

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	16721718
Filing Date	December 19, 2019
First Named Inventor	Jennifer E. Tomes
Title	Cather Tray, Packaging Sytem, Instruction Insert, and Associated Methods
Art Unit	3781
Examiner Name	Adam M Marcetich
Attorney Docket Number	BPMDL10055UCIP3C1C1C1

SIGNATURE of Applicant or Patent Practitioner

Signature	/Philip H. Burrus, IV/	Date (Optional)	2022-10-19
Name	Philip H. Burrus, IV	Registration Number	45432
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			
NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.			
☐ *Total of _____ forms are submitted.			

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

- ☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:
- OR**
- ☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

- ☒ The address associated with the above-mentioned Customer Number
- OR**
- ☐ The address associated with Customer Number:
- OR**

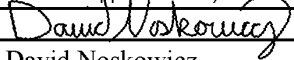
Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

- ☐ Inventor or Joint Inventor (title not required below)
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	David Noskowicz		
Title	Associate General Counsel		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt	
EFS ID:	46852730
Application Number:	16721718
International Application Number:	
Confirmation Number:	7602
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	27939
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	BPMDL10055UCIP3C1C1C1
Receipt Date:	19-OCT-2022
Filing Date:	19-DEC-2019
Time Stamp:	16:56:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	10055UCIP3C1C1C1_2022-10-19_MDLCustNo_189038_2022-9-16.pdf	300016 09b4121d73bdf4a0a22e88573625933319721997	no	2

Warnings:

Information:	
Total Files Size (in bytes):	300016
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

27939 7590 10/26/2022
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3781

DATE MAILED: 10/26/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	12/19/2019	Jennifer E. Tomes	BPMDL10055UCIP3C1C1C1	7602

TITLE OF INVENTION: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	01/26/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27939 7590 10/26/2022
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	12/19/2019	Jennifer E. Tomes	BPMDL1005UCIP3C1C1C1	7602

TITLE OF INVENTION: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	01/26/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3781	604-540000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	12/19/2019	Jennifer E. Tomes	BPMDL10055UCIP3C1C1C1	7602
27939	7590	10/26/2022		
Philip H. Burrus, IV Burrus Intellectual Property Law Group LLC 222 12th Street NE Suite 1803 Atlanta, GA 30309			EXAMINER MARCETICH, ADAM M	
			ART UNIT	PAPER NUMBER
			3781	
DATE MAILED: 10/26/2022				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/721,718	Applicant(s) Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 07 October 2022.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-20 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)	5. ☒ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.	

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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EXAMINER'S COMMENT / REASONS FOR ALLOWANCE

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Examiner's Comment

The objections to claims 4 and 7 for minor informalities are withdrawn in view of the amendments filed 07 October 2022.

Terminal Disclaimer

The terminal disclaimer filed on 07 October 2022 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of:

- Tomes; Jennifer E. et al. (US 10624614 B2)
- Tomes; Jennifer E. et al. (US 10640243 B2)
- Tomes; Jennifer E. et al. (US 9745088 B2)
- Tomes; Jennifer E. et al. (US 10946992 B2)
- Tomes; Jennifer E. et al. (US 9808596 B2)
- Tomes; Jennifer E. et al. (US 10512752 B2)
- Lockwood; Robert et al. (US 10946169 B2)
- Dickinson; Sarah et al. (US 11116937 B2)

has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Claims

Claims 1-20 are allowed.

Reasons for Allowance

Applicant's arguments filed 07 October 2022 have been considered and are persuasive. Examiner advances additional reasons for allowance.

Reif; Thomas H. et al. (US 4811847 A), the closest art of record, discloses a catheter assembly including a tray, one syringe and a catheter (Fig. 2). However, Reif lacks a second syringe, and does not arrange the syringe and catheter in separate compartments.

Another cited reference, **Pilger; Nicholas J. (US 3485352 A)**, discloses a procedure kit including a tray, coiled catheter and one syringe (Fig. 5). However, Pilger lacks a second syringe and a second compartment. Instead, Pilger arranges one syringe and a catheter in one compartment (Figs. 1, 2, syringe 15 and catheter 8 are both arranged inside wall 3).

Also of record, **Rauschenberger; Richard A. (US 4160505 A)** discloses a catheterization tray comprising multiple compartments (col. 1, lines 50-55, Tray 10 is formed with a dished portion 11; col. 2, lines 1-5, Compartments 23 and 24 are defined within dish 11 by walls 27, 28 and 29), and a medical assembly comprising a urinary catheter (col. 1, lines 60-65, Channel 21 is adapted to receive a conventional urethral catheter which is positioned within channel 21).

However, Rauschenberger lacks first and second syringes containing lubricating jelly and water. Instead, Rauschenberger describes a separate lubricant packet (col. 2, lines 20-30, The remaining components generally are arranged ... in the order: gloves, lubricant ... and specimen container). Rauschenberger also lacks a coiled tubing coupled between a fluid drain bag and a Foley catheter, and at most discloses a urinary catheter (Fig. 1, conventional urethral catheter stored in channel 21).

The following newly cited references fail to teach or suggest all limitations of the amended claims.

Nishizawa; Yasushi et al. (JP 2002068309 A) discloses a catheterization tray comprising several compartments (¶ [0001], [0004], [0008], [0031], In the vicinity of the center of the first sheet material 28, a first concave portion 231 having a substantially square planar shape is formed); including a catheter (¶ [0024], FIG. 1, the package 1A is A has a configuration in which a catheter 7 and a container 8 in which a liquid 89 is sealed are housed in A), and a container of liquid (¶ [0024], before opening the package 1A, the user strongly presses the container 8 to break it, and wets the catheter 7 with the liquid 89). However, Nishizawa lacks medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter and at most describes a catheter (Figs. 1, 2, 5, 6, catheter 7).

Shimura; Kenichi et al. (JP 2000281144 A) describes a catheterization package comprising several compartments (¶ [0001], [0017], [0035], a package 1 includes a packaging material 2 having a first space and a second space; ¶ [0037], The partition 22 divides the inside of the packaging material 2 into a first space 4 and a second space 5), including a urinary catheter (¶ [0046], The catheter 7 is inserted into, for example, the trachea, digestive tract, urethra ... and other living tissues). However, Shimura lacks a tray and instead discloses a bag-type container (¶ [0036], The packaging material 2 is a bag-like material). Shimura also lacks first and second syringes containing lubricating jelly and water.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590
Fax 571-273-2590
Email Adam.Marcetich@uspto.gov

The Examiner can be reached 8am-4pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached at 571-272-1115. The fax phone number for the organization where this application is assigned is 571-273-8300.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>.

Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Primary Examiner, Art Unit 3781

<i>Notice of References Cited</i>	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
	A					
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N	JP-2002068309-A	03-2002	JP	Nishizawa; Yasushi et al.	
	O	JP-2000281144-A	10-2000	JP	Shimura; Kenichi et al.	
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	JP-2002068309-A Machine translation 17 Oct 2022.
	V	JP-2000281144-A Machine translation 17 Oct 2022.
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Search Notes</i> 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B50/30, A61B50/33, A61B46/00, A61B2050/3008, A61B46/23, A61B2050/0065, A61B42/40, A61B50/20, A61B90/92, A61B50/31, A61B2050/3007, A61B2050/3011, A61B90/94, A61B2050/005	06/30/2022	AMM
A61M25/002, A61M25/0017, A61M5/002, A61M25/00, A61M5/14, A61M5/008, A61M2209/06, B65D1/34, B65D1/36, A61F15/001	06/30/2022	AMM
update search	10/14/2022	AMM

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor search in US-PGPUB, USPAT	06/29/2022	AMM
Review cited art for related cases 12495148, 12647515, 13153265, 13153300, 13155053, 14165044, 15640224, 15977944	06/29/2022	AMM
Review IPR cases IPR2015-00511, IPR2015-00513, IPR2015-00514 , IPR2019-00109	06/29/2022	AMM
update search	10/14/2022	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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<i>Search Notes</i> 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	update search	10/14/2022	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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Issue Classification 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

CPC						
Symbol					Type	Version
A61B	/	10	/	007	F	2013-01-01
A61M	/	25	/	00	I	2013-01-01
A61M	/	25	/	002	I	2013-01-01
A61B	/	50	/	30	I	2016-02-01
A61B	/	50	/	33	I	2016-02-01
A61B	/	46	/	23	A	2016-02-01
A61M	/	25	/	0017	A	2013-01-01
A61B	/	2050	/	3015	A	2016-02-01
A61B	/	2050	/	3008	A	2016-02-01
A61B	/	42	/	00	A	2016-02-01
A61B	/	46	/	00	A	2016-02-01

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) _____ (Date) 17 October 2022		O.G. Print Claim(s) 1	O.G. Print Figure 7

Issue Classification 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61B50/30	/	50	/ 30
A61B50/33	/	50	/ 33

NON-CLAIMED			
A61M25/00	/	25	/ 00
A61B42/00	/	42	/ 00

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE (Assistant Examiner)		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner)		17 October 2022 (Date)	
		O.G. Print Claim(s) 1	O.G. Print Figure 7

Issue Classification 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) _____ (Date) 17 October 2022		O.G. Print Claim(s) 1	O.G. Print Figure 7

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L166	1	16/721718.app.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/06/28 04:16 PM
L167	12	(12/495148 12/647515 13/153265 13/153300 13/155053 14/165044 15/640224).app.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/06/29 07:26 AM
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L170	1	("8,678,190").pn.	(USPAT)	OR	ON	ON	2022/06/29 11:09 AM
L171	1	("9,795,761").pn.	(USPAT)	OR	ON	ON	2022/06/29 11:12 AM
L172	1140	Tomes-Jennifer-E\$.in. Tomes-Jennifer\$.in. Dickinson-Sarah\$.in. Medline-Ind-Inc\$.as. Medline-Inc\$.as. Medline-Ind\$.as. Medline\$.as. Medline-Ind-Inc\$.aanm. Medline-Inc\$.aanm. Medline-Ind\$.aanm. Medline\$.aanm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/06/29 12:34 PM
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		5007535-A OR US- 8448786-B2 OR US- 8678190-B2 OR US- D442697-S OR US- 4858821-A OR US- 5868250-A).did. AND USPT.dbnm.) OR ((US- 20150034521-A1 OR US-20100252473-A1 OR US-20080272023- A1 OR US- 20070161971-A1 OR US-20040004019-A1 OR US-20030038475- A1 OR US- 20170216558-A1 OR US-20060009742-A1 OR US-20060025753- A1 OR US- 20080281254-A1 OR US-20050241986-A1 OR US-20060104856- A1 OR US- 20070095699-A1 OR US-20090236259-A1 OR US-20040055925- A1 OR US- 20070026472-A1 OR US-20040076564-A1 OR US-20040074593- A1 OR US- 20110192115-A1 OR US-20110033137-A1 OR US-20020185406- A1 OR US- 20050022822-A1 OR US-20100186754-A1 OR US-20020064478- A1 OR US- 20050079093-A1 OR US-20060067855-A1 OR US-20090152160- A1 OR US- 20070225687-A1 OR US-20110214679-A1 OR US-20060185326- A1 OR US- 20200121301-A1 OR US-20060264822-A1 OR US-20090184026- A1 OR US- 20100307942-A1 OR US-20100311026-A1 OR US-20030159966- A1 OR US- 20070197998-A1 OR US-20060011506-A1 OR US-20050256453-				
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		A1 OR US-20070142786-A1 OR US-20080121553-A1 OR US-20080125722-A1 OR US-20070158234-A1 OR US-20110284410-A1 OR US-20120267272-A1).did. AND PGPB.dbnm.) OR ((US-3542019-A OR US-2734543-A OR US-3329261-A OR US-3485352-A).did. AND USOC.dbnm.)					
L202	2066	(A61B50/30 A61B50/33 A61B2050/3008).cpc. AND @ad<"20110603"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/17 08:03 AM
L203	8291	(A61B50/30 A61B50/33 A61B2050/3008).cpc. AND @ad<"20110603"	(FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, UA, VN, VN, WO, WO); FPRS)	OR	OFF	OFF	2022/10/17 08:04 AM
L204	161	L203 AND (tray box pack package) SAME (compartment partition\$3 divid\$3 division wells) AND (catheter canula cannula foley)	(FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, UA, VN, VN, WO, WO); FPRS)	OR	OFF	OFF	2022/10/17 08:05 AM
L205	262	L203 AND (tray box pack package container) SAME (chamber segment\$3 sector compartment\$3 section\$3) AND (catheter canula cannula foley) NOT L204	(FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH,	OR	OFF	OFF	2022/10/17 09:19 AM

L206	281	L202 AND (tray box pack package container) SAME (compartment partition\$3 divid\$3 division wells chamber segment\$3 sector compartition\$3 section\$3) AND (catheter canula cannula foley)	TN, TR, TW, UA, UA, VN, VN, WO, WO); FPRS) (US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/17 09:31 AM
L207	29111	(A61B46/23 A61B90/92 A61B50/00 A61B90/94 A61B2017/0023 A61B2050/005 A61B50/34 A61M25/002 A61M5/002 A61M25/0017 A61M2209/06 B65D1/34 B65D1/36 B65D1/24 B65D81/3813).cpc. AND @ad<"20110603"	(FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, UA, VN, VN, WO, WO); FPRS)	OR	OFF	OFF	2022/10/17 10:21 AM
L208	1650	L207 AND (tray box pack package container) SAME (compartment partition\$3 divid\$3 division wells chamber segment\$3 sector compartition\$3 section\$3) AND (catheter canula cannula foley) NOT (L204 L205)	(FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, UA, VN, VN, WO, WO); FPRS)	OR	OFF	OFF	2022/10/17 10:22 AM
L210	1404	L208 AND (tray box pack package container) WITH (compartment partition\$3 divid\$3 division wells chamber segment\$3 sector compartition\$3 section\$3 barrier wall)	(FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, UA, VN, VN, WO, WO); FPRS)	OR	OFF	OFF	2022/10/17 10:22 AM

L211	5302	(A61B46/23 A61B90/92 A61B50/00 A61B90/94 A61B2017/0023 A61B2050/005 A61B50/34 A61M25/002 A61M5/002 A61M25/0017 A61M2209/06 B65D1/34 B65D1/36 B65D1/24 B65D81/3813).cpc. AND @ad<"20110603"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/17 11:09 AM
L212	383	L211 AND (tray box pack package container) WITH (compartment partition\$3 divid\$3 division wells chamber segment\$3 sector compartition\$3 section\$3) AND (catheter canula cannula foley) NOT L206	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/17 11:10 AM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N170	1248	((tray box pack package container) WITH (compartment partition\$3 divid\$3 division wells chamber segment\$3 sector compartition\$3 section\$3) AND (catheter canula cannula foley)).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/17 11:20 AM
N171	132	N170 AND (lubricant\$1 lubricating jell jel jelly gell gel).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/17 11:20 AM

Receipt date: 10/08/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4085845		1978-04-25	Perfect, Alan	
		4554156		1985-11-19	Fischer, Herbert	
		5289919		1994-03-01	Fischer	
		5887749		1999-03-30	Schommer, Philip	
		10640243		2020- 05-05	Tomes et al.	
U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20040031721		2004-02-19	Mann, David M.	
		20100272669		2010-10-28	Malessa, Ralf	
		20110017621		2011-01-27	Zoland, Mark	
		20110225726		2011-09-22	Dominguez, Angel	
		20170202699		2017-07-20	Zani et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0809

Receipt date: 10/08/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

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	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

		2017021 6558		2017-08- 03	Hughett et al.	
		2017036 8302		2017-12- 18	Brooks, Christopher	
		2019034 4044		2019-11- 14	Dickinson et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
		C. R. Bard, Inc. v. Medline Industries, Inc., 2020-1900, 2020-1905, 2020-1908, 2020-1910 Slip Opinion (Fed. Cir. 2021). Dated August 13, 2021,	
		"Ex Parte Reexamination Request", Reexamination Control No 90/015,051 for Patent No. 9522753; Mailed June 28, 2022; Request and Exhibits 1-28,	
		"Request for Ex Parte Reexamination", Reexam Control No. 90/014,964 for Patent No. 8,448,786; Mailed March 8, 2022; Request and Exhibits 1-35,	

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Bard Exhibit 1004.0810

Receipt date: 10/08/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

		"Summons to Attend Oral Proceedings", EP Application 11854003.8; Mailed December 22, 2020; 10055U CIP4 EP,	
		"Summons to Attend Oral Proceedings", EP Application 12792423.1; Mailed December 22, 2020; 10055U CIP6 EP,	
		"Summons to Attend Oral Proceedings", EP Application 12793939.5; Mailed December 23, 2020; 10055U CIP5 EP,	
		ARBLE, JESSICA , "Final OA", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed August 5, 2020,	
		ARBLE, JESSICA , "NonFinal Office Action", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed April 28, 2020,	
		ARBLE, JESSICA , "NonFinal Office Action", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed February 3, 2021,	
		ARBLE, JESSICA , "Notice of Allowance", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed August 17, 2021,	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0811

Receipt date: 10/08/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

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	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit		3781
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number		BPMDL0005JT.P3.C1.C1.C1

		POON, ROBERT , "Final Office Action", USSN 16/258,231; Filed January 25, 2019; Attorney Docket No. 10055U D1 C2 C1; Mailed July 15, 2020,	
		POON, ROBERT , "Final Office Action", USSN 16/258,231; Filed January 25, 2019; Attorney Docket No. 10055U D1 C2 C1; Mailed October 7, 2021,	
		POON, ROBERT , "Final Office Action", USSN 16/986,803; Filed August 6, 2020; Attorney Docket 1037-001-03US; Mailed July 5, 2022,	
		POON, ROBERT , "Final Office Action", USSN 17/180,680; Filed February 19, 2021; Attorney Docket No. 1037-002-10US; Mailed September 16, 2022,	
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		POON, ROBERT , "Notice of Allowance", USSN 15/703,514; Filed September 13, 2017; Attorney Docket No. 1037-002-09US; Mailed November 23, 2020,	
		POON, ROBERT , "Notice of Allowance", USSN 15/803,383; Filed November 3, 2017; Attorney Docket No. 1037-002-08US; Mailed November 27, 2020,	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0812

Receipt date: 10/08/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

		REIP, DAVID OWEN , "Ex Parte Reexamination Order - Request Granted", Reexam Control No. 90/014,964 for Patent No. 8,448,786; Mailed April 19, 2022,	
		REIP, DAVID OWEN , "Ex Parte Reexamination Order - Request Granted", Reexamination Control No 90/015,051 for Patent No. 9522753; Mailed July 7, 2022,	
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EXAMINER SIGNATURE

Examiner Signature	/Adam Marcetich/	Date Considered	10/14/2022
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0813

Receipt date: 10/08/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

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	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2022-10-05
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Bard Exhibit 1004.0814

(19) 日本国特許庁 (J P)

(12) 公開特許公報 (A)

(11) 特許出願公開番号

特開2000-281144

(P2000-281144A)

(43) 公開日 平成12年10月10日 (2000. 10. 10)

(51) Int.Cl. ⁷	識別記号	F I	テーマコード* (参考)
B 6 5 D 81/26		B 6 5 D 81/26	K 3 E 0 6 7
A 6 1 M 25/00	4 6 0	A 6 1 M 25/00	4 6 0

審査請求 未請求 請求項の数15 O L (全 20 頁)

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(71) 出願人 000109543

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テルモ株式会社内

(74) 代理人 100091292

弁理士 増田 達哉

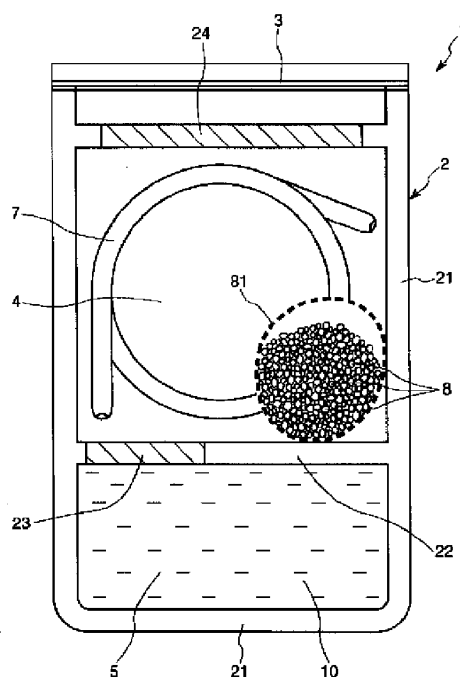
最終頁に続く

(54) 【発明の名称】 包装体

(57) 【要約】

【課題】 簡便にかつ無菌的に器具と液体との接触を可能にし、器具の使用後、外部への臭気の放散や、汚染、感染等を防止することができる包装体を提供すること。

【解決手段】 包装体1の包材2は、シート材と融着して得られたものであり、その内部には、仕切部22で区画された第1の空間4と第2の空間5とが形成されている。仕切部22には、弱シール部23が形成されている。第1の空間4内には、カテーテル7と、通気性を有する容器81に入れられた脱臭剤8とが収納されている。また、第2の空間5には、流動性物質10が収納されている。弱シール部23が剥離され、流動性物質10が第1の空間4内に流入し、カテーテル7と接触すると、カテーテル7の表面は、湿潤して摩擦抵抗が低減する。



【特許請求の範囲】

【請求項１】 仕切部により互いに隔離され、必要時に連通可能な第１の空間および第２の空間を有する包材と、

前記第１の空間に収納され、生体に挿入または装着して使用される器具と、

前記第１の空間に収納され、臭気を消滅または低減させる物質と、

前記第２の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質とを備えることを特徴とする包装体。

【請求項２】 前記臭気を消滅または低減させる物質の主成分が酸化チタンである請求項１に記載の包装体。

【請求項３】 仕切部により互いに隔離され、必要時に連通可能な第１の空間および第２の空間を有する包材と、

前記第１の空間に収納され、生体に挿入または装着して使用される器具と、

前記第１の空間に収納され、少なくとも微生物の増殖を抑制する機能を有する物質と、

前記第２の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質とを備えることを特徴とする包装体。

【請求項４】 前記微生物の増殖を抑制する機能を有する物質の主成分が酸化チタンである請求項３に記載の包装体。

【請求項５】 仕切部により互いに隔離され、必要時に連通可能な第１の空間、第２の空間および第３の空間を有する包材と、

前記第１の空間に収納され、生体に挿入または装着して使用される器具と、

前記第２の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質と、前記第３の空間に収納され、液体を吸収、保持し得る物質とを備えることを特徴とする包装体。

【請求項６】 仕切部により互いに隔離され、必要時に連通可能な第１の空間、第２の空間および第３の空間を有する包材と、

前記第１の空間に収納され、生体に挿入または装着して使用される器具と、

前記第２の空間に収納された血液抗凝固剤と、

前記第３の空間に収納され、液体を吸収、保持し得る物質とを備えることを特徴とする包装体。

【請求項７】 前記第１の空間と前記第２の空間とが隣接して形成され、かつ、前記第１の空間と前記第３の空間とが隣接して形成されている請求項５または６に記載の包装体。

【請求項８】 前記第２の空間は、前記第１の空間の内側に形成されている請求項１ないし７のいずれかに記載の包装体。

【請求項９】 前記仕切部は、前記包材を構成するシート材を融着してなるシール部で構成されている請求項１ないし８のいずれかに記載の包装体。

【請求項１０】 前記仕切部の少なくとも一部が、他の部分より接合強度が弱い弱シール部で構成されている請求項１ないし９のいずれかに記載の包装体。

【請求項１１】 前記第１の空間から前記器具を取り出すための開封部と、該開封部を開封後、その開封口を封止する封止手段とを有する請求項１ないし１０のいずれかに記載の包装体。

【請求項１２】 前記包材は、水蒸気バリアー性を有するものである請求項１ないし１１のいずれかに記載の包装体。

【請求項１３】 前記器具は、カテーテルまたはガイドワイヤーである請求項１ないし１２のいずれかに記載の包装体。

【請求項１４】 前記器具は、尿道に挿入して使用されるカテーテルである請求項１ないし１２のいずれかに記載の包装体。

【請求項１５】 前記器具の少なくとも一部の表面に、湿潤により潤滑性が発現する化合物が付与されている請求項１ないし１４のいずれかに記載の包装体。

【発明の詳細な説明】

【０００１】

【発明の属する技術分野】本発明は、例えばカテーテルのような器具を包装した包装体に関する。

【０００２】

【従来の技術】気管、消化管、尿道、血管、その他の体腔や、各種臓器、生体組織等へ挿入されるカテーテル、該カテーテルに挿入されるガイドワイヤー等の医療器具の表面は、一般に、血栓、組織接着または異物反応が数多く確認される。従って、生体組織への損傷を低減し、目的部位へ確実に挿入することが必要となる。また、生体組織内での留置の際の粘膜炎症や粘膜損傷を抑制するために、器具表面に潤滑性を持たせることが必要とされる。

【０００３】このため、低摩擦材料を基材として用いたり、使用に先立ち、器具表面に水、生理等張液もしくは潤滑剤を塗布したりしている。より詳しく説明すると、カテーテルの基材を多層積層構造とし、その最外層（または最内層）に、フッ素樹脂やポリエチレン樹脂等の低摩擦素材を用いたり、器具表面に水、生理等張液、グリセリン、オイル等の潤滑剤を塗布したりしている。

【０００４】しかしながら、カテーテル基材の材質の選択では、摺動性の向上に限界があり、満足できるレベルに到達することが困難である。

【０００５】また、潤滑剤等を付与する場合、これらを医療器具と接触させた状態で製品化を行おうとすれば、医療器具が使用されるまでの長時間の間に、潤滑剤の変質、劣化や、医療器具表面からの剥離等が懸念

され、安定性（保存性）およびこれに伴う安全性の面で課題があった。

【0006】さらに、使用時に医療用器具と潤滑剤とを無菌的に接触させることは非常に困難であり、細菌感染等のおそれがあるという問題もある。

【0007】また、緊急時には、患者の生命を維持することが最優先であるため、潤滑剤の塗布の作業が煩わしいものとなり、場合によっては、潤滑剤を塗布せず、表面が乾燥状態のままで使用されることがある。

【0008】医療用器具の表面に湿潤すると潤滑性を発現する化合物を存在させる方法として、国際出願WO9001344には、ポリウレタン表面にコーティング操作により、アルカリ金属アルコラート、アミノ基、アルカリ金属アミド基、カルボン酸基、スルホン酸基、マグネシウムハライド基およびフッ素ホウ素系錯体基の少なくとも一つを導入し、さらにコーティング操作により、これら官能基と反応しうる親水性ポリマーを表面に固定化する技術が開示されている。

【0009】また、同様に、医療用器具の表面に湿潤すると潤滑性を発現する化合物を存在させる方法は、特公平6-32652号、特開平6-7426号、国際出願WO9219289、特表平10-502854号、特表平10-502855号、特表平10-502856号等にも開示されている。

【0010】しかしながら、これらの方法では、乾燥では潤滑性を発現することはなく、使用時には、医療用器具を包材から取り出し、その医療用器具の表面に水、生理等張液等の液体を供給し、接触させる操作が必須である。しかも、この操作を無菌的に行うことは、特別な操作や施設を利用する場合を除き、非常に困難であった。そのため、前述したように、感染のおそれを免れず、また、緊急時に、表面が乾燥状態のまま、直接、気管、消化管、尿道、血管等へ挿入することもあり、粘膜等の損傷が懸念されるものであった。

【0011】一方、血液が血管内皮細胞以外の異物と接触すると、異物表面に血漿タンパク、血小板の粘着、血液凝固が惹起され、血栓が生成される。この血栓形成は、カテーテル、ガイドワイヤー等の医療用器具の使用時において問題となる。

【0012】そのため、血液中にヘパリン等の血液抗凝固剤を投与するか、あるいは医療用器具の表面に血液抗凝固剤等を付与したり基材として抗血栓性材料を用いたりすることが行われている。

【0013】しかしながら、前者の場合には、患者に出血傾向等の弊害をもたらし、また、後者の場合には、使用時に液体との接触操作が必要であり、この操作を無菌的に行うことは、非常に困難であるという点で、前記と同様である。

【0014】さらに、緊急時には、患者の生命を維持することが最優先であるため、抗凝固操作を行わずに直接

使用することもあり、血栓形成による弊害が懸念されるものであった。

【0015】また、これら医療用器具の使用後は、医療廃棄物として廃棄処理されるが、通常は、体液や血液中の細菌、ウイルスなどの不活化操作（消毒・殺菌操作）や脱臭操作を施さずに、感染性を有したまま、あるいは臭気の放出を許容したままの状態で廃棄されていた。

【0016】そのため、医療用器具の使用後、焼却処分されるまでの間に、臭気が放散されたり、尿や血液等の体液が漏れ出し、周囲の汚染や感染を生じることがあった。

【0017】

【発明が解決しようとする課題】本発明は、上述した問題点を鑑みてなされたもので、その目的は、簡便にかつ無菌的に器具と液体との接触を可能にし、また、器具の使用後、外部への臭気の放散や、汚染、感染等を防止することができる包装体を提供することにある。

【0018】

【課題を解決するための手段】このような目的は、下記（1）～（15）の本発明により達成される。

【0019】（1） 仕切部により互いに隔離され、必要時に連通可能な第1の空間および第2の空間を有する包材と、前記第1の空間に収納され、生体に挿入または装着して使用される器具と、前記第1の空間に収納され、臭気を消滅または低減させる物質と、前記第2の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質とを備えることを特徴とする包装体。

【0020】（2） 前記臭気を消滅または低減させる物質の主成分が酸化チタンである上記（1）に記載の包装体。

【0021】（3） 仕切部により互いに隔離され、必要時に連通可能な第1の空間および第2の空間を有する包材と、前記第1の空間に収納され、生体に挿入または装着して使用される器具と、前記第1の空間に収納され、少なくとも微生物の増殖を抑制する機能を有する物質と、前記第2の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質とを備えることを特徴とする包装体。

【0022】（4） 前記微生物の増殖を抑制する機能を有する物質の主成分が酸化チタンである上記（3）に記載の包装体。

【0023】（5） 仕切部により互いに隔離され、必要時に連通可能な第1の空間、第2の空間および第3の空間を有する包材と、前記第1の空間に収納され、生体に挿入または装着して使用される器具と、前記第2の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質と、前記第3の空間に収納され、液体を吸収、保持し得る物質とを備えることを特徴とする包装体。

【００２４】（６）仕切部により互いに隔離され、必要時に連通可能な第１の空間、第２の空間および第３の空間を有する包材と、前記第１の空間に収納され、生体に挿入または装着して使用される器具と、前記第２の空間に収納された血液抗凝固剤と、前記第３の空間に収納され、液体を吸収、保持し得る物質とを備えることを特徴とする包装体。

【００２５】（７）前記第１の空間と前記第２の空間とが隣接して形成され、かつ、前記第１の空間と前記第３の空間とが隣接して形成されている上記（５）または（６）に記載の包装体。

【００２６】（８）前記第２の空間は、前記第１の空間の内側に形成されている上記（１）ないし（７）のいずれかに記載の包装体。

【００２７】（９）前記仕切部は、前記包材を構成するシート材を融着してなるシール部で構成されている上記（１）ないし（８）のいずれかに記載の包装体。

【００２８】（１０）前記仕切部の少なくとも一部が、他の部分より接合強度が弱い弱シール部で構成されている上記（１）ないし（９）のいずれかに記載の包装体。

【００２９】（１１）前記第１の空間から前記器具を取り出すための開封部と、該開封部を開封後、その開封口を封止する封止手段とを有する上記（１）ないし（１０）のいずれかに記載の包装体。

【００３０】（１２）前記包材は、水蒸気バリア性を有するものである上記（１）ないし（１１）のいずれかに記載の包装体。

【００３１】（１３）前記器具は、カテーテルまたはガイドワイヤーである上記（１）ないし（１２）のいずれかに記載の包装体。

【００３２】（１４）前記器具は、尿道に挿入して使用されるカテーテルである上記（１）ないし（１２）のいずれかに記載の包装体。

【００３３】（１５）前記器具の少なくとも一部の表面に、湿潤により潤滑性が発現する化合物が付与されている上記（１）ないし（１４）のいずれかに記載の包装体。

【００３４】

【発明の実施の形態】以下、本発明の包装体を添付図面に示す好適実施例に基づいて詳細に説明する。

【００３５】図１は、本発明の包装体の第１実施例を示す平面図（内部透視図）である。同図に示すように、包装体１は、第１の空間および第２の空間を有する包材２を有している。

【００３６】包材２は、後述するようなシート材を融着（または接着）により所望のパターンにシールして袋状としたものである。包材２の外周部等には、帯状のシール部２１が形成されている。

【００３７】また、包材２の途中には、仕切部２２が形

成されている。この仕切部２２は、前記シール部２１と同様にシート材を帯状に融着（または接着）したものである。この仕切部２２により、包材２内は、それぞれ独立した（互いに隔離された）第１の空間４および第２の空間５に区画されている。

【００３８】図１中斜線を施して示すように、仕切部２２の一部は、他の部分（シール部２１）より接合強度（剥離強度）が弱い弱シール部（イージーピールシール部）２３で構成されている。この弱シール部２３を剥離（破断）することにより、第１の空間４と第２の空間５とが連通する。

【００３９】シール部２１は、対向するシート材同士が完全に融着され、強固な接合状態であるのに対し、弱シール部２３は、それより低温で融着する等により、対向するシート材同士の融着がある程度不完全であるような状態とされる。ただし、弱シール部２３においても、液密性（気密性）は、確保されている。そして、その効果は、経時的に持続する。

【００４０】弱シール部２３を剥離（破断）するには、包材２の第２の空間５を画成する部分を押圧（圧迫）し、第２の空間５の内圧を高めることにより可能となる。また、その他、弱シール部２３を手で揉みほぐしてもよく、さらには、これらの方法を併用してもよい。このように、極めて簡単な操作で、第１の空間４と第２の空間５とを連通させることができる。

【００４１】なお、弱シール部２３は、仕切部２２の２箇所に形成されていてもよく、あるいは、仕切部２２のほぼ全体にわたって形成されていてもよい。

【００４２】また、包材２の図１中上端部のシール部２１にも、前記弱シール部２３と同様の弱シール部（開封部）２４が形成されている。この弱シール部２４を剥離（破断）して包材２を開封し、第１の空間４内の収納物を出し入れすることができる。

【００４３】また、弱シール部２４の図１中上端側の近傍には、開閉可能なジッパー（封止手段）３が設けられている。弱シール部２４を剥離（破断）して包材２を開封した後でも、このジッパー３を閉じることにより、この開封口を封止することができる。また、ジッパー３を開ければ、再び開封口を開放することができる。

【００４４】なお、ジッパー３としては、例えば、互いに嵌合する溝および突条で構成されたもの等、公知の任意の構成のものが使用可能である。

【００４５】第１の空間４には、生体に挿入または装着して使用される器具と、臭気を消滅または低減させる物質とが収納されている。生体に挿入または装着して使用される器具としては、カテーテルまたはガイドワイヤーが好ましく、本実施例では、第１の空間４内に、カテーテル７と脱臭剤（消臭剤）８とが収納されている。

【００４６】カテーテル７としては、例えば、気管、消化管、尿道、臍、血管、リンパ管、胆管、その他の体腔

や、例えば肺、心臓、腎臓等の各種臓器、その他の生体組織等へ挿入される種々のカテーテル、バルーンカテーテルが挙げられるが、特に、尿道に挿入して使用されるカテーテル（尿道カテーテル、導尿カテーテル）が好ましい。

【0047】排尿障害における導尿法は、留置カテーテルではなく無菌間歇導尿法が好ましいが、近年、患者自身がカテーテルを使って尿を排出する自己導尿が有効な治療方法として普及してきている。排尿障害は、前立腺肥大症、結石、腫瘍などによる尿道閉塞や、脳・脊髄および骨盤神経などの障害により見られる神経因性膀胱によって起こるが、尿を完全に出しきれない状態になると、尿路内圧が上がって腎臓に負担をかけるので、定期的に尿を排出する必要がある。この際に行われる自己導尿法は、低圧で完全に尿を排出できるので、既にある尿感染が低減する、頻尿、尿失禁が治る、膀胱と腎臓に負担をかけない等の利点があり、患者自身が1日4～6回程度、尿道から膀胱内にカテーテルを挿入し、尿の排出が終了したら抜去する。その頻度は、例えば、昼間は4～5時間毎、夜間は就寝前とされる。

【0048】カテーテル7の表面には、例えば、湿潤により潤滑性を発現する物質が付与されているのが好ましい。このような物質としては、例えば、特開昭60-259269、特開平1-195863号公報に記載されているような親水性ポリマーが挙げられる。また、例えば、特公平6-32652号、特開平6-7426号、国際出願WO8802623、国際出願WO8907521、国際出願WO8909246、国際出願WO9001344、国際出願WO9219289、国際出願WO9311751、国際出願WO9529722、特表平10-502854号、特表平10-502855号、特表平10-502856号に開示されている物質や方法を用いてもよい。このような物質は、カテーテル7の表面に、湿潤していない状態（乾燥状態）で存在している。

【0049】このような物質は、カテーテル7の基材表面に化学結合されたポリマーであって、カテーテル7の基材表面からの剥離は、水、生理等張液、その他潤滑剤等への溶出が生じ難いものが、潤滑性の持続性、安全性の点から好ましい。

【0050】脱臭剤（消臭剤）8は、市販されている脱臭剤、消臭剤、芳香剤等、いずれのものを使用してもよい。この場合、脱臭剤8の臭気除去機構においても、物理的消臭法（活性炭、ゼオライト等の多孔性物質）、化学的消臭法（各種有機・無機化合物、植物抽出物、オゾン、貴金属系酸化触媒）、生物学的消臭法（微生物、人工酵素）、感覚的消臭法（芳香系化合物、植物製油）等、第1の空間4に収納可能であればいかなるものでもよい。

【0051】脱臭剤8として特に好ましいものとして

は、酸化チタン（ TiO_2 ）が挙げられる。この酸化チタンは、次のような利点を有する。

【0052】1）無害な無機酸化物であり、環境との調和が可能である。

2）紫外光励起の結果、強力な酸化力を有し、吸着した有機物の常温分解が可能である。

3）吸着した酸素を酸素ラジカルに変化させ、このラジカルにより吸着した有機物の常温分解が可能である。

4）上記2）3）の効果が、日常の生活空間の照明光で惹起される。

【0053】このような酸化チタンの持つ優れた機能により、脱臭効果のみならず、抗菌、抗カビ効果も得られる。このような酸化チタンは、好ましくは、紙、不織布などの有機合成繊維や、パルプなどの有機化合物から構成される繊維の基材に担持させたものが好ましい。

【0054】このような脱臭剤8は、通気性を有する容器（包材）81に収納された状態とされている。この容器81は、気体は透過するが液体は透過できないような材料で構成されているのが好ましい。このような容器81の構成材料としては、例えば、ポリエチレン製不織布、ポリテトラフルオロエチレン製多孔質体のような水不透過性多孔質体が挙げられる。

【0055】第2の空間5には、前記カテーテル7の表面と接触してその摩擦抵抗を低減させることができる流動性物質（液状または半液状物）10が収納（充填）されている。

【0056】この流動性物質10の例としては、水、生理等張液（生理食塩水）、グリセリン、シリコーンオイル、オリーブオイル等のオイル類、キシロカインゼリー等（以下、これらを総称して「潤滑剤」と言う）が挙げられる。

【0057】カテーテル7の表面に前述したような湿潤により潤滑性を発現する物質が付与されている場合、流動性物質10は、この物質を湿潤させることができるものであればいかなるものでもよく、その典型例としては、水、生理等張液（生理食塩水）、グリセリン水溶液等が選択される。

【0058】包材2（好ましくは包材2全体）は、水蒸気バリア性を有するのが好ましい。ここで、水蒸気バリア性とは、水蒸気透過度が、好ましくは $30\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\text{ }\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下、より好ましくは $10\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\text{ }\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下、さらに好ましくは $1\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\text{ }\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下であることを言う。この水蒸気透過度は、JIS K7129（A法）に記載の方法により測定される。

【0059】このように包材2が水蒸気バリア性を有することにより、包材2の内部、特に第2の空間5からの水分の蒸散が防止できる。その結果、第2の空間5内の液剤（流動性物質10等）の減少、濃縮を防止するこ

とができるとともに、該液剤の量が必要最少限の量で済み、包装体1全体の容積や重量を小さくすることができる。また、包材2の外部や第2の空間5からの第1の空間4内への水蒸気の侵入も防止することができる。

【0060】包材2を構成するシート材（フィルム）、特に前記水蒸気バリア性を有するシート材としては、例えば、ポリエチレン、ポリプロピレン等のポリオレフィン樹脂、これらポリオレフィン樹脂のブレンド樹脂、ポリエチレンテレフタレート等のポリエステル樹脂、ポリ塩化ビニリデン、塩化ビニル-塩化ビニリデン共重合体等の単層フィルム、これらのフィルムにアルミニウム、シリカ等を蒸着したもの、アルミニウムフィルム、アルミニウムラミネートフィルム等の金属箔または金属箔を含むフィルムを使用することができる。さらには、これら各フィルムを2層以上積層したものをを用いることもできる。

【0061】なお、弱シール部23、24においては、直接融着に関与する層（シーラント層）が2種以上の互いに相溶しないポリオレフィン樹脂のブレンド樹脂、もしくは2種以上の互いに相溶しないポリオレフィンをセグメントに有するランダムもしくはブロック共重合体で構成されていることが好ましい。

【0062】本発明では、包材2全体または包材2の少なくとも第2の空間5を画成する部分が、水蒸気バリア性を有するシート材で構成されているのが好ましい。このようなシート材は、例えば、[1]1種のポリオレフィン樹脂で構成される単層フィルム、[2]2種以上の互いに相溶しないポリオレフィン樹脂のブレンド樹脂より構成される単層フィルム、[3]シーラント層（融着に関与する層）にポリオレフィン樹脂（ポリオレフィン樹脂のブレンド樹脂も使用可能）を用いたポリオレフィン樹脂もしくはポリエステルの多層フィルム、等が挙げられる。

【0063】より高い水蒸気バリア性を得るには、例えば、[4]シーラント層がポリオレフィン樹脂（ポリオレフィン樹脂のブレンド樹脂も使用可能）より構成されるフィルム、外層がポリ塩化ビニリデンをコーティングしたポリオレフィンまたはポリエステルのフィルム等で構成される多層フィルム、[5]シーラント層がポリオレフィン樹脂（ポリオレフィン樹脂のブレンド樹脂も使用可能）より構成されるフィルム、外層がアルミ蒸着もしくはシリカ蒸着されたポリオレフィンフィルムまたはポリエステルのフィルム等で構成される多層フィルム、が挙げられる。

【0064】さらに、極めて高い水蒸気バリア性を得るには、例えば、[6]シーラント層がポリオレフィン樹脂（ポリオレフィン樹脂のブレンド樹脂も使用可能）より構成されるフィルム、中間層がアルミニウムフィルム、最外層がポリエステルのフィルム等で構成される多層フィルム、が挙げられる。この場合、対向する一対のシ

ート材のうち的一方を不透明なアルミニウムフィルム、他方をシリカ蒸着フィルム等の透明な水蒸気バリア性フィルムとすれば、包材2の内容物の視認による確認が行えるので、さらに好ましい。なお、アルミニウムフィルムは、必要に応じその一部もしくは全部が剥離除去可能であつてもよい。

【0065】包材2を構成するシート材（単層または多層積層体）の厚さは、その層構成や用いる素材の特性（柔軟性、強度、水蒸気透過性、耐熱性等）等に応じて適宜決定され、特に限定されるものではないが、通常は、60～700 μ m程度であるのが好ましく、100～500 μ m程度であるのがより好ましい。

【0066】このような包材2を構成するシート材は、例えば、インフレーション法、Tダイ法、ブロー成型法、ドライラミネート法、ホットメルトラミネート法、共押出インフレーション法、共押出Tダイ法、ホットプレス法等の種々の方法により製造することができる。

【0067】次に、本発明の包装体の第2実施例について、前記第1実施例との相違点を中心に説明し、同様の事項の説明は省略する。

【0068】第2実施例の包装体は、図1に示す包装体1において、脱臭剤8に代え、少なくとも微生物（細菌、ウイルス等）の増殖（繁殖）を抑制する機能を有する物質を収納したものである。この物質の代表的なものとしては、抗菌剤が挙げられ、以下、この抗菌剤で代表的に説明する。ここで、抗菌剤とは、殺菌、消毒、除菌、抗菌または制菌作用を有する物質の総称を言う。

【0069】抗菌剤としては、有機系抗菌剤、無機系抗菌剤のいずれでもよいが、耐性菌の出現の防止等、安全性をより重視するという点では、例えば、金属、金属酸化物、各種セラミックス等の無機系抗菌剤が好ましい。

【0070】また、抗菌剤は、その作用機序から、細胞壁合成阻害、細胞膜障害、蛋白合成阻害、DNA合成障害、細胞内代謝障害等に分類できるが、本発明では、いかなる作用機序のものでもよい。

【0071】このような抗菌剤の特に好ましいものとしては、前述した酸化チタン（ TiO_2 ）が挙げられる。この酸化チタンについては、前述した通りである。

【0072】また、抗菌剤は、例えば、織布、メッシュ（網状体）等で構成された通気性および通液性を有する容器（包材）、あるいは前述した容器（包材）81に収納された状態で、第1の空間4内に収納されているのが好ましい。

【0073】図2は、本発明の包装体の第3実施例を示す平面図（内部透視図）である。以下、第3実施例の包装体について、前記第1実施例との相違点を中心に説明し、同様の事項の説明は省略する。

【0074】図2に示すように、第3実施例の包装体1は、包材2の第1の空間4内に抗菌剤（少なくとも微生物の増殖を抑制する機能を有する物質）として、シート

状の抗菌剤、すなわち、抗菌シート9を収納したものである。

【0075】抗菌シート9としては、例えば、シート、多孔質体等の基材に、有機系抗菌剤、銀、銅、亜鉛などの抗菌活性を有する金属、セラミックス等の抗菌剤を担持させたものが挙げられる。特に、耐性菌の出現の懸念の少ない無機系抗菌剤が好ましい。

【0076】なお、図示の構成では、抗菌シート9は、第1の空間4の一部分に配置されているが、第1の空間4のほぼ全域をカバーするような大きさの抗菌シートを用いることもできる。また、抗菌シート9は、複数枚収納されていてもよい。

【0077】第2および第3実施例のように、第1の空間4内に抗菌剤を収納したことにより、包材2の開封前または開封後のカテーテル7は勿論のこと、使用済みのカテーテル7を第1の空間4内へ戻した際にも、カテーテル7に対し抗菌作用を発揮することができ、廃棄までの間の運搬や廃棄処理を衛生的で安全に行うことができる。

【0078】図3は、本発明の包装体の第4実施例を示す平面図（内部透視図）である。以下、第4実施例の包装体について、前記第1実施例との相違点を中心に説明し、同様の事項の説明は省略する。

【0079】図3に示すように、第4実施例の包装体1は、第2の空間5が第1の空間4の内側に形成されているものである。すなわち、包材2は、第1の空間4を有し、その中には、前述したカテーテル7と、脱臭剤8（または抗菌剤）と、小包材（袋体）11とが収納されている。

【0080】小包材11は、前述した包材2を構成するシート材と同様のシート材を重ね、その外周部を融着（または接着）によりシールして袋状としたものであり、その内部には、第2の空間5が形成される。この第2の空間5には、前述した流動性物質10が収納（充填）されている。

【0081】小包材11の外周のシール部は、第2の空間5と第1の空間4とを区画する仕切部22を構成する。この仕切部22の一部には、前記と同様の弱シール部23が形成されている。この弱シール部23を剥離（破断）することにより、第1の空間4と第2の空間5とが連通し、流動性物質10を第1の空間4へ流入させることができる。

【0082】このような構成の包装体1は、次のような効果（利点）を有する。まず第1に、第1の空間4内に入れる小包材11の容量を選択することにより、小包材11の内容物（流動性物質10等）の量や重量を容易に設定することができる。第2に、小包材11が第1の空間4内で移動可能であるため、弱シール部23を剥離（破断）する操作や、その後小包材11内から流動性物質10等をしごき出す操作を容易に行うことができる。

第3に、2重包装であるため、流動性物質10の容器である小包材11には、要求される水蒸気バリアー性のレベルが前記第1～第3実施例に比べて低くてよく、よって、小包材11の構成材料の選択の自由度が広がり、また、シート厚をより薄くできる等、製造上有利となる。第4に、小包材11は単独で製造可能なので、製造・管理がしやすい。

【0083】なお、第4実施例の包装体1の場合、小包材11のみが、水蒸気バリアー性を有するものであってもよい。

【0084】次に、上述した各包装体1の使用方法（作用）について説明する。

【0085】例えば前述したような方法により弱シール部23を剥離（破断）すると、第1の空間4と第2の空間5とが連通し、第2の空間5内に収納されていた流動性物質10が第1の空間4内に流入し、カテーテル7の表面に接触する。これにより、カテーテル7の表面に潤滑性が発現し、摩擦抵抗が低減する。なお、弱シール部23を剥離（破断）後、必要に応じ、包材2の外部から手で押圧（圧迫）する等して、第2の空間5から流動性物質10等をしごき出す操作を行ってもよい。

【0086】第1の空間4および第2の空間5は、予め滅菌処理がなされており、しかも、このようなカテーテル7の表面に潤滑性を発現させる操作は、密閉された包材2の内部で外気と接触することなく行われるため、カテーテル7は、無菌性を保持することができる。

【0087】なお、第1の空間4に流入した流動性物質10は、容器81を透過することはできないので、容器81内の脱臭剤8は、流動性物質10で濡れることはなく、よって、脱臭機能（消臭機能）の低下を生じることが防止される。

【0088】従来では、細菌感染を防ぐために、カテーテルを生体内に挿入する前に、そのカテーテルを例えば1%ポピドンヨードグリセリン液のような消毒液に浸漬し、消毒する操作を行っていた。しかし、消毒液の調整が非常に煩雑なことや、消毒液の入手自体が困難な場合も多々あり、患者自身への負担が大きく、安全性の確保が十分ではなかった。また、同一のカテーテルに対し、消毒を繰り返し行って複数回使用すると、カテーテル表面へのバイオフィルムの形成等により細菌繁殖の温床になることもあった。これに対し、本発明では、前述したように、包材2を開封することなくカテーテル7を使用可能な状態（低摩擦状態）とすることができ、かつ、カテーテル7の無菌性を保持したままそのような状態とすることができるので、かかる従来の問題点が解消される。

【0089】カテーテル7の表面に潤滑性を発現させる操作が終了したら、弱シール部24を剥離（破断）し、ジッパー3を開いて、第1の空間4内のカテーテル7を取り出し、生体の目的部位に挿入または装着する。カテ

ーテル7が尿道カテーテル（導尿カテーテル）である場合には、そのカテーテル7を尿道および膀胱に挿入し、該カテーテル7を介して排尿する。このとき、カテーテル7の挿入は、カテーテル7の表面が潤滑性を有しているため、円滑かつ安全に行うことができる。排尿が終了したら、カテーテル7を尿道から抜き取る。

【0090】使用済みのカテーテル7は、廃棄されるが、カテーテル7を単独で廃棄するのではなく、カテーテル7を再び包材2の第1の空間4内に戻し、ジッパー3を閉じ、包材2ごと廃棄するのが好ましい。

【0091】特に、患者による自己導尿においては、外出時においてトイレの個室内でカテーテル7を使用した後、設置してあるゴミ箱にそれを捨てることは難しく、そのため、自宅に持ち帰り、廃棄することを希望する。また、帰宅途中（運搬移動中）において、使用したカテーテル7から発せられた尿臭気が外部へ漏れることは好ましくない。さらに、カテーテル7に残存する尿により、尿中の細菌、ウイルス等が繁殖することが懸念され、衛生的に好ましくない。

【0092】本発明では、使用済みのカテーテル7を包材2の第1の空間4内に収納した際、脱臭剤8がカテーテル7から発せられる尿臭気等の臭気を消滅または減少させる。また、抗菌剤（酸化チタン、抗菌シート9等）が細菌、ウイルス等の増殖を抑制する。これにより、上記のような問題が解消され、使用済みのカテーテル7を臭気の放散を生じることなく、衛生的に搬送することができる。

【0093】図4は、本発明の包装体の第5実施例を示す平面図（内部透視図）である。以下、第5実施例の包装体について、前記第1実施例等との相違点を中心に説明し、同様の事項の説明は省略する。

【0094】図4に示すように、第5実施例の包装体1は、包材2内に、仕切部25により仕切られた第1の空間4、第2の空間5および第3の空間6を有するものである。

【0095】包材2の外周部等には、包材2を構成するシート材を融着（または接着）した帯状のシール部21が形成されている。

【0096】仕切部25は、シール部21と同様にシート材を帯状に融着（または接着）したものであり、T字状をなしている。この仕切部25により、包材2内は、それぞれ独立した（互いに隔離された）第1の空間4、第2の空間5および第3の空間6に区画されている。

【0097】この場合、第1の空間4、第2の空間5および第3の空間6は、互いに隣接して配置されている。従って、後述するような第2の空間5から第1の空間4への液体の移動、および第1の空間4から第3の空間6への移動等を迅速、確実に行うことができる。

【0098】仕切部22には、前記弱シール部23と同様の弱シール部26および27が形成されている。弱シ

ール部26を剥離（破断）することにより、第1の空間4と第2の空間5とが連通し、弱シール部27を剥離（破断）することにより、第1の空間4と第3の空間6とが連通する。

【0099】第1の空間4内には、前述したカテーテル7が収納されており、第2の空間5には、前述した流動性物質10が収納されている。

【0100】第3の空間6内には、液体を吸収、保持し得る物質として、吸水性材料12が収納されている。この吸水性材料12としては、例えば、ポリアクリル酸塩系、ポリビニルアルコール系、ポリアクリルアミド系、ポリオキシエチレン系またはマレイン酸系材料などの合成ポリマーや、デンプン、セルロース、アルギン酸のような多糖類材料などの天然材料などのような高分子吸水性材料が好ましい。また、その他、例えば、スポンジ、綿、ガーゼ、不織布や、それらに上記高分子吸水性材料を担持したもの（例えば、おむつ、生理用品などに用いられているもの）が挙げられる。これらの吸水性材料12は、例えば、粉末状、フィルム状、シート状、繊維状（繊維の集合体）などの種々の形態をとることができる。

【0101】なお、第1の空間4または第3の空間6に、前述した脱臭剤および／または抗菌剤が収納されていてもよい。特に、第3の空間6にこれらを収納する場合、吸水性材料12に、前述したような脱臭剤（脱臭機能を有する成分）および／または抗菌剤（抗菌機能を有する成分）が担持された構成とすることが好ましい。

【0102】図5は、本発明の包装体の第6実施例を示す平面図（内部透視図）である。以下、第6実施例の包装体について、前記第5実施例等との相違点を中心に説明し、同様の事項の説明は省略する。

【0103】図5に示すように、第6実施例の包装体1は、第1の空間4と第3の空間6とが弱シール部27を有する仕切部25により隔離され、第2の空間5が第1の空間4の内側に形成されているものである。すなわち、包材2の第1の空間4内には、前述したカテーテル7と、前記と同様の小包材（袋体）11とが収納されている。

【0104】小包材11の外周部は、弱シール部23を有する仕切部22で構成され、その内側には、第2の空間5が形成されている。この第2の空間5には、前述した流動性物質10が収納（充填）されている。弱シール部23を剥離（破断）することにより、第1の空間4と第2の空間5とが連通し、流動性物質10を第1の空間4へ流入させることができる。

【0105】また、第3の空間6内には、前記と同様の吸水性材料（液体を吸収、保持し得る物質）12が収納されている。

【0106】このような構成の包装体1は、前記第4実施例の包装体1と同様の効果（利点）を有する。

【0107】図6は、本発明の包装体の第7実施例を示す平面図（内部透視図）である。以下、第7実施例の包装体について、前記第5実施例、第6実施例等との相違点を中心に説明し、同様の事項の説明は省略する。

【0108】図6に示すように、第7実施例の包装体1は、第2の空間5および第3の空間6がそれぞれ第1の空間4の内側に形成されているものである。すなわち、包材2の第1の空間4内には、前述したカテーテル7と、小包材（袋体）14とが収納されている。

【0109】小包材14は、前述した包材2を構成するシート材と同様のシート材を重ね、その外周部および途中を融着（または接着）によりシールして袋状としたものであり、その内部には、仕切部28を介して第2の空間5と第3の空間6とが形成されている。

【0110】第2の空間5には、前述した流動性物質10が収納（充填）され、第3の空間6には、前述した吸水性材料（液体を吸収、保持し得る物質）12が収納されている。

【0111】小包材14の外周部および途中を横断するシール部は、第1の空間4、第2の空間5および第3の空間6を隔離（区画）する仕切部28を構成する。この仕切部28の一部には、第2の空間5を開封するための弱シール部26と、第3の空間6を開封するための弱シール部27とが形成されている。なお、本実施例では、弱シール部27は、2箇所に設けられている。

【0112】このような構成の包装体1は、次のような効果（利点）を有する。まず第1に、第1の空間4内に入れる小包材14の容量（第2の空間5および第3の空間6のそれぞれの容量）を選択することにより、小包材14の内容物（流動性物質10および吸水性材料12）の量や重量を容易に設定することができる。第2に、小包材14が第1の空間4内で移動可能であるため、弱シール部26、27を剥離（破断）する操作や、第2の空間5から流動性物質10等をしごき出す操作、第3の空間6へ液体を回収する操作を容易に（適正な位置で）行うことができる。また、前述した小包材11の第3および第4の利点についても同様である。

【0113】なお、本実施例では、1つの小包材14に第2の空間5および第3の空間6が形成されているが、これに限らず、第1の空間4内に2つの分離された小包材が収納され、それらの小包材にそれぞれ第2の空間5および第3の空間6が形成された構成であってもよい。この構成の場合にも、前記と同様の効果が得られる。

【0114】図7は、本発明の包装体の第8実施例を示す平面図（内部透視図）である。以下、第8実施例の包装体について、前記第5実施例等との相違点を中心に説明し、同様の事項の説明は省略する。

【0115】図7に示すように、第8実施例の包装体1は、その下端部側にU字状の第2の空間5を有し、該第2の空間5内には、前述した流動性物質10が収納（充

填）されている。

【0116】また、第2の空間5の内側（包材2の中心側）には、U字状の仕切部29を介して第3の空間6が形成され、該第3の空間6内には、前述した吸水性材料（液体を吸収、保持し得る物質）12が収納されている。

【0117】仕切部25は、第1の空間4と第2の空間5、および第1の空間4と第3の空間6とをそれぞれ隔離している。この仕切部25には、第3の空間6を開封するための弱シール部27が形成されている。

【0118】仕切部25の一方の側部には、破断して開封可能な封止部材13が設置されている。この封止部材13は、仕切部25と交差するように仕切部25に挟まれて融着されている。以下、封止部材13の構成について説明する。

【0119】図8は、封止部材13の構成例を示す縦断面図である。同図に示すように、封止部材13は、例えば軟質ポリ塩化ビニルのような可撓性を有する樹脂により構成された短チューブ131と、この短チューブ131内に液密に嵌入され、中実柱状部133によりその一端が閉塞された筒体132とで構成されている。

【0120】短チューブ131の図8中上端部は、第1の空間4に連通し、筒体132の図8中下端部は、第2の空間5に連通している。

【0121】筒体132の途中の外周には、薄肉で脆弱な破断部134が形成されている。手指等により短チューブ131の外から短チューブ131ごと中実柱状部133を折り曲げて破断部134を破断し、中実柱状部133を分離することにより、封止部材13の内部流路が開通する。これにより、第1の空間4と第2の空間5とが連通し、第2の空間5内の流動性物質10を第1の空間4へ流入させることができる。

【0122】筒体132の構成材料としては、例えば、硬質ポリ塩化ビニル、ポリカーボネート、ポリエステル等の硬質材料が挙げられる。

【0123】また、中実柱状部133の上端部135は、くさび形状（扁平形状）をなしている。これにより、中実柱状部133の破断分離後に中実柱状部133が短チューブ131を閉塞せず、十分な液流通を確保することができる。

【0124】また、短チューブ131の図8中上端部は、その内径が縮径しており、破断分離後の中実柱状部133がこの縮径部136を通過することができないようになっている。これにより、破断分離された中実柱状部133が第1の空間4内に入り、第1の空間4内で自由に移動することを防止することができる。

【0125】前記第5実施例、第6実施例、第7実施例および第8実施例においては、第2の空間5には流動性物質10が収納されていたが、これらの各実施例において、流動性物質10に代わり、第2の空間5内に血液抗

凝固剤（抗血栓剤）を含有する液体が収納されていてもよい。これにより、カテーテル7を使用するに際し、カテーテル7に血液抗凝固機能を付与することができる。血液抗凝固剤としては、例えば、下記表1に示すものが

挙げられる。
【0126】
【表1】

表 1

ACD液	クエン酸ナトリウム	2.2%
	クエン酸	0.8%
	ブドウ糖	2.2%
CPD液	クエン酸ナトリウム	2.63%
	クエン酸	0.327%
	ブドウ糖	2.32%
	リン酸・1・ナトリウム	0.222%
CPDA - 1 液	クエン酸ナトリウム	2.63%
	クエン酸	0.327%
	ブドウ糖	2.9%
	リン酸・1・ナトリウム	0.222%
	アデニン	0.0275%
ヘパリン	塩化ナトリウム	0.9%
	ヘパリンナトリウム	1000単位/30ml

【0127】以上の各実施例では、包材2として、可撓性を有するシート材で構成されたものを挙げたが、これに限らず、例えば、一部が比較的硬質な材料で構成されたものでもよい。その具体例としては、いわゆるプリスター容器と呼ばれるものが挙げられる。このプリスター容器は、比較的硬質な材料で構成され、収納空間（例えば第1の空間）を形成する凹部を有する本体と、前記凹部の開口部を気密的に封止するフィルムとで構成され、該フィルムを剥がすことにより開封するものである。

【0128】次に、第5～第8実施例の各包装体1の使用（作用）について説明する。弱シール部23または26を剥離（破断）すると（第8実施例の場合には、封止部材13の中実柱状部133を破断分離すると）、第1の空間4と第2の空間5とが連通し、第2の空間5内に収納されていた流動性物質10が第1の空間4内に流入し、カテーテル7の表面に接触する。これにより、カテーテル7の表面に潤滑性が発現し、摩擦抵抗が低減

する。なお、必要に応じ、包材2の外部から手で押圧（圧迫）する等して、第2の空間5から流動性物質10等をしごき出す操作を行ってもよい。

【0129】第1の空間4および第2の空間5は、予め滅菌処理がなされており、しかも、このようなカテーテル7の表面に潤滑性を発現させる操作は、密閉された包材2の内部で外気と接触することなく行われるため、カテーテル7は、無菌性を保持することができる。このように、包材2を開封することなくカテーテル7を使用可能な状態（低摩擦状態）とすることができ、かつ、カテーテル7の無菌性を保持したままそのような状態とすることができるので、前述した従来の問題点が解消される。

【0130】カテーテル7の表面に潤滑性を発現させる操作が終了したら、弱シール部24を剥離（破断）し、ジッパー3を開いて、第1の空間4内のカテーテル7を取り出し、生体の目的部位に挿入または装着する。カテ

ーテル7が尿道カテーテル（導尿カテーテル）である場合には、そのカテーテル7を尿道および膀胱に挿入し、該カテーテル7を介して排尿する。このとき、カテーテル7の挿入は、カテーテル7の表面が潤滑性を有しているため、円滑かつ安全に行うことができる。排尿が終了したら、カテーテル7を尿道から抜き取る。

【0131】使用済みのカテーテル7は、廃棄されるが、カテーテル7を単独で廃棄するのではなく、カテーテル7を再び包材2の第1の空間4内に戻し、ジッパー3を閉じ、包材2ごと廃棄するのが好ましい。

【0132】このとき、前述したような方法により、弱シール部27を剥離（破断）し、開封する。これにより、第1の空間4と第3の空間6とが連通し、カテーテル7の表面に付着し、またはカテーテル7内に残存している尿等の体液を、第3の空間6内に収納されている吸水性材料12で吸収し、保持することができる。その結果、尿等の体液の漏れ出しをより確実に防止することができ、使用済みのカテーテル7を包材2ごと衛生的に搬送し、廃棄することができる。

【0133】特に、吸水性材料12に、脱臭剤（脱臭機能を有する成分）および／または抗菌剤（抗菌機能を有する成分）が担持されている場合には、臭気の放散や細菌、ウイルス等の増殖を抑制し、より衛生的で安全に搬送、廃棄処理を行うことができる。

【0134】以上のように、本発明の包装体1によれば、簡便にかつ無菌的に潤滑剤、血液抗凝固剤等とカテーテルとの接触を可能にし、患者等による運搬、開封操作等も簡単であるばかりでなく、カテーテルの使用後も衛生的に安全に運搬し、廃棄することができる。

【0135】本発明において、第1の空間4に収納される器具としては、以下のようなものが挙げられる。

【0136】・ 胃管カテーテル、栄養カテーテル、経管栄養用チューブ、酸素カテーテル、酸素カヌー、気管内チューブのチューブやカフ、気管切開チューブのチューブやカフ、気管内吸引カテーテル等の経口または経鼻的に挿入、留置されるカテーテル類。

【0137】・ 吸引カテーテル、排液カテーテル、腹腔カテーテル、直腸カテーテル、トロッカー等の各種体腔、臓器、組織内に挿入、留置されるカテーテル類。

【0138】・ 血管造影用カテーテル、PTCA用バルーンカテーテル、IABP用バルーンカテーテル、静脈留置カテーテル、動注用カテーテル等の血管内に挿入、留置されるカテーテル類。

【0139】・ 単独で、または、前記各カテーテル類とともに使用される各種ガイドワイヤー。

・ 人工血管、ステント、人工肛門、人工骨、人工関節、補綴物、義眼。

・ 注射針、留置針、シース、カテーテルイントロデューサ。

【0140】・ 内視鏡、心拍出量測定器具、超音波測

定・診断器具、超音波破砕プローブ、ペースメーカー、体温計。

・ 縫合用または結さつ用の糸
・ 浣腸
・ コンタクトレンズ
・ コンドーム等の避妊具

【0141】また、本発明において、第1の空間4、第2の空間5、第3の空間6の配置は、図示の各実施例のものに限らず、例えば、第2の空間、第1の空間および第3の空間が、この順に一例に配置された構成であってもよい。また、包材は、さらに第4の空間を有していてもよい。

【0142】また、第1の空間4、第2の空間5および第3の空間6には、それぞれ、前述した以外の任意のものが収納されていてもよい。

【0143】

【実施例】以下、実施例を挙げて本発明を具体的に説明する。

【0144】（実施例1A）ポリプロピレン（XF1800、チッソ（株）製）60重両部とスチレン系エラストマー（ハイブラHVS-3、クラレ（株）製）40重量部を用いて、共押出成形によるインフレーションシート（厚さ300 μ m、水蒸気透過度15g/m²・24hrs・25 μ m厚・40℃・90%RH）を得た。このシートを熱融着によりシールして、図1に示す構成の包材を成形した。

【0145】包材の第1の空間には、尿道に挿入して使用されるカテーテルとしてのネラトンカテーテル（サフィード、14Fr、テルモ（株）製）と、水不透過性多孔質体であるポリエチレン製不織布（商標名：タイベック、旭・デュポンフラッシュスパンプロダクツ（株）製）により包装された消臭・芳香剤（商標名：エアニップ、有限会社タクト製）とを入れた。なお、このネラトンカテーテルとしては、表面が、0.2wt%ポリビニルピロリドンクロロホルム溶液（商標名：コリドンK30、BASFジャパン（株）製）でコーティングされ、親水性高分子材料の層が形成されているものを用いた。また、包材の第2の空間には、水10mlを入れ、密封した。

【0146】包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高圧蒸気滅菌を行った。

【0147】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、水とカテーテルとの接触はなかった。

【0148】次に、包材を手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の水が第1の空間内へ流出し、カテ

ーテルと接触した。これにより、簡便にかつ無菌的に水とカテーテルとの接触が可能であることが確認された。

【0149】また、水とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。

【0150】その後、カテーテルを下記表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを開けて密封し、所定

時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。

【0151】よって、患者は、カテーテル使用后、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩しないため、衛生上も好ましいことが示唆された。

【0152】

【表2】

表 2 人工尿の成分

化合物	含有量 (g/L)	化合物	含有量 (g/L)	化合物	含有量 (g/L)
$\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$	0.65	$\text{Na}_2\text{H}_2\text{C}_6\text{H}_5\text{O}_7$	0.65	NH_4Cl	2.00
$\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$	0.65	$(\text{COONa})_2$	0.02	NH_2CONH_2	12.00
NaCl	4.60	KH_2PO_4	2.80	$\text{C}_6\text{H}_7\text{N}_3\text{O}$	1.10
Na_2SO_4	2.30	KCl	1.60	pH	5.7~5.8

【0153】（実施例2A、3A、4A）実施例1Aと同様のインフレーションシートを熱融着によりシールして、図1に示す構造の包材を成形した。

【0154】包材の第1の空間には、前記と同様のネラトンカテーテル（表面のコーティングなし）を入れ、第2の空間には、下記表3に示す組成の潤滑剤を入れ、そ

れぞれを密封した。また、第1の空間には、下記表3に示す水不透過性多孔質体で包装された消臭剤、芳香剤等を入れた。

【0155】

【表3】

表 3 第1、第2の空間の収納物

実施例	潤滑剤等	水不透過性多孔質体（包装体）	消臭剤、芳香剤等
2A	グリセリン水溶液 （健栄製薬（株）製）	タイバック （旭・デュボンフラッシュスバンプロダクツ（株）製）	エアニップ （有限会社タクト製）
3A	生理食塩水 （テルモ（株）製）	プレスロン （日東電工（株）製）	微香空間 （小林製薬（株）製）
4A	ミルトン液 （マックスファクター（株）製）	ジュラガード （ポリプラスチックス（株）製）	ピーターラビット消臭剤 （積水化学工業（株）製）

【0156】包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高圧蒸気滅菌を行った。

【0157】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、第2の空間内の液体とカテーテルとの接触はなかった。

【0158】次に、包材を手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥

離し、第2の空間内の液体が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に液体とカテーテルとの接触が可能であることが確認された。

【0159】また、第2の空間内の液体とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、カテーテルが乾燥状態のときと比較して、表面の摺動抵抗値が低減しており、体腔への挿入操作の操作性向上が示唆された。

【0160】その後、カテーテルを表2に示す成分の人

工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封し、所定時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。

【0161】よって、患者は、カテーテル使用后、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩しないため、衛生上も好ましいことが示唆された。

【0162】（実施例5A、6A）実施例1Aと同様の

表 4 第1、第2空間の収納物

実施例	潤滑剤等	抗菌シート
5A	グリセリン水溶液 (健栄製薬(株)製)	アバタッチ (旭光学工業(株)製)
6A	ミルトン液 (マックスファクター(株)製)	お弁当用抗菌シート (リンデック(株)製)

【0165】包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高压蒸気滅菌を行った。

【0166】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、第2の空間内の液体とカテーテルとの接触はなかった。

【0167】次に、包材を手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の液体が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に液体とカテーテルとの接触が可能であることが確認された。

【0168】また、第2の空間内の液体とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、カテーテルが乾燥状態のときと比較して、表面の摺動抵抗値が低減しており、体腔への挿入操作の操作性向上が示唆された。

【0169】その後、カテーテルを表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封し、所定時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。さらに、抗菌シートの抗菌作用により、カテーテルに付着、残存している尿中の細菌、ウイルス等の増殖が抑制された。

【0170】よって、患者は、カテーテル使用后、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩せず、細菌感染のおそれもないため、衛生上も好ましいことが示唆された。

【0171】（実施例7A）実施例1Aと同様のインフ

レーションシートを熱融着によりシールして、図2に示す構造の包材を成形した。

【0163】包材の第1の空間には、前記と同様のネラトンカテーテル（表面のコーティングなし）を入れ、第2の空間には、下記表4に示す組成の潤滑剤を入れ、それぞれを密封した。また、第1の空間には、下記表4に示す抗菌シートを入れた。

【0164】

【表4】

レーションシートを熱融着によりシールして、図2に示す構造の包材を成形した。

【0172】包材の第1の空間には、前記と同様のネラトンカテーテル（表面に実施例1Aと同様のコーティングを施したもの）を入れ、第2の空間には、水10mlを入れ、それぞれを密封した。また、第1の空間には、酸化チタンを含む脱臭・抗菌シート（商標名：PM-IN-CD、三菱製紙(株)製）を入れた。

【0173】包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高压蒸気滅菌を行った。

【0174】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、第2の空間内の液体とカテーテルとの接触はなかった。

【0175】次に、包材を手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の水が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に水とカテーテルとの接触が可能であることが確認された。

【0176】また、第2の空間内の水とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、カテーテルが乾燥状態のときと比較して、表面の摺動抵抗値が大幅に低減しており、体腔への挿入操作の操作性向上が示唆された。

【0177】その後、カテーテルを表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封し、所定時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。さらに、脱臭・抗菌シートの抗菌作用により、カテーテルに付着、残存している尿中の細菌、ウイルス等の増殖が抑制された。

【0178】 によって、患者は、カテーテル使用後、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩せず、細菌感染のおそれもないため、衛生上も好ましいことが示唆された。

【0179】（実施例8A）実施例1Aと同様のインフレーションシートを熱融着によりシールして、図3に示す構造の小包材を内蔵する包材を成形した。

【0180】 包材の第1の空間には、実施例1Aと同様のネラトンカテーテルと小包材とを入れ、密封した。小包材の第2の空間には、水20mlを入れ、密封した。また、第1の空間には、水不透過性多孔質体であるポリエチレン製不織布（商標名：タイベック、旭・デュポンフラッシュスパンプロダクツ（株）製）により包装された消臭・芳香剤（商標名：エアニップ、有限会社タクト製）を入れた。

【0181】 包材および小包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高圧蒸気滅菌を行った。

【0182】 滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、第2の空間内の液体とカテーテルとの接触はなかった。

【0183】 次に、小包材を包材の上から手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の水が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に水とカテーテルとの接触が可能であることが確認された。なお、包材内で小包材を好適な位置へ移動してこの操作を行ったため、小包材の開封操作をより簡便、確実に行うことができた。

【0184】 また、第2の空間内の水とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、カテーテルが乾燥状態のときと比較して、表面の摺動抵抗値が大幅に低減しており、体腔への挿入操作の操作性向上が示唆された。

【0185】 その後、カテーテルを表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封し、所定時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。さらに、脱臭・抗菌剤の抗菌作用により、カテーテルに付着、残存している尿中の細菌、ウイルス等の増殖が抑制された。

【0186】 によって、患者は、カテーテル使用後、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩せず、細菌感染のおそれもないため、衛生上も好ましいことが示唆さ

れた。

【0187】（実施例1B）ポリプロピレン（XF1800、チッソ（株）製）60重両部とスチレン系エラストマー（ハイブラHVS-3、クラレ（株）製）40重量部を用いて、共押出成形によるインフレーションシート（厚さ300μm、水蒸気透過度15g/m²・24hrs・25μm厚・40℃・90%RH）を得た。このシートを熱融着によりシールして、図4に示す構造の包材を成形した。

【0188】 包材の第1の空間には、前記実施例1Aと同様のネラトンカテーテルを入れ、第2の空間には、水10mlを入れ、第3の空間には、吸水性材料である架橋ポリアクリル酸ナトリウム（商標名：アクアリック、日本触媒化学工業（株）製）1gを入れ、それぞれを密封した。

【0189】 包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、2Mradでγ線滅菌を行った。

【0190】 滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、水とカテーテルとの接触および水と吸水性材料との接触はなかった。

【0191】 次に、包材を手で押圧、圧迫し、弱シール部26に負荷をかけたところ、弱シール部26のみが剥離し、第2の空間内の水が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に水とカテーテルとの接触が可能であることが確認された。

【0192】 また、水とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。

【0193】 その後、カテーテルを牛血に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封した。

【0194】 次に、弱シール部27を開封して第1の空間と第3の空間とを連通させ、包材を振動させたところ、カテーテルの表面および内部に付着、残存していた血液が第3の空間内の吸水性材料に吸収され、保持された。そのため、ジッパーを開封しても血液の漏洩は生じなかった。

【0195】 によって、使用済みのカテーテルを包材に入れて搬送し、包材ごと廃棄しても、その間に血液の漏洩がなく、血液による汚染、感染が防止され、安全性が高いことが示唆された。

【0196】（実施例2B）実施例1Bと同様のインフレーションシートを熱融着によりシールして、図5に示す構造の小包材を内蔵する包材を成形した。

【0197】 包材の第1の空間には、前記実施例1Aと

同様のネラトンカテーテルおよびガイドワイヤー（カテーテルの内腔に挿入された状態）と、小包材とを入れ、密封した。小包材の第2の空間には、血液抗凝固剤液として前記表1に示すCPDA-1液18mlを入れ、密封した。包材の第3の空間には、吸水性材料である架橋ポリアクリル酸ナトリウム（商標名：アクアリック、日本触媒化学工業（株）製）2gを入れ、密封した。

【0198】包材および小包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、2Mradでγ線滅菌を行った。

【0199】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、抗凝固剤液とカテーテルとの接触および抗凝固剤液と吸水性材料との接触はなかった。

【0200】次に、小包材を包材の上から手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の抗凝固剤液が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に抗凝固剤液とカテーテルとの接触が可能であることが確認された。なお、包材内で小包材を好適な位置へ移動してこの操作を行ったため、小包材の開封操作をより簡便、確実にを行うことができた。

【0201】また、抗凝固剤液とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、抗凝固剤液の水分によりカテーテル表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。また、カテーテルの表面には、抗凝固剤が付着しているため、血管内へ挿入した際に、優れた抗凝固作用を発揮するものと考えられる。

【0202】その後、カテーテルを牛血に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封した。

【0203】次に、弱シール部27を開封して第1の空間と第3の空間とを連通させ、包材を振動させたところ、カテーテルの表面および内部に付着、残存していた血液が第3の空間内の吸水性材料に吸収され、保持された。そのため、ジッパーを開封しても血液の漏洩は生じなかった。

【0204】よって、使用済みのカテーテルを包材に入れて搬送し、包材ごと廃棄しても、その間に血液の漏洩がなく、血液による汚染、感染が防止され、安全性が高いことが示唆された。

【0205】（実施例3B）実施例1Bと同様のインフレーションシートを熱融着によりシールして、図6に示す構造の小包材を内蔵する包材を成形した。

【0206】包材の第1の空間には、前記実施例1Aと同様のネラトンカテーテルおよびガイドワイヤー（カテ

ーテルの内腔に挿入された状態）と、小包材とを入れ、密封した。小包材の第2の空間には、血液抗凝固剤液として前記表1に示すヘパリン液18mlを入れ、第3の空間には、吸水性材料である架橋ポリアクリル酸ナトリウム（商標名：アクアリック、日本触媒化学工業（株）製）2gを入れ、それぞれを密封した。

【0207】包材および小包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、2Mradでγ線滅菌を行った。

【0208】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、抗凝固剤液とカテーテルとの接触および抗凝固剤液と吸水性材料との接触はなかった。

【0209】次に、小包材の図6中上半分を包材の上から手で押圧、圧迫し、弱シール部26に負荷をかけたところ、弱シール部26のみが剥離し、第2の空間内の抗凝固剤液が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に抗凝固剤液とカテーテルとの接触が可能であることが確認された。なお、包材内で小包材を好適な位置へ移動してこの操作を行ったため、弱シール部26の開封操作をより簡便、確実にを行うことができた。

【0210】また、抗凝固剤液とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、抗凝固剤液の水分によりカテーテル表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。また、カテーテルの表面には、抗凝固剤が付着しているため、血管内へ挿入した際に、優れた抗凝固作用を発揮するものと考えられる。

【0211】その後、カテーテルを牛血に30秒間浸し、次いで、このカテーテルとガイドワイヤーとを包材の第1の空間に戻し、ジッパーを閉じて密封した。

【0212】次に、小包材の弱シール部27を開封して第1の空間と第3の空間とを連通させ、包材を振動させたところ、カテーテルの表面および内部に付着、残存していた血液が第3の空間内の吸水性材料に吸収され、保持された。そのため、ジッパーを開封しても血液の漏洩は生じなかった。なお、包材内で小包材を好適な位置へ移動してこの操作を行ったため、弱シール部27の開封操作および残存血液の吸収をより簡便、確実にを行うことができた。

【0213】よって、使用済みのカテーテルを包材に入れて搬送し、包材ごと廃棄しても、その間に血液の漏洩がなく、それによる汚染、感染が防止され、安全性が高いことが示唆された。

【0214】（実施例4B、5B、6B）実施例1Bと同様のインフレーションシートを熱融着によりシールし

て、図7に示す構造の包材を成形した。

【0215】包材の第1の空間には、前記実施例1Bと同様のネラトンカテーテル（表面のコーティングなし）を入れ、第2の空間には、下記表5に示す組成の潤滑剤

等を入れ、それぞれを密封した。また、第3の空間には、下記表5に示す吸水性材料を入れ、密封した。

【0216】

【表5】

表 5 第2、第3の空間の収納物

実施例	潤滑剤等	吸水性材料
4B	グリセリン水溶液 (健栄製薬(株)製)	サンウエット (三洋化成(株)製)
5B	生理食塩水 (テルモ(株)製)	スミカゲル (住友化学(株)製)
6B	ミルトン液 (マックスファクター(株)製)	アクアリザーブGP (日本合成化学(株)製)

【0217】包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、2Mradでγ線滅菌を行った。

【0218】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離や封止部材の破断は観察されず、潤滑剤とカテーテルとの接触および潤滑剤と吸水性材料との接触はなかった。

【0219】次に、包材の外側から封止部材（図8に示す構造）を手で折り曲げ、中実柱状部を破断部にて破断分離し、包材の第2の空間の部分を圧迫したところ、第2の空間内の潤滑剤が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に潤滑剤とカテーテルとの接触が可能であることが確認された。

【0220】また、潤滑剤とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。

【0221】その後、カテーテルを表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封した。

【0222】次に、弱シール部27を開封して第1の空間と第3の空間とを連通させ、包材を振動させたところ、カテーテルの表面および内部に付着、残存していた人工尿が第3の空間内の吸水性材料に吸収され、保持された。そのため、ジッパーを開封しても人工尿の漏洩は生じなかった。

【0223】よって、使用済みのカテーテルを包材に入れて搬送し、包材ごと廃棄しても、その間に尿等の体液の漏洩がなく、それによる汚染、感染が防止され、安全性が高いことが示唆された。

【0224】（実施例1C）包材を構成するシートとして、ポリプロピレン（三菱化学(株)製、SPX9600）の単層フィルム（フィルム厚300μm、水蒸気透過度21g/m²・24hrs・25μm厚・40℃・

90%RH）を用いた以外は、実施例1Aと同様にし、図1に示す構成の包装体を製造した。包材の第1の空間および第2の空間内の収納物も、実施例1Aと同様である。

【0225】（実施例2C）包材を構成するシートとして、直鎖状低密度ポリエチレン（日本ポリケム(株)製、ノバテックLL UF340）とポリプロピレン（チッソ(株)製、チッソポリプロ K7714）とのポリマーブレンドによる単層フィルム（フィルム厚300μm、水蒸気透過度18g/m²・24hrs・25μm厚・40℃・90%RH）を用いた以外は、実施例1Aと同様にし、図1に示す構成の包装体を製造した。包材の第1の空間および第2の空間内の収納物も、実施例1Aと同様である。

【0226】（実施例3C）包材を構成するシートとして、直鎖状低密度ポリエチレンとポリプロピレンとのポリマーブレンドフィルムによる第1層、およびシリカ蒸着ポリエチレンテレフタレートフィルムによる第2層から構成される2層積層フィルム（大日本印刷(株)製、フィルム厚300μm、水蒸気透過度0.6g/m²・24hrs・25μm厚・40℃・90%RH）を、第1層同士が接合されるように用いた以外は、実施例1Aと同様にし、図1に示す構成の包装体を製造した。包材の第1の空間および第2の空間内の収納物も、実施例1Aと同様である。

【0227】（実施例4C）包材を構成するシートとして、直鎖状低密度ポリエチレンとポリプロピレンとのポリマーブレンドフィルムによる第1層、アルミニウムフィルムによる第2層、およびポリエチレンテレフタレートフィルムによる第3層から構成される3層積層フィルム（東洋アルミニウム(株)製、フィルム厚300μm、水蒸気透過度0.3g/m²・24hrs・25μm厚・40℃・90%RH）を、第1層同士が接合されるように用いた以外は、実施例1Aと同様にし、図1に示す構成の包装体を製造した。包材の第1の空間および第2の空間内の収納物も、実施例1Aと同様である。

【0228】（実施例5C）第2の空間に収納した液体

をグリセリン水溶液（健栄製薬（株）製、グリセリン濃度：84～87％）10mlとした以外は、実施例4Cと同様の包装体を製造した。

【0229】＜試験1＞実施例1C～5Cの各包装体を温度40℃、湿度75％RHの環境下で4週間放置し、1週間後、2週間後および4週間後に、それぞれ、第2の空間内に収納された液体の減少率の経時変化を調べ

た。その結果を下記表6に示す。ここで、液体の減少率は、次式により算出した。

$$\text{【0230】減少率（％）} = (W_0 - W) / W_0 \times 100$$

ここで、 W_0 ：試験開始時の液体の総重量（10g）

W ：1、2、4週間後のそれぞれの液体の重量

【0231】

【表6】

表 6 液体の減少率

実施例	1週間後	2週間後	4週間後
1C	0.5%	1.1%	2.0%
2C	0.4%	0.9%	1.7%
3C	0.2%	0.3%	0.7%
4C	0.1%	0.1%	0.3%
5C	0.0%	0.0%	0.1%

【0232】表6に示すように、実施例1C～5Cの包装体は、いずれも、包材が水蒸気バリア性を有するため、液体の減少率が低く、従って、第2の空間内の液体の減少、濃縮を防止することができるとともに、第1の空間内への水蒸気の侵入も防止することができることが確認された。

【0233】特に、水蒸気透過度が $1\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下の実施例3C～5Cの包装体は、液体の減少率が極めて少なく、このような効果がより顕著に発現する。なお、実施例5Cにおいては、第2の空間内に収納される液体が、水よりも揮発性の低いグリセリン水溶液であったため、液体の減少は、ほとんど生じなかった。

【0234】＜試験2＞実施例1C～5Cの各包装体について、前記環境下でさらに4週間放置したが、弱シール部23、24の剥離は認められず、第2の空間からの水の漏れ出しは生じなかった。

【0235】また、その後、包材の第2の空間を形成する部分を手で押圧、圧迫したところ、いずれの包装体についても、弱シール部23を容易かつ確実に剥離することができ、イージーピールシール性が確保されていることが確認された。

【0236】＜包装体の有効保存期間の検討＞本実施例の包装体において、第2の空間内に収納されている液体が蒸散により減少し、その重量が約半分以下になると、加圧による弱シール部の開封（剥離）がし難くなってくる。従って、本試験条件下において、第2の空間内に収納されている液体の量が半分まで減少する時間を次式により算出した。

【0237】

$$\text{時間（年）} = (5\text{ g} / \Delta W) \times (28\text{ 日} / 365\text{ 日})$$

ここで、 ΔW ：4週間後の液体の減少量

$$\Delta W = 10\text{ g} \times (\text{4週間後の液体の減少率} / 100)$$

【0238】その結果、実施例1Cで1.9年、実施例2Cで2.2年、実施例3Cで5.4年、実施例4で12.7年、実施例5Cで38.0年となる。

【0239】以上の結果より、実施例1C～5Cのような水蒸気バリア性を有する包材を用いることにより、収納される液体の減少を抑制し、長期間保持することが可能であることが分かった。

【0240】

【発明の効果】以上述べたように、本発明によれば、簡便にかつ無菌的にカテーテル等の器具と液体とを接触させることができる。特に、包材内の隔離された空間同士との連通操作や、包材の開封操作を容易かつ確実に行うことができる。

【0241】また、第2の空間に収納する液体の種類、組成、量等の選択により、器具に対し種々の機能、特に、表面の潤滑性、抗凝固性（抗血栓性）等の、器具を生体に挿入または装着するに際しての有利な機能を付与することができる。

【0242】また、使用済みの器具を包材内に収納することにより、外部への臭気の放散、微生物の増殖、または器具に付着または残存した液体の漏れ出しによる汚染、感染等を防止することができ、安全性の向上にも寄与する。また、包装体の小型化にも有利である。そのため、使用済みの器具の廃棄処理、または廃棄処理までの間の運搬、保管に有利となる。

【0243】特に、患者自身がカテーテルを使って排尿する自己導尿においては、外出時の使用済みカテーテルの搬送、廃棄において、労力や精神的負担が軽減されるため、患者の快適な生活（クオリティー・オブ・ライフ）に大きく貢献する。

【図面の簡単な説明】

【図1】本発明の包装体の第1実施例を示す平面図（内部透視図）である。

【図2】本発明の包装体の第3実施例を示す平面図（内部透視図）である。

【図3】本発明の包装体の第4実施例を示す平面図（内部透視図）である。

【図4】本発明の包装体の第5実施例を示す平面図（内部透視図）である。

【図5】本発明の包装体の第6実施例を示す平面図（内部透視図）である。

【図6】本発明の包装体の第7実施例を示す平面図（内部透視図）である。

【図7】本発明の包装体の第8実施例を示す平面図（内部透視図）である。

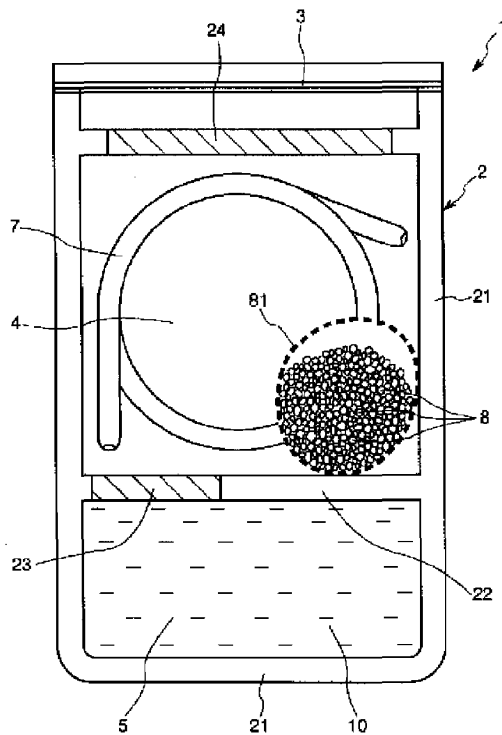
【図8】封止部材の構成例を示す縦断面図である。

【符号の説明】

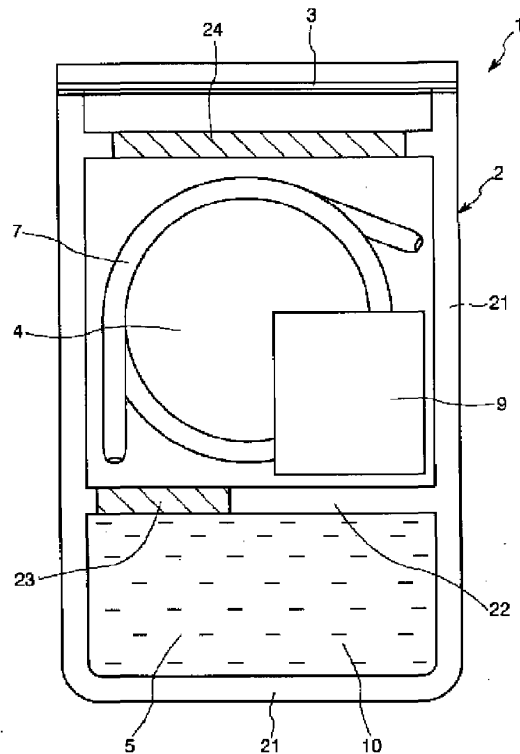
1 包装体
2 包材
21 シール部
22 仕切部
23、24 弱シール部
25 仕切部

26、27 弱シール部
28、29 仕切部
3 ジッパー
4 第1の空間
5 第2の空間
6 第3の空間
7 カテーテル
8 脱臭剤
81 容器
9 抗菌シート
10 流動性物質
11 小包材
12 吸水性材料
13 封止部材
131 短チューブ
132 筒体
133 中実柱状部
134 破断部
135 上端部
136 縮径部
14 小包材

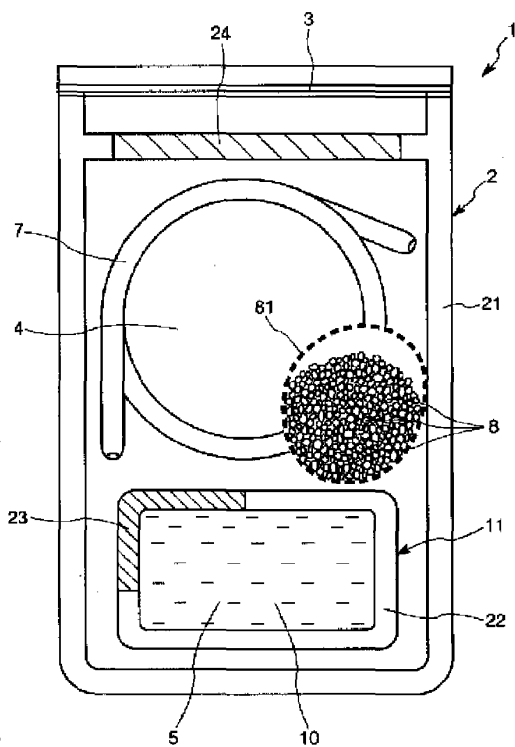
【図1】



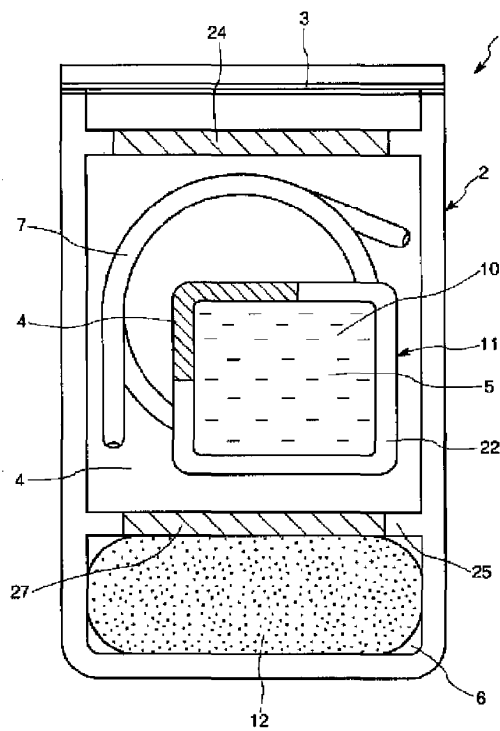
【図2】



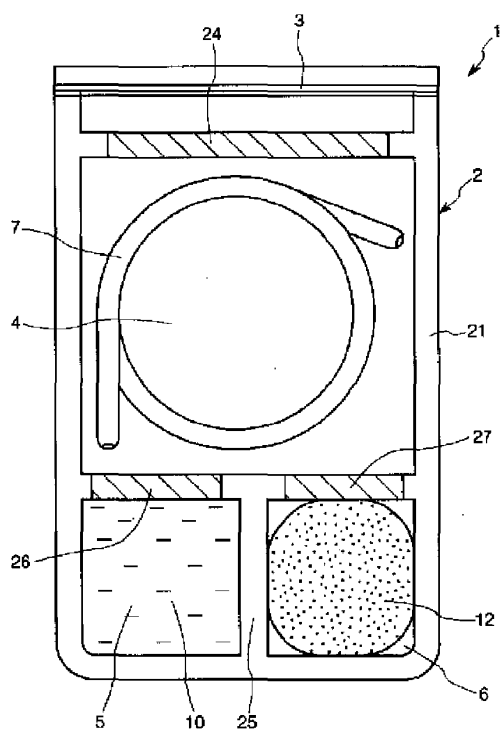
【图3】



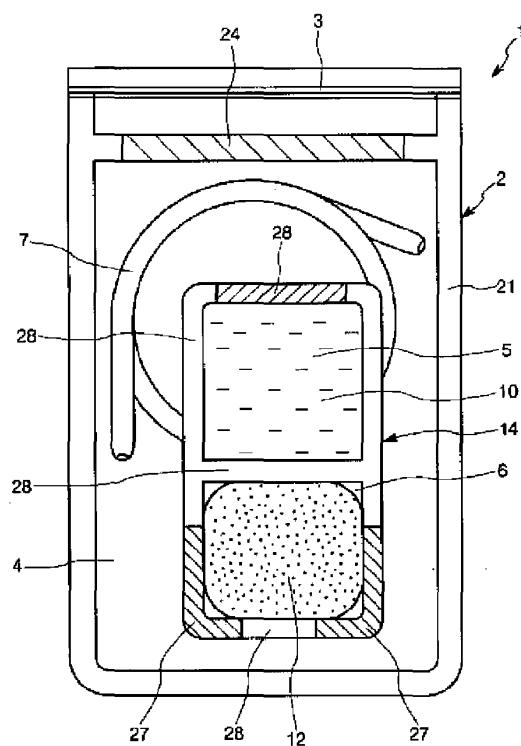
【图5】



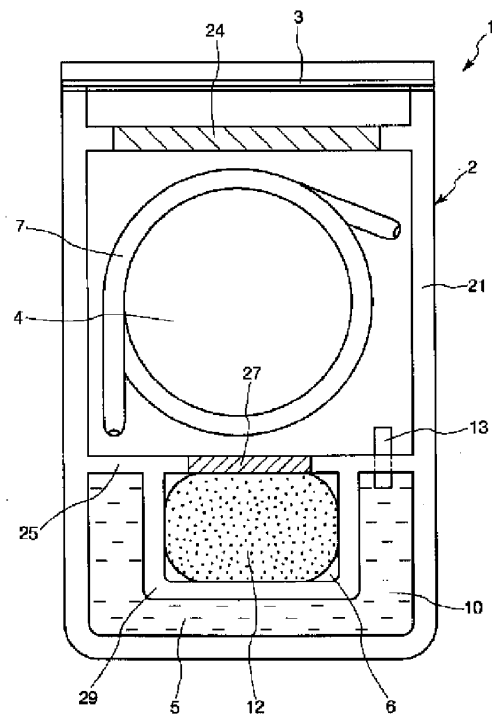
【图4】



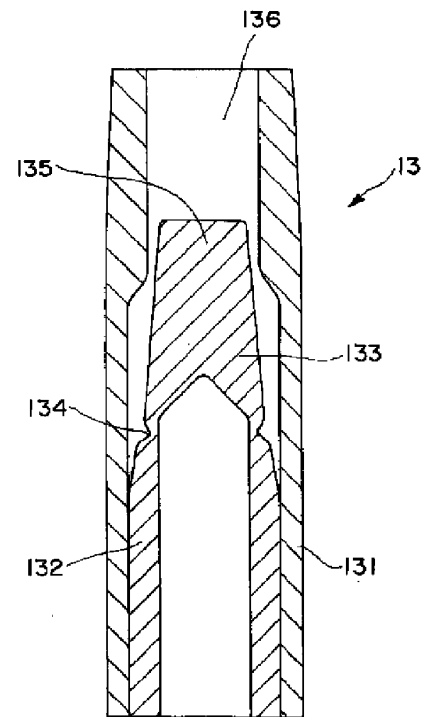
【图6】



【図 7】



【図 8】



フロントページの続き

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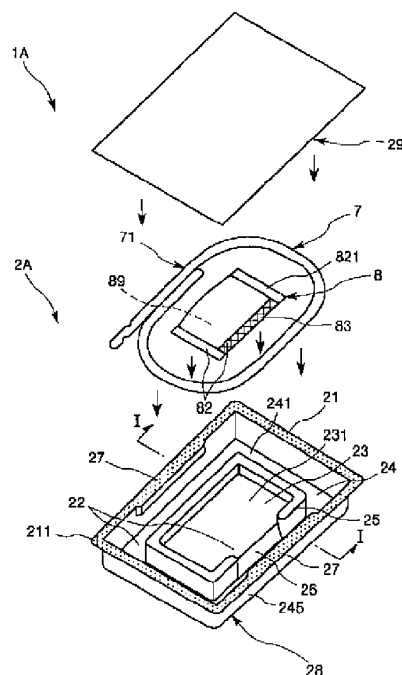
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(54) 【発明の名称】 包装体

(57) 【要約】

【課題】 内部の容器が不本意に破断しにくい包装体を提供すること。

【解決手段】 包装体1Aは、第1シート材28と第2シート材29とで構成された包材2A内に、カテーテル7と、液体89を密封した容器8とが収納された構成となっている。第1シート材28の中央部付近には、第1凹部231が形成され、この第1凹部231の周囲には、壁状の突出部25が形成されている。突出部25の外側には、第2凹部241が形成されている。第1凹部231には、容器8が収納され、第2凹部241には、カテーテル7が収納される。このような包装体1Aでは、容器8が収納された部分の包材2Aの厚さは、カテーテル7が収納された部分の包材2Aの厚さよりも薄くなっている。また、突出部25は、液体89が密封された部位がカテーテル7と重ならないように、容器8の位置を規定している。



【特許請求の範囲】

【請求項 1】 生体に挿入または挿着して使用される器具と、

流動性の物質が密封された容器と、

前記器具と前記容器とを収納する包材とを有する包装体であって、

前記容器の一部または全部が、前記器具に重ならないよう前記容器の位置を規制する位置規制手段を有することを特徴とする包装体。

【請求項 2】 生体に挿入または挿着して使用される器具と、

流動性の物質が密封された容器と、

前記器具と前記容器とを収納する包材とを有する包装体であって、

前記容器の前記流動性の物質が密封された部位が、前記器具に完全に重ならないよう前記容器の位置を規制する位置規制手段を有することを特徴とする包装体。

【請求項 3】 前記位置規制手段は、前記包材の内部に突出した突出部により構成されている請求項 1 または 2 に記載の包装体。

【請求項 4】 前記突出部は、壁状をなしている請求項 3 に記載の包装体。

【請求項 5】 前記突出部は、前記包材を成型して形成されたものである請求項 3 または 4 に記載の包装体。

【請求項 6】 前記突出部は、前記突出部と反対側の包材に隣接または接触している請求項 3 ないし 5 のいずれかに記載の包装体。

【請求項 7】 生体に挿入または挿着して使用される器具と、

流動性の物質が密封された容器と、

前記器具と前記容器とを収納する包材とを有する包装体であって、

前記容器が収納された部分の前記包材の厚さが、前記器具が収納された部分の前記包材の厚さよりも薄いことを特徴とする包装体。

【請求項 8】 前記容器が収納された部分の前記包材の厚さが、前記器具が収納された部分の前記包材の厚さの 4/5 以下である請求項 7 に記載の包装体。

【請求項 9】 前記包材は、前記器具および前記容器を収納可能な膨らみを有するシート材と平坦なシート材とを重ね、これらの縁部をシールしたものである請求項 1 ないし 8 のいずれかに記載の包装体。

【請求項 10】 前記容器は、前記包材を開封しないで前記包材内で開封可能である請求項 1 ないし 9 のいずれかに記載の包装体。

【請求項 11】 前記容器は、シート材をシール部によりシールしてなるものであり、

前記容器に前記シール部よりも接合強度が小さい弱シール部を設けたことにより、前記容器を開封可能とした請求項 10 に記載の包装体。

【請求項 12】 前記容器から流出した前記流動性の物質を前記器具に案内するガイド面を有する請求項 10 または 11 に記載の包装体。

【請求項 13】 前記容器を収納する凹部を有し、この凹部の形状は、前記容器の形状に対応している請求項 1 ないし 12 のいずれかに記載の包装体。

【請求項 14】 前記器具は、長尺の器具であり、前記容器の周りを囲むように、前記包材内に設置される請求項 1 ないし 13 のいずれかに記載の包装体。

【請求項 15】 前記器具は、カテーテルである請求項 1 ないし 14 のいずれかに記載の包装体。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、包装体に関するものである。

【0002】

【従来の技術】神経因性膀胱をはじめとして様々な排尿障害に対する治療方法として、間歇式自己導尿法（Clean Intermittent Catheterization；以下「CIC」と略す）が、普及してきている。CICとは、医療関係者以外の人、主に患者自身がカテーテルを膀胱内に挿入し、膀胱内に溜まった尿を排出する療法である。このCICにより、膀胱内に溜まった尿によって引き起こされる尿路感染や腎臓障害の危険性が、低減される。このCICは、患者自身が必要な時に行うことができ、しかも、外出先でも行うことができるため、患者のQOL（Quality of Life＝生活の質）を向上する上で、極めて有効である。

【0003】このようなCICでは、カテーテルを膀胱内へ挿入する際に粘膜炎症や粘膜損傷が起きるのを防止するため、カテーテルは、表面に潤滑性を有することが必要とされる。現在、CICには、表面を湿潤させると潤滑性が発現するようなカテーテルが用いられるようになってきている。このようなカテーテルは、使用直前まで乾燥状態が保たれるため、カテーテルが使用されるまでの長期間の間に、潤滑剤が変質したり、劣化したり、カテーテルの表面から剥離したりすることが好適に防止される。

【0004】

【発明が解決しようとする課題】このようなカテーテルの潤滑性を円滑かつ無菌的に行えるようにするため、本願特許出願人は、カテーテルと流動性の物質を入れた容器とを1個の包材内に収納した包装体を提案した（特願平11-084854）。この包装体では、包装体内に収納した容器を包装体内で破断させることにより、カテーテルを湿潤させることができる。この包装体を用いれば、カテーテルの使用直前に、包装体内で無菌的に、カテーテルの表面に潤滑性を付与することができる。これにより、細菌感染の危険性が低減し、より安全にCICを行える。

【0005】このような包装体では、非使用時に、不本意に容器が破裂しないようにする必要がある。例えば保管中や運搬中に、包装体中の容器が破裂しては困る訳である。特に、CICは、患者が外出先で行う場合がある。このため、患者が靴やバッグ等に包装体を強引に押し込んだ場合でも、包装体中の容器が破裂しないようにすることが望ましい。

【0006】そこで、本発明の目的は、内部の容器が不本意に破断しにくい包装体を提供することにある。

【0007】

【課題を解決するための手段】このような目的は、下記の本発明により達成される。

【0008】（１） 生体に挿入または挿着して使用される器具と、流動性の物質が密封された容器と、前記器具と前記容器とを収納する包材とを有する包装体であって、前記容器の一部または全部が、前記器具に重ならないよう前記容器の位置を規制する位置規制手段を有することを特徴とする包装体。

【0009】（２） 生体に挿入または挿着して使用される器具と、流動性の物質が密封された容器と、前記器具と前記容器とを収納する包材とを有する包装体であって、前記容器の前記流動性の物質が密封された部位が、前記器具に完全に重ならないよう前記容器の位置を規制する位置規制手段を有することを特徴とする包装体。

【0010】（３） 前記位置規制手段は、前記包材の内部に突出した突出部により構成されている上記（１）または（２）に記載の包装体。

【0011】（４） 前記突出部は、壁状をなしている上記（３）に記載の包装体。

【0012】（５） 前記突出部は、前記包材を成型して形成されたものである上記（３）または（４）に記載の包装体。

【0013】（６） 前記突出部は、前記突出部と反対側の包材に隣接または接触している上記（３）ないし（５）のいずれかに記載の包装体。

【0014】（７） 生体に挿入または挿着して使用される器具と、流動性の物質が密封された容器と、前記器具と前記容器とを収納する包材とを有する包装体であって、前記容器が収納された部分の前記包材の厚さが、前記器具が収納された部分の前記包材の厚さよりも薄いことを特徴とする包装体。

【0015】（８） 前記容器が収納された部分の前記包材の厚さが、前記器具が収納された部分の前記包材の厚さの4/5以下である上記（７）に記載の包装体。

【0016】（９） 前記包材は、前記器具および前記容器を収納可能な膨らみを有するシート材と平坦なシート材とを重ね、これらの縁部をシールしたものである上記（１）ないし（８）のいずれかに記載の包装体。

【0017】（１０） 前記容器は、前記包材を開封しないで前記包材内で開封可能である上記（１）ないし

（９）のいずれかに記載の包装体。

【0018】（１１） 前記容器は、シート材をシール部によりシールしてなるものであり、前記容器に前記シール部よりも接合強度が小さい弱シール部を設けたことにより、前記容器を開封可能とした上記（１０）に記載の包装体。

【0019】（１２） 前記容器から流出した前記流動性の物質を前記器具に案内するガイド面を有する上記（１０）または（１１）に記載の包装体。

【0020】（１３） 前記容器を収納する凹部を有し、この凹部の形状は、前記容器の形状に対応している上記（１）ないし（１２）のいずれかに記載の包装体。

【0021】（１４） 前記器具は、長尺の器具であり、前記容器の周りを囲むように、前記包材内に設置される上記（１）ないし（１３）のいずれかに記載の包装体。

【0022】（１５） 前記器具は、カテーテルである上記（１）ないし（１４）のいずれかに記載の包装体。

【0023】

【発明の実施の形態】以下、本発明を添付図面に示す好適実施形態に基づいて詳細に説明する。図１は、本発明の包装体の第１実施形態を示す分解透視図である。図２は、図１に示す包装体のI-I線端面図である。

【0024】同図に示すように、包装体１Ａは、包材２Ａ内に、カテーテル７と、液体８９を密封した容器８とが収納された構成となっている。この包装体１Ａは、例えば、間歇式自己導尿法などに用いられる。例えば、使用者は、包装体１Ａの開封前に、容器８を強く押圧して破断し、液体８９でカテーテル７を湿らせる。その後、包装体１Ａを開封してカテーテル７を取り出し、このカテーテル７を、患者の体内（例えば尿道等）に挿入する。まず始めに、包材２Ａについて説明する。

【0025】包材２Ａは、一対のシート材、第１シート材２８と第２シート材２９とで構成されている。図１に示すように、これら第１シート材２８および第２シート材２９の平面形状（平面視形状）は、ほぼ同形状をなし、いずれも略四角形状をなしている。これに対応して、包材２Ａの平面形状も、略四角形状をなしている。

【0026】包材２Ａは、第１シート材２８と第２シート材２９とを重ね、これらの縁部を融着（熱融着、高周波融着、超音波融着等）または接着（接着剤や溶剤による接着）によりシールして、袋状としたものである。図１では、シールされた部分をシール部２１として、網掛けを付して示す。同図に示すように、シール部２１は、包材２Ａの外周部に沿って、帯状に形成されている。

【0027】図１および図２に示すように、第２シート材２９は、平坦な形状に成形（形成）されている。これに対し、第１シート材２８は、カテーテル７および容器８を収納可能な突出形状（プリスター形状）に、成形（形成）されている。換言すれば、第１シート材２８

は、カテーテル7および容器8を収納できるように、膨らみを有している。そして、この膨らみの内部（以下、「収納空間22」という）に、カテーテル7と容器8とが収納される。

【0028】この収納空間22は、第1シート材28と第2シート材29とシール部21とで囲まれており、外部から隔離されている。したがって、収納空間22内に収納されたカテーテル7および容器8は、使用時まで好適に無菌状態が保たれる。

【0029】この包材2Aの少なくとも一つの角部には、シート材をシールしないことにより形成したピールタブ（開封部）211が設けられている。このピールタブ211で例えば第2シート材29を第1シート材28から離間する方向に引っ張ることにより、シール部21を剥離し、包材2Aを開封することができる。

【0030】以下、収納空間22が開放している側（図1、図2中の上、すなわち第2シート材29が位置する側）を「上」といい、上と反対側（図1、図2中の下、すなわち第1シート材28が位置する側）を「下」という。

【0031】第1シート材28の中央部付近には、平面形状が略四角形の第1凹部231が形成されている。包材2Aは、この第1凹部231内に容器8を収納する。この第1凹部231は、第1シート材28を成型することにより形成されたものである。本実施形態では、この第1凹部231により、容器8を収納する部分である容器収納部23が構成されている。この容器収納部23の形状、大きさ、すなわち第1凹部231の形状、大きさは、容器8の形状、大きさに対応している。

【0032】この第1凹部231の周囲には、包材2Aの内部（収納空間22内）に突出した壁状の突出部25が形成されている。図1に示すように、この突出部25の平面形状は、四角形の一辺が開放したような形状（角ばったCの字状）をなし、容器収納部23を囲んでいる。この突出部25は、容器収納部23に収納された容器8の位置を規制する機能を有している。具体的には、この突出部25は、液体89が密封された部位（内部空間81）がカテーテル8と重ならないように、容器8の位置を規定している。このように、包装体1Aでは、突出部25により、液体89が密封された部位がカテーテル8と重ならないように容器8の位置を規制する位置規制手段が、構成されている。なお、突出部25は、壁状としなくてもよい。

【0033】図2に示すように、突出部25は、突出部25と反対側の包材2A、すなわち第2シート材29に隣接または接触している。これにより、例えば包装体1Aを激しく揺り動かしたりして、容器8が包材2A内で激しく動いた場合でも、容器8が突出部25を乗り越えて容器収納部23の外に飛び出すことが、極めて好適に防止されるようになる。つまり、突出部25が第2シ

ート材29に隣接または接触していると、容器8の内部空間81が、カテーテル7に、より重なりにくくなる。このような効果は、突出部25と第2シート材29との間隙（突出部25と第2シート材29との距離）を、容器8の厚さの半分以下とすると、より効果的に得られる。

なお、本実施形態の包材2Aでは、突出部25は、ほぼ全周にわたって第2シート材29に隣接または接触しているが、突出部25は、部分的に第2シート材29に隣接または接触していればよい。また、突出部25は、第2シート材29に隣接または接触していなくてもよい。

【0034】このような突出部25は、第1シート材28を成型することにより形成されたものである。このように、突出部25を第1シート材28と一体的に形成すると、包材2Aの構成部材の数を削減することができ、包材2Aの製造をより簡易に行うことができるようになる。なお、突出部25は、設けなくてもよい。

【0035】突出部25の外側には、平面形状が口の字状の第2凹部241が形成されている。包材2Aは、この第2凹部241内に、カテーテル7を収納する。この第2凹部241は、第1シート材28を成型することにより形成されたものである。本実施形態では、この第2凹部241により、カテーテル7を収納する部分であるカテーテル収納部24が構成されている。

【0036】このカテーテル収納部24には、図1に示すように、包材2Aの長辺に沿って、リブ（係合部）27が設けられている。図2に示すように、このリブ27は、第2凹部241の外周側の内壁245に突出形成され、第2シート材29の近傍、すなわちカテーテル7の上方に位置している。このリブ27は、第1シート材28を成型することにより形成されたものである。

【0037】このリブ27は、カテーテル7が相対的に上方に移動した場合、カテーテル7に係合（接触）することができる。このため、例えば第2シート材29を勢いよく引っ張って包装体1Aを開封し、カテーテル7が上方に弾んだ場合でも、かかるカテーテル7が、リブ27に引っかかり（係合し）、包材2Aから飛び出すことが防止される。このように、包装体1Aでは、リブ27により、包材2Aの開封時にカテーテル7が包材2Aから飛び出すのを防止する飛び出し防止手段が構成されている。

【0038】包材2Aでは、第1凹部231の底面232は、第2凹部241の底面242とほぼ平行になっている。したがって、第2凹部241の底面242が接地するように包装体1Aを置くと、第1凹部231の底面232は、ほぼ水平になる。

【0039】図1に示すように、カテーテル収納部24と容器収納部23との間の突出部25が形成されていない部分には、ガイド面26が、形成されている。このガイド面26は、容器8から流出した液体89を、カテーテル収納部24、すなわちカテーテル7に案内する。図

1に示すように、ガイド面26は略四角形状をなしており、一辺の縁部は容器収納部23に隣接し、その反対側の縁部は、カテーテル収納部24に隣接している。図2に示すように、ガイド面26は、第2凹部241の底面242から所定角度傾斜して、テーパ状をなしている。

【0040】図1に示すように、このガイド面26は、突出部25が構成する四角形の一边上に、位置している。換言すれば、包材2Aを平面視した場合、ガイド面26と突出部25とで、容器収納部23の周囲は、完全に囲まれている。

【0041】このような包装体1Aでは、容器8が収納された部分の包材2Aの厚さT1は、カテーテル7が収納された部分の包材2Aの厚さT2よりも薄くなっている。

【0042】これにより、包装体1Aの保管時、運搬時等、包装体1Aの使用前に、容器8が破断し、液体89が漏れることが好適に防止されるようになる。後述するように、容器8は、強く押圧される等して内部空間81の内圧が高まると、破断し、液体89が容器8の外に流出するようになっている。本発明の包装体1Aでは、厚さT1が厚さT2よりも薄いため、第1シート材29や第2シート材28に物が当たり、包装体2Aが圧縮される方向に力が加わった場合でも、かかる力は、主にカテーテル収納部24にかかり、容器収納部23には、あまりかからない。したがって、保管や運搬のため、多数の包装体1Aを箱等の中に押し込んだ場合でも、各包装体1Aでは、包装体1Aに対する押圧力は、主としてカテーテル収納部24にかかるようになる。このため、容器8に加わる押圧力は低減され、容器8の内部空間89の内圧が極度に増大することが、防止されるようになる。これにより、容器8の不用意な破断が防止される。

【0043】特に、包装体1Aでは、厚さT1を、好ましくは厚さT2の4/5以下に、より好ましくは2/3以下に設定すると、このような効果を、さらに効果的に得られるようになる。

【0044】また、本発明の包装体1Aでは、前述した位置規制手段（突出部25）によっても、容器8の不用意な破断が防止される。前述したように、カテーテル収納部24は、外からの押圧力がかかりやすい部分である。このため、カテーテル収納部24が変形した場合等には、カテーテル7にも、外からの押圧力がかかる可能性がある。この場合、容器8の内部空間81がカテーテル7に重なってしまうと、外からの包装体1Aへの押圧力が、カテーテル7を介して、容器8の液体89が密封された部位にかかってしまう可能性がある。

【0045】本発明の包装体1Aでは、位置規制手段により、このような事態が防止される。本発明の包装体1Aでは、位置規制手段が、内部空間81がカテーテル7と重なることを防止するので、カテーテル7が容器8の液体89が密封された部位を押圧することが、防止され

る。本発明の包装体1Aでは、これによっても、内部空間81の内圧が高まることが防止され、容器8の破断が防止される。したがって、例えば、靴やバッグ等の中で、包装体1Aの縁部が局所的に強く押圧された場合でも、容器8が破断することが、好適に防止されるようになる。

【0046】さらには、本実施形態の包装体1Aでは、突出部25が第2シート材29に隣接または接触していることも、容器8が強く押圧されにくくなることに貢献している。包装体1Aでは、中央部付近、すなわち容器収納部23が押圧された場合、突出部25がこの押圧力にある程度抗することができる。このため、容器8に加わる押圧力が緩和される。特に、本実施形態の包装体1Aのように、突出部25が壁状をなしていると、このような効果がより効果的に得られるようになる。さらには、本実施形態の包装体1Aのように、第1凹部231の形状、大きさが容器8の形状、大きさに対応していると、突出部25が容器8の近傍に位置するようになる。かかる点も、このような効果の向上に貢献している。また、このような効果は、突出部25が容器収納部23を囲むように形成されていると、さらに効果的に得られる。

【0047】このような効果を好適に得る観点からは、包材2A、特に第1シート材28は、保形性を有することが望ましい。これにより、前述した効果がより効果的に得られ、容器8が、より不本意に破断しにくくなる。また、包材2A、特に第1シート材28は、ある程度の柔軟性を有することが好ましい。これにより、使用時には、容器8を好適に破断させることができるようになる。包材2Aには、好ましくは、エチレンオキサイド、オートクレーブ、放射線、電子線等の滅菌に対応可能なガス透過性や耐熱性を有する材料、あるいは、滅菌後に無菌性を維持できる材料が用いられる。また、包材2Aには、カテーテルの劣化を防ぐために、UV遮蔽効果のある材料を用いることもできる。なお、内容物の視認性を確保するために、第1シート材28、第2シート材29のうち少なくとも一方は、透明であることが好ましい。

【0048】このような観点からは、第1シート材28、第2シート材29には、例えば、ポリエチレン、ポリプロピレン等のポリオレフィン樹脂、これらポリオレフィン樹脂のブレンド樹脂、ポリエチレンテレフタレート等のポリエステル樹脂、ポリスチレン、ポリ塩化ビニリデン、塩化ビニル-塩化ビニリデン共重合体等の単層フィルム、これらのフィルムにアルミニウム、シリカ等を蒸着したもの、アルミニウムフィルム、アルミニウムラミネートフィルム等の金属箔または金属箔を含むフィルムなどが、好適に用いられる。さらには、これら各フィルムを2層以上積層したものを用いることもできる。また、前記シート材としてプラスチック製不織布や紙を

用いてもよい。なお、第1シート材28および第2シート材29を、これ以外の材料で構成してもよいことは言うまでもない。

【0049】第1シート材28、第2シート材29（単層または多層積層体）の厚さは、その層構成や用いる素材の特性（柔軟性、強度、水蒸気透過性、耐熱性等）等に応じて適宜決定され、特に限定されないが、通常は、60～700 μ m程度であるのが好ましく、100～500 μ m程度であるのがより好ましい。なお、第1シート材28、第2シート材29の厚さは、異なるものとしてもよいし、ほぼ同じものとしてもよい。

【0050】このような第1シート材28、第2シート材29は、例えば、インフレーション法、Tダイ法、ブロー成型法、ドライラミネート法、ホットメルトラミネート法、共押出インフレーション法、共押出Tダイ法、ホットプレス法等の種々の方法により製造することができる。

【0051】以下、このような包材2Aに収納されるカテーテル7および容器8について説明する。

【0052】包材2A内に収納されるカテーテル7は、生体に挿入または装着して使用される長尺の器具である。このカテーテル7は、外部からの押圧力に対して容易に破壊されにくい（特に容器8よりも）強い器具である。このため、カテーテル7にある程度の外力が加わった場合でも、カテーテル7は、この外力に抗することができる。

【0053】図1に示すように、カテーテル7は、容器8の周りを囲むように環状に曲げられ（湾曲され）、カテーテル収納部24内に収納される。このように、カテーテル7を環状に湾曲させて包材2A内に収納するようにすると、包材2Aの長さを短くすることができる。このため、包装体1Aがコンパクトになり、鞘やバッグへの収納が便利になる。また、容器8の周りを囲むようにカテーテル7が設置されると、例えば、包装体1Aに、様々な方向から力が加わった場合でも、容器8は、カテーテル7で好適にガードされ、容器8には、あまり力が加わらないようになる。

【0054】カテーテル7は、生体内に挿入される挿入部71を有している。挿入部71は、好ましくは可撓性を有する管体で構成されている。この挿入部71は、生体内への挿入を円滑に行うことが必要とされ、そのために、挿入部71の表面の全体または一部には、湿潤により潤滑性を発現する物質が付与されているのが好ましい。

【0055】このような物質としては、例えば、特開昭60-259269号、特開平1-195863号公報に記載されているような親水性ポリマーが挙げられる。また、例えば、特公平6-32652号、特開平6-7426号、国際出願WO8802623、国際出願WO8907521、国際出願WO8909246、国際出

願WO9001344、国際出願WO9219289、国際出願WO9311751、国際出願WO9529722、特表平10-502854号、特表平10-502855号、特表平10-502856号に開示されている物質や方法を用いてもよい。このような物質は、通常、挿入部71の表面に、湿潤していない状態（乾燥状態）で存在している。

【0056】このような物質は、挿入部71の基材表面に化学結合されたポリマーであって、該基材表面からの剥離や、水、生理等張液、その他潤滑剤等への溶出が生じ難いものが、潤滑性の持続性、安全性の点から好ましい。このようなことから、カテーテル7の使用に先立ち、容器8から噴出した液体89を挿入部71に接触させ、湿潤により潤滑性を発現させる。

【0057】包材2A内に収納されるカテーテル7の種類、用途等は、特に限定されず、例えば、気管、消化管、尿道、膣、血管、リンパ管、胆管、その他の体腔や、例えば、肺、心臓、腎臓等の各種臓器、その他の生体組織等へ挿入される種々のカテーテル、バルーンカテーテル等が挙げられる。この中でも、特に、尿道に挿入して使用されるカテーテル（尿道カテーテル、導尿カテーテル）が好ましい。

【0058】排尿障害における導尿法は、留置カテーテルではなく無菌間歇導尿法が好ましいが、近年、患者自身がカテーテルを使って尿を排出する自己導尿が有効な治療方法として普及してきている。排尿障害は、前立腺肥大症、結石、腫瘍などによる尿道閉塞や、脳・脊髄および骨盤神経などの障害により見られる神経因性膀胱によって起こるが、尿を完全に出しきれない状態になると、尿路内圧が上がって腎臓に負担をかけるので、定期的に尿を排出する必要がある。この際に行われる自己導尿法は、低圧で完全に尿を排出できるので、既にある尿感染が低減する、頻尿、尿失禁が治る、膀胱と腎臓に負担をかけない等の利点があり、患者自身が1日4～6回程度、尿道から膀胱内にカテーテルを挿入し、尿の排出が終了したら抜去する。その頻度は、例えば、昼間は4～5時間毎、夜間は就寝前とされる。

【0059】容器8は、内部に内部空間81を有し、この内部空間81内に、液体89を密封・貯留している。本実施形態では、この容器8は、第1シート材28のみならず、第2シート材29にも接触または隣接している。

【0060】この容器8は、例えば、平坦なシート材（インフレーションシート材）の中央部を折り曲げ三方を融着（または接着）によりシールし、袋状としたものである。この袋の内部に内部空間81が形成され、ここに、液体89が貯留（充填）される。以下、容器8のシート材がシールされた部分を、シール部82という。なお、容器8は、図示のように形成したものに限定されず、例えば、筒状に成形されたシート材の両端部を融着

(または接着)し、袋状としたもの、あるいは、2枚のシート材を重ね、その外周部全周を融着(または接着)し、袋状としたものでもよい。

【0061】図1で格子を施して示すように、シール部82の一部は、他の部分(シール部821)より接合強度(剥離強度)が弱い弱シール部(イージーピールシール部)83で構成されている。シール部821は、対向するシート材同士が完全に融着され、強固な接合状態であるのに対し、弱シール部83は、それより低温で融着する等により、対向するシート材同士の融着がある程度不完全であるような状態とされる。ただし、弱シール部83においても、液密性(気密性)は、確保されている。そして、その効果は、経時的に持続する。

【0062】したがって、例えば、容器8の液体89が貯留された部分を押圧(圧迫)し、内部空間81の内圧を高めると、弱シール部83が優先的に剥離(破断)する。これにより、内部空間81と容器8の外周部とが連通し、液体89が容器8の外に流出する。このように、容器8では、弱シール部83により、容器8を開封する部分である開封口が構成されている。

【0063】本実施形態の包装体1Aでは、容器8を、第1シート材28および第2シート材29越しに押圧できる。特に、本実施形態の包装体1Aのように、容器8が第1シート材28および第2シート材29に隣接または接触していると、かかる操作がさらに容易となる。したがって、包装体1Aでは、包装体1Aが未開封の状態で、極めて簡単な操作で、容器8を開封することができる。また、本実施形態では、第1凹部23の底面232が第2シート材29と略平行であることも、容器8の押圧がさらに容易となることに、寄与している。なお、弱シール部83を剥離する方法は、上記方法に限定されず、例えば、弱シール部83を、シート材越しに手で揉みほぐしてもよい。なお、開封口は、例えば、シール部82のシール幅を、局所的に他の部分のシール幅よりも狭くするような構成としてもよい。

【0064】このような容器8の厚さは、カテーテル7の厚さ(外径)よりも薄いことが好ましい。これにより、包装体1Aに強い力が加わり、第1シート材28が圧縮され、変形しても、包装体1Aに加わる力は、主としてカテーテル7に加わることになる。このため、容器8に加わる力はより好適に低減され、容器8の破損がより好適に防止される。

【0065】また、容器8は、内部空間81に貯留される流動性物質の蒸気バリア性を有するのが好ましい。例えば、前記流動性物質が水である場合、この蒸気バリア性とは、水蒸気透過度が、好ましくは $3.0\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 2.5\text{ }\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下、より好ましくは $1.0\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 2.5\text{ }\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下、さらに好ましくは $1\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 2.5\text{ }\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下

であることを言う。この水蒸気透過度は、JIS K7129(A法)に記載の方法により測定される。容器8が水蒸気バリア性を有することにより、容器8の内部からの水分の蒸散が防止できる。その結果、内部空間81内の液体89の減少、濃縮を防止することができる。とともに、液体89の量が必要最少限の量で済み、包装体1A全体の容積や重量を小さくすることができる。

【0066】容器8を構成するシート材(フィルム)、特に水蒸気バリア性を有するシート材としては、例えば、下記のものなどが挙げられる。

[1] 1種のポリオレフィン樹脂で構成される単層フィルム、[2] 2種以上の互いに相溶しないポリオレフィン樹脂のブレンド樹脂より構成される単層フィルム、

[3] シーラント層(融着に関与する層)にポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)を用いたポリオレフィン樹脂もしくはポリエステル樹脂の多層フィルム、[4] シーラント層がポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)より構成されるフィルム、外層がポリ塩化ビニリデンをコーティングしたポリオレフィンまたはポリエステルフィルム等で構成される多層フィルム、[5] シーラント層がポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)より構成されるフィルム、外層がアルミ蒸着もしくはシリカ蒸着されたポリオレフィンフィルムまたはポリエステルフィルム等で構成される多層フィルム、[6] シーラント層がポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)より構成されるフィルム、中間層がアルミニウムフィルム、最外層がポリエステルフィルム等で構成される多層フィルム、[7] シーラント層がポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)、中間層がナイロンフィルム、最外層がアルミ蒸着もしくはシリカ蒸着されたポリオレフィンまたはポリエステルフィルム等で構成される多層フィルム、この場合、対向する一対のシート材のうちの一方を不透明なアルミニウムフィルム、他方をシリカ蒸着フィルム等の透明な水蒸気バリア性フィルムとすれば、容器8の内容物の視認による確認が行えるので、さらに好ましい。なお、アルミニウムフィルムは、必要に応じその一部もしくは全部が剥離除去可能であってもよい。

【0067】なお、弱シール部83においては、直接融着に関与する層(シーラント層)が2種以上の互いに相溶しないポリオレフィン樹脂のブレンド樹脂、もしくは2種以上の互いに相溶しないポリオレフィン樹脂をセグメントに有するランダムもしくはブロック共重合体で構成されていることが好ましい。

【0068】容器8を構成するシート材(単層または多層積層体)の厚さは、その層構成や用いる素材の特性(柔軟性、強度、水蒸気透過性、耐熱性等)等に応じて適宜決定され、特に限定されるものではないが、通常

は、20～700 μ m程度であるのが好ましく、40～500 μ m程度であるのがより好ましい。

【0069】このような容器8を構成するシート材は、例えば、インフレーション法、Tダイ法、ブロー成型法、ドライラミネート法、ホットメルトラミネート法、共押出インフレーション法、共押出Tダイ法、ホットプレス法等の種々の方法により製造することができる。

【0070】なお、以上述べた特性を有する容器8は、例えば特願平11-084854を参照することにより、好適に製造することができる。

【0071】このような容器8を備えた包装体1Aは、次のような効果（利点）を有する。第1に、包材2A内に入れる容器8の容量を選択することにより、容器8の内容物（液体89等）の量や重量を容易に設定することができる。第2に、容器8は、包材2Aとは別個に単独で製造可能なので、製造・管理がしやすい。

【0072】このような容器8内に収納される液体89は、カテーテル7の挿入部71の表面と接触して、その摩擦抵抗を低減させることができる物質（液状または半液状物）であるのが好ましい。

【0073】このような液体89としては、特に限定されないが、例えば、水、生理等張液（生理食塩水）、グリセリン、シリコーンオイル、オリーブオイル等のオイル類、キシロカインゼリー等が挙げられる。

【0074】以下、包装体1Aの使用法（作用）の一例について説明する。前述したように、本発明の包装体1Aは、保管中に、容器8が破損しにくい。保管後、包装体1A内の医療器具を使用する際には、下記のような操作を行う。

【0075】まず、包材2Aの外部から容器8を指等で押圧・圧迫する。これにより、弱シール部83が剥離（破断）して、かかる剥離した部分から、液体89が流出する。

【0076】容器8から流出した液体89は、ガイド面26上を伝わり、カテーテル収納部24内へ流入する。そして、このカテーテル収納部24へ流入した液体89は、第2凹部241の底面242で広がる。これにより、カテーテル7の挿入部71が濡れ（湿潤し）、挿入部71の表面に、潤滑性が発現する。つまり、挿入部71表面の摩擦抵抗が低減する。このとき、必要に応じて、包装体1Aの両端（短辺を構成する端部、あるいは長辺を構成する端部）を交互に上下させる等の操作を行ってもよい。これにより、液体89がより好適にカテーテル収納部24内に広がり、挿入部71が、より満遍なく、より均一に濡れるようになる。なお、容器8を開封後、必要に応じて、包装体1Aの外部から容器8を指等で押圧（圧迫）する等して、容器8内の液体89を残らず排出する操作を行ってもよい。

【0077】本実施形態の包装体1Aのように、容器収納部23の形状、大きさが容器8の形状、大きさにほぼ

対応していると、容器収納部23内（第1凹部231の底面232）に残存しカテーテル収納部24に流れない液体89の量が減少する。このため、比較的少ない液体89の量で、より効率よくカテーテル7の挿入部71を濡らすことができる。

【0078】以上のようにして、カテーテル7の挿入部71の表面に潤滑性が発現したら、ピールタブ211を引っ張って、包材2Aを開封する。そして、カテーテル7を包材2A内から取り出す。

【0079】包材2Aから取り出されたカテーテル7は、生体の目的部位に挿入または装着される。カテーテル7が尿道カテーテル（導尿カテーテル）である場合には、挿入部71を先端側から尿道および膀胱に挿入する。このとき、挿入部71の表面が潤滑性を有しているため、カテーテル7の挿入操作を、円滑かつ安全に行うことができる。その後、患者は、カテーテル7を介して排尿を行う。

【0080】このように、包装体1Aを用いれば、カテーテル7の挿入部71の表面に潤滑性を発現させる操作を、密閉された包材2A内で外気と接触することなく行うことができる。したがって、本発明の包装体1Aでは、カテーテル7は、使用直前まで、無菌性が良好に保たれる。

【0081】以下、本発明の包装体の第2実施形態について説明する。なお、以下の説明では、第1実施形態の包装体と共通する事項については説明を省略し、相違する事項を中心に説明する。図3は、本発明の包装体の第2実施形態を示す端面図である。なお、本実施形態の上下の概念は、第1実施形態と同様である。

【0082】同図に示すように、包装体1Bでは、第1凹部231の底面232'が、第2凹部241の底面242に対して所定角度傾斜し、テーパ状をなしている。詳しくは、底面232'は、ガイド面26の方向に下がるように（第2シート材29から離開し第2凹部241の底面242に近づくように）、テーパ状をなしている。これに対応して、容器8は、弱シール部83が下がるように（第2シート材29から離開し第2凹部241の底面242に近づくように）、容器収納部23に設置されている。また、ガイド面26'は、第2凹部241の底面242とほぼ直行している。

【0083】包材2Aをこのような構成にすると、包装体1Bを傾ける等の操作をあまりしなくても、液体89が、カテーテル収納部24内に、円滑に流れて行くようになる。

【0084】本実施形態のように、容器8が収納された部分の包材2Bの厚さT1が均一でない場合は、例えば、容器8が収納された部分の中央付近の厚さを、厚さT1の指標とすることができる。

【0085】以下、本発明の包装体の第3実施形態について説明する。なお、以下の説明では、第1実施形態の

包装体と共通する事項については説明を省略し、相違する事項を中心に説明する。図4は、本発明の包装体の第3実施形態を示す端面図である。なお、本実施形態の上下の概念は、第1実施形態と同様である。

【0086】同図に示すように、包装体1Cでは、第2凹部241の外周側の内壁245が、テーパ状をなしている。詳しくは、内壁245は、第2凹部241の底面242の法線に対して所定角度傾斜しており、その上部（底面242と反対側の部分）が、収納空間22の内部に向かってせり出している（突出している）。

【0087】この内壁245上部のせり出した部分（以下、せり出し部27'という）は、包材2Cの長辺に沿って、形成されている。このせり出し部（係合部）27'は、カテーテル7の上方に位置している。このせり出し部（凸部）27'は、カテーテル7が上方に相対的に移動した場合、カテーテル7に係合（接触）することができる。

【0088】しかも、本実施形態の包装体1Cでは、カテーテル7が上方に弾んだ場合、カテーテル7は、第2凹部241の外周側の内壁245に当接して、上方への移動が規制されることとなる。

【0089】このため、本実施形態の包装体1Cでは、包材2Cの開封時にカテーテル7が包材2Cから飛び出すことが、極めて好適に防止されるようになる。本実施形態では、飛び出し防止手段は、テーパ状の内壁245と、せり出し部27'とにより、構成されている。

【0090】以下、本発明の包装体の第4実施形態について説明する。なお、以下の説明では、第1実施形態の包装体と共通する事項については説明を省略し、相違する事項を中心に説明する。図5は、本発明の包装体の第1実施形態を示す分解透視図である。図6は、図5に示す包装体のII-II線端面図である。

【0091】同図に示すように、包装体1Dでは、第1凹部231'および容器収納部23'は、一方の長辺に接近して位置している。また、突出部25'の平面形状は、図5に示すように、四角形の三辺を構成するコの字状をなし、容器収納部23'を囲んでいる。そして、突出部25'は、長辺に向かって、開放している。

【0092】本実施形態の包装体1Dでは、容器収納部23'が、第2凹部241'の外周側の内壁245に接近して設置されているため、図6に示すように、容器8の開封部（弱シール部83）は、内壁245に当接または隣接している。このため、容器8から流出した液体89は、内壁245に接触し、この内壁245を伝って、カテーテル収納部24'に案内されることとなる。このように、本実施形態の包装体1Dでは、容器8の開封部に臨む第2凹部241'の外周側の内壁245により、液体89をカテーテル7に案内するガイド面26"が構成されている。

【0093】前述したように、容器収納部23'は、包

材2Dの中央部から一方の長辺側に若干ずれたところに位置している。このため、容器収納部23'が第2凹部241'の外周側の内壁245に接近した側では、第2凹部241'の底面（以下、底面242aという）の面積が小さくなっている。これに対し、容器収納部23'が内壁245から離間した側では、底面（以下、底面242bという）の面積が大きくなっている。

【0094】そして、本実施形態の包装体1Dでは、底面242b上に、すなわち底面242b側のカテーテル収納部24'内に、液体89等を吸収し、保持することができる吸収体9が設置される。吸収体9を包材2D内に入れることにより、吸収体9に、カテーテル7を濡らした後の余剰の液体89を吸収させることが可能となる。

【0095】吸収体9としては、特に限定されないが、例えば、ポリアクリル酸塩系、ポリビニルアルコール系、ポリアクリルアミド系、ポリオキシエチレン系またはマレイン酸系材料等の合成ポリマーや、デンプン、セルロース、アルギン酸のような多糖類材料等の天然材料等のような高分子吸収材料で構成されたものが好ましい。また、その他、例えば、スポンジ、綿、ガーゼ、不織布やそれらに前記高分子吸水性材料を担持したもの（例えば、おむつ、生理用品等に用いられているもの）も可能である。このような吸収体9は、ブロック状、粉末状、フィルム状、シート状（板状）、繊維状などの形態（形状）をとることができる。図5、6では、一例として、ブロック状の吸収体9を示した。

【0096】このように、本実施形態の包材2Dでは、内部にカテーテル7および容器8以外の部材を設置するスペースを確保することが容易となり、かかるスペースに、吸収体9等の新たな部材を設置することが容易となる。

【0097】吸収体9のようなカテーテル7および容器8以外の新たな部材としては、特に限定されないが、吸収体9の他に、例えば、カテーテル挿入前後に尿道口付近を消毒することができるシート、使用済みカテーテルを廃棄するまでに発生する臭気を抑制する脱臭剤、細菌、ウイルス等の微生物の繁殖を抑制する抗菌剤などが挙げられる。

【0098】以上、本発明を図示の好適実施形態に基づいて説明してきたが、本発明はこれに限定されるものではない。

【0099】本発明において、生体に挿入または装着して使用される長尺のカテーテル7としては、例えば、以下のようなものが挙げられる。

・胃管カテーテル、栄養カテーテル、経管栄養用チューブ、酸素カテーテル、酸素カヌー、気管内チューブのチューブやカフ、気管切開チューブのチューブやカフ、気管内吸引カテーテル等の経口または経鼻的に挿入、留置されるカテーテル類。

・吸引カテーテル、排液カテーテル、腹腔カテーテル、直腸カテーテル、トロッカー等の各種体腔、臓器、組織内に挿入、留置されるカテーテル類。

・血管造影用カテーテル、P T C A用バルーンカテーテル、I A B P用バルーンカテーテル、静脈留置カテーテル、動注用カテーテル等の血管内に挿入、留置されるカテーテル類。

【0100】さらには、生体に挿入または挿着して使用される長尺の器具としては、カテーテルの他に、例えば、以下のようなものが挙げられる。

・単独で、または、前記各カテーテル類とともに使用される各種ガイドワイヤー。

・人工血管、ステント。
・注射針、留置針、カテーテルイントロデューサ。
・内視鏡、超音波破砕プローブ。
・縫合用または結紮用の糸。

【0101】さらには、生体に挿入または挿着して使用される器具は、長尺状のものでなくてもよい。包装体に収納される生体に挿入または挿着して使用される器具としては、上述したもの以外に、例えば、以下のようなものが挙げられる。

・心拍出量測定器具、超音波測定・診断器具、ペースメーカー、体温計。
・人工肛門、人工骨、人工関節、補綴物、義眼。
・シース。
・浣腸。
・コンドーム等の避妊具。

【0102】以上述べた実施形態では、容器8に収納される流動性の物質として、液体89を挙げたが、容器8には、液体89以外の流動性を有する物質、例えば、ゲル状、ゼリー状の物、粉体、粒体などを収納してもよい。なお、包装体内には、前述した以外の任意のものが収納されていてもよい。

【0103】

【発明の効果】以上述べたように、本発明によれば、内部の容器が不本意に破断しにくい包装体を提供することができる。したがって、例えば本発明を間歇式自己導尿法に適用した場合、患者は、本発明の包装体を安心して携行することができ、しかも、外出先においても、簡便かつ確実に自己導尿を行うことができる。よって、本発明は、患者の生活の質の向上に、大きく貢献できる。

【図面の簡単な説明】

【図1】本発明の包装体の第1実施形態を示す分解透視図である。

【図2】図1に示す包装体のI-I線端面図である。

【図3】本発明の包装体の第2実施形態を示す縦端面図である。

【図4】本発明の包装体の第3実施形態を示す縦端面図である。

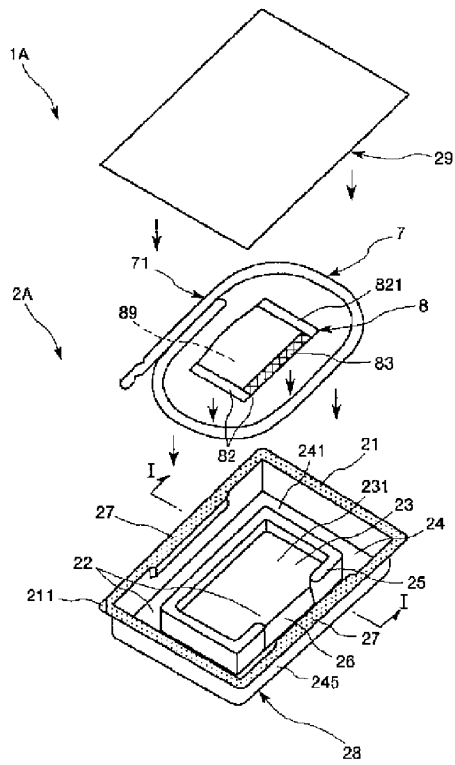
【図5】本発明の包装体の第4実施形態を示す分解透視図である。

【図6】図5に示す包装体のII-II線端面図である。

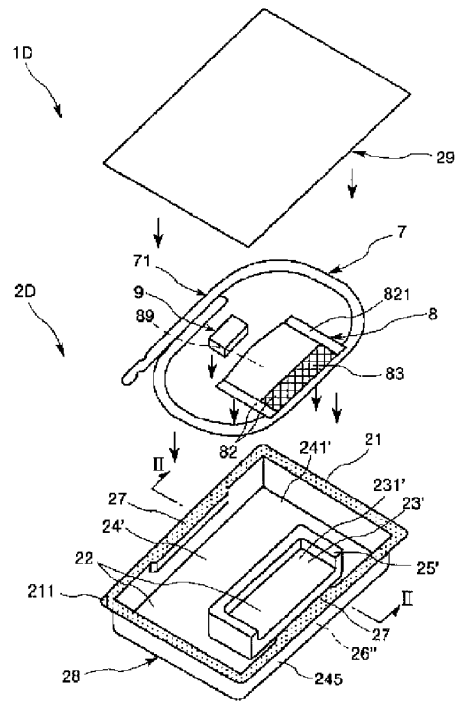
【符号の説明】

1 A、1 B、1 C、1 D	包装体
2 A、2 B、2 C、2 D	包材
2 1	シール部
2 1 1	ピールタブ
2 2	収納空間
2 3、2 3'	容器収納部
2 3 1、2 3 1'	第1凹部
2 3 2、2 3 2'	底面
2 4、2 4'	カテーテル収納部
2 4 1、2 4 1'	第2凹部
2 4 2、2 4 2 a、2 4 2 b	底面
2 4 5	外周側の内壁
2 5、2 5'	突出部
2 6、2 6'、2 6''	ガイド面
2 7	リブ
2 7'	せり出し部
2 8	第1シート材
2 9	第2シート材
7	カテーテル
7 1	挿入部
8	容器
8 1	内部空間
8 2	シール部
8 2 1	弱シール部以外のシール部
8 3	弱シール部
8 9	液体
9	吸収体
T 1	容器が収納された部分の包材の厚さ
T 2	カテーテルが収納された部分の包材の厚さ

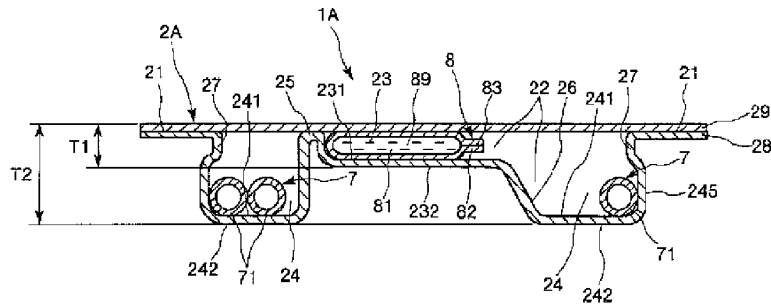
【图 1】



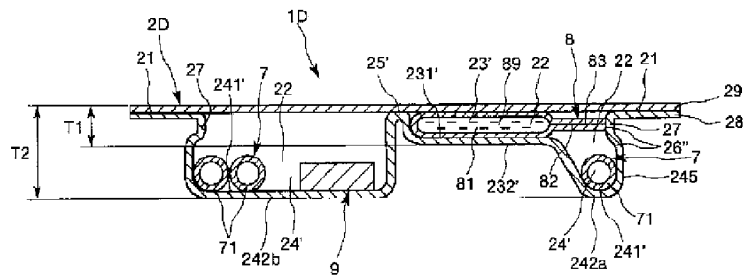
【图 5】



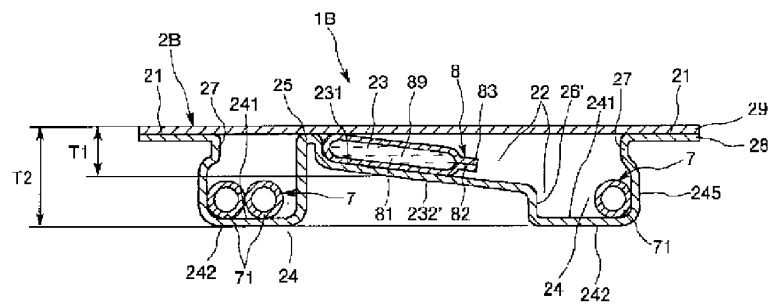
【图 2】



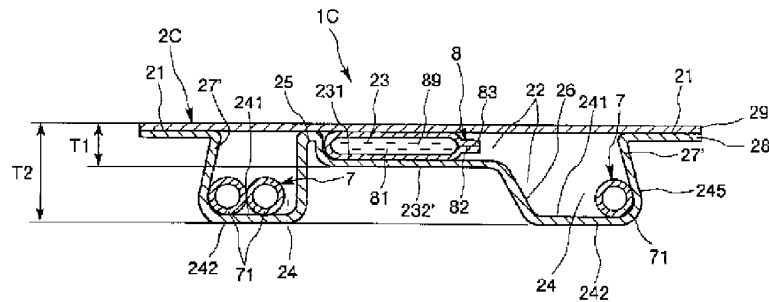
【图 6】



【図 3】



【図 4】



フロントページの続き

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Verified and Acknowledged:

/Adam Marcetich/

Examiner's Signature

Initials

Title:

Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
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CONTINUING DATA

This application is a CON of 15640224 06/30/2017 PAT 10624614

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13155053 is a CIP of 12495148 06/30/2009 PAT 8631935

12495148 has PRO of 61183629 06/03/2009

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CONFIRMATION NO. 7602

POWER OF ATTORNEY NOTICE

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OC000000136670333

Date Mailed: 11/01/2022

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This is in response to the Power of Attorney filed 10/19/2022.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/byemane/



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POA ACCEPTANCE LETTER

189038
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Date Mailed: 11/01/2022

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

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/byemane/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
							T ⁵
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		POON, ROBERT , "NonFinal Office Action", USSN 17/835,747; Filed June 8, 2022; Attorney Docket NO. 10055U D1 C2 C1 C1; Mailed October 12, 2022,					
EXAMINER SIGNATURE							
Examiner Signature					Date Considered		

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PTO/SB/08a (01-10)

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	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

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⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2022-12-06
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Patent Application Fee Transmittal				
Application Number:		16721718		
Filing Date:		19-Dec-2019		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		BPMDL10055UCIP3C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
Total in USD (\$)				260

Electronic Acknowledgement Receipt	
EFS ID:	47155984
Application Number:	16721718
International Application Number:	
Confirmation Number:	7602
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	BPMDL10055UCIP3C1C1C1
Receipt Date:	06-DEC-2022
Filing Date:	19-DEC-2019
Time Stamp:	18:12:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$260
RAM confirmation Number	E2022B6I13254544
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP3_C1_C1_USA_2022-12-6_IDS.pdf	134208	no	3
			38d8e79bb7574b46cf5daa3d07d18c702040e16f		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	10055U_D1_C2_C1_C1_USA_2022-10-12_NonFinalOA.pdf	676814	no	10
			49c76c3738d9c349cb332ddab6421a326499861d		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	38271	no	2
			75d6c7cc3912d5b9b21f1834c7e9f30c1bbab1407		
Warnings:					
Information:					
Total Files Size (in bytes):			849293		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Receipt date: 12/06/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS							
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
U.S.PATENT APPLICATION PUBLICATIONS							
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
FOREIGN PATENT DOCUMENTS							
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear T ⁵
NON-PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ⁵
/AMM/		POON, ROBERT , "NonFinal Office Action", USSN 17/835,747; Filed June 8, 2022; Attorney Docket NO. 10055U D1 C2 C1 C1; Mailed October 12, 2022,					
EXAMINER SIGNATURE							
Examiner Signature		/Adam Marcetich/		Date Considered		12/19/2022	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0858

Receipt date: 12/06/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2022-12-06
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0859

Receipt date: 12/06/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0860

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL **(Submitted Only via EFS-Web)**

Application Number	16721718	Filing Date	2019-12-19	Docket Number (if applicable)	10055U CIP3 C1 C1 C1	Art Unit	3781
First Named Inventor	Jennifer E. Tomes			Examiner Name	Adam M Marcetich		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
 Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☐ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
 (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to
 Deposit Account No 503608

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-01-18
Name	Philip H. Burrus, IV	Registration Number	45432

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		4439184		1984-03-27	Wheeler, Robert P.			
U.S.PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
		REIP, DAVID O. , "Re-Exam Non-Final Office Action", USSN 90/015,051; Filed June 8, 2022; Reference No. 10055U CIP2 D1; Mailed December 14, 2022,						
EXAMINER SIGNATURE								

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Examiner Name	Adam Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

Examiner Signature		Date Considered	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT			
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OR			
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☐ See attached certification statement.			
☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.			
☒ None			
SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-01-18
Name/Print	Philip H. Burrus	Registration Number	45,432

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

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Electronic Patent Application Fee Transmittal				
Application Number:		16721718		
Filing Date:		19-Dec-2019		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		BPMDL10055UCIP3C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
RCE- 1ST REQUEST	1801	1	1360	1360
Total in USD (\$)				1360

Electronic Acknowledgement Receipt	
EFS ID:	47390706
Application Number:	16721718
International Application Number:	
Confirmation Number:	7602
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	BPMDL10055UCIP3C1C1C1
Receipt Date:	18-JAN-2023
Filing Date:	19-DEC-2019
Time Stamp:	16:19:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$1360
RAM confirmation Number	E20231HG20103149
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	10055U_CIP3_C1C1C1_USA_2023-1-18_RCE.pdf	1350083	no	3
			d02e2f1954fc9bddf6ea12050ae2aa1c33b2ea5f		
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP3_C1C1C1_USA_2023-1-18_IDS.pdf	135256	no	3
			4299142868a3fbd9b0b52e972c7a01e24fd7e7f4		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	10055U_CIP2_D1_USA_2022-12-14_ReexamOA.pdf	815869	no	12
			c0bf0db045dfe6d550c198d8437db88f1522ebbd		
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	38128	no	2
			832b623cc4f3d923dc521f606a12b4f5f3c2f533		
Warnings:					
Information:					
Total Files Size (in bytes):			2339336		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		4411656		1983-10-25	Cornett III, Walter			
		9693756		2017-07-04	Tomes, Jennifer			
		9745088		2017-08-29	Tomes, Jennifer			
		9808596		2017-11-07	Tomes, Jennifer			
		10512752		2019-12-24	Tomes, Jennifer			
		10946169		2021-03-16	Lockwood, Robert			
		10946992		2021-03-16	Tomes, Jennifer			
U.S.PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
		KLEIN, BENJAMIN , "Non-Final Office Action", USSN 16/688,185; Filed November 19, 2019; Attorney Docket No. BPMDL10055U P1C2D1; Mailed January 31, 2023,	
EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).
OR

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-02-01
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt	
EFS ID:	47465732
Application Number:	16721718
International Application Number:	
Confirmation Number:	7602
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	BPMDL10055UCIP3C1C1C1
Receipt Date:	01-FEB-2023
Filing Date:	19-DEC-2019
Time Stamp:	16:40:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP3_C1C1C1_USA_2023-2-1_IDS.pdf	137712 8e069a8e554f344c849762a9af599463bf8e5fa4	no	3

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	10055U_CIP_C2_D1_USA_2023-1-31_NonFinalOA.pdf	748254	no	11
			7230c6ecd248bc633128bb097ce1013af507e638		
Warnings:					
Information:					
Total Files Size (in bytes):			885966		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

189038 7590 02/09/2023
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE
Suite 1803
Atlanta, GA 30309

EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3781

DATE MAILED: 02/09/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	12/19/2019	Jennifer E. Tomes	BPMDL10055UCIP3C1C1C1	7602

TITLE OF INVENTION: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	05/09/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

189038 7590 02/09/2023
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE
Suite 1803
Atlanta, GA 30309

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	12/19/2019	Jennifer E. Tomes	BPMDL1005UCIP3C1C1C1	7602

TITLE OF INVENTION: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	05/09/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3781	604-540000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	12/19/2019	Jennifer E. Tomes	BPMDL10055UCIP3C1C1C1	7602
189038	7590	02/09/2023	EXAMINER	
Philip H. Burrus, IV Burrus Intellectual Property Law Group LLC (MDL) 222 12th Street NE Suite 1803 Atlanta, GA 30309			MARCETICH, ADAM M	
			ART UNIT	PAPER NUMBER
			3781	
DATE MAILED: 02/09/2023				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/721,718	Applicant(s) Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 18 January 2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-20 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☒ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.	

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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EXAMINER'S COMMENT / REASONS FOR ALLOWANCE

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 January 2023 has been entered.

Examiner's Comment

The objections to claims 4 and 7 for minor informalities are withdrawn in view of the amendments filed 07 October 2022.

Terminal Disclaimer

The terminal disclaimer filed on 07 October 2022 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of:

- Tomes; Jennifer E. et al. (US 10624614 B2)
- Tomes; Jennifer E. et al. (US 10640243 B2)
- Tomes; Jennifer E. et al. (US 9745088 B2)
- Tomes; Jennifer E. et al. (US 10946992 B2)
- Tomes; Jennifer E. et al. (US 9808596 B2)
- Tomes; Jennifer E. et al. (US 10512752 B2)

- Lockwood; Robert et al. (US 10946169 B2)
 - Dickinson; Sarah et al. (US 11116937 B2)
- has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Claims

Claims 1-20 are allowed.

Reasons for Allowance

All references on the IDS's filed 18 January 2023 and 01 February 2023 have been considered.

Wheeler; Robert P. (US 4439184 A) and Cornett, III; Walter G. (US 4411656 A) each describes a syringe configured to hold lubricant. However, neither Wheeler nor Cornett discloses a tray having separate compartments separated by a barrier. At most, Wheeler and Cornett describe the construction of their respective syringes.

Also cited on the recent IDS, the Re-Exam Non-Final Office Action for USSN 90/015,051 cites **Pilger Nicholas J. (US 3485352 A) in view of Wheeler; Robert P. (US 4439184 A), McMichael; Donald J. et al. (US 6896141 B2) and Serany Jr.; Frank J et al. (US 3329261 A)**. However, the cited combination of references fails to teach or suggest the features of pending claims 1-20.

Pilger lacks a tray having separate compartments separated by a barrier, wherein first and second syringes are disposed in a first compartment and a medical assembly is stored in a second compartment. At most, Pilger constrains a catheter with a series of posts (col. 2, lines 40-50, Extending upwardly from bottom 2 are a series of posts 5, 6 and 7 which are near but spaced from the side wall 3. As illustrated in FIGURE 1, a flexible catheter 8 is held in a generally circular coil between the posts and

the upstanding wall). Pilger discloses only a single syringe which is stored in the same compartment as the catheter (col. 2, lines 60-65, hypodermic syringe 15 which is shown in the dish portion of the film member within a coil formed by the catheter).

The Office Action for USSN 90/015,051 does not reject claim 25 of Tomes; Jennifer E. et al. (US 9522753 B2), which describes “the at least two compartments further comprising a second compartment separated from the first compartment by a wall, further comprising placing the coiled medical device within the second compartment.”

Also cited on the recent IDS, the Non-Final Office Action for USSN 16/688,185 cites **Cornett, III; Walter G. (US 4411656 A), Paikoff; Myron et al. (US 4523679 A), Reif; Thomas H. et al. (US 4811847 A), Gawarecki; Herbert (US 6142152 A), Kubalak; Thomas P. et al. (US 7789873 B2), Misra; Vijay K. (US 6012586 A), Solazzo; Anthony (US 7278987 B2) and Beddow; David V. (US 4226328 A)** in a statement of reasons for the indication of allowable subject matter.

Beddow discloses a catheterization package comprising a tray (col. 2, lines 30-35, a generally rectangular box-like outer tray 11); a catheter (col. 2, lines 50-55, catheter 13); and one syringe (col. 2, lines 50-55, syringe 14).

However, Beddow lacks a second syringe and coiled tubing. Beddow also lacks a syringe containing lubricating jelly and instead stores lubricant in a different container, which is not stored in the same tray as the catheter or syringe (col. 3, lines 10-15, an individually sealed foil container 26 of lubricating jelly 27 packed within an elongated rectangular recess 28).

Applicant's arguments filed 07 October 2022 have been considered and are persuasive. Examiner advances additional reasons for allowance.

Reif; Thomas H. et al. (US 4811847 A), the closest art of record, discloses a catheter assembly including a tray, one syringe and a catheter (Fig. 2). However, Reif lacks a second syringe, and does not arrange the syringe and catheter in separate compartments.

Another cited reference, **Pilger; Nicholas J. (US 3485352 A)**, discloses a procedure kit including a tray, coiled catheter and one syringe (Fig. 5). However, Pilger lacks a second syringe and a second compartment. Instead, Pilger arranges one syringe and a catheter in one compartment (Figs. 1, 2, syringe 15 and catheter 8 are both arranged inside wall 3).

Also of record, **Rauschenberger; Richard A. (US 4160505 A)** discloses a catheterization tray comprising multiple compartments (col. 1, lines 50-55, Tray 10 is formed with a dished portion 11; col. 2, lines 1-5, Compartments 23 and 24 are defined within dish 11 by walls 27, 28 and 29), and a medical assembly comprising a urinary catheter (col. 1, lines 60-65, Channel 21 is adapted to receive a conventional urethral catheter which is positioned within channel 21).

However, Rauschenberger lacks first and second syringes containing lubricating jelly and water. Instead, Rauschenberger describes a separate lubricant packet (col. 2, lines 20-30, The remaining components generally are arranged ... in the order: gloves, lubricant ... and specimen container). Rauschenberger also lacks a coiled tubing

coupled between a fluid drain bag and a Foley catheter, and at most discloses a urinary catheter (Fig. 1, conventional urethral catheter stored in channel 21).

The following newly cited references fail to teach or suggest all limitations of the amended claims.

Nishizawa; Yasushi et al. (JP 2002068309 A) discloses a catheterization tray comprising several compartments (¶ [0001], [0004], [0008], [0031], In the vicinity of the center of the first sheet material 28, a first concave portion 231 having a substantially square planar shape is formed); including a catheter (¶ [0024], FIG. 1, the package 1A is A has a configuration in which a catheter 7 and a container 8 in which a liquid 89 is sealed are housed in A), and a container of liquid (¶ [0024], before opening the package 1A, the user strongly presses the container 8 to break it, and wets the catheter 7 with the liquid 89). However, Nishizawa lacks medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter and at most describes a catheter (Figs. 1, 2, 5, 6, catheter 7).

Shimura; Kenichi et al. (JP 2000281144 A) describes a catheterization package comprising several compartments (¶ [0001], [0017], [0035], a package 1 includes a packaging material 2 having a first space and a second space; ¶ [0037], The partition 22 divides the inside of the packaging material 2 into a first space 4 and a second space 5), including a urinary catheter (¶ [0046], The catheter 7 is inserted into, for example, the trachea, digestive tract, urethra ... and other living tissues). However, Shimura lacks a tray and instead discloses a bag-type container (¶ [0036], The

packaging material 2 is a bag-like material). Shimura also lacks first and second syringes containing lubricating jelly and water.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590
Fax 571-273-2590
Email Adam.Marcetich@uspto.gov

The Examiner can be reached 8am-4pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Weiss can be reached at 571-270-1775. The fax phone number for the organization where this application is assigned is 571-273-8300.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is

available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>.

Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Primary Examiner, Art Unit 3781

<i>Search Notes</i> 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B50/30, A61B50/33, A61B46/00, A61B2050/3008, A61B46/23, A61B2050/0065, A61B42/40, A61B50/20, A61B90/92, A61B50/31, A61B2050/3007, A61B2050/3011, A61B90/94, A61B2050/005	06/30/2022	AMM
A61M25/002, A61M25/0017, A61M5/002, A61M25/00, A61M5/14, A61M5/008, A61M2209/06, B65D1/34, B65D1/36, A61F15/001	06/30/2022	AMM
update search	10/14/2022	AMM
update search	02/03/2023	AMM

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor search in US-PGPUB, USPAT	06/29/2022	AMM
Review cited art for related cases 12495148, 12647515, 13153265, 13153300, 13155053, 14165044, 15640224, 15977944	06/29/2022	AMM
Review IPR cases IPR2015-00511, IPR2015-00513, IPR2015-00514, IPR2019-00109	06/29/2022	AMM
update search	10/14/2022	AMM
update search	02/03/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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<i>Search Notes</i> 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	update search	10/14/2022	AMM
	update search	02/03/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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Issue Classification 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

CPC						
Symbol					Type	Version
A61B	/	10	/	007	F	2013-01-01
A61M	/	25	/	00	I	2013-01-01
A61M	/	25	/	002	I	2013-01-01
A61B	/	50	/	30	I	2016-02-01
A61B	/	50	/	33	I	2016-02-01
A61B	/	46	/	23	A	2016-02-01
A61M	/	25	/	0017	A	2013-01-01
A61B	/	2050	/	3015	A	2016-02-01
A61B	/	2050	/	3008	A	2016-02-01
A61B	/	42	/	00	A	2016-02-01
A61B	/	46	/	00	A	2016-02-01

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version
/				

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) _____ (Date) 03 February 2023		O.G. Print Claim(s) 1	O.G. Print Figure 7

Issue Classification 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61B50/30	/	50	/ 30
A61B50/33	/	50	/ 33

NON-CLAIMED			
A61M25/00	/	25	/ 00
A61B42/00	/	42	/ 00

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE (Assistant Examiner)		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner)		03 February 2023 (Date)	
		O.G. Print Claim(s) 1	O.G. Print Figure 7

Issue Classification 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) _____ (Date) 03 February 2023		O.G. Print Claim(s) 1	O.G. Print Figure 7

Receipt date: 02/01/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4411656		1983-10-25	Cornett III, Walter	
		9693756		2017-07-04	Tomes, Jennifer	
		9745088		2017-08-29	Tomes, Jennifer	
		9808596		2017-11-07	Tomes, Jennifer	
		10512752		2019-12-24	Tomes, Jennifer	
		10946169		2021-03-16	Lockwood, Robert	
		10946992		2021-03-16	Tomes, Jennifer	

U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0894

Receipt date: 02/01/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

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	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
		KLEIN, BENJAMIN , "Non-Final Office Action", USSN 16/688,185; Filed November 19, 2019; Attorney Docket No. BPMDL10055U P1C2D1; Mailed January 31, 2023,	
EXAMINER SIGNATURE			
Examiner Signature	/Adam Marcetich/	Date Considered	02/02/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).
OR

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0895

Receipt date: 02/01/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-02-01
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0896

Receipt date: 01/18/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam Marcetich	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		4439184		1984-03-27	Wheeler, Robert P.			
U.S.PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
		REIP, DAVID O. , "Re-Exam Non-Final Office Action", USSN 90/015,051; Filed June 8, 2022; Reference No. 10055U CIP2 D1; Mailed December 14, 2022,						
EXAMINER SIGNATURE								

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0897

Receipt date: 01/18/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam Marcetich
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

Examiner Signature	/Adam Marcetich/	Date Considered	02/02/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT			
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):			
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).			
OR			
☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).			
☐ See attached certification statement.			
☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.			
☒ None			
SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-01-18
Name/Print	Philip H. Burrus	Registration Number	45,432

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0898

Receipt date: 01/18/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam Marcetich
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0899

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL **(Submitted Only via EFS-Web)**

Application Number	16721718	Filing Date	2019-12-19	Docket Number (if applicable)	10055U CIP3 C1 C1 C1	Art Unit	3781
First Named Inventor	Jennifer E. Tomes			Examiner Name	Adam M Marcetich		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
 Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☐ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
 (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to
 Deposit Account No 503608

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-03-17
Name	Philip H. Burrus, IV	Registration Number	45432

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	7602	
	Examiner Name	Marcetich, Adam M	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		4460360		1984-07-17	Finegold, Aaron			
U.S.PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		20110218520		2011-09-08	Andrich, Daniela			
		20090301927		2009-12-10	Fvlbrook, Jason			
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
		MARCETICH, ADAM , "Notice of Allowance", USSN 16/833,575; Filed March 28, 2020; Attorney Docket No 10055UCIP2D1C1C1C1C1; Mailed February 24, 2023,						

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	7602
	Examiner Name	Marcetich, Adam M
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

		MARCETICH, ADAM , "Notice of Allowance", USSN 16/944,667; Filed July 31, 2023; Attorney Docket No. 10055U CIP2 D1 C1 C1 C1 C1 C1; Mailed March 2, 2023,	
		MARCETICH, ADAM M. , "NonFinal Office Action", USSN 16/944,667; Filed July 31, 2020; Attorney Docket 10055U CIP2D1C1C1C1C1C1; Mailed October 7, 2022,	
EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).
OR
☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	7602
	Examiner Name	Marcetich, Adam M
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).			
☐ See attached certification statement.			
☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.			
☒ None			
SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-3-17
Name/Print	Philip H. Burrus	Registration Number	45,432
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			

Electronic Patent Application Fee Transmittal				
Application Number:		16721718		
Filing Date:		19-Dec-2019		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		BPMDL10055UCIP3C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
RCE- 2ND AND SUBSEQUENT REQUEST	1820	1	2000	2000
Total in USD (\$)				2000

Electronic Acknowledgement Receipt	
EFS ID:	47703125
Application Number:	16721718
International Application Number:	
Confirmation Number:	7602
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	BPMDL10055UCIP3C1C1C1
Receipt Date:	17-MAR-2023
Filing Date:	19-DEC-2019
Time Stamp:	17:53:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$2000
RAM confirmation Number	E20233GH54449873
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	10055U_CIP3_C1C1C1_USA_2023-3-17_RCE.pdf	1349938	no	3
			18626324884038ea5d46660d58f08c8697106116		
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP3C1C1C1_USA_2023-3-17_IDS.pdf	197390	no	3
			8af9240db9a4340e213cfc15ed1018c75b47f3ee		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	10055U_CIP2_D1C1C1C1C1_USA_2023-2-24_NoticeOfAllowance.pdf	1651123	no	20
			48f1b3c288dfaded11cd697cbd2881c5a4bb74f7		
Warnings:					
Information:					
4	Non Patent Literature	10055U_CIP2_D1C1C1C1C1C1_USA_2022-10-7_NonFinalOA.pdf	1713361	no	25
			38d3f8d1e63cb8084f8e7966a15794b0aba70211		
Warnings:					
Information:					
5	Non Patent Literature	10055U_CIP2D1C1C1C1C1C1_USA_2023-3-2_NoticeOfAllowance.pdf	1834556	no	22
			660e46f13dfdd9e6275eca1dbdf9bba878806702		
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	38173	no	2
			ba94723365ebc7711c27692b5a34ae4f9563448a		
Warnings:					

Information:	
Total Files Size (in bytes):	6784541
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Marcetich, Adam	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS							
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
U.S.PATENT APPLICATION PUBLICATIONS							
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
FOREIGN PATENT DOCUMENTS							
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
							T ⁵
NON-PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ⁵
		REIP, DAVID O. , "Notice of Intent to Issue Ex Parte Reexam Certificate", USSN 90/014,964; Patent Under Reexam 8448786; Mailed March 21, 2023,					
EXAMINER SIGNATURE							
Examiner Signature					Date Considered		

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Marcetich, Adam
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-03-22
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

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	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Marcetich, Adam
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt	
EFS ID:	47728201
Application Number:	16721718
International Application Number:	
Confirmation Number:	7602
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	BPMDL10055UCIP3C1C1C1
Receipt Date:	22-MAR-2023
Filing Date:	19-DEC-2019
Time Stamp:	18:19:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP3_C1C1C1_USA_2023-3-22_IDS.pdf	134310 5fe4d66585866d7d56075a68c9c9af4ff5cd15c	no	3

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	10055U_CIP2_USA_2023-3-21_NoticeIntentToIssueReexamCertificate.PDF	321460 fec8f1b0fc3aa40caa811a7125a62a353d1ccb2e	no	6
Warnings:					
Information:					
Total Files Size (in bytes):			455770		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

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	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit		
	Examiner Name		
	Attorney Docket Number		BPMDL0005JT.P3.C1.C1.C1

U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
U.S.PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Figures Appear	T ⁵
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
		REIP, DAVID O. , "Notice of Intent to Issue Ex Parte Reexam Certificate", USSN 90/014,964; Patent Under Reexam 8448786; Mailed March 21, 2023						
		REIP, DAVID O. , "ReExamination Final Office Action", USSN 90/015,051; Filed June 8, 2022; Patent Under Reexam 9522753; Mailed April 4, 2023						

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).
OR
☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).
☐ See attached certification statement.
☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
☒ None

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-04-06
Name/Print	Philip H. Burrus	Registration Number	45,432
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			

Electronic Acknowledgement Receipt	
EFS ID:	47805121
Application Number:	16721718
International Application Number:	
Confirmation Number:	7602
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	BPMDL10055UCIP3C1C1C1
Receipt Date:	06-APR-2023
Filing Date:	19-DEC-2019
Time Stamp:	16:54:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP3_C1C1C1_USA_2023-4-6_IDS.pdf	190097 ec366038968ed14614aa8b2b0986e2d4a45d9fb2	no	3

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	10055U_CIP2_D1_USA_2023-4-4_ReExamFinalOA.pdf	1009043	no	14
			6b217249c6fd0167dcc30808b5dbed09cfd70a19		
Warnings:					
Information:					
3	Non Patent Literature	10055U_CIP2_USA_2023-3-21_NoticeIntent_IssueReexamCertificate.pdf	382839	no	6
			07a5f6bf3e161b973ca6289bac64961932f0518e		
Warnings:					
Information:					
Total Files Size (in bytes):			1581979		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

189038 7590 04/11/2023
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE
Suite 1803
Atlanta, GA 30309

EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3781

DATE MAILED: 04/11/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	12/19/2019	Jennifer E. Tomes	BPMDL10055UCIP3C1C1C1	7602

TITLE OF INVENTION: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	07/11/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

189038 7590 04/11/2023
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE
Suite 1803
Atlanta, GA 30309

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	12/19/2019	Jennifer E. Tomes	BPMDL10055UCIP3C1C1C1	7602

TITLE OF INVENTION: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	07/11/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3781	604-540000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via Patent Center or EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	12/19/2019	Jennifer E. Tomes	BPMDL10055UCIP3C1C1C1	7602
189038	7590	04/11/2023	EXAMINER	
Philip H. Burrus, IV Burrus Intellectual Property Law Group LLC (MDL) 222 12th Street NE Suite 1803 Atlanta, GA 30309			MARCETICH, ADAM M	
			ART UNIT	PAPER NUMBER
			3781	
DATE MAILED: 04/11/2023				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/721,718	Applicant(s) Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 17 March 2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-20 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☒ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.	

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
---	--

EXAMINER'S COMMENT / REASONS FOR ALLOWANCE

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 March 2023 has been entered.

Examiner's Comment

The objections to claims 4 and 7 for minor informalities are withdrawn in view of the amendments filed 07 October 2022.

Terminal Disclaimer

The terminal disclaimer filed on 07 October 2022 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of:

- Tomes; Jennifer E. et al. (US 10624614 B2)
- Tomes; Jennifer E. et al. (US 10640243 B2)
- Tomes; Jennifer E. et al. (US 9745088 B2)
- Tomes; Jennifer E. et al. (US 10946992 B2)
- Tomes; Jennifer E. et al. (US 9808596 B2)
- Tomes; Jennifer E. et al. (US 10512752 B2)

- Lockwood; Robert et al. (US 10946169 B2)
 - Dickinson; Sarah et al. (US 11116937 B2)
- has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Claims

Claims 1-20 are allowed.

Reasons for Allowance

All references on the IDS forms filed 17 March 2023 and 22 March 2023 have been considered.

Finegold; Aaron N. (US 4460360 A) discloses anesthetic devices (col. 1, lines 10-20; col. 2, lines 35-50); including a syringe that contains lubricating jelly (col. 3, lines 20-25, The syringe body 12 contains a suitable anesthetic, such as a lidocaine hydrochloride solution or jelly).

However, Finegold does not arrange the syringe in a tray. Instead, the syringe and other accessories are provided as freestanding components (col. 2, lines 55-60, An elongated hollow barrel 28 having a smooth exterior surface is connected to the free end of coupler 18).

Andrich; Daniela (US 20110218520 A1) discloses a device and a related method for urinary catheterisation (§ [0001], [0010], [0027], [0068]); including a Foley catheter (§ [0068], a catheter 10 having a flexible elongate shaft 12);

first and second syringes containing lubricating jelly and water (§ [0086], the balloon 24 is inflated by inserting a syringe filled with water or saline solution into the inflation channel side arm 28 ... until the balloon 24 is filled; § [0097], Additionally housed within the external wrapping 104 is a syringe 108 pre-filled with water for

lubricating the guidewire 38 ... the external wrapping 104 houses two syringes filled with water; one for lubricating the guidewire and one for inflating the balloon).

However, Andrich does not arrange the syringes in a single layer tray with first and second compartments. At most, Andrich arranges both of the syringes and a catheter in a compartment of a nested wrapper (¶ [0096] The device of the invention (not shown) is contained within a sterile internal wrapping 90, which is typically made from plastic ... and is substantially rectangular in shape; ¶ [0097] The internal wrapping 90 is housed within a sterile external wrapping 104, which is typically made of plastic or paper).

All references on the IDS's filed 18 January 2023 and 01 February 2023 have been considered.

Wheeler; Robert P. (US 4439184 A) and Cornett, III; Walter G. (US 4411656 A) each describes a syringe configured to hold lubricant. However, neither Wheeler nor Cornett discloses a tray having separate compartments separated by a barrier. At most, Wheeler and Cornett describe the construction of their respective syringes.

Also cited on the recent IDS, the Re-Exam Non-Final Office Action for USSN 90/015,051 cites **Pilger Nicholas J. (US 3485352 A) in view of Wheeler; Robert P. (US 4439184 A), McMichael; Donald J. et al. (US 6896141 B2) and Serany Jr.; Frank J et al. (US 3329261 A)**. However, the cited combination of references fails to teach or suggest the features of pending claims 1-20.

Pilger lacks a tray having separate compartments separated by a barrier, wherein first and second syringes are disposed in a first compartment and a medical assembly is stored in a second compartment. At most, Pilger constrains a catheter with a series of posts (col. 2, lines 40-50, Extending upwardly from bottom 2 are a series of posts 5, 6 and 7 which are near but spaced from the side wall 3. As illustrated in FIGURE 1, a flexible catheter 8 is held in a generally circular coil between the posts and the upstanding wall). Pilger discloses only a single syringe which is stored in the same compartment as the catheter (col. 2, lines 60-65, hypodermic syringe 15 which is shown in the dish portion of the film member within a coil formed by the catheter).

The Office Action for USSN 90/015,051 does not reject claim 25 of Tomes; Jennifer E. et al. (US 9522753 B2), which describes “the at least two compartments further comprising a second compartment separated from the first compartment by a wall, further comprising placing the coiled medical device within the second compartment.”

Also cited on the recent IDS, the Non-Final Office Action for USSN 16/688,185 cites **Cornett, III; Walter G. (US 4411656 A), Paikoff; Myron et al. (US 4523679 A), Reif; Thomas H. et al. (US 4811847 A), Gawarecki; Herbert (US 6142152 A), Kubalak; Thomas P. et al. (US 7789873 B2), Misra; Vijay K. (US 6012586 A), Solazzo; Anthony (US 7278987 B2) and Beddow; David V. (US 4226328 A)** in a statement of reasons for the indication of allowable subject matter.

Beddow discloses a catheterization package comprising a tray (col. 2, lines 30-35, a generally rectangular box-like outer tray 11); a catheter (col. 2, lines 50-55, catheter 13); and one syringe (col. 2, lines 50-55, syringe 14).

However, **Beddow** lacks a second syringe and coiled tubing. **Beddow** also lacks a syringe containing lubricating jelly and instead stores lubricant in a different container, which is not stored in the same tray as the catheter or syringe (col. 3, lines 10-15, an individually sealed foil container 26 of lubricating jelly 27 packed within an elongated rectangular recess 28).

Applicant's arguments filed 07 October 2022 have been considered and are persuasive. Examiner advances additional reasons for allowance.

Reif; Thomas H. et al. (US 4811847 A), the closest art of record, discloses a catheter assembly including a tray, one syringe and a catheter (Fig. 2). However, **Reif** lacks a second syringe, and does not arrange the syringe and catheter in separate compartments.

Another cited reference, **Pilger; Nicholas J. (US 3485352 A)**, discloses a procedure kit including a tray, coiled catheter and one syringe (Fig. 5). However, **Pilger** lacks a second syringe and a second compartment. Instead, **Pilger** arranges one syringe and a catheter in one compartment (Figs. 1, 2, syringe 15 and catheter 8 are both arranged inside wall 3).

Also of record, **Rauschenberger; Richard A. (US 4160505 A)** discloses a catheterization tray comprising multiple compartments (col. 1, lines 50-55, Tray 10 is

formed with a dished portion 11; col. 2, lines 1-5, Compartments 23 and 24 are defined within dish 11 by walls 27, 28 and 29), and a medical assembly comprising a urinary catheter (col. 1, lines 60-65, Channel 21 is adapted to receive a conventional urethral catheter which is positioned within channel 21).

However, Rauschenberger lacks first and second syringes containing lubricating jelly and water. Instead, Rauschenberger describes a separate lubricant packet (col. 2, lines 20-30, The remaining components generally are arranged ... in the order: gloves, lubricant ... and specimen container). Rauschenberger also lacks a coiled tubing coupled between a fluid drain bag and a Foley catheter, and at most discloses a urinary catheter (Fig. 1, conventional urethral catheter stored in channel 21).

The following newly cited references fail to teach or suggest all limitations of the amended claims.

Nishizawa; Yasushi et al. (JP 2002068309 A) discloses a catheterization tray comprising several compartments (¶ [0001], [0004], [0008], [0031], In the vicinity of the center of the first sheet material 28, a first concave portion 231 having a substantially square planar shape is formed); including a catheter (¶ [0024], FIG. 1, the package 1A is A has a configuration in which a catheter 7 and a container 8 in which a liquid 89 is sealed are housed in A), and a container of liquid (¶ [0024], before opening the package 1A, the user strongly presses the container 8 to break it, and wets the catheter 7 with the liquid 89). However, Nishizawa lacks medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter and at most describes a catheter (Figs. 1, 2, 5, 6, catheter 7).

Shimura; Kenichi et al. (JP 2000281144 A) describes a catheterization package comprising several compartments (¶ [0001], [0017], [0035], a package 1 includes a packaging material 2 having a first space and a second space; ¶ [0037], The partition 22 divides the inside of the packaging material 2 into a first space 4 and a second space 5), including a urinary catheter (¶ [0046], The catheter 7 is inserted into, for example, the trachea, digestive tract, urethra ... and other living tissues). However, Shimura lacks a tray and instead discloses a bag-type container (¶ [0036], The packaging material 2 is a bag-like material). Shimura also lacks first and second syringes containing lubricating jelly and water.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590
Fax 571-273-2590
Email Adam.Marcetich@uspto.gov

The Examiner can be reached 8am-4pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sarah Al-Hashimi can be reached at 571-272-7159. The fax phone number for the organization where this application is assigned is 571-273-8300.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>.

Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Primary Examiner, Art Unit 3781

<i>Search Notes</i> 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B50/30, A61B50/33, A61B46/00, A61B2050/3008, A61B46/23, A61B2050/0065, A61B42/40, A61B50/20, A61B90/92, A61B50/31, A61B2050/3007, A61B2050/3011, A61B90/94, A61B2050/005	06/30/2022	AMM
A61M25/002, A61M25/0017, A61M5/002, A61M25/00, A61M5/14, A61M5/008, A61M2209/06, B65D1/34, B65D1/36, A61F15/001	06/30/2022	AMM
update search	10/14/2022	AMM
update search	02/03/2023	AMM
update search	04/04/2023	AMM

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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<i>Search Notes</i> 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

Search Notes		
Search Notes	Date	Examiner
Inventor search in US-PGPUB, USPAT	06/29/2022	AMM
Review cited art for related cases 12495148, 12647515, 13153265, 13153300, 13155053, 14165044, 15640224, 15977944	06/29/2022	AMM
Review IPR cases IPR2015-00511, IPR2015-00513, IPR2015-00514, IPR2019-00109	06/29/2022	AMM
update search	10/14/2022	AMM
update search	02/03/2023	AMM
update search	04/04/2023	AMM

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	update search	10/14/2022	AMM
	update search	02/03/2023	AMM
	update search	04/04/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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Issue Classification 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

CPC						
Symbol					Type	Version
A61B	/	10	/	007	F	2013-01-01
A61M	/	25	/	00	I	2013-01-01
A61M	/	25	/	002	I	2013-01-01
A61B	/	50	/	30	I	2016-02-01
A61B	/	50	/	33	I	2016-02-01
A61B	/	46	/	23	A	2016-02-01
A61M	/	25	/	0017	A	2013-01-01
A61B	/	2050	/	3015	A	2016-02-01
A61B	/	2050	/	3008	A	2016-02-01
A61B	/	42	/	00	A	2016-02-01
A61B	/	46	/	00	A	2016-02-01

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781	05 April 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	7

Issue Classification 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61B50/30	/	50	/ 30
A61B50/33	/	50	/ 33

NON-CLAIMED			
A61M25/00	/	25	/ 00
A61B42/00	/	42	/ 00

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE (Assistant Examiner)		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner)		05 April 2023 (Date)	O.G. Print Claim(s) 1
		O.G. Print Figure 7	

Issue Classification 	Application/Control No. 16/721,718	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) _____ (Date) 05 April 2023		O.G. Print Claim(s) 1	O.G. Print Figure 7

Receipt date: 03/17/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	7602	
	Examiner Name	Marcetich, Adam M	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		4460360		1984-07-17	Finegold, Aaron			
U.S.PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		20110218520		2011-09-08	Andrich, Daniela			
		20090301927		2009-12-10	Fvlbrook, Jason			
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
		MARCETICH, ADAM , "Notice of Allowance", USSN 16/833,575; Filed March 28, 2020; Attorney Docket No 10055UCIP2D1C1C1C1C1; Mailed February 24, 2023,						

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

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Receipt date: 03/17/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	7602
	Examiner Name	Marcetich, Adam M
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

		MARCETICH, ADAM , "Notice of Allowance", USSN 16/944,667; Filed July 31, 2023; Attorney Docket No. 10055U CIP2 D1 C1 C1 C1 C1 C1; Mailed March 2, 2023,	
		MARCETICH, ADAM M. , "NonFinal Office Action", USSN 16/944,667; Filed July 31, 2020; Attorney Docket 10055U CIP2D1C1C1C1C1C1; Mailed October 7, 2022,	
EXAMINER SIGNATURE			
Examiner Signature	/Adam Marcetich/	Date Considered	04/04/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).
OR
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Doc description: Information Disclosure Statement (IDS) Field

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	7602
	Examiner Name	Marcetich, Adam M
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-3-17
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Marcetich, Adam	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS							
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
U.S.PATENT APPLICATION PUBLICATIONS							
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
FOREIGN PATENT DOCUMENTS							
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear T ⁵
NON-PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ⁵
		REIP, DAVID O. , "Notice of Intent to Issue Ex Parte Reexam Certificate", USSN 90/014,964; Patent Under Reexam 8448786; Mailed March 21, 2023,					
EXAMINER SIGNATURE							
Examiner Signature		/Adam Marcetich/		Date Considered		04/04/2023	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0942

Receipt date: 03/22/2023

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Marcetich, Adam
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-03-22
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application

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Bard Exhibit 1004.0943

Receipt date: 03/22/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Marcetich, Adam
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit		
	Examiner Name		
	Attorney Docket Number		BPMDL0005JT.P3.C1.C1.C1

U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
U.S.PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
/AMM/		REIP, DAVID O. , "Notice of Intent to Issue Ex Parte Reexam Certificate", USSN 90/014,964; Patent Under Reexam 8448786; Mailed March 21, 2023						
/AMM/		REIP, DAVID O. , "ReExamination Final Office Action", USSN 90/015,051; Filed June 8, 2022; Patent Under Reexam 9522753; Mailed April 4, 2023						

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0945

Receipt date: 04/06/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit		
	Examiner Name		
	Attorney Docket Number		BPMDL0005JT.P3.C1.C1.C1

EXAMINER SIGNATURE			
Examiner Signature	/Adam Marcetich/	Date Considered	04/14/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).
OR
☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).
☐ See attached certification statement.
☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
☒ None

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0946

Receipt date: 04/06/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-04-06
Name/Print	Philip H. Burrus	Registration Number	45,432
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0947

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/721,718
	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Marcetich, Adam M.	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS							
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
U.S.PATENT APPLICATION PUBLICATIONS							
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
FOREIGN PATENT DOCUMENTS							
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
							T ⁵
NON-PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ⁵
		Marcetich, Adam M. , "Corrected Notice of Allowability after QPIDS", USSN 16/833,575; Filed March 28, 2020; Attorney Docket No. 10055U CIP2 D1 C1 C1 C1 C1; Mailed April 14, 2023					
		Marcetich, Adam M. , "Corrected Notice of Allowability after QPIDS", USSN 16/944,667; Filed July 31, 2020; Attorney Docket No. 10055U CIP2 D1 C1 C1 C1 C1 C1; Mailed April 14, 2023					

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	Filing Date		Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Marcetich, Adam M.	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT	
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):	
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OR	
☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).	
☐ See attached certification statement.	
☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.	
☐ None	

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Filing Date	Dec 19, 2019
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	Art Unit	3781
	Examiner Name	Marcetich, Adam M.
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-05-11
Name/Print	Philip H. Burrus	Registration Number	45,432
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			

Electronic Patent Application Fee Transmittal				
Application Number:		16721718		
Filing Date:		19-Dec-2019		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		BPMDL10055UCIP3C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
Total in USD (\$)				260

Electronic Acknowledgement Receipt	
EFS ID:	47988644
Application Number:	16721718
International Application Number:	
Confirmation Number:	7602
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	BPMDL10055UCIP3C1C1C1
Receipt Date:	11-MAY-2023
Filing Date:	19-DEC-2019
Time Stamp:	16:05:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$260
RAM confirmation Number	E20235AG05538311
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP3_C1C1C1_USA_2023-5-11_IDS.pdf	135696	no	3
			6821acf034c09d18130972e3bfb73cda042c8ad6		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	10055U_CIP2_D1_C1C1C1C1_USA_2023-4-14_NoticeAllowance.pdf	753541	no	13
			6c843d97d0657e6a0f15ee443c9a6da22387d73a		
Warnings:					
Information:					
3	Non Patent Literature	10055U_CIP2_D1_C1C1C1C1C1_USA_2023-4-14_CorrectedNoticeAllowance.pdf	1043126	no	15
			23b77a4bd9031f0cb7414fad122eac6cf243519c		
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	38271	no	2
			518a5a51786d6cd8f3a92ae5cf88868676cee0b		
Warnings:					
Information:					
Total Files Size (in bytes):			1970634		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Document Description: Issue Fee Payment (PTO-85B)

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
16721718	19-Dec-2019	Jennifer E. Tomes	BPMDL10055UCIP3C1C1	7602

TITLE OF INVENTION :

Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Regular Undiscounted	Utility under 35 USC 111(a)	3781	540000	ADAM MARCETICH
Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
\$1200	\$0	\$1200	11-Jul-2023	\$0

1.Change of Correspondence Address and/or Indication Of Fee Address (37 CFR 1.33 & 1.363)

Current Correspondence Address:	Current Indicated Fee Address :
189038 Philip H. Burrus, IV Burrus Intellectual Property Law Group LLC (MDL) 222 12th Street NE Suite 1803 Atlanta GA 30309 UNITED STATES 404-797-8111 ~~BIPLaw_docketing@burrusiplaw.com~~	
☐ Change of correspondence address requested, system generated AIA/122-EFS form attached	☐ Fee Address indication requested, system generated SB/47-EFS form attached

2.Entity Status**Change in Entity Status**

Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.

Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.



Applicant asserting small entity status. See 37 CFR 1.27.

Note: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.



Applicant changing to regular undiscounted fee status.

Note: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.



Document Description: Issue Fee Payment (PTO-85B)

3.The Following Fee(s) Are Submitted:☒ Issue Fee☐ I authorize USPTO to apply my previously paid issue fee to the current fees due☐ Publication Fee☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____

If **in addition to** the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number _____.

☐ The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed**NOTE: If no name is listed, no name will be printed**

For printing on the patent front page, list to be displayed as entered

1. Philip H. Burrus, IV

2.

3.

5.Assignee Name(s) and Residence Data To Be Printed

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

Name	City	State	Country	Category
Medline Industries, LP	Northfield	ILLINOIS	UNITED STATES	corporation

6.Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application. I also certify that this Fee(s) Transmittal form is being transmitted to the USPTO via EFS-WEB on the date indicated below.

Signature	/Philip H. Burrus, IV/	Date	05-11-2023
Name	Philip Henry Burrus	Registration Number	45432

Electronic Patent Application Fee Transmittal				
Application Number:		16721718		
Filing Date:		19-Dec-2019		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		BPMDL10055UCIP3C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1200

Electronic Acknowledgement Receipt	
EFS ID:	47988672
Application Number:	16721718
International Application Number:	
Confirmation Number:	7602
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	BPMDL10055UCIP3C1C1C1
Receipt Date:	11-MAY-2023
Filing Date:	19-DEC-2019
Time Stamp:	16:10:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$1200
RAM confirmation Number	E20235AG10498706
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	60281	no	2
			b114512a420e00d22f2f75de2f724027dcd42834		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	40496	no	2
			a8950ab173633f1b182e00f64698a0ad0175ac79		
Warnings:					
Information:					
Total Files Size (in bytes):			100777		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Receipt date: 05/11/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Filing Date		Dec 19, 2019
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	Art Unit	3781	
	Examiner Name	Marcetich, Adam M.	
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1	

U.S.PATENTS							
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
U.S.PATENT APPLICATION PUBLICATIONS							
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
FOREIGN PATENT DOCUMENTS							
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear T ⁵
NON-PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ⁵
/AMM/		Marcetich, Adam M. , "Corrected Notice of Allowability after QPIDS", USSN 16/833,575; Filed March 28, 2020; Attorney Docket No. 10055U CIP2 D1 C1 C1 C1 C1; Mailed April 14, 2023					
/AMM/		Marcetich, Adam M. , "Corrected Notice of Allowability after QPIDS", USSN 16/944,667; Filed July 31, 2020; Attorney Docket No. 10055U CIP2 D1 C1 C1 C1 C1 C1; Mailed April 14, 2023					

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0962

Receipt date: 05/11/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

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	Art Unit	3781
	Examiner Name	Marcetich, Adam M.
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

EXAMINER SIGNATURE			
Examiner Signature	/Adam Marcetich/	Date Considered	05/17/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).
OR
☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).
☐ See attached certification statement.
☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
☐ None

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0963

Receipt date: 05/11/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/721,718
	Filing Date	Dec 19, 2019
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Marcetich, Adam M.
	Attorney Docket Number	BPMDL0005JT.P3.C1.C1.C1

SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-05-11
Name/Print	Philip H. Burrus	Registration Number	45,432
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0964



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/721,718	06/27/2023	11684347	BPMDL10055UCIP3C1C1C1	7602

189038 7590 06/07/2023
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE
Suite 1803
Atlanta, GA 30309

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at <https://patentcenter.uspto.gov/>. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at <https://certifiedcopycenter.uspto.gov/index.html>. The Certified Copy Center may be reached at (800)972-6382.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment is 459 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional inventors):

Jennifer E. Tones, Mundelein, IL;
Sarah Dickinson, Chicago, IL;

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Medline Industries, LP, Northfield, IL;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address : COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.
16/721,718	27-JUN-23	11684347

Philip H. Burrus, IV Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE Suite 1803
Atlanta, GA 30309

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at <https://patentcenter.uspto.gov>

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit <https://www.uspto.gov/electronicgrants>

U.S.S.N. 16/721,718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/721,718
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: BPMDL0005JT.P3.C1.C1.C1 (10055U CIP3 C1 C1 C1)
Appn. Filed: December 19, 2019
Applicants: Tomes, Jennifer et al.

Title: Catheter Tray, Packaging System, Instruction Insert, and
Associated Methods

November 30, 2023

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

PETITION CORRECT INVENTORSHIP UNDER 37 CFR §1.324 PURSUANT TO
35 USC §256

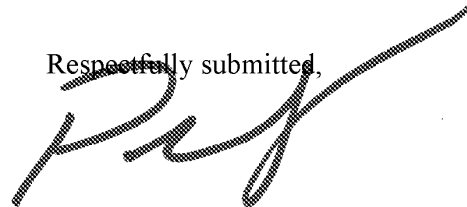
This Petition is filed under 37 CFR §1.324 to correct inventorship of US Patent No. 11,684,347. The Petition is being submitted concurrently with affidavits of the named inventors, and inventors petitioning to be named, and the assignee of record. The Petition Fee is enclosed herewith. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-3608.

Statement of Facts and Request for Relief:

Susan E. Macinnes, Deborah B. Adler, Jack E. Maze, Kenneth Chua, and Alberto Savage are each petitioning to be added as a named inventor. A declaration from each of Susan E. Macinnes, Deborah B. Adler, Jack E. Maze, Kenneth Chua, and Alberto Savage in accordance with 37 CFR 1.324(b)(1), is included herewith. Declarations from the named inventors in accordance with 37 CFR 1.324(b)(2) are included herewith. A declaration from the Assignee of record, Medline Industries, LP, in accordance with 37 CFR 1.324(b)(3) is included. The fee in accordance with 37 CFR 1.324(b)(4) is included.

As the requirements of 37 CFR 1.324 have been met, and as the inventorship error of failing to include each of Susan E. Macinnes, Deborah B. Adler, Jack E. Maze, Kenneth Chua, and Alberto Savage as an inventor of the patent occurred without any deceptive intention on the part of either Susan E. Macinnes or Deborah B. Adler or Jack E. Maze or Kenneth Chua or Alberto Savage, it is respectfully requested that each of Susan E. Macinnes, Deborah B. Adler, Jack E. Maze, Kenneth Chua, and Alberto Savage be added to this patent via a Certificate of Correction.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Burrus', with a long, sweeping horizontal line extending to the right.

Philip H. Burrus, IV

Attorney for Applicant

Registration No.: 45,432

404-797-8111

404-880-9912 (fax)

pburrus@burrusiplaw.com

U.S.S.N. 16/721,718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/721,718
US Pat. No.: 11,684,347
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: BPMDL0005JT.P3.C1.C.C1 (10055U CIP3 C1 C1 C1)
Appn. Filed: December 19, 2019
Applicants: Tomes, Jennifer et al.

Title: Catheter Tray, Packaging System, Instruction Insert, and
Associated Methods

**AFFIDAVIT OF MEDLINE INDUSTRIES, LP, ASSIGNEE, PURSUANT TO 37
CFR §1.324**

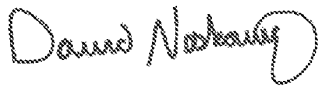
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I, David S. Noskowicz, declare as follows:

1. I am Patent Counsel for Medline Industries, LP, assignee of one hundred percent (100%) interest in the above-identified US Patent Application, which has now issued as US Patent No. 11,684,347.
2. I am authorized to sign declarations on behalf of Medline Industries, LP.
3. Medline Industries, LP, is the assignee of the patent by way of an assignment from inventors Jennifer E. Tomes and Sarah Dickinson (formally Sarah Zyburt) to Medline Industries, Inc., which was recorded in the Patent Office at Reel 026749, beginning at Frame 0907, on August 15, 2011, with a corporate conversion converting Medline Industries, Inc. to Medline Industries LP, with

said conversation being recorded in the Patent Office at Reel 057977, beginning at Frame 0436, on October 31, 2021.

4. Medline Industries, LP, understands that each of Susan E. Macinnes, Deborah B. Adler, Jack E. Maze, Kenneth Chua, and Alberto Savage is filing a Petition to be added as an inventor to this patent.
5. Medline Industries, LP., the assignee of record, agrees this requested change in inventorship in the patent by way of the addition of each of Susan E. Macinnes, Deborah B. Adler, Jack E. Maze, Kenneth Chua, and Alberto Savage as an inventor.
6. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



David S. Noskowitz

DATE: 12/01/2023

U.S.S.N. 16/721,718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/721,718
US Pat. No.: 11,684,347
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: BPMDL0005JT.P3.C1.C1.C1 (10055U CIP3 C1 C1 C1)
Appn. Filed: December 19, 2019
Applicants: Tomes, Jennifer et al.

Title: Catheter Tray, Packaging System, Instruction Insert, and
Associated Methods

AFFIDAVIT OF JENNIFER E. TOMES, PURSUANT TO 37 CFR §1.324

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I, Jennifer E. Tomes, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,684,347.
2. I understand that Susan E. Macinnes, Deborah B. Adler, Jack E. Maze, Alberto Savage, and Kenneth Chua are each filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares

U.S.S.N. 16/721,718

that all statements made herein are true, and all statements made on
information and belief are believed to be true.



Jennifer E. Tomes

DATE: 10/19/2023

U.S.S.N. 16/721,718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/721,718
US Pat. No.: 11,684,347
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: BPMDL0005JT.P3.C1.C1.C1 (10055U CIP3 C1 C1 C1)
Appn. Filed: December 19, 2019
Applicants: Tomes, Jennifer et al.

Title: Catheter Tray, Packaging System, Instruction Insert, and
Associated Methods

AFFIDAVIT OF SARAH DICKINSON, PURSUANT TO 37 CFR §1.324

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I, Sarah Dickinson, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,684,347.
2. I understand that Susan E. Macinnes, Deborah B. Adler, Jack E. Maze, Alberto Savage, and Kenneth Chua are each filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares

U.S.S.N. 16/721,718

that all statements made herein are true, and all statements made on
information and belief are believed to be true.

Sarah Dickinson

Sarah Dickinson

DATE: 10/17/2023

U.S.S.N. 16/721,718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/721,718
US Pat. No.: 11,684,347
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: BPMDL0005JT.P3.C1.C1.C1 (10055U CIP3 C1 C1 C1)
Appn. Filed: December 19, 2019
First Inventor: Tomes, Jennifer E.

Title: Catheter Tray, Packaging System, Instruction Insert, and
Associated Methods

AFFIDAVIT OF SUSAN E. MACINNES, PURSUANT TO 37 CFR §1.324

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I, Susan E. Macinnes, declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,684,347.
2. I was not listed as an inventor with the application was filed.
3. I am now hereby petitioning to be added as a named inventor to the issued patent.
4. The inventorship error of failing to include me as an inventor of the patent occurred without any deceptive intention on the part of me, Susan E. Macinnes.
5. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares

U.S.S.N. 16/721,718

that all statements made herein are true, and all statements made on
information and belief are believed to be true.

Susan E. MacInnes

Susan E. Macinnes

DATE: 09/18/2023

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

**COMBINATION DECLARATION AND ASSIGNMENT
FOR UTILITY AND DESIGN APPLICATIONS**

United States Patent Rights Plus
All Foreign Rights

INVENTION TITLE:

CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED
METHODS

DECLARATION UNDER 37 CFR §1.63:

As a below named inventor, I hereby declare that:

This declaration is directed to the application attached hereto, OR, if the application is not attached hereto, the application is as identified by the attorney docket number as set forth above and/or the following:

United States Application Number 16/721,718, now US Pat. No. 11,684,347;

Which was filed on December 19, 2019.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of the claimed invention in the application.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 CFR 1.56, including 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.

ASSIGNMENT OF RIGHTS AND AGREEMENT:

WHEREAS, as a below named inventor, I hereby declare that I have invented certain new and useful improvements described in the application identified; and

WHEREAS, Medline Industries, LP, a limited partnership organized and existing under the laws of Illinois, having its principal place of business at Three Lakes Drive, Northfield, IL 60093 (hereinafter referred to as "ASSIGNEE"), is desirous of acquiring my entire right, title and interest in and to the invention, and in and to the said application and any Letters Patent that may issue thereon;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I do hereby sell, assign and transfer unto ASSIGNEE, its successors, assigns and legal representatives my entire right, title and interest in and to said invention and in and to said applications and all patents which may be granted therefore, and all provisionals, nonprovisionals, continuations, continuations-in-part, divisionals, designs, appeals, reissues, substitutions and extensions thereof; and I hereby authorize and request the Commissioner of Patents and Trademarks to issue all patents for said invention, or patents resulting therefrom, insofar as my interest is concerned, to the said ASSIGNEE of my entire right, title and interest.

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

I also hereby sell and assign to said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive rights, title and interest to the invention disclosed in said applications throughout the world, including the right to file applications and obtain patents, utility models, industrial models and designs for said invention in its own name throughout the world including all rights of priority, all rights to publish cautionary notices reserving ownership of said invention and all rights to register said invention in appropriate registries; and

I further agree to execute any and all powers of attorney, applications, assignments, declarations, affidavits, and any other papers in connection therewith necessary to perfect such rights, title and interest in ASSIGNEE, its successors, assigns and legal representatives. This includes executing all papers necessary in connection with this application and any continuing, divisional, conversion or reissue applications thereof, and also to execute separate assignments that may be necessary in connection with such applications, as the ASSIGNEE may deem necessary or expedient. I further agree to execute all papers and documents and to perform any act that may be necessary in connection with claims or provisions of the International Convention for the Protection of Industrial Property or similar agreements, and to perform all affirmative acts which may be necessary to obtain a grant of (a) valid United States of America patent(s) or a grant of (a) valid United States of America and any foreign patent(s) to the ASSIGNEE, and to vest all rights therein hereby conveyed to said ASSIGNEE as fully and entirely as the same would have been held by the undersigned if this Assignment and sale had not been made.

I hereby further agree that I will communicate to said ASSIGNEE, or its successors, assigns and legal representatives, any facts known to me respecting any improvements; and, at the expense of said ASSIGNEE, to testify in any legal proceedings, sign all lawful papers, execute all provisional, nonprovisional, continuation, continuation-in-part, divisional, design, appeals, reissue and substitute applications, make all lawful oaths, and generally do everything possible to vest title in said ASSIGNEE and to aid said ASSIGNEE, its successors, assigns and legal representatives to obtain and enforce proper protection for said invention in all countries.

I further authorize and direct the ASSIGNEE and its attorneys to insert above the serial number and filing date of said application now identified as Atty. Docket No. 10055U CIP3 C1 C1 C1 as soon as the same shall have been made known to them by the United States Patent and Trademark Office, and/or to insert any further identification which may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office.

The undersigned hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

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 of not more than five (5) years, 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.

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

IN WITNESS WHEREOF, I have hereunto set my hand and seal on
09/18/2023.

Susan E. Macinnes

Name: Susan E. Macinnes

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

**COMBINATION DECLARATION AND ASSIGNMENT
FOR UTILITY AND DESIGN APPLICATIONS**

United States Patent Rights Plus
All Foreign Rights

INVENTION TITLE:

CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED
METHODS

DECLARATION UNDER 37 CFR §1.63:

As a below named inventor, I hereby declare that:

This declaration is directed to the application attached hereto, OR, if the application is not attached hereto, the application is as identified by the attorney docket number as set forth above and/or the following:

United States Application Number 16/721,718, now US Pat. No. 11,684,347

Which was filed on December 19, 2019.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of the claimed invention in the application.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 CFR 1.56, including 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.

ASSIGNMENT OF RIGHTS AND AGREEMENT:

WHEREAS, as a below named inventor, I hereby declare that I have invented certain new and useful improvements described in the application identified; and

WHEREAS, Medline Industries, LP, a limited partnership organized and existing under the laws of Illinois, having its principal place of business at Three Lakes Drive, Northfield, IL 60093 (hereinafter referred to as "ASSIGNEE"), is desirous of acquiring my entire right, title and interest in and to the invention, and in and to the said application and any Letters Patent that may issue thereon;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I do hereby sell, assign and transfer unto ASSIGNEE, its successors, assigns and legal representatives my entire right, title and interest in and to said invention and in and to said applications and all patents which may be granted therefore, and all provisionals, nonprovisionals, continuations, continuations-in-part, divisionals, designs, appeals, reissues, substitutions and extensions thereof; and I hereby authorize and request the Commissioner of Patents and Trademarks to issue all patents for said invention, or patents resulting therefrom, insofar as my interest is concerned, to the said ASSIGNEE of my entire right, title and interest.

I also hereby sell and assign to said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive rights, title and interest to the invention disclosed in said applications throughout the world, including the right to file applications and obtain patents, utility models, industrial models and designs for said invention in its own name throughout the world including all rights of priority, all rights to publish cautionary notices reserving ownership of said invention and all rights to register said invention in appropriate registries; and

I further agree to execute any and all powers of attorney, applications, assignments, declarations, affidavits, and any other papers in connection therewith necessary to perfect such rights, title and interest in ASSIGNEE, its successors, assigns and legal representatives. This includes executing all papers necessary in connection with this application and any continuing, divisional, conversion or reissue applications thereof, and also to execute separate assignments that may be necessary in connection with such applications, as the ASSIGNEE may deem necessary or expedient. I further agree to execute all papers and documents and to perform any act that may be necessary in connection with claims or provisions of the International Convention for the Protection of Industrial Property or similar agreements, and to perform all affirmative acts which may be necessary to obtain a grant of (a) valid United States of America patent(s) or a grant of (a) valid United States of America and any foreign patent(s) to the ASSIGNEE, and to vest all rights therein hereby conveyed to said ASSIGNEE as fully and entirely as the same would have been held by the undersigned if this Assignment and sale had not been made.

I hereby further agree that I will communicate to said ASSIGNEE, or its successors, assigns and legal representatives, any facts known to me respecting any improvements; and, at the expense of said ASSIGNEE, to testify in any legal proceedings, sign all lawful papers, execute all provisional, nonprovisional, continuation, continuation-in-part, divisional, design, appeals, reissue and substitute applications, make all lawful oaths, and generally do everything possible to vest title in said ASSIGNEE and to aid said ASSIGNEE, its successors, assigns and legal representatives to obtain and enforce proper protection for said invention in all countries.

I further authorize and direct the ASSIGNEE and its attorneys to insert above the serial number and filing date of said application now identified as Atty. Docket No. 10055U CIP3 C1 C1 C1 as soon as the same shall have been made known to them by the United States Patent and Trademark Office, and/or to insert any further identification which may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office.

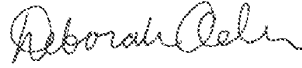
The undersigned hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

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 of not more than five (5) years, 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.

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

IN WITNESS WHEREOF, I have hereunto set my hand and seal on
11/29/2023.



Name: Deborah B. Adler

U.S.S.N. 16/721,718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/721,718
US Pat. No.: 11,684,347
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: BPMDL0005JT.P3.C1.C1.C1 (10055U CIP3 C1 C1 C1)
Appn. Filed: December 19, 2019
Applicants: Tomes, Jennifer et al.

Title: Catheter Tray, Packaging System, Instruction Insert, and
Associated Methods

AFFIDAVIT OF DEBORAH B. ADLER, PURSUANT TO 37 CFR §1.324

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

I, Deborah B. Adler, declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,684,347.
2. I was not listed as an inventor with the application was filed.
3. I am now hereby petitioning to be added as a named inventor to the issued patent.
4. The inventorship error of failing to include me as an inventor of the patent occurred without any deceptive intention on the part of me, Deborah B. Adler.
5. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the

U.S.S.N. 16/721,718

validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



Deborah B. Adler

DATE: 11/29/2023

U.S.S.N. 16/721,718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/721,718
US Pat. No.: 11,684,347
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: BPMDL0005JT.P3.C1.C1.C1 (10055U CIP3 C1 C1 C1)
Appn. Filed: December 19, 2019
First Inventor: Tomes, Jennifer E.

Title: Catheter Tray, Packaging System, Instruction Insert, and
Associated Methods

AFFIDAVIT OF ALBERTO SAVAGE, PURSUANT TO 37 CFR §1.324

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I, Alberto Savage, declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,684,347.
2. I was not listed as an inventor with the application was filed.
3. I am now hereby petitioning to be added as a named inventor to the issued patent.
4. The inventorship error of failing to include me as an inventor of the patent occurred without any deceptive intention on the part of me, Alberto Savage.
5. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the

U.S.S.N. 16/721,718

validity of the application or any registration stemming therefrom, declares
that all statements made herein are true, and all statements made on
information and belief are believed to be true.



Alberto Savage

DATE: 09/21/2023

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

**COMBINATION DECLARATION AND ASSIGNMENT
FOR UTILITY AND DESIGN APPLICATIONS**

United States Patent Rights Plus
All Foreign Rights

INVENTION TITLE:

CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED
METHODS

DECLARATION UNDER 37 CFR §1.63:

As a below named inventor, I hereby declare that:

This declaration is directed to the application attached hereto, OR, if the application is not attached hereto, the application is as identified by the attorney docket number as set forth above and/or the following:

United States Application Number 16/721,718, now US Pat. No. 11,684,347

Which was filed on December 19, 2019.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of the claimed invention in the application.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 CFR 1.56, including 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.

ASSIGNMENT OF RIGHTS AND AGREEMENT:

WHEREAS, as a below named inventor, I hereby declare that I have invented certain new and useful improvements described in the application identified; and

WHEREAS, Medline Industries, LP, a limited partnership organized and existing under the laws of Illinois, having its principal place of business at Three Lakes Drive, Northfield, IL 60093 (hereinafter referred to as "ASSIGNEE"), is desirous of acquiring my entire right, title and interest in and to the invention, and in and to the said application and any Letters Patent that may issue thereon;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I do hereby sell, assign and transfer unto ASSIGNEE, its successors, assigns and legal representatives my entire right, title and interest in and to said invention and in and to said applications and all patents which may be granted therefore, and all provisionals, nonprovisionals, continuations, continuations-in-part, divisionals, designs, appeals, reissues, substitutions and extensions thereof; and I hereby authorize and request the Commissioner of Patents and Trademarks to issue all patents for said invention, or patents resulting therefrom, insofar as my interest is concerned, to the said ASSIGNEE of my entire right, title and interest.

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

I also hereby sell and assign to said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive rights, title and interest to the invention disclosed in said applications throughout the world, including the right to file applications and obtain patents, utility models, industrial models and designs for said invention in its own name throughout the world including all rights of priority, all rights to publish cautionary notices reserving ownership of said invention and all rights to register said invention in appropriate registries; and

I further agree to execute any and all powers of attorney, applications, assignments, declarations, affidavits, and any other papers in connection therewith necessary to perfect such rights, title and interest in ASSIGNEE, its successors, assigns and legal representatives. This includes executing all papers necessary in connection with this application and any continuing, divisional, conversion or reissue applications thereof, and also to execute separate assignments that may be necessary in connection with such applications, as the ASSIGNEE may deem necessary or expedient. I further agree to execute all papers and documents and to perform any act that may be necessary in connection with claims or provisions of the International Convention for the Protection of Industrial Property or similar agreements, and to perform all affirmative acts which may be necessary to obtain a grant of (a) valid United States of America patent(s) or a grant of (a) valid United States of America and any foreign patent(s) to the ASSIGNEE, and to vest all rights therein hereby conveyed to said ASSIGNEE as fully and entirely as the same would have been held by the undersigned if this Assignment and sale had not been made.

I hereby further agree that I will communicate to said ASSIGNEE, or its successors, assigns and legal representatives, any facts known to me respecting any improvements; and, at the expense of said ASSIGNEE, to testify in any legal proceedings, sign all lawful papers, execute all provisional, nonprovisional, continuation, continuation-in-part, divisional, design, appeals, reissue and substitute applications, make all lawful oaths, and generally do everything possible to vest title in said ASSIGNEE and to aid said ASSIGNEE, its successors, assigns and legal representatives to obtain and enforce proper protection for said invention in all countries.

I further authorize and direct the ASSIGNEE and its attorneys to insert above the serial number and filing date of said application now identified as Atty. Docket No. 10055U CIP3 C1 C1 C1 as soon as the same shall have been made known to them by the United States Patent and Trademark Office, and/or to insert any further identification which may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office.

The undersigned hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

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 of not more than five (5) years, 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.

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

IN WITNESS WHEREOF, I have hereunto set my hand and seal on
09/21/2023



Name: Alberto Savage

U.S.S.N. 16/721,718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/721,718
US Pat. No.: 11,684,347
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: BPMDL0005JT.P3.C1.C1.C1 (10055U CIP3 C1 C1 C1)
Appn. Filed: December 19, 2019
First Inventor: Tomes, Jennifer E.

Title: Catheter Tray, Packaging System, Instruction Insert, and
Associated Methods

AFFIDAVIT OF JACK E. MAZE, PURSUANT TO 37 CFR §1.324

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I, Jack E. Maze, declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,684,347.
2. I was not listed as an inventor with the application was filed.
3. I am now hereby petitioning to be added as a named inventor to the issued patent.
4. The inventorship error of failing to include me as an inventor of the patent occurred without any deceptive intention on the part of me, Jack E. Maze.
5. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the

U.S.S.N. 16/721,718

validity of the application or any registration stemming therefrom, declares
that all statements made herein are true, and all statements made on
information and belief are believed to be true.

Jack E Maze

Jack E. Maze

DATE: 09/26/2023

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

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FOR UTILITY AND DESIGN APPLICATIONS**

United States Patent Rights Plus
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INVENTION TITLE:

CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED
METHODS

DECLARATION UNDER 37 CFR §1.63:

As a below named inventor, I hereby declare that:

This declaration is directed to the application attached hereto, OR, if the application is not attached hereto, the application is as identified by the attorney docket number as set forth above and/or the following:

United States Application Number 16/721,718, now US Pat. No. 11,684,347

Which was filed on December 19, 2019.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of the claimed invention in the application.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 CFR 1.56, including 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.

ASSIGNMENT OF RIGHTS AND AGREEMENT:

WHEREAS, as a below named inventor, I hereby declare that I have invented certain new and useful improvements described in the application identified; and

WHEREAS, Medline Industries, LP, a limited partnership organized and existing under the laws of Illinois, having its principal place of business at Three Lakes Drive, Northfield, IL 60093 (hereinafter referred to as "ASSIGNEE"), is desirous of acquiring my entire right, title and interest in and to the invention, and in and to the said application and any Letters Patent that may issue thereon;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I do hereby sell, assign and transfer unto ASSIGNEE, its successors, assigns and legal representatives my entire right, title and interest in and to said invention and in and to said applications and all patents which may be granted therefore, and all provisionals, nonprovisionals, continuations, continuations-in-part, divisionals, designs, appeals, reissues, substitutions and extensions thereof; and I hereby authorize and request the Commissioner of Patents and Trademarks to issue all patents for said invention, or patents resulting therefrom, insofar as my interest is concerned, to the said ASSIGNEE of my entire right, title and interest.

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

I also hereby sell and assign to said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive rights, title and interest to the invention disclosed in said applications throughout the world, including the right to file applications and obtain patents, utility models, industrial models and designs for said invention in its own name throughout the world including all rights of priority, all rights to publish cautionary notices reserving ownership of said invention and all rights to register said invention in appropriate registries; and

I further agree to execute any and all powers of attorney, applications, assignments, declarations, affidavits, and any other papers in connection therewith necessary to perfect such rights, title and interest in ASSIGNEE, its successors, assigns and legal representatives. This includes executing all papers necessary in connection with this application and any continuing, divisional, conversion or reissue applications thereof, and also to execute separate assignments that may be necessary in connection with such applications, as the ASSIGNEE may deem necessary or expedient. I further agree to execute all papers and documents and to perform any act that may be necessary in connection with claims or provisions of the International Convention for the Protection of Industrial Property or similar agreements, and to perform all affirmative acts which may be necessary to obtain a grant of (a) valid United States of America patent(s) or a grant of (a) valid United States of America and any foreign patent(s) to the ASSIGNEE, and to vest all rights therein hereby conveyed to said ASSIGNEE as fully and entirely as the same would have been held by the undersigned if this Assignment and sale had not been made.

I hereby further agree that I will communicate to said ASSIGNEE, or its successors, assigns and legal representatives, any facts known to me respecting any improvements; and, at the expense of said ASSIGNEE, to testify in any legal proceedings, sign all lawful papers, execute all provisional, nonprovisional, continuation, continuation-in-part, divisional, design, appeals, reissue and substitute applications, make all lawful oaths, and generally do everything possible to vest title in said ASSIGNEE and to aid said ASSIGNEE, its successors, assigns and legal representatives to obtain and enforce proper protection for said invention in all countries.

I further authorize and direct the ASSIGNEE and its attorneys to insert above the serial number and filing date of said application now identified as Atty. Docket No. 10055U CIP3 C1 C1 C1 as soon as the same shall have been made known to them by the United States Patent and Trademark Office, and/or to insert any further identification which may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office.

The undersigned hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

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 of not more than five (5) years, 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.

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

IN WITNESS WHEREOF, I have hereunto set my hand and seal on
09/26/2023.

Jack E Maze

Name: Jack E. Maze

U.S.S.N. 16/721,718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/721,718
US Pat. No.: 11,684,347
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: BPMDL0005JT.P3.C1.C1.C1 (10055U CIP3 C1 C1 C1)
Appn. Filed: December 19, 2019
First Inventor: Tomes, Jennifer E.

Title: Catheter Tray, Packaging System, Instruction Insert, and
Associated Methods

AFFIDAVIT OF KENNETH CHUA, PURSUANT TO 37 CFR §1.324

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I, Kenneth Chua, declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,684,347.
2. I was not listed as an inventor with the application was filed.
3. I am now hereby petitioning to be added as a named inventor to the issued patent.
4. The inventorship error of failing to include me as an inventor of the patent occurred without any deceptive intention on the part of me, Kenneth Chua.
5. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the

U.S.S.N. 16/721,718

validity of the application or any registration stemming therefrom, declares
that all statements made herein are true, and all statements made on
information and belief are believed to be true.

Kenneth Su Chua

Kenneth Chua

DATE: 09/29/2023

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

**COMBINATION DECLARATION AND ASSIGNMENT
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METHODS

DECLARATION UNDER 37 CFR §1.63:

As a below named inventor, I hereby declare that:

This declaration is directed to the application attached hereto, OR, if the application is not attached hereto, the application is as identified by the attorney docket number as set forth above and/or the following:

United States Application Number 16/721,718, now US Pat. No. 11,684,347

Which was filed on December 19, 2019.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of the claimed invention in the application.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 CFR 1.56, including 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.

ASSIGNMENT OF RIGHTS AND AGREEMENT:

WHEREAS, as a below named inventor, I hereby declare that I have invented certain new and useful improvements described in the application identified; and

WHEREAS, Medline Industries, LP, a limited partnership organized and existing under the laws of Illinois, having its principal place of business at Three Lakes Drive, Northfield, IL 60093 (hereinafter referred to as "ASSIGNEE"), is desirous of acquiring my entire right, title and interest in and to the invention, and in and to the said application and any Letters Patent that may issue thereon;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I do hereby sell, assign and transfer unto ASSIGNEE, its successors, assigns and legal representatives my entire right, title and interest in and to said invention and in and to said applications and all patents which may be granted therefore, and all provisionals, nonprovisionals, continuations, continuations-in-part, divisionals, designs, appeals, reissues, substitutions and extensions thereof; and I hereby authorize and request the Commissioner of Patents and Trademarks to issue all patents for said invention, or patents resulting therefrom, insofar as my interest is concerned, to the said ASSIGNEE of my entire right, title and interest.

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

I also hereby sell and assign to said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive rights, title and interest to the invention disclosed in said applications throughout the world, including the right to file applications and obtain patents, utility models, industrial models and designs for said invention in its own name throughout the world including all rights of priority, all rights to publish cautionary notices reserving ownership of said invention and all rights to register said invention in appropriate registries; and

I further agree to execute any and all powers of attorney, applications, assignments, declarations, affidavits, and any other papers in connection therewith necessary to perfect such rights, title and interest in ASSIGNEE, its successors, assigns and legal representatives. This includes executing all papers necessary in connection with this application and any continuing, divisional, conversion or reissue applications thereof, and also to execute separate assignments that may be necessary in connection with such applications, as the ASSIGNEE may deem necessary or expedient. I further agree to execute all papers and documents and to perform any act that may be necessary in connection with claims or provisions of the International Convention for the Protection of Industrial Property or similar agreements, and to perform all affirmative acts which may be necessary to obtain a grant of (a) valid United States of America patent(s) or a grant of (a) valid United States of America and any foreign patent(s) to the ASSIGNEE, and to vest all rights therein hereby conveyed to said ASSIGNEE as fully and entirely as the same would have been held by the undersigned if this Assignment and sale had not been made.

I hereby further agree that I will communicate to said ASSIGNEE, or its successors, assigns and legal representatives, any facts known to me respecting any improvements; and, at the expense of said ASSIGNEE, to testify in any legal proceedings, sign all lawful papers, execute all provisional, nonprovisional, continuation, continuation-in-part, divisional, design, appeals, reissue and substitute applications, make all lawful oaths, and generally do everything possible to vest title in said ASSIGNEE and to aid said ASSIGNEE, its successors, assigns and legal representatives to obtain and enforce proper protection for said invention in all countries.

I further authorize and direct the ASSIGNEE and its attorneys to insert above the serial number and filing date of said application now identified as Atty. Docket No. 10055U CIP3 C1 C1 C1 as soon as the same shall have been made known to them by the United States Patent and Trademark Office, and/or to insert any further identification which may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office.

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Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP3 C1 C1 C1

IN WITNESS WHEREOF, I have hereunto set my hand and seal on
09/29/2023.

Kenneth Su Chua

Name: Kenneth Chua



UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION # 16/721,718	RECEIPT DATE / TIME 12/01/2023 04:51:23 PM Z ET	ATTORNEY DOCKET # BPMDL10055UCIP3C1C1C1
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Title of Invention

Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	11684347
CONFIRMATION #	7602	FILED BY	Kayla Burrus
PATENT CENTER #	63460095	AUTHORIZED BY	Phillip Burrus
CUSTOMER #	189038	FILING DATE	12/19/2019
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jennifer E. Tomes

Payment Information

PAYMENT METHOD CARD / 3000	PAYMENT TRANSACTION ID E2023B1G51S29910	PAYMENT AUTHORIZED BY Kayla Burrus
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FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
1816	PROCESSING FEE FOR CORRECTING INVENTORSHIP IN A PATENT	160.00	1	160.00
TOTAL AMOUNT:				\$160.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES
PATENT AND TRADEMARK OFFICEP.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
16/721,718RECEIPT DATE / TIME
12/01/2023 04:51:23 PM Z ETATTORNEY DOCKET #
BPMDL10055UCIP3C1C1C1**Title of Invention**

Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

Application InformationAPPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # 11684347

CONFIRMATION # 7602

FILED BY Kayla Burrus

PATENT CENTER # 63460095

FILING DATE 12/19/2019

CUSTOMER # 189038

FIRST NAMED INVENTOR Jennifer E. Tomes

CORRESPONDENCE ADDRESS -

AUTHORIZED BY Philip Burrus

Documents**TOTAL DOCUMENTS: 1**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
10055U_CIP3_C1C1C1_USA_ _2023-11-30_Petition.pdf	33	Petition for review by the Technology Center Special Program Examiner(SPPE)	2352 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
10055U_CIP3_C1C1C1_USA_ 2023-11-30_Petition.pdf	8BDE4DB33C1D9ED6EDB6A61739D31C0018449A09975719E33 57C091AE273B27625C91325272A0BFFA9C07A9508D57B573A4 5BF2EEFC00825788F5E71D98273CF

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