

Sani-Cloth HyPerOxide - Information for Use (IFU)

Sani-Cloth HyPerOxide are pre-dosed disposable sporicidal disinfection and cleaning wipes for non-invasive medical devices; non-porous hard surfaces.

Uses: Disinfection for general surfaces in the Medical Area.

Directions: Dispense wipe and open, clean surface in S-motion from top to bottom of area. Ensure the surface remains visibly wet for the required contact time, use another wipe if needed. Allow surface to air dry.

Caution: Wear protective gloves when using the wipes. Wash hands thoroughly after handling. For external use only. Avoid contact with eyes. Causes serious eye irritation. If in eyes; rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical advice. Do not use on invasive medical devices. Follow the medical device manufacturers cleaning and disinfecting guidelines. For Professional Use Only. Keep product closed and stored upright in a cool dry place away from direct sunlight. Keep below 23°C.

PPE: Use gloves.

Address: PDI Ltd, Aber Park, Flint, Flintshire, CH6 5EX

Storage: Keep product below 23°C. Store upright. Keep out of direct sunlight.

Product Usage: This product is single use. Once a wipe is dispensed from the packaging, it can only be used once and then must be disposed. Overuse and re-use will not provide the efficacy required for correct product use. Do not use if the packaging appears damaged. Do not use any wipes that are dry.

Composition: 7.5% w/w Hydrogen Peroxide, <1% Surfactant

Regulatory Classification: CE marked 93/42/EEC

| | Product Code | Pack Format | Wipes per Pack | Packs per Case | Wipe Size | NHS Code |
|---|--------------|-------------|----------------|----------------|-----------|----------|
|  | XP00398 | Canister | 100 wipes | 6 | 195x180mm | N/A |

How to Use the Wipe

1 Before you start always wear the correct PPE.

1. Check with your internal protocols to ensure that the correct PPE is used for the product, area and equipment you are about to clean and/or disinfect.

2 Refer to label instructions and 'Use by' date.

2. Check the expiry date.

3

3. Instructions are available for opening the canisters.

4 **VISIBLY CLEAN ? VISIBLY SOILED**
Remove any visible soiling with first wipe before using additional wipes.

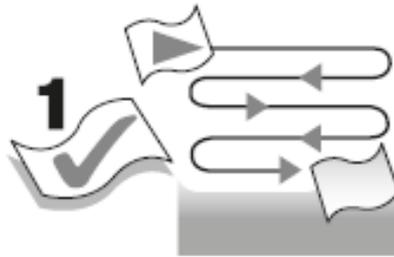
4. Wipe use instructions - Remove any visible soiling with the first wipe, then use an additional wipe to disinfect.

5 **1** **2**

5. Remove only one wipe at a time. Open out the wipe.

6

**For 1 application
use 1 wipe and
follow this wipe
direction.**



6. Wipe direction should be 'dirty to clean', top to bottom, taking care not to go over the same area twice to prevent any cross contamination.

7



**Recommended surface area
coverage 1 m square.
Allow disinfectant to dry
on surface- Contact time.**



**Dispose of used wipe into
clinical waste.**

7. Contact Time & Drying Time

- a. One wipe covers an approximate surface area of one (1) metre square. Do not overuse the wipe, if it becomes dry or soiled discard and use another wipe to complete the area.
- b. Allow the disinfected area to air dry.
- c. Dispose of used wipes in the clinical waste bin.
- d. After use ensure the packaging lid is closed. Once empty, dispose of the packaging in the recycling bin, or according to local protocol

| PRODUCT EFFICACY | |
|--|----------------------------|
| EN 16615 4-Field Test (Mechanical Action) | BACTERIA |
| Pseudomonas aeruginosa | 60 sec (c) |
| Staphylococcus aureus | 60 sec (c) |
| Enterococcus hirae | 60 sec (c) |
| EN 13727 | BACTERIA |
| Pseudomonas aeruginosa | 30 sec (d) |
| Staphylococcus aureus | 30 sec (d) |
| Enterococcus hirae | 30 sec (d) |
| MRSA | 15 sec (d) |
| EN 16615 4-Field Test (Mechanical Action) | YEAST |
| Candida albicans | 60 sec (c) |
| EN 13624 | YEAST |
| Candida albicans | 30 sec (c) |
| Candida auris | 30 sec (c) |
| EN 14476 | ENVELOPED VIRUS |
| Vaccinia virus (HBV, HCV, HIV, H5N1, SARS, Corona) | 30 sec (c) |
| EN 14476 | NON ENVELOPED VIRUS |
| Norovirus | 30 sec (c) |
| Adenovirus | 60 sec (c) |
| EN 16615 | SPORES |
| Clostridium difficile | 60 sec (c) |
| *EN 13704 | SPORES |
| Clostridium difficile | 2min (c) |
| EN 17126 | SPORES |
| Clostridioides difficile | 15min (c) |
| MBEC | BIOFILM |
| Pseudomonas aeruginosa | 2min (c) |
| Staphylococcus aureus | 2min (c) |

* EN13704 was tested to the new 2018 standard using mature spores

Product Efficacy /Product Claims: the time listed can be followed by letters that indicate the test conditions used during the testing of the product (c) for clean conditions or (d) for dirty conditions.

Packaging Symbols

Here are some of the most common symbols you may find on PDI product packaging and their description:

| Title of Symbol | Description of Symbol | Symbol (Colours may vary) |
|------------------------------|---|---|
| Do not flush | Do not flush |  |
| Do not macerate | Do not macerate |  |
| Consult instructions for use | Indicates the need for the user to consult the Instructions for use, available on the website at www.pdihc.com/global |  |
| CE mark | CE mark Medical Device Directive Class IIa |  |
| Do not re-use | Indicates a medical device (wipe) that is intended for one use, or for use on a single patient during a single procedure |  |
| Manufacturer | Indicates the medical device manufacturer, as defined in EU directives 90/385/EEC, 93/42/EEC and 98/79/EC |  |
| Expressed liquid | Stability and testing completed on liquid expressed from the wipe, rather than bulk liquid. |  |
| PAO | Period after opening – the period of time the product can be used once the product has been opened. |  |
| Wipe count | How many wipes are in the pack. |  |
| LOT | Allocated LOT or batch number of the product |  |
| Expiry | The expiry date of the product |  |

| | | |
|----------------------------------|---|---|
| High Density Polyethylene (HDPE) | HDPE 2 is a high density-to-strength ratio and is commonly recycled, and has the number “2” as its resin identification code. |  |
|----------------------------------|---|---|

Label Elements

2.2. Label elements

Label elements:

Hazard statements: H319: Causes serious eye irritation.

Hazard pictograms: GHS07: Exclamation mark



Signal words: Warning

Precautionary statements: P264: Wash hands thoroughly after handling.

P280: Wear <protective gloves/protective clothing/eye protection/face protection>.

P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+313: If eye irritation persists: Get medical <advice/attention>.

[cont...]

Authorised Representative in the European Community



NEX MEDICAL ANTISEPTICS S.r.l.

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FAQ's

What is contact time and what happens if the surface dries before the stated contact time on a Sani-Cloth product label?

The contact time listed on the **Sani-Cloth** product label is the total amount of time that it takes to inactivate the microorganisms listed on the product label. This time is typically referred to in minutes, and should be communicated to staff members that are utilising the disinfectant. In certain geographies and also in settings where temperature, relative humidity, and air changes may vary, it is possible that the surface may not remain visibly wet for the designated contact time. Current industry guidance requires that the treated environmental surface or equipment remains wet for the contact time stated on product label. Additional wipes may be needed in order to comply with the industry guidance, however the overall contact time does not change.

While the current industry guidance requires the treated environmental surfaces to remain wet for the stated contact time, leading researchers in infection prevention offer an alternate view. In a commentary published in Infection Control and Hospital Epidemiology (March 2018, vol. 39, no. 3, pp 229-331), Dr. W.A. Rutala and Dr. D. J. Weber suggest that contact time and treatment time are mutually exclusive. They suggest that treatment time, irrelevant of wet time, should be followed by healthcare workers for wipes and sprays (except bleach products.) PDI will continue to monitor the science closely and provide their customers with the latest information.

Following cleaning and disinfection the surface should be allowed to fully air dry.

Additional Information

Printed copies of this IFU are available upon request. Email: sales@pdi-hc.co.uk
Previous revisions of IFU's are available upon request. Email: sales@pdi-hc.co.uk
Document language: English (EN)