Study Protocol:

A randomized trial to evaluate the effect of point-of-use water filtration on the incidence of gastrointestinal illness and dehydration in acute and long term care facilities

Submitted to David J. Swiderski

Pentair Healthcare

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1275 K Street NW, Suite 1000 Washington, DC 20005
Phone: 202.464.4252 – Fax: 202.789.1901
www.apicconsulting.com

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A. ABSTRACT

A1. Background

Hospital water distribution systems have been shown to be frequently contaminated with pathogenic organisms and are a source of nosocomial infections. Patients who are immunocompromised due to age, cancer, transplantation, or infection with Human Immunodeficiency Virus (HIV) are disproportionately affected. Transmission occurs through ingestion of drinking water or ice, or may occur through other sources such as contact with contaminated medical equipment that has been rinsed in tap water or through the hands of healthcare workers. Hospital drinking water can be treated by a variety of disinfection methods, however low levels of harmful bacteria, mycobacteria, fungi, and protozoa may remain. Point-of-use water filtration has been shown to be effective in preventing waterborne nosocomial infections. The objective of this study is to evaluate the effect of point-of-use water filtration on the incidence of gastrointestinal illness and dehydration in acute and long term care facilities.

A2. Methods/Designs

This is a randomized controlled trial which will be conducted in acute and long term care facilities. A pilot study will be completed to test logistics and feasibility prior to a larger study, in order to improve the latter's quality and efficiency.

Units of similar characteristics will be selected in order to facilitate the stratification of data (for example medical units, surgical units, etc). Once similar units have been selected, half of these units will be randomly selected to receive the Everpure Microguard™ Pro 4 filter on all of the unit's ice machines. The Everpure Microguard™ Pro 4 filter provides a multi-stage filter for ice machines that combines membrane and carbon block technology for filtration results down to 0.15 microns. Hollow space fiber membrane filtration reduces 99.9999% of bacteria, asbestos fibers, and cysts such as Cryptosporidium and Giardia according to Pentair's published literature. Submicron filtration reduces dirt and particles.

All patients on these intervention units will only consume water and ice that has been filtered with the Everpure device. The other units (control units) will not have the Everpure Microguard™ Pro 4 filter installed on their ice machines which will continue to dispense water that meets all current water standards. All ice machines will be maintained with the same cleaning protocol.

Patients and staff on each unit, as well the investigators responsible for analysis of the data will be blinded as to whether they are in the intervention or control group.

We will evaluate the occurrence of gastrointestinal illness and dehydration among units receiving drinking water and ice that has been filtered with the Everpure Microguard™ Pro 4 filter compared to the units with no special filtering device using a test of two proportions.
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A3. Discussion

This will be the first study to examine the relationship between the consumption of tap water, point-of-use filters and the incidence of gastrointestinal illness and dehydration among patients in acute and long term care facilities.

B. BACKGROUND

B1. Introduction

The Centers for Disease Control and Prevention (CDC) estimates that health-care associated infections (HAIs) account for 1.7 million infections per year in the United States and result in 99,000 associated deaths annually.[1] Contaminated hospital water systems have been recognized as a source of such infections and have been described as the most overlooked, important, and controllable source of nosocomial pathogens. [2]

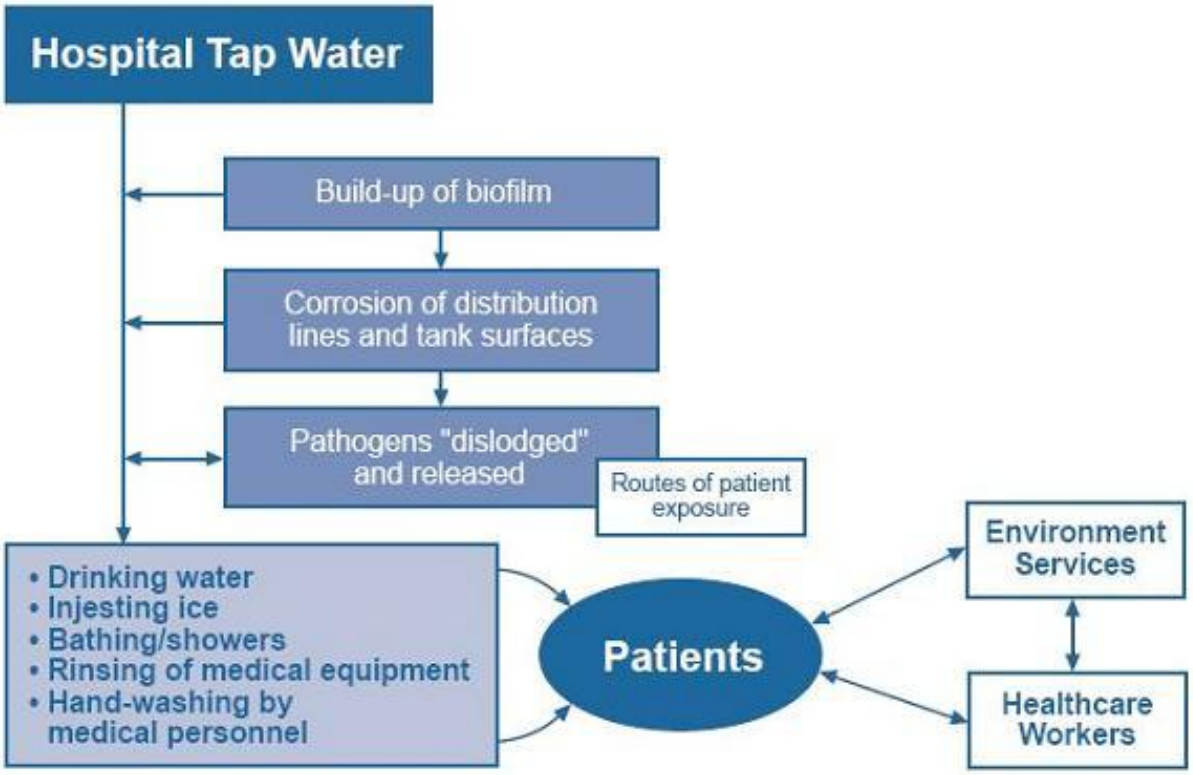
B2. Reservoirs and Transmission

Hospital tap water is most frequently drawn from a municipal water source which may contain low concentrations of organisms such as *Legionella, P. aeruginosa,* non-*tuberculosis Mycobacteria, Acinetobacter spp, Aeromonas spp,* and *Aspergillis*. Once the microorganisms enter the healthcare facility plumbing system they may form biofilms, in which the cells adhere to each other or to plumbing surfaces; these biofilm-forming organisms are more resistant to antibiotics as well as disinfectants.[3] The formation of biofilm is affected by such factors as pipeline and storage tank age and corrosion, materials of pipe construction, stagnation, high water sheer stress and flushing.[4,5] When biofilms are formed near the point of use they may disperse pathogenic organisms into the water which may then colonize patients, healthcare workers, medical devices and instruments as well as any environmental surface that comes into contact with water.[5] Patients become exposed to these pathogenic organisms through the ingestion of water or ice, or through contact with medical equipment which has been rinsed with tap water. [6,7,8] Figure 1 illustrates potential transmission routes of waterborne pathogens in the healthcare facility.

Individuals who are immunocompromised such as recipients of bone marrow and solid organ transplants, oncology and burn patients, critically ill patients in the intensive care unit (ICU), those with congenital or acquired immunodeficiency syndromes such as Human Immunodeficiency Virus (HIV) infection, and patients who are elderly are at high risk for infection from exposure to these organisms. The mortality rate among these sensitive subpopulations is also higher.[2]

The World Health Organization Guidelines for Drinking Water Quality declares that hospitals are a high-risk environment due to the complex nature of their water distribution system and the vulnerability of their occupants. [9]

Figure 1: Transmission route of waterborne pathogens in healthcare facilities. Adapted from Anaissie et al. [2]



B3. Waterborne Pathogens in Healthcare Facilities

A number of waterborne pathogens have been linked to infections. These include bacteria, mycobacterium, fungi, protozoa, and viruses.

B3a. Bacteria

HAIs caused by waterborne infections include bacteremias, tracheobronchitis, pneumonias, sinusitis, urinary tract infections, meningitis, wound infections, peritonitis as well as gastroenteritis (Figure 2). A wide variety of bacteria, fungi, viruses and protozoa has been associated with nosocomial waterborne outbreaks and has been isolated from hospital drinking water supplies. Pathogenic bacteria include *Legionella pneumophila, Pseudomonas spp. (*especially *P. aeruginosa), Stenotrophomonas maltophilia, Aeromonas spp., Acinetobacter spp. Enterobacter spp., Flavobacterium spp.* and *Serratia spp.*[3,10,11,12,13] Sources include potable water, ice baths, ice machines, sink and wash basins, distilled, sterile and nonsterile water, and a variety of liquid solutions (Table 1). Many of these organisms have been shown to be resistant to antibiotics. The establishment of a genetic link between bacterial strains isolated from drinking water and those isolated from patients has been substantiated in numerous studies (Table 2). [2, 5, 14,15] Anaissie estimates that 1400 deaths occur each year in the U.S as a result of waterborne nosocomial pneumonias caused by *Pseudomonas aeruginosa* alone. [2]

B3b. Mycobacterium

Municipal water distribution systems serve as a major environmental reservoir for Non-*tuberculosis Mycobacterium* (NTM). A 1999 study found that 83% of U.S dialysis centers had water that was colonized with NTM.[16] NTM grow in both hot and cold systems and are resistant to a wide variety of disinfectants. Pathogenic mycobacteria have been identified as the source of numerous serious nosocomial outbreaks and pseudo-outbreaks including surgical site infections, injection abscesses, dialysis and catheter related infections. [16,17]

B3c. Fungi

Fungi such as molds and yeasts are also commonly cultured from hospital water. [5,18] Ortolano reports that among 126 potable water samples, two-thirds of which came from healthcare facilities, molds were present in nearly 83% and yeast from 11%. [5] *Aspergillis* was recovered from 42% of samples. *Aspergillis* species pose a serious threat to patients; invasive aspergillosis is a principle cause of infectious mortality among immunocompromised patients. [19]

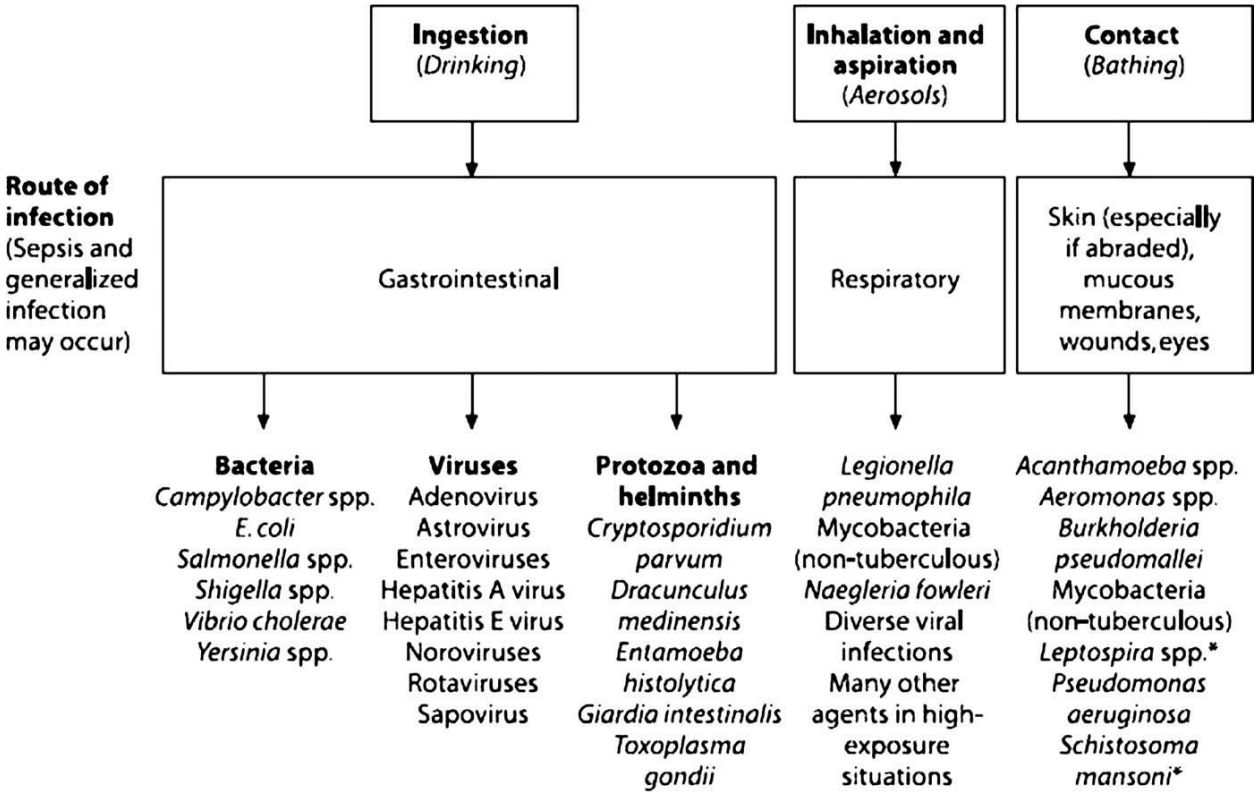
B3d. Protozoa

The pathogenicity of community-acquired waterborne protozoa infections such as *Cryptosporidium* and *Giardia* are well documented in the literature. *Cryptosporidium* oocysts are ubiquitous in surface waters and small numbers of oocysts have been detected in 17-55% of U.S cites with surface water supplies. [20,21] A massive waterborne outbreak of *Cryptosporidium* infection occurred in Milwaukee, Wisconsin in 1993 that affected over 400,000 individuals. Data indicates that nosocomial infections with these parasites are on the rise. [22,23]

B3e. Viruses

While viruses are an uncommon source of nosocomial waterborne infections, they have been identified as the source of waterborne-pathogen outbreaks in the community. [24]

Figure 2: Disease Transmission pathways of waterborne organisms, from Exner et al.[25]



* Primarily from contact with highly contaminated surface waters.

Table 1. Gram-negative bacilli linked to waterborne infection, from Squier et al.[23]

Gram-negative bacilli	Water source(s) in hospital
Acinetobacter species	Sink or wash basin; distilled, sterile, and nonsterile water
Burkholderia cepacia	Distilled, sterile, and nonsterile water
Chryseobacterium species	Potable water
Ewingella species	Ice baths
Legionella species	Potable water, ice machines
Pseudomonas species	Potable water, liquid solutions
Serratia marcescens	Liquid solutions including medications; sink or wash basin
Stenotrophomonas maltophilia	Potable water; sink or wash basin

Table 2. Evidence correlating infection in patients with microorganisms found in hospital water, from Ortolano et al.[5]

Organism	Site of infection	Molecular-relatedness evidence	Number of reports
Bacteria			
Pseudomonas aeruginosa	Blood, CVC, lungs, peritoneum, sinuses, trachea, urine	PCR; DNA macrorestriction analysis, PFGE, ERIC-PCR, RAPD, DNA fingerprinting, DNA typing, serotyping, phage typing, serogrouping, genotyping, ExoA DNA probe, biotyping, electrophoretic esterase typing	10
Stenotrophomonas maltophilia	Blood, peritoneum, respiratory tract, skin, stools, throat, trachea, urine	PFGE, RAPD	4
Serratia marcescens	Eye, stools	PFGE	1
Acinetobacter baumannii	Skin, wound	PFGE, biotyping	1
Aeromonas hydrophila	Blood	electrophoretic esterase typing	1
Chryseobacterium species	Blood	AP-PCR	1
Mycobacterium			
Mycobacterium avium	Disseminated	PFGE	1
Mycobacterium fortuitum	Disseminated, respiratory tract, sputum, sternal wound infection wound	AP-PCR, PFGE, phenotype analysis, plasmid profiles,	4
Mycobacterium xenopi	Various, spine	PCR-based techniques, chromosomal restriction fragment patterns	2
Mycobacterium kansasii	Abscess, blood, bone, sputum, stomach, urine	RFLP, PFGE	1
Mycobacterium chelonae	Sternal wound infection, prosthetic valve	Electrophoresis of enzymes, plasmid profiling	1
Fungi			
Fusarium solani	Disseminated	RFLP, RAPD, IR-PCR	1
Exophiala jeanselmaei	Disseminated	RAPD	1
Aspergillus fumigates	Lungs	PCR, SSPD	1

Adapted from Anaissie et al.[2] *CVC*, central venous catheter; *AP*, arbitrarily primed; *PCR*, polymerase chain reaction; *PFGE*, pulse-field gel electrophoresis; *ERIC*, enterobacterial repetitive intergenic consensus sequencing; *RAPD*, random amplified polymorphic DNA; *ExoA*, exotoxin A; *RFLP*, restriction fragment-length polymorphism; *AFLP*, amplified fragment-length polymorphism; *IR*, interrepeat; *SSPD*, sequence-specific DNA primer analysis.

B4. Prevention

Hospital water may be systemically disinfected with a variety of methods such as superheat and flush, copper silver ionization, hyperchlorination, chlorine dioxide, and ultraviolet light. However, they vary in maintenance costs, efficacy against specific organisms and compatibility with plumbing materials and low concentrations of harmful bacteria may remain.

The efficacy of point-of-use (POU) filters in experimental as well as clinical studies is overwhelmingly positive. POU filters provide a barrier to free-floating organisms that have survived exposure to disinfectants, broken away from biofilm colonies or have traveled to the point-of-use from stagnant locations in the water system. Numerous studies have demonstrated their value in reducing infections due to waterborne pathogens as well as providing a clear economic benefit. These studies have focused extensively upon *Legionella* and *P. aeruginosa*, although other significant waterborne pathogens such as *Acinetobacter, S. maltophilia,* and *Aspergillis fumigatus* have been examined.[18,26,27,28]

In August 2007, 17 of 24 patients residing in a subacute care unit in California cultured positive for *P. aeruginosa.* The following month P. *aeruginosa* was cultured from the unit's water supply. POU filters were subsequently installed on all ice machines, sink faucets and shower heads on the unit which resulted in statistically significant reductions in the number of ventilator-associated pneumonia (VAP), positive cultures for *Pseudomonas* and upper respiratory colonization with *Pseudomonas*. The net cost savings in patient care costs were $231,036 during the five month study period. [30]

Disposable POU filters have been highly effective in preventing and controlling waterborne nosocomial infections among sensitive populations in high risk units.[10,28,29] Trautmann et al. was able to demonstrate a reduction in the monthly rate of *P. aeruginosa* infections in a surgical intensive care unit from 2.5 per month before POU filters were installed to 0.8 infections/month after POU filter installation over a two-year period.[31]

In a similar study Van der Mee-Marquet et al. detailed the reduction of *pseudomonas* infections among ICU patients from 8.7 per 1000 patient-days to 3.2 infections per 1000 patient-days in the 5 years following the installation of POU filters.[32]

Sheffer et al. contributed to the growing body of evidence supporting the efficacy of POU filters by demonstrating that POU filters completely eliminated *L. pneumophila* and *Mycobacterium gordonae* from hot water samples.[27] After identifying faucets and showers as the source of *P. aeruginosa* bacteremia infections in a hematology unit, Vianelli et al. installed POU water filters on all water outlets and demonstrated highly statistically significant reductions in bloodstream infections.[33] Vonberg et al. were able to eliminate *Legionella* from 99.6% of water samples in a 2005 using POU water filtration devices.[26] Warris et al. examined the effect of POU filtration for the prevention of fungal contamination of hospital water and concluded that the filters were highly effective in reducing the number of colony-forming units.[18]

This growing body of literature substantiates the role of POU filtration in reducing the risk of nosocomial waterborne infections.

B5. Gastrointestinal Illness

The association between the consumption of tap water, POU filters and the incidence of gastrointestinal (GI) illness has been examined in several community studies. The first randomized, controlled drinking water intervention trial was published in 1991 by Payment et al. in a Montreal suburb.[34] Filters were installed in 299 households and 307 households acted as a control. The investigators were able to conclude after a 15-month study period that 35% of the self-reported GI illness was attributable to tap water. A second study by Payment et al. examined GI illness among participants receiving tap water, tap water from a continuously purged tap, bottled treatment plant water, or purified bottled plant water concluded that 14-40% of GI illness could be attributed to tap water.[35]

Colford et al. published results in 2005 from a randomized, controlled trial among households in Iowa that found no evidence that in-home drinking water treatment with combined filtration and ultraviolet light is effective in reducing the incidence of GI illness.[36]

However, in a more recent study Colford et al. conducted a randomized, triple-blinded crossover trial among older adults in 714 households which used active and sham water filters devices for 6 months each. They found evidence of 12% mean reductions in population incidence and prevalence of GI illness per year with combined filtration and ultraviolet light.[37]

To date however, there have been no studies examining the relationship between the consumption of tap water, POU filters and the incidence of GI illness and dehydration among patients in acute and long term care facilities.

C. STUDY OBJECTIVES

The objective of this study is to evaluate the effect of point-of-use water filtration on the incidence of gastrointestinal illness and dehydration in acute and long term care facilities.

D. METHODS/DESIGN

D1. Structure of study

This is a randomized controlled trial. Randomization ideally will distribute both known and unknown confounders evenly among the groups. Units of similar characteristics should be selected in order to facilitate the stratification of data (for example medical units, surgical units, etc). Once similar units have been selected, half of these units will be randomly selected to receive the Everpure Microguard™ Pro 4 filter on the unit's ice machine(s). The Pro 4 filter provides a multi-stage filter for ice machines that combines membrane and carbon block technology for filtration results down to 0.15 microns. Hollow space fiber membrane filtration reduces 99.9999% of bacteria, asbestos fibers, and cysts such as Cryptosporidium and Giardia according to Pentair's published literature. Submicron filtration reduces dirt and particles.

All patients on the selected unit (intervention unit) will receive drinking water and ice that has been filtered by the Everpure device. The other units (control units) will continue to distribute drinking water and ice from their ice machine which will not have the Everpure filter device installed. Both intervention and control unit ice machines will be maintained with the same disinfection protocol. No participants, including patients, staff, and the investigators responsible for analysis of the data, shall know which units have been selected to receive the Pro 4 filter device.

We will evaluate the incidence of episodes of GI illness and dehydration for the intervention units compared to the control units. A pilot study will be completed to test logistics and feasibility prior to a larger study, in order to improve the latter's quality and efficiency.

D2. Outcome Variables

Two outcome variables will be examined:

1. The primary outcome variable is an episode of "highly credible gastrointestinal illness" (HCGI), a measure which has been previously published in the literature. [35-39] An episode is defined as any of the following four conditions :
   1) vomiting,
   2) watery diarrhea,
   3) soft diarrhea and abdominal cramps, or
   4) nausea and abdominal cramps.

   If patient has more than one episode, there should be a minimum of six HCGI-free days between episodes in order to increase the likelihood that each episode represents distinct infections.

2. The secondary outcome variable is dehydration which will be defined as <800mL of urine output in 24 hours, a commonly used parameter to measure dehydration. [39,40]

D3. Subject Selection and Withdrawal

D3a. Participants

Individuals to be approached for participation in this study will include all adult (age ≥ 18 years old) patients who are receiving medical care in the selected units at the participating facilities. The racial, gender and ethnic characteristics of the individuals approached for participation in this study shall reflect the demographics of patients receiving medical care at the participating centers. We shall attempt to recruit participants in accordance with these demographics. No individuals shall be excluded from participation based on race, ethnicity, gender or HIV status.

D3b. Inclusion criteria

To be eligible for enrollment in this study, participants must be admitted to one of the units selected by the healthcare facility to participate in this study. Units must be able to ensure that patients only receive drinking water from the specified source.

D3c. Exclusion criteria

Patients will be excluded if they are: aged < 18 years, have a ileostomy/colostomy, are pregnant, a prisoner of correctional institution, are receiving tube feeding, have an admission diagnoses of GI related illness (ICD-9 codes 001 to 009.9 and 558.9) or associated general symptoms such as electrolyte disorders (ICD-9 276), nausea and vomiting (ICD-9 787) and abdominal pain (ICD-9 789), or significant renal impairment (creatinine >250 µmol/l). Patients who are NPO (Nil Per Os) will be excluded until the time when they can drink oral fluids. The participation of patients who are mentally incapacitated (e.g., comatose, unresponsive) will not be sought (i.e., during the period in which they are mentally incapacitated).

D3d. Recruitment Procedures

All patients who meet the study criteria and are receiving medical care on the selected units in the participating centers will be invited to participate in the study. Potential participants will be approached by the study investigator and will be asked to review a copy of the informed consent form (Appendix H1). The investigator will review the informed consent form with potential participants and address any questions or concerns prior to obtaining written informed consent. The investigator will also address any future questions or concerns of study participants. Data will only be collected from patients who have provided their written informed consent for study participation.

D3e. Data collection

Retrospective chart reviews will be completed by the study investigators for those patients who have enrolled in the study. Data obtained from the chart review includes demographic information, the patient's medical & surgical history, a list of current medications, and daily vital signs. Neutrophil count, if known, will be noted to determine if patient is immunocompromised. Neutrophils fight against infection and represent a subset of the white blood count. An absolute neutrophil count (ANC) of less than 1000 indicates moderate to severe neutropenia and patient is at high risk of infection.

Fluid intake and urine output will be recorded on a daily basis daily for the duration of the patient's stay on the participating unit by nursing staff. Complaints of nausea, abdominal cramps, vomiting and diarrhea will be recorded by the charge nurse on each participating unit at the end of each shift. Data collection forms are located in Appendix H2.

D3f. Potential Risks

It is anticipated that patients will experience no more than minimal risk or discomfort. Participation in this study does involve the potential risks of a breach of confidentiality of the medical record information and associated privacy of the participants. Such risk will be minimized by 1) removing direct participant identifiers (i.e. names, social security numbers, medical record numbers) from information collected and stored; 2) securing, in a separate location, and limiting access to information linking codes (i.e. linkage codes assigned to the study data with direct participant identifiers; 3) storing paper records in locked file cabinets; and 4) using a secure network to enter data. The computer system will be password protected, meaning no unauthorized users will be able to access the electronic data.

D3g. Potential Benefits of Participation

Patients receiving water filtered by the Everpure Microguard™ Pro 4 filter may enjoy better tasting and better smelling drinking water. Hollow space membrane filtration reduces 99.9999% of bacteria, asbestos fibers, and cysts and may reduce the risk of nosocomial infection according to Pentair's published literature.

The analysis of the data from this study may be of future benefit to patients in acute and long term facilities.

D3h. Ethical Issues

This study will receive Institutional Review Board (IRB) approval from each facility involved in the study prior to the commencement of data collection.

D3i. Informed Consent Process

Informed consent will be presented as a written document that is signed by both the subjects and the investigator (Appendix H1). A copy will be kept in the study files and another copy will be provided to the subject to keep.

D3j. Data Confidentiality

Only members of the study team will have access to patient information. A unique identification code will be assigned to each patient to protect confidentiality. The research coordinator will keep the identification coding system in a secure place so it cannot be decoded. Paper records are to be kept in locked file cabinet. A secure network will be used to enter data. The computer system will be password protected, meaning no unauthorized users will be able to access the electronic data.

D4. Cartridge Filter Installation and Operation

The Everpure Microguard™ Pro 4 filter will be installed on all ice machines on the intervention units by Pentair (or by healthcare facility maintenance department) using the protocol dictated in Appendix H3. The model and brand of existing filtration systems must be documented on the 'Ice Machine Log of Existing Filtration Systems'(Appendix H4). Specifications for the Everpure equipment (Microguard ™ Pro 4, Twin Series Head, 4JT Flushing/Sanitizing Cartridge, Filter Bowl Series, MH2 Filter Cartridge) can be found in Appendix H5. Patients and staff on each unit must remain blinded as to whether they are in the intervention or control group. Either nursing or environmental services personnel shall identified to be responsible for the routine cleaning of unit ice machines. Responsible personnel will assure the Unit ice machines are disinfected twice daily at 0800 and 2000 using a chlorine disinfectant wipe to clean the ice chute, lever arm, water dispensing chute, and dispensing nozzle. Time of disinfection and initials shall be documented on the Ice Machine Disinfection Log (Appendix H6).

Maintenance staff is responsible for monitoring the dynamic pressure of both the inlet pressure gauge and outlet pressure gauge on a weekly basis. Cartridges should be changed when a ≥20psi differential pressure is noted. Date and time of pressure checks should be noted on the Ice Machine Disinfection Log (Appendix H6).

E. STATISTICAL PLAN

E1. Statistical Methods

Although this trial is randomized (which ideally will produce comparable groups in terms of general participant characteristics, such as age or gender, and other key factors that affect the outcome), we will also conduct a multivariate analysis to adjust for potential confounding by other variables. Relevant characteristics of participants between the groups will be compared in order to assure that a balance was achieved. The primary statistical analysis will evaluate the effect of filtered water on two outcomes, the occurrence of an episode of HCGI and the occurrence of mild dehydration. To test the incidence rate between the filtered and unfiltered water groups, a test of two proportions can be used.

E2. Sample Size Determination and Power

The power analysis reveals 1963 patient days per group are required (e.g. equivalent to approximately 22 beds in a unit for 90 days (i.e. 3 months) in each of the control and intervention groups. This is based on reduction of *pseudomonas* infections among ICU patients from 8.7 per 1000 patient-days to 3.2 infections per 1000 patient-days in the 5 years following the installation of POU filters in the 2005 study by Van der Mee-Marquet et al. [33] If the incidence of other/combined side effects gives a bigger difference then the power analysis will reveal a smaller patient day number.

E2a. Control of Type-1 Error

All statistical tests will be conducted at the 0.05 alpha level, meaning that probability (P)≤ 0.05 will be considered "nominally significant".

E3. Potential Sources of Bias

The process of randomization will eliminate selection bias, and produces a low probability of confounding. Blinding the study also minimizes the potential for bias. Results will be adjusted for potential confounding factors which include age, gender, race, unit of admission, length-of-stay, admission from a long-term care facility, and medication which may affect outcome variables.

E4. Other Considerations

- A cross-over study design may be used as an alternative to this study protocol. Units would receive the filtered water for a specified period of time then the unfiltered water for the same time period. The order is randomized for the units. The time period could be based on previous studies. Colford et al. used active and sham water filtration devices for 6 months each in his 2009 randomized, triple-blinded, crossover trial, however a test period of 3 months each may be more manageable for healthcare facilities.[33]

- A crossover study has two advantages over a non-crossover longitudinal study.
    - First, the influence of confounding covariates is reduced because each crossover unit would serve as its own control. This helps to produce more balanced characteristics among the groups.
    - Second, optimal crossover designs are statistically efficient and so require fewer subjects than do non-crossover designs.

- Major budget items include study coordinator (e.g. liaise with hospital, obtain IRB approval, train/educate nurses on participating units, perform retrospective chart reviews, keep track of units ice machine disinfection logs), and a statistician (enter data, analyze data, write report).

- Different hospitals will have different policies on whether subjects have to be told about getting filtered/unfiltered water. Some will consider this as chart review and will not require individual patient consent. A public hospital will be more amenable to this than a university hospital.

F. LIST OF ABBREVIATIONS

AFLP Amplified fragment-length polymorphism
ANC Absolute Neutrophil Count
AP Arbitrarily primed
CDC Centers for Disease Control and Prevention
CVC Central venous catheter
ERIC Enterobacterial repetitive intergenic consensus sequencing
ExoA Exotoxin A
GI Gastrointestinal
HAI Healthcare- associated infection
HCGI Highly credible gastrointestinal illness
HIV Human Immunodeficiency Virus
ICD-9 International Classification of Diseases, 9th Edition
ICU Intensive Care Unit
IR Interrepeat
IRB Institutional Review Board
LTCF Long term care facility
NPO Nil Per Os
NTM Non-*tuberculosis Mycobacterium*
P Probability
PCR Polymerase chain reaction
PFGE Pulse-field gel electrophoresis
POU Point-of-use
RAPD Random amplified polymorphic DNA
RFLP Restriction fragment-length polymorphism
SSPD Sequence-specific DNA primer analysis
VAP Ventilator-associated pneumonia

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H. APPENDICES

H1. Informed Consent

Informed Consent

You are being invited to participate in a research study, which the (facility name) Institutional Review Board (IRB) has reviewed and approved for conduct by the investigators named here. This form is designed to provide you - as a human subject - with information about this study. The investigator or his/her representative will describe this study to you and answer any of your questions. If you have any questions or complaints about the informed consent process of this research study or your rights as a subject, please contact the contact the research subjects protection advocate in the *(your institution's)* Subjects Protection Office at *(phone number.) This document explains your rights as a research subject. If you have questions regarding your participation in this research study, please contact the investigators using the information below.*

Study Title: A randomized trial to evaluate the effect of point-of-use water filtration on the incidence of gastrointestinal illness and dehydration in acute and long term care facilities

Primary Investigator:
Other investigators:
IRB protocol # :

Voluntary Status: You have met the requirements for enrollment as a volunteer in a research study conducted by the researchers listed above. You are now being invited to participate in this study.

Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team will discuss with you the details, and they will provide you this consent form to read. You may also decide to discuss it with your family and/or friends. Some of the language may be difficult to understand and if this is the case, please ask the researcher and/or the research team for an explanation. If you decide to participate, you will be asked to sign this form. Your participation is voluntary. You may withdraw any time without penalty and there will be no loss of any benefits to which you are entitled.

Purpose: This research study is being done to find out if patients who drink water that has been filtered through a special water filter will have less gastrointestinal illness such as nausea, abdominal cramps, vomiting or diarrhea than patients who drink the usual hospital tap water. We are also interested to see whether patients who drink water that has been filtered with the special water filter will be less dehydrated than patients who drink the usual hospital tap water. The water filter is designed to reduce 99.9999% of bacteria, and parasites from drinking water.

Procedures: Some hospital units will have the special water filter *(*Everpure Microguard™ Pro 4 filter) installed on all of their ice machines. Other units will not receive the water filter on their ice machines which will continue to dispense hospital tap water which meets all current water quality standards.

We will collect information on your age, gender, race, medical history, and medications. Every day we will monitor your vital signs (temperature, pulse, respirations, blood pressure). We will measure your fluid intake daily as well as your urine output. We will record any complaints of nausea, vomiting, abdominal cramps and diarrhea. The research team may use the following sources of health information: History and physical examination, Progress notes, Diagnostic/Laboratory reports, Discharge summary. After the information has been collected, all names will be removed. Your name will be assigned a code number. Only the code number will be left as an identifier.

Commitment and Compensation: If you agree to take part in this study, we will collect information for the length of your stay in this unit. The study investigator will be responsible for completing the information forms.

Your involvement will last until you are discharged from this unit. You will not receive any compensation for being in this research study.

Possible Risks and Benefits: It is expected that participation in this study will provide you with no more than minimal risk or discomfort, which means that you should not experience any more difficulty than what would occur in your normal daily life. However, there is always the chance of an unexpected risk. The foreseeable risks in this study include an accidental disclosure of your private information, or discomfort by answering questions that are perceived as embarrassing. If you feel uncomfortable or distressed, please tell the researcher and he/she will ask you whether you wish to continue. You can withdraw from the study at any time without penalty.

Patients receiving water filtered by the Everpure Microguard™ Pro 4 filter may enjoy better tasting and better smelling drinking water. These filters may reduce the risk of a hospital-acquired infection. However, there is no guarantee that you will benefit from being in this research study. All patients will receive water that meets or exceeds current water quality standards at all times.

Information from this study may be of future benefit to patients in acute and long term facilities.

Confidentiality and Consent: The investigator and staff involved with the study will not reveal the personal information which they collect about you. Any information that is obtained in connection with this study -- and that can be identified with you -- will remain private and will be disclosed only with your permission or as required by law. To help protect your confidentiality, we will only allow members of the study team to access your information. We will store paper records in locked file cabinets. We will assign an ID code to use instead of your name, to ensure that we do not use your name when it is not needed. The research coordinator will keep the ID coding system in a secure place so it cannot be decoded. We will use a secure network to enter data. The computer system will be password protected, meaning no unauthorized users will be able to access the electronic data.

New Information: During the course of this study, the investigators may discover information that could be important to you. They will notify you as soon as possible when such information becomes available.

Consent: I consent to participate in the study. I understand that my participation in this study is entirely voluntary and that I may refuse to participate or withdraw from the study at any time without penalty. I have received a copy of this consent form for my records.

_____

Printed name of participant Signature Date

_____

Signature of primary investigator Date:

H2. Data Collection Form 1 (To be completed by retrospective chart review)

Admission Data:

Medical record number:_____ Patient Identifier Code: (to be assigned by investigator):_____

Admission Date:_____

Unit:_____

Age:_____ **Gender (circle)**: Male /Female

Race (circle):

1. White
2. African-American/Black/Negro
3. Asian
4. American-Indian or Alaska Native
5. Native Hawaiian or Other Pacific Islander
6. Other
7. Unknown

Is this person of Hispanic, Latino or Spanish origin (circle)? Yes/ No or Unable to assess

Has patient been admitted from a skilled nursing facility/long-term care facility (circle): Yes/No

Admitting Diagnosis:_____

Medical History:

Please check if patient has any of the following:

Chronic Renal Failure _____
Cancer: _____
Colitis: _____
Heart Disease: _____
Anemia: _____
Gallbladder disease: _____
Ulcers: _____
Diabetes: _____
Congestive Heart Failure: _____

Surgical History (past year):

Please check if patient has any of the following in the past year:

Gastrointestinal surgery: _____
Abdominal surgery: _____
Urology surgery: _____

List of current medications: Please attach list of medications on admission

Data Collection Form 1 (To be completed by retrospective chart review)
Daily Data:

Medical record number:_____

Patient Identifier Code: (assigned by investigator):_____

Date:_____
Unit:_____

Vital Sign Sheet (to be recorded on admission and daily until discharge)

Date	Temp	BP	Pulse	Respirations	Notes

24 Hour Intake and Output Record

Date	Oral	IV	Other intake	Urine	Notes

Laboratory Values

Date	Absolute neutrophil count (ANC) if known

Record of Gastrointestinal Illness

Date	Vomiting	Watery Diarrhea	Soft Diarrhea AND Abdominal Cramps	Nausea AND Abdominal Cramps	Notes

Data Collection Form 1 (To be completed by retrospective chart review)

Discharge Data: (to be completed upon discharge or withdrawal from the study)

Medical record number:_____ Patient Identifier Code: (assigned by investigator)_____

Date of discharge:_____
Length of hospital stay:_____

Unit:_____

Was patient diagnosed with a health-care associated infection (HAI) during this hospital stay? (circle) Yes/No

If yes, then circle all that are applicable:
Urinary-tract infection
Central-line related bloodstream infection
Ventilator-associated pneumonia
Surgical site infection
Other: List_____

Was patient diagnosed with a *Clostridium-difficile* (C-diff) infection? (circle) Yes/No

Reason for patient discharge (please circle):
1. Discharge to another unit
2. Discharge to another healthcare facility
3. Discharged home
4. Expired
5. Other: (List)_____

Did patient drop out of study? (Circle) Yes/No
If yes, why?

Data Collection Form 2: (to be completed by charge nurse on each participating unit at the end of each shift)

The objective of this study is to evaluate the effect of point-of-use water filtration on the incidence of gastrointestinal illness and dehydration in acute and long term care facilities. We wish to collect data on all patients who experience the following:

1) vomiting,
2) watery diarrhea,
3) soft diarrhea and abdominal cramps, or
4) nausea and abdominal cramps.

If any patients on your units do experience any of these symptoms please complete the chart below:

Record of Gastrointestinal Illness

Date	Name	Medical Record #	Symptom experienced (please circle all that apply)	Notes
			1) vomiting, 2) watery diarrhea, 3) soft diarrhea AND abdominal cramps, or 4) nausea AND abdominal cramps.	
			1) vomiting, 2) watery diarrhea, 3) soft diarrhea AND abdominal cramps, or 4) nausea AND abdominal cramps.	
			1) vomiting, 2) watery diarrhea, 3) soft diarrhea AND abdominal cramps, or 4) nausea AND abdominal cramps.	
			1) vomiting, 2) watery diarrhea, 3) soft diarrhea AND abdominal cramps, or 4) nausea AND abdominal cramps.	
			1) vomiting, 2) watery diarrhea, 3) soft diarrhea AND abdominal cramps, or 4) nausea AND abdominal cramps.	

H 3. Cartridge Filter Installation, Sanitization and Operation Protocol

A. Filtration System Installation and Sanitization

1. Log model and brand of current filtration on filtration log for both controlled and uncontrolled points of use.
2. Verify if EV9272-24 Twin Head Assembly manifold already exists if so cartridges can be adapted without need for a different manifold. If EV9272-24 already exists verify if EV9795-90 Prefilter is being used for sediment prefiltration.
    i. If neither exists EV9272-24 Twin Head Assembly and EV9272-24 Prefilter Assembly will need to be installed to feed controlled Ice Machines. An EV6500-23 Filter Bowl Sleeve to prevent algae growth will need to be fitted to Prefilter.
    ii. If both exist install EV6500-23 Filter Bowl sleeve assembly to the Prefilter to prevent algae growth.
3. Once assembly is installed maintain water shut off feeding into the system. Install EV9608-00 4JT Sanitizing cartridge filled with ¼ cup of 10 % H_2O_2 hydrogen peroxide in head position number one. (Position number one is the Twin Head Assembly closest to the inlet water line. Place flush plug EV3113-94 into the second head position.
4. Turn on incoming water to flush lines and follow Ice Machine Manufacturer recommendations for sanitization procedure. If manufacturer does not specify rinsing the line going to the ice machine do so for 3 minutes. Let sanitizing solution sit for 10 minutes contact time then final rinse to flush out sanitizer for an additional 5 minutes.
5. Shut off incoming water supply and place a bucket or container under each of the QC heads. Remove the 4JT cartridge next dry both and place in a sealed bag for future use when sanitization is necessary. Remove both the EV9613-21 MH2 and EV9637-02 Microguard Pro 4 cartridge from boxes. Proceed to wash hands or use hand sanitizer and remove plastic shrink wrap. Carefully remove the plastic cap from the head of the cartridge without touching it. In the first head position install the EV9613-21 MH2 cartridge. Proceed to follow the rinse guidelines printed on the MH2 cartridge rinsing to drain. Shut off water supply again after rinsing is completed. Proceed to remove the plug EV3113-94 in position 2 and install the EV9637-02 Microguard Pro4 in the second position turn on water supply and rinse according to the guidelines printed on the cartridge rinsing to drain. After completed shut drain and open all water flow to the ice machine. Dry off the 4JT cartridge and flush plug and place in a sealed bag for future use when sanitation is necessary.
6. Swab ice chute, lever arm, water dispensing chute, lever arm and nozzle with a chlorine disinfectant wipe. Proceed to make one batch of ice and purge water dispenser for 2 minutes. Throw away first batch of ice and put into normal operation thereafter.

B. Long Term Operation and Maintenance Protocols

1. Twice daily use a chlorine disinfectant wipe to disinfect the ice chute, lever arm and water dispensing chute, lever arm and dispensing nozzle. This must be performed on both controlled and uncontrolled ice machines.
2. Indication of change outs can be monitored on controlled machines by reading the dynamic pressure (i.e. when there is flow) of both the inlet pressure gauge and outlet pressure gauge and when a ≥20psi differential pressure is noted cartridges should be changed.

H4. Ice Machine Log of Existing Filtration Systems

Location	Filtration System Brand	Cartridge #1 Model	Cartridge # 2 Model	Cartridge # 3 Model	Controlled or Uncontrolled

H5. Everpure Equipment Specifications

H5a. MicroGuard™ Pro 4 Filter

EVERPURE

EV9637-02

MicroGuard™ Pro 4 Filter

Delivers premium quality drinking water for bottleless coolers and drinking fountains

MicroGuard™ Pro 4 Replacement Cartridge: EV9637-02

BENEFITS

Everpure's multi-stage filter for drinking water applications combines membrane and carbon block technology for superior filtration results down to 0.15 microns

Capillary membrane filtration reduces 99.9999% of bacteria, asbestos fibers, and cysts such as Cryptosporidium and Giardia

Submicron filtration reduces dirt and particles

Delivers taste, odor and chlorine reduction

Reduces wear and abrasion on coolers and other water-using equipment

Sanitary cartridge replacement is simple, quick and clean. Internal filter parts are never exposed to handling or contamination

INSTALLATION TIPS

Never use saddle valve for connection

Use 3/8" water line

Install vertically with cartridge hanging down

Allow 2-1/2" clearance below the cartridge for easy cartridge replacement

Flush MicroGuard™ Pro 4 cartridge by running water through filter for three minutes at full flow

OPERATION TIPS

Change cartridges on a regular 6 month preventative maintenance program

Change cartridges when capacity is reached or when pressure falls below 10 psi

Service flow rate must not exceed 1 gpm

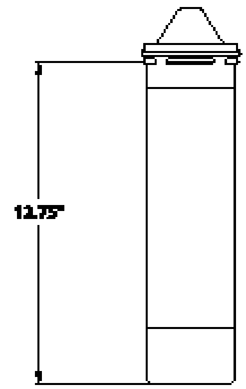
Always flush the filter cartridge at time of installation and cartridge change

APPLICATION/SIZING

For coolers and drinking water applications

Rated Capacity: 3,600 gallons (13,600 L)

MicroGuard™ Pro 4 Filter



SPECIFICATIONS

Overall Dimensions:
14.5"H x 3.25"Diameter

Service Flow Rate:
Maximum 1 gpm (3.8 Lpm)

Rated Capacity: 3,600 gallons (13,600 L)

Pressure Requirements:
10 - 125 psi (0.7 – 8.6 bar), non-shock

Temperature: 35 - 100°F (2 - 38°C)

No electrical connection required

The contaminants or other substances removed or reduced by this drinking water system are not necessarily in your water. Do not use with water that is microbiologically unsafe or of unknown quality without adequate disinfection before or after the system. Systems certified for cyst reduction may be used with disinfected water that may contain filterable cysts.

WARRANTY

Everpure water treatment systems (excluding replaceable elements) are covered by a limited warranty against defects in material and workmanship for a period of five years after date of purchase. Everpure replaceable elements (filter cartridges and water treatment cartridges) are covered by a limited warranty against defects in material and workmanship for a period of one year after date of purchase. See printed warranty for details. Everpure will provide a copy of the warranty upon request.

[illegible]

In Europe:
N.V. EVERPURE (EUROPE) S.A.
[illegible]

In Japan:
EVERPURE JAPAN LLC
[illegible]

Everpure
1040 Muirfield Drive
Hanover Park, IL 60133

H5b. Twin Series Head

EV9272-24

Twin Series Head

Series filter head exclusively for Everpure replacement cartridges

Twin Series Head:
EV9272-24

BENEFITS

New redesigned commercial quality filter head for Everpure filter cartridges

Series plumbed for use with a fine filter cartridge and any Everpure problem solving cartridge

Built-in water shut off valve and flushing valve makes cartridge change outs easy

A cartridge seating feature provides a more secure and durable fit

Includes mounting box bracket and screws for fast and easy installation. No extra mounting plate is required

New modular design of box bracket allows for future retrofitting of add-on components without disassembly of system. Optional wing bracket kits available

All wetted parts have passed NSF extraction tests

Engineered for durability, strength and longevity. Will not corrode

INSTALLATION TIPS

Mounts directly onto flat surface

Install vertically so cartridge hangs down

Allow 2-1/2" clearance below the cartridge for easy cartridge replacement

Flush filter by running water through filter according to cartridge instructions

OPERATION TIPS

Change cartridges on a regular 6 month preventative maintenance program

Change cartridges when capacity is reached or when pressure decreases

Always flush the filter cartridge at time of installation and cartridge change

APPLICATION/SIZING

For foodservice applications

Plumbed in series configuration.

Capacity; varies according to filter cartridge used

SPECIFICATIONS

Overall Dimensions: 6.3"H x 16.6"W x 5.5"D

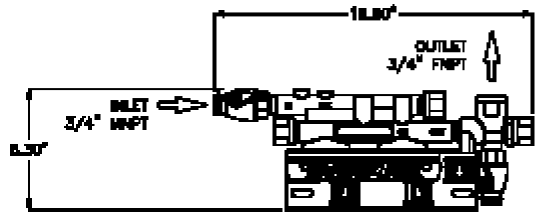
Inlet connection: 3/4"

Outlet connection: 3/4"

No electrical connection required

Shipping Weight: 3 lbs.

Twin Series Head



WARRANTY

Everpure water treatment systems (excluding replaceable elements) are covered by a limited warranty against defects in material and workmanship for a period of five years after date of purchase. Everpure replaceable elements (filter cartridges and water treatment cartridges) are covered by a limited warranty against defects in material and workmanship for a period of one year after date of purchase. See printed warranty for details. Everpure will provide a copy of the warranty upon request.

EVERPURE

Worldwide Headquarters
EVERPURE, LLC
[illegible]
[illegible]
Toll Free [illegible]
Tel [illegible]
Fax [illegible]
http://www.everpure.com

In Europe
[illegible]
[illegible]
[illegible]
[illegible]
BELGIUM
TEL: [illegible]
FAX: [illegible]

In Japan
[illegible]
[illegible]
[illegible]
JAPAN
TEL: [illegible]
FAX: [illegible]

H5c. 4JT Flushing/Sanitizing Cartridge

EVERPURE

EV9608-00

4JT Flushing/Sanitizing Cartridge

Ultimate flushing tool for Everpure systems

4JT Cartridge: EV9608-00

2JT Cartridge: EV9608-10

BENEFITS

The preferred way to introduce ScaleKleen™ scale removers or other sanitizing agents, such as bleach into all water-using equipment and vending machines

Fits into existing Everpure filter heads

Eliminates the need for difficult component disassembly

It's an easy and convenient tool to help you clean and maintain your equipment

Approved by NAMA

INSTALLATION TIPS

This cartridge must be installed and used according to the Installation and Use instructions provided with the product

OPERATION TIPS

For use in Everpure quick change filter heads

APPLICATION/SIZING

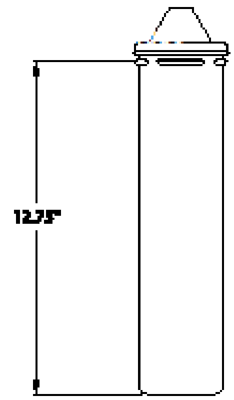
Model 4JT can size is 14.5 inches in length

Model 2JT can size is 10.25 inches in length

SPECIFICATIONS

Overall Dimensions:
14.5"H x 3.25"Diameter

4JT Flushing/Sanitizing Cartridge



WARRANTY

Everpure water treatment systems (excluding replaceable elements) are covered by a limited warranty against defects in material and workmanship for a period of five years after date of purchase. Everpure replaceable elements (filter cartridges and water treatment cartridges) are covered by a limited warranty against defects in material and workmanship for a period of one year after date of purchase. See printed warranty for details. Everpure will provide a copy of the warranty upon request.

EVERPURE

Worldwide Headquarters
EVERPURE, LLC
1040 Muirfield Drive
Hanover Park, Illinois 60133
Toll Free (800) 323-7873
Tel (630) 307-3000
Fax (630) 307-3030
http://www.everpure.com

In Europe
Pentair Water Belgium B.V./S.A.
Industriepark Wolfstee
Toekomstlaan 30
B-2200 Herentals
BELGIUM
TEL: +32(0)14.283.500
FAX: +32(0)14.283.505

In Japan
Hashimoto MN Bldg. 3F
3-25-1 Hashimoto Sagamihara-shi
Kanagawa 229-1103
JAPAN
TEL: 81(0)42.775.3011
FAX: 81(0)42.775.3013

H5d. Filter Bowl Sleeves

FILTER BOWL SLEEVES

EVERPURE

APPLICATIONS

FEATURES AND BENEFITS

Filter Bowl Sleeves: 10" EV6500-22
20" EV6500-23

OPERATIONAL TIPS

SPECIFICATIONS

Pentair Foodservice

FILTER BOWL SLEEVES

EV6500-22, EV6500-23

INSTALLATION TIPS

EVERPURE reserves the right to update specifications, change prices, or make substitutions without notice.

Everpure-Shurflo India
A-25
Mohan Co-operative Industrial Estate
Mathura Road
New Delhi, 110044
INDIA
TEL: 011.661.188.00
FAX: 011.661.188.22

Everpure-Shurflo Japan LLC
Hashimoto MN Bldg. 7F
3-25-1 Hashimoto Sagamihara-Shi
Kanagawa 229-1103
JAPAN
TEL: 81.(0)42.775.3011
FAX: 81.(0)42.775.3015

Everpure-Shurflo China
21F Cloud 9 Plaza, No 1118,
West Yan'an Road, Changning District
Shanghai, 200052
CHINA
TEL: 86.21.3211.4588
FAX: 86.21.3211.4580

EVERPURE
WATER YOU CAN TRUST.
Visit our website at www.everpure.com

Pentair Filtration Solutions, LLC
World Headquarters-EverpureShurflo
North and South America Sales
1040 Muirfield Dr.
Hanover Park, Illinois 60133
USA
TEL: 800.323.7873 (US only)
TEL: 630.307.3000
FAX: 630.307.3030

Everpure-Shurflo Australia
2 Redwood Drive
Notting Hill
Victoria, 3168
AUSTRALIA
TEL: 011.61.39.574.4000
FAX: 011.61.39.562.7237

Everpure-Shurflo Southeast Asia
18 Boon Lay Way
#04-110/111
TradeHub 21, 609966
SINGAPORE
TEL: 65.6795.2213
FAX: 65.6795.2219

Everpure-Shurflo Europe bvba
Industriepark Wolfstee
Toskamsdaan 30
B-2200 Herentals
BELGIUM
TEL: +32.(0).14.283.500
FAX: +32.(0).14.283.505

H5e. MH2 Filter Cartridge

EVERPURE

EV9613-21

MH² Filter Cartridge

Delivers premium quality water for coffee applications

MH² Replacement Cartridge: EV9613-21

BENEFITS

New and improved Micro-Pure II media with AgION™ antimicrobial protection inhibits any potential bacterial growth

Provides clear, fresh, premium quality ingredient water for consistently great tasting coffee and beverages

Everpure's unique filter blend using activated carbon reduces chlorine taste and odor and other offensive contaminants

Saves energy by reducing scale build-up. Self-contained scale inhibitor feed dramatically prevents limescale from forming in brewing equipment (as tested by Everpure)

Precoat submicron technology reduces dirt and particles as small as 1/2 micron in size

Reduces health contaminants such as asbestos fibers and Cryptosporidium and Giardia cysts

Sanitary cartridge replacement is simple, quick and clean. Internal filter parts are never exposed to handling or contamination

NSF Certified under NSF/ANSI Standards 42

INSTALLATION TIPS

Install vertically with cartridge hanging down

Allow 2-1/2" clearance below the cartridge for easy cartridge replacement

Flush cartridge by running water through filter for three minutes at full flow

OPERATION TIPS

Change cartridges on a regular 6 month preventative maintenance program

Change cartridges when capacity is reached or when pressure falls below 10 psi

Always flush the filter cartridge at time of installation and cartridge change

APPLICATION/SIZING

For coffee applications

High flow, higher volume coffee urns

Rated Capacity: 9,000 gallons (34,068L) or 18,000 pots

SPECIFICATIONS

Overall Dimensions:
20.75"H x 3.25"Diameter

Service Flow Rate:
Maximum 1.67 gpm (6.3 Lpm)

Rated Capacity: 9,000 gallons

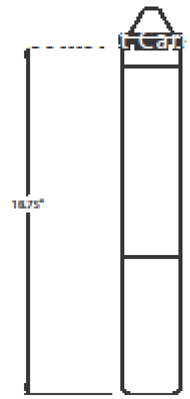
Pressure Requirements:
10 - 125 psi (0.7 - 8.6 bar), non-shock

Temperature: 35 - 100°F (2 - 38°C)

No electrical connection required

The contaminants or other substances removed or reduced by this drinking water system are not necessarily in your water. Do not use with water that is microbiologically unsafe or of unknown quality without adequate disinfection before or after the system. Systems certified for cyst reduction may be used with disinfected water that may contain filterable cysts.

MH² Filter Cartridge



WARRANTY

Everpure water treatment systems (excluding replaceable elements) are covered by a limited warranty against defects in material and workmanship for a period of five years after date of purchase. Everpure replaceable elements (filter cartridges and water treatment cartridges) are covered by a limited warranty against defects in material and workmanship for a period of one year after date of purchase. See printed warranty for details. Everpure will provide a copy of the warranty upon request.

System Tested and Certified by NSF International against NSF/ANSI Standard 42 and 53 for the reduction of:

Standard No. 42: Aesthetic Effects
Chemical Unit
Taste and Odor Reduction
Chlorine Reduction
Mechanical Filtration Unit
Nominal Particulate Reduction, Class I
[illegible] reduction of particles one-half micron and larger in size.
Standard No. 53: Health Effects
Mechanical Filtration Unit
Turbidity Reduction
Cyst Reduction
Asbestos Reduction

EVERPURE

EVERPURE, LLC
1040 Muirfield Drive
Hanover Park, Illinois 60133
Toll Free (800) 323-7873
Tel (630) 307-3000
Fax (630) 307-3030
http://www.everpure.com

In Europe:
N.V. EVERPURE (EUROPE) S.A.
[illegible]

In Japan:
EVERPURE JAPAN LLC
[illegible]
Japan

H6. Ice Machine Disinfection Log

Nursing personnel shall be responsible for the routine cleaning of unit ice machines. Unit ice machines shall be **disinfected twice daily at 0800 and 2000** using a chlorine disinfectant wipe to clean the ice chute, lever arm, water dispensing chute, and dispensing nozzle. Time of disinfection and initials shall be documented on this log.

Maintenance staff is responsible for monitoring the dynamic pressure of both the inlet pressure gauge and outlet pressure gauge on a weekly basis. Cartridges should be changed when a ≥20psi differential pressure is noted. Date and time of pressure checks and cartridge changes should be noted below.

Location	Action	Date	Time	Initials	Comments	Name of Device (For Investigator Use)