CLEANPatch-V

Clinical Validation Study - Determining the durability of CleanPatch-V for repairing vinyl surfaces in a hospital setting.

A Case Study – April 16th, 2018

Background

Surfaces play a key role in the transmission of healthcare-acquired infections, and thorough cleaning of the healthcare environment is crucial to patient safety. Damaged soft surfaces cannot be properly cleaned and may harbor pathogens that pose a risk of cross contamination.¹ CleanPatch-V is newly developed Health Canada and FDA registered Class 1 medical device specifically designed to restore damaged vinyl surfaces to an intact and hygienic state.

Opportunity

Vinyl upholstery is a common material used in the production of many soft surfaces in healthcare, including wheelchairs, examination tables and geriatric chairs. Healthcare assessments have revealed that vinyl is frequently damaged in many facilities today, ranging from small punctures to extensive cracking². Current solutions to address this problem include purchasing new equipment, which is expensive, and reupholstery, which is inconvenient. Validation studies of CleanPatch-V in two healthcare facilities were conducted to determine the product durability in a real hospital setting.

Method

Two hospitals were selected to conduct the CleanPatch-V validation trial, which lasted 12 weeks. Staff identified all damage vinyl surfaces that were suitable for repair (i.e. no signs of fluid ingress, not on a 3-dimensional corner and/or damage size less than 6 inches).

An appropriate size of CleanPatch-V (either 1.75×4 inch strip or 6×8 inch rectangle) was applied to the damaged area following manufacturer's instructions. Hospital staff was instructed to clean and disinfect the surface and CleanPatch-V according to regular protocols.

Patches were inspected and photographs were taken at regular intervals during the trial period. Any evidence of flagging, peeling or lifting was noted during each inspection. A total of 26 vinyl surfaces were repaired using CleanPatch-V. Examples of repaired equipment include:

- Geriatric Chairs
- Examination Tables
- Procedure Chairs
- Waiting Room Furniture
- Diagnostic Imaging Pads

Results

Of the 26 vinyl surfaces repaired with CleanPatch-V, 96% held up without any evidence of peeling, flagging or lifting during the study period.

Please see Appendix 1 for examples of repaired damage over the study period.

Conclusion

Two different sizes of CleanPatch-V were durable over a 12 week period in the repair of various damaged vinyl surfaces in a healthcare setting.

For more information about this case study, please contact Tony Abboud at <u>tony@surfacemedical.ca</u>

References:

- FDA Safety Communication: Damaged or worn covers for medical bed mattresses pose risk of contamination and patient infection. April 19, 2013
- Based on MIA projects at four large Canadian teaching hospitals. SMI internal data, 2015-2017

Appendix 1

