

UMF Corporation Tracking Form for New Technology Add-on Payment Acute IPPS
Fiscal Year 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850



**Tracking Form for Applicants for New Technology Add-on Payments under the Acute
Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2012**

1. Technology Name: Healthcare Associated Infection (HAI) Prevention System &
Methodology Utilizing a Rechargeable Antimicrobial that Eliminates Both
Bacteria & Virus.

2. Manufacturer Name: UMF Corporation

3. Trade Brand of Technology: PerfectCLEAN with Micrillon[®]

4. Brief Description of Service or Device: An established HAI Prevention methodology supported by a system of high performance re-chargeable, antimicrobial, color coded micro-denier textiles that Remove, Trap & Eliminate HAI pathogens such as Methicillin Resistant Staph. Aureus (MRSA), Clostridium difficile (C dif.) and the H1N1 flu virus, from health care environmental surfaces. Once removed and trapped within the micro-denier fibers. The micro-organisms are exposed to high levels of chlorine bound to the surface of the fiber by chemical receptors embedded in each and every fiber. The organism comes into contact with the bound chlorine, the bacteria is killed and/or the virus is inactivated thus exhausting (consuming) some of the chlorine. This unique non-leaching chlorination system built in to every fiber recharges in the wash process attracting and binding free molecules of chlorine and recharging back to its original strength and efficacy. According to the Center for Disease Control (CDC) chlorine is preferred as it is the most effective antimicrobial and the only disinfectant effective against Clostridium difficile spores as well as vegetative forms of bacteria such as MRSA and other HAI-causing organisms.

When used following prescribed procedures, most of these HAI-causing microorganisms are eliminated within five minutes of being removed from the surface and trapped in the textile, contributing to a safe patient environment and mitigating the risk of infection, treatment, liability and the increasing cost of litigation.

Newness Criterion:

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

Does not apply; the PerfectCLEAN with Micrillon[®] System & Methodology falls under the purview of the Environmental Protection Agency (EPA) and currently is not regulated by the Food and Drug Administration.

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6. Was the product available on the market immediately after FDA approval?

Does not apply.

7. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

Does not apply; at present, there is no single International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code assigned to this infection prevention system & methodology.

8. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system?

An application for outpatient pass-through payments under the Medicare outpatient prospective payment system will be submitted concurrent with this application, however no tracking number is available at this time.

Cost Criterion:

8. The average Standardized Charge for these new technologies is anticipated to be \$100.00 per patient day. Because this technology is applicable to all MS-DRGs, the Standard Charge per MS-Drg will vary.

9. The total estimated Cost per patient day for these new procedures and systems, including labor, are anticipated to be in the range of \$45.00 and \$58.00. The anticipated cost breakdown would be comprised of the following:

- Payroll associated costs; \$12.00 - \$20.00
- Treated Textiles (to remove, trap and eliminate contaminants); \$25.00 - \$30.00
- Packaging, protective gloves and collection units for soiled textiles; \$3.00
- Laundering/re-charging costs; \$3.00
- Storage and distribution: \$2.00

10. The PerfectCLEAN with Micrillon[®] methodology and tools are applicable to the current roster of all Medicare Severity Diagnosis-Related Groups (MS-DRGs) procedures, both before and after treatment.

11. The annual volume of Medicare cases involving this technology is anticipated to exceed 10,000,000 cases.

Clinical Improvement Criterion:

12. The PerfectCLEAN with Micrillon[®] HAI Prevention System embodies a break-through improvement compared to traditional methods in the removal and elimination of micro-organisms responsible for HAI from environmental surfaces. These improvements are tied to three innovations.

The first is that rather than the traditional method of applying liquid disinfectants then wiping or mopping up the non-evaporated liquids, the PerfectCLEAN with Micrillon[®] System and Methodology

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s first remove the HAI-causing micro organisms from those surfaces using specially designed microscopic fibers that then trap and eliminate them in the textile.

The second key innovation is the formulation of a chlorine-binding technology that is introduced at the pellet-stage of fiber extrusion that is present throughout the fiber, as opposed to a finish or coating process that wears off as the textiles are used and laundered. This second innovation maintains the systems' efficacy throughout the life of the textiles and consistently assures that potent levels of chlorine, covalently bound to the fibers upon laundering, are available to eliminate these micro-organisms in minutes, rather than hours. These rapid elimination efficacies further reduce cross-contamination of those persons handling soiled textiles after the people contact surfaces have been cleaned of harmful micro-organisms.

The third innovation relates to training in the use of color-coded textiles that affords superior monitoring and compliance supervision of the hygiene specialists charged with responsibility to reduce cross-contaminations that lead to HAIs.

Following the practices of hand hygiene, these new methodologies and systems reduce the cross-contamination that arises when clean hands come in contact with an infected hand rail, stethoscope, IV pole, computer keyboard, doorknob or restroom handle.

Related peer-review articles and supportive publications include:

1. *"The Role of Environmental Cleaning in the Control of Hospital-Acquired Infection"*; S. J. Dancer, Journal of Hospital Infection (2009) 73, 378-385.
2. *"Favorable Impact of an Infection Control Network on Nosocomial Infection Rates in Community Hospitals"*; Keith S. Kayne, MD; John J. Engemann, MD; Evelyn M. Fulmer, RN; Connie C. Clark, RN; Edwin M Noga, MHA; Daniel J. Sexton, MD; Infection Control and Hospital Epidemiology, March 2006, Vol. 27, No.3.
3. *"Efficacy of Selected Hand Hygiene Agents Used to Remove Bacillus atrophaeus (a Surrogate of Bacillus anthracis) From Contaminated Hands"*; David J. Weber, MD, MPH; Emily Sickbert-Bennett, MS; Maria F. Gergen, (MT (ASCP); William A. Rutala, PhD, MPH; Journal of the American Medical Association, Vol. 289 No. 10, 1274-1277, March 12, 2003.
4. *"Antimicrobials Go Molecular: An Update on the Latest Technology"*; Kelly M Pyrek, Infection Control Today, (posted on 01/21/2010) (see page 5 of 6).
5. *"Sharing a Hospital Room Increases Risk of Superbugs"*, Virgo Publishing; Infection Control Today, (posted 01/05/2010).
6. *H.A.I. Fact Sheet*; George Clarke, UMF Corporation, 2010 (Updated stats and literature references).