

## Sani-Cloth CHG 2% - Information for Use (IFU)

**Sani-Cloth CHG 2%** are pre-dosed, alcohol and CHG non linting disposable disinfection wipes for non-invasive medical devices; non-porous hard surfaces.

**Uses:** Disinfection wipes for Hubs and Connection Ports.

**Directions:** Tear open the sachet, remove and unfold the wipe. use the wipe to disinfect the desired surface area. Allow surface to air dry.

**Caution:** Wear protective gloves, IF ON SKIN: Wash with plenty of soap and water, Avoid contact with eyes, IF IN EYES: Rinse cautiously for several minutes. Remove contact lenses; if present and easy to do so. Continue rinsing. Get medical advice. Keep away from heat – No Smoking. Dispose of container in accordance with local regulation. Do not use on invasive medical devices. Follow the medical device manufacturers cleaning and disinfecting guidelines. For Professional Use Only.

**PPE:** We recommend using gloves.



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

**Storage:** Store upright. Keep out of direct sunlight. Keep away from naked flame.

**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:** 70% v/v Isopropyl Alcohol and 2%w/v Chlorhexidine Gluconate.

**Regulatory Classification:** CE marked 93/42/EEC

	Product Code	Pack Format	Wipes per Pack	Packs per Case	Wipe Size	NHS Code
	XP00220	Sachet	100 wipes	12	150x129mm	VJT516
	XP00314	Sachet	200 wipes	8	150x129mm	VJT560

## 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**

**VISIBLY CLEAN ? VISIBLY SOILED**

**Remove any visible soiling with first wipe before using additional wipes.**

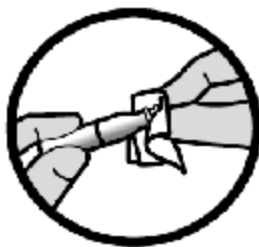
3. Wipe use instructions - Remove any visible soiling with the first wipe, then use an additional wipe to disinfect.

**4**



4. Tear open the sachet and remove the wipe.

**5**



5. Disinfect using a semi-circular scrubbing motion on the hub ensuring full contact between the wipe and the needleless connector. Ensure the grooves and threads are thoroughly scrubbed and the surface at the end of the device.













6. Allow the surface to completely dry before using the medical device.
7. Contact Time & Drying Time
  - a. 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.  
Dispose of used wipes in the clinical waste bin.

<b>PRODUCT EFFICACY</b>	
<b>EN 16615 4-Field Test (Mechanical Action)</b>	<b>BACTERIA</b>
Pseudomonas aeruginosa	60 sec (c)
Staphylococcus aureus	60 sec (c)
Enterococcus hirae	60 sec (c)
<b>EN 13727</b>	<b>BACTERIA</b>
Pseudomonas aeruginosa	30 sec (c)
Staphylococcus aureus	30 sec (c)
Enterococcus hirae	30 sec (c)
<b>EN 16615 4-Field Test (Mechanical Action)</b>	<b>YEAST</b>
Candida albicans	60 sec (c)
<b>EN 13624</b>	<b>YEAST</b>
Candida albicans	30 sec (c)
<b>EN 14476</b>	<b>ENVELOPED VIRUS</b>
Vaccinia virus (HBV, HCV, HIV, H5N1, SARS, Corona)	15 sec (c)
<b>EN 14348</b>	<b>TB</b>
Mycobacterium terrae	60 sec (c)




**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 <a href="http://www.pdihc.com/global">www.pdihc.com/global</a>	
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.	
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	

## Label Elements

<b>SYMBOLS</b>			
<b>Signal Word</b>	<b>DANGER</b>		
<b>Hazard Statements</b>			
<b>H225</b>	Highly flammable liquid and vapour		
<b>H319</b>	Causes serious eye irritation		
<b>H336</b>	May cause drowsiness or dizziness		
<b>H410</b>	Very toxic to aquatic life with long lasting effects.		
<b>Precautionary Statements</b>			
<b>P273</b>	Avoid release to the environment		
<b>P280</b>	Wear protective gloves/protective clothing		
<b>P210</b>	Keep away from heat/sparks/open flames/hot surfaces – No Smoking		
<b>P235</b>	Keep Cool.		
<b>P302+P350</b>	IF ON SKIN: Wash with plenty of soap and water.		
<b>P305+P351+P338+P337+P313</b>	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses; if present and easy to do so. Continue rinsing. If eye irritation persists: Get medical advice/attention.		
<b>P501</b>	Dispose of contents/container in accordance with local/regional/national regulation.		

## Authorised Representative in the European Community



NEX MEDICAL ANTISEPTICS S.r.l.  
Via Per Arluno 37/39 20010 CASOREZZO ( MI ) Italy



## 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](mailto:sales@pdi-hc.co.uk)  
Previous revisions of IFU's are available upon request. Email: [sales@pdi-hc.co.uk](mailto:sales@pdi-hc.co.uk)  
Document language: English (EN)