Not relevant | Health | Not relevant | Patient State | Not relevant |

Intended Users

This medical device is intended to be used only by healthcare professionals such as doctors and medical personnel (e.g., research nurse or physician)

Residual Risks

There is no residual risk with this medical device after conducting risk management activities.

Precautions and warnings

- This product is disposable and reuse is strictly prohibited.
- This product should not be used if the package is damaged or opened.
- Do not use if expired expiration date.
- It should be used only for intended purpose.
- Do not use the device perpendicularly. Please use the device in an oblique direction.

Attention

- Take care as this may break if excessive force is applied during specimen collection.
- If this product is exposed to chemical and physical sterilization or micro-biostatic process, its intended performance may not be achieved.

PMW RAYON SWAB

- User should fully aware of usage before use.
- When handling specimen, be sure to have protective equipment to avoid any risk of infection and tested in accordance with bio-safety guidelines.
- Do not use unless peel-pouch is intact.
- Please be aware that the head part should not be touched.
- It should be disposed in a disposal box after used.

Undesirable Side-effects

If the device goes too deep into the patient's nose and throat during the use, the patient can be uncomfortable

Preparatory Treatment or Handling

- Storage at room temperature(1~30°C) as of sealed status.
- Check the sealed status if damaged or abnormalities and product damage before use and do not use if the package is damaged or opened.
- Check the expiration date of the product before use and do not use if expired.
- User should fully understand how to use this product.
- Wear gloves to prevent any infection.

Shelf-life (Life time)

- 3 years from the date of manufacture

Single Use

- This medical device is intended for single use.
- Information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used
- There is a risk of infection if the device is reused.

Information for Safe Disposal

- This device is disposable for single use only.
- Once used, it must be disposed of in accordance with the regulations, and reuse is prohibited.
- Wear gloves to prevent any infection.
- It should be disposed in a disposal box after used.

Notice to Users/Patients

Any serious incident that has occurred in relation to this medical device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.













Product Components

PMW RAYON SWAB that is included in one blister packaging.

How to Use

- ① Peel off the sealed film package then, pull the product out after grab the body handle.
- ② Collecting specimen from the mouth, nasal cavity, ear or anus. In order to reduce the possibility of other contamination, the TIP part of the head is in contact with the suspected infection area quickly.
- ③ Rotate the body handle a few times to ensure that the specimen are effectively collected to the head end.

Symbols of Packaging

| | | | | | |
|---|---|---|----------------------|---|----------------------------------|
|  | CE marking |  | Medical Device |  | Manufacturer |
|  | Authorized representative in the European Community |  | Date of manufacturer |  | Use-by date |
|  | Lot Number |  | Catalogue Number |  | Do not use if package is damaged |
|  | Temperature limit |  | Do not re-use |  | Caution |



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