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A B O G A D O S

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## SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISION DE NUEVAS CREACIONES

E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

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Tra. 2 PATENTES

Eve: 1 REGDEPOSITO

Art 128 TRANSFORMACION Folio: 50

Ref.: Expediente No. 06-109.493  
Solicitud de Patente a nombre de  
, Ethicon, Inc.

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 A No. 94-76, of. 305, obrando como apoderada de la sociedad Ethicon, Inc., domiciliada en Somerville, New Jersey, Estados Unidos de América, solicitante de la patente de la referencia, atentamente me permito presentar copia certificada de la solicitud de patente número 11/263,010 presentada en Estados Unidos de América el día 31 de octubre de 2005, con la debida traducción de lo pertinente.

Señor Superintendente,

  
JIMENA ESCOBAR URIBE  
C.C.39.779.452 de Usaquén  
T.P. 68228  
Cód. 5376

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**ESTADOS UNIDOS DE AMERICA  
A TODOS AQUELLOS A QUIENES EL PRESENTE LLEGUE:**

**DEPARTAMENTO DE COMERCIO DE LOS ESTADOS UNIDOS  
Oficina de Patentes y Marcas de los Estados Unidos**

23 de octubre de 2006

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada más adelante, que cumplieron con los requerimientos para concederse una fecha de presentación de acuerdo con 35 USC 111.

Número de Solicitud: 11/263,010

Fecha de Presentación: 31 de octubre de 2005

**EL CÓDIGO DEL PAÍS Y EL NÚMERO DE SU SOLICITUD DE  
PRIORIDAD, PARA SER USADA EN LA PRESENTACIÓN  
EXTRANJERA BAJO EL CONVENIO DE PARÍS ES US11/263,010.**

Por la autoridad de  
Bajo el Secretario de Comercio para la Propiedad Intelectual y el Director de la  
Oficina de Patentes y Marcas de los Estados Unidos de América

(fdo) L. EDELEN  
Oficial Certificador  
Sello oficial de la Oficina de Patentes y Marcas de los  
Estados Unidos de América

PA 703521

**THE UNITED STATES OF AMERICA**

**TO ALL TO WHOM THESE PRESENTS SHALL COME**

**UNITED STATES DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**October 23, 2006**

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.**

**APPLICATION NUMBER: 11/263,010**

**FILING DATE: October 31, 2005**

**THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US11/263,010**

**By Authority of the**

**Under Secretary of Commerce for Intellectual Property  
and Director of the United States Patent and Trademark Office**



*L. Edelen*

**L. EDELEN  
Certifying Officer**

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| UTILITY<br>PATENT APPLICATION<br>TRANSMITTAL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                    | Attorney Docket No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | ASP-8089USNP                                                  |      |                  |                 |           |                    |  |      |                  |  |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                    | Title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | APPARATUS AND METHOD FOR PROVIDING FLOW TO ENDOSCOPE CHANNELS |      |                  |                 |           |                    |  |      |                  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                    | Express Mail Label No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | EL981541857US                                                 |      |                  |                 |           |                    |  |      |                  |  |
| 17224<br>U.S.<br>Only for new nonprovisional applications under 37 CFR 1.53(b)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                    | 12821<br>U.S. PTO<br>1/263010<br>103106                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                               |      |                  |                 |           |                    |  |      |                  |  |
| APPLICATION ELEMENTS<br>See MPEP Chapter 800 concerning utility patent application contents.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                    | ADDRESS TO: Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, VA 22313-1450                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                               |      |                  |                 |           |                    |  |      |                  |  |
| <p>1. <input checked="" type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17)<br/>(submit an original and a duplicate for fee processing)</p> <p>2. <input type="checkbox"/> Applicant claims small entity status.</p> <p>3. <input checked="" type="checkbox"/> Specification [Total Pages 30]<br/>(Preferred arrangement set forth below)</p> <ul style="list-style-type: none"><li>- Descriptive Title of the Invention</li><li>- Cross Reference to Related Applications</li><li>- Statement Regarding Fed sponsored R&amp;D</li><li>- Reference to sequence listing, a table, or a computer program listing appendix</li><li>- Background of the Invention</li><li>- Brief Summary of the Invention</li><li>- Brief Description of the Drawings (if filed)</li><li>- Detailed Description</li><li>- Claim(s)</li><li>- Abstract of the Disclosure</li></ul> <p>4. <input checked="" type="checkbox"/> Drawing(s) (35 USC 113) [Total Sheets 8]</p> <p>5. Oath or Declaration [Total Pages 3]</p> <ul style="list-style-type: none"><li>a. <input checked="" type="checkbox"/> unexecuted</li><li>b. <input type="checkbox"/> Copy from a prior application (37 CFR 1.63(d))<br/>(for continuation/divisional with Box 18 completed)</li><li>i. <input type="checkbox"/> <b>DELETION OF INVENTOR(S)</b><br/>Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).</li></ul> <p>6. <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76</p> |                    | <p>7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)</p> <p>8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)</p> <ul style="list-style-type: none"><li>a. <input type="checkbox"/> Computer Readable Form (CRF)</li><li>b. <input type="checkbox"/> Specification Sequence Listing on:<ul style="list-style-type: none"><li>i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or</li><li>ii. <input type="checkbox"/> paper</li></ul></li><li>c. <input type="checkbox"/> Statement verifying identity of above copies</li></ul> <p><b>ACCOMPANYING APPLICATION PARTS</b></p> <p>9. <input type="checkbox"/> Assignment Papers (cover sheet &amp; document(s))</p> <p>10. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney<br/>(when there is an assignee)</p> <p>11. <input type="checkbox"/> English Translation Document (if applicable)</p> <p>12. <input type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations</p> <p>13. <input type="checkbox"/> Preliminary Amendment</p> <p>14. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503)<br/>(Should be specifically itemized)</p> <p>15. <input type="checkbox"/> Certified Copy of Priority Document(s)<br/>(if foreign priority is claimed)</p> <p>16. <input type="checkbox"/> Request and Certifications under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.</p> <p>17. <input type="checkbox"/> Other</p> |                                                               |      |                  |                 |           |                    |  |      |                  |  |
| <p>18. <input type="checkbox"/> If a CONTINUING APPLICATION, check appropriate box and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:</p> <p><input type="checkbox"/> Continuation <input type="checkbox"/> Divisional <input type="checkbox"/> Continuation-in-Part (CIP) of prior application No.: , filed .</p> <p>Prior application information: Examiner Group Art Unit:</p> <p>For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                               |      |                  |                 |           |                    |  |      |                  |  |
| <p>19. CORRESPONDENCE ADDRESS</p> <p><input checked="" type="checkbox"/> Customer Number or Bar Code Label 000027777 or <input type="checkbox"/> Correspondence Address below</p> <p>Name: Philip S. Johnson, Esq.<br/>Address: Johnson &amp; Johnson<br/>One Johnson &amp; Johnson Plaza<br/>New Brunswick, NJ 08933-7003 USA</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                               |      |                  |                 |           |                    |  |      |                  |  |
| <p>20. TELEPHONE CONTACT</p> <p>Please direct all telephone calls or telefaxes to Andrew C. Farmer at:<br/>Telephone: (732) 524-2825 Fax: (732) 524-2808</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                               |      |                  |                 |           |                    |  |      |                  |  |
| <p>21. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED</p> <table border="1"><tr><td>NAME</td><td>Andrew C. Farmer</td><td>Reg. No. 35,888</td></tr><tr><td>SIGNATURE</td><td>/Andrew C. Farmer/</td><td></td></tr><tr><td>DATE</td><td>October 31, 2005</td><td></td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                               | NAME | Andrew C. Farmer | Reg. No. 35,888 | SIGNATURE | /Andrew C. Farmer/ |  | DATE | October 31, 2005 |  |
| NAME                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Andrew C. Farmer   | Reg. No. 35,888                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                               |      |                  |                 |           |                    |  |      |                  |  |
| SIGNATURE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | /Andrew C. Farmer/ |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                               |      |                  |                 |           |                    |  |      |                  |  |
| DATE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | October 31, 2005   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                               |      |                  |                 |           |                    |  |      |                  |  |

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| <b>FEE TRANSMITTAL</b> | <i>Complete if Known</i> |                                                        |
|                        | Application Number       |                                                        |
|                        | Filing Date              | October 31, 2005                                       |
|                        | Inventors                | Sau-Min Lin, Robert C. Platt, Jr.,<br>Vinod Michandani |
|                        | Group Art Unit           |                                                        |
|                        | Examiner Name            |                                                        |
|                        | Attorney Docket Number   | ASP-5039USNP                                           |

**FEE CALCULATION**

**CLAIMS AS FILED**

| (1)                                                                                                                                                                                                                                                                  | (2)          | (3)          | (4)                                                                                                                        | (5)                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|----------------------------------------------------------------------------------------------------------------------------|--------------------|
| FOR:                                                                                                                                                                                                                                                                 | NUMBER FILED | NUMBER EXTRA | RATE                                                                                                                       | BASIC FEE \$300.00 |
| TOTAL CLAIMS                                                                                                                                                                                                                                                         | 17 - 20 =    | 0            | x 50.00                                                                                                                    | \$ 0.00            |
| INDEPENDENT CLAIMS                                                                                                                                                                                                                                                   | 2 - 3 =      | 0            | x 200.00                                                                                                                   | \$ 0.00            |
| SEARCH FEE                                                                                                                                                                                                                                                           | NA           | NA           | NA                                                                                                                         | \$ 500.00          |
| EXAMINATION FEE                                                                                                                                                                                                                                                      | NA           | NA           | NA                                                                                                                         | \$ 200.00          |
| APPLICATION SIZE FEE<br><small>If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(3) and 37 CFR 1.16(a).</small> | 0 - 100 =    | /50          | x 250.00 (If the specification and drawings exceed 100 sheets of paper, for each additional 50 sheets or fraction thereof) | \$                 |
| MULTIPLE DEPENDENT CLAIMS <input checked="" type="checkbox"/>                                                                                                                                                                                                        |              | N/A          | \$360.00                                                                                                                   |                    |
|                                                                                                                                                                                                                                                                      |              |              | TOTAL FEES                                                                                                                 | \$ 1000.00         |

**METHOD OF PAYMENT**

- ☒ Please charge Deposit Account No. 10-0750/ASP-5039USNP/ACF in the amount of \$1,000.00. Three copies of this sheet are enclosed.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the filing of this communication, or credit any overpayment, to Account No. 10-0750/ASP-5039USNP/ACF. Three copies of this sheet are enclosed.

|                       |                    |                        |                                 |
|-----------------------|--------------------|------------------------|---------------------------------|
| <b>SUBMITTED BY:</b>  |                    |                        | <i>Complete (if applicable)</i> |
| Typed or Printed Name | Andrew C. Farmer   |                        | Reg. No. 35,868                 |
| Signature             | /Andrew C. Farmer/ | Date: October 31, 2005 | Deposit Account No. 10-0750     |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Szu-Min Lin et al.

For : APPARATUS AND METHOD FOR PROVIDING FLOW  
TO ENDOSCOPE CHANNELS

Express Mail Certificate

"Express Mail" mailing number: EL961541857US

Date of Deposit: October 31, 2005

I hereby certify that this complete application, including specification pages, claims, informal drawings and an unexecuted Declaration and Power of Attorney, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Ruthann Kreiger  
(Typed or printed name of person mailing paper or fee)

\ Ruth Ann Kreiger \  
(Signature of person mailing paper or fee)

**APPARATUS AND METHOD FOR PROVIDING FLOW  
TO ENDOSCOPE CHANNELS**

**5 BACKGROUND OF THE INVENTION**

The present invention relates to the decontamination arts including the sterilization arts. It finds particular application in conjunction with the decontamination of medical devices, especially medical devices such as endoscopes and other devices  
10 having channels or lumens that must be decontaminated after use.

Endoscopes and similar medical devices having channels or lumens formed therethrough are being used on an ever increasing basis in the performance of medical procedures. The popularity of these devices has led to calls for improvements in the  
15 decontamination of these devices between use, both in terms of the speed of the decontamination and the effectiveness of the decontamination.

One popular method for cleaning and disinfection or sterilization of such endoscopes employs an automated endoscope reprocessor which both washes and then  
20 disinfects or sterilizes the endoscope. Typically such a unit comprises a basin with a selectively opened and closed cover member to provide access to the basin. Pumps connect to various channels through the endoscope to flow fluid therethrough and an additional pump flows fluid over the exterior surfaces of the endoscope. Typically, a detergent washing cycle is followed by rinsing and then a sterilization or disinfection  
25 cycle and rinse.

Traditionally, connections are made to each of the various ports on the endoscope and fluids for washing and sterilization or disinfection are flowed through these ports and from there through the channels to clean and sterilize or disinfect the  
30 channels. The number of connections is not insignificant and due to the difference in channels sizes each port must be connected to the proper supply tube on the endoscope processor. The present invention eases this process by providing fewer connections and further helps to eliminate errors in making the connections.

**SUMMARY OF THE INVENTION**

5 A method, according to the present invention, provides flow to multiple channels in an endoscope during an endoscope decontamination procedure. The method comprises the steps of: inserting a first member into a first chamber in a body of an endoscope through an opening into the first chamber, the first chamber being intersected by a first lumen and a second lumen; separating fluidly the first lumen from the second lumen in the first chamber via the first member; flowing fluid through a first  
10 channel through the first member into the first lumen; and flowing fluid through a second channel through the first member into the second lumen.

In one aspect of the invention, a third lumen intersects the first chamber, and the method further comprises the steps of separating fluidly the third lumen from the first  
15 lumen and the second lumen via the first member and flowing fluid through a third channel through the first member into the third lumen.

In another aspect of the invention, a second member is inserted into a second chamber in the body of the endoscope through an opening into the second chamber.  
20 The second chamber is intersected by a third lumen and a fourth lumen. The method further includes the steps of separating fluidly the third lumen from the fourth lumen in the second chamber via the second member; flowing fluid through a third channel through the second member into the third lumen; and flowing fluid through a fourth channel through the second member into the fourth lumen. Preferably, the first  
25 member and second member are connected to each other.

The fluid can comprise a cleaning fluid and/or a disinfectant or a sterilant and is preferably liquid.

30 To reduce occlusions formed between the channel connector and the endoscope, the method preferably includes the step of moving the first member within the first chamber. One way in which this can be accomplished comprises flowing fluid under pressure into the first chamber to move the first member outwardly thereof. It can

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further comprise urging the first member back into the first chamber via a biasing member, such as a spring.

A channel connector according to the present invention is adapted to provide flow to multiple channels in an endoscope during an endoscope decontamination procedure. The channel connector comprises a first member sized and shaped to fit within a first chamber in a body of an endoscope through an opening into the first chamber. A first channel passes through the first member and has one end facing a first lumen in the endoscope when the first member is received within the first chamber and another end terminating in a first connector. A second channel passes through the first member and has one end facing a second lumen in the endoscope when the first member is received within the first chamber and another end terminating in a second connector. Isolation means on the first member fluidly separates the first lumen from the second lumen at the first chamber.

The channel connector can further comprise a third channel through the first member and additional isolation means on the first member for isolating the third channel from the first lumen and from the second lumen when the first member is fully received within the first chamber. Fluid introduced through the third channel under pressure will tend to urge the first member outwardly of the first chamber. Rather than provide a separate channel, the first member can comprise a recess where the first channel exits the first member, which location is opposite the opening into the first chamber, so that fluid flowing through the first channel under pressure will create a pressure in the recess tending to urge the first member outwardly of the first chamber. An excess of fluid or an increase in its pressure can be used to control the force urging the first member outwardly.

# BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take form in various components and arrangements of components and in various steps and arrangements of steps. The drawings are for

purposes of illustrating preferred embodiments only, and are not to be construed as limiting the invention.

FIG. 1 is a front elevational view of a decontamination apparatus in accordance with the present invention;

FIG. 2 is a diagrammatic illustration of the decontamination apparatus shown in FIG. 1, with only a single decontamination basin shown for clarity;

FIG. 3 is a cut-away view of an endoscope suitable for processing in the decontamination apparatus of FIG. 1;

FIG. 4 is a detailed cut-away view of the head of the endoscope of FIG. 3, showing a channel connector according to the present invention;

FIG. 5 is a detailed cut-away view of a portion of an alternative channel connector in the endoscope of FIG. 3 according to the present invention; and

FIG. 6 is a detailed cut-away view of a portion of another alternative channel connector in the endoscope of FIG. 3 according to the present invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 shows a decontamination apparatus for decontaminating endoscopes and other medical devices which include channels or lumens formed therethrough; FIG. 2 shows the apparatus in block diagram form. The decontamination apparatus generally includes a first station 10 and a second station 12 which are at least substantially similar in all respects to provide for the decontamination of two different medical devices simultaneously or in series. First and second decontamination basins 14a, 14b receive the contaminated devices. Each basin 14a, 14b is selectively sealed by a lid 16a, 16b, respectively, preferably in a microbe-blocking relationship to prevent the entrance of

environmental microbes into the basins 14a, 14b during decontamination operations. The lids can include a microbe removal or HEPA air filter formed therein for venting.

A control system 20 includes one or more microcontrollers, such as a programmable logic controller (PLC), for controlling decontamination and user interface operations. Although one control system 20 is shown herein as controlling both decontamination stations 10, 12, those skilled in the art will recognize that each station 10, 12 can include a dedicated control system. A visual display 22 displays decontamination parameters and machine conditions for an operator and at least one printer 24 prints a hard copy output of the decontamination parameters for a record to be filed or attached to the decontaminated device or its storage packaging. The visual display 22 is preferably combined with a touch screen input device. Alternatively, a keypad or the like is provided for input of decontamination process parameters and for machine control. Other visual gauges 26 such as pressure meters and the like provide digital or analog output of decontamination or medical device leak testing data.

FIG. 2 diagrammatically illustrates one station 10 of the decontamination apparatus. Those skilled in the art will recognize that the decontamination station 12 is preferably similar in all respects to the station 10 illustrated in FIG. 2. However, the station 12 has not been shown in FIG. 2 for clarity. Further, the decontamination apparatus can be provided with a single decontamination station or multiple stations.

The decontamination basin 14a receives an endoscope 200 (see FIG. 3) or other medical device therein for decontamination. Any internal channels of the endoscope 200 are connected with flush lines 30, preferably via a flexible interconnect tube 108 between an outlet 31 of the flush line a connection on the endoscope 200. Each flush line 30 is connected to an outlet of a pump 32. The pumps 32 are preferably peristaltic pumps or the like that pump fluid, such as liquid and air, through the flush lines 30 and any internal channels of the medical device. Specifically, the pumps 32 either can draw liquid from the basin 14a through a filtered drain 34 and a first valve S1, or can draw decontaminated air from an air supply system 36 through a valve S2. The air supply system 36 includes a pump 38 and a microbe removal air filter 40 that filters microbes from an incoming air stream. It is preferable that each flush line 30 be provided with a

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dedicated pump 32 to ensure adequate fluid pressure and to facilitate the individual monitoring of the fluid pressure in each flush line 30. A pressure switch or sensor 42 is in fluid communication with each flush line 30 for sensing excessive pressure in the flush line. Any excessive pressure sensed is indicative of a partial or complete blockage, e.g., by bodily tissue or dried bodily fluids, in a device channel to which the relevant flush line 30 is connected. The isolation of each flush line 30 relative to the others allows the particular blocked channel to be easily identified and isolated, depending upon which sensor 42 senses excessive pressure.

The basin 14a is in fluid communication with a water source 50 such as a utility or tap water connection including hot and cold inlets and a mixing valve 52 flowing into a break tank 56. A microbe removal filter 54, such as a 0.2  $\mu\text{m}$  or smaller absolute pore size filter, decontaminates the incoming water which is delivered into the break tank 56 through the air gap to prevent backflow. A pressure type level sensor 59 monitors liquid levels within the basin 14a. An optional water heater 53 can be provided if an appropriate source of hot water is not available.

The condition of the filter 54 can be monitored by directly monitoring the flow rate of water therethrough or indirectly by monitoring the basin fill time using a float switch or the like. When the flow rate drops below a select threshold, this indicates a partially clogged filter element that requires replacement.

A basin drain 62 drains liquid from the basin 14a through an enlarged helical tube 64 into which elongated portions of the endoscope 200 can be inserted. The drain 62 is in fluid communication with a recirculation pump 70 and a drain pump 72. The recirculation pump 70 recirculates liquid from the basin drain 62 to a spray nozzle assembly 60 which sprays the liquid into the basin 14a and onto the endoscope 200. Coarse and fine screens 71 and 73, respectively, filter out particles in the recirculating fluid. The drain pump 72 pumps liquid from the basin drain 62 to a utility drain 74. A level sensor 76 monitors the flow of liquid from the pump 72 to the utility drain 74. The pumps 70 and 72 can be simultaneously operated such that liquid is sprayed into the basin 14a while it is being drained to encourage the flow of residue out of the basin

and off of the device. Of course, a single pump and a valve assembly could replace the dual pumps 70, 72.

5 An inline heater 80, with temperature sensors 82, downstream of the recirculation pump 70 heats the liquid to optimum temperatures for cleaning and disinfection. A pressure switch or sensor 84 measures pressure downstream of the circulation pump 70.

10 Detergent solution 86 is metered into the flow upstream of the circulation pump 70 via a metering pump 88. A float switch 90 indicates the level of detergent available. Typically, only a small amount of disinfectant 92 is required. To more accurately meter this, a dispensing pump 94 fills a pre-chamber 96 under control of a hi/low level switch 98 and of course the control system 20. A metering pump 100 meters a precise quantity of disinfectant as needed.

15 Endoscopes and other reusable medical devices often include a flexible outer housing or sheath 102 surrounding the individual tubular members and the like that form the interior channels and other parts of the device. This housing 102 thus forms a closed interior space 104, between it and the interior parts of the endoscope, which is  
20 isolated from patient tissues and fluids during medical procedures. It is important that the sheath be maintained intact, without cuts or other holes that would allow contaminants into the interior space 104. The interior space can also be compromised by an internal leak, such as through a cut in an endoscope lumen. Therefore, the decontamination apparatus includes means for testing the integrity of such as sheath.

25 An air pump, either the pump 38 or another pump 110, pressurizes the interior space 104 through a conduit 112 and a valve S5 and a test connection 106, preferably one of the flexible tubes 108 connects to port 254 which leads to the interior space 104 (see FIG. 3). These structures will be more fully described in the full description of  
30 FIG. 3 to follow. Preferably, a filter 113 removes particles from the pressurizing air. An overpressure switch 114 prevents accidental over pressurization of the sheath. Upon full pressurization, the valve S5 is closed and a pressure sensor 116 looks for a drop in pressure in the conduit 112 which would indicate the escape of air through the

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sheath. A valve S6 selectively vents the conduit 112 and the sheath through an optional filter 118 when the testing procedure is complete. An air buffer 120 smoothes out pulsation of pressure from the air pump 110.

5           The air buffer 120 can also be used to determine whether the test connection 106 is properly mated with the port 254. The test connection 106 incorporates a normally closed valve 109 which opens only upon proper connection to the flexible tube 108. If the connection is not made the aforementioned leak determination test will not by itself identify this failed connection. The air buffer 120 would pressurize and no  
10   leakage would occur due to the closed valve at the test connection 106. Similarly the port 254 incorporates a normally closed valve which opens only upon proper connection to the tube 108. When both these connections are not properly made the leak test of the interior space 104 may give false results. Unconnected status can be  
15   examined by determining whether a volume other than the air buffer 120 is being pressurized.

          First the air buffer 120 and interior space 104 are pressurized to a predetermined level, such as 250 mbar. Then valve S5 is closed, thus isolating the air buffer 120 from the test connection 106. Pressure is vented through valve S6, which if the test  
20   connection 106 is properly attached should be venting the interior space 104, but if not properly attached this merely vents a portion of the conduit 112. Valve S6 is closed and valve S5 opened to put the test connection 106 back into fluid communication with the air buffer 120. After the pressure settles, it is measured. It should have dropped to a measurable degree through the action of air in the air buffer 120 filling the interior  
25   space 104. If however, it drops by a small amount that indicates that air is not flowing into the interior space 104 but is trapped by the valve in the test connection 106. Proper pressures can be easily determined based upon the volume of the air buffer 120 and interior space 104. To accommodate most commercial endoscopes the air buffer 120 should have a volume of between about 20 ml (which is about 10% of small  
30   endoscope) to about 1000 ml (which is about 300% of large endoscope). Ideally the volume should be between about 50% and 200% of the volume of the endoscope and most ideally it would approximate the volume of the endoscope interior space 104. Given the variability in endoscope volumes, the volume of the air buffer can be

adjustable, such as by providing multiple air buffers 120 and control valves for each one. Given the starting pressure of 250 mbar, a proper connection should typically result in a final pressure below 190 mbar. Proper pressure for a particular endoscope can be calculated based upon the volumes of the air buffer 120 and endoscope interior space 104. The interconnection piping should be kept to a minimal volume to enhance the accuracy.

An alternative method to check the proper connection at the test connection 106 is to close valve S5 while pressurizing the air buffer 120, let the pressure settle, and then open valve S5. Accurate pressurization of the air buffer 120 would require a pressure sensor (not shown) at the air buffer 120 so located as to not be blocked by closure of valve S5. Pressure is then checked. If the pressure has not dropped sufficiently it indicates that air is not flowing into the interior space 104, but is instead being blocked at the test connection 106 by the valve 109.

Preferably, each station 10 and 12 each contain a drip basin 130 and spill sensor 132 to alert the operator to potential leaks.

An alcohol supply 134 controlled by a valve S3 can supply alcohol to the channel pumps 32 after rinsing steps to assist in removing water from the endoscope channels.

Flow rates in the supply lines 30 can be monitored via the channel pumps 32 and the pressure sensors 42. The channels pumps 32 are peristaltic pumps which supply a constant flow. If one of the pressure sensors 42 detects too high a pressure the associated pump 32 cycles off. The flow rate of the pump 32 and its percentage on time provide a reasonable indication of the flow rate in an associated line 30. These flow rates are monitored during the process to check for blockages in any of the endoscope channels. Alternatively, the decay in the pressure from the time the pump 32 cycles off can also be used to estimate the flow rate, with faster decay rates being associated with higher flow rates.

A more accurate measurement of flow rate in an individual channel may be desirable to detect more subtle blockages. A metering tube 136 having a plurality of level indicating sensors 138 fluidly connects to the inputs of the channel pumps 32. One preferred sensor arrangement provides a reference connection at a low point in the metering tube and a plurality of sensors 138 arranged vertically thereabove. By passing a current from the reference point through the fluid to the sensors 138 it can be determined which sensors 138 are immersed and therefore determine the level within the metering tube 136. Other level sensing techniques can be applied here. By shutting valve S1 and opening a vent valve S7 the channel pumps 32 draw exclusively from the metering tube. The amount of fluid being drawn can be very accurately determined based upon the sensors 138. By running each channel pump in isolation the flow therethrough can be accurately determined based upon the time and the volume of fluid emptied from the metering tube. A flow rate which is too slow indicates a blocked channel and a flow rate which is too fast indicates that the channel is probably disconnected and therefore providing no resistance to the flow.

In addition to the input and output devices described above, all of the electrical and electromechanical devices shown are operatively connected to and controlled by the control system 20. Specifically, and without limitation, the switches and sensors 42, 59, 76, 84, 90, 98, 114, 116, 132 and 136 provide input I to the microcontroller 28 which controls the decontamination and other machine operations in accordance therewith. For example, the microcontroller 28 includes outputs O that are operatively connected to the pumps 32, 38, 70, 72, 88, 94, 100, 110, the valves S1-S7, and the heater 80 to control these devices for effective decontamination and other operations.

Turning also to FIG. 3, an endoscope 200 has a head part 202, in which openings 204 and 206 are formed, and in which, during normal use of the endoscope 200, an air/water valve and a suction valve are arranged. A flexible insertion tube 208 is attached to the head part 202, in which tube a combined air/water channel 210 and a combined suction/biopsy channel 212 are accommodated.

A separate air channel 213 and water channel 214, which at the location of a joining point 216 merge into the air/water channel 210, are arranged in the head part

202. Furthermore, a separate suction channel 217 and biopsy channel 218, which at the location of the joining point 220 merge into the suction/biopsy channel 212, are accommodated in the head part 202.

5 In the head part 202, the air channel 213 and the water channel 214 open into the opening 204 for the air/water valve. The suction channel 217 opens into the opening 206 for the suction valve. Furthermore, a flexible feed hose 222 connects to the head part 202 and accommodates channels 213', 214' and 217' which via the openings 204 and 206, are connected to the air channel 213, the water channel 214 and  
10 the suction channel 217, respectively. In practice, the feed hose 222 is also referred to as the light-conductor casing.

The mutually connecting channels 213 and 213', 214 and 214', 217 and 217' will be referred to below overall as the air channel 213, the water channel 214 and the  
15 suction channel 217.

A connection 226 for the air channel 213, connections 228 and 228a for the water channel 214 and a connection 230 for the suction channel 217 are arranged on the end section 224 (also referred to as the light conductor connector) of the flexible hose  
20 222. When the connection 226 is in use, connection 228a is closed off. A connection 232 for the biopsy channel 218 is arranged on the head part 202.

A channel separator 240 is shown inserted into the openings 204 and 206. It comprises a body 242, and plug members 244 and 246 which occlude respectively  
25 openings 204 and 206. A coaxial insert 248 on the plug member 244 extends inwardly of the opening 204 and terminates in an annular flange 250 which occludes a portion of the opening 204 to separate channel 213 from channel 214. By connecting the lines 30 to the openings 226, 228, 228a, 230 and 232, liquid for cleaning and disinfection can be flowed through the endoscope channels 213, 214, 217 and 218 and out of a distal tip  
30 252 of the endoscope 200 via channels 210 and 212. The channel separator 240 ensures the such liquid flows all the way through the endoscope 200 without leaking out of openings 204 and 206 and isolates channels 213 and 214 from each other so that each has its own independent flow path. One of skill in the art will appreciate that

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various endoscopes having differing arrangements of channels and openings will likely require modifications in the channel separator 240 to accommodate such differences while occluding ports in the head 202 and keeping channels separated from each other so that each channel can be flushed independently of the other channels. Otherwise a

5 blockage in one channel might merely redirect flow to a connected unblocked channel.

The leakage port 254 on the end section 224 leads into the interior portion space 104 of the endoscope 200 and is used to check for the physical integrity thereof, namely to ensure that no leakage has formed between any of the channels and the interior 256

10 or from the exterior to the interior 256.

Some endoscope channels, such as the suction/biopsy channel 212 in some endoscopes have internal diameters which are too large to adequately assess their connection status with the metering tube 136. For these channels, pressure pulses

15 induced by the pumps 32 can be examined to assess proper connection.

Connection is made at connection 230 to the suction channel 217 and at connection 232 for the suction/biopsy channel 212. Each of these connections is made via one of the flexible tubes 108. By examining the pressure measured at the

20 corresponding pressure sensor 42 the connection status between the connections 232, 230 and their corresponding flush line outlet 31 can be examined.

For instance, if the pump 32 in the flush line 30 connected (via one of the tubes 108) to the connection 230 is turned off and the pressure sensor 42 in this same flush

25 line 30 is read, pressure pulses from the pump 32 in the flush line 30 connected to the connection 232 should be read. The suction channel 217 and suction/biopsy channel 212 meet internally inside the endoscope 200 putting the connections 230 and 232 in fluid communication with each other. The pumps 32 are peristaltic pumps which produce a known pressure wave at about 10 Hz, which of course will vary with the

30 speed of the pump. Other methods could be used to induce the pressure pulses or waves, but the pumps 32 are quite convenient. Preferably the readings from the pressure sensor 42 are filtered electronically to remove noise above and below the target frequency (in the present example 10 Hz). If a significant pressure signal is not

measured at the target frequency that indicates that one of the connections is not made; proper connection must be made between the flexible tube 108 and connection 230, and at the opposite end of that flexible tube and the appropriate outlet 31, as well as between a second of the flexible tubes 108 and the connection 232 and at the opposite  
5 end of this flexible tube and the appropriate outlet 31.

It is not necessary to stop one of the pumps 32 to assess proper connection. The pumps will never be in perfect synchronization and at the exact same frequency and therefore with two of the pumps running through the connections 230 and 232 a beat  
10 frequency formed by the difference in each pump's frequency should be detectable at each of the pressure sensors 42 associated therewith. Only one of the pressure sensors 42 need be measured.

Readings at the pressure sensors 42 can also detect improper connection at  
15 either connection 230, connection 232, or some other connection, by listening for the reflection of the pressure waves. Here, the pressure sensor 42 in the flush line 30 connected via a flexible tube 108 to connection 232 would be listening for reflections from the pump 32 in that flush line 30. These reflections would come from any discontinuities in the path between the pump 32 and where the biopsy/suction channel  
20 212 leaves the distal end of the insertion tube 208. When properly connected, the major echo should come from the open end of the channel 212 at the distal end of the insertion tube 208. Other reflections would come from the connection between the flexible tube 108 and the connection 232, the connection between the flexible tube 108 and the outlet 31, the intersection of channels 217 and 212 and perhaps other surfaces and discontinuities therein. When one end of the tube 108 is not connected a different  
25 echo signature would be presented.

Echo signatures from different types of endoscopes 200 can be stored in the controller 28 and compared with the measured results to determine whether it matches  
30 that of a properly connected endoscope. Signatures for a disconnection at the connection 232 or a disconnection at the outlet 31 could also be stored for comparison. Different types and configurations of the flexible tube 108 may be used for different endoscope types which should be taken into consideration. Similar signatures can be

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stored for the connection 230 or any other connection on the endoscope. Although it is possible to prepare and store signatures for individual endoscope models, there is sufficient similarity among related endoscopes that signatures for broad classes of endoscopes could be used. If signatures for each endoscope model are stored, they could also be used to verify that the proper endoscope model has been entered into the controller.

Turning also now to FIG. 4, an alternative way of providing flow to the endoscope channels will be discussed. Connecting the many flexible tubes 108 in the proper fashion presents somewhat of a challenge to the user. If it is not performed correctly either the cleaning and disinfection process may not be completed correctly or one of the aforementioned detection methods for detecting proper connection will catch the mistake and stop the cycle, necessitating that the user open the endoscope processor 10 and redo the connections properly.

Rather than use the channel separator 240, a channel connector 400 fits into the openings 204 and 206 in similar fashion to the channel separator. However, it functions to provide flow rather than merely to direct flow. It comprises a body 402 having a first insertion leg 404 for insertion into the opening 204 and a second leg 406 for insertion into the opening 206. A first conduit 408 through the passes through the body 402 including the first leg 404 to terminate at the air channel 213 where it meets the first opening 204. A second conduit 410 similarly passes through the body 402 and first leg 404 to meet the water channel 214, a third conduit 412 meets the channel 214', and a fourth conduit 414 meets the channel 213'. A fifth conduit 416 passes through the body 402 and the second leg 406 to meet the suction channel 217 and a six conduit 418 passes through the body 402 and second leg 406 to meet channel 217'. Some endoscopes have only one such opening, and an endoscope could have more such openings than two and one of skill in the art would recognize how to modify the channel connector 400 to accommodate such endoscopes.

Preferably the body 402 is formed of an elastomeric substance such as silicone which seals it within the openings 204 and 206. Rather than fit tightly against all surfaces therein, it is preferred that the channel connector 400 not touch the surfaces in

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the openings 204 and 206 except adjacent the intersections with the channels (213, 214 etc.) whereby to minimize occlusions. Alternative body materials such as metals or polymers compatible with cleaning and disinfecting fluids could be substituted, preferably with some form of elastomeric seal at the intersections with the channels.

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Out of the body 402 extends a plurality of flexible tubes 420 terminated with connectors 422, similar to the tubes 108. Connectors could be provided on the channel connector 400 and the flexible tubes 108 employed, or a manifold could be provided so that one connection only need be made to the endoscope processor 10.

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With one piece, the channel connector 400, multiple connections are achieved. Fluid for washing and disinfection or sterilization can flow through the channel connector to the various channels in the same fashion as was described using the flexible tubes 108 and connections to the ports such as 230. The biopsy port 232 and the test connector 254 are not served by the channel connector 400 and will require connection as described above.

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Turning also now to FIG. 5, to prevent occlusion between the channel connector 400 and surfaces within the openings 204 and 206 provision can be made for movement of the channel connector 400 during a cleaning process. FIG. 5 illustrates only the opening 206 for clarity, yet similar principles can be applied to opening 204. Here, a channel connector 430 has a first conduit 432 which meets the channel 217' and a second conduit 434 which meets the channel 217. A third conduit 436 and fourth conduit 438 terminate at a distal end 440 of a leg 442 of the channel connector 430 received within the opening 206, but do not connect to the channels 217 or 217' when the channel connector 430 is fully seated within the opening 206. A spring 444 or other biasing means urges the channel connector 430 inwardly of the opening 206. It can operate against a surface 446 within the endoscope processor, or can be positioned between a clip 448 attached to the endoscope housing 202 (see FIG. 4).

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The third conduit 436 opens into a first open chamber 450 in the channel connector 430 and the fourth conduit 438 opens into a second open chamber 452. When fluid under pressure flows through the third and fourth conduits 436 and 438 into

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the first and second chambers 450 and 452, pressure in the chambers urges the channel connector 430 outwardly of the opening 206. As it moves outwardly it allows some of that fluid to flow into the channels 217 and 217' and as it moves further outwardly it can escape past a neck 454 in the opening 206. The neck 454 occurs at a point where the opening 206 transitions from a narrow diameter distal portion 456 to a larger diameter proximal portion 458. Annular flanges 460 on the leg 442 ride within the proximal portion to stabilize movement of the channel connector. Openings 462 through the flanges allow fluid to flow outwardly further relieving the pressure urging the channel connector outwardly. The pressure applied by the spring 444 can be set so that the channel connector 430 continually moves outwardly under fluid pressure until that pressure is relieved sufficiently by flowing either through the channels 217 and 217' or through the channels 217 and 217' and past the neck such that the spring drives the channel connector 430 back inwardly. Alternatively, the spring force could be set to never exceed the outward force when fluid is flowing through the third and fourth conduits 436 and 438 in which case movement of the channel connector 430 would be controlled by the flow of fluid through the conduits 436 and 438. Of course more active motor operated or other mechanical mechanisms could be used to move the channel connector 430 back and forth within the opening 206.

Turning also now to FIG. 6, a channel connector 470 has a first conduit 472 which opens into a first open chamber 474 which meets the channel 217' and a second conduit 476 which opens into a second open chamber 478 which meets the channel 217. No separate conduits are provided for moving the channel connector 470. Rather, an over supply of fluid provided through the first and second conduits 472 and 476 provides the pressure sufficient to drive the channel connector 470 outwardly.

The cleaning and sterilization cycle in detail comprises the following steps.

**Step 1. Open the Lid**

Pressing a foot pedal (not shown) opens the basin lid 16a. There is a separate foot pedal for each side. If pressure is removed from the foot pedal, the lid motion stops.

8225  
\$**Step 2. Position and connect the endoscope**

The insertion tube 208 of the endoscope 200 is inserted into the helical circulation tube 64. The end section 224 and head section 202 of the endoscope 200 are situated within the basin 14a, with the feed hose 222 coiled within the basin 14a with as wide a diameter as possible.

The flush lines 30, preferably color-coded at the connectors 31, are attached, to channel connector 400 via the flexible tubes 420 and connectors 422, preferably also color-coded. A separate color-coded flexible tube 108 connects the endoscope opening 232 not served by the channel connector 400 and . The air line 112 is also connected to the connector 254 via an addition color-coded flexible tube 108. A guide located on the on the station 10 provides a reference for the color-coded connections.

**Step 3. Identify the user, endoscope, and specialist to the system**

Depending on the customer-selectable configuration, the control system 20 may prompt for user code, patient ID, endoscope code, and/or specialist code. This information may be entered manually (through the touch screen) or automatically such as by using an attached barcode wand (not shown).

**Step 4. Close the basin lid**

Closing the lid 16a preferably requires the user to press a hardware button and a touch-screen 22 button simultaneously (not shown) to provides a fail-safe mechanism for preventing the user's hands from being caught or pinched by the closing basin lid 16a. If either the hardware button or software button is released while the lid 16a is in the process of closing the motion stops.

**Step 5. Start Program**

The user presses a touch-screen 22 button to begin the washing / disinfection process.

03 29  
 [Signature]

**Step 6. Pressurize the endoscope body and Measure the Leak Rate**

The air pump is started and pressure within the endoscope body is monitored. When pressure reaches 250 mbar, the pump is stopped, and the pressure is allowed to stabilize for 6 seconds. If pressure has not reached 250 mbar in 45 seconds the program is stopped and the user is notified of the leak. If pressure drops to less than 100 mbar during the 6-second stabilization period, the program is stopped and the user is notified of the condition.

Once the pressure has stabilized, valve S5 is closed and valve S6 opened to vent pressure from the interior space 104 beneath the sheath 102. Valve S6 is closed and S5 opened. Pressure is allowed to stabilize for one to six seconds and the new pressure is checked. If it is greater than 190 mbar, it is determined that the test connection 106 is not connected properly or at all to the port 254. The cycle is stopped and the user notified of the condition. Assuming proper connection, pressure is then monitored over the course of 60 seconds. If pressure drops more than 10 mbar within 60 seconds, the program is stopped and the user is notified of the condition. If the pressure drop is less than 10 mbar in 60 seconds, the system continues with the next step. A slight positive pressure is held within the endoscope body during the rest of the process to prevent fluids from leaking in.

**Step 7. Check Connections**

A second leak test checks the adequacy of connection to the port 232 and to the channel connector 400. A quantity of water is admitted to the basin 14a so as to submerge the distal end of the endoscope in the helical tube 64. Valve S1 is closed and valve S7 opened and the pumps 32 are run in reverse to draw a vacuum and to ultimately draw liquid into the endoscope channels 210 and 212. The pressure sensors 42 are monitored to make sure that the pressure in any one channel does not drop by more than a predetermined amount in a given time frame. If it does, it likely indicates that one of the connections was not made correctly and air is leaking into the channel. In any event, in the presence of an unacceptable pressure drop the control system 20 will cancel the cycle and indicate a likely faulty connection, preferably with an indication of which channel failed. For larger

channels, proper connection is checked using the aforementioned method of reading the pressure of the beat frequency of pumps 32.

#### **PRE-RINSE**

- 5      The purpose of this step is to flush water through the channels to remove waste material prior to washing and disinfecting the endoscope 200.

#### **Step 8, Fill basin**

The basin 14a is filled with filtered water and the water level is detected by the pressure sensor 59 below the basin 14a.

10      **Step 9, Pump water through channels**

The water is pumped via the pumps 32 through the interior of the channels 213, 214, 217, 218, 210 and 212 directly to the drain 74. This water is not recirculated around the exterior surfaces of the endoscope 200 during this stage.

#### **Step 10, Drain**

- 15      As the water is being pumped through the channels, the drain pump 72 is activated to ensure that the basin 14a is also emptied. The drain pump 72 will be turned off when the drain switch 76 detects that the drain process is complete.

#### **Step 11, Blow air through channels**

- 20      During the drain process sterile air is blown via the air pump 38 through all endoscope channels simultaneously to minimize potential carryover.

#### **WASH**

#### **Step 12, Fill basin**

- 25      The basin 14a is filled with warm water (35 °C ). Water temperature is controlled by controlling the mix of heated and unheated water. The water level is detected by the pressure sensor 59.

**Step 13. Add detergent**

The system adds enzymatic detergent to the water circulating in the system by means of the peristaltic metering pump 88. The volume is controlled by controlling the delivery time, pump speed, and inner diameter of the peristaltic pump tubing.

**5 Step 14. Circulate wash solution**

The detergent solution is actively pumped throughout the internal channels and over the surface of the endoscope 200 for a predetermined time period, typically of from one to five minutes, preferably about three minutes, by the channel pumps 32 and the external circulation pump 70. The inline heater 80 keeps the temperature at about 35 °C.

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**Step 15. Start block test**

After the detergent solution has been circulating for a couple of minutes, the flow rate through the channels is measured. If the flow rate through any channel is less than a predetermined rate for that channel, the channel is identified as blocked, the program is stopped, and the user is notified of the condition. The peristaltic pumps 32 are run at their predetermined flow rates and cycle off in the presence of unacceptably high pressure readings at the associated pressure sensor 42. If a channel is blocked the predetermined flow rate will trigger the pressure sensor 42 indicating the inability to adequately pass this flow rate. As the pumps 32 are peristaltic, their operating flow rate combined with the percentage of time they are cycled off due to pressure will provide the actual flow rate. The flow rate can also be estimated based upon the decay of the pressure from the time the pump 32 cycles off.

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**Step 16. Drain**

The drain pump 72 is activated to remove the detergent solution from the basin 14a and the channels. The drain pump 72 turns off when the drain level sensor 76 indicates that drainage is complete.

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**Step 17. Blow air**

During the drain process sterile air is blown through all endoscope channels simultaneously to minimize potential carryover.

**RINSE****5    Step 18. Fill basin**

The basin 14a is filled with warm water (35 °C). Water temperature is controlled by controlling the mix of heated and unheated water. The water level is detected by the pressure sensor 59.

**Step 19. Rinse**

- 10    The rinse water is circulated within the endoscope channels (via the channel pumps 32) and over the exterior of the endoscope 200 (via the circulation pump 70 and the sprinkler arm 60) for 1 minute.

**Step 20. Continue Block test**

- 15    As rinse water is pumped through the channels, the flow rate through the channels is measured and if it falls below the predetermined rate for any given channel, the channel is identified as blocked, the program is stopped, and the user is notified of the condition.

**Step 21. Drain**

- 20    The drain pump is activated to remove the rinse water from the basin and the channels.

**Step 22. Blow air**

During the drain process sterile air is blown through all endoscope channels simultaneously to minimize potential carryover.

**Step 23. Repeat rinse**

Steps 18 through 22 are repeated to ensure maximum rinsing of enzymatic detergent solution from the surfaces of the endoscope and the basin.

**DISINFECT****5    Step 24. Fill basin**

The basin 14a is filled with very warm water (53 °C). Water temperature is controlled by controlling the mix of heated and unheated water. The water level is detected by the pressure sensor 59. During the filling process, the channel pumps 32 are off in order to ensure that the disinfectant in the basin is at the in-use concentration prior to circulating through the channels.

**Step 25. Add disinfectant**

15    A measured volume of disinfectant 92, preferably CIDEX OPA orthophalaldehyde concentrate solution, available from Advanced Sterilization Products division Ethicon, Inc., Irvine, CA, is drawn from the disinfectant metering tube 96 and delivered into the water in the basin 14a via the metering pump 100. The disinfectant volume is controlled by the positioning of the fill sensor 98 relative to the bottom of the dispensing tube. The metering tube 96 is filled until the upper level switch detects liquid. Disinfectant 92 is drawn from the metering tube 96 until the level of the disinfectant in the metering tube is just below the tip of the dispensing tube. After the necessary volume is dispensed, the metering tube 96 is refilled from the bottle of disinfectant 92. Disinfectant is not added until the basin is filled, so that in case of a water supply problem, concentrated disinfectant is not left on the endoscope with no water to rinse it. While the disinfectant is being added, the channel pumps 32 are off in order to insure that the disinfectant in the basin is at the in-use concentration prior to circulating through the channels.

**Step 26. Disinfect**

The in-use disinfectant solution is actively pumped throughout the internal channels and over the surface of the endoscope, ideally for a minimum of 5 minutes, by the

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channel pumps and the external circulation pump. The temperature is controlled by the in-line heater 80 to about 52.5 °C.

**Step 27. Flow check**

5 During the disinfection process, flow through each endoscope channel is verified by timing the delivering a measured quantity of solution through the channel. Valve S1 is shut, and valve S7 opened, and in turn each channel pump 32 delivers a predetermined volume to its associated channel from the metering tube 136. This volume and the time it takes to deliver provides a very accurate flow rate through the channel. Anomalies in the flow rate from what is expected for a channel of that diameter and length are flagged by the control system 20 and the process stopped.

**Step 28. Continue Block Test**

As disinfectant in-use solution is pumped through the channels, the flow rate through the channels is also measured as in Step 15.

**Step 29. Drain**

15 The drain pump 72 is activated to remove the disinfectant solution from the basin and the channels.

**Step 30. Blow air**

During the drain process sterile air is blown through all endoscope channels simultaneously to minimize potential carryover.

20 **FINAL RINSE**

**Step 31. Fill basin**

The basin is filled with sterile warm water (45 °C ) that has been passed through a 0.2 µ filter.

89 30  
92

**Step 32. Rinse**

The rinse water is circulated within the endoscope channels (via the channel pumps 32) and over the exterior of the endoscope (via the circulation pump 70 and the sprinkler arm 60) for 1 minute.

5 **Step 33. Continue Block test**

As rinse water is pumped through the channels, the flow rate through the channels is measured as in Step 15.

**Step 34. Drain**

10 The drain pump 72 is activated to remove the rinse water from the basin and the channels.

**Step 35. Blow air**

During the drain process sterile air is blown through all endoscope channels simultaneously to minimize potential carryover.

**Step 36. Repeat rinse**

15 Steps 31 through 35 are repeated two more times (a total of 3 post-disinfection rinses) to ensure maximum reduction of disinfectant residuals from the endoscope 200 and surfaces of the reprocessor.

**FINAL LEAK TEST**

**Step 37. Pressurize the endoscope body and measure leak rate**

20 Repeat Step 6.

**Step 38. Indicate program completion**

The successful completion of the program is indicated on the touch screen.

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PB**Step 39. De-pressurize the endoscope**

From the time of program completion to the time at which the lid is opened, pressure within the endoscope body is normalized to atmospheric pressure by opening the vent valve S5 for 10 seconds every minute.

**5    Step 40. Identify the user**

Depending on customer-selected configuration, the system will prevent the lid from being opened until a valid user identification code is entered.

**Step 41. Store program information**

10    Information about the completed program, including the user ID, endoscope ID, specialist ID, and patient ID are stored along with the sensor data obtained throughout the program.

**Step 42. Print program record**

If a printer is connected to the system, and if requested by the user, a record of the disinfection program will be printed.

**15    Step 43. Remove the endoscope**

Once a valid user identification code has been entered, the lid may be opened (using the foot pedal as in step 1, above). The endoscope is then disconnected from the flush lines 30 and removed from the basin 14a. The lid can then be closed using both the hardware and software buttons as described in step 4, above.

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The invention has been described with reference to the preferred embodiments. Obviously, modifications and alterations will occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations insofar as they come  
25    within the scope of the appended claims or the equivalents thereof.

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94**NOVEDAD DE LA INVENCION****REIVINDICACIONES**

5                   1.- Un método para proveer flujo a canales múltiples en un  
endoscopio durante un procedimiento de descontaminación de endoscopio, el  
método comprendiendo los pasos de: insertar un primer miembro en una  
primera cámara en un cuerpo de un endoscopio a través de una abertura  
hacia la primera cámara, la primera cámara siendo intersecada por un primer  
10 lumen y un segundo lumen; separar en cuanto a fluidos el primer lumen del  
segundo lumen en la primera cámara a través del primer miembro; hacer fluir  
el fluido a través de un primer canal a través del primer miembro hacia el  
primer lumen; y hacer fluir el fluido a través de un segundo canal a través del  
primer miembro en el segundo lumen.

15                   2.- El método de conformidad con la reivindicación 1,  
caracterizado además porqué un tercer lumen interseca la primera cámara, y  
comprendiendo además los pasos de separar en cuanto a fluidos el tercer  
lumen del primer lumen y el segundo lumen a través del primer miembro y  
hacer fluir el fluido a través de un tercer canal a través del primer miembro  
20 hacia el tercer lumen.

3.- El método de conformidad con la reivindicación 1,  
caracterizado además porque comprende el paso de insertar un segundo  
miembro en una segunda cámara en el cuerpo de un endoscopio a través de

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una abertura hacia la segunda cámara, la segunda cámara siendo intersecada por un tercer lumen y un cuarto lumen; separar en cuanto a fluidos el tercer lumen del cuarto lumen en la segunda cámara a través del segundo miembro; hacer fluir el fluido a través de un tercer canal a través del segundo miembro  
5 hacia el tercer lumen; y hacer fluir el fluido a través de un cuarto canal a través del segundo miembro en el cuarto lumen.

4.- El método de conformidad con la reivindicación 3, caracterizado además porque el primer miembro y el segundo miembro están conectados uno a otro.

10 5.- El método de conformidad con la reivindicación 1, caracterizado además porque el fluido es un fluido de limpieza.

6.- El método de conformidad con la reivindicación 1, caracterizado además porque el fluido es un desinfectante o un esterilizante.

15 7.- El método de conformidad con la reivindicación 1, caracterizado además porque el fluido es líquido.

8.- El método de conformidad con la reivindicación 1, caracterizado además porque comprende el paso de mover el primer miembro dentro de la primera cámara para reducir así la oclusión.

20 9.- El método de conformidad con la reivindicación 8, caracterizado además porque el paso de mover el primer miembro dentro de la primera cámara comprende hacer fluir fluido bajo presión hacia la primera cámara para mover el primer miembro hacia fuera del mismo.

10.- El método de conformidad con la reivindicación 9,

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caracterizado además porque el paso de mover el primer miembro dentro de la primera cámara comprende impulsar el primer miembro hacia la primera cámara mediante un miembro de desviación.

11.- Un conector de canales adaptado para proveer flujo a  
5 canales múltiples en un endoscopio durante un procedimiento de descontaminación de endoscopio, el conector de canales comprendiendo: un primer miembro dimensionado y configurado para ajustarse dentro de una primera cámara en un cuerpo de un endoscopio a través de una abertura hacia la primera cámara; un primer canal en el primer miembro, el primer  
10 canal teniendo un extremo que mira hacia un primer lumen en el endoscopio cuando el primer miembro es recibido dentro de la primera cámara, el primer canal teniendo otro extremo que termina en un primer conector; un segundo canal en el primer miembro, el segundo canal teniendo un extremo que mira hacia un segundo lumen en el endoscopio cuando el primer miembro es  
15 recibido dentro de la primera cámara, el segundo canal teniendo otro extremo que termina en un segundo conector; y medios de aislamiento en el primer miembro para separar en cuanto a fluidos el primer lumen del segundo lumen en la primera cámara.

12.- El conector de canales de conformidad con la reivindicación  
20 11, caracterizado además porque comprende además un tercer canal en el primer miembro, el tercer canal teniendo un extremo que mira hacia el tercer lumen en el endoscopio cuando el primer miembro es recibido dentro de la primera cámara, el tercer canal teniendo otro extremo que termina en un

tercer conector y medios de aislamiento adicionales en el primer miembro para aislar en cuando a fluidos el tercer lumen del primer lumen y el segundo lumen en la primera cámara.

13.- El conector de canales de conformidad con la reivindicación 11, caracterizado además porque comprende un segundo miembro conectado al primer miembro, el segundo miembro siendo dimensionado y configurado para ajustarse dentro de una segunda cámara en el cuerpo del endoscopio a través de una abertura hacia la segunda cámara; un tercer canal en el segundo miembro, el tercer canal teniendo un extremo que mira hacia un tercer lumen en el endoscopio cuando el segundo miembro es recibido dentro de la segunda cámara, el tercer canal teniendo otro extremo que termina en un tercer conector; un cuarto canal en el segundo miembro, el cuarto canal teniendo un extremo que mira hacia un cuarto lumen en el endoscopio cuando el segundo miembro es recibido dentro de la segunda cámara, el cuarto canal teniendo otro extremo que termina en un cuarto conector, y un segundo medio de aislamiento en el segundo miembro para separar en cuanto a fluidos el tercer lumen del cuarto lumen en la segunda cámara.

14.- El conector de canales de conformidad con la reivindicación 11, caracterizado además porque comprende un medio de desviación para desviar el primer miembro de la primera cámara.

15.- El conector de canales de conformidad con la reivindicación 14, caracterizado además porque el medio de desviación comprende un resorte.

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16.- El conector de canales de conformidad con la reivindicación 11, caracterizado además porque comprende un tercer canal a través del primer miembro y medios de aislamiento adicionales en el primer miembro para aislar el tercer canal del primer lumen y del segundo lumen cuando el primer miembro es completamente recibido dentro de la primera cámara por la cual el fluido introducido a través del tercer canal bajo presión tenderá a impulsar al primer miembro hacia fuera de la primera cámara.

17.- El conector de canales de conformidad con la reivindicación 11, caracterizado además porque el primer canal sale del primer miembro en una porción opuesta a la primera abertura de la primera cámara cuando el primer miembro es recibido en la misma y en donde el primer miembro comprende una depresión en donde el primer canal sale del primer miembro por el cual el fluido que fluye a través del primer canal bajo presión creará una presión en la depresión que tiende a impulsar al primer miembro hacia fuera de la primera cámara.

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**WHAT IS CLAIMED IS:**

1. A method of providing flow to multiple channels in an endoscope during an endoscope decontamination procedure, the method comprising the steps of:

5 inserting a first member into a first chamber in a body of an endoscope through an opening into the first chamber, the first chamber being intersected by a first lumen and a second lumen;

separating fluidly the first lumen from the second lumen in the first chamber via the first member;

10 flowing fluid through a first channel through the first member into the first lumen; and

flowing fluid through a second channel through the first member into the second lumen.

15 2. A method according to claim 1 wherein a third lumen intersects the first chamber, and further comprising the steps of separating fluidly the third lumen from the first lumen and the second lumen via the first member and flowing fluid through a third channel through the first member into the third lumen.

20 3. A method according to claim 1 and further comprising the step of inserting a second member into a second chamber in the body of the endoscope through an opening into the second chamber, the second chamber being intersected by a third lumen and a fourth lumen;

25 separating fluidly the third lumen from the fourth lumen in the second chamber via the second member;

flowing fluid through a third channel through the second member into the third lumen; and

30 flowing fluid through a fourth channel through the second member into the fourth lumen.

4. A method according to claim 3 wherein the first member and second member are connected to each other.

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5. A method according to claim 1 wherein the fluid is a cleaning fluid.
6. A method according to claim 1 wherein the fluid is a disinfectant or a sterilant.

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7. A method according to claim 1 wherein the fluid is liquid.
8. A method according to claim 1 and further comprising the step of moving the first member within the first chamber whereby to reduce occlusion.

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9. A method according to claim 8 wherein the step of moving the first member within the first chamber comprises flowing fluid under pressure into the first chamber to move the first member outwardly thereof.

15

10. A method according to claim 9 wherein the step of moving the first member within the first chamber further comprises urging the first member into the first chamber via a biasing member.

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11. A channel connector adapted to provide flow to multiple channels in an endoscope during an endoscope decontamination procedure, the channel connector comprising:

a first member sized and shaped to fit within a first chamber in a body of an endoscope through an opening into the first chamber;

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a first channel in the first member, the first channel having one end facing a first lumen in the endoscope when the first member is received within the first chamber, the first channel having another end terminating in a first connector;

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a second channel in the first member, the second channel having one end facing a second lumen in the endoscope when the first member is received within the first chamber, the second channel having another end terminating in a second connector; and

isolation means on the first member for fluidly separating the first lumen from the second lumen at the first chamber.

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12. A channel connector according to claim 11 and further comprising a third channel in the first member, the third channel having one end facing a third lumen in the endoscope when the first member is received within the first chamber, the third channel having another end terminating in a third connector and additional isolation means on the first member for isolating fluidly the third lumen from the first lumen and the second lumen at the first chamber.

13. A channel connector according to claim 11 and further comprising a second member connected to the first member, the second member being sized and shaped to fit within a second chamber in the body of the endoscope through an opening into the second chamber;

a third channel in the second member, the third channel having one end facing a third lumen in the endoscope when the second member is received within the second chamber, the third channel having another end terminating in a third connector;

a fourth channel in the second member, the fourth channel having one end facing a fourth lumen in the endoscope when the second member is received within the second chamber, the fourth channel having another end terminating in a fourth connector; and

a second isolation means on the second member for fluidly separating the third lumen from the fourth lumen at the second chamber.

14. A channel connector according to claim 11 and further comprising a biasing means for biasing the first member into the first chamber.

15. A channel connector according to claim 14 wherein the biasing means comprises a spring.

16. A channel connector according to claim 11 and further comprising a third channel through the first member and additional isolation means on the first member for isolating the third channel from the first lumen and from the second lumen when the first member is fully received within the first chamber whereby fluid introduced through the third channel under pressure will tend to urge the first member outwardly of the first chamber.

17. A channel connector according to claim 11 wherein the first channel exits the first member on a portion opposite the first opening of the first chamber when the first member is received therein and wherein the first member comprises a recess where the first channel exits the first member whereby fluid flowing through the first  
5 channel under pressure will create a pressure in the recess tending to urge the first member outwardly of the first chamber.

**ABSTRACT**

A method provides flow to multiple channels in an endoscope during an endoscope decontamination procedure. A member is inserted into a chamber in a body of an endoscope through an opening into the chamber, the chamber being intersected by a first lumen and a second lumen. The member separates fluidly the first lumen from the second lumen. Fluid is flowed through a first channel through the member into the first lumen and through a second channel through the member into the second lumen. Additional lumens can be so treated at the same time. Fluids can include detergents and other cleaning fluids, disinfectants and sterilants.

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ASP-5039USNP

PTO/SB/01 (10-03)

Approved for use through 10/1/2002. OMB 0581-0002

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>DECLARATION<br/>AND<br/>POWER OF ATTORNEY<br/>FOR UTILITY OR DESIGN<br/>PATENT APPLICATION<br/>(37 CFR 1.63)</b><br><br><input checked="" type="checkbox"/> Declaration Submitted with<br>Initial Filing      OR <input type="checkbox"/> Declaration Submitted after<br>Initial Filing (Surcharge<br>(37 CFR 1.16(e)) required)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Attorney Docket Number | ASP-5039USNP                     |                                                                                                              |                                                                                                              |                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | First Named Inventor   | Szu-Min Lin                      |                                                                                                              |                                                                                                              |                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | COMPLETE IF KNOWN      |                                  |                                                                                                              |                                                                                                              |                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Application Number     |                                  |                                                                                                              |                                                                                                              |                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Filing Date            | October 31, 2005                 |                                                                                                              |                                                                                                              |                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Group Art Unit         |                                  |                                                                                                              |                                                                                                              |                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Examiner Name          |                                  |                                                                                                              |                                                                                                              |                                                                                                              |
| <b>As a below named inventor, I hereby declare that:</b><br><br>My residence, mailing address, and citizenship are as stated below next to my name.<br>I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:<br><br><b>APPARATUS AND METHOD FOR PROVIDING FLOW TO ENDOSCOPE CHANNELS</b><br><br><i>(Title of the invention)</i><br><br>the specification of which<br><br><input checked="" type="checkbox"/> is attached hereto<br><br>OR<br><br><input type="checkbox"/> was filed on (MM/DD/YYYY) <input type="text"/> as United States Application Number or PCT International Application Number <input type="text"/><br><input type="checkbox"/> and was amended on (MM/DD/YYYY) <input type="text"/><br><br>I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.<br><br>I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.<br><br>I hereby claim foreign priority benefits under 36 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT International application having a filing date before that of the application on which priority is claimed. |                        |                                  |                                                                                                              |                                                                                                              |                                                                                                              |
| Prior Foreign Application Number(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Country                | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed                                                                                         | Certified Copy Attached?<br>YES      NO                                                                      |                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                        |                                  | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> |
| <input type="checkbox"/> Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                        |                                  |                                                                                                              |                                                                                                              |                                                                                                              |

DECLARATION - Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

| Application Number(s) | Filing Date (MM/DD/YYYY) |                                                                                                                                                  |
|-----------------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
|                       |                          | <input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/025 attached hereto. |

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT International filing date of this application:

| Application Serial No. | Filing Date | Status |
|------------------------|-------------|--------|
|                        |             |        |

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|------|---------------------|
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as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Address all telephone calls to Andrew C. Farmer at telephone number (732) 524-2825.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

|                                                  |          |                                                                               |                 |
|--------------------------------------------------|----------|-------------------------------------------------------------------------------|-----------------|
| <b>NAME OF SOLE OR FIRST INVENTOR:</b>           |          | <input type="checkbox"/> A petition has been filed for this unsigned inventor |                 |
| Given Name<br>(first and middle (if any)) Su-Min |          | Family Name<br>or Surname Lin                                                 |                 |
| Inventor's<br>Signature                          |          | Date                                                                          |                 |
| Residence: City Irvine                           | State CA | Country USA                                                                   | Citizenship USA |
| Mailing Address 28 Trailing Ivy                  |          |                                                                               |                 |
| City Irvine                                      | State CA | ZIP 92620                                                                     | Country USA     |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

|                                                     |          |                                                                               |                 |
|-----------------------------------------------------|----------|-------------------------------------------------------------------------------|-----------------|
| <b>NAME OF SECOND INVENTOR:</b>                     |          | <input type="checkbox"/> A petition has been filed for this unsigned inventor |                 |
| Given Name<br>(first and middle (if any)) Robert C. |          | Family Name<br>or Surname Platt, Jr.                                          |                 |
| Inventor's<br>Signature                             |          | Date                                                                          |                 |
| Residence: City Laguna Niguel                       | State CA | Country USA                                                                   | Citizenship USA |
| Mailing Address 5 Saint Croix                       |          |                                                                               |                 |
| City Laguna Niguel                                  | State CA | ZIP 92677                                                                     | Country USA     |

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|                                                 |          |                                                                               |                 |
|-------------------------------------------------|----------|-------------------------------------------------------------------------------|-----------------|
| <b>NAME OF THIRD INVENTOR:</b>                  |          | <input type="checkbox"/> A petition has been filed for this unsigned inventor |                 |
| Given Name<br>(first and middle (if any)) Vinod |          | Family Name<br>or Surname Mirchandani                                         |                 |
| Inventor's<br>Signature                         |          | Date                                                                          |                 |
| Residence: City San Ramon                       | State CA | Country USA                                                                   | Citizenship USA |
| Mailing Address 1116 Bellingham Square          |          |                                                                               |                 |
| City San Ramon                                  | State CA | ZIP 94582                                                                     | Country USA     |

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FIG. 1

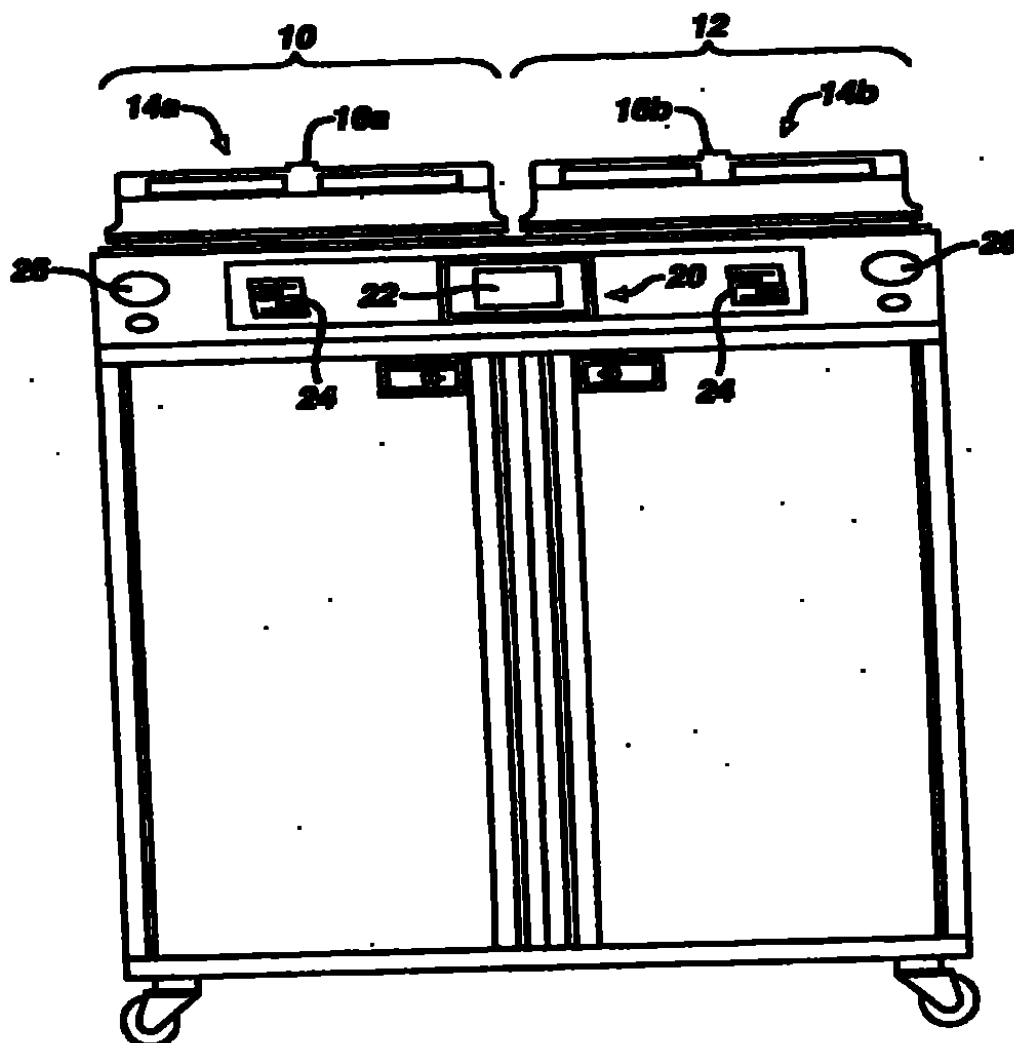
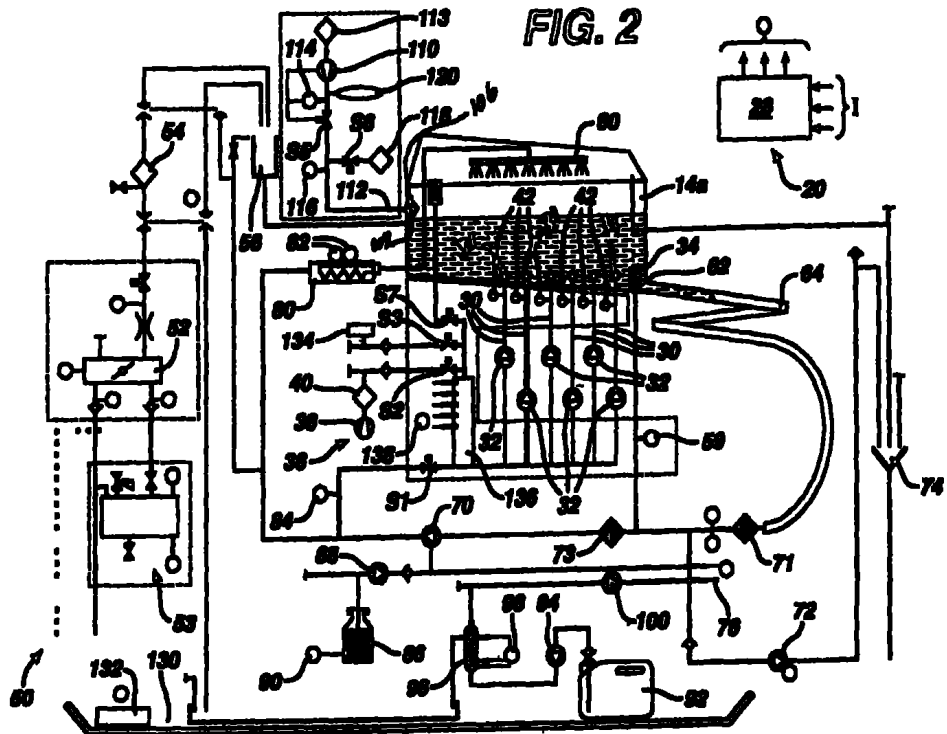
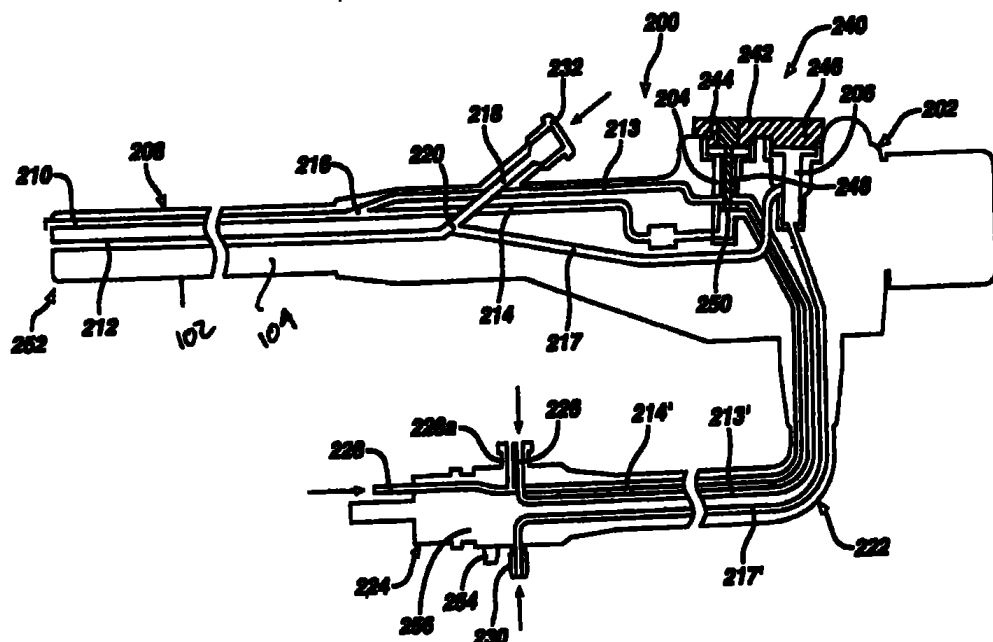


FIG. 2



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FIG. 3



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FIG. 5

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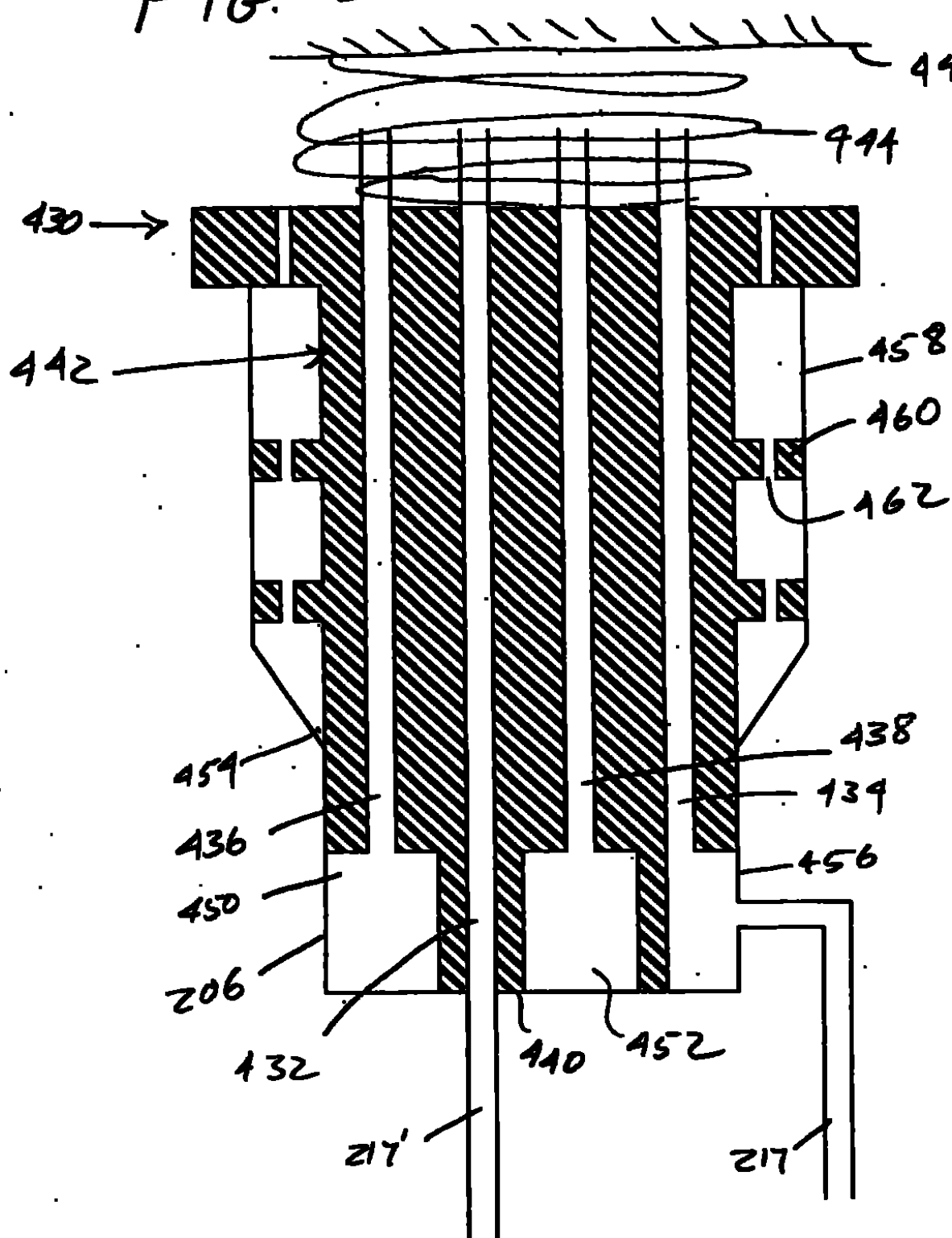


FIG. 6

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