



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (lcs)
FOLDER: K103254 - 225 pages
COMPANY: COLOPLAST A/S (COLOASA)
PRODUCT: TUBES, GASTROINTESTINAL (AND ACCESSORIES) (KNT)
SUMMARY: Product: PERISTEEN ANAL IRRIGATION SYSTEM, IRRIGATION
ACCESSORY UNIT, IRRIGATIO
DATE REQUESTED: Sep 17, 2014
DATE PRINTED: Sep 17, 2014
Note: Printed



K103254
page 1 of 2

JAN 31 2011

3. 510(k) SUMMARY

510(K) Owner's Name: Coloplast A/S

Address: Hortedam 1
3050 Humlebaek, Denmark
Establishment Registration: 9610694
Owner/Operator: 8010144

Phone/Fax/Email: Office: (612) 302-4987
Mobile: (612) 968-9567
Fax: (612) 287-4138
email: usbcs@coloplast.com

Name of Contact Person: Brian Schmidt
Regulatory Affairs Manager

Address/Contact: 1601 West River Road
Minneapolis, MN 55411

Date Prepared: November 2, 2010

Trade Name: Peristeen™ Anal Irrigation System

Common Name: Rectal Catheter and accessories and
Enema kit

Classification Name: 876.5980 Gastrointestinal tube & accessories
Class II and
876.5210 Enema kit
Class I (Exempt)

Product Code: KNT and FCE

Legally Marketed Devices To Which Your Firm Is Claiming Equivalence:

The Peristeen™ Anal Irrigation System is substantially equivalent in performance, indications, design and materials to the Peristeen™ Anal Irrigation System cleared on November 23, 2009 under premarket notification 510(k) number K083770.

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Page 2 of 2

Description Of The Device:

The Peristeen™ Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system may be purchased with a carrying case (toilet bag). The rectal catheter is single-use, but the other components may be used multiple times. Accessory kits are available for the components. The PAI system does not contain natural rubber latex components.

Intended Use Of The Device:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Technological Characteristics Compared To Predicate Device:

The proposed Peristeen™ Anal Irrigation System (expanded indications for use) is substantially equivalent to the Peristeen™ Anal Irrigation System.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence of the Peristeen™ Anal Irrigation System is supported by a comparison of the design, materials, and intended use compared to the predicate, as well as acceptable results from functional performance and biocompatibility testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Coloplast A/S
c/o Mr. Brian Schmidt
Regulatory Affairs Manager
Coloplast Manufacturing US, LLC
1601 West River Road North
MINNEAPOLIS MN 55411

JAN 3 1 2011

Re: K103254
Trade/Device Name: Peristeen™ Anal Irrigation System
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Codes: KNT and FCE
Dated: November 2, 2010
Received: November 3, 2010

Dear Mr. Schmidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

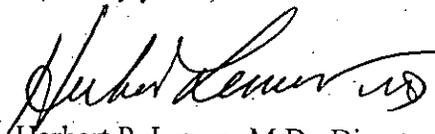
Page 2

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21-CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

2. STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K103254

Device Name: Peristeen™ Anal Irrigation System

Indications for Use:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K103254



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Coloplast A/S
c/o Mr. Brian Schmidt
Regulatory Affairs Manager
Coloplast Manufacturing US, LLC
1601 West River Road North
MINNEAPOLIS MN 55411

JAN 31 2011

Re: K103254
Trade/Device Name: Peristeen™ Anal Irrigation System
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Codes: KNT and FCE
Dated: November 2, 2010
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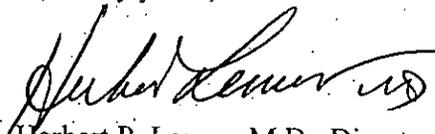
Page 2

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Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K103254

Device Name: Peristeen™ Anal Irrigation System

Indications for Use:

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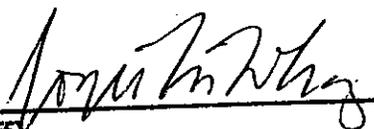
Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K103254



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center 6 WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

November 05, 2010

COLOPLAST A/S
 COLOPLAST MANUFACTURING US, LLC
 1601 WEST RIVER ROAD NORTH
 MINNEAPOLIS, MINNESOTA 55411
 UNITED STATES
 ATTN: BRIAN SCHMIDT

510k Number: K103254

Received: 11/3/2010

Product: PERISTEEN ANAL IRRIGATION SYST

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff



 **Coloplast**

**Peristeen Anal Irrigation System-Expanded Indications
Traditional 510(k)**

November 02, 2010

K103254



Ostomy care
Urology & Continence care
Wound & Skin care

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC

November 2, 2010

NOV 3 2010

RE: **510(k) Notification (21 CFR 807.90(e)).
Traditional 510(k)
Peristeen Anal Irrigation (PAI) System (expanded indications for use)**

Received *K-43*

Coloplast Corp.
1601 West River Rd N.
Minneapolis, MN 55411
USA

To Whom It May Concern:

Tel. 612-337-7800

Coloplast A/S hereby submits this Traditional Premarket Notification 510(k) in duplicate to request clearance for **expanded indications for use** for the Peristeen Anal Irrigation (PAI) System. Coloplast also provides an electronic version copied to CD per FDA's instructions, "Electronic Copies for Pre-Market Submissions" dated March 5, 2007. The electronic copy is an exact duplicate of the paper copy. A Microsoft Word version of this document is available upon request.

Toll Free Number:
1-800-788-0293

www.us.coloplast.com

The PAI System is comprised of a Class II rectal catheter and accessories per 21 CFR 876.5980, Product Code KNT and a Class I enema kit per 21 CFR 876.5210, Product Code FCE. The appropriate Review Panel is Gastroenterology/Urology. The PAI System was originally cleared on November, 23 2009 via 510(k) #K083770. As recommended in the document "Format for Traditional and Abbreviated 510(k)s," key questions related to the PAI System are summarized in **Table 1**.

Brian E. Schmidt
Manager

Regulatory Affairs

Tel. 612-302-4987
Mob. 612-968-9567
Fax 612-287-4138
usbes@coloplast.com

Table 1 – Design and Use of the Device

Question	YES	NO
Is device intended for prescription use (21 CFR 801 Subpart D)	X	
Is device intended for OTC use (21 CFR 807 Subpart C)		X
Does device contain tissue derived/biologic source components		X
Is device provided sterile		X
Is device intended for single use	X Catheter	X Control Unit, Water Bag, Tubing
Is device reprocessed single use device		X
If yes, does device type require reprocessed validation data		NA
Does device contain a drug		X
Does device contain a biologic		X
Does device use software		X
Does submission include clinical information		X
Is device implanted		X

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Ostomy care
Urology & Continence care
Wound & Skin care

Medical Device User Fee Cover Sheet (Form OMB 0910-511) with Payment Identification Number **MD6052115-956733** is attached to this cover letter.

Coloplast considers the existence and contents of this submission to be confidential and exempt from public disclosure.

Please contact me with questions or if further information is needed.

Best regards,

A handwritten signature in black ink, appearing to read "Brian E. Schmidt". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Brian E. Schmidt

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.		
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html				
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) COLOPLAST CORP 1601 West River Road N Minneapolis MN 55411 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8988	2. CONTACT NAME Elizabeth Boots 2.1 E-MAIL ADDRESS usbb@coloplast.com 2.2 TELEPHONE NUMBER (include Area code) 612-302-4992 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 612-287-4138			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice </td> <td style="vertical-align: top;"> 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table>			<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:				
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)				
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td style="vertical-align: top;"> <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially </td> </tr> </table>			<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO				
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION		07-Oct-2010		

(b) (4)

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.	
Date of Submission 1/2/2010	User Fee Payment ID Number (b) (4)		FDA Submission Document Number (if known) TBD	
SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA &HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Coloplast A/S		Establishment Registration Number (if known) 9610694		
Division Name (if applicable) Coloplast Corp		Phone Number (including area code) (612) 302-4987		
Street Address Holtedam I		FAX Number (including area code) (612) 287-4138		
City 3050 Humlebaek	State / Province NA	ZIP/Postal Code NA	Country Denmark	
Contact Name Elizabeth Boots				
Contact Title VP, US Regulatory Affairs		Contact E-mail Address usbb@coloplast.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name Coloplast A/S				
Division Name (if applicable) Coloplast Manufacturing US, LLC		Phone Number (including area code) (612) 302-4987		
Street Address 1601 West River Rd North		FAX Number (including area code) (612) 287-4138		
City Minneapolis	State / Province MN	ZIP/Postal Code 55411	Country USA	
Contact Name Brian Schmidt				
Contact Title Regulatory Affairs Manager		Contact E-mail Address usbes@coloplast.com		

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (specify):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input checked="" type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	KNT	2	FCE	3	
		6		7	
				8	

510 (k) summary attached
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)					
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K083770	1	Peristeen Anal Irrigation System	1	Coloplast A/S
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 876.5980 Gastrointestinal tube & accessories; 876.5210-Enema Kit

	Trade or Proprietary or Model Name for This Device	Model Number
1	Peristeen Anal Irrigation System	1 29121
2	Peristeen Anal Irrigation Accessory Unit	2 29122
3	Peristeen Anal Irrigation Rectal Catheter	3 29123
4	Peristeen Anal Irrigation System Strap	4 29124
5	Peristeen Anal Irrigation Tube	5 29125

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code KNT	C.F.R. Section (if applicable) 21 CFR 876.1500 Gastroenterology-Urology Devices	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel		

Indications (from labeling)
 The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - 2 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known) TBD	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Coloplast A/S		Establishment Registration Number 9610694	
Division Name (if applicable)		Phone Number (including area code) () +45 4911 2418	
Street Address Holtedam 1		FAX Number (including area code) () +45 4911 1310	
City 3050 Humlebaek		State / Province NA	ZIP/Postal Code NA
Country Denmark			
Contact Name Brian Schmidt		Contact Title Regulatory Affairs Manager	Contact E-mail Address usbes@coloplast.com
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code
Country			
Contact Name		Contact Title	Contact E-mail Address
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code
Country			
Contact Name		Contact Title	Contact E-mail Address

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1			See Section 8 and Standards forms provided in Attachment 1 of this 510(k) for a summary of standards referenced in this submission.		
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

A agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

See OMB Statement on Reverse, Form Approved: OMB No. 0910-0616, Expiration Date: 08-30-2008



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Coloplast A/S	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES November 2 2010
3. ADDRESS (Number, Street, State, and ZIP Code) Holtedam I 3050 Humleback Denmark	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 612-302-4987 (Fax) 612-287-4138

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Common name: Rectal Catheter and accessories and Enema Kit; 29121, 29122, 29123, 29124, 29125, 29126, 29127, 29128

Classification names: 876.5980 Gastrointestinal tube & accessories

Trade/proprietary name: Peristeen Anal Irrigation System

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
 IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See Instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.**

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Brian Schmidt (Title) Regulatory Affairs Manager
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 1601 West River Road North Minneapolis, MN 55411	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 612-302-4987 (Fax) 612-287-4138
15. DATE OF CERTIFICATION 11/02/2010	



Application for a
Traditional 510(k)
Peristeen™ Anal Irrigation (PAI) System-Expanded Indications
for Use

Submitted By:
Brian Schmidt

November 2, 2010

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1. SCREENING CHECKLIST

for all Premarket Notification [510(k)] Submissions

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4**

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	Present; See pages 1-2	
Table of Contents.	Present; See pages 11-12	
Truthful and Accurate Statement.	Present; See page 21	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Present; See page 18	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Present; See page 18	
Proposed Labeling, including the material listed on page 3-4 of the Premarket Notification [510] Manual.	Present; See page 47	
Statement of Indications for Use that is on a separate page in the premarket submission.	Present; See page 17	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	Present; See page 45	
<u>510(k) Summary</u> 510(k) Statement.	Present; See page 18	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Present; See page 27	
Identification of legally marketed predicate device. *	Present; See page 18	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	Present; See page 24	
Class III Certification and Summary. **	Present; See page 22	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	Present; See page 23	
510(k) Kit Certification ***	Not Applicable	

*May not be applicable for Special 510(k)s.

**Required for Class III devices, only.

***See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:
*****Not Applicable*****

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities including the method or test used to demonstrate acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Not Applicable

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

*****Not Applicable*****

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard , which is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

Not Applicable

*When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	Present; see page 52	
b) Sterilization and expiration dating information:	Not Applicable; See page 51	
i) sterilization process	Not Applicable; See page 51	
ii) validation method of sterilization process	Not Applicable; See page 51	
iii) SAL	Not Applicable; See page 51	
iv) packaging	Not Applicable; See page 51	
v) specify pyrogen free	Not Applicable; See page 51	
vi) ETO residues	Not Applicable; See page 51	
vii) radiation dose	Not Applicable; See page 51	
viii) Traditional Method or Non-Traditional Method	Not Applicable; See page 51	
c) Software Documentation:	Not Applicable; See page 53	

Items with checks in the Present or Adequate column do not require additional information from the sponsor. Items with checks in the Missing or Inadequate column must be submitted before substantive review of the document.

Passed Screening ____ Yes ____ No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

2. STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known):

Device Name: **Peristeen™ Anal Irrigation System**

Indications for Use:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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3. 510(K) SUMMARY

510(K) Owner's Name: Coloplast A/S

Address: Holtedam 1
3050 Humlebaek, Denmark
Establishment Registration: 9610694
Owner/Operator: 8010144

Phone/Fax/Email: Office: (612) 302-4987
Mobile: (612) 968-9567
Fax: (612) 287-4138
email: usbes@coloplast.com

Name of Contact Person: Brian Schmidt
Regulatory Affairs Manager

Address/Contact: 1601 West River Road
Minneapolis, MN 55411

Date Prepared: November 2, 2010

Trade Name: Peristeen™ Anal Irrigation System

Common Name: Rectal Catheter and accessories and
Enema kit

Classification Name: 876.5980 Gastrointestinal tube & accessories
Class II and
876.5210 Enema kit
Class I (Exempt)

Product Code: KNT and FCE

Legally Marketed Devices To Which Your Firm Is Claiming Equivalence:

The Peristeen™ Anal Irrigation System is substantially equivalent in performance, indications, design and materials to the Peristeen™ Anal Irrigation System cleared on November 23, 2009 under premarket notification 510(k) number K083770.

Description Of The Device:

The Peristeen™ Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system may be purchased with a carrying case (toilet bag). The rectal catheter is single-use, but the other components may be used multiple times. Accessory kits are available for the components.

Intended Use Of The Device:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Technological Characteristics Compared To Predicate Device:

The proposed Peristeen™ Anal Irrigation System (expanded indications for use) is substantially equivalent to the Peristeen™ Anal Irrigation System.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence of the Peristeen™ Anal Irrigation System is supported by a comparison of the design, materials, and intended use compared to the predicate, as well as acceptable results from functional performance and biocompatibility testing.

4. STANDARDS DATA REPORT FOR 510(K)s - FDA 3654

The Standards Data Reports for 510(K)s - Forms FDA 3654 are provided as **Attachment A**.

6. CLASS III CERTIFICATION

Since this 510(k) does not pertain to a Class III device, the referenced Certification is not applicable to this application.

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7. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section does not apply, as there is no information from clinical studies presented within this premarket notification; therefore, financial disclosures are not required.

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8. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

The Coloplast Peristeen™™ Anal Irrigation (PAI) system is in compliance with the standards listed in **Table 1**. Copies of FDA Form FDA-3654, *Standards Data Report for 510(k)s* for each of the voluntary standards listed below are provided in **Attachment A**.

Table 1: Voluntary Standards

Number and Title of Voluntary Standard		Recognized Standard#
Biological		
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing	Yes 2-156
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Yes 2-153
ISO 10993-6:2007	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	Yes 2-120
ISO 10993-10:2002 Amd 1:2006	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed type hypersensitivity	Yes 2-152
ISO 10993-11:2006	Biological evaluation of medical devices - Part 11: Test for Systemic Toxicity	Yes 2-118
ISO 10993-12:2007	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	Yes 2-135
Labeling		
EN 980: 2008	Graphical symbols for use in the labeling of medical devices	No
EN 1041: 2008	Information supplied by the manufacturer with medical devices	No
Risk Management		
ISO 14971:2007	Medical devices – Application of risk management to devices	Yes 5-40

9. EXECUTIVE SUMMARY

Coloplast wishes to expand the indications for use for the Peristeen™ Anal Irrigation (PAI) system and add an additional rectal catheter size. As outlined in this premarket notification, the Peristeen™ Anal Irrigation System is substantially equivalent in performance, indications, design and materials the Peristeen™ Anal Irrigation (PAI) system cleared on November 23, 2009 under premarket notification 510(k) number K083770.

This premarket notification has been prepared based upon formatting recommendations outlined in FDA's *Format for Traditional and Abbreviated 510(k)s*.

A. Product Description

The Peristeen™ Anal Irrigation system is a Class II device, consisting of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times (as specified in the Quick Reference Guide and User Guide; See **Section 12, Labeling**. All System components are also provided separately in various accessory packages.

B. Device Classification Name and Number

Gastrointestinal tube & accessories 876.5980 Class II
Enema kit 876.5210 Class I (Exempt)

C. Device Trade Name

Coloplast Peristeen™ Anal Irrigation (PAI) System

D. Name of Applicant

Coloplast A/S
Holtedam 1
3050 Humlebaek, Denmark
Establishment Registration: 9610694
Owner/Operator: 8010144

E. Submission Contact

Brian Schmidt
Regulatory Affairs Manager
Telephone: 612.302.4987
Fax: 612.287.4138
Email: usb@coloplast.com

F. Manufacturing Site Name and Address

Manufacturer

Coloplast A/S
 Høltedam 1
 3050 Humlebæk, Denmark
 Establishment Registration: 9610694

G. Performance Standards

There are no performance standards listed for the Peristeen™ Anal Irrigation (PAI) System in effect under Section 514.

H. Device Catalog Numbers and Description

The Coloplast Peristeen™ Anal Irrigation (PAI) System catalog numbers are provided in **Table 2**.

Table 2: PAI Catalog Numbers

Product	Catalog number	Components
Peristeen™ Anal Irrigation System	(b) (4)	
Peristeen™ Anal Irrigation Accessory Unit		
Peristeen™ Anal Irrigation Rectal Catheter		
Peristeen™ Anal Irrigation Strap		
Peristeen™ Anal Irrigation Tube		
Peristeen™ Anal Irrigation System		
Peristeen™ Anal Irrigation Accessory Unit		
Peristeen™ Anal Irrigation Rectal Catheter		

I. Indications for Use

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

10. DEVICE DESCRIPTION

The Peristeen™ Anal Irrigation (PAI) System is a Class II device intended for intermittent use that facilitates emptying of the colon/bowel in patients with neurogenic bowel dysfunction. The PAI system consists of a single-use irrigation catheter that incorporates an inflatable balloon to keep the catheter in place during the procedure and retain the water that flows into the colon. The rectal catheter is non-sterile, intended for single-use, and packaged and labeled accordingly. The other components may be used multiple times; usage guidelines are detailed in the labeling. All System components are also provided separately in various accessory packages. **Figure 1** provides a photograph of the System and accessories. Descriptions of individual components follow.



Figure 1: Peristeen™ Anal Irrigation (PAI) System

A. PAI System Rectal Catheter

The PAI rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is made of dip-molded polyvinyl chloride (PVC). The inflatable balloon is made of chloroprene; it is attached around the proximal end of the catheter. The catheter is pre-lubricated with a hydrophilic polyvinylpyrrolidone coating over a basecoat of polyurethane to aid in insertion. The distal end of the catheter has a blue connector that attaches to the control unit tubing. The catheter is provided non-sterile and is intended for single use only. Photographs of the two sizes of the rectal catheter are provided in **Figure 2**. Inflated and a simulated use model of the catheter are provided in **Figure 3** and **Figure 4**.



Figure 2: Large and Small Size Comparison Un-inflated PAI Rectal Balloon Catheter

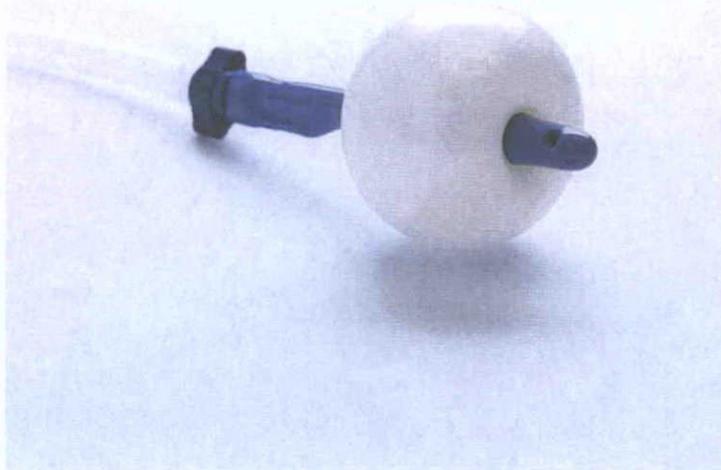


Figure 3: PAI Balloon Catheter



Figure 4: PAI Catheter, Simulated Model

B. PAI System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake. The control unit housing has a manually operated knob that has the following four positions:

-  Resting/Device storage
-  Inflate the balloon on the catheter
-  Pump water into catheter/rectum
-  Deflate the balloon on the catheter



Figure 5: PAI Control Unit

The rectal catheter and the water bag are connected to the Control Unit via double lumen silicone tubing with color-coded male ABS connectors. Water flows through the larger lumen and air flows through the smaller lumen. A blue connector attaches to the distal tip of the rectal catheter; a gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.



Figure 6: PAI Lid/Connector/Tubing

C. PAI System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The lid is made of (b) (4)

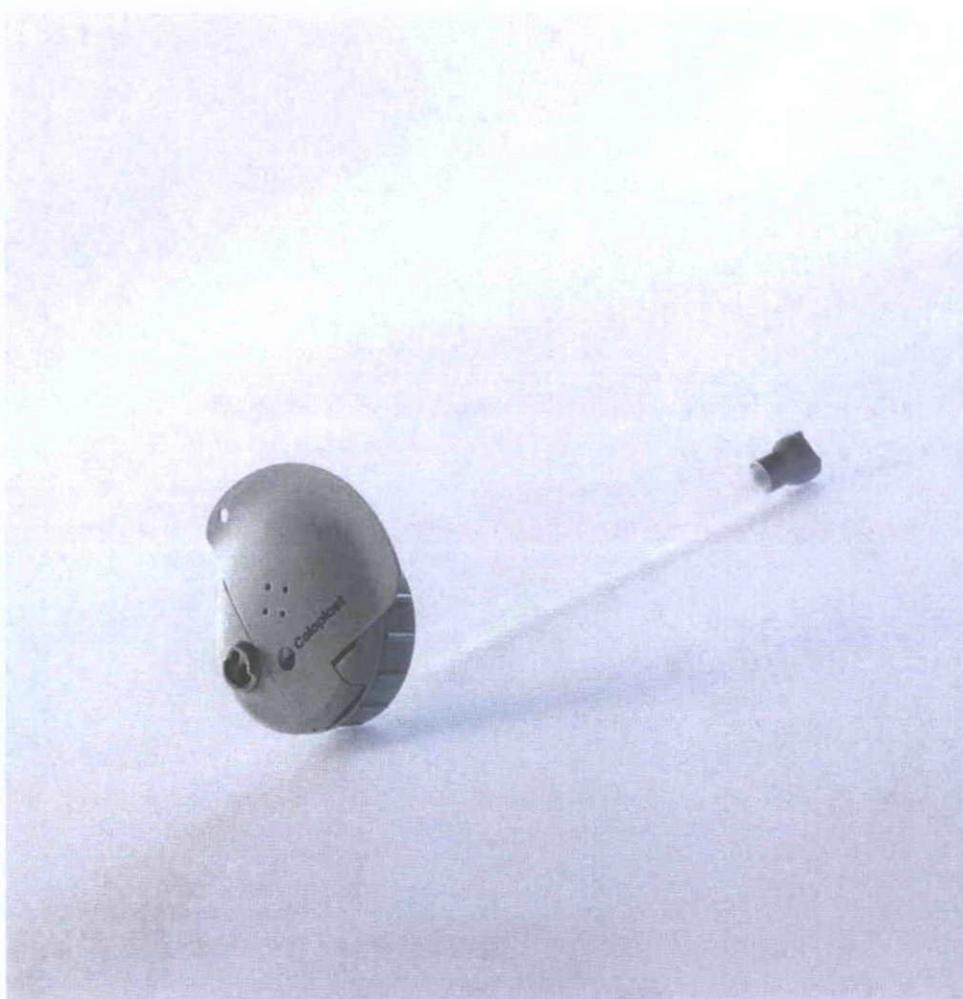


Figure 7: PAI Lid/Suction Tube Assembly

D. PAI System Water Bag

(b) (4) bag is designed to hold the water or isotonic saline solution used to perform the irrigation. There is a (b) (4) threaded neck (b) (4) the bag for attaching the lid. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.



Figure 8: PAI Water Bag & Tubing

E. PAI System Accessories

For ease of use, (b) (4) [redacted] ps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the [redacted] (case provided with the PAI System; the storage case also protects the components from exposure to direct sunlight.

)
(
4
)



Figure 9: PAI System Storage Case

F. PAI System Packaging

The PAI Rectal Balloon Catheter is provided non-sterile in a sealed (b) (4) pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Quick Reference Guide and the User Guide). The catheter is intended for single use only.

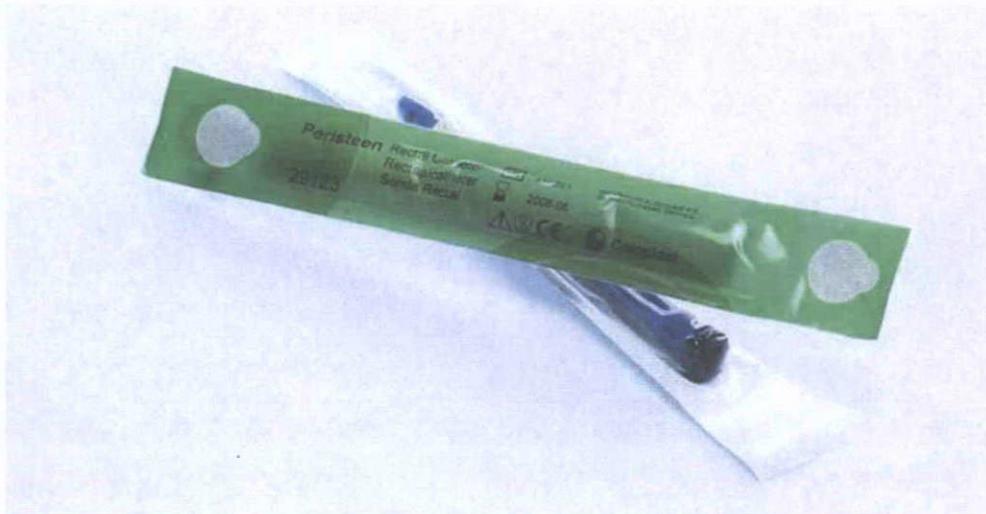


Figure 10: PAI Rectal Balloon Catheter package

The other components of the PAI system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.

G. PAI System Performance Test Summary

Table 3 provides a summary of the physical properties and tests performed on the Coloplast **Peristeen™** Anal Irrigation (PAI) System, which were provided in the original 510(k) K083770. **Table 4** provides a summary of physical properties and tests performed on the smaller size rectal catheter which is included in this submission. More detailed information is provided in **Section 17, Performance Testing**.

Table 3: Peristeen™ Anal Irrigation Performance Test Summary

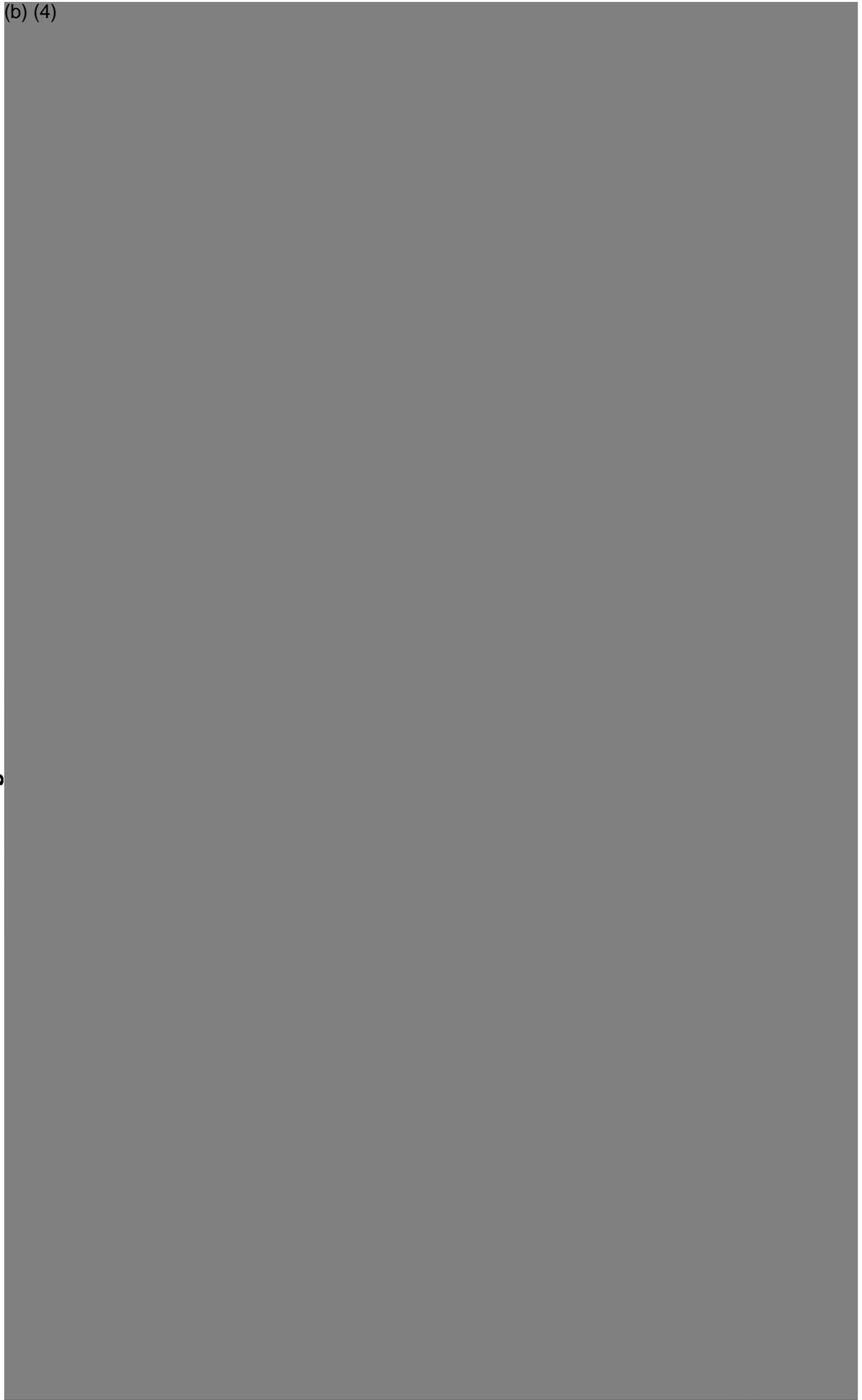
PAI System Rectal Catheter	
1.	Verification of dimensions
2.	Leakage test
3.	Balloon Burst Volume
PAI System Control Unit	
4.	Opening pressure for valve
5.	Leakage test
6.	Wear test
PAI System Lid/Tubing	
7.	Measure leakage in water bag position
8.	Measure leakage in balloon position
9.	Evaluate air escape valve
10.	Evaluate turning of selector
11.	Evaluate positioning the selector
PAI System Water Bag	
12.	Pressure test
13.	Wear test

Table 4: Peristeen™ Anal Irrigation Small Rectal Catheter Performance Test Summary

PAI System Small Rectal Catheter	
1.	Verification of dimensions
2.	Leakage test
3.	Balloon Burst Volume

H. PAI System Assembly Overview

**Peristeen Anal Irrigation System
Manufacturing Process**



I. PAI System Materials Summary

Table 5 summarizes the materials used to manufacture the Peristeen™ Anal Irrigation assemblies. The engineering drawing for the Peristeen™ Anal Irrigation System and subassemblies were provided in the original 510k. The engineering drawing for the smaller size catheter is provided as **Attachment B**.

Table 5 : Materials in the Peristeen™ Anal Irrigation System

Components	Raw Materials
Rectal Catheter	(b) (4)
Catheter	
Balloon	
Lubricant Coating	
Base Coating	
Control Unit	
Internal Tubes	
One-way Valve	
Hand Pump Black	
Control Unit housing	
Female Luer Connector	
Lid/Suction Tube	
Lid	
Filling Nozzle	
Gasket	
Valve Seat	
Pressure Valve	
Female Luer Connector	
Suction Hose	
Cover Oneway Valve	
Water Bag	
Bag	
Volume Indicator	
Threading Socket	

11. SUBSTANTIAL EQUIVALENCE COMPARISON

A. Substantial Equivalence Overview

The Coloplast Peristeen™ Anal Irrigation (PAI) System is substantially equivalent in design, indications, usage, and materials to the Coloplast Peristeen™ Anal Irrigation (PAI) system cleared on November 23, 2009 under premarket notification 510(k) number K083770.

Design

The design of the PAI system remains unchanged for the PAI system originally cleared in K083770. The only difference is the addition of a small catheter size (shorter total length and shorter balloon length) which was added based upon customer feedback.

Intended Use

The original intended use for the Coloplast Peristeen™ Anal Irrigation (PAI) System specified use in spinal cord injury (SCI) patients with neurogenic bowel dysfunction (NBD). Although spinal cord injury is one specific cause of neurogenic bowel dysfunction, other diseases and conditions can also lead to neurogenic bowel dysfunction, such as Myelomeningocele (spina bifida) and multiple sclerosis (MS). Coloplast wishes to broaden the indications for use to patients with neurogenic bowel dysfunction without specifying the exact cause.

According to a review of the most common diseases causing neurogenic bowel dysfunction the pathophysiology is fundamentally the same in patients with spinal cord injury (SCI), multiple sclerosis (MS) and Myelomeningocele (spina bifida).¹

The symptoms of neurogenic bowel dysfunction are fecal incontinence and constipation. Fecal incontinence in SCI, MS and spina bifida is considered to be due to abnormal recto-sigmoid compliance and recto-anal reflexes, loss of recto-anal sensibility and loss of voluntary control of the external anal sphincter. Constipation in SCI, spina bifida and MS is mainly due to immobilization, abnormal colonic contractility, tone and recto anal reflexes or side effects from medication.

Treatment with Trans-anal irrigation (TAI) aims to ensure emptying of the colon and the rectum and if successful, prevent fecal leakage and constipation. The pathophysiology of neurogenic bowel dysfunction (NBD) varies somewhat between patient groups but evaluation and treatment algorithms are similar if not identical.^{2 3}

Expanding the indications for use to include patients with neurogenic bowel caused by conditions other than spinal cord injury does not raise new questions regarding safety and effectiveness.

¹ Krogh K, Christensen P. Neurogenic colorectal and Pelvic floor dysfunction. Best Practice and Research Clinical Gastroenterology 2009;23:531-543.

² Krogh K, Christensen P. Transanal irrigation for disordered defecation: A systematic review. Scandinavian Journal of gastroenterology 2010;45:517-527.

³ Emmanuel A. Review of the efficacy and safety of transanal irrigation for neuro-genic bowel dysfunction. Spinal Cord 2010;1-10

With regard to the request to include the pediatric patient population of 2-11 year old patients, please consider the following. In the original Peristeen™™ Anal Irrigation (PAI) System 510k submission the FDA proposed the following question in regards to device use in adolescent patients.

“You have indicated your device for use in adolescent patients. Please indicate if you have assessed the risks to this population and appropriate technique to use, size of the catheter, and volume of water, especially when considering Myelomeningocele (spina bifida) patients, who tend to be smaller in size. Please present this assessment and consider the benefit of physician labeling to address concerns that may remain, if any, for the adolescent population that would use your device”

In response to this question, Coloplast made an assessment of risks to the adolescent population, and potential concerns were identified. These issues were organized as follows and addressed in the original 510k:

(b) (4)



Dependence on parent/caregiver

(b) (4)



(b) (4)

These informational labeling documents are provided in the Attachments as follows:

	Document Name	Provided in....
1.	Caregiver Brochure	Attachment C-1
2.	Health Care Notes form	Attachment C-2
3.	Anatomy Notes sheet (Pictorial of PAI in use)	Attachment C-3
4.	Product brochure	Attachment C-4
5.	User Guide	Attachment C-5
6.	Quick Reference Guide	Attachment C-6
7.	Simplified Quick Reference Guide	Attachment C-7

Differences in cognitive abilities

Coloplast acknowledges that a child (2 to <12 year old) using PAI will have different cognitive abilities than an adolescent or adult. In addition, adults may have permanent impairments that result in cognitive limitations no different than a 2 year old. To address potential cognitive differences among PAI users, instructions for use have been drafted that seek to provide steps of use in simplified language. This **Simplified Quick Reference Guide** is provided as **Attachment C-7**. The **Simplified Quick Reference Guide** is not intended to take the place of the caregiver/physician in children but in some instances it would be a beneficial tool for children, i.e, older children who are able to maintain independence by administering their own care though proper training, practice and supervision. In addition, tools have been created for physicians and patients that will assist in informing and training patients. These tools are intended to be used as needed to remind patients and caregivers of specific, individualized instructions. The tools include:

- Health Care Notes form; providing specific recommendations for individual patients
- Anatomy Notes sheet (Pictorial of PAI in use); tool used to provide further clarification on device use

The Health Care Notes form is provided as **Attachment C-2**; the Pictorial-PAI in use is provided as **Attachment C-3**.

Differences in anatomy

Because of the variability of the anatomy in the indicated patient population, which may include children, adolescents and adults who have been injured, or have congenital physical abnormalities that contribute to their condition, Coloplast recommends that *all* patients work closely with their health care providers to ensure that individualized treatment regimens are identified. Based on the individual physician's standard of care, it is reasonable to expect that a health care provider will utilize a variety of diagnostic tools to assess patients' individual needs.

The existing Peristeen™ Anal Irrigation User Guide emphasizes that patients must carefully consult with their physician or health care provider to determine the proper use of the device, including the insertion depth for the catheter, amount of air to pump into the balloon, and amount of water to pump into the lower colon. Specifically, in the Quick Reference Guide and User Guide Operating Instructions section, Step 7, patients are directed to "Insert the rectal catheter carefully into the rectum

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in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly... When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. **Your doctor or nurse will work with you to decide how many times you should squeeze the pump, but it is usually 3 to 4 times.**” Step 8 advises, “...Turn the knob on the control unit counter-clockwise to the water symbol. Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. **Your doctor or nurse will train you on how much water to use.**” In addition to these recommendations, the *Troubleshooting* section of the User Guide indicates that “...The required amount of water is individual and your doctor or nurse will tell you how much water to use. An average procedure normally calls for a volume of ½-1 liter of water...”

Since the patient is advised to rely on the expertise of the physician/healthcare provider, Coloplast has provided additional labeling for physicians/healthcare providers to highlight the unique information needed to ensure proper device use and to stress their role and responsibilities to the indicated patient population. Along with available training for physicians and health care providers, Coloplast has drafted a Physician Instructions for Use document. In addition, Coloplast will provide a comprehensive Physician Information Package that includes specific information for the healthcare provider as well as tools to assist them in informing and training the patient.

The packet consists of the following:

- Caregiver Brochure
- Health Care Notes form; providing specific recommendations for individual patients
- Anatomy Notes sheet (Pictorial of PAI in use); tool used to provide further clarification on device use
- Product brochure
- User Guide
- Quick Reference Guide
- Simplified Quick Reference Guide
- Physician Instructions for Use

The Physician Information Package documents are provided in the Attachments as follows:

	Document Name	Provided in....
1.	Caregiver Brochure	Attachment C-1
2.	Health Care Notes form	Attachment C-2
3.	Anatomy Notes sheet (Pictorial of PAI in use)	Attachment C-3
4.	Product brochure	Attachment C-4
5.	User Guide	Attachment C-5
6.	Quick Reference Guide	Attachment C-6
7.	Simplified Quick Reference Guide	Attachment C-7
8.	Physician Instructions for Use	Attachment C-8

Coloplast has also determined that the issue of anatomical differences necessitates appropriate wording in the User Guide and the Quick Reference Guide in order to highlight differences that might exist among patients, in particular the importance of relying on your physician/healthcare provider to determine how far to insert the catheter, proper balloon inflation, and the proper amount of water to use during the irrigation procedure. These concerns are specifically addressed in steps 7 & 8 of the

User Guide (page 5) and the Quick Reference Guide (page 3) and the 4th item of the *Troubleshooting* section in the User Guide

Frequency/Duration of Use

The PAI System is intended for regular use; the user generally needs 30-45 minutes for the bowel management procedure daily or every other day. This remains unchanged from the original 510(k)

Material

The small rectal catheter is composed of identical materials and has identical processing as the larger catheter from the original 510(k). Materials of the other components remain unchanged.

Table 6. summarizes the material and functional similarities between the predicates and the proposed PAI System.

Table 6: Peristeen™ Anal Irrigation System Predicate Comparisons

Device Feature/ Component	Peristeen™ Anal Irrigation-expanded indications for use (this submission)	Peristeen™ Anal Irrigation (PAI)
Manufacturer	(b) (4)	Coloplast A/S
510 (k) number		K083770; cleared 23 Nov 2009
Regulation name		Gastrointestinal tube and accessories
Regulation number		21 CFR § 876.5980
Classification product code		KNT
Classification		II
Prescription device		Yes
Intended use/Indications for Use		The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by) adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.
Contra-indications		<p>Peristeen™ Anal Irrigation must not be used in the following situations:</p> <ul style="list-style-type: none"> • During the spinal shock phase . • Known obstruction of the large bowel • Acute inflammatory bowel disease • Diverticulitis <p>If you are pregnant and have never used anal irrigation before, you should not start the irrigation procedure during pregnancy.</p>
Target population;		Spinal cord injured patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.
Age Groups		Adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients
Anatomical sites;		Rectum (and lower colon)
Where used (hospital, home, ambulance, etc);		Health Care Facility and home use

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Device Feature/ Component	Peristeen™ Anal Irrigation-expanded indications for use (this submission)	Peristeen™ Anal Irrigation (PAI)
Energy used and/or delivered;	(b) (4)	NA - Manual
Design;	(b) (4)	Rectal balloon catheter inflated with air; connected to water bag that instills water into lower colon
Performance;	(b) (4)	Testing of system and components including leakage, pressure, flow, wear; biocompatibility evaluation and testing, shelf life testing to support 1 year shelf life
Materials	(b) (4)	PVC catheter Chloroprene balloon
Bowel retention	(b) (4)	Rectal balloon catheter
Bowel irrigation	(b) (4)	Irrigation fluid bag and pump provided
Stool sampling	(b) (4)	No stool sampling
Enema/ medication administration	(b) (4)	Allows for irrigation; No medication administration
Drainage/collection	(b) (4)	No drainage/collection
Single use	(b) (4)	Yes (rectal balloon catheter)
Duration of use/insertion	(b) (4)	<1 hour/intermittent every second day or daily as prescribed by physician
Fluid for irrigation	(b) (4)	Water or isotonic saline
Latex free	(b) (4)	Yes
Placement of catheter	(b) (4)	Rectum-Balloon inflated above sphincter
Balloon is inflated with	(b) (4)	Air
Biocompatibility per ISO 10993	(b) (4)	Meets Standard
Sterility	(b) (4)	Provided non-sterile

B. Substantial Equivalence Conclusion

Based upon the device comparisons, the PAI System s substantially equivalent in performance, indications, design, and materials to the Coloplast Peristeen™ Anal Irrigation (PAI) system cleared on November 23, 2009 under premarket notification 510(k) number K083770.

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12. PROPOSED LABELING

A. Draft Labeling – Peristeen™ Anal Irrigation (PAI) System for expanded indications for use

The draft caregiver and patient labeling/user guides, as mentioned in Section 11 above, is summarized below. This draft labeling can be found in **Attachment C**.

	Document Name
1.	Caregiver Brochure
2.	Health Care Notes Form
3.	Anatomy Notes Sheet (Pictorial of PAI in Use)
4.	Product Brochure
5.	User Guide
6.	Quick Reference Guide
7.	Simplified Quick Reference Guide
8.	Physician Instructions for Use

Draft retail box and device labeling is provided in the figures below.

Figure 12. PAI System Box Label



Figure 13. PAI Accessory Unit Box Label

(b) (4)



Figure 14: PAI Rectal Balloon Catheter Set Box Label

(b) (4)



Figure 15: PAI Rectal Balloon Catheter Pouch Labels

(b) (4)



Figure 16: PAI Extra Tube Box Label

(b) (4)



Figure 17: PAI Extra Straps Pouch Label

(b) (4)



B. Predicate Labeling (IFU)

The labeling submitted in the original Peristeen 510k (Predicate Labeling) can be found in **Attachment D**.

13. STERILIZATION AND SHELF LIFE

A. Sterilization

The Peristeen™ Anal Irrigation (PAI) System components are provided non-sterile; this is appropriate based on the intended use. The Rectal Balloon Catheter is packaged in a (b) (4) pouch; the other components are supplied in (b) (4) pouches and cardboard shelf boxes. The PAI System comes with a (b) (4) storage case that holds all System components and protects them from exposure to direct sunlight. The Rectal Balloon Catheter is intended for single use only. Instructions for cleaning the other system components are provided in the Quick Reference Guide and the User Guide (See **Section 12, Labeling**).

B. Shelf Life

Testing to Support Shelf Life

A (b) (4) shelf-life was granted for the Coloplast Peristeen™ Anal Irrigation (PAI) System in the original 510(k) based upon successful completion of real-time and accelerated aging testing. A (b) (4) shelf life on the small size rectal catheter is proposed based upon successful completion of real time aged testing out to (b) (4) presented in *Section 17, Performance Testing*. Shelf life may be extended based on acceptable data from additional testing using the same criteria.

14. BIOCOMPATIBILITY

A. Biocompatibility Testing Summary

Biocompatibility testing on the Peristeen™ Anal Irrigation (PAI) System was provided in the original 510(k) K083770.

The small size Peristeen™ Anal Irrigation Catheter is manufactured with identical materials and manufacturing processes therefore the testing provided in the original 510(k) is applicable to the smaller size catheter.

15. SOFTWARE

This section is not applicable to this 510(k) application; the device does not incorporate software.

16. ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

This section is not applicable to this 510(k) application; the device does not incorporate electrical components.

17. PERFORMANCE TESTING – BENCH

Functional, reliability, and stability/shelf life testing of the Peristeen™ Anal Irrigation (PAI) System subassemblies was conducted to assess the device's conformance to the established specifications and to support repeated use and shelf life. This testing was provided in the original Peristeen™ 510(k) K083770.

Additional performance testing was performed on the smaller size Peristeen™ Anal Irrigation catheter. A similar battery of tests performed for the rectal catheter in the original Peristeen™ Anal Irrigation System 510(k) were also conducted on the smaller size catheter and are included in this submission. This testing is summarized below.

A. Peristeen™ Anal Irrigation (PAI) System Small Catheter Testing

(b) (4)



3) Test Results-Rectal Balloon Catheter

Table 7. PAI System Rectal Balloon Catheter Functional Testing

(b) (4)



18. PERFORMANCE TESTING – ANIMAL

This section does not apply as there were no animal studies conducted to support substantial equivalence of this device other than biocompatibility testing provided in the original Peristeen™ 510(k).

19. PERFORMANCE TESTING – CLINICAL

There were no human clinical trials conducted to support substantial equivalence of this device.

ATTACHMENTS

Attachment A: Standards Data Report Forms
Attachment B: Engineering Drawing for Small Catheter
Attachment C: Draft PAI Labeling
Attachment D: Predicate (Previously Submitted) PAI Labeling

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Required biocompatibility training and toxicological profile for evaluation of medical devices (G95-1)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: tests for in vitro cytotoxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

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Is there an FDA guidance⁶ that is associated with this standard?
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Title of guidance: Required biocompatibility training and toxicological profile for evaluation of medical devices (G95-1)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 10993-6:2007 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³: # 2-120

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Title of guidance: Required biocompatibility training and toxicological profile for evaluation of medical devices (G95-1)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 10993-10:2002 AC 2006 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed type hypersensitivity

Please answer the following questions Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 2-152

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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Title of guidance: Required biocompatibility training and toxicological profile for evaluation of medical devices (G95-1)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 10993-11:2006 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 2-120

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 10993-12:2007 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 2-135

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Traditional Special Abbreviated

STANDARD TITLE¹

EN 980 (2008): Graphical symbols for use in the labeling of medical devices

Please answer the following questions

Yes No

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FDA Recognition number³ #

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⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
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DESCRIPTION		
JUSTIFICATION		
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Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

EN 1041 (2008): Information supplied by the manufacturer with medical devices

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 14971:2007 Medical devices - Application of risk management to medical devices.

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprag.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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SUMMARY REPORT TABLE**

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Rockville, MD 20850

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Peristeen Anal Irrigation Caregiver Guide

Young people (children and adolescents) or adults with impaired abilities who are born with or develop bowel problems can experience a variety of different issues. They may have no feeling in the rectum so they are unable to control their bowel movements. They may have normal sensations; however, the muscles that move waste through the bowels do not work, leading to chronic constipation. The concern about having an accident can have a major impact on quality of life.

Peristeen Anal Irrigation is one treatment to help empty the bowel reliably and conveniently, preventing bowel accidents and/or chronic constipation.

Coloplast has created this information package to provide you with information about the Peristeen Anal Irrigation (PAI) System. The package contains a complete description of the PAI System, instructions for use, a quick reference guide, as well as a few tools to note specific instructions for your patient.

It is Coloplast's hope that with training and consultation with your patient's physician, you can use the information in this package to utilize the PAI system most effectively. If you have additional concerns or need more information please contact your physician or health care provider.

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.



Figure 1: Peristeen Anal Irrigation (PAI) System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	STRAP	The STRAPS wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

PAI System Rectal Catheter

The PAI rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2**.



Figure 2: Un-inflated, Inflated, and Simulated Model PAI Rectal Balloon Catheter

PAI System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:



Figure 3: PAI Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

PAI System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.



Figure 4: PAI Lid/Connector/Tubing Figure , PAI Lid/Suction Tube Assembly

PAI System Water Bag

The polyethylene bag is designed to hold water or isotonic saline solution for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

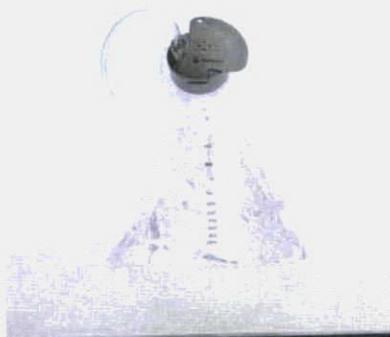


Figure 5: PAI Water Bag & Tubing

PAI System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the PAI System; the storage case also protects the components from exposure to direct sunlight.

The PAI Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Quick Reference Guide and the User Guide). The catheter is intended for single use only.

The other components of the PAI system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.



Figure 6: PAI System Storage Case, Catheter package

This Caregiver Information Package includes the following:

	Name	Purpose	Intended for...
1.	Health Care Notes form	Physician writes down specific notes for your patient	You and your patient to remind you of key information related to your PAI system
2.	Pictorial of PAI in use	You or your physician write down notes or questions; use the anatomical drawings to help explain how the system works or to remind you of tips and tricks for system usage	You and your physician; you and your patient
3.	Product brochure	Pictures of system and ordering information	You
4.	User Guide	Complete operating instructions with troubleshooting guide, contraindications and warnings	Your health care provider, you, and your patient (as applicable)
5.	Quick Reference Guide	Step-by-step Instructions for using system	You and your patient
6.	Simplified Quick Reference Guide	Step-by-step instructions for using system to be used by a younger patient or adult with cognitive limitations	You and your patient

Coloplast A/S is a Danish company founded in 1957 with more than 7,000 employees. Coloplast A/S has sales and subsidiary companies worldwide.

Coloplast develops, manufactures and markets medical devices and services to improve quality of life of the people who depend on these devices:

- Ostomy products
- Continence care products for people with bladder and bowel management problems
- Urology products used in surgery procedures of the urinary system and male reproductive system
- Wound dressings for the treatment of chronic wounds
- Skin care products for prevention and treatment of conditions from simple irritation to fungal infections and skin breakdown

Manufactured by:
Coloplast A/S
Holtedam 1
DK-3050 Humlebæk

Distributed by:
Coloplast Corp.
1601 West River Road North
Minneapolis, Minnesota 55411

www.coloplast.com

Health care notes

Hospital: _____

Tel.: _____ Office hours: _____

Nurse's/doctor's name: _____

Anal irrigation to be performed:

Every day Every other day Other: _____

I need to pump _____ times to inflate the balloon. I need to use _____ ml of water

The anal irrigation set is available to order from _____



Product code	Illustration	Item	Content	Quantity	Frequency
29121		System	1 control unit 2 rectal catheters 1 bag 2 straps		
29122		Accessory unit	15 rectal catheters 1 bag		
29123		Rectal catheters	10 rectal catheters		
29124		Strap	1 set of 2 straps		
29125		Tube	2 tubes with blue connectors		



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DK-3050 Humlebæk
Denmark

Peristeen Expanded Indications 510k

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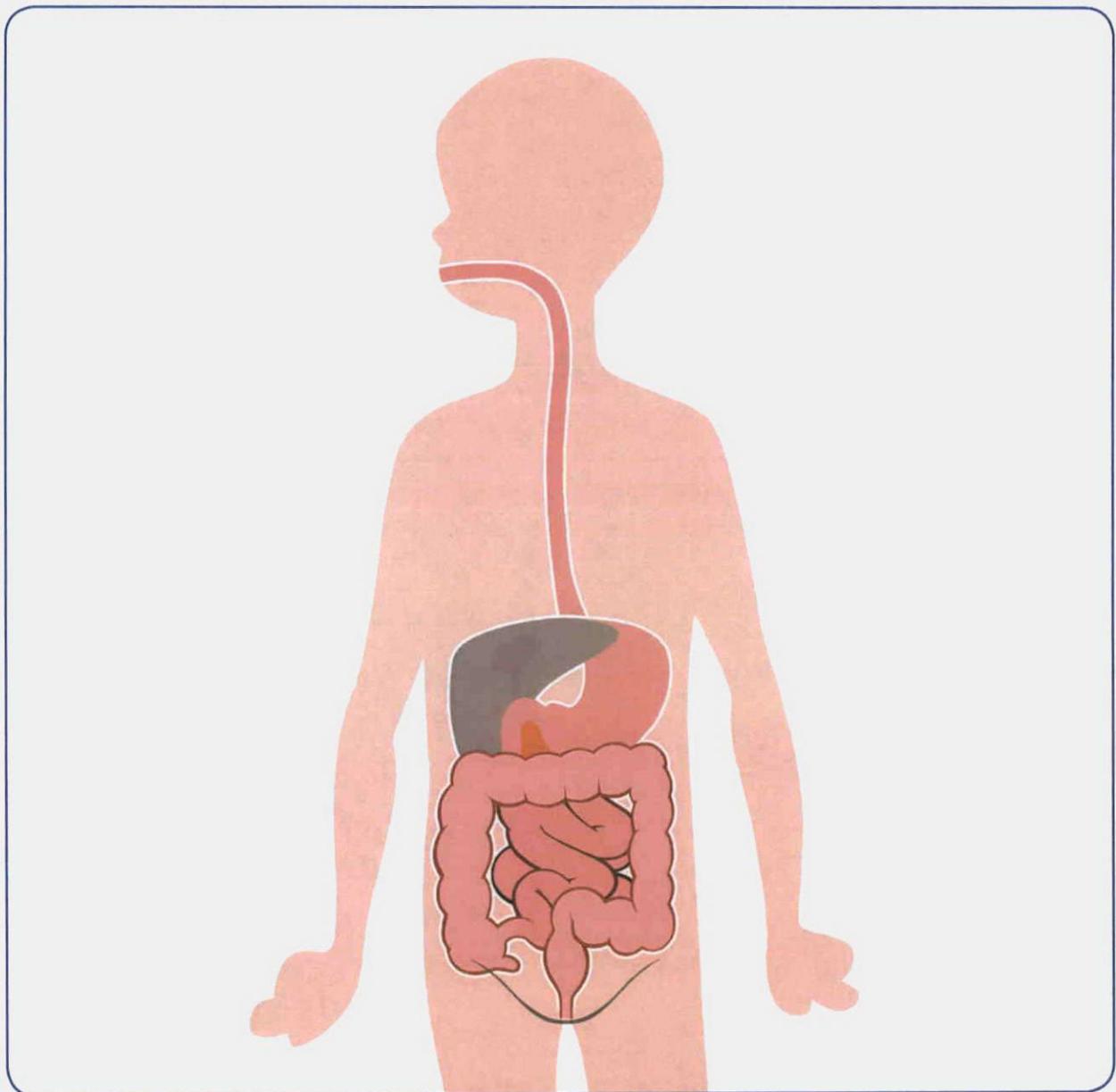
135

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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 Manufacturer: Coloplast A/S, DK-3050 Humlebæk, Denmark.

Peristeen Anal Irrigation

Four horizontal lines for handwritten notes, each with a small blue icon on the left side.



Peristeen

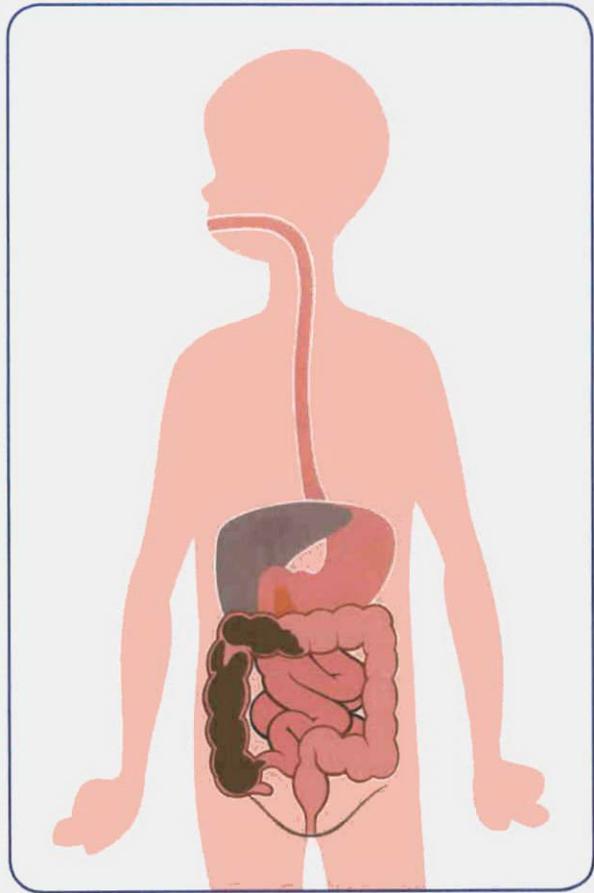
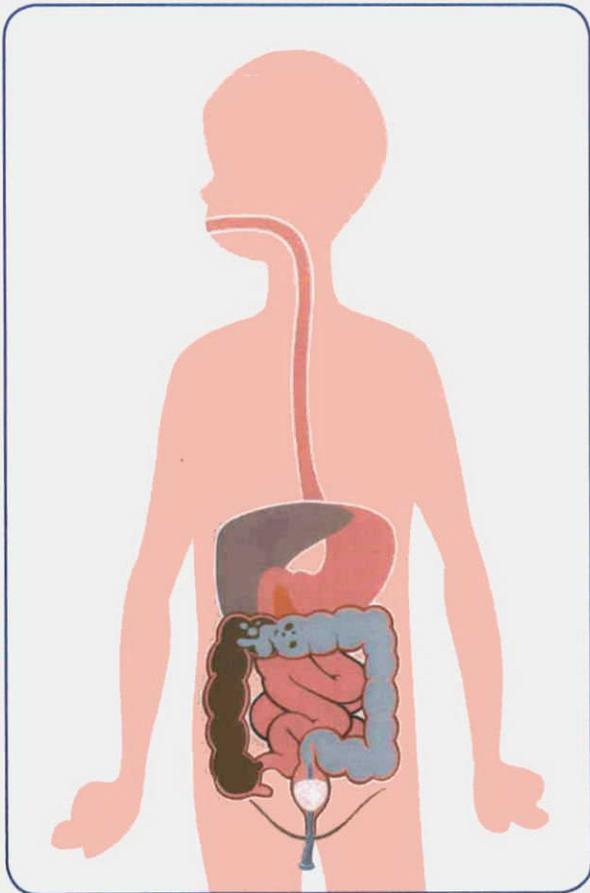
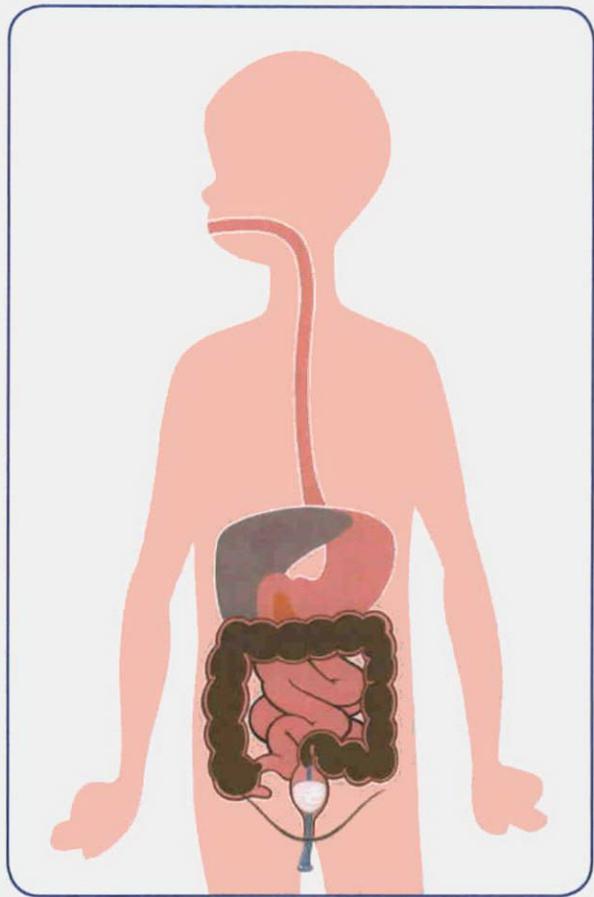
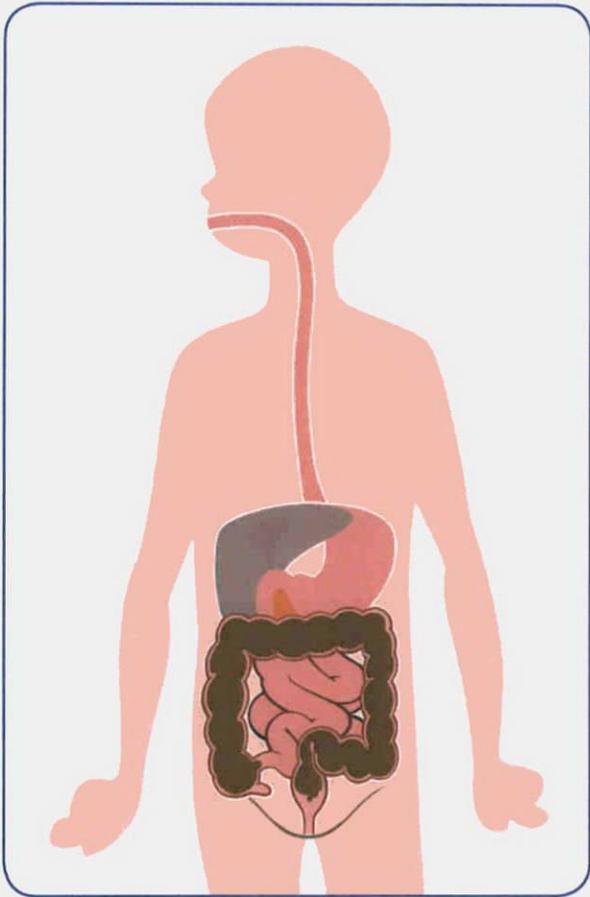


Peristeen Expanded Indications 510k

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Peristeen Expanded Indications 510k

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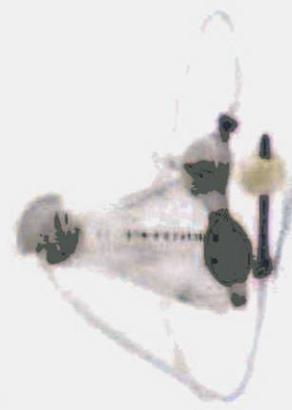
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Ordering information

Product code	
29121	System 1 control unit with tubes 2 rectal catheters 1 water bag 1 set of straps 1 toilet bag
29122	Accessory unit 15 rectal catheters 1 water bag
29123	Rectal catheter 10 rectal catheters
29124	Strap 1 set of straps
29125	Tube 2 tubes with blue connectors

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Peristeen
Anal Irrigation
Information

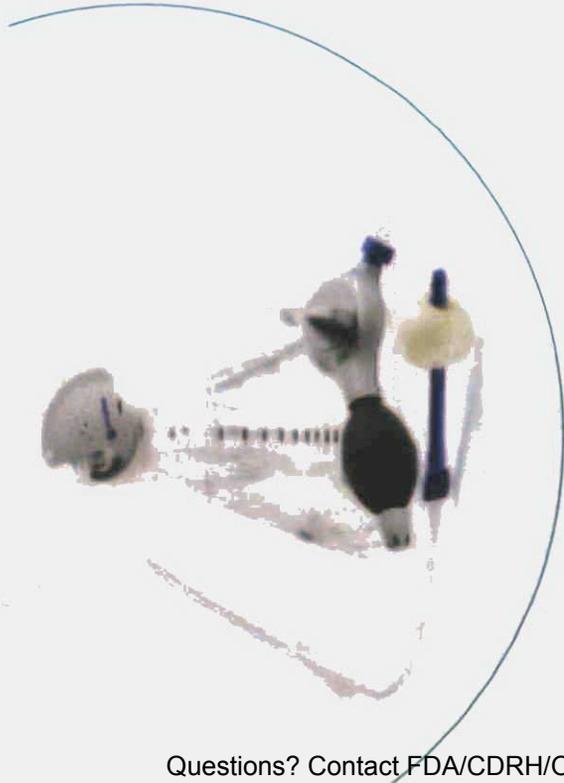
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Peristeen Expanded Indications 510k



Welcome to **Peristeen** Anal Irrigation

Peristeen Anal Irrigation (also known as transanal irrigation or rectal irrigation) is a unique way of emptying the bowel and is used to prevent incontinence, constipation or to reduce the amount of time spent on bowel management.

Peristeen Anal Irrigation is an innovative irrigation system from Coloplast. **Peristeen** has been developed for patients who suffer from incontinence or chronic constipation and for patients who have to spend a long time on bowel management procedures due to neurogenic bowel dysfunction.

The system has been specially designed to make it portable and easy to use. This offers independence and a sense of confidence to the user.

How does it work?

Peristeen Anal Irrigation is a technique for emptying the bowel by introducing warm tap water (36–38°C) into the rectum using a catheter.

The user sits on the toilet while the water is pumped into the rectum. The water is then emptied from the bowel along with the stools, into the toilet.

How does a person start?

Individuals must be assessed by a qualified health care professional to ensure this method is appropriate for them. They can then be taught the procedure to ensure the best results.



PERISTEEN™ ANAL IRRIGATION USER GUIDE

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I. DESCRIPTIVE INFORMATION

Non Sterile. Single Patient Use Only. Latex Free.

Caution: Federal (USA) law restricts the use of this device to sale by or on the order of a physician.

A. Indications for Use

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

B. Description of the device:

Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.



Figure 1: Peristeen Anal Irrigation (PAI) System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (every other day for 1 month)
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7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

PAI System Rectal Catheter

The PAI rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2**.



Figure 2: Un-inflated, Inflated, and Simulated Model PAI Rectal Balloon Catheter

PAI System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:



Figure 3: PAI Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

PAI System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.



Figure 4: PAI Lid/Connector/Tubing Figure , PAI Lid/Suction Tube Assembly

PAI System Water Bag

The polyethylene bag is designed to hold water or isotonic saline solution for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

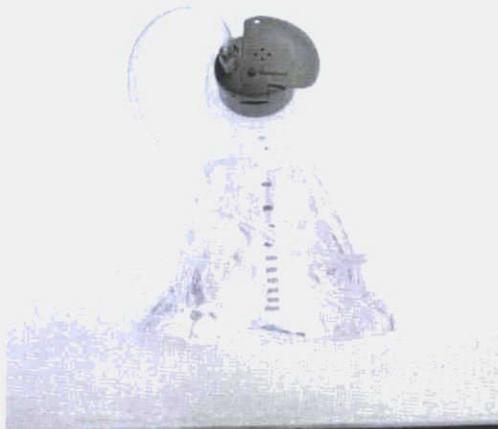


Figure 5: PAI Water Bag & Tubing

PAI System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the PAI System; the storage case also protects the components from exposure to direct sunlight.

The PAI Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Quick Reference Guide and the User Guide). The catheter is intended for single use only.

The other components of the PAI system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.



Figure 6: PAI System Storage Case, Catheter package

C. When the device should not be used (contraindications):

Peristeen Anal Irrigation must not be used in the following situations:

- During the spinal shock phase
- Known obstruction of the large bowel
- Acute inflammatory bowel disease
- Diverticulitis
- Pregnancy if t and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy.

D. Warnings and Precautions

WARNINGS:

<p style="text-align: center;">WARNING</p> <p style="text-align: center;">Contact your doctor or nurse immediately if you notice during or after anal irrigation:</p> <p style="text-align: center;">Severe anal bleeding Severe and sustained abdominal pain or back pain, with or without fever</p> <p style="text-align: center;">Anal irrigation should always be carried out with care. Although bowel perforation is extremely rare, it is a potential complication to anal irrigation and will require immediate admission to hospital.</p>

PRECAUTIONS:

Always consult your health care professional before starting up the irrigation procedure. When anal irrigation is initiated, special caution must be shown if you:

- Suffer from an inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Have any anorectal condition which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids
- Have had irradiation therapy in the abdominal or pelvic region
- Have had recent abdominal or anal surgery
- Suffer from autonomic dysreflexia
- Have a regular intake of anticoagulant medication with vitamin K antagonists, as normally small and harmless rectal bleedings may be difficult to stop
- Are pregnant and have previous experience with anal irrigation, please consult your doctor to carefully evaluate if you may continue irrigating.
- Have diarrhea, as the cause for diarrhea must be identified.
- Use rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.

If any of the above conditions apply to you, anal irrigation must only be initiated after careful consideration and instruction by your health care professional.

Do not use soap or any other cleanser to clean the inside of the system and do not run a soap solution or cleanser through the system. The soap or cleanser or soap may react with the materials of the system and may cause irritation.

II. OPERATING INFORMATION

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

-  = **RESTING/DEVICE STORAGE**
-  = **INFLATE BALLOON**
-  = **PUMP WATER**
-  = **DEFLATE BALLOON/RELEASE AIR**

PREPARATION

Anal irrigation is usually done while sitting on the toilet.



1

Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with lukewarm water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID by clicking it in place.



2

Put the TUBE with the grey connector into the LID. Lock the CONNECTOR by turning it one-half turn clockwise.



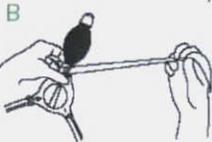
3

Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE with the blue CONNECTOR into the RECTAL CATHETER. Lock the CONNECTOR by turning it one-half turn clockwise.



4

Attach the catheter package to a wall or door next to the toilet by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



5

Attach the CONTROL UNIT and attached TUBES to the thigh with the STRAP:

A. Put the strap around the base of the pump

B. Slide the strap through the buckle and pull tight

C. Adjust the strap to fit comfortably around your thigh



6

Turn the knob on the CONTROL UNIT to the water symbol . Squeeze the pump 2 to 3 times; this will fill the catheter package with water. Turn the knob on the control unit to the balloon symbol  to prevent any more water from going into the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put it into the rectum.

INSERTING THE RECTAL CATHETER



7

Make sure the knob on the control unit is pointing to the balloon symbol . Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly.

When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump. For an average size adult it is approximately 3 to 4 times. For smaller individuals and adolescents it will be less. Your doctor or nurse will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol  to deflate it.

Turn the knob to the balloon symbol  if you want to inflate the balloon again.

IRRIGATION (PUMPING WATER INTO COLON)



8

Turn the knob on the control unit counter-clockwise to the water symbol . Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use, and they will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If water leaks past the BALLOON, you can inflate the balloon more by turning

the knob on the control unit clockwise to the balloon symbol  and squeezing the PUMP one more time. Turn the knob counter-clockwise to the water symbol  to continue irrigation.

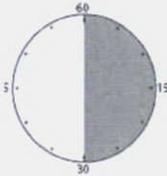
REMOVING THE RECTAL CATHETER

9

To deflate the balloon, turn the knob on the control unit counter-clockwise to the

air symbol 

Often the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.

EMPTYING THE BOWELS

10

Within a few minutes, the colon will start to empty into the toilet.

If nothing happens, you can push on the lower part of your abdomen, cough, or move the upper part of your body to help encourage the emptying process.

The amount of time it takes for to empty the bowels will be different for each person, but usually it will take about thirty minutes. After doing the irrigation a few times, you will become more comfortable and have a better idea of how long it will take.

STORAGE AND MAINTENANCE OF SYSTEM

11

1. Unlock the connectors from the lid and the catheter.
2. Discard the single use catheter.
3. Open the flip-top on the LID and pour excess water out of the bag.
4. Rinse the outer surface of all the parts with warm water and a small amount of mild soap. Rinse all the soap off. So not run soap solution or cleanser through the system.
5. Set the knob on the CONTROL UNIT to the Resting Symbol 
6. Allow the parts to dry and pack them loosely in the nylon bag
7. Make sure that the tubes with connectors and the tube in the water bag do not get kinked in the storage case.
8. Do not keep the parts or the storage case in direct sunlight
9. Store the case in a place where the temperature is between 35° and 77° F.

III. TROUBLESHOOTING INFORMATION:**Who can perform anal irrigation?**

Anal irrigation is for people who suffer from fecal incontinence, chronic constipation or have to spend a long time on bowel management procedures. You must be examined by a health care professional and receive professional instruction before starting the irrigation. After receiving instruction and training, the majority will be able to perform anal irrigation on their own.

How often should I irrigate?

Anal irrigation may be performed every other day or as recommended by your doctor or nurse.

How long does the irrigation take?

The time used for irrigation is individual. When using anal irrigation you approximately use 30-45 minutes on bowel management daily.

How much air and water should I use?

The required amount of air to pump into the balloon and water to pump into the rectum is individual and your doctor or nurse will tell you how much to use. They will write the amounts of air and water to pump on your Health Care Notes form. You should not increase the amount of water uncritically since the bowel may retain it and release it over time in small amounts.

Why is the temperature of the water important?

The water must have body temperature (approx. 36-38°C). If it is too hot, it may harm the delicate lining of the rectum; if it is too cold, cramps may occur.

How quickly should I pump the water?

If the water is pumped too quickly into the bowel, you may experience discomfort such as sweating, dizziness and stomach ache. We recommend approximately one pump per second or more slowly as recommended by your doctor or nurse.

Can I stop the irrigation if I want a break?

In case of discomfort and you feel the need for a break, stop the water flow and wait until it subsides. When you are ready, resume pumping. If the discomfort does not disappear, contact your health care professional immediately.

What should I do if the irrigation water and/or feces do not come out (no emptying)?

You may be heavily constipated and a clean-out of the bowel is necessary. Contact your health care professional for assistance.

The reason could also be that you have not had enough to drink and are dehydrated, so the bowel has absorbed the irrigation water. Try irrigating once more using the normal amount of water and remember to drink more water. If another attempt at irrigation does not help, contact your doctor or nurse.

What should I do if water seeps into the toilet?

If water seeps past the balloon and into the toilet there is no need to change the irrigation procedure if the irrigation still works.

You can stop the pumping of water, wait for a while and fill some more water into the bowel. Make sure the catheter is placed in the correct position right above the sphincters. If water still seeps into the toilet, you can fill more air into the balloon and resume pumping water into the bowel.

What if I experience leakages after irrigation?

If you experience leakages after irrigation you might have used too much water. Make sure to use the amount of water recommended by your health care professional. You can also try to stay a little longer at the toilet. Contact your health care professional if you continue experiencing leakages.

What if I experience defecation between irrigations?

If you experience defecation between irrigations, the cause may be insufficient emptying after irrigation owing to constipation or hard stools. Contact your health care professional for different solutions, e.g. frequency of irrigation, amount of water and/or medication.

How should I store my Peristeen Anal Irrigation system?

The system and the rectal catheters should be stored at a temperature of between 2° and 25° Celsius and away from direct sunlight. Ensure the tubing is not kinked when stored.

How do I clean my Peristeen Anal Irrigation system?

The tube can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. You may choose to change the tube with the blue connectors more frequently if you desire. The surface of all the components (excluding the single use catheter) can be washed in mild soapy water, and rinsed thoroughly. Remember to keep the Control Unit knob in the Resting/Storage position when you are not using the PAI System.

What do I do when travelling?

The bowels absorb water, so when travelling in countries where it is not safe to drink the water, care should be taken to use distilled water or isotonic saline for irrigation.

Flatulence

Anal irrigation empties the bowel of feces and air. Experience shows that the release of gas from the rectum will be considerably reduced once irrigation is practiced regularly.

Adaptation period

An adaptation period of approx. 10 days may be expected. The procedure must be individually adjusted together with your health care professional regarding the amount of air to pump into the balloon, water to pump into the rectum, as well as recommended frequency of irrigating.

IV. DISEASE AND SELF-CARE INFORMATION**The bowel system**

The bowels are part of the digestive system, the primary function of which is to break down the food we eat. The food passes through the stomach and the small bowel (small intestine), where it is broken down and useful components are absorbed into the body. What is left continues to the large bowel (colon and rectum).

The large bowel receives a liquid mixture of digested food and juices from the small bowel. The main function of the large bowel is to absorb water and salts and to store the waste products (feces) before they are transported to the rectum. The large bowel in an average size adult receives about 1,500 ml small bowel content a day and converts this into 150-200 ml of fecal matter. The bowel absorbs the remainder.

On average it takes 1-3 days for food to pass through the entire digestive tract, though this can vary greatly from person to person. The time it takes for food to pass through the digestive system is called the transit time.

The large bowel has two muscles, which make peristaltic movements when contracting. With the aid of peristalsis, the feces are moved onward from the large bowel into the rectum. Peristalsis is affected by a number of factors such as diet, posture and exercise.

Peristalsis is a wavelike muscular contraction that transports digested food through the intestines to the rectum. The two colon muscles; one longitudinal muscle along the colon and one circular muscle around the colon make the contraction.

There are two sphincters in the rectum controlling the defecation process. The internal sphincter is an extension of the colon musculature and is controlled by reflex, i.e. we cannot consciously control it. The external sphincter can be controlled consciously by the brain.

There are two sphincters in the rectum affecting the evacuation – the internal and the external sphincter. The function of the anal sphincters is to maintain continence and prevent leakage.

Once the rectum receives feces from the large bowel, it is registered in a set of nerve endings. These nerve endings send a signal to the brain that the rectum is full and that it is time to go to the toilet. At this point you can choose to wait for a more suitable time. If you wait too long however, the urge will disappear and the feces will be forced back into the large bowel.

When you decide to go to the toilet, you activate the defecation reflex by relaxing the external sphincter. Typically, the presence of approx. 150 ml of feces will result in a reflex relaxation of the internal sphincter. The external sphincter relaxes and the feces are expelled with the aid of gravity and muscle contractions in the rectum.

Causes of bowel dysfunction

There are many causes of bowel dysfunction and reasons for initiating anal irrigation. The most frequent reasons are mentioned below. In order to receive appropriate and effective treatment, a diagnosis from your health care professional is essential.

Neurological disorders

The defecation mechanism, i.e. the nerves that send a signal to your brain telling you when you need to go to the toilet, may be impaired due to a medical condition or disease, such as: a spinal cord injury, spina bifida, multiple sclerosis, Parkinson's disease, apoplexia, Alzheimer's disease or brain tumors.

Sensory disorders

The sensory function of the rectal mucosa may be impaired. This can occur after surgery, as a result of colitis, compaction, rectal prolapse or as a result of surgical correction of congenital absence or abnormality of the anal opening (anal atresia).

Muscular disorders

Damage to the sphincter muscle due to external injuries, tumours or their surgical removal, perineal tear from a vaginal birth, straining from constipation or rectal prolapse.

Psychological/psychiatric disorders

Caused by psychoses, depression, depersonalisation or role conflicts (in children and adults) as well as a result of sexual abuse.

Reduced tissue elasticity

Frequent in old age or after multiple births.

The effect of food and exercise

Food plays an important role in managing your bowels. It is important to find the right balance of stool consistency to avoid either constipation or liquid stools, which will increase the risk of fecal incontinence.

Dietary fiber generally soften stool and reduce the passage time. Too much fiber, however, can worsen symptoms of bloating and stomach pain.

It is worth noting that some food and liquids such as coffee and artificial sweeteners have a mild laxative effect. It is always important to drink plenty of fluids.

Finally physical exercise has a mechanical effect on the bowels, which improves bowel movement.

Constipation

Constipation and fecal incontinence are both symptoms of bowel dysfunction and you often experience both fecal incontinence and constipation at the same time.

Bowel function and defecation habits vary from one person to another. Some have daily bowel movements, others every second or third day. Owing to the extensive variation in the normal defecation pattern, it is difficult to offer a clear definition of constipation.

Constipation occurs when the bowel's movements are reduced. This prolongs transit time in the large bowel and more fluid is absorbed from the feces than with normal transit time, resulting in hard and lumpy stools. This will often result in general discomfort and in some cases disturbed bladder-emptying patterns.

Constipation is generally perceived as:

- Fewer than three defecations a week.
- Prolonged lavatory visits with straining and soreness in the rectum.
- Hard, sparse and lumpy stools.

Because of this natural variation, changes in digestive and bowel movement patterns will be perceived differently depending on what one is accustomed to.

Fecal incontinence

Fecal incontinence can be defined as lack of control of bowel evacuation resulting in involuntary defecation. Anal incontinence also includes incontinence for air (flatus).

In many cases, fecal incontinence occurs as the result of insufficient sensation in the rectal region. In other words, you do not register the urge to defecate. At the same time, control of the internal and external sphincters may be entirely or partially lacking.

Chronic constipation, in which the rectum wall is severely over-stretched, may result in fecal incontinence as the normal defecation reflexes are deactivated by the chronic stretch. At the same time, fluid passes around the fecal mass in the bowel. Often the internal sphincter has reduced function because it is expanded and liquid stools mixed with dry and hard stool may pass.

V. USER ASSISTANCE INFORMATION:

Coloplast in brief

Coloplast A/S is a Danish company founded in 1957 with more than 7,000 employees.

Coloplast develops, manufactures and markets medical devices and services to improve quality of life of the people who depend on these devices:

- Ostomy products for people with a stoma
- Continence care products for people with bladder and bowel management problems
- Urology products used in surgery procedures of the urinary system and male reproductive system
- Wound dressings for the treatment of chronic wounds
- Skin care products for prevention and treatment of conditions from simple irritation to fungal infections and skin breakdown

Coloplast A/S has sales and subsidiary companies worldwide.

Coloplast A/S
Holtedam I
DK-3050 Humlebæk
www.coloplast.com

Coloplast accepts no liability for injury or loss that may arise if this product is not used entirely according to the company's recommendations.

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Manufacturer: Coloplast A/S, DK-3050 Humlebæk, Denmark.

QUICK REFERENCE GUIDE FOR THE USER PERISTEEN ANAL IRRIGATION SYSTEM

Non-Sterile. Single Patient Use Only. Latex Free.

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Intended Use:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

For more information on the Peristeen Anal Irrigation System, including complete user instructions, intended use, contra-indications, and precautions, consult the **Peristeen Anal Irrigation User Guide**.

To use this system safely and effectively, you should get training from your doctor or home health care nurse before using it.

The first time you use this system, you should do so when your doctor or health care nurse is present.

PERISTEEN ANAL IRRIGATION - DESCRIPTION

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	STRAP	The STRAPS wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

-  = **RESTING/DEVICE STORAGE**
-  = **INFLATE BALLOON**
-  = **PUMP WATER**
-  = **DEFLATE BALLOON/RELEASE AIR**

PREPARATION

Anal irrigation is usually done while sitting on the toilet.



1

Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with lukewarm water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID by clicking it in place.



2

Put the TUBE with the grey connector into the LID. Lock the CONNECTOR by turning it one-half turn clockwise.



3

Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE with the blue CONNECTOR into the RECTAL CATHETER. Lock the CONNECTOR by turning it one-half turn clockwise.



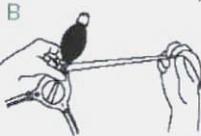
4

Attach the catheter package to a wall or door next to the toilet by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



Attach the CONTROL UNIT and attached TUBES to the thigh with the STRAP:

A. Put the strap around the base of the pump



5

B. Slide the strap through the buckle and pull tight



C. Adjust the strap to fit comfortably around your thigh



6

Turn the knob on the CONTROL UNIT to the water symbol . Squeeze the pump 2 to 3 times; this will fill the catheter package with water. Turn the knob on the control unit to the balloon symbol  to prevent any more water from going into the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put it into the rectum.

INSERTING THE RECTAL CATHETER



7

Make sure the knob on the control unit is pointing to the balloon symbol . Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly.

When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump. For an average size adult it is approximately 3 to 4 times. For smaller individuals and adolescents it will be less. Your doctor or nurse will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol  to deflate it.

Turn the knob to the balloon symbol  if you want to inflate the balloon again.

IRRIGATION (PUMPING WATER INTO COLON)



8

Turn the knob on the control unit counter-clockwise to the water symbol . Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use, and they will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If water leaks past the BALLOON, you can inflate the balloon more by turning the knob on the control unit clockwise to the balloon symbol  and squeezing the PUMP one more time. Turn the knob counter-clockwise to the water symbol  to continue irrigation.

REMOVING THE RECTAL CATHETER

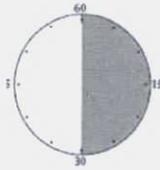


9

To deflate the balloon, turn the knob on the control unit counter-clockwise to the air symbol . Often the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.

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EMPTYING THE BOWELS



10

Within a few minutes, the colon will start to empty into the toilet. If nothing happens, you can push on the lower part of your abdomen, cough, or move the upper part of your body to help encourage the emptying process. The amount of time it takes for to empty the bowels will be different for each person, but usually it will take about thirty minutes. After doing the irrigation a few times, you will become more comfortable and have a better idea of how long it will take.

STORAGE AND MAINTENANCE OF SYSTEM



11

1. Unlock the connectors from the lid and the catheter.
2. Discard the single use catheter.
3. Open the flip-top on the LID and pour excess water out of the bag.
4. Rinse the surface of all the parts with warm water and a small amount of mild soap. Rinse all the soap off.
5. Set the knob on the CONTROL UNIT to the Resting Symbol 
6. Allow the parts to dry and pack them loosely in the nylon bag
7. Make sure that the tubes with connectors and the tube in the water bag do not get kinked in the storage case.
8. Do not keep the parts or the storage case in direct sunlight
9. Store the case in a place where the temperature is between 35° and 77° F.

PAI Catalog Numbers

Product	Catalog number	Components
Peristeen Anal Irrigation System	29121	1 Control unit 2 rectal catheters 1 Bag 2 straps
Peristeen Anal Irrigation Accessory Unit	29122	15 rectal catheters 1 Bag
Peristeen Anal Irrigation Rectal Catheter	29123	10 rectal catheters
Peristeen Anal Irrigation Strap	29124	1 set of 2 straps
Peristeen Anal Irrigation Tube	29125	2 tubes with blue connectors
Peristeen Anal Irrigation System	29126	1 Control unit 2 rectal catheters-small 1 Bag 2 straps
Peristeen Anal Irrigation Accessory Unit	29127	15 rectal catheters-small 1 Bag
Peristeen Anal Irrigation Rectal Catheter	29128	10 rectal catheters-small

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PERISTEEN ANAL IRRIGATION SYSTEM SIMPLIFIED QUICK REFERENCE GUIDE

	Part Name	What does it do?	How many times can I use it?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	1 time only
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP blows up or lets the air out of the balloon & makes the water go through the catheter	6 months**
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	6 months**
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	6 months**
5.	WATER BAG	The WATER BAG holds the water for the irrigation	1 month
6.	STRAP	If you want to, you can use the STRAPS to wrap around your leg and hold the CONTROL UNIT and TUBES	6 months**
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	Whenever you need to

** If you irrigate every other day.

If your doctor has you on a different schedule, make sure you write down how many times you should use yours before getting a new one.

Make sure you ask all the questions you have about using the irrigation system before you use it. You should always ask for help from your parent or helper if you need it.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are in the instruction steps and this is what they mean:



= **REST**



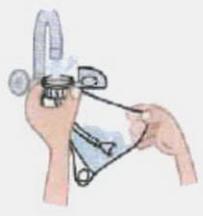
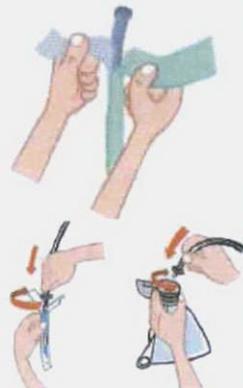
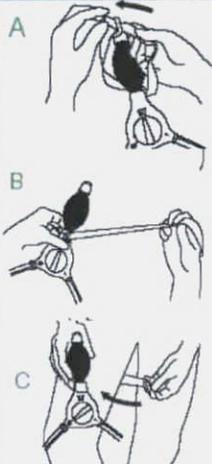
= **BLOW UP BALLOON**



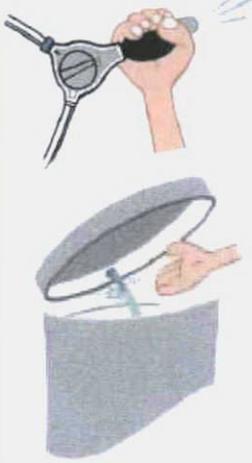
= **PUMP WATER**



= **LET AIR OUT OF BALLOON**

Instructions for the User		
	<p>1.</p>	<p>Gather all the parts for your Peristeen system.</p>
	<p>2.</p>	<p>Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with <u>lukewarm</u> water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID.</p>
	<p>3.</p>	<p>Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE and LID parts together. Grey goes with Grey and Blue goes with Blue.</p>
	<p>4.</p>	<p>Stick the catheter package next to the toilet by taking off the paper circles from the package and putting it on the wall or door.</p>
	<p>5.</p>	<p>If you want to, you can attach the CONTROL UNIT to your leg with the STRAP like this:</p> <p>A. Put the strap around the bottom of the pump B. Slide the strap through the buckle and pull tight C. Put the strap around your leg so it stays put and is comfortable</p>

	<p>6.</p>	<p>Turn the knob on the CONTROL UNIT to the water symbol .</p> <p>Squeeze the pump 2 to 3 times; this will fill the catheter package with water. Turn the knob to the balloon symbol . Count to 10 slowly, 3 times. That will make the catheter soft and smooth and it will be easier to put it in.</p>
 	<p>7.</p>	<p>Make sure the knob on the control unit is pointing to the balloon symbol .</p> <p>Put the rectal catheter slowly and carefully into your rectum the way that your doctor or nurse told you to. Then, pump the balloon while you hold the catheter in place.</p> <p>Your doctor or nurse will tell you how much air to pump.</p> <p>Amount of air to pump: _____</p> <p>With the air in the balloon, the catheter should stay in place. If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol  to let air out. Turn the knob to the balloon symbol  if you want to inflate the balloon again.</p>
	<p>8.</p>	<p>Sit on the toilet and then turn the knob to the water symbol . Squeeze the PUMP slowly – about once time per second – until you have pumped in the right amount of water.</p> <p>Your doctor or nurse will tell you how much water to pump in.</p> <p>Amount of air to pump: _____</p> <p>If water leaks past the BALLOON, you can try putting more air in the balloon more by turning the knob to the balloon symbol  and slowing squeezing the PUMP one more time. Turn the knob counter-clockwise to the water symbol  to start irrigating again.</p>

	<p>9.</p>	<p>When you have pumped in the right amount of water, turn the knob to the air symbol . Sometimes the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.</p> <p>Put the catheter back in the package and throw it away.</p>
	<p>10.</p>	<p>Wait for a few minutes and you will start to have a bowel movement. If it doesn't start, you can help by pushing a little on your stomach. Sometimes you will have a result after a little more time passes; about 10 minutes or so.</p>
	<p>11.</p>	<p>Turn the knob to the Resting Symbol , and be sure to wipe with toilet paper.</p> <p>Empty the water bag and wash your hands. You are done irrigating.</p>
	<p>12.</p>	<p>Rinse the outside of all the parts with warm water and a little bit of soap. Rinse all the soap off. Let all the parts dry and put them in the nylon bag. Don't let the tubes get too crowded or bent in the bag. Don't put the case in the sunlight. Keep it in a cool, dry place.</p>

**Peristeen Anal Irrigation
Physician Instructions for Use**

Device Description:

Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.



Figure 1: Peristeen Anal Irrigation (PAI) System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	STRAP	The STRAPS wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

PAI System Rectal Catheter

The PAI rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2**.



Figure 2: Un-inflated, Inflated, and Simulated Model PAI Rectal Balloon Catheter

PAI System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:

- 

Storage
- 

Inflate balloon
- 

Pump water into rectum
- 

Deflate balloon



Figure 3: PAI Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

PAI System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

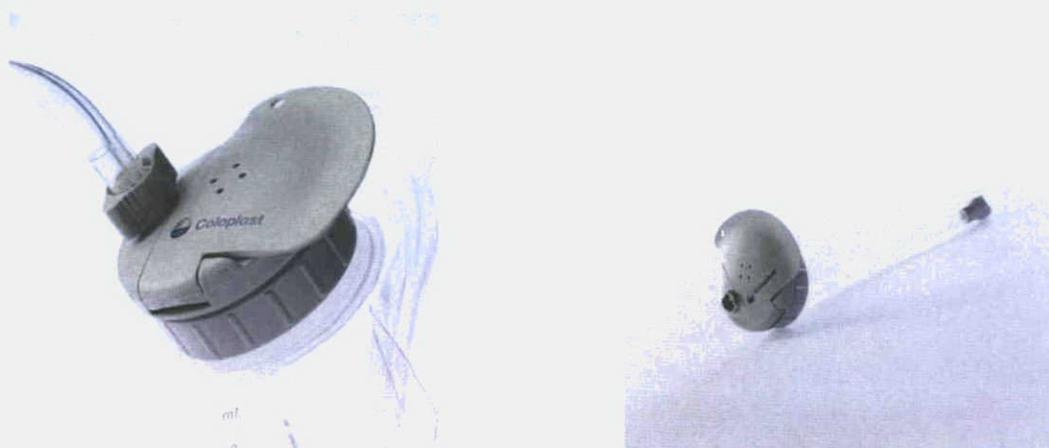


Figure 4: PAI Lid/Connector/Tubing Figure , PAI Lid/Suction Tube Assembly

PAI System Water Bag

The polyethylene bag is designed to hold water or isotonic saline solution for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.



Figure 5: PAI Water Bag & Tubing

PAI System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the PAI System; the storage case also protects the components from exposure to direct sunlight.

The PAI Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Quick Reference Guide and the User Guide). The catheter is intended for single use only.

The other components of the PAI system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.



Figure 6: PAI System Storage Case, Catheter package

Indications:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Contraindications:

Peristeen Anal Irrigation must not be used in the following situations:

- During the spinal shock phase
- Known obstruction of the large bowel
- Acute inflammatory bowel disease
- Diverticulitis
- Pregnancy if t and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy.

Warnings and Precautions:

Warnings:

Make sure that your patients know that they must contact you immediately if they notice during or after anal irrigation:

- Severe anal bleeding
- Severe and sustained abdominal pain or back pain, with or without fever

Anal irrigation should always be carried out with care. Although bowel perforation is extremely rare, it is a potential complication to anal irrigation and will require immediate admission to hospital.

Precautions:

Patients should be advised of contraindications, warnings, precautions, and instructions for use before starting up the irrigation procedure. When anal irrigation is initiated, special caution must be shown for the following patient conditions:

- Inflammatory bowel disease (e.g. Crohn’s disease or ulcerative colitis)
- Any anorectal condition which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids
- Previous irradiation therapy in the abdominal or pelvic region
- Recent abdominal or anal surgery
- Autonomic dysreflexia
- Regular intake of anticoagulant medication with vitamin K antagonists; normally small and harmless rectal bleeding may be difficult to stop
- Patient who are pregnant and who have had previous experience with anal irrigation; evaluate carefully to determine if irrigating is recommended
- Patients with diarrhea; the cause for diarrhea must be identified.
- Use of rectal medication for other diseases as the effect of such medication may be diluted by the anal irrigation.

If any of the above conditions apply, anal irrigation must only be initiated after careful consideration and instruction.

Instructions for Use:

Each patient and/or caregiver should be trained in the following steps and should perform these steps with physician assistance to ensure that all steps are understood and can be accomplished independently.

Operating Information

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

- | | | |
|---|---|------------------------------------|
|  | = | RESTING/DEVICE STORAGE |
|  | = | INFLATE BALLOON |
|  | = | PUMP WATER |
|  | = | DEFLATE BALLOON/RELEASE AIR |

PREPARATION

Anal irrigation is usually done while sitting on the toilet.



1

Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with lukewarm water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID by clicking it in place.



2

Put the TUBE with the grey connector into the LID. Lock the CONNECTOR by turning it one-half turn clockwise.



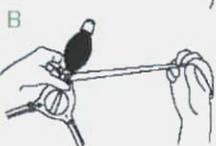
3

Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE with the blue CONNECTOR into the RECTAL CATHETER. Lock the CONNECTOR by turning it one-half turn clockwise.



4

Attach the catheter package to a wall or door next to the toilet by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



5

Attach the CONTROL UNIT and attached TUBES to the thigh with the STRAP:

- A. Put the strap around the base of the pump
- B. Slide the strap through the buckle and pull tight
- C. Adjust the strap to fit comfortably around your thigh



6

Turn the knob on the CONTROL UNIT to the water symbol . Squeeze the pump 2 to 3 times; this will fill the catheter package with water. Turn the knob on the control unit to the balloon symbol  to prevent any more water from going into the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put it into the rectum.

INSERTING THE RECTAL CATHETER



7

Make sure the knob on the control unit is pointing to the balloon symbol . Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly.

When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump. For an average size adult it is approximately 3 to 4 times. For smaller individuals and adolescents it will be less. Your doctor or nurse will write down the number of times to pump on the Health Care Notes form that they gave you.

If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol  to deflate it.

Turn the knob to the balloon symbol  if you want to inflate the balloon again.

IRRIGATION (PUMPING WATER INTO COLON)



8

Turn the knob on the control unit counter-clockwise to the water symbol .

Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use, and they will write down the number of times to pump on the Health Care Notes form that they gave you. If water leaks past the BALLOON, you can inflate the balloon more by turning the knob on the control unit clockwise to the balloon symbol  and squeezing the PUMP one more time. Turn the knob counter-clockwise to the water symbol  to continue irrigation.

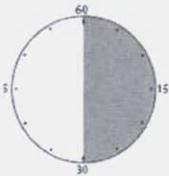
REMOVING THE RECTAL CATHETER



9

To deflate the balloon, turn the knob on the control unit counter-clockwise to the air symbol . Often the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.

EMPTYING THE BOWELS



10

Within a few minutes, the colon will start to empty into the toilet. If nothing happens, you can push on the lower part of your abdomen, cough, or move the upper part of your body to help encourage the emptying process.

The amount of time it takes for to empty the bowels will be different for each person, but usually it will take about thirty minutes. After doing the irrigation a few times, you will become more comfortable and have a better idea of how long it will take.

STORAGE AND MAINTENANCE OF SYSTEM



11

1. Unlock the connectors from the lid and the catheter.
2. Discard the single use catheter.
3. Open the flip-top on the LID and pour excess water out of the bag.
4. Rinse the surface of all the parts with warm water and a small amount of mild soap. Rinse all the soap off.
5. Set the knob on the CONTROL UNIT to the Resting Symbol 
6. Allow the parts to dry and pack them loosely in the nylon bag
7. Make sure that the tubes with connectors and the tube in the water bag do not get kinked in the storage case.
8. Do not keep the parts or the storage case in direct sunlight
9. Store the case in a place where the temperature is between 35° and 77° F.

Physician Notes:

Peristeen Anal Irrigation is designed to be carried out independently or with the assistance of a caregiver in the user's home. It is important that a healthcare professional supervises the first use of Peristeen Anal Irrigation to help the patient use the system safely, optimally and with confidence. Once a patient and/or caregiver has completed irrigation under supervision, they may try the procedure alone. Sometimes more than one training session is required so each patient should be considered individually in terms of their readiness and capability to do so. Subsequent irrigations should be followed-up by consultations in person or by telephone until the patient and/or caregiver has fully adapted the procedure to meet the individual needs and until they are confident to continue the procedure independently. If a patient is heavily and/or chronically constipated, it may be necessary to thoroughly clean out their bowels before starting Peristeen Anal Irrigation.

Physicians should prescribe irrigation based upon a comprehensive evaluation of the nature of the patient's fecal incontinence and the frequency of either constipation or soiling episodes. Generally, Coloplast recommends that anal irrigation be performed every other day; more or less frequent irrigation may be advised depending upon individual patient needs.

Prior to starting Peristeen Anal Irrigation for the first time, please take time to describe the procedure to your patient, answer any questions, and help manage their expectations. To avoid potential disappointment or concern that anal irrigation does not work for them, explain that an initial period of adjustment is perfectly normal and is required to establish their personalised routine. An anal irrigation bowel diary is a good way of keeping track of progress during this period (see table). Peristeen Anal Irrigation can work successfully within a few days but for some individuals it can take 4 to 6 weeks for the treatment to settle down and become routine.

Table 1. Example extract from an anal irrigation bowel diary

Date	Time	Number of balloon pumps	Water volume	Comments
10 June	8.35 am	2 + 1	700 mL	Small amount of water leaked during irrigation. Evacuation after approx 25 minutes
11 June	8.30 am	3	700 mL	No water leakage. Good evacuation
12 June	8.30 am	3	700 mL	No faeces passed. Bowel still empty from yesterday?
13 June	8.40 am	3	700 mL	Good evacuation today after approx. 20 minutes

For new users of Peristeen Anal Irrigation, the irrigation routine should be tailored to meet their individual requirements. It is helpful to ensure the patient understands that, at first, some trial and error will be required to optimise the process and establish their personalised routine. For some people it can take 4 to 6 weeks to adapt the routine. Make sure to complete a **Health Care Notes form** for the patient and/or caregiver to refer to. The **Anatomy Notes** sheets can also be used to make notes and special recommendations on an individual basis.

There are several parameters that can be adjusted if required:

1. Amount of air in the catheter balloon
2. Amount of water used for irrigation
3. Frequency of irrigation

Amount of air in the catheter balloon

The function of the balloon is to hold the catheter in place in the rectum; the degree to which the balloon must be inflated to achieve this (i.e. the number of pumps of air required) depends on the condition of the individual's sphincter and rectum. The average size adult will probably require 3 to 4 pumps of air in the balloon (maximum 5 pumps); for smaller patients, 1 to 2 pumps may be sufficient. Insufficient air can cause water to leak or the catheter to slide out of the rectum. If water leaks during the procedure, patients and/or caregivers should attempt pumping one more time to a maximum of 5 pumps in total. Conversely, too much air can cause the balloon to be expelled. If this happens, repeating the procedure using a little less air should be attempted. The frequency of expulsions often decreases as a patient becomes used to the procedure.

Please use the following notes to guide the amount of air pumped into the balloon for an average size adult patient:

- Intact sphincter reflexes and muscle tone: 1 to 3 pumps
- Flaccid bowels or low sphincter tone: 3 to 5 pumps. If the catheter still slides out of the rectum, it may be supported by holding in place
- Strong anorectal reflexes: The balloon may be expelled after only 1 to 2 pumps; careful insertion and inflation of the balloon is necessary, using less air

For smaller patients, 1 to 2 pumps is recommended.

Amount of water for irrigation

The volume of water required to effectively empty the bowel depends on several factors including the patient's bowel condition, their diet and the frequency of irrigation.

When first using Peristeen Anal Irrigation in adults, a water volume of 500 ml is recommended, and irrigation should be performed daily. This volume can be gradually increased, over the next few weeks, until the individual feels they are completely empty and have no accidents between irrigations. Increases in volume should be done slowly, especially in younger patients and patients with spina bifida. Many adult patients eventually use a volume in the region of 750 ml; however, studies have shown that the amount of water varies from 200 to 1500 ml in adults. Some patients with upper neurone damage experience evacuation of the bowel at low water volumes (e.g. 200 to 300 ml); in some cases the irrigation procedure might need to be repeated to ensure sufficient emptying.

If leakage occurs after the irrigation try:

- Advising the patient to stay on the toilet a little longer to allow complete emptying of the bowel
- Reducing the volume of water
- Two half volume irrigations (e.g. two 250 ml irrigations instead of one 500 ml irrigation)

If irrigation water is not expelled after sitting on the toilet for 20 to 30 minutes, it could be that the bowel has absorbed the water because the patient is dehydrated or that the irrigation fluid is captured in impacted stools:

- Repeat the irrigation using the same volume of water
- Advise the patient to drink more fluids - at least 1.5 litres per day and more in hot weather

The recommended rate for pumping water into the bowel is one pump per second. Pumping water into the bowel too quickly may cause discomfort, sweating, dizziness and stomach pain; if this occurs, the procedure can be paused at any time and resumed when the discomfort has passed and the patient feels ready. If the discomfort does not pass, the irrigation should be stopped and the patient's usual bowel care routine followed to achieve emptying.

Water should be at body temperature (36 to 38°C). If the water is too hot it may damage the mucous membranes lining the bowel and if it is too cold it may trigger reflexes and increase spasms. Plain tap water is recommended or bottled water when travelling in countries where drinking tap water is not recommended.

Frequency of irrigation

For patients who are new to Peristeen Anal Irrigation, it is recommended to irrigate on a daily basis. After one or two weeks some patients find that irrigation can be tried every second day. As the frequency of irrigation is decreased, it may be necessary to adjust other parameters; for example, the volume of water may need to be increased to achieve complete emptying. Some patients will find it necessary to irrigate every day but eventually most patients settle into a routine of irrigation every other day. Conducting irrigation at approximately the same time each day seems to work best for most people, but is not essential. Eating and drinking stimulate the bowel, so about 30 minutes after a meal gives the best chance of the irrigation working with the natural activity of the bowel and achieving the best emptying. The most convenient time can be chosen by the patient to fit in with their daily routine. Alternatively, it can be varied to fit around a changing routine giving the patient the maximum possible freedom.

The system and the rectal catheters should be stored at a temperature of between 2° and 25° Celsius and away from direct sunlight. The tubing should not be kinked when being stored.

The tubes can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. Patients may choose to change the tube with the blue connectors more frequently if desired. The outer surface of all the components (excluding the single use catheter) can be washed in mild soapy water and rinsed thoroughly. The Control Unit knob should be in the Resting/Storage position when the PAI System is not in use.

Product Evaluation:

Coloplast requests physicians to notify the company of any complications which may develop with the use of this device, and requests return of any used devices or components associated with the complication. For safe handling during shipment and upon receipt, Coloplast requests that devices be decontaminated prior to shipment. This is requested even though Coloplast will autoclave-sterilize any opened product returned. Alteration for the purposes of venting to prevent additional damage will be performed as required. If necessary, Coloplast may analyze the device, and the patient and physician may be asked to allow Coloplast to perform tests that might alter the condition of the device.

Any complications from the use of this device should be brought to our immediate attention by contacting: Quality Assurance, Product Evaluations Department, Coloplast Corp., 1601 West River Road North, Minneapolis, MN 55411
Toll-free telephone (800) 338-7908 in USA; or outside USA: (612) 337-7800

Product Order Information

To order, please contact your local sales representative or Coloplast Customer Service Department at: Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free telephone: (800) 258-3476; or outside USA: (612) 337-7800; or fax (866) 216-4161 or outside USA: (612) 337-7803.

Peristeen Anal Irrigation Caregiver Guide

Young people or adults with impaired abilities who are born with or develop bowel problems can experience a variety of different issues. They may have no feeling in the rectum so they are unable to control their bowel movements. They may have normal sensations; however, the muscles that move waste through the bowels do not work, leading to chronic constipation. The concern about having an accident can have a major impact on quality of life.

Peristeen Anal Irrigation is one treatment to help empty the bowel reliably and conveniently, preventing bowel accidents and/or chronic constipation.

Coloplast has created this information package to provide you with information about the Peristeen Anal Irrigation (PAI) System. The package contains a complete description of the PAI System, instructions for use, a quick reference guide, as well as a few tools to note specific instructions for your patient.

It is Coloplast's hope that with training and consultation with your patient's physician, you can use the information in this package to utilize the PAI system most effectively. If you have additional concerns or need more information please contact your physician or health care provider.

The Peristeen Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter - which incorporates an inflatable balloon - inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by adolescent (12 years - <18 years old), transitional adolescent (18 - <21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.



Figure 1: Peristeen Anal Irrigation (PAI) System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	STRAP	The STRAPS wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

PAI System Rectal Catheter

The PAI rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2**.



Figure 2: Un-inflated, Inflated, and Simulated Model PAI Rectal Balloon Catheter

PAI System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:



Figure 3: PAI Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

PAI System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

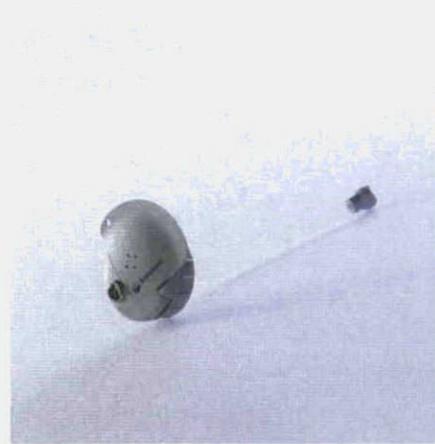


Figure 4: PAI Lid/Connector/Tubing Figure , PAI Lid/Suction Tube Assembly

PAI System Water Bag

The polyethylene bag is designed to hold water or isotonic saline solution for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

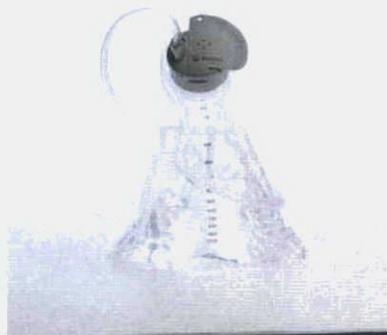


Figure 5: PAI Water Bag & Tubing

PAI System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the PAI System; the storage case also protects the components from exposure to direct sunlight.

The PAI Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Quick Reference Guide and the User Guide). The catheter is intended for single use only.

The other components of the PAI system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.



Figure 6: PAI System Storage Case, Catheter package

This Caregiver Information Package includes the following:

	Name	Purpose	Intended for...
1.	Health Care Notes form	Physician writes down specific notes for your patient	You and your patient to remind you of key information related to your PAI system
2.	Pictorial of PAI in use	You or your physician write down notes or questions; use the anatomical drawings to help explain how the system works or to remind you of tips and tricks for system usage	You and your physician; you and your patient
3.	Product brochure	Pictures of system and ordering information	You
4.	User Guide	Complete operating instructions with troubleshooting guide, contraindications and warnings	Your health care provider, you, and your patient (as applicable)
5.	Quick Reference Guide	Step-by-step Instructions for using system	You and your patient
6.	Simplified Quick Reference Guide	Step-by-step instructions for using system to be used by a younger patient or adult with cognitive limitations	You and your patient

Coloplast A/S is a Danish company founded in 1957 with more than 7,000 employees. Coloplast A/S has sales and subsidiary companies worldwide.

Coloplast develops, manufactures and markets medical devices and services to improve quality of life of the people who depend on these devices:

- Ostomy products
- Continence care products for people with bladder and bowel management problems
- Urology products used in surgery procedures of the urinary system and male reproductive system
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Manufactured by:
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Holtedam 1
DK-3050 Humlebæk

Distributed by:
Coloplast Corp.
1601 West River Road North
Minneapolis, Minnesota 55411

www.coloplast.com

Health care notes

Hospital: _____

Tel.: _____ Office hours: _____

Nurse's/doctor's name: _____

Anal irrigation to be performed:

Every day Every other day Other: _____

I need to pump _____ times to inflate the balloon. I need to use _____ ml of water

The anal irrigation set is available to order from _____



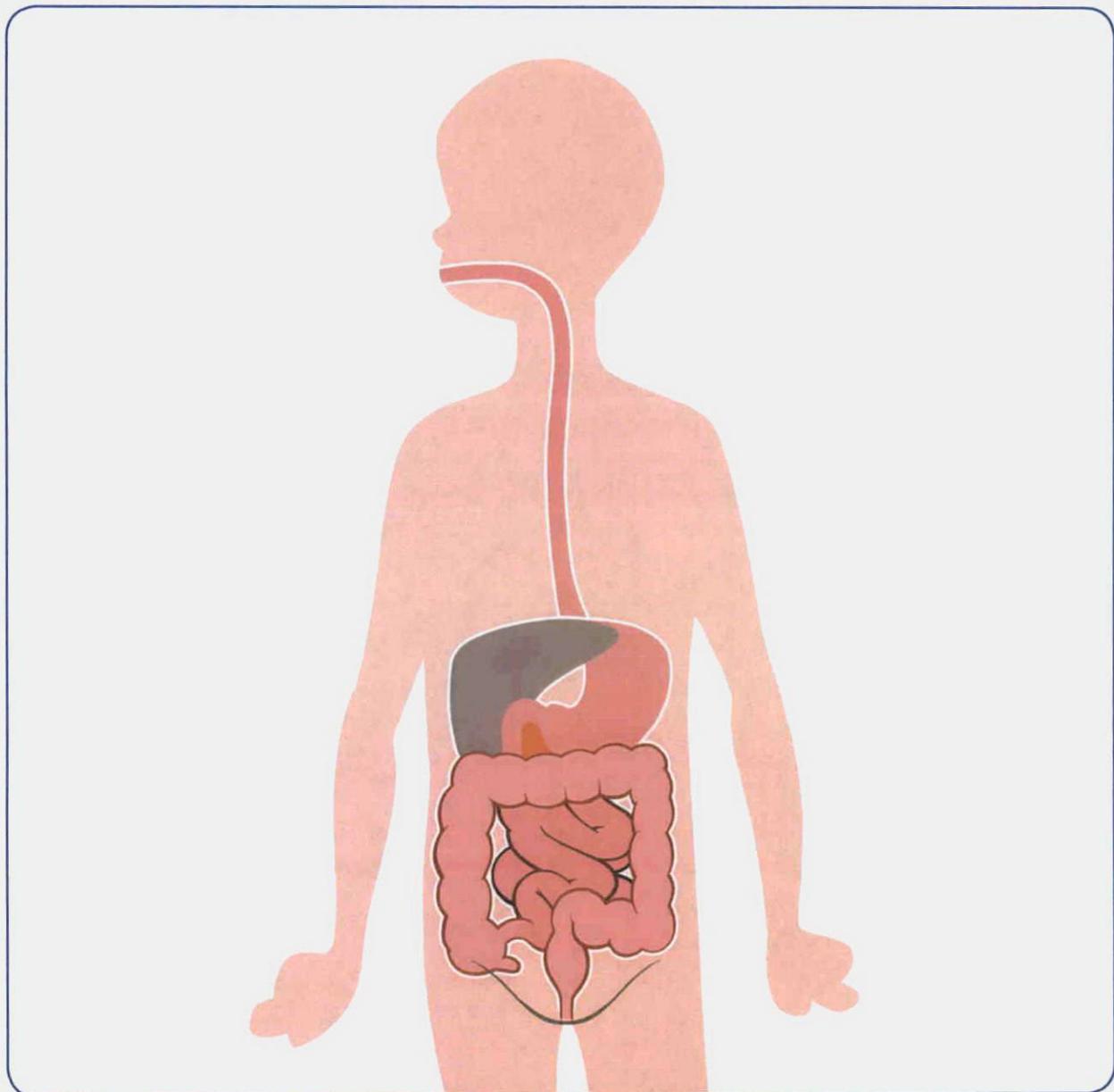
Product code	Illustration	Item	Content	Quantity	Frequency
29121		System	1 control unit 2 rectal catheters 1 bag 2 straps		
29122		Accessory unit	15 rectal catheters 1 bag		
29123		Rectal catheters	10 rectal catheters		
29124		Strap	1 set of 2 straps		
29125		Tube	2 tubes with blue connectors		



Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
Denmark

Peristeen Anal Irrigation

Four horizontal lines for handwritten notes, each starting with a small blue paperclip icon on the left side.



Peristeen

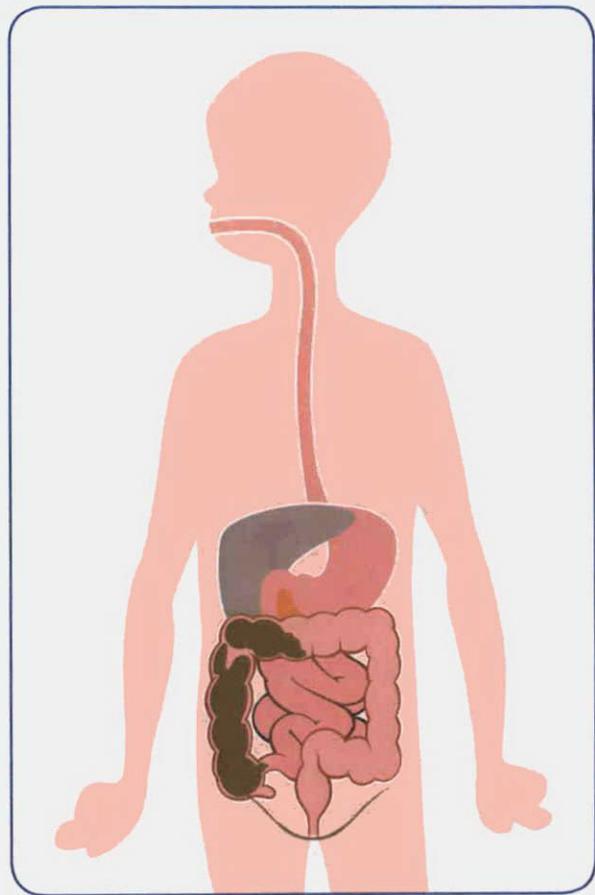
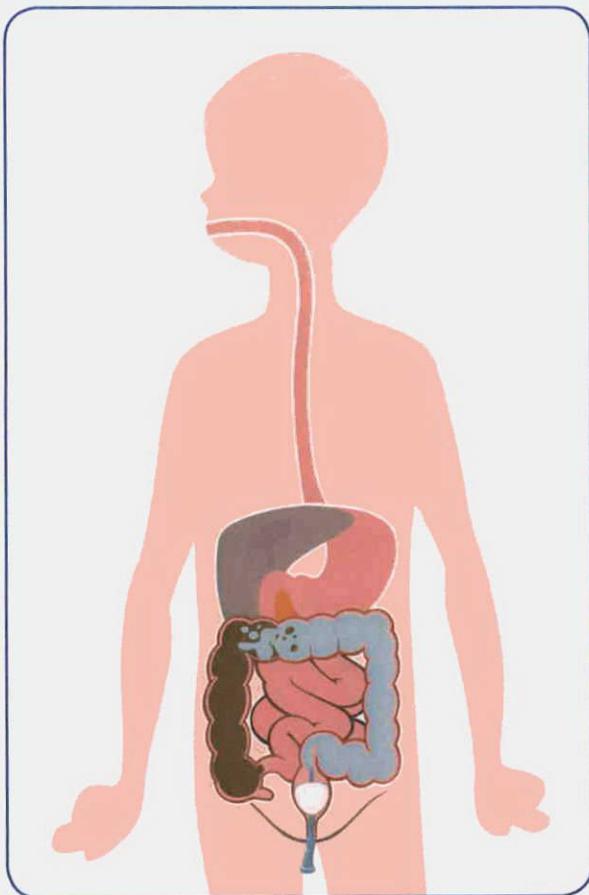
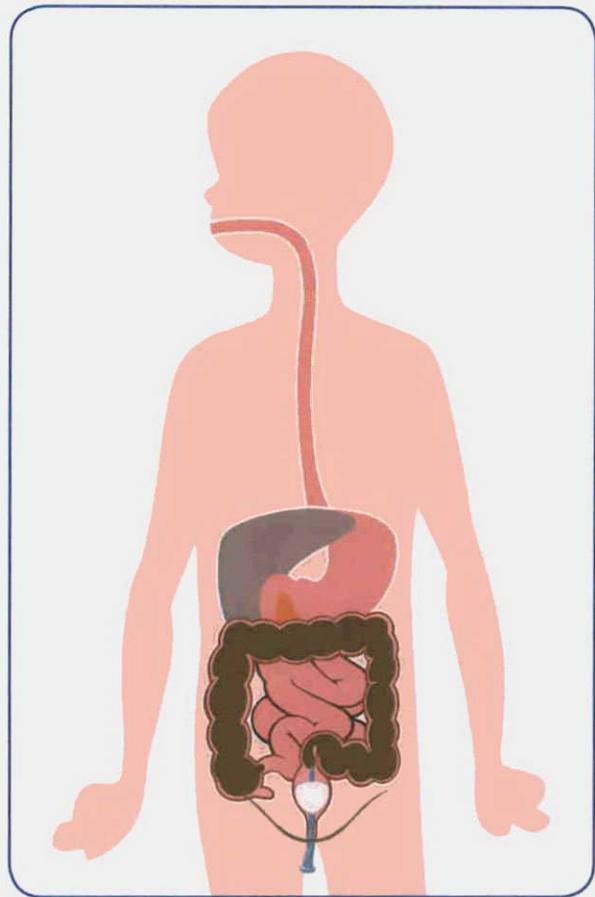
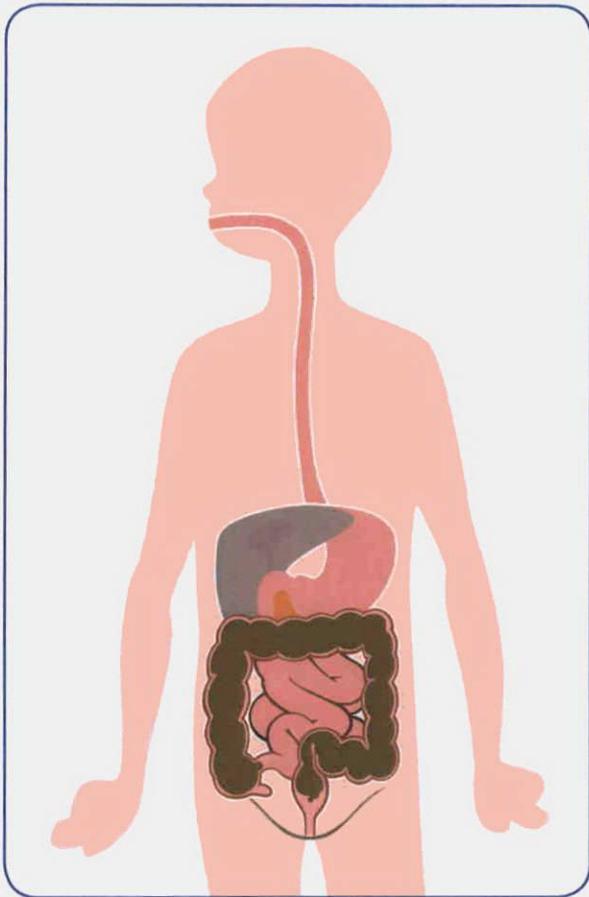
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Peristeen Expanded Indications 510k



Peristeen Expanded Indications 510k

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CONFIDENTIAL
CONTROL BRINGS

Ordering information

Product code	System
29121	1 control unit with tubes 2 rectal catheters 1 water bag 1 set of straps 1 toilet bag
29122	Accessory unit 15 rectal catheters 1 water bag
29123	Rectal catheter 10 rectal catheters
29124	Strap 1 set of straps
29125	Tube 2 tubes with blue connectors

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Peristeen Anal Irrigation Information

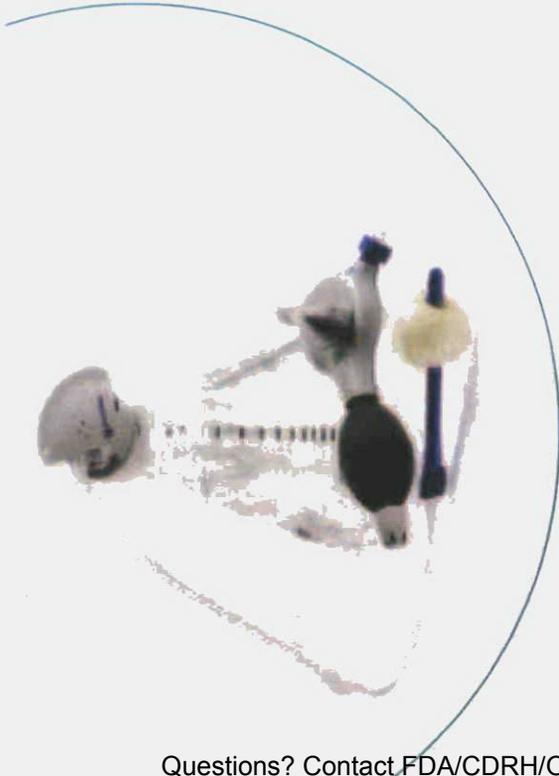
Peristeen

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Continence Care
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Denmark
www.coloplast.com

Peristeen Expanded Indications 510k



How does a person start?

Individuals must be assessed by a qualified health care professional to ensure this method is appropriate for them. They can then be taught the procedure to ensure the best results.

How does it work?

Peristeen Anal Irrigation is a technique for emptying the bowel by introducing warm tap water (36–38°C) into the rectum using a catheter.

The user sits on the toilet while the water is pumped into the rectum. The water is then emptied from the bowel along with the stools, into the toilet.

Welcome to **Peristeen** Anal Irrigation

Peristeen Anal Irrigation (also known as transanal irrigation or rectal irrigation) is a unique way of emptying the bowel and is used to prevent incontinence, constipation or to reduce the amount of time spent on bowel management.

Peristeen Anal Irrigation is an innovative irrigation system from Coloplast. **Peristeen** has been developed for patients who suffer from incontinence or chronic constipation and for patients who have to spend a long time on bowel management procedures due to neurogenic bowel dysfunction.

The system has been specially designed to make it portable and easy to use. This offers independence and a sense of confidence to the user.



PERISTEEN™ ANAL IRRIGATION USER GUIDE

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I. DESCRIPTIVE INFORMATION

Non Sterile. Single Patient Use Only. Latex Free.

Caution: Federal (USA) law restricts the use of this device to sale by or on the order of a physician.

A. Indications for Use

The Peristeen Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter – which incorporates an inflatable balloon – inserted into the rectum to promote evacuation of the contents of the lower colon in patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

B. Description of the device:

Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.



Figure 1: Peristeen Anal Irrigation (PAI) System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	STRAP	The STRAPS wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

PAI System Rectal Catheter

The PAI rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2**.



Figure 2: Un-inflated, Inflated, and Simulated Model PAI Rectal Balloon Catheter

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PAI System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:



Figure 3: PAI Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

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PAI System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

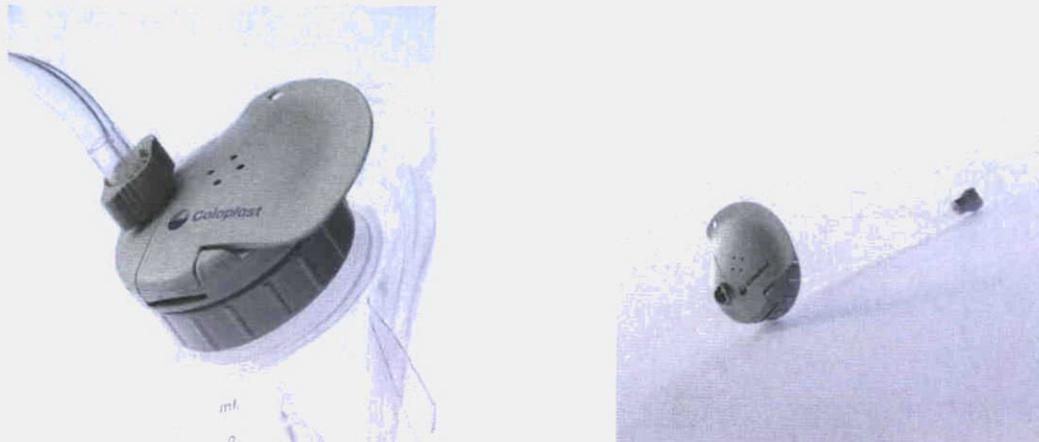


Figure 4: PAI Lid/Connector/Tubing Figure , PAI Lid/Suction Tube Assembly

PAI System Water Bag

The polyethylene bag is designed to hold water or isotonic saline solution for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.



Figure 5: PAI Water Bag & Tubing

PAI System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the PAI System; the storage case also protects the components from exposure to direct sunlight.

The PAI Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Quick Reference Guide and the User Guide). The catheter is intended for single use only.

The other components of the PAI system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.



Figure 6: PAI System Storage Case, Catheter package

C. When the device should not be used (contraindications):

Peristeen Anal Irrigation must not be used in the following situations:

- During the spinal shock phase
- Known obstruction of the large bowel
- Acute inflammatory bowel disease
- Diverticulitis
- Pregnancy if t and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy.

D. Warnings and Precautions

WARNINGS:

<p style="text-align: center;">WARNING</p> <p style="text-align: center;">Contact your doctor or nurse immediately if you notice during or after anal irrigation:</p> <p style="text-align: center;">Severe anal bleeding Severe and sustained abdominal pain or back pain, with or without fever</p> <p style="text-align: center;">Anal irrigation should always be carried out with care. Although bowel perforation is extremely rare, it is a potential complication to anal irrigation and will require immediate admission to hospital.</p>

PRECAUTIONS:

Always consult your health care professional before starting up the irrigation procedure. When anal irrigation is initiated, special caution must be shown if you:

- Suffer from an inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Have any anorectal condition which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids
- Have had irradiation therapy in the abdominal or pelvic region
- Have had recent abdominal or anal surgery
- Suffer from autonomic dysreflexia
- Have a regular intake of anticoagulant medication with vitamin K antagonists, as normally small and harmless rectal bleedings may be difficult to stop
- Are pregnant and have previous experience with anal irrigation, please consult your doctor to carefully evaluate if you may continue irrigating.
- Have diarrhea, as the cause for diarrhea must be identified.
- Use rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.

If any of the above conditions apply to you, anal irrigation must only be initiated after careful consideration and instruction by your health care professional.

Do not use soap or any other cleanser to clean the inside of the system and do not run a soap solution or cleanser through the system. The soap or cleanser or soap may react with the materials of the system and may cause irritation.

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II. OPERATING INFORMATION

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:



= **RESTING/DEVICE STORAGE**



= **INFLATE BALLOON**



= **PUMP WATER**



= **DEFLATE BALLOON/RELEASE AIR**

PREPARATION

Anal irrigation is usually done while sitting on the toilet.



1

Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with lukewarm water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID by clicking it in place.



2

Put the TUBE with the grey connector into the LID. Lock the CONNECTOR by turning it one-half turn clockwise.



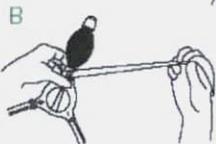
3

Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE with the blue CONNECTOR into the RECTAL CATHETER. Lock the CONNECTOR by turning it one-half turn clockwise.



4

Attach the catheter package to a wall or door next to the toilet by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



5

Attach the CONTROL UNIT and attached TUBES to the thigh with the STRAP:

A. Put the strap around the base of the pump

B. Slide the strap through the buckle and pull tight

C. Adjust the strap to fit comfortably around your thigh



6

Turn the knob on the CONTROL UNIT to the water symbol . Squeeze the pump 2 to 3 times; this will fill the catheter package with water. Turn the knob on the control unit to the balloon symbol  to prevent any more water from going into the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put it into the rectum.

INSERTING THE RECTAL CATHETER



7

Make sure the knob on the control unit is pointing to the balloon symbol . Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly.

When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump. For an average size adult it is approximately 3 to 4 times. For smaller individuals and adolescents it will be less. Your doctor or nurse will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol  to deflate it.

Turn the knob to the balloon symbol  if you want to inflate the balloon again.

IRRIGATION (PUMPING WATER INTO COLON)



8

Turn the knob on the control unit counter-clockwise to the water symbol . Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use, and they will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If water leaks past the BALLOON, you can inflate the balloon more by turning

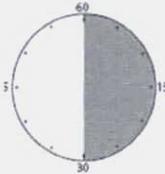
the knob on the control unit clockwise to the balloon symbol  and squeezing the PUMP one more time. Turn the knob counter-clockwise to the

water symbol  to continue irrigation.

REMOVING THE RECTAL CATHETER

9

To deflate the balloon, turn the knob on the control unit counter-clockwise to the air symbol . Often the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.

EMPTYING THE BOWELS

10

Within a few minutes, the colon will start to empty into the toilet. If nothing happens, you can push on the lower part of your abdomen, cough, or move the upper part of your body to help encourage the emptying process. The amount of time it takes for to empty the bowels will be different for each person, but usually it will take about thirty minutes. After doing the irrigation a few times, you will become more comfortable and have a better idea of how long it will take.

STORAGE AND MAINTENANCE OF SYSTEM

11

1. Unlock the connectors from the lid and the catheter.
2. Discard the single use catheter.
3. Open the flip-top on the LID and pour excess water out of the bag.
4. Rinse the outer surface of all the parts with warm water and a small amount of mild soap. Rinse all the soap off. So not run soap solution or cleanser through the system.
5. Set the knob on the CONTROL UNIT to the Resting Symbol .
6. Allow the parts to dry and pack them loosely in the nylon bag
7. Make sure that the tubes with connectors and the tube in the water bag do not get kinked in the storage case.
8. Do not keep the parts or the storage case in direct sunlight
9. Store the case in a place where the temperature is between 35° and 77° F.

III. TROUBLESHOOTING INFORMATION:**Who can perform anal irrigation?**

Anal irrigation is for people who suffer from fecal incontinence, chronic constipation or have to spend a long time on bowel management procedures. You must be examined by a health care professional and receive professional instruction before starting the irrigation. After receiving instruction and training, the majority will be able to perform anal irrigation on their own.

How often should I irrigate?

Anal irrigation may be performed every other day or as recommended by your doctor or nurse.

How long does the irrigation take?

The time used for irrigation is individual. When using anal irrigation you approximately use 30-45 minutes on bowel management daily.

How much air and water should I use?

The required amount of air to pump into the balloon and water to pump into the rectum is individual and your doctor or nurse will tell you how much to use. They will write the amounts of air and water to pump on your Health Care Notes form. You should not increase the amount of water uncritically since the bowel may retain it and release it over time in small amounts.

Why is the temperature of the water important?

The water must have body temperature (approx. 36-38°C). If it is too hot, it may harm the delicate lining of the rectum; if it is too cold, cramps may occur.

How quickly should I pump the water?

If the water is pumped too quickly into the bowel, you may experience discomfort such as sweating, dizziness and stomach ache. We recommend approximately one pump per second or more slowly as recommended by your doctor or nurse.

Can I stop the irrigation if I want a break?

In case of discomfort and you feel the need for a break, stop the water flow and wait until it subsides. When you are ready, resume pumping. If the discomfort does not disappear, contact your health care professional immediately.

What should I do if the irrigation water and/or feces do not come out (no emptying)?

You may be heavily constipated and a clean-out of the bowel is necessary. Contact your health care professional for assistance.

The reason could also be that you have not had enough to drink and are dehydrated, so the bowel has absorbed the irrigation water. Try irrigating once more using the normal amount of water and remember to drink more water. If another attempt at irrigation does not help, contact your doctor or nurse.

What should I do if water seeps into the toilet?

If water seeps past the balloon and into the toilet there is no need to change the irrigation procedure if the irrigation still works.

You can stop the pumping of water, wait for a while and fill some more water into the bowel. Make sure the catheter is placed in the correct position right above the sphincters. If water still seeps into the toilet, you can fill more air into the balloon and resume pumping water into the bowel.

What if I experience leakages after irrigation?

If you experience leakages after irrigation you might have used too much water. Make sure to use the amount of water recommended by your health care professional. You can also try to stay a little longer at the toilet. Contact your health care professional if you continue experiencing leakages.

What if I experience defecation between irrigations?

If you experience defecation between irrigations, the cause may be insufficient emptying after irrigation owing to constipation or hard stools. Contact your health care professional for different solutions, e.g. frequency of irrigation, amount of water and/or medication.

How should I store my Peristeen Anal Irrigation system?

The system and the rectal catheters should be stored at a temperature of between 2° and 25° Celsius and away from direct sunlight. Ensure the tubing is not kinked when stored.

How do I clean my Peristeen Anal Irrigation system?

The tube can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. You may choose to change the tube with the blue connectors more frequently if you desire. The surface of all the components (excluding the single use catheter) can be washed in mild soapy water, and rinsed thoroughly. Remember to keep the Control Unit knob in the Resting/Storage position when you are not using the PAI System.

What do I do when travelling?

The bowels absorb water, so when travelling in countries where it is not safe to drink the water, care should be taken to use distilled water or isotonic saline for irrigation.

Flatulence

Anal irrigation empties the bowel of feces and air. Experience shows that the release of gas from the rectum will be considerably reduced once irrigation is practiced regularly.

Adaptation period

An adaptation period of approx. 10 days may be expected. The procedure must be individually adjusted together with your health care professional regarding the amount of air to pump into the balloon, water to pump into the rectum, as well as recommended frequency of irrigating.

IV. DISEASE AND SELF-CARE INFORMATION**The bowel system**

The bowels are part of the digestive system, the primary function of which is to break down the food we eat. The food passes through the stomach and the small bowel (small intestine), where it is broken down and useful components are absorbed into the body. What is left continues to the large bowel (colon and rectum).

The large bowel receives a liquid mixture of digested food and juices from the small bowel. The main function of the large bowel is to absorb water and salts and to store the waste products (feces) before they are transported to the rectum. The large bowel in an average size adult receives about 1,500 ml small bowel content a day and converts this into 150-200 ml of fecal matter. The bowel absorbs the remainder.

On average it takes 1-3 days for food to pass through the entire digestive tract, though this can vary greatly from person to person. The time it takes for food to pass through the digestive system is called the transit time.

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The large bowel has two muscles, which make peristaltic movements when contracting. With the aid of peristalsis, the feces are moved onward from the large bowel into the rectum. Peristalsis is affected by a number of factors such as diet, posture and exercise.

Peristalsis is a wavelike muscular contraction that transports digested food through the intestines to the rectum. The two colon muscles; one longitudinal muscle along the colon and one circular muscle around the colon make the contraction.

There are two sphincters in the rectum controlling the defecation process. The internal sphincter is an extension of the colon musculature and is controlled by reflex, i.e. we cannot consciously control it. The external sphincter can be controlled consciously by the brain.

There are two sphincters in the rectum affecting the evacuation – the internal and the external sphincter. The function of the anal sphincters is to maintain continence and prevent leakage.

Once the rectum receives feces from the large bowel, it is registered in a set of nerve endings. These nerve endings send a signal to the brain that the rectum is full and that it is time to go to the toilet. At this point you can choose to wait for a more suitable time. If you wait too long however, the urge will disappear and the feces will be forced back into the large bowel.

When you decide to go to the toilet, you activate the defecation reflex by relaxing the external sphincter. Typically, the presence of approx. 150 ml of feces will result in a reflex relaxation of the internal sphincter. The external sphincter relaxes and the feces are expelled with the aid of gravity and muscle contractions in the rectum.

Causes of bowel dysfunction

There are many causes of bowel dysfunction and reasons for initiating anal irrigation. The most frequent reasons are mentioned below. In order to receive appropriate and effective treatment, a diagnosis from your health care professional is essential.

Neurological disorders

The defecation mechanism, i.e. the nerves that send a signal to your brain telling you when you need to go to the toilet, may be impaired due to a medical condition or disease, such as: a spinal cord injury, spina bifida, multiple sclerosis, Parkinson's disease, apoplexia, Alzheimer's disease or brain tumors.

Sensory disorders

The sensory function of the rectal mucosa may be impaired. This can occur after surgery, as a result of colitis, compaction, rectal prolapse or as a result of surgical correction of congenital absence or abnormality of the anal opening (anal atresia).

Muscular disorders

Damage to the sphincter muscle due to external injuries, tumours or their surgical removal, perineal tear from a vaginal birth, straining from constipation or rectal prolapse.

Psychological/psychiatric disorders

Caused by psychoses, depression, depersonalisation or role conflicts (in children and adults) as well as a result of sexual abuse.

Reduced tissue elasticity

Frequent in old age or after multiple births.

The effect of food and exercise

Food plays an important role in managing your bowels. It is important to find the right balance of stool consistency to avoid either constipation or liquid stools, which will increase the risk of fecal incontinence.

Dietary fiber generally softens stool and reduces the passage time. Too much fiber, however, can worsen symptoms of bloating and stomach pain.

It is worth noting that some food and liquids such as coffee and artificial sweeteners have a mild laxative effect. It is always important to drink plenty of fluids.

Finally physical exercise has a mechanical effect on the bowels, which improves bowel movement.

Constipation

Constipation and fecal incontinence are both symptoms of bowel dysfunction and you often experience both fecal incontinence and constipation at the same time.

Bowel function and defecation habits vary from one person to another. Some have daily bowel movements, others every second or third day. Owing to the extensive variation in the normal defecation pattern, it is difficult to offer a clear definition of constipation.

Constipation occurs when the bowel's movements are reduced. This prolongs transit time in the large bowel and more fluid is absorbed from the feces than with normal transit time, resulting in hard and lumpy stools. This will often result in general discomfort and in some cases disturbed bladder-emptying patterns.

Constipation is generally perceived as:

- Fewer than three defecations a week.
- Prolonged lavatory visits with straining and soreness in the rectum.
- Hard, sparse and lumpy stools.

Because of this natural variation, changes in digestive and bowel movement patterns will be perceived differently depending on what one is accustomed to.

Fecal incontinence

Fecal incontinence can be defined as lack of control of bowel evacuation resulting in involuntary defecation. Anal incontinence also includes incontinence for air (flatus).

In many cases, fecal incontinence occurs as the result of insufficient sensation in the rectal region. In other words, you do not register the urge to defecate. At the same time, control of the internal and external sphincters may be entirely or partially lacking.

Chronic constipation, in which the rectum wall is severely over-stretched, may result in fecal incontinence as the normal defecation reflexes are deactivated by the chronic stretch. At the same time, fluid passes around the fecal mass in the bowel. Often the internal sphincter has reduced function because it is expanded and liquid stools mixed with dry and hard stool may pass.

V. USER ASSISTANCE INFORMATION:

Coloplast in brief

Coloplast A/S is a Danish company founded in 1957 with more than 7,000 employees.

Coloplast develops, manufactures and markets medical devices and services to improve quality of life of the people who depend on these devices:

- Ostomy products for people with a stoma
- Continence care products for people with bladder and bowel management problems
- Urology products used in surgery procedures of the urinary system and male reproductive system
- Wound dressings for the treatment of chronic wounds
- Skin care products for prevention and treatment of conditions from simple irritation to fungal infections and skin breakdown

Coloplast A/S has sales and subsidiary companies worldwide.

Coloplast A/S
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DK-3050 Humlebæk
www.coloplast.com

Coloplast accepts no liability for injury or loss that may arise if this product is not used entirely according to the company's recommendations.

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Manufacturer: Coloplast A/S, DK-3050 Humlebæk, Denmark.

QUICK REFERENCE GUIDE FOR THE USER PERISTEEN ANAL IRRIGATION SYSTEM

Non-Sterile. Single Patient Use Only. Latex Free.

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Intended Use:

The Peristeen Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter – which incorporates an inflatable balloon – inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by adolescent (12 years - <18 years old), transitional adolescent (18 - <21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

For more information on the Peristeen Anal Irrigation System, including complete user instructions, intended use, contra-indications, and precautions, consult the **Peristeen Anal Irrigation User Guide**.

To use this system safely and effectively, you should get training from your doctor or home health care nurse before using it.

The first time you use this system, you should do so when your doctor or health care nurse is present.

PERISTEEN ANAL IRRIGATION - DESCRIPTION

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	STRAP	The STRAPs wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

-  = **RESTING/DEVICE STORAGE**
-  = **INFLATE BALLOON**
-  = **PUMP WATER**
-  = **DEFLATE BALLOON/RELEASE AIR**

PREPARATION

Anal irrigation is usually done while sitting on the toilet.



1

Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with lukewarm water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID by clicking it in place.



2

Put the TUBE with the grey connector into the LID. Lock the CONNECTOR by turning it one-half turn clockwise.



3

Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE with the blue CONNECTOR into the RECTAL CATHETER. Lock the CONNECTOR by turning it one-half turn clockwise.



4

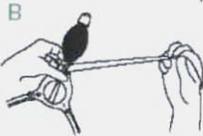
Attach the catheter package to a wall or door next to the toilet by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.

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Attach the CONTROL UNIT and attached TUBES to the thigh with the STRAP:

A. Put the strap around the base of the pump



5

B. Slide the strap through the buckle and pull tight



C. Adjust the strap to fit comfortably around your thigh



6

Turn the knob on the CONTROL UNIT to the water symbol . Squeeze the pump 2 to 3 times; this will fill the catheter package with water. Turn the knob on the control unit to the balloon symbol  to prevent any more water from going into the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put it into the rectum.

INSERTING THE RECTAL CATHETER



7

Make sure the knob on the control unit is pointing to the balloon symbol . Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly.

When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump. For an average size adult it is approximately 3 to 4 times. For smaller individuals and adolescents it will be less. Your doctor or nurse will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol  to deflate it.

Turn the knob to the balloon symbol  if you want to inflate the balloon again.

IRRIGATION (PUMPING WATER INTO COLON)



8

Turn the knob on the control unit counter-clockwise to the water symbol . Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use, and they will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If water leaks past the BALLOON, you can inflate the balloon more by turning the knob on the control unit clockwise to the balloon symbol  and squeezing the PUMP one more time. Turn the knob counter-clockwise to the water symbol  to continue irrigation.

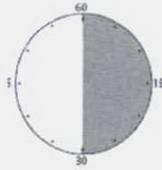
REMOVING THE RECTAL CATHETER



9

To deflate the balloon, turn the knob on the control unit counter-clockwise to the air symbol . Often the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.

EMPTYING THE BOWELS



10

Within a few minutes, the colon will start to empty into the toilet. If nothing happens, you can push on the lower part of your abdomen, cough, or move the upper part of your body to help encourage the emptying process. The amount of time it takes for to empty the bowels will be different for each person, but usually it will take about thirty minutes. After doing the irrigation a few times, you will become more comfortable and have a better idea of how long it will take.

STORAGE AND MAINTENANCE OF SYSTEM



11

1. Unlock the connectors from the lid and the catheter.
2. Discard the single use catheter.
3. Open the flip-top on the LID and pour excess water out of the bag.
4. Rinse the surface of all the parts with warm water and a small amount of mild soap. Rinse all the soap off.
5. Set the knob on the CONTROL UNIT to the Resting Symbol 
6. Allow the parts to dry and pack them loosely in the nylon bag
7. Make sure that the tubes with connectors and the tube in the water bag do not get kinked in the storage case.
8. Do not keep the parts or the storage case in direct sunlight
9. Store the case in a place where the temperature is between 35° and 77° F.

PAI Catalog Numbers

Product	Catalog number	Components
Peristeen Anal Irrigation System	29121	1 Control unit 2 rectal catheters 1 Bag 2 straps
Peristeen Anal Irrigation Accessory Unit	29122	15 rectal catheters 1 Bag
Peristeen Anal Irrigation Rectal Catheter	29123	10 rectal catheters
Peristeen Anal Irrigation Strap	29124	1 set of 2 straps
Peristeen Anal Irrigation Tube	29125	2 tubes with blue connectors

PERISTEEN ANAL IRRIGATION SYSTEM SIMPLIFIED QUICK REFERENCE GUIDE

	Part Name	What does it do?	How many times can I use it?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	1 time only
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP blows up or lets the air out of the balloon & makes the water go through the catheter	6 months**
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	6 months**
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	6 months**
5.	WATER BAG	The WATER BAG holds the water for the irrigation	1 month
6.	STRAP	If you want to, you can use the STRAPS to wrap around your leg and hold the CONTROL UNIT and TUBES	6 months**
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	Whenever you need to

** If you irrigate every other day.

If your doctor has you on a different schedule, make sure you write down how many times you should use yours before getting a new one.

Make sure you ask all the questions you have about using the irrigation system before you use it. You should always ask for help from your parent or helper if you need it.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are in the instruction steps and this is what they mean:



= **REST**



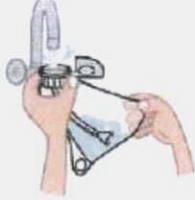
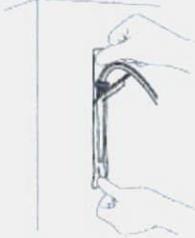
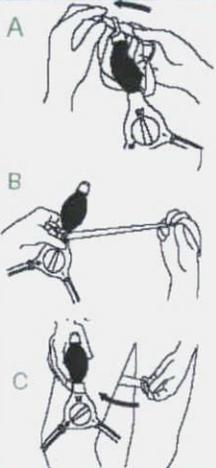
= **BLOW UP BALLOON**



= **PUMP WATER**



= **LET AIR OUT OF BALLOON**

Instructions for the User		
	<p>1.</p>	<p>Gather all the parts for your Peristeen system.</p>
	<p>2.</p>	<p>Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with <u>lukewarm</u> water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID.</p>
	<p>3.</p>	<p>Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE and LID parts together. Grey goes with Grey and Blue goes with Blue.</p>
	<p>4.</p>	<p>Stick the catheter package next to the toilet by taking off the paper circles from the package and putting it on the wall or door.</p>
	<p>5.</p>	<p>If you want to, you can attach the CONTROL UNIT to your leg with the STRAP like this:</p> <p>A. Put the strap around the bottom of the pump B. Slide the strap through the buckle and pull tight C. Put the strap around your leg so it stays put and is comfortable</p>

	<p>6.</p>	<p>Turn the knob on the CONTROL UNIT to the water symbol .</p> <p>Squeeze the pump 2 to 3 times; this will fill the catheter package with water. Turn the knob to the balloon symbol . Count to 10 slowly, 3 times. That will make the catheter soft and smooth and it will be easier to put it in.</p>
 	<p>7.</p>	<p>Make sure the knob on the control unit is pointing to the balloon symbol .</p> <p>Put the rectal catheter slowly and carefully into your rectum the way that your doctor or nurse told you to. Then, pump the balloon while you hold the catheter in place.</p> <p>Your doctor or nurse will tell you how much air to pump.</p> <p>Amount of air to pump: _____</p> <p>With the air in the balloon, the catheter should stay in place. If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol  to let air out. Turn the knob to the balloon symbol  if you want to inflate the balloon again.</p>
	<p>8.</p>	<p>Sit on the toilet and then turn the knob to the water symbol . Squeeze the PUMP slowly – about once time per second – until you have pumped in the right amount of water.</p> <p>Your doctor or nurse will tell you how much water to pump in.</p> <p>Amount of air to pump: _____</p> <p>If water leaks past the BALLOON, you can try putting more air in the balloon more by turning the knob to the balloon symbol  and slowing squeezing the PUMP one more time. Turn the knob counter-clockwise to the water symbol  to start irrigating again.</p>

	<p>9.</p>	<p>When you have pumped in the right amount of water, turn the knob to the air symbol . Sometimes the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.</p> <p>Put the catheter back in the package and throw it away.</p>
	<p>10.</p>	<p>Wait for a few minutes and you will start to have a bowel movement. If it doesn't start, you can help by pushing a little on your stomach. Sometimes you will have a result after a little more time passes; about 10 minutes or so.</p>
	<p>11.</p>	<p>Turn the knob to the Resting Symbol , and be sure to wipe with toilet paper.</p> <p>Empty the water bag and wash your hands. You are done irrigating.</p>
	<p>12.</p>	<p>Rinse the outside of all the parts with warm water and a little bit of soap. Rinse all the soap off. Let all the parts dry and put them in the nylon bag. Don't let the tubes get too crowded or bent in the bag. Don't put the case in the sunlight. Keep it in a cool, dry place.</p>

**Peristeen Anal Irrigation
Physician Instructions for Use**

Device Description:

Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.



Figure 1: Peristeen Anal Irrigation (PAI) System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	STRAP	The STRAPS wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

PAI System Rectal Catheter

The PAI rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2**.



Figure 2: Un-inflated, Inflated, and Simulated Model PAI Rectal Balloon Catheter

PAI System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:

- 
Storage
- 
Inflate balloon
- 
Pump water into rectum
- 
Deflate balloon



Figure 3: PAI Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

PAI System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

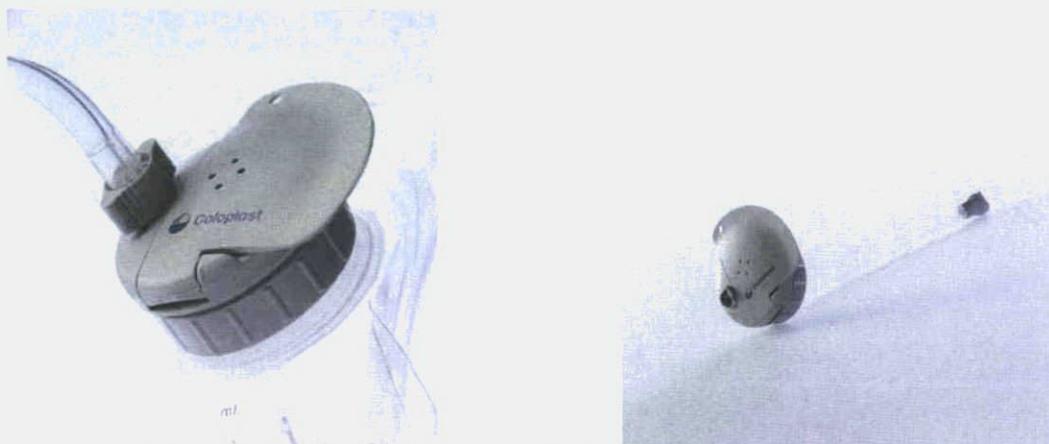


Figure 4: PAI Lid/Connector/Tubing Figure , PAI Lid/Suction Tube Assembly

PAI System Water Bag

The polyethylene bag is designed to hold water or isotonic saline solution for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

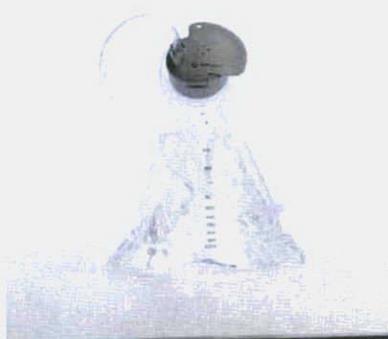


Figure 5: PAI Water Bag & Tubing

PAI System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the PAI System; the storage case also protects the components from exposure to direct sunlight.

The PAI Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Quick Reference Guide and the User Guide). The catheter is intended for single use only.

The other components of the PAI system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.



Figure 6: PAI System Storage Case, Catheter package

Indications:

The Peristeen Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter – which incorporates an inflatable balloon – inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by adolescent (12 years - <18 years old), transitional adolescent (18 - <21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Contraindications:

Peristeen Anal Irrigation must not be used in the following situations:

- During the spinal shock phase
- Known obstruction of the large bowel
- Acute inflammatory bowel disease
- Diverticulitis
- Pregnancy if t and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy.

Warnings and Precautions:

Warnings:

Make sure that your patients know that they must contact you immediately if they notice during or after anal irrigation:

- Severe anal bleeding

- Severe and sustained abdominal pain or back pain, with or without fever
- Anal irrigation should always be carried out with care. Although bowel perforation is extremely rare, it is a potential complication to anal irrigation and will require immediate admission to hospital.

Precautions:

Patients should be advised of contraindications, warnings, precautions, and instructions for use before starting up the irrigation procedure. When anal irrigation is initiated, special caution must be shown for the following patient conditions:

- Inflammatory bowel disease (e.g. Crohn’s disease or ulcerative colitis)
- Any anorectal condition which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids
- Previous irradiation therapy in the abdominal or pelvic region
- Recent abdominal or anal surgery
- Autonomic dysreflexia
- Regular intake of anticoagulant medication with vitamin K antagonists; normally small and harmless rectal bleeding may be difficult to stop
- Patient who are pregnant and who have had previous experience with anal irrigation; evaluate carefully to determine if irrigating is recommended
- Patients with diarrhea; the cause for diarrhea must be identified.
- Use of rectal medication for other diseases as the effect of such medication may be diluted by the anal irrigation.

If any of the above conditions apply, anal irrigation must only be initiated after careful consideration and instruction.

Instructions for Use:

Each patient and/or caregiver should be trained in the following steps and should perform these steps with physician assistance to ensure that all steps are understood and can be accomplished independently.

Operating Information

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

- | | | |
|---|---|------------------------------------|
|  | = | RESTING/DEVICE STORAGE |
|  | = | INFLATE BALLOON |
|  | = | PUMP WATER |
|  | = | DEFLATE BALLOON/RELEASE AIR |

PREPARATION

Anal irrigation is usually done while sitting on the toilet.



1

Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with lukewarm water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID by clicking it in place.



2

Put the TUBE with the grey connector into the LID. Lock the CONNECTOR by turning it one-half turn clockwise.



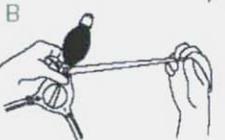
3

Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE with the blue CONNECTOR into the RECTAL CATHETER. Lock the CONNECTOR by turning it one-half turn clockwise.



4

Attach the catheter package to a wall or door next to the toilet by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



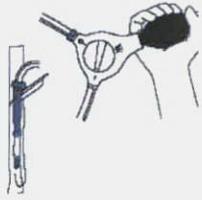
5

Attach the CONTROL UNIT and attached TUBES to the thigh with the STRAP:

A. Put the strap around the base of the pump

B. Slide the strap through the buckle and pull tight

C. Adjust the strap to fit comfortably around your thigh



6

Turn the knob on the CONTROL UNIT to the water symbol .
Squeeze the pump 2 to 3 times; this will fill the catheter package with water.
Turn the knob on the control unit to the balloon symbol  to prevent any more water from going into the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put it into the rectum.

INSERTING THE RECTAL CATHETER



7

Make sure the knob on the control unit is pointing to the balloon symbol .
Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly.

When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump. For an average size adult it is approximately 3 to 4 times. For smaller individuals and adolescents it will be less. Your doctor or nurse will write down the number of times to pump on the Health Care Notes form that they gave you.

If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol  to deflate it.

Turn the knob to the balloon symbol  if you want to inflate the balloon again.

IRRIGATION (PUMPING WATER INTO COLON)



8

Turn the knob on the control unit counter-clockwise to the water symbol .

Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use, and they will write down the number of times to pump on the Health Care Notes form that they gave you. If water leaks past the BALLOON, you can inflate the balloon more by turning the knob on the

control unit clockwise to the balloon symbol  and squeezing the PUMP

one more time. Turn the knob counter-clockwise to the water symbol  to continue irrigation.

REMOVING THE RECTAL CATHETER



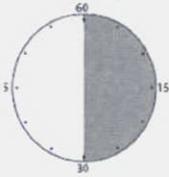
9

To deflate the balloon, turn the knob on the control unit counter-clockwise to

the air symbol .

Often the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.

EMPTYING THE BOWELS



Within a few minutes, the colon will start to empty into the toilet. If nothing happens, you can push on the lower part of your abdomen, cough, or move the upper part of your body to help encourage the emptying process.

The amount of time it takes for to empty the bowels will be different for each person, but usually it will take about thirty minutes. After doing the irrigation a few times, you will become more comfortable and have a better idea of how long it will take.

STORAGE AND MAINTENANCE OF SYSTEM



11

1. Unlock the connectors from the lid and the catheter.
2. Discard the single use catheter.
3. Open the flip-top on the LID and pour excess water out of the bag.
4. Rinse the surface of all the parts with warm water and a small amount of mild soap. Rinse all the soap off.
5. Set the knob on the CONTROL UNIT to the Resting Symbol 
6. Allow the parts to dry and pack them loosely in the nylon bag
7. Make sure that the tubes with connectors and the tube in the water bag do not get kinked in the storage case.
8. Do not keep the parts or the storage case in direct sunlight
9. Store the case in a place where the temperature is between 35° and 77° F.

Physician Notes:

Peristeen Anal Irrigation is designed to be carried out independently or with the assistance of a caregiver in the user's home. It is important that a healthcare professional supervises the first use of Peristeen Anal Irrigation to help the patient use the system safely, optimally and with confidence. Once a patient and/or caregiver has completed irrigation under supervision, they may try the procedure alone. Sometimes more than one training session is required so each patient should be considered individually in terms of their readiness and capability to do so. Subsequent irrigations should be followed-up by consultations in person or by telephone until the patient and/or caregiver has fully adapted the procedure to meet the individual needs and until they are confident to continue the procedure independently. If a patient is heavily and/or chronically constipated, it may be necessary to thoroughly clean out their bowels before starting Peristeen Anal Irrigation.

Physicians should prescribe irrigation based upon a comprehensive evaluation of the nature of the patient's fecal incontinence and the frequency of either constipation or soiling episodes. Generally, Coloplast recommends that anal irrigation be performed every other day; more or less frequent irrigation may be advised depending upon individual patient needs.

Prior to starting Peristeen Anal Irrigation for the first time, please take time to describe the procedure to your patient, answer any questions, and help manage their expectations. To avoid potential disappointment or concern that anal irrigation does not work for them, explain that an initial period of adjustment is perfectly normal and is required to establish their personalised routine. An anal irrigation bowel diary is a good way of keeping track of progress during this period (see table). Peristeen Anal Irrigation can work successfully within a few days but for some individuals it can take 4 to 6 weeks for the treatment to settle down and become routine.

Table 1. Example extract from an anal irrigation bowel diary

Date	Time	Number of balloon pumps	Water volume	Comments
10 June	8.35 am	2 + 1	700 mL	Small amount of water leaked during irrigation. Evacuation after approx 25 minutes
11 June	8.30 am	3	700 mL	No water leakage. Good evaluation
12 June	8.30 am	3	700 mL	No faeces passed. Bowel still empty from yesterday?
13 June	8.40 am	3	700 mL	Good evacuation today after approx. 20 minutes

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For new users of Peristeen Anal Irrigation, the irrigation routine should be tailored to meet their individual requirements. It is helpful to ensure the patient understands that, at first, some trial and error will be required to optimise the process and establish their personalised routine. For some people it can take 4 to 6 weeks to adapt the routine. Make sure to complete a **Health Care Notes form** for the patient and/or caregiver to refer to. The **Anatomy Notes** sheets can also be used to make notes and special recommendations on an individual basis.

There are several parameters that can be adjusted if required:

1. Amount of air in the catheter balloon
2. Amount of water used for irrigation
3. Frequency of irrigation

Amount of air in the catheter balloon

The function of the balloon is to hold the catheter in place in the rectum; the degree to which the balloon must be inflated to achieve this (i.e. the number of pumps of air required) depends on the condition of the individual's sphincter and rectum. The average size adult will probably require 3 to 4 pumps of air in the balloon (maximum 5 pumps); for smaller patients, 1 to 2 pumps may be sufficient. Insufficient air can cause water to leak or the catheter to slide out of the rectum. If water leaks during the procedure, patients and/or caregivers should attempt pumping one more time to a maximum of 5 pumps in total. Conversely, too much air can cause the balloon to be expelled. If this happens, repeating the procedure using a little less air should be attempted. The frequency of expulsions often decreases as a patient becomes used to the procedure.

Please use the following notes to guide the amount of air pumped into the balloon for an average size adult patient:

- Intact sphincter reflexes and muscle tone: 1 to 3 pumps
- Flaccid bowels or low sphincter tone: 3 to 5 pumps. If the catheter still slides out of the rectum, it may be supported by holding in place
- Strong anorectal reflexes: The balloon may be expelled after only 1 to 2 pumps; careful insertion and inflation of the balloon is necessary, using less air

For smaller patients, 1 to 2 pumps is recommended.

Amount of water for irrigation

The volume of water required to effectively empty the bowel depends on several factors including the patient's bowel condition, their diet and the frequency of irrigation.

When first using Peristeen Anal Irrigation in adults, a water volume of 500 ml is recommended, and irrigation should be performed daily. This volume can be gradually increased, over the next few weeks, until the individual feels they are completely empty and have no accidents between irrigations. Increases in volume should be done slowly, especially in younger patients and patients with spina bifida. Many adult patients eventually use a volume in the region of 750 ml; however, studies have shown that the amount of water varies from 200 to 1500 ml in adults. Some patients with upper neurone damage experience evacuation of the bowel at low water volumes (e.g. 200 to 300 ml); in some cases the irrigation procedure might need to be repeated to ensure sufficient emptying.

If leakage occurs after the irrigation try:

- Advising the patient to stay on the toilet a little longer to allow complete emptying of the bowel
- Reducing the volume of water
- Two half volume irrigations (e.g. two 250 ml irrigations instead of one 500 ml irrigation)

If irrigation water is not expelled after sitting on the toilet for 20 to 30 minutes, it could be that the bowel has absorbed the water because the patient is dehydrated or that the irrigation fluid is captured in impacted stools:

- Repeat the irrigation using the same volume of water
- Advise the patient to drink more fluids - at least 1.5 litres per day and more in hot weather

The recommended rate for pumping water into the bowel is one pump per second. Pumping water into the bowel too quickly may cause discomfort, sweating, dizziness and stomach pain; if this occurs, the procedure can be paused at any time and resumed when the discomfort has passed and the patient feels ready. If the discomfort does not pass, the irrigation should be stopped and the patient's usual bowel care routine followed to achieve emptying.

Water should be at body temperature (36 to 38°C). If the water is too hot it may damage the mucous membranes lining the bowel and if it is too cold it may trigger reflexes and increase spasms. Plain tap water is recommended or bottled water when travelling in countries where drinking tap water is not recommended.

Frequency of irrigation

For patients who are new to Peristeen Anal Irrigation, it is recommended to irrigate on a daily basis. After one or two weeks some patients find that irrigation can be tried every second day. As the frequency of irrigation is decreased, it may be necessary to adjust other parameters; for example, the volume of water may need to be increased to achieve complete emptying. Some patients will find it necessary to irrigate every day but eventually most patients settle into a routine of irrigation every other day. Conducting irrigation at approximately the same time each day seems to work best for most people, but is not essential. Eating and drinking stimulate the bowel, so about 30 minutes after a meal gives the best chance of the irrigation working with the natural activity of the bowel and achieving the best emptying. The most convenient time can be chosen by the patient to fit in with their daily routine. Alternatively, it can be varied to fit around a changing routine giving the patient the maximum possible freedom.

The system and the rectal catheters should be stored at a temperature of between 2° and 25° Celsius and away from direct sunlight. The tubing should not be kinked when being stored.

The tubes can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. Patients may choose to change the tube with the blue connectors more frequently if desired. The outer surface of all the components (excluding the single use catheter) can be washed in mild soapy water and rinsed thoroughly. The Control Unit knob should be in the Resting/Storage position when the PAI System is not in use.

Product Evaluation:

Coloplast requests physicians to notify the company of any complications which may develop with the use of this device, and requests return of any used devices or components associated with the complication. For safe handling during shipment and upon receipt, Coloplast requests that devices be decontaminated prior to shipment. This is requested even though Coloplast will autoclave-sterilize any opened product returned. Alteration for the purposes of venting to prevent additional damage will be performed as required. If necessary, Coloplast may analyze the device, and the patient and physician may be asked to allow Coloplast to perform tests that might alter the condition of the device.

Any complications from the use of this device should be brought to our immediate attention by contacting: Quality Assurance, Product Evaluations Department, Coloplast Corp., 1601 West River Road North, Minneapolis, MN 55411
Toll-free telephone (800) 338-7908 in USA; or outside USA: (612) 337-7800

Product Order Information

To order, please contact your local sales representative or Coloplast Customer Service Department at: Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free telephone: (800) 258-3476; or outside USA: (612) 337-7800; or fax (866) 216-4161 or outside USA: (612) 337-7803.



COVER SHEET MEMORANDUM

From: Reviewer Name David Paduill
Subject: 510(k) Number K103254
To: The Record

Please list CTS decision code SE
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 Hold (Additional Information or Telephone Hold).
 Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	Attach A
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		9a	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			N/A
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age ≤ 21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days - < 2 years old)			✓
Child (2 years - < 12 years old)		✓	
Adolescent (12 years - < 18 years old)		✓	
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Nanotechnology		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Regulation Number 876.5980 Class* II Product Code KNT

Additional Product Codes: FCE (*If unclassified, see 510(k) Staff)

Review: Candyn Y Newland GRDB 1/31/11
 (Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 1/31/11
 (Division Director) (Date)

510(k) SUMMARY REQUIREMENTS 21 CFR 807.92				
All 510(k) summaries shall contain the following information:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared	✓		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	✓		
3	An identification of the legally marketed device to which the submitter claims equivalence.	✓		
4	A description of the device that is the subject of the premarket notification submission, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	✓		
5	A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. Or, if the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled	✓		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. Or, if the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section	✓		
510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence	✓		
8	A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence			✓
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section	✓		



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional**

K103254

Date: 1/31/2011
To: The Record
From: David Pudwill, Biomedical Engineer

Office: ODE
Division: DRGUD
Branch: GRDB

510(k) Holder: Coloplast A/S
Device Name: Peristeen™ Anal Irrigation (PAI) System
Contact: Brian Schmidt, Regulatory Affairs Manager
Address: 1601 West River Road
Minneapolis, MN 55411
Phone: (612) 302-4987
Fax: (612) 287-4138
Email: usbes@coloplast.com

I. Purpose and Submission Summary

The 510(k) holder has modified the Peristeen™ Anal Irrigation (PAI) System (K083770) for use in children. This is my first review of this traditional 510(k). The proposed device is the Peristeen™ Anal Irrigation (PAI) System manufactured by Coloplast A/S ("the sponsor"). The device is regulated under **21 CFR §876.5980** Gastrointestinal tube and accessories, and is a **Class II** device. The product codes for this device are **KNT and FCE**.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: <u>Prescription</u> or OTC)	Rx		
Truthful and Accuracy Statement	✓		
<u>510(k) Summary</u> or 510(k) Statement	✓		
Standards Form #3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf (Attachment A)	✓		
Clinical Trials Form http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf	9a		✓

III. Indications for Use

Proposed Indication

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Predicate Indication (K083770)

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter — which incorporates an inflatable balloon — inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by adolescent (12 years - < 18 years old), transitional adolescent (18 - < 21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

(b) (5)

IV. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	
Does the device design use software?		✓	
Is the device sterile?		✓	
Is the device reusable (not reprocessed single use)?	✓*		
Are "cleaning" instructions included for the end user?	✓*		

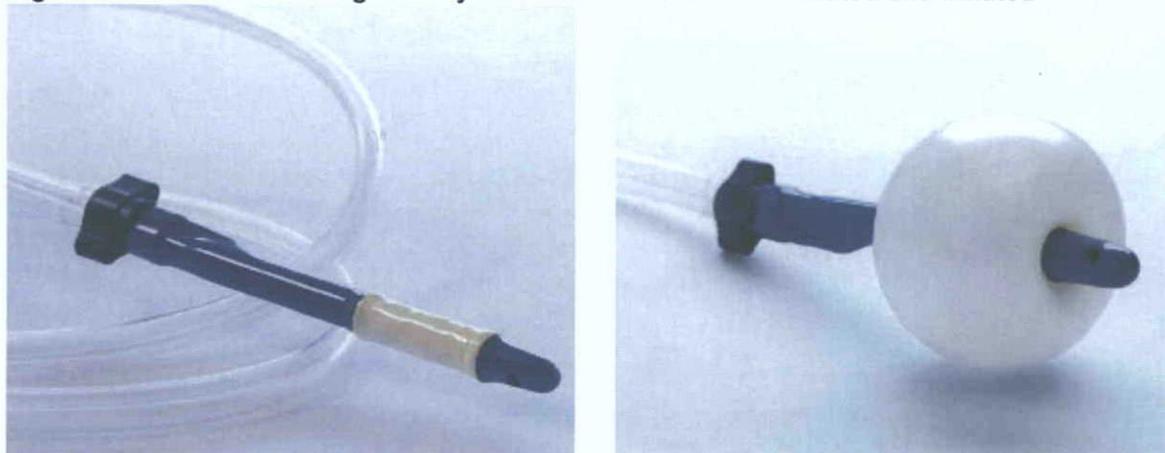
*All components are reusable for a specified number of times except for the rectal catheters which are labeled as single use only. The end user is instructed to clean the reusable components with soap and water.

Figure 1: Peristeen Anal Irrigation System



The Peristeen Anal Irrigation (PAI) System (see Figure 1) is intended for intermittent use to allow the flow of water into the colon that facilitates emptying of the colon/bowel in spinal cord injury patients with neurogenic bowel dysfunction. The PAI System consists of a single-use irrigation catheter (see Figure 2) that incorporates an inflatable balloon to keep the catheter in place during the procedure and retain the water that flows into the colon, preventing leakage while irrigating. The catheter is made of dip-molded polyvinyl chloride (PVC). The inflatable balloon is made of chloroprene and is attached around the proximal end of the catheter. The catheter is pre-lubricated with a hydrophilic polyvinylpyrrolidone coating over a basecoat of polyurethane to aid in insertion. The distal end of the catheter has a blue connector that attaches to the control unit tubing. The rectal catheter is non-sterile, intended for single-use.

Figure 2: Peristeen Anal Irrigation System Rectal Catheter Un-inflated and Inflated



A materials list was provided on page 38 of the submission, but the sponsor should be asked to provide an identification of all materials and colorants (manufacturer and formulation) used in each of the components. This was listed as a deficiency and the sponsor has adequately addressed this concern in Supplement 1.

The control unit (see Figure 3) is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake. The control unit housing has a manually operated knob that has the four positions indicated in Figure 3:

Figure 3: Peristeen Anal Irrigation System Control Unit



The rectal catheter and the water bag are connected to the control unit via double lumen silicone tubing with color-coded male ABS connectors. Water flows through the larger lumen and air flows through the smaller lumen. A blue connector attaches to the distal tip of the rectal catheter; a gray connector attaches to the gray lid for the water bag. The control unit is provided non-sterile and can be used up to 90 times before replacement.

A gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The lid is made of molded ABS with a nitrile butadiene rubber gasket; a silicone safety valve in the lid prevents pressure build-up. The suction tube is made of polyethylene and polypropylene. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

The polyethylene bag is designed to hold the water or isotonic saline solution used to perform the irrigation. There is a polyethylene threaded neck welded to the bag for attaching the lid. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

Polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh. All the system components can be stored in the nylon case provided with the PAI System; the storage case is also intended to protect the components from exposure to direct sunlight.

(b) (5)

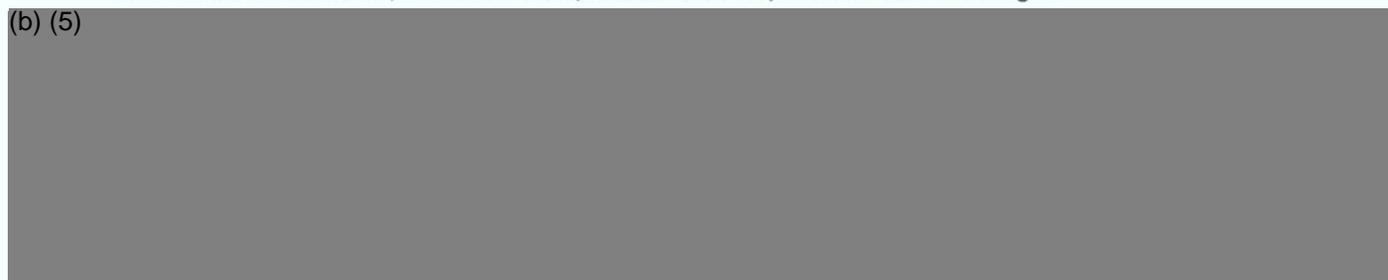


Figure 4: Large and Small Size Comparison for the PAI Rectal Balloon Catheter



V. Predicate Device Comparison

The sponsor has provided a substantial equivalence comparison in Section 11 of the submission.

Dependence on parent/caregiver

Coloplast acknowledges that some patients will be dependent on a parent or other caregiver. This would be most true for children (ages 2-11) but would also include adolescents and some patients into adulthood. This will naturally lead to unique questions or concerns related to the device. To adequately inform caregivers of their role and responsibility related to the use of PAI, a Caregiver Packet has been created that provides full product and use information. The Caregiver Packet was first created in response to the FDA's original question regarding adolescents and would address the same questions or concerns a Caregiver could potentially have, regardless of the age of the patient. It includes the following:

- Caregiver Brochure (provides introduction to system and product description)
- User Guide
- Quick Reference Guide
- Simplified Quick Reference Guide
- Health Care Notes form; providing specific recommendations for individual patients
- Anatomy Notes sheet (Pictorial of PAI in use); tool used to provide further clarification on device use
- Product brochure, providing ordering and part number information

Differences in cognitive abilities

Coloplast acknowledges that a child (2 to <12 year old) using PAI will have different cognitive abilities than an adolescent or adult. In addition, adults may have permanent impairments that result in cognitive limitations no different than a 2 year old. To address potential cognitive differences among PAI users, instructions for use have been drafted that seek to provide steps of use in simplified language. This Simplified Quick Reference Guide is provided as Attachment C-7. The Simplified Quick Reference Guide is not intended to take the place of the caregiver/physician in children but in some instances it would be a beneficial tool for children, i.e. older children who are able to maintain independence by administering their own care though proper training, practice and supervision. In addition, tools have been created for physicians and patients that will assist in informing and training patients. These tools are intended to be used as needed to remind patients and caregivers of specific, individualized instructions. The tools include:

- Health Care Notes form; providing specific recommendations for individual patients
- Anatomy Notes sheet (Pictorial of PAI in use); tool used to provide further clarification on device use

Differences in anatomy

(b) (4)



Frequency/Duration of Use

The PAI System is intended for regular use; the user generally needs 30-45 minutes for the bowel management procedure daily or every other day. This remains unchanged from the original 510(k)

Material

The small rectal catheter is composed of identical materials and has identical processing as the larger catheter from the original 510(k). Materials of the other components remain unchanged. Table 1 summarizes the material and functional similarities between the predicates and the proposed PAI System.

Table 1: Comparison of the proposed and predicate devices

	Peristeen Anal Irrigation (PAI) System K103254	Peristeen Anal Irrigation (PAI) System K083770
Target Population	Patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.	Spinal cord injured patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures
Age Groups	Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients	Adolescent (12 years - < 18 years old), transitional adolescent (18 - < 21 years old) and adult patients
Contraindications	Same	Peristeen™ Anal Irrigation must not be used in the following situations: <ul style="list-style-type: none"> • During the spinal shock phase • Known obstruction of the large bowel • Acute inflammatory bowel disease • Diverticulitis If you are pregnant and have never used anal irrigation before, you should not start the irrigation procedure during pregnancy.
Use Setting	Same	Health Care Facility and Home use
Design	Same	Rectal balloon catheter inflated with air; connected to water bag that instills water into lower colon
Materials	Same	PVC catheter Chloroprene balloon
Bowel Retention	Same	Rectal balloon catheter
Bowel Irrigation	Same	Irrigation fluid bag and pump provided
Enema / Medication Administration	Same	Allows for irrigation; No medication administration
Single Use	Same	Yes (rectal balloon catheter)
Duration of Use / Insertion	Same	<1 hour/intermittent every second day or daily as prescribed by physician
Fluid for Irrigation	Same	Water or isotonic saline
Placement of Catheter	Same	Rectum-Balloon inflated above sphincter
Balloon Inflation	Same	With air
Latex	Same	Does not contain natural rubber latex
Sterilization	Same	Non-Sterile

(b) (5)

VI. Labeling

Proposed draft labeling is provided in section 12 of the submission and a Caregiver Guide, a User Guide, a Quick Reference Guide, a Physician Guide, and other labeling are provided in Attachment C. Rx only is included in the draft labeling.

The existing Peristeen™ Anal Irrigation User Guide emphasizes that patients must carefully consult with their physician or health care provider to determine the proper use of the device, including the insertion depth for the catheter, amount of air to pump into the balloon, and amount of water to pump into the lower colon. Specifically, in the Quick Reference Guide and User Guide Operating Instructions section, Step 7, patients are directed to "Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly...When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump, but it is usually 3 to 4 times." Step 8 advises, "...Turn the knob on the control unit counter-clockwise to the water symbol. Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use." In addition to these recommendations, the *Troubleshooting* section of the User Guide indicates that "...The required amount of water is individual and your doctor or nurse will tell you how much water to use. An average procedure normally calls for a volume of ½-1 liter of water..."

Since the patient is advised to rely on the expertise of the physician/healthcare provider, Coloplast has provided additional labeling for physicians/healthcare providers to highlight the unique information needed to ensure proper device use and to stress their role and responsibilities to the indicated patient population. Along with available training for physicians and health care providers, Coloplast has drafted a Physician Instructions for Use document. In addition, Coloplast will provide a comprehensive Physician Information Package that includes specific information for the healthcare provider as well as tools to assist them in informing and training the patient.

The packet consists of the following:

- Caregiver Brochure
- Health Care Notes form; providing specific recommendations for individual patients
- Anatomy Notes sheet (Pictorial of PAI in use); tool used to provide further clarification on device use
- Product brochure
- User Guide
- Quick Reference Guide
- Simplified Quick Reference Guide
- Physician Instructions for Use

Coloplast has also determined that the issue of anatomical differences necessitates appropriate wording in the User Guide and the Quick Reference Guide in order to highlight differences that might exist among patients, in particular the importance of relying on your physician/healthcare provider to determine how far to insert the catheter, proper balloon inflation, and the proper amount of water to use during the irrigation procedure. These concerns are specifically addressed in steps 7 & 8 of the User Guide (page 5) and the Quick Reference Guide (page 3) and the 4th item of the *Troubleshooting* section in the User Guide

VII. Sterilization/Shelf Life/Reuse

Sterilization and shelf life information was provided on page 52 of the submission. The PAI Rectal Balloon Catheter is provided non-sterile and packaged in the same manner as the predicate device.

A one year shelf-life is proposed based on functional testing after accelerated and real-time aging.

The rectal catheter is labeled for single use only. The water bag is reusable for up to 15 times (every other day for a month), while all other components of the device are reusable for up to 90 times (every other day for 6 months).

VIII. Materials

The sponsor has provided the following list of materials on page 39 of their submission:

Table 2: Peristeen Anal Irrigation (PAI) System Materials

Components	Raw Materials
Rectal Catheter	(b) (4)
Catheter	
Balloon	
Lubricant Coating	
Base Coating	
Control Unit	
Internal Tubes	
One-way Valve	
Hand Pump Black	
Control Unit housing	
Female Luer Connector	
Lid/Suction Tube	
Lid	
Filling Nozzle	
Gasket	
Valve Seat	
Pressure Valve	
Female Luer Connector	
Suction Hose	
Cover Oneway Valve	
Water Bag	
Bag	
Volume Indicator	
Threading Socket	

IX. Biocompatibility

Biocompatibility testing on the Peristeen™ Anal Irrigation (PAI) System was provided in the original 510(k) K083770.

The sponsor has indicated on page 52 of their submission that the small size Peristeen™ Anal Irrigation Catheter is manufactured with identical materials and manufacturing processes therefore the testing provided in the original 510(k) is applicable to the smaller size catheter.

X. Software

Not applicable.

XI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XII. Performance Testing – Bench

(b) (4)



XIII. Performance Testing – Animal

Not applicable.

XIV. Performance Testing – Clinical

Not applicable.

XV. Postmarket Surveillance Information

Not Evaluated.

XVI. Substantial Equivalence Discussion

(b) (4)



	Yes	No	
1. Same Indication Statement?		✓	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		✓	If YES = Stop NSE
3. Same Technological Characteristics?	✓		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?	✓		If NO = Request Data
9. Data Demonstrate Equivalence?	✓		Final Decision: SE

Note: See link for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC

(b) (4)

XVII. Deficiencies

None.

XVIII. Contact History

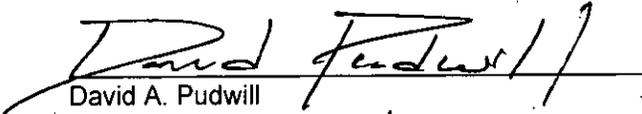
On Thursday, January 20, 2011, I sent Brian Schmidt an email with several minor labeling deficiencies and a request to modify the language "Latex Free" to "Does not contain natural rubber latex components." I also left Brian Schmidt an voicemail message on January 20, 2011. We spoke by phone on January 21, 2011 and he indicated that he should have responses to my concerns by early the next week. On January 24, 2011, Brian Schmidt provided the requested information and revisions.

On Wednesday, January 26, 2011, Brian Schmidt and I exchanged several emails to resolve issues with the Indications for Use form (prescription use checked) and obtaining a clean copy of the revised 510(k) Summary. I received all of the necessary documents on January 26, 2011.

XIX. Recommendation: SE

The subject device Coloplast™ Peristeen Anal Irrigation System is substantially equivalent to predicate devices under the following classification:

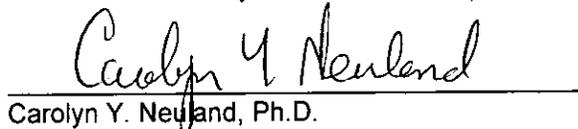
- Regulation Number: 21 CFR §876.5980
- Regulation Name: Gastrointestinal tube and accessories
- Regulatory Class: Class II
- Product Code: KNT, FCE



 David A. Pudwill

01/31/11

 Date



 Carolyn Y. Neuland, Ph.D.

1/31/11

 Date

Pudwill, David A

From: Brian Schmidt [USBES@Coloplast.com]
Sent: Wednesday, January 26, 2011 3:03 PM
To: Pudwill, David A
Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System
Attachments: K103254 Revised 510k Summary.pdf

Best Regards,

Brian

From: Pudwill, David A [mailto:David.Pudwill@fda.hhs.gov]
Sent: Wednesday, January 26, 2011 1:48 PM
To: Brian Schmidt
Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System

Brian Schmidt

(b) (4)



I thank you,

David A. Pudwill
Biomedical Engineer
Gastroenterology and Renal Devices Branch
HHS/FDA/CDRH/ODE/DRGUD/GRDB
White Oak Building 66 (WO66) - G225
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
(301) 796-5590 (ph)
(301) 847-8111 (fax)
david.pudwill@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

From: Brian Schmidt [mailto:USBES@Coloplast.com]
Sent: Wednesday, January 26, 2011 2:38 PM
To: Pudwill, David A

20

Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System

Hello Mr. Pudwill

(b) (4)

Best Regards,

Brian

From: Pudwill, David A [mailto:David.Pudwill@fda.hhs.gov]

Sent: Wednesday, January 26, 2011 1:35 PM

To: Brian Schmidt

Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System

Brian Schmidt,

(b) (4)

Thank you!

David A. Pudwill
Biomedical Engineer
Gastroenterology and Renal Devices Branch
HHS/FDA/CDRH/ODE/DRGUD/GRDB
White Oak Building 66 (WO66) - G225
10903 New Hampshire Ave.
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david.pudwill@fda.hhs.gov

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From: Brian Schmidt [mailto:USBES@Coloplast.com]

Sent: Tuesday, January 25, 2011 11:17 AM

To: Pudwill, David A

Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System

Dear Mr. Pudwill,

(b) (4)

Best Regards,

Brian Schmidt

Manager, Regulatory Affairs
Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411

Work: 612-302-4987
Cell: 612-968-9567

From: Pudwill, David A [mailto:David.Pudwill@fda.hhs.gov]
Sent: Monday, January 24, 2011 3:50 PM
To: Brian Schmidt
Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System

Mr. Schmidt,

(b) (4)

Thank you again,

David A. Pudwill
Biomedical Engineer
Gastroenterology and Renal Devices Branch
HHS/FDA/CDRH/ODE/DRGUD/GRDB
White Oak Building 66 (WO66) - G225
10903 New Hampshire Ave.
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david.pudwill@fda.hhs.gov

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From: Brian Schmidt [mailto:USBES@Coloplast.com]
Sent: Monday, January 24, 2011 4:43 PM
To: Pudwill, David A
Subject: FW: K103254 - Coloplast Peristeen Anal Irrigation System

Dear Mr. Pudwill,

(b) (4)

22

(b) (4) [Redacted]

[Redacted]

[Redacted]

Best Regards,

Brian Schmidt

Manager, Regulatory Affairs
Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411

Work: 612-302-4987
Cell: 612-968-9567

From: Pudwill, David A [mailto:David.Pudwill@fda.hhs.gov]
Sent: Thursday, January 20, 2011 4:59 PM
To: Brian Schmidt
Subject: K103254 - Coloplast Peristeen Anal Irrigation System

Brian Schmidt,

(b) (4) [Redacted]

(b) (4)



Thank you,

David A. Pudwill
Biomedical Engineer
Gastroenterology and Renal Devices Branch
HHS/FDA/CDRH/ODE/DRGUD/GRDB
White Oak Building 66 (WO66) - G225
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3. 510(K) SUMMARY

510(K) Owner's Name: Coloplast A/S

Address: Holtedam 1
3050 Humlebaek, Denmark
Establishment Registration: 9610694
Owner/Operator: 8010144

Phone/Fax/Email: Office: (612) 302-4987
Mobile: (612) 968-9567
Fax: (612) 287-4138
email: usb@coloplast.com

Name of Contact Person: Brian Schmidt
Regulatory Affairs Manager

Address/Contact: 1601 West River Road
Minneapolis, MN 55411

Date Prepared: November 2, 2010

Trade Name: Peristeen™ Anal Irrigation System

Common Name: Rectal Catheter and accessories and
Enema kit

Classification Name: 876.5980 Gastrointestinal tube & accessories
Class II and
876.5210 Enema kit
Class I (Exempt)

Product Code: KNT and FCE

Legally Marketed Devices To Which Your Firm Is Claiming Equivalence:

The Peristeen™ Anal Irrigation System is substantially equivalent in performance, indications, design and materials to the Peristeen™ Anal Irrigation System cleared on November 23, 2009 under premarket notification 510(k) number K083770.

Description Of The Device:

The Peristeen™ Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system may be purchased with a carrying case (toilet bag). The rectal catheter is single-use, but the other components may be used multiple times. Accessory kits are available for the components. The PAI system does not contain natural rubber latex components.

Intended Use Of The Device:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Technological Characteristics Compared To Predicate Device:

The proposed Peristeen™ Anal Irrigation System (expanded indications for use) is substantially equivalent to the Peristeen™ Anal Irrigation System.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence of the Peristeen™ Anal Irrigation System is supported by a comparison of the design, materials, and intended use compared to the predicate, as well as acceptable results from functional performance and biocompatibility testing.

Pudwill, David A

From: Brian Schmidt [USBES@Coloplast.com]
Sent: Wednesday, January 26, 2011 2:38 PM
To: Pudwill, David A
Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System
Attachments: K103254 Peristeen Indications for Use.pdf

Hello Mr. Pudwill,

(b) (4)

Best Regards,

Brian

From: Pudwill, David A [mailto:David.Pudwill@fda.hhs.gov]
Sent: Wednesday, January 26, 2011 1:35 PM
To: Brian Schmidt
Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System

Brian Schmidt,

(b) (4)

Thank you!

David A. Pudwill
Biomedical Engineer
Gastroenterology and Renal Devices Branch
HHS/FDA/CDRH/ODE/DRGUD/GRDB
White Oak Building 66 (WO66) - G225
10903 New Hampshire Ave.
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david.pudwill@fda.hhs.gov

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From: Brian Schmidt [mailto:USBES@Coloplast.com]
Sent: Tuesday, January 25, 2011 11:17 AM

27

To: Pudwill, David A
Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System

Dear Mr. Pudwill,

(b) (4)

Best Regards,

Brian Schmidt

Manager, Regulatory Affairs
Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411

Work: 612-302-4987
Cell: 612-968-9567

From: Pudwill, David A [mailto:David.Pudwill@fda.hhs.gov]
Sent: Monday, January 24, 2011 3:50 PM
To: Brian Schmidt
Subject: RE: K103254 - Coloplast Peristeen Anal Irrigation System

Mr. Schmidt,

(b) (4)

Thank you again,

David A. Pudwill
Biomedical Engineer
Gastroenterology and Renal Devices Branch
HHS/FDA/CDRH/ODE/DRGUD/GRDB
White Oak Building 66 (WO66) - G225
10903 New Hampshire Ave.
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From: Brian Schmidt [mailto:USBES@Coloplast.com]
Sent: Monday, January 24, 2011 4:43 PM
To: Pudwill, David A
Subject: FW: K103254 - Coloplast Peristeen Anal Irrigation System

Dear Mr. Pudwill,

(b) (4)



A response to confirm receipt of this email would be appreciated.

Do not hesitate to call me if you need any additional clarifications.

Best Regards,

Brian Schmidt

Manager, Regulatory Affairs
Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411

Work: 612-302-4987
Cell: 612-968-9567

From: Pudwill, David A [mailto:David.Pudwill@fda.hhs.gov]
Sent: Thursday, January 20, 2011 4:59 PM
To: Brian Schmidt
Subject: K103254 - Coloplast Peristeen Anal Irrigation System

Brian Schmidt,

(b) (4)



(b) (4)

Thank you,

David A. Pudwill
Biomedical Engineer
Gastroenterology and Renal Devices Branch
HHS/FDA/CDRH/ODE/DRGUD/GRDB
White Oak Building 66 (WO66) - G225
10903 New Hampshire Ave.
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(301) 796-6526 (ph)
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david.pudwill@fda.hhs.gov

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30

2. STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known):

Device Name: **Peristeen™ Anal Irrigation System**

Indications for Use:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Pudwill, David A

From: Brian Schmidt [USBES@Coloplast.com]
Sent: Monday, January 24, 2011 4:43 PM
To: Pudwill, David A
Subject: FW: K103254 - Coloplast Peristeen Anal Irrigation System
Attachments: Attachment 1-added proposed product codes.pdf; Attachment 2-Added -small- clarification to table.pdf; Attachment 3-Pregnancy typo fix.pdf; Attachment 4-Latex clarification.pdf; Table 1-Materials Summary.pdf

Dear Mr. Pudwill,

(b) (4)



Best Regards,

Brian Schmidt

Manager, Regulatory Affairs
Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411

Work: 612-302-4987
Cell: 612-968-9567

From: Pudwill, David A [mailto:David.Pudwill@fda.hhs.gov]

Sent: Thursday, January 20, 2011 4:59 PM
To: Brian Schmidt
Subject: K103254 - Coloplast Peristeen Anal Irrigation System

Brian Schmidt,

(b) (4)



Thank you,

David A. Pudwill
Biomedical Engineer
Gastroenterology and Renal Devices Branch
HHS/FDA/CDRH/ODE/DRGUD/GRDB
White Oak Building 66 (WO66) - G225
10903 New Hampshire Ave.
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33

3. 510(K) SUMMARY

510(K) Owner's Name: Coloplast A/S

Address: Hortedam 1
3050 Humlebaek, Denmark
Establishment Registration: 9610694
Owner/Operator: 8010144

Phone/Fax/Email: Office: (612) 302-4987
Mobile: (612) 968-9567
Fax: (612) 287-4138
email: usbes@coloplast.com

Name of Contact Person: Brian Schmidt
Regulatory Affairs Manager

Address/Contact: 1601 West River Road
Minneapolis, MN 55411

Date Prepared: November 2, 2010

Trade Name: Peristeen™ Anal Irrigation System

Common Name: Rectal Catheter and accessories and
Enema kit

Classification Name: 876.5980 Gastrointestinal tube & accessories
Class II and
876.5210 Enema kit
Class I (Exempt)

Product Code: KNT and FCE

Legally Marketed Devices To Which Your Firm Is Claiming Equivalence:

The Peristeen™ Anal Irrigation System is substantially equivalent in performance, indications, design and materials to the Peristeen™ Anal Irrigation System cleared on November 23, 2009 under premarket notification 510(k) number K083770.

Description Of The Device:

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Intended Use Of The Device:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Technological Characteristics Compared To Predicate Device:

The proposed Peristeen™ Anal Irrigation System (expanded indications for use) is substantially equivalent to the Peristeen™ Anal Irrigation System.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence of the Peristeen™ Anal Irrigation System is supported by a comparison of the design, materials, and intended use compared to the predicate, as well as acceptable results from functional performance and biocompatibility testing.

Device Feature/ Component	Peristeen™ Anal Irrigation-expanded Indications for use (this submission)	Peristeen™ Anal Irrigation (PAI)
Energy used and/or delivered:	Same as PAI	NA - Manual
Design:	Same as PAI	Rectal balloon catheter inflated with air, connected to water bag that instills water into lower colon
Performance:	Same as PAI	Testing of system and components including leakage, pressure, flow, wear, biocompatibility evaluation and testing, shelf life testing to support 1 year shelf life
Materials	Same as PAI	PVC catheter Chloroprene balloon
Bowel retention	Same as PAI	Rectal balloon catheter
Bowel irrigation	Same as PAI	Irrigation fluid bag and pump provided
Stool sampling	Same as PAI	No stool sampling
Enema/ medication administration	Same as PAI	Allows for irrigation; No medication administration
Drainage/collection	Same as PAI	No drainage/collection
Single use	Same as PAI	Yes (rectal balloon catheter)
Duration of use/insertion	Same as PAI	< 1 hour/intermittent every second day or daily as prescribed by physician
Fluid for irrigation	Same as PAI	Water or isotonic saline
Does not contain natural rubber latex components	Same as PAI	Yes
Placement of catheter	Same as PAI	Rectum-Balloon inflated above sphincter
Balloon is inflated with	Same as PAI	Air
Biocompatibility per ISO 10993	Same as PAI	Meets Standard
Sterility	Same as PAI	Provided non-sterile

B. Substantial Equivalence Conclusion

Based upon the device comparisons, the PAI System s substantially equivalent in performance, indications, design, and materials to the Coloplast Peristeen™ Anal Irrigation (PAI) system cleared on November 23, 2009 under premarket notification 510(k) number K083770.

I. DESCRIPTIVE INFORMATION

Non Sterile. Single Patient Use Only. **Does not contain natural rubber latex.**

Caution: Federal (USA) law restricts the use of this device to sale by or on the order of a physician.

A. Indications for Use

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21



3. 510(K) SUMMARY

510(K) Owner's Name: Coloplast A/S

Address: Hortedam 1
3050 Humleback, Denmark
Establishment Registration: 9610694
Owner/Operator: 8010144

Phone/Fax/Email: Office: (612) 302-4987
Mobile: (612) 968-9567
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Date Prepared: November 2, 2010

Trade Name: Peristeen™ Anal Irrigation System

Common Name: Rectal Catheter and accessories and
Enema kit

Classification Name: 876.5980 Gastrointestinal tube & accessories
Class II and
876.5210 Enema kit
Class I (Exempt)

Product Code: KNT and FCE

Legally Marketed Devices To Which Your Firm Is Claiming Equivalence:

The Peristeen™ Anal Irrigation System is substantially equivalent in performance, indications, design and materials to the Peristeen™ Anal Irrigation System cleared on November 23, 2009 under premarket notification 510(k) number K083770.

Description Of The Device:

The Peristeen™ Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system may be purchased with a carrying case (toilet bag). The rectal catheter is single-use, but the other components may be used multiple times. Accessory kits are available for the components. **The PAI System does not contain natural rubber latex components.**

Intended Use Of The Device:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Technological Characteristics Compared To Predicate Device:

The proposed Peristeen™ Anal Irrigation System (expanded indications for use) is substantially equivalent to the Peristeen™ Anal Irrigation System.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence of the Peristeen™ Anal Irrigation System is supported by a comparison of the design, materials, and intended use compared to the predicate, as well as acceptable results from functional performance and biocompatibility testing.

Device Feature/ Component	Peristeen™ Anal Irrigation-expanded Indications for use (this submission)	Peristeen™ Anal Irrigation (PAI)
Energy used and/or delivered:	Same as PAI	NA - Manual
Design:	Same as PAI	Rectal balloon catheter inflated with air, connected to water bag that instills water into lower colon
Performance:	Same as PAI	Testing of system and components including leakage, pressure, flow, wear, biocompatibility evaluation and testing, shelf life testing to support 1 year shelf life
Materials	Same as PAI	PVC catheter Chloroprene balloon Rectal balloon catheter
Bowel retention	Same as PAI	Irrigation fluid bag and pump provided
Bowel irrigation	Same as PAI	No stool sampling
Stool sampling	Same as PAI	Allows for irrigation; No medication administration
Enema/ medication administration	Same as PAI	No drainage/collection Yes (rectal balloon catheter)
Drainage/collection	Same as PAI	<1 hour/intermittent every second day or daily as prescribed by physician
Single use	Same as PAI	Water or isotonic saline Yes
Duration of use/insertion	Same as PAI	
Fluid for irrigation	Same as PAI	
Does not contain natural rubber latex components	Same as PAI	
Placement of catheter	Same as PAI	Rectum-Balloon inflated above sphincter
Balloon is inflated with	Same as PAI	Air
Biocompatibility per ISO 10993	Same as PAI	Meets Standard
Sterility	Same as PAI	Provided non-sterile

B. Substantial Equivalence Conclusion

Based upon the device comparisons, the PAI System s substantially equivalent in performance, indications, design, and materials to the Coloplast Peristeen™ Anal Irrigation (PAI) system cleared on November 23, 2009 under premarket notification 510(K) number K083770.

I. DESCRIPTIVE INFORMATION

Non Sterile. Single Patient Use Only. **Does not contain natural rubber latex.**

Caution: Federal (USA) law restricts the use of this device to sale by or on the order of a physician.

A. Indications for Use

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

B. Description of the device:

Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.

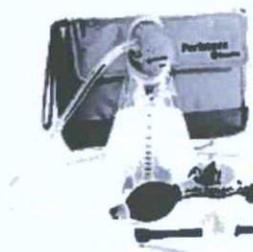


Figure 1: Peristeen Anal Irrigation (PAI) System

QUICK REFERENCE GUIDE FOR THE USER PERISTEEN ANAL IRRIGATION SYSTEM

Non-Sterile. Single Patient Use Only. Does not contain natural rubber latex

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Intended Use:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

For more information on the Peristeen Anal Irrigation System, including complete user instructions, intended use, contra-indications, and precautions, consult the **Peristeen Anal Irrigation User Guide**.

To use this system safely and effectively, you should get training from your doctor or home health care nurse before using it.

The first time you use this system, you should do so when your doctor or health care nurse is present.

PERISTEEN ANAL IRRIGATION - DESCRIPTION

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only. discard after use
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON ; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	STRAP	The STRAPS wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired. they have been tested to be sure that they will work for the number of times listed

Table 1 provides a summary of the components, materials, and user contact of the various components of the PAI system.

Table 1: Components, Materials, & User Contact – PAI System

	Components	Material	User Contact
Hydrophilic coated balloon catheter	Catheter	PVC	Direct contact rectal mucosal membrane
	Balloon	Chloroprene	Direct contact rectal mucosal membrane
	Coating	PVP	Direct contact rectal mucosal membrane
	Luer connector	ABS (Terluran GP22)	Direct contact rectal mucosal membrane
	Adhesive	Medicure 222 Gel	Direct contact rectal mucosal membrane
Connectors	Male luer connector	MABS (Terlux 2802 TR)	Indirect contact through flushing water
	Luer screw cap	ABS (Terluran GP22)	No contact
	Adhesive	Loctite 3321	Indirect contact through flushing water
Control Unit	Internal tubes	Silicone (Biosil)	Indirect contact through flushing water
	Internal tube coating	Talcum	Indirect contact through flushing water
	Tube connector	ABS (Terluran GP22)	Indirect contact through flushing water
	Silicone grease	Molykote 111	No contact
	One-way valve	PP / PVC / Silicone	No contact
	Black hand pump	PVC	No contact
	Exhaust cover	ABS (Terluran GP22)	No contact
	Female luer connector	ABS (Terluran GP22)	No contact
	Bottom cover	ABS (GPM 5500-1000)	No contact
	Top cover	ABS (GPM 5500-1000)	No contact
	Knob	ABS (GPM 5500-1000)	No contact
	CAM disk	PC / ABS	No contact
	Y-adaptor	ABS (Terluran GP22)	No contact
	Adhesives	Loctite 3321 Loctite 4031	Indirect contact through flushing water
	Washer	Stainless Steel	No contact
	Screw	Stainless Steel	No contact
	Insert nut	Brass	No contact
	Spring	Steel	No contact
	Valve spring	POM	No contact
	Tubing	Double-lumen tubes	PVC
Water bag	Bag	PA25/PE75	Indirect contact through flushing water
	Lid	ABS (GPM 5500)	No contact
	Filling nozzle	ABS (GPM 5500)	No contact
	Gasket	Silicone	No contact
	Silicone lubricant	Silicone paste	No contact
	O-ring	NBR	No contact
	Valve seat	ABS (GPM 5500)	No contact
	Pressure valve	Silicone	No contact
	Female luer connector	ABS (GPM 5500)	No contact
	Threading socket	PE	No contact
	Suction hose	Polyolefin	Indirect contact through flushing water
	Cover one-way valve	ABS (Cyclocac GPM 5500)	Indirect contact through flushing water
	Valve lip	EVA	Indirect contact through flushing water
	Volume indicator	Glue foil	No contact
	Adhesives	Loctite 3321 Loctite 4031	Indirect contact through flushing water

Pudwill, David A

From: Pudwill, David A
Sent: Thursday, January 20, 2011 5:59 PM
To: Brian Schmidt
Subject: K103254 - Coloplast Peristeen Anal Irrigation System

Brian Schmidt,

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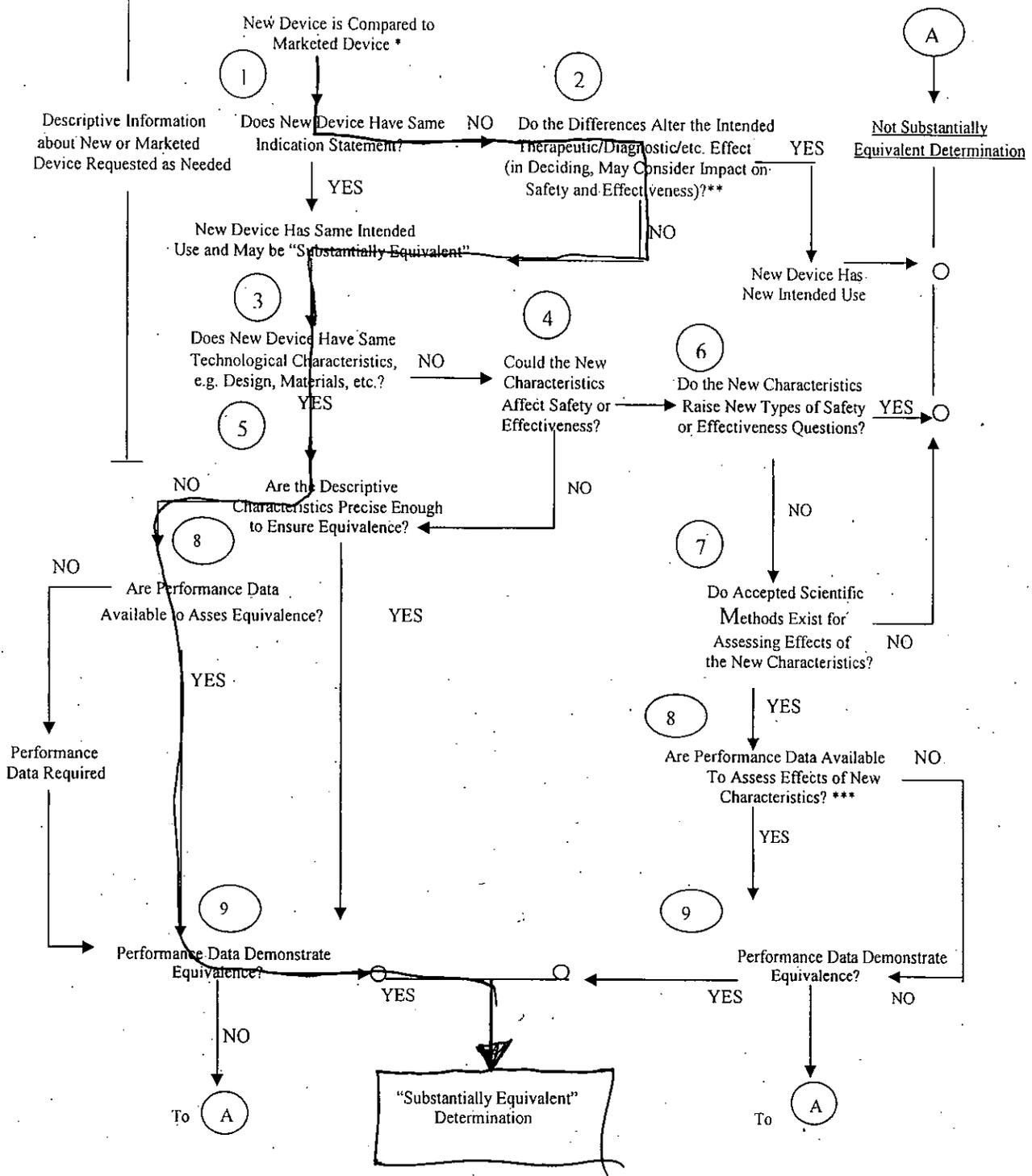
Thank you,

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510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.