Super Sani-Cloth Plus - Information for Use (IFU)

Super Sani-Cloth Plus are pre-dosed, alcohol, non linting disposable disinfection 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, 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.

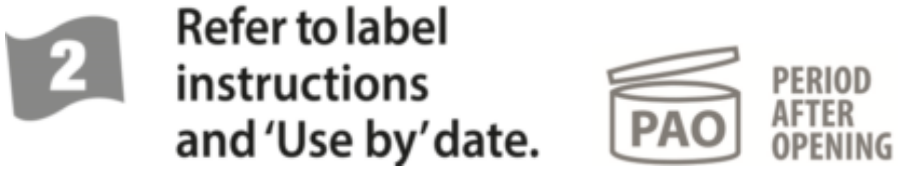
Composition: Isopropyl Alcohol B.P 70% v/v, Alkyl Dimethyl benzyl ammonium chloride 0.25%, Alkyl Dimethyl Ethyl benzyl ammonium chloride 0.25%.

Regulatory Classification: CE marked 93/42/EEC

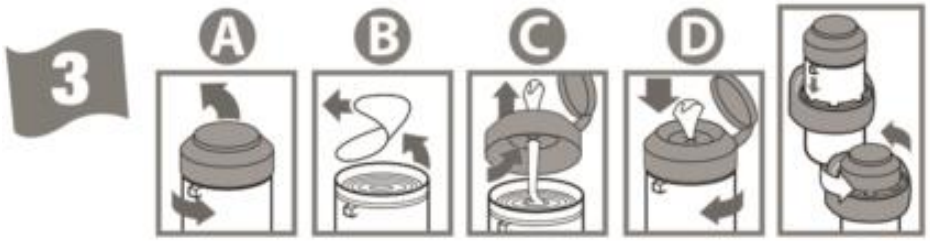
	Product Code	Pack Format	Wipes per Pack	Packs per Case	Wipe Size	NHS Code
	XP00141	Canister	200 wipes	6	200x200mm	VJT007
	XP00192	Canister	125 wipes	6	185x133mm	VJT594

How to Use the Wipe

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. Check the expiry date.



3. Instructions are available for opening the canisters.

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

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

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. 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**
Staphylococcus aureus	60 sec (d)
Escherichia coli	60 sec (d)
Pseudomonas aeruginosa	60 sec (d)
Enterococcus hirae	60 sec (d)
EN 13697	**BACTERIA**
Escherichia coli	60 sec (d)
Enterococcus hirae	60 sec (d)
Staphylococcus aureus	60 sec (d)
Pseudomonas aeruginosa	60 sec (d)
EN 14561	**BACTERIA**
Methicillin resistant Staphylococcus aureus (MRSA)	2 min (d)
EN 1276	**BACTERIA**
Pseudomonas aeruginosa	30 sec (c+d)
Escherichia coli	30 sec (c+d)
Enterococcus hirae	30 sec (c+d)
Staphylococcus aureus	30 sec (c+d)
EN 16615 4-Field Test (Mechanical Action)	**FUNGI & YEAST**
Candida Albicans (Yeast)	60 sec (c)
EN 13624	**FUNGI & YEAST**
Candida Albicans (Yeast)	30 sec (d)
EN 13697	**FUNGI & YEAST**
Candida Albicans (Yeast)	60 sec (d)
EN 14476	**ENVELOPED VIRUS**
Vacciniavirus (HBV, HCV, HIV, H5N1, SARS, Corona)	15 sec (c+d)
EN 14348	**TB**
Mycobacterium terrae	30 sec (c)

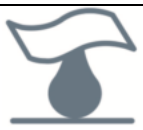
Product Efficacy /Product Claims: the time listed can be followed by letters that indicate the test conditions used during the testing of the product (c) for clean conditions or (d) for dirty conditions.

PRODUCT EFFICACY – EPA Test Results (USA)	
US EPA Guidelines (wipe test)-	**BACTERIA**
Pseudomonas aeruginosa ATCC 15442	5min (d)
Escherichia coli O157:H7 (ATCC 35150)	5min (d)
Staphylococcus aureus ATCC 6538	5min (d)
Klebsiella pneumoniae ATCC 4352	4min (d)
Salmonella Choleraesuis ATCC 10708	5min (d)
Methicillin resistant Staph aureus (MRSA) (ATCC 33591)	5min (d)
Vancomycin Resistant Enterococcus faecalis	5min (d)
US EPA Guidelines (wipe test)-	**FUNGI & YEAST**
Candida albicans ATCC 11651 (Yeast)	4min (d)
US EPA Guidelines (wipe test)-	**ENVELOPED VIRUS**
HIV - 1 Type 1	1min (d)
Influenza A Hong Kong	1min (d)
Vaccinia virus	1min (d)
Herpes simplex type 2	1min (d)
US EPA Guidelines (wipe test)-Southern Research Inst.	**NON ENVELOPED VIRUS**
Adenovirus	1min (d)
Rhinovirus	1min(d)
US EPA Guidelines (wipe test)-	**TB**
Mycobacterium bovis	1min (d)

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 define in EU directives 90/385/EEC, 93/42EEC 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

SYMBOLS		
	IRRITANT	**HIGHLY FLAMMABLE**
Signal Word	**DANGER**	
Hazard Statements		
H225	Highly flammable liquid and vapour	
H319	Causes serious eye irritation	
H336	May cause drowsiness or dizziness	
H412	Harmful to aquatic life with long lasting effects	
Precautionary Statements		
P280	Wear protective gloves/protective clothing	
P210	Keep away from heat/sparks/open flames/hot surfaces – No Smoking	
P235	Keep Cool.	
P302+P350	IF ON SKIN: Wash with plenty of soap and water.	
P305+P351+P338+P313	IF IN EYES: Rinse cautiously for several minutes. Remove contact lenses; if present and easy to do so. Continue rinsing. Get medical advice/attention.	
P501	Dispose of contents/container in accordance with local/regional/national regulation.	

Authorised Representative in the European Community

EC REP

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