

Q: What products do you manufacture to repair damaged treatment surfaces?

A: We manufacture three repair products:

1. CleanPatch is a blue polyurethane patch that repairs damaged mattress covers and stretchers, but it can also be used to repair vinyl surfaces when a more pliable patch is required.
2. CleanPatch-V is a black vinyl patch that repairs vinyl surfaces such as wheelchairs and treatment tables.
3. CleanPatch-P is a clear polyurethane patch that repairs patient gel pads and positioners.

Q: Is CleanPatch safe for clinical use?

A: All CleanPatch products are medical grade, latex-free, non-cytotoxic, and hypoallergenic.

Q: How thick are the patches?

A: The thickness varies between product lines: CleanPatch is 0.18mm, CleanPatch-V is 1.11mm, and CleanPatch-P is 0.155mm.

Q: Does CleanPatch comply with regulatory bodies?

A: CleanPatch is an FDA, Health Canada, CE MDR, UKCA, and TGA-registered Class 1 medical device. The CleanPatch FDA Establishment License Number is 3010580775, and the Health Canada MDEL Number is 5358.

Q: How long does CleanPatch last?

A: There is no set time limit for how long CleanPatch will last because its performance depends on the equipment type, area of clinical use, frequency of cleaning, and type of disinfectant used. In our initial 12-month clinical study, CleanPatch remained intact after one year, and all CleanPatch located at 22 months remained intact. CleanPatch may be used as long as it remains fully adhered and the surface to which it is applied remains suitable for use. However, CleanPatch should not be used to repair equipment that is older than the manufacturer's recommended use-by date.

Q: What does the Use-by Date on the CleanPatch package refer to?

A: CleanPatch is a Class 1 Medical Device, so every package must be assigned a lot number and shelf life. The use-by date on the CleanPatch product refers to the final date the product should be applied; it does not refer to the product once it has been applied to the treatment surface.

CleanPatch is designed to adhere to a damaged surface permanently. Once applied, it can remain fully adhered to the surface for years, even with frequent and rigorous cleaning and use. There is no expiration date for when the patch will need to be replaced.

Q: Is CleanPatch compatible with my hospital disinfectant?

A: CleanPatch products are compatible with common disinfectants such as Accelerated Hydrogen Peroxide (Diversey Oxivir), Sodium Hypochlorite (Clorox Bleach), Isopropanol (Metrex CaviCide), and Quaternary Ammonium (Ecolab Quaternary). CleanPatch products are also compatible with ultraviolet light.

The table below shows the concentrations of disinfectant that have been tested:

Cleaning Agent	Active Concentration	Parts per Million
Hydrogen Peroxide	1%	10,000 ppm
Sodium Hypochlorite	3%	28,500 ppm
Isopropanol	17.2%	n/a
Quaternary Ammonium	2.4%	24,000 ppm

Q: What steps should I take before applying CleanPatch?

A: The damaged surface should be cleaned and disinfected with a cleaning agent per hospital protocol. Ensure the surface is dry before application.

Q: What fire-retardant status does CleanPatch have?

A: CleanPatch has a crib 5 eco flame retardant, Directive 2011/65/EU Compliant.

Q: The CDC Guidelines for Environmental Infection Control in Health-Care Facilities (2003) says I should not patch holes or tears but must replace the mattress.

A: We have an encouraging response from the CDC regarding the use of CleanPatch in healthcare facilities:

While it is true that the Guideline indicates that patches do not provide a good seal sufficient to prevent fluid permeation, we recognize that technology in healthcare textile repair is improving. The key word in the CDC discussion and recommendation is "impermeable." If the FDA-cleared patch is intended specifically for mattress/mattress cover repair and if there are instructions for use and you can test in your laundry whether or not the patch effectively seals the tear or hole, it should be suitable for use provided the repair is truly impermeable.

Please note that CleanPatch has been independently tested and proven impervious to fluids.

Q: Is CleanPatch Joint Commission (TJC) Compliant?

A: The Joint Commission recognizes patching with an approved product as a valid solution for damaged patient surfaces. Joint Commission Resources published a guide in 2018 titled *Environmental Infection Prevention: Guidance for Continuously Maintaining a Safe Patient Care and Survey-Ready* that states: "Avoid tears or holes in upholstery or mattresses. Patch any holes or tears with an approved product that can be cleaned and disinfected (that is, no tape)."

When staff are properly trained to use CleanPatch and have access to the relevant documentation, CleanPatch will be compliant with your TJC inspection. CleanPatch is already used by many TJC-accredited facilities.

Q: Can CleanPatch repair other surfaces besides mattresses and stretchers?

A: CleanPatch can repair other patient support surfaces such as stretchers, treatment tables, wheelchairs, OR pads, positioners, exam tables, and more.

Q: Is CleanPatch available in other colours?

- CleanPatch is available in imperial blue because it is the most common colour of mattress covers. Mattresses are usually covered by bed linens, so CleanPatch is invisible to patients while still protecting their safety.

- CleanPatch-V is available in black.
- CleanPatch-P is clear with a white watermark, and it is recommended to be used only on surgical gel pads and positioners.

Q: What happens if CleanPatch becomes damaged or requires replacement?

A: If CleanPatch becomes damaged or begins to peel away from the surface, it should be replaced. It may be difficult to remove as the adhesion of CleanPatch builds over time. Carefully try to peel off the patch, and if it comes off, you should assess and clean the damaged area, then replace the patch. If the patch does not come off, or if the mattress cover or upholstery starts to tear, cover the old patch with a new CleanPatch, preferably larger in size, to ensure the new patch extends beyond all edges of the damage by the recommended margin.

Q: Can CleanPatch be cut to fit a damaged area?

A: CleanPatch is die-cut, meaning each patch has a precise edge, and cutting into a patch may affect its ability to adhere to the surface to which it is applied. As the manufacturer, we cannot stand behind the product's performance once it has been modified; however, CleanPatch is available in various shapes and sizes so that you can choose the most appropriate patch for the repair.

Q: Can you provide product demonstrations?

A: YouTube videos demonstrating the application and utility of CleanPatch products can be found here: <https://www.youtube.com/@SurfaceMedicalInc>.

Q: Can I use CleanPatch to repair corners?

A: CleanPatch should be applied to surfaces where it can adhere with no folds or wrinkles. CleanPatch can bend around an edge in 2 dimensions (e.g. around one side to another side or from the top cover down one side) but not around a 3-dimensional corner, which results in folding the patch.

Q: How many CleanPatch can I use on one piece of equipment?

A: Equipment may have more than one area of damage. We recommend that a maximum of six areas be repaired, for example, on one mattress cover or exam table. The value of the equipment and the availability of a replacement may influence your decision.

Q: How long does it take for CleanPatch to adhere fully?

A: While it is true that the strength of the adhesive increases over time, CleanPatch does not require time to cure before using your newly repaired equipment.

Q: Does CleanPatch interfere with X-rays? Is CleanPatch radiopaque?

A: No, CleanPatch is radiolucent.

Do you have a question not covered here? We can help! Please email us at info@surfacemedical.ca.